DESIGN, DEVELOPMENT AND CLINICAL EVALUATION OF A NEW PROSTHETIC SUSPENSION SYSTEM FOR LOWER LIMB AMPUTEES

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ABSTRACT

Momentum, gravity, and other ambulation forces tend to displace lower limb prosthesis on residual limb. Thus, suspension systems have considerable effects on the amputee's mobility, comfort, and satisfaction with prosthesis. Negative effects of poor suspension on rehabilitation, as well as the comfort and activity level of lower limb amputees, were previously stated. This research aimed to develop a prosthetic suspension system and to explore the biomechanics of prosthesis that incorporates the new system for transtibial amputees. A prosthetic suspension system was designed and fabricated based on magnetic field. Factors that were influenced by the prosthetic suspension were derived through an extensive literature review, and an experimental protocol was subsequently developed. The mechanical properties of the designed suspension system were tested using the universal testing machine. The magnetic suspension system (MPSS) could withstand 350.9 N of tensile loading before the coupling failed. The system was equipped with an acoustic alarm system as an added safety feature: the safety alarm system would buzz a micro-controller unit if the suspension is going to fail. For validation, the MPSS was compared with two other common suspension systems, i.e. the pin/lock and the Seal-In suspension for validation. The MPSS and pin/lock caused comparable amounts of pistoning, whereas the least pistoning resulted from the Seal-In system. Interface pressure was evaluated by the Tekscan F-Socket transducers during level walking, as well as stair and ramp negotiation. The findings indicate that the mean peak pressure (in kilopascal) was lower with the MPSS than with the pin/lock over the anterior and posterior aspects during one gait cycle ($P < 0.05$). Overall, the average peak pressure values were higher with the Seal-In system than the MPSS and the pin/lock system. Particularly important was that the MPSS may reduce the pain and discomfort at the distal residual limb by decreasing

the pressure within the prosthetic socket in comparison to the pin/lock system during gait. The MPSS caused significantly different peak pressures at the anterior proximal region compared with the pin/lock ($P = 0.022$) and Seal-In ($P = 0.001$) during the stair ascent and descent, and ramp negotiation. Motion analysis showed that several kinetic and kinematic variables were affected by the suspension type. The ground reaction force data revealed that lower load was applied to the joints with the MPSS compared with the pin/lock suspension. The resulting gait deviation index was considerably different from the normal with all the systems, although the index did not significantly differ among the systems. Main significant effects of the suspension type were evident in the vertical and fore-aft ground reaction forces, knee, and ankle angles. The MPSS showed comparable effects in the remaining kinetic and kinematic gait parameters. Finally, the results of the questionnaire survey revealed significantly high satisfaction rates with the MPSS, especially for donning and doffing, walking, uneven walking, and stair negotiation ($P < 0.05$). The MPSS may be used as an alternative suspension system for lower limb amputees because the biomechanical findings fell within the ranges found in the literature and were comparable to two other common suspension systems.

ABSTRAK

Momentum, graviti, dan kuasa-kuasa lain ketika berjalan cenderung untuk mengakibatkan pergerakan prostesis pada anggota residual. Oleh itu, sistem suspensi mempunyai kesan yang besar ke atas pergerakan amputi, keselesaan, dan kepuasan dengan prostesis. Kesan negatif daripada suspensi yang lemah terhadap pemulihan serta keselesaan dan tahap aktiviti amputi telah dinyatakan sebelum ini. Kajian ini bertujuan untuk membangunkan satu sistem suspensi prostesis, dan untuk meneroka biomekanik prostesis yang menggabungkan sistem baru untuk amputi bawah lutut. Sistem suspense prostesis telah direka dan dibentuk berasaskan kepada medan magnet. Faktor-faktor yang mempengaruhi suspensi prostesis diperoleh melalui kajian literatur secara meluas dan kemudian satu protokol eksperimen telah dibangunkan. Sifat mekanikal sistem suspense yang direka telah diuji menggunakan mesin ujian universal. Sistem sistem suspensi magnet (MPSS) dapat menahan 350.9N tegangan muatan sebelum system tersebut gagal. Sistem ini dilengkapi dengan sistem penggera akustik sebagai ciri keselamatan tambahan. Sistem penggera keselamatan akan menghantar isyarat kepada unit pengawal-mikro jika suspensi itu akan gagal. Sebagai pengesahan MPSS, system ini dibandingkan dengan dua sistem suspensi lain, iaitu pin/lock dan Seal-In. Sistem MPSS dan pin/lock mencatatkan jumlah pergerakan yang setanding, manakala pergerakan paling kurang dicatatkan oleh sistem Seal-In. Tekanan antara-permukaan telah dinilai oleh transduser Tekscan F-Socket ketika berjalan di permukaan rata, tangga dan jalan bercerun. Dapatan kajian menunjukkan bahawa purata tekanan puncak (kPa) adalah lebih rendah dengan MPSS daripada pin/lock di kawasan hadapan (anterior) dan belakang (posterior) dalam satu kitaran berjalan (P<0.05). Secara keseluruhan, nilai purata tekanan puncak lebih tinggi dengan sistem Seal-In daripada MPSS dan sistem pin/lock. Satu kepentingan sistem MPSS adalah kemungkinan system ini berupaya mengurangkan kesakitan dan ketidakselesaan di hujung anggota residual dengan

mengurangkan tekanan dalam soket prostesis berbanding dengan sistem pin/lock semasa berjalan. Sistem MPSS menunjukkan perbezaan tekanan puncak yang ketara di kawasan hadapan proksimal berbanding dengan system pin/lock (P=0.022) dan Seal-In (P=0.001) ketika naik-turun tangga dan di atas jalan bercerun. Analisis pergerakan menunjukkan bahawa beberapa pembolehubah kinetik dan kinematik terjejas bergantung kepada jenis suspensi. Data daya tindak balas tanah menunjukkan bahawa beban yang lebih rendah telah dikenakan pada sendi oleh sistem MPSS berbanding dengan suspensi pin/lock. Indeks deviasi berjalan menunjukkan perbezaan antara individu normal dengan semua sistem, walaupun perbezaa antara system suspense tidak ketara. Kesan ketara yang paling utama bagi jenis suspensi adalah daya tindakbalas tanah menegak dan melintang, sudut lutut dan buku lali. Sistem MPSS menunjukkan kesan setanding dalam parameter kinetik dan kinematik yang lain ketika berjalan. Akhirnya, keputusan soal selidik mendedahkan kadar kepuasan tinggi yang ketara dengan MPSS, terutamanya ketika memakai dan menanggal prostesis, berjalan di atas permukaan rata dan tidak sekata, serta naik-turun tangga (P<0.05). Sistem MPSS boleh digunakan sebagai sistem suspensi alternatif untuk amputi anggota badan bawah kerana penemuan biomekanik termasuk dalam julat yang terdapat dalam literatur dan setanding dengan dua lagi sistem suspensi biasa.

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

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DEDICATION PAGE

To my **mother** whose love is the eternal motive of my life

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LIST OF ABBREVIATIONS

3D	:	Three dimensional
AP	:	Antro posterior
ROM	:	Range of motion
ICEROSS	:	Icelandic Roll on Silicone Socket
PVD	:	Peripheral vascular disease
SD	:	Standard deviation
BK	:	Below knee
TSB	:	Total surface bearing
WHO	:	World health organization
MPSS	:	Magnetic prosthetic suspension system
TT	:	Transtibial
TF	:	Transfemoral
GRF	:	Ground reaction force
ANOVA	:	Analysis of variance
UMCIC	:	University of Malaya Center of Innovation and Commercialization
PTB	:	Patellar Tendon Bearing
PEQ	:	Prosthesis evaluation questionnaire
SACH	:	Solid ankle cushion heel
POP	:	Plaster of Paris
IC	:	Ischial containment
QL	:	Quadrilateral
KBM	:	Kondylen bettung munster
SCSP	:	Supra condylar supra patellar
OI	:	Osseointegration

LIST OF SYMBOLS

%	:	Percentage
mm	:	Millimeter
g	:	Gram
N	:	Newton
HZ	:	Hertz
kPa	:	Kilopascal
η_p^2	:	Partial eta square
P	:	Probability value
V	:	Volt
mAh	:	Milliampere hour
ms	:	Millisecond
KHz	:	Kilo hertz

CHAPTER 1

INTRODUCTION

1.1. Background

Lower limb loss is mainly caused by trauma, diabetes, tumors, congenital limb deficiency, and peripheral vascular disease (PVD) (Smith *et al.*, 2004). According to Smith et al. (2004), lower limb amputations worldwide were mainly attributed to PVD, which is frequently linked to diabetes mellitus. A hasty look at the statistics reveals the increasing number of diabetic patients worldwide. The rate of lower limb amputations in individuals with diabetes is 15 times higher than the healthy people. In the United States alone, 82% of all amputations occur because of vascular disease (Seymour, 2002). The incidence of diabetes mellitus in the Malaysian population has been recorded to be 8.2% in 1966 (second national health and morbidity survey). Additionally, the World Health Organization (WHO) predicted that the prevalence of diabetes will increase to 10.8% (2.48 million people) in Malaysia by 2030. The risk of lower limb amputation, especially foot or above the ankle amputation, has been reported to be 27.7 times higher in diabetic patients (Malaysian Diabetes Association, 2009). Figure 1.1 illustrates the different amputation levels of the lower limb.

Prosthesis or artificial limb is the foremost element in the rehabilitation process of limb loss. Prosthetic components and systems have evolved tremendously in the recent decades to a level that enables amputees to participate in the Olympic Games. However, even with key advances in prosthetic device research and development, numerous amputees remain reluctant to use prostheses because of various physiological and psychological problems. Therefore, the development of new prosthetic systems would

be beneficial in overcoming current prosthetic drawbacks, which will, in turn, result in higher user satisfaction with the artificial limbs.

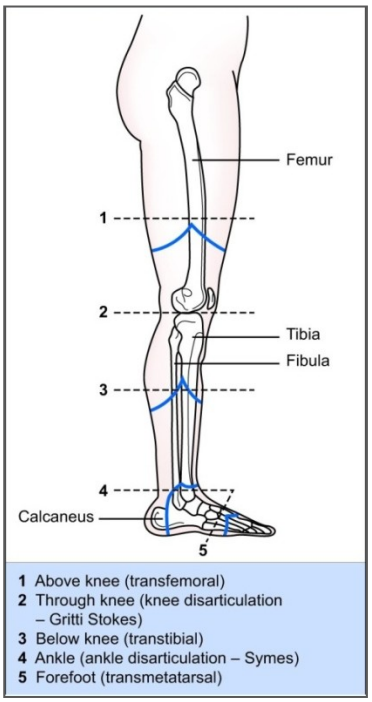


Figure 1.1: Levels of lower limb amputations (Harker, 2006).

1.2. Prosthesis

The rehabilitation of individuals with amputated lower limbs is primarily aimed at reinstating efficient walking ability in the amputee. Achieving this goal requires well-designed artificial limbs or prostheses. The first prosthesis is believed to be fabricated in 300 BC from bronze and wood, and was suspended to the residual limb by a leather skirt (Seymour, 2002). The first printed report of prosthetic use was between 3500 BC to 1800 BC in the Rig-Veda period (Lim, 1997). Modern prosthetic designs were inspired by several famous individuals, such as Lenorado da Vinci and Ambroise Pare. The field of prosthetics is constantly evolving, and rapid developments have materialized in the past decades. In each decade, growth in other fields has been applied to prosthetics by prosthetic professionals. Thus, prosthetic devices have been created to fulfil or surpass user expectations. To date, stronger and lighter materials are being used

in prosthesis fabrication (Cochrane *et al.*, 2001), such as titanium, carbon fiber, silicone, and thermoplastic materials. These construction materials have led to lighter prostheses and better function.

Prosthesis should substitute for the body part that was lost because of amputation throughout the amputee's lifespan, and various components are incorporated in the prosthesis to restore the missing functions. The present study concentrates on lower limb prostheses. Prosthetic limbs for lower limb amputees typically consist of a socket, a soft liner as cushion at the skin-socket interface, a pylon that corresponds to the amputated thigh or shank, a suspension system to securely maintain the prosthetic limb in place, and the prosthetic foot and prosthetic knee (in the case of transfemoral or above-knee prosthesis). These components are connected through adapters, and alignment adjustments may be made between each pair of components. Figure 1.2 depicts the current modular transtibial and transfemoral prostheses.

Figure 1.2: Modular transtibial (left) and transfemoral (right) prostheses (Otto Bock, 2013).

1.3. Prosthetic components for transtibial prosthesis

1.3.1. Socket design

A prosthetic socket encompasses the residual limb and connects other distal parts of the prosthesis to the amputee's remaining leg. The conventional socket design for transtibial amputees is called patellar tendon-bearing or PTB, which is usually fabricated of thermoplastic or lamination material (Radcliffe *et al.*, 1961). This design, which was first introduced in 1959, is supposed to have an intimate fit with the body part (Fergason & Smith, 1999). The anterior socket wall covers the distal third of the patella. An inward bar or counter is located immediately below the patella and at the center of the patellar ligament, and is considered a weight-bearing surface for the prosthesis. The lateral and medial socket walls lie at about the level of the femur adductor tubercle and provide mediolateral/rotary stability. The medial wall is dented at the medial tibial flare, which is the key weight-bearing area and pressure-tolerant surface. A relief area for the distal fibula and fibula head is formed on the lateral wall. The posterior wall applies force in the anterior direction to keep the patellar tendon on the bar and terminates proximally somewhat higher than the patellar bar. Comfortable knee flexion is ensured by the proximal flare of the posterior wall, which is also contoured to relieve the hamstring tendons. The PTB socket maintains the residual limb in 5 to 10 degrees of initial flexion so that the patellar bar converts to a more horizontal force bearing surface. Figure 1.3 shows the lateral view of PTB prosthesis.

The total surface-bearing socket or TSB design is accompanied by a gel or silicone liner. In comparison to the PTB design, this socket-type prosthesis distributes the loads consistently all over the residual limb without any undercut or relief areas to reduce the peak pressure (Beil & Street, 2004). The gel or silicone liner also provides cushioning for the sensitive bony areas. The modification techniques for the TSB are considerably

different from the PTB as there is no need to add plaster to the positive cast. The gel or silicone liner will dissipate the load all over the socket.

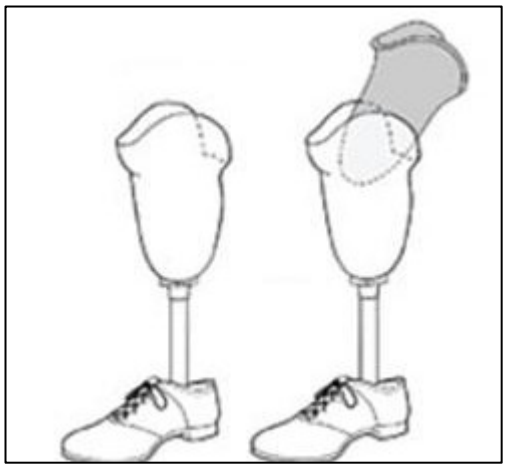


Figure 1.3: Lateral view of the PTB prosthesis (Bosker & Walden, 2008).

1.3.2. Liner

Liners are soft inserts that lie at the residual limb-socket interface and offer additional protection and comfort. The conventional liner, i.e., Pelite liner that is made of polyethylene foam sheet, is used with the PTB socket (Figure 1.4). However, this closed-cell foam liner was reported to cause problems such as perspiration (Lake & Supan, 1997), dermatitis (Hirai *et al.*, 1993), skin abrasions, adventitious bursae (Ahmed *et al.*, 1994), and patellar tendon excessive pressure (Hachisuka *et al.*, 2001). Moreover, the users are at times required to add or remove socks over the residual limb because of volume fluctuation (Coleman *et al.*, 2004).

Figure 1.5 shows the skin problem in prosthetic users.

ICEROSS, or Icelandic Roll-On Silicone Socket, was developed by Kristinsson in the mid-1980s to overcome some of these problems (Kristinsson, 1993). This prefabricated elastic silicone liner is rolled over the residual limb, and then friction or suction is developed between the skin and the gel to hold the liner in place (Baars &

Geertzen, 2005). Gel liners can be used for persons with PVD, individuals with sensitive, thin, or scarring skin, and bony residual limbs. These liners are also particularly convenient for highly active amputees because of the added cushioning.

Figure 1.4: Pelite liner made of the polyethylene foam sheet used with the PTB socket.

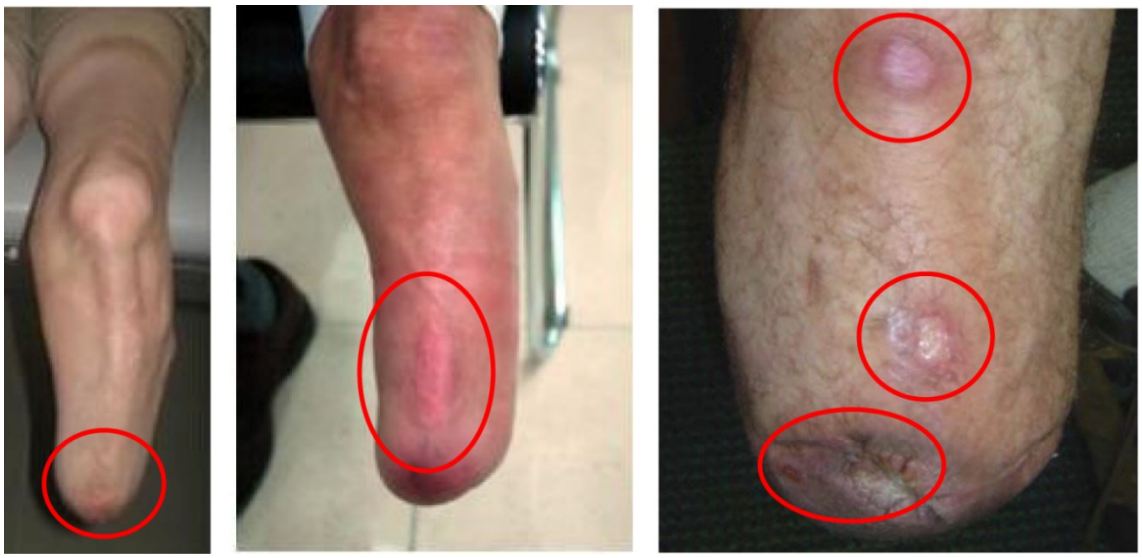


Figure 1.5: Skin problems of the residual limb of prosthetic users.

1.3.3. Prosthetic foot

The prosthetic foot is considered as the interface between the ground and amputee's body, and should replace the lost ankle and foot complex. The prosthetic foot should closely imitate not only the foot function, but also the form (Romo, 1999). Until 1950, the only available prosthetic foot was the one with single-axis ankle joint, which had movement in the sagittal plane. However, the prosthesis was heavy and should be reserved for amputees with knee instability (Smith *et al.*, 2004).

Recent advances have resulted in more cosmetic, light-weight feet. The new prosthetic foot generation, namely, energy-storing foot, was introduced in 1980s (Lim, 1997). The name was derived from the prosthesis ability to store energy and release it at a later stage of walking. These prostheses are also called dynamic-response feet and are more effective if made of carbon fiber (Gitter *et al.*, 1991; Smith *et al.*, 2004). The selection of different designs of dynamic-response feet is dependent on the amputee's body weight, functional needs, and level of activity. Once introduced for high-demanding functions such as jogging, these designs are very popular nowadays even for walking. Several benefits of energy-storing feet are as follows: increased propulsive force at prosthetic side, increased self-selected velocity of walking, higher stride length, and decreased force of weight acceptance at sound side (Gailey, 2005; Hafner *et al.*, 2002). Examples of prosthetic feet can be seen in Figure 1.6. In the current research, the Talux® Flex-Foot (Össur; Reykjavik, Iceland) was utilized.

Figure 1.6: Various types of currently available prosthetic feet.

1.3.4. Suspension systems

Momentum, gravity, and other ambulation forces, predominantly during the swing phase of the gait, tend to displace the prosthesis on the residual limb (Smith *et al.*, 2004). Therefore, various systems were developed to suspend the prosthetic leg securely on the residual limb. The amputee's gait can be improved, and energy expenditure decreased, by the proper suspension system (Schmalz *et al.*, 2002). Several consequences of poor suspension include gait deviation, vertical movement or pistoning within the socket, discomfort, skin breakdown, and decreased user satisfaction (Bruno & Kirby, 2009; Dillingham *et al.*, 2001; Grevsten, 1978; Kapp, 1999; Narita *et al.*, 1997; Schmalz *et al.*, 2002).

Suspension is attained either anatomically or externally through various components. These systems range from socket designs such as supra-condylar/supra patellar system, supra-condylar/supra-patellar system, supracondylar system or PTS, to suprapatellar strap, waist belt, thigh corset, sleeve, vacuum or suction, and locking liner (Figure 1.7). In the case of osseointegration, suspension is achieved through direct attachment of the prosthesis to the residual bone (Webster *et al.*, 2009).

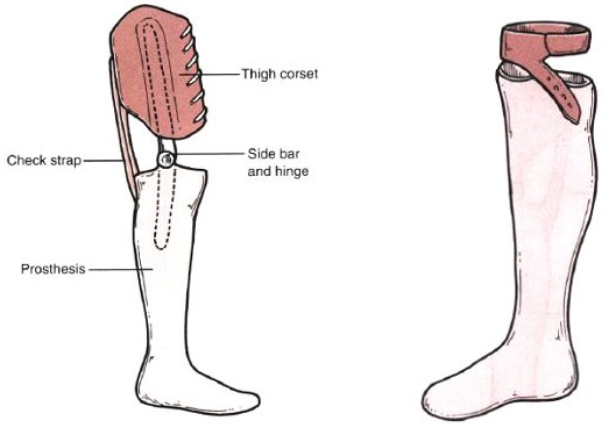


Figure 1.7: Examples of transtibial suspension systems. Left: Thigh corset with side bar & hinge. Right: Cuff strap (Seymour, 2002).

In this research, the suspension systems that were compared with the new prosthetic suspension system developed in this thesis were as follows (Figure 1.8):

i. Pin/lock liner, consisting of Dermo silicone liner and shuttle lock (Icelock-clutch 4 H214 L 214000) by Össur (Reykjavik, Iceland)

ii. Seal-In X5 liner with Icelock expulsion valve 551

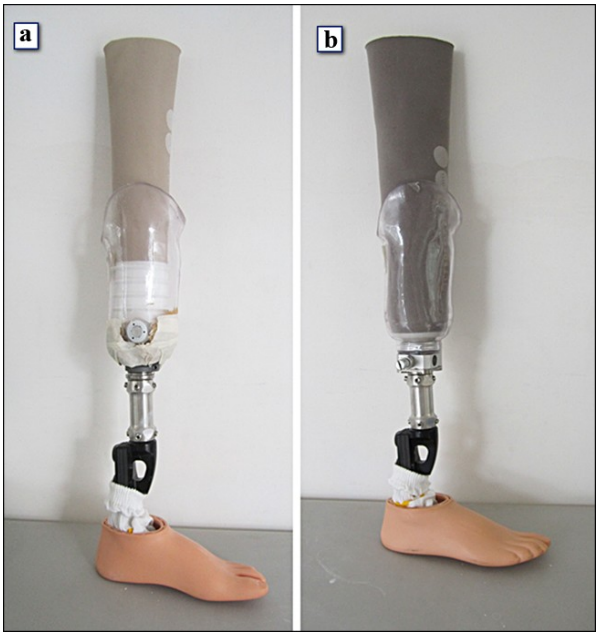


Figure 1.8: Prosthetic suspension systems used in this research. a) Seal-In X5 liner with Icelock expulsion valve 551; b) Dermo silicone liner and shuttle lock (Icelock-clutch 4 H214 L 214000) (Gholizadeh *et al.*, 2012c).

1.4. Prosthesis fabrication process (with silicone liner)

1.4.1. Amputee evaluation

Thorough evaluation of patient background information and physical examination is performed by the rehabilitation team, including the prosthetist, prior to the selection of the socket, components, and suspension systems. Prosthetics prescription is based on several factors, including level of activity, time since amputation, lifestyle, soft tissue health, medical condition, skin problems of residual limb, joint range of motion, muscle strength, amputee's employment status, and extra activities such as sports (Figure 1.9).

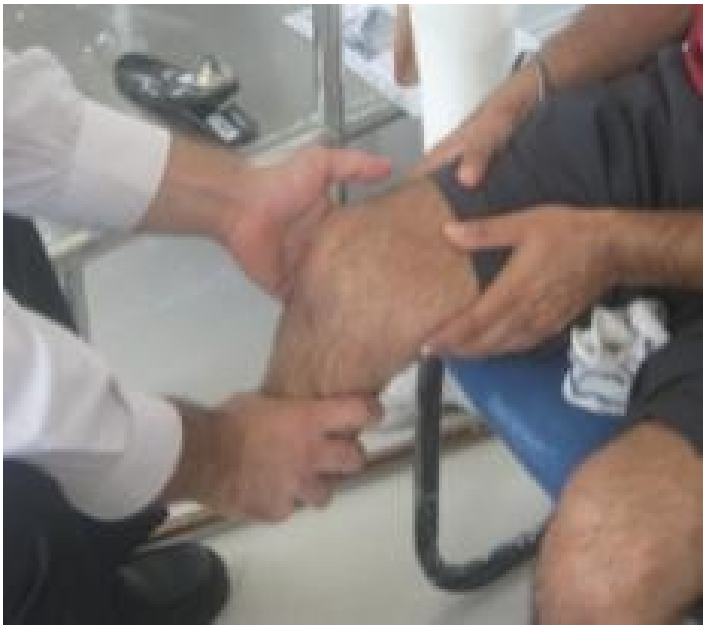


Figure 1.9: Physical examination of amputee.

1.4.2. Measurement

A qualified prosthetist should measure the residual limb circumference at different areas, anterior-posterior width, medial-lateral width, residual limb length, and patient height (Figure 1.10).

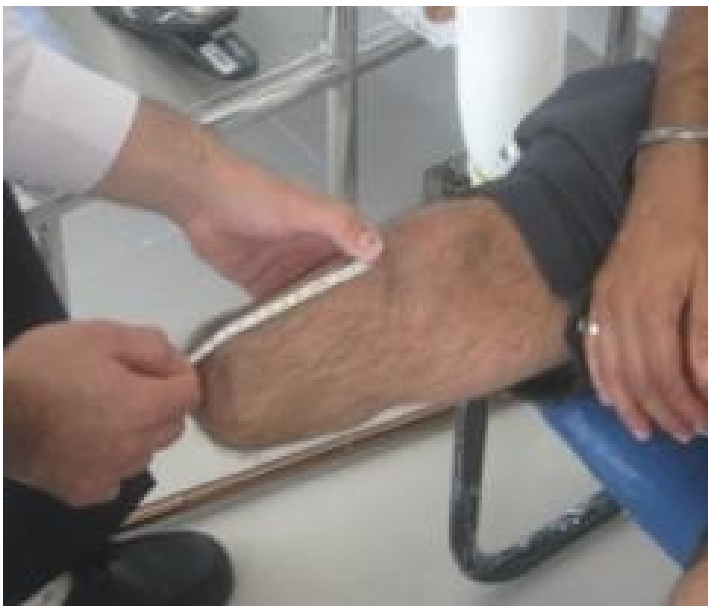


Figure 1.10: Measurement of the residual limb.

1.4.3. Taking impression (casting)

To ensure the precise impression of the residual limb, a negative cast is mandatory. Plaster of Paris (POP) bandages are commonly used for casting (Figure 1.11), which is done using two methods: manually and through the computer aided design/computer aided manufacturing (CAD/CAM) machine. The most common practice is manual casting.

Figure 1.11: Taking an impression of residual limb using the Plaster of Paris.

1.4.4. Positive cast and modification

At this stage, the negative cast is filled with a mixture of water and POP powder, and the resultant product is called a positive cast (Figure 1.12). The process also involves modifying the positive mold by the prosthetist according to the biomechanics of prosthesis design (Figure 1.12). In the present research, the total surface bearing (TSB) socket required a balanced distribution of the loads over the residual limb soft tissue.

Figure 1.12: Procedure of cast modification.

1.4.5. Check socket and testing on amputee

A check or test socket is typically fabricated from transparent thermoplastic sheets that enables to see through its walls. The plastic is draped over the modified positive cast in a process called thermoforming (Figure 1.13). Subsequently, a specialized jig is used to check the fitting of the socket on the amputee's residuum. The transparent socket permits checking the areas under high or low pressure.

Figure 1.13: Procedure of check socket fabrication and fitting.

1.4.6. Definitive socket, prosthesis assembly, and aligning

After ensuring of the socket fit, a definitive socket is fabricated from epoxy resin or polypropylene sheet. Afterwards, prosthetic components are assembled by the prosthetist, followed by bench, static, and dynamic alignments (Figure 1.14).

Figure 1.14: Bench and dynamic aligning of the definite prosthesis using the laser liner.

1.4.7. Functional gait training

The amputee should undergo functional training to learn walking with the prosthesis, as well as stair and ramp negotiation (Figure 1.15). The amputee should be also able to walk on uneven terrain and cross curbs as part of daily living activities.

Figure 1.15: Gait training with the prosthesis in the parallel bars and on stairs.

1.5. Problem statement

The socket fit and suspension system have considerable influence on amputee's mobility, comfort, and satisfaction with artificial leg (Ali *et al.*, 2012b; Baars & Geertzen, 2005; Gholizadeh *et al.*, 2013; Kristinsson, 1993). The suspension system is meant to prevent translation, rotation, and pistoning (vertical movement) of the residual limb in relation to the prosthesis socket. Negative effects of poor suspension on rehabilitation, as well as the comfort and activity level of lower limb amputees, had been reported previously (Kristinsson, 1993; Van de Weg & Van der Windt, 2005). A survey on 146 prosthetic users showed that the majority were not satisfied with the prostheses because of skin problems and pain (Dillingham *et al.*, 2001). A study by Kark and Simmons (2011) also revealed that the amputee participants were not content with their prostheses (Kark & Simmons, 2011). In total, 77% of the users were less satisfied with the polyethylene foam liner than with the pin/lock system (Coleman *et al.*, 2004). In contrast, nearly all the participants of a prospective study favored the polyethylene foam liner (Boonstra *et al.*, 1996). Thus, to clarify these controversial findings, a retrospective study was conducted by the research team, including the author of this thesis. The majority of lower limb amputees were revealed to be dissatisfied with their prostheses. The questionnaire survey was performed on 243 males with traumatic unilateral transtibial amputation. The commonly used suspension systems were identified as the pin/lock system, the polyethylene foam liner, and the Seal-In suspension. Satisfaction with suspension system is a multifaceted issue. Based on the literature, the modified prosthetic evaluation questionnaire (PEQ) surveyed the common problems and satisfaction items (Table 1.1).

The findings indicated that the participants were more satisfied with the Seal-In suspension, compared with the pin/lock and the polyethylene foam liner (Gholizadeh *et al.*, 2013). Significant differences were found in the perceived problems among the suspension systems, except for sweating; mainly, the polyethylene foam and the Seal-In suspension caused high levels of sweating. The overall satisfaction was higher with the Seal-In system than with the pin/lock and the polyethylene foam liner. The participants also preferred the pin/lock and Seal-In liner over the polyethylene liner, which contradicted the studies by Boonstra *et al.* (1996) and Coleman *et al.* (2004). The findings of both studies were against the pin/lock system; however, McCurdie et al. (1997) clearly established the preference for the pin/lock (McCurdie *et al.*, 1997). Later, Van der Linde et al. (2004) designated that professionals in the field of prosthetics favored the pin/lock system, as well (Van der Linde *et al.*, 2004).

Table 1.1: The questionnaire items related to satisfaction and problems with suspension systems.

Satisfaction Items	Problems & Complaints
Fitting	Sweating
Donning & Doffing	Wound
Sitting	Irritation
Walking-Even Surface	In-socket Pistoning
Walking-Uneven Surface	In-socket Rotation
Stair Negotiation	Inflation
Quality of Suspension	Bad Odor
Cosmesis	Irritating Sound
Durability	Pain
Overall Satisfaction	Overall Problems

Aström and Stenström (2004) and Hatfield and Morrison (2001) revealed that amputees were more comfortable with the pin/lock than the polyethylene foam liner (Åström & Stenström, 2004; Hatfield & Morrison, 2001). The same was observed in our study, as the participants were more satisfied with the pin/lock and the Seal-In

suspension during walking (even and uneven ground) and stair negotiation (Gholizadeh *et al.*, 2013). Enhanced cosmesis and suspension of the prosthesis have positive effects on function and satisfaction (Wirta *et al.*, 1990). Improved suspension was shown with the pin/lock and Seal-In suspension, compared with the polyethylene foam liner in our study. This result was consistent with the findings of Cluitmans et al. (1994) and Baars and Greetzen (2005), who observed improved suspension with the pin/lock system (Baars & Geertzen, 2005; Cluitmans *et al.*, 1994).

The ease of donning and doffing is essential for prosthetic users (Baars *et al.*, 2008; Baars & Geertzen, 2005). In our study, the users found that the Seal-In suspension was more difficult to don and doff than the pin/lock and polyethylene liners. Previous reports stated that the amputees were more satisfied with the Seal-In suspension than the pin/lock system because of lower pain and enhanced suspension (Gholizadeh *et al.*, 2012b). Majority of the participants were found to have fewer problems with the Seal-In than with the other systems. Nevertheless, donning and doffing the system was challenging.

Research has shown that the pin/lock system exerts 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. This milking phenomenon is probably the cause of the observed short- (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, discomfort, and residual limb atrophy or volume loss. Similarly, the satisfaction survey compared the Seal-In and pin/lock systems and revealed higher pain with the pin/lock (Gholizadeh *et al.*, 2013).

The previous literature reported the main problems of lower limb amputees with the common suspension systems incorporating the soft silicone liners. The survey studies by the author of this thesis also indicated the controversy over the optimal suspension system for lower limb prostheses. No single suspension system was shown to be efficient in all aspects for all types of users. For instance, one system was easier to don and doff but was painful during walking, whereas the other caused reverse issues. The durability and high maintenance with the current suspension systems that incorporate mechanical components was also a concern (Gholizadeh *et al.*, 2013). From the insights provided by the literature reviews and survey studies, designing a new suspension system is deemed necessary to enhance the positive qualities of the current systems, while reducing their drawbacks. Therefore, this research focused on the design, development, and in vivo evaluation of a suspension system for lower limb amputees.

1.6. Purpose of the Study

This research attempted to develop a new prosthetic suspension system, as well as to explore the biomechanics of the prosthesis incorporating the new system of suspension for transtibial amputees. To achieve this research aim, the subsequent objectives were identified:

i. To develop a new prosthetic suspension system for individuals with lower limb amputation;
ii. To evaluate pistoning with the new prosthetic suspension system in comparison with two other existing suspension systems;
iii. To investigate the interface pressure with the new prosthetic suspension system in comparison with two other existing suspension systems;

iv. To examine the kinetics & kinematics of gait with the prosthesis incorporating new prosthetic suspension system in comparison with two other existing suspension systems; and,

v. To determine the satisfaction and perceived problems with the new prosthetic suspension system in comparison with two other existing suspension systems.

1.7. Organization of the thesis

This thesis was written in the format of peer-reviewed published papers and may therefore contain certain redundancies, particularly in the Introduction and Literature Review chapters. This research exploited the area of prosthetic suspension systems and attempted to design, develop, and evaluate a new prosthetic suspension system for lower limb prostheses. **Chapter 1** provides a concise overview of prosthesis background, prosthetic components, fabrication, aligning, and fitting process for common lower limb prosthesis. The problem addressed in this research and the objectives are presented, followed by an account of the research progress in the form of published articles.

Chapter 2 of this thesis presents the current knowledge concerning various prosthetic suspension systems for lower limb amputees and respective methods of efficiency evaluation. In this review of literature, the advantages and disadvantages of current prosthetic suspension systems are also critically discussed.

Chapters 3 to 7 comprise published findings of this thesis as ISI articles in high quality journals. These articles describe the design and development procedures of a novel prosthetic suspension system and its effects on pistoning, interface pressure, and

gait kinetics and kinematics. **Chapter 3** describes the development and specifications of the new magnetic suspension system (MPSS), as well as how the system functions. It will also elucidate on the acoustic alarm system for the suspension system, which had been designed and developed for the first time.

Chapter 4 provides a quantitative and qualitative evaluation of the new prosthetic suspension system in terms of pistoning inside the prosthetic socket, as well as satisfaction and perceived problems among the transtibial amputees.

Chapter 5 evaluates and compares the interface pressure within the prosthetic sockets suspended with the new magnetic suspension system, pin/lock and Seal-In systems during level walking.

Chapter 6 covers the evaluation of interface stress at the socket-residual limb interface with transtibial prosthetic suspension systems including the MPSS during locomotion on slopes and stairs.

Chapter 7 provides a detailed explanation on the gait kinetics and kinematics with prostheses incorporating the MPSS, the pin/lock and Seal-In suspension systems. The gait deviation index was also calculated and compared among the suspension systems.

Finally, **Chapter 8** deliberates on the outcomes of the research, their impact on this thesis, and explores implications for future research.

CHAPTER 2

LITERATURE REVIEW

2.1. Overview

This chapter provides a review of the related literature on the research subject and ends by identifying prospective challenges. The literature review aims to provide an outline of the body of knowledge concerning the existing prosthetic suspension systems for lower limb amputees. Figure 2.1 depicts the focal point and the different aspects of this research. The relevance and rationale of prosthetic suspension systems, as well as the advantages and disadvantages, will be examined. The review also elaborates on the methods of assessing the suspension systems' efficiency. This chapter presents an inclusive literature review composed of reputable publications.

The publication trend shows that lower limb amputation has been a topic that generated considerable interest in the recent years. Figure 2.2, Figure 2.3 and figure 2.4 illustrate the distribution of published/cited articles per year for the last three decades extracted from the Web of Science®. A systematic literature review by the author of this thesis showed that suspension systems for transtibial prostheses have been studied since 1990. Interestingly, 8 out of 20 articles on the suspension systems were published between 2011 and 2012, showing a positive trend in research on prosthetic suspension systems. Preliminary filtering was based on the academic impacts of authors, i.e. h-index. H-index for every scientist means that at least h citations has been gained by his/her Np papers, whereas other papers (Np−h) have no more than h citations each (Hirsch, 2005).

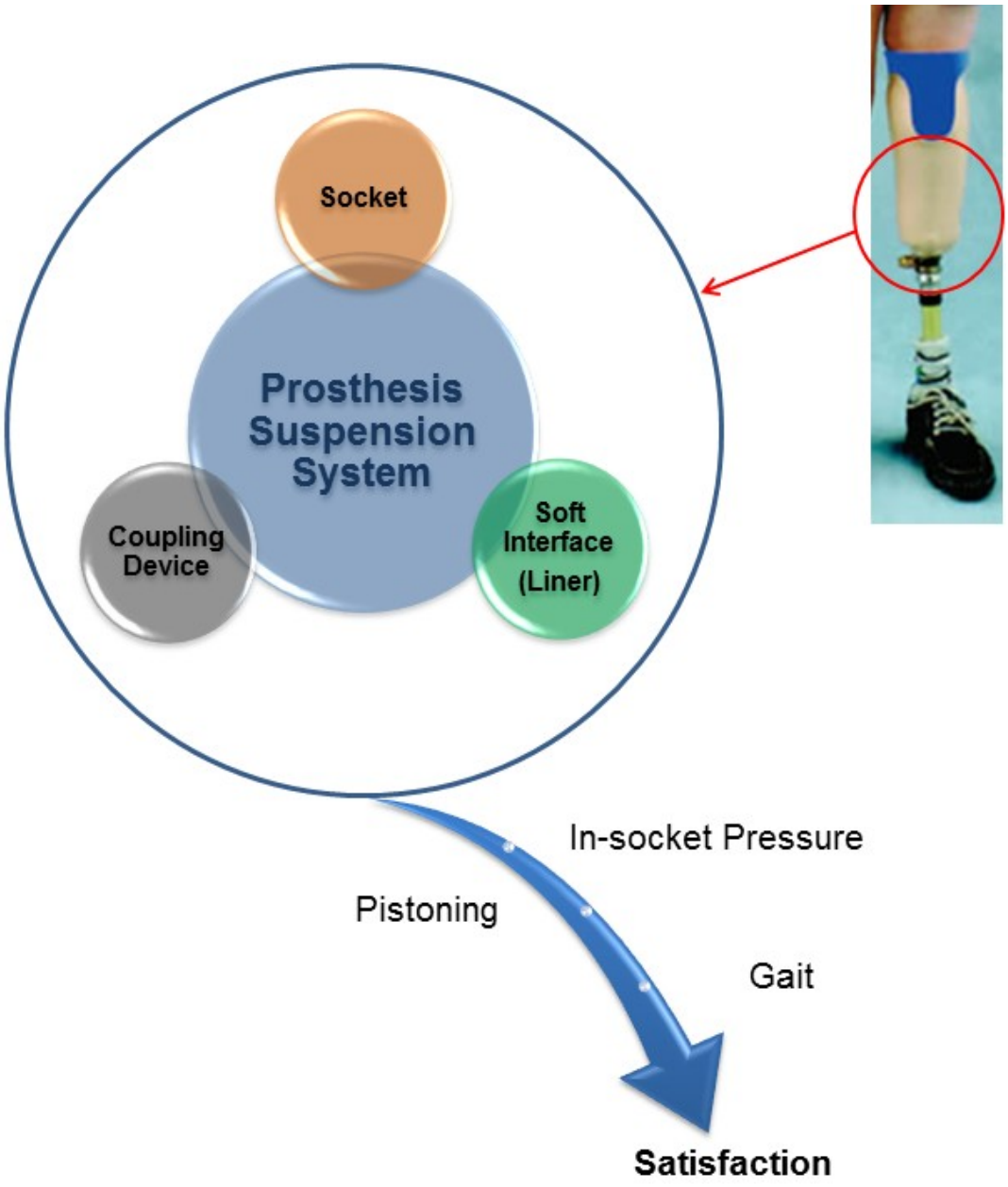


Figure 2.1: The focal point and the different aspects of this research.

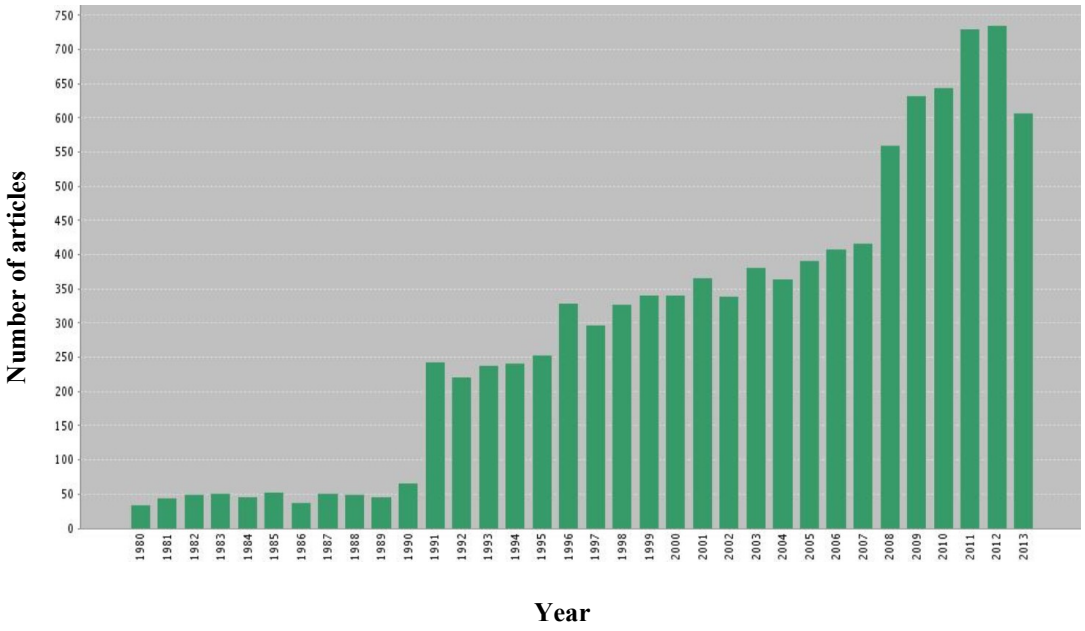


Figure 2.2: Publication trend related to amputation (Web of Science®, 2013).

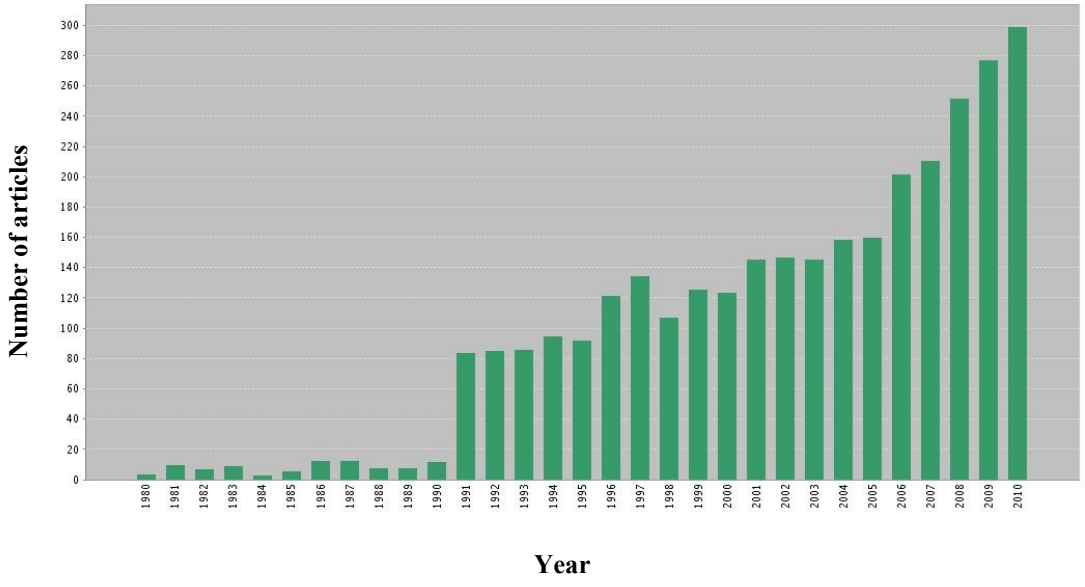


Figure 2.3: Publication in the field of lower limb amputation (Web of Science®, 2010).

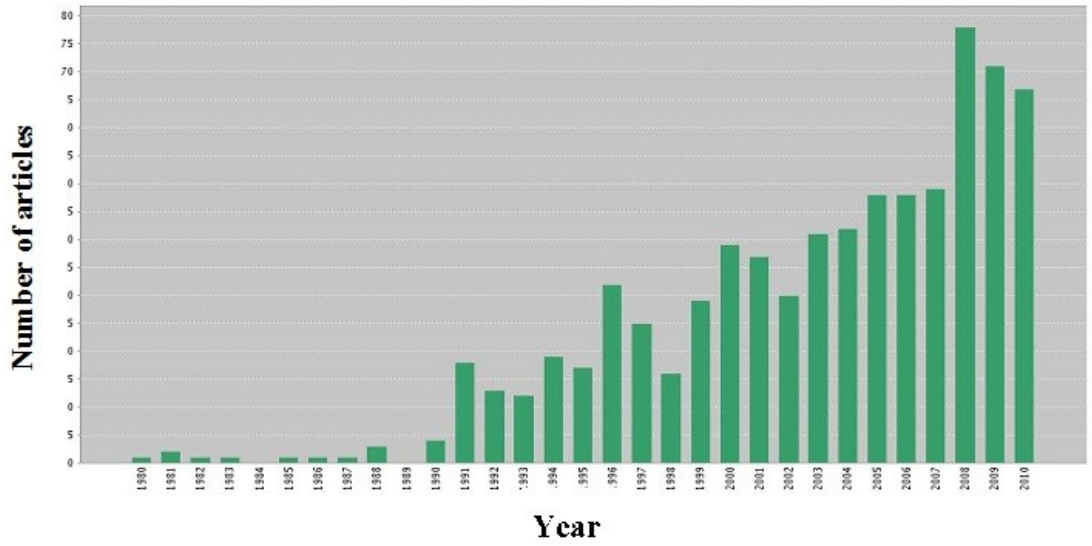


Figure 2.4: Publication trend in the lower limb prosthesis (Web of Science®, 2010).

2.2. Suspension of prosthesis

Various forces, such as momentum and gravity, tend to displace the lower limb prosthesis on the residual limb during ambulation, mainly at the swing phase of gait. 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 (Eshraghi *et al.*, 2012a; Garrison, 2003; Gholizadeh *et al.*, 2012c; 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.*, 2012a; Eshraghi *et al.*, 2012b; Gholizadeh *et al.*, 2012a; Gholizadeh *et al.*, 2011; 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; 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;

Gholizadeh *et al.*, 2012c; Papaioannou *et al.*, 2010; Peery *et al.*, 2005; Smith *et al.*, 2004).

Although prosthesis tremendously aids in improving the amputee's quality of life, this sophisticated system may have drawbacks that cannot be ignored. For instance, residual limb soft tissue and skin are not meant to bear loads, particularly of the prosthetic socket. Moreover, daily volume fluctuations are of concern to the prosthetic providers and users. The positive pressure applied to the soft tissue results in fluid loss and volume change (Fernie & Holliday, 1982; Goswami *et al.*, 2003). The residual limb is also subjected to high abnormal shear and compressive pressures (Jia *et al.*, 2004; Sanders *et al.*, 1992; Silver-Thorn *et al.*, 1996), which is of particular concern to amputees with bony residual limbs.

2.3. Suspension systems for lower limb prosthesis

Several prosthetic suspension systems are available for lower limb amputees. Not only the amputee's functional needs, but also satisfaction with prosthesis should be the taken into account when selecting an appropriate suspension system. A clearer insight into suspension systems leads to easier selection for prosthetist (Eshraghi *et al.*, 2012a; Garrison, 2003; Gholizadeh *et al.*, 2012c; Kapp, 1999; Nelson *et al.*, 2006; Schaffalitzky *et al.*, 2012; Zhang *et al.*, 1998). A systematic literature review by the author showed that prosthetic suspension systems have been studied as early as 1994. The trend of research on suspension systems in various countries can be seen in Figure 2.5.

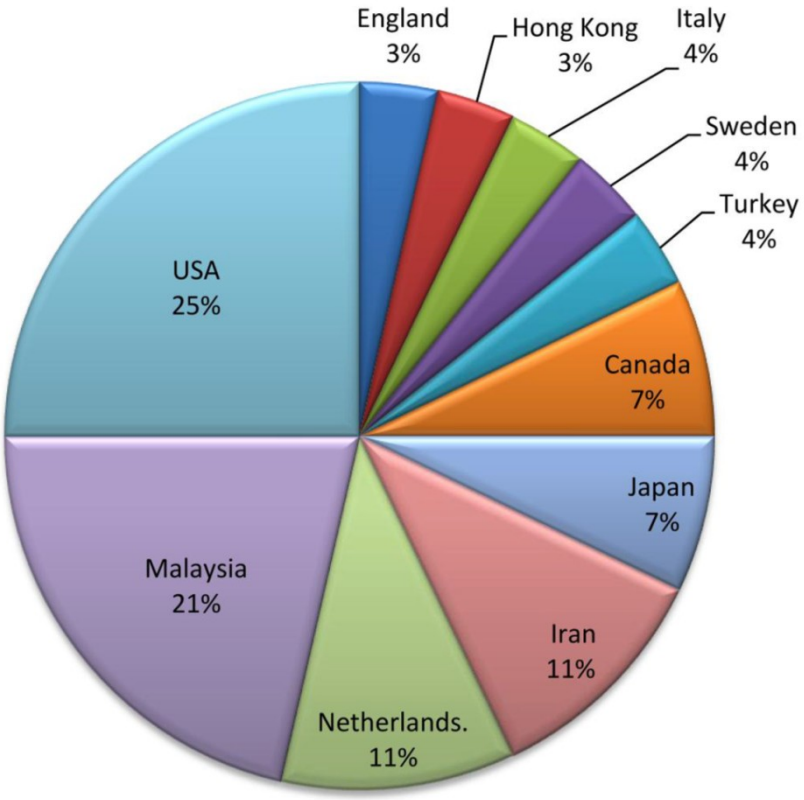


Figure 2.5: The percentage of published articles in the field of prosthetic limb suspension (Gholizadeh *et al.*, 2014).

The introduction of new designs and materials revolutionized the design of transtibial prosthetic after World War II (Sewell *et al.*, 2000). A thigh corset was used as suspension for years prior to the introduction of the patellar-tendon bearing (PTB) prosthesis (Radcliffe *et al.*, 1961). The latter can off-load the residual limb to a degree because weight is borne proximally inside the socket. The PTB socket quickly became popular, and various materials and suspension methods were subsequently applied (Sewell *et al.*, 2000). Afterwards, the 3S (Fillauer *et al.*, 1989) and ICEROSS sockets (Kristinsson, 1993) were introduced to the market. These systems were characterized by improved technique of suspension, total surface bearing (TSB), and hydrostatic loading (Sewell *et al.*, 2000; Staats & Lundt, 1987). The main objectives of prosthetic socket are to stabilize the residual limb in the sagittal and coronal planes, to attain body weight support, to control the prosthetic knee voluntarily, to ensure proper function of muscles,

and to achieve harmony of appearance, function, and comfort, both dynamically and statically (Michael *et al.*, 1990; Radcliffe, 1955). Two main recent socket designs for transfemoral prosthesis are ischial containment socket and the quadrilateral socket (IC and QL) (Kapp, 1999; Schuch & Pritham, 1999). The proximal brim contours differentiate these two designs; in the IC socket, the ischium is inside the socket, whereas the ischium is not contained in the QL socket. An evolution to the IC socket is the M.A.S. socket, which was developed by Marlo in 1999.

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 (Kristinsson, 1993). Patients who cannot manage the challenging process of donning suction systems benefit from silicone liners. The silicone liner, composed of elastomeric gel, is slid or rolled over the residual limb. Friction or suction between the skin and the gel clamps the limb to the liner. The gel is said to decrease the shear forces transferred to the residual limb, and thus, guard the skin. Various suspension methods are used, such as a suction seal, distal pin, hook and Velcro adhesion, or lanyard. Puncturing or tearing of the liner may result in suspension failure (Kapp & Fergason, 2004) These types of suspension are usually costly and should be replaced frequently, generally within a year (Hatfield & Morrison, 2001). A silicone locking liner has a pin and shuttle lock. Pin suspension incorporates a distal metal pin attached to the liner that is locked into the socket distal end. Volume fluctuations are controlled by adding prosthetic socks.

Although the use of liners is not novel, various materials and designs have been developed in the past decade. Developing more comfortable sockets with good cosmesis, while decreasing the frequency of skin breakdown, has been attempted. Liners as prosthetic suspension were first developed in the 1980s. These internal mechanisms of suspension eliminated exterior strapping and belt systems, which were

usually cumbersome, bulky, and less cosmetic. In addition, the liner suspension mechanisms reduced the pistoning motion between the residual limb and prosthesis, and increased the freedom of activity (Dietzen *et al.*, 1991).

During 1990s, new materials for prosthetic liners were investigated to improve upon the weaknesses of earlier liners by intensifying the advantage of cushioning to prevent skin breakdown and promote comfort. These liners aimed to make a total contact fit, dispersing pressure over the residual limb, and to restrict excess movement of the residual limb (Emrich & Slater, 1998). Several believed that high coefficient of friction between the residuum-liner and the liner-socket will diminish the piston movement (Emrich & Slater, 1998). Furthermore, low transmission of the force from the liner to the residual limb was assumed to prevent ill effects. After dealing with high coefficient of friction, volume fluctuation necessitates that the materials allow for variability in fit, while preserving proper alignment and contact on the residual limb.

As the liner bears constant loading either through compressive stress during ambulation and donning, or tensile stress (as the liner is pulled downwards by the prosthesis and simultaneously upwards by the residual limb), durability is a major concern (Cochrane *et al.*, 2001). Although low in durability, the polyurethane and silicone liners are said to decrease the quantity of shear forces that may cause skin breakdown. Durability issues have been addressed by subsequent designs through the addition of cloth liners and matrix materials to increase the resilience. Furthermore, the enhanced cushioning properties decreased shear forces, but certain problems are still unsolved. Nevertheless, silicone is seen as the safest and most hypoallergenic available biomaterial; skin reactions may be caused by antioxidants or rubber accelerators, and does not generally exist in silicone.

Advances in materials and custom fitting have provided improved suction suspension to offer total contact sockets to amputees (Pasquina *et al.*, 2006). Otto Bock Health Care and Tech Harmony have introduced a vacuum-assisted socket system (VASS) (Figure 2.6). The principle is to suspend the prosthesis by generating negative pressure inside the socket, especially during the swing phase of gait. This system is claimed by the manufacturers to improve perfusion of the residual limb, reduce changes in limb volume, and improve comfort and fit. The cumbersome system comprised a suspension sleeve, a liner, and air evacuation pump. The system either uses a mechanical or an electronic pump, using a sensor to control the necessary negative pressure within a definite range. Figure 2.7 shows an electronic pump. A gel-coated sleeve seals the negative pressure system on the exterior.

Figure 2.6: Vacuum-assisted socket system (VASS).

However, only a few objective clinical trials show the efficiency of this system. Sanders et al. (2011) measured the fluid volume of the residual limb in seven transtibial amputees by bioimpedance analysis using both non-elevated and elevated vacuum sockets. The findings of this case series study did not consistently establish that limb fluid volume was maintained or increased by the elevated vacuum. The system was also shown to affect only certain measures of fluid volume change at the residual limb (Sanders *et al.*, 2011). One of the disadvantages of the system is the heavy weight and the bulky appearance caused by the sleeve. Another randomized controlled trial revealed that that early use of the Harmony system in amputees with open wounds/ulcers at the residual limb did not increase pain, nor hinder healing (Traballesi *et al.*, 2012). The ICEROSS Seal-In liner is also a simpler suction suspension that incorporates a circumferential membrane lip around the liner's distal aspect to generate a negative pressure during gait from the stance to the swing phase. The system will be discussed in more detail in the next section.

Figure 2.7: Harmony electronic pump (Otto Bock, 2013).

Although a number of prosthetic suspension systems are available, physicians and prosthetists set the selection criteria mainly based on subjective experiences (Van der Linde *et al.*, 2004). The end user or amputee requires further knowledge as quality of care is gaining more attention. Ideally, prosthetic prescription should follow the biomechanical characteristics to fulfil the amputees' needs. Clinical prescription

guidelines should be provided for prosthetic suspension systems to ensure efficient and consistent health care.

A systematic literature review by the author showed that the following transtibial suspension systems were mainly used in the former studies:

i. TSB socket with pin/lock systems that uses Dermo liner, TEC liner, Alpha liner (3,6, and 9 mm), elastomeric gel liner, and ICEX system;
ii. TSB socket with suction or vacuum system that uses Seal-In X5 liner, polyurethane liner, and neoprene sleeve;
iii. TSB socket with magnetic lock system;
iv. PTB and KBM sockets (i.e., Supra Condylar Supra Patellar (SCSP), Supra Condylar (SC), cuff, waistband, figure of eight suprapatellar strap, rubber sleeve, articulated supracondylar wedge);
v. Osseointegration.

Several suspension systems are used with transfemoral prostheses, including hip joint with pelvic band, the Silesian belt, silicone liners with or without a shuttle lock and suction socket (Carroll & Edelstein, 2006; Dietzen *et al.*, 1991; Kapp, 2000; Klute *et al.*, 2010). Hip joints with pelvic band and the Silesian belt are preferred by geriatric amputees for ease, and by amputees with short residual limb because of good suspension (Dietzen *et al.*, 1991; Smith *et al.*, 2004).

Bone anchorage is another alternative to conventional suspension techniques. Osseointegration (OI) was introduced in Sweden (Branemark *et al.*, 2001) and is recently used in other countries, such as in the United Kingdom (Smith *et al.*, 2004; Sullivan *et al.*, 2003). 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). This method entails surgical procedures, which was not intended in the current dissertation. Lower-limb amputees discontinue the use of prosthesis not only because of high energy expenditure, but also as a result of skin problems, discomfort, and perspiration (Baars & Geertzen, 2005; Branemark *et al.*, 2001; Carroll & Edelstein, 2006; Cumming *et al.*, 2006; Dillingham *et al.*, 2001; Fairley, 2004; Gauthier-Gagnon & Grisé, 2006; Hagberg *et al.*, 2008; Pohjolainen *et al.*, 1989). 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 (Hachisuka *et al.*, 2001; Hagberg & Brånemark, 2001; Hagberg & Brånemark, 2009; Hagberg *et al.*, 2005; Klotz *et al.*, 2011). According to Hagberg et al. (2001), the hip joint range of motion is significantly decreased and discomfort in sitting is increased with conventional socket in comparison to osseointegration (Hagberg & Brånemark, 2001). Osseointegrated prosthesis hoped to help in the rehabilitation of transfemoral amputees by increasing quality of life. Yet, several unsolved problems exist with the technique, such as risk of infection and fracture, long process of rehabilitation, and not being a good option for patients with higher levels of activity.

At present, two suspension systems for lower limb amputees are commonly used worldwide, namely, the pin/lock suspension and the Seal-In system, which were studied in this research in comparison with the newly designed magnetic lock (MPSS). The specifications of each system are provided with more details below.

2.3.1. Pin/lock suspension

Several pin lock designs are currently available, and new pin locks are being presented in the market each year, making the choice of pin/locks more difficult for prosthetists than other prosthetic components. Notably, no one best pin lock design exists. Every pin lock has particular features that may be favorable or unfavorable for a certain patient. This suspension liner secures the socket to the liner via a distal stainless steel pin attached to a shuttle lock installed in the distal socket (Figure 2.8). The liner, together with the pin, is released from the socket (shuttle lock) by pressing a button on the exterior wall of the socket.

Figure 2.8: The pin/lock liner.

Several coupling designs exist in the market, such as the clutch lock (pull lock, or pull-in lock), shuttle lock and smooth lock (with ball bearings) (Figure 2.9). Shuttle locks (also known as push-in lock, push lock or ratchet lock) are the most common pin lock styles. These locks have a one-way gear mechanism that assists in engaging and locking the pin. The end cogs align with the pin serrations when the pin moves into the gear mechanism (Figure 2.10). Several bushings in line with roller bearings enrich the

gear mechanism. Linear and rotary bearings are occasionally combined. The linear bearings aid the gear mechanism to have free rotation in one direction, but the rotation in the opposite direction is not allowed because of the canted surface of certain bearings (Figure 2.11). As the rotation is only possible in one direction, the pin cannot come out of the mechanism until the gear mechanism is moved away from the pin with the pull/push button.

Figure 2.9: The current lock systems for lower limb prosthesis suspension.

Figure 2.10: Geared pin and gear mechanism. The rotation of gear mechanism is only possible in one direction, not allowing the pin to lift out of the lock. The gear mechanism slides away from the pin only if the pull/push button is operated.

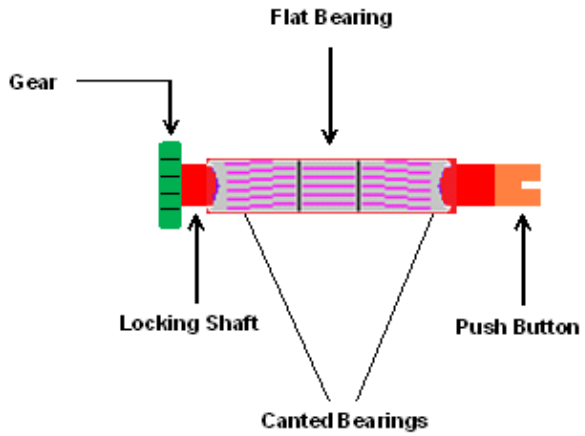


Figure 2.11: Gear mechanism, roller bearings and adjacent bushings.

2.3.1.1. Donning procedure

To don the liner, the liner should be turned inside out and gripped with one hand. The inside of the liner should be dry, clean, and free from any skin irritating foreign objects. Next, the distal end of the liner should be exposed to its maximum, positioned against the residual limb, and rolled up over the limb with light compression. The patient should ensure that no air pocket is present. Extra care should be taken not to damage the liner with fingernails, or by pulling or tugging (Figure 2.12).

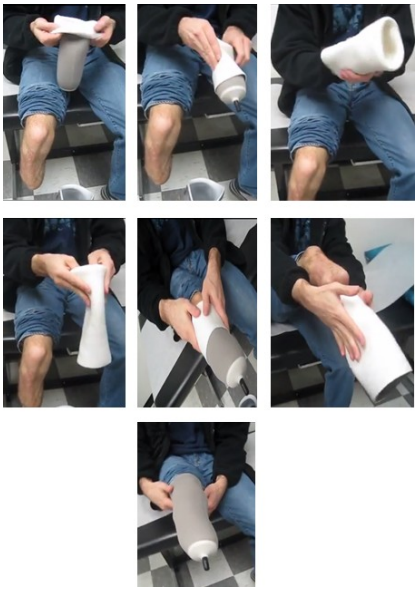


Figure 2.12: The donning procedure of a pin/lock liner.

After that, the patient should position the prosthesis under his residual limb and push the limb together with the pin into the socket. Then, he/she should stand up and push the limb all the way down into the socket until the pin is fully engaged in the pin lock mechanism (Figure 2.13).

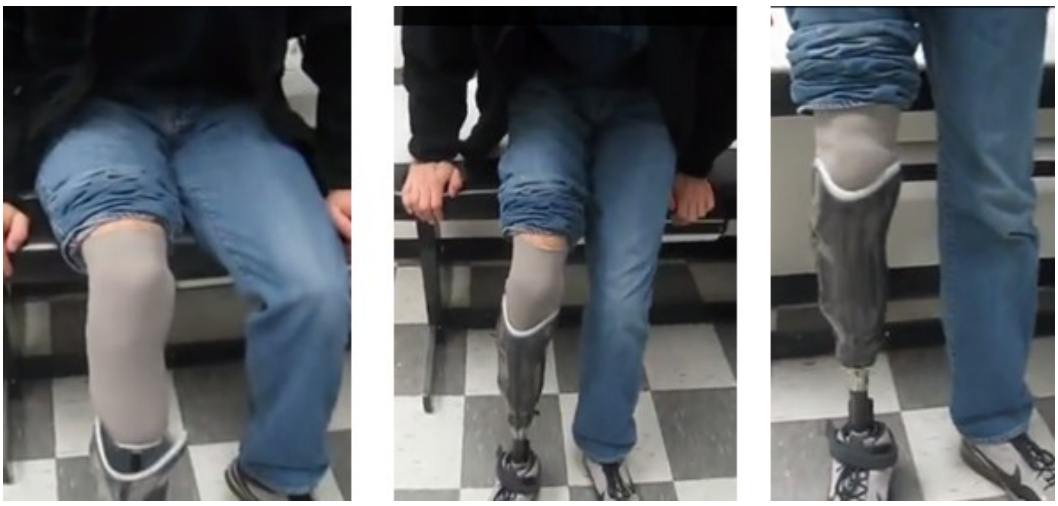


Figure 2.13: The procedure to don the prosthetic socket with the pin/lock suspension.

2.3.2. Seal-In suspension

Recently, Össur (Reykjavik, Iceland) introduced the Seal-In® X5 as a new suction suspension having hypobaric sealing membrane that is said to increase contact with the socket wall to suspend the prosthesis (Figure 2.14). Therefore, no additional lock system or external sleeve is needed to ensure the suspension.

Figure 2.14: The Seal-In X5 transtibial liner suspension.

There are one or more hypobaric sealing membranes around the ICEROSS Seal-In liners in order to follow the shape of the interior socket wall, developing an airtight seal. Made of exclusive silicone blend, hypobaric sealing membrane(s) is attached distally to the liner. The location of the hypobaric sealing membranes is critical, and is precisely designed to warrant the quick expel of air through an expulsion valve positioned at the distal socket end. Good rotational control and suspension of the prosthesis are ensured through the hypobaric condition underneath the membrane. The needed suspension force and the pressure are always proportional inversely, warranting superior comfort, stability, and control. A push button helps releasing the hard socket. The one-way, auto expulsion valve used with ICEROSS Seal-In liner should have a push-button release for suction, because the socket cannot be removed without a release mechanism that directs air back into the socket (Figure 2.15).

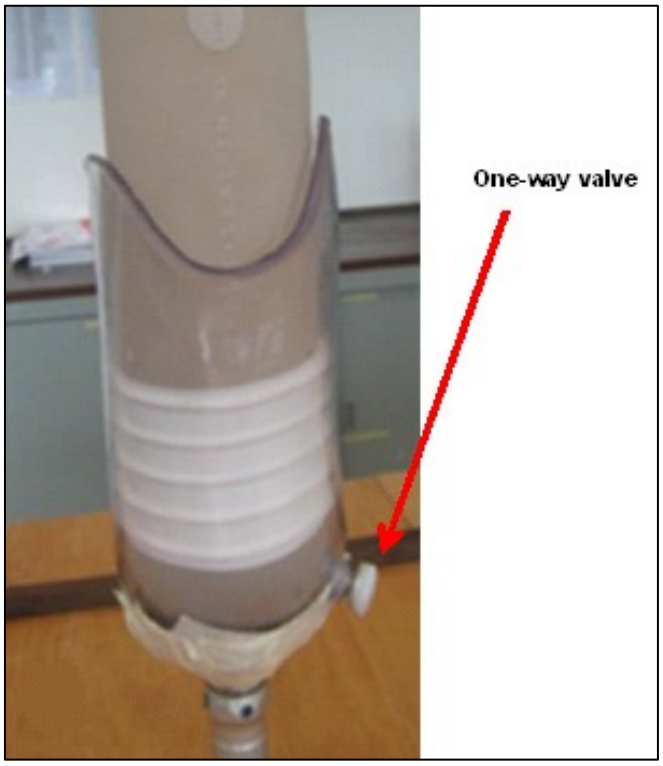


Figure 2.15: The suction socket with one-way expulsion valve for transtibial prosthesis.

2.3.2.1. Donning technique

The liner should be first cleaned with lukewarm water and dried. The following procedures should then be implemented: the liner is turned inside out. The top of the liner is gripped and slid over the hand to fully expose the inner surface. For easier rolling, lubricant spray is applied into the inverted liner. The liner is positioned against the residual limb and rolled upward with a small compression (Figure 2.16). No air pockets should be present as these pockets can result in excessive perspiration or skin complaints. Extra care should be taken not to damage the liner with fingernails, or by pulling or tugging. The seals should be positioned horizontally all around the liner.

Afterwards, the steps below are followed to don the prosthesis:

i. The Seal(s) and inside the socket are sprayed lightly for smoother entry.

ii. The prosthesis is aligned as trained by the prosthetist and is pushed into the socket to move out air. Sometimes it is challenging for the amputee to don the prosthesis, so it should be checked if the valve is blocked or more lubricant should be applied (Figure 2.17).

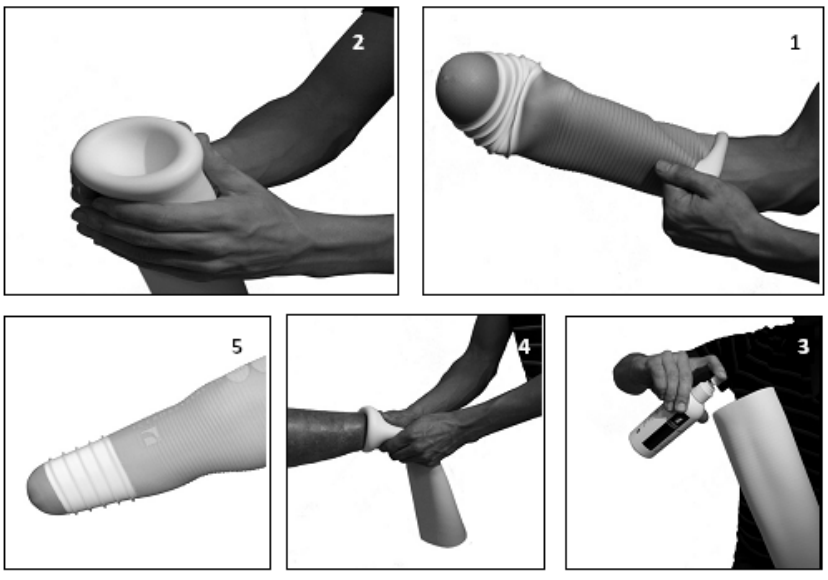


Figure 2.16: The procedures of donning the Seal-In liner.

Figure 2.17: The technique for donning the prosthesis with Seal-In suspension.

2.3.3. Advantages and disadvantages

Research into the liner suspension mechanisms has revealed the advantages and disadvantages of various suspension types. Each of these should be considered when evaluating the individual amputee and his/her needs. Silicone suspension liners are said to decrease shear forces between the socket and residual limb, improve suspension, and control the volume fluctuation of the residual limb in transtibial prostheses (Baars & Geertzen, 2005; Fillauer *et al.*, 1989). The roll-on silicone liner offers enhanced suspension, comfort, stability, and cushioning, in comparison to suction sockets and polyethylene foam liners (Beil *et al.*, 2002; Coleman *et al.*, 2004; Sanders *et al.*, 2004). Considering that supracondylar suspension is unnecessary with the use of the pin/lock suspension, the socket walls can be trimmed lower to facilitate donning procedure. In spite of the originality of the design, certain intrinsic weaknesses of liner suspensions include the following (Cochrane *et al.*, 2001):

i. Complications of donning the prosthesis as a result of upper limb deficiencies, in terms of dexterity or strength, and at the presence of impaired vision;
ii. Inadequate space that inhibits the installation of the coupling mechanisms;
iii. Extra prosthesis mass, as well as required time and cost of fabrication;

iv. Inconsistent distal shrinkage of residual limb because of milking phenomenon developed by the prosthesis;
v. Decreased simplicity (Haberman *et al.*, 1992).

Also, Lake and Supan (1997) recognized the following problems with the use of silicone liners in a literature review article (Lake & Supan, 1997):

i. Initial extreme perspiration and irritation that subsides over time. (notably, antiperspirants could help diminishing the amount of perspiration);
ii. Rise in moisture and warmth within the socket in summer months and warm climate, stimulating skin maceration and invasion of bacteria into the hair follicles;
iii. Physiological skin changes with aging reduce the shear force threshold and the contact surface (the proximal trimline of the liner and posterior distal part of the residual limb are mostly at risk of shear abrasions);
iv. Combination of rise in pressure and oily skin results in folliculitis;
v. Increased heat rash due to the interference between and the body's natural mechanisms of heat dissipation (convection, radiation, evaporation, and conduction) and the liner;
vi. Potential allergy to silicone, which results in dermatitis;
vii. Pain, provoked by the liner's pulling action on the residual limb and posterior knee irritation attributed to wrinkling/bunching of socks/liner with knee flexion.

Age, cause of amputation, use of deodorants, powders, or sheaths, level of activity and preceding methods of suspension were considered as other contributing factors to skin problems (Lake & Supan, 1997). Traumatic amputees, those with high perspiration because of high activity levels, and prosthetic users with previous dermatological problems were at risk for liner-associated dermatological problems. Although certain

literature supports the use of deodorants and powders with the liner, greater dermatological problems resulted. These materials often produce a residue over the skin surface that causes irritation. However, use of sheaths reduced the skin problems. The sheaths are useful because they facilitate to eliminate direct contact between the skin and the liner; remove moisture like a wick; and allow circulation of some air around the residual limb. Sheaths also decrease shear forces at the proximal liner trimline (Lake & Supan, 1997).

2.3.3.1. Advantage and disadvantages of Seal-In suction suspension

Various techniques are used to couple the liner and residual limb in the lower limb sockets, including lanyard, distal pin and shuttle lock, and vacuum/suction seals (Trieb *et al.*, 1999; Wirta *et al.*, 1990). The Seal-In system incorporates an exterior hypobaric sealing membrane to enhance attachment between the liner and socket. The resultant vacuum reduces the rotation, translation, and pistoning movements inside the lower limb socket (Ali *et al.*, 2012b; Gholizadeh *et al.*, 2013).

The main advantages of shuttle locks are as follows:

i. Simple and secure primary or secondary suspension method of prosthesis;
ii. Extremely adjustable;
iii. In a sitting position, use of a coin or key to engage the pin with the pin lock is possible. More specifically, patients with excess residual tissue can wind the residuum into the socket;
iv. Pin/lock system does not need a sleeve. Suspension sleeves frequently are creased, particularly in the popliteal fossa, which bothers transtibial amputees by preventing knee flexion, mainly during sitting. Similarly,

amputees with poor hand dexterity usually have difficulty to don sleeves. However, sleeves remain a good option of secondary suspension together with a pin/lock;

v. Pin/lock is less bulky than many other suspension systems, such as thigh corsets, supracondylar cuffs, and Silesian belts;

vi. Prosthesis donning and doffing is quick and easy with a pin lock. However, sufficient hand dexterity is necessary to don a locking liner;

vii. Several pin locks generate audible feedback when the lock is engaged; thereby the patient is reassured of secure bonding between the prosthesis and residual limb. This feature is particularly valuable for patients with poor sight, blind patients, or those who are not confident about prosthesis suspension.

The pin lock mechanisms also have several weaknesses, including:

i. Tissue stretch at the distal end of residual limb, or "milking," as well as pistoning of the prosthesis. Milking can both result in permanent elongation of distal tissue and increased pistoning. It can also result in pain, mainly along the tibial crest and the tibia or femur end among transtibial and transfemoral amputees, respectively. During the swing phase, milking occurs and distal tissue is stretched (Beil & Street, 2004). Padding at the cut end or the bony ridge of bone is then reduced, which can be painful. Prolonged and extreme milking can even cause an invagination, usually near or along a suture line. In fact, pistoning and distal tissue stretching are caused by the longitudinal elongation of locking liner, and therefore both are associated with the use of pin lock.

ii. Nearly all silicone liners with pin have a distal feature in a shape of an umbrella. Weight bearing over this feature sometimes results in distal pain, particularly if the positive cast is excessively reduced at the distal end during modification.

However, this problem has been partially ameliorated by reducing the size of umbrellas, or increasing cushioning and flexibility.

iii. Despite the easy and quick donning of pin/lock prosthesis, aligning the pin with the pin hole of the plunger is done with difficulty. This issue mainly occurs in patients with poor strength, flexibility, and/or hand dexterity. Frequently, an amputee pushes the limb into the socket forcefully to engage the pin. Consequently, the umbrella's metal insert may be pushed out in the liner or the amputee's limb. Engaging the pin with the lock can be difficult because of corrosion or jamming of locking mechanism with debris; liners with no or tiny umbrellas can create in a wobbly or flaccid liner distal end. Thus, the pin may bounce away from the pin hole and recurrently smash into the socket distal end when the amputee tries to engage the pin lock; a pin that is too short; flaccid end of the liner due to excessive redundant tissue; incorrect donning of the liner. Often, the pin skews when the amputee dons the liner, or a large air pocket is found between the distal end of the liner and the limb. These issues can also lead to the distal flaccidness; and occasionally, the amputee has difficulty in engaging a pin lock, which is due to increased volume of the residual limb as he/she cannot push the residual limb down sufficiently into the socket to engage the pin.

iv. Difficulty and time of fabrication can increase with pin/lock, depending on the pin lock design and the recommended method of fabrication by the manufacturer. Although lamination of numerous pin/locks is done in a single phase, certain locks necessitate dual lamination. The dual lamination enables alignment alterations, especially linear changes, into the prosthesis. However, lamination will significantly increase the time of fabrication, the amount of material, and the socket mass.

v. Despite the wide range of cost, pin locks are somehow expensive. Unfortunately, several pin/lock kits have only one pin while most amputees have two liners. Although simple in appearance, pin/locks can be expensive, especially those with extra features or prolonged wear characteristics.

vi. Unwanted noises, such as squeaking, rushing air, or clicking, are occasionally produced during ambulation, even when the pin is in a good state. Certain techniques are used to reduce noise, such as covering push latch/button pin or the pin with a foam washer. Even though controlling the noise is typically easy, locating undesirable noise can be inconvenient in certain situations.

vii. Pin/locks fail in different ways over time. Several common complications include jamming of the push/pull button, rusting (if not waterproof), wear of lock mechanism and/or the plunger pin hole, wear of pin (can cause numerous problems, particularly unwanted pistoning and noise of the prosthesis), function failure due to the accumulation of dirt and dust within the lock, and ultimately, loosening of the push/pull button.

viii. Trouble in unlocking the pin due to jamming, which often happens to amputees that make holes in residual limb socks. Failure to disengage the pin from the lock occasionally results from over-tightening of the unit's screws. Sometimes, patient cannot release the pin if the locking mechanism is under pressure, the mechanism is damaged, or the pin serrations are worn out. Occasionally, the patient needs to apply a certain load into the pin lock to make doffing easier. Also, old amputees, those with poor hand dexterity, flexibility, and arthritis may reach or trigger the button with difficulty.

ix. Improper fabrication. Several problems may occur if the pin lock is wrongly incorporated into the prosthesis, such as jamming of the push/pull button, undesirable noise, direct weight bearing onto the pin's proximal end if the depth

of the socket distal end is inadequate for the pin, and breaking or faulty performance of the pin/lock because of over-torque screws.

x. Despite providing a simple and secure form of suspension, the pin/lock does not offer good rotational control. Additionally, alignment changes, especially linear adjustments, are sometimes restricted after the fabrication.

xi. A major problem is the unintentional pin release of the lock. If the suspension fails, the amputee may be uncomfortable if other people are around, and/or can be wounded in the case of trip or fall. Inadvertent unlocking usually happens when the amputee unintentionally hits against the push button.

xii. Cosmesis. Despite the use of foam cover, pin locks may protrude unpleasantly. On the other hand, too short push buttons can make a dimple in the prosthetic cover.

Finally, pin/lock increases the prosthesis mass, and the lock mechanism is likely to oxidize easily, thus limiting its use in wet environments and generally need a higher frequency of maintenance because of rapid failure once dirt and gunk amass around and in the locking mechanism. An additional disadvantage of locking liners is that long residual limbs may limit the space necessary for the shuttle lock hardware that can cause a discrepancy of knee center. The addition of a belt can solve the rotational problem due to redundant tissue or weak musculature.

2.3.3.2. Advantage and disadvantages of the Seal-In suction suspension

Certain advantages of suction suspension system include greater use of residual muscles, higher mobility, good appearance and comfort (Dietzen *et al.*, 1991). The Seal-In suspension maintains secure suspension when volume fluctuations are present.

Furthermore, the distal pad and seal adhesion enhance rotational stability. In addition, the hypobaric pressure is constantly in direct proportion to the needed suspension force through the hypobaric sealing membranes, safeguarding superior control, comfort and stability.

With the Seal-In liner, proprioceptive feedback is increased, and amputees that have used the Seal-In suspension often state that the prosthesis suspended by the Seal-In feels more closely bonded to their residual limb, in comparison to a prosthesis suspended by pin lock (Ali *et al.*, 2012b; Gholizadeh *et al.*, 2013). Also considering that the suction develops a close socket fit, a superior feeling of stability inside the socket is attained, particularly because rotation and pistoning of the socket are well-managed (Gholizadeh *et al.*, 2013). The distribution of prosthesis mass over a wider area with the Seal-In suspension diminishes moments and pressure between the residual limb and prosthesis, thus reducing pain.

The Seal-In liners are tougher and stiffer to roll on and don in comparison with the pin/lock liner. The use of spacer socks to accommodate change in residual limb shape due to volume fluctuation poses considerable challenge. At times, suction is lost after sitting for a while but is recovered upon the first step. In geriatric users, or those with vascular disease, suction sockets may cause edema at the end of the residual limb (Dietzen *et al.*, 1991; Fillauer *et al.*, 1989; Gholizadeh *et al.*, 2013).

The positive effect of easy donning and doffing on user's satisfaction with prosthesis has been reported previously (Baars *et al.*, 2008; Gholizadeh *et al.*, 2012a; Gholizadeh *et al.*, 2012b; Gholizadeh *et al.*, 2013; Haberman *et al.*, 1992). According to the literature, transtibial prosthesis users did not favor the Seal-In liner because of challenging donning and doffing. The donning procedure is more difficult and takes

longer than the pin/lock system as hand dexterity is more important and air passage through the valve takes time.

Gholizadeh et al. (2013) reported higher satisfaction and fewer problems with the Seal-In liner on 90 traumatic transfemoral amputees (vacuum and silicone liner) compared with a common suction socket (Gholizadeh *et al.*, 2013). Only durability was stated to be higher with the suction socket system. Additionally, findings on appearance, walking on level and uneven grounds, and stair negotiation did not demonstrate a significant difference between the two systems. Research revealed the negative effect of the silicone liner, leading to simultaneous movement of the skin and liner (Haberman *et al.*, 1992). Suction is generated by the Seal-In liners at the inner wall of socket through the vacuum at the socket-seal interface, and the soft tissue is saved from the pressures in other methods.

Durability is a concern in silicone liners because of becoming subjected to tensile and compressive loading frequently (Cochrane *et al.*, 2001; Hatfield & Morrison, 2001). Residual limb pain is decreased, while patient confidence is increased by the silicone liner in the residual limb during walking. This result can be partly attributed to the enhanced volume control and skin protection as a result of coupling between the skin and liner compared with the suction socket (Erikson & James, 1973; Gholizadeh *et al.*, 2013).

2.4. Measures of suspension efficiency

2.4.1. Pistoning (vertical movement)

The lower limb prosthesis may be displaced on the residual limb through the forces applied to the lower limb during standing and walking, which is known as pistoning or piston motion. Torque and ground reaction force cause pistoning during the swing phase of gait, which is reversed during the stance through the weight bearing (Smith *et al.*, 2004). This vertical motion within the socket is considered as one of the key signs of effective suspension (Newton et al., 1988). Failure in suspension negatively affects amputee's comfort, gait, and residual limb skin (Dillingham *et al.*, 2001; Meulenbelt *et al.*, 2006; Narita *et al.*, 1997; Schmalz *et al.*, 2002).

The pistoning assessment enables the evaluation of the suspension quality in lower limb prosthesis (Commean *et al.*, 1997; Madsen *et al.*, 2000; Sanders *et al.*, 2006b). Pistoning is a relative movement, either between the residual limb and bone, skin and liner/socket, or the liner and socket. Various techniques of measurement have been utilized, such as spiral computerized tomography (CT) (Madsen *et al.*, 2000), ultrasound (Convery & Murray, 2000), cineradiography and radiography (Narita *et al.*, 1997), and Roentgenology (Söderberg *et al.*, 2003). Custom-made transducers and photoelectric sensors have also been employed (Abu Osman *et al.*, 2010; Sanders *et al.*, 2006b). Recently, two new methods of pistoning measurement were introduced using the reflective markers, camera, and 3D motion analysis system (Gholizadeh *et al.*, 2012b; Gholizadeh *et al.*, 2012c; Gholizadeh *et al.*, 2011). Despite its relevance, pistoning has not been investigated extensively in the lower limb prosthesis. The literature on the suspension and socket fitting has primarily addressed pressure distribution, friction, and shear force (Zhang et al., 1998; Abu Osman et al., 2010b). A literature review by the author of this thesis explored various studies that evaluated the pistoning quality in

lower limb prostheses (Eshraghi *et al.*, 2012a). The number of participants, excluding case studies, ranged from 7 (Lilja *et al.*, 1993) to 22 (Grevsten & Erikson, 1975). The subjects' age varied widely, from 15 years (Yigiter *et al.*, 2002) to 81 years (Bocobo *et al.*, 1998). A limited number of papers only reported the study on single subjects (Commean *et al.*, 1997; Convery & Murray, 2000; Sanders *et al.*, 2006b; Söderberg *et al.*, 2003; Tanner & Berke, 2001). Both bilateral and unilateral amputees were involved; however, the participants were mainly unilateral transtibial amputees. Both females and males were studied, but male subjects were dominant. Table 2.1 presents several specifications of the study populations.

Prosthetic sockets for transtibial amputees mostly included total surface bearing (TSB) and patellar tendon bearing (PTB) prostheses. The only transfemoral prosthesis incorporated quadrilateral suction socket, mechanical knee joint, and single axis foot. Various suspension systems were studied, including waistband with cuff, supracondylar/suprapatellar (SC/SP), cuff, supracondylar (SP), supracondylar wedge and elastic sleeve. The studies had not indicated the type of the liners, and only a few identified the silicone liner, Pelite, and urethane liner. Soderberg et al. (2003) used four different suspension systems (cuff, supracondylar, pin and lock, and vacuum) with the same soft liner (TEC liner) and same socket, for one 69-year-old transtibial amputee (Söderberg *et al.*, 2003). Gholizadeh et al. (2012) fabricated TSB sockets with Talux feet and two different suspension systems (pin and lock system and suction system) (Gholizadeh *et al.*, 2012b). Four studies had reported the individual data for every subject. Table 2.2 presents the sample size, study design, and data presentation among the studies.

Table 2.1: The characteristics of participants.

Study (n=19)	Age (year)	Cause of amputation (%)	Stump length (cm)
Grevsten & Erikson (1975)	28-66	Unknown	5 - 22.5
Newton et.al. (1988)	Unknown	Unknown	Unknown
Wirta et al. (1990)	23-76	Trauma, infection, diabetes, congenital	8-19
Lilja et al. (1993)	61-79	Diabetes (5), arteriosclerosis (2)	10-20
Commean et al. (1997)	56	Unknown	Unknown
Narita et al. (1997)	19-74	Trauma (6), tumors (2), burns (1)	13-29
Bocobo et al. (1998)	39-81	Vascular disease, trauma	Unknown
Convery & Murray (2000)	39	Industrial accident	18
Madsen et al. (2000)	Unknown	Unknown	Unknown
Board et al. (2001)	32-64	Trauma	Unknown
Tanner & Berke (2001)	37	Trauma	Short stump
Yigiter et al. (2002)	15-37	Trauma	12.5-17.5
Soderberg et al. (2003	69	Trauma	10
Sanders et al. (2006)	60	Trauma	Unknown
Papaioannou et al. (2010)	Unknown	Unknown	14.8
Gholizadeh et al. (2011)	22-71	Diabetes, trauma	13-17
Gholizadeh et al. (2011)	38- 54	Diabetes, trauma	13-16
Gholizadeh et al. (2011)	51*	Vascular disease	14, 15
Brunelli et al. (2013)	24-54	Vascular disease, trauma, infection	At least 11

*Bilateral transtibial patient

Various techniques were used to measure pistoning in previous literature. Imaging methods, such as roentgenology, cineradiography (Figure 2.18), fluoroscopy, and roentgen stereophotogrammetric analysis were used to evaluate the position of bones inside the prosthetic socket. Ultrasonic methods utilized transducers that were fixed over the socket. Roentgenological examinations are valuable when the position of the stump relative to the prosthetic socket is evaluated (Grevsten & Erikson, 1975). Spiral or helical computerized tomography (CT) also provides a high resolution, 3-D image of the stump and prosthesis (Madsen *et al.*, 2000). A simple photographic method was recently reported by (Gholizadeh *et al.*, 2011). Vicon motion analysis system is the most advanced method used to evaluate pistoning in transtibial amputees (Gholizadeh *et al.*, 2012b; Gholizadeh *et al.*, 2012c).

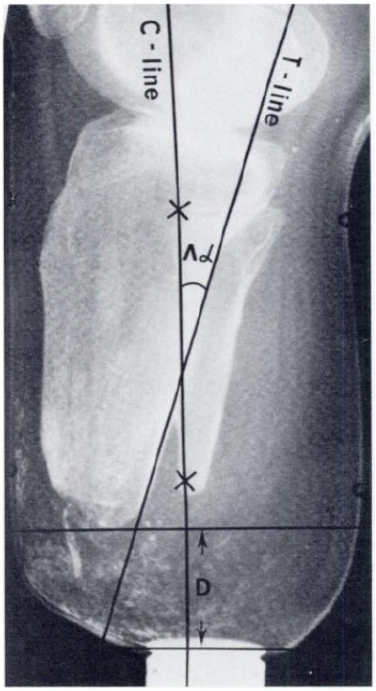


Figure 2.18: Measuring the tibia vertical movement by radiographic method (Grevsten & Erikson, 1975).

Table 2.2: Status of the studied articles with regards to the sample size, study design and data presentation.

Study (n=19)	Sample size	Study design	Data presentation per patient
Grevsten & Erikson (1975)	22	CSS	Yes
Newton et al. (1988)	8	CSS	No
Wirta et al. (1990)	20	CSS	No
Lilja et al. (1993)	7	CSS	Yes
Commean et al. (1997)	1	CS	Yes
Narita et al. (1997)	9	CSS	No
Bocobo et al. (1998)	12	CSS	No
Convery & Murray (2000)	1	CS	Yes
Madsen et al. (2000)	19	CSS	Yes
Board et al. (2001)	11	CSS	Yes
Tanner & Berke (2001)	1	CS	Yes
Yigiter et al. (2002)	20	CSS	No
Soderberg et al. (2003)	1	CS	Yes
Sanders et al. (2006)	1	CS	Yes
Papaioannou et al. (2010)	10	CSS	No
Gholizadeh et al. (2011)	6	CSS	No
Gholizadeh et al. (2011)	5	CSS	Yes
Gholizadeh et al. (2011)	1*	CS	Yes
Brunelli et al. (2013)	10	CS	Yes

CS= Case Study; CSS= Case Series
*Bilateral transtibial

Based on the literature review, most researchers checked the pistoning inside the socket by measuring the displacement between the bone and the socket, the liner and socket or the soft tissue by using different techniques in a static position (Madsen *et al.*, 2000; Newton *et al.*, 1988; Söderberg *et al.*, 2003; Tanner & Berke, 2001; Yigiter *et al.*, 2002) or during dynamic tasks (Bocobo *et al.*, 1998; Convery & Murray, 2000; Lilja *et al.*, 1993; Papaioannou *et al.*, 2010; Sanders *et al.*, 2006b). Thus, methods were classified according to static or dynamic pistoning (Table 2.3).

2.4.1.1. Static pistoning

Grevsten and Erikson (1975), followed by Newton et al. (1988), were among the first researchers to study PTB prosthesis using roentgenology (Grevsten & Erikson, 1975; Newton *et al.*, 1988). The pistoning motion was studied in four and two weight bearing positions. Some researchers tried to mimic the human gait by adding loads to the prosthesis in static position (Commean *et al.*, 1997; Narita *et al.*, 1997). In a previous study, pistoning of the tibial end was assessed in four simulated phases of the gait cycle. Researchers used a board tilted at 15 degrees to locate the limb in the position of heel strike and toe-off. To imitate the swing phase, researchers positioned the prosthetic limb at 45 degrees relative to the floor (Lilja *et al.*, 1993). The same positions were used in a study using roentgen stereophotogrammetry for four types of suspension (supracondylar, patellar tendon bearing strap, distal pin suspension, and vacuum suspension with expulsion valve) (Figure 2.19). One kilogram load was applied to the prosthetic foot to replicate centrifugal force (Söderberg *et al.*, 2003).

Table 2.3: Distribution of studies based on the methodology and prosthetic components.

Study	Year	Method		Instrument	Level of amputation	Socket type	Soft liner type	Measurement Interface (range of pistoning) (mm)		
		Static	Dynamic					Skin/soft tissue-liner/socket	Bone-soft tissue/socket	Liner-socket
Grevsten & Erikson	1975	#		Roentgenology	TT	SS	None	No	Yes (20-74)	No
Newton et.al.	1988	#		X-ray	TT	PTB	Soft liner	Yes (10-20)	No	No
Wirta et al.	1990		# (W)	Plunger and potentiometer	TT	PTB	Polyethylene foam liner	Yes (6-31)	No	No
Lilja et al.	1993	#		X-ray	TT	PTB	None	No	Yes (20-81)	No
Commean et al.	1997	#		Spiral X-ray CT (SXCT)	TT	PTB	Sponge insert	Yes (6.5)*	Yes (10.5)*	No
Narita et al.	1997	#	# (W)	X-ray & Cineradiography	TT	PTB TSB	Silicon liner (ICEROSS)	No	Yes (25-36)	No
Bocobo et al.	1998		# (W)	Videofluoroscopy	TT	PTB	Polyethylene foam liner Kemblo insert	Yes (NA)	No	No
Convery & Murray	2000	#		X-ray	TF	Quadrilateral-SS	None	No	Yes (39.5-40.5)	No
Madsen et al.	2000	#		CT Scanner	TT	Unknown	Unknown	Yes (0-32)	No	No
Board et al.	2001	#		X-ray	TT	SS VS	Urethane liner Sleeve	Yes (42-45)	Yes (33-40)	Yes (1-5)
Tanner & Berke	2001	#		X-ray	TT	TSB	Neoprene Silicon liner	Yes (2-20)	Yes (31-33)	No
Yigiter et al.	2002	#		Marker and measuring tape	TT	PTB TSB	Soft liner	No	No	Yes (4-16)

Table 2.3 continued

Study	Year	Method		Instrument	Level of amputation	Socket type	Soft liner type	Measurement Interface (range of pistoning) (mm)		
		Static	Dynamic					Skin/soft tissue-liner/socket	Bone-soft tissue/socket	Liner-socket
Söderberg et al.	2003	#		Roentgen stereophotogrammetry	TT	TSB KBM	Silicon liner (TEC)	No	Yes (7-35)	No
Sanders et al.	2006		# (W)	Photoelectric sensor	TT	PTB	None	Yes (39.8-43.5)	No	No
Papaioannou et al.	2010		#	Dynamic roentgen stereophotogrammetry	TT	PTB VS	Silicon liner	Yes (19-151)	Yes (3-11)	No
Gholizadeh et al.	2011	#		Vicon motion system	TT	TSB	Silicon liner (Seal-In® X5 & Dermo®)	No	No	Yes (0-5)
Gholizadeh et al.	2011	#		Camera and markers	TT	TSB	Silicon liner (Dermo®)	No	No	Yes (0-9)
Gholizadeh et al.	2011	#		Camera and markers	TT	TSB	Silicon liner (Seal-In® X5 & Dermo®)	No	No	Yes (0-4)
Brunelli et al.	2013		#	Camera and markers	TT	TSB	Silicon liner (Seal-In® X5) & Urethane sleeve	No	No	Yes (3.6-12.4)

TT=transtibial; TF=transfemoral; TSB=total surface bearing; PTB=patellar tendon bearing; KBM=kondylen betting munster; SS=suction socket; VS=vacuum socket; W=walking; the pistoning was measured during gait. *Only the mean pistoning value was reported

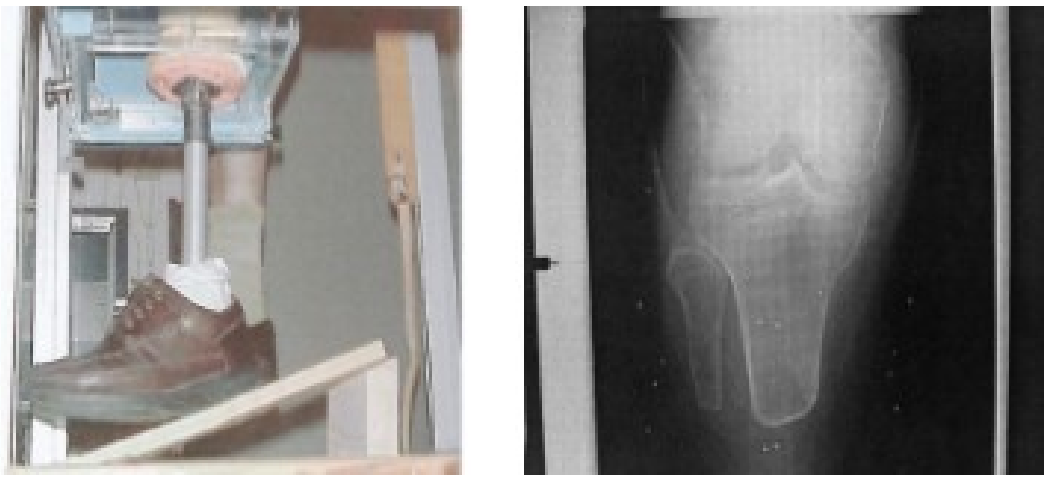


Figure 2.19: Radiographic method of pistoning measurement (Söderberg *et al.*, 2003).

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

An X-ray study determined the femur position in weight-bearing and non-weight bearing transfemoral prosthetic limb. Two 5 MHz linear transducers were used to obtain quality imaging of the femur. A separate ultrasound scanner was used for each transducer (Convery & Murray, 2000). The amputee was asked walk with a normal stride. Researchers pulled the prosthetic heel of the weigh-bearing limb backwards to mimic stance and pulled the toe to mimic swing stance. Abduction and adduction were replicated by pushing the prosthetic foot laterally or medially, respectively.

The effect of a neoprene sleeve on the vertical tibia and stump displacement was evaluated using the shuttle lock suspension system (Tanner & Berke, 2001). The pistoning motion was derived from a total of six radiographs for two suspension systems in three weight-bearing positions (full, partial, and none). The distance between

each a) end of the tibia and b) the distal residual limb soft tissue of the proximal lock was measured on the X-ray films (Tanner & Berke, 2001). A prosthesis with a shuttle lock was fabricated, but the pin was removed to evaluate the neoprene sleeve.

Yigiter et al. (2002) assessed the suspension of PTB and TSB sockets by marking the anterosuperior edge of the socket in both standing and swing phase (Yigiter *et al.*, 2002). However, the researchers did not present data on how measurements were taken. In a study on pistoning using X-ray, loads of 44.5 and 88.9 N were used to simulate the swing phase during walking and running, respectively. The X-rays were taken with the subject in supine position. The data of loaded and unloaded positions were compared (Board *et al.*, 2001). Some researchers tried to find means to apply weight to the prosthetic limb. Commean et al. (1997) used a harness to apply force to the prosthesis by the shoulders (Commean *et al.*, 1997). In another study, Madsen et al. (2000) designed a loading device for the Spiral CT method that allowed researchers to apply large loads (Figure 2.20) (Madsen *et al.*, 2000). The applied load was determined by the subject's weight (full and half body mass).

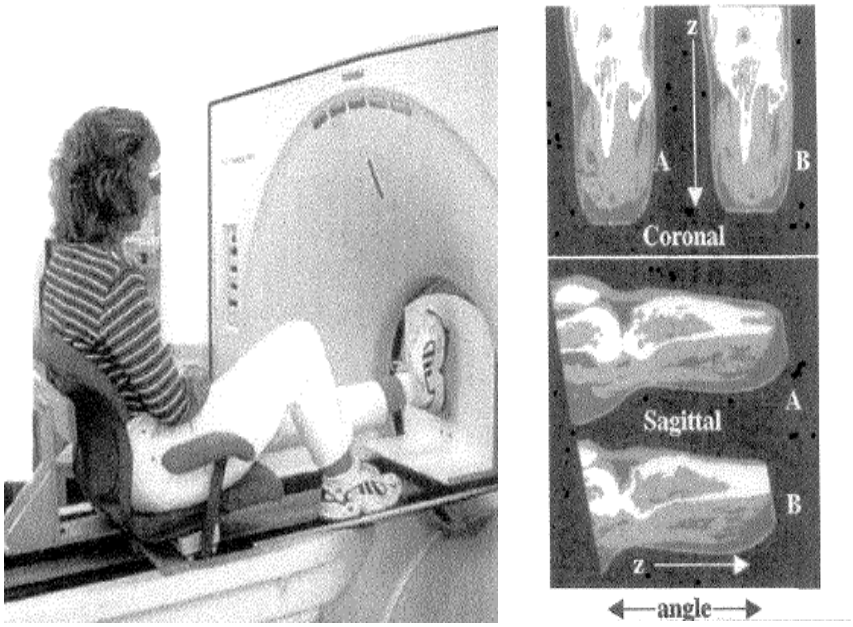


Figure 2.20: Spiral CT examination used for pistoning measurement (Madsen *et al.*, 2000).

Cameras, reflective markers, and rulers were used in the photographic method, which was introduced as a new approach in pistoning measurement (Gholizadeh *et al.*, 2011). Photos were taken in five loading conditions (Figure 2.21), and the images were analyzed on a computer to measure pistoning. The photographic method was reported to have good reproducibility of measurements. Brunelli et al. (2013) adopted the photographic method to measure pistoning in transtibial amputees to compare two different suspension systems (Brunelli *et al.*, 2013).

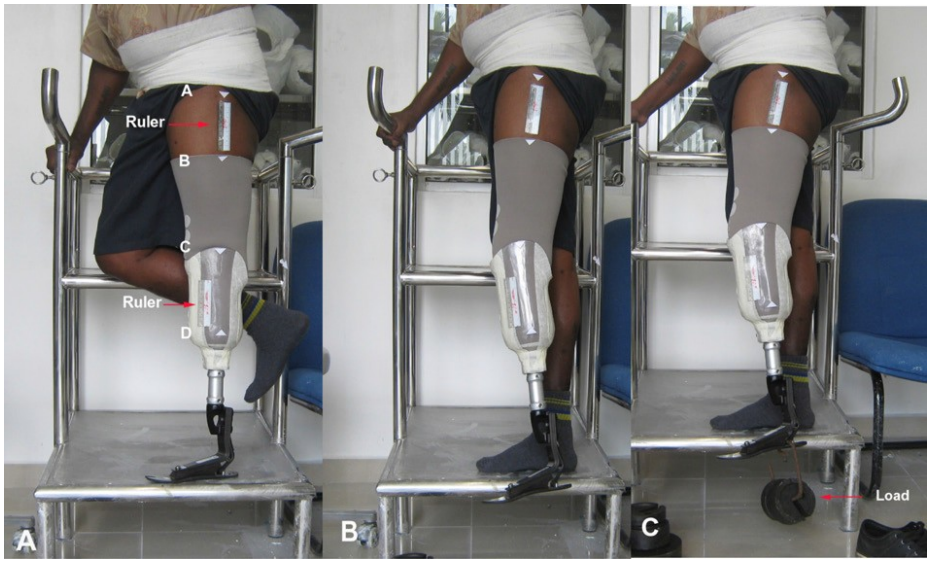


Figure 2.21: Photographic method of pistoning measurement in various loading positions. A) full weight bearing; B) non weight bearing; C) adding load (Gholizadeh *et al.*, 2011).

Researchers used the Vicon motion system in a recent study to evaluate pistoning in transtibial amputees in static position (Gholizadeh *et al.*, 2012b). In the static method, the researchers attempted to simulate ambulation by adding three different loads (3, 6, and 9 kg) to the prosthetic foot (Figure 2.22). The Vicon motion system can easily and quickly detect the occurrence of pistoning between the liner and socket. Furthermore, the motion system was presented as a preferable alternative to X-ray exposure.

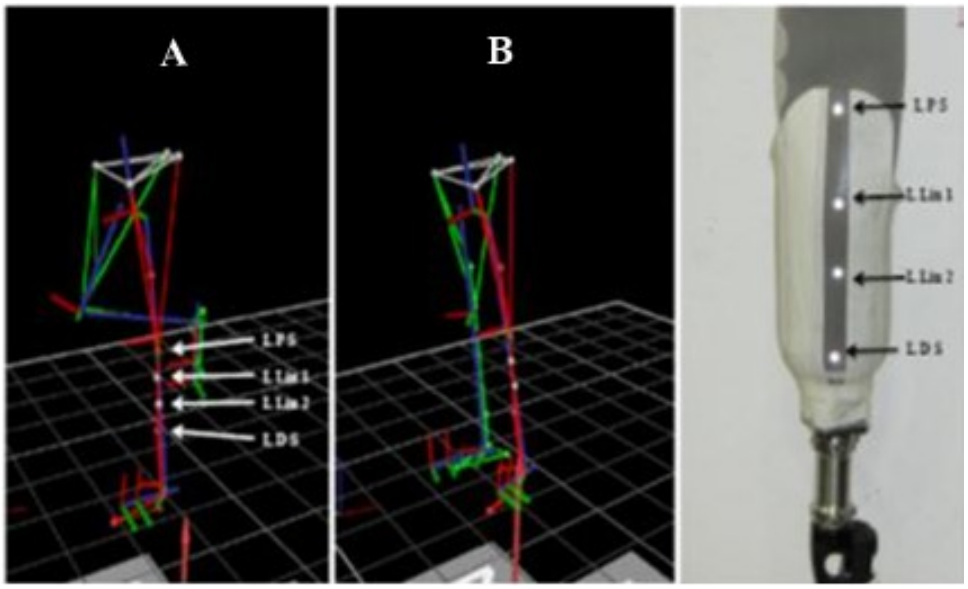


Figure 2.22: Position of markers in the static technique of measurement with the Vicon system in full weight bearing position (A) and semi weight bearing position (B). On the left: the position of markers on the socket and the liner (Gholizadeh *et al.*, 2012b).

2.4.1.2. Dynamic pistoning

Some studies have focused on pistoning during gait (Table 2.3). Sanders et al. (2006) used a non-radiological tool to measure the position of the distal end of the residual limb surface in relation to the socket when walking on an 18.5 meter walkway (Sanders *et al.*, 2006b). A holder containing the photoelectric sensor was mounted on the inside distal socket wall (Figure 2.23).

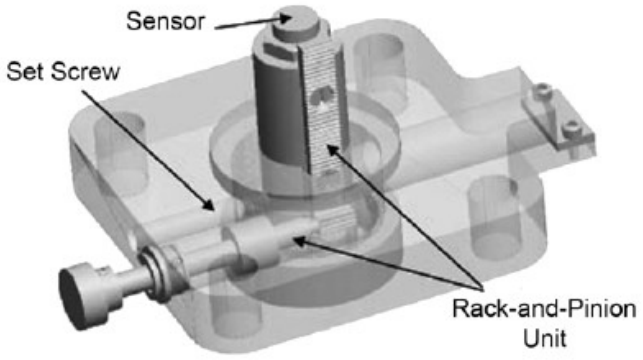


Figure 2.23: Non-contact sensor for measuring pistoning inside the socket (Sanders *et al.*, 2006b).

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

In a study on the effect of below-knee suspension systems, Wirta et al. (1990) placed a potentiometer as an axial movement detector at the distal end of the socket (Figure 2.24). The subjects were asked to walk a 7.5 meter distance at usual, fast, and slow speed. The following seven suspension systems were compared: cuff (PTB/C), supracondylar, supracondylar (SC), figure-of-eight supracondylar strap, waistband and cuff, suprapatellar (SCSP), rubber sleeve and supracondylar wedge (Wirta *et al.*, 1990).

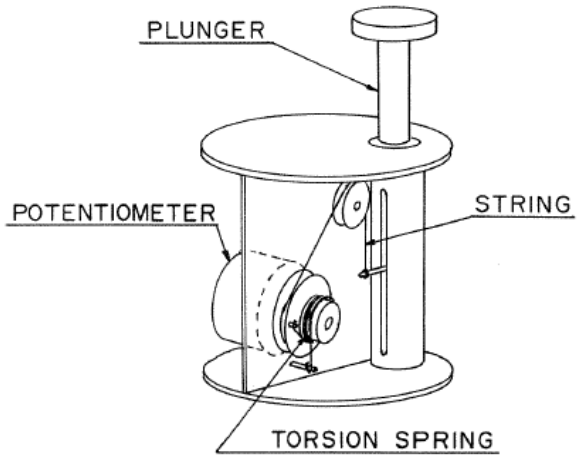


Figure 2.24: Axial movement detector (Wirta *et al.*, 1990).

In a videofluroscopic research study, participants were asked to walk at a comfortable speed on a treadmill. The treadmill was elevated so that the knee and stump were fully visible. Leaded elastic markers were attached to some prosthetic components outside and inside the socket. Three exposure rates (50, 80 and 110) were selected and the results were compared. Anteroposterior and mediolateral views were taken. A video

camera was used to record the treadmill gait during the mean trial time of 40 s (Bocobo *et al.*, 1998). Two researchers evaluated the recorded videos and their agreement over the detection of a particular component (stump or prosthesis) was taken as the reference.

Papaioannou et al. (2010) presented a new method called 3D socket–stump telescopic movement evaluation to be used when performing tasks on the force plate (Papaioannou *et al.*, 2010). Researchers measured the piston motion between the skin and socket by roentgen stereogrammetric system with the attachment of tantalum pigments on the bone, skin, and socket. The researchers claimed that the 3D socket–stump telescopic movement evaluation is an accurate technique for the assessment of pistoning between the stump, socket, and bone (Figure 2.25). In an ultrasound study on trans-femoral prosthesis, two video recorders were utilized to capture the femur motion at 25 HZ during gait (Convery & Murray, 2000).

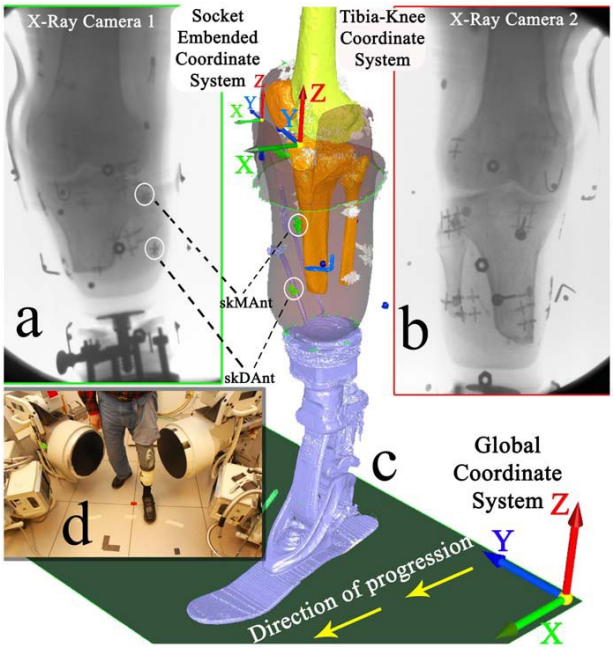


Figure 2.25: Measuring pistoning using Roentgen Stereogrammetric Analysis (Papaioannou *et al.*, 2010).

Finally, a new technique for measurement of pistoning using 3D motion system was introduced (Gholizadeh *et al.*, 2012c). The Vicon motion system with seven infrared cameras was used. The sampling rate of 200 Hz was adopted. Sixteen reflective markers from the Helen Hayes marker set were attached to the subjects' prostheses and sound lower limbs. On the prosthetic side, the knee and tibia markers were placed on the lateral proximal socket wall (LPS) and lateral distal end of the socket (LDS), respectively (Figure 2.26). To measure the liner vertical movement, two extra markers were attached to a) the lateral liner below the knee joint (LLin1) and b) 5 cm below the LLin1 (LLin2). To calculate pistoning within the socket, the distance between the markers on the liner and on the socket during the gait was used to identify pistoning movement (Gholizadeh *et al.*, 2012c).

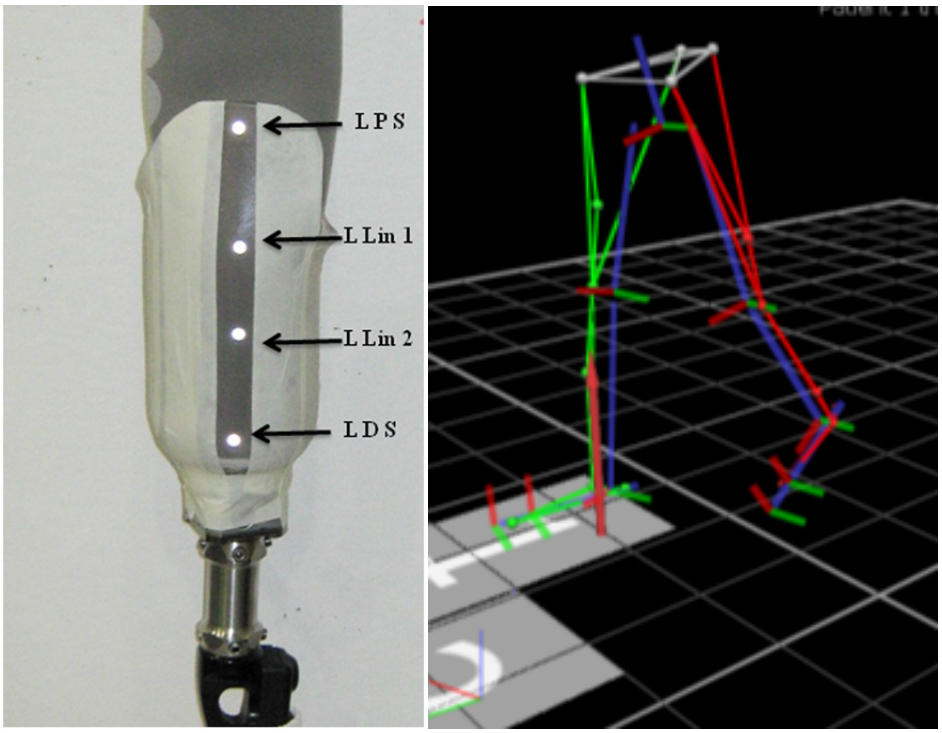


Figure 2.26: The dynamic method of pistoning measurement using the motion analysis system and the positions of markers on the socket (left) (Gholizadeh *et al.*, 2012c).

2.4.1.3. Amount of pistoning

Grevesten and Erikson (1975) found an 11.3 mm bone displacement in relation to the socket with suction-based PTB prosthesis. In another study on PTB prosthesis, the average vertical movement of the distal tibia during a gait cycle was 57 mm (Lilja *et al.*, 1993). Wirta et al. (1990) compared the vertical movement of conical and cylindrical residual limb shapes and reported a mean pistoning movement of 19.1 mm at the end of the residual limb. In both conical and cylindrical stumps, the rubber sleeve had the least pistoning among the seven evaluated systems(Wirta *et al.*, 1990).

In 1997, the slippage between the skin and socket and the tibia movement was monitored to evaluate the prosthetic fit in a transtibial subject. To simulate gait, the researchers used two axial loadings of 44.5 and 178 N. Tibial slippage of 10 mm and about 7 mm of slippage in the distal end of the skin relative to the socket was observed (Commean *et al.*, 1997). However, the suspension system used by Commean et al. (1997) was not identified.

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

Bocobo et al. (1998) described two case reports from a total of 12 cases. Only one case was reported to have PTB socket. However, the value of pistoning was not reported (Bocobo *et al.*, 1998). Significant pistoning action was observed, possibly by

comparison between two phases of gait. However, the researchers failed to mention which phase elicited the greatest pistoning action. The pistoning movement was measured by subtracting the position of the patellar tendon bar marker of the knee joint during two gait phases.

A spiral CT study did not represent any specific value for pistoning. A figure legend shows the difference of the displacement between full body weight and non-loading conditions ranging from 0 to 32 mm (Madsen *et al.*, 2000). When the normal valve transtibial socket is compared with an electric vacuum prosthesis, the amounts of liner displacement and tibia bone relative to the end of socket marker were 40 and 70 mm less, respectively. The amount of pistoning with normal suction was reported to be 50 mm. Although the pistoning was measured statistically under loads, the majority of subjects stated that they felt less pistoning with the vacuum prosthesis compared with the normal suction prosthesis when walking (Board *et al.*, 2001).

When the shuttle lock system was evaluated against the no-lock condition, the value of tibial end displacement from the proximal edge of the lock was almost equal in both suspension conditions in three different loading positions. However, less soft tissue displacement was noted with the shuttle lock. The patient also preferred the shuttle lock because it created minimal pistoning sensation. The researchers concluded that the amputee's opinion about pistoning was mostly related to soft tissue movement rather than tibial movement (Tanner & Berke, 2001).

The pistoning of the tibia within the KBM socket with supracondylar strap was approximately 35 mm. The pin and sleeve resulted in approximately 17 mm pistoning (Söderberg *et al.*, 2003). Sanders et al. (2006) pointed out that the residual limb came out of the socket about 30 mm after toe-off. Overall, a 40 mm stump displacement was observed in the proximal direction at the end of the swing phase. Additionally, the

researchers stated that pistoning in the PTB was higher when a strap was not used compared with when a strap was used (0.8 mm more). After a five-minute rest, 3.7 mm of additional pistoning was observed (before rest: 39.8 mm, after rest: 43.5 mm for the PTB with supracondylar strap).

The latest roentgen stereogrammetric study surprisingly showed 151 mm pistoning movement in the fast stop task and 19 mm in the step down between the markers on the skin and socket. Except for one case that used a customized vacuum socket with silicone liner, the type of suspension systems used were not indicated (Papaioannou *et al.*, 2010). In one study on transfemoral prosthesis, Convery and Murray (2000) measured the amount of vertical movement of the femur during gait by using two ultrasonic transducers. The displacement was monitored by X-ray images, and the pistoning was determined by the distance between the end of the femur and distal transducer. After the subject changed his position from full weight to non-weight bearing, the femur displacement was found to be 1 mm.

Gholizadeh et al. (2012) compared the pistoning between two different transtibial liners (Seal-In® X5 and Dermo® liner) and sockets using a motion analysis system (Gholizadeh *et al.*, 2012b). Data analysis showed that maximum pistoning within the socket occurred after 90 N was added to the prosthetic limb. On average, 2 mm (SD 1) pistoning occurred with the Seal-In®X5 (60% less than Dermo® liner) and 5 mm (SD 1.5) with the Dermo® liner ($P < 0.02$) after the 90 N load was added.

Suspension systems facilitate firm prosthetic attachment to the limb. With suspension systems based on the suction concept, the displacement of the stump's bones is assumed to be reduced by half. Reducing the displacement will in turn result in increased stability between the stump and socket, and skin sores are also prevented (Grevsten & Erikson, 1975). Less pistoning results in a more normal gait. Moreover, less pistoning

makes the amputee feel like the prosthesis is a part of his or her body (Goswami *et al.*, 2003; Newton *et al.*, 1988).

Different methods were used to evaluate pistoning in lower limb prosthesis. Most methods evaluated pistoning in a static position. Radiological methods used to be popular in measuring pistoning. However, some radiologic methods are rarely available to prosthetists because of costly equipment and complex time consuming data collection. Furthermore, the need for repeated exposure of the patient to X-ray is a concern (Kendall *et al.*, 1992). In addition, measurements taken by X-ray examinations still have some inaccuracies (Grevsten & Erikson, 1975). The discrepancy in measurements can be attributed to minor changes in the distance between the extremity and film. To get higher resolution images, some studies tried different exposure rates.

Using CT scanners has some advantages, such as high spatial resolution and ability to show 3D information on the prosthesis and internal tissues of the stump. Subjects must be in the supine position when CT scanners are used. Madsen et al. (2000) stated that with the evolution in CT imaging systems, their device could be easily adapted to perform more sophisticated loading protocols. The harness that Commean et al. (1997) used to apply load had several limitations because the procedure required a long period of time to set up and necessitated complete cooperation from the subject.

The use of photoelectric sensor was reported to have some limitations. Photoelectric sensors were not wireless and a cable connected the sensor to a data acquisition system. However, the problem of not having a wireless system can be solved by radio-frequency telemetry systems. Another problem of photoelectric sensors was that a liner with the shuttle lock and pin could not be used as it was impossible to make a hole at the end of the liner (Sanders *et al.*, 2006b). The use of a Vicon motion system in static pistoning measurement was recently reported (Gholizadeh *et al.*, 2012b). The technique was said

to be accurate; however, one of the main problems with the Vicon motion system is the fact that it requires a motion laboratory that may not be accessible to every rehabilitation or prosthetic center. Additionally, the Vicon motion system cannot be employed to monitor the tibial movement within the soft tissue.

Diagnostic ultrasound was said to have no known side effects. However, concerns about the accuracy and frequency of data acquisition were raised. Also, utilizing the ultrasound during gait can be labor intensive and not clinically feasible (Convery & Murray, 2000). Only in three studies were trials repeated three to five times (Gholizadeh *et al.*, 2012b; Narita *et al.*, 1997; Sanders *et al.*, 2006b), which can raise concerns about the reliability of the data presentation. However, to some extent, the ethical issue of X-ray exposure is the main concern. Finally, to our knowledge, no one has set a limit for the acceptable amount of pistoning. Only Newton et al. (1988) stated that a vertical displacement of 10 mm or less is considered ideal and comfortable; nevertheless, the researchers did not provide any evidence to support the said statement (Newton *et al.*, 1988).

Most studies measured pistoning by simulating the gait through the application of static loads. The load appliance simulates centrifugal or inertial force that acts on the limb during walking (mostly swing). Some say that the pendulum dynamic applies to the swinging lower limb (Doke *et al.*, 2005). Therefore, inertial force is influenced by the segment weight (the prosthesis mass). Nevertheless, similar loads were used for different subjects that are controversial. Many researchers who employed radiological methods reported that the radiographic apparatus and calibration cage restricted the system.

Overall, some important points can be inferred from the evaluation of available literature. With regard to the complicated equipment and techniques, existing methods seem to be far from being practical in a clinical setting and may only be suitable for manufacturers when evaluating suspension system products, including liners. Given that reducing the pistoning significantly contributes to optimal prosthetic fit, further research with a larger sample size seems necessary to invent and evaluate accurate, safe, and simple methods of pistoning measurement that can be widely available to prosthetists. At present, numerous suspension systems have not been studied from the pistoning point of view. Given that prostheses are the core element of these study practices, researchers should ensure that the fabrication and fitting process will be performed by a single prosthetist to avoid bias.

In summary, the methods for pistoning measurement require complicated devices and settings. Thus, it is not possible for every rehabilitation clinic to provide such costly imaging systems. Even if the amputee is referred to an imaging center, the risk of repeated exposure to the X-ray still exists. The studies were mostly limited to the laboratory and were not conducted clinically.

2.4.2. Gait pattern

Every motor task involves the interaction between skeletal, muscular, and neural systems with the external environment through the end segment of extremities (e.g., feet). The foot is missing in individuals with lower limb amputation. Therefore, the residual limb acts as the end part of the motor system (Esquenazi, 2014). Enhancing the characteristics of gait in an individual who suffered amputation may improve the gait pattern; but more significantly, influence the efficiency of ambulation, comfort, and

reduce compensatory movements that can be detrimental to a patient over time. Quality of gait and speed are among the outcome measures in amputees (Perry, 1999; Treweek & Condie, 1998; Winter & Sienko, 1988). Effective assessment of the gait characteristics in lower limb amputees necessitates understanding of the normal gait and the usual deviations of gait. As such, an index of recognized gait abnormalities can be used to identify and compare specific gait abnormalities to distinguish the likely contributing factors and accessible interferences from comprehensive biomechanical knowledge.

Inadequate prosthetic alignment is the most common origin of an atypical gait pattern in lower extremity amputees. The translational and angular position of the socket in relation to the foot and pylon is a significant factor in the pattern of walking. Main secondary causes are discrepancies in leg length, either true or associated with inefficient suspension or faulty position of the residuum inside the socket.

Practitioners and prosthetists that care for lower limb amputees need to improve their proficiency in the observational analysis of gait. Observational analysis of gait is a kind of clinical evaluation that entails practice and skill. One cannot merely think of the cause of the atypical gait pattern, one must also adopt a corrective approach to perceive progress by observing the body motion and relating it to recognized abnormalities and causal mechanisms (Esquenazi, 2014).

Clinical gait analysis aims to enhance the kinematic gait pattern in to enable amputees to walk as typical as possible. Whether or not a typical kinematic pattern is essentially the most proficient pattern of gait for the amputees is controversial. Some researchers believe that walking with a different kinematic pattern to enhance the biomechanical function of a prosthetic limb can be hypothetically beneficial for an amputee (Esquenazi, 2014). Many amputees tend to reduce any exterior sign of

disability. Although a close-to-normal gait may have a metabolic drawback, its psychosocial benefits may overshadow the comparative significance of other concerns. Today, computerized analysis of gait reduces the incessant gait process into several distinct parameters for evaluation, measurement, and comparison. Frequent gait analysis during the rehabilitation process is valuable in the assessment and optimization of the amputee gait.

2.4.2.1. Normal gait

From a clinical viewpoint, one should know the events of the gait cycle. Five basic motor issues should be addressed simultaneously in functional locomotion: (1) the mechanical energy generation for skillful forward progression, (2) energy absorption to reduce shock and/or to minimize the body's forward progression, (3) the maintenance of a stable standing position, (4) control of the lower limb position to guarantee suitable articulation with the walking surface during the stance phase and foot clearance during the swing phase, and (5) support of the trunk on the lower limb during the stance phase (Esquenazi, 2014). Figure 2.27 demonstrates the normal phases of gait when the right leg is the reference.

Comfortable gait velocity under normal circumstances equals to the velocity at which the cost of energy per distance unit is reduced. Energy efficacy is contingent on unlimited joint motion and the accurate intensity and timing of muscle action. Abnormal biomechanics of gait leads to higher energy consumption, typically with reduction in walking velocity, which is a compensatory strategy. Frequently, the compensatory actions necessary may cause exaggerated shifts on the center of gravity, resulting in high consumption of energy. Lower limb amputees who have a normal nutritional and

cardiopulmonary status do not normally consume more energy per unit of time compared with healthy individuals, even though the required energy per unit distance rises. Impaired sensation, balance, and difficulty of foot clearance may increase the amputee's anxiety and incidence of balance loss and falls.

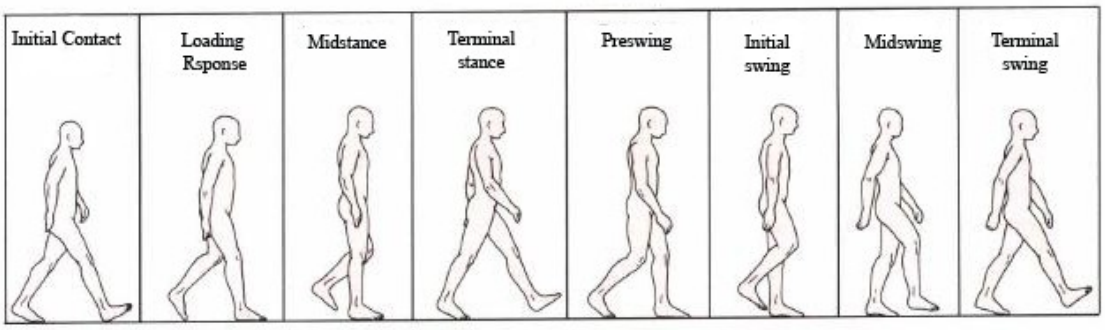


Figure 2.27: Normal gait cycle.

Briefly, thorough clinical judgment with gait analysis has important functions in clarifying the factors causing pathologic gait with prosthesis and selection of existing interventions to improve it. Comprehensive clinical evaluation of gait is used in analyzing walking with the use of prosthesis. However, laboratory assessment of the gait through kinetic and kinematic data is often essential to measure and best recognize the exact contributions of numerous gait variables. Laboratory assessment can also evaluate intervention results. The similar approach may be considered when selecting prosthetic components and suspension systems (Esquenazi, 2014).

2.4.2.2. Prosthetic gait

The primary goal in the rehabilitation of lower limb amputees is to resume normal gait as much as possible. Indeed, walking is deemed to be one of the most significant independence aspects (Sansam *et al.*, 2009). Prosthetic devices should allow normal gait

function using the most appropriate components. Gait asymmetry is one of the main concerns in unilateral lower limb amputees to avoid exertion of excessive load on the sound limb (Macfarlane *et al.*, 1991; Nolan & Lees, 2000). The gait pattern of a person with lower limb amputation is not as symmetrical as that of healthy individuals, especially in terms of ground reaction force (GRF), time, distance of walking, and joint angles (Bateni & Olney, 2002; Isakov *et al.*, 2000). Bateni et al. (2002) reported that a higher range of motion was observed 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 because of the shorter stance time on the prosthetic side (Bateni & Olney, 2002).

Previous research findings on the kinetic and kinematic differences between the amputated and sound legs were controversial. Several studies indicated higher reliance on the sound leg by increased loading and stance time, which was attributed to ankle loss in transtibial amputees (Lemaire & Fisher, 1994; Melzer *et al.*, 2001). On the other hand, some literature supported the idea that amputees may not need to rely on the intact leg because of the compensatory mechanisms adopted by the amputated leg (Silverman *et al.*, 2008). Winter and Sienko (1988) explained that amputee-related literature increasingly referred to variables that measure gait symmetry (Winter & Sienko, 1988). Therefore, a scientific justification is needed to encourage a more symmetrical walking pattern.

The influence of various prosthetic components on the gait of lower limb amputees was evaluated. Extensive research was conducted on the effects of prosthetic foot as transtibial amputees lose normal ankle mechanics ,while retaining the anatomical knee joint (Goujon *et al.*, 2006; Schmalz *et al.*, 2002; Torburn *et al.*, 1995; Van der Linden *et al.*, 1999). The improper fit of the prosthetic socket and failure of the suspension system can result in pistoning, which in turn will affect the walking pattern. The TSB socket

was introduced as new concept and the resultant total contact was said to eliminate pistoning during walking (Hachisuka *et al.*, 1998b; Kristinsson, 1993; Narita *et al.*, 1997; Yigiter *et al.*, 2002). Researchers also studied the effects of prosthetic liners on the gait of transtibial amputees and revealed that liner thickness can affect gait variables (Boutwell *et al.*, 2012).

Proper fit of the stump inside the prosthetic socket and appropriate selection of prosthetic suspension have positive effects on the gait of amputees and decreases energy consumption during ambulation (Baars & Geertzen, 2005; Bateni & Olney, 2002; Czerniecki *et al.*, 1996; Isakov *et al.*, 2000; Sanderson & Martin, 1997). The pin/lock systems are said to cause pain and discomfort inside the prosthetic socket, leading to long-term skin changes (Beil & Street, 2004). Discomfort may cause changes in gait parameters because the amputee becomes reluctant to bear load over the prosthetic socket during walking. The Seal-In suspension can relieve the distal end pressure by applying more load to the proximal tissues of the residual limb. Both systems control pistoning. However, the Seal-In liner is more successful in limiting pistoning (Gholizadeh *et al.*, 2012b; Gholizadeh *et al.*, 2012c). Recently, Bruneli et al. (2013) reported that the Seal-in liner caused a reduction in the energy cost of walking compared with the suction socket and sleeve, especially when walking on a slope. Furthermore, the amputees could walk faster with the Seal-In suspension system. However, no statistical significance was observed between the Seal-in liner and the suction socket and sleeve (Brunelli *et al.*, 2013).

In the rehabilitation of lower limb amputees, one of the main goals is to improve the amputee's gait pattern so that it appears similar to the gait of a healthy individual. Many researchers have used 3D motion analysis to investigate the gait parameters of transtibial amputees during different activities using various prosthetics components (Bateni & Olney, 2002; Rusaw & Ramstrand, 2010; Sanderson & Martin, 1997)

(Figure 2.28). Therefore, the gait analysis system can be used as a diagnostic tool to make decisions for rehabilitation protocols.

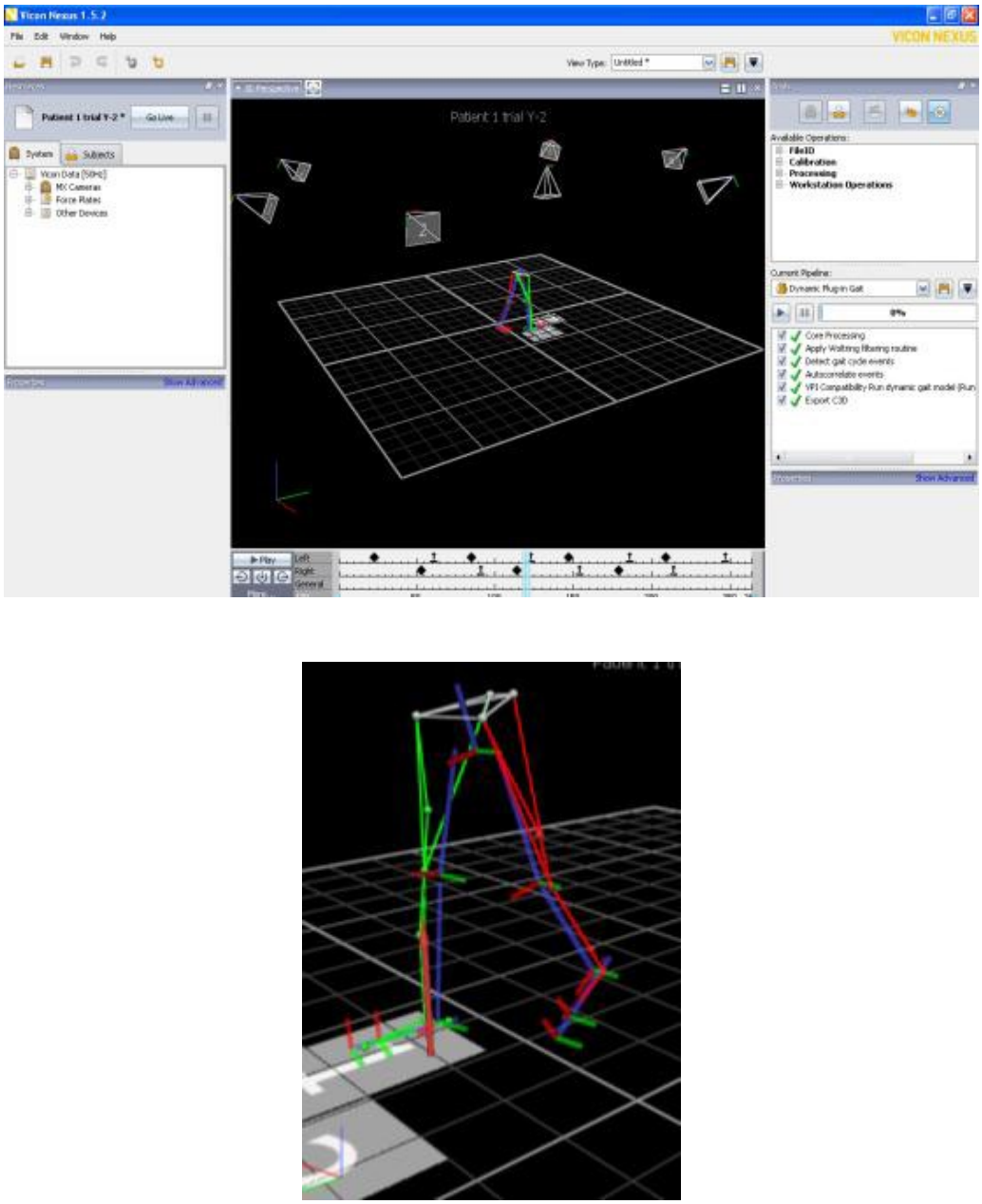


Figure 2.28: Three dimensional motion analysis is widely used to analyze gait pattern of normal and amputee subjects.

2.4.2.3. Gait parameters

In previous studies, spatio-temporal parameters were often measured. Walking speed is the most reported parameter, followed by step length, cadence, and stride length (Sagawa *et al.*, 2011). The said parameters characterize a global predictor of gait (Montero-Odasso *et al.*, 2005; Montero-Odasso *et al.*, 2004). Other spatio-temporal parameters for amputee gait analysis include step time ratio and stance time. Sagawa et al. (2011) reported that the most frequently-used parameters for gait analysis in lower limb amputees from 89 articles (Sagawa *et al.*, 2011). Some of the most frequently used parameters and their frequency of use (out of 89 articles) are listed in Table 2.4.

The stance phase on the intact leg is somewhat longer than that of the prosthetic limb during the gait cycle. Thus, leading to a more asymmetrical gait (Board *et al.*, 2001; Isakov *et al.*, 2000; McNealy & Gard, 2008; Sanderson & Martin, 1997). Individuals with unilateral amputation depend on their intact leg to compensate for the prosthesis' deficiencies (Su *et al.*, 2007). However, the higher loading time worsen the problems of the sound limb (Pinzur *et al.*, 1991). Some studies reported the positive effects from certain prosthesis components. For instance, some prosthesis users stated more confidence with their prosthetic foot and applied less force on the sound limb (Van der Linden *et al.*, 1999). The use of a proper socket and appropriate fitting enabled a reduced degree of gait asymmetry by improved control over the prosthesis position (Board *et al.*, 2001).

Pelvic range of motion is increased in the frontal plane in lower limb amputees compared with healthy individuals. At slow speed, a significant difference was found in the pelvic ROM compared with able-bodied subjects (Su *et al.*, 2007). Lower limb amputees lift the pelvis (hip hiking) on the swing leg. The said motion is frequently seen in unilateral amputees and is supposed to restore the incapability to dorsiflex the

prosthetic ankle. The foot clearance is increased by hip hiking. but may also necessitate extra metabolic energy and decrease gait efficiency (Sagawa *et al.*, 2011). Bilateral hip hiking is observed in persons with bilateral transtibial amputation display, which possibly needs higher energy expenditure than the unilateral amputees (Su *et al.*, 2007).

Table 2.4: List of some of the most common parameters used in the gait analysis of lower limb amputees.

Parameter		**Frequency (%)**
Spatio-temporal	Speed	48.31
	Step length	22.47
	Stride length	19.10
	Cadence	17.97
	Stance time	17.97
Kinetic	GRF vertical	33.70
	GRI anteroposterior	19.10
	GRF anteroposterior	15.73
Kinematic	Knee angles	34.83
	Knee moment	30.33
	Hip power	29.21
	Ankle angles	24.71
	Ankle moment	20.22
	Knee power	23.59
	Ankle power	17.97
	Hip moment	14.60
	Hip angles	13.48
	Max knee flex at LR	11.23

GRI=ground reaction force; GRI=ground reaction impulse; Max=maximum; Flex=flexion; LR=loading response.

During the loading phase, knee flexion acts as a shock-absorber that is vital to prevent the wear and tear of lower limb joints (Isakov *et al.*, 2000). The value of knee flexion for able-bodied individuals or the sound side of lower limb amputees is almost

15° to 188° (Sagawa *et al.*, 2011). For transtibial amputees, the value of knee flexion is only 9° to 128° (Isakov *et al.*, 2000; Powers *et al.*, 1998; Su *et al.*, 2007). Knee flexion is often negative or absent for transfemoral amputees (Segal *et al.*, 2006). Knee flexion can be affected by many factors, such as type of socket (Isakov *et al.*, 2000), barefoot or shoed walking (Han *et al.*, 2003), and rehabilitation protocol (Sjödahl *et al.*, 2002).

In the early stance phase, plantar flexion shows the capabilities of prosthetic foot to land flat (more ground contact) on the floor, which improves stability. The prosthetic foot design may alter this parameter significantly. Prosthetic feet mostly do not have an articulated ankle joint. The ankle plantar flexion motion is mainly a result of heel compression. Postema et al. (1997) reported this feature because they noticed better plantar flexion with the Multiflex articulated foot in both normal and high speeds compared with flexible feet, such as Carbon copy II, Springlite II, and Seattle light foot (Postema *et al.*, 1997). The dorsiflexion during the late stance phase is another important parameter. Less ankle motion is allowed in the prosthetic feet during the stance phase compared with the natural ankle motion (Postema *et al.*, 1997; Powers *et al.*, 1998).

The total ankle range of motion in the sagittal plane is another important parameter. Nolan and Lee (2000) reported higher ROM for the intact limb because of the inadequate prosthetic ankle movement. Thus, lower limb amputees should increase the length of the sound limb to clear the prosthesis during the swing phase. Moreover, the prosthesis type can alter lower-limb kinematics (Nolan & Lees, 2000). Transtibial amputees had lower ankle ROM on the prosthetic side with the SACH foot and greater ankle ROM on the intact ankle compared with the multi-axis foot.

The effect of the prosthesis mass on gait was also studied. In a study by Gailey et al. (1997), two masses (4.54 kg or 9.07 kg) were added to the transtibial prosthesis. The weight was consistently dispersed over the prosthesis shank (Gailey *et al.*, 1997). The values of energy cost showed no significant difference. However, the energy cost of the transtibial amputees was more than the able-bodied subjects (about 13%). Hillery et al. (1997) added 1.460 kg to the transtibial prosthesis and calculated ground reaction force. The lower the mass added to the transtibial prosthesis, the higher the cadence (Hillery *et al.*, 1997). The hip flexion and extension at both sides were increased to some extent with the addition of mass. The knee kinematics showed no significant changes. Hekmatfard et al. (2013) added the following masses to the prosthesis: 300 and 600 g to the ankle, 300 and 600 g at 10 cm below the knee (Hekmatfard *et al.*, 2013). The researchers found no significant difference in the knee kinematics and the spatiotemporal parameters for both the intact and prosthetic limbs. When the mass was added to the ankle, stride and step lengths, and stepping speed of the prosthetic limb were significantly higher than the sound limb. The researchers established that the altered distribution of prosthetic mass had no significant and immediate effect on the knee kinematic and spatiotemporal characteristics of the transfemoral amputees. However, the altered distribution of prosthetic mass can change the spatiotemporal gait symmetry (Hekmatfard *et al.*, 2013).

In the literature, only a few studies on the biomechanics of gait for lower limb amputees took into account various prosthetic components and their characteristics, such as center of mass, mass, moment of inertia, and center of articulation (Sagawa *et al.*, 2011). Most studies reported that the prosthetic components were aligned and adjusted by an experienced prosthetist. Individual characteristics of fitting may have an effect on motion analysis and cause error. The socket of transtibial prosthesis, for example, is often fabricated with a primary flexion for ease of support during walking.

Therefore, if there is not explicit information, understandings of lower limb amputee gait analysis may be biased. Many different related parameters have been reported. However, most of them were not explored in detail. The diversity of outcomes to designate the gait of lower limb amputees might be attributed to the differences in research objectives and prosthetic components. The diversity of outcomes also denotes to a lack of consensus among researchers about the important aspects of gait when assessing outcomes of lower limb amputees. Based on the literature, the analyses of gait in transtibial amputees provide reliable results to comprehend walking strategies. Nevertheless, the influence of the different prosthetic components and experimental protocols necessitate new studies that deliberate on all the explicit characteristics of amputation and prosthesis.

2.4.3. Prosthesis pressure profile

The prosthetic socket and suspension system are the only means of load transmission between the residual limb and prosthesis. Therefore, the prosthetic socket and suspension system are important components in transtibial amputee performance. The socket should be designed appropriately to attain satisfactory stability, load transfer, and efficient mobility control. Better understanding of the residual limb-socket interaction can result in better socket design. In-socket pressure estimation is done to recognize the interaction between the residual limb and prosthetic socket. The patient's ability to produce and bear forces and moments in the residuum during ambulation may be an indication of the rehabilitation progress. Gait improvements are linked with the amputee's ability to tolerate weight on the prosthetic leg, which is indicative of the ability to bear pressure on the residual limb. Quantitative evidence can be provided by measurements on the forces and moments during gait. Quantitative evidence can

provide prosthetists, orthopaedic surgeons, physiatrists, and physical therapists with objective data to improve prosthetic usage.

The ability to measure the forces and moments transferred to the residual limb can contribute to the socket comfort and design. Measurement of forces and moments would also allow researchers to study the effect of different suspension methods and socket designs on pressure distribution and comfort level. The socket design and suspension methods for different activities require a better understanding of interface pressures. The soft tissues of the residuum are not accustomed to weight bearing. The physiological and biological structure of residual limb determines load tolerance (Silver-Thorn *et al.*, 1996). Once tissues undergo prolonged or extreme load, tissue trauma may occur as a result of abrasion and/or local vascular deficits. To reduce possible tissue trauma and discomfort, great care is taken when designing the prosthetic socket for individuals with lower limb amputation.

Considering the residuum anatomy and its biomechanical principles, the transtibial PTB socket and the quadrilateral suction socket for transfemoral amputees were developed (Lyon *et al.*, 2000; Radcliffe *et al.*, 1961). The designs were said to allow better distribution of loads over the residual limb. In the sockets, the sensitive areas are given relief, and the load is mainly taken by the load-tolerant areas. The hydrostatic load-bearing principle and the concept of TSB were presented by the 1980s. Later, the ICEROSS (Kristinsson, 1993), the silicone suction socket (Fillauer *et al.*, 1989), and liners fabricated from gel materials were introduced. The PTB socket was thought to be successful in balancing the load-bearing and physiological factors for patients with transtibial amputee (Silver-Thorn *et al.*, 1996). The basic concept of the PTB prosthetic socket is to distribute the load over areas of the residual limb in proportion to the ability of the tissues to tolerate the weight.

The biomechanics of coupling between the socket and the skeleton considerably affects the socket fit. The slippages between the prosthetic socket and the amputee's skin, as well as the tissue deformation of the residuum have effects on the coupling. The stiffness of coupling is influenced by the tightness of fit. On the other hand, tightness of fit and the pressure distribution may be altered by the socket shape (Mak *et al.*, 2001). In general, pistoning is caused by a loose fit that can decrease stability. A more stable connection is provided by a tight fit. However, the interface pressures are increased, as reported for the Seal-In suspension (Ali *et al.*, 2012a; Eshraghi *et al.*, 2013a). Another main factor affecting slippage is the friction between the prosthetic surface and the residual limb's skin. Extreme slippage should be controlled at the socket surface. However, some problems can be caused by the absence of pistoning. For instance, discomfort may be experienced by the amputee when a cushion is inserted between the socket and skin to decrease slippage, which is the result of the increased perspiration due to high interface temperature (Mak *et al.*, 2001). When friction exists, shear forces are exerted to the skin surface. Friction is harmful because it causes tissue distortion due to shear stress, which may interrupt tissue function. On the other hand, friction can help support the load during ambulation and in the prosthesis suspension during swing phase. Therefore, the decrease of interface friction cannot always relieve the tissue problems of the residual limb. Having an acceptable coefficient of friction to avoid unwanted slippage and support the load is ideal (Mak *et al.*, 2001). Tissue distortion and high local stresses may be caused by large surface friction during ambulation and when donning the socket. In conclusion, reduction of interfacial risks and effective prosthetic suspension should be balanced by an appropriate choice of friction (Zhang *et al.*, 1996).

Several studies have evaluated and measured the load distribution on the residual limb by either simulation techniques (Commean *et al.*, 1997; Lin *et al.*, 2004; Silver-Thorn *et al.*, 1996) or clinical measurements. In-socket friction has been investigated in

terms of the skin's coefficient of friction with different interface materials (Sanders *et al.*, 1998; Zhang & Mak, 1999), interface slippage (Commean *et al.*, 1997), shear stresses (Sanders & Daly, 1999; Zhang *et al.*, 1998), and the motion between the prosthetic socket and skeleton (Convery & Murray, 2000; Lilja *et al.*, 1993; Murray & Convery, 2000). Frictional characteristics of skin were studied. Recently, various interface materials used as suspension medium were studied by Zhang and Mak (1999) and Sanders *et al.* (1998). Eight interface materials were tested by Sanders et al. (1999) to measure the skin's coefficient of friction (Sanders & Daly, 1999). When a sock was used, the coefficient of friction was significantly lower. Zhang and Mak (1999) evaluated silicone, aluminum, nylon, Pelite, and a cotton sock using the Measurement Technology Skin Friction Meter. Silicone showed the highest value (0.61), whereas nylon had the lowest (0.37) among the five materials (Zhang & Mak, 1999). Triaxial transducers were developed and tested on transtibial sockets by Sanders et al. (Sanders, 1995; Sanders & Daly, 1999; Sanders *et al.*, 1993; Sanders *et al.*, 1992). A small triaxial transducer was also developed by Williams et al. (1992) to measure shear and normal force in two orthogonal directions (Williams *et al.*, 1992). Later, Zhang et al. (1998) used transducers to quantify the stresses exerted to the skin at eight locations of the five below-knee sockets. The maximum shear stress at the medial tibia was 61 kPa with the PTB sockets during gait (Zhang *et al.*, 1998). In situ pressure measurements were taken using commercially-designed systems, such as the Tekscan F-Socket pressure measurement system, Rincoe socket fitting system, and Novel Pliance System (Figure 2.29).

The F-socket transducer (types 9810 and 9811) is a force-sensing resistor (Polliack *et al.*, 2000). Every sensor array consists of printed circuits divided into load sensing regions. The smallest sensing element of sensor consisting of two thin, flexible mats holding the pressure-sensitive ink applied in columns and rows between them. The

juncture of 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 are satisfactory sensitivity, flexible and thin sheet, frequency response and good resolution (Buis & Convery, 1997). The system has some disadvantages including signal drift, hysteresis, unidentified shear coupling effects, and sensitivity to temperature (Buis & Convery, 1997; Polliack *et al.*, 2000).

Figure 2.29: Transducers for in-socket pressure mapping; the Novel Pliance 16P System (Right; (Novel, 2014) and the Tekscan F-Socket system (Left).

A polyvenilidyne fluoride strip covers the Rincoe sensors that are 0.36 mm thick (Polliack *et al.*, 1999). Six separate strips consisting of 60 cells are arranged on them, with each strip consisting 10 sensors. The Novel Pliance 16P System has a sensor pad comprising of 434 matrix capacitance sensors with a thickness of 1 mm. Up to 16 sensor pads can be used with the system concurrently. Polliack et al. (1999) compared signal drift, accuracy, response to curvature, and hysteresis of the above-mentioned systems (Polliack *et al.*, 1999; Polliack *et al.*, 2000). The socket pressures vary extensively among individuals, sites, and clinical conditions. The highest stated measurement is 400 kPa, reported as the maximum peak pressure for the PTB socket (Meier *et al.*, 1973). However, usually the maximum interface pressure for PTB sockets is less than 220 kPa during walking (Engsberg *et al.*, 1992; Sanders *et al.*, 1993; Zhang *et al.*, 1998). The wide difference can be contributed to the difference in soft tissue

thickness, residual limb dimension, gait pattern, diversity of fitting techniques and prostheses, different sites of residual limb, and diverse characteristics of each specific mounting and measurement method.

A variety of silicone suspensions in use are coupled to the hard socket either by a distal single pin or through circumferential seal or seals that produce a vacuum at the socket wall. Prosthetic hard sockets that are used with silicone suspension should be undersized to ensure a TSB fit. Research revealed that a TSB socket exposes the soft tissue to tolerable compression (Laing *et al.*, 2011). Bony structures are stabilized within the residual limb. Therefore, the skin may not be damaged because to unbearable excessive pressure when liners are in use. Moreover, TSB sockets coupled with enhanced vacuum (for instance by Seal-In liners) can control volume fluctuation and perspiration. At the same time, piston motion or displacement within the socket and shear force is reduced. Friction within the prosthetic socket has a two-fold effect as it helps to retain the prosthesis on the residuum and distort the soft tissue (Mak *et al.*, 2001). If substantial friction occurs at an interface, stress may be localized and lead to the deformation of the remaining tissue. Conversely, Zhang et al. (1996) found that lubricating the skin will increase the interface pressure (Zhang *et al.*, 1996). Few research studies have dealt with the effect of liners and prosthetic sockets on the pressure applied to the residual limb. Without understanding the changes imposed on the soft tissue and skin by different socket designs and suspension systems, evaluating the overall prosthetic fit is not possible. Moreover, prosthetic interface pressure is believed to be a determinant of the amputee's comfort (Dou *et al.*, 2006; Jia *et al.*, 2004; Sanders *et al.*, 2006a; Sewell *et al.*, 2000).

A number of studies investigated the effect of different casting techniques and prosthetic components, including suspension and alignment changes, on the in-socket interface pressure (Boutwell *et al.*, 2012; Jia *et al.*, 2004; Sanders *et al.*, 1998; Sanders *et al.*, 1997; Wolf *et al.*, 2009). Different suspension systems suspend the prosthetic leg by applying pressure at dissimilar regions of the residual limb, which can significantly affect the comfort of amputees when ambulating. Users of the pin/lock liners feel a stretch at the distal tissue of the residual limb during the swing phase (Beil & Street, 2004). At the same time, proximal tissues are exposed to high compressive pressures that will disrupt the normal fluid flow. The milking phenomenon is probably the cause of the short (edema and redness) and long-term (discoloration and thickening) transformations that are observed, particularly at the distal end of the residuum. Compression can result in pain, discomfort, and residual limb atrophy or volume loss (Beil & Street, 2004). The use of a suction system resulted in a more homogenous distribution of interface pressure. The average pressures for the suction and TSB socket were 68.6 and 66.4 kPa, respectively, at the posterior proximal region.

The mean peak pressures are reported to be generally higher with the Seal-In liner than the pin/lock suspension (Ali *et al.*, 2012a; Eshraghi *et al.*, 2013a). The results of the study revealed that the peak pressure of the Seal-In X5 liner was significantly higher at the anterior and posterior regions of the residual limb compared with the Dermo pin/lock liner with shuttle lock (Figure 2.30). The average difference was 34.04% at the anterior and 24.04% at the posterior region. The interface pressure of the Seal-In X5 was higher at the middle sub-region of the residual limb than the distal and proximal sub regions, both in the anterior/posterior and the medial/lateral aspects. The high pressure can be associated with the five seals around the liner, which provide an airtight fit inside the socket. The peak pressure at the posterior-proximal region was as 56.6 and 67.4 kPa for the pin/lock and Seal-In X5 liner, respectively.

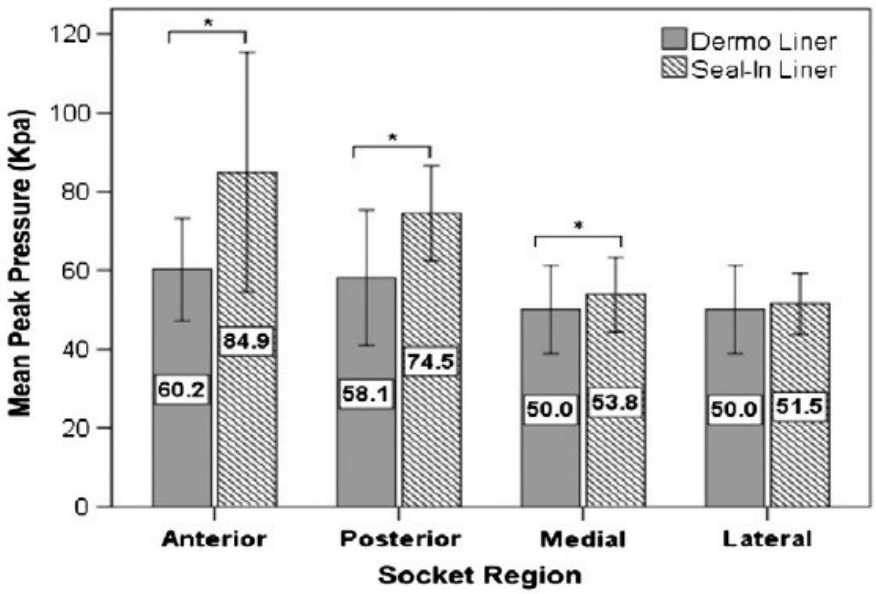


Figure 2.30: Comparison of peak pressure between the Dermo and Seal-In suspension. The significant differences are shown by asterisk (Ali *et al.*, 2012a).

2.4.4. Satisfaction

The rehabilitation of people with amputation is a challenge because it requires teamwork and necessitates a person's willingness to accomplish a time-consuming and costly prosthetic training. Satisfaction with prosthesis is a multi-factorial issue. Some factors are dependent on the level of amputation, prosthetic components and alignment, prosthetist skill, level of activity, and socket fit (Kent & Fyfe, 1999; Legro *et al.*, 1998; Raichle *et al.*, 2008; Subbarao & Bajoria, 1995). 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 be defined by related studies. Thus, achieving a consensus regarding the importance of proper selection of prosthetic components is possible.

Several tools have been developed to evaluate a patient's satisfaction with prostheses and orthoses. 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, Prosthesis Evaluation Questionnaire (PEQ), Perceived Social Stigma Scale, Socket Comfort Score, and the Trinity Amputation and Prosthesis Experience Scales are some of the tools used to assess patient's satisfaction (Berke *et al.*, 2010; Gallagher & MacLachlan, 2000; Gauthier-Gagnon & Grise, 1994; Grise *et al.*, 1993; Heinemann *et al.*, 2003; Legro *et al.*, 1998; Van der Linde *et al.*, 2007). To date, the majority of researchers have evaluated differences in function, performance, and satisfaction between different prosthetic components or techniques using the PEQ (Ali *et al.*, 2012b; Legro *et al.*, 1998; Van der Linde *et al.*, 2007). The PEQ measures prosthetic-related quality of life. The PEQ consists of 82 items grouped into nine subscales. In addition, a number of individual questions pertaining to satisfaction, pain, ambulation, prosthetic care, and self-efficacy are also included in the PEQ. 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 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 focused on patients with transtibial amputation (Ali *et al.*, 2012b; 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 (Dillingham *et al.*, 2001). More than half of the participants (57%) were not satisfied with their prostheses. The correlation between the suspension system and patients' satisfaction was not investigated (Dillingham *et al.*, 2001).

Only a few studies on the relationship between the suspension system and satisfaction exists (Haberman *et al.*, 1992; Koike *et al.*, 1981; Levy *et al.*, 1962; Trieb *et al.*, 1999). The common suction socket system is said to cause discomfort and edema.

Koike et al. (1981) introduced a new transfemoral double socket (Koike *et al.*, 1981). Koike et al. (1981) reported that the participants were satisfied with the new system in comparison with the common suction socket, particularly for donning and doffing. The main reason for this finding was reported to be the flexibility of the inner socket that maintained close contact with the residual limb at all times and reduced edema associated with the common suction socket. Gholizadeh et al. (2013) conducted a satisfaction survey on 90 transfemoral amputees (Gholizadeh *et al.*, 2013). The participants were more satisfied with the Seal-In liner because it acted like a soft inner socket. Participants also reported experiencing less swelling using the Seal-In liner compared with the common suction socket system.

Based on the literature, the TSB socket with pin/lock system is favored by the majority of amputees. An Online worldwide survey revealed that the silicone liner with pin/lock system is the first choice of prosthetists among three different suspension systems, namely, PTB with Pelite soft liner, ICEROSS with pin/lock, and suction system (Gholizadeh *et al.*, 2013). Thus far, no clinical evidence is available to prove that the ICEROSS is the standard system for all transtibial amputees (Cluitmans *et al.*, 1994). 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 (Coleman *et al.*, 2004; Selles *et al.*, 2005). In a prospective study, Trieb et al. (1999) compared 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. Similarly, participants in the study by Gholizadeh et al. (2013) were more satisfied with the Seal-In silicone liner and experienced less problems (Gholizadeh *et al.*, 2013). Based on a study by Haberman (1995), the silicone liner created a negative pressure, resulting in concurrent movement

of the liner and skin (Haberman, 1995). The Seal-In liners also generated suction at the inner socket wall through a vacuum between the seals and socket. Therefore, the soft tissue is protected from the stresses associated with the common suction socket. Haberman (1995) concluded that silicone liners resulted in a level of suspension and comfort that is not possible with the common suction socket system. Heim et al. (1997) also claimed that the use of silicone liners greatly improved the function of the prosthesis because of enhanced suspension, skin protection, and cushioning (Heim *et al.*, 1997).

Ease of donning and doffing had a positive effect on an amputee's experience with prosthesis (Baars *et al.*, 2008; Gholizadeh *et al.*, 2012a; Gholizadeh *et al.*, 2012b; Haberman, 1995). Easy donning and doffing is important in relation to the night time toilet habits of amputees. The tasks of 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 (Ali *et al.*, 2012b; Eshraghi *et al.*, 2012b; Gholizadeh *et al.*, 2012a; Gholizadeh *et al.*, 2012b; Gholizadeh *et al.*, 2012c). The participants in the study by Gholizadeh et al. (2013) were more satisfied with the process of donning and doffing using the Seal-In liner compared with the common suction socket. An elastic bandage is used to lessen friction when the patient dons the residual limb into the hard socket in the common suction socket. However, the findings suggested that it was challenging to don a suction socket using an elastic bandage. The silicone liner can be donned in a sitting position with less effort and does not require balance skills normally associated with donning the common suction socket when standing (Haberman *et al.*, 1992). The said findings were consistent with the findings of Koike et al. (1981) on 440 transfemoral subjects. The researchers observed easier donning while sitting with a flexible internal socket in comparison to the suction socket. However, individuals with transtibial

amputation were not satisfied with the Seal-In liner due to the difficulty of donning and doffing (Ali *et al.*, 2012b; Gholizadeh *et al.*, 2012b; Gholizadeh *et al.*, 2013). One possible explanation is that the mass of transfemoral prostheses is higher than the transtibial prostheses. Therefore, enhanced fit by the Seal-In suspension possibly resulted in higher satisfaction in the transfemoral subjects. Furthermore, soft tissue of the residual limb is less firm in patients with transfemoral amputation than transtibial amputation. Ali et al. (2012a) found that donning and doffing are more difficult to perform in the suction system (Seal-In liner) compared with the PTB (with polyethylene soft insert) and ICEROSS with pin/lock (Ali *et al.*, 2012b). This finding is similar to that of prospective studies (Brunelli *et al.*, 2013; Cluitmans *et al.*, 1994; Eshraghi *et al.*, 2012c; Gholizadeh *et al.*, 2012b; Gholizadeh *et al.*, 2012c). Furthermore, the polyethylene foam insert is more durable than silicone liners, which is in accordance with the finding 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.

Transfemoral amputees were more satisfied with the static items of satisfaction (Gholizadeh et al, 2013); no significant difference was seen in satisfaction during ambulation (walking on level ground, walking on uneven surface, and stair negotiation) (Gholizadeh *et al.*, 2013). However, the improved results with the Seal-In suspension in comparison to the common suction socket as static scenarios are critical in activities of daily living is notable. The durability of silicone liners has long been debated. Since the liner is constantly under compressive and tensile loadings, its longevity is a concern (Cochrane *et al.*, 2001). Research has shown that Alpha cushion and locking liners have a durability of 6.6 and 6.7 months, respectively (Hatfield & Morrison, 2001). Similarly, Össur Company provides a warranty of six months for Seal-In liners (Össur, 2010). Low durability necessitates frequent replacements of the liners, which will be costly for

users. Thus, the question is raised of how durability might be enhanced. Some authors have addressed this issue by the addition of cloth and matrix material to the surface of liners (Cochrane *et al.*, 2001; Coleman *et al.*, 2004). In another study, significantly less durability was reported for the Seal-In liner compared with the common suction socket. Despite the low durability, the participants were more satisfied with the Seal-In liner (Gholizadeh *et al.*, 2013). Further research and development is needed to help enhance the longevity of suspension systems. If the suspension system must be replaced frequently, cheaper materials such as plant-based substances should be used. Another alternative is to provide two liners to each prosthetic user because alternating use may increase the liner's lifetime (Gholizadeh *et al.*, 2014).

The Seal-In suspension decreases pistoning inside the socket and increases patient confidence during walking (Gholizadeh *et al.*, 2012b; Gholizadeh *et al.*, 2012c). Less pistoning problems were observed with the Seal-In liner compared with the common suction socket and pin/lock suspension (Ali *et al.*, 2012b; Gholizadeh *et al.*, 2013), which may be attributed to the total contact between the seals and socket wall. The participants also experienced less pain in the residual limb, possibly as a result of better skin protection, volume control, less friction, suction, and edema at the end of the residual limb. Although both suspension systems are considered suction suspension, one applies suction to the skin (common suction socket), whereas the other creates suction mainly between the liner and socket wall. The silicone liners are used to reduce skin irritation or breakdown. Similarly, less irritation, pain, and wounds were reported with the Seal-In liner and pin/lock suspension (Ali *et al.*, 2012b; Gholizadeh *et al.*, 2013).

Both transtibial and transfemoral amputees reported fewer problems with the irritant sound in the common suction socket during walking. Moreover, sweating and smell decreased with the Seal-In suspension compared with the common suction socket, possibly because of the enhanced fit between the skin and the liner. Ali et al. (2012a)

found that with the exception of the "sweat complaint", significant differences were found between different transtibial suspension systems with respect to perceived problems. Sweating was reported more often with the pin/lock suspension (55%) than the polyethylene foam and Seal-In liners. The overall satisfaction rate was higher with Seal-In liner (83.10%) compared with the pin/lock liner (75.94%) and polyethylene foam liner (63.14%). 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. The reason is that more space and better ventilation is achieved between the skin and the soft liner. Hachisuka et al. (1998b) reported that perspiration in prosthesis is less in female amputees than in males. Datta et al. (1996) observed that perspiration increases when using the ICEROSS, but decreases after three weeks (Datta *et al.*, 1996). Daily wash of the stump and silicone liner is important to control odor, perspiration, itching, and eruption (Baars & Geertzen, 2005; Hachisuka *et al.*, 2001). Ferraro (2011) found greater vertical movement inside the socket with the pin/lock systems compared with the vacuum suspension (Ferraro, 2011). The observation is consistent with that of other studies (Eshraghi *et al.*, 2012a; Gholizadeh *et al.*, 2012c). Furthermore, amputees with excessive soft tissue at the popliteal fossa found that using a sleeve or a silicone liner difficult due to the creases created during knee flexion (Hachisuka *et al.*, 1998a; Hachisuka *et al.*, 2001).

Thicker liners are more comfortable and can distribute the pressure more evenly over residual limbs. However, an amputee's 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. In both open- and close-eyed conditions, balance is better as well. Better balance is associated with overall contact of the TSB socket to the skin, which provides improved proprioception and pressure distribution.

2.5. Conclusion

All aspects of prosthetics have been affected by several changes in the last decade. Changes often come as a natural advancement of preceding developments that are constantly challenged by a growing number of educated and skilled prosthetic professionals and more demanding amputee population. Although the componentry has evolved greatly, knowing if the advancement is remarkable is needed. The capability to evaluate and validate a certain prosthetic device, practice, or procedure can be considered as progress and is deemed to assist in future research. The preceding decade carries on the prosthetic evolutionary process, offering the prosthesis user the option of satisfying his/her preferred lifestyle.

Choosing the proper prosthetic components for a patient is a difficult task. The enormous diversity of components accessible for a prosthetist makes choosing the appropriate prosthetic difficult. Also, prosthetists should consider several factors related to the amputee including body mass, amputation level, activity level, shape and length of residual limb, and preceding condition. Prosthetists frequently test multiple components over a period of time and choose from a limited number of components that are used more commonly in their practices contingent on their failure or success with these components, and other aspects, such as cost and accessibility of the components. However, some components may not best satisfy the expectations of a certain patient. Unfortunately, prosthetists often serve their patients with unsuitable components from a pre-set variety of components. In summary, researchers and manufacturers should consider other characteristics for the design of new prosthetics suspension systems with emphasis on safety, donning and doffing, cost, pistoning, environmental issues, adjustability, maintenance, and weight.

2.6. Novel contributions of the current thesis

There are several suspension systems available for individuals with lower limb amputation. However, the users experience various problems during ambulation with prosthesis that can lead to dissatisfaction. There are extensive works in the literature looking into effects of various prosthetic components on the function and satisfaction of lower limb amputees. However, there remain clear gaps in the literature regarding the biomechanical aspects of suspension systems. There is a lack of systematic analysis aimed at identifying the advantages and disadvantages of various suspension systems for lower limb amputees. Therefore, one of the purposes of this research was to provide an inclusive review of current suspension concepts for lower limb prostheses.

As the literature review indicated, the current suspension systems have certain drawbacks that should be addressed in new designs. Therefore, the main objective of this thesis was to develop a new prosthetic suspension system that can enhance the suspension quality, especially for ambulation. It was intended to follow up the results of the mechanical testing and provide experimental and clinical supports for the proposed suspension system. In addition, another objective of the current thesis was to investigate the biomechanical qualities of commonly used suspension systems to validate the new system of suspension.

In short, the current thesis introduces a new suspension concept for lower limb prosthesis. The study also provides insight into influential factors in clinical evaluation of suspension system for lower limb prostheses that can be potentially used as a guideline for prescription. This is an important step forward, considering that the current understanding of prosthetic suspension systems remains incomplete.

CHAPTER 3

DEVELOPMENT AND EVALUATION OF NEW COUPLING SYSTEM FOR LOWER LIMB PROSTHESES WITH ACOUSTIC ALARM SYSTEM

Individuals with lower limb amputation need a secure suspension system for their prosthetic devices. A new coupling system was developed that is capable of suspending the prosthesis. The system's safety is ensured through an acoustic alarm system. This article explains how the system works and provides an in vivo evaluation of the device with regard to pistoning during walking. The system was designed to be used with silicone liners and is based on the requirements of prosthetic suspension systems. Mechanical testing was performed using a universal testing machine. The pistoning during walking was measured using a motion analysis system. The new coupling device produced significantly less pistoning compared with a common suspension system (pin/lock). The safety alarm system would buzz if the suspension was going to fail. The new coupling system could securely suspend the prostheses in transtibial amputees and produced less vertical movement than the pin/lock system.

3.1. Introduction

The demand for prosthetic devices, particularly as a result of lower limb amputation, is growing (Ziegler-Graham *et al.*, 2008). Amputees face a permanent disability that can only be addressed by artificial limbs (prostheses). As such, advancements in prosthetics technology are of utmost importance to improving the quality of amputees' life. When lower limb prosthesis is in use, the lower limb residuum is required to bear weight, but its soft tissues are not physiologically accustomed to such weight bearing activities (Dudek *et al.*, 2005; Meulenbelt *et al.*, 2007). Therefore, advancements in prosthetics technology are of utmost importance to amputees' life. Lower limb residuum should bear weight while its soft tissues are not physiologically accustomed to weight bearing.

Prosthetic suspension systems play important role in the amputee's ability to perform the various activities associated with everyday life, from quiet standing to intense sport activities (Eshraghi *et al.*, 2012a). Suspension systems have evolved tremendously to provide more secure ambulation for prosthetic users. Liners are a fundamental element of the suspension system and they not only act as a cushion but also contribute to the overall function of the prosthesis. Roll-on liners, which are mostly made of silicone, are popular due to the fact that they offer improved suspension, cushion and durability (Klute *et al.*, 2010). Modern suspension systems are a combination of a roll-on silicone liner and either a pin lock system or a rubber seal. Although these systems have been proven to be successful in suspending above-knee and below-knee prostheses, amputees have reported some difficulties using them (Boonstra *et al.*, 1996; Dillingham *et al.*, 2001; Kark & Simmons, 2011).

Pin/lock and Seal-In liners are believed to be superior to other suspension methods as they cause the least pistoning (vertical movement) inside the prosthetic socket; this is particularly true of the Seal-In liner (Cluitmans *et al.*, 1994; Eshraghi *et al.*, 2012b;

Gholizadeh *et al.*, 2012b). Nevertheless, objective and subjective evaluations imply that pin/lock systems are associated with pain and skin problems, particularly at the distal end of the residuum (Beil & Street, 2004; Street, 2006). Seal-In systems are also said to cause high interface pressure inside the prosthetic socket. Both systems cause discomfort in terms of donning and doffing and this can be particularly challenging for amputees that have poor hand dexterity (Eshraghi *et al.*, 2012b; Gholizadeh *et al.*, 2012c).

Bearing in mind the above-mentioned pros and cons, the authors of this paper developed a new coupling system. This paper aims to describe the newly designed system and to evaluate its effectiveness when used for lower limb amputees. The researchers assumed that the new concept of suspension would effectively secure the prostheses to the amputees' residual limbs and have a positive effect on the biomechanics of the prostheses.

3.2. Methodology

3.2.1. Mechanical coupling device

Prosthetic sockets are important components in prosthesis. Suspension systems are, in effect, coupling devices that are positioned between the prosthetic socket and the distal components of the prosthesis, such as prosthetic foot, ankle and pylon. The main factors that should be taken into account when designing prostheses are durability, cosmetic appearance, comfort, function and cost. With these factors in mind, a 3D mechanical computer-aided design (CAD) program (SolidWorks 2009) was used to accomplish the design. Every lower limb prosthesis for persons with lower limb amputation is consisted of the following components but not limited to: socket, pylon

(shank), knee and foot (Kutz *et al.*, 2003). The prosthetic suspension system is usually positioned either inside the socket or between the prosthetic socket and the pylon. Considering the limited space available at this interface, the dimensions of the coupling system used in this study were designed so that it could fit the socket end of an adult amputee. The limited space also dictated the height of the coupling system so that it could also be used with long residual limbs. The new system was designed to be used with silicone liners as they are widely available and commonly in use. To this end, a cap was designed that matched both the main body of the new coupling device, and the liner's distal end. The dimensions were purposely formulated to match with those of the liner. The cross section was circular and, in order to reduce weight, the cap was hollow. The hollow space incorporated a central screw in the middle and was filled with silicone adhesive to promote firm attachment to the liner. The new coupling idea was based on the magnetic field. As such, the cap was made of mild steel to produce high gripping force.

The body of the coupling device was the source of magnetic power. A permanent Neodymium Iron Boron magnet was utilized that was small but was capable of generating a strong magnetic power. The housing intensified the magnetic field by flanges. In order to control the magnetic power, a mechanical switch was affixed to the housing and the magnet. When the rotary switch was in the "On" position the cap was attracted to the housing, whereas it was released from the lower body of the coupling device when the switch was in the "Off" position.

3.2.2. Acoustic alarm system

A coupling alarm system was designed that is capable of detecting any failure in the newly designed coupling system for the lower limb prosthesis. This system consists of an interface, process unit and power supply (Figure 3.1 and Figure 3.2). The signals are detected and processed through a micro-controller unit that subsequently makes the appropriate decision as to whether to energize the output or not. The interface consists of two inputs and one output. One hall-effect sensor detects the magnetic field and a contact sensor ensures that the joint remained in total contact with the limb. The output is a buzzer which is energized through a transistor to amplify the microcontroller signals and produce the required alarm. The buzzer produces an audible alarm signal at the level of 97 dB with the frequency of 2 KHz.

Power in the range of 2.5 to 5 V was required for the microcontroller. The buzzer and Hall-effect sensor required a 9 V battery. Therefore, a 9-Volt battery, a 1 V regulator and two transistors were utilized. The transistors are responsible for switching the voltage between the microprocessor output and the desired voltage for the Hall-effect sensor and buzzer. The microprocessor is required to distinguish whether the coupling is successfully attained or had failed. If the signals from the Hall-effect sensor show that the magnetic field has activated the coupling, the contact sensor signals are analyzed.

The microcontroller samples every one millisecond for 3 ms. If all data are the same, it would be replaced by the previous. This process is also repeated for three times to ensure that the sensor detected the vibration of coupling; not the detachment (Figure 3.3). The final result will be processed by the microprocessor to make appropriate decision. This device is equipped with one 1200 mAh, 9V battery. Energy consumption of different parts is shown in Table 3.1.

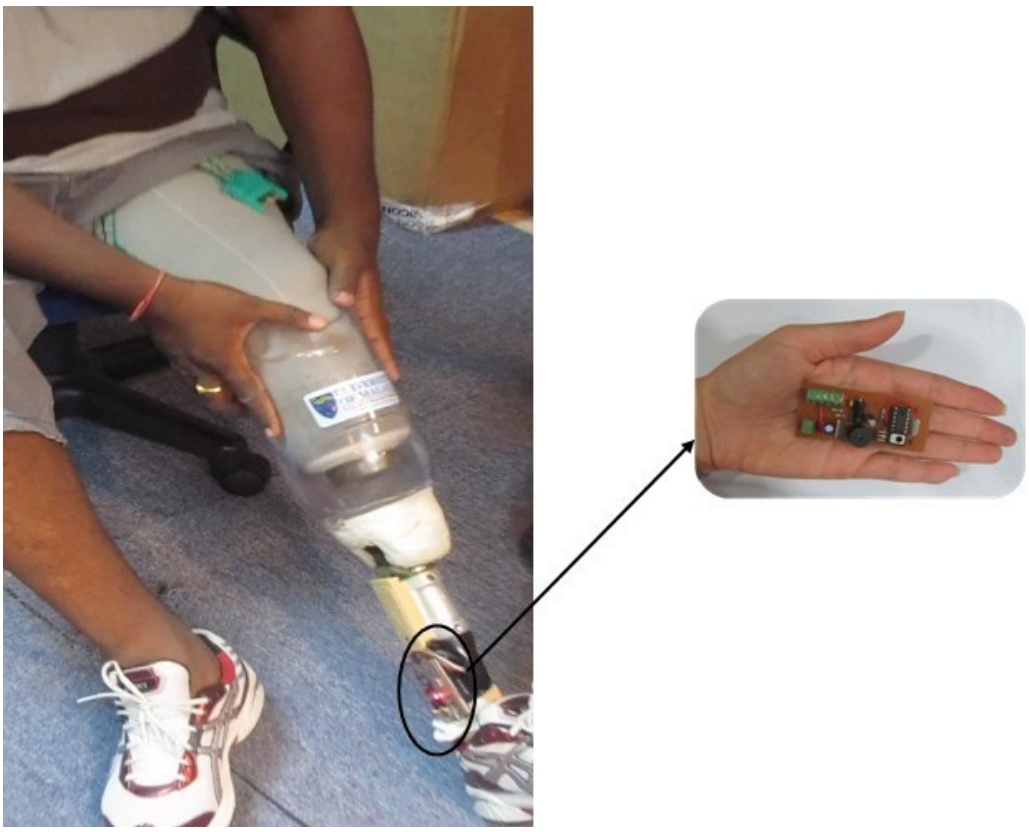


Figure 3.1: New prosthetic coupling system. A participant is donning a prosthesis that is fitted with the new prosthetic coupling system and the coupling alarm.

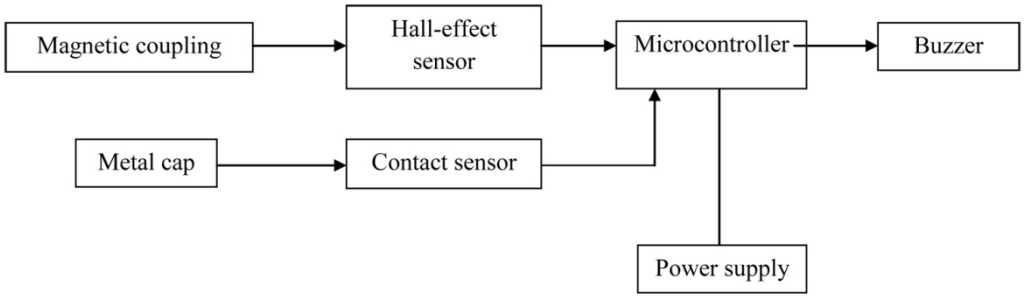


Figure 3.2: Alarm system. Block diagram of the coupling alarm system.

3.2.3. Participants and experiment

The study was approved by the Medical Ethics committee, University of Malaya Medical Centre (Reference No. 907.26). Thirteen transtibial amputees participated in the study as sample of convenience. All the participants were using a pin/lock liner with shuttle lock. Following a written informed consent, each participant was provided with a transtibial prosthesis that incorporated the new coupling and alarm system. To ensure consistent prosthetic quality, fabrication and alignment technique, the participants also received one prosthesis with pin/lock coupling system. The participants attended gait training sessions at the Brace and Limb Laboratory, University of Malaya.

Table 3.1: The energy consumption of different components of the alarm system.

System component	Energy consumption (μA)
Microprocessor unit	15 (in work mode) 2 (in standby mode)
Magnetic sensor	10
Buzzer	700 (in alarm mode)
Other parts, transistors and regulators	500

The suspension system was tested both mechanically and experimentally as the subjects engaged in basic walking activities. Mechanical testing under tensile loading was performed using the universal testing machine INSTRON 4466 through a special jig (Figure 3.4). The experimental testing of pistoning during gait was carried out using a 6-camera Vicon motion system. The detailed protocol developed by the authors has been explained elsewhere (Gholizadeh *et al.*, 2012c). However, a brief description is

presented here. The Helen Hayes marker set was modified to include 18 reflective markers for the lower limbs. Two extra markers were used specifically to measure the vertical movement or pistoning at the liner-socket interface. The displacement of markers indicated the pistoning. Finally, SPSS 20.0 (SPSS, Chicago, IL) was used to analyze the data through paired-samples t tests with Bonferroni adjustment. The level of significance was set at 0.05.

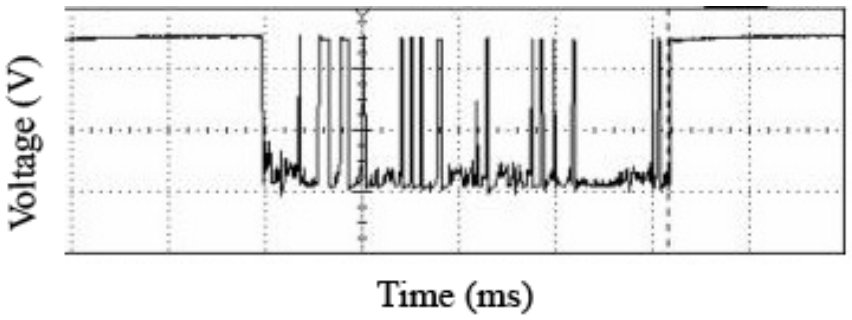


Figure 3.3: Decision making by the microcontroller. The microprocessor samples data every one millisecond for 3ms to ensure that the sensor detected the vibration of coupling.

3.3. Results

The maximum tensile load that the system could bear was 350.9 N (SD 0.5) of tensile loading before the coupling failed. The pin/lock system could tolerate loading of 580.4 N (SD 0.1); however, the lock system lost its function after three trials. The pistoning values for the two systems showed significant differences during the gait cycle. The most significant difference was evident during the swing phase ($P < 0.05$). With the pin/lock, 4.8 mm (SD 0.3) of pistoning was observed between the liner and the socket at initial contact. This was reduced to 3.5mm with the new coupling system. From mid stance to initial swing, no pistoning was observed between the liner and socket with any of the systems. Figure 3.5 shows the pattern of pistoning observed during walking with the two suspension systems.

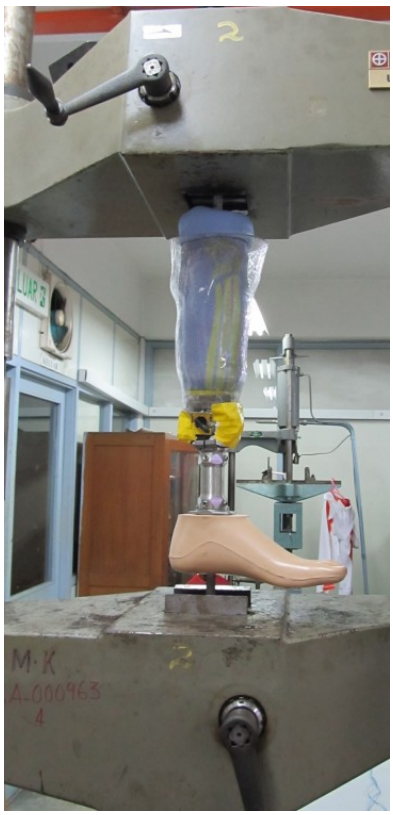


Figure 3.4: Mechanical testing. Tensile testing for the new prosthesis coupling system.

3.4. Discussion

This article explained the specifications of a new coupling device that could be incorporated in lower limb prostheses. The researchers conjured that the new device was able to retain the prosthesis securely on the amputee's residual limb during ambulation. Mechanical testing showed that the new device could resist tensile loading of up to 350.9 N and therefore the prosthetic leg should stand the centripetal force during walking. The force is calculated based on the mass of the prosthetic leg, the distance to the center of mass of the lower leg and the time taken to swing the prosthetic leg during walking (Winter, 2009). Based on our previous studies, the maximum force that was applied to the prosthetic leg during fast walking was 90 N (Gholizadeh *et al.*, 2012b). Therefore, it can be concluded that the system enables successful suspension of prosthesis.

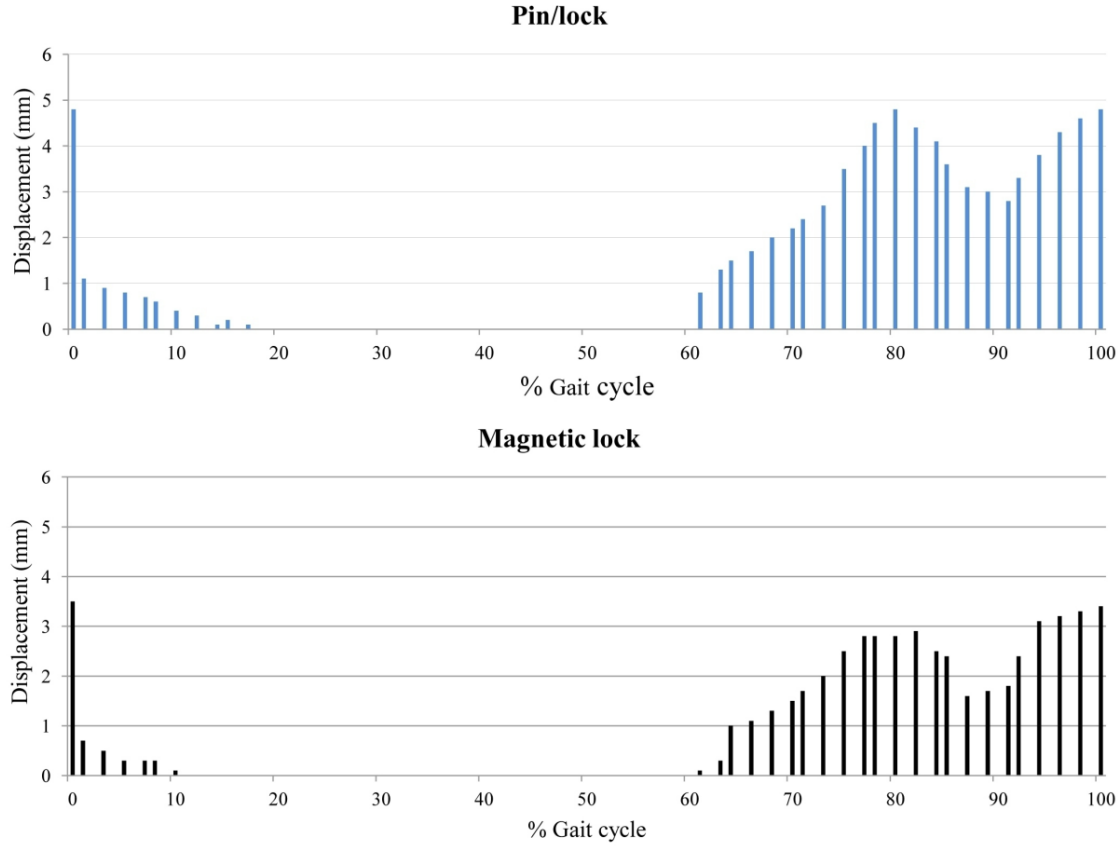


Figure 3.5: Pistoning measurement. The average pistoning values with the pin/lock and new prosthesis suspension systems during one gait cycle. (n=13)

One of the most suitable measures for assessing the effectiveness of suspension is pistoning (Eshraghi *et al.*, 2012a). Pistoning occurs either between the bone and soft tissue or the skin/liner and socket. This study evaluated the pistoning between the skin-liner and socket wall (Eshraghi *et al.*, 2012a). The pistoning values during walking with the new device were compatible with that of the pin/lock suspension system. Mainly in the swing phase, the systems demonstrated substantial difference and lower vertical displacement was resulted using the new suspension system. The pistoning was previously evaluated by a static simulation system (Eshraghi *et al.*, 2012b). However, in this study the newly designed protocol by the authors was adopted to investigate the pistoning during real walking (Gholizadeh *et al.*, 2012c). The results were compared with the previous findings through the simulation protocol (Eshraghi *et al.*, 2012b). There was not considerable difference between the pistoning values with the two protocols (gait simulation and during real gait).

In healthy individuals, the neurons are responsible for detecting any failure in the body and sending awareness signals to the brain. Users of artificial limbs face many problems as parts of body limbs are missing and prosthetic limbs cannot communicate with the brain to control sensory and motor mechanisms. As such, any failure in the prosthetic components may cause irreparable injuries that can aggravate the challenges that are already present in an amputee's life. Fall risk is high among lower limb amputees, particularly older amputees (Miller *et al.*, 2001; Zhang *et al.*, 2011); consequently, generating detectable signals at the first moment of failure can reduce fall risk. To the authors' knowledge this is the first prosthesis suspension system that incorporates an alarm system. The coupling alarm system was successfully tested on transtibial amputees. The buzzer can produce a buzz-type alarm for one second. The power supply (1200mAh 9V battery) enables the system to be functional up to 2200 hours. The authors are working to improve the alarm system as a wireless connection to the mobile gadgets in order to and show data such as the battery level, and degree of safety by evaluation of the coupling force, and buzzer testing. Furthermore, due to very low power consumption of the new device, it can be equipped with magnetic energy harvesting device to produce required energy. As such, the battery can be simply eliminated from the system that will lead to dramatic system improvement as the user does not need to replace the battery.

The main challenges were to place the sensors so that they could detect the desired signals while ensuring that the system remained user friendly. The sensitivity of the contact sensor was also crucial. If the sensor was too sensitive, a slight vibration during walking could activate the output alarm. This fake alarm could mislead the prosthesis user about the risk of suspension failure.

3.5. Conclusion

The new coupling device for the lower limb prosthesis can suspend prosthesis on the amputee's residual limb during walking. The pistoning values observed during walking were comparable to other suspension systems, and in some points of gait cycle were considerably lower. This can be considered the first prosthetic suspension system incorporating a safety alarm system. The alarm system may increase safety level by reducing the risk of fall. Nevertheless, the new coupling system can be both utilized with or without the safety alarm system.

CHAPTER 4

QUANTITATIVE AND QUALITATIVE COMPARISON OF A NEW PROSTHETIC SUSPENSION SYSTEM WITH TWO EXISTING SUSPENSION SYSTEMS FOR LOWER LIMB AMPUTEES

The objectives of this study were to compare the effects of a newly designed magnetic suspension system with that of two existing suspension methods on pistoning inside the prosthetic socket and to compare satisfaction and perceived problems among transtibial amputees. In this prospective study, three lower limb prostheses with three different suspension systems were fabricated for ten transtibial amputees. The participants used each of the three prostheses for one month in random order. Pistoning inside the prosthetic socket was measured by motion analysis system. The Prosthesis Evaluation Questionnaire was used to evaluate satisfaction and perceived problems with each suspension system. The lowest pistoning motion was found with the suction system compared with the other two suspension systems ($P < 0.05$). The new suspension system showed peak pistoning values similar to that of the pin lock system (P=0.086). The results of the questionnaire survey revealed significantly higher satisfaction rates with the new system than with the other two systems in donning and doffing, walking, uneven walking, stair negotiation, and overall satisfaction ($P < 0.05$). The new suspension system has the potential to be used as an alternative to the available suspension systems. The pistoning motion was comparable to that of the other two systems. The new system showed compatible prosthetic suspension with the other two systems (suction and pin lock). The satisfaction with donning and doffing was high with the magnetic system. Moreover, the subjects reported fewer problems with the new system.

4.1. Introduction

Transtibial prosthetic designs incorporate suspension systems consisting of liners and coupling components. Manufacturers continuously seek improvement in prosthetic components (Trieb *et al.*, 1999; Wirta *et al.*, 1990). The contours and build-ups on polyethylene foam liner (Pelite) worn inside the prosthetic hard socket help retain the prosthesis. A belt or strap also sometimes provides an extra means of security. Suspension sleeves, pulled over the prosthesis to give extra suspension, were introduced as an added feature, and later, silicone liners were invented to improve suspension by establishing a firm bond between the residual limb and the liner (Baars & Geertzen, 2005; Kristinsson, 1993). Internal pin lock systems, and recently, single or multiple hypobaric seals around the liners were developed as alternatives to external accessories. Improved suspension has been reported in objective and subjective studies as an advantage of silicone liners (Baars & Geertzen, 2005). Silicone liners are less bulky than other types of suspension. Enhanced suspension and cosmesis have produced higher satisfaction rates among transtibial amputees (Coleman *et al.*, 2004; Gholizadeh *et al.*, 2012b).

Satisfaction is said to be correlated with low piston motion, decreased unwanted sounds during functional tasks, and ease of don and doff (Beil *et al.*, 2002; Grevsten, 1978; Sanders *et al.*, 2006b). A suspension system should not only retain the prosthesis to the residual limb, but also provide comfort, enhanced function, and ease of don and doff. The ease and simplicity of donning and doffing is of critical importance among prosthetic users (Baars *et al.*, 2008; Gauthier-Gagnon & Grise, 1994). Users have reported difficulty in the proper alignment of pins in the pin lock systems. These systems may also cause a phenomenon called “milking” due to tissue stretch at the pin site, particularly during the swing phase of gait (Beil & Street, 2004; Street, 2006). This

milking might be the cause of pain and discomfort at the distal end of the residual limb, particularly during swing.

Researchers have investigated the pros and cons of different transtibial suspension systems both objectively and subjectively. The studies have targeted different determinants of successful prosthetic provision; lack of pistoning has been one of the main variables that indicate proper socket fit (Eshraghi *et al.*, 2012a). Some research studies have shown preferences for pin lock, and suction systems with total surface bearing (TSB) sockets over the polyethylene foam liners used with patellar tendon bearing (PTB) sockets, which exert high pressures on the residual limb (Baars & Geertzen, 2005; Beil *et al.*, 2002; Cluitmans *et al.*, 1994; McCurdie *et al.*, 1997).

Pistoning is defined as the vertical displacement mainly occurring within the prosthetic socket either between the residual limb and liner or the liner and socket wall (Michael, 2004). Improper suspension might result in residual limb skin problems, gait deviations and discomfort (Grevsten, 1978; Narita *et al.*, 1997). Several methods have been used for measuring the pistoning inside the prosthetic socket (Cluitmans *et al.*, 1994). They have been mostly conducted by radiography (Grevsten, 1978; Narita *et al.*, 1997), ultrasound (Convery & Murray, 2000) and computerized tomography (CT) (Madsen *et al.*, 2000). A recent method used a photographic technique for evaluation of piston motion between the liner and socket (Gholizadeh *et al.*, 2012a; Gholizadeh *et al.*, 2011). Finally, the use of motion analysis systems by reflective markers was recently introduced to measure the pistoning (Beil *et al.*, 2002). The very same method was adopted in this study to evaluate the effect of newly designed suspension system on pistoning (Beil *et al.*, 2002). Pistoning measurement have been mostly performed through gait simulation as evaluation during the real gait had been either detrimental to the amputee or some technical limitations hindered the measurement during real gait (Eshraghi *et al.*, 2012a).

Qualitative surveys in the field of prosthetics have frequently used the prosthetic evaluation questionnaire (PEQ) to investigate the effects of prostheses on the quality of life among individuals with amputation. Good reliability and validity have been reported for PEQ (Legro *et al.*, 1998). PEQ research on prosthesis satisfaction has revealed that donning and doffing might play important roles in amputees' satisfaction (Gholizadeh *et al.*, 2012c).

While silicone suspension systems such as pin lock and hypobaric seal-in liners are said to provide enhanced suspension for the lower limb prostheses, some disadvantages such as increased pain at the residual limb and difficulty of donning and doffing are also attributed to them (Baars & Geertzen, 2005; Beil *et al.*, 2002). To overcome some of the disadvantages of pin lock, and suction suspension systems, the authors of the current study invented, produced, and evaluated a new prosthetic suspension system compared with the pin lock and suction systems. The purposes of this study were to compare a new suspension system with two existing methods of suspension in terms of pistoning motion between the prosthetic liner and socket, and satisfaction and perceived problems of transtibial amputees. We hypothesized that the new suspension system will cause less pistoning compared with the pin lock while the resultant pistoning will be higher than the suction suspension. Our other hypothesis was that there will be significant increase in satisfaction rates with the new suspension system than the other two systems.

4.2. Methodology

4.2.1. Participants

Ten individuals with transtibial amputation were selected as sample of convenience to participate in this prospective study. The inclusion criteria were unilateral transtibial

amputation, activity levels of K2-K3 according to the American Academy of Orthotists and Prosthetists (2010), residual limbs free of wound and pain, no upper limb disability, experience with silicone liners, no volume fluctuation in the residual limb, and the ability to ambulate independently. The stump length, measured from the inferior edge of the patella to the distal end of the stump, had to be no less than 13 cm. All the participants used transtibial prostheses with pin lock suspension system prior to the initiation of the study. Table 4.1 lists the individual characteristics of all subjects. The University of Malaya Ethics Committee Ethics Committee approved the research study. The subjects were required to sign a consent form to enter the study and the researchers considered each subject as his own control.

Three prostheses were fabricated for each subject by a single registered prosthetist to ensure uniform design, alignment, and fit. Three suspension systems were selected, including the new lower limb suspension design (Figure 4.1). The other two systems were a) shuttle lock and pin (Dermo® Liner with Icelock-clutch 4 H214 L 214000) and b) the suction suspension (Seal-In®X5 Liner with Icelock Expulsion Valve 551). Other prosthetic components were common between the three prostheses (Flex-Foot Talux® and Tube adaptor).

Transparent thermoplastic material ensured that the sockets were Total Surface Bearing (TSB), and had visible walls, through which the researchers could detect the internal features (Beil *et al.*, 2002). The processes of checkout, gait evaluation, and gait training were performed in the Brace & Limb Laboratory, University of Malaya. Furthermore, the PEQ questionnaire required at least one-month of prosthetic use for each prosthetic type to allow for adaptation to new prostheses.

Table 4.1: Subjects characteristics.

Subject no.	Age	Height (cm)	Mass (Kg)	Amputated side	Cause of amputation	Stump length (cm)[a]	Mobility grade[b]
1	42	173	75	Left	Diabetic	13	K2
2	37	168	90	Left	Trauma	14.5	K3
3	30	182	60	Left	Trauma	15	K3
4	72	166	75	Left	Diabetic	13.5	K2
5	46	167	64	Right	Trauma	16	K3
6	35	170	99	Right	Diabetic	14	K2
7	49	164	57	Right	Diabetic	15	K3
8	53	177	60	Left	Diabetic	14	K3
9	41	168	72	Right	Trauma	13	K2
10	33	171	86	Left	Trauma	17	K3

4.2.2. New suspension system

The new suspension system used in this study consisted of a) a cap matched to the distal end of the silicone liner and b) a magnetic lock system embedded in the distal end of the hard socket (Figure 4.1). The cap was a cup-shaped metal component with the same diameter of the distal liner. It was connected to the liner by a screw in the middle and silicone adhesive. The cap was filled with the silicone adhesive all around the central screw. A mechanical switch button enabled two modes of connecting or disconnecting the liner and the hard socket; it was designed so that allowed easy detachment of the liner from the socket. Nevertheless, the lock did not fail after it was switched on, which is an advantage as security assurance for amputees. When the switch button was turned on, a magnetic field was produced and switching off the button would weaken the magnetic field so that the suspension failed (the liner was detached from the socket). The system was tested under tensile loading by the universal

testing machine (Instron 4466). It could tolerate 350 N tensile loading before the liner was released from the socket.

4.2.3. Equipment and experiments

After the completion of four weeks of prosthetic use for each system, the subjects attended the motion laboratory for quantitative study. The order of prosthetic suspension system use was randomized for every subject. In order to investigate the pistoning inside the prosthetic socket, researchers adopted the static method using a 7-camera Vicon 612 motion system (Oxford Metrics; Oxford, UK). Sixteen reflective markers of 5 mm diameter were attached to each subject's prosthetic and sound lower limbs according to the Helen Hayes marker set. The lateral distal end of the socket and the lateral proximal socket wall were selected to locate the tibia and knee markers on the prosthesis, respectively. As it was attempted to measure the pistoning between the liner and socket, two extra markers (paper-thin) were attached to the liner under the functional knee joint level and 5 cm below that (Beil *et al.*, 2002). The accuracy level of the motion analysis system was less than ± 0.1 mm (Jenkins, 2001).

The subjects stood on a platform. The researchers measured the pistoning by the gait simulation method through load application (Beil *et al.*, 2002; Board *et al.*, 2001; Eshraghi *et al.*, 2012a; Narita *et al.*, 1997). Double limb and single limb support with the prosthesis were considered compressive loadings. The subjects were required to perform single-limb stance on the prosthetic limb (full weight bearing). Then they stood on both limbs to fulfill the semi-weight bearing step. For tensile loading, the subjects had to hang their prosthetic leg from the platform edge (non-weight bearing). Next, three loads of 30, 60, and 90 N were added consecutively to the prosthetic foot. The

swing phase of gait has been previously replicated by similar loads (Beil *et al.*, 2002; Board *et al.*, 2001; Gholizadeh *et al.*, 2012a; Narita *et al.*, 1997). In order to determine the pistoning, the distance between the markers on the liner and on the socket was calculated in each loading condition.

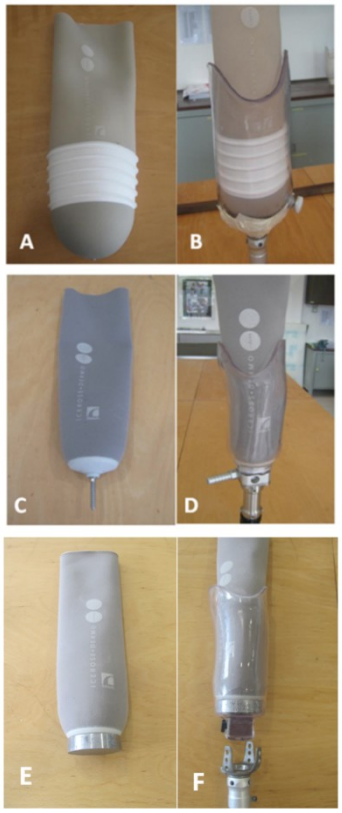


Figure 4.1: Three suspension systems used in this study. A, Seal-In X5 liner; B, transparent socket and valve; C, Dermo liner with pin; D, transparent socket and shuttle lock; E, Dermo liner with distal cap; F, transparent socket and new magnetic lock.

To ensure safety of participants, a hand rail was located close to the platform during the experiments. The subjects could hold the hand rail if they could not maintain their balance. The entire loading process was repeated five times for each subject. Mean and peak displacement values for each single trial were calculated. Average values of five trials were employed for the statistical analyses. All the experiments were also repeated in two separate sessions (with one week interval) by two different observers to

investigate the reliability of the method. Moreover, we wanted to examine if marker placement by different observers might introduce error.

4.2.4. Questionnaire

The PEQ questionnaire is a self-report instrument commonly used to evaluate prosthetic users' satisfaction with prostheses. The original version is subdivided to 9 sections comprising of 82 questions. As the questions are not dependent on each other, it is possible to use them as appropriate to a given study (Legro *et al.*, 1998). For the qualitative analysis, a questionnaire was designed that utilized selected questions of the PEQ under scales of demographic data, satisfaction and problems. The subjects completed a separate questionnaire for each prosthetic type after they finished four weeks of prosthetic use. The questionnaire included the following three scales:

i. Demographic data (age, cause of amputation, weight, height, and time since amputation)

ii. Satisfaction (fitting, sitting, ability to walk on level surface, uneven ground, up and down the stairs; cosmesis; suspension; don and doff; overall satisfaction)

iii. Problems (sweating, wound, skin irritation, pain, pistoning within the socket, residual limb rotation inside the socket, swelling, unwanted sounds and bad odor).

For the overall satisfaction, the participants were asked to report how overall satisfied they were with their prosthesis for the past month. Linear analogue scale response format was employed (Van de Weg & Van der Windt, 2005). Each response was scaled on a 100-mm line from 0 to 100, where 0 indicated "dissatisfaction or

extreme problems" with the system and 100 showed "complete satisfaction or no problems" (Legro *et al.*, 1998). A standard ruler was used to measure the distance between 0 and the vertical mark on the line.

4.2.5. Data analysis

Statistical data analysis employed SPSS 18.0, where p-values of 0.05 or less were set as the level of significance. Preliminary analyses were performed to ensure the assumption of normality and homogeneity of variance. Kolmogorov-Smirnov test showed normal distribution of all the data; therefore, parametric statistical analyses were adopted. Differences in pistoning values were examined using a 6 × 3 (loadings × suspension systems) Repeated Measure Analysis of Variance (ANOVA). If significant differences were obtained from ANOVA, paired-samples t tests compared positions among the three suspension systems.

Intraclass correlation coefficient (ICC) was used to evaluate the repeatability of the measurements. Qualitative analyses were used to analyze the demographic information of the respondents. To analyze patients' satisfaction and to examine problems related to the suspension types, 18 × 3 (questions × suspension systems) Repeated Measure Analysis of Variance (ANOVA) computed the mean scores for each question of the questionnaire to determine significant differences among the three suspension systems. If significant effect of suspension type was found, paired-samples t tests were employed to find significant differences among each two suspension systems.

4.3. Results

4.3.1. Demographic information

All the participants were males. The mean age, height, and weight of the participants were 42 years (SD 12.8), 172 cm (SD 5.1), and 79.5 kg (SD 12.2), respectively. The cause of amputation was either diabetes or trauma. The average prosthetic mass for suction, pin and lock and new prosthetic suspension system among the ten subjects was 1.75, 1.86 and 1.92 kg, respectively. The intraclass correlation coefficient (ICC) of intraobserver intersession and interobserver intersession and intraobserver intrasession were 0.80 and 0.72 and 0.93, respectively.

4.3.2. Pistoning evaluation

The main effect of the suspension type in adding and removing ($F(2,18)=124.11$, $P=0.000$) through ANOVA demonstrated a significant difference between the three suspension systems. There was also significant difference between different positions of adding and removing ($P=0.000$). Therefore, paired-samples t tests were used to determine significant differences between each pair of suspension systems. When the base measurement at full weight bearing was compared with the peak pistoning at 90 N loading, the new magnetic system caused approximately the same amounts of pistoning as the pin and lock ($P=0.086$). However, the suction system (Seal-In®X5) showed less pistoning compared with both the pin and lock and new magnetic system ($P < 0.05$ for both comparisons). From semi to non-weight bearing, mean pistoning was lower with the new magnetic lock than the pin lock system (1.0±0.6 cm vs. 1.5±0.5 cm; $P = 0.016$), while the new magnetic lock had higher mean pistoning in comparison to the suction

suspension (1.0±0.6 cm vs. 0.2±0.1 cm; P=0.007). When 30 N load was added, significant difference was seen in the displacement with the new magnetic lock compared with the pin lock system as the new lock resulted in less displacement (P=0.004). Conversely, less pistoning occurred with the suction system than the new magnetic lock (P=0.000). Same significant differences were seen in the pairs of magnetic-pin lock and magnetic-suction system when 60 N loads were added (both $P < 0.05$). Table 4.2 presents the mean displacements between the liner and hard socket with the three suspension types under different static conditions (adding and removing loads). As we expected, the pistoning reduced in the process of removing the loads for all the three systems. Nevertheless, the reduction did not follow the same trend that was found during the adding procedure, as significant differences were found between the pistoning values in adding and removing (for 30 N, 60 N and non-weight bearing) when each system was individually studied. Figure 4.2 illustrates the mean pistoning values (±SD) in each weight-bearing condition for three studied suspension systems.

4.3.3. Satisfaction

There was a significant effect for the suspension type among all the questions of the questionnaire, $F(2, 18)=153.18$, P=0.000. The questionnaire survey revealed that the overall satisfaction rate with the magnetic system was higher than the pin lock and suction systems ($P < 0.05$ for both comparisons). To compare the new magnetic suspension system to the pin lock suspension, the undesirable noise of locking systems was significantly lower, while the amputee still felt secure from the audible feedback of the primary contact between the distal and proximal portions of the new system. Amputees can use the new system with their old liners as the cap is attached to the liner by silicone adhesive and a screw which is similar to the screw diameter for most of the

locking silicone liners in the market. However, the socket needs to be replaced to embed the distal part of the new magnetic system at the distal end of the socket. To compare the new magnetic suspension system to the pin lock suspension, the undesirable noise of locking systems was significantly lower, while the amputee still felt secure from the audible feedback of the primary contact between the distal and proximal portions of the new system. Amputees can use the new system with their old liners as the cap is attached to the liner by silicone adhesive and a screw which is similar to the screw diameter for most of the locking silicone liners in the market. However, the socket needs to be replaced to embed the distal part of the new magnetic system at the distal end of the socket (Table 4.3).

Donning and doffing were easier with the magnetic suspension system compared with pin lock system (mean score: 79.68 vs. 71.44; P=0.000) and suction system (mean score: 79.68 vs. 57.24; P=0.000) with 95% confidence intervals. Subjects stated that they were more satisfied during walking and stair climbing with the new magnetic system over two other systems ($P < 0.05$ for both comparisons). Suspension satisfaction with the new magnetic system was similar to the pin lock system (P=0.062, two tailed), while the suction suspension resulted in higher satisfaction score in comparison to the new system (P=0.000). The statistical analysis showed significant differences in some of the complaint/problem items ($P < 0.05$) among the three suspension systems. Pain score with the new magnetic system was significantly less than the pin lock suspension (90.18 vs 70.62, respectively; P=0.000). Also, problems with the unwanted sound was higher with the pin and lock system compared with the new system; however, the subjects experienced less unwanted sound with the suction system than the new system ($P < 0.05$ for both comparisons). Table 4.3 demonstrates the mean, standard deviation (SD) and significance values of suspension systems with respect to the problems.

4.4. Discussion

This research study compared a new suspension system with two existing methods of suspension to investigate their effects on pistoning and patients' satisfaction. The study revealed that the new design of prosthetic suspension had the potential for use with transtibial amputees. Based on the results, the repeatability of the measurements was high and there was no significant difference between the observers.

When evaluating our hypothesis regarding the difference between the pistoning with pin lock and magnetic system, pistoning appeared comparable from full weight bearing to 90 N for the pin lock system and the magnetic suspension. The statistical analyses revealed higher peak pistoning with the new magnetic system in comparison to the suction system from full weight bearing to addition of 90 N load ($P < 0.05$). Researchers have performed various evaluations of piston motion with a variety of prosthetic sockets and soft interfaces. Studies have found that TSB sockets with silicone liners result in significantly less piston motion between the liner and socket (Narita *et al.*, 1997; Yigiter *et al.*, 2002). In the current study, the suction system (Seal-In®X5) system resulted in the least pistoning among the three systems, which supports the findings of Gholizadeh et al. (2011). Mean pistoning with the pin lock system from full weight bearing to 90 N was 5.8 mm (SD, 0.6), which is similar to the results of Tanner and Berke (2001), Board *et al.* (2001) and Gholizadeh *et al.* (2011).

None of the three studied systems demonstrated pistoning movement from full to semi-weight bearing which is not surprising as in the full weight bearing position, the limb moved distally in the socket and large force was developed between the liner and socket that restricted pistoning strongly. Slight differences were seen in the systems' behaviors between adding loads and the reversed process of loading (removing loads), particularly for the suction system (Seal-In®X5). The mean pistoning values for 60 N,

30 N and non-weight bearing did not statistically approach the same that were seen during adding loads (non-weight bearing, 30 N and 60 N) when each suspension system was individually studied ($P < 0.05$ for all three systems). The exception was that with the suction system, no significant difference was seen between each single step from 60 N to non-weight bearing. This denotes a delay in the process, which might be associated with the increased friction and suction between the Seal-In®X5 and the socket wall (Figure 4.2). Nevertheless, further research is needed to prove this assumption.

One of our hypotheses was that there will be significant increase in satisfaction rates with the new suspension system than the other two systems. All three suspension systems studied in this research showed approximately high satisfaction rates among the participants. Nevertheless, the qualitative survey demonstrated significant differences in satisfaction and perceived problems with the new design compared with the pin lock and suction systems. The new magnetic suspension system resulted in higher satisfaction scores than pin lock and suction systems only on a number of items.

Table 4.2: Mean pistoning values of three suspension systems in different static positions during adding and removing loads (n=10).

All values are in millimeter.

	Adding Load							Removing Load						
	FWB	**SWB**	**NWB**	**30N**	**60N**	**90N**	**ANOVA**	**90N**	**60N**	**30N**	**NWB**	**SWB**	**FWB**	**ANOVA**
	Mean(SD)	**Mean(SD)**	**Mean(SD)**	**Mean(SD)**	**Mean(SD)**	**Mean(SD)**		**Mean(SD)**	**Mean(SD)**	**Mean(SD)**	**Mean(SD)**	**Mean(SD)**	**Mean(SD)**	
Suction[1]	0	0	0.2(0.1)	0.9(0.4)	1.7(0.5)	2.8(0.5)	0.000[a]	2.8(0.5)	2.6(0.5)	2.6(0.5)	2.6(0.5)	1.0(0.2)	0	0.000[a]
Magnetic Lock[2]	0	0	1.0(0.6)	2.0(0.5)	3.3(1)	5.3(0.7)		5.3(0.7)	4(0.7)	2.8(0.8)	1.0(0.4)	0	0	
Pin Lock[3]	0	0	1.5(0.5)	2.7(0.7)	4.3(1.1)	5.8(0.8)		5.8(0.8)	5.4(0.5)	4.0(1.2)	3.6(0.5)	0	0	
Significance (two tailed)	-	-	1-2 (0.007) 1-3 (0.000) 2-3 (0.016)	1-2 (0.000) 1-3 (0.000) 2-3 (0.004)	1-2 (0.000) 1-3 (0.000) 2-3 (0.002)	1-2 (0.000) 1-3 (0.000) 2-3 (0.000)		1-2 (0.000) 1-3 (0.000) 2-3 (0.000)	1-2 (0.000) 1-3 (0.000) 2-3 (0.000)	1-2 (0.045) 1-3 (0.000) 2-3 (0.001)	1-2 (0.000) 1-3 (0.000) 2-3 (0.000)	1-2 (0.000) 1-3 (0.000) 2-3 (0.000)	-	

SD=standard deviation; FWB=full weight bearing; SWB=semi weight bearing; NWB=non weight bearing.

[a] Indicates significant differences among the three suspension systems from the Repeated measure ANOVA.

"1-2", "1-3" and "2-3" indicate that significant differences ($P < 0.05$) were found between each two suspension systems in each loading position based on the paired-samples t test

The new magnetic suspension system seems to be similar to the current systems in function as it can retain the prosthesis on the residual limb during ambulation. Furthermore, the new suspension system produced less noise during walking and donning compared with the pin lock suspension (P=0.003), was much easier to don and doff compared with the suction suspension and pin lock system ($P < 0.05$ for both), and resulted in higher overall satisfaction in comparison to both suction and pin lock systems ($P < 0.05$ in both cases). Vacuum suspension is said to improve proprioception in prosthetic users (Street, 2006); however, our subjects stated preference to the magnetic lock over the suction system. The pin lock system resulted in higher satisfaction than the suction suspension (Seal-In®X5) system, which is consistent with the results of Gholizadeh *et al.* (2011).

To compare the new magnetic suspension system to the pin lock suspension, the undesirable noise of locking systems was significantly lower, while the amputee still felt secure from the audible feedback of the primary contact between the distal and proximal portions of the new system. Amputees can use the new system with their old liners as the cap is attached to the liner by silicone adhesive and a screw which is similar to the screw diameter for most of the locking silicone liners in the market. However, the socket needs to be replaced to embed the distal part of the new magnetic system at the distal end of the socket.

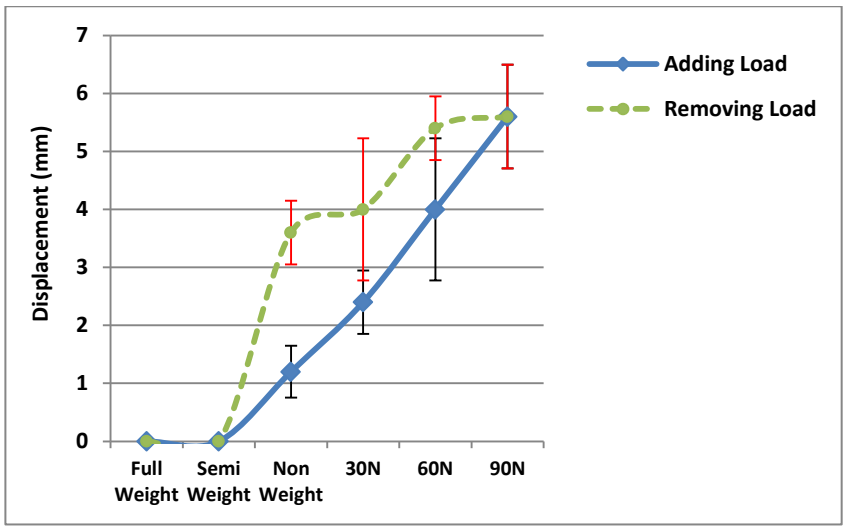
Table 4.3: Mean scores of satisfaction and problems with three suspension systems.

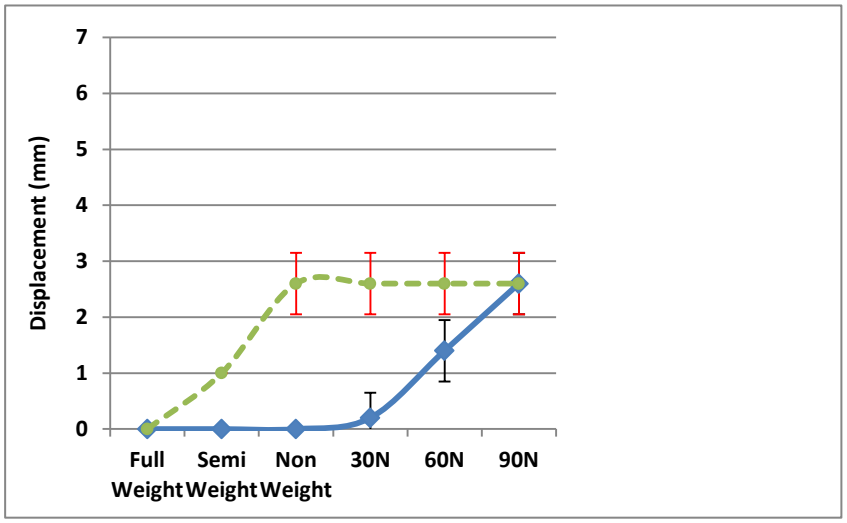
		Suction (1)	Magnetic lock (2)	Pin/lock (3)	Sig. (t test)
Satisfaction	Fitting	87.09	76.82	79.59	1-2(0.002) 1-3(0.003) 2-3(0.044)
	Donning and doffing	57.24	79.68	71.44	1-2(0.000) 1-3(0.016) 2-3(0.000)
	Sitting	79.41	76.44	68.80	1-3(0.001) 2-3(0.041)
	Walking	65.21	84.66	72.80	1-2(0.000) 1-3(0.008) 2-3(0.000)
	Uneven walking	63.91	77.93	54.30	1-2(0.000) 1-3(0.030) 2-3(0.000)
	Stair	68.83	80.60	65.75	1-2(0.001) 2-3(0.000)
	Suspension	93.71	81.72	75.20	1-2(0.000) 1-3(0.000)
	Cosmesis	83.10	73.27	69.05	1-2(0.004) 1-3(0.000)
	Overall satisfaction	63.14	83.10	75.94	1-2(0.000) 1-3(0.000) 2-3(0.008)
Problems	Sweat	64.78	60.16	55.00	1-2(0.009) 1-3(0.019)
	Wound	95.17	75.04	81.85	1-2(0.000) 1-3(0.000) 2-3(0.017)
	Irritation	94.66	75.10	81.28	1-2(0.000) 1-3(0.000) 2-3(0.021)
	Pistoning within the socket	96.47	63.95	84.18	1-2(0.000) 1-3(0.000) 2-3(0.000)
	Rotation within the socket	99.57	81.65	80.18	1-2(0.000) 1-3(0.000) 2-3(0.017)
	Swelling	94.91	89.64	86.75	1-2(0.017) 1-3(0.000)
	Bad smell	77.83	63.94	72.49	1-2(0.000) 1-3(0.007) 2-3(0.002)
	Unwanted sound	96.81	80.28	70.21	1-2(0.000) 1-3(0.000) 2-3(0.003)
	Pain	80.67	90.18	70.62	1-2(0.000) 1-3(0.000) 2-3(0.000)

"1-2", "1-3" and "2-3" indicate that significant differences ($P < 0.05$) were found between each two suspension systems in each satisfaction/problems item based on the paired-samples t tests.

Our subjects reported that they felt more secure with the new system compared with the pin lock suspension. They believed that with the pin lock system they felt like they were walking on an unstable moving rod (pin), while when they walked with the new system they experienced a firm, stable base of support under the residual limb. That might be associated with the cross-sectional difference between the single pin (the pin lock system) and the cup-shaped cap of the new system. Nevertheless, their subjective reports revealed that suction system resulted in higher confidence during walking which is consistent with the study by Gholizadeh et al. (2012) that the participants reported they felt the leg with the suction system to be a normal part of their body (Gholizadeh *et al.*, 2012b). The cosmesis of the new system was almost the same as the pin lock system (P=0.185). Conversely, the subjects were more satisfied with the suction system compared with the new magnetic system in terms of cosmesis which can be attributed to the added components. Additionally, the same problem of the pin lock system may arise with long stumps due to limited space below the socket for installation.

Effortless donning and doffing appears to result in higher overall satisfaction (Baars *et al.*, 2008; Gauthier-Gagnon & Grise, 1994). The Seal-In®X5 liner has solved some of the problems with pin lock systems; however, patients still require more time and effort when donning and doffing. They also need to use lubricant sprays (Clean & Simple Lubricant spray, Össur) to facilitate donning process of both the liner and the socket. Moreover, hand dexterity is more critical for donning and doffing a Seal-In®X5 liner compared with the Dermo® liner. Rolling the Seal-In®X5 is more difficult as the seals do not smoothly slide over each other unless some lubricant spray is used. The subjects of this study were mainly dissatisfied with donning and doffing of the Seal-In®X5 system; donning and doffing was significantly easier with the magnetic system.





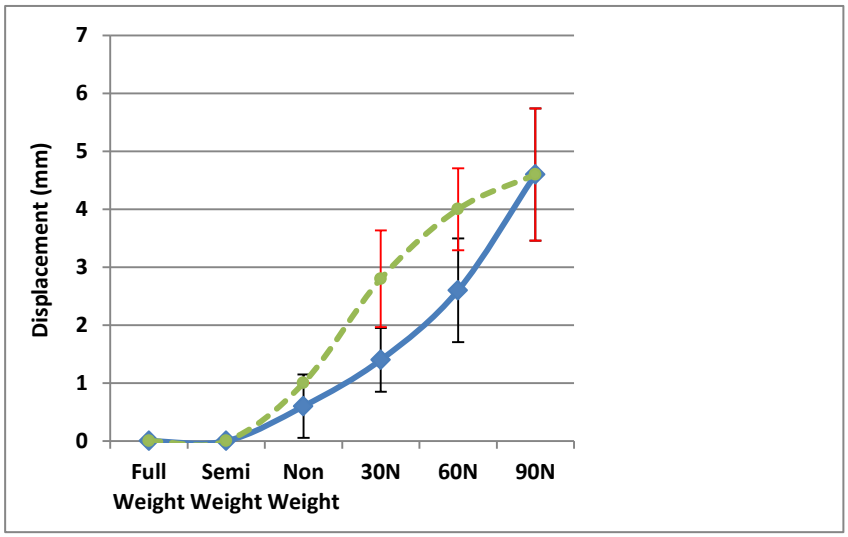


Figure 4.2: Pistoning results for adding and removing loads in static positions for three suspension systems. (n = 10; displacement ± standard deviation).

Meanwhile, our subjects experienced less pistoning and rotation within the prosthetic socket with the suction system compared with the new magnetic lock which is consistent with the results obtained from the pistoning measurement by motion analysis system. Subjects stated preference for the new magnetic system over the Seal-In®X5 and pin lock for long-term use.

Some patients have trouble aligning the pin when donning the prosthesis. In the proposed system, the distal and proximal components at the distal end of the liner and socket are easily connected as soon as the residual limb is located into the hard socket. The total contact fit also deteriorates, especially if the residual limb is pointed and bony. The new system might resolve the so-called problem of "milking" or distal tissue stretching caused by the pin and lock (Beil & Street, 2004; Street, 2006). This milking phenomenon can also result in pain, particularly at the end of the tibia and along the tibial crest. Pin/lock suspension is said to have short- and long-term negative effects on the residual limb (Beil & Street, 2004). Short-term effects are discoloration and swelling at the distal end of the residual limb which will result in the change in soft tissue shape, skin thickness and color in long term. These changes might be the result of liner elongation which develops milking. As a result, the residual limb is compressed at the proximal end and stretches the distal soft tissue, particularly during the swing phase (Beil & Street, 2004). Nevertheless, further studies are needed to investigate the effect of this new system on milking.

Although we did not measure the pressure interface within the prosthetic socket, the subjects in the current study had significantly less pain with the new magnetic system compared with the pin lock suspension (P=0.000). This reduction in pain may be attributed to the evenly distributed contact pressure between the proximal part of the magnetic suspension system and the distal end of the liner. There is full contact between the proximal cap of our new system and the distal end of the liner in contrast to the pin

lock suspension; therefore, it is anticipated to reduce the milking. Based on the available literature and the findings of this study, it is possible to conclude that pistoning alone might not be a good indicator of clinically superior suspension system. Satisfaction, particularly with donning and doffing, should also be taken into account when choosing a prosthetic suspension system for a lower limb amputee.

4.4.1. Study limitations

The population was small with respect to the number of variables that were analyzed in the questionnaire. Long-term follow-up of the new system may further prove its potential as an alternative prosthetic suspension method. Research is ongoing on the effects of the new system on the pistoning and interface pressure during walking.

4.5. Conclusion

This study introduced a new prosthetic suspension system for transtibial prostheses. The new magnetic suspension system and pin lock cause comparable pistoning but higher pistoning than the suction system. Satisfaction was improved in terms of donning and doffing, noise and overall satisfaction with the new magnetic lock compared with the pin lock, and suction systems.

CHAPTER 5

AN EXPERIMENTAL STUDY OF THE INTERFACE PRESSURE PROFILE DURING LEVEL WALKING OF A NEW SUSPENSION SYSTEM FOR LOWER LIMB AMPUTEES

Different suspension systems that are used within prosthetic devices may alter the distribution of pressure inside the prosthetic socket in lower limb amputees. This study aimed to compare the interface pressure of a new magnetic suspension system with the pin/lock and Seal-In suspension systems. Twelve unilateral transtibial amputees participated in the study. The subjects walked on a level walkway at a self-selected speed. The resultant peak pressure with the three different suspension systems was recorded using F-Socket transducers. There were significant statistical differences between the three studied suspension systems. Pair-wise analyses revealed that the mean peak pressure (kPa) was lower with the magnetic system than it was with the pin/lock system over the anterior and posterior aspects during one gait cycle (89.89 vs. 79.26 & 47.22 vs. 26.01, respectively). Overall, the average peak pressure values were higher with the Seal-In system than they were with the new magnetic lock and pin/lock system. The new magnetic system might reduce the pressure within the prosthetic socket in comparison to the pin/lock and Seal-In system during one gait cycle. This is particularly important during the swing phase of gait and may reduce the pain and discomfort at the distal residual limb in comparison to the pin/lock system.

5.1. Introduction

Suspension systems are necessary components of lower limb prostheses and they are used to create a secure coupling between the residual and prosthetic limbs. The majority of contemporary suspension systems utilize silicone liners as the preferred suspension system (McCurdie *et al.*, 1997). Lower limb amputees have stated preference towards these silicone liners as a result of the fact that these systems provide a close match to the residual limb, superior suspension, improved appearance and better function (Baars & Geertzen, 2005). In general, there is a high overall satisfaction with prosthetic devices that incorporate silicone liners as suspension systems (Eshraghi *et al.*, 2012a). There are a variety of silicone suspensions in use that are coupled to the hard socket either by a distal single pin or through circumferential seal or seals that produce vacuum at the socket wall. Prosthetic hard sockets that are used with silicone suspension should be undersized to ensure a total-surface bearing fit. Research has revealed that a total-surface bearing socket exposes the soft tissue to tolerable compression (Laing *et al.*, 2011). On the other hand, bony structures are stabilized within the residual limb; therefore the skin may not be damaged due to unbearable excessive pressure when these liners are in use (Wlodarczyk, 2007). Moreover, total surface bearing sockets coupled with enhanced vacuum (for instance by Seal-In liners) might control volume fluctuation and perspiration. At the same time, piston motion or displacement within the socket and thereby shear force will be reduced.

Some researchers have attempted to evaluate the load applied to the residual limb either through completion of clinical assessments that use different types of transducers (Convery & Buis, 1999; Laing *et al.*, 2011; Sanders *et al.*, 1998; Zhang *et al.*, 1998) or through simulation techniques (Commean *et al.*, 1997; Lin *et al.*, 2004; Silver-Thorn & Childress, 1996). Friction within the prosthetic socket has a two-fold effect as it helps to

retain the prosthesis on the residuum but at the same time it may distort the soft tissue (Mak *et al.*, 2001). If large friction occurs at an interface, stress may be localized and this can lead to the deformation of the remaining tissue. Conversely, Zhang et al. found that lubricating the skin will increase the interface pressure (Zhang *et al.*, 1996). Few research studies have dealt with the effect of liners and prosthetic sockets on the pressure applied to the residual limb. Without understanding the changes imposed on the soft tissue and skin by different socket designs and suspension systems, it is not possible to evaluate the overall prosthetic fit. Moreover, prosthetic interface pressure is believed to be a determinant of the amputees' comfort (Dou *et al.*, 2006; Jia *et al.*, 2004; Sanders *et al.*, 2006a; Sewell *et al.*, 2000).

Research has shown that pin liners exert compression on the residual limb proximally and tension distally during the swing phase of gait. This skin stretch at the pin site is called milking. This milking phenomenon is probably the cause of the short (edema and redness) and long-term (discoloration and thickening) transformations that are observed, particularly at the distal end of the residuum (Beil & Street, 2004). This compression can result in pain, discomfort and residual limb atrophy or volume loss.

A new prosthetic suspension system has been developed by the authors (Eshraghi *et al.*, 2012b). This study aimed to compare the effect of this new prosthetic suspension system with pin/lock and Seal-In systems with regards to the interface pressure that is produced between the liner and socket. The researchers hypothesized that the new suspension system would result in less traction at the distal end of the residual limb and lower compression proximally in comparison to the pin/lock liner. The researchers also assumed that the Seal-In liner would offer similar interface pressure to the new suspension system, particularly at the distal region of the stump.

5.2. Methodology

Fifteen amputees agreed to participate in the study as sample of convenience and were asked to sign a written consent form. Ethical approval was obtained from the University of Malaya Ethics Committee prior to the study. The subjects were required to conform to the following criteria in order to be included in the study: no ulcer on the residuum, no volume change at the residual limb and the ability to ambulate without assistance. As the minimum length for eligibility to use Seal-In liners is 11 cm based on the manufacturer guidelines, only those amputees with adequate residuum length were eligible to participate. The subjects were also considered for participation if they had used prosthesis in the last 6 months.

Each subject was provided with three new prostheses, each of which incorporated a different suspension system: (a) the new magnetic suspension system, (b) a pin/lock liner and (c) a suction Seal-In suspension. All the procedures from the casting to prosthetic alignment were performed separately for each prosthesis by one of the researchers (a registered prosthetist). All the prostheses incorporated a Flex-Foot Talux. All the experiments were carried out in the Motion Analysis Laboratory at the University of Malaya, while the subjects walked on the level ground wearing each of the three prostheses.

The new suspension system comprised (a) a mounting plate coupled to the distal end of the silicone liner and b) a magnet assembly embedded in the distal end of the hard socket (Figure 5.1). The plate was a cup-shaped metal part that had a diameter that matched that of the distal liner. A screw through the middle of the plate connected the plate to the liner. The plate was filled with the silicone adhesive all around the central screw (Eshraghi *et al.*, 2012b). A mechanical switch knob enabled the attachment and detachment to/from the liner and the hard socket. When the switch knob was rotated, a

magnetic field was produced and rotation in the opposite direction weakened the magnetic field so that the suspension failed (the liner was detached from the socket).

Figure 5.1: New magnetic suspension system.

Dermo® liner (Össur, Reykjavik, Iceland) was used with both of the new suspension systems and the pin/lock suspension. The suction Seal-In system was a Seal-In®X5 liner (Össur, Reykjavik, Iceland) and an expulsion valve was mounted on the hard socket (Figure 5.1). In order to check the interface pressure, four F-Socket transducers 9811E (Tekscan Inc., South Boston, USA) were employed. It is generally accepted that the sensors used to measure for interface pressure should be as thin as possible (Kim *et al.*, 2003). The paper-thin F-socket sensors had a thickness of 0.18mm, good flexibility and high resolution. The sensor mats were trimmed according to the residuum counters and were located on the anterior (Ant), posterior (Pos), medial (Med) and lateral (Lat) surfaces of the residuum. In order to avoid displacement, adhesive spray (3M Spray Mount Adhesive, 3M corporate, St. Paul, USA) was employed to secure the sensor mats to the residual limb before the silicone liners were rolled on the transducers (Figure 5.2).

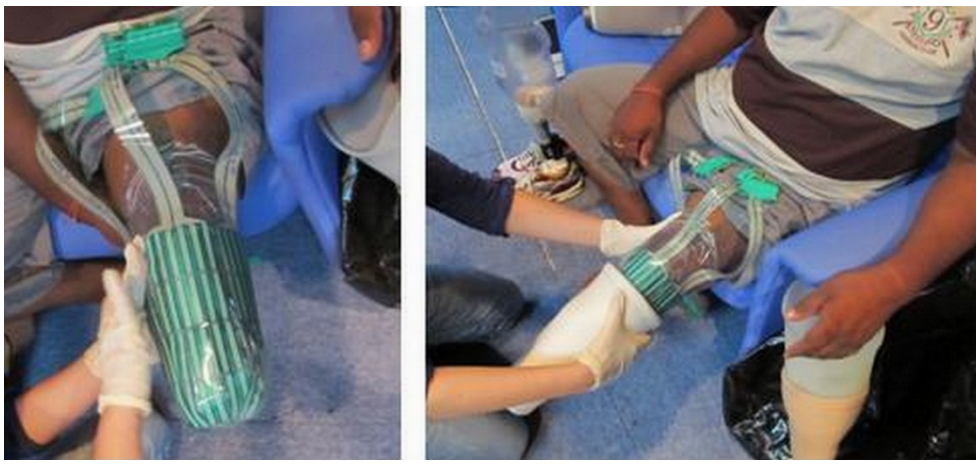


Figure 5.2: The sensor arrays mounted on the subject's residual limb.

Prior to the experiments, the transducers were calibrated to eliminate variation between each load cell. Following the manufacturer's instructions, two processes of equilibration and calibration were performed. The sensors were inserted individually into a pressure bladder connected to an air compressor and a constant pressure of 100 kPa (20 psi) was applied for equilibration. Next, the calibration was accomplished according to each subject's body weight.

In order to identify the gait cycle, force plate data was simultaneously gathered alongside the pressure data using two Kistler force plates at 50 Hz. The subjects were asked to walk at a self-selected speed on a 10-meter walkway. Prior to the data collection, the participants practiced the procedure. The frequency of data acquisition was 50 Hz. The subjects completed five trials on the walkway. The average of the middle steps (excluding the two first and the two last) for the five trials was chosen for the analyses.

The assumption of normality and homogeneity of variance was verified using the Kolmogorov-Smirnov test. Afterwards, the differences in peak pressure values were defined within four transducer sites (anterior, posterior, medial, lateral) and suspension systems using a 4 × 3 (sensor × suspension systems) Repeated Measure Analysis of

Variance (ANOVA). If the ANOVA showed significant differences, paired-samples t tests were used to compare mean peak pressures in different regions of the socket among the three suspension systems. Each sensor was further divided into three sub-regions of proximal, middle and distal. All the statistical analyses were accomplished using SPSS 20.0 (SPSS, Chicago, IL).

5.3. Results

Out of 15 subjects, three subjects were withdrawn from the study as they failed to complete the fitting and gait training sessions. The demographic data of the remaining 12 subjects is depicted in Table 5.1.

Table 5.1: Demographic characteristics of the participants.

Variable	Results
Sex	9 Males (75%) 3 Females (25%)
Age (year)	46.86 (12.3)
Height (cm)	170.46 (4.9)
Body mass (kg)	73.60 (11.5)
Side of amputation (%)	Right (66.6%) Left (33.3%)
Cause of amputation (%)	Diabetic (58.3%) Trauma (41.6%)
Residual limb length (mm)	14.96 (1.2)

The analyses of data for four sensor arrays (three regions for each) were performed for the three suspension systems. First, the data was normalized to 100 percent of gait cycle. Repeated Measure Analysis of Variance showed significant differences between

the studied systems in some of the sensor sites during one gait cycle. Table 5.2 represents the average peak pressure values and the significant differences observed. There were also significant differences evident between the four sensor sites for each system. In the case of the magnetic lock, there was significant increase in the mean peak pressure at the anterior surface in comparison to the posterior, medial and lateral (79.26 vs. 26.01, 38.07, and 27.41 respectively). The same was true for the pin/lock and Seal-In systems (Table 5.2).

Table 5.2: Average peak pressure (kPa) for whole sensor sites at anterior, posterior, medial and lateral residual limb.

Suspension type	**Ant**	**Pos**	**Med**	**Lat**
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
Pin/lock[1]	89.89	47.22	39.21	31.65
	(26.4)	(17.7)	(18.1)	(15.2)
New magnetic lock[2]	79.26	26.01	38.07	27.41
	(23.2)	(13.3)	(12.5)	(9.8)
Seal-in liner[3]	119.43	65.29	53.50	52.55
	(30.8)	(16.6)	(21.7)	(14.5)
Sig. (two tailed)[*]	1,2 (0.042)	1,2 (0.003)	1,3 (0.034)	1,3 (0.023)
	1,3 (0.017)	1,3 (0.011)	2,3 (0.027)	2,3 (0.015)
	2,3 (0.026)	2,3 (0.000)		

Ant=Anterior; Pos=Posterior; Med=Medial; Lat=Lateral.

[*] "1,2", "1,3" and "2,3" indicate that significant differences ($P<0.05$) were found between each two suspension systems based on the paired-samples t tests.

For the Seal-In liner, the mean peak pressures (APP) were higher in the proximal and middle of the sensor compared with the distal region at the anterior, posterior and medial surfaces of the residuum. Overall, the APP of the four sensor array sites during

one gait cycle was higher for the Seal-In system compared with both the pin/lock liner and the new magnetic system.

The whole surface APP at the anterior aspect was lower with the magnetic system than it was with the pin/lock system during one gait cycle (79.26 vs. 89.89 kPa, P=0.034, t=2.581). There was also increased APP with the pin/lock system at the posterior aspect of the residual limb during gait cycle (47.22 vs. 26.01 kPa, P=0.000, t=9.254). Comparative analysis of the pin/lock system to the new magnetic system revealed that there was no significant difference between the two during the stance. Nevertheless, significantly less mean peak pressures were seen with the new system during the swing phase of gait (Table 5.3).

Overall, the highest percentage of change was recorded for the posterior sensor between the new magnetic lock and Seal-In system (60.16%) and the least was between the pin/lock and new magnetic lock at the medial surface (2.90%). When comparing the new magnetic lock with the pin/lock system, the percentage of change for all four sensor sites was more than 10%, with the exception of the medial site.

Table 5.3: Average peak pressures (kPa) based on the liner type and sensor sites during the swing phase of gait (n=12).

Suspension type	**Ant** Mean (SD)			**Pos** Mean (SD)			**Med** Mean (SD)			**Lat** Mean (SD)		
	P	**M**	**D**	**P**	**M**	**D**	**P**	**M**	**D**	**P**	**M**	**D**
Pin/lock[1]	21.74 (7.3)	10.07 (2.4)	20.03 (7.8)	24.77 (9.6)	11.06 (3.2)	17.74 (7.1)	14.03 (4.9)	15.77 (5.7)	13.24 (6.3)	13.77 (2.2)	14.23 (4.0)	10.12 (2.1)
Magnetic lock[2]	9.65 (3.5)	10.01 (4.9)	9.74 (5.7)	9.53 (1.1)	9.83 (3.4)	9.92 (2.5)	11.20 (4.2)	10.96 (4.7)	11.68 (3.1)	11.07 (4.8)	11.47 (3.7)	10.14 (3.6)
Seal-in[3]	72.26 (25.1)	74.2 (17.6)	76.2 (22.3)	40.19 (10.0)	44.80 (15.6)	45.30 (18.4)	30.13 (9.1)	32.51 (12.7)	31.53 (6.5)	34.37 (10.2)	32.50 (9.1)	31.40 (7.7)
Sig. (two tailed)[*]	1,2 (0.032) 1,3 (0.001) 2,3 (0.000)	1,3 (0.000) 2,3 (0.000)	1,2 (0.024) 1,3 (0.003) 2,3 (0.000)	1,2 (0.008) 1,3 (0.000) 2,3 (0.000)	1,3 (0.000) 2,3 (0.000)	1,3 (0.000) 2,3 (0.000)	1,3 (0.034) 2,3 (0.012)	1,3 (0.013) 2,3 (0.005)	1,3 (0.003) 2,3 (0.003)	1,3 (0.004) 2,3 (0.011)	1,3 (0.006) 2,3 (0.005)	1,3 (0.001) 2,3 (0.000)

Ant=Anterior; Pos=Posterior; Med=Medial; Lat=Lateral; P=Proximal; M=Middle; D=Distal.

[*]"1,2", "1,3" and "2,3" indicate that significant differences ($P < 0.05$) were found between each two suspension systems based on the paired-samples t tests.

With regards to the distribution of pressure over the anterior surface, the largest change was seen immediately after heel strike for the pin/lock and Seal-In systems during one gait cycle. Conversely, the largest change was observed at late stance with the new magnetic system (Figure 5.3). As for the posterior surface, a more homogenous pattern was seen for all the suspension systems during gait, with the greatest change at early stance (Figure 5.3).

All over stance, the average peak pressure at the distal region of the anterior surface remained higher than the proximal portion for all three suspension types (Figure 5.4). The distal area of the posterior surface demonstrated lower pressure than the proximal region. The only exception was the Seal-In system, which produced higher pressure at the middle region in comparison to the proximal area.

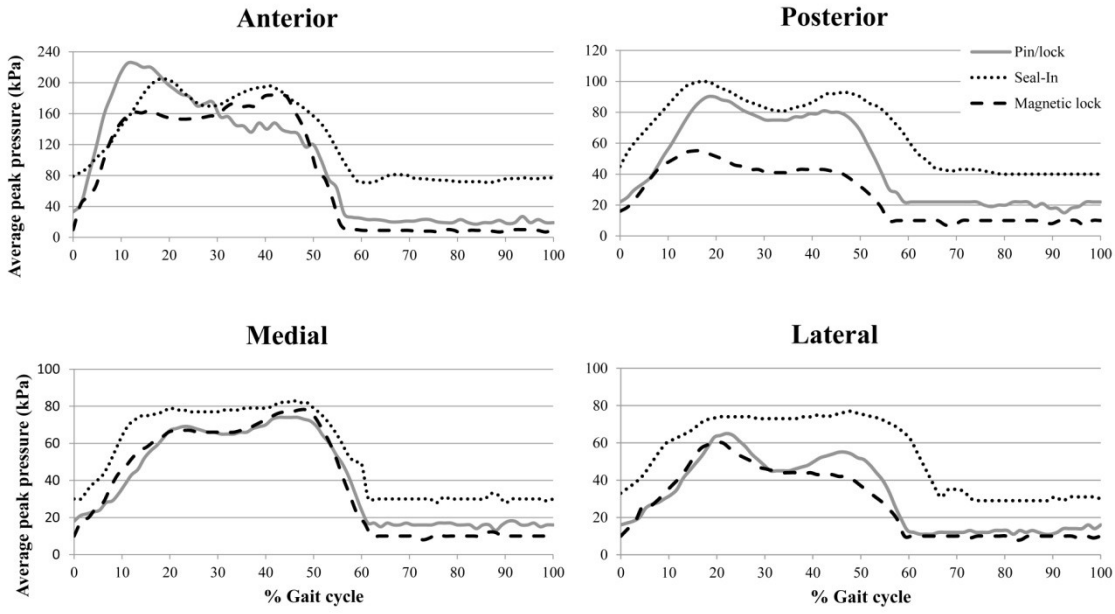


Figure 5.3: Pattern of pressure acceptance over four sensor sites with three suspension systems during one gait cycle.

5.4. Discussion

A number of studies have investigated the effect of different casting techniques and prosthetic components, including suspension and alignment changes, on the in-socket interface pressure (Boutwell *et al.*, 2012; Jia *et al.*, 2004; Sanders *et al.*, 1998; Sanders *et al.*, 1997; Wolf *et al.*, 2009). Even distribution of pressure is considered to be the ideal condition in a prosthetic socket (Mak *et al.*, 2001). This study assessed the effect of a newly-designed magnetic suspension system on pressure profile within a prosthetic socket compared with two existing systems (pin/lock and Seal-In).

When each suspension type was individually evaluated, the pressure was almost distributed evenly at the posterior, medial and lateral surfaces. Nevertheless, the anterior surface accepted the highest pressure magnitudes of all the four limb surfaces (Table 5.2). The average pressure magnitudes during one gait cycle were less than 200 kPa that mirrored the findings of previous studies that had assessed total surface bearing systems (Beil *et al.*, 2002; Dumbleton *et al.*, 2009; Sanders *et al.*, 1992; Zachariah & Sanders, 2001).

In the current study, pressure magnitudes at the anterior aspect of the limb were higher than the posterior for all the three systems during stance. These findings were contrary to those of Sanders *et al.* (1992). At initial stance (first peak), the average peak pressures for the posterior distal and anterior proximal areas of the magnetic system were lower than the posterior proximal and anterior distal (16.78% and 54.41%, respectively). This pattern was also repeated at the second peak (late stance), which contradicts the patterns reported by Dumbleton et al. (2009) and Sanders et al. (1992).

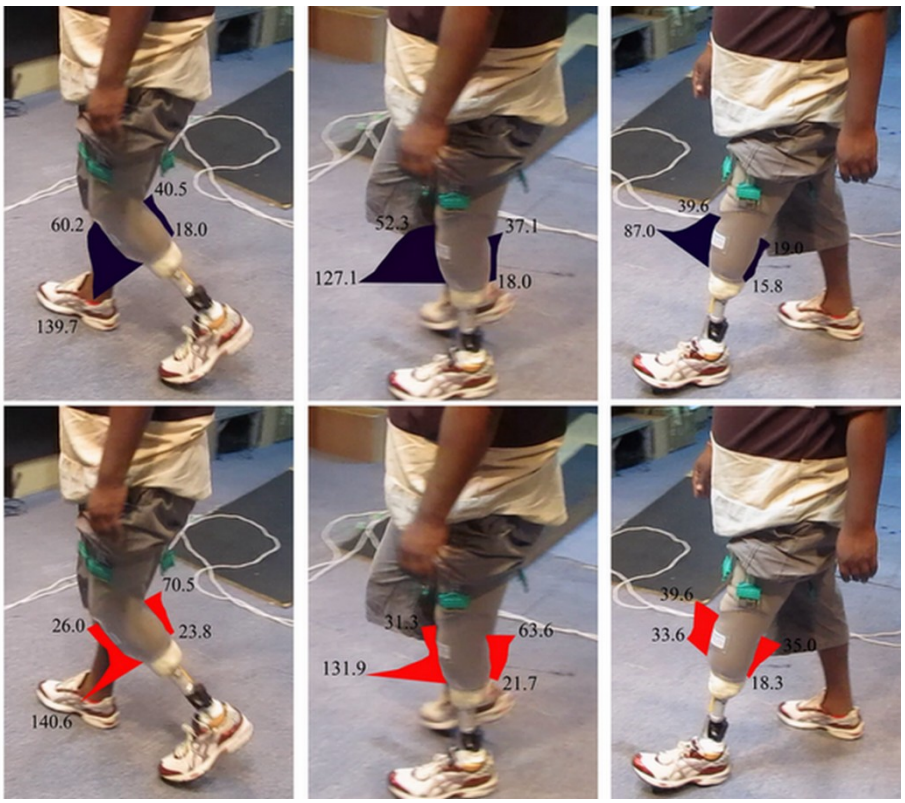


Figure 5.4: Pressure profile with new magnetic lock (top) and pin/lock systems (bottom) during stance; right to left: early stance, mid stance, late stance. All values (average peak pressure) are in kPa.

High interface pressures have been reported at the anterior proximal area (PTB bar) with the patella tendon bearing (PTB) sockets. Throughout stance, the distal region of the anterior surface demonstrated higher pressure than the proximal area with all the studied suspension systems. This conforms to the findings of Dumbleton et al (2009) and suggests that a flexion moment was created at the knee. However, large differences in pressure magnitudes were seen at late stance for the anterior surface, which is similar to the findings of Goh et al. (Goh *et al.*, 2003a, 2003b) but opposes the findings of Dumbleton et al. (2009). At late stance (50% of gait cycle), all the three studied systems showed lower pressure at the anterior proximal area, while Goh *et al.* (2003b) found a pattern similar to the PTB socket.

5.4.1. Magnetic lock vs. pin/lock

Different suspension systems suspend the prosthetic leg by applying pressure at dissimilar regions of the residual limb. This might significantly affect the comfort with which the amputees ambulate. Users of the pin/lock liners feel a stretch at the distal tissue of the residual limb during the swing phase (Beil & Street, 2004). At the same time, proximal tissues are exposed to high compressive pressures that will disrupt the normal fluid flow. This milking phenomenon can lead to edema and vein problems and could be the reason why pin/lock users experience skin thickening and color change, particularly at the distal region of their residuum (Beil & Street, 2004). The current study hypothesized that the new system would reduce the traction by increasing the contact area. When the results of each sensor sub region (proximal, middle, and distal) were compared between the two systems, significant differences were evident for the anterior and posterior surfaces of the residual limb (Table 5.3). Lower peak pressures were produced at the anterior and posterior surfaces during the swing phase of gait with the magnetic system in comparison to the pin/lock. This was in agreement with the findings by Beil and Street (2004) pertaining to high average pressure with the pin/lock system. The average peak pressures at the medial and lateral sensor sites (mean of whole surface) were also lower with the magnetic system than they were with the pin/lock suspension (10.33 and 9.75 vs. 16.41 and 13.83, respectively). Yet, the statistical analyses did not show them to be statistically different.

5.4.2. Magnetic lock vs. Seal-In suspension

The average pressure magnitudes recorded with the Seal-In system were different from the magnetic system during swing (Table 5.3). A study by Beil and Street (2004)

showed that the use of a suction system resulted in a more homogenous distribution of interface pressure. The current study supports their results as the pressure distribution with the pin/lock was less homogenous compared with the new magnetic lock and Seal-In systems. As compared with the magnetic system, the pressure with the Seal-In liner was mainly concentrated at the middle and distal region of the posterior sensor during stance. This might be due to the location of seals and the fact that suction is developed mainly at the distal end where the valve is located. The mean peak pressures were generally higher with the Seal-In liner than they were with the other two systems (P values were less than 0.05 for both comparisons). This was compatible with the results of Ali *et al.* (2012a). In the current study, the pressure values increased by 34.75% at the posterior aspect of the limb with the Seal-In liner in comparison to the pin/lock system. This difference was 40.97% for the new suspension system. The greatest change of pressure with TSB sockets and pin/lock liners in transtibial gait have been shown to occur at late stance (50% of gait cycle) (Dumbleton *et al.*, 2009). The largest change occurred at late stance with the new system. In contrast, pin/lock and Seal-In systems showed the greatest changes at early stance.

The Seal-In suspension system has been shown to cause the least pistoning within the prosthetic socket compared with the pin/lock and new magnetic suspension systems (Eshraghi *et al.*, 2012b; Gholizadeh *et al.*, 2012a; Gholizadeh *et al.*, 2012c). This study indicated higher-pressure magnitudes with the Seal-In system, which might clarify the lower pistoning observed previously. It can be inferred that while suction systems, such as the Seal-In, may increase the prosthetic fit, the enhanced fit and the resultant increased pressure might bring about residual limb atrophy, skin problems and interruption in blood flow to the limb (Board *et al.*, 2001). This volume loss is commonly compensated by the addition of socks, which can worsen the atrophy.

It was a challenge to compare the results of the current study with the existing literature, as the majority of previous studies used single-spot transducers as opposed to the full-length sensors that were used in this study. Variation in geometry of residual limb could also affect the pressure measurement sites; therefore, a bigger sample size might find a relationship between the residual limb geometry and pressure profile. It is also worth investigating the pressure profile in various activities on diverse walking surfaces. Further investigations may also find association between pressure and pistoning within the prosthetic socket which can be invaluable in the design of a more balanced socket.

5.5. Conclusion

The current study provided some biomechanical insight into different methods of prosthetic suspension. The new magnetic suspension system might reduce the pressure over the residual limb, particularly during swing, to offer the advantages of the other suspension systems while overcoming some of their weaknesses.

CHAPTER 6

INTERFACE STRESS IN SOCKET/RESIDUAL LIMB WITH TRANSTIBIAL PROSTHETIC SUSPENSION SYSTEMS DURING LOCOMOTION ON SLOPES AND STAIRS

This study aimed to compare the effects of different suspension methods on the interface stress inside the prosthetic sockets of transtibial amputees when negotiating ramps and stairs. Three transtibial prostheses, with a pin/lock system, a Seal-In system, and a magnetic suspension system (MPSS), were created for the participants in a prospective study. Interface stress was measured as the peak pressure by using the F-Socket transducers during stairs and ramp negotiation. Twelve individuals with transtibial amputation managed to complete the experiments. During the stair ascent and descent, the greatest peak pressure was observed in the prosthesis with the Seal-In system. The MPSS caused significantly different peak pressure at the anterior proximal region compared with the pin/lock (P=0.022) and Seal-In (P=0.001) during the stair ascent. It was also observed during the stair descent and ramp negotiation. The prostheses exhibited varying pressure profiles during the stair and ramp ascent. The prostheses with the pin/lock and magnetic suspension systems exhibited lower peak pressures compared with the Seal-In system. The intra-system pressure distribution at the anterior and posterior regions of the residual limb was fairly homogenous during the stair and ramp ascent and descent. Nevertheless, the intra-system pressure mapping revealed a significant difference among the suspension types, particularly at the anterior and posterior sensor sites.

6.1. Introduction

The increased incidence of diabetes mellitus worldwide has led to higher rates of lower-limb amputations (Boulton *et al.*, 1987; Pecoraro *et al.*, 1990). Individuals with limb amputation endure high ambulatory loading when wearing prosthesis during their daily activities. This loading is mostly applied by the prosthesis to the skeletal structure through the socket walls, with the interface located between the soft tissues of the residual limb and the prosthetic socket as part of the suspension means. The soft tissue of the residual limb is not adapted to high shear loading and epidermal pressure during locomotion. A large number of lower-limb amputees experience pressure sores because of their use of prostheses. Therefore, many persons with amputation avoid using prostheses, which considerably decreases their daily activities. Individuals with amputation also develop skin problems, such as cysts, blisters, dermatitis, and edema because of their use of prostheses (Levy *et al.*, 1962; Lyon *et al.*, 2000; Nielsen, 1991).

The interface pressure is significantly influenced by ambulation tasks, among other factors, such as residual limb site, clinical condition, and socket alignment (Mak *et al.*, 2010). Socket walls, soft insert (liner), and coupling devices such as pins and seals comprise the suspension system of lower-limb prostheses. These constituents can alter the pressure profile of the residual limb within the prosthetic socket. Various suspension systems are found to affect the interface pressure during level walking (Beil & Street, 2004; Eshraghi *et al.*, 2013a).

The stress profile between the prosthetic socket and the interface of the residual limb is crucial to the socket design (Mak *et al.*, 2001). Quantification methods use either the transducers that are embedded into the socket or the thin sensor pad between the skin and liner/socket (Goh *et al.*, 2003b; Polliack *et al.*, 2000; Sanders & Daly, 1993; Williams *et al.*, 1992). The pressure profiles of various suspension systems during level

walking have been evaluated (Convery & Buis, 1999; Goh *et al.*, 2003b; Silver-Thorn & Childress, 1996). The pressures at the socket/skin interfaces vary considerably among individuals, sites, and clinical conditions. The highest peak pressure for the patellar-tendon-bearing (PTB) socket has reportedly surpassed 300 kPa, which can be attributed to different prostheses and fitting methods as well as the divergence of soft-tissue thickness, site, and residual-limb geometry (Dou *et al.*, 2006; Meier *et al.*, 1973; Sanders *et al.*, 2005; Sanders & Daly, 1993). The pressures also vary depending on the walking styles and socket alignments (Dou *et al.*, 2006; Jia *et al.*, 2004; Sanders *et al.*, 2000).

Individuals with amputation are required to negotiate ramps and stairs when performing most of their daily activities. Therefore, the biomechanics of the residual limb when a person performs these tasks should be investigated. The ability to negotiate various surfaces enables an individual to conduct more strenuous activities (Gill *et al.*, 1994; Jones *et al.*, 2006). The absence of foot and ankle joints, in addition to altered balance, stability, and decreased muscle power during rigorous activities, negatively affects the activity level of prosthesis users (Jones *et al.*, 2006). Only a few studies have investigated the pressure when negotiating inclines or stairs (Dou *et al.*, 2006; Wolf *et al.*, 2009). Individuals with lower limb amputation are greatly affected by environmental barriers because of their loss of foot and ankle lever mechanism (Jones *et al.*, 2006). They have reported a high interface pressure when negotiating ramps and stairs. For instance, compared with the level walking, the conventional PTB socket increases the pressure by 30% when negotiating stairs (Dou *et al.*, 2006).

Silicone soft liners increase comfort by decreasing friction (Cluitmans *et al.*, 1994). Some soft liners use a coupling system, such as pin and seal. Few studies have evaluated the interface pressure with suspension systems that incorporate silicone liners during level walking (Ali *et al.*, 2012a; Eshraghi *et al.*, 2013a). However, the interface

pressure between the residual limb and the socket during ramp negotiation is unclear. A suspension system with a silicone liner has been introduced (Eshraghi *et al.*, 2013b). The interface pressure with the magnetic prosthetic suspension system (MPSS) is shown to be different from other systems during level walking. Therefore, this study aimed to investigate the pressure profile with the MPSS, and to compare it with those of the pin/lock and Seal-In suspension systems during ramp and stairs negotiation. These two suspension systems were selected as they are commonly used systems that are widely available. The study hypothesized a significant difference among the pressure magnitudes of the three systems.

6.2. Methodology

6.2.1. Participants and prostheses

Thirteen individuals with transtibial amputation were selected as samples in a clinical trial study. In order to enter the study, a registered prosthetist checked the subject's medical record and performed physical examination, especially on the residual limb. A person was deemed eligible for the study if he/she was a unilateral transtibial, could ambulate independently, had a residual limb that was free from ulcer and pain, had undergone amputation at least one year prior to the study, and had upper limbs that were healthy enough to independently don and doff the prosthesis. Those who had moderate residual limb length, had no significant problems with their residual limb, had no heart problem, could independently negotiate stairs and ramps, and had no orthopedic, rheumatic, neurologic, or cognitive impairments were selected to participate in the study. The participants were also asked to report taking any medication that could influence their balance. Persons with amputation who experienced residual limb

problems within three months prior to the study, had abnormalities in their limbs or took medication affecting the balance were excluded from the sample. The study secured the approval of the University of Malaya Medical Centre ethics committee, and informed written consents were obtained from all study participants.

The differences in the prosthetic fabrication techniques, alignment, and fitting could significantly influence the results of the study. Therefore, one of the authors, a registered prosthetist, created three prostheses for each participant. These prostheses used three different suspension systems: (a) pin/lock suspension system (Dermo liner with shuttle lock), (b) new magnetic lock MPSS and (c) Seal-In system (Seal-In X5 liner). The third system required a separate negative cast, and the two other systems were created from a single negative cast. The characteristics of the MPSS have been described in other studies (Eshraghi *et al.*, 2013b). Prior to the fabrication of final sockets, each participant was fitted with a transparent check socket to ensure its total surface bearing (TSB). The prosthetic foot of all prostheses was a carbon fiber flex-foot Talux (Össur). The participants were asked to use each prosthesis for at least four weeks and were requested to visit the Brace and Limb Laboratory once a week to monitor the health of the stump and the fitting changes.

6.2.2. Equipment and protocol

To better understand the socket and residual limb interface, four 8 in-long, 3 in-wide F-socket transducers 9811E (Tekscan Inc., South Boston, USA) of 0.2 mm thickness were used in this study. Every sensor array is comprised of printed circuits divided into load sensing regions. The smallest sensing element of sensor consists of two thin, flexible mats holding the pressure-sensitive ink applied in columns and rows between

them. The juncture of column and row forms the smallest element of area sensing known as the sensel. Each 9811E sensor has 96 sensels. The pressure profiles were recorded using Tekscan software version 6.51. Each sensor array was affixed to the anterior, posterior, medial, and lateral compartments of the stump. The sensors were first trimmed according to the contours of the residual limb to allow for 90% coverage. To ensure that the sensor arrays were accurately positioned, the residual limb was covered with wrapping plastic and the trimmed sensor arrays were attached to the plastic using an adhesive spray.

Prior to the experiment, the sensor arrays were equilibrated and calibrated using the Tekscan pressure bladder to eliminate the variation among the load cells. Following the instructions of the manufacturer, we placed each sensor array individually inside the pressure bladder and coupled it to an air compressor that provided a 100 kPa steady pressure for equilibration. After the equilibration, the calibration was accomplished according to the body mass.

Two separate experiments were conducted for the stair and ramp negotiations. The order of the experiments was randomized for each participant. The participants were required to ascend to and descend from, with a comfortable cadence, a 4-m custom-made ramp with a 7.5° inclination. They were also asked to ascend to and descend from a custom-made 82 cm-wide staircase with four steps that were 14 cm high and 32 cm apart from each other. Transtibial amputees usually observe two patterns when negotiating stairs, namely, the step-to gait and the step-over-step patterns. The participants in this study adopted the step-to gait pattern to ensure consistency.

Data was recorded for the two consecutive trials at a 50 Hz sample rate for at least six cycles of ascending and descending the ramp and stairs. Prior to the experiments, each participant practiced the protocol to accustom himself/herself to the experimental

protocol and the sensors. All the participants underwent the same procedure to reduce the variations in the recorded data. The participants completed five consecutive trials. The area within each array of sensors was further subdivided into a proximal region and a distal region. The middle step of each trial and the average peak pressure of the trials were used in the statistical analyses.

6.2.3. Data analysis

The assumption of normality was verified for most of the variables. A Repeated Measure Analysis of Variance (ANOVA) with Bonferroni adjustment was adopted for the analysis. The peak pressures (PP) were varied within the four transducer sites (anterior, posterior, medial, and lateral) and the suspension systems using a 4 × 3 (sensor × suspension systems) Repeated Measure ANOVA. The non-parametric statistical analysis and the Friedman test were applied in few cases. The Wilcoxon Signed Rank (Bonferroni adjusted α value) test was applied if a significant difference was observed among the three systems. Statistical analyses were conducted using SPSS 20.0 (SPSS, Chicago, IL). The level of significance was set at 0.05.

6.3. Results

6.3.1. Demographics

Twelve participants completed the study. Their mean age, body weight, and height were 46.8 years (SD, 12.3), 73.6 kg (SD, 11.5), and 170.4 cm (SD, 4.9), respectively. The mean residual limb length was 14.9 cm (SD, 1.2). Trauma and diabetes were identified as the main causes of amputation.

6.3.2. Stair negotiation

A significant difference in the PPs among the four major regions in every suspension system was revealed through the statistical analysis ($P < 0.05$). The proximal and distal regions among the three systems also had significantly different pressures during the stair ascent and descent. Considering the four sensor sites, the main differences among the systems were evident at the anterior and posterior regions. The average pressure values at the medial and lateral sites of the residual limb were less than those at the anterior and posterior sites (Table 6.1).

During the stair ascent, a significantly higher magnitude of PP was found in the Seal-In system compared with the pin/lock and MPSS systems both at the posterior (90.44 kPa vs. 63.13 kPa and 57.79 kPa; both P=0.000) and anterior regions (80.14 kPa vs. 63.14 kPa and 51.03 kPa; P=0.001 & 0.000, respectively). A significant difference was also observed at the medial region in the pin/lock and MPSS systems compared with the Seal-In system (49.21 kPa and 44.81 kPa versus 66.04 kPa; P=0.013 & 0.000, respectively). These systems had significantly different PPs at the anterior and posterior proximal sub-regions. The anterior proximal region showed the highest pressure among all the systems during the stair ascent. No statistical difference was found in the lateral regions of these systems. However, the PP at the medial distal sub-region of the residual limb exhibited a significant difference (Table 6.1).

During the stair descent, the PP was significantly higher with the Seal-In system than with the pin/lock and MPSS systems in the entire anterior (80.41 kPa versus 67.11 kPa and 58.41 kPa; P=0.021 & 0.000, respectively), posterior (88.24 kPa versus 64.12 kPa and 50.04 kPa; both P=0.000), and medial (65.11 kPa versus 47.33 kPa and 42.32 kPa; P=0.011 & 0.023, respectively) regions. No significant difference was observed at the

lateral region among the three systems (P=0.713). Figure 6.1 shows the differences among the PPs of the three suspension systems during the stair ascent and descent.

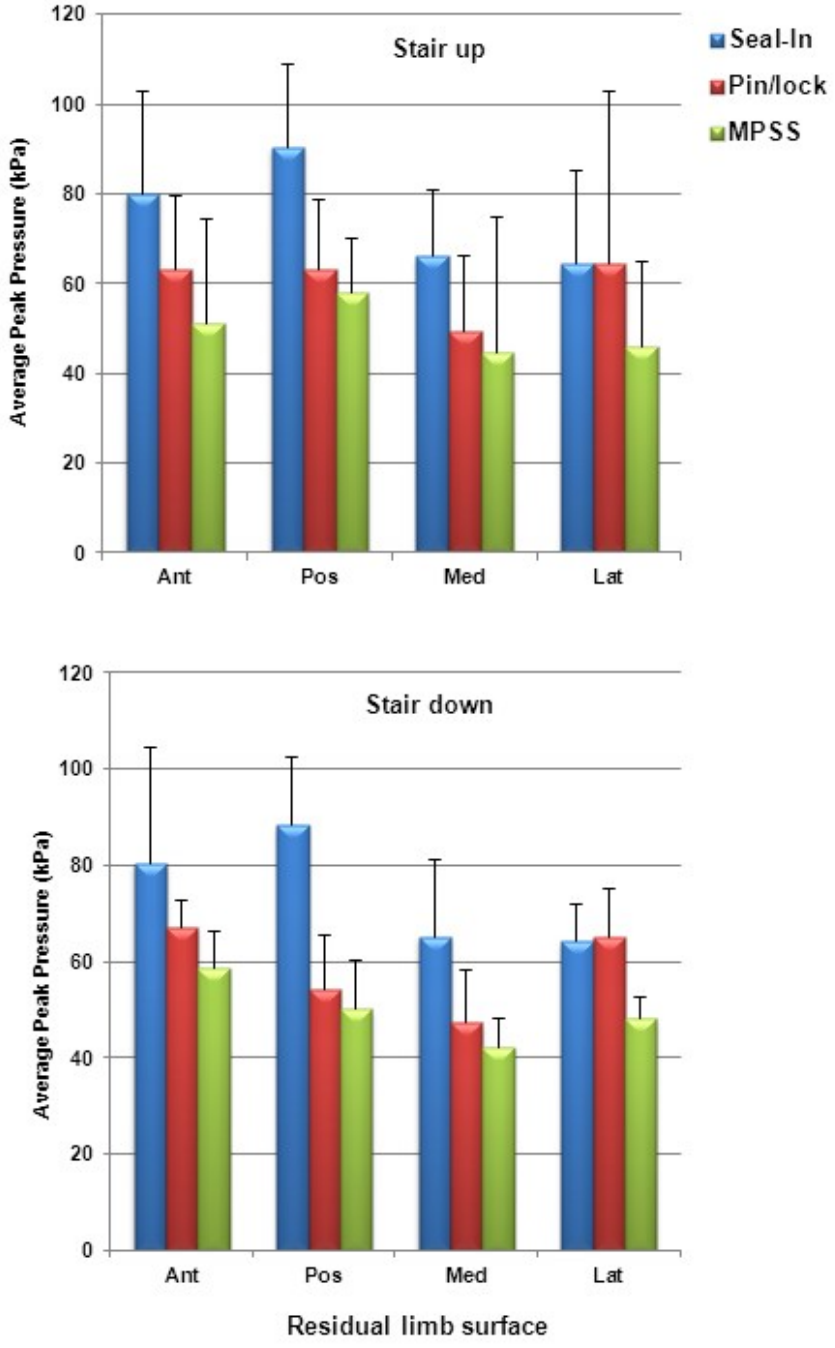


Figure 6.1: The peak pressure pattern at residual limb surface during stairs negotiation.

Table 6.1: The peak pressure values (kPa) at the residual limb regions and sub-regions during stairs negotiation. Mean (SD)

Surface	Sub-region	Ascent				Descent			
		Pin/lock[1]	Seal-In[2]	MPSS[3]	*P*-value 1-2[a] 2-3 1-3	Pin/lock[1]	Seal-In[2]	MPSS[3]	*P*-value 1-2 2-3 1-3
Ant	Prox	56.10 (10.54)	69.02 (18.43)	48.30 (19.21)	0.032* 0.001* 0.022*	59.11 (18.10)	65.61 (23.14)	46.01 (20.51)	0.282 0.003* 0.000*
	Dis	58.03 (11.10)	64.04 (22.40)	50.15 (11.2)	0.370 0.041* 0.210	54.11 (17.25)	67.05 (24.16)	41.70 (31.72)	0.021* 0.004* 0.034*
Pos	Prox	57.10 (10.26)	80.40 (48.20)	47.42 (20.30)	0.051* 0.011* 0.043*	52.10 (15.52)	82.14 (38.31)	42.23 (15.50)	0.002* 0.000* 0.021*
	Dis	54.01 (12.60)	59.10 (17.51)	43.20 (10.18)	0.574 0.022* 0.011*	58.16 (14.45)	68.56 (23.83)	49.06 (27.63)	0.283 0.017* 0.061
Lat	Prox	58.31 (20)	61.13 (19.44)	42.78 (14.82)	0.442 0.031* 0.002*	60.42 (22.10)	55.45 (19.03)	56.70 (14.55)	0.385 0.664 0.075
	Dis	63.13 (16.36)	60.01 (11.21)	45.05 (19.54)	0.200 0.005* 0.001*	55.15 (29.17)	57.30 (12.20)	50.17 (30.31)	0.641 0.063 0.540
Med	Prox	45.56 (10.54)	52.25 (35.04)	43.15 (24.21)	0.952 0.457 0.720	45.05 (13.31)	54.20 (41.54)	41.70 (22.03)	0.953 0.232 0.934
	Dis	43.03 (15.04)	52.20 (12.24)	41.21 (19.04)	0.000* 0.001* 0.643	43.35 (17.33)	50.24 (13.03)	38.91 (10.00)	0.041* 0.001* 0.023*

[a] Significant differences between the pair suspension systems are presented as 1-2 (pin/lock-Seal-In), 2-3 (Seal-In-MPSS) & 1-3 (pin/lock-MPSS). Asterisks show $P<0.05$.

6.3.3. Ramp ascent/descent

Significant differences were found in the PPs of the three interface systems at the three aspects of the residual limb (anterior, posterior, and lateral) during the ramp negotiation ($P < 0.05$). The maximum and minimum peak pressures were 90.03 kPa and 45.93 kPa with the Seal-In and MPSS systems, respectively. The PP was significantly lower with the pin/lock system (60.57 kPa, 64.50 kPa, and 60.54 kPa, respectively) and MPSS (56.60 kPa, 54.04 kPa, and 58.13 kPa, respectively) compared with the Seal-In system (83.48 kPa, 83.08 kPa, and 71.35 kPa, respectively) during the ramp ascent. No significant difference was found in the medial regions with the three suspension systems (Table 6.2).

Significant differences were found among the three systems at the residual limb sub-regions (distal and proximal) during the ramp ascent. The pressure was significantly lower with the pin/lock and MPSS systems compared with the Seal-In system at the proximal anterior (57.42 kPa and 48.21 kPa versus 71.14 kPa; P=0.031 & 0.000, respectively), posterior proximal (59.64 kPa and 49.54 kPa versus 81.66 kPa; both P=0.000), and posterior distal (51.73 kPa and 43.71 kPa versus 65.28 kPa; P=0.041 & 0.016, respectively) regions. The same finding was observed at the lateral proximal, medial proximal, and medial distal regions.

Table 6.2: Peak pressure values (kPa) at the anterior, posterior, lateral and medial sub-regions during ramp negotiation.

	Suspension system	Ant		Post		Lat		Med	
		Prox	**Dis**	**Prox**	**Dis**	**Prox**	**Dis**	**Prox**	**Dis**
Ramp Up	Seal-In[1]	71.14 (9.35)	63.67 (32.12)	81.66 (18.92)	65.28 (12.88)	66.89 (17.27)	69.56 (10.74)	63.95 (13.79)	60.83 (17.36)
	Pin/lock[2]	57.42 (7.12)	50.15 (15.31)	59.64 (18.29)	51.73 (20.01)	56.86 (20.29)	62.99 (19.34)	44.16 (11.12)	39.14 (18.32)
	MPSS[3]	48.21 (10.35)	45.02 (12.41)	49.54 (10.88)	43.71 (14.20)	54.18 (9.88)	61.32 (14.01)	42.31 (11.17)	40.08 (12.08)
***P*-value**	1-2[a]	0.001*	0.130	0.000*	0.021*	0.002*	0.210	0.000*	0.000*
	1-3	0.000*	0.042*	0.000*	0.003*	0.000*	0.321	0.000*	0.000*
	2-3	0.031*	0.074	0.025*	0.041*	0.073	0.063	0.130	0.721
Ramp Down	Seal-In[1]	67.22 (25.38)	74.20 (28.30)	72.07 (13.24)	83.00 (20.23)	55.67 (20.75)	61.19 (19.62)	49.63 (14.19)	54.11 (18.18)
	Pin/lock[2]	52.22 (10.99)	60.81 (20.02)	57.34 (13.56)	53.80 (18.55)	49.32 (11.09)	56.34 (12.74)	44.26 (18.11)	39.82 (19.02)
	MPSS[3]	45.21 (11.24)	53.50 (18.29)	48.82 (10.31)	55.04 (13.79)	51.13 (18.02)	54.41 (9.12)	41.02 (11.12)	40.61 (13.04)
***P*-value**	1-2	0.033*	0.024*	0.000*	0.000*	0.150	0.291	0.430	0.011*
	1-3	0.001*	0.003*	0.000*	0.000*	0.121	0.130	0.052	0.004*
	2-3	0.041*	0.037*	0.022*	0.240	0.719	0.542	0.302	0.781

[a] Significant differences between the pair suspension systems are presented as 1-2 (pin/lock-Seal-In), 2-3 (Seal-In-MPSS) & 1-3 (pin/lock-MPSS). Asterisks show $P < 0.05$.

Significant differences were observed at the anterior, posterior, and medial regions with the three systems during the ramp ascent. The participants experienced a significantly lower PP with the pin/lock and MPSS systems compared with the Seal-In system at the anterior (both P=0.000), posterior (P=0.001 and 0.000), and lateral regions (both P=0.000). No statistically significant difference was found during the ramp ascent at the medial region among the three systems.

During the ramp descent, the PP was lower with the pin/lock and MPSS systems compared with the Seal-In system at the anterior proximal (22.31% and 32.74%, respectively), anterior distal (18.04% and 27.89%, respectively), posterior proximal (20.43% and 32.26%, respectively), and posterior distal (35.18% and 33.68%, respectively) sub-regions. The lateral and medial proximal sub-regions among the systems showed no significant difference. Figure 6.2 presents the magnitudes of the interface pressure with the suspension systems during the ramp negotiation.

6.4. Discussion

Although able-bodied individuals can easily negotiate ramps and stairs, these tasks become challenging when the motor functions of a person are altered, as in the case of the elderly or limb amputees. Plantar pressure and foot ulcer are suggested to be correlated with socket pressure and ulceration (Bacarin *et al.*, 2009). Pressure mapping provides insights into the enhancement of prosthesis designs. The pressure profile among the pin/lock, Seal-In and MPSS systems had been previously assessed during level walking. In this study, it was intended to evaluate pressure distribution inside the prosthetic socket with these systems during dynamic activities of slope and stairs negotiation.

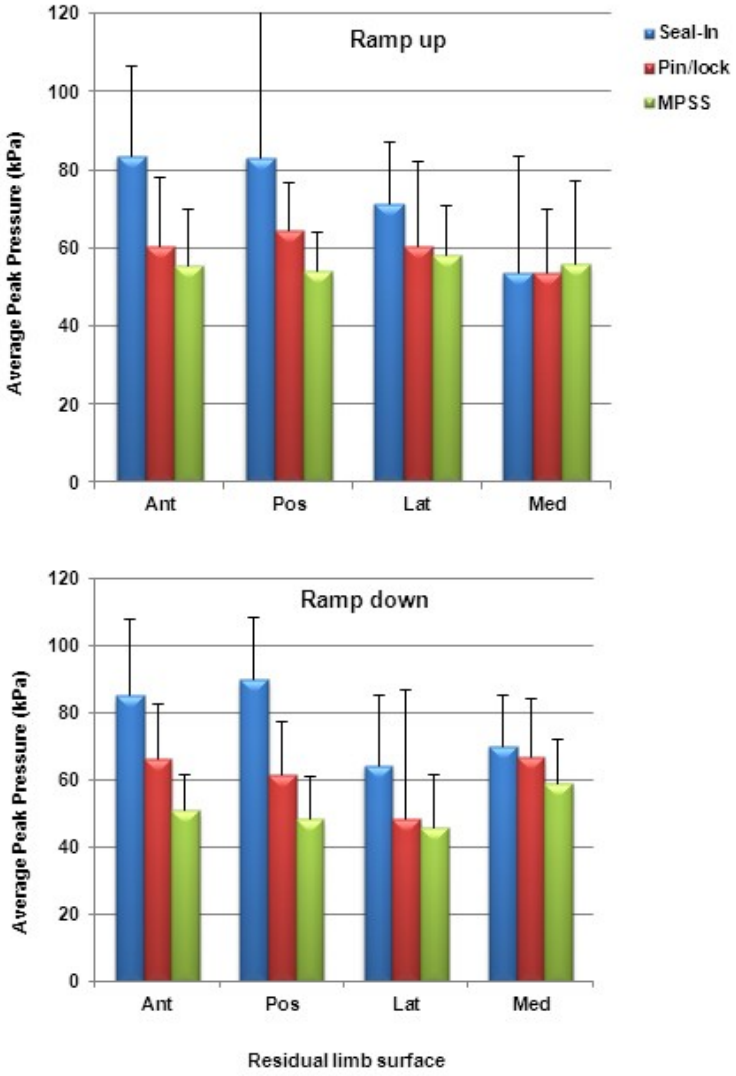


Figure 6.2: The peak pressure values at four major residual limb surfaces when walking on the slope.

6.4.1. Stair negotiation

The peak pressure was significantly higher at the anterior, posterior, and medial regions with the Seal-In system compared with the pin/lock and MPSS systems both during the stair ascent and descent. These results are consistent with those in our previous study on level walking (Eshraghi *et al.*, 2013a). The PP was lower with the pin/lock and MPSS systems compared with the Seal-In system at the distal and proximal sub-regions.

The anterior proximal socket area exhibited a significantly higher mean peak pressure during the stair ascent, which was consistent with the findings of Dou et al. (2006). However, Wolf et al. (2009) reported a high pressure at the anterior distal region during the stair ascent, which was contrary to our findings. The pressure magnitude was higher at the posterior proximal area, which was contrary to the findings of Dou et al. (2006).

Wolf et al. (2009) found the most obvious changes in the distal area close to the end of the residual limb during the stair and ramp ascent, which opposed the findings of Dou et al. (2006) who observed the most obvious changes in the anterior proximal regions. Such changes resulted from the increase in knee flexion and moments of knee flexing as compared with the level walking (McIntosh *et al.*, 2006). The distal end of the tibia posteriorly shifted away from the anterior socket, which distally decreased the peak pressure in the anterior region.

The alignment of the ankle in a neutral position during the stair ascent limits the external knee flexion moments. Therefore, the dominant pressure is located at the anterior proximal socket. However, the knee would become more flexed with a dorsiflexed ankle and the ground reaction force would move further behind the knee joint. Therefore, the pressure load would distally increase as the external flexion moments grew larger (Wolf *et al.*, 2009). In the current study, a higher pressure was observed at the anterior distal area during the stair descent with the Seal-In system than with the pin/lock and MPSS systems, which was consistent with the findings of Wolf *et al.* (2009). Also, to ensure their stability, the individuals with transtibial amputation position their prostheses onto the lower step with a longer knee extension during the stair descent to decrease and increase the pressure proximally and distally, respectively (Jones *et al.*, 2006; Wolf *et al.*, 2009).

The Seal-In system was reported to have less pistoning compared with the pin/lock and MPSS systems (Eshraghi *et al.*, 2012b). Possibly, there is a relation between higher PP and low pistoning with the Seal-In interface system. The extent of pistoning decreased as the socket fit was improved. A higher pressure could also be detrimental to the residual limb as it might interrupt blood circulation and promote skin problems (Beil & Street, 2004).

6.4.2. Ramp ascent/descent

All the participants exhibited a higher pressure with the Seal-In system, and significant differences were observed at the anterior, posterior, and lateral regions during the ramp ascent. Significant statistical differences were also observed at the anterior, posterior, and medial regions. Dou *et al.* (2006) observed increased pressure at the anterior proximal and posterior proximal (popliteal area) sockets during the ramp ascent (Dou *et al.*, 2006), which was consistent with our observations (Table 6.2). We also found a lower pressure at the anterior distal sub-region (kick point), which opposed the findings of Wolf *et al.* (2009).

Contrary to the level walking, the knee flexion moment was larger during the ramp descent (Riener *et al.*, 2002). To guarantee stability, the individual with transtibial amputation position their prostheses down the ramp with a longer extended knee, which decreases the magnitude of the pressure at the anterior proximal region and increased the pressure at the anterior distal area (Jones *et al.*, 2006). Our results were consistent with the aforementioned biomechanical changes of the knee during the ramp descent. In all of the systems, the mean peak pressure was higher at the anterior distal sub-region compared with the anterior proximal sub-region, which was also consistent with the

findings of Dou *et al.* (2006) The pressure magnitude during ramp negotiation was observed to be lower with the MPSS system compared with the pin/lock system, except for the anterior distal during the ramp ascent and the posterior distal during the ramp descent, as well as for the medial and lateral regions.

The development of pressure at the anterior, proximal, and distal areas were comparable during the stair and ramp ascent. The differences among the pressures at these sites were even more significant during the ramp negotiation, which reflected that a 7.5° ramp ascent was more challenging than a regular stair ascent (Wolf *et al.*, 2009). The pressure distribution within the socket varied the most during the ramp descent than during the level walking. Flexion and extension were the main movements at the knee joints during the stair and ramp negotiation, which was reflected in the pressure profile of all the systems as there was almost no significant difference in the medial and lateral socket pressures. Most of the participants stated that they felt more pressure on their residual limb when they used the Seal-In system.

Finally, the study might have clinical implications for the selection of one suspension system over others in active users of prostheses who frequently negotiate ramps/stairs. For instance, clinicians should be more cautious to choose the Seal-In suspension due to higher in-socket pressure typically found with this system in our study. Between the MPSS and pin/lock, some significantly lower pressure values were found with the MPSS in this study. The satisfaction survey had formerly shown that the participants were more satisfied with the MPSS than the pin/lock during stair negotiation (P=0.000) (Eshraghi *et al.*, 2012b). The overall satisfaction was also significantly higher with the MPSS. Thus, it can be taken into account when prescribing the suspension system for lower limb prosthesis.

6.4.3. Study limitations

The comparisons among the findings of various studies could be affected by the type of prosthetic foot used in a particular study. Two studies used dynamic carbon feet, whereas Dou *et al.* (2006) used a prosthesis that incorporated a solid-ankle-cushion-heel (SACH) foot. The properties of each prosthetic foot could influence the pressure distribution within the socket. The few available studies did not clearly explain the strategies of amputees when negotiating stairs, which might also affect the comparison of findings.

6.5. Conclusion

Intra-system pressure distribution at the anterior and posterior surfaces of the residual limb was fairly homogenous during the stair and ramp ascent or descent. Nevertheless, inter-system pressure mapping revealed significant differences among the suspension types, particularly at the anterior and posterior sensor sites.

CHAPTER 7

GAIT BIOMECHANICS OF INDIVIDUALS WITH TRANSTIBIAL AMPUTATION: EFFECT OF SUSPENSION SYSTEM

Prosthetic suspension system is an important component of lower limb prostheses. Suspension efficiency can be best evaluated during one of the vital activities of daily living, i.e. walking. A new magnetic prosthetic suspension system has been developed, but its effects on gait biomechanics have not been studied. This study aimed to explore the effect of suspension type on kinetic and kinematic gait parameters during level walking with the new suspension system as well as two other commonly used systems (the Seal-In and pin/lock). Thirteen persons with transtibial amputation participated in this study. A Vicon motion system (six cameras, two force platforms) was utilized to obtain gait kinetic and kinematic variables, as well as pistoning within the prosthetic socket. The gait deviation index was also calculated based on the kinematic data. The findings indicated significant difference in the pistoning values among the three suspension systems. The Seal-In system resulted in the least pistoning compared with the other two systems. Several kinetic and kinematic variables were also affected by the suspension type. The ground reaction force data showed that lower load was applied to the limb joints with the magnetic suspension system compared with the pin/lock suspension. The gait deviation index showed significant deviation from the normal with all the systems, but the systems did not differ significantly. Main, significant effects of the suspension type were seen in the GRF (vertical and fore-aft), knee and ankle angles. The new magnetic suspension system showed comparable effects in the remaining kinetic and kinematic gait parameters to the other studied systems. This study may have implications on the selection of suspension systems for transtibial prostheses.

7.1. Introduction

The primary goal of rehabilitation of lower limb amputees is to resume normal gait as much as possible. Prosthetic devices should allow normal gait function using the most appropriate components. Gait asymmetry is one of the main concerns in unilateral lower limb amputees to avoid exertion of excessive load on the sound limb (Macfarlane *et al.*, 1991; Nolan & Lees, 2000). Previous research findings have been controversial over the kinetic and kinematic differences between the amputated and sound legs. Several studies indicated higher reliance on the sound leg by increased loading and stance time, which has been attributed to ankle loss in transtibial amputees (Lemaire & Fisher, 1994; Melzer *et al.*, 2001). On the other hand, some literature supported the idea that amputees may not need to rely on the intact leg owing to the compensatory mechanisms adopted by the amputated leg (Silverman *et al.*, 2008). Winter and Sienko (1988) explained that the amputee-related literature increasingly refers to variables that measure gait symmetry. Therefore, a scientific justification is needed to encourage more symmetrical walking pattern.

The influence of various prosthetic components on the gait of lower limb amputees has been evaluated. Extensive research has been conducted on the effects of prosthetic foot as transtibial amputees lose normal ankle mechanics while retain the anatomical knee joint (Goujon *et al.*, 2006; Schmalz *et al.*, 2002; Torburn *et al.*, 1990; Van der Linden *et al.*, 1999). Moreover, the improper fit of the prosthetic socket and failure of the suspension system can result in pistoning, which in turn will affect the walking pattern. Total surface bearing (TSB) socket was introduced as new concept, and its total contact was said to eliminate pistoning during walking (Hachisuka *et al.*, 1998a; Kristinsson, 1993; Narita *et al.*, 1997; Yigiter *et al.*, 2002). Researchers have also

studied the effects of prosthetic liner on the gait of transtibial amputees and revealed that liner thickness can affect the gait variables (Boutwell *et al.*, 2012).

Current suspension systems for transtibial amputees are either pin/lock or seal liners, which are both provided with TSB sockets. Suspension systems have been investigated in terms of interface pressure, interface dynamics (pistoning) and comfort. Pin/lock systems are said to cause pain and discomfort inside the prosthetic socket, leading to skin changes in the long term. Discomfort may cause changes in gait parameters as the amputee would be reluctant to bear load over the prosthetic socket during walking. The Seal-In suspension liner can relieve the distal end pressure by applying more loads to the proximal tissues of the residual limb. Both systems control pistoning, but the Seal-In liner is more successful. These two suspension types have not been studied in terms of gait parameters during level walking.

A new magnetic prosthetic suspension system (MPSS) has been introduced, and compared with the pin/lock and Seal-In liners in terms of pistoning through gait simulation, as well as interface pressure (Eshraghi *et al.*, 2013a; Eshraghi *et al.*). This hypothesis-generating study aimed to examine the changes in gait characteristics of transtibial amputees with the MPSS, pin/lock and Seal-In suspension systems. We were interested to find out what gait parameters show significant changes. It was also intended to see how deviated was the gait pattern with every suspension type from the gait of normal individuals. The main hypothesis of this study was that the type of suspension may significantly alter the kinetic and kinematic gait parameters as well as pistoning. Furthermore, it was assumed that the sound and prosthetic legs would exhibit significantly different patterns.

7.2. Methodology

The ethics committee of the University of Malaya Medical Center approved the study. The subjects signed consent forms prior to participation. In a clinical trial, fifteen individuals with transtibial amputation were selected to participate in the study as sample of convenience. Amputees were eligible for the study if they were unilateral transtibial, could ambulate independently, had a stump free of ulcer and pain, had undergone amputation at least one year prior to the study, and had healthy upper limbs to don and doff the prosthesis without help. The subject recruitment was performed from March 2012 to March 2013.

Inconsistency of the prosthetic fabrication techniques, alignment, and fitting can significantly influence the outcome. Therefore, one of the authors (a registered prosthetist) fabricated three prosthetic systems for each participant. The only difference between the prostheses was the suspension system. The suspension systems were: a) pin/lock suspension (Dermo liner with shuttle lock), b) new magnetic lock (MPSS), and c) Seal-In system (Seal-In X5 liner) (Figure 7.1). The third system required a separate negative cast; whereas the first two systems were fabricated from a single negative cast. The prosthetist ensured the fit of each prosthetic socket through a transparent check socket (Northplex, North Sea Plastic Ltd.) while standing in the alignment frame and during walking. The sockets were required to be TSB; therefore, the transparent material allowed close inspection of fit.

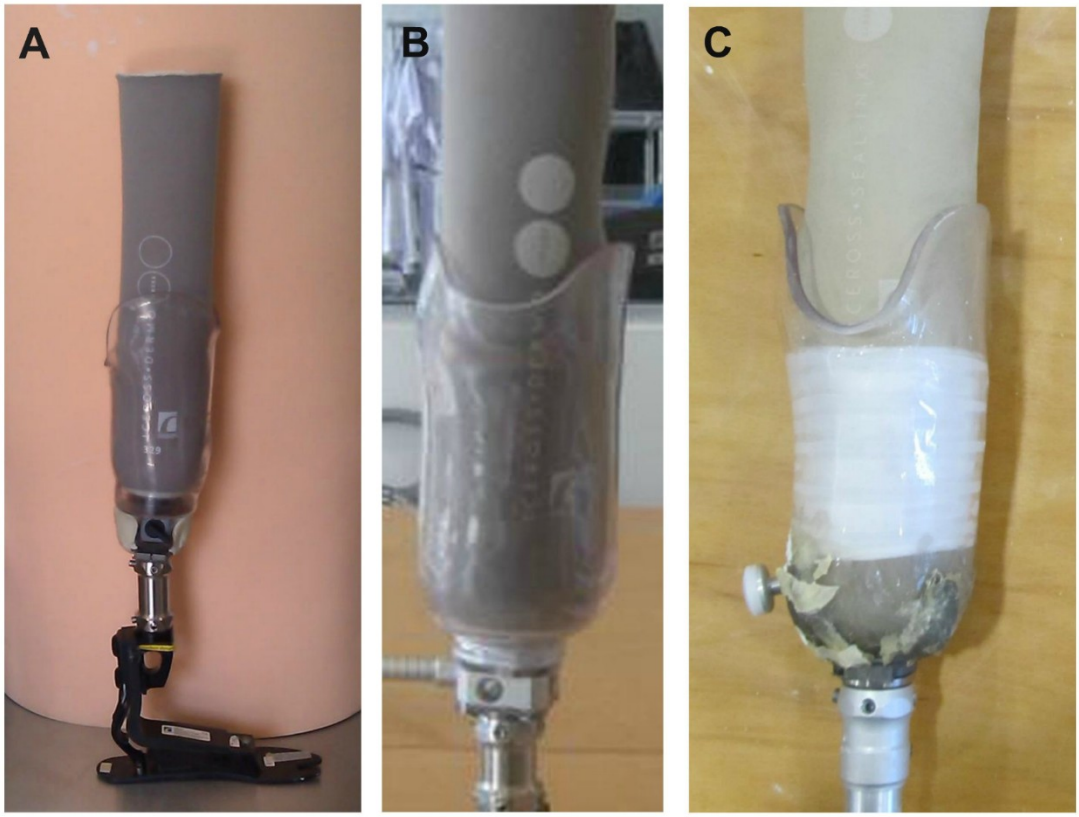


Figure 7.1: The suspension systems used in this study. A) MPSS; B) Pin/lock and C) Seal-In suspension systems.

The characteristics of the new prosthetic suspension system have been described elsewhere (Eshraghi *et al.*, in press). In brief, the new system was designed to be used with silicone liners as they are commonly used. To this end, a cap was designed that matched both the main body of the new coupling device, and the liner's distal end. The dimensions were purposely designed to match the liner proportions. A central screw enabled coupling to the liner. The body of the coupling device was source of magnetic power. As such, the cap was made of mild steel to produce high gripping force. A permanent magnet was utilized that was capable of generating a strong magnetic power. The housing intensified the magnetic field by flanges. In order to control the magnetic power, a mechanical switch was affixed to the housing and the magnet. When the rotary switch was in the "On" position, the cap was attracted to the housing, whereas it was released from the lower body of the coupling device when the switch was in the "Off" position.

Pyramid adapters connected the TSB sockets to the aluminum alloy pylon and prosthetic foot (Flex-foot Talux, Ossur). The subjects were also provided with three definitive sockets for the acclimation period of four weeks. The aligning procedure was performed using a laser liner to ensure accuracy. The subjects were trained for walking with the new prosthetic legs as follows. After ensuring the fit of prosthetic sockets, the training prostheses were fabricated. Every participant was required to attend the Brace & Limb Laboratory, University of Malaya for the gait training during one week. The gait training was performed in the parallel bars to check the dynamic alignment during level walking. Next, the amputees participated in training out of the parallel bars, climbing the stairs and ramp in real environment. Necessary adjustments were applied so that the participants were fully confident to ambulate without pain or discomfort. The subjects used identical shoes in all the experiments.

A Vicon motion analysis system (612 Oxford Metrics; Oxford, UK) with six cameras (MXF20) was utilized to evaluate the gait kinematics and pistoning between the prosthetic socket and liners. Kinetic data was recorded using two Kistler force platforms (type 28112A2-3S, Kistler Holding AG, Switzerland). The synchronized frequency was set at 200 Hz. For the pistoning measurement, the authors introduced a new measurement technique using the Vicon motion system (Gholizadeh et al., 2012b); the same method was adopted in this study. The location of the ankle reflective marker on the prosthetic foot approximated the axis of rotation for the sound ankle. The subjects walked with each prosthesis type adopting self-selected speed on a 10-meter level walkway. Five successful trials were selected for the kinetic and kinematic analyses. A trial was considered as appropriate if both feet landed properly on the force plates (whole foot was on the force plate). The participants could rest between the trials. All data was collected at the motion laboratory of Center for Applied Biomechanics,

University of Malaya. Butterworth filter with a cutoff frequency of 10 Hz was used to filter the data.

7.2.1. Data analysis

Kinematic and kinetic gait parameters were processed using the Vicon Nexus (Oxford Metrics, Ltd.) software. Data was analyzed based on the percentage of gait cycle. The average values of the five trials were used for the analysis. Statistical analyses were performed using SPSS 18.0. The normality of variables was verified by the Kolmogorov-Smirnov test. The one-way Repeated Measures Analysis of Variance (ANOVA) with the Bonferroni test was used to compare the three suspension systems. The paired samples t test was adopted to compare between the sound and prosthetic legs. In comparisons among the suspension systems, only the prosthetic limb was considered. The level of significance was set at 0.05. The Cohen's *d* of 0.2 to 0.3 might show a "small" effect, around 0.5 is a "medium" effect and 0.8 to infinity may be considered a "large" effect. The pistoning was measured during the stance and swing phases of gait. The parameter values were averaged over 5 trials, not over the suspension systems. That is, every individual was tested separately with each of the suspension systems, which is considered as repeated measure. Additionally, each testing procedure with each suspension system was repeated for 5 times. Then, the average score of 5 trials with each system was separately used in the repeated measures ANOVA.

The following kinetic and kinematic gait parameters were evaluated: step length, walking speed, stance and swing time (percentage), vertical ground reaction force (GRF), fore-and-aft GRF hip, knee and ankle angles. The step cycle for both legs started

with the heel strike. Data for each time frame were normalized to the whole stride time due to the variability in walking speed (Farahmand *et al.*, 2006). Furthermore, the fore-aft and vertical GRF were normalized to the body weight.

The gait deviation index (GDI) was also calculated for each system. The electronic template of the developers was used to calculate the GDI (Schwartz & Rozumalski, 2008). This template compares the input data with a database of 166 normal subjects. The measures were calculated for the prosthetic limbs of every subject and for each suspension system. The sound limb may exhibit higher kinematic deviations than the prosthetic limb because of the compensatory mechanisms. Thus, the average data for every gait summary measure was used to generate a one-dimensional gait deviation measure.

GDI calculation necessitated a matrix of healthy control data. In brief, the data comprised rows of kinematic data at 2% increments of the gait cycle (459 datum=9 angles 51 points), as well as columns of data from different subjects (Schwartz & Rozumalski, 2008). Kinematic data included ankle dorsi/plantarflexion, knee flex/extension, hip and pelvic angles in all three planes, and foot progression.

The GDI for amputee subject α based on the distance between the normal control (TD) and the amputee subject was calculated from the following equation (Schwartz & Rozumalski, 2008):

$$GDI^{\alpha} = 100 - [10 \times \frac{GDI^{\alpha}_{raw} - Mean(GDI^{TD}_{raw})}{S.D.(GDI^{TD}_{raw})}] \quad (1)$$

As GDI determines the distance from the mean normal gait, GDI of 100 or greater shows that gait pathology is absent. With every deviation of 10 points from 100, the gait is one standard deviation away from the normal. For instance, if GDI^{α}=55, the gait of subject α is 4.5 standard deviation away from the normal.

7.3. Results

From the 15 participants, only the data for thirteen individuals were included in the statistical analysis. The protocol required the subjects to participate in several casting, fitting and training sessions for three different prosthesis types in addition to the experiment sessions. Two subjects did not manage to complete the sessions due to their job limitations and were excluded from the study. The individual characteristics of participants are shown in Table 7.1 .

7.3.1. Pistoning

The repeated measures ANOVA indicated significant differences among the three studied suspension systems during gait ($F(2,24)=27.81$, $P=0.000$ and $\eta_p^2=0.70$). In the swing phase, $F(2,24)=46.49$, $P=0.000$ and $\eta_p^2=0.79$, while it was $F(2,24)=27.13$, $P=0.000$ and $\eta_p^2=0.69$ during stance. Overall, the magnitude of pistoning with the Seal-In suspension was considerably lower compared with the pin/lock and MPSS during swing ($P=0.000$ and $P=0.001$, respectively).

Comparisons between the MPSS and Seal-In systems revealed higher vertical displacements (piston motion) when the prosthetic limb was suspended using the MPSS ($P=0.001$). This significantly higher pistoning was evident during the swing phase; yet, the magnitudes of pistoning were higher for the Seal-In liner during the stance ($P=0.000$). Statistical analyses indicated lower pistoning values with the MPSS compared with the pin/lock system during the swing phase ($P=0.035$). During one gait cycle, 4.06 mm and 2.88 mm of pistoning was observed with the pin/lock and MPSS ($P=0.019$).

Table 7.1: Characteristics of the participants.

Subject no.	Age	Height (cm)	Mass (Kg)	Amputated side	Cause of amputation
1	42	173	75	Left	Diabetes
2	37	168	90	Left	Trauma
3	30	182	60	Left	Trauma
4	72	166	75	Left	Diabetes
5	46	167	64	Left	Trauma
6	35	170	99	Left	Diabetes
7	49	164	57	Right	Diabetes
8	53	177	60	Right	Diabetes
9	41	167	66	Right	Trauma
10	33	162	94	Left	Trauma
11	26	170	79	Left	Trauma
12	60	176	83	Right	Diabetes
13	59	169	75	Right	Diabetes

7.3.2. Kinetics and kinematics

The suspension type did not alter the walking speed, stance and swing time significantly ($P > 0.05$). The swing time of the prosthetic side were significantly longer than the sound limb with the three suspension systems ($P < 0.05$) (Table 7.2). However, the stance time was significantly lower on the prosthetic limb than the sound limb. Significant differences were found between the suspension systems in the first peak of vertical GRF (loading response) ($F(2,24)=13.01$, $P=0.000$, $\eta_p^2=0.52$). The comparison between the MPSS and pin/lock as well as the Seal-In and pin/lock revealed significant differences ($P=0.042$ & $P=0.006$, respectively). With all three systems, weight transfer

during the transition from double- to single-limb support occurred in a shorter period for the sound leg compared with the prosthetic leg (Table 7.2).

The vertical GRF during the loading response (2nd peak) was significantly different among the three systems ($F(2,24)=18.80$, $P=0.000$, $\eta_p^2=0.79$). None of the systems showed significant difference between the sound and prosthetic leg. From the double- to single-limb support (swing time), the weight shift occurred at a considerably shorter period for the sound limb compared with the prosthetic limb for all the systems (all $P=0.000$).

The suspension systems not only changed the first peak of the fore-aft GRF significantly ($F(2,24)=14.57$, $P=0.003$, $\eta_p^2=0.65$), but also there was significant difference between the sound and prosthetic legs within every suspension type (all Cohen's $d > 0.8$) (Table 7.2). The magnitudes of 1st peak fore-aft GRF were significantly lower on the prosthetic leg compared with the sound leg for all the systems (all $P=0.000$, $d > 0.8$) (Table 7.2). The lowest mean difference was seen with the Seal-In system (2.40).

The average knee range of motion (ROM) was significantly different among the three studied systems ($F(2,24)=46.48$, $P=0.000$, $\eta_p^2=0.79$). The highest knee ROM with the prosthetic leg was seen with the Seal-In (70.7°). There was no significant difference between the pin/lock and MPSS ($P=0.075$). The knee ROM was significantly different between the legs for the Seal-In, pin/lock and MPSS ($P=0.000$; $d=4.4$, $d=2.7$, $d=2.1$, respectively). A significant difference was observed among the three systems in the maximum knee flexion ($F(2,48)=18.40$, $P=0.000$, $\eta_p^2=0.60$). The highest knee flexion was seen with the Seal-In, followed by the MPSS and pin/lock ($P=0.006$ & 0.001, respectively). Table 7.2 and Table 7.3 show the mean values, confidence intervals and effect sizes of kinetic and kinematic gait parameters based on the suspension type.

Figure 7.2 illustrates the comparison of kinematic values among the suspension systems for the prosthetic limb.

7.3.3. GDI

The mean GDI for 13 subjects were 43.33, 40.57, and 39.87 with the Seal-In, pin/lock, and MPSS, respectively. Suspension type did not result in significant difference of the GDI values ($F(2,24)=2.11$, $P=0.143$, $\eta_p^2=0.15$). Figure 7.3 presents the comparison of mean GDI index values among the suspension systems.

7.4. Discussion

The gait of lower limb amputees has long been studied to understand the kinematic and kinetic deviations resulting from the loss of ankle-foot (transtibial amputees) or knee-ankle-foot complex (transfemoral amputees). The effects of various prosthesis components on the gait of individuals with amputation have been investigated. Primarily, this study attempted to examine the effect of suspension type on walking kinetics and kinematics, pistoning and gait deviation with three different suspension systems. The previous research showed that the interface pressure with the suspension systems used in the current study were considerably different (Eshraghi *et al.*, 2013a). Thus, we hypothesized that gait characteristics would also be notably different among the MPSS, Seal-In, and pin/lock systems.

Transtibial amputees have different gait patterns from healthy individuals. As a result, the intact limb is said to undergo higher loading. To compensate, amputees adopt mechanisms, such as decreased walking speed, increased knee and hip moments and

higher ankle ROM on the sound limb (Nolan & Lees, 2000). Based on the literature, the asymmetry in amputee gait reduces the time of stance (Baker & Hewison, 1990; Breakey, 1976; Cheung *et al.*, 1983) and the ground reaction forces (Baker & Hewison, 1990; Dingwell *et al.*, 1996; Skinner & Effeney, 1985) of the prosthetic limb compared with the sound limb. Healthy individuals have a gait velocity of 1.2 m/s–1.5 m/s (Isakov *et al.*, 2000; Winter, 1991). No significant difference was observed in gait speed among the three suspension systems (P=0.075). Also, previous studies revealed higher walking speed for transtibial amputees than our findings (Boutwell *et al.*, 2012; Supan *et al.*, 2010; Vanicek *et al.*, 2009).

7.4.1. Pistoning

Pistoning is used as a measure of suspension efficiency (Eshraghi *et al.*, 2012a). The findings in this study revealed that pistoning values were significantly different among the suspension systems during level walking both in the stance and swing phase with medium and large effect sizes of 0.69 and 0.79, respectively. The magnitudes of pistoning with the MPSS and pin/lock systems were compatible. The Seal-In system exhibited significantly lower pistoning during the swing phase compared with the pin/lock (2.0 vs. 4.9 mm, P=0.002, η_p^2=0.57) and MPSS (2.0 vs. 3.3 mm, P=0.002, η_p^2=0.57). The values were well-matched to those obtained during gait simulation in our previous study (Eshraghi *et al.*, 2012b); the gait simulation showed a pistoning range of 0 to 5.8 mm and the pistoning in the current study ranged between 0 to 5.1 mm.

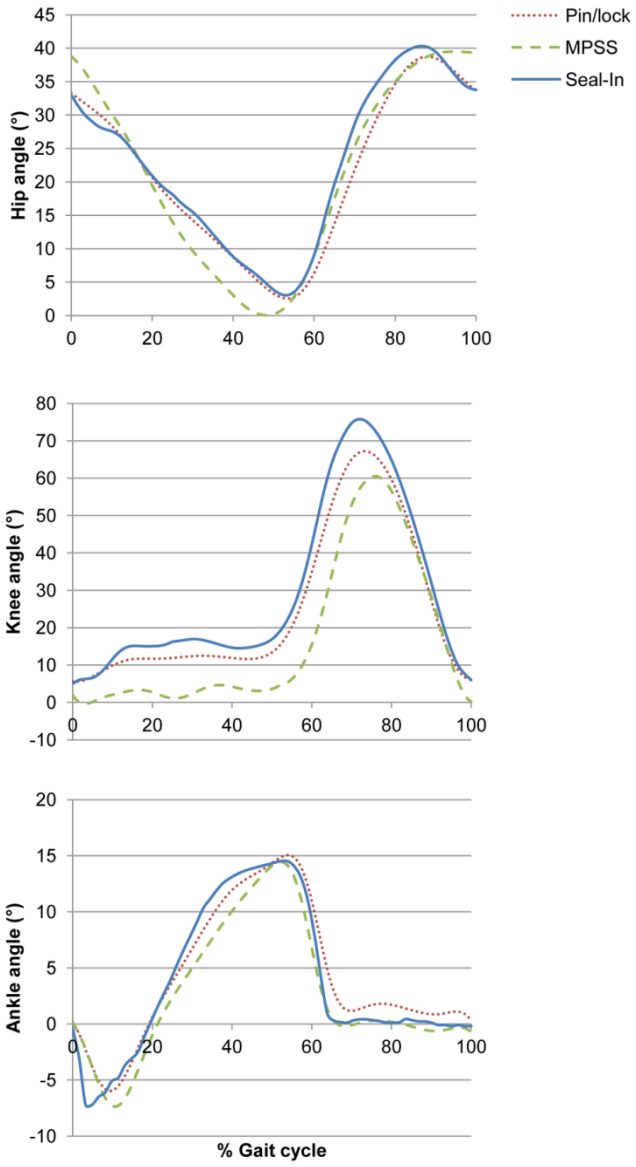


Figure 7.2: Kinematic values based on the suspension type. Comparison of kinematic values for prosthetic limbs among the different suspension systems (n=13).

7.4.2. Ground reaction force

The external forces exerted on the lower limbs during walking are defined as GRFs (Engsberg *et al.*, 1993; Stergiou *et al.*, 2002). The magnitude of peak GRF can determine level of shock absorption. All the suspension systems exhibited significant differences in the first peak of vertical GRF between the sound and prosthetic limbs. The sound limb exhibited significantly higher first peak vertical GRF compared with the prosthetic leg in the previous literature (Bateni & Olney, 2002; Gailey *et al.*, 2008; Vanicek *et al.*, 2009). Our findings were consistent with those findings as the

participants showed higher first peak value for the sound limb with all the systems (Table 7.2). Also, the suspension systems showed significantly different 1st peak GRF values ($F(2,24)=13.01$, $P=0.000$, $\eta_p^2=0.52$). High magnitude of first peak GRF indicates higher loading transferred to the limb joints. The MPSS showed lower values than the pin/lock (mean difference=7.8; $P=0.006$), which may indicate that lower external loading was applied to the joints (Figure 7.4).

Generally, there was significant difference between the suspension systems in the 2nd peak of vertical GRF ($F(2,24)=18.80$, $P=0.000$, $\eta_p^2=0.61$). None of the suspension systems showed significant differences between the prosthetic and sound legs. Thus, it can be deduced that the dynamic foot used in this study (Talux) generated an added force during push off by storing energy and simulating the anatomical ankle plantar flexion. However, the magnitude of the second peak of vertical GRF was lower with the MPSS than the pin/lock (mean difference = 7.67). This result may be associated with the lower interface pressure within the prosthetic socket observed in the previous study (Eshraghi *et al.*, 2013a).

Table 7.2: Kinetic and kinematic differences between the sound and prosthetic limbs within every suspension type; Mean (95% CI).

Parameters	Seal-In		*P* value	MD (CI)	*d*	Pin/lock		*P* value	MD (CI)	*d*	MPSS		*P* value	MD (CI)	*d*
	Sound	Prosthesis				Sound	Prosthesis				Sound	Prosthesis			
Step length (m)	0.57 (0.53-0.61)	0.61 (0.55-0.66)	0.320	0.04 (-0.84 - 3.09)	0.1	0.54 (0.47-0.62)	0.62 (0.54-0.69)	0.134	0.08 (-0.03 - 0.17)	0.5	0.56 (0.5-0.62)	0.59 (0.51-0.67)	0.536	0.03 (-0.07 - 0.12)	0.2
Cadence (step/min)	94.09 (92.73-95.46)	95.21 (94.02-96.41)	0.183	1.12 (-0.85 - 3.09)	0.2	93.03 (91.77-94.3)	95.60 (94.13-97.25)	**0.031**	2.57 (0.28 - 4.03)	0.4	93.03 (91.77-94.3)	95.06 (93.37-96.75)	0.145	2.03 (-0.73 - 4.4)	0.6
Stance time (% of gait cycle)	65.56 (64.1-67.03)	62.28 (60.89-63.70)	**0.002**	3.28 (-5.11 - -1.45)	1.3	66.7 (65.53-67.87)	60.73 (59.74-61.73)	**<0.001**	5.97 (-7.38 - -4.55)	3.4	65.57 (64.34-66.8)	62.31 (61.19-63.42)	**0.001**	3.26 (-4.77 - -1.75)	1.7
Swing time (% of gait cycle)	34.46 (33.31-35.61)	37.70 (65.60-67.80)	**0.001**	32.24 (30.74 - 33.75)	1.4	33.32 (31.64-35)	38.30 (36.95-39.65)	**<0.001**	4.98 (3.32 - 6.64)	2.1	34.14 (32.75-35.52)	37.56 (36.39-38.73)	**0.001**	3.42 (1.83 - 5.02)	1.7
Vertical GRF, 1st peak (%BW)	121.11 (118.05-124.17)	99.68 (97.15-102.22)	**<0.001**	21.43 (-25.15 - -17.7)	4.8	126.68 (123.88-129.48)	104.22 (101.58-106.87)	**<0.001**	22.46 (-26.03 - -18.89)	4.9	115.27 (109.13-121.42)	96.42 (91.84-101.02)	**<0.001**	18.85 (-25.2 - -12.49)	2.3
Vertical GRF, 2nd peak (%BW)	101.99 (99.59-104.4)	102.63 (100.19-105.06)	0.706	0.64 (-1.69 - 2.96)	0.1	101.12 (98.87-103.38)	99.09 (96.34-101.85)	0.301	2.03 (-6.12 - 2.06)	0.4	105.18 (102.38-107.98)	91.69 (88.51-94.87)	**<0.001**	13.49 (-17.49 - -9.49)	2.4
Fore-aft GRF, 1st peak (%BW)	7.86 (7.1-8.62)	5.45 (4.79-6.12)	**<0.001**	2.41 (-3.34 - -1.47)	2.1	9.34 (8.4-10.28)	4.66 (3.98-5.35)	**<0.001**	4.68 (-5.7 - -3.66)	3.9	9.86 (8.94-10.78)	4.11 (3.43-4.80)	**<0.001**	5.75 (-6.87 - -4.61)	4.8
Fore-aft GRF, 2nd peak (%BW)	-7.51 (-8.25--6.77)	-8.10 (-8.76- -7.43)	0.208	0.59 (-1.37 - 0.19)	0.5	-7.13 (-8.84- -6.45)	-8.11 (-8.91- -7.31)	0.058	0.98 (-2.04 - 0.04)	0.7	-7.01 (-8.10- -6.25)	-7.41 (-8.13- -6.69)	0.390	0.40 (-1.25 - 0.52)	0.3
Hip position-initial contact	35.89 (33.81-37.97)	32.8 (30.95-34.65)	0.193	3.09 (-5.38 - -0.8)	0.9	32.6 (30.94-34.26)	33.11 (31.04-35.17)	0.543	0.51 (-1.26 - 2.27)	0.2	34.15 (32.11-35.81)	33.04 (31.08-35.00)	0.318	1.11 (-3.44 - 1.21)	0.4
Max Hip Ext	-2.13 (-2.46--1.81)	3.06 (2.71-3.42)	**<0.001**	5.19 (4.83 - 5.56)	3.6	-2.42 (-2.98--1.85)	2.62 (2.18-3.05)	**<0.001**	5.04 (4.36 - 5.71)	3.6	-2.42 (-2.75- -1.67)	2.5 (1.97-3.04)	**<0.001**	4.92 (4.29 - 5.53)	5.4
Hip ROM	38.42 (37.37-39.47)	37.31 (35.83-38.79)	0.193	1.11 (-2.66 - 0.43)	0.5	37.23 (35.03-38.80)	36.13 (34.92-37.33)	0.121	1.1 (-2.55 - 0.34)	0.5	37.52 (35.67-39.45)	36.7 (35.25-38.16)	0.261	0.82 (-2.18 - 0.65)	0.4

Table 7.2 continued

Parameters	Seal-In		*P* value	MD (CI)	*d*	Pin/lock		*P* value	MD (CI)	*d*	MPSS		*P* value	MD (CI)	*d*
	Sound	Prosthesis				Sound	Prosthesis				Sound	Prosthesis			
Knee position-initial contact	1.41 (1.14-1.67)	5.4 (4.55-6.25)	**<0.001**	3.99 (3.12 - 4.87)	3.8	4.1 (3.17-5.02)	5.73 (4.9-6.57)	**0.022**	1.63 (0.28 - 2.99)	1.1	3.9 (3.35-4.45)	5.53 (4.34-6.71)	**0.023**	1.63 (0.27 - 2.98)	1.1
Max Knee Flex –stance	15.12 (14.09-16.15)	13.72 (12.59-14.86)	0.059	1.40 (-2.98 - 0.18)	0.8	13.43 (11.86-15.01)	12.47 (11.08-13.85)	0.302	0.96 (-2.93 - 0.99)	0.4	14.24 (12.66-15.82)	12.84 (11.5-14.19)	0.235	1.40 (-3.83 - 1.04)	0.6
Max Knee Flex-swing	55.17 (53.58-56.75)	75.40 (73.21-77.57)	**<0.001**	20.23 (17.32 - 23.13)	6.4	52.52 (51.08-53.96)	66.92 (64.77-69.08)	**<0.001**	14.4 (11.49 - 17.32)	4.7	54.02 (52.06-55.97)	70.81 (68.7-72.93)	**<0.001**	16.79 (14.21 - 19.38)	5.0
Knee ROM	56.14 (54.57-57.7)	70.68 (68.34-73.04)	**<0.001**	14.54 (11.54 - 17.57)	4.4	52.61 (51.12-54.09)	61.42 (58.99-63.81)	**<0.001**	8.81 (6.28 - 11.31)	2.7	52.79 (51.28-54.3)	58.25 (56.55-59.94)	**<0.001**	5.46 (3.02 - 7.89)	2.1
Ankle position-initial contact	2.12 (1.59-2.65)	-0.81 (-1.21- -0.41)	**<0.001**	2.93 (-3.67 - -2.19)	3.8	-4.21 (-4.88--3.54)	0.27 (0.07-0.46)	**<0.001**	4.48 (3.76 - 5.19)	5.5	-2.29 (-2.81--1.77)	-0.6 (-0.93- -0.28)	**<0.001**	1.69 (1.01 - 2.37)	2.3
Max ankle PF-stance	-6.68 (-8.33--5.02)	-7.19 (-8.3- -6.07)	0.583	0.51 (-2.75 - 1.73)	0.2	-5.92 (-7.23--4.62)	-5.89 (-6.98- -4.81)	0.951	0.03 (-1.09 - 1.15)	0.0	-6.12 (-7.41--4.82)	-3.02 (-3.73- -2.31)	**0.002**	3.10 (1.42 - 4.77)	1.8
Max ankle DF-stance	7.3 (6.23-8.37)	14.49 (13.34-15.63)	**<0.001**	7.19 (5.44 - 8.93)	3.9	8.09 (7.07-9.1)	15.11 (14.24-15.98)	**<0.001**	7.02 (5.72 - 8.32)	4.5	7.92 (6.78-9.06)	14.67 (13.93-15.41)	**<0.001**	6.75 (5.43 - 8.06)	4.2
Max ankle PF-swing	-13.2 (-14.7--11.7)	0.33 (0.12-0.55)	**<0.001**	13.53 (12.02 - 15.05)	7.6	-12.15 (-13.2--11.1)	1.37 (1.13-1.67)	**<0.001**	13.52 (12.45 - 14.64)	5.7	-12.17 (-13.05--11.29)	1.13 (0.93-1.33)	**<0.001**	13.30 (12.38 - 14.21)	5.2
Ankle ROM	20.67 (19.1-22.24)	21.73 (20.35-23.1)	0.280	1.06 (-1.23 - 3.35)	0.4	20.08 (18.68-21.48)	20.87 (19.32-22.43)	0.508	0.79 (-1.74 - 3.33)	0.3	20.25 (18.5-21.99)	20.69 (19.55-21.83)	0.700	0.44 (-2.00 - 2.88)	0.2

CI=Confidence interval; PF=plantar flexion; DF=dorsiflexion; Flex=flexion; Ext=extension; ROM=range of motion; MD=mean difference.
*Values of significance ($P < 0.05$) have been shown in bold. *d* equals to values of Cohen's d; 0.2=small, 0.5=medium, > 0.8=large.

The pattern of resultant fore-aft GRF revealed comparable acceleration forces for all the suspension systems ($F(2,24)=2.45$, $P=0.107$), and for both limbs. A larger deceleration force (braking force) was observed with the sound limb ($P=0.000$ for all the systems), which conforms to the previous finding by Zmitrewicz *et al.* (2006). However, several minor differences in magnitudes are evident between the two studies, possibly due to the variations in prosthetic components, particularly the foot and walking velocity. The highest actual mean difference between the legs was seen with the MPSS (5.75). Braking peaks of prosthetic limb were lower with the MPSS than the pin/lock ($P=0.016$, $d=0.78$). This result possibly indicates better shock absorption with the MPSS. The duration of deceleration force was also dissimilar between the limbs, as the prosthetic side showed a larger value than the sound limb, which is compatible with the findings of Zmitrewicz *et al.* (2006). Propulsive force contributes to symmetrical gait pattern, balanced loading and steady walking speed. All the systems demonstrated similar magnitudes of propulsion force (for-aft GRF, 2nd peak) for both limbs. This observation may reveal symmetry between the lower limbs.

7.4.3. Spatiotemporal parameters

Compared with the normal individuals, the amputee gait is characterized by lower velocity, greater swing time, longer step length, and increased cadence (Winter, 1991). These characteristics are compensatory means of reducing instability and imbalance. In this study, cadence (number of steps per time unit) did not differ considerably between the sound and prosthetic legs for all suspension systems. However, the Seal-In system exhibited more homogenous cadence values between the legs (Table 7.2). The magnitudes were similar to the cadence values of other studies (Isakov *et al.*, 2000; Winter, 1991).

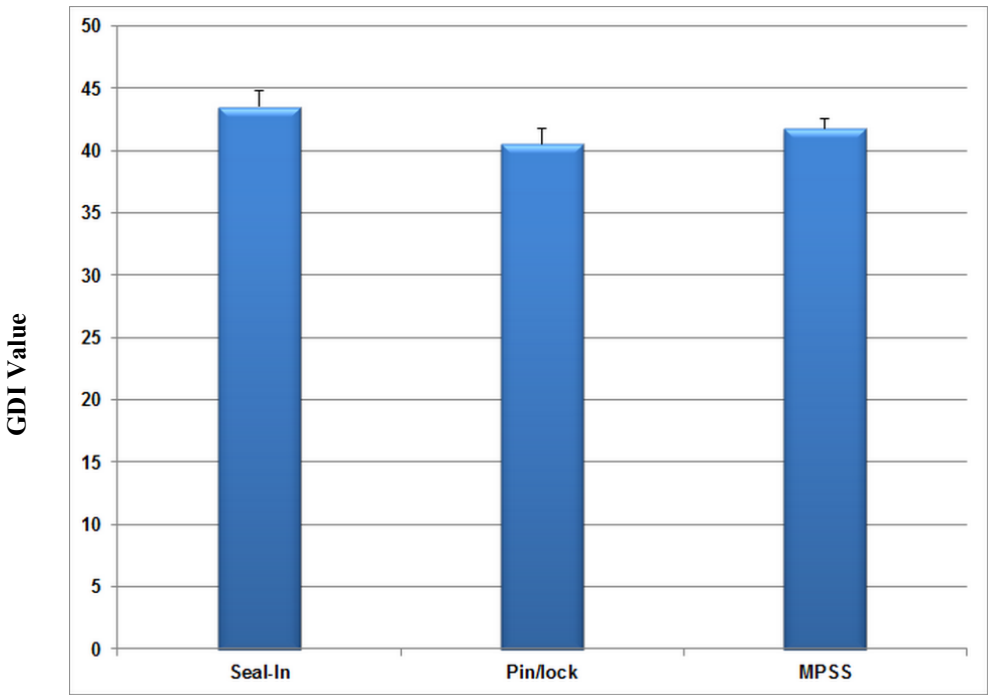


Figure 7.3: The comparison of GDI values among the suspension systems. Error bars show the standard error values.

Inconsistent step length is generally the result of uneven weight bearing through the lower limbs. Longer step length helps in relieving the load off the residual limb. There was no significant difference among the three systems ($F(2,24=0.13$, $P=0.817$) and between the limbs. This was not consistent with the previous studies that showed significant difference in step length between the legs (Supan *et al.*, 2010).

Table 7.3: Comparison of kinetics and kinematic variables with regards to the suspension system type in the prosthetic limb.

Parameter	Suspension type Mean (95% CI)			*P* value	Effect size
	Seal-In	Pin/lock	MPSS		
Step length (m)	0.61 (0.55-0.66)	0.62 (0.54-0.69)	0.60 (0.51-0.67)	0.817	0.03
Cadence (step/min)	95.21 (94.02-96.41)	95.70 (94.13-97.25)	95.06 (93.37-96.75)	0.844	0.14
Velocity (m/s)	0.94 (0.91-0.98)	0.91 (0.86-0.96)	0.98 (0.95-1.01)	0.075	0.23
Stride length (m)	1.21 (1.14-1.29)	1.12 (1.03-1.20)	1.08 (0.95-1.22)	0.118	0.16
Stance time (% of gait cycle)	62.28 (60.89-63.70)	61.73 (59.74-61.73)	62.50 (61.19-63.42)	0.062	0.39
Swing time (% of gait cycle)	37.70 (65.60-67.80)	38.30 (36.95-39.65)	37.56 (36.39-38.73)	0.435	0.06
Vertical GRF, 1st peak (%BW)	99.68 (97.15-102.22)	104.22[a,c] (101.58-106.87)	96.42[b] (91.84-101.02)	**<0.001**[*]	0.52
Vertical GRF, 2nd peak (%BW)	102.63 (100.19-105.06)	99.09 (96.34-101.85)	91.69[a,b] (88.51-94.87)	**<0.001**[*]	0.61
Fore-aft GRF, 1st peak (%BW)	5.45 (4.79-6.12)	4.66[a] (3.98-5.35)	4.11[a,b] (3.43-4.80)	**0.003**[*]	0.65
Fore-aft GRF, 2nd peak (%BW)	-8.02 (-8.76- -7.43)	-8.11 (-8.91- -7.31)	-7.41 (-8.13- -6.69)	0.095	0.34
Hip position-initial contact	32.8 (30.95-34.65)	33.11 (31.04-35.17)	33.04 (31.08-35)	0.931	0.006
Max Hip Ext	3.06 (2.71-3.42)	2.62 (2.18-3.05)	2.5 (1.97-3.04)	0.210	0.12
Hip ROM	37.31 (35.83-38.79)	36.13 (34.92-37.33)	36.7 (35.25-38.16)	0.278	0.10
Knee position-initial contact	5.4 (4.55-6.25)	5.73 (4.9-6.57)	5.53 (4.34-6.71)	0.876	0.01
Max Knee Flex - stance	13.72 (12.59-14.86)	12.47 (11.08-13.85)	12.84 (11.5-14.19)	0.291	0.09
Max Knee Flex-swing	75.40 (73.21-77.57)	66.92[a] (64.77-69.08)	70.81[a,b] (68.7-72.93)	**<0.001**[*]	0.60
Knee ROM	70.68 (68.34-73.04)	61.42[a] (58.99-63.81)	58.25[a] (56.55-59.94)	**<0.001**[*]	0.79
Ankle position-initial contact	-0.81 (-1.21- -0.41)	0.27[a] (0.07-0.46)	-0.6[b] (-0.93- -0.28)	**0.001**[*]	0.71
Max ankle PF-stance	-7.19 (-8.3- -6.07)	-5.89 (-6.98- -4.81)	-3.02[a,b] (-3.73- -2.31)	**<0.001**[*]	0.80
Max ankle DF-stance	14.49 (13.34-15.63)	15.11 (14.24-15.98)	14.67 (13.93-15.41)	0.556	0.04
Max ankle PF-swing	0.33 (0.12-0.55)	1.37[a] (1.13-1.67)	1.13[a] (0.93-1.33)	**<0.001**[*]	0.76
Ankle ROM	21.73 (20.35-23.1)	20.87 (19.32-22.43)	20.69 (19.55-21.83)	0.417	0.07

CI=Confidence interval; PF=plantar flexion; DF=dorsiflexion; Flex=flexion; Ext=extension; ROM=range of motion.

[a] Mean difference is significant at the 0.05 level compared with the Seal-In suspension.

[b] Mean difference is significant at the 0.05 level compared with the pin/lock suspension.

[*] shows significant differences among the three suspension systems.

Prosthesis users tend to shift weight to the sound leg; consequently, the timing of prosthesis stance phase is lower (Bateni & Olney, 2002). Similarly, the stance phase was shorter with the prosthetic leg than the sound limb for all the suspension systems in our study (d=1.3, 3.4 and 1.7 for the Seal-In, pin/lock and MPSS, respectively). The highest actual difference was seen with the pin/lock (66.7 vs. 61.7), while the lowest with the Seal-In (65.6 vs. 62.3) (Table 7.2). These results indicate that possibly the participants were more comfortable to walk with the Seal-In system, while probably the milking phenomenon resulted in pain and discomfort with the pin/lock suspension. Although statistically different, the actual differences might not be clinically relevant. The longer swing phase may be the result of the lighter prosthetic foot (carbon Talux) than the anatomical one (Supan *et al.*, 2010).

7.4.4. Kinematics

The previous literature on amputee's gait biomechanics demonstrated slight deviations from the able-bodied gait pattern (Bateni & Olney, 2002; Winter, 1991). Also, there are differences between the sound and amputated legs in unilateral amputees. In our study, the magnitudes of hip ROM were slightly higher with the sound leg than the prosthetic leg; however, the statistical analysis did not show any significance. Similarly, Bateni and Olney (2002) showed relative smaller ranges of hip angle for the amputated side. There was no significant difference among the three systems on the prosthetic side (P=0.240).

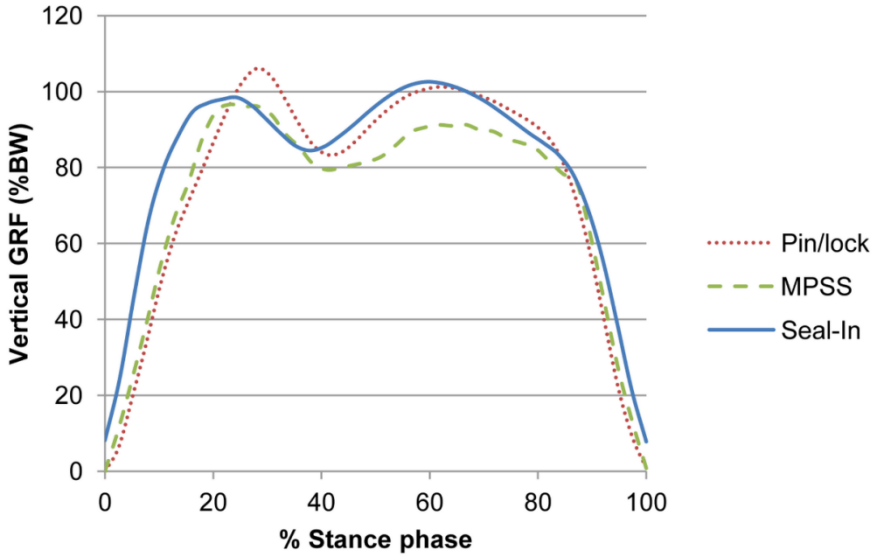


Figure 7.4: Vertical GRF for each suspension type. The vertical ground reaction force (GRF) pattern of the prosthetic limb for the three suspension systems.

In the previous studies, less knee flexion was observed on the amputated side in comparison with the normal values in stance phase. Similarly, less knee flexion was seen in our study. This finding can be attributed to the inability of the prosthetic foot to produce the controlled plantar flexion as dorsiflexor eccentric contraction is missing (Smidt, 1990). Knee and foot motions are often synchronized. In most prosthetic feet, the ankle does not allow plantar flexion when weight is transferred to the toe section. If the knee at the amputated side is flexed to the mean normal value, excessive trunk lowering would produce an abnormal, inept gait (Bateni & Olney, 2002). However, the dynamic Talux foot allowed certain degrees of plantar flexion in this study.

Significant differences were seen in the maximum knee flexion on the prosthetic leg during the swing phase among the three suspension systems ($F(2,24)=18.40$, $P=0.000$, $\eta_p^2=0.60$). Significantly higher flexion was observed with the Seal-In system than the MPSS ($P=0.006$). Also, the maximum knee flexion with the MPSS was higher than the pin/lock suspension ($P=0.041$). The actual mean difference was higher between the Seal-In and pin/lock systems (8.48). The knee ROM was significantly higher on the

prosthetic limb than the sound limb with all the systems and effect sizes were large (Table 7.2). The highest actual mean difference was seen with the Seal-In system (14.54), which may be clinically relevant as the knee ROM is important for foot clearance and demanding activities such as running. This finding is consistent with Colborne *et al.* (1992). The amputees often flex the amputated knee more than the sound knee to ensure foot clearance during the swing.

Gait progression is affected by the absence of anatomical ankle as more than 80% of mechanical power is generated by the plantar flexion in healthy individuals. The maximum ankle plantar flexion during the swing phase was significantly different among the systems ($F(3,53)=38.57$, $P=0.000$, $\eta_p^2=0.76$), and higher with the sound limb compared with the prosthetic limb with all the suspension systems (large effect sizes). The actual mean differences may be clinically relevant as the differences were high (more than 10°). Significant differences also existed in the ankle dorsiflexion in the stance phase between the sound and prosthetic limbs; the values were higher with the prosthetic leg (the actual mean differences were less than 8°). This can be attributed to the stiffness of prosthetic foot. The Talux foot has been reported to produce similar gait characteristics to the human foot (Supan *et al.*, 2010). Our participants also indicated that the Talux foot was more comfortable than their previous foot, particularly at heel strike and push off.

7.4.5. GDI

Gait summary measures have been recently adopted as an index of gait deviations for various pathologies, such as cerebral palsy, Parkinson's, and lower limb loss (Cimolin *et al.*, 2011; Kark *et al.*, 2012; Schwartz & Rozumalski, 2008). We adopted the GDI to

investigate the possible gait deviation from the normal pattern with every suspension system. Kark et al. (2010) reported that the GDI is an appropriate measure for those with lower limb amputation. They reported an average GDI of 84.2 (SD 9.4) for transtibial amputees. Nevertheless, our subjects showed GDI values from 39.87 to 43.33. The difference in findings may be attributed to the fact that Kark *et al.* (2012) did not consider hip rotation in their calculations. In our study, the Seal-In, MPSS and pin/lock were 5.54, 5.89, and 5.94 standard deviations away from the normal kinematics. There was no significant difference among the three suspension systems; only slight mean differences were seen. The previous studies showed high interface pressure and discomfort during walking with the Seal-In (Ali *et al.*, 2012a; Eshraghi *et al.*, 2013a). In the current study, it showed the least deviation from the normal gait kinematics, which can be attributed to lower pistoning during gait reported in the former literature (Eshraghi *et al.*, in press).

A previous study on the MPSS revealed higher satisfaction rates compared with the Seal-In and pin/lock suspension systems (Eshraghi *et al.*, in press). Lower peak pressure than the pin/lock suspension, particularly during the swing phase, has been also demonstrated (Eshraghi *et al.*, 2013a). Not surprisingly, the GDI scores revealed inferior gait kinematics than the normal individuals; yet, the three suspension systems exhibited similar clinical outcomes that enabled the amputees to ambulate. These findings need to be further investigated on amputees with different activity levels, and with various prosthetic feet. Moreover, the effect of parameters such as the residual limb length, volume, cause of amputation, skin conditions can be further studied on the gait pattern with various suspension systems. Although, the main differences among the suspension types had high effect sizes, larger sample size may provide stronger evidence for the current findings. It is likely that those parameters that showed no difference exhibit significance if tested on higher number of amputees.

While it is common to observe significant differences between the sound and prosthetic limbs in amputees, non-significance may be considered as positive effect of prosthetic components. On the other hand, several kinetic and kinematic parameters did not show high actual mean differences among the suspension systems in this study. The main differences with high effect sizes were seen for the 2nd peak of vertical GRF and the knee range of motion between the Seal-In and MPSS (10.94 and 12.43, respectively). In summary, it may be concluded from the overall findings that the new prosthetic suspension system (MPSS) can be used clinically as an alternative suspension system for lower limb amputees.

7.5. Conclusion

Gait biomechanics was significantly influenced by the suspension type. Main differences between the suspension systems were evident in the GRF (vertical and fore-aft), knee and ankle angles; yet, not all of them are considered clinically relevant. Most specifically, the ankle angles are mainly influenced by the type of prosthetic foot, not the suspension system. The MPSS may reduce the loading over the proximal limb joints compared with the pin/lock system. Pistoning was also significantly altered by the types of suspension system. The Seal-In liner was the most effective suspension system in reducing the vertical movement during level walking. We should emphasize that prosthetic foot characteristics and alignment will also influence the gait pattern in addition to the suspension system. This study is hoped to enhance the knowledge of clinicians on gait biomechanics with various available suspension systems.

CHAPTER 8

CONCLUSIONS AND FUTURE DIRECTIONS

The findings of publications and their contributions are summarized in this chapter. Furthermore, directions for forthcoming research are suggested to expand the research outcomes.

8.1. Summary and conclusions

The contribution of research can be assessed through the degree of achievement with regards to the objectives of the research, and by the efficiency of the system developed. Specifically, the current study had five objectives, which are stated in the following:

i. To develop a new prosthetic suspension system for individuals with lower limb amputation;

ii. To evaluate pistoning with the new prosthetic suspension system in comparison with two other existing suspension systems;

iii. To investigate the interface pressure with the new prosthetic suspension system in comparison with two other existing suspension systems;

iv. To examine the kinetics & kinematics of gait with the prosthesis incorporating new prosthetic suspension system in comparison with two other existing suspension systems; and,

v. To determine the satisfaction and perceived problems with the new prosthetic suspension system in comparison with two other existing suspension systems.

Accordingly, the following conclusions are drawn for each specific objective.

I. **The MPSS could suspend the prosthesis securely on the amputee's residual limb during ambulation. For the first time, suspension system for prosthesis was equipped with safety alarm system.**

The results of this research showed that the new coupling device could stand the forces that tend to displace prosthesis on the residual limb during walking. Any failure of the prosthesis coupling may result in severe trauma that can exacerbate the challenges of amputees. To prevent this, the prosthesis suspension system was equipped with an optional alarm system. To the author's best of knowledge this is the first suspension system for prosthesis with added safety system. The new suspension system developed in this research can be used with or without the alarm system.

II. **Generally, pistoning with the MPSS falls within the ranges found for the other studied suspension systems and the values showed some improvement on certain phases of gait.**

The findings of this study indicate that pistoning during gait was significantly altered by the type of suspension system. Both during the gait simulation and in real walking, the amounts of pistoning were comparable for the pin lock system and the magnetic suspension system, while higher in comparison to the suction system. Yet, all the systems showed pistoning values that fall within the ranges reported in the literature. The repeatability of the measurements was high and there was no significant difference between the observers. The Seal-In suspension was the most effective suspension system in the reduction of the vertical movement during level walking.

III. The MPSS might reduce the pressure over the residual limb, particularly during swing phase of gait.

Even distribution of pressure is considered to be the ideal condition in a prosthetic socket. Users of the pin/lock liners feel a stretch at the distal tissue of the residual limb during the swing phase (milking phenomenon). Lower peak pressures were produced at the anterior and posterior surfaces during the swing phase of gait with the MPSS in comparison to the pin/lock. The peak pressure was significantly higher with the Seal-In suspension compared with the pin/lock and MPSS systems during level walking, stair and slope negotiation. As compared with the MPSS and pin/lock, the pressure was mainly concentrated at the middle and distal region of the posterior sensor with the Seal-In liner. This might be due to the location of seals and the fact that suction is developed mainly at the distal end where the valve is located. Overall, intra-system pressure distribution at the anterior and posterior surfaces of the residual limb was fairly homogenous with all the suspension systems during the stair and ramp negotiation. Nevertheless, inter-system pressure mapping revealed significant differences among the suspension types, particularly at the anterior and posterior sensor sites.

IV. The MPSS showed enhanced qualities in some gait kinetic and kinematic parameters in comparison to the Seal-In and pin/lock systems.

The suspension type altered some gait kinetics and kinematics; main differences were evident in the GRF (vertical and fore-aft), knee and ankle angles. The walking speed, stance and swing time were not significantly influenced by the type of suspension. Based on the GRF findings, the MPSS may reduce loading over the proximal limb joints compared with the pin/lock system. The GDI scores revealed inferior gait kinematics than the normal individuals; yet, the three suspension

systems exhibited similar clinical outcomes that enabled the amputees to ambulate successfully. This further verifies that the MPSS is a comparable suspension alternative for lower limb amputees.

V. The new magnetic suspension system resulted in higher satisfaction scores than the pin/lock and Seal-In systems on a number of items, which are clinically relevant.

All the suspension systems studied in this research showed approximately high satisfaction rates among the participants. Yet, the qualitative survey demonstrated significant differences in satisfaction and perceived problems with the new design compared with the pin lock and suction systems. The new suspension system produced less noise during walking and donning compared with the pin/lock suspension, it was much easier to don and doff the MPSS compared with the Seal-In suspension and pin/lock system, and resulted in higher overall satisfaction both in comparison to the Seal-in and pin/lock systems. The users felt more secure with the new magnetic system compared with the pin/lock suspension. The cosmesis of the new system was almost similar to the pin/lock system. On the contrary, the subjects were more satisfied with the suction system compared with the new magnetic system in terms of cosmesis, which can be attributed to the additional components used for the magnetic suspension. The participants of this study were mainly dissatisfied with donning and doffing of the Seal-In system; donning and doffing was significantly easier with the magnetic system. The participants stated preference for the MPSS over the Seal-In and pin/lock for long-term use. The participants had significantly less pain with the new magnetic system compared with the pin lock suspension.

In short, the Seal-In system resulted in less pistoning compared with the pin/lock and MPSS systems. There is a possible relation between higher peak pressure and low pistoning with the Seal-In interface system. This study indicated higher-pressure magnitudes with the Seal-In system, which might clarify lower amounts of pistoning observed previously. It can be inferred that while suction systems, such as the Seal-In, may increase the prosthetic fit, the enhanced fit and the resultant increased pressure might bring about residual limb atrophy, skin problems and interruption in blood flow to the limb. It is possible to conclude that pistoning alone might not be a good indicator of clinically superior suspension system. Satisfaction, particularly with the donning and doffing, should also be taken into account when choosing a prosthetic suspension system for a lower limb amputee.

To conclude, as the needs and abilities of amputees vary widely, development of new suspension systems can offer broader choices to clinicians to select the system that best fulfils their patients' needs. Our study introduced a new prosthetic suspension system. The merits of our system were verified through biomechanical and clinical evaluations. Several economical components are available. However, different professionals do not have a consensus in terms of the main criteria for selection of proper suspension system that corresponds to the amputees' needs and abilities. Prosthetic components are typically prescribed based on pragmatic knowledge. Consequently, a reliable and objective criterion for prosthetic prescriptions should be created. Knowledge and expertise, along with methodical assessment, provided in this study can contribute to the selection of a suitable type of prosthesis for an amputee.

8.2. Practical application

The outcome of this study is a new prosthetic suspension system for individuals with lower limb amputation. The results of our study suggest that the system has the potential to successfully suspend lower limb prosthesis. Therefore, our system can be alternatively used by a majority of lower limb prosthesis users. Our main finding is empirically and theoretically reliable, supported by the literature, and experimental and qualitative analyses. Further contributions of the research are presented briefly in the appendices.

One of the added contributions of this study is a critical review of various prosthetic suspension systems based on a comprehensive literature study. For the first time, our study provides a review of literature on the strengths and weaknesses of various empirical methods of pistoning measurement in lower limb amputees. Identifying the strengths and weaknesses of existing systems can help prosthetists and researchers to choose the best available method and develop new techniques. We hope that our findings contribute to the discovery of new knowledge in terms of practice and theory in prosthetic suspension systems, and the development of a new suspension system through this research. Specifically, the present study is crucial in the following key aspects:

i. The study identifies current suspension systems for lower limb prosthetics and evaluates the weaknesses and merits of each system through a comprehensive literature review.
ii. The study offers a new suspension system based on the criteria required for a successful suspension method in the literature and satisfaction surveys.
iii. The study provides insight on the mechanical and biomechanical characteristics of the suspension system developed in this research (MPSS).

iv. The study provides a practical guide for prosthetists and biomedical engineers by providing a comparative analysis of the MPSS and two other common systems.

In a successful attempt, two world-renowned manufacturers of prosthesis components have shown interest to commercialize the system and negotiations are in process with the legal unit of University of Malaya Centre of Innovation and Commercialization (UMCIC). Market value survey has been conducted by a reputable company, which is presented as CD attached to this thesis.

8.3. Direction for future research

Our study proposed a promising suspension system for lower limb amputees with enhanced satisfaction rates, improved interface pressure distribution, and gait biomechanics during walking. However, future research can add to the merits of the system by addressing other concerns. Sweat control is currently a major concern in relation to the available suspension liners. The airtight fit of liners accumulates sweat that can cause allergic reactions and bacterial infections. The donning and doffing procedure for soft liners is problematic for some users, particularly those with upper limb weakness. Also, the use eco-friendly material to produce prosthesis components, including the suspension can be beneficial.

In addition, the alarm system of the MPSS can be enhanced as a wireless connection to mobile gadgets that can show data, such as battery level and degree of safety by evaluation of the coupling force and buzzer testing. Furthermore, given the low power consumption of the new device, it can be equipped with magnetic energy harvesting device to produce the required energy. As such, the battery can be simply eliminated

from the system that will lead to a dramatic system improvement as the user will no longer need to replace the battery. Variation in the geometry of the residual limb could also affect the pressure measurement sites. Therefore, a bigger sample size might be needed to demonstrate relationship between the residual limb geometry and pressure profile.

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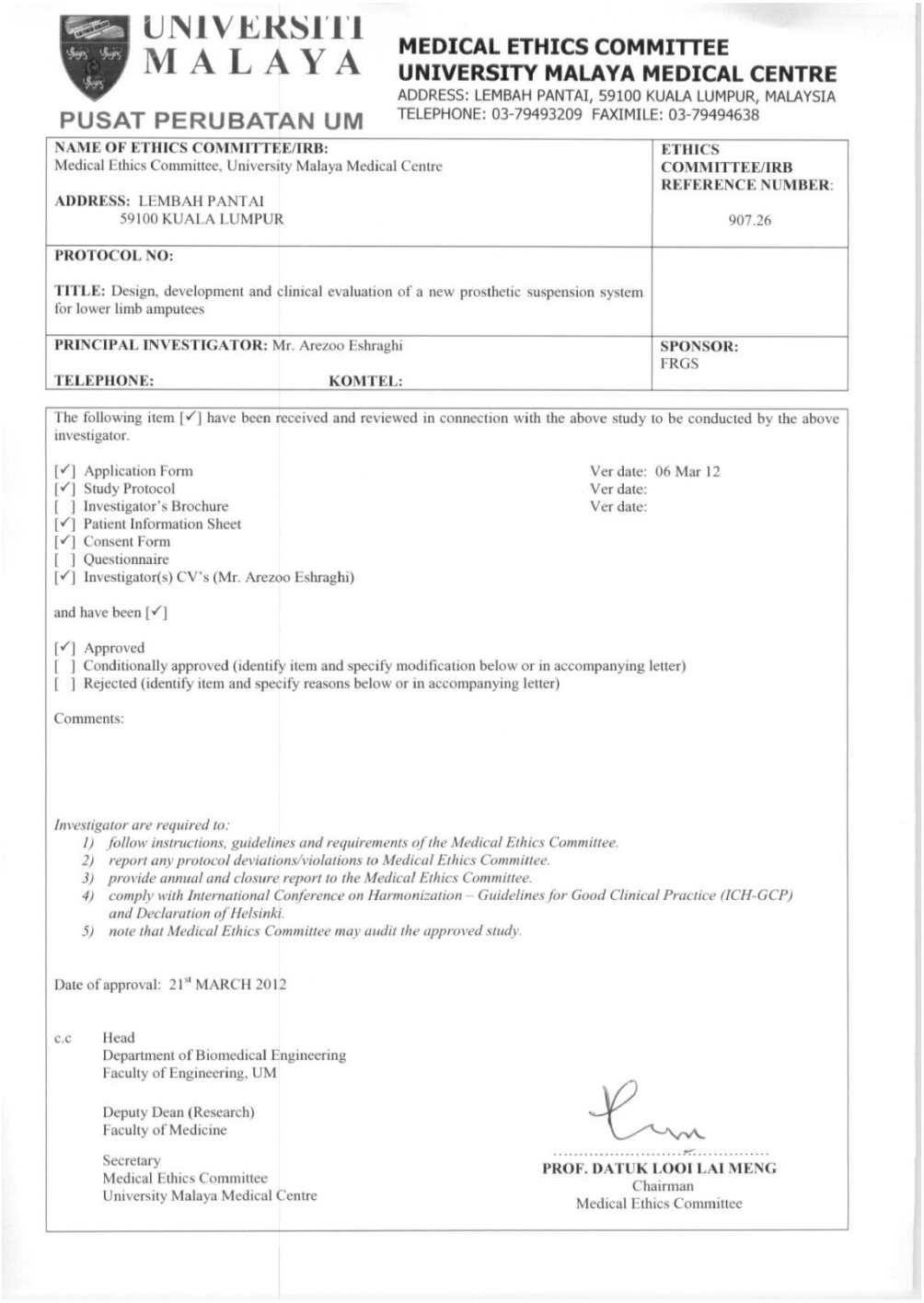
APPENDICES

Appendix A: Ethics approval



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

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

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

[✓] Application Form — Ver date: 06 Mar 12
[✓] Study Protocol — Ver date:
[ ] Investigator's Brochure — Ver date:
[✓] Patient Information Sheet
[✓] Consent Form
[ ] Questionnaire
[✓] Investigator(s) CV's (Mr. Arezoo Eshraghi)

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: 21st 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 B: Questionnaire

A questionnaire survey on the effects of suspension methods on patient satisfaction and perceived problems among lower limb amputees

File number: ……..

Date: ……..

Instructions

Dear Respondent,

As you read each question, remember there is no right or wrong answer. Just state your OWN OPINION on the topic.

If you use different prostheses for different activities, please answer about the ONE that you use more often and answer all the questions as though you are using that prosthesis.

For parts B & C, please make a mark THROUGH the line anywhere along the line from one end to the other to show us your opinion.

As in this example, make a mark across the line rather than using an X or an O.

Please answer all the questions.

Thank you very much!

A: Patient Information

Sex: ☐ Male ☐ Female Marital status:

Age: …… Weight (Kg): ……

Height (cm): ……...

Education: ☐ elementary ☐ high school ☐ Diploma ☐ Graduate

Years since first prosthesis: …….

Cause of amputation: ☐ Trauma ☐ Vascular disease

Level of amputation: ☐ Transtibial ☐ Transfemoral

Amputation side: ☐ Right ☐ Left

Suspension system:

☐ Pin/lock

☐ Seal-In

☐ Magnetic lock (MPSS)

Level of Activity (Prosthetic K Level):

☐ A1L ☐ A2L ☐ A3L ☐ A4L

How many hours do you use prosthesis every day? ……

How many times (per year) do you go to the clinic for prosthesis maintenance? ……..

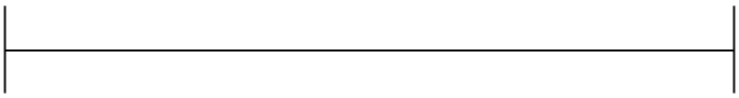
Durability of the liner: ……. months

B. Use and satisfaction.

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

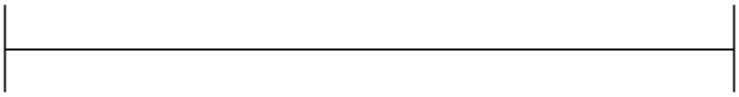
How satisfied are you with the following?

A: Fit of prosthesis (comfort to wear):



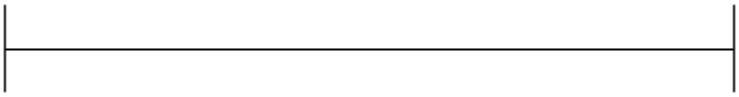
Unsatisfied Completely satisfied

B: Ability to don and doff prosthesis:



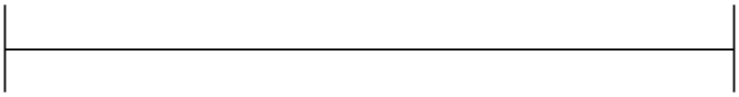
Unsatisfied Completely satisfied

C: Ability to sit with prosthesis:



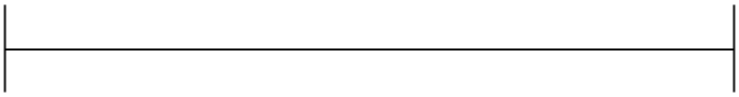
Unsatisfied Completely satisfied

D: Ability to walk with prosthesis:



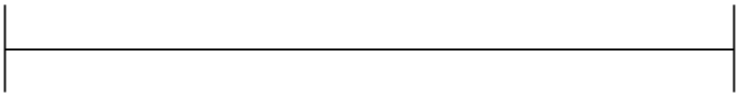
Unsatisfied Completely satisfied

E: Ability to walk on uneven terrain:



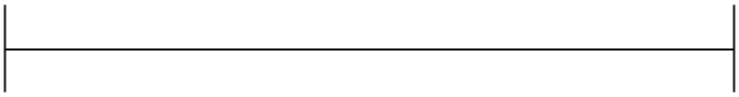
Unsatisfied Completely satisfied

F: Ability to walk up and down stairs:



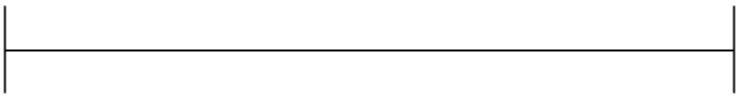
Unsatisfied Completely satisfied

G: Suspension:



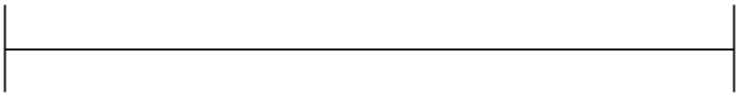
Unsatisfied Completely satisfied

H: Appearance of prosthesis:



Unsatisfied Completely satisfied

I: Overall satisfaction with the prosthesis:



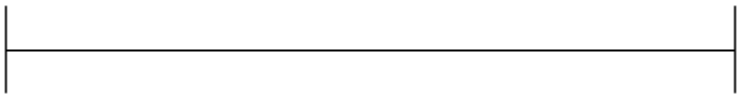
Unsatisfied Completely satisfied

C. Prosthesis related problems/complaints

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

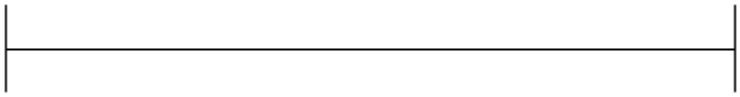
How bothered were you with any of the following problems during the last 4 weeks?

A: Sweating:



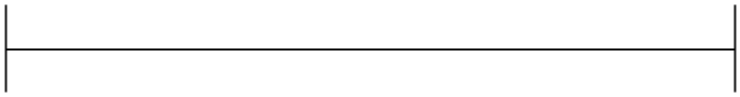
Extremely bothered Not at all

B: Wounds/ingrown hairs/blisters:



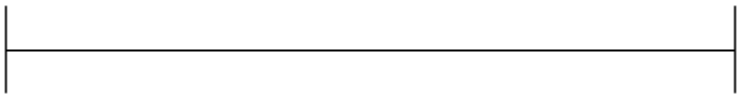
Extremely bothered Not at all

C: Skin irritations:



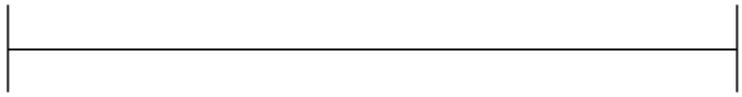
Extremely bothered Not at all

D: Pistoning within the socket:



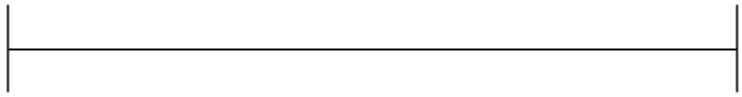
Extremely bothered Not at all

D: Rotation within the socket:



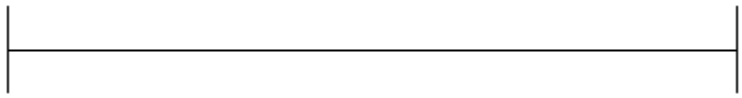
Extremely bothered Not at all

E: Swelling stump:



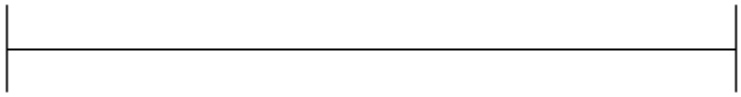
Extremely bothered Not at all

F: Unpleasant smells of prosthesis or stump:



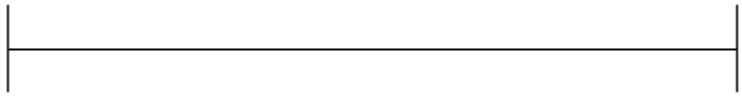
Extremely bothered Not at all

G: Unwanted sounds:



Extremely bothered Not at all

I: Pain in stump:



Extremely bothered Not at all

Please share with us anything else about you or your prosthesis that you think would be helpful for us to know (continue on the back of this page if you need more space).

Appendix C: General contributions of the research

Appendix C1- Malaysia Patent

TRADEMARK2U
INTELLECTUAL PROPERTY

Our Ref : 2012/PT/TMI/PTA4.62/APP/0378/HNM
Your ref : UM.TNC2/UMCIC/603/399
Date : 30th MARCH 2012

By Email, Fax: 03 - 7967 6291
(without enclosure) & post

UNIVERSITY OF MALAYA
PUSA INOVASI DAN PENGKOMERSILAN (UMCIC),
ARAS 5 KOMPLEKS IPPP DAN MAKMAL KEMUDAHAN
BERPUSAT, UNIVERSITI MALAYSIA,
50603, KUALA LUMPUR, MALAYSIA.
[Attn: DR. YUSNIZA KAMARULZAMAN/
PROF. DR. MISNI MISRAN]

Dear Sir/Madam,

PATENT APPLICATION: "A MAGNETIC COUPLING DEVICE OF A LIMB PROSTHESIS"
YOUR OLD TITLE: "MAGNETIC SUSPENSION SYSTEM FOR LOWER AND UPPER LIMB PROSTHESIS"

We refer to the matter above.

We would like to inform you that we have submitted your patent application to the Intellectual Property Corporation of Malaysia on **25th APRIL 2012** with application number **PI 2012700220**. The client's copy of the patent application in Malaysia is enclosed herewith for your records.

Please be advised that we are given a time frame of **12 months** according to the Paris Convention from the application date as mentioned above in order to claim the **Priority Date** to file in the similar patent overseas or via the **Patent Cooperation Treaty (PCT)**.

If you are interested in filing your patent overseas or **Patent Cooperation Treaty,** please do not hesitate to contact us to obtain the relevant information and quotation. Enclosed herewith the list of "States party to the PCT and Paris Convention and Members of the World Trade Organization".

Kindly be informed that the patent application is subject to further examination. At this stage, you are allowed to display "Patent Pending" over your invention.

Please acknowledge receipt by signing and returning the duplicate copy of this letter via e-mail or fax for our record. We shall attend to the necessary and keep you duly informed. Alternatively, you may log in to our CRM system to check on the status of your application(s). Kindly visit to www.trademark2u.my and key in the following particulars:-
- Log-in ID : **unimalaya**
- Password : tpipr123 (you may customize it to your personal password at any time)

We shall attend to the necessary and keep you duly informed. Should you require further information, please do not hesitate to contact us. Kindly confirm upon receipt of this document by fax or email for our own record.

Thank you.

Yours sincerely,
TRADEMARK2U SDN BHD

ROHANIM IBRAHIM
[PATENT DEPARTMENT]

I/We hereby acknowledge receipt of the above stated document(s)

.....
(Signature & Company stamp)

Name :
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,
Bandar Sri Damansara,52200 Kuala Lumpur, Malaysia.
Tel: (603) 6274 5352 Fax: (603) 6274 4795, 6273 6388
Email:sales@trademark2u.com Website: www.trademark2u.com

THE MALAYSIA BOOK of RECORDS

ISO 9001 Registered

Certificate No. : 19668

Appendix C2- US Patent

US 20130289743A1

(19) **United States**

(12) **Patent Application Publication**

Abu Osman et al.

(10) **Pub. No.: US 2013/0289743 A1**

(43) **Pub. Date: Oct. 31, 2013**

(54) **MAGNETIC COUPLING DEVICE OF A LIMB PROSTHESIS**

(71) Applicant: **UNIVERSITI MALAYA**, Kuala Lumpur (MY)

(72) Inventors: **Madya Noor Azuan Abu Osman**, Kuala Lumpur (MY); **Arezoo Eshrughi**, Kuala Lumpur (MY)

(73) Assignee: **UNIVERSITI MALAYA**, Kuala Lumpur (MY)

(21) Appl. No.: **13/865,677**

(22) Filed: **Apr. 18, 2013**

(30) **Foreign Application Priority Data**

Apr. 25, 2012 (MY) ..... PI 2012700220

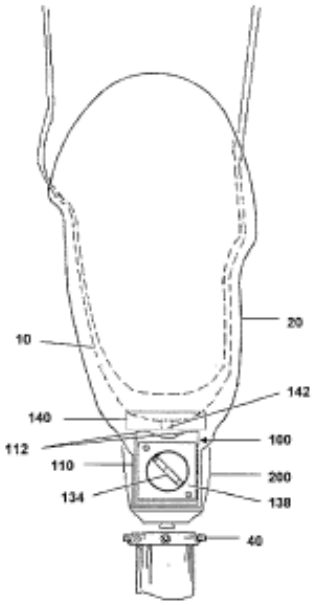
Publication Classification

(51) **Int. Cl.**
A61F 2/78 (2006.01)

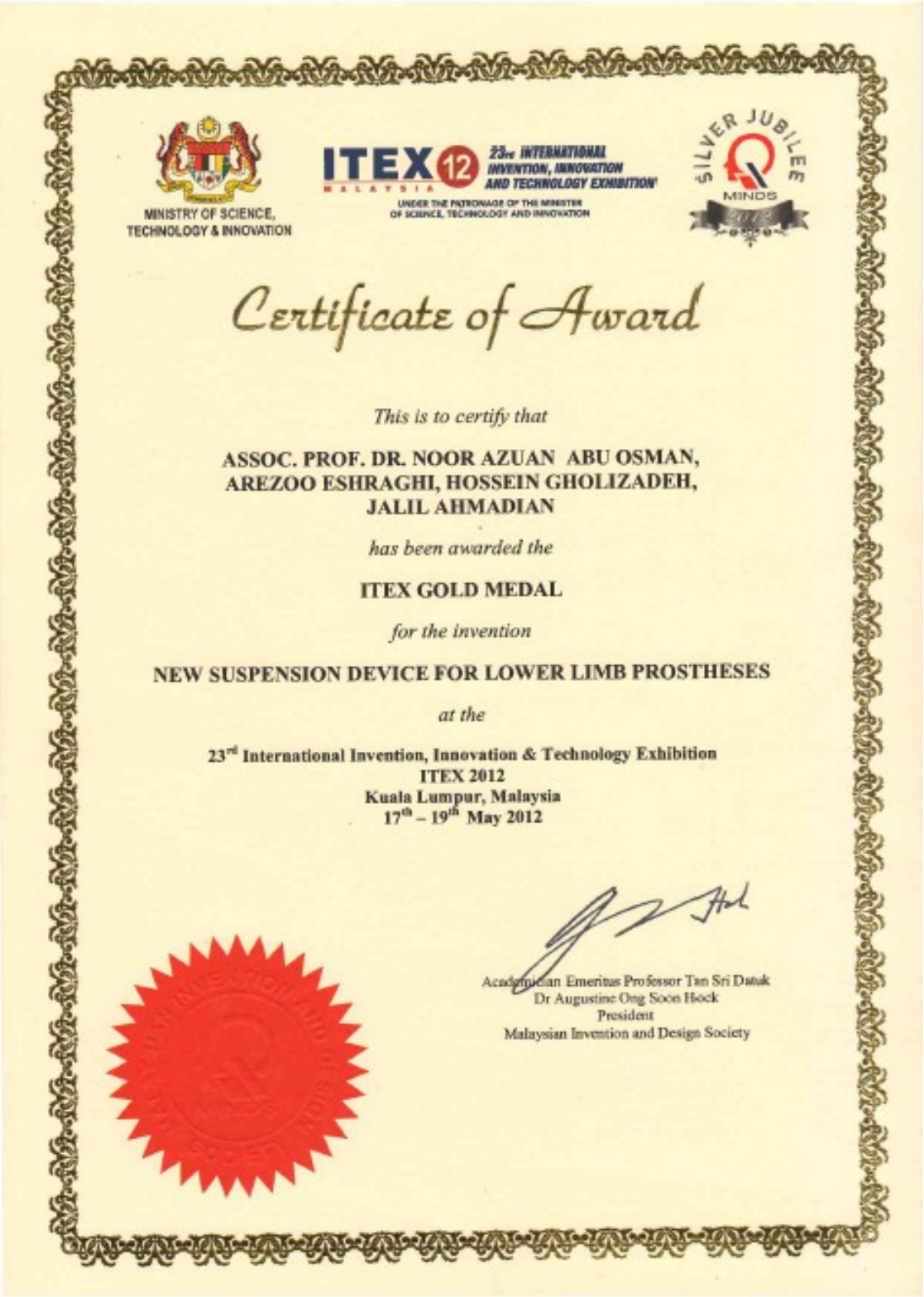
(52) **U.S. Cl.**
CPC *A61F 2/7812* (2013.01)
USPC **623/36**

(57) **ABSTRACT**

The present invention relates to a coupling device (**100**) for connecting a residual limb liner (**10**) to a residual limb socket (**20**) of a limb prosthesis, characterised by: a magnet assembly (**120**) compeising a permanent magnet (**122**) sandwiched by a pair of iron bars (**124**) for creating a magnetic field; a housing (**110**) comprising a protrusion (**112**) for intensifying magnetic field and a cavity (**114**) for receiving the magnet assembly (**120**), wherein said housing (**110**) is embedded at a distal end of the residual limb socket (**20**); a controlling means (**130**) coupled to the housing (**110**) and the magnet assembly (**120**) for controlling the magnetic field by rotating the magnet assembly (**120**); and a mounting plate (**140**) coupled to the residual limb liner (**10**); wherein the mounting plate (**140**) is attracted to the protrusion (**112**) of the housing (**110**) when the permanent magnet (**122**) is vertically aligned, thereby attaching the residual limb liner (**10**) to the residual limb socket (**20**); and wherein the mounting plate (**140**) is repelled from the protrusion (**112**) of the housing (**110**) when the permanent magnet (**122**) is horizontally aligned, thereby detaching the residual limb liner (**10**) from the residual limb socket (**20**).



Appendix C3- ITEX Gold Medal



MINISTRY OF SCIENCE, TECHNOLOGY & INNOVATION

ITEX 12 MALAYSIA

23rd INTERNATIONAL INVENTION, INNOVATION AND TECHNOLOGY EXHIBITION

UNDER THE PATRONAGE OF THE MINISTER OF SCIENCE, TECHNOLOGY AND INNOVATION

SILVER JUBILEE MINDS

Certificate of Award

This is to certify that

ASSOC. PROF. DR. NOOR AZUAN ABU OSMAN, AREZOO ESHRAGHI, HOSSEIN GHOLIZADEH, JALIL AHMADIAN

has been awarded the

ITEX GOLD MEDAL

for the invention

NEW SUSPENSION DEVICE FOR LOWER LIMB PROSTHESES

at the

23rd International Invention, Innovation & Technology Exhibition
ITEX 2012
Kuala Lumpur, Malaysia
17th – 19th May 2012

Academician Emeritus Professor Tan Sri Datuk
Dr Augustine Ong Soon Hock
President
Malaysian Invention and Design Society

Appendix C4- Malaysia Technology Expo (MTE) 2012, Silver Medal

Appendix C5- Best Free Paper in “Advancing Technology”

14th ISPO World Congress 2013

ISPO

INTERNATIONAL SOCIETY FOR PROSTHETICS AND ORTHOTICS

Presents

The Best Free Paper Prize
in the Category “Advancing Technology”

to

Arezoo Eshraghi

for the Paper

“Biomechanical Analysis Of A New Prosthetic Suspension System For Lower Limb Amputees”

Jan H. B. Geertzen
President

14th ISPO World Congress
4-7 February 2013 – Hyderabad, India

Appendix C6- Second Place in 4th Amirkabir University of Technology Robotic Competitions, League of Medical Robots

Appendix C7- WHO 2013 Compendium of Innovative Health Technologies

http://www.who.int/medical_devices/innovation/compendium_assit_dev2013_4.pdf

Magnetic prosthetic suspension system

Country of origin | Malaysia

Health problem addressed

A prosthesis is used as part of amputee rehabilitation and the suspension system is an important feature that affects prosthesis users' quality of life. Individuals with lower limb amputation need to wear prosthesis to perform activities of daily life, especially walking.

Product description

The magnetic suspension system is a magnetic coupling device, which holds the residual part of the limb (stump) inside the prosthesis (artificial limb). It consists of three parts: a metal plate inside the socket, which is attached to a prosthetic soft liner; a magnetic assembly (the source of magnetic power), which remains outside of the socket - positioned between the prosthetic socket and the pylon (internal frame of the prosthetic leg); and a switch, which connects or disconnects the coupling device. The soft liner acts as a sort of "second skin" between the movable soft tissue of the stump and the hard shell of the socket. The soft liner provides comfort and holds the stump inside the prosthesis with the help of the magnetic coupling device.

Product functionality

After donning the prosthetic soft liner, the user puts the stump inside the prosthesis. The mechanical switch is positioned in the "On" mode. The magnetic field will hold and retain the stump within the prosthesis. While removing, the user needs to position the switch to the "Off" mode, which will then allow the user to withdraw the stump from the prosthesis. The system comes with an optional acoustic safety alarm, which can warn the user about imminent possibilities of suspension failure.

Developer's claims of products benefits

The system is easy to fabricate, cheaper than other suspension systems, more durable and easy to use. It requires less maintenance, reduces pain in the residual limb, decreases interface pressure and reduces pistoning.

Development stage

The system patent is pending both in Malaysia (PI2012700220) and the US (13/865,677). The technical aspects have been approved by the University of Malaya Medical Ethics Committee and the product has been clinically tested by lower limb amputees. The findings of a technical evaluation have been published in the Institute for Scientific Information (ISI) journals. A paper on the biomechanical evaluation of the system was awarded with the best research in the field of "Advancing technologies" in the 14th International Society for Prosthetics and Orthotics (ISPO) world congress.

Future work and challenges

Future work includes implementation of large scale manufacturing and worldwide distribution.

Use and maintenance

User: Self-use

Training: Not required

Maintenance: On-site once a year

Environment of use

Settings: Rural, urban, ambulatory, at home

Requirements: A trained prosthetist to fit the product into a prosthesis

Product specifications

Dimensions (mm): 30 x 30 x 30

Weight (kg): 0.25

Consumables: Batteries, if used with safety alarm

Life time (years): 5

Retail price (USD): 500

List price (USD): 250

Other features: Reusable

Year of commercialization: Ready to be commercialized

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Please see disclaimer on following page

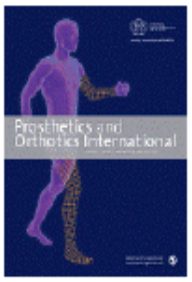
Appendix C8- Must Read Article by the Editor of Prosthetics & Orthotics International (Nov 2012)

Prosthetics and Orthotics International (POI)

What the Editor is Reading

POI Editor Sarah Curran has selected the following "must read" articles from *POI*'s latest issue. Check these out:

- ***Pistoning assessment in lower limb prosthetic sockets***. **A Eshragi *et al***
- ***Development of a Best Practice Statement on the Use of Ankle-Foot Orthoses Following Stroke in Scotland***. **R Bowers & K Ross**
- ***Skin problems of the stump and hand function in lower limb amputees: A historic cohort study***. **E C T Baars *et al***



POI eTOC alerts

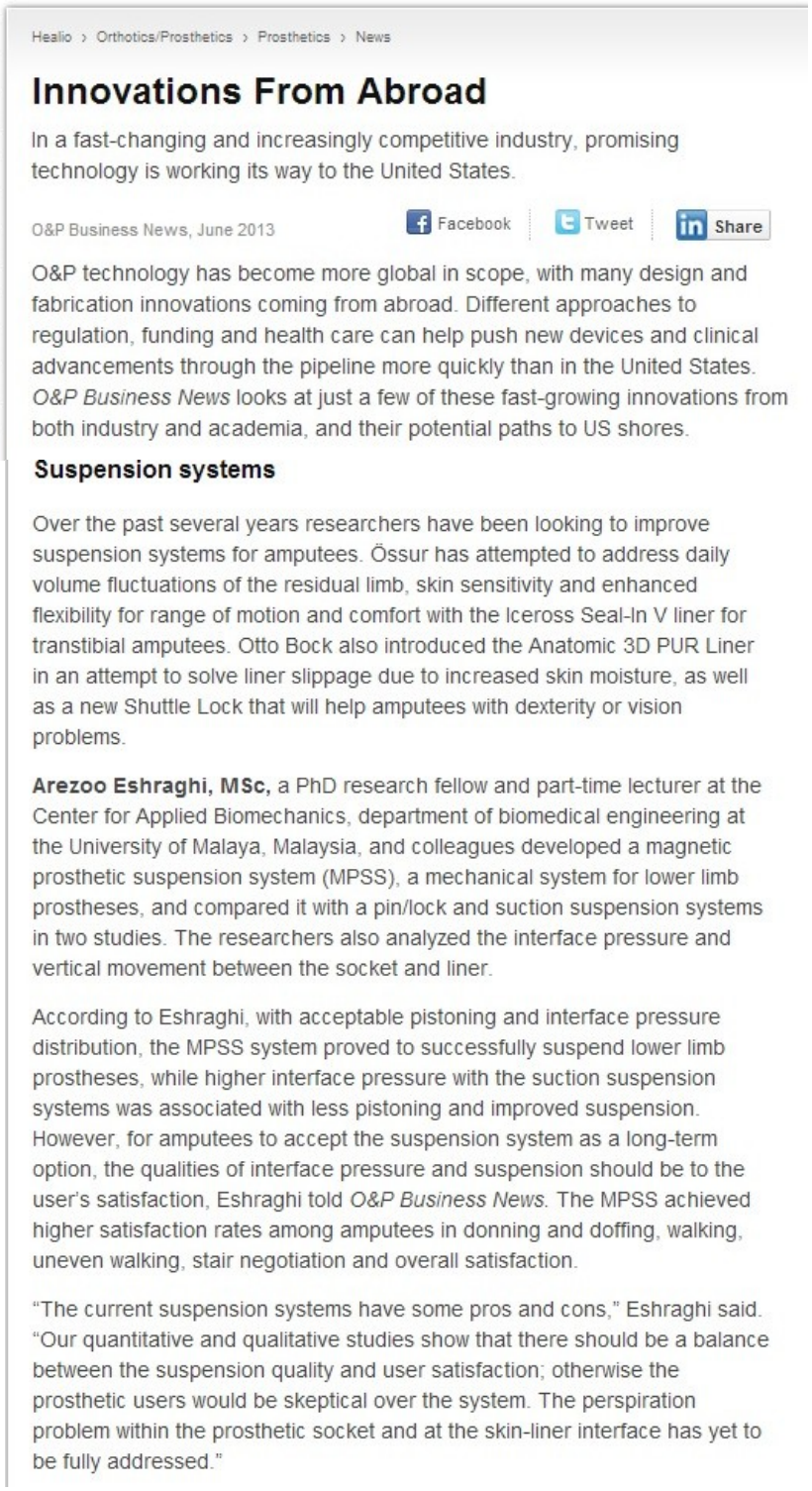
Be the first to know about newly published *POI* issues and articles! Sign up for email alerts here for *POI* table of contents and 'Online First' articles.

Publish your Latest Research in ISPO's Official Journal

Prosthetics and Orthotics International publishes review articles, experimental and clinical research papers, case studies, technical notes, reports on prosthetics, orthotics and rehabilitation engineering practice, and book reviews. Submit your latest article here.

Appendix C9- O&P Business News Cover Story, June 2013

http://www.healio.com/orthotics-prosthetics/prosthetics/news/print/o-and-p-business-news/%7Bee892388-aabb-4850-88a3-c72c57bc88a8%7D/innovations-from-abroad



Healio › Orthotics/Prosthetics › Prosthetics › News

Innovations From Abroad

In a fast-changing and increasingly competitive industry, promising technology is working its way to the United States.

O&P Business News, June 2013

Facebook Tweet Share

O&P technology has become more global in scope, with many design and fabrication innovations coming from abroad. Different approaches to regulation, funding and health care can help push new devices and clinical advancements through the pipeline more quickly than in the United States. *O&P Business News* looks at just a few of these fast-growing innovations from both industry and academia, and their potential paths to US shores.

Suspension systems

Over the past several years researchers have been looking to improve suspension systems for amputees. Össur has attempted to address daily volume fluctuations of the residual limb, skin sensitivity and enhanced flexibility for range of motion and comfort with the Iceross Seal-In V liner for transtibial amputees. Otto Bock also introduced the Anatomic 3D PUR Liner in an attempt to solve liner slippage due to increased skin moisture, as well as a new Shuttle Lock that will help amputees with dexterity or vision problems.

Arezoo Eshraghi, MSc, a PhD research fellow and part-time lecturer at the Center for Applied Biomechanics, department of biomedical engineering at the University of Malaya, Malaysia, and colleagues developed a magnetic prosthetic suspension system (MPSS), a mechanical system for lower limb prostheses, and compared it with a pin/lock and suction suspension systems in two studies. The researchers also analyzed the interface pressure and vertical movement between the socket and liner.

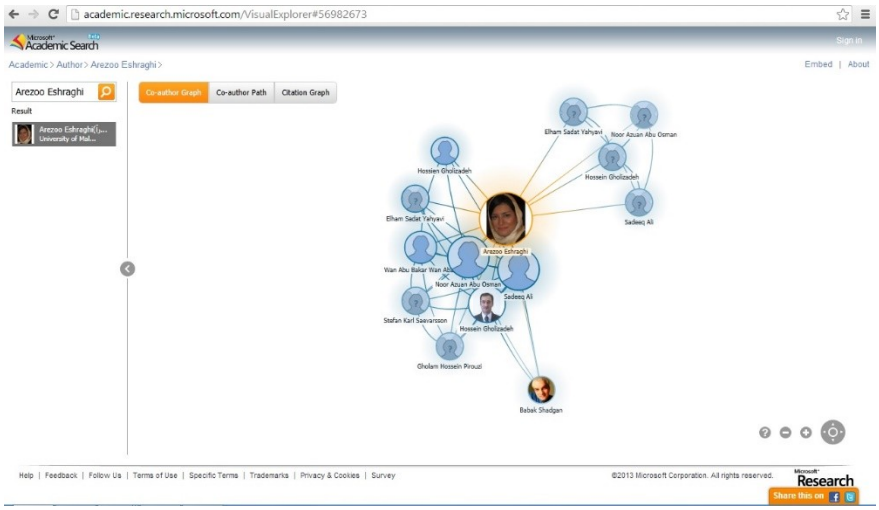
According to Eshraghi, with acceptable pistoning and interface pressure distribution, the MPSS system proved to successfully suspend lower limb prostheses, while higher interface pressure with the suction suspension systems was associated with less pistoning and improved suspension. However, for amputees to accept the suspension system as a long-term option, the qualities of interface pressure and suspension should be to the user's satisfaction, Eshraghi told *O&P Business News*. The MPSS achieved higher satisfaction rates among amputees in donning and doffing, walking, uneven walking, stair negotiation and overall satisfaction.

"The current suspension systems have some pros and cons," Eshraghi said. "Our quantitative and qualitative studies show that there should be a balance between the suspension quality and user satisfaction; otherwise the prosthetic users would be skeptical over the system. The perspiration problem within the prosthetic socket and at the skin-liner interface has yet to be fully addressed."

Appendix C10- Visualization of the research

1. Microsoft Academic research

   http://academic.research.microsoft.com/VisualExplorer#56982673



2. ResearcherID http://labs.researcherid.com/mashlets/rid/?rid=A-4405-2011
3. ResearchGate https://www.researchgate.net/profile/Arezoo_Eshraghi2/?ev=hdr_xprf
4. Academia https://malaya.academia.edu/arezooeshraghi
5. CiteULike http://www.citeulike.org/user/drirwan1/author/Eshraghi:A
6. UM Research Repository

   http://eprints.um.edu.my/view/creators/Eshraghi=3AA=2E=3A=3A.html

Appendix D: List of ISI publications

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

Journal Articles

1. **Eshraghi, A.**, Abu Osman, N. A., Gholizadeh, H., Ahmadian, J., Rahmati, B., & Abas, W. A. B. (2013). Development and evaluation of new coupling system for lower limb prostheses with acoustic alarm system. *Scientific Reports*, 3.

2. **Eshraghi, A.**, Abu Osman, N. A., Karimi, M. T., Gholizadeh, H., Ali, S., & Wan Abas, W. A. B. (2012). Quantitative and qualitative comparison of a new prosthetic suspension system with two existing suspension systems for lower limb amputees. *American Journal of Physical Medicine & Rehabilitation*, 91(12), 1028-1038.

3. **Eshraghi, A**., Abu Osman, N. A., Gholizadeh, H., Ali, S., Sævarsson, S. K., & Wan Abas, W. A. B. (2013). An experimental study of the interface pressure profile during level walking of a new suspension system for lower limb amputees. *Clinical Biomechanics*, 28(1), 55-60.

4. **Eshraghi, A.,** Abu Osman, N.A., Gholizadeh, H., Ali, S., Wan Abas, W.A.B. (in press) Interface stress in socket/residual limb with transtibial prosthetic suspension systems during locomotion on slopes and stairs. *American Journal of Physical Medicine and Rehabilitation.*

5. **Eshraghi, A.**, Abu Osman, N.A., Karimi, M.T, Gholizadeh, H., Ali, S., Soodmand, E., Wan Abas, W.A.B. (in press) Gait biomechanics of individuals with transtibial amputation: effect of suspension system. *PLOS ONE*.

6. **Eshraghi, A.**, Abu Osman, N.A., Gholizadeh, H., Karimi, M.T., Ali, S. (2012). Pistoning assessment in lower limb prosthetic sockets. *Prosthetics and Orthotics International*. 36, 15-24.

7. **Eshraghi, A.**, Abu Osman N. A. , Gholizadeh, H., Ali, S., Shadgan, B. (2013). 100 top-cited scientific papers in limb prosthetics. *Biomedical Engineering Online*. 12, 119.

8. **Eshraghi, A.**, Gholizadeh, H., Abu Osman, N.A. (2011). Comments on Assessment of amputee socket-stump-residual bone kinematics during strenuous activities using dynamic roentgen stereogrammetric analysis (Volume 43, Issue 5, 2010), *Journal of Biomechanics*. 44, 2851-2852.

Proceedings

1. **Eshraghi A.**, Abu Osman N. A., Karimi M. T., Gholizadeh. H., Ali. S. (2013). Biomechanical analysis of a new prosthetic suspension system for lower limb amputees. 14th International Society for Prosthetists and Orthotists (ISPO) World Congress, Hyderabad, India

2. **Eshraghi A.**, Abu Osman N. A., Karimi M. T., Gholizadeh. H., Ali. S. (2011). Pistoning measurement in lower limb prostheses–a literature review. In N. A. Abu Osman, W.A.B. Wan Abas, A. K. Abdul Wahab and Hua-Nong Ting (Eds.) 5th Kuala Lumpur International Conference on Biomedical EngineeringIFMBE Volume 35, Part 16, (pp. 758-761). Berlin Heidelberg: Springer. DOI: 10.1007/978-3-642-21729-6_185