THE INFLUENCE OF PROSTHETIC FOOT TYPES AND ALTERED SENSORY CONDITIONS ON THE POSTURAL STABILITY OF BELOW-KNEE AMPUTEES DURING UPRIGHT STANDING

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

FACULTY OF ENGINEERING
UNIVERSITY OF MALAYA
KUALA LUMPUR

2016

UNIVERSITI MALAYA

ORIGINAL LITERARY WORK DECLARATION

Name of Candidate: **Nooranida binti Arifin**

Registration/Matric No: **KHA120003**

Name of Degree: **PhD of Engineering**

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

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

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PREFACE

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ABSTRACT

For individuals with below-knee amputation, the loss of the biological ankle joint and associated musculatures may adversely affect amputees' ability to maintain upright posture successfully, particularly in altered sensory conditions. While postural stability performance among below-knee amputees has been explored, no research to date has systematically evaluated postural stability with different prosthetic foot types and modified sensory input. This research primarily aims to systematically evaluate the control of postural stability during primary sensory modifications among below-knee prosthesis users when wearing different types of prosthetic feet. This research also demonstrates the possibility of objective quantification of postural stability in below-knee amputees obtained from a commercially available computed posturography device. The mechanical properties of solid ankle cushioned heel (SACH) foot, single axis (SA) foot and energy storage and release (ESAR) Talux® foot were tested using a universal tensile machine. The intrarater test-retest reliability of static and dynamic postural stability indexes measurement using the Biodex® Balance System (BBS) was performed on 20 able-bodied participants. 19 participants (ten below-knee amputees and nine controls) took part in several studies including postural stability assessment of upright standing during visual, somatosensory and vestibular sensory modifications while wearing three different prosthetic types. Participants were asked to stand quietly with eyes-closed, on different surfaces (rigid, unstable and compliant) and with head tilting backward to simulate modified visual, proprioception and vestibular sensory input, respectively. The mechanical testing results showed that the ESAR foot had the lowest heel stiffness followed by SACH and SA. Similarly, the forefoot stiffness was the lowest for ESAR foot while SACH and SA had similar forefoot stiffness. The reliability results indicated that postural stability assessment using the BBS provides 'good to excellent' test-retest reliability over a one-week time interval. The findings

from the posturography assessment suggested that postural stability in below-knee amputees during quiet upright standing was not affected by the prosthetic foot factor, but was significantly affected when one of the primary sensory inputs was altered. When visual cues were absent, overall stability was reduced in SACH and ESAR feet, medio-lateral stability was reduced in SACH foot while anterior-posterior stability was reduced in ESAR foot. Standing on a compliant surface was demonstrated to significantly reduce the overall stability in SACH foot compared to that of an ESAR foot. Additionally, this study revealed that the differences between amputees and able-bodied participants can be distinguished when standing on a compliant surface. During vestibular sensory modification, postural instability in medial-lateral direction was significantly greater in all prosthetic feet compared to able-bodied individuals. From the time domain data, the loading time percentage on amputees' intact limb was significantly longer than the amputated limb in all sensory conditions for all three prosthetic feet. The amputees also had a significant strong positive relationship between overall and medio-lateral stability indexes with all prosthetic feet types and altered sensory conditions. The analysis of Activities-specific Balance Confidence (ABC) score demonstrated a significantly higher score in ESAR compared to SACH and SA. In conclusion, the novel results presented in this thesis have important implications for amputee rehabilitation program and encourage an evidence-based practice during amputee assessment. These include identifying postural stability responses towards different sensory modifications and how these changes can be quantified and monitored using a reliable and practical computed posturography device.

ABSTRAK

Bagi individu dengan amputasi bawah-lutut, kehilangan sendi buku lali biologi dan struktur otot yang berkaitan boleh memberi kesan kepada keupayaan amputi untuk mengekalkan postur tegak, terutamanya dalam keadaan deria diubah. Walaupun prestasi kestabilan postur amputi bawah-lutut telah diterokai, tiada penyelidikan setakat ini yang menilai secara sistematik kestabilan postur dengan jenis kaki palsu yang berbeza dan input deria diubahsuai. Kajian ini terutamanya bertujuan untuk menilai secara sistematik kawalan kestabilan postur semasa pengubahsuaian deria utama di kalangan pengguna prostesis bawah-lutut apabila memakai pelbagai jenis kaki palsu. Kajian ini juga menunjukkan kemampuan peranti posturografi komersial dalam penilaian kuantitatif kestabilan postur amputi bawah-lutut. Sifat mekanik kaki *solid ankle cushioned heel* (SACH), *single axis* (SA) dan *energy storage and release (ESAR)* Talux® telah diuji menggunakan mesin ujian universal. Kebolehpercayaan pengukuran-semula penilai dalaman bagi indeks kestabilan postur statik dan dinamik menggunakan Sistem Kestabilan Biodex® (BBS) telah dijalankan ke atas 20 orang peserta normal. 19 peserta (sepuluh amputi bawah-lutut dan sembilan normal) telah mengambil bahagian dalam beberapa kajian termasuk penilaian kestabilan postur berdiri tegak semasa pengubahsuaian deria visual, sentuhan dan vestibular ketika memakai tiga jenis kaki palsu yang berbeza. Para peserta telah diminta untuk berdiri dengan mata tertutup, di atas permukaan yang berbeza (keras, tidak stabil dan lembut) dan dengan kepala didongakkan ke belakang untuk mensimulasikan pengubahsuaian input visual, sentuhan dan vestibular. Keputusan ujian mekanikal menunjukkan kaki ESAR mempunyai kekakuan tumit yang paling rendah diikuti oleh SACH dan SA. Kekakuan hadapan kaki adalah paling rendah untuk kaki ESAR manakala SACH dan SA mempunyai kekakuan kaki hadapan yang sama. Keputusan menunjukkan bahawa kebolehpercayaan pengukuran-semula penilaian dalaman ketika ujian kestabilan postur menggunakan

BBS adalah antara 'baik hingga cemerlang' untuk tempoh selang masa seminggu. Dapatan daripada penilaian posturografi mencadangkan bahawa kestabilan postur amputi bawah-lutut ketika berdiri tegak tidak dipengaruhi oleh faktor kaki palsu, tetapi telah terjejas dengan ketara apabila salah satu input deria utama diubah. Apabila isyarat visual tiada, kestabilan keseluruhan telah berkurangkan bagi kaki SACH dan ESAR, kestabilan sisi kiri-kanan berkurangan bagi kaki SACH manakala kestabilan depan-belakang berkurangan bagi kaki ESAR. Berdiri di atas permukaan yang lembut telah mengurangkan kestabilan keseluruhan kaki SACH berbanding dengan kaki ESAR. Selain itu, kajian ini mendedahkan bahawa perbezaan antara peserta amputi dan normal boleh dibezakan apabila berdiri di atas permukaan yang lembut. Semasa pengubahsuaian deria vestibular, ketidakstabilan postur sisi kiri-kanan adalah jauh lebih besar dalam semua kaki palsu berbanding individu normal. Daripada data domain masa, peratusan masa bebanan pada anggota normal amputi adalah jauh lebih lama daripada anggota badan residu untuk kesemua keadaan deria dan kaki palsu. Amputi juga mempunyai hubungan positif yang sangat signifikan di antara indeks kestabilan postur keseluruhan dan sisi kiri-kanan untuk semua jenis kaki palsu dan pengubahsuaian isyarat deria. Analisis Keyakinan Kestabilan Aktiviti Khusus (ABC) menunjukkan skor yang signifikan lebih tinggi dalam ESAR berbanding SACH dan SA. Kesimpulannya, keputusan novel yang dibentangkan di dalam tesis ini mempunyai implikasi yang penting bagi program pemulihan amputi dan menggalakkan amalan berasaskan bukti semasa penilaian amputi. Ini termasuk mengenal pasti tindak-balas kestabilan postur ketika pengubahsuaian deria berbeza dan bagaimana perubahan ini boleh diukur dan dipantau menggunakan peranti posturografi yang dipercayai dan praktikal.

ACKNOWLEDGMENT

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

I would like to express my gratitude to the following people and organization for their help and valuable contribution to the completion of this thesis.

First and foremost, I would like to thank Prof. Ir. Dr. Noor Azuan Abu Osman and Prof. Ir. Dr. Wan Abu Bakar Wan Abas for their invaluable supervisory support and guidance during the duration of this study. I am forever grateful to Ministry of Higher Education Malaysia and University of Malaya for their financial sponsorship. I would especially like to thank all the participants for their enthusiasm and commitment. I would also like to thank Dr. Arezoo Eshragi, Dr. Sadeeq Ali, Dr. Hossein Gholizadeh and Mr. Firdaus Omar for their technical support throughout data collection. I would like to thank my fellow members of Center of Applied Biomechanics (CAB) for all the hours of friendly conversation and insightful advice.

I would like to thank my parents: Arifin Mohd Isa and Rosyani Nordin for their prayers, love and encouragement throughout my entire life. This thesis is dedicated to them. I'd also like to thank my sisters and brothers, Azua, Ashikin, Fahmi and Fakhri, and their wonderful families for their continuous support. To Wafiq, Alia, Rizqi, Akif and Riyad, thank you for constantly being the reason for me to smile and laugh. To my parents in law, Hasbollah Hj Mohamad and Yah Awg Nik, thank you for your support and prayers.

Lastly, and most importantly, I'd like to thank my wonderful husband, Dr. Hasif Rafidee Hasbollah, for his constant love, for motivating me in loving and caring ways and for the happiness he has brought into my life. His determination and endurance during his PhD years has been inspirational.

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LIST OF ABBREVIATIONS

ABC	Activities-specific Balance Confidence
ADL	Activities of daily living
AOPA	American Orthotic & Prosthetic Association
AP	Anterior-posterior
APSI	Anterior/ posterior stability index
BBS	Berg Balance Scale
BI	Balance Index
BoS	Base of Support
BSS	Biodex® Stability System
CAD-CAM	Computer Aided Design –Computer Aided Manufacturing
CNS	Central Nervous System
CoM	Centre of Mass
CoP	Centre of Pressure
CTSIB	Clinical Test of Sensory Interaction and Balance
CI	Confidence Interval
ES	Equilibrium Score
ESAR	Energy Storage and Return
FDA	Food and Drug Administration
HCFA	Health Care Financing Administration
ICC	Interclass correlation of coefficient
IDF	International Diabetes Federation
ISO	International Standards Organization
ISPO	International Society of Prosthetics and Orthotics
MEC	Medical Ethics Committee
MCS	Mental Component Summary

ML	Medial-lateral
MFCL	Medicare Functional Classification Level
MLSI	Medial/ lateral Stability Index
NASD	National Amputee Statistical Database
NHMS	National Health and Morbidity Survey
OSI	Overall Stability Index
PCS	Physical Component Summary
PDC	Patient Data Collection Software Utility
PEQ	Prosthesis Evaluation Questionnaire
PPA	Prosthetic Profile of the Amputee
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PTB	Patellar Tendon Bearing
SA	Single Axis
SACH	Solid Ankle and Cushioned Heel
SEBT	Star Excursion Balance Test
SEM	Standard Error Measurement
SOT	Sensory Organization Testing
TSB	Total Surface Bearing
PTB-SC	PTB supracondylar
PTB-SCSP	PTB supracondylar-suprapatella
UK	United Kingdom
UMMC	University Malaya Medical Centre
USA	United States of America
VAPC	Veteran Administration Prosthetic Centre
WHO	World Health Organisation

LIST OF EQUATIONS

$$\text{OSI} = \frac{\sqrt{\sum(0\text{-Y})^2 + \sum(0\text{-X})^2}}{\text{number of samples}} \tag{3.1}$$

$$\text{APSI} = \frac{\sqrt{\sum(0\text{-Y})^2}}{\text{number of samples}} \tag{3.2}$$

$$\text{MLSI} = \frac{\sqrt{\sum(0\text{-X})^2}}{\text{number of samples}} \tag{3.3}$$

$$\text{Transformed scale} = \left[\frac{\text{Actual raw score} - \text{Lowest possible raw score}}{\text{Possible raw score range}}\right] * 100 \tag{3.4}$$

CHAPTER 1

INTRODUCTION

1.1 Background

Generally, limb loss resulted from acquired amputation is often due to disease, injury or surgery whereas congenital limb loss is present at birth (Nielsen, 2007; Smith, 2004). According to Tseng and associates (2007), lower limb loss can be further classified as ‘major’ such as amputation above- or below- the knee, or the foot while ‘minor’ involves amputation of the toes. In the United States of America (USA) alone, 664,000 persons were estimated living with major limb loss and more than 900,000 with minor limb loss in 2005 (Ziegler-Graham, MacKenzie, Ephraim, Travison & Brookmeyer, 2008). Amputation has been known not only to affect a person physically and psychologically, but also renders a major challenge for the nation (Gitter & Bosker, 2005; Nielsen, 2007). Hence, amputations cause significant implication in increasing the costs of healthcare systems globally, with annual costs of lower extremity amputations in the USA reaching USD4.3 billion (Dillingham, Pezzin & Shore, 2005).

Lower limb amputations are often resulted from vascular-related diseases (such as neuropathy and peripheral vascular disease), trauma, cancer and congenital anomalies (Nielsen, 2007). Specifically, vascular-related diseases (with or without diabetes) account for 80-90% of all amputations in Western countries (Dilingham, Pezzin & MacKenzie, 2002). Particularly, a person with diabetes has 10–30 times greater risk of undergoing lower limb amputation compared with the general population (Vamos *et al*., 2010). Moreover, it is estimated that around 20–50% of diabetes amputees will require second leg amputation within one to three years, and more than 50% of the amputees will need another amputation within five years (Van Gils *et al*., 1999). On the other hand, in some countries with history of recent war, such as Cambodia and Zimbabwe, amputation due to trauma can account for more than 80% of all amputations (World Health Organisation [WHO], 2004).

Generally, below-knee (transtibial) and above-knee (transfemoral) amputations are the most common amputation levels followed by the ankle, hip and knee disarticulations (47%, 31%, 3%, 2%, 1%, respectively) (WHO, 2004). In fact, lower limb amputations are performed eleventh times more frequent than upper limb amputations, making lower-limb amputees constitute 80–85% of the total amputees (Shurr & Michael, 2000; Yazicioglu, Taskaynatan, Guzelkucuk & Tugcu, 2007). Due to improved awareness and success in retaining the knee joint, the ratio of above-knee amputations to below-knee amputations showed significant changes in ratio from 70:30 in 1965 to 30:70 in 1975. The level of amputation and its percentage is illustrated in Figure 1.1.

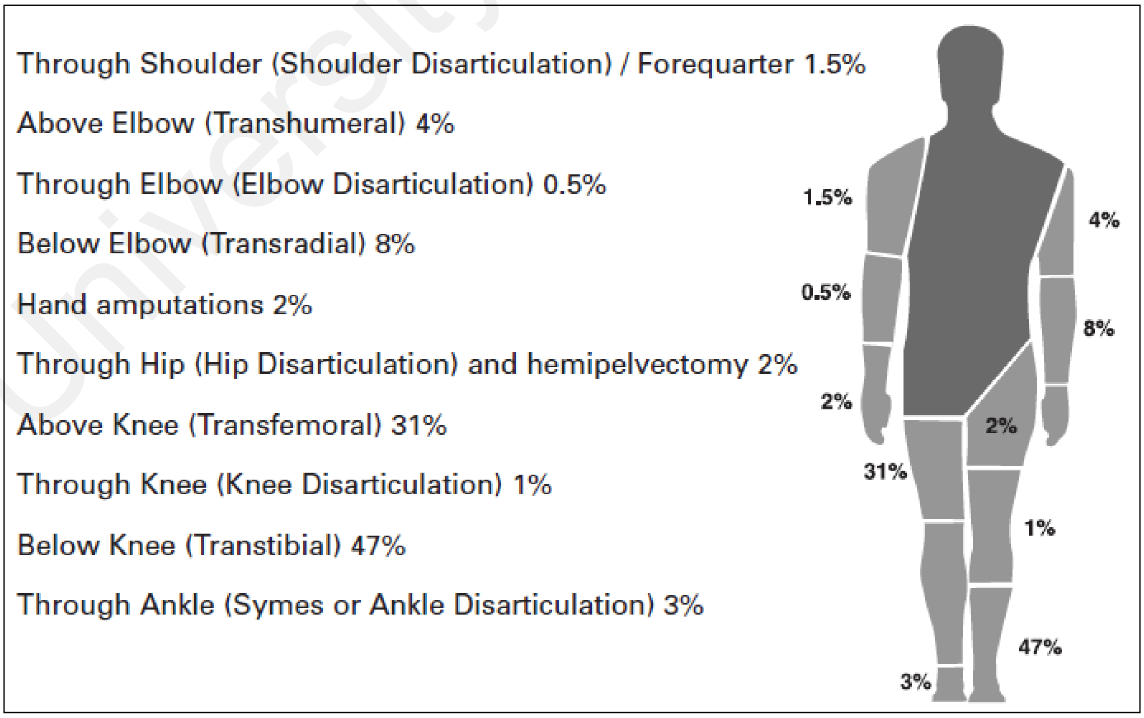


Figure 1.1: Percentage of amputation at all levels (Reproduced from WHO, 2004).

1.2 Worldwide prevalence of lower- limb amputation

The incidence of lower limb amputation is high across the globe and continues to be a major threat to morbidity and mortality (Moxey *et al*., 2011). Nevertheless, the current information on worldwide prevalence of amputation is difficult to obtain, possibly because of minimal attention and resources as well as the lack of standardised approach in gathering data (Aleccia, 2010; Nielsen, 2007). In the United Kingdom (UK), there are an estimated 5,000 new referrals to prosthetic service centres annually (National Amputee Statistical Database [NASD], 2005). Specifically, vascular-related diseases has accounted for 77% of lower limb amputation while diabetes currently accounts for 42% of the total referral in the UK (NASD, 2005). In comparison with the USA, an estimation of 1.6 million persons were living with limb loss in 2005 of which 54% had amputation secondary to dysvascular disease with over two thirds being diabetic (Ziegler-Graham *et al*., 2008). The most striking fact is that amputations due to dysvascular conditions are estimated at 2.3 million in 2050 (Ziegler-Graham *et al*., 2008).

In terms of annual prevalence of diabetes-related amputation per 100 000 person, the Netherlands recorded 18-20 incidences (Rommers, Vos, Groothoff, Schuiling & Eisma, 1997), 176 incidences in Ireland (Buckley *et al*., 2002), 251 incidences in England (Holman, Young & Jeffcoate, 2012) and the USA with 500 incidences (National Center for Health Statistics, 2012). In low income countries, for example Tanzania, 40% of lower limb amputation incidence was due to tumours (Loro & Franceschi, 1999). For countries with on-going conflict and landmine issues, 159 incidences were estimated in Afghanistan, 102 incidences in Iraq and 300 incidences in Angola (Aleccia, 2010).

1.3 Amputation prevalence in Malaysia

According to WHO (2005), 0.5% of a population in a developing country represent individuals with disability whom will require prosthesis and/ or orthosis and related rehabilitation services. When populations of all developing countries are combined, an estimated 25 million inhabitants are in need of prosthetic and/ or orthotic device (WHO, 2005). In relation to this prediction, among the 31 million current population in Malaysia (Malaysia Statistics Department, 2015), around 155000 individuals will be in need of prosthetic and/ or orthotic devices. Furthermore, the population is projected to reach 38.5 million people by the year of 2040 (Malaysia Statistics Department, 2015), recording a staggering number of 192500 individuals with physical disability.

The first National Health and Morbidity Survey (NHMS I) in 1986 reported the prevalence of diabetes mellitus among Malaysian was at 6.3% and during the NHMS II assessment in 1996, the prevalence percentage was increased to 8.2% (Mafauzy, 2006). Surprisingly in 2006, the prevalence increased to 11.6% as revealed in NHMS III report (Letchuman *et al*., 2010) which exceeded the estimation of 11-14% prevalence by 2025 in Malaysia (International Diabetes Federation [IDF], 2003). The increasing trend of diabetes prevalence in this country seems to continue, as the recent study revealed 22.6% prevalence, almost twofold increase from previously reported in 2006 (Wan Nazaimoon *et al*., 2013). Despite the proactive efforts initiated from the Ministry of Health, such as the establishment of Diabetes Resource Centres in hospitals and the national steering committee for improving the screening and management of diabetes in clinics, the national prevalence of diabetes is expected to rise around 22% in year 2020 (Figure 1.2) (Letchuman *et al*., 2010; Mafauzy, 2006).

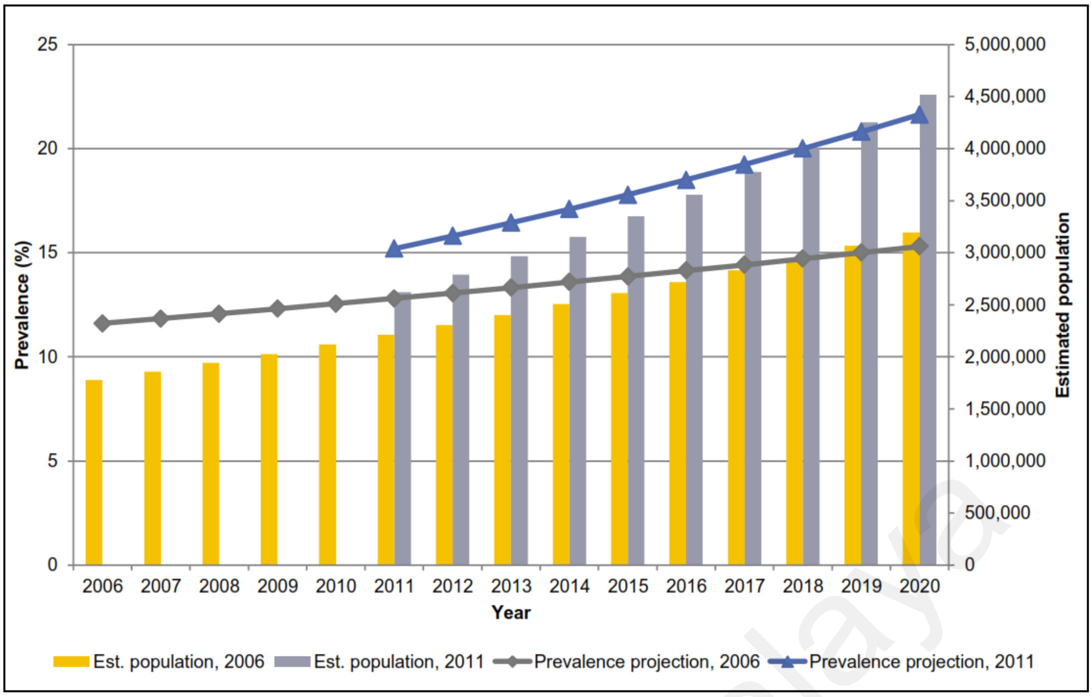


Figure 1.2: Trends and projection of national prevalence of diabetes among Malaysian age ≥18 years. (Retrived January 6, 2015, from www2.moh.gov.my/attachments/7168)

This alarming increasing trend may be associated with the increase in prevalence of obesity and overweight in Malaysia (Wan Mohamud *et al.*, 2011). Moreover, evidence from previous research indicates that obesity and overweight were significantly related with diabetes (IDF, 2003; Lazar, 2005; Mokdad *et al.*, 2001; Resnick, Valsania, Halter & Lin, 2000). Consequently, scientific study has shown that diabetes mellitus is a key risk factor leading to lower limb amputation (Resnick, Valsania & Phillips, 1999), such that in 2005, a lower limb loss was estimated for every 30 seconds due to diabetes in some part of the world (IDF, 2005). Hence, diabetes epidemic remains a serious threat and burden to Malaysia that can potentially increase the number of physically-disabled persons in the country.

1.4 Effects of amputation on the control of postural stability

Following amputations, one of the rehabilitation goals is to restore the amputee's activities of daily living by reducing the dependency on others and increasing mobility function. One of the essential and basic skills during early rehabilitation training is to control balance during upright standing (Geurts & Mulder, 1992). In fact, standing has been reported to be the most frequent indoor acticity performed by the unilateral below-knee amputees in comparison to sitting, lying, transitions and other movement-related activities (Bussmann *et al*., 1998). Maintaining balance, also known as postural stability, involves the integration of six important components which are biomechanical constraints, movement strategies (hip and ankle), sensory (visual, somatosensory, vestibular) strategies, orientation in space, control of dynamics and cognitive processing (Horak, 2006). However, this simple task is very challenging due to the loss of muscular and skeletal structures as well as major impairments in both afferent and efferent inputs which are responsible in controlling postural stability (Vanicek, Strike, McNaughton & Polman, 2009; Guskiewicz & Perrin, 1996).

Often during upright standing, persons with lower limb amputation are characterised with poor postural stability (Buckley *et al*., 2002; Vrieling *et al*., 2008a), rely heavily on the intact limb and primarily dependent on visual information (Buckley *et al*., 2002, Vanicek *et al*., 2009) during static and dynamic postural stability control. Therefore, amputees exhibit high prevalence for falls and fear of falling when compared to age-matched able-bodied individuals (Miller, Deathe & Speechley, 2003), with the risk of falling being the same as that for the elderly (Sattan, 1992). In addition to the deteriorating postural stability control due to the proprioception loss in individuals with lower limb amputation, several other intrinsic factors were thought to influence the control of stability during upright standing. Findings from previous studies suggested that the reason of amputation (Hermodsson, Ekdahl, Persson & Roxendal, 1994), length of residual limb (Lenka & Tiberwala, 2007) and level of amputation (Rougier & Bergeau, 2009) are associated with poor stance balance. Although other extrinsic factors such as the type of suspension and socket may alter the control of postural stability, they are yet to be confirmed (Kamali, Karimi, Eshraghi & Omar, 2013).

Recent advancements in technology have engendered tremendous transformations in the design and materials used to manufacture prosthetic feet. Although the prosthesis allows amputees to perform many activities of daily living, amputation remains as physical and psychological challenges for an amputated person. One of the most important elements of a prosthetic device that should be taken into consideration when selecting appropriate ankle-foot prosthesis is the stiffness of the joint. The stiffness of the prosthetic ankle-foot joint is intended to substitute for the loss of muscles and other soft tissues that surround the ankle-foot complex. Interestingly, recent studies suggested that extrinsic factor from the mechanical properties of the prosthetic foot, such as the stiffness, may influence the stability control in anterior-posterior direction among below-knee amputees (Nederhand, Van Asseldonk, Der Kooij & Rietman, 2012; Buckley, O'Driscoll & Bennett, 2002).

However, it is not clear how the stiffness influences the control of postural stability during upright standing in individuals with below-knee amputation when the sensory inputs are altered or challenged. As a result, decision making pertaining to the prosthetic prescription ascribed to patients mainly involves empirical knowledge that is based on a prosthetist's subjective experience of prosthetic devices (van der Linden *et al.*, 2004; Stark, 2005; Hofstad, van der Linden, van Limbeek and Postema 2009).

1.5 Problem statement

Previous studies have examined the compensatory strategies in postural stability control during upright standing in persons with below-knee amputation (Barnett, Vanicek and Polma, 2012; Buckley *et al.*, 2002; Kaufman *et al.*, 2007; Jayakaran, Johnson and Sullivan, 2015; Matjacic and Burger, 2003; Nederhand *et al.*, 2012). However, the amputees from those studies were equipped with a variety of different prosthetic feet. While the overall findings described in previous studies adequately explained the control mechanism of postural stability in amputated individuals, the variation in prosthetic feet may have had an influence on an individual's response to the balance task. As a matter of fact, researchers had speculated that stiffness of the ankle muscle might play an important role in maintaining balance and joint stability (Blackburn *et al.*, 2000; Vrieling, 2008a).

For amputees, it was reported that a significant relationship between dynamic balance control and prosthetic foot stiffness may justify the potential of stiffer prosthetic foot in enhancing the safety of postural stability in this population (Nederhand *et al.*, 2012). Regardless, the influence of prosthetic foot stiffness has received less attention among the researches than many other elements of a prosthetic device, such as the socket type and suspension. Therefore, variations between prosthetic feet must be considered during objective assessment of postural stability control in individuals with lower-limb amputation and their performance should be quantified from postural stability measurement results.

Often, most research studied the influence of variations in prosthetic feet from dynamic task such as during level, ramp or stairs ambulation (Agrawal *et al.*, 2013a; Agrawal *et al.*, 2014; MacFarlane, Nielsen, Shurr and Meier, 1991). Although these assessments provides informative insight into the control of postural stability at a higher level, other foundational task such as standing upright should be given the same attention. The act of standing has been known as an unstable posture that requires constant muscle contraction particularly in the lower extremity that causes body sway in all directions (Isakov *et al*., 1992). More importantly, controlling stability while standing upright involves a more complex system that requires learning processes before it is mastered in a person who has undergone amputation (Loram, Maganaris and Lakie, 2005). Thence, a person with lower-limb amputation must first acquires the ability to achieve a stable quiet standing to improve gait ability, increase gait asymmetry as well as the prevention of falls (Hendrickson, Patterson, Inness, McIlroy & Mansfield, 2014; Yanohara *et al*., 2014).

Although balance confidence and stability have shown to be associated with walking performance and social activity (Miller *et al*., 2001a), studies on postural balance with different foot category are scarce compared with research on other biomechanical areas (Hafner, 2006). In relation to this, distinguished researchers have suggested that the assessment of postural stability should evaluate how changes in support surface and sensory conditions will influence the coordination of the lower limbs to maintain postural stability (Horak, 1997; Kaufman, 2004). This is vital due to the complex interactions between the musculoskeletal and sensory information in reorganizing postural stability for a person with lower limb amputation (Geurts and Mulder, 1992).

While postural sway of lower-limb amputees have been shown to increase when visual and support surface were altered (Hermodsson *et al*., 1994; Nadollek *et al*., 2002; Vanicek *et al*., 2009), these studies' aim was focused toward comparing the effect of sensory modifications on postural control but did not explore the possible interaction between prosthetic foot types and sensory conditions to facilitate the maintenance of static postural stability. As proposed by Hafner (2005), the standardisation of prosthetic foot characteristics or mechanical behaviour should be considered as a better research method to provide scientific evidence for prescription of prosthetic foot. However, studies on how or to what extent prosthetic feet types may influence the control of postural stability during altered sensory has not been examined to date. Thus, manipulating prosthetic foot types and sensory conditions could give a valuable insight into whether or not prosthetic foot variations will influence the performance of amputees during upright standing with alteration in sensory information.

1.6 Aim and objectives

The overall aim of this thesis was to investigate the influence of prosthetic foot types and altered sensory conditions on the postural stability of below-knee amputees during upright standing. To achieve this aim, six objectives have been identified as follows:

i. to determine the intrarater test-retest reliability measures of postural stability indexes over a specific time interval during static and dynamic unilateral stance using the computed posturography
ii. to determine the influence of different prosthetic foot types to the control of postural stability during quiet standing when visual inputs were altered
iii. to determine the effect of different prosthetic foot types on the control of postural stability under various support surface conditions between persons with below-knee amputation and able-bodied individuals
iv. to examine the effects of different prosthetic feet and head extension on the postural stability and whether balance between persons with below-knee

amputation and able-bodied individuals could be distinguished by using computed posturography

v. to demonstrate the use of stability indexes, time percentage on concentric zones and quadrants for postural stability assessment under various sensory manipulations

vi. to quantify the movement strategies in anterior-posterior and medial-lateral directions in predicting the overall postural stability wearing three types of prosthetic feet when sensory inputs were altered

1.7 Outline of Thesis

Including the first introductory chapter, this thesis consists of ten chapters. Several chapters are written in the format of peer-reviewed published papers, and may therefore contain certain redundancies, particularly in the Introduction and Methodology sections. The thesis begins with Chapter 1 which presents the general background, amputation prevalence, adverse effects of amputation on the postural stability, identified problem statement and purpose of this thesis.

Chapter 2 provides a comprehensive review of the pertinent literatures related to the biomechanics of maintaining postural stability. This includes: the overview research trend in lower limb amputation, general history, amputation levels, components of below-knee prosthesis, postural stability during quiet standing in healthy and amputated individuals, as well as the summary of instrumented measures and outcome measures related to postural stability assessment.

A general methodology section is presented in Chapter 3. It describes the participants' inclusion exclusion and criteria, ethical approval, as well as experimental procedures which justify and describe the biomechanical and functional analysis tools used within the thesis. This chapter further details the mechanical testing procedure in determining the linear stiffness of each prosthetic foot and describes the perceptive analyses which determine the prosthesis use, functional balance status and balance confidence among individuals with below knee amputation and able-bodied participants.

Chapter 4 examines the intrarater test-retest reliability measures of postural stability indexes over a specific time interval during static and dynamic unilateral stance using the chosen computerised posturography device.

Chapter 5 to 7 focus on the assessment of postural stability control with three different prosthetic foot types during altered visual, proprioceptive and vestibular sensory information, respectively.

Chapter 8 contains a detailed description regarding the use of stability indexes, time percentage on concentric zones and quadrants for postural stability assessment under various sensory manipulations.

Chapter 9 reports the biomechanical analyses to quantify the movement strategies in anterior-posterior and medial-lateral directions in predicting the overall postural stability wearing three types of prosthetic feet with modified sensory inputs.

Finally, Chapter 10 provides a summary based on the findings of this thesis and limitations are explored. This chapter closes with recommendations for future studies in improving the understanding of postural stability control of persons with below-knee amputation.

CHAPTER 2

LITERATURE REVIEW

This chapter provides a comprehensive review on areas related to postural stability control in below-knee amputees. The review of previous and current literatures provide an outline of the body of knowledge that explores the aspects of both prosthesis intervention and balance assessment in persons with below-knee amputation. The first part of this chapter will discuss the overview of previous and current trend of research in lower limb amputation. Topics relevant to below-knee amputation such as general history, amputation levels and components of below-knee prosthesis are reviewed in the second part of this chapter. It continues with the third part which explains postural stability during quiet standing and its underlying biomechanics in healthy and amputated individuals. This section will contrast normal control of postural stability with that of pathologic control in below-knee amputees. The fourth part summarizes the instrumented measures of balance found from systematic search of published literatures. Next, the outcome measures related to balance are also elaborated. Finally, this chapter ends with a summary of the contribution of the current thesis to the body of knowledge related to postural stability control in people with below-knee amputation.

2.1 Overview of lower limb amputation research

In the last decade of the 20th century, several contributing factors such as technological advances in componentry and fabrication, emergence of new materials as well as increased awareness in evidence-based practice have encouraged the positive growth of lower limb amputation research. Generally, prosthetic research is primarily based on two purposes, which are to expand understanding to the body of knowledge or to solve an identified practical problem (Geil, 2009). The publication trend based on a search in the Web of Science database indicates that the distribution of published articles has increased in the last three decades from 1981 to 2014 (Figure 2.1). However, there is still insufficient evidence related to balance in lower-limb amputees based on the total published articles per year as shown in Figure 2.2.

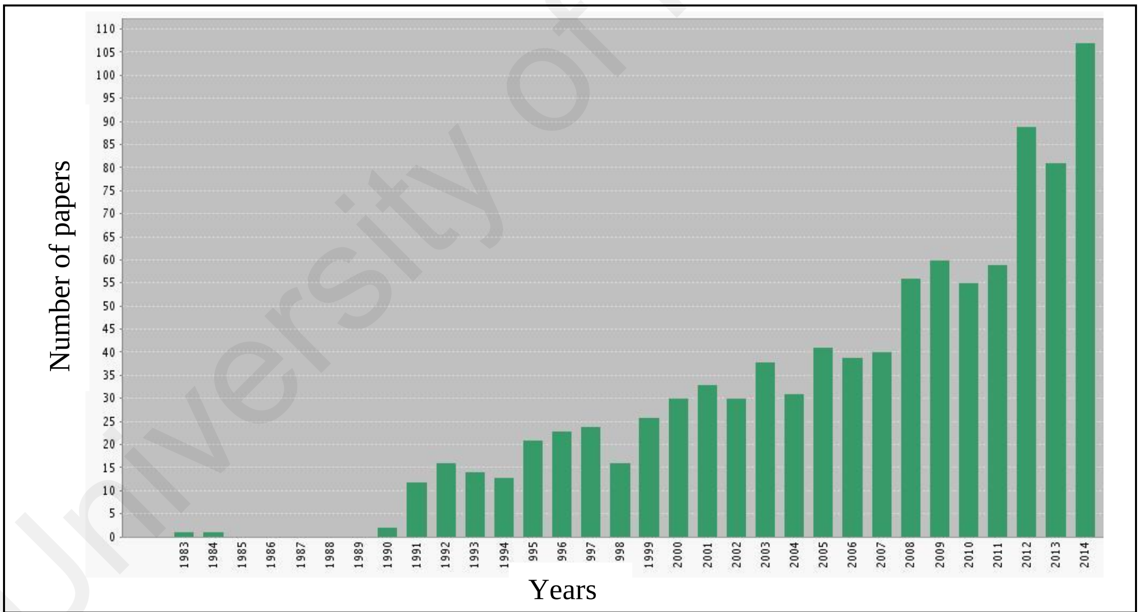


Figure 2.1: Publication trend for research related to lower limb amputation prosthesis from 1983 to 2014.

According to previous literature studies, most of the research in the field of prosthesis and lower limb amputation focused on the common measures of biomechanics such as kinetics (derived from force data), kinematics (motion analysis), temporal characteristics, muscle activity and energy expenditure (Hafner, 2005; Sagawa *et al.*, 2011). Moreover, the lack of research pertaining balance assessment in amputees is reflected by the list of the first top ten articles in the field of lower limb prosthetics, where only two studies on static balance in below-knee amputees and dynamic balance in above-knee amputees were recorded at 7th and 8th place, respectively (Eshraghi, Abu Osman, Gholizadeh, Ali and Shadgan, 2013). Despite numerous published studies on lower limb amputees, limitation in the studies conducted to date on balance control in persons with lower limb amputation warrants further investigation.

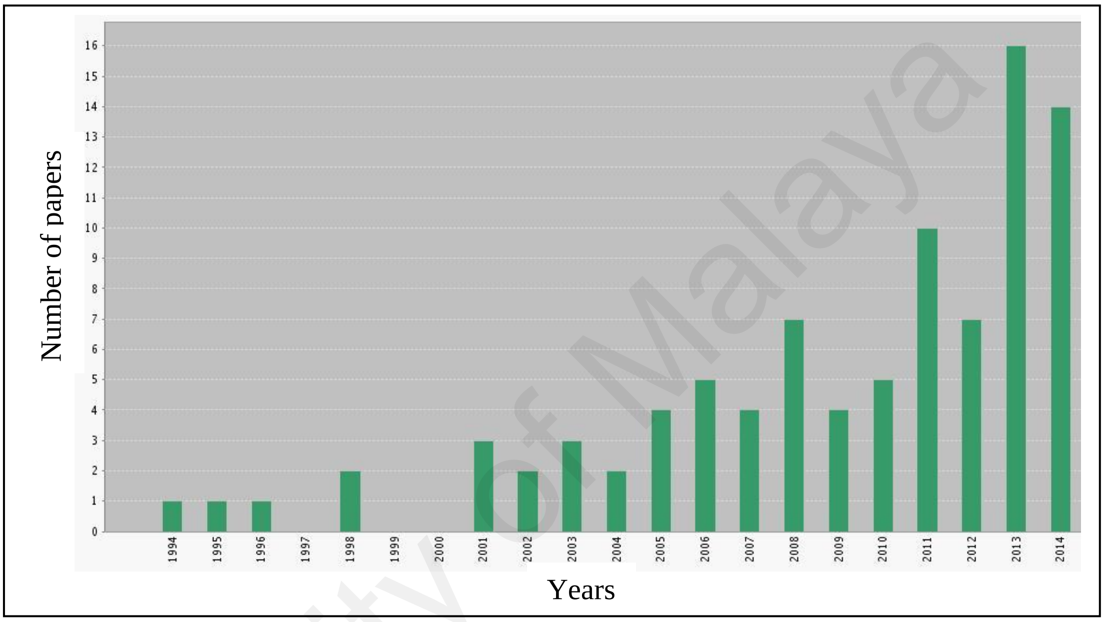


Figure 2.2: Published articles per year for research related to balance in lower limb amputees from 1994-2014.

2.2. Below-knee amputation and prosthesis

2.2.1. History of amputation and prosthetics

Lower-limb amputation has been known as one of the oldest surgical procedures performed since prehistoric times (Wilson, 1992). During the Renaissance era from the 14th to 16th centuries, Hippocrates indicates that amputation was performed mainly due to gangrene (Bowker and Pritham, 2004). Later, it was Ambroise Pare (from 1509 to 1590) who became known for his significant contribution to the development of modern surgery. Following the innovation of gunpowder, more amputations were undertaken as a result from shot and cannon ball injuries. One of the well-known battle field surgeons was Lisfranc (from 1790 to 1847) who was famous for foot amputation procedure that was later named after him.

Meanwhile, the history of prosthesis began as early as 1800 BC as described in Rig-Veda, where the Indian warrior was fitted with iron prosthesis following amputation caused by war. The oldest discovered prosthetic devices were the two artificial toes found in Luxor, Egypt as shown in Figure 2.3 (Finch, Heath, David and Kulkarni, 2012). The first design was made of wood and leather between 950 and 710 BC. The second design was known as Greville Cartonnage from before 600 BC which was made of cartonnage (a mixture of linen, glue and plaster). Because of the wear and tear appearances on both designs, researchers believed that both prostheses could have been used as an aid for walking, in addition to cosmesis purposes (Finch *et al.*, 2012).

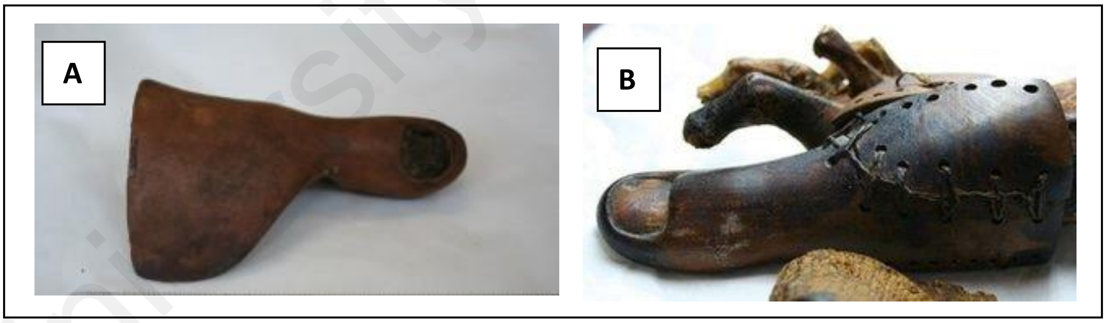


Figure 2.3: Ancient toes prosthesis found in Luxor, Egypt; (A) the Greville Cartonnage toe and (B) leather and wood toe. Reproduced from Finch *et al*. (2012)

During historical period, prostheses were fabricated using wood, fiber, bone and metals with leather corset as the suspension system (Seymour, 2002). The privileged person wore protective armour to conceal their disabilities while the common person used peg leg made of wood as illustrated in Figure 2.4 (Seymour, 2002). Prosthesis designs continued to evolve as a result of World War I and II. In recent decades, additional refinements have been added in line with advancement in materials with lighter and durable properties such as silicone, thermoplastic, carbon fibre and titanium. Fabrication of prosthesis socket has been computerised with the use of Computer Aided Design–Computer Aided Manufacturing (CAD-CAM) which increased the manufacturing efficiency and time savings when compared to the manual process (Bowker and Pritham, 2004).

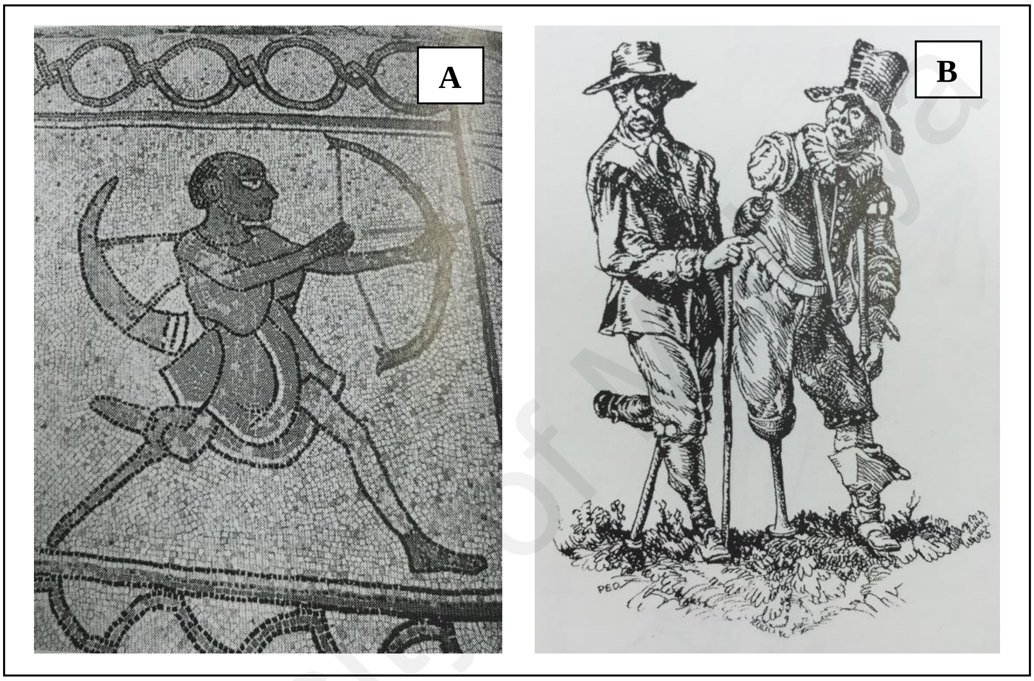


Figure 2.4: Peg leg prostheses during (A) Gallo-Roman era and (B) Renaissance era. Reproduced from Seymour (2002).

2.2.2. Levels of lower-limb amputation

Standard nomenclature for levels of amputation was developed by the International Society of Prosthetics and Orthotics (ISPO) in 1973 to improve international communication related to the field (Schuch & Pritham, 1994). In 1989, the terms were minimally modified and endorsed by the International Standards Organization (ISO). This standardised nomenclature is adopted to replace traditional terminologies such as above-knee and below-knee used in American practice previously. For amputation performed across the axis of a long bone such as tibia, the term transtibial is used, while amputation between long bones or through a joint is known as disarticulation (ISO, 1989a). Figure 2.5 depicts the acquired amputation level and its ISO terms.

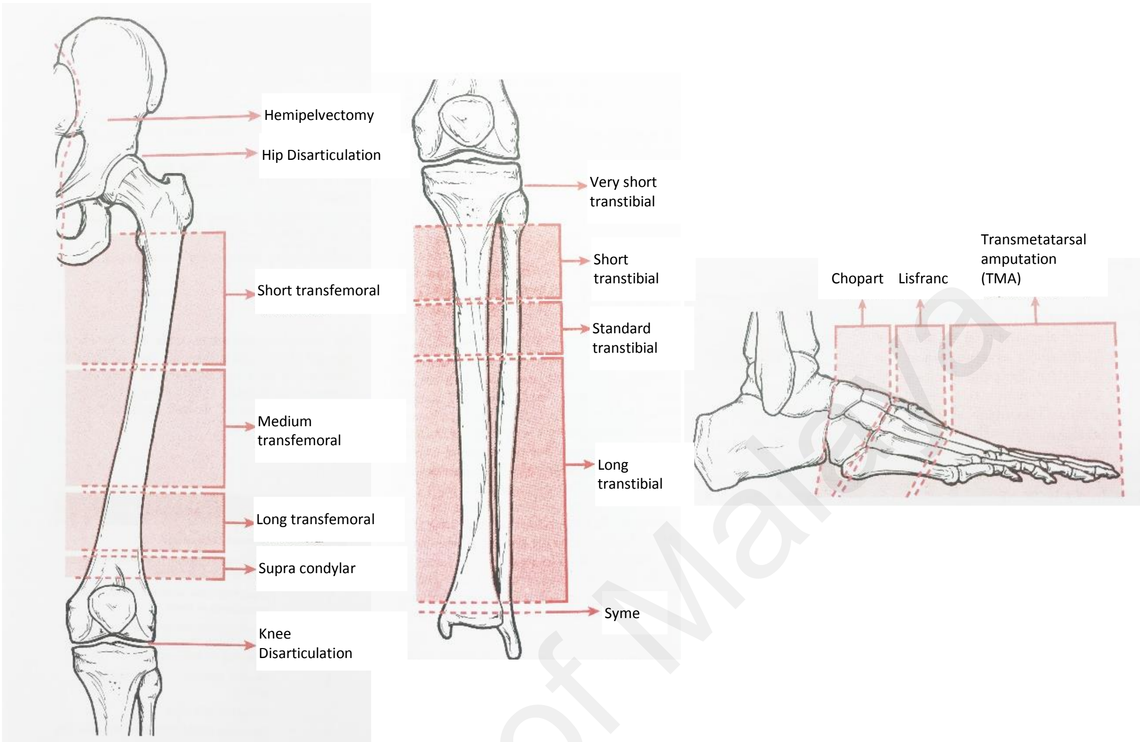


Figure 2.5: Levels of amputation according to ISO nomenclatures. Reproduced from Seymour (2002).

2.2.3 Components of transtibial prosthesis

Prosthesis or prosthetic device is defined as 'externally applied device used to replace wholly, or in part, an absent or deficient limb segment' (ISO, 1989b). The present thesis focused on lower-limb prosthesis, particularly for transtibial amputees. Generally, the endoskeletal or modular transtibial prosthesis consists of prosthetic foot, pylon, suspension system and socket (Figure 2.6) Along with these components, soft liners are prescribed when necessary according to the conditions of the residual limb. In addition to the patient's current condition, the range of prosthetic components is mainly determined based on the functional classification system (K-level) describing the functional abilities of persons who had undergone lower-limb amputation (Gailey and Clark, 2007). The following paragraphs briefly discuss each of the components.

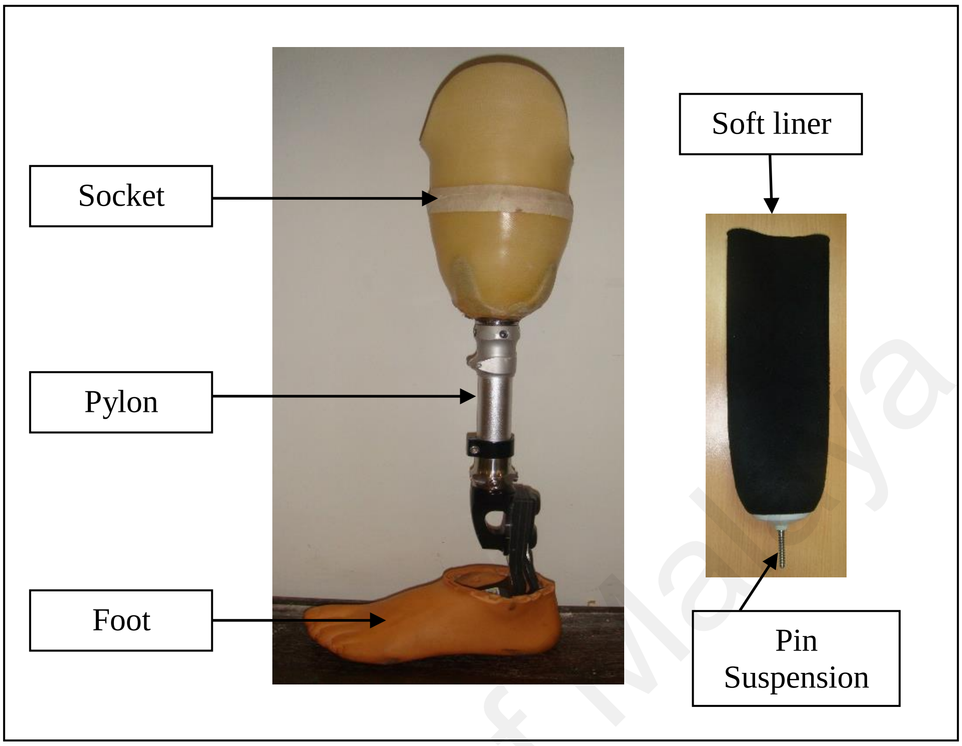


Figure 2.6: Components of a modular transtibial prosthesis with silicone soft liner and pin suspension system.

Ideally, a prosthetic ankle-foot unit should be prescribed and carefully designed to adjust its mechanical characteristics to the functional needs of the prosthesis user (Cortes, Viosca, Hoyos, Prat and Sanchez-Lacuesta, 1997). This includes the ability of the foot to replicate the biomechanical characteristics of anatomical foot as close as possible (Fergason, 2007). Often, prosthetic prescription for person with lower-limb amputation is primarily based on empirical knowledge along with other factors such as the body weight, muscle strength, residual length and activity level (Stark, 2005). From a manufacturer's practice, the combination of mobility grade and amputee's weight is used to determine the stiffness level of the prosthetic foot for prescription purposes (Geil, 2001). However, there seem to be no consensus among the manufacturers on the stiffness level in such that the choice of stiffness is left to both the prosthetist's and amputee's subjective interpretation.

Nevertheless, to provide general guidelines during the prescription process, prosthetic feet are classified into four primary types according to the motion they permit, mechanical behaviour and physical design (Hafner, 2005). They are: conventional, single-axis, multi axis and energy storage and return (ESAR). The conventional foot is the basic design, non-articulated solid ankle cushion heel (SACH) which was developed at the University of California in the early 1950's (Michael, 2004). It consists of an internal keel that extends to the ball of foot and a cushion wedge built into the heel (Figure 2.7 A). In some designs, belting is added from the keel to the end of toes to stimulate toe flexors (Fergason, 2007). The SACH foot has been commonly prescribed due to its durability, simplicity, minimal maintenance and low cost (Fergason, 2007). As the name suggests, the single-axis (SA) foot permits 15^0 plantarflexion and $5\text{-}7^0$ dorsiflexion (Figure 2.7 B). The front bumper substitutes for the gastrocnemius-soleus eccentric contraction while the rear bumper mimics eccentric contraction of the anterior tibialis (Seymour, 2002). One of the advantage of this design is its ability to reach foot flat quickly during early stance. On the other hand, major drawbacks include increased weight and frequent maintenance (Fergason, 2007).

The multi-axis foot consists of rubber block which allow dorsiflexion and plantarflexion in the sagittal plane, with additional motions in transverse plane such as inversion, eversion and rotation (Figure 2.7 C). This foot benefits most during uneven terrain locomotion and ascending slope (Seymour, 2002). However, due to its multiplanar motions, this design provides less static stability to amputees with weaken leg muscles (Fergason, 2007).

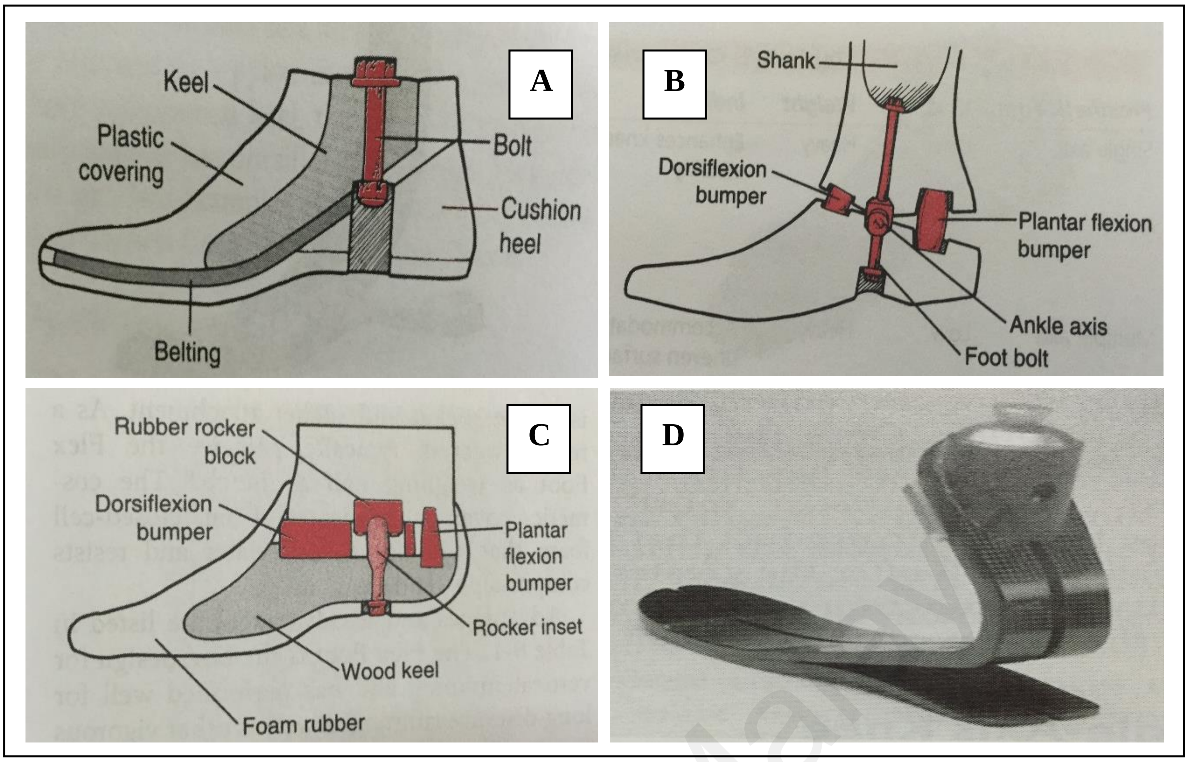


Figure 2.7: Four types of prosthetic feet: (A) solid ankle cushion heel (SACH), (B) single-axis, (C) multi-axis, and (D) energy saving and return (ESAR). Reproduced from Seymour (2002) and Fergason (2007).

For amputees leading active lifestyle with high activity levels, they are often prescribed with energy storage and return (ESAR) foot (Figure 2.7 D). The notion of the name is related to its light weight, carbon graphite composites which store forces during loading and release this stored energy during pre-swing (Fergason, 2007). This type of foot has been known to improve walking speed, greater stride length and more symmetrical gait pattern when compared to a conventional SACH foot (Hafner, 2005; van der Linde *et al*., 2004). However, the range of motion at the ankle of a single-axis foot was demonstrated to be greater than the ESAR foot (van der Linde *et al*., 2004). Nevertheless, results from these studies should be interpreted carefully due to variability between studies such as subject selection and experimental protocols.

The next component of a transtibial prosthesis is the pylon which is a cylindrical rod used to connect the distal end of prosthetic foot to the socket adapter at the proximal end. In recent years, shock-absorbing pylon and flexible pylon have been introduced in addition to the conventional rigid pylon. A study conducted on a group of transtibial amputees during self-selected walking speed demonstrated that the use of shock-absorbing pylon was effective as a rigid pylon (Berge, Czerniecki and Klute, 2005). Meanwhile, the use of flexible nylon pylon in transtibial amputees was shown to improve gait quality and comfort than that of rigid aluminium pylon (Coleman, Boone, & Czerniecki, 2001).

The prosthetic socket serves as a connection between the residual limb and the prosthetic foot. Since weight-bearing capability of the residual limb differs from the foot, the design and fit of a socket are vital to ensure a successful rehabilitation for amputees (Goh, Lee and Chong, 2004). Moreover, the shape of the socket is one of the factors which can possibly influence the occurrence of pressures and shear stresses at the residual limb-prosthetic socket interface (Sanders, Zachariah, Baker, Greve and Clinton, 2000). Generally, two types of socket are commonly used for transtibial prosthesis which are the patellar tendon bearing (PTB) and the total surface bearing (TSB) (Seymour, 2002).

The PTB socket was first introduce by Radcliffe in 1950s that relied on the weight-bearing capabilities of the patellar tendon area (Goh *et al*., 2004). As such, an indentation known as ‘patellar tendon bar’ was created on the socket to reduce weight loading on the pressure-intolerant areas (Figure 2.8 A) (Laing, Lee and Goh, 2011). Despite being used for more than 40 years and known for providing good fit, the PTB socket has been reported with suspension problem and unbearable pressure on the patella tendon (Fergason and Smith, 1999; Yigiter, Sener & Bayar, 2002). In addition, a skilled and experienced prosthetist is required in order to produce a good PTB socket fit (Laing *et al*., 2011).

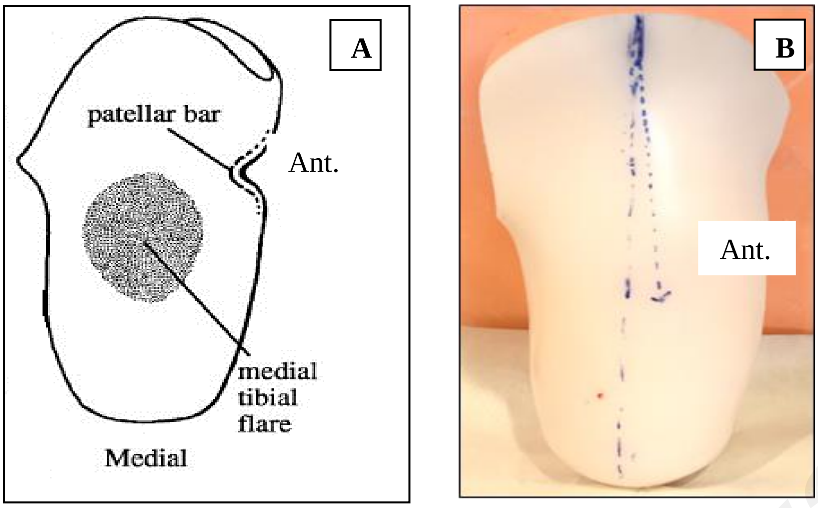


Figure 2.8: Two common prosthetic sockets for transtibial prosthesis; (A) PTB and (B) TSB socket. Note the significant indention on the patellar tendon area in PTB socket design. Figure A was reproduced from Kapp and Cummings (1992).

In recent years, the TSB socket has been recognised as an effective alternative to the conventional PTB socket (Figure 2.8 B). The TSB socket, which was introduced by Ossur Kristinsson in 1993, is based on the concept of distributing equal pressure on the entire residual limb and commonly used together with the silicone liner (Cavenett, Aung, White and Streak, 2012). Recent research findings on amputees' satisfaction survey showed that the TSB socket is favoured by the majority of amputees (Gholizadeh, Abu Osman, Eshraghi, Ali & Abd Razak, 2014). This could be linked to the previous study which demonstrated significant improvement in suspension, weight acceptance on amputated side, as well as lighter prosthesis mass when ambulating with TSB socket in transtibial subjects (Yigiter *et al.*, 2002).

Suspension and prosthetic fit have been linked to influence functional efficiency and comfort levels (Beil, Street and Covey, 2002). Good suspension is vital to secure the prosthesis on the residual limb during activities of daily living (Seymour, 2002). Several types of prosthetic suspension systems are available for transtibial amputees. Generally the suspension system for a transtibial prosthesis are categorized into four general categories which are atmospheric pressure, anatomic, straps and hinges (Michael, 2004). The atmospheric pressure system, as shown in Figure 2.9A, includes roll-on locking liners with shuttle/pin, vacuum systems, hypobaric socks and elastomeric knee sleeves which offer minimal pistoning and greatest range of motion (Michael, 2004). The anatomic suspension system takes advantage of bony area such as the femoral condyles to hold the prosthesis on the residual limb (Figure 2.9 B). The two designs for this system, which are the PTB supracondylar (PTB-SC) and PTB supracondylar-suprapatella (PTB-SCSP), are often prescribed for amputee who requires additional knee stability (Michael, 2004).

Suspension system using straps (Figure 2.9 C) is efficient for amputees with a mid-length residual limb to control unwanted knee hyperextension (Berke, 2007). However, this type of suspension is not suitable for obese amputee as soft tissue impingement problem may arise and does not provide mediolateral and anteroposterior stability in unstable knee (Berke, 2007). The hinges system, which comprise of corset and joints, is most suited for amputee with very short, painful and scarred residual limb (Berke, 2007). Although this design provides knee stability and absorbs vertical loading, this suspension type is bulky; hence it is often rejected by the user (Berke, 2007; Michael, 2004). Recent review demonstrated that transtibial amputees perceived more satisfaction with pin/lock suspension system coupled with TSB socket (Gholizadeh *et al*., 2014). Nonetheless, there is no conclusive notion on which particular suspension system should be possessed by all transtibial amputees.

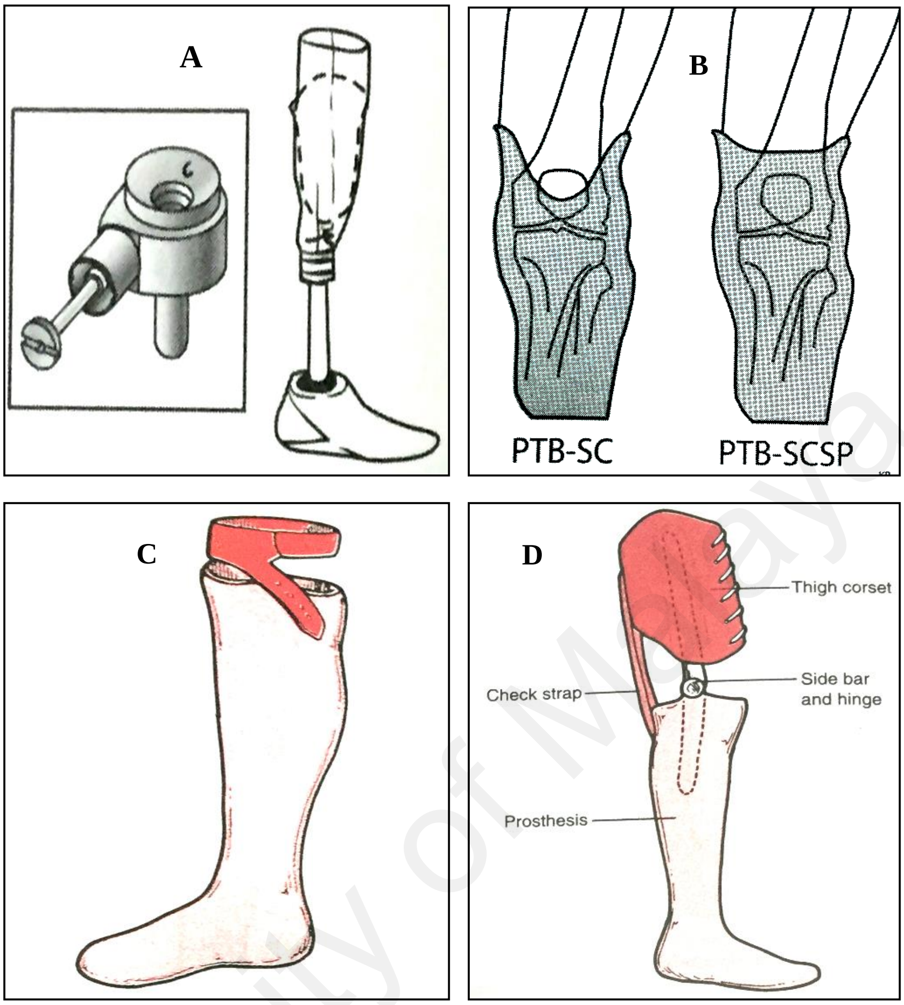


Figure 2.9: Four general categories which are: (A) atmospheric pressure, (B) anatomic, (C) straps and (D) hinges. Reproduced from Michael (2004), Carroll and Binder (2006) and Seymour (2002).

Soft liners are used to protect the residual limb and providing total contact between the limb and socket (Seymour, 2002). Two types of soft liners which are commonly used are Pelite® and viscoelastic liner (Seymour, 2002). Pelite® liner is made of lightweight closed-cell polyethylene foam, while viscoelastic liner (or known as roll-on liner) is made of gel or silicone. Choosing a liner depends on the condition of residual limb. For example; scarred, sensitive or bony residual limb is often prescribed with the Pelite® liner, while residual limb which has irregular shape is often prescribed with viscoelastic liner (Kapp and Fergason, 2007). A recent finding from the work of

Ali *et al.* (2012) showed that amputees were more satisfied with polyethylene liner than viscoelastic liner during donning and doffing.

In brief, the variations in the commercially available prosthetic components offers wide range of alternatives for prosthetists in making the optimum decision pertaining components selection. Most importantly, the choice of prosthetic components not only depends on the thorough understanding of its underlying mechanism, but also relies heavily on the ability of the amputee to function with such choices.

2.3 Control of postural stability in human

2.3.1 General background

Postural control is known as the foundation to achieve independent standing and walking (Melzer, Benjuya and Kaplanski, 2004). It has been defined as the control of the body's position in space for the purpose of balance and orientation (Shumway-Cook & Woollacott, 2001).Therefore, it is considered as an important aspect in the rehabilitation process among the elderly (Baldwin, Thomas, Ploutz-snyder & Lori, 1999; Parraca *et al*., 2011), impaired (Salsabili, Bahrpeyma, Forogh and Rajabali, 2011; Testerman and Griend, 1999) and amputee (Vrieling *et al*., 2008a; Vanicek *et al*., 2009) populations. Poor control of postural stability is often associated with the risk of falling which consequently leads to death, injuries and loss of mobility (Winter, Patla and Frank, 1990a). The maintenance of stable posture is controlled by the sensory system (vestibular, visual, proprioceptive systems), the central nervous system and musculoskeletal system (Winter *et al*., 1990a). Hence, any deficits of these components will greatly affect the ability to maintain postural stability during standing and walking.

2.3.2 Definition and related terms

The word ‘balance’ is a common term which had been utilised widely in various clinical purposes. It has been used interchangeably with other related terms such as stability and postural control (Pollock, Durward and Rowe, 2000; Seeger, 2003). For instance, Shumway-Cook and Woollacott (2007) defined postural stability, or balance, as the ability to maintain the body in equilibrium. On the other hand, Hinman (2000) defined balance, or postural stability, as the ability to maintain the body’s center of mass (CoM) within its base of support (BoS). The BoS is defined as the area within the border of the contact surface between the feet and the support surface (Wallace, 2007). Specifically, posture is defined as the geometric relation between two or more body segments relative to the environment (Balasubramaniam & Wing, 2002). Whereas stability is defined as the sensitivity of a dynamic system to external and internal perturbations (e.g., changing muscle activity in response to gravity) that occur during posture (Stergiou, 2004). Hence, Pollock and associates (2000) described human stability as the person’s natural capability to maintain, achieve or restore balance by integrating the sensory and motor systems. Interestingly, despite the frequent use of the term ‘balance’ among the healthcare professionals, no standard terminology has been established (Shumway-Cook and Wollacott, 2007). Various interpretation of postural stability is shown in Table 2.1.

From these definitions, it is reasonable to conclude that the term *postural stability* is the process of postural control which consist of a complex integration of somatosensory, visual and vestibular inputs along with motor coordination to maintain the center of mass (CoM) within the base of support (BoS). (Blackburn, Prentice, Guskiewicz and Busby, 2000; Shumway-Cook and Woollacott, 2000).

Table 2.1: Definition of 'postural stability' from selected published literatures.

Authors (Year)	Definition
Winter (1995)	The maintenance of postural stability involves the integration of sensory systems (visual, proprioceptive and vestibular), central nervous systems and musculoskeletal systems
Shumway-Cook and Woollacott (2001)	The ability to maintain the projected COM within the limits of the base of support
Pollock *et al*. (2000)	The ability of a person to achieve, maintain or return to equilibrium by positioning the CoM within its base of support
Massion and Woollacott (2004b)	Maintaining an upright body alignment against gravitational force and preserving the equilibrium of the CoM in an individual's base of support
Mackey and Robinovitch (2005)	The ability to maintain an upright posture during quiet stance during static condition; or the recovery of balance following external perturbation or displacement of the support surface during dynamic condition
Ruhe, Fejer and Walker (2010)	A system that depends on the unimpaired ability to correctly perceive the environment through peripheral sensory systems, as well as to process and integrate vestibular, visual and proprioceptive inputs at the central nervous system (CNS) level.

2.3.3 Functions of postural stability

Researchers suggest that postural stability is inseparable from the action or from the environment in which the action occurs (Huxham, Goldie and Patla, 2001). This is related to the two functional goals of postural stability which are to control postural orientation and postural equilibrium (Horak, 2006; Massion and Woollacott, 2004b; Pollock *et al*., 2006). The control of postural orientation involves the active control of body alignment and muscle tone as antigravity function to maintain a specified posture such as sitting or standing (Massion and Woollacott, 2004b; Pollock *et al*., 2006). On the contrary, the control of postural equilibrium involves the coordination of sensorimotor system to accomplish self-initiated movements (for example, movement from sitting to standing) or to restore stability in reaction to external disturbances (for example, a trip or a push) (Horak, 2006; Massion and Woollacott, 2004b; Pollock *et al*., 2006).

Overall, researchers agreed on the notion that the success to maintain postural stability depends on the adaptive postural control which modifies the motor as sensory system in response to the task characteristics (for example, normal walking versus walking on toes) and environmental context (for example, standing on stable versus moving support surface) (Huxam *et al*., 2001; Massion and Woollacott, 2004b; Shumway-Cook and Woollacott, 2007). In addition, other mechanisms of postural control include the anticipatory postural control which is based on the previous experience and learning, as well as motivation and intention of the subject (Shumway-Cook and Woollacott, 2007).

In relation to this, several models of postural control have been developed to provide understanding in human control of postural stability. The most commonly discussed models of postural control are the genetic, hierarchical and system models. In the genetic model of posture, three main functions are identified which are to orient the body segments against gravity, preserve whole body balance and adapting the body's segments to the ongoing movement. (Massion, Alexandrov & Frolov, 2004a). However, the concept of genetic model of posture was criticized for its lacking in considering the important role of anticipation from learning and experience during the organization of posture and movement (Massion *et al*., 2004a). In addition, this model neglects the nature of flexibility of postural reactions following external disturbance in fine-tuning the postural control (Massion *et al*., 2004a).

Due to this argument, it appears that the postural control mechanism requires a higher level of postural organization. Hence, the hierarchical model of postural control was proposed by Nicholai Bernstein that combined both genetic approach and learning aspects in controlling postural stability (Massion *et al*., 2004a). In this model, the CNS system is thought to organize the control of posture in an ascending hierarchical manner in such that the control of reflexes occur at the spinal cord (lower level) and brain stem (higher level) while the equilibrium response occurs at the cortical brain area (highest level) (Seeger, 2003; Mattiello and Wollacott, 1997, 2004b; Woollacott and Shumway-Cook, 1990). Accordingly, reflexes and response occur at lower level will disappear as control is taken over by the higher centres (Mattiello and Wollacott, 1997). Although the hierarchical model has been widely accepted, it was scrutinised because movement and posture control is not an independent result of sensory input eliciting predetermined movement patterns but rather the postural control emerges from the interaction of multiple body system with the changes in task and environment (Mattiello and Wollacott, 1997).

Hence, the systems model was proposed which suggest that it is not only dependent on the CNS hierarchical organization from higher and lower level, but rather from interrelation between several systems in a concerted manner as shown in Figure 2.10 (Mattiello and Wollacott, 1997). As such, the flexibility of this interrelation permits adaptation of the postural control system to changes in environmental, physical and task constraints (Mattiello and Wollacott, 1997). This model consists of three essential elements in the control of postural stability which are: combinations of sensory information from visual, vestibular and somatosensory systems, motor processes that involve muscle synergies and finally integration of sensory and motor processes at the CNS level that includes adaptive and anticipatory postural control (Shumway-Cook and Woollacott, 2007). The systems model represents a sensory-motor control loop which the CNS continuously monitors the environment's context condition from the afferent feedback and regulating corresponding postural movements based on the transmitted efferent feedback (Yim-Chiplis and Talbot, 2000; Tucker *et al.*, 2015). The adaptive postural control functions in adapting the sensory and motor system in response to changing task and environmental demands while the anticipatory postural control works based on previous experience and learning (Shumway-Cook and Woollacott, 2007). The use of systems model in balance assessment has been suggested to aid in determining the fundamental cause of balance deficit in order to plan for specific rehabilitation management (Horak, 1997). The sensory and motor strategies for postural stability control based on the systems model are described in the following sections.

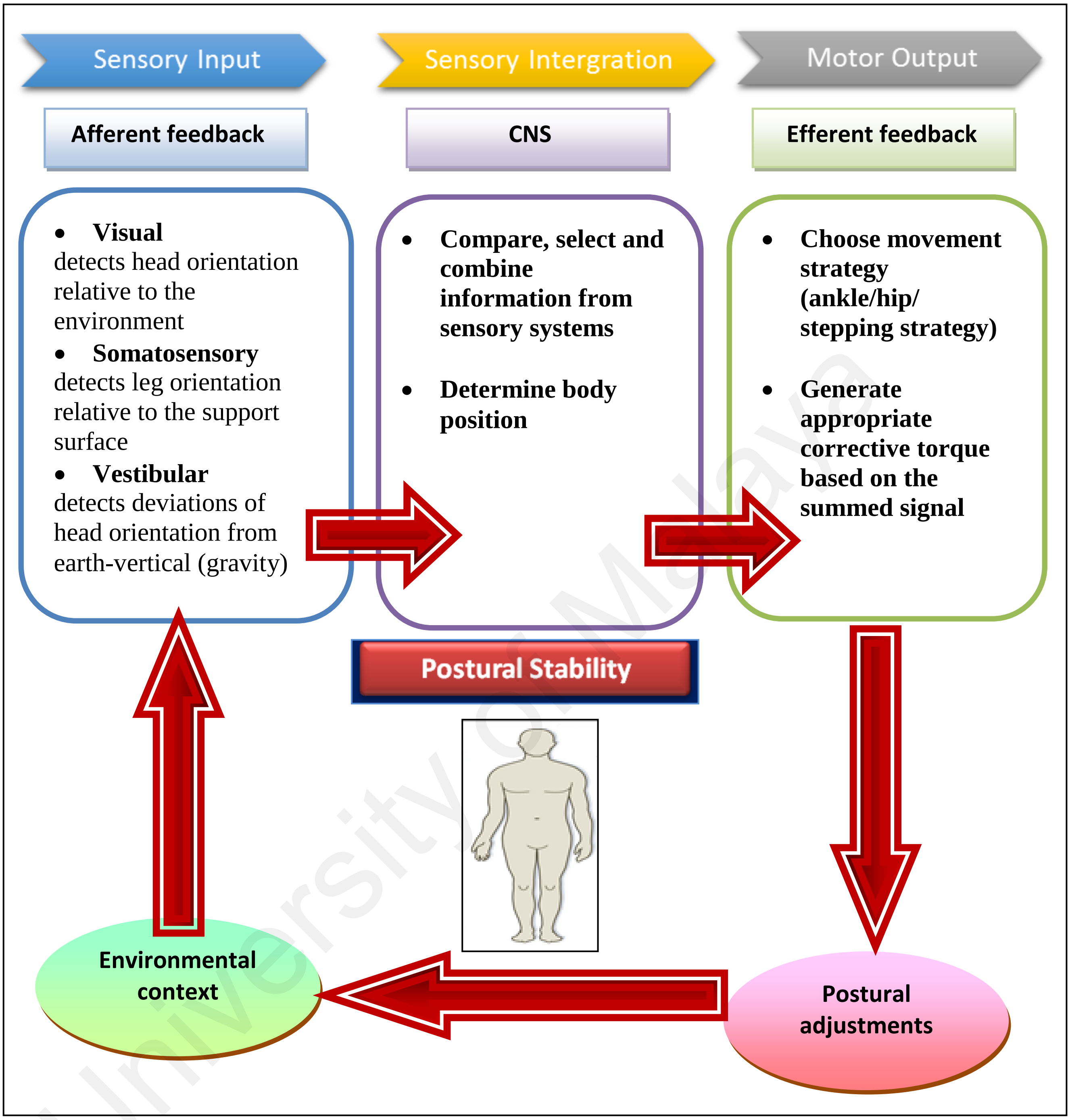


Figure 2.10: Organization of postural stability control according to systems model approach (Adapted from Peterka 2002; Shumway-Cook and Woollacott, 2007).

2.3.4 Components and organization of postural stability

In this thesis, the postural stability control system is viewed based on the systems model (Horak, 2006; Shumway-Cook and Woollacott, 2007). According to the systems model, the maintenance of postural stability involves the integration of six important components which are biomechanical constraints, movement strategies, sensory strategies, orientation in space, control of dynamics and cognitive processing as illustrated in Figure 2.11 (Horak, 2006). Impairments in one or more of the components will lead to postural instability and increase the risk of fall especially in the elderly and person with neurological or musculoskeletal disorders.

The biomechanical subcomponents of postural control demonstrates the ability of a person to accomplish the desired motor task depending on the muscles strength, joint range of motion, flexibility and body alignment in postures such as standing and sitting (Horak, 1997). Most importantly, the alignment of body segments' CoM over the BoS must be within the limits of stability to ensure appropriate selection of movement and sensory strategies (Horak, 2006). Variations in the body's demographics such as height, weight, age and gender have been proposed to affect the individual limit of stability which consequently influences the selection of appropriate movement strategies to maintain postural stability (Guskiewicz and Perrin, 1996).

Hence, three common movement strategies have been hypothesized as a mechanism to keep the body's postural stability in a variety circumstances (Figure 2.12). The ankle and hip strategy are strategies that keep the feet on a fixed-support, while stepping strategy involves changes-in–support of the feet (Pollock *et al.*, 2000). The selection of appropriate strategy often relies on the magnitude size of the perturbation, type of support surface and on experience and expectation (Horak, 1997).

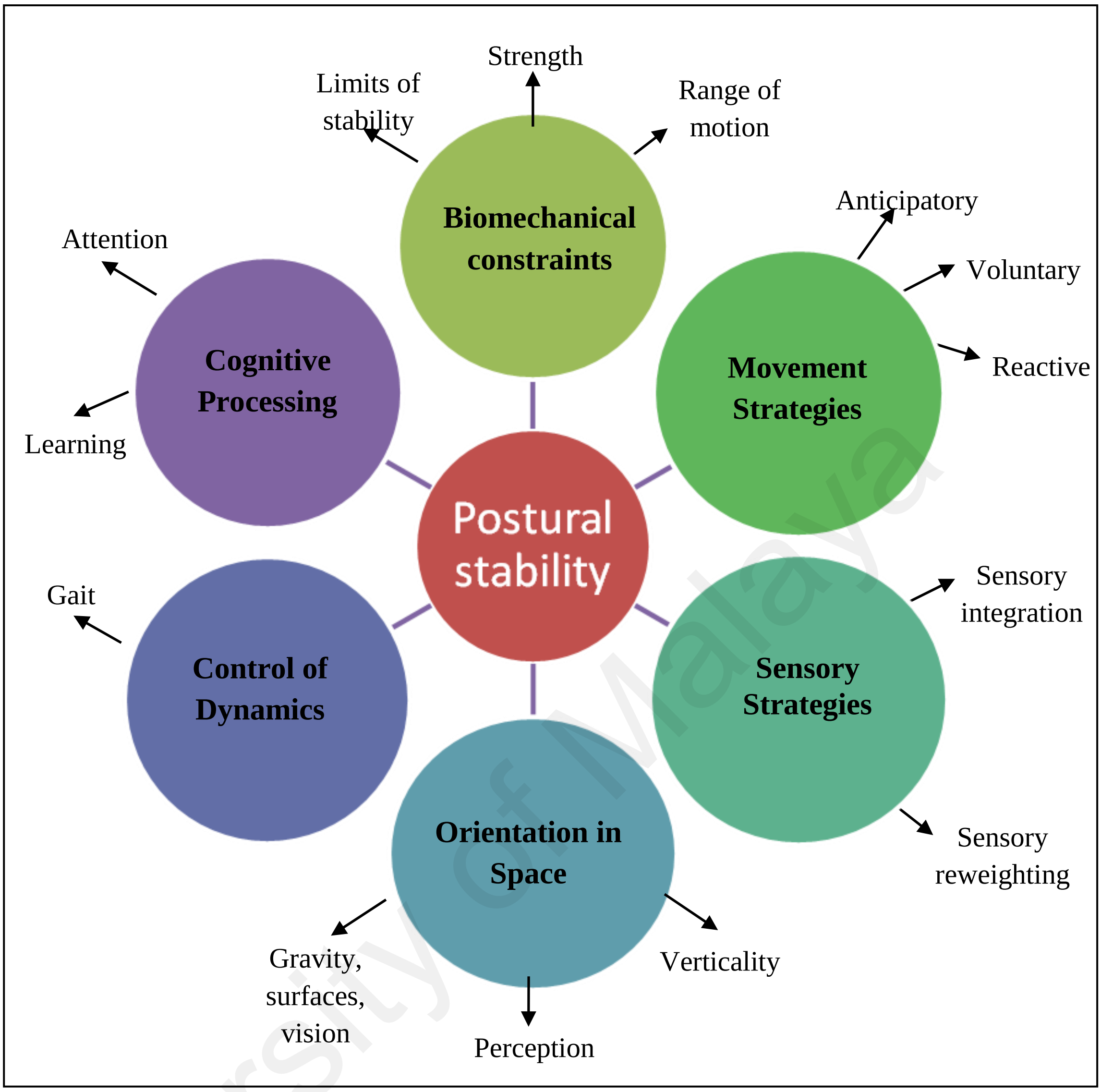


Figure 2.11: Vital components contributing to postural stability (Reproduced from Horak, 2006).

Previous work of notable researchers concluded that the ankle strategy will be executed to shift the CoM by rotating the body around the ankle joint during small perturbation while on a rigid-flat surface (Horak, 2006). In contrast, the hip strategy is required during events such as significant body sway around the hips and trunk, larger perturbation magnitude, standing on narrow beam or complaint surface or no previous experience with the perturbation (Horak, 1997). For conditions with very fast or large perturbations such as walking or hopping, the stepping or stumbling strategy is used to reposition the CoM within the changing base of support (Horak, Shupert and Mirka, 1989).People with high risk of falling or fear of falling use the hip and stepping strategy more often than the ankle strategy in maintaining postural stability (Horak, 2006).

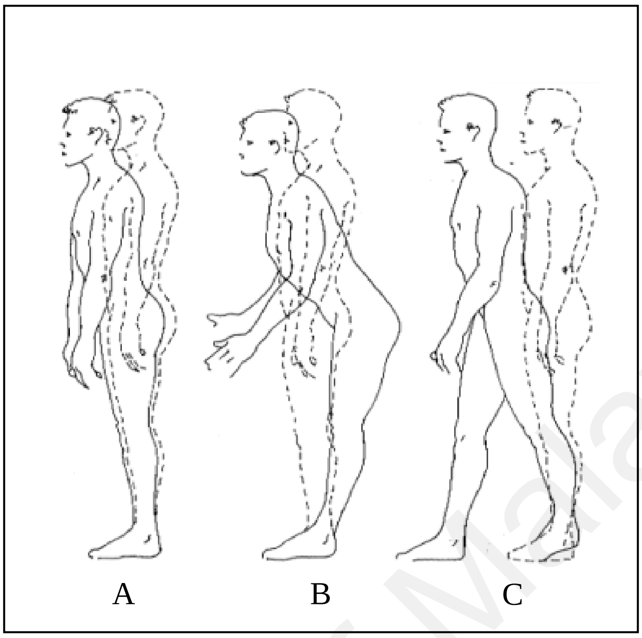


Figure 2.12: Three common movement strategies to maintain postural stability during upright standing; A. ankle strategy, B. hip strategy and C. stepping strategy (Adapted from Seeger, 2003).

The selection of movement strategies also relies on the types of perturbation applied on the balance system. For instance, reactive controls will response to unexpected external perturbation applied without the knowledge of a person (for example, tilted support surface) (Winter, 1995). Reactive movement strategies help a person to develop coordinated multi-joint movement to ensure the body is located within the stability limits boundary (Salsabili *et al.*, 2011). On the other hand, proactive control will respond to voluntary initiated internal perturbation (for example, leg raising) and also to anticipatory well-learnt perturbation (for example, walking) (Winter, 1995).

The next sub-component is the sensory strategies which help a person to identify and select appropriate sensory information for the control of postural stability. Horak (2006) proposed two function of sensory strategies which are sensory integration and sensory reweighting. These two functions are important to maintain stability during altered sensory conditions (for example: eyes closed, visual conflict, compliant surface) as well as during determination of stability limit and vertical position relative to the environment (Horak, 1997). Sensory information from the visual, somatosensory and vestibular systems is integrated by the CNS system to appropriately interpret the environment condition (Horak, 2006).

Sensory cues from the visual system originate from the retina that detects motion to determine self-motion or movement of the environment (Redfern, Yardley and Bronstein, 2001). Deficiencies in visual cues may cause detrimental effects on postural stability of a healthy person such as postural changes, disequilibrium and motion sickness (Redfern *et al.*, 2001). Tanaka and co-workers (2000) suggested that the visual sensory plays the most crucial role in maintaining stability for the elderly than the younger individuals. Moreover, visual cues are thought necessary for maximal stability (Fitzpatrick, Rogers and McCloskey, 1994).

Another sensory component involved in postural stability control is the somatosensory system, which comprise of muscle proprioception, joint and cutaneous afferents (Figure 2.13) (Horak, Nashner and Diener, 1990). Proprioceptors which are located in muscles, joints, ligaments and tendons are very sensitive to stretch or pressure in the surrounding tissue (Shumway-Cook and Woollacott, 2001). Muscle spindles and Golgi tendon organs are considered as important proprioceptors which provide information to the CNS system to determine the relative positions and movements of the body (Fitzpatrick *et al.*, 1994). The cutaneous receptors function via the tactile senses of touch, pressure, vibration, temperature and pain (Guskiewicz and Perrin, 1996).

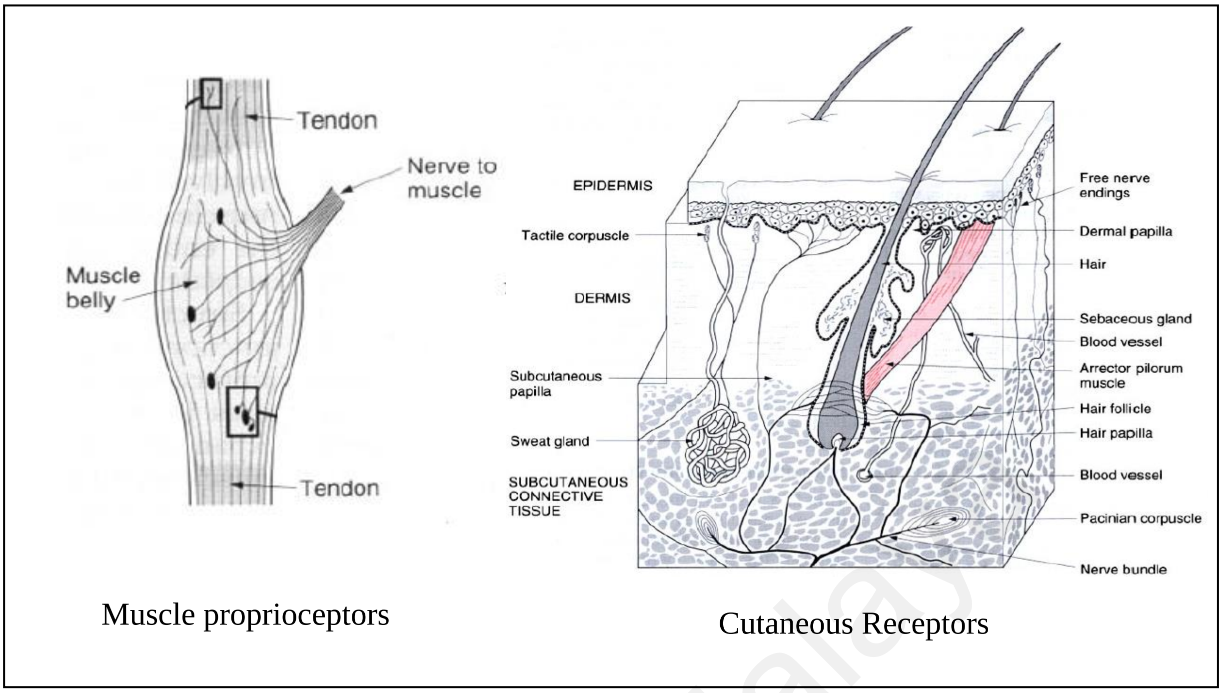


Figure 2.13: Somatosensory system which consist of muscle proprioception, joint and cutaneous afferents (Retrieved from Palastanga, Field and Soames, 2002).)

Sensory cues from the somatosensory information provided by feet in contact with the support surface appears to be preferred in healthy adults in maintaining postural stability (Gutierrez *et al.*, 2001; Shumway-Cook and Horak, 1986). It is proposed that the tactile and proprioceptive information from the sole of the feet and flexor muscle around the ankle joint are used to indicate the body's movement relative to the standing surface and the quality of the surface (for example: soft, hard or uneven) (Kavounoudias, Roll and Roll, 2001). On the other hand, Fitzpatrick and associates (1994) proposed that the proprioceptive signals from receptors in the leg muscles are sufficient to maintain a stable upright stance. In relation to this, a person with reduced somatosensory input such as in the case of peripheral neuropathy and amputation, the ability to control postural stability is reduced (Geurts and Mulder, 1992). Due to partial or total loss of somatosensory information from the feet, the hip strategy is used instead of ankle strategy to regain postural stability (Horak *et al.*, 1990).

The vestibular system (Figure 2.14), which is located in the inner ear (known as labyrinth), consists of vestibular apparatus such as vertical semicircular canals, otolith organs, vestibular neural processing and the vestibulospinal reflex (Black, 2001). This system detects angular motion as well as linear acceleration and deceleration especially during resolving conflicts between vision and proprioception sensory (Guekiewicz and Perrin, 1996; Nashner, Black and Wall, 1982).

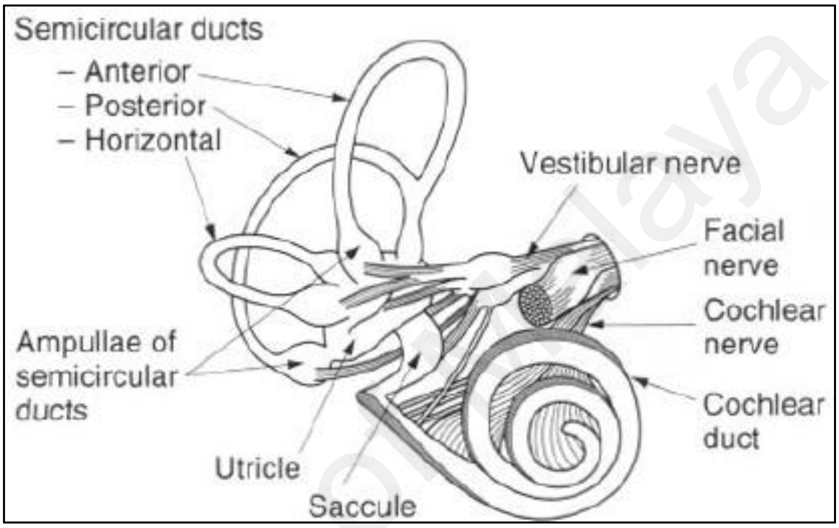


Figure 2.14: The vestibular system which is responsible for maintaining postural stability (Retrieved from Palastanga, Field and Soames, 2002).

According to Horak and co-workers (1990), the execution of hip strategy requires vestibular information. Despite the critical role of the vestibular system, the vestibular information is proposed as unnecessary for postural stability during quiet standing when visual (eyes-opened) and proprioception (firm and stable support surface) information is accurate (Horak *et al.*, 1990). However, several studies showed that postural stability during undisturbed upright stance was decrease when the head was tilted, causing the otolith organs to be positioned beyond their working range (Jackson and De l'Aune, 1996; Jackson and Vuillerme and Rougier, 2005).

The postural stability system receives multiple sensory inputs, hence sensory re-weighting is another vital component for maintenance of postural stability. As such, when a person changes his position from one sensory condition to another, he must also re-weight his dependency on each sensory (Horak, 2006). For instance, a healthy person walking from a well-lit room to a dark room on a firm surface will rely most on somatosensory system but will change his dependency on visual and vestibular system when standing on an unstable surface. Thus, these unique interactions among the three primary sensory inputs to maintain postural stability has encouraged Nashner and associates (1982) to propose the sensory organization testing (SOT) for a comprehensive assessment of sensory interactions in balance.

The recent version of this test is known as the Clinical Test of Sensory Interaction and Balance (CTSIB), where the subjects are required to stand quietly for 20s under six different conditions which altered the visual and somatosensory information (Table 2.2) (Shumway-Cook and Horak, 1986). This testing altered the visual cues by standing with eyes-closed or wearing visual-conflict dome while somatosensory input was altered by standing on a firm or on medium-density foam. The theory behind the SOT and CTSIB is that a healthy subject should be able to ignore the inaccurate sensory input and maintain postural stability by utilising information available from other accurate sensory inputs (Guekiewicz and Perrin, 1996). Hence, an understanding of the different components and their contribution to the control of postural stability will aid to systematically determine the underlying cause of balance deficit in a particular person (Horak, 2006).

Table 2.2: Sensory information available during sensory organization tests. Abbreviations; vis: visual, vest: vestibular, prop: proprioceptive, sway-ref'd: sway referenced (Reproduced from Black, 2001)

SOT condition	Visual surround	Platform	Accurate sensory feedback	Altered sensory feedback
1	fixed	fixed	vis, vest, prop	—
2	eyes closed	fixed	vest, prop	—
3	sway-ref'd	fixed	vest, prop	vis
4	fixed	sway-ref'd	vis, vest	prop
5	eyes closed	sway-ref'd	vest	prop
6	sway-ref'd	sway-ref'd	vest	vis, prop

The next element required for postural stability is the orientation in space. For a stable posture, the ability to orient the body parts in relative to gravity, support surface, visual surrounds and internal references is very crucial (Horak, 2006). Failure to response to a tilted or inaccurate internal representation will cause postural alignment that is not aligned with the gravitational vertical and therefore will result in postural instability (Horak, 2006). Another aspect of postural stability is the control of dynamics such as during walking or changing from one posture to another. This is because during these activities, the CoM is not located within the BoS (Horak, 2006). Finally, good postural stability also requires cognitive processing from attentional and learning resources (Teasdale and Simoneau, 2001). Attentional resources is important since additional attention is required when postural stability task becomes more difficult such as solving simple mathematical question during quiet upright standing (Horak, 1997).

2.3.5 Postural stability during unperturbed upright standing

An unperturbed, upright quiet standing seems like a breeze and easy task. However, the body is a flexible system consisting of multiple segments connected together by the muscles surrounding the joints. As such, maintaining upright standing posture requires the same process like other movement which requires proper planning and execution strategies (Loram *et al.*, 2005). In a healthy person, any deviation of the body's CoM from its equilibrium position will be detected by a collective of sensory inputs to produce corrective motor response to keep the CoM over the BoS within the limit of stability (Horak, 2006; Kaufman, 2004). During an upright standing task, a cone has been used to represent the limits of stability when standing with the feet together on a flat surface as illustrated in Figure 2.15 (McCollum and Leen, 1989; Wallace, 2007). Hence, the posture of upright quiet standing is deemed as challenging because of the high location of the CoM with two third of the body mass having to be balanced over a small base of support, which is the feet (Loram *et al*., 2005; Winter, 1990a).

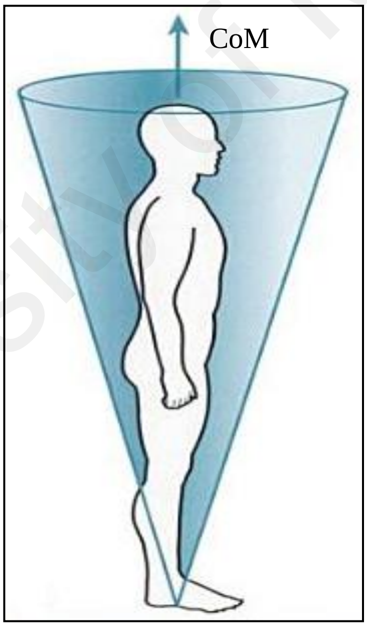


Figure 2.15: The CoM is located within the limits of stability conical-shaped area during upright standing (Reproduced from Wallace, 2007).

The regulation of stability control during upright standing has been described as an inverted pendulum model which is pivoted at the ankle (Fitzpatrick *et al*., 1992; Winter *et al*., 1998). As such, this model indicates that the movement of the body's CoM is controlled through the movement of the centre of pressure (CoP) under the feet (Winter *et al*., 1998) and that the CoP follows closely the CoM as long as the person stands like an inverted pendulum (Borg and Laxaback, 2010). According to the work of Winter and associates (1998), the CoM is located approximately 5cm anteriorly to the ankle joint in the anterior-posterior direction when standing upright. As a result, the angular velocity (ω) is produced, causing forward sway (Figure 2.16). To correct the body's forward sway, the CoP must be located anteriorly to the CoM. Consequently, further forward sway will generate angular acceleration (α) which causes backward sway. When the CNS senses the posterior shift needing correction, the angular acceleration will be reversed so that the CoP lies behind CoM and the body returns to its initial condition. This observation indicates that the CoP is continuously moving closely following the CoM while increasing and decreasing the angular velocity and acceleration to keep the CoM within the BoS (Aoyama *et al.*, 2006; Winter, 1998).

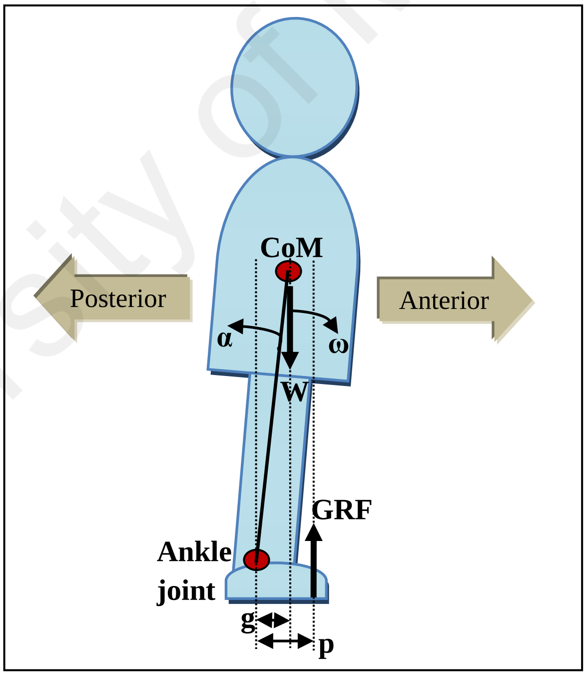


Figure 2.16: Relative position of CoM and CoP during swaying while standing quietly on a firm surface. Abbreviations; W: body weight, GRF: ground reaction force, g: CoM position, p: CoP position, α: angular acceleration and ω: angular velocity.

Due to the dynamic nature of upright quiet standing, this task requires continuous muscular activity to immobilize joints that causes body movements intervening along the anterior-posterior (AP) and medial-lateral (ML) axes

(Balasubramaniam & Wing, 2002). It is also proposed that the restoration torque produced by the muscles around the joint is subjected to the setting of appropriate joint stiffness to control body's CoM during quiet standing (Winter *et al.*, 1998). Researchers had found an important relationship between functional ankle stability and the ability to maintain balance (Pintsaar *et al*., 1996). Consequently, other researchers theorized that the stiffness of the ankle muscle might play an important role in maintaining balance and joint stability (Blackburn *et al*., 2000; Vrieling, 2008a). In the absence of perturbation, the muscle contracts eccentrically to resist the gravitational forces. However, in order to maintain postural stability during perturbation, concentric muscle contraction is essential. Hence, stiffer muscles potentially increase the efficiency of balance control mechanism. In a healthy person, the ankle plantarflexors and dorsiflexors are considered sufficient to control the net ankle moment during quiet standing in anterior-posterior direction with minimal movement of hip or knee joints (Winter, 1995).

Moreover, Winter *et al*. (1998) measured the CoP and CoM excursion during quiet standing and showed that an increase in ankle joint stiffness will reduce the amount of postural instability. However, maintaining postural stability by controlling ankle joint stiffness alone was reported as insufficient (Loram and Lakie, 2001). To control the postural stability in medial-lateral direction, the abductor and adductor muscles of the hip initiate the load/ unloading mechanism along the frontal plane (Winter, 1995). In addition, it is evident that other leg muscles as illustrated in Figure 2.17 are also involved in the control of balance in anterior-posterior and medial-lateral direction which produce stretch reflex to resist the lengthening of the muscle (Shumway-Cook and Woollacott, 2007; Wallace, 2007; Winter, 1995). For instance, Gatev *et al.* (1999) demonstrated that body sway can be restricted by the control of ankle stiffness with the activated of gastrocnemius muscle working in a spring-like manner.

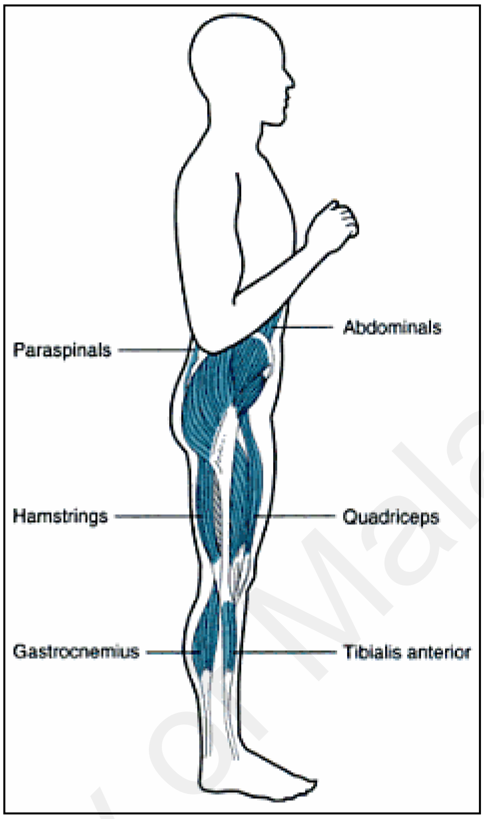


Figure 2.17: Main muscle groups that control the CoM during standing (Reproduced from Wallace, 2007).

Generally, it has been reported that for normal subjects, body sway occurs more in anterior-posterior than medial-lateral direction, eyes-closed trials produce greater sway than eyes-open trials and older subjects demonstrate greater sway than younger subjects (Guskiewicz and Perrin, 1996). However, quiet upright standing in people with motor and sensory deficit, such as individuals with lower limb amputation and knee osteoarthritis, is often characterised by an increase of body sway compared to age-matched healthy controls (Duclos *et al.*, 2009; Knoop *et al.*, 2011) and weight-bearing asymmetry due to the CoM position towards the unaffected side (Clark and Zernicke, 1981; Yanohara *et al.*, 2014).

2.3.6 Postural stability during perturbed upright standing

During activities of daily living, we are often faced with unexpected perturbation which may jeopardize the postural stability system. Such external perturbations include tripping, sudden stop or start, being pushed or pulled and slippery or uneven surface. Hence, response to destabilisation caused by unexpected perturbation is vital to examine the integrity of the sensory and motor processes involved in stability control (Winter *et al.*, 1990a). To create the unexpected perturbation, researchers used movable support surface (translation or tilting surface) and/ or visual conditions while a person maintains his postural stability (Mancini and Horak, 2010). For instance, postural stability during platform tilting requires the activation of posterior muscles of the leg and trunk to control forward sway while the anterior muscles of the leg and trunk are responsible to control back sway (Winter, 1995). Sensory perturbations also serve as an alternative to determine whether a person can re-weight the available sensory information by identifying sensory conditions and to increase reliance on the accurate sensory available to maintain postural stability in altered environments (Mancini and Horak, 2010).

2.3.7 Postural stability control during upright standing in lower-limb amputees

Individuals with lower limb amputation represent a unique rehabilitation group due to the total loss of neuromuscular and skeletal muscles. Specifically in a below-knee amputee, the significant role of the ankle joint complex in maintaining balance is jeopardized due to the replacement of the joint complex with prosthetic components with reduced joint mobility and muscle strength (Blackburn *et al*., 2000; Vanicek *et al*., 2009). Moreover, it has been shown that an injured ankle joint suffers not only from damaged anatomical structures, but also causes deficit to the mechanoreceptors to convey appropriate information to the CNS (Blackburn *et al*., 2000). As such, it is reasonable to corroborate that a total loss of such joint will give major impact to the ability of controlling postural stability in person with below-knee amputation. In fact, excessive postural instability which may cause falling can occur especially in challenging sensory conditions due to the loss of somatosensory input from the muscles, tendon and skin of the amputated leg (Horak, Shupert and Mirka, 1989). Hence it is not surprising when community-living lower-limb amputees are reported with increased risk of falling compared with age-matched, able-bodied people, with 52% of amputees having experienced a fall within a 12-month period (Miller, Speechley and Deathe, 2001b).

Realizing the importance of understanding the reorganization of postural stability in individuals with lower limb amputation, researchers have shown interest in providing evidence-based studies to identify the underlying factors controlling postural stability. Previous studies reported that amputees suffer deteriorating balance function due to several influential factors. Although changes in postural control in amputees have been studied, the results have been conflicting. In general, it was accepted that the person with lower-limb amputation exhibited greater body sway than the healthy person (Buckley *et al.*, 2002; Duclos *et al*., 2009; Jayakaran, Johnson and Sullivan, 2015 Orechovska *et al.*, 2015a).

Particularly when compared to a healthy normal group, the below-knee amputee group demonstrated significant increased postural instability in medial-lateral direction during upright standing while looking straight ahead and with eyes-closed (Hermodssson *et al*, 1994). Similarly, dysvascular elderly amputees with lower scores of circulatory status were associated with greater standing instability in medial-lateral direction (Quai, Brauer and Nitz, 2005). Whereas Bolger and associates (2014) found conflicting evidence that the CoM displacement and stability margin were similar between individuals with transtibial limb loss and matched controls during randomly applied multi-directional support surface translations. Nevertheless, greater CoP displacement was found in the intact leg during anterior-posterior perturbations, and under the prosthetic leg in medial-lateral perturbations (Bolger *et al.*, 2014).

Cause of amputation is another parameter that can influence standing stability. It has been shown that standing imbalance is more apparent in vascular amputees compared to non-vascular amputees (Hermodsson *et al.*, 1994; Molina-Rueda *et al.*, 2016). In contrast, another study showed that postural control in the dysvascular amputation group was not different from the traumatic amputation group in altered sensory conditions (Jayakaran *et al.*, 2015). Additionally, shorter residual limb is associated with poor stance balance due to major loss of proprioceptive sensory at the lower leg (Lenka and Tiberwala, 2007; Orechovska *et al.*, 2015b). In regards to the level of amputation, transfemoral amputees exhibit poor balance performance compared to transtibial amputees due to the missing knee joint combined with greater asymmetry in the loading distribution and increased deviations of the CoM in intact leg (Fernie and Holliday, 1978; Rougier and Bergeau, 2009). Another common consensus from previous studies was that standing load distribution was greater on the intact leg than the amputated leg (Nederhand *et al.*, 2012; Hlavackova *et al.*, 2011; Duclos *et al.*, 2009; Vrieling *et al.*, 2009). Overall, person with lower-limb amputation faced with poor postural stability control despite the amputation aetiology or level which suggests that the residual limb is not sufficient to completely compensate for the foot as a source for proprioception sensory inputs (Quai *et al.*, 2005).

Although the type of prosthetic knee joint, suspension and socket may influence the standing stability, there is not enough evidence to support such notion (Kamali *et al.*, 2013; Lenka and Tiberwala, 2010). Nevertheless, modifications of prosthetic alignment in the sagittal plane was shown to negatively affect the movement strategy in controlling postral stability in belo-knee amputees (Kolarova, Janura, Svoboda and Elfmark, 2013)

Interestingly, the passive mechanical properties of the prosthetic foot, one of which is the stiffness, have been suggested to influence stability control in anterior-posterior direction among below-knee amputees (Buckley *et al*., 2002; Curtze *et al*., 2012; Kamali *et al*., 2013; Nederhand *et al*., 2012). In fact, the work of Vittas and associates (1986) showed a reduced body sway in AP and ML direction compared to healthy person which may be due to the stiff ankle of the prosthetic foot. Some researchers suggested the stiffness of prosthetic foot provides an external torque to the knee joint to sustain its stability (Johannesson *et al*., 2010, Mackenzie *et al*., 2004).

While these previous studies hypothesized the possible role of prosthetic stiffness in postural stability control, only Nederhand and co-workers (2012) objectively assessed the relationship between the ankle stiffness of the different prosthetic feet of the amputees and the balance performance during the platform perturbations. From the findings, the prosthetic ankle stiffness was significantly correlated with the dynamic balance control in above- and below-knee amputees. By considering the positive correlation between stiffness and balance control, it may augment the hypothesis that the choice of prosthetic feet with specific properties can influence the postural stability during upright standing. As such, they argued that stiffer prosthetic foot coupled with balance training could improve the motor skills in utilizing the prosthetic foot as a stabilising mechanism. However, due to the heterogeneity in terms of amputation level and prosthetic feet types involved in this study, the authors urged for further investigation with repeated testing using different prosthetic feet in one user.

2.4 Quantitative instrumented assessment of postural stability balance

2.4.1 Overview

Previous studies have assessed balance during upright standing in lower limb amputees using various approaches. Balance can be assessed by means of four conditions which are static, dynamic, anticipatory and reactive (Yim-Chiplis and Talbot, 2000). Static balance is defined as the ability to maintain the CoM within BoS during quiet upright standing or sitting. Dynamic balance occurs when upright posture is maintained while both CoM and BoS are moving. Anticipatory balance is the ability to maintain balance during expected perturbation. Reactive balance is the ability to respond to unexpected perturbation. Due to the complexity of balance control, qualitative and quantitative assessments have been developed to evaluate balance in individuals with balance deficits. In clinical practice, general functional balance of amputees is assessed using the qualitative clinical screening instruments in order to determine whether or not balance deficit exists and if treatment is needed (Horak, 1997).

Several validated questionnaire tools such as Prosthesis Evaluation Questionnaire (Miller *et al*., 2001a), Houghton Scale (Devlin, Pauley, Head and Garfinkel, 2004), Berg Balance Scale (Wong, Chen and Welsh, 2013) and Locomotor Capabilities Index (Franchignoni *et al*., 2007) have been used to assess self-perceived balance capability. While these assessments provide useful information on the balance abilities, they provide limited information on the underlying balance impairments. Technological advancements have introduced quantitative measurements to objectively assess balance to identify the cause of balance deficits, assess balance improvement as well as for balance training purposes (Yim-Chiplis and Talbot, 2000). Assessments using the force platform (Buckley *et al*., 2002; Curtze *et al*., 2012; Hermodsson *et al*., 1994; Nederhand *et al*., 2012), motion analysis system (Lee, Lin and Soon, 2007), and computerized dynamic posturography (Barnett *et al*., 2012; Vanicek *et al*., 2009) have been used to objectively quantify balance in people with lower limb amputation.

The most common clinical instrument used for postural stability assessment is the measurement of center of pressure (CoP) using the force platform, which is not sufficient to explain the control of standing posture (Winter *et al*., 1990a; Winter, 1995; Yim-Chiplis and Talbot, 2012). Results from other assessment methods such as star excursion balance test (SEBT) are difficult to relate to activity of daily living (Cachupe, Shifflett, Kahanov and Wughalter, 2001). Therefore, postural balance assessment with various standing conditions coupled with alterations of sensory input is necessary in order to obtain a more comprehensive analysis of the mechanism underlying the postural control of human.

Since balance is considered as one of the critical deciding factors that affect prosthesis prescriptions (Stark, 2005), several studies related to balance in amputees have been designed to explore the mechanism involved in the control of balance. Hence, the current systematic review aims to summarize the available evidence on the quantitative instrumental aspects of balance assessment on individuals with lower limb amputation during upright standing.

2.4.2 Methodology for systematic review

A computerized search was performed with the use of four online databases: PsychInfo (from 1806 to 2014, PubMed (from 1949 to 2014), Embase (from 1949 to 2014), and Web of Knowledge (from 1980 to 2014). The searched terms used included #1: stabil* OR balance OR equilibrium OR postur*, #2: amput*, #3: assessment OR evaluation OR measurement, and #4: walk* OR run* OR* stairs*. Then, these specific search phases were combined using the Boolean operators for the search of (#1 AND #2 AND #3) NOT (#4). A supplementary manual search from the reference list of retrieved articles was also performed to identify any relevant articles that were not listed in the database search.

The next stage is to determine the selection criteria for articles obtained from the search. The titles and abstracts of all articles found from electronic and manual search were independently screened for potential eligibility. A risk of bias assessment was conducted independently by two reviewers in order to determine the quality of the included studies. Next, all eligible articles were further screened for inclusion and exclusion criteria. Articles were included if they met the following selection criteria: (1) written in English, (2) instrumented assessment of static and dynamic balance in lower-limb amputees, and (3) amputees participant aged 18 years and above. The exclusion criteria were as follows: (1) studies on balance during activities other than standing, (2) studies in which the stepping strategy was used, (3) single-case studies, (4) not original article (e.g: expert opinions, literature reviews, comment/ letter to Editor, proceedings, dissertation) and (5) articles that were published in magazines or newsletters. An additional exclusion criterion for selected articles was those studies that involved participants with other medical conditions that can affect their balance, such as orthopedic, neurologic, or rheumatic disorders. Full-text articles were assessed if information from the titles and abstracts was not sufficient for article selection decision. Disagreements between the two reviewers were resolved by discussion with a third reviewer to reach a consensus.

Validated assessment tool to critically appraise balance studies in lower limb amputees has not been yet established. Therefore, the methodology quality of the selected articles was evaluated with a purpose-designed checklist adapted from previous studies (Downs and Black, 1998; Mazaheri, Coenen, Parnianpour, Kiers and van Dieen , 2013; van der Linde *et al*., 2004). This checklist consists of three major aspects with a total of 14 criteria (Table 2.3). The first aspect, which was ‘participants’ selection’, consists of the following eight criteria on randomization and functional homogeneity: gender, age, weight, height, activity level, cause of amputation, and level of amputation. According to the Medicare Functional Classification Level (MFCL), the four activity levels are as follows: household ambulator (K1), limited community ambulator (K2), community ambulator (K3) and high level user (K4) (Gailey *et a*l., 2002).

The ‘balance assessment’ aspect consists of the following four criteria: acclimation period, type of balance assessment, parameters of the outcome measures, and the information on the prosthesis. The final aspect was ‘statistical validity’, in which two criteria were assessed in terms of the appropriate statistical test (parametric or non-parametric) and information on the statistical results. The possible maximum score is 14, with a higher score indicating better methodology quality. Each criterion was scored as either “1” for a “yes” answer or “0” for a “no/invalid/not provided/not clear” answer. When a criterion was not applicable, it was not counted for the final scoring. Consultation from the third reviewer was required when disagreement occurred between the two reviewers (during the scoring process. In this review, a comparison was made on the methodological quality of the studies rather than on the differences between the control and transtibial or transfemoral groups.

Table 2.3: Criteria used for quality assessment of the reviewed articles.

Criteria	Indication	Scores
Participants selection		
1.Randomization	Sequence of test	1=Yes, 0=No/ Not reported
2.Control of functional homogeneity		1=For study that consider confounding effect of each parameters, 0=Not considered / Not reported
2A Gender	M/F	
2B Age	Years	
2C Weight	Kilogram, kg	
2D Height	Meter, m	
2E Activity level	K1/K2/K3/K4 or high/ low	
2F Cause of amputation	Vascular/ Non-Vascular (VD,T,C, CR)	
2G Level of amputation	PFA/ TT/ TF	
Balance assessment		
3.Acclimation period	Days/ weeks/ months	1=For study that provide any information for each item, 0= Not provided /not clear / invalid
4.Type of balance assessment	Static/Dynamic	
5.Outcome measures parameters	For example: Stability index/ CoP-related parameters/ load distribution/ joint moments	
6. Prosthesis information	Prosthetic foot/ knee/ socket / suspension	
Statistical validity		
7. Use of appropriate statistical test	Appropriate statistical tests were used to assess differences in balance	1=Yes, 0=No/ Not provided
8. Sufficient information on statistical results	Actual probability (e.g p=0.035 rather than p<0.05) and standard deviation was reported	

Note. F: Female: M: Male: K: activity level based on Medicare Functional Classification Level (MFCL); VD: Vascular disease; T: Traumatic; C: Congenital, CR: Carcinoma; Static: assessment during quiet standing without perturbation; Dynamic: assessment during standing with internal or external perturbation; PTB: Patellar tendon bearing; SPTB: Supracondylar patellar tendon bearing; TSB: Total surface bearing; PFA: Partial foot amputation; TT: Transtibial; TF: Transfemoral.

After the final selection of articles, important information listed in the methodology quality criteria was extracted. Other additional pieces of information, such as the first author's name, year of publication, study size, participants' demographic data, type of balance assessment, type of perturbation, test conditions, foot position, test equipment, and outcomes measured, were tabulated.

Furthermore, because prosthetic mechanisms may affect the control of standing posture in lower limb amputees, we extracted information on the types of prosthetic knee, foot, suspension, and socket. The results on muscle strength and subjective balance test scores were not extracted. Instead of using their commercial names, we classified the prosthetic feet used in the studies according to its type: conventional, single-axis, multi-axis, and energy savings and return (ESAR) foot (Hafner, 2006).

2.4.3 Results obtained from systematic search

A total of 461 articles were initially retrieved from the electronic search: 150 from PsychInfo, 166 from Medline, 69 from Embase, and 76 from Web of Knowledge. Another 12 articles were found from the references of related articles. After the articles were further screened for duplicates, 451 articles remained for title and abstacts screening (Figure 2.18). After applying the inclusion/ exclusion criteria, another 407 articles were eliminated. The most common rejection reasons were due to studies being unrelated to balance, not original articles, studies other than standing and only recruited able-bodied participants. A total of 44 articles were assessed for eligibility. Of these, 10 articles had to be excluded because of the absence of a full-text version. In total, 34 articles were included in the review. The process of inclusion and exclusion was based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram (Moher, Liberati, Tetzlaff and Altman, 2009).

For this section, references from reviewed articles are tabulated in a table in Appendix B. A summary of the participants of the studies included in the review is reported in Table 2.3. In total, 552 people with lower limb amputation (356 or 65% transtibial, 167 or 30% transfemoral, 21 or 4% partial-foot amputation, 8 or 1% knee disarticulation) and 425 able-bodied people had participated in the studies. Twenty-eight studies were conducted based on the same type of amputation, which was transtibial, transfemoral, or partial foot. Another eight studies failed to separate the participants according to their types of amputation (Appendix B1).

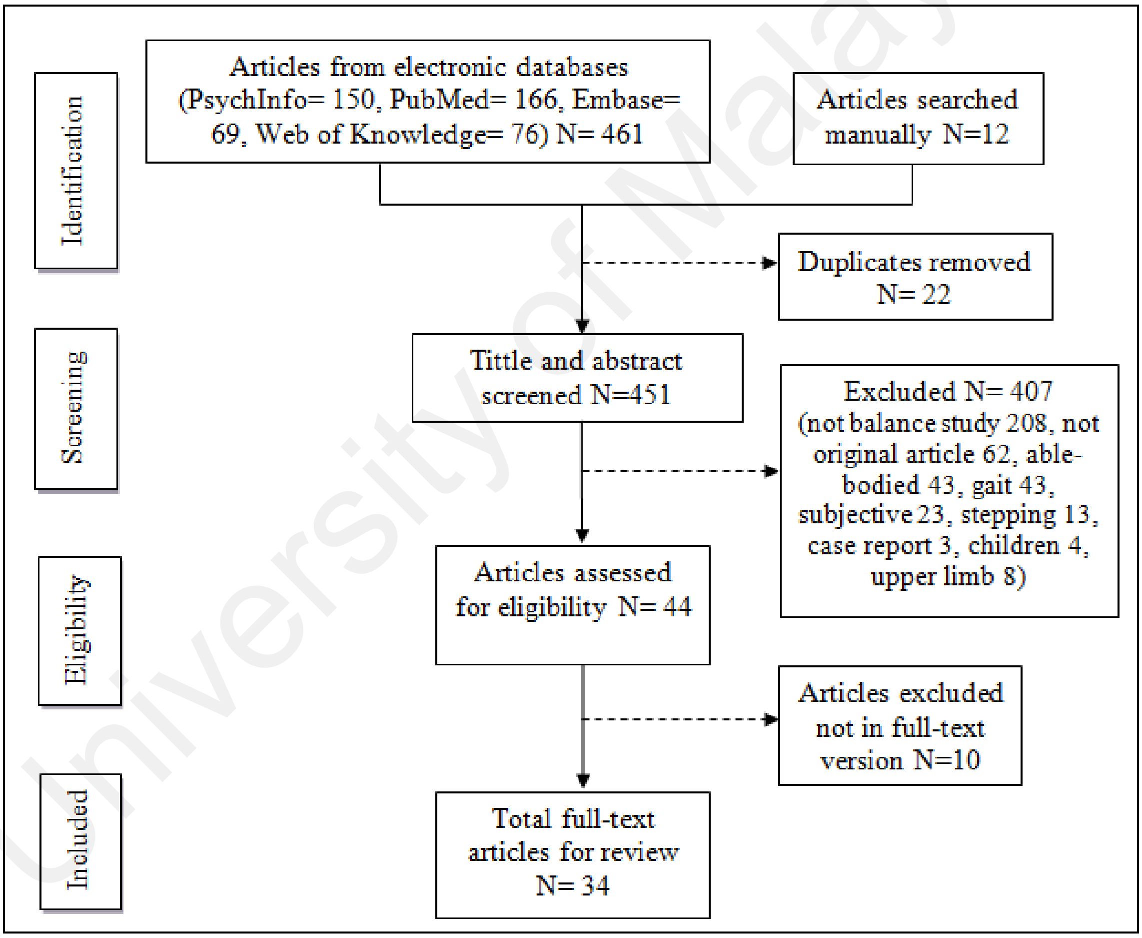


Figure 2.18: Flow chart of article selection process according to PRISMA guidelines.

The age of the amputee participants ranged from 24 to 72 years. A total of 18 studies (53%) included a control group in their protocol, whereby 15 of them involved age-matched able-bodied adults (Appendix B2). In addition, four studies mentioned about the amputees' activity level based on the Medicare Functional Classification

Level (MFCL), nine studies provided complete demographic information (age, weight, height, gender) of all participants, 20 studies reported on the years of post-amputation, and only two studies mentioned the acclimation period to test the prostheses (Appendix B3). Among the selected studies, 16 studies grouped the participants into either the vascular or non-vascular group (Appendix B4). Of the reported etiology, 185 of the amputation had been an outcome of vascular reason and 202 of non-vascular (trauma, carcinoma, congenital, unknown disease) reason. However, five of the reviewed studies have not mentioned the cause of amputation (Appendix B5).

About 94% of the studies (32/34) provided incomplete information on the prosthesis components used during the evaluation of balance in the amputees (Appendix B6). In addition, only three studies were found to have amputees wearing the same type of prosthetic foot and six studies using the same type of socket for each of the participants to control the confounding effect it may cause (Appendix B7). Among the studies that mentioned the type of prosthetic foot, eight studies used the conventional foot, seven used the ESAR foot, seven used the multiaxial foot, and two used the single axis foot (Appendix B8). The most common prosthetic knee joint used for transfemoral amputees was the microprocessor knee, followed by the polycentric, hydraulic and mechanical passive knees.

The details of the experimental protocols used in the reviewed studies are listed in Table 2.4. A total of 25 studies measured balance during static double leg standing, four during single leg standing on intact leg and two during single leg standing on prosthetic leg (Appendix B9). Dynamic balance because of unexpected or expected perturbations during bipedal standing was reported (Appendix B10). Balance was mostly assessed with the use of a force platform in 53% (18/34) of the studies, followed by computerized posturography, displacement transducers and motion analysis system

(Appendix B11). A combined assessment approach involving the force platform and motion analysis system or goniometer was reported in seven studies (Appendix B12).

Table 2.4: Summary of study characteristics.

First author (Year)	Study size (N)	Sex (F/M)	Age range/ mean(s.d) (years)	Weight range/ mean(s.d) (kg)	Height range/ mean (s.d) (m)	Amputa -tion Cause	Activity level	Post-amp	Acclim. time	Prosthesis intervention
Nederhand *et al*. [2012]	6TF 8TT 6AB	5M 1F 7M 1F NP	45-63 33-62 NP	60-90 60-105 NP	1.64-1.84 1.73-1.94 NP	9T, 1CG, 2VD, 2C	K3 K3	1-32	NP NP	Knee : HYD, MP, POLY Foot : SA, ESAR Susp. : PL, S Socket: NP
Barnett *et al*. [2012]	7TT	7M	44-70	77-107	1.74-1.93	4VD, 3 non-VD	NP	NP	NP	Foot : MA, ESAR Susp.: NP Socket: NP
Curtze *et al*. [2012]	15TT 13AB	15M 13M	55.1 (9.8) 53.1 (10.6)	92.5 (13.9) 87.2 (10.1)	1.83 (0.5) 1.87 (0.6)	10T, 1CG, 4VD	NP	2-44	NP	Foot : CF, MA, ESAR Susp.: NP Socket: NP
Mayer *et al*. [2011]	10TT[a] 18TT[b]	8M 2F 12M 6F	61.1 (10.5) 64.8 (9.5)	82.9 (17.2) 65.8 (16)	1.72 (0.1) 1.64 (0.1)	21 VD	NP	4.2 5.6	NP	Foot : CF Susp.:CL Socket: PTB
Hlavackova *et al*.[2011]	8TF	NP	26.1 (13.5)	NP	NP	8VD	NP	6	NP	NP
Mohieldin *et al*. [2010]	14TT/ 7TF, 20AB	20M 1F 18M 2F	45.2 (1.8) 41.3 (3.1)	NP NP	NP NP	15T, 6VD	NP	0.2	NP	Knee : NP Foot : CF, MA, ESAR Susp. : PL Socket: NP
Lenka & Tiberwala [2010]	20TT	NP	34.3 (9.6)	63.3 (3.7)	1.61 (2.8)	NP	NP	NP	NP	Foot : CF Susp.: NP Socket: PTB

Table 2.4, Continued

First author (Year)	Study size (N)	Sex (F/M)	Age range/ mean(s.d) (years)	Weight range/ mean(s.d) (kg)	Height range/ mean (s.d) (m)	Ampu-tation Cause	Activity level	Post-amp	Acclim. time	Prosthesis intervention
Vanicek *et al.* [2009]	5TT[e] 4TT[f] 5AB[e] 4AB[f]	5M 2M 2F 4M 1F 1M 3F	54 (14) 64 (15) 52 (16) 72 (5)	76(13) 77(21) 78 (13) 82 (14)	1.77(0.1) 1.66(0.2) 1.78(0.2) 1.67(0.1)	6T, 1CG, 2VD	NP NP	4 13	NP NP	Foot : MA Susp.: NP Socket: NP
Hlavackova *et al*.[2009]	12TF	NP	64.7 (6.3)	NP	NP	12T	NP	14	NP	NP
Rougier & Bergeau [2009]	15TT 11TF	13M 2F 9M 2F	41.7 (11.3) 49.6 (16.8)	74(14.3) 75.9(17.1)	1.75(0.1) 1.7 (0.1)	15T 11T	NP NP	NP NP	NP NP	Knee : NP Foot :MA, ESAR Susp. : NP Socket: NP
Kozakova *et al.* [2009]	21TT	16M 5F	64.4 (9.2)	85(16.3)	1.74 (7.5)	8T, 1C, 12VD	K1/ K3	0.4	NP	NP
Kanade *et al.* [2008]	16PFA 22TT	15M 1F 20M 2F	62.1(8.8) 62.9(6.1)	93.9 (18.9) 95.5 (14.7)	1.76 (8.7) 1.74 (5.3)	38VD	NP	NP	NP	Foot : NP Susp.: NP Socket: TSB/ PTB
Vrieling *et al*. [2008a]	5TT/ 3TF 9AB	6M 2F 8M 1F	51.8(12.7) 44.8(9.9)	83.3(9.7) 85.6(9.1)	1.78(0.09) 1.84(0.07)	5T, 1VD, 2C	NP	21	NP	Knee : POLY Foot : CF,MA, ESAR Susp.: NP Socket: NP
Duclos *et al*. [2007]	9TT/ 4TF/ 1KD, 18AB	NP NP	43(10) 37(10)	NP NP	NP NP	13T, 1C	NP	5	NP	NP

Table 2.4, Continued

First author (Year)	Study size (N)	Sex (F/M)	Age range/ mean(s.d) (years)	Weight range/ mean(s.d) (kg)	Height range/ mean (s.d) (m)	Ampu-tation Cause	Activity level	Post-amp	Acclim. time	Prosthesis intervention
Yazicioglu *et al.* [2007]	9TT/3PFA[g] 10TT/2PFA[h]	NP	28.3(4.6) 29.8(1.4)	NP	NP	24T	NP	12	NP	NP
van der Kooij *et al.* [2007]	4TF 6AB	3M 1F NP	49-63 NP	NP NP	NP NP	2T, 1VD, 1C	K3	NP	NP	Knee : MP, POLY Foot : CF,SA, ESAR Susp. : NP Socket: NP
Lee *et al*. [2007]	7TT	5M 2F	24-60	53-70	1.53-1.67	NP	NP	9	NP	NP
Kaufman *et al*. [2007]	15TF	12M 3F	26-57	NP	NP	7T, 6C, 1VD, 1CG	K3/ K4	20	18 weeks	Knee : MC, MP Foot: NP Susp. : NP Socket: NP
Mouchnino *et al.* [2006]	5TT 5AB	5M 5M	34 (15) NP	NP NP	NP NP	5T	NP	NP	NP	NP
Quai *et al*. [2005]	22TT	16M 6F	54-86	44-123	1.5-1.8	22VD	NP	3	NP	NP
Matjacic & Burger [2003]	14TT	NP	38-70	NP	NP	14T	NP	9	NP	Foot : NP Susp.: NP Socket: SPTB
Buckley *et al*. [2002]	3TT/3TF 6AB	6M 6M	25.7 (5.8) 24.7 (2.7)	NP NP	NP NP	6T	NP	NP	NP	Knee : HYD, MP Foot : MA Susp.: PL, WB Socket: PTB, QD

Table 2.4, Continued

First author (Year)	**Study size (N)**	**Sex (F/M)**	**Age range/ mean(s.d) (years)**	**Weight range/ mean(s.d) (kg)**	**Height range/ mean (s.d) (m)**	**Ampu-tation Cause**	**Activity level**	**Post-amp**	**Acclim. time**	**Prosthesis intervention**
Nadollek *et al*. [2002]	22TT	NP	71.7 (9.6)	80.9 (22)	1.7 (0.1)	22 VD	NP	3	NP	Foot : NP Susp.: CU, PL Socket: SPTB, PTB
Viton *et al*. [2000]	5TT 5AB	5M 5M	34.8 NP	NP NP	NP NP	5T	NP	NP	NP	Foot :CF Susp.: NP Socket: TSB
Blumentritt *et al*. [1999]	5TT	NP	37-70	61-105	1.68-1.83	4T, 1D	NP	4-52	NP	Foot : CF, ESAR Susp.: NP Socket: SPTB
Mouchnino *et al*. [1998]	5TT 5AB	5M 5M	24-59 24-59	NP NP	NP NP	5T	NP	NP	NP	NP
Aruin *et al*. [1997]	6TT 6AB	5M 1F 5M 1F	53.3 (8.1) 54.5 (10.5)	80.4(3.1) 77.8(3.7)	1.76(0.02) 1.72 (0.04)	NP	NP	22	NP	NP
Hermodsson *et al*. [1994]	18TT[c] 18TT[d] 27AB	12M 6F 15M 3F 19M 8F	68.8 (12) 63.9 (10) 69.6 (9.8)	NP NP NP	NP NP NP	18VD 18T	NP NP	6 24	NP NP	NP NP NA
Geurts & Mulder [1994]	3TF/4TT/5KD 12AB 8AB	9M3F 9M3F 4M4F	59.4 (18.3) 58.9 (18.3) 24.9 (2.4)	NP NP NP	NP NP NP	9 VD, 3 non-VD	NP	0.2	NP	NP

Table 2.4, (Continued)

First author (Year)	Study size (N)	Sex (F/M)	Age range/ mean(s.d) (years)	Weight range/ mean(s.d) (kg)	Height range/ mean (s.d) (m)	Ampu-tation Cause	Activity level	Years post-amp	Acclim. time	Prosthesis intervention
Isakov *et al*. [1992]	11TT 9AB	11M 9M	64.8 (9.2) 65.6 (8.6)	NP NP	NP NP	11 VD	NP	NP	1-2 days, 3-4 week	NP
Vittas *et al*. [1986]	20TT	18M 2F	16-76	NP	NP	8T, 12VD	NP	NP	NP	Foot : NP Susp.: NP Socket: PTB
Fernie & Holliday [1978]	50TF 29TT 134AB	NP NP NP	53 58 50	NP NP NP	NP NP NP	NP	NP	NP	NP	NP
Dornan *et al*. [1978]	39TF 105AB	NP NP	55 50	NP NP	NP NP	NP	NP	NP	NP	NP

Note. AB: Able-bodied; PFA: Partial foot amputation; TT: Transtibial; KD: Knee disarticulation; TF: Transfemoral; F: Female; M: Male; VD: Vascular Disease; T: Traumatic; CG: Congenital; C: Cancer; D: Disease; K –level: Medicare functional classification; CF: conventional foot; SA: single axis; MA: multi axial; ESAR: Energy storage and return; MC: Mechanical passive knee; POLY: Polycentric; HYD: Hydraulic; MP: Microprocessor; CL: Cotton liner; CU: Cuff; L: Liner; S: Suction; PL: Pin-Lock; WB: Waist-belt; PTB: Patellar tendon bearing; SPTB: Supracondylar patellar tendon bearing; TSB: Total surface bearing; QD: Quadrilateral; NP: Not provided; NA: Not applicable; a: skilled prosthesis users; b: first-fitted amputees; c: vascular group; d: trauma group; e: faller; f: non-faller; g: footballer amputees; h: non-footballer amputees.

During the balance assessment, the standardization of the stance position was reported in 62% of the studies, another 18% allowed the self-selected stance and 20% did not mention such information (Appendix B13). The distance between the two feet ranged from 3 cm to 30cm with an angle of 9^0 to 30^0 from the sagittal plane. For studies that reported the number of trials and its durations, most authors had conducted between two to five repetitions of measurements with 20-30 seconds trial duration (Appendix B14). Twelve studies instructed the participants to place their arms at the side of their body, whereas eight studies instructed the participants to place their arms at their hip, back or across their chest (Appendix B15). However, the remaining 14 studies failed to mention this information in their article. Regarding the instruction given, the three most common instructions provided were to "stand as still as possible", "stand upright" and "stand stationary" (Appendix B16).

All included studies manipulated a selection of three major sensory inputs (visual, vestibular, and somatosensory) to challenge the balance of the participants. A total of 33 (97%) studies were conducted on the firm surface condition, while only one study assessed standing balance on a compliant surface by using a 5cm-width foam. (Appendix B17). In addition, 15 (44%), four (12%), and 15 (44%) studies were performed with the participants' eyes open, close and both, respectively (Appendix B18).

The study protocols and main parameters measured in the reviewed studies are summarized in Table 2.5. Balance was mainly assessed from the CoM and CoP variables, such as excursion, velocity, amplitude, and area in 26 (76%) studies (Appendix B19). Additionally, the weight distribution between the intact and prosthetic legs was examined in 13 studies (Appendix B19). Stability indexes such as equilibrium score (ES) and composite score were obtained from the NeuroCom Smart Equitest in four studies, while the Balance Index (BI) score was calculated from KAT Balance System (Appendix B19). Additionally, the total standing duration during which the subject maintained balance was reported in four studies (Appendix B19). Results from other outcomes such as kinematics and moments of the ankle, knee and hip, muscle activity and strength, limits of stability which assessed the ability to volitionally perturb balance, as well as the vertical and horizontal components of the ground reaction force were found to be limited.

The methodological quality scores for all of the reviewed studies are presented in Table 2.6. Overall, the rating score for half of the reviewed studies (17 articles) satisfied at least 50% of the listed criteria. The quality score ranged from 21% to 72%. However, consistent and noticeable weaknesses among the remaining studies with low scores lie in the absence of information on functional homogeneity of the subjects and the specific *p*-value of significant findings.

Table 2.5: Summary of study protocols.

First author (Year)	Type of balance assessment	Type of perturbation	Conditions	Foot position	Research Instruments	Outcomes Measured
Nederhand *et al*. [2012]	Static & dynamic bipedal	Unperturbed & Unexpected	F, EO. One 10s static trial, three 90s dynamic trials	20cm between medial malleoli, 9^0 outward rotation from sagittal midline	Force platform, Vicon motion system	Weight distribution, CoP shift, dynamic balance contribution.
Barnett *et al*. [2012]	Static & dynamic bipedal	Unperturbed & Unexpected	F, 6 SOT, Three 20s trials each.	Ankle joint were aligned with the axis of rotation of the support platform	Equitest System	Equilibrium and strategy scores, limit of stability
Curtze *et al*. [2012]	Dynamic bipedal	Unexpected	F, EO, Three trials each in backward, forward, towards intact/ prosthetic leg	Self-selected parallel	Force platform, Vicon motion system	Ankle and hip moment
Mayer *et al*. [2011]	Static bipedal & intact leg	Unperturbed	F, EO, Three 20s trials on each leg	Self-selected parallel	Force platform	Balance test variables (radius of the circle, total CoP excursion length, A-P excursion length), load distribution differences
Hlavackova *et al*.[2011]	Static bipedal	Unperturbed	F, EC, Three 30s trials each.	Feet parallel 10cm apart	Force platform	CoP excursions, weight distribution
Mohieldin *et al*. [2010]	Static & dynamic bipedal	Unperturbed & Unexpected	F, 6 SOT, Three 20s trials each	NR	Equitest System	Equilibrium scores
Lenka *et al.* [2010]	Static bipedal	Unperturbed	F, EO-EC, 2min trial each	Heels 10 cm apart at an angle of 30^0 from sagittal	Force platform	CoP variables: shifts, velocity, power frequency, sway area
Vanicek *et al*. [2009]	Static & dynamic bipedal	Unperturbed & Unexpected	F, 6 SOT, Motor Control Test. Three 20s trials each	According to manufacturer's instructions	Equitest System	Equilibrium and strategy scores, latency scores, weight distribution
Hlavackova *et al*.[2009]	Static bipedal	Unperturbed	F, EO, mirror feedback Three 30s trials each.	Feet parallel 10cm apart	Force platform	CoP excursions, weight distribution

Table 2.5, Continued

First author (Year)	Type of balance assessment	Type of perturbation	Conditions	Foot position	Research Instruments	Outcomes Measured
Kozakova *et al.* [2009]	Static bipedal	Unperturbed	F-C, EO-EC, 30s trials each for four standing condition	NR	Force platform	Load distribution, CoP excursion & velocity
Rougier & Bergeau [2009]	Static bipedal	Unperturbed	F, EO, Five 32s trials	9 cm between heels, 30° angle between the inner edges of the feet	Force platform	Weight bearing, CoP trajectories
Vrieling *et al.* [2008a]	Dynamic bipedal	Unexpected	F, EO-EC single task, EO double task, 60s trial each	Self-selected	Force platform	CoP excursion, weight bearing index (WBI), GRFy, GRFz
Kanade *et al.* [2008]	Static bipedal	Unperturbed	F, EO, Three 30s trials	Self-selected parallel	Force platform	CoP excursion, weight distribution
Duclos *et al*. [2007]	Static bipedal	Unperturbed	F, EC , 60s trial	Feet 3cm apart	Force platform	CoP variables: shifts, velocity, position
Yazicioglu *et al.* [2007]	Static single intact, dynamic bipedal	Unperturbed Expected	F, EO, 1 trial	NR	KAT 2000, dynamometer	Balance index (BI), muscle strength
van der Kooij *et al*. [2007]	Static bipedal	Unperturbed	F, EO-EC, Two 90s trials	20cm between medial malleoli, 9^0 outward rotation from sagittal midline	Force platform, Vicon motion system	Weight bearing, CoP shift, CoM sway, dynamic balance contribution (DBC)
Kaufman *et al*. [2007]	Static & dynamic bipedal	Unperturbed & Unexpected	F, 6 SOT, Three 20s trials each.	Self-selected parallel	Equitest System	Equilibrium and composite scores
Lee *et al*. [2007]	Static single intact	Unperturbed	F, EO, Six trials	NR	Zebris motion system	CoM displacement, Standing duration
Mouchnino *et al*. [2006]	Dynamic lateral leg raising	Expected	F, EO, Twenty 2s trials	Heels 10 cm apart at an angle of 30^0 from sagittal	Force platform, ELITE motion system	Kinematics, CoM displacement

Table 2.5, Continued

First author (Year)	Type of balance assessment	Type of pertur bation	Conditions	Foot position	Research Instruments	Outcomes Measured
Quai *et al*. [2005]	Static & dynamic bipedal	Unperturbed & Expected	F, EO-EC, Three 40s trials each	17 cm between heel centers and 14˚ between long axes of the feet	Force platform	CoP excursion, weight distribution, limits of stability, relationship between circulatory/ somatosensory status and balance.
Matjacic & Burger [2003]	Dynamic bipedal	Expected	F, EO, Five trials	NR	Balance ReTrainer	Balance duration on prosthesis
Buckley *et al*. [2002]	Static & dynamic bipedal	Unperturbed & Unexpected	F, EO-EC, Three trials each for 30s static, 20s dynamic	15cm between medial malleoli	Force platform	CoP excursion, balance time
Nadollek *et al*. [2002]	Static bipedal	Unperturbed	F, EO-EC, One trial each	17 cm between heel centers and 14˚ between long axes of the feet	Force platform	CoP excursion, weight distribution
Viton *et al*. [2000]	Dynamic bipedal to monopedal	Expected	F, EO, 45^0 lateral leg raise, Twenty 3s trials each	Feet parallel 10cm apart	Force platform, ELITE motion system	Kinematics, CoM and CoP displacement, EMG
Blumentritt *et al*. [1999]	Static bipedal	Unperturbed	F, EO, 5s	NR.	Force platform	Distance from joint center to load line
Mouchnino *et al*. [1998]	Dynamic single intact/ prosthetic	Expected	F, EO, Twenty 2s trials	Heels 8 cm apart at an angle of 30^0 from sagittal	Force platform, ELITE motion system	CoP variables , CoM shift
Aruin *et al*. [1997]	Dynamic bipedal	Expected	F, EO, Six trials during shoulder movement & catching loads	Feet 30cm apart	Force platform , goniometer, EMG electrodes	CoP displacement, Joint kinematic, EMG

Table 2.5, Continued

First author (Year)	Type of balance assessment	Type of pertur bation	Conditions	Foot position	Research Instruments	Outcomes Measured
Hermodsson et al. [1994]	Static bipedal, single intact & prosthetic leg	Unperturbed	F, EO, EC (only during double stance), Three 30s trials on each leg	Feet close together	Force platform	CoP deviation, standing time
Geurts & Mulder [1994]	Static & dynamic bipedal	Unperturbed & Expected	F, EO Five 30s trials	8.4cm between medial side of heel, 9^0 outward rotation from sagittal midline	Force platform	CoP displacement, velocities, amplitude , Weight shift
Isakov *et al.* [1992]	Static bipedal	Unperturbed	F, EO-EC, Two 25s trials	30 cm between heels 20° angle between the inner edges of the feet	Force platform	CoP sway, asymmetry, weight bearing imbalance
Geurts *et al*. [1991]	Static bipedal	Unperturbed	F, EO single task, double task, Two 10s trial each	8.4cm between medial side of heel, 9^0 outward rotation from sagittal midline	Force platform	Root mean square (RMS) of CoP velocity
Vittas *et al*. [1986]	Static bipedal	Unperturbed	F, EC, 3 mins	Feet 3cm apart	Force platform	CoP excursion
Fernie & Holliday [1978]	Static bipedal	Unperturbed	F, EO-EC, Two 60s trial each	Self-selected	Potentiometric displacement transducer	CoM sway velocity, displacement, EO/EC ratio
Dornan *et al.* [1978]	Static bipedal	Unperturbed	F, EO-EC, Two 60s trial each	NR	Potentiometric displacement transducer	CoM sway, displacement, EO/EC ratio

Note. EC: Eyes-closed; EO: Eyes-open; A-P: Anterior-Posterior; M-L: Medial-lateral; GRF: Ground Reaction Force; CoM: Center of Mass; CoP: Center of Pressure; EMG: electromyogram; F: Firm surface, C: Compliant surface; SOT: Sensory Organization Test; NR: Not reported

Table 2.6: Assessment of methodological quality scores of reviewed papers.

First author [Year]	Assessed criteria														Total (%)
	1	2A	2B	2C	2D	2E	2F	2G	3	4	5	6	7	8	
Nederhand *et al*. [2012]	1	0	0	0	0	1	0	0	0	1	1	1	1	0	**6 (43)**
Barnett *et al*.[2012]	0	1	0	0	0	0	0	1	0	1	1	1	1	1	**7 (50)**
Curtze *et al*. [2012]	1	1	1	0	1	0	0	1	0	1	1	1	1	1	**10 (72)**
Mayer *et al*. [2011]	0	0	0	0	1	0	0	1	0	1	1	1	1	1	**7 (50)**
Hlavackova *et al*.[2011]	0	0	0	0	0	0	1	1	0	1	1	0	1	0	**5 (36)**
Mohieldin *et al*. [2010]	0	0	1	0	0	0	0	0	0	1	1	1	1	0	**5 (36)**
Lenka *et al*. [2010]	0	0	0	0	0	0	0	1	0	1	1	1	1	1	**6 (43)**
Vanicek *et al*.[2009]	0	0	1	1	1	0	0	1	0	1	1	1	1	1	**9 (64)**
Hlavackova *et al*.[2009]	1	0	0	0	0	0	1	1	0	1	1	0	1	0	**6 (43)**
Rougier & Bergeau [2009]	0	0	0	0	0	0	1	1	0	1	1	1	1	0	**6 (43)**
Kozakova *et al*. [2009]	0	0	0	0	0	0	0	1	0	1	1	1	1	0	**5 (36)**
Kanade *et al*. [2008]	0	0	1	1	1	0	1	1	0	1	1	1	1	1	**10 (72)**
Vrieling *et al*.[2008a]	1	1	1	1	1	0	0	0	0	1	1	1	1	1	**10 (72)**
Duclos *et al*. [2007]	0	0	1	0	0	0	0	0	0	1	1	0	1	1	**5 (36)**
Yazicioglu *et al*. [2007]	0	0	1	1	0	0	1	0	0	1	1	0	1	1	**7 (50)**
van der Kooij *et al*. [2007]	1	0	0	0	0	1	0	0	0	1	1	1	0	0	**5 (36)**
Lee *et al*. [2007]	1	0	0	0	0	0	0	1	0	1	1	0	0	0	**4 (29)**
Kaufman *et al*. [2007]	0	0	0	0	0	0	0	1	1	1	1	1	1	0	**6 (43)**
Mouchnino *et al*. [2006]	1	1	1	0	0	0	1	1	0	1	1	0	1	0	**8 (57)**
Quai *et al*.[2005]	1	0	0	0	0	0	1	1	0	1	1	1	1	1	**8 (57)**
Matjacic & Burger [2003]	1	0	0	0	0	0	1	1	0	1	1	1	1	0	**7 (50)**
Buckley *et al*. [2002]	1	1	1	0	0	0	0	0	0	1	1	1	1	1	**8 (57)**
Nadollek *et al*. [2002]	1	0	0	0	0	0	1	1	0	1	1	1	1	1	**8 (57)**
Viton *et al*. [2000]	1	1	1	0	0	0	1	1	0	1	1	1	1	0	**9 (64)**
Blumentritt *et al*. [1999]	1	0	0	0	0	0	0	1	0	1	1	1	0	0	**5 (36)**
Mouchnino *et al*. [1998]	1	1	1	0	0	0	1	1	0	1	1	0	1	0	**8 (57)**
Aruin *et al*. [1997]	0	0	0	0	0	0	0	1	0	1	1	0	1	0	**4 (29)**
Hermodsson *et al*.[1994]	0	0	1	0	0	0	1	1	0	1	1	0	1	1	**7 (50)**
Geurts & Mulder [1994]	0	0	1	0	0	0	0	0	0	1	1	0	1	1	**5 (36)**
Isakov *et al*. [1992]	0	1	1	0	0	0	1	1	1	1	1	0	1	1	**9 (64)**
Geurts *et al*. [1991]	0	1	1	0	0	1	0	0	0	1	1	1	1	0	**7 (50)**
Vittas *et a*l. [1986]	0	0	0	0	0	0	0	1	0	1	1	1	1	0	**5 (36)**
Fernie & Holliday [1978]	0	0	0	0	0	0	0	1	0	1	1	0	0	0	**3 (21)**
Dornan *et al*. [1978]	1	0	0	0	0	0	0	1	0	1	1	0	1	1	**6 (43)**

Note. 1 indicates randomization during selection of participants; 2A: control of gender; 2B: control of age; 2C: control of weight; 2D: control of height; 2E: control of activity level; 2F: control of amputation level; 3: adequate information on acclimation period; 4: adequate information on type of balance assessment; 5: adequate information on outcome measures parameters, 6A: adequate information on prosthetic foot type; 6B: adequate information on knee type; 6C: adequate information on socket type; 6D: adequate information on liner type; 7: appropriate statistical test; 8: sufficient information on statistical results.

2.4.4 Discussion

This systematic review aims to provide an exhaustive summary of previous and current evidence on the methodological aspects of studies on balance during standing in individuals with lower limb amputation. The data on the methodological aspects were synthesized and evaluated from 34 selected studies. The key finding of this review demonstrates that there is no ‘gold standard’ guideline available but rather a ‘state-of-the-art’ practice in the assessment of balance in amputees. Moreover, findings from this review reveal that some shortcomings of the studies examined are attributed to the lack of information on participant’s demographic background and the failure to report the actual probability (*p*) value for findings which were statistically significant. Different experimental setups and protocols have been reported in terms of varied types of surfaces used (firm versus compliant), different durations of testing, number of trial recordings, and the instructions issued to the participants. These variations should be carefully considered by the researcher because such variations can critically affect the CoP measures as demonstrated by patients with low back pain (Mazaheri *et al*, 2013). Details of each methodological aspect are further elaborated in the sub-section below.

In regard to the amputee population according to the amputation type, transtibial amputation serves to be the major group as determined from all selected studies. This result is expected because transtibial amputation is the most common type (47%) of lower limb amputation (WHO, 2004). While the majority of the studies grouped the participants according to their amputation type, other studies have incorporated both the transtibial and transfemoral groups into one, but doing so may be inappropriate because the compensatory mechanism of balance differs between transtibial and transfemoral amputees (Rougier and Bergeau, 2009). Another aspect that should be considered when comparing between able-bodied control group and amputee group is that these groups must have similar body mass because it has been shown that the body mass is an important risk factor for falling and a predictor of balance (Hue, 2007).

Studies on the balance of amputees should also mention the activity level based on the MFCL because this tool is considered as the best rehabilitation guidance in terms of predicting prosthetic outcome (Miller and McCay, 2006). An acclimation period of at least one week for below-knee amputees and three weeks for above-knee amputees is suggested before the assessment of the functional effectiveness of the prosthesis (English, Hubbard and McElroy, 1995). Similarly, lower limb amputees can take part in balance studies if they have a post-operative period of at least eight weeks because this period is needed for them to adjust to the static requirements of balance (Geurts, Mulder, Nienhuis and Rijken, 1991). This review shows that information on acclimation and the post-operative period of the amputees has not been reported in the majority of the reviewed studies.

Furthermore, the review indicates that the etiology of lower limb amputation is mostly due to vascular diseases. This result further supports the previous evidence that amputations occur as a result of complications in the vascular system, which account for the majority (82%) of lower limb loss (Dillingham *et al.*, 2002). Since the balance capacity in individuals with unilateral amputations due to vascular disease is reduced than that of non-vascular reasons (Hermodsson *et al.*, 1994), researchers should group their participants into either one of the amputation groups to obtain a result that is specific to such a population.

In this review, we noticed that evaluating balance in lower limb amputees is challenged by the heterogeneous types of prosthetic feet used across the studies. The stiffness characteristics of prosthetic feet have been hypothesized to affect the performance in standing balance (Nederhand *et al*., 2012). However, only three of the reviewed studies used the same prosthetic foot for all the participants in the assessment. The rest of the studies had the amputees wore their usual prostheses causing variations in types of prosthetic feet which may have influenced the balance performance. The inconsistencies in the prosthetic components used made the assessment of its effects on an individual's response to perturbations difficult. However, this is expected due to the different goals and objectives in each of the reviewed studies. Future studies which aim to determine the effect of prosthetic ankle stiffness on the balance of amputees should systematically manipulate the type of prosthetic foot (for example, a crossover study with repeated testing) (Nederhand *et al*., 2012). Additionally, the tested prosthetic foot should be mechanically evaluated to obtain its stiffness value, which can be used to establish an objective measure on the relationship between prosthetic stiffness and balance performance.

The evaluation of balance during bilateral unperturbed standing is the most common assessment found in this review. Due to the fact that loss of balance occurs most frequently during movement-related activities, unperturbed (static) tests have been criticized as inefficient in representing the dynamic nature of balance (Aydog, Bal, Aydog and Cakei, 2006). Hence, the dynamic balance assessment serves to examine the ability to accomplish appropriate postural adjustments in responding to expected or unexpected perturbations in the balance system (Winter *et al*., 1990a). Our review further demonstrates that almost all of the studies examined have used bilateral standing, with the maintaining balance on both limbs as the preferred mechanism. Balance control during unilateral stance is considered as equally important to avoid fall in response to unexpected perturbation. Moreover, it has also been used as an indicator of fall incidence in the amputees (Vanicek *et al*., 2009), and this factor can be utilized to determine the optimal prosthetic stiffness according to an individual's balance performance.

This review indicates that balance assessment with the use of a force platform is commonly used to obtain various parameters derived from CoP measures, such as displacement, velocity, amplitude, and area (Melzer *et al*., 2004). The CoP has been suggested as the net response of the neuromuscular system at the ankle to the movement of the CoG, which, although it provides valid outcomes, it is insufficient to explain the control of posture in both the anterior-posterior and medio-lateral directions (Winter *et al*., 1990a). Future studies should be cautious in interpreting parameters that use minimal, maximal, or peak-to-peak readings, such as the parameter of maximal amplitude, for instance, because this uses only one or two data points which may cause great variance and low reliability results (Ruhe, Fejer and Walker, 2010).

Furthermore, comprehensive instruments, such as the NeuroCom Smart Equitest system (NeuroCom International Inc., Clackamas, US), have been used in several studies to assess the balance response during dynamic perturbations. The SOT from this system provides information on the integration of the visual, proprioceptive, and vestibular components that affect the balance organization (Shumway-Cook and Horak, 1986). General SOT entails measuring postural sway during six different conditions which calculate the equilibrium score and strategy score. Equilibrium score denotes the sway amplitude during the maintenance of balance in all SOT conditions, while the strategy score represents the ability to use the hip/ ankle strategy movements to maintain balance (Barnett *et al*., 2012). However, despite the comprehensive data that NeuroCom Equitest provides, the size and cost of the device prohibit their application in most of clinical rehabilitation settings (Hinman, 2000). Additionally, the BI score from the Kinesthetic Ability Trainer (KAT) Balance System may be utilized to evaluate balance in lower limb amputees. This device uses computerized compressed air bladder which controls the degree of surface instability for dynamic balance assessment and training (Yim-Chilis and Talbot, 2000).

Some studies have incorporated the motion analysis system to measure the joint kinematics and center of the mass sway pattern. Although motion analysis has been shown to provide useful information in measuring total balancing movements of the body while standing upright in able-bodied people (Kejonen and Kauranen, 2002), the reliability and validity of this approach in people with amputations are yet to be reported. Findings from this review highlight the lack of assessment regarding muscle activity and strength of both intact and amputated legs, while this may exhibit compensatory changes in postural muscles and the overall pattern of standing in lower-limb amputees (Aruin, Nicholas and Latash, 1997), we suggest that these factors should be explored in future research. While a few studies have offered other alternatives in balance assessment such as using the displacement transducer, this approach may not be clinically practical.

Another option that we can suggest for future studies is the use of the Biodex® Stability System (BSS) to enable clinicians to assess neuromuscular control. This system quantifies the ability to maintain balance on a static or unstable surface on the basis of computed stability indexes. In contrast to the force platform, this device consists of a moveable platform which can be adjusted to provide varying degrees of stability which allows up to 20^0 of platform tilt in a 360^0 range of motion. Thus, the BSS may provide more specific information on ankle joint movements due to its ability to measure the degree of platform tilt about anterior-posterior and medial-lateral axes under dynamic conditions (Arnold and Schmitz, 1998; Salsabili *et al*., 2011). Moreover, the BSS system is less expensive and more portable which can be readily used in a clinical setting (Hinman, 2000; Yim-Chiplis and Talbot, 2000). Although previous studies have established the reliability of this system, it has not been utilized to quantify balance in amputees (Baldwin *et al*., 2004; Parraca *et al*., 2011).

Additionally, the standardization of the position of the feet to 0.17 m between heel centers, at an angle of 14^0 between the long axes of the feet, has been hypothesized to eliminate between-subject variability or biased results (Mcllroy and Maki; 1995). However, this requirement depends on the specific purpose of the research and the participants' physical condition. The most commonly used position of the arms is alongside the body of the participant because this position helps in maintaining a natural position during the assessment. Regarding the number and duration of trials on a single day of assessment, most of the reviewed studies considered the possibility of fatigue in the amputee population with balance deficit. We also suggest that an average of three to five trials (Ruhe *et al*., 2010) that last from 20s to 30s (LeClair and Riach, 1996) should be considered sufficient to obtain reliable data in balance studies. Similarly, a standardized explicit instruction to "stand as still as possible" while looking straight ahead should be given to the participants for consistency (Zok, Mazza and Cappozzo, 2008).

To understand the integration between the sensory inputs from the somatosensory (proprioceptive, cutaneous and joint), visual, and vestibular systems, a combination of sensory modifications was adopted to determine the underlying mechanism on the balance reorganization of individuals with balanced deficits (Guskiewicz and Perrin, 1996; Shumway-Cook and Horak, 1986). Overall, most studies manipulate visual inputs with the participants' eyes open, close, or with visual conflict during balance assessment. Other studies investigated the effect of somatosensory input by having the amputees stand on a rigid or compliant surface, a static or moving platform, or a single or bilateral stance. However, none of the studies manipulated vestibular input by requiring the participants to tilt their head while performing their balance test.

2.4.5 Limitations of the study

Although we believe that this review presents an up-to-date overview of the methodology to evaluate balance during standing in persons with lower limb amputation, a number of limitations in this review must be acknowledged. While extensive electronic databases and manual searching were conducted, the failure to identify all relevant studies is possible. Furthermore, we only included studies that were published in English, and doing so may have introduced publication bias (McGauran *et al*., 2010). The purpose-designed checklist was adopted from previous studies that emphasized on the confounding factors and prosthesis components, and most of the studies included in this review are lacking these criteria, which may also have attributed to the low final quality score observed. However, the listings of all details from the previous studies are important in providing concise and unbiased information for future balance assessment in amputees. The exclusion of unpublished data such as from theses or dissertations, as well as conference proceedings may have overlooked some important information regarding the area of standing balance in amputees.

2.4.6 Conclusion

This review identifies studies presented in scientific articles that assess the balance of individuals with lower limb amputation. All the reviewed studies provided general information regarding the instrumentation and outcomes of their studies. However, the results of this systematic review indicated the non-existence of a standardized methodology to access balance in amputees and the outcomes measured are varied among different instrumentations used in each study. Nevertheless, the methodological aspects and measurement outcomes presented in this systematic review should assist clinicians in choosing the appropriate assessment method according to their specific goals. Furthermore, most of the studies are lacking important information on the balance-related factors such as the prosthesis componentry, cause of amputation, length of residual limb and activity level. Therefore, to enhance our understanding in this matter, future studies should control these confounding factors which can potentially influence balance during standing in people with lower limb amputation.

2.5 Self-report and functional outcome assessment of balance

The general term of outcome measures are described as "quantifiable instruments used to define functional capabilities in relation to an intervention or other influencing variables" (Gailey *et al.*, 2012). Specifically, the term 'prosthetic outcomes' has been defined as "changes in the functional level, health, and quality of life attributable to the prosthetic device" (Agrawal, 2013b). Often, clinicians who involve in the clinical prescription, evaluation and rehabilitation of people with limb-loss may need a tool that can measure the effectiveness of treatment and aid in evaluating different prosthesis interventions.

Additionally, outcome measures can also be used to determine functional capabilities, rehabilitation progress, comfort and satisfaction for differentiating prosthetic intervention (Roach, 2006; Gailey *et al.*, 2012). Ideally, objective or subjective functional improvement experienced by the amputee should be measurable. For an example, if a particular prosthetic foot has significantly different characteristics than another, then it must in some capacity improve the function measured either objectively or subjectively by the prosthetic user. According to the 6th American Academy of Orthotists and Prosthetists state-of-the-science conference, the outcome measures instruments can be categorised into three different groups which are self-report, professional report and physical performance instruments (Miller & McCay, 2006). While performance-based measurement instruments have been known to provide objective and accurate outcome measures to determine physical abilities, the self-report measures offers minimal resources which are easy to administer (Gailey *et al*., 2012). In this thesis, five different outcome measurement tools related to lower limb prosthetics were utilised as discussed in the following sub-sections.

2.5.1 Medicare Functional Classification Level (MFCL) (K-Level)

The MFCL consists of five levels classification system that uses code modifiers known as K-levels which are specified by the Health Care Financing Administration (HCFA). The functional K-levels ranges from amputee whom are bedbound (K0) to those engaged in high-level activities (K4) (Table 2.7). The MFCL serves as an indicator of the capacity and potential of people with lower-limb amputation to accomplish their activities of daily living (ADL). In relation to this, the MFCL classification is used by the Durable Medical Equipment Regional Carrier (DMERC) to establish the prosthesis necessity for the amputees.

2.5.2 Health status questionnaire (SF-12v2)

The Medical Outcomes Study Short-Form version 2 (SF-12v2) is a standardized, multidimensional health status questionnaire comprised of a 12-items subset of the SF-36 version 2 (SF-36v2) without substantial loss of information (Cheak-Zamora, Wyrwich, & McBride, 2009). In fact, the SF-12v2 has been shown to reproduce physical and mental health summary measures more than 90% of the variance in the longer version of SF-36 (Ware, Kosinski & Keller, 1996). Scores can be directly compared between persons with or without impairment due to its non-disease-specific features. Ware and colleagues have demonstrated good internal consistency reliability for the Physical Component Summary (PCS) and Mental Component Summary (MCS) (Cronbach's alpha of 0.89 and 0.86, respectively); as well as good validity (Ware, Kosinski, Turner-Bowker & Gandek, 2002).

Table 2.7: Definitions for MFCL

K-Level*	Mobility Level
0	Does not have the ability or potential to ambulate or transfer safely with or without assistance, and a prosthesis does not enhance quality of life or mobility.
1	Has the ability or potential to use prosthesis for transfers or ambulation in level surfaces at a fixed cadence. Typical of the limited and unlimited household ambulator.
2	Has the ability or potential for ambulation with the ability to transverse low-level environmental barriers such as curbs, stairs, or uneven surfaces. Typical of the limited community ambulator.
3	Has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to transverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic use beyond simple locomotion.
4	Has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic demands of the child, active adult, or athlete.

*K is an arbitrary letter assigned by the HCFA. Adapted from Gailey *et al.* (2002).

2.5.3 Houghton Scale

When prosthetic usage is a topic of interest, a reliable and easy-to-administer tool which can measure prosthetic use is crucial during routine clinical follow-up, rehabilitation program evaluation, and research (Devlin *et al.*, 2004). Consequently, The Houghton Scale has been introduced to provide avenue in reflecting a person's perception of prosthetic use and wear, rather than a clinician's viewpoint. This tool, which has 4 questions giving a total maximum score of 12, provides a quick measure of prosthetic use since it is easy to administer and score. It has been used in previous studies of prosthetic use within the amputee population (Akarsu, Tekin, Safaz, Goktepe & Yazicioglu, 2013; Leung, Rush & Devlin, 1996). In addition, Leung *et al*. (1996) have demonstrated that the Houghton score could help to distinguish between those who achieved rehabilitation goal (Houghton score > 9) and those who did not (Houghton score <9).

When compared to other tools that compare prosthetic use such as Prosthesis Evaluation Questionnaire (PEQ) and the Locomotor Capabilities Index of the Prosthetic Profile of the Amputee (PPA), the Houghton Scale has shown acceptable internal consistency (Cronbach's alpha of 0.66), good test-retest reliability (ICC=0.85), appropriate validity and was the only scale that could discriminate between people with transtibial and transfemoral amputations (Miller *et al*., 2001a). Although the Houghton Scale's has considerably less internal consistency than the other two scales, this aspect is believed to be unnecessary for psychometric tools. Later, Devlin *et al.* (2004) highlighted that the Houghton Scale showed moderate internal consistency (Cronbach's alpha of > 0.7), high test-retest reliability (ICC=0.96) and appropriate responsiveness to change in prosthetic use. Therefore, this scale is recommended for use during routine clinical session (Devlin *et al*., 2004).

2.5.4 Berg Balance Score (BBS)

Balance ability was clinically assessed using BBS questionnaires to ensure similar functional balance status between persons with below-knee amputation and normal participants. The Berg balance score was developed to measure balance among adults with impairment in balance function by assessing the performance of functional tasks. It consists of 14 everyday common tasks which include sitting, standing, reaching, leaning over, turning and looking over each shoulder, turning in a complete circle and stepping. Generally, most items require the subject to maintain balance in a given position for a specific time. During the test, score points will be deducted if the subject fails to perform within the given time, the subject touches an external support or when the subject's performance involves supervision and assistance from the examiner.

Each item is scored on a scale from 0 to 4, for a maximum of 56 points. A score of 0–20 indicates a high risk, 21–40 indicates a medium risk, and 41–56 indicates a low risk of falling. Previous study ascertained that BBS has moderate validity, strong internal consistency (Cronbach's alpha >0.7) as well as excellent intra-rater (ICC=0.97) and inter-rater (ICC=0.98) reliability in geriatric population (Berg, Wood-Dauphinee & Williams, 1995). Hence, the BBS is a reliable instrument used for the evaluation of the effectiveness of interventions and for quantitative descriptions of function in clinical practice and research (Berg *et al*., 1995).

Due to its effectiveness, studies of BBS feasibility in unilateral transtibial amputees have been conducted. The BBS exhibited high internal consistency (Cronbach's alpha >0.9), good internal consistency (Cronbach's alpha=0.83) and has no floor or ceiling effects (Lung *et al*., 2006). A Rasch rating scale analysis by Wong, Chen and Welsh (2013) indicated excellent validity and high reliability properties of the BBS when tested in community dwelling adults with leg amputation. Therefore, with good psychometric properties, the BBS can be considered as a valid and reliable clinical instrument for assessing balance in people with lower-limb amputation.

2.5.5 Activities-specific Balance Confidence (ABC)

The evaluation of balance self-efficacy will be evaluated using the ABC scale which is a psychometric measure that comprised of 16 items questioning about an individual's balance confidence in different situations. High test-retest reliability for the overall scale has been reported among community dwelling elderly (ICC=0.92) and lower limb amputees (ICC=0.91) (Miller, Deathe & Speechley, 2003; Powell & Myers, 1995). The scale has been showed to have excellent internal consistency (Cronbach's alpha of 0.95) and good validity (Miller *et al*., 2003).

In recent years, the ABC scale has been applied in research involving people with lower-limb amputation. Researchers utilised the ABC score to evaluate gait performance (Ferraro, 2011; Vrieling *et al*., 2007) and balance control (Curtze *et al*., 2012; Vrieling *et al*., 2008b) in persons with unilateral lower limb amputation. However, none have used this outcome measures to differentiate between prosthetic interventions.

2.6 Overall conclusion

In summary, the ability to maintain postural stability is integral to safely execute activities of daily living. However, deficits in controlling postural stability are apparent due to the loss of proprioceptive receptors resulting from amputation. The review of literatures from previous studies showed the inadequacy in methodological aspects which may hinder accurate interpretations and results in study of postural stability control among the amputees. Hence, this research will propose a more systematic and objective approach in understanding the mechanism of balance control during quiet standing in below-knee amputees.

2.7 Novel contributions of the current thesis

In the past, there are extensive literatures that have investigated postural stability control during independent upright standing. However, the influence of the different prosthetic components, particularly the foot, on the control of standing posture is still uncertain. Specifically, the control of postural stability during altered visual, somatosensory and vestibular inputs while wearing different prosthetic feet categories is yet to be investigated.

As discussed earlier, there is still lacking of systematic analysis of confounding factors from sensory and prosthetic foot which may affect the control of stability during upright standing. Hence, the purpose of this study was to investigate whether the control of postural stability will be influenced by the prosthetic foot types when standing in different altered sensory situations. In addition, this current thesis also explored the feasibility of a commercially available balance device to assess postural stability in below-knee amputees and whether their unique stability profile could be distinguished from that of an able-bodied person. Quantitative posturography was utilised as a method to isolate the individual orientation inputs from the visual, somatosensory and vestibular systems contributing to postural stability control. These works provide new insights into the possibility of implementing objective assessment as an evidence-based practice to enhance the understanding of the underlying mechanisms of postural stability control with changes of sensory information and prosthetic foot. The need of such evidence is paramount, considering the ambiguity that surrounds the current findings of stability control in below-knee amputees.

In short, this current thesis examined the relative influence of each sensory and prosthetic foot types on the postural stability of independent bilateral stance in person with below-knee amputation. The sensory influence assessment coupled with prosthetic components factors revealed additional information in understanding the standing posture mechanism in unilateral below-knee amputees. Consequently, these results potentially provide the means of a new approach to the improvement of the rehabilitation programme and to prosthetic prescription for individuals with below-knee amputation.

CHAPTER 3

GENERAL MATERIALS AND METHODS

The current chapter discusses the overall flow of the study, ethical review procedure, inclusion/exclusion criteria for participation in this study, and also the demographics of amputee and able-bodied participants. The mechanical testing procedures used to determine prosthetic feet stiffness are elaborated in this chapter. Considerations for the use of equipment and outcome measures are also included. Moreover, stability indexes as well as zones and quadrants variables are described in this chapter. Following this, the testing protocols for sensory alterations with three different prosthetic feet and subjective assessment of balance function and confidence are further described. Descriptive and statistical data analyses procedures are detailed in the methodology section of the associated experiment.

3.1 Flowchart of the overall study.

Generally, the methodology process of this current study can be divided into six different phases. The phases involved are: (1) systematic literature review, (2) ethical review, (3) preliminary studies, (4) subjects recruitment, (5) main studies, (6) data management, and finally (7) thesis writing. The flowchart of these phases is outlined in Figure 3.1.

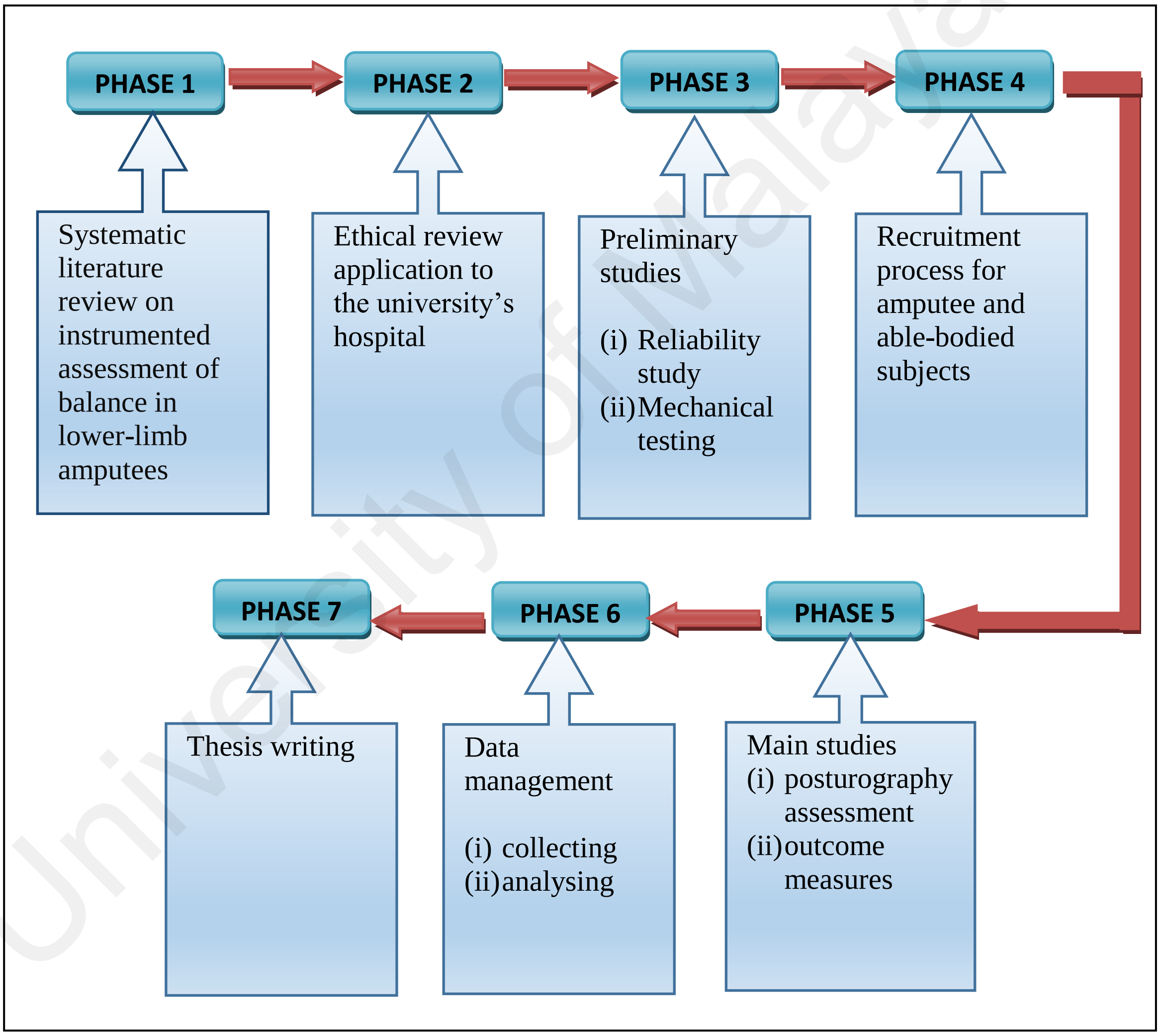


Figure 3.1: The flowchart of the overall methodology of this study.

3.2 Systematic literature review

Literature searching via the internet and manually was conducted in January 2013. This particular search was focused on articles pertaining instrumented assessment of balance in people with lower-extremity amputation. The final articles were selected based on the four-phases of information of a systematic literature review according to PRISMA guidelines. Detailed information of the search strategy, included articles and findings can be found in Section 2.4.

3.3 Ethical review

As required by the Medical Ethics Committee (MEC) of University Malaya Medical Centre (UMMC), any research involving humans must obtain clearance from the committee prior commencement of the study. This is to ensure the rights, safety and well-being of human research volunteers and to ensure that the proposed study abide by the existing laws and regulations. Therefore, this study was reviewed and granted approval in August 2012 (MEC reference number: 938.9). The ethics approval statement, participation information sheet, informed consent form and related questionnaires used in this study which were approved by the committee can be found in the Appendix C at the end of this thesis.

3.4 Inclusion and exclusion criteria

Prospective amputee participants were identified by the researcher and certified prosthetist at the rehabilitation clinics of UMMC. For able-bodied group, participants were recruited from local community by word of mouth. In order to participate, we have outlined the participant's selection criteria both for amputee and able-bodied control group which can be referred to in Table 3.1. Anyone who does not meet the inclusion criteria was not included in the study.

Table 3.1: Inclusion and exclusion criteria for amputee and control group.

	Amputee	Control
Inclusion criteria		
• age between 20-65 years	✓	✓
• in good general health condition	✓	✓
• able to walk without aids or assistance	✓	✓
• satisfactory range of joint motion at both hips and knees	✓	✓
• Berg balance score >20	✓	✓
• unilateral lower-limb amputation below the knee	✓	
• residuum in good condition (no scars/infections/pain)	✓	
• non-amputated side in good condition	✓	
• at least one year use of prosthesis	✓	
Exclusion criteria		
• attention deficits, visual problems or deafness	✓	✓
• with neurological disorders which may affect balance	✓	✓
• unable to understand verbal or written information given in English or Malay language	✓	✓
• symptoms of dizziness	✓	✓
• unilateral above-knee or bilateral lower-limb amputee	✓	

3.5 Participants included in this study

From a total of 41 male amputees from the rehabilitation clinic, ten unilateral below-knee amputees were found to fulfil all the inclusion and exclusion criteria. Twelve amputees failed to fulfil the criteria which include less than one year use of prosthesis, using wheel chair or walking stick, age over 65 years, tremor, bilateral amputatations as well as being partial blind. The flow of amputee participants' recruitment is presented in Figure 3.2. Following the selection of amputee participants, a total of nine male able-bodied subjects were selected to match with the age, height and weight of the amputee group. The demographic characteristics of all participants for this study are summarized in Table 3.2.

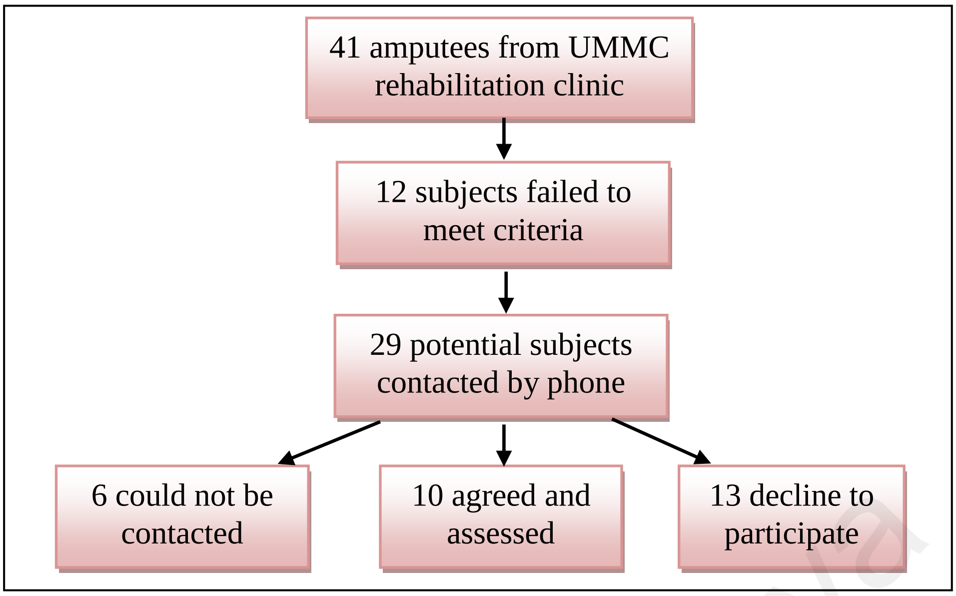


Figure 3.2: Flow diagram of amputee subject recruitment.

All participants gave written informed consent prior to testing. Using the MFCL indicators, persons with below-knee amputation were categorized as K2 and K3 community ambulator which is defined as someone who has the ability to ambulate with variance cadences and overcome low-barriers such as curbs or uneven surfaces (Gailey *et al*., 2002). Prior to testing, all participants were instructed to wear flat, full-covered shoes (preferably sport shoes), comfortable short-sleeve shirts and pants. The body weight and height were measured using a standard dial column medical scale with height rod. All participants are required to wear flat shoes with rubber sole throughout the study for safety purposes (Hinman, 2000) and to provide better fitting for the prosthetic foot. Therefore, height and weight measurements were taken while wearing shoes.

Subjects were tested with their own socket and suspension components throughout the study. Prosthetic foot was standardized across subjects with three types of feet namely SACH, SA and ESAR. Details for each foot type can be found in Section 3.6. Although the types of socket and suspension may influence standing stability, there is not enough evidence on the effects of this component on standing balance of amputees (Kamali *et al*., 2013). Therefore, we did not standardize the socket and suspension type. Nevertheless, to minimize the confounding factors from socket and suspension types, our registered research prosthetist evaluated the overall quality of the two components such as fitting quality and free from any cracks. If the socket or suspension was deemed not suitable, the subject was provided with a new unit. The same prosthetist evaluated and ensured that the subjects' existing prosthetic sockets and components were well fit before the testing trials. The amputees' current prosthetic sockets and components were optimally aligned using a laser liner during bench and static alignment. In addition, dynamic assessment of prosthesis alignment was determined by the prosthetist as the subject ambulates along the parallel bars (Figure 3.3).

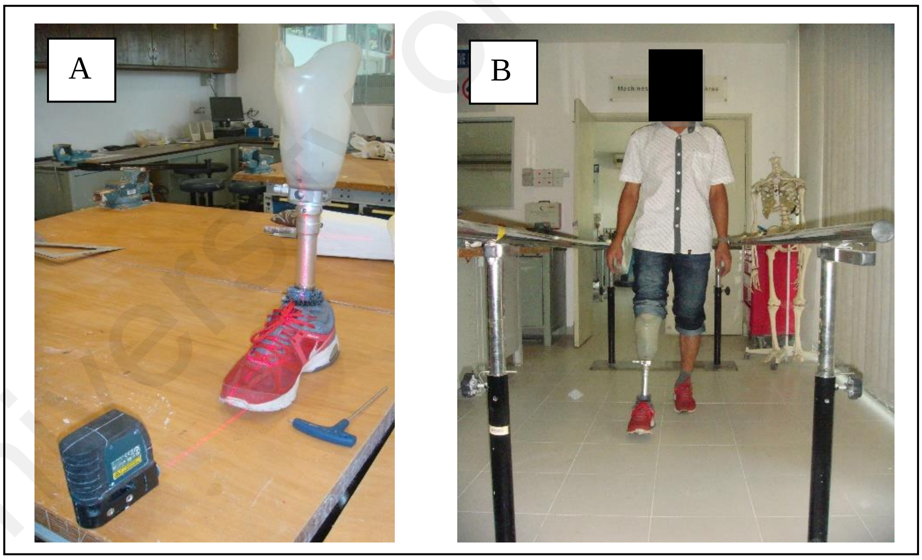


Figure 3.3: Bench (A) and dynamic (B) alignment during each testing session.

Table 3.2: Amputee and able-bodied participant characteristics

Subject	**Age (y)**	**Height (m)**	**Mass (kg)**	**Etiology**	**Mobility grade**[†]	**Time since amputation (years)**	**Prosthetic foot**	**Suspension**	**BBS (max 56)**
Amputees									
1	59	1.71	75	Diabetic	K2	6	SA	PTB with pelite	52
2	23	1.62	88	Trauma	K3	2	SA	PTB with pelite	56
3	45	1.78	84	Trauma	K3	25	SA	PTB with pelite	56
4	52	1.67	64	Trauma	K3	5	ESAR	TSB with pin lock	56
5	42	1.72	58	Trauma	K3	9	SA	TSB with pin lock	56
6	38	1.75	100	Diabetic	K2	5	SA	TSB with pin lock	56
7	44	1.77	109	Diabetic	K2	3	ESAR	TSB with pin lock	49
8	25	1.65	55	Tumor	K3	3	ESAR	TSB with pin lock	56
9	61	1.62	69	Diabetic	K2	7	SA	TSB with pin lock	51
10	59	1.66	68	Diabetic	K2	6	SA	TSB with pin lock	41
Mean	**44.8**	**1.70**	**77.0**			**7.1**			**52.9**
SD	**13.5**	**0.06**	**17.9**			**6.6**			**4.9**
Able-bodied									
1	59	89.0	1.68						56
2	42	75.0	1.75						56
3	22	74.0	1.63						56
4	44	81.0	1.61						56
5	57	74.0	1.61						56
6	35	70.0	1.64						56
7	50	69.0	1.63						56
8	27	57.0	1.67						56
9	61	76.0	1.7						56
Mean	**44.1**	**1.66**	**73.9**						**56**
SD	**14.0**	**0.05**	**8.7**						
***p*-value**	0.91	0.68	0.15						0.08

Note. [†]Based on Medicare K-level (Gailey *et al*., 2002). SA: Single axis, ESAR: Energy storage and release, PTB: Patellar tendon bearing socket, TSB: Total surface bearing socket, BBS: Berg Balance Score. The *p*-value indicates no significant differences between the groups for age, height, weight and BBS score.

3.6 Determination of prosthetic foot stiffness from the standard mechanical testing

3.6.1 Introduction

As mentioned in Section 2.3.7, mechanical design of prosthetic foot is suggested to influence the control of balance in persons with below-knee amputation. Moreover, the prosthetic ankle-foot mechanism is considered as an important part of the prosthesis (Hofstad *et al*., 2009). In relation to this, comparative studies on prosthetic feet have been focused on the biomechanical outcomes such as spatial, temporal, kinetics, kinematics, muscle activity and energy expenditure (Hafner, 2005; Hofstad *et al*., 2009). In fact, the majority of previous studies used walking speed and ankle range of motion to investigate differences between specific components of the prosthetic feet (Postema *et al*., 1997; Ventura, 2010; van der Linden *et al*, 2004). Although these parameters are useful indicators which can be used in prosthetic feet assessment, they were not sufficient on their own to fully explain the important mechanical properties of the prosthesis in influencing the amputee performance and comfort.

Therefore, several researchers have conducted structural mechanical testing to explore the intrinsic properties of prosthetic foot (Cortes *et al*., 1997; van der Linden *et al*., 1999). Previous studies measured fatigue and strength of prosthetic foot (Rooyen, 1997; Toh, 1993), while others used the roll-over shape to describe the mechanism of prosthetic foot (Hansen, 2005; Sam, 2000). Earlier, researches started to investigate the stiffness of prosthetic foot which is represented by the slope of a force-deformation curve (Gaw, 2008; Lehman *et al*, 1993; Mason *et al*., 2011; van Jaarveld, 1990; Zeller, 2007). The prosthetic foot stiffness is usually measured at the heel and forefoot (Geil, 2001; Haberman, 2008; Rooyen, 2008; van Jaarsveld, 1990) as well as at the lateral and medial borders (Gaw, 2008; Zeller, 2007). This type of testing has been done on prosthetic foot at different loading angles that correspond to anatomical shank movement when walking (Postema *et al*., 1997; van Jaarsveld *et al*., 1990) or during heel to toe loading of the prosthetic ankle-foot similar to that seen during normal walking. The loading is applied by a static or quasi-static (slow) manner using mechanical testing apparatus (Geil, 2001; Geil, 2002; Lehman *et al*., 1993; Ventura, 2010; Zeller, 2007). Another type of loading is the dynamic loading (faster loading) which is performed to combine the effects of the stiffness and damping of the prosthetic ankle-foot system (Hansen, 2005). Geil (2001) reported that when a range of prosthetic feet undergone mechanical testing, they are self-classified into four different linear stiffness categories. These categories were based on the mechanical testing on eleven energy storage and return (ESAR) prosthetic feet from six different manufacturers, and they are shown in Table 3.3. Alternatively, studies that measures stiffness of medial and lateral borders of prosthetic feet at various slope angles demonstrated significant differences in stiffness between foot designs (Gaw, 2008; Zeller, 2007).

Table 3.3: Stiffness categories according to the mechanical testing on ESAR prosthetic feet at the forefoot region, with vertical compression load of 800N. Note that the stiffness value in this study is the load-deformation curve slope (Geil, 2001).

Averaged Stiffness Value kN/mm	Stiffness Category
0.0760	Most stiff
0.0606	More stiff
0.0384	Less stiff
0.0277	Least stiff

According to the US Food and Drug Administration (FDA), prosthetic foot is identified as an external limb prosthetic and classified as Class I medical device. Hence, structural or performance test is not required for prosthetic foot before releasing the product to the market. However, the American Orthotic & Prosthetic Association

(AOPA) strongly urged the manufacturers to perform standard mechanical test to validate certain characteristics of a prosthetic foot (AOPA, 2010). Preceding studies adopted mechanical testing proposed by the Veteran Administration Prosthetic Centre (VAPC), which requires the foot to be tested at the forefoot and the heel respectively under the load of 667N. The VAPC recommended the use of 30° forefoot block for dorsiflexion and toe extension tests, while the 15° heel block is for plantarflexion test (Figure 3.4).

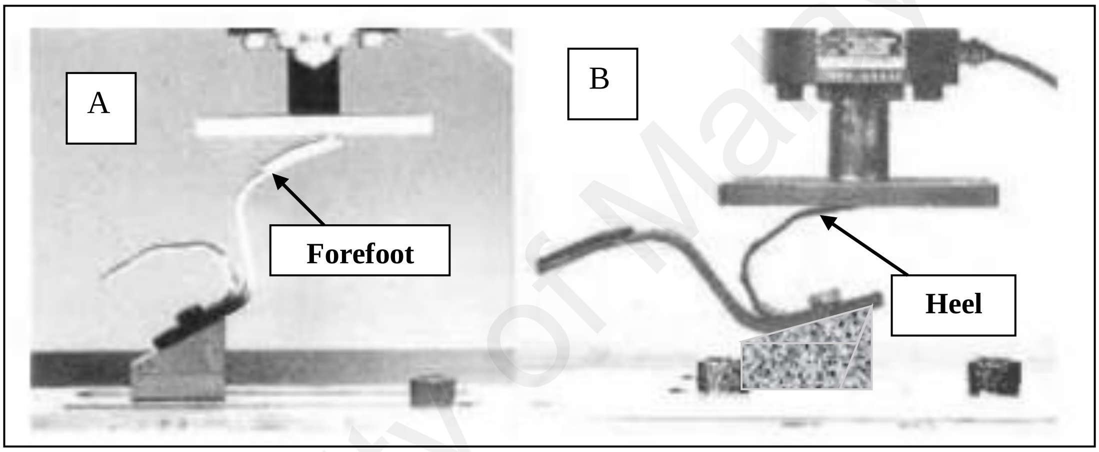


Figure 3.4: Static tests on the Lambda foot using VAPC 1973 procedure at (a) forefoot, and (b) heel region. (Reproduced from Toh *et al*., 1993)

Additionally, the ISPO also recommended similar standard to those proposed by the VAPC except for the load which is 1350N. However, the load proposed by the VAPC may be too low that the results obtained are not reliable, while higher load suggested by the ISPO may only represent active amputees or amputees from Western countries which generally have higher body mass compare to Asians (Toh *et al*., 1993). For this reason, a loading force between the recommended loads of 1350N and 667N should be appropriate when performing static mechanical test (Toh *et al*., 1993).

In 2010, the ISPO has reached consensus to adhere to the ISO 10328:2006 procedures for structural testing of lower limb prostheses (Jensen and Sexton, 2010).

This standard specifies the procedures for principal static and cyclic strength test on lower-limb prosthesis (ISO, 2006). This includes the use of 15^0 block for heel loading and 20^0 block for forefoot loading to represent different instants during the stance phase of walking. An example of utilising the ISO 10328:2006 standard includes the practice of AOPA that requires the foot manufacturers to perform structural mechanical test in determining the specific coding of prosthetic feet based on the certain characteristics of the prosthetic foot.

The stiffness values from some of the previous studies are tabulated in Table 3.4. Nevertheless, results of these studies should be interpreted with caution due to the heterogeneous methods including different maximum loading values and different apparatus (custom made versus standard device) used during the mechanical test. Often, researchers investigated the effects of different prosthetic feet interventions in prosthetic-amputees interface environment. However, without knowing the specific feature of the prosthesis, for example the stiffness, most of the studies used different types of commercially available prosthetic feet with various mechanical characteristics, causing the interpretation of the findings difficult. Accordingly, this study aims to provide independent measurement of structural stiffness for three categories of prosthetic feet which will be used later in this study.

Table 3.4: Summary of Linear stiffness (kN/mm) value at the heel and forefoot regions for SACH, SA and ESAR foot from previous studies.

Author	Type of test	Heel region kN/mm			Forefoot region kN/mm		
		SACH	SA	ESAR	SACH	SA	ESAR
Van Jaarsvald *et al.*, (1990)	VA Standard 1973, 15^0 heel, 30^0 toe, F=1000N	0.054[1]	0.055[1]	0.044[1]	0.029[1]	0.034[1]	0.017[1]
Rooyen (2008)	F=600N	0.0655[1] 0.0526[2]	-	-	0.124 [1] 0.144[2]	-	-
Geil, 2001	VA Standard 1973, 15^0 heel, F=800N	-	-	-	-	-	0.0277[3] 0.0384[1] 0.0606[4,5] 0.0760[2,5]
Mason *et al.*, 2011	ISO 10328, N=2240N	-	-	0.1728[6] 0.0779[7] 0.0592[4]	-	-	0.01[6] 0.0488[7] 0.0559[4]

Note. 1=Ottobock; 2=Kingsley;3=College Park; 4=Ohio Willow Wood, 5= Trulife; 6= Freedom Innovations; 7=Ossur

3.6.2 Methodology

3.6.2.1 Prosthetic feet

The prosthetic feet used in this study were two SACH, two SA and one ESAR, resulting in a total sample size of five. The SACH and SA feet were chosen due to their common use in patient care (Goh *et al.*, 1984; Noonan, 2010), while ESAR represents modern prosthetic foot (Hafner, 2005). Each of the prosthetic foot types represents a different mechanism of movement at the ankle joint. For ESAR category, Talux foot low impact category 4 was chosen for body weight range from 78-88kg to match with the majority of participants' body weight. All manufacturers were not informed about the mechanical testing in order to obtain regular-production feet. All feet were inspected before the test to ensure no physical defects were present. The prostheses and their characteristics can be seen in Table 3.5 and Figure 3.5 to Figure 3.7.

Table 3.5: The characteristics of prosthetic feet used in this study.

Foot	Weight, kg	Length, cm	Manufacturer	Material
SACH	0.673	25	Enjoylife, Fujian, China	Wooden keel and high-density rubberized foam heel
Single axis	0.765	25	Enjoylife, Fujian, China	Metal keel with ankle joint and rubber heel
ESAR (Talux®) with cover	0.740	25	Ossur, Reykjavik, Iceland	Carbon fibre keel and heel

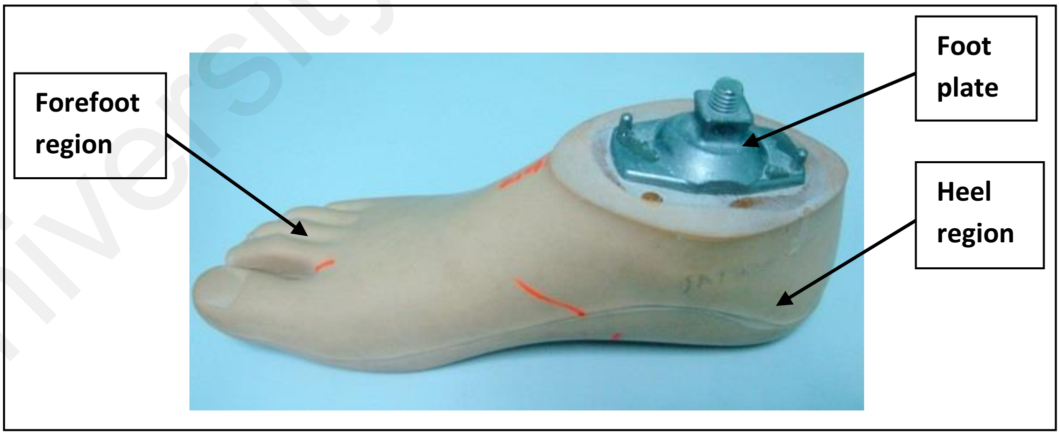


Figure 3.5: Components of Solid Ankle Cushioned Heel (SACH) foot

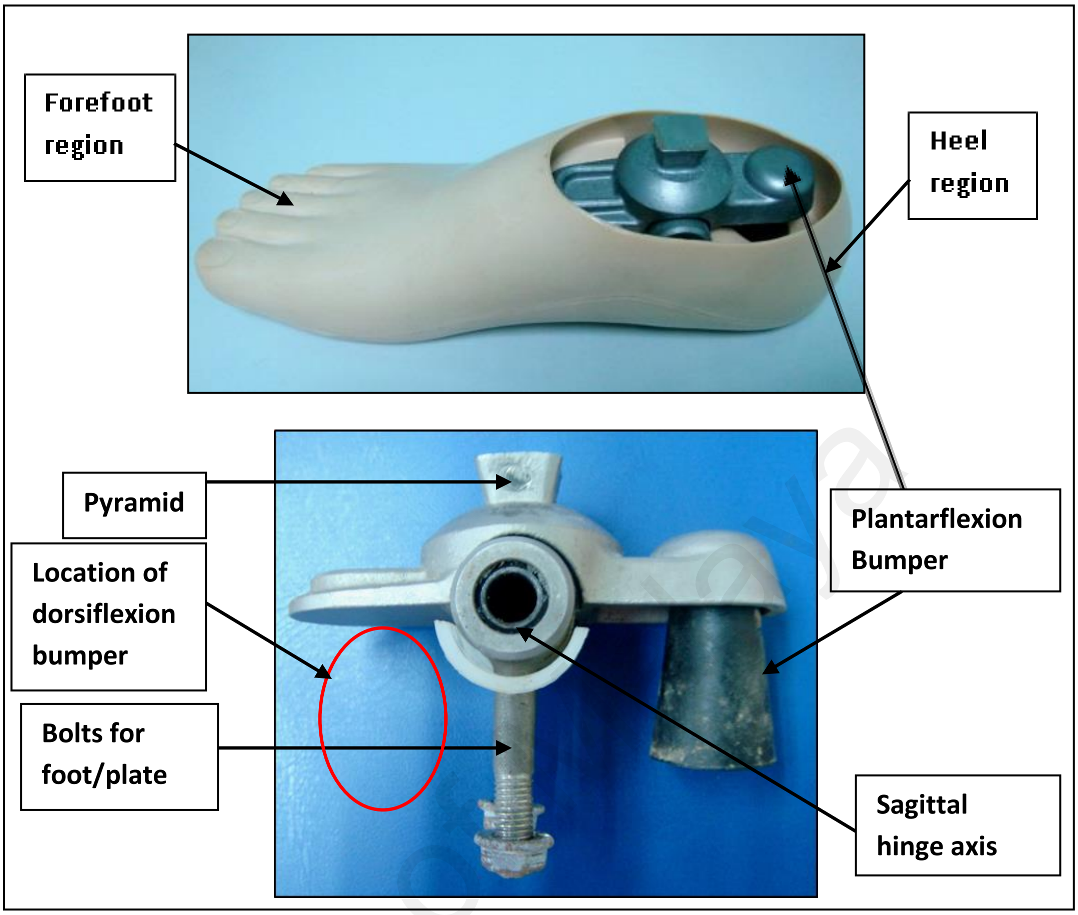


Figure 3.6: Components of Single Axis (SA) foot

Figure 3.7: Components of Energy Storage and Return foot (ESAR) Talux

3.6.2.2 Mechanical structural testing

Material test was performed using an Instron 4469 universal tensile machine (Figure 3.8) according to ISO 10328 protocols. The testing machine consist of Instron load cells, which are the precision force transducers with strain gauges attached to internal loading bearing structures in the machine. The load cells are stressed during a material test by applying vertical tension or compression forces (Instron, 1996). The crosshead was set at a constant speed of 1mm/min. Some of the specifications of the machine are listed in Table 3.6.

Table 3.6: Selected Instron 4469 load frame specifications.

Specifications	Descriptions
Position measurement accuracy	±0.01mm or 0.15% of displacement of displayed reading, whichever is greater
Position repeatability	±0.05mm
Speed accuracy	±0.1% steady state, measured over 100mm or 30sec, whichever is greater, no load
Load weighing accuracy	±0.5% of full scale to 1/50 of load cell capacity, or ±1 count on the display, whichever is greater
Strain measurement accuracy	0.6% of reading ± 25% of calibration point ±1 count on the display, whichever is greater

Next, the test prosthetic foot was attached to a standard pylon via the ankle bolt and pyramid adapter. Prior to testing, the prosthetic foot was aligned so that the longitudinal axis of the foot was positioned at 7^0 external rotations (toe out). During the alignment process, the foot was placed on an L-shape heel-support to compensate for the heel height of the prosthetic foot. (Figure 3.9). A laser pointer was used to ensure the accuracy of the alignment, such that the laser line should pass at the middle of the pylon posteriorly and laterally (Figure 3.10).

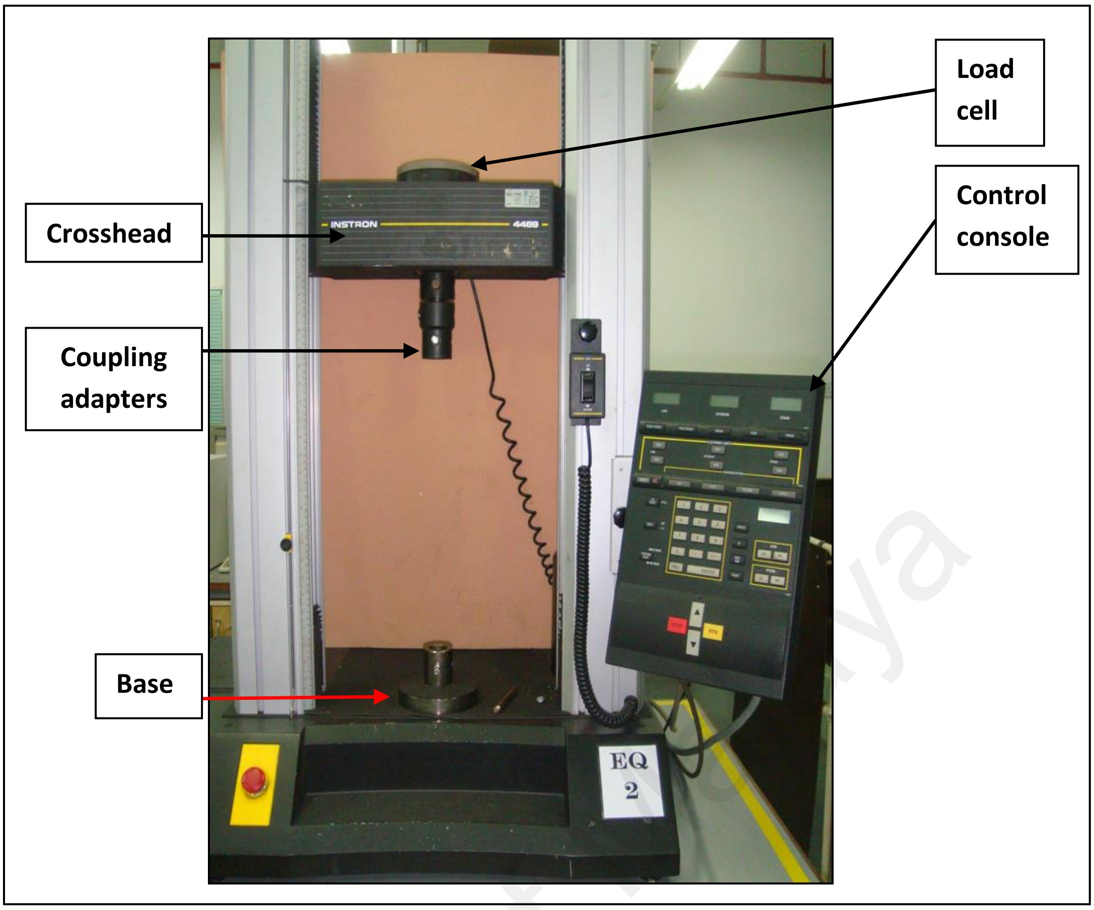


Figure 3.8: Instron 4469 universal tensile machine.

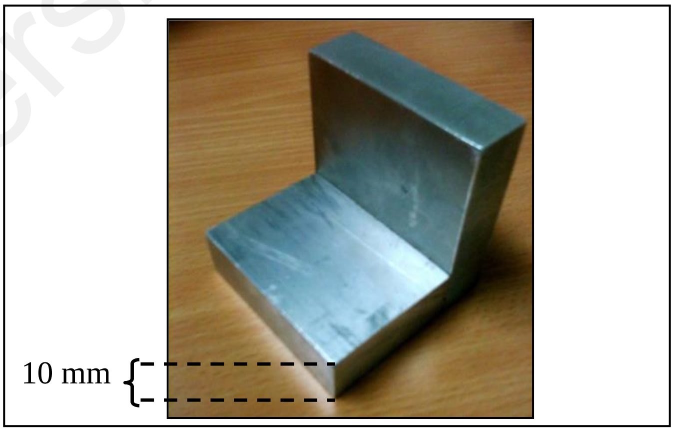


Figure 3.9: L-shape heel block with the height of 10 mm.

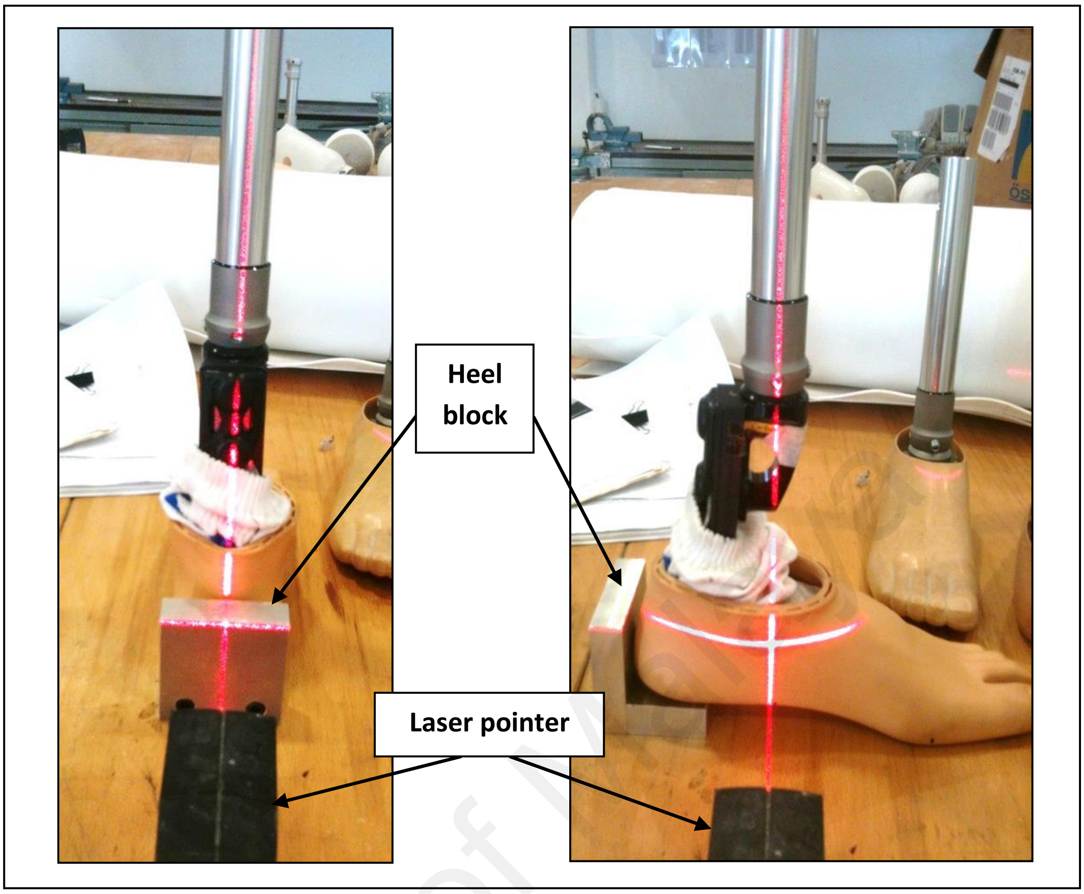


Figure 3.10: Alignment using laser pointer and heel block from posterior and anterior aspect of the foot.

Once the alignment was confirmed, the pylon was securely attached to the test jig by a custom cylindrical adaptor to ensure a snug fit between the pylon and coupling adapter. Two holes were drilled across the cylindrical adaptor and at the top of pylon. The cylindrical adaptor-pylon-coupling adapter interfaces were secured with a dowel pin that passed through the holes in the adaptors and pylon (Figure 3.11). The static proof test was conducted by applying the test force initially to the heel and subsequently to the forefoot of the same test sample. Measurements at the heel were taken at an angle of 15^0 simulating loading during early stance phase and forefoot loading at an angle of 20^0 simulating loading during late stance. This was accomplished by using the foot platforms, which are the heel and forefoot blocks (Figure 3.12).

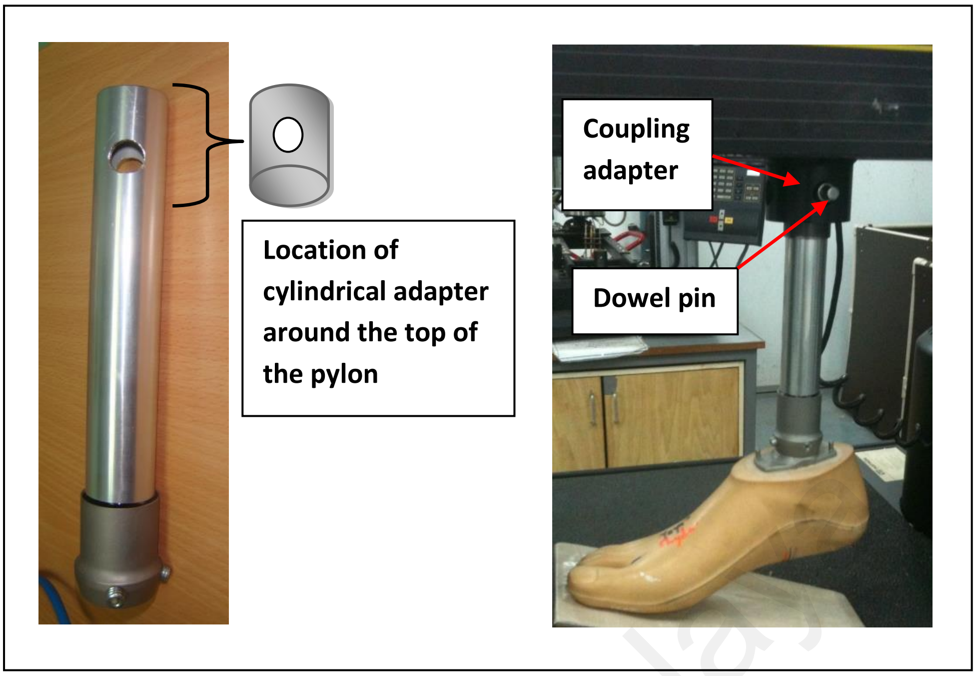


Figure 3.11: The attachment configuration of the cylindrical adaptor, pylon and coupling adapter via a dowel pin.

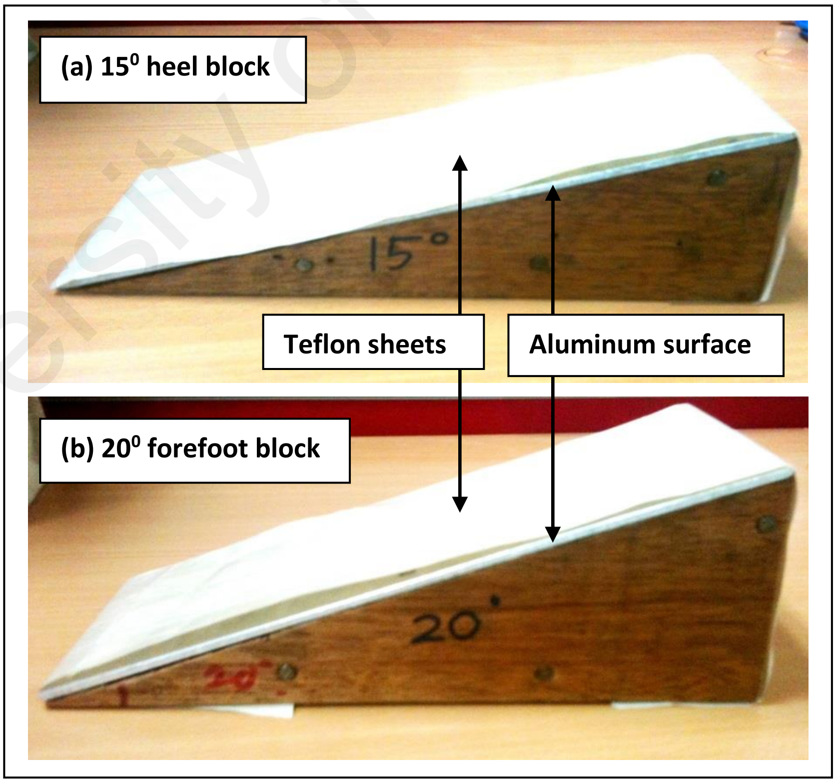


Figure 3.12: The foot platforms: (a) 15^0 heel block and (b) 20^0 forefoot block

These blocks were made out of wood with a 4mm thick aluminium surface to minimize surface deformation during the test (Carpenter, Hunter and Rheaume, 2008).

Teflon sheet was placed on each of the foot platforms to reduce shear forces between the surface of the foot and the loading surface. The heel or forefoot block was placed on the base of the testing machine. Next, the jig is set to a zero displacement position, determined by the point where the foot platform made initial contact with the heel or forefoot region. A stabilizing force of 50N was applied, before resetting the load to zero. Constant loading rates of 0.1mm/sec were applied to 800N of vertical compression (Geil, 2001; Toh *et al*, 1993). Load and deformation data were collected from the load cell during all tests for further analysis. As required by the ISO, each sample was tested twice, and in a randomized order to minimize testing bias. An example of experimental set up is illustrated in Figure 3.13.

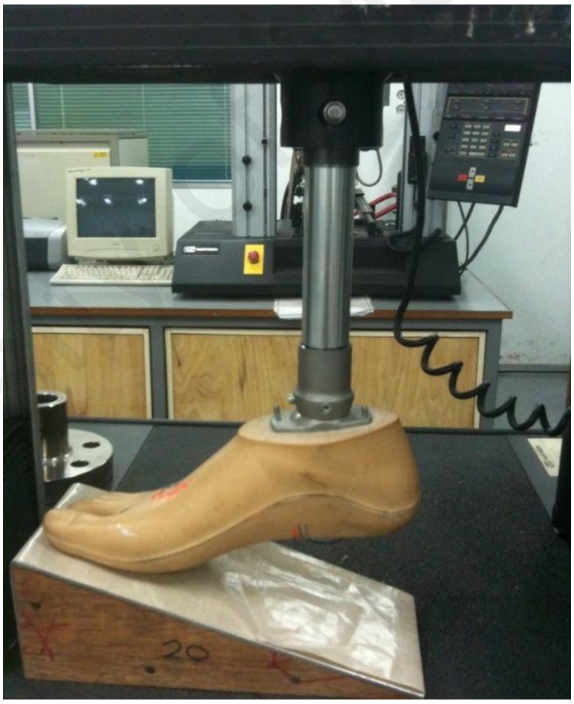


Figure 3.13: Experimental setup. A sample of prosthetic foot is shown aligned on an Instron 4469 universal tensile machine. Vertical compression loading transferred a bending load to the foot.

3.6.2.3 Calculation of stiffness at the heel and forefoot region

Stiffness of each foot was determined by finding a linear best-fit approximation of the slope from the load-deformation curve during the static proof loading test.The assessment of the adequacy of linear regression is based on the significance of the model (p-value) and coefficient of determination (R^2) value. The model's goodness of fit is confirmed when $p \leq 0.05$ and $R^2 > 0.8$. Often, trade-off between accuracy and simplicity occurs when choosing the best regression model. Hence, linear regression was chosen due to its simplicity in providing meaningful information to represent stiffness of the prosthetic feet. Although higher polynomial curve fitting will give perfect presentation of the experimental data, adding another independent variable to the regression model to increase accuracy by a few more percent may give meaningless information to the clinical and research application. All statistical analysis was performed using SPSS v16.0 (SPSS Inc., Chicago, IL, USA).

3.6.3 Results

Independent mechanical characteristics obtained from all three feet designs provide the necessary information to quantify the differences between types of feet at the heel and forefoot regions.

3.6.3.1 Mechanical structural testing

The illustration of initial and final conditions for each foot types are presented in Figure 3.14 to Figure 3.16.

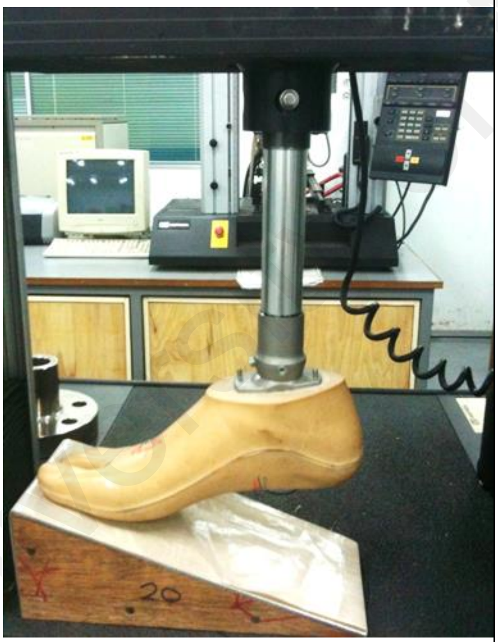
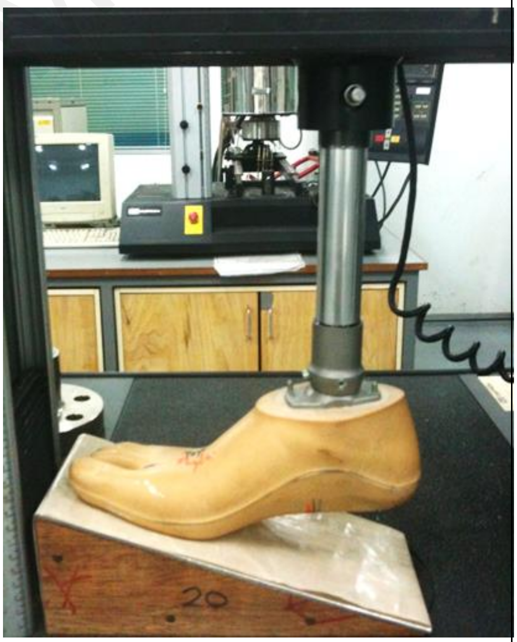
Initial loading	Final loading
Heel at 15^0	
	
Forefoot at 20^0	
	

Figure 3.14: Initial and final conditions during loading at the heel and forefoot regions of SACH foot.

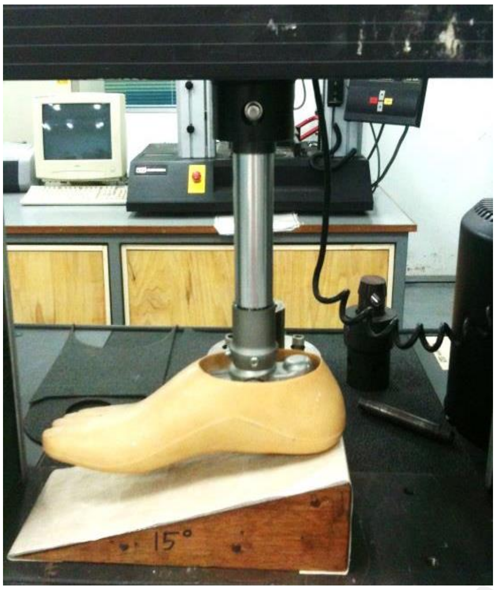
Initial loading	**Final loading**
Heel at 15^0	
	
Forefoot at 20^0	
	

Figure 3.15: Initial and final conditions during loading at the heel and forefoot regions of SA foot.

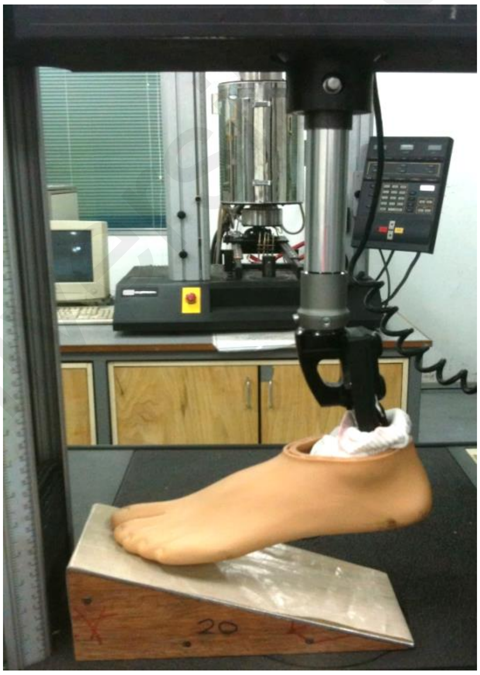
Initial loading	Final loading
Heel at 15^0	
	
Forefoot at 20^0	
	

Figure 3.16: Initial and final conditions during loading at the heel and forefoot regions of ESAR foot.

3.6.3.2 Linear stiffness value at the heel and toe regions

Force and deformation data were analysed to determine the stiffness at the heel and forefoot regions for all prosthetic feet. Figure 3.17 shows the typical load-deformation curve for a sample of SACH foot, in which the stiffness at the heel region was determined from the slope of the curve. Figure 3.18 and Figure 3.19 illustrate the load- deformation for all feet samples, while Figure 3.20 illustrates the hierarchy of stiffness among the feet.

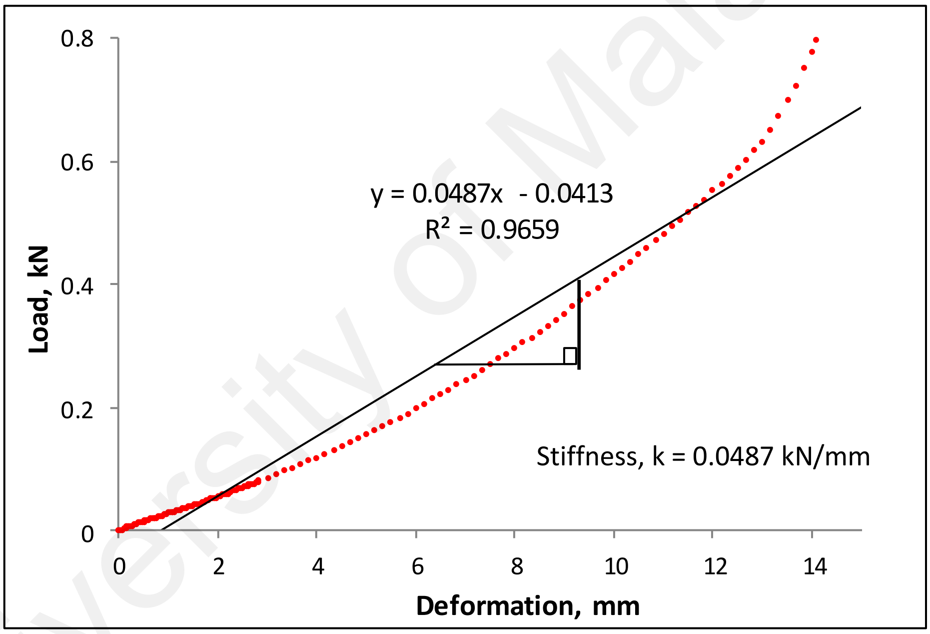


Figure 3.17: Determination of stiffness from the slope of load- deformation curve for a sample of SACH foot during loading at the heel region.

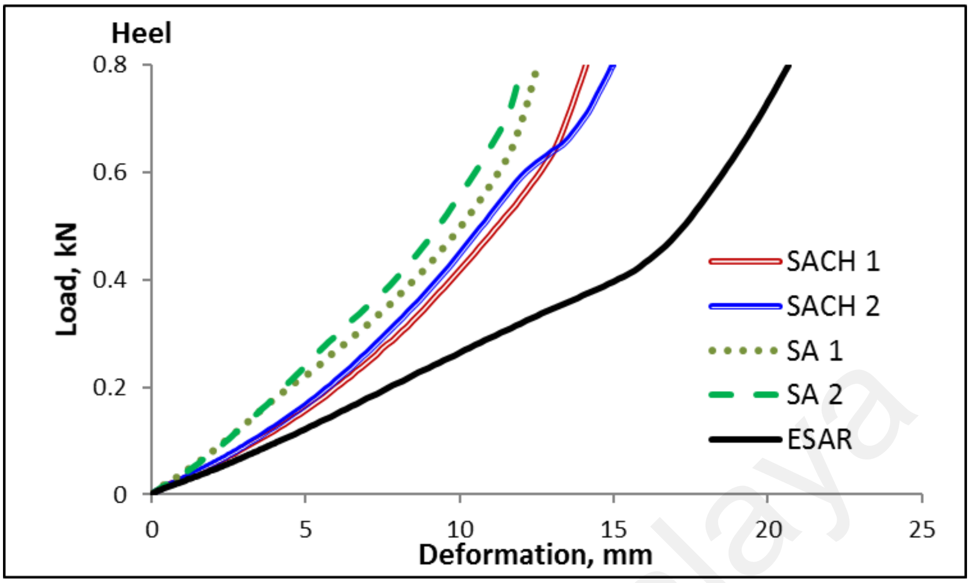


Figure 3.18: Plot of load- deformation curve to determine the stiffness at the heel region for five samples of prosthetic feet.

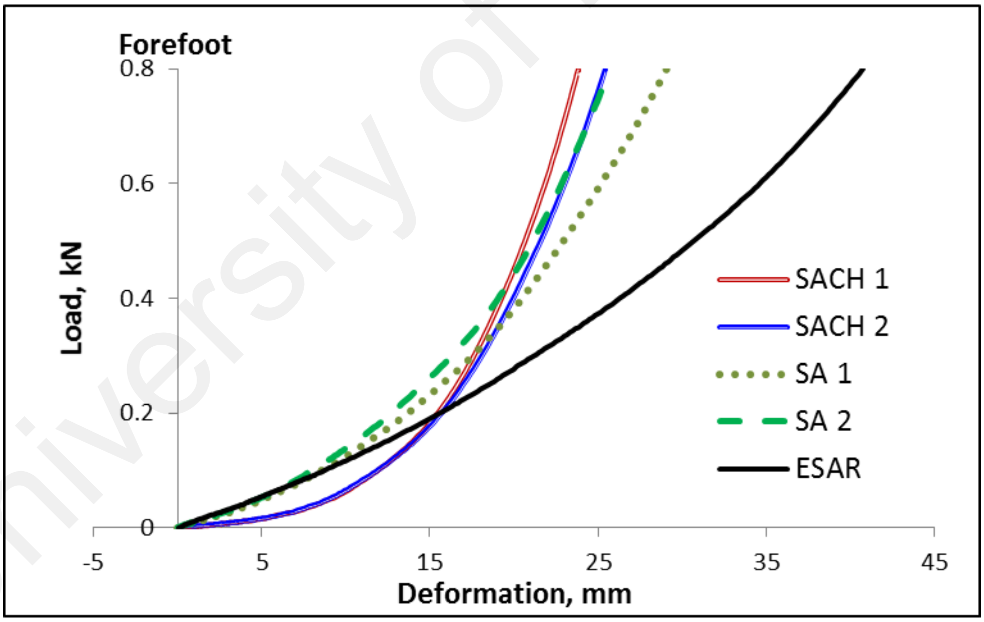


Figure 3.19: Plot of load-deformation curve to determine the stiffness at the forefoot region for five samples of prosthetic feet.

Table 3.7 summarizes the means of these data for each sample. Loading to 800N produced a range of deformation of 14.13 cm to 20.66 cm at the heel region, and 23.84 cm to 40.78 cm at the forefoot region. Among all feet, the ESAR Talux® foot demonstrated the highest deformation both at the heel and forefoot regions. Overall, deformation at the forefoot region was higher than the heel region in all tested feet.

Table 3.7: Maximum deformation and stiffness values at the heel and forefoot region for all samples of prosthetic feet.

Prosthetic foot	Max deformation, mm		Stiffness (kN/mm)	
	Heel	**Forefoot**	**Heel**	**Forefoot**
SACH 1	14.13	23.84	0.0487	0.0251
SACH 2	14.97	25.45	0.0507	0.0247
Single axis 1	12.56	29.10	0.0541	0.0243
Single axis 2	12.04	25.73	0.0593	0.0262
ESAR	20.66	40.78	0.0319	0.0179

The averaged deformation and stiffness properties of each foot types were tabulated in Table 3.8. At the heel region, the ESAR foot exhibited the lowest stiffness followed by SACH and SA. In specific, the heel region of ESAR foot was 56% and 78% less stiff than SACH and SA, respectively. Whereas at the forefoot region, the ESAR showed the lowest stiffness followed by SACH and SA. The differences between ESAR and non-ESAR feet were such that the forefoot stiffness of ESAR was 28% and 41% less stiff than SACH and SA, respectively.

Table 3.8: Averaged deformation and stiffness for each type of foot, where R^2 is coefficient of determination, K is stiffness and p-value <0.05 indicates the significant of the model.

Foot type	Averaged max deformation, mm		R^2		Averaged Stiffness, k (kN/mm)		p-value
	Heel	**Forefoot**	**Heel**	**Forefoot**	**Heel**	**Forefoot**	
SACH[1]	14.55	24.65	0.98	0.85	0.0497	0.0249	0.000
SA[2]	12.30	27.42	0.98	0.94	0.0567	0.0253	0.000
ESAR[3]	20.66	40.78	0.98	0.97	0.0319	0.0179	0.000
	% Differences,mm				% Differences,kN/mm		
2-1	-18.3	10.1			14.1	1.6	
3-1	42.0	65.4			-55.8	-28.1	
3-2	68.0	48.7			-77.7	-41.3	

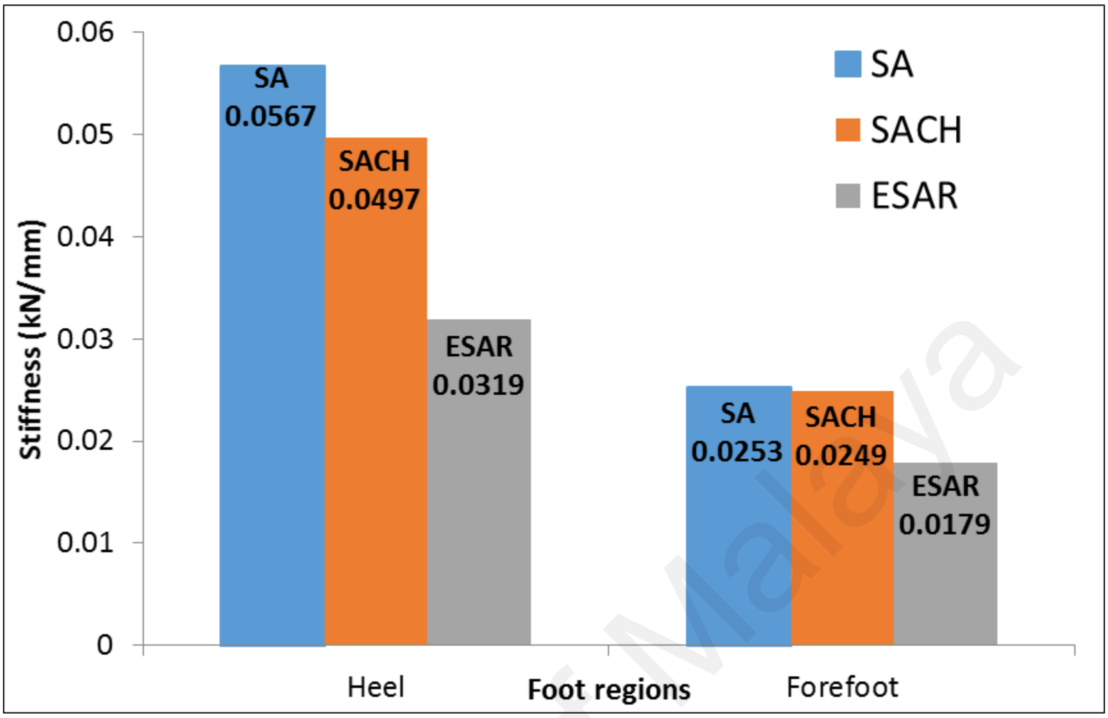


Figure 3.20: Linear stiffness of each prosthetic foot at the heel and forefoot region obtained from static structural test in descending order.

3.6.4 Discussion

Stiffness profile is considered as one of the important criteria that need to be considered before prescribing a prosthetic foot. Yet, prosthetist based on their experience prescribed prosthetic foot according to patient's activity level and body weight. Moreover, manufacturers often provide limited property information, coupled with variations in mechanical testing procedures of their prosthetic feet.

Therefore, this study provides independent assessment of structural stiffness to gain better understanding of the intrinsic profile of three types of prosthetic feet. Moreover, the mechanical test is conducted in a controlled environment which eliminates variability between- and within-subjects (Geil, 2001). This initial study is important before different prosthetic feet interventions can be clinically compared in another study. The variances between feet types are quite apparent in the maximum deformation data. The ESAR foot deformed 42% and 68% more than the SACH and SA foot at the heel region, respectively. Similarly at the forefoot region, the ESAR showed 65% and 49% more deformation compared to SACH and SA, respectively. The results of this study indicate that the SACH and SA feet which are made mainly from rubber material displayed similar deformation data while the carbon fiber ESAR foot not only showed the highest deformation at the heel, but also at the forefoot region.

The findings of this study demonstrated that stiffness profiles at the heel and forefoot can also be utilized to explain the differences between non-ESAR (SACH and SA) and ESAR foot. When comparing mechanical stiffness features of the tested feet in this study, the findings suggested that the differences between feet are more obvious at the heel region (14% for SACH-SA, 56% for ESAR-SACH, 78% for ESAR-SA) compared to forefoot region (1.6% for SACH-SA, 28% for ESAR-SACH, 41% for ESAR-SA). Overall, the ESAR foot demonstrated the lowest heel and forefoot stiffness among the feet, followed by SACH and SA foot. This showed that the ESAR foot was more compliant than SACH and SA foot. However, the difference was very minimal (1.6%) between SACH and SA foot for the forefoot region. The finding that the heel region of SA foot is stiffer than that same region of SACH foot was in agreement with previous studies (Goh *et al*., 1984; Toh *et al*, 1993). Similarly, this study was in agreement with previous finding (Van Jaarsvald *et al*., 1990) that reported the lowest stiffness at the heel and forefoot region for ESAR compared to SACH and SA. This may be related to the greater flexibility of the carbon fibre material which may influence the mechanical characteristics of the ESAR foot.

There are few limitations in this study that should be taken into consideration. Firstly, only three types of prosthetic feet from two different manufacturers were used as test samples, and a total of five prosthetic feet were tested. Also, the cyclic test which involved sinusoidal load applied at the heel and forefoot was not performed on the foot due to its time-consuming procedures. Moreover, the standardized ISO 10328 protocols only represent loading condition in an ideal gait at the heel and forefoot regions. This condition may not present other loading conditions such as uneven surfaces or loading at the medial and lateral borders of the prosthetic foot. Additionally, the influence of different footwear to the foot stiffness is not discussed in this study. Lastly, structural mechanical testing does not fully describe the principal function of a prosthesis foot. Hence, it is as important to access prosthetic foot function during amputee-prosthesis interface.

3.6.5 Conclusion

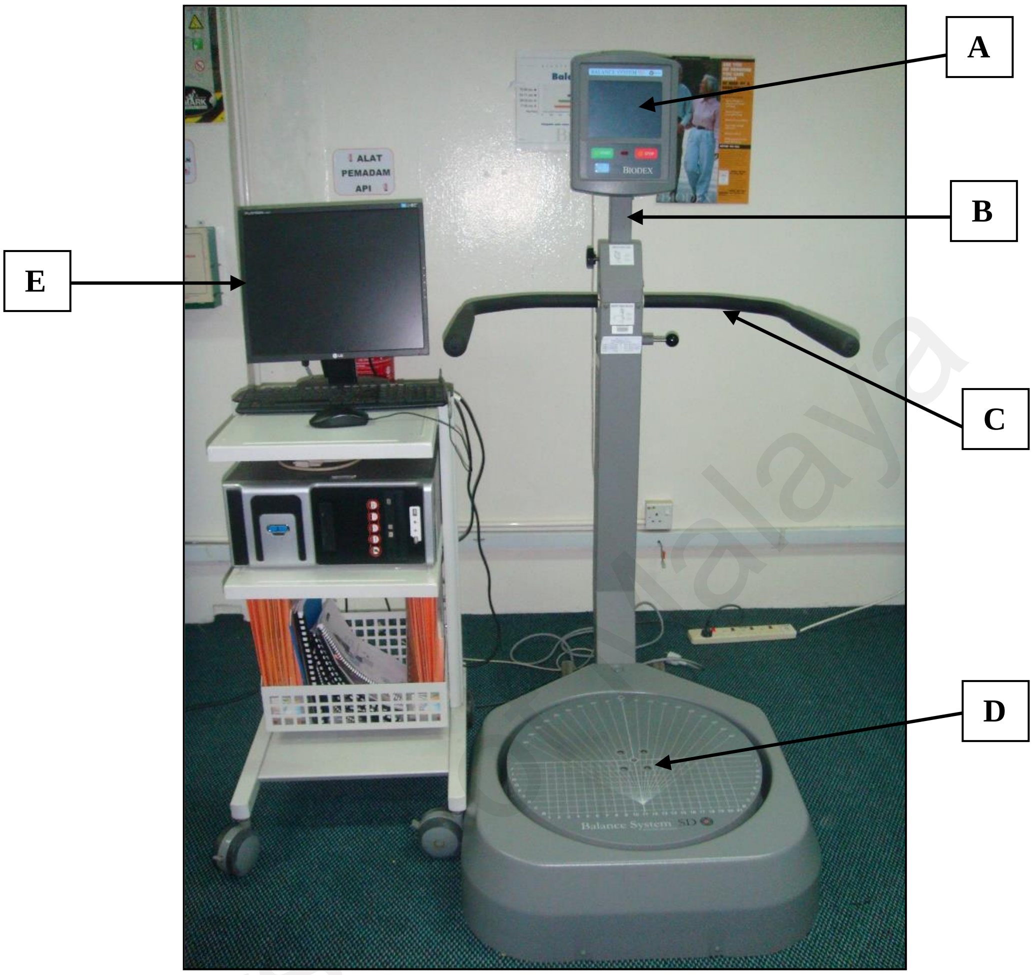
This study showed a successful use of universal tensile machine to determine stiffness of various prosthetic feet by following the standardized mechanical test procedures. It was found that differences between non-ESAR and ESAR prosthetic feet used in this study can be characterized based on their stiffness profile at the heel and forefoot regions. The ESAR foot showed the highest deformation and the lowest stiffness at both regions when compared to SACH and SA foot. Future biomechanical study is necessary to demonstrate the definitive functional differences of prosthetic feet in user-prosthesis environment.

3.7 Balance assessment using Biodex Stability System (BSS)

3.7.1 Overview

The postural stability of amputee and healthy participants was assessed using the Biodex® stability system (BSS) model 950-302 (Biodex Medical System, Shirley, NY, USA) (Figure 3.21). BSS measures the overall stability index (OSI), anterior/ posterior stability index (APSI), and medial/ lateral stability index (MLSI), which represent the standard deviation of the angular fluctuations from the centre of the platform (zero point) at a sampling rate of 20Hz (Arnold & Schmitz, 1998). This device consists of a circular platform which provides up to 20° of surface tilt in a 360^0 free movement about the AP and ML directions simultaneously.

The BSS system has been known for its reliability in objective assessment of postural stability based on the findings from previous literatures. Good reliability of the BSS during dynamic double stance standing have been reported in active adults with interclass correlation of coefficient (ICC) of OSI=0.94, APSI=0.95 and MLSI= 0.93 (Cachupe *et al*., 2001) and older adults with ICCs of OSI=0.69 (Baldwin *et al*., 2004) using stability level of 2 and 8. Similarly, good reliability has been demonstrated by the BSS system during static double stance standing among older adults with ICC OSI=0.69 (Parraca *et al*., 2011). Pincivero, Lephart and Henry (1995) reported the ICC during dynamic single leg standing among university students for OSI at resistance level 2 (ICC dominant and non-dominant= 0.60) and level 8 (ICC dominant=0.95, non-dominant=0.78). With respect to intra-tester and inter-tester reliability, Schmitz and Arnold (1998) found the BSS as a reliable assessment device during dynamic single leg standing among university students using resistance level 8. They reported the intra-tester and inter-tester reliability for OSI as 0.82 and 0.70, respectively.



	Item	Description
A	Colour touch-screen LCD display and its adjustment knob	Resolution: 800 x 600
B	Adjustable height display	Adjustable from 135-173 cm above platform
C	Support handles and its adjustment knob	Adjustable from 64 to 93 cm above platform
D	Adjustable platform	Stability Levels: 12 dynamic levels, plus locked for static measurements
E	Computer	For download and transfer of patient data

Figure 3.21: The Biodex Stability System (BSS)

In BSS system, the neuromuscular control aspect of balance is challenged by requiring the subject to maintain the CoM over the base of support to keep the platform level. In a dynamic test, the patient's ability to control the platform angle is quantified as a variance from the level position; while static testing measures the angular excursion of the patient's CoM. Generally, testing in static mode can be used as a baseline testing before progressing into dynamic testing and training for patients with movement disorder. Moreover, the display monitor of BSS provides visual biofeedback to the subject via the moving trace of their CoM.

Platform stability, which ranged from 1 (least stable) to 12 (most stable), was varied in terms of spring resistance levels. The stability of the platform can be adjusted by varying the springs' resistance force applied to the platform via series of strain gauges embedded within the platform (Arnold & Schmitz, 1998). Previous studies suggested the use of resistance level 2 for athletic, 4 for active person and 8 for neuropathic and rheumatoid arthritis subjects (Aydog *et al*., 2006; Paterno *et al*., 2004; Testerman *et al*., 1999; Salsabili *et al*., 2011). Therefore, considering that amputees have more serious balance deficit due to their amputation, this current study has chosen the resistance level of 10 for dynamic testing. In addition, by controlling the resistance level of the platform, differences found for stability indexes between prosthetic feet were likely attributed to a change in local stability and not a change in resistance level.

The top surface of the 55cm diameter circular platform was marked with 5^0 increment lines and coordinate grids for feet placement recordings (Figure 3.22). The platform was integrated with computer software (Biodex, Version 3.1, Biodex Medical Systems) that enables the device to calculate stability indexes. The stability score is based on the deviation from the centre, thus, higher stability index means greater amount of body movement which is associated with an unstable posture. On the other hand, lower stability index indicates little movement which is associated with a more stable posture.

Figure 3.22: The stability platform with adjustable stability level.

The BSS has been previously showed to successfully quantify postural stability in arthritis patients and person with ankle instability (Aydog *et al*., 2006; Testerman & Griend, 1999). Although these studies found differences in dynamic balance between people with balance problem and healthy group, it is uncertain whether BSS could also be utilised to differentiate between persons with below-knee amputation and healthy during static balance. Hence, due to its reliability, practicality, easy to administer and cost-effectiveness (Parraca *et al*., 2011; Guskiewicz & Perrin, 1996), BSS may be a potential approach in the evaluation of postural stability in persons with below-knee amputation for rehabilitation purposes. Furthermore, the OSI generated from the system is considered as an efficient balance indicator of the ability to control balance (Testerman & Griend, 1999).

3.7.2 Stability index parameters

This section highlights the variables that were analysed for the stability tests in this study. From the degrees of platform tilt (during dynamic testing) or from CoM excursion (during static testing) about the anterior- posterior and medial-lateral axes, the

BSS measures the OSI, APSI and MLSI. These indexes are standard deviations assessing fluctuations around the centre point (horizontal) of the platform. The OSI is a composite of the MLSI and APSI and, thus, is sensitive to changes in both directions. On the other hand, the APSI and MLSI indicate the variance of platform displacement in degrees from level for movements in the sagittal and frontal plane, respectively.

Technically, the Stability Index is obtained from the average radial distance from the centre at (0,0) coordinate. On the platform surface, the *x* and *y* coordinates are scaled to 2000 pixels wide and long (Biodex Medical Systems, 2014). The APSI and MLSI were calculated as the maximal displacement in the anterior-posterior and medial-lateral direction, respectively. Subsequently, the OSI score was obtained according to the Pythagorean Theorem which calculate the distance from the centre as the square root of [(x*x) + (y*y)]. The OSI, MLSI, and APSI scores were calculated for each data point according to Equation 3.1, Equation 3.2 and Equation 3.3, respectively.

$$\text{OSI} = \frac{\sqrt{\sum(0\text{-}Y)^2 + \sum(0\text{-}X)^2}}{\text{number of samples}} \tag{3.1}$$

$$\text{APSI} = \frac{\sqrt{\sum(0\text{-}Y)^2}}{\text{number of samples}} \tag{3.2}$$

$$\text{MLSI} = \frac{\sqrt{\sum(0\text{-}X)^2}}{\text{number of samples}} \tag{3.3}$$

where Y is the total anterior-posterior deviation in the sagittal plane and X is the total medial-lateral deviation in the frontal plane. In addition to stability indexes, the BSS calculates the percentage of test time the subject spent in specific zones and quadrant (Figure 3.23). The concentric circles were arranged at 5^0 increments as follows: Zone A: 0-5^0, Zone B: 6-10^0, Zone C: 11-15^0 and Zone D: 16-20^0. For double stance protocol, quadrants were defined as Quadrant I: right anterior, Quadrant II: left anterior, Quadrant III: left posterior and Quadrant IV: right posterior.

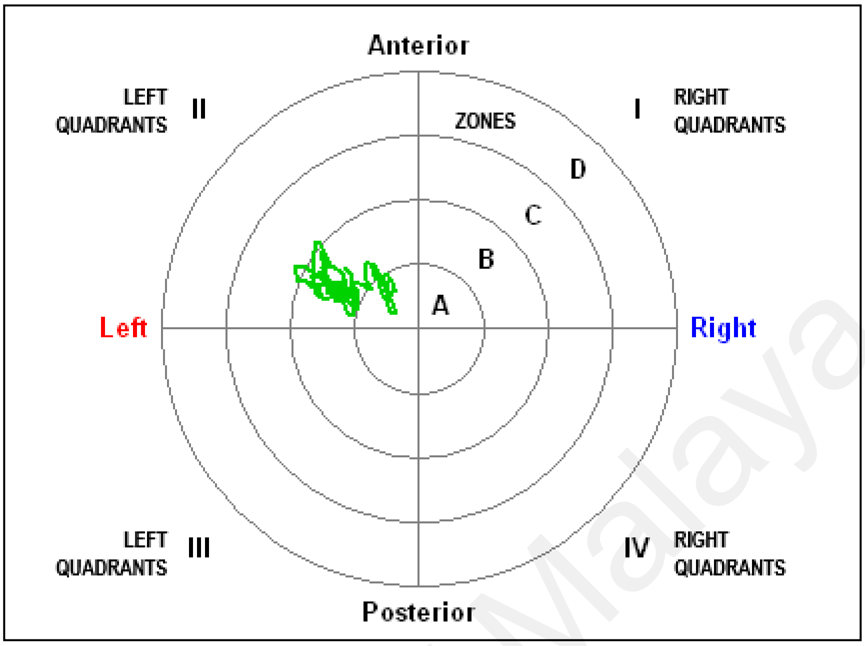


Figure 3.23: An example of a subject's trajectory of CoM displacement within zones and quadrants from the platform's centre during eyes-closed condition.

3.7.3 Patient data management

The platform was integrated with Biodex® software (Version 3.1 Biodex® Medical Systems) that enables the device to calculate stability indexes. In order to access the software, a special user access code was entered in the System Utilities screen. With this safety feature, data of all subjects were secured safely and can only be retrieved by authorised personnel. The software contained Patient Data Collection Software Utility (PDC) program allowing the exporting of all patient test results in a single .csv file. For this purpose, a serial interface cable from the BSS display was connected to the computer with Windows operating system. The software allowed patient data storage up to 2 MB, which is approximately equivalent to 200 patient tests.

The test result can be viewed as a graphic report with display of CoM trace and stability indexes, or in a *.csv* compatible program like Excel.

3.8 Self-report and functional outcome assessment of the participants.

3.8.1 Introduction

In the field of prosthetic research, outcome measures from the combination of biomechanical studies and perceptive assessment serves as scientific evidence to assess prosthetic intervention (Hafner, 2006). However, most of the research mainly focus on the biomechanical aspects of prosthetic function and performance from the quantitative outcome such as temporal and spatial parameters, kinetic, kinematic, energy expenditure as well as muscular activity. Perceptive analyses can be defined as studies that evaluate prosthetic devices through the use of patient assessment via descriptive dialog, functional assessment questionnaires and numerical rating scales (Hafner, 2005). Often, the limited use of perceptive outcome measures is linked to the unfamiliarity to administer the appropriate assessment as well as inadequate knowledge on choosing the assessment tools (Condie *et al.*, 2006). Although evaluations obtained from functional performance and patient's perception are considered vital to achieve the goal of scientific prosthetic research (Hafner, 2006), there is no consensus by far on the best assessment tools for the amputee population due to the complexity of amputation rehabilitation (Deathe *et al.*, 2002).

This study adopted several different assessment tools to determine the current status of prosthesis use in below-knee amputees and functional balance of both amputee and normal groups (Table 3.9).

Table 3.9. Outcome measurement tools related to lower limb prosthetics used in this study. The type of outcome measures is based on the guidelines proposed by Miller & McCay (2006).

Outcome measures	Assessment type
Medicare functional classification Level (K-Level)	Self-report
Health status questionnaire (SF-12v2)	Self-report
Houghton scale	Self-report
Berg balance test	Functional performance
Activities-specific Balance Confidence (ABC)	Functional performance

The MFCL consists of five levels classification system which is used to categorize below-knee amputees of this study into respected functional K-level. This classification serves as an indicator of the capacity and potential of people with lower-limb amputation to accomplish their activities of daily living (ADL). Additionally, the Medical Outcomes Study Short-Form version 2 (SF-12v2) measures the physical and mental health status of participants prior to testing (Ware *et al*., 1996). The Houghton Scale questionnaire serves as a subjective measure of prosthetic use and function (Devlin *et al*., 2004). On the other hand, the BBS has been implemented in amputee population to determine functional balance performance (Wong *et al*., 2013). Finally, the ABC scale aids in assessing fear of falling among individuals with lower-limb amputation. The aim of this study were to first, determine the prosthesis use among the amputee participants; secondly to determine functional balance status for both amputee and normal groups; and finally to investigate whether balance confidence scale is capable to discriminate differences between selected prosthetic feet.

3.8.2 Methodology

3.8.2.1 Participants

Ten transtibial amputees and nine matched able-bodied participants completed two self-report (SF-12v2 and Houghton scale) and two functional performance assessment (BBS and ABC scale) throughout the study. All participants gave written informed consent prior to data collection. Demographic details of each participant can be found in Section 3.5 (Table 3.2).

3.8.2.2 Self-report assessment

All amputated participants were categorized into respected K-level based on the MFCL guidelines. Prior to testing, all participates were required to complete the SF-12v2 health status questionnaire to confirm that their postural stability is not affected by confounding factors from poor mental and physical conditions. The SF-12v2 measures 8 different health concepts. The Bodily Pain (BP), General Health (GH), Vitality (VT), and Social Functioning (SF) concepts are represented with one item each. In addition, Physical Functioning (PF), Mental Health (MH), Role Physical (RP) and Role Emotional (RE) domains are represented with two items each. The PF, RP, BP and GH scales yield a Physical Component Summary (PCS) measure, and the MH, RE, VT, and SF scales reveal a Mental Component Summary (MCS) measure (Ware *et al*., 1996; Cheak-Zamora *et al*., 2009). Actual raw score for all eight subsets were transformed into a maximum of 100 score scores using equation as shown below (Ware *et al*., 2002). Additional information necessary to apply this formula for each scale is shown in Table 3.10.

$$\text{Transformed scale} = \left[\frac{\text{Actual raw score} - \text{Lowest possible raw score}}{\text{Possible raw score range}}\right] * 100 \quad (3.4)$$

Table 3.10: Aggregated scale items and range of possible scores.

Component Summary	**SF12v Scale Items**	**Sum Final Item Values**	**Lowest and highest possible raw scores**	**Possible raw score range**
Physical Component Summary (PCS)	General Health (GH)	Items 5	2,6	4
	Physical Functioning (PF)	Items 2a + 2b	2,10	8
	Role Physical (RP)	Items 3a + 3b	1,5	4
	Bodily Pain (BP)	Items 5	1,5	4
Mental Component Summary (MCS)	Vitality (VT)	Items 6b	1,5	4
	Social Functioning (SF)	Items 7	1,5	4
	Mental Health (MH)	Items 6a + 6c	2,10	8
	Role Emotional (RE)	Items 4a + 4b	2,10	8

The Houghton scale was completed by each amputee in order to determine their perception of prosthetic use and function prior to the start of study. The first three items evaluate hours of prosthesis use, how the prosthesis is used and the use of an assistive device with prosthesis on a 4-point scale. The fourth item assesses perceived stability when walking on three different terrains with Yes/No options. The result for each amputee was reported as maximum possible score of 12 points, with higher score representing better performance and comfort (Devlin *et al.*, 2004). A score greater than 9 was defined as successful prosthetic rehabilitation (Leung *et al.*, 1996). The questionnaire was completed face-to-face in the laboratory.

3.8.2.3 Functional performance assessment

The BBS was administered to ensure similar balance status between amputees and able-bodied participants. The test consisted of 14 common daily tasks, such as sitting, standing, reaching, turning, and stepping. Each item was scored from 0 to 4 with a maximum score of 56 points: 0 to 20 indicates a high risk of falling; 21 to 40 a medium risk of falling; and 41 to 56 a low risk of falling. Subjects who scored less than 20 points during the test were excluded from the study.

All amputees completed the ABC scale at each testing session to rate their balance confidence for a particular test foot. The overall score out of 100 was calculated by taking the average score of all items (maximum possible score= 1600 divided by 16). For items #2, #9, #11, #14 or #15 which may have different ratings for "up" vs "down" or "onto" vs "off", the lowest score of the two was used for the final score. All of the functional tests were performed by the main researcher and an experienced prosthetist on the same day.

3.8.2.4 Statistical analysis

Descriptive data was presented for Houghton score by using the individual score of each item as well as the mean and standard deviation for all amputees. On the other hand, the SF12v2, BBS and ABC data were initially screened for normality of distribution by using the Shapiro Wilk's test. The SF12v2 and BBS data were normally distributed and therefore, parametric analysis using independent-samples t-test was used to distinguish the balance status between amputee and able-bodied groups. However, non-parametric statistical analyses were adopted for ABC data by using the Friedman's repeated measures analysis to compare the score of sixteen items for the three prosthetic feet. When differences were identified between groups, post-hoc pairwise comparison using the Wilcoxon-signed rank test was conducted to determine where the significant differences occurred. The alpha level for significance was set a priori at 0.05. Statistical analyses were performed using SPSS v16.0 (SPSS Inc., Chicago, IL, USA).

3.8.3 Results

3.8.3.1 Self-report data

All participants demonstrated good health and mental status. The PCS data provided by SF-12v2 gives the population mean (SD) for healthy group as 82(11)% and for amputee group as 65(20)%. For MCS, the healthy and amputee groups obtained a score of 93(4)% and 89(10)%, respectively. From the independent-samples t-test, the PCS score in healthy group was significantly higher than amputee group. Conversely, the MCS score between both groups did not differ significantly (Table 3.11).

Table 3.11: Mean (SD) of PCS and MCS score for healthy and amputee groups.

No	PCS (%)		MCS (%)	
	Amputee	Healthy	Amputee	Healthy
1	88	71	94	100
2	71	88	94	91
3	85	92	97	97
4	82	92	94	91
5	67	79	94	91
6	35	92	63	94
7	74	61	94	88
8	74	74	91	94
9	37	92	81	91
10	40	-	88	-
Mean(SD)	**65(20)**	**82(11)**	**89(10)**	**93(4)**
p-value	0.04		0.28	

An average Houghton score of 10.5 ± 0.9 was reported for all persons with below-knee amputation prior to the study (Table 3.12).

Table 3.12: Individual and overall Houghton scores for all amputees (A1-10).

Item	A1	A2	A3	A4	A5	A6	A7	A8	A9	A10
1. Hours of prosthesis use	2	3	3	2	3	3	3	3	3	2
2. How the prosthesis is used	3	3	3	3	3	3	3	3	3	3
3. Use of an assistive device	2	3	3	3	3	3	3	3	3	2
4. Walking on various terrains										
(a) flat surface	1	1	1	1	1	1	1	1	1	1
(b) slope	0	0	1	1	0	1	0	1	0	1
(c) rough ground	1	1	0	1	1	0	0	0	1	0
Total	9	11	11	11	11	11	10	11	11	9
Mean ± SD	**10.5 ± 0.85**									

3.8.3.2 Functional performance score

All participants were able to complete the Berg balance test successfully without falling. Overall, the mean BBS score for the persons with below-knee amputation was lower than the able-bodied group (52.9 and 56, respectively). From the scored items, participants with below-knee amputation had the most difficulty during standing on one leg, tandem standing, 360^0 turning and placing alternate foot on a stool. However, statistical analysis showed that there was no significant difference in functional balance status between the amputee and able-bodied groups (p=0.08). The results are presented in Table 3.13.

Table 3.13: Individual and overall mean BBS score presented for the amputees and able-bodied controls.

	Amputees										BBS items	Able-bodied								
	10	**9**	**8**	**7**	**6**	**5**	**4**	**3**	**2**	**1**		**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**
	4	4	4	4	4	4	4	4	4	4	**1**	4	4	4	4	4	4	4	4	4
	4	4	4	4	4	4	4	4	4	4	**2**	4	4	4	4	4	4	4	4	4
	1	3	4	3	4	4	4	4	4	2	**3**	4	4	4	4	4	4	4	4	4
	3	4	4	3	4	4	4	4	4	4	**4**	4	4	4	4	4	4	4	4	4
	3	4	4	3	4	4	4	4	4	4	**5**	4	4	4	4	4	4	4	4	4
	2	3	4	3	4	4	4	4	4	4	**6**	4	4	4	4	4	4	4	4	4
	1	4	4	3	4	4	4	4	4	4	**7**	4	4	4	4	4	4	4	4	4
	4	4	4	4	4	4	4	4	4	4	**8**	4	4	4	4	4	4	4	4	4
	4	4	4	3	4	4	4	4	4	4	**9**	4	4	4	4	4	4	4	4	4
	4	4	4	4	4	4	4	4	4	4	**10**	4	4	4	4	4	4	4	4	4
	3	4	4	4	4	4	4	4	4	4	**11**	4	4	4	4	4	4	4	4	4
	4	4	4	4	4	4	4	4	4	4	**12**	4	4	4	4	4	4	4	4	4
	3	4	4	3	4	4	4	4	4	4	**13**	4	4	4	4	4	4	4	4	4
	1	1	4	4	4	4	4	4	4	2	**14**	4	4	4	4	4	4	4	4	4
Total	**41**	**51**	**56**	**49**	**56**	**56**	**56**	**56**	**56**	**52**		**56**	**56**	**56**	**56**	**56**	**56**	**56**	**56**	**56**
Mean ± SD	**52.9 ± 4.93**										**p=0.08**	**56**								

Results from the ABC questionnaires are presented in Figure 3.24 and Table 3.14, respectively. Significant differences between the prosthetic feet were found for some individual ABC items. The four items that distinguished between prosthetic feet were: (8) walk outside the house to a car parked in the driveway, (11) walk up or down a ramp, (14) step onto or off of an escalator while you are holding onto a railing and finally, (15) step onto or off an escalator while holding onto parcels such that you cannot hold onto the railing.

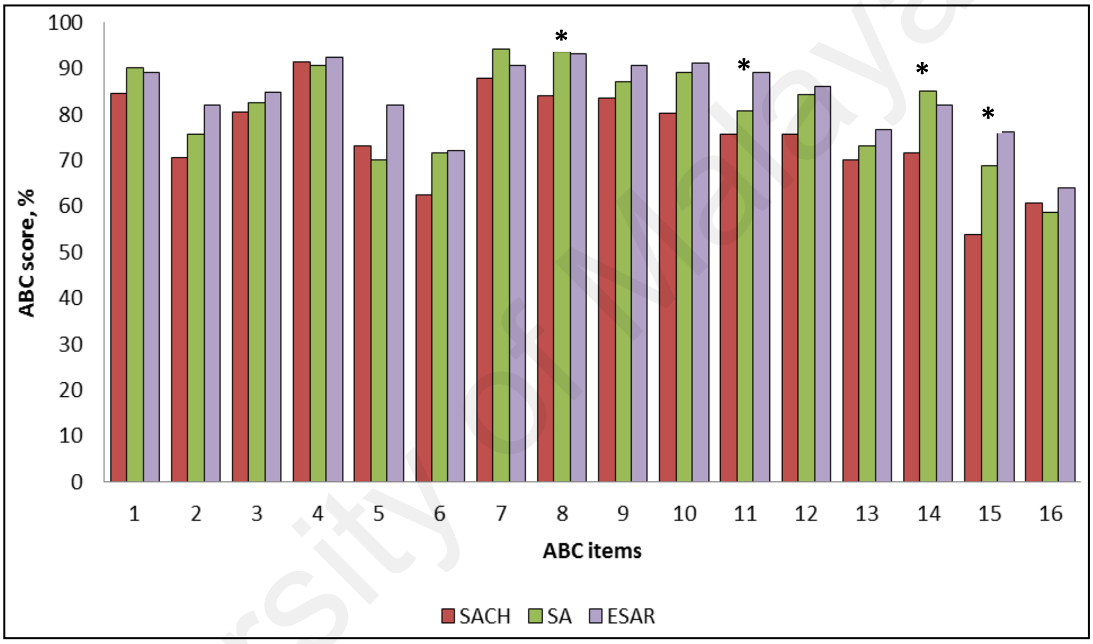


Figure 3.24: Mean ABC score for each ABS items according to prosthetic foot type. The asterisk sign (*) indicates significant different between prosthetic feet.

Table 3.14: Mean ABC scores of perceived balance confidence for three prosthetic feet.

Items	SACH[1]	SA[2]	ESAR[3]	p-value (t-test) #
1. Walk around the house	84.5	90	89	0.62
2. Walk up or down stairs	70.5	75.5	82	0.20
3. Bend over and pick up a slipper from front of a closet floor	80.3	82.3	84.8	0.17
4. Reach for a small can off a shelf at eye level	91.3	90.5	92.3	0.64
5. Stand on tip toes and reach for something above your head	73	70	82	0.13
6. Stand on a chair and reach for something	62.3	71.5	72	0.45
7. Sweep the floor	87.7	94	90.5	0.09
8. Walk outside the house to a car parked in the driveway	84	93.5	93	0.05* **1,2 (0.02)**
9. Get into or out of a car	83.5	87	90.5	0.08
10. Walk across a parking lot to the mall	80	89	91	0.10
11. Walk up or down a ramp	75.5	80.5	89	0.02* **1,3 (0.02)**
12. Walk in a crowded mall where people rapidly walk past you	75.5	84.2	86	0.08
13.Are bumped into by people as you walk through the mall	70	73	76.5	0.75
14. Step onto or off of an escalator while you are holding onto a railing	71.5	85	82	0.04* **1,2 (0.03)**
15. Step onto or off an escalator while holding onto parcels such that you cannot hold onto the railing	53.7	68.8	76	0.04* **1,3 (0.01)**
16. Walk outside on slippery sidewalks	60.5	58.5	64	0.38
Overall Mean	79	86.1	90.6§	
S.D	13.8	7.5	7.1	

Note. *Significant at $p \leq 0.05$, #Post-hoc testing using Wilcoxon Signed Rank Tests, §significant different when compared to SACH and SA.

The post-hoc test revealed that for item 8 and 14, the ABC score for SA foot was significantly higher than the SACH foot (p=0.02 and p=0.03, respectively). As for items 11 and 15, the ESAR foot scored significantly greater than the SACH foot (p=0.02 and p=0.01, respectively). The results also showed that the SACH foot showed the lowest score for item 15 and the highest for item 4. On the other hand, the SA foot scored the lowest and highest for items 16 and 7, respectively. Items 16 and 8 were the lowest and highest scores, respectively, for ESAR foot. The overall score for ESAR was significantly higher than that of SACH (p=0.04) and SA (p=0.03) feet.

3.8.4 Discussion

This study adopted two types of perceptive analyses tools to evaluate several aspects of prosthesis and physical functions of participants from amputee and able-bodied groups. The SF-12v2 health status questionnaire has provided overall physical and mental status with good reliability and validity (Ware *et al*., 2002). From the MCS results, all participants in this study are in good mental status which may not be a confounding factor that could affect the control of balance. However, the amputee group exhibited significant lower physical PCS score than that of the healthy group, which may be due to the loss of the lower limb. The Houghton score has been used in previous studies to evaluate habitual prosthesis use in terms of duration, places, assistive device use and negotiating on various surfaces (Akarsu *et al*., 2012; Leung *et al*., 1996). All below-knee amputees in this study demonstrated intensive use of the prosthesis based on the average Houghton Scale prior to the study. In addition, the current amputees can be considered as active based on the score obtained (10.5 ± 0.85) which is comparable to the score obtained from active (8 ± 0.74) and non-active (7.6 ± 0.9) below-knee amputees from a previous study (Yazicioglu *et al*., 2007). Furthermore, a Houghton score greater than 9 has been recommended as a standard score to indicate successful rehabilitation (Houghton *et al*., 1992). Interestingly, lower-limb amputees who led an active lifestyle has been shown to have higher Houghton score which is associated with improved balance and quality of life (Yazicioglu *et al*., 2007).

When referring to the BBS score guidelines, all amputees in this study exhibited low risk of falling. This finding is comparable to that of previous study which assessed functional balance in active below-knee amputees with an average score of 53.7 (Yazicioglu *et al*., 2007). Similar to previous findings (Wong *et al*., 2013), participants from the amputee group experienced more difficulties in tandem standing (standing with one foot in front of the other), 360^0 turning, placing alternate foot on a stool and standing on one leg. The able-bodied group obtained maximum Berg balance scale. Surprisingly, this study found that the functional balance of participants with below-knee amputations were equally capable of maintaining balance during Berg balance assessment as unimpaired participants. In that case, with the balance capabilities of both groups determined, researchers of this current study were well informed of the balance status prior to experimental sessions. Hence, any differences revealed between the two groups following experimental study will be likely due to the balance deficiency caused by the amputation.

Balance confidence while wearing prosthesis was identified as one of the important issues in persons living with lower limb amputations (Legro *et al*., 1999). Hence, when it comes to qualitative surveys on perceived balance confidence, the ABC scale has been adopted due to its good reliability and validity in reporting the effects of prostheses on their level of confidence during activities of daily living among individuals with amputation (Miller *et al*., 2003). An earlier work reported an averaged ABC score of 88.4 in lower limb amputees (Vrieling *et al*., 2008b). However, this study consisted of below-knee amputation subjects wearing various types of prosthetic feet. Overall, amputees in this study perceived their lowest confidence in more challenging task such as walking on slippery surface and using the escalator while not holding onto the railing. On the contrary, the highest perceived confidence level was noted for less challenging activity such as walking outside the house to the driveway as well as for activities which offer supporting avenue in case when balance is lost such as sweeping the floor and reaching object on the shelf at eye level.

Our finding demonstated that only 25% of the ABC items (4 out of 16 items) were shown to distinctly differentiate between prosthetic feet. Specifically, all four items assessed perceived balance confidence during dynamic activities such as walking outside the house, negotiating ramps and when using the escalator. From the current results, it is also reasonable to suggest that these four items aid in distinguising between articulated and non-articulated prosthetic foot. This is based on the higher overall ABC score of ESAR and SA compared to that of SACH foot. Hence, this study further supports the notion that the dissimilarity of prosthetic function between articulated and non-articulated can be revealed when the amputees engage in more dynamic activities (van der Linde *et al*., 2004). However, comparing this current findings are difficult as there is no prior study which adopted ABC scale as an outcome measure when comparing prosthesis interventions.

Nevertheless, the significant difference of overall ABC scores between articulated and non-articulated foot were consistent with the mechanical properties revealed from the mechanical testing results (Section 3.6). The ESAR foot was found to exhibit the lowest stiffness at the heel and forefoot regions, which may improve the comfort and performance during dynamic activities as shown in previous gait studies (Lehman *et al*., 1993; MacFarlane *et al*., 1991; Postema *et al*., 1997; Snyder *et al*., 1991). Moreover, the higher perceived balance score may probably be the result of greater range of motion provided at the single-axis ankle joint of SA and from the flexibility of the ESAR as compared with the rigid ankle and keel of the SACH foot.

This study was subjected to several limitations, nonetheless. In this study, a convenient sample of amputees and able-bodied participants were recruited to complete the self-report and functional performance assessment. Thus, the result of this study may not be generalized to new or elderly amputees as well as amputees with other amputation levels. In addition, selecting participants in a non-randomized fashion might introduce bias to the study. Another limitation that should be considered was the short accommodation time for each of the prosthetic foot prior to the testing. Although the duration of one week accommodation was considered adequate for below-knee amputees for functional prosthesis assessment (English *et al.*, 1995), a longer accommodation period may change the opinions and ratings of the feet. Future study involving more amputees with similar amputation etiology may reveal useful outcome measures to distinguish between prosthetic interventions.

3.8.5 Conclusion

The findings from this study demonstrate that all amputees are categorized as active ambulators with efficient use of prosthesis. In addition, the amputees exhibited similar functional balance status with the matched able-bodied group. Although the overall balance confidence score was able to differentiate between prosthetic feet, only four individual items were shown to further distinguish the feet. Nevertheless, knowledge about self-report and functional assessment outcome measures may thus be important for both the identification of amputees with an increased fall risk and low balance confidence. More specifically, information from these outcomes may help to design rehabilitative programs as well as to assist during findings interpretation from the biomechanical study.

3.9 Experimental protocol

This study employed a repetitive crossover study in which all of the amputees underwent a total of three testing sessions for three weeks with three different prosthetic feet (Figure 3.25). The control group was subjected to only one session for the completion of data collection. Familiarization of the test procedures was conducted during the first visit where the testing protocol was briefly explained and participants were required to complete one practice trial with BSS (Baldwin *et al*., 2004). Following the familiarization session, the differences found in any data collected related to learning effects or fatigue were minimized (Hinman, 2000; Pincivero *et al*., 1995).

Amputee participants were instructed to wear their corresponding prostheses which allowed the interchange of foot components. The same socket and suspension components were used throughout the study to eliminate any confounding effect of these variables. Subjects completed the Short Form Health Survey (SF12v2) to evaluate their quality of life status (Ware & Sherbourne, 1992) and to confirm that their postural stability is not affected by confounding factors from poor mental and physical conditions.

A preliminary assessment was conducted with amputees standing on intact leg and standing on prosthetic leg. However, most of the amputees were not able to maintain stability in both tasks. Therefore, the single leg standing was deemed unsuitable and for safety reason, only double leg standing was considered in this study. Prior to testing, subjects were required to complete the Houghton scale, BBS and ABC questionnaires whose details can be found in Appendix F.

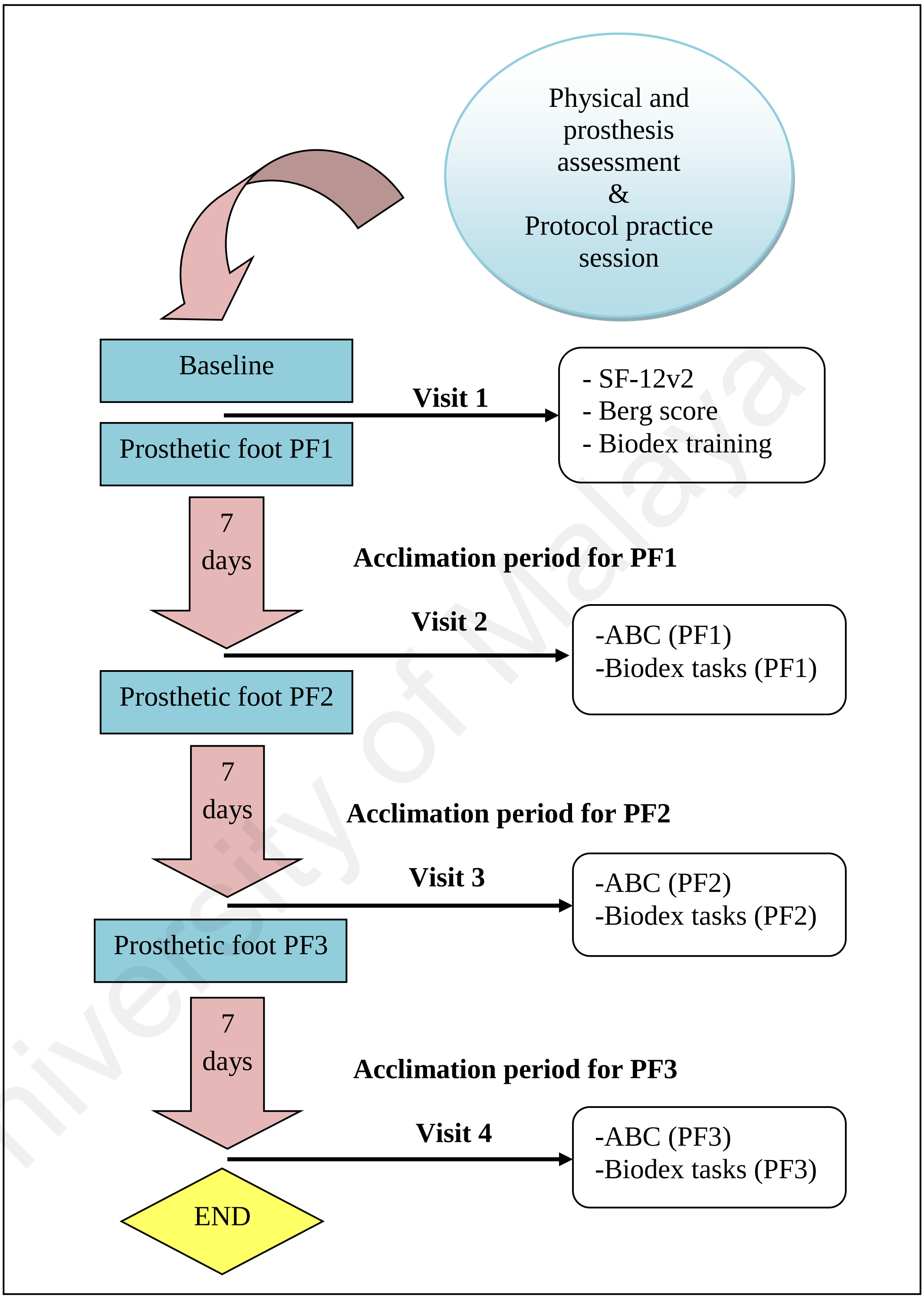


Figure 3.25: The overall protocol for amputee participants in this study with each prosthetic foot (PF).

Subjects were instructed to step on the BSS platform and stand with a standardized position with each foot positioned 17 cm between the heel centres and 14° between the long axes of the feet to eliminate between-subject variability or biased results during balance testing (Mcllroy & Maki, 1995). The defined heel width was adopted according to the findings of McIlroy and Maki (1995) as the distance between the midlines of the right and left heels. Hence, the midlines of the posterior aspects of the calcaneus were placed accordingly on the platform grid. Similarly, using guidelines from McIlroy and Maki (1995), the feet angle was determined between the lines joining the centre of the heel and the great toe of each foot. Moreover, the great toe was used due to better reliability for foot tracing compared to the more conventional use of the space between the 2nd and 3rd metatarsals (McIlroy and Maki, 1995). To ensure this standardized position was maintained accurately for each test across all subjects, the positions were marked on the balance platform.

During the test, subjects were asked to maintain their arms alongside the body, and look straight ahead at a point on the wall approximately 1.5m away at eye level to prevent vestibular distraction and head movement. The platform was then locked into stable position, and foot placement was recorded as per manufacturer's guidelines (Arnold & Schmitz, 1998). Each testing trial lasted for 20 seconds and three testing trials were measured for reliable measures (Cachupe *et al.*, 2001). Moreover, the location of the CoM of an obese person is more anteriorly at the base of support which may desensitize the foot's mechanoreceptors and causes postural instability (Hue *et al.*, 2007). As such, to minimize this effect, the stability indexes must be averaged from at least three trials (Salavati *et al.*, 2009). The participant's position on the BSS is illustrated in Figure 3.26.

Figure 3.26: Position of participant on the BSS device.

A standardized instruction was given to all subjects to "stand as still as possible" to ensure high consistency in their body sway during static posturography assessment (Zok *et al.*, 2008). Subject was allowed to a 30s rest periods (Gear, Bookhout and Solyntjes, 2011) in a sitting position between trials and were instructed not to change the position of their feet on the platform (Figure 3.27). The handrails on both sides of the BSS were positioned and could only be used to prevent falling if the subjects totally lost their balance. In addition, an assistant stood at the back of the subject for additional safety. In the event of malposition of the feet or loss of balance, the trial was deleted and data collection was continued until all trials were completed.

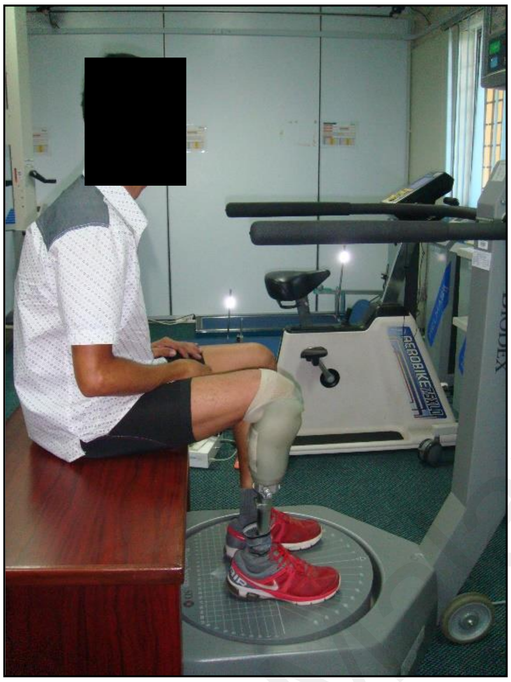


Figure 3.27: Participant taking a rest between trials, with unchanged feet position.

3.10 Sensory conditions

In order to assess the control of postural stability among the participants, several modified sensory manipulations were introduced based on the Sensory Organization Test (SOT) adopted from Guskiewicz & Perrin (1996) and Clinical Test of Sensory Interaction and Balance (CTSIB) from Shumway-Cook & Horak (1986). All participants were tested in four different sensory conditions. Each condition was presented with all three sensory cues (visual, proprioception, vestibular) or disruption of sensory information. In this study, the influence of changing the prosthetic feet on the control of postural stability during each sensory alteration was discussed in depth in the following associated chapters. General descriptions of sensory conditions are demonstrated in Figure 3.28.

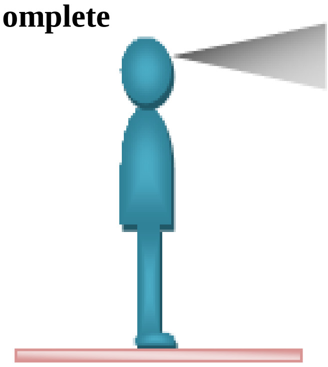
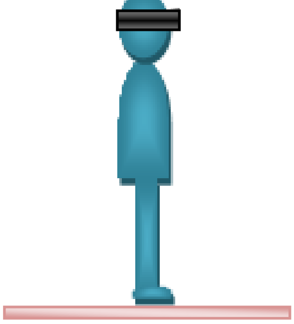
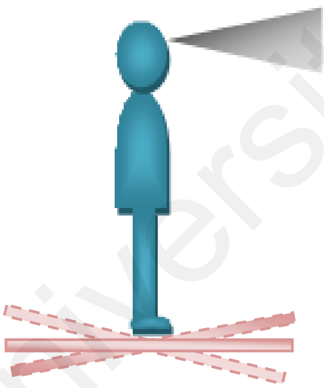
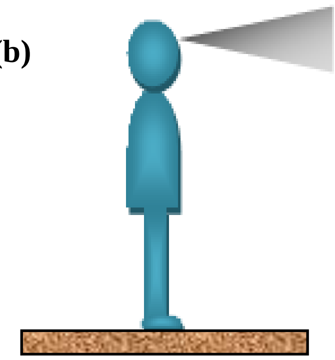
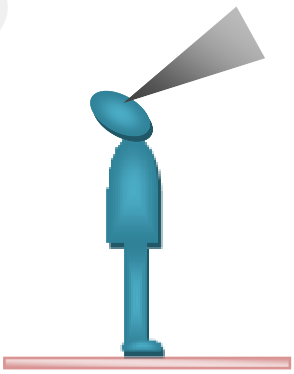
<table>
<tr><th>Sensory conditions</th><th>Descriptions</th></tr>
<tr><td>1. Complete
</td><td>• Visual, proprioception & vestibular sensory cues are present
• Subject focuses on a mark on the wall, standing on a stable and rigid surface & head in neutral position
• Known as ideal/ baseline condition</td></tr>
<tr><td>2. Altered visual sensory
</td><td>• Proprioception & vestibular sensory cues are present
• Visual information unavailable
• Subject standing on a stable and rigid surface & head in neutral position</td></tr>
<tr><td colspan="2">3. Altered proprioception sensory
• Visual & vestibular sensory cues are present
• Subject focuses on a mark on the wall, standing on (a) moving rigid surface, (b) foam surface; & head in neutral position
(a)  (b) </td></tr>
<tr><td>4. Altered vestibular sensory
</td><td>• Visual & proprioception sensory cues are present
• Head is positioned at maximum extension
• Subject focuses on a mark on the ceiling, standing on a stable and rigid surface
• Vestibular sensory is altered by tilting the head backward</td></tr>
</table>

Figure 3.28: Different types of sensory alterations conducted in this study for all participants.

3.11 Statistical analyses

All experimental data were initially screened for normality of distribution to ensure that appropriate statistical method was chosen for all analyses. Although numerical methods such as skewness and kurtosis coefficient can be used for checking normality of data, a specific normality test provides more formal method to determine whether the data is normally distributed. For this reason, the Shapiro Wilk's normality test was chosen because the total sample in this study was less than 50 (Razali & Wah, 2011). A non-significant result indicates normality (p-value >0.05). Hence, for normally distributed data, a parametric statistical analysis was adopted. Conversely, a non-parametric statistical analysis was used when the normality of the data is violated. All statistical analyses were performed using SPSS v16.0 (SPSS Inc., Chicago, IL, USA), with the level of significance set at $p \leq 0.05$ for all analyses. The details of the statistical methods used in each experiment are discussed in the methods section of each associated chapter.

CHAPTER 4

INTRARATER TEST-RETEST RELIABILITY OF STATIC AND DYNAMIC STABILITY INDEXES MEASUREMENT USING THE BIODEX® STABILITY SYSTEM DURING UNILATERAL STANCE

The degree of agreement among repeated assessment performed by the researcher must be first established to minimize errors which affect the precision and accuracy of experimental data. In most of the existing clinical rehabilitation research, the ability to produce reliable measures is a prerequisite for an accurate assessment of an intervention after a period of time. Although clinical balance assessment has been performed in previous study, none has determined the intrarater test-retest reliability of static and dynamic stability indexes during dominant single stance. In this study, one rater examined twenty healthy university students in two sessions separated by seven days intervals. Three stability indexes which are OSI, APSI, and MLSI in static and dynamic conditions were measured during single dominant stance. Intraclass correlation coefficient (ICC), standard error measurement (SEM) and 95% confidence interval (95% CI) were calculated. Test-retest ICCs for OSI, APSI, and MLSI were 0.85, 0.78, and 0.84 during static condition while 0.77, 0.77, and 0.65 during dynamic condition, respectively. We concluded that the postural stability assessment using Biodex stability system (BSS) demonstrates ‘good to excellent’ test-retest reliability over a one-week time interval.

4.1 Introduction

Balance and postural control are vital to ensure safe locomotion activities of human (Winter *et al*., 1990a). Postural control is also known as the foundation to achieve independent standing and walking (Melzer *et al*., 2004). Therefore, it is considered as an important aspect in rehabilitation process among the elderly (Baldwin *et al*., 2004; Parraca *et al*., 2011), impaired (Salsabili *et al*., 2011; Testerman & Griend, 1999) and amputee (Vanicek *et al*., 2009; Vrieling *et al*., 2008a) populations. Postural stability is defined as the ability to maintain an upright posture during quiet stance during static condition; or the recovery of balance following external perturbation or displacement of the support surface during dynamic condition (Mackey & Robinovitch, 2005). Poor control of postural stability is often associated with the risk of falling which consequently leads to death, injuries and loss of mobility (Winter, Patla, Frank & Walt, 1990b).

Postural stability assessment using the force platform is commonly used to obtain various parameters derives from the center of pressure measures such as displacement, velocity, and area (Melzer *et al*., 2004). Although it provides valid outcomes, it is not sufficient to explain the control of standing posture in both anterior-posterior and medio-lateral direction (Winter *et al*., 1990a). Results from other assessment method such as star excursion balance test (SEBT) are difficult to relate to activity of daily living (Cachupe *et al*., 2001). Recently, the Biodex stability system (BSS) (Biodex, Inc, Shirley, NY) has been presented as a method that is capable in producing clinical data measurements with application for all range of populations (Hinman, 2000). The BSS measures the overall stability index (OSI), anterior/ posterior stability index (APSI) and medial/ lateral stability index (MLSI) from the variance of platform deflection in degrees from a level position in providing explicit information on movement of the ankle joint. More importantly, it has been showed as reliable tool for objective assessment of postural stability (Baldwin *et al*., 2004; Cachupe *et al*., 2001; Parraca *et al*., 2011; Schmitz & Arnold, 1998).

Although previous studies on intratester and intertester reliability were reported to be clinically reliable for OSI, APSI, and MLSI (Baldwin *et al*., 2004; Cachupe *et al*., 2001; Hinman, 2000; Parraca *et al*., 2011; Pincivero *et al*., 1995; Schmitz & Arnold, 1998) only two studies reported on test-retest reliability assessed on the same subjects during static bilateral stance (Baldwin *et al*., 2004; Parraca *et al*., 2011). In addition, previous studies reported fair to excellent test-retest reliability on the same day assessment which may not be sufficient to inform intervention research that requires more time intervals (Hinman, 2000; Pincivero *et al*., 1995; Schmitz & Arnold, 1998). Other study which assessed different subjects during different sessions reported excellent reliability may give false interpretation of the reliability of the BSS system (Cachupe *et al*., 2001). During the evaluation of an intervention, it is critical that researchers are confident that any changes observed are caused by the treatment itself, not by normal variations in task performance or instrumentation error (van Uden & Besser, 2004).

While maintaining balance on both limbs has been used as the preferred mechanism, balance control during unilateral stance is considered as equally important to avoid fall in response to unexpected perturbation. It has also been used as indicator of fall incident among elderly and amputees (Mackey & Robinovitch, 2005; Vanicek *et al*., 2009). Thus, the aim of this study is to determine the intrarater test-retest reliability measures of postural stability indexes over a specific time interval during static and dynamic unilateral stance using the BBS. This study involves healthy adult population to characterize the normal week-to-week variation without the confounding effects found in impaired balance population.

4.2 Methodology

4.2.1 Participants

A total of 20 healthy university students (8 males, 12 females; age = 21.2 ± 0.4 years; weight = 58.65 ± 13.32 kg; height = 1.61 ± 0.09 m) gave informed consent to participate in this study. All subjects had no previous lower limb musculoskeletal injury, neurological or vestibular impairment, or balance disorders. None of the subjects had any experience with BSS prior to the study. This study was approved by the Institutional Review Board in accordance with the Helsinki Declaration.

4.2.2 Instrumentation

Postural stability indexes during unilateral stance were measured using the Biodex stability system (BSS) (Biodex, Inc, Shirley, NY) which consist of a circular platform that tilt up to 20^0 in any direction (Schmitz & Arnold, 1998). The stability of the platform was varied according to the spring resistance levels which ranged from 1 (least stable) to 12 (most stable). The OSI was calculated from the combined degrees of tilt about the anterior-posterior (AP) and medial-lateral (ML) axes, which was suggested as the best balance indicator (Testerman & Griend, 1999). Similarly, the APSI and MLSI were calculated based on the average amount of platform tilt about the AP and ML axes, respectively (Arnold & Schmitz, 1998). Further discussion on the underlying theory of BSS can be found in Section 3.7.

4.2.3 Protocols

Prior to testing trials, one familiarization trial was performed for each condition to negate potential effects of learning and fatigue (Hinman, 2000; Pincivero *et al*., 1995). A brief explanation of the testing protocols was provided to all subjects. The testing protocol consisted of a unilateral stance stability test during static and dynamic conditions. Subjects removed their footwear before instructed to step on the BSS platform. During the static condition, subjects stood on their dominant leg in full extension while permitting slight knee flexion on the contralateral side. Dominant leg was defined by asking the subjects which leg they preferred to kick a ball (Schmitz & Arnold, 1998). Then, subjects were asked to position their foot at the centre of the platform, arms at their sides, and look ahead at the feedback display adjusted at their eyes level to prevent vestibular distraction and head movement. Following this, the subjects were asked to adjust their foot position to a comfortable standing position while maintaining the moving pointer at or near the centre point of the display. The platform was then locked into stable position, and foot placement was recorded as manufacturer's guidelines (Mcllroy & Maki, 1995). The position of the foot remained constant throughout static and dynamic test.

Each testing trial lasted for 20 seconds and five testing trials were measured for reliable measures (Cachupe *et al*., 2001). During the 10 seconds rest periods between trials, subjects were encouraged to bear their weight on the contralateral leg to minimize fatigue on the test leg. The same protocol was applied to dynamic condition, excluding the platform stability level. During this test, the subjects were instructed to maintain an upright position on the unstable surface of the BSS which was set at level-eight resistance (Parraca *et al*., 2011; Paterno *et al*., 2004; Pincivero *et al*., 1995; Schmitz & Arnold, 1998). Subjects were instructed to place the contralateral leg at the back corner of the BSS in any occasion when they lost their balance. Handrails could only be used to prevent falling if the subjects totally lost their balance. In the event of this, the trial was deleted and data collection was continued until all trials was completed. It was assumed that all differences in the results obtained were not related to the subjects' ability to learn and master the process. The order of testing during both conditions was randomized.

To assess the test-retest reliability of the postural stability measurements, all subjects were evaluated again one week later (Parraca *et al*., 2011; van Uden & Besser, 2004). This timeframe is generally believed to be reasonable in avoiding unwanted clinical changes in the rater and subjects involved. Additionally, test-retest repeatability and reproducibility guidelines of the National Institute of Standards and Technology (Taylor & Kuyatt, 1994) were adhered to, which are as follows: using the same measurement protocol, tester, measuring instrument, conditions, time, and location.

4.2.4 Statistical Analysis

The mean and standard deviation of stability index scores (OSI, APSI, MLSI) were extracted from BSS software and were manually entered into statistical software. All data was initially screened for normal distribution using the Shapiro-Wilk normality test. Paired t-test was adopted to compare mean of the test (Week 1) and retest (Week 2) stability index scores in each condition to confirm the absence of systematic bias (Atkinson & Nevill, 1998).

Relative measure of test-retest reliability for all stability scores were determined according to the intraclass correlation coefficient ($ICC_{3,1}$) which is a two-way mixed effects reliability model (Shrout & Fleiss, 1979). This calculation was based on a standard repeated-measures ANOVA which also calculated the mean differences across trials to assess systematic error (Weir, 2005). Fleiss classification of ICC was used to describe the degree of reliability: ICC > 0.75 indicated excellent reliability, 0.4< ICC< 0.75 signified fair to good reliability, and ICC < 0.4 were considered poor reliability (Fleiss, 1986).

Absolute reliability was determined according to the standard error of measurement (SEM) using the following equation: $SEM = SD\sqrt{1 - ICC}$; where SEM indicates the standard error of measurement (precision) (Shrout & Fleiss, 1979) and the SD is the mean SD of Week 1 and 2 (Adsuar, Olivares, Parraca & Gusi, 2011; Weir, 2005). The 95% CI of ICC values were also calculated for all variables to demonstrate how closely the measurements agree on different occasions (Brenton-Rule *et al*., 2012). All statistical analysis was performed using SPSS v16.0 (SPSS Inc., Chicago, IL, USA), with p≤0.05.

4.3 Results

The analysis of normality test showed that all data was normally distributed. There was no significant difference between Week 1 and Week 2 mean stability index scores in all condition, which indicates the absence of any systematic bias (Table 4.1).

In static condition, all stability indexes showed excellent intrarater test-retest relative reliability as indicated by the ICC (OSI=0.85, APSI=0.78, MLSI=0.84). During dynamic condition, however, good to excellent intrarater test-retest relative reliability were exhibited in all stability indexes (OSI=0.77, APSI=0.77, MLSI=0.65). Absolute reliability for stability indexes were nearly zero for static condition (SEM=0.08 to 0.1) condition compared to dynamic condition indicated more precise score during the latter condition. The analysis of 95% CI revealed narrower band in static compared to dynamic condition.

4.4 Discussion

We found that the BSS was a reliable tool for postural assessment because intrarater agreement were very good or excellent ranged from 78% to 85% and 65% to 77% during static and dynamic condition, respectively. High ICC score (ICC > 0.75) for most of the stability scores suggested that the measurement error is small relative to the between-session variability (Walter *et al*., 1998). To our knowledge, although previous studies (Paterno *et al*., 2004; Schmitz & Arnold, 1998) assessed intrarater reliability during unilateral dynamic stance, comparison of result to our study is difficult due to different stability levels, small sample size, and same day assessment in those studies.

In this study, the measurement of balance score during static condition was more accurate than that of dynamic condition, as reflected in the SEM values. The analysis of 95% CI for all stability indexes indicated good measurements agreement between sessions during static than dynamic condition. We found that the absence of postural assessment during unilateral static stance from previous literatures limits the possibility to associate our results with others. In our opinion, the BSS should also be used for static condition testing as it serves as baseline assessment before progressing into dynamic testing for populations with deteriorate musculoskeletal condition.

Table 4.1: Summary of the stability index score, SEM, ICC, and 95% CI during unilateral stance in static and dynamic postural stability assessment with seven days separation period.

	Static						Dynamic					
Stability Index	**Week 1 Mean (SD)**	**Week 2 Mean (SD)**	***p*-value**	**SEM**	**ICC**	**95% CI**	**Week 1 Mean (SD)**	**Week 2 Mean (SD)**	***p*-value**	**SEM**	**ICC**	**95% CI**
OSI	0.74 (0.25)	0.70 (0.25)	.338	0.10	0.85	0.61-0.94	1.51 (0.90)	1.28 (0.51)	.129	0.34	0.77	0.42-0.91
APSI	0.46 (0.16)	0.45 (0.17)	.643	0.08	0.78	0.45-0.91	1.14 (0.75)	0.98 (0.45)	.206	0.29	0.77	0.43-0.91
MLSI	0.46 (0.20)	0.40 (0.18)	.076	0.08	0.84	0.60-0.94	0.77 (0.50)	0.66 (0.24)	.210	0.22	0.65	0.12-0.86

Note. OSI: overall stability index, APSI: anterior/ posterior stability index, MLSI: medial/ lateral stability index, ICC: intraclass correlation coefficient, SEM: standard error of measurement, CI: confidence interval.

While static balance requires maintaining the body's center of mass within the base of support, dynamic balance involves motion in response to effects of ground reaction force and the ankle's muscle forces (Pollock *et al*., 2000). Therefore, difference results between static and dynamic conditions are anticipated due to greater muscular activity around the ankle joint in maintaining postural balance on an unstable BSS platform, and inherent variability of postural stability parameters among the studied subjects (Schmitz & Arnold, 1998). The BSS provides more specific information on ankle joint movements (Arnold & Schmitz, 1998; Salsabili *et al*., 2011) due to its ability to measure the degree of platform tilt about AP and ML axis during dynamic conditions. The amount of tilting of the platform indicates amount of instability associated at the ankle joint under dynamic stress which is theoretically related to proprioception and neuromuscular feedback (Testerman & Griend, 1995). This means that the application of BSS is sufficient in assessing the status of postural balance in determining the outcome after lower limb injuries or impairment of specific population.

In this study, several limitations which may hinders generalization of the results were considered. First, all subjects adopted their own comfortable foot position during testing which may increase the inter-subject variability as well as affecting the control of medial-lateral stability (Mcllroy & Maki, 1995). However, because healthy subjects were shown to adopt the same range of preferred foot position, this variation is not clinically significant (Mcllroy & Maki, 1995). Secondly, this study recruited university students who shares similar characteristics in terms of age, mass and living style which may not represent other populations, such as geriatrics. Finally, although gender differences have been found in postural sway (Guskiewicz & Perrin, 1996), the reliability of these measures is not influenced by such factor (Mcllroy & Maki, 1995).

4.5 Conclusion

In summary, the stability indexes produced from BSS are reliable when scored by a single rater between days of interval during static and dynamic unilateral stance. The application of this approach should be used in quantifying postural balance in assessing effectiveness of a specific clinical or research intervention for repeated measurement design.

CHAPTER 5

THE EFFECTS OF PROSTHETIC FOOT TYPES AND VISUAL ALTERATION ON POSTURAL STEADINESS IN BELOW-KNEE AMPUTEES.

Achieving independent upright posture has known to be one of the main goals in rehabilitation following lower limb amputation. As discussed in Section 2.3, visual cues are one of the important sensory inputs that contribute to the control of postural stability in individuals with lower limb amputation. The purpose of this study was to compare postural steadiness of below knee amputees with visual alterations while wearing three different prosthetic feet. Objective assessment of postural stability was completed using Biodex® balance platform under different visual input conditions. Perceived balance assessment of each foot was evaluated using Activities-specific Balance Confidence (ABC) score. The results of this study suggested that postural steadiness in below-knee amputees was not affected by the types of prosthetic foot during quiet upright standing, but was significantly affected during the absence of visual cues.

5.1 Background

The ability to maintain postural stability is the foundation of achieving independent standing and walking (Melzer *et al*., 2004). It is a complex task that integrates somatosensory (proprioceptive, cutaneous and joint), visual and vestibular inputs along with motor coordination to maintain the center of mass (CoM) within the base of support (Blackburn *et al*., 2000; Shumway-Cook & Woollacott, 2000; Shumway-Cook & Horak, 1986). Any deficits in these components will result in poor control of body posture, which is often associated with the risk of falling and has been identified as a major health problem (Winter *et al*., 1990). In people with lower limb amputations, they must compensate for the challenging task in maintaining postural stability by increasing dependence on visual and vestibular information (Shumway-Cook & Woollacott, 2000). Due to the important role of visual information, postural stability assessment with eyes-closed condition is necessary to determining the utilization of other sources of sensory information during postural control in addition to the eyes-open condition which serves as baseline clinical assessment (Redfern *et al*., 2001). In fact, previous study showed that the absence of vision input will increase the postural sway and asymmetry of stance in below-knee amputees (Isakov *et al*., 1992).

In able-bodied person, the motor coordination responsible for postural stability maintenance consists of ankle and hip strategies which produce corrective torque in order to counter the destabilizing torque due to gravity that causes deviation of the CoM (Horak, 2006). In the absence of perturbation, the muscle contracts eccentrically to resist the gravitational forces. However, in order to maintain postural stability during perturbation, concentric muscle contraction is essential. Hence, stiffer muscles potentially increase the efficiency of postural control mechanism. Researchers theorized that stiffness of the ankle muscle might play an important role in maintaining balance and joint stability (Blackburn *et al*., 2000; Vrieling *et al*., 2008). However, loss of muscular structures as results of below-knee amputation causes deficits in sensory input from proprioceptive component at the feet and ankle. As a result, amputees exhibit a higher incidence of falling than able-bodied people because of the former's deficits in controlling horizontal movements in medial-lateral or anterior-posterior directions (Miller *et al.*, 2001).

Consequently, to substitute for the loss of the ankle-foot complex, the prosthetic foot is prescribed for the amputees. Along with advancements in technology, prosthetic foot has gone through tremendous transformations in terms of design and materials used. From previous postural balance assessment in the amputee subjects, researchers suggested that reduced sway may be due to the relatively stiff ankle of the prosthetic foot which limits the dorsiflexion or plantarflexion movement (Nederhand *et al.*, 2012; Buckley *et al*., 2002). However, the effect of such stiffness to the postural balance remains unclear due to the variations in types of prosthetic feet tested in such studies that may have had influenced their balance performance.

Although balance confidence and stability has shown to associate with walking performance and social activity (Miller *et al*., 2001), studies on postural balance with different foot category are scarce compared with research on other biomechanical areas (Hafner, 2006). The primary purpose of this study is to systematically assess the influence of three different prosthetic foot types to the overall, medial-lateral, and anterior-posterior control of postural steadiness in person with below-knee amputation. The secondary purpose was to compare postural steadiness during quiet standing when visual inputs were altered.

5.2 Methodology

5.2.1 Participants

A convenience sample of ten male unilateral below-knee amputees gave written consent to participate in this study. All subjects had at least one year experience in current prosthesis and able to walk without the use of assistive device. Subjects with visual or vestibular impairment, residuum pain, other neurological deficits or musculoskeletal injury were excluded. This study was approved by the Institutional Review Board in accordance with the Helsinki Declaration. Subjects are all recruited via the University of Malaya Medical Centre that undergone the same rehabilitation programs. In this study, each subject served as his own control. Details of participants' demographic and prosthetic information are shown in Section 3.5 (Table 3.2).

5.2.2 Equipment and protocol

Three different foot types were tested: solid ankle cushion heel foot (Enjoylife, Fujian, China), single-axis foot (Enjoylife, Fujian, China) and energy saving and return foot Talux® (Ossur, Reykjavik, Iceland). Detailed discussion on the material, design and mechanical characteristic of each foot type can be found in Section 3.6. Each test foot was attached to the patient’s existing prosthesis and optimally aligned by the same registered prosthetist. After completed the static and dynamic alignments, subjects walked for 15 minutes to familiarize with the foot. Subjects were tested with their own socket and suspension components throughout the study.

Familiarization of the test procedures was conducted during the first visit. Subjects completed the Short Form Health Survey (SF12v2) and the Berg balance test prior testing. Details on these outcome measures are outlined in Section 3.8. Subjects who failed to maintain equilibrium during the test were excluded from the study. The first foot type was fitted during the first visit. After one week of accommodation period, subjects return to the laboratory for assessment. All subjects completed the Activities-specific Balance Confidence (ABC) scale at each testing session to rate their balance confidence of a particular test foot. The test was counterbalance across subjects to negate order effects.

For this specific study, the postural stability indexes during quiet standing was assessed using the Biodex Stability System (BSS) (Biodex Medical System, Shirley, NY, USA) as discussed in Section 3.7. Participants stood with eyes-opened (EO) and eyes-closed (EC) while wearing three different prosthetic feet. A detailed description of the protocol can be found in Section 3.9.

5.2.3 Statistical analysis

All data were initially screen for normality of distribution by using the Shapiro Wilk's test. Therefore, non-parametric statistical analyses were adopted. The Friedman's repeated measures test were used to compare the overall ABC score and stability indexes for the three prosthetic feet. When differences were identified between groups, post-hoc pairwise comparison was conducted to determine where the significant differences occurred. The Wilcoxon-signed rank test was used to compare between EO versus EC conditions and APSI versus MLSI score for each prosthetic foot. Statistical analysis was performed using SPSS v16.0 (SPSS Inc., Chicago, IL, USA), with level of significance was set at $p \leq 0.05$ for all analysis.

5.3 Results

5.3.1 Participants' characteristics

The mean age, weight and height for all ten participants were 44.8 ±13.5 years, 77.0 ±17.9 kg and 1.70±0.06 m, respectively. No significant differences were observed among the amputees in terms of age, height, and body mass. The Berg balance score indicated that all participants have a low risk of falling. According to the Medicare Functional Classification Level (Agrawal *et al.*, 2013a), participants engaged in K2-K3 activity level.

5.3.2 Comparison between prosthetic foot types

The average and mean values for all outcome parameters with the significant differences observed are depicted in Table 5.1. When Friedman test were made between prosthetic foot types (SACH vs SA vs ESAR), the stability indexes score (OSI, APSI, MLSI) revealed non-statistically significant differences during both eyes-opened condition (p=0.651, p=0.607, p=0.317 respectively) and eyes-closed condition (p=0.651, p=0.630, p=0.891 respectively). The MLSI was statistically higher than APSI for ESAR foot in both eyes-opened and eyes-closed conditions (p= 0.034 and p=0.017, respectively).

5.3.3 Comparison between eyes-opened and eyes-closed

Comparative Wilcoxon-signed rank analysis between visual conditions (EO-EC) revealed that the OSI, APSI and MLSI score were higher during eyes-closed compared to that of eyes-opened condition for all foot types (Figure 5.1). However the differences of stability scores between the two conditions were only statistical significant in SACH foot and ESAR foot. Differences of stability scores for SA foot failed to reach any significant differences during eyes-closed and eyes-opened conditions (Figure 5.2).

Table 5.1: The mean and (standard deviation) of stability indexes score and ABC score for three types of prosthetic foot during eyes-opened and eyes-closed conditions.

Outcomes parameters	Visual cues	Types of prosthetic foot		
		SACH	**SA**	**ESAR**
APSI mean (sd)	EO	1.08 (1.02)*	0.80 (0.68)	0.65 (0.34)[¥] *
	EC	1.89 (0.96)	1.33 (0.61)	1.80 (1.03)[¥]
MLSI mean (sd)	EO	1.09 (0.92)*	1.58 (1.94)	1.59 (1.35)[¥]*
	EC	2.52 (1.19)	2.30 (1.18)	2.76 (1.37)[¥]
OSI mean (sd)	EO	1.71 (1.25)*	1.90 (1.99)	1.86 (1.34)*
	EC	3.43 (1.17)	2.91 (1.06)	3.58 (1.49)
ABC score mean (sd)		79 (13.8)[a]	86.1 (7.5)[b]	90.6 (7.1) [a,b]

Note.[¥]$p<0.05$: significant difference in comparison to MLSI and APSI; *$p<0.05$: significant difference in comparison to eyes-opened (EO) and eyes-closed (EC); [a]$p<0.05$: significant difference when compared with ABC score between SACH and ESAR using post-hoc analysis; [b]$p<0.05$: significant difference when compared with ABC score between SA and ESAR using post-hoc analysis.

5.3.4 Perceived-balance assessment

The analysis of ABC score demonstrated a statistically significant differences between the SACH, SA and ESAR foot (p=0.016). Further post-hoc analyses revealed that the differences occurred between ESAR and SACH (p=0.043) as well as ESAR and SA (p=0.028).

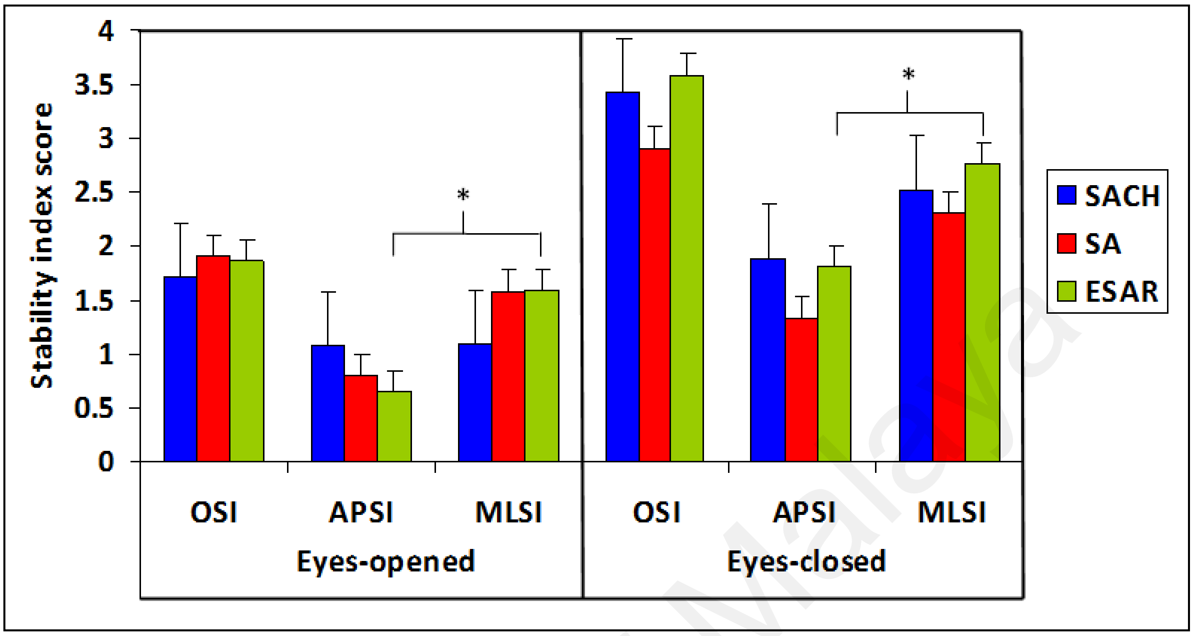


Figure 5.1: Overall (OSI), anterior-posterior (APSI) and medial-lateral (MLSI) stability indexes score in mean (± standard error) between prosthetic foot types during eyes-opened and eyes-closed conditions. The asterisk sign indicates statistically significant differences (p<0.05) between APSI and MLSI within the same visual condition.

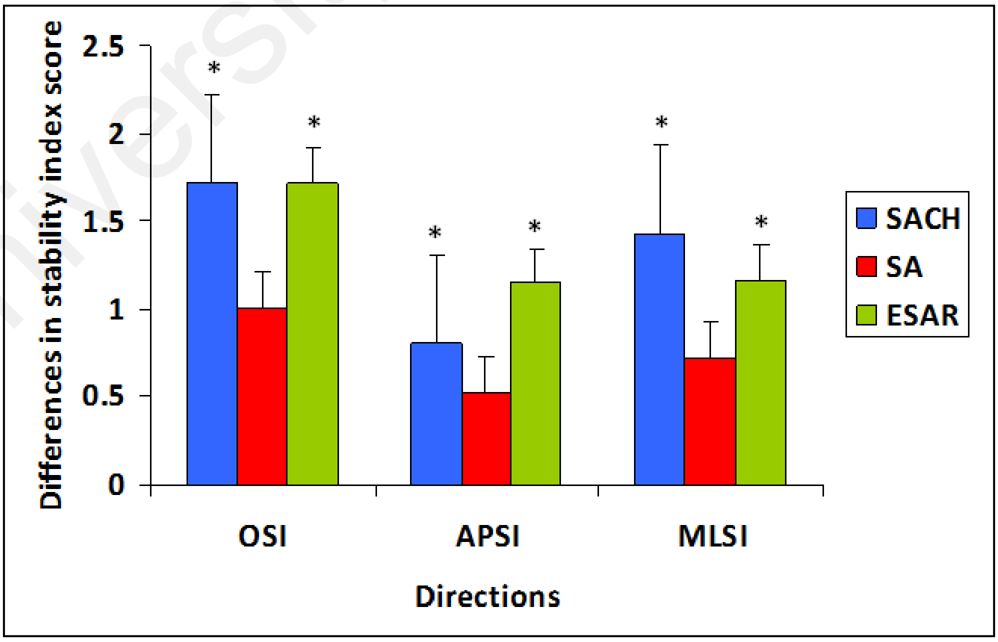


Figure 5.2: Differences of overall (OSI), anterior-posterior (APSI) and medial-lateral (MLSI) stability index score between eyes-closed and eyes-opened conditions in mean (± standard error) according to prosthetic foot type. The asterisk sign indicates statistically significant differences (p<0.05).

5.4 Discussion

In this study, the influence of three prosthetic foot types to the postural steadiness in person with below-knee amputation was assessed during unperturbed standing. Additionally, the contribution of visual information in maintaining postural balance was evaluated. We demonstrated the possibilities of using Biodex stability system to provide clinical static balance assessment before progression into dynamic testing and training for populations with lower-limb amputation. Moreover, static balance has become an essential skill in rehabilitation process for the amputee populations to achieve independent standing and walking (Melzer *et al*., 2004; Vrieling *et al*., 2008)

Prosthetic foot was prescribed to help amputees regulate the body's CoM within the base of support to achieve postural equilibrium during quiet standing, as opposed to the plantarflexors-dorsiflexors mechanism in able-bodied person (Winter *et al*., 1990a). The primary findings in our study revealed that the control of postural steadiness during unperturbed bilateral standing was unaffected by the types of prosthetic foot used. Nevertheless, it is important to note that the SACH foot scored the lowest OSI indicating the least body sway when standing with the eyes-opened. This result may be due to the rigid ankle which offers no articulation thus minimizing the excursion of the CoM. Additionally, it further supports the notion from previous study that stiffer prosthetic foot maybe a potential justification in enhancing the safety of postural stability in this population by decreasing the body sway (Nederhand *et al*., 2012). Similarly, our results were in accordance with previous study which proposed that the CoM excursion may have been constrained by the stiffness of the prosthetic ankle complex (Buckley *et al*., 2002). However, our study did not quantify the contribution from the intact limb or musculature of the residual limb which may influence the control of postural steadiness (Vrieling *et al*., 2008).

In contrast, the SA foot was considered most stable compared to other types of feet when visual input was removed as indicated by the lowest OSI. This finding suggested that the elimination of visual will increase utilization of other source of sensory information input in the organization of postural control. Particularly, the residual limb has been suggested to enhance the limited proprioceptive information (Buckley *et al*., 2002) as the body weight is transmitted to the soft tissues via the socket to control the postural responses initiated at the ankle joint (Winter *et al*., 1990a). Additionally, the proprioception input from residual limb muscles may cause some movements at the ankle joint in the SA foot to counterbalance the body's natural fluctuation in response to gravity during quiet standing. Our results agreed with the suggestion of prosthetic ankle range of motion as an important characteristic in foot-ankle component selection (Mayer *et al*., 2011).

In able-bodied person, the lateral stability is controlled by alternating the activation of the hip abductors and adductors in order to transfer the body's CoM between the legs (Zmitrewicz *et al*., 2006). However, lower limb amputation leads to insufficient control of weight-shifting to maintain posture which has caused instability in medial-lateral direction. We found that the deviation of CoM was greater in frontal plane as depicted by higher MLSI scores compared to APSI scores in both eyes-opened and eyes closed conditions for all foot types. The results of our study were in agreement with previous findings that an increase of CoM excursion in the medial-lateral direction maybe the results of compensation strategy to the impairment in controlling balance in the anterior-posterior direction (Mayer *et al.*, 2011). However, the MLSI was significantly higher than APSI score in ESAR foot during eyes-opened and eyes-closed. This may be possibly due to the flexibility of the carbon fibre ESAR foot which provides eversion and inversion causing more sway movement and instability to the most of the subjects where single-axis foot is their habitual prosthesis. Additionally, the fear of falling which often occurs among the amputees can also lead to additional use of the hip strategy (Adkin *et al.*, 2000), which is reflected by the high stability indexes in medial-lateral direction in all prosthetic feet. Therefore, the medial-lateral instability experienced by the amputees can be utilized as a predictor for risk of falling (Maki *et al.*, 2000). This finding highlights the importance of learning how to balance over the prosthetic foot in order to control the displacement of CoM over the base of support for the amputees. Our results suggest that it is necessary to validate the improvement of postural stability in frontal plane following fall prevention program among the amputees.

Vision has been suggested as the main source of information used in the regulation of posture control under normal situation (Shumway-Cook and Horak, 1986). The findings of this current study corroborate with previous studies on amputees that showed greater postural instability when visual cues was occluded (Vanicek *et al.*, 2009). Explicitly, regardless of foot type, this study showed that the stability indexes were higher during eyes-closed condition which indicated greater deviation of CoM. The differences in balance indices between eyes-opened and eyes-closed conditions were only significance for SACH and ESAR, suggesting habitual adaptation to SA foot for most of the subjects.

Significant differences in the ABC scores found between prosthetic feet suggested that the amputees perceived disparities between the passive stability offered by the ankle mechanisms. Their perceived balance confidence was the highest in ESAR foot, followed by SA and SACH foot. This finding may be due to improved gait performance in lower-limb amputees such as increased tibial forward progression and adaptability to uneven terrain when using ESAR foot as reported previously (Mayer *et al*., 2011; Zmitrewicz *et al*., 2006).

We acknowledged that lack of previous studies comparing the influence of prosthetic foot types on the control of postural stability limits the possibility to associate our results with others. In addition, variations found in the length of residual limb among the subjects may affect postural stability where shorter residual limb exhibited larger body sway than that of medium length (Lenka and Tiberwala, 2007). Additionally, the current results are only indicative for lower limb amputees whom are typical community ambulator and may not be generalized to all amputees. While the present study assessed balance control during quiet standing, future research should investigate the response of different prosthetic feet during more challenging situations to resemble real life situations. Results in this study were based on balance performance from a mixture of traumatic and diabetes caused of amputation. Researchers reported that person with amputation due to vascular adopted different balance control strategy with those of non-vascular reason due to poor somatosensory status found in dysvascular amputees, which caused an increase of body sway during quiet standing (Quai, Brauer, & Nitz, 2005). Therefore, larger sample size with similar characteristics might find a statistically significant difference in terms of postural control between prosthetic foot designs.

5.5 Conclusion

The current study demonstrated that prosthetic foot types did not influence the maintenance of postural steadiness in below-knee amputees although there was a trend of better stability with rigid ankle foot. Nevertheless, visual cues were shown to affect postural stability in SACH and ESAR foot. This initial finding should be considered when prescribing the prosthetic foot to the amputees.

CHAPTER 6

POSTURAL STABILITY CHARACTERISTICS OF TRANSTIBIAL AMPUTEES WEARING DIFFERENT PROSTHETIC FOOT TYPES WHEN STANDING ON VARIOUS SUPPORT SURFACES.

For amputees to return to their daily life activities, the ability to maintain postural balance is essential while adapting to various support surface conditions. In Section 2.3, the vital role of somatosensory system (which consist of muscle proprioception, joint and cutaneous afferents) in contributing to the control of postural stability has been discussed. This study aimed to evaluate the effects of prosthetic foot types on the postural stability among transtibial amputees when standing on different support surfaces. Stability indexes were measured by computed posturography in an upright stance on firm, foam, and unstable support surfaces. The mean OSI score of SACH foot was significantly lower than that of an ESAR foot when the participants were standing on a compliant surface. When compared to able-bodied group, MLSI score was significantly higher for each of the prosthetic foot while OSI score was significantly higher for ESAR foot only in foam condition. Differences between prosthetic foot types and groups (amputees versus able-bodied) can be distinguished only when individuals were standing on a compliant surface. Amputees exhibited an increased postural instability in the medio-lateral direction than able-bodied individuals. Hence, the restoration of stability in the frontal plane and the enhancement of proprioception at the residual limb should be the basis of rehabilitation programs.

6.1. Introduction

Postural stability is achieved by maintaining an upright body alignment against gravitational force and preserving the equilibrium of the center of mass (CoM) in an individual's base of support (Massion and Woollacott, 2004). Successful postural control requires the contribution from a complex sensory system comprising visual, somatosensory, and vestibular modalities as well as motor control systems (Horak *et al*., 1990; Shumway-Cook and Woollacott, 2000). Healthy individuals greatly rely on somatosensory (70%), vestibular (20%), and visual (10%) perceptions when they stand on a firm surface under well-lit conditions (Peterka, 2002). By comparison, individuals mainly rely on vestibular and vision stimuli when the support surface changes because of inaccurate inputs from somatosensory components. Particularly, proprioception is one of the specialized components in the somatosensory system that provides information on the perceptions and awareness of joint movements and positions (passive and active) (Lephart *et al*., 1992; Newton, 1982). Afferent inputs from mechanoreceptors located at the joints and muscles surrounding the ankle possibly influence the proprioceptive control of balance (Allum *et al*., 1998; Richie, 2001). Researchers suggested that the perception of the support conditions is necessary to retain the CoM within the support area in an erect human stance (Horak, 2006; Mouchnino *et al*., 1998). As such, the ability to reorganize postural strategies depending on different support surface is a key in maintaining balance (Horak, 2006).

Ankle and hip strategies are considered responsible for the control of horizontal CoM movements in anterior-posterior and medio-lateral directions, respectively (Horak, 2006; Buckley *et al*., 2002). However, postural stability is decreased after individuals are subjected to below-knee amputation because of several factors, such as the lack of active ankle torques produced to restore balance in the sagittal plane, deficiency in weight shifting to control balance in the frontal plane, and distorted somatosensory inputs from the amputated side (Geurts and Mulder, 1992). These factors can be explained by the loss of the biological ankle joint and a considerable amount of muscles in the lower leg, which functions as the source of proprioception in mobility and equilibrium (Newton, 1982). As such, reduced proprioception is associated with asymmetry in weight bearing and decreased confidence of amputees (Nadollek *et al*., 2002). Therefore, people with amputation are likely to refuse participation in daily and social activities because of a higher incidence of falling than able-bodied people (Miller *et al*., 2002).

For amputees to return to their daily life activities, the ability to maintain postural balance is essential while adapting to various support surface conditions. Balance can be relatively well managed in the comfort of an individual's house, but may be very challenging when outdoor terrains are considered. For example, compliant (e.g., carpet, sand, and grass) or unstable surfaces reduce the ability to detect body orientation accurately (Wu and Chiang, 1996). Horak (1997) also recommended that balance strategies on different support conditions should be evaluated in balance assessment to identify functional limitations and adaptation strategies of individuals with balance disorders. Previous studies on postural stability in unilateral below-knee amputees reported greater postural sway during quiet standing on a firm surface than able-bodied control subjects (Nederhand *et al*., 2012; Vrieling *et al*., 2008). Thus far, only one study has reported an increased level of body sway on a prosthetic leg compared with a sound leg during natural stance on a foam surface (Kozakova *et al*., 2009). Considering previous studies, researchers suggested that the diversity in the mechanical designs of prosthetic feet is possibly one of the factors that contribute to unstable standing (Buckley *et al*., 2002; Nederhand *et al*., 2012).

Although prosthetic foot has been hypothesized to influence standing stability, knowledge about how or to what extent it controls stability remains unclear because of variations in the types of prosthetic feet tested in studies that may have determined the balance performance. Hence, it is vital for the clinician to understand the mechanism underlying integration of prosthesis limb into the balance system to compensate for the limb loss. This study aimed to determine the effect of different prosthetic foot types on the control of postural stability under various support surface conditions. This study was also designed to compare the results with those of able-bodied control subjects**.**

6.2 Methodology

6.2.1 Participants

Using convenience sampling method, we enrolled 10 male unilateral below-knee amputees. All of the amputees were recruited from the University of Malaya Medical Centre rehabilitation clinics. The inclusion and exclusion criteria for the amputees are listed in Table 3.1, Section 3.4. A comparison control group consist of nine male able-bodied participants were also included. This study was approved by the Institutional Ethics Committee Board, and written informed consent was obtained from each of the participants. The demographics summary of the participants is presented in Table 3.2.

The subjective measure of prosthetic use and function was determined using a Houghton scale questionnaire, which consists of four questions with a maximum possible score of 12 points (Devlin *et al*., 2004). The Berg balance test (Wong *et al*., 2013) was conducted to ensure similar balance status between amputees and able-bodied participants. Subjects who failed to maintain equilibrium during the test were excluded from the study. All of the subjects completed SF12v2 to evaluate the health-related quality of life status of the participants (Ware and Sherbourne, 1992).

6.2.2 Instrumentation and procedures

The study employed a repetitive crossover study in which all of the amputees underwent a total of three testing sessions for three weeks. The control group was subjected to only one session for the completion of data collection. The amputees wore their corresponding prostheses that allowed the interchange of foot components. The same socket and suspension components were used throughout the study to eliminate any confounding effect of these variables. The amputees' current prosthetic sockets and components were optimally aligned using a laser liner before the assessment by the same registered prosthetist. The three prosthetic feet that were tested in this study included a solid ankle cushion heel (SACH) foot, a single-axis (SA) foot, and energy-saving and return (ESAR) foot Talux®. All of the tested feet were prescribed according to the subject's foot size and body weight in addition to the activity level of the Talux® foot. All subjects wore identical covered shoes and the same shoes was used in all the experiments.

The subjects familiarized themselves of the test procedures during their first visit. At the end of the first session, the prosthetic foot in the subject's prosthesis was exchanged for the first test foot. The subjects then returned to the laboratory to undergo postural stability assessment after one week of accommodation period (English *et al*., 1995). The second test foot was subsequently attached to the prosthesis in the following week. The process was repeated until the subject had tested the third foot. Prosthetic foot and surface conditions was counterbalanced across subjects to negate order effects. In the last procedure, the test foot was replaced with the original foot. The flowchart of the test procedure is illustrated in Figure 3.25, Section 3.9.

Postural stability test was conducted using a Biodex® stability system (BSS; Biodex® Medical System, Shirley, NY, USA) for its known reliability in objective assessment of postural stability (Arifin *et al*., 2014a). Platform stability, which ranged from 1 (least stable) to 12 (most stable), was varied in terms of spring resistance levels. BSS measures the overall stability index (OSI), anterior/ posterior stability index (APSI), and medial/ lateral stability index (MLSI), which represented the standard deviation of platform fluctuation from a horizontal position (zero point). The platform was integrated with a computer software (Version 3.1 Biodex® Medical Systems) that enables the device to calculate the stability indexes. A detailed desciption of BSS can be found in Section 3.7.

Postural control was assessed under three different surface conditions: rigid; compliant; and unstable (Figure 6.1). For the rigid condition, the participants were asked to stand directly on a rigid and static platform. To simulate a compliant surface, we placed low-density polyethylene foam with a circular radius of 22 cm and a thickness of 2.5 cm on the platform as shown in Figure 6.2 (Borg and Laxaback, 2010).

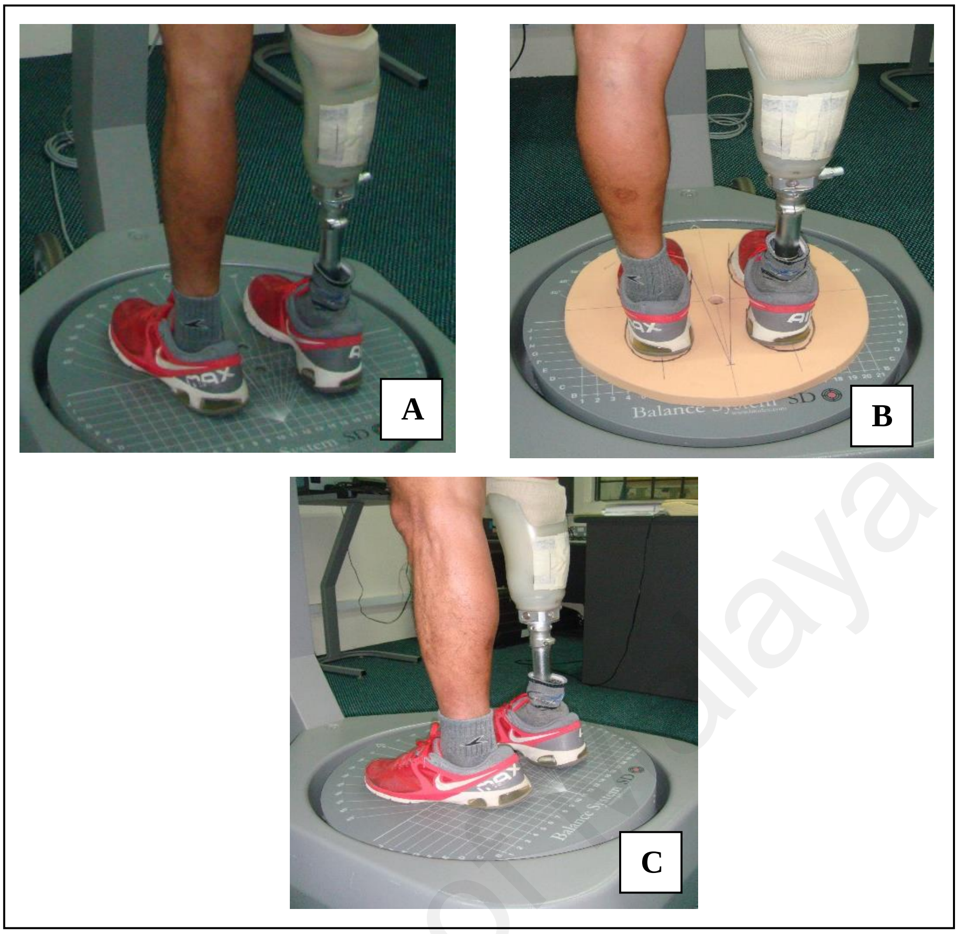


Figure 6.1: Surface conditions used in this study: (a) rigid, (b) compliant and (c) unstable.

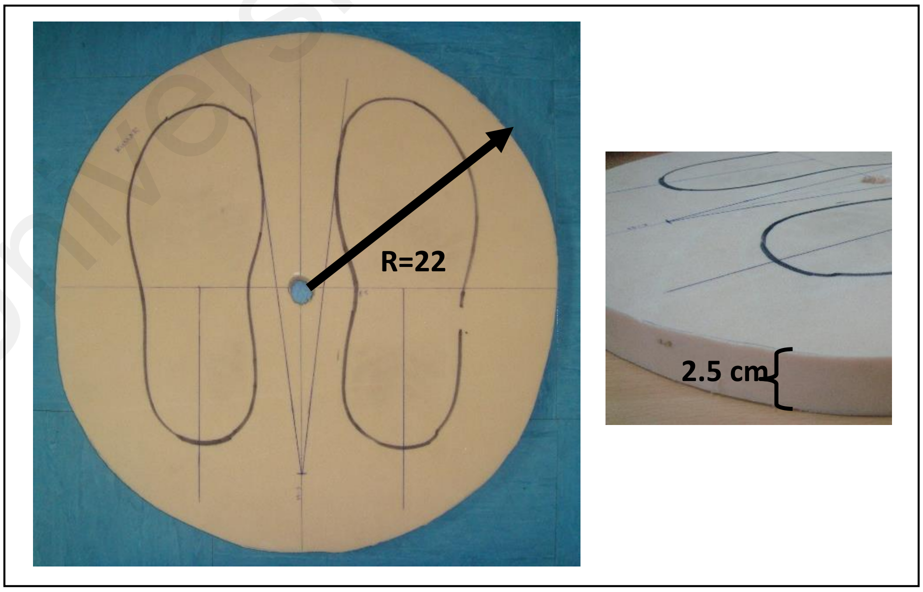


Figure 6.2: Low-density polyethylene foam with a circular radius of 22 cm and a thickness of 2.5 cm to simulate compliant surface.

Platform stability was then set at level 10 under an unstable condition. The subjects were instructed to step on the BSS platform and stand in a standardized position, in which each foot was positioned 17 cm between the heel centers and 14° between the long axes of the feet to eliminate between-subject variability during balance testing (Mcllroy and Maki, 1995). To ensure that this standardized position was maintained accurately for each test with all of the subjects, we marked and recorded the positions. During the test, the subjects were asked to keep their arms alongside the body and look straight ahead at a point on the wall approximately 1.5 m away at eye level to stabilize the head. All of the subjects stood on the platform for 20 s under all of the conditions. A mean score was calculated from the results of the three tests. The standard instruction “stand as still as possible” was given to all of the subjects to ensure consistency during assessment (Zok *et al.*, 2008). All subjects were allowed to rest for 30s in a sitting position between trials and instructed not to change the position of their feet on the platform. Handrails could only be used to prevent falling if the subjects totally lost their balance. An assistant stood at the back of the subject for additional safety. Any trial with changes in foot position or balance loss was excluded.

6.2.3 Statistical analysis

A total of 27 data sets from nine conditions (three support surface conditions and three prosthetic feet) for each of the stability indexes (OSI, APSI, and MLSI) were obtained. All of these data were initially screened to determine the normality of distribution and homogeneity of variance by using Shapiro-Wilk test. All of the data showed normal distribution. A 3×3 (support surface × prosthetic foot) repeated-measures analysis of variance (ANOVA) was used to examine the significance of differences between stability indexes. After the differences between groups were identified, post-hoc HSD Tukey's test was applied to detect the specific area in which statistical differences were observed. Independent *t*-test was employed to compare the able-bodied control group with each prosthetic foot group. $p \leq 0.05$ was considered significant. The effect size was also determined to indicate the significance of the results because of the small sample size used in this study. On the basis of Cohen's guidelines, we considered the effect size values > 0.14 as significantly different (Cohen, 1998). Statistical analysis was performed using SPSS v16.0 (SPSS Inc., Chicago, IL, USA).

6.3 Results

6.3.1 Participants' summary

No significant differences were observed between the amputees and able-bodied group in terms of age, height, and body mass. The Berg balance score also showed no statistical difference between the groups (Table 3.2).

6.3.2 Postural stability between prosthetic feet

The average values of OSI, APSI, and MLSI and the corresponding significant differences are shown in Table 6.1. When comparison were made between the prosthetic feet, our results showed that OSI was significantly higher in the ESAR foot than in the SACH foot (p=0.04) when the subjects were standing on a foam surface compared with a firm and unstable support surface. A large effect size of 0.38 indicated that the differences were significant. Nevertheless, there was a noticeable trend of stability indexes being the lowest for SACH foot and highest for ESAR foot in most of the conditions. Postural stability of the amputees as measured from the OSI, APSI, and

MLSI indexes were not significantly affected by the interaction between prosthetic foot types and sensory conditions (*p*=0.57, *p*=0.08, *p*=0.66).

6.3.3 Postural stability between prosthetic and able-bodied group

Although the stability indexes in prosthetic feet were higher than those of the able-bodied participants, significant differences were observed only in several conditions (Table 6.1). For instance, the MLSI scores of the SACH foot and the SA foot were significantly higher than those of the able-bodied subjects (*p*=0.05 and *p*=0.03, respectively) when the subjects were standing on a foam surface. The OSI (*p*=0.04) and MLSI (*p*=0.04) of ESAR were significantly higher than those of able-bodied subjects standing on a foam surface. The effect size under all of the conditions was large (ranged from 0.20 to 0.39). No significant difference was evident in the APSI scores of the three prosthetic groups and able-bodied group under all of the support surface conditions.

Table 6.1: The average and standard deviation of each prosthetic foot and control group during standing on different support surface configurations

Groups	OSI			APSI			MLSI		
	Foam	**Firm**	**Un stable**	**Foam**	**Firm**	**Un stable**	**Foam**	**Firm**	**Un stable**
SACH[1]	1.88 (1.55)	1.71 (1.25)	2.01 (1.29)	0.95 (0.68)	1.08 (1.02)	1.24 (0.77)	1.31 (1.29)	1.09 (0.92)	1.35 (1.19)
SA[2]	2.28 (1.82)	1.9 (1.99)	1.81 (1.07)	1.26 (0.81)	0.80 (0.68)	1.09 (0.86)	1.68 (1.74)	1.58 (1.94)	1.22 (0.77)
ESAR[3]	2.55 (1.84)	1.86 (1.34)	2.29 (2.52)	1.48 (1.38)	0.65 (0.34)	1.12 (0.99)	1.88 (1.39)	1.59 (1.35)	1.82 (2.30)
Able-bodied[4]	1.13 (0.92)	1.1 (0.94)	1.52 (0.66)	1.02 (0.95)	0.91 (0.79)	1.11 (0.62)	0.33 (0.16)	0.49 (0.53)	0.76 (0.42)
Sig. two tailed ($p \leq 0.05$)	1,3§ 3,4*						1,4* 2,4* 3,4*		

Note. * (1,4), (2,4) and (3,4) indicate significant difference between able-bodied and prosthetic foot based on the independent samples *t*-test. §(1,3) indicates significant difference between SACH and ESAR foot based on the post-hoc analysis.

6.4 Discussion

This study investigated the effect of a prosthetic foot on the control of postural stability by comparing three types of prosthetic feet using the Biodex® stability system. In addition, the importance of proprioception sensory information was examined by comparing the postural stability of able-bodied and below-knee amputee groups. Following amputation, complete loss of cutaneous, muscle, and joint receptors of the residual limb as well as distorted sensory feedback from the intact limb could affect postural stability (Winter *et al*., 1990). However, the skin of the residual limb at the skin-socket interface, which has become more sensitive to the exerted pressure, possibly facilitates the movement of a prosthetic limb (Viton *et al*., 2000). Hence, amputees should be able to control their prostheses to regulate the CoM in the support base to maintain stability during quiet standing.

Our results provided evidence that different prosthetic ankle mechanisms provided by various designs may influence postural stability in different support surface configurations. The stiffness of a prosthetic ankle has been proposed as the basis of stability in the unperturbed standing of amputees (Kamali *et al*., 2013). In particular, SACH, which provides no articulation at the ankle joint, likely minimizes the excursion of CoP when individuals are standing on a compliant surface, thereby increasing the overall stability. For the ESAR foot, such as the Talux®, the flexibility of the carbon fiber causes the body to to exhibit larger excursion of CoP and consequently reduces the overall stability of upright standing on a compliant surface. These findings further supported those of a previous study, in which a stiffer prosthetic foot may be used to enhance postural stability by decreasing body sway (Buckley *et al*., 2002; Nederhand *et al*., 2012).

In the three foot types, the control of stability in anterior-posterior and medio-lateral positions is unlikely affected by different mechanisms on the ankle and support surface. No statistically significant difference was observed in the SA foot because of the control of the plantar flexion at the rear bumper, which is similar to the pre-tibial muscles of a normal foot (Goh *et al*., 1984). Nevertheless, various contributing factors, such as restricted ankle mobility, weak hip abductor muscle strength, deficit in sensory organization, and low balance confidence (Buckley *et al*., 2002; Nadollek *et al*., 2012) have been linked to the altered balance conditions in amputees. To the best of our knowledge, this study is the first to investigate the effects of prosthetic foot types on the control of postural stability when subjects were standing on different support surface configurations.

In normal subjects, postural instability during quiet standing is resisted by muscle contraction to control ankle joint stiffness and counterbalance the destabilizing gravitational torque in anterior-posterior and medio-lateral directions (Peterka, 2002). For the amputees in this study, our findings suggested that postural stability requires more control in the medio-lateral direction when standing on a compliant surface by utilizing the hip strategy. Moreover, increasing the use of hip musculature at the amputated limb was proposed as a strategy to receive more somatosensory inputs to compensate for the lack of sensory input due to amputation (Isakov *et al*., 1992). The ability to utilize the abductors and adductors of the hip possibly promotes an efficient weight transfer and prevents unnecessary compensation strategies, such as lateral trunk bending (Matjacic and Burger, 2003). High postural instabilities in medio-lateral directions can be used as an indicator of falling and confidence of amputees; with this information, amputees could understand their corresponding balance conditions and rehabilitation that they need to improve balance. Although significant difference was only observed under foam conditions, a decrease in postural stability of the amputees were showed when they were standing on firm or unstable surfaces compared with that of able-bodied participants.

We found that different postural stability characteristics can be determined between prosthetic foot types as well as between amputees and able-bodied groups when individuals are standing on a compliant surface. This was because the firm and flat surface provides accurate orientation information of body from the intact limb and residual limb while the compliant and tilting surface reduced the accuracy of information (Maclellan and Patla, 2006). When standing on complaint surface, the normal ground reaction forces exerted at the feet was altered and this increased the movement of body's CoM due to decreased effectiveness of the ankle to generate stabilisation torque to maintain equilibrium (Desai *et al*., 2010; Patel *et al*., 2008).

Limitations in our study are acknowledged. We noted that the lack of significant differences under firm and unstable conditions may be caused by an increase in the dependence on other accurate sensory inputs from visual and vestibular systems. Therefore, future studies should occlude more than two sensory modalities for the differences between feet and groups to become apparent. Furthermore, the absence of prosthetic foot effect may be attributed to a less challenging nature of the task during quiet standing on firm and unstable platforms because the amputees were experienced and skilled prosthetic users. In addition, the small number of the subjects in this study may provide great differences between prosthetic feet and between groups, but such differences may not be statistically significant**.** Results in this study represent balance performance of transtibial amputees in general, which did not specifically distinguised between dysvascular and non-dysvascular amputees. Although static balance has become an essential skill in rehabilitation process for the amputee populations to achieve independent standing and walking (Vrieling *et al*., 2008), further research should include stability assessment during walking and dual tasking.

6.5 Conclusions

The results suggest that prosthetic foot design affected the overall stability of below-knee amputees, particularly when subjects were standing on a compliant surface. Therefore, clinicians should consider this factor when prosthetic feet are prescribed to amputees who ambulate mostly on soft surfaces. Furthermore, amputees utilised the hip strategy to control postural stability in medio-lateral directions in an upright stance on a compliant surface. These findings can be utilised to develop intervention during rehabilitation using different support surfaces which may lead to improvement in postural stability and reduce risk of falls in person with lower limb amputations.

CHAPTER 7

THE EFFECTS OF DIFFERENT PROSTHETIC FEET AND HEAD EXTENSION ON THE POSTURAL STABILITY IN PERSONS WITH BELOW-KNEE AMPUTATION DURING QUIET STANDING.

The vestibular system, which is the third component in the sensory system, plays a vital role in the maintenance of postural stability as deliberated in Section 2.3. The purposes of this study were to examine the effects of different prosthetic feet types and head extension on the postural stability in persons with below-knee (BK) amputations; and to determine whether computed posturography can be used to distinguish between amputated and able-bodied individuals across sensory conditions. Results indicated that all stability indexes were significantly affected by sensory conditions, but not by the prosthetic feet types. Postural stability was reduced significantly under conditions where visual or vestibular inputs were disrupted. Postural instability in medial-lateral direction was greater in amputated compared to able-bodied group in most of the sensory conditions. For overall postural stability however, significant difference between the groups can only be found during eyes closed-head neutral condition. This study suggests that head extension which represents vestibular system disruption increases the difficulty to maintain postural stability in person with BK amputation. Moreover, the BSS appeared to distinguish between amputated and able-bodied individuals mostly in the medial-lateral direction.

7.1 Introduction

Postural stability in human is the ability of a person to achieve, maintain or return to equilibrium by positioning the centre of mass (CoM) within its base of support (Pollock, Durward, & Rowe, 2000). The regulations of a complex sensory (somatosensory, visual, vestibular) and motor systems have been suggested to contribute in attaining postural stability (Shumway-Cook & Woollacott, 2000). The visual system detects changes in body orientation in upright stance by identifying head and body displacement with respect to the environment, the somatosensory system senses the position and velocity of all body segments, and the vestibular system detects head orientation with respect to the vertical axis (Massion & Woollacott, 2004).

Accurate labyrinth information from otolith organs of the vestibular system is used to resolve inter-sensory conflict condition, for example when a person stands near a moving bus (Shumway-Cook & Woollacott, 2000). In this situation, the visual input would suggest false impression that the body was moving, rather than the bus. However, at the same time the somatosensory system senses that the body is stationery. Consequently, to elucidate this sensory conflict, the central nervous system would rely on accurate sensory information provided by the somatosensory and vestibular systems which determine no movement of the body (Shumway-Cook & Horak, 1986). The otolith-spinal inputs from the vestibular system is also known for its fast-acting mechanism in stabilizing postural stability corrections by triggering the lower-leg muscle activity as early as 60 milliseconds following perturbations (Allum and Shepard, 1999).

However, compromised lower limb somatosensation and circulation is linked to poor balance and frequent falls in persons with BK amputations (Quai, Brauer, & Nitz, 2005; Miller *et al*., 2001b). While able-bodied person has the ability to utilize the ankle joint and lower limb musculature to produce torque in resisting gravitational force to sustain standing stability (Winter *et al*., 1998), persons with BK amputations rely on the passive stability offered by the prosthetic foot-ankle system. Additionally, researchers hypothesized that aside from poor muscle strength and fear of falling (Kozakova *et al*., 2009), the different types of prosthetic feet might also affect postural stability during quiet standing in persons with BK amputations (Vrieling *et al*., 2008; Nederhand *et al*., 2012). Despite the notions that the prosthetic foot may influence standing stability, there is lack of understanding about how different designs contribute to the control of stability due to the heterogeneity of prosthetic foot used in previous studies. Hence, a detailed study has yet to be conducted to identify the influence of different prosthetic feet to the standing balance of persons with BK amputations.

Besides relying on the prosthetic foot, intact musculatures and sensory systems provide a compensatory mechanism to maintain postural orientation after a BK amputation (Curtze *et al*., 2012). Several studies reported that ankle strategy, which involves the active ankle function of the sound limb and the passive ankle function of the prosthetic foot, is effective in controlling postural stability (Curtze *et al*., 2012; Vanicek *et al*., 2009). Conversely, other studies reported that the hip strategy controlled from intact and prosthetic limb are the main approach when controlling postural stability (Mayer *et al*., 2011). Researchers suggested that in able-bodied person, the utilization of the ankle strategy requires adequate surface somatosensory whereas the vestibular system is thought to play an essential role in organizing the hip strategy for postural control (Horak *et al*., 1990).

Manipulation of sensory information to control the posture in persons with BK amputations has been studied by measuring the excursion of center of pressure (CoP) under altered or diminished sensory input. Researchers showed that eliminating visual information (Barnett *et al*., 2012; Vrieling *et al*., 2008) or reducing proprioception input (Kozakova *et al*., 2009; Buckley *et al*., 2002) increases CoP displacement, which is associated with instability. Moreover, manipulating more than one sensory input will further deteriorate standing stability in persons with BK amputations (Barnett *et al*., 2012). Previous studies manipulated the vestibular system by head tilting in persons with low back pain, elderly, and healthy able-bodied adults (Mientjes & Frank, 1999; Hu & Woollacott, 1994; Paloski *et al*., 2006). However, a study manipulating the vestibular system by head tilting in persons with BK amputations has yet to be conducted. Therefore, it seems reasonable to determine the effects of head extension during standing since this condition occurs when persons with BK amputations reach for objects or surfaces that are beyond eye level.

Computed posturography such as the Biodex® Stability System (BSS) has been used to evaluate postural stability by measuring the angular shift from the horizontal. It has been previously shown to successfully quantify postural stability in persons with rheumatoid arthritis and ankle instability (Aydog *et al*., 2006; Testerman & Griend, 1999). Although these studies found differences in dynamic balance between people with balance problem and healthy group, it is uncertain whether BSS could also be utilized to differentiate between persons with BK amputations and able-bodied during static balance. Hence, due to its reliability, practicality, ease to administer and cost effectiveness (Parraca *et al*., 2011; Guskiewicz & Perrin, 1996), BSS may be effective in the evaluation of postural stability in persons with BK amputations for rehabilitation purposes. This study aims to examine the effects of different prosthetic feet and head extension during quiet standing on the postural stability in persons with BK amputations. This study also aims to quantitatively determine whether balance between persons with BK amputations and able-bodied individuals could be distinguished by using BSS.

7.2 Methodology

7.2.1 Participants' characteristics

A convenience sample of ten males with unilateral BK amputation from rehabilitation clinics in University Malaya Medical Centre participated in this study. The demographic characteristics of amputees for this study are summarized in Table 3.2, Section 3.5. Nine age-matched able-bodied males served as the control group. The mean age, height, and weight for the control group were 44.1 ± 14.04 years, 1.66 ± 0.05 m, and 73.9 ± 8.7 kg, respectively. No significant differences in age, height, and body mass were observed between participants with BK amputations and able-bodied. Using the Medicare Functional Classification Level (MFCL) indicators, persons with BK amputations were categorized as K2 and K3 community ambulators, who have the ability to ambulate with variable cadence and overcome low-barriers such as curbs or uneven surfaces (Gailey *et al*., 2002).

Participants with at least one year experience in their current prostheses and with the ability to walk without the use of any assistive device were included in this study. Other inclusions and exclusions criteria for included participants are listed in Section 3.4. Prior to testing, amputee participants were assessed using the Houghton Scale and Berg balance score (BBS) questionnaires. All persons with BK amputations demonstrated intensive use of the prosthesis based on the average Houghton Scale (10.5

± 0.9). Initial analysis showed that there was no significant difference in functional balance status between the groups (p=0.08). Details of these assessments can be found in Section 3.8. This study was approved by the Institutional Ethics Committee Board.

7.2.2 Experimental protocol

A two-factor (prosthetic feet types, sensory condition) repeated-measures design for each outcome was employed in this study. Prior to the tests, all participants completed one familiarization trial for each sensory condition to negate potential effects of learning and fatigue as suggested by Hinman (2000). Three types of prosthetic feet were evaluated in this study: solid ankle cushioned heel (SACH) foot (Enjoylife, Fujian, China), single axis (SA) foot (Enjoylife, Fujian, China) and energy storage and release (ESAR) Talux® foot (Ossur, Reykjavik, Iceland). The same registered prosthetist completed fittings and alignments of each prosthetic foot. Each test foot was attached to the participant's existing prosthesis using their own socket and suspension. Although the structure of the prosthetic foot can be seen by the participant, the mechanical differences between the test feet were not disclosed.

The first foot type was fitted during the first visit before returning to the laboratory for the next assessment. Based on a study by English and co-workers (1995), one week of accommodation period was assigned for each prosthetic foot as this was reported sufficient for persons with BK amputations before functional assessment of the prosthesis. The test was counterbalanced across persons with BK amputations to account for order effects. After the assessments were completed for all prosthetic feet, all participants attended the final visit during the fourth week to change the test foot with their original foot. Control participants were only required to attend one single session to complete the assessment.

The BSS (Biodex® Medical System, Shirley, NY, USA), was used because of its reliability in objective assessment of postural stability (Aydog *et al*., 2006). BSS measures the overall stability index (OSI), anterior/ posterior stability index (APSI), and medial/ lateral stability index (MLSI), which represent the standard deviation of the angular fluctuations from the centre of the platform (zero point) at a sampling rate of 20Hz (Arnold & Schmitz, 1998). The platform was integrated with Biodex® software (Version 3.1 Biodex® Medical Systems) that enables the device to calculate the stability indexes. Detailed description of operational principal of this device can be found in Section 3.7.

All participants stood on a stable, rigid platform surface under four different conditions: 1: Eyes open, head neutral (EO-Neut), 2: Eyes open, head extended (EO-Ext), 3: Eyes closed, head extended (EC-Ext) and 4: Eyes closed, head neutral (EC-Neut) (Figure 7.1).

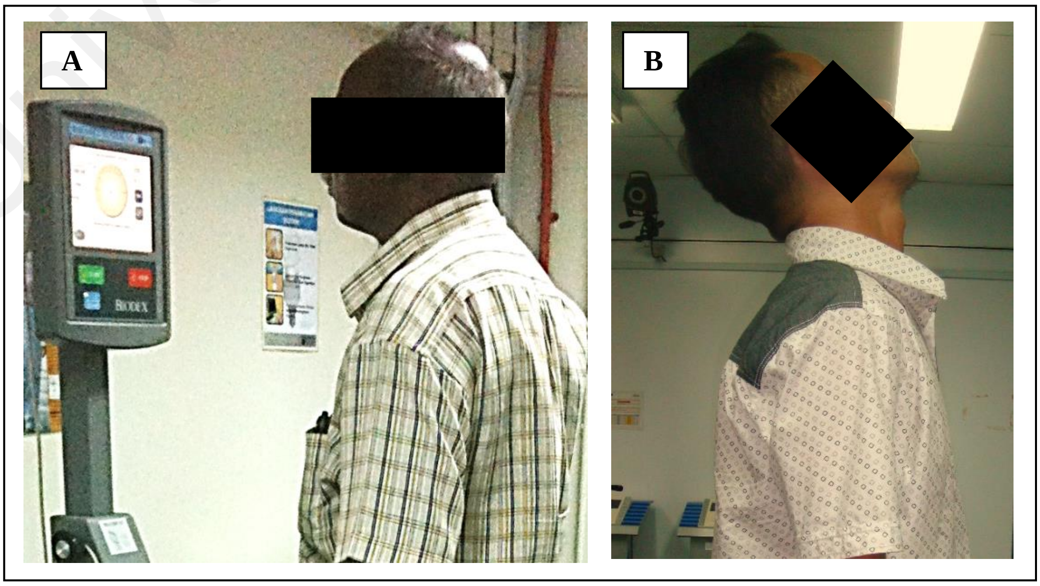


Figure 7.1: The position of the head in (A) neutral and (B) extended positions.

Condition 1 served as the baseline where all sensory cues (visual, proprioception and visual) were accurate. In order to isolate the influence of vision on postural control, condition 3 and 4 were performed in the absence of visual information (Paloski *et al*., 2006). In Neutral condition, participants were asked to keep their gaze in a straight-ahead direction to stabilize the head. In Extended condition (1 and 2), the head was tilted backward at each participant's maximal head extension, allowing them to look at the ceiling (Hu & Woollacott, 1994). Head extension introduced imbalance due to vestibular system disruption sensed by the otolith organs because of the change of head position (Brandt, Krafczyk, & Malsbenden, 1981). The experimenter stood at the side of each subject to monitor the head position throughout the assessments. Further information on the positions of the feet and arms, testing durations, resting period and standardized instruction have been discussed in Section 3.9.

7.2.3 Statistical Analysis

Means and standard deviations (SD) of the stability variables were calculated for each condition. All stability data were initially screened using Shapiro-Wilk test and showed normal distributions. Three 3 x 4 (prosthetic foot types by sensory conditions) repeated-measures analysis of variance (ANOVA) was performed to determine any main effect of foot types (SACH, SA, ESAR), sensory conditions (EO-Neut, EO-Ext, EC-Neut, EC-Ext) or interaction between foot types and conditions on the stability indexes (OSI, APSI, MLSI). Post-hoc analysis was performed using the HSD Tukey when significant main effect existed. Independent t-test analysis was used to compare the comparison control group with each prosthetic foot group. Significance was accepted at $p \leq 0.05$ for all analyses. We did not adjust the alpha level for multiple testing to avoid the inflation of type II error (Perneger, 1998). The effect size was also evaluated to indicate the significance of the results because of the small sample size used in this study. The effect size was obtained from SPSS results (partial eta squared, η_p^2) and values higher than 0.14 (large effect) were considered significant (Daniel, 2013). All statistical analysis was performed using SPSS v16.0 (SPSS Inc., Chicago, IL, USA).

7.3 Results

7.3.1 Influence of prosthetic foot types and sensory conditions

The average stability indexes for all prosthetic feet during four sensory conditions are shown in Table 7.1. Results from ANOVA analyses reported that the interaction effect between types of prosthetic feet and sensory conditions was not statistically significant for all stability indexes ($F_{6,54}$=.546, p=.771, η^2=.06). There was a statistically significant main effect of sensory conditions on the OSI score ($F_{3,27}$=10.63, p<.001, η^2=.54), APSI score ($F_{3,27}$=7.94, p=.001, η^2=.47) and MLSI score($F_{3,27}$=6.49, p=.002, η^2=.42) (Table 7.2). Post-hoc pair-wise comparisons showed that the OSI and APSI scores during the presence of all sensory inputs (condition 1) were significantly lower than conditions with missing of one or more sensory inputs (conditions 2, 3, 4). For MLSI score however, condition 1 demonstrated significant lower mean score than conditions 2 and 4 only. The main effect for the types of prosthetic feet did not reach statistical significance ($F_{2,18}$=.34, p=.716, η^2=.04). The effect size was large for all significant findings.

Table 7.1: The average and standard deviation of stability indexes for each prosthetic foot during standing in various conditions.

Stability indexes/ Conditions	Prosthetic foot						Able-bodied	
	SACH		SA		ESAR			
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
OSI								
EO-Neut	1.71	1.25	1.90	1.98	1.86	1.34	1.10	0.94
EO-Ext	3.08	1.26	2.62	1.48	2.89	0.95	2.11	1.07
EC-Ext	2.97	1.67	2.75	1.19	3.12	0.72	2.77	1.44
EC-Neut	3.43	1.17	2.91	1.06	3.58	1.49	2.02	1.13
APSI								
EO-Neut	1.08	1.02	0.80	0.68	.65	0.34	0.91	0.79
EO- Ext	1.93	0.98	1.11	0.53	1.42	0.80	1.89	1.19
EC- Ext	1.79	1.12	1.76	0.76	1.95	0.92	2.61	1.41
EC- Neut	1.89	0.96	1.33	0.61	1.80	1.03	1.84	1.13
MLSI								
EO-Neut	1.09	0.92	1.58	1.94	1.59	1.35	0.49	0.53
EO- Ext	1.94	1.35	2.11	1.65	2.15	1.17	0.58	0.42
EC- Ext	2.05	1.42	1.78	1.17	1.98	0.94	0.66	0.46
EC- Neut	2.52	1.19	2.30	1.18	2.76	1.37	0.59	0.28

Note. OSI= Overall stability index; APSI= anterior/ posterior stability index; MLSI= medial/ lateral stability index; EO-Neut= eyes open, head neutral; EO-Ext= eyes open, head extended; EC-Ext= eyes closed, head extended, EC-Neut= eyes closed, head neutral; SACH= solid ankle cushioned heel; SA= single axis; ESAR = energy storage and release.

Table 7.2: Analyses of Variance for stability indexes.

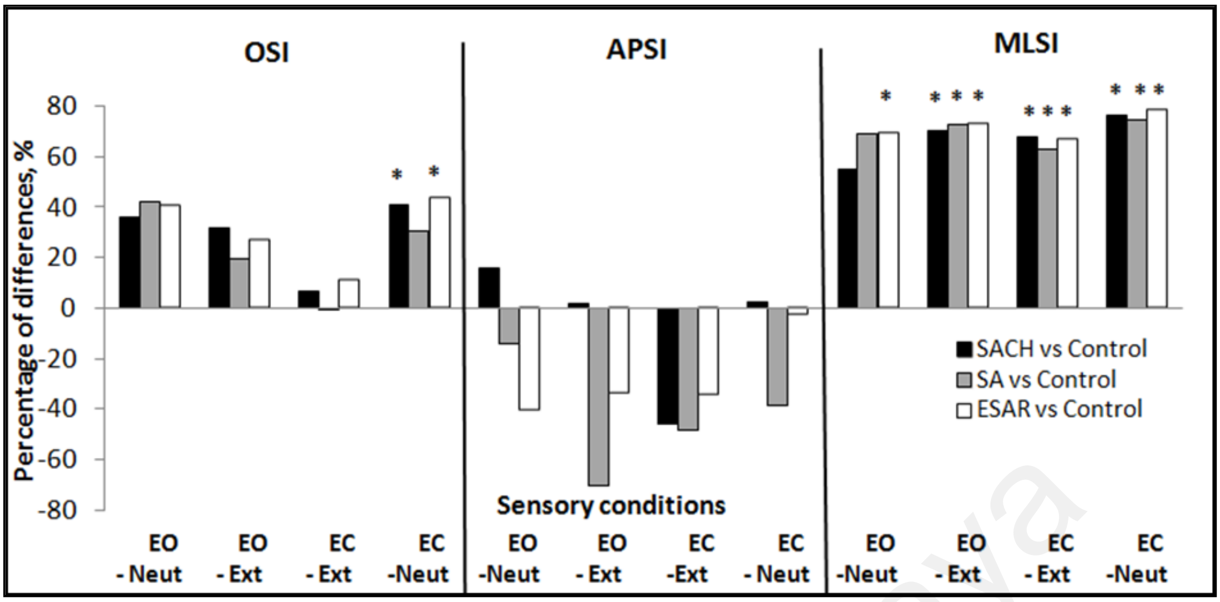
Source	df	error	F	η^2	*p*-value
OSI					
Prosthetic foot (A)	2	18	.34	.04	.72
Sensory conditions (B)	3	27	10.63*	.54	<.001
Interaction (AxB)	6	54	.55	.06	.77
APSI					
Prosthetic foot (A)	2	18	1.28	.12	.30
Sensory conditions (B)	3	27	7.94*	.47	.001
Interaction (AxB)	6	54	1.46	.14	.21
MLSI					
Prosthetic foot (A)	2	18	.21	.02	.81
Sensory conditions (B)	3	27	6.49*	.42	.002
Interaction (AxB)	6	54	.63	.07	.71

Note. *p<.05

7.3.2 Comparison between control and prosthetic groups

The differences of stability indexes between each prosthetic foot and comparison group are illustrated in Figure 7.2. The SACH and ESAR foot group demonstrated significant higher overall stability score (OSI) than the comparison group (p=0.017 and p=0.021, respectively) during EC-Neutral condition. Furthermore, postural instability in medial-lateral direction (MLSI index) was significantly greater in the SACH, SA and ESAR foot than in the comparison group during EO-Ext (p=0.01, p=0.015, p= 0.001, respectively), EC-Neut (p<0.001, p=0.01, p<0.001, respectively) and EC-Ext (p=0.012, p=0.015, p=0.001, respectively). In addition, only ESAR foot showed higher stability index than comparison group in medial-lateral direction during EO-Neutral condition (p=0.035).

Although the postural stability of the amputees decreased in OSI and APSI, no significant difference in postural stability was observed between the three prosthetic foot groups and the comparison group. The effect size was large, between 0.2 to 0.6, for all significant findings. Generally, the MLSI score were greater by 50% to 80% in all types of prosthetic foot types in all four conditions. In regards to OSI score, most of the prosthetic feet exceeded the comparison group by 30% to 40%. Conversely, APSI score was mostly 20% to 70% lower in most of the prosthetic group than the comparison group.



Note. OSI= Overall stability index; APSI= anterior/ posterior stability index; MLSI= medial/ lateral stability index; EO-Neut= eyes open, head neutral; EO-Ext= eyes open, head extended; EC-Ext= eyes closed, head extended, EC-Neut= eyes closed, head neutral; SACH= solid ankle cushioned heel; SA= single axis; ESAR = energy storage and release.

Figure 7.2: The change of OSI, APSI and MLSI expressed as percentage increase or decrease between each prosthetic foot and normal groups. Note that the asterisk sign (*) indicate significant difference between prosthetic foot and control. Deficit in balance leads to greater increase in stability index score. Positive value indicates the stability score of amputees are greater than that of control subjects.

7.4 Discussion

The primary aim of this study was to determine the effects of wearing different prosthetic feet and head extension on the postural stability of persons with BK amputations during upright quiet standing. In the present study, the types of prosthetic feet did not appear to adversely or positively affect postural stability in persons with BK amputations during quiet standing. The non-significant foot effect may be attributed to the good adaptation mechanism of the persons with BK amputations, which minimized the differences between prosthetic feet. Moreover, from the Berg balance score and Houghton score, persons with BK amputations in this study demonstrated good balance status with intensive use of prosthesis which helps them to minimize body sway when standing with all tested prosthetic feet without demonstrating instability.

Postural stability in persons with BK amputations during quiet upright standing was challenged when one or two sensory modalities were disrupted. This can be seen from the decreased stability reflected form the stability indexes when persons with BK amputations stood with either the eyes closed or with the head tilted backwards or when both sensory modalities were altered during quiet standing wearing all three prosthetic foot types. These findings were similar to those of Mientjes *et al*. (1999) which reported increased postural sway in persons with chronic low back pain when visual input was removed and during more complex task. Moreover, the decrease of postural stability has been suggested as a result of tilting the otolith organs exceeding its optimal working range (Paloski *et al*., 2006; Vuillerme and Rougier, 2005) and the absence of visual input which plays important role in maintenance of balance (Redfern *et al*., 2001).

The neck proprioceptors input provides the necessary information about head movements relative to the trunk, hence, extending the head reduces the accuracy of sensory inputs detected from the stretch receptor in the neck (Jackson & Epstein, 1991; Massion and Wollacott, 2000). Additionally, this head position was chosen because it significantly affects postural stability more than flexion or lateral tilt of the head (Paloski *et al*., 2006). In addition, researchers previously demonstrated that adding head extension task in postural stability evaluation enhances the sensitivity of posturography in detecting abnormalities of balance in people with chronic low back pain and multiple sclerosis (Mientjes & Frank, 1999; Jackson *et al*., 1995). Moreover, balance training with head extension and closed eyes has demonstrated previously to improve the ability to maintain postural stability (Brandt *et al*., 1981).

Previous studies reported that manipulating more than one sensory system further deteriorates the postural stability of persons with BK amputations (Barnett *et al*., 2012). In the present study, the addition of the eyes-closed task under the head extension condition in persons with BK amputations did not result in falling or loss of stability. These results suggested that persons with BK amputations were able to prioritize accurate somatosensory inputs during maintenance of stability when more than two sensory inputs were challenged. It was hypothesized that persons with BK amputations utilized the somatosensory cues from non-affected leg, as well as haptic cues from the contact of the residual limb with the inner wall of the socket which may be used as a reference frame, to regain body orientation to efficiently stabilize the posture (Massion & Woollacott, 2004b).

The secondary aim of our study was to determine whether BSS can be used to distinguish between persons with BK amputations and able-bodied individuals. Computerized posturography using BSS has been shown to successfully quantify postural stability in various populations (Aydog *et al*,. 2006; Testerman & Griend, 1999). The current investigation showed that compared to able-bodied participants, persons with BK amputations had significantly greater postural instability in medial-lateral direction during head extension with both eyes open and closed for all prosthetic feet tested. This finding further supports the previous study that demonstrated postural stability in frontal plane can be used to discriminate healthy person from person with impaired balance condition (Mientjes & Frank, 1999). Furthermore, the current findings showed higher percentage of differences in MLSI score between all prosthetic feet groups and comparison group during three (out of four) sensory conditions. The large effect size values indicate that these differences between groups were meaningful. Overall, incorporating head extension into computerized posturography assessment in able-bodied and persons with BK amputations caused more postural sway with eyes opened and closed, compared to when all sensory inputs were present, as previously shown in healthy population (Paloski *et al*., 2006).

Although there is no evidence of statistically significant different of balance between persons with BK amputations and able-bodied group in anterior-posterior direction, there is a trend of lower APSI score in persons with BK amputations group than that of able-bodied group. This may be explained by the limited body sway associated with relatively stiff prosthetic ankle and reduced muscle capacity on the intact limb in controlling postural stability (Buckley *et al*., 2002; Nederhand *et al*., 2012). Other possible explanations to this finding include the unwillingness of persons with BK amputations to initiate movement at the prosthetic ankle in the sagittal plane due to lack of confidence and fear of falling (Miller *et al*., 2001; Buckley *et al*., 2002). Therefore, our findings suggest that persons with BK amputations utilized the hip strategy in controlling balance during quiet standing as opposed to the ankle strategy used in able-bodied persons as reported previously (Mayer *et al*., 2011; Horak *et al*., 1990).

The finding of our study suggested that the MLSI score provided by the BSS computed posturography can be used as distinguishing feature between persons with BK amputations and able-bodied persons. Hence, results obtained from this device provides avenue to the assessment of balance and consequently aids in providing tailored rehabilitation programs for persons with lower-limb amputation. Moreover, previous study reported that normal adults and multiple sclerosis significantly improved overall postural stability when head extension task was incorporated in their training programs (Brandt *et al*., 1981; Hebert, Corboy, Manago, and Schenkman, 2011; Hu and

Woollacott, 1994). As such, clinicians should expose persons with BK amputations to situations which produce body instability, such as standing with head extended, in order to improve sensorimotor rearrangement and consequently increasing the effectiveness of the training.

In our study, we were limited to a small sample size as well as the ease of the task used. Thus, these limitations may have prevented us finding significant differences between prosthetic feet (SACH *vs* SA *vs* ESAR) and between groups (BK amputations *vs* comparison). The small sample size was due to the difficulty in recruiting persons with BK amputations to make multiple visits for data collection. Moreover, the head extension angle should be standardized to reduce variability and monitored using sensors for accuracy.

7.5 Conclusions

Vestibular system disruptions due to head extension present a challenge to persons with BK amputations by increasing postural instability mostly in medial-lateral direction during upright standing. However, postural stability during quiet standing was not affected by the types of prosthetic feet. In addition, this study demonstrates that the BSS can be used to distinguish functional postural stability status in medial-lateral direction between persons with BK amputations and able-bodied individuals. Rehabilitation programs should consider including the head extension task which is commonly encountered in activities of daily living. This is to improve the control of medial-lateral postural stability particularly for individuals recovering from balance control deficits.

CHAPTER 8

EVALUATION OF POSTURAL STEADINESS IN BELOW-KNEE AMPUTEES WHEN WEARING DIFFERENT PROSTHETIC FEET DURING VARIOUS SENSORY CONDITIONS USING THE BIODEX® STABILITY SYSTEM (BSS).

In recent years, computerized posturography has become an essential tool in quantitative assessment of postural steadiness in the clinical settings. The potential of using a portable, user-friendly posturography device, such as the Biodex Stability System (BSS), has been highlighted in Section 3.7. The purpose of this study was to explore the ability of the BSS to quantify postural steadiness in below-knee amputees. The overall (OSI), anterior-posterior (APSI) and medial-lateral (MLSI) stability indexes as well as percentage of time spent in left and right quadrants and four concentric zones were measured under altered sensory conditions while standing with solid ankle cushion heel (SACH), single axis (SA) and energy storage and release (ESAR) foot. Significant difference was found between sensory conditions in SACH and ESAR foot for all stability indexes. The percentage of time spent in Zone A (0^0-5^0) was significantly greater than the other three concentric zones ($p<0.01$). The loading time percentage on their intact limb was significantly longer than the amputated limb in all conditions for all three prosthetic feet. The findings highlight that the characteristics of postural stability in amputees can be clinically assessed by utilizing the outcomes produced by the BSS.

8.1 Introduction

The ability to control equilibrium in posture is the foundation of independent standing and walking (Melzer *et al*., 2004). In upright static standing, the dynamics of postural control in maintaining balance is defined as postural steadiness (Prieto *et al*., 1993). Movement and sensory strategies are known as part of the subcomponents of postural control, which also comprise biomechanical constraints, cognitive processing, dynamic control and spatial orientation (Horak, 2006). Moreover, the control of posture is a complex integration of somatosensory (proprioceptive, cutaneous and joint), visual and vestibular inputs along with motor coordination to maintain the center of mass (CoM) within the base of support (BoS) (Blackburn *et al*., 2000; Shumway-Cook and Woollacott, 2000). Any deficits in these components will result in poor control of body posture, which is often associated with the risk of falling and limited physical activities (Winter *et al*., 1990).

People with lower limb amputations exhibit a higher incidence of falling than able-bodied because of the deficits in controlling movements in medial-lateral or anterior-posterior directions (Miller *et al*., 2001a). This is due to the loss of biological ankle joint and a considerable amount of muscles in the lower leg which has caused lack of active ankle torques produced to restore balance in sagittal plane, deficiency in weight-shifting to control balance in frontal plane, and distorted somatosensory input from the amputated side (Geurts and Mulder, 1992). Therefore, prosthetic foot is prescribed to provide passive stability by reducing the amount of body sway regulated at the relatively stiff ankle joint (Blumentritt *et al*., 1999; Buckley *et al*., 2002). During altered-sensory conditions, researchers showed that standing with eyes-closed (Barnett *et al*., 2002; Isakov *et al*., 1992) or standing on compliant surface (Kozakova *et al*.,

2009) contributes to the decrease of standing stability in people with lower limb amputation.

In previous years, computed posturography such as the EquiTest system (NeuroCom International Inc., Oregon, USA) has been utilized to quantify postural balance in below-knee amputees (Barnett *et al*., 2002; Vanicek *et al*., 2009). However, the applications of the system maybe limited due to its sophisticated system which requires trained tester, large size, not portable, and expensive (Yim-Chiplis and Talbot, 2000). Alternatively, the Biodex stability system (BSS) (Biodex, Inc, Shirley, New York, USA) has been shown capable in producing clinical data measurements on postural stability (Hinman, 2000). BSS is a portable, economical, and reliable tool for objective assessment of postural stability (Testerman and Griend, 1999) and has been utilized in patients with arthritis and ankle instability (Aydog *et al*., 2006; Salsabili e*t al*., 2011). However, information is lacking on the quantification of the upright postural steadiness of below-knee amputees using the same device. This study aims to fully utilize the measurement outputs provided by the BSS to determine the postural steadiness of below-knee amputees who are wearing different prosthetic foot types under various sensory manipulations.

8.2 Methodology

8.2.1 Subjects

Ten subjects with unilateral below-knee amputation participated in this study. Subject inclusion criteria were as follows: male unilateral below-knee amputees with at least one year experience in their current prosthesis and able to walk without the use of any assistive device. Subjects must obtained a score of >5 for Houghton scale (Devlin *et al*., 2004) to indicate active use of prosthesis and >41 for Berg balance scale (BBS) (Wong *et al*., 2013) to ensure that only subjects with low risk of falling were selected. Subjects were excluded from this study if they had poor fittings of prosthesis, residuum pain, visual or vestibular impairment (vertigo or dizziness), lower limb musculoskeletal injury and other neurological deficits. This study was approved by the Institutional Ethics Committee Board.

8.2.2 Procedures and equipment

All subjects completed one familiarization trial for each condition to negate the potential effects of learning and fatigue (Hinman, 2000). Amputees underwent a total of three consecutive testing sessions and were asked for a time commitment of 4 weeks period. Each foot was worn for one week of functional walking to allow accommodation for each prosthetic foot. This period has been suggested as sufficient before clinical decision could be made regarding the effectiveness of prosthesis components (English *et al*., 1995). At the end of the one week period, the subject returned to the laboratory and postural stability was quantitatively evaluated using the BSS. Following the entire testing procedure for each foot, the foot was removed and replaced with the next foot, and the process was repeated until each subject had tested all three feet. The test was counterbalance across amputees to negate order effects. After the assessments were completed for all prosthetic feet, amputees attended the final visit to change the test foot to their original foot.

The three types of prosthetic foot used in this study were: SACH foot (Enjoylife, Fujian, China), SA foot (Enjoylife, Fujian, China) and ESAR Talux® foot (Ossur, Reykjavik, Iceland). The SACH was a non-articulating foot with wooden keel and rubberized cushioned heel. The SA foot allowed plantarflexion-dorsiflexion motion at the single hinge joint. The Talux® was a Flex-Foot with J-shaped multiaxial ankle and heel-to-toe carbon fiber footplate designs. The SACH and SA feet were chosen due to their common use in patient care (Goh *et al*., 1984; Hafner, 2005) while ESAR represents modern prosthetic foot (Noonan, 2014). The same registered prosthetist completed the fittings and alignments of each prosthetic foot. Each test foot was attached to the subject's existing prosthesis using their own socket and suspension. Each prosthetic foot was covered with sock to obscure the foot structures from the participants. The same sock was also worn at the intact foot.

Postural stability during upright static standing was evaluated using the BSS which measures the overall (OSI), anterior/ posterior (APSI), and medial/ lateral (MLSI) stability indexes. These indices are standard deviations that assess the displacement of CoM around the centre of the platform (zero point) (Arnold and Schmitz, 1998). Higher stability index indicated greater amount of body movement which is associated with an unstable posture, while lower stability index is associated with more stable posture. The platform was integrated with Biodex® software (Version 3.1 Biodex® Medical Systems) which enables the calculation of the stability indexes at a sampling rate of 20 Hz.

In addition to stability indexes, the BSS calculates the percentage of test time the subject spent in concentric zones and left/right quadrant (Figure 8.1). During static assessment, each concentric circle of the zone represents the angular displacement of the CoM from the center of the foot platform (Arnold and Schmitz, 1998). The concentric circles were arranged at 5^0 increments as follows: Zone A: 0-5^0, Zone B: 6-

10^0, Zone C: 11-15^0 and Zone D: 16-20^0. For double stance protocol, quadrants were defined as Quadrant I: right anterior, Quadrant II: left anterior, Quadrant III: left posterior and Quadrant IV: right posterior. In this study, we defined Quadrant I and IV as right quadrant and Quadrant II and III as left quadrant to determine percentage of time spent between amputated and intact leg. Previous studies using force platform showed that the time spent on the intact side was evidently longer than that spent on the amputated limb (Burke, Roman and Wright, 1978). In this study, the term *loading time percentage* was described as the total time spent on the intact and prosthetic side throughout the 20s assessment period during each altered sensory conditions.

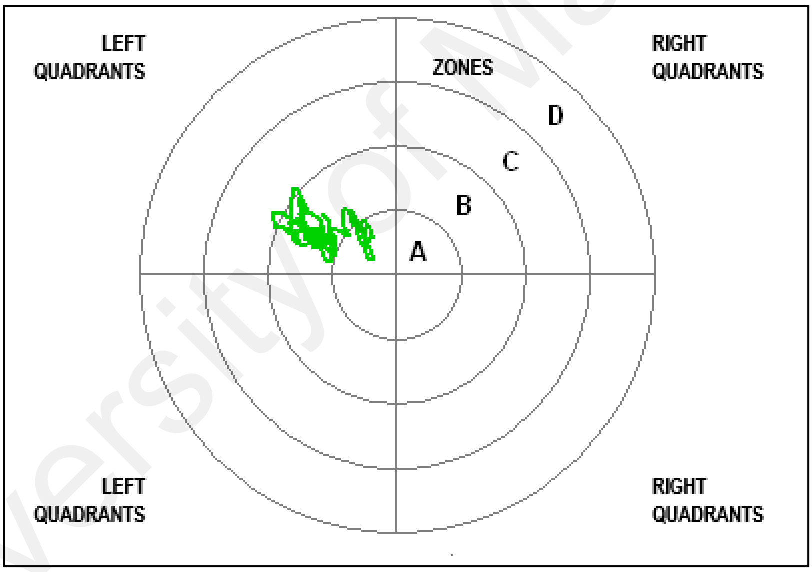


Figure 8.1: Positions of the concentric zones (A, B, C, D) in relatives to right and left quadrants.

Subjects were instructed to place their feet in a standardized position to eliminate between-subject variability during balance testing (Mcllroy and Maki, 1995). The position of the feet was marked and recorded for consistency throughout the test. During the test, subjects were asked to keep their arms alongside the body and to stand as still as possible. All subjects were tested under four altered sensory conditions: (1) firm support surface, eyes opened, head neutral (EO), (2) firm support surface, eyes closed, head neutral (EC), (3) compliant support surface, eyes opened, head neutral (Foam) and (4) firm support surface, eyes opened, head extended (HExt). To simulate a compliant surface, low density polyethylene foam with a circular radius of 220 mm and 25 mm thick was place on the platform (Borg and Laxaback, 2010). Under the head extended condition, the head was tilted backward at each subject's maximum head extension, which allowed them to look at the ceiling (Hu and Woollacott. 1994). The experimenter stood at the side of each subject to monitor the head position and for additional safety. For condition 1 and 3, subjects were asked to focus on a fixed point adjusted at each subject's height, mounted on the wall approximately 1.5m in front of them to stabilize the head. Participants stood on the platform for 20s until three successful trials were obtained for reliable measures (Cachupe *et al*., 2001). Any trial with changes in foot position or balance loss was excluded. Resting period of 30s in a sitting position was allowed between trials and subjects were instructed not to change the position of their feet on the platform. Handrails could only be used to prevent falling if the participants completely lost their balance.

8.2.3 Statistical Analysis

The mean and standard deviations (SD) were calculated for each stability variables. All data were initially screened using Shapiro-Wilk test and showed normal distribution. We performed repeated-measures analysis of variance (ANOVA) to test the significance of differences between sensory conditions for each prosthetic foot for each outcome (OSI, APSI, MLSI and percentage of time in concentric zones). Post-hoc analysis was performed using the Honestly Significant Difference Tukey's test to determine where differences occurred. A paired t-test was used to compare loading time percentage on amputated and intact leg. Level of significance was accepted at $p \leq 0.05$ for all analyses.

The effect size was evaluated to indicate the significance of the results considering the small sample size used in this study. The effect size (ES) was obtained from SPSS results (partial eta squared, η_p^2). According to Cohen (1998), the ES was defined as small (0.01), medium (0.06), and large (0.14). All statistical analyses were performed using SPSS v16.0 (SPSS Inc., Chicago, IL, USA).

8.3 Results

8.3.1 Participants' characteristics

A total of ten male unilateral below-knee amputees with activity level of K2-K3 successfully completed the four weeks assessments. The mean (SD) for age, height and weight of the subjects were 44.8(13.5) years, 170(6) cm, and 77.0(17.9) kg, respectively. At the time of admission, all subjects demonstrated intensive use of the prosthesis based on the average Houghton Scale and low risk of falling as showed by the BBS. Demographic data and prosthesis information are provided in Table 3.2, while detailed findings on the functional assessment can be found in Section 3.8.

8.3.2 Stability indexes during sensory modifications

Figure 8.2 shows the line plot of all measured parameters. Statistically significant difference was found between sensory conditions in SACH foot for OSI (p=0.002), APSI (p=0.036) and MLSI (p=0.008). Similarly for ESAR foot, sensory conditions differed significantly in OSI (p=0.005), APSI (p=0.003) and MLSI (p=0.05). The ES for all analyses was large (ranging from 0.63 to 0.86). The mean value for MLSI was closer to OSI than the APSI. Overall, postural instability was the highest in

EC condition followed by HEXt, Foam and EO. The post-hoc analysis revealed that for SACH and ESAR feet, all stability indexes in EC were significantly higher than EO condition. In addition, SACH demonstrated significant higher instability for all indexes in EC than Foam condition as well as in HExt than EO condition. Meanwhile, only OSI and APSI in HExt condition were significantly higher than Foam condition. ESAR foot showed significantly higher OSI and MLSI scores in EC than Foam, and significantly higher OSI and APSI scores in HExt condition compared to EO. The differences in stability indexes were not significant between EO *vs* Foam and EC *vs* HExt conditions for SACH and ESAR feet. As for the SA foot, no significant difference between conditions was observed.

8.3.3 Percentage of time in concentric zones for each sensory condition

The results of repeated-measures ANOVA revealed significant differences in the time spent in the four concentric zones (Table 8.1). The post-hoc test showed that the percentage of time spent in Zone A (0^0-5^0) was significantly greater than the other three zones ($p<0.01$) for all prosthetic foot types during each sensory condition. In addition, a significantly higher percentage of time was shown in Zone B (6^0-10^0) than Zone C (11^0-15^0) and Zone D (16^0-20^0) for SACH and SA foot, but only evident under the EC condition. Less than 1% of time was spent in Zone C and D in all tests. The effect size for all analyses was large (ranging from 0.9 to 1).

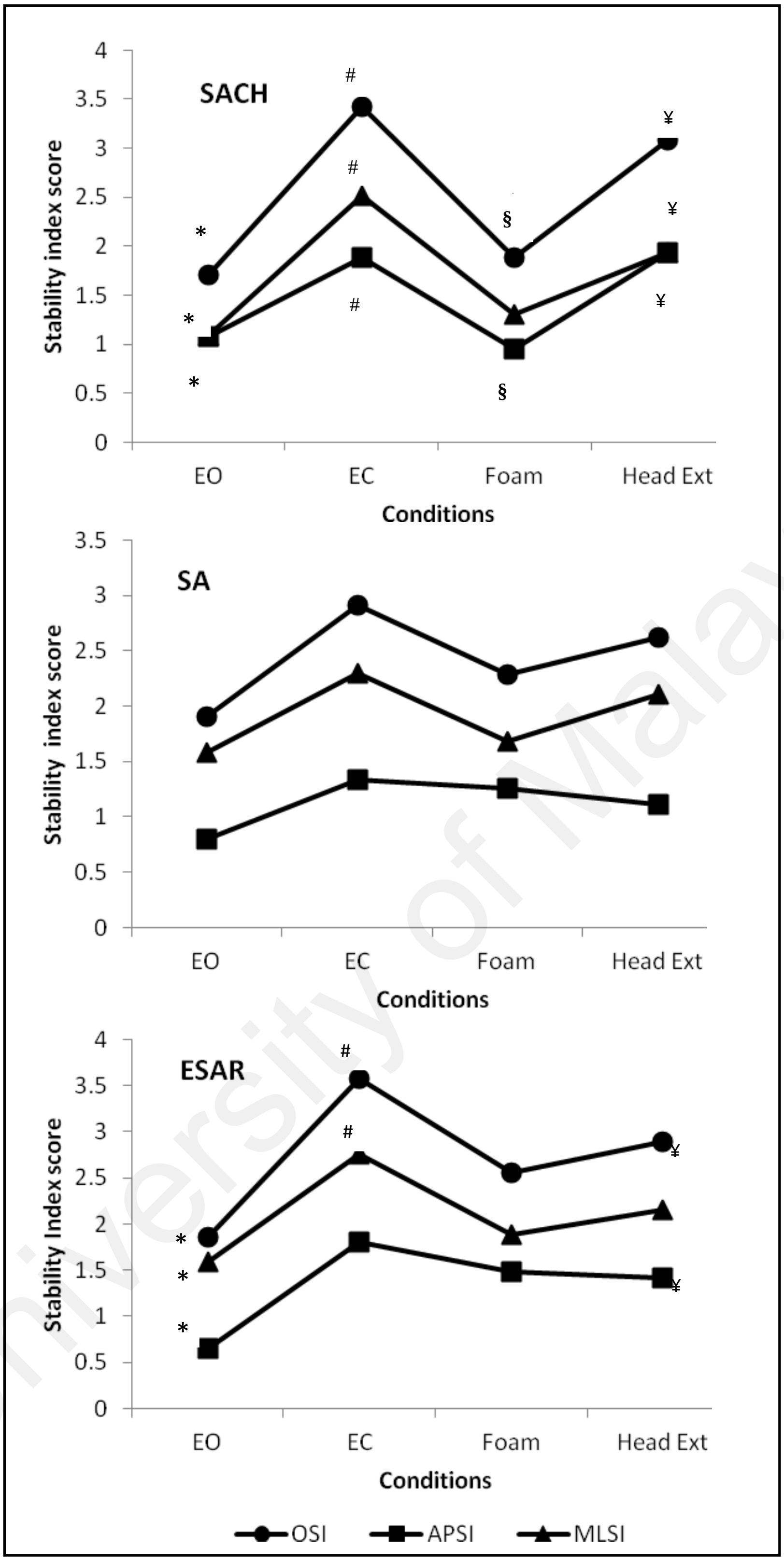


Figure 8.2: Stability indexes (OSI, APSI, MLSI) in SACH, SA and ESAR prosthetic feet during four sensory conditions. Significant differences between two sensory conditions were indicated as *(EO vs EC), ¥(EO vs HExt), #(EC vs Foam) and §(Foam vs HExt).

Table 8.1: Mean (SD) of percentage of time in concentric zones for SACH, SA and ESAR foot during different sensory conditions.

Conditions	**Concentric Zones**											
	SACH Mean(SD)				**SA** Mean(SD)				**ESAR** Mean(SD)			
	A	**B**	**C**	**D**	**A**	**B**	**C**	**D**	**A**	**B**	**C**	**D**
EO	97.8* (5.7)	2.2 (5.7)	0#	0€	89.1* (29.0)	10.9 (29.0)	0#	0€	93.9 * (14.2)	6.1 (14.2)	0#	0 €
EC	83.8* (17.9)	16.1§,Σ (17.6)	1# (0.3)	0€	93.6 * (8.3)	6.4§, Σ (8.3)	0#	0€	82.1* (29.2)	17.5 (28.3)	0.4# (1.0)	0€
Foam	89.8* (31.2)	10.2 (31.2)	0#	0€	89* (31.4)	11 (31.4)	0#	0€	86.3* (25.6)	13.7 (25.6)	0#	0€
HeadExt	92.9* (9.5)	5.8 (8.9)	0.5# (1.6)	0.8€ (2.5)	89* (18.4)	11 (18.4)	0#	0€	91.9* (13.0)	8.1 (13.0)	0#	0€

Note. Significant differences between two concentric zones were indicated as *(A vs B), #(A vs C), €(A vs D), §(B vs C) and Σ(B vs D).

8.3.4 Loading time percentage in left and right quadrants for each sensory condition

The mean, standard deviation and range of values recorded during all condition for each prosthetic foot are presented in Table 8.2. Overall, the percentage of loading time in the intact limb (80 to 94%) was significantly longer than that of amputated limb (20 to 6%) during all sensory conditions for all three prosthetic feet. Similarities were shown in all three prosthetic feet whereby longer loading time on intact limb was most profound during EC and HExt conditions (p<0.001).

Table 8.2: Percentage of loading time over the test period on the amputated and intact leg with SACH, SA and ESAR foot during different sensory conditions.

Conditions	SACH			SA			ESAR		
	Intact	Amp.	*p*-value	Intact	Amp.	*p*-value	Intact	Amp.	*p*-value
EO									
Mean	89.3	10.7	<0.001	83.5	16.5	0.004	85.9	14.1	0.001
SD	10.2	10.2		27.7	27.7		22.8	22.8	
Min	69	0		8	0		0	36	
Max	100	31		100	92		64	100	
EC									
Mean	94.3	5.7	<0.001	90.3	9.7	<0.001	90.4	9.6	<0.001
SD	8.6	8.6		15.8	15.8		19.1	19.1	
Min	80	0		53	0		39	0	
Max	100	20		100	47		100	61	
Foam									
Mean	81.6	18.4	0.005	80.90	19.1	0.008	83.3	16.7	0.003
SD	26.7	26.7		28.8	28.8		25.9	25.9	
Min	0	11		11	0		20	0	
Max	89	100		100	89		100	80	
HeadExt									
Mean	88.8	11.2	<0.001	90.6	9.4	<0.001	91.9	8.1	<0.001
SD	12.9	12.9		16.6	16.6		12.9	12.9	
Min	63	0		50	0		62	0	
Max	100	37		100	50		100	38	

Note. A p-value <0.05 indicates a significant difference between intact and amputated limb.

8.4 Discussion

This study determined the postural steadiness of below-knee amputees by fully utilizing the measurement outputs provided by the BSS. Although previous study has demonstrated the use of stability indexes, time percentage on concentric zones and quadrants in healthy subjects (Arnold and Schmitz, 1998), none has employed the same approach in amputee populations. Amputees were assessed during quiet upright standing to provide a baseline testing before progression into dynamic testing and training. Moreover, quiet standing with prosthesis is considered a vital skill during the early phase of rehabilitation to achieve independent standing posture before returning to their daily life activities (Geurts and Mulder, 1992).

Previous studies reported that amputees had poor balance control when visual input was absence compared to when accurate vision was present (Buckley *et al.,* 2002; Vanicek *et al*., 2002). The result of this current study was in agreement with previous research which demonstrated significant postural instability of amputees during eyes-closed condition, followed by standing with head-extended and standing on foam. The finding that postural stability was similar during conditions where the eyes were opened (EO and Foam conditions) further highlights the importance of visual cues in detecting changes in body orientation with respect to the environment (Horak, 2006; Shumway-Cook and Woollacott, 2000). Nevertheless, the complete loss of cutaneous, muscle, and joint receptors of the residual limb as well as distorted sensory feedback from the intact limb of the amputees caused inaccurate information, which affected the perceptions and awareness of joint movements and positions (Geurts and Mulder, 1992; Horak and Nashner, 1986; Vanicek *et al*., 2009). Therefore, the increase of CoM displacement when amputees were standing on foam surface was expected. In condition where the head was extended, the control of postural stability in below-knee amputees was significantly destabilized due to the tilting of otolith organs exceeding its optimal working range (Hu and Woollacott, 1994).

Our findings that MLSI values are higher than APSI further support previous studies that suggesting dominant control of CoM movements in mediolateral direction during upright standing in amputees (Mayer *et al.*, 2011). This control is known as hip strategy where both intact hip joints are used to stabilize the body CoM to compensate for the lack of ankle movement at the prosthetic joint (Buckley *et al.*, 2002; Horak, 2006). The differences in balance indices between sensory conditions were only significance for SACH and ESAR feet, suggesting habitual adaptation to SA foot for most of the subjects in this study. The insignificant findings for SA foot may also suggest that the subjects utilized the design of single axis mechanical ankle joint that permits movement in the sagittal plane. That is, subjects were able to maintain anterior-posterior and medial-lateral balance by controlling movements at the prosthetic ankle and hip joints. Hence, differences of stability indexes between conditions were not statistically significant for SA foot.

For the percentage of time spent in concentric zones, amputees demonstrated their ability to sustain CoM excursion within the 0^0-5^0 margins which can be considered as the area of stability. This suggests that constant contractions and relaxations of the muscles in intact and amputated limb during double-stance quiet standing are well controlled, that the CoM remains close to its zero centre point in all the tests. In comparison to healthy subjects that spent 85% of time within the 0^0-5^0 zone (Arnold and Schmitz, 1998), amputees spent between 82-98% in the same zone. The differences among the four sensory conditions were more significantly apparent in eyes-closed and head extension conditions, suggesting the possible use of these conditions during rehabilitation trainings.

This study demonstrated the possibilities of using the BSS to determine percentage of loading time on the intact and amputated limb during quiet standing. Previous study on able-bodied showed 45% and 55% of time spent on right and left quadrant (Arnold and Schmitz, 1998). Amputees in our study showed 80 to 94% versus 20 to 6% loading time on intact and amputated limb, respectively. This is consistent with previous study that amputees spent more time and consequently bear more weight on non-affected side than the amputated side (Burke *et al*., 1978; Isakov *et al*., 1992; Nadollek *et al*., 2002). A possible explanation for this is that the amputee's CoM was located closer to their intact limb than their prosthetic limb during normal standing (Clark and Zernicke, 1981). Reduced proprioception on the amputated side, due to loss of foot and leg muscles, was also thought to increase the dependency on the intact limb (Isakov *et al.*, 1992). Consequently, the asymmetrical loading between intact and amputated leg has been associated with secondary physical conditions such as osteoarthritis on the intact limb, osteoporosis on the amputated limb and back pain (Gailey *et al*., 2008).

Moreover, an evidence of visual reliance was showed during eyes-closed condition, where the time spent on amputated side was apparent in all prosthetic foot types. The findings suggest that amputation leads to insufficient control of weight-shifting to maintain an erect posture which caused more instability in medial-lateral direction (Isakov *et al*., 1992). Other possible explanations include the unwillingness of the amputees to initiate movement at the relatively stiff prosthetic ankle due to lack of confidence, deficit in sensory organization and fear of falling (Barnett *et al*., 2012;

Horak and Nashner, 1986; Miller *et al.*, 2001a). These results can be used during rehabilitation to determine the direction of the sway to predict fall direction which significantly increases the chances of a hip fracture. Future research should evaluate postural stability of amputees using larger sample size to achieve more significant differences during challenging condition such as dual tasking activities. In addition, upcoming research should establish the reliability and validity of stability scores derived from BSS in people with lower limb amputation.

8.5 Conclusion

This study showed that postural stability impairment in below-knee amputees worsens when sensory input was obstructed despite passive stability provided by the prosthesis. Additionally, the BSS may provide avenue for clinical assessment of functional postural stability for the purpose of rehabilitation and prosthesis evaluation.

CHAPTER 9

POSTURAL STABILITY STRATEGIES IN TRANSTIBIAL AMPUTEES DURING QUIET STANDING IN ALTERED SENSORY CONDITIONS WEARING THREE TYPES OF PROSTHETIC FEET.

As previously mentioned in Section 2.3, one of the subcomponents of postural stability control is the movement strategies. Individuals with transtibial amputation exhibit altered movement strategies to sustain stability during quiet standing due to reduced proprioception on the amputated limb. The aim of this study is to determine the movement strategies in anterior-posterior and medial-lateral directions in predicting the overall postural stability. In this crossover study, postural stability of ten transtibial amputees was assessed using computed posturography while wearing different prosthetic foot types. Three stability indexes were measured during four modified sensory conditions. From the standard multiple regression analysis, 63% to 99% of the OSI score in all sensory conditions were explained from the MLSI score, while 11% to 56% from the APSI score. The Pearson's r indicated significant strong positive relationship between OSI and MLSI ($r = 0.82$ to 0.99, $p \leq .001$) during all sensory conditions. The APSI score was significantly lower than OSI during eyes-closed and head extended conditions for all prosthetic feet ($p < .05$). Adjustments in postural stability strategies in transtibial amputees mostly occurred in medial-lateral direction regardless of prosthetic feet types and altered sensory conditions.

9.1 Introduction

The maintenance of postural stability involves the integration of sensory systems (visual, proprioceptive and vestibular), central nervous systems and musculoskeletal systems (Winter, 1995). The available input from the sensory systems is evaluated by the central nervous systems, and the musculoskeletal systems will execute appropriate movement strategies to maintain postural stability (Yim-Chiplis and Talbot, 2000). Healthy individuals have been shown to heavily rely on somatosensory (70%), vestibular (20%) and vision (10%) when standing on firm surface in a well-lit condition (Horak, 2006). However, the loss of biological ankle joint and a considerable amount of muscles in the lower leg as a result of amputation causes distortion in proprioception input which adversely reduces postural stability (Geurts and Mulder, 1992). In addition, passive stability provided by the prosthetic foot has been suggested to reduce the amount of body sway in lower limb amputees due to the relatively stiff ankle joint (Buckley *et al*., 2002; Curtze *et al*., 2012). Nevertheless, people with lower-limb amputation have been reported to exhibit higher risk of falling compared with able-bodied due to the balance instability (Miller, Speechley and Deathe, 2001b).

In order to compensate for the proprioceptive deficits, amputees therefore develop sensory reorganization to attain postural stability by increasing their reliance on visual cues (Vanicek *et al*., 2009). Researchers showed that standing with eyes-closed (Barnett *et al*., 2012; Vrieling *et al*., 2008) or standing on compliant surface (Kozakova *et al*., 2009) contributed to a decrease in standing stability for people with lower limb amputation. Moreover, manipulating more than one sensory input will further deteriorate standing stability in amputees (Barnett *et al*., 2012). Although the vestibular system has been suggested to resolve inter-sensory conflict (Shumway-Cook and Horak, 1986), the effect of vestibular disruption in amputees has yet to be conducted.

The coordination of movement strategies in maintaining postural equilibrium is selected based on the characteristics of perturbations, task goal and previous experience (Horak, 2006). As suggested by Winter (1995), three main movement strategies are generally utilized to return the center of mass (CoM) to its base of support (BoS). The ankle strategy has been known as sufficient to maintain postural stability when the perturbation is small; the hip strategy is utilized during large and quick perturbation; and stepping strategy is used when the BoS changes (Horak, 2006). During quiet standing when the feet are side-by-side, able-bodied individuals commonly utilize ankle movement strategy to control the excursion of center of mass CoM in the anterior-posterior direction (Winter, 1995). However for amputees, consensus on which strategy is used to maintain postural stability remains contradictory. Several studies reported that in transtibial amputees, the ankle strategy which involves the active ankle function of the sound limb and the passive ankle function of the prosthetic foot, is effective in controlling postural stability in anterior-posterior direction (Curtze *et al*., 2012; Vanicek *et al*., 2009). Conversely, other study reported that postural stability in transtibial amputees are dominantly controlled using the hip strategy in medial-lateral direction (Mayer *et al*., 2011).

For amputees to return to their daily life activities, the ability to reorganize postural stability based on available sensory information and accomplishing appropriate movement strategies is important in achieving independent upright posture (Geurts and Mulder, 1992). Hence, prosthetic foot is prescribed to transtibial amputee to facilitate a safe standing balance (Nederhand *et al*., 2012) which has been known as a basic and vital skill that must be re-learned by amputees (Geurts and Mulder, 1992). Interestingly, previous studies (Buckley *et al*., 2002; Curtze *et al*., 2012; Vanicek *et al*., 2009; Vrieling *et al*., 2008) suggested that variations in prosthetic feet used may influence the amputees' response in maintaining postural stability. Thus, the purpose of the present study was to quantify the movement strategies in anterior-posterior and medial-lateral directions in predicting the overall postural stability wearing three types of prosthetic feet when sensory inputs were altered. It is hypothesized that both movement in anterior-posterior and medial-lateral directions are equally related to overall postural stability during quiet standing with sensory alteration while wearing different prosthetic feet.

9.2 Methodology

9.2.1 Participants

Subjects were approached at the rehabilitation clinics in the university's medical centre. Inclusion criteria were age over 20 years, male unilateral transtibial amputees with at least one year experience in their current prostheses and the ability to walk without the use of any assistive device. A detailed description of inclusion and exclusion criteria can be found in Table 3.1, Section 3.4. This study was approved by the Institutional Ethics Committee Board. All subjects were subjectively evaluated for their perception of prosthetic use with the Houghton Scale (Devlin *et al*., 2004) while the functional balance status was ascertained using the Berg balance scale (Wong *et al*., 2013). More information regarding these questionnaires can be found in Section 3.8. Participants who failed to maintain equilibrium during the test were excluded from the study.

9.2.2 Prosthetic feet

Three types of prosthetic feet were used in this study for each condition: SACH foot (Enjoylife, Fujian, China), SA foot (Enjoylife, Fujian, China) and ESAR Talux® foot (Ossur, Reykjavik, Iceland). The SACH was a non-articulating foot with wooden keel and rubberized cushioned heel. The SA foot allows plantarflexion-dorsiflexion motion at the single hinge joint. The Talux® is a type of Flex-Foot with J-shaped multiaxial ankle and heel-to-toe carbon fiber footplate designs. The amputees' current prosthetic sockets and components were optimally aligned using a laser liner before the assessment by the same registered prosthetist. Each test foot was attached to the patient's existing prosthesis using their own socket and suspension. Subjects wore socks to disclose the structure of the prosthetic foot.

9.2.3. Procedures

Prior to the tests, all participants completed one familiarization trial for each condition to negate the potential effects of learning and fatigue (Hinman, 2000). Amputees attended three consecutive sessions on separate days at one week accommodation intervals to complete the assessment (English *et al*., 1995). Each amputee tested one prosthetic foot for each session. The test was counterbalance across amputees to negate order effects. After the assessments were completed for all prosthetic feet, amputees attended the final visit to change the test foot with their original foot. Balance indexes data for conditions (1) firm support surface, eyes opened, head neutral (EO), (2) firm support surface, eyes closed, head neutral (EC) and (3) compliant support surface, eyes opened, head neutral (Foam) were obtained from previous published studies (Arifin *et al*., 2014b; Arifin *et al*., 2014c). In this study, the same subjects were asked to perform condition (4) firm support surface, eyes opened, head extended (HeadExt). To simulate vestibular disruption, the head was tilted backward at each subject's maximum head extension, which allowed them to look at the ceiling (Hu and Woollacott, 1994). The experimenter stood at the side of each subject to monitor the head position throughout the assessments. Illustrations of these conditions can be referred to Section 3.10.

Postural stability of the amputees was evaluated with the BSS (Biodex® Medical System, Shirley, NY, USA) which measures the deviation of center of mass during static condition and degree of platform tilt in frontal and sagittal axes during dynamic conditions (Arnold and Schmitz, 1998). Based from the amount of deviation or tilt from the centre of the platform (zero point), the system computes the overall stability index (OSI), anterior/ posterior stability index (APSI), and medial/ lateral stability index (MLSI). A greater amount of body movement is associated with an unstable posture which resulted in higher stability index. A lower index indicated little movement and is associated with more stable posture. The platform was integrated with Biodex® software (Version 3.1 Biodex® Medical Systems) which enables the device to calculate the stability indexes. The software sampled the deviation from level at rate of 20Hz which the signals were converted to OSI, MLSI, and APSI scores using formula expressed in Section 3.7 as Eq. (1), Eq. (2) and Eq. (3), respectively.

Participants were instructed to step on the BSS platform and the feet were positioned 17cm between the heel centres and 14˚ between the long axes of the feet to eliminate between-subject variability during balance testing (Mcllroy and Maki, 1995). The position of the feet was marked and recorded to ensure consistency in all trials. During the test, the participants were asked to keep their arms alongside the body.

Participants stood on the platform for 20s under all conditions for three successful trials. Any trial with changes in foot position or balance loss was excluded. A standard instruction of "stand as still as possible" was given to all participants to ensure consistency (Zok *et al.*, 2008). Participants were allowed to rest for 30s in a sitting position between trials and instructed not to change the position of their feet on the platform. Handrails could only be used to prevent falling if the participants totally lost their balance. An assistant stood at the back of the subject for additional safety.

9.2.4 Statistical Analysis

Means and standard deviations (SD) were calculated for each stability variables. All of the demographic and balance assessment data were initially screened using Shapiro-Wilk test and showed normal distribution. The movement strategies in anterior-posterior and medial-lateral directions in predicting the overall postural stability was determined by means of the standard multiple regression analysis. This analysis was performed to determine the relative contribution of MLSI and APSI scores to the OSI score; as well as the statistical significance of the model and individual independent variables.

A sample size of ten events per independent variable in the regression model was considered adequate for the accuracy and significance of the estimated coefficients (Peduzzi *et al.*, 1995). The MLSI and APSI were treated as the independent (predictors) variables, while the OSI as dependent (outcome) variable. The Beta value was used to determine which of the independent variables contributed to the prediction of the dependent variable. Due to the small sample size in this study, the adjusted R^2 was used to explain the variance in the OSI explained by the model. The squared semi-partial correlations (sr^2) explained the relationship between each predictor and the outcome variable (Pallant, 2011).

The Pearson's product-moment correlation (Pearson's r) obtained from the multiple regression analysis was used to indicate the relationships between OSI and APSI as well as between OSI and MLSI in each condition. Classification of r was used to describe very weak relationships when r=0.0 to 0.2, weak when r = 0.20 to 0.4, moderate when r =0.4 to 0.7, strong when r = 0.7 to 0.9 and very strong when r =0.9 to 1.0 (Rowntree, 1991). Additionally, a one-way analysis of variance (ANOVA) was performed to test differences between stability indexes during each sensory condition. Post-hoc analysis was performed using the Honestly Significant Difference Tukey's test to determine where differences occurred. Significance was accepted at $p \leq 0.05$ for all analyses. The effect size (ES) was also evaluated to indicate the significance of the results because of the small sample size used in this study. The ES was determined based on partial eta squared (η_p^2) and defined as small (0.01), medium (0.06), and large (0.14) effects (Laken, 2013). All statistical analysis was performed using SPSS v16.0 (SPSS Inc., Chicago, IL, USA).

9.3 Results

9.3.1 Subjects' characteristics

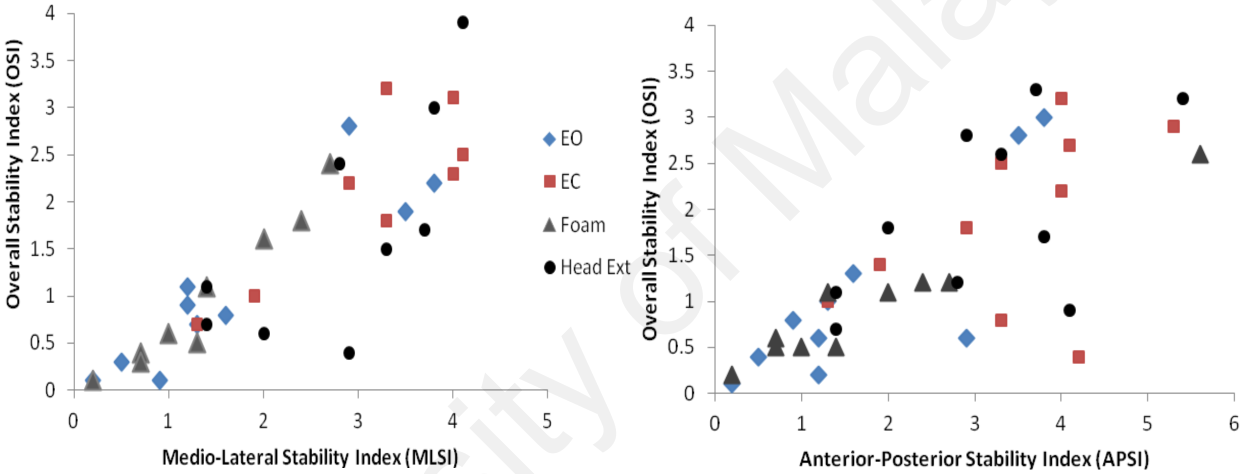
Ten male below-knee amputee subjects gave their informed consent to participate in this study. The mean ± SD for age, height and weight of the subjects were 44.8 ± 13.5 years, 170 ± 6 cm, and 77.0 ± 17.9 kg, respectively. All subjects demonstrated intensive use of the prosthesis based on the average Houghton Scale (10.5

± 0.9) and low risk of falling as showed by the Berg balance scale (52.9 ± 4.9). Demographic data and prosthesis information are given in Table 3.2, Section 3.5.

9.3.2 Movement strategies in predicting the overall postural stability.

Figure 9.1 illustrates the scatter plot of the distribution of OSI, APSI and MLSI for SACH, SA and ESAR foot.

(a) SACH foot



(b) SA foot

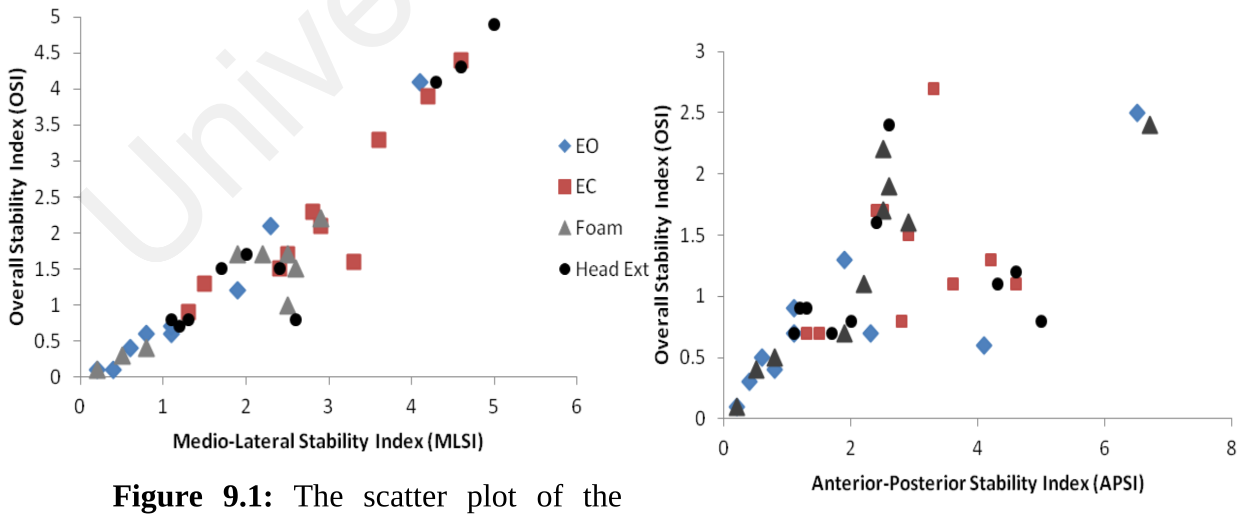


Figure 9.1: The scatter plot of the distribution of Overall Stability Index (OSI), Anterior-Posterior Stability Index (APSI) and Media-Lateral Stability Index (MLSI) for (a) SACH foot, (b) SA foot and (c) ESAR foot.

(c) ESAR foot

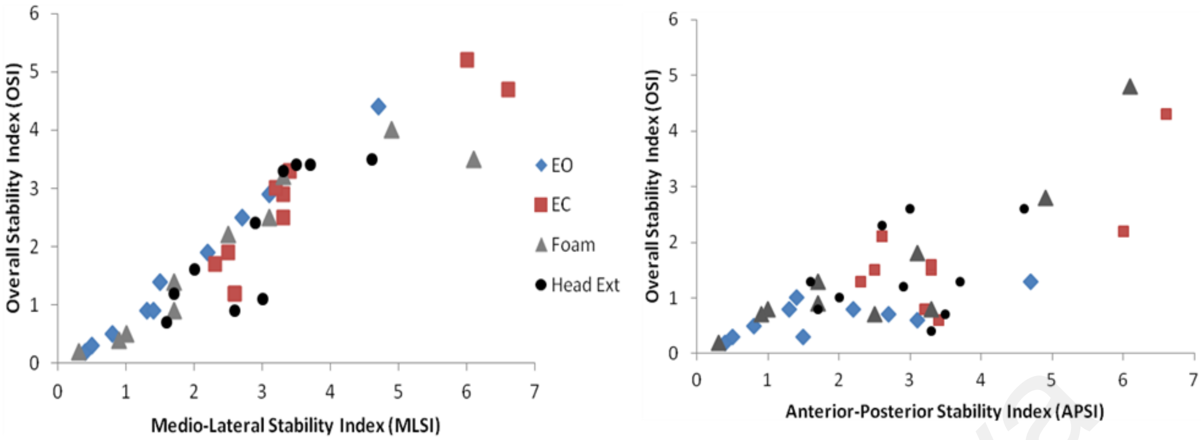


Figure 9.1, continued.

The Pearson's r indicated significant strong to very strong positive relationship between OSI and MLSI (r = 0.82 to 0.99, p ≤ .001) during all sensory conditions for all prosthetic feet (Table 9.1). However, significant moderate to very strong positive relationship (r= 0.58 to 0.97, p<.05) between OSI and APSI were shown in all conditions except during eyes closed for SACH and SA, and head extended for SA and ESAR.

Table 9.1: Correlations (Pearson's r) between the variables in the analysis (N=10).

Correlations between	SACH r	SACH p-value	SA r	SA p-value	ESAR r	ESAR p-value
EO						
OSI and APSI	0.846	.001*	0.828	.002*	0.735	.008*
OSI and MLSI	0.899	<.001*	0.994	<.001*	0.996	<.001*
EC						
OSI and APSI	0.489	.076	0.268	.227	0.698	.012*
OSI and MLSI	0.876	<.001*	0.919	<.001*	0.922	<.001*
Foam						
OSI and APSI	0.968	<.001*	0.831	.001*	0.896	<.001*
OSI and MLSI	0.988	<.001*	0.971	<.001*	0.936	<.001*
HeadExt						
OSI and APSI	0.576	.041*	0.150	.340	0.323	.182
OSI and MLSI	0.821	.002*	0.954	<.001*	0.831	.001*

Note. *p ≤ .05, indicate significant relationship between every pair of variables.

According to Beta values from the regression analysis, 61% to 99% of the OSI score in all sensory conditions could be contributed from the MLSI score, while 11% to 56% was explained by the APSI score (Table 9.2). Specifically the MLSI contribution was shown highest during EC condition (86%) for SACH foot as well as during HeadExt for SA and ESAR feet (99% and 97%, respectively).

The ANOVA analysis for the stability indexes produced a significant difference among OSI, APSI and MLSI indexes during EC (SACH: $F_{2,27}$ =4.84, p=.016; SA: $F_{2,27}$ =6.60, p=.005; ESAR: $F_{2,27}$ =4.62, p=.019) and HeadExt (SACH: $F_{2,27}$ =3.00, p=.05; SA: $F_{2,27}$ =3.40, p=.048; ESAR: $F_{2,27}$ =5.58, p=.009) conditions. The post-hoc test revealed that the APSI score was significantly smaller than OSI with all prosthetic feet during EC and HeadExt conditions. The MLSI was significantly lower than OSI only in HeadExt condition for SACH foot. Also, MLSI exhibited significantly higher score than APSI in EC condition for SA foot (Table 9.3).

Table 9.2: The summary of standard multiple regression analysis for APSI and MLSI in predicting the OSI during sensory alterations for all prosthetic feet (N=10).

Condition/ Variables	**SACH**					**SA**					**ESAR**				
	Model R^2	***Model p-value***	**Beta**	**sr^2**	***p-value***	**Model R^2**	***Model p-value***	**Beta**	**sr^2**	***p-value***	**Model R^2**	***Model p-value***	**Beta**	**sr^2**	*p-value*
EO	0.994	<.001				.999	<.001				0.999	<.001			
APSI			0.512	0.187	<.001			0.167	0.012	<.001			0.113	0.007	<.001
MLSI			0.625	0.280	<.001			0.866	0.314	<.001			0.920	0.460	<.001
EC	0.980	<.001				.986	<.001				0.989	<.001			
APSI			0.466	0.216	<.001			0.381	0.144	<.001			0.407	0.142	<.001
MLSI			0.864	0.744	<.001			0.964	0.918	<.001			0.767	0.504	<.001
Foam	0.944	<.001				.999	<.001				0.994	<.001			
APSI			0.370	0.020	.001			0.323	0.057	<.001			0.476	0.118	<.001
MLSI			0.645	0.059	<.001			0.753	0.308	<.001			0.607	0.192	<.001
HeadExt	0.968	<.001				.997	<.001				0.977	<.001			
APSI			0.548	0.300	<.001			0.301	0.088	<.001			0.556	0.291	<.001
MLSI			0.802	0.643	<.001			0.999	0.976	<.001			0.965	0.878	<.001

Note. The dependent variable was OSI. Beta: standardized coefficient and sr^2: squared semi-partial correlations.

Table 9.3: The mean (standard deviation) of stability indexes score for three types of prosthetic foot during four sensory conditions.

Sensory conditions	SACH Mean(SD)			SA Mean(SD)			ESAR Mean(SD)		
	OSI	APSI	MLSI	OSI	APSI	MLSI	OSI	APSI	MLSI
EO	1.71 (1.25)	1.08 (1.02)	1.09 (0.92)	1.90 (1.99)	0.80 (0.68)	1.58 (1.94)	1.86 (1.34)	0.65 (0.34)	1.59 (1.35)
EC	3.43 (1.17)	1.89* (0.96)	2.52 (1.19)	2.91 (1.06)	1.33*£ (0.61)	2.30 (1.18)	3.58 (1.49)	1.80* (1.03)	2.76 (1.37)
Foam	1.88 (1.55)	0.95 (0.68)	1.31 (1.29)	2.28 (1.82)	1.26 (0.81)	1.68 (1.74)	2.55 (1.84)	1.48 (1.38)	1.88 (1.39)
Head Ext	3.08 (1.26)	1.93* (0.98)	1.94† (1.35)	2.62 (1.48)	1.11* (0.53)	2.11 (1.65)	2.89 (0.95)	1.42* (0.80)	2.15 (1.17)

Note. *p ≤ .05, indicate significant different between OSI and APSI
†p ≤ .05, indicate significant different between OSI and MLSI
£p ≤ .05, indicate significant different between APSI and MLSI

9.4 Discussion

This study investigated the hypothesis that movement strategies in anterior-posterior and medial-lateral directions presented by the APSI and MLSI indexes equally contribute in predicting the overall postural stability during sensory inputs alterations. This study is the first to assess the relationship of stability score in anterior-posterior and medial-lateral direction to the overall stability score by using computed posturography in amputee population. Previous study on healthy adults revealed that the APSI score was accounted for 95% of the variance in the OSI score (Arnold and Schmitz, 1998). Conversely, findings from this current study demonstrated that MLSI score (61% to 99%) significantly contributed to the prediction of the OSI than that of

APSI score (11% to 56%). Thus, the hypothesis was rejected. The multiple regression analysis indicated that the MLSI was highly related with OSI score in all sensory conditions and foot types.

The results of this study supported previous study which demonstrated that most adjustments strategies in amputees occurred in medial-lateral direction, indicated by the greater deviation of CoM in the frontal plane (Mayer *et al*., 2011). Lower limb amputation leads to insufficient control of weight-shifting to maintain an erect posture which caused instability in medial-lateral direction as a result of compensation strategy to the impairment in controlling balance in the anterior-posterior direction (Aruin *et al*., 1997; Hermodsson *et al*., 1994). Therefore, the amputees utilized the hip strategy by activating hip muscle contraction as opposed to ankle strategy used in able-bodied persons (Horak, 2006). In addition, increasing the use of intact hip musculature at the amputated limb was suggested as a strategy to increase somatosensory inputs in regulating the movement of CoM (Vrieling *et al*., 2008). Other possible explanations to this finding include the unwillingness of the amputees to initiate movement at the relatively stiff prosthetic ankle in the sagittal plane due to lack of confidence, deficit in sensory organization and fear of falling (Barnett *et al*., 2012; Horak, 2006; Miller *et al*., 2001b; Vanicek *et al*., 2009). Thus, the MLSI could potentially become the predictor factor of postural stability in amputees during quiet standing. Although the APSI contributes less than the MLSI, instabilities in anterior-posterior direction may be important for specific amputee. Therefore, the MLSI and APSI scores should be interpreted separately rather than using only the OSI for clinical diagnosis.

In addition to the regression analysis, the ANOVA results suggested that the APSI was significantly lower than the OSI, suggesting small contribution to the overall stability index score, when sensory input from visual and vestibular system was altered. In these two conditions, the OSI and MLSI scores were almost identical such that no significant different was showed between the scores. This study showed that the postural stability of amputees was most affected during eyes-closed and head-extended conditions. This finding demonstrated that amputees were heavily dependent upon visual information to detect changes in body orientation with respect to the environment, as reported previously (Isakov *et al*., 1992; Massion and Woollacott, 2004b; Vanicek *et al*., 2009). Moreover, the control of postural stability in transtibial amputees was significantly destabilized when the head is extended compared to neutral head position. Previous studies which manipulated the vestibular system by head tilting in elderly and healthy adults reported a decreased in postural stability. This decrease has been suggested as a result of tilting the otolith organs exceeding its optimal working range (Mientjes and Frank, 1999; Paloski *et al*., 2006). Furthermore, the complete loss of cutaneous, muscle, and joint receptors of the residual limb as well as distorted sensory feedback from the intact limb of the amputees were often linked to the deterioration in postural stability (Geurts and Mulder, 1992; Vanicek *et al*., 2009).

The findings from this study is in agreement with previous study which reported increased CoM displacement when amputees were standing on a compliant surface (Kozakova *et al*., 2009). The compliant support surface has been suggested to reduce the accuracy of information on the perceptions and awareness of joint movements and positions (passive and active) (MacLellan and Patla, 2006; Newton, 1982). Overall, it is reasonable to suggest that postural stability of below-knee amputees is compromised even when one sensory modality is altered during quiet standing. Thus, it is rational to suggest that specific rehabilitation trainings should be provided to the amputees to enhance the skills in sensory inputs reweighting and executing appropriate movement strategies in maintaining standing stability. Moreover, our study demonstrated that the BSS may be utilized during trainings and assessments of balance in person with lower limb amputation due to its objective outcomes.

Limitations in our study include the small sample size due to the difficulty in recruiting amputees to involve in a long-term study, the mixed cause of amputation and less challenging tasks. Hence, caution should be exercised when generalizing our results to other amputees with different levels of amputation. In addition, the use of 'Enter" method for the standard multiple regression analysis only assessed the stability indexes without controlling for other variables (such as age, weight, height). However, no significant differences were observed among the amputees in terms of demographic data, demonstrating the appropriateness of using the standard multiple regression analysis. All subjects were skilled and experienced amputees, hence, the results of this study may not be generalized to amputees who are still in postoperative phase.

9.5 Conclusion

Adjustments strategies in amputees mostly occurred in medial-lateral direction regardless of prosthetic feet types. In addition, this study showed that the postural stability in transtibial amputees deteriorate under the manipulation of different sensory information. Therefore, it is crucial for the amputees to be able to maintain their postural stability by depending on reliable sensory information and selecting appropriate movement strategies according to changes in the environment.

CHAPTER 10

CONCLUSIONS AND FUTURE RECOMMENDATIONS

10.1 Conclusions

The consequences of having a below-knee amputation on a person's ability to maintain an upright postural stability have been well-reported biomechanically (Nederhand *et al*., 2012; Barnett *et al*., 2012; Hlavackova *et al*., 2011) and psychologically (Miller *et al*., 2002; Miller *et al*., 2003) in previous literatures. However, the current study is the first to systematically evaluate the influence of prosthetic feet types and sensory modifications in controlling postural stability in below-knee amputees. Specifically, to the author's best knowledge, this is the first study to quantify the biomechanics of postural stability adaptations in an amputee population using the Biodex Stability System (BSS). Presently, the only published literatures on this matter have initiated from this thesis.

The overall aim of the current thesis was to investigate the postural stability response that occurred within unilateral below-knee amputees wearing different prosthetic foot types during primary sensory alterations during upright standing. As stated in Section 1.6, there are six objectives that have been recognised to achieve this aim. Accordingly, the following conclusions are drawn for each specific objective.

I. **The stability indexes produced from BSS are reliable when scored by a single rater between seven days of interval during static and dynamic unilateral stance.**

The results for this study showed that the application of computerised posturography should be used in quantifying postural balance in assessing effectiveness of a specific clinical or research intervention for repeated measurement design. Although this thesis only involved bilateral stance assessment for the safety factor of the amputees, this finding serves as evidence that the author of this thesis (who is also the rater) is capable of producing reliable output when operating the device.

II. The maintenance of postural stability during upright standing in below-knee amputees was not affected by the prosthetic foot types but was reduced when the visual cues were absent.

The current study demonstrated that loss of vision, but not prosthetic foot types, significantly impaired the maintenance of overall, anterior-posterior and medial-lateral postural stability in below-knee amputees. Although there was a trend of better overall stability with SACH foot during eyes-opened and SA foot during eyes closed, the differences between feet were not significant. However, significant differences between the prosthetic foot types are revealed from the ABC scores, which suggested that the amputees were able to perceive disparities between the passive stability offered by the ankle mechanisms during the subjective assessment. The findings in this study are important as they highlight the importance of incorporating balance practice with altered visual information to avoid amputees' over-dependence on this source of information. Thus, amputees will be encouraged to utilise other sensory information from somatosensory and vestibular system.

III. The overall stability of below-knee amputees was affected by the prosthetic foot design particularly when subjects were standing on a compliant surface. Postural stability performance in anterior-posterior and medial-lateral between persons with below-knee amputation and able-bodied individuals can be distinguished only when standing on compliant surface.

Standing on a compliant surface while wearing ESAR foot was shown to significantly reduce the overall stability compared to SACH foot. This illustrates that clinicians should consider the types of articulation at the ankle joint when prescribing prosthetic foot to amputees who ambulate mostly on soft surfaces. When postural stability outcomes were compared between able-bodied individuals and each prosthetic foot group, it was found that the difference between able-bodied persons and those with below-knee amputation was apparent only in compliant surface. The results from this study concur with the notions that standing on a compliant surface causes greater postural sway due to the reduced accuracy of information needed to detect body orientation. Findings depicted from this study suggest that practice of balance whilst on surfaces made from materials of varying densities may be beneficial to enhance their ability to safely stand on various support surface conditions during daily life activities.

IV. **Standing with head extension reduced the postural stability control in persons with below-knee amputation. Postural stability between persons with below-knee amputation and able-bodied individuals could be distinguished particularly in medial-lateral direction.**

The overall, anterior-posterior and medial-lateral stability indexes in individuals with below-knee amputation were significantly affected by sensory conditions, but not by the prosthetic foot types. Specifically in below-knee amputees, overall and anterior-posterior control of postural stability control was most challenged when either visual or vestibular sensory was modified. From the computerised posturography assessment, amputees were reported to have significantly reduced postural stability than the able-bodied group mostly in medial-lateral direction. This study suggests that head extension, which represents vestibular system disruption, increases the difficulty to maintain postural stability in persons with below-knee amputation. Hence, it is reasonable to suggest that rehabilitation program should incorporate head extension task as one of the modalities to improve the ability to maintain postural stability during reaching activities beyond eye level.

V. The characteristics of postural stability in below-knee amputees under various sensory manipulations can be clinically assessed by utilising the outcomes produced by the Biodex® Stability System (BSS).

This study demonstrates that computerised posturography assessment using the BSS device can be useful for an evidence-based clinical practice. In particular, differences in postural stability index between sensory conditions can be distinguished in SACH and ESAR foot. The BSS also determined that the amputees successfully maintained their upright postural stability within the safe area of stability during all sensory modifications and prosthetic feet types. From the BSS outcome, below-knee amputees in this study exhibited the lowest postural stability during eyes-closed condition followed by head-extended, standing on foam and eyes-opened conditions. Moreover, amputees were shown to have significant percentage of loading time on the intact limb than the amputated limb especially during eyes-closed condition and head-extended condition. Thus, the use of the intact limb may be hypothesised as a vital adaptation for a successful postural control. Nevertheless, the tendency to heavily rely on the intact limb may suggest for training which can improve the function of the amputated limb for a better overall stability control. Since standing with eyes-closed was reported to be the most challenging task, it can be proposed that the amputees may have relied heavily on the accurate visual information over the somatosensory or vestibular information to maintain postural stability. Hence, it is recognisable that rehabilitation training that can increase the amputee's ability to utilise the somatosensory or vestibular input may aid the progression of maintaining postural stability.

VI. Adjustments in postural stability strategies in below-knee amputees mostly occurred in medial-lateral direction with all prosthetic feet types during altered sensory conditions.

Regardless of types of prosthetic foot or sensory conditions, below-knee amputees exhibited dominant control in frontal plane in maintaining upright standing stability. From the standard multiple regression analysis, the overall postural stability in all sensory conditions was attributed to the stability in medial-lateral direction than in anterior-posterior direction. Particularly, contribution from medial-lateral stability was prominent during eyes-closed condition for SACH foot and during head extended condition for SA and

ESAR foot. Due to the high instability in medial-lateral direction as reported in these findings, it is reasonable to suggest the utilisation of MLSI index as an indicator of falling in below-knee amputee. The results from this study highlights the importance of specific rehabilitation trainings in providing amputees with the skills in sensory inputs reweighting and executing appropriate movement strategies in maintaining standing stability.

In regards to the outcome measures, the current study adds to our understanding of how Activities-specific Balance Confidence instrument can be used to reveal the differences in perceived balance confidence between articulated and non-articulated prosthetic feet during dynamic activities such as walking, stairs and escalator negotiations. Thus, it is strongly recommended to incorporate this instrument during clinical evaluations of amputee rehabilitation as it provides quick, reliable and easy assessment. Additionally, balance capacity of amputees should be evaluated using the functional performance test, such as the Berg balance test, prior to the planning of rehabilitation program. The results from outcome measures, coupled with findings from objective assessment, provide valuable information to the clinical team in planning rehabilitation goal and prosthetic management for the amputees.

Overall, this thesis contributes an important addition to the body of knowledge by focusing on one of the key research areas in amputee rehabilitation: postural stability. The current thesis provides further insight into the influence of prosthetic feet types and sensory modification to the control of postural stability that occurs in below-knee amputees. This includes the assessment of postural stability using computed posturography and outcome measures instruments. The systematic approach developed in this study helps to identify that the sensory information, but not prosthetic feet types, plays a vital role in the maintenance of postural stability during upright standing. In addition, the knowledge provided by the current thesis can enhance our understanding of the feasibility of Biodex stability system to be employed as an objective measure of postural stability assessment and training depending on the rehabilitation goal. As such, the Biodex system can be useful for the prosthetist to optimally adjust the alignment by checking the position of the CoM from the Biodex display. To conclude, findings from the current thesis have pertinent implications in encouraging clinicians to include evidence-based practice during decision making in rehabilitation planning and for the justification of prosthetic prescription for below-knee amputees.

10.2 Recommendations for future research

Forthcoming research directions are recommended for greater understanding of how below-knee amputees regulate their postural stability when wearing different prosthetic feet in altered sensory conditions. The current study investigated postural stability control during a static upright standing condition. Although static upright standing has been known as a fundamental task in achieving independent living, amputees faced with more challenging task during their daily activities. Therefore, future study examining amputees during dynamic activities, such as walking with different speeds, stairs and ramp negotiations, may elicit the influence of different prosthetic feet types to the control of postural stability. Similarly, postural stability assessment during unexpected and voluntarily-initiated perturbation or during dual-activities should be included in the experimental protocol to enhance our understanding on how amputees respond to these challenging situations.

Due to the different comorbidities between vascular-related and traumatic below-knee amputees which may affect the homogeneity of the amputees, future research should evaluate the amputees separately according to their cause of amputation. This approach aids in improving the understanding of postural stability control as a result from compromised peripheral vascular condition. As the musculatures of intact and amputated limb play such a vital role in regulating the movement of the body, future research would also benefit from undertaking the electromyogram analysis to explicitly identify the activation of related muscles contributing to the control of postural stability during upright standing in various sensory and prosthesis conditions. The ankle joint is known to generate torque in response to the external perturbation imposed on the CoM. It is acknowledged in this current study that the generated ankle torque was not measured during the assessment with different prosthetic feet and sensory conditions. Therefore, future studies should measure the contribution from the intact and prosthetic ankle joints in generating the necessary ankle torque to control postural stability during activities of daily living. This would provide a valuable insight into the specific adaptation that may occur due to the amputation.

Equally important, future research may explore the relationship between the stability indexes and prosthetic ankle stiffness to further clarify whether foot stiffness influences the enhancement of postural stability mechanism in below-knee amputees. In addition, greater interest for future study is to expand the application of this research to the above-knee amputees to understand the postural stability reorganisation with the inclusion of artificial knee joint to the prosthesis. As evidenced by previous studies, the one-week accommodation period for each prosthetic foot given to below-knee amputees in this study was considered sufficient to reveal functionality differences between the feet. Nevertheless, prospective research should provide longer acclimatization period which may produce different results that may be more meaningful to reflect the longer time use of the prosthesis.

In terms of improving rehabilitation training program, future research should also investigate the utilisation of Biodex stability system to monitor the progress of postural stability performance when amputee first prescribed with the most basic prosthetic foot to a more flexible foot according to their individual functional needs. Another important aspect that should be considered in future research is to increase the numbers of amputee participant base from sample size calculation. Having more participants may improve the statistical power and consequently produce more significant findings between the prosthetic interventions. Furthermore, findings obtained from a larger sample size may be generalised as a representative of the overall population of below-knee amputees.

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Appendix A: List of Peer-reviewed ISI Publications

1. **Arifin, N**., Abu Osman, N.A. & Wan Abas, W.A.B. (2014). Intrarater Test-Retest Reliability of Static and Dynamic Stability Indexes Measurement Using the Biodex Balance System During Unilateral Stance. *Journal of Applied Biomechanics*, 30(2), 300-304.

2. **Arifin, N**., Abu Osman, N. A., Ali, S., Abas, W. A. W. 2014. The effects of prosthetic foot type and visual alteration on postural steadiness in below-knee amputees. *Biomedical Engineering Online*, 13:23, 1-10.

3. **Arifin, N**., Abu Osman, NA., Ali, S., Gholizadeh, H. & Wan Abas, W.A.B. (2015). The effects of different prosthetic feet and head extension on the postural stability of below-knee amputees during quiet standing. *Adapted Physical Activity Quarterly*. (Accepted)

4. **Arifin, N**., Abu Osman, NA. ,Ali, S., Gholizadeh, H. & Wan Abas, W.A.B. (2015). Evaluation of postural steadiness in below-knee amputees when wearing different prosthetic feet during various sensory conditions using the Biodex Stability System (BSS). *Journal of Engineering in Medicine, 229(7), 491-498.*

5. **Arifin, N**., Abu Osman, NA; Ali, S; Gholizadeh, H & Wan Abas, WAB. (2014). Postural Stability Characteristics of Transtibial Amputees Wearing Different Prosthetic Foot Types When Standing on Various Support Surfaces. *The Scientific World Journal*, 2014, 6.

Under review in:

Journal of Mechanics in Medicine and Biology. Arifin, N., Abu Osman, NA. ,Ali, S., Gholizadeh, H. & Wan Abas, W.A.B. Postural Stability Strategies In Transtibial Amputees During Quiet Standing In Altered Sensory Conditions Wearing Three Types Of Prosthetic Feet. SAGE Publication.

Journal of Engineering in Medicine. Arifin, N., Abu Osman, NA. & Wan Abas, W.A.B. Quantitative instrumental approach to the evaluation of balance during standing in people with lower limb amputation: A systematic review. SAGE Publication.

Proceedings:

Arifin, N., Abu Osman, N.A. & Wan Abas, W.A.B. (2014). Postural Movement Strategies During Sensory Alterations in Transtibial Amputees: a Comparative Study with Able-Bodied Subjects, IEEE Conference on Biomedical Engineering and Sciences, 8-10 December 2014, Miri, Sarawak. Malaysia. (ISI Conference)

Appendix B: References obtained for systematic review.

No	References
Participants characteristics	
1	**Mixed amputation level:** Nederhand, van Asseldonk, Der Kooij and Rietman (2012), Buckley, O'Driscoll and Bennett (2002), Vrieling *et al.* (2008), Duclos, Roll, Kavounoudias, Roll and Forget (2007), Yazicioglu, Taskaynatan, Guzelkucuk and Tugcu (2007), Mohieldin, Chidambaram, Sabapathivinayagam and Al Busairi (2010), Geurts and Mulder (1994), Geurts and Mulder (1991)
2	**18 control groups** **Age-matched:** Curtze, Hof, Postema and Otten (2012), Mohieldin *et al*. (2010), Vanicek *et al.* (2009), Vrieling *et al*. (2008), Duclos *et al*. (2007), Yazicioglu *et al.* (2007), Kanade, van Deursen, Harding and Price (2008), Vrieling *et al*. (2008), Mouchnino *et al*. (2006), Buckley *et al*. (2002), Viton *et al*. (2000), Mouchnino *et al*.(1998), Hermodsson , Ekdahl , Persson and Roxendal (1994), Geurts and Mulder (1994), Isakov *et al*. (1992), Geurts and Mulder (1991) **Non-aged matched:** Aruin, Nicholas and Latash (1997), Fernie and Holliday (1978), Dornan, Fernie and Holliday (1978)
3	**Amputees' activity level:** Nederhand *et al.* (2012), Kozakova, Svoboda, Janura, Elfmark and Nedvědová (2009), van der Kooji, van Asseldonk and Nederhand (2007), Kaufman *et al*. (2007) **Complete demographic information:** Barnett, Vanicek and Polma (2012), Curtze *et al.* (2012), Mayer *et al*. (2011), Vanicek *et al*. (2009), Rougier and Bergeau (2009), Kozakova *et al*. (2009), Kanade *et al*. (2008), Vrieling *et al*. (2008), Lee, Lin and Soon (2007), Quai, Brauer and Nitz (2005), Aruin *et al*. (1997) **Post-amputation years:** Nederhand *et al*. (2012), Curtze *et al*. (2012), Mayer *et al*. (2011), Hlavackova, Franco, Diot and Vuillerme (2011), Mohieldin *et al*. (2010), Vanicek *et al*. (2011), Hlavackova *et al*.(2009), Kozakova *et al*. (2009), Vrieling *et al*. (2008), Duclos *et al.* (2007), Yazicioglu *et al*. (2007), Lee *et al*. (2007), Kaufman *et al*. (2007), Quai *et al*.(2005), Matjacic and Burger (2003), Nadollek, Brauer and Isles (2002), Blumentritt, Schmalz , Jarasch and Schneider (1999), Aruin *et al*. (1997), Hermodsson *et al*. (1994), Geurts *et al*.(1994) **Acclimation period:** Kaufman *et al*. (2007), Isakov, Mizrahi, Ring, Susak and Hakim (1992)
4	**Vascular:** Kanade *et al*. (2008), Isakov *et al*. (1992), Nadollek *et al*. (2002), Mayer et al. (2011), Quai et al. (2005), Hlavackova *et al*. (2011) **Non-vascular:** Rougier and Bergeau (2009), Buckley *et al*. (2002), Duclos *et al*. (2007), Yazicioglu *et al*. (2007), Blumentritt *et al*. (1999), Viton *et al*. (2000) , Mouchnino *et al*.(1998), Mouchnino *et al*.(2006), Matjacic and Burger (2003), Hlavackova *et al*. (2009)
5	**Etiology not mentioned:** Lee *et al*. (2007), Dornan *et al.* (1978), Aruin *et al*. (1997), Fernie and Holliday (1978)

Appendix B (continued)

No	References
	Prosthetic componentry
6	**Complete information:** Mayer *et al*. (2011), Buckley *et al.* (2002)
7	**Same prosthetic foot:** Vanicek *et al.* (2009), Mayer *et al*. (2011), Viton *et al.* (2000) **Same socket type:** Lenka & Tiberwala (2010), Mayer *et al*. (2011), Blumentritt *et al*.(1999), Viton *et al*. (2000), Matjacic and Burger (2003), Vittas , Larsen and Jansen (1986)
8	**SACH:** Curtze *et al*. (2012), Mayer *et al*. (2011), Mohieldin *et al*. (2010), Lenka & Tiberwala (2010), Vrieling et al. (2008), van der Kooij *et al.* (2007), Viton *et al.* (2000),Blumentritt *et al*. (1999) **ESAR:** Nederhand *et al*. (2012), Barnett *et al*. (2012), Curtze *et al*. (2012), Mohieldin *et al.* (2010), Rougier et al. (2009), van der Kooij et al. (2007), Blumentritt *et al*. (1999) **Multiaxial foot:** Barnett *et al*. (2012), Curtze *et al*. (2012), Mohieldin *et al*. (2010), Vanicek *et al*. (2009), Rougier *et al*. (2009), Vrieling *et al*.(2008) Buckley et al. (2002) **Single axis foot:** Nederhand *et al*. (2012), van der Kooij *et al*.(2007)
	Instrumentations and protocols
9	**Static bipedal:** Nederhand *et al*. (2012), Barnett *et al*. (2012), Mayer *et al*. (2011), Hlavackova *et al*.(2011), Mohieldin *et al.* (2010), Lenka *et al*. (2010), Vanicek *et al.* (2009), Hlavackova *et al*.(2009), Kozakova *et al*. (2009), Rougier *et al*. (2009), Kanade *et al*.(2008), Duclos *et al*. (2007), van der Kooij *et al*. (2007), Kaufman *et al*. (2007), Quai *et al*. (2005), Buckley *et al*. (2002), Nadollek *et al*. (2002), Blumentritt *et al*. (1999), Hermodsson *et al*. (1994), Geurts *et al*. (1994), Isakov *et al.* (1992), Geurts *et al*. (1991), Vittas *et al*. (1986), Fernie *et al*. (1978), Dornan *et al.* (1978) **Single leg on intact:** Mayer *et al*. (2011), Mayer *et al*. (2011), Yazicioglu *et al*. (2007), Lee *et al.* (2007), Mouchnino *et al*. (2006), Hermodsson *et al*. (1994) **Single leg prosthetic:** Hermodsson *et al*. (1994), Mouchnino *et al*. (2006
10	**Dynamic unexpected:** Nederhand *et al*. (2012), Barnett *et al*. (2012), Curtze *et al*. (2012), Mohieldin *et al.* (2010), Vanicek *et al.* (2009), Vrieling *et al*.(2008), Kaufman *et al*.(2007), Buckley *et al.* (2002) **Dynamic expected perturbations:** Yazicioglu *et al*. (2007), Mouchnino *et al*. (2006), Quai *et al*. (2005), Matjacic *et al*. (2003), Viton *et al.* (2000), Mouchnino *et al*. (1998), Aruin *et al*. (1997), Geurts *et al*. (1994)
11	**Force platform**: Mayer *et al*. (2011),,Hlavackova *et al*.(2011), Lenka *et al*. (2010), Hlavackova *et al*.(2009), Kozakova *et al*. (2009), Rougier *et al.* (2009),Vrieling *et al*. (2008), Kanade *et al*. (2008), Duclos *et al*. (2007), Quai *et al.* (2005), Buckley *et al*. (2002), Nadollek *et al*. (2002), Blumentritt *et al*. (1999), Hermodsson *et al.* (1994), Geurts *et al*. (1994), Isakov *et al*. (1992), Geurts *et al.* (1991), Vittas *et al*. (1986) **Computerized posturography:** Barnett *et al*. (2012), Mohieldin *et al*. (2010), Vanicek *et al.* (2009),Yazicioglu *et al*. (2007), Kaufman *et al*. (2007), Matjacic and Burger (2003) **Displacement transducer:** Dornan *et al.* (1978), Fernie & Holliday (1978) **Motion analysis system:** Lee *et al*. (2007)

Appendix B (continued)

No	References
	Instrumentations and protocols
12	**Combined assessment:** Nederhand *et al*. (2012), Curtze *et al*. (2012), van der Kooij *et al*. (2007), Mouchnino *et al*. (2006), Viton *et al*. (2000), Mouchnino *et al*. (1998), Aruin *et al*. (1997)
13	**Standardized:** Vanicek *et al*. (2009), Hermodsson *et al*. (1994), Lenka & Tiberwala (2010), Rougier and Bergeau (2009), Nederhand *et al*. (2012), Buckley *et al*. (2002), Barnett *et al*. (2012), Duclos *et al*.(2007), Geurts and Mulder (1994), Geurts and Mulder (1991), Isakov *et al*. (1992), Nadollek *et al*. (2002), Quai *et al*.(2005), Hlavackova *et al*. (2011), Viton *et al*. (2000), Mouchnino *et al*.(1998), Mouchnino *et al*.(2006), Hlavackova *et al*.(2009), Aruin *et al*. (1997), Vittas *et al*. (1986), van der Kooij *et al*. (2007) **Self-selected:** Curtze *et al*. (2012), Vrieling *et al*. (2008), Kanade *et al*. (2008), Mayer *et al.* (2011), Fernie and Holliday (1978), Kaufman *et al*. (2007) **No information:** Lee *et al*. (2007), Yazicioglu *et al.* (2007), Mohieldin *et al*. (2010), Blumentritt *et al*. (1999), Matjacic and Burger (2003), Dornan *et al*. (1978), Kozakova *et al*. (2009)
14	**2 to 5 repetitions:** Vanicek *et al*. (2009), Hermodsson *et al*. (1994), Rougier and Bergeau (2009), Nederhand *et al*. (2012), Buckley *et al*. (2002), Curtze *et al*. (2012), Barnett *et al*. (2012), Mohieldin *et al*. (2010), Geurts and Mulder (1994), Geurts and Mulder (1991), Kanade *et al*. (2008), Isakov *et al*. (1992), Mayer *et al*. (2011), Quai *et al*.(2005), Hlavackova *et al*. (2011), Matjacic and Burger (2003), Hlavackova *et al*. (2009), Dornan *et al*. (1978), Fernie and Holliday (1978), Kaufman *et al*. (2007), van der Kooij *et al*. (2007) **20-30 seconds:** Vanicek *et al*. (2009), Hermodsson *et al*. (1994), Buckley *et al*. (2002), Barnett *et al*. (2012), Mohieldin *et al*. (2010), Geurts and Mulder (1994), Geurts and Mulder (1991), Kanade *et al*. (2008), Isakov *et al*. (1992), Mayer *et al*. (2011), Hlavackova *et al*. (2011), Hlavackova *et al*.(2009), Kaufman *et al*. (2007), Kozakova *et al*. (2009)
15	**At side of their body:** Vanicek *et al*. (2009), Hermodsson *et al*. (1994), Lenka & Tiberwala (2010), Rougier and Bergeau (2009), Nederhand *et al*. (2012), Vrieling *et al*. (2008), Kanade *et al*. (2008), Mayer *et al*. (2011), Hlavackova *et al*. (2011), Hlavackova *et al*.(2009), Aruin *et al*. (1997) , Vittas *et al*. (1986) **At the hip**: Buckley *et al*. (2002) **At the back:** Geurts and Mulder (1994), Geurts and Mulder (1991), Viton *et al*. (2000), Mouchnino *et al*.(1998), Mouchnino *et al*.(2006) **Across the chest:** Lee *et al.* (2007), Yazicioglu *et al.* (2007)
16	**Stand as still as possible:** Lenka & Tiberwala (2010), Geurts and Mulder (1994), Geurts and Mulder (1991), Isakov et al. (1992), Hlavackova *et al*. (2011), Hlavackova *et al*.(2009), Fernie and Holliday (1978) **Stand upright:** Vanicek *et al*. (2009), Curtze *et al*. (2012), Barnett *et al*. (2012), Kaufman *et al*. (2007) **Stand stationary:** Buckley *et al*. (2002), Mouchnino *et al*.(1998), Mouchnino *et al*. (2006)

Appendix B (continued)

No	References
Types of sensory manipulations	
17	**Compliant surface**: Kozakova *et al*., 2009
18	**Eyes open:** Rougier and Bergeau (2009), Nederhand *et al*. (2012), Buckley *et al*. (2002), Lee *et al*. (2007), Yazicioglu *et al*.(2007), Geurts and Mulder (1994), Geurts and Mulder (1991), Mayer *et al*. (2011), Blumentritt *et al*. (1999), Viton *et al.* (2000), Mouchnino *et al*.(1998), Mouchnino *et al*.(2006), Matjacic and Burger (2003), Hlavackova *et al*.(2009), Aruin *et al*. (1997) **Close:** Hlavackova *et al*. (2011), Duclos *et al*.(2007), van der Kooij *et al.* (2007), Vittas *et al*. (1986) **Both:** Vanicek *et al*. (2009), Hermodsson *et al*. (1994), Lenka & Tiberwala (2010), Buckley *et al*. (2002), Barnett *et al*. (2012), Vrieling *et al*. (2008), Mohieldin *et al*. (2010), Isakov *et al*. (1992), Nadollek *et al*. (2002), Quai *et al*.(2005), Dornan *et al*. (1978), Fernie and Holliday (1978), Kaufman *et al*. (2007), van der Kooij *et al*. (2007), Kozakova *et al*. (2009)
Main outcome measures	
19	**CoM and/ or CoP variables:** Mayer *et al*. (2011), Hlavackova *et al*.(2011), Lenka *et al*. (2010), Hlavackova *et al*.(2009), Kozakova *et al*.(2009), Rougier *et al*. (2009), Vrieling *et al*. (2008), Kanade *et al*. (2008), Duclos *et al*.(2007), Quai *et al.* (2005), Buckley *et al*. (2002), Nadollek *et al*.(2002), Blumentritt *et al*. (1999), Hermodsson *et al.* (1994), Geurts *et al*. (1994), Isakov *et al*. (1992), Geurts *et al*. (1991), Vittas *et al*. (1986), Lee *et al*. (2007), Nederhand *et al*. (2012), Curtze *et al*. (2012), van der Kooij et al. (2007), Mouchnino et al. (2006), Viton et al. (2000), Mouchnino et al. (1998), Aruin et al. (1997) **Weight distribution:** Rougier and Bergeau (2009), Nederhand *et al*. (2012), Geurts and Mulder (1994), Kanade *et al*. (2008), Isakov et al. (1992), Nadollek *et al*. (2002), Mayer et al. (2011), Quai et al.(2005), Hlavackova et al. (2011), Hlavackova *et al*.(2009), van der Kooij *et al*. (2007), Kozakova *et al*. (2009) **Equilibrium and composite score:** Barnett *et al*. (2012), Mohieldin *et al.* (2010), Vanicek *et al*. (2009), Kaufman *et al*. (2007) **Balance Index (BI):** Yazicioglu *et al*. (2007) **Standing duration:** Hermodsson *et al.* (1994), Buckley *et al*. (2002), Lee *et al*. (2007), Matjacic and Burger (2003)

Appendix C: Ethical 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:** 938.9
PROTOCOL NO: **TITLE:** The quantitative and qualitative influence of prosthetic foot stiffness on transtibial amputee gait biomechanics	
PRINCIPAL INVESTIGATOR: Puan Nooranida Arifin **TELEPHONE:** **KOMTEL:**	**SPONSOR:** UM\KPT

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: 18 Jul 12
[✓] Study Protocol — Ver date:
[ ] Investigator Brochure — Ver date:
[✓] Patient Information Sheet
[✓] Consent Form
[ ] Questionnaire
[✓] Investigator (s) CV's (Puan Nooranida Arifin)

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: 15th AUGUST 2012

c.c Head
Department of Biomedical Engineering

Deputy Dean (Research)
Faculty of Medicine

Secretary
Medical Ethics Committee
University Malaya Medical Centre

....
PROF. KULENTHRAN ARUMUGAM
Deputy Chairman
Medical Ethics Committee

Appendix D: Participants information sheets

Title of Study: The Influence of Prosthetic Foot Types on the Postural Control of Below-Knee Amputees

Subject's Identification Form

Control healthy/ Transtibial amputee

Name: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ Date of Birth: _ _ _ _ _ _ _ _ _ _ _ _ _ _

Age: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ Gender: Male / Female.

Height (m):_ _ _ _ _ _ _ _ _ _ _ _ _ _ Mass (kg): _ _ _ _ _ _ _ _ _ _

Shoes size: _ _ _ _ _ _ _ _ _ _ _ _ _ _ Foot size (cm): _ _ _ _ _ _ _ _

Amputation side/ Dominant : Left / Right Left / Right

Years of amputation :___________ years Liner :_____________________

Cause of amputation :___________________ Suspension:_____________________

Type of foot :___________________ Socket :_____________________

Residual length :___________________(from mid-patellar tendon to distal end)

Wearing hours/day :___________________

ADL (K-level) :___________________

Any disease :___________________

Sight/ hearing impairments : _____________________

Phantom pain/ sensations : _____________________

Recent falls or have experienced falls since amputation : _____________________

Appendix E: Informed consent

Borang Keizinan (Consent Form)

Tajuk Kajian: The influence of prosthetic foot on the stiffness on the postural control transtibial amputee.

Nama Penyelidik: Nooranida Arifin

Sila tanda

1. Saya sahkan yang saya telah membaca ***Lampiran A: Participant Information Statement*** dan memahami projek ini. Saya faham bahawa penyelidik akan menjawab sebarang soalan yang mungkin ada. ☐

2. Saya faham bahawa penyertaan saya adalah secara sukarela dan saya boleh menarik diri pada bila-bila masa dan ia tidak akan menggangu apa-apa rawatan yang sedang saya terima. ☐

3. Saya faham bahawa projek ini telah diberi kebenaran oleh Kejuruteraan Bioperubatan, Fakulti Kejuruteraan, Universiti Malaya. ☐

4. Saya faham bahawa maklumat daripada borang kaji-selidik yang telah lengkap akan disimpan dengan cermat dan keselamatannya terjamin. Saya faham bahawa maklumat yang dikumpul hanya untuk kegunaan saintifik dan nama saya tidak akan diterbitkan dalam buku dan jurnal. ☐

5. Saya memberi kebenaran kepada Koordinator projek dan Koordinator projek Negara untuk meIihat maklumat yang telah saya beri didalam kajian ini. ☐

6. Saya bersetuju untuk mengambil bahagian didalam kajian ini. ☐

Tandatangan Saksi,	Tandatangan Subjek,
_______________	_____________
Nama:	Nama:
Jawatan:	No K/P:
Jabatan:	

Appendix F: Questionnaires

F1: Health Survey Questionnaire

Name:____________________________
Date:__________________

Health Survey (SF-12 v2 Standard, US Version 2.0)

Directions: This survey asks for your views about your health. This information will help you keep track of how you feel and how well you are able to do your usual activities. If you are unsure about how to answer a question, please give the best answer you can. Circle only one answer for each question. Please ask the researcher for any question.

1. **In general, would you say your health is: (GH01)**

Excellent	Very Good	Good	Fair	Poor
1	2	3	4	5

The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
2. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf (PF3b).	1	2	3
3. Climbing several flights of stairs (PF3d).	1	2	3

During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
4. Accomplished less than you would like (RP4b).	1	2	3	4	5
5. Were limited in the kind of work or other activities (RP4c).	1	2	3	4	5

During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
6. Accomplished less than you would like (RE5b).	1	2	3	4	5
7. Did work or activities less carefully than usual (RE5c).	1	2	3	4	5

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)? (BP02)

Not at all	A little bit	Moderately	Quite a bit	Extremely
1	2	3	4	5

These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks...

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
9. Have you felt calm and peaceful (MH9d).	1	2	3	4	5
10. Did you have a lot of energy (VT9e).	1	2	3	4	5
11. Have you felt downhearted and depressed (MH9f).	1	2	3	4	5
12. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?(SF10).	1	2	3	4	5

F2: Berg Balance Scale

Name:____________________________
Date:__________________

The Berg Balance Scale (BBS) has an overall range of 0–56 and comprises 14 items (or tasks), with each item score ranging from 0–4.The Berg Balance Scale includes the following tests:

	Score
1. The ability to place the feet together independently up to 1 minute	...……
2. Standing unsupported for up to 1 minute	………
3. Standing with one foot in front of the other for up to 30 seconds	………
4. Sitting to standing	………
5. Transferring from one chair to another	………
6. Turning 360°	………
7. Stoll stepping	………
8. Sitting with the back unsupported	………
9. Standing to sitting	………
10. Standing with eyes closed for 10 seconds	………
11. Reaching forward while standing	………
12. Turning to look behind over the left and right shoulders while standing	………
13. Retrieving object from floor	………
14. Standing on 1 leg for up to 20 seconds	………

F3: Houghton Scale

Items	Descriptions	Score
1. Do you wear your prosthesis:	0: <25% of walking hours (1-3 hours) 1: 25-50% of walking hours (4-8 hours) 2: >50% of walking hours (>8 hours) 3: All walking hours (12-16 hours)	
2. Do you wear your prosthesis to walk:	0: Just when visiting doctor/ limb-fitting center 1: At home but not to go outside 2: Outside the home on occasion 3: Inside and outside all the time	
3. When going outside wearing your prosthesis, do you:	0: Use a wheelchair 1: Use two crutches, two canes, or a walker 2: Use one cane 3: Use nothing	
4. When walking with your prosthesis outside, do you feel unstable when:		
(a) Walking on a flat surface	0: Yes, 1: No	
(b) Walking on slopes	0: Yes, 1: No	
(c) Walking on rough ground	0: Yes, 1: No	

F4: Activities-Specific Balance Confidence Scale

Name:__________________________ Date:__________________

For each of the following activities, please indicate your level of self-confidence by choosing a corresponding number from the following rating scale. If you do not currently do the activity in question, try and imagine how confident you would be if you had to do the activity.

How confident are you that you will not lose your balance or become unsteady when you . .

0% 10 20 30 40 50 60 70 80 90 100%
No confident Completely confident

1. . . . walk around the house? _________%

2. . . . walk up or down stairs? _________%

3. . . . bend over and pick up a slipper from front of a closet floor? _________%

4. . . . reach for a small can off a shelf at eye level? _________%

5. . . . stand on tip toes and reach for something above your head? _________%

6. . . . stand on a chair and reach for something? _________%

7. . . . sweep the floor? _________%

8. . . . walk outside the house to a car parked in the driveway? _________%

9. . . . get into or out of a car? _________%

10. . . . walk across a parking lot to the mall? _________%

11. . . . walk up or down a ramp? _________%

12. . . . walk in a crowded mall where people rapidly walk past you? _________%

13. . . . are bumped into by people as you walk through the mall? _________%

14. . . . step onto or off of an escalator while you are holding onto a railing? _________%

15. . . . step onto or off an escalator while holding onto parcels such hold that onto the you cannot railing? _________%

16. . . . walk outside on slippery sidewalks? _________%