The Effects of Insoles on Biomechanics of Standing Balance and Walking of Trans-Femoral Amputees

Tahmineh Rezaeian

Submitted in accordance with the requirements for

the degree of PhD

The University of Leeds
Faculty of Biological Sciences

Biomedical Sciences School

March, 2020

بسم الله الرّحمن الرّحیم

به نام خدای بخشنده مهربان

In the Name of Almighty God, the most Compassionate, ever Compassionate

All men and women are to each other
the limbs of a single body, each of us drawn
from life's shimmering essence, Almighty God's perfect pearl;
and when this life we share wounds one of us,
all share the hurt as if it were our own

Abu-Mohammad Muslih-ud-Din Saadi Shirazi (1210-1292)
Translated from Persian by Richard Jeffrey Newman, Selections from Saadi's Gulistan, 2004

بنی آدم اعضای یک پیکرند
که در آفرینش ز یک گوهرند

چو عضوی به درد آورد روزگار
دگر عضوها را نماند قرار

شیخ مصلح الدین سعدی شیرازی

To my dearest Mother and my late Dad: With my wish to continue life the best way they would have taught and showed their children;

To my lovely Late Grandmother, Maman Bozog, for her pure, priceless and unique love and affection which have filled my heart and each moment of my life;

To every single participant in the survey and the biomechanical tests. I actually have no words to appreciate their time and sincere contribution;

تقدیم به

مادر نازنیم و روح پدر عزیزم، با آرزوی عمل به آموزه هایشان در زندگی ام؛

روح مامان بزرگ، مادربزرگ دوست داشتنی ام که محبت خالص و بی مانندش در لحظه لحظه زندگی ام جاریست؛

تک تک شرکت کنندگان در این پژوهش، دست و زبانم از قدردانی لطف و انسان دوستی شان (که در قالب مشارکت در این کار بروز یافت)، ناتوان است.

In memory of my inspiring Late Teacher, Ostad AliAkbar Kameli.

به یاد استاد عزیز و درگذشته ام، استاد علی اکبر کاملی و آنچه از درس زندگی به من آموخت.

I salute those who sacrificed their life and those whose health suffered whilst defending their Motherland.

با احترام به آنان که در راه پاسداشت مام میهن، جان شیرین فدا کردند و یا دچار درد و رنج و نقصان شدند.

Acknowledgements

I have dedicated more than 4 years to my PhD. It has been a period of learning, not only in the scientific field, but also on a personal level. I would like to reflect on the people who have supported and helped me so much throughout this time.

I would first like to express my gratefulness to University of Leeds' Postgraduate Scholarship body, which awarded me a “Leeds International Research Scholarship” and provided this great opportunity to perform my research as a PhD student in this university. I would like to show my sincere gratitude to my supervisors Dr Neil Messenger and Dr Daniella Strauss for their support, motivation and immense knowledge. I need to appreciate help and advices of Dr Graham Askew, Dr Hossein Karimi and Dr Farzam Farahmand during last months of preparing this thesis.

This research would not have been possible without the help of several academic and non-academic individuals in Leeds and Iran, as well as that of amputee-related groups and organizations around the world. I have nothing but praise for their technical help, inspiring presence, support and assistance: Pouyan Mehryar, Brendan McDermott, Ehsan Abdollahi, Amir Reza Khandan, Robin Layton, James Hopwood, Zahra Rafiei, Mina Bani-Asad, Haj Mansour Nam-Nam, Morteza Mohammadi, Masoud Saqqaeian, Mohammad Mobin-Ali, Mohammad Reza Rohani, Mohammad Reza Hakimi Nasrabadi, Mr Mirshafiei, Safie Ghourchi and Mr Aarvan (Iranian Handicapped Society), Ahmad Beig Mohammadloo, Dr Parviz Mojhgani, Zahra Moradi, Mojtaba Jaafarian, Mahammad Maghami, Tomeu Munar, Elle McDonough, Christopher Hinton-Lewis, Tyron Mullins, Thomas Richards, Masoud Ghalaii, Hesam Maleki, Navid Mehryar, Mehran Mehryar, Mehdi Hamidi, Asghar Goharzad, Dr Sohrab Rezvani, Torab-Ali Abavisani, Siamak Choghaei, Hojatollah Harandi, Mansour Qamari, Manouchehr Khoshnevisan, Mr Majlesipour, Jahangir Heidari, Rahim Omidbakhsh, Abbas Abdolhoseini, and Hossein Abdam, Sarah Smith, Peter Walthew, Lynne Taylor, Brian Chenier, Mark Randall, Camille Poulin, Amy Joan Zahra, Carl Crisp, James Wilde, Phil Weston, Kevin Hickman, David Bickers, George Gondo, Melissa Noonan, and Graham Facey.

I would like to express my deep gratitude to my unique and wonderful friends for their help and their presence in my life, particularly during my research: Maryam Jalali, Kowsar Shahbazi, Mansoureh Abdi, Zahra Sadeghi, Zahra Safaei-Pour, Saeideh Seyed Mohseni, Robabe Vatanparast, Sima Taghizadeh Dabagh, Shaparak Shadrawan, Abdoreza Hesam Mohseni, Nastaran Amini, Mahboobeh Mehdikhani, Fatemeh Zarezadeh, Marjan Akhavansafa, Zahra Saqqaei, Parisa Khateri, Ostad Fatemeh Esfandiarpour, Atieh Ghaffari, Fatemeh Eskandari, Hifza Rasheed and her angels Areefa nd Mahad, Antonio Martínez-Arboleda, Christopher and Friederike Jeans, Iman, and Farhat Yaqoob.

And finally, last but by no means least, I would like to thank my family for their support and care: my better half dear Syed Adeel and his family members, my lovely mother, dearest siblings, other adorable relatives, and everyone who sent their positive energy and prayers from so far away to support me in this period of my life.

Abstract

As the world's population ages, it is expected that the number of people having experienced amputations will grow, alongside comorbidities. Lifestyle adaptations associated with lower limb amputation are likely to occur and, with this, there is likely an impact on mobility and balance.

This research has initially investigated, via a comprehensive survey, the impact of lower limb amputation and prosthetic use on the lives of amputees with a focus on their balance and mobility during daily activities. The survey consisted of parts of the Prosthesis Evaluation Questionnaire (PEQ), the Activities-Specific Balance Confidence (ABC) Scale, and the Oswestry Disability Index (ODI). The results of the survey (155 participants in all levels of lower limb amputation) showed that the majority of LLAs suffered from stump and intact-side pain, frequent falling, LBP with impact on their functionality, and a lower level of balance confidence. A considerable proportion of respondents were at risk of falling and needed intervention to improve their balance.

According to the mentioned problems which LLAs deal with on a daily basis and the effectiveness of insoles use on similar balance problems and lower limb pains among non-amputees, it was supposed the insoles used on the intact side of LLAs would improve their situation. Therefore, biomechanical research was conducted to examine the effect of insoles use on perturbed standing balance and self-selected speed walking of TF amputees (11 participants) and a group of non-amputees (14 participants). Data was collected via 3D motion analysis systems, including high-speed cameras and force platforms. The function level of amputee participants was evaluated according to spatio-temporal variables of their walking and their responses to the ABC scale and PEQ-Mobility parts of the survey. Lower self-selected speed and asymmetrical walking compared to non-amputees indicated that amputee participants had lower levels of function. Results of the ABC scale questionnaire showed that most of them had moderate functional level (three amputees with good and one with a low level of functionality). These results corresponded with their PEQ-M scores. The kinematic and kinetic results of walking showed asymmetrical performance of amputees' limbs with a prominent role of the intact limb. However, the relationship between the centre of mass (COM) and centre of pressure (COP) with lateral borders of BOS as the balance did not exhibit any difference between amputees and non-amputees, which shows proper balance maintenance of amputees during walking. For studying the biomechanics of standing balance, a perturbation was applied by a front/back-pulling load (2.5% of body weight) to the waist of each participant which, upon release, respectively induced backwards and forward falling. The observed changes in COP, COM, ground reaction forces and joint moments during standing and in response to the perturbation indicated that the intact limb of TF amputees had the main role in their balance, which resulted in an asymmetrical posture. Both groups used ankle movements to maintain balance in reaction to the perturbation.

Insoles use was associated with changes in a very limited number of biomechanical variables for non-amputees and in none of the amputees' biomechanical variables. But, the quantitative evaluation of insoles showed most participants were satisfied with insoles and felt more comfortable in their daily activity during their use.

The results of this research (including both survey and biomechanical studies) affirm the necessity of providing more support (in the form of medical and musculoskeletal rehabilitation interventions) for LLAs to address the current issues, particularly with balance and their function in daily activities. The use of insoles in the initial phase of gait training after the first prosthesis fit might be beneficial for LLAs.

List of Publications

Publications from this Thesis (Rezaeian, T. main author)

1. **Rezaeian, T.**, Mehdikhani, M., Messenger, N., and Strauss, D., 2019, October. Balance Confidence in Lower Limb Amputees, *ISPO 17th World Congress*, 2019, October 5-8, Kobe, Japan.

2. **Rezaeian, T**., Mehryar, P., Khandan, A., Mehdikhani, M., Messenger, N., and Strauss, D., 2019, October. Spatio-temporal Variables of Trans-femoral Amputees Walking, *ISPO 17th World Congress,* 2019, October 5-8, Kobe, Japan.

3. **Rezaeian, T.**, Jalali, M., Mojgani, P., Messenger, N., and Strauss, D., 2019, August. Balance and mobility during daily activities, low back pain, amputated and intact side pain in Iranian lower limb amputees, *Journal of Military Medicine (Iranian)*, 2019, 21 (3): 262-271.

4. **Rezaeian, T**., Mehryar, P., Khandan, A., Abdollahi, E., McDermott, B., Messenger, N., and Strauss, D., 2019, August. Ground Reaction Forces in Perturbed Standing Balance of Above-knee Prosthesis Users (Poster), *ISB/ASB 2019*, July 31-August 4, Calgary, Canada.

5. **Rezaeian, T.**, Messenger, N., Strauss, D., Jalali, M., and Mojgani, P., Pain in Lower Limb Amputees, *22nd Annual Iranian Congress of Physical Medicine, Rehabilitation and Electro-diagnosis*, 2018, December 26 – 28, Tehran, Iran.

Related Publications (Rezaeian, T. co-author)

1. Mehryar, P., Shourijeh, M.S., **Rezaeian, T**., Khandan, A.R., Messenger, N., O'Connor, R., Farahmand, F. and Dehghani-Sanij, A., Differences in muscle synergies between healthy subjects and transfemoral amputees during normal transient-state walking speed, *Gait and Posture,* 2020, 76: 98-103.
2. Mehryar, P., **Rezaeian, T**., Shourijeh, M.S., Raveendranathan, V., Messenger, N., O'Connor, R. and Dehghani-Sanij, A., 2017. Changes in knee joint kinetics of transfemoral amputee's intact leg: An osteoarthritis indication? *ESMAC 2017*, *Gait and Posture,* 57: 151-152.

3. Mehryar, P., Shourijeh, M.S., **Rezaeian, T.**, Crisp, C., Messenger, N., and Dehghani-Sanij, A.A., Do activation & synergy of above knee amputees' intact leg change? *School and Symposium on Advanced Neurorehabilitation (SSNR2017), 2017, Sep. 17-22, Baiona, Spain*.

4. Mehryar, P., Shourijeh, M.S., **Rezaeian, T.**, Iqbal, N., Messenger, N., and Dehghani-Sanij, A.A., 2017, August. Changes in synergy of trans-tibial amputee during gait: A pilot study. *2017 IEEE EBMS International Conference on Biomedical and Health* Informatics (BHI), February 16-19, Orlando, USA.

Table of Contents

Chapter 4

List of Tables

List of Figures

Abbreviations

ABC	Activities-specific Balance Confidence
AK	Above Knee (prosthesis)
BB	Balance against Back pulling load (Back Balance)
BK	Below Knee (prosthesis)
COM	Centre of Mass
COP	Centre of Pressure
FB	Balance against Front pulling load (Front Balance)
IL/PL	Intact Limb/ Prosthetic Limb (for lower limb amputees)
LBP	Lower Back Pain
LLA	Lower Limb Amputee
M	Mean
MED	Median
ODI	Oswestry Disability Index
QOL	Quality of Life
PEQ	Prosthesis Evaluation Questionnaire
RL/LL	Right Limb/ Left Limb (for non-amputees)
S1	Session 1, without insoles
S2	Session 2, with insoles
SD	Standard Deviation
TF	Trans-femoral (amputee)
TT	Trans-tibial (amputee)

Chapter 1
Introduction

Amputation is the removal of the entire or a part of a lower or upper limb. Lower limb amputation, especially in the loss of a major portion of the limb (for example, in trans-femoral amputation), affects the amputee's mobility and possibly his/her independence in normal life, besides changing the appearance of the body (Gitter, A and Bosker, 2005b). An amputated limb is usually replaced by a prosthetic device, but there are considerable differences between the characteristics and function of a prosthetic limb with a natural one. This fact, coupled with the consequences of limb loss surgery (e.g., phantom sensation or pain) plus body adaptations to limb loss, affects various aspects of an amputee's daily routine. With regard to musculoskeletal issues, lower back pain (LBP) is common among lower limb prosthesis users (Gailey et al., 2008; Ehde et al., 2001; Ephraim et al., 2005; Kusljugic et al., 2006; Sattar, 2007; Devan et al., 2012). In addition, biomechanical studies have shown people with unilateral lower limb amputation rely more upon their opposite intact limb (Ku et al., 2014; Gailey et al., 2008; Nadollek et al., 2002), hence the intact limb will become painful, and its joints can be susceptible to osteoarthritis due to overloading (Vrieling et al., 2008a; Struyf et al., 2009; Lloyd et al., 2010; Morgenroth et al., 2012; Mehryar et al., 2017). Besides these problems, there is a balance deficit and a higher risk of falling in lower limb prosthesis users (Kulkarni et al., 1996; Hunter et al., 2017; Buckley et al., 2002). A further significant factor related to prosthesis users' issues is their age. It is well-known that ageing in the general population might be associated with similar problems, such as a higher risk of osteoarthritis, falling, and lower back pain. Although amputation due to military conflicts and non-combatant traumas (for example, road traffic accidents and military exercise events) generally affects young people to a greater extent (NHSScotland, 2005), vascular deficiencies (including diabetes mellitus) are the main reason for lower limb amputation in older age groups (Stewart, C.P.U., 2008). According to the Amputee Statistical Database for the United Kingdom (2004-05) report, more than half of lower limb amputees (LLA) in the UK are aged 65 years or over (NHSScotland, 2005). It should also be highlighted that the world's population is getting older (WHO, 2016; UN, 2017). Thus, it is expected that the number of people subjected to age-related issues like vascular diseases (including diabetes and peripheral arterial disease) and, consequently, the number of LLAs, will grow. Furthermore, current younger amputees will live into advanced old age and most likely will face ageing musculoskeletal problems in addition to the common problems of LLAs.

To date, the majority of studies related to improving LLA locomotion, understandably, has been focused on solving post-surgery stump problems (such as phantom sensations) and improving existing prosthetic devices because these are the most urgent and basic needs of amputees. Thus, the advice provided by treatment teams to amputees has been concentrated less on the intact limb (IL) of LLAs, even though they have a key role in the amputees' balance and locomotion. On the other hand, there are published studies which address orthotic interventions for non-amputees with similar issues to LLAs. Insoles seem to have certain features required of an accepted biomechanical intervention, such as being inexpensive and having feasible usage. These might lead to the users more readily accepting and using them for long time (Yardley et al., 2008). The effectiveness of insoles in decreasing lower back and lower limb pain (Dananberg and Guiliano, 1999; Mundermann et al., 2001; Larsen et al., 2002; Shabat et al., 2005; Mattson, 2008; Almeida et al., 2009; Cambron, J.A. et al., 2011; Castro-Méndez et al., 2013; Ferrari, 2013; Williams et al., 2013; Kendall et al., 2014; Sin Lee et al., 2015; Mehra et al., 2016; Cambron, J. et al., 2017), lessening overuse injuries (Mundermann et al., 2001; Larsen et al., 2002; Mulford et al., 2008; House et al., 2013), improving stability (Hijmans et al., 2007; Perry, S.D. et al., 2008; Liu et al., 2012; Losa Iglesias et al., 2012; Bateni, 2013) and lower limb kinetics, especially in the risk of knee osteoarthritis groups (Nester et al., 2003; Kakihana et al., 2005; Kakihana et al., 2004; Segal, N.A. et al., 2009; Nakajima et al., 2009; Abdallah and Radwan, 2011; Kang et al., 2013; Russell and Hamill, 2011; Radzimski et al., 2012), has been reported in non-amputees. These suggest an opportunity to alleviate the same problems suffered by LLAs (especially in major limb losses). This is a novel idea in LLA research.

To have an up-to-date understanding of the problems of LLAs which might be managed by orthotic interventions, a primary questionnaire-based study was designed. It was intended to explore LLAs' issues, the solutions to which might be matters of interest in biomechanical studies, as well as for rehabilitation service provider organizations. The study was conducted through an online questionnaire, which was administered to collect information about the experience of falling, lower back pain and several aspects of prosthesis use in lower limb amputees (the **P**rosthesis **E**valuation **Q**uestionnaire (PEQ) and **O**swestry Low Back Pain **D**isability **I**ndex (ODI) questionnaires and the **A**ctivity specified **B**alance **C**onfidence (ABC scale)). This study refreshes our knowledge related to these aspects of lower limb amputees' daily life, in addition to their effects on the LLAs' functionality and illustrates an up-to-date understanding of their problems and needs. The results of the survey related to balance deficiency in LLAs and its effect on their functionality was the fundamental reason for conducting the biomechanical study. The main objective of the research was to investigate the effectiveness of insoles use as a potential solution to the problems faced by prosthesis-wearers, particularly the dynamic and static balance deficiencies. Therefore, in this research, the instant effects of using a commercial insole for non-amputee participants and with the intact limb of trans-femoral amputees on the biomechanical variables of their normal self-selected speed walking and perturbed standing balance were investigated, and the two groups were compared. Further to this, the functional level of amputee volunteers in biomechanical tests was evaluated separately and the results reported, according to their spatio-temporal variables of walking and their self-reported answers to the PEQ-M and ABC scale questionnaire.

Research questions

The research questions that will be answered in the following chapters and which will help to achieve the objectives of the thesis are:

- What are the global causes of lower limb amputation and its prevalence? What is found in the literature about the biomechanical evaluation of balance by using force platforms in amputees?
- How does insoles use affect balance and overuse injuries in non-amputees?
- What are the main issues LLAs are facing regarding their amputation and prosthetic use, particularly related to their functionality in daily activities and balance deficiency? Is there any relationship between these issues?
- What are the biomechanical characteristics of trans-femoral amputees and non-amputees walking?
- How does insoles use affect the biomechanical variables of the amputees and non-amputees’ self-selected speed walking?
- What are the biomechanical characteristics of standing balance of trans-femoral amputees and non-amputees against a front/back-pulling load?
- How does insoles use affect the biomechanical variables of the amputees’ and non-amputees’ perturbed standing balance?

Thesis structure

The introductory chapter provides the general background to the importance of the study, and introduces the research questions, as well as the following chapters. Chapter 2 presents overall information about the prevalence of lower limb amputation and its causes, prosthetics device structure and the biomechanics of gait and standing balance. It also provides a review of the literature related to biomechanical studies of non-amputees’ and LLAs’ standing and gait, in addition to insoles application for improving balance and gait among non-amputees. The first and second research questions will be answered in this chapter. In addition, the aims and objectives of the research will be stated in its conclusion. Chapter 3 delineates the results of the online survey related to mobility and balance of LLAs on a self-reporting basis (the ABC scale questionnaire and PEQ-M questions). The third research question will be discussed in Chapter 3 based on the results of the survey, with a focus on balance and the mobility of the participants in the survey. The results of other parts of the survey are presented in Appendix D. Chapter 4 will provide the methodology of the biomechanical tests, including insoles selection, participant recruitment procedures, the utilized motion analysis systems and data collection procedures, in addition to the function level of amputees who participated in the biomechanical tests and a biomechanical evaluation/comparison of walking of trans-femoral amputees and non-amputees during self-selected speed in with/without insoles conditions. Research questions numbers 4 and 5 will be answered in Chapter 4. A biomechanical assessment of the perturbed standing balance of trans-femoral amputees and non-amputees in with/without insoles conditions, including a description of the perturbation set-up and tests, and answers to research questions 6 and 7 will be presented in Chapter 5. Chapter 6 will provide a summary of the research, a general conclusion and recommendations for future works.

Chapter 2
Literature review

2.1 Introduction

As was mentioned in the first chapter, the research idea which resulted in conducting the experiments presented in this thesis was developed due to the observed problems of lower limb amputees (LLAs) regarding their daily life. Therefore, related topics, including a brief background to the study (a definition of lower limb amputation, its common causes and prevalence; a brief review of lower limb prosthetic devices; and a biomechanical evaluation of human movement), the literature related to biomechanics of balance and walking of LLAs, in addition to the effect of insoles on balance and walking of non-amputees, will be presented in this chapter. This chapter provides the background of the studies presented in Chapters 3-5 and justifications for their methodologies and variables.

2.2 Lower limb amputation

Lower limb amputation is a surgical intervention below the pelvis to remove useless sections of the limb (e.g., because of deformities or deficiencies) or as a life-saving surgery intervention to cut out incurable parts (e.g., due to severe trauma and injuries, infection, poor blood circulation or cancerous tissues). Amputation might be unilateral (in one limb) or bilateral (in both lower limbs). The common levels of lower limb amputation are shown in Figure 2.1.

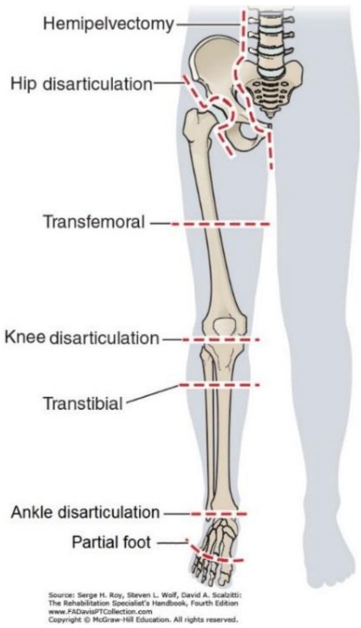


Figure 2.1 Lower limb amputation levels (modified from Roy et al. (2013))

Minor lower limb amputation refers to removing part or whole of the foot below the ankle joint versus major amputation, which happens above the ankle joint. Trans-tibial (TT) amputations occur below the knee, and include removing a portion of the shank, the ankle joint and the foot. Trans-femoral (TF) amputations happen between the hip and knee, whereby a portion of the femur, the knee joint, the whole of the shank, ankle joint and foot are removed (Bowker et al., 2002).

The statistical data related to the global rate of lower limb amputation are unclear because not all countries provide and publish up-to-date information in this regard. However, it is known that most amputations happen in lower limbs and at TT or TF levels (respectively, 47% and 31% of total limb amputation surgeries). The incidence of other levels of lower limb amputations, including joint disarticulation (where the amputation occurs through a joint and may be at the hip, knee, or ankle) and through the foot, are very limited (WHO, 2004). The majority of amputations occur due to diseases or trauma, while fewer lower limb amputation incidents are related to congenital deformities; work/farm machinery-related incidences; renal problems; complications resulting from orthopaedic injuries, such as serious infection or necrosis; failed orthopaedic internal prosthetic replacements and, finally, medical mistakes (WHO, 2004).

The causes of lower limb amputation are various and vary between, and even within, countries. More than 50% of amputations in developing countries happen due to traumatic causes (Iran (Sabzi Sarvestani and Taheri Azam, 2013; Rouhani and Mohajerzadeh, 2013), Pakistan (Soomro et al., 2013), India (Pooja and Sangeeta, 2013), Nigeria (Agu and Ojiaku, 2016)), while more than 50% of lower-limb amputations in developed countries (UK (Stewart, C P U, 2008), Australia (Lazzarini, P. A. et al., 2012), USA (Dillingham et al., 2002; Lazzarini, P. A. et al., 2012)) happen as the consequence of dysvascular diseases (mostly peripheral arterial and diabetes). Age and the cause of amputation are obviously interrelated. Lower limb amputation in war-involved countries is more common among the young persons (under 40), while limb loss due to diabetes or peripheral vascular (arterial) disease mainly occurs among the elderly (over 50) (NHSScotland, 2005; Wan-Nar Wong, 2005).

Diabetes as a dysvascular disease is one of the main reasons for lower limb amputation due to its complications in the form of lower limb neuropathy and poor blood circulation. The number of people with diabetes increased by about four times during 1980-2014 and reached approximately 420 million in 2017. In the same period of time, the incidence of diabetes in adults over 18 has grown dramatically (4.7% vs 8.5%) (WHO, 2017). It can be considered a source of worry that the rate of diabetes is high in the two most populated countries in the world. In 2013, around 10.4% of the Chinese population over 18 were diagnosed with diabetes, and 35.4% were in prediabetes stages (Wang et al., 2017). In India, 8.3% (approximately 60 million people) of the Indian population between the ages of 20-70 suffer from diabetes (WDF, 2016), and around 10% of the adult population are in prediabetes stages (Anjana et al., 2017). It is estimated that the number of Indians with diabetes will increase to 100 million in 2030 (WDF, 2016). A review article related to published databases related to lower limb amputation incidence-related diabetes (during the years 1989-2010 and including databases from Australia, Denmark, East Asia, Finland, France, Germany Japan, Italy, Netherland, Norway, Spain, Sweden, Switzerland, Taiwan, UK and the USA) shows that the incidence is highly variable around the world and is ethnic/area/gender-dependent (Moxey et al., 2011). The paper represents the wide range of major lower limb amputation incidence, reporting a lower rate for women: 46.1 to 9600 per 100,000 (Spain vs Louisiana, USA) in a population with diabetes; 1.5-20 per 100,000 (Spain vs Germany) in a population without diabetes; and 5.8-31 per 100,000 (Italy vs Germany) for a total population. The reviewed paper introduced diabetes as the reason for almost 40% of all lower limb amputations. In the USA, the rate of amputation was higher for African American and Native American than Non-African American. In the UK, the rate for Asians is lower than for white Caucasians, and the lower limb amputation incidence for British African Caribbean population is lower than in the European population (Moxey et al., 2011). According to a WHO report in 2010, in developed countries, lower limb amputation is 10 times more likely to happen in people with diabetes than in those living without diabetes. In addition, the cause of more than 50% of non-traumatic lower-limb amputations is diabetes (WHO, 2010). However, a recent study has shown the incidence of amputations due to diabetes decreased in the UK between 2003 and 2013, in spite of a growing rate of the condition. However, the ratio of major lower limb amputations among persons with diabetes remained six times more than among the non-diabetes population. Interestingly, about half of the amputations were due to non-diabetic reasons. It shows the successful implementation of health care programs for persons with diabetes have led to a reduction in the amputation rate (Ahmad et al., 2016)

Patients with peripheral arterial disease as another main dysvascular disease are also at risk of lower-limb loss due to poor blood circulation and as a consequence of changing to ischemic limb and infection. Peripheral arterial disease is an unclear/multi-causal disease, with diabetes a likely risk factor for it. Incidence is strongly age-related and increases from about 5% at middle age (45-49 years) to 15-20% at old age (85-89 years) (Fowkes et al., 2017). A study in China has shown more than 60% of lower-limb amputations in elderly patients were due to a vascular deficiency (Wan-Nar Wong, 2005). It seems the disease incidence is related to the economic condition of the societies it occurs in as well. In 2010, approximately 70% of about 200 million worldwide patients with peripheral artery disease were living in low/middle-income countries. In addition, the incident of the disease grew by about 28% in low/middle-income countries and by about 13% in high-income countries during the years 2000-2010 (Fowkes et al., 2017).

Besides diseases which might lead to amputation, severe traumatic events may also result in limb loss. Amputation because of weapon explosions is the main reason for trauma-related amputation in countries involved in recent wars or terrorist attacks. However, even after the cessation of hostilities, the hazards to life and health due to unexploded ordnance, such as landmines, continue to exist. There are approximately

110 million landmines, or similar exploding devices, in 70 countries around the world. Eighty percent of landmine blast victims are civilians, particularly children. Each year, 15000-25000 persons are injured or killed due to explosions. Fifty percent of the victims lose their lives during the first hours of injury and 1/3 of the survivors need amputations, mostly in lower extremities (Walsh and Walsh, 2003). For better understanding of the danger, it is worthwhile knowing that, according to the Landmine Monitor 2005 report, there are stockpiles of more than 160 million antipersonnel mines in six countries (approximately 110 million in China, 26.5 million in Russia, 10.4 million in the USA, 6 million in Pakistan, 4-5 million in India and 2 million in South Korea). The report also mentions the name of 13 countries as producers or right keeper of producing antipersonnel mines (Burma, China, Cuba, India, Iran, North Korea, South Korea, Nepal, Pakistan, Russia, Singapore, United States and Vietnam) (Landmine and Cluster Munition Monitor, 2005). This information reminds us of the existence of a large potential for further amputations.

Traffic accidents are another traumatic cause of lower limb amputation, but the rate is not globally well-documented. During 1988-1996 in the USA, lower limb loss because of traffic accidents made up approximately 1/3 of traumatic amputations, and most involved pedestrians and motorcyclist (Dillingham et al., 2002). According to a report related to injuries due to motorcycle crashes in the USA, 3% of all leg injuries led to lower limb amputations (Hanna and Austin, 2008). In a study related to traumatic amputations during 2009-2013 in China, about 70% of lower limb amputations were due to traffic accidents (Dou et al., 2016).

In addition to these data, we know, in spite of health care discrepancies, worldwide life expectancy has increased (WHO, 2016): the world’s population is getting older (UN, 2017). This implies that, along with an expectation of an increase of incidences due to the growing world population, the number of people involved in complications related to older age (such as dysvascular diseases, including diabetes and peripheral arterial disease) will also grow. These facts remind us that, in addition to the longer life of current amputees, amputation will continue to exist and to pose challenges in different aspects of life for different parts of society.

2.2.1 Prosthetic device

Lower limb amputation changes the appearance of the body, affects amputees’ mobility and, possibly, their independence in normal life (Gitter, A and Bosker, 2005a). Humans since ancient times have tried to retain lost limb function by adding an external replacement. The replacement (called a prosthesis) has considerably improved over time, particularly after World War II and during recent years, due to scientific progress in material and computer sciences. A prosthesis can be simply defined as an artificial device to substitute the function and cosmetics of a missing part of the body. As the main task of a normal lower limbs is both weight bearing and locomotion, their loss affects these performances. Thus, the lower limb prosthesis must provide and restore stability, mobility and an appropriate appearance for an LLA (Bowker et al., 2002).

To fulfil these purposes, the lower limb prosthesis has different components based on the level of amputation. There is less function lost in a minor amputation, and often a shoe filler might restore the most part of foot function and appearance. But major amputations need more complicated structures. A prosthesis for TT amputees is called a below-knee (BK) prosthesis and has four main structural components, including an artificial foot-ankle, shank, socket, and suspension system. An above-knee (AK) prosthesis has a knee unit as an additional component (Bowker et al., 2002) (Figure 2.2).

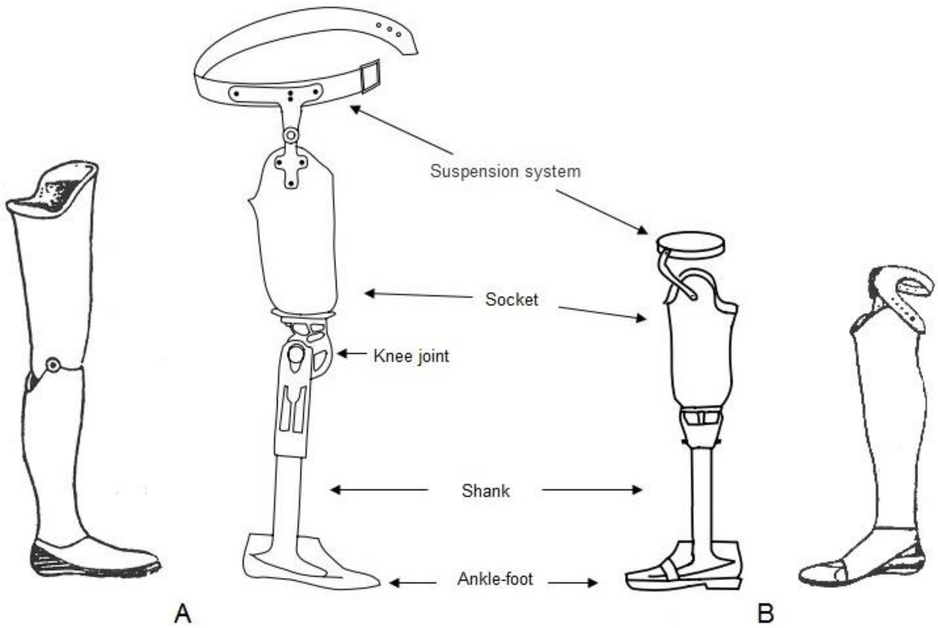


Figure 2.2 Main components of Above-knee (A) and Below-knee (B) prostheses (Modified from Berger and Fishman (1997); WHO (2004))

The foot-ankle complex is the most distal part of the lower limb prosthesis and is in contact with the base of support during locomotion. It must resemble the appearance and function of the normal foot by providing stability, simulating ankle motions and perform shock absorbing during standing and walking. The ankle-foot can have a moving ankle joint (such as in single-axis or multi-axis prosthetic feet) or the ankle movement may be mimicked by mechanical features and the structure of the prosthetic foot (such as in the SACH foot and Dynamic-Response Foot). In recent years, a new category of ankle-foot complex has been developed which uses computer-controlled sensors to receive information related to the limb position, velocities and acceleration from other limbs and environments to provide an appropriate position (Microprocessor-controlled feet). The role of the prosthetic shank, as in the normal leg, is to transfer the weight of the body to the foot and ankle. The shank section fills the distance between the socket and foot-ankle component in a BK prosthesis. For an AK prosthesis, it is located between the knee unit and the foot-ankle component.

Prosthetic knees have to simulate normal knee function by supporting the body weight during standing, by flexing and extending smoothly and in a controlled manner during walking, and by supplying unrestricted flexion for sitting and activities requiring knee bending for knee disarticulated and TF amputees (Bowker et al., 2002). Prosthetic knee joints are categorized as mechanical or computerized according to their control system of flexion. Mechanical knees (including single-axis or multi-axis knee systems) passively control the knee motion during stance and swing phases via constant friction, weight-activated friction or fluid-controlled (pneumatic or hydraulic) mechanisms. Computerized systems, which are more sophisticated and expensive prosthetics, have been developed during recent decades. They are featured by sensors, a microprocessor, software, a resistance system and a battery. The knee component of computerized prostheses is programmable and it regulates the knee joint dynamics through the analysis of the sensor feedback and the simulation of eccentric muscle activities to resist knee flexion and provide more precise adjustments to walking demands, such as walking on stairs or a hillside or changing the speed of walking (Gard, 2016). Most prosthetic knees are passive but, recently, several commercial designs of active microprocessor knees have become available for TF amputees. These prosthetic knees simulate both the eccentric and concentric activity of knee muscles. In addition, they control knee motion while providing its active motion by utilizing an electronic motor (Creylman et al., 2016). But these advanced prostheses are expensive and require specialists to adjust/readjust them for amputees with different needs. In addition, they require a high level of particular care for maintenance and optimized performance. Thus, despite their advantages, it is passive mechanical prosthetic devices that are more commonly found around the world.

The anatomical residual part of an amputated limb is called the stump. The socket is the part of the prosthesis that is directly in contact with the stump and surrounds it firmly. It is fabricated individually for each amputee based on a positive cast of the stump. As bodyweight transfers from stump to the socket and then onto the other prosthetic components, a proper ‘fit’ between the stump and socket is important. This is gained by the modifications that are applied to the positive cast of the stump. The socket is distally attached to the upper end of the knee component (for shorter stumps, to the proximal part of a filler between the end of the stump and knee joint to gain thigh length) in an AK prosthesis and to the shank component in a BK prosthesis (Bowker et al., 2002).

Another important component of any limb prosthesis is the suspension mechanism. The suspension system is related to how the prosthesis remains on the user’s residual limb properly and continuously during daily activities. The design of the socket (for example, a suction socket) provides suspension in most prosthetic limbs. Using additional devices, such as a pelvic belt for AK prostheses and supracondylar strap in BK prostheses, also helps to maintain congruity of the prosthesis and the stump during daily application (Bowker et al., 2002).

Prosthetic devices might be categorised according to their main structures as exoskeletal (Figure 2.2-A-left and B-right) or endoskeletal (Figure 2.2-A-right and B-left). These terms also refer to how the weight of the body is transferred to the ground via the prosthesis and how cosmetic appearance of the prosthesis is provided. The outside part of an exoskeletal prosthesis (also called conventional or crustacean) is hard and is formed by laminating the shaped light wood or hard foam attached to the socket to restore the appearance of lost parts (part of the shank and/or thigh) and to transfer weight to the ankle-foot component. In an AK prosthesis, the knee joint (which may have a simple structure and/or control system) will be embedded between the thigh and shank segments. Due to inadequate space for bulky exoskeletal prosthetic knee joints, these prostheses are not appropriate for amputees with long TF stumps or for knee disarticulated amputees. In endoskeletal prostheses, a light metal tube plays the role of the central limb structure. If an amputee prefers a natural appearance, a body-coloured compact foam covering is applied to the prosthesis. The prosthetic components' alignment cannot be changed in the final exoskeletal prostheses, but adjustment is possible in the endoskeletal prosthesis. Endoskeletal prostheses have been more favoured and used in recent years because of their lightweight, their better cosmetic options, the availability of more advanced knee and foot components, being proper for all levels of amputation, having the possibility of feasible alignment changes and the shorter time needed for fabrication. However, in comparison to the exoskeletal prosthesis, they are less durable and more expensive (Kumar and Kumar, 2001).

2.2.2 Lower limb amputees' problems

A large number of studies have investigated different aspects of being an LLA and using a prosthesis in their daily lives. There are many studies which have evaluated psychometric conditions, *Quality of Life* (QOL), prosthetic function, mobility levels and physical issues in LLAs. Some studies have shown that musculoskeletal issues are part of many LLAs' lives. Lower back pain (Ehde et al., 2000; Hagberg and Branemark, 2001; Ehde et al., 2001; Kulkarni et al., 2005; Ephraim et al., 2005; Kusljugic et al., 2006; Abdul-Sattar, 2007; Smith et al., 2008; Taghipour et al., 2009; Ebrahimzadeh and Fattahi, 2009; Ebrahimzadeh and Hariri, 2009; Hammarlund et al., 2011; Hafner B et al., 2013; Devan et al., 2017; Morgan et al., 2017), falling incidents (Kulkarni et al., 1996; Miller, W C. et al., 2001; Wong et al., 2016; Steinberg et al., 2019) and injuries due to falling (Wong et al., 2016; Hunter et al., 2017) are seen too frequently among LLAs. In addition, some biomechanical research has shown unilateral LLAs rely more upon their contralateral intact limb (Nadollek et al., 2002; Farahmand et al., 2006; Vrieling et al., 2008a; Lloyd et al., 2010; Morgenroth et al., 2012). As a consequence of higher loading on the intact limb, it can be painful (Ehde et al., 2000; Hagberg and Branemark, 2001; Ephraim et al., 2005; Abdul-Sattar, 2007; Ebrahimzadeh and Fattahi, 2009; Ebrahimzadeh and Hariri, 2009; Hafner B et al., 2013; Morgan et al., 2017) and prone to osteoarthritis (Gailey et al., 2008; Struyf et al., 2009; Farrokhi et al., 2016).

The level of amputation is also important in the active parts of amputees' daily routines. Higher levels of amputation and bilateral amputations are associated with more problems and complications. TT and TF amputees spend, in turn, about 30% and 70% more energy than a normal person during activities such as walking (Stewart, C.P.U., 2008).

The musculoskeletal problems have been addressed by rehabilitation programs, including exercises and training in occupational therapy or physiotherapy disciplines. The effectiveness of musculoskeletal rehabilitation programs on gait, balance and the mobility of LLAs has been documented by Ülger et al. (2018). In various studies, the positive effects of muscle strengthening on LLA's LBP (Shin, M.K. et al., 2018; Gordon and Bloxham, 2016; Anaforoglu et al., 2016), their balance enhancement via training on balance boards (Sethy et al., 2009), and the positive effect of exercise on the QOL and mobility of bilateral amputees (Li et al., 2019) have been reported. Moreover, the use of new technologies (using home video games with a balance platform (Andrysek et al., 2012), computerized dynamic posturography systems (Mohamadtaghi, B. et al., 2016), and vibratory feedback (Rusaw, D. et al., 2012)) for improvement in the balance of LLAs has been associated with successful results. In addition, the effects of various prosthetic components and their alignment, or socket designs, on different aspects of lower limb prosthesis users' locomotion have been presented in many papers which lie beyond the scope of this study. However, it can be said that these show a heavier focus of research on the prosthesis aspect of amputees in comparison to their intact limb.

It has also been reported that lower limb amputation and prosthetic use might affect the QOL of amputees. The QOL is a multidimensional concept and is affected by different factors, including the level of health and social interactions, education, experiences of life, one's employment, economic safety and income, basic rights, and one's natural and living environment (Eurostat, 2017). Concerning areas of interest for this study, the level of health and social interactions aspects of QOL can be covered by mobility, balance confidence and pain experience in LLAs. In addition, changes in physical performance after amputation (including falls and being worried about them) can negatively affect more aspects of the QOL, such as one's overall experience of life, employment activities, and economic and income security. Accordingly, one of the studies presented in this thesis (with details in Chapter 3) was designed to conduct a comprehensive online survey in order to collect up-to-date information about the problems suffered by LLAs and their inter-relationships, with a focus on balance, functionality and mobility in daily activities.

2.3 Biomechanical evaluation of human locomotion

Human locomotion can be studied from different points of view, including biomechanics. According to the late Professor Herbert Hatze's definition, "Biomechanics" is:

> *"The study of the structure and function of biological systems by means of the methods of mechanics."*
>
> Hatze (1974), page 189

Motion analysing techniques as part of biomechanics provide a quantitative evaluation of different human movements. Motions can be studied without reference to the forces causing them: for example, the description of linear and angular displacement and velocities (kinematics) or in the examination of forces and accelerations making the movement (kinetics) (DeLisa, 1998). Static and dynamic analysis are other ways of categorizing biomechanical studies. In static analysis, the biomechanical characteristics of a stable object (without movement or not moving at a constant speed, such as standing) is evaluated while, in dynamic analysis, the object has acceleration (such as walking) (Hamill et al., 2015). Studying and comparing the kinetic and kinematic characteristics of locomotion in normal and affected groups (such as LLAs) helps us to gain an understanding of how adaptation strategies are used in the altered tasks (Sanderson and Martin, 1997). Motion analysis can also help to evaluate the effects of a particular treatment (e.g., neuromuscular surgical interventions or rehabilitation treatments, including orthotic and prosthetic devices) on movement performance (DeLisa, 1998).

Currently, a wide variety of instruments are used in human motion analysis. A basic motion analysis system usually includes cameras for recording the patterns of the motion tasks, from which the kinematic data can be extracted later. Although there are marker-less motion analysing systems, normally, movements are recorded via attached reflective markers to body segments and their path is tracked during motion tasks. Kinematic characteristics of body segments are calculated by related software using the position of the markers. Inverse dynamics calculations permit the lower limb joint movements and joint forces to be considered part of kinetics. These can be derived by using kinematic data and spontaneous force data obtained from force platforms, in combination with anthropometric data (Winter, 1995). Force platforms are the most commonly used devices to evaluate human postural function in different conditions and groups (Paillard and Noe, 2015). Force platforms also provide a centre of pressure (COP) measurement whilst the feet are in contact with them, which is useful for balance evaluation and kinetics calculations. COP is the action point of the ground reaction force vertical component on the plantar surface of the foot (Winter, 1995). In addition to these instruments, electro-goniometers and accelerometers are also used for recording joint angles and the acceleration of body parts. Foot switches are fitted in shoes and provide only the temporal characters of gait (e.g. duration of step and stride, stance, swing, and double support), while gait mats are portable walking paths. These also give spatial characters of walking (e.g. step and stride length). Pressure insoles and pressure mats can be used to obtain and record the pressure applied beneath the feet. Electromyography (EMG) systems can be utilized to record muscle activation patterns during any activity (DeLisa, 1998).

The biomechanical tests of this study to evaluate standing balance and gait of TF amputees were conducted in two separate locations and by using two different but similar marker-based motion analysis systems: the Qualisys Motion Capture system (comprising infra-red cameras with two AMTI force platforms) and the Vicon motion capture system (comprising infra-red cameras with two Kistler force platforms). More details are available in Chapter 4, the methodology section.

2.4 Standing Balance

Stability can be defined as equilibrium, which means the ability to withstand a force trying to alter linear or angular speeds. The ability of an object to maintain stability is called balance. The stability of an object depends on several mechanical factors: the relationship between the position of the centre of mass (COM) and the base of support (BOS), the size of the area of the BOS, the height of the COM and the mass of the object (Hamill et al., 2015). The COM is an imaginary point at which the total body mass can be assumed to be concentrated. Balance in human biomechanics refers to the ability to control the body position (COM) related to the BOS during a static or dynamic activity. For example, in standing, if a body's centre of gravity (COG: the vertical projection of the centre of mass on the ground (Winter, 1995)) remains in the area between the margins of two feet (BOS), the person will have balance and will not fall (Knudson, 2012). But, it is important to remember, the human centre of mass is placed at around 55%-60% of the height above ground (Pawlowski and Grabarczyk, 2003; Virmavirta and Isolehto, 2014; Hamandi, 2012), which makes our body a mechanically unstable object. Thus, the presence of a control system is necessary to continuously maintain stability in static and dynamic conditions. The control is provided by the central nervous system (CNS) commands to the musculoskeletal system. It stabilizes the body proactively (when imbalance happens intentionally: for example, due to the movement of part of the body) or reactively (in response to an unexpected external imbalance). Besides the mechanical factors, three sensory systems (the vestibular, somatosensory and visual systems) are involved in the balance maintenance of humans. The visual system is primarily utilized to know about the circumstance of the body's location and head position and, accordingly, plan themaintenance of balance. The somatosensory system receives information about the position and movement of all body segments (including the skin, joints and muscles, each with different receptors inside of them) relative to each other, in addition to the external environment. It provides a conscious perception of touch, pressure, pain, temperature and vibration. The vestibular system senses directional information and accelerations. It is related to the head position and the middle ears (Winter, 1995). In an environment with enough light, a healthy person depends on the somatosensory system (70%) more than the vestibular (20%) and visual (10%) systems to maintain postural stability (Horak, 2006). The system model of postural stability shows that balance achievement is dependent on the task a person needs to do, and the environment. The CNS receives information from the environment by the sensory system and interprets it to know the position of the body in space. Then, it decides which movement or prevention of movement are needed and, subsequently, sends commands to the related muscles in the trunk and lower limbs to provide postural adjustments. Postural control has a constant and cyclical nature (Figure 2.3) (Allison, 2012).

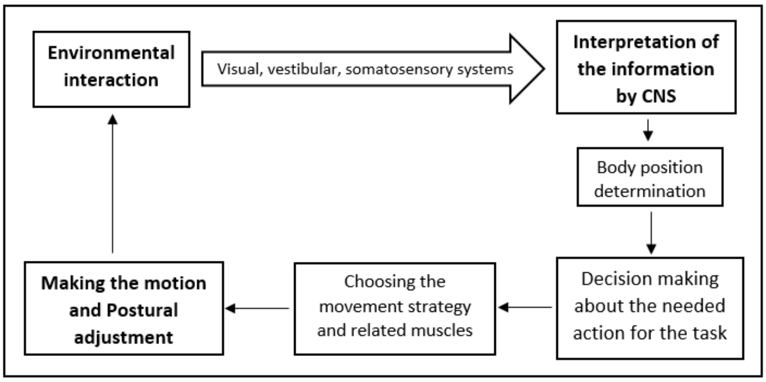


Figure 2.3 Model of postural control (reproduced from (Allison, 2012)

Moving strategies are reactive and automatic responses to external perturbation during standing to keep stability. In reaction to a small, slow, and anteroposterior perturbation on a stable surface, the body rotates about the ankle joints on fixed feet to keep the COM over BOS (Figure 2.4-A). When the perturbation is bigger and faster, for example when standing on an unstable surface, or disturbed in a mediolateral direction, (or combinations of these conditions), the addition of a hip control strategy is used to assist the maintainance of stability. In the hip strategy, movement of the upper body and hip are in opposite directions (Figure 2.4-B). Due to a large perturbation which results in movement of COM out of BOS, a stepping strategy happens to move the boundary of the BoSs (Figure 2.4-C), or a reaching movement by upper limbs occure tp counter the the movement of the COM. The suspensory strategy is another movement strategy which has been mentioned less frequently in the literature. As seen in Figure 2.4-D, in this strategy, stability is increased by lowering the COM height via knee flexion. This strategy is used in more complex tasks, such as windsurfing, which need stability during the movement of the body and the BOS together (Allison, 2012). It is interesting to note that for an old person at risk of falling, the preferred strategy is to use the stepping, reaching and hip strategies, while a person with a lower risk of falling favours the ankle strategy (Horak, 2006).

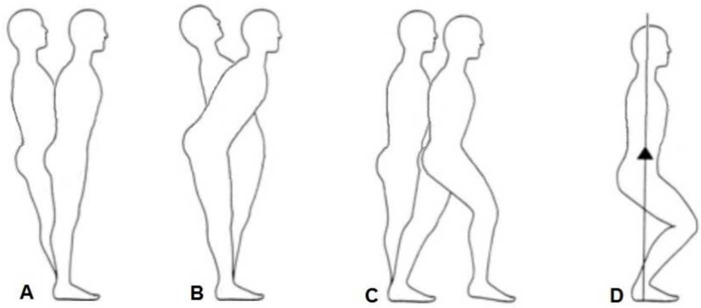


Figure 2.4 Movement strategies. A: Ankle strategy, B: Hip strategy, C: Stepping strategy, D: Suspensory strategy (modified from Allison (2012))

Postural control is achieved via interaction between several subcomponents; these are shown in Table 2.1. In the assessment of balance and investigation into imbalance, all of these factors need to be considered. Impairment in any of these subcomponents, or combinations of them, might lead to instability in different tasks or environmental conditions. Experience and practice are also important factors in the maintenance of stability (Horak, 2006).

Table 2.1 Subcomponents of postural stability (Allison, 2012; Horak, 1997; Horak, 2006)

Subcomponent	Elements	Description
Biomechanical features	• Stability limits • Alignment of body's segments • Joints movement • Muscles contraction	The relation between BoS and CoM, joints' ROM and stiffness, muscles' strength and tone (especially abdominals, paraspinals, hamstrings, quadriceps, gastrocnemius, tibialis anterior)
Movement strategies	Automatic or reactive responses	COM maintenance over BoS in response to an external perturbation by the implementation of the ankle, hip, or stepping strategies
	Anticipatory	In the prediction of destabilisation due to a voluntary movement of body segments
	voluntary	Changing of the COM position to facilitate performing of different tasks
Sensory strategies	Combining	Integration of information from the sensory system
	Reassessment and reweighting	Continuously reassessment of the information from the sensory system to recognize the changes, and then execution of a proper response to them including sensory dependence
Orientation in space	• Motion perception • Gravity, surface vision • Verticality perception	For example, aligning body to gravitational while visual inputs are eliminated
Control of dynamics	• Locomotion (gait) • Moving of body segments	The COM taking place out of the BOS during locomotion
Cognitive processing	• Attention • Learning	The more complex postural tasks need more Cognitive processing

Falling as an imbalanced condition can happen due to a deficiency or combination of several impairments to the subcomponents of postural control. A fall is defined by the WHO as *"inadvertently coming to rest on the ground, floor or other lower level, excluding intentional change in position to rest in furniture, wall or other objects"* (WHO, 2008).

Around 30% of physically active older adults in developed countries fall every year. Most falls will not lead to life loss, but 5%–10% of falls result in serious injuries, such as head injuries or bones fractures (Deandrea et al., 2010). It is possible to categorize the factors involved in falling occurrences into intrinsic (related to the person) and extrinsic (outside of the person, such as the environment) elements. Old age, an experience of a previous fall, muscle weakness, gait and balance problems, poor vision, postural hypotension, chronic illness such as arthritis, diabetes or neurological disease (for example, stroke, Parkinson's), and fear of falling are the intrinsic factors. While environmental risks such as a lack of handrails, stairs, a lack of bars in the bathroom, weak lighting, slippery and uneven surfaces, psychoactive medications, and improper use of assistive devices contribute to the extrinsic aspects of a fall occurring (STEADI, 2017).

A review study has shown that injuries due to falling are common among LLAs (40-60%). In addition, it is known that there are a number of common risk factors among older people and LLAs (Hunter et al., 2017). The risk of falling is higher in older people with gait problems and who have a history of falling, who use walking aids, and/or who experience vertigo (Deandrea et al., 2010), all of which can exist for LLAs irrespective of age.

To date, numerous studies have investigated human balance from different angles, including biomechanics during different activities, especially walking and the transition from walking to standing or sitting, and vice versa. Due to the focus of our study being on standing balance, the literature related to biomechanical studies about standing balance in fallers and non-fallers and in LLAs and non-amputees that utilize a force platform will be reviewed in this section. The parameters related to the COP and the COM (such as location with regard to foot parts, sway or displacements, and velocities) are traditional variables for biomechanical evaluation of standing balance when using single or two force platforms (Palmieri et al., 2002; Ruhe, A. et al., 2010; Paillard and Noe, 2015). In fact, changes in the COP and COG represent neuromuscular functions during postural stability (Winter, 1990). The COP excursion area is the total area covered due to displacements of COP in mediolateral and anteroposterior directions. The COP path length or excursion refers to the distance the COP travels during the balance task. The COP's velocities are calculated by dividing the anteroposterior or mediolateral displacements by the trial time. The COP's root mean square (RMS) is another common variable used in balance assessment. The amplitude of each of these variables is obtained by subtracting their lowest value from their highest value. Smaller values for the path and velocities are indicators of better balance control. Postural sway is related to COP displacement and body sway refers to COM displacements (Paillard and Noe, 2015). Different factors are attributed in the sway, such as the noise within the human neuromuscular system, as the result of an active anticipatory search process, or as an output of a control process to maintain postural control (Ruhe, A. et al., 2011).

In this thesis, we decided to use a mechanical disturbation in the form of a pulling/releasing load to study the bipedal standing balance of TF amputees (presented in Chapter 5). Bearing in mind the subcomponents of postural stability (Table 2.1), the postural conditions might be disturbed mechanically or by sensory/cognitive manipulation to challenge the control system. In mechanical disturbance, destabilization happens due to an external disturbation which changes the position of the COM and impels the person to restabilize the body: e.g., by applying a pushing or pulling force to the trunk. Some researchers focus on the effects of visual inputs and the somatosensory system on balance. For these purposes, they respectively design open-eyes/closed-eyes and moving/unstable BOS or surrounding environment test conditions. Postural control is assessed via the COG position, and sways in computerised dynamic posturography (CDP), during manipulation of the visual, vestibular and somatosensory inputs (Lipp and Longridge, 1994). Another way to evaluate balance control in a manipulated cognitive system is by adding an attention-demanding task, such as counting, to the balance tests (Paillard and Noe, 2015).

The evaluation of standing balance's variables in different foot positions (Figure 2.5) is common and offers a better understanding of balance control in groups which are facing balance challenges: e.g., older people with falling experience (Paillard and Noe, 2015). However, methodologies have not been completely standardised. For example, (Pinsault and Vuillerme, 2009) found that the COP features during more than two repetitions of 30 seconds standing trials are reliable for evaluation of balance, while (Ruhe, A. et al., 2010), after reviewing 32 related papers, suggested averaging 3–5 trials with 90s duration as a proper data set for assessment of bipedal standing balance.

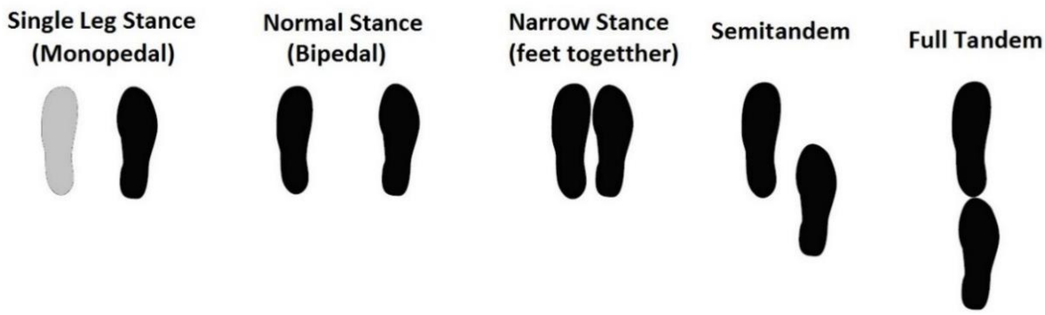


Figure 2.5 Possible foot positions in different balance studies (modified from Paillard and Noe (2015))

In the following section, having a focus on the study of balance in LLAs, only statistically significant results (p-value<0.05) of studies related to bipedal open-eyes balance on a stable BOS since 2000 are represented.

2.4.1 Biomechanics of standing balance in non-amputees (fallers and those suffering from LBP)

As mentioned in the previous section (standing balance), assessment of the COP and COM excursion during standing balance is the most common method of biomechanical evaluation of human balance; this will be assessed in this thesis too. There is a huge interest in analysing healthy fallers (without any impaired balance due to vestibular or nervous system disease), particularly elderlies' standing balance, through utilizing force platforms. As standing balance on a stable force platform will be studied in this research, only related papers, and not those with moving BOS, will be reviewed. As in many research subjects, contradictions are seen among the published results.

COP excursion during any movement is unconscious and reflects the activity of the motor system in moving the COM and, very frequently, is used to evaluate human balance characteristic. Several studies have shown the movement of the COP in a mediolateral direction during standing balance might be a proper variable to distinct fallers. A greater mediolateral COP sway for fallers during simple standing (Bergland et al., 2003; Stel et al., 2003; Melzer, I. et al., 2004; Melzer, I et al., 2010) and dual tasks (Bergland and Wyller, 2004) has been reported in several studies. However, in observations of a larger mediolateral displacement of the COP during dual tasks (such as trunk bending/ erection, cyclical arm raised/ lowered) in both elderly fallers and non-fallers, the displacement was smaller for fallers (Park, J.W. et al., 2014). In addition, decreased mediolateral displacement of the COP of fallers was recorded during dynamic tasks such as arm lifting or trunk bending while standing (Park, J.W. et al., 2014).

It has been shown that if the BOS has enough width, mediolateral motion of the COP does not differ between fallers and non-fallers. Instead, it has been reported that the anteroposterior stability is more challenging, with a larger sway of the COP in this direction for fallers (Howcroft et al., 2017; Muir et al., 2013). Pajala et al. (2008) also considered the observation of a greater COP displacement, particularly in the anteroposterior direction during standing balance, as a predictor of indoor falling in old age. Since outdoor falls are more often due to environmental or task-related reasons in comparison to impaired balance control as the cause of indoor falls, a higher anteroposterior COP velocity also has been reported for elderly fallers during comfortable standing (Hewson et al., 2010; Muir et al., 2013). However, observation of no difference between the COP sway of fallers and non-fallers during a standing comfortably position or with feet together has also been reported (Sihvonen et al., 2004; Lajoie and Gallagher, 2004). A larger range of mediolateral and anteroposterior displacements, total length of sway, speeds and acceleration of the COM have been reported in elderly fallers compared with non-fallers during quiet and semi-tandem standing (Doheny et al., 2012).

In a study of perturbed standing balance of fallers (via a lateral pulling load to the waist), the COP was more medially located in fallers before recovery stepping, which resulted in a smaller distance between the COP and COG locations. It was considered to be the formation of smaller functional boundaries for the BOS according to the distance between the COP and COG, while the fallers' traditional BOS was equal or larger than the non-fallers' (Fujimoto et al., 2015).

Similar to the biomechanical differences between fallers and non-fallers during standing balance, balance features in people with non-specific low back pain (LBP) are also different from individuals without the pain (Berenshteyn et al., 2018). We know LBP is a common phenomenon among LLAs, with a reported prevalence of 39% in (Morgan et al., 2017) study to 77% in (Taghipour et al., 2009) study, in research which had more than 100 participants from all levels of lower limb amputation. As the COP is a common variable to evaluate balance, the studies which concentrated on COP excursion during standing balance of individuals with LBP might suggest matters of interest. Equivocal COP characteristics are observed in the related literature. A forward trunk inclination and a position of COP in the forefoot was observed among young persons with LBP in comparison with a healthy group during closed-eyes trials (Brumagne et al., 2008). MacRae et al. (2018) and (Mok, N. et al., 2004) did not observe any differences between COP displacements but did detect a lower velocity of COP during standing balance of individuals with LBP. Lafond et al. (2009) reported higher levels of both 60 s mediolateral and anteroposterior COP frequencies (around twice as many), less than double the mediolateral COP speed, and around two-fold of anteroposterior COP displacements during prolonged standing (30 minutes) for healthy subjects in comparison to persons with chronic LBP. In contrast to Lafond’s study, larger mediolateral and anteroposterior COP displacements (Mann et al., 2010; Mazaheri et al., 2014) and larger areas of COP excursion (Braga et al., 2012) were reported for individuals with LBP in comparison to healthy participants during shorter quiet standing (30 s). Ruhe, A. et al. (2011) reported almost the same results with larger COP excursion and speeds for people with LBP in a review of studies related to their standing balance. In addition, these researchers found a positive relationship between the intensity of pain and the mean velocity of COP in anteroposterior and mediolateral direction (Ruhe, Alexander et al., 2011). Interestingly, the decreased COP sways following manual interventions were associated with the decline of pain intensity (Ruhe, A et al., 2012). A larger COP velocity in the anteroposterior direction, in addition to a greater range of COP displacement in both anteroposterior and mediolateral directions, and longer recovery time to reach a stable COP, was observed in the perturbed balance of subjects with chronic LBP (Lee et al., 2016).

As a conclusion, the results of different studies show inconsistent outcomes related to COP changes during balance tests in individuals with falling experience. It is beneficial to remember that most of the faller-related studies have been conducted with elderly participants. It seems a lower level of health and fitness in old age might affect balance control (Roman-Liu, 2018). The changes occurring in the nervous system and muscle activities during the ageing process affect control of the body posture and may contribute to age-related balance deficiencies (Melzer, I et al., 2010). The conflicting results might be due to the difference of participants’ BOS largeness, the length of data collection and even the definition of a “faller”. Melzer considered standing on a narrow base of support a more challenging condition and provides an opportunity to observe differences between fallers and non-fallers’ COP excursion (Melzer, I. et al., 2004; Melzer, I et al., 2010). In addition, some studies categorize a person with just one falling event as a faller, while there are studies which consider repeated events as a requirement of being defined a faller (Rugelj et al., 2013). It is also important to know the origin of imbalance (Table 2.1) in fallers and the mechanisms their body applies to compensate for the deficit. The presence of pain and the intensity of it, age groups, footwear, or person to person differences in balance characteristics and differences in muscle co-activation and sensory system involvements can affect results. Abrahamova and Hlavacka (2008) found larger body sway and COP excursion in the standing balance of people older than 60 years of age. In fact, body sway and COP velocities are related to age and are higher in older in comparison to younger people (Roman-Liu, 2018). Greater body sway has also been observed in obese individuals and, consequently, they suffer a higher risk of falling (Frames et al., 2018). Unexpectedly, Jorgensen et al. (2012) reported balance data that were statistically different when testing before and after noon. Even the orientation of the feet on the force platform (Azzi et al., 2017) and the distance between them (Bonnet, 2012) can affect the balance data. Sway changes in individuals with LBP can be due to proprioception changes or them being conscious of their pain (Karimi and Saeidi, 2013). At the same time, it has been seen that people with chronic LBP have a stiff posture and, consequently, might have less sway (Lafond et al., 2009). On the other hand, fatigue of the spinal muscles in individuals with LBP happens faster (Kendall et al., 2014), which might reduce their control on body sway. Interestingly, visual inputs seem an important factor in balance control of individuals with LBP (Mann et al., 2010; Mok, N.W. et al., 2004) and older people (Roman-Liu, 2018). Balance and LBP are multivariate phenomena and to have an isolated sample to study is almost impossible. A trend has been developing in recent studies related to standing balance whereby classical raw COP data is used as the input for innovative balance scoring calculations or non-linear models (Fino et al., 2016; Barton et al., 2016; Zhou et al., 2017; Audiffren et al., 2016; Tuunainen et al., 2014; Swanenburg et al., 2010). These methods might open new perceptions of differences in the balance biomechanics of individuals with impaired balance, those at risk of falling, and those with LBP. It seems to be beneficial to use the new models of balance evaluation, combining force platform data with the results of questionnaires related to balance confidence and LBP disability levels for fallers and individuals with LBP. Interestingly, two-point discrimination on the first toe of elderly fallers is different from non-fallers (Melzer, I. et al., 2004). In addition, decreased skin sensation of feet plantar surfaces in fallers (Fujimoto et al., 2015) and individuals with chronic LBP (Lee et al., 2016) has been observed. Thus, to examine these sensations as well as the COP displacements might provide more precise information about the balance of these groups of people. Yet the body sway and COP parameters during standing can still be considered a reliable tool for balance evaluation (Pinsault and Vuillerme, 2009; Ruhe, A. et al., 2010), (Mengarelli et al., 2018).

2.4.2 Standing balance in amputees

It should be remembered that the risk of falling is higher in older people with gait problems and a history of falling, those who use walking aids and those experiencing vertigo (Deandrea et al., 2010), all of which might be common features of LLAs at any age. Lower limb amputation affects dynamic and static balance due to the loss of the part of the body which is in direct contact with the BOS, and which normally transfers bodyweight to it. The role of transferring body weight will be compensated by the prosthetic limb, but this limb, as an artificial structure, is not able to provide sensory feedback to the somatosensory system in the process of postural control (Figure 2.3). The lack of muscles and joint/s due to amputation results in a loss of some subcomponents of postural stability (Table 2.1) and, consequently, leads to balance deficiency in LLAs. In the following section, a review of various studies is provided which evaluate the balance of prolonged unilateral lower limb prosthetic users with different levels of amputation in terms of COP or COM changes during perturbed/ unperturbed standing by utilizing the stabilometry system or force measurement devices, such as force platforms.

The ability of amputees to keep their balance on a stabilometer (especially in the anteroposterior direction) is lower than in non-amputees (Buckley et al., 2002). Asymmetrical standing balance with more reliance on the intact limb (Nadollek et al., 2002; Vrieling et al., 2008b; Duclos et al., 2009; Vatanparast et al., 2009; Hlavackova et al., 2011; Ku et al., 2014) and a larger COP excursion (particularly in the anteroposterior direction) of that limb (Buckley et al., 2002; Vrieling et al., 2008b; Kozáková et al., 2009; Hlavackova et al., 2011; Bolger et al., 2014; Ku et al., 2014; Rusaw, DF., 2018) are reported frequently for LLAs. These differences have been attributed to the role of the ankle in the displacement of the COP in anteroposterior balance maintenance, and this is a more important role than that of both hip joints, which is absent in amputated limbs of unilateral LLAs (Buckley et al., 2002; Curtze et al., 2012). Nadollek et al. (2002) also reported a larger anteroposterior COP displacement in the intact-side, but the same mediolateral displacements for both legs of TT amputees. The study of (Kozáková et al., 2009) had similar results, except that they recorded a greater mediolateral COP sway of the prosthetic side. An impaired balance has been reported for vascular TT amputees with lower scores of somatosensory response and circulation, which was associated with larger mediolateral COP displacement for amputees with poor blood circulation, more symmetrical weight bearing in amputees with poor sensory touch, and a history of falling for those with weaker vibration sensation. However, those with poor blood circulation had larger forward reach distance, which might be the result of changes in perception by the person regarding the position of body parts (Quai et al., 2005).

The results of studying perturbed balance in the form of moving BOS showed more load on the intact-side, larger intact-side COP anteroposterior displacement but smaller displacement for the prosthetic side, in addition to greater anteroposterior ground reaction force (GRF) of both limbs of TT and TF amputees in comparison to non-amputees. In addition, a larger anteroposterior GRF was observed in the intact side. These results were ascribed to the compensatory role of the hip muscles in the absence of the contribution of the ankle muscles in the amputated side, in addition to control of the COM position for maintaining a locked knee (Vrieling et al., 2008b).

As with static balance, a greater contribution in dynamic balance on a moving BOS has been recorded for the intact-side of LLAs (Nederhand et al., 2012). In addition, the possibility of achieving a better dynamic balance by prosthetic feet with stiffer ankles has been suggested (Nederhand et al., 2012). However, the effect of a stiff prosthetic ankle on dynamic activities such as walking balance is questionable.

Interestingly, the hip of both limbs and the prosthetic ankle showed more contribution in the balance of TT amputees when a lateral perturbation was applied (Curtze et al., 2012). Bolger et al. (2014) also reported a higher contribution of the prosthetic side of TT amputees in mediolateral perturbation.

The reviewed studies have shown that even LLAs with a high level of physical activity suffer from a lower level of balance (Buckley et al., 2002). By recalling the vital factors for postural control (Table 2.1), it is clear balance impairment for a person with lower limb amputation is primarily due to lost and weakened biomechanical features, as well as somatosensory system deficiency, in the amputated side. The most common point of almost all the studies was the more prominent role of the intact-side in balance maintenance of LLAs. The majority of the studies considered asymmetrical weight distribution towards the intact-side as the amputees' adaptation strategy and increased anteroposterior COP displacement as the potential mechanical reasons for the imbalance. Interestingly, symmetrical balance was reported in TT amputees who had the opportunity to have regular physical therapy and walking practice sessions (Mayer et al., 2011). Reduced somatosensory response (tested by touch and vibration) and blood circulation in amputated and intact-side limbs resulted in a possible deficiency in feeling precise body segment position. These features are associated with a lower level of standing balance and falls history in vascular TT amputees (Quai et al., 2005). An increase in COP movements has been reported with an increase of the interval between amputation and prosthetic fit (Kozáková et al., 2009). The effect of prosthetic components on balance in LLAs cannot be ignored. It has been shown that utilizing more advanced prosthetic components (such as those which are micro-processor-controlled, with standing support mode at the knee and hydraulic self-alignment of the ankle joint of the prosthetic foot) leads to more symmetrical weight distribution and improved standing balance of TF amputees (McGrath et al., 2018). Perturbations, such as a simulation of daily activities with changing balance (for example, hand raising, BOS movements or applying pulling loads to the waist), disturb the balance in LLAs' more than non-amputees (Vrieling et al., 2008b; Vatanparast et al., 2009; Nederhand et al., 2012; Curtze et al., 2012). In addition. an increase in the role of the prosthetic side was observed in perturbation (Curtze et al., 2012). One reason for the deficient contribution of a lower limb prosthesis device in balance might be its inability to apply force to the BOS, similar to the intact-side during balance (Bolger et al., 2014). Only a few studies were related to TF amputees standing balance (with three participants in Buckley et al. (2002) and Vrieling et al., 2008b; eight people in Hlavackova et al. (2011) and six Nederhand et al. (2012)) and no studies were found related to the biomechanics of their disturbed balance in the form of instant base of support and applying an external load, which might be a simulation of a push by someone when standing in a crowd. These show the value of performing such studies in extending our current knowledge about TF amputees' postural balance.

2.5 Level walking

This section presents an overall review of level-walking biomechanics.

2.5.1 Normal gait pattern

The term "gait cycle" refers to the rhythmic and consecutive movements of the lower extremities during walking which results in the forward progression of the body. Each gait cycle includes events during weight bearing by the leading leg (stance phase), then its forward movement through the air, while the contralateral leg is supporting the weight (swing phase) (Whittle, 2002).

Figure 2.7 illustrates the phases of a single gait cycle (A to G stages), including five stance's stages and three swing's stages, which are as follows (Whittle, 2002):

(A) Initial contact (heel contact): the heel strikes the ground at the start of the stance phase.

(B) Loading response (the period of time between the initial contact of one foot to toe-off in the contralateral foot)**:** the foot comes in full contact with the ground during this stage, and the stance limb fully bears the weight of the body (foot-flat, initial double support).

(C) Mid-stance (the period of time after the loading response until the heel rises, single support): It begins when the contralateral foot leaves the ground and continues its forward movement before its heel resumes contact with the ground.

(D) Terminal stance (the period of time between the heel-rise of a foot until the initial contact of the contralateral foot, single support) **and (E) Pre-swing** (the period of time between the initial contact of the contralateral foot and the toe-off in the initiating foot, terminal double support): During these phases, the body continues its forward movement on the supporting foot, and the weight moves to the forefoot (heel off), the stance limb gets ready to be unloaded and the body weight is gradually transferred onto the contralateral limb (toe-off).

Three subdivisions are considered for the swing phase:

(F) Initial swing (acceleration, the period of time between the toe-off of the foot until the time of reaching the side of the contralateral leg)**:** It starts when the foot leaves the ground and continues until maximum knee flexion occurs.

Mid-swing begins following maximum knee flexion and ends when the tibia is in a perpendicular position. During this period of time, limb advancement and foot clearance continue.

(G) Terminal swing (deceleration, the weight of the body gradually transfers to the toes of the contralateral limb): The tibia passes beyond the perpendicular position and the knee fully extends to prepare for the heel strike.

The duration of the gait phases depends on the speed of walking. In normal speed, a gait cycle is comprised of approximately 40% swing phase and about 60% stance phase, including two double support periods in which both feet are in contact with the ground (20% of the gait cycle). With an increase in the speed of the stance phase, the double support periods decrease, while the swing phase length increases. In running, the double support disappears, and the ratio of stance/swing phases may even be reversed.

The stride and step length are spatial variables and are utilized to characterize foot transfer during walking. A step is defined as the distance that a foot travels from a definite event in the gait cycle of one extremity (usually the heel strike) to the same event in the opposite extremity. The distance from a definite event in the gait cycle of one extremity (almost the heel strike) to its next repetition in the same extremity (two consequent steps) is called a stride.

Gait normally starts from a standing position. Thus, there is a transient period from standing to steady-state walking (Figure 2.6, (Park, S. et al., 2009). There is no certain agreement about the number of steps needed to be taken before reaching steady-state walking. It has been suggested from one step (Breniere and Do, 1986) to three steps (Park, S. et al., 2009) for the kinematical and kinetical studies, and even 10 gait cycles for EMG studies of walking on a treadmill (Kibushi et al., 2018).

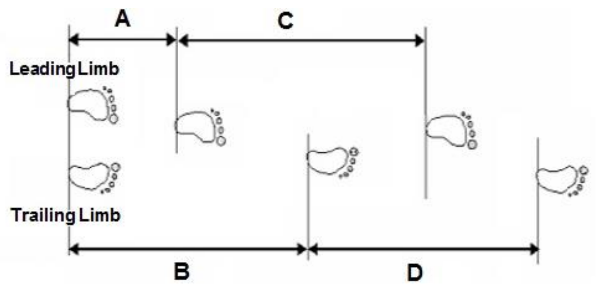


Figure 2.6 Walking initiation from standing position: initiation period (A, B) and gait cycle (C, D) (modified from Park, S. et al. (2009))

2.5.1.1 Joints angle

The main motion during gait occurs in the sagittal plane. The angles of the lower limb joints, including hip, knee and ankle joint, mainly alter in the sagittal plane during the gait cycle as follows (Figure 2.8-A) (Whittle, 2002):

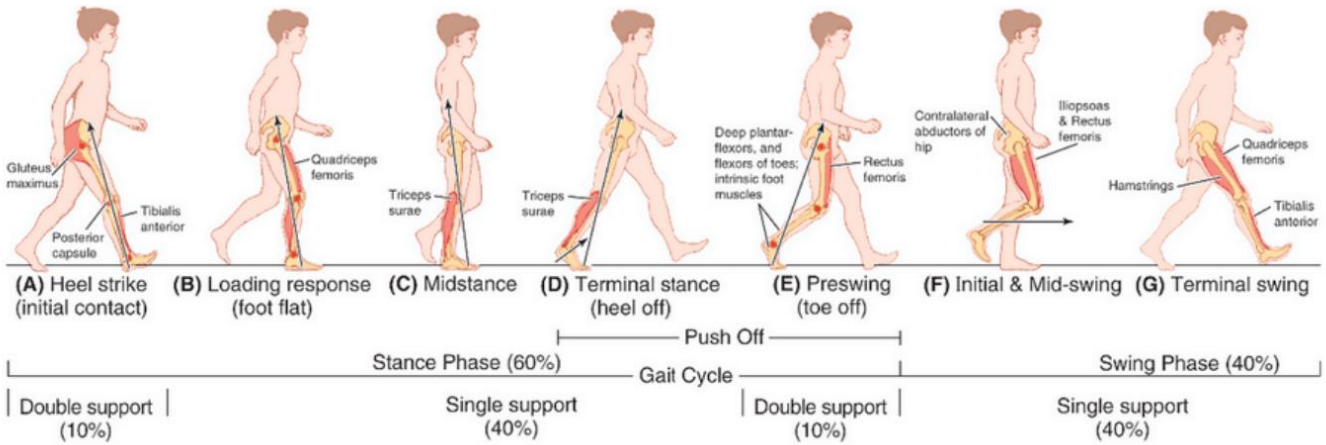


Figure 2.7 Main active muscles, the GRF vector position and the consecutive stages of a gait cycle of right limb (Rajťúková et al., 2014)

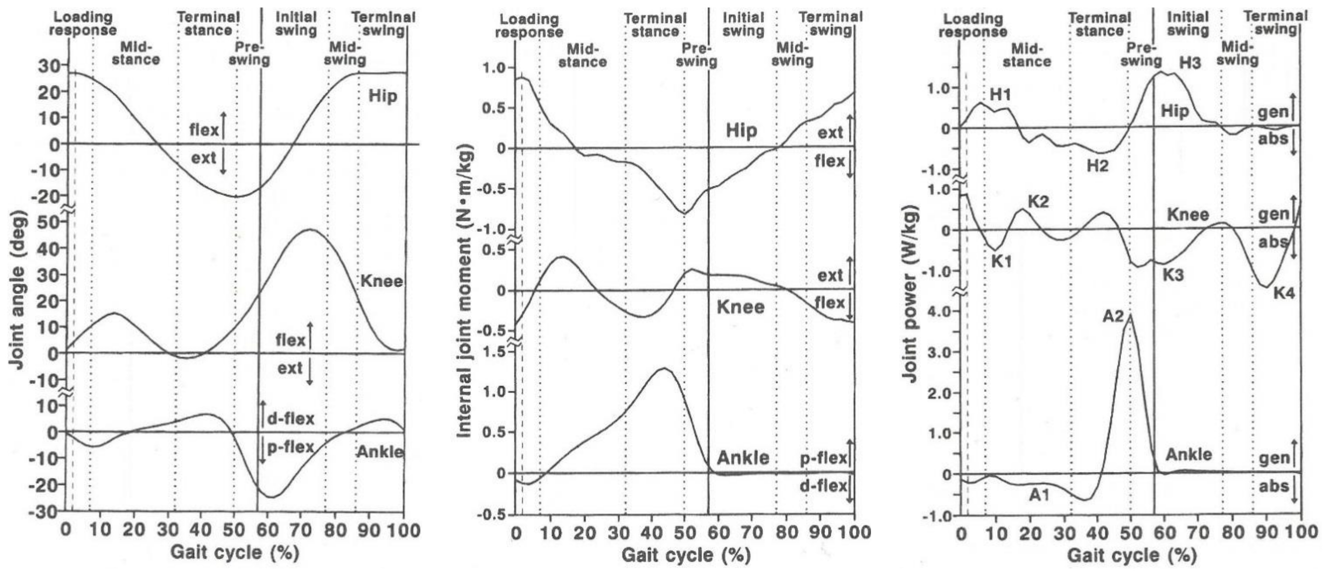


Figure 2.8 Joint angles change (A), Internal joint moments in sagittal plane (B) and joint powers (C) during a gait cycle (Whittle, 2002)

- **In initial contact:** The ankle joint is almost in a neutral position. Then, the ankle plantar-flexes to bring the foot down to the ground. The knee is in full extension. The hip is in maximum flexion and accepting the weight of the body by the leg.
- **Loading response:** At the time period immediately after initial contact, ankle plantar flexion and knee flexion occur to bring the foot to the ground and the stance limb is ready for full weight acceptance. The hip starts to extend.
- **Mid-stance:** As the shank moves forward on the foot during mid-stance, dorsi-flexion occurs in the ankle. The small knee flexion in the stance reaches its maximum and then changes to extension. The hip continues its extension and reaches a neutral position.
- **Terminal stance:** The ankle plantar-flexes gradually. The knee starts to flex. The hip extension continues.
- **Pre-swing:** The maximum ankle plantar flexion is seen in the toe-off. The knee flexion continues. The hip reaches maximum extension.
- **Initial swing:** During the swing, the ankle joint again starts to dorsi-flex for toe clearance. The knee flexion continues, mostly due to the hip flexion. The hip starts to flex.
- **Mid-swing:** The ankle continues dorsi-flexion. The knee reaches maximum flexion and starts its extension. The hip flexion continues and the joint reaches the neutral position.
- **Terminal swing:** The ankle remains in the neutral position until the next initial contact. The knee continues to extend until it reaches full extension at the end of the swing and the next initial contact. The hip flexion continues until initial contact.

2.5.1.2 Joint moment and power

Typical patterns of lower limb internal joint moments in the sagittal plane and powers are shown in Figure 2.8-B and C.

The moment is calculated by multiplying the force (muscle force or weight of segment) by its perpendicular distance from a pivot point (joint) through a process of inverse dynamics. The moments are indicators of the muscles' role in stabilizing or the motion of the related joints during a movement. 'Active' internal moments are produced by muscle contractions. 'Passive' internal moments are generated by joint reaction forces and by tension in the soft tissues (particularly the ligaments). External moments (also referred to as 'reaction moments') are generally produced due to gravitational forces.

Joint power is the product of a joint moment and joint angular velocity (ω):

P (Watts)= **M** (Newton. Meters) **.** ω (Radians per Second)

When, at a particular joint, the moment of force (M) and joint motion (ω) are in the same direction, power has a positive quantity and energy is produced by concentric contraction in the muscles crossing that joint. Contrarily, when M and the direction of the joint motion are opposite, the power is negative and the work is done by the eccentric contraction of muscles and/or the lengthening of other soft tissue around the joint (Whittle, 2002).

In the following section, a brief description of lower limb joint moment in the sagittal plane and joint power changes (Whittle, 2002) will be presented.

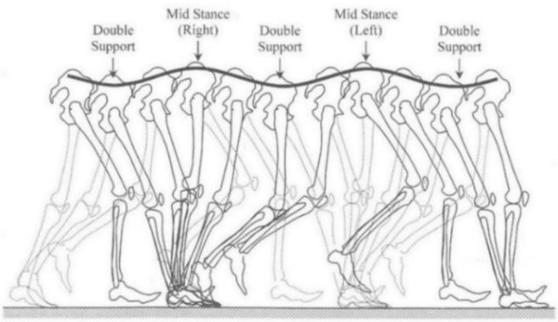
Ankle Joint - Little moment or power change occurs at the ankle during initial contact. In 'heel strike', elastic tissues of the heel and materials in the footwear absorb the hit energy. During loading response, the GRF vector remains behind the ankle joint (Figure 2.7) and generates an external plantar-flexor moment. The eccentric contraction of the tibialis anterior produces a small flexor moment (Figure 2.8-B) and controls the ankle plantar flexion (seen in the form of very small negative power: Figure 2.8-C). At early mid-stance, the line of the GRF starts to move forward along the foot (Figure 2.7). As a result of this, the internal dorsi-flexor moment at the ankle decreases, and then reverses to become a plantar-flexor moment. Little power exchange occurs at the ankle at this time. The internal plantar-flexor moment in the ankle increases as the force vector moves into the forefoot throughout mid-stance and into terminal stance (Figure 2.8-B). This moment is generated by the eccentric contraction of the plantar-flexor muscles (including the soleus and gastrocnemius). Thus, a power absorption occurs during foot-flat (A1 in Figure 2.8-C). During heel-rise, the plantar-flexor moment continues to increase due to the position of the GRF vector in front of the ankle and the increasing concentric contraction of the plantar-flexor muscles, which results in the highest generation of power in the whole of the gait cycle (A2 in Figure 2.8-C). The immediate effect of this power generation is to accelerate the limb forward into the swing phase and body progression. During the initial swing, the foot leaves the ground and then the magnitude of the GRF decreases to zero. The ankle moment remains very small, with very little power changes during remaining of the swing (Figure 2.8-C).

Knee joint - In initial contact, an internal flexor moment is seen in the knee (Figure 2.8-B). This is due to concentric contraction of the knee flexors (hamstrings) to prevent knee hyperextension at the end of the swing phase. Due to this concentric contraction and the releasing of energy stored in the ligaments of the extended knee, a short period of positive power is seen. At early mid-stance and during the small knee flexion, the GRF vector lies behind the joint and then produces an external flexor moment. This is opposed by an internal extensor moment (Figure 2.8-B), produced by the eccentric contraction of the knee extensor muscle (quadriceps muscles) to control the knee flexion; this leads to power absorption (K1 in Figure 2.8-C). During mid-stance, the GRF vector remains behind the joint, but a concentric contraction of the quadriceps opposes it and produces an internal extensor moment (Figure 2.8-B). During this time, the knee orientation alters from flexion to extension and power generation occurs (K2 in Figure 2.8-C). During terminal stance, flexion of the knee leads to placement of the GRF vector behind the joint (Figure 2.7), then the external flexor moment appears, which is opposed by the extensor moment produced via eccentric contraction of the knee extensors (Figure 2.8-B). In fact, the eccentric contraction of the knee extensor muscle controls the rate of knee flexion during terminal stance-initial swing phases and causes power absorption (K3 in Figure 2.8-C). When the tibia passes the vertical position and the knee starts extending in mid-swing, an increasing internal flexor moment is seen in the knee (Figure 2.8-B), which is produced by the eccentric contraction of the knee flexors, with power absorption at end-swing (K4 in Figure 2.8-C).

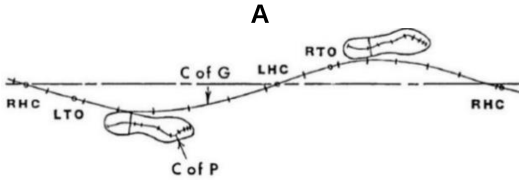
Hip joint - In a gait cycle, at the time of initial contact, there is an internal extensor moment at the hip, due to the concentric contraction of the hip extensors (the gluteus maximus and the hamstrings), that continues during loading response. This concentric contraction of the hip extensors is associated with hip extension; thus, it produces positive power in the hip (H1 in Figure 2.8-C). During mid-stance, the internal extensor moment at the hip decreases, disappears and then changes to a flexor moment at the terminal stance (Figure 2.8-B), which is the result of the eccentric co-contraction of the hip flexors (the adductor longus and rectus femoris), in addition to the lengthening of the ligaments during the hip extension. Then, negative power is seen (H2 in Figure 2.8-C). As the hip orientation changes from extension to flexion via the hip flexors' concentric action during initial swing, an internal flexor moment and large power generation is seen (Figure 2.8-B and H3 in Figure 2.8-C). This power accelerates the swinging leg forward. An increasing internal extensor moment is seen at the hip during hip flexion at the swing phase (Figure 2.8-B). It is mainly produced by eccentric contractions of the hip extensors (the hamstrings and, later, the gluteus maximus). As the hip angle is constant during terminal swing, a very small power change is seen at the joint during the remainder of the swing phase.

2.5.1.3 COM displacements

The COM moves down/up and side to side (lateral/medial) during each gait cycle (Figure 2.9).



A



B

Figure 2.9 A: Vertical (Rose and Gamble, 2006), B: Mediolateral (Winter, 1987) displacement of COM during one stride

Sanders and Inman proposed a direct relationship between COM vertical displacement and walking energy cost, which has been disputed in recent studies. They introduced six determinants which influence sinusoidal vertical displacement of the COM and make its movement smooth during walking: pelvic rotation in the transverse plane; pelvic tilt in the coronal plane; knee flexion atthe initiation of the stance phase; ankle-knee angular changes during the stance; and the lateral displacement of the body during each limb's stance. As can be seen in Figure 2.9, the COM displacement during walking happens via the transfer of the body weight from one leg over to the other. It moves vertically through two full oscillations during each gait cycle; thus, the curve has two high points (during each limb's single support, at mid-stance of both limbs) and two low points (during initial and terminal double supports). The COM also oscillates laterally over the supporting leg during each gait cycle. The largest amount of excursion occurs at mid-stance of both limbs (the single support phase). The increased lateral displacement of the COM might happen due to weakness in the hip joint abductor muscle (the gluteus medius) or pure balance (Rose and Gamble, 2006).

2.5.1.4 Ground reaction forces

The feet exert a force (produced via muscles action, gravity and inertia) to the supporting surface during walking, which is opposed by GRFs. GRFs are measured by force platforms, and they may be resolved into horizontal (mediolateral and anteroposterior) and vertical components. The vector of the GRF regarding the position of the joints helps us to understand the role of the different major lower limbs' muscles during gait. The profile of the GRF changes occurring during one gait cycle has been shown in Figure 2.10.

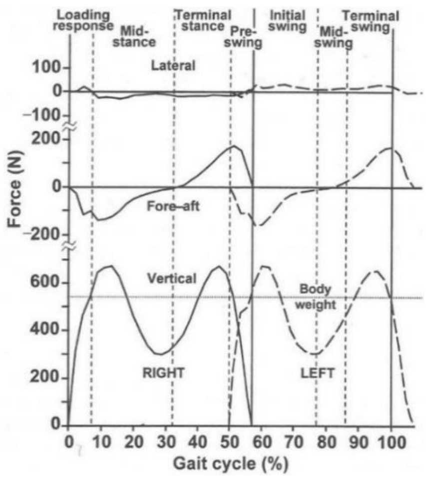


Figure 2.10 Changes of GRF during one gait cycle (adapted from (Whittle, 2002)

The GRF changes are connected to the motions of the COM during walking. As is seen in Figure 2.10, the largest component of the GRF is the vertical component, which might exceed the bodyweight during single support. It has an "M" shaped pattern, with two humps at the beginning and end of single support, in addition to a dip at the middle of single support. During loading response (initial double support), weight is gradually transferred from one limb to the other, while vertical GRF gradually increases from zero to the weight of the body. The slope of this part of the vertical GRF indicates the loading rate. The first maximum amount of vertical GRF coincides with the upward acceleration of the COM and the maximum backward GRF (which opposes the forward push by the foot to the ground). The valley of the vertical GRF occurs when the COM upwardly decelerates and reaches its highest position. This point almost corresponds with the posterior force (braking) changing to the anterior force (propulsive), which is called the crossover in the anteroposterior GRF profile. During the terminal stance, the plantar-flexors muscles' force increases the COM's forward and upward acceleration and the forward (propulsive) force appears, which reaches its maximum magnitude at pre-swing to push the body and start the swing phase, together with the second peak of the vertical force.

Feet experience mediolateral GRF during stance, which has a small magnitude (less than 10% of the bodyweight) and is too variable. Modifications of the shoe and orthotic managements in the coronal plane might affect this component of the GRF more than the other two factors. The force is lateral during initial contact, changes to medial in loading response, and remains medial during the rest of the stance phase (Rose and Gamble, 2006; Whittle, 2002; Richards, 2008).

2.5.2 Lower limb amputees' gait

In TF amputees, the sensory and motor functions of the foot, ankle, knee and shank do not exist. These need to be compensated for by a prosthetic device and the body's adaptation mechanisms. The artificial foot-ankle must absorb the impact force at initial stance and simulate the plantar-dorsi-flexor muscle actions in the gait cycle. In addition, the structure of the foot-ankle complex must generate enough mechanical power and produce propulsion force to accelerate the leg. The artificial knee unit must also be able to act like a normal knee by absorbing forces transmitted from the shank and mimic the normal knee kinematics in the AK prosthesis. Practically, the components of artificial limbs cannot act exactly like anatomical structures and this leads to kinematic and kinetic differences between the amputees' prosthetic limb and the normal limb. This further leads to compensatory kinematic and kinetic changes in the intact side and the remaining part of the limb in the amputated side (the residual limb). A large number of studies related to the biomechanics of LLAs' gait have investigated the effects of different prosthetic components (socket designs, suspension systems, prosthetic knees and ankle/foot) which is not a matter of interest in this study. Thus, only the general characteristic of unilateral LLAs' gait, with a focus on TF amputees walking using mechanical passive prosthetic components, will be reviewed in the following.

2.5.2.1 Biomechanics of TF amputees' walking

Spatio-temporal variables: The variables related to timing and distances in the walking of LLAs are significantly different from able-bodied individuals, and the differences become more prominent in higher levels of amputation. Their self-selected speed of walking is lower than the age-matched group of non-amputees. In addition, they have shorter stride length, and the stance time of their intact limb is longer than their prosthetic limb, which results in an asymetrical pattern of walking, including shorter intact limb and longer prosthetic limb steps (Jaegers et al., 1995; Nolan, Lee et al., 2003; Farahmand et al., 2006; Berke et al., 2008; Uchytil et al., 2013; De Asha et al., 2014; Khiri et al., 2015; Jarvis et al., 2017). The longer loading on the intact limb, due to its longer stance, and, in contrast, the shorter time of weight bearing on the prosthetic limb are a matter of concern because these might lead to tissue pain or joint damage in the intact limb and a decrease in the bone density of the residual limb over a long period of time (Berke et al., 2008).

Kinematics: The joint motion of the intact lower limb of TF amputees during normal walking is similar to non-amputees, but there are various differences in the kinematics of their prosthetic side (Figure 2.11). The range of motion of prosthetic limbs has limitations in comparison to natural limbs. As can be seen in Figure 2.11-A_A, a prosthetic ankle joint might provide similar plantar flexion at initial contact. But, the main difference between the prosthetic ankle joint and the natural ankle is its inability to simulate plantar-flexor muscle functions to produce plantar flexion in the late stance, which is needed for active push-off. Figure 2.11-B_A also shows that mechanical passive prosthetic knees do not have knee flexion during loading acceptance. In fact, amputees cannot control the knee flexion during the loading response by generating an active extension moment in the mechanical prosthetic knee. Thus, the stance phase knee flexion is restricted by the prostheses' alignment and features (such as the increasing friction between the moving components of the prosthetic knee during weight bearing) (Gard, 2016). Both limbs of TF amputees have a hip range of motion similar to non-amputees, with a difference in timing of its maximum extension (due to the longer stance duration), which happens at the end of the stance (Figure 2.11-C_A) (Seroussi, R. et al., 1996).

Lower limb amputees have a sinusoidal pattern of COM displacement similar to non-amputees, as is shown in Figure 2.9. The range of TF amputees' COM vertical displacement during walking does not differ from non-amputees (Gitter, A. et al., 1995; Weinert-Aplin et al., 2017). But, the intact and affected limb's gait cycles are less symmetrical. They represent a higher position of the COM at the prosthesis's toe-off in comparison to non-amputees. This might happen as the result of a prosthetic limb's insufficient propulsion and the absence of plantar flexion (Nolan, Lee et al., 2003). Mediolateral displacement of the COM is larger for TF amputees than for non-amputees, which is associated with a wider BOS (Weinert-Aplin et al., 2017).

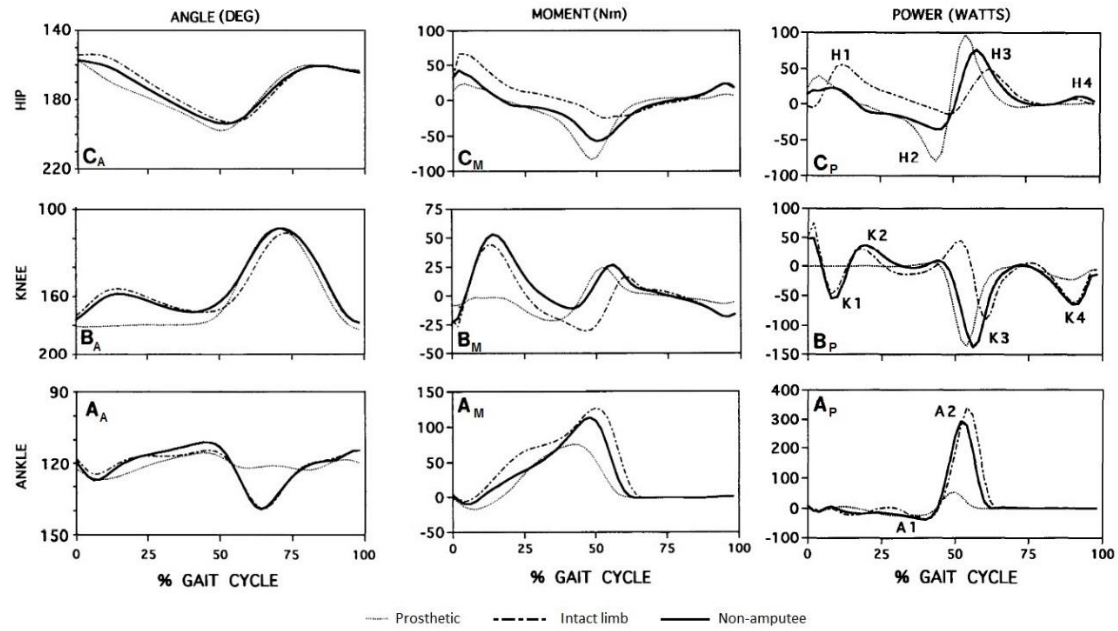


Figure 2.11 Pattern of lower limb joints' angles, moments and powers in non-amputees (solid line), intact limb of TF amputees (dashed line) and their prosthetic side (dotted line) (Modified from Seroussi, R. et al. (1996))

Kinetics: In general, the peak values of joint moment and power are larger for the affected limb hip joint as it requires adjustment with amputation and the compensating limitations of a prosthetic device (Winter, 1987). On the other hand, the ankle and hip of TF amputees' intact limbs also experience a change in kinetics due to their compensatory and supporting role for the amputated limb (Nolan, L. and Lees, 2000). As seen in Figure 2.11, the longer stance of the intact side has a more obvious impact on the joint powers of the ending stance in the form of observed delays in A2, K3 and H3 of the intact limb. A prosthetic ankle-foot has a small plantar-flexor moment due to the lack of plantar-flexor muscles and, consequently, an inability to push-off actively. As the passive prosthesis remains extended during the stance phase, the knee moment is negligible (Figure 2.11-B_M), and no power generation or absorption are seen in the prosthetic knee during weight acceptance (K1 and K2 in Figure 2.11-Bp). However, it has a small flexor moment and large power absorption (K3) due to the damping mechanism of the prosthetic knee (Winter, 1987).

The hip extensor moment at early stance is greater for the intact limb of amputees in comparison to the affected limb and to non-amputees, which leads to greater power generation. This is an indicator of a dramatic hip extensor concentric contraction (H1 Figure 2.11-Cp), which is supposed to compensate for the contralateral prosthetic limb's weak push-off via facilitating forward movement of the body. The second noticeable difference in the kinetics of the hip joint is seen between the hip flexor moment and the eccentric hip flexor contractions (hip power absorption, H2) of the affected limb in comparison to non-amputees and the intact limb of TF amputees (Figure 2.11-C_M and Cp). In the absence of knee flexion and the consequent smaller hip flexion during initial stance, the COM is placed posterior to the hip joint. This raises the need for a larger eccentric contraction of the hip flexors (which is seen as a hip flexor moment and hip power absorption) to control the extension of the hip and to pull the body on an extended prosthetic leg. A sudden transition from H2 to H3 is seen in the affected hip joint of TF amputees, which is needed to unlock the prosthetic knee joint before the swing and to push the body forward in the absence of ankle push-off power (Seroussi, R. et al., 1996; Sjodahl et al., 2002).

Figure 2.12 demonstrates the pattern of vertical and anteroposterior ground reaction force changes of the prosthetic and intact sides of TF amputees during walking at different speeds. As is seen, the first peak of vertical force changes with a sharp slope after initial contact (which is an indicator of fast loading) and its peak increases at higher speed. In addition, the A/P forces are greater for the intact limb (Schaarschmidt et al., 2012). Castro et al. (2014) have reported similar findings. However, they mentioned the second peak of vertical GRF for amputees (the prosthetic side lower than in the intact limb) was lower than for non-amputees. In addition, they reported larger mediolateral force for both limbs of the TF amputees compared to non-amputees, which has been related to the movement of the COM in the coronal plane. The lower A/P forces might show that the amputees' initial contact is more vertical; they might face difficulty when trying to decelerate the prosthetic limb and it has a lower capacity for braking (Castro et al., 2014).

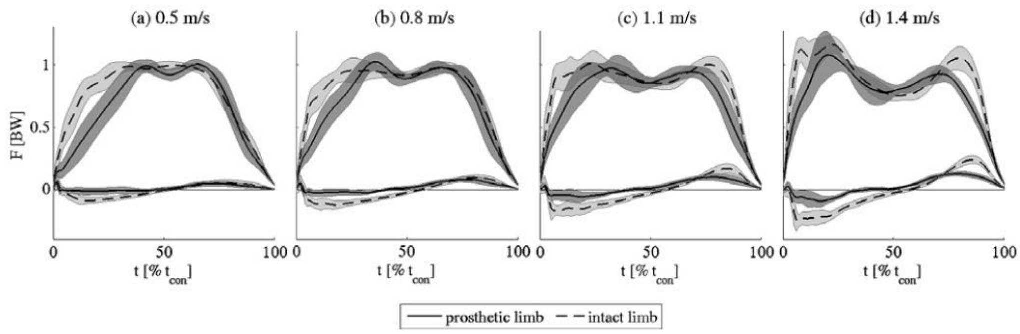


Figure 2.12 Pattern of Vertical and A/P GRF of TF amputees using a passive mechanical knee joint in different walking speed (Adapted from (Schaarschmidt et al., 2012)

2.5.2.2 Gait deviations of above-knee prosthesis users

A simple observation of how LLAs walk might reveal several deviations of their gait from normal walking. The pattern of walking might have alterations due to the consequences of amputation (i.e. joint contractures, stump pain, muscle weakness) or improper construction and alignment of the prosthetic limb (i.e. loose/tight socket, length discrepancy between the prosthetic limb and the intact limb, extra stiff or easy motion of the prosthetic knee or foot-ankle). The common walking deviations of TF amputees (as the amputees who will be studied in this thesis) have been depicted in Figure 2.13 (A, B, D, I, J during stance and E, F, G during swing of the prosthetic limb) and their descriptions have been presented in Table 2.2 (Berger and Fishman, 1997; Berke et al., 2008; Rajťúková et al., 2014).

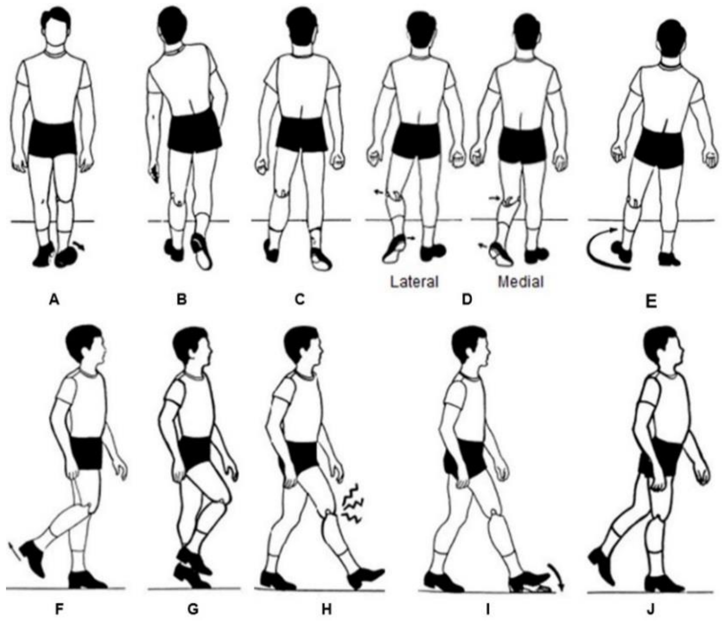


Figure 2.13 Common above-knee prosthesis users' walking deviations: (A) Foot rotation at heel strike, (B) Lateral bending, (C) Wide walking base, (D) Swing phase whips, (E) Circumduction, (F) Uneven heel rise, (G) Vaulting, (H) Terminal impact, (I) Foot slap, (J) Excessive lordosis (adapted from (Berger and Fishman, 1997).

2.6 Use of Insoles

According to the practical definition of orthotic insoles or foot orthoses by Dr Kirby:

> *"An in-shoe medical device which is designed to alter the magnitudes and temporal patterns of the reaction forces acting on the plantar aspect of the foot in order to allow more normal foot and lower extremity function and to decrease pathologic loading forces on the structural components of the foot and lower extremity during weight-bearing activities".*
>
> Scherer, P.R. (2011), page 1

Insoles provide a foot-bed for the lower extremity. The design and the materials used for insoles define how they affect the relationship between the sections of the foot and the more proximal musculoskeletal segments of the limb. The flexibility and rigidity of insoles (soft, semi-rigid, rigid), as well as their length (full-length, three-quarter length, heel) and contours, provide different levels of control and correction. Insoles might be prefabricated to standard patterns or customized individually from the positive cast of the patient's foot. The impacts of insoles are evaluated technically by utilizing different instruments, including 3D motion analysis systems, force platforms, pressure plates and mats, besides questionnaires and clinical methods (Hsu et al., 2008; Scherer, P., 2011).

A wide variety of studies have been conducted on the effectiveness of insoles on motion tasks (Ball and Afheldt, 2002a; Ball and Afheldt, 2002b), including reducing LBP, overuse injuries, improving and helping balance control, as well as correcting the biomechanics of lower extremities and improving lower limb alignment, which can be beneficial in rectifying joint loading.

Table 2.2 Description of the common above-knee prosthesis walking deviations demonstrated in Figure 2.13 (Berger and Fishman, 1997; Berke et al., 2008; Rajťúková et al., 2014)

Deviation	Description and reasons
A- Foot rotation at heel strike	It might happen due to an excessive hard heel or plantar-flexor mechanism of prosthetic foot-ankle component or socket's poor fit.
B- Lateral bending	Or Trendelenburg pattern which is associated with lateral leaning toward prosthetic limb during weight bearing (back or front view). It might have several reasons to occure including painful hip joint or stump, weakness of hip abductor muscles, contracture of hip in abduction position, short prosthesis device, pure socket fit, incorrect alignment of socket or prosthetic feet.
C- Wide walking base	Or abducted gait which might be seen in double support and mid-stance (back view). It might occure due to incorrect shape of socket which leads to pain and discomfort in medial side, too long prosthesis, hip abduction contracture, habit or insecure feeling of prosthetic wearer about balance.
D- Swing phase whips	The whips are seen at toe off (pre-swing) of prosthetic limb (back view). Wrong alignment of the prostehtic knee in frontal plane (with external/internal rotation), wearing of the socket with rotation, suspension belt with external/ internal rotation, socket rotated alignment.
E- Circumduction	It might be observed in mid-swing while the prosthetic limb circulate outward in a curviture manner (back or front view). It might happen beacause of insufficient prosthetic knee flexion due to its high resistance/stiff extensor assistant mechanisms or manual lock, discomfort due to high medial brim of socket, long prosthetic limb, weak hip flexors, plantar flexion alignment of prosthetic ankle, poor socket fit or poor suspension.
F- Uneven heel rise	Excessive/inadequate heel rise of prosthetic ankle-foot (side view) at the initial swing might be seen in trun because of low resistance of prosthetic knee to flextiom, extream hip flexion/stiff prosthetic knee (due to tight knee flexion resisstance and extonsor assistance mechanisms), amputee's feeling of insecurity about prosthetic knee flexion.
G- Vaulting	Raising body on intact limb via early ankle plantar flexion during midstance (side or back view) might be due to long prosthetic limb, stiff prosthetic knee (due to tight knee flexion resisstance and extonsor assistance mechanisms), poor socket fit, weak hip flexors of amputated limb, or amputee's habit
H- Terminal impact	It is a sudden stop of shank which can be visible (side view) or associated with sound impact at terminal swing and full extension of prosthetic knee. It might occure due to very strong extensor assisstant of prosthetic knee, worn extension bumper, intentional and fast hip extension of amputated limb for secure full knee extension.
I- Foot slap	A fast plantar-flexion movement immediately after heel contact of prosthetic limb (side view) might happen because of inadequate plantar-flexion resistance in the prosthetic foot (too soft plantar-flexion bumper or heel).
J- Excessive lordosis	It might be seen during weight bearing on prosthetic limb with trunk leaning posteriorly (side view). Insufficient socket flexion, short front brim of socket, painful ischial tuberosity, hip flexion contracture, weak hip extensors, and weak abdominal muscles might cause this deviation.
K- Uneven step length	The differnce between prosthetic and intact limbs' step lengths might happen due to uneven stance/swing proportion of two limbs, pain in resudual limb, feeling unsecure weight bearing by prosthethsis, hip flexion contracture or insufficient socket flexion, uncontrolled motion of prosthetic shank during prosthesis swing due to inadequate flexion resistance of prosthetic knee or loose knee extension assistant component.

However, all researchers do not support the positive effects of the application of insoles. This may be due to the insoles recipients' biomechanical-physiological differences. Or it could be due to the fact that different results may be obtained for the same insole type manufactured by various practitioners (Chevalier and Chockalingam, 2012). But, taking all of this into consideration, the studies which support using insoles are considerable. As unilateral lower-limb amputees are a group of people with a greater chance of experiencing imbalance/falling, LBP and intact-side injuries, several studies related to the effects of insoles on musculoskeletal problems (including balance, LBP, and lower limb injuries) of non-amputees are reviewed in the following section.

2.6.1 Use of insoles for standing balance improvement in non-amputees

The reported effectiveness of edged/boundaries tubed (Perry, S.D. et al., 2008; Hijmans et al., 2007), arch support (Mulford et al., 2008) and textured insoles (Palluel et al., 2009); (Qiu et al., 2012; Wheat et al., 2014; Kenny et al., 2019) on decreasing postural sways and/or the risk of falling might be due to their act of somatosensory stimulation. The positive effect of commercial insoles in the reduction of fallers' COP sway (Liu et al., 2012) or soft/hard insoles on the COP displacements of older people (Losa Iglesias et al., 2012; Qiu et al., 2012) during standing balance also might also be based on the same reason. The effectiveness of vibrating (Priplata et al., 2003; Lipsitz et al., 2015) and magnetic insoles (Suomi and Koceja, 2001) insoles can be derived from their effect on blood circulation as well as on sensory stimulation. The long-term use of custom-made insoles (correcting the malalignment of foot joints, such as forefoot varus- (Cobb et al., 2006) and pronated foot- (Rome and Brown, 2004), or any observed flexible abnormalities- (Gross et al., 2012)) reduces postural sway by stabilizing the foot joints. In addition, using custom-made insoles which have been cast with the subtalar joint in a neutral position also led to a reduction of the COP sway after the plantar/dorsi-flexor muscles fatigue. It might be due to the contributory function of the insoles to control the joint in weakened action of the fatigued muscles (Ochsendorf et al., 2000). In fact, the custom-made insoles provide a correct relationship between the components of the foot and, consequently, help to provide a balanced function of the muscles passing through the ankle joint which, possibly, helps to send better postural feedback to the CNS (Leardini et al., 2014). In addition, (Shin, J.Y. et al., 2016) showed that there might be a relationship between the amount of contact there is between the surface of the insoles and the user's feet and static balance. They have reported that insoles with full contact and partial contact with the medial arch of the foot improved static balance.

However, several studies have reported no effects of textured/cupped/rigid insoles (Qu, 2015; Hatton, A. et al., 2012) and insoles with toe-grip bars and short medial support heel cups (Nakano et al., 2017) on the static balance of older people.

The mentioned literature shows that there are equivocal results regarding the positive effects of insoles on balance. It is not possible to reach a firm conclusion without considering the reasons balance is impaired in the target groups (Table 2.1). According to the reviewed papers, it seems insoles and, particularly, textured insoles can improve balance in people with sensory deficiency. It is known that older people suffer sensory deprivation (Shaffer and Harrison, 2007), and the mean sensory threshold of their feet is higher than young people (Priplata et al., 2003). This might negatively affect balance (Cruz-Almeida et al., 2014). In addition, skin sensation of the foot plantar surface decreases in fallers (Fujimoto et al., 2015) and individuals with chronic LBP (Lee et al., 2016). However, the effectiveness of not only textured insoles, but also those with a flat surface, on the clinical balance performance of older individuals without sensory impairment has also been reported (de Morais Barbosa et al., 2018). In fact, as the insoles make a better contact with the BOS through the plantar surface of the feet, they can stimulate somatosensory mechanisms (Qiu et al., 2012) and increase input data from the environment (the foot's contact surface) to the CNS and might, thus, improve stability. Using rigid materials for insoles may have a similar effect. The mechanoreceptors of the foot sole are stimulated when they are in touch with the insoles, which leads them to sending more feedback from the environment to the CNS, resulting in an improvement in stability (Robbins et al., 1998). Hatton, A.L. et al. (2013) presumed the effect of textured insoles on balance depends on having a baseline level of balance control in addition to providing an adaption period for cutaneous mechanoreceptors after changing the plantar sole contact surface. Many older people prefer to use slippers at home, which increases the risk of falling in comparison to walking barefoot. Walking barefoot or with socks can also multiply the risk of falling compared to walking with athletic or canvas shoes (Ambrose et al., 2013). Thus, as using insoles with socks improves the balance in elderly people (Ma et al., 2018), this might be a better option for use at home to decrease indoor falling incidences. Interestingly, many participants have expressed their desire to continue using insoles following involvement in the related studies (Perry, S.D. et al., 2008; Mulford et al., 2008). Accordingly, insoles might be a low cost and easily available way to improve the balance of persons at risk of falling, such as elderly people and, probably, unilateral LLAs.

2.6.2 Use of insoles in walking (dynamic balance) and for pain reduction or prevention of musculoskeletal injuries in non-amputees

Besides using insoles to alter the foot pressure in diabetic feet (Martinez Santos, 2016; Paton et al., 2011), a huge focus of biomechanical research related to insoles use during walking is concerned with the effectiveness of lateral-wedged insoles on lower limb kinetics in people at risk of knee osteoarthritis or suffering from it (Arnold et al., 2016; Xing et al., 2017; Shaw et al., 2018; Zhang et al., 2018). A review of these studies is beyond the scope of our research because the nature of the utilized custom-made insoles, with a considerable number of modifications, which is contrary to the aim of this study, with employing prefabricated insoles, resulting in the least amount of alteration to the shape of the normal sole. Another area of interest in the field of research looking to evaluate insoles used during walking is how their specific design affects the alignment of the components of the foot. This is also far from the aims of this study. The results of the following studies are more in line with ours. The improvement in dynamic balance in the form of an increase in the stability margin (the distance between the extrapolated centre of mass and lateral border of the feet) during walking on a treadmill has been reported, comparing hard insoles and soft ones (Qu, 2015). The margin has been related to the increased somatosensory feedback, the maintenance of the foot in a neutral position and, consequently, enhancement of the muscle function in the stability of the ankle joint (Qu, 2015). Surprisingly, Hatton, A. et al. (2012) reported an inverse effect of textured insoles on the spatio-temporal variables of older fallers in the form of decreasing walking velocity and stride/step length. However, no differences were observed in step width (as a variable related to balance during walking) after the immediate/long-term use of textured insoles (Wilson et al., 2008). Hartmann et al. (2010) also found no differences between the walking spatio-temporal variables of two groups of elderly people who had 12 weeks of training exercises with and without insoles (with projections to stimulate the somatosensory system). However, both training groups showed improvement in walking speed and step length compared to a control group without any intervention. But, a reduction in the variability of elderly fallers' temporal features of walking (stride, stance and swing time (Galica et al., 2009)) and the spatial variables of the healthy elderly (stride length and step width (Stephen et al., 2012)) after using vibrating insoles has been reported. The results were thought to be due to the effectiveness of the insoles on affecting dynamic balance and have been related to the stimulation of the sensorimotor system. Based on similar reasons, the use of edged insoles was associated with improving dynamic balance control in the form of an increase of the COM-BOS' lateral border distance during walking (Perry, S.D. et al., 2008; Maki et al., 2008). The disagreement between the results of these studies might be due to the diversity in the level of somatosensory stimulation provided by the experimental insoles and the differences in the variables studied.

We know walking is a routine human cyclical activity, which is associated with repetitive loading and unloading of the lower limbs. The lower limb presents a force to the ground via the foot after initial contact, which might exceed the body weight, and is considered to be an indicator of the load on the limb. Hence, numerous researchers have studied insoles use from this point of view. Creaby et al. (2011) found flat insoles, as opposed to an insole with a short heel cup and medial arch support, reduced the first peak of vertical reaction force during the walking of healthy people. The rate of this loading is also a matter of concern as a particular factor might facilitate lower limb injuries (Riskowski et al., 2005). Adding a shock absorber to the footwear might change the loading rate. It has been seen that using commercial shock absorber insoles changes the acceleration of the tibia in the initial stance phase; this is considered a reduction of the loading rate of the limb (Johnson, 1988). Using insoles with arch supports decreases the loading rate and the vertical force of the initial stance due to better adjustment of the feet to the walking surface (Jafarnezhad Gero et al., 2015). The use of shock absorber insoles was also associated with a decrease in pain and the improvement of the physical function of patients with knee osteoarthritis, but the biomechanical variables of their walking (including vertical tibial acceleration, knee adduction moment peaks, and impulses) did not change (Turpin et al., 2012). The studies mentioned indicate insoles might have mechanical effects, including supporting the neutral structure and alignment of the feet, providing even pressure distribution and reducing the impact in walking. In addition, insoles might increase the sensory input to the plantar mechanoreceptor (Hatton, A.L. et al., 2013).

The evaluation of insoles use in the reduction of injuries is another field of footwear research. Many studies use qualitative variables, such as pain intensity, to evaluate the effectiveness of different custom-made or commercial insoles in the alleviation of pain. Longitudinal studies have shown that insoles might affect pain and injuries incidence in the lower back and limbs. In fact, a rich body of literature is related to the application of insoles for chronic low back pain as a broad musculoskeletal problem. Several such studies have recruited military personnel for their research into the effectiveness of insoles because participants are available in large numbers (>200), and these participants are subject to back and lower limb injuries due to physically demanding long-term physical training.

Foot function has relation with LBP (Bird, A.R. and Payne, 1999) and numerous studies confirmed the effectiveness of orthotic interventions in the reduction of the condition (Dananberg and Guiliano, 1999; Mundermann et al., 2001; Larsen et al., 2002; Shabat et al., 2005; Mattson, 2008; Almeida et al., 2009; Cambron, J.A. et al., 2011; Castro-Méndez et al., 2013; Ferrari, 2013; Williams et al., 2013; Kendall et al., 2014; Sin Lee et al., 2015; Mehra et al., 2016; Cambron, J. et al., 2017). Several studies also have reported a positive capacity of insoles in the reduction of lower limb soft tissue and/or the incidence of bone pain/overuse injuries (Mundermann et al., 2001; Larsen et al., 2002; Franklyn-Miller et al., 2011; House et al., 2013) or foot pain reduction and comfort improvement during daily activities (Mulford et al., 2008; Cho et al., 2009; Turpin et al., 2012; Amer et al., 2013; de Morais Barbosa et al., 2013; Bahramian et al., 2017). Meanwhile, there are studies which did not show a positive effect of insoles use as well (reporting effectiveness of semirigid and soft custom-made insoles on LBP incidence among foot soldiers (Milgrom et al., 2005);effectiveness of 3 commercial insoles including a flat insole made of rough plastic with a fabric top and two insoles with shock-absorbing materials, on lower limb injuries of air force personnel (Withnall et al., 2006); the effectiveness of a rigid custom-made insole on overused lower limb injuries of soldiers (Mattila et al., 2011) during their military service training, with a high level of physical activities). There is no single interpretation of the mechanism explaining the effectiveness of insoles on pain. Insoles may change the timing of the activity of muscles around the lumbar region during walking (Kendall et al., 2014). As walking is a repetitive daily activity, changing the muscle activities is associated with altering lower back loads (Bird, A. et al., 2003). It should be noted that people with chronic LBP experience fatigue of the lumbo-pelvic muscles quicker than those without LBP (Kendall et al., 2014). Insoles might make delays in the fatigue occurrence via changing the timing of muscle activity. The abnormal alignment of the components of the foot (for example, foot pronation) might lead to pelvic tilt and mechanical LBP (Kendall et al., 2014). Insoles can change foot alignment and, consequently, affect the alignment of the lower limb (Castro-Méndez et al., 2013; Kendall et al., 2014; Ball and Afheldt, 2002b), which is linked to the pelvis and affects their relationship. It is even possible that the foot orthosis has emotional and psychological aspects (Williams et al., 2013). Interestingly, a combination of using insoles and other LBP treatments, such as chiropractic, has led to a reduction of LBP (Kendall et al., 2014; Mattson, 2008; Ferrari, 2013; Cambron, J. et al., 2017). The performance of insoles in the prevention of lower limb overuse injuries is not clear. Repeated impact stress is a common feature of such injuries (House et al., 2013). In addition, a less pronated foot at heel contact has been reported to be associated with an increased risk of overuse injuries (Hesar et al., 2009). Hence, the insoles might be effective in preventing lower limb injuries by changing the activation of the musculature controlling the ankle during the gait cycles (Murley et al., 2009), correcting the malalignment of the foot/lower limb (Urabe et al., 2014) or reducing the impact force in shock-absorbing insoles (House et al., 2013). However, it is necessary to keep in mind the following facts about the cited studies. The studies were heterogonous from many points of view. There were differences in the age and activities of the participants, the aetiology of pain, biopsychosocial factors (including such biological factors as genetic and biochemical factors, etc.; psychological factors, such as mood, personality, behaviour, etc.; and social factors, such as cultural, familial, socioeconomic, medical, etc.), as well as the effect of the practitioner on the custom-made insoles, all of which might have affected the results. Furthermore, the length of follow-up, the definition of pain/injury, or the design of the utilised insoles vary across the studies, which might also have resulted in dissimilar results (Kelly and Valier, 2018). Finally, as Bonanno et al. (2017) expressed in their review paper, the generalisation of these findings must be done with care because the participants in most of the studies, which are related to the successful use of insoles to prevent injuries and pain, were military personnel in military training conditions, which is different from the general population going about their normal daily activities. However, these probable reasons for the diversity in the results should not stop new studies being set up to evaluate insoles effectiveness (as a feasible intervention, with unclear underlying mechanisms of effect and a significant level of supporting research) on musculoskeletal problems.

2.7 Discussion and conclusion

Lower limb prosthesis users might suffer from various musculoskeletal problems due to a lack of part of their lower limb, and body adjustments to this loss. A higher rate of LBP, loading on the intact side, intact-side pain and falling are some critical problems in lower limb amputees' daily life. In addition, it has been established that the problems of lower limb amputees increase in the more proximal location of the amputation due to the loss of a greater part of the musculoskeletal system. There are fewer studies available related to the biomechanics of TF amputees' locomotion and balance in comparison to TT amputees, which encourages us to consider it as an opportunity to enhance biomechanical knowledge regarding balance and walking. The referred studies have shown that biomechanical evaluation of the daily activities of impaired people - including the balance of fallers and lower limb amputees (as a group which is at risk of falling in addition to lacking part of their locomotion structure) - through using motion analysis systems can give better insight into the biomechanical differences between them and non-impaired people, and can be beneficial in seeking the solutions required to enhance their balance and safety in their regular daily activities.

To date, the work related to improving the biomechanics of amputees' locomotion has mostly been focused on the amputated side, and on prosthetic design. It is necessary to remember that the capacity of the prosthetic device has limitations, and in the end, it is the intact-side that adjusts to different conditions to restore balance; thus, its health and support are a matter of great concern. It seems less attention has been paid to solving or preventing intact-side problems. This gap provides an opportunity for investigation into the possibility of enhancing the functionality of amputees (in terms of improving their balance and the spatio-temporal characteristics of walking to bring them closer to non-amputees' balance and walking characteristics) and preventing unwanted events (such as falling) in their daily activities by applying external changes in the intact side; e.g., using orthotic devices to correct biomechanical variables. The position of the COP in the BOS, and its relationship with the COG, influence human balance during standing and walking. As has been mentioned, the COP is the action point of the ground reaction forces on the plantar surface of the foot (Winter, 1995). Thus, the manipulation of the COP position and GRF distribution by using insoles might affect balance. In spite of equivocal studies about the effectiveness of insoles on the musculoskeletal system and the mechanism of their effects, more studies about different groups of people with musculoskeletal problems can help to enlighten us regarding their use. It should be noted, no study has been found related to the use of insoles among lower limb prosthesis users. Although, some studies confirm the effectiveness of insoles on decreasing lower limb musculoskeletal injuries and pain, or in the improvement of the static and dynamic balance of non-amputees.

By considering the mentioned facts about lower limb amputees' problems, and according to the different aspects of insoles effectiveness in non-amputees, this thesis assumes that insoles are useful for improving lower limb amputees' intact-side conditions.

2.7.1 Aims and objectives

The three main purposes of conducting this research were: 1) to provide an up-to-date data collection related to LLAs' problems, which might be improved via biomechanical interventions; 2) to investigate the effectiveness of insoles use on the biomechanics of perturbed standing balance and level walking of above-knee prosthetic users,; 3) to characterise the biomechanics of above-knee prosthetic users' perturbed standing balance, and to compare these with the same activities being performed by non-amputees. To achieve these aims, the following objectives were considered:

- To investigate LLAs' issues in the areas of functionality (mobility and balance during daily living, in addition to fear of falling and falling experience) via a comprehensive online survey and literature review
- To assess the function level of the TF amputees who participated in the biomechanical tests in this study, according to the spatio-temporal variables of level walking and their ABC scale and PEQ-M scores
- To characterise and compare selected biomechanical features of TF amputees and non-amputees walking. These selected variables are: the spatio-temporal variables of walking (including walking speed, step/stride length, stride time, duration of stance and the swing phases of each limb), COM displacements (vertical, mediolateral), the mediolateral displacement of the COP, the distance between the COP- lateral border of the BOS at mid-stance, the distance between the COG and the lateral border of the BOS at mid-stance, the angular motion of the ankle joint in the sagittal plane, the initial stance loading rate, the lower limb's joint powers and the moments in the sagittal plane
- To investigate the effects of insoles use on the previously mentioned selected biomechanical features of TF amputees' and non-amputees' walking
- To characterise and compare the selected biomechanical features of TF amputees' and non-amputees' perturbed standing balance. These selected biomechanical features are: the amplitude of each limb's COP displacements (in anteroposterior and mediolateral directions), the amplitude of the distance between each limb's COP and COG, the amplitude of each limb's GRF (anteroposterior, mediolateral, vertical forces), the load sharing of each limb during one second before load release (anteroposterior, mediolateral vertical forces), the load sharing of each limb at five seconds after load release (anteroposterior, mediolateral vertical forces), the amplitude of the joint (ankle and hip) moments in the sagittal plane due to load release, the contribution of the ankle and hip of each limb in the SUM moment during one second before

load release, and the contribution of the ankle and hip of each limb in the SUM moment at five seconds after load release

- To investigate the effects of insoles use on the previously mentioned selected biomechanical features of the amputees’ and non-amputees’ perturbed standing balance

Chapter 3

Study 1: Balance and Mobility in Lower Limb Amputees

3.1 Introduction

Healthcare services have been enhanced globally (Ortiz-Ospina and Roser, 2017), which has resulted in a worldwide increase in life expectancy (WHO, 2016). The world's population is getting older, and this is more obviously apparent in developed countries (United Nations. Department of Economic and Social Affairs. Population Division., 2010). These facts show that, besides the possible increase in traumatic amputations among a growing world population, the number of people experiencing complications related to older age (such as dysvascular diseases including diabetes and peripheral arterial disease, which are the main causes of amputation in older age) will also increase, which means that amputations will continue to exist and affect different aspects of life for a significant section of society. The consequences of amputation include changes to the appearance of the body (cosmesis) and the psychological impacts of this, impaired mobility and, possibly, independence in normal life (Gitter, A and Bosker, 2005a).

The lost limb function and cosmetic normally are regained partially by using an external artificial device (prosthesis). The loss of lower limbs affects the role of the limbs in locomotion and weight bearing in standing. However, a prosthetic device is not as good as a natural limb, and its usage can be associated with numerous problems. Different studies have frequently reported the prevalence of lower back pain (Gailey et al., 2008; Ehde et al., 2001; Ephraim et al., 2005; Kusljugic et al., 2006; Sattar, 2007; Devan et al., 2012), falling incidents (Kulkarni et al., 1996; Miller, W C. et al., 2001; Arnold et al., 2016; Steinberg et al., 2019) and injuries due to falling (Arnold et al., 2016; Hunter et al., 2017) among LLAs. In addition, the incidence of osteoarthritis in the intact limb joints of LLAs is higher (Gailey et al., 2008; Struyf et al., 2009; Farrokhi et al., 2016) due to there being more dependence on the limb (Nadollek et al., 2002; Farahmand et al., 2006; Vrieling et al., 2008a; Lloyd et al., 2010; Morgenroth et al., 2012). At the same time, the QOL as a multidimensional concept with different factors [108][108][23](23) might be disturbed in LLAs. Mobility, balance confidence, physical performance and pain experience might affect different aspects of the sufferer's QOL. Thus, conducting frequent research related to prosthetic use can be helpful to find ways of improving LLAs' QOL. Our related research plane was designed in early 2015. The published research before it comprised of separate studies, each one focusing on a limited aspect of an LLA problem. In addition, the studies were bound to specific geographical areas or were restricted to a specific level of amputation. The fewest studies evaluated possible relationships between balance/mobility deficiencies, LBP and its disabling effects. Accordingly, while the participants in the biomechanical tests of this study (Chapters 4 and 5) were from Iran, no prior research was found reporting balance confidence and functional disability due to LBP in Iranian LLAs. Based on this situation, a comprehensive questionnaire needed to be developed to explore the problems experienced by LLAs in a global setting and to collect up-to-date information about the issues associated with prosthetic use by users from around the world. The object of designing of this self-report survey was to examine the inter-relationship between different general variables (such as *age-at-amputation*, amputation cause, level of amputation) and mobility, balance self-evaluation and lessened functionality due to low back pain. This questionnaire, in contrast to most others, collected data regarding several aspects of LLAs' routine life at a single point in time (including the ability to move around, falling experiences, balance confidence during specific daily activities, and low back pain felt at points during several daily activities). The sections related to mobility evaluation and balance will help us to have a better understanding of the functionality of LLAs during their daily activities which are affected by these issues. In addition, this understanding will add to the present knowledge about any possible relationships existing between unpleasant conditions, such as intact-side or low back pain, and balance or mobility deficiencies, in LLAs. The survey also helps to have a more precise understanding about LLAs' needs and problems which can be handled and improved by various experts from different scientific fields, including physiotherapist, prosthetists, biomechanists and engineers. On the other hand, The online nature of the survey permitted us to collect data from participants from a range of countries. It provided knowledge about LLAs regardless of where they lived and the technological level of devices they might be using.

This chapter presents the results of the online questionnaire and investigates the statistical relationship between its various parameters. The objective of this chapter is to answer the following research questions:

- Focusing on their amputation and prosthetic use, and particularly related to their mobility (PEQ-M score) and balance (ABC Scale score, falling experience, worry about falling, aided walking), what are the main issues LLAs face during their daily activities?
- Is there any inter-relationship between balance and mobility?
- Is there any association between body sensations/LBP and balance/mobility deficiencies?

3.2 Methodology

3.2.1 Structure of the Questionnaire

The questionnaire was developed to evaluate functionality and significant physical issues, such as balance problems, contralateral limb and low back pain conditions, in addition to certain aspects of daily prosthesis use encountered by LLAs, in a cross-sectional study design. The survey was formed by combining three standard questionnaires and is comprised of 52 questions drawn from the Prosthesis Evaluation Questionnaire (PEQ) (Legro MW et al., 1998), the Activities-specific Balance Confidence

(ABC) Scale (Powell and Myers, 1995), Oswestry Low Back Pain Disability Index (ODI) Questionnaire (Fairbank and Pynsent, 2000). Only the first questionnaire is specifically related to amputees and, together with the two other questionnaires, was adapted to fit the study's goals. For example, the original PEQ questionnaire uses a visual analogue scale format. In addition, for both the PEQ and ABC questionnaires, scores should be given on a 0-100-point scale. This was changed to a 0-10-point scale. It is important to know that the ABC Scale questionnaire was originally developed to examine the physical functioning of older people from a balance confidence point of view. However, its reliability and validity have been confirmed for LLAs as well (Miller et al., 2003) and, accordingly, it has been adapted to the survey. Similarly, the Oswestry Disability Questionnaire which was developed to evaluate levels of disability in daily life caused by LBP, has been shown to be a valid tool. These questionnaires are freely available[1] in the public domain, available from various research organizations and sources. Three attempts were made to contact The Prosthetic Research Study (the developers of the PEQ) via the email address on their website (email addresses: info@prs-research.org, peq@prs-research.org) to inform them that we were using their questionnaire (as requested on the web site) but no response was received. The mixed, new questionnaire had 15 main sections containing 116 questions (Appendix A). These covered: background questions (e.g., age, gender, country location); questions about general health; the level of amputation; *time since amputation*; pain on the non-amputated side and where it is situated ; prosthetic satisfaction; self-determined QOL; body sensations; the social and *emotional aspects* of using a prosthesis; mobility; the most important aspects of a lower limb prosthesis for the respondents; balance confidence during given daily activities; falling experience; and any experience of low back pain and related details (e.g. intensity and its effect on different aspects of routine life, such as personal care, sitting, standing, sleeping, etc.). The questions were Yes/No or multiple choice; in addition, a Likert type scale (0 to 10) or nominal choices were used for rating questions. The questionnaire was initially prepared in English and later translated to Persian (Appendix A1 and A2). The validity and reliability of the Persian versions of these questionnaires have been approved separately (Adel Gomnam et al., 2016); (Hassan et al., 2015); (Zarrinkoob et al., 2017); (Mousavi et al., 2006). The online questionnaire was created by using a BOS online survey tool[2] and was published after receiving approval from the Faculty of Biological Sciences Research Ethics Committee (Reference number BIOSCI 15-005; Appendix B). As part of the ethical principles of the research, a general explanation, including the purpose, its parts and assuring to keep the information confidential, was provided on the first page of the survey. The participants proceeded with the survey only after accepting the conditions. The software provided the

[1] PEQ survey at http://www.prs-research.org/Texts/PEQ_A4.pdf, ABC Scale questionnaire at https://geriatrictoolkit.missouri.edu/Activities-specific-Balance-Confidence-Scale.rtf, and the ODI questionnaire at http://www.rehab.msu.edu/_files/_docs/oswestry_low_back_disability.pdf
[2] Available at https://www.onlinesurveys.ac.uk/

participants with the opportunity to leave the study at any time they wished. It was possible for participants to leave their contact address on the last page if they were interested in receiving information about the results (Appendix A). The translated Persian version was also published by the same tool.

3.2.2 Participant Recruitment

The inclusion criteria for participation were as follows: older than 18 years of age, being a lower limb amputee with any level of amputation (from ankle-foot to hemipelvectomy), must be more than six months post amputation surgery, to have experience of prosthesis use of more than two months, to be able to understand questions in English or Persian. The recruitment process for the English and Persian versions followed different stages. At the start of November 2015, an online search was conducted to find LLA support groups in the UK. The keywords used in the search were: amputees, LLAs, limbless, limb loss, amputee support group and prosthetic user groups. An introductory message (Appendix C) was sent to all of those found to request sharing the English survey with their members. Some of them replied positively about sending the survey on to their mailbox contacts and by advertising the survey on their webpage/electronic newsletter or Facebook pages. The email was resent to the non-responding groups at about two months and at 1.5-years. As only 64 respondents participated in the survey, a further online search was performed to find related web pages/Facebook groups or pages in other English-speaking countries, including Australia, Canada, Ireland, New Zealand, South Africa and the USA, at the start of July 2017. Messages or emails were sent to the found web pages or Facebook pages and groups which had more than 500 members.

Publicising the Persian version was conducted by using a different procedure. Efforts to communicate by email with probable amputee networks/webpages totally failed, and no feedback was received in reply to the survey-related messages. Therefore, the researcher decided to promote the Persian survey through face-to-face communication or phone contact during her two months stay in Iran to perform biomechanical tests (Sept. and Oct. 2016). The Persian version was partly publicised during the recruitment process for the biomechanical tests. The researcher attended the Iranian Red Crescent prosthetic clinic in Tehran and advertised the questionnaire verbally to the attendants and prosthetists. As Telegram Messenger[3] is the most popular and widespread online messaging service in Iran, the researcher explored the possibility of finding channels and groups related to communities of the disabled in this android application and advertised the Persian version of the survey by sending a request to their admins. In addition, the researcher asked her friends who are rehabilitation professionals (14 colleagues) to introduce the survey in their networks and publicise the hard copy of it in their communication with LLAs (this part was closed after one year). The amputees who participated in the biomechanical tests (13 participants) completed the hard copy of the

Available at https://telegram.org/

questionnaire while attending their test sessions. Finally, the researcher transferred the hard copy of the completed Persian questionnaires to a BOS online survey tool for later statistical analysis.

3.2.3 Statistical Analysis

All the continuous variables were checked for normality of distribution. Descriptive data, such as frequencies and percentages of participants in each category of nominal variables, are presented. The Chi-square test was used to assess the association between categorical variables (nominal and ordinal variables). In the case of the Chi-square's assumption violation (more than 20% of the cells had an expected count of less than 5), the p-value of the likelihood ratio Chi-square was considered for assessment of significant association (McHugh, 2013). In addition, the Phi coefficient (for 2 by 2 tables) and Cramer's V (for tables more than 2 by 2) are reported to indicate the strength of association in the Chi-square tests. The value interpretation depends on the number of categories of compared variables. The df^* is the smallest number gained from the number of categories for each variable (-1), which will be considered as the criteria of association magnitude. Table 3.1 (Pallant, 2016).

Table 3.1 interpretation of Phi coefficient and Cramer's V as criteria of relation magnitude in Chi-square test (Kim, 2017)

	Strength level		
df^*	small	medium	large
1	0.10	0.30	0.50
2	0.07	0.21	0.35
3	0.06	0.17	0.29
4	0.05	0.15	0.25
5	0.04	0.13	0.22

Independent-samples t-test and one-way ANOVA were used to evaluate the differences of the numerical variables with normal distribution between two groups or more. The effect size, which was calculated using Etta squared (η^2) in the t-test and ANOVA, interprets 0.01-0.059 as a small effect, 0.06-0139 as a moderate effect and ≥0.14 as a large effect. The Kruskal-Wallis H was utilized as a non-parametric alternative to ANOVA for non-normal variables. The Pearson product-moment correlation coefficient, and Spearman's correlation as its non-parametric replacement, were used to investigating the relationship between two numerical variables (the strength of the relationship can be interpreted by the value of the extracted "r" or "rho", according to the values in the first row of Table 3.1) (Pallant, 2016). The statistical analyses were conducted using SPSS version 23.0 (IBM Corp, 2015), with the level of significance set at $p \leq 0.05$ for all analyses.

3.3 Results

The focus of this thesis, which will be presented in Chapter 4 and 5, is on the biomechanics of balance and the functionality/mobility of trans-femoral amputees. These features are partly assessable through PEQ-M and ABC scale questionnaires. Accordingly, the related results of LLA participants in the survey will be presented and discussed in the following sections. Other parts of the survey also gave valuable information about the condition and problems of lower limb amputees. The results related to other parts of the survey (including body sensation (intact and amputated limbs); prosthesis use (quality and effects); the self-efficiency aspects of prosthesis use (emotional/social aspects, satisfaction, important aspect for amputees); the total scores of prosthesis evaluation; and the results related to the ODI) and a comparison of the PEQ-M, ABC scale and ODI of participants from various countries will be presented in Appendix D.

3.3.1 General information

A total number of 167 responses were collected. Ten participants were not LLAs and their data were eliminated from the analysis. Two more responses were excluded because of a very young age (3 years) and one because the respondent was a recent amputee who had no experience of using a prosthetic device. The mean age of the majorly male (61.9%) participants was 54.7 years (SD±12.1). Most of the respondents learned about the survey via Facebook Groups (70 persons, 45.2% of respondents), support group newsletters (34 persons, 21.9% of respondents) and biomechanical tests/face-to-face encounters with the researcher in Iran (18 persons, 11.6% of respondents). Most participants were in their 6th (53 persons, 34% of participants) and 7th (43 persons, 28% of participants) decades of life (Figure 3.1).

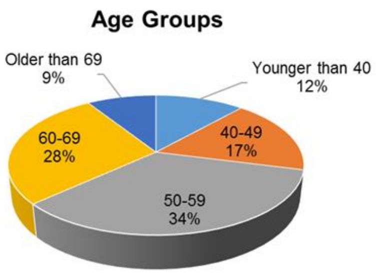


Figure 3.1 Participants age groups percentage

The largest proportion of respondents were below-knee amputees (71 persons, 46% of participants), followed by above-knee amputees (57 persons; 37% of participants). Twelve percent of participants (18 persons) were bilateral amputees (Figure 3.2). Fifty-nine percent of female participants were below-knee amputees and 49% of male participants were above-knee amputees. In addition, all hip-disarticulated participants (2 persons), half of the bilateral amputees (9 persons) or those with knee disarticulation (2 persons) were female.

The respondents' (155 persons) general characteristics, including country, the cause of amputation, years with amputation and age-at-amputation, are outlined in Table 3.2.

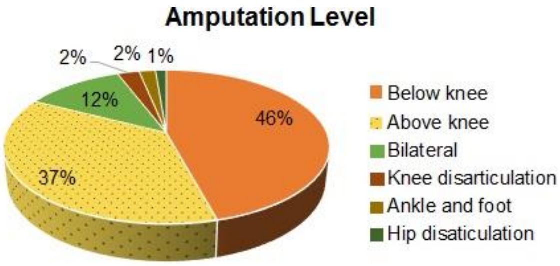


Figure 3.2 Amputation level and location

Table 3.2 Respondents general characteristics

Characteristic	Frequency
Gender: Male (female)	Male: 96, Female: 59
Country	
UK	50 (32%)
Iran	37 (24%)
Australia	33 (21%)
USA	20 (13%)
Other Countries*	15 (10%)
Cause of amputation** (%)	
Serious trauma/injury (including war-related injuries)	73 (47.1%)
Severe infection	31 (20%)
Limited function due to deformity or severe pain	16 (10.3%)
Peripheral arterial disease	12 (7.7%)
Secondary to Diabetes	12 (7.7%)
Other***	12 (7.7%)
Cancer	10 (6.45%)
Congenital condition	8 (5.16%)
Time since amputation (years) ±SD	16.74 ±17.42 (Median= 8.38)
Min-Max (years)	0.48-66.9
under 5 years	64 (41.3%)
More than 20 years	52 (33.5%)
6-10 years	25 (16.1%)
11-20 years	16 (10.3%)
Age-at-amputation M±SD	37.93 ±19.47 (Median=41.3)
Min-Max (years)	0-72.2
Under20 years (percentage)	34 (21.9%)
20-39 years (percentage)	39 (25.2%)
40-59 years (percentage)	61 (39.4%)
Over 59 years (percentage)	21 (13.5%)

* including Canada (7), South Africa (3), New Zealand (2), Mexico (1), Malta (1), Northern Ireland (1).
** Multiple answers were allowed, thus, the total percentages may be more than 100.
*** other causes including blood clot (2), Burst blood vessel via Ehlers-Danlos Syndrome, Causelga. Reflex sympathetic dystrophy, Charcot Marie Tooth Disease, Complications from complex regional pain syndrome, Deep Vein Thrombosis, Elective amputation after several failed orthopaedic, Eosinophilic Fasciitis/Gout/Cellulitis, Ollier Disease (Tumour), Tumour, Medical Mistake

In the description of the stump condition, most participants expressed no problems with their stump (80 persons, 51.6% of respondents). However, the majority of them reported phantom pain (102 persons, 65.8% of respondents) (Figure 3.3).

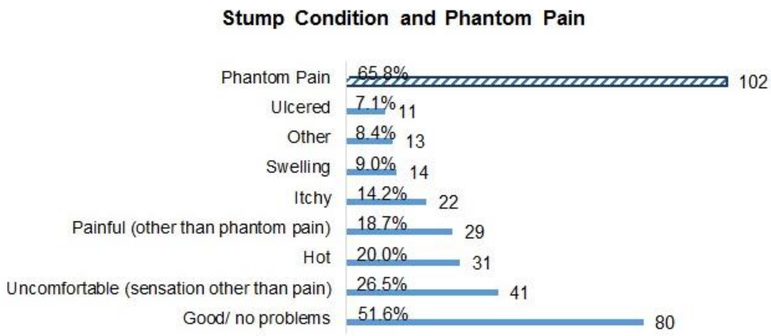


Figure 3.3 Stump condition and phantom pain (question number 22 and 23, Multiple answers were allowed, thus, the total percentages may be more than 100).

Figure 3.4 and Table 3.3 indicate the prevalence of pain in the residual limb (stump pain), painful phantom limb sensation and non-painful phantom limb sensation (questions 48, 51, and 55).

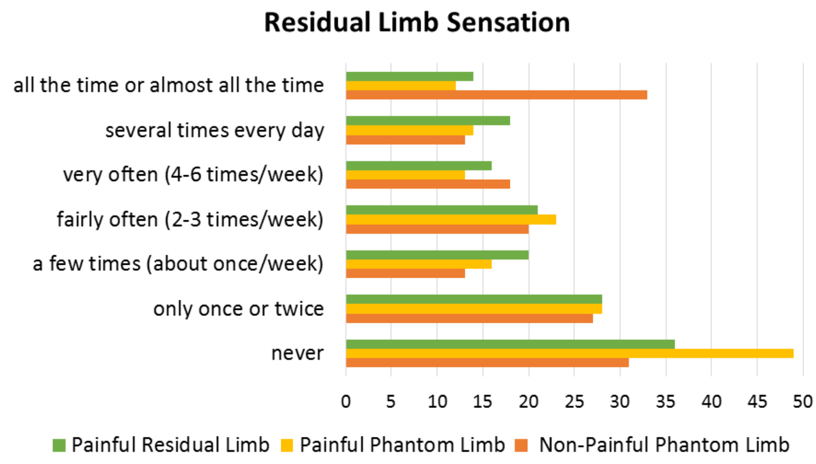


Figure 3.4 Frequency of painful/non-painful phantom limb and pain in stump (questions number 48, 51, 55)

Table 3.3 Frequency of painful/non-painful phantom limb and pain in stump

sensation frequency	Non-painful phantom limb	Phantom pain	Stump pain
never	20.6%	31.6%	23.5%
only once or twice	17.4%	18.1%	18.3%
a few times (about once per week)	8.4%	10.3%	13.0%
fairly often (2-3 times per week)	12.9%	14.8%	13.7%
very often (4-6 times per week)	11.6%	8.4%	10.5%
several times every day	8.4%	9.0%	11.8%
all the time or almost all the time	21.3%	7.7%	9.2%
Total number of responses	155	155	153

Most subjects experienced some sensation at some time in each of the three sensation categories, while 21.3%, 7.7% and 9.2% of participants experienced non-painful phantom pain, painful phantom limb and stump pain respectively (-, - -) all of the time or almost all of the time.

Pain experience in the non-amputated side, and its location during walking or after, have been presented in Figure 3.5. Among 137 participants (the unilateral amputees), the more frequent pain in the non-amputated side was related to the knee joint (37.2%) and hip joint (31.4%). Almost one third of the participants reported no pain in their intact limb.

Figure 3.6 shows the percentage of respondents in different categories and their intact-side pain frequency. Twenty-seven percent of unilateral amputee respondents had never felt pain in their intact side. However, 10% of the participants had these feelings all the time or almost all the time.

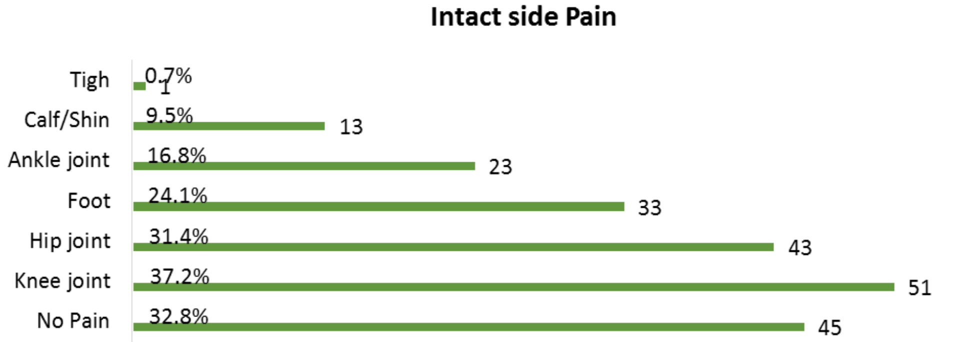


Figure 3.5 Pain condition of the non-amputated side during last 4 weeks (Multiple answers were allowed, thus, the total percentages may be more than 100)

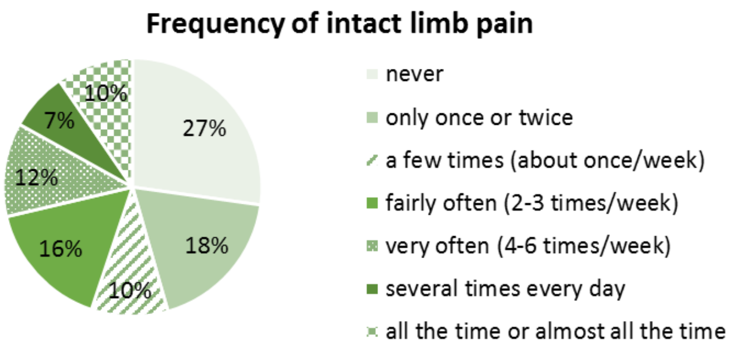


Figure 3.6 Frequency of pain experience in the intact limb during last 4 weeks (Q58)

Table 3.4 gives a picture of the prevalence of sensations, pains and balance-related qualities among the participants.

Table 3.4 Prevalence of body sensations, LBP, falling experiences during last 12 months, being worried to fall among the participants

	Body sensations							
	Phantom limb	Phantom pain	Stump pain	Intact limb pain	LBP	Walking aids	Faller	Worried about falling
Frequency (% of responses to the question)	124 (80%)	102 (66%)	117 (76.5%)	99 (64%)	117 (75.5%)	91 (59%)	96 (62%)	111 (72%)

The majority of participants wore their prosthetic device the whole day or most of the day (118 persons, 76.1% of respondents), and only two participants currently do not use their prosthesis and three rarely use it (Figure 3.7).

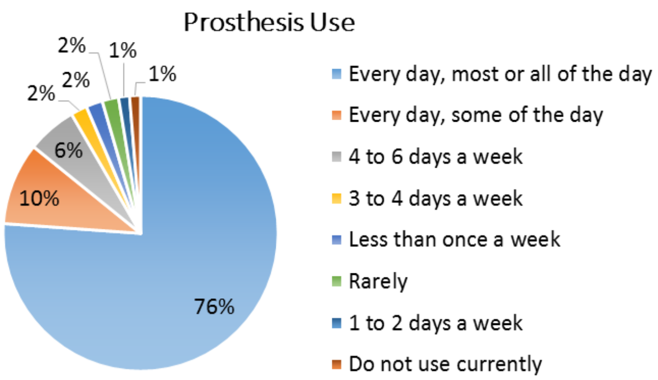


Figure 3.7 Frequency of prosthesis use (Q21)

Figure 3.8 provides the level of satisfaction respondent's felt related to their prosthesis, walking, QOL and the training received when they started using the prosthesis (19.7% stated that they received no training). The respondents were asked to score from 0 to 10 in reply to each question. Generally, the majority of respondents were satisfied with each condition.

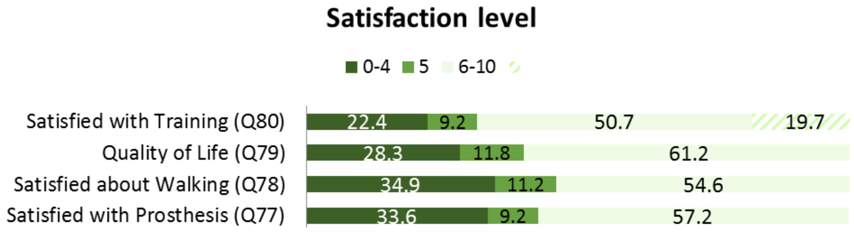


Figure 3.8 Percentage of lower scores (0-4), neutral (5) and higher scores (6-10) for questions 77-80. The dashed pattern shows the number of respondents without receiving training sessions.

The scores given to several selected important aspects of prosthesis use are displayed in Figure 3.9. The selected items include the *importance of prosthesis appearance*, the *importance of the ability to wear different shoes*, *bothersome swelling of the residual limb*, and the *importance of the ability to walk up steep hills*. Respondents were asked to score from 0 to 10 to show the level of each item's importance, where a 0 score was for least importance and 10 was the indicator of the highest level of importance. However, the scores for *bothersomeness of stump swelling* were inverted to adjust to the previous question's scoring. The figure indicates that all items, except *bothersomeness of stump swelling*, had a high level of importance for more than 50% of respondents. The lowest percentage of respondents had a concern about the *bothersome swelling of residual limb* (33.1% of respondents), and most gave importance to *walking up steep hills* (73.9% of respondents).

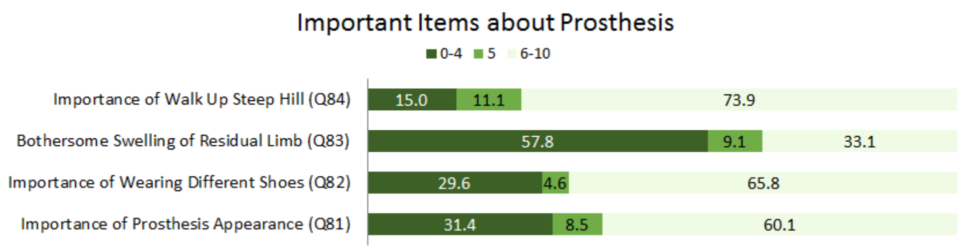


Figure 3.9 Percentage of lower scores (0-4), neutral (5) and higher scores (6-10), given to questions related to the importance level of the certain aspects of prosthesis use.

3.3.2 PEQ-M (Mobility)

Figure 3.10 shows the responses to the questions about the ability to move around and perform some routine tasks (PEQ-M, questions number 64-76). The respondents were asked to score from 0 to 10 in reply to each question. In this diagram, the darkest colour lying most to the left is for the score 0, which is worst score, versus the lightest colour, lying most to the right, which shows the score 10, which represents the best score. The total score had an average value of 5.74 (± 2.38, MED=5.92, N=153). The lowest scores were given to questions about the ability to walk on a slippery surface and the ability to walk down/up a steep hill, followed by the ability to sit down/get up from a low/soft chair. The ability to move up/down stairs seems to be the most difficult tasks for the respondents.

Figure 3.11 shows the percentage of responses to the same questions (Figure 3.10) in the form of weaker scores (0-4), a neutral score (5) and higher scores (6-10)). Most of the respondents gave higher scores to questions related to the ability to sit down and get up from a chair (70.1%), the ability to take a shower/bath safely (69.5%), the ability to walk in a closed space (68.2%), the ability to sit down and get up from the toilet (66.9%), the ability to walk (66%), and the ability to walk on pavements and streets (61.7%). More than 40% of participants selected the lowest scores for questions related to the ability to walk down (68%)/up (60.5%) a steep hill, the ability to walk on a slippery surface (63.6%), and the ability to sit down and get up from a low/soft chair (43.5%).

The PEQ-M score was gained by averaging the scores of questions numbered 64-76. There was no significant relationship between the PEQ-M score–age (p=0.21) and the score across males (n=96, MED=6.41) and females (n=59, MED= 5.93), with 77 as the mean rank of both (p=1).

No difference was observed between the PEQ-M score of: 1 - *age-at-amputation* groups (p=0.795); 2 - *amputation cause* groups (p=0.23); 3 - *time since amputation* categories (p=0.88); 4 - *location of amputation* groups (p=0.24); and 5 - *age-at-amputation* (p=0.58).

No significant differences were observed (p=0.27) between the PEQ-M score of participants with phantom limb (Mean rank=75.02, n=122, MED=5.73) and without phantom limb (Mean rank=84.79, n=31, MED= 6.85). However, there was a significant difference (χ^2(1)= 14.29, n=153, p<0.001) between the PEQ-M score of participants with phantom pain (Mean rank=67.71, n=104, MED=5.54) and without phantom pain (Mean rank=96.72, n=49, MED=7.23). Similarly, there was a significant difference (χ^2(1)= 11.68, n=151, p=0.001) between the score of participants with stump pain (Mean rank=69.2, n=115, MED=5.69) and without stump pain (Mean rank=97.74, n=31, MED= 7.38).

There was a positive relationship between the *bodily sensation-both sides* score and the PEQ-M score (rho=0.52, n=144, p<0.001). A moderate-strong positive relationship was also observed between the “amputated-side bodily sensation” score and the score of the PEQ-M (rho=0.49, n=137, p<0.001).

A significant difference (χ^2(1)= 12.52, n=134, p<0.001) was found between the PEQ-M score of participants with intact limb pain (Mean rank=60.17, n=97, MED=5.69) and without intact limb pain (Mean rank=86.72, n=37, MED= 7.38).

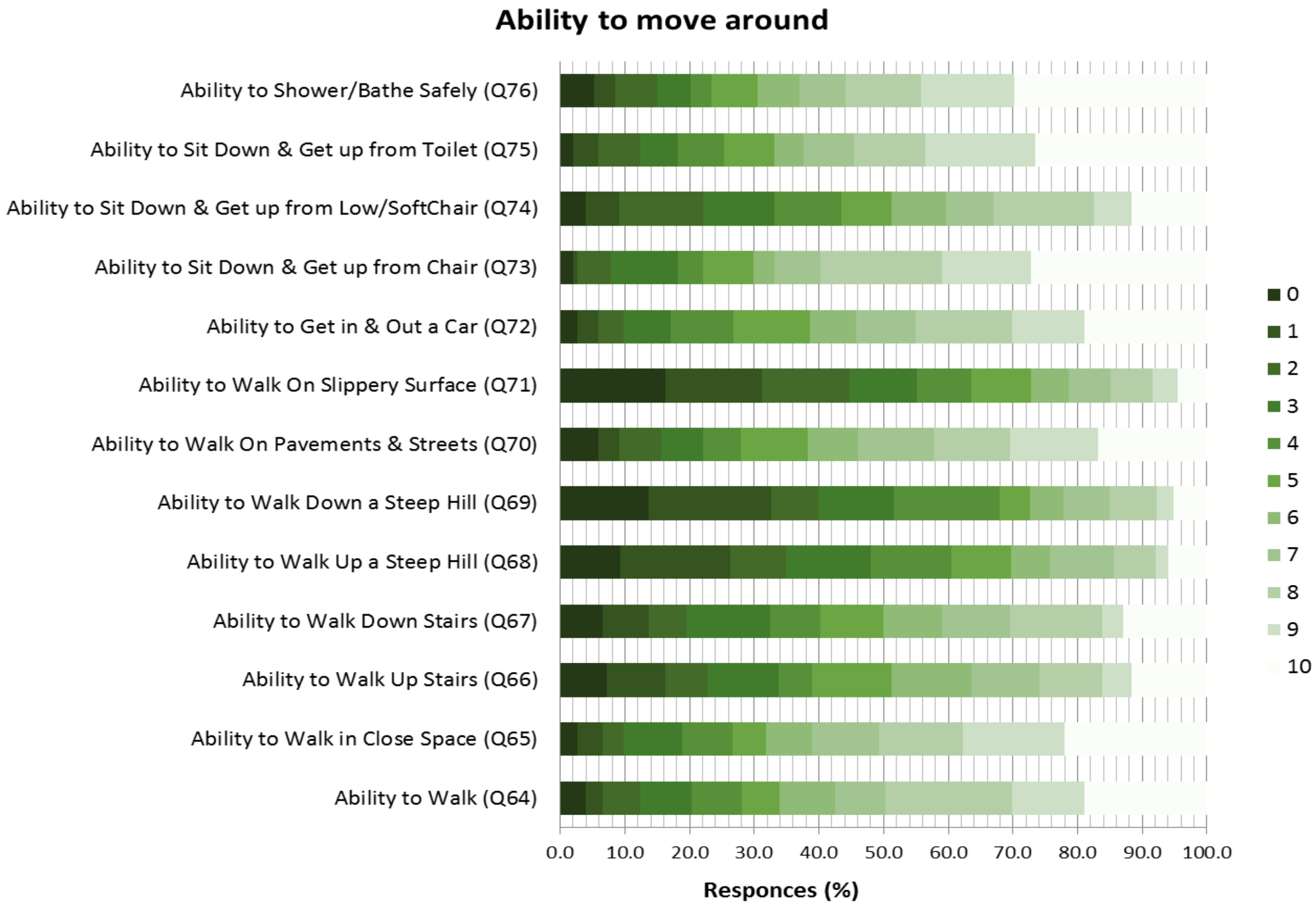


Figure 3.10 Responses to questions related to the ability to move with prosthesis, darkest colour represents worst score (0) and lightest colour is for highest score (10).

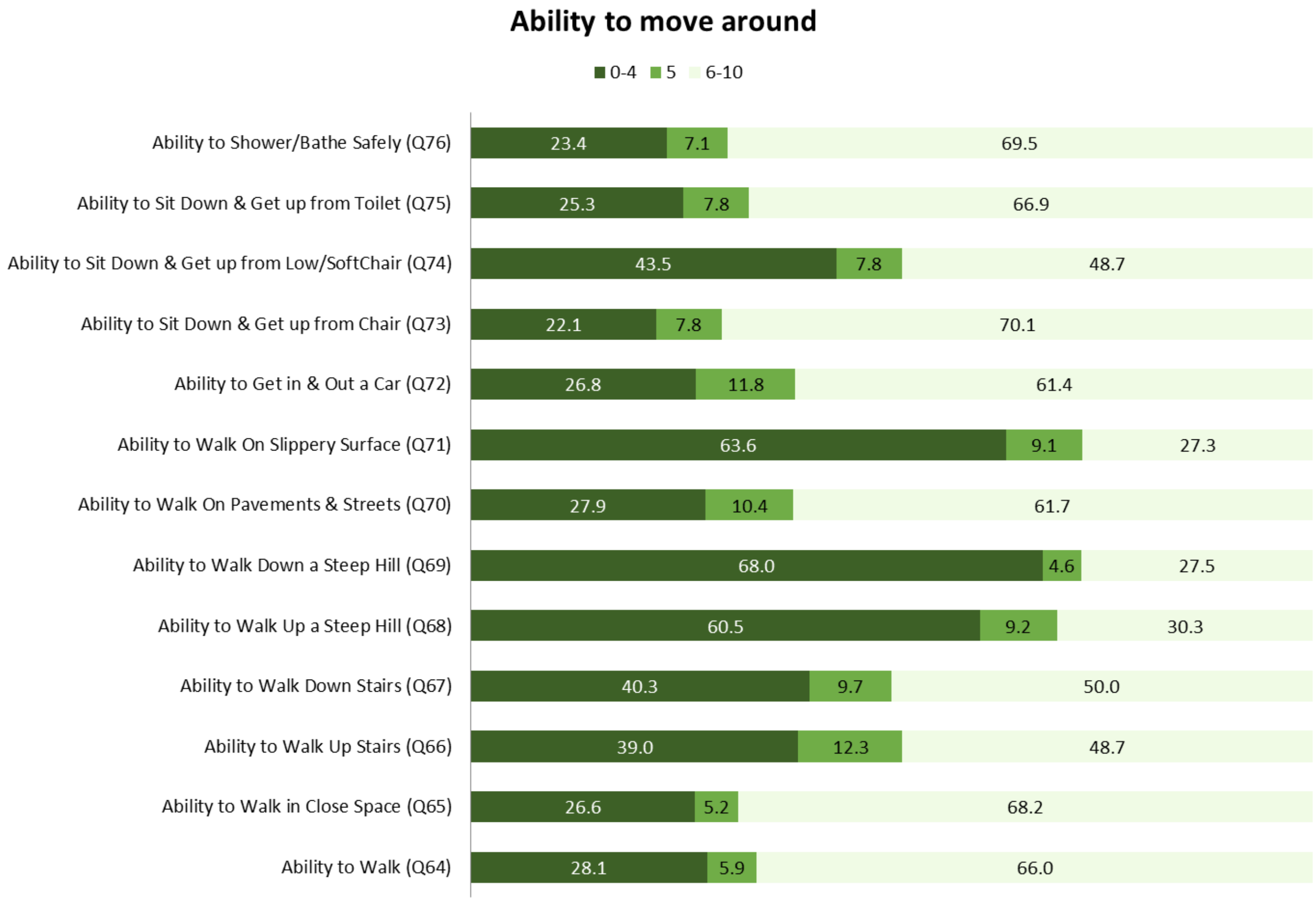


Figure 3.11 Percentage of worse scores (0-4), neutral (5) and better scores (6-10) to questions related to PEQ-M

There was a positive moderate relationship between the *intact limb bodily sensation* score and the PEQ-M score (rho=0.475, n=96, $p<0.001$).

There was a positive strong relationship between the *emotional/social aspects* score and the PEQ-M score (rho=0.604, n=153, $p<0.001$). A positive strong relationship was also found between the “satisfaction” score and the PEQ-M score (rho=0.74, n=153, $p<0.001$).

There was a strong positive relationship between the PEQ-M score and the *emotional aspects* score (rho=0.604, n=153, $p<0.001$). The high/low scores of each variable were associated with the high/low scores of the other item.A strong positive relationship between the PEQ-M score and *being satisfied with prosthesis* score was observed (rho=0.743, n=153, $p<0.001$). The high/low scores of each variable were associated with the high/low scores of the other item.

There was a significant difference between the score across three categories of *QOL* (χ^2(2)= 68.105, n=152, $p<0.001$). The mean rank and median were highest for the best level (98.86, MED=7.15, n=92, M±SD=6.98±1.7) and lowest for the worst level (31.73, MED=2.96, n=42, M±SD=3.25±1.76). For the neutral level (score 5), the values were: mean rank=66.67, MED=5.04, n=18, M±SD=5.35±1.7. The post hoc test revealed a significant difference between the best-worst scores ($p<0.001$), best-neutral level ($p=0.014$), worst-neutral level ($p=0.015$).

The relationship between the PEQ-M score and the *Quality of Life* score was in agreement with the above results. A strong positive relationship between two variables existed: rho=0.69, n=152, $p<0.001$. The high/low scores of each variable were associated with the high/low scores of the other item.

3.3.3 Results related to balance

Balance of participants was evaluated via questions related to history of fall experience during the last 12 months, their feeling of worry about falling, their use of aids to walk, and their scores from the ABC questionnaire.

3.3.3.1 Falling experience

Questions 87 and 88 asked the respondents about being *worried about falling* when using their prosthesis, including the level of worry, their falling experience and the number of fall events they had experienced during the last 12 months.

Among the total number of 155 respondents, 96 (61.9% of total respondents) had an experience of falling during the last 12 months (question 88). Among fallers, the most frequent number of falls were two, three and more than 10 times, experienced by 18, 16 and 13 participants, respectively.

No statistical association was found between falling experience and: 1 - frequency of prosthetic use (p=0.086). The percentage of falling participants was highest (79%) among those using their prosthesis every day, all or most of the day; 2 - gender (p=0.402); 3 - *age groups* and previous fall experiences (p=0.86); 4 - participants' country of residence (p=0.113); 5 - *time since amputation* categories (p=0.702); 6 - *amputation cause* categories (p=0.84); and 7- amputation location categories (p=0.13).

There was a moderate difference between the experience of falling in *age-at-amputation* groups ($\chi^2[Pearson](3, n = 155) = 9.46$, p=0.024, $df^* = 1$, Cramer's V=0.247). As is seen in Table 3.5, the highest rate of fall experience was experienced by participants suffering an amputation before the age of 20 (79.4%) and the lowest rate is for those having an amputation after the age of 59.

There was no significant difference (p=0.379) in age for participants with falling experience (M±SD=54.51±12.66) and without it (M±SD=54.9±11.34). No significant differences were observed between the *time since amputation* as well as *age-at-amputation* among participants with or without falling experience (respectively, p=0.176 and p=0.18).

A moderate association existed between experience of falling and worries about falling ($\chi^2[Pearson](1, n = 155) = 14.15$, p<0.001, $df^* = 1$, Phi=0.302) (Table 3.5).

Table 3.5 Association between *age-at-amputation* groups and falling experience during last 12 months

Age-at-amputation groups (years)		Fall experience: yes	Fall experience: no	Total
≤19	Count	27	7	34
	% within the amputation age-group	79.4%	20.6%	
	% within fall experience	28.1%	11.9%	
	% of Total	17.4%	4.5%	21.9%
20-39	Count	19	20	39
	% within the amputation age-group	48.7%	51.3%	
	% within fall experience	19.8%	33.9%	
	% of Total	12.3%	12.9%	25.2%
40-59	Count	40	21	61
	% within the amputation age-group	65.6%	34.4%	
	% within fall experience	41.7%	35.6%	
	% of Total	25.8%	13.5%	39.4%
≥60	Count	10	11	21
	% within the amputation age-group	47.6%	52.4%	
	% within fall experience	10.4%	18.6%	
	% of Total	6.5%	7.1%	13.5%

As can be seen in Table 3.6, a moderate association existed between experience of falling and worries about falling ($\chi^2[Pearson](1, n = 155) = 14.15$, p<0.001, $df^* = 1$, Phi=0.302).

A significant difference was seen between the PEQ-M score of faller/non-faller participants (χ^2(1)= 6.055, n=153, p=0.014). Mean rank and median for faller participants (70.21, MED=5.69, n=96, MEDM±SD=5.36±2.3) were lower than for non-faller participants (88.44, MED=6.31, n=57, MEDM±SD=6.38±2.38).

Table 3.6 Association between falling experience during last 12 months and being worried about falling

			Worried to fall		Total
			yes	no	
Fall experience	yes	Count	79	17	96
		% within the fall experience	82.3%	17.7%	
		% within worried about falling	71.2%	38.6%	
		% of Total	51.0%	11.0%	61.9%
	no	Count	32	27	59
		% within the fall experience	54.2%	45.8%	
		% within worried about falling	28.8%	61.4%	
		% of Total	20.6%	17.4%	38.1%

3.3.3.1.1 Worried about falling

Among the total number of 155 respondents, 111 (71.6% of respondents) were worried about falling during prosthesis usage (question 87).

As majority of participants were worried about falling, no statistical association was observed between being worried and: 1- frequency of prosthetic use (p=0.184); 2 - gender (p=0.926); 3 - *age groups* (p=0.67); 4 - participants' country of residence (p=0.314); 5 - *time since amputation* categories (p=0.966); 6 - *age-at-amputation* groups (p=0.328); 6 - *amputation cause* categories (p=0.366); and 7 - amputation location categories (p=0.075).

There was no significant difference (p=0.66) in age for participants with falling worry (M±SD=54.93±12.84) and without it (M±SD=53.98±10.29).

No significant differences were found between the *time since amputation* as well as *age-at-amputation* among participants with or without being *worried about falling* (in turn p=0.85 and p=0.775).

However, a significant difference was observed between the PEQ-M score of participants with/without worry about falling ($\chi^2(1)$= 33.19, n=153, p<0.001). The mean rank and median for worried participants (63.89, MED=5.38, n=109, M±SD=5.05±2.18) were lower than for participants without the worry (109.48, MED=7.58, n=44, M±SD=7.45±1.96).

3.3.3.2 Aided walking

Forty-one percent of respondents (64 persons) walked unaided and, among 45 of them who recorded their aids, the use of a single walking stick was the most frequent aid. The six respondents who chose other aids stated that they used aides occasionally: for example, when walking long distances or when in crowded areas, when going for a countryside walk or just when they felt a need for one. One person mentioned using a scooter during shopping and another respondent said they sometimes used a walking frame with sitting part. A small association was found between aided walking and gender

($\chi^2[Pearson](1, n = 155) = 6.12$, p=0.013, $df^* = 1$, Phi=-0.199). Only 28.8% female participants walked unaided (Table 3.7).

Table 3.7 Association between unaided walking and gender

			walking unaided		Total
			No	Yes	
Gender	Male	Count	49	47	96
		% within gender	51.0%	49.0%	
		% within walk unaided	53.8%	73.4%	
		% of Total	31.6%	30.3%	61.9%
	Female	Count	42	17	59
		% within gender	71.2%	28.8%	
		% within walk unaided	46.2%	26.6%	
		% of Total	27.1%	11.0%	38.1%

A moderate association was observed between *time since amputation* categories and unaided walking ($\chi^2[Pearson](3, n = 155) = 8.73$, p=0.033, $df^* = 1$, Cramer's V=0.237). Table 3.8 shows that a large proportion of participants in groups who suffered amputation less than 21 years earlier used aids to walk, while around 60% of participants with more than 20 years' experience walked unaided.

Table 3.8 Association between unaided walking and *time since amputation* categories

			Time since amputation				Total
			≤ 5	6-10	11-20	≥21	
Unaided walking	No	Count	41	17	11	22	91
		% within unaided-walking	45.1%	18.7%	12.1%	24.2%	
		% within the time	66.1%	68.0%	68.8%	42.3%	
		% of Total	26.5%	11.0%	7.1%	14.2%	58.7%
	Yes	Count	21	8	5	30	64
		% within unaided-walking	32.8%	12.5%	7.8%	46.9%	
		% within the time	33.9%	32.0%	31.3%	57.7%	
		% of Total	13.5%	5.2%	3.2%	19.4%	41.3%

A small association was found between aided walking and *age-at-amputation* groups ($\chi^2[Pearson](3, n = 155) = 9.67$, p=0.022, $df^* = 1$, Cramer's V=0.25). Table 3.9 shows around 60% of participants who suffered amputation before 20 years of age, walked unaided, while the majority of participants who suffered amputation after 39 years of age used aids to walk.

Table 3.9 Association between unaided walking and *age-at-amputation* groups

			***Age-at-amputation* groups**				Total
			≤19	20-39	40-59	≥60	
Unaided walking	No	Count	14	20	41	16	91
		% within unaided-walking	15.4%	22.0%	45.1%	17.6%	
		% within the age group	41.2%	51.3%	**67.2%**	**76.2%**	
		% of Total	9.0%	12.9%	26.5%	10.3%	58.7%
	Yes	Count	20	19	20	5	64
		% within unaided-walking	31.3%	29.7%	31.3%	7.8%	
		% within the age group	**58.8%**	48.7%	32.8%	23.8%	
		% of Total	12.9%	12.3%	12.9%	3.2%	41.3%

No association was found between aided walking and: 1 - *age groups* (p=0.24); 2 - frequency of prosthetic use (p=0.19); 3 - *amputation cause* categories p=0.054); and 4 - amputation location categories (p=0.12).

There was a significant difference (t(153)=2.024, p=0.045, two-tailed) in age for participants walking without aids (M±SD=52.33±11.92 years) and with them (M±SD=56.3±12.09 years). The magnitude of the differences in the means (mean difference=3.97, 95% CI: 0.094-7.84) was very small (η^2=0.026).

A significant difference was found between the *time since amputation* and unaided/aided walking (χ^2(1)= 4.84, n=155, MED=8, p=0.028). Mean rank and median of the *time since amputation* were higher for participants without using aids (87.45, MED=16.37, n=64) in comparison with the *time since amputation* of aided-walking participants (71.36, MED=7, n=91).

The difference between *age-at-amputation* of participants with/without the walking aides was significant (χ^2(1)= 8.31, n=155, p=0.004). Mean rank and median of *age-at-amputation* were higher for participants using aids (86.71, MED=47, n=91) in comparison with the amputation age of participant without walking aids (65.61, MED=25, n=64).

A moderate association existed between aided walking and worries about falling ($\chi^2[Pearson](1, n = 155) = 25.05$, p<0.001, $df^* = 1$, Phi=0.402). Eighty-seven percent of participants who had worries about falling walked with aids, while 72.7% of non-worried participants walked without aids. However, half of the participants in each group of *worried* and *not-worried about falling* did not use aids (Table 3.10).

Table 3.10 Association between aided walking and being worried about falling

			walking unaided		Total
			No	Yes	
Worried to fall	Yes	Count	79	32	111
		% within worried about falling	71.2%	28.8%	
		% within walk unaided	86.8%	50.0%	
		% of Total	51.0%	20.6%	71.6%
	No	Count	12	32	44
		% within worried about falling	27.3%	72.7%	
		% within walk unaided	13.2%	50.0%	
		% of Total	7.7%	20.6%	28.4%

A small association was observed between experience of falling and aided walking ($\chi^2[Pearson](1, n = 155) = 4.97$, p=0.026, $df^* = 1$, Phi=0.179). Table 3.11 shows a greater percentage of aided participants (69.2% of them) had falling experience. However, around half of the participants without using aids took place in each group of falling experience.

A significant difference was found between the PEQ-M score of aided/unaided participants (χ^2(1)= 24.64, n=153, p<0.001). The mean rank and median for aided participants (61.92, n=89, MED=5.15, M±SD=4.92±2.24) were lower than for unaided participants (mean rank=97.97, n=64, MED=7.38, M±SD=6.85±2.11).

Table 3.11 Association between aided walking and falling experience

			walking unaided		Total
			No	Yes	
Falling experience	Yes	Count	63	33	96
		% within falling experience	65.6%	34.4%	
		% within walk unaided	69.2%	51.6%	
		% of Total	40.6%	21.3%	61.9%
	No	Count	28	31	59
		% within falling experience	47.5%	52.5%	
		% within walk unaided	30.8%	48.4%	
		% of Total	18.1%	20.0%	38.1%

3.3.3.3 Activities-specific Balance Confidence (ABC) scale

The self-reported ABC scale questionnaire (Powell and Myers, 1995) was used to evaluate balance confidence among the respondents and their functionality. This questionnaire consisted of 16 rating questions about various daily activities. Figure 3.12 presents the responses to the questions about the level of balance confidence participants felt while performing several specific activities. Respondents were asked to score their balance confidence from 0 to 10, where 0 indicated no confidence and 10 complete confidence. In this diagram, the darkest colour is for a score of 0 and the lightest colour represents a score of 10. There was also an option for choosing "I never do this" if the respondent never performed the activity. This option has been displayed by the darkest colour with the dotted pattern, on the left in Figure 3.12. The lowest scores were in response to questions about confidence during standing on a chair to reach an object, stepping onto/off an escalator without holding the handrail, and walking on an icy pavement. For some activities, a greater number of participants chose "I do not do this" (in turn 55, 52 and 53 persons). Fifty-eight people gave a score of 10 for balance confidence when reaching for objects at eye-level.

Figure 3.13 shows the percentage of responses to the same questions (Figure 3.12) in the form of weaker scores (0-4), neutral score (5), higher scores (6-10) and a dashed pattern for those who never do the activity. More than 60% of participants had high balance confidence to bend and pick up an object from the floor, reaching an object at eye-level, reaching an object at above-head height, sweeping the floor, walking outside, getting into/out of the car and walking across car-parking spaces.

More than 30% of respondents chose lower balance confidence scores for walking up/down stairs, walking up/down a ramp, walking in a crowd, being bumping into by people (walking in town), stepping onto/off an escalator without holding the handrail, and walking on an icy pavement. The overall level of confidence was 54.3% for higher scores (6-10), 26.4% for lower scores (1-4), 8.3% for the moderate score (5), and 10.9% for never having done some of these activities.

To obtain an ABC score, the sum of scores for each respondent was divided by the number of questions posed (16). A score of >80, scores of 50-80 and scores of <50, in turn, indicate high level, moderate level and low level of functioning (Powell and Myers, 1995). In addition, a score of <67 suggests a considerable risk of future falling (Lajoie and Gallagher, 2004). The average total score was 55.24 (±25.88, MED=58.75, N=155, Min-Max=0-100). The initial evaluation of the ABC score shows that among 155 respondents, 34 respondents (21.9% of participants) had a high level of functioning, 61 respondents (39.4% of participants) had a moderate level of functioning, and 60 respondents (38.7% of participants) had a low level of functioning. In addition, 96 respondents (61.9% of participants) had a score of <67 and, so, were at risk of future falling.

Relation between ABC score and general variables

No difference was found between the score of: 1 - genders (p=0.23); 2 - *age groups* (p=0.42); 3 - *time since amputation* categories (p=0.404); 4 - *age-at-amputation* groups (p=0.46); 5 - *amputation cause* groups (p=0.092); and 6 - amputation location (p=0.27).

There was no significant relationship between the ABC score - age (p=0.624); the score - *time since amputation* (p=0.1); and the score - *age-at-amputation* (p=0.217).

No association was seen between the ABC categories and: 1- gender (p=0.276); 2 - *age groups* (p=0.542); 3 - time since amputation categories (p=0.536); 4 - *age-at-amputation* groups (p=0.45); and 5 - amputation location (p=0.333).

A moderate association was seen between participants' *cause of amputation* and the ABC score’s categories ($\chi^2[Likelihood\,ratio](14, n = 155) = 24.81$ p=0.037, $df^* = 2$, Cramer’s V=0.261). Only 50% and 33.3% of participants with amputation due to cancer and other causes respectively chose high level of functioning and no participants with amputation due to peripheral arterial disease were placed in this category. Fifty percent of participants with diabetes and severe infection as causes of their amputation and around 42% of participants with amputation due to peripheral arterial diseases and serious trauma/injuries were placed in the moderate functioning category. Around 62.5% of amputees with congenital conditions, 58% with peripheral arterial diseases, 54.5% with limited function/severe pain, 45.5% with severe infection, 44.4% with other causes, and 40% with diabetes as a *cause of amputation* were placed in the low functioning category. Participants with amputation due to cancer and serious trauma/injuries had the lowest rate of functioning (respectively, 20% and 30%).

A moderate association was found between *cause of amputation* and being at risk of falling ($\chi^2[Likelihood\,ratio](7, n = 155) = 19.15$ p=0.008, $df^* = 1$, Cramer’s V=0.337). Around 56% and 50% respectively of participants with amputation due to other causes and cancer/serious trauma/injuries were not at risk of falling. In other causes of amputation, 70% and 92% of participants (respectively, amputees with diabetes and peripheral arterial disease amputation cases) at risk of falling (ABC score <67).

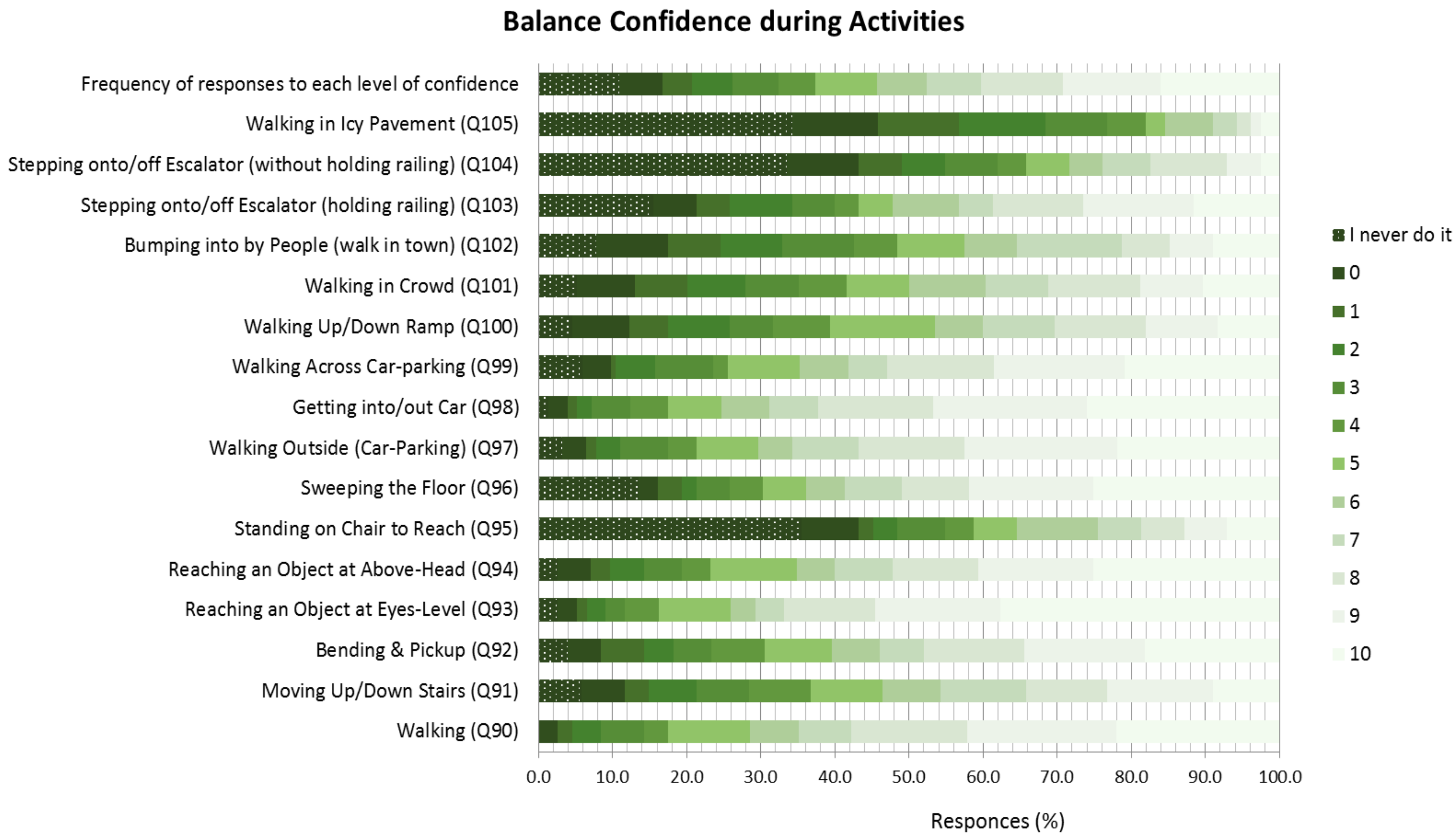


Figure 3.12 Activities-specific balance confidence scale questions

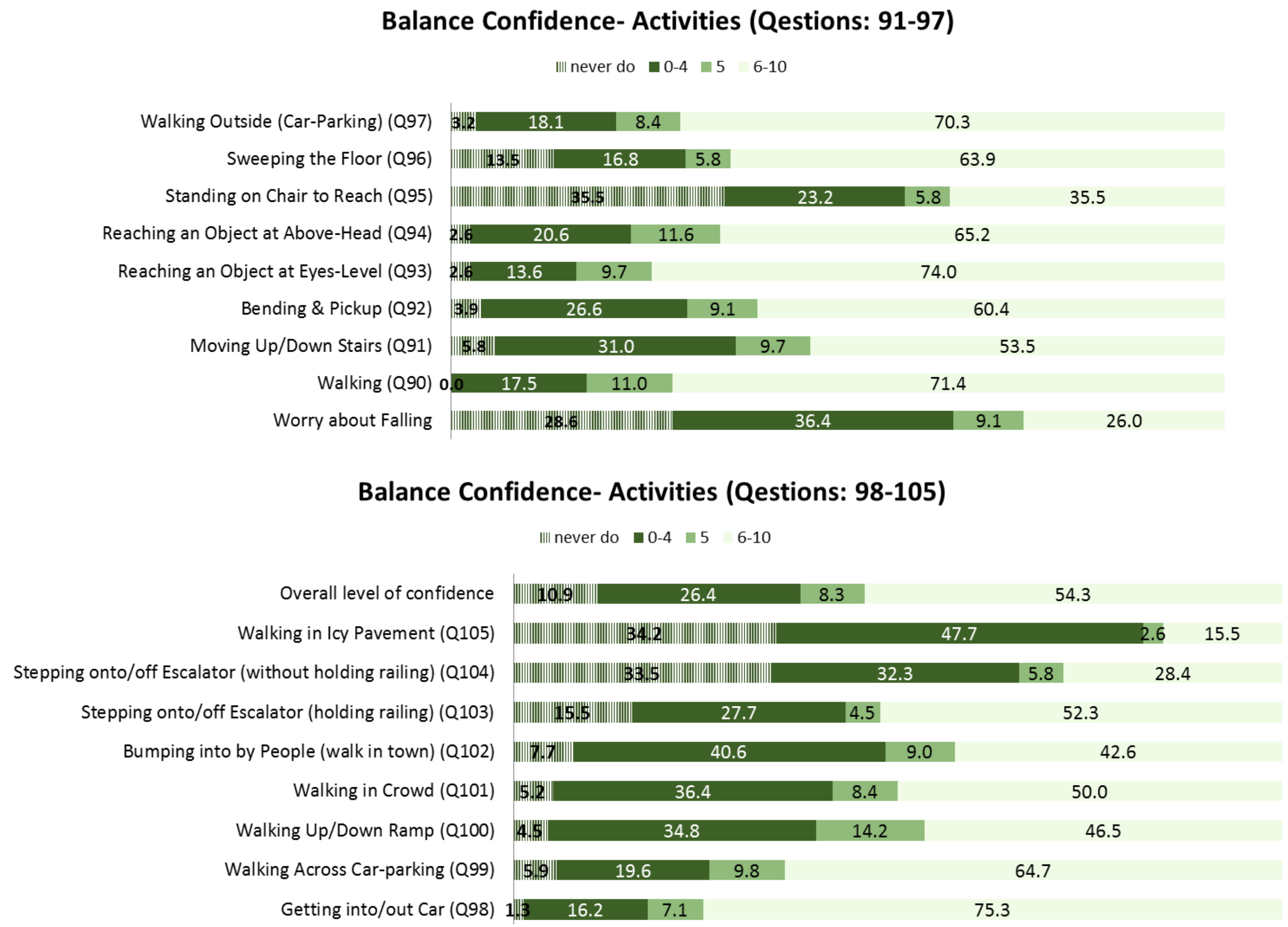


Figure 3.13 Percentage of lower scores (0-4), neutral (5) and higher scores (6-10) for the questions related to the specific activities confidence

No significant differences were found between *time since amputation* and *age-at-amputation* across the ABC score's categories (respectively, p=0.22 and p=0.21).

There was no significant difference (p=0.816) in age of participants at risk of falling (M±SD=54.48±11.78) and not at risk (M±SD=54.95±12.805).

No association was observed between being at risk of falling and: 1 - gender (p=0.129); 2 - *age groups* (p=0.603); 3 - participants' country of residence (p=0.104); 4 - *time since amputation* categories (p=0.236); 5 - *age-at-amputation* groups (p=0.4); and 6 - amputation location (p=0.101).

A significant difference was seen between the *time since amputation* of participants at risk of falling (mean rank=72.26, M±SD=13.24±15.27, n=96, MED=7) and those with ABC score >67 (mean rank=87.34, M±SD=17.78±16.09, n=59, MED=14) (χ^2(1)= 4.14, n=155, MED=8, p=0.042). It seems participants with a shorter time since amputation are at higher risk of falling.

But, the difference between *age-at-amputation* of participants at risk of falling and others was not significant (χ^2(1)= 1.53, n=155, MED=41, p=0.216).

ABC score and frequency of prosthesis use

A significant difference was found between the ABC score of participants with different frequencies of prosthetic use (χ^2(7)= 16.64, n=155, p=0.02). Mean rank and median were highest for every day most/all day (85.37, MED=63.13, n=118). The lowest mean rank and median was for 1-2 days a week (12.5, MED=11.875, n=2). The adjusted significance level for the pairwise tests was not <0.05 for any pairs of prosthetic use frequencies.
A moderate association was observed between ABC score categories and frequency of prosthesis use ($\chi^2[Likelihood\,ratio](14, n = 155) = 24.174$, p=0.044, $df^* = 2$, Cramer's V=0.246) but no association was found between the prosthesis use frequency of participants at risk of falling and others ($\chi^2[Likelihood\,ratio](7, n = 155) = 12.9$, p=0.075, $df^* = 1$, Cramer's V=0.253).

The rate of participants who used their prosthesis every day/most part of the day was high in all ABC score categories, but its proportion decreased from 97% of participants in the higher level of functioning to 66.7% of participants in the low level of functioning category. Only participants who used their prostheses all the time (every day whole of the day or some part of the day) were in the high level of functioning category. All respondents who used their prostheses 3 -4 days and 1 -2 days a week were at risk of falling and in the low level of functioning.

ABC score and bodily sensations

A significant difference was observed between the scores of participants with or without intact limb pain (χ^2(1)= 7.3, n=136, p=0.007). The mean rank and median were higher for participants without intact limb pain (83.43, MED=72.5, n=37) and lower for participants with the pain (62.92, MED=53.13, n=99).

No significant association was seen between ABC score categories and the presence of intact limb pain (p=0.125). However, the ABC categories were not statistically different; the percentage of participants with intact limb pain in high level functioning was less than the percentage in the low-level functioning category (67% versus 83%).

A small association existed between having intact limb pain and being at risk of falling ($\chi^2[Pearson](1, n = 136) = 6.43,$ p=0.011, $df^* = 1,$ Phi=-0.217). More than 80% of the participants at risk of falling had intact limb pain, while the rate was 61% for participants with a lower risk of falling (Table 3.12).

Table 3.12 Association between ABC scale categories and presence of intact limb pain

			Intact limb pain		
			No	Yes	Total
ABC Categories	High level of functioning (scores >80)	Count	11	22	33
		% within ABC category	33.3%	66.7%	
		% within intact limb pain	29.7%	22.2%	
		% of total	8.1%	16.2%	24.3%
	Moderate level of functioning (scores 50-80)	Count	18	37	55
		% within ABC category	32.7%	67.3%	
		% within intact limb pain	48.6%	37.4%	
		% of total	13.2%	27.2%	40.4%
	Low level of functioning (scores ≤50)*	Count	8	40	48
		% within ABC category	16.7%	83.3%	
		% within intact limb pain	21.6%	40.4%	
		% of total	5.9%	29.4%	35.3%
	At risk of falling ** (scores <67)*	Count	15	64	79
		% within ABC category	19.0%	81.0%	
		% within intact limb pain	40.5%	64.6%	
		% of total	11.0%	47.1%	58.1%
	Lower risk of falling** (score>67)	Count	22	35	57
		% within ABC category	38.6%	61.4%	
		% within intact limb pain	59.5%	35.4%	
		% of total	16.2%	25.7%	41.9%

No significant difference was found (p=0.6) between the distribution of the score among participants with phantom limb sensation (mean rank=77.06, MED=57.19, n=124) and without it (mean rank=81.74, MED=60, n=31). No association was seen between the ABC score category – the presence of phantom limb (p=0.99), nor between being at risk of falling and the presence of phantom limb p=0.186).

A significant difference existed between the distribution of the ABC score among participants with phantom pain and without it (χ^2(1)= 11.12, n=155, p=0.001). The mean rank and median were higher for participants without phantom pain (95.68, MED=67.5, n=49) and lower for participants with the pain (69.83, MED=51.88, n=106).

A small association was found between the ABC score categories and the presence of phantom pain ($\chi^2[Pearson](2, n = 155) = 6.54,$ p=0.038, $df^* = 1,$ Cramer's V=0.205) and between having phantom pain and being at risk of falling ($\chi^2[Pearson](1, n = 155) = 5.1,$ p=0.024, $df^* = 1,$ Phi=-0.181). All the categories of ABC score had a higher rate of participants with phantom pain, and the rate decreased from 78.3% in the low level of functioning to 52.9% of participants in the high level of functioning. Three-quarters of participants at risk of falling had phantom pain, while the rate was less than three-fifth for participants with a lower risk of falling (A significant difference existed between the distribution of the ABC score among participants with stump pain and without it (χ^2(1)=5.86, n=153, p=0.015). The mean rank and median were higher for participants without stump pain (92.64, MED=68.44, n=36) and lower for participants with the pain (72.19, MED=52, n=117).

Table 3.13).

A significant difference existed between the distribution of the ABC score among participants with stump pain and without it (χ^2(1)=5.86, n=153, p=0.015). The mean rank and median were higher for participants without stump pain (92.64, MED=68.44, n=36) and lower for participants with the pain (72.19, MED=52, n=117).

Table 3.13 Association between ABC score's categories and presence of phantom pain

			Phantom pain		
			No	Yes	Total
ABC Categories	High level of functioning* (scores >80)	Count	16	18	34
		% within ABC category	47.1%	52.9%	
		% within phantom pain	32.7%	17.0%	
		% of total	10.3%	11.6%	21.9%
	Moderate level of functioning (scores 50-80)	Count	20	41	61
		% within ABC category	32.8%	67.2%	
		% within phantom pain	40.8%	38.7%	
		% of total	12.9%	26.5%	39.4%
	Low level of functioning (scores ≤50)*	Count	13	47	60
		% within ABC category	21.7%	78.3%	
		% within phantom pain	26.5%	44.3%	
		% of total	8.4%	30.3%	38.7%
	At risk of falling ** (scores <67)	Count	24	72	96
		% within ABC category	25.0%	75.0%	
		% within phantom pain	49.0%	67.9%	
		% of total	15.5%	46.5%	61.9%
	Lower risk of falling (score>67)	Count	25	34	59
		% within ABC category	42.4%	57.6%	
		% within phantom pain	51.0%	32.1%	
		% of total	16.1%	21.9%	38.1%

* p=0.038, **p=0.024

No significant association was observed between the ABC score categories and the presence of stump pain (p=0.064). However, a small association was seen between having stump pain and being at risk of falling ($\chi^2[Pearson](1, n = 153) = 4.422,$ p=0.035, $df^* = 1,$ Phi=-0.17). Eighty-two percent of participants with stump pain were at risk of falling, while 67% of them were at lower risk of falling (ABC score and QOL score, score of being satisfied with the prosthesis/ being frustrated with prosthesis

There was a strong significant positive relationship between the QOL score and ABC score (rho=0.64, n=53, p<0.001, two-tailed). A strong positive relationship was found between being satisfied with the prosthesis and the ABC score (rho=0.64, n=153, p<0.001, two-tailed). The positive relationship the above-compared pairs means that the high level of each score is associated with the high level of the corresponding one.

Table 3.14).

ABC score and QOL score, score of being satisfied with the prosthesis/ being frustrated with prosthesis

There was a strong significant positive relationship between the QOL score and ABC score (rho=0.64, n=53, p<0.001, two-tailed). A strong positive relationship was found between being satisfied with the prosthesis and the ABC score (rho=0.64, n=153, p<0.001, two-tailed). The positive relationship the above-compared pairs means that the high level of each score is associated with the high level of the corresponding one.

Table 3.14 Association between ABC score's categories and presence of stump-pain

			Stump pain		
			No	Yes	Total
ABC Categories	High level of functioning (scores >80)	Count	9	24	33
		% within ABC category	27.3%	72.7%	
		% within stump pain	25.0%	20.5%	
		% of total	5.9%	15.7%	21.6%
	Moderate level of functioning (scores 50-80)	Count	19	42	61
		% within ABC category	31.1%	68.9%	
		% within stump pain	52.8%	35.9%	
		% of total	12.4%	27.5%	39.9%
	Low level of functioning (scores ≤50)	Count	8	51	59
		% within ABC category	13.6%	86.4%	
		% within stump pain	22.2%	43.6%	
		% of total	5.2%	33.3%	38.6%
	At risk of falling (scores <67)	Count	17	78	95
		% within ABC category	17.9%	82.1%	
		% within stump pain	47.2%	66.7%	
		% of total	11.1%	51.0%	62.1%
	Lower risk of falling (score>67)	Count	19	39	58
		% within ABC category	32.8%	67.2%	
		% within stump pain	52.8%	33.3%	
		% of total	12.4%	25.5%	37.9%

A moderate negative relationship was observed between the level of being frustrated with the prosthesis and the ABC score (rho=-0.44, n=153, p<0.001, two-tailed), which means the lower level of frustration was associated with a higher ABC score and higher level of functioning.

ABC score and PEQ-M score

There was a strong, significant positive relationship between the ABC score and PEQ-M score (rho=0.831, n=155, p<0.001, two-tailed), with high levels of each score associated with high levels of the corresponding one.

A significant difference existed between the PEQ-M score of the ABC categories (χ^2(2)= 89.012, n=153, p<0.001). The mean rank and median were highest for the high level of functioning category (124.68, MED=8.08, n=34). The lowest mean rank and median were for the low level of functioning category (28.75, MED=3.62, n=59). The difference between the PEQ-M score of all categories of the ABC scores was statistically significant at p<0.001: low level of functioning and moderate level of functioning (mean rank=88.33, MED=6.46, n=60), low level of functioning and high level of functioning, high level of functioning and moderate level of functioning.

A significant difference was found between the distribution of the PEQ-M score of participants at risk of falling (mean rank=55.42, M±SD=4.61±2.03, n=95, MED=4.85) and those with ABC score >67 (mean rank=112.35, M±SD=7.6±1.62, n=58, MED=7.54) (χ^2(1)= 59.476, n=153, MED=5.92, p<0.001The lower levels of the PEQ-M score were at risk of falling.

ABC score and the total score of prosthesis evaluation

There was a strong significant positive relationship between the ABC score and total score of prosthesis evaluation (rho=0.704, n=154, p<0.001, two-tailed), with high levels of each score associated with high levels of the corresponding score.

The distribution of the prosthesis evaluation total score across the ABC score categories was significantly different (χ^2(2)= 66.55, n=154, p<0.001). The mean rank and median were highest for the high level of functioning category (115.4, MED=7.275, n=34). The lowest mean rank and median were for the low level of functioning category (42.25, MED=3.74, n=59). The difference between prosthesis evaluation total score of all categories of ABC score was statistically significant: low level of functioning and moderate level of functioning (mean rank=90.47, MED=6.44, n=61) (p<0.001), low level of functioning and high level of functioning (p<0.001), high level of functioning and moderate level of functioning (p=0.027).

A significant difference was seen between the distribution of prosthesis evaluation total score among participants at risk of falling (mean rank=60.59, MED=4.8, M±SD=4.7±2.03, n=95) and those with ABC score>67 (mean rank=104.72, MED=6.8, M±SD=6.86±1.7, n=59) (χ^2(1)= 35.627, n=154, MED=5.9, p<0.001). Lower levels of prosthesis evaluation total score were associated with ABC scores less than 67.

ABC score and falling experience

A significant difference was observed between the distribution of the ABC score among participants with experience of falling during last 12 months (mean rank=69.05, M±SD=50.33±24.8, n=96, MED=51.25) and non-fallers (mean rank=92.56, M±SD=63.23±25.81, n=59, MED=67.5) (χ^2(1)= 10.023, n=155, MED=58.75, p=0.002).

Lower levels of ABC score were associated with falling experience. Mean and median of the score for the faller group was in the lower margin of a moderate level of functioning.

A moderate association was found between experience of falling- ABC score (p=0.008) and between fall experience-being at risk of falling according to ABC score ($\chi^2[Pearson](1, n = 155) = 8.47,$ p=0.004, $df^* = 1,$ Phi=0.234). Table 3.15 demonstrates the percentage of faller participants grows with lowering level of functioning from 47.1% of high level functioning to 76.7% in the low level of functioning. In addition, around 71% of fallers are at risk of future falling while the rate is 47.5% for non-fallers.

Table 3.15 Association between ABC score's categories and fall experiences during last 12 months

			Falling experiences when using prosthesis		
			Yes	No	Total
ABC Categories	High level of functioning (scores >80)	Count	16	18	34
		% within ABC category	47.1%	52.9%	
		% within fall experience	16.7%	30.5%	
		% of total	10.3%	11.6%	21.9%
	Moderate level of functioning (scores 50-80)	Count	34	27	61
		% within ABC category	55.7%	44.3%	
		% within fall experience	35.4%	45.8%	
		% of total	21.9%	17.4%	39.4%
	Low level of functioning (scores ≤50)*	Count	46	14	60
		% within ABC category	76.7%	23.3%	
		% within fall experience	47.9%	23.7%	
		% of total	29.7%	9.0%	38.7%
	At risk of falling (scores <67)**	Count	68	28	96
		% within ABC category	70.8%	29.2%	
		% within fall experience	70.8%	47.5%	
		% of total	43.9%	18.1%	61.9%
	Lower risk of falling (score>67)	Count	28	31	59
		% within ABC category	47.5%	52.5%	
		% within fall experience	29.2%	52.5%	
		% of total	18.1%	20.0%	38.1%

* p=0.008, **p=0.004

ABC score and being worried about falling

A significant difference was observed between the distribution of the ABC score among participants with worries about falling (mean rank=53.51, MED=48.75, M±SD=47.26±23.6, n=111) and without it (mean rank=114.56, MED=82.19, M±SD=75.37±19.85, n=44) (χ^2(1)= 40.76, n=155, MED=58.75, p<0.001). Lower levels of ABC score were associated with worries about falling.

A significant difference was seen between the distribution of the score across different levels of being *worried about falling* (χ^2(2)= 37.086, n=110, p<0.001). Mean rank and median were highest for scores 6-10 means less worried participants (76.4, MED=63.75, n=40). The lowest mean rank and median were for scores 0-4, which means participants were more worried (37.5, MED=30.31, n=56). The ABC score was statistically different between these pairs of categories: very worried (scores 0-4) and less worried (p<0.001), neutral (mean rank= 67.79, MED=53.75, n=14) and very worried (p=0.004). There was no significant difference between the neutral and less worried categories.

A strong association existed between being *worried about falling* and the ABC score categories ($\chi^2[Pearson](2, n = 155) = 43.85$, p<0.001, $df^* = 1$, Cramer's V=0.532). A moderate association was seen between being *worried about falling* and being at risk of falling, according to the ABC score ($\chi^2[Pearson](1, n = 155) = 35.55$, p<0.001, $df^* = 1$, Phi=0.48). A moderate association was observed between the worry levels and being at risk of falling according to the ABC score ($\chi^2[Pearson](2, n = 110) = 10.57$, p=0.005, $df^* = 1$, Cramer's V=0.31).

Table 3.16 also shows the number of worried participants grew with lowering the level of functioning. In addition, worried participants (88.5%) are at significantly higher risk of falling, according to their ABC scores.

Table 3.16 Association between ABC score's categories and being worried about falling

			Worried about falling when using a prosthesis		
			Yes	No	Total
ABC Categories	High level of functioning (scores >80)	Count	10	24	34
		% within ABC category	29.4%	70.6%	
		% within worries about falling	9.0%	54.5%	
		% of total	6.5%	15.5%	21.9%
	Moderate level of functioning (scores 50-80)	Count	45	16	61
		% within ABC category	73.8%	26.2%	
		% within worries about falling	40.5%	36.4%	
		% of total	29.0%	10.3%	39.4%
	Low level of functioning (scores ≤50)*	Count	56	4	60
		% within ABC category	93.3%	6.7%	
		% within worries about falling	50.5%	9.1%	
		% of total	36.1%	2.6%	38.7%
	At risk of falling (scores <67)	Count	85	11	96
		% within ABC category	88.5%	11.5%	
		% within worries about falling	76.6%	25.0%	
		% of total	54.8%	7.1%	61.9%
	Lower risk of falling (score>67)	Count	26	33	59
		% within ABC category	44.1%	55.9%	
		% within worries about falling	23.4%	75.0%	
		% of total	16.8%	21.3%	38.1%

The percentage of very worried participants grows with lowering level of functioning. In addition, very worried participants (89.3%) significantly are at higher risk of falling according to their ABC scores.

ABC score and unaided walking

The Kruskal-Wallis test indicated a significant difference between the distribution of the ABC score among participants walking with an aid (mean rank=58.85, M±SD=44.4±23.95, n=91, MED=42.5) and without one (mean rank=105.23, M±SD=70.66±20.15, n=64, MED=75.31) (χ^2(1)= 40.11, n=155, MED=58.75, p<0.001). Lower levels of ABC score were associated with aided walking.

The Chi-square test indicated a strong association between unaided/aided walking and ABC score categories ($\chi^2[Pearson](2, n = 155) = 38.7$, p<0.001, $df^* = 1$, Cramer's V=0.5).The same test showed a moderate association between unaided/aided walking and being at risk of falling, according to the ABC score ($\chi^2[Pearson](1, n = 155) = 31.25$, p<0.001, $df^* = 1$, Phi=0.449). Weaker levels of functioning were associated with a higher percentage of participants using walking aids: 17.6%, 57% and 83% of participants who used aids to walk chose the high, moderate and low levels of functioning respectively, according to the ABC scores. Around 76% of participants at risk of falling were aided walkers (Table 3.17).

Table 3.17 Association between ABC score's categories and unaided walking

			Unaided walking		
			No	Yes	Total
ABC Categories	High level of functioning (scores >80)	Count	6	28	34
		% within ABC category	17.6%	82.4%	
		% within unaided walking	6.6%	43.8%	
		% of total	3.9%	18.1%	21.9%
	Moderate level of functioning (scores 50-80)	Count	35	26	61
		% within ABC category	57.4%	42.6%	
		% within unaided walking	38.5%	40.6%	
		% of total	22.6%	16.8%	39.4%
	Low level of functioning (scores ≤50)	Count	50	10	60
		% within ABC category	83.3%	16.7%	
		% within unaided walking	54.9%	15.6%	
		% of total	32.3%	6.5%	38.7%
	At risk of falling (scores <67)	Count	73	23	96
		% within ABC category	76.0%	24.0%	
		% within unaided walking	80.2%	35.9%	
		% of total	47.1%	14.8%	61.9%
	Lower risk of falling (score>67)	Count	18	41	59
		% within ABC category	30.5%	69.5%	
		% within unaided walking	19.8%	64.1%	
		% of total	11.6%	26.5%	38.1%

ABC score, balance and LBP

A small association was observed between the ABC score categories - LBP ($\chi^2[Pearson](2, n = 155) = 10.823$, p=0.004, $df^* = 1$, Cramer's V=0.264) and between having LBP and being at risk of falling ($\chi^2[Pearson](1, n = 155) = 8.4$, p=0.004, $df^* = 1$, Phi=0.233). The number of participants with LBP was highest in the low level of functioning category and decreased from 88% to 59% in the high level of functioning. Only 17% of participants without LBP were at risk of falling. However, 63% of participants with LBP were in the lower risk of falling (Table 3.18).

There was no association between LBP and being *worried about falling* (p=0.08). A small association existed between having LBP and having a falling experience ($\chi^2[Pearson](1, n = 155) = 13.45$, p<0.001, $df^* = 1$, Phi=-0.295). Eighty-five percent of faller participants and 59% of non-fallers had LBP. A higher proportion of the LBP group were fallers (70%), and 63% of participants without LBP were non-fallers.

Table 3.18 Association between ABC score's categories and LBP

			Lower back pain		
			yes	no	Total
ABC Categories	High level of functioning (scores >80)*	Count	20	14	34
		% within ABC category	58.8%	41.2%	
		% within LBP presence	17.1%	36.8%	
		% of total	12.9%	9.0%	21.9%
	Moderate level of functioning (scores 50-80)	Count	44	17	61
		% within ABC category	72.1%	27.9%	
		% within LBP presence	37.6%	44.7%	
		% of total	28.4%	11.0%	39.4%
	Low level of functioning (scores ≤50)	Count	53	7	60
		% within ABC category	88.3%	11.7%	
		% within LBP presence	45.3%	18.4%	
		% of total	34.2%	4.5%	38.7%
	At risk of falling (scores <67)	Count	80	16	96
		% within ABC category	83.3%	16.7%	
		% within LBP presence	68.4%	42.1%	
		% of total	51.6%	10.3%	61.9%
	Lower risk of falling (score>67)	Count	37	22	59
		% within ABC category	62.7%	37.3%	
		% within LBP presence	31.6%	57.9%	
		% of total	23.9%	14.2%	38.1%

A small association was seen between LBP and using an aid to walk ($\chi^2[Pearson](1, n = 155) = 4.055$, p=0.044, $df^* = 1$, Phi=-0.162). Eighty-one percent of participants with LBP used an aid to walk (63%) while 55% of the group without LBP were unaided.

A significant difference was observed between the distribution of the ABC score among participants with lower back pain and without it (χ^2(1)= 10.677, n=155, p=0.001). The mean rank and median were higher for participants without pain (98.67, MED=71.25, n=38) and lower for participants with pain (71.29, MED=51.88, n=117).

3.4 Discussion

This study was conducted to have an up to date understanding of the problems of LLAs which might be managed by orthotic interventions. It has explored the problems and the relationships between them via an online published survey. It is important to note that in this study, all of the scoring items related to aspects of prosthesis use have been derived from the PEQ questionnaire responses which had mean or median values of around 5, and that most responses were less than 7 out of 10 (score of total bodily sensation = 5.06±3.88, including amputated-side = 4.97±2.46, intact limb = 5.1±2.62; score of *prosthetic quality and effects* = 5.94±2.1, MED = 6.29; score of PEQ-M = 5.74±2.38, MED = 5.92; score of emotional aspects = 4.9±3.11, MED = 4.67; score of satisfaction = 5.88±2.78, MED = 6.5; total score = 5.52±2.18, MED = 5.9). These values, on average, are near to the neutral score (5) and in the lower border of better scores (6-10). This indicates the need to improve these aspects during rehabilitation procedures and in the health care of LLAs.

The overarching purpose of participating in surveys is to share opinions/experiences (Brüggen et al., 2011) and to help prevent/solve problems for others (Soule et al., 2016). The majority of respondents (67.7%) in this survey expressed a wish to receive further information on the results. This may suggest that the participants were from that group of amputees who needed to talk about their problems and/or did not have good feelings related to their prosthesis/amputation/ daily activities and they supposed their participation would be beneficial in improving any current deficiencies in the future. This may, in turn, have biased the results towards negative responses. It should be noted that the sample size is low compared to the number of questions asked and the analysis undertaken, and this may will reduce the power of the statistical analysis. However, the results are indicative of issues being faced by, and are important to, lower limb amputees and, ideally, all will be followed up in more detail.

Within the constraints of this research, the focus was chosen to be on balance, lower back pain and the mobility of LLAs during daily activities. The ABC questionnaire is an activity-based scale which covers the mobility/functionality of the amputees. In addition, mobility will be discussed as part of the PEQ. In Table 3.19, the meaningful relationships between the ABC scale and PEQ-M are presented. The variables listed in the first column are significant as they play an important role in participants' mobility/stability.

Table 3.19 Important relation of the scores and several aspects of the prosthetic use, number of participants in each categories has been mentioned in parenthesis

		ABC score (best 100)		Mobility score (best 10)	
		Mean (n)	median	Mean (n)	median
Phantom pain	Yes	**50.42**[1](106)	51.88	**5.24**[5] (104)	5.54
	No	**65.66**[1] (49)	67.5	**6.8**[5] (49)	7.23
Stump pain	Yes	**52.5**[2] (117)	52.5	**5.38**[1] (115)	5.69
	No	**64.12**[2] (36)	68.44	**6.86**[1] (36)	7.38
Intact limb pain	Yes	**53.26**[3] (99)	53.13	**5.49**[5] (97)	5.69
	No	**67.01**[3] (37)	72.5	**7.07**[5] (37)	7.38
Falling experience	Yes	**50.33**[4] (96)	51.25	**5.36**[8] (96)	5.69
	No	**63.23** (59)	67.5	**6.38**[8] (57)	6.31
Walking aid	Yes	**44.4**[5] (91)	42.5	**4.94**[5] (89)	5.15
	No	**70.66**[5] (64)	75.31	**6.45**[5] (64)	7.38
Worried about falling	Yes	**47.26**[5] (111)	48.75	**5.61**[5] (110)	6
	No	**75.37**[5] (44)	82.19	**7.61**[5] (44)	8
LBP	Yes	**51.51**[1] (117)	51.88	**5.37**[1] (115)	5.62
	No	**66.73**[1] (38)	71.25	**6.86**[1] (38)	7.34
Risk of falling	High	**39.16**[5] (96)	40.63	**4.6**[5] (95)	4.85
	lower	**81.4**[6] (59)	81.88	**7.6**[5] (58)	7.54
Total Average		55.24 ±25.88	58.75	5.74 ±2.38	5.92

Significant differences (scores with bold font and superscript number in each cell): [1] p=0.001, [2] p=0.015, [3] p=0.007, [4] p=0.002, [5] p<0.001, [6] p=0.005, [7] p=0.014

3.4.1.1 Mobility

The score of 13 questions related to the “ability to move around while using prosthesis” called PEQ-M is considered a criterion for the assessment of prosthesis users’ mobility in daily life. The average of the mobility score was low (5.74 out of 10) but comparable to (Harness and Pinzur, 2001; Trantowski-Farrell and Pinzur, 2003) studies on dysvascular TT amputees (respectively 55.3 and 65.9 out of 100), and (Hafner et al., 2017), with a score 2.4 out of 4, which is equivalent to 6 out of 10. As can be seen in Table 3.19, the PEQ-M of participants with phantom pain, stump pain, intact limb pain, LBP, falling experience, using a walking aid, worried about falling, and at risk of falling was lower than those without these problems. The score had a positive relationship with the score of other sections of the PEQ questionnaire and, specifically, the self-determined QOL. This can be an indication of the importance of all aspects of prosthesis use (such as bodily sensation, emotional views, satisfaction, etc.) in the mobility of LLAs, in addition to the inter-relationship between mobility and QOL. Similarly, it has been reported in previous studies that LLAs who had a lower score of PEQ-M, also had lower scores for QOL (Asano et al., 2008), and that QOL and satisfaction had direct relationships with the mobility of LLAs (Wurdeman et al., 2017). The mobility of fallers and aid-user participants had lower scores. This was similar for participants with worries about falling and is in agreement with Miller et al. (2001). In spite of their sample being older, the score in our study was lower (the mean of 5.05 for worried and 7.45 for non-worried compared with 6.1 and 8.2, respectively). This might indicate that our participants intentionally limited their mobility to avoid a fall.

The strong positive relationship between the ABC score/categories and the PEQ-M score is thought-provoking, and it shows that those with lower levels of confidence in having balance during daily activities had lower levels of mobility, as well. These results are logical, as those with lower confidence in their balance during daily activities avoid performing them and are less mobile. Consequently, the participants with lower mobility scores were at higher risk of future falling (ABC score <67).

3.4.1.2 Balance

The results of this survey showed that 41% of participants walked without aids (comparable with rates of 43.3% and 47.6% in Miller et al. (2002); Miller et al. (2003), and 59% in Hammarlund et al. (2011)). It is interesting to note that the lowest percentage of participants who used walking aids were in the *more than 20 years since amputation* category. In addition, unaided participants had experienced longer *time since amputation.* A similar trend was observed regarding the *age-at-amputation* groups; most of the respondents in the *age-at-amputation* group of younger than 20 years of age did not use aids to walk, and those who were aided walkers had an older *age-at-amputation*. These results suggest that as their amputation happened at a young age, they had adapted better to their amputation, and had got used to unaided walking. On the other hand, the use of walking aids increased with age in the sample. This is logical as, in the non-amputee population as well, physical *ability* decreases with age, which might lead to the use of walking aids by the elderly (Resnik et al., 2009).

The number of participants with a fear of falling and falling experience was high (71.6% and 62% in comparison to Miller, W. C. et al. (2001) with, respectively, rates of 49.2% and 52.4%, and 56% for fallers in Wong et al. (2016)). Due to these high rates, the number of participants worried about falling was high among those with falling experience. There were even many participants with no fall experience during the last 12 months who were still worried about falling. In spite of no significant relationship, neither between the age of fallers/non-fallers nor between their *age-at-amputation*, around 80% of participants in an *age-at-amputation* group less than 20 years of age had falling experience.

No significant association was observed between *age-at-amputation* groups and worries of falling and most of the participants in this group did not feel the need for aids for walking. This group had a mean of age 49.35 (±12.47 years), which is not considered old-aged, which had a higher rate of falling (Deandrea et al., 2010). This finding needs more investigation. As it was mentioned in the methodology section, the ABC self-report scale has been reported to be a reliable and valid tool to evaluate the balance of LLAs (Miller et al., 2003). In this study also, the ABC score was logically and correctly lower for participants with balance issues (using walking aids, having falling experience or being worried about falling). The mean ABC score was in the lower border of the moderate functioning level (with a mean of 55.24 and median of 58.75) which is lower than past studies (62.8 for Miller, W. C. et al. (2001); 67.6 for Miller and Deathe (2004); around 70 for low active LLAs in Mandel et al. (2016); 65.1 for Wong et al. (2014); 2.4 out of 4 (equivalent to 60 out of 100) for Hafner et al. (2017)).

Only 21.9% of participants were in the high level of functioning category, which is lower than in past studies (33% and 35% in Miller, W. C. et al. (2001); Miller et al. (2002), 35% for Asano et al. (2008)). The rate of being in a low level of functioning, according to the ABC score, is high (39%) in this study (comparable with 25% of LLAs in Miller and Deathe (2004)). The statistical tests did not show significant differences between the ABC scores regarding the causes of amputation. This might be due to the small number of participants with amputation causes other than trauma. However, participants with amputation because of peripheral arterial diseases had the lowest mean and median scores (respectively, 41.56 and 42.5), whilst the same parameters were higher for participants with amputation due to diabetes in comparison with three non-vascular *amputation causes,* including severe infection, limited function and congenital condition. When comparing the ABC score categories, the highest rate of respondents with ABC >80 (high functioning level) was related to participants who had an amputation because of cancer. Meanwhile, most amputees with congenital and peripheral arterial disease as a *cause of amputation* had an ABC score <50 (low functioning level) and the highest rate of participants with ABC score = 50-80 (moderate functioning level) was related to participants whose amputations were due to diabetes and infection. Participants with amputation due to peripheral arterial disease had the highest rate of ABC score <67 (an indicator of being at risk of falling). In a study dividing a sample of amputees into two groups with vascular (including diabetes and peripheral arterial disease) and non-vascular (including trauma, infection, cancer, and congenital conditions) causes of amputation, the mean ABC score = 54.13 was recorded for the vascular group (Miller et al., 2002). This score is higher than our score but is in the lower border of moderate functioning level and less than 67, which shows they were at risk of falling, the same as with our participants. It may be that if the study had used similarly broad causal categories, the differences would be significant.

Length of *time since amputation* for the participants at risk of falling (ABC <67) was shorter. This could be due to the shorter time available to adjust to amputation, but it is not related to the age of the participants.

The ABC score was higher for the participants who used their prostheses every day/most of the day. The percentage of participants who used their prostheses every day/most of the day decreased with the decline of the functional level, according to the ABC score categories. This potentially shows how using a prosthesis most of the day adds to balance confidence or could simply be that those with higher balance confidence are more likely to use their prostheses for longer periods during the day.

As Table 3.19 shows, the ABC score was lower for participants with intact limb pain and the majority of them were at risk of future falls (ABC score <67). The pain in the intact limb may lead to reduced reliance on the non-amputated side, which is natural, but the intact limb is more stable in comparison to a prosthesis device and so a greater reliance on the prosthesis for balance, in fact, reduces overall balance confidence. In addition, participants with phantom pain and stump pain had lower ABC scores. Three-quarters of participants with phantom pain were in the low functioning level and at risk of falling. These results suggest that these sensations might be imposing psychological effect on balance confidence.

In this study, 59% of participants used aids to walk (similar to the rates for Hammarlund et al. (2011) with 59%, and Hafner et al. (2017) with 57%). The mean of the ABC score for aided participants was 44.4 - a low level of functioning - while unaided participants had a much better level of functioning, with 70.66 as the mean ABC score. This is comparable to Miller et al. (2002) study with 58% aided LLAs and an ABC score of 44.9, whilst the ABC for unaided participants was 82.6. Still, these results show that the majority of the participants needed intervention to improve their balance (ABC<80, Myers et al. (1998). As was expected, the ABC score of participants with falling experience and worries about falling was lower, and the number of participants at risk of falling was more among these groups.

Interestingly, but not surprising, higher ABC scores (high level of functioning) were associated with higher scores of QOL, satisfaction with the prosthesis, PEQ-M, prosthesis evaluation and less feeling of being frustrated with the prosthesis. These results indicate the level of balance confidence is connected to other aspects of prosthetic use. In addition, (Miller et al., 2002) also mentioned depression as an additional indicator for the low level of balance confidence besides other parameters (including fall experience, fear to fall, and mobility level), which supports our results regarding the QOL and satisfaction with balance confidence.

These results, in addition to the observed relationship of ABC scores and mobility scores, suggest the strong need for improving LLA balance. Schafer et al. (2016) found that traditional balance exercises did not greatly improve ABC scores (in the range of 62-84) of faller LLAs, but (Mandel et al., 2016) commented on the effectiveness of the exercises in reducing falls. Schafer et al. (2018), in a more recent paper, reported on the success of a 12 weeks personalised program (focusing on strength, balance, flexibility and walking endurance) in reducing falling incidents in lower limb amputees. It is important to remember that lower limb amputation might be frequently associated with some complications, such as a shortened stump length or stump contractions, which negatively affect the balance (Lenka and Tiberwala, 2010; Ghazali et al., 2017) and which should be considered in balance improvement programs for LLAs. These facts indicate a strong need for tailoring balance exercises for LLAs. According to biomechanical studies, including the evaluation of balance based on COP features, TT amputees who received regular physical therapy sessions and walking practice after prosthetic fit had better balance and less body sway in comparison to newly fitted amputees (Mayer et al., 2011). Using new technologies also can be effective in balance improvement in LLAs. Sethy et al. (2009) reported balance improvements using a balance trainer board (Phyaction), in addition to normal balance exercises in comparison to a group of LLAs with traditional balance exercises. Another study showed prolonged intervention in the form of home videogames with a balance platform involving standing weight shifting as an active game controller improved the COP displacements of adolescent TF amputees (Andrysek et al., 2012). Mohamadtaghi, B. et al. (2016) also reported balance improvement of TT amputees after a set of regular (five times per week) and prolonged (over four weeks) balance exercises by using a computerized dynamic posturography system with the manipulation of visual, vestibular and proprioceptive inputs. The alance scores of a group of TT amputees improved by allowing the performance of the balance exercises in front of a mirror in comparison to those without it (Mohamadtaghi, M. et al., 2018). Vibratory feedback has also improved TT amputees standing balance (Rusaw, D. et al., 2012). Besides these issues, the fact that prosthetic devices have a lower capacity than the natural limb to produce, various forces at play might be a reason that there is a balance deficiency in lower limb prosthesis users (Bolger et al., 2014) which must be considered in prosthetic fabrication technologies and rehabilitation procedures.

3.4.2 Limitations

The number of participants, considering the duration of the survey was open (two and half years for the English version and one year and three months for the Persian one), and the attempts to publicise and advertise it by sending over a hundred emails and messages to LLA support groups and Facebook amputees' pages, was disappointing. As the survey was formed by combining several questionnaires, it may be that the number of questions and the time required to complete the questionnaire was a reason few were interested to participate in the survey. As indicated previously, to share an opinion (Brüggen et al., 2011) and help to prevent/solve the same problems for others (Soule et al., 2016) are the main personal reasons many take part in surveys. But these reasons may be diminished among the huge numbers of those invited to participate in this study. At the same time, the survey was online and many LLAs were older and, therefore, might have been less familiar with such a means of collecting data. These reasons can lead to a small number of participants.

Several results, such as low scores among British participants, need more investigation. Furthermore, it would be beneficial to access each question in the ABC scale and Oswestry Low Back Disability Questionnaire separately, as well as to investigate different sections of the PEQ part of the survey. Further, a more advanced statistical analysis, such as multiple regression tests or principal component analysis, would be useful to find the predictors of LBP and falling among LLAs. As the recruitment method was different for Iranian participants, and that seemed to affect their responses, it would be beneficial to analyse their data and the data from other participants separately.

3.5 Conclusion

The survey which has been designed for and published in this study has provided an expanded (due to its online availability and not being limited to a certain geographical region) and comprehensive (due to combining three standard questionnaires) database about the condition of LLAs related to their amputations and subsequent prosthetic use in daily activities. This study has shown how LLA participants face common problems related to their balance, mobility and their ability to perform daily activities. No association between the problems and their residence has been proven. However, it is clear their issues are interrelated.

The high number of participants with balance deficiency (ABC scores less than 80, with worries about falling and falling experience) indicates that the balance of LLAs must be monitored regularly, and proper intervention (such as balance exercises and muscle strengthening) should be organised for those amputees with lower levels of confidence.

As the level of LLAs' mobility, balance confidence and functionality of LLAs have a positive relationship with satisfaction and self-perception of QOL, it is necessary to give special importance to these aspects when seeking to improve their ability to use their prostheses during ambulation and transfer their skills to the performance of daily activities.

Finally, this study has shown that the problems related to pain, prosthetic evaluation, mobility and balance have effects on the judgment of LLAs regarding their QOL. Such problems might affect their wellbeing and independence besides having a negative impact on the performance of daily activities, and possibly threaten further injuries (for example, due to falls). It is necessary to observe and solve the issues as a whole package rather than separately. In addition, in spite of global improvements in health, which have led to an increase in the ageing population, it is necessary to remember this increase can be associated with different threats at the same time. From a prosthetist's/orthotist's point of view, it must be noted that, as a consequence of the increasing age of the world population, current LLAs will live to a longer age, too. Unfortunately, a large proportion of lower limb amputations may result from comorbidities associated with old age. Being aware of their difficulties and performing regular screening programs to become updated about the various problems and needs amputees have, and providing better physical/mental health care - including prosthetic monitoring and services - should be part of the preparation for the increasing numbers of elderly people. Furthermore, the results related to the deficient mobility and balance of LLAs became a supporting fact to evaluate effect of insoles on these problems in next 2 chapters.

Chapter 4

Study 2: Trans-femoral Amputees' Level of Walking

4.1 Introduction

Lower limb loss and the consequent use of artificial limbs might be associated with changes in walking characteristics of LLAs which may be used to evaluate their functionality. Spatio-temporal variables of walking (including step/stride lengths, stance/ swing/ double support duration for each limb) (Perry, J. and Burnfield, 1992) and of the symmetry between the right and left limbs (Ellis et al., 2013) are considered the main indicators for the assessment of walking performance and human levels of functionality. Accordingly, an objective of this study has been to evaluate TF amputee participants' functionality through these variables. In the next step, the variables will be compared between amputee and non-amputee participants. A motion analysis system will be used to collect spatio-temporal data of self-selected speed walking. In addition, the answers given by amputee participants to the survey (Chapter 3) have been collected. Here, the ABC scale and PEQ-Mobility parts of the questionnaire will be used to evaluate the amputee participants' self-reported level of functionality. As has been reported through the details in Chapter 3, these responses have provided the opportunity to recorda respondent's perception of her/his ability to perform several daily activities. An ABC score >80 is considered to reflect a high level of functionality. The scores 50-80 and scores <50 indicate moderate and low levels of functionality, respectively (Powell and Myers, 1995). Respondents were asked to score from 0, which is the worst score, to 10, which represents the best score, in a PEQ-M questionnaire to evaluate their mobility.

An assessment of the effects of insoles on biomechanical aspects of walking is another main goal of this chapter. Insoles may be bespoke (to fit a specific patient and condition) or relatively inexpensive off-the-shelf and generally commercially available. There is evidence that footwear influences a number of spatio-temporal and biomechanical variables of non-amputees' walking, such as step/stride lengths, stance/swing duration, knee/ankle range of motion, ground reaction forces and lower limb joint moments (Franklin et al., 2015). Similarly, modifications to footwear, through the use of insoles, for example, have been shown to have the potential to impact the relative orientation of lower limb segments and, subsequently, the loading and functioning of the limb during standing balance or walking, via their particular shape (Ball and Afheldt, 2002b; Nester et al., 2003; Nakajima et al., 2009; Castro-Méndez et al., 2013; Kendall et al., 2014; Jafarnezhadgero et al., 2018) or material of construction (Perry, S.D. et al., 2008; Losa Iglesias et al., 2012; Liu et al., 2012; Qiu et al., 2012; Stern and Gottschall, 2012; Bateni, 2013; Qu, 2015). It is known that the pattern and biomechanics of walking in lower limb amputees are different from non-amputees. This is because of amputees' impaired musculoskeletal system, and the use of an artificial limb which is not able to provide the exact function of a natural limb. These differences might express themselves through compensatory strategies, including higher reliance on the intact limb (IL), which is seen in the form of a longer stance time, shorter step length and larger IL joint moments (Prinsen et al., 2011; Sagawa et al., 2011). In addition, deficient somatosensory information sent to the CNS following limb loss leads to a higher risk of amputees falling (Buckley et al., 2002). Wearing insoles might affect the peak of vertical ground reaction force (Creaby et al., 2011; Muthukrishnan, 2016; Jafarnezhadgero et al., 2015), loading rate (Jafarnezhadgero et al., 2015), spatio-temporal variables (Aboutorabi et al., 2014) due to them having a shock-absorbing feature. These features of insoles might be beneficial and have a supporting role for the IL which is subjected to higher and longer periods of load-bearing due to amputees' greater reliance on it. The effect of insoles on the biomechanics of walking and the balance improvement of non-amputees has been reported, but there is no documentation of the effect on amputees in the current literature. This fact has created the main motive to study the effect of insoles on walking for above-knee prosthesis users. A motion analysis system was used for the precise evaluation of the potential effects. Commercial insoles are easily available and relatively inexpensive for people living in middle-low incomes countries. Based on the facts about insoles noted above, a commercial insoles with heel shock-absorbers and light medial support was selected for use with the IL of amputees and both limbs of non-amputees during biomechanical tests. In this chapter, the biomechanics of a one gait cycle of each limb of 10 unilateral above-knee prosthesis users and 14 non-amputees, as a control, during walking at a self-selected comfortable speed will be evaluated by using a motion analysis system in two conditions: with and without insoles. It is expected that the insoles will influence several kinematic (COM mediolateral and vertical displacements, COP mediolateral displacements, the relationship between the COG/COP and the lateral border of the BOS during late mid-stance as variables related to dynamic balance, and the ankle range of motion in the sagittal plane) and kinetic (initial vertical force loading rate, sagittal joint moments and powers) walking variables due to their mechanical feature at the heel (a shock absorber, which is compressed in the sagittal plane). Thus, first these variables will be measured in unilateral TF amputee and non-amputee participants in a without insoles condition and, in the next step, the effects of insoles use on the same variables during walking of both groups will be evaluated and will be compared. In the final section, the results will be discussed.

The following hypotheses have been considered:

1. The function of unilateral TF amputees is lower than non-amputees according to the spatio-temporal variables of walking (including walking speed, step/stride length, stride time, duration of stance and swing phases of each limb) and symmetry index
2. The unilateral TF amputee participants in the biomechanical tests of this study have a moderate level of functioning and mobility, according to their answers to the ABC scale and PEQ-M scores.

3. There are significant differences between paired biomechanical variables, including each limb's:
    - Spatio-temporal variables, except speed of walking
    - COM displacements (Vertical, Mediolateral)
    - Mediolateral displacement of the COP
    - The distance between the COP- lateral border of the BOS at mid-stance
    - The distance between the COG and lateral border of the BOS at mid-stance
    - The angular motion of the ankle joint in the sagittal plane
    - The initial stance loading rate
    - The lower limb's joint powers and moments in the sagittal plane

   during the gait cycles of the IL and prosthetic limb (PL) of amputees in a without insoles session
4. No significant differences exist between paired variables including each limb's:
    - Spatio-temporal variables, except speed of walking
    - COM displacements (vertical, mediolateral)
    - The mediolateral displacement of the COP
    - The distance between the COP and lateral border of the BOS at mid-stance
    - The distance between the COG and lateral border of the BOS at mid-stance
    - The angular motion of the ankle joint in the sagittal plane
    - The initial stance loading rate
    - The lower limb's joint powers and moments in the sagittal plane

   during gait cycles of right and left limbs of non-amputees in a without insoles session
5. The extracted variables including each limb's:
    - Spatio-temporal variables, except speed of walking
    - COM displacements (vertical, mediolateral)
    - The mediolateral displacement of the COP
    - The distance between the COP- lateral border of the BOS at mid-stance
    - The distance between the COG and lateral border of the BOS at mid-stance
    - The angular motion of the ankle joint in the sagittal plane
    - The initial stance loading rate
    - The lower limb's joint powers and moments in the sagittal plane

   of amputees have significant differences with the variables of non-amputees during without insoles walking
6. The use of insoles does not change the similarity which exists between the right and left limbs of non-amputees, according to the paired biomechanical variables, including each limb's:
    - Spatio-temporal variables, except speed of walking
    - COM displacements (vertical, mediolateral)
    - The mediolateral displacement of the COP
    - The distance between the COP- lateral border of the BOS at mid-stance

- The distance between the COG and lateral border of the BOS at mid-stance
- The angular motion of the ankle joint in the sagittal plane
- The initial stance loading rate
- The lower limb's joint powers and moments in the sagittal plane

7. The observed differences between amputees IL's paired biomechanical variables including:
    - Spatio-temporal variables, except speed of walking
    - COM displacements (vertical, mediolateral)
    - The mediolateral displacement of the COP
    - The distance between the COP- lateral border of the BOS
    - The distance between the COG and lateral border of the BOS
    - The angular motion of the ankle joint in the sagittal plane
    - The initial stance loading rate
    - The lower limb's joint powers and moments in the sagittal plane

    and if the variables of non-amputees decrease after insoles use.

4.2 Methodology

4.2.1 Participant recruitment

The inclusion criteria were that all subjects should be: aged 18-70 years, with the normal cognitive ability to read and understand instructions and related materials provided for them by the researcher; be active ambulator and be able to walk without assistive devices (e.g., a stick); and be healthy or with controlled medical conditions. Additional criteria for the amputee group were: being a unilateral TF amputee; the amputation should have been performed more than two years earlier; having had experience of their current prosthesis for over one year; being free from any musculoskeletal issues (except for amputation in the lower limb) during the previous six months, having intact skin condition of the residual limb; using their prosthesis on a daily basis; using a passive mechanical prosthetic knee (i.e., no computerized or intelligent prosthetic knee); and having a conventional prosthetic ankle-foot (i.e., having no energy-storage or a carbon leaf structure). Suffering from medically diagnosed musculoskeletal/neuromuscular or balance issues during the last six months, having a medically diagnosed ankle/foot issue, having a wound/ulcer on the foot, wearing orthopaedic shoes or any foot orthosis or insoles were considered as exclusion criteria. The ethics committees of the Biological Sciences Faculty in the University of Leeds and the “Djavad Mowafaghian Research Centre of Intelligent Neuro-Rehabilitation Technologies” - Sharif University of Technology, had separately approved the study protocol and the participants' recruitment procedure (Appendix E). All subjects were free to withdraw at any time.

4.2.1.1 Amputees

Efforts for recruitment of TF amputees with the mentioned inclusion criteria (using a passive prosthesis) in Leeds were not successful. Thus, with the agreement of my supervisor, the University of Leeds and the manager of the “Djavad Mowafaghian Research Centre of Intelligent Neuro-Rehabilitation Technologies”, the recruitment of amputees, and the biomechanical tests data collection were carried out in Iran. Twelve unilateral lower limb male amputees, including one knee disarticulation and 11 TF amputees, agreed to participate in the study. They were recruited using a convenience sampling method from the “Disabled Iranian Veterans” prosthetic clinic, a sports complex related to the “Disabled Iranian Veterans” community and the “Iranian Handicapped Society” in Tehran. The participant’s treatment and/or care was not subject to the taking part in this study.

4.2.1.2 Non-Amputees

Fourteen non-amputee males, including eight persons in Leeds and six in Iran, participated in the study as the control group. When it was decided to perform the amputees’ data collection in Iran, we had already collected the eight non-amputees’ data in Leeds. The non-amputee participants were recruited using a convenience sampling method via advertising in the University of Leeds and Djavad Mowafaghian Research Centre.

4.2.1.3 Participant data

One amputee participant out of 12 was unable to complete the insole tests due to time constraints and was eliminated from the study. The characteristics of the 11 remaining amputees including 10 with trans-femoral amputation and 1 with knee disarticulation, (M_{age}±SD=55.9 ±8.53 yrs) and 14 non-amputee (M_{age}±SD=27.4±5.8 yrs) volunteers are shown in Table 4.1. There was no significant difference (p=0.203) between the BMI of the amputees (M_{BMI}±SD = 27.7± 4.6 kg/m^2) and the non-amputees (M_{BMI}±SD= 25.3± 4.8 kg/m^2).

All the non-amputees’ were right leg dominant. Six amputees had had an amputation on their left side. The cause of the amputation for all the amputees was trauma (5 Warfield). The time since amputation was more than 28 years for 10 participants and 18 years for one (M±SD=34.45±7.61 years). All of them had experienced amputation before their 30th year (M±SD=21.82±4.83 years). Except for one amputee with an Ottobock exoskeletal single-axis knee prosthesis (3P19), all the amputees used endoskeletal prostheses. All ankle-foot components, except for one amputee with SACH foot, were single-axis ankle-foot. The majority of the mechanical passive prosthetic knee components were products of the Ottobock company, including one 3R21 (polycentric prosthetic knee for a participant with a knee disarticulation), 3R15 (single axis), 3R20 (polycentric joint), and

3R36 (polycentric joint). Five amputees used a pelvic belt as an additional suspension system to their suction sockets.

Table 4.1 Participants characteristics

subject	Non-amputees		Amputees				
	Age (yrs)	BMI (kg/m^2)	Age (yrs)	Time post-amputation	Cause of amputation	Side of amputation	BMI (kg/m^2)
1	22	25.3	49	31 (yrs)	Warfield	Right	31.8
2	27	20.6	52	32 (yrs)	Warfield	Left	21.5
3	24	30.0	48	30 (yrs)	Warfield	Right	24.6
4	29	25.3	61	46 (yrs)	Work accident	Left	19.6
5	25	37.9	53	38 (yrs)	Traffic accident	Right	31.7
6	25	22.8	58	36 (yrs)	Warfield	Right	27.3
7	42	25.1	66	38 (yrs)	Traffic accident	Left	29.9
8	23	26.6	57	29 (yrs)	Traffic accident	Left	25.0
9	29	27.3	70	45 (yrs)	Traffic accident	Left	28.2
10	27	25.9	40	18 (yrs)	Traffic accident	Right	32.8
11	24	22.1	59	35 (yrs)	Warfield	Left	32.52
12	38	25.8					
13	26	21.2					
14	23	18.1					
Average	**27.4**	**25.3**	**55.9**	**34.5** (yrs)	**All trauma**	**6 Left, 5 Right**	**27.71**
SD	5.8	4.8	8.53	7.61 (yrs)	**-**	**-**	4.6

4.2.2 Procedure

4.2.2.1 Insole selection

A major aim of this research was to determine if readily available and relatively inexpensive insoles can be used to improve the balance (and, secondarily, comfort during daily activity) of lower limb amputees. It was important that the insole chosen was low cost and easy to obtain as many amputees worldwide do not have access to high-cost health care. There are a number of insoles marketed that may meet this criterion. To some extent, the choice was subjective, but it was based on the information a potential patient may have when choosing such a device for themselves: cost, makers claims and, if possible, a trial for comfort in their current shoes. In addition to the cost (less than £30), the shape and material of the insoles were the key points in the selection. It was important that the insole fitted the shape of the sole of a natural foot and did not interfere with its natural motion. Accordingly, Dr Scholl's® P.R.O. Pain Relief Orthotics for Lower Back Pain was chosen. It has narrow contouring for the heel and a medial arch with a soft shock-absorbing pad (approximately 1cm thick) located under the heel. In addition, a semi-rigid curved structure between the heel and midfoot helped to prevent medial arch flattening. The insoles could be adjusted to shoe size by trimming according to the guidelines provided by the manufacturer (Figure 4.1).

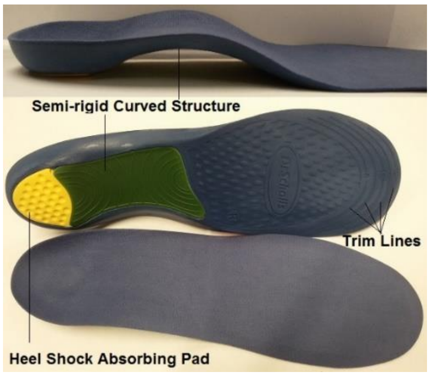


Figure 4.1 The insoles used in the study

4.2.2.2 Biomechanical tests

The volunteers signed an informed consent form (Appendix G) when they attended the lab. A hard copy of the questionnaire in Chapter 3 (Appendix B) was completed by each amputee participant on their attendance for biomechanical tests. Testing took place at two separate test locations in Iran, using a Vicon motion capture system (Vicon Motion Systems, Oxford, UK) and at the University of Leeds by using a Qualisys motion capture system (Gothenburg, Sweden). These two motion analysis systems are accurate and established as the golden standard systems in human motion studies. The accuracy of their performance depends on the precision of the camera and the force platform calibrations. To analyse any movement by a motion analysis system, it is necessary to calibrate the space in which the motion is happening. Camera calibration provides the capture volume and the accurate scale of the system and enables it to produce accurate 3D data. Camera calibration was considered achieved if the standard deviation of the wand length was less than 1mm. The force platforms were calibrated at instalment time and were checked generally according to the mass of a subject in test sessions. In the case of obvious differences or the transposition of the force platforms, these were re-calibrated by specialist technicians at the labs.

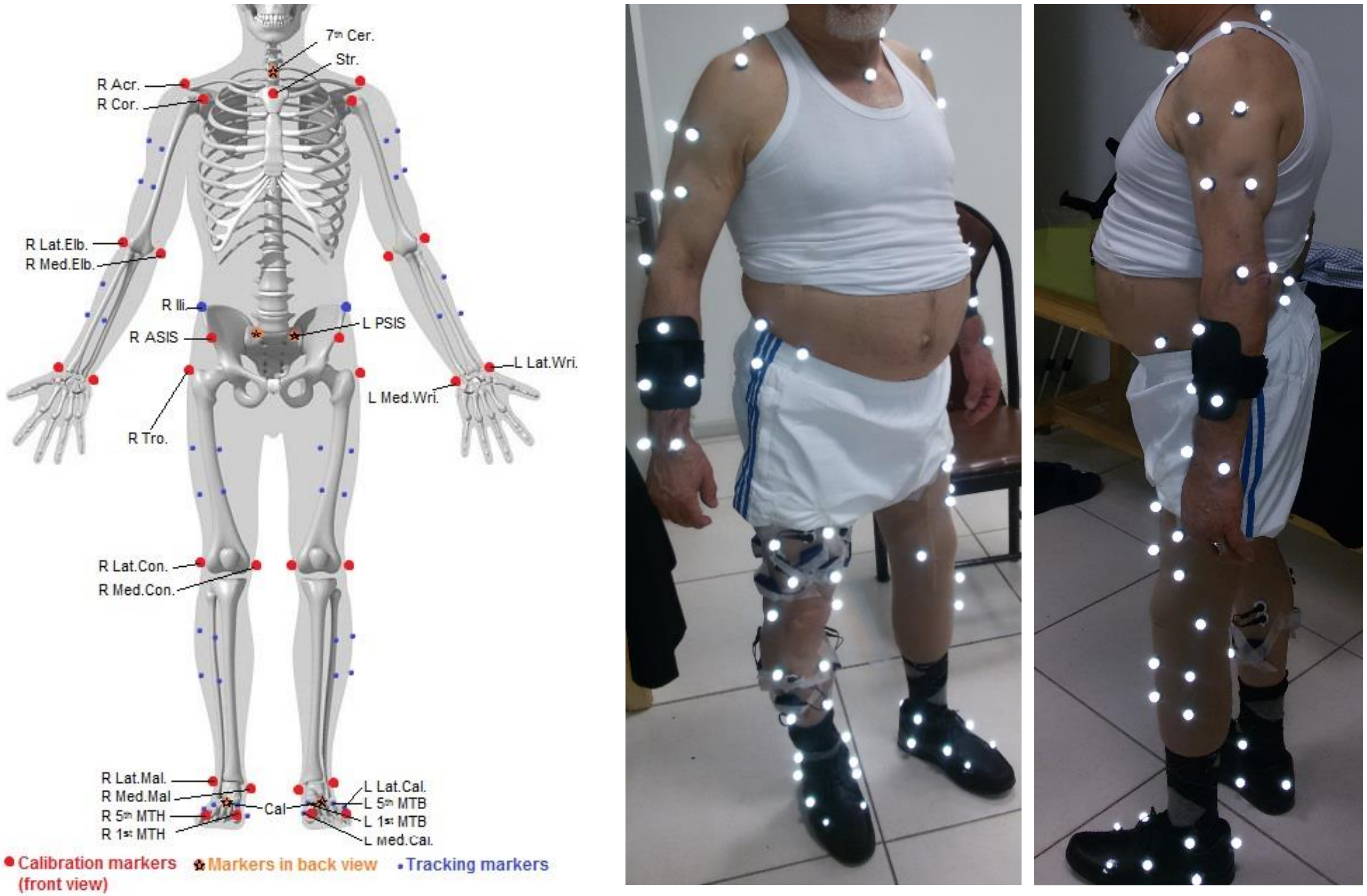
The calibration of the motion space was separately performed in both test sites according to the instructions issued for the Vicon and Qualisys motion analysis systems. The subjects wore a vest and short pants and their own comfortable shoes during the test sessions. The marker placement and test protocols were the same for all participants. The same person (the main researcher) placed markers of all the participants to improve the reliability of the data collection. After the calibration of the movement space, 14 mm spherical passive reflective markers were fixed on the skin, using double-sided adhesive tape, to define the body segments. The anatomical landmarks were identified for marker placement by palpation in accordance with the Qualysis track manager's user manual, and the body modelling requirements for the visual 3D software on the basis of the markers being visible for as much of the test time as possible during the tests. Visual 3D software requires a full body model, including upper limbs and trunk, to calculate a body's COM (Figure 4.2-A). In this software, the calibration markers are used to define the

proximal and distal ends of each segment. Thus, the following markers were placed on the body as calibration markers: right/left 1st and 5th metatarsal heads (MTH), right/left mediolateral calcaneus, right/left medial and lateral malleolus (Med.Mal., Lat.Mal.), medial and lateral epicondyles of the right/left femurs (Med.Con., Lat.Con.), right/left greater trochanters (Tro.), right/left iliac crests (Ili.), right/left anterior superior iliac spines (ASIS), right/left posterior superior iliac spines (PSIS), right/left acromion processes (Acr.), right/left coracoid processes (Cro.), medial and lateral epicondyles of the right/left humorous (Med.Elb., Lat.Elb.), medial and lateral of right/left wrists (Med.Wri, Lat.Wri), 7th cervical spine (Cer.) and sternal notch (Ster.). In addition, tracking markers must be introduced in a visual 3D model to make a segment recognised. Hence, four markers in the quadrilateral order were attached to the right/left shanks, femurs, and upper arms, three markers with fixed positions were attached to the right/left forearms and five extra markers on each foot, including 1st/ 5th metatarsal base (MTB), mediolateral calcaneus (Med.Cal., Lat.Cal.) and calcaneus (Cal.). These were used as tracking markers. The markers for the prosthesis were placed in accordance with the intact side and the rotational axis of the prosthetic knee (Figure 4.2-B).
After the marker placement and at the starting of each test session, the participants stood in an anatomical position in the middle of the calibrated space to record a static data set. The static test was used to calculate the joint centre locations and the relative locations of the tracking and anatomical markers in the modelling stage.

4.2.2.2.1 Tests in Iran

The experimental sessions for the amputee group and six non-amputee volunteers took place in the Motion Analysing Lab at the “Djavad Mowafaghian Research Centre of Intelligent Neuro-Rehabilitation Technologies”; in Tehran, Iran.

For use in a parallel study (please see the list of publications I cooperated in by conducting the related biomechanical tests and extracting the results), the data collection included a recording of the electrical activity of several lower limb muscles which are not presented in this thesis. The location of markers and force data were collected by using a Vicon motion capture system (Vicon Motion Systems, Oxford, UK). The system was composed of two 40cm×60cm and 80cm×60cm Kistler force platforms embedded in the floor, and six infra-red cameras (Vicon MX-T40), which were fixed at a height of 2m around a 2m×5m walking path to cover the measurement field of view of approximately 1.5m×4m×2m around the force platform area. Camera calibration of the system was done for each test session separately, according to Vicon protocol and guidelines. The ground reaction forces (GRF) from the two Kistler force platforms and the position of the markers were recorded synchronically, at a sampling frequency of 1200 Hz and 120 fps respectively, during each test.



A B

Figure 4.2 A) Schematic demonstration of marker placement, B) Marker placements for an amputee participant

4.2.2.2.2 Tests in Leeds

The tests for eight non-amputees in Leeds were conducted at the Gait and Motion Analysis Laboratory at the University of Leeds by using a 3D Qualisys Motion Capture system (Gothenburg, Sweden) and two AMTI force platforms (Watertown, MA, USA). Thirteen ProReflex AQUS4 cameras were fixed around an 8m×8m testing space at the height of 3m to cover a measurement field of view approximately 5m×5m×2.5m. Calibration of the system was done for each test session according to the Qualisys protocol and guidelines. The 3D coordination of markers and force data from the force platforms were recorded synchronically at the rate of 400 fps and 1200 Hz, respectively. The 3D tracker had a prediction error of 30 mm and a maximum residual of 10 mm.

4.2.2.2.3 Walking Test Sessions

The tests were conducted in two different experimental conditions: with and without insoles inside the shoes. A pair of the mentioned commercial insoles (Dr Scholl's® P.R.O.) was provided for each participant. Each test session included a range of daily activities, but only standing balance and walking tests are represented in this thesis.

Each participant was asked to walk at his comfortable self-selected speed across a walk-way in the laboratory with two force platforms embedded in the middle. Each participant reached the first force platform by at least their third step. The tests were repeated in case of inappropriate placement of a foot on just one force platform. Three successful walking trials per participant with full foot support (clean hits) on both force plates were recorded for each insoles condition. For insoles sessions, the insoles were used for both feet of the non-amputees and the intact foot of the amputees. Amputee participant number 11 had a different walking pattern, with short steps, which led to one force platform remaining in touch with both feet during each step; this resulted in inappropriate walking data. Therefore, his walking data was not processed.

All participants were asked to continue using the insoles during their outdoor activities and to give their feedback on them by filling the qualitative evaluation form used for insoles selection (Appendix F) after four weeks of using the insoles.

4.2.3 Data Analysis

The 3D coordinates of the markers at the two testing sites were obtained by a marker tracking process using separately Nexus 2.5 (Vicon Motion Systems, Oxford, UK) and Qualisys Track Manager software (QTM, Gothenburg, Sweden). The C3D files resulting from the marker tracking software (including the force platform data) were used as input for the visual 3D software (the University of Leeds, Visual3D X64 Professional v5, and v6) to develop a body model, to determine the phases of each gait cycle and, finally, to extract the basic variables outlined in Table 4.2.

4.2.3.1 Rigid body model and extracting variables

A 12 segment full body model for each participant was created according to the visual 3D guidelines by using tracking and calibration markers (as reported in section 4.2.1.3, Figure 4.2-A) of static tests. The segments included the feet, shanks, thighs, arms and forearms of both right and left sides, in addition to the pelvis and trunk (Figure 4.3).

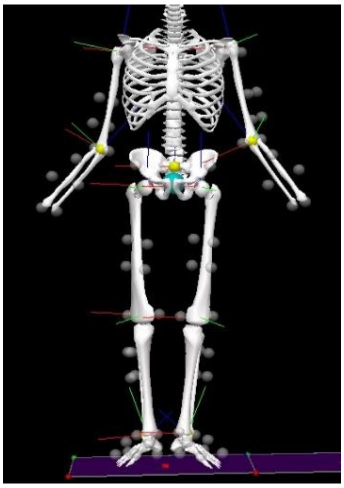


Figure 4.3 Body model included right and left feet, shanks, thighs, arms, and forearms in addition to pelvic and trunk segments

The ‘V3D_Composite’ was selected to model the pelvis segment. It uses left and right ASIS and PSIS to define the pelvis, and produces hip joint centres. Consequently, the thighs segments were defined by using the hip joint centres as the proximal joint and the medial and lateral epicondyles of the femur markers as the distal joint (knee) in addition to four tracking markers on the thigh. The shank segments were defined using the medial and lateral epicondyles of the femurs as the proximal joint (knee) and the medial and lateral malleolus markers as the distal joint (ankle), in addition to the four tracking markers on the shank. The foot segment was determined by the medial and lateral malleolus as the proximal joint (ankle) and 1st and 5th metatarsal head markers as the distal joint (toes), in addition to 1st and 5th metatarsal bases and mediolateral calcaneus markers as tracking markers. Extra tracking markers on the feet were permitted in case of any missing feet tracking markers. Markers on the right/left PSIS, right/left acromion processes, 7th cervical spine and the sternal notch were used for the trunk segment (called the thorax/abdomen in the visual 3D model). Using a similar method, the upper extremities, including the arms and forearms, were defined via related markers. By including the mass of each subject in the “subject data” in the modelling section of the visual 3D, anthropometric data needed for later variable computations, such as joint moments or the COM, were automatically calculated. Thus, the default mass proportions in the visual 3D were used for all the ILs and the non-amputee subjects. The mass of the PL was estimated from prosthesis manufacturers catalogues and the approximate values were entered into the related fields in the software. Hence, a full body model was built which permitted calculation of the body’s COM position by visual 3D software.

The visual 3D software is able to detect walking events, including the initial contact and toe-off for each lower limb as indicators of the start of the stance (end of swing) and end of stance (start of swing) respectively, during level walking. For each trial, the data of each limb's single stride (a clean touch of each foot to only one force platform in a consecutive manner) was processed (Figure 4.4). The data related to the tests in which the participant's foot did not place properly only on one force platform were excluded.

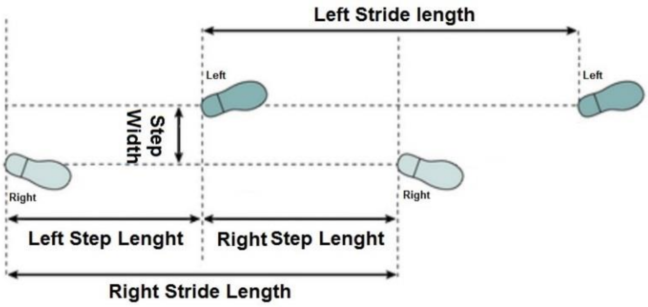


Figure 4.4 Stride and step lengths and width (adapted from (Whittle, 2002)

After building the body model and defining the walking events, the kinematic and kinetic variables of the trials were calculated and extracted. A second-order Butterworth low pass filter with a cut-off frequency of 6Hz was applied to the 3D coordinates by markers (Winter, 2005). The spatio-temporal variables were calculated and extracted by using heel marker displacements and the automatic detection of stance and swing phase events. The Computer_Model-Based_Data commands in the visual 3D software also provided various pipelines to calculate the pre-defined kinematic/kinetic variables. Figure 4.5 is an example of the visual 3D pipelines used to calculate the right ankles angles, moments and power.

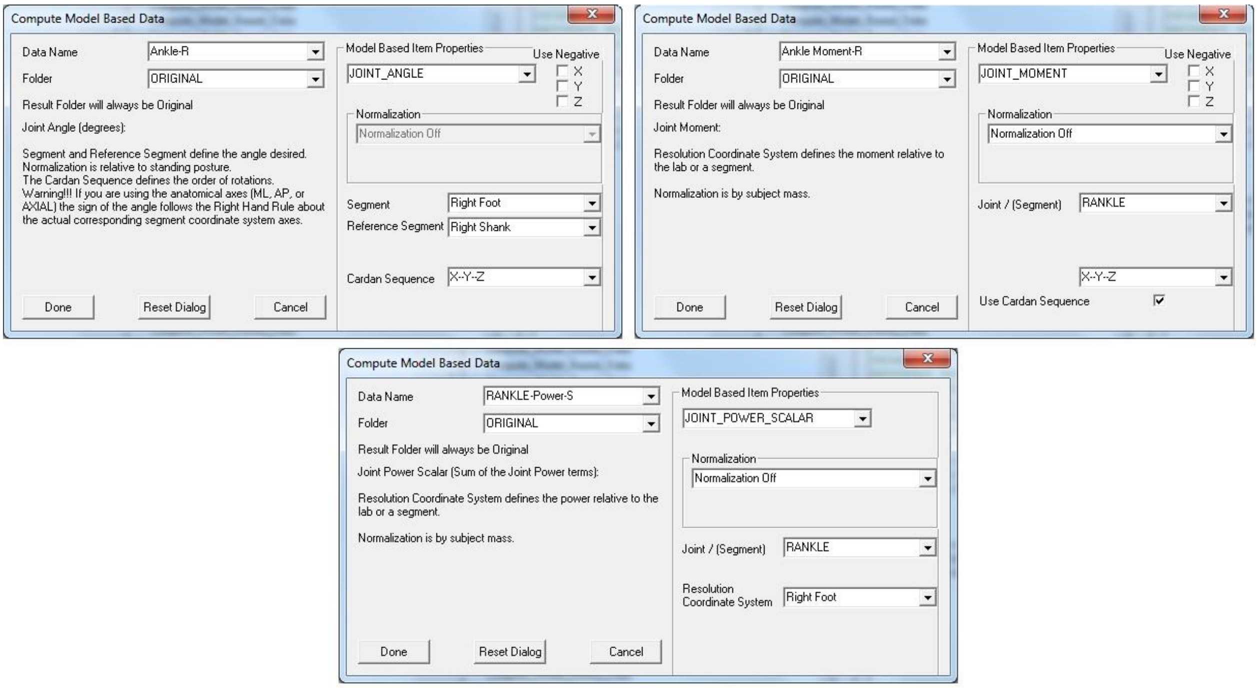


Figure 4.5 Examples of using visual 3D's pipeline to calculate right ankles angles, moments and power

As can be seen, the user defines the data name, the model-based variable (for example, Joint_Angle or Joint_Moment or Joint_Power), the segment which must be used from the model and the Cardan sequences. The default Cardan sequence for the calculation of joint angles in visual 3D is x-y-z, which is equivalent to the flexion/extension-abduction/adduction-axial rotation. After execution of the pipelines, the user will be able to build a report in visual 3D. In this report, variables can be exported in a text file after specifying the beginning and ending events. For walking data, variables were extracted for one stride and were normalized to 100 points (as 100% of a gait cycle). The exported files were later analysed in Excel.

4.2.3.2 Study variables

Table 4.2 shows the biomechanical variables which were extracted in the visual to be used in the examination of hypotheses numbers 1 and 3-8 in the later comparison between the limbs, groups and insoles sessions.

Table 4.2 Extracted data by utilizing visual 3D software

Variable	Description
Spatio-temporal	**Walking speed:** Forward speed of COM to pass the right and left consecutive strides (calculated by visual 3D software)
	Step length (distance): Anteroposterior distance between the heel markers of two feet during their consecutive heel strikes
	Step Width (distance): Mediolateral distance between the heel markers of two feet during their consecutive heel strikes
	Stride length (distance): Anteroposterior distance the heel marker travels during two consecutive heel strikes of one limb
	Stride time: The duration of one stride, measured in seconds
	Stance duration (time): The proportion of a stride one leg is in contact with the ground, expressed as percentage of gait cycle
	Swing duration (time): The proportion of a stride one leg is not in contact with the ground, expressed as percentage of gait cycle
	Terminal double support (time): The proportion of a stride at end of stance of a limb which is coincide with initial stance of contralateral limb, expressed as percentage of gait cycle
Kinematic	**COM 3D coordinates:** COM's x, y and z coordinates during one gait cycle of each limb
	COP 2D coordinates: COP's x, y coordinates during stance phase of each foot on one force platform
	Three dimensional coordinates of the metatarsal and lateral heel markers: x, y and z coordinates of these markers during one gait cycle of each limb
	Ankle angle changes: Ankle angle in sagittal plane during one gait cycle of each limb
Kinetic	**Vertical GRF changes:** Changes of the vertical component of GRF during stance phase of each foot on one force platform
	Ankle, knee and hip joints moment changes in sagittal plane: Lower limb joint moments in sagittal plane during one gait cycle of each limb
	Ankle, knee and hip joints power changes: Lower limb joint scalar powers during one gait cycle of each limb

As was mentioned in the Introduction, the spatio-temporal variables were used to evaluate the participants' level of functionality. The heel's soft shock-absorbing pad was the main feature of the insoles, which is expected to affect the biomechanical variables (including the ankle angle, lower limb joints moments and powers) in the sagittal plane as a mechanical intervention. Therefore, the kinematic and kinetic variables in Table 4.2, were selected to evaluate the effect of the insoles on walking. The mediolateral displacements of the COP, the mediolateral and vertical displacement of the COM during the right and left steps and the strides are related to the dynamic balance and might be affected by the insoles. The displacements of the COM and COP were normalised to the line of progression.

In addition to the variables mentioned in Table 4.2, the vertical GRF loading rate during the initial stance, mid-stance, the distance of the COP and COG to the lateral border of the feet (the line between the 5th metatarsal head and the lateral heel markers), and the symmetry index for the spatio-temporal variables were calculated separately, as follows:

Loading rate: The initial stance's vertical force loading rate was calculated in three time-points. These time-points are demonstrated in Figure 4.6 (which is a profile of the average vertical ground reaction force for three without insoles walking trials of the right limb of non-amputee number 14). The loading rate is force changes during a particular time: LR=$\frac{\Delta \mathrm{F}}{\Delta t}$ in which "LR" stands for loading rate, "F" for force and "t" for time. In the first method (1^{st} in Figure 4.6), the point with a magnitude equal to 80% of the first peak of vertical force was found. The LR was calculated by knowing its timing as a stance percentage and the stance duration in seconds (Stacoff et al., 2005). But, as is seen in Figure 4.6, the point is after the initial impact, which is expected to be influenced by the heel of the insole. Thus, a point before the initial impact must be recognized. As the timing of the impact was not constant, in the second method, the corresponding force change during the first three percent of the stance phase was used to calculate the loading rate. In the force profile of several amputee subjects, there was a close to horizontal slope for the force profile of PL during the first percentages of the stance, which did not permit us to use this method for all. Accordingly, the third method was developed following inspiration from (Ueda et al., 2016) methods provided for the loading rate during running; hence, the loading rate during the three percent after the force equal to 20% of the first peak of the vertical force was calculated. In all these methods, time was converted from percentage to second according to the length of the stance phase and the force was normalised to the bodyweight of the participants in kgs.

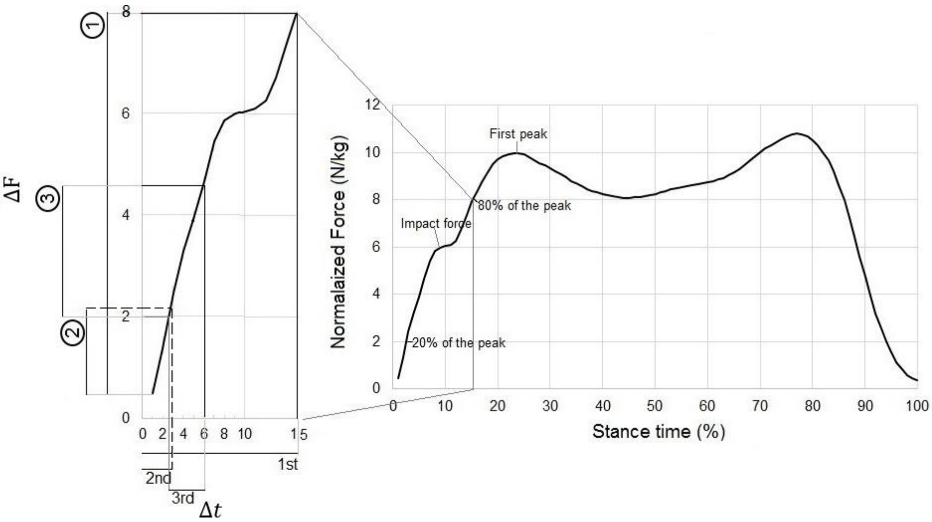


Figure 4.6 Three utilized time-points to calculate the loading rate

<u>Symmetry index:</u> When similar measurements were performed for right and left lower limbs (in a similar way to the intact and the PLs for lower limb amputees) during a rhythmic activity like walking, their symmetry might be an indicator of the matching functions of both limbs. In addition, the symmetrical gait is associated with optimal mechanical and metabolic costs, thus efficient walking (Ellis et al., 2013). Accordingly, the similarity of these variables for intact and the PLs of amputees (and right and left limbs of non-amputees) was calculated by using the symmetry index (SI) in Equation 4.1

$SI = \frac{|X_L - X_R|}{0.5 \times (X_L + X_R)} \times 100\%$ (Blazkiewicz et al., 2014) **Equation 4.1**

In which X might stand for all gait variables of right (R) and left (L) sides. The amounts equal to zero/≥100% show complete symmetry/asymmetry between two limbs. In this chapter, SI<10% will be considered a reasonable level of symmetry for the variables (Wu and Wu, 2015).

<u>Relationship between the COG/COP and BOS' lateral border:</u> The lateral positioning of the COP and the distance between the COG (the projection of the centre of mass on the ground (Winter, 1995)) and lateral border of BOS might be used to evaluate the dynamic balance control during walking, according to (Kendell et al., 2010) and (Nagano and Begg, 2018) respectively). The distance between the COG-lateral border of the BOS and the COP-lateral border of the BOS (as the lateral positioning of the COP) was defined in this study to evaluate the differences between amputees and non-amputees' balance control in single support, in addition to an assessment of the insoles use on these variables. The lateral border of the BOS was defined by a line between the 5th metatarsal head and the lateral heel markers. Three-dimensional coordinates of the metatarsal and lateral heel markers during one gait cycle of each limb were extracted by using visual 3D software. The Equation 4.2 was used to calculate the distance between a point (point A with x_A and y_A as its coordinates, i.e., the COP or COG) and a line (formed by points 1 and 2 with x_1, x_2 and y_1, y_2 as their coordinates: i.e., the 5th metatarsal head and lateral heel markers, which represents the lateral border of the BOS):

$$distance\ (P_1, P_2, P_A) = \frac{|(y_2 - y_1)x_A - (x_2 - x_1)y_A + x_2 y_1 - x_1 y_2|}{\sqrt{(y_2 - y_1)^2 + (x_2 - x_1)^2}} \qquad \textbf{Equation 4.2}$$

The moment of changing posterior force to anterior force in the force profile of each limb was considered as the late mid-stance point of time (Richards, 2008). The relationship between the COG/COP and the BOS lateral border were calculated in this point of the gait cycle as a recognisable moment in single support.

4.2.3.3 Reliability of data collection

The reliability (repeatability) and validity of the data collection systems were tested by repeated measurements of several known lengths, angles and weights. The results presented in tables H-Q-1 to H-Q-6 and tables H-V-1 to H-V-6 of Appendix H are respectively related to the repeatability and validity of the Qualysis motion analysis system and Vicon motion capture system, including their force platforms. As can be seen, the level of repeatability and validity of the systems were high. The calculated coefficient of variance for all angular/linear measures and forces were less than 1% during 10 times repetition of measurements. In addition, the percentage error (PE) as a criterion of validity for all measurements was smaller than 1%.

4.2.4 Statistical analysis

Mean values of each variable during the repeated tests for each participant were used to compare the two limbs in each group and between groups, in addition to the two insoles conditions. As it is a study with intervention (insoles conditions as pre-post) and a control group, mixed between-within subjects ANOVA (2 limbs × 2 groups × 2 insoles condition), was used to compare groups-limbs-insoles conditions. When significant differences were found, an independent sample t-test (between 2 groups) and paired t-test (pre-post insoles use) were utilized to find the exact differences between the data. The statistical analyses were conducted using SPSS version 25.0 (IBM Corp, 2017), with the level of significance set at $p \leq 0.05$ for all analyses.

The Coefficient of Variance ($CV = \frac{\mathrm{STDE}}{\mathrm{Mean}} \times 100$) as a criterion for assessment of the variability level of the selected variables was calculated and is reported for each spatio-temporal variable in both groups. CV<10-15% will be considered as the acceptable (low) level of variability (Standing and Maulder, 2017; Thomas et al., 2018; Me et al., 1998).

4.3 Results

The results of walking at a self-selected speed of 10 TF amputees and 14 non-amputees in two insoles conditions are presented in 3 main parts: the level of function, homogeneity of groups, the effect of insoles on walking (including spatio-temporal variables and the kinematics and kinetics of walking).

4.3.1 Level of Function

The time and distance-related variables of walking might be considered indicators of functionality (Perry, J. and Burnfield, 1992). Accordingly, the level of the function of participants was evaluated via assessment of the variables in Table 4.2.

For each amputee participant, the answers to the PEQ-M part (related to mobility) of the survey, as well as Activities-specific Balance Confidence (ABC) Scale questions and their total scores, will be presented to give a more precise insight into their functional level during the selected daily activities, including walking.

4.3.1.1 Non-Amputees

The averages of three trials of the spatio-temporal variables for 14 non-amputees during self-selected speed level walking without insoles are shown in Table 4.4. The group average of self-selected walking speed was 1.1 m/s (±0.14 m/s). The average and standard deviation of spatial variables in the non-amputee group are as follows: 0.09 m (±.04) for right step width; 0.68 m (±.05) for length of right step; 0.10 m (±.05) for left step width; 0.65 m (±.04) for length of left step; 1.32 m (±.07) for right stride length; 1.35 (±.09) for left stride length. The average and standard deviation of temporal variables in the group are as follows: 1.21 s (±.10) for duration of right gait cycle; 1.23 s (±.09) for duration of left gait cycle; 63.72% (±2.05) for right stance phase; 36.28% (±2.05) for right swing phase; 13.88% (±1.89) for terminal double support of right gait cycle; 63.29% (±2.08) for left stance phase; 36.71% (±2.08) for left swing phase; 13.73% (±2.05) for terminal double support of left gait cycle.

As can be seen in the table, the convenient speed of walking for all non-amputee participants, apart from two (one with less than 1 and another with 1.5 m/s speed) was a little more than 1m/s. The step width was highly variable, particularly due to the catwalk pattern (negative width stepping) of three participants (number 9, 13 and 14). Strides and steps length, strides' time, stance and swing time had low variability among the non-amputee participants (CV<10-15% (Standing and Maulder, 2017; Thomas et al., 2018; Me et al., 1998)).

The calculated SI for the spatio-temporal variables of non-amputee participants is shown in Table 4.3. As is seen in this table, the step width had the highest level of SI (more than 10) among the participants. Step length and double support time for only three participants had SI values more than 10. The average SI of variables (except the step width) in the group suggested a reasonable level of symmetry between the right and left side (SI <10%).

Table 4.3 Symmetry Index of average spatio-temporal variables of non-amputee participants during self-selected speed level walking without insoles

	SI (%)						
Non-Amputee Participants	Step length	Step width	Stride Length	Stance time	Swing time	Step DS	Stride Time
1	**14.09**	5.81	2.88	2.81	4.49	2.38	7.21
2	1.61	**12.68**	1.54	0.99	1.63	7.9	0.95
3	0.74	**15.62**	0.36	3.21	5.48	11.1	0.68
4	**11.47**	**67.30**	5.84	3.44	6.37	8.26	3.43
5	5.53	**20.82**	5.53	0.89	1.8	6.18	3.22
6	5.18	**16.79**	4.05	0.95	1.93	4.16	1.15
7	**14.75**	2.12	8.38	4.83	7.94	6.65	5.52
8	2.27	**10.95**	1.76	5.06	8.38	5.67	0.88
9	4.32	**59.29**	1.11	3.26	5.39	**11.74**	1.12
10	1.58	**46.82**	0.52	1.67	2.92	**18.85**	0.49
11	0.81	**32.04**	2.88	0.81	1.3	14.3	1.14
12	0.12	2.84	1.39	0.74	1.39	6.84	0.14
13	0.28	**48.56**	2.29	2.01	3.58	1.27	1.25
14	5.19	**134.81**	0.74	1.44	2.37	3.58	1.91
Mean	4.85	**34.03**	2.81	2.29	3.93	7.78	2.08

4.3.1.2 Amputees

- **Spatio-temporal variables**

The averages of three trials of the spatio-temporal variables for 10 amputees during self-selected speed level walking without insoles are presented in Table 4.5. The amputee group's average of self-selected walking speed was 0.76 m/s (±0.15 m/s). The average and standard deviation of spatial variables in this group are as follows: 0.16 m (±.04) for IL step width; 0.53 m (±.03) for length of IL step; 0.17 m (±.03) for PL step width; 0.56 m (±.05) for length of PL step; 1.1 m (±.08) for IL's stride length; 1.1 (±.06) for PL stride length. The average and standard deviation of the temporal variables in the group are as follows: 1.47 s (±.23) for duration of IL's gait cycle; 1.45 s (±.21) for duration of PL gait cycle; 70.77% (±3.6) for IL's stance phase; 29.23% (±3.6) for IL's swing phase; 15.82% (±1.2) for terminal double support of IL's gait cycle; 62.34% (±2.7) for PL stance phase; 37.66% (±2.7) for PL swing phase; 17,14% (±2.1) for terminal double support of PL gait cycle. Amputee numbers 8, 6 and 4 had the lowest speed of walking (0.45, 0.61 and 0.65 m/s, respectively), while amputee numbers 10 and 1 walked with a speed close to that of the non-amputee participants. No step width was less than 10 cm, and this was larger for PL steps in the majority of participants (except for three participants who had same step length for both sides). The average step length of the IL was smaller than for PL for five amputees (three had the same values and two had smaller step lengths in the PL). The PL had a shorter stance than the IL (62.34% vs 70.77%) and a contrarily longer swing (37.66% vs 29.23%) and double support (17.14% vs 15.82%) phases.

Table 4.4 Spatio-temporal variables of non-amputee participants during self-selected speed level walking without insoles

Non-Amputee	V (m/s)	R step		L step		R Stride		L stride		R Stance (%)	R Swing (%)	R step DS (%)	L Stance (%)	L Swing (%)	L step DS (%)
		W (m)	Le (m)	W (m)	Le (m)	Le (m)	T (s)	Le (m)	T (s)						
1	1.07	0.08	0.71	0.075	0.61	1.32	1.19	1.36	1.28	62.37	37.63	14.01	60.64	39.36	14.34
2	1.08	0.10	0.64	0.11	0.63	1.27	1.16	1.29	1.17	62.6	37.4	13.9	61.98	38.02	12.84
3	1.03	0.13	0.63	0.15	0.64	1.27	1.24	1.26	1.23	62.02	37.98	12.15	64.05	35.95	13.58
4	1.08	0.05	0.68	0.09	0.61	1.29	1.19	1.37	1.24	66.05	33.95	15.11	63.82	36.18	16.41
5	0.87	0.13	0.59	0.16	0.58	1.17	1.36	1.24	1.4	66.59	33.41	18.32	67.18	32.82	17.22
6	1.01	0.13	0.62	0.15	0.59	1.21	1.21	1.25	1.2	67.21	32.79	16.94	66.57	33.43	16.25
7	1.5	0.11	0.78	0.11	0.67	1.46	0.98	1.58	1.04	63.67	36.33	13.97	60.67	39.33	13.07
8	1.2	0.07	0.68	0.06	0.67	1.32	1.13	1.35	1.12	60.77	39.23	12.92	63.93	36.07	12.2
9	1.12	0.02©	0.69	0.01©	0.66	1.35	1.18	1.34	1.2	63.3	36.7	13.3	61.27	38.73	11.83
10	1.11	0.10	0.67	0.06	0.66	1.32	1.19	1.33	1.2	64.15	35.85	12.44	63.08	36.92	15.02
11	1.2	0.05	0.67	0.07	0.66	1.33	1.09	1.37	1.1	61.32	38.68	12.73	61.82	38.18	11.03
12	1.06	0.06	0.67	0.06	0.67	1.3	1.21	1.27	1.21	65.45	34.55	11.69	64.97	35.03	10.92
13	1.06	0.09	0.71	0.05	0.70	1.38	1.34	1.41	1.32	64.69	35.31	14.27	63.41	36.59	14.45
14	1.03	0.01©	0.75	0.03©	0.71	1.47	1.43	1.48	1.45	61.84	38.16	12.54	62.73	37.27	12.99
Mean	**1.10**	**0.09**	**0.68**	**0.10**	**0.65**	**1.32**	**1.21**	**1.35**	**1.23**	**63.72**	**36.28**	**13.88**	**63.29**	**36.71**	**13.73**
(SD)	**(±.14)**	**(±.04)**	**(±.05)**	**(±.05)**	**(±.04)**	**(±.07)**	**(±.10)**	**(±.09)**	**(±.09)**	**(±2.05)**	**(±2.05)**	**(±1.89)**	**(±2.08)**	**(±2.08)**	**(±2.05)**
CV (%)	**13**	**42**	**7**	**49**	**6**	**5**	**8**	**7**	**8**	**3**	**6**	**14**	**3**	**6**	**15**

Note: ©: cat walking pattern, V: walking velocity, R: right limb, L: left limb, W: width, Le: length, T: Time, DS: double support

Table 4.5 Spatio-temporal variables of amputee participants during self-selected speed level walking without insoles

Amputee Participant	V (m/s)	IL step		PL step		IL Stride		PL stride		IL Stance (%)	IL Swing (%)	IL step DS (%)	PL Stance (%)	PL Swing (%)	PL step DS (%)
		W (m)	Le (m)	W (m)	Le (m)	Le (m)	T (s)	Le (m)	T (s)						
1	0.98	0.10	0.57	0.14	0.57	1.17	1.26	1.14	1.23	69.23	30.77	14.93	59.91	40.09	16.22
2	0.7	0.11	0.53	0.15	0.52	1.105	1.47	1.09	1.46	68.23	31.77	15.60	63.9	36.1	16.28
3	0.82	0.20	0.53	0.21	0.64	1.14	1.43	1.14	1.43	67.3	32.7	13.76	61.13	38.87	14.8
4	0.65	0.15	0.50	0.17	0.60	1.07	1.65	1.10	1.58	69.28	30.72	14.23	62.45	37.55	15.76
5	0.74	0.21	0.51	0.21	0.59	1.10	1.49	1.10	1.49	71.07	28.93	16.6	57	43	16.01
6	0.61	0.14	0.49	0.13	0.49	0.92	1.54	0.97	1.6	78.87	21.13	16.26	63.16	36.84	21.13
7	0.76	0.18	0.55	0.15	0.58	1.13	1.44	1.12	1.43	69.84	30.16	17.2	64.96	35.04	17.3
8	0.45	0.16	0.56	0.19	0.49	1.04	2	1.02	1.9	74.34	25.66	16.35	64.7	35.3	20.17
9	0.83	0.15	0.50	0.17	0.50	1.01	1.19	1.01	1.19	69.92	30.08	16.33	64.89	35.11	18.25
10	1.1	0.15	0.60	0.13	0.65	1.3	1.18	1.26	1.15	69.62	30.38	16.91	61.34	38.66	15.45
Mean	**0.76**	**0.16**	**0.53**	**0.17**	**0.56**	**1.10**	**1.47**	**1.10**	**1.45**	**70.77**	**29.23**	**15.82**	**62.34**	**37.66**	**17.14**
(SD)	**(±.15)**	**(±.04)**	**(±.03)**	**(±.03)**	**(±.05)**	**(±.08)**	**(±.23)**	**(±.06)**	**(±.21)**	**(±3.6)**	**(±3.6)**	**(±1.2)**	**(±2.7)**	**(±2.7)**	**(±2.1)**
CV (%)	**20**	**24**	**5**	**18**	**10**	**7**	**16**	**6**	**15**	**5**	**12**	**7**	**4**	**7**	**12**

Note: V: walking velocity, IL: intact limb, PL: prosthetic limb, W: width, Le: length, T: Time, DS: double support

The calculated SI for the spatio-temporal variables of amputees is shown in Table 4.6. Being the same as the non-amputee group, but with a better SI, the step width had a lower level of symmetry between the IL and PL. As was expected after observing the differences between the IL and PL's stance and the swing duration, the average SI was higher for these variables too. The calculated SI for double support had larger amount for amputees number 6, 7 and 8 which shows lower level of symmetry.

Table 4.6 Symmetry Index of spatio-temporal variables of amputee participants during self-selected speed level walking without insoles

	SI (%)						
Amputee Participants	Step length	Step width	Stride Length	Stance time	Swing time	Step DS	Stride time
1	0.00	33.33	2.60	14.43	26.31	8.28	2.41
2	1.90	30.77	1.37	6.55	12.76	4.27	0.68
3	18.80	4.88	0.00	9.61	17.24	7.28	0.00
4	18.18	12.50	2.76	10.37	20.01	10.20	4.33
5	14.55	0.00	0.00	21.97	39.12	3.62	0.00
6	0.00	7.41	5.29	22.12	54.20	26.05	3.82
7	5.31	18.18	0.89	7.24	14.97	0.58	0.70
8	13.33	17.14	1.94	13.87	31.63	20.92	5.13
9	0.00	12.50	0.00	7.46	15.43	11.10	0.00
10	8.00	14.29	3.13	12.65	23.99	9.02	2.58
Mean	**8.01**	**15.10**	**1.80**	**12.63**	**25.57**	**10.13**	**1.96**

- **Self-report level of function**

The mobility part of the prosthetic evaluation questionnaire (PEQ-M) and Activities-specific Balance Confidence (ABC) scale in the survey presented in Chapter 3 (respectively, questions 64-76 and 90-105, Appendix A) was utilized to evaluate the level of functionality of the amputee participants in biomechanical tests. The self-reported scores of 10 amputee participants in the biomechanical study given to the related questions and their total scores are presented in Table 4.7 and Table 4.8.

The following categories were considered for PEQ-M score assessment: 0-<5 as weaker scores, 5 for a neutral score and >5-10 for better scores. The average PEQ-M score was 7.03 (±1.5), which places it in the good level of mobility category.

The lowest scores were for question number 71 (walking on a slippery surface, with score 5.2±3), questions number 69 and 68 (walking down/up a steep hill, with scores respectively 5.3±3.1 and 5.9±2.3), and highest scores were given to question number 64 (walking in general, with score 9±1.41), question number 65 (walking in a closed space, score 9±1.8) and question number 76 (safely taking a shower, score 8.9±1.6). The average score of seven amputee participants placed in the category of better scores (6-10), two in the neutral-better category (scores between 5 and 6) and one amputee showed weak mobility scores (amputee number 8, with average scores less than 5).

For assessment by ABC scale, the scores of >80, scores 50-80 and scores <50 indicate high level, moderate level and low levels of functioning, respectively (Powell and Myers, 1995). The average score of the group was 70.5 (±13), which shows a moderate level of functioning and balance confidence. Very similar to the PEQ-M results, the lowest scores were for questions related to walking on an icy pavement (Q105, score 3.7±3), stepping onto/off an escalator without holding the rail (Q103, score 6.5±3.7) and walking up/down a ramp (Q100, score 6.5±2.1).

Table 4.7 The scores of amputee participants for PEQ-M questions (0 is the worst score versus the score 10 which represents the best score given to the ability of the person to perform mentioned activities in PEQ-M questionnaire)

Participants Abstract of Questions	1	2	3	4	5	6	7	8	9	10	**Mean (±SD)**
Walk (Q64)	10	8	10	10	10	8	10	6	8	10	**9 (1.41)**
Walk in Close Space (Q65)	10	8	10	10	10	10	10	5	7	10	**9 (1.8)**
Walk Up Stairs (Q66)	7	6	6	6	9	6	5	4	6	10	**6.5 (1.8)**
Walk Down Stairs (Q67)	8	5	7	4	9	5	6	3	6	10	**6.3 (2.2)**
Walk Up a Steep Hill (Q68)	6	5	5	4	8	7	7	2	5	10	**5.9 (2.3)**
Walk Down a Steep Hill (Q69)	3	4	10	4	4	7	3	1	7	10	**5.3 (3.1)**
Walk On Pavements & Streets (Q70)	8	7	8	6	8	9	9	5	8	10	**7.8 (1.5)**
Walk On Slippery Surface (Q71)	5	4	8	4	3	4	9	0	5	10	**5.2 (3)**
Get in & Out a Car (Q72)	6	7	5	5	6	5	8	7	6	10	**6.5 (1.6)**
Sit Down & Get up from Chair (Q73)	8	6	10	6	10	8	8	6	7	10	**7.9 (1.7)**
Sit Down & Get up from Low/Soft Chair (Q74)	6	5	7	4	6	7	5	4	7	10	**6.1 (1.8)**
Sit Down & Get up from Toilet (Q75)	7	5	9	6	6	7	7	5	8	10	**7 (1.5)**
Shower/Bathe Safely (Q76)	10	6	10	6	10	10	9	9	9	10	**8.9 (1.6)**
Mean total score	**7.23**	**5.85**	**8.08**	**5.77**	**7.62**	**7.15**	**7.38**	**4.38**	**6.85**	**10**	**7.03 (1.5)**

4.3.2 Homogeneity of groups

Levene’s Test for Equality of Variances indicated the two groups had about the same amounts of variability for the selected variables ($p>0.05$) during walking without insoles. Figure 4.7 and Figure 4.8 show box-plots of spatio-temporal variables for both groups. It shows the variability in each group was low. As was expected, amputee number 10 (with values near to non-amputees) and number 8 (with the lowest speed and level of functionality) in addition to non-amputee number 7 (who had the highest speed) and number 5 (with the lowest speed) had several outlier values for some variables. As can be seen in Figure 4.7, the amputees number 6 and 8 had the longest IL stance and shortest swing time.

Table 4.8 The scores of amputee participants to ABC scale questions (0 indicated no confidence and 10 completely confident to perform the activity)

Participants / Abstract of Questions	1	2	3	4	5	6	7	8	9	10	**Mean (±SD)**
Walking (Q90)	9	8	10	8	9	9	8	6	9	10	**8.6 (1.2)**
Moving Up/Down Stairs (Q91)	6	5	10	5	5	7	8	4	8	10	**6.8 (2.15)**
Bending & Pickup (Q92)	10	5	10	10	9	7	9	5	9	10	**8.4 (2)**
Reaching an Object at Eyes-Level (Q93)	10	7	10	6	9	10	9	7	9	10	**8.7 (1.5)**
Reaching an Object at Above-Head (Q94)	7	6	10	5	9	8	9	5	9	10	**7.8 (1.9)**
Standing on Chair to Reach (Q95)	6	9	10	5	ND	5	8	4	8	ND	**6.9 (3.5)**
Sweeping the Floor (Q96)	10	7	10	6	ND	7	9	7	8	10	**8.2 (3)**
Walking Outside (Car-Parking) (Q97)	10	6	10	5	9	8	8	5	9	10	**8 (2)**
Getting into/out Car (Q98)	10	7	10	8	9	6	8	7	9	10	**8.4 (1.4)**
Walking Across Car-parking (Q99)	10	5	10	6	9	9	9	5	8	10	**8.1 (2)**
Walking Up/Down Ramp (Q100)	7	5	9	6	6	8	6	3	5	10	**6.5 (2.1)**
Walking in Crowd (Q101)	8	7	8	6	6	7	7	5	6	10	**7 (1.4)**
Bumping into by People (walk in town) (Q102)	8	7	10	6	5	7	7	5	5	10	**7 (1.9)**
Stepping onto/off Escalator (holding railing) (Q103)	9	10	10	8	9	ND	9	5	6	8	**8.2 (3.1)**
Stepping onto/off Escalator (without holding railing) (Q104)	8	10		4	ND	ND		4	5	8	**6.5 (3.7)**
Walking in Icy Pavement (Q105)	4	4	6	2	2	ND	2	0	3	10	**3.7 (3)**
Total score (sum of score/1.6)	**82.5**	**67.5**	**89.4**	***60***	***60***	***61.25***	**72.5**	**48.12**	**72.5**	**91.2**	**70.5 (13)**
Level of function according to ABC scale categories	**High**	**Mod.**	**High**	**Mod.**	**Mod.**	**Mod.**	**Mod.**	**Low**	**Mod.**	**High**	**Mod.**

Note: ND= never do, Mod.: Moderate

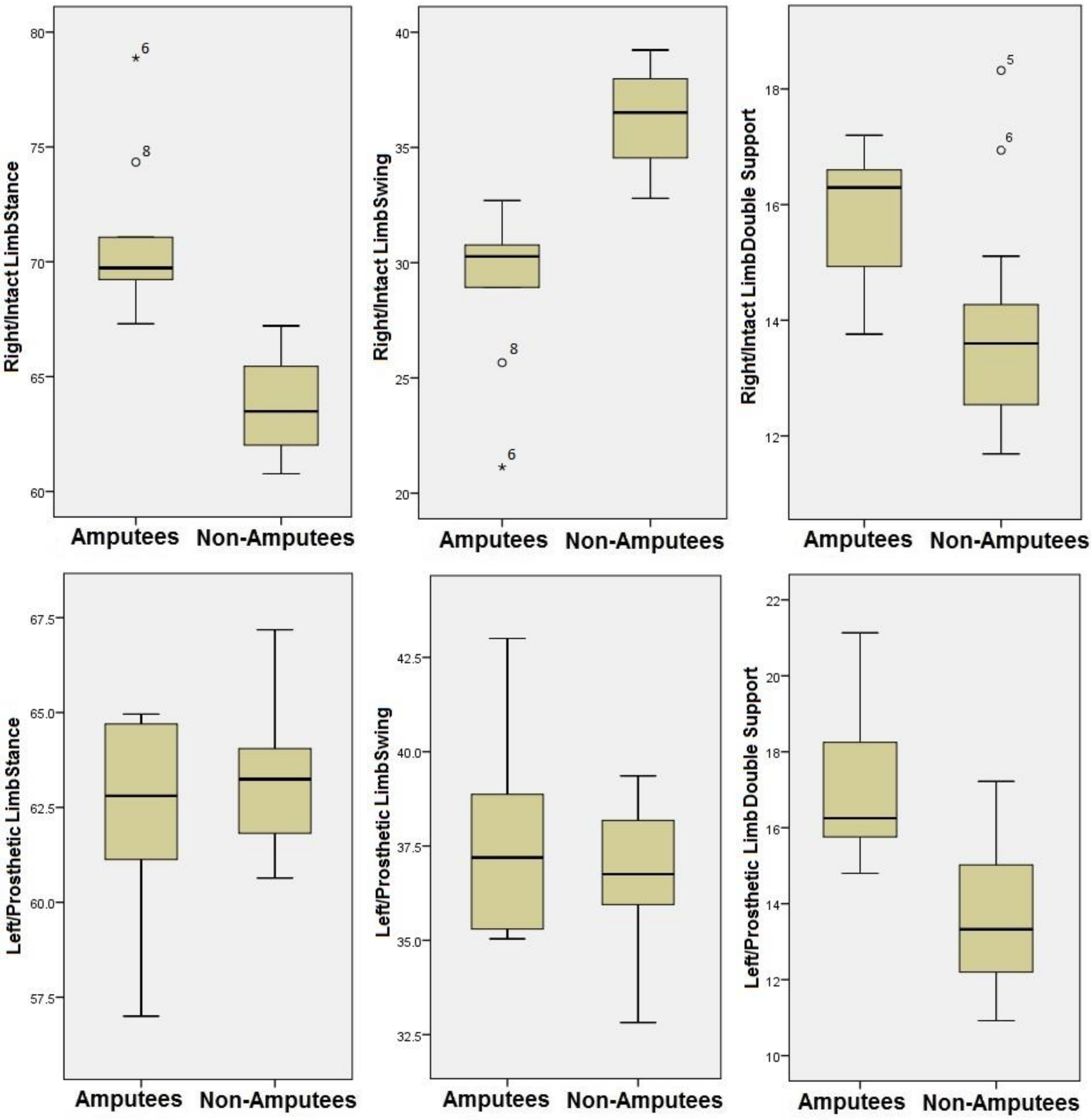


Figure 4.7 The box-plot of stance, swing and double-support durations.

The non-amputee participant number 5, with a speed of 0.87 m/s, was obese and had the highest BMI among non-amputee and amputee participants (37.52 kg/m^2). It might be the reason for his lower speed of walking and shorter steps and stride. It was not surprising to observe a longer double support time for both sides of his step due to a lower speed. But these had not affected the symmetry of his walking. The fastest participant (number 7) had a normal BMI (23.9 kg/m^2), with similarities in other variables with the group except the variables which impacted on the speed (i.e., shorter stride time and longer stride length). Non-amputee number 14 had the longest stride time. This may be a personal difference between him and the others.

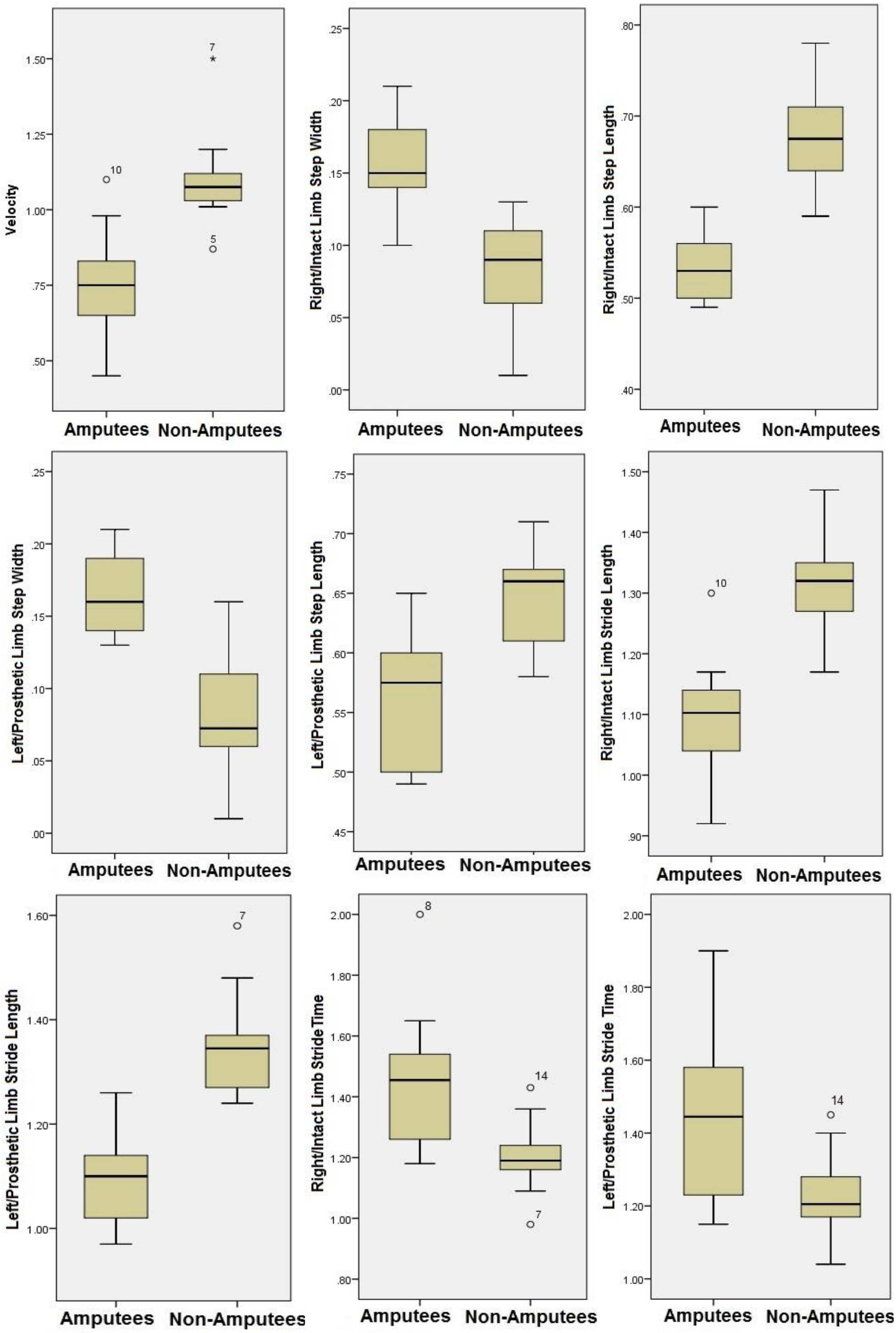


Figure 4.8 Box-plot illustration of first nine spatio-tempral variables in Table 4.5.

The high level of step width variability might be due to the assessment of only one step in a relatively short walking path for each limb instead of several strides in a long walking distance. Hence, in spite of the obvious difference between the amputees (with wider steps) and non-amputees, the step width is not considered a suitable variable to assess the level of functionality and the effect of insoles in this study.

4.3.3 Effect of insoles on walking

4.3.3.1 Spatio-temporal variables of walking

An independent sample t-test was conducted to compare the amputees' and non-amputees' spatio-temporal variables. All the listed variables except stance and swing phase percentages for the PL of the amputee group were significantly different from the non-amputees during walking without insoles (Table 4.9). As can be seen the lower velocity of amputees in the without insoles session was associated with longer stride time and shorter stride and step lengths. In addition, they had wider steps and spent a longer time on their IL, while their PL stance phase was the same as non-amputees with both limbs.

Table 4.10 and Table 4.11 show the spatio-temporal variables of the two groups during walking with insoles. The symmetry index of variables did not change significantly after insoles use. Levene's Test for Equality of Variances revealed that the two groups had about the same amount of variability during walking with insoles ($p>0.05$), except for the R/IL stance ($p=0.049$) and R/IL swing ($p=0.046$). In fact, the variability of these variables increased for non-amputee participants. Table 4.12 shows the results of comparing two groups' insoles session's spatio-temporal variables. The results are similar to the without insoles session; however, the stance/swing phases of non-amputees became significantly longer ($p=0.001$)/shorter ($p=0.003$) than the amputees' PL's stance/swing phases. No significant effect of insoles was observed for most variables ($p>0.05$). It increased the length of stance of the non-amputees' limbs and decreased the stance duration of PL of the amputees ($p=0.002$), which led to an increase in the swing phase of the PL ($p=0.044$).

4.3.3.2 Kinematics

4.3.3.2.1 COM and COP displacements

Table 4.13 shows the mean amplitude of mediolateral COP displacement during each foot stance phase, in addition to the mediolateral and vertical displacement of the COM during one stride of IL/R and PL/L of amputees and non-amputees during walking without (S1) and with (S2) insoles. As is seen, the COM's mediolateral displacement is largest for the IL of amputees and the vertical displacement is smallest for their PL. In addition, the COP mediolateral displacement is larger for both feet of the amputees.

Table 4.9 Comparison of Spatio temporal variables between amputee and non-amputee groups during without insoles walking

Participants	V (m/s)	R/IL step		L/PL step		R/IL Stride		L/PL stride		R/IL Stance (%)	R/IL Swing (%)	R/IL DS (%)	L/PL Stance (%)	L/PL Swing (%)	L/PL DS (%)
		W (m)	Le (m)	W (m)	Le (m)	Le (m)	T (s)	Le (m)	T (s)						
Non-Amputees	**1.10[1]**	**0.09[1]**	**0.68[1]**	**0.10[1]**	**0.65[1]**	**1.32[1]**	**1.21[2]**	**1.35[1]**	**1.23[3]**	**63.72[1]**	**36.28[1]**	**13.88[4]**	**63.29**	**36.71**	**13.73[5]**
	(±.14)	(±.04)	(±.05)	(±.05)	(±0.04)	(±.07)	(±.10)	(±.09)	(±.09)	(±2.05)	(±2.05)	(±1.89)	(±2.08)	(±2.08)	(±2.05)
Amputees	**0.76**	**0.16[1]**	**0.53[1]**	**0.17[1]**	**0.56[1]**	**1.10[1]**	**1.47[2]**	**1.10[1]**	**1.45[3]**	**70.77[1]**	**29.23[1]**	**15.82[4]**	**62.34**	**37.66**	**17.14[5]**
	(±.15)	(±.04)	(±.03)	(±.03)	(±.05)	(±.08)	(±.23)	(±.06)	(±.21)	(±3.6)	(±3.6)	(±1.2)	(±2.7)	(±2.7)	(±2.1)

Note: V: walking velocity, R/IL: right limb of non-amputees/Intact limb of amputees, L/PL: left limb of non-amputees/Prosthetic limb of amputees, W: width, Le: length, T: Time, DS: double support.

Significant differences in comparing of amputees and non-amputees: [1] p<0.001, [2] p=0.002, [3] p=0.004, [4] p=0.008, [5] p=0.001

Table 4.10 Spatio-temporal variables of non-amputee participants during self-selected speed level walking with insoles

Non-Amputee	V (m/s)	R step		L step		R Stride		L stride		R Stance (%)	R Swing (%)	R step DS (%)	L Stance (%)	L Swing (%)	L step DS (%)
		W (m)	Le (m)	W (m)	Le (m)	Le (m)	T (s)	Le (m)	T (s)						
1	1.04	0.08	0.75	0.08	0.57	1.31	1.22	1.38	1.30	64.79	35.21	14.08	62.34	37.66	15.86
2	1.17	0.06	0.67	0.10	0.64	1.31	1.12	1.33	1.13	63.68	36.32	13.43	62.46	37.54	14.31
3	1.01	0.13	0.64	0.15	0.61	1.25	1.23	1.29	1.24	65.62	34.38	15.84	65.93	34.07	16.15
4	0.96	0.07	0.66	0.13	0.57	1.23	1.29	1.30	1.32	65.45	34.55	15.68	66.06	33.94	17.51
5	1.08	0.13	0.68	0.12	0.57	1.24	1.15	1.34	1.19	64.65	35.35	15.73	66.51	33.49	17.10
6	1.09	0.14	0.67	0.18	0.61	1.28	1.18	1.35	1.19	65.64	34.36	16.00	66.52	33.48	16.75
7	1.56	0.11	0.81	0.10	0.74	1.54	1.00	1.61	1.03	62.75	37.00	12.78	63.25	39.92	13.09
8	1.22	0.05	0.72	0.04	0.69	1.41	1.17	1.40	1.17	63.97	36.03	14.30	65.15	34.85	15.08
9	1.11	0.04[©]	0.66	0.03[©]	0.67	1.35	1.20	1.33	1.19	63.62	36.38	13.67	63.94	36.06	14.20
10	1.19	0.13	0.67	0.07	0.66	1.33	1.14	1.36	1.14	65.11	34.89	14.15	63.78	36.22	14.81
11	1.15	0.06	0.67	0.06	0.67	1.34	1.18	1.36	1.18	60.84	39.16	11.97	62.63	37.37	11.25
12	1.08	0.07	0.63	0.10	0.68	1.33	1.23	1.31	1.22	65.97	34.03	16.47	66.12	33.88	15.89
13	1.15	0.06	0.70	0.05	0.77	1.50	1.31	1.47	1.26	63.61	36.39	14.88	64.20	35.80	14.72
14	1.00	0.03[©]	0.75	0.02[©]	0.68	1.43	1.44	1.47	1.48	62.93	37.07	13.34	63.45	36.55	14.12
Mean	**1.13**	**0.08**	**0.69**	**0.09**	**0.65**	**1.35**	**1.20**	**1.38**	**1.22**	**64.19**	**35.79**	**14.45**	**64.45**	**35.77**	**15.06**
(SD)	0.15	0.04	0.05	0.05	0.06	0.09	0.10	0.09	0.10	1.42	1.40	1.35	1.56	1.93	1.67
CV (%)	**13**	**44**	**7**	**54**	**10**	**7**	**9**	**6**	**9**	**2.21**	**3.91**	**9.37**	**2.42**	**5.40**	**11.09**

Note: [©]: cat walking pattern, V: walking velocity, R: right limb, L: left limb, W: width, Le: length, T: Time, DS: double support

Table 4.11 Spatio-temporal variables of amputee participants during self-selected speed level walking with insoles

Amputee Participant	V (m/s)	IL step W (m)	IL step Le (m)	PL step W (m)	PL step Le (m)	IL Stride Le (m)	IL Stride T (s)	PL stride Le (m)	PL stride T (s)	IL Stance (%)	IL Swing (%)	IL step DS (%)	PL Stance (%)	PL Swing (%)	PL step DS (%)
1	0.88	0.11	0.59	0.14	0.55	1.15	1.30	1.13	1.29	69.23	30.77	15.83	60.28	39.72	15.47
2	0.65	0.11	0.46	0.16	0.50	0.96	1.45	0.96	1.46	68.44	31.56	17.01	62.18	37.82	14.61
3	0.86	0.20	0.56	0.21	0.66	1.20	1.41	1.22	1.40	67.97	32.03	14.14	60.20	39.80	14.73
4	0.66	0.17	0.49	0.16	0.59	1.08	1.64	1.09	1.61	70.13	29.87	16.00	60.26	39.74	15.70
5	0.64	0.25	0.48	0.25	0.54	1.00	1.50	1.25	1.52	75.70	24.30	17.44	58.90	41.10	16.24
6	0.63	0.12	0.51	0.11	0.48	0.92	1.58	0.98	1.59	78.30	21.70	15.65	57.06	42.94	19.26
7	0.72	0.12	0.54	0.17	0.55	1.08	1.49	1.12	1.47	70.15	29.85	17.39	64.58	35.42	16.45
8	0.48	0.17	0.51	0.22	0.52	1.03	2.06	0.97	2.04	71.07	28.93	15.03	65.85	34.15	21.77
9	1.00	0.15	0.56	0.17	0.55	1.11	1.14	1.14	1.12	68.95	31.05	12.21	58.37	41.63	15.04
10	0.98	0.19	0.61	0.11	0.67	1.28	1.32	1.28	1.33	69.61	30.39	16.03	62.28	37.72	15.21
Mean	**0.75**	**0.16**	**0.53**	**0.17**	**0.56**	**1.08**	**1.49**	**1.11**	**1.48**	**70.96**	**29.05**	**15.67**	**61.00**	**39.00**	**16.45**
(SD)	0.17	0.05	0.05	0.05	0.06	0.11	0.25	0.11	0.24	3.36	3.36	1.59	2.75	2.75	2.30
CV (%)	**23**	**29**	**9**	**28**	**11**	**10**	**17**	**10**	**16**	**4.74**	**11.58**	**10.17**	**4.51**	**7.05**	**13.99**

Note: V: walking velocity, IL: intact limb, PL: prosthetic limb, W: width, Le: length, T: Time, DS: double support

Table 4.12 Comparison of Spatio temporal variables between amputee and non-amputee groups during insoles walking

Participants	V (m/s)	R/IL step W (m)	R/IL step Le (m)	L/PL step W (m)	L/PL step Le (m)	R/IL Stride Le (m)	R/IL Stride T (s)	L/PL stride Le (m)	L/PL stride T (s)	R/IL Stance (%)	R/IL Swing (%)	R/IL DS (%)	L/PL Stance (%)	L/PL Swing (%)	L/PL DS (%)
Non-Amputees	**1.13**[1] (±.15)	**0.08**[1] (±.04)	**0.69**[1] (±.05)	**0.09**[1] (±.05)	**0.65**[2] (±0.06)	**1.35**[1] (±.09)	**1.20**[3] (±.10)	**1.38**[1] (±.09)	**1.22**[3] (±.10)	**64.19**[1] (±1.42)	**35.79**[1] (±1.40)	**14.45** (±1.35)	**64.45**[3] (±1.56)	**35.77**[4] (±1.93)	**15.06** (±1.67)
Amputees	**0.75**[1] (±.17)	**0.16**[1] (±.05)	**0.53**[1] (±.05)	**0.17**[1] (±.05)	**0.56**[2] (±.06)	**1.08**[1] (±.11)	**1.49**[3] (±.25)	**1.11**[1] (±.11)	**1.48**[3] (±.24)	**70.96**[1] (±3.36)	**29.05**[1] (±3.36)	**15.67** (±1.59)	**61.00**[3] (±2.75)	**39.00**[4] (±2.75)	**16.45** (±2.3)

Note: V: walking velocity, R/IL: right limb of non-amputees/Intact limb of amputees, L/PL: left limb of non-amputees/Prosthetic limb of amputees, W: width, Le: length, T: Time, DS: double support.

Significant differences in comparing of amputees and non-amputees: [1] $p<0.001$, [2] $p=0.002$, [3] $p=0.001$, [4] $p=0.003$

Table 4.13 Amplitude of COM and COP displacements

	Limb/Test condition	Amplitude of displacements (m)						
		COM Vertical			COM Mediolateral			Mediolateral COP
		stance	swing	stride	stance	swing	stride	stance
Amputees (10)	IL-S1	**0.038** (±0.005)	**0.016** (±0.004)	**0.039** (±0.005)	**0.066** (±0.018)	**0.022** (±0.006)	**0.079** (±0.021)	**0.056** (±0.018)
	IL-S2	**0.037** (±0.005)	**0.017** (±0.008)	**0.039** (±0.006)	**0.067** (±0.019)	**0.02** (±0.008)	**0.08** (±0.024)	**0.056** (±0.015)
	PL-S1	**0.027** (±0.004)	**0.029** (±0.018)	**0.038** (±0.005)	**0.059** (±0.018)	**0.021** (±0.008)	**0.076** (±0.022)	**0.04** (±0.013)
	PL-S2	**0.026** (±0.005)	**0.03** (±0.006)	**0.038** (±0.007)	**0.061** (±0.018)	**0.024** (±0.007)	**0.079** (±0.018)	**0.04** (±0.016)
Non-Amputees (14)	RL-S1	**0.034** (±0.006)	**0.029** (±0.004)	**0.036** (±0.005)	**0.039** (±0.017)	**0.015** (±0.006)	**0.040** (±0.018)	**0.049** (±0.02)
	RL-S2	**0.036** (±0.007)	**0.032** (±0.004)	**0.039** (±0.006)	**0.038** (±0.011)	**0.014** (±0.005)	**0.038** (±0.015)	**0.046** (±0.019)
	LL-S1	**0.034** (±0.004)	**0.028** (±0.008)	**0.036** (±0.005)	**0.034** (±0.016)	**0.013** (±0.004)	**0.036** (±0.015)	**0.048** (±0.022)
	LL-S2	**0.037** (±0.005)	**0.028** (±0.008)	**0.038** (±0.005)	**0.032** (±0.011)	**0.012** (±0.003)	**0.035** (±0.012)	**0.047** (±0.018)

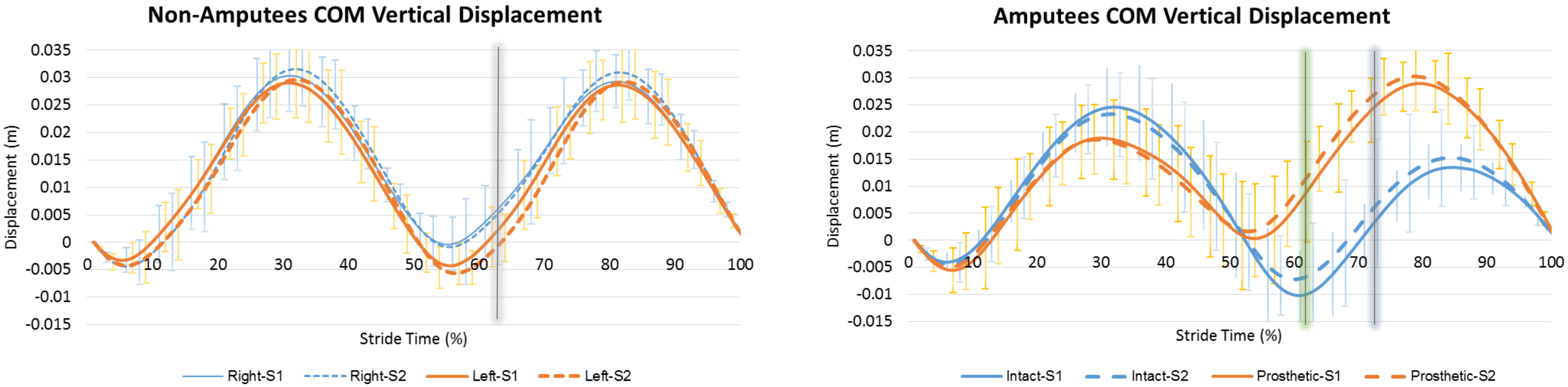
S1: without insoles, S2: with insoles, RL/IL: right limb/Intact limb, LL/PL: left limb/Prosthetic limb

Figure 4.9 shows the pattern of the COM's vertical and lateral displacements (normalised to a progression line) during one stride which depicts Table 4.13 data. The COM is in its lowest position during the initial and terminal stance (double support phase), while it is at its highest position at mid-stance and mid-swing (single support phase). Non-amputees have an almost symmetrical COM vertical displacement, as opposed to amputees. The COM height asymmetrically decreases during the swing of the IL, which is matched with a single support of PL stance phase, and vice versa - it is rising during the swing phase of the PL. In addition, the increased mediolateral displacement is observed. Figure 4.9-B displays obvious differences between amputees and non-amputees in terms of the COM mediolateral displacement. The peak of the mediolateral displacement corresponds to the peak of the COM vertical displacement at mid-stance.

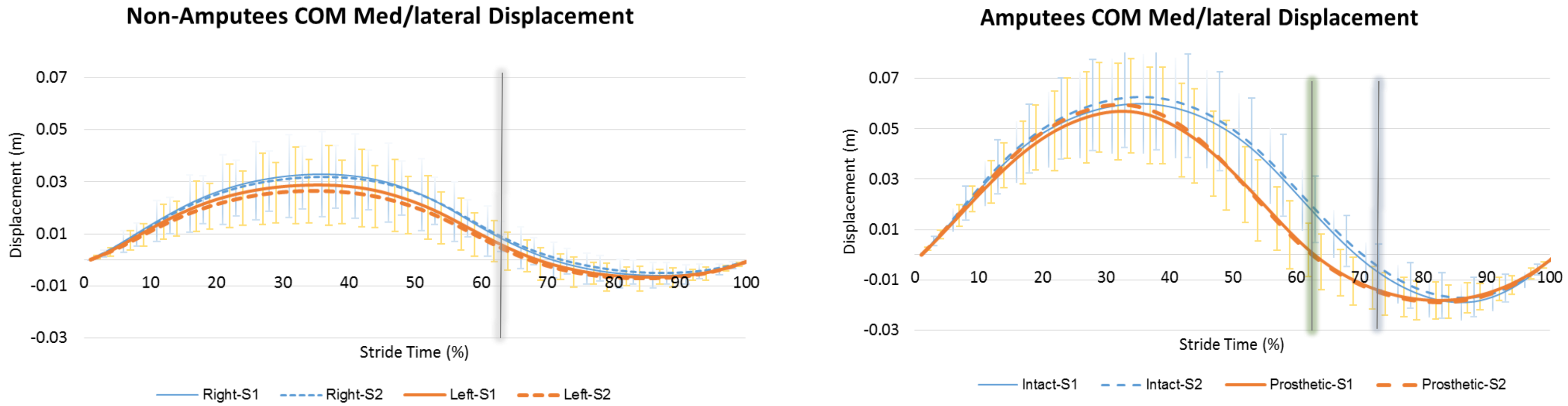
The statistical test (mixed between-within subjects ANOVA) showed a significant difference existing between limbs COP mediolateral displacement ($p=0.032$), which was due to the significantly larger displacement of amputees' IL and smaller displacement for PL.

The amplitude of the COM vertical displacement was not significantly different between each limb and insoles conditions. But, as was expected from the related graph and table, the amplitude of the COM vertical displacement during the stance of the IL and non-amputees' limbs was significantly larger than the PL's displacement ($p<0.001$). The displacement during the swing of the IL was smaller than the PL ($p<0.001$) and the non-amputees' swing ($p<0.001$). The mediolateral displacement of the COM during both limbs' strides of the amputees was larger than in the non-amputees ($p<0.001$), which corresponds to the significant differences during stance phase ($p<0.001$) and swing phase displacements ($p<0.001$) between the two groups.

The insoles use did not have any significant effect on the variables ($p>0.05$).



A



B

Figure 4.9 Average vertical (A) and mediolateral (B) displacements of COM of amputee and non-amputee groups (time normalised to 100% of gait cycle, the perpendicular lines indicate the end of stance phase) during with insoles (S1) and without insoles (S2) walking

4.3.3.2.2 Relationship between COP/COM and the lateral borders of the base of support at late mid-stance

The distance between the COG and COP points and the lateral border of the BOS were calculated by using Equation 4.2. The average (±SD) of the calculated distances for both groups and insoles' sessions are presented in Table 4.14.

Table 4.14 Distance between COM and COP with the lateral border of BOS at mid-stance

		COG-Lateral border of BOS (m)	COP- Lateral border of BOS (m)
Amputees (10)	IL-S1	**0.112** (±0.018)	**0.039** (±0.005)
	IL-S2	**0.107** (±0.021)	**0.036** (±0.01)
	PL-S1	**0.126** (±0.015)	**0.04** (±0.007)
	PL-S2	**0.131** (±0.023)	**0.043** (±0.008)
Non-Amputees (14)	RL-S1	**0.098** (±0.021)	**0.039** (±0.011)
	RL-S2	**0.102** (±0.02)	**0.043** (±0.01)
	LL-S1	**0.095** (±0.01)	**0.035** (±0.01)
	LL-S2	**0.093** (±0.01)	**0.036** (±0.008)

S1: without insoles, S2: with insoles, RL/IL: right limb/Intact limb, LL/PL: left limb/Prosthetic limb

The statistical analysis revealed that the amputees' COG is at a greater distance with the lateral border of the BOS at mid-stance. The distribution of the COG-BOS border distance was normal (Shapiro-Wilk test, P>0.05), except for the distance of the COG and the lateral border of the prosthetic BOS with insoles (p=0.02). A significant difference between the groups' COG-BOS border distances was seen (p=0.007), which was likely due to the significant differences between the distance for both limbs of the amputees in comparison with the non-amputees (p=0.001). The insoles use did not have any significant effect on the value (p>0.05).

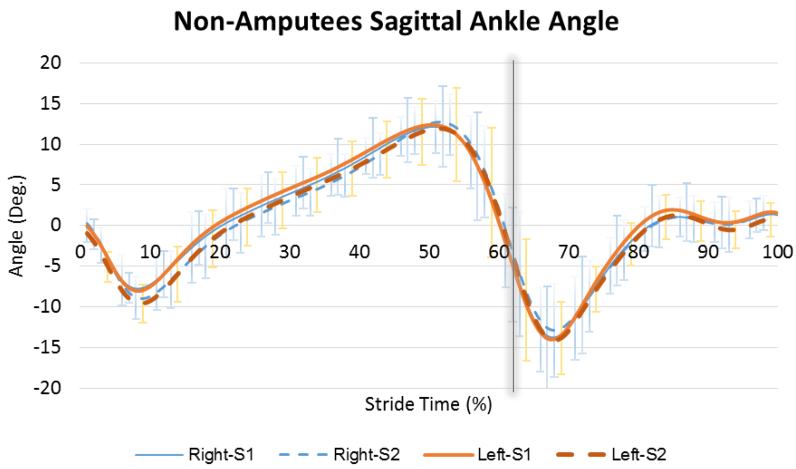
4.3.3.2.3 Ankle angles

The ankle joint range of motion for the right and left limbs in the sagittal plane during stance and swing phases might be affected by insoles use during amputees and non-amputees walking. Table 4.15 represents the range of motion of the ankle joint in the sagittal plane during one gait cycle, the range of motion during stance and swing phases, the peak of the plantar flexion at initial stance, and the peak of the dorsi-flexion at the end of stance. The patterns of the ankle joint motion during one stride of each limb are illustrated in Figure 4.10. The main motion of the ankle joint (as the articulation between tibia, fibula and talus bones) occurs in the sagittal plane in the form of plantar flexion (extension of the foot) and dorsi-flexion (flexion of the foot). The motion in the coronal plane occurs between the talus and calcaneus but is seen in the motion analysis of the ankle joint. The motions of the ankle in the coronal plane are inversion or adduction (leading to a tilt of the foot palmar surface toward the midline of the body) and eversion or abduction (results in a tilt of the foot palmar surface away from the midline of the body).

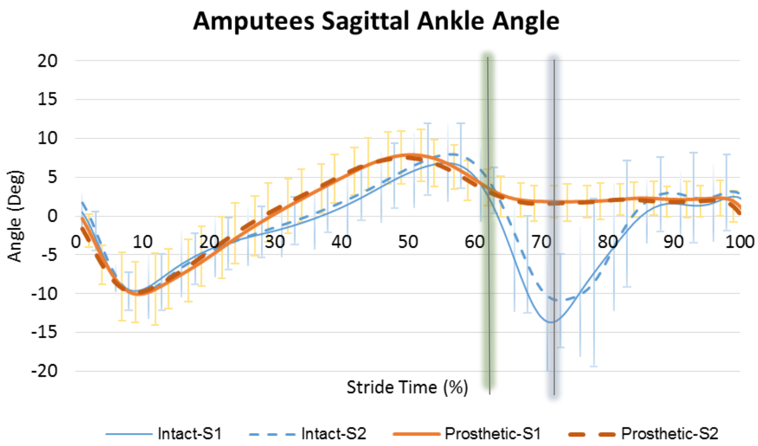
Table 4.15 Participants' ankle angle changes in the sagittal plane during one gait cycle

		Flex/Extention (Deg)					
		Total	**stance**	**swing**	**IS PL**	**TS DF**	
Amputees (10)	**IL-S1**	**26.2** (±5.8)	**24.3** (±4.6)	**20.8** (±9.6)	**10.5** (±3.2)	**7** (±5)	
	IL-S2	**26.2** (±5.6)	**23.3** (±6.3)	**21.3** (±7.9)	**10.7** (±2.7)	**8.4** (±4.2)	
	PL-S1	**18.4** (±4.1)	**18.4** (±4.1)	**3.8** (±2.5)	**9.9** (±4.4)	**8.5** (±2.2)	
	PL-S2	**18.1** (±4.4)	**18.1** (±4.4)	**4.6** (±2.7)	**8.5** (±3.9)	**9.6** (±3.6)	
Non-Amputees (14)	**RL-S1**	**27** (±5.4)	**23** (±4.1)	**16.8** (±5.3)	**8.2** (±3)	**12.5** (±3.2)	
	RL-S2	**27.45** (±5.7)	**25.6** (±4.8)	**16.6** (±5.5)	**9.4** (±2.4)	**12.9** (±3.5)	
	LL-S1	**28.3** (±6.3)	**24.2** (±3.3)	**18.2** (±5.7)	**8.2** (±5.7)	**12.9** (±4.8)	
	LL-S2	**27.9** (±4.95)	**25.65** (±3.9)	**17.5** (±5.2)	**9.9** (±2)	**12.4** (±4.8)	

S1: without insoles, S2: with insoles, IS: Initial stance, PL: plantar-flexion, TS: Terminal stance, DF: Dorsi-flexion, RL/IL: right limb/Intact limb, LL/PL: left limb/Prosthetic limb



A



B

Figure 4.10 Ankle's range motion in sagittal plane (-ve for plantar-flexion and +ve for dorsi-flexion) during with insoles (S1) and without insoles (S2) walking

As seen in Figure 4.10, the ankle of the IL of amputees and both limbs of the non-amputees follows the typical pattern of motion in the sagittal plane, as mentioned in the normal gait section (Chapter 2): it is in an almost neutral position at initial contact. Then, it plantar-flexes to bring the foot to the ground. The shank moves forward on the foot during mid-stance, then dorsi-flexion occurs. However, in Figure 4.10, it can be seen that the IL ankle of the amputees has a prolonged plantar flexion, and changes toward dorsi-flexion with delay. This remaining in plantar flexion for a longer time results in a vaulting gait, which is common among above-knee prosthesis users during their IL stance (Drevelle et al., 2014). During terminal stance, the foot goes to heel raise and the ankle gradually plantar-flexes. It reaches its maximum plantar flexion angle almost at the end of the stance and the initiation of the swing. During the swing, the ankle joint needs to dorsi-flex to prevent the toe hitting the ground (toe clearance). But its dorsi-flexion decreases to reach a neutral position for the next initial contact. Figure 4.10 shows the range of motion of the PL is limited and smaller than the IL's ROM. However, the prosthetic foot-ankle had a similar plantar flexion at initial stance and dorsi-flexion in terminal stance. As ankle-foot devices are not an active part of the PL, it is not surprising to see they have been aligned to a fixed small dorsi-flexion by prosthetists to help toe clearance during the swing phase of the PL.

There was a significant difference between the limbs' ankle range of motion in the sagittal plane ($p=0.007$), which was due to the significantly smaller prosthetic ankle-foot range of motion. The insoles use did not have a significant effect on the value ($p>0.05$).

Unsurprisingly, similar significant differences existed between the sagittal plane range of motion of the prosthetic device and the ILs in stance phase ($p=0.009$), in addition to the swing phase ($p<0.001$). There was a significant increase in the stance range for the non-amputees after using insoles ($p=0.008$) for the right and left limb ($p=0.005$). No significant difference was observed between the magnitude of plantar flexion during the initial stance of limbs in either groups or insoles sessions ($p>0.05$). But the dorsi-flexion angle in the terminal stance was significantly larger for non-amputee feet ($p=0.008$). Insoles use did not affect significantly ($p>0.05$).

4.3.3.3 Kinetics

4.3.3.3.1 Loading Rate

The force loading rate as an indicator of force impact at initial contact was extracted from the vertical force data during each limb stance. The amount of the calculated loading rate is shown in Table 4.16.

The loading rate of the PL was significantly lower than of the IL, and for the non-amputees with both limbs and for all three time-points ($p<0.05$). In addition, the insoles use for the intact side did not influence the loading rate. But the insoles effect in the form of reducing the loading rate was observed in the results of the 3rd method for the non-amputee group (p=0.014 for right and p=0.043 for left limbs).

Table 4.16 Initial stance loading rate

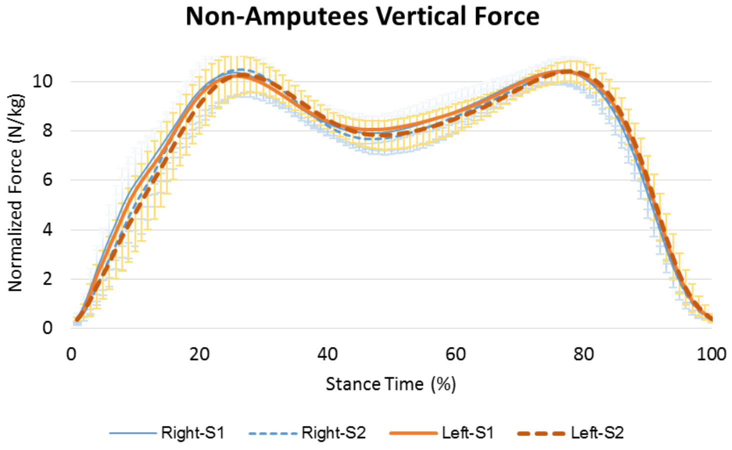
	Limb/Test condition	Loading rate (N/s.kg)		
		Time-point1	Time-point2	Time-point3
Amputees (10)	IL-S1	**72.35** (±13.04)	**90.89** (±33.52)	**76.68** (±26.62)
	IL-S2	**78.28** (±27.98)	**82.81** (±38.01)	**67.21** (±30.69)
	PL-S1	**47.34** (±15.55)	**41.8** (±27.39)	**40.89** (±14.66)
	PL-S2	**49.15** (±20.83)	**39.69** (±21.71)	**41.47** (±21.65)
Non-Amputees (14)	RL-S1	**81.37** (±22.7)	**95.74** (±49.78)	**99.54** (±48.12)
	RL-S2	**75.98** (±23.3)	**81.30** (±33.21)	**70.39** (±42.25)
	LL-S1	**74.47** (±19.45)	**92.64** (±45.23)	**80.65** (±43.97)
	LL-S2	**71.86** (±20.67)	**74.27** (±28.84)	**60.94** (±32.39)

S1: without insoles, S2: with insoles, RL/IL: right limb/Intact limb, LL/PL: left limb/Prosthetic limb

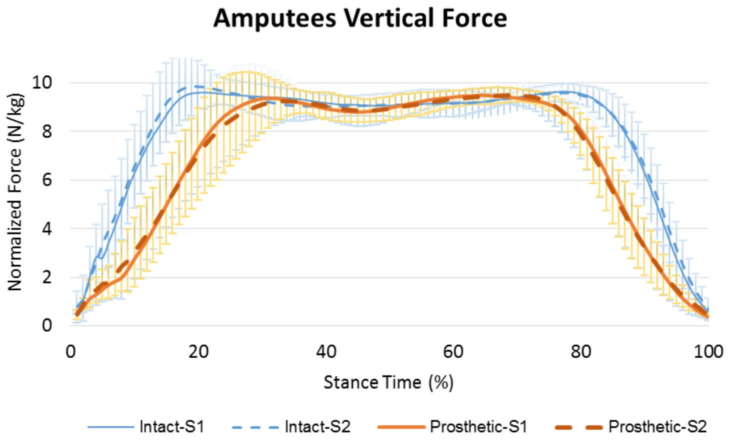
As it is apparent in the profile of the vertical force (Figure 4.11), both limbs of non-amputees and the IL of amputees have a sharper slop for their initial change after heel strike than in the PL of amputees, which corresponds with the higher loading rate results. In addition, the forces profile displays smaller peaks for both limbs of the amputees group in comparison to the non-amputees (less than 10 N/kg as the force equal to body weight). Furthermore, the force of the IL of the amputees did not have a single narrow mid-stance dip in comparison to the amputees due to vaulting on it. The maximum points and the depth of the GRF's dip are related to the speed, the ability of the limb to bear weight properly and a strong push-off (Richards, 2008). The depth was smaller for the PL of amputees, which might be due to their feeling of insecurity about the limb, besides their lower speed. Furthermore, the smaller peaks of the GRF of amputees show their weaker push-off.

4.3.3.3.2 Joint moments

The calculated internal moments at ankle, knee and hip joints in the sagittal plane as interpreters of muscle activities are of interest to evaluate the effect of insoles use in this study. Moments are normalized to the bodyweight of the participants.



A



B

Figure 4.11 Changes of vertical GRF during with insoles (S1) and without insoles (S2) walking, A: Non-Amputees, B: Amputees

Peaks of ankle moment in the sagittal plane are shown in Table 4.17, which show larger dorsi-flexor moments and smaller plantar-flexor moments for amputees in both limbs in comparison to non-amputees. Figure 4.12-a1 and -b1 also illustrate the pattern of ankle moment changes for the two groups. The overall pattern is similar for all four limbs: it has a small dorsi-flexor moment at initial stance which changes to a big plantar-flexor a moment before the terminal stance. However, the prosthetic moment remained positive (dorsi-flexor) for a longer time (more than 1/3 of the stance) and its maximum plantar-flexor moment is the smallest in the groups. In addition, there is a notable hump on the plantar-flexor moment graph of amputees' IL during mid-stance, which is an indicator of the vaulting of amputees on their IL stance (Drevelle et al., 2014).

The statistical analysis showed the plantar-flexor moment of the PL was smaller than the IL ($p<0.001$) and non-amputees limb ($p<0.001$). Compared to the moment in insoles conditions, its magnitude is reduced after insoles use ($p=0.006$). But its dorsi-flexor moment at initial stance did not have any significant differences to the IL ($p=0.744$) and to non-amputees ($p=0.368$). The IL displayed a smaller plantar-flexor moment in comparison to the non-amputees in both insoles conditions (S1: p=0.028, S2: p=0.007). In addition, its magnitude decreased after insoles use (p<0.001). But its dorsi-flexor moment was not significantly different from the non-amputees' limbs (p=0.086). However, the differences between the limbs' dorsi-flexor moments after insoles use increased (p=0.028), but the insoles had no significant effect on its magnitude in comparison to the without insoles condition (p=0.82).

Table 4.17 Ankle moment in sagittal plane during one gait cycle

		Flex/extensor Ankle Joint Moment (N.m/kg)	
		Dorsi-flexor	**Plantar-flexor**
Amputees (10)	**IL-S1**	**0.24** (±0.06)	**1.30** (±0.14)
	IL-S2	**0.29** (±0.08)	**1.26** (±0.15)
	PL-S1	**0.23** (±0.08)	**1.05** (±0.20)
	PL-S2	**0.22** (±0.07)	**0.99** (±0.21)
Non-Amputees (14)	**RL-S1**	**0.19** (±0.06)	**1.43** (±0.13)
	RL-S2	**0.21** (±0.07)	**1.44** (±0.13)
	LL-S1	**0.20** (±0.06)	**1.43** (±0.17)
	LL-S2	**0.21** (±0.05)	**1.43** (±0.12)

S1: without insoles, S2: with insoles, RL/IL: right limb/Intact limb, LL/PL: left limb/Prosthetic limb

Table 4.18 displays the peaks of knee moment for all groups/limbs/insoles conditions. As was mentioned in the normal gait section (Chapter 2), two extensor peaks (K1 and K3 at weight acceptance and push-off, respectively) and two flexor peaks (K2 and K4 during mid-stance and terminal swing, respectively) are important peaks of knee moment in the sagittal plane during each gait cycle. As can be seen in Figure 4.12-a2 and –b2, the pattern of knee moment for the IL of the amputees and both limbs of the non-amputees is similar, but with smaller peaks for the amputees. The shape for the IL and non-amputees' limbs follows more or less the subsequent stages of moment change as was described in the normal gait section (Chapter 2). But, the moment for the PL seems smaller, except for K2 (the flexor moment before terminal, which is produced by the extensor assistant mechanism of the prosthetic knee) and its swing flexor moment (K4) is near to zero due to the lack of flexor muscles.

The statistical analysis found a significant difference in K1 between the PL and non-amputees (p<0.008), K2 between the IL and non-amputees during the without insole session (p=0.03), and K4 between the IL of amputees, in addition to the non-amputees' limbs and PL (p<0.001). The changes due to insoles use were very small and insignificant (p>0.05).

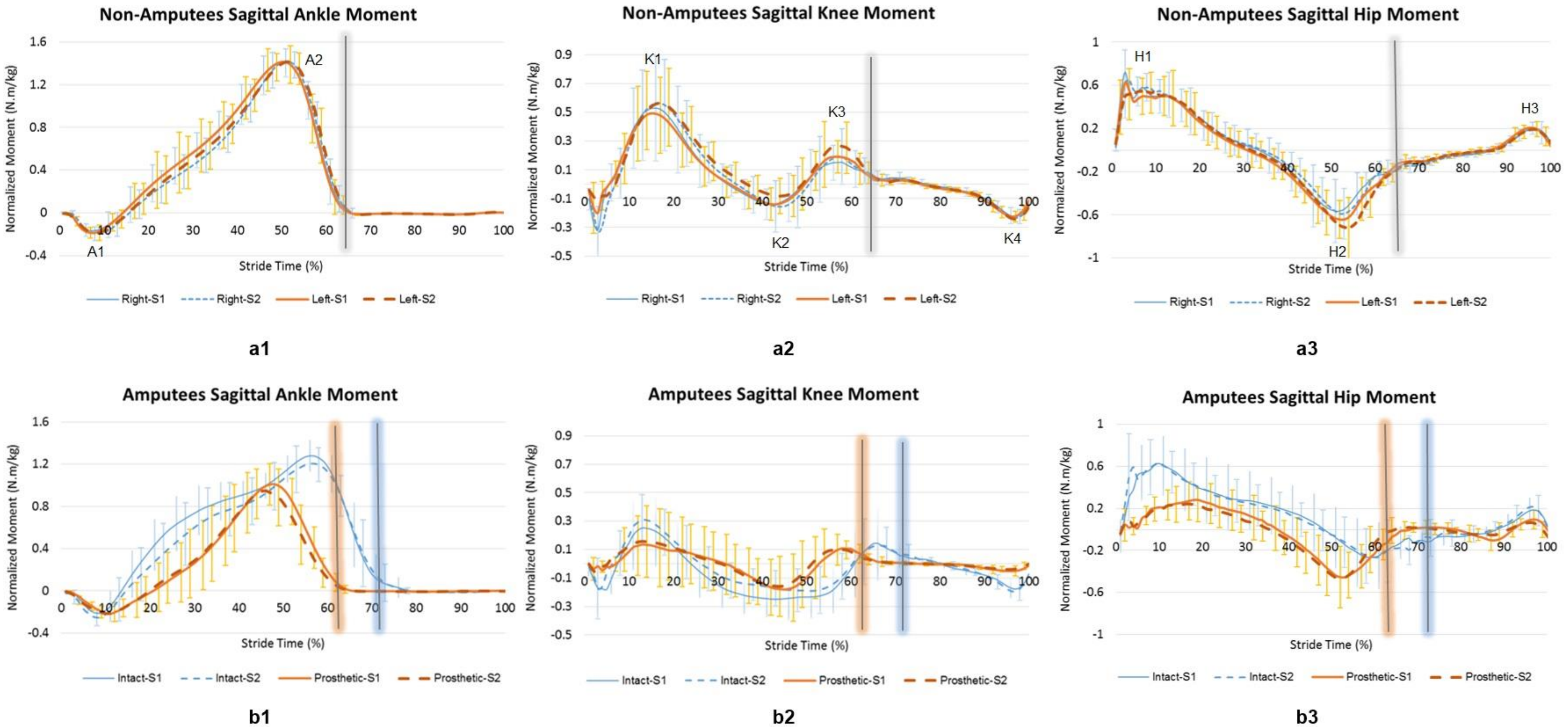


Figure 4.12 Non-amputees (a) and amputees (b) both lower limb joints moments in sagittal plane (+ve for extension and -ve for flexion, the perpendicular lines show end of stance phase) during with insoles (S1) and without insoles (S2) walking

Table 4.18 Knee moment in the sagittal plane during one gait cycle

		Flex/extensor Knee Joint Moment (N.m/kg)			
		K1	**K2**	**K3**	**K4**
Amputees (10)	**IL-S1**	**0.32** (±0.22)	**-0.29** (±0.15)	**0.22** (±0.20)	**-0.23** (±0.11)
	IL-S2	**-0.37** (±0.16)	**-0.23** (±0.13)	**0.19** (±0.15)	**-0.22** (±0.07)
	PL-S1	**0.22** (±0.20)	**-0.22** (±0.20)	**0.12** (±0.08)	**-0.05** (±0.04)
	PL-S2	**0.22** (±0.19)	**-0.20** (±0.21)	**0.10** (±0.06)	**-0.04** (±0.02)
Non-Amputees (14)	**RL-S1**	**-0.56** (±0.35)	**-0.17** (±0.11)	**0.16** (±0.11)	**-0.23** (±0.06)
	RL-S2	**0.57** (±0.33)	**-0.17** (±0.17)	**0.19** (±0.14)	**-0.24** (±0.05)
	LL-S1	**0.50** (±0.27)	**-0.15** (±0.11)	**0.18** (±0.12)	**-0.23** (±0.04)
	LL-S2	**0.57** (±0.28)	**-0.10** (±0.13)	**0.26** (±0.17)	**-0.24** (±0.04)

S1: without insoles, S2: with insoles, RL/IL: right limb/Intact limb, LL/PL: left limb/Prosthetic limb, +ve is extensor moment and -ve is flexor moment

Figure 4.12-a3 and –b3 demonstrate the pattern of the hip moment changes for the two groups. The pattern for the IL and non-amputees' limbs follows the hip moment changes as mentioned in the normal gait section (Chapter 2). In spite of the similarity of the pattern of hip moment change with the non-amputees' limbs, the intact hip has a smaller terminal stance flexor moment (H2). Contrary to the flexor moment (H2) of the amputated limb, which is larger than the IL and close to the magnitude of the non-amputees' H2, its first extensor moment (H1) is very small. The first (H1), second (H3) extensor and the flexor (H2) moments are shown in Table 4.19. H2 for both limbs of the amputees and H1 for the residual limb are smaller than the same moment of non-amputees' limbs. But H3 for the IL has almost the same magnitude of H3 for non-amputees. It seems the hip flexor moment of non-amputees has a tiny increase after using insoles.

Table 4.19 Hip moment in the sagittal plane during one gait cycle

		Flex/extensor Hip Joint Moment (N.m/kg)		
		H1	**H2**	**H3**
Amputees (10)	**IL-S1**	**0.70** (±0.28)	**-0.41** (±0.20)	**0.22** (±0.13)
	IL-S2	**0.75** (±0.28)	**-0.41** (±0.20)	**0.26** (±0.12)
	PL-S1	**0.37** (±0.12)	**-0.54** (±0.25)	**0.12** (±0.08)
	PL-S2	**0.29** (±0.15)	**-0.53** (±0.22)	**0.09** (±0.05)
Non-Amputees (14)	**RL-S1**	**0.81** (±0.23)	**-0.60** (±0.31)	**0.21** (±0.06)
	RL-S2	**-0.81** (±0.20)	**-0.61** (±0.23)	**0.21** (±0.07)
	LL-S1	**0.77** (±0.19)	**-0.68** (±0.19)	**0.18** (±0.11)
	LL-S2	**0.76** (±0.19)	**-0.74** (±0.28)	**0.20** (±0.07)

S1: without insoles, S2: with insoles, RL/IL: right limb/Intact limb, LL/PL: left limb/Prosthetic limb, +ve is extensor moment and -ve is flexor moment

The first extensor hip moment was significantly different between limbs and groups ($p<0.001$). H1 for the IL was smaller than in non-amputees ($p=0.02$), while the differences between the residual limb and both the IL ($p=0.002$)/non-amputees' limbs ($p<0.001$) was larger. However, after using insoles, a significant difference was observed between the non-amputees' left limb and IL ($p=0.004$), and close to significant with the amputated limb ($p=0.054$). H2 (end stance's flexor moment) was smallest for the IL of amputees, with significant differences with the residual limb ($p=0.04$) and non-amputees ($p=0.034$). The difference with non-amputees increased a little after insoles use ($p=0.001$). The differences of H3 between the non-amputees' limbs and IL was not significant ($p>0.05$). But the difference was significant between the amputated limb and IL ($p=0.042$), in addition to non-amputees' limbs ($p<0.001$). No significant differences were observed between with and without insoles sessions ($p>0.05$).

4.3.3.3.3 Joint powers

The calculated joints powers at the ankle, knee and hip joints as indicators of muscle activities are of interest when evaluating the effect of insoles use in this study. The powers are normalized to the bodyweight of the participants.

The first and second ankle power peaks for limbs/groups/insoles conditions are noted in

Table 4.20. Figure 4.13-a1 and b1 depict the changes of ankle joint power during one stride of each limb for both groups and insoles conditions. The non-amputees' graphs correspond to the pattern described in the normal gait section (Chapter 2). As is seen in the table and figure, the absorbed and generated powers of the prosthetic device are very small due to the lack of plantar-flexor muscles and the inability of the prosthesis structure to compensate for this absence completely.

Table 4.20 Ankle joint power during one gait cycle

		Ankle Joint Power (W/kg)	
		AP1	**AP2**
Amputees (10)	**IL-S1**	**-0.65** (±0.27)	**+2.22** (±1.43)
	IL-S2	**-0.63** (±0.22)	**+2.12** (±0.87)
	PL-S1	**-0.50** (±0.28)	**+0.37** (±0.23)
	PL-S2	**-0.46** (±0.23)	**+0.34** (±0.24)
Non-Amputees (14)	**RL-S1**	**-0.94** (±0.32)	**+2.38** (±0.66)
	RL-S2	**-1.12** (±0.36)	**+2.47** (±0.74)
	LL-S1	**-0.96** (±0.38)	**+2.41** (±0.47)
	LL-S2	**-0.98** (±0.48)	**+2.62** (±0.67)

S1: without insoles, S2: with insoles, RL/IL: right limb/Intact limb, LL/PL: left limb/Prosthetic limb, -ve are for power absorption and +ve for power generation

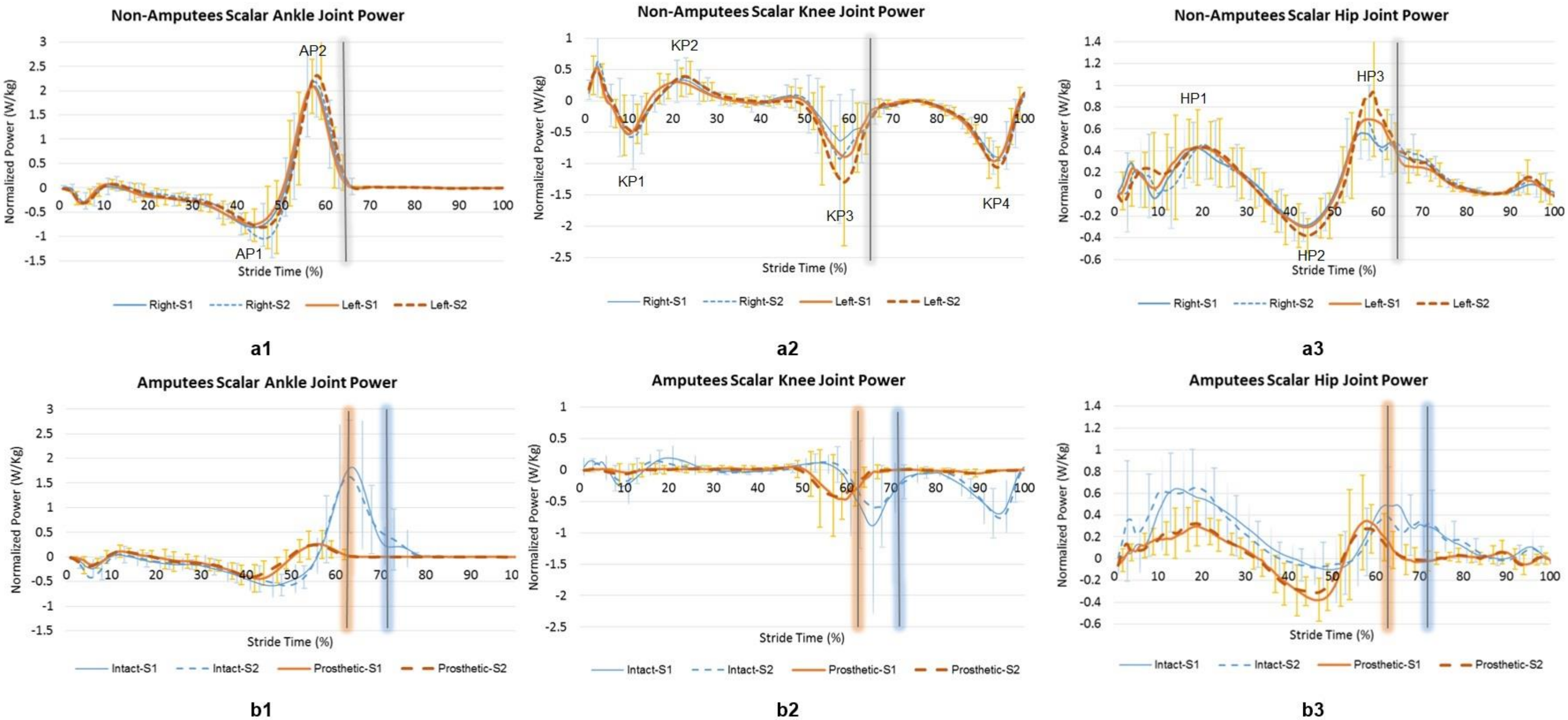


Figure 4.13 Non-amputees (a) and amputees (b) both lower limb joints power (-ve for power absorption and +ve for power generation, the perpendicular lines show the end of stance phase) during with insoles (S1) and without insoles (S2) walking

There was a significant difference between the AP1 of non-amputees' limbs and the IL (S1: p=0.02 and S2: p=0.001) and PL (p<0.005). The differences of two amputees' limbs with regard to AP1 was non-significant (p>0.1). No significant difference was seen when comparing the non-amputees' AP2 with the IL (S1: p=0.713, S2: p=0.301), while the AP2 of the PL was smaller than the IL (p=0.002) and non-amputees' limbs (p<0.001). The insoles use, except for AP1 of the non-amputee's right limb (p=0.05), did not lead to any differences in the ankle power variables.

The average knee power changes during one gait cycle for the limbs/groups/insoles condition has been illustrated in Figure 4.13-a2 and b2. No power generation was observed for the prosthetic knee, and there was only a small power absorption in the terminal stance, which is due to the extensor stop mechanism of the prosthetic knee. The initial stance's power absorption and the mid-stance power generation of the IL's knee are also very small (almost half of that of the non-amputees). Table 4.21 shows the peaks of knee power; the KP3 measurements, in particular, are highly variable.

Table 4.21 Knee joint power during one gait cycle

		Knee Joint Power (W/kg)			
		KP1	**KP2**	**KP3**	**KP4**
Amputees (10)	**IL-S1**	**-0.37** (±0.24)	**+0.38** (±0.27)	**-1.03** (±1.34)	**-0.75** (±0.43)
	IL-S2	**-0.28** (±0.21)	**+0.27** (±0.17)	**-0.75** (±0.81)	**-0.79** (±0.44)
	PL-S1	**-0.07** (±0.10)	**+0.06** (±0.1)	**-0.64** (±0.61)	**-0.07** (±0.06)
	PL-S2	**-0.1** (±0.15)	**+0.07** (±0.08)	**-0.61** (±0.58)	**0.07** (±0.06)
Non-Amputees (14)	**RL-S1**	**-0.62** (±0.6)	**+0.67** (±0.5)	**-0.83** (±0.59)	**-0.94** (±0.33)
	RL-S2	**-0.67** (±0.73)	**+0.77** (±0.47)	**-1.12** (±0.87)	**-1.01** (±0.32)
	LL-S1	**-0.58** (±0.42)	**+0.61** (±0.42)	**-1.03** (±0.51)	**-0.99** (±0.34)
	LL-S2	**-0.56** (±0.53)	**+0.68** (±0.39)	**-1.49** (±1.08)	**-1.09** (±0.34)

S1: without insoles, S2: with insoles, RL/IL: right limb/Intact limb, LL/PL: left limb/Prosthetic limb, -ve are for power absorption and +ve for power generation

The statistical analysis also shows significant differences between all power peaks of the PL and both non-amputees' limbs and the IL (p<0.01) except for KP3 (p>0.05). The difference between the IL and non-amputees' limbs, in addition to the insoles effect, were non-significant (p>0.05).

Figure 4.13-a3 and b3 display the average hip power changes during one gait cycle for limbs/groups/insoles conditions. The general pattern is similar for all limbs, which follows the typical change of hip power presented in the normal gait section (Chapter 2). However, the magnitude of peaks varies among limbs of amputees and non-amputees. The magnitude of two absorbed and one generated powers are shown in Table **4.22**. The first power generation (HP1) is largest for the IL and smallest for the PL of amputees. While, in contrast, the residual limb represented the largest hip power absorption (HP2) and the IL had its smallest magnitude. HP3 was larger than HP1 for all limbs in the

without insoles session. However, the magnitude of HP1 increased and HP3 decreased after insoles use in both limbs of the amputees.

Table 4.22 Hip joint power during one gait cycle

		Hip Joint Power (W/kg)		
		HP1	**HP2**	**HP3**
Amputees (10)	**IL-S1**	**+0.82** (±0.32)	**-0.17** (±0.16)	**+0.89** (±0.53)
	IL-S2	**+0.84** (±0.3)	**-0.15** (±0.15)	**+0.69** (±0.34)
	PL-S1	**+0.33** (±0.19)	**-0.43** (±0.21)	**+0.53** (±0.41)
	PL-S2	**+0.58** (±0.37)	**-0.42** (±0.11)	**+0.47** (±0.4)
Non-Amputees (14)	**RL-S1**	**+0.52** (±0.24)	**-0.31** (±0.16)	**+0.73** (±0.21)
	RL-S2	**+0.52** (±0.28)	**-0.36** (±0.12)	**+0.83** (±0.42)
	LL-S1	**+0.54** (±0.29)	**-0.36** (±0.16)	**+0.85** (±0.16)
	LL-S2	**+0.58** (±0.37)	**-0.42** (±0.19)	**+1.14** (±0.62)

S1: without insoles, S2: with insoles, RL/IL: right limb/Intact limb, LL/PL: left limb/Prosthetic limb, -ve is for power absorption and +ve for power generation

The statistical analysis also shows significant differences between all hip power peaks of the IL and residual limbs in both insoles sessions: HP1/S1 and S2 ($p<0.001$); HP2/S1 ($p=0.002$) and HP2/s2 ($p=0.001$); HP3/S1 ($p=0.026$) and HP3/S2 ($p=0.045$). HP1 of the IL was significantly larger than its value for non-amputees ($p_{s1}=0.017$, $p_{s2}=0.015$) and its HP2 was smaller ($p_{s1}=0.034$, $p_{s2}=0.001$). The difference between non-amputees' limbs and the residual limb alone was significant for HP3 ($p_{s1}=0.016$, $p_{s2}=0.007$). The differences between the right and left HP3 of non-amputees was significant in both insoles sessions ($p_{s1}=0.038$, $p_{s2}=0.005$). However, the differences between the insoles sessions for none of the limbs was significant.

4.3.4 Insoles qualitative evaluation

All participants were asked to continue using the insoles after the biomechanical tests and to fill in a short evaluation form (Table 4.23) after four weeks. The feedback form was inspired by the Orthotics and Prosthetics Users' Survey (OPUS) ((Heinemann et al., 2003)), and it was used to check insoles fit, comfort of use, the presence of any abrasions/soreness/pain, and any positive effects, such as the feet feeling less tired. It is beneficial to remember that the patients who use orthotic devices, such as insoles, are not firmly dependent on their device in their daily activities and, normally, are prescribed with them for only a limited time. Therefore, orthotic patients will easily reject a device if it disturbs them and they are satisfied with it ((Peaco et al., 2011)). Uncomfortable insoles also influence their performance (Che et al., 1994).

Table 4.23 Qualitative evaluation of the insoles

	Participants	Strongly Agree	Agree	Neither Agree/ Nor Disagree	Disagree	Strongly Disagree	Do not know /Not Applicable
The insole fits well	A	2	2	1	2		1
	NA	7	5				
The insole is comfortable throughout the day	A	4	4		1		
	NA	7	5				
The insole does not cause abrasions or soreness	A	4	4		1		
	NA	9	3				
The insole is pain free to wear	A	4	5				
	NA	9	3				
I feel using of insole, makes my feet less tired	A	4		3	1		1
	NA	5	5	2			
I am happy with the insole	A	3	5	1			
	NA	6	5				
I would like to continue using the insole	A	4	2	1	2		
	NA	7	5				

A: amputees, NA: non-amputees

Twelve non-amputees (with an average time of use: 6±1 days per week and 9.2±3 hours per day) and nine amputees (with an average time of use: 6.75±0.7 days per week and 9.1±2.6 hours per day) responded to the questions. As seen in Table 4.23, the majority of the participants gave positive feedback about the insoles (choosing strongly agree and agree). A Chi-square test did not find a difference between the two groups in terms of their answers to the questions ($p>0.05$). However, the non-amputees seemed more satisfied with the insoles. All of the non-amputees stated that they would continue to use the insoles, while only six out of nine amputees wished to do so. One non-amputee declared that he felt the insoles negatively affected his balance. Three amputees specifically noted their satisfaction and said that they felt better in outdoor activities and long-distance walking when using the insoles. Two amputees felt that the insoles made their shoes too tight and decreased the depth of the shoes.

4.4 Discussion

This study was conducted to describe the function of TF amputees according to their walking performance, and to evaluate and compare the biomechanics of their walking with non-amputees in with/without insoles conditions. The results of the study will be discussed separately in different related sections:

4.4.1 Level of function

The observed differences between the spatio-temporal variables of the amputee and non-amputee participants and their SI fully support the first hypothesis (the lower functional level of amputee participants in comparison with non-amputee participants).

In this study, amputee participants adapted a lower self-selected speed than non-amputees. The natural consequences of limb loss (including muscle damage) and using an artificial limb, with its limitations which do not permit walking in exactly the same way as individuals without musculoskeletal deficiencies, forces lower limb amputees to apply different adjustments when performing their daily activities. They try to manage energy expenditure during walking (i.e. O_2 intake) by controlling their speed (Waters and Mulroy, 1999). In addition, lowering walking speed is a known strategy to increase stability among normal individuals, particularly old people (Orendurff et al., 2004; Lamoth et al., 2010), which might be applicable to any group, including lower limb amputees. However, (Prinsen et al., 2011) published a literature review related to lower-limb amputees walking studies and found the majority of them reported a higher self-selected speed of amputee participants and control groups than in this study (1.12±0.17-1.4±0.16 m/s for control groups and 1.2±0.1 m/s for TF amputees). It is worth remembering that, according to the inclusion criteria of this study, all participants were active ambulators and were able to walk without assistive devices; their health condition was good or under managed medical control, free from any musculoskeletal or balance issues during the previous six months. Therefore, the observed low speed is unlikely to be related to their health. All the amputee participants in this study used passive mechanical prosthetic knees which have a constant speed of knee flexion/extension. This feature makes changing walking speed more challenging. In addition, it is established that there is a negative relationship between speed of walking and age (Patterson et al., 2012). Thus the differences between the ages of the participants in the different studies must also be considered when evaluating walking speed. The participants in the reported studies in (Prinsen et al., 2011) had a different range of age, including a 62.3±6.9 year-old TT amputees with a speed of 1.06±0.18 m/s and 30-44 year-old TF amputees with a speed of 1.2±0.1 m/s which, even considering the speed of the elder group, is higher than the present study, with a speed of 0.76 ±0.15 m/s for 55.9 ±8.53 year-old participants. It is also known that the test environmental conditions (i.e., the limited walking path length in the laboratory setting, the targeting of the force platform, the feeling of being in a controlled situation) and the natural differences between individuals might have affected aspects of the biomechanical data, such as the walking velocity. The walking path at the Iranian site of testing was approximately 5 m and the speed in this study was measured during only one right and one left stride, passing the force platforms. Another point to consider is that as the majority of participants were Iranian (10 amputees and 8 non-amputees), the lower walking speed might be part of their lifestyle, which would agree with my personal routine observations regarding people’s walking pace. As can be seen in Table 4.24, there is a similarity between the several spatio-temporal variables, including walking speed, for Iranian non-amputees and TF amputees in separated studies (F Farahmand et al., 2006; Hekmatfard et al., 2013; Khiri et al., 2015). Jalalvand et al. (2016) also reported the walking speed of healthy Iranians close to this present study (n=15, age=48.8±6.61 years, speed=1.19 m/s). However, (Rastegar et al., 2016) and (Sadeghi and Norouzi, 2010) reported self-selected speed for healthy Iranian males higher than here (in turn n=15 age= 26.46±3.34, speed=1.48 m/s; n=57, age= 25±8.5, speed=1.29 m/s). These differences reveal the importance of individual differences, and the effect of the testing environment on the variables.

Table 4.24 Sample of results for gait spatio-temporal variables in 3 studies related to Iranian TF amputees

		Non-amputees (Right limb)	Lower Limb Amputees	
			IL	PL
Step length (m)	Farahmand et al.	0.62	0.46	0.49
	Hekmatfard et al.	-	52. 6	53.4
	Khiri et al.	-	-	-
	Present study	0.68	0.53	0.56
Stride length (m)	Farahmand et al.	1.24	1.00	1.00
	Hekmatfard et al.	-	1.05	1.08
	Khiri et al.	1.25	1.15	-
	Present study	1.32	1.10	1.10
Stance time (%)	Farahmand et al.	59.5	65	60
	Hekmatfard et al.	-	76	63
	Khiri et al.	61	60	-
	Present study	64	71	62
Self-selected walking speed (m/s)	Farahmand et al.	0.96	0.67	
	Hekmatfard et al.	-	0.79	
	Khiri et al.	60 m/min (~1 m/s)	45.6 m/min (~0.76 m/s)	
	Present study	1.1	0.76	

(F Farahmand et al., 2006): 5 Non-amputees (age= 24.2 ±0.83 years, BMI= 24.55±2.99 kg/m^2) and 5 TF amputees (age= 37.8±4.48 years, BMI= 24.63±2.99 kg/m^2)
(Hekmatfard et al., 2013): 10 TF amputees (age: 40.93±12.57 years, BMI=24.44±3.42 kg/m^2)
(Khiri et al., 2015): 5 Non-amputees (age= 45 ±4.5 years, height 1.74±0.03 m, weight: 64±2.6 kg) and 5 TF amputees (age= 44.2±4.1 years, height 1.75±0.035 m, weight: 63±3.2 kg)

As expected, the level of symmetry between the two limbs' spatio-temporal variables was higher for non-amputees (SI<10%, except for step width) which can be interpreted as a higher level of functioning related to their walking. Interestingly, the least significant relationship between age and symmetry of walking parameters has been observed (Jaegers et al., 1995; Patterson et al., 2012). Thus, in spite of the differences in the groups' age, the observed asymmetry between the intact and PLs of the amputee group should be considered as a consequence of their adaptation with amputation, not their age. The lack of sensor-motor control on the PL, its less accurate functionality and the prosthetic foot placement due to the absence of lateral ankle control of the prosthetic feet led to the forming of a compensatory strategy involving shorter weight bearing on the affected limb (Schaarschmidt et al., 2012). The greater reliance on the IL is well-known, and the subsequent longer stance duration and shorter step length of the IL have been documented in textbooks (Winter, 1987; Silver-Thorn, B. and L. Glaister, 2009; Lusardi and Nielsen, 2007). Accordingly, Prinsen et al. (2011) believe it is not correct to evaluate the functionality of lower limb amputees based on the symmetry of their walking. (Hof et al., 2007) has also suggested that the focus of rehabilitation should not be on improving the temporal symmetry of lower limb amputees' walking because the observed asymmetries are unavoidable due to passive control of the PL. Furthermore, the prosthetic components have a significant effect on the symmetry of gait in lower limb amputees. For example, bionic knees (Uchytil et al., 2013) or microprocessor knees (Kaufman et al., 2012) in comparison to mechanically passive knee joints significantly improve the symmetry of stance/swing proportion of intact and the PL of TF amputees and lower extremity joint kinetics. It has been observed that energy-storing prosthetic feet also improve the step length symmetry of TT amputees (Houdijk et al., 2018). These might suggest that the symmetry of walking due to its dependence on extrinsic factors, such as prosthetic components, the testing environment, unavoidable adaptation with amputation and prosthesis and personal differences, is not a proper criterion for the evaluation of lower limb amputees' functionality.

The second hypothesis (amputee participants' moderate level of functioning) is supported by the results of the ABC scale and PEQ-M questionnaires. The average ABC score of participants in biomechanical tests was 70.5 (±13), which is considered a moderate level of balance confidence. It was higher than the average scores of participants in the survey (55.24 ±25.88) and 37 Iranian participants (63.63±21.96). Amputees number 1, 3 and 10's ABC score showed their high level of functioning and balance confidence, while only amputee number 8 had a low level of function and confidence; the other amputees placed between them (a moderate level of functioning and balance confidence). However, the score of less than 80 needs intervention for improving balance, which is needed by the remaining eight amputees (Myers et al., 1998). In addition, the self-reported score for the amputees numbered 4, 5 and, 6 were <67, which is considered to be at risk of future falling. Amputees numbered 4 and 6 already had reported fall experience during the 12 months prior to participating in the tests. The average ABC score for the amputee participants is comparable with the literature, which similarly reported a moderate level of functioning for the lower limb amputee participants in their studies; however, they recorded lower scores (62.8 for (Miller, W. C. et al., 2001); 67.6 for (Miller and Deathe, 2004); around 70 for low active lower limb amputees for (Mandel et al., 2016); 65.1 for (Wong et al., 2014); and 2.4 out of 4 for (Hafner et al., 2017) (the equivalent 60 out of 100)). This shows that, if the participants in this study were not at a high level of functionality according to the ABC scale (the average score being more than 80), they were also not exceptional, and that they had a lower level of functionality in comparison to other studies. At the same time, they were better than others. By looking at individual data, amputee number 8 had the lowest self-selected speed of walking, which agreed with his self-reported low scores of mobility (PEQ-M questions) and on the ABC scale. The average PEQ-M score of amputee participants (7.03 ±1.5) was better than the average scores of 155 participants in the survey presented in Chapter 3 (5.74 ±2.38) and better than even the 37 Iranian participants (6.34±2.17), as well as the results of the previous studies; for example, (Harness and Pinzur, 2001), with reported scores of 55.3 and 65.9 out of 100 respectively for TT amputees and (Hafner et al., 2017), with a recorded score of 2.4 out of 4, which is equivalent to 6 out of 10. In addition, our participants gave the highest score to their ability to walk in different situations, which shows they had a positive view of their mobility in routine activities.

The Levene's Test showed both groups had a similar level of variability (or homogeneity) for the spatio-temporal variables (p>0.05). As can be seen in Figure 4.7 and Figure 4.8, in spite of the observed variability within the groups, neither had outliers for 10 out of 15 spatio-temporal variables and in the remaining five variables, only one or two outliers were recorded. The outliers were related to amputee participant number 10, with data close to non-amputee levels (velocity, IL stride length), number 8 (longer IL stance and its shorter swing, longer IL stride), and number 6 (longer IL stance and its shorter swing) in the amputees group, and participant number 5 (lower velocity and longer double support time), number 6 (longer double support time), number 7 (higher velocity, longer left stride length, shorter right stride time), and number 14 (longer right stride time, shorter left stride time) in the non-amputee group. The calculated coefficient of variation (CV) as a criterion for evaluating the variety inside the groups had lower values for the non-amputees' spatio-temporal variables (CV<15%). Only their width of step had a high CV (42% and 49% for right and left steps). The different pattern of participants numbered 9 and 14 had a considerable effect on their mobility. They walked with crossed steps (cat walking), which led to very small step width. On the other hand, non-amputee number 7 had the widest step. These are personal differences which were observed in the non-amputee group. The magnitude of CV was larger in the amputee group. As is seen in Table 4.5, walking speed, steps width and IL stride time have a CV>15%. The data of participants numbered 8 and 10 for the speed and stride length are different from the other participants. A CV>15% can be seen for the spatio-temporal variables of a group of highly functional TF amputees (Jarvis et al., 2017). Accordingly, the differences among the lower limb amputees as a group having experienced a serious change of the musculoskeletal system is expected and reasonable.

Finally, in addition to remembering that the amputee volunteers participated in the study of their own free will, and due to their perception about being active in daily life was a criterion for entry, the assessment of the spatio-temporal variables, PEQ-M and ABC scores of the amputee participants in this study are not far from the literature, and the amputee participants were at a reasonable level of functionality. In fact, the amputees had experienced a long time post-traumatic amputation (34.4±8 years), with limb loss at young ages (21.5±5 year-old), which led to the high level of adjustment to the amputation and prosthetic device usage (Kahle et al., 2016). Among the amputees, only amputee number 8 seemed to have a low level of functionality, which suggests his data should be considered with caution.

4.4.2 Biomechanics of walking and insoles effects

4.4.2.1 Spatio-temporal variables

The spatio-temporal results (in both with and without insoles conditions) of TF amputees participating in this study are typical of the characteristics of lower limb amputees' walking and are definitely in agreement with previous studies (F Farahmand et al., 2006;

Hekmatfard et al., 2013; Uchytil et al., 2013; De Asha et al., 2014; Khiri et al., 2015; Jarvis et al., 2017).

As seen in Table 4.9 and Table 4.12, the differences between the amputees' and non-amputees' spatio-temporal variables in both insoles conditions are significant. The amputees, in comparison to the non-amputees, had a slower walking speed (S1: 0.76 vs 1.1 m/s, S2: 0.75 vs 1.13 m/s) resulting in longer stride times (1.5 s vs 1.2 s) and shorter stride/step lengths (1.1/(0.53-0.56) m vs 1.4/(0.65-0.68) m). The observed speed differences between the two groups have several dimensions. As was discussed in the "Level of function" section, passive mechanical prosthetic knees have a constant speed of knee flexion/extension which cannot be adjusted with fast walking. On the other hand, when a person decreases the walking speed, s/he gives more time for the motor control to evaluate the situation and apply the proper orders (Orendurff et al., 2004). Accordingly, the lower speed helps LLAs to optimise their locomotion. In addition, the longer swing phase of the PL provides more time for its transfer and leads to a longer step on this side. Amputees had longer double support time (S1: 16% (IL)-17% (PL) vs 14 % for non-amputees) and the stance phase of their IL was longer (71% vs 64%), which shows prolonged loading on the IL. Walking is a very regular routine human activity. Hence, the repetitive action of a longer spell of loading on the IL and a shorter spell of weight bearing on the PL might result in secondary knee pain or joint osteoarthritis of the IL, and osteopenia (low bone density) of the residual limb (Berke et al., 2008). As the severed bone of the residual limb decreases its ability to transfer the bodyweight directly to the prosthetic device, the increased time on the IL might be an adjustment to protect the residual limb's soft tissues (Silver-Thorn, M.B. et al., 1996). In addition, the amputees had wider stepping, which shows they were trying to increase the base of support and, consequently, have more stable walking. Interestingly, a wide step is not related to lateral leaning (Jaegers et al., 1995), which was seen in five participants. It is known that the walking energy cost of lower limb amputees is higher than non-amputees, regardless of the magnitude of their selected speed (Detrembleur et al., 2005). On the other hand, the increased base of support in lower limb amputees is associated with their higher energy expenditure (Weinert-Aplin et al., 2017). The higher energy cost of walking leads to higher pressure on the heart and induces fatigue quicker. These reasons might be the basis of their lower speed. The results do not support a part of hypothesis number 3 (the significant differences between paired spatio-temporal variables of IL and PL). The differences between the two limbs of the amputees were only observed in the form of a longer stance and shorter swing duration for the IL. However, the results support the part of hypothesis number 4 related to the non-significant difference between the two limbs of the non-amputees in terms of paired spatio-temporal variables. The results also support the part of hypothesis number 5 which supposes the spatio-temporal variables of amputees' walking is significantly different from non-amputees' variables, except for the differences between stance and swing duration of the PL, which was no different from non-amputees.

The insoles do not change the similarities between the right and left limbs' spatio-temporal variables and, accordingly, the related part of hypothesis number 6 is supported. On the other hand, the part of hypothesis number 7 related to the decrease in difference between the spatio-temporal variables of the IL of amputees' and non-amputees' limbs is rejected. Insoles use did not affect the spatio-temporal variables and their symmetry ($p>0.05$). But, the non-significant increase of double support time for non-amputees' left limb (from 13.73% to 15.06%) and the decreased double support time in the prosthetic side of amputees (from 17.14% to 16.45%) led to a change in the observed difference between the variables of amputees and non-amputees to a non-significant difference. In addition, the length of the non-amputees' limb stance time non-significantly increased (from 63.29% to 64.45), the stance duration of the PL of amputees also non-significantly decreased (from 62.34% to 61%), which led to an increase in the swing phase of the PL (from 37.66% to 39%). These led to the observation that there is a significant difference between the stance/swing duration of the prosthetic side and the non-amputees' left limb, which did not exist in the without insoles session (Table 4.9 and Table 4.12). However, these changes are not a matter of interest when considering the goal of this study.

4.4.2.2 Kinematics

The effects of insoles on the kinematics of walking was evaluated by an assessment of the COM vertical and mediolateral displacements, the COG/COP-BOS lateral border, the COP mediolateral displacement, and ankle angular displacements in the sagittal and coronal planes during one gait cycle of both limbs of each participant.

Kinematics of the COP and COM

COM displacements: The results support a part of hypothesis numbers 3-5 related to the observed differences between the COM displacements during stance and swing of the intact/PLs and between groups. During the stance phase of the IL, the vertical position of the COM was higher than its position for the stance of the PL. On the other hand, it reached a lower position during the IL's swing phase in comparison with the PL's (hypothesis number 3). The difference between the COM vertical displacement of non-amputees' right and left limbs was not significant (hypothesis number 4). Hypothesis number 5 (the existence of a difference between amputees and non-amputees) is supported by the observed differences in the COM vertical displacement during the stance of the PL/swing of ILs and the displacements in the same phases of non-amputees' limbs. The amplitudes of the COM vertical displacement were the same for both groups and for insoles sessions (~0.04 m). However, the displacement was greater during the stance and smaller during the swing of the IL in comparison to the PL (~0.04/0.02 vs ~0.03/0.03). It did have a symmetrical pattern in the non-amputees (Figure 4.9-A). This means that the COM experienced greater vertical amplitude during weight bearing of the IL, while this limb (as opposed to the PL) had initial stance knee flexion, which lowers the COM. But, as the ankle moment profile shows, amputees had vaulting on the IL which leads to a higher position of the COM during the IL's stance. In addition, the COM was in a higher position on the prosthetic side's end of stance compared to the IL's COM position at the same event. It might be the result of the prosthetic device's limited plantar flexion and its deficiency when propelling the body forward at toe-off (Nolan, Lee et al., 2003).

For mediolateral displacement of the COM, the displacements during the gait cycle of both limbs of the amputees were the same (a rejection of hypothesis number 3). The displacements were also the same for both limbs of the non-amputees (supporting hypothesis number 4). Hypothesis number 5 (the existence of a difference between amputees and non-amputees) is supported by the observed greater COM mediolateral displacement of both amputees' limbs' during the gait cycle in comparison with non-amputees limbs. The COM mediolateral displacements were greater during both limbs' strides in the amputees group. A greater mediolateral movement of the COM during normal walking is considered a sign of probable loss of balance (Niiler, 2018). But the observed wider steps of the amputees might be the basic cause of this greater mediolateral COM displacement or, in other words, their strategy to maintain dynamic balance. There was a long-held belief about the direct relationship the COM vertical displacement and energy cost of walking based on Saunders and Inman's six determinants of gait theory, which recent studies have shown to be incorrect about able-bodied walking (Rose and Gamble, 2006). But, the increased vertical displacement of lower limb amputees' COM is not linked to their higher energy expenditure (Detrembleur et al., 2005). Instead, increased mediolateral displacements of the COM during walking is connected to higher energy expenditure (Weinert-Aplin et al., 2017), which is expressed in the oxygen consumption of TF amputees whilst walking being higher than in able-bodied individuals' (Jarvis et al., 2017). In this study also, the mediolateral displacements of the amputees' COM (~0.08 m) during both limb strides were almost twice those of the non-amputees (~0.04). Accordingly, we can conclude that the amputees' walking is less energy efficient, which results in their getting tired more quickly and having a lower speed. It has been shown that walking speed has a direct relationship with vertical COM displacement and an inverse relationship with its mediolateral displacements in healthy individuals (Orendurff et al., 2004). Surprisingly, (Orendurff et al., 2004) the reported mediolateral and vertical COM displacements were close to those of the amputee group in this study (6.99 ± 1.34 cm and 2.74 ± 0.52 cm, respectively) for the 10 young healthy individuals (26.9 ± 5.7 years-old, walking with a speed of 0.7 m/s). Therefore, with a speed similar to that of the amputees, we can expect a smaller vertical and larger mediolateral displacement of the COM for non-amputees, which might decrease the differences between the two groups. But, in such conditions, the larger COM vertical displacement might be related to the vaulting of the amputees, and their greater mediolateral displacement might be due to their wider base of support.

Note: Amputee number 8 had a greater mediolateral COM Mediolateral displacement of the IL stride and both limbs' stance during the with insole session, which corresponds to his Trendelenburg gait pattern.

COP mediolateral displacement: The displacement, during the stance phase of non-amputees' limbs (~0.05 m), was not significantly different in the amputees. But, the displacement for the intact foot of amputees (0.056 m) was greater than that of the prosthetic foot (0.04 m). The biological foot has a more flexible structure in comparison to the almost rigid nature of the prosthetic foot, the shape of which undergoes minimal change to its breadth during weight bearing, and a smaller mediolateral displacement of the COP is expected. As the mediolateral displacement of the COP is considered a balance-related feature for LLAs (Kendell et al., 2010), the observed similar displacement indicates their proper dynamic balance.

The results support a part of hypothesis number 3 as the mediolateral displacement of the IL was larger than the PL. The difference between the mediolateral displacement of the COP for non-amputees' right and left limbs was not significant (hypothesis number 4). Hypothesis number 5 (existence of differences between amputees and non-amputees) is rejected because the differences between the two groups were not significant.

COG-BOS lateral border distance at mid-stance: The results of the COG-BOS' lateral border distance at mid-stance do not support hypothesis number 3 (existence of differences between intact and PL of amputees). They do, however, support hypotheses number 4 and number 5 (no difference between both limbs of amputees and significant differences between non-amputees and amputees). This relationship might be considered a criterion for stability during walking (Nagano and Begg, 2018). In this study, the relationship at mid-stance as a moment in the single support period was evaluated. A larger distance was observed for both amputees' limbs' stance in comparison to non-amputees (~0.11 m for IL and 0.13 m for PL vs ~0.1/0.09 m for non-amputees, Table 4.14) which might be the result of efforts to achieve a stable condition. The wider steps of the amputees indicate outward placement of their foot, which also increases the distance. This may be a strategy to maintain balance during walking.

COP-BOS lateral border distance: No significant difference was seen between the limbs and groups in terms of the COP-BOS lateral border distance (~0.04 com for all limbs). As the lateral position of the COP in the base of support is associated with a higher level of instability (Kendell et al., 2010), this result might be interpreted as the strategy of foot placement (including wide step) by the amputee participants to gain a balance close to that of the non-amputees at mid-stance.

Not seeing a significant difference between the distance between the COP-BOS' lateral border at mid-stance of limbs/groups supports hypothesis number 4 (difference between limbs of non-amputees). However, it does not support hypotheses number 3 (difference between limbs of amputees) or number 4 (difference between amputees and non-amputees)

The insoles use did not have an effect on any of the variables related to the COP and COM except the COP-BOS lateral border distance. This variable had a slight increase in all limbs but the statistical analysis showed a meaningful increase of the distance for non-amputees' right limb after insoles use. The right leg was the dominant side of all non-amputees and, probably, the small medial support of the insoles provided a proper bed for the foot to bear the weight more on the medial side of the foot and, consequently, increase the distance of its COP position to the BOS lateral border.

The undetected effect of the insoles on the COM and COP variables supports hypothesis number 6 (similarity between two limbs of amputees did not change) but does not support hypothesis number 7 (change of difference between IL of amputees and non-amputees limbs).

Ankle angle: The pattern of the ankle joint angle in the sagittal plane corresponds to previous studies (Seroussi, R. et al., 1996); (Segal, A.D. et al., 2006; Grimmer and Seyfarth, 2014). The range of motion of the ankle in the sagittal plane for the IL of amputees was similar to non-amputees (~26 Deg. vs ~27 Deg., Table 4.15). Nine out of 10 amputees used single-axis prosthetic feet, which provide a limited range of motion during the stance phase. Thus, the limited mobility of prosthetic feet (particularly in the terminal stance and swing) has led to a smaller range of motion for this limb (~18 Deg.). None of the significant differences between initial stance's plantar flexion of prosthetic feet and natural feet (~10 Deg. Vs 10.5 for IL and 8.2 for non-amputees' limbs) shows the prosthetic feet successfully were able to successfully replicate the natural motion of the ankle during loading response. The profile of the ankle angle shows that the intact ankle of the amputees remained in plantar flexion for a longer time. It started to be in the dorsi-flexion position at around 40% of the stride (Figure 4.10), while the timing for the prosthetic foot was earlier than 30%, and for non-amputees, it was before 20% of the stride. In spite of the sensitivity of the ankle angles to marker placement, which leads to relatively imprecise interpretations about their function, by combining the ankle angles with their moment profile (Drevelle et al., 2014), we can conclude that the observed difference surely is an indicator of vaulting on the IL of amputees. The terminal stance's dorsi-flexion of IL was smaller than in the non-amputees, which might be the result of remaining plantarflexed for a longer period and having a shorter time to reach maximum dorsi-flexion.

The results support hypotheses number 3 and 4 (existence of differences between intact and PLs of amputees and no difference between both limbs of non-amputees). Hypothesis 5 is partly supported because the only observed difference was between the PL of amputees and both limbs of the non-amputees, in addition to the larger dorsi-flexion of the non-amputees' ankle at terminal stance.

Insoles use was associated with increased initial stance plantar flexion for the non-amputees, which might be due to compression of the insoles shock absorber during loading response. This was not seen in amputees because of their slower speed and, consequently, the smaller loading on the IL, which might not fully compress the shock absorber.

The insoles did not change the similarity between the flexion/extension of neither of the non-amputees ankles; thus, the sixth hypothesis is supported. There was no difference between the flexion/extension of amputees' and non-amputees' IL before insoles use Therefore, the lack of difference between them after insoles use does not support hypothesis number 7.

4.4.2.3 Kinetics

The effects of insoles on the kinetics of walking was evaluated by assessment of the vertical ground reaction force's loading rate, the lower limb joint moments in the sagittal plane and the lower limb joint powers during one gait cycle of each participant.

Loading rate: The force loading rate can affect the impact of the applied load and potentially cause musculoskeletal injuries. In animal studies, it has been reported that a higher loading rate during gait increased the risk of knee osteoarthrosis development due to the resulting stiffening and breaking of the articular cartilage (Ewers et al., 2002). The profile of the vertical GRF during barefoot walking normally has a sudden increase (which is called the initial impact) after heel contact. This derives from the rapid deceleration of the shank and foot after the initial contact of the foot with the ground. Its magnitude is under the influence of walking speed, cadence and stride length (Collins and Whittle, 1989), in addition to the material properties of footwear's heel in shoed walking. Its vanishing was expected due to the shock-absorbing feature of the utilized insoles in this study. In without insoles sessions (S1), the impact was not seen for amputee number 8 due to his lower speed of walking (0.45 m/s). It was not seen for non-amputees numbered 2, 5 and 10, which might be due to the materials used in the soles of their footwear as their speed was more than the average speed of the amputees who had the impact force (1.08, 0.87 and 1.11 m/s vs 0.80 m/s as the average speed of the amputees with impact) and their stride length was also not far from the average of the other non-amputee participants. The prosthetic side of the amputees experienced very early initial impact force. The impact force was not seen after the insoles were used on all the ILs of the amputees and both limbs of 11 non-amputees. As it was not seen as a constant, the loading rate was chosen to evaluate the shock-absorbing effect of the insoles. The loading rate indicates force changes in time. The calculated loading rate was highly variable (Table 4.16). The average of the loading rate was smallest for the PL of amputees (41 N/s.kg) in the without insoles session, and largest for the non-amputees (~100±48 and 81±44 N/s.kg for right and left limbs, respectively), which might have been affected by a higher speed. The average loading rate decreased to almost the same for non-amputees (71±42 and 61±32 N/s.kg for right and left limbs, respectively) and the IL (from 77±27 N/s.kg to 67±31 N/s.kg) after insoles use. The higher loading rate of the IL in comparison to the PL has been reported for TT amputees in the early stages of receiving a prosthetic device after amputation. This decreased in the long term of prosthetic walking. However, in the same study, TFAs experienced a higher IL loading rate being continuously present (Pruziner et al., 2014). In spite of the insoles effect on eliminating the impact force from the GRF profile of amputees' IL, the loading rate reduction was significant only for the non-amputees group, which corresponds to previous studies on using insoles for healthy subjects (Jafarnezhad Gero et al., 2015). As non-amputees had a higher speed, this effect of the insoles might be seen in higher speeds of amputees, too.

The differences between the loading rate of the PL and IL of amputees during the without insoles sessions support hypothesis number 3. The similarity between the loading rate of both limbs of non-amputees before insoles use and after it supports hypotheses numbered 4 and 6. The lower loading rate of the PL than on non-amputees' limbs supports hypothesis number 5. There was no difference between the loading rate of the amputees' IL and non-amputees before insoles use Therefore, this lack of difference is not supporting evidence for hypothesis number 7.

Ankle moment in the sagittal plane and ankle power: The ankle moment pattern in the sagittal plane for both limbs of the amputees and non-amputees had the typical patterns mentioned in the literature (Winter, 1987; Sjodahl et al., 2002; F Farahmand et al., 2006; Vanicek, N. et al., 2009a; Drevelle et al., 2014). There was a visible hump on the average plantar-flexor moment diagram of the IL of amputees, while a less marked one on the non-amputees' limbs. It is an indicator of vaulting (Drevelle et al., 2014), which was seen in the sagittal plane's ankle joint moment of all amputees' IL and in five non-amputees (numbers 2, 7, 8, 10, 14). The vaulting might be a habitual pattern (especially in non-amputees) or a way to secure foot clearance of the contralateral limb (a probable reason for the lower limb amputees). The PL had a dorsi-flexor moment similar to the IL and to the non-amputees' limbs (0.23 N.m/kg vs 0.24 N.m/kg for IL and 019/0.20 N.m/kg for non-amputees right/left limbs). The increased dorsi-flexor moment of the IL after insoles use (0.29 N.m/kg) resulted in a significant difference with the PL (0.22 N.m/kg), in addition to the non-amputees' limbs (0.21 N.m/kg), but not to its own magnitude in the without insoles session. The insoles probably transferred the GRF line of action to a more posterior position. Consequently, this produces a greater external plantar-flexor moment, which needs to be controlled by a larger internal dorsi-flexor moment. The initial dorsi-flexor moment of the PL was prolonged beyond 20% of the gait cycle (vs 10-15% for IL and non-amputees' limbs). This might be due to the resistance of the dorsi-flexor bumper in a single-axis prosthetic foot, and the locked prosthetic ankle, which is not able to have motion toward dorsi-flexion in the SACH foot (Winter, 1987). The ankle plantar-flexor moment in the terminal stance was largest for the non-amputees' limbs (1.43 N.m/kg) and smallest for the PL (1.05 N.m/kg). The smaller moment produced by the prosthetic device is due to the lack of plantar-flexor muscles and then its inability to plantar-flex at push-off (Winter, 1987; Seroussi, R. et al., 1996). But the intact side did not exhibit a stronger push-off ankle moment than in the non-amputees. This corresponds with the shallow depth of its vertical GRF, valley which is considered to be related to the strength of the push-off (Richards, 2008). The insoles use was associated with the reduction of this moment in the IL (changing from 1.3 N.m/kg to 1.26, p=0.033) and the PL (changing from 1.05 N.m/kg to 0.99, p=0.006) of amputees. The reduction was seen across the entire moment profile after insole use, which might reflect the effect of a decrease in walking speed during with insole use.

The observed smaller ankle plantar-flexor moment of the PL supports hypothesis number 3. The similarity between the two limbs of the non-amputees during both insoles sessions support hypotheses 4 and 6. The moment has a smaller magnitude for both limbs of the amputees in comparison with non-amputees, which supports hypothesis number 5. The insoles use was associated with a reduction of the moment of the IL which increased its deference with non-amputees. Therefore, hypothesis number 7 is rejected in this case.

The power generated and absorbed by amputees both ankles were smaller than non-amputees (

Table 4.20). However, the differences was significant only when comparing both the power peaks of the PLs with non-amputees (AP1:-0.5 W/kg and AP2: +0.37 W/kg vs 0.9 W/kg and 2.4 W/kg), in addition to its power generation with the IL (AP2: +0.37 W/kg vs 2.22 W/kg). The plantar-flexor muscles, which do not exist in the prosthetic foot, have a main role in ankle power absorption during mid-stance (eccentric contraction) and power generation in terminal stance (concentric contraction). Therefore, the observed small ankle powers of prosthetic feet might be caused just by the type of materials used in the prosthetic foot. Although (Seroussi, R. et al., 1996) reported that the power of the IL was greater than in non-amputees. This might be due, in the current study, to the slower walking speed of the participants and their smaller push-off moment. The ankle power absorption of non-amputees' right limb increased after insoles use.

Hypothesis number 3 is partly supported due to the lack of difference in terms of AP1 between the two limbs of the amputees and the record of a smaller AP2 for the PL. Hypotheses number 4 and 5 are supported due to the similarity of both the non-amputees' limbs, in addition to a smaller AP1 of both limbs of the amputees, and a smaller AP2 of PL compared to the non-amputees. The non-amputees' left ankle had a larger power absorption, which led to the rejection of hypothesis 6. The insoles use did not change the ankle powers of the IL and, therefore, hypothesis number 7 is not supported.

Knee moment in the sagittal plane and knee power: The four established peaks of knee moment were identifiable in the profiles of all the limbs, but their magnitudes were highly variable (with a standard deviation of around 50% or more of mean values). The non-amputees had a larger extensor moment at early mid-stance (K1: 0.56 N.m/kg vs 0.32 N.m/kg for the IL and 0.22 N.m/kg for the prosthetic knee), which resulted from the eccentric contraction of the extensors. However, the difference between the K1 of limbs was only significant in the prosthetic knee. It shows how the amputees attempted to keep knee stability through controlling the GRF vector close to the knee joint, which happens due to the absence of knee flexion in a prosthetic knee and the smaller knee flexion of the IL, in addition to the knee flexor and extensor muscles co-contracting. This helps amputees to prevent knee collapse at the initial part of the stance. The stance flexor moment started earlier (before 30% of the stride vs after 30%, for non-amputees) and was prolonged and larger for the IL (K2: 0.29 N.m/kg vs 0.17/0.15 N.m/kg for non-amputees). The amputees presented a vaulting pattern on the IL during the same period of time, which is an indicator of a more anterior position for the GRF line toward the knee joint (due to prolonged ankle plantar flexion, which is associated with keeping the shank back) and which needs higher knee flexor muscle activity to confront it. The flexor moment of the PL is due to the resistance of the extension stop component of the prosthetic knee against the knee hyperextension. The statistical analysis did not show any significant difference between the extensor moment peaks before the swing phase of the limbs (K3), which is related to the knee extensors control of the flexion of the knee. The terminal swing flexor moment was negligible (K4: 0.05 N.m/kg vs 0.23 N.m/kg for IL and amputees' limbs) for the prosthetic side due to the mechanism of the prosthetic device, which permitted the knee extension to prepare the limb for heel contact. A small flexor moment was seen in the non-amputees and IL, which was produced by the eccentric contraction of the knee flexors to control the extension of the knee before initial contact.

Hypothesis number 3 is partly supported due to the detection of a smaller K1 and K4 for the PL compared to the IL. The similar knee moments of both limbs of the non-amputees support hypotheses number 4 and 6. But the larger K2 for IL and the smaller K1, K3 and K4 of PL in comparison to the same moment of non-amputees partly support hypothesis 5. The insoles use reduced the K2 of the IL and non-amputees insignificantly, but it led to support for hypothesis number 7.

Knee power generation and absorption were negligible for the PL (except around -0.6 W/kg power absorption before toe-off (KP3), which is related to energy absorption by the knee damper). These are because the prosthetic knee presents very small joint moments during the stance, and then it remains in full extension, then moves at low angular speed. The reason of observing a near to zero power absorption at the terminal swing of the PL (which corresponds with its close to zero flexor moment at the same time) was because of the slower movement and lighter weight of the prosthetic shank (Winter, 1987), in addition to its small moment at this time. The IL also presented a smaller power absorption at the initial stance (KP1: -0.4 W/kg vs -0.6 W/kg for non-amputees) and terminal swing (KP4: -0.75 W/kg vs ~-1 W/kg for non-amputees), in addition to a smaller power generation (KP2: +0.38 W/kg vs +0.67/0.61 W/kg for non-amputees' right/left knees). But, it had a large power absorption during the terminal stance-initial swing (KP3: -1 W/kg vs -0.8/-1 W/kg for non-amputees' right/left knees). However, the differences between the IL and the non-amputees' knee powers were not significant due to the high level of variability (SD >50%-100% of mean values). Interestingly, the profile of the IL's knee power resembled the profile reported for the affected limb of TT amputees (Vanicek, N. et al., 2009a). This might show the function of the intact knee of TF amputees has a level of functionality more similar to the affected limb of TT amputees than the knees of non-amputees. The insoles use had no effect on knee powers.

Hypotheses number 3 and 5 are supported by the smaller knee powers of the prosthetic knee in comparison to the IL and non-amputees. The similarity of both of the non-amputees' limbs' knee moments supports hypotheses number 4 and 6. The insoles effect on knee powers was not significant; therefore, hypothesis number 7 is not supported.

Hip moment in the sagittal plane and hip power: The IL of the amputees had a prolonged extensor hip moment, which is consistent with the results of previous studies (Seroussi, R.E. et al., 1996; Nolan, L. and Lees, 2000; F Farahmand et al., 2006). It shows the concentric contraction of the hip extensors extended to late mid-stance. A large hip extensor moment at the initial stance of the IL was reported by (Seroussi, R. et al., 1996) as an adaptation to assist lower limb amputees' walking. Although the magnitude of the hip extensor moment for the IL was larger than on the affected side, it was smaller than the non-amputees in this study (H1: 0.7 N.m/kg vs 0.81/0.77 N.m/kg for right/left hips of non-amputees). In addition, (Winter, 1987) reported a larger hip extensor moment of the affected limb at initial stance (contrary to this study and (Seroussi, R. et al., 1996), and interpreted it as a strategy of TF amputees to use the hip extensors to keep the prosthetic side in an extended locked condition for safe weight bearing on the prosthetic device. In our study, the prolonged extensor moment corresponds to the vaulting pattern of amputees' walking, and its smaller magnitude might be due to the passage of the GRF line being closer to the hip joint. The extensor moment was followed by a flexor moment controlling the hip extension at the end of the stance, which was smallest for the IL (H2: ~0.4 N.m/kg vs ~0.5 N.m/kg for the affected limbs of amputees and ~0.6/~0.7 N.m/kg for the right/left hips of non-amputees). This small flexor moment is a consequence of the prolonged hip extensor moment at the initiation of the stance, which remained for more than 70% of the stance phase (Seroussi,

R. et al., 1996). The observed larger flexor moment of the prosthetic side in comparison to the IL coincided with its smaller ankle plantar-flexor moment. This has been linked to a compensatory role of the hip extensors to make up for the lack of a plantar-flexor muscle propulsion act in the terminal stance (Rietman et al., 2002). In addition, the smaller hip flexor moment in both limbs of amputees shows the GRF passed posterior to the hip joint, but its distance was closer to the joint. It seems one strategy of TF amputees for maintaining their stability is regulation of the GRF line close to the joint centres. The extensor hip moment at the terminal swing of the amputees' affected the limb (which is a result of the eccentric contraction of the hip extensor muscles used to control hip flexion) was almost half of other limbs (H3: 0.12 N.m/kg vs 0.22 N.m/kg for IL and 0.21 for non-amputees' limbs). It corresponded with the smaller hip flexion of this limb and, thus, the smaller eccentric contraction of the hip extensors. Insoles use had no effect on the hip moments of any of the limbs.

The observed differences relating to H1, H2 and H3 of the residual limb and the IL support hypothesis number 3. The similarity of the hip moments of both of the non-amputees' limbs in both insoles sessions support hypotheses number 4 and 6. The recorded differences between the residual and ILs of amputees and non-amputees support hypothesis number 5. Insoles use did not lead to a decrease in the differences between hip moments of the amputees and non-amputees. Accordingly, hypothesis number 7 is rejected.

The joint is extended due to the concentric contraction of the hip extensors at the initial stance; thus, the observed hip extensor moment coincides with hip power generation (HP1). HP1 was largest for the IL of amputees (0.82 W/kg vs 0.33 W/kg for affected limb and ~0.5 W/kg for non-amputees' limbs). (Seroussi, R. et al., 1996) supposes that, as it coincides with the weak push-off of the PL, it helps to compensate for that and helps the forward movement of the body. The same applies to the extensor hip moment at initial stance, the magnitude of the affected limb's HP1 in our study, and the fact that what (Seroussi, R. et al., 1996) reported was much smaller than what (Winter, 1987) did. He explained it as the hip extensors acting to produce propulsion energy. On the other hand, (Vanicek, N. et al., 2009a) observed a smaller HP1 in the prosthetic side of TT amputee fallers compared to non-fallers. This similarity might be considered a negative sign for our TF amputee participants. The eccentric co-contraction of the hip flexors resulted in HP2 power absorption, which was smallest for the IL of amputees (-0.17W/kg vs -0.43 W/kg for the affected limb and -0.31/-0.36 W/kg for non-amputees' right/left limbs). The large affected limb's HP2 is due to the lack of knee flexion during the stance phase and the consequent placement of the amputee's COM posterior to the joint, which needs a larger flexor moment to pull the body over the extended leg (Seroussi, R. et al., 1996). The IL showed greater power generation by the hip flexor muscles in the terminal stance during the without insoles session (HP3: ~0.9 W/kg vs ~0.5 W/kg for the affected limb and ~0.7/0.85 W/kg for the non-amputees' right/left limbs). This power after AP2 is important for the propulsion of the limb. The power is smallest on the affected side (unlike (Winter, 1987) and (Seroussi, R. et al., 1996), which show, in spite of the role of the hip flexors at terminal stance propulsion, they were not able to produce a push-off as powerful as normal limbs. The insole use did not significantly increase the power of the non-amputees limb and slightly decreased the power of the amputees.

Hypotheses number 3 and 5 are supported by the larger hip power absorption and smaller hip power generation of the residual limb in comparison to the IL and the non-amputees. In addition, the larger first hip power generation of the IL compared to the non-amputee limbs. The similarity of both of the non-amputees' limbs' hip powers during both insoles sessions supports hypotheses number 4 and 6. The changes resulting from insoles use were not significant for any limb. Therefore, hypothesis number 7 is not supported.

The pattern of joint moments in the sagittal plane and the joint powers in this study were similar to previous studies investigating the biomechanics of above-knee prosthesis users' walking. However, the magnitude of peaks was smaller in this study, which might be due to differences between participants in terms of age, speed of walking, prosthesis components and time since amputation (Winter, 1987; Seroussi, R.E. et al., 1996; Nolan, L. and Lees, 2000; Sjodahl et al., 2002; F Farahmand et al., 2006; Drevelle et al., 2014). It is worth remembering that the amputees in this study had slow walking speeds, decreased step lengths, increased double support time, and increased stance time, which are considered to connected to a lack of increased moments at the contralateral lower limb joints (particularly, the knee joint) (Berke et al., 2008). In addition, the vaulting pattern of their walking influenced their IL joint moments and powers. The propulsive powers (AP2, KP3 and HP3) of the IL had large SD and was not greater than in non-amputees. It is suggested that their adaptation to prosthetic use was not associated with the compensatory power mechanisms in the propulsion phase (Vanicek, N. et al., 2009a). However, the compensatory role of the IL hip extensors for weak propulsion of the PL was seen in the form of a greater HP1 coinciding with the terminal stance of the affected limb, which helps the pelvis to forward transition (Seroussi, R. et al., 1996).

4.5 Summary and Conclusion

This chapter aimed to present the biomechanics of TF amputees' walking, comparing them with a non-amputee control group, and to investigate the probable effects of insoles use on the two group's gait as a routine activity. The level of functionality of the amputee participants and the homogeneity of the sample were evaluated based on the participants' spatio-temporal variables.

The general response of the spatio-temporal variables was similar to previous studies of lower limb amputees walking. The main features of the amputees' gait were slower speed, resulting from longer temporal and shorter spatial variables, and spending a longer time on their IL (resulting in a longer stance and double supports and a longer prosthetic swing phase and step). The functional level of the non-amputees was higher, according to the spatio-temporal features and symmetry of their walking, while the amputees' level was lower and, according to the self-reported PEQ-Mobility questionnaire and ABC scale scores, they had a moderate level of functioning (except amputee number 8, with a low level). The lower level of functionality for the lower limb amputees compared to the non-amputees is common. The spatio-temporal variables of the two limbs were asymmetrical, but the observed asymmetry in the lower limb amputees' walking is part of their adaptation strategy and, thus, is acceptable, according to the literature. The amputee participants in this study used mechanically passive knee prosthetic devices and conventional feet (including SACH and single-axis prosthetic feet), which are the most commonly used prostheses components for lower limb amputees (Versluys et al., 2008). On the other hand, it has been reported that the spatio-temporal variables of the two main mechanically controlled prosthetic knees (with constant friction and the hydraulic knee) did not make any significant difference to the slow walking speed (Murray et al., 1983). It should be noted that the amputee participants in this study had had long experience of prosthetic device usage (with a range of 19-46 years) and had worn prostheses without active control or advanced technologies; therefore, their walking pattern was a reflection of their adaptation to the amputation and provided an acceptable sample for the study of above-knee prosthetic users.

This fact must be kept in mind that the neuromuscular control of the knee and ankle of the amputated limb does not exist in TF amputees, and their control of the hip joint decreases due to the loss of muscle and the lever arm (the length of the femur) resulting from amputation. Hence, most of the compensatory adjustments will be seen in the IL (Winter, 1987).

The results of this study indicate the effect of insoles on several biomechanical variables. The COP-BOS lateral border distance increased in the non-amputees' right (dominant) limb after using insoles. The greater distance is considered to be a better balance condition. The insoles increased the plantar flexion at the initial stance for the non-amputee participants. This might have been due to the compression of the heel shock absorber. The insoles decreased the vertical loading rate of the non-amputees, who had a higher speed compared to the amputee participants. As walking is repeated thousands of times in the routine life of every human, and the lower limb amputees rely more on their ILs, the positive effect of insoles use in removing the impact force on the IL might be beneficial for preventing overuse of and repetitive stress injuries to this limb. However, the effect of insoles on joint powers seemed complicated and inconsistent, which shows the need for more investigation into the effect of insoles use on other biomechanical variables, such as muscle activities. It is worth remembering that the propulsion powers (AP2, KP3 and HP3) of the PL had the smallest magnitude among the limbs. This is not surprising because of the use of passive prosthetic devices by the participants. The adaptation in the IL was observed in the form of larger KP3 and HP3 than in non-amputees. The AP2 for the IL was smaller than in non-amputees but the difference was not significant, which shows its normal role. To have the largest magnitude of HP1 (which is an indicator of the extensor muscles' concentric contraction) in the IL might be considered another adaptation of the TF amputee participants in this study. It shows that they relied extensively on their hip extensor muscles to provide limb stability during the initial stance. The insoles did not affect these main powers. Instead, a reduction was seen in the plantar-flexor moment of the IL after insoles use. The insole use led to increased dorsi-flexor moment differences between limbs. An increase was observed in the ankle power absorption of non-amputees' right limb after insoles use. The insole use decreased the variability of the hip flexor moment in non-amputees and, consequently, its difference, with the IL smaller moment increasing. Among powers, only the ankle power's absorption of the non-amputee's right limb increased after insoles use.

In spite of observing very limited evidence of insoles effectiveness on the biomechanical variables, the participants admitted to having felt better after the long-term (four weeks) use of the insoles, according to the qualitative self-reporting evaluation of the insoles (Table 4.23). Thought-provoking, (Castro et al., 2014) observed greater pressure in the latter and mid part of the IL of TF amputees' foot soles during their stance. It has been reported that insoles with a high medial wall corrected the alignment of the rear/forefoot in persons with flat foot (Dehghani and Saeedi, 2015). The mechanical effects of insoles might include their support for the feet's neutral structure, providing even pressure distribution and reducing impact in walking (Hatton, A.L. et al., 2013). Hence, and as the main outdoor activity of the participants was walking, the reported positive feeling after long-term use of the insoles (with their short heel cap and medial arch, the initial effects of which can be on the rear and midfoot) might be due to their providing better foot pressure distribution. Therefore, the positive view of the participants might have been derived from either the effect of the insoles on non-studied variables (such as muscle activities) or changes in the current biomechanical variables, which might be seen after long-term use of the insoles. Particularly regarding amputees who have established motion strategies to adapt to limb loss and prosthetic device usage and who received their first prosthetic device many years earlier, more time may be needed for them to adjust to a small intervention such as insoles. It is also possible that the insoles had positive psychological effects on the participants or they had been unaware of mild feet issues, such as mild/flexible flat foot, which were reformed by the insoles, and which led to their positive judgment about them. In my opinion, it is worth considering the insoles as a less expensive and easier intervention in the support of the IL and as assistance contributing to the improvement of functionality in lower limb amputees. Surely, the effectiveness of insoles needs further clinical and biomechanical evaluation.

Finally, it is worth remembering that the replacement of lost parts with an artificial limb for LLAs requires adjustments so that they may utilize a device integrated with the body and which is not under the control of the biological system. Lower limb amputees learn how to use their prosthetic devices and their IL to optimise their locomotion. Normally, amputees receive a gait training program after receiving their first prosthesis. It is fascinating to know that amputees number 2 and 8 did not have training for walking after receiving their first prosthetic devices (according to their answers to the survey questions). Amputee number 2 did not have any particular walking deviation, which differentiated him from the other amputee participants. But, according to his answer to the survey, he was the only participant with a high level of worry about falling, and he had experienced six falling experiences during the 12 months prior to the study, which was the highest number of falling events among the four faller participants. Amputee number 8 had several walking deviations (bent slightly forward, bending laterally on both limbs but more prominently on the prosthetic limb during the single support phases) and a lower functional level. He also had outlier values in the amputee group for mediolateral COM displacement. These might be key points, and they must be specifically considered in lower limb amputees' gait training. As for gait training, different studies have shown that walking re-educational programs (Sjodahl et al., 2002), treadmill training (Darter et al., 2013) and a personalized exercise program with a focus on improving muscle strength and walking endurance (Schafer et al., 2016) improved walking speed, symmetry of walking, and the function of both limbs in terms of joint powers and moments in experienced lower limb amputees. It is worth remembering that proper rehabilitation programs are more effective than prosthetic components in the improvement of lower limb amputees' walking (Jarvis et al., 2017). Accordingly, it is suggested that, in addition to the necessary walking training after receiving a prosthetic device, it would be beneficial to perform regular walking assessments and offer retraining programs (including those for muscle strength and walking deviation corrections) to improve walking among LLAs. It might be beneficial to add insoles to such rehabilitation programs, particularly in the early stages of receiving a prosthetic device and in gait training. Additional foot assessment or the provision of custom-made insoles might also be needed.

Chapter 5

Study 3-Lower Limb Amputees' Perturbed Standing Balance

5.1 Introduction

Improved life expectancy (WHO, 2016), age-associated vascular problems (Fowkes et al., 2017), a growing rate of people with diabetes (WHO, 2017), military conflicts in different parts of the world and severe accidents are associated with different health-related deficiencies, including lower limb amputations. As the primary task of the lower limbs is locomotion, and their absence initially affects this aspect of routine life, there is a heavy focus on the design of prosthetic components and the improvement of the biomechanics and functionality of present designs. It is important to remember that unilateral lower limb amputation also affects the intact limb (IL) as a result of adaptation strategies employed during prosthesis use to compensate for the lack of complete natural performance of the prosthetic device. In addition, lower limb amputees are at a higher risk of falling (Kulkarni et al., 1996; Buckley et al., 2002; Hunter et al., 2017). A major part of biomechanical studies tries to determine the kinematics, kinetics, ground reaction forces (GRF) components and centre of pressure (COP) changes during LLAs' locomotion in order to investigate these adaptations after amputation and after prosthesis use, or to compare and evaluate the biomechanical differences of various prosthetic components (e.g., the ankle-foot and knee joints). In the light of the studies related to the effectiveness of insoles in Chapter 2, and the problems LLAs are facing in their daily lives, which was investigated in detail in Chapter 3, this study was designed to investigate the biomechanical characteristics of perturbed balance in unilateral AK prosthesis users, and to examine the possibility of balance improvement based on the use of insoles in their IL. By increasing the knowledge about effective postural responses, it will be possible to help in falls prevention and in the treatment programs of amputees (Vanicek, N. et al., 2009b). The ability of a person to maintain balance might be tested during a static posture, moving tasks or an external perturbation. Many of the studies related to the balance of LLAs have been conducted during quiet standing on a stable force platform. However, it is reasonable to suggest that falls frequently occur due to the influence of external perturbation or the disturbance of balance. For TF amputees, an external perturbation is challenging as their balance is affected by the lack of muscular control of ankle and knee joints, in addition to the structural deficiency of some muscles working in the hip joint of the affected side. Some studies of balance perturbation have used disturbances of the support surface, such as balance boards or instrumented treadmills, etc. However, these techniques need additional complex and/or expensive equipment, and balance on moving surfaces are not the only challenging situations in which people with balance problems may fall. It has been shown that LLAs face the most difficulties in balance control in the anteroposterior direction (Vrieling et al., 2008b). In this study, therefore, a front/back-pulling load was applied to the waist of participants to act as perturbation of quiet standing in the anteroposterior direction. It could be said to simulate being pushed or being bumped into in a crowd. This perturbation method has been used only in one balance study of below-knee prosthesis users (Curtze et al., 2012), and no similar study has been found related to the assessment of TF amputees' perturbed standing balance. The following three objectives were the main goals of this study, and these will be presented in this chapter:

1- To characterise the biomechanics of perturbed standing balance by evaluating the CoP/COM/net COP displacements and their inter-relationships, the ground reaction force changes, and the ankle and hip moment changes during front/back pulling/releasing load as perturbation conditions;

2- To determine the differences between the perturbed balance of unilateral AK prosthesis users and non-amputees in terms of the mentioned variables;

3- To investigate whether insoles for both sides of non-amputees and the IL of amputees affect these variables?

The following hypotheses were considered based on the aims of this chapter:

1- There are significant differences between "paired biomechanical variables (related to both lower limbs)" including:

- The amplitude of each limb's COP displacements (in anteroposterior and mediolateral directions)
- The amplitude of distance between each limb's COP and COG
- The amplitude of each limb's GRF (anteroposterior, mediolateral, vertical forces)
- The load sharing of each limb one second before load release (anteroposterior, mediolateral vertical forces)
- The load sharing of each limb five seconds after load release (anteroposterior, mediolateral vertical forces)
- The amplitude of the joint (ankle and hip) moments in the sagittal plane due to load release
- The contribution of the ankle and hip of each limb in the SUM moment one second before load release
- The contribution of the ankle and hip of each limb in the SUM moment five seconds after load release

of the IL and prosthetic limb (PL) of amputee participants in each perturbation condition, without insoles (comparing the IL and PLs of amputees).

2- No significant differences exist between the "paired biomechanical variables (related to both lower limbs)" (mentioned in hypothesis 1) of the amputee participants' limbs in standing balance against a back-pulling load and front-pulling load (comparing two perturbed standing balance conditions of the amputees) in without insoles condition

3- There are no significant differences between the “paired biomechanical variables (related to both lower limbs)” (mentioned in hypothesis 1) of the right and left limbs of the non-amputee participants in each perturbation condition in without insoles condition (comparing the right and left limbs of non-amputees)

4- No significant differences exist between the “paired biomechanical variables related to both lower limbs” (mentioned in hypothesis 1) of the non-amputee participants’ limbs in standing balance against a back-pulling load and front-pulling load (comparing two perturbed standing balance conditions of non-amputees) in without insoles condition

5- There are significant differences between the “paired biomechanical variables related to both lower limbs” (mentioned in hypothesis 1) of non-amputee and amputee participants’ limbs in each perturbation condition (comparing the balance of amputees and non-amputees in two perturbation conditions)

6- No significant differences exist between the “individual biomechanical variables” including:

- The amplitude of the COM displacements (in anteroposterior and mediolateral directions)
- Amplitude of the net COP displacements (in anteroposterior and mediolateral directions)
- Amplitude of the distance between the COP of the two feet
- Amplitude of the Sum moment

of amputee participants in standing balance against a back-pulling load and front-pulling load (comparing two perturbed standing balance conditions of amputees) in without insoles condition

7- No significant differences exist between the “individual biomechanical variables” (mentioned in hypothesis 6) of the non-amputee participants in standing balance against a back-pulling load and front-pulling load (comparing two perturbed standing balance conditions of non-amputees) in without insoles condition

8- There are significant differences between the “individual biomechanical variables” (mentioned in hypothesis 6) of non-amputee and amputee participants in each perturbation condition (comparing the balance of amputees and non-amputees)

9- The use of insoles does not change the “paired” and “individual” biomechanical variables (listed in hypothesis 1 and 6) of non-amputees in each perturbation condition

10- The use of insoles leads to the reduction of the observed differences between amputees' IL's paired biomechanical variables (listed in hypothesis 1) and their "individual biomechanical variables (listed in hypothesis 6) with non-amputees in two perturbations and without insoles condition

5.2 Methodology

The inclusion/exclusion criteria, participant recruitment procedure and their characteristics, in addition to the selected insoles features have been explained in Chapter 4, the Methodology section.

5.2.1.1 Participant data

The characteristics of the participants have been presented in the "Participants' data" section of Chapter 4.

All the amputee participants in the biomechanical study replied to the survey questions (presented in Chapter 3). In spite of the small size of the sample, which makes statistical analysis ineffectual, some facts can be derived about their balance and function from their responses in the survey. The results related to the PEQ-M and ABC scale questionnaire have been discussed in Chapter 4. Table 5.1, indicates that the amputee participants in the biomechanical tests had fewer problems and better PEQ scores than the average data of the participants in the survey (Chapter 3). However, the trends were similar; for example, those with pain (two subjects had phantom pain and three had phantom and stump pain) had relatively poor balance scores compared to those without pain. The majority of the participants (seven out of 11) had IL pain, and the ABC score was higher than 80 for those who did not suffer this pain.

Nine out of 11 participants were worried about falling, five of them reported a falling experience in the previous 12 months, and the same number had ABC scores <67 (at risk of falling).

5.2.2 Procedure

The motion analysis systems and the protocol of the participants' preparation for the biomechanical tests, including marker placement, have been laid out in Chapter 4.

5.2.2.1.1 Test Sessions

As mentioned in the "test sessions" section of Chapter 4, the tests were conducted in two experimental conditions of with and without insoles inside the shoes. Each test session included a range of daily activities, of which results from the standing balance tests are represented in this chapter.

Table 5.1 Relation between the scores and several aspects of the prosthetic use among amputee participants

		ABC score		Oswestry score		Mobility score (PEQ-M)		QOL score		Prosthesis Satisfaction score		Prosthesis evaluation	
		Mean	median	Mean (n)	median	Mean	median	Mean	median	Mean	median	Mean	median
Phantom pain (n)	Yes (2)	65	65	27 (2)	22.2	**4.5***	4.5	**5***	5	**4.54***	4.54	**4.3***	4.3
	No (9)	67.71	72	28.87 (3)	27	**6.86***	7.23	**8.89***	10	**7.89***	8.25	**8.08***	7.96
Stump pain (n)	Yes (3)	**58.75**	61.2	24.67 (3)	30.55	**4.33***	4	**4.67***	4	**5.03***	6	**5.03***	6.48
	No (8)	**70.4**	72.5	33.3 (2)	20	**7.22***	7.3	**9.5***	10	**8.12***	8.35	**8.28***	8.015
Intact limb pain (n)	Yes (7)	**58.22***	59.4	28.12 (5)	22.2	**5.44***	5.77	**7.14***	8	**6.41***	7	7.02	5.82
	No (4)	**87.77***	85			**8.17***	7.73	**10***	10	**8.81***	9.12	8.82	8.69
Falling experience (n)	Yes (5)	64.9	61.2	24.05 (4)	22.1	**5.37***	5.77	**6.4***	8	**6.41***	7	**6.43***	6.51
	No (6)	69.2	72.5	44.4 (1)	44.4	**7.32***	7.3	**9.67***	10	**8***	8.25	**8.2***	8.01
Walking aid use some times (n)	Yes (3)	**49.4***	46.2	28.8 (3)	22	5.33	4.85	7.33	8	6.33	6	6.67	6.51
	No (8)	**73.9***	72.5	27.1 (2)	27.1	6.85	7.3	8.5	10	7.63)	8.25	7.67	8.01
Worried about falling (n)	Yes (9)	**63.1***	61.2	28.12 (5)	22.2	6.16	6.85	7.78	10	7.01	7.75	7.12	7.33
	No (2)	**89.52***	85.9			7.65	7.65	10	10	8.5	8.5	8.63	8.63
LBP (n)	Yes (5)	**55.1***	58.7	28.12 (5)	22.2	**4.72***	4.85	**6***	8	**5.46***	6	**5.97***	6.5
	No (6)	**77.3***	77.5	NA	NA	**7.86***	7.5	**10***	10	**8.79***	8.75	**8.58***	8.48
Risk of falling (n)	High (5)	**53.2***	58.7	27.15 (4)	11.54	5.88	5.77	8	8	7.05	7	7.33	7.02
	Lower (6)	**78.8***	77.5	32 (1)		6.9	7.3	8.33	10	7.47	8	7.45	8.01
Total mean	**N=11**	**67.22**	**68.75**	**28.12 (5)**	**22.2**	**6.43**	**7.15**	**8.18**	**10**	**7.28**	**7.75**	**7.4**	**7.75**

Perturbed standing balance was simulated in backward and forward falling situations: the participants stood against a pulling load under open-eyes and closed-eyes conditions separately, with a comfortable and stable erect posture with feet shoulder-width apart and each foot on one force platform. Two similar pieces of equipment (Iran and Leeds sites) were designed to apply the pulling load to the front and back of the participants' waists during the tests. The participant stood 2-3 m distant from the perturbation system. The design of the equipment was adapted from Curtze et al. (2012) study. There was a cubic aluminium frame (height: 1.05 m, length: 0.8 m, wide: 0.4 m) with a pulley over which a rope was draped and attached to a hanging weight held in place by a release mechanism. Attached to the release mechanism was a second, longer, rope connected to the subject's waist. The release mechanism was an electromagnet component in the Leeds equipment and a mechanical pin in the Iranian equipment. A weight equal to 2.5% of the subject's body weight was used as the pulling load (Curtze et al., 2012) (Figure 5.1).

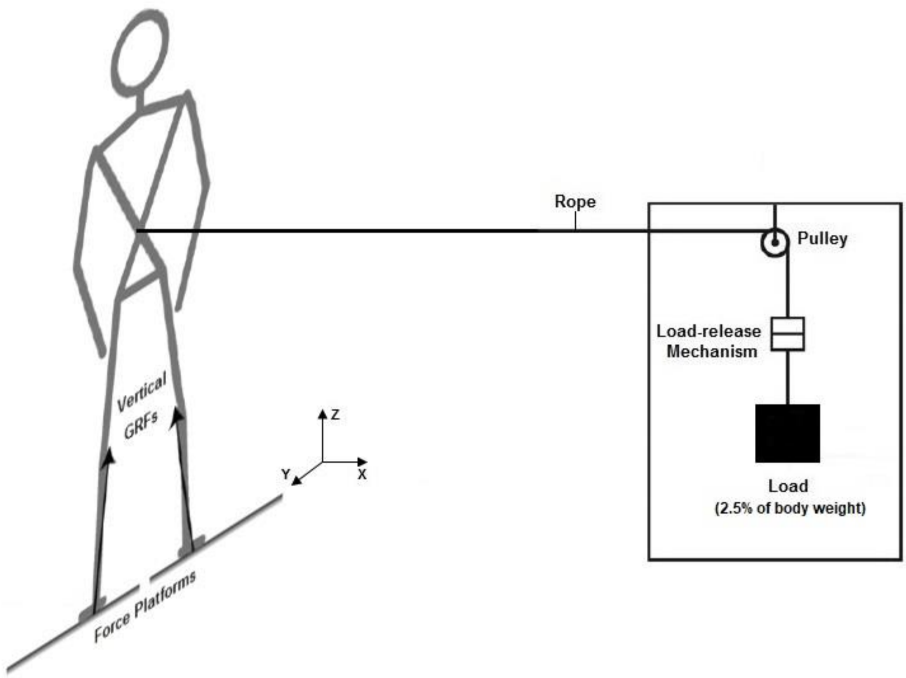


Figure 5.1 Schematic design of front/back-pulling apparatus, adapted from (Curtze et al., 2012)

A marker was attached to the rope to indicate the load release moment in later image processing. The load was released by a test performer 15-30 seconds after the participant had standing balance to simulate perturbation in the form of a backward fall (front-pulling test) or a forward fall (back-pulling test). The participant was asked to continue standing until a rest command was given by the test performer 15-30 seconds following the load release. The whole-time duration was 60-65 seconds for non-amputees and less than 40 seconds for amputee participants due to the difficulty of standing for an extended period of time. Three tests were conducted in each combination of the open/closed-eyes condition and front/back-pulling load applications. A ceiling rail and safety harness were used to prevent possible falls during the tests in the Leeds sessions. In the Iranian sessions, the ceiling rail was not available; thus, a person stood near to the participants to catch them in the case of a possible fall situation.

After each test, to prevent fatigue, the subjects were asked if they needed to take a rest or not. There was a two-minute interval at least between every two tests. A follow-up session was designed to evaluate the long-term (after four weeks) insole use. Participants were asked to wear the same shoes during the follow-up tests. Three above-knee amputees and 11 non-amputee participants completed the follow-up sessions.

An evaluation of the reliability and repeatability of the perturbation system has been presented in Appendix H.

5.2.3 Data Analysis

Data analysis, including marker tracking and body model building, has been explained in Chapter 4.

The open-eyes perturbed standing balance was fully analysed to be presented in this chapter but the results of the closed-eyes tests are not presented here. Each test was monitored after applying the body model in Visual 3D and the tests with foot displacement during the recorded time period were withdrawn. The marker fixed on the rope to identify the load release moment was not recognized in any of the tests; therefore, anteroposterior total force diagrams of each test were used to indicate the load release time instant. A gross and sudden change in the diagram was considered to be the load release point. The duration of the analysis period was considered one second before and five seconds after this time point (Figure 5.2).

The Butterworth low pass filter with a cut-off frequency of 6Hz has been applied to the 3D coordinates of the markers (Winter, 2005), and the same filter with a cut-off frequency of 5Hz was applied to the COP raw data (Bateni, 2013). After defining the events and applying the filter, the appropriate pipelines were executed in the Visual 3D to extract the basic variables (

Table 5.2).

Table 5.2 The basic variables extracted in Visual 3D software

Test	Variables	Description
Standing balance (1 second before load release to 5 seconds after it)	Kinetics	Ankle and hip sagittal/coronal joint moments
		GRF magnitude in 3 directions for each side
	Kinematics	Anteroposterior and Mediolateral displacements of COP for each foot
		COM displacements in sagittal and coronal planes

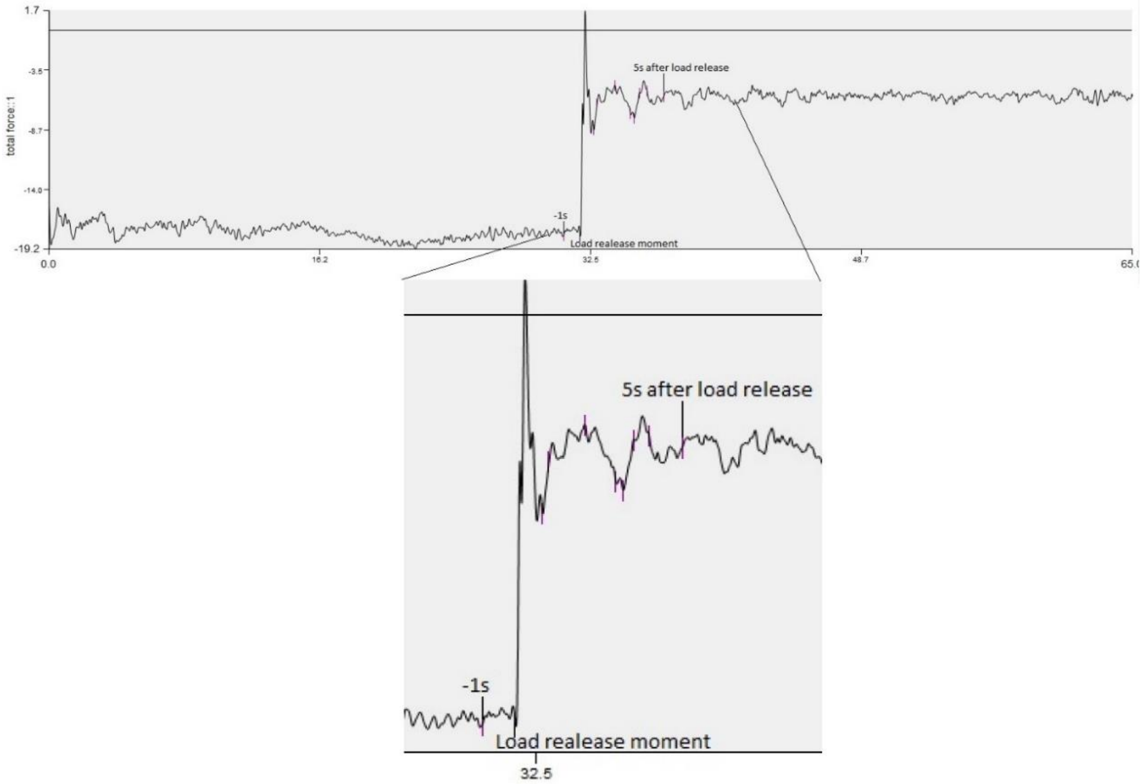


Figure 5.2 Indicating 3 main events in anteroposterior total force diagram in standing balance tests: 1 second before load release, load release moment, and 5 seconds after load release

5.2.3.1 Study's variables

As was mentioned in the literature review, the COP and COM related quantities are traditional variables for the evaluation of balance. The net effect of muscle activity at a joint can be calculated in terms of net muscle moments (Winter, 1995). Motion analysis software computes moments by using kinematics data and ground reaction forces. The hip and ankle joints have key roles in maintaining standing balance without stepping via the ankle or hip strategies. In addition, (Curtze et al., 2012) introduced the Sum of Moment variable to judge the contribution of the ankle and hip moments of both lower limbs to balance, In addition, there is the GRF magnitude (anteroposterior, mediolateral, vertical forces). The final variable (Table 5.3) for comparing participants and test conditions was developed by applying a calculation formula to the basic variables (

Table 5.2) in Microsoft Excel 2013.

The sum moment was calculated as a representative of the role of the hip and ankle in producing the moment in perturbed standing balance. The amplitude for each variable was calculated by the subtraction of its minimum from its maximum values. The Sum moment components were determined by adding the same direction hip and ankle joint moments of both lower limbs (Equation 5.1) (Curtze et al., 2012). X indicates the flex/extension:

$$Sum\ Moment_x = Right\ Hip\ joint\ Moment_x + Left\ Hip\ joint\ Moment_x + Right\ Ankle\ joint\ Moment_x + Left\ Ankle\ joint\ Moment_x$$ **Equation 5.1**

Table 5.3 The final calculated variables for standing balance tests

Variables	Description
Kinetics	Peak value and amplitude of changes for Ankle and Hip Sagittal joint moments
	Peak value and amplitude of changes for Sum Moment in Sagittal/ planes
	Percentage of each ankle and hip joint contribution in Sum moment during Max-Min moment changes in Sagittal/coronal planes
	Peak value and amplitude of changes for GRF magnitude in 3 directions for each side
	Each side contribution in experienced forces during Max-Min changes, 1st second and 5 seconds after load release
Kinematics	Anteroposterior and Mediolateral displacements of right/left CoP
	Anteroposterior and Mediolateral displacements of net CoP
	Anteroposterior and Mediolateral displacement of COM
	The amplitude of changes for COPnet-each foot COP resultant distance
	The distance between COP of right/left feet during 1st second and 5 seconds after load release
	The distance between net COP and COG during 1st second and 5 seconds after load release

The X and Y components of the net COP, as indicators of the anteroposterior and mediolateral displacements of the variable, were calculated from the COP of each foot and the vertical GRF (Equation 5.2 and Equation 5.3) (Winter, 1995):

$$COPnet_x = Right\ COP_x \frac{Right\ GRF_z}{Right\ GRF_z + Left\ GRF_z} + Left\ COP_x \frac{Left\ GRF_x}{Right\ GRF_z + Left\ GRF_z}$$ **Equation 5.2**

$$COPnet_y = Right\ COP_y \frac{Right\ GRF_z}{Right\ GRF_z + Left\ GRF_z} + Left\ COP_y \frac{Left\ GRF_z}{Right\ GRF_z + Left\ GRF_z}$$ **Equation 5.3**

The resulting values were calculated by using the x and y components of the desired variables' coordinates in Equation 5.4:

$$Resultant\ value = \sqrt{(x_B - x_A)^2 + (y_B - y_A)^2}$$ **Equation 5.4**

The normalized displacements of the CoP, COM and net COP are relative values to the initial position of these variables at the point of one second before load release.

5.3 Results

In this study, the biomechanical variables of perturbed standing balance against a front or back-pulling load in TF amputees and non-amputee participants were investigated. The load release, in the front and back-pulling sessions respectively, induced backwards and forward fall tendency. The moderate load (2.5% of body weight) was chosen, assuming it would allow the participants to regain their balance without stepping (Curtze et al., 2012); that is, without completely lifting the foot and repositioning it to change the base of support. However, some of the participants responded to the load release by raising the heel and going on to the toes in back-pulling or by using forefoot raise and going onto the heels in front-pulling on the intact side. The reactive movement of the prosthetic foot, when it occurred, tended to be a turning of the foot or a short relocation movement. The data in cases of relocation of the foot were eliminated.

The biomechanical results of perturbed open-eyes standing balance are presented in two main parts: kinematics (including the results related to the COP and COM) and kinetics (including the moments and forces). The variables were extracted for the time period of one second before and five seconds after perturbation. The tests consisted of: two perturbation conditions – maintaining balance against a back-pulling load (called BB) and maintaining a balance against a front-pulling load (called FB) - and in two insoles conditions - without insoles (called S1) and with insoles (called S2). The mean values of each variable during the repeated tests for each participant were used to compare the two subject groups: insoles use and perturbation conditions. Just as in the level walking tests, as it is a study with an intervention (insoles conditions as pre-post) and with a control group (non-amputees), mixed between-within subjects ANOVA (2 limbs ×2 groups × 2 insoles conditions× 2 perturbation conditions) was utilized to compare groups-limbs-insoles conditions. As follow-up data of only three amputee participants was collected, the comparison between the two groups is conducted for with and without insoles sessions. However, the effect of insoles in the follow-up sessions of 11 non-amputees will be investigated.

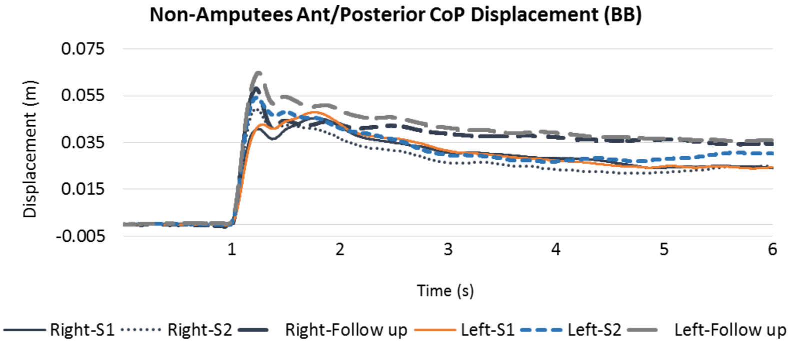
5.3.1 Kinematics

5.3.1.1 COP

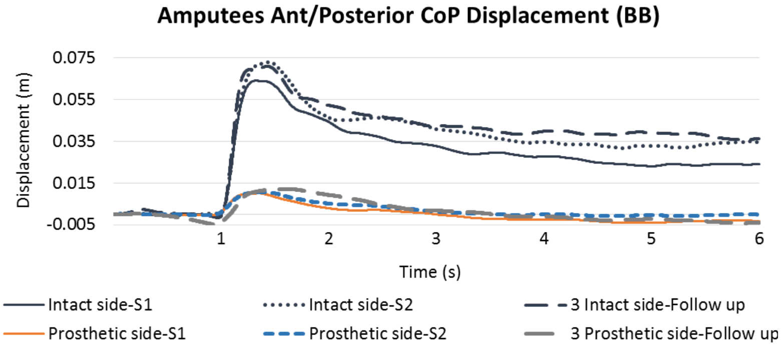
The derived variables related to the COP included the amplitude of COP displacements (the difference between the maximum and minimum values of the COP in the anteroposterior and mediolateral directions) and the linear distance between the right and left centres of pressure.

5.3.1.1.1 COP displacements

Figure 5.3 represents the normalized anteroposterior displacement of the COP (relative to the initial position of the CoP, one second before load release) and shows that in back-pulling balance, the COP position of the non-amputees and the IL of the amputees followed a similar pattern. But the pattern was asymmetrical for the intact and prosthetic side of the amputees. The COP, located in the rear foot and after load release, moved toward the forefoot. After balance was retained, it moved a little backward and remained in front of the ankles. But in the prosthetic side, in addition to the smaller anteroposterior displacement of the COP following load release and the less sharp slope of change, its position changed only during load release and had almost the same position before and after this event (Figure 5.3-B).



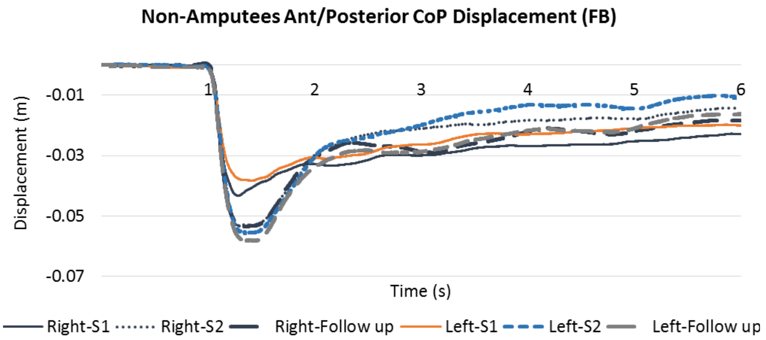
A



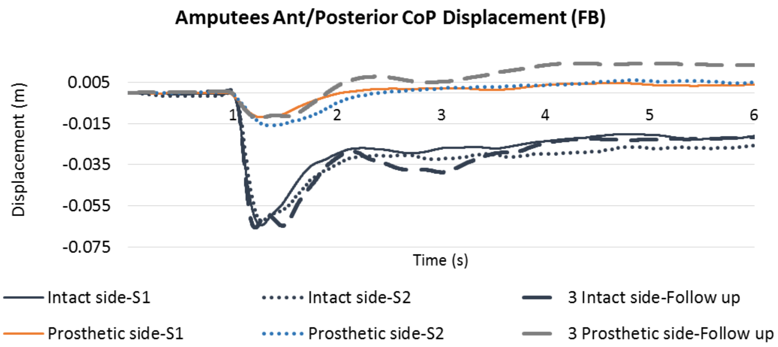
B

Figure 5.3 Normalized anteroposterior COP displacement during back-pulling perturbation, A: Non-Amputees, B: Amputees

The front-pulling perturbation exhibited a contrary pattern. The COP was located in the forefoot and, in reaction to load release, it moved toward the heels and moved forward a little after balance was regained (Figure 5.4). The anteroposterior COP displacement in the prosthetic feet was smaller and the same as the back-pulling balance and the initial/final position was almost the same (Figure 5.4-B).



A



B

Figure 5.4 Normalized anteroposterior COP displacement during front-pulling perturbation, A: Non-amputees, B: Amputees

The mediolateral displacement of the COP in the back-pulling perturbation is shown in Figure 5.5. As expected, the size of the displacement was very small for the prosthetic side of the amputees and it took more time to reach its peak (the shallower slope). But, in spite of the similar pattern of changes, its magnitude seems larger for the IL of the amputees when compared to the non-amputees. Initially, it was located laterally and, after load release, it moved medially.

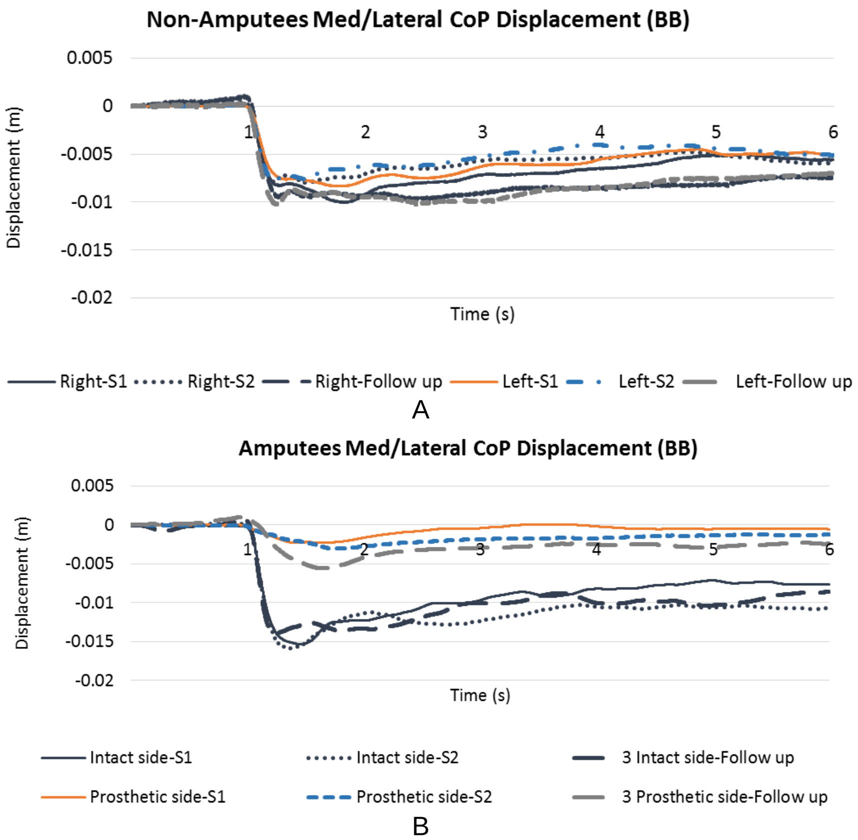
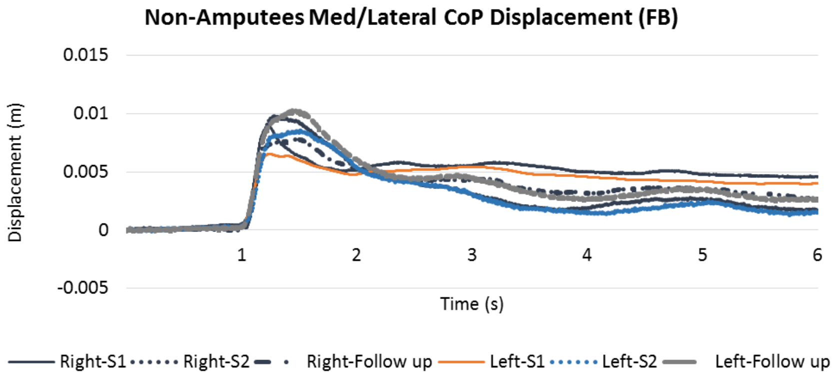


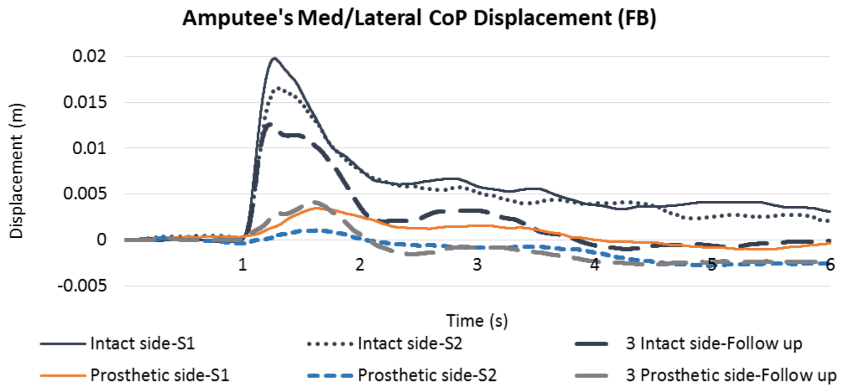
Figure 5.5 Normalized mediolateral COP displacement during back-pulling perturbation, A: Non-Amputees, B: Amputees

In the front-pulling perturbation, the COP in both feet of all participants was initially located medial and moved laterally after load release. As in the back-pulling sessions, the prosthetic side had a very small amount of displacement and took more time to reach its peak (the smaller slope). Again, the amount seems larger for the IL of amputees in comparison to non-amputees. In addition, it seems it move closer to this position before load release (Figure 5.6).

In all tests conditions, the amplitudes of the COP displacements (max-min values) were larger for the IL of the amputees in comparison to the magnitudes on the prosthetic side and of the non-amputees, which indicates the amputees’ obvious asymmetrical COP displacements. The magnitudes of the COP displacements on the prosthetic side were smaller than for the IL of amputees and for both sides of the non-amputees (Table 5.4).



A



B

Figure 5.6 Normalized mediolateral COP displacement during front-pulling perturbation, A: Non-Amputees, B: Amputees

Table 5.4 Amplitude of COP displacements during standing balance against back/ front-pulling loads

			Prturbation condition							
			Balance against back pulling load (BB)				**Balance against front pulling load (FB)**			
		limb	**Ant/post Dis. (m)**	**SD**	**Med/lat Dis. (m)**	**SD**	**Ant/post Dis. (m)**	**SD**	**Med/lat Dis. (m)**	**SD**
Amputees	S1 (n=11)	Prosthetic	**0.021**	0.009	**0.005**	0.003	**0.023**	0.011	**0.009**	0.008
		Intact	**0.076**	0.017	**0.018**	0.011	**0.070**	0.022	**0.023**	0.012
	S2 (n=11)	Prosthetic	**0.019**	0.009	**0.006**	0.003	**0.030**	0.013	**0.007**	0.004
		Intact	**0.077**	0.020	**0.018**	0.010	**0.071**	0.021	**0.021**	0.012
	Follow-up (n=3)	Prosthetic	**0.022**	0.006	**0.007**	0.001	**0.029**	0.022	**0.008**	0.003
		Intact	**0.078**	0.026	**0.016**	0.012	**0.071**	0.010	**0.018**	0.007
Non-Amputees	S1 (n=14)	Left	**0.058**	0.017	**0.011**	0.006	**0.049**	0.016	**0.010**	0.007
		Right	**0.058**	0.023	**0.013**	0.008	**0.055**	0.015	**0.012**	0.007
	S2 (n=14)	Left	**0.065**	0.022	**0.010**	0.005	**0.066**	0.015	**0.012**	0.006
		Right	**0.065**	0.026	**0.011**	0.007	**0.066**	0.021	**0.013**	0.007
	Follow-up (n=11)	Left	**0.071**	0.013	**0.014**	0.008	**0.064**	0.016	**0.013**	0.009
		Right	**0.065**	0.023	**0.015**	0.010	**0.064**	0.016	**0.01**	0.006

S1: without insoles, S2: with insoles, Follow-up: after at least 4 weeks of using insoles, Dis.: displacement

There was a significant difference between the groups' anteroposterior amplitude of COP displacement: Pillai's trace = 0.747, F(3, 20) = 19.72, p<0.001, the partial eta squared effect = 0.75; in addition, between the intact and prosthetic side of the amputees: Pillai's trace = 0.753, F(3, 20) = 20.33, p<0.001, partial eta squared effect = 0.75; and between the insoles sessions of non-amputees: Pillai's trace = 0.774, F(1, 22) = 6.42, p = 0.019, partial eta squared effect = 0.23. The insole use had no effect on the amputees but it increased the displacement in the non-amputee group, and made it more symmetrical between the right and left feet (Table 5.4). When comparing the three sessions of insole use in the non-amputee group (without insoles, using insoles and after at least four weeks' use), there were no significant differences between the anteroposterior displacements of the COP in the back-pulling perturbation ($p=0.655$) and the insoles sessions ($p=0.11$). However, the insoles sessions saw a significant increase in the displacement during front-pulling perturbation: $F= 5.363$, $p = 0.014$, partial eta squared effect = 0.349.

A significant difference was observed between the groups' mediolateral amplitude of COP displacement: Pillai's trace = 0.436, $F(3, 20) = 5.15$, $p = 0.008$, partial eta squared effect = 0.44; in addition, between the intact and prosthetic side of amputees: Pillai's trace = 0.551, $F(3, 20) = 8.19$, $p = 0.001$, partial eta squared effect = 0.55. The amount of mediolateral COP displacement was significantly larger for the IL in comparison to the PL and to the non-amputees' feet (Table 5.4). The insole use did not affect the mediolateral displacement of the COP in two perturbation sessions ($p=0.889$) and groups ($p=0.424$).

5.3.1.1.2 Distance between COP of right/left feet

The distance between the feet COP was calculated by using each foot's COP as a point with x and y coordinates in Equation 5.4. The magnitudes were extracted for the 1st second of balance before load release, five seconds after load release, and the amplitude of its change. These can be considered an estimation of the base of support width and how the weight shifts to the lateral or medial part of the feet in various test conditions. The differences between the amount before and after load release are matched with the observed mediolateral COP displacements. In front-pulling, after the load release, the COP moved medially, which led to a decrease in the distance between the two feet's CoP. In contrast, the COP moved laterally in back-pulling, and the distance increased. The use of insoles decreased the distance but it was not statistically significant (Figure 5.7).

The mixed between-within subjects ANOVA test showed no significant difference between the amplitude of distance changes between the two feet (according to their COP) due to load release in groups, or in the two perturbation ($p=0.108$) and insoles sessions ($p=0.688$) for both groups (Table 5.5).

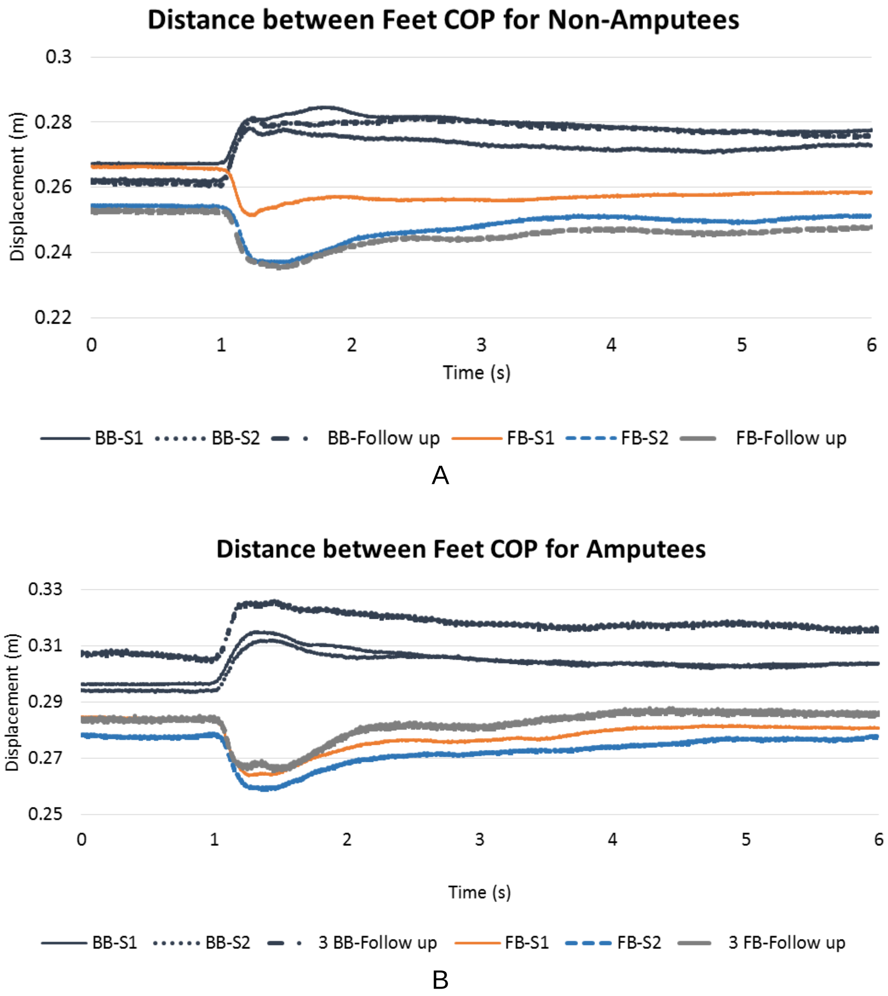


Figure 5.7 Changes of distance between right and left CoP, A: Non-Amputees, B: Amputees (BB: back-pulling balance, FB: front-pulling balance)

The average distance between the two COPs during one second before load release was bigger for the back-pulling tests in comparison to the front-pulling of amputees: Wilks' lambda = 0.77, $F(1, 22) = 6.72$, $p = 0.017$, partial eta squared effect = 0.234. The test showed no significant difference between the variable among groups ($p=0.81$) and insoles sessions ($p=0.106$) (Table 5.6).

Table 5.5 Amplitude of changes in distance between 2 feet's COP

	Test condition	Mean (m)	SD	Median	Min-Max
Amputees	BB-S1 (n=11)	**0.025**	0.010	0.025	0.01-0.05
	BB-S2 (n=11)	**0.024**	0.013	0.021	0.01-0.05
	BB-Follow up (n=3)	**0.025**	0.011	0.029	0.01-0.03
	FB-S1 (n=11)	**0.029**	0.011	0.031	0.01-0.04
	FB-S2 (n=11)	**0.030**	0.010	0.029	0.01-0.04
	FB-Follow up (n=3)	**0.025**	0.008	0.022	0.02-0.03
Non-Amputees	BB-S1 (n=14)	**0.024**	0.013	0.025	0.01-0.05
	BB-S2 (n=14)	**0.023**	0.011	0.024	0.01-0.04
	BB-Follow up (n=11)	**0.029**	0.018	0.029	0-0.06
	FB-S1 (n=13)	**0.023**	0.014	0.020	0.01-0.05
	FB-S2 (n=14)	**0.025**	0.011	0.028	0-0.05
	FB-Follow up (n=11)	**0.023**	0.014	0.018	0.01-0.05

BB: balance during back-pulling, FB: balance during front-pulling, S1: without insoles, S2: with insoles, Follow-up: after at least 4 weeks of using insoles

Similar to the results of the distance between the two COPs during one second before load release, the average distance between the two COPs during the five seconds after load release was larger for the back-pulling in comparison to front-pulling of amputees: Wilks' lambda = 0.44, $F(1, 22) = 28.24$, $p<0.001$, partial eta squared effect = 0.562. The test showed no significant difference between the variable among the perturbation sessions of the groups ($p=0.283$) or in insole use ($p=0.79$) for both groups (Table 5.6).

Table 5.6 Average distance between 2 feet's COP during 1 second before and 5s after load release

		Distance between 2 feet's COP			
		1s before load release		5s before load release	
	Test condition	Mean (m)	SD	Mean (m)	SD
Amputees	BB-S1 (n=11)	**0.296**	0.039	**0.306**	0.036
	BB-S2 (n=11)	**0.294**	0.047	**0.305**	0.043
	BB-Follow up (n=3)	**0.307**	0.053	**0.319**	0.054
	FB-S1 (n=11)	**0.284**	0.025	**0.277**	0.026
	FB-S2 (n=11)	**0.278**	0.041	**0.272**	0.042
	FB-Follow up (n=3)	**0.284**	0.025	**0.282**	0.023
Non-Amputees	BB-S1 (n=14)	**0.277**	0.044	**0.267**	0.044
	BB-S2 (n=14)	**0.262**	0.047	**0.273**	0.047
	BB-Follow up (n=11)	**0.261**	0.047	**0.278**	0.047
	FB-S1 (n=13)	**0.266**	0.048	**0.257**	0.051
	FB-S2 (n=14)	**0.254**	0.052	**0.248**	0.054
	FB-Follow up (n=11)	**0.253**	0.048	**0.245**	0.046

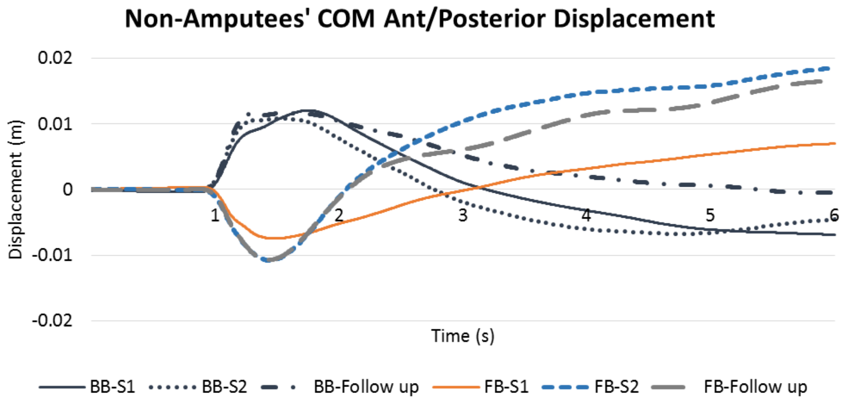
BB: balance during back-pulling, FB: balance during front-pulling, S1: without insoles, S2: with insoles, Follow-up: after at least 4 weeks of using insoles

5.3.1.2 COM displacements

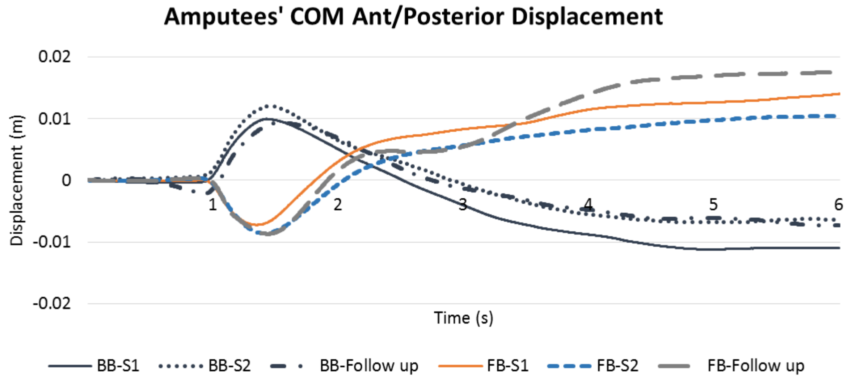
Figure 5.8 presents the normalized anteroposterior displacement of the COM (relative to its initial position one second before load release). It shows that in the back-pulling balance, after load release, it moved forward and, after retaining balance, it moved backward and remained behind the initial position. The opposite pattern occurred in the front-pulling balance: after load release, the COM moved backward and, after recovering balance, it moved forward and remained in front of the initial position.

Table 5.7 indicates the anteroposterior displacement of the COM was almost the same among all groups, in addition to all perturbation and insoles sessions.

No significant difference was observed between the amplitude of the anteroposterior COM displacements of the two perturbation sessions for both groups ($p=0.27$) (Table 5.7). But, the insoles group experienced a significant increase in the displacement in the non-amputee group in the front-pulling perturbation: Pillai's trace = 0.226, $F(1, 22) = 6.408$, $p = 019$, partial eta squared effect = 0.226. When comparing the three insoles sessions of the non-amputees, the repeated measures test showed that the anteroposterior displacement of the COM in front-pulling was bigger than in the back-pulling sessions: $F = 6.421$, $p = 0.03$, partial eta squared effect = 0.391. But the test did not show the insoles significantly affecting the value (F = 2.218, p = 0.138, partial eta squared effect = 0.182).



A



B

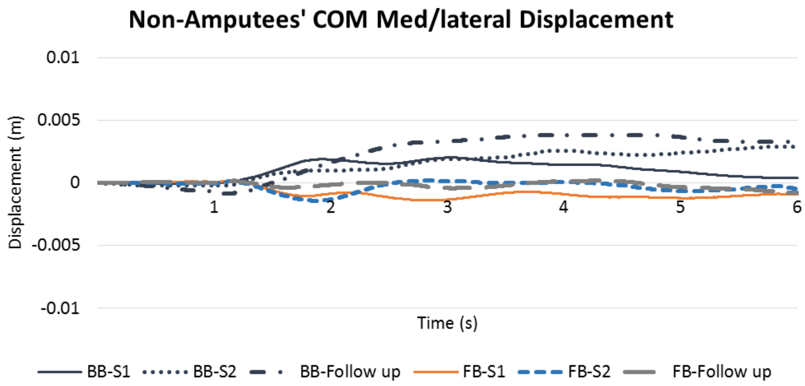
Figure 5.8 Normalized anteroposterior COM displacement, A: Non-Amputees, B: Amputees (BB: back-pulling balance, FB: front-pulling balance)

Table 5.7 Amplitude of anteroposterior and mediolateral displacements of COM

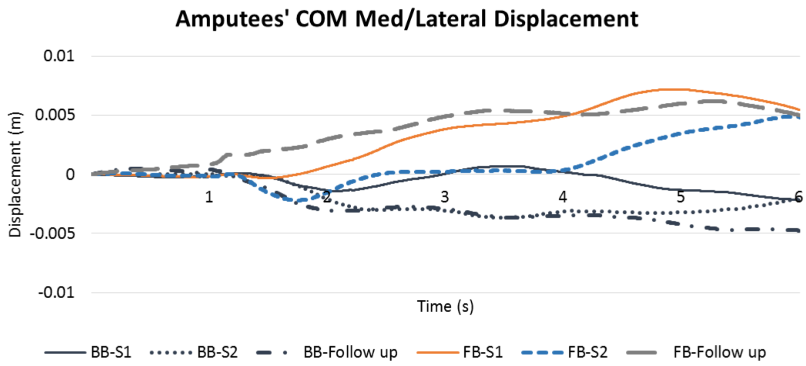
		COM displacements (m)			
		antroposterior		**mediolateral**	
	Test condition	**Mean (m)**	**SD**	**Mean (m)**	**SD**
Amputees	BB-S1 (n=11)	**0.027**	0.012	**0.010**	0.009
	BB-S2 (n=11)	**0.022**	0.010	**0.012**	0.006
	BB-Follow up (n=3)	**0.020**	0.005	**0.012**	0.003
	FB-S1 (n=11)	**0.024**	0.010	**0.017**	0.008
	FB-S2 (n=11)	**0.023**	0.008	**0.017**	0.011
	FB-Follow up (n=3)	**0.027**	0.020	**0.010**	0.002
Non-Amputees	BB-S1 (n=14)	**0.018**	0.011	**0.005**	0.002
	BB-S2 (n=14)	**0.021**	0.008	**0.007**	0.005
	BB-Follow up (n=11)	**0.021**	0.011	**0.008**	0.002
	FB-S1 (n=13)	**0.022**	0.014	**0.005**	0.002
	FB-S2 (n=14)	**0.032**	0.018	**0.006**	0.003
	FB-Follow up (n=11)	**0.030**	0.009	**0.005**	0.001

BB: balance during back-pulling, FB: balance during front-pulling, S1: without insoles, S2: with insoles, Follow-up: after at least 4 weeks of using insoles

The pattern of the mediolateral COM motion was extremely variable among participants in both groups. In fact, almost all the participants had several changes of COM toward the right and left, which resulted in small average values (Figure 5.9). In this case, the correct statistical comparisons were not possible to perform.



A



B

Figure 5.9 Normalized mediolateral COM displacement, A: Non-Amputees, B: Amputees (BB: back-pulling balance, FB: front-pulling balance)

The amplitude of the mediolateral displacement of the COM was small but highly variable, particularly in the amputee group. The mean displacement appears to be larger in this group (Table 5.7).

No significant difference was seen between the amplitude of the mediolateral COM displacement during the two perturbation and insoles sessions for either of the groups ($p = 0.072$ and $p = 0.592$). However, the amputee group had a significantly larger amplitude than the non-amputee group: Pillai's trace = 0.164, $F(1, 22) = 4.327$, p = 049, partial eta squared effect = 0.164. When comparing the three insoles sessions of the non-amputees, the repeated measures test showed that the mediolateral displacement of the COM in the follow-up session to the back-pulling condition was significantly larger than the follow-up value for front-pulling: $F = 5.23$, $p = 0.045$, partial eta squared effect = 0.343. But the test did not show that the insoles were significantly affecting the value ($F = 0.426$, $p = 0.601$, partial eta squared effect = 0.041).

5.3.1.3 Net COP

The position of the net COP and its absolute value were respectively calculated by using Equation 5.2, Equation 5.3, and Equation 5.4. The derived variables related to the net COP consisted of the amplitude of the net COP displacements (in anteroposterior and mediolateral directions), their velocities after load release, the linear distance between the right/left absolute COP and COPnet, and the linear distance between the COPnet and CoG.

5.3.1.3.1 COPnet displacements

Figure 5.10 represents the normalized anteroposterior displacement of the COPnet (relative to its initial position one second before load release).

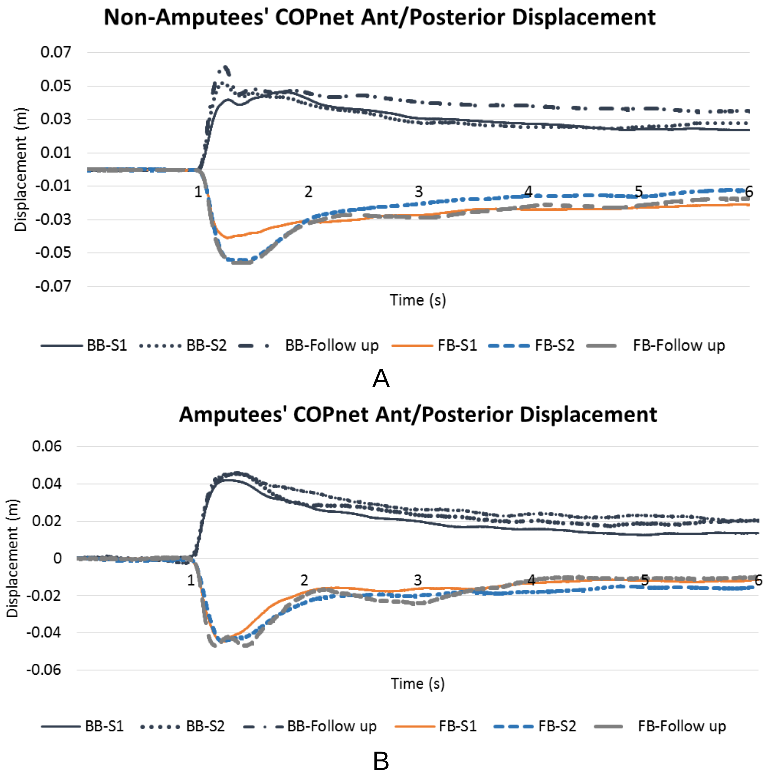


Figure 5.10 Normalized anteroposterior net COP displacement A: Non-Amputees, B: Amputees (BB: back-pulling balance, FB: front-pulling balance)

The displacement has a pattern similar to the anteroposterior COP displacement. In back-pulling balance, after load release, it moved forward and, after balance was regained, it moved backward and remained in front of the initial position. The opposite happened in front-pulling balance: after load release, the COPnet moved backward and, after balance was regained, it moved forward and remained at the back of the initial position.

The amplitude of the anteroposterior net COP displacement in both groups and in the perturbation sessions appears similar during S1 (without insoles sessions). But, an increase was observed in the anteroposterior amplitude of the COPnet displacement in non-amputees after insole use (Table 5.8).

The insole use increased the anteroposterior displacement of the COPnet in both perturbation sessions of non-amputees: Wilks' lambda = 0.823, $F(1, 22) = 4.723$, $p = 0.04$, partial eta squared effect = 0.177. Repeated measure tests for three conditions of Insole use showed an increase of the displacement: $F = 5.24$, p 0.025, partial eta squared effect = 0.344.

Table 5.8 Amplitude of anteroposterior and mediolateral displacements of net COP

		COPnet displacements			
		antroposterior		mediolateral	
	Test condition	Mean (m)	SD	Mean (m)	SD
Amputees	BB-S1 (n=11)	**0.052**	0.008	**0.020**	0.014
	BB-S2 (n=11)	**0.051**	0.013	**0.026**	0.010
	BB-Follow up (n=3)	**0.053**	0.010	**0.023**	0.005
	FB-S1 (n=11)	**0.051**	0.010	**0.034**	0.020
	FB-S2 (n=11)	**0.053**	0.013	**0.028**	0.010
	FB-Follow up (n=3)	**0.054**	0.009	**0.022**	0.009
Non-Amputees	BB-S1 (n=14)	**0.058**	0.019	**0.011**	0.004
	BB-S2 (n=14)	**0.065**	0.023	**0.012**	0.007
	BB-Follow up (n=11)	**0.068**	0.016	**0.014**	0.004
	FB-S1 (n=13)	**0.053**	0.015	**0.013**	0.005
	FB-S2 (n=14)	**0.066**	0.016	**0.015**	0.009
	FB-Follow up (n=11)	**0.064**	0.013	**0.012**	0.002

BB: balance during back-pulling, FB: balance during front-pulling, S1: without insoles, S2: with insoles, Follow-up: after at least 4 weeks of using insoles

As seen in Figure 5.11, the displacements in the mediolateral part had small amplitudes (though they were a little larger for the amputees) and were similar to the mediolateral COM displacement, having many fluctuations. However, the sudden change following load release was still recognizable in the diagram.

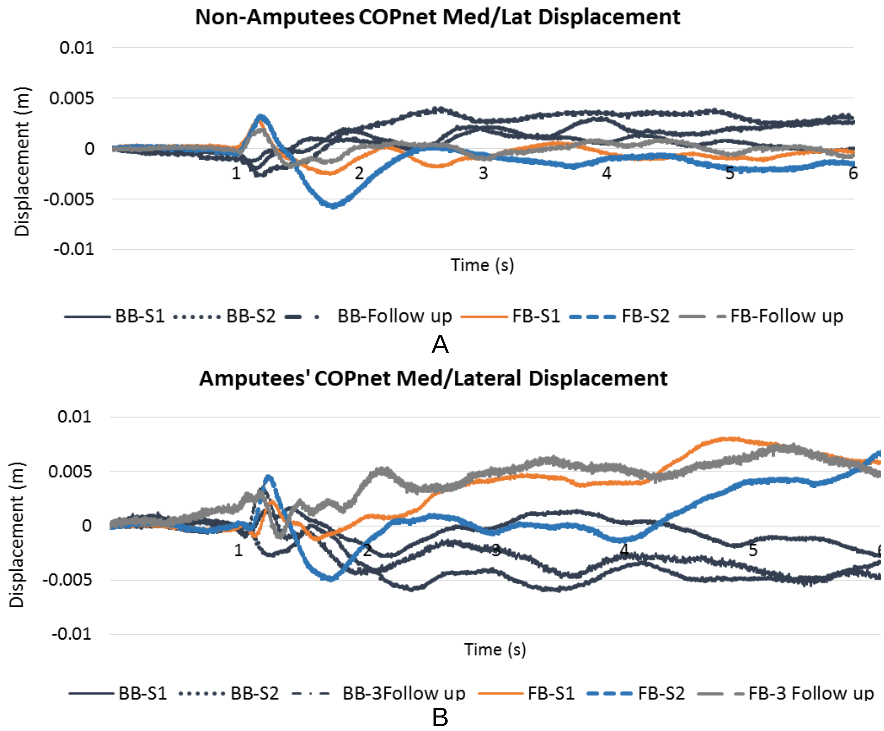
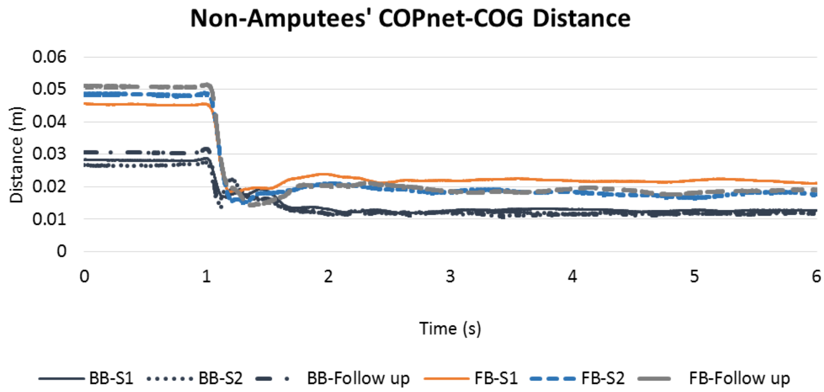


Figure 5.11 Normalized mediolateral net COP displacement, A: Non-Amputees, B: Amputees (BB: back-pulling balance, FB: front-pulling balance)

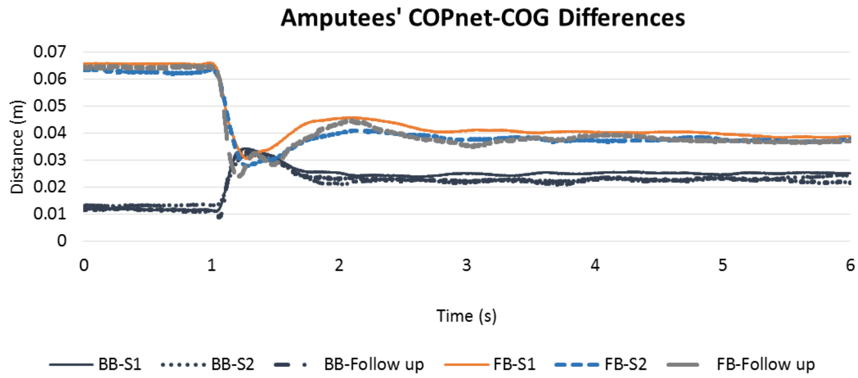
The amplitude of the mediolateral displacement of the COPnet in the without insoles front-pulling session among the amputee group was significantly greater than all the other sessions and the non-amputees: Pillai's Trace = 0.176, $F(1, 22) = 4.702$, $p = 0.041$, partial eta squared effect = 0.176. The test found no significant difference between the variable in the insoles sessions (p=0.912). A pairwise comparison showed that the mediolateral amplitude of the COPnet in the amputees was larger than in the non-amputees (p<0.001). However, the variability in S1 was high among the amputee group, while the Min-Max values shows that the insoles had decreased the maximum mediolateral displacement (Table 5.8).

5.3.1.3.2 Distance between net COP and COG

The distance between the net COP and COG (the COM projection on the ground) was calculated by using the x and y coordinates of each in Equation 5.4. The values were extracted for the 1st second of balance before load release, five seconds after load release, and the amplitude of its change. These can be considered an estimation of balance as, in the ideal balance, there was the least distance between the COPnet and COG. The changes in the distance during one second before load release and five seconds after it are presented in Figure 5.12.



A



B

Figure 5.12 Changes of distance between COPnet and CoG, A: Non-Amputees, B: Amputees (BB: back-pulling balance, FB: front-pulling balance)

Interestingly, the distance was smaller during one second before load release of the back-pulling session in amputees and, after load release, it increased. The distance in the front-pulling of the amputees and both perturbation conditions of the non-amputees was larger during one second before load release. The distance decreased greatly after load release in the non-amputees and in the back-pulling sessions of amputees. It is interesting that the diagrams show that the peak value of the distance was the same (around 3 cm) for both perturbation sessions among the amputee group. Table 5.9 shows the amplitude of the distance was bigger in the front-pulling condition and was similar in both groups.

Table 5.9 Amplitude of COG -COPnet distance

	Test condition	**Mean** (m)	**SD**	**Median**	**Min-Max**
Amputees	BB-S1 (n=11)	**0.034**	0.012	0.036	0.017-0.050
	BB-S2 (n=11)	**0.033**	0.010	0.035	0.020-0.048
	BB-Follow up (n=3)	**0.030**	0.008	0.032	0.021-0.037
	FB-S1 (n=11)	**0.040**	0.007	0.038	0.032-0.055
	FB-S2 (n=11)	**0.042**	0.011	0.044	0.029-0.063
	FB-Follow up (n=3)	**0.043**	0.003	0.043	0.040-0.046
Non-Amputees	BB-S1 (n=14)	**0.032**	0.012	0.031	0.012-0.056
	BB-S2 (n=14)	**0.032**	0.010	0.033	0.018-0.049
	BB-Follow up (n=11)	**0.038**	0.015	0.040	0.016-0.075
	FB-S1 (n=13)	**0.037**	0.011	0.033	0.022-0.053
	FB-S2 (n=14)	**0.043**	0.008	0.040	0.032-0.059
	FB-Follow up (n=11)	**0.044**	0.010	0.045	0.030-0.058

BB: balance during back-pulling, FB: balance during front-pulling, S1: without insoles, S2: with insoles, Follow-up: after at least 4 weeks of using insoles

The amplitude of the distance between the COG and COPnet was significantly larger in the front-pulling of amputees: Pillai's Trace = 0.457, $F(1, 22) = 12.199$, $p = 0.002$, partial eta squared effect = 0.357. But, the insoles did not have a significant effect on the variable among the groups ($p=0.414$) and perturbation conditions ($p=0.193$). The repeated measures test revealed that insole use increased the distance in the non-amputee group: $F = 5.219$, $p = 0.015$, partial eta squared effect = 0.343.

Table 5.10 indicates that the average distance between the COG and COPnet during one second before load release was bigger for front-pulling, particularly in the amputee group. In addition, its variability (Min-Max values) were large in both groups.

Table 5.10 Average COG-COPnet distance during 1 second before and 5s after load release

		Distance between COG-copnet			
		1s before load release		**5s before load release**	
	Test condition	**Mean (m)**	**SD**	**Mean (m)**	**SD**
Amputees	BB-S1 (n=11)	**0.012**	0.006	**0.025**	0.012
	BB-S2 (n=11)	**0.013**	0.011	**0.023**	0.012
	BB-Follow up (n=3)	**0.012**	0.004	**0.023**	0.006
	FB-S1 (n=11)	**0.066**	0.010	**0.041**	0.008
	FB-S2 (n=11)	**0.063**	0.010	**0.038**	0.008
	FB-Follow up (n=3)	**0.064**	0.007	**0.038**	0.010
Non-Amputees	BB-S1 (n=14)	**0.028**	0.016	**0.013**	0.009
	BB-S2 (n=14)	**0.027**	0.014	**0.013**	0.009
	BB-Follow up (n=11)	**0.031**	0.021	**0.012**	0.008
	FB-S1 (n=13)	**0.045**	0.015	**0.022**	0.014
	FB-S2 (n=14)	**0.048**	0.013	**0.019**	0.013
	FB-Follow up (n=11)	**0.051**	0.015	**0.019**	0.013

BB: balance during back-pulling, FB: balance during front-pulling, S1: without insoles, S2: with insoles, Follow-up: after at least 4 weeks of using insoles

The average distance between the COG and COPnet during one second before load release was bigger for front-pulling tests in comparison to back-pulling in both groups: Wilks' lambda = 0.224, $F(1, 22) = 76.37$, $p<0.001$, partial eta squared effect = 0.776; in addition, the two perturbation conditions of amputees and non-amputees had different values (bigger for back-pulling and smaller for front-pulling sessions among the non-amputees): Wilks' lambda = 0.632, $F(1, 22) = 12.792$, $p = 0.001$, partial eta squared effect = 0.368. Insole use did not affect the amount in the perturbation sessions ($p = 0.853$) and groups ($p = 0.422$). However, the repeated measures test showed that the insoles increased the distance in non-amputees: $F = 1.78$, $p = 0.049$, partial eta squared effect = 0.27.

As can be seen in Table 5.10, the average distance between the COG and COPnet five seconds after load release was greater for front-pulling, particularly in the amputee group.

The average distance between the COG and COPnet five seconds after load release was bigger for the front-pulling in comparison to the back-pulling tests: Wilks' lambda = 0.338, $F(1, 22) = 43.117$, $p<0.001$, partial eta squared effect = 0.662. But, there was no significant difference between the groups ($p=0.068$), including the insoles sessions ($p = 0.36$).

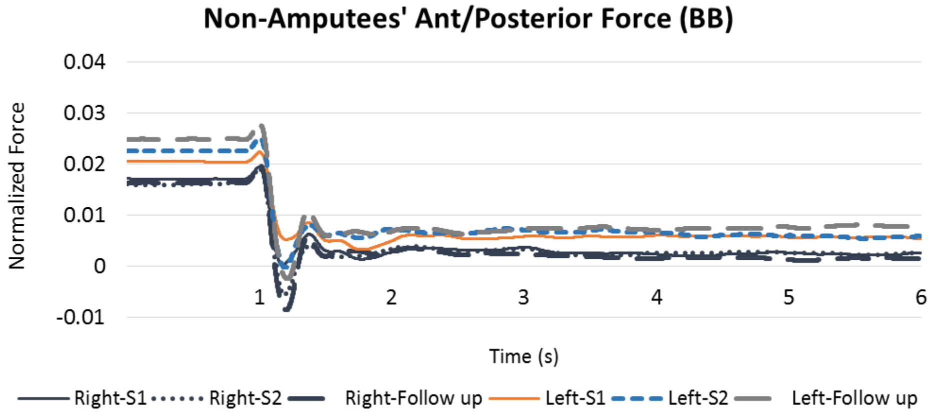
5.3.2 Kinetics

5.3.2.1 Ground reaction forces

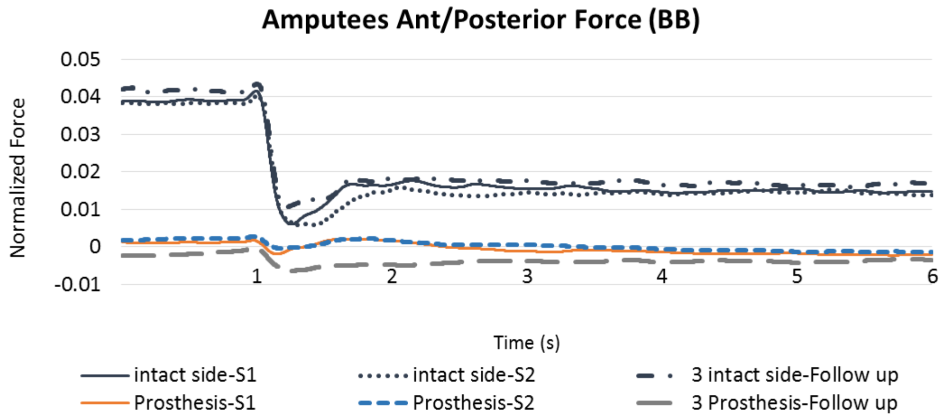
The derived variables related to the forces include the amplitude of force changes in anteroposterior, mediolateral and vertical directions (the difference between the maximum and minimum value of the forces), and the peak value of forces in each direction and for each side of the participants. All forces were normalized to the body weight in Newtons; thus, they are scale-less.

5.3.2.1.1 Anteroposterior Forces

During back-pulling perturbation (Figure 5.13), the GRF was in a forward (+ve) direction before load release, to counteract the perturbation load, in both non-amputees feet and in the IL of amputees. However, the force was near to zero in the prosthetic side, indicating that the resistance to the perturbation load was supplied by the intact side alone. After load release, there was a slight reversal of the force direction before stabilising closer to zero as balance was resumed. The magnitude was larger on the IL of amputees, and it remained positive throughout the whole of the assessed time period.



A



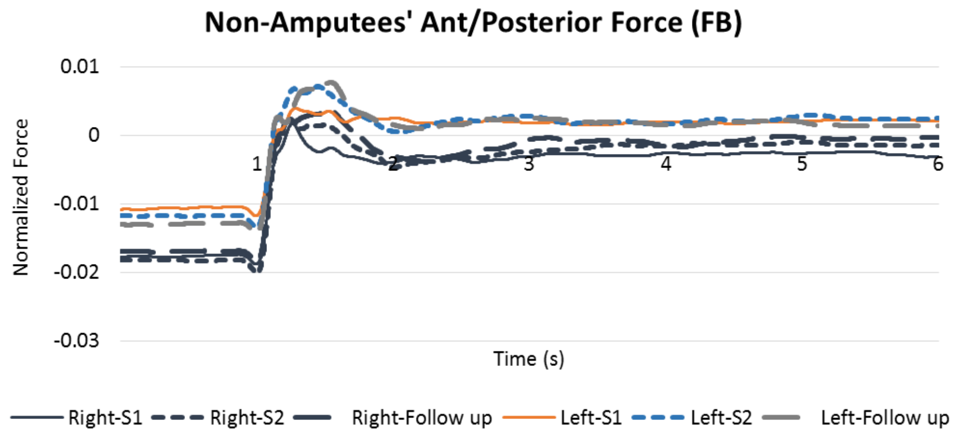
B

Figure 5.13 Changes of anteroposterior GRF during back-pulling sessions, A: Non-Amputees, B: Amputees. +ve values indicate a forward (anterior) direction

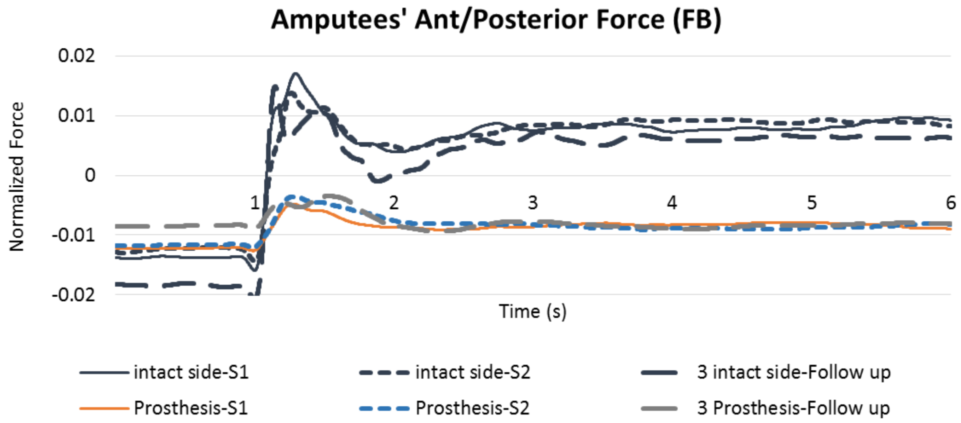
During front-pulling perturbation (Figure 5.14), the trend was similar but reversed compared to the back-pulling perturbation. However, the difference between the non-amputees and amputees' intact and prosthetic sides was more prominent after load release. As the slope of the diagram shows, the reaction of the IL was quicker, and the force remained positive (forward) after load release and during the balance retention period. In addition, the force returned to zero for the non-amputees but continued to be negative (backward) in the prosthetic side on balance resumption.

Table 5.11 presents the amplitude of anteroposterior GRF during back-pulling perturbation. The amount for the IL of amputees was almost 4-folds larger than their prosthetic side, and it was also larger than for the non-amputees.

As is seen in Table 5.11, the amplitude of the anteroposterior GRF during front-pulling perturbation was similar to the back-pulling perturbation but was increased on the prosthetic side.



A



B

Figure 5.14 Changes of anteroposterior GRF during front-pulling sessions, A: Non-Amputees, B: Amputees. +ve values indicate a forward (anterior) direction

Table 5.11 Amplitude of anteroposterior GRF during standing balance against back/ front-pulling loads

			Balance against back pulling load (BB)		Balance against front pulling load (FB)	
		Side	**A-P GRF/BWT**	**SD**	**A-P GRF/BWT**	**SD**
Amputees	S1 (n=11)	Intact	**0.037**	0.011	**0.037**	0.009
		Prosthetic	**0.009**	0.004	**0.011**	0.005
	S2 (n=11)	Intact	**0.038**	0.008	**0.035**	0.011
		Prosthetic	**0.008**	0.003	**0.012**	0.007
	Follow-up (n=3)	Intact	**0.036**	0.007	**0.038**	0.013
		Prosthetic	**0.007**	0.003	**0.010**	0.005
Non-Amputees	S1 (n=14)	Right	**0.025**	0.007	**0.025**	0.009
		Left	**0.024**	0.006	**0.022**	0.006
	S2 (n=14)	Right	**0.027**	0.008	**0.028**	0.008
		Left	**0.028**	0.011	**0.025**	0.007
	Follow-up (n=11)	Right	**0.030**	0.012	**0.029**	0.006
		Left	**0.033**	0.006	**0.027**	0.006

S1: without insoles, S2: with insoles, Follow-up: after at least 4 weeks of using insoles, A-P: anteroposterior, BWT: body weight

There was a significant difference between the groups' amplitude of anteroposterior GRF (Pillai's trace = 0.78, $F(3, 19) = 22.393$, $p<0.001$, partial eta squared effect = 0.78) and between the intact and prosthetic side of the amputees (Pillai's trace = 0.812, $F(3, 19) = 27.327$, $p<0.001$, partial eta squared effect = 0.812). Insole use did not affect either groups (p = 0.224) nor did the results of the two perturbation sessions (p = 0.781). When comparing the three sessions of insole use in the non-amputee group (without insoles, using insoles and after at least four weeks of using them), no significant differences between the anteroposterior GRF in the perturbation sessions and the right/left sides values (p = 0.37) in the insoles sessions (p = 0.075) were observed.

Table 5.12 shows that the peak value of the anteroposterior GRF for the intact side was more than 2.5-fold that of the prosthetic side and almost 2-fold that of the non-amputees.

Table 5.12 Peak value of anteroposterior GRF during standing balance against back/ front-pulling loads

			Balance against back pulling load (BB)		**Balance against front pulling load (FB)**	
		Side	**A-P GRF/BWT**	**SD**	**A-P GRF/BWT**	**SD**
Amputees	S1 (n=11)	Intact	**0.041**	0.014	**0.026**	0.009
		Prosthetic	**0.017**	0.011	**0.016**	0.011
	S2 (n=11)	Intact	**0.042**	0.013	**0.028**	0.008
		Prosthetic	**0.016**	0.010	**0.018**	0.010
	Follow-up (n=3)	Intact	**0.043**	0.017	**0.031**	0.012
		Prosthetic	**0.021**	0.008	**0.018**	0.006
Non-Amputees	S1 (n=14)	Right	**0.020**	0.005	**0.019**	0.005
		Left	**0.023**	0.007	**0.015**	0.006
	S2 (n=14)	Right	**0.020**	0.006	**0.021**	0.007
		Left	**0.025**	0.008	**0.016**	0.004
	Follow-up (n=11)	Right	**0.022**	0.006	**0.022**	0.007
		Left	**0.028**	0.008	**0.016**	0.003

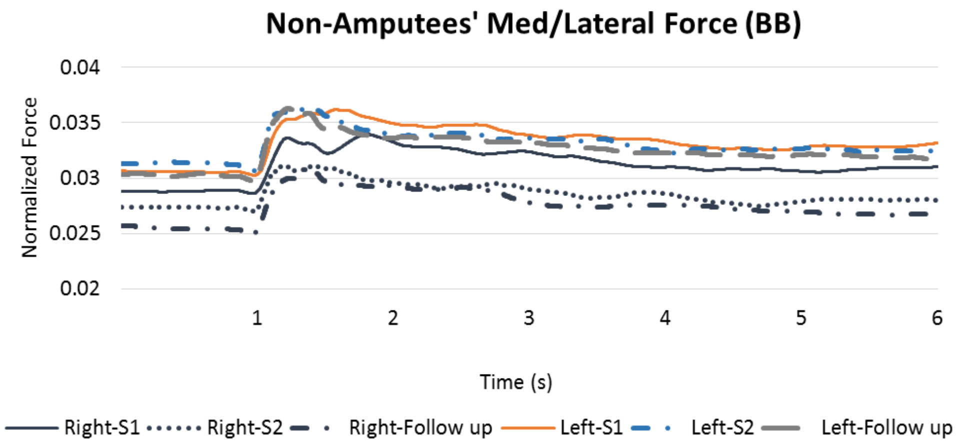
S1: without insoles, S2: with insoles, Follow-up: after at least 4 weeks of using insoles, A-P: anteroposterior, BWT: body weight

In addition, the peak value of the anteroposterior force for the intact side in front-pulling was less than that in back-pulling but the value for the prosthetic side was very similar to that in back-pulling. The magnitudes for the non-amputees appeared asymmetrical between the right and left sides.

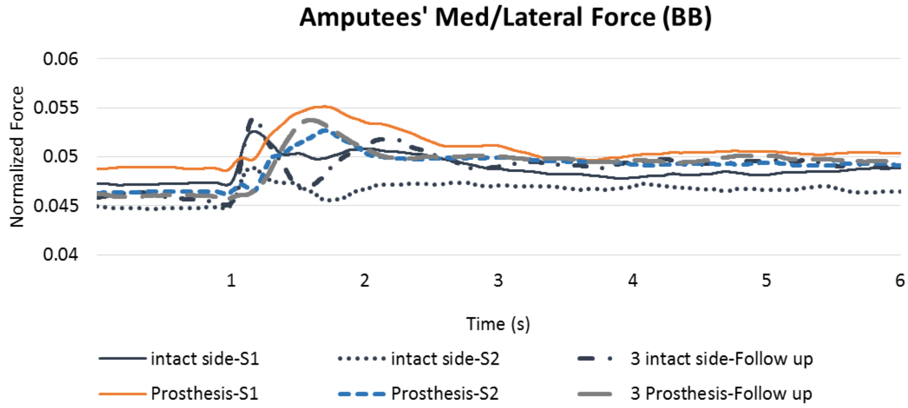
There was a significant difference between the groups' peak anteroposterior GRF: Wilks' lambda = 0.188, F(3, 19) = 27.421, p<0.001, partial eta squared effect = 0.812; in addition, between the intact and prosthetic sides of the amputees and the perturbation sessions: Wilks' lambda = 0.154, F(3, 19) = 34.844, p<0.001, partial eta squared effect = 0.846. Insole use did not affect either group (p = 0.913), nor the results of the two perturbation sessions (p = 0.886). When comparing the three sessions of insole use in the non-amputee group (without insoles, using insoles and after at least four weeks of using them), there was a significant difference between the anteroposterior GRF in the perturbation sessions (between the value of back-pulling and front-pulling in the left foot: F = 6.655, p = 0.007, partial eta squared effect = 0.425). But, the insoles made no significant difference (p = 0.181).

5.3.2.1.2 Mediolateral Forces

As seen in Figure 5.15, the GRF value was positive on both feet, which represents forces toward the medial side. This increased on load release and, though it generally reduced in magnitude, it tended to remain larger than before load release. The prosthetic side had a pattern of changes similar to the non-amputee group and IL; however, the forces were larger in the amputee group, throughout.



A

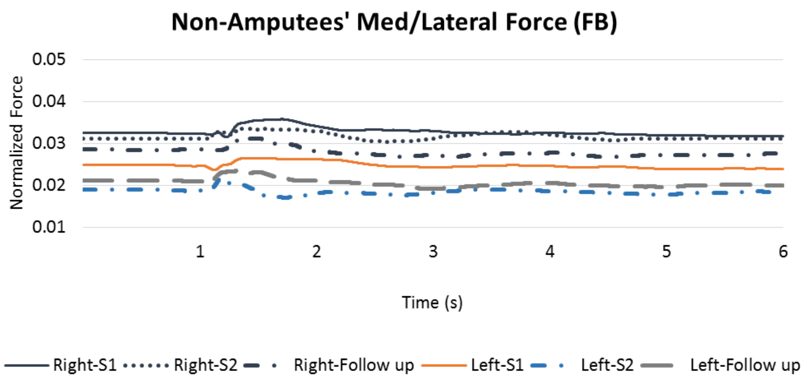


B

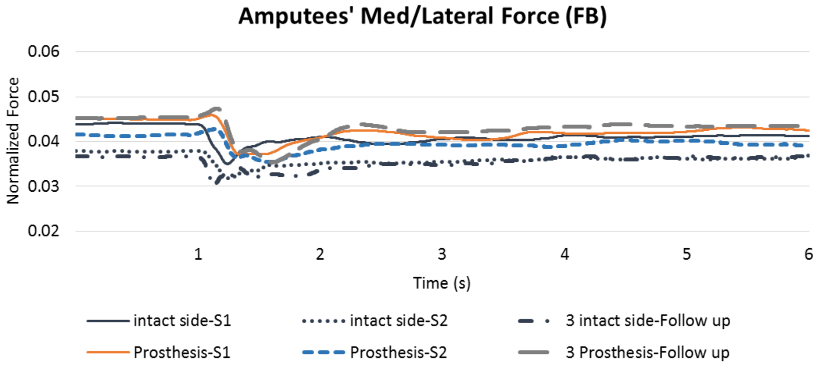
Figure 5.15 Changes of mediolateral GRF during back-pulling sessions, A: Non-Amputees, B: Amputees. +ve indicates medial force.

The forces in the front-pulling perturbation were similar for both groups prior to load release (Figure 5.16). However, the reaction to load release in the front-pulling perturbation was different from back-pulling and between the two groups. After load release, the forces remained relatively stable with only slight fluctuations in the non-amputee group. In the amputee group, there was a small reduction in the medial force before it returned to a similar magnitude as prior to load release.

The amplitude of the mediolateral GRF during back-pulling perturbation can be seen in Table 5.13. The magnitudes were very small and almost the same in both legs in the two groups. The amplitude of the mediolateral GRF during front-pulling perturbation was similar to the back-pulling perturbation, but a little larger for the amputee group.



A



B

Figure 5.16 Changes of mediolateral GRF during front-pulling sessions, A: Non-Amputees, B: Amputees. +ve indicates medial force.

Table 5.13 Amplitude of mediolateral GRF during standing balance against /front-pulling loads

			Balance against back pulling load (BB)		Balance against front pulling load (FB)	
		Side	**M-L GRF/BWT**	**SD**	**M-L GRF/BWT**	**SD**
Amputees	S1 (n=11)	Intact	**0.009**	0.005	**0.012**	0.006
		Prosthetic	**0.008**	0.002	**0.013**	0.008
	S2 (n=11)	Intact	**0.012**	0.005	**0.012**	0.005
		Prosthetic	**0.011**	0.009	**0.012**	0.006
	Follow-up (n=3)	Intact	**0.011**	0.005	**0.012**	0.004
		Prosthetic	**0.010**	0.004	**0.014**	0.002
Non-Amputees	S1 (n=14)	Right	**0.008**	0.003	**0.009**	0.005
		Left	**0.007**	0.003	**0.007**	0.004
	S2 (n=14)	Right	**0.008**	0.004	**0.009**	0.003
		Left	**0.008**	0.003	**0.011**	0.005
	Follow-up (n=11)	Right	**0.008**	0.002	**0.009**	0.002
		Left	**0.009**	0.004	**0.009**	0.004

S1: without insoles, S2: with insoles, Follow-up: after at least 4 weeks of using insoles, M-L: Mediolateral, BWT: body weight

The amplitude of the mediolateral GRF changes during the standing balance of amputee and non-amputee participants exhibited no significant difference between perturbation sessions, sides or groups ($p = 0.474$). Insole use did not affect either groups ($p = 0.3065$) or the results of the two perturbation sessions ($p = 0.78$). In comparing the three sessions of insole use in the non-amputee group (without insoles, using insoles and after at least four weeks of using them), no significant differences between the mediolateral GRF in perturbation sessions and right/left sides values (p = 0.625) in the insoles sessions (p=0.259) were observed.

Table 5.14 shows that the peak values of the mediolateral force were the same for both sides of the two groups and in both perturbation conditions; however, the magnitude was larger for the amputee group.

Table 5.14 Peak value of mediolateral GRF during standing balance against back/front-pulling loads

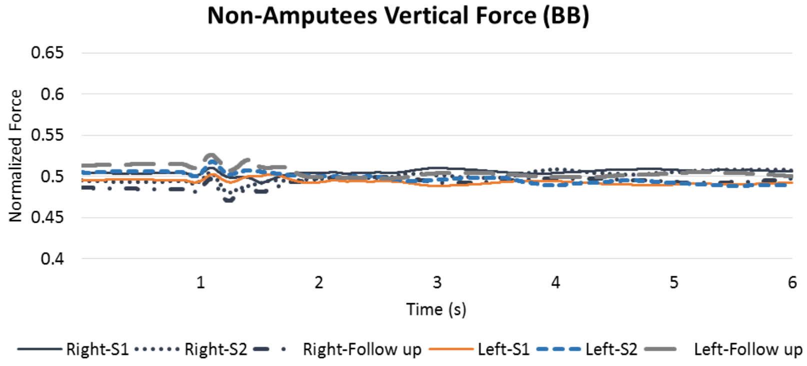
			Balance against back pulling load (BB)		Balance against front pulling load (FB)	
		Side	**M-L GRF/BWT**	**SD**	**M-L GRF/BWT**	**SD**
Amputees	S1 (n=11)	Intact	**0.054**	0.012	**0.045**	0.016
		Prosthetic	**0.051**	0.010	**0.041**	0.017
	S2 (n=11)	Intact	**0.055**	0.024	**0.040**	0.002
		Prosthetic	**0.057**	0.017	**0.048**	0.016
	Follow-up (n=3)	Intact	**0.055**	0.012	**0.045**	0.012
		Prosthetic	**0.055**	0.023	**0.049**	0.013
Non-Amputees	S1 (n=14)	Right	**0.036**	0.015	**0.038**	0.015
		Left	**0.033**	0.016	**0.037**	0.012
	S2 (n=14)	Right	**0.032**	0.017	**0.033**	0.013
		Left	**0.038**	0.010	**0.029**	0.017
	Follow-up (n=11)	Right	**0.038**	0.010	**0.026**	0.013
		Left	**0.038**	0.013	**0.027**	0.018

S1: without insoles, S2: with insoles, Follow-up: after at least 4 weeks of using insoles, M-L: Mediolateral, BWT: body weight

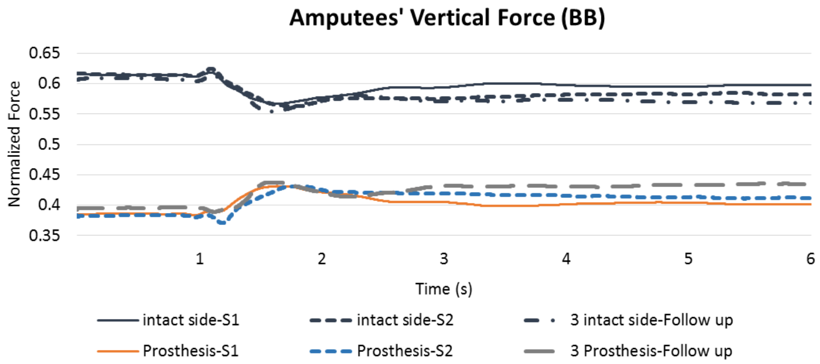
There was a significant difference between the groups' peak mediolateral GRF (Pillai's trace = 0.448, F(3, 19) = 5.138, p = 0.009, partial eta squared effect = 0.448); and between both sides of the amputees and the perturbation sessions (with larger magnitudes in the back-pulling sessions): (Pillai's trace = 0.568, F(3, 19) = 8.318, p = 0.001, partial eta squared effect = 0.568). Insole use did not affect either group (p = 0.191) or the results of the two perturbation sessions and sides (p = 0.816). When comparing the three sessions of insole use in the non-amputee group (without insoles, using insoles and after at least four weeks of using them), there was a significant differences between the mediolateral GRF of the right and left foot in front-pulling (F = 7.541, p = 0.007, partial eta squared effect = 0.519). But the effect of insoles was not significant (p = 0.937).

5.3.2.1.3 Vertical forces

Figure 4.11 shows that the vertical force on the right and left side of the non-amputees was approximately 50% of the body weight (BWT), indicating that the weight was being carried symmetrically, on each limb. Whilst there was a small oscillation following load release, the effect was relatively small. In contrast, in the amputees, the IL load was 60% of bodyweight prior to load release (40% on the prosthesis side). Following load release, and a period of rebalance lasting approximately 0.5 – 0.75 seconds, the loads stabilised, with the PL taking a little more of the load, but still with asymmetry.



A



B

Figure 5.17 Changes of vertical GRF during back-pulling sessions, A: Non-Amputees, B: Amputees

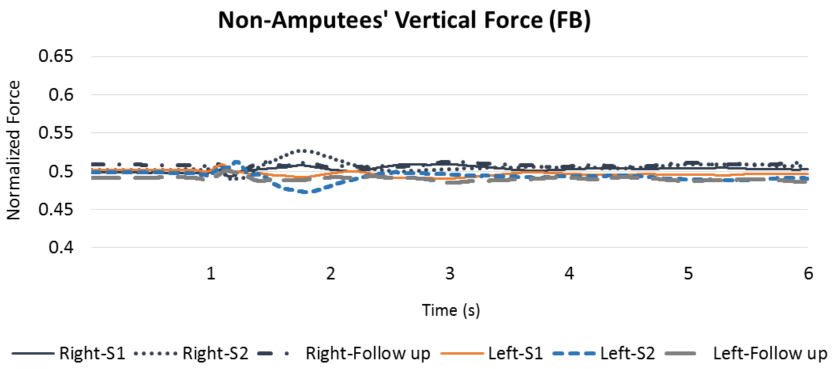
Table 5.15 indicates the amplitude of vertical force change was small on both sides of the amputees (7-8% of weight) but larger than both sides of the non-amputees during the back-pulling perturbation.

Table 5.15 Amplitude of vertical GRF during standing balance against back/front-pulling loads

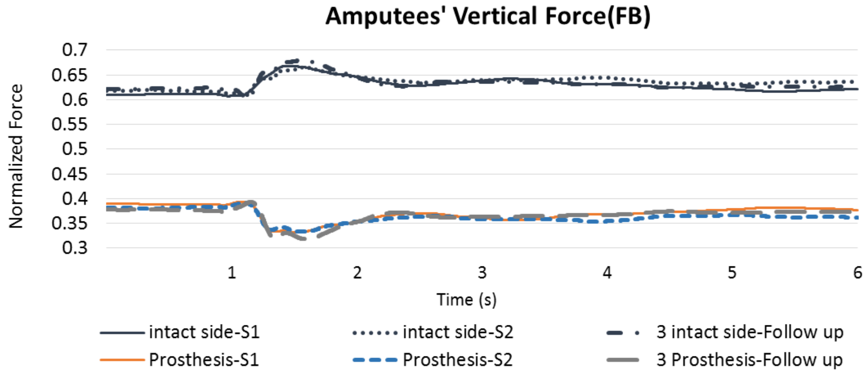
			Balance against back pulling load (BB)		Balance against front pulling load (FB)	
		Side	**Vertical GRF/BWT**	**SD**	**Vertical GRF/BWT**	**SD**
Amputees	S1 (n=11)	Intact	**0.073**	0.049	**0.107**	0.061
		Prosthetic	**0.073**	0.050	**0.113**	0.061
	S2 (n=11)	Intact	**0.083**	0.030	**0.097**	0.038
		Prosthetic	**0.084**	0.029	**0.101**	0.034
	Follow-up (n=3)	Intact	**0.071**	0.005	**0.084**	0.018
		Prosthetic	**0.071**	0.007	**0.091**	0.030
Non-Amputees	S1 (n=14)	Right	**0.043**	0.019	**0.047**	0.020
		Left	**0.040**	0.022	**0.049**	0.020
	S2 (n=14)	Right	**0.051**	0.031	**0.069**	0.051
		Left	**0.050**	0.031	**0.071**	0.052
	Follow-up (n=11)	Right	**0.057**	0.020	**0.053**	0.020
		Left	**0.054**	0.020	**0.051**	0.018

S1: without insoles, S2: with insoles, Follow-up: after at least 4 weeks of using insoles, BWT: body weight

Figure 5.18 displays the pattern of vertical force during front-pulling perturbation. The results are similar to the back-pulling vertical force data. The noticeable difference, however, was that the intact side of the amputee group took a greater share of bodyweight immediately after load release, returning closer to almost initial share after approximately one second.



A



B

Figure 5.18 Changes of vertical GRF during front-pulling sessions, A: Non-Amputees, B: Amputees

As can be seen in 15, the amplitudes of vertical force during front-pulling perturbation were larger than for back-pulling in the amputee group (10-11%BWT) and in the insoles sessions of non-amputees.

The amplitude of the vertical GRF changes during the standing balance of amputee and non-amputee participants was significantly larger on both sides of the amputee group compared to the non-amputees (Pillai's trace = 0.382, $F(3, 19) = 3.909$, $p = 0.025$, partial eta squared effect = 0.382). Insole use did not affect either group ($p = 0.479$) or the results of the two perturbation sessions ($p=0.825$). When comparing the three sessions of insole use in the non-amputee group (without insoles, using insoles and after at least four weeks of use), there was no significant difference between the vertical GRF in the perturbation sessions and right/left sides values ($p = 0.531$) or insoles sessions ($p = 0.278$).

Table 5.16 shows that the peak values of vertical force for the IL was almost 1.5 times that of the prosthetic side, and was larger than the non-amputees in both perturbation situations. On average, the intact side bore more than 60%-68% BWT, while the mean value for the prosthetic side was 40%-46%. The weight bearing in both lower limbs of non-amputees was near to 50%.

Table 5.16 Peak vertical GRF during standing balance against back/front-pulling loads

			Balance against back pulling load (BB)		Balance against front pulling load (FB)	
		Limb	Vertical GRF/BWT	SD	Vertical GRF/BWT	SD
Amputees	S1 (n=11)	Intact	**0.627**	0.072	**0.683**	0.081
		Prosthetic	**0.446**	0.057	**0.425**	0.083
	S2 (n=11)	Intact	**0.630**	0.060	**0.684**	0.083
		Prosthetic	**0.453**	0.036	**0.412**	0.073
	Follow-up (n=3)	Intact	**0.616**	0.110	**0.682**	0.007
		Prosthetic	**0.456**	0.113	**0.405**	0.017
Non-Amputees	S1 (n=14)	Right	**0.527**	0.018	**0.526**	0.032
		Left	**0.513**	0.026	**0.523**	0.037
	S2 (n=14)	Right	**0.523**	0.029	**0.541**	0.046
		Left	**0.527**	0.048	**0.529**	0.041
	Follow-up (n=11)	Right	**0.516**	0.028	**0.530**	0.030
		Left	**0.537**	0.031	**0.518**	0.031

S1: without insoles, S2: with insoles, Follow-up: after at least 4 weeks of using insoles, BWT: body weight

A significant difference was observed between the peak vertical force of the intact and the prosthetic side in the amputee group (Pillai's trace = 0.786, $F(3, 19) = 23.282$, $p<0.001$, partial eta squared effect = 0.786); and in non-amputees (Pillai's trace = 0.716, $F(3, 19) = 15.968$, $p<0.001$, partial eta squared effect = 0.716). Insole use did not affect either group ($p = 0.6$) or the results of the two perturbation sessions and sides ($p = 0.911$). When comparing the three sessions of insole use in the non-amputee group (without insoles, using insoles and after at least four weeks of use), there was no significant difference between the peak vertical GRF in the perturbation sessions and the right/left sides values ($p = 0.89$) and insoles sessions ($p = 0.727$).

5.3.2.1.4 Limbs' role in load sharing

Table 5.17 and

Table 5.18 represent the magnitude of ground reaction forces during one second before load release in terms of the percentage of total bodyweight.

Table 5.17 Mean forces experienced by each limb during the 1st second of back-pulling standing balance (in terms of participants' BWT percentage)

	BB Test conditions	Force %BWT side	A/P	SD	M/L	SD	Vertical	SD
Amputees	S1 (n=11)	Intact	**3.8%**	1.5%	**5%**	1%	**61%**	7%
		Prosthetic	**0.1%**	1.7%	**5%**	1%	**39%**	7%
	S2 (n=11)	Intact	**3.8%**	1.6%	**4%**	1%	**61%**	7%
		Prosthetic	**0.2%**	1.7%	**5%**	1%	**39%**	7%
	Follow-up (n=3)	Intact	**4.2%**	1.8%	**5%**	2%	**61%**	12%
		Prosthetic	**0.2%**	2.4%	**5%**	2%	**39%**	12%
Non-Amputees	S1 (n=14)	Right	**1.7%**	0.5%	**3%**	1%	**50%**	2%
		Left	**2.1%**	0.7%	**3%**	1%	**50%**	2%
	S2 (n=14)	Right	**1.6%**	0.6%	**3%**	1%	**50%**	2%
		Left	**2.3%**	0.7%	**3%**	2%	**49%**	4%
	Follow-up (n=11)	Right	**1.7%**	0.8%	**3%**	1%	**51%**	4%
		Left	**2.5%**	0.8%	**3%**	2%	**48%**	3%

BB: balance during back-pulling, A/P: anteroposterior, M/L: mediolateral, S1: without insoles, S2: with insoles, Follow-up: after at least 4 weeks of using insoles, BWT: body weight

Table 5.18 Mean forces experienced by each limb during the 1st second of front-pulling standing balance (in terms of participants' BWT percentage)

	FB Test conditions	Force %BWT side	A/P	SD	M/L	SD	Vertical	SD
Amputees	S1 (n=11)	Intact	**1.4%**	1.4%	**4%**	2%	**61%**	7%
		Prosthetic	**1.2%**	1.5%	**4%**	1%	**39%**	7%
	S2 (n=11)	Intact	**1.2%**	1.5%	**4%**	2%	**62%**	7%
		Prosthetic	**1.2%**	1.4%	**4%**	1%	**38%**	7%
	Follow-up (n=3)	Intact	**1.9%**	2.1%	**4%**	0%	**62%**	3%
		Prosthetic	**0.8%**	1.6%	**5%**	2%	**38%**	3%
Non-Amputees	S1 (n=12)	Right	**1.1%**	0.6%	**3%**	1%	**50%**	3%
		Left	**2.8%**	0.8%	**2%**	2%	**50%**	3%
	S2 (n=14)	Right	**1.8%**	0.8%	**3%**	1%	**50%**	2%
		Left	**1.2%**	0.3%	**2%**	1%	**50%**	2%
	Follow-up (n=11)	Right	**1.7%**	1.0%	**3%**	1%	**51%**	2%
		Left	**1.3%**	0.4%	**2%**	2%	**49%**	2%

FB: balance during front-pulling, A/P: anteroposterior, M/L: mediolateral, S1: without insoles, S2: with insoles, Follow-up: after at least 4 weeks of using insoles, BWT: body weight

The IL produced greater anteroposterior forces than the prosthetic side and both limbs of the non-amputees during back-pulling sessions. Non-amputees had a slightly larger anteroposterior load on their left side during back-pulling sessions but the loads were small (<2.5% BWT). The mediolateral forces in both the perturbation conditions and the anteroposterior forces in the front-pulling sessions were the same for both sides of the amputees. The vertical force shows that, while non-amputees have symmetrical weight bearing, the prosthetic side only bore about 40% of the amputee's weight.

As expected, significant differences were seen among the forces during the one second before load release. These were:

1- the anteroposterior forces of the prosthetic and intact side of the amputees in back-pulling sessions ($p<0.001$, Partial Eta Squared = 0.983), between the groups in back-pulling ($p<0.001$, Partial Eta Squared = 0.742) and for insole use in the front-pulling of non-amputees ($p = 0.008$, Partial Eta Squared = 0.293);

2- the mediolateral forces in the two perturbation sessions among the amputees ($p = 0.009$, Partial Eta Squared = 0.448), and between the two groups ($p = 0.023$, Partial Eta Squared = 0.386);

3- between the weight-bearing contribution of the prosthesis and the IL of the amputees ($p<0.001$, Partial Eta Squared = 0.667), and the difference between the two 2 groups ($p<0.001$, Partial Eta Squared = 0.651).

The differences between the insole use and anteroposterior forces among the groups ($p = 0.182$), the mediolateral ($p = 0.138$), and the vertical forces ($p = 0.339$) was not statistically significant.

Table 5.19 and Table 5.20 present the magnitude of ground reaction forces during five seconds after load release in terms of % of BWT.

Table 5.19 Mean forces experienced by each limb during 5 seconds after load release in back-pulling standing balance (in terms of participants' BWT percentage)

	BB Test conditions	Force %BWT side	A/P	SD	M/L	SD	Vertical	SD
Amputees	S1 (n=11)	Intact	**1.6%**	1.6%	**5%**	1%	**59%**	6%
		Prosthetic	**0.1%**	1.7%	**5%**	1%	**41%**	6%
	S2 (n=11)	Intact	**1.4%**	1.6%	**5%**	1%	**58%**	4%
		Prosthetic	**0.0%**	1.7%	**5%**	1%	**42%**	4%
	Follow-up (n=3)	Intact	**1.7%**	2.0%	**5%**	2%	**57%**	10%
		Prosthetic	**0.4%**	2.3%	**5%**	2%	**43%**	10%
Non-Amputees	S1 (n=14)	Right	**0.3%**	0.5%	**3%**	1%	**51%**	2%
		Left	**0.6%**	0.7%	**3%**	1%	**49%**	2%
	S2 (n=14)	Right	**0.3%**	0.5%	**3%**	2%	**50%**	3%
		Left	**0.7%**	0.5%	**3%**	1%	**50%**	3%
	Follow-up (n=11)	Right	**0.2%**	0.7%	**3%**	2%	**49%**	3%
		Left	**0.7%**	0.6%	**3%**	1%	**50%**	3%

BB: balance during back-pulling, A/P: anteroposterior, M/L: mediolateral, S1: without insoles, S2: with insoles, Follow-up: after at least 4 weeks of using insoles, BWT: body weight

Table 5.20 Mean forces experienced by each limb during 5 seconds after load release in front-pulling standing balance (in terms of participants' BWT percentage)

	FB Test conditions	Force %BWT side	A/P	SD	M/L	SD	Vertical	SD
Amputees	S1 (n=11)	Intact	**0.8%**	1.4%	**4%**	2%	**63%**	8%
		Prosthetic	**0.8%**	1.3%	**4%**	1%	**37%**	8%
	S2 (n=11)	Intact	**0.8%**	1.4%	**4%**	2%	**64%**	8%
		Prosthetic	**0.8%**	1.3%	**4%**	1%	**36%**	8%
	Follow-up (n=3)	Intact	**0.5%**	2.0%	**4%**	0%	**63%**	2%
		Prosthetic	**0.8%**	1.7%	**4%**	1%	**36%**	2%
Non-Amputees	S1 (n=12)	Right	**0.3%**	0.4%	**3%**	1%	**50%**	3%
		Left	**0.2%**	0.4%	**2%**	2%	**49%**	3%
	S2 (n=14)	Right	**0.2%**	0.5%	**3%**	1%	**51%**	3%
		Left	**0.2%**	0.4%	**2%**	1%	**49%**	2%
	Follow-up (n=11)	Right	**0.1%**	0.9%	**3%**	1%	**51%**	3%
		Left	**0.2%**	0.4%	**2%**	2%	**49%**	3%

FB: balance during front-pulling, A/P: anteroposterior, M/L: mediolateral, S1: without insoles, S2: with insoles, Follow-up: after at least 4 weeks of using insoles, BWT: body weight

As can be seen, the IL produced greater posterior forces than the prosthetic side and both limbs of the non-amputees during back-pulling sessions. The vertical force shows that, while non-amputees have symmetrical weight bearing, the prosthetic side's contribution in weight bearing increased in back-pulling and decreased in front-pulling. The mediolateral forces in both the perturbation conditions and the groups remained almost the same as before load release. The anteroposterior forces in the non-amputees were very small and remained backward and asymmetrical in back-pulling and the opposite during front-pulling sessions.These significant differences were observed among the following forces during five seconds after load release:

1. the anteroposterior forces of the prosthetic and intact sides of the amputees in back-pulling sessions ($p<0.001$, Partial Eta Squared = 0.845) and the value between groups in back-pulling ($p=0.038$, Partial Eta Squared = 0.35);

2. the mediolateral forces in the two perturbation sessions among amputees ($p<0.001$, Partial Eta Squared = 0.624) and between the two groups ($p = 0.008$, Partial Eta Squared = 0.456);
3. between the weight-bearing contribution of the prosthetic limb and the IL of the amputees ($p<0.001$, Partial Eta Squared = 0.709) and the difference between the two groups ($p<0.001$, Partial Eta Squared = 0.629).

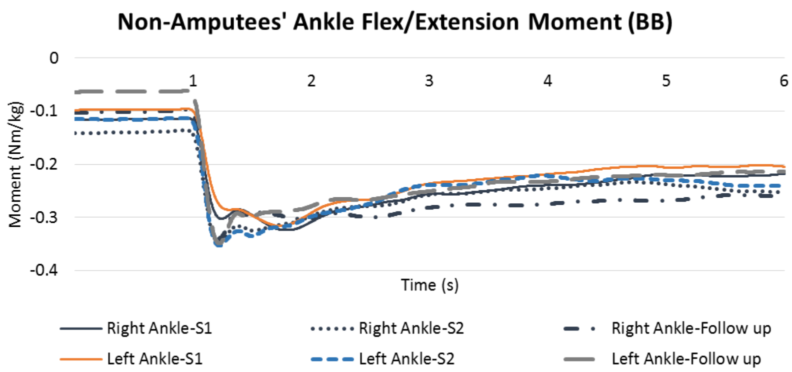
The differences between the insole use session for the anteroposterior forces ($p = 0.879$), the mediolateral ($p = 0.128$), and the vertical forces ($p = 0.223$) was statistically not significant.

5.3.2.2 Moments

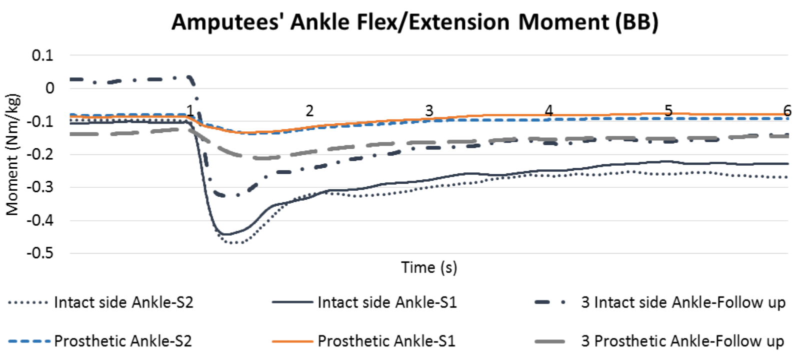
The derived variables related to moments in this study include the amplitude of ankle and hip joint moments changes in the direction of the pulling perturbations (flex/extension moments) in both lower limbs, the peak value of these moments, as well as the amplitude and maximum magnitude of the sum of moments in the sagittal plane. The moments in the coronal plane (abd/adduction moments) were very small, thus are not presented. The magnitudes of all moments were normalized to the mass of the participants in kilograms.

5.3.2.2.1 Ankle Flex/Extension Moment

The ankle moments in the back-pulling test are presented in Figure 5.19. The positive and negative values were, respectively, the dorsi-flexor and plantar-flexor joint moments.



A



B

Figure 5.19 Changes of ankle moments in sagittal plane during back-pulling sessions, A: Non-Amputees, B: Amputees. -ve indicates plantar flexor moments.

There was a negative moment (plantar-flexor moment) in both groups and in both sides during the whole of the test. The load release was associated with a rapid increase in a plantar-flexor moment, which remained once balance was retained. In the amputee group, a similar trend was observed, but the moments were generally smaller in the prosthetic ankle.

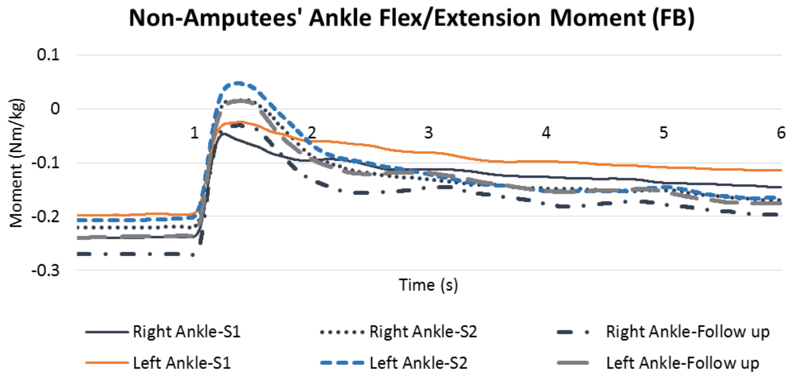
As is seen in Table 5.21, the amplitude of the ankle moment changes during back-pulling perturbation for the IL of amputees was more than five times larger than their prosthetic side, and it was also larger than in the non-amputees.

Table 5.21 Amplitude of ankle moment in sagittal plane during standing balance against back/front pulling loads

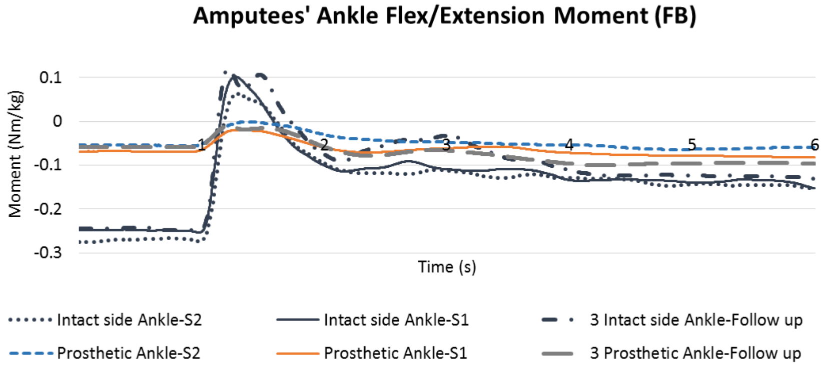
			Prturbation condition			
			Balance against back pulling load (BB)		Balance against front pulling load (FB)	
		Limb	Moment (Nm/kg)	SD	Moment (Nm/kg)	SD
Amputees	S1 (n=11)	Intact	**0.401**	0.086	**0.393**	0.119
		Prosthetic	**0.079**	0.031	**0.091**	0.051
	S2 (n=11)	Intact	**0.401**	0.109	**0.392**	0.113
		Prosthetic	**0.078**	0.038	**0.093**	0.046
	Follow-up (n=3)	Intact	**0.400**	0.067	**0.384**	0.057
		Prosthetic	**0.096**	0.017	**0.105**	0.070
Non-Amputees	S1 (n=14)	Right	**0.263**	0.094	**0.245**	0.072
		Left	**0.265**	0.092	**0.223**	0.066
	S2 (n=14)	Right	**0.282**	0.109	**0.296**	0.087
		Left	**0.299**	0.106	**0.294**	0.082
	Follow-up (n=11)	Right	**0.276**	0.088	**0.282**	0.053
		Left	**0.323**	0.060	**0.277**	0.073

S1: without insoles, S2: with insoles, Follow-up: after at least 4 weeks of using insoles

Figure 5.20 shows the ankle moment in the sagittal plane during front-pulling perturbation. In non-amputees and the intact side of amputees, the moment was initially plantar-flexor, which reduced rapidly and, in some cases, became a dorsi-flexor moment at load release, but then returned to a plantar-flexor moment, though smaller than the initial moment, once balance was retained. The initial moment in the IL and in the non-amputees was larger when compared to the back-pulling sessions. This moment was close to zero in the prosthetic side in amputees throughout, indicating that the prosthetic ankle contributed little to balance stability in these tests. As seen in Figure 5.20, the amplitude of the prosthetic ankle moment in the front-pulling sessions was a little more than in the back-pulling and was approximately one-quarter of the moments in the IL. There was a significant difference between group amplitudes of the sagittal plane's ankle moment changes during standing balance (Pillai's trace = 0.834, $F(3, 20) = 33.604$, $p<0.001$, partial eta squared effect = 0.834), and between the intact and prosthetic side of amputees (Pillai's trace = 0.832, $F(3, 20) = 33.002$, $p<0.001$, partial eta squared effect = 0.832.) Insole use did not affect either group ($p = 0.084$) or the results of the two perturbation sessions ($p = 0.699$). When comparing the three sessions of insole use in the non-amputee group (without insoles, using insoles and after at least for weeks of use), there was a significant increase in the amplitude after using the insoles ($F = 3.981$, p = 0.044, partial eta squared effect = 0.285). However, no difference was found between the perturbation sessions and right/left data (p = 0.47).



A



B

Figure 5.20 Changes of ankle moments in sagittal plane during front-pulling sessions, A: Non-Amputees, B: Amputees. -ve indicates plantar flexor moments.

Table 5.22 presents the absolute maximum sagittal plane ankle moments of each limb of the participants in both groups. All peak values among the non-amputees and in the IL of amputees were plantar-flexor moments, but five moments in S1 and four moments in S2 were dorsi-flexor for the prosthetic side. The amount was more than 2.5 times larger in the IL compared to the prosthetic side.

Table 5.22 Peak value of ankle moment in sagittal plane during standing balance against back/front pulling loads

<table>
<tr><th></th><th></th><th></th><th colspan="4">Prturbation condition</th></tr>
<tr><th></th><th></th><th></th><th colspan="2">Balance against back pulling load (BB)</th><th colspan="2">Balance against front pulling load (FB)</th></tr>
<tr><th></th><th></th><th>Limb</th><th>Moment (Nm/kg)</th><th>SD</th><th>Moment (Nm/kg)</th><th>SD</th></tr>
<tr><td rowspan="6">Amputees</td><td rowspan="2">S1 (n=11)</td><td>Intact</td><td>0.483</td><td>0.129</td><td>0.297</td><td>0.097</td></tr>
<tr><td>Prosthetic</td><td>0.181</td><td>0.137</td><td>0.147</td><td>0.138</td></tr>
<tr><td rowspan="2">S2 (n=11)</td><td>Intact</td><td>0.489</td><td>0.135</td><td>0.305</td><td>0.119</td></tr>
<tr><td>Prosthetic</td><td>0.173</td><td>0.164</td><td>0.118</td><td>0.114</td></tr>
<tr><td rowspan="2">Follow-up (n=3)</td><td>Intact</td><td>0.362</td><td>0.025</td><td>0.322</td><td>0.088</td></tr>
<tr><td>Prosthetic</td><td>0.219</td><td>0.178</td><td>0.179</td><td>0.051</td></tr>
<tr><td rowspan="6">Non-Amputees</td><td rowspan="2">S1 (n=14)</td><td>Right</td><td>0.358</td><td>0.160</td><td>0.245</td><td>0.111</td></tr>
<tr><td>Left</td><td>0.353</td><td>0.163</td><td>0.215</td><td>0.111</td></tr>
<tr><td rowspan="2">S2 (n=14)</td><td>Right</td><td>0.389</td><td>0.160</td><td>0.247</td><td>0.099</td></tr>
<tr><td>Left</td><td>0.398</td><td>0.178</td><td>0.229</td><td>0.087</td></tr>
<tr><td rowspan="2">Follow-up (n=11)</td><td>Right</td><td>0.370</td><td>0.144</td><td>0.274</td><td>0.085</td></tr>
<tr><td>Left</td><td>0.380</td><td>0.145</td><td>0.242</td><td>0.093</td></tr>
</table>

S1: without insoles, S2: with insoles, Follow-up: after at least 4 weeks of using insoles

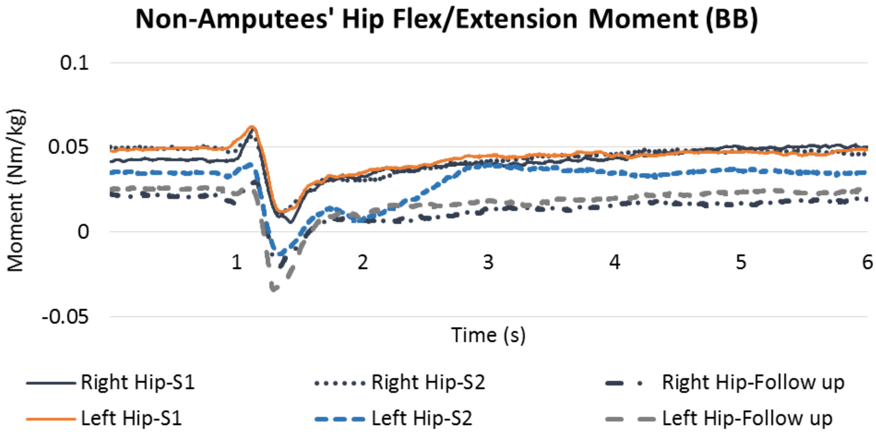
All peak magnitudes among the non-amputees, except one in S1, were plantar-flexor moments in the front-pulling perturbation, but the direction of peak values was more variable among the prosthetic ankle and IL data for the amputee group. For the IL, four moments in S1 and three moments in S2 were dorsi-flexor, while four moments in S1 and five moments in S2 were dorsi-flexor for the prosthetic ankle. The amount was more than two times larger in the IL compared to the prosthetic side; however, the magnitudes were smaller than in the back-pulling sessions.

There was a significant difference between the groups' peak value of ankle moment in the sagittal plane (Pillai's trace = 0.542, $F(3, 20) = 7.886$, $p = 0.001$, partial eta squared effect = 0.542;) and between the perturbation sessions and the intact/prosthetic side of the amputees (Pillai's trace = 0.768, $F(3, 20) = 22.116$, $p<0.001$, partial eta squared effect = 0.768). Insole use did not affect either group ($p = 0.422$) or the results of the two perturbation sessions ($p = 0.718$). When comparing the three sessions of insole use in the non-amputee group (without insoles, using insoles and after at least four weeks of use), the use of insoles did not change the peak moment ($p = 0.58$).

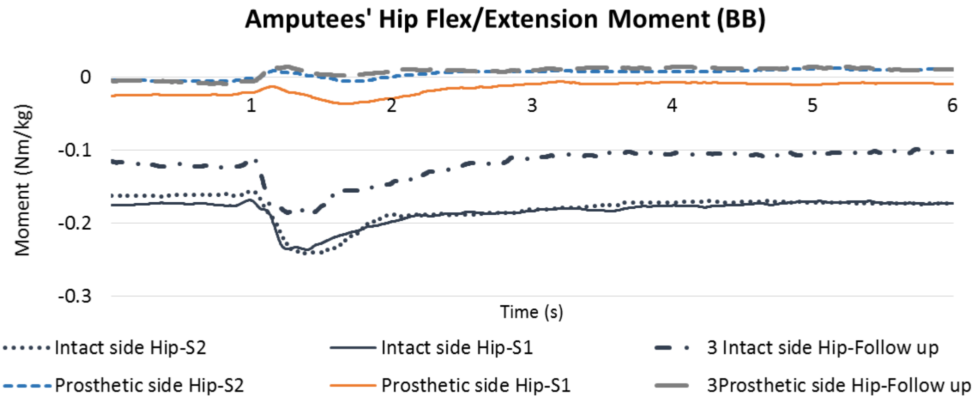
5.3.2.2.2 Hip Flex/Extension Moments

The positive and negative values are, respectively, flexor and extensor joint moments. Figure 5.21 indicates that a positive moment (hip flexor moment) was prominent in the non-amputee group, while the moment for the IL of amputees was a large hip extensor and in the prosthetic side an alteration of around zero. These moment changes have a sinusoidal pattern: initially, a small flexor moment appears in reaction to the load release which, in a short time, converts to an extensor moment and, again, to a flexor moment to retain balance in both legs. The changes here were sharper and happened over a shorter time in the non-amputees compared to the IL, particularly in the prosthetic side of the amputees.

As seen in Table 5.23, the amplitude of the sagittal plane hip moment changes during back-pulling perturbation for the IL of the amputees was 2-3 times larger than their prosthetic side; it was also larger than in the non-amputees. Similar to the back-pulling perturbation, Table 5.23 also shows the amplitude of the sagittal plane hip moment changes during front-pulling perturbation for the IL of amputees was 2-3 times greater than their prosthetic side; it was also greater than in the non-amputees.



A



B

Figure 5.21 Changes of hip moments in sagittal plane during back-pulling sessions, A: Non-Amputees, B: Amputees. -ve indicates hip extensor moments.

Table 5.23 Amplitude of hip moment in sagittal plane during standing balance against back/ front pulling loads

			Prturbation condition			
			Balance against back pulling load (BB)		**Balance against front pulling load (FB)**	
		Limb	**Moment (Nm/kg)**	**SD**	**Moment (Nm/kg)**	**SD**
Amputees	S1 (n=11)	Intact	**0.109**	0.039	**0.130**	0.040
		Prosthetic	**0.050**	0.039	**0.059**	0.029
	S2 (n=11)	Intact	**0.114**	0.040	**0.185**	0.081
		Prosthetic	**0.038**	0.011	**0.059**	0.041
	Follow-up (n=3)	Intact	**0.123**	0.049	**0.174**	0.126
		Prosthetic	**0.038**	0.016	**0.055**	0.043
Non-Amputees	S1 (n=14)	Right	**0.081**	0.038	**0.098**	0.072
		Left	**0.080**	0.033	**0.102**	0.071
	S2 (n=14)	Right	**0.071**	0.033	**0.084**	0.026
		Left	**0.089**	0.061	**0.097**	0.027
	Follow-up (n=11)	Right	**0.070**	0.023	**0.083**	0.035
		Left	**0.091**	0.030	**0.083**	0.036

S1: without insoles, S2: with insoles, Follow-up: after at least 4 weeks of using insoles

Figure 5.22 shows that the hip moment changes in the sagittal plane during front-pulling perturbation sessions. Though the magnitudes varied, similar patterns were observed in the moments from both feet in the non-amputee group and the intact side of amputees. However, as in the back-pulling sessions, the moments were flexor moments for non-amputees but extensor moments for the IL of amputees, and around zero for the prosthetic side. The prosthetic side has a simple and different pattern at load release: it changes to a small extensor moment and, after reaching its peak point, gradually changes back to a small flexor moment.

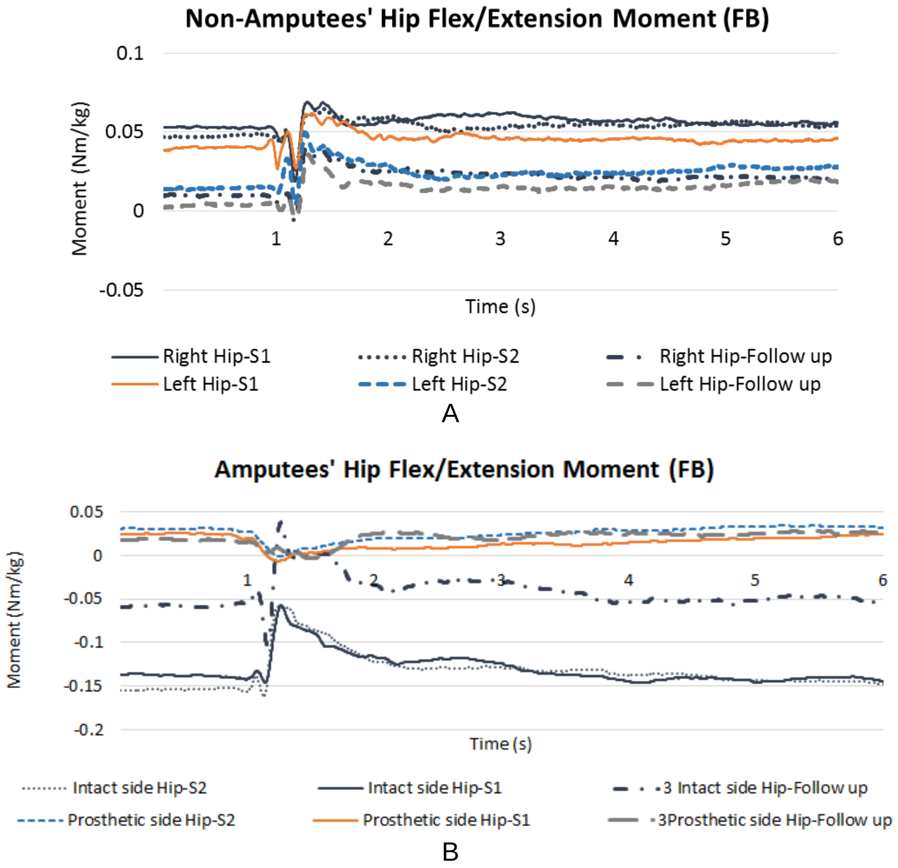


Figure 5.22 Changes of hip moments in sagittal plane during front-pulling sessions, A: Non-Amputees, B: Amputees. -ve indicates hip extensor moments.

There was a significant difference between the groups' amplitude of sagittal plane hip moment changes during the standing balance (Pillai's trace = 0.76, $F(3, 20) = 21.06$, $p<0.001$, partial eta squared effect = 0.76), and between the intact and prosthetic side of the amputees (Pillai's trace = 0.721, $F(3, 20) = 17.263$, $p<0.001$, partial eta squared effect = 0.721). Insole use did not affect either group ($p = 0.276$) or the results of the two perturbation sessions ($p = 0.343$). When comparing the three sessions of insole use in the non-amputee group (without insoles, using insoles and after at least four weeks of use), there was no significant difference between the flex/extension hip moments in the perturbation sessions and right/left sides values ($p=0.553$) and insoles sessions ($p=0.846$).

Table 5.24 presents the absolute maximum sagittal plane hip moments which were experienced by each hip joint during back-pulling and front-pulling perturbations. As was expected from Figure 5.21-A, the peak value was positive (flexor moment) for most of the non-amputees during standing balance against a back-pulling load. Only six peak values for the right-S1, three for the right-S2, six for the right follow-up, three for the left-S1, four for the left-S2 and five for the left follow-up sessions had negative values (extensor moment). Meanwhile, for the IL of amputees, only two peak values were positive and, in the prosthetic side, five for the S1 and six for the S2 had positive values. The absolute magnitude for the IL of amputees was 3-4 times larger than their prosthetic side, and it was also more than two times larger than for non-amputees.

Table 5.24 Peak value of hip moment in sagittal plane against back/ front pulling loads

			Prturbation condition			
			Balance against back pulling load (BB)		Balance against front pulling load (FB)	
		Limb	Moment (Nm/kg)	SD	Moment (Nm/kg)	SD
Amputees	S1 (n=11)	Intact	**0.291**	0.160	**0.226**	0.120
		Prosthetic	**0.097**	0.047	**0.078**	0.036
	S2 (n=11)	Intact	**0.293**	0.168	**0.250**	0.174
		Prosthetic	**0.079**	0.046	**0.102**	0.049
	Follow-up (n=3)	Intact	**0.211**	0.103	**0.135**	0.036
		Prosthetic	**0.079**	0.036	**0.067**	0.045
Non-Amputees	S1 (n=14)	Right	**0.101**	0.057	**0.130**	0.070
		Left	**0.095**	0.045	**0.115**	0.036
	S2 (n=14)	Right	**0.086**	0.050	**0.114**	0.062
		Left	**0.110**	0.063	**0.124**	0.036
	Follow-up (n=11)	Right	**0.114**	0.045	**0.148**	0.075
		Left	**0.118**	0.048	**0.112**	0.059

S1: without insoles, S2: with insoles, Follow-up: after at least 4 weeks of using insoles

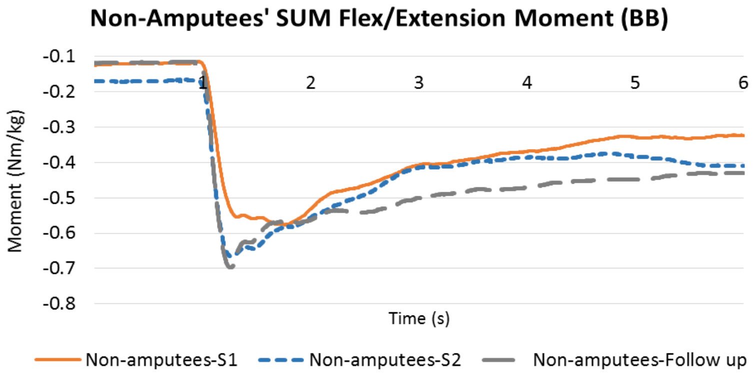
As with the back-pulling sessions, the peak value was not in the same direction for all participants. Three moments in S1 and two moments in S2 were flexor moments for the IL of amputees. Meanwhile, the number of positive values for the prosthetic side was six moments in both S1 and S2 sessions. Non-amputees had nine and 10 positive values, respectively, in their right and left sides during the S1 and S2 sessions, and both sides presented six maximum positive moments in the follow-up session. The absolute magnitude for the IL of amputees was 2-3 times larger than on their prosthetic side. The value for the non-amputees was close to that of the prosthetic side of the amputees.

A significant difference was seen between the groups' peak value of hip moment in the sagittal plane (Wilks' lambda = 0.469, $F(3, 20) = 7.535$, $p = 0.001$, partial eta squared effect = 0.531) and between the intact/prosthetic side of the amputees (Wilks' lambda = 0.545, $F(3, 20) = 5.56$, $p = 0.006$, partial eta squared effect = 0.455). Insole use did not affect either group ($p=0.466$) or the results of the two perturbation sessions ($p = 0.368$). When comparing the three sessions of insole use in the non-amputee group (without insoles, using insoles and after at least four weeks of use), the use of insoles did not change the peak moment ($p = 0.435$).

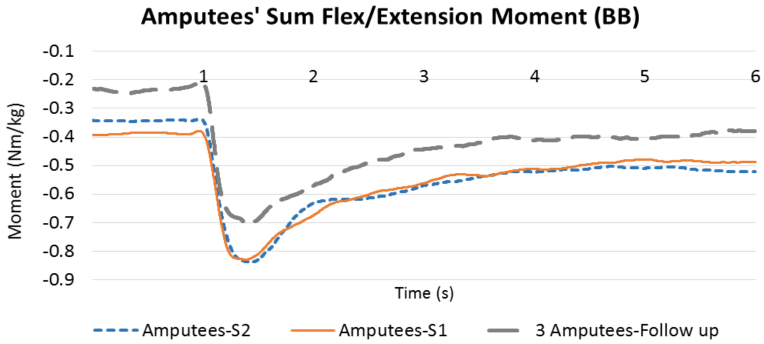
5.3.2.2.3 Sum Flex/Extension Moments

As was noted in the methodology section, the sum moment was calculated by adding the ankle and hip moments of each lower limb in each plane separately. Positive and negative values are, respectively, flexor and extensor moments.

Figure 5.23 shows a prominent extensor moment occurring during the whole of the evaluated time in both groups during back-pulling sessions, which was not unexpected since the ankle flex/extension moment was bigger than the hip moment, and so it was the main contributor to the sum of the moment value.



A

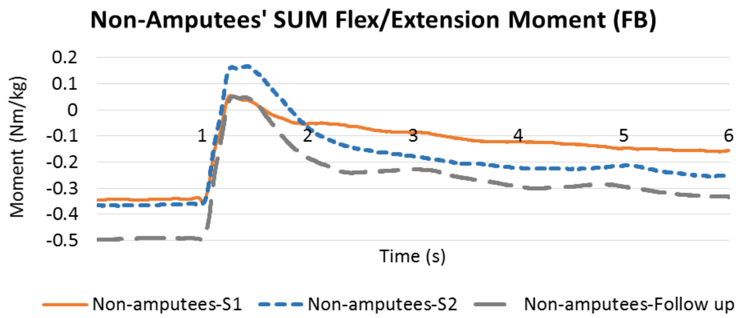


B

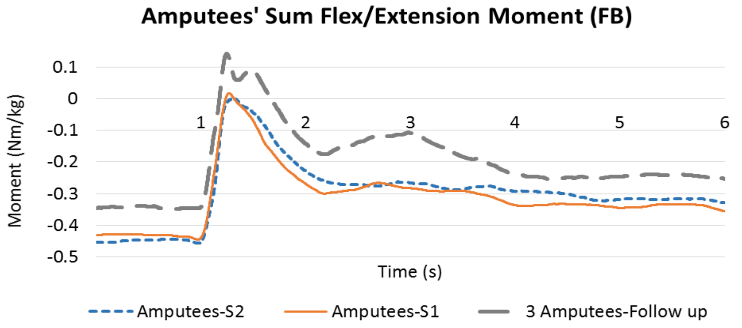
Figure 5.23 Changes of Sum-moment in sagittal plane during back-pulling sessions, A: Non-Amputees, B: Amputees. -ve indicates hip extensor moments.

As seen in Figure 5.24, and as with the back-pulling session, an extensor moment occurred during most of the evaluated time in both groups during front-pulling, only moving to a flexion moment briefly, in some tests, a short time after load release was seen. However, unlike in the back-pulling tests. The extensor moment here reduces on load release (sometimes with overshoot, hence the small flexor moment in some cases) before returning to an extensor moment. This is to prevent the subject from falling backward, whilst in the back-pulling tests, the increase in extensor moment is to prevent the subject from falling forwards.

Table 5.25 presents the amplitude of sum moment changes. After using the insoles, the mean of the sum moment shows an increase in the non-amputee group.



A



B

Figure 5.24 Changes of sum-moment in sagittal plane during front-pulling sessions, A: Non-Amputees, B: Amputees. -ve indicates hip extensor moments.

Table 5.25 Amplitude and peak value of sum-moment in each test condition

		Sum Moment (N.m/kg)			
		Amplitude		Peak value	
	Test condition	**Mean**	**SD**	**Mean**	**SD**
Amputees	BB-S1 (n=11)	**0.555**	0.114	**0.894**	0.318
	BB-S2 (n=11)	**0.552**	0.146	**0.870**	0.339
	BB-Follow up (n=3)	**0.519**	0.083	**0.726**	0.214
	FB-S1 (n=11)	**0.514**	0.123	**0.509**	0.206
	FB-S2 (n=11)	**0.560**	0.162	**0.521**	0.252
	FB-Follow up (n=3)	**0.545**	0.072	**0.503**	0.068
Non-Amputees	BB-S1 (n=14)	**0.590**	0.228	**0.672**	0.340
	BB-S2 (n=14)	**0.646**	0.227	**0.764**	0.359
	BB-Follow up (n=11)	**0.654**	0.155	**0.759**	0.298
	FB-S1 (n=13)	**0.524**	0.212	**0.449**	0.099
	FB-S2 (n=14)	**0.631**	0.155	**0.459**	0.131
	FB-Follow up (n=11)	**0.612**	0.129	**0.543**	0.169

BB: balance during back-pulling, FB: balance during front-pulling, S1: without insoles, S2: with insoles, Follow-up: after at least 4 weeks of using insoles

There was no significant difference in the amplitude of the sagittal plane sum moment changes during standing balance between groups ($p = 0.866$), between perturbation sessions ($p = 0.545$) or in insole use ($p = 0.066$). When comparing the three sessions of insole use in the non-amputee group (without insoles, using insoles and after at least four weeks of use), use of insoles was associated with an increased moment amplitude in S2, which was maintained in the follow-up ($F = 4.054$, $p = 0.041$, partial eta squared effect = 0.288).

The absolute maximum amount of the sum-moment was expressed by an extensor in back-pulling for both amputees and non-amputees. However, in front-pulling, only a few peak values were positive (flexor moments). Two in the S1 and three in S2 sessions of amputees, and four values in S1/S2 and one in the follow-up sessions of non-amputees, were flexor moments. Min-Max values indicate the peak value was highly variable among both groups, but the mean value was greater in back-pulling compared to front-pulling.

There was no significant difference between group peak values of sum moment in the sagittal plane (p=0.254) or in insoles use (p=0.557), but there was a significant difference between perturbation sessions, which recorded larger values for back-pulling sessions (Wilks' lambda = 0.349, F(1, 22) = 41.076, p<0.001, partial eta squared effect = 0.651). When comparing the three sessions of insole use in the non-amputee group (without insoles, using insoles and after at least four weeks of use), the use of insoles did not significantly change the peak value (p = 0.241).

Table 5.26 represents the percentage of each joint's (ankle and hip) contribution to the sagittal plane sum moment during back-pulling and front-pulling perturbation.

Table 5.26 Contribution of each joint moment as percentage of sum-moment's amplitude in the sagittal plane during standing balance against back/front pulling loads

			Balance against back pulling load (BB)		Balance against front pulling load (FB)	
		Limb joint	**Percent of sum moment (%)**	**SD**	**Percent of sum moment (%)**	**SD**
Amputees	S1 (n=11)	Intact ankle	**62.6**	6.6	**57.7**	10.1
		Prosthetic ankle	**13.1**	6.1	**14.1**	8.9
		Intact hip	**16.9**	3.5	**19.4**	5.2
		Prosthetic-side hip	**7.5**	4.2	**8.7**	4.2
	S2 (n=11)	Intact ankle	**63.5**	6.1	**53.6**	7.5
		Prosthetic ankle	**12.5**	5	**13.9**	8.7
		Intact hip	**17.9**	4.1	**24.8**	7.8
		Prosthetic-side hip	**6.1**	1.5	**7.7**	3.7
	Follow-up (n=3)	Intact ankle	**61**	4.1	**56.5**	17.0
		Prosthetic ankle	**15.1**	4.6	**14.1**	6.9
		Intact hip	**18.3**	3.9	**22.5**	9.0
		Prosthetic-side hip	**5.6**	1.3	**6.9**	3.2
Non-Amputees	S1 (n=14)	Right ankle	**37.9**	4.9	**37.7**	6.1
		Left ankle	**38.6**	5.3	**34.3**	5.8
		Right hip	**11.8**	3.7	**13.6**	6.1
		Left hip	**11.6**	3.4	**14.4**	4.8
	S2 (n=14)	Right ankle	**38.5**	6.2	**38.1**	6.4
		Left ankle	**40.7**	6.3	**38.0**	5.8
		Right hip	**9.6**	2.1	**11.1**	3.4
		Left hip	**11.2**	4.2	**12.7**	2.8
	Follow-up (n=11)	Right ankle	**35.7**	5.3	**38.2**	6.3
		Left ankle	**43.2**	6	**37.9**	6.3
		Right hip	**9.1**	2.2	**11.6**	4.7
		Left hip	**12.0**	3.0	**11.1**	3.3

BB: balance during back-pulling, S1: without insoles, S2: with insoles, Follow-up: after at least 4 weeks of using insoles

As seen, the ankle moment contributes more than the hip to the sum moment. Its percentage contribution in non-amputees was almost the same for both right and left feet, but, in the amputee group, the IL ankle moment was by far the largest contributor to the sum moment. Interestingly, the hip moment of the IL also had a larger contribution than on the prosthetic side and was more of a contributor to the sum moment than it was to the sum moment in the non-amputee group. The contribution of each joint in the sagittal plane's sum moment amplitude during front-pulling perturbation was similar to back-pulling. Again, the ankle moment contributed more than the hip in the sum moment. Its percentage in non-amputees was almost the same for the right and left sides, and insole use increased its symmetry. The IL ankle moment in the amputee group contributed most to the sum moment. The contribution of the IL's hip moment was larger in the front-pulling compared to the back-pulling.

These significant differences in the contribution by joints to the magnitudes of amplitude of the sagittal plane in the sum moment were found to be as follows:

1- The contribution of the prosthetic and IL ankle moment in amputees (Wilks' lambda = 0.11, $F(3, 20) = 54.072$, $p<0.001$, Partial Eta Squared = 0.89), and the value between groups (Wilks' lambda = 0.109, $F(3, 20) = 54.233$, $p<0.001$, Partial Eta Squared = 0.891);
2- The contribution of the prosthetic and IL hip moment, as well as the difference between the perturbation sessions, in amputees (Wilks' lambda = 0.223, $F(3, 20) = 23.176$, $p<0.001$, Partial Eta Squared = 0.777), and the value between groups (Wilks' lambda = 0.224, $F(3, 20) = 23.057$, $p<0.001$, Partial Eta Squared = 0.776).

But, the differences between insole use sessions regarding the contribution of ankle moments ($p = 0.879$) and hip moments ($p = 0.597$) was not significant. Non-significant differences were seen in ankle and hip joint contributions ($p = 0.064$) when comparing the three insole use sessions among the non-amputee group.

5.4 Discussion

The significant differences between the kinematics and kinetics of the perturbed standing balance of the amputee and non-amputee participants will be discussed in the following section. Before this, and by reviewing Table 5.1, it should be noted the pain had the greatest negative effect on mobility (PEQ-M score), prosthetic use satisfaction/evaluation and participants' comprehension concerning the QOL of TF amputees. In addition, those with stump/IL and lower back pain had relatively lower ABC scores compared to those without pain. The average ABC score was higher than 80 for those who did not suffer IL pain. As was expected, the ABC score presented the most extensive information about the balance problems of the participants. Those with falling experience or worries about falling or about using a walking aid occasionally had significantly lower ABC scores than the group without these problems. These results remind us of the importance of pain management to improve mobility and balance in amputees.

5.4.1 Kinematics

COP displacements: The amplitude of anteroposterior and mediolateral COP displacements were significantly larger for the IL of amputees compared to the non-amputees, while the displacement was smaller for the prosthetic side (Figure 5.3-Figure 5.6) (supporting hypotheses number 1-4 about COP displacements). In the literature, similar features have been reported for quiet standing (Buckley et al., 2002; Nadollek et al., 2002; Hlavackova et al., 2011) or the perturbed standing balance of lower limb prosthesis users (Vrieling et al., 2008b; Vatanparast et al., 2009; Bolger et al., 2014). But, (Kozáková et al., 2009) reported a greater COP speed and mediolateral COP sway in the prosthetic side, and the same anteroposterior displacement for both limbs in TT amputees and in quiet standing balance. The smaller prosthetic COP anteroposterior displacement might be due to the absence of ankle muscle performance in the artificial foot. These muscles have been shown to play a role in regulating the COP position and their absence in the prosthetic side requires a greater reliance on the IL. Greater COP displacements are considered signs of a lower level of balance control during standing (Paillard and Noe, 2015). Ku et al. (2014), in their review paper, also reported inadequate balance was associated with larger COP displacements in the IL of amputees. Interestingly, several studies have reported larger COP displacement in the quiet standing balance of fallers compared with non-fallers (Melzer, I. et al., 2004; Pajala et al., 2008; Muir et al., 2013). It is important to consider these findings alongside the results related to lower limb amputees as a group at risk of falling due to an impaired musculoskeletal system and deficient somatosensory information sent to CNS following limb loss.

The distance between the right and left sides' COPs can be considered as representing the combined mediolateral displacement of both feet's COP, the base of support width and the mediolateral displacement of the COM. It was larger in back-pulling sessions in comparison to front-pulling (Figure 5.7) (rejecting hypotheses number 6 and 8, yet supporting hypothesis number 7). This might be seen to be due to the participants feeling the need to increase the base of support in this perturbation condition. This may be due to an initial greater concern about falling when being pulled backwards due to having fewer visual clues, Although, the amplitude of mediolateral COP displacement of both of the amputees' limbs was similar to front pulling, indicating that the participants were equally capable of regaining balance mediolaterally in both of these perturbation directions.

COM displacements: No significant differences were detected between the amplitude of the COM displacement in the anteroposterior direction for amputees and non-amputees, nor between the two perturbation conditions (Figure 5.8) (supporting hypotheses number 6-8 related to anteroposterior COM displacement). It might be an indicator of proper control of the CNS on the COM to keep it at the base of support and, consequently, maintain balance. In fact, the anteroposterior COP displacement is always larger than the COM displacement, which is necessary for balance maintenance: if the

COM moves forward, the CNS sends messages to the plantar-flexor muscles to contract and bring the COP in front of the COG in order to recover balance (Palmieri et al., 2002).

The amputees had a larger amplitude of mediolateral COM displacement (Figure 5.9) (supporting hypotheses number 6-8 related to mediolateral COM displacement). Bolger et al. (2014) reported no difference between the COM displacements of TT amputees and non-amputees during perturbed standing balance. However, (Doheny et al., 2012) reported a wider range of mediolateral displacement for elderly fallers during standing balance. This biomechanical similarity of our TF amputee participants and fallers is worthy of consideration.

Net COP displacements: The amplitude of anteroposterior displacement of the net COP was similar in both groups and in the perturbation conditions (Figure 5.10) (supporting hypotheses number 6-7 and rejecting hypothesis number 8). However, in spite of there being no differences between such conditions, the mediolateral displacement of the net COP was larger in the amputees group (Figure 5.11) (supporting hypotheses number6-8). It seems part of the amputees' standing balance strategy is to maintain balance by alternating the weight bearing of the intact and prosthetic sides. This can also be interpreted as a lower level of balance.

Net COP distance with COG: The amplitude of the distance between the COG and the net COP was significantly larger in front-pulling perturbation of the amputees (Figure 5.12) (rejecting hypotheses number 6 and 8, supporting hypotheses number 7). The distance between the COG and net COP during one second before and five seconds after load release was greater for the front-pulling condition in comparison to back-pulling in both groups (rejecting hypotheses number 6 and 7). The value was larger for back-pulling and smaller for front-pulling conditions among non-amputees compared to amputees during one second before load release (supporting hypothesis number 8). According to Winter (1995) inverted pendulum model of the body in standing balance, a larger distance between the COG and net COP leads to a larger acceleration of the COM. These findings have indicated that front-pulling is a challenging condition, particularly for amputees. It should be noted that front-pulling induces a backward fall tendency, which produces an insecure balance situation due to the absence of visual control related to the forced falling direction.

5.4.2 Kinetics

Anteroposterior GRF: As was seen in Figure 5.13 and Figure 5.14, the changes of the anteroposterior GRF following load release was larger for the IL of amputees (almost 3-5 times that of the prosthetic side and 1.5 times of non-amputees) during both perturbation conditions (Table 5.11), which supports hypotheses number 1-5. The peak of the force for the IL was also larger than the prosthetic side and the non-amputee group (Table 5.12). The anteroposterior GRF adjusted the movements of the COP and COM to the perturbations (Vrieling et al., 2008b). This finding matches a larger anteroposterior

COP displacement on the IL. Bolger et al. also reported the same pattern in the force magnitude for TT amputees. They suggested that this was due to the inability of the prosthetic device to generate an active plantar flexion moment (Bolger et al., 2014). Vrieling et al. (2008b) also reported a larger anteroposterior force for the IL of LLAs compared to non-amputees during perturbed standing balance, but they observed the same large force on the prosthetic side and related it to the use of hip muscles on the amputated side and the need to keep the knee joint locked by controlling the COM position.

Mediolateral GRF: The peak and amplitude of the mediolateral GRF had greater values for both sides of the amputees compared to the non-amputees (Table 5.13), which means hypothesis number 1 and supporting hypothesis number 5 are rejected. In addition, the amputees exhibited a larger peak of mediolateral force in the back-pulling sessions compared to their front-pulling sessions (supporting hypothesis number 2). Bolger et al. (2014) also recorded the same mediolateral forces in the prosthetic and intact sides of the TT amputees in standing balance. It has already been observed that there was a larger amplitude of mediolateral displacement of the COM and net COP in the amputee group. This shows that the prosthetic device could produce mediolateral force similar to the IL in response to the mediolateral displacement of the COM, possibly due to the greater rigidity of the prosthesis in this direction (i.e., limited inversion/eversion at the ankle).

Vertical GRF: The amplitude of vertical force changes due to the applied perturbation for both sides of the amputees was almost the same (10-11% of body weight), but larger than in non-amputees (5-7% of body weight). Meanwhile, the peak values of the vertical force were 60-68% of body weight for the IL compared to 40-46% of body weight in the prosthetic side and 51-53% of body weight for non-amputees (15) (supporting hypotheses number 1-5). This asymmetrical vertical force is expected from the observed prosthetic and intact side's COP-COPnet distance, which had already shown greater reliance on the IL. It is part of the general balance strategy of LLAs to trust more in their intact side. The asymmetrical loading on IL/PLs has been reported in previous balance studies (Vrieling et al., 2008b; Vatanparast et al., 2009; Hlavackova et al., 2011). However, Bolger et al. (2014) recorded the same vertical GRF magnitude for the intact and prosthetic side of TT amputees during perturbed standing balance and suggested, in their study, that the subjects were using the prosthesis in a similar way to the IL. This apparent difference with the current study is possibly due to the difference between TT and TF amputees. However, Vrieling et al. (2008b) and Vatanparast et al. (2009) also had TT subjects with a greater reliance on the IL. Interestingly, Mayer et al. (2011) reported a more symmetrical role of the limbs in the standing balance of TT amputees who had received regular physical therapy, in addition to walking practice sessions. These findings indicate the importance of walking practice on standing balance.

Role of limbs in load sharing: The contribution of the limbs in bearing the GRF during the one second before load release. Table 5.17 and

Table 5.18 showed that the IL had the major and the prosthetic side had the minor role in the production of anteroposterior force during the back-pulling sessions in within and between groups' comparisons (supporting hypotheses number 1 and 5), while the contribution of the limbs in these forces was the same for both sides of the amputees during front-pulling. In addition, the symmetrical mediolateral forces were greater in the back-pulling sessions for the amputees (rejecting hypothesis number 2 and supporting hypothesis number 5). The IL was the main contributor to vertical force bearing (on average, 61% of weight) in both perturbation sessions, while the right/left sides of non-amputees took the same load (supporting hypotheses number 1 and 3-5, rejecting hypothesis number 2). During the five seconds after load release (Table 5.19 and Table 5.20), the contribution of the limbs decreased for the anteroposterior forces but, still, the role of the IL was greater than the prosthetic side and the non-amputees in the back-pulling sessions (supporting hypotheses number 1 and 3-5, rejecting hypothesis number 2). It did not return to zero net force, as would be expected for a quiet standing after load release and which had been seen in the non-amputees. This may indicate a residual postural adjustment was made initially to balance the perturbing load or as a consistent strategy to compensate for a PL in all situations. It is not possible to clearly state what this means in the present study, but it may be worth further investigation. Load release did not have an effect on the roles of the limbs in producing mediolateral forces in both group and perturbation conditions. Similar to one second before load release, the IL contributed the main vertical force during the five second period after load release; however, the contribution involved a non-significant decrease of a few percentage points during back-pulling and a slight increase during front-pulling (supporting hypotheses number 1-5). At the same time, the right/left side of the non-amputees had played the same part in both perturbation conditions. These findings again display the dominant role of the IL of amputees in their balance. One reason for the lower contribution of prosthesis devices in balance might be their inability to transmit forces similar to the IL during balance (Bolger et al., 2014), or the discomfort if the user tries to do this. Furthermore, it can also be part of the lower limb amputees' adaptation or compensation strategy to optimise their balance (Ku et al., 2014). Symmetrical standing improves the balance of healthy people (Kozáková et al., 2009), but for lower limb amputees, it might deteriorate the balance. Vanicek, N. et al. (2009a) also reported a greater contribution by the PL in weight bearing in TT amputee fallers in comparison with non-fallers. It seems natural that amputees rely on the limb which they can fully control instead of the limb which is without physiological control of its knee and ankle joints.

Ankle flex/extension moment: The amplitude and peak of flex/extension ankle moments were largest in the IL of amputees and smallest in the prosthetic side during both perturbation conditions when compared within and between groups (Table 5.21 and Table 5.22) (supporting hypotheses number 1 and 3-5, rejecting hypothesis number 2).

These findings are not far from expectations as the lack of a natural ankle joint and its musculature had already led to smaller COP displacements and a lower ability to produce anteroposterior forces on the prosthetic side. The intact side compensates for the deficient role of the prosthetic side; however, the stiffness of the prosthetic ankle-foot component can produce a passive moment and, in this way, the prosthetic side might have a role in recovering balance, as mentioned in Nederhand et al. (2012) study. Unfortunately, the stiffness characteristics of the prostheses used were not collected, and so a correlation between the stiffness and joint moments could not be verified. Curtze et al. (2012) also observed greater ankle moment by the IL of TT amputees in reaction to load release, but they reported that the contribution of the prosthetic ankle in front-pulling (backwards falling) increased. They related this to the contribution of the passive properties of the prosthetic ankle in balance recovery (Curtze et al., 2012). The peak moment was larger for both limbs and groups during back-pulling sessions, which might be due to the feeling of insecurity in the participants when confronting a pulling load at their backs, which unseen. In response to this, they lean slightly forward. This may lead to a larger distance between the action line of the GRF and the ankle joint. This consequently produced greater external moments, which were countered by larger internal moments.

Hip flex/extension moment: Similar to trends in the ankle moments but with smaller magnitudes, the amplitude and peak of the hip flex/extension moments were largest in the IL of amputees and smallest in the prosthetic side, during both perturbation conditions, when compared within and between groups (Table 5.23, Table 5.24) (supporting hypotheses number 1-5). This is clearly not due to the deficiency in the musculature about the hip. Curtze et al. (2012) observed a larger hip moment for the IL of TT amputees in reaction to load release, but only in a back-pulling session (front fall). Furthermore, the IL of the amputees represented an extensor moment, while the non-amputees displayed a small flexor hip moment (Figure 5.21, Figure 5.22). The prosthetic side’s hip moment was altering around zero, indicating little contribution from the hip on the prosthetic side to help balance control. These findings suggest that the line of gravity was passing very close to the hip joint on the prosthetic side, the front of the IL hip and slightly behind the non-amputee’s hips. The difference between the hip moments of the amputees’ intact and prosthetic sides might be part of their postural adjustment to have better control of the prosthetic device and to maintain balance, and it indicates greater confidence in weight bearing through the IL (and a lack of confidence in and/or willingness to rely on the PL). This behaviour may lead to asymmetrical loading of the lower back and, consequently, LBP.

SUM flex/extension moment: The sum moment was calculated as being representative of the contribution of the ankle and hip jointsof both lower limbs’ to balance. The amplitude of the sum moment had a higher level of variety among non-amputees, but the difference between amputees and non-amputees in both perturbation sessions was non-significant (supporting hypotheses number 6 and 7, rejecting hypothesis number 8).

The peak values were also not statistically different between the two groups, but the peak was greater in the back-pulling sessions (rejecting hypotheses number 6-8). When comparing each joints' contribution to the amplitude of the sagittal planes sum-moments (Table 5.26), obvious differences were observed between the amputees' limbs and non-amputees (supporting hypothesis number 1-5). The main contribution was made by the ankle moment in both groups. However, the proportion of its role was around 60% for the IL compared to 13-14% for the prosthetic ankle moment, and an almost symmetrical 34-43% of ankle moments for both sides of the non-amputees. The hip moments had a smaller contribution to the sum moment in amputees; it was almost symmetrical for the non-amputees (9-12%) but bigger for the IL (17-25%) and smaller for the prosthetic side (6-9%). In front-pulling, the contribution of the IL hip moment increased by only a few percent compared to the back-pulling. Curtze et al. (2012) reported similar findings (a 69% contribution of the IL ankle moment) for TT perturbed balance. These findings indicate that there was a prominent ankle strategy in the balance of both groups, while the amputees were more reliant on the IL ankle function.

5.4.3 Insoles effect

The insole use did not affect the amputee group's variables (a rejection of hypothesis number 10) and its influence on non-amputees was limited. Even its significant effects might be considered to act against better balance control. It increased the anteroposterior COP and COM displacement of the non-amputees in front-pulling (rejecting hypothesis number 9). The mediolateral displacement of the COM in the follow-up of the back-pulling session was significantly greater than the value for follow-up to the front-pulling for non-amputees (rejecting hypothesis number 9). Use of insoles increased the anteroposterior velocity of the COM in both groups and in the perturbation conditions (rejecting hypotheses number 9 and 10). Insole use increased the anteroposterior displacement of the COPnet in both of the perturbation sessions of non-amputees (rejecting hypothesis number 9). It increased the amplitude and distance between the COG and COPnet in the non-amputee group before load release (rejecting hypothesis number 9). A significant ankle moment increase was observed after using insoles in the non-amputee group (rejecting hypothesis number 9). These results might be due to the small height of the insoles under the heel, which changes the COPnet and ankle joint position related to the line of gravity.

5.5 Conclusion

Lower limb amputees are confronted with postural control challenges due to a lack of part of the musculoskeletal system, which is important in locomotion and standing, in addition to suffering unavoidable impairment of the somatosensory system due to the amputation of the limb. The aim of the study presented in this chapter was to evaluate the biomechanics of the perturbed standing balance of TF amputees and compare it with non-amputees, in addition to investigating the effect of insoles for both groups. This study has confirmed that the derived pair values were almost the same for both legs of non-amputees but there was a significant asymmetry between the IL and PLs of amputees. This showed that the amputees were more dependent on their IL. In addition, the role of the ankle joint was more prominent in maintenance of the balance which, in the absence of an ankle with characteristics similar to the natural ankle and plantar-flexor action in the PL, led to an increased role of the IL ankle. The amputees experienced greater COP displacement and velocity in their IL, which bears similarities with non-amputee fallers data and corresponds to the characteristics of low balance. The results also showed that the IL of amputees is subjected to larger loads and weight than the prosthetic side and the limbs of non-amputees. The majority of studies consider these changes to be adjustments made by amputees after amputation and prosthesis use. However, these alterations might lead to IL problems, such as overuse injuries and pain, features which were reflected in the results of the survey (chapter 3) and experienced by a majority of the participants in this study (7 out of 11). Thus, providing some kind of support for the IL would be highly beneficial for lower limb amputees. The idea of using insoles was proposed on the basis of providing external support for the IL.

The use of insoles did not lead to any significant changes in the main biomechanical variables, particularly among amputees. However, it might have affected some of the participants' data individually. It should be remembered that only three amputees participated in the follow-up session, which does not permit us to judge the long-term effects of insole use on their biomechanical data. In fact, the amputee participants were reluctant to rely symmetrically on their prosthetic device; therefore, overall changes were not observed in their balance parameters after insoles use. It might be due to their experience of having better balance with less prosthetic weight bearing. Even the effects of insoles on the variables involved in balance in the non-amputee group were associated with an increase of COP displacements, which are thought to lower the level of balance. This might be due to the soft material of the insoles, which leads to less control of COP displacements. It may be that the biomechanical data was influenced by differences between participants' footwear. It is also possible that the selected variables were not suitable for reflecting the effects of the insoles on balance or that the biomechanical effects of insoles will only be observable following long-term use. In addition, it cannot be ignored that both groups had healthy somatosensory systems in the feet which received the insole (the IL of the amputees and both limbs of the non-amputees). However, the quantitative evaluation of insoles use showed that almost all the participants were happy with them, which shows they had an unknown positive effect on their daily locomotion.

To the best of my knowledge, there is neither any similar published study related to the biomechanical evaluation of TF amputees' perturbed standing balance by the method presented in this thesis nor is there any study that evaluates insoles use for LLAs. Thus this study has added to the current knowledge about regarding the characteristics of AK prosthesis users' balance and the possibility of insoles use for improving this.

Chapter 6
Discussion

Summary

Introduction: Lower limb amputation is one of the musculoskeletal deficiencies which people can face mostly as a result of an unfortunate incident or through dysvascular diseases, particularly in old age. Based on WHO reports, the rate of people with diabetes as the main reason for dysvascularity is increasing globally. In addition, as life expectancy increases, the health issues associated with ageing will continue to grow. These facts add to our concerns about the problems of current and future lower limb amputees (LLAs). The primary need after lower limb amputation is to regain mobility; therefore, the main focus of healthcare systems regarding LLAs is on providing prosthetic devices. After using a prosthetic device as a compensator for limb loss, LLAs might experience several secondary health conditions, such as lower back and intact-side pain, frequent falling (Gailey et al., 2008) and, finally, a lower level of quality of life (QOL) due to the problems associated with amputation (Asano et al., 2008). In fact, amputees normally increase their reliance on their intact-side, which leads to asymmetrical posture and possible LBP, resulting in a higher load being placed on the limb, and consequences such as lower limb joint pain or degeneration, as well as a reduction in balance. A gap exists in assigning appropriate importance to the intact-side of LLAs in comparison to their prosthetic side. It is necessary to improve current prosthesis devices and to provide support for the intact-side in order to protect this limb from the consequences of the high level of dependence amputees may place on it. This current study was developed from these facts and from perceived amputee needs. The study consists of two main parts: 1) an online survey (Chapter 3); and 2) a biomechanical assessment of LLAs' balance and level walking (Chapters 4 and 5). The survey was designed to provide broad and up-to-date information about LLA issues related to amputation and prosthesis use, which might be managed by orthotic intervention. The particular focus was to determine how the problems affect the function/mobility of LLAs and if the problems are connected to deficient balance. It was a comprehensive survey as it was administered online, which resulted in it not being limited to a certain geographical area. Furthermore, it included respondents with all levels of lower limb amputation. It was based on three standard questionnaires and contained more than 100 questions. This was presented in the form of a single study, as opposed to multiple surveys, which permitted an investigation into the inter-relationship between the various problems experienced by LLAs. These aspects of the survey have additional advantages when compared to the simple separate reviews of previous studies used to investigate different problems in order to reach a conclusion. The biomechanical tests were developed according to the LLAs' issues and

the available knowledge about the effectiveness of insoles in confronting the balance and musculoskeletal problems encountered by non-amputees. This was a novel idea in the field of LLA locomotion studies to use insoles for them. The objective of biomechanical tests was to evaluate insoles' effects on the biomechanical features of perturbed standing balance and walking of TF amputees, and the possibility of considering their use as external support for the LLAs' intact-side. In addition, the level of functionality of TF amputees was evaluated according to their spatio-temporal variables of walking.

The reviewed literature (Chapter 2) indicated the biomechanical results by using motion analysis systems commonly used to differentiate between persons with and without deficit balance: for example, the centre of pressure (COP) and centre of mass (COM) displacements of fallers are greater than they are for non-fallers. These systems can also reveal differences between the kinematics and kinetics of non-amputees and lower limb amputees when walking. A considerable number of the studies evaluating insoles effects on balance, back and lower limb pains or injuries confirm their positive effectiveness. These findings have provided a basis to examine the possibility of insoles having positive effects when used with intact-side limbs by LLAs. Furthermore, the literature has confirmed that the study of standing balance and walking of affected groups such as LLAs by using motion analysis systems (including force platforms) is reliable and conventional.

Survey: The survey presented in Chapter 3 was composed of three standard questionnaires in order to collect a broad range of information regarding LLA issues in daily life, and the fields which require more work. As mentioned in the aims and objectives section of Chapter 2, the survey was designed to investigate LLAs' main issues with regard to their amputation and prosthetic use, particularly concerning their functionality in daily activities and balance deficiency, and the relationship between these issues. As the survey was online and not paper-based, it provided an opportunity to gather answers from participants living in several parts of the world. In total, 155 respondents with different levels of lower limb amputation participated in the study. The responses to the questions in the Prosthesis Evaluation Questionnaire (PEQ) (Legro MW et al., 1998) section of the survey indicated a large number of participants suffered from phantom limb (79%), phantom pain (68%), stump pain (76%), intact-side pain (72%) and lower back pain (75%). The mobility score of the participants with these pains was lower than those without them. The mobility score had a positive relationship with the satisfaction and QOL scores. The average score of the overall prosthesis evaluation was neutral (approximately 5 out of 10) which means many of the participants were in a 'not bad/not good' condition. The Activities-Specific Balance Confidence (ABC) Scale questionnaire (Powell and Myers, 1995) provided information about the level of the participants' functionality in daily activities and their risk of falling, according to their balance confidence. The results of this questionnaire indicated 4/5th of respondents needed intervention to improve their balance (Myers et al., 1998). In addition, 3/5th had a score of less than 67, which is an indicator of being at risk of falling (Lajoie and Gallagher, 2004). A majority of participants (62%) had a history of falling during the 12 months prior to entering the study, and a greater number of participants (72%) expressed concern regarding falling during prosthesis usage. The participants using walking aids and those who were suffering pain in various parts of their body recorded lower mobility and ABC scores. In addition, the respondents with a lower level of balance confidence had worse mobility and QOL scores. Furthermore, there were associations between the presence of pain and lower levels of QOL, balance confidence levels, and falling experience. As an online survey, we had LLAs who had experienced almost the same issues responding from various geographical locations around the world. This allowed us to consider their problems as global issues. The findings of the survey emphasized the necessity of paying special attention to the management of these issues by related institutions (providers of medical treatment and musculoskeletal rehabilitation). The results of the survey (concerning mobility and balance deficiency) encouraged us to evaluate more carefully the possible effects of insoles use as a means of improving LLAs' balance and walking through conducting a biomechanical analysis of perturbed standing balance and self-selected walking among two volunteer groups of TF amputees and non-amputees.

Biomechanical research: The biomechanical tests were performed by using motion analysis systems; these consist of the motion capture system (multiple high-speed cameras) and force platforms. These systems provide precise three-dimensional kinematic and kinetic analysis of motion tasks. The main aims of the biomechanical studies, presented in chapters 4 and 5, were to evaluate the effect of insoles use on the perturbed standing balance and level walking of TF amputees (using mechanical passive prosthetic devices) and non-amputees, and then comparing the two groups. The novelty of the biomechanical part of the research was related to the evaluation of the effects of insoles use on the balance and walking of the TF amputees, as well as applying this specific perturbation method for assessment of AK prosthesis users' balance. As was mentioned in the aims and objectives section of Chapter 2, the biomechanical tests were conducted to assess the level of functionality of the TF amputees participating in this study according to the spatio-temporal variables of level walking and their ABC scale and PEQ-M scores. These data would be used to characterise and compare the biomechanical features of TF amputees and non-amputees walking; to investigate the effects of insoles use on the biomechanical features of TF amputees and non-amputees' walking; to characterise and compare the biomechanical features of TF amputees and non-amputees perturbed standing balance; and to investigate the effects of insoles use on the biomechanical features of the amputees and non-amputees' perturbed standing balance.

Level walking: The amputee participants' level of functionality and the insoles effects on dynamic daily activities were evaluated via a gait analysis of TF amputees and non-amputees' walking at a self-selected speed. The amputees had lower levels of functionality according to the spatio-temporal variables of their walking, which corresponded with their moderate levels of functionality based on their answers to the ABC scale and PEQ-M questionnaires. Two amputees did not have any experience of walking training, while one of them had experienced recurrent falling in the previous 12 months and another had severe gait deviation besides also having the lowest level of functionality. These might be considered as the reason gait training for LLAs after receiving their first prosthetic device is so important. The amputees had shorter spatial and longer temporal variables, which led to a slower speed of walking and asymmetrical gait patterns, along with them spending more time on their intact limb (longer double support and stance phases). These features corresponded with the literature (F Farahmand et al., 2006; Uchytil et al., 2013; Jarvis et al., 2017). The kinematic and kinetic variables of intact limb, besides their spatio-temporal characteristics, when compared to their affected side showed the key role of the intact limb in TF locomotion and adaptation to prosthetic use. The prominent ankle and hip powers of intact limbs showed the crucial part played by plantar-flexor and hip extensor muscles in TF amputees' walking (Seroussi, R. et al., 1996). The intact limb's propulsion powers were not greater than in the non-amputees, which shows the limbs did not exhibit a kinetic compensatory role (Vanicek, N. et al., 2009a). However, the intact limb's larger hip power generation at initial stance compensated for the affected limbs' simultaneous deficient propulsion due to the lack of plantar-flexor power generation (Seroussi, R. et al., 1996). Another interesting and new finding was the observation of the dynamic balance of the TF amputee participants being similar to the non-amputees on the basis of the mediolateral displacement of the COP (Kendell et al., 2010) and the relationship between the COP/COG and BOS (Kendell et al., 2010; Nagano and Begg, 2018) at mid-stance.

Perturbed standing balance: As was explained in chapter 5, the perturbations were applied to the standing balance of participants through two separate sessions of front and back pull/releasing load which, respectively, induced back and front falls. The load was adequate enough to disturb the balance without the need for a step to recover from it. The results showed extreme differences within the limbs of the amputees and between the balance characteristics of the amputees and non-amputees. The amplitude of the COP displacements and their velocities, the maximum amount of anteroposterior forces, the vertical forces, and the ankle and hip moments were greatest on the intact-side and least on the prosthetic side for amputees. The larger COP displacements and velocities are considered indicators of lower levels of balance control (Paillard and Noe, 2015). The mediolateral COM displacement of amputees was also larger than in non-amputees. This observation is a matter of concern as the same feature has been reported for non-amputee fallers (Doheny et al., 2012). Both groups used ankle moments to maintain their balance (ankle strategy) but the magnitude of the intact-side's moment was significantly larger than the amputee group's prosthetic side and either leg of the non-amputee group. The prosthetic side moment was smaller than in the non-amputee group too. These findings are close to Vrieling et al. (2008b) study of TT amputees' standing balance with a similar perturbation system. The Intact-side hip moment of the amputees had an opposite pattern to the non-amputee's moments as it was an extension moment in the amputees but a flexion moment in the non-amputees. It was also larger in magnitude than on the prosthetic side, which can be interpreted as producing an asymmetrical loading on the lumbo-pelvic area of the amputees' body. This is a potential mechanism which can lead to lower back pain in TF amputees. The weight distribution was asymmetrical, with the intact limb offering a greater contribution, which is common in LLAs and is part of their adaptation to prosthetic use (Ku et al., 2014). The same applies to the level walking: the results of the perturbed standing balance study also showed how the intact-side of amputees played a key role in their balance, while both legs of the non-amputees demonstrated similar features. In contrast to the gait, the level of balance during standing was lower for amputees because of the larger displacements of the COP. The main reason for this might be the nature of perturbed standing tests, which are not experienced by amputees as frequently as an activity such as walking in daily life.

Insoles effectiveness: Insoles had the least influence on the biomechanical variables, and the few observed cases were only related to the non-amputee group (such as the initial loading rate in walking). An interesting observation was the elimination of the initial impact force in the vertical GRF profile after insoles use in walking; however, only the loading rate of the non-amputees was affected by insoles use. Considering the fact that LLAs rely more on their intact limb, such an effect of insoles on the impact force might decrease the risk of them suffering limb damage. It is known that balance control strategies are re-developed during a six months' period after the first prosthetic fitting in lower limb amputees, and it becomes fixed during the subsequent balance-challenging conditions and probable falls. In this study, considerable time (more than eighteen years) had passed after initial prosthetic use for the participants and, therefore, the lack of statistical significance noted for insole use might be due to this and the difficulty of manipulating participants' long-term established balance strategies. From another perspective, insoles effectiveness might not be observed through the studied variables but through other variables. However, in spite of the non-significant immediate effects of insoles on the studied biomechanical variables, a qualitative evaluation of insoles after four weeks of daily use showed that the majority of the participants in both groups had positive views about insoles and accordingly, expressed their decision to continue using them after finishing the study. This was due to the overall greater comfort they felt. A further influence is that greater pressure in the rear and mid part of the intact foot of TF amputees was reported during walking (Castro et al., 2014). This might have been affected by insoles use in this study and resulted in the participants feeling more comfortable during their daily activities. In addition, it has been reported that a mechanical effect of insoles use might be the even distribution of plantar pressure (Hatton, A.L. et al., 2013). Hence, insoles might improve pressure distribution on the foot sole and have led to the positive feedback from the participants.

Limitations

Like any other research, this study had a number of limitations related to the approach to the study design. Regarding the biomechanical studies, we used a convenience sampling method which is based on available volunteers for the study and, consequently: 1- the non-amputee and amputee groups were not age-matched; 2- the amputees' ages differed widely; 3- only males volunteered to participate in the study. All of these factors might have affected the results. The literature related to insoles effectiveness was generally based on larger sample sizes. In addition, the follow-up session for evaluating the longer-term effects of the insoles were attended by only a few amputee participants (3 out of 11). Commercial insoles were chosen as they are a cost/time effective orthotic device with minimal interference from practitioners in the fabrication process. However, using custom-made insoles might have led to a more participant-specific response to the insoles and the subsequent biomechanical measures. In this study, the strength of the lower limb muscles (in both sides), muscle activation patterns, limb length discrepancies and pelvic obliquity were not evaluated. Participants used their normal daily shoes, which were diverse in terms of materials and design and this might have affected the results. Furthermore, in spite of all amputee participants using mechanical passive prosthetic components, the variety of prosthetic knees controlling systems might have had an effect, particularly concerning the spatio-temporal variables of walking.

The survey included a large number of questions and was time-consuming to answer. This probably resulted in fewer LLAs wishing to participate. In addition, the online nature of it led to there being a limited pool of respondents: i.e., only those who used social media and were used to working with a computer.

Recommendations for future research

Future studies should consider the limitations of this work and how to avoid them. In addition, the following suggestions might be useful. In further research, it would be worth considering the use of custom-made insoles with a corrective function for any foot malalignment on balance and the different daily activities of LLAs. Using pressure insoles and 3D modelling of the foot might provide more precise information about the insoles underlying effect on the foot's segments. In addition, the muscle activity (EMG) information of the lower limb and lumbar muscles should be collected and analysed to provide a precise assessment of the impact of the insoles. The neuromuscular analysis of the lower limb muscles may shed light on the neuromechanical behaviour of the LLAs during such activities. It is likely that muscle activity function differs in TT amputees due to the location of the amputation and, as a result, insoles might be more beneficial for them. The effect of insoles on the balance and daily activities of a group of amputees with specific additional problems, such as LBP or falling, might be associated with different results. It would be helpful to investigate whether insole use during the first prosthesis fitting could be of benefit for lower limb amputees or not. Another interesting area of future study might be an assessment of insoles use together with muscle strengthening and balance exercises, or other therapeutic activities designed to improve the LLAs' musculoskeletal condition. In this study, this type of prosthesis was neglected in order to illustrate the overall differences in gait and balance of TF amputees and non-amputees. The amputee participants in this study used mechanical passive prosthetic devices. The use of insoles for the intact-side of LLAs with more advanced prosthetic components, such as microprocessor controlled knees and hydraulic ankle-foot prostheses, might lead to a more symmetrical performance of the lower limbs and increase the affected limb contribution during the balance and locomotion of amputees. In addition, the reduction of somatosensory sensitivity and blood circulation in the amputated and intact-side lower limb amputees have been reported (Quai et al., 2005); these are factors which might affect their standing balance. It is necessary to consider how the contribution of the amputated side can be increased by improving the somatosensory feedback from the prosthetic leg. Moreover, the results of this study related to the key role of the ankle joint and its musculature in balance and walking might be a matter of interest for prosthetic manufacturers to focus on when designing prosthetic devices with the simulation of cuff muscle function. With a larger sample size, the comparison between the biomechanical variables of amputees sub-groups, such as for those with/without LBP, fallers/non-fallers, different ABC categories or with/without pain in different sites of lower limbs, might be worthwhile research.

Finally, it is important to remember that the survey results emphasized that the majority of LLAs struggled with multiple issues related to their amputation and prostheses and these need to be addressed. There was an inter-relationship between these issues, which affected the participants' judgment about their QOL and wellbeing. These issues can be a matter of interest to health service providers. There is a need to plan proper programs, such as regular prosthetic evaluation, retraining and exercises for walking and balance activities, muscle strengthening exercises for both lower limbs, or a combination of these methods, and to investigate how these approaches are likely to improve the highlighted problems and consequently improve LLAs' perception about their QOL.

Conclusion

The data collected via the survey has laid out fresh and broad information about the problems of LLAs and the relationship of these problems with their functionality and mobility in routine life. A prominent outcome of the survey is the low level of balance and mobility in lower limb amputees which affects their functionality. In addition, there is an inter-relationship between these deficiencies and their other problems, such as pain and their negative judgment about their QOL. I strongly believe that the results of the survey have added to current knowledge about amputees' problems. The results of this survey, as a comprehensive piece of research, might inspire other researchers (e.g., in the fields of biomechanics, neuromuscular medicine, orthotics and prosthetics) to investigate solutions to the problems of LLAs. The range of survey participants' geographical locations has highlighted the fact that the LLA's issues are broad and common, regardless of where they live, even though there might be differences in the services or the level of prosthetic technology available. Considering other facts, such as the global increase in life expectancy and population age, in addition to the comorbidities associated with old age (including those which lead to lower limb amputations), giving credence to the results of the survey will be more critical. The results are worth being considered and investigated by health/rehabilitation organizations and researchers.

To the best of my knowledge, the examination of insoles use in lower limb amputees is the first of its kind. In addition, there is no similar research to study the balance of TF amputees by using this perturbation system. The biomechanical research was designed on the basis of the survey results highlighting the related problems of LLAs and the effectiveness of insoles as a response to these problems. The conducted biomechanical tests broaden our knowledge about perturbed standing balance and walking of trans-femoral amputees using mechanical passive prosthetic devices. The most significant result of these studies was the dominant role of the intact limb in the balance and walking of the TF amputees. The posture of the amputees during standing balance according to the spatio-temporal features of their walking was asymmetrical with a tendency to rely heavily on the intact limb. Furthermore, the amputees had a dynamic balance similar to the non-amputees, according to their COP mediolateral displacement and the COM/COP and BOS lateral border distance in the single support phase of walking. It shows their adaptation to prosthesis use during walking seems accomplished, which might be due to them having been established prosthesis users (for more than 18 years) and being active ambulators. Concerning balance, the plantar-flexor muscles of the intact limb had a key role to play by producing large ankle moments to maintain balance, while in walking, the hip joint muscles of both limbs were active parts, in addition to the ankle muscles, to prevent limb collapse and provide body propulsion. The intact limb of the amputees had too great a contribution in standing balance. The observed asymmetrical function of lower limbs in LLAs might contribute to more musculoskeletal complications, such as LBP and intact-side overuse. These findings affirm the need for supporting this limb. Moreover, an important result of the evaluation of the amputee participants' functionality was the need for gait training to achieve a better level of physical performance. The tests found very few significant changes in the biomechanical characteristics of balance and walking due to insoles use. Those which were observed were mostly present in the non-amputee group. Although Despite this, one observed effect of insoles use in walking was the elimination of the initial impact of vertical ground reaction force in non-amputees. As walking is a repetitive daily activity, and lower limb amputees rely more on their intact limbs, this effect of insoles use might be beneficial for preventing repetitive stress injuries of this limb when they walk at a speed close to that of non-amputees. A further observation is that a majority of the participants endorsed the long-term use of insoles. Finally, this study has provided the framework for further studies to assess new ideas of insoles use in the daily activities of LLAs.

At the end of all my endeavours to conduct this research, I like to share Louis Pasteur's words, one of the most inspiring people in my life:

> *"And, whatever your career may be, do not let yourselves become tainted by a deprecating and barren scepticism, do not let yourselves be discouraged by the sadness of certain hours which pass over nations. Live in the serene peace of laboratories and libraries. Say to yourselves first: 'What have I done for my instruction? 'and, as you gradually advance, 'What have I done for my country?' until the time comes when you may have the immense happiness of thinking that you have contributed in some way to the progress and to the good of humanity. But, whether our efforts are or not favoured by life, let us be able to say, when we come near the great goal: 'I have done what I could'."*

List of References

Abdallah, A.A. and Radwan, A.Y. 2011. Biomechanical changes accompanying unilateral and bilateral use of laterally wedged insoles with medial arch supports in patients with medial knee osteoarthritis. *Clin Biomech (Bristol, Avon).* **26**(7), pp.783-789.

Abdul-Sattar, A. 2007. Amputation-related back pain: Prevalence, Associated Risk Factors and Correlation with Functional Disability. *Egypt Rheumatology Rehabilitation.* **34**, pp.183–195.

Aboutorabi, A., Saeedi, H., Kamali, M., Farahmand, B., Eshraghi, A. and Dolagh, R.S. 2014. Immediate effect of orthopedic shoe and functional foot orthosis on center of pressure displacement and gait parameters in juvenile flexible flat foot. *Prosthet Orthot Int.* **38**(3), pp.218-223.

Abrahamova, D. and Hlavacka, F. 2008. Age-related changes of human balance during quiet stance. *Physiol Res.* **57**(6), pp.957-964.

Adel Gomnam, M., Kamali, M., Mobaraki, H. and Saeedi, H. 2016. Validity and Reliability Determination of the Persian Version of Prosthesis Evaluation in Individuals with Lower Limb Amputations Questionnaire. *Iranian Journal of War and Public Health.* **8**(1), pp.9-16.

Agu, T.C. and Ojiaku, M.E. 2016. The indications for major limb amputations: 8 years retrospective study in a private orthopaedic and trauma centre in the south-east Nigeria. *J Clin Orthop Trauma.* **7**(4), pp.242-247.

Ahmad, N., Thomas, G.N., Gill, P. and Torella, F. 2016. The prevalence of major lower limb amputation in the diabetic and non-diabetic population of England 2003–2013. *Diabetes and Vascular Disease Research.* **13**(5), pp.348-353.

Allison, L. 2012. Balance and vestibular dysfunction. In: Umphred, D.A., et al. eds. *Neurological Rehabilitation.* 6th ed. USA: Mosby, pp.653-709.

Almeida, J.S., Carvalho Filho, G., Pastre, C.M., Padovani, C.R. and Martins, R.A.D.M. 2009. Comparison of plantar pressure and musculoskeletal symptoms with the use of custom and prefabricated insoles in the work environt. *Brazilian Journal of Physical Therapy.* **13**, pp.542-548.

Ambrose, A.F., Paul, G. and Hausdorff, J.M. 2013. Risk factors for falls among older adults: A review of the literature. *Maturitas.* **75**(1), pp.51-61.

Amer, A.O., Jarl, G.M. and Hermansson, L.N. 2013. The effect of insoles on foot pain and daily activities. *Prosthetics and Orthotics International.* **38**(6), pp.474-480.

Anaforoglu, B., Erbahceci, F. and Aksekili, M.A. 2016. The effectiveness of a back school program in lowerlimb amputees: a randomized controlled study. *Turk J Med Sci.* **46**(4), pp.1122-1129.

Andrysek, J., Klejman, S., Steinnagel, B., Torres-Moreno, R., Zabjek, K.F., Salbach, N.M. and Moody, K. 2012. Preliminary Evaluation of a Commercially Available Videogame System as an Adjunct Therapeutic Intervention for Improving Balance Among Children and Adolescents With Lower Limb Amputations. *Archives of Physical Medicine and Rehabilitation.* **93**(2), pp.358-366.

Anjana, R.M., Deepa, M., Pradeepa, R., Mahanta, J., Narain, K., Das, H.K., Adhikari, P., Rao, P.V., Saboo, B., Kumar, A., Bhansali, A., John, M., Luaia, R., Reang, T., Ningombam, S., Jampa, L., Budnah, R.O., Elangovan, N., Subashini, R., Venkatesan, U., Unnikrishnan, R., Das, A.K., Madhu, S.V., Ali, M.K., Pandey, A., Dhaliwal, R.S., Kaur, T., Swaminathan, S. and Mohan, V. 2017. Prevalence of diabetes and prediabetes in 15 states of India: results from the ICMR-INDIAB population-based cross-sectional study. *Lancet Diabetes Endocrinol.* **5**(8), pp.585-596.

Arnold, J.B., Wong, D.X., Jones, R.K., Hill, C.L. and Thewlis, D. 2016. Lateral Wedge Insoles for Reducing Biomechanical Risk Factors for Medial Knee Osteoarthritis Progression: A Systematic Review and Meta-Analysis. *Arthritis Care Res (Hoboken).* **68**(7), pp.936-951.

Asano, M., Rushton, P., Miller, W.C. and Deathe, B.A. 2008. Predictors of quality of life among individuals who have a lower limb amputation. *Prosthet Orthot Int.* **32**(2), pp.231-243.

Audiffren, J., Bargiotas, I., Vayatis, N., Vidal, P.-P. and Ricard, D. 2016. A Non Linear Scoring Approach for Evaluating Balance: Classification of Elderly as Fallers and Non-Fallers. *PLoS ONE.* **11**(12), pe0167456.
Azzi, N.M., Coelho, D.B. and Teixeira, L.A. 2017. Automatic postural responses are generated according to feet orientation and perturbation magnitude. *Gait Posture.* **57**, pp.172-176.
Bahramian, F., Abootorabi, A., Zarezadeh, F. and Rezaeian, T. 2017. Research Paper: Effect of Custom-Molded Insole With New Technique on Pain and Function in Females With Flexible Flat Foot: A Pilot Study. *Archives of Rehabilitation.* **17**(4), pp.318-325.
Ball, K.A. and Afheldt, M.J. 2002a. Evolution of foot orthotics—part 1: Coherent theory or coherent practice? *Journal of Manipulative and Physiological Therapeutics.* **25**(2), pp.116-124.
Ball, K.A. and Afheldt, M.J. 2002b. Evolution of foot orthotics—part 2: Research reshapes long-standing theory. *Journal of Manipulative and Physiological Therapeutics.* **25**(2), pp.125-134.
Barton, J.E., Graci, V., Hafer-Macko, C., Sorkin, J.D. and R, F.M. 2016. Dynamic Balanced Reach: A Temporal and Spectral Analysis Across Increasing Performance Demands. *J Biomech Eng.* **138**(12).
Bateni, H. 2013. Changes of postural steadiness following use of prefabricated orthotic insoles. *J Appl Biomech.* **29**(2), pp.174-179.
Berenshteyn, Y., Gibson, K., Hackett, G.C., Trem, A.B. and Wilhelm, M. 2018. Is standing balance altered in individuals with chronic low back pain? A systematic review. *Disabil Rehabil.* pp.1-10.
Berger, N. and Fishman, S. 1997. *Lower-limb Prosthetics.* New York: Prosthetic-Orthotic Publications.
Bergland, A., Jarnlo, G.B. and Laake, K. 2003. Predictors of falls in the elderly by location. *Aging Clin Exp Res.* **15**(1), pp.43-50.
Bergland, A. and Wyller, T.B. 2004. Risk factors for serious fall related injury in elderly women living at home. *Inj Prev.* **10**(5), pp.308-313.
Berke, G.M., Buell, N.C., Fergason, J.R., Gailey, R.S., Hafner, B.J., Hubbard, S.M., Smith, D.G. and Willingham, L.L. 2008. *Transfemoral Amputation: The Basics and Beyond.* Prosthetics Research Study.
Bird, A., Bendrups, A. and Payne, C. 2003. The effect of foot wedging on electromyographic activity in the erector spinae and gluteus medius muscles during walking. *Gait & Posture.* **18**(2), pp.81-91.
Bird, A.R. and Payne, C.B. 1999. Foot function and low back pain. *The Foot.* **9**(4), pp.175-180.
Blazkiewicz, M., Wiszomirska, I. and Wit, A. 2014. Comparison of four methods of calculating the symmetry of spatial-temporal parameters of gait. *Acta Bioeng Biomech.* **16**(1), pp.29-35.
Bolger, D., Ting, L.H. and Sawers, A. 2014. Individuals with transtibial limb loss use interlimb force asymmetries to maintain multi-directional reactive balance control. *Clinical biomechanics (Bristol, Avon).* **29**(9), pp.1039-1047.
Bonanno, D.R., Landorf, K.B., Munteanu, S.E., Murley, G.S. and Menz, H.B. 2017. Effectiveness of foot orthoses and shock-absorbing insoles for the prevention of injury: a systematic review and meta-analysis. *Br J Sports Med.* **51**(2), pp.86-96.
Bonnet, C.T. 2012. Broad Stance Conditions Change Postural Control and Postural Sway. *Journal of Motor Behavior.* **44**(2), pp.125-131.
Bowker, J.H., Michael, J.W. and American Academy of Orthopaedic Surgeons. 2002. *Atlas of limb prosthetics : surgical, prosthetic, and rehabilitation principles.* 2nd ed. St. Louis: Mosby Year Book.
Braga, A.B., Rodrigues, A.C.d.M.A., de Lima, G.V.M.P., de Melo, L.R., de Carvalho, A.R. and Bertolini, G.R.F. 2012. Comparison of static postural balance between healthy subjects and those with low back pain. *Acta Ortopedica Brasileira.* **20**(4), pp.210-212.
Breniere, Y. and Do, M.C. 1986. When and how does steady state gait movement induced from upright posture begin? *J Biomech.* **19**(12), pp.1035-1040.

Brüggen, E., Wetzels, M., De Ruyter, K. and Schillewaert, N. 2011. Individual Differences in Motivation to Participate in Online Panels:The Effect on Reponse Rate and Reponse Quality Perceptions. *International Journal of Market Research.* **53**(3), pp.369-390.

Brumagne, S., Janssens, L., Janssens, E. and Goddyn, L. 2008. Altered postural control in anticipation of postural instability in persons with recurrent low back pain. *Gait Posture.* **28**(4), pp.657-662.

Buckley, J.G., O'Driscoll, D. and Bennett, S.J. 2002. Postural sway and active balance performance in highly active lower-limb amputees. *Am J Phys Med Rehabil.* **81**(1), pp.13-20.

Cambron, J., Dexheimer, J., Duarte, M. and Freels, S. 2017. Shoe Orthotics for the Treatment of Chronic Low Back Pain: A Randomized Controlled Trial. *Archives of Physical Medicine and Rehabilitation.* **98**(9), pp.1752-1762.

Cambron, J.A., Duarte, M., Dexheimer, J. and Solecki, T. 2011. Shoe orthotics for the treatment of chronic low back pain: A randomized controlled pilot study. *J Manipulative Physiol Ther.* **34**.

Castro-Méndez, A., Munuera, P.V. and Albornoz-Cabello, M. 2013. The short-term effect of custom-made foot orthoses in subjects with excessive foot pronation and lower back pain: A randomized, double-blinded, clinical trial. *Prosthetics and Orthotics International.* **37**(5), pp.384-390.

Castro, M.P., Soares, D., Mendes, E. and Machado, L. 2014. Plantar pressures and ground reaction forces during walking of individuals with unilateral transfemoral amputation. *Pm r.* **6**(8), pp.698-707.e691.

Che, H., Nigg, B.M. and de Koning, J. 1994. Relationship between plantar pressure distribution under the foot and insole comfort. *Clinical Biomechanics.* **9**(6), pp.335-341.

Chevalier, T.L. and Chockalingam, N. 2012. Effects of foot orthoses: How important is the practitioner? *Gait & Posture.* **35**(3), pp.383-388.

Cho, N.S., Hwang, J.H., Chang, H.J., Koh, E.M. and Park, H.S. 2009. Randomized controlled trial for clinical effects of varying types of insoles combined with specialized shoes in patients with rheumatoid arthritis of the foot. *Clin Rehabil.* **23**(6), pp.512-521.

Cobb, S.C., Tis, L.L. and Johnson, J.T. 2006. The effect of 6 weeks of custom-molded foot orthosis intervention on postural stability in participants with >or=7 degrees of forefoot varus. *Clin J Sport Med.* **16**(4), pp.316-322.

Collins, J.J. and Whittle, M.W. 1989. Influence of gait parameters on the loading of the lower limb. *Journal of Biomedical Engineering.* **11**(5), pp.409-412.

Creaby, M.W., May, K. and Bennell, K.L. 2011. Insole effects on impact loading during walking. *Ergonomics.* **54**(7), pp.665-671.

Creylman, V., Knippels, I., Janssen, P., Biesbrouck, E., Lechler, K. and Peeraer, L. 2016. Assessment of transfemoral amputees using a passive microprocessor-controlled knee versus an active powered microprocessor-controlled knee for level walking. *BioMedical Engineering OnLine.* **15**(3), p142.

Cruz-Almeida, Y., Black, M.L., Christou, E.A. and Clark, D.J. 2014. Site-specific differences in the association between plantar tactile perception and mobility function in older adults. *Frontiers in Aging Neuroscience.* **6**(68).

Curtze, C., Hof, A.L., Postema, K. and Otten, B. 2012. The relative contributions of the prosthetic and sound limb to balance control in unilateral transtibial amputees. *Gait Posture.* **36**(2), pp.276-281.

Dananberg, H. and Guiliano, M. 1999. Chronic low-back pain and its response to custom-made foot orthoses. *J Am Podiatr Med Assoc.* **89**.

Darter, B.J., Nielsen, D.H., Yack, H.J. and Janz, K.F. 2013. Home-Based Treadmill Training to Improve Gait Performance in Persons With a Chronic Transfemoral Amputation. *Archives of Physical Medicine and Rehabilitation.* **94**(12), pp.2440-2447.

De Asha, A.R., Munjal, R., Kulkarni, J. and Buckley, J.G. 2014. Impact on the biomechanics of overground gait of using an 'Echelon' hydraulic ankle–foot device in unilateral trans-tibial and trans-femoral amputees. *Clinical Biomechanics.* **29**(7), pp.728-734.

de Morais Barbosa, C., Barros Bertolo, M., Marques Neto, J.F., Bellini Coimbra, I., Davitt, M. and de Paiva Magalhaes, E. 2013. The effect of foot orthoses on balance, foot pain

and disability in elderly women with osteoporosis: a randomized clinical trial. *Rheumatology (Oxford).* **52**(3), pp.515-522.
de Morais Barbosa, C., Bertolo, M.B., Gaino, J.Z., Davitt, M., Sachetto, Z. and de Paiva Magalhaes, E. 2018. The effect of flat and textured insoles on the balance of primary care elderly people: a randomized controlled clinical trial. *Clin Interv Aging.* **13**, pp.277-284.
Deandrea, S., Lucenteforte, E., Bravi, F., Foschi, R., La Vecchia, C. and Negri, E. 2010. Risk factors for falls in community-dwelling older people: a systematic review and meta-analysis. *Epidemiology.* **21**(5), pp.658-668.
Dehghani, F. and Saeedi, H. 2015. Investigating the Influence of Prefabricated Insole with Medial Flange on Forefoot and Rearfoot Alignment Changes at Females with Flexible Flat Foot. *Archives of Rehabilitation.* **15**(4), pp.70-77.
DeLisa, J.A. 1998. *Gait analysis in the science of rehabilitation.* Washington, D.C.: Dept. of Veterans Affairs, Veterans Health Administration, Rehabilitation Research and Development Service, Scientific and Technical Publications Section.
Detrembleur, C., Vanmarsenille, J.M., De Cuyper, F. and Dierick, F. 2005. Relationship between energy cost, gait speed, vertical displacement of centre of body mass and efficiency of pendulum-like mechanism in unilateral amputee gait. *Gait Posture.* **21**(3), pp.333-340.
Devan, H., Hendrick, P., Hale, L., Carman, A., Dillon, M.P. and Ribeiro, D.C. 2017. Exploring Factors Influencing Low Back Pain in People With Nondysvascular Lower Limb Amputation: A National Survey. *Pm r.* **9**(10), pp.949-959.
Devan, H., Tumilty, S. and Smith, C. 2012. Physical activity and lower-back pain in persons with traumatic transfemoral amputation: a national cross-sectional survey. *J Rehabil Res Dev.* **49**(10), pp.1457-1466.
Dillingham, T.R., Pezzin, L.E. and MacKenzie, E.J. 2002. Limb amputation and limb deficiency: epidemiology and recent trends in the United States. *South Med J.* **95**(8), pp.875-883.
Doheny, E.P., McGrath, D., Greene, B.R., Walsh, L., McKeown, D., Cunningham, C., Crosby, L., Kenny, R.A. and Caulfield, B. 2012. Displacement of centre of mass during quiet standing assessed using accelerometry in older fallers and non-fallers. *Conf Proc IEEE Eng Med Biol Soc.* **2012**, pp.3300-3303.
Dou, C., Liu, Y., Wang, Q. and Zhang, Y. 2016. Case report: Characteristics and outcomes of traumatic major extremity amputations in Chinese population. *Int J Clin Exp Med.* **9**(3), pp.6963-6967.
Drevelle, X., Villa, C., Bonnet, X., Loiret, I., Fode, P. and Pillet, H. 2014. Vaulting quantification during level walking of transfemoral amputees. *Clin Biomech (Bristol, Avon).* **29**(6), pp.679-683.
Duclos, C., Roll, R., Kavounoudias, A., Mongeau, J.-P., Roll, J.-P. and Forget, R. 2009. Postural changes after sustained neck muscle contraction in persons with a lower leg amputation. *Journal of Electromyography and Kinesiology.* **19**(4), pp.e214-e222.
Ebrahimzadeh, M.H. and Fattahi, A.S. 2009. Long-term clinical outcomes of Iranian veterans with unilateral transfemoral amputation. *Disabil Rehabil.* **31**(22), pp.1873-1877.
Ebrahimzadeh, M.H. and Hariri, S. 2009. Long-term outcomes of unilateral transtibial amputations. *Mil Med.* **174**(6), pp.593-597.
Ehde, D.M., Czerniecki, J.M., Smith, D.G., Campbell, K.M., Edwards, W.T., Jensen, M.P. and Robinson, L.R. 2000. Chronic phantom sensations, phantom pain, residual limb pain, and other regional pain after lower limb amputation. *Arch Phys Med Rehabil.* **81**(8), pp.1039-1044.
Ehde, D.M., Smith, D.G., Czerniecki, J.M., Campbell, K.M., Malchow, D.M. and Robinson, L.R. 2001. Back pain as a secondary disability in persons with lower limb amputations. *Arch Phys Med Rehabil.* **82**(6), pp.731-734.
Ellis, R.G., Howard, K.C. and Kram, R. 2013. The metabolic and mechanical costs of step time asymmetry in walking. *Proceedings of the Royal Society B: Biological Sciences.* **280**(1756).
Ephraim, P.L., Wegener, S.T., MacKenzie, E.J., Dillingham, T.R. and Pezzin, L.E. 2005. Phantom pain, residual limb pain, and back pain in amputees: results of a national survey. *Arch Phys Med Rehabil.* **86**(10), pp.1910-1919.

Eurostat. 2017. *Quality of life indicators - measuring quality of life.* [Online]. [Accessed 23 Jan]. Available from: https://ec.europa.eu/eurostat/statistics-explained/pdfscache/30610.pdf

Ewers, B.J., Jayaraman, V.M., Banglmaier, R.F. and Haut, R.C. 2002. Rate of blunt impact loading affects changes in retropatellar cartilage and underlying bone in the rabbit patella. *J Biomech.* **35**(6), pp.747-755.

F Farahmand, T Rezaeian, R Narimani and Dinan, P. 2006. Kinematic and dynamic analysis of the gait cycle of above-knee amputees. *Scientia Iranica* **13**(3), pp.261-271.

Fairbank, J. and Pynsent, P. 2000. *Oswestry Low Back Pain Disability Questionnaire* [Online]. [Accessed 6th Mar.]. Available from: http://www.rehab.msu.edu/_files/_docs/Oswestry_Low_Back_Disability.pdf

Farahmand, F., Rezaeian, T., Narimani, R. and Dinan, P. 2006. Kinematic and dynamic analysis of the gait cycle of above-knee amputees. *Scientia Iranica* **13**(3), pp.261-271.

Farrokhi, S., Mazzone, B., Yoder, A., Grant, K. and Wyatt, M. 2016. A Narrative Review of the Prevalence and Risk Factors Associated With Development of Knee Osteoarthritis After Traumatic Unilateral Lower Limb Amputation. *Military Medicine.* **181**(suppl_4), pp.38-44.

Ferrari, R. 2013. Effects of customized foot orthotics on reported disability and analgesic use in patients with chronic low back pain associated with motor vehicle collisions. *J Chiropr Med.* **12**(1), pp.15-19.

Fino, P.C., Mojdehi, A.R., Adjerid, K., Habibi, M., Lockhart, T.E. and Ross, S.D. 2016. Comparing Postural Stability Entropy Analyses to Differentiate Fallers and Non-fallers. *Ann Biomed Eng.* **44**(5), pp.1636-1645.

Fowkes, F.G., Aboyans, V., Fowkes, F.J., McDermott, M.M., Sampson, U.K. and Criqui, M.H. 2017. Peripheral artery disease: epidemiology and global perspectives. *Nat Rev Cardiol.* **14**(3), pp.156-170.

Frames, C.W., Soangra, R., Lockhart, T.E., Lach, J., Ha, D.S., Roberto, K.A. and Lieberman, A. 2018. Dynamical Properties of Postural Control in Obese Community-Dwelling Older Adults. *Sensors.* **18**(6), p1692.

Franklin, S., Grey, M.J., Heneghan, N., Bowen, L. and Li, F.X. 2015. Barefoot vs common footwear: A systematic review of the kinematic, kinetic and muscle activity differences during walking. *Gait Posture.* **42**(3), pp.230-239.

Franklyn-Miller, A., Wilson, C., Bilzon, J. and McCrory, P. 2011. Foot Orthoses in the Prevention of Injury in Initial Military Training:A Randomized Controlled Trial. *The American Journal of Sports Medicine.* **39**(1), pp.30-37.

Friel, K., Domholdt, E. and Smith, D.G. 2005. Physical and functional measures related to low back pain in individuals with lower-limb amputation: an exploratory pilot study. *J Rehabil Res Dev.* **42**(2), pp.155-166.

Fujimoto, M., Bair, W.N. and Rogers, M.W. 2015. Center of pressure control for balance maintenance during lateral waist-pull perturbations in older adults. *J Biomech.* **48**(6), pp.963-968.

Gailey, R., Allen, K., Castles, J., Kucharik, J. and Roeder, M. 2008. Review of secondary physical conditions associated with lower-limb amputation and long-term prosthesis use. *J Rehabil Res Dev.* **45**(1), pp.15-29.

Galica, A.M., Kang, H.G., Priplata, A.A., D'Andrea, S.E., Starobinets, O.V., Sorond, F.A., Cupples, L.A. and Lipsitz, L.A. 2009. Subsensory vibrations to the feet reduce gait variability in elderly fallers. *Gait & Posture.* **30**(3), pp.383-387.

Gard, S.A. 2016. The Influence of Prosthetic Knee Joints on Gait. In: Müller, B., et al. eds. *Handbook of Human Motion.* Cham: Springer International Publishing, pp.1-24.

Ghazali, M.F., Razak, N.A.A., Osman, N.A.A. and Gholizadeh, H. 2017. Effect of stump flexion contracture with and without prosthetic alignment intervention towards postural stability among transtibial prosthesis users. *IOP Conference Series: Materials Science and Engineering.* **210**(1), p012002.

Gitter, A. and Bosker, G. 2005a. Chapter 61: Upper and lower extremities prosthetics. In: Joel A. DeLisa, B.M.G., Nicholas E. Walsh ed. *Physical Medicine and Rehabilitation: Principles and Practice.* pp.1325-1354.

Gitter, A. and Bosker, G. 2005b. Upper and lower extremities prosthetics In: Joel A. DeLisa, et al. eds. *Physical Medicine and Rehabilitation: Principles and Practice.* 4th ed. Pennsylvania: Lippincott Williams & Wilkins.
Gitter, A., Czerniecki, J. and Weaver, K. 1995. A reassessment of center-of-mass dynamics as a determinate of the metabolic inefficiency of above-knee amputee ambulation. *Am J Phys Med Rehabil.* **74**(5), pp.332-338.
Gordon, R. and Bloxham, S. 2016. A Systematic Review of the Effects of Exercise and Physical Activity on Non-Specific Chronic Low Back Pain. *Healthcare.* **4**(2), p22.
Grimmer, M. and Seyfarth, A. 2014. Mimicking Human-Like Leg Function in Prosthetic Limbs. In: Artemiadis, P. ed. *Neuro-Robotics: From Brain Machine Interfaces to Rehabilitation Robotics.* Springer Netherlands, pp.105-155.
Gross, M.T., Mercer, V.S. and Lin, F.-C. 2012. Effects of Foot Orthoses on Balance in Older Adults. *Journal of Orthopaedic & Sports Physical Therapy.* **42**(7), pp.649-657.
Hafner B, Amtmann D, Abrahamson D, Morgan S, Kajlich A and R, S. 2013. Normative PEQ-MS and ABC scores among persons with lower limb loss. In: *American Academy of Orthotists & Prosthetists (AAOP) 39th Annual Meeting and Scientific Symposium*, *February 20-23, 2013, Orlando, FL*.
Hafner, B.J., Gaunaurd, I.A., Morgan, S.J., Amtmann, D., Salem, R. and Gailey, R.S. 2017. Construct Validity of the Prosthetic Limb Users Survey of Mobility (PLUS-M) in Adults With Lower Limb Amputation. *Arch Phys Med Rehabil.* **98**(2), pp.277-285.
Hagberg, K. and Branemark, R. 2001. Consequences of non-vascular trans-femoral amputation: a survey of quality of life, prosthetic use and problems. *Prosthet Orthot Int.* **25**(3), pp.186-194.
Hamandi, F. 2012. Design a Model for Human Body to Determine the Center of Gravity. In: *First national conference for Iraqi women Iraq, Baghdad*. Ministry of science and technology.
Hamill, J., Knutzen, K. and Derrick, T.R. 2015. *Biomechanical basis of human movement.*
Hammarlund, C.S., Carlstrom, M., Melchior, R. and Persson, B.M. 2011. Prevalence of back pain, its effect on functional ability and health-related quality of life in lower limb amputees secondary to trauma or tumour: a comparison across three levels of amputation. *Prosthet Orthot Int.* **35**(1), pp.97-105.
Hanna, R. and Austin, R. 2008. *Lower-Extremity Injuries in Motorcycle Crashes.* U.S. Department of Transportation, National Highway Traffic Safety Administration.
Harness, N. and Pinzur, M.S. 2001. Health related quality of life in patients with dysvascular transtibial amputation. *Clin Orthop Relat Res.* (383), pp.204-207.
Hartmann, A., Murer, K., de Bie, R.A. and de Bruin, E.D. 2010. The effect of a training program combined with augmented afferent feedback from the feet using shoe insoles on gait performance and muscle power in older adults: a randomised controlled trial. *Disability and Rehabilitation.* **32**(9), pp.755-764.
Hassan, H., Zarrinkoob, H., Jafarzadeh, S. and Akbarzade Baghban, A. 2015. Psychometric evaluation of Persian version of Activities-specific Balance Confidence scale for elderly Persians. *Auditory and Vestibular Research.* **24**(2), pp.54-63.
Hatton, A., Dixon, J., Rome, K., Newton, J. and Martin, D. 2012. Altering gait by way of stimulation of the plantar surface of the foot: the immediate effect of wearing textured insoles in older fallers. *Journal of Foot and Ankle Research.* **5**, pp.11-11.
Hatton, A.L., Rome, K., Dixon, J., Martin, D.J. and McKeon, P.O. 2013. Footwear interventions: a review of their sensorimotor and mechanical effects on balance performance and gait in older adults. *J Am Podiatr Med Assoc.* **103**(6), pp.516-533.
Hatze, H. 1974. Letter: The meaning of the term "biomechanics". *J Biomech.* **7**(2), pp.189-190.
Heinemann, A.W., Bode, R.K. and O'Reilly, C. 2003. Development and measurement properties of the Orthotics and Prosthetics Users' Survey (OPUS): a comprehensive set of clinical outcome instruments. *Prosthet Orthot Int.* **27**(3), pp.191-206.
Hekmatfard, M., Farahmand, F. and Ebrahimi, I. 2013. Effects of prosthetic mass distribution on the spatiotemporal characteristics and knee kinematics of transfemoral amputee locomotion. *Gait & Posture.* **37**(1), pp.78-81.

Hesar, N.G.Z., Van Ginckel, A., Cools, A., Peersman, W., Roosen, P., De Clercq, D. and Witvrouw, E. 2009. A prospective study on gait-related intrinsic risk factors for lower leg overuse injuries. *British Journal of Sports Medicine.* **43**(13), pp.1057-1061.
Hewson, D.J., Singh, N.K., Snoussi, H. and Duchêne, J. 2010. Classification of elderly as fallers and non-fallers using Centre of Pressure velocity. In: *2010 Annual International Conference of the IEEE Engineering in Medicine and Biology, Aug. 31 2010-Sept. 4 2010*, pp.3678-3681.
Hijmans, J.M., Geertzen, J.H., Dijkstra, P.U. and Postema, K. 2007. A systematic review of the effects of shoes and other ankle or foot appliances on balance in older people and people with peripheral nervous system disorders. *Gait Posture.* **25**(2), pp.316-323.
Hlavackova, P., Franco, C., Diot, B. and Vuillerme, N. 2011. Contribution of Each Leg to the Control of Unperturbed Bipedal Stance in Lower Limb Amputees: New Insights Using Entropy. *PLOS ONE.* **6**(5), pe19661.
Hof, A.L., van Bockel, R.M., Schoppen, T. and Postema, K. 2007. Control of lateral balance in walking. Experimental findings in normal subjects and above-knee amputees. *Gait Posture.* **25**(2), pp.250-258.
Horak, F.B. 1997. Clinical assessment of balance disorders. *Gait & Posture.* **6**(1), pp.76-84.
Horak, F.B. 2006. Postural orientation and equilibrium: what do we need to know about neural control of balance to prevent falls? *Age and Ageing.* **35**(suppl_2), pp.ii7-ii11.
Houdijk, H., Wezenberg, D., Hak, L. and Cutti, A.G. 2018. Energy storing and return prosthetic feet improve step length symmetry while preserving margins of stability in persons with transtibial amputation. *Journal of NeuroEngineering and Rehabilitation.* **15**(1), p76.
House, C., Reece, A. and Roiz de Sa, D. 2013. Shock-absorbing insoles reduce the incidence of lower limb overuse injuries sustained during Royal Marine training. *Mil Med.* **178**(6), pp.683-689.
Howcroft, J., Lemaire, E.D., Kofman, J. and McIlroy, W.E. 2017. Elderly fall risk prediction using static posturography. *PLOS ONE.* **12**(2), pe0172398.
Hsu, J.D., Michael, J.W., Fisk, J.R. and American Academy of Orthopaedic, S. 2008. *AAOS atlas of orthoses and assistive devices.* Philadelphia: Mosby/Elsevier.
Hunter, S.W., Batchelor, F., Hill, K.D., Hill, A.M., Mackintosh, S. and Payne, M. 2017. Risk Factors for Falls in People With a Lower Limb Amputation: A Systematic Review. *PM R.* **9**(2), pp.170-180 e171.
Jaegers, S.M., Arendzen, J.H. and de Jongh, H.J. 1995. Prosthetic gait of unilateral transfemoral amputees: a kinematic study. *Arch Phys Med Rehabil.* **76**(8), pp.736-743.
Jafarnezhad Gero, A., Farahpour, N. and Damavandi, M. 2015. *The Immediate Effects of Arch Support Insole on Ground Reaction Forces during Walking.*
Jafarnezhadgero, A., Alavi-Mehr, S.M. and Majlesi, M. 2015. Immediate Effect of Arch Support Foot Orthoses on Lower Limb Intera-Joint Coupling Angles during Walking in Children with Flat Foot. *Journal of Research in Rehabilitation Sciences.* **7**, pp.65-75.
Jafarnezhadgero, A., Madadi-Shad, M., Alavi-Mehr, S.M. and Granacher, U. 2018. The long-term use of foot orthoses affects walking kinematics and kinetics of children with flexible flat feet: A randomized controlled trial. *PLOS ONE.* **13**(10), pe0205187.
Jalalvand, A., Anbarian, M. and Ahanjan, S. 2016. Comparison of spatial-temporal gait parameters in male patients with different degrees of knee osteoarthritis. *Scientific Journal of Kurdistan University of Medical Sciences (Persian).* **21**(3), pp.113-124.
Jarvis, H.L., Bennett, A.N., Twiste, M., Phillip, R.D., Etherington, J. and Baker, R. 2017. Temporal Spatial and Metabolic Measures of Walking in Highly Functional Individuals With Lower Limb Amputations. *Arch Phys Med Rehabil.* **98**(7), pp.1389-1399.
Johnson, G.R. 1988. The effectiveness of shock-absorbing insoles during normal walking. *Prosthetics and Orthotics International.* **12**(2), pp.91-95.
Jorgensen, M.G., Rathleff, M.S., Laessoe, U., Caserotti, P., Nielsen, O.B. and Aagaard, P. 2012. Time-of-day influences postural balance in older adults. *Gait Posture.* **35**(4), pp.653-657.
Kahle, J.T., Highsmith, M.J., Schaepper, H., Johannesson, A., Orendurff, M.S. and Kaufman, K. 2016. Predicting Walking Ability Following Lower Limb Amputation: An Updated Systematic Literature Review. *Technology and innovation.* **18**(2-3), pp.125-137.

Kakihana, W., Akai, M., Nakazawa, K., Takashima, T., Naito, K. and Torii, S. 2005. Effects of laterally wedged insoles on knee and subtalar joint moments. *Arch Phys Med Rehabil.* **86**(7), pp.1465-1471.
Kakihana, W., Akai, M., Yamasaki, N., Takashima, T. and Nakazawa, K. 2004. Changes of joint moments in the gait of normal subjects wearing laterally wedged insoles. *Am J Phys Med Rehabil.* **83**(4), pp.273-278.
Kang, J.W., Park, H.S., Na, C.K., Park, J.W., Hong, J. and Lee, S.H. 2013. Immediate coronal plane kinetic effects of novel lateral-offset sole shoes and lateral-wedge insole shoes in healthy individuals. *Orthopedics.* **36**(2), pp.e165-171.
Karimi, A. and Saeidi, M. 2013. A Review of Relationship between Fear Avoidance Beliefs and Postural Stability in Non Specific Chronic Low Back Pain. *Journal of Spine.* **2**(139).
Kaufman, K.R., Frittoli, S. and Frigo, C.A. 2012. Gait asymmetry of transfemoral amputees using mechanical and microprocessor-controlled prosthetic knees. *Clinical biomechanics (Bristol, Avon).* **27**(5), pp.460-465.
Kelly, J.L. and Valier, A.R. 2018. The Use of Orthotic Insoles to Prevent Lower Limb Overuse Injuries: A Critically Appraised Topic. *J Sport Rehabil.* **27**(6), pp.591-595.
Kendall, J.C., Bird, A.R. and Azari, M.F. 2014. Foot posture, leg length discrepancy and low back pain – Their relationship and clinical management using foot orthoses – An overview. *The Foot.* **24**(2), pp.75-80.
Kendell, C., Lemaire, E.D., Dudek, N.L. and Kofman, J. 2010. Indicators of dynamic stability in transtibial prosthesis users. *Gait Posture.* **31**(3), pp.375-379.
Kenny, R.P.W., Eaves, D.L., Martin, D., Hatton, A.L. and Dixon, J. 2019. The effects of textured insoles on quiet standing balance in four stance types with and without vision. *BMC Sports Science, Medicine and Rehabilitation.* **11**(1), p5.
Khiri, F., Karimi, M.T., Fatoye, F. and Jamshidi, N. 2015. An assessment of stability, gait performance and energy consumption in individuals with transfemoral amputation. *Journal of Mechanics in Medicine and Biology.* **15**(04).
Kibushi, B., Hagio, S., Moritani, T. and Kouzaki, M. 2018. Speed-Dependent Modulation of Muscle Activity Based on Muscle Synergies during Treadmill Walking. *Frontiers in Human Neuroscience.* **12**(4).
Kim, H.-Y. 2017. Statistical notes for clinical researchers: Chi-squared test and Fisher's exact test. *Restorative Dentistry & Endodontics.* **42**(2), pp.152-155.
Knudson, D.V. 2012. *Fundamentals of biomechanics.* New York: Springer.
Kozáková, D., Svoboda, Z., Janura, M., Elfmark, M. and Nedvědová, I. 2009. Assessment of postural stability in patients with a transtibial amputation with various times of prosthesis use. *Acta Universitatis Palackianae Olomucensis. Gymnica.* **39**(3), pp.51-59.
Ku, P.X., Abu Osman, N.A. and Wan Abas, W.A. 2014. Balance control in lower extremity amputees during quiet standing: a systematic review. *Gait Posture.* **39**(2), pp.672-682.
Kulkarni, J., Gaine, W.J., Buckley, J.G., Rankine, J.J. and Adams, J. 2005. Chronic low back pain in traumatic lower limb amputees. *Clin Rehabil.* **19**(1), pp.81-86.
Kulkarni, J., Toole, C., Hirons, R. and Wright, S. 1996. Falls in patients with lower limb amputations: prevalence and contributing factors. *Physiotheraphy* **82**(2), pp.130-136.
Kumar, A. and Kumar, P. 2001. Endoskeletal prosthesis: A new era for amputee. *Medical Journal, Armed Forces India.* **57**(2), pp.93-94.
Kusljugic, A., Kapidzic-Durakovic, S., Kudumovic, Z. and Cickusic, A. 2006. Chronic low back pain in individuals with lower-limb amputation. *Bosn J Basic Med Sci.* **6**(2), pp.67-70.
Lafond, D., Champagne, A., Descarreaux, M., Dubois, J.D., Prado, J.M. and Duarte, M. 2009. Postural control during prolonged standing in persons with chronic low back pain. *Gait Posture.* **29**(3), pp.421-427.
Lajoie, Y. and Gallagher, S.P. 2004. Predicting falls within the elderly community: comparison of postural sway, reaction time, the Berg balance scale and the Activities-specific Balance Confidence (ABC) scale for comparing fallers and non-fallers. *Arch Gerontol Geriatr.* **38**(1), pp.11-26.
Lamoth, C.J., Ainsworth, E., Polomski, W. and Houdijk, H. 2010. Variability and stability analysis of walking of transfemoral amputees. *Med Eng Phys.* **32**(9), pp.1009-1014.

Landmine and Cluster Munition Monitor. 2005. *Landmine monitor report 2005: Major Findings* [Online]. [Accessed 7th Jan.]. Available from: http://www.the-monitor.org/en-gb/reports/2005/landmine-monitor-2005/major-findings.aspx

Larsen, K., Weidich, F. and Leboeuf-Yde, C. 2002. Can custom-made biomechanic shoe orthoses prevent problems in the back and lower extremities? A randomized, controlled intervention trial of 146 military conscripts. *J Manipulative Physiol Ther.* **25**(5), pp.326-331.

Lazzarini, P.A., O'Rourke, S.R., Russell, A.W., Clark, D. and Kuys, S.S. 2012. What are the key conditions associated with lower limb amputations in a major Australian teaching hospital? *J Foot Ankle Res.* **5**(1), p12.

Lazzarini, P.A., O'Rourke, S.R., Russell, A.W., Clark, D. and Kuys, S.S. 2012. What are the key conditions associated with lower limb amputations in a major Australian teaching hospital? *Journal of Foot and Ankle Research.* **5**(1), p12.

Leardini, A., O'Connor, J.J. and Giannini, S. 2014. Biomechanics of the natural, arthritic, and replaced human ankle joint. *Journal of Foot and Ankle Research.* **7**(1), p8.

Lee, P.Y., Lin, S.I., Liao, Y.T., Lin, R.M., Hsu, C.C., Huang, K.Y., Chen, Y.T. and Tsai, Y.J. 2016. Postural Responses to a Suddenly Released Pulling Force in Older Adults with Chronic Low Back Pain: An Experimental Study. *PLoS One.* **11**(9), pe0162187.

Legro MW, Reiber GD, Smith DG, del Aguila M, Larsen J and D, B. 1998. *Prosthesis Evaluation Questionnaire.* [Online]. [Accessed 8th Feb.]. Available from: http://www.prs-research.org/Texts/PEQ_A4.pdf

Lenka, P. and Tiberwala, D.N. 2010. Effect of Stump Length on Postural Steadiness During Quiet Stance in Unilateral Trans-Tibial Amputee. *Al Ameen J Med Sci.* **3**(1), pp.50-57.

Li, W.S., Chan, S.Y., Chau, W.W., Law, S.W. and Chan, K.M. 2019. Mobility, prosthesis use and health-related quality of life of bilateral lower limb amputees from the 2008 Sichuan earthquake. *Prosthet Orthot Int.* **43**(1), pp.104-111.

Lipp, M. and Longridge, N.S. 1994. Computerised dynamic posturography: its place in the evaluation of patients with dizziness and imbalance. *J Otolaryngol.* **23**(3), pp.177-183.

Lipsitz, L.A., Lough, M., Niemi, J., Travison, T., Howlett, H. and Manor, B. 2015. A Shoe Insole Delivering Subsensory Vibratory Noise Improves Balance and Gait in Healthy Elderly People. *Archives of Physical Medicine and Rehabilitation.* **96**(3), pp.432-439.

Liu, Y., Liu, K. and Yang, S. 2012. Efficacy of different insole designs on fall prevention of the elderly. *Gerontechnology.* **11**(2), p341

Lloyd, C.H., Stanhope, S.J., Davis, I.S. and Royer, T.D. 2010. Strength asymmetry and osteoarthritis risk factors in unilateral trans-tibial, amputee gait. *Gait Posture.* **32**(3), pp.296-300.

Losa Iglesias, M.E., Becerro de Bengoa Vallejo, R. and Palacios Pena, D. 2012. Impact of soft and hard insole density on postural stability in older adults. *Geriatr Nurs.* **33**(4), pp.264-271.

Lusardi, M.M. and Nielsen, C.C. 2007. *Orthotics & prosthetics in rehabilitation.* 2nd ed. St. Louis: Saunders Elsevier.

Ma, C.Z.-H., Wong, D.W.-C., Wan, A.H.-P. and Lee, W.C.-C. 2018. Effects of orthopedic insoles on static balance of older adults wearing thick socks. *Prosthetics and Orthotics International.* p0309364617752982.

MacRae, C.S., Critchley, D., Lewis, J.S. and Shortland, A. 2018. Comparison of standing postural control and gait parameters in people with and without chronic low back pain: a cross-sectional case–control study. *BMJ Open Sport & Exercise Medicine.* **4**(1), pe000286.

Maki, B.E., Cheng, K.C., Mansfield, A., Scovil, C.Y., Perry, S.D., Peters, A.L., McKay, S., Lee, T., Marquis, A., Corbeil, P., Fernie, G.R., Liu, B. and McIlroy, W.E. 2008. Preventing falls in older adults: new interventions to promote more effective change-in-support balance reactions. *J Electromyogr Kinesiol.* **18**(2), pp.243-254.

Mandel, A., Paul, K., Paner, R., Devlin, M., Dilkas, S. and Pauley, T. 2016. Balance confidence and activity of community-dwelling patients with transtibial amputation. *J Rehabil Res Dev.* **53**(5), pp.551-560.

Mann, L., Kleinpaul, J.F., Pereira Moro, A.R., Mota, C.B. and Carpes, F.P. 2010. Effect of low back pain on postural stability in younger women: influence of visual deprivation. *J Bodyw Mov Ther.* **14**(4), pp.361-366.

Martinez Santos, A. 2016. *An investigation into the effect of customised insoles on plantar pressures in people with diabetes*. PhD thesis, University of Salford.

Mattila, V.M., Sillanpää, P.J., Salo, T., Laine, H.J., Mäenpää, H. and Pihlajamäki, H. 2011. Can orthotic insoles prevent lower limb overuse injuries? A randomized-controlled trial of 228 subjects. *Scandinavian Journal of Medicine & Science in Sports.* **21**(6), pp.804-808.

Mattson, R.B. 2008. Resolution of Chronic Back, Leg and Ankle Pain Following Chiropractic Intervention and the Use of Orthotics. *Journal of Vertebral Subluxation Research.* **March**, pp.1-4.

Mayer, Á., Tihanyi, J., Bretz, K., Csende, Z., Bretz, É. and Horváth, M. 2011. Adaptation to altered balance conditions in unilateral amputees due to atherosclerosis: a randomized controlled study. *BMC Musculoskeletal Disorders.* **12**, pp.118-118.

Mazaheri, M., Heidari, E., Mostamand, J., Negahban, H. and van Dieen, J.H. 2014. Competing Effects of Pain and Fear of Pain on Postural Control in Low Back Pain? *Spine.* **39**(25), pp.E1518-E1523.

McGrath, M., Laszczak, P., Zahedi, S. and Moser, D. 2018. Microprocessor knees with 'standing support' and articulating, hydraulic ankles improve balance control and inter-limb loading during quiet standing. *J Rehabil Assist Technol Eng.* **5**, p2055668318795396.

McHugh, M.L. 2013. The chi-square test of independence. *Biochem Med (Zagreb).* **23**(2), pp.143-149.

Me, D., Kee, T., Cheung, B., Sai, M. and Yun, F. 1998. *Vicon Reliability.* [Online]. [Accessed 27th March]. Available from: http://www.clinicalgaitanalysis.com/faq/reliability/

Mehra, S., Kumar, R., Sinha, A. and Kumari, P. 2016. Effectiveness of Customized Foot Insoles in Nursing Staff with Mechanical Low Back Pain and Pronated Feet. *International Journal of Health Sciences and Research (IJHSR)* **6** (6), pp.225-232.

Mehryar, P., Rezaeian, T., Sharif Shourijeh, M., Raveendranathan, V., Messenger, N., O'Connor, R. and Dehghani-Sanij, A. 2017. Changes in knee joint kinetics of transfemoral amputee's intact leg: An osteoarthritis indication? *Gait & Posture.* **57**, pp.151-152.

Melzer, I., Benjuya, N. and Kaplanski, J. 2004. Postural stability in the elderly: a comparison between fallers and non-fallers. *Age and Ageing.* **33**(6), pp.602-607.

Melzer, I., Kurz, I. and Oddsson, L.E. 2010. A retrospective analysis of balance control parameters in elderly fallers and non-fallers. *Clinical Biomechanics.* **25**(10), pp.984-988.

Mengarelli, A., Cardarelli, S., Fioretti, S., Burattini, L., Di Nardo, F. and Verdini, F. 2018. Center of Pressure based Assessment of Balance Responses to Repeated Perturbations of Upright Stance. In: *Singapore*. Springer Singapore, pp.262-265.

Milgrom, C., Finestone, A., Lubovsky, O., Zin, D. and Lahad, A. 2005. A controlled randomized study of the effect of training with orthoses on the incidence of weight bearing induced back pain among infantry recruits. *Spine.* **30**.

Miller, W.C. and Deathe, A.B. 2004. A prospective study examining balance confidence among individuals with lower limb amputation. *Disabil Rehabil.* **26**(14-15), pp.875-881.

Miller, W.C., Deathe, A.B. and Speechley, M. 2003. Psychometric properties of the Activities-specific Balance Confidence Scale among individuals with a lower-limb amputation. *Arch Phys Med Rehabil.* **84**(5), pp.656-661.

Miller, W.C., Deathe, A.B., Speechley, M. and Koval, J. 2001. The influence of falling, fear of falling, and balance confidence on prosthetic mobility and social activity among individuals with a lower extremity amputation. *Arch Phys Med Rehabil.* **82**(9), pp.1238-1244.

Miller, W.C., Speechley, M. and Deathe, A.B. 2002. Balance confidence among people with lower-limb amputations. *Phys Ther.* **82**(9), pp.856-865.

Miller, W.C., Speechley, M. and Deathe, B. 2001. The prevalence and risk factors of falling and fear of falling among lower extremity amputees. *Archives of Physical Medicine and Rehabilitation.* **82**(8), pp.1031-1037.

Mohamadtaghi, B., Hejazi Dinan, P. and Shamsipour Dehkordi, P. 2016. Effect of the Selected Balance Program on Postural Control of Amputees under Manipulation of Visual, Vestibular and Proprioceptive Systems. *Quarterly of Iranian Journal of War & Public Health (Persian).* **8**(1), pp.1-8.

Mohamadtaghi, M., Hejazidinan, P., Shamsipourdehkordi, P., Saemi, E. and Kovalev, D. 2018. The effect of a balance training program with and without mirror on postural control of lower limb amputees. *International Journal of Applied Exercise Physiology.* **7**(4), pp.50-61.

Mok, N., Brauer, S. and Hodges, P. 2004. Hip Strategy for Balance Control in Quiet Standing Is Reduced in People With Low Back Pain. *Spine.* **29**(6), pp.E107-E112.

Mok, N.W., Brauer, S.G. and Hodges, P.W. 2004. Hip strategy for balance control in quiet standing is reduced in people with low back pain. *Spine (Phila Pa 1976).* **29**(6), pp.E107-112.

Morgan, S.J., Friedly, J.L., Amtmann, D., Salem, R. and Hafner, B.J. 2017. Cross-Sectional Assessment of Factors Related to Pain Intensity and Pain Interference in Lower Limb Prosthesis Users. *Arch Phys Med Rehabil.* **98**(1), pp.105-113.

Morgenroth, D.C., Gellhorn, A.C. and Suri, P. 2012. Osteoarthritis in the disabled population: a mechanical perspective. *Pm R.* **4**(5 Suppl), p003.

Mousavi, S.J., Parnianpour, M., Mehdian, H., Montazeri, A. and Mobini, B. 2006. The Oswestry Disability Index, the Roland-Morris Disability Questionnaire, and the Quebec Back Pain Disability Scale: translation and validation studies of the Iranian versions. *Spine* **31**(14), pp.E454-459.

Moxey, P.W., Gogalniceanu, P., Hinchliffe, R.J., Loftus, I.M., Jones, K.J., Thompson, M.M. and Holt, P.J. 2011. Lower extremity amputations--a review of global variability in incidence. *Diabet Med.* **28**(10), pp.1144-1153.

Muir, J.W., Kiel, D.P., Hannan, M., Magaziner, J. and Rubin, C.T. 2013. Dynamic parameters of balance which correlate to elderly persons with a history of falls. *PLoS One.* **8**(8), pe70566.

Mulford, D., Taggart, H.M., Nivens, A. and Payrie, C. 2008. Arch support use for improving balance and reducing pain in older adults. *Applied Nursing Research.* **21**(3), pp.153-158.

Mundermann, A., Stefanyshyn, D.J. and Nigg, B.M. 2001. Relationship between footwear comfort of shoe inserts and anthropometric and sensory factors. *Med Sci Sports Exerc.* **33**(11), pp.1939-1945.

Murley, G.S., Landorf, K.B., Menz, H.B. and Bird, A.R. 2009. Effect of foot posture, foot orthoses and footwear on lower limb muscle activity during walking and running: A systematic review. *Gait & Posture.* **29**(2), pp.172-187.

Murray, M.P., Mollinger, L.A., Sepic, S.B., Gardner, G.M. and Linder, M.T. 1983. Gait patterns in above-knee amputee patients: hydraulic swing control vs constant-friction knee components. *Arch Phys Med Rehabil.* **64**(8), pp.339-345.

Muthukrishnan, R. 2016. *The effects of visco-elastic insole on peak ground reaction forces (GRF) during gait in patients with acute and chronic low back pain.*

Myers, A.M., Fletcher, P.C., Myers, A.H. and Sherk, W. 1998. Discriminative and evaluative properties of the activities-specific balance confidence (ABC) scale. *J Gerontol A Biol Sci Med Sci.* **53**(4), pp.M287-294.

Nadollek, H., Brauer, S. and Isles, R. 2002. Outcomes after trans-tibial amputation: the relationship between quiet stance ability, strength of hip abductor muscles and gait. *Physiother Res Int.* **7**(4), pp.203-214.

Nagano, H. and Begg, R.K. 2018. Shoe-Insole Technology for Injury Prevention in Walking. *Sensors (Basel).* **18**(5).

Nakajima, K., Kakihana, W., Nakagawa, T., Mitomi, H., Hikita, A., Suzuki, R., Akai, M., Iwaya, T., Nakamura, K. and Fukui, N. 2009. Addition of an arch support improves the biomechanical effect of a laterally wedged insole. *Gait Posture.* **29**(2), pp.208-213.

Nakano, H., Murata, S., Abiko, T., Sakamoto, M., Matsuo, D., Kawaguchi, M., Sugo, Y. and Matsui, H. 2017. Effect of Insoles with a Toe-Grip Bar on Toe Function and Standing Balance in Healthy Young Women: A Randomized Controlled Trial. *Rehabilitation Research and Practice.* pp.1-6.

Nederhand, M.J., Van Asseldonk, E.H.F., der Kooij, H.v. and Rietman, H.S. 2012. Dynamic Balance Control (DBC) in lower leg amputee subjects; contribution of the regulatory activity of the prosthesis side. *Clinical Biomechanics.* **27**(1), pp.40-45.
Nester, C.J., van der Linden, M.L. and Bowker, P. 2003. Effect of foot orthoses on the kinematics and kinetics of normal walking gait. *Gait Posture.* **17**(2), pp.180-187.
NHSScotland. 2005. *The Amputee Statistical Database for the United Kingdom: 2004/05 Report.* Edinburgh
Niiler, T.A. 2018. Measures to Determine Dynamic Balance. *Handbook of Human Motion.* Cham: Springer International Publishing, pp.887-913.
Nolan, L. and Lees, A. 2000. The functional demands on the intact limb during walking for active trans-femoral and trans-tibial amputees. *Prosthet Orthot Int.* **24**(2), pp.117-125.
Nolan, L., Wit, A., Dudziñski, K., Lees, A., Lake, M. and Wychowañski, M. 2003. Adjustments in gait symmetry with walking speed in trans-femoral and trans-tibial amputees. *Gait & Posture.* **17**(2), pp.142-151.
Ochsendorf, D.T., Mattacola, C.G. and Arnold, B.L. 2000. Effect of orthotics on postural sway after fatigue of the plantar flexors and dorsiflexors. *Journal of athletic training.* **35**(1), pp.26-30.
Orendurff, M., Segal, A., K Klute, G., Berge, J., Rohr, E. and Kadel, N. 2004. The effect of walking speed on center of mass displacement. **41**, pp.829-834.
Ortiz-Ospina, E. and Roser, M. 2017. *Financing Healthcare.* [Online]. [Accessed 12th Jan.]. Available from: https://ourworldindata.org/financing-healthcare
Paillard, T. and Noe, F. 2015. Techniques and Methods for Testing the Postural Function in Healthy and Pathological Subjects. *Biomed Research International.*
Pajala, S., Era, P., Koskenvuo, M., Kaprio, J., Törmäkangas, T. and Rantanen, T. 2008. Force Platform Balance Measures as Predictors of Indoor and Outdoor Falls in Community-Dwelling Women Aged 63–76 Years. *The Journals of Gerontology: Series A.* **63**(2), pp.171-178.
Pallant, J.F. 2016. *SPSS survival manual : a step by step guide to data analysis using IBM SPSS / Julie Pallant.* Sydney: Allen & Unwin.
Palluel, E., Olivier, I. and Nougier, V. 2009. The lasting effects of spike insoles on postural control in the elderly. *Behav Neurosci.* **123**(5), pp.1141-1147.
Palmieri, R.M., Ingersoll, C.D., Stone, M.B. and Krause, B.A. 2002. Center-of-Pressure Parameters Used in the Assessment of Postural Control. *Journal of Sport Rehabilitation.* **11**(1), pp.51-66.
Park, J.W., Jung, M. and Kweon, M. 2014. The Mediolateral CoP Parameters can Differentiate the Fallers among the Community-dwelling Elderly Population. *J Phys Ther Sci.* **26**(3), pp.381-384.
Park, S., Choi, H., Ryu, K., Kim, S. and Kim, Y. 2009. Kinematics, kinetics and muscle activities of the lower extremity during the first four steps from gait initiation to the steady-state walking. *Journal of Mechanical Science and Technology.* **23**(1), pp.204-211.
Paton, J., Bruce, G., Jones, R. and Stenhouse, E. 2011. Effectiveness of insoles used for the prevention of ulceration in the neuropathic diabetic foot: a systematic review. *J Diabetes Complications.* **25**(1), pp.52-62.
Patterson, K.K., Nadkarni, N.K., Black, S.E. and McIlroy, W.E. 2012. Gait symmetry and velocity differ in their relationship to age. *Gait & Posture.* **35**(4), pp.590-594.
Pawlowski, B. and Grabarczyk, M. 2003. Center of body mass and the evolution of female body shape. *Am J Hum Biol.* **15**(2), pp.144-150.
Peaco, A., Halsne, E. and Hafner, B. 2011. Assessing Satisfaction With Orthotic Devices and Services: A Systematic Literature Review. *JPO: Journal of Prosthetics and Orthotics.* **23**(2), pp.95-105.
Perry, J. and Burnfield, J. 1992. *Gait Analysis: Normal and Pathological Function.* New York: Slack.
Perry, S.D., Radtke, A., McIlroy, W.E., Fernie, G.R. and Maki, B.E. 2008. Efficacy and effectiveness of a balance-enhancing insole. *J Gerontol A Biol Sci Med Sci.* **63**(6), pp.595-602.
Pinsault, N. and Vuillerme, N. 2009. Test–retest reliability of centre of foot pressure measures to assess postural control during unperturbed stance. *Medical Engineering & Physics.* **31**(2), pp.276-286.

Pooja, G.D. and Sangeeta, L. 2013. Prevalence and aetiology of amputation in Kolkata, India: A retrospective analysis. *Hong Kong Physiotherapy Journal.* **31**(1), pp.36-40.
Powell, L.E. and Myers, A.M. 1995. *The Activities-specific Balance Confidence (ABC) Scale.* [Online]. [Accessed 8th Feb.]. Available from: https://drayerpt.com/content/uploads/2015/10/Balance-Gait-Falls-ABC-Scale.pdf
Prinsen, E.C., Nederhand, M.J. and Rietman, J.S. 2011. Adaptation Strategies of the Lower Extremities of Patients With a Transtibial or Transfemoral Amputation During Level Walking: A Systematic Review. *Archives of Physical Medicine and Rehabilitation.* **92**(8), pp.1311-1325.
Priplata, A.A., Niemi, J.B., Harry, J.D., Lipsitz, L.A. and Collins, J.J. 2003. Vibrating insoles and balance control in elderly people. *The Lancet.* **362**(9390), pp.1123-1124.
Pruziner, A.L., Werner, K.M., Copple, T.J., Hendershot, B.D. and Wolf, E.J. 2014. Does Intact Limb Loading Differ in Servicemembers With Traumatic Lower Limb Loss? *Clinical Orthopaedics and Related Research®.* **472**(10), pp.3068-3075.
Qiu, F., Cole, M.H., Davids, K.W., Hennig, E.M., Silburn, P.A., Netscher, H. and Kerr, G.K. 2012. Enhanced somatosensory information decreases postural sway in older people. *Gait Posture.* **35**(4), pp.630-635.
Qu, X. 2015. Impacts of different types of insoles on postural stability in older adults. *Applied Ergonomics.* **46**, pp.38-43.
Quai, T.M., Brauer, S.G. and Nitz, J.C. 2005. Somatosensation, circulation and stance balance in elderly dysvascular transtibial amputees. *Clinical Rehabilitation.* **19**(6), pp.668-676.
Radzimski, A.O., Mundermann, A. and Sole, G. 2012. Effect of footwear on the external knee adduction moment - A systematic review. *Knee.* **19**(3), pp.163-175.
Rajťúková, V., Michalíková, M., Bednarčíková, L., Balogová, A. and Živčák, J. 2014. Biomechanics of Lower Limb Prostheses. *Procedia Engineering.* **96**, pp.382-391.
Rastegar, M., Hoseini, S., Naser Melli, M. and Taffah, M. 2016. The Effects of Age and Walking Speeds on Vertical Ground Reaction Force in Younger and Older Adults *Journal of Rehabilitation (Persian).* **17**(4), pp.290-299.
Resnik, L., Allen, S., Isenstadt, D., Wasserman, M. and Iezzoni, L. 2009. Perspectives on Use of Mobility Aids in a Diverse Population of Seniors: Implications for Intervention. *Disability and health journal.* **2**(2), pp.77-85.
Richards, J. 2008. *Biomechanics in Clinic and Research: An Interactive Teaching and Learning Course.* Churchill Livingstone/Elsevier.
Rietman, J.S., Postema, K. and Geertzen, J.H.B. 2002. Gait analysis in prosthetics: Opinions, ideas and conclusions. *Prosthetics and Orthotics International.* **26**(1), pp.50-57.
Riskowski, J.L., Mikesky, A.E., Bahamonde, R.E., Alvey, T.V., 3rd and Burr, D.B. 2005. Proprioception, gait kinematics, and rate of loading during walking: are they related? *J Musculoskelet Neuronal Interact.* **5**(4), pp.379-387.
Robbins, S., Waked, E. and Krouglicof, N. 1998. Improving balance. *J Am Geriatr Soc.* **46**(11), pp.1363-1370.
Roman-Liu, D. 2018. Age-related changes in the range and velocity of postural sway. *Archives of Gerontology and Geriatrics.* **77**, pp.68-80.
Rome, K. and Brown, C. 2004. Randomized clinical trial into the impact of rigid foot orthoses on balance parameters in excessively pronated feet. *Clinical Rehabilitation.* **18**, pp.624-630.
Rose, J. and Gamble, J. 2006. *Human walking.* 3rd ed. ed. Philadelphia: Lippincott Williams & Wilkins.
Rouhani, A. and Mohajerzadeh, S. 2013. An epidemiological and etiological report on lower extremity amputation in northwest of iran. *Arch Bone Jt Surg.* **1**(2), pp.103-106.
Roy, S.H., Wolf, S.L. and Scalzitti, D.A. 2013. *The Rehabilitation Specialist's Handbook.* F.A. Davis Company.
Rugelj, D., Tom, #x161, #x10d, , M., Sev, #x161 and ek, F. 2013. Do Fallers and Nonfallers Equally Benefit from Balance Specific Exercise Program? A Pilot Study. *BioMed Research International.* **2013**, p8.

Ruhe, A., Fejer, R. and Walker, B. 2010. The test-retest reliability of centre of pressure measures in bipedal static task conditions--a systematic review of the literature. *Gait Posture.* **32**(4), pp.436-445.
Ruhe, A., Fejer, R. and Walker, B. 2011. Center of pressure excursion as a measure of balance performance in patients with non-specific low back pain compared to healthy controls: a systematic review of the literature. *Eur Spine J.* **20**(3), pp.358-368.
Ruhe, A., Fejer, R. and Walker, B. 2011. Is there a relationship between pain intensity and postural sway in patients with non-specific low back pain? *BMC Musculoskeletal Disorders.* **12**, pp.162-162.
Ruhe, A., Fejer, R. and Walker, B. 2012. Pain relief is associated with decreasing postural sway in patients with non-specific low back pain. *BMC Musculoskeletal Disorders.* **13**, pp.39-39.
Rusaw, D. 2018. Adaptations from the prosthetic and intact limb during standing on a sway-referenced support surface for transtibial prosthesis users. *Disability and Rehabilitation: Assistive Technology.* pp.1-10.
Rusaw, D., Hagberg, K., Nolan, L. and Ramstrand, N. 2012. Can vibratory feedback be used to improve postural stability in persons with transtibial limb loss? *J Rehabil Res Dev.* **49**(8), pp.1239-1254.
Russell, E.M. and Hamill, J. 2011. Lateral wedges decrease biomechanical risk factors for knee osteoarthritis in obese women. *J Biomech.* **44**(12), pp.2286-2291.
Sabzi Sarvestani, A. and Taheri Azam, A. 2013. Amputation: a ten-year survey. *Trauma Mon.* **18**(3), pp.126-129.
Sadeghi, H. and Norouzi, H.R. 2010. Spatio-Temporal Parameters' Changes in Gait of Male Elderly Subjects. *Salmand, Iranian Journal of Ageing (Persian).* **4**(2), pp.71-76.
Sagawa, Y., Jr., Turcot, K., Armand, S., Thevenon, A., Vuillerme, N. and Watelain, E. 2011. Biomechanics and physiological parameters during gait in lower-limb amputees: a systematic review. *Gait Posture.* **33**(4), pp.511-526.
Sanderson, D.J. and Martin, P.E. 1997. Lower extremity kinematic and kinetic adaptations in unilateral below-knee amputees during walking. *Gait & Posture.* **6**(2), pp.126-136.
Sattar, A.B.A.A. 2007. Amputation-related back pain: Prevalence, associated risk factors and correlation with functional disability. *Egypt. Rheumatol. Rehabil.* **34**(1-2), pp.183-196.
Schaarschmidt, M., Lipfert, S.W., Meier-Gratz, C., Scholle, H.C. and Seyfarth, A. 2012. Functional gait asymmetry of unilateral transfemoral amputees. *Hum Mov Sci.* **31**(4), pp.907-917.
Schafer, Z.A., Lee, A., Hancock, A., Salawu, A., White, H.S.F. and Vanicek, N. 2016. The effect of 12-week individualised exercise programme on postural control, balance confidence and falls prevention, for persons with lower-limb amputation. *Physiotherapy.* **102**, pe180.
Schafer, Z.A., Perry, J.L. and Vanicek, N. 2018. A personalised exercise programme for individuals with lower limb amputation reduces falls and improves gait biomechanics: A block randomised controlled trial. *Gait Posture.* **63**, pp.282-289.
Scherer, P. 2011. *Recent Advances in Orthotic Therapy: Improving Clinical Outcomes with a Pathology-specific Approach.* [Online]. Albany; Ashland: Lower Extremity Review; BookMasters Distribution Services (BDS) Distributor.
Scherer, P.R. 2011. *Recent Advances in Orthotic Therapy: Improving Clinical Outcomes with a Pathology-specific Approach.* Lower Extremity Review LLC.
Segal, A.D., Orendurff, M.S., Klute, G.K., McDowell, M.L., Pecoraro, J.A., Shofer, J. and Czerniecki, J.M. 2006. Kinematic and kinetic comparisons of transfemoral amputee gait using C-Leg and Mauch SNS prosthetic knees. *J Rehabil Res Dev.* **43**(7), pp.857-870.
Segal, N.A., Foster, N.A., Dhamani, S., Ohashi, K. and Yack, H.J. 2009. Effects of concurrent use of an ankle support with a laterally wedged insole for medial knee osteoarthritis. *PM R.* **1**(3), pp.214-222.
Seroussi, R., Gitter, A., Czerniecki, J. and Weaver, K. 1996. Mechanical work adaptations of above-knee amputee ambulation. *Archives of Physical Medicine and Rehabilitation.* **77**(11), pp.1209-1214.

Seroussi, R.E., Gitter, A., Czerniecki, J.M. and Weaver, K. 1996. Mechanical work adaptations of above-knee amputee ambulation. *Arch Phys Med Rehabil.* **77**(11), pp.1209-1214.
Sethy, D., Kujur, E.S. and Sau, K. 2009. Effect of balance exercise on balance control in unilateral lower limb amputees. *The Indian Journal of Occupational Therapy.* **XLI**(3), pp.63-68.
Shabat, S., Gefen, T., Nyska, M., Folman, Y. and Gepstein, R. 2005. The effect of insoles on the incidence and severity of low back pain among workers whose job involves long-distance walking. *Eur Spine J.* **14**(6), pp.546-550.
Shaffer, S.W. and Harrison, A.L. 2007. Aging of the Somatosensory System: A Translational Perspective. *Physical Therapy.* **87**(2), pp.193-207.
Shaw, K.E., Charlton, J.M., Perry, C.K.L., de Vries, C.M., Redekopp, M.J., White, J.A. and Hunt, M.A. 2018. The effects of shoe-worn insoles on gait biomechanics in people with knee osteoarthritis: a systematic review and meta-analysis. *British Journal of Sports Medicine.* **52**(4), p238.
Shin, J.Y., Ryu, Y.U. and Yi, C.W. 2016. Effects of insoles contact on static balance. *J Phys Ther Sci.* **28**(4), pp.1241-1244.
Shin, M.K., Yang, H.S., Yang, H.-E., Kim, D.H., Ahn, B.R., Kwon, H., Lee, J.H., Jung, S., Choi, H.C., Yun, S.K., Ahn, D.Y. and Sim, W.S. 2018. Effects of Lumbar Strengthening Exercise in Lower-Limb Amputees With Chronic Low Back Pain. *Annals of Rehabilitation Medicine.* **42**(1), pp.59-66.
Sihvonen, S., Era, P. and Helenius, M. 2004. Postural balance and health-related factors in middle-aged and older women with injurious falls and non-fallers. *Aging Clin Exp Res.* **16**(2), pp.139-146.
Silver-Thorn, B. and L. Glaister, C. 2009. *Functional Stability of Transfemoral Amputee Gait Using the 3R80 and Total Knee 2000 Prosthetic Knee Units.*
Silver-Thorn, M.B., Steege, J.W. and Childress, D.S. 1996. A review of prosthetic interface stress investigations. *J Rehabil Res Dev.* **33**(3), pp.253-266.
Sin Lee, Y., Hun Yu, S. and Su Kim, S. 2015. The Effect of Insole Height on Lumbosacral Angle and Body Function in Male University Students. *Journal of the Ergonomics Society of Korea.* **34**(4), pp.303-312.
Sjodahl, C., Jarnlo, G.B., Soderberg, B. and Persson, B.M. 2002. Kinematic and kinetic gait analysis in the sagittal plane of trans-femoral amputees before and after special gait re-education. *Prosthet Orthot Int.* **26**(2), pp.101-112.
Smith, E., Comiskey, C. and Ryall, N. 2008. Prevalence and patterns of back pain and residual limb pain in lower limb amputees at the National Rehabilitation Hospital. *Ir J Med Sci.* **177**(1), pp.53-57.
Soomro, N., Khan, M., Ahmed, S.I. and Minhas, M.A. 2013. Determinants of lower extremity amputations: an institutional experience. *J Coll Physicians Surg Pak.* **23**(7), pp.491-494.
Soule, M.C., Beale, E.E., Suarez, L., Beach, S.R., Mastromauro, C.A., Celano, C.M., Moore, S.V. and Huffman, J.C. 2016. Understanding Motivations to Participate in an Observational Research Study: Why do Patients Enroll? *Social work in health care.* **55**(3), pp.231-246.
Stacoff, A., Diezi, C., Luder, G., Stussi, E. and Kramers-de Quervain, I.A. 2005. Ground reaction forces on stairs: effects of stair inclination and age. *Gait Posture.* **21**(1), pp.24-38.
Standing, R. and Maulder, P. 2017. The Biomechanics of Standing Start and Initial Acceleration: Reliability of the Key Determining Kinematics. *Journal of sports science & medicine.* **16**(1), pp.154-162.
STEADI, C. 2017. *Fact sheet, Risk Factors for Falls.* [Online]. [Accessed 23 Jan]. Available from: https://www.cdc.gov/steadi/pdf/risk_factors_for_falls-a.pdf
Steinberg, N., Gottlieb, A., Siev-Ner, I. and Plotnik, M. 2019. Fall incidence and associated risk factors among people with a lower limb amputation during various stages of recovery - a systematic review. *Disabil Rehabil.* **41**(15), pp.1778-1787.
Stel, V.S., Smit, J.H., Pluijm, S.M. and Lips, P. 2003. Balance and mobility performance as treatable risk factors for recurrent falling in older persons. *J Clin Epidemiol.* **56**(7), pp.659-668.

Stephen, D.G., Wilcox, B.J., Niemi, J.B., Franz, J.R., Kerrigan, D. and D'Andrea, S.E. 2012. Baseline-dependent effect of noise-enhanced insoles on gait variability in healthy elderly walkers. *Gait & posture.* **36**(3), pp.537-540.
Stern, K.A. and Gottschall, J.S. 2012. Altering footwear type influences gait during level walking and downhill transitions. *J Appl Biomech.* **28**(5), pp.481-490.
Stewart, C.P.U. 2008. *Synopsis of causation: amputation of the lower limb.* Veterans UK and Ministry of Defence.
Synopsis of Causation; Lower Limb Amputation. 2008. Stewart, C.P.U. dir. UK Ministry of Defence.
Struyf, P.A., van Heugten, C.M., Hitters, M.W. and Smeets, R.J. 2009. The prevalence of osteoarthritis of the intact hip and knee among traumatic leg amputees. *Arch Phys Med Rehabil.* **90**(3), pp.440-446.
Suomi, R. and Koceja, D.M. 2001. Effect of Magnetic Insoles on Postural Sway Measures in Men and Women during a Static Balance Test. *Perceptual and Motor Skills.* **92**(2), pp.469-476.
Swanenburg, J., de Bruin, E.D., Uebelhart, D. and Mulder, T. 2010. Falls prediction in elderly people: a 1-year prospective study. *Gait Posture.* **31**(3), pp.317-321.
Taghipour, H., Moharamzad, Y., Mafi, A.R., Amini, A., Naghizadeh, M.M., Soroush, M.R. and Namavari, A. 2009. Quality of life among veterans with war-related unilateral lower extremity amputation: a long-term survey in a prosthesis center in Iran. *J Orthop Trauma.* **23**(7), pp.525-530.
Thomas, T.D.C., Comfort, P. and Jones, P.A. 2018. Comparison of Change of Direction Speed Performance and Asymmetries between Team-Sport Athletes: Application of Change of Direction Deficit. *Sports (Basel).* **6**(4).
Tinkler, L. 2015. *Measuring National Well-being: Personal Well-being in the UK, 2014 to 2015.* [Online]. [Accessed 13/04]. Available from: https://www.ons.gov.uk/peoplepopulationandcommunity/wellbeing/bulletins/measuringnationalwellbeing/2015-09-23
Trantowski-Farrell, R. and Pinzur, M.S. 2003. A Preliminary Comparison of Function and Outcome in Patients with Diabetic Dysvascular Disease. *JPO: Journal of Prosthetics and Orthotics.* **15**(4), pp.127-132.
Turpin, K.M., De Vincenzo, A., Apps, A.M., Cooney, T., MacKenzie, M.D., Chang, R. and Hunt, M.A. 2012. Biomechanical and Clinical Outcomes With Shock-Absorbing Insoles in Patients With Knee Osteoarthritis: Immediate Effects and Changes After 1 Month of Wear. *Archives of Physical Medicine and Rehabilitation.* **93**(3), pp.503-508.
Tuunainen, E., Rasku, J., Jantti, P. and Pyykko, I. 2014. Risk factors of falls in community dwelling active elderly. *Auris Nasus Larynx.* **41**(1), pp.10-16.
Uchytil, J., Jandacka, D., Zahradnik, D., Farana, R. and Janura, M. 2013. Temporal–spatial parameters of gait in transfemoral amputees: Comparison of bionic and mechanically passive knee joints. *Prosthetics and Orthotics International.* **38**(3), pp.199-203.
Ueda, T., Hobara, H., Kobayashi, Y., Heldoorn, T.A., Mochimaru, M. and Mizoguchi, H. 2016. Comparison of 3 Methods for Computing Loading Rate during Running. *Int J Sports Med.* **37**(13), pp.1087-1090.
Ülger, Ö., Yıldırım Şahan, T. and Çelik, S.E. 2018. A systematic literature review of physiotherapy and rehabilitation approaches to lower-limb amputation. *Physiotherapy Theory and Practice.* **34**(11), pp.821-834.
UN. 2017. *World Population Ageing 2015.*
United Nations. Department of Economic and Social Affairs. Population Division. 2010. *World population ageing 2009.* New York, N.Y.: United Nations, Dept. of Economic and Social Affairs, Population Division.
Urabe, Y., Maeda, N., Kato, S., Shinohara, H. and Sasadai, J. 2014. Effect of shoe insole for prevention and treatment of lower extremity injuries. *J Phys Fitness Sports Med.* **3**(4), pp.385-398.
Vanicek, N., Strike, S., McNaughton, L. and Polman, R. 2009a. Gait patterns in transtibial amputee fallers vs. non-fallers: Biomechanical differences during level walking. *Gait & Posture.* **29**(3), pp.415-420.

Vanicek, N., Strike, S., McNaughton, L. and Polman, R. 2009b. Postural responses to dynamic perturbations in amputee fallers versus nonfallers: a comparative study with able-bodied subjects. *Arch Phys Med Rehabil.* **90**(6), pp.1018-1025.

Vanicek, N.K. 2009. *Biomechanical and psychological factors that distinguish fallers from non-fallers : a comparative study of transtibial amputees and able bodied individuals*. PhD thesis, University of Hull.

Vatanparast, R., Karimi, H., Bahrami, F. and Narimani, R. 2009. A Biomechanical Comparison Of Postural Control Mechanisms Between Healthy Adults And Below Knee Amputees During Voluntary Arm Movements. *Iranian Journal of Bimedical Sciences.* **2**(3), pp.171-178.

Versluys, R., Desomer, A., Lenaerts, G., Beyl, P., Van Damme, M., Vanderborght, B., Vanderniepen, I., Perre, G. and Lefeber, D. 2008. From Conventional Prosthetic Feet to Bionic Feet: A Review Study. In: *2nd IEEE RAS & EMBS International Conference on Biomedical Robotics and Biomechatronics, Scottsdale, AZ, USA*. pp.49-54.

Virmavirta, M. and Isolehto, J. 2014. Determining the location of the bodys center of mass for different groups of physically active people. *J Biomech.* **47**(8), pp.1909-1913.

Vrieling, A.H., van Keeken, H.G., Schoppen, T., Otten, E., Halbertsma, J.P., Hof, A.L. and Postema, K. 2008a. Gait initiation in lower limb amputees. *Gait Posture.* **27**(3), pp.423-430.

Vrieling, A.H., van Keeken, H.G., Schoppen, T., Otten, E., Hof, A.L., Halbertsma, J.P.K. and Postema, K. 2008b. Balance control on a moving platform in unilateral lower limb amputees. *Gait & Posture.* **28**(2), pp.222-228.

Walsh, N.E. and Walsh, W.S. 2003. Rehabilitation of landmine victims--the ultimate challenge. *Bull World Health Organ.* **81**(9), pp.665-670.

Wan-Nar Wong, M. 2005. Changing dynamics in lower-extremity amputation in China. *Arch Phys Med Rehabil.* **86**(9), pp.1778-1781.

Wang, L., Gao, P., Zhang, M. and et al. 2017. Prevalence and ethnic pattern of diabetes and prediabetes in china in 2013. *JAMA.* **317**(24), pp.2515-2523.

Waters, R.L. and Mulroy, S. 1999. The energy expenditure of normal and pathologic gait. *Gait Posture.* **9**(3), pp.207-231.

WDF. 2016. *Prevention and care of diabetes among indigenous people, Nagaland, WDF15-1245.* [Online]. [Accessed 26 Jan]. Available from: https://www.worlddiabetesfoundation.org/projects/india-wdf15-1245

Weinert-Aplin, R.A., Twiste, M., Jarvis, H.L., Bennett, A.N. and Baker, R.J. 2017. Medial-lateral centre of mass displacement and base of support are equally good predictors of metabolic cost in amputee walking. *Gait Posture.* **51**, pp.41-46.

Wheat, J.S., Haddad, J.M., Fedirchuk, K. and Davids, K. 2014. Effects of Textured Socks on Balance Control During Single-leg Standing in Healthy Adults. *Procedia Engineering.* **72**, pp.120-125.

Whittle, M. 2002. *Gait analysis: an introduction.* 3rd ed. Oxford: Butterworth-Heinemann.

WHO. 2004. *The Rehabilitation of People with Amputations.* [Online]. [Accessed 1st May]. Available from: https://www.medbox.org/the-rehabilitation-of-people-with-amputations/preview

WHO. 2008. *WHO global report on falls prevention in older age.* Geneva: WHO.

WHO. 2010. *Global status report on non-communicable diseases* [Online]. [Accessed 7th Jan.]. Available from: http://www.who.int/nmh/publications/ncd_report_full_en.pdf

WHO. 2016. *Life expectancy increased by 5 years since 2000, but health inequalities persist.* [Online]. [Accessed 12th Jan.]. Available from: http://www.who.int/mediacentre/news/releases/2016/health-inequalities-persist/en/

WHO. 2017. *Diabetes, Fact sheet.* [Online]. [Accessed 7th Jan.]. Available from: http://www.who.int/mediacentre/factsheets/fs312/en/

Williams, A.E., Hill, L.A. and Nester, C.J. 2013. Foot orthoses for the management of low back pain: a qualitative approach capturing the patient's perspective. *J Foot Ankle Res.* **6**, p17.

Wilson, M.L., Rome, K., Hodgson, D. and Ball, P. 2008. Effect of textured foot orthotics on static and dynamic postural stability in middle-aged females. *Gait & Posture.* **27**(1), pp.36-42.

Winter, D.A. 1987. *Biomechanics and Motor Control of Human Gait: Normal, Elderly and Pathological.* Waterloo Biomechanics.
Winter, D.A. 1990. *Biomechanics and Motor Control of Human Movement.* Hoboken, N.J. Wiley.
Winter, D.A. 1995. Human balance and posture control during standing and walking. *Gait & Posture.* **3**(4), pp.193-214.
Winter, D.A. 2005. *Biomechanics and motor control of human movement.* 3rd ed. Holboken, New Jersey: John Wiley & Sons.
Withnall, R., Eastaugh, J. and Freemantle, N. 2006. Do shock absorbing insoles in recruits undertaking high levels of physical activity reduce lower limb injury? A randomized controlled trial. *J R Soc Med.* **99**(1), pp.32-37.
Wong, C.K., Chen, C.C., Benoy, S.A., Rahal, R.T. and Blackwell, W.M. 2014. Role of balance ability and confidence in prosthetic use for mobility of people with lower-limb loss. *J Rehabil Res Dev.* **51**(9), pp.1353-1364.
Wong, C.K., Chihuri, S.T. and Li, G. 2016. Risk of fall-related injury in people with lower limb amputations: A prospective cohort study. *J Rehabil Med.* **48**(1), pp.80-85.
Wu, J. and Wu, B. 2015. The novel quantitative technique for assessment of gait symmetry using advanced statistical learning algorithm. *BioMed research international.* **2015**, pp.528971-528971.
Wurdeman, S.R., Stevens, P.M. and Campbell, J.H. 2017. Mobility Analysis of AmpuTees (MAAT I): Quality of life and satisfaction are strongly related to mobility for patients with a lower limb prosthesis. *Prosthet Orthot Int.* p309364617736089.
Xing, F., Lu, B., Kuang, M.-J., Wang, Y., Zhao, Y.-L., Zhao, J., Sun, L., Wang, Y., Ma, J.-X. and Ma, X.-L. 2017. A systematic review and meta-analysis into the effect of lateral wedge arch support insoles for reducing knee joint load in patients with medial knee osteoarthritis. *Medicine.* **96**(24), pp.e7168-e7168.
Yardley, L., Kirby, S., Ben-Shlomo, Y., Gilbert, R., Whitehead, S. and Todd, C. 2008. How likely are older people to take up different falls prevention activities? *Preventive Medicine.* **47**(5), pp.554-558.
Zarrinkoob, H., Salarifar, S., Naser Moghadasi, A. and Akbarzadeh Bagheban, A. 2017. Validity and reliability of Persian version of activities-specific balance confidence scale in patients with multiple sclerosis. *Auditory and Vestibular Research.* **26**(2), pp.64-70.
Zhang, J., Wang, Q. and Zhang, C. 2018. Ineffectiveness of lateral-wedge insoles on the improvement of pain and function for medial knee osteoarthritis: a meta-analysis of controlled randomized trials. *Archives of orthopaedic and trauma surgery.* **138**(10), pp.1453-1462.
Zhou, J., Habtemariam, D., Iloputaife, I., Lipsitz, L.A. and Manor, B. 2017. The Complexity of Standing Postural Sway Associates with Future Falls in Community-Dwelling Older Adults: The MOBILIZE Boston Study. *Scientific Reports.* **7**, p2924.

Appendix A

A1: English Version of the Survey

Balance and lower back pain in lower limb amputees

Introduction

Dear participant

We are inviting you to take part in a research study that we are conducting to better understand how lower back pain and balance problems affect lower limb prosthesis users. If you would like to be involved, you will simply be asked to complete a questionnaire that includes questions about your health, balance confidence, and experience of low back pain. If you are a prosthesis user you will also be asked about your reason for using a prosthesis, the type of prosthesis used and your experience of using your prosthesis. The questionnaire will take approximately 15-30 minutes to complete.

You do not need to be suffering from back pain or balance problems for your answers to be useful to us.

The data and information we obtain will be published, but no individual will be identified. We will also use the results to help us understand other research we are doing to help improve lower back pain and balance problems in lower limb amputees.

All responses will be treated in confidence and you do not need to give us your name or contact details. **If you do not wish to continue then we thank you for taking the time to read this introduction.**

If you do wish to continue, we will consider that you have given consent for us to use the data obtained as described above only once you have submitted your responses by selecting "Finish" button at the end of the questionnaire.

As you read each question, remember there is no right or wrong answer. Just think of YOUR OWN OPINION on the topic and choose the best available option to show us your opinion. Some of the questions require a response in order for us to be able to analyse the results appropriately. If you feel unable to answer these questions, then you may withdraw from the research by closing the questionnaire and none of your responses will be saved. As we do not automatically collect your contact details, once you finish the survey by pressing the "Finish" button at the end of the questionnaire, we will not be able to withdraw your data from the study.

Thank You.

Dr Neil Messenger (Project supervisor)

Ms Tahmineh Rezaeian (Researcher)

1- Do you wish to proceed?

- Yes, I understand the nature and purpose of this survey and agree to participate.
- No, I do not wish to participate in this survey

About you and your health

2- Do you classify yourself as: Male Female

3- Age (date of birth)

4- How did you find out about this survey?

- Web search (e.g. google)
- Friend or Family
- Facebook Group
- Medical Professional (e.g. Doctor or Physiotherapist)
- Support group newsletter
- News or magazine article
- Other

If you selected Other, please specify:

5- Where do you normally live?

6- Do you have any Hearing Loss?

- Normal hearing
- Slight hearing loss
- Mild hearing loss
- Moderate hearing loss
- Moderately severe hearing loss
- Severe hearing loss
- Profound hearing loss

7- Do you have any visual impairment?

- None
- Mild - Longsighted and use glasses for reading clearly
- Mild - Shortsighted and use glasses to see objects at a distance clearly
- Have been classified as sight impaired
- Have been classified as severely sight impaired

8- Have you ever been diagnosed as suffering from vertigo?

Yes No

Is this diagnosis current (is this a current problem)?

Yes No

9- Do you smoke?

Smoker Ex-smoker Non-smoker

10- Thinking about your normal week, would you say that you drink alcohol:

- Daily
- Nearly every day
- 3 to 4 times a week
- 2 times a week
- Once a week
- Less than once a week
- Do not drink alcohol
- Other

If you selected Other, please specify:

11- Do you have any of the following diseases?

- Heart and pulmonary diseases
- Parkinson's disease
- Stroke
- Multiple Sclerosis
- Peripheral neuropathy
- Osteo or rheumatoid arthritis
- None of these

12- Medication (please list any regular medication you are taking)

13- Do you have a lower limb amputation?
- Yes
- No

About your prosthesis

This section of the questionnaire will ask you about your prosthesis.

If you are a bilateral amputee, please complete this for your right leg**, we will then ask you to repeat the questions but for your left leg in the next section.**

14- What was the date of your amputation? (if you do not remember the exact date please give your best guess)

15- What was the cause of your amputation?
- Peripheral arterial disease
- Secondary to Diabetes
- Cancer
- Severe infection
- Serious trauma/injury
- Congenital condition
- Limited function due to deformity or sever pain.
- Other

If you selected Other, please specify:

16- Amputation location
- Above knee
- Knee disarticulation
- Below knee
- Ankle and foot
- Hip disarticulation
- Hemipelvectomy

17- When did you first start to use a prosthetic limb?

18- When did you start to use your current prosthetic limb?

19- If you know it, please indicate the makers name and model of your current prosthesis.

20- Who provided/funded your prosthesis?
- National Health Service
- Charitable Organisation
- Privately Funded
- Other

If you selected Other, please specify:

21- How often do you use your prosthesis?
- Every day for most or all of the day
- Every day for some of the day
- 4 to 6 days a week
- 3 to 4 days a week
- 1 to 2 days a week
- Less than once a week
- Rarely
- Other

If you selected Other, please specify:

22- Thinking about most days, how would you describe the condition of your stump? (Please select as many as are relevant)

- Good/ no problems
- Swelling
- Painful (other than phantom pain)
- Itchy
- Uncomfortable (sensation other than pain)
- Hot
- Ulcered
- Other

If you selected Other, please specify:

23- Do you have phantom pain?

- Yes
- No

24- On which leg do you use a prosthesis?

- Right
- Left
- Both (Bilateral)

About your intact limb

25- Do you suffer pain in your intact leg when walking or after walking?

- Yes
- No

If yes where is this usually *(select as many as apply)*

- The hip joint
- The knee joint
- The ankle joint
- In the foot
- In the shins
- Other

If you selected Other, please specify

<u>Your bilateral prosthesis</u>

This section of the questionnaire will ask you about your prosthesis for your left leg assuming that you answered for your right leg in the previous section. If you did not, do not worry, just answer for the opposite leg to that in the previous section.

26- What was the date of your amputation?

27- What was the cause of your amputation?

- Peripheral arterial disease
- Secondary to Diabetes
- Cancer
- Severe infection
- Serious trauma/injury
- Congenital condition
- Limited function due to deformity or sever pain
- Other

If you selected Other, please specify:

28- Amputation location

- Above knee
- Knee disarticulation
- Below knee
- Ankle and foot
- Hip disarticulation
- Hemipelvectomy

29- When did you first start to use a prosthetic limb on this side? *(Please leave blank if it was at the same time as your other limb).*

30- When did you start to use your current prosthetic limb on this side? *(Please leave blank if it was at the same time as the other limb)*

31- If you know it, please indicate the makers name and model of your current prosthesis

32- Thinking about most days, how would you describe the condition of your stump? *(Please select as many as are relevant).*

- Good/ no problems
- Painful (other than phantom pain)
- Uncomfortable (sensation other than pain)
- Ulcered
- Swelling
- Itchy
- Hot
- Other

If you selected Other, please specify:

33- Do you have phantom pain?

- Yes
- No

<u>Prosthesis Evaluation Questionnaire (PEQ)</u>

The questions in this part of the questionnaire are designed to find out how using a prosthesis affects you and your everyday life. If you use a prosthesis on both legs, please think about your prosthesis use in general.

For each of the following questions, please indicate your answer by marking a number 0-10.

Please try to complete them all.

These questions are about <u>YOUR PROSTHESIS</u>.

34- Over the past four weeks, rate how happy you have been with your current prosthesis.

	0	1	2	3	4	5	6	7	8	9	10	
Extremely Unhappy	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Extremely Happy

35- Over the past four weeks, rate the fit of your prosthesis.

	0	1	2	3	4	5	6	7	8	9	10	
Terrible	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Excellent

36- Over the past four weeks, rate the weight of your prosthesis.

	0	1	2	3	4	5	6	7	8	9	10	
Terrible	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Excellent

37- Over the past four weeks, rate your comfort while standing when using your prosthesis.

	0	1	2	3	4	5	6	7	8	9	10	
Terrible	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Excellent

38- Over the past four weeks, rate your comfort while sitting when using your prosthesis.

	0	1	2	3	4	5	6	7	8	9	10	
Terrible												Excellent

39- Over the past four weeks, rate how often you felt off balance while using your prosthesis.

	0	1	2	3	4	5	6	7	8	9	10	
All the Time												Not at All

40- Over the past four weeks, rate how much energy it took to use your prosthesis for as long as you needed it.

	0	1	2	3	4	5	6	7	8	9	10	
Completely Exhausting												None at All

41- Over the past four weeks, rate how often your prosthesis made squeaking, clicking, or belching sounds.

	0	1	2	3	4	5	6	7	8	9	10	
Always												Never

42- If it made sounds in the past 4 weeks, rate how bothersome these sounds were to you.

	0	1	2	3	4	5	6	7	8	9	10	
Extremely bothersome												Not at All

OR It made no sounds.

43- Over the past four weeks, rate the damage done to your clothing or prosthesis cover by your prosthesis.

	0	1	2	3	4	5	6	7	8	9	10	
Extensive Damage												None

44- Over the past four weeks, rate your ability to wear the shoes (different heights, styles) you prefer.

	0	1	2	3	4	5	6	7	8	9	10	
Can not												No problem

45- Over the past four weeks, rate how much of the time your residual limb was swollen to the point of changing the fit of your prosthesis.

	0	1	2	3	4	5	6	7	8	9	10	
All the Time												Never

46- Over the past four weeks, rate any rash(es) that you got on your residual limb.

	0	1	2	3	4	5	6	7	8	9	10	
Extremely bothersome												Not at All

47- Over the past four weeks, rate any blisters or sores that you got on your residual limb.

	0	1	2	3	4	5	6	7	8	9	10	
Extremely bothersome	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Not at All

Bodily sensations

This section will ask you about pain and other sensations you may experience where:

- SENSATIONS are feelings like "pressure", "tickle" or a sense of position or location, such as the toes being curled. Amputees have described sensations in their missing (phantom) limb such as "the feeling that my (missing) foot is wrapped in cotton."
- PAIN is a more extreme sensation described by terms such as "shooting", "searing", "stabbing", "sharp", or "ache".
- PHANTOM LIMB refers to the part that is missing. People have reported feeling sensations and/or pain in the part of the limb that has been amputated — that is, in their phantom limb.
- RESIDUAL LIMB (STUMP) refers to the portion of your amputated limb that is still physically present.

48- Over the past four weeks, rate how often you have been aware of non-painful sensations in your phantom limb.

- ○ never
- ○ only once or twice
- ○ a few times (about once/week)
- ○ fairly often (2-3 times/week)
- ○ very often (4-6 times/week)
- ○ several times every day
- ○ all the time or almost all the time

49- If you had non-painful sensations in your phantom limb during the past month, rate how intense they were on average.

	0	1	2	3	4	5	6	7	8	9	10	
Extremely intense	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Extremely Mild

OR ○ I did not have non-painful sensations in my phantom limb.

50- Over the past month, how bothersome were these sensations in your phantom limb?

	0	1	2	3	4	5	6	7	8	9	10	
All the Time	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Never

OR ○ I did not have non-painful sensations in my phantom limb.

51- Over the past four weeks, rate how often you had pain in your phantom limb.

- ○ never
- ○ only once or twice
- ○ a few times (about once/week)
- ○ fairly often (2-3 times/week)
- ○ very often (4-6 times/week)
- ○ several times every day
- ○ all the time or almost all the time

52- How long does your phantom limb pain usually last?

- I have none
- a few seconds
- a few minutes
- several minutes to an hour
- several hours
- a day or two
- more than two days

53- If you had any pain in your phantom limb this past month, rate how intense it was on average.

	0	1	2	3	4	5	6	7	8	9	10	
Extremely intense	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Extremely Mild

OR I did not have any pain in my phantom limb.

54- In the past four weeks how bothersome was the pain in your phantom limb?

	0	1	2	3	4	5	6	7	8	9	10	
Extremely bothersome	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Extremely Mild

OR I did not have any pain in my phantom limb.

55- Over the past four weeks, rate how often you had pain in your residual limb.

- never
- only once or twice
- a few times (about once/week)
- fairly often (2-3 times/week)
- very often (4-6 times/week)
- several times every day
- all the time or almost all the time

56- If you had any pain in your residual limb over the past four weeks, rate how intense it was on average.

	0	1	2	3	4	5	6	7	8	9	10	
Extremely intense	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Extremely Mild

OR I did not have any pain in my residual limb.

57- Over the past four weeks how bothersome was the pain in your residual limb?

	0	1	2	3	4	5	6	7	8	9	10	
Extremely bothersome	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Extremely Mild

OR I did not have any pain in my residual limb.

58- Over the past four weeks, rate how often you had pain in your other (non-amputated) leg or foot.

- never
- only once or twice
- a few times (about once/week)
- fairly often (2-3 times/week)
- very often (4-6 times/week)
- several times every day
- all the time or almost all the time

59- If you had any pain in your other leg or foot over the past four weeks, rate how intense it was on average.

	0	1	2	3	4	5	6	7	8	9	10	
Extremely intense	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Extremely Mild

OR I did not have any pain in my other leg or foot.

60- Over the past four weeks how bothersome was the pain in other leg or foot?

	0	1	2	3	4	5	6	7	8	9	10	
Extremely bothersome	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Extremely Mild

OR check ○ I had no pain in my other leg or foot.

Social and emotional aspects of using a prosthesis

61- Over the past four weeks, rate how frequently you were frustrated with your prosthesis.

	0	1	2	3	4	5	6	7	8	9	10	
All the Time	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Never

62- If you were frustrated with your prosthesis at any time over the past month, think of the most frustrating event and rate how you felt at that tune.

	0	1	2	3	4	5	6	7	8	9	10	
Extremely Frustrated	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Not at All

63- Over the past 4 weeks, rate how much your prosthesis has hindered you socially.

	0	1	2	3	4	5	6	7	8	9	10	
A great deal	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Not at All

Your ability to move around

64- Over the past four weeks, rate your ability to walk when using your prosthesis.

	0	1	2	3	4	5	6	7	8	9	10	
Can not	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	No problem

65- Over the past four weeks, rate your ability to walk IN CLOSED SPACES when using your prosthesis.

	0	1	2	3	4	5	6	7	8	9	10	
Can not	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	No problem

66- Over the past four weeks, rate your ability to walk up stairs when using your prosthesis.

	0	1	2	3	4	5	6	7	8	9	10	
Can not	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	No problem

67- Over the past four weeks, rate your ability to walk down stairs when using your prosthesis.

	0	1	2	3	4	5	6	7	8	9	10	
Can not	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	No problem

68- Over the past four weeks, rate your ability to walk up a steep hill when using your prosthesis.

	0	1	2	3	4	5	6	7	8	9	10	
Can not	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	No problem

69- Over the past four weeks, rate your ability to walk down a steep hill when using your prosthesis.

	0	1	2	3	4	5	6	7	8	9	10	
Can not	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	No problem

70- Over the past four weeks, rate your ability to walk on pavements and streets when using your prosthesis.

	0	1	2	3	4	5	6	7	8	9	10	
Can not	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	No problem

71- Over the past four weeks, rate your ability to walk on slippery surfaces (e.g. wet tile, snow, a rainy street, or a boat deck) when using your prosthesis.

	0	1	2	3	4	5	6	7	8	9	10	
Can not	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	No problem

72- **Over the past four weeks, rate your ability to get in and out of a car when using your prosthesis.**

	0	1	2	3	4	5	6	7	8	9	10	
Can not	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	No problem

73- Over the past four weeks, rate your ability to sit down and get up from a chair with a high seat (e.g., a dining chair, a kitchen chair, an office chair).

	0	1	2	3	4	5	6	7	8	9	10	
Can not	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	No problem

74- Over the past four weeks, rate your ability to sit down and get up from a low or soft chair (e.g. an easy chair or deep sofa).

	0	1	2	3	4	5	6	7	8	9	10	
Can not	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	No problem

75- Over the past four weeks, rate your ability to sit down and get up from the toilet.

	0	1	2	3	4	5	6	7	8	9	10	
Can not	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	No problem

76- Over the past four weeks, rate your ability to shower or bathe safely.

	0	1	2	3	4	5	6	7	8	9	10	
Can not	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	No problem

Your satisfaction with your prosthesis

77- Over the past four weeks, rate how satisfied you have been with your prosthesis.

	0	1	2	3	4	5	6	7	8	9	10	
Extremely dissatisfied	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Extremely satisfied

78- Over the past four weeks, rate how satisfied you have been with how you are walking.

	0	1	2	3	4	5	6	7	8	9	10	
Extremely dissatisfied	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Extremely satisfied

79- Over the past four weeks, how would you rate your quality of life?

	0	1	2	3	4	5	6	7	8	9	10	
Worst possible life	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Best possible life

80- Overall, how satisfied are you with the walking and prosthetic training you have received since your amputation.

	0	1	2	3	4	5	6	7	8	9	10	
Extremely dissatisfied	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Extremely satisfied

OR ○ I have not had any training since my amputation.

<u>What is important about your prosthesis?</u>

81- How important is the appearance of your prosthesis (how it looks)?

	0	1	2	3	4	5	6	7	8	9	10	
Not at All	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Extremely important

82- How important is it to you to be able to wear different kinds of shoes (heights or styles

	0	1	2	3	4	5	6	7	8	9	10	
Not at All	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Extremely important

83- How bothersome to you is swelling in your residual limb (stump)?

	0	1	2	3	4	5	6	7	8	9	10	
Extremely bothersome	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Not at All

84- How important is being able to walk up a steep hill?

	0	1	2	3	4	5	6	7	8	9	10	
Not at All	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Extremely important

85- If any of the following have happened in the past four weeks, please check off and give a brief description:

☐ a serious medical problem (yours) ☐ a noticeable change in pain

☐ a serious personal problem (yours) ☐ a serious problem in the family
☐ some other big change has occurred in your life

If you checked any of the five previous items, please give a brief description.

86- Please share with us anything else about you or your prosthesis that you think would be helpful for us to know.

Balance confidence

This section will ask you questions about your balance confidence

87- Do you worry about falling when using your prosthesis? ○ Yes ○ No

If yes, rate how worried you are about falling?

	0	1	2	3	4	5	6	7	8	9	10	
Extremely worried and it severely limits the things I can do	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Only a little worried and it does not limit my activities

88- Have you ever fallen when using your prosthesis **in the last 12 months**?
○ Yes ○ No

If yes, how many times have you fallen in the last 12 months?
○ 1 ○ 2 ○ 3
○ 4 ○ 5 ○ 6
○ 7 ○ 8 ○ 9
○ 10 ○ more than 10

89- Do you normally walk unaided (i.e. without using sticks, crutches or walking frames etc)?)
☐ Yes ☐ No

If **NO**, which of the following do you normally use?
○ Single walking stick ○ Single elbow crutch
○ Two walking sticks ○ Two elbow crutches
○ Walking frame without wheels ○ Walking frame with wheels
○ Other

If you selected Other, please specify:

The Activities-specific Balance Confidence (ABC) Scale

This part of questionnaire is about your balance confidence in performing different activities. For each of the following activities, please indicate your level of self-confidence by marking a number 0-10; Zero stands for “no confidence” and 10 stands for “completely confident".

Please answer all questions.

90- How confident are you that you will not lose your balance or become unsteady when you walk around the house?

	0	1	2	3	4	5	6	7	8	9	10	
No confidence	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Completely confident

91- How confident are you that you will not lose your balance or become unsteady when you up or down stairs?

	0	1	2	3	4	5	6	7	8	9	10	
No confidence	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Completely confident

OR ○ I never do this

92- How confident are you that you will not lose your balance or become unsteady when you bend over and pick up something from the floor such as a slipper or shoe?

	0	1	2	3	4	5	6	7	8	9	10	
No confidence	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Completely confident

OR ○ I never do this

93- How confident are you that you will not lose your balance or become unsteady when you reach for a small can off of a shelf at eye level?

	0	1	2	3	4	5	6	7	8	9	10	
No confidence	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Completely confident

OR ○ I never do this

94- How confident are you that you will not lose your balance or become unsteady when you reach for something above your head?

	0	1	2	3	4	5	6	7	8	9	10	
No confidence	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Completely confident

OR ○ I never do this

95- How confident are you that you will not lose your balance or become unsteady when you stand on a chair and reach for something?

	0	1	2	3	4	5	6	7	8	9	10	
No confidence	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Completely confident

OR ○ I never do this

96- How confident are you that you will not lose your balance or become unsteady when you sweep the floor?

	0	1	2	3	4	5	6	7	8	9	10	
No confidence	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Completely confident

OR ○ I never do this

97- How confident are you that you will not lose your balance or become unsteady when you walk outside the house to a car parked in the driveway?

	0	1	2	3	4	5	6	7	8	9	10	
No confidence	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Completely confident

OR ○ I never do this

98- How confident are you that you will not lose your balance or become unsteady when you get into or out of a car?

	0	1	2	3	4	5	6	7	8	9	10	
No confidence	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Completely confident

OR ○ I never do this

99- How confident are you that you will not lose your balance or become unsteady when you walk across a car park to a supermarket?

	0	1	2	3	4	5	6	7	8	9	10	
No confidence	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Completely confident

OR ○ I never do this

100- How confident are you that you will not lose your balance or become unsteady when you walk up or down a ramp or slope?

	0	1	2	3	4	5	6	7	8	9	10	
No confidence	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Completely confident

OR ○ I never do this

101- How confident are you that you will not lose your balance or become unsteady when you walk in a crowded space where people rapidly walk past you?

	0	1	2	3	4	5	6	7	8	9	10	
No confidence	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Completely confident

OR ○ I never do this

102- How confident are you that you will not lose your balance or become unsteady when you are bumped into by people as you walk through town or a shopping arcade?

	0	1	2	3	4	5	6	7	8	9	10	
No confidence	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Completely confident

OR ○ I never do this

103- How confident are you that you will not lose your balance or become unsteady when you step onto or off an escalator while you are holding onto a railing?

	0	1	2	3	4	5	6	7	8	9	10	
No confidence	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Completely confident

OR ○ I never do this

104- How confident are you that you will not lose your balance or become unsteady when you step onto or off an escalator while holding onto parcels such that you cannot hold onto the railing?

	0	1	2	3	4	5	6	7	8	9	10	
No confidence	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Completely confident

OR ○ I never do this

105- How confident are you that you will not lose your balance or become unsteady when you walk outside on icy pavements?

	0	1	2	3	4	5	6	7	8	9	10	
No confidence	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	Completely confident

OR ○ I never do this

Low back pain

The next section of the questionnaire deals with lower back pain. If you do not suffer from lower back pain and you chose this option you will be taken to the final section of the questionnaire.

106- Do you suffer pain in your lower back? ○ Yes ○ No

Oswestry Low Back Pain Disability Questionnaire

This part of questionnaire has been designed to give us information as to how your back pain is affecting your ability to manage in everyday life. Please answer by checking ONE box in each section for the statement which best applies to you. We realise you may consider that two or more statements in any one section apply but please just shade out the spot that indicates the statement which most clearly describes your problem.

107- Pain intensity

○ The pain is very mild at the moment
○ The pain is moderate at the moment
○ The pain is fairly severe at the moment
○ The pain is very severe at the moment
○ The pain is the worst imaginable at the moment

108- Personal care (washing, dressing etc)

○ I can look after myself normally without causing extra pain
○ I can look after myself normally but it causes extra pain
○ It is painful to look after myself and I am slow and careful
○ I need some help but manage most of my personal care
○ I need help every day in most aspects of self-care
○ I do not get dressed, I wash with difficulty and stay in bed

109- Lifting

- I can lift heavy weights without extra pain
- I can lift heavy weights but it gives extra pain
- Pain prevents me from lifting heavy weights off
- the floor, but I can manage if they are conveniently placed eg. on a table
- Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned
- I can lift very light weights
- I cannot lift or carry anything at all

110- Walking

- Pain does not prevent me walking any distance
- Pain prevents me from walking more than 2 kilometres
- Pain prevents me from walking more than 1 kilometre
- Pain prevents me from walking more than 500 metres
- I can only walk using a stick or crutches
- I am in bed most of the time

111- Sitting

- I can sit in any chair as long as I like
- I can only sit in my favourite chair as long as I like
- Pain prevents me sitting more than one hour
- Pain prevents me from sitting more than 30 minutes
- Pain prevents me from sitting more than 10 minutes
- Pain prevents me from sitting at all

112- Standing

- I can stand as long as I want without extra pain
- I can stand as long as I want but it gives me extra pain
- Pain prevents me from standing for more than 1 hour
- Pain prevents me from standing for more than 3 minutes
- Pain prevents me from standing for more than 10 minutes
- Pain prevents me from standing at all

113- Sleeping

- My sleep is never disturbed by pain
- My sleep is occasionally disturbed by pain
- Because of pain I have less than 6 hours sleep
- Because of pain I have less than 4 hours sleep
- Because of pain I have less than 2 hours sleep
- Pain prevents me from sleeping at all

114- Sex life (if applicable) if you prefer not to answer this question please move to next question

- My sex life is normal and causes no extra pain
- My sex life is normal but causes some extra pain
- My sex life is nearly normal but is very painful
- My sex life is severely restricted by pain
- My sex life is nearly absent because of pain
- Pain prevents any sex life at all

115- Social life

- My social life is normal and gives me no extra pain
- My social life is normal but increases the degree of pain
- Pain has no significant effect on my social life apart from limiting my more energetic interests eg, sport
- Pain has restricted my social life and I do not go out as often
- Pain has restricted my social life to my home
- I have no social life because of pain

116- Travelling

- I can travel anywhere without pain
- I can travel anywhere but it gives me extra pain
- Pain is bad but I manage journeys over two hours
- Pain restricts me to journeys of less than one hour
- Pain restricts me to short necessary journeys under 30 minutes
- Pain prevents me from travelling except to receive treatment

Thank you

Dear participant

Thank you for completing the questionnaire; we greatly appreciate your participation.

It will take some time for us to finish the analysis of the data obtained in this study but we hope that the results obtained will eventually help us to improve the quality of life of amputees and those with balance and low back pain problems.

We do not automatically collect email or computer IP addresses so your response is currently totally anonymous but if you would like to be kept informed of the progress of our work or would be interested in participating in future studies you can do so by leaving your email address. We will not publish, sell, or otherwise divulge your address unless you give us written informed permission to do so.

If you would like to find out more about Biomedical Sciences at the University of Leeds please visit www.fbs.leeds.ac.uk/research/

Further information

○ I would like to leave my email address and receive further information

○ I do not wish to receive any further information form you

For further information

You have selected to receive further information. If you have changed your mind, please select the back button below. Otherwise please enter your email address and select the type of information you would like to receive.

Please enter a valid email address.

Please select

○ I would like to receive information about the outcome of this research

○ I would like to receive information about future research projects in which I may be able to participate

Submit

Clicking the “Finish” button below will submit your responses and indicate that you give consent for us to use these in our research. We cannot see your responses until this action is performed but once you do so we will not be able to remove them from database.

Please select

○ I am ready to finish and submit my responses and understand that once I do so my data cannot be withdrawn

○ I do not wish to submit my responses

References

This survey incorporates the Activities-Specific Balance Confidence (ABC) Scale [1,2,3], the Oswestry Low Back Pain Disability Questionnaire [4,5,6] and the Prosthetics Research Study. Prosthesis Evaluation Questionnaire (PEQ) [7,8].

1- Powell, L E; Myers, A M. The Activities-specific Balance Confidence (ABC) Scale. The journals of gerontology. Series A, Biological sciences and medical sciences, 1995, 50(1):M28-34

2- Myers, A M; Fletcher, P C; Myers, A H; Sherk, W. Discriminative and evaluative properties of the activities-specific balance confidence (ABC) scale. The journals of gerontology. Series A, Biological sciences and medical sciences, 1998, 53:M287-M294.

3- Lajoie, Y; Gallagher, S.P. Predicting falls within the elderly community: comparison of postural sway, reaction time, the Berg balance scale and the Activities-specific Balance Confidence (ABC) scale for comparing fallers and non-fallers. Archives of Gerontology and Geriatrics, 2004, 38:11-26.

4- Fairbank JCT & Pynsent, PB (2000) The Oswestry Disability Index. Spine, 25(22):2940-2953.

5- Davidson M & Keating J (2001) A comparison of five low back disability questionnaires: reliability and responsiveness. Physical Therapy 2002;82:8-24.

6- Lajoie, Y; Gallagher, S.P. Predicting falls within the elderly community: comparison of postural sway, reaction time, the Berg balance scale and the Activities-specific Balance Confidence (ABC) scale for comparing fallers and non-fallers. Archives of Gerontology and Geriatrics, 2004, 38:11-26.

7- Prosthetics Research Study, http://www.prs-research.org/htmPages/PEQ.html

8- Boone, D A, Coleman, K L: Use of the Prosthesis Evaluation Questionnaire (PEQ) Journal of Prosthetics & Orthotics: 2006, 18 (6):68-79.

A2: Persian Version of the Survey

ارزیابی وضعیت تعادل و کمر درد در افراد دچار قطع اندام تحتانی

مقدمه

هموطن گرامی

بدین وسیله از شما دعوت می‌شود به این پرسشنامه که برای درک بهتر چگونگی وضعیت تعادل و کمر درد در افراد دچار قطع عضو اندام تحتانی طراحی شده است، پاسخ دهید.

نتایج حاصل از این پرسشنامه بدون نام افراد شرکت کننده منتشر خواهند شد. امیدواریم این نتایج در درک ما از مشکل افراد دچار قطع عضو و تلاش برای بهبود مشکلات مرتبط با تعادل و کمردرد در آنها موثر باشد.

همگی پاسخ ها محرمانه خواهند بود و نیازی نیست نام و نشانی خود را درج فرمائید.

اگر به پاسخگویی تمایل دارید؛ این امر به منزله اجازه نامه شما برای استفاده از اطلاعات درج شده در آینده خواهد بود.

لطفا به خاطر داشته باشید هیچ پاسخ درست و نادرستی وجود ندارد؛ فقط به نظر خود درباره هر پرسش فکر کنید و بهترین گزینه موجود در پاسخها را انتخاب کنید

توجه داشته باشید همه سؤالات نیازمند پاسخ هستند؛ در غیر این صورت پرسشنامه به پیش نمی رود و اطلاعات شما ثبت نخواهد شد.

با سپاس

تهمینه رضائیان – پژوهشگر

دکتر نیل مسنجر – استاد راهنما

پرسش‌های عمومی

تاریخ تولد:

چطور از وجود این پژوهش پرسشنامه‌ای آگاه شدید؟

وضعیت شنوایی شما چطور است؟

- شنوایی نرمال
- ضعف جزئی شنوایی
- ضعف جزئی- متوسط شنوایی
- ضعف متوسط شنوایی
- ضعف نسبتا شدید شنوایی
- ضعف شدید شنوایی
- ناشنوا

وضعیت بینایی شما چطور است؟

- نرمال
- ضعف جزئی- استفاده از عینک برای خواندن
- ضعف جزئی- استفاده از عینک برای دیدن اجسام دور
- فقدان جزئی بینایی
- فقدان شدید بینائی

آیا بر اساس تشخیص پزشک دچار حالت سرگیجه هستید؟

- بله
- خیر

آیا این تشخیص مربوط به زمان حال است؟

- بله
- خیر

آیا سیگاری هستید؟

- بله
- قبلا سیگار می کشیدم
- خیر

آیا دچار یکی از بیماری‌های زیر هستید؟

- بیماری قلب و تنفسی
- پارکینسون
- سکته مغزی
- ام اس
- نوروپاتی محیطی
- آرتروز یا روماتیسم مفصلی
- هیچ کدام

لطفا نام داروهایی را که به شکل منظم مصرف می‌کنید، درج فرمائید

این بخش از پرسشنامه درباره پروتز شماست.

اگر دچار قطع عضو دوطرفه هستید، لطفا ابتدا برای سمت راست آن را پر کنید و سپس در بخش بعدی سوالات درباره پای چپ تکرار خواهند شد.

تاریخ قطع عضوتان کی بوده است (تاریخ تقریبی کافیست)؟

علت قطع عضو

- ☐ بیماری عروق محیطی ☐ دیابت
- ☐ سرطان ☐ عفونت شدید
- ☐ آسیب شدید در اثر ضربه ☐ محدودیت عملکرد در اثر بدشکلی یا درد شدید
- ☐ نقصهای مادرزادی ☐ موارد مرتبط با جنگ (در میدان جنگ یا انفجار مین)
- ☐ موارد دیگر

اگر موارد دیگر را انتخاب کرده اید؛ لطفا توضیح دهید.

سطح قطع عضو

تاریخ استفاده از اولین پروتز

تاریخ شروع استفاده از پروتز

در صورت امکان نوع قطعات پروتز و کمپانی سازنده آن را ذکر بفرمائید

پروتز را از کجا تهیه کرده اید

- ☐ بنیاد جانبازان ☐ هلال احمر ☐ کلینیک خصوصی
- ☐ بهزیستی ☐ موارد دیگر

اگر موارد دیگر را انتخاب کرده اید؛ لطفا توضیح دهید.

چقدر از پروتز خود استفاده می‌کنید؟

- ○ هر روز بیشتر ساعات یا کل روز ○ هر روز چند ساعت
- ○ چهار تا 6 روز در هفته ○ سه تا 4 روز در هفته
- ○ یک تا 2 روز در هفته ○ کمتر از یکبار در هفته
- ○ به ندرت ○ موارد دیگر

اگر موارد دیگر را انتخاب کرده اید؛ لطفا توضیح دهید.

اگر به بیشتر روزها فکر کنید؛ وضعیت استمپ خود را چگونه توصیف خواهید کرد؟

- ☐خوب/بدون مشکل ☐دردناک (منظور درد خیالی نیست)
- ☐ ناراحت (احساسی به جز درد) ☐دچار تاول
- ☐ متورم ☐دچار خارش
- ☐داغ ☐موار دیگر

اگر موارد دیگر را انتخاب کرده اید؛ لطفا توضیح دهید.

آیا دچار درد خیالی هستید؟

در کدام سمت پروتز میپوشید؟

سمت سالم (بدون قطع عضو)

آیا بعد از راه رفتن در سمت سالم خود درد احساس می‌کنید؟

☐ بله ☐ خیر

اگر درد دارید محل آن را مشخص کنید (می‌توانید بیش از یک مورد را انتخاب کنید)

☐ فصل لگن (هیپ) ☐ مفصل زانو ☐ مفصل مچ پا

☐ پنجه پا ☐ ساق پا ☐ موارد دیگر

اگر موارد دیگر را انتخاب کرده اید؛ لطفا توضیح دهید.

بخش ارزیابی پروتز (PEQ)

پرسش‌های این قسمت برای این طراحی شده که بدانیم پروتزتان چگونه بر زندگی روزمره تان تأثیر می‌گذارد. برای هریک از سؤالات یک عدد را از صفر تا 10 انتخاب کنید.

لطفا به همه پرسشها پاسخ دهید.

لطفا به میزان رضایت خود از پروتز کنونیتان طی 4 هفته گذشته نمره دهید.

	0	1	2	3	4	5	6	7	8	9	10	
به شدت ناراضی	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	بسیار راضی

به میزان فیت بودن پروتز طی 4 هفته گذشته نمره دهید.

	0	1	2	3	4	5	6	7	8	9	10	
بسیار بد	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	عالی

به وزن پروتزتان طی 4 هفته گذشته نمره دهید.

	0	1	2	3	4	5	6	7	8	9	10	
بسیار بد	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	عالی

به میزان راحتی ایستادن با پروتز طی 4 هفته گذشته نمره دهید.

	0	1	2	3	4	5	6	7	8	9	10	
بسیار بد	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	عالی

به میزان راحتی نشستن با پروتز طی 4 هفته گذشته نمره دهید.

	0	1	2	3	4	5	6	7	8	9	10	
بسیار بد	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	عالی

طی 4 هفته گذشته چقدر در زمان استفاده از پروتز، تعادلتان را از دست دادید؟

	0	1	2	3	4	5	6	7	8	9	10	
همواره	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	هرگز

به میزان انرژی مورد نیاز برای استفاده از پروتز طی 4 هفته گذشته نمره دهید.

	0	1	2	3	4	5	6	7	8	9	10	
کاملا خسته کننده و انرژی بر	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	بسیار راحت

به میزان تولید صدا به وسیله پروتزتان طی 4 هفته گذشته نمره دهید.

	0	1	2	3	4	5	6	7	8	9	10	
هرگز	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	همواره

اگر پروتزتان طی 4 هفته گذشته صدا داشته است، به میزان آزار دهنده بودن آن نمره دهید.

	0	1	2	3	4	5	6	7	8	9	10	
بدون اهمیت	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	به شدت آزاردهنده

یا ○ هیچ صدایی ایجاد نمی‌کند

به میزان آسیبی که پروتزتان به پوشش خود یا لباستان طی 4 هفته گذشته وارد کرده است، نمره دهید.

	0	1	2	3	4	5	6	7	8	9	10	
بدون آسیب	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	به شدت آسیب رسان

به امکان استفاده از کفشهای مختلف با پروتز طی 4 هفته گذشته نمره دهید.

	0	1	2	3	4	5	6	7	8	9	10	
بدون دشواری	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	غیرممکن

به میزان تورم استمپ خود طی 4 هفته گذشته که فیت پروتز را تغییر داده است، نمره دهید.

	0	1	2	3	4	5	6	7	8	9	10	
هرگز	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	همواره

به وجود حس خارش در استمپ طی 4 هفته گذشته نمره دهید.

	0	1	2	3	4	5	6	7	8	9	10	
بدون اهمیت	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	به شدت آزاردهنده

به وجود تاول یا زخم در استمپ طی 4 هفته گذشته نمره دهید.

	0	1	2	3	4	5	6	7	8	9	10	
بدون اهمیت	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	به شدت آزاردهنده

حسهای مربوط به بدن

این بخش درباره درد یا حسهای دیگریست که ممکن است احساس کنید

به میزان رخداد حس‌های غیردردناک در اندام خیالی خود طی 4 هفته گذشته نمره دهید.

○ هرگز ○ فقط یکبار یا دوبار ○ تقریبا یکبار در هفته ○ دو تا سه بار در هفته ○ چهار تا 5 بار در هفته ○ چندین بار هر روز

○ تقریبا همیشه

اگر طی ماه گذشته حس غیردردناک در اندام خیالی خود داشته اید؛ به شدت آن نمره دهید.

	0	1	2	3	4	5	6	7	8	9	10	
بسیار خفیف	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	بسیار شدید

یا حس غیردردناک در اندام خیالی خود نداشته‌ام

طی ماه گذشته حس غیردردناک در اندام خیالیتان چقدر آزار دهنده بوده است؟

	0	1	2	3	4	5	6	7	8	9	10	
همواره	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	هرگز

یا حس غیردردناک در اندام خیالی خود نداشته‌ام

به میزان رخداد حسهای دردناک در اندام خیالی خود طی 4 هفته گذشته نمره دهید.

- هرگز
- فقط یکبار یا دو بار
- تقریبا یکبار در هفته
- دو تا سه بار در هفته
- چهار تا پنج بار در هفته
- چندین بار هر روز
- تقریبا همیشه

معمولا درد خیالی چقدر طول میکشد؟

- درد خیالی ندارم
- چند ثانیه
- چند دقیقه
- چند دقیقه تا یک ساعت
- چند ساعت
- یک تا 2 روز
- بیش از دو روز

اگر طی ماه گذشته در اندام خیالی خود درد داشته اید؛ به شدت آن نمره دهید.

	0	1	2	3	4	5	6	7	8	9	10	
بسیار شدید	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	بسیار خفیف

یا حس دردناک در اندام خیالی خود نداشته‌ام

طی ماه گذشته حس دردناک در اندام خیالیتان چقدر آزار دهنده بوده است؟

	0	1	2	3	4	5	6	7	8	9	10	
همواره	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	هرگز

یا حس دردناک در اندام خیالی خود نداشته‌ام

به میزان رخداد حس‌های دردناک در استمپ خود طی 4 هفته گذشته نمره دهید.

- هرگز
- فقط یکبار یا دو بار
- تقریبا یکبار در هفته
- دو تا سه بار در هفته
- چهار تا پنج بار در هفته
- چندین بار هر روز
- تقریبا همیشه

اگر طی ماه گذشته در استمپ خود درد داشته‌اید؛ به شدت آن نمره دهید.

	0	1	2	3	4	5	6	7	8	9	10	
بسیار شدید	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	بسیار خفیف

یا ○ حس دردناک در استمپ خود نداشته‌ام

اگر طی ماه گذشته در استمپ خود درد داشته‌اید؛ به میزان آزاردهندگی آن نمره دهید.

	0	1	2	3	4	5	6	7	8	9	10	
بسیار آزاردهنده	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	بسیار خفیف

یا ○ حس دردناک در استمپ خود نداشته‌ام

به میزان رخداد درد در پای سالم خود طی 4 هفته گذشته نمره دهید.

○ هرگز ○ فقط یکبار یا دو بار

○ تقریبا یکبار در هفته ○ دو تا سه بار در هفته

○ چهار تا پنج بار در هفته ○ چندین بار هر روز

○ تقریبا همیشه

اگر طی ماه گذشته در پای سالم خود درد داشته‌اید؛ به شدت آن نمره دهید.

	0	1	2	3	4	5	6	7	8	9	10	
بسیار شدید	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	بسیار خفیف

یا ○ در پای دیگرم درد نداشته‌ام

اگر طی ماه گذشته در پای دیگر خود درد داشته‌اید؛ به میزان آزاردهندگی آن نمره دهید.

	0	1	2	3	4	5	6	7	8	9	10	
بسیار آزاردهنده	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	بسیار خفیف

یا ○ در پای دیگرم درد نداشته‌ام

جنبه‌های اجتماعی استفاده از پروتز

به میزان رخداد حس ناامیدی یا خشم نسبت به پروتزتان طی 4 هفته گذشته نمره دهید.

	0	1	2	3	4	5	6	7	8	9	10	
همواره	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	هرگز

به میزان رخداد حس ناامیدی یا اگر طی 4 هفته گذشته نسبت به پروتزتان خشمگین یا ناامید بوده اید؛ به بدترین حالت آن فکر کنید و نمره دهید.

	0	1	2	3	4	5	6	7	8	9	10	
به شدت ناامید و خشمگین	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	هرگز

به میزان احساس دست و پاگیر بودن پروتز در اجتماع طی 4 هفته گذشته نمره دهید.

	0	1	2	3	4	5	6	7	8	9	10	
بسیار	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	نه اصلا

توانایی تحرک شما در محیط اطراف

به میزان توانایی خود در راه رفتن با پروتز طی 4 هفته گذشته نمره دهید.

	10	9	8	7	6	5	4	3	2	1	0	
مشکلی ندارم	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	قادر نیستم

به میزان توانایی خود در راه رفتن در یک محیط بسته با پروتز طی 4 هفته گذشته نمره دهید.

	10	9	8	7	6	5	4	3	2	1	0	
مشکلی ندارم	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	قادر نیستم

به میزان توانایی خود در *بالا رفتن از پله* با پروتز طی 4 هفته گذشته نمره دهید.

	10	9	8	7	6	5	4	3	2	1	0	
مشکلی ندارم	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	قادر نیستم

به میزان توانایی خود در *پائین آمدن از پله* با پروتز طی 4 هفته گذشته نمره دهید.

	10	9	8	7	6	5	4	3	2	1	0	
مشکلی ندارم	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	قادر نیستم

به میزان توانایی خود در *بالا رفتن از شیب تپه* با پروتز طی 4 هفته گذشته نمره دهید.

	10	9	8	7	6	5	4	3	2	1	0	
مشکلی ندارم	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	قادر نیستم

به میزان توانایی خود در *پائین آمدن از شیب تپه* با پروتز طی 4 هفته گذشته نمره دهید.

	10	9	8	7	6	5	4	3	2	1	0	
مشکلی ندارم	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	قادر نیستم

به میزان توانایی خود در راه رفتن در پیاده‌رو و خیابان با پروتز طی 4 هفته گذشته نمره دهید.

	10	9	8	7	6	5	4	3	2	1	0	
مشکلی ندارم	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	قادر نیستم

به میزان توانایی خود در راه رفتن روی یک سطح لغزنده (مثل سطح خیس کاشی یا خیابان خیس از باران یا یخ بسته) با پروتز طی 4 هفته گذشته نمره دهید.

	10	9	8	7	6	5	4	3	2	1	0	
مشکلی ندارم	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	قادر نیستم

به توانایی خود در سوار و پیاده شدن از خودرو با استفاده از پروتز، طی 4 هفته گذشته نمره دهید.

	10	9	8	7	6	5	4	3	2	1	0	
مشکلی ندارم	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	قادر نیستم

به توانایی خود در نشستن و برخاستن از یک صندلی با ارتفاع صندلی اداری؛ آشپزخانه یا نهارخوری با استفاده از پروتز، طی 4 هفته گذشته نمره دهید.

	0	1	2	3	4	5	6	7	8	9	10	
قادر نیستم	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	مشکلی ندارم

به توانایی خود در نشستن و برخاستن از یک صندلی کوتاه یا نیمکت به عنوان مثال با ارتفاع کاناپه در هنگام استفاده از پروتز، طی 4 هفته گذشته نمره دهید.

	0	1	2	3	4	5	6	7	8	9	10	
قادر نیستم	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	مشکلی ندارم

به توانایی خود در نشستن و برخاستن از بخش نشیمن توالت فرنگی در هنگام استفاده از پروتز، طی 4 هفته گذشته نمره دهید.

	0	1	2	3	4	5	6	7	8	9	10	
قادر نیستم	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	مشکلی ندارم

به توانایی خود در دوش گرفتن یا حمام کردن با خیال آسوده، طی 4 هفته گذشته نمره دهید.

	0	1	2	3	4	5	6	7	8	9	10	
قادر نیستم	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	مشکلی ندارم

رضایت شما از پروتزتان

به میزان رضایت خود از پروتزتان، طی 4 هفته گذشته نمره دهید.

	0	1	2	3	4	5	6	7	8	9	10	
به شدت ناراضی	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	بسیار راضی

به میزان رضایت خود از راه رفتنتان، طی 4 هفته گذشته نمره دهید.

	0	1	2	3	4	5	6	7	8	9	10	
به شدت ناراضی	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	بسیار راضی

به میزان رضایت خود از زندگی، طی 4 هفته گذشته نمره دهید.

	0	1	2	3	4	5	6	7	8	9	10	
در بدترین حد ممکن	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	در بهترین حد ممکن

به طور کلی چقدر ار تمرینات و آموزشهای راه رفتن و استفاده از پروتز که بعد از قطع عضو دریافت کردید؛ راضی هستید؟

	0	1	2	3	4	5	6	7	8	9	10	
به شدت ناراضی	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	بسیار راضی

یا ○ هیچ آموزشی بعد از قطع عضو دریافت نکردم

چه چیزهایی درمورد پروتز برایتان مهم هستند؟

ظاهر پروتزتان چقدر مهم است؟

	0	1	2	3	4	5	6	7	8	9	10	
بدون اهمیت	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	بسیار مهم

چقدر مهم است که بتوانید کفش‌های مختلف بپوشید (با ارتفاع یا مدل گوناگون)؟

	0	1	2	3	4	5	6	7	8	9	10	
بدون اهمیت	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	بسیار مهم

چقدر ورم استمپ برایتان آزاردهنده است؟

	0	1	2	3	4	5	6	7	8	9	10	
بسیار آزاردهنده	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	مشکلی نیست

چقدر برایتان مهم است که از شیب تپه بالا بروید؟

	0	1	2	3	4	5	6	7	8	9	10	
بدون اهمیت	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	بسیار مهم

لطفا موارد زیر را بخوانید و به هر تعداد که طی 4 هفته گذشته اتفاق افتاده اند، مشخص کنید و توضیح مختصری بدهید.

☐ یک مشکل پزشکی جدی (برای خودتان) ☐ یک تغییر قابل توجه در درد

☐ یک مشکل شخصی جدی برای خودتان ☐ یک مشکل جدی در خانواده

☐ تغییرات بزرگ دیگری در زندگیتان اتفاق افتاده است

لطفا برای هر یک از مواردی که انتخاب کردید توضیح مختصری ارائه دهید.

لطفا هر مورد دیگری که تصور می‌کنید دانستنش برای ما مفید است، اعلام فرمائید

اطمینان به حفظ تعادل

این بخش پرسش‌هایی درباره اطمینان شما به حفظ تعادل مطرح می‌کند

آیا در مورد افتادن در زمان استفاده از پروتز نگرانی دارید؟

○ بله ○ خیر

اگر پاسختان مثبت است؛ به میزان نگرانی خود نمره دهید.

	0	1	2	3	4	5	6	7	8	9	10	
به شدت نگران که این نگرانی سبب ایجاد محدودیت در عملکردم شده است	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	اندکی نگران که فعالیتهایم را محدود نکرده است

آیا طی 12 ماه گذشته و در زمان استفاده از پروتز افتاده‌اید؟

○ بله ○ خیر

اگر پاسختان مثبت است، طی 12 ماه گذشته چند بار افتاده‌اید؟

- 1
- 2
- 3
- 4
- 5
- 6
- 7
- 8
- 9
- 10
- بیش از ده بار

آیا معمولا بدون وسایل کمکی (بدون استفاده از عصا یا کراچ و ..) راه می‌روید؟

بله ☐ خیر ☐

اگر با وسایل کمکی راه می‌روید از لیست زیر نام آن را انتخاب کنید:

- عصای دستی در یک طرف
- عصای زیر بغل در یک طرف
- عصای دستی در دو طرف
- عصای زیر بغل در دو طرف
- کراچ بدون چرخ
- کراچ با چرخ
- موارد دیگر

اگر سایر موارد را انتخاب کرده‌اید، لطفا توضیح دهید.

اطمینان از حفظ تعادل در فعالیت‌های خاص (ABC)

این بخش از پرسشنامه درباره حس اطمینان شما درباره حفظ تعادل خود طی انجام فعالیت‌های مختلف است. لطفا میزان اعتماد به نفس خود را برای هریک از فعالیت‌های ذکر شده، با شماره از 0 تا 10 مشخص کنید. صفر معادل بدون اعتماد به نفس و 10 معادل اطمینان کامل است.

لطفا به همه پرسشهای مطرح شده پاسخ دهید.

1- وقتی اطراف خانه راه میروید، چقدر اطمینان دارید که تعادل خود را از دست نخواهید داد؟

	10	9	8	7	6	5	4	3	2	1	0	
کاملا مطمئن	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	هیچ

2- وقتی از پله ها بالا میروید یا پائین می‌آئید، چقدر اطمینان دارید که تعادل خود را از دست نخواهید داد؟

	10	9	8	7	6	5	4	3	2	1	0	
کاملا مطمئن	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	هیچ

یا ◯ من هیچ وقت این کار را نمی‌کنم

3- وقتی خم می‌شوید تا چیزی را از روی زمین بردارید، چقدر اطمینان دارید که تعادل خود را از دست نخواهید داد؟

	10	9	8	7	6	5	4	3	2	1	0	
کاملا مطمئن	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	هیچ

یا ◯ من هیچ وقت این کار را نمی‌کنم

4- وقتی تلاش می‌کنید شیئی در ارتفاع چشم خود را بردارید، چقدر اطمینان دارید که تعادل خود را از دست نخواهید داد؟

	10	9	8	7	6	5	4	3	2	1	0	
کاملا مطمئن	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	هیچ

یا ◯ من هیچ وقت این کار را نمی‌کنم

5- وقتی سعی می‌کنید دستتان را به چیزی بالاتر از سرتان برسانید، چقدر اطمینان دارید که تعادل خود را از دست نخواهید داد؟

	0	1	2	3	4	5	6	7	8	9	10	
هیچ	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	کاملا مطمئن

یا ○من هیچ وقت این کار را نمی‌کنم

6- وقتی روی صندلی می ایستید تا دستتان به چیزی برسد، چقدر اطمینان دارید که تعادل خود را از دست نخواهید داد؟

	0	1	2	3	4	5	6	7	8	9	10	
هیچ	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	کاملا مطمئن

یا ○من هیچ وقت این کار را نمی‌کنم

7- وقتی زمین را جارو میزنید، چقدر اطمینان دارید که تعادل خود را از دست نخواهید داد؟

	0	1	2	3	4	5	6	7	8	9	10	
هیچ	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	کاملا مطمئن

یا ○من هیچ وقت این کار را نمی‌کنم

8- وقتی خارج از خانه به سمت یک خودروی پارک شده در خیابان راه میروید، چقدر اطمینان دارید که تعادل خود را از دست نخواهید داد؟

	0	1	2	3	4	5	6	7	8	9	10	
هیچ	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	کاملا مطمئن

یا ○من هیچ وقت این کار را نمی‌کنم

9- وقتی سوار خودرو یا از آن پیاده می‌شوید، چقدر اطمینان دارید که تعادل خود را از دست نخواهید داد؟

	0	1	2	3	4	5	6	7	8	9	10	
هیچ	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	کاملا مطمئن

یا ○من هیچ وقت این کار را نمی‌کنم

10- وقتی در یک پارکینگ به سمت یک فروشگاه راه می‌روید، چقدر اطمینان دارید که تعادل خود را از دست نخواهید داد؟

	0	1	2	3	4	5	6	7	8	9	10	
هیچ	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	کاملا مطمئن

یا ○من هیچ وقت این کار را نمی‌کنم

11- وقتی از یک سطح شیب بالا میروید یا پائین می آئید، چقدر اطمینان دارید که تعادل خود را از دست نخواهید داد؟

	0	1	2	3	4	5	6	7	8	9	10	
هیچ	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	کاملا مطمئن

یا ○من هیچ وقت این کار را نمی‌کنم

12- وقتی در محیط شلوغ که مردم سریع از کنارتان رد می‌شوند راه می‌روید، چقدر اطمینان دارید که تعادل خود را از دست نخواهید داد؟

	0	1	2	3	4	5	6	7	8	9	10	
هیچ	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	کاملا مطمئن

یا ○من هیچ وقت این کار را نمی‌کنم

13- وقتی هنگام راه رفتن در شهر یا خرید با کسی برخورد می‌کنید، چقدر اطمینان دارید که تعادل خود را از دست نخواهید داد؟

	10	9	8	7	6	5	4	3	2	1	0	
کاملا مطمئن	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	هیچ

یا ○من هیچ وقت این کار را نمی‌کنم

14- وقتی روی پله برقی میروید یا از آن خارج می‌شوید در حالی که دستگیره آنر ا نگاه میدارید، چقدر اطمینان دارید که تعادل خود را از دست نخواهید داد؟

	10	9	8	7	6	5	4	3	2	1	0	
کاملا مطمئن	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	هیچ

یا ○من هیچ وقت این کار را نمی‌کنم

15- وقتی روی پله برقی میروید یا از آن خارج می‌شوید در حالی که دستتان پر است و نمی‌توانید دستگیره آن را نگاه دارید، چقدر اطمینان دارید که تعادل خود را از دست نخواهید داد؟

	10	9	8	7	6	5	4	3	2	1	0	
کاملا مطمئن	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	هیچ

یا ○من هیچ وقت این کار را نمی‌کنم

16- وقتی روی پیاده‌روی یخ زده راه میروید، چقدر اطمینان دارید که تعادل خود را از دست نخواهید داد؟

	10	9	8	7	6	5	4	3	2	1	0	
کاملا مطمئن	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	هیچ

یا ○من هیچ وقت این کار را نمی‌کنم

کمردرد

بخش بعدی این پرسشنامه درباره کمردرد است. اگر شما کمردرد ندارید و گزینه مربوط را انتخاب کنید به صورت خودکار به بخش پایانی پرسشنامه دست پیدا خواهید کرد.

آیا کمردرد دارید؟

○بله ○خیر

پرسشنامه ارزیابی ناتوانی ناشی از کمردرد اسوستری

(Oswestry Low Back Pain Disability Questionnaire)

این بخش از پرسشنامه برای این طراحی شده تا بدانیم کمردرد بر زندگی روزمره شما چه اثری دارد. لطفا برای هر سؤال گزینه ای را انتخاب کنید که بیش از بقیه در مورد شما صدق می‌کند حتی اگر چند گزینه به نظرتان صحیح است فقط آن مورد را انتخاب کنید که بیشتر از سایرین مشکل شما را توصیف می‌کند

شدت درد

- در حال حاضر درد بسیار ملایم است
- در حال حاضر درد ملایم است
- در حال حاضر درد شدید است
- در حال حاضر درد بسیار شدید است
- در حال حاضر درد در شدیدترین حالت قابل تصور است

بهداشت و مراقبتهای شخصی (نظیر شستشو، لباس پوشیدن)

- می‌توانم بدون افزایش کمردرد به کارهای شخصی خود برسم
- می‌توانم به کارهای شخصی خود برسم اما با کمی درد در کمر همراه است
- انجام کارهای شخصی همراه با کمردرد است و باید با دقت و آهسته آنها را انجام دهم
- می‌توانم از عهده بیشتر کارهای شخصی خودم برآیم اما به کمک نیاز دارم
- در بیشتر کارهای شخصی ام به دلیل کمردرد به کمک نیاز دارم
- نمی‌توانم لباسم را بپوشم، به سختی شستشو را انجام می دهم و باید در بستر باشم

بلند کردن اجسام

- می‌توانم اجسام سنگین را بدون افزایش کمردرد بلند کنم
- می‌توانم اجسام سنگین را بلند کنم اما همراه با افزایش درد کمر خواهد بود
- درد مانع از بلند کردن اجسام سنگین از روی زمین است اما اگر بار روی سطحی مثل میز باشد، می‌توانم آن را مدیریت کنم
- درد مانع از بلند کردن اجسام سنگین از روی زمین است اما اگر بار سبک یا متوسط روی سطحی مثل میز باشد، می‌توانم آن را مدیریت کنم
- فقط می‌توانم بارهای سبک را بلند کنم
- هیچ باری را نمی‌توانم بلند یا حمل کنم

راه رفتن

- درد مانع از راه رفتن در هیچ فاصله ای نمی‌شود
- درد مانع از راه رفتن بیش از 2 کیلومتر می‌شود
- درد مانع از راه رفتن بیش از 1 کیلومتر می‌شود
- درد مانع از راه رفتن بیش از 500 متر می‌شود
- فقط با استفاده از عصا یا کراچ می‌توانم راه بروم
- بیشتر اوقات در بستر هستم

نشستن

- می‌توانم روی هر نوع صندلی به هر اندازه بنشینم
- می‌توانم روی صندلی مورد علاقه خودم به هر اندازه بنشینم
- کمردرد مانع از آن می‌شود که بیش از 1 ساعت بنشینم

- کمردرد مانع از آن می‌شود که بیش از 30 دقیقه بنشینم
- کمردرد مانع از آن می‌شود که بیش از 10 دقیقه بنشینم
- کمردرد کلا مانع از آن می‌شود که بنشینم

ایستادن

- می‌توانم هرقدر بخواهم بایستم
- می‌توانم هرقدر بخواهم بایستم اما این امر سبب افزایش کمردردم می‌شود
- کمر درد مانع از آن می‌شود که بیش از 1 ساعت بایستم
- کمر درد مانع از آن می‌شود که بیش از 30 دقیقه بایستم
- کمر درد مانع از آن می‌شود که بیش از 10 دقیقه بایستم
- کمر درد کلا مانع از آن می‌شود که بایستم

خوابیدن

- کمردرد هیچوقت در خوابیدنم اختلال ایجاد نمی‌کند
- خوابیدنم گاهی اوقات به دلیل کمردرد مختل می‌شود
- به دلیل کمردردم کمتر از 6 ساعت می‌خوابم
- به دلیل کمردردم کمتر از 4 ساعت می‌خوابم
- به دلیل کمردردم کمتر از 2 ساعت می‌خوابم
- کمردرد کلا مانع از خوابیدنم می‌شود

رابطه جنسی اگر به پاسخگویی در این باره تمایل ندارید، می‌توانید این بخش را بدون پاسخ بگذارید و به پرسش‌های بخش بعد بروید

- رابطه جنسی عادی دارم و انجام آن سبب کمردرد نمی‌شود
- رابطه جنسی عادی دارم ولی انجام آن سبب افزایش کمردرد می‌شود
- رابطه جنسی تقریبا عادی دارم ولی انجام آن سبب کمردرد را شدید می‌کند
- رابطه جنسی ام به دلیل کمردرد، به شدت محدود شده است
- رابطه جنسی به دلیل کمردرد، تقریبا در زندگی ام حذف شده است
- کمردردم کلا مانع از رابطه جنسی می‌شود

زندگی اجتماعی

- فعالیت اجتماعی‌ام عادیست و سبب افزایش کمردردم نمی‌شود
- زندگی اجتماعی‌ام عادیست ولی سبب افزایش کمردردم می‌شود
- درد اثر شدیدی بر فعالیت‌های اجتماعی‌ام ندارد، هرچند علائق پر جنب و جوشی نظیر ورزش کردن را محدود کرده است
- کمردرد فعالیت‌های اجتماعی‌ام را محدود کرده است و مثل سابق بیرون نمی‌روم
- کمردرد فعالیتهای اجتماعی‌ام را به خانه محدود کرده است
- به دلیل کمردرد فعالیت اجتماعی ندارم

مسافرت

- به هرجایی می‌توانم بدون درد سفر کنم
- به هرجایی می‌توانم سفر کنم اما این امر سبب افزایش کمردردم می‌شود
- کمردردم آزاردهنده است اما سفر تا 2 ساعت را مدیریت می‌کنم
- کمردرد سبب محدود شدن سفرم به یک ساعت می‌شود
- کمردرد سبب محدود شدن سفرم به کمتر از نیم ساعت می‌شود
- کمردرد مانع از مسافرتم می‌شود مگر اینکه برای دریافت درمان باشد

سپاسگزاری

پاسخگوی گرامی

از اینکه به سؤالات این پرسشنامه پاسخ دادید از شما بسیار سپاسگزاریم

تحلیل داده‌های این پرسشنامه نیازمند زمان است اما امیدوارم نتایج حاصل برای افزایش کیفیت زندگی افراد دچار قطع عضو کمک کننده باشد. تا این لحظه پاسخ‌های شما کاملا ناشناس ثبت شده‌اند اما اگر تمایل دارید در مطالعات آینده شرکت کنید، می‌توانید ای‌میل خود را ثبت کنید. ای‌میل شما بدون اجازه‌تان، در اختیار هیچ‌کس قرار نخواهد گرفت.

- تمایل دارم ای میل خود را ثبت کنم و اطلاعات بعدی را دریافت کنم
- نمیخواهم اطلاعات بیشتر از شما دریافت کنم

نشانی پست الکترونیکی (ای میل)

لطفا انتخاب کنید

- علاقه‌مندم اطلاعاتی درباره نتایج این پژوهش دریافت کنم
- علاقه‌مندم اطلاعاتی درباره پژوهش‌هایی در آینده که ممکن است بتوانم در آنها مشارکت کنم؛ دریافت نمایم

لطفا انتخاب کنید

- آماده‌ام تا پاسخ‌های خود را در اختیار اجرا کنندگان این پژوهش بگذارم و می‌دانم بعد از انتخاب این گزینه قادر به تغییر نظر خود نخواهم بود
- تمایل ندارم پاسخ‌هایم در اختیار اجرا کنندگان این پژوهش قرار گیرد

Appendix B

Ethics approval

Performance, Governance and Operations
Research & Innovation Service
Charles Thackrah Building
101 Clarendon Road
Leeds LS2 9LJ Tel: 0113 343 4873
Email: ResearchEthics@leeds.ac.uk

UNIVERSITY OF LEEDS

Biological Sciences Faculty Research Ethics Committee
University of Leeds

Dr Neil Messenger
School of Biomedical Sciences
University of Leeds
LS2 9JT

5 November 2015

Dear Neil

Title of study: **Balance and lower back pain in lower limb amputees**
Ethics reference: **BIOSCI 15-005**

I am pleased to inform you that the above research application has been reviewed by the Faculty of Biological Sciences Research Ethics Committee and following receipt of your response to the Committee's initial comments, I can confirm a favourable ethical opinion as of the date of this letter. The following documentation was considered:

Document	Version	Date
BIOSCI 15-005 Committee Provisional.doc	1	07/10/15
BIOSCI 15-005 amputee questionnaire ethics application following revciew.doc	1	07/10/15
BIOSCI 15-005 amputee questionnaire ethics application.doc	1	21/09/15
BIOSCI 15-005 amputee questionnaire email to web manageror editor .docx	1	21/09/15
BIOSCI 15-005 amputee questionnaire web-newsletter notice.docx	1	21/09/15
BIOSCI 15-005 amputee questionnaire online questionnaire.pdf	1	21/09/15
BIOSCI 15-005 amputee questionnaire structure.png	1	21/09/15

Please notify the committee if you intend to make any amendments to the original research as submitted at date of this approval, including changes to recruitment methodology. All changes must receive ethical approval prior to implementation. The amendment form is available at http://ris.leeds.ac.uk/EthicsAmendment.

Please note: You are expected to keep a record of all your approved documentation, as well as documents such as sample consent forms, and other documents relating to the study. This should be kept in your study file, which should be readily available for audit purposes. You will be given a two week notice period if your project is to be audited. There is a checklist listing examples of documents to be kept which is available at http://ris.leeds.ac.uk/EthicsAudits.

We welcome feedback on your experience of the ethical review process and suggestions for improvement. Please email any comments to ResearchEthics@leeds.ac.uk.

Yours sincerely

Jennifer Blaikie
Senior Research Ethics Administrator, Research & Innovation Service
On behalf of Prof Edward White, Chair, BIOSCI Faculty Research Ethics Committee

Appendix C

The email text

To Whom It May Concern

We recently (end of November 2015) sent you the following request . We know you would be busy but we think this is an important research project that would be of interest to your members. We appreciate your cooperation in advance.

The University of Leeds is carrying out a number of research projects aimed at improving the design and function of prosthetic legs. Part of this work is about improving balance confidence and reducing lower back pain. So that we can get a better understanding of the effect these have on the everyday lives of prosthetic leg users. We have designed an online questionnaire and we are contacting you to ask if we may publicise it on your webpage/group page/newsletter.
The online questionnaire "Balance and lower back pain in lower limb amputees" is available on: https://leeds.onlinesurveys.ac.uk/amputee_questionnaire

Any question about this, please get back to me and I would be happy to help.

Thank you

Tahmineh Rezaeian
PhD Student

Biomedical Sciences

University of Leeds

bstr@leeds.ac.uk

Dr Neil Messenger
Biomedical Sciences

University of Leeds

n.messenger@leeds.ac.uk

0113 3435084

Appendix D

Results of the ODI questionnaire and PEQ parts

(Except mobility part) of the Survey (Chapter 3)

Relations between general characteristics

There was no significant difference in age between genders (p=0.379) (Males M±SD=55.33±13.02, Females M±SD=53.56±10.56).

There was a moderate difference in age between countries (F(4, 150)= 5.936, p<0.001, η^2=0.137). The mean age (±SD) for British (59.02±10.51 years) and Iranian (47.43±12.31 years) were significantly different (as were Australians (56.57±12.53 years) and Iranians). The age of participants from USA (52.85±9.72 years) and Other Countries (56.13±11.67 years) did not differ significantly from other groups.

There were no significant differences in age between *amputation cause* groups (p=0.823) but there was a moderate difference in age between *time since amputation* groups (F(3, 151)= 3.032, p=0.031, η^2=0.06). The mean age (±SD) was significantly different only between the group with amputation for 11-20 years (46.69±15.36 years) and the group with amputation for more than 20 years (56.92±10.49 years). The age of participants with amputation less than 5 years (54.61±11.45 years) and 6-10 years (55.16±13.32 years) did not differ significantly from other groups. There was no relation between age and *time since amputation* (p=0.591).

A medium association was observed between participants' gender and their country ($\chi^2[pearson](4, n = 155) = 29.072,$ p<0.001, $df^* = 1,$ Cramer's V=0.433). Only 1 female from Iran participated in the survey. Sixty percent of participants from USA were female while the rate was 40% for british respondents.

No association was seen between gender and *cause of amputation* (p=0.151), in addition to gender and groups of *time since amputation* (p=0.064). Male participants had longer *time since amputation than females* (respectively mean rank=87.76, MED[1]=11, n=96 vs mean rank=62.12, MED=5, n=59, χ^2(1)= 11.97, n=155, MED=8, p=0.001). It is seen that most of female participants had experienced amputation in their 40-59 years age (50.8% of participants in the age group) while larger percentage of other age groups was related to male participants ($\chi^2[Pearson](3, n = 155) = 7.67,$ p=0.053, $df^* = 1,$ Cramer's V = 0.22).

The difference of *Age-at-amputation* between male (MED= 20.325) and female (MED=17.72) participants was non-significant (p=0.235).

A strong association between countries of participants and cause of their amputation was seen ($\chi^2[Likelihood\ ratio](28, n = 155) = 42.846,$ p=0.034, $df^* = 4,$ Cramer's V=0.253). The highest rate of trauma/sever injuries including war-related causes was for Iranian participants (75.7% of them including 35% with war-related amputation). It was the *cause of amputation* for 44.0%, 33.3%, 20.0% and 53.3% of participants in turn from UK, Australia, USA and Other Countries. In UK, 14% and 12% of participants recorded severe infection and peripheral arterial diseases as their cause of amputation. Fifty percent and 40% of amputations due to peripheral arterial disease and cancer were recorded from UK. While none of the Iranians recorded peripheral arterial disease as cause of their amputation. Amputation secondary to diabetes, sever infection and

[1] MED stands for Median

peripheral arterial disease were causes of amputation in 20%, 20% and 15% of American participants. American participants recorded 40% of amputations secondary to diabetes. Mean rank and median of *age-at-amputation* were highest for participants from Australia (in turn 94.38 and 51) and lowest for participants from Iran (in turn 39.85 and 20). The difference between *age-at-amputation* of Iranians and participants from all other countries was significant: Iranians and Australians (p<0.001), Iranians and Americans (MED=46, p<0.001), Iranians and British participants (MED=47, p<0.001), Iranians and participants from Other Countries (MED=47, p=0.012).

More than 90% of Iranians had amputation before being 39 years. While more than 75%, 66% and 60% of participants from Australia, UK and USA/Other Countries experienced amputation after their 40 years age.

A strong association was observed between *age-at-amputation* groups and *cause of amputation* ($\chi^2[Likelihood\ ratio](21, n = 155) = 47.45,$ o p=0.001, $df^* = 3,$ Cramer's V=0.327). The rate of amputation due to trauma/serious injuries was higher in young-age. In turn, 58.8% of participants younger than 20 years, 64.1% of participants at age of 20-39, 34.4% of participants at age of 40-59 and 33.3% of participants older than 60 years experienced amputation due to trauma/serious injuries. Around 58% and 25% of amputations due to peripheral arterial disease happened in 40-59 and elder than 60 years age. Similarly, amputations secondary to diabetes happened in 40-59 and more than 60 years age (in turn 70% and 20% of participants within the *amputation cause* category).

Age-groups

There was no significant association between age- groups, and gender of participants (p=0.32).

A relatively strong association between *age-groups* and participants countries was found ($\chi^2[Likelihood\ ratio](16, n = 155) = 37.89,$ p=0.002, $df^* = 4,$ Cramer's V=0.248). Younger respondents tending to be Iranian and older respondents tending to be from the UK.

There was no significant association between participants' age-group and *cause of amputation* (p=0.262).

Amputation location

No differences were seen between amputation location groups in terms of their age (p=0.714). There was no association between the *age-groups* and amputation location (p=0.073).A medium association between gender of participants and their amputation location was observed ($\chi^2[Likelihood\ ratio](5, n = 155) = 20.285,$ p=0.001, $df^* = 1,$ Cramer's V=0.346).

There was a medium association between participants' country and *location of amputation* ($\chi^2[Likelihood\ ratio](20, n = 155) = 35.89,$ p=0.016, $df^* = 3,$ Cramer's V=0.235). Majority of bilateral amputees were British (55%) and 40% of above-knee amputees were from Iran. Seventy-five percent of Americans were below-knee amputee.

A medium association was observed between *age-at-amputation* groups and location of amputation ($\chi^2[Likelihood\ ratio](15, n = 155) = 26.02,$ p=0.037, $df^* = 3,$ Cramer's V=0.227). The *age-at-amputation* of around 58% of below-knee amputees was 40-59 years and 31.6% of above-knee amputees experienced the amputation at their age of younger than 20 and 20-39 years.

Results related to bodily sensation

Thirteen questions of the PEQ questionnaire were used to assess bodily sensation of amputee participants (questions number 48-60). Questions number 49-57 and 59-60 includes assessment of bodily sensation of in turn amputated and non-amputated side. Each question could be scored 0-10, while 0 was for worst sensation, 5 for neutral opinion and 10 was for the mildest condition. There was an option to choose when the sensation did not exist. The total score of each participant was calculated by summing score of the questions and then calculating the average score for each person (M±SD=5.06 ±2.39, N=146). Thus 3 “Bodily sensation scores” were produced: 1- for both sides, 2- for the amputated-side, 3- for intact-side. Total bodily sensation score for the 8 questions gained by averaging scores of the questions. There was no significant difference (p=0.07) in scores for males (M±SD=5.355±2.33) and females (M±SD= 4.63±2.42).

No difference was found between mean of the total bodily sensation score in groups of: 1- *participants’ age-groups* (p=0.68), 2- *time since amputation* groups (p=0.22), 3- participants’ *age-at-amputation*-groups (p=0.08), 4- *cause of amputation* (p=0.37), 5- amputation location (p=0.86).

A moderate difference in the total bodily score of participants from various countries was seen (F(4, 141)= 4.99, p=0.001 η2 (0.124)). The mean score (±SD) for these pairs of countries was significantly different: British participants (4.1±1.96) and Iranians (6.2±2.34); British participants and Australians (5.63±2.67). The score of participants from USA (4.52±2.06) and Other Countries (5.25±2.34) did not differ significantly from other groups.

No relation between the total bodily score- *time since amputation* (p=0.778) and *age-at-amputation* (p=0.532) was found.

- **<u>Frequency of bodily sensations in amputated limb</u>**
- **Non-painful phantom limb**

There was no significant difference between the age of participants in the frequency categories of non-painful phantom limb (p=0.56) and there were no significant association between frequency of non-painful phantom limb and: 1- gender (p=0.156), 2- age of participants (p=0.403) or 3- amputation location (p =0.302).

The *cause of amputation* had a strong association with frequency of feeling non-painful phantom limb ($\chi^2[Likelihood\,ratio](42, n = 155) = 66.27,$ p=0.01, $df^* = 6,$ Cramer’s V=0.256). The rate of all categories of non-painful phantom limb feeling frequency was higher for serious trauma/injury cause. No participants with amputation due to peripheral arterial disease or diabetes chose the “never” frequency. Sixty percent of those with cancer as *cause of amputation* selected “only once or twice” as frequency of feeling phantom limb. Fifty percent, 36.4%, 22.2%, 21.9%, 12.5%, 10% and 4.5% of participants with, in turn, peripheral arterial disease, limited function, other causes, trauma/ injuries, congenital conditions, cancer and sever infection as cause of amputation, chose “all the time” had the feeling.

A medium association between *time since amputation* categories and frequency of feeling non-painful phantom limb ($\chi^2[Likelihood\,ratio](18, n = 155) = 35.52,$ p=0.008, $df^* = 3,$ Cramer’s V=0.268).

There were differences between *time since amputation* across the non-painful phantom limb frequency categories (χ^2(6)= 29.204, n=155, MED=8, p<0.001). Mean rank and median were highest for “never” feeling of the sensation during last 4 weeks (110.75, MED=23.5, n=32). Lowest mean rank and median were for “very often-4 to 6 times per week” (55.26, MED=4, n=17) and “fairly often-2 to 3 times per week” (60.62, MED=3.5, n=20). The difference between *time since amputation* of these pairs of non-painful phantom limb frequency categories was statistically significant: “very often” and “never” (p=001), “all the time” (mean rank= 66.47, n=33, MED=4) and “never” (p=0.001), “fairly often” and “never” (p=0.002), “several time every day” (mean rank= 62.38, n= 13, MED=5) and “never” (p=0.022).

There were no differences between two other frequency categories nor with the above categories: “only once or twice” (mean rank= 85.89, n=27, MED=12), “a few times (1-2 times per week)” (mean rank= 82.35, n=13, MED=8).

There was a medium association between *age-at-amputation* and frequency of non-painful phantom limb ($\chi^2[Likelihood\,ratio](24, n = 155) = 37.9,$ p=0.004, $df^* = 3,$ Cramer’s V=0.267). Younger participants tended to experience a lower incidence of the sensation whilst the older participants were more likely to experience the sensation most frequently.

The *age-at-amputation* was difference across the non-painful phantom limb frequencies (χ^2(6)=17.97, n=155, MED=41, p=0.006). Mean rank and median were highest for “several times every day” feeling of the sensation during last 4 weeks (99.92, MED=46, n=13) and “all the time” (92.38, MED=47, n=33). Lowest mean rank and median were for “never” (56.45 and MED=25.5, n=32) and “only once or twice” (63.13, MED=23, n=27). The difference between *age-at-amputation* of “never” and “all the time” categories was statistically significant (p=0.026).

There were no differences between three other frequency categories nor with the above categories: “a few times- about once per week” (n=13, MED=49), “fairly often-2 to 3 times per week” (n=20, MED=48), “very often- 4 to 6 times per week” (n=17, MED=44).

- **Phantom pain**

No significant difference between the age of participants in the frequency categories of phantom pain was observed (p=0.47). No association between frequency of phantom pain and: 1- gender (p=0.39), 2- age-groups and phantom pain (p=0.6), 3- cause of amputation (p=0.31), 4- location of amputation (p=0.17), 5- countries (p=0.11,).

The association between time since amputation categories and frequency of phantom pain was significant ($\chi^2[Likelihood\,ratio](18, n = 155) = 29.83$ p=0.04, $df^* = 3,$ Cramer’s V=0.241). More than half of participants who stated never to have the feeling had their amputation for more than 20 years. While more than half of those who expressed “all the time” and “several times every day” have the feeling lived ≤5 years with amputation.

A significant difference was seen between the *time since amputation across* the phantom pain frequency categories (χ^2(6)= 19.16, n=155, MED=8, p=0.004). Mean rank and median were highest or “never” feeling of the sensation during last 4 weeks (95, MED=16.74, n=49). Lowest mean rank and median were for “all the time” (59.33 and MED=4, n=12) and “fairly often -2 to 3 times per week” (56.28, MED=5, n=23). The difference between *time since amputation of* “fairly often -2 to 3 times per week” and “never” was statistically significant (p=0.013). There were no differences between *time since amputation* of other frequency categories nor with the above categories: “a few times- about once per week” (n=16, MED=9.5), “very often-4 to 6 times per week” (n=13, MED=18), “several times every day” (n=14, MED=4.5).

There was a medium association between phantom pain frequency and *age-at-amputation* groups ($\chi^2[Likelihood\,ratio](18, n = 155) = 37.86,$ p=0.004, $df^* = 4,$

Cramer's V=0.246). Forty-seven percent and 38.5% of participants in *age-at-amputation* groups of earlier than 20 and at 20-39 years chose "never" having phantom pain during last 4 weeks. While the rate for same frequency was only 19.7% and 28.6% of participants with amputation at 40-59 and over 59 years age-groups. The percentage of participants with amputation before their 20 years age, decreased with increase of phantom pain frequency.

No significant differences were observed between the *age-at-amputation* across the phantom pain frequency categories (p=0.313).

There was no significant difference between the age of participants in the frequency categories of stump pain (p=0.69).

No association was found between frequency of stump pain and: 1- gender (p=0.13), 2- *participants' age-groups* of (p=0.73), 3- *age-at-amputation* groups (p=0.15), 4- participants' living countries (p=0.17), 5- *location of amputation* (p=0.14), 6- *time since amputation* categories (p=0.466).

A strong association was observed between frequency of stump pain and *cause of amputation* ($\chi^2[Likelihood\ ratio](42, n = 153) = 61.595$, p=0.026, $df^* = 6$, Cramer's V=0.260). *Cause-of-amputation* for 61.1% of participants without stump pain during last month was serious trauma/injuries. No participant with peripheral arterial disease as *cause of amputation* chose "never" frequency. Each frequency of "never" and "only once or twice" were chosen by 30% of participant with amputation due to diabetes. Rate of all categories of stump pain frequency was higher than other causes for serious trauma/injury cause. Around 42% of participants with peripheral arterial disease chose "all the time" had the sensation. Around 36% of amputees with limited function/pain as *cause of amputation* had the pain "several times every day". While this rate was 0% for congenital amputees and 7% for participants with serious trauma/injuries as *cause of amputation* for same frequency. Forty percent of amputees due to cancer chose "very often- 4 to 6 times per week" experience of stump pain.

No significant differences were found between the *time since amputation* as well as *age-at-amputation* across the stump pain frequency categories (in turn p=0.713 and p=0.69).

- **<u>Presence of bodily sensations in amputated limb</u>**
- **Non-painful phantom limb**

No significant difference between the age of participants with (M±SD= 54.43±12.29 years) and without (M±SD= 55.55±11.69 years) non-painful phantom limb was observed (p=0.65).

A small association between feeling a non-painful sensation in phantom limb and gender was seen ($\chi^2[Pearson](1, n = 155) = 7.91$, p=0.005, $df^* = 1$, Phi=-0.226). Around 73% of male participants had the sensation while the rate was 91.5% for female respondents.

A medium association between non-painful phantom limb and *time since amputation* was found ($\chi^2[Pearson](3, n = 155) = 19.44$, p<0.001, $df^* = 1$, Cramer's V=0.354). However, the rate of sensation was high in all the time categories, but it decreased from 93.5% among participants with less than 6 years of amputation to 61.5% of those with more than 20 years amputation.

No association was observed between the feeling of non-painful phantom limb and: 1- *participants' age-groups* (p=0.703), 2- *cause of amputation* (p=0.06), or 3- amputation location (p=0.1).

A medium association between the sensation and participants original countries was found ($\chi^2[Pearson](4, n = 155) = 19.103$, p=0.001, $df^* = 1$, Cramer's V=0.35). More than 81% (for Australians and 100% for American) of participants except Iranians (56.8%) had the feeling of non-painful phantom limb.

A small association was observed between *age-at-amputation* and feeling a non-painful phantom limb ($\chi^2[Pearson](3, n = 155) = 9.564$, p=0.02, $df^* = 1$, Cramer's V=0.248). Around 70% of participants under 40 years had the feeling while the rate increased to 87% and 95.2% for participants in 40-59 years and over 59 years *age-at-amputation* groups.

A significant difference was found between *time since amputation* for participants with non-painful phantom limb and without it ($\chi^2(1, n = 155) = 21.724$, p<0.001). Mean rank and median of *time since amputation* were higher for participants without the sensation (111.55, MED=24, n=31) in comparison with the *time since amputation* of participant with the non-painful phantom limb (69.61, MED=7, n=124).

Age-at-amputation of participants with and without the non-painful phantom limb was different (χ^2(1)= 8.88, n=155, p=0.003). Mean rank and median of *age-at-amputation* were lower for participants without the sensation (56.52, MED=25, n=31) in comparison with the amputation age of participant with the non-painful phantom limb (83.37, MED=44, n=124).

- **Phantom pain**

No difference was found between the mean age of participants with (54.41±12.24 years) and without (55.18±12.02 years) phantom pain was observed (p=0.715) .But there was a small association between the presence of phantom pain and gender ($\chi^2[Pearson](1, n = 155) = 4.04$, p=0.04, $df^* = 1$, Phi = 0.162). Seventy-eight percent of females suffered from phantom pain while the rate was 62.5% for males. In spite of the smaller proportion of female participants, 43.4% of respondents with phantom pain were female.

No significant differences were observed between phantom pain and: 1- participates' *age-groups* (p=0.33), 2- *cause of amputation* (p=0.76), or 3- *location of* amputation (p=0.18).But there was an association between the presence of phantom pain and the participants' country ($\chi^2[Pearson](4, n = 155) = 18.18$, p=0.001, $df^* = 1$, Cramer's V = 0.343). The rate was lowest among Iranians and highest for British participants. Only 48.6% of Iranian participants reported phantom pain while this rate was 86%, 80%, 73% and 54.5% in turn for participants from the UK, the USA, Other Countries and Australia.

A medium association was found between the presence of phantom pain and the *time since amputation* ($\chi^2[Pearson](3, n = 155) = 14.16$, p=0.003, $df^* = 1$, Cramer's V = 0.302). Half of participants with more than 20 years of amputation were without phantom pain. This rate was 12% for 6-10 years, 24% for less than 6 years, and 31% for 11-20 years of amputation.

A small association was observed between *age-at-amputation* groups and phantom pain ($\chi^2[Pearson](3, n = 155) = 8.71$, p=0.033, $df^* = 1$, Cramer's V=0.237). Amputation at a younger age was associated with lower rate of phantom pain. Fifty-three percent of participants with amputation in before 20 years age had phantom pain but the rate increased to 61.5% at 20-39 years age, 80.3% at 40-59 years age and 71.4% at older than 60 years age. Participants with amputation in their age of 40-59 years had lowest percentage of phantom pain absence.

A significant difference was found between *time since amputation* for participants with pain (mean rank=70.14, n=106, MED=7) and without (mean rank=95, n=49, MED=16.74) it ($\chi^2(1, n = 155) = 10.31$, p=0.001). There was also a significant difference between *age-at-amputation* of participants with (mean rank=83.26, n=106, MED=44.5) phantom pain and without (mean rank=66.62, n=49, MED=29) it (χ^2(1)= 4.61, n=155, p=0.03).

- **Stump pain**

No significant difference (p=0.71) was seen between the age of participants with (M±SD= 55.08±12.33 years) and without (M±SD= 54.22±11.31 years) stump pain (mean difference=-0.85, 95% CI: -5.41-3.7).

A small association was found between the presence of stump pain and gender ($\chi^2[Pearson](1, n = 153) = 6.82$, p=0.009, $df^* = 1$, Phi=-0.21). Around 80% of participants without stump pain (n=29), and 56.4% of those with stump pain (n=66) were males. The rate of stump pain was 87.9% of females and 69.5% of males.

There was no significant relation between presence of stump pain and: 1- *age-groups* (p=0.381), 2- *time since amputation* categories (p=0.334), 3- amputation location (p=0.243), 4- *age-at-amputation* groups (p=0.131), 5- *amputation cause* (p=0.091).

A medium association was observed between the presence of stump pain and country of participants ($\chi^2[Pearson](4, n = 153) = 19.03$, p=0.001, $df^* = 1$, Cramer's V=0.353). ()The highest rate of stump pain presence was observed among British and American participants (92% and 85% respectively) and the lowest rate was related to Iranians (52.8%).

No significant differences (p=0.439) were found between *age-at-amputation* of participants with (mean rank=78.54, n=117) and without (mean rank=72, n=36) stump pain and no significant difference (p=0.315) existed between *time since amputation* for participants with stump pain (mean rank=75.01, n=117) and without (mean rank=83.47, n=36) it.

- **<u>Intensity and bothersomeness of the sensations in amputated-side</u>**

Figure 1 shows responses to questions about the bodily sensations of the amputated limb (questions number 49, 50, 53, 54, 56, 57). Respondents scored 0-10 in reply to each question where score 0 stood for "Extremely Intense or bothersome" and 10 showed "Extremely Mild". In this chart, the most left (darkest colour) shows frequency of scores from 0-4 (worse scores), neutral score (5) and scores 6-10 (mild scores). Twenty-two to 30% of the participants did not have categorized sensations, 38.1%, 40.6% and 41.4% of participants have chosen worse scores for in turn intensity of phantom pain, level of being bothersome for phantom pain and level of being bothersome for stump pain (comparable with 23.2% and 23.8% of giving better scores to same sensation questions).

- **Non-painful phantom limb**

Among the participants with non-painful phantom limb; 44.8%,9.5%, and 45.7% chose in turn worst scores (1-4), neutral score (5) and mild scores (6-10). No significant difference was found between the age of 3 categories of non-painful phantom limb intensity (p=0.094). Similarly there was no association between intensity sensation of non-painful phantom limb and gender (p=0.31, for 11 intense scores and p=0.68for 3 categories of the intense) or with participants age-group (p=0.09 for 11 intense scores and p=0.213 for 3 categories of the intense).

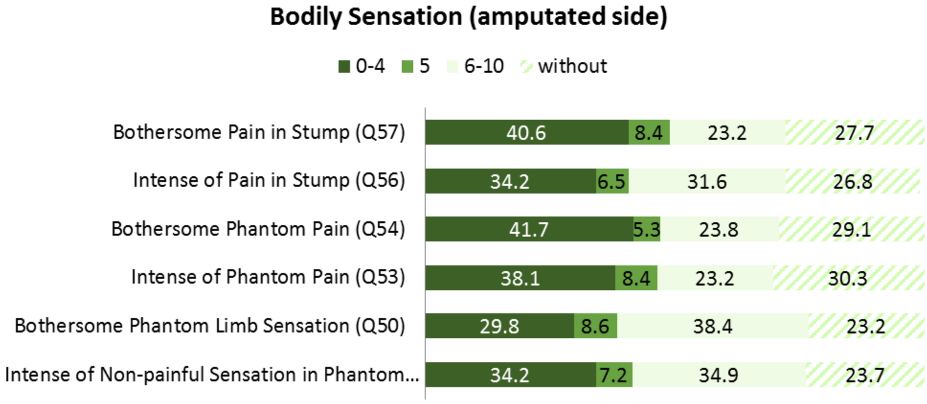


Figure 1 Bodily sensations of amputated limb, darkest colour represents worst scores (1-4) and lightest colour is for mild scores (6-10). The dashed pattern shows the absence of a response.

Country had a significant association with the intense of the non-painful phantom limb in terms of 11 points scoring ($\chi^2[Likelihood\ ratio](40, n = 116) = 55.23$, p=0.055, $df^* = 4$, Cramer's V=0.33) but the association was no significant in terms of 3 categories of the intensity ($\chi^2[Likelihood\ ratio](8, n = 116) = 12.07$, p=0.148, $df^* = 2$, Cramer's V=0.226). The worst scores was related to American and lowest for Iranian participants (60% versus 21.1%). The rate of worst scores for other countries was 52.6% for British participants, 46.2% for participants from Other Countries and 38.5% for Australians.

No association was seen between intensity of non-painful phantom limb and *age-at-amputation* in terms of 11 points scoring (p=0.068) but a medium association was observed in terms of 3 categories of the intensity ($\chi^2[Likelihood\ ratio](6, n = 116) = 20.998$, p=0.002, $df^* = 2$, Cramer's V=0.279). Sixty-four percent of participants with amputation in their 20-39th years chose worst scores while the rate was 11.1% for those with amputation over their 60th birthday. The rate was 51% for 40-59 years and 36.4% for participants with amputation in their age of younger than 19. The mild scores were chosen inversely to the participants' *age-at-amputation*: 66.7% of those with amputation over 59, 63.3% of younger than 20, 39.2% of 40-59, and 28% of 20-39 years.

No association was observed between intensity of non-painful phantom limb and: 1- *cause of amputation* (p=0.13for 11 intense scores and p=0.48), 2- *time since amputation* categories (p=0.09for 11 intense scores and for 3 categories of the intense), 3- *location of amputation* (p=0.67for 11 intense scores and p=0.117).

Among the participants with non-painful phantom limb, in turn: 38.7%, 11.2%, and 50% chose worst scores (1-4), neutral score (5) and best scores (6-10) for when rating the bothersomeness of their sensation. No significant difference in age of 3 categories of non-painful phantom limb bothersomeness was found (p=0.39).No association was observed between non-painful phantom limb's level of bothersomeness and: 1- gender (p=0.086), 2- *age-groups* (p=0.5), 3- participant' living country (p=0.49), 4- *amputation cause* (p=0.19), 5- amputation location (p=0.867).

No significant difference was seen between bothersomeness of the non-painful phantom limb in terms of their age (p=0.116), No association was found between *age-at-amputation* groups and bothersomeness of the non-painful phantom limb in terms of 11 points scoring p=0.227), but a relative association was observed in terms of 3 categories of the bothersomeness ($\chi^2[Likelihood\ ratio](6, n = 116) = 12.22$, p=0.057, $df^* = 3$, Cramer's V=0.218). Around 78% of participants who had amputation after their 60 years age, chose best scores while 55%, 51.9% and 37.3% of those with *age-at-amputation* younger than 20, 20-39 years and 40-59 years selected these scores. The rate of worst scores was inverse among amputation *age-groups* (11.1% for over 59 years, 40% for younger than 20, 40.7% for 20-39 years and 47.1% for 40-59 years).

There was not any association between the bothersomeness of non-painful phantom limb and: 1- gender (p=0.086), 2- participants' country (p=0.487), 3- *age-groups* (p=0.499), 4- *amputation cause* (p=0.186), 5- the *time since amputation* categories (p=0.499), 6- amputation location (p=0.867).

- **Phantom Pain**

Among the participants with phantom pain, 54.6%, 12%, and 33.3% chose the worst scores (1-4), neutral score (5) and mild scores (6-10) for intensity of sensation. No significant difference was seen between the age of 3 categories of phantom pain (p=0.9). No association was found between intensity of phantom pain and: 1- gender (p=0.81for 11 intense scores and p=0.96for 3 categories of the pain intense), 2- participants *age-groups* (p=0.245for 11 intense scores and p=0.23for 3 categories of the pain intense), 3- *country of residence* (p=0.08for 11 intense scores and p=0.07for 3 categories of the pain intense), 4- *age-at-amputation* (p=0.32 for 11 intense scores and p=0.19for 3 categories of the pain intense), 5- *time since amputation* categories (p=0.094for 11 intense scores and p=0.299for 3 categories of the intense), 6- *cause of amputation* (p=0.32for 11 intense scores and p=0.22for 3 categories of the pain intense), 7- *location of amputation* (p=0.85 for 11 intense scores and p=0.63for 3 categories of the pain intense)

Among the participants with phantom pain, in turn, 58.9%, 7.5%, and 33.6% chose worst scores (1-4), neutral score (5) and mild scores (6-10) for the bothersomeness of their sensation. No significant difference was seen in age of phantom pain bothersomeness categories (p=0.12). No association between phantom pain's level of bothersomeness and: 1- gender (p=0.26), 2- *age-groups* was observed (p=0.1), 3- participant' living country (p=0.8), 4- *age-at-amputation* groups (p=0.11), 5- *amputation cause* (p=0.17), 6- the *time since amputation* categories (p=0.094), 7- amputation location (p=0.66).

- **Stump pain**

Among the participants with stump pain, in turn, 53.6%, 15.2%, and 31.3% selected worst scores (1-4), neutral score (5) and mild scores (6-10) for showing an intense level of their sensation. One-way ANOVA showed no significant difference between the age of 3 categories of stump pain intensity (F(2, 109)= 0.16, p=0.86).

No association was found between intense of stump pain and following variables was observed: 1- gender (p=0.57 for 11 intense scores and p=0.65 for 3 categories of the pain intense), 2- *age-groups* (p=0.39for 11 intense scores and p=0.74for 3 categories of the pain intense), 3- *time since amputation* categories (p=0.199 for 11 intense scores and p=0.974, for 3 categories of the intense), 4- participants' living country (p=0.14for 11 intense scores and p=0.08 for 3 categories of the pain intense), 5- *age-at-amputation* groups (p=0.31for 11 intense scores and p=0.206 for 3 categories of the pain intense), 6- amputation location (p=0.79for 11 intense scores and p=0.305for 3 categories of the pain intense).

No significant association was observed between *amputation cause* and the stump pain in comparing of 11 scores of intense (p=0.33,). But, a medium association was observed in comparing of 3 pain intense categories and *cause of amputation* ($\chi^2[Likelihood\ ratio](14, n = 112) = 24.49$, p=0.04, $df^* = 2$, Cramer's V=0.311).

The participants with a congenital condition and peripheral arterial diseases as causes of amputation had the highest rate of worst scores and the lowest rate of the mild scores (in turn 85.7%-14.3% and 83.3%-16.7% of participants in the cause category). While participants with amputation secondary to diabetes represented the lowest rate of worst scores (14.3%) and the highest rate for mild scores (57.1%).

Among the participants with stump pain, in turn; 56.2%, 11.6%, and 32.1% chose worst scores (1-4), neutral score (5) and best scores (6-10) for the bothersomeness of their sensation. No significant difference was found in age of stump pain bothersomeness categories (p=0.14). No association was seen between bothersomeness of stump pain and: 1- gender (p=0.59), 2- *age-groups* was observed (p=0.38), 3- participant' living country (p=0.08), 4- *age-at-amputation* groups (p=0.47), 5- *amputation cause* (p=0.20), 6- the *time since amputation* categories (p=0.181), 7- amputation location (p=0.93).

- **<u>Amputated-side bodily sensation score</u>**

A total score for amputated-side bodily sensation gained by averaging scores of answered questions related to intensity and bothersomeness of the sensations (Q 49, 50, 53, 54, 56, 57) for each participant (M± SD=4.97 ±2.46, N=139). No relation was found between age and the amputated-side sensation's score (p=0.08). No significant difference in the scores (p=0.23) was seen between males (M±SD=5.18±2.405) and females (M±SD= 4.67±2.52).

No differences were found between mean of bodily sensation score of amputated-side in groups of: 1- *participants' age-groups* (p=0.24), 2- *time since amputation* categories (p=0.34), 3- *cause of amputation* (p=0.53), 4- amputation location (p=0.76).

A small significant difference in the score of participants for the countries was observed (F(4, 141)= 3.36, p=0.012, η^2=0.09). The mean score (±SD) between British participants (4.15±2.2) and Iranians (6.08±2.48) was significantly different. The score of participants from the USA (4.59±2.15), Australia (5.48±2.66) and Other Countries (5.08±2.45) did not differ significantly from other groups.

A moderate difference was seen in the score of *age-at-amputation* groups (F(3, 135)= 3.44, p=0.019, η^2=0.07). The mean score (±SD) for participants with amputation in their 40-59 years age (4.5±2.31) and over 59 years age-group (6.43±1.76) was significantly different. The score of participants with amputation: before 20 years age (5.28±2.66) and 20-39 years age (4.69±2.6) had no difference with each other and other age-groups.

There was no relation between the amputated-side bodily score- *time since amputation* (p=0.981) and *age-at-amputation* (p=0.229).

- **<u>Non-amputated side</u>**

The average score related to questions 59-60 for intact limb bodily score was 5.1±2.65 (N=98). No significant difference (p=0.714) was found between age of participants with (M±SD= 54.36±12.96 years) and without (M±SD= 55.24±10.83 years) intact-side pain

No association was seen between the presence of intact-side pain in these groups: 1- gender (p=0.298), 2- participates' *age-groups* (p=0.482), 3- *time since amputation* categories (p=0.455), 4- participants' country (p=0.116), 5- *age-at-amputation* groups (p=0.584), 6- *cause of amputation* (p=0.29), 7- *location of amputation* (p=0.41,).

No significant difference exists between *time since amputation* of participants with (mean rank= 66.99, n=99) and without (mean rank= 72.54, n=37) intact-side pain (p=0.464) or between *age-at-amputation* of participants with (mean rank= 69.55, n=99) and without (mean rank= 65.7, n=37) intact-side pain (p=0.613).

No difference was observed in age between the frequencies of the intact-side pain (p=0.66). No significant association was found between frequency of intact-side pain and: 1- gender (p=0.95), 2- age of participants (p=0.167), 3- *time since amputation* categories (p=0.97), 4- *age-at-amputation* groups (p=0.69), 5- *amputation cause* (p=0.69), 6- amputation location (p =0.568). But, there was a significant difference between the frequency of intact-limb pain among participants from different countries ($\chi^2[Likelihood\ ratio](24, n = 136) = 41.96$, p=0.013, $df^* = 4$, Cramer's V=0.246). No participants from Australia and Other Countries expressed "all the time" having the pain during last 4 weeks. Highest rate of choosing "never" option was 43% and 39% for participants from Other Countries and Iranians. 32.1% and 28.6% of participants from Australia and Other Countries chose "only once or twice" frequency.

- **Intensity and bothersomeness of intact-side pain**

Figure 2 shows responses to questions about the bodily sensations of the intact limb. Respondents were asked to give scores 0-10 points for each related question where score 0 stood for "Extremely Intense or bothersome" and score 10 showed "Extremely Mild". In this chart, the most left and darkest colour shows frequency of score for groups 0-4 as worst scores, neutral score (5) and scores 6-10 as mild scores. The categories have an almost uniform rate.

Among the participants with intact-side pain, 38.7%, 18.4%, and 42.8% chose in turn worst scores (1-4), neutral score (5) and mild scores (6-10) for intensity of sensation. No significant difference was seen in age of 3 categories of intact-side pain intensity (p=0.2). A low association was found between 3 categories of intact-side pain intensity and gender ($\chi^2[Pearson](2, n = 98) = 5.87$, p=0.05, $df^* = 1$, Cramer's V=0.245) but no association between gender and 11 scores of pain intense p=0.09). Thirty percent of male participants and 52.6% of female participants chose 1st four worst scores while 73.8% and 26.2% of participants who selected 4 mild scores were in turn male and female respectively.

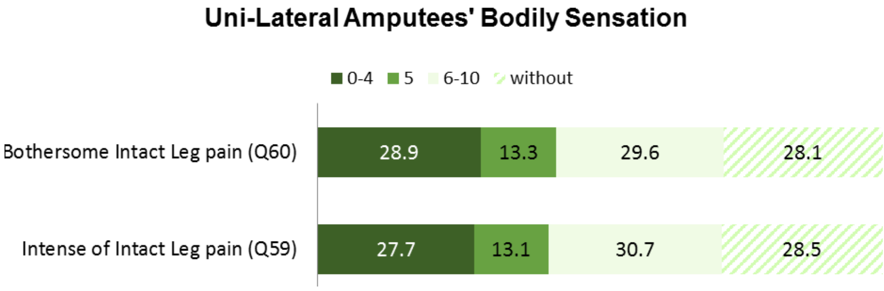


Figure 2 Bodily sensations of intact-side, darkest colour represents worst scores (1-4) and lightest colour is for mild scores (6-10). The dashed pattern shows the absence of the questioned quality

There was no significant association between intensity of intact-side pain and: 1- participants *age-groups* (p=0.413 for 11 intense scores andp=0.24for 3 categories of intact-side pain intensity), 2- *time since amputation* categories (p=0.886 for 11 intense scores and p=0.992 for 3 categories of intact-side pain intensity), 3- participants' *country of residence* (p=0.06, for 11 intense scores and p=0.09 for 3 categories of intact-side pain intensity), 4- *age-at-amputation* groups (p=0.185for 11 intense scores and p=0.21for 3 categories of intact-side pain intensity), 5- *cause of amputation* (p=0.24for 11 intense scores and p=0.24 for 3 categories of intact-side pain intensity), 6- and *location of amputation* (p=0.55 for 11 intense scores and p=0.235for 3 categories of intact-side pain intensity).

Among the participants with intact-side pain, in turn; 40.2%, 18.6% and 41.2% of participants chose worst scores (1-4), neutral score (5) and best scores (6-10) for the bothersomeness of their sensation. No significant difference was seen in age of 3 intact-side pain bothersomeness categories (p=0.26).

An association was observed between bothersomeness of intact-side pain and gender ($\chi^2[Likelihood\ ratio](10, n = 97) = 24.204$, p=0.007, $df^* = 1$, Cramer's V=0.457 for 11 intense scores and $\chi^2[Pearson](2, n = 97) = 8.24$, p=0.019, $df^* = 1$, Cramer's V=0.286 for 3 categories of the bothersomeness). The three mentioned categories of scores were chosen by in turn 52.6%, 23.7% and 23.7% of female participants while the rate for the same categories of bothersomeness was 32.2%, 15.3% and 52.5% for male participants with intact-side pain.

No association was observed between bothersomeness of the intact-side pain and: 1- *age-groups* was observed (p=0.27), 2- participant' living country (p=0.176), 3- *age-at-amputation* groups (p=0.507), 4- *amputation cause* (p=0.21), 5- *time since amputation* categories (p=0.215), 6- amputation location (p=0.726).

- **Intact-side bodily sensation score**

Total score for intact-side bodily sensation were gained by averaging scores of questions number 59 and 60 (related to intensity and bothersomeness of the pain) for each participant. No relation was seen between age and the intact-side score (p=0.69). A moderate difference (t(96)=2.89, p=005, two-tailed, η^2=0.08) in the score between males (M±SD= 5.69±2.36) and female (M±SD= 4.16±2.845). The actual difference in mean score (mean difference=1.53, 95%CI: 0.48-2.58) was moderate according to the effect size, calculated using).

No difference was found between mean of intact-side's bodily sensation scores in groups of: 1- *participants' age-groups* (p=0.35), 2- *cause of amputation* (p=0.55), 3- amputation location (p=0.86), 4- *time since amputation* categories (p=0.49), 5- *age-at-amputation* groups (p=0.42).

But, a large difference was observed in the intact-side bodily sensation score between participants from different countries (F(4, 93)= 5.556, p=0.01, η^2=0.132). The mean (±SD) score was significantly different between Americans (3.57±2.305) and Iranians (6.43±2.27). The score of British participants (4.56±2.8), Australians (5.325±2.67) and Other Countries (5.94±1.78) did not differ significantly from other groups and each other. The relationship between the total bodily score and *time since amputation as* a non-normal variable was investigated using Spearman's correlation non-parametric test. There was no relation between total bodily score -*time since amputation* (p=0.114) and between the intact-side bodily sensation score - *age-at-amputation* as a non-normal variable (p=0.62).

Results related to prosthesis use

No significant difference in age of participants in different prosthetic use frequency categories was found (p=0.72). No significant association was observed between frequency of prosthetic use and: 1- gender (p=0.3), 2- *age-groups* (p=0.72,), 3- countries of participants (p=0.2), 4- *age-at-amputation* groups (p=0.21), 5- *cause of amputation* (p=0.545), 6- *location of amputation* (p=0.22).

- **Prosthesis quality and effects**

Figure 3 shows responses to questions about the prosthesis use (questions number 34-47). Respondents were asked to score from 0 to 10 their prosthesis in reply to each question (average score ± SD=5.94 ±2.1, MED=6.29, N=151). In this diagram, the most left /darkest colour is for a score 0 which is worst score versus the most right/lightest colour shows score 10 which represents the best score. The least scores were given to questions about the possibility of using different shoes with their prosthesis and the noisiness of the prosthesis. The respondents had fewer problems with changes prosthesis fit due to stump swelling, stump rashes/soreness due to prosthesis use and damage to cloths by their prosthesis.

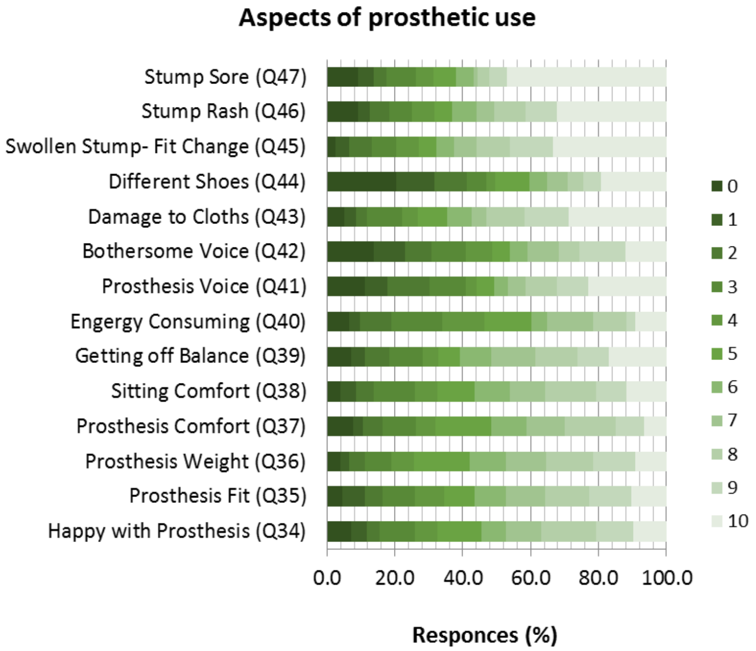
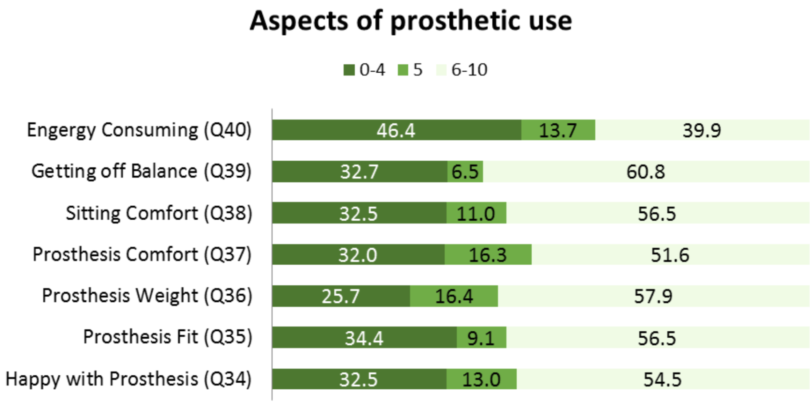


Figure 3 Responses to question about prosthesis qualities and effects, darkest colour represents worst score (0) and lightest colour is for best score (10)

Figure 4 shows the percentage of responses to the prosthesis use related to questions in form of weakest scores (0-4), neutral score (5) and higher scores (6-10).
In total and on average, 35.4% of respondents chose weakest scores, 9.4% neutral score and 55.2% highest scores. In fact, 25.7%-49.7% of responses are related to scores 0-4, 3.9%-16.4% for score 5, 46.6%-67.8% for scores 6-10. Total score for prosthesis effects and qualities gained by averaging scores of questions number 34-47.
There was a near to significant relation between age and the score (p=0.054) and no significant differences (p=0.126) were seen between the score for males (mean rank=80.24) and females (mean rank=69.01).

The difference in scores was no significant between 1- *participants' age-groups* (p=0.141), 2- *amputation causes* (p=0.188)3- *location of amputation* groups (p=0.117)
The score of participants had significant difference according to their *country of residence* (χ^2(4)= 12.08, n=151, p=0.017). Mean rank and median were highest for Iranian participants (90.65, MED=6.85) and lowest mean rank and median was for British participants (59.01, MED=4.79). The difference between the score of British (n=47) and Iranian (n=37) participants was statistically significant. There were no significant differences between or with the other countries of residence: Australians (n=32, MED=6.19), American (n=20, MED=6.64), Other Countries (n=15, MED=6.29).



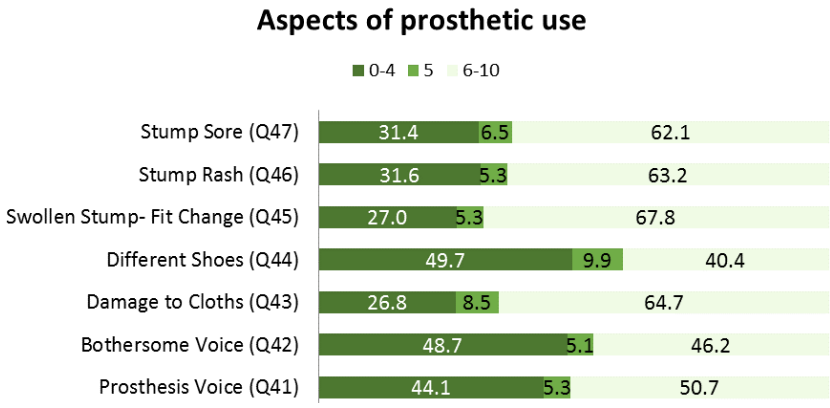


Figure 4 Percentage of worse scores (0-4), neutral (5) and better scores (6-10) given to the questions related to the prosthesis effects and qualities

A significant difference was observed among participants regarding their score across *time since amputation* categories (χ^2(3)= 8.51, n=151, MED=6.29, p=0.037). Mean rank and median were highest for participants with 5 years or less amputation (82.86, MED=6.64, n=59) and lowest mean rank and median was for those with 6-10 years amputation (55, MED=4.7, n=24). The difference between the score of these 2 categories was statistically near to significant (p=0.051) but there were no significant differences between or with participants in 2 other categories: amputation for 11-20 years (n=16, MED=5.22), amputation for more than 20 years (n=52, MED=6.38). No relation was seen between "*prosthetic quality and effects*" score -*time since amputation* (p=0.81) and the score- *age-at-amputation* (p=0.2)

But, the difference between the score of the *age-at-amputation* groups was significant (χ^2(3)= 8.57, n=151, p=0.036). Mean rank and median were highest for participants with amputation over their 59 years age (100.1, MED=7.405, n=20) and lowest mean rank and median was for participants with amputation in their 40-59 years age (67.59, MED=6.07, n=59). The difference between these two groups of *age-at-amputation* was statistically significant. There were no differences between score of either other *age-at-amputation* groups nor with the above groups: amputation age-group <20 years (mean rank= 73.13, MED=6.29, n=34), 20-39 years (mean rank= 78.93, MED=6.18, n=38).

Self-efficacy aspects of the prosthetic use

Self-efficacy aspects of the prosthetic use were evaluated by 2 series of question: 3 questions about emotional/social aspects of the prosthesis use (the frustration intensity/frequency and feel of being hindered by prosthetic device socially) and 4 questions related to the level of satisfaction with prosthesis and life in general.

- **<u>Emotional/social aspects of the prosthesis using</u>**

Figure 5 shows the categories of the worst score (0-4), neutral (5) and better scores (6-10) to questions related to the emotional/social aspects of the prosthesis use (questions number 61-63). It indicates *intensity of frustration* is high in the respondents (57.2%). But the percentage of responses about the level of social hindering by prosthesis is same for participants with both lower scores and higher scores of frustration due to the prosthesis (45.5%).

The total score for *emotional aspects* of prosthesis use was gained by averaging scores of questions number 61-63 (N=153, M± SD=4.9 ±3.115, MED=4.67).

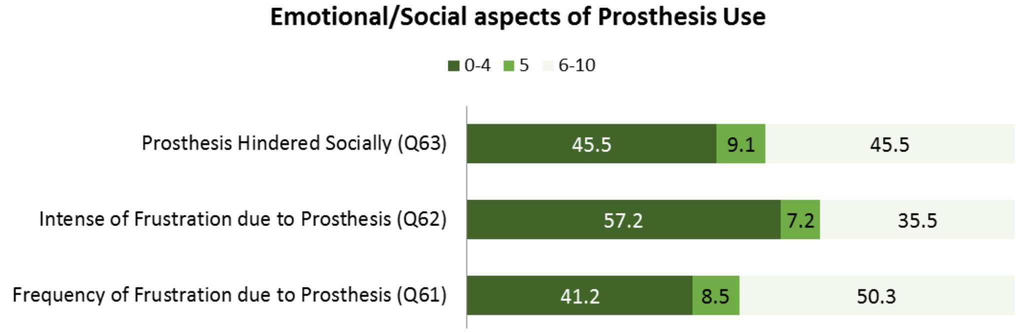


Figure 5 Percentage of worse scores (0-4), neutral (5) and better scores (6-10) to questions related to the emotional/social aspects of the prosthesis using

No difference was observed (p=0.171) between scores of 1- males (M± SD=5.18 ±3.2, MED=4.84) and females (M± SD=4.43 ±2.94, MED=4.33), 2- *age-groups* (p=0.153), 3- *age-at-amputation* groups (p=0.098), 4- *amputation cause* groups (p=0.08).

A significant difference between the score of participants in different groups of amputation location (χ^2(5)= 11.16, n=153, p=0.048). Mean rank and median were highest for participants with Hip-disarticulation (128, MED=8.3, n=1) and knee-disarticulation (112, MED=7.33, n=4). Lowest mean rank and median were for bilateral amputees (51.39, MED=3.17, n=18). But the adjusted significance level for the pairwise tests was not <0.05 for any pairs of groups.

A significant difference was found between the score of participants from different countries (χ^2(4)= 28.454, n=153, p<0.001). Mean rank and median were highest for Iranians (103.54, MED=7.33, n=37) and participants from Other Countries (93.67, MED=7.33, n=15). Lowest mean rank and median were for British participants (54.1, MED=3, n=48). The difference between the score of these pairs of participants' groups was statistically significant: British participants and Iranians (p<0.001), British participants and participants from Other Countries (p=0.025), a near to significant difference between Australians (mean rank=74, n=33, MED=4.67) and Iranians (p=0.053). There were no differences between scores of Americans (mean rank=75.3, MED=4.5, n=20) with above groups.

A significant difference was observed between the score of participants in different categories of *time since amputation* (χ^2(3)= 13.62, n=153, p=0.003). Mean rank and median were highest for participants with more than 20 years with amputation (91.22, MED=6, n=52). Lowest mean rank and median were for those with 6-10 years of amputation (51.21, MED=2.5, n=24). The difference between the score of these two groups of participants was statistically significant. There were no differences between scores of neither two other groups nor with above groups: less than 5 years of amputation (mean rank=75.6, n=61, MED=4.67), 11-20 years with amputation (mean rank=75.3, n=16, MED=5).

The relationship between the emotional aspects' score (as a non-normal variable) and age was investigated using Spearman's correlation non-parametric test. There was no relation between 2 variables, rho=0.071, n=155, p=0.385. The same test showed no significant relation between *age-at-amputation* and the score (rho=-0.09, n=153, p=0.263).

The relationship between the score and *time since amputation a*lso was investigated using Spearman's correlation non-parametric test. There was a small positive relation between 2 variables which means the score increased with the growing of the time (rho=0.18, n=153, p=0.026, two-tailed).

- **Frustration**

In Figure 5, zero score indicated "all the time" and 10 stood for "never" as the worst and best scores of frustration respectively. Among 153 responses to related questions, the scores 0, 5 and 10 of *frustration frequency* were chosen in turn by 12.4%, 8.5% and 15.7% of respondents.

No differences were observed between the age of participants in *frustration frequency* categories (p=0.736). No association was found between frequency of the frustration and gender (p=0.26) nor between *frustration frequency* and participants *age-groups* (p=0.2). The *country of residence* had a strong association with the *frustration frequency* ($\chi^2[Likelihood\,ratio](40, n = 153) = 90.606$, p<0.001, $df^* = 4$, Cramer's V=0.384 for 11 points scoring and $\chi^2[Likelihood\,ratio](8, n = 153) = 19.79$, p=0.01, $df^* = 2$, Cramer's V=0.247 for 3 categories of the frequency). The rate of choosing score 0 was highest for British participants (30.6% of them). Forty-five percent of Iranian participants stated never had the feeling. In same way, the highest versus lowest rate of choosing most frequent scores was related to British versus Iranian participants (59.2% versus 21.6%). The rate for other participants was more than 35% and less than 41%.

No association was found between *frustration frequency* and *age-at-amputation* groups in terms of 11 points scoring (p=0.206).

An association existed between *frustration frequency* and *time since amputation* categories ($\chi^2[Likelihood\,ratio]\,(30, n = 153) = 59.94$, p=0.002, $df^* = 3$, Cramer's V=0.342 for 11 point scoring frequency and $\chi^2[Likelihood\,ratio]\,(6, n = 153) = 12.86$, p=0.045, $df^* = 2$, Cramer's V=0.201 for 3 categories of the frequency). Around 37% of participants with 6-10 years of amputation, expressed to have frustration "all the time", while 28.8% of participants with amputation for more than 20 years stated they never had the frustration. The majority of participants with amputation for 6-10 years (62.5%) chose most frequent scores and most of participants with amputation more than 20 years (65.4%) selected least frequent scores to state their *frustration frequency*.

An association was observed between *frustration frequency* and *cause of amputation* in terms of 11 point scoring ($\chi^2[Likelihood\,ratio](70, n = 153) = 95.72$ p=0.02, $df^* = 7$, Cramer's V=0.277) but not in terms of the 3 categories of worst, neutral and best frequencies (($\chi^2[Likelihood\,ratio](14, n = 153) = 20.456$ p=0.116, $df^* = 2$, Cramer's V=0.249). Thirty percent of participants with amputation due to cancer or limited function due to deformity/severe pain and 25% of participants with amputation due to peripheral arterial disease indicated that they felt frustration all of the time and this group were also less likely to state that they never felt frustrated while 22.2% of participants with other *cause of amputation* and 21.9% of those with amputation due to serious trauma/injuries stated that they never had the feeling. Seventy-five percent of participants with amputation due to peripheral arterial disease versus only 22.2% of those with other causes and 28.6% of amputees due to sever infection chose the worst categories of frustration (scores 0-4). The frequency for the more favourable scores (score 6-10) was lowest for peripheral arterial disease (25%) and highest for other causes and secondary to diabetes (66.75% and 60%).

No association was found between *frustration frequency -location of amputation* (p=0.304) and *frustration frequency- age-at-amputation* (p=0.147). A significant difference was observed between *time since amputation* across *frustration frequency* categories (χ^2(2)= 6.68, n=153, p=0.035). Mean rank and median were highest for score 6-10 (85.58, MED=15, n=77). Lowest mean rank and median were for neutral score (53.04, MED=5, n=13). But the adjusted significance level for the pairwise tests was not <0.05 for any pairs of groups. Scores 0-4 had mean rank=70.42, n=63 and MED=7 years.

Frustration intense was expressed by zero score as "Extremely frustrated" and 10 stood for "not at all" as the worst and best scores (Figure 5). Around 18% of participants chose "Extremely frustrated" to describe intense of their frustration with the prosthesis while the rate was 15.5% for "not at all" option and 7.2% for a neutral score (5). The worst scores (0-4) had been selected by around 57% of the respondents and only 35.5% had chosen better scores (6-10).

No differences were found between the age of participants in frustration intense categories (p=0.9). A small association existed between intensity of the frustration with the prosthetic device- gender ($\chi^2[Pearson](2, n = 152) = 6.59,$ p=0.037, $df^* = 1,$ Cramer's V=0.208). Majority of females took place in worst and neutral category while around 42% of male had scores 6-10.

No difference was observed in the intensity of frustration for 1- *age-groups* (p=0.44), 2- *time since amputation* categories (p=0.2), 3- *age-at-amputation* groups (p=0.161), 4- *cause of amputation* (p=0.28), 5- *location of amputation* (p=0.445), 5- the *time since amputation* (p=0.193), *and 6- age-at-amputation* (p=0.61).

A medium association between participants' country and intense of the frustration ($\chi^2[Likelihood\,ratio](8, n = 152) = 26.74$ p=0.001, $df^* = 2,$ Cramer's V=0.297). Iranians were less frustrated (67.6% chose scores 6-10) while around 77% of British participants were very frustrated with their prosthesis (scores 0-4). This rate of was 65% for American, 60% for Australians, 53.3% of participants from Other Countries and 27% of Iranians.

- <u>**The feeling of being hindered by the prosthetic device**</u>

In assessing how the prosthesis hindered the participants a zero score indicated "A great deal" and 10 stood for "Not at all". The scores were group into the worst score (0-4), neutral (5) and better scores (6-10) with 45.5%, 9.1% and 45.5% of participants placed in each one.

No differences were seen between the age of participants in hindering categories (p=0.119). No association was observed between feeling to be hindered categories and: 1- gender (p=0.675), 2- *time since amputation* categories (p=0.061), 3- *age-at-amputation* (p=0.29), 4- *amputation cause* (p=0.16), 5- amputation location (p=0.53).

A significant association existed between the "feeling to be socially hindered by prosthesis" categories and participants *age-groups* ($\chi^2[Likelihood\,ratio](40, n = 153) = 47.255,$ p=0.035, $df^* = 4,$ Cramer's V=0.273 for 11 point scoring and $\chi^2[Likelihood\,ratio](8, n = 154) = 21.69,$ p=0.006, $df^* = 2,$ Cramer's V=0.243 for 3 categories of the hindering). Around 43% of respondent in the more than 69 years group and 24.5% of those in 50-59 years group chose score 10 while the rate for other *age-groups* were less than 20%. Around 86% of participants over 69 years chose the best scores (6-10) while this was least chosen response for participants in 60-69 years group with rate of 35% of respondents. It was surprising to see that group with the highest rate of choosing the worst scores (0-4) was observed among participants in age-group of 40-49 years.

A significant association was found between the feeling of being socially hindered and participants from different countries ($\chi^2[Likelihood\ ratio](40, n = 154) = 66.8$, p=0.005, $df^* = 4$, Cramer's V=0.317 for 11 point scoring and $\chi^2[Likelihood\ ratio](8, n = 154) = 18.276$, p=0.019, $df^* = 2$, Cramer's V=0.235 for 3 categories of the hindering). Around 26% of British participants and 5% of Iranians expressed their feeling by choosing score 0, versus 10% of British participants and 53% of participants from Other Countries who chose score 10. Around 63% of British participants selected worst scores (0-4) while it was least for participants from Other Countries (26.7%). Around 73% of participants from Other Countries chose better scores (6-10).

A significant difference existed between *time since amputation* across the *feeling of being hindered* categories (χ^2(2)=6.18, n=154, p=0.045). Mean rank and median were highest for neutral score (93.14, MED=15.87, n=14). Lowest mean rank and median were for worst scores (68.15, MED=7, n=70). But the adjusted significance level for the pairwise tests was not <0.05 for any pairs of groups. Scores 6-10 had mean rank=83.72, n=70 and MED=13 years. No significant difference was seen between *age-at-amputation* across hindering categories (p=0.372).

Satisfaction level

Total score for prosthesis use satisfaction was gained by averaging scores of questions number 77-80 (N=154, M± SD=5.9 ±2.72, MED=6.5). No difference was observed between the score of 1- genders (p=0.646), 2- *age-groups* (p=0.243), 3- *time since amputation categories* (p=0.108), 4- *age-at-amputation* groups (p=0.72), 5- *amputation cause* groups (p=0.15), and 6- amputation location (p=0.155).

A significant difference was found between the satisfaction score of participants from different countries (χ^2(4)= 17.12, n=154, p=0.002). Mean rank and median were highest for participants from Other Countries (99.13, MED=8.5, n=15). Lowest mean rank and median were for British participants (56.66, MED=4.75, n=49). The difference between the score of these pairs of participants' groups was statistically significant: British participants and Iranians (mean rank=87.04, n=37, MED=7) (p=0.018), British participants and participants from Other Countries (p=0.012), British participants and Australians (mean rank=85.17, n=33, MED=7) (p=0.045). There were no differences between scores of Americans (mean rank=82.03, n=20, MED=6.85) with above groups. No relation was seen between the satisfaction score-age (p=0.115), the score- *time since amputation* (p=0.922) and the score-*age-at-amputation* (p=0.248).

- **<u>Satisfied with prosthesis</u>**

For the question related to the level of being satisfied with the prosthesis during last 4 weeks (question 77), zero score stood for "Extremely dissatisfied" and 10 for "Extremely satisfied" as the worst and best scores. Opposite to intense of participants' frustration, the best scores (6-10) for the question related to satisfaction about prosthetic had been selected by around 57% of the respondents and only 33.6% had chosen worst scores (0-4). No differences were observed between prosthesis satisfaction categories and 1-

the age groups (p=0.2), 2- *time since amputation* (p=0.65), 3- *age-at-amputation* (p=0.65). No association was seen between satisfaction with the prosthetic device and: 1- gender (p=0.427), 2- *age-groups* (p=0.38), 3- *time since amputation* categories (p=0.16), 4- *age-at-amputation* groups (p=0.74), 5- *cause of amputation* (p=0.42), 6- *location of amputation* (p=0.48).

A medium association was seen between participants' country and the satisfaction categories ($\chi^2[Likelihood\ ratio](8, n = 152) = 23.88$ p=0.002, $df^* = 2$, Cramer's V=0.262). Iranians were less dissatisfied (16.7%) while around 54% of British participants were dissatisfied with their prosthesis (scores 0-4). Twenty-five percent of American, 27.3% of Australians and 33.3% of participants from Other Countries chose the worst scores whilst for the better scores was 75% for American, 66.7% of participants from Other Countries, 69.4% of Iranians, 57.6.3% for Australians, and 37.5% of British participants.

- **<u>Satisfied with walking</u>**

For the question related to the level of satisfaction with walking with the prosthesis during last 4 weeks (question 78), zero score stood for "Extremely dissatisfied" and 10 for "Extremely satisfied". The best scores (6-10) had been selected by around 55% of the respondents and only 35% had chosen worst scores (0-4). No differences were seen between the age of participants in walking satisfaction categories (p=0.2). No association was found between walking satisfaction and: 1- gender (p=0.336), 2- *age-groups* (p=0.5), 3- *time since amputation* categories (p=0.48), 4- *age-at-amputation* groups (p=0.164), 5- *cause of amputation* (p=0.2), 6- *location of amputation* (p=0.38).

A medium association was observed between participants' country and the satisfaction categories ($\chi^2[Likelihood\ ratio](8, n = 153) = 27.83$ p=0.001, $df^* = 2$, Cramer's V=0.291). Iranians were less dissatisfied (13.9%) while around 59% of British participants were dissatisfied with their walking (scores 0-4). The rate of choosing of the worst score was 35% for American, 33.3% of participants from Other Countries, and 21.2% for Australians. The rate of choosing of the better scores was 66.7% for Iranians, Australians and participants from Other Countries, 50% for American, 34.7% for British participants.

No significant differences were seen between the *time since amputation* or *age-at-amputation* across the walking satisfaction categories (in turn p=0.83 and p=0.122).

- **<u>Quality of Life (QoL)</u>**

For the question related to the rating *Quality of Life* during last 4 weeks (question 79), zero score stood for "Worst possible life" and 10 for "Best possible life. As it was seen in Figure 3-15, the best scores (6-10) for the question had been selected by around 61% of the respondents and only 28.3% had chosen worst scores (0-4). No differences were seen between the age of participants in QOL categories (p=0.68).

No association was observed between QoL's categories and: 1- gender (p=0.2), 2- *age-group* (p=0.56), 3- *time since amputation* categories (p=0.58), 4- *age-at-amputation* groups (p=0.84), 5- *cause of amputation* (p=0.22), 6- *location of amputation* (p=0.3).

A medium association was found between participants' country and the QoL's categories ($\chi^2[Likelihood\ ratio](8, n = 154) = 21.06$ p=0.007, $df^* = 2$, Cramer's V=0.259). Participants from Other Countries seemed to be less un-happy with QoL (13.3%) while around 42% of British participants were not happy with their QoL (scores 0-4). The rate of choosing of the worst score was 35% for American, 19.4% for Iranians, and 18.2% for

Australians. The rate of choosing of the better scores was 80% of participants from Other Countries, 75.8% of Australians, 75% of Iranians, 50% of American, and 38% of British participants.

No significant differences were seen between the *time since amputation* as well as *age-at-amputation* across the QoL rating categories (in turn $\chi^2(2)$= 1.824, n=154, MED=8, p=0.4 and $\chi^2(2)$= 1.65, n=154, MED=41, p=0.44). But, a positive small relation was observed between *time since amputation* and QoL score (rho=-0.163, n=154, p=0.044, two-tailed) with higher scores for QoL associated with longer *time since amputation*.

- **<u>Satisfaction with training received after amputation</u>**

For the question 80 (rate of being satisfied with the prosthetic training you have received since your amputation), zero score stood for “Extremely dissatisfied” and 10 for “Extremely satisfied”. There was an option to choose “no-training was received” and 20% of respondents selected this option. The best scores (6-10) were selected by around 51% of the respondents and only 22.4% chose worst scores (0-4).

No differences were seen between the age of participants in prosthesis satisfaction categories (p=0.075). No association existed between the satisfaction and: 1- gender (p=0.68), 2- *age-groups* (p=0.485), 3- *amputation cause* (p=0.11), 4- participants’ country (p=0.085).

A small association was observed between *time since amputation* categories and the level of satisfaction with the training ($\chi^2[Likelihood\ ratio](9, n = 155) = 23.89$ p=0.004, $df^* = 2$, Cramer’s V=0.23). More than one-third of participants with amputation for more than 20 years did not received training (36.5%) while this rate was 4% for participants with 6-10 years of amputation. Around 63% of respondents with less than 6 years of amputation were satisfied with the training while only 37.5% of those with 11-20 years of amputation chose scores 6-10.

A small association existed between *age-at-amputation* groups and the level of satisfaction with the training ($\chi^2[Likelihood\ ratio](9, n = 155) = 19.53$ p=0.021, $df^* = 2$, Cramer’s V=0.2). Around one-third of participants with *age-at-amputation* before 20 years did not received training (32.4%) while this rate was 4.8% for participants with amputation after 59 years. It seems the rate of satisfaction increases with increasing of *age-at-amputation* in the groups. Around 76% of respondents with *age-at-amputation* more than 59 years were satisfied with the training while this rate was 26.5% for those experienced amputation before their 20 years age. Around 26% of respondents with *age-at-amputation* between 20 and 39 years did not receive the training and same percentage were dissatisfied with the training.

A medium association was observed between amputation location and the level of satisfaction with the training ($\chi^2[Likelihood\ ratio](15, n = 155) = 18.13$ p=0.021, $df^* = 2$, Cramer’s V=0.239). As most of participants (around 83% of total respondents) had below-knee and above-knee amputations, the focus will be on their results. In fact, a small number of respondents had knee-disarticulation (n=4), ankle-foot amputation (n=3) or hip-disarticulation (n=2), the percentage of 1 person is huge among them and it makes bias in interpreting of the results. Around 30% of below-knee amputees and only 8.8% of above-knee respondents did not receive the training. Around 32% of above-knee amputees chose scores 0-4 while the rate was 11.3% for below-knee amputees and 52% of them were satisfied with the received training (scores 6-10). Around 40% of bilateral amputees were satisfied and same percentage were dissatisfied with the training.

A significant difference existed between *time since amputation* across satisfaction with training categories (χ^2(3)=14.16, n=155, p=0.003). Mean rank and median were highest for no-training option (102.18, MED=23, n=30). Lowest mean rank and median were for satisfied scores (67.27, MED=5, n=77). The *time since amputation* was significantly different between these two categories (p=0.002). There was no difference between neither two other categories nor with above categories: dissatisfied scores (mean rank=76.18, n=34 and MED=9.5 years), and neutral scores (mean rank=89.64, n=14 and MED=14 years).

A significant difference was observed between *age-at-amputation* across satisfaction with training categories (χ^2(3)=21.98, n=155, p<0.001). Mean rank and median were highest for satisfied scores (93.81, MED=51 years, n=77). Lowest mean rank and median were for no-training option (51.27, MED=22 years, n=30). The *age-at-amputation* was significantly different between these two categories (p<0.001). But, the difference between dissatisfied category (mean rank=69.68, n=34 and MED=35 years) and satisfied group was near to significant (p=0.053). There was no difference between the *age-at-amputation* of neutral group (mean rank=68.75, n=14 and MED=40 years) with above groups.

Important aspects of the prosthetic use

Total score for *important aspects of prosthesis u*se was gained by averaging scores of questions number 81-84 (M± SD=5.83 ±1.99, MED=6.25, N=155). A significant difference (χ^2(1)= 4.11, n=155, p=0.043) was observed between the score of males (mean rank= 72.28, M± SD=5.59 ±2.07, MED=5.875) and females (mean rank=87.31, M± SD=6.2 ±1.83, MED=6. 5). There was also a significant difference between the score of different *age-groups* (χ^2(4)= 13.75, n=155, p=0.008). Mean rank and median were highest for the age-group younger than 40 years (108.28, MED=7, n=18). Lowest mean rank and median were for the age-group older than 69 years (57.86, MED=5.5, n=14). The important parameters score was significantly different between these 2 pairs: age-group younger than 40 years and age-group older than 69 years (p=016), age-group 60-69 years (mean rank=69.44, n=43, MED=5.5) and younger than 40 years (0.02). There was no difference between the score either between two other groups or with above groups: 40-49 years (mean rank=86.63, n=27 and MED=6.5), 50-59 years (mean rank=75.58, n=53 and MED=6).

A significant difference existed between the score of important aspects for participants from different countries (χ^2(4)= 15.135, n=155, p=0.004). Mean rank and median were highest for Iranian participants (98.47, MED=7, n=37). Lowest mean rank and median were for participants from other countries (53.43, MED=4.75, n=15). The important parameters score was significantly different between these 2 pairs: participants from Other Countries and Iranians (p=0.01), Americans (mean rank=60.98, n=20, MED=5.5) and Iranians (p=0.026). There was no difference between the score of either the British participants (mean rank=78.03, n=50, MED=6.25) and Australians (mean rank=76.48, n=33, MED=6), or with above groups.

A significant difference was also observed between the score across *time since amputation* categories (χ^2(3)= 10.34, n=155, p=0.016). Mean rank and median were highest for participants with 11-20 years of amputation (98.38, MED=7, n=16). Lowest mean rank and median were for those with less than 6 years of amputation (64.55, MED=5.375, n=62). But the adjusted significance level for the pairwise tests was not <0.05 for any pairs of groups. However, the p-value was 0.054 in comparing of above groups. There was not difference between neither he groups with amputation 6-10 years (mean rank=81.78, n=25, MED=6.5) and more than 20 years (mean rank=86.57, n=52, MED=6.5), nor with above groups.

A significant difference was seen between the score of *age-at-amputation* groups (χ^2(3)= 16.48, n=155, p=0.001). Mean rank and median were highest for the *age-at-amputation* group younger than 20 years (99.06, MED=7, n=34). Lowest mean rank and median were for the *age-at-amputation* group elder than 59 years (51.29, MED=4.25, n=21). The important parameters score was significantly different between these 2 pairs of *age-at-amputation* groups: younger than 20 and older than 59 years (p=0.001), younger than 20 and 40-59 years (mean rank=72.2, n=61, MED=6) (p=031). There was a near to significant difference (p=0.053) between *age-at-amputation* groups older than 59 and 40-59 years. There was no difference between the score between 20-39 years group (mean rank=83.1, n=39 and MED=6. 5) and above groups.

A significant difference existed between the score of important aspects for participants with different causes of amputation (χ^2(7)= 15.612, n=155, p=0.029). Mean rank and median were highest for congenital condition cause (108, n=8, MED=7.125) and cancer cause (105, MED=6.875, n=10). Lowest mean rank and median were for secondary to diabetes cause (40.35, MED=3.75, n=10). The important parameters score was significantly different between these 2 pairs: secondary to diabetes and cancer (p=0.035), secondary to diabetes and congenital conditions (p=0.041). There was no difference between the score of neither peripheral arterial disease (mean rank=71.38, n=12, MED=5.625), limited function/sever pain (mean rank=88.91, n=11, MED=6.25), severe infection (mean rank=78.68, n=22, MED=6.25), serious trauma/injuries (mean rank=76.51, n=73, MED=6), other causes (mean rank=69.06, n=9, MED=6), nor with above groups.

But, no significant difference was found between the score of participants with different amputation locations (p=0.365).

There was a small negative relation between the score of important parameters –age (rho=-0.257, n=155, p=0.001, two-tailed) with higher scores associated with younger age, in addition to a small positive relation between the score-*time since amputation* (rho=0.243, n=155, p=0.002, two-tailed), with higher scores associated with longer *time since amputation*.

A moderate negative relation was seen between the score and *age-at-amputation* (rho=-0.351, n=155, p<0.001, two-tailed), with higher scores associated with younger *age-at-amputation*.

- **<u>Importance of prosthesis appearance</u>**

For the question related to the importance of prosthesis appearance (question 81), zero score stood for “Not at all” and 10 for “Extremely important”. The higher scores (6-10) for the question were selected by around 60% of the respondents and only 31.4% chosen lower scores (0-4).

A small significant difference existed in age of the *importance of prosthesis appearance* categories (F(2, 150)= 5.09, p=0.007, η^2=0.06). The mean age for the pair of lower scores (M±SD= 58.85±10.2) and higher scores (M±SD= 52.2±12.37) were different. The age of participants who chose neutral scores (M±SD= 56.15±13.4) did not differ significantly from other categories.

A near to significant association was seen between categories of the prosthesis appearance importance and gender ($\chi^2[Pearson](2, n = 153) = 5.68$, p=0.058, $df^* = 1$, Cramer's V=0.193). Around 53% of males expressed the level of importance by choosing scores 6-10, while the rate was 71.2% of females. Same trend was recorded for lower scores with 38.3% of males versus 20.3% of females.
No significant difference was found between the *importance of prosthesis appearance* and *cause of amputation* (p=0.12), or *location of amputation* (p=0.93).

A medium association existed between *participants' age-groups* and importance of appearance categories ($\chi^2[Likelihood\ ratio](8, n = 153) = 15.55$ p=0.049, $df^* = 2$, Cramer's V=0.211). The level of being important decreases with the increase of age.
A moderate association was observed between participants' country and the *importance of prosthesis appearance* categories ($\chi^2[Likelihood\ ratio](8, n = 153) = 29.48$ p<0.001, $df^* = 2$, Cramer's V=0.281). Iranians and Australians gave more importance to appearance of their prosthesis. Only one Iranian (2.8% of Iranian participants) and 24.2% of Australian participants chose lower scores while the rate was 53.3% of participants from Other Countries, 45% for American and British participants. The rate of higher scores also was highest for Iranians (86.1% of them).
A medium association was found between participants' *time since amputation* categories and importance of appearance categories ($\chi^2[Likelihood\ ratio](8, n = 153) = 13.63$ p=0.034, $df^* = 2$, Cramer's V=0.205). The level of importance increases with increase of *time since amputation*.
A significant difference existed between *time since amputation* across the *importance of prosthesis appearance* categories (χ^2(2)=15.064, n=153, p=0.001). Mean rank and median were highest for neutral score (91.69, MED=15, n=13). Lowest mean rank and median were for less important (56.62, MED=4, n=48). The difference was significance between these two pairs of groups: less important and more important levels (mean rank=85.55, n=92, MED=11.5) (p=0.001), less important and neutral levels (p=0.034).
A significant difference was seen between *age-at-amputation* across the *importance of prosthesis appearance* categories (χ^2(2)=23.6, n=153, p<0.001). Mean rank and median were highest for lower score (102.72, MED=53 years, n=48). Lowest mean rank and median were for more important level (64.99, MED=29 years, n=92). The difference was significance between these two pairs of groups: less important and more important levels (p<0.001), less important and neutral (mean rank=67, n=13, MED=35 years) levels (p=0.03).

- **<u>Importance of being able to wear different shoes</u>**

For the question related to the level of *importance for being able to wear different shoes* (question 82), zero score stood for "Not at all" and 10 for "Extremely important" as the lowest and highest level of importance for the respondents. The higher scores (6-10) for the question had been selected by around 66% of the respondents and only 30% had chosen lower scores (0-4).

No significant difference was found in age between the *importance of wearing different shoes* categories (p=0.092): lower scores (M±SD= 57.33±8.83 years, n=45), neutral scores (M±SD= 56.15±13.4, n=7), higher scores (M±SD= 53.07±13.09, n=100).

No significant association was seen between the *importance of wearing different shoes* and: 1- gender (p=0.113) 2- participants' country (p=0.31), 3- *age-at-amputation* groups (p=0.28), 4- *location of amputation* (p=0.443).
A medium association was observed between *participants' age-groups* and *importance of being able to wear different shoes* categories ($\chi^2[Likelihood\,ratio](8, n = 152) = 19.94$, p=0.01, $df^* = 2$, Cramer's V=0.22). The rate of higher level of importance is related to respondents younger than 40 years (94% of respondents in the age-group), the proportion of higher scores remain high among groups but decreases gradually with increase of age to 69.2%, 60.4% and finally 58.5% in age-group 60-69 but in the age group older than 69 increases to 64.3%.
A medium association was seen between participants' *time since amputation categories* and "importance of being able to wear different shoes" ($\chi^2[Likelihood\,ratio](8, n = 152) = 14.84$ p=0.022, $df^* = 2$, Cramer's V=0.209). Around only half of participants with less than 6 years of being amputated chose higher scores while 88% of participants with amputation for 6-10 years selected same category of scores and the rate decreased with increase of the time to 68.6% in respondents with more than 20 years of amputation experience.
A medium association was found between the *cause of amputation* and "importance of being able to wear different shoes" categories ($\chi^2[Likelihood\,ratio](14, n = 152) = 24.63$, p=0.038, $df^* = 2$, Cramer's V=0.258). The rate of higher level of the importance was 100% for cancer group, 87.5% for congenital condition group, 80% for limited function/severe pain group, and 71.4% for severe infection group as *cause of amputation* while 70% of participants with amputation due to diabetes chose lower level of importance.
No significant differences were observed between the *time since amputation* as well as *age-at-amputation* across the "importance of being able to wear different shoes" categories (in turn p=0.18 and p=0.073).

- **<u>Bothersome swelling of the stump</u>**

For the question related to the level of stump swelling bothersomeness (question 83), zero score stood for "Extremely bothersome" and 10 for "Not at all" as the highest and lowest level of importance for the respondents. For being able to calculate the total scores for the important parameter, the scoring inversed by subtracting original score from 10. The lower level of importance for the question had been selected by around 58% of the respondents and only 33% had expressed having more concern about the swelling of the stump.
No significant difference of age was found between the stump swelling bothersomeness categories (p=0.766. No significant association was seen between the importance of stump swelling and: 1- gender (p=0.25), 2- *participants' age-groups* (p=0.93), 3- *time since amputation* categories (p=0.204), 4- *age-at-amputation* groups (p=0.74), 5- *amputation cause* (p=0.95), and 6- amputation location (p=0.45).
A near to significant association was seen between stump swelling importance and participants' country ($\chi^2[Likelihood\,ratio](8, n = 152) = 15.35$ p=0.053, $df^* = 2$, Cramer's V=0.221). The lower importance had been chosen by in turn more by Iranians (72%), Australians (66.7%), American (65%) and participants from Other Countries

(60%) while the rate was 38% for British participants. With an inverse trend 52% of British participants expressed the swelling was more bothersome for them while the rate was 16.7% of Iranians.

No significant differences were observed between the *time since amputation* or *age-at-amputation* across the importance (bothersomeness) of stump swelling categories (in turn p=0.86 and p=0.786).

- **Importance of walk up a steep hill**

For the question related to the level of importance for being able to walk up a steep hill (question 84), zero score stood for “Not at all” and 10 for “Extremely important” as the lowest and highest level of importance for the respondents. The higher scores (6-10) for the question had been selected by around 74% of the respondents and only 15% had chosen lower scores (0-4).

No significant difference of age was seen between the *importance of wearing different shoes* categories (p=0.433). No significant association existed between the *importance of walking up steep hill* and: 1- gender (p=0.35), 2- *participants' age-groups* (p=0.54), 3- participants' country (p=0.48), 4- *time since amputation* categories (p=0.075), 5- *amputation cause* (p=0.134), and 6- amputation location (p=0.42).

A moderate difference was observed across *age-at-amputation* groups of the *importance of walking up a steep hill* categories ($\chi^2[Likelihood\,ratio](6, n = 153) = 20.135$, p=0.003, $df^* = 2$, Cramer's V=0.247). The more important scores had highest rate for the *age-at-amputation* group younger than 20 years (91.2%) and lowest rate for 40-59 years group (56.7%).

A significant difference between *age-at-amputation* across the *importance of walking up a steep hill* categories (χ^2(2)=9.03, n=153, p=0.01). Mean rank and median were highest for neutral score (100.94, MED=53 years, n=17). Lowest mean rank and median were for more important level (70.83, MED=35 years, n=113). The difference was significance between these groups (p=0.027). There was no significant difference between *age-at-amputation* of less important category (mean rank=89.63, n=23, MED=47 years) and above categories.

A significant difference was found between *time since amputation* across the *importance of walking up a steep hill* categories (χ^2(2)=6.71, n=153, p=0.035). Mean rank and median were lowest for neutral score (51.53, MED=4, n=17). Highest mean rank and median were for more important level (81.22, MED=10, n=113). The difference was significance between these pairs (p=0.03). There was no significant difference between *time since amputation* of less important category (mean rank=75.09, n=23, MED=9) and above categories.

Total score of prosthesis evaluation

The average of scores for each respondent given to 42 questions related to bodily sensations (8 questions: 49, 50, 53, 54, 56, 57, 59, 60), prosthesis effects and qualities (14 questions: 34-47), PEQ-M (13 questions: 64-76), *emotional aspects* of prosthesis use (3 questions: 61-63) and satisfaction (4 questions: 77-80) was calculated to give a total score of prosthetic device evaluation (M± SD=5.52 ±2.18, MED=5.9, N=154). The questions related to important parameters of prosthetic use were not considered because the nature of the questions and scoring were opposite to other questions.

No significant difference was found between the score of: 1- genders (p=0.202), 2- *age-groups* (p=0.21), 3- *age-at-amputation* groups (p=0.38), 4- *amputation causes* (p=0.07), and 5- amputation location (p=0.122).

A significant difference was observed between the total score of participants from different countries (χ^2(4)= 25.47, n=154, p<0.001). Mean rank and median were highest for Iranian participants (99.64, MED=6.75, n=37). Lowest mean rank and median were for British participants (53.42, MED=4.69, n=49). The total score was significantly different between these 2 pairs: British participants and Iranians (p<0.001), participants from Other Countries (mean rank=93.27, n=15, MED=6.62) and British participants (p=0.025). There was no difference between the score of either Australians (mean rank=80.86, n=33, MED=6.05) and Americans (mean rank=78.18, n=20, MED=5.885) or with above groups.

A significant difference was found between the score of *time since amputation* categories (χ^2(3)= 7.82, n=154, p=0.05). But the adjusted significance level for the pairwise tests was not <0.05 for any pairs of groups. Mean rank and median were highest for participants with more than 20 years of amputation (86.29, MED=6.345, n=52) and participants with less than 6 years of amputation (80.42, MED=5.91, n=61). Lowest mean rank and median were for the group with 6-10 years of amputation (mean rank=57.72, n=25, MED=4.97) and participants with 11-20 years of amputation (mean rank=68.72, n=16 and MED=4.78).

There was no relation between the total score -age of participants (p=0.352), between *time since amputation* -this score (p=0.376) and between the score- *age-at-amputation* (p=0.998).

A near to significant difference was observed (χ^2(1)= 3.82, n=154, p=0.051) between the score of participants with phantom limb (mean rank=73.97, n=123, MED=5.62) and those without it (Mean rank=91.5, n=31, MED=6.44). The total score of participants with phantom pain (mean rank=65.83, n=105, MED=5.02) was significantly lower than participants without it (χ^2 (1)= 22.58, n=154, p<0.001) (mean rank=102.5, n=49, MED=7.02). Similarly, the total score of participants with stump pain (mean rank=66.99, n=116, MED=5.4) significantly (χ^2 (1)= 22.85, n=152, p<0.001) was lower than participants without it (mean rank=107.14, n=36, MED=7.36). A significant difference was seen (χ^2(1)= 6.77, n=154, p=0.009) between the score of participants with intact-side pain (mean rank=62.62, n=98, MED=5.82) and without it (mean rank=82.26, n=37, MED=6.64).

A significant difference was found between the “total prosthesis evaluation” score of participants with/without worry about falling (χ^2(1)= 14.44, n=154, p<0.001). Mean rank and median for worried participants (68.86, MED=5.49, n=110) were lower than participants without the worry (99.09, MED=6.57, n=44). A significant difference was seen between the “total prosthesis evaluation” score of faller/non-faller participants (χ^2(1)= 11.39, n=154, p=0.001). Mean rank and median for faller participants (68.07, MED=5.26, n=96) were lower than non-faller participants (93.1, MED=6.45, n=58). A significant difference existed between the “total prosthesis evaluation” score of aided/unaided participants (χ^2(1)= 15.26, n=154, p<0.001). Mean rank and median for aided participants (65.66, MED=4, n=90.98) were lower than unaided participants (94.25, MED=6.53, n=64).

Results related to lower back pain experience

A small association was found between lower back pain (LBP) and gender ($\chi^2[Pearson](1, n = 155) = 10.595$, p=0.001, $df^* = 1$, Phi=-0.261). Ninety percent of females (53 persons) had LBP while the rate was 66.7% for males (64 persons).

A small association was seen between LBP and *amputation cause* categories ($\chi^2[Likelihood\, ratio](7, n = 155) = 14.256$, p=0.047, $df^* = 1$, Cramer's V=0.268). All amputees with amputation due to peripheral arterial diseases, 91% of participants with *amputation cause* of limited function due to deformity/severe pain, 90% of those with amputation secondary to diabetes, 87.5% of those with congenital conditions, 72.6% of participants with amputation due to serious trauma/injuries, 72% of those with amputation due to cancer, 66.7% of participants with Other causes of amputation and 59.1% of those with amputation due to severe infection expressed having LBP.

No significant association was observed between LBP and 1- *age-groups (*p=0.63), 2- participants' country (p=0.096), 3- *time since amputation* categories (p=0.5), 4- *age-at-amputation* groups (p=0.549), 5- amputation location categories (p=0.342) was observed.

There was no significant difference (p=0.725) in age for participants with LBP (M±SD=54.85±11.98) and without it (M±SD=54.05±12.76).

No significant differences was found between distribution of the *time since amputation* and *age-at-amputation* among participants with or without LBP (in turn p=0.72 and p=0.396).

A small association was seen between LBP and phantom limb sensation ($\chi^2[Pearson](1, n = 155) = 8.92$, p=0.003, $df^* = 1$, Phi=-0.24). Eighty-one percent of participants with phantom limb sensation had LBP while almost equal percentage of participants without the sensation were with and without LBP.

A small association also existed between LBP and phantom pain ($\chi^2[Pearson](1, n = 155) = 4.01$, p=0.045, $df^* = 1$, Phi=-0.16). Eighty percent of participants with phantom pain and of 65% of participants without it had LBP.

A moderate association was observed between LBP and stump pain ($\chi^2[Pearson](1, n = 155) = 20.99$, p<0.001, $df^* = 1$, Phi=-0.37). Eighty-five percent of participants with stump pain had LBP while almost equal percentage of participants without LBP were with and without stump pain.

A small association was found between LBP and intact-side pain ($\chi^2[Pearson](1, n = 136) = 10.86$, p=0.001, $df^* = 1$, Phi=-0.28). Eighty-two percent of participants with intact-side pain had LBP while almost equal percentage of participants without the sensation were with/ without LBP.

There was no significant association between LBP and frequency of prosthesis use (p=0.308).

A significant difference was seen between the PEQ-M score of participants with/without LBP (χ^2(1)= 11.96, n=153, p=0.001). Mean rank and median for participants with LBP (69.88, MED=5.62, M±SD=5.37±2.35, n=115) were lower than participants without the pain (98.55, MED=7.345, M±SD=6.86±2.11, n=38).

A significant difference was observed between the "total prosthesis evaluation" score of participants with/without LBP (χ^2(1)= 14.148, n=154, p<0.001). Mean rank and median for participants with LBP (69.76, MED=5.47, M±SD=5.15±2.1, n=116) were lower than participants without LBP (101.12, MED=7.08, M±SD=6.67±2.05, n=38).

Level of being worried about falling

One Hundred-ten participants recorded the level of their *worry about falling*. The level of worry was presented by 0-10 scoring choices in which 0 stands for “Extremely worried and it severely limits the things I can do” and 10 stands for “Only a little worried and it does not limit my activities”. As it is seen in Figure 6 most of respondents indicated some degree of worry about falling.

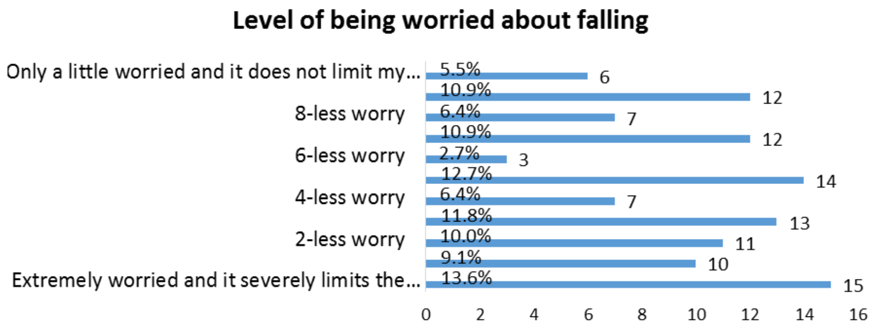


Figure 6 Level of being worried about falling

By grouping into three categories, 56 participants (50.91% of worried respondents) showed the highest level of worry (scores 0-4) vs 40 participants (36.36% of worried respondents) for a lower level of worry (scores 6-10). Fourteen persons (12.73% of worried respondents) chose the neutral score. There was no significant association between level of being worried and the frequency of prosthetic use (p=0.31). Around 70% of participants with score 0-4, used their prosthesis every day, most/all the day.

Oswestry Disability Questionnaire

“Oswestry Disability Index (ODI)” questionnaire assesses the negative effect of LBP on routine activities performance and thus might be consider as a tool to evaluate functionality of individuals with LBP. ODI has 10 sections to evaluate intensity of LBP and its effect on performing nine routine activities including: personal care (Q108), ability to lift objects (Q109), walking (Q110), sitting (Q111), standing (Q112), sleeping (Q113), sex life (Q114), social life (Q115) and ability to travel (Q116). The respondents were allowed to leave question number 114 without answering and among total 117 persons with LBP, almost 30% of respondents (35 persons) chose not answering this question. Then due to the high rate of missed scores, the result related to it is not presented here. The intensity of the pain was very mild or moderate for most of the respondents with LBP (69% of total respondent and 92% of participants with LBP). Among 116 respondents with LBP, 55% were able to look after themselves (including washing, dressing, etc.) without the feeling of pain increasing and only 3% needed help due to increase in pain for this part of routine life. LBP had a more limiting effect on the ability to lift objects. Only 19% of respondents with LBP expressed that they can lift even heavy objects without pain raise and 3% were not able to lift/carry anything at all. Only 19% of the respondents reported ability of walking any distance in spite of the LBP and 1% indicated that most of the time they were in bed. Most of the respondents with LBP were able to sit in any chair or their favourite chair without extra pain (in order 38% and 21%) while 27%, 11%, and 3% indicated that they could sit for less than 1 hour, less than 30 minutes and less than 10 minutes respectively. Standing was associated with pain increase in most of the respondents with low back pain. Only 7% of the respondent could stand as long as they wish without pain raise.LBP occasionally disturbed most of the respondents sleeping or had no effect on it (52% vs 19% of respondents). Although 2% were not able to sleep due to the pain. LBP did not change 50% of respondents' social life even they experience extra pain (24%). However, more than 30% of respondent felt the pain has restricted their social life. Most the respondents could travel anywhere without or with extra pain (22% vs 49%) whilst almost 10% of them have limited their journeys to those with less than 1-hour traveling time.

To gain Oswestry score, the first option in each section was allocated a score of 0. A score of 5 was given to last option and 1-4 score was respectively given for the other options. After that, the sum of scores of all sections for each respondent was divided by 5 multiplied by the number of answered questions. The resulting number was multiplied by 100 to have a percentage. Table 1 demonstrates the disability level according to the ODI score (Fairbank and Pynsent, 2000). It means higher ODI scores are indicator of higher levels of disability due to LBP.

Table 1 Interpretation of ODI score (Fairbank and Pynsent, 2000)

Oswestry score	Level of disability due to LBP	Brief description
0-20%	Minimal	The patient can cope with most living activities. Usually, no treatment is indicated apart from advice on lifting sitting and exercise
21-40%	Moderate	The patient experiences more pain and difficulty with sitting, lifting and standing. Travel and social life are more difficult and they may be disabled from work. Personal care, sexual activity, and sleeping are not grossly affected and the patient can usually be managed by conservative means.
41-60%	Severe	Pain remains the main problem in this group but activities of daily living are affected. These patients require a detailed investigation
61-80%	Crippled	Back pain impinges on all aspects of the patient's life. Positive intervention is required.
81-100%		These patients are either bed-bound or exaggerating their symptoms

The average of total score was 30.21 (±17.36, MED=27.45, N=116, Min-Max=0-80). Among 116 participants who replied to ODI questions, 42 persons (36.2% of respondents) were in the minimal disability category, 40 persons (34.5% of respondents) in the moderate disability category, 28 persons (24.1% of respondents) in the severe disability category and 6 persons (5%) in the crippled category.

Relation between ODI score and general variables

No difference was seen between ODI score of: 1- genders (p=0.56), 2- *age-groups* (p=0.33), 3- *time since amputation* categories (p=0.77), 4- *age-at-amputation* groups (p=0.30), 5- *amputation cause* groups (p=0.087), and 6- amputation location (p=0.6).

There was no significant relation between ODI score- age (p=0.216), the score- *time since amputation* (p=0.397), nor a relation between the score and *age-at-amputation* (p=0.955).

A moderate association was found between ODI score's categories and gender ($\chi^2[Likelihood\ ratio](3, n = 116) = 11.28$, p=0.01, $df^* = 1$, Cramer's V=0.306). Around 45% of female participants with LBP took place in minimal disability category while around 48% of males had a moderate disability according to their ODI scores.

No association was seen between ODI score's categories and: 1- *age-groups* (p=0.242), 2- *time since amputation* categories (p=0.557), 3- *age-at-amputation* groups (p=0.135), 4- amputation location (p=0.426).

The association between ODI score's categories and *amputation cause* was not significant (p=0.056). No significant differences was found between the distribution of the *time since amputation (*p=0.17*)* as well as *age-at-amputation* across the ODI score's categories (p=0.226).

ODI score and frequency of prosthesis use

No significant difference was seen between ODI score across prosthetic use frequencies (p=0.192). However not statistically significant but, it seems with decreasing of use of prosthesis the score increases. A strong association existed between ODI score's categories and frequency of prosthesis use ($\chi^2[Likelihood\ ratio](21, n = 116) = 32.71$ p=0.05, $df^* = 3,$ Cramer's V=0.315). It is due to high frequent of everyday use of prosthesis. Sixty seven to 81 percent of participants in each ODI score's category (in turn, for crippled and minimal disability categories), used their prosthesis every day, most /whole of day.

ODI score and intact limb bodily sensations

No significant difference (p=0.06) was observed in score of the participant with intact limb pain (mean rank=53.23, M±SD=31.1±17.92, MED=30, n=80) and without it (mean rank=39.58, M±SD=22.92±14.38, MED=21, n=20). Participants with intact limb pain had higher ODI score which is associated with increasing disability level.
No association was seen between the presence of intact limb pain and ODI score's categories (p=0.18).

There was no significant difference (p=0.866) between distribution of the ODI score among participants with phantom limb sensation (mean rank=59.44, MED=30, n=99) and without it (mean rank=53.03, MED=22, n=17).
No association was found between ABC score's categories and presence of phantom limb (p=0.959). There was a significant difference between the distribution of the ODI score among participants with phantom pain and without it (χ^2(1)= 7.805, n=116, p=0.005). Mean rank and median were lower for participants without phantom pain (44.38, MED=20, n=32) and higher for participants with the pain (63.88, MED=31, n=84). No association was observed between ODI score's categories and presence of phantom pain (p=0.078).
No significant difference was found (p=0.63) between the distribution of the ODI score among participants with stump-pain (mean rank= 60.41, MED=30.55, n=98) and without it (mean rank= 44.12, MED=20, n=17). No association was seen between ODI score's categories and presence of stump- pain (p=0.263).

ODI score and QOL score, score of being satisfied with the prosthesis, being frustrated with the prosthesis

There was a strong significant negative relation between QOL score and ODI score (rho=-0.58, n=116, p<0.001, two-tailed). A moderate negative relation existed between being satisfied with the prosthesis and ODI score (rho=-0.38, n=114, p<0.001, two-tailed). The negative relation in above compared pairs means that high level of each score is associated with low levels of another one.
A moderate positive relation was observed between the level of being frustrated with the prosthesis and ODI score (rho=0.42, n=114, p<0.001, two-tailed) which means lower level of frustration was associated with lower scores of disability due to LBP.

ODI score and PEQ-M score

There was a strong significant negative relation between ODI score and PEQ-M score (rho=-0.668, n=114, p<0.001, two-tailed) with high levels of each score associated with low levels of another score.

A significant difference was seen between the distribution of PEQ-M score across ODI score's categories (χ^2(3)= 42.484, n=114, MED=5.58, p<0.001). Mean rank and median were highest for minimal disability category (80.33, MED=7.23, n=41). Lowest mean rank and median was for crippled category (25.8, MED=2.54, n=5). The difference between PEQ-M score of these 4 pairs of ODI score categories was statistically significant: severe disability (mean rank=30.79, MED=3.345, n=28) and minimal disability (p<0.001), crippled and minimal disability (p=0.003), moderate disability (mean rank=56.76, MED=5.73, n=40) and minimal disability (p=0.008), severe disability and moderate disability (p=0.009). There was not difference between crippled and moderate disability (p=0.29) nor crippled and severe disability (p=1).

ODI score and total score of prosthesis evaluation

There was a strong significant negative relation between ODI score and "total score of prosthesis evaluation" (rho=-0.604, n=115, p<0.001, two-tailed) with high levels of each score associated with low levels of another score.
A significant difference was found between the distribution of "total score of prosthesis evaluation" score across ODI score's categories which (χ^2 (3)= 36.167, n=115, MED=5.39, p<0.001). Mean rank and median were highest for minimal disability category (76.85, MED=6.415, n=42). Lowest mean rank and median was for crippled category (22, MED=1.49, n=5). The difference between "total score of prosthesis evaluation" for these 3 pairs of ODI score categories was statistically significant: severe disability (mean rank=32.29, MED=3.32, n=28) and minimal disability (p<0.001), crippled and minimal disability (p=0.003), moderate disability (mean rank=60.71, MED=5.74, n=40) and severe disability (p=0.003). There was not difference between crippled and moderate disability (p=0.086), moderate disability and minimal disability (p=0.17) nor crippled and severe disability (p=1).

ODI score and falling experience

No significant difference (p=0.4) existed between the distribution of the ODI score among faller participants M± and non-fallers M±. However, the score of non-fallers is a little smaller. No significant association was seen between experience of falling and ODI score's categories (p=0.718).

ODI score and being worried about falling

A significant difference was observed between the distribution of ODI score among participants with worries about falling (mean rank=65.76, M±SD=33.858±17.02, n=88, MED=32) and without it (mean rank=35.68, M±SD=18.725±13.04, n=28, MED=13.8) (χ^2(1)= 40.76, n=116, MED=27.45, p<0.001). Larger ODI scores were associated with worries about falling.
A significant difference existed between the distribution of score among different levels of being *worried about falling* (χ^2(2)= 37.086, n=110, p<0.001). Mean rank and median were lowest for scores 6-10 means less worried participants (31.64, MED=23, n=28). Highest mean rank and median was for scores 0-4 means more worried participants (53.33, MED=42.2, n=49). The ODI score was statistically different between these two categories (p=0.001). There was no significant difference between the score of neutral category (mean rank= 37.91, MED=24, n=11) and above categories.
There was a moderate association between being *worried about falling* and ODI score's categories ($\chi^2[Likelihood\, ratio](3, n = 116) = 13.001,$ p=0.005, $df^* = 1,$ Cramer's V=0.305). The number of worried participants grows with worsening level of disability

due to LBP. All participants in the crippled category and 93% of those in severe disability category were worried about falling.

A moderate association was found between worry levels and ODI score's categories ($\chi^2[Likelihood\,ratio](6, n = 88) = 17.42,$ p=0.008, $df^* = 2,$ Cramer's V=0.291). The percentage of very worried participants grows with worsening level of disability due to LBP. More than 80% of participants in sever disability and crippled categories were very worried about falling.

ODI score and unaided walking

A significant difference was seen between the distribution of the ODI score among participants walking with aid (χ^2(1)= 6.12, n=116, MED=27.45, p=0.013). Mean rank and median of ODI score were higher for participants with aids (64.32, MED=31.55, n=74) and lower for participants without it (48.25, MED=24, n=42).

A moderate association was observed between unaided/aided walking and ODI score categories ($\chi^2[Likelihood\,ratio](3, n = 116) = 16.86,$ p=0.001, $df^* = 1,$ Cramer's V=0.349). Worst levels of disability due to LBP was associated with the highest percentage of participants using walking-aids (crippled category with 100% and sever disability with 86% of their participants with aid walking). Interestingly, the highest rate of unaided participants took place in the moderate disability level not the minimal disability.

ODI score and ABC score

A strong significant negative relation existed between ODI score and ABC score (rho=-0.627, n=116, p<0.001, two-tailed) with high levels of each score associated with low levels of another score. It means with worsening of disability due to LBP (larger amounts for ODI score) the functionality of the respondents decreases (smaller amounts for ABC score).

A strong association also was observed between ODI score's categories and ABC score's categories ($\chi^2[Likelihood\,ratio](6, n = 116) = 42.94,$ p<0.001, $df^* = 2,$ Cramer's V =0.394). Around 46% of participants with LBP, had a low level of function as well. The number of participants in low level of functioning of ABC categories increased with worsening of disability due to LBP. In contrast, the number of participants in moderate functioning level decrease with worse disability levels.

A moderate association was seen between ODI score's categories and being at risk of falling (ABC score<67) ($\chi^2[Likelihood\,ratio](3, n = 116) = 26.49,$ p<0.001, $df^* = 1,$ Cramer's V =0.431). Percentage of participants at risk of falling increase with worsening of disability level due to LBP.

There was a significant difference between ODI score of ABC scale categories (χ^2(2)= 39.51, n=116, p<0.001). Mean rank and median were highest for the low level of functioning category (79.12, MED=44.4, n=53). Lowest mean rank and median was for the high level of functioning category (30.42, MED=15.6, n=19). The difference between ODI score of these pairs of ABC score categories was statistically significant at p<0.001: high level of functioning and low level of functioning, Moderate level of functioning (mean rank=45.78, MED=21, n=44) and low level of functioning, There was no significant difference between high level of functioning and moderate level of functioning (p=0.29).

A significant difference between the distribution of ODI score among participants at risk of falling (mean rank=68.75, M±SD=35.41±17.18, n=80, MED=34) and those with ABC score>67 (mean rank=35.72, M±SD=18.63±11.13, n=36, MED=17) (χ^2(1)= 23.97, n=116, MED=27.45, p<0.001). Higher values of ODI score which indicate the worst level of disability due to LBP, were associated with ABC scores <67 (an indicator of being at risk of falling).

Summary of findings

General parameters

LLAs at the age range of 19-83 years (M±SD=54.7 ±12.1, MED=55 years) participated in this study. The *time since amputation* length varied from 6 months to 70 years (M±SD=16.74 ±17.42, MED= 8.38 years). *Age-at-amputation* had a broad range (0-72.2 years) and its mean was 37.93 years (±19.47 with MED=41.3 years). A bigger portion of participants were male, aged 40-59 years, were below-knee amputees, had experience of amputation less than 5 years, with amputation due to injuries (including war-related causes), and with an amputation age of 40-59 years. The highest percentage of female participants was also in 40-59 years age group.

Male participants (62% of total respondents) had passed the longer time since amputation (with a MED= 11.5 years versus MED= 5 years for females). The majority of female respondents were below-knee amputees (59%) whilst the bigger portion of males were above-knee amputee (49%).

The eldest age-groups also had the oldest age-at-amputation. Below-knee amputees had older age-at-amputation and above-knee amputees had experienced amputation at a younger age.

Youngest age-at-amputation was related to congenital conditions and serious trauma/injuries while eldest age-at-amputation was due to peripheral arterial disease and diabetes. Participants with youngest age-at-amputation had the longest time since amputation.

Bodily sensations

The mean of total bodily sensation score (for both legs) was 5.06 out of 10 (±2.39, MED=4.94, N=146) where 10 is the best or most favourable score. The prevalence of amputated-side sensations was high (79.4% for phantom limb, 69.4% for phantom pain and 76.5% for stump pain). The mean of the amputated-side bodily sensation score was less than 5 out of 10 (4.97 ±2.46, n= 139, MED=4.83). The prevalence of intact limb pain was 67.2% among unilateral amputees. The reported location of pain for participants with intact limb pain (92 persons) was for 55.4% in the knee joint, 46.7% in hip joint, 35.9% in the foot, 25% in ankle joint, 14.1% in calf/shin, and 1.1% in the thigh. The mean of the intact limb bodily sensation score was 5.1 out of 10 (±2.65, n= 98, MED=5).

Almost all female participants reported phantom limb sensation (91.5% versus 73% of males). All participants with vascular causes of amputation (peripheral arterial disease and diabetes) had phantom limb sensation and three-fifths of participants with amputation because of cancer had recorded an incidence of the sensation “only once-twice” during last 4 weeks. The rate of phantom limb sensation was lower among participants with longer time since amputation. According to association of time since amputation and age-at-amputation in this study, there was an expectation that the youngest age-at-amputation group and the longest time since amputation would have the least rate of the phantom limb. This was observed, however, the intensity of the sensation was worst for participants with age-at-amputation of 20-39 years and was mildest for participants with amputation after 59 years of age.

The rate of phantom limb sensation was less than the rate of phantom pain but the trend of its significant characteristics were similar. The rate of phantom pain was higher for females (78% versus 62.5% for males). Participants with longer time since amputation had less frequency of phantom pain sensation. Due to an inverse association of age-at-amputation and time since amputation in this study (as was expected), the presence of phantom pain was lower among participants who had their amputation at the youngest ages.

The prevalence of stump pain sensation was higher among females (88% versus 69.5% of males). All participants with amputation due to peripheral arterial diseases experienced stump pain and 42% of them expressed that they had the pain “all the time”. Stump pain was worse in participants whose amputation was the result of congenital conditions or peripheral arterial

The bodily sensation score of amputated-side (including phantom limb, phantom pain, and stump pain) was worst for participants in 40-59 years age-at-amputation group had and was best for over 59 years age-at-amputation group. It shows that, in spite of higher rate of the sensations presence among participants with elder age-at-amputation, the intensity and bothersomeness is less for these participants. In gerneal, the bigger portion of female participants reported worst intensity and bothersomeness of intact limb pain.

- **Prosthesis quality and effects**

The mean of “the *prosthetic quality and effects*” score was 5.94 out of 10 (±2.1, N=151, MED=6.29). Participants with amputation less than 6 years had the highest scores (MED=6.64) whilst those with 6-10 years of amputation had chosen the lowest score (MED=4.75). Similarly, the score of participants in the eldest *age-at-amputation* group was highest (MED=7.4) and the lowest score was for participants in the 40-59 *age-at-amputation* group (MED=6.07).

- **Self-efficiency aspects**

The mean score for emotional aspects of prosthesis use was 4.9 out of 10 (±3.115, N=153, MED=4.67). The score was lowest for bilateral amputees. There was a positive correlation of the mean score with time since amputation indicating that those who had longest history of amputation had fewer emotional issues with their prosthesis

Females were more frustrated. Most of the participants with amputation due to peripheral arterial disease had most frequent frustration while participants with amputation because of diabetes and other causes had the least frequent frustration. Participants with longest time since amputation had least frequent frustration feeling. It is thought-provoking that the majority of participants in age-group older than 69 had the least feeling of being hindered socially by the prosthesis. In contrast, those in the age-group of 40-49 years felt more hindered socially by the prosthesis. Shorter time since amputation was associated with a worst score of “feeling to be socially hindered by prosthesis”.

The mean of the total score for satisfaction aspects was 5.9 out of 10 as highest level of satisfaction (±2.72, N=154, MED=6.5).

Participants with more than 20 years of amputation experience indicated lower rates of training whilst participants with less than 6 years of amputation were more likely to indicate that they had training. As there was a negative relation between *age-at-amputation* and time since amputation, the number of participants who received the training was lower for those with experience of amputation before 20 years age. This

suggests that training of participants has improved in recent years and more attention has been given to the training of amputees in older ages.
Almost all above-knee and bilateral amputees had received the walking training, while 30% of below-knee amputees expressed had no-training but most of them were satisfied with the received training.

- **Important parameters related to prosthesis**

The mean of the total score for important aspects related to prosthesis was 5.83 (±1.99, n=155, MED=6.25) out of 10.
The results showed the selected items were more important for females, younger participants, participants with younger *age-at-amputation* participants with cancer and congenital condition as causes of amputations and those with a longer *time since amputation*. The appearance of the prosthesis was more important for younger participants, those with longer *time since amputation* and younger *age-at-amputation* suggesting perhaps that those who lose their limb at a young age continue to have higher expectations at an older age than those who become amputees at the older age.
Being able to wear different shoes was more important for younger participants, those with longer *time since amputation* and amputees due to congenital condition and cancer. Participants with younger *age-at-amputation* and longer *time since amputation* gave more importance to be able to walk steep hill up.

Total score of prosthesis evaluation

The mean of the total score for the evaluation prosthesis use was 5.52 (±2.18, N=154, MED=5.9) out of 10. Scores of participants with more than 20 years of amputation were the highest. The prosthesis evaluation total score was lower for participants with worries about falling, the experience of falling, using aids to walk, and participants with pain feeling related to amputated and intact sides.

LBP and ODI score

LBP prevalence was high in this study (75% of total participants and 90% of females), with the majority of participants describing the intensity of the pain as mild or moderate. The ODI score showed the level of disability resulting from LBP was minimal or moderate in 70% of respondents with pain. A point of interest to note was that as the ODI score increased, the score of Activities-specific Balance Confidence (ABC) decreased. That is; as participants experienced a higher level of disability due to LBP, they had a lower level of functioning due to poor balance confidence. The same trend was seen in the relation of ODI score and the total score of prosthesis evaluation as well as the score related to the ability of amputees to move around with their prosthesis. In fact, respondents with lower scores for both parameters had a higher score of ODI scale which shows increasing of disability level due to LBP. In addition, there was a significant association between LBP and bodily sensations including phantom limb, phantom pain, stump pain, and intact-side pain. As the relation between ABC score and ODI score revealed, it was not surprising to observe a significant association between the presence of LBP and being *worried about falling* as well as having fall experience during last 12 months, being at risk of future falling (ABC score<67), and using aids to walk.
In addition, higher ODI scores (means a higher level of disability) were associated with smaller scores of QOL, satisfaction with the prosthesis and less feeling of frustrated with

prosthesis in addition to being worried about falling, having fall experience during last 12 months, being at risk of future falling, and using aids to walk.

Differences between participants from various countries

Investigation of the difference between participants according to their place of living was not a fundamental aim of this study but several statistically significant results of the survey were related to the country of residence of the participants. In fact, the thesis is related to a PhD student in a British University and it was expected to recruit British amputee volunteers for biomechanical tests of this study, but the prospected cooperative role of a prosthetic manufacture company to provide amputee subjects did not achieved which challenged completing the study. After that, it got possible to recruit TF amputee participants in Iran, thus the biomechanical tests of the thesis (chapter 4 and 5) were conducted in both Leeds and Tehran with British/Iranian participants. On the other hand, the survey's variety of participants' country of residence provided the opportunity to see the LLA's problems are very broad and common among different countries, in spite of the probable differences of their prosthesis advancement and structure of service providers. Accordingly, the related significant results are mentioned in this section.

Iranian participants had lowest mean age (47.43±12.31 years) and British participants were oldest (59.02±10.51 years). Iranians had experienced the lower limb loss at a younger age (20±12.34 years) while Australians had oldest amputation age (51±15.11 years). Longest *time since amputation* was related to Iranian participants (30±13.52) and shortest time was related to Americans (2.5±8.44). Only one female participant was from Iran while 60% of Americans were females.

Cause-of-amputation for 75% of Iranians was serious trauma/injury while it was the *cause of amputation* for only 20% of American participants, 33% of Australians and 44% of British participants. Forty percent of Americans were amputated due to diabetes and 40% due to severe infection. These are in relative agreement with overall trend of amputation in developing countries with majority of amputation due to trauma/injuries and in younger population (Sabzi Sarvestani and Taheri Azam, 2013; Rouhani and Mohajerzadeh, 2013; Soomro et al., 2013; Pooja and Sangeeta, 2013; Agu and Ojiaku, 2016) and developed countries with a big portion of amputation due to vascular deficiencies and in elder age (Stewart, C P U, 2008; Lazzarini, Peter A. et al., 2012; Dillingham et al., 2002).

The total bodily sensation score was lowest for participants from the UK and the USA (in turn, 4.1±1.96 and 4.52±2.06), while the mean score was highest for Iranians and Australians (in turn, 6.2±2.34 and 5.63±2.67).

Fewer Iranians reported experiencing phantom limb sensation "all the time" (2 persons, 6.1% of the group) and a large portion of them did not have the sensation at all (17 persons, 53% of the group), whilst around one-third of British participants had chosen "all the time" as the frequency of the sensation.

Around three-fifths of Iranians (the lowest rate) and all Americans (highest rate) recorded presence of the phantom limb sensation. This is in agreement with results related to *time since amputation which* showed an association of longer the time with a lower rate of the sensation. Americans had the shortest *time since amputation* while the time was longest for Iranians.

Iranians and Australians had the lowest rate of suffering from phantom pain (48.6% and 54.5%) while the rate was 86% and 80% for British and American participants.

The bodily sensation score of amputated-side (including phantom limb, phantom pain, and stump pain) was lowest for British participants (4.15±2.2) and highest for Iranians (6.08±2.5).

The intact limb pain was less frequent for participants from Other Countries, Iranians, and Australians. The bodily sensation score of intact limb was smallest for Americans (3.6±2.3) and largest for Iranians (6.43±2.3).

Overall satisfaction score was highest for participants from Other Countries (MED=8.5 out of 10) and lowest for British participants (MED= 4.75 out of 10). The *feeling of being hindered* by prosthesis was expressed more by British participants (63%) and less by participants from Other Countries (27%). Iranians were less dissatisfied with their prosthesis (16.7%) while British participants had lowest scores and more than half of them chose the worst level of “satisfaction about prosthesis” (54%). The best scores were picked by more participants from the USA (75%).

British participants had most problems related to the features associated with prosthesis use (Lowest scores, MED=4.79 out of 10) and it was the least problematic for Iranians (MED=6.85 out of 10). However even for Iranians the scores is not ideal.

British participants had the lowest score of PEQ-M (MED=4.8 out of 10) and *emotional aspects* of using the prosthesis (MED=3 out of 10) while Iranians took opposite position (in turn MED=6.85 and MED=7.33). Although, the PEQ-M score of them is far from 10 and is not ideal.

The majority of British participants (76.6%) most frequently felt frustration in the high-intensity level while most of the Iranians had chosen “never frustrated” or mild scores (67%) to show the *frustration frequency*.

A considerable portion of British participants (59%) were not “satisfied with walking” and had chosen lower scores which were in contrast to Iranians with 66.7% satisfied participants..

Participants from Other Countries were less un-happy with QOL (13.3%) while around 42% of British participants were not happy with their QOL (scores 0-4).

The score of selected important items related to prosthesis showed these items were more important for Iranians (MED=7) and less for participants from Other Countries (4.75). Majority of Iranians (86%) gave the highest level of importance to the appearance of the prosthesis while it was important just for half of the British and American participants.

Aided-walking rate was least among Iranians (30%) and highest for British participants (76%).

Total score of prosthesis evaluation and the ABC score were lowest for British (in turn MED= 4.69 and MED=40.6) and highest for Iranians (in turn MED=6.75 and MED=68.75) and participants from other Countries (in turn MED=6.6 and MED=65).

A large portion of Australian participants (58%) had a moderate level of functioning and majority of British participants (64%) took place in a low level of functioning according to their ABC score.

As the above results showed, for several parameters, the results of participants from Iran indicate that they were in a better condition in contrast British amputees (and sometimes Americans) who were generally in the worst state. It is important to remember, as was mentioned in the methodology section, that the recruitment of Iranian participants (in spite of consistency of the results about their age and cause of amputation with the literature) was different from others and most of them participated due to direct face to face or verbal interaction. This could be one of the reasons for significant differences as the participants may be less willing to show perceived weakness or were less from the groups with problems and wish to share. It is worthy to note, (Friel et al., 2005) in their study related to LBP found that recruitment method has effects on results and participants referred by prosthetists had reported better responses than those who participated in their study through support groups. On the other hand, many volunteers participate in various surveys to announce their negative opinion/experiences (Brüggen et al., 2011) or to assist problems prevention/solving (Soule et al., 2016). It is possible these reasons inspired specifically the participants from UK more and accordingly most of those with complains contributed in this survey. In addition, the survey is a self-reported tool and it is possible people from various parts of the world have different perceptions and criteria about same conceptions such as QOL or satisfaction. Although, by considering the results related to satisfaction and frustration scores as a reflection of well-being, scores of the British participants in this survey were lower than national survey averages (Tinkler, 2015). Moreover, shown above, overall condition of British LLA participants in this survey seems lower than other amputees which is a matter of serious concern and needs more precise investigation for improving their situation.

Appendix E

Iran's Tests Ethics Approval

مرکز تحقیقات فناوری های توان بخشی عصبی هوشمند جواد موفقیان

Djavad Mowafaghian Research Center for Intelligent NeuroRehabilitation Technologies

Dr Neil Messenger
School of Biomedical Sciences
University of Leeds
LS2 9JT

9 October 2016

Subject: Approval of the study "Balance and lower back pain in lower limb amputees" by the Ethics Committee

Dear Dr Messenger

I am glad to inform you that the above research application has been reviewed by the Ethics Committee of the Djavad Mowafaghian Research Center for Intelligent Neuro-Rehabilitation Technologies. The committee considered sample informed consent forms for non-amputee and amputee subjects in addition to protocol of the tests in Persian Language which are translation of the approved English version by the Faculty of Biological Sciences Research Ethics Committee in University of Leeds. The committee approved the trials to be conducted in the presented form in the Gait Lab of the Djavad Mowafaghian Research Center for Intelligent Neuro-Rehabilitation Technologies.

Yours sincerely

Farzam Farahmand

Director

تهران، خیابان انقلاب، خیابان خارک، پلاک ۱۱، کد پستی ۱۳۸۱۳-۱۱۳۳۹. تلفن:۶۶۷۱۶۱۰۰، نمابر: ۶۶۷۱۶۱۰۱

No 11, Khark St, Enghelab St, 11339-13813 Tehran, Iran. Tel: +98(21) 66716100, Fax: +98(21) 66716101

Appendix F

Feedback about Selected insoles

1- Orthosole – medium density

Code of the participant: RL	Date:23/6/15

- Frequency of insole use: Average days per week --5--- average hours per day:--4-
- Please mark the response that most closely reflects your opinion.

	Strongly Agree	Agree	Neither Agree/ Nor Disagree	Disagree	Strongly Disagree	Don't know /Not Applicable
The insole fits well		Y		Y		
The insole is comfortable throughout the day				Y		
The insole does not cause abrasions or soreness			Y			
The insole is pain free to wear			Y			
I feel using of insole, makes my feet less tired					Y	
I am happy with the insole				Y		
I would like to continue using the insole				Y		

The insole felt too thick for my shoes, making it uncomfortable

2- Orthosole – Slimflex 3/4 Length Insoles

Code of the participant: RL	Date:23/6/15

- Frequency of insole use: Average days per week --4--- average hours per day:--2-
- Please mark the response that most closely reflects your opinion.

	Strongly Agree	Agree	Neither Agree/ Nor Disagree	Disagree	Strongly Disagree	Don't know /Not Applicable
The insole fits well		Y				
The insole is comfortable throughout the day					Y	
The insole does not cause abrasions or soreness					Y	
The insole is pain free to wear				Y		
I feel using of insole, makes my feet less tired			Y			
I am happy with the insole					Y	
I would like to continue using the insole					Y	

I found it uncomfortable and felt that it caused discomfort at the plantar fascia

3- FootSupports – medium density

Code of the participant: RL	Date:23/5/15

- Frequency of insole use: Average days per week --5--- average hours per day:--4--
- Please mark the response that most closely reflects your opinion.

	Strongly Agree	Agree	Neither Agree/ Nor Disagree	Disagree	Strongly Disagree	Don't know /Not Applicable

The insole fits well		*Y*				
The insole is comfortable throughout the day					*Y*	
The insole does not cause abrasions or soreness				*Y*		
The insole is pain free to wear				*Y*		
I feel using of insole, makes my feet less tired					*Y*	
I am happy with the insole				*Y*		
I would like to continue using the insole					*Y*	

4- Footsupport – High density

Code of the participant: RL	Date:10/6/15

- Frequency of insole use: Average days per week --2--- average hours per day:--3-
- Please mark the response that most closely reflects your opinion.

	Strongly Agree	Agree	Neither Agree/ Nor Disagree	Disagree	Strongly Disagree	Don't know /Not Applicable
The insole fits well					*Y*	
The insole is comfortable throughout the day					*Y*	
The insole does not cause abrasions or soreness				*Y*	*Y*	
The insole is pain free to wear				*Y*	*Y*	
I feel using of insole, makes my feet less tired					*Y*	
I am happy with the insole				*Y*	*Y*	
I would like to continue using the insole					*Y*	

The insole was too rigid and felt painful/uncomfortable on the bottom of my feet

5- Dr Scholl's insole

Code of the participant: RL	Date:8/7/15

- Frequency of insole use: Average days per week --7--- average hours per day:--5-
- Please mark the response that most closely reflects your opinion.

	Strongly Agree	Agree	Neither Agree/ Nor Disagree	Disagree	Strongly Disagree	Don't know /Not Applicable
The insole fits well	**Y**					
The insole is comfortable throughout the day	**Y**					
The insole does not cause abrasions or soreness		**Y**				
The insole is pain free to wear	**Y**					
I feel using of insole, makes my feet less tired			**Y**			
I am happy with the insole		**Y**				
I would like to continue using the insole		**Y**				

Was slightly sore on the base of the foot but once worn a couple of times it was fine (Felt best to build up use day by day)

Appendix G

Information sheet and consent form

Research Project investigating the kinematics and kinetics of normal movement tasks in in lower limb prosthetics wearers.

INFORMATION FOR PARTICIPANTS

Introduction

We are inviting you to take part in a research study. Before you decide whether or not you would like to take part, it is important for you to understand the purpose of the research and what it will involve. Please ask us if you would like more information or if there is anything that is unclear. The decision to take part in this study is entirely yours and you should not feel under any pressure to participate.

Purpose of the study

The main purpose of this research is to better understand the way the intact and amputated side with prosthesis in above knee amputees behaves in a verity of different everyday movement tasks. In addition the use of insoles during same movement tasks will be compared with condition of without insoles. So that we can see of this is different from a non-amputee locomotion and balance; we need similar data from a group of uninjured healthy people such as you. The information from this study will add to the knowledge about biomechanics of lower limb amputees' locomotion and possibility of insole effectiveness on improving their movement tasks and balance.

If you agree to participate you will be asked to perform and repeat a variety of common movements such as: sitting down and standing up from a seated position, walking, standing while doing simple activities e.g. reaching an object and close eyes and open eyes standing against a pulling force in each of 4 main directions. The tests will be performed in 2 sessions on same day, including "with" and "without" using insole. A pair of normal commercial insoles will be provided for you to use in shoes during "with" insole session. Your motion will be recorded using IR cameras and specialist motion tracking equipment and the forces exerted between their foot and the floor will be measured. The recording of motion will require you to wear shorts and vest and have small reflective markers placed on your body. The location of these markers will be recorded using a high speed 3D motion analysis system and cameras. Force data will be obtained from force platforms located in the floor. You will be asked to continue using of the insoles and come again to the lab approximately after 4 weeks to perform same tests with insoles. The data obtained from these test will be analysed and will be used to compare with amputee subjects data.

Am I a suitable participant for this study?

The only limits to participation in the study are that you are generally healthy, have had no injuries in the past 6 months and that you are between the ages of 18 and 70.

Is there any pressure to take part?

There is no pressure to take part and you can withdraw from the study at any time.

What will happen if I take part?

You will be invited to attend the biomechanics Laboratory at the University of Leeds on two occasions at a time convenient to you. The second visit will normally be within 4 weeks of your first.

What do I have to do?

You will be asked to bring with you a pair of shorts and a vest, though we can provide these if necessary. Small, lightweight reflective markers will be attached to your arms and legs with double side tape. These will be used to measure your motion whilst you sit down and stand up from a normal bench, walk a short distance, standing while doing simple activities e.g. reaching an object and close eyes and open eyes standing against a pulling force in each of 4 main directions. The tests will be performed in 2 sessions on same day, including "with" and "without" using insole. A normal commercial insole will be provided for you to use in your shoes during "with" insole session. You will be asked to repeat these movements 5 times in each session.

What are the possible benefits of taking part in this study?

There are no direct benefits to your resulting from the research but the objective of the research is to increase the knowledge about biomechanics of lower limb amputees' locomotion and possibility of insole effectiveness on improving their movement tasks and balance those can be beneficial for all users of lower limb prosthesis in the medium and long term.

What happens if something goes wrong?

As with all research using human subjects, there are some risks but these are similar to those you would experience doing these activities in your normal life. There is no high risk for you more than what anyone faces in normal life although the risk assessment has been done about the tests and the Lab equipment. For preventing falling during the tests; safety harness is provided. If your body shows reaction to insole materials, the using of insole will be ended. A member of staff who is first aid trained will always be present. Please note that the University of Leeds is liable only if negligent.

Will data and information about me be kept confidential?

You will not be identifiable from the other data obtained during the tests. We will be taking video recordings of the test procedures but these will be stored on a secure computer and only the researchers involved in the study will have access to these. These will be deleted once the data is no longer needed for the research.

What will happen to the results of the study?

The results from the study maybe used to allow the design of a better knee joint based on the principles of robotics. Some of the results will appear in published papers and presented at scientific meetings. You will not be identified in any of these papers or presentations.

Contact for further information

If you would like more information about the study please feel free to ask as many questions as you would like. The researchers principally involved in this aspect of the study are:

Dr Neil Messenger

School of Biomedical Sciences,

Biological Sciences,

University of Leeds,

Leeds,

LS2 9JT

0113 343 5084

n.messenger@leeds.ac.uk

Dr Todd Stewart

Institute of Medical & Biological Engineering (School of Mechanical Engineering), University of Leeds,

Leeds,

LS2 9JT

0113-343-2133
t.d.Stewart@leeds.ac.uk

Dr Daniella Strauss

School of Biomedical Sciences,

Biological Sciences

University of Leeds,

Leeds,

LS2 9JT

0113 343 7123

d.n.strauss@leeds.ac.uk

Subject Consent Form

Title: Evaluation of the effects of insoles on biomechanics of daily activities and balance in lower limb prosthetics wearers

		Please delete as applicable
1	I have read the Information for Participants sheet.	Yes/No
2	I have had the opportunity to ask questions and discuss the research study.	Yes/No
3	I am satisfied with the answers to my questions.	Yes/No
4	I have received enough information about this study.	Yes/No
5	I understand that I am free to withdraw from the study at any time without giving reason and without affecting my future care.	Yes/No

Signature ______________________________________ Date___/___/___	
Name (block capitals) ____	
Signature of person ________________________________ Date___/___/___ taking consent Name (block capitals) ____	

Persian Information sheet and consent form

اطلاعاتی برای شرکت کنندگان

- **مقدمه:**

بدینوسیله از شما دعوت می‌شود در پژوهشی که **"سینماتیک و سینتیک چند حرکت روزمره را در افراد استفاده کننده از پروتز اندام تحتانی بررسی می‌کند"**، شرکت فرمائید. برای ما اهمیت دارد که شما از هدف این پژوهش آگاه باشید. لطفا در صورت نیاز به اطلاعات بیشتر یا واضح نبودن اطلاعات ارائه شده، موضوع را حتما از ما بپرسید. شما برای هرگونه تصمیم‌گیری برای شرکت در این پژوهش کاملاً آزادید و نباید احساس کنید تحت فشار هستید.

- **هدف مطالعه حاضر:**

هدف اصلی این پژوهش درک بهتر چگونگی عملکرد سمت سالم و دچار قطع عضو افراد استفاده کننده از پروتز بالای زانو در برخی فعالیت‌های روزمره و حفظ تعادل است. علاوه بر این استفاده از نوعی از کفی در این فعالیت‌ها با حالت بدون کفی مقایسه خواهد شد. بدین منظور نیازمندیم یک گروه افراد دچار قطع عضو اندام تحتانی چون شما داشته باشیم تا متغیرهای مشابه را در آنها ثبت و سپس با گروه بدون قطع عضو مقایسه کنیم. اطلاعات حاصل از این مطالعه به دانش ما درباره بیومکانیک تحرّک افراد دچار قطع عضو اندام تحتانی و امکان اثرگذاری مثبت کفی بر فعالیت‌های حرکتی و تعادل خواهد افزود.
در صورت تمایل شما به شرکت در این پژوهش؛ از شما درخواست خواهد شد که تعدادی حرکت را تکرار کنید: نشستن و برخاستن از روی نیمکت و مجددا نشستن؛ راه رفتن در سه سرعت آهسته، معمولی و سریع؛ حفظ تعادل در حالت ایستاده و در دفعات جداگانه با چشم باز و بسته در حالیکه نیروی کششی به کمر اعمال می‌شود و سپس بار آزاد می‌شود؛ حفظ تعادل در حالت ایستاده با شبیه‌سازی حالتی که سعی در دسترسی به جسمی در جلوی خود و در ارتفاع سر دارید. آزمایش‌ها در دو مرحله با و بدون کفی انجام می‌شوند که بسته به تمایل شما می‌تواند در یک روز یا دو روز جداگانه باشند. یک جفت کفی تجاری برای شما تهیه شده که در اختیارتان گذاشته می‌شود. حرکت شما با استفاده از دوربین‌های مادون قرمز سرعت بالا مخصوص تحلیل سه‌بعدی حرکت و نیروهای وارد به کف پا با استفاده از دو صفحه نیروی نصب شده در کف آزمایشگاه ثبت می‌شوند. همچنین در زمان مشابه فعالیت عضلانی تعدادی از ماهیچه های اندام تحتانی و تنه با استفاده از حسگرهای EMG نصب شده روی بدن با چسب دوطرفه ثبت خواهند شد. از آنجا که برای ثبت حرکات نیازمند نصب مارکرهای بازتابنده نور روی اندام‌های فوقانی و تحتانی و تنه هستیم؛ از شما می‌خواهیم لباس آستین حلقه‌ای و شلوارک کوتاهی بپوشید. برای ثبت داده‌های EMG و نصب حسگرهای آن، پوست ناحیه باید تمیز شود و موهای آن تراشیده شوند. ممکن است از شما بخواهیم استفاده از کفی‌ها را تا 4 هفته ادامه دهید و سپس آزمایش‌های مشابه فقط با کفی انجام خواهد گرفت. داده‌های حاصل از این آزمایش‌ها بعد از تحلیل با داده‌های افراد بدون قطع عضو مقایسه خواهد شد.

- **چه افرادی برای شرکت در آزمایش‌ها مناسب هستند؟**

شرکت کنندگان باید مردان استفاده کننده از پروتز اندام تحتانی، در فاصله سنی 18–70 سال باشند که در 6 ماه گذشته دچار آسیب اسکلتی–عضلانی دیگری نبوده‌اند.

- **آیا برای شرکت در آزمایش‌ها اجبار وجود دارد؟**

شما برای شرکت در این پژوهش کاملا آزادید و هر زمان که تمایل داشته باشید می‌توانید از شرکت در آن انصراف دهید.

- **در صورت تمایل برای شرکت کردن در پژوهش چه اتفاقی خواهد افتاد؟**

از شما دعوت می‌شود برای انجام آزمایش‌ها در زمان مناسب هماهنگ شده با شما در آزمایش تحلیل حرکت مرکز تحقیقات توانبخشی پیشرفته جواد موفقیان حضور یابید. ممکن است از شما بخواهیم استفاده از کفی‌ها را تا 4 هفته ادامه دهید و سپس برای انجام آزمایش‌های مشابه فقط با کفی مجددا در زمان هماهنگ شده به مرکز مراجعه فرمائید.

- **شما چه کار باید بکنید؟**

از شما می‌خواهیم لباس آستین حلقه‌ای و شلوارک کوتاهی با خود بیاورید یا از لباس‌هایی که در آزمایشگاه است، استفاده کنید. برای ثبت داده‌های EMG و نصب حسگرهای آن با استفاده از چسب دوطرفه، پوست ناحیه باید تمیز شود و موهای آن تراشیده شوند. مارکرهای بازتابنده نور نیز با استفاده از چسب دو طرفه بر روی دست‌ها، تنه و پاها نصب می‌شوند. این مارکرها برای ثبت حرکات شما حین فعالیت‌های ذیل استفاده می‌شوند:

نشستن و برخاستن از روی نیمکت و مجددا نشستن؛ راه رفتن در سه سرعت آهسته، معمولی و سریع؛ حفظ تعادل در حالت ایستاده و در دفعات جداگانه با چشم باز و بسته در حالیکه نیروی کششی به کمر اعمال می‌شود و سپس بار آزاد می‌شود؛ حفظ تعادل در حالت ایستاده با شبیه‌سازی حالتی که سعی در دسترسی به جسمی در جلوی خود و در ارتفاع سر دارید.

آزمایش‌ها در دو مرحله با و بدون کفی انجام می‌شوند که بسته به تمایل شما می‌تواند در یک روز یا دو روز جداگانه باشند. یک جفت کفی تجاری برای شما تهیه شده که در اختیارتان گذاشته می‌شود. هر فعالیت در هر سری آزمایش 3 بار تکرار خواهد شد. ممکن است از شما بخواهیم استفاده از کفی‌ها را تا 4 هفته ادامه دهید و سپس آزمایش‌های مشابه فقط با کفی انجام خواهد گرفت.

- **فایده شرکت در این پژوهش چیست؟**

فایده مستقیمی برای شرکت‌کنندگان وجود ندارد اما اطلاعات حاصل از این مطالعه به دانش ما درباره بیومکانیک تحرّک افراد دچار قطع عضو اندام تحتانی و امکان اثرگذاری مثبت کفی بر فعالیت‌های حرکتی و تعادل خواهد افزود که این امر ممکن است برای استفاده کنندگان از پروتزهای اندام تحتانی در میان مدت یا طولانی مدت مفید باشد.

- **آیا خطری برای شرکت کنندگان وجود دارد؟**

برای هر کار پژوهشی ریسک‌هایی وجود دارد اما نوع و سطح آن مانند فعالیت‌هائیست که در زندگی روزمره دارید. ریسک بیشتری از مقدار ریسکی که هر کس در زندگی روزمره با آن مواجه است، وجود نخواهد داشت. هرچند ارزیابی ریسک درباره تجهیزات آزمایشگاه انجام شده است. اگر بدنتان نسبت به مواد به کار رفته در کفی‌ها واکنش آلرژیک نشان دهد؛ به استفاده از آنها پایان دهید. کمک‌های اولیه و فرد آشنا به آنها برای موارد ضروری در مرکز تحقیقات وجود دارد.

- **آیا اطلاعات و داده‌ها به صورت محرمانه خواهند بود؟**

اطلاعات هر یک از شرکت کنندگان کاملا محرمانه، بدون نام و با کد دهی ثبت و نگهداری خواهند شد. اطلاعات تصویری بر روی کامپیوتر خاص و بدون دسترسی سایرین ثبت می‌شود. بعد از پایان پروژه و پایان نیاز به داده‌ها همه اطلاعات پاک خواهند شد.

- **چه اتفاقی برای نتایج مطالعه می‌افتد؟**

نتایج مطالعه ممکن است برای طراحی زانوی پروتزی استفاده شوند. همچنین نتایج به صورت مقالات علمی منتشر خواهند شد. نام شرکت کنندگان در این انتشارات علمی آشکار نخواهد بود.

- **اطلاعات تماس**

در صورت نیاز به اطلاعات بیشتر درباره این پروژه می‌توانید با اینجانب تهمینه رضائیان (bstr@leeds.ac.uk) تماس بگیرید. اساتید این پروژه شامل دکتر فرزام فرهمند (farahmand@sharif.edu) در مرکز تحقیقات توانبخشی پیشرفته موفقیان و دکتر نیل مسنجر (n.messenger@leeds.ac.uk)؛ دکتر دانیلا استراوس (d.n.strauss@leeds.ac.uk)؛ دکتر تد استوارت (t.d.Stewart@leeds.ac.uk) در دانشگاه لیدز هستند.

- **فرم موافقت شرکت داوطلبان در مطالعه**

عنوان: ارزیابی اثر کفی بر بیومکانیک فعالیتهای روزمره و تعادل در افراد استفاده کننده از پروتز اندام تحتانی

1	اطلاعات ارائه شده برای شرکت کنندگان را خواندم	بله/خیر
2	از فرصت پرسیدن سوالات و گفتگو درباره مطالعه برخوردار بوده‌ام	بله/خیر
3	از پاسخ‌های ارائه شده راضی‌ام	بله/خیر
4	اطلاعات کافی درباره این مطالعه دریافت کرده‌ام	بله/خیر
5	می‌دانم هر زمان که تمایل داشته باشم، از شرکت در مطالعه انصراف دهم و این امر در خدمات آینده اثر نخواهد داشت	بله/خیر

نام و نام خانوادگی شرکت کننده

امضاء و تاریخ

نام و نام خانوادگی پژوهشگر

امضاء و تاریخ

Appendix H

Psychometric Properties of Measurements

This section provides evidences for validity and reliability of utilized motion analysis systems and standing balance perturbation system. The testing procedure of motion analysis systems' validity and reliability was inspired by Dr Vanicek, N.K. (2009) thesis. For table captions, "H" stands for Appendix H, "Q" for Qualisys system, "V" for Vicon system and "P" for perturbation system. As it is seen in the tables in following parts, the average, standard deviation, Coefficient of Variation (CV[1]), the difference between measured value and real value (R&M), in addition to absolute differences (AbsD), percentage error (PE[2]) of measurements and Root Mean Square Error (RMSE[3]) were calculated. Real length of wands was recorded on each wand by manufacturer. The results are presented in 2 main sections including motion analysis systems (for each motion capture system separately) and perturbation system.

A) Motion analysis systems

As it was mentioned in Chapter 4, the biomechanical tests were carried out in two different sites by using two commercial motion analysis systems (including Qalisys and Vicon motion capture systems). Each motion analysis system included two force platforms. Detailed description of systems and the rate of data collections are presented in methodology section of Chapter 4. To examine reliability and validity of linear measurements, 2 wands (not used in calibration process) with 2 reflective markers (14 mm diameter) mounted on them in known distances were utilized. For angular measurements a goniometer was used with 2 markers attached to its each arms and one to its axis. Goniometer was fixed in 3 angles (45, 90 and 180 degrees). After calibration of motion spaces according to the user guides of the motion analysis systems, each of these instruments were moved in calibrated space for 15 seconds and were repeated 10 times. The distances between 2 markers on moving wands and angles of moving goniometer were obtained via the markers' 3D positions in each motion analysis system. The ground reaction forces applied by known weights (5 kg, 10 kg. 25 kg, 40 kg) placed on each force platform were recorded for 15 seconds during 10 repeated trials to determine reliability and validity of force platforms.

A-1) Qualisys Motion Capture System

Table H-Q-1 shows the length of wands measured by Qualisys Motion Capture System and their differences with real lengths during 10 trials. The difference between measured values and real values (R&M) are less than 1 mm. In addition, the percentage error is close to zero. The calculated RMSE for Wand1 was 0.25 mm, and for Wand 2 was 0.13 mm. From these data, the high level of validity of the system can be concluded. SD and the CVs have small values which shows the linear measurements were repeatable.

---

1 $CV = \frac{Standard\ Deviation}{Mean} \times 100$

2 $\mathrm{PE} = \frac{|Real-measured|}{\mathrm{Real}} \times 100$

3 $\mathrm{RMSE}=\sqrt{\frac{\sum_1^N (Measured-Real)^2}{N}}$

Table H-Q-1 Measured length of the wands by Qualisys system

	Wand number 1 with real length of 751.2 mm				Wand number 2 with real length of 301.5 mm			
Trial	**Measured (mm)**	**R&M (mm)**	**AbsD (mm)**	**PE (%)**	**Measured (mm)**	**R&M (mm)**	**AbsD (mm)**	**PE (%)**
1	751.1	-0.09	0.09	0.0	301.6	0.08	0.08	0.0
2	750.9	-0.30	0.30	0.0	301.4	-0.09	0.09	0.0
3	750.8	-0.40	0.40	0.1	301.4	-0.07	0.07	0.0
4	751.1	-0.08	0.08	0.0	301.5	-0.04	0.04	0.0
5	751.1	-0.11	0.11	0.0	301.4	-0.07	0.07	0.0
6	751.1	-0.13	0.13	0.0	301.3	-0.21	0.21	0.1
7	750.7	-0.52	0.52	0.1	301.4	-0.14	0.14	0.0
8	751.3	0.10	0.10	0.0	301.3	-0.23	0.23	0.1
9	751.1	-0.12	0.12	0.0	301.5	-0.02	0.02	0.0
10	751.0	-0.22	0.22	0.0	301.3	-0.19	0.19	0.1
Mean	**751.0**	-0.19	0.21	0.0	**301.4**	-0.10	0.11	0.0
SD	**0.18**	0.18	0.15	0.0	**0.10**	0.10	0.07	0.0
CV	**0.02%**				**0.03%**			

Table H-Q-2 Measured goniometer's angles by Qualisys system

	45 deg.				90 deg.				180 deg.			
Trial	**Measured (deg.)**	**R&M (deg.)**	**AbsD (deg.)**	**PE (%)**	**Measured (deg.)**	**R&M (deg.)**	**AbsD (deg.)**	**PE (%)**	**Measured (deg.)**	**R&M (deg.)**	**AbsD (deg.)**	**PE (%)**
1	44.2	-0.78	0.78	1.7	90.0	-0.03	0.03	0.0	179.6	-0.41	0.41	0.2
2	44.2	-0.77	0.77	1.7	90.1	0.05	0.05	0.1	179.5	-0.45	0.45	0.3
3	44.2	-0.82	0.82	1.8	90.9	0.95	0.95	1.1	179.9	-0.12	0.12	0.1
4	44.3	-0.74	0.74	1.6	90.0	0.00	0.00	0.0	180.0	-0.04	0.04	0.0
5	44.2	-0.75	0.75	1.7	88.8	-1.17	1.17	1.3	179.0	-1.03	1.03	0.6
6	44.2	-0.81	0.81	1.8	90.0	-0.02	0.02	0.0	179.9	-0.06	0.06	0.0
7	44.2	-0.81	0.81	1.8	89.8	-0.22	0.22	0.2	180.1	0.12	0.12	0.1
8	44.2	-0.76	0.76	1.7	90.1	0.08	0.08	0.1	179.9	-0.12	0.12	0.1
9	44.3	-0.72	0.72	1.6	90.0	0.02	0.02	0.0	179.9	-0.09	0.09	0.0
10	44.2	-0.78	0.78	1.7	89.2	-0.80	0.80	0.9	179.9	-0.09	0.09	0.0
Mean	**44.2**	-0.77	0.77	1.7	**90.1**	-0.11	0.33	0.4	**179.8**	-0.23	0.25	0.1
SD	**0.03**	0.03	0.03	0.1	**0.52**	0.56	0.45	0.5	**0.33**	0.33	0.31	0.2
CV	**0.07%**				**0.57%**				**0.18%**			

Table H-Q-2 displays the measured angles by Qualisys Motion Capture System and their differences with real measures during 10 trials. The difference between measured values and real value (R&M) are less than 1 degree. But, the percentage errors are larger than the linear measures, particularly for 45 degree which is more than 1%. However, RMSE values (0.77°, 0.54° and 0.39° respectively for 45°, 90°. and 180°) indicate the angular measures were accurate. Standard deviations are less than 1 degree and the CVs are less than 1% which indicates the angular measurements were repeatable.

Table H-Q-3 to Table H-Q-6 display the measured weights by force platforms of Qualisys Motion Capture System and their differences with real measures during 10 trials. The difference between measured values and real value (R&M) are less than 1 N. But, the percentage error for 5 kg weight-Force platform number 1 is more than 1%. The accuracy of measurements are in good level and RMSE for all weights are less than 2 N. Standard deviations are less than 1 N and CVs are less than 1% which shows the measurements were repeatable.

Table H-Q-3 Weight 5 kg (49.05 N) measured by force platforms of Qualisys system

	Force Plate 1				Force Plate 2			
Trial	**Measured (N)**	**R&M (N)**	**AbsD (N)**	**PE (%)**	**Measured (N)**	**R&M (N)**	**AbsD (N)**	**PE (%)**
1	49.6	0.57	0.57	1.2	49.0	-0.06	0.06	0.1
2	49.6	0.55	0.55	1.1	49.1	0.06	0.06	0.1
3	49.6	0.57	0.57	1.2	49.2	0.15	0.15	0.3
4	49.6	0.55	0.55	1.1	49.2	0.14	0.14	0.3
5	49.6	0.56	0.56	1.1	49.3	0.25	0.25	0.5
6	49.7	0.61	0.61	1.2	49.3	0.30	0.30	0.6
7	49.7	0.61	0.61	1.3	49.4	0.33	0.33	0.7
8	49.6	0.58	0.58	1.2	49.4	0.36	0.36	0.7
9	49.7	0.64	0.64	1.3	49.4	0.39	0.39	0.8
10	49.7	0.61	0.61	1.2	49.5	0.50	0.50	1.0
Mean	**49.6**	0.59	0.59	1.2	**49.3**	0.24	0.25	0.5
SD	**0.03**	0.03	0.03	0.1	**0.17**	0.17	0.15	0.3
CV	**0.06%**				**0.34%**			
RMSE=0.59 N					RMSE=0.29 N			

Table H-Q-4 Weight 10 kg (98.1 N) by force platforms of Qualisys system

	Force Plate 1				Force Plate 2			
Trial	**Measured (N)**	**R&M (N)**	**AbsD (N)**	**PE (%)**	**Measured (N)**	**R&M (N)**	**AbsD (N)**	**PE (%)**
1	98.1	0.04	0.04	0.0	98.2	0.14	0.14	0.1
2	98.2	0.08	0.08	0.1	98.3	0.24	0.24	0.2
3	98.3	0.18	0.18	0.2	98.3	0.25	0.25	0.3
4	98.3	0.23	0.23	0.2	98.4	0.31	0.31	0.3
5	98.4	0.25	0.25	0.3	98.5	0.37	0.37	0.4
6	98.4	0.26	0.26	0.3	98.5	0.39	0.39	0.4
7	98.4	0.34	0.34	0.3	98.6	0.46	0.46	0.5
8	98.4	0.32	0.32	0.3	98.6	0.48	0.48	0.5
9	98.5	0.37	0.37	0.4	98.6	0.52	0.52	0.5
10	98.5	0.42	0.42	0.4	98.6	0.54	0.54	0.6
Mean	**98.3**	0.25	0.25	0.3	**98.5**	0.37	0.37	0.4
SD	**0.12**	0.12	0.12	0.1	**0.13**	0.13	0.13	0.1
CV	**0.12%**				**0.14%**			
RMSE=0.28 N					RMSE=0.39 N			

Table H-Q-5 Weight 25 kg (245.25 N) by force platforms of Qualisys system

	Force Plate 1				Force Plate 2			
Trial	**Measured (N)**	**R&M (N)**	**AbsD (N)**	**PE (%)**	**Measured (N)**	**R&M (N)**	**AbsD (N)**	**PE (%)**
1	245.3	0.06	0.02	0.0	245.7	0.49	0.49	0.2
2	245.5	0.24	0.24	0.1	246.0	0.72	0.72	0.3
3	245.6	0.33	0.32	0.1	246.2	0.90	0.90	0.4
4	245.6	0.43	0.40	0.2	246.2	0.95	0.95	0.4
5	245.8	0.50	0.50	0.2	246.3	1.02	1.02	0.4
6	245.8	0.55	0.55	0.2	246.3	1.07	1.07	0.4
7	245.9	0.66	0.65	0.3	246.4	1.15	1.15	0.5
8	245.9	0.66	0.62	0.3	246.4	1.15	1.15	0.5
9	246	0.74	0.73	0.3	246.5	1.20	1.20	0.5
10	246.1	0.83	0.80	0.3	246.5	1.25	1.25	0.5
Mean	**245.8**	0.50	0.48	0.2	**246.2**	0.99	0.99	0.4
SD	**0.25**	0.24	0.24	0.1	**0.25**	0.24	0.24	0.1
CV	**0.10%**				**0.10%**			
RMSE=0.55 N					RMSE=1.02 N			

Table H-Q-6 Weight 40 kg (392.4 N) by force platforms of Qualisys system

	Force Plate 1				Force Plate 2			
Trial	**Measured (N)**	**R&M (N)**	**AbsD (N)**	**PE (%)**	**Measured (N)**	**R&M (N)**	**AbsD (N)**	**PE (%)**
1	392.6	0.19	0.19	0.0	391.6	-0.78	0.78	0.2
2	390.0	-2.36	2.36	0.6	392.1	-0.31	0.31	0.1
3	390.3	-2.12	2.12	0.5	392.2	-0.24	0.24	0.1
4	390.4	-2.04	2.04	0.5	392.2	-0.16	0.16	0.0
5	390.5	-1.93	1.93	0.5	392.2	-0.18	0.18	0.0
6	390.5	-1.89	1.89	0.5	392.3	-0.14	0.14	0.0
7	390.6	-1.81	1.81	0.5	392.3	-0.13	0.13	0.0
8	390.7	-1.73	1.73	0.4	392.3	-0.06	0.06	0.0
9	390.7	-1.69	1.69	0.4	392.4	0.00	0.00	0.0
10	390.7	-1.69	1.69	0.4	392.5	0.06	0.06	0.0
Mean	**390.7**	-1.71	1.75	0.4	**392.2**	-0.19	0.20	0.1
SD	**0.70**	0.70	0.59	0.1	**0.23**	0.23	0.22	0.1
CV	**0.18%**				**0.06%**			
RMSE=1.83 N					RMSE=0.29 N			

A-2) Vicon Motion Capture System

Table H-V-1 shows the measured length of wands by Vicon Motion Capture System and their differences with real measures during 10 trials. The difference between measured values and real values (R&M) are less than 1 mm. In addition, the percentage error is close to zero. The calculated RMSE for Wand1 was 0.39 mm, and for Wand 2 was 0.24 mm. From these data, the high level of accuracy of the system can be concluded. Standard deviations and the CVs have small values which shows the linear measurements were repeatable.

Table H-V-2 displays the measured angles by Vicon Motion Capture System and their differences with real measures during 10 trials. The difference between measured values and real value (R&M) are less than 1 degree. But, the percentage errors are larger than the linear measures, particularly for 45 degree which has mean PE% near to 1%. However, RMSE values (0.45°, 0.35° and 0.57° respectively for 45°, 90°. and 180°) indicate the angular measures were accurate. Standard deviations are less than 1 degree and the CVs are less than 1% which indicates the angular measurements were repeatable.

Table H-V-3 to Table H-V-6 display the measured weights by force platforms of Vicon Motion Capture System and their differences with real measures during 10 trials. The difference between measured values and real value (R&M) are less than 1 N for Force platform number 1 during using 5kg, 10 kg and 20 kg weights.

Table H-V-1 Measured length of the wands by Vicon system

	Wand number 1 with real length of 550 mm				Wand number 2 with real length of 200 mm			
Trial	**Measured (mm)**	**R&M (mm)**	**AbsD (mm)**	**PE (%)**	**Measured (mm)**	**R&M (mm)**	**AbsD (mm)**	**PE (%)**
1	550.2	0.15	0.15	0.0	199.8	-0.19	0.19	0.1
2	550.4	0.41	0.41	0.1	199.9	-0.10	0.10	0.0
3	550.4	0.45	0.45	0.1	199.9	-0.07	0.07	0.0
4	550.3	0.34	0.34	0.1	199.7	-0.31	0.31	0.2
5	550.4	0.39	0.39	0.1	199.8	-0.18	0.18	0.1
6	550.5	0.47	0.47	0.1	199.7	-0.34	0.34	0.2
7	550.2	0.20	0.20	0.0	199.7	-0.26	0.26	0.1
8	550.4	0.38	0.38	0.1	199.7	-0.27	0.27	0.1
9	550.6	0.58	0.58	0.1	199.8	-0.20	0.20	0.1
10	550.3	0.31	0.31	0.1	199.7	-0.33	0.33	0.2
Mean	**550.4**	0.37	0.37	0.1	**199.8**	-0.22	0.22	0.1
SD	**0.13**	0.13	0.13	0.0	**0.09**	0.09	0.09	0.0
CV	**0.02%**				**0.05%**			

Table H-V-2 Measured goniometer's angles by Vicon system

	45 deg.				90 deg.				180 deg.			
Trial	**Measured (deg.)**	**R&M (deg.)**	**AbsD (deg.)**	**PE (%)**	**Measured (deg.)**	**R&M (deg.)**	**AbsD (deg.)**	**PE (%)**	**Measured (deg.)**	**R&M (deg.)**	**AbsD (deg.)**	**PE (%)**
1	45.7	0.67	0.67	1.5	90.6	0.56	0.56	0.6	179.3	-0.70	0.70	0.4
2	45.4	0.44	0.44	1.0	90.5	0.54	0.54	0.6	179.0	-0.95	0.95	0.5
3	45.4	0.39	0.39	0.9	90.0	-0.05	0.05	0.1	179.2	-0.78	0.78	0.4
4	45.4	0.40	0.40	0.9	90.0	0.02	0.02	0.0	180.0	0.04	0.04	0.0
5	45.3	0.31	0.31	0.7	90.2	0.17	0.17	0.2	179.3	-0.69	0.69	0.4
6	45.3	0.30	0.30	0.7	90.4	0.44	0.44	0.5	179.4	-0.55	0.55	0.3
7	45.6	0.56	0.56	1.2	89.8	-0.18	0.18	0.2	179.6	-0.43	0.43	0.2
8	45.2	0.21	0.21	0.5	90.2	0.23	0.23	0.3	179.9	-0.15	0.15	0.1
9	45.3	0.32	0.32	0.7	89.8	-0.25	0.25	0.3	179.6	-0.44	0.44	0.2
10	45.6	0.61	0.61	1.4	90.5	0.53	0.53	0.6	179.8	-0.25	0.25	0.1
Mean	**45.4**	0.42	0.42	0.9	**90.2**	0.20	0.30	0.3	**179.5**	-0.49	0.50	0.3
SD	**0.15**	0.15	0.15	0.3	**0.31**	0.31	0.21	0.2	**0.31**	0.31	0.29	0.2
CV	**0.33%**				**0.34%**				**0.17%**			

However, the mean of R&M for all weights measuring by Force platform number 2 and the 40 kg weight for Force platform number 1 were larger. Although, only the percentage error for 10 kg weight- Force platform number 2 is more than 1%. RMSE for all weights are less than 2 N (except for 40 kg measured by Force platform number 2) which indicates the accuracy of measurements. Standard deviations are less than 1 N and CVs are less than 1% which shows the measurements were repeatable.

Table H-V-3 Weight 5 kg (49.05 N)

	Force Plate 1				Force Plate 2			
Trial	**Measured (N)**	**R&M (N)**	**AbsD (N)**	**PE (%)**	**Measured (N)**	**R&M (N)**	**AbsD (N)**	**PE (%)**
1	49.0	-0.10	0.10	0.2	48.9	-0.17	0.17	0.4
2	49.0	-0.09	0.09	0.2	48.9	-0.19	0.19	0.4
3	48.9	-0.13	0.13	0.3	48.9	-0.19	0.19	0.4
4	48.9	-0.17	0.17	0.3	48.9	-0.13	0.13	0.3
5	48.9	-0.15	0.15	0.3	48.9	-0.12	0.12	0.3
6	48.9	-0.14	0.14	0.3	49.0	-0.06	0.06	0.1
7	48.9	-0.17	0.17	0.3	48.9	-0.12	0.12	0.2
8	48.9	-0.15	0.15	0.3	48.9	-0.10	0.10	0.2
9	48.8	-0.23	0.23	0.5	49.0	-0.07	0.07	0.1
10	48.8	-0.22	0.22	0.5	48.9	-0.11	0.11	0.2
Mean	**48.9**	-0.15	0.15	0.3	**48.9**	-0.13	0.13	0.3
SD	**0.05**	0.05	0.05	0.1	**0.05**	0.05	0.05	0.1
CV	**0.09%**				**0.09%**			
RMSE=0.16 N					RMSE=0.13 N			

Table H-V-4 Weight 10 kg (98.1 N)

	Force Plate 1				Force Plate 2			
Trial	**Measured (N)**	**R&M (N)**	**AbsD (N)**	**PE (%)**	**Measured (N)**	**R&M (N)**	**AbsD (N)**	**PE (%)**
1	97.5	-0.59	0.59	0.6	96.9	-1.16	1.16	1.2
2	97.6	-0.53	0.53	0.5	97.0	-1.13	1.13	1.1
3	97.6	-0.51	0.51	0.5	97.0	-1.07	1.07	1.1
4	97.6	-0.53	0.53	0.5	97.0	-1.08	1.08	1.1
5	97.6	-0.50	0.50	0.5	97.0	-1.09	1.09	1.1
6	97.7	-0.45	0.45	0.5	97.1	-1.04	1.04	1.1
7	97.6	-0.50	0.50	0.5	97.1	-1.03	1.03	1.0
8	97.6	-0.48	0.48	0.5	97.1	-1.04	1.04	1.1
9	97.6	-0.50	0.50	0.5	97.1	-1.00	1.00	1.0
10	97.6	-0.48	0.48	0.5	97.1	-0.95	0.95	1.0
Mean	**97.6**	-0.51	0.51	0.5	**97.0**	-1.06	1.06	1.1
SD	**0.04**	0.04	0.04	0.0	**0.06**	0.06	0.06	0.1
CV	**0.04%**				**0.06%**			
RMSE=0.51 N					RMSE=1.06 N			

Table H-V-5 Weight 25 kg (245.25 N)

	Force Plate 1				Force Plate 2			
Trial	**Measured (N)**	**R&M (N)**	**AbsD (N)**	**PE (%)**	**Measured (N)**	**R&M (N)**	**AbsD (N)**	**PE (%)**
1	244.4	-0.88	0.88	0.4	243.4	-1.89	1.89	0.8
2	243.5	-1.74	1.74	0.7	244.6	-0.69	0.69	0.3
3	244.6	-0.66	0.66	0.3	243.5	-1.73	1.73	0.7
4	244.6	-0.63	0.63	0.3	243.6	-1.65	1.65	0.7
5	244.7	-0.52	0.52	0.2	243.8	-1.50	1.50	0.6
6	244.8	-0.50	0.50	0.2	243.8	-1.47	1.47	0.6
7	244.8	-0.43	0.43	0.2	243.8	-1.48	1.48	0.6
8	244.8	-0.43	0.43	0.2	243.8	-1.43	1.43	0.6
9	244.9	-0.38	0.38	0.2	243.8	-1.42	1.42	0.6
10	244.9	-0.34	0.34	0.2	243.8	-1.47	1.47	0.6
Mean	**244.6**	-0.65	0.65	0.3	**243.8**	-1.47	1.47	0.6
SD	**0.41**	0.41	0.41	0.2	**0.31**	0.31	0.31	0.1
CV	**0.17%**				**0.13%**			
RMSE=0.76 N					RMSE=1.5 N			

Table H-V-6 Weight 40 kg (392.4 N)

	Force Plate 1				Force Plate 2			
Trial	**Measured (N)**	**R&M (N)**	**AbsD (N)**	**PE (%)**	**Measured (N)**	**R&M (N)**	**AbsD (N)**	**PE (%)**
1	390.6	-1.83	1.83	0.5	390.1	-2.28	2.28	0.6
2	390.9	-1.50	1.50	0.4	390.3	-2.11	2.11	0.5
3	390.9	-1.47	1.47	0.4	390.3	-2.09	2.09	0.5
4	391.0	-1.40	1.40	0.4	390.4	-2.05	2.05	0.5
5	391.0	-1.35	1.35	0.3	390.4	-2.03	2.03	0.5
6	391.2	-1.24	1.24	0.3	390.4	-2.00	2.00	0.5
7	391.2	-1.18	1.18	0.3	390.5	-1.91	1.91	0.5
8	391.3	-1.13	1.13	0.3	390.4	-1.95	1.95	0.5
9	391.3	-1.09	1.09	0.3	390.5	-1.94	1.94	0.5
10	391.4	-1.03	1.03	0.3	390.5	-1.90	1.90	0.5
Mean	**391.1**	-1.32	1.32	0.3	**390.4**	-2.03	2.03	0.5
SD	**0.24**	0.24	0.24	0.1	**0.12**	0.12	0.12	0.0
CV	**0.06%**				**0.03%**			
RMSE=1.34 N					RMSE=2.03 N			

B) Standing Balance Perturbation System

To evaluate repeatability and validity of perturbation system, a Noraxon DTS Force Sensor with SML Load Cell (500 lbf) was used (Figure H-1). The Linear Force SmartLead allows a user to determine the magnitude of force executed along its single axis. The free head of rope of perturbation system (which in biomechanical tests was fixed to waist of a participant in standing balance tests) was attached to one side of the force cell. Other side of the force cell was fixed to the wall in height of perturbation system pulley and in 3m distance with the system. Three known weights (1.5 kg, 2 kg, 2.5 kg and 3 kg) were used to examine reliability and validity of the load applied by perturbation system. Each load applied a pulling force to force sensor. The load was released after 15 s by researcher. This procedure was repeated 10 times for each load. The applied loads by weights were recorded with sampling rate of 1500 Hz by using MyoResearch XP Master (Edition 1.08.38) product of Noraxon.

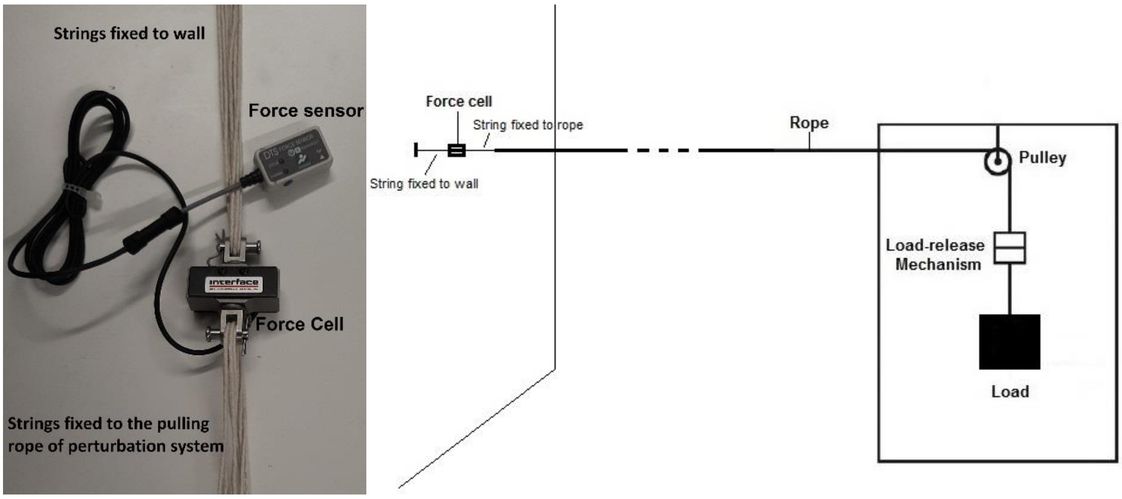


Figure H-p-1 Force sensor and

Table H-P-1 displays the repeated measured loads and their differences with real measures during 10 trials. The difference between measured values and real value (R&M) are less than 1 N. The mean of percentage error for all loads was less than 3%. RMSE as indicator of accuracy of measurements, for all weights was less than 1 N.

Standard deviations are less than 1 N, but CVs are 1-3.1% which is in range of acceptable coefficient of variation[1].

Table H-P-1 The measured loads applied by perturbation system

	1.5 kg weight equal to 14.715 N				2 kg weight equal to 19.62 N			
Trial	**Measured (N)**	**R&M (N)**	**AbsD (N)**	**PE (%)**	**Measured (N)**	**R&M (N)**	**AbsD (N)**	**PE (%)**
1	14.720	0.005	0.005	0.0	18.92	-0.70	0.70	3.6
2	14.294	-0.421	0.421	2.9	19.07	-0.55	0.55	2.8
3	13.986	-0.729	0.729	5.0	19.18	-0.44	0.44	2.3
4	14.312	-0.403	0.403	2.7	18.93	-0.69	0.69	3.5
5	14.251	-0.464	0.464	3.2	19.42	-0.20	0.20	1.0
6	14.558	-0.157	0.157	1.1	19.07	-0.55	0.55	2.8
7	14.643	-0.072	0.072	0.5	19.36	-0.26	0.26	1.3
8	14.405	-0.310	0.310	2.1	19.62	0.00	0.00	0.0
9	14.450	-0.265	0.265	1.8	19.91	0.29	0.29	1.5
10	14.481	-0.234	0.234	1.6	19.89	0.27	0.27	1.4
Mean	**14.410**	-0.305	0.306	2.1	**19.335**	-0.29	0.40	2.0
SD	**0.213**	0.213	0.211	1.4	**0.37**	0.37	0.23	1.2
CV	**1.5%**				**2%**			
RMSE=0.366 N					RMSE=0.451 N			

Continued

	2.5 kg weight equal to 24.525 N				3 kg weight equal to 29.43 N			
Trial	**Measured (N)**	**R&M (N)**	**AbsD (N)**	**PE (%)**	**Measured (N)**	**R&M (N)**	**AbsD (N)**	**PE (%)**
1	24.144	-0.381	0.381	1.6	30.13	0.70	0.70	2.4
2	25.445	0.920	0.920	3.8	29.88	0.45	0.45	1.5
3	23.837	-0.688	0.688	2.8	29.76	0.33	0.33	1.1
4	23.736	-0.789	0.789	3.2	29.53	0.10	0.10	0.3
5	24.458	-0.067	0.067	0.3	29.27	-0.16	0.16	0.5
6	25.508	0.983	0.983	4.0	29.47	0.04	0.04	0.1
7	25.685	1.160	1.160	4.7	29.84	0.41	0.41	1.4
8	24.430	-0.095	0.095	0.4	28.98	-0.45	0.45	1.5
9	25.393	0.868	0.868	3.5	29.93	0.50	0.50	1.7
10	24.020	-0.505	0.505	2.1	28.66	-0.77	0.77	2.6
Mean	**24.666**	0.141	0.646	2.6	**29.55**	0.12	0.39	1.3
SD	**0.762**	0.762	0.373	1.5	**0.46**	0.46	0.24	0.8
CV	**3.1%**				**1.6%**			
RMSE=0.736 N					RMSE=0.453 N			

[1] Standing, R. and Maulder, P. 2017. The Biomechanics of Standing Start and Initial Acceleration: Reliability of the Key Determining Kinematics. *Journal of sports science & medicine.* **16**(1), pp.154-162.
Me, D., Kee, T., Cheung, B., Sai, M. and Yun, F. 1998. *Vicon Reliability.* [Online]. [Accessed 27th March]. Available from: http://www.clinicalgaitanalysis.com/faq/reliability/