JÖNKÖPING UNIVERSITY
School of Health and Welfare

Doctoral Thesis

Functioning in prosthetic users provided with and without a microprocessor-controlled prosthetic knee

– relative effects on mobility, self-efficacy and attentional demand

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Jönköping University
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Start by doing what´s necessary;

Then do what´s possible; and

Suddenly you are doing the

Impossible Francis of Assisi

Abstract

Background: to undergo a lower limb amputation is a traumatic experience affecting the individual on physical as well as psychological levels and often leading to limitations in a person´s daily life. Following an amputation individual often receive a prosthesis to address impairments in mobility and functioning. The mechanical properties of the prosthesis can vary, and the choice of specific components to include in the device has been demonstrated to influence patient outcomes. Studies investigating the relative effects of different prosthetic knee components have generally focused upon physical and biomechanical outcomes, providing a rather narrow view of health-related states in prosthetic users. There is a need to view health and wellbeing of prosthetic users from a broader perspective by evaluating outcomes that reflect a variety of different factors that can influence their functioning.

Aim: The overall aim of this thesis was to describe and compare functioning in individuals with a trans-femoral amputation or knee disarticulation and to evaluate the relative effects of using non-microprocessor-controlled prosthetic knees (non-MPK) or microprocessor-controlled prosthetic knees (MPK).

Methods: The four studies presented in this thesis used a cross-sectional, quantitative design with different types of data collection methods. These included self-report measures, capacity tests, a survey with two questionnaires and a measure of cortical brain activity during normal level waking and while performing a secondary task. One group of 42 individuals with lower-limb amputations, using a prosthetic knee with or without microprocessor-control was included in the survey study. Another group of 29 individuals with a lower limb amputation, using a prosthetic knee with or without a microprocessor-control and a control group (n=16) participated in the remaining studies. Statistical tests were used to compare differences between groups using different knee joints, between prosthesis users and controls.

Results: Individuals using a non-MPK had lower self-reported mobility and balance confidence as well as poorer results on mobility tests compared to those using an MPK. Results revealed no significant differences in self-rated health, daily step count or general self-efficacy. Increased cortical brain activity was seen in frontal cortex in individuals using a non-MPK in single-task walking compare to the MPK group and controls. A significant increase in brain activity was also seen in prefrontal cortex in dual-task walking compared to single-task walking in those walking with an MPK and controls.

Conclusion: Combined results of all four studies suggest that persons provided with an MPK had better mobility, both self-rated and objectively evaluated, and better self-rated balance confidence than those who were using a non-MPK. Results also showed that an individual's belief in their own ability was associated with the number of hours they use their prosthesis per week. Participants using a non-MPK had higher levels of cortical brain activity in the frontal cortex during walking, suggesting that the attentional demand required to walk was greater than for individuals using an MPK.
Of particular interest for health professionals involved in prosthetic rehabilitation was the finding that significant increases in attentional demand were not always reflected in temporospatial gait parameters. This suggests that cognitive demands may not always be reflected in variables that are commonly evaluated in the clinical setting.

Keywords: amputation, trans-femoral amputation, adaptive prosthetic knee, prosthetic limb, self-report, mobility, self-efficacy, attention, brain, gait, neuroimaging, functional near-infrared spectroscopy, cognitive load, brain activity.

Original papers

This thesis is based on the following papers which are referred to by their Roman numeral in the text.

Paper I

Möller, S., Ramstrand, N., Rusaw, D., Hagberg, K. *Differences in mobility for individuals using a non-microprocessor-controlled versus a microprocessor-controlled prosthetic knee*. Submitted.

Paper II

Möller, S., Hagberg, K., Samuelsson, K., Ramstrand, N. (2017) *Perceived self-efficacy and specific self-reported outcomes in persons with lower limb amputation using a non-microprocessor-controlled versus a microprocessor-controlled prosthetic knee*. Disability and Rehabilitation: Assistive Technology, 13:3, 220-225, DOI:10. 1080/17483107.2017.1306590.

Paper III

Möller, S., Rusaw, D., Hagberg, K., Ramstrand, N. (2018) *Reduced cortical brain activity with the use of microprocessor-controlled prosthetic knees during walking*. Prosthetics and Orthotics International, 1-9. DOI: 10.1177/0309364618805260 journals.sagepub.com/home/poi.

Paper IV

Möller, S., Ramstrand, N., Hagberg, K., Rusaw, D. *Cortical brain activity of transfemoral or knee-disarticulation prosthesis users performing single and dual-task walking activities*. Manuscript.

Contents

Definitions

Attention – Characteristics associated with consciousness, awareness, and cognitive effort as they relate to the performance of skills (Magill, 2010).

Body Functions – Physiological functions of body systems, including psychological functions (World Health Organization [WHO], 2001).

Cognition – Attention, planning, problem solving, motivation and emotional aspects of motor control (Shumway-Cook & Woollacott, 2012).

Capacity – An individual's ability to execute a task or an action in a standardised setting: what people can do (WHO, 2001).

Dual-task - "The simultaneous performance of two tasks with distinct goals" e.g., walking and counting backwards (McIsaac, Lamberg, & Muratori, 2015).

Executive functions – Also called executive control or cognitive control, higher order top-down mental processes that require concentration and attention (Diamond, 2013).

Functioning – Including body functions, activities and participation (WHO, 2001).

Knee disarticulation – Amputation of the lower limb at the knee joint (International Organization for Standardization [ISO], 2015).

Mobility – The process of moving oneself and of changing and maintaining postures (Bennekom van, Jelles, & Lankhorst, 1995).

Motor control – "The ability to regulate or direct the mechanisms essential to movement" (Shumway-Cook & Woollacott, 2012).

Motor learning – The acquisition and/or modification of movement (Shumway-Cook & Woollacott, 2012).

Participation – Involvement in life situations (WHO, 2001).

Performance – What an individual does in his or her current environment (WHO, 2001).

Physical activity – Any bodily movement produced by skeletal muscle that results in a substantial increase in the resting energy expenditure (Caspersen, Powell, & Christenson, 1985).

Single-task – Performance of one task e.g., finger tapping or walking.

Trans-femoral amputation – Amputation of the lower limb between the hip joint and the knee joint (ISO, 2015).

Trans-tibial amputation – Amputation of the lower limb between the knee joint and the ankle joint (ISO, 2015).

Abbreviations

De-oxyHb	De-oxygenated haemoglobin
EEG	Electroencephalography
fNIRS	Functional near-infrared spectroscopy
ICF	International Classification of Functioning Disability and Health
KD	Knee disarticulation
MPK	Microprocessor-controlled prosthetic knee
MRI	Magnetic resonance imaging
Non-MPK	Non-microprocessor-controlled prosthetic knee
oxyHb	Oxygenated haemoglobin
TF	Trans-femoral
TT	Trans-tibial

Preface

"Wow, what a relief, this prosthetic knee feels much smoother to walk with."

"With this knee I don´t have to concentrate on every step I take."

Comments from patients transitioning to a microprocessor-controlled prosthetic knee joint.

As a physiotherapist involved in prosthetic rehabilitation, I have heard these and similar comments from patients on many occasions. It trigged my curiosity. How might different prosthetic components affect the patient´s daily living? How might this be measured?

In my clinical work, my ambition has been to identify ways of supporting each individual patient in achieving their rehabilitation goals. On numerous occasions I have seen patients struggling with the challenge of controlling a prosthesis, especially if the prosthesis contains a knee joint. For some patients, the rehabilitation process is quite easy and they develop confidence in—and good function with—their prosthesis. Others have a much more difficult time and express fear and anxiety in using the prosthesis. This limits their daily activities and their social participation. Some even choose to abandon use of their prosthesis. This thesis has been conducted with the intention of increasing knowledge about functioning with a prosthesis and to contribute a piece to the puzzle of optimal prosthetic rehabilitation.

Introduction

To undergo a lower limb amputation is a traumatic experience affecting the individual on physical as well as psychological levels and often leads to limitations in a person’s daily life. Individuals with lower limb amputations have a significantly lower quality of life, reduced activity level and fall more frequently than their age-matched peers (Gyllensvärd, 2009). More proximal amputations are associated with poorer function and pose greater challenges for fitting and using a prosthesis (Fortington, Rommers, Geertzen, Postema, & Dijkstra, 2012; van Eijk et al., 2012).

After undergoing a lower limb amputation, individuals often receive a prosthesis to address impairments in mobility and function. The mechanical properties of the prosthesis can vary depending upon the specific components prescribed. Prescription of prosthetic componentry has been demonstrated to influence patient outcomes, including ambulation and balance confidence (Hafner & Askew, 2015; Paradisi et al., 2015).

One of the major advancements in prosthetic technology over the past two decades has been in the development of adaptive prosthetic knees, otherwise termed microprocessor-controlled prosthetic knees (MPK). Compared to non-microprocessor-controlled prosthetic knees (non-MPK), MPK joints have been demonstrated to improve safety (balance confidence, reduced numbers of stumbles and falls) and patient satisfaction (Hafner & Smith, 2009; Hafner, Willingham, Buell, Allyn, & Smith, 2007).

Studies investigating the effects of different prosthetic knee components have typically focused upon physical and biomechanical outcomes. There is a lack of studies that focus on other factors and how these variables may affect functioning and health-related states in prosthesis users.

This thesis focuses on persons using a lower limb prosthesis containing either a non-MPK or MPK knee joint and attempts to describe how functioning may differ in groups of individuals using knee joints with different mechanical properties.

Conceptual framework

International Classification of Functioning Disability and Health (ICF)

An amputation can affect an individual on many levels. While there are obvious physical limitations resulting from the loss of a major body segment, it is important to also consider the broader aspects of human functioning and social interactions. The ICF provides a framework within which one can operationalise the biopsychosocial model of health. The biopsychosocial model was developed by the late Engel (1977) who was critical of the long-held notion that body and soul were separate entities. As such, he proposed a more holistic approach that acknowledged the interaction between biological, psychological and social factors on person's well-being.

The biopsychosocial model proposes that health and illness are products of an interaction between biological functioning; psychological and social factors. The model can be considered as a philosophy of care as well as a way of understanding the patient's subjective experience of their own well-being (Borrell-Carrió, Suchman, & Epstein, 2004). The goal of ICF, which is published by the World Health Organisation (WHO), is to promote a unified language for classifying health and health status while acknowledging the multiple and diverse factors that can affect a person's well-being (WHO, 2001). The ICF has also proved useful for research into health and well-being, providing a framework and structure to efficiently design and execute studies and interventions which target a broad aspect of factors that have the potential to influence health outcomes.

Figure 1 presents the ICF framework. The framework suggests that an individual's functioning may be influenced on three levels; body, activity and participation in society. The way a health condition impacts functioning should also take into consideration personal factors and the context of the environment. In the ICF, the term "functioning" is used as an umbrella term that includes body functions and structures, activity and participation, as well as environmental factors. It also describes functioning in terms of capacity: what a person can do in a standardised setting and performance; what a person does in the current setting. When evaluating functioning it is important to have access to information related to both capacity and performance in order to determine what a person is capable of doing and what they actually do in their daily life (WHO, 2001).

According to the ICF, disabilities should be classified in terms of functional limitations, structural anomalies, activity limitations and participation limitations. It is also important to consider environmental factors and personal factors and attempt to determine how these hinder or facilitate functioning. Environmental factors can include techniques and products (e.g., drugs, computers, gait aids) that facilitate mobility and activities in daily life. Of relevance to this thesis, prosthetic limbs are classified as environmental factors within the ICF. Personal factors include items such as gender, age, coping styles and other variables that affect a person's experience of disability.

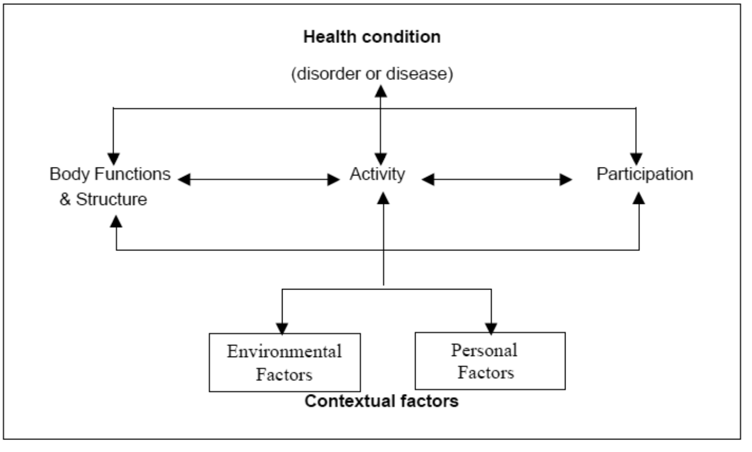

Figure 1. Structure of International Classification of Function (ICF), adapted from (WHO, 2001).

A goal of this thesis was to capture a broader perspective of functioning with a prosthesis. The perspective was intended to go beyond just the physical or biomechanical aspects of prosthetic rehabilitation and capture a range of interrelated factors that can influence everyday functioning. As such the ICF is used throughout this thesis to describe variables of interest and to facilitate understanding of the interrelationship between factors that may influence rehabilitation.

Background

Lower limb amputation

The vast majority of lower limb amputations (~90%) are due to vascular disease and performed on elderly individuals (Imam, Miller, Finlayson, Eng, & Jarus, 2017; Johannesson et al., 2009; Pohjolainen & Alaranta, 1998). In Sweden, the incidence of lower limb amputation was 33 / 100 000 inhabitants in 2016 (Swedamp, 2017). Other causes of amputation include trauma, tumour or congenital limb deficiency. Individuals amputated for these reasons are generally younger, more active and have a longer life expectancy (Amtmann, Morgan, Kim, & Hafner, 2015; Stern et al., 2017).

The three most common levels of lower limb amputation in Sweden are below the knee (trans-tibial (TT)), through the knee (knee disarticulation (KD)) and above the knee (trans-femoral (TF)) (Figure 2). The focus of this thesis is individuals who have undergone knee disarticulation and trans-femoral amputations. These levels represents at least a third of all major lower limb amputations performed in Sweden (Swedeamp, 2017).

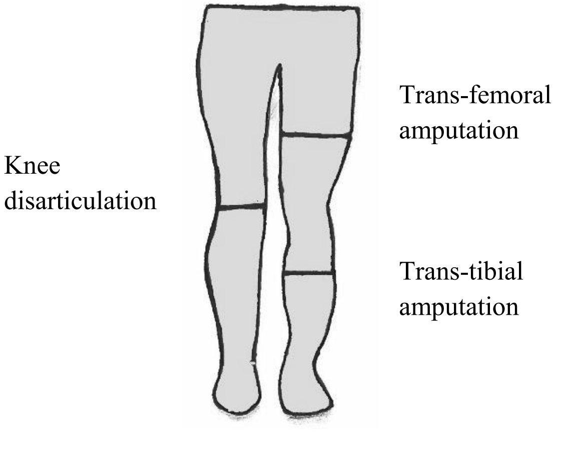

Figure 2. Amputation levels.

The main difference between a TT and TF amputation is lack of an anatomical knee joint and loss of an extensive amount of muscles. In KD and TF amputations the loss of muscles and shortened lever arms, together with pain and immobility have been shown to increase the risk in developing muscle atrophy and hip muscle and/or joint contractures (Gottschalk, 2016; Pauley, Devlin, & Madan-Sharma, 2014). This has a negative effect on walking ability and balance with a prosthesis (Lin, Winston, Mitchell, Girlinghouse, & Crochet, 2014; Penn-Barwell, 2011; Raya, Gailey, Fiebert, & Roach, 2010).

Phantom limb pain, phantom limb sensation and residual limb pain are commonly reported among 68–86% of individuals with a lower limb amputation (Davidson, Khor, & Jones, 2010; van der Schans, Geertzen, Schoppen, & Dijkstra, 2002). Other common residual limb problems are blisters, skin irritation and volume changes. These are typically related to the mechanism by which the prosthesis is attached to the limb (suspension) (van Eijk et al., 2012) and these problems have been shown to be related to avoidance of using the prosthesis and to reduce quality of life (Dillingham, Pezzin, MacKenzie, & Burgess, 2001; Hagberg & Branemark, 2001; Legro et al., 1999).

Functioning with a lower limb prosthesis

Rehabilitation after a lower limb amputation

Rehabilitation after a lower limb amputation aims to restore function and to maximise independence in daily life while promoting good health and well-being. The rehabilitation process should be managed by a specialist multidisciplinary team who carefully consider the individual's pre-amputation status, expectations and medical limitations (Broomhead et al., 2012). To reduce the risk of falls and maximise functional outcomes physiotherapy and prosthetic management are considered essential.

A prosthesis effectively compensates for the loss of a limb in terms of functional utility and cosmetic appearance (Webster et al., 2012). It is typically provided by a registered prosthetist who generates a prescription on the basis of the patient's physical presentation and goals that should be specified on four levels including those related to participation, activity, body functions and structures and technical requirements of the device (Jarl and Ramstrand, 2018). Physiotherapy should be administered by a registered physiotherapist and aims to improve joint range of motion, muscle strength, balance, fitness, motor learning and recovery of ambulation (Christiansen, Fields, Lev, Stephenson, & Stevens-Lapsley, 2015; Raya et al., 2010). Physiotherapy also includes transfers and ambulation techniques, ambulation with assistive devices, gait training as well as residual skin care and prosthetic management (Broomhead et al., 2012; Krajbich, 2016) .

Prosthetic prescription

The proportion of individuals who go on to receive a prosthesis following lower limb amputation varies greatly in the literature, mainly because of differences in aetiology, amputation level and age of participants included in the various studies. Having said this, individuals amputated at the TF level are significant less likely to be prescribed a prosthesis than individuals amputated at the TT level (Webster et al., 2012). Webster et al. (2012) reported that 29% of those amputated at the TF level receive a prosthesis four months post amputation while Johannesson et al. (2010) found that those amputated at TT level had rates of 55%. Both aforementioned studies included participants who had undergone amputations due to vascular disease. One would expect individuals who have been amputated for other reasons to be younger and healthier. They would subsequently be expected to have a higher rate of prosthetic provision. This was the case in another prospective study from Sweden that included individuals with or without vascular disease (Johannesson, Larsson, & Oberg, 2004). In this study, 35% of those amputated at TF and KD level received a prosthesis.

Several factors that affect prosthetic use have been suggested including balance and safety; feeling independent; mobility; the need to think or concentrate on every step; pain and discomfort; ability to don the prosthesis, and depression (Gauthier-Gagnon, Grise, & Potvin, 1999; Hagberg & Branemark, 2001; Schaffalitzky, Gallagher, Maclachlan, & Ryall, 2011; Webster et al., 2012) .

The number of hours per day that people use their prosthesis also varies due to aetiology, amputation, age and time since amputation. Gauthier-Ganon et al. (1999) reported that 65% of those with a TF amputation used their prosthesis 9 hours per/day or more (Gauthier-Gagnon et al., 1999).
A relationship has been reported between greater prosthetic use (more hours per day) and more distal amputations, trauma-related amputations and absence of phantom pain (Raichle et al., 2008; van Eijk et al., 2012). Moreover, prosthetic prescription and prosthetic use have been shown to reduce functional limitations and enhance the possibility to participate in daily activities (Asano, Rushton, Miller, & Deathe, 2008).

Prosthetic management involves fabrication and fitting of a prosthesis that is comfortable to wear and offers the patient an appropriate amount of stability and mobility (ISO, 2015). A lower limb prosthesis consists of an appropriately designed socket, suspended on the residual limb and coupled with components that effectively replace the shank and thigh (if necessary), knee (if necessary) and foot (Figure 3). The socket is manufactured to minimise and/or avoid tissue brake down on the residual limb (blisters and sores) (Legro et al., 1999), bear the weight of the person and be stable. Appropriate alignment of the prosthesis (i.e., positioning of the socket relative to the knee and foot) is required in order to maximise function for the individual. Depending on the characteristics of the individual and the mechanical properties of the prosthetic knee and foot, the position of these components can be placed in a more, or less stable position.

This thesis has a specific focus on different types of prosthetic knee mechanisms. The International Organization for Standardization (ISO) classifies and describes prosthetic knees based on their mechanical function and by means of the controlled motions (ISO, 2015).

Prosthetic knees are designed to mimic the bending (flexion) and swinging (extension) of the anatomical knee joint as a person walk. The ISO classification describes six specific design characteristics of the knee including motion of the knee (flexion/extension and axial translation); axis of rotation (monocentric or polycentric); stance-phase control (stability controlled by lock or brake); swing phase control (resistance during flexion/extension) and the transition between swing and stance (control between swing and stance). Under each of the six functional characteristics, a detailed description of the mechanical property in the knee is included (ISO, 2015).

While the ISO classification of prosthetic knees provides a detailed description of the knee’s characteristics, it is not widely used in practice or research settings. Berke and Geil (2013) suggest describing the prosthetic knees in relation to their brake mechanism. This description is not standardised but is used by several research groups (Hafner & Askew, 2015; Howard, Wallace, Perry, & Stokic, 2018; Sawers & Hafner, 2013).

Under this classification the knees are categorised by their brake-control mechanism; passive, adaptive or active (Figure 4). Passive knees are locked either with a manual lock, mechanical friction brake or hydraulic/pneumatic resistance mechanism (Michael, 1999; Romo, 2000) (Figure 4 A-B). The adaptive control system includes senses (e.g., joint position in space, direction of movement and ground reaction force) and an ability to alter the resistance mechanism on the basis of the sensed information (Berke & Geil, 2013). Typically, the sensed information is run through a computer to alter the braking resistance. These knees are often termed microprocessor-controlled prosthetic knees (MPK) or computerised knees (Figure 4 C-D). The intention of this adaptive mechanism is to have the knee continuously adjust its resistance properties and in doing so adapt to the user´s needs in varying conditions (e.g., altering walking speed, predict stumbling, walking up and down stairs (Sawers & Hafner, 2013). Active knees include, in addition to an adaptive knee control-system, a motor to either assist or resist joint motion (Berke & Geil, 2013).

Prosthetic knees in this thesis have been classified according to their brake-control system. Only passive and adaptive prosthetic knees are included, and they will be termed as non-microprocessor-controlled knees (non-MPK) and microprocessor-controlled prosthetic knees (MPK) respectively.

MPK units are considerably more expensive than non-MPK alternatives (Brodtkorb, Henriksson, Johannesen-Munk, & Thidell, 2008; Cutti et al., 2017) and this has led to greater demands on clinicians to justify component prescription to both funding agencies and patients (Theeven et al., 2011). There is a growing body of evidence supporting prescription of MPK. A systematic review has indicated that MPK units are preferred by patients as they are perceived to facilitate increased mobility and to reduce the cognitive effort required to ambulate (Sawers & Hafner, 2013). MPK units have also been found to be associated with improved gait mechanics, increased confidence and safety in ambulation, increased satisfaction, improved comfort and balance as well as reducing the number of falls compared to non-MPK units (Berry, Olson, & Larntz, 2009; Hafner & Smith, 2009; Hafner et al., 2007; Kahle, Highsmith, & Hubbard, 2008; Kaufman et al., 2008).

Figure 3. An example of a TF prosthesis consisting of a socket, a prosthetic knee and a prosthetic foot. Picture reprinted with permission (©2018 Ottobock).

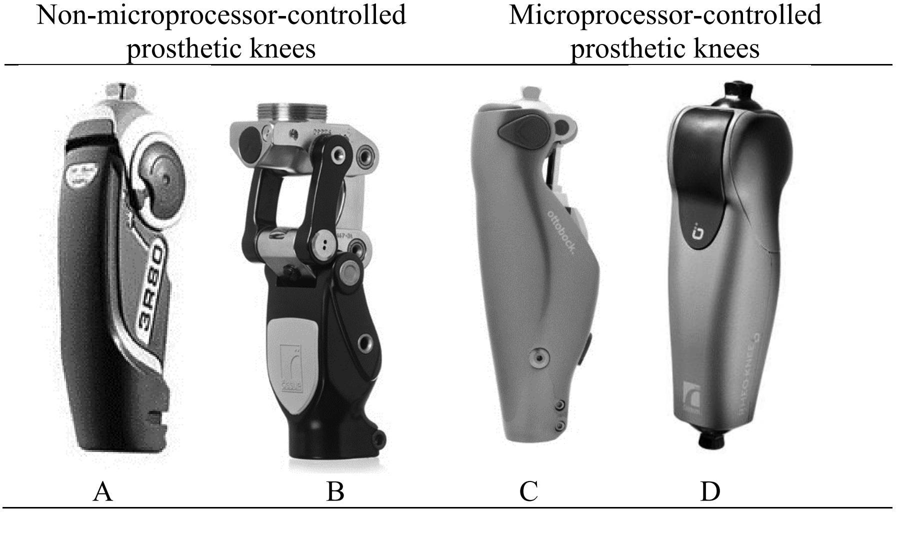

Figure 4. Example of prosthetic knee joints included in this thesis.
Non-MPK: non-microprocessor-controlled knees; A:3R80 (©2018 Ottobock) and B: Total Knee® 2000 (Össur);
MPK: microprocessor-controlled prosthetic knees; C:C-leg (©2018 Ottobock) and D: RHEO KNEE® II (Össur). Pictures reprinted with permission.

Mobility

In ICF, mobility is categorized within the component activity and participation and referred to as changing body position or transferring from one place to another (WHO, 2001). Mobility is the outcome that has received most attention in literature related to patients with lower limb amputation and the design and provision of prostheses. It is widely accepted that individuals using lower limb prostheses have reduced mobility compared to their able-bodied peers (Amtmann et al., 2015; Wurdeman, Stevens, & Campbell, 2018). Mobility has also been shown as directly related to quality of life, satisfaction with life (Norvell, Turner, Williams, Hakimi, & Czerniecki, 2011; Suckow et al., 2015) and cognitive functioning (Kelly, Morgan, Amtmann, Salem, & Hafner, 2018; Williams et al., 2015). Level and cause of amputation, co-morbidities, joint contractures, shorter residual limb length, anxiety and depression have all been identified as contributing to reduced mobility (Gaunaurd et al., 2013; Norvell et al., 2011; Raya et al., 2010)

Self-efficacy

Perceived self-efficacy originates from social cognitive theory and refers to the extent to which an individual believes that they are capable of performing in a specific situation (Bandura, 1997). Self-efficacy has been described as being directly related to positively-valued characteristics such as motivational levels, self-control and improved coping (Parschau et al., 2014) while it is negatively related to depression, anxiety, and helplessness (Löve, Moore, & Hensing, 2012; Schwarzer, Mueller, & Greenglass, 1999). Generalised self-efficacy is a term used to describe an individual's belief that they can perform in any situation while domain specific self-efficacy explains behaviour in more specific contexts (i.e., pain, balance).

General self-efficacy has received little attention in literature related to lower limb amputations. Specific self-efficacy has however been included in several studies. Miller, Speechley, and Deathe (2002) have shown that a worse score on a balance specific self-efficacy measure—the Activity-Specific Balance Confidence scale (ABC)—correlates with reduced prosthetic mobility, capability, and reduced participation in social activities in persons with a lower limb amputation. Moreover, Hafner and Askew (2015) reported an increase in ABC when persons with a lower limb amputation changed from a non-MPK to an MPK unit. To the author's knowledge, study II in this thesis is the first to describe general self-efficacy in relation to prosthesis users.

Attention

A number of theories illustrate the importance of cognitive mechanisms in motor behaviour and several of these highlight the important role that attention plays in regulation of the motor system (Lohse, Jones, Healy, & Sherwood, 2014).

Specific theories of attention may help us to understand why individuals with impairments at the body level, such as a lower limb amputation, have difficulty walking while performing a simultaneous task (e.g., walking while talking). Early theories of attention suggested that information processing was carried out in a serial manner—passing through a filter—before a response could occur (bottle neck theory). Later theories moved from the idea of a filter towards a central reservoir of resources. An example of this central resource concept is Kahneman's Attention Theory (Kahneman, 1973). Kahneman (1973) suggests that attention can be regarded as cognitive effort and that attentional resources available to perform an activity at any given time are limited. This attentional capacity can be visualised as a vessel with a fixed volume of available attention that a person can selectively allocate to one or several activities at the same time (Figure 5).

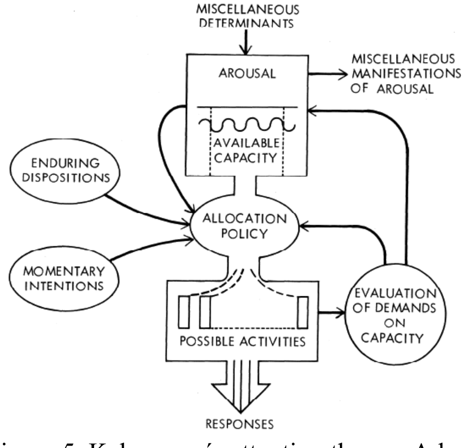

Figure 5. Kahneman´s attention theory. Adapted from (Kahneman, 1973)

For many people with disabilities it has been shown that tasks such as walking require a higher degree of attention and it is therefore more difficult to complete several tasks simultaneously (Kelly, Eusterbrock, & Shumway-Cook, 2012; Rochester, Galna, Lord, & Burn, 2014). According to Kahneman's theory, this suggest that a large portion of their attentional capacity is required to perform the task of walking, leaving and that limited resources remain for performing secondary activities. The concept of allocating resources to more than one task simultaneously has been described as divided attention while the process of focusing cognitive resources on one task is termed selective attention (Hahn et al., 2008).
The idea that people with a disability need to allocation more attentional resources to walked is supported by comments commonly made by prosthetic users suggesting that they have to concentrate much more when they walk (Gauthier-Gagnon et al., 1999; Miller, Speechley, & Deathe, 2001). In a two-group, crossover trial, Williams et al (2006) reported a subjective reduction in the self-reported need of attention when walking with an MPK (C-leg, Otto Bock) compared to a non-MPK. Interestingly, differences in objective measures of cognitive load, walking while performing a serial subtraction were not observed (Williams et al., 2006).

Little is known about how performance on a secondary task interferes with gait when walking with a prosthesis. Howard, Wallace, Abbas, and Stokic (2017) showed that stride length become significantly shorter when a secondary-task is added. One recently published review suggested an interaction between attentional demand and postural tasks and recommend that future research should include a standardised self-report measure and neural imaging to assess attentional demand in individuals walking with a prosthesis (Morgan, Hafner, & Kelly, 2017).

A premise of this thesis is that the use of a lower limb prosthesis requires individuals to allocate a greater portion of their attentional resources to maintaining balance and stability and that this limits the amount of resources remaining for performance of other activities.

Measuring functioning with a lower limb prosthesis

Mobility

Mobility can be measured in laboratory environments as well as in naturalistic settings. Laboratory based studies investigating individuals walking with lower limb prostheses typically utilise two- or three-dimensional gait analysis to study gait patterns and efficiency of movement. These studies typically measure energy expenditure, gait kinematics and kinetics (Bellmann, Schmalz, & Blumentritt, 2010; Iosa et al., 2014). One criticism of laboratory-based studies is that they capture an overview of what an individual is capable of (i.e., capacity) but not what they actually do in their daily life, i.e., performance. As such, a number of studies have attempted to quantify mobility in naturalistic settings. These studies have utilised self-report instruments and activity monitors to evaluate mobility. Self-report measures that address issues related to mobility include quality of life measures, satisfaction with life and prosthetic mobility measures (Davie-Smith, Paul, Nicholls, Stuart, & Kennon, 2016; Norvell et al., 2011; Suckow et al., 2015; Wurdeman et al., 2018). Activity monitors are typically worn around the ankle or waist and measure the number of steps taken by the wearer. Studies involving activity monitors have demonstrated that individuals with a lower limb amputation take fewer steps every day (1942–2204 steps/day) (Hafner & Askew, 2015) compared to older adults (50–94 years) who take on average 2000–9000 steps/day (Tudor-Locke, Hart, & Washington, 2009).

Self-efficacy

Self-efficacy is typically measured using a self-report questionnaire. Questionnaires related to self-efficacy can be general or specific. General self-efficacy measures address an individual's overall belief that they can achieve their goals whatever they may be. An example of a question related to general self-efficacy is "I can always manage to solve difficult problems if I try hard enough". Specific measures of self-efficacy address the individual's belief that they can succeed in a specific task (e.g., balance or falls) or despite the existence of a specific impairment (e.g., pain). An example of a question related to specific balance self-efficacy is "how confident are you that you will not lose your balance or become unsteady when you walk around the house?"

Attention

Quantitative measures of attention are difficult to capture. Within gait research, the most popular method of evaluating attentional demand has been to use a dual-task paradigm, while studies within psychology more often quantify attention using neuroimaging techniques such as magnetic resonance imaging (MRI), Electroencephalography (EEG) and functional near-infrared spectroscopy (fNIRS).

Dual-task paradigms investigate attentional demand and available attentional capacity by comparing performance on a single-task (e.g., walking on level ground) to performance of two tasks simultaneously (e.g., walking while counting backwards). The type of dual-task used in research studies involving gait varies but includes cognitive, e.g., serial subtraction (LaRoche, Greenleaf, Croce, & McGaughy, 2014) and motor dual-tasks, e.g., carrying a full glass of water (McIsaac et al., 2015). The more attention that is required to perform a dual-task, the more it is expected to interfere with performance of the primary activity. Dual-task interference during walking has been associated with an increased risk of falls, slower gait, an increased number of steps and reduced stability in elderly persons (Beauchet et al., 2009; Beauchet et al., 2007) and persons with Parkinson's disease (Rochester et al., 2014).

Attentional demand can be observed neurologically as an increase in brain activity in the pre-frontal cortex which, among other things, is associated with planning actions and making decisions (Magill, 2010). Traditional neuroimaging techniques such as fMRI provide a detailed picture of brain activity in both the cortical and subcortical structures. However, these are limited in their use as they cannot capture performance on dynamic activities such as walking. Over the past decade there have been major advancements in imaging technology which allow visualization of brain activity in dynamic settings.

One method that is increasingly used is functional near-infrared spectroscopy (fNIRS) (Mirelman et al., 2014). fNIRS is a non-invasive optical method similar to fMRI and measures haemodynamic response to a stimulus as a result of neural activity. While fMRI measures activity in the brain using the paramagnetic properties of de-oxyhaemoglobin (de-oxyHb), fNIRS is based on the absorption of infrared light in the blood. fNIRS can measure the concentration in both oxy-haemoglobin (oxyHb), de-oxy haemoglobin and total haemoglobin (HbT). fNIRS consist of a light source that is coupled to the participant's head and through fibre-optical bundles with a detector that receives the light after it has been scattered through the skull and brain tissue. A major advantage of fNIRS is its portability (Yucel, Selb, Boas, Cash, & Cooper, 2014) and ability to be used during dynamic activities (Holtzer et al., 2015) and over long periods of time (Zhang & Khatami, 2015). However, there are disadvantages that include relatively low spatial resolution and the lack of sensitivity to sub-cortical structures of the brain (Boas, Elwell, Ferrari, & Taga, 2014; Cutini & Brigadoi, 2014).

fNIRS has been proven sensitive to cortical brain activity (Fishburn, Norr, Medvedev, & Vaidya, 2014) and provides a unique opportunity to explore the effect that rehabilitation interventions have on cognitive processes. A number of studies are now emerging in which fNIRS has been used to study cognitive processes of individuals performing a variety of dynamic motor activities. Patient groups studied to date include persons with multiple sclerosis (Stojanovic-Radic, Wylie, Voelbel, Chiaravalloti, & DeLuca, 2015), stroke (Brunetti et al., 2015; Rea et al., 2014), cerebral palsy (Khan et al., 2010; Tian et al., 2010) and Parkinson's disease (Maidan et al., 2015). Of interest to this thesis are studies that have investigated cortical brain activity during walking.

To the author's knowledge, studies III and IV in this thesis represent the first-time cortical brain activity has been investigated during a dynamic motor task in individuals with a lower limb amputation.

Rationale

Persons with TF or KD amputations experience impairment of body functions, and limitations in activity and participation.

Prosthetic prescription and in particular the knee joint prescription, may play a key role in addressing these issues. To date, research and clinical practice has largely focused on biomechanical outcomes related to prosthetic prescription and little consideration has been given to other areas that may affect human functioning.

To determine how an individual's life is affected by an amputation, it is necessary to apply a holistic view and to include outcome measures that address all the areas with the potential to affect functioning with a prosthesis for individuals with a lower limb amputation.

Therefore, in this thesis, activity and participation, body function and structure as well as environmental factors are explored in relation to individuals with a lower limb amputation using different types of prosthetic knee components, i.e., knees including a microprocessor or not.

Aim

Aims of the thesis

The overall aim of this thesis was to describe and compare functioning in individuals with a trans-femoral amputation or knee disarticulation and the relative effects of using non-microprocessor-controlled prosthetic knees (non-MPK) or microprocessor-controlled prosthetic knees (MPK).

Specific aims of each paper

Article I.
To investigate potential differences in persons using non-MPKs versus MPKs, with a focus on mobility.

Article II.
a/ To measure self-efficacy in a group of individuals who have undergone a lower limb amputation and investigate the relationship between self-efficacy and prosthetic-specific outcomes including prosthetic use, mobility, amputation-related problems and global health.
b/ To examine if differences exist in outcomes based upon the type of prosthetic knee unit being used.

Article III.
To assess cortical brain activity during level walking in individuals using different prosthetic knee components and compare them to healthy controls.

Article IV.
To investigate effects of increased cognitive load on cortical brain activity and temporospatial gait parameters in individuals using a prosthesis with either a non-microprocessor-controlled prosthetic knee (non-MPK) or microprocessor-controlled prosthetic knee (MPK) and healthy controls.

Materials and methods

Design and measures

The studies in this thesis used a cross-sectional, quantitative design and different types of data collection methods were used (Table 1). The first study included both self-report data, tests of capacity and performance. The second study was a survey which included two questionnaires. Studies III and IV used a neuroimaging technique to quantify cortical brain activity during gait. As depicted in Table 1, a variety of different outcome measures were used. In selecting different measures attempts were made to cover all components of the ICF.

Table 1. Overview of papers I–IV in this thesis.

Paper	Study design	Sample	Measures	Data analysis
I	Descriptive Cross-sectional, Quantitative	14 non-MPK 15 MPK	EQ-5D-5L; Prosthetic use score; ABC; PLUS-M; 6MWT; AMP; SAI; StepWatch	Descriptive statistics
II	Survey, Cross-sectional Quantitative	23 non-MPK 19 MPK	Q-TFA; GSE	Descriptive statistics and Ordinal logistic regression
III	Cross-sectional Quantitative	14 non-MPK 15 MPK 16 controls	fNIRS; the time and number of steps taken during level walking	Descriptive statistics and statistical parametric mapping
IV	Cross-sectional, Quantitative	14 non-MPK 15 MPK 16 controls	fNIRS and two dual-task tests; velocity; cadence and time to complete TWT.	Descriptive statistics and ANOVA

Non-MPK: non-microprocessor-controlled prosthetic knee; MPK: microprocessor-controlled prosthetic knee; EQ-5D-5L: European Questionnaire-5 dimension- 5 Level; ABC: Activity Balance Confidence; PLUS-M: Prosthetic Limb Users Survey of Mobility; 6MWT: 6-minute Walk Test; AMP: Amputee Mobility Predictor; SAI: Stair Assessment Index; Q-TFA: Questionnaire for Persons with a Transfemoral Amputation; GSE: General Self-Efficacy scale; fNIRS: Functional near-infrared Spectroscopy system.

Linking of outcome measures according to the ICF

By including the ICF as a framework it is possible to gain a more comprehensive understanding of mobility with a prosthesis which is not just limited to body and prosthetic function. All measures included in this thesis (Table 1) have subsequently been linked to the ICF coding system of function to demonstrate how aspects of functioning with a prosthesis are addressed (Table 2).

The coding structure of ICF is hierarchical. The prefix within the ICF represents the codes for body functions (b), body structure (s), activity and participation (d) and environmental factors (e). The category activity and participation can be used as one component or be divided. When divided, activities are defined as actions and tasks executed by individuals while participation is defined as involvement in life situations. In this thesis, activity and participation were divided where chapters 1–4 of the ICF represented activity (a) and chapters 5–9 represented participation (p) (WHO, 2001). A digit from one to three was then used for second-level categories. In accordance with recommendations in the ICF practical manual, the component was first selected and then the category best describing the aspect of functioning illustrated in the specific outcome measures. Classification were chosen with consideration of the purpose of recording information (WHO, 2001). Some of the measures included in this thesis consisted of several scores or items. Every score or item has been read several times to find the category describing it best and was then linked to one single component. For example, the Questionnaire for Persons with a Transfemoral Amputation (Q-TFA) involves both questions about different aspects of mobility in daily activities and problems related to sensations of pain and temperature. In this case mobility was linked to activity while sensations of pain were linked to body function (Table 2).

Table 2. Linking of measures used in this thesis according to ICF coding system

Self-report measures	**Study**	**Component**	**Chapter**	**Definition**
ABC	I	Body functions	b1	Mental functions
EQ-5D-5L index	I	Activity	d4-5	Mobility, Self-care
		Participation	d6	Domestic life
		Body functions	b1-2	Mental functions, sensory functions and pain
EQ-5D VAS	I	Not definable		
GSE scale	II	Activity	d1-2	Learning and applying knowledge, General tasks and demands
		Body functions	b1	Mental functions
PLUS-M	I	Activity	d4	Mobility
Q-TFA	II	Activity	d4	Mobility
		Body functions	b1-2	Mental functions, sensory functions and pain
		Environmental factors	e1	Products and technology
Capacity and performance				
AMP	I	Body functions	b7	Neuromusculoskeletal and movement-related functions
		Activity	d4	Mobility
fNIRS	III-IV	Body structure	s1	Structure of brain
KEY	IV	Activity	d1	Learning and applying knowledge
TWT	IV	Activity	d1	Learning and applying knowledge
6MWT	I, III, IV	Activity	d4	Mobility
SAI up/down	I	Activity	d4	Mobility
		Environmental factors	e1	Products and technology
SW	I	Activity	d4	Mobility

ABC: Activity Balance Confidence; EQ-5D-5L: European Questionnaire-5 dimension- 5 Level; VAS: Visual Analog Scale; GSE: General Self-Efficacy scale; PLUS-M: Prosthetic Limb Users Survey of Mobility; Q-TFA: Questionnaire for Persons with a Transfemoral Amputation; AMP: Amputee Mobility Predictor; fNIRS: Functional near-infrared Spectroscopy system; KEY: Sorting through keys test; TWT: The trail-walking test; 6MWT: 6-minute Walk Test; SAI: Stair Assessment Index; SW: Step Watch.

Outcome measures

Generic measures are developed for application across a variety of conditions and subsequently allow for comparison to other groups and healthy controls. Specific outcome measures are typically developed to be applied on individuals who have a common condition. As specific outcome measures are designed for a particular condition, they may be more sensitive in detecting change in a specific group (Patrick & Deyo, 1989). To be able to summarise a broad spectrum of the concepts of health and well-being, both generic and specific outcome measures have been used in this thesis.

In recent years there has been increasing attention directed towards the importance of measuring the individual patient's own experience of health care and health-related outcomes. Outcome measures that are designed to capture this information are termed Patient Report Outcomes Measures (PROMs). While traditional biomechanical and physiological outcome measures may demonstrate benefits of an intervention at the body structure and functional level, PROMs can provide a more holistic assessment of the intervention. These instruments are often self-rated questionnaires of quality of life, functional status and symptoms such as anxiety or fear (Weldring & Smith, 2013). To get a comprehensive understanding of a person's health and health status it is of importance to evaluate both the individual's own experience, capacity—what the person is capable to do—as well as performance — what the person actually do in their daily life.

This thesis includes a broad range of outcome measures, each one described below.

European Questionnaire-5 Dimension-5 Level (EQ-5D-5L) (Study I)

EQ-5D is a generic instrument widely used to measure health-related quality of life and consists of five domains including physical mobility, self-care, usual activities, pain/discomfort and anxiety/depression. The instrument was developed by the EuroQol group, an international network of multidisciplinary researchers (Brooks, 1996). The EQ-5D has been tested and used on both general populations and disease specific populations and has been translated to more than 130 languages. It is the most commonly used measure for calculating quality-adjusted life years (Rasanen et al., 2006) by use of the preference-based EQ-5D index value. The earlier version EQ-5D had three levels of answers for each of the five questions, but a recently developed version now includes five levels (EQ-5D-5L). The five-level version was developed in an attempt to increase sensitivity and to reduce ceiling effects (Herdman et al., 2011).

Each domain is rated on a five-level scale (no problem, slight problem, moderate problem, severe problem and extreme problem). It also includes a visual analogue scale (VAS), which is used to rate the respondent's perception of their current overall health status and is rated from 0 to 100. EQ-5D-5L has good psychometric properties in general populations and has been evaluated for use with a number of specific conditions which include stroke (Golicki et al., 2015), Parkinson's disease (Xin & McIntosh, 2017), and chronic diseases (Sakthong, Sonsa-Ardjit, Sukarnjanaset, & Munpan, 2015). While the EQ-5D-3L has previously been used to calculate quality-adjusted life years in economic evaluations comparing the non-MPK and MPK (Cutti et al., 2017; Gerzeli, Torbica, & Fattore, 2009) the EQ5D-5L has not previously been utilised. EQ-5D-3L is validated in the Swedish language (Burstrom, Johannesson, & Diderichsen, 2001).

The dimensions of EQ-5D-5L address issues related to body function, activity and participation domain within the ICF. Physical mobility is linked to the domain activity, while self-care and usual-activities are linked to participation. The dimensions of pain/discomfort and anxiety/depression are linked to body functions (Table 2).

Questionnaire for Persons with a Transfemoral Amputation (Q-TFA) (Study II)

The Q-TFA is a condition specific questionnaire which includes information related to prosthetic use, prosthetic mobility, amputation and prosthesis related problems and global health for persons with a TF amputation. The Q-TFA has been found to correlate with most of the sub-scales of the SF-36 health survey and has been demonstrated to be valid and reliable (Hagberg, Brånemark, & Hägg, 2004). Q-TFA generates four separate scores: a prosthetic use score, prosthetic mobility score, global score and problem score. Each score ranges from 0 to 100 where 100 indicate that the prosthesis is normally used more than 15 hours every day, best possible prosthetic mobility and best possible overall situation. The problem score is inverted, and a higher score indicates more serious problems. In Study II all four scores of Q-TFA were included. In Study I, III and IV only the prosthetic use score was included. Questions in Q-TFA cover aspects of prosthetic functioning from three components of the ICF, activity, body functions and environmental factors (Table 2).

Mobility

Prosthetic Limb Users Survey of Mobility (PLUS-M) (Study I)

The PLUS-M™ 12-item Short Form (1.2) Swedish and Norwegian versions were used in study I. PLUS-M was specifically developed for adults with a lower limb amputation and measures a prosthetic user´s mobility (Amtmann et al., 2014). This version of PLUS-M consists of 12 items where individuals are asked to rate their perceived ability to carry out a range of activities ranging from household ambulation to outdoor reactional activities. Answers are given on a five-level scale from “not able to do” to “able to do without any difficulty”. The PLUS-M instrument provides a T-score between 17.5 to 76.6 (SD 10): a higher score indicates a greater level of mobility and a T-score of 50 represents the mean reported by the development sample of persons with a lower limb amputation (Amtmann et al., 2014). The PLUS-M has been demonstrated to have good reliability and convergent validity with the AMP and the Timed Up and Go test (Gaunaurd et al., 2015; Hafner, Morgan, Askew, & Salem, 2016).

When reviewed against the ICF framework, questions in PLUS-M relate to the activity component (Table 2).

Amputee Mobility Predictor (AMP) (Study I)

AMP is a functional mobility test specifically developed to evaluate persons with lower limb amputation with or without a prosthesis (Gailey et al., 2002). The AMP consists of 21 items and includes tasks such as sitting and standing balance and gait symmetry. When applying this measure, a therapist rates performance according to predetermined criteria. The total score is 47 points, with a higher score representing better mobility. The AMP has been shown to be valid and reliable and is recommended for clinical and research use (Gailey et al., 2002). The minimal detectable change for the AMP has been proposed to be 3.4 points (CI 90%) (Resnik & Borgia, 2011). The AMP correlates strongly to the 6MWT (Gailey et al., 2002) and is positively correlated to PLUS-M (Hafner et al., 2016).

Most items in the AMP have been linked to the activity component of ICF. The exception is items involving specific gait asymmetry (item 15–19) which are linked to the body functions component (Table 2).

Stair Assessment Index (SAI) (Study I)

The Stair Assessment Index (SAI) was specifically developed to assess gait performance of individuals with lower limb amputations as they ambulate up and downstairs (Buell, Waddingham, Allyn, Hafner, & Smith, 2004). This outcome measure utilises a 14-point scale (0–13) which describes the strategy used by the individual to ascend or descend stairs. The maximum score is given when a person can ambulate step-over-step without using a handrail or assistive device. Psychometric evaluations have demonstrated the SAI to be stable for assessing stair ambulation in a population of persons with TF amputations (Hafner et al., 2007; Highsmith et al., 2016).

While the SAI was developed as a functional test to be applied using a standardised staircase, in the present study participants were simply asked to describe their typical strategy for ascending and descending stairs. This was necessary as data collection took place within different facilities and it was not possible to access a standardised staircase. Within the ICF framework, the SAI is classified under mobility within the activity component (Table 2).

Step Watch (Study I)

Activity monitors are increasingly being used to provide an indication of mobility outside of the laboratory environment. They can measure home and community activity continuously and can be used as an assessment of daily physical activity (Yang & Hsu, 2010). In this research the StepWatch™ 3.1 activity monitoring system (Modus Health Edmonds, WA) (SW) was used. StepWatch have been shown to be valid and reliable across populations, including persons with limb loss (Coleman, Smith, Boone, Joseph, & del Aguila, 1999; Stepien, Cavenett, Taylor, & Crotty, 2007). In study I, the StepWatch™ 3.1 was pre-set to record the number of steps taken every minute for 14 days and the device was attached to the prosthetic pylon at the level of the ankle. Each participant was instructed to wear the StepWatch for 14 days. Daily activity as measured with a step counter was linked to the activity component of the ICF (Table 2).

6-minute Walk Test (6MWT) (Study I and III–IV)

The widely used 6MWT is a generic measure of sub-maximal functional capacity (Butland, Pang, Gross, Woodcock, & Geddes, 1982). The 6MWT measures the distance a person can ambulate on flat surface for six minutes. It has been used extensively in assessment of individuals affected by lung and heart disease but is also common as a measure of overall mobility and physical functioning in older populations (Lord & Menz, 2002) and in individuals with lower limb amputation´s (Gailey et al., 2002). The 6MWT has been demonstrated to have high convergent validity when compared to the AMP and ABC (Gailey et al., 2002; Resnik & Borgia, 2011). A minimal detectable change of 45 m (CI 90%) has been proposed (Resnik & Borgia, 2011). The 6MWT has been used in earlier research comparing prosthetic components (Howard et al., 2018). Due to limited space, the 6MWT in this research was conducted on a 20 m track rather than recommended 30 m track. The 6MWT was classified as mobility in the activity component of the ICF (Table 2).

Temporospatial data (Study III and IV)

During single-task and dual-task walking, the researchers recorded the number of steps, time taken to walk 10 m as well as the time to complete the tests. Earlier research has indicated that the addition of a secondary task has a negative effects on gait performance. Lundin-Olsson, Nyberg, and Gustafson (1997) showed worse mobility and a unsafe gait during dual-task walking and Dubost et al. (2006) showed that there was a correlation between dual-task walking, increased stride time and double-limb support in older adults.
Temporospatial data was linked to the activity component of the ICF (Table 2).

Self-efficacy

Activities-Specific Balance Confidence Scale (ABC) (Study I)

The ABC is a generic self-efficacy measure which evaluates confidence in performing specific activities without losing balance or becoming unsteady (Powell & Myers, 1995). The ABC has been translated and validated in several languages, including Swedish (Nilsagård & Forsberg, 2012) and for a number of populations (Park, Lee, & Choi, 2018). In the ABC, respondents are required to self-rate their balance confidence in performing 16 different activities. Each activity is scored from 0% to 100% with higher scores representing higher levels of balance confidence. Activities range from picking an object up from the floor or above one´s head, walking in a parking lot or on an icy sidewalk. Psychometric properties of the ABC in people with lower limb amputation have been evaluated extensively. It has excellent reliability and good convergent validity with the 2-minute walk test and Timed Up and Go test (Miller, Deathe, & Speechley, 2003; Sakakibara, Miller, & Backman, 2011). The ABC has also been found to be associated with PLUS-M scores (Hafner et al., 2016). The ABC addresses "confidence" and in this thesis it was linked to the body functions component within the ICF as confidence is an aspect of emotional functions (Table 2).

General Self-efficacy (GSE) (Study II)

The GSE is a generic measure of an individual's perceived self-efficacy in several daily activities. Although it has not previously been used in lower limb amputation populations, it has been shown to be positively correlated in both emotional, physical and social quality of life domains in adolescents with physical disabilities (Cramm, Strating, Roebroeck, & Nieboer, 2013). The GSE has also been shown to be positively related to daily activity, functional ability and life satisfaction while it is negatively related to falls and depressive symptoms in persons with Parkinson's disease (Nilsson, Hagell, & Iwarsson, 2015).

The GSE consists of ten statements. Examples of questions include, "I can always manage to solve difficult problems if I try hard enough" and "I can remain calm when facing difficulties because I can rely on my coping abilities". Answers to the GSE scale are rated on a four-point Likert scale ("not at all true" to "exactly true"). A total score can vary from 10 to 40, where a

higher score indicates higher self-efficacy. Individuals scoring high self-efficacy have been shown to be likely to have a better ability to set goals that are more challenging and to overcome difficult situations (Carlstedt, Lexell, Pessah-Rasmussen, & Iwarsson, 2015; Fliess-Douer, van der Woude, & Vanlandewijck, 2011; Löve et al., 2012). The GSE scale has been demonstrated to have high reliability, stability and construct validity (Leganger, Kraft, & Roysamb, 2000; Scholz, Dona Gutiérrez, Sud, & Schwarzer, 2002; Schwarzer & Jerusalem, 1995). The Swedish translation of the GSE scale (Koskinen-Hagman, 1999) has been demonstrated as valid (Löve et al., 2012; Nilsson et al., 2015).
The questions included in GSE cover aspects of the ICF which fall within the body function and activity component (Table 2).

Attention

Functional Near-Infrared Spectroscopy (fNIRS) (Study III and IV)

fNIRS is a neuroimaging technique that measures the brain's haemodynamic response to a stimulus by recording relative changes in the concentration of oxygenated (oxyHb) and de-oxygenated (de-oxyHb) haemoglobin. The NIRSport™ tandem system (NIRx Medical Technologies LLC) used in this research is wireless, portable, and uses a continuous wave light source to capture relative changes in haemoglobin concentration in user-defined regions of the brain. fNIRS has been used to demonstrate an association between an increased hemodynamic response in the medial primary sensorimotor cortices and the supplementary motor areas of the brain during human walking (Miyai et al., 2001). It has also been used to demonstrate that activity in the left prefrontal cortex and the supplementary motor areas increases when walking at a higher intensity and that activation in the prefrontal cortex is greater in subjects with reduced gait capacity (Harada, Miyai, Suzuki, & Kubota, 2009). fNIRS is an emerging technique that is sensitive to cognitive load (Fishburn et al., 2014) and has been validated against fMRI for motor and cognitive tasks (Cui, Bray, Bryant, Glover, & Reiss, 2011). The measure of oxyHb and de-oxyHb has been linked to the body structure component of ICF (Table 2).

Dual-task tests (Study III and IV)

Sorting through keys while walking (KEY test) is a dual-motor task that measures the ability to walk and simultaneously find a specific key on a keyring. The test was developed to involve a real-world motor task. The KEY test has been used to investigate differences in performance of prosthetic users (Howard, Wallace, Rock, & Stokic, 2013). The test consists of a keyring with coloured and numbered keys. Participants are requested to walk on flat surface and simultaneously identify a pre-determined specific key (Figure 9). Whenever one or both tasks show a decrement it is assumed to indicate the occurrence of cognitive-motor interference. This test has not been validated or tested for reliability.

The trail-walking test (TWT) is a generic dual-motor task that measures the ability to negotiate one's way around randomly placed cones. The test consists of 15 numbered (from 1–15) cones in an area of 5 × 5 metres. The participant walks in sequence from cone 1 to cone 15 as quickly and correctly as possible while the time to complete the test is recorded with a stopwatch. The TWT has been shown to predict an increased risk of falling in elderly healthy individuals (Yamada & Ichihashi, 2010). In this study, the TWT was modified to fit in a corridor at the different facilities used during data collection. The modified TWT consisted of six cones numbered from 1 to 6 and placed in an area of 4 × 1 metres (Figure 11). The order of the cones was altered for each walking trial but remained the same between participants. Participants were asked to walk in sequence from cone 1 to cone 6 at a self-selected walking velocity.

The two dual-task tests included in Study IV were linked to the activity component of ICF (Table 2).

Setting and participants

Participants

Participants with amputations included in Studies I, III and IV

Studies I, III and IV are derived from the same cross-sectional data collection. Participants were recruited from prosthetic and orthotic clinics in Sweden and Norway (Table 3). Inclusion criteria were; individuals aged over 18 years, having a unilateral TF or KD amputation and using a prosthesis. Participants were required to be a minimum of one-year post-amputation, having used their current prosthetic knee joint for a minimum of three months, being able to walk continuously for 500 m indoors with no more than one gait aid (i.e., a crutch or a stick) and able to read and understand Swedish or Norwegian. Individuals who had been provided with a bone-anchored prosthesis or had any additional physical limitations or cognitive impairments (Mini Mental State Examination TEST < 27) (Palmqvist, Hansson, Minthon, & Londos, 2009) were excluded from the study. Out of 41 individuals fulfilling these criteria 30 agreed to participate in the research. Of the 11 who did not participate, 7 were MPK users.
All but two of the included participants used a prosthetic socket suspended using a pressure-differential suspension method (with or without liner). Two participants in the MPK-group had a liner with a mechanical coupling. All participants were provided with an unjointed, energy restoring prosthetic foot (International Organization for Standardization, 2015).

Participants in Study II

Participants included in Study II were extracted from a previous data collection consisting of 74 participants aged between 18–88 years. 42 individuals from the original 74 were selected for inclusion in this study on the basis that they were between 18–66 years; had a unilateral TF or KD amputation; been provided with a prosthetic knee joint during the period January 2008 to December 2012 and had the ability to read and understand Swedish. Individuals provided with a bone-anchored prosthesis were excluded. The cause of amputation in the larger group of 74 participants were tumour, trauma, vascular disease or other non-vascular causes and the mean age of participants using an MPK was 46 years while those using a non-MPK were significantly ($p < 0.001$) older (mean age 68 years). Due to the significant differences in age between the two groups using non-MPK versus an MPK joint, attempts were made in Study II to achieve a more homogenous group by including only individuals aged between 19 and 66 years, based on the oldest person using an MPK joint. The cause of amputation for the final group ($n = 42$) was tumour, trauma or other non-vascular causes: the groups are described in detail in Table 4.

Controls in Studies III and IV

A control group was included in studies III and IV (Table 5). Individuals in the control group were recruited on the basis that they were able-bodied individuals over the age of 18 years, could understand and read Swedish or Norwegian, did not have any physical limitation that could affect performance or that they did not have any cognitive impairments (MMSE < 27) (Palmqvist et al., 2009). Stratified sampling was used to ensure that groups were homogeneous in terms of age and sex as compared to the participants with amputations.

Table 3. Participant characteristics in individuals with a lower limb amputation, Study I, III and IV.

Study I, III–IV	**Non-MPK $n = 14$**	**MPK $n = 15$***
Mean age (years)	51 (15.5)	50 (10.9)
Female/male (*n*)	2/12	4/11
Time since amputation (years)	19 (13.4)	18 (15.8)
Amputation level TF/KD (*n*)	12/2	12/4
Cause of amputation (*n*)		
Tumour	5	7
Trauma	7	6
Vascular	1	3
Infection	1	-
Mean prosthetic use score (0–100)	74 (36)	86 (18)

Mean (SD) or *n* are reported. TF: trans-femoral amputation; KD: knee disarticulation; Non-MPK: non-microprocessor-controlled prosthetic knee; MPK: microprocessor-controlled prosthetic knee.

*In Study III results of haemodynamic response in level walking is missing in one participant.

Table 4. Participant characteristics Study II.

Amputees study II	**Non-MPK $n = 23$**	**MPK $n = 19$**
Mean age (years)	55 (8.5)	41 (13.1)
Female/male (*n*)	7/16	7/12
Time since amputation (years)	29 (13.0)	16 (13.0)
Amputation level TF/KD (*n*)	17/6	15/4
Cause of amputation (*n*)		
Tumour	6	7
Trauma	13	11
Other	4	1
Mean prosthetic use score (0–100)	81 (24.2)	81 (23.5)

Mean (SD) or *n* are reported. TF: trans-femoral amputation; KD: knee disarticulation; Non-MPK: non-microprocessor-controlled prosthetic knee; MPK: microprocessor-controlled prosthetic knee.

Table 5. Participants characteristics, control group Studies III and IV.

	Control $n = 16$
Mean age (years)	47 (13.8)
Female/male (*n*)	5/11

Mean (SD) or *n* are reported

Data collection procedure Study I, III and IV

All participants were requested to attend one testing session and, when possible, testing was conducted at their local rehabilitation facility. If this was not possible the participants were tested in a biomechanics laboratory at Jönköping University or Oslo Metropolitan University (the former University College of Oslo and Akershus). Before testing sessions, the researcher demonstrated the full testing procedures and any questions the participants may have were answered. Participants then underwent a physical assessment conducted by a registered physiotherapist (the author) to ensure that they did not have any additional physical limitations which may have negatively affected their performance. Background information was also collected to determine the cause of amputation, amputation level, time since amputation and prosthetic use (Table 3) (Hagberg et al., 2004). The type of prosthetic knee joint is shown in Table 6. The physiotherapist then collected a series of PROMs, capacity and performance-based tests (these have been described above).

Table 6. Prosthetic knee component information of participants in Study I, III and IV.

Non-MPK *n* = 14	**MPK *n* = 16**
3R60[a] *n* = 1	C-leg[a] *n* = 4
3R80[a] *n* = 4	Genium[a] *n* = 4
Mauch® Knee[b] *n* = 3	Rheo Knee®[b] *n* = 7
Total Knee®[b] *n* = 5	VGK[d] *n* = 1*
Ultimate Knee[c] *n* = 1	

TF: trans-femoral amputation; KD: knee disarticulation; Non-MPK: non-microprocessor-controlled prosthetic knee; MPK: microprocessor-controlled prosthetic knee; VGK: Very good Knee. All prosthesis users were provided with an energy storing prosthetic foot.
*The participant with a VGK were excluded from Study I and IV.
[a]Ottobock Scandinavia AB, Sweden.
[b]Ossur Hf, Grjothals, Reykjavik, Iceland.
[c]Ortho Europe Headquarters, Oxfordshire, IRL.
[d]Orthomobility Ltd. Abingdon, UK.

To capture cortical brain activity (oxyHb and deoxyHb) during walking (Study III) and while performing dual-task tests (Study IV), a portable wireless continuous wave fNIRS system (NIRsport Core System Unit, NIRx Medizintechnik GmbH, Germany) was used together with NIRStar acquisition software (NIRx Medical; NIRx Medical Technologies LLC). The fNIRS system included a laptop which was placed in a backpack carried by the participants during data collection (Figure 6). Subjects were initially fitted with an elasticised cap with pre-determined holes to ensure placement of the optodes according to the international 10-20 system (Okamoto et al., 2004) (Figure 6). Thirty-two optodes, consisting of 16 sources and 16 detectors resulting in 40 channels, were positioned to cover both hemispheres of the brain in the regions of the prefrontal (Brodmanns area 9 and 10) and the motor cortex (Supplementary motor area, SMA and BA 6 and 4) (Figure 7). A black head-cap was used to stabilize optodes during testing and to reduce the likelihood of interference from ambient light. All trials were performed in quiet rooms with no distracting noises or activity.

Figure 6. Equipment worn by participants, the elasticised cap with pre-determined holes and the backpack in which the laptop was placed. Pictures courtesy of Day Fotografi and NIRx Medical Technologies.

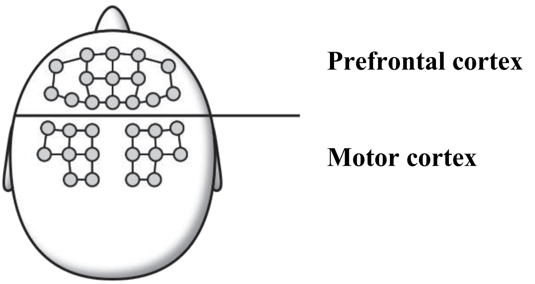

Figure 7. Topographical layout of 16 sources and 16 detectors resulting in 40 channels to cover both hemispheres, prefrontal and motor cortex of the brain. New picture will be inserted.

To ensure that all participants received the same verbal instructions during testing, NIRStim software (NIRx Medical Technologies LLC) was used in which prerecorded voice instructions were incorporated. This software was synchronised with the data collection software NIRStar^{TM} and placed a marker in the data file to indicate start of each event, e.g., start of walking. After calibration and optimisation of the signal-to-noise ratios and prior to the walking trials, baseline measures were recorded in accordance with recommendations from the manufacturer. During the baseline measure (A) (Figure 8) participants were asked to sit still on a chair and remain quiet with their eyes closed for one period of 30 seconds. After the baseline measures, walking trails were performed. During walking trials, participants were requested to walk at a self-selected velocity on level ground. If required, they were permitted to use their normal assistive device for ambulation. Walking trails were performed in the following order:

- Walking (single-task) (Study III) (Figure 9)
- Dual-task 1, walking while performing the KEY test (Study IV) (Figure 10)
- Dual-task 2, walking while performing the modified TWT (Study IV) (Figure 11).

Figure 8. Description of walking procedure where A represents the baseline of 30 seconds, B quiet standing for 30 seconds to allow signals to return to pre-test levels and C walking trial. A was repeated only once, B and C were repeated four times.

The walking track distance was marked with one cone which were placed 14 m from the starting position. During the first 10 m of walking number of steps and time taken were recorded. Each trial was repeated four times and prior to each trial participants were required to stand quietly for 30 seconds (B) (Figure 8). This was done to avoid non-linear effects of the hemodynamic refractory period and allowed signals to return to a pre-test level before any new trial was initiated. The refractory period, in the modified TWT, was performed with eyes closed to avoid pre-learning of the order of the cones for the subsequent trial.

Figure 9. Description of single-task walking in a 14 m track: Time and number of steps to negotiate the first 10 m was recorded.

Figure 10. Description of dual-task 1: walking on the 14 m track while performing KEY test. Time and number of steps to negotiate the first 10 m was recorded.

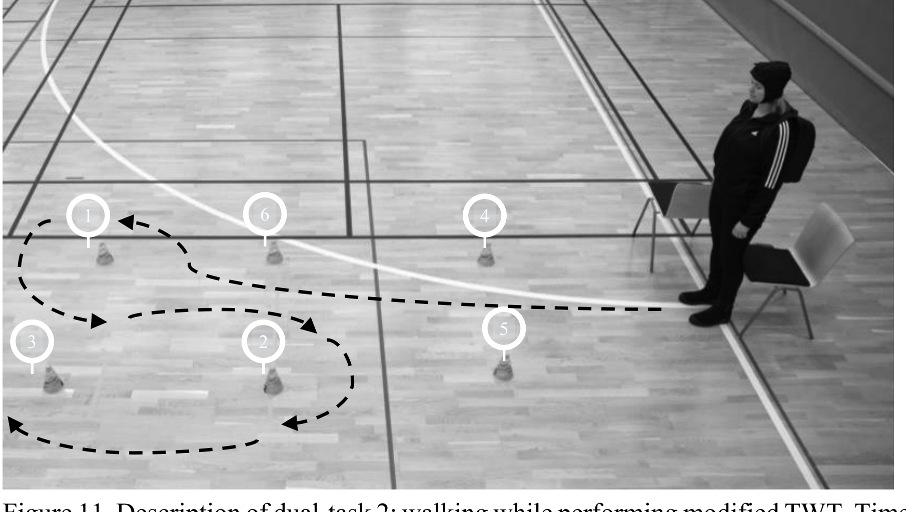

Figure 11. Description of dual-task 2: walking while performing modified TWT. Time to negotiate the test was recorded.

Data processing Study III and IV

OxyHb and de-oxyHb concentrations were analysed separately. NirsLAB software was used to create a general linear model (GLM) of the fNIRS haemodynamic-state time series and to evaluate the position-dependent relationships between computed data channel responses and the temporal model (montage) used for data collection (NirsLAB 2016.5, NIRx Medical; NIRx Medical Technologies LLC). Ten seconds of straight level walking from trials two, three and four were selected to be included in the analysis. The ten second period extracted from the data excluded the interference of acceleration and deceleration phases of the walking trial. The first trial was considered a practice run and was excluded from the analysis.

Haemodynamic signals for each channel were converted to concentrations using the modified Beer-Lambert Law (Baker et al., 2014; Cope & Delpy, 1988; Kocsis, Herman, & Eke, 2006). A canonical hemodynamic response function (hrf) was used with six seconds' delay to model the waveform in the haemodynamic response. Concentration changes of oxyHb and deoxyHb were then calculated relative to baseline values. The signal quality for each channel was reviewed and channels with a gain factor higher than three were removed from the analysis, as were channels with a coefficient of variation higher than 7.5%. The coefficient of variation (CV), which is an indication of signal to noise ratio was calculated as 100 times the standard deviation, calculated from all raw data points in the measurement series, divided by the mean of all data points. Discontinuities and spike artefacts in the time series data were removed using the algorithm described in the NirsLAB manual. A standard deviation threshold of five was set as the cut-off for eliminating discontinuities and spike artefacts. A Bandpass filter was then applied to all data to eliminate fluctuations related to factors such as heartbeat and respiration as well as low frequency signal drift (Lu, Liu, Yang, Wu, & Wang, 2015; Piper et al., 2014). This filter was applied with a low-cut-off frequency of 0.01 Hz and a high cut-off frequency of 0.2 Hz.

In Study IV a region of interest (ROI) was derived to represent the left and right prefrontal cortex. The ROI comprised of channels 3, 4, 6, 7 and 11 on the left side and 13, 14, 16, 19 and 20 on the right side (Figure 12). These locations roughly targeted left and right Brodmanns area 10, which is associated with executive functions during dual-task walking conditions (Holtzer et al., 2015). Time series data for each of the three 10 second trials for each condition were block averaged for each participant over the region of interest.

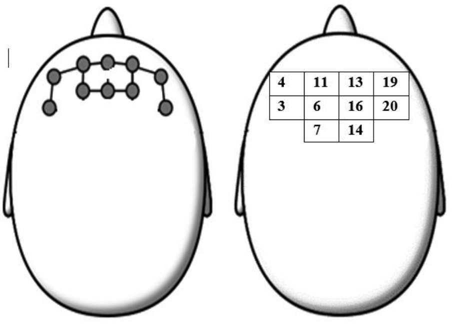

Figure 12. Region of interest (ROI). Circles indicate probes and the lines in-between indicate channels. Numbers indicate channel designation and position.

Data collection Study II

A postal with questionnaires was sent to 224 possible participants via prosthetic and orthotic clinics in Sweden. Participants were asked to return the questionnaire by post in a pre-paid envelope, which was addressed to the researcher. Recipients were requested to answer a series of questionnaires which included the GSE scale, the Q-TFA and general questions related to basic characteristics such as, amputation cause, amputation level, time since amputation and type of prosthetic knee joint used. As people using a prosthesis were unlikely to know the specific type of prosthetic knee that was incorporated into their prosthesis they were asked if they had a knee that does not require charging (non-MPK) or that requires charging (MPK). Of the 224 questionnaires that were sent, 74 participants returned the questionnaire and fulfilled the inclusion criteria.

Statistical analysis

Non-parametric tests were used for all studies included in this thesis as violations of normality were indicated in the data. An exception was the statistical parametric mapping that was used in study III. Statistical analyses were performed using IBM SPSS Statistics 21 (SPSS Inc., Chicago, IL, USA) and NirsLAB software. The critical alpha level was set at 0.05 for all analyses unless otherwise stated.

Study I

Descriptive statistics were used to characterise the sample (age, time since amputation and prosthetic use score). To determine if differences existed between the two groups; non-MPK and MPK, in PROMs and capacity tests the Mann-Whitney U test and the Chi-square test were used.

Study II

Strength of correlation between the GSE scale and Q-TFA scores were calculated using a Spearman's correlation coefficient (r^2). Ordinal logistic regression was used to explore the relationship between groups and to control for confounding factors. Mann-Whitney U-tests were used to explore differences between the two prosthetic knee-joint groups and to explore differences in Q-TFA scores for individuals with low versus high GSE.

Study III and IV

To establish if significant differences existed between all three groups, a Kruskal-Wallis test was performed. When significance was indicated, a post-hoc test with pairwise comparison was applied with Bonferroni corrections for multiple comparisons. A Mann-Whitney U test was used for group comparisons involving only two groups.

Study III

In study III haemodynamic response was analysed separately using NirsLAB software. An analysis of variance (ANOVA) was performed to assess statistical significance by comparing the GLM model-fitting coefficients (β)

across conditions (control, non-MPK and MPK). An F-test contrast matrix was constructed to compare the hemodynamic response between groups (non-MPK, MPK and controls). In instances where significant differences were found ($p < 0.05$), a post-hoc *t*-test was performed with a Bonferroni multiple-comparison adjustment ($p < 0.0167$).

Study IV

In study IV signal averaging was conducted and the mean value of oxyHb and de-oxyHb was calculated for each walking condition. To establish if significant differences existed within groups for single versus dual-tasks, a Friedman´s test or Wilcoxon signed-rank test was used.

Ethical considerations

This thesis has taken into account the ethical principles; to do good not harm, autonomy and justice, according to the Helsinki declaration (World Medical Association, 2002). Study II received ethical approval from the regional ethical review board in Linköping, Sweden (No. 2013 / 301-31) while studies I, III-IV received ethical approval from the Regionala etikprövningsnämnden i Linköping (2015 / 215-21) and the Regionale komitter for Medisinsk og helsefaglig forskningsetikk in Norway (2015/1526 / COR South-east).

Consent

In each of the studies included in this thesis consent from all participants was requested and received both verbally and written. Consent forms were available in both Swedish and Norwegian. The consent forms included information about the aim of the research, potential publications, confidentiality, anonymity, the right to withdraw and contact information to the researchers. Groups of individuals included in Study II were identified with help of professionals at prosthetic and orthotic clinics in Sweden while individuals included in studies I, III and IV were recruited from clinics both in Sweden and Norway. Because the group of individuals with lower limb amputation in Sweden and Norway is relatively small, there is an increased risk that they may be identified. It has therefore been carefully explained that participation in the studies will in no way affect future treatment received at the various prosthetic and orthotic clinics that have been active in the project.

Confidentiality / Anonymity

To further account for the increased risk of identification, participants from Study II were coded using a keycode during collection of the questionnaires. The keycode was only available to the contact person at each prosthetic and orthotic clinic and the researcher had no access to any information that could be linked to a specific person. Questionnaires completed in Study II were sent directly to the researcher and the clinics did not receive information related to the responses of individual participants.

There was a possibility that, during the physical assessment of participants involved in the data collection for studies I and III–IV, problems unknown to them may have been identified. If this occurred it was decided that the researchers would discuss these issues with the participant and, with their permission, their local physiotherapist and/or prosthetist would be contacted. No problems were identified in the participants involved in the studies.

Conflict of interest

Another dilemma in research can be conflicts of interest which may unduly influence or be reasonably perceived to influence research outcomes. Studies in this thesis have been partly funded by industry (Össur and TeamOlmed), introducing the potential for conflict of interest. According to Kazdin (2017) there exist several variations of conflicts, one of them is where results of a research can have an effect of the commercial outcome. He emphasizes the importance of agreements which are concluded between interested parties. The agreement needs to precisely define the researcher's freedom to publish data and results, and clearly state that the researcher shall in no way disclose the identity of the persons (Kazdin, 2017). In this research, an agreement was reached between the two parties; Össur and Jönköping University. The agreement included clauses ensuring that the researchers may publish all results despite the outcome and that they retain ownership of the data that was collected.

Results

Results are presented for Study I and II separately while results for Study III and IV are presented together as both studies evaluate cortical brain activity.

Study I

There were no significant differences between the two groups (Non-MPK and MPK) regarding age, time since amputation or amount of prosthetic use ($p > 0.05$).

Results for each outcome measure are described in Table 7. Results related to perceived mobility (PLUS-M) and balance confidence (ABC) revealed significantly higher levels in the group using an MPK compared to those using a non-MPK. Self-rated health (EQ-5D-5L index and VAS) did not reveal any significant differences between the groups.

The MPK-group had significantly better score on tests of capacity (AMP, SAI up and down and 6MWT) than the non-MPK-group. Differences exceeded minimal detectable change in the AMP (> 3.4 points) and 6MWT (> 45 m) while performance in their current setting (daily StepWatch data) did not reveal any significant differences between the two groups.

Table 7. Results of outcome measures evaluated in Study I.

	Non-MPK *n* = 14 **Median (IQR)** **Mean (SD)**	**MPK *n* = 15** **Median (IQR)** **Mean (SD)**	***p*-value**
PLUS-M(t-score)	49 (8.0) 49 (6.9)	54 (7.9) 55 (6.2)	.030
ABC	71 (31.5) 62 (26.2)	84 (17.5) 84 (11.1)	.005
EQ-5D-5L index	0.707 (0.3) 0.621 (0.3)	0.735 (0.1) 0.713 (0.1)	.599
EQ-5D-5L VAS	78 (33.0) 73 (22.4)	80 (20.0) 79 (15.5)	.553
AMP	37 (6.0) 37 (4.4)	43 (4.0) 42 (4.4)	.003
SAI up	3.0 (1.0) 3.3 (1.6)	3.0(4.0) 5.6 (3.3)	.026
SAI down	3.0 (1.0) 3.0 (1.0)	11(7.0) 11.1(8.0)	.000
6MWT (metres)	334(207.0) 374(181.6)	441(104.0) 460(108.8)	.035
SW (steps/day)	1408 (1869.6) 1780 (1537.0)	2407 (1340.6) 2494 (1039.3)	.118

Non-MPK: non-microprocessor-controlled prosthetic knee; MPK: microprocessor-controlled prosthetic knee; PLUS-M: Prosthetic Limb Users Survey of Mobility; ABC: Activity Balance Confidence; VAS: Visual Analog Scale; AMP: Amputee Mobility Predictor; SAI: Stair Assessment Index; SW: Step Watch

Study II

Data for this study was extracted from the previously applied survey of 74 participants (19–88 years). In attempts to obtain a more homogenous group 42 participants (19–66) were included in the final sample. There were significant differences between the two groups (Non-MPK and MPK) regarding age ($p < 0.001$) and time since amputation ($p = 0.003$) where those with a non-MPK were older and had been amputated for a longer time. There was no significant difference between the groups regarding amount of prosthetic use ($p > 0.05$).

Results in this study indicate that persons using a TF or KD prosthesis experienced relatively high self-efficacy and high prosthetic use (median 32 out of 40 and 90 out of 100 respectively). When analysing the groups based on the type of knee joint used, no significant difference was found in GSE or any of the Q-TFA scores. When looking at each item in the Q-TFA mobility score, a trend was seen where those with an MPK consistently scored higher, but there was no significant difference.

When divided into groups based upon low or high GSE scores (> 30), a statistically significant ($p = 0.011$) difference was observed in prosthetic use score. Those with high GSE used their prosthesis to a higher degree (median Q-TFA prosthetic use scores 71 and 90 respectively) compared to those with low GSE scores. Moreover, high GSE scores were shown to positively correlate with Prosthetic use score ($r = 0.52$, $p < 0.001$), Mobility score ($r = 0.40$, $p < 0.01$) and were negatively correlated to self-rated problems (Problem score) ($r = 0.43$, $p < 0.01$). There was only a weak correlation between GSE and Q-TFA global score. Time since amputation was significantly related to increased prosthetic use ($p < 0.05$) but the GSE was not able to discriminate between prosthetic knee components (non-MPK and MPK).

Study III and IV

There were no significant differences observed between the groups (non-MPK, MPK and controls) regarding age or between the two groups with amputations with regards to time since amputation or amount of prosthetic use ($p > 0.05$).

Persons using a prosthesis demonstrated an increase in cortical brain activity (oxyHb) in the frontal cortex when walking on level ground (Study III) when compared to controls. Moreover, they took more steps/minute (cadence in single-task walking and KEY), took longer time to complete the TWT (Study III and IV) and walked a shorter distance in the 6MWT.

When the two groups of prosthetic users were compared, the non-MPK-group revealed increased cortical brain activity in the prefrontal and motor cortex when walking on level ground (Study III) (Figure 13). No significant differences were observed in cortical brain activity between the two groups during dual-task walking tests (KEY or modified TWT) (Study IV). The results of the temporospatial data did not indicate any between group differences in time, number of steps or 6MWT during level walking in study III, while a significant reduced cadence was observed in the non-MPK group for level walking and the KEY test as well as a reduced time to complete the modified TWT in Study IV.

When the results from single-task walking was compared with dual-task walking, significantly increased cortical brain activity (oxyHb) in the prefrontal cortex was observed when an additional task was performed in the MPK- and control-groups (Study IV). There were no significant differences in the temporospatial data in any of the groups when a secondary task was added (Study IV).

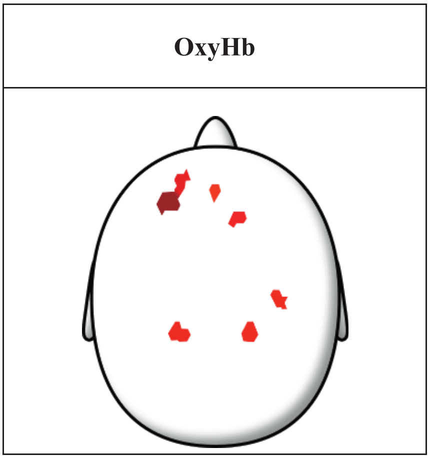

Figure 13. t-maps of significant (P<0.0167) increased oxyHb channels are viewed. Increased oxyHb in prefrontal and motor cortex for Non-MPK compared with MPK; Non-MPK=non-microprocessor-controlled prosthetic knee, MPK=microprocessor-controlled prosthetic knee. OxyHb= oxygenated haemoglobin.

Discussion

Methodological considerations

To ensure trustworthiness of the studies in this thesis, which have all used a quantitative approach, issues related to validity and reliability must be considered. These issues are discussed below.

External validity

The external validity of a study refers to whether the outcome can be transferred to other groups, contexts or situations, often discussed as generalisation (Kazdin, 2017). External validity in the context of this thesis relates to the extent to which results can be generalised to the Swedish population of individuals with TF or KD amputations and to an international population of individuals with similar levels of amputation.

In Sweden, TF amputations and KD are rare in individuals under the age of 75 (Johannesson et al., 2009). The mean age of those with a KD or TF amputation in Sweden is typically around 77 years, with the major cause of amputation being for vascular reasons (Swedeamp, 2017). Internationally, studies from developed countries report similar results where the majority of those amputated at TF and KD levels are aged over 70 and amputated due to vascular diseases (Imam et al., 2017; Pohjolainen & Alaranta, 1998). The sample of individuals with amputations in this thesis were relatively young (mean range 44–51 years) compared to the general Swedish and international TF and KD population. This is due to inclusion criteria which limited participation to persons who were able to walk 500 m or more, using no more than one gait aid in Studies I, III and IV and exclusion of people above 66 years in study II. While the relative age of participants limits generalisation, the inclusion criteria was considered necessary to ensure safety for participants during physical tests (Study I, III and IV) and to ensure that groups of non-MPK and MPK users were comparable in study II.

Internal validity

The term internal validity addresses issues related to design or execution of studies and includes factors other than the independent variable that may have influenced the results (Kazdin, 2017). A major aim of this thesis was to address differences between a group of individuals fitted with MPKs and a group of individuals fitted with non-MPKs. A major threat to internal validity when comparing groups is selection bias; individual differences that may have existed before participants were recruited for the study (Kazdin, 2017). This can include differences in activity levels, gender, age and cause of amputation.

Throughout the thesis, every attempt was made to control for selection bias. In studies I, III and IV, activity level was considered by including only participants with a well-functioning prosthesis, who could walk at least 500 m and did not have any additional physical limitations. In addition, there were no significant between-group differences in relation to age, cause of amputation or prosthetic use. In study II, attempts were made to reduce selection bias by excluding persons above 66 years. Despite this, the non-MPK group was significantly older than the MPK group. There was no difference in the cause of amputation between groups in study II. As such, despite best attempts to reduce selection bias, it is still possible that there were baseline differences between groups. An obvious solution to resolve the issue of selection bias would be to conduct a longitudinal study in which participants are randomly assigned to conditions (Kazdin, 2017). Unfortunately, this requires prohibitively large amounts of time and the cost of providing individuals with both a non-MPK and an MPK was beyond the budget constraints for this research.

The expectations of participants are also an issue that may have contributed to baseline differences between groups of individuals using prostheses. The participants included in this thesis who used an MPK were most likely aware that they had been provided with newer and more expensive technology. As a consequence, there is a risk that these individuals were more positive in their response on self-reported measures than those who were prescribed with a non-MPK.

Learning effects have been attributed to factors such as patient familiarity with the walking track, overcoming anxiety, feeling more confident, and improved coordination. To try to control for this, the first of the four fNIRS trials was removed in studies III and IV. One limitation however is that the order of tests was not randomised, as such participants would be more familiar with the test environment towards the end and less anxious about the testing procedures. While these issues might affect internal validity, the conditions were the same across groups and would not have affected between group results.

An additional issue that may have affected internal validity is the fact that we did not control for prosthetic component prescription beyond the knee unit. Having said this, the remaining prosthetic components that made up the prostheses were quite consistent between participants. For instance, in studies I, III and IV all participants were provided with an unjointed, energy-storing prosthetic foot and all, but two participants, were using a prosthetic socket with pressure-differential suspension.

Instrument bias can be affected by both the use of a physical measurement device and the actions of the researcher (Kazdin, 2017). fNIRS is a fairly new technology and there is currently no standard procedure regarding measurement protocols or data analysis procedures. Every attempt was made to standardise procedures and minimise interference during fNIRS measurement. This included using the same researcher to apply probes and utilising pre-recorded voice instructions for participants.

When collecting fNIRS data, there is always a risk that other physiological variables interfere with measurement of the haemodynamic response. These variables can include heartrate, respiration and task-related haemodynamics; in particular, changes of blood flow in the scalp layer. Recent recommendations promote the use of short channels for removal of local scalp-hemodynamic artefacts. Short channels are placed so that the distance between the probes is reduced, limiting the depth of detection and allowing researchers to separate out artefacts that are not related to activity in the brain (Sato et al., 2016). This technology was not available to us at the time of data collection.

During post-processing of fNIRS data, bad channels were identified and removed as per manufacturer recommendations. Inspection of the distribution of bad channels did not indicate any systematic errors in the data collected. While some researchers argue that all bad channels should be included and filtered instead of excluded, there is no consensus on post-processing of fNIRS data (Tak & Ye, 2014).

Data-evaluation validity

In this thesis, no a-priori statistical power analyses were performed. Data-evaluation validity refers to the factors influencing statistical evaluation (Kazdin, 2017). A key determinant in statistical evaluation is statistical power (Kazdin, 2017). Power is the likelihood of finding differences between conditions when, in fact, there truly are differences. Central to statistical power is size of the sample (Faul, Erdfelder, Lang, & Buchner, 2007). Attempts were made in this thesis to maximise the sample size by including participants from both Sweden and Norway and travelling to participants' home towns to collect data. Despite these efforts, the sample size in this thesis is relatively small.

It is important to recognise however, that the population of TF and KD amputees in Sweden is small which influences the proportion of the population represented in this thesis. In comparison to previous published work, the research presented in this thesis includes a relatively large number of participants. In a review of 27 studies evaluating differences between non-MPK and MPK users, only 2 studies were reported to include a greater number of participants than studies in this thesis (> 29) (Sawers, 2013).

Reliability

To be trusted, a measure must be reliable. The measure must be uniform across time, observers and samples. Care was taken in selection of outcome measures to ensure that they have been tested for reliability. However, there were some instruments used in which the reliability was not known. While fNIRS has been tested for reliability in healthy groups levels for oxyHb and considered as highly stable (Plichta et al., 2006). To the author's knowledge, fNIRS has not been tested for reliability in individuals using lower limb prostheses. Similarly, the GSE has been tested for reliability in a large cross-national sample (n = 19 120) using data from 25 countries (Scholz et al., 2002), but has not previously been applied on a population with a lower limb amputation. The KEY test used in study IV has not been tested for reliability which is a limitation within this study. The KEY test was selected as it had previously been demonstrated in individuals with a lower limb amputation (Howard et al., 2013).

Discussion of the results

This thesis comprises of four studies, each evaluating a different perspective of walking with a prosthesis incorporating a prosthetic knee with or without microprocessor-control. To undergo a lower limb amputation is considered a major health event that can negatively impact a person´s functioning. Studies included in this thesis evaluated functioning in prosthesis users from a broad perspective and investigated issues related to mobility, self-efficacy and attentional demand.

Combined results of all four studies suggest that persons provided with an MPK had better mobility—both self-rated and objectively evaluated—and better self-rated balance confidence than those who were using a non-MPK. Results also showed that an individual's belief in their own ability is associated with the number of hours they use their prosthesis. Studies III and IV indicated that participants using a non-MPK had higher levels of cortical brain activity in the frontal cortex during walking, suggesting that the attentional demand required to walk was greater than for individuals using an MPK.

Of particular interest for individuals involved in prosthetic rehabilitation was the finding that significant increases in attentional demand were not always reflected in temporospatial gait parameters. This suggests that cognitive demands may not always be reflected in variables that are commonly evaluated in the clinical setting.

Mobility

To gain a comprehensive understanding of a person's everyday functioning one must evaluate both the participants opinion of their functioning as well as measuring what they are capable of. As such, mobility was measured in this thesis using both self-report measures and tests of participants' capacity.

Self-report measures of mobility used in this thesis included PLUS-M, Q-TFA and EQ-5D-5L. Significant differences were demonstrated between the group using a non-MPK versus those using an MPK, with those using an MPK reporting higher levels of mobility in daily activities (PLUS-M, Study I) while no differences were seen in mobility scores in the Q-TFA (Study II) or EQ-5D-5L (Study I). To the author's knowledge, PLUS-M and Q-TFA have not previously been used to compare prosthetic knee units. Previous research using other self-report measures of mobility (e.g., Prosthetic Evaluation Questionnaire, SF-36) have demonstrated no significant differences in individuals' perceived mobility between groups using a non-MPK and MPK (Hafner & Askew, 2015; Hafner et al., 2007; Prinsen, Nederhand, Olsman, & Rietman, 2015). In recently published research of older prosthetic users with a lower activity levels (mean age of 69 and Medicare Functional Classification Level K2), it was shown that there was significantly increased mobility, measured with Prosthetic Evaluation Questionnaire, after transitioning to an MPK (Kaufman, Bernhardt, & Symms, 2018). Further investigation is recommended to understand how self-reported mobility is affected when using different prosthetic knee components.

On tests related to capacity (AMP and 6MWT), the MPK-group outperformed the non-MPK group. Results are consistent with Howard et al. (2018) who demonstrated similar results in the AMP and 6MWT when individuals transitioned from a non-MPK to an MPK. However, there are others who report no differences in mobility (as measured by AMP) after transitioning to an MPK (Hafner et al., 2007).

The ability to ascend and descend stairs is an interesting measure of mobility as it reflects a walking situation commonly encountered in everyday situations. Results indicate that persons fitted with an MPK use a step over step walking pattern to descend stairs while those using a non-MPK use a step-to pattern. Hafner et al. (2007) reported similar results in relation to descending stairs. It should be mentioned that in this research, participants were asked to describe their normal behaviour during descending and ascending stairs rather than observing stair walking behaviour.

Another important aspect of mobility is an individual's level of activity when going about their normal daily routine. Continual recording of step count is a viable means for monitoring activity outside the laboratory environment. Daily step count was collected in study I for a period of 14 days. Results revealed no significant difference between the non-MPK-group and the MPK group. This data is consistent with earlier reports of daily steps indicating that transitioning to an MPK did not significantly increase the number of daily steps (Hafner & Askew, 2015). Though not statistically significant, there was a tendency for individuals using a non-MPK to take fewer steps than those walking with an MPK (1780 and 2494 steps/day, respectively). The number of daily steps recorded by participants in study I is also similar to an earlier report of individual with a TF amputation which reported an average of 1540 steps/day (Halsne, Waddingham, & Hafner, 2013). In comparison, the average steps/day for low active healthy adults is reported as being 5000–7400 steps/day (Tudor-Locke & Bassett, 2004).

Restoring mobility following a lower limb amputation is considered a primary goal of the rehabilitation process (Hafner et al., 2017). As mobility has been shown to be associated with satisfaction with life and has an impact on quality of life (Norvell et al., 2011; Suckow et al., 2015; Wurdeman et al., 2018), it is somewhat surprising that results of improved mobility for the MPK group compared to the non-MPK group were not reflected in health-related quality of life between the groups. While EQ-5D-5L has not earlier been used to compare users of non-MPK and MPK, previous research using EQ-5D-3L has reported differences in health-related quality of life favouring the MPK (Cutti et al., 2017; Gerzeli et al., 2009). Health economic benefits have also been reported (Chen et al., 2018). This difference in results could be due to a limited sample size in this thesis, as compared to the previous studies which included more than 100 participants.

Self-efficacy associated with prosthetic use

General self-efficacy has not, to the author's knowledge, previously been evaluated in a sample of individuals using limb prostheses. Results in this thesis suggest that individuals with high self-efficacy use their prosthesis for more hours every week and report higher levels of mobility than those with low self-efficacy. This result was not dependent upon the type of knee joint prescribed (MPK or non-MPK). Results related to general self-efficacy (Study II) are consistent with earlier research investigating older patients with mobility disabilities and demonstrates that people with high self-efficacy also scored high on measures of physical quality of life, including mobility (Strupeit, Wolf-Ostermann, Buss, & Dassen, 2014).

While general self-efficacy scores did not show any differences between the groups using different prosthetic knee mechanisms, differences were observed in relation to balance self-efficacy. In this case the group using an MPK reported better balance confidence (Study I). Similar results have been reported regarding balance confidence and favouring the MPK by several groups (Burnfield et al., 2012; Fuenzalida Squella, Kannenberg, & Brandao Benetti, 2018; Kannenberg, Zacharias, & Probsting, 2014; Sawers & Hafner, 2013).

The fact that this thesis has demonstrated differences between knee components in a measure of specific self-efficacy (ABC) and not in the general measure of self-efficacy could be due to the fact that the GSE score is not intended to predict a particular behaviour. Instruments developed for a specific disease or condition have been suggested to be more sensitive in detecting changes in the condition or disease specific groups (Patrick & Deyo, 1989) and Schwarzer and Fuchs (1996) suggest that researchers should design their own items to target a specific behavioural construct when evaluating self-efficacy. To the author's knowledge there is no self-efficacy measure currently available to capture issues specifically related to lower limb prosthetic use.

Attentional demand

In this thesis we observed a greater relative increased in frontal cortical brain activity in the group provided with a non-MPK during level walking when compared to the controls and MPK-group. Moreover, dual-task walking compared to single-task walking was associated with an increase in pre-frontal cortex activity in the MPK group and controls but not in the non-MPK-group. To the author's knowledge no earlier research has evaluated cortical brain activity in individuals walking with a prosthesis. Results contribute to further understanding of prosthesis users' attentional demand during walking and seem to support previous research demonstrating similar increases in frontal cortex activity in other populations with pathologies that affect gait and posture (Al-Yahya et al., 2016; Caliandro et al., 2012; Maidan et al., 2015; Maidan et al., 2016) .

An increase in cortical brain activity in the frontal cortex has been interpreted in this thesis as an increase in the attentional demand required for locomotion. This presumption is based on results of numerous fNIRS studies which have linked activity in the frontal cortex with various dimensions of attention including working memory (Vermeij et al., 2017) response inhibition (Xiao et al., 2012) and joint attention (Zhu & Godavarty, 2013).

One of the key principles in theories of attention is that there is a limited capacity for attending to activities and tasks (Kahneman, 1973). When considering this, results from this thesis suggest that individuals using a prosthesis have increased attentional demand during ambulation compared to healthy adults and individuals using a non-MPK have increased attentional demand compared to those walking with an MPK. Objective measures of attention, in studies III and IV, support subjective findings presented in earlier work on individuals with a lower limb amputation which reported these individuals having to concentrate on every step they take (Gauthier-Gagnon et al., 1999) and suggest greater cognitive effort (Kelly et al., 2018). Results are also consistent with earlier research of reduced self-reported cognitive effort when transitioning from a non-MPK to an MPK (Williams et al., 2006). This could be a factor contributing to the increased number of falls and fear of falling experienced by people who use a prosthesis (Kaufman et al., 2018; Kim, Major, Hafner, & Sawers, 2018). Fear of falling and fall history were not evaluated in this thesis and this would be important to include in future research.

No significant differences were observed in cortical brain activity between single- and dual-task walking in the non-MPK group. This was a surprising finding as, theoretically, allocation of attentional resources to a task should increase as the task becomes more difficult. One potential explanation could be that this group already reached their maximum capacity during level walking and therefore no additional increase could be achieved. If this were the case, one would expect to see a decrease in performance on either the primary or secondary task (Leone, Patti, & Feys, 2015). In this thesis performance on secondary task was not evaluated. Gait performance was assessed using temporospatial measures, but no significant differences were observed when comparing single-task and dual-task walking. Given that increased demand on attention is associated with postural instability and increased risk of falling, results in this thesis support earlier research that suggested assessments of cognitive functioning should be used to a greater extent in the rehabilitation settings (Gramigna et al., 2017; Lombard-Vance et al., 2019; Yogev-Seligmann, Hausdorff, & Giladi, 2012).

This thesis used fNIRS to capture signals from both hemispheres of the brain in the regions of the prefrontal (Brodmanns area 9 and 10) and motor cortex (Supplementary motor area, SMA and BA 6 and 4). These areas have, in previous neuroimaging research, been reported as areas to be associated with allocation of attention (Carlen, 2017; Chaparro et al., 2017; Maidan et al., 2016) while other researchers suggests more specific regions (i.e., dorsolateral prefrontal cortex, bilateral inferior frontal gyrus, somatosensory association cortex) to be associated with attention (Rosenbaum et al., 2018). Further research is needed to clarify connections between specific areas of neural activity and cognitive processes.

Earlier research has shown that with continued practice, a skilled action requires less attentional demand. This is often referred to as automaticity (Malone & Bastian, 2010). Based upon this premise, one would expect that attentional demand would be seen to decrease in prosthesis users as they become more proficient at using their prosthesis. When a movement becomes a learned skill, attentional resources can be used for other activities. As such, interventions that help an individual to train specific skills can assist in facilitating automaticity (Malone & Bastian, 2010). Another interesting example is cognitive training programs as an intervention. Cognitive training programs are specifically developed to detect cognitive functioning in older adults and involve attention and working memory training (Haimov, Hanuka, & Horowitz, 2008). It has been demonstrated that after a period of 8-weeks of cognitive training, gait velocity during normal walking and walking while talking improved (Verghese, Mahoney, Ambrose, Wang, & Holtzer, 2010). A second interesting example is psychological awareness education that has been found to increase gait speed and reduce low-back pain in individuals with a trans-femoral prostheses (Sjodahl, Jarnlo, & Persson, 2001). This suggests an association between cognitive training and improved ambulation and could be of relevance for prosthetic gait training.

For professionals involved in prosthetic rehabilitation it has become clear that the development of more effective rehabilitation processes and techniques require a better understanding of what is affecting overall functioning of individuals using a prosthesis. This thesis highlights a need for increased understanding of physical factors, prosthetic components factors and the influence of cognitive factors might have on individual´s using a lower limb prosthesis.

Conclusion

The overall aim of this thesis was to describe and compare functioning in individuals with a trans-femoral amputation or knee disarticulation and to evaluate the relative effects of using non-microprocessor-controlled prosthetic knees (non-MPK) or microprocessor-controlled prosthetic knees (MPK). Combined results from all four studies suggest that persons provided with an MPK had better mobility, both self-rated and objectively evaluated, and better self-rated balance confidence than those who were using a non-MPK. Results also showed that an individual's belief in their own ability was associated with the number of hours they normally use their prosthesis per week. Participants using a non-MPK had higher levels of cortical brain activity in the frontal cortex during walking, suggesting that the attentional demand required to walk was greater than for individuals using an MPK.

Of particular interest for health professionals involved in prosthetic rehabilitation was the finding that significant increases in attentional demand were not always reflected in temporospatial gait parameters. This suggests that cognitive demands may not always be reflected in variables that are commonly evaluated in the clinical setting.

Health related quality of life, measured with EQ-5D-5L and self-efficacy, measured with the GSE scale was not able to detect any differences between the two groups using different prosthetic knee components.

Implications

Prosthetic rehabilitation for individuals with a TF or KD amputation should address a comprehensive view of functioning including the following.

- Evaluation of self-reported mobility as well as capacity tests.
- Acknowledgement that instruments designed for general use across a variety of conditions may not be sensitive to issues that specifically affect individuals with a lower limb amputation.
- Evaluation of effects of prosthetic prescription and training on cognitive load.

Future research

- Randomised, longitudinal studies with a crossover design to be able to better control for group differences.
- Studies of functioning with a prosthesis involving older persons with lower activity levels and increased risk of falling.
- Further evaluation of outcome instruments previously not used in a group of individuals amputated at TF and KD levels and using different prosthetic knee components.
- Longitudinal studies evaluating prosthetic learning effects on attentional demand.
- Intervention studies focusing on cognitive learning effects and functioning with a prosthesis.

Summary in Swedish

Bakgrund: En amputation av nedre extremiteten är en traumatisk upplevelse som påverkar den drabbade personen både fysisk och psykiskt och som ofta leder till begränsningar i det dagliga livet. Efter amputationen utprovas vanligen en protes för att möjliggöra mobilitet och god funktion. Protesens mekaniska egenskaper kan variera och valet av specifika proteskomponenter har visat sig påverka individens funktionsförmåga. Studier avseende relativa effekter av olika typer av protesknäleder har generellt sett fokuserat på fysiska och biomekaniska variabler, vilket ger en ganska snäv bild av protesanvändarens hälsorelaterade tillstånd. Det finns ett behov av att bredda perspektivet av hälsa och välmående hos protesanvändare genom att studera en större variation av faktorer som kan påverka individens funktionstillstånd.
Syfte: Det övergripande syftet med avhandlingen var att beskriva och jämföra funktionen hos personer med en transfemoral amputation eller en knädisartikulation och att utvärdera den relativa effekten av att använda en icke-datastyrd protesknäled (non-MPK) respektive en datastyrd protesknäled (MPK).
Metod: Samtliga fyra studier i avhandlingen är kvantitativa tvärsnittsstudier, men innefattar olika datainsamlingsmetoder. Dessa innefattar självskattningsinstrument, funktionstester, enkätstudie med två frågeformulär samt mätning av hjärnaktivitet vid vanligt gående på plan mark samt vid gående med tillägg av en ytterligare samtidig uppgift. En grupp bestående av 42 personer med benamputation som använder en protesknäled med eller utan datastyrning inkluderades i enkätstudien. En annan grupp bestående av 29 personer som använder en protesknäled med eller utan datastyrning samt en kontrollgrupp (n=16) deltog i de övriga studierna. Statistiska analyser utfördes för att jämföra grupperna som använde olika protesknäleder samt för att jämföra protesanvändare och kontroller.
Resultat: Personer som använde en non-MPK rapporterade sämre mobilitet och tillit till sin balans och hade sämre resultat på funktionstesterna än de som använde en MPK. Resultatet påvisade ingen signifikant skillnad mellan grupperna vad gäller självskattad generell hälsa, tilltro till sin egen förmåga eller antal steg per dag. Resultatet påvisade ökad frontal hjärnaktivitet vid vanligt gående på plan mark hos de individer som använde en non-MPK jämfört med de som använde en MPK och jämfört med kontrollgruppen.

Signifikant ökad hjärnaktivitet i prefrontala cortex sågs även hos MPK-gruppen och kontrollgruppen då ytterligare en uppgift adderades vid gång i jämförelse med gående utan annan uppgift.
Slutsatser: Det sammanslagna resultatet av de fyra studierna tyder på att personer som har blivit försedda med en MPK har bättre mobilitet, både självskattat och objektivt värderad, samt rapporterar bättre tillit till sin balans än de som är försedda med en non-MPK. Resultatet visar också att hög tilltro till sin egen förmåga är associerat med att man använder sin protes mer. Deltagare som använde en non-MPK uppvisade mer hjärnaktivitet vid gång vilket tyder på att de behöver rikta mer uppmärksamhet åt att gå än de som använde en MPK.
Av särskilt intresse för yrkesverksamma inom protesrehabilitering är de fynd som visade att ökad grad av uppmärksamhet inte belystes i de temporospatiala gångparametrarna. Detta skulle kunna indikera att kognitiv belastning inte reflekteras i de gångvariabler som vanligtvis undersöks i klinisk verksamhet.

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