Lower-limb Prosthetics in the Age of Advanced Solutions

Understanding People's Needs and Future Benefits

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Thesis for the degree of Philosophiae Doctor

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Ágrip

Síðustu tvo áratugi hefur gríðarleg framþróun átt sér stað á sviði gervigangllima, en sífellt háþróaðri lausnir verða aðgengilegar á ári hverju. Engu að síður hefur ekki enn tekist að endurheimta fyrri virkni til fulls í kjölfar aflimunar á fæti. Mótordrifnir gerfiganglimir ásamt taugabúnaði geta dregið úr því misræmi sem er til staðar á milli helbrigðra ganglima og gervigangllima með virkri aðstoð, miðlun skynupplýsinga og viljastýringu þar sem taugavöðvamerki eru notuð til að stjórna gervigangllimum. Þrátt fyrir niðurstöður nýlegra rannsókna sem benda til þess að slíkar lausnir geti aukið velferð fólks í samanburð við eldri búnað er notkunartíðni áhyggjuefni og áhrif nýrra hátæknilausna tiltölulega óljós. Ennfremur gætu núverandi matsaðferðir á sviði gervigangllima skort prófræðileg gæði, verið óviðeigandi fyrir þýðið eða ekki ekki að fanga alla þá spönn hugsmíða sem þeim er ætlað að meta.

Í þessu verkefni tóku hagsmunaaðilar á sviðinu þátt í hálfstöðluðum viðtölum, rýnishópsumræðum og samhengisrannsókn, þar á meðal einstaklingar með gervigangllimi. Einnig rýndum við markvisst í matsaðferðir fyrir gervigangllimi, sérstaklega með tilliti til hátæknigervigangllima. Markmið verkefnisins var að; 1) Kanna óuppfylltar þarfir einstaklinga með gervigangllimi; 2) Bera kennsl á núverandi og áætlaðan ávinning hátæknigervigangllima sem bjóða upp á virka aðstoð, miðlun skynupplýsinga og viljastýringu; 3) Skilja þær áskoranir sem felast í þróun og mati á slíkum búnaði, ásamt því að; 4) Meta gagnsemi núverandi matsaðferða í ljósi nýrra framfara á sviðinu.

Niðurstöður okkar benda til þess að gnægð óuppfylltra notendaþarfa geti mögulega verið fullnægt með taugavöðvabúnaði og virkri aðstoð hátæknigervigangllima. Við bárum einnig kennsl á fjölda áskorana í þróun og mati á háþróuðum gervigangllimum ásamt þörf fyrir nýjar eða endurnýaðar matsaðferðir. Að lokum tiltökum við þætti sem einstaklingar með gervigangllimi telja mikilvæga og atriði sem að skipta máli fyrir þróun notendavæns búnaðs.

Lykilorð: Hátækni-gervigangllimir, mótordrifin gervihné, aflimun á fæti, notendaþarfir, matsaðferðir.

Abstract

The field of lower limb prosthetics has advanced rapidly in the past two decades with increasingly sophisticated devices becoming available each year. Nevertheless, function has yet to be fully restored for people with lower limb amputation. Active microprocessor-controlled prostheses and neuromuscular interfacing can decrease the gap between intact- and prosthetic limbs, providing active assistance, sensory feedback, and intent control where signals from the neuromuscular system are used to implement intended action. While recent evidence suggests that such solutions may improve peoples' function when compared to earlier technology, device abandonment rates are still a concern, and the impact of novel functions is relatively unclear. Furthermore, current evaluation strategies in the field may be psychometrically invalid, inappropriate for the population, or may not capture the whole range of constructs they are intended to measure.

We conducted semi structured interviews, focus group discussions and a contextual inquiry with multiple stakeholders in the field, coupled with a systematic literature search in order to; 1) Explore unfulfilled lower-limb prosthetic user needs; 2) Identify the current and future benefits of advanced lower-limb prosthetic systems, including ones providing active motion, sensory feedback, and intent control; 3) Understand the challenges associated with developing and evaluating such functions; and 4) Assess the relevance of current evaluation methods in light of new developments within the field of lower limb prosthetics.

Our results indicate that numerous unmet user requirements may be addressed with neuromuscular interfacing and active motion provided by advanced prostheses. We further identified several challenges in the development and evaluation of advanced prostheses as well as a need for new or updated evaluation strategies. Finally, we present perspectives on factors important for user satisfaction and the actualization of a usable system that reaches end users.

Keywords:

Neuroprostheses, active microprocessor-controlled knees, lower limb amputation, user requirements, evaluation.

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The Psychology department at the University of Iceland has been akin to a second home to me for almost a decade, and four years ago, I was also so fortunate as to receive a warm welcome by the wonderful people of Össur. Without the incredible individuals I have had the privilege to meet both at the University and Össur I would not be who I am today. I would further like to thank our co-authors, Jóna Sigrún Sigurðardóttir, Knut Lechler, and Lisa Tronicke, as well as Allie Doersch for her illustrations for our publications. The Icelandic Research Fund, Rannís, provided me with a doctoral grant and to them I am eternally grateful. Additionally, I thank the amazing people who took part in the studies presented in this thesis.

In my experience music is never far away when researchers are involved. Össur's Randi band and the musical and karaoke-crazed members of the Icelandic Vision Lab have definitely brightened the mood and provided a creative outlet throughout my studies. I also feel especially blessed in meeting Magnús Oddsson and Hekla Arnardóttir who have taken me on multiple musical journeys outside the lab and office.

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Contents

List of Abbreviations

10MWT, 10-Meter Walk test

2MWT: 2-Minute Walk Test

6MWT: 6-Minute Walk Test

AMP: Amputee Mobility Predictor

A-MPK: Active Microprocessor-controlled Knee

A-MPA: Active microprocessor-controlled ankle

BAMS: Basic Amputee Mobility Score

BBS: Berg Balance Scale

CB&M: Community Balance and Mobility Scale

CHAMP: Comprehensive High-level Activity Mobility Predictor

CS-PFP10: Continuous Scale Physical Functional Performance 10

C-TUG: Component Timed Up and Go

EMG: Electromyography

F8WT: Figure of Eight Walk Test

FIM: Functional Independence Measure

FSST: Four-Square Step Test

HAI: Hill Assessment Index

LEMOCOT: Lower-Extremity Motor Coordination Test

LLA: Lower Limb Amputation

MFCL/**K**-**level**: Medicare Functional Classification Levels

MPA: Microprocessor-controlled Ankle

MPK: Microprocessor-controlled Knee

N-MPA: Non-microprocessor-controlled Ankle

N-MPK: Non-microprocessor-controlled Knee

NBWT: Narrowing Beam Walking Test

P-MPK: Passive Microprocessor-controlled Knee

P-MPA: Passive Microprocessor-controlled Ankle

SAI: Stair Assessment Index

SWOC: Standardized Walking Obstacle Course

TFA: Transfemoral Amputation

TTA: Transtibial Amputation

TUG: Timed Up and Go

ULA: Upper Limb Amputation

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List of Original Papers

This thesis is based on the following original publications, which are referred to in the text by their Roman numerals:

I. Valgeirsdóttir, V. V., Sigurðardóttir, J. S., Jóhannesson, Ó. I., Alexandersson, Á., & Kristjánsson, Á. (2021). Multistakeholder Perceptions on Lower-Limb Prosthetic User Requirements and the Development of Neuroprostheses: A Contextual Inquiry. JPO: Journal of Prosthetics and Orthotics, Online First. https://doi.org/10.1097/JPO.0000000000000354

II. Valgeirsdóttir, V. V., Sigurðardóttir, J. S., Lechler, K., Tronicke, L., Jóhannesson, Ó. I., Alexandersson, Á., & Kristjánsson, Á. (2021). How Do We Measure Success? A Review of Performance Evaluations for Lower-Limb Neuroprosthetics. *JPO: Journal of Prosthetics and Orthotics*.

III. Valgeirsdóttir, V. V., Ásgeir Alexandersson, Knut Lechler, Ómar I. Jóhannesson & Árni Kristjánsson What a Knee Should Be: Perspectives of Highly Active Prosthetic Users. Submitted for publication.

All papers are reprinted by kind permission of the publishers.

Declaration of Contribution

The PhD candidate's contributions for each paper are as following:

Paper I

The candidate planned the contextual inquiry in collaboration with a co-author. Both authors partook in the data collection and primary analysis. The candidate entered the data, conducted the main data analysis, and wrote the paper, revising according to co-author feedback. All figures presented in the paper were illustrated by Allie Doersch.

Paper II

The candidate planned the systematic search, defined the research question and inclusion/exclusion criteria, receiving guidance from instructors and colleagues when needed. The candidate further executed the systematic search, completed data analysis at levels 1): screening titles and abstracts; 2) full text screening; and 3) data extraction from selected papers. The candidate further wrote the paper and revised it according to co-author comments. One co-author conducted the data analysis at levels 1 and 2 independently prior to a consensus-based discussion on the final list of papers to include.

Paper III

The candidate wrote the protocol, conducted data collection and analysis. The candidate wrote the paper and revised according to co-author feedback.

1 Introduction

In the eighteenth century the Irish philosopher George Berkeley challenged the widely held Descartian notion that all perception is based on unconscious and innate sensory ideas (Gorham, 2002). Instead, Berkeley postulated a multisensory theory of perception and maintained that associations between co-occurring sensations lead to our understanding of the world. According to him, distance perception is based not only on vision, but tactile cues and bodily movements as well (Moore et al., 2019). His ideas correspond well with modern day psychology and neuroscience where the importance of multimodal perception champions isolated sensory experience for our understanding of the world and our interactions with it.

Sensorimotor learning develops rapidly during infancy as we learn to respond to and act upon our environment. At first, perception and action are ill coordinated, and motor skills such as walking only become achievable when all their fundamental components have developed, been integrated, and practiced sufficiently well (Thelen et al., 2002). Later, walking becomes largely automated and generally requires little thought. However, in the event of significant damage to the peripheral neuromuscular system later in life, previously mastered skills may become significantly affected. Following lower limb amputation, somatosensory- and motor systems are disrupted leading to functional changes at neurological, physical, and psychosocial levels. Nevertheless, human beings are incredibly resilient and have the ability to adapt to even the most challenging of circumstances. Providing people with appropriate rehabilitation and prostheses post-amputation is integral to aiding such adaption and the reclamation of lost function.

Immense progress has been made in lower limb prosthetics in recent years following technological breakthroughs and improvements in healthcare. Imagining early prostheses, one might think back to Berkeley's era and the golden age of piracy, picturing people with hooks for hands and pegs for legs. However, the oldest documented lower limb prostheses, estimated at 3000 years old, is a rather more sophisticated toe with remarkably lifelike features such as anatomic appearance and mobility (Nerlich et al., 2000). The field has naturally evolved tremendously since then, with today's limbs spanning a wide array of devices ranging from mechanical solutions to advanced robotics.

1.1 Amputation & Rehabilitation

Major lower limb amputation (LLA) defined as amputation above the ankle can be performed at different levels, including hip disarticulation (HD) through the hip joint, transfemoral amputation (TFA) above the knee, knee disarticulation (KD) through the knee joint and transtibial amputation (TTA) below the knee. Although demographics vary between countries, the majority of amputations occur in people over 65 years of age (Dillingham et al., 2005) with the predominant cause being vascular in nature, followed by trauma, cancer and infection (Al Agha et al., 2017; Dillingham et al., 2005).

Appropriate rehabilitation strategies lay the foundation for peoples' return to the community following limb loss. Such strategies are not restricted to surgical procedures and prosthetic prescription. Well-being post amputation is heavily reliant on effective rehabilitation strategies involving physiotherapists, physiatrists, nurses, prosthetists, psychologists and other experts involved from pre-amputation throughout life (Keszler et al., 2020)

For those who are prescribed a prosthesis, mechanical or non-microprocessor-controlled solutions have been the standard of care. During the past decades, however, microprocessor-controlled solutions have emerged, providing increased adaptability to the environment by using information detected by sensors integrated in the prosthesis. The majority of microprocessor-controlled devices is passive, meaning that they cannot fully restore muscle function and require the user to compensate for their limited assistance. Active solutions can address these limitations by generating power with a motor, decreasing physical demands. A broad overview of prosthetic ankles and knees and their respective abbreviations is presented in Table 1

Table 1. Broad overview of prosthetic ankles and knees

Component	Abbreviation
Non-microprocessor-controlled (mechanical) ankle	NMPA
Non-microprocessor-controlled (mechanical) knee	NMPK
Passive microprocessor-controlled ankle	P-MPA
Passive microprocessor-controlled knee	P-MPK
Active microprocessor-controlled ankle	A-MPA
Active microprocessor-controlled knee	A-MPK

1.1.1 Activity Levels

The Medicare Functional Classification Levels (MFCL), also referred to as K-levels, are applied to indicate rehabilitation potential for people who have undergone lower-limb amputation (R. Gailey et al., 2010). Assigned K-levels have a large impact on whether an individual receives a prosthesis or not, and what kind of prostheses might suit them. Medicare definitions (Borrenpohl et al., 2016) of each level are described in Table 2.

Table 2. Medicare Functional Classification Levels

Levels	Classification
K0	This patient does not have the ability or potential to ambulate or transfer safely with or without assistance, and a prosthesis does not enhance his/her quality of life or mobility.
K1	This patient has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence, a typical limited or unlimited household ambulator.
K2	This patient has the ability or potential for ambulation with the ability to traverse low-level environmental barriers such as curbs, stairs, or uneven surfaces, a typical community ambulator.
K3	This patient has the ability or potential for ambulation with variable cadence, a typical community ambulator with the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic use beyond simple locomotion.
K4	This patient has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels typical of the prosthetic demands of the child, active adult, or athlete.

In some cases, people might receive a less sophisticated device due to their assigned K-level, even when they might benefit from a more advanced solution. Recent reports indicate that people classified at the K2-level, who predominantly receive non-microprocessor-controlled prostheses, may be reclassified at K3 when provided with microprocessor-controlled components (Hafner, 2009). Furthermore, Chen et al. (2018) reviewed the literature on the clinical and economic impact of microprocessor-controlled knees (MPKs) and found that providing individuals classified at the K2-level with advanced prosthetic components compared to NMPKs is not only associated with greater economic benefits, but also improves individual health status. Despite their widespread application in decision making, K-levels should thus be applied with caution during prosthetic prescription.

1.2 Prosthetic Limitations and User Requirements

Although lower limb prostheses can reduce the limitations induced by amputation (World Health Organization, 2001), their function does not fully match that of a healthy neuromuscular system, impacting both physical- and psychological function as well as well-being (Devan et al., 2015, 2017; Fogelberg et al., 2016; Gallagher et al., 2010, 2011; Klute et al., 2009; McDonald et al., 2019; Sinha et al., 2014).

1.2.1 The Socket

The fundamental requirement for lower limb prosthetic use can be stated in rather simple terms: Make sure the leg stays on. The solution to this precondition, however, is not as straightforward. Numerous socket and liner systems have been developed in order to keep the prosthesis in place so people can comfortably go about their daily lives without worrying about it staying in place or even slipping off. If a socket fits well, is safe and comfortable, people are obviously more inclined to don it as well as their prosthesis. An ill-fitting socket, however, can deter use and cause numerous complications. Skin health is a major concern as friction between the residual limb and the socket and liner can cause irritation and wounds (Quintero-Quiroz et al., 2019) that can prevent use. Even well fitted sockets have limited capacity to adjust to limb volume fluctuations (Paternò et al., 2021) and can also lead to pressure, discomfort, fatigue, and pain.

Another challenge in socket and suspension design is sweat management. Some individuals may simply be more prone to perspiring while environmental conditions and certain activities are likely to cause mild to excessive sweating (Notley et al., 2019). Beside discomfort, sweating can increase the likelihood of the residual limb getting displaced within the socket (McGrath et al., 2021), risking pain and injury. Sweating can further give rise to hygiene concerns and the need to remove the socket, both to clean it and the residual limb (Klute et al., 2016).

Osseointegration, where the prosthesis is fitted via surgical implants has recently become available to those who experience socket-related complications. Reports indicate that the procedure can encourage prosthetic use, reduce activity restrictions during daily life, improve quality of life and increase mobility. Furthermore, it may improve osseoperception or multisensory perception through tactile and auditory feedback (Clemente et al., 2017). Osseointegration can, however, be accompanied by a host of problems of its own, such as infection and soft tissue damage (Hebert et al., 2017), and the traditional socket is still the standard of care.

1.2.2 Prosthetic Function

In addition to socket related limitations, people may encounter various challenging scenarios in their daily lives. The current lack of sufficient degrees of freedom, ankle adjustment, knee resistance and active motion may be among contributing factors. For instance, people may experience trouble in positioning their foot (Batten et al., 2019; Klute et al., 2009), assuming particular positions (Fogelberg et al., 2016), navigating obstacles (Devan et al., 2015), maneuvering on uneven (Fogelberg et al., 2016) or slippery terrain (Batten et al., 2019; Devan et al., 2015; Fogelberg et al., 2016; Klute et al., 2009) and in confined spaces (Fogelberg et al., 2016; Klute et al., 2009). Further difficulties have been reported during transitions between activities (Fogelberg et al., 2016), sitting (Devan et al., 2015), ambulating in slopes and stairs (Fogelberg et al., 2016) as well as walking or sitting during prolonged periods of time (McDonald et al., 2019).

1.2.3 Microprocessor-controlled functions

Reports indicate that many user problems can be addressed with microprocessor-controlled solutions. For instance, when compared with mechanical devices, microprocessor-controlled knees (MPKs) can improve satisfaction (Lansade et al., 2018, 2021), walking speed (Kahle et al., 2008; Orendurff et al., 2006; Segal et al., 2006), abnormalities during gait (Kaufman et al., 2012), ambulation on uneven terrain (Kahle et al., 2008), obstacle negotiation (Hafner et al., 2007; Hafner & Smith, 2009; Seymour et al., 2007) and reduce the frequency of falls (Wong et al., 2015) as well as energy expenditure (Datta et al., 2005; Johansson et al., 2005; Schmalz et al., 2002; Seymour et al., 2007). Performance can, however, be suboptimal under certain conditions as they do not always offer spontaneous interaction between the user and device. Development has prioritized performance during certain actions, including standing up, cyclic movements, such as walking, and the transitions between them. Non-cyclic movements and the disruption of triggered functions can be cumbersome or impossible altogether. For instance, active MPKs will follow a defined trajectory when people stand up and will push them up until the knee is fully extended and the action is completed. Therefore, the user cannot disrupt the phase and decide to sit back down before the knee has been fully extended. Similarly, some modes must be intentionally triggered. Examples include transitions between walking on level ground and stair negotiation or from sitting to standing.

1.2.4 Adapting to Limb Loss and Compensatory Behavior

Prosthetic limitations can lead to short- and long-term repercussions of varying severity. A common strategy is compensating with physical strength, by altering ones posture (Devan et al., 2015, 2017) and relying heavily on the intact limb (Devan et al., 2015; McDonald et al., 2019). Consequential physical complications can include ailments and pain in the, residual, contralateral and upper limbs, back, and other intact structures (Devan et al., 2015, 2017). Adverse events, such as falls, can not only lead to injuries, or even death, but also impact psychological function. Hypervigilance due to fear of falling can lead to physical- and mental fatigue as well as mobility challenges (Wong et al., 2014; Yu & Ennion, 2019). Neuro- and psychological consequences can cause further problems such as limited prosthetic embodiment, i.e. experiencing the device as a part of one's body (Mills, 2013), phantom limb pain (Allami et al., 2019) and increased cognitive load during ambulation (Morgan et al., 2018). The interaction between psychosocial, neurological, and physical factors can result in activity restrictions where people avoid certain places or scenarios and decrease their social participation (Gallagher et al., 2010; Sinha et al., 2014), sparking a vicious cycle of even further inactivity and decreased quality of life.

1.2.4.1 Prosthetic Use & Abandonment

The frequency of prosthetic use is positively correlated with quality of life (Akarsu et al., 2013) while nonuse is associated with high health care expenses (Riemer-Reiss & Wacker, 2000). However, prosthetic limitations and comorbid conditions can lead some to only use their prosthesis occasionally (Callaghan et al., 2008; Hagberg & Brånemark, 2001), abandon their prosthesis for a less sophisticated device, or discontinue use altogether (Callaghan et al., 2008; Hagberg & Brånemark, 2001; Roffman et al., 2014). High maintenance and weight of the device (R. Gailey et al., 2010) are amongst causes for abandonment although some stop using their device due fear of falling or phantom limb pain (Chamlian & Chamlian, 2014).

1.3 Addressing Limitations in Prosthetic Function

One approach to promote prosthetic use involves improving current sensor technology and user intent recognition for increased usability. Tschiedel et al. (2020) conducted a systematic review on environmental sensors and their role in device control for increased safety and usability. Over half of the studies reviewed involved improving transitions between different modes of locomotion, most commonly via improved prediction for upcoming changes in terrain with kinematic-, distance and depth sensors.

Another strategy involves transmitting information to and from the neuromuscular system via neuroprostheses that can work with prosthetic limbs. Such devices may be used to enhance people’s control over their prosthesis and restore sensory feedback.

1.3.1 Intent Control

While improving sensors integrated in prostheses could facilitate terrain change detection and gait adaption, disruption of cyclic functions still remains a challenge. Unpredictable environmental factors and changes in task demands can require compensatory behavior, such as manually picking up their prosthesis to step over an obstacle rather than raising the foot itself (Fogelberg et al., 2016). On the other hand, the neuromuscular system can spontaneously respond to any scenario based on people’s intentions. Intent control, where control strategies dependent on neuromuscular signals are used to implement intended movements, is a feasible solution to overcome many of the current limitations posed by environmental conditions.

Intent control is most commonly based on signal detection via electromyography (EMG) where electrical activity of muscle contractions is used to control a prosthesis. The activity can be detected via intramuscular sensors or electrodes placed on the skin’s surface. While non-invasive solutions are available to people with upper limb amputation (ULA), no such system is commercially available to people with LLA.

Several studies have, nevertheless, indicated that EMG based intent control can potentially improve mobility in people with LLA. Although the majority involve performance in non-weight-bearing tasks without participants wearing their prosthesis (for review, see Fleming et al., 2021), there are several studies where participants perform activities with control over a wearable device.

Au et al. (2008) tested a powered ankle with one participant where surface EMG was used to control the prosthesis. The participant was able to walk comfortably and transition seamlessly between level-ground walking and stair ambulation. Similarly, Simon et al. (2013) provided two individuals with TFA control over a powered knee- and ankle prosthesis with EMG sensors embedded in the socket. The participants were able to walk, reposition their leg while sitting without manually moving the prosthesis and transfer between standing and sitting while dispersing load on both limbs. Another study on a powered knee and ankle prostheses with surface EMG control indicated that participants could negotiate in stairs and slopes as well as transfer to them from level ground. They were able to ignore perturbations or signal classification errors during all activities except stair ascent, where they had to stop before continuing when errors occurred (Hargrove et al., 2015). Other studies on A-MPKs have also demonstrated the feasibility of EMG control during similar activities (Kristjansson et al., 2017; Spanias et al., 2018; Zhang et al., 2014).

1.3.1 Sensory Feedback

Neuroprostheses do not only have the potential to restore the efferent signals of the neuromuscular system via intent control, but also the afferent sensory input traditionally provided by an intact limb. Currently, input is mostly limited to sensory feedback from the socket and liner, or bone anchored components in the case of osseointegration, as well as incidental sounds from the prosthesis itself. Lack of feedback has been regarded as a drawback of available solutions (Klute et al., 2009), both with regards to mobility and neuropsychological factors.

1.3.1.1 Visual & Auditory Feedback

Feedback can be applied during rehabilitation in order to train people in conducting themselves while wearing a prosthesis, or to replace the missing information from the limb itself in daily life. People with LLA rely more on visual cues than those who have two intact limbs, such as when maintaining balance (Ku et al., 2014), rendering visual feedback impractical during activities of daily living (van Gelder et al., 2018). Correspondingly, visual feedback has mainly been applied during prosthetic training and to ameliorate phantom limb pain in a clinical setting. During rehabilitation people may be encouraged to look in a mirror while they practice using their device to learn how to maintain proper posture and balance (Mohamadtaghi et al., 2018). In some cases, biomechanical information during walking is provided on a screen in real-time to improve gait (Esposito et al., 2017). Visual treatment paradigms for phantom limb pain include mirror therapy, motor imagery and visual therapy. The strategies all involve recreating motor imagery of the missing limb by utilizing virtual reality, mirroring the intact limb or asking people to mentally visualize movements and sensations of the phantom limb (for review, see Herrador Colmenero et al., 2018).

Provision of auditory feedback is less common than that of visual feedback in gait training (Escamilla-Nunez et al., 2020) and is often delivered concurrently with other modes of stimulation (Wilcher et al., 2011). In some cases, people are trained with audio cues to provide them with information on asymmetrical leg loading and postural sway (Lee et al., 2007), although systems intended for daily use have also been developed (Yang et al., 2012).

Visual and auditory feedback schemes used for other than training purposes can be considered as pure sensory substitution paradigms; they are intended to convey information that has been lost following amputation through another sensory modality. Although people can look down or listen to understand where their leg is and what it is doing, a “natural” feeling of proprioception is theoretically unobtainable. Somatosensory feedback can, however, be conveyed through what remains of the injured modality. Strategies can range from “unnatural” paradigms with non-somatotopic stimulation to modality-matched somatotopic solutions.

1.3.1.2 Somatosensory Feedback

Tactile-, kinesthetic- and proprioceptive information is crucial for the coordination of limb function during interaction with the environment (Kavounoudias et al., 2008) and feelings of ownership over ones limbs (Shehata et al., 2020). Without such feedback people must rely on other senses to know where their limbs are and what they are doing. As a result, they may spend a considerable amount of cognitive resources to compensate for the lost sensation (Morgan et al., 2018).

Different strategies have been implemented to restore somatosensory feedback for people with LLA, including non-invasive feedback applied on the skin’s surface such as mechanotactile-, vibrotactile- and electrotactile stimulation. Invasive intraneural electrodes can also be surgically implanted, either with non-somatotopic stimulation or modality-matched somatotopic stimulation (Guclu, 2021). Evidence from research on upper limb feedback indicates that a combination of both approaches may be necessary. D’Anna et al. (2019) conveyed modality-matched somatotopic tactile sensations for touch but used non-somatotopic sensations to deliver proprioceptive information to two people with ULA.

Compared to research on upper-limb neuroprostheses, the body of literature on sensory feedback for lower-limb solutions is quite sparse. No large-scale trials have been conducted and sample sizes are often in the single digits. Nevertheless, several studies indicate that feedback may improve both mobility and neuropsychological function.

Crea et al. (2017) provided three elderly individuals with TFA with a device that delivered feedback on important gait events. Shoes with pressure sensors were used to detect the events and three vibratory tactors placed on participant's residual thigh were activated to deliver the information. Participants all improved gait symmetry while walking on a treadmill after training with the system. Furthermore, results showed no indications of increased cognitive load and usability ratings were good for all three patients. Results from studies on similar systems with pressure-sensitive insoles suggest that vibrotactile feedback can assist people with LLA to detect differences between ground conditions (Wan et al., 2016) and accurately locate their prosthesis in stairs when they cannot rely on vision (Rokhmanova & Rombokas, 2019). In addition, Dietrich et al. (2018) conveyed information on toe and heel strike detected with insoles to 14 people with LLA via electrotactile feedback. While no differences were found on two standardized mobility tests before and during use of the system, participants reported improved mobility during interviews. Significant reduction in phantom limb pain was associated with the use of the system. In one case, a patient who experienced the phantom limb as shorter than it should feel, said he felt the amputated limb had reverted to its previous length.

One drawback of non-invasive strategies is that they are usually non-modality-specific. One example is applying tactile stimulation on the residual limb to indicate the angle of a prosthetic ankle. While touch plays a role in proprioception, kinesthetic receptors in tendons, joints and muscles convey the bulk of information needed for proprioceptive perception. Furthermore, some devices require intensive training and can be unintuitive for the user. Invasive solutions, while risky and expensive, have the potential to produce sensations homologous to those of an intact neuromuscular system and be somatotopic, meaning they activate the same pathways and cortical areas responsible for the sensations to be invoked.

Petrini, Valle, et al. (2019) tested three participants with TFA where intraneural electrodes conveyed tactile and proprioceptive feedback on the flexion of a P-MPK as well as ground forces measured with pressure insoles. Participants improved their balance and walking performance and reported significantly higher levels of prosthetic embodiment with sensory feedback than without. Additionally, Petrini, Bumbasirevic, et al. (2019) demonstrated that intraneural feedback improved walking capacity in two individuals with TFA and reduced cognitive load during ambulation.

The effects of providing intraneural sensory feedback on plantar pressure and their association with balance have been explored further. Charkhkar et al. (2020) used a sensory organization test where somatosensory- and visual feedback were missing or perturbed. Sensors on shoe insoles recorded the load distribution of a prosthetic foot and relayed information on plantar pressure to intraneural electrodes implanted in two persons with TTA. When visual input and somatosensory input of the intact leg were perturbed, participants showed improved balance when receiving feedback from the prosthesis.

1.3.2 Bidirectional Neuroprostheses

Being able to coordinate the in- and output of the neuromuscular system is integral to interact with the world and maintain proper posture and balance (Wolfe et al., 2009). Very little information is available on the effects of bidirectional lower limb neuroprosthetic systems which incorporate both intent control and sensory feedback. However, in 2018, Clites et al. implanted a myoneural interface with surgically constructed agonist-antagonist muscle tendons in one individual with TTA. The tendons mimicked native anatomy where one contracted and the other stretched during muscle contraction and vice versa. The participant could control the ankle- and subtalar joints with muscle contraction detected by EMG electrodes placed on the surface of his skin. Additional proprioceptive feedback from the prosthetic ankle was delivered by electrically stimulating the grafted tendons. When compared to four other individuals with traditional TTA, the participant had better control capabilities over the prosthesis and demonstrated natural reflexes in stairs not observed in the control group (Clites et al., 2018).

1.3.3 Active Motion

Benefits of neuroprosthetic functions will always be constrained by the software and functional capabilities of the prosthesis itself. One such constraint is the lack of active motion, especially for people with TFA. Those with passive devices must compensate for the lack of active assistance and recruit other intact structures to ambulate, such as muscles in the trunk. In one study, participants with TFA showed significantly higher spinal load during gait when compared to a control group without amputation (Shojaei et al., 2016). Other studies have yielded similar results (e.g. Morgenroth et al., 2018), and indicate that compensatory movements may contribute to physical ailments and pain (Devan et al., 2015) which can affect people's daily function (Jensen et al., 2001). Active MPKs (A-MPKs) may reduce the strain placed on the body and facilitate ambulation.

Most evidence on A-MPKs is based on small sample sizes with prototypes in laboratory settings (Lechler et al., 2018; Windrich et al., 2016). Furthermore, there is little consistency between evaluation methods between studies, which makes comparisons between publications difficult (Lechler et al., 2018). Nevertheless, there are indications that when equipped with active A-MPKs, people with TFA may show more symmetric gait patterns and reduced hip torque (Creylman et al., 2016) and decreased energy consumption during stair negotiation (Wolf et al., 2012). Jayaraman et al. (2018) tested a prosthesis with both A-MPK and A-MPA components. When using an A-MPK, participants with TFA showed similar gait characteristics as people with two healthy limbs, increased symmetry in muscle activation and loading, and could vary their walking speed both within the laboratory and in real world settings.

1.4 Challenges in the Development and Evaluation of Advanced Prostheses

1.4.1 Identifying Potential Benefits

The first and most obvious challenge in the development and evaluation of advanced components is their novelty. There is limited research on active motion, intent control and sensory feedback specifically designed for people with LLA. Furthermore, there are no guidelines for their design and the effects of adding functions not available before are unclear.

1.4.2 Matching Human Needs and Prosthetic Function

Prosthetic design and function must match the physical and psychosocial needs of the user. Abandonment rates are considerable where people may discontinue use or only use their prosthesis occasionally due to structural or functional limitations (Callaghan et al., 2008; Hagberg & Brånemark, 2001; Roffman et al., 2014). Dunne et al. (2015) suggest a perspective proposed by

Sousa et al. (2009), dichotomizing prosthetic factors into mobility, where people can go about their daily activities, and feelings of independence and autonomy. They argue that prosthetic use provides people with benefits beyond mobility that affect use. The results of interviews with people with LLA suggest that when prosthetic function is suboptimal people may feel alienated from their prosthesis, experience it as *a* leg rather than “their leg”, resulting in less frequent use or abandonment. However, feeling autonomous and in control could contribute, not only to agency during daily life but also to overcoming psychosocial challenges (Dunne et al., 2015).

Physical facets of limb loss have received considerably more attention than psychological ones (Baumann et al., 2020; Klute et al., 2009; Schaffalitzky et al., 2012) until recently. The latter may have greater impact on wellbeing, mobility and physical function than generally acknowledged (Baumann et al., 2020; Gallagher et al., 2010; McDonald et al., 2019; Sinha et al., 2014). Factors considered important by prosthetic users vary between individuals although some may be related to specific groups of people based on characteristics such as gender, cause of amputation or level of amputation (Baars et al., 2018). Researchers have expressed a lack of understanding of psychological aspects, nature of prosthetic use and how to match function with individual needs (Klute et al., 2009).

Understanding indirect psychosocial outcomes important to people with LLA can help guide advanced prosthetic development, especially for novel functions (McDonald et al., 2019). Qualitative research can address such aspects of prosthetic use and provide a deeper understanding of people’s interactions with their device than self-reports or performance-based tests alone. Several studies have applied qualitative methodology to assess patient needs, wants, daily experiences, limitations, environmental barriers, pain and other factors deemed important by prosthetic users (Batten et al., 2019; McDonald et al., 2019; Day et al., 2019; Fogelberg et al., 2016; Gallagher et al., 2011; Klute et al., 2009). Little information is, however, available on people’s needs when it comes to advanced prosthetic components and functions. McDonald et al. (2019) suggest applying qualitative methods to understand factors important to people with amputation by exploring what people with experience of different components recognize as significant to their lives. The results can then be used to match outcomes with appropriate evaluation strategies.

1.4.3 Evaluation

In addition to a gap in the literature on how to match human needs with advanced functions, there is a lack of consensus on how to evaluate such functions. Currently, there are no official guidelines for lower limb prosthetic evaluation on the whole, although a plethora of instruments have been developed and validated for people with LLA (Yildiz et al., 2021). However, several reviews have been published in recent years where the applicability and psychometric properties of available tests has been questioned.

Concerns on lower limb prosthetic evaluation have been raised for almost two decades, both for self-reported questionnaires and functional tests where people are asked to perform activities with or without their device. For instance, Condie et al. (2006) concluded that several assessment tools are inadequate for lower limb prosthetic evaluation. They further identified and recommended the use of validated instruments such as level-ground walking tests. Two years later, a review by Chamlian and Melo (2008) was published in which they reached a similar conclusion, recommending validated instruments, again highlighting the applicability of level-ground walking tests. Numerous reviews have been published on the topic since, where the general consensus is that further validation of instruments currently in use is required (Deathe et al., 2009; R. S. Gailey, 2006; Hart-Hughes et al., 2014; Heinemann et al., 2014) in addition to new and updated instruments (McDonald et al., 2019; Hart-Hughes et al., 2014)

The rapid advancements in prosthetics in recent years pose a new challenge for evaluation. Previously recommended tests, such as level-ground walking tests, may not capture function for people that are fairly active and may only be useful during early rehabilitation or for people that are less active (Sawers & Hafner, 2018). Current strategies are often sufficient to capture meaningful differences between vastly different devices but may be less sensitive to subtle differences between similar devices, such as microprocessor-controlled solutions (Bell et al., 2016).

In 2019, McDonald et al. noted that many evaluation methods used to compare prosthetic feet are indeed unlikely to capture the differences important to users, which researchers may further deem irrelevant. In turn, they conducted a focus group study with five individuals with LLA to identify outcomes important to prosthetic users and corresponding measures. They found that several important outcomes are not addressed with standardized measurements, and these measures might not be representative during laboratory tests and that metrics applied during tests do not encompass all important aspects of the activities in question. They recommended qualitative strategies to identify outcomes of importance, including ones for microprocessor-controlled devices and myoelectric control (McDonald et al., 2019)

The aforementioned challenges have partially been addressed for the advanced functions offered by A-MPKs (Hafner et al., 2007). However, no systematic appraisal has been conducted on evaluation strategies for intent control and sensory feedback for people with LLA to our knowledge. The utility of current testing strategies in neuroprosthetic evaluation is currently ambiguous and may necessitate the development of new instruments to assess their potential benefits. Here a combination of qualitative methodology and a systematic literature search is applied to identify the potential benefits of advanced components and the potential utility of current performance-based evaluation strategies in their appraisal.

2 Aims

The research involves in-depth interviews on advanced lower limb prostheses (**Papers I & III**), a contextual inquiry with multiple stakeholders (**Paper I**) as well as a systematic search on testing strategies with people with LLA (**Paper II**).

The project's main aims were to:

1. Explore unfulfilled lower-limb prosthetic user needs. (**Papers I** & **III**)
2. Identify the current and future benefits of advanced lower-limb prosthetic systems, including ones providing active motion, sensory feedback, and intent control. (**Papers I** & **III**)
3. Understand the challenges associated with developing such functions. (**Papers I** & **III**)
4. Understand the challenges associated with evaluating novel functions of advanced prosthetic components. (**Papers I & II**)
5. Assess the relevance of current evaluation methods in light of new developments within the field of lower limb prosthetics. (**Paper II**)

3 Materials and methods

All experimental procedures described in the thesis were approved by the National Bioethics Committee, Iceland, and conformed to the Declaration of Helsinki for testing human participants.

3.1 Paper I

Paper I is based on the results of semi-structured interviews and focus group discussions with experts in the field of lower limb prosthetics. A contextual inquiry (Privitera, 2015) was further conducted with individuals with major lower limb amputation.

These qualitative methods were selected due to the limited information available on lower limb neuroprosthetic systems, as well as the heterogeneity of people with lower limb amputation. They have various needs, preferences, and circumstances, and as such, qualitative research can prove valuable insight into people's interactions with their device and unmet user requirements. Interviews and focus group discussions can shed light on topics not easily grasped with quantitative research, and contextual inquiries can provide even further information not easily obtained with these methods alone.

3.1.1 Participants

The expert participants included a psychologist, physiotherapist, physician, prosthetist, and groups of engineers and prosthetic designers. They were employed at a rehabilitation center, a prosthetic manufacturing company, a hospital, and four prosthetic clinics in Europe. Additionally, five participants with transtibial or transfemoral amputation classified as K2-K3 according to the MFLC (World Health Organization, 2001) took part in the contextual inquiry. Some participants in the study had previous experience with EMG based intent control.

3.1.2 Procedure

Physiotherapists, physicians, biomedical engineers, and a PhD student in psychology were present during data collection. Interviews and discussions followed predefined open-ended questions based on previous literature. Each session was led by at least two researchers with one researcher acting as a moderator to ensure that all involved stayed on topic. While each interview followed the same structure, further information relevant to each participant was pursued. After interviews with participants from the LLA group, topics relevant to each individual were identified and pursued further in daily environments. There they could discuss and demonstrate the activities of interest that emerged from the interview. Four such sessions were conducted, as the fifth participant only took part in the interview. Two participants invited the researchers home and two sessions took place in a kitchen and living room environment at an office building when home visits were not feasible. The predefined topics for participants with LLA and expert participants are presented in Table 3 and Table 4.

Table 3. Interview themes with participants in the LLA group in Paper I.

Theme	Topics
Daily life	Day-to-day routine, leisure activities and hobbies, occupation, situational avoidance, challenging scenarios.
Environmental factors	Challenging environments, slippery surfaces, weather, confined spaces.
Sensations & perception	Sensations from prosthesis, feelings of control over prosthesis and voluntary movement, pain.
Socket and Liner	Donning/Doffing, sweating, suspension adherence.
Psychological factors	Trust in prosthesis, feeling uncomfortable or uncertain, mental fatigue, cognitive load.
Personal factors	Cosmesis, prosthetic preferences and required improvements.

Table 4. Interview- and focus group discussion themes with expert participants in Paper I.

Theme	**Topics**
User requirements	Current problems and unmet requirements, challenging circumstances, and scenarios
Current state in the field	Perspectives on different types of prostheses and suspension systems available today
Sensory feedback	Perspectives on potential benefits and challenges of sensory feedback. Current sensations from non-neuroprosthetic systems.
Intent control	Voluntary behavior, current control strategies, perspectives on EMG control and other intent control strategies, benefits and challenges.

3.1.3 Analysis

When permission was granted, audio and video were recorded and later transcribed. Additionally, researcher notes were used. Each session was then transcribed and reviewed by two separate researchers. Salient themes were identified, some based on their inclusion in the predetermined script while others were identified inductively. Codes were appointed to data points based on whether they were regarded as problems, their potential solutions, or goals to achieve. Additional codes were included based on participant group and whether they were related to people, devices, or environmental conditions. Subsequently, further codes based on reoccurring ideas and words were used to meaningfully group and cluster the data. Researcher interpretation was used to further sort the data into a thematic hierarchy. All disagreements were resolved via consensus-based discussions. The clusters and themes were not mutually exclusive as many data points could be applied to more than one theme or cluster. Direct quotes and researcher notes were translated to English. Table 5 shows how the results are presented in Paper I.

Table 5. Overview of data type representation in Paper I

Data representation		**Data type**
Main body	Text	Summary of multiple data points and themes
Quotation marks	“ “	Direct quotes
Square brackets	[ ]	Altered/substituted wording
Curly brackets	{ }	Researcher notes
Ellipsis	[…]	Consciously omitted words and sentences

3.2 Paper II

A systematic search was conducted by two independent researchers in the literature review software Distiller (DistillerSR | Systematic Review and Literature Review Software, n.d.) in three databases; 1) PubMed; 2) Web of Science; and 3) Cochrane. Disagreements between researchers were resolved via consensus-based discussion. The time period spanned the years 2013-2019. The inclusion criteria defined were the following: Lower limb AND (prosthesis OR amputee) AND (metrics OR assessment) NOT (dental OR arthroplasty). Articles had to be 1) peer-reviewed; 2) full-text, in Icelandic or English; 3) involve testing with human participants with major lower limb amputation above the ankle; 4) and contain measures based on performance where participants were asked to perform activities with scoring methods not solely based on self-report instruments or biomechanical measures. Articles describing surgical procedures or mechanical dimensions were excluded unless they were reliably associated with outcome measures not specific to the intervention. Secondary sources published in the past two decades that fulfilled the criteria above were further included to avoid strictly limiting the review to the period, potentially excluding relevant outcome measures and information on instrument development.

Sample size and power analyses were not applied as a criterion during the selection process as the field of lower limb prosthetics is relatively restricted and studies often include small sample sizes with limited power. People with lower limb amputation make up a small portion of the general population and participant recruitment as well as researcher blinding can prove difficult (Kannenberg et al., 2014). Therefore, small scale studies were included during the analysis where their strengths and weaknesses were discussed.

3.3 Paper III

Paper III Involves semi-structured interviews with five individuals with unilateral transfemoral amputation (TFA) who have experience with active microprocessor-controlled knees (A-MPK). A qualitative approach was applied, as in Paper I, due to the limited amount of information available on A-MPKs and user experiences. There is only a single A-MPK commercially available and a relatively low proportion of people with TFA, usually highly active males, have tried a motor-driven prosthesis. The interview structure and content were based on the results of Paper I.

3.3.1 Participants

All participants were males classified as K3-4 according to the MFCL (Borrenpohl et al., 2016) with unilateral TFA. Their mean age was 51 years (range: 19-52) and weighed 73 kg on average (range 63-79). They all used non-microprocessor-controlled ankles (N-MPA) and passive microprocessor-controlled knees (N-MPKs) in their daily lives. Three participants had previously used an A-MPK as their main prosthesis for several months or longer. The other two received a brief introduction to an A-MPK two weeks before the study began. All participants had extensive experience with various prosthetic components and were familiar with terminology in the field.

3.3.2 Procedure

The study included two phases, the interview described in Paper III, as well as an acclimation period of 1.5 days with a novel A-MPK unit in both community- and laboratory settings. While interconnected, these two phases can be considered as separate facets of the same study with different aims. The former, explored participant's prosthetic history, experiences, and perspectives on advanced lower limb prostheses while the latter centered around level-ground walking and performance with the new unit. Only the results of the interviews are detailed in Paper III. The content and structure of the interview is presented in Table 6 (for interview guide, see Appendix I). While each interview followed the same structure, individually relevant topics to each participant were pursued. One researcher conducted the interview, although an interpreter was present when necessary.

Table 6. Interview Structure & Content in Paper III.

Category	**Theme**	**Topics**
Daily Life	Daily use and requirements	Daily routine, occupation, hobbies, effort/enjoyment during activities, situational avoidance.
Current Prosthesis	Attitudes towards prosthesis	Knee & ankle unit, additional prostheses, trust, safety, satisfaction, intuitiveness, downsides/improvements, functions/modes.
Previous prostheses	Experience with prosthetic components	Previous daily components, NMPK, A-MPK, N-MPA and MPA experience, transitioning between prostheses, satisfaction, downsides, extent of experience.
Learning & Training	Enthusiasm and motivation for new experiences, learning to use new prostheses	Attitudes to new experiences, technology, and prostheses. Length of acclimation periods, intuitiveness, risk tolerance.
Properties of Components	Relevance to the user	Weight, charging, aesthetics, cosmesis, volume.
Connection to Prosthesis	Integration of self and prosthesis	Donning/doffing, perception of prosthesis as body part/tool, concealment or display of prosthesis.
Opinions on A-MPK unit	Attitudes towards new unit after very short acclimation period	Intuitiveness, safety, ability to perform/enjoy activities, daily life relevance.

3.3.3 Analysis

Analysis was conducted in a similar manner to that of Paper I. Audio was recorded, as well as video when participants preferred to demonstrate activities rather than solely giving verbal accounts. The results were transcribed and reviewed at a later time where salient themes were identified. The themes were either predetermined in the interview script or identified after the fact. Each data point was appointed a code based on prosthetic components- and function, activities, as well as human- and environmental factors. Data points were then clustered based on reoccurring words and ideas and researcher interpretation. To provide a common language, the data was appointed additional codes based on interpreted association with high-level categories of the Classification of Functioning, Disability and Health (ICF) (World Health Organization, 2001). The data was represented in the same manner as the data in Paper I (see Table 5)

4 Results & Discussion

The findings of each paper correspond well with the project's aims and can be summarized as follows:

Paper I: The focus group discussions, semi-structured interviews and contextual inquiry shed light on several challenges people with lower limb amputation face in their daily lives. Responses from multiple stakeholders in the field indicate that neuromuscular interfacing can potentially address many of the issues identified and increase people's mobility, wellbeing, and quality of life. Furthermore, perspectives on criteria regarded as integral for the development of neuroprostheses are presented along with considerations for actualizing and evaluating a usable system

Paper II: The literature review on evaluation methods in lower limb prosthetics provides a broad overview of performance metrics in the field. The review further contains an appraisal of the utility of such tests in the assessment of neuroprosthetic systems. The findings indicate that there is a need for further development of performance-based metrics and tests, not only for current technology, but also for novel functions of advanced components in particular.

Paper III: Several challenges people with transfemoral lower limb amputation may face were identified as well as factors perceived as important for prosthetic use and satisfaction. In addition, considerations on how to make advanced functions more accessible to users are presented.

4.1 Perspectives on Advanced Prosthetic Components

Being able to control ankle and knee movement, position, and resistance with intent control-based adjustment could potentially allow people to maneuver and ambulate in ways not achievable before. Assuming particular positions, transitioning between activities, dispersing weight evenly, disrupting cyclic activities and responding to sudden changes in the environment are among the factors participants regarded as prospective neuroprosthetic benefits. Reduced strain on intact body structures may in turn promote physical wellbeing and mobility, especially when active motion is provided (Paper I & III).

Although numerous physical benefits could be associated with neuroprosthetic systems, their greatest impact might be neuro- and psychological in nature. Improved prosthetic embodiment and decreased phantom limb pain following restoration of sensory feedback and muscle function could lead to increased prosthetic acceptance and use. Increased self-efficacy and trust in the prosthesis could further ensure full utilization of available functions with increased control, allowing people to build their confidence. Neuroprosthetic systems could thus break the vicious cycle of inactivity and promote health, mobility, and quality of life (Paper I).

4.1.1 Advanced Functions & Development

There was a general consensus that sensory feedback and intent control should be delivered in real time in an intuitive manner perceived as “natural”. Additionally, the interface should not interfere with other perceptual processing or demand a lot of cognitive resources (Paper I). Advanced functions in general must be easy to initiate, preferably unconsciously and automatically, so people will actually use them and gain benefits over less advanced solutions (Paper I & III)

4.1.2 Neuroprosthetic Evaluation

Many of the anticipated benefits of neuroprostheses have not been addressed with the instruments currently available in lower limb prosthetics. A number of questionnaires and performance-based tests where people perform various activities have been developed. Participants in the study presented in Paper I had reservations about the usefulness of questionnaires and the external validity of frequently applied instruments. They pointed out that current testing strategies might not necessarily capture the benefits of neuroprosthetic functions, especially due to their novelty.

4.1.2.1 Relevance of Current Evaluation Methods & Considerations for Neuroprostheses

A systematic search was conducted to assess the relevancy of performance-based instruments for neuroprosthetic evaluation (Paper II). The search results presented in Figure 1 show that of the 646 emerging articles, 72 fulfilled the inclusion criteria and were included in the analysis.

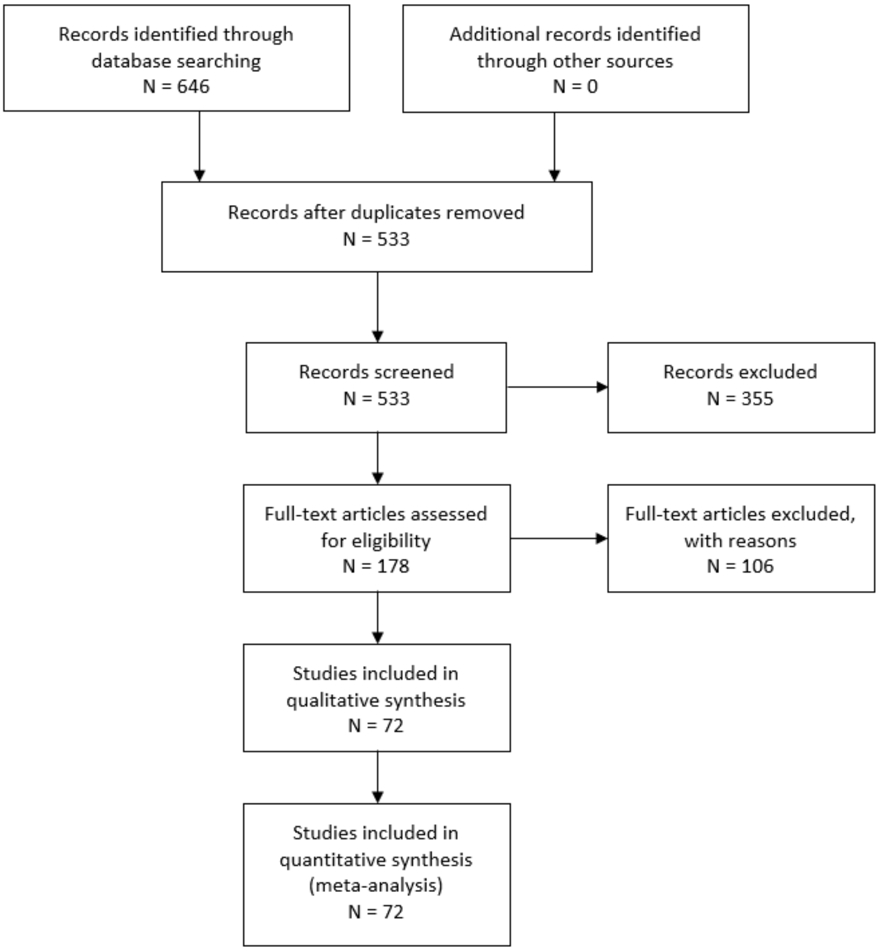


Figure 1. Prisma flow diagram demonstrating article selection during the systematic search in Paper II

Several performance-based instruments used in lower limb prosthetic evaluation were identified. An overview of the instruments is presented in Table 7 along with a description on their conduction and metrics.

4.1.2.2 The Good, the Bad & the Poorly Validated

Many instruments currently in use in the field may lack psychometric qualities necessary for reliable and valid assessments and some have yet to be validated for the population (Paper II). Despite having good psychometric properties, some instruments may only be appropriate for a certain part of the population or during a limited period of time. Further, an instrument can have excellent psychometric properties for the population and yet fail to capture clinically relevant aspects (Paper II).

> *{We are very focused on looking at people going up and down stairs, sitting and standing, and moving around in slopes, but these are all things you can do with a peg leg. We aren't covering everything. Some people's gait might be great, but everything else surrounding it is something they have difficulties with and require a lot of effort.} (Expert – Paper I)*

Considering aspects other than cyclic movements, notably transfers between them and their disruption, might prove beneficial when choosing instruments to evaluate neuroprosthetic functions. Such considerations, based on the results of Paper I, are presented along with information on test content in Table 7.

Table 7. Test content of performance-based instruments in Paper II.

Test	Conduction Involves	Metrics	Considerations for Neuroprostheses
2MWT	Walking for 2 min	Distance traveled	Only include cyclical behavior on a flat surface in a straight line
6MWT	Walking for 6 min	Distance traveled	Only include cyclical behavior on a flat surface in a straight line
10MWT	Walking 10 m	Assistive need, use of assistive devices, handrail use, and stepping pattern	Only include cyclical behavior on a flat surface in a straight line
HAI	Walking up and down an incline	Assistive need, use of assistive devices, handrail use, and stepping pattern	Include two transitions between cyclical activities
SAI	Ascending and descending stairs	Assistive need, use of assistive devices, handrail use, and stepping pattern	Include two transitions between cyclical activities
TUG and C-TUG	Sitting on a chair, standing up, walking 3 m, turning back, and sitting down again	Time duration	Involve two transitions, cyclical behavior on a flat surface in a straight line and a single turn
180° turn	Sitting on a	Number of steps	Involves two

Table 7. Test content of performance-based instruments in Paper II.

Test	**Conduction Involves**	**Metrics**	**Considerations for Neuroprostheses**
test	chair, standing up, walking 3 m, turning back, and sitting down again	taken during turn, turn time, fluidity of motion	transitions, cyclical behavior on a flat surface in a straight line and two different turns
L-test	Sitting on a chair, standing up, walking 10 m in an L shape, turning 180°, going back the same way, and sitting down again	Time duration	Involves two transitions, cyclical behavior on a flat surface in a straight line and two different turns
FSST	Stepping clockwise in four squares formed by two canes and then repeating the process in the counterclockwise direction	Time duration	Involves stepping in four different directions over an obstacle, repeated for both prosthetic and sound side
AMP	Performing several incrementally complex activities from sitting balance to obstacle negotiation	Quality of gait, need for assistance	Includes various activities requiring transitions, obstacles, turning as well as both cyclical and noncyclical ambulation
F8WT	Walking in a	Time duration,	Involves avoiding

Table 7. Test content of performance-based instruments in Paper II.

Test	Conduction Involves	Metrics	Considerations for Neuroprostheses
	figure of eight between two cones placed 5 ft apart	width of path, step count	obstacles and turning
FIM	Evaluation of activities of daily living, mobility, and cognitive function	Need for functional assistance	Involves transitions, cyclical ambulation on flat surface and stairs
CHAMP	Performing several high-level athletic activities	Time duration	Includes turning, stepping in various directions, avoiding obstacles and transfers between lying on floor and standing
SWOC	Navigating an obstacle by rising from a chair, sitting back down, stepping over and avoiding obstacles, ambulating on visually challenging and rough terrain	Time duration, number of steps, step-offs, and stumbles	Involves two transitions, obstacle avoidance, and cyclical walking on different terrain types
BAMS	Laying down on a bed, sitting on its edge, transferring to a	Need for functional assistance and guiding	Includes transfers of a rudimentary nature

Table 7. Test content of performance-based instruments in Paper II.

Test	**Conduction Involves**	**Metrics**	**Considerations for Neuroprostheses**
	wheelchair, and performing single limb standing		
CS-PFP10	Performing everyday tasks of incremental difficulty	Quality of functional performance	Involves cyclical ambulation on flat surface with and without external loads as well as in stairs. Also includes transferring to and from sitting on floor
BBS	Performing 14 functional activities such as stepping, standing, sitting, and reaching	Independence, time duration, number of steps, and distance traveled	Includes several transfers and turns
CB&M	Performing several activities, ranging from simple movements to more difficult tasks	Distance traveled, quality of performance	Involves incrementally challenging ambulation on floor and stairs, both cyclical and noncyclical; further includes interruption of cyclical behavior, numerous transitions, external loads, and attention
LEMOCOT	Sitting on a chair and moving unaffected leg as quickly and	Accuracy during a 20-s period	Evaluates intentional leg coordination

Table 7. Test content of performance-based instruments in Paper II.

Test	Conduction Involves	Metrics	Considerations for Neuroprostheses
	accurately as possible between two targets on the floor, and repeating for affected leg		
NBWT	Walking on a narrowing beam	Distance traveled	Involves incrementally challenging cyclical walking in a straight line on a raised surface; requires agility, balance, and coordination

2MWT, 2-Minute Walk Test; **6MWT**, 6-Minute Walk Test; **10MWT**, 10-Meter Walk Test; **HAI**, Hill Assessment Index; **SAI**, Stair Assessment Index; **TUG**, Timed Up and Go; **C**-TUG, Component Timed Up and Go; **FSST**, Four-square Step Test; **AMP**, Amputee Mobility Predictor; **F8WT**, Figure of Eight Walk Test; **FIM**, Functional Independence Measure; **CHAMP**, Comprehensive High-level Activity Mobility Predictor; **SWOC**, Standardized Walking Obstacle Course; **BAMS**, Basic Amputee Mobility Score; **CS-PFP10**, Continuous Scale Physical Functional Performance 10; **BBS**, Berg Balance Scale; **CB&M**, Community Balance and Mobility Scale; **LEMOCOT**, Lower-Extremity Motor Coordination Test; **NBWT**, Narrowing Beam Walking Test.

4.2 The Real World

One key point in all evaluation, prosthetic or not, is its applicability outside the laboratory. Does performance in clinical settings actually reflect what occurs in the real world? People with LLA tend to alter their behavior when observed (Malchow & Fiedler, 2016), as stated by a clinical expert interviewed in Paper I:

> *{When I ask people to walk, they do it very well, but as soon as they are not diligently trying to do it properly, they are not as good. That's why I take notice of people's gait as they walk in the door and do not know that I am evaluating them}*

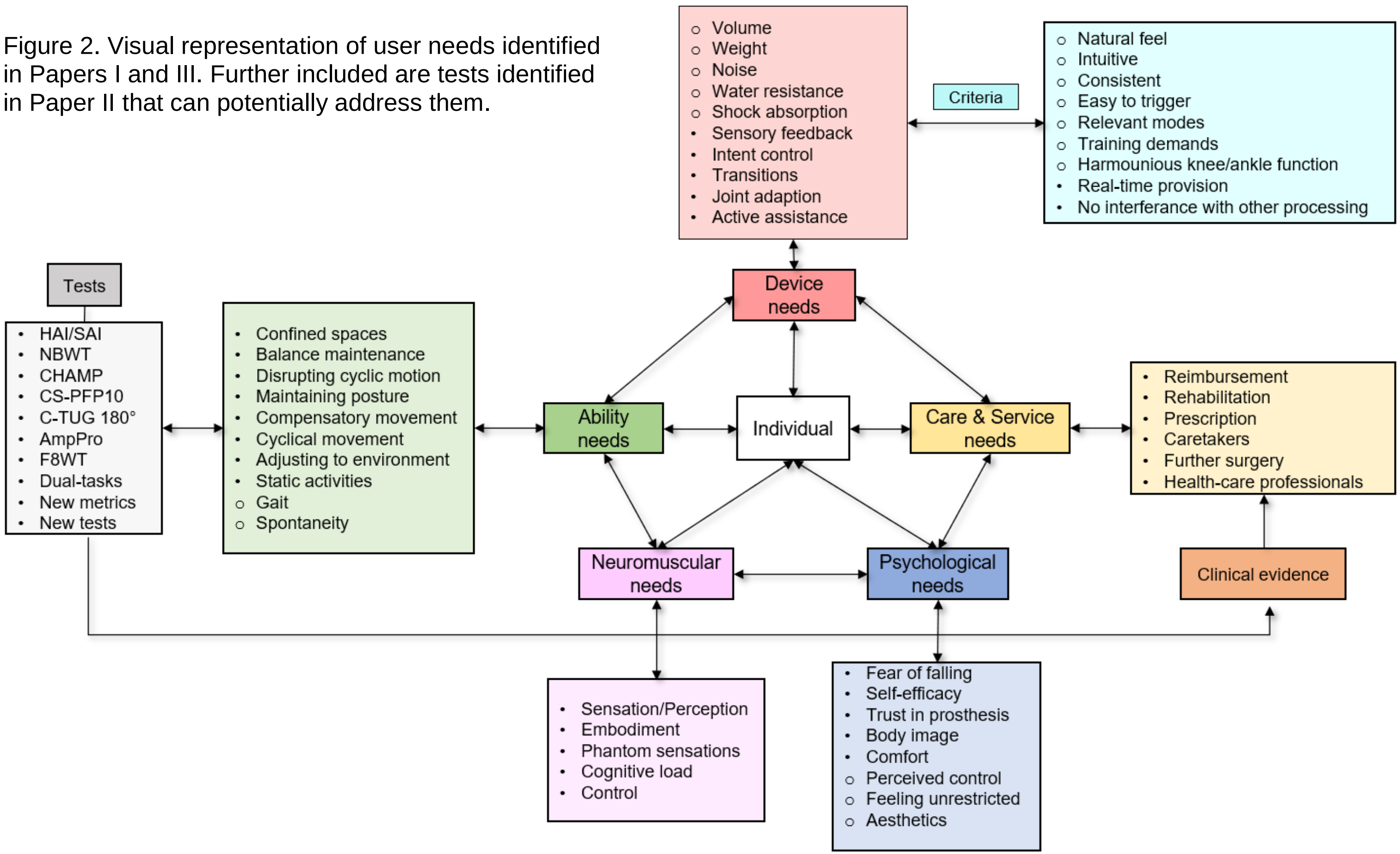
Such trends are notable with regards to the use of available microprocessor-controlled functions. The Stair Assessment Index (SAI) where people are asked to ascend and descend stairs, was developed specifically for MPKs. Stepping patterns factor into the resulting scores where a distinction is made between a step-over-step pattern and step-by-step pattern. While performance might be indicative of physical capabilities, it is questionable whether they represent how people approach stairs on a day-to-day basis. Just because someone can ascend stairs with a step-over-step pattern and receive high marks, this does not mean that they will do so in real life. One of the most staggering quotes found in Paper I concern the usability of MPK functions in stairs:

> *{Stair ascent can't really be done well with current knees and is mostly a party trick, not something users use.}*

The lack of active motion was identified not only as a barrier to neuroprosthetic benefits, but also for currently available solutions for people with TFA. Even with the power generated by A-MPKs, their function must be easy to use or people will not trigger them and opt for other methods to achieve their intentions (Paper I & III). People are naturally inclined to use simple solutions, as one expert noted: "What is quickest is best" (Paper I).

"A summary of findings from papers I-III are visualized in Figure 2. Relationships between different needs identified during the project are presented in addition to performance based tests potentially suited to evaluate them. Needs and criteria emerging from Paper III are marked with °".

Figure 2. Visual representation of user needs identified in Papers I and III. Further included are tests identified in Paper II that can potentially address them.



5 Conclusions

In recent years, the field of lower limb prosthetics has made fast paced strides towards decreasing the gap between human and machine. Nevertheless, there is still room for improvement as the restoration of neuromuscular function has yet to be fully accomplished. Matching people's needs and prosthetic properties is integral to facilitate adjustment to limb loss and promote quality of life. We have identified numerous unfulfilled prosthetic user requirements, opportunities, and challenges in addressing them with advanced prosthetic functions. In addition, considerations for testing such solutions are presented.

Innovation necessitates evaluation if the prospective benefits of a device are actually going to reach end users and impact their well-being. Currently, performance-based tests in the laboratory or clinical settings as well as self-report have been dominant in assessing the performance of prosthetic components and functions. The findings in this project indicate that many frequently used instruments might not be relevant when assessing advanced functions and that new strategies could be beneficial for future evaluation. Although the exploration of the psychological aspects of prosthetic use has gained traction in the past few years, the literature is quite sparse compared to studies focused on biomechanical device performance. In depth accounts of prosthetic user experiences should be considered as a powerful tool on their own and as complementary to quantitative research.

On the whole, our findings indicate that neuromuscular interfacing and provision of active motion has great potential to harmoniously match human needs and device function, impacting people's wellbeing and quality of life.

5.1 Strengths and Limitations

The project‘s main limitation is its generalizability. Papers I and III are based on qualitative research with samples that only include people with unilateral amputation at the transtibial or transfemoral level. Transferability to people with bilateral- or other levels of amputation, such as hip- or knee disarticulation is thus limited. Further, Paper III included a homogenous sample that did not include females, less active individuals, or people who use NMPKs. Additionally, the COVID-19 pandemic restricted sample size in Paper III and led to only one researcher being present during the interviews. Information may further have been lost in translation when an interpreter was present.

However, the project‘s limitations also contribute to its greatest strengths: Qualitative research allows for in-depth information that is not easily extracted via other methods, such as questionnaires. Although qualitative research on lower limb prosthetics is gradually increasing, there are relatively few published studies, especially ones focusing on advanced components and future developments in the field. Finally, the systematic approach applied during the review provides a comprehensive overview of the literature on evaluation methods for lower limb prostheses, not intrinsically included in other search strategies

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Paper I

Paper I

The following chapter contains a manuscript published in the Journal of Prosthetics and Orthotics: "*Multistakeholder Perceptions on Lower-Limb Prosthetic User Requirements and the Development of Neuroprostheses: A Contextual Inquiry*". The authors are Vigdís Vala Valgeirsdóttir, Jóna Sigrún Sigurðardóttir, Ómar I. Jóhannesson, Ásgeir Alexandersson, Árni Kristjánsson. Formatting and figure numbers of the published article have been altered for continuity with the thesis on the whole. Any references to the chapter's content should be as follows:

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5.2 Abstract

Introduction: Neuroprosthetic systems that can work with prosthetic legs are currently being developed to provide individuals with lower-limb amputation with intent control over their device and sensory feedback. No such system is commercially available, and the effects of providing functions that have previously not been available to lower-limb prosthetic users are unclear.

Methods: Here we present investigations of the perceptions of multiple stakeholders (prosthetic users, physician, psychologist, physiotherapist, prosthetist, and groups of prosthetic designers and engineers) on prosthetic user problems and the development of neuroprosthetics. The investigation entailed semi structured interviews, focus group discussions, and a contextual inquiry.

Results: Our findings indicate that prosthetic users may face several challenges that can potentially be addressed via neurological interfacing. We further identified criteria perceived as integral for the development of lower-limb neuroprostheses as well as considerations for the actualization of a usable system that reaches end users.

Conclusions: On the whole, the field of neuroprosthetics has great potential to increase the wellbeing, mobility, and quality of life of persons with lower-limb amputation.

5.3 Introduction

Despite the development of increasingly sophisticated prostheses, limb function has not yet been fully restored for people with lower-limb amputations (LLAs). Although prostheses fulfill the requirements for many activities, their performance is suboptimal under certain conditions, which can result in compensatory behavior and activity restrictions.[1] The current lack of sufficient ankle adjustment, knee resistance, degrees of freedom, and active motion may contribute to several difficulties such as positioning the foot,[2,3] maintaining posture and balance,[4,5] assuming particular positions,[6] maneuvering in confined spaces[2,6] and on uneven terrain,[6] and transitioning between activities.[6] Users also experience problems while standing and walking for a prolonged duration,[4] sitting,[5] and walking in slopes and stairs.[6] Environmental factors such as slippery or uneven surfaces[2,3,5,6] and obstacles on the ground5 can lead to tripping and falling. Compensatory behavior for these limitations can have both short- and long-term repercussions of varying severity. In addition to injuries from trips and falls, overreliance on the intact side,[4,5] altered posture,[5,7] and compensation with physical strength5 have been reported as causes of residual limb, back,[5,8] and upper-limb ailments and pain, negatively affecting health and function over time.

LLA can further have neurological and psychological consequences such as phantom limb pain,[9] limited prosthetic embodiment,[10] and increased mental effort required for ambulation (for review, see Morgan et al.[11]). Psychological effects and adjustment to limb loss have received less attention than physical consequences[2,12,13] until recently and may play a larger role than generally acknowledged in wellbeing, physical function, and mobility.[4,12,14,15] For instance, hypervigilance associated with the fear of falling can not only lead to mental and physical fatigue[5] but also mobility challenges.[16,17] Altered self-perception and social interactions can furthermore influence quality of life[18,19] and behavior, where the level of prosthetic integration into the body schema may be important for prosthetic use and activity.[20] Activity restriction3 and decreased social participation may negatively affect quality of life,[14,15] creating a vicious cycle of further inactivity.

Many users resort to other means of ambulation such as using a wheelchair.[21] Roffman et al.[22] found that 11% of LLAs did not use a prosthesis 4 months post discharge from rehabilitation, increasing to 19% 12 months after discharge. Others have found that 5% to 20% of LLAs do not use a prosthesis, and approximately 20% of prosthetic users only used their prosthesis occasionally.[23,24]. The frequency of prosthetic use is positively correlated with quality of life,[25] and nonuse is also associated with high health care expenses.[26] One way of addressing prosthetic limitations involves further decreasing the prosthesis-to-user gap with neurological interfacing. Advanced neuroprostheses are currently being developed, which include control schemes that can better detect user intent and provide sensory feedback (for review on lower-limb feedback, see Escamilla-Nunez et al.[27]). Neuroprostheses involve interfaces that can replace or supplement the nervous system's input and output and may be used to restore function of individuals with neural deficits. Here, we discuss neuroprostheses that can relay signals to and from the nervous system and work with prosthetic limbs to provide users with intent control over their prosthesis and sensory feedback. We further define intent control as prosthetic control strategies that use detected neuromuscular signals to implement the intended movement of the user. Intent control is most commonly provided with electromyography (EMG) where electrodes placed on the skin's surface record signals from the nervous system via electrical activity of muscle contractions that can then be used to control a prosthesis.

Recent evidence indicates that neuroprostheses may improve mobility[28–30] and prosthetic embodiment[31] and can decrease phantom limb pain.[28–30] There are, however, numerous challenges for developing effective lower-limb neuroprostheses. There are no concrete guidelines for development, and the impact of adding new functions to current designs is unclear. Moreover, current testing strategies can have several limitations,[2,32–37] and as neuroprostheses provide new functions not available before, the challenges associated with their evaluation can be expected to be even greater than those for current devices. Qualitative research can provide useful information on user problems and needs,[2–6,16] but no such in-depth research is available on neuroprostheses. A contextual inquiry (CI) is a powerful tool to explore constraints of medical devices, to explore how new systems can address them, and to understand unfulfilled user needs.[38] CIs can provide information not easily extracted from interviews or questionnaires alone, as they involve observing users' interactions with their devices in their everyday environment.[38]

We describe the results of interviews and group discussions with multiple stakeholders as well as a CI involving LLAs to 1) gain insight into perceptions of unfulfilled lower-limb prosthetic user requirements, 2) gain insight into problems that could potentially be addressed with neuroprostheses, and 3) discern the main challenges in development and evaluation of neuroprostheses. In our results section, we first report perceptions on functional limitations and the psychological aspect of limb loss before delving into their possible association with neurological interfacing. We then discuss challenges and criteria involved in neuroprosthetic development and evaluation.

5.4 Methods

5.4.1 Participants

Several experts in the field of prosthetics and LLA participated (expert group), including a physician, psychologist, physiotherapist, prosthetist, and groups of prosthetic designers and engineers. The experts were employed at a hospital, rehabilitation center, a prosthetic manufacturing company, and four different prosthetic clinics in Europe. Furthermore, five individuals with transfemoral LLA (TFAs) or transtibial LLA (TTAs) classified as K2 to K3 according to the Medicare Functional Classification Levels (MFCL) participated (LLA group). LLA group participants had to be older than 18 years and have a major LLA above the ankle. Some stakeholders had previous experience with EMG control.

5.4.2 Procedure

All experimental procedures were approved by the National Bioethics Committee, Iceland, and conformed to the Declaration of Helsinki for testing human participants. The researchers involved in data collection included physicians, physiotherapists, biomedical engineers, and a PhD student in psychology.

5.4.3 Expert Group

Interviews and discussions followed predefined open-ended questions led by at least two researchers who moderated the sessions and guided the experts to stay on topic.

5.4.4 LLA Group

Participants with LLA were contacted by a prosthetist and screened for inclusion criteria. They signed an informed consent form and were invited to a semi structured interview at a prosthetic clinic. The interview followed the same structure for all five interviewees, whereas further information on issues relevant to each participant was pursued. A visit to the individual's daily environment followed where participants discussed and demonstrated activities emerging during the interview. The researchers conducted four such contextual sessions: at home for two LLA participants and in a living room and kitchen environment not at home for two additional ones where a home visit was not feasible. One participant only completed the semi structured interview.

5.4.5 Analysis

When participants granted permission, audio and video were recorded and later transcribed. Otherwise, researcher notes were used. Two researchers separately reviewed the transcripts and notes to identify salient themes. Although some themes were predetermined by their inclusion in the interview script, others were inductively identified. First, data points were appointed a code based on participant group, human, environmental, or device relation, and whether they were regarded as problems or goals to achieve or potential solutions. Reoccurring words and ideas were subsequently used to create further codes to meaningfully cluster the data. The clusters were then sorted into a thematic hierarchy based on researcher interpretation. Disagreements were settled via a consensus-based discussion. Many data points applied to more than one cluster or theme, so they were not mutually exclusive. Direct quotes and researcher notes in languages other than English were translated. In the results section, the main body of text represents a summary of multiple themes and data points from the interviews, discussions, and inquiries. Quotation marks represent direct quotes, square brackets represent altered or substituted wording, and curly brackets represent quotes transcribed during interviews where audio was not recorded. Consciously omitted words and sentences are further denoted by ellipsis.

5.5 Results

5.5.1 Rehabilitation, Prosthetic Prescription, and Clinical Considerations

Not everyone who has the potential to use a prosthesis receives one. Medical staff generally try to prescribe a prosthesis as they facilitate daily activities. Even the most rudimentary prostheses allow people to stand upright, stimulating circulation. Those who have walking potential but are unable to don a prosthetic liner (e.g., because of upper-limb disability) are less likely to be fitted with a prosthesis, unless they have a caretaker who can assist them. Older prosthetic users in nursing homes or who receive homecare might only wear their prosthesis when a staff member who can assist with donning and doffing is on duty.

A variety of prosthetic components can be prescribed depending on people's capabilities and needs. Solutions have been expanded from mechanical to microprocessor-controlled prostheses with integrated sensors that adapt to the environment. Powered prostheses can further provide active motion, replacing the lack of muscle function. Despite the commercial availability of microprocessor-controlled limbs, not everyone is fitted with one. Lower-activity individuals are less likely to receive microprocessor-controlled ankles and knees than higher-activity LLAs; advanced devices tend to be heavier and bulkier than mechanical options and are more expensive, and financial reimbursement is not easily obtainable.

Comorbidities, issues with the intact side, and pain in various body parts can additionally hinder use in general. Further, users do not all go through comparable rehabilitation, and today's regimes are fairly novel; older individuals who have been prosthetic users for a long time are unlikely to have received the same rehabilitation as more recent LLAs. In addition, prosthetic use and quality of gait can decline post discharge. Finally, approaches vary between prosthetists, who might recommend different prostheses.

Prosthetic Fit, Socket Fit and the Residual Limb Ambulation quality depends heavily on prosthetic fit, highlighting the importance of skilled prosthetists. One of the greatest deterrents to prosthetic use is an ill-fitting socket; an uncomfortable prosthesis is less likely to be donned. Pressure and friction can lead to wounds on the residual limb that prevent use. The necessity to don and doff the socket can additionally place limitations on spontaneity.

> "Naturally I don't sleep with my prosthesis […] When the child cried, I hadn't thought to don the prosthesis. Suddenly I was just standing on one leg […] I can't do anything for him unless I go back and don [the prosthesis]." (TT/K3)

One common drawback of prosthetic sockets is their lack of sufficient adaption to short- and long-term changes in the volume of the residual limb. Discomfort, fatigue, and pain can lead users to remove their prosthesis to rest the residual limb. Although osseointegration has become increasingly available to those who experience socket-related issues, traditional sockets are still standard. Improvements in socket designs, with, for example, a volume-changing socket and better fitting of current solutions should thus ameliorate or prevent many user problems.

The residual limb can further be affected by external factors. Cold weather is sometimes associated with increased residual and phantom limb pain, whereas heat and sweating are associated with the residual limb's displacement within the socket, and people may remove the prosthesis to clean and dry the socket. Materials such as sand can also get into the socket, leading to irritation and discomfort.

> “If you are active and go out and sweat, you must be careful. When I mow the lawn in the summer, I can pour liquid or sweat out [of the socket]. It's disgusting […] You have to stop and just dry it. It's incredibly tedious.” (TT/K3)

When people receive more than one prosthesis for different purposes, their use varies depending on individual and environmental factors. For instance, a person who has a microprocessor-controlled leg is unlikely to use it on the beach to prevent salt and sand from causing problems. The user might instead don a leg that can handle high moisture levels, but when bathing, people also want to wash their residual limb, and a shower leg specifically intended for bathing might therefore not be used frequently.

> “It's difficult to walk in sand because when I go to the beach I wear a bad leg, a shower leg that is not good for walking. I don't wear my favorite leg in sand and get sand in it so I kind of avoid it.” (TT/K3)

> “While you stand on one leg in the shower you are of course very unstable.” (TT/K3)

5.5.2 Limitations of Prosthetic Function and Capacity

Limitations in adjusting ankle angle and knee resistance were perceived as common drawbacks of current solutions, both by prosthetic users and experts. Difficulties can emerge during stance as prostheses usually do not allow for many positions like a healthy limb does. This prevents people from being able to disperse their weight evenly between limbs and sway. Although many prefer sitting to standing, sitting can also produce its own problems; the socket can cause pressure and discomfort in the residual limb, and the prosthetic side can cause further problems:

> “I think it is more difficult to sit a lot [than to be on the go]. [The prosthesis] just hangs there.” (TT/K3)

Assuming particular positions can further be difficult, such as squatting, kneeling, crawling, and standing in an incline. Figures Figure 3 to Figure 6 illustrate restrictions in maneuverability due to prosthetic function.

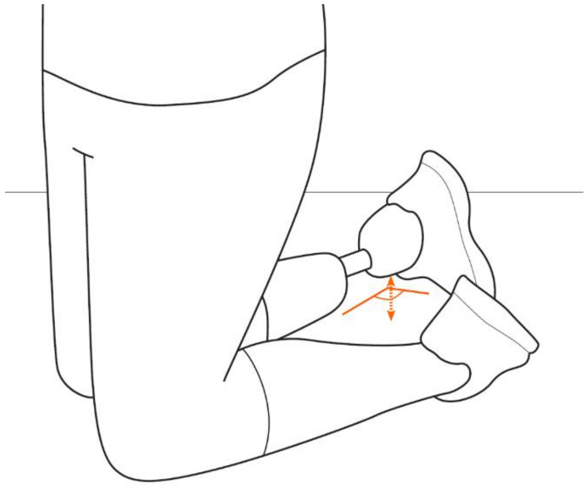

Figure 3. Limited ankle adjustment leads to asymmetrical and uncomfortable kneeling

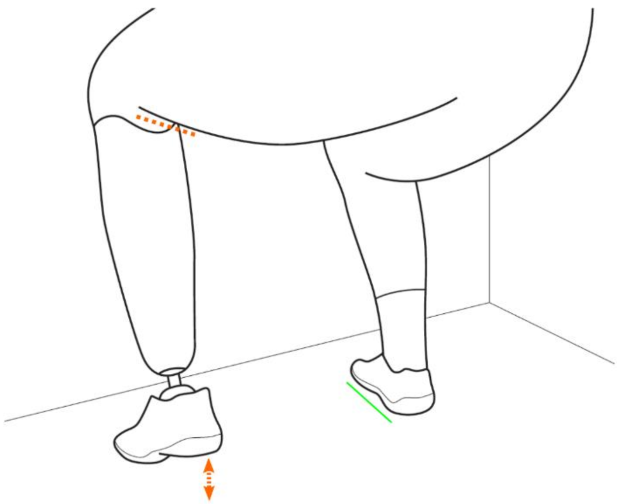

Figure 4. The socket and ankle angle prevent deeper squatting without mainly relying on the intact side.

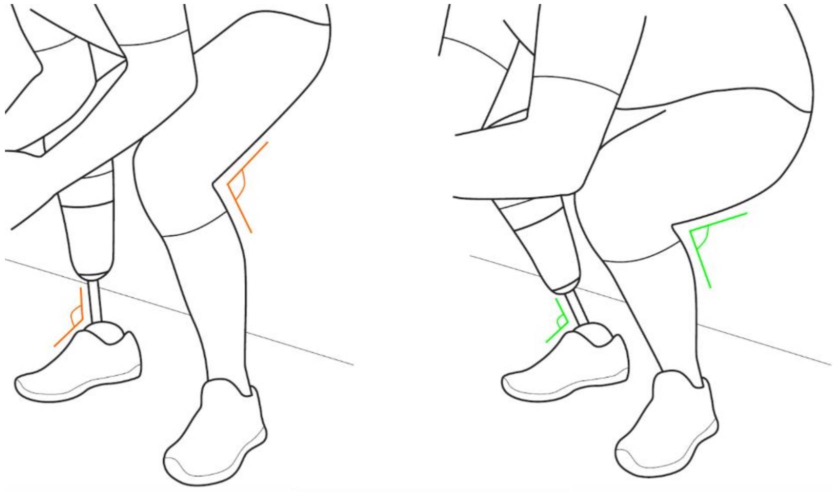

Figure 6. Ankle adjustment allows for a deeper squat than a fixed ankle.

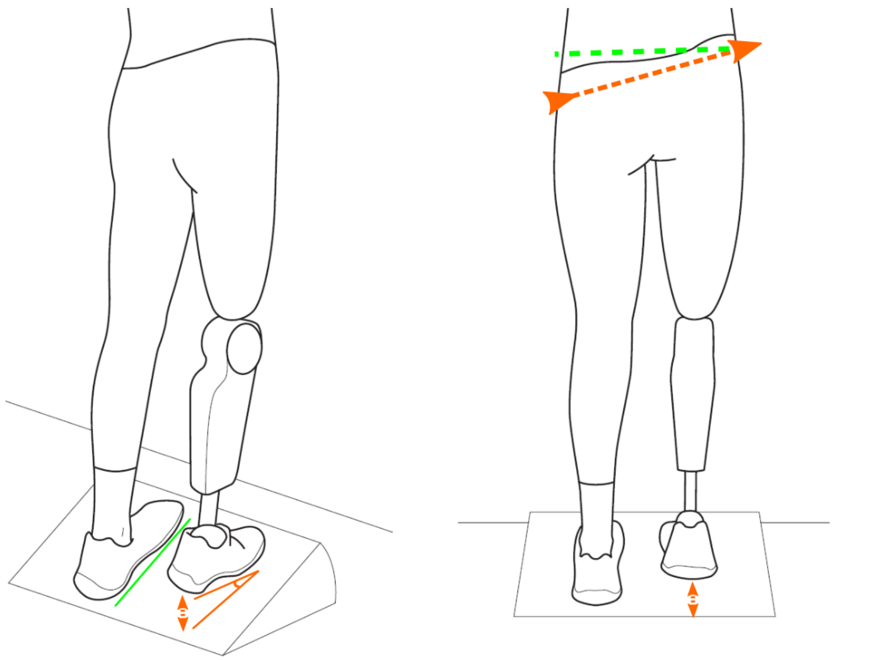

Figure 5. Ankle adjustment results in more symmetrical loading, reduces hip hiking and allows for a more comfortable stance while standing in an incline.

Similarly, ambulating on uneven terrain or stepping on obstacles can be challenging as people can misplace their foot in a position it cannot physically adjust to or react quickly enough to prevent tripping and falling.

> "I fell holding onto my mother; I was trying to help her [cross hummocks]. Regular people also become unstable in hummocks, but when you step down in a certain way, you don't have anything to pull you up." (TT/K3)

Other maneuverability and disruption of cyclical activities can be cumbersome, namely, changing direction while walking, stopping suddenly, walking backwards, turning, and sidestepping. Figure 7 shows how slight ankle adjustment can affect the leg's disposition when stepping on an obstacle.

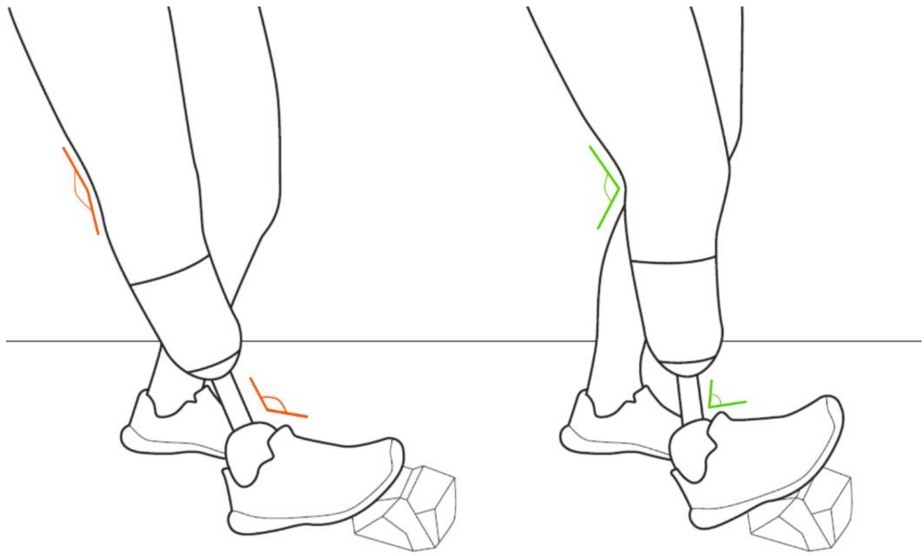

Figure 7. Increased ankle adjustment allows the user to step on obstacles in a more comfortable manner.

> "Look, [the ankle angle] is 90°. I step on the rock, what happens? It throws me backwards […]. If the toe is raised, can you see my knee, [it is not extended]. This is it, [what I want]." (TT/K3)

The lack of active motion produced by the prostheses coupled with difficulties in positioning one's foot can further affect mobility. When transitioning between activities such as standing and sitting, positioning the foot under the chair can help to increase the base of support, which can be difficult to achieve with current solutions. Standing up from the ground, such as after a fall, is furthermore considerably more difficult than from a chair, requiring even more physical effort and more flexibility in positioning one's prosthesis. Lack of power was associated with physical demands for TFAs with nonpowered prostheses during stair ascension and ambulation on compliant surfaces such as sand or snow, which can also lead to the prosthesis becoming stuck or slipping off.

> "You have to lift [your hip walking upstairs] and then you are always straining the muscles. I have developed chronic [back/hip] pain and constantly have to have it massaged out." (TF/K2)

Microprocessor-controlled ankles and knees with ankle and knee adjusting functions are available to facilitate transitions between activities. However, training and initiating functions and different modes can be demanding, and unintentional triggering of modes can be annoying or dangerous. Some modes require intentional triggering and a brief latency during activation. To save time and effort, many users therefore rely on other compensatory strategies. For instance, many active TFAs prefer stepping over obstacles with the prosthetic side first, using the intact side to propel themselves forward. Instead of waiting for the knee to adapt, some might instead kick obstacles and curbs to force it to quickly bend and extend. As for transtibial users with microprocessor-controlled prosthesis, ankle adaption does not always occur immediately during transitions, requiring added effort for the user.

> "[The microprocessor-controlled ankle] works great [on slopes]. But the first two steps are always the most difficult. [...] it always needs [time] to calculate." (TT/K3)

> "To make [the mode] work right away [on stairs] I need to step first with my intact side; I need to change the way I approach the stairs […] To make it work I need to think about which foot I use first […] Did you see how I tiptoed to make sure I would [transition correctly]?" (TT/K3)

5.5.2.1 Confined Spaces

Although the aforementioned activities are not considered problematic by everyone, they can become difficult or impossible in confined spaces. For instance, the effort required to enter or exit a car depends on the height of the car, whether the prosthesis enters or exits first, and the space available. When the intact side is used first to exit a car, the prosthesis needs to be manually raised by hand or dragged and cramped backseats can result in the prosthesis becoming stuck. Similarly, as leg space is limited during air travel, some opt for removing the prosthesis to lessen discomfort. Activities such as car and household repairs and gardening are affected.

> "I was painting the [lowest part of the walls on the] outside of my house […] I didn't think too much about [the prosthesis] and started dragging it as it was hanging loose [in] the trouser leg. I didn't bother to stand up to fix it. That would probably have been the sensible thing to do." (TT/K2)

Walking in crowds is substantially more difficult than in open spaces as the lack of visual feedback is coupled with a lack of feedback from the prosthesis and unpredictable movements of the surrounding people. Without visual feedback, the effort required increases considerably, especially in confined spaces.

> "When it is pitch black, in situations like at the movies. When the movie is over, and you head out and they maybe haven't turned on the lights and everybody has to leave If there is no handrail to go down the stairs, it is awful as it is dark, and I can't see the floor…I can be in serious trouble. You don't realize this when you have both legs as you have balance and everything, but when you are missing a leg you cannot feel it… This causes me great anxiety… And in large crowds where I can't see the ground properly… It is [extremely difficult for] me." (TF/K2)

Although some are insecure and fear for their safety, others are more concerned with inconveniencing others and stepping on them. External load such as carrying a child or heavy equipment can induce both fear for one's own safety and over dropping a child or breaking something expensive. Similarly, walking an energetic dog or holding the hand of a small tugging child can induce safety concerns.

5.5.3 Compensatory Behavior and Adjustment To Limb Loss

5.5.3.1 Physical Factors

Many experienced prosthetic users do not perceive themselves as facing a lot of difficulties in their daily lives. However, behavioral or environmental adaptions are common solutions to previously encountered hindrances. Although noticeable recently after amputation, behavior proceduralizes over time and the individual is unlikely to reflect on it unless specifically prompted.

> "You are reminding me of many aspects you don't think of everyday! It suddenly begins to come back to me." (TT/K3)

Examples of compensatory behavior include leaning on walls and countertops for support, installing handrails, making sure that the floor is always clear to prevent tripping, always wearing the same shoes, wearing shoes indoors, buying new furniture, receiving help from family members, or allowing the prosthesis and assistive devices to bang into objects and walls when maneuvering in a confined space. Some will always plan ahead and be prepared, such as carrying a shoehorn everywhere or bringing a set of prostheses suited for different purposes when traveling. There are, however, several limitations to such compensatory behavior. Strategies involving environmental modification, such as to the home, car, or workplace, are not applicable in novel surroundings, and even when solutions have been installed in the community, their design is not always optimal.

> "I will never forget when I went [to a pool] that was really nice. They had an elevator to get [up the hill] to the building for wheelchairs and the like. However, when you arrived at the front door there was a large curb." (TF/K2)

Overreliance on the intact limb and compensation via physical strength were commonly associated with the aforementioned limitations in knee and ankle adjustability and lack of active motion from the prosthesis. Moreover, they can lead prosthetic users to compromise their posture in order to perform certain activities: "I do not think it is difficult to do this, […] but I feel like I am not doing it correctly at all." (TT/K3). Such behavior was perceived as a cause for physical ailments such as hand and upper-body ailments, osteoarthritis, and lower back pain.

> “I am of course injuring my back and [the intact side which] does everything […] You lift something heavy and then [you rely on] the back and the [intact side]. I do things like I should not do them. I'm not using my legs to lift things off the ground, I use the back.” (TF/K2)

Psychological, Psychosocial, and Neurological Factors In addition to physical and prosthetic capacity, psychological, psychosocial, and neurological factors influence people's interactions with their prosthesis and other people. For instance, attentional or cognitive demands are perceived as an issue as prosthetic users often need to think about where their prosthesis is, how it is positioned, and how they can avoid tripping. This can prevent them from utilizing their cognitive resources for other processing during ambulation such as talking on the phone or to another person. Slippery surfaces, like wet floors or ice, were regarded as very physically and mentally demanding due to lack of balance and fear of falling.

> “… I hate ice…you become way too careful…The fear of falling [is the worst].” (TT/K3)

> “[I haven't fallen in the past year but] I have tripped, and if you trip you can jerk and twist within the socket which is incredibly painful.” (TT/K3)

> “I mostly fall if it is icy… I can't really afford to fall anymore.” (TF/K2)

Microprocessor-controlled prostheses can increase confidence, reducing the levels of physical and perceived mental effort during ambulation.

> “If you are walking on gravel, uneven, or soft terrain… just walking on grass is completely different from walking on a concrete floor. It really makes a difference being able to raise the toe [with the microprocessor-controlled ankle on such terrain] … It becomes easier to walk… [with mechanical prostheses where] the toe [does not lift], a resistance occurs in your gait and you have to [overcome it] …” (TF/K3)

Mechanical prostheses that do not include such functions can lead even highly active people to proceed with more caution than with a microprocessor-controlled prosthesis, as misplacing the foot can easily lead to a fall. Trust in both the microprocessor-controlled functions and one's ability is integral should their benefits actually reach the user. However, people may trust their microprocessor-controlled prosthesis in some scenarios, but not others.

> “Look, the thing with the [microprocessor-controlled knee] is that if you are going to make it work well, you have to trust it a hundred percent and you can not hesitate at all when walking on it.” (TF/K2)

> “I have, naturally, become used to walking on the [microprocessor- controlled knee], so I completely trust it now […] The foundation is a good and dependable surface; if it is dependable and good, I can walk a lot without concern. But if it is icy or there is gravel or clutter [on the ground], it becomes more dangerous. The [knee] will catch you if [the ground] is misaligned. But it all depends on you trusting it.” (TF/K2)

> “There was gravel where I was walking […] and I felt uncomfortable. There was additional motion [in the microprocessor-controlled ankle] that I didn't want. It made me a bit insecure.” (TF/K2)

When people do not feel safe utilizing a function or its initiation is too demanding, they are more likely to avoid using it.

> {TF users are shutting off ankle functions since the ankle needs to be stabilized by the knee. If you have difficulties controlling what the knee does, you are better off not using ankle adaption functions during negotiation in slopes for example.} (Expert)

> {Even though the function might exist in a prosthesis, if the activation of modes is not intuitive, they are not used. It is partly due to users having a hard time activating the mode because of the mental effort. There is a lot of training that users must go through in order to be able to use these modes. As soon as there are people around, the controls become too complicated.} (Expert)

> {Stair ascent can't really be done well with current knees and is mostly a party trick, not something users use.} (Expert)

Multiple participants mentioned consistency as a key factor in prosthetic use; users can adapt to a consistent prosthesis, even if it is consistently wrong. Lacking trust in the prosthesis' consistency can lead to activity restrictions where people who can ambulate in a particular manner will not. Some experts argued that lower-activity people are inclined to use microprocessor-controlled prostheses in a similar manner to mechanical ones. For instance, they might display the same gait characteristics and, as such, will not receive benefits over mechanical solutions. However, other experts noted that although lower-activity people cannot always use microprocessor-controlled prostheses to their fullest potential due to mental and physical demands involved in mode triggering, they can still prove more beneficial than mechanical options.

> "You are much more likely to trip and fall with a mechanical knee than a [microprocessor-controlled] knee, because the mechanical one doesn't catch you." (Expert)

> {Traditionally, the "low mobility" patient group has been overlooked by advances in new technology when the reality is that they are the very people who could benefit most from developments.} (Expert)

5.5.3.2 Bodily Experiences

Losing a limb means losing both muscle function and sensory feedback from the missing limb, meaning that people's perceptions of their own body are altered, and then altered even further with prosthetic use. In some cases, young people who see themselves as one-limbed in their dreams can later on start to dream of themselves wearing their prosthesis.

> "I do think that using prostheses continuously and thoroughly really has the potential to change your own body image." (Expert)

Changes in body image are in some cases accompanied by decreased confidence and low self-esteem after limb loss. Moreover, experiencing sensations perceived as originating from the missing limb after amputation can be mildly to extremely debilitating, especially when these sensations become painful. Phantom pain varies in intensity both within and between individuals and is perceived to be induced by diverse causes. Some report that simply thinking about phantom pain or watching violent television content can trigger painful sensations. Other factors include different temperatures and high activity levels throughout the day, especially with increased activity in muscles in the residual limb.

> "[Phantom pain] can be completely disruptive… I know people who have a lot of phantom pain and they are out for maybe 24 hours… You are in a lot of pain and then you don your socket and with increased pressure the pain is magnified a hundred times over." (TT/K3)

> "When I am lying in bed, it's like somebody has connected two [electrical] wires and 'bzzzz!' They are so intense and painful. They come and go. When you are just about to fall asleep and they [hit you…], you are suddenly sitting up." (TF/K3)

> The prosthesis can be experienced as a part of one's body to a certain extent, a phenomenon referred to as prosthetic embodiment. There is large individual variability in embodiment levels. Some people further prefer to wear their prosthesis constantly, whereas others regard it as a tool to be discarded when no longer useful. "I would prefer to wear the prostheses 24/7. It sucks losing your leg every single night." (TT/K3)

> "Around dinnertime I have had enough… The prosthesis becomes a burden and an accessory, […] at that point I like to remove it." (TF/K2)

> In addition to self-perception, the prosthetic experience includes interaction with other people: "People see the disability first, not the person" (Expert).

Although some are curious, others overtly express alarm or even aversion in response to seeing the residual limb.

> "Although I am not shy about [my residual limb], you still have to answer questions from a lot of children [at the pool] and some of them find it repulsive." (TT/K3)

> "I don't really care what people think, but it is disappointing that some get the heebie-jeebies. I don't like causing others discomfort […] Once there was even a nurse […] I was supposed to go for a checkup, and they were supposed to push

> me in a wheelchair, and they just went: ‘Can you put on the leg! Can you put on the leg!’ Then they just brought a blanket and covered it up.” (TF/K2)

Unexpected behavior of the prosthesis can lead to unwanted responses and attention, especially if it falls off or breaks. Finally, comparisons with other persons with amputation presented in the media, where others expect the person to show abilities like that of Olympic athletes, can be irritating.

> “People [who didn't know I was an amputee] would shout ‘His leg is broken! He fell and broke his leg!’ […] The leg was at a certain angle [after falling off] and I looked like I was severely injured.” (TF/K2)

> “If somebody on TV has been running a lot and is missing both legs, people will go ‘that guy could run a lot’… You are like ‘yeah okay, great for him, but I can't do it.’ You can't put everybody in the same category.” (TT/K3)

Cosmesis allows people to manage how visible their limb loss is to others to a certain extent. Although many desire a prosthesis identical to a healthy human limb, expectations are adjusted to what people know is available. Function is often chosen over fashion and many settle for a shape that appears natural when clothed. People are, however, considerably less likely to compromise cosmesis when it is kinetic in nature; they want their movements and gait to appear natural and fluent even if it requires an “unnatural” looking prosthesis.

> “Cosmesis has two aspects: first is the appearance, the look, and the second is the kinetics. From my experience talking to lower extremity amputees, for them the kinetic cosmesis is priority number one. Because the movement is supposed to be as fluent and natural as with [an intact limb]…for a lot, not for all of them, and I think this is also culture dependent, age dependent, gender dependent… for a lot of them, if the kinetics are fine, it's also fine to show carbon and metal…” (Expert)

5.5.3.3 A Vicious Cycle

The interaction between physical, neurological, and psychosocial factors can result in perhaps the most detrimental compensatory behavior: people start to avoid certain situations or places, leading to decreased participation in society and negative affect and health outcomes. Leisurely activities enjoyed before amputation may be impacted leading people to avoid hobbies. In some cases, people even lose employment after limb loss.

> “I really loved dancing but now I don't enjoy it at all.” (TT/K3)

> “I'm not comfortable going to the pool. It is a great deal of hassle. You need to take a [shower] prosthesis along. There is not a chance that you can hop around on one leg. I know of a person who went to a spa with some friends. They needed to be carried to the hot tub and assisted into the shower. They never received a shower leg!” (TT/K3) “

> It affected me at work. And then of course the financial depression occurred. The first ones to be let go were those who weren't fully [fit].” (TF/K2)

> “There must be an association between mental health, I'm thinking depression, for example, and level of activity; [aren't they related]? You learn when activity goes down that your health goes down and when your mental health goes down the level of activity goes down…a good prosthesis that creates certain responses in your social environment increases your psychological wellbeing, and through that, increases your level of activity in some way. Shouldn't that somehow fraction [into evaluation and reimbursement], I mean, these are not distinct things, right? These go together.” (Expert)

5.5.4 Problems Potentially Addressed with Neuroprostheses

Intent control-based adjustment of ankle and knee movement, position and resistance may allow LLAs to maneuver in ways not possible before, regardless of how unpredictable the situation is. Although sensors integrated in prostheses can detect intent to a certain extent, the most straightforward execution would be based directly on the users themselves. Despite highly positive reactions to recent advances in microprocessor-controlled solutions, as previously mentioned, there are limitations in interrupting initiated functions, and there is still a delay between user intent and device execution during transitions. The user knows beforehand that a transition is about to take place but must wait for the prostheses to register and implement the already predicted adjustments. For instance, atypical terrain such as natural slopes and hills involve variable inclines. With ever-changing surfaces, microprocessor-controlled algorithms will constantly recalculate the ankle angle, where the appropriate angle might be achieved only after a new transition has begun. Intent control-based adjustment could eradicate extended acclimation periods allowing the user to adapt to the environment and transition between states depending on their own preferences. The benefits might also allow people to squat further down, kneel more comfortably, and disperse their weight more symmetrically during stance and sway due to increased possible positions of the leg, reducing intact side strain and improving mobility. Although intent control-based adjustment is likely to include conscious voluntary motion at first, the process may potentially become automated, much like the operation of an intact limb.

> "Is it a good thing to have a prosthesis where you have to […] consciously flex the muscles for an electrode to pick it up? […] When you learn how to use it […], at the very beginning it is a very conscious process […] But the thing is, if you do that several hundred times a day, over the course of several years, it completely proceduralizes. You don't have to think about that anymore […] so in that regard, if something is intuitive enough that it has the potential to proceduralize, it actually eventually will. So, I don't think that is such a problem." (Expert)

Although there may be numerous physical benefits of neuroprostheses, the greatest effects might be psychological in nature. The restoration of sensory feedback and muscle function may facilitate the integration of the prostheses into the user's body schema, influencing prosthetic embodiment and phantom sensations.

> "[They] felt like [their] brain registered that [they had a leg] more than before [after trying intent control]. Phantom pain [seemed to decrease and feel] different. [They] became much better at controlling [the phantom pain]."(Expert)

Increased prosthetic use and acceptance might follow, increasing social participation. Altered behavior may in turn influence mobility and thus physical health. Furthermore, enabling intent control of a microprocessor-controlled prosthesis may increase people's trust in their prosthesis, self-efficacy, and ensure full utilization of available functions, such as increased weight placed on the prosthetic side. Whether or not the prosthesis is perceived as a part of the user's body, some feel as if the prosthesis controls them, not vice versa.

> “What would you say if I told you I was going to make your ankles rigid? Would you agree to that? […] Even though I like my microprocessor-controlled ankle], it controls what it does; I'm not controlling it … It's my body. I should be able to [control] it […] Why should some machine do it for me? I trust [the prosthesis] […], but I trust myself a lot more.” (TT/K3)

> “[I would like to control my prosthesis more since] I don't really trust anybody but myself.” (TF/K2)

> “It's really weird. You adapt to what you have… You just get used to it. It is more about building trust toward the prosthesis you have. It is a little bit like… you trust it and then you start placing more weight on it.” (TF/K3)

5.5.5 Challenges in Developing Neuroprostheses

Although some participants in the study expressed reservations or only moderate expectations about neuroprosthetic devices, others were more optimistic. Nevertheless, the general consensus was that as long as neuroprostheses fulfilled certain requirements, they would provide benefits above the most high-tech prostheses without intent control or sensory feedback schemes. The most common remark on neuroprosthetic requirements in the expert group was the necessity of real-time control and sensory feedback, such as pressure under the foot and kinesthetic feedback, as well as the importance of establishing an intuitive interface. Just as microprocessor-controlled functions can be shut off by users, neuroprosthetic features may be less likely to be used if they demand both time to initiate as well as physical and mental effort. An intensive training regime can further be deterring, and the sensory feedback must not lead to discomfort or become irritating. Although users can use mobile applications and nonintuitive mode triggering to adjust a microprocessor-controlled prosthesis, real-time intuitive interfaces have a greater probability of being accepted. Another key point is that the benefits of neuroprosthetic functions will always be constrained by the environment they can be initiated in, which is determined by the software and functional capabilities of the prostheses. For instance, when reaching an object on a high shelf, people often stand on their tiptoes. Currently, LLAs can only stand on their tiptoes on their intact side. With increased adjustability, the prosthetic side could be used to enlarge the base of support, increasing balance. However, if no active motion is provided by the prosthesis and the function cannot be initiated during stance, users will need to first stand on their tiptoes on the intact side and then adjust their prothesis after it has been elevated from the ground, requiring time and effort, decreasing the likelihood that the function will be used. If, however, the prosthetic side could perform the action at the same time as the intact one, the increased balance and more symmetrical leg loading might not only apply after the motion had been initiated, but also during the motion. People naturally strive for efficiency: “What is quickest is best” (Expert). When the prosthesis slows people down or hinders them in any way, they might solely rely on physical strength and compensatory movements instead of the prosthesis. Identifying which user problems neuroprostheses could influence entails several challenges. First, prosthetic users are highly heterogenous. There are significant variations in factors such as amputation cause and level, the anatomy of the residual limb, muscular atrophy, physical abilities, comorbidities, preferences, and personality.

> “I have my reservations about systems [using muscle-based control]…I might be wrong…but the muscles in my residual limb are greatly damaged […] The [neuromuscular] connections are questionable…” (TF/K2)

Second, prosthetic user perceptions are obviously limited by personal experience. For instance, some congenital LLAs may be less likely to consider sensory feedback than those who lose their limbs later in life. Third, people's perspectives and interaction with their prosthesis changes over time; experienced users have adjusted their expectations of prostheses to the norm and what they know is available. Recent LLAs may become frustrated when they hear that they will not be receiving a “brain-controlled” prosthesis, whereas those more familiar with available technology restrict their anticipation, which in turn influences the feedback they provide. Those with recent amputation can often provide information on requirements not easily obtained from experienced LLAs.

> “You approach users differently as a prosthetist and evaluate what you do. Is the user new or established? Established users know the norm and the limitations.” (Expert)

> “I always say that the first 2 years […] are the adjustment period. For those who have maybe recently lost [a limb ask]: ‘Two

> years!?' You are not [helpless] for 2 years, but you are learning. There are so many things we learn how to do [...], we can not learn it all in 1 month." (TT/K3)
>
> "Two years ago, I only thought about how it looked: now I only think about comfort." (TT/K3)
>
> "It's strange recalling how little you can do at first, and what you can do now." (TT/K3)

Fourth, expert views on neuroprosthetic development are similarly influenced by specialization and experience. Academics have great freedom in investigating neuroprosthetic opportunities and conducting basic research that can lay the foundation for further investigations, although the results do not always transfer well to the daily life and challenges of LLAs. Industrial developers are constrained by market requirements, which can place a limit on what solutions are viable for exploration. Clinicians such as prosthetists, doctors, and physiotherapists may focus on fundamental issues such as mobility, socket fit, residual limb health, and rehabilitation rather than uncertain technological advances, although they believe they could prove useful. Some neuroprosthetic expectations can also be limited by what is covered by health insurance and governmental health services. Currently, it is difficult to justify prescription and reimbursement of microprocessor-controlled solutions due to cost, especially for lower-activity individuals, even if health care providers believe they will benefit the client. Establishments such as nursing homes might invest in a wheelchair rather than a prosthesis due to a limited budget. Reimbursement application processes can, furthermore, be arduous for both users and clinicians. Finally, they might not recommend something that can be used "incorrectly," as it could have detrimental physical consequences. Third-party payers prioritize reimbursement of devices that have been shown to reduce health care costs such as back pain, residual limb issues, osteoarthritis, and risk of falls. Evaluation of such factors requires longitudinal research in large samples. Psychological and neurological factors such as phantom pain, embodiment, and affect are largely ignored due to the lack of concrete evidence directly linking them to the highest health care cost factors. Even with a plethora of available prevalence statistics and indicators that psychological factors indirectly influence cost factors, there are large gaps in the literature that must be filled to facilitate reimbursement, and the flow of information between prosthetic stakeholders is not always optimal. Fifth, the effects of adding intent control and sensory feedback schemes to currently available lower-limb prostheses are relatively unclear. Sixth, design needs to account for volume fluctuations of residual limbs, residual muscles, and the capacity to activate them, changes of muscle signals, and fatigue.

> "A city holiday in the summer… You run around all day sightseeing and then in the evening you go out for dinner, and maybe you go out to a bar or a club. You know, those days are terrible because it is a lot of sweat, but you also tire out so that in the evening you get really [terrible] signals." (Expert)

Intramuscular and intraneural solutions are furthermore expensive and associated with risks due to their invasiveness. Even with reimbursement, users might not want to risk sacrificing the function they have with an operation or new components although they would like to have the functions they provide.

> "If I had been asked 10 years ago, I would have wanted to try everything… The [intact] knee has started to deteriorate so I am not as eager to try new things in case I get injured." (TF/K2)

Finally, prosthetic user problems are not only complex, but interactive and their effects can be difficult to tease apart. A large proportion of user requirements could potentially be met via other means, and some are unlikely to be influenced by neuroprosthetic functions at all. For instance, socket-related problems that hinder prosthetic use and daily activities could be present regardless of prosthetic capabilities. Similarly, issues related to a lack of physical strength could partially be addressed by providing people with powered prostheses, and mode triggering and adaption could be enhanced via improved sensors in the prostheses for smoother transitions and joint adaptions.

5.5.6 Challenges in Demonstrating Neuroprosthetic Benefits

The novelty of neuroprostheses contributes to the first and most obvious challenge in the demonstration of their benefits; there is no clear consensus on how they might benefit prosthetic users as there is no commercially available product and limited clinical experience. The user requirements identified in the inquiry necessitate adequate testing strategies and instruments tailored to evaluate whether a prosthetic function fulfills them. There is no criterion standard in prosthetic testing, and standardized instruments with good psychometrical properties may not always capture the whole range of the variables measured. Moreover, many potential benefits of neuroprostheses have never been addressed in current testing strategies. Both users and experts expressed concerns about the usefulness of questionnaires due to variations in how their content can be interpreted and relevance to each individual. “I despise questionnaires!” (Expert). Expert participants further pointed out that people behave differently when observed, and performance in the laboratory does not always translate into everyday life.

> {We are very focused on looking at people going up and down stairs, sitting and standing, and moving around in slopes, but these are all things you can do with a peg leg. We aren't covering everything. Some people's gait might be great, but everything else surrounding it is something they have difficulties with and require a lot of effort.} (Expert)

> {When I ask people to walk, they do it very well, but as soon as they are not diligently trying to do it properly, they are not as good. That's why I take notice of people's gait as they walk in the door and do not know that I am evaluating them.} (Expert)

Designing new testing methods during developmental stages can be useful, but they must be standardized and normalized for the intended population at later stages, should they be used to justify prescription and reimbursement for a particular system. Without such evidence, the device is less likely to reach the users and benefit them. Establishing causal relationships between systems and improvements on certain clinical outcomes with validated instruments is more likely to result in reimbursement than others. It can, however, be difficult to demonstrate improvements on outcomes that are not stable over time, such as back pain.

> “How does leg length discrepancy link to back pain? You have prevalence data of this and that, but the link is not there. So that's a gap in the literature” (Expert).

Establishing a causal relationship between variables that might indirectly affect physical ones can also pose challenges. Psychological and neurological aspects further tend to be overlooked and are unlikely to be considered during reimbursement processes.

5.6 Discussion

We conducted semi structured interviews, focus group discussions, and a CI with multiple stakeholders to gain insight into perceptions of lower-limb prosthetic user problems and to better understand how unfulfilled requirements could potentially be addressed with neuroprostheses. We further investigated perceptions on the main challenges in the development and evaluation of neuroprostheses. Although the general user problems identified largely echo previous literature, our findings reveal problems and challenges that have not been previously addressed with in-depth qualitative research.

5.6.1 User Problems and Neuroprosthetic Benefits

Intent control adjustment of ankle and knee movement, position and resistance coupled with sensory feedback could potentially improve mobility by allowing people to alter their posture at will and maneuver in new ways regardless of situation predictability. Furthermore, the disruption of cyclic activities could be facilitated and the latency between user intent and device execution of microprocessor-controlled devices significantly reduced. Although potential functional benefits could improve mobility and in turn health, psychological impact may far outweigh the physical. Psychological aspects associated with functional benefits may lead to a positive feedback loop, increasing the likelihood of prosthetic acceptance and use. Intent control and sensory feedback could increase enthusiasm, trust in the prostheses, self-efficacy, and prosthetic embodiment, and decrease phantom limb pain, influencing function through increased engagement in activities and social participation.

5.6.1.1 Criteria

Several criteria must be met for benefits of neuroprosthetic devices to reach users, which resemble requirements reported for solutions intended to increase mobility in other populations. [39] First, the system must be consistent to ensure safety and promote the user's trust. Second, control and sensory feedback schemes must be provided in real time through an intuitive interface.[2] Perceived “naturalness” of sensory feedback is important to prosthetic users.[4] Third, they should not demand a lot of cognitive resources, require intensive training, or interfere with other perceptual processing. Finally, they need to be comfortable and should not cause irritation. The system must be usable in the sense that people can use not only its functions but also will actually do so, preferably as unconsciously and automatically as with an intact limb. Otherwise, they will not gain any advantages over less advanced solutions.

5.6.1.2 Constraints

When muscle activity is used for intent detection, limb volume fluctuations and the status of the residual limb and muscles can affect the quality of signals. Surface electrodes placed on the skin are more likely to involve a lower signal-to-noise ratio than invasive solutions. The financial cost and risks of invasive solutions can, however, be a deterrent from the perspective of both clinicians and users. Moreover, neuroprosthetic functions will always be constrained by the environment in which they can be initiated as the software and functional capabilities of the prostheses place limitations on where and how the functions can be used. Finally, the processing capacity of the nervous system places restrictions on how particular information can be conveyed and interpreted, which is not always considered during the development of solutions intended to increase people's mobility.[39]

5.6.1.3 Considerations

No lower-limb neuroprosthetic solutions are commercially available, with most being in developmental stages. Their novelty requires further understanding of how the nervous system integrates and relays multisensory information postamputation. Neuroplastic reorganization has been reported in individuals with unilateral amputation where sensory input from other cortical areas can activate the primary somatosensory cortex of the lost limb.[40,41] Altered cortical representation has further been observed in areas corresponding to the intact limb after amputation[42,43] with muscle contractions on the prosthetic side leading to greater activity in the ipsilateral somatosensory cortex than in nonamputated individuals.[44] Functional changes in LLAs postamputation have been observed; persons with LLA show delayed muscular responses,[45] decreased touch and angular movement sensitivity,[46] and reduced obstacle avoidance,[47] not only for the prosthetic side, but also the intact side. In general, there is conflicting evidence on the effects of altered cortical representations, with some evidence indicating that such changes are associated with increased phantom limb pain,[48] whereas other evidence associates phantom pain with maintenance of structural integrity of the somatosensory cortex.[49] Furthermore, recent evidence indicates that cortical reorganization occurs on a much larger scale than previously assumed, where activity and connections between subcortical structures progressively transform over time in addition to those in the sensory motor areas.[50–52]

Effective production of neuroprosthetic systems necessitates further research on neurological changes postamputation and how the nervous system subsequently processes sensory information and implements motor control. There are several studies demonstrating that providing persons with amputation with sensory feedback about information usually perceived by the missing limb can both improve functional performance,[53–55] prosthetic embodiment,[31,56] and decrease phantom limb pain.[31,55] However, encoding methods, type of stimulation, the perception to be evoked, and control strategies and their interaction must be considered for optimized development of neuroprosthetic systems. For instance, some encoding strategies are more likely to yield feedback perceived as "natural" by the user, whereas others enable better functional performance.[56] D'Anna et al.[57] demonstrated that different encoding strategies may be required for different types of sensory information should it be perceived as "natural" by persons with amputation; stimulating proprioceptive nerves does not lead to proprioception without coactivation of muscles. In the absence of muscle structure, they used a nontopographical sensory substitutional encoding strategy to deliver proprioception, whereas tactile sensations were conveyed with somatotopic methods.[57]

Although understanding neural processes postamputation is integral to create "natural" neuroprostheses, understanding the function of an intact nervous system is equally, if not more, important. For instance, research has emphasized understanding of how foreign objects can become integrated into the body schema, largely ignoring perceptions of ownership over intact limbs.58 Without such understanding, limitations will always be present in identifying optimal encoding strategies to evoke "natural" sensations and allow for intuitive control over a prosthesis. Finally, the development of a neuroprosthetic system necessitates appropriate testing methods to evaluate their benefits. Some current prosthetic testing strategies for commercially available devices may not encompass the whole range of constructs they are intended to measure, be psychometrically intact, be appropriate for individuals with LLA, or include information needed to properly interpret their scores in the population.[2,32–37] Current strategies for administration and scoring can furthermore limit the applicability and interpretation of some tests,[59] and some variables have not received attention in the field of prosthetics.[4] Moreover, as neuroprostheses include novel functions not available or evaluated before, their assessment can be presumed to be even more challenging than that of microprocessor-controlled prostheses, which can already be difficult.[4]

5.7 Conclusions

Although some unfulfilled user requirements might not be solved solely with neuroprostheses, there are still a number of problems that could be addressed with neurological interfacing. However, the development of neuroprosthetic systems that can work with prosthetic legs requires a greater understanding of intact neuromuscular systems, people's physical, behavioral, and psychological responses to amputation and prosthetic use, as well as their interaction and how they are influenced by the restoration of lost input and output. Finally, their design needs to take the constraints of the nervous system into account and be based on sound evaluation providing a comprehensive picture of people's interaction with their device; a system with a plethora of functions will neither be prescribed nor used if it does not fulfill certain basic requirements and will thus not benefit anyone. By avoiding the potential pitfalls in neuroprosthetic development, this new and exciting field has great potential to facilitate the participation of people with LLA in various activities and increase their wellbeing and quality of life.

5.7.1 Strengths and Limitations

Although our study provides a detailed in-depth overview of perceptions on prosthetic user problems and neuroprostheses from multiple stakeholders, determination of causal relationships and generalizability of the results is limited in a qualitative study. Few LLAs participated in the study, with experience limited to the prosthetic ankles and knees they have used before. Finally, no individuals with bilateral amputation took part, and as such the LLA input is restricted to individuals with unilateral amputation. Our results nevertheless correspond rather well with previous findings, providing support for some conclusions.

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Paper II

Paper II

The following chapter contains a manuscript published in the Journal of Prosthetics and Orthotics: "*How Do We Measure Success? A Review of Performance Evaluations for Lower-Limb Neuroprosthetics*". The authors are Vigdís Vala Valgeirsdóttir, Jóna Sigrún Sigurðardóttir, Knut Lechler, Lisa Tronicke, Ómar I. Jóhannesson, Ásgeir Alexandersson, Árni Kristjánsson. Formatting and table numbers of the published article have been altered for continuity with the thesis on the whole. Any references to the chapter's content should be as follows:

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5.9 Abstract

Introduction: Neuroprostheses that can relay signals to and from the nervous system and work with lower-limb prostheses are currently being developed to provide users with sensory feedback and/or intent control over their prostheses. Such systems incorporate functions not available to persons with lower-limb amputation before, and many of their potential benefits have not yet been addressed in performance-based outcome measures. As such, the evaluation of neuroprosthetic systems is considerably more difficult than that of current devices, which are already difficult due to limitations of testing strategies. This review includes an overview of performance-based measures for lower-limb prostheses as well as an appraisal of their utility for neuroprosthetic assessment.

Methods: Electronic searches were conducted (2013–2019) in the PubMed (PM) database, the Web of Science (WOS), and Cochrane (CC), resulting in 72 included articles.

Conclusions: There is an urgent need for further development of performance tests and metrics, as well as new strategies specifically intended for the evaluation of lower-limb neuroprosthetic systems.

5.10 Introduction

The rapidly advancing field of prosthetics has long since moved beyond providing individuals with lower-limb amputation (LLA) with purely cosmetic prostheses, and increasingly sophisticated artificial limbs become available each year. Although lower-limb prostheses (LLPs) have progressed from the crude wooden peg leg to the powered bionic knees and feet available today, current technology does still not allow all the operations desired by users.[1–3] To meet their demands, it is imperative to better understand which needs available devices do not fulfill. Although there is extensive research on user needs and activities, the majority is based on data collection methods that do not provide a comprehensive picture of the user's interaction with the device.[1] Consequently, it is difficult to predict the impact of adding new functions to current designs. Historically, function has mainly been restored with mechanical solutions, with recent additions of microprocessor-controlled prostheses, whereas future LLPs will likely involve neurological interfacing, further decreasing the gap between the user's lost function and device performance. Currently, the most advanced commercially available LLP rely on sensors to adapt to the environment, whereas neuroprostheses provide feedback to the user and/or include control schemes that can directly detect users' intent and respond accordingly. In general, neuroprostheses refer to interfaces that can replace or supplement the nervous system's input and output and may be used to restore function of individuals with neural deficits. In this review, we discuss neuroprostheses that can relay signals to and from the peripheral nervous system and work with prosthetic limbs to provide users with intent control over their prostheses and/or sensory feedback.

5.10.1 Potential Impact of Neuroprostheses

Lower-limb prosthesis users deal with various scenarios in their everyday lives such as traversing uneven and slippery surfaces as well as maneuvering in small and confined spaces.[1,2] Because of limitations, individuals with amputation may produce compensatory movements during ambulation that can lead to secondary physical ailments.[3] The limitations may make some people with LLA lack confidence, limiting their activity and social participation.[2,4–6] For some advanced solutions, there is a latency between the user's intent and device execution, so when using these devices, users must take a couple of steps on an incline or stairs for the device to adjust itself even if the user has knowledge of changes in the terrain in advance. Moreover, developments in microprocessor-controlled prostheses have focused on cyclic movements, such as gait, and particular actions, such as standing up, as well as the transitions between them. They may, however, lack in offering features that allow for spontaneous interaction with the prosthesis for specific activities. For instance, when standing up with a powered knee, the knee will follow a defined trajectory and push the user up until the knee is fully extended and the phase has completed. Intent control, where people's intention to perform an action is detected and then used to control a device almost immediately, could potentially allow users to manipulate their prostheses depending on the situation, including within the defined trajectory to interrupt and change the device cycle, reducing the need for compensatory behavior and activity restriction.

One key point is that the nervous system requires sensory feedback to match motor actions with outcomes and thereby optimize intentional movement. The lack of feedback has already been identified as a drawback of current nonneuroprosthetic lower-limb devices,[2] highlighting the need for implementing feedback in the next generation of prosthetics. People with LLA have, for example, reported safety concerns when walking up and down stairs because they must rely on visual feedback to determine the next step and know where their prosthesis is.[2] Furthermore, some prosthetic users have difficulty walking and performing other tasks at the same time, such as talking on the phone or looking at another person, indicating that some devices demand too much attention and cognitive effort.[7] Microprocessor-controlled solutions may require fewer such demands when compared with mechanical solutions.[8] Recent studies further suggest that the addition of sensory feedback to microprocessor-controlled devices improves both walking capacity and energy expenditure and reduces attentional demands on the prosthetic user.[9,10]

Neuroprostheses could potentially not only improve ambulation, physical complications, and perception, but may also reduce pain. For instance, the treatment of pain from a missing (phantom) limb is especially difficult, and the benefits are not necessarily long-lasting.[11] One theory maintains that the pain reflects maladaptive plasticity in the nervous system,[12] which can potentially be modified with sensory feedback and intent control.[13] Similarly, prosthetic embodiment or how well the prosthesis is integrated into the body schema could be increased with neuroprosthetics.[10,14]

Overall, the field of neuroprosthetics shows great promise for improving clinical outcomes and quality of life through physical and psychological factors, but several challenges need to be overcome to develop usable, intuitive, and robust lower-limb systems.

5.10.2 Challenges in the Development of Neuroprostheses

The most common method for provision of intent control involves myoelectric control where the electrical activity of muscle contractions (electromyography [EMG]) is recorded with electrodes placed on the skin's surface. This approach has been favored over brain and nerve signals because it is easier to access the muscle signals and interpreting brain activity is far more difficult. Systems with the capacity to classify upper-limb surface EMG signals with over 95% accuracy have been reported.[15] However, no neuroprostheses that enable EMG intent control are commercially available for people with LLA, and even though such systems are available for those with upper-limb amputation (ULA), a big gap exists between solutions tested within academia and those available on the market.[16] This may reflect the lack of external validity of laboratory settings that often do not resemble users' daily challenges[15,17] and a lack of consensus on methods of assessment.[18] Upper-limb research has emphasized increasing classification accuracy while largely ignoring other important factors for the usability of myoelectric control, such as adaption to changes in EMG signals.[17] Classification accuracy measured with upper-limb neuroprostheses in a laboratory setting may not reliably predict clinical performance,[15] and demonstrating what clinical benefits these systems can offer has proven difficult. For instance, various laboratory performance metrics have little correlation with clinical outcomes.[15,19–21] Further, although numerous studies on the feasibility of feedback systems for both upper and lower limbs exist, ranging from noninvasive, nonintuitive vibrotactile feedback,[22] to invasive direct nerve stimulation,[10,13,14,23,24] no large-scale trials have been conducted, and few such systems are commercially available.

One of the greater challenges in neuroprosthetic evaluation stems from the lack of official consensus on LLP evaluation.[25] Furthermore, current testing methods are limited by several factors. Many traditional performance metrics include time and distance traversed during level-ground walking. Assessing level-ground walking capacity is useful,[25,26] but it is obviously ill-suited to assess the more complex functions users call for that might be addressed with neuroprosthetics. Moreover, some tests only distinguish the abilities of low-activity but not high-activity users,[26] whereas others cannot distinguish between people with unilateral and bilateral amputation. Therefore, they may lack known-group validity to discriminate between groups known to differ regarding a particular variable.[27] This also applies to sensitivity between devices with considerable differences in function; although some tests can detect differences between mechanical and microprocessor-controlled prostheses, this is not always the case (for review, see Kannenberg et al.[28]). Accordingly, it can be argued that such tests are unlikely to capture subtle differences between more technically advanced devices, especially when they provide functions not available or accounted for before. Further, considerable ceiling and floor effects occur,[29,30] and many instruments that might suffer from these effects are still being used.[25] Some tests cannot detect clinically meaningful changes[25] or have little correlation with rehabilitation dose, defined as duration of rehabilitation, number of clinic visits, and specific intervention modes.[31] Finally, some standardized instruments may not capture some clinically relevant aspects[32,33] and are even unsuitable for assessing people with LLA.[25]

To summarize, some tests may be inappropriate for some groups of people with LLA; may be psychometrically invalid; lack specificity, sensitivity, validity, and reliability; or are unable to capture the whole range for aspects of interest. Further, some tests may apply to older systems but cannot reveal the potential benefits of novel neuroprosthetic functions.

Appropriate research strategies are crucial for successfully developing neuroprostheses and demonstrating their clinical benefits. This review provides an overview of the evaluation methods used in the field of lower-limb prosthetics as well as an appraisal of which tests might prove useful during the testing of neuroprosthetic features. Although several literature reviews on the topic of LLA outcome measures are available,[25,26,34–40] none discuss testing strategies in the context of neuroprosthetics and the unique challenges posed by neural interfacing. For an overview of previous literature reviews, see Table 8.

Table 8. Previous literature reviews on lower-limb prosthetic outcome measurements

Citation	**Aim**
Chamlian & Melo[37]	Identifying instruments used for functional assessment of people with LLA between 1985 and 2005 without evaluation of quality
Condie, Scott, & Treweek[25]	Reviewing measures of prosthetic outcomes between 1995 and 2005, evaluating them and make recommendations about their use
Deathe et al.[36]	Identifying outcome measures of prosthetic

	rehabilitation between 1980 and 2006, and evaluating them to assist clinicians in choosing the most appropriate measures
Gailey[26]	Discussing functional and predictive outcome measures for people with LLA
Hafner[40]	Describing outcome measures used to evaluate lower limb prosthetic intervention, including biomechanical parameters
Hart-Hughes et al.[106]	Reviewing balance, fall and gait related outcomes for people with LLA
Hawkins, Henry, Crandell, & Nguyen[35]	Systematically reviewing available functional outcome measures and quality of life assessment instruments for people with LLA between 2001 and 2012, as well as appraising the need for the development of new instruments
Hawkins & Riddick[38]	Systematically reviewing performance outcome measures for people with LLA
Heinemann, Connelly, Ehrlich-Jones, & Fatone[34]	Updating information on available outcome measures in prosthetic practice in the years 2006 and 2013, and providing information on their psychometric properties
Morgan, Hafner, Kartin & Kelly[154]	Reviewing dual-task testing with people with LLA
Rommers, Vos, Groothoff, & Eisma[39]	Comparing mobility scales used with people with LLA between 1978 and 1998

5.11 Methods

Systematic electronic searches in the PubMed (PM) database, the Web of Science (WOS), and Cochrane (CC) databases (November 1, 2019) were conducted on the literature of evaluation methods for lower-limb prosthetics limited to the period between 2013 and 2019. The following criteria were used: Lower limb AND (prosthesis OR amputee) AND (metrics OR assessment) NOT (dental OR arthroplasty). Search results were analyzed in the software Distiller. The articles had to be full-text, peer-reviewed, in English or Icelandic, and on human users. The content of titles and abstracts of the articles were then evaluated independently by two reviewers to assess whether they fulfilled the following criteria: 1) involved LLA and not ULA; 2) involved major LLA defined as amputation at or above the ankle; 3) involved measuring user performance and outcomes rather than evaluating surgical procedures or mechanical dimensions, unless they were reliably associated with specific outcome measures not specific to the intervention; 4) contained information about evaluation methods or outcome measures; and 5) included performance tests where users are asked to perform activities with scoring methods not only based on self-reports or biomechanical measures. After removing duplicates, a total of 533 titles and abstracts were narrowed down to 178 articles for full-text screening, resulting in 72 included articles. Relevant articles cited in the selected articles were further included based on their content if they were on the performance tests used, fulfilled the aforementioned criteria, and were not older than 20 years, unless they were on the original instrument development. This was done to avoid strictly limiting the review to a particular time frame, potentially excluding relevant studies. Disagreements on studies were resolved via consensus-based discussion.

5.12 Results

5.12.1 Level-Ground Walking Tests

Level-ground walking tests are a common measure of the function and mobility of people with LLA. In some tests, users are asked to walk a fixed distance, commonly at their self-selected walking speed, and the time taken is recorded. The 10-m walking test (10MWT) is one example, but 5- and 400-m tests have also been conducted.[43] Users may also walk for a fixed amount of time, and the distance traveled is recorded to estimate physical capacity, such as in the 2-minute walking test (2MWT) and 6-minute walking test (6MWT). Fixed time tests are carried out on walkways or treadmills, occasionally at different inclines.[44]

5.12.1.1 Fixed Distance Tests

The literature on 10MWT is generally considered both reliable and valid,[35,36] and its guidelines have been adapted for people with LLA,[36] although the test was originally created to assess people with spinal injuries.[45] Studies indicate that gait speeds of people with LLA are slower during 10-m walking than that of able-bodied individuals.[46,47] Performance on the 10MWT in early stages of rehabilitation has been used to predict prosthetic abandonment 12 months postamputation, has high clinical utility, 48 and correlates with performance on other mobility tests such as the L-test.[29] The test can differentiate between people with unilateral and bilateral LLA[49] and the prostheses types used. LLA levels and prostheses used during the 10MWT can, however, affect results, demonstrating that additional metrics should be considered for accurate evaluations under some conditions. For instance, Iosa et al.[50] found a significant difference in the walking speed between people with transtibial amputation (TTA) and transfemoral amputation (TFA) with locked-knee prostheses, but not individuals with TTA and TFA using unlocked-knee prostheses on the 10MWT. The performance difference between those with TTA and TFA using an unlocked-knee prosthesis was, however, significant when other aspects of gait were considered, such as upper-body stability, harmony, and symmetry. In Tekin et al.,[51] there was no difference in the walking speed of participants with traumatic amputation and those with a salvaged limb, although other types of measures, such as for quality of life and pain, resulted in better scores for those with an amputation.

5.12.1.2 Fixed Time Tests

Scores on the 2MWT and 6MWT are highly correlated.[52] As performance depends on all systems involved in an exercise, they can be confounded by comorbid conditions.[53] These tests are unlikely to be influenced by cognitive impairment.[54]

The 6MWT has shown concurrent validity with the AmpPRO[55] as well as good within-day test-retest reliability,[56] and the scores correlate with Prosthetic Evaluation Questionnaire (PEQ) scores on satisfaction with prostheses and wellbeing after amputation.[57] The 2MWT also has high interrater and intrarater reliability[58] and convergent validity with several other measures: PEQ,[59] L-test of functional mobility,[29] the Berg Balance Scale (BBS),[60] Prosthetic Limb Users Survey of Mobility (PLUS-M),[61] and the Activities-Specific Balance Confidence Scale (ABC).[62] Both the 2MWT and 6MWT have been used by practitioners when assigning K-levels.[63]

Despite good psychometric qualities, caution is advised when fixed-time tests are used on their own to estimate energy expenditure in persons with LLA. Although heart rate increases throughout the test[64] and there is a correlation between oxygen cost and walking capacity over a short distance, it is not always significant and other measures should also be used.[65] One study found no difference in 2MWT performance between persons with LLA who underwent hyperbaric oxygenation therapy and those who did not, although other measures indicated increased function posttherapy and faster rehabilitation.[66]

There is evidence that the 2MWT and 6MWT can reveal functional changes in early- and mid-rehabilitation as well as clinically meaningful changes.[67] When performance at initial prosthetic fitting or first independent ambulation postamputation is compared with performance at follow-up appointments after discharge, significant improvements in walking capacity are seen.[31,68,69] Furthermore, performance in early rehabilitation can predict prosthetic nonuse after 12 months,[48] and ceiling and floor effects are minimal at midrehabilitation.[70] Sometimes, small yet significant differences found between baseline and post discharge walking capacity are associated with rehabilitation dose,[71] although that is not always the case.[31] It should be noted that there is a possible training effect of these time tests as significant changes have occurred overnight, although they might reflect true functional changes happening in inpatient rehabilitation,[69] and specific training interventions may improve performance.[72]

Fixed timed walking tests can, furthermore, be indicative of physical activity levels of low-activity individuals,[73] who make up most of the population with LLA. Significant increases in self-selected walking pace of low-activity users on the 6MWT were found 4 weeks after they switched from a prosthetic ankle without a joint to ankles with multiaxial joints that allow more stable loading symmetry and propulsion to walk.[74] In addition to faster self-selected walking speeds, perceived effort can decrease when low-activity people switch from one foot to another.[47]

Although no significant difference in 6MWT performance was found in another study comparing feet with different joint flexibility, the users in the sample were more active and therefore not likely to increase their self-selected, already fast walking speeds.[75] Although timed tests are not always sensitive to known-group differences,[70] they have been used to differentiate between abilities of people with unilateral and bilateral LLAs as well as TTA and TFA,[76] even in samples of young, highly active people with traumatic LLA.[77] However, a third variable can sometimes hinder performance improvements on walking tests. Changing to vacuum-assisted socket systems for the first time only significantly increased walking capacity 4 weeks after fitting in elderly people with dysvascular LLA if they did not display residual-limb blistering.[78] Those who experience residual limb–related issues can, correspondingly, improve their performance on the 6MWT after osseointegration.[79] Other studies further show that prosthetic users who do not experience socket- or residual limb–related issues can increase their walking capacity by using different prosthetic components.[80,81] For instance, 2MWT performance improved when participants in one study switched from a nonmicroprocessor-controlled knee to a microprocessor-controlled knee.[82]

Beausoleil et al.[64] found significant differences in kinematic measures during different segments of the 6MWT in a sample largely composed of people with dysvascular LLA. Performance on the 6MWTmay in fact be predictive of gait deviations in adults with LLA.[83] However, Feick et al.[84] demonstrated that, although able-bodied children outperformed and showed less gait asymmetry during swing and step than LLA children on both the 6MWT and 10MWT, there was no significant relationship between gait deviations and walking capacity in the group with LLA.

5.12.1.3 Discussion

Although level-ground walking tests are generally considered good estimates of functional abilities associated with LLA and can be useful for predicting and detecting changes in early rehabilitation as well as in low-activity people with LLA, they have several drawbacks. They only measure the time taken or distance traveled, and although they can be used as mobility predictors, they do not provide information about other important gait characteristics. Higher walking speeds are sometimes associated with less gait harmony[50] and insufficient increase of toe clearance,[85] potentially increasing fall risk. However, higher walking speeds may also be associated with better postural control and balance in children.[84] Children apply different balance and control strategies than adults, which may explain this difference. [86] Moreover, performance on level-ground walking tests does not always significantly differ between known groups.[26,70] It is therefore not advisable to compare walking speeds of heterogenous samples across studies. Finally, there may be an interaction between amputation cause and activity levels, as performance on walking tests of low-activity individuals may improve after certain interventions or prosthetic components, if their amputation was not due to dysvascularity. In fact, those affected by vascular problems are less likely to improve their walking speed in general.[78,80,81]

The aforementioned drawbacks of level-ground walking tests imply that providing people with LLA with neuroprosthetic components might not necessarily result in faster self-selected walking speeds. High-activity individuals often already walk at high self-selected walking speeds on level ground, and the low-activity ones are often limited by other physical ailments. In addition, level-ground walking is cyclic and neuroprostheses will not necessarily affect self-selected walking speed beyond that of microprocessor-controlled prostheses in walking in straight lines indoors. The benefits might, however, become more apparent in naturalistic settings, which can include unexpected objects appearing in the individual's path or tasks requiring user reaction, different types of terrain, or even changes from one type of terrain or incline to another.

A recent study by Petrini et al.[9] demonstrated how providing intraneural sensory feedback increased walking capacity in two high-activity individuals with TFA during a test based on the 6MWT, which involved walking in a figure of eight on sand for 6 minutes. In addition, Petrini et al.[10] found that walking performance was improved on a fixed distance test when intraneural sensory feedback was provided. The test required participants to walk on a straight line for 5 m, without stepping off the line where the ratio of steps off the line to total number of steps served as a metric.

It seems that level-ground walking tests in their simplest form are unlikely to be useful for demonstrating the advantages of neuroprosthetic features during walking. Modified versions, on the other hand, could potentially be sensitive enough to capture their benefits and provide a more informative portrayal of ambulation of people with LLA.

5.12.2 Stairs and Hills

Stairs and slopes are more demanding than level-ground walking. Stair ascension requires the capability to lift your leg and propel your body upwards, whereas stair descension requires power and shock absorption on the way down. People with TFA typically climb stairs step-by-step, taking one step at a time where the intact limb usually goes first. Step-over-step (SOS) patterns are more efficient and seem more natural but are more difficult. Similarly, hill negotiation can involve various stepping patterns, some more difficult than others. The Stair Assessment Index (SAI) and Hill Assessment Index (HAI) are ordinal scales from 0 to 11, representing how well a person can negotiate standard stairs/hills by accounting for need of assistance from another person, use of assistive devices, handrail use, and stepping patterns,[87] and were specifically developed for people with TFA to test microprocessor knees. Microprocessor-controlled knees show advantages over mechanical ones, most strikingly highlighted in a study where some individuals were reclassified to higher Medicare Functional Classification Levels (MFCL) after using advanced knees over the course of several months.[88]

Several studies provide evidence that people with TFA can improve their performance on both the HAI and SAI when using microprocessor rather than mechanical knees,[83–86] although in some cases, the significant differences are only found for ascent, not descent, and vice versa.[87] Furthermore, the HAI and SAI have shown that performance of low-activity TTA users can improve when switching from a nonarticulated to a multiaxial foot,[74] whereas ceiling effects are likely to mask performance differences of high-activity people with TTA using different prosthetic components.[44]

Although the indexes seem to be sensitive to differences between vastly different prosthetic components, even for people with TTA, their utility is not as clear when more advanced components are compared; Bell et al.[89] found that participants with TFA significantly improved their HAI scores when switching from a mechanical to a microprocessor knee. However, no such difference was found for those who switched from one microprocessor knee to another, even though biomechanical measures indicated improved function with the second microprocessor-controlled knee.

Performance in stairs and hills has additionally been estimated by recording the time taken to complete negotiation.[68] Although one study reported a difference in speeds during hill negotiation with microprocessor-controlled knees as opposed to mechanical ones,[88] other results have not been as positive. Although Fuenzalida et al.[82] found significant differences in walking speed between mechanical and microprocessor-controlled knees on level ground and uneven terrain, neither stair nor hill negotiation times differed. Another study revealed no differences in stair negotiation times between mechanical and microprocessor-controlled knees.[90] Further, Schnall et al.[68] found no differences between negotiation times on stairs and hills at the first independent ambulation of people with TFA and a follow-up appointment 47 to 300 days later, but they reported increased confidence levels at follow-up.

5.12.2.1 Discussion

The HAI and SAI seem well suited for comparing different prostheses such as mechanical versus microprocessor-controlled knees,[87–89,91] as well as nonarticulated and multiaxial feet.[74] When the differences between devices are more subtle, it seems that the indexes sometimes cannot capture clinically relevant changes, better measured by other means.[68] Moreover, it could depend on amputation and activity levels whether the tests can capture any differences at all; high-activity people with TTA are likely to have high scores, and the scales leave little room for improvement, whereas low-activity people with TFA might lack the physical strength needed to compensate for the loss of their limb, again leaving little room for improvement. The indexes could, however, possibly capture benefits for low-activity individuals should they receive a powered prosthesis compensating for their reduced physical capabilities.

Despite the apparent lack of sensitivity of time measurements for the comparison of prosthetic components with subtle differences, studies indicate that sensory feedback could improve walking capacity[9] and stair negotiation times.[10] Timed negotiation in neuroprosthetic testing should thus not be written off without further investigation.

Several interesting aspects should be considered regarding stair and hill negotiation not directly covered by the indexes and time measurements. First, they do not specifically address transitions from level ground, one aspect where intent control might help people with TFA, so they do not have to stop to activate/deactivate a mode before starting negotiation. Second, they do not capture benefits in unexpected situations that people frequently encounter in daily life such as steps that are misaligned or vary in height, different inclines within one hill, encounters with people or animals, and slippery and wet elements like ice or water. Interrupting cyclic activities might be one of the greatest benefits of intent control as adaption to unexpected circumstances is made possible in any scenario. Third, neuroprostheses could lead to better sensory and reflex abilities to prevent tripping and falling and thus increased confidence on stairs and slopes. Fourth, interpreting results can in some cases be difficult; although less handrail use and increased speed in SAI can be interpreted as increased confidence during negotiation, handrail use could also reflect that support is needed to compensate for a lack of physical strength even though confidence is high. Finally, the tests do not directly address tripping and falling. The addition of complementary metrics to the indexes and time measurements, either as a part of the tests themselves or in the form of new tests, should be considered to shed further light on how neuroprostheses can influence stair and hill negotiation.

5.12.3 Other Timed Mobility Tests

5.12.3.1 Five Times Sit to Stand Test

The five times sit to stand (5XSTS) test was developed to measure transfers, balance, and strength in clinical populations.[92] Participants sit on a standard chair with their arms crossed and are instructed to stand up and sit down five times as fast as they can. Although the test has good psychometric properties in several populations,[92–95] no information is available on its reliability and validity in the LLA population. One study on people with LLA suggests that the test is more sensitive to differences in performance with two different prosthetic feet when compared with the timed up and go (TUG) test, four-square step test (FSST), and comprehensive high-level activity mobility predictor (CHAMP). However, none of the differences were significant, presumably due to small sample size.[96]

5.12.3.2 Timed Up and Go Test

The TUG was originally intended to evaluate the fall risk of elderly people97 but has also been used frequently with people with LLA.[48,56,98,99] Participants sit on a standard chair with a back and armrests and, when ready, are instructed to “go,” standing up and walking 3 m at their self-selected walking speed, using their regular ambulatory aids, turning around and siting back down. The time until the users' buttocks touch the chair again is used as an indicator of general physical mobility.[99]

Schoppen et al.[99] evaluated the reliability and validity of the TUG test with older adults with dysvascular LLA, finding that it had excellent interrater and intrarater reliability (see also Resnik and Borgia67). The test also had a low yet significant correlation with the Groningen Activity Restriction Scale (GARS) and the mobility subscales of the 68-item version of the Sickness Impact Profile (SIP-68). In addition, shorter TUG times have been associated with longer distances on the 6MWT[56] and less frequent falls in people with LLA.98 The test can also predict prosthetic nonuse in people with TTA 12 months postdischarge.[48]

Age at amputation and balance standing on the intact limb as well as cognitive impairment could explain 42% of the variance of TUG results a few weeks after amputation in elderly people with dysvascular LLA.[100] Further associations have been found between cognitive function and times in addition to amputation level,101 although not all studies have found such a relationship. 99 The TUG has been used to demonstrate how people with LLA with socket- and fit-related issues were able to significantly improve their mobility after osseointegration,[79,81] and performance has improved with specific training strategies.[102]

The TUG has moderate convergent validity with the Houghton Scale, Locomotor Capabilities Index of the Prosthetic Profile of the Amputee (PPA-LCI), and the PEQ mobility subscale (PEQ-MS),[59] as well as the PLUS-M103 and Locomotor Capabilities Index 5 (LCI-5).104 Furthermore, TUG times are associated with Barthel Index (BI) scores for geriatric individuals with dysvascular LLA.[101]

Considerable ceiling effects on the TUG have been reported for high-activity people with LLA,[29,44] indicating that the test is not a good measure for higher functioning individuals. In fact, when a microprocessor-controlled foot was compared with a non-microprocessor-controlled one with high-activity individuals, kinematics improved, but the difference was not reflected in TUG times.[44] On a similar note, when microprocessor-controlled knees have been compared with non-microprocessor-controlled knees with high-activity users, TUG scores do not necessarily differ while other scores change.[82,90] Moreover, TUG time is not always sensitive to rehabilitation dose[31,71] or associated with patient satisfaction in people with LLA.57 Even so, the TUG is often used when clinicians assign K-levels.[63] Sawers and Hafner[105] suggest that the TUG is most useful during early rehabilitation, whereas other tests may be more useful when prosthetic users become accustomed to their prostheses.

5.12.3.3 The Component Timed Up and Go Test

The component timed up and go (C-TUG) test was originally intended to aid clinicians in identifying functional limitations of individuals more specifically than the TUG.[106] The test is identical to the TUG, except that floor markers are used to indicate where to turn.[107] The floor markers divide the test into components scored individually with a tablet application and then combined for a total score. The components are composed of 1) standing up, 2) walking forward, 3) turning, 4) walking back, and 5) sitting back down. The test has good test-retest reliability for total time as well as for the components, moderate convergent validity with the PLUS-M and ABC, as well as discriminant validity for people with TTA and TFA.[107]

5.12.3.4 The L-test of Functional Mobility

The L-test of functional mobility is a modified version of the TUG test, designed to counter ceiling effects on the TUG and incorporates aspects of function important to home ambulation.[29,41] Participants stand up from a standard chair, walk 10 m in an L shape, turn 180°, and return the same way. Individuals with lower cognitive function tend to take longer to complete the test,[54] suggesting that much like the TUG, it is more cognitively demanding than simple level-ground walking. As such, it has been used with a concurrent cognitive task to evaluate the relationship between cognitive load (CL) and gait parameters.[108]

In Deathe and Miller,[29] interrater and intrarater reliability of the L-test was excellent and good convergent validity was found with TUG, 10MWT, 2MWT, ABC scale, and Frenchay Activities Index, with the exception of the PEQ-MS. Good convergent validity for the BBS has also been reported by others.[60] Furthermore, Deathe and Miller[29] used the test to distinguish between performance of clinically different groups depending on level and cause of amputation, use of walking aids, age, and automation or the concentration needed to take each step.[29] In addition, the L-test is sensitive to differences in mobility for persons with diabetes with LLA at 3 and 9 months postrehabilitation,[73] predicts social activity 3 months after inpatient rehabilitation,[109] and may be sensitive to meaningful clinical changes.[110] Hints of ceiling effects have, however, been reported for high-activity users.[29]

5.12.3.5 The Four-Square Step Test

The FSST was designed to identify fall risk of community-dwelling individuals older than 65 years[111] but has been used with people with LLA.[78,98,112] Participants step clockwise into four squares formed by two canes as fast as they can and then repeat the process in the counterclockwise direction. The completion time is the main measure of performance.[111] The test is more demanding than traditional walking tests[48] as it requires both direction changes and overstepping obstacles.

Performance on the FSST at rehabilitation discharge has been used to predict prosthetic use 12 months post discharge. Dite et al.[98] showed that scores at the end of rehabilitation could identify people who often fell versus those who did not 6 months later and was also sensitive to the differences between the groups at the follow-up appointment.

Other results have indicated that the FSST may not always be applicable. In one study, scores on the ABC scale improved when participants switched from a non-microprocessor-controlled knee to a microprocessor-controlled knee, but FSST scores did not improve.[82] Roffman et al.[48] concluded that the test has limited clinical utility as 25% of prosthetic users could not perform the test at discharge.[48] In another study 35% of prosthetic users performed near the test's lowest possible score. In addition, no differences were found in the performance of well-established prosthetic users with different fall histories in the whole sample. The authors suggested that the use of the FSST should thus be limited to early rehabilitation.[105]

5.12.3.6 The Comprehensive High-Level Activity Mobility Predictor

The CHAMP was specifically developed due to the high performance of service members who were recently fitted with a prosthesis and associated ceiling effects for this population.[113] The CHAMP consists of the following subtests: single-limb stance (SLS), Edgren Side-Step Test (ESST), t-test, and Illinois Agility Test (IAT). The SLS is a traditional single-limb test, such as the one included in the AMP, where users stand on each leg for a maximum of 30 seconds. The t-test involves running forwards and backwards as well as sidestepping between cones, whereas the IAT further includes standing up from a lying position and weaving between cones. The SLS, t-test, and IAT are all scored based on time while participants receive points on the ESST for each meter traveled in 10 seconds during a sidestepping task. A final score is then calculated from the four tests. Original findings indicated excellent interrater and test-retest reliability, [113] and Mahon et al.[114] created benchmarks for young healthy males with unilateral TFA. The test has good convergent validity with the 6MWT and the AmpPRO.[77] Halsne et al.[96] found evidence of within-day practice effects on the CHAMP, although they should be minimal if the test is conducted on separate days. Although performance on the CHAMP differed between two different prosthetic feet, the difference was not significant, which may reflect the small sample size.[96]

5.12.3.7 Discussion

Known-group validity of the TUG, L-test, and FSST as well as their sensitivity to detecting changes between vastly different prosthetic components can be questioned considering the results mentioned above. Moreover, they all share the drawback of only measuring completion time and do not directly assess other important aspects of mobility and ambulation other than speed. Although a skilled clinician can evaluate the quality of turning, transferring, and stepping over obstacles, such assessment is not directly included in the tests themselves but may have a higher clinical relevance, for example, for assessing balance difficulties. Although ceiling effects reported in the TUG are reduced in the L-test, they are not fully eliminated, making the tests ill-suited for assessing high-activity people with LLA, especially if they are already using microprocessor-controlled prostheses, a powered prosthesis, or can readily compensate with physical strength. Although the CHAMP test was designed for very active people with LLA, ambulation quality is not assessed, only time and distance traveled. Nevertheless, as performance during walking and on obstacle courses may improve with neuroprosthetic components,[9,10] CHAMP could potentially reveal any general added ambulatory benefits, especially because it incorporates complicated movements that require agility. Additional measures on ambulatory qualities could be included to get a better overview of the changes in people's ability with their new prostheses.

5.12.4 Mobility Tests Not Based On Completion Time

5.12.4.1 Functional Independence Measure

The Functional Independence Measure (FIM) was developed to assess function based on the assistance a person requires for activities of daily living, moving in an environment, and cognitive function. As such, the measure is split into a motor subscale (mFIM) and a cognitive subscale (cFIM).[115]

Hawkins et al.35 argue that the FIM lacks construct validity and responsivity. In addition, there are reports of ceiling effects for high-activity[35,116] and floor effects for low-activity individuals with comorbidities,[117] although retrospective studies have associated FIM scores with perceived quality of life[118] and different rehabilitation types[117,119] in cohorts of lower-activity war veterans with LLA. Despite ceiling and floor effects, the FIM has been deemed useful in assessing low-activity LLP users. Hershkovitz et al.[120] showed that functional levels measured with the FIM at admission to post-acute rehabilitation was associated with prosthetic fit 1 year after discharge, although the sample mainly included elderly patients who were physically and/or mentally disabled before their limb loss. Batten et al.[121] further showed that scores on mFIM significantly differed between individuals with dysvascular and nonvascular causes of amputation, both at admission and discharge. Although another study found significant correlations between gait speed and FIM scores at discharge from rehabilitation, the authors postulated that the test might nonetheless involve ceiling effects.[46]

5.12.4.2 The Basic Amputee Mobility Score

The Basic Amputee Mobility Score (BAMS) was recently devised to evaluate the performance of elderly people with dysvascular LLA shortly after amputation. The test assesses the ability to lie down on a bed and then sit on its edge, transfer from bed to wheelchair, as well as wheelchair mobility and single-limb standing. Original findings indicate promising reliability and responsivity for low-activity individuals, although further information is needed to validate the instrument.[122]

5.12.4.3 Continuous Scale Physical Functional Performance 10

The Continuous Scale Physical Functional Performance 10 (CS-PFP10) was developed to evaluate physical performance of older adults when conducting everyday tasks of incremental difficulty, such as carrying a pot or walking for 6 minutes. Scores include a total score in addition to five physiological scores: upper-body strength (UBS), upper-body flexibility (UBF), balance and coordination (BAL), lower-body strength (LBS), and endurance (END). For instance, being able to put on a jacket or secure a seatbelt is considered a sign of UBF.[123] Although the scale has not been validated for people with LLA, it has been used to demonstrate differences in performance between people with TFA using two different microprocessor-controlled knees. All scores differed, except for the two evaluating strength.[124]

5.12.4.4 Amputee Mobility Predictors (AMP:AmpPRO, AMPnoPRO)

The amputee mobility predictor (AMP) was designed to predict the ambulatory potential of people with LLA and assist in assigning MFCL for prosthetic prescription. In the United States, most clinicians use the AMP when prescribing a prosthesis. [63] The test can both be administered with (AmpPRO) or without (AMPnoPRO) a prosthesis to aid prescription. The AMP has showed good construct and convergent validity and good interrater and intrarater reliability, yielding significantly different scores by activity levels.[55,77,103,125] In one study, the AMP yielded significantly different scores for people with different LLA.[126] Test-retest reliability has been found to be relatively high,[67] and a recent study[103] showed that the instrument has good psychometric qualities. People with unilateral TTA with socket-related discomfort have additionally showed significant improvement on AMP after osseointegration and may even be reclassified at a higher MFCL postsurgery.[81] Furthermore, Spaan et al.[127] found that the AMPnoPRO was a better predictor of mobility outcomes than the Lower-Extremity Motor Coordination Test (LEMOCOT) and single-limb balance tests, which are discussed later. However, results on the test were not clearly distinguished by activity levels related to MFCL with little differences between K1 and K2 users, although they had lower scores than K3s and K4s.

5.12.4.5 Standardized Walking Obstacle Course

The Standardized Walking Obstacle Course (SWOC) was developed to measure abilities of individuals with various vestibular problems and includes stepping over and avoiding obstacles, turns, and sitting down in a chair. Although the test has not been validated for the LLA population, Prinsen et al.[90] used it to compare mechanical and microprocessor-controlled knees using number of steps, step-offs, stumbles, and time to completion as metrics. In contrast with expectations, the microprocessor-controlled knee resulted in more steps taken during the obstacle course than the mechanical knee while no other metrics showed significant differences.[90]

5.12.4.6 180° Turn Test

The 180° turn test was developed to measure turning in older individuals and their risk of falling[128] and has moderate interrater and test-retest reliability. The test could identify multiple fallers and was deemed sensitive to differences between elderly individuals with LLA and able-bodied comparisons. The measures of interest include the number of steps during the turn in the TUG test, turn time, and how steady and fluent the motions appear. Although it could identify 85% of the fallers in one study, it neither seemed to be as sensitive nor as predictive as the FSST.[98] Although the test provides more insight into people's mobility than the TUG test on its own, it has not been validated for use with people with LLA.41

5.12.4.7 Figure of Eight Walk Test

The figure of eight walk test (F8WT) was designed to evaluate walking skills of older individuals. Participants walk in a figure of eight around two cones placed 5 ft a part in an area that is 4 ft wide. Although the time taken to complete the test affects scoring, other aspects are included, such as the number of steps and width of the ambulatory path.[129] Although the test has been applied with persons with LLA,[130] no studies on psychometric properties with that population were found.

5.12.4.8 Discussion

The FIM motor scale assesses the amount of assistance needed to complete daily activities such as eating, grooming, dressing, and managing bladder and bowel movements. Further, the BAMS only includes the most fundamental aspects of mobility, such as safe transfers, and the tasks on the CS-PFP10 are not of much higher difficulty. These tests are therefore of limited use for those able to go about their day unassisted and are more active. In contrast, the AMP not only considers people's ability to complete a task without assistance but also assesses quality, whether they need to support themselves during the task, such as using handrails or armrests. Furthermore, the perceived balance and safety determined by the observer affects scoring. The AMP is useful for predicting prosthetic outcomes and determining K-levels, but like the FIM, it does not quantify compensatory behavior beyond a certain extent. Additional tests or metrics should be considered for a more comprehensive profile of the function of higher-activity people with LLA, preferably ones that resemble everyday tasks. Although the 180° turn test includes subjective quality of motion as well as number of steps taken in addition to time, the test needs to be validated with people with LLA and should thus be interpreted with caution. The SWOC requires people to perform actions that can be regarded as more difficult than the timed mobility tests. However, little information on its applicability in the LLA population is available, and the singular result emerging from the review does not seem promising. Nonstandardized obstacle courses have, however, been applied during neuroprosthetic testing in scenarios which more closely mimic conditions where neuroprosthetic features could be useful. In Petrini et al.,[10] for instance, people with LLA were prevented from seeing where the obstacles in front of them were. Participants were less likely to fall when provided with sensory feedback from their prosthesis. Finally, the F8WT requires validation with people with LLA.

5.12.5 Balance and Coordination

5.12.5.1 Berg Balance Scale

The BBS was developed to measure balance in the elderly. The scale comprises 14 functional activities, including stepping, standing, sitting, reaching, leaning over, looking over both the left and right shoulders, and turning in a circle.[131] The BBS has been used to assess balance in people with LLA,[60,70,132,133] has excellent interrater reliability in the population,[60,134] and has convergent validity with the ABC scale, PEQ-MS, the 2MWT, the L-test,[60] and the narrowing beam test.[105] Wong et al.[132] reported that the BBS is unidimensional, although one item, standing on the prosthetic leg, did not fit well within the scale's model.

The BBS has been used to demonstrate that using a vacuum-assisted socket system improves balance[78] and that multiaxial feet result in greater stability than nonarticulated feet.[74] Further, significant differences have been found on BBS scores when two different microprocessor-controlled knees were compared.[135] Ceiling effects have, however, been reported,[60,70,132] and Gremeaux et al.[70] found the 2MWT to be a better predictor of prosthetic walking limitations in people with LLA than the BBS.

5.12.5.2 Community Balance and Mobility Scale

The Community Balance and Mobility Scale (CB&M) was created to measure balance in patients with traumatic brain injury. Measured items include standing, walking backwards and forwards, pivoting, scooting, hopping, picking up objects, walking while maintaining gaze, bending down and carrying objects, descending stairs, and stepping rapidly on and off a step.[136] Each task is scored from 0 to 5 in a customized manner, depending on both time and distance traveled as well as performance quality. For instance, being able to carry a laundry basket up a stairway yields a higher score than ascending the stairs without the basket. Feick et al.84 used the scale to compare children with unilateral LLA and able-bodied controls. The children with LLA received significantly lower scores than the controls on the CB&M as well as walking capacity and gait asymmetry. Postural control measured via force plate, which can measure ground reaction forces generated by the person on top of it, was strongly correlated with the CB&M, although no association with spatiotemporal gait deviations was found.

5.12.5.3 Lower-Extremity Motor Coordination Test

The LEMOCOT was developed to measure lower-limb coordination in stroke patients. Users sit in a chair and move their unaffected leg as quickly and accurately as they can between two targets, 30 cm apart, in 20 seconds, and accurate hits are counted. The test is then repeated for the other leg and the differences between the two evaluated.[137]

Spaan et al.[127] used the LEMOCOT, AMPnoPRO, and a balance test to predict the mobility of people with LLA at discharge from rehabilitation, measured with the TUG and 2MWT. Their balance test involved users standing on their intact limb with or without their eyes closed and with or without distraction. Balance testing is often included in performance tests. In the AMPnoPRO for instance, participants must stand on their intact side for 30 seconds, and in another condition, the instructor lightly nudges the subject when standing on one leg.

The AMPnoPRO was a better predictor of performance for the mobility tests than the balance test and LEMOCOT.[127] The AMPnoPRO includes more complex scenarios than the LEMOCOT, which is only performed while the participant is sitting, and takes quality into account, not only time, like the balance test did.[127] However, Burger et al.[138] demonstrated that single-limb balance on the prosthetic side by itself was significantly different between two types of prosthetic feet. It is, however, very challenging for people to balance on a prosthetic limb, and a small change can lead to statistically significant results.

5.12.5.4 Narrowing Beam Walking Test

The narrowing beam walking test (NBWT) was recently developed due to the psychometric limitations of traditional balance measures used with the LLA population. Participants cross their arms over their chest to exclude potential influences of variations in compensatory hand movements and walk on a beam that is a few centimeters above the ground. The beam is 7.3 m long and is made of four sequential 1.83 m segments of 18.6 cm, 8.6 cm, 4 cm, and 2 cm width and so narrows toward the end. The score is calculated depending on the distance walked without stepping off. Sawers and Hafner[105] tested 40 people with LLA of various activity levels, where no participant found the task too easy and only one thought it was too hard. The test was significantly correlated with other measures such as the FSST, BBS, the

TUG, and the ABC scale.[105] Furthermore, the NBWT differentiated between participants, depending on amputation level, history of falls, and activity levels.[139]

5.12.5.5 Discussion

Due to the test's design, the BBS is unlikely to reflect improvements beyond basic balance activities. The CB&M contains items of higher difficulty than those in the BBS, perhaps capturing more complex balance-related factors, but there is little information about psychometric properties with people with LLA. Several items on the CB&M could be influenced by the ability to directly control a prosthetic ankle or knee and/or receive feedback from the prosthesis. Walking and crouching, running, and stopping suddenly, transitioning repeatedly into stairs, and walking while looking elsewhere and carrying an object are all considerably more difficult than items on the BBS and might thus cause less ceiling effects.

The LEMOCOT, although not as predictive of ambulation as the AMPnoPRO (used without a prosthesis), focuses on coordination and the difference in function between legs. There is, however, little information on psychometrical validation of the LEMOCOT on people with LLA. Nevertheless, when validated for stroke patients, the test did not indicate ceiling effects while other coordination tests did have such effects.[137] It is difficult to draw strong conclusions about the use of the CB&M and the LEMOCOT on people with LLA without further validation. The NBWT, on the other hand, has good psychometric properties in the LLA population and should be considered during balance assessments.

5.12.6 Cognitive Load

People have limited attentional capacity and cognitive resources, [140] so it is important to minimize the cognitive demands of using a prosthesis.[7,141] A task requiring few resources is said to have low CL, whereas those involving more load are referred to as high-load tasks.[142]

Several instruments for measuring general CL are available such as the Stroop test, where respondents are presented with words describing colors, such as “red” and “blue” that are drawn with inconsistent ink colors. Because reading is automatic and well-practiced, color naming is slowed.[143] The auditory Stroop test is similar to the visual version, but instead of reading color words, participants hear the words “high” or “low” in a high-pitched or low-pitched tone and respond whether the pitch, not the word, was high or low.[141,144] Other studies involve arithmetic tasks where users add or subtract numbers[145–148] or verbally repeat numbers they hear in reverse order.[87,88] On the controlled oral word association test (COWAT), people have to name as many words beginning with a certain letter as they can in 1 minute, and the category test works the same way except the words need to belong to a specific category.[147] On Shepard and Metzler's 3D mental rotation task,[149] object pairs are presented and people judge whether they are mirrored or the same.[150] Finally, psychophysiological measurements such as skin conductance, skin temperature, electrocardiography, breathing frequency, or EEG can be used to evaluate CL.[10,150,151]

Hunter et al.[152] demonstrated that gait and cognitive performance of people with LLA were both negatively affected when they performed a dual task involving walking on a walkway and counting backwards in threes. Hunter et al.[108] further demonstrated excellent reliability of a dual-task protocol for three different LLA subgroups.

5.12.6.1 Discussion

Evaluating CL is very important in neuroprosthetic development and testing. Implementation of sensory feedback can lead to increased load,[153] which might affect the usability of a device. Control and feedback schemes need to be designed so that they reduce the strain on users, so they can use cognitive resources for aspects other than mobility. In addition, variables such as trust and confidence in the prosthesis can decrease CL, because those who trust their prosthesis will spend less time thinking about every step than those who worry that their device will buckle and lead to tripping and falling. This is for example seen when microprocessor-controlled prostheses with safety features are compared with devices without such functions.[154] However, the literature on CL in prosthetic testing is quite young, and the methods used to address the topic vary greatly. Participant groups are heterogeneous, and important information on cognitive tasks is often left out, which makes their interpretation, comparison, and generalizability difficult. A recent review article by Morgan et al.[42] highlights these issues as well as trends in testing CL with prostheses, where the authors conclude that low-activity individuals have greater trouble maintaining balance than able-bodied individuals during highly demanding cognitive tasks.[144,145,155] Studies on CL and walking, however, have mainly involved high-activity individuals, typically showing no differences between their performance and able-bodied controls.[146,156,157] Morgan et al.[141] pointed out that these studies involved level-ground walking, which is not very challenging for high-activity individuals. In addition, many self-reports suggest that there is indeed a difference between people with LLA and controls, even when functional results are similar, and those with LLA mainly express concern during icy, slippery, or uneven terrain and in unpredictable scenarios, not during level-ground walking.[87,88,147] Morgan et al.[158] only found significant differences in gait asymmetry between controls and people with LLA when conducting a cognitive task while walking on a compliant surface, not on a regular level-ground surface. They suggest that future studies should include representative samples regarding amputation level, cause, mobility and age, larger subject numbers, and with more difficult scenarios.[158]

5.12.7 Activity Monitoring

One downside of standardized tests is that they are conducted in artificial laboratory settings. People tend to behave differently when they are being watched,[159] and therefore laboratory results are not always representative of actual behavior. One way to overcome this is to remotely monitor behavior with sensors on, for example, cell phones or smart watches.[73,160,161] Depending on device, different types of data can be gathered, such as the number of steps taken or the type and frequency of activities (for overview, see Hafner and Sanders[162]).

Remote activity monitoring could provide useful functional information about people with LLA. For instance, two studies by Albert et al.[160,161] indicated that K-levels are associated with step count and activity intensity for high-activity users. Another more recent study further showed that step count and activity intensity were significantly associated with gait speed and performance on the TUG and L-test, both at 3 and 9 months after hospital discharge.[73] Step watches have been shown to accurately measure step counts during fixed time walking tests.[130] There is, however, conflicting evidence whether step count activity during fixed time walking tests actually represent how active people are in the community.[26,73,163]

5.12.7.1 Discussion

Activity monitoring that provides broad and general data on steps taken and the intensity of activity does not provide detailed information about specific activities, gait anomalies, and other important aspects of ambulation and mobility. Integration of multiple sensors could provide more precise information on such specific activities, which could in turn be useful to understand how people use neuroprosthetics.[162] Reviewing the status of monitoring technologies, however, lies outside the scope of this review.

5.13 Conclusions

Although there is no criterion standard in lower-limb prosthetic testing, many instruments assessing various aspects of amputation are available (see Table 2). Some are better suited for people with LLA than others because of psychometric qualities and relevance to amputation-specific concerns, whereas little evidence supports using others. Our review reveals that many frequently used instruments involve ceiling effects and lack known-group validity. Although several tests seem to have moderate to good psychometric properties, their usefulness in testing neuroprostheses is not very clear. Despite these limitations, most of the tests seem to be useful tools during rehabilitation to predict abilities of prosthetic users at later stages. Nevertheless, the goal of this review is not to draw conclusions on the clinical utility of these tests, but rather to estimate their usefulness for the development and assessment of neuroprosthetic components.

Table 9. Test content of performance-based instruments and considerations for neuroprostheses presented in Paper II.

Test	Conduction Involves	Metrics	Considerations
2MWT	Walking for 2 min	Distance traveled	Only include cyclical behavior on a flat surface in a straight line
6MWT	Walking for 6 min	Distance traveled	Only include cyclical behavior on a flat surface in a straight line
10MWT	Walking 10 m	Assistive need, use of assistive devices, handrail use, and stepping pattern	Only include cyclical behavior on a flat surface in a straight line
HAI	Walking up and down an incline	Assistive need, use of assistive devices, handrail use, and stepping pattern	Include two transitions between cyclical activities
SAI	Ascending and descending stairs	Assistive need, use of assistive devices, handrail use, and stepping pattern	Include two transitions between cyclical activities
TUG and C-TUG	Sitting on a chair, standing up, walking 3 m, turning back, and sitting down again	Time duration	Involve two transitions, cyclical behavior on a flat surface in a straight line and a single turn

180° turn test	Sitting on a chair, standing up, walking 3 m, turning back, and sitting down again	Number of steps taken during turn, turn time, fluidity of motion	Involves two transitions, cyclical behavior on a flat surface in a straight line and two different turns
L-test	Sitting on a chair, standing up, walking 10 m in an L shape, turning 180°, going back the same way, and sitting down again	Time duration	Involves two transitions, cyclical behavior on a flat surface in a straight line and two different turns
FSST	Stepping clockwise in four squares formed by two canes and then repeating the process in the counterclockwise direction	Time duration	Involves stepping in four different directions over an obstacle, repeated for both prosthetic and sound side
AMP	Performing several incrementally complex activities from sitting balance to obstacle negotiation	Quality of gait, need for assistance	Includes various activities requiring transitions, obstacles, turning as well as both cyclical and noncyclical ambulation
F8WT	Walking in a figure of eight between two cones placed 5 ft apart	Time duration, width of path, step count	Involves avoiding obstacles and turning
FIM	Evaluation of activities of daily living, mobility, and cognitive function	Need for functional assistance	Involves transitions, cyclical ambulation on flat surface and stairs

CHAMP	Performing several high-level athletic activities	Time duration	Includes turning, stepping in various directions, avoiding obstacles and transfers between lying on floor and standing
SWOC	Navigating an obstacle by rising from a chair, sitting back down, stepping over and avoiding obstacles, ambulating on visually challenging and rough terrain	Time duration, number of steps, step-offs, and stumbles	Involves two transitions, obstacle avoidance, and cyclical walking on different terrain types
BAMS	Laying down on a bed, sitting on its edge, transferring to a wheelchair, and performing single limb standing	Need for functional assistance and guiding	Includes transfers of a rudimentary nature
CS-PFP10	Performing everyday tasks of incremental difficulty	Quality of functional performance	Involves cyclical ambulation on flat surface with and without external loads as well as in stairs. Also includes transferring to and from sitting on floor.
BBS	Performing 14 functional activities such as stepping, standing, sitting, and reaching	Independence, time duration, number of steps, and distance traveled	Includes several transfers and turns

CB&M	Performing several activities, ranging from simple movements to more difficult tasks	Distance traveled, quality of performance	Involves incrementally challenging ambulation on floor and stairs, both cyclical and noncyclical; further includes interruption of cyclical behavior, numerous transitions, external loads, and attention
LEMOCOT	Sitting on a chair and moving unaffected leg as quickly and accurately as possible between two targets on the floor, and repeating for affected leg	Accuracy during a 20-s period	Evaluates intentional leg coordination
NBWT	Walking on a narrowing beam	Distance traveled	Involves incrementally challenging cyclical walking in a straight line on a raised surface; requires agility, balance, and coordination

2MWT indicates 2-minute walking test; **6MWT**, 6-minute walking test; **10MWT**, 10-m walking test; **HAI**, Hill Assessment Index; **SAI**, Stair Assessment Index; **TUG**, timed up and go; **C**-TUG, component timed up and go; **FSST**, four-square step test; **AMP**, amputee mobility predictor; **F8WT**, figure of eight walk test; **FIM**, Functional Independence Measure; **CHAMP**, comprehensive high-level activity mobility predictor; **SWOC**, Standardized Walking Obstacle Course; **BAMS**, Basic Amputee Mobility Score; **CS-PFP10**, Continuous Scale Physical Functional Performance 10; **BBS**, Berg Balance Scale; **CB&M**, Community Balance and Mobility Scale; **LEMOCOT**, Lower-Extremity Motor Coordination Test; **NBWT**, Narrowing beam walking test.

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Paper III

Paper III

The following chapter contains a manuscript submitted in the Journal of Prosthetics and Orthotics: "*What a Knee Should Be: Perspectives of Highly Active Prosthetic Users*". The authors are Vigdís Vala Valgeirsdóttir, Ómar I. Jóhannesson, Ásgeir Alexandersson & Árni Kristjánsson. Formatting and table numbers of the submitted manuscript have been altered for continuity with the thesis on the whole. Any references to the chapter's content should be as follows:

Vigdís Vala Valgeirsdóttir, Ásgeir Alexandersson, Knut Lechler, Ómar I. Jóhannesson & Árni Kristjánsson (submitted). *Prosthetics and Orthotics International.*

5.15 Abstract

Background: In recent years, microprocessor-controlled knees have become available to people with lower-limb amputation. While they may be associated with greater economic benefits and improved clinical outcomes when compared with non-microprocessor-controlled knees, some individuals discontinue use or do not utilize all the functions they provide. Better understanding of how the relationship between human factors and prosthetic function influences peoples' experience is needed to make microprocessor-controlled knees and their functions more accessible to users.

Objectives: To explore the prosthetic history of highly active individuals with transfemoral amputation, identify factors important for prosthetic satisfaction, use and acceptance as well as opportunities in advanced prosthetic development.

Study Design: Qualitative study design.

Methods: Semi-structured interviews were conducted with 5 highly active people with transfemoral amputation who have microprocessor-controlled knees.

Results: We identified several factors important for prosthetic satisfaction and use; 1) Feeling in control of prosthesis; 2) Consistent Prosthesis; 3) Intuitive Prosthesis; 4) Feeling unrestricted by prosthesis; 5) Spontaneity; 6) Easy to walk and change speed; 7) Noise; 8) Easy to trigger and transition between modes; 9) Individually relevant modes; 10) Harmonious function with ankle; 11) Shock absorption; 12) Waterproof; 13) Appearance; 14) Weight.

Conclusions: Fostering trust through consistent and intuitive functions that can be used during various activities is perceived as highly important for satisfaction with prosthetic devices. Furthermore, expected long-term benefits associated with advanced devices are, alone, not sufficient motivation for their use. More intuitive triggering methods coupled with active assistance are necessary to make advanced solutions and their functions more accessible and beneficial. Finally, a multitude of individual characteristics and needs influence use and acceptance, highlighting the necessity of taking human factors into account in prosthetics.

5.16 Introduction

In recent years, increasingly sophisticated prosthetic solutions have become available to people with transfemoral lower limb amputation (TFAs). Nevertheless, prosthetic function has yet to fully match that of a healthy neuromuscular system, affecting both physical- and psychological function and well-being.[1–9] Providing people with appropriate prostheses is integral to their rehabilitation following major limb loss and reducing the limitations[10] caused by the amputation. Non-microprocessor-controlled knees (NMPKs) have been the standard of care for people with TFA, although microprocessor-controlled knees (MPKs) with integrated sensors that adapt to the environment have become available in the past two decades. MPKs may provide users with greater clinical benefits than NMPKs; reports indicate improvements in walking speed,[11–13] obstacle negotiation,[14–16] ambulation on uneven terrain[12] and satisfaction[17] as well as reductions in energy expenditure,[16,18–20] abnormalities during gait[21] and frequency of falls.[22] Most MPKs are passive (P-MPK) and do not actively generate power to restore lost muscle function in adaptation to gait or the environment. The user must therefore compensate for this lack of muscle function. Active MPKs (A-MPKs) can address this limitation and assist the user by generating motion with a motor, potentially improving gait abnormalities even further than P-MPKs.[23]

Despite the benefits MPKs may offer, financial reimbursement is often difficult to obtain due to their high cost. However, recent evidence suggests that the economic benefits of MPKs are at least equivalent, if not greater, than NMPKs[24] and may encourage prosthetic use[25] which can promote quality of life.[14,15,25–32] Nevertheless, some individuals may discontinue use due to the weight and high maintenance requirements associated with MPKs[33] while others do not fully utilize the functions due to unintuitive triggering methods, cognitive demands and the physical exertion they require.[34] Harmonious matching of user needs and the properties of the prosthesis requires greater understanding of how device functionality influences satisfaction, acceptance, and use. Individual needs and preferences vary depending on peoples' experience, lifestyles, clinical- and psychosocial factors, and as such, qualitative research can provide valuable insights into considerations for future design. We conducted semi-structured interviews with highly active MPK users to explore their prosthetic history, needs and use, as well as their first responses to an A-MPK after very brief exposure. The goal was to identify factors important for the acceptance of MPKs and opportunities for advanced prosthetic development.

5.17 Methods

5.17.1 Participants

Five males with unilateral transfemoral lower limb amputation classified as K3-4 according to the Medicare Functional Classification Levels (MFCL)[35] participated in the study. Their average age and weight were 51 years (range: 19-52) and 73kg (range: 63-79). They were all daily users of P-MPKs and non-microprocessor-controlled ankles (NMPAs). Three participants had previously used an A-MPK as their main prosthesis for several months or more, while two received a brief introduction to an A-MPK two weeks prior to testing. All participants had a good understanding of terminology regarding prosthetic components and gait.

5.17.2 Procedure

All experimental procedures were approved by the National Bioethics committee, Iceland, and conformed to the Declaration of Helsinki for testing human participant. Participants were recruited through prosthetic clinics in Europe and signed an informed consent form. After a short acclimation period (1.5 days) centered around level-ground walking each with a novel A-MPK unit in both laboratory- and community settings with researchers present, as well as during the evening at home by themselves, a semi-structured interview was conducted by a PhD student in psychology. An interpreter was present to facilitate the interview when necessary. The interview was not intended to predominantly address responses to the new A-MPK unit, but to explore participants' history with different MPKs in general, as they had extensive experience with various prosthetic components. Therefore, while interconnected, the walking tests and interview can be regarded as distinct facets of the same study. Here, only the results of the interview will be reported. The script followed the same structure for each participant while further information on individually relevant topics was pursued. Interview content, described in Table 10, was defined based on previous literature findings.[34]

Table 10. Interview Structure & Content.

Category	Theme	Topics
Daily Life	Daily use and requirements	Daily routine, occupation, hobbies, effort/enjoyment during activities, situational avoidance.
Current Prosthesis	Attitudes towards prosthesis	Knee & ankle unit, additional prostheses, trust, safety, satisfaction, intuitiveness, downsides/improvements, functions/modes.
Previous prostheses	Experience with prosthetic components	Previous daily components, NMPK, A-MPK, N-NPA and MPA experience, transitioning between prostheses, satisfaction, downsides, extent of experience.
Learning & Training	Enthusiasm and motivation for new experiences Learning to use new prostheses	Attitudes to new experiences, technology, and prostheses. Length of acclimation periods, intuitiveness, risk tolerance.
Properties of Components	Relevance to the user	Weight, charging, aesthetics, cosmesis, volume.
Connection to Prosthesis	Integration of self and prosthesis	Donning/doffing, perception of prosthesis as body part/tool, concealment or display of prosthesis.
Opinions on A-MPK unit	Attitudes towards new unit after very short acclimation period	Intuitiveness, safety, ability to perform/enjoy activities, daily life relevance.

5.17.3 Analysis

Audio was recorded during each interview and later transcribed. In some instances, the participants demonstrated activities recorded on video instead of relying solely on verbal explanation. The transcripts were later reviewed, and salient themes identified. Some themes were predetermined in the script, while others were identified a posteriori. A code was appointed to each data point based on environmental- and human factors, activities, prosthetic components and function. Additional codes, such as “spontaneity” and “feelings of restriction” discussed in the results section, were created from reoccurring ideas and words which were then used to create meaningful clusters arranged by relation based on researcher interpretation. The data points and clusters were then appointed additional codes based on their association with high-level International Classification of Functioning, Disability and Health (ICF) categories[10] to provide a common language. In the results section, translated, altered, and substituted wording is represented by [square brackets], interpreter statements and researcher notes by {curly brackets} and direct quotes by “quotation marks”. Words and sentences consciously omitted are additionally denoted by […]. Participant IDs, P1-P5, are presented within (brackets). Finally, ICF category relations are presented in italics within (*brackets*).

5.18 Results

An overview of the results is presented in Table 11, followed by a more detailed account that reflects its content.

Table 11. Important factors, selected into International Classification of Functioning (World Health Organization, 2001), Disability and Health (ICF) categories and considerations for device satisfaction of highly active MPK users.

Important factors	**ICF Categories**	**Considerations**
Feeling in control of prosthesis	Activity	Necessity of behavioral adjustments to the MPK negatively perceived despite them becoming automated. Examples include altering gait to trigger stair mode or avoiding sitting in chairs of a certain height.
Consistent prosthesis	Activity	Establishes trust which is integral to acceptance and use.
Intuitive prosthesis	Activity	Short training period and “natural” function fosters satisfaction.
Feeling unrestricted by prosthesis	Activity	Safety features must minimize feelings of restriction.
Spontaneity	Participation	Being able to use the prosthesis in multiple scenarios, regardless of their specificity, fosters satisfaction. Preference for NMPAs due to flexibility.
Easy to walk and change speed	Activity	Low energy expenditure and - cognitive requirements increase satisfaction.

Noise	Participation	Can be annoying. Should not attract attention in social scenarios. Sometimes beneficial as sensory feedback to increase confidence.
Easy to trigger and transition between modes	Activity	Modes will not be used if they are unintuitive, or the activity is physically difficult once triggered. Stair ascension and standing/sitting a priority.
Individually relevant modes	Body Functions	One specific mode may be a deciding factor for the user.
Harmonious function with ankle	Activity	Ankle can limit abilities during activities despite increased knee function. E.g. lack of ankle adjustability while standing up.
Shock absorption	Body Functions	Less strain on the body increases comfort and satisfaction.
Waterproof	Activity	Possible to submerge in water and withstand dirt and sand without damage. Fosters spontaneity.
Appearance of prosthesis	Participation	Important that it does not require a cosmetic cover to look “good” or cause any embarrassment and does not mimic “natural” aesthetics.
Individually appropriate volume	Participation	Volume matches the shape of the intact limb without being in the way.
Weight	Activity	Can be perceived as beneficial or hindering depending on the individual. Suspension, residual limb, and height relevant.

Participants all expressed high satisfaction levels with their current P-MPK, primarily due to feelings of safety, trust, consistency, and control over their prosthesis.

> "[…] I am not aware of having a [disability]. I just do not have to think. It just does not get in my way. It can […] be intuitive like […] with two legs. […] I do not have to worry about where it is, it is just going to be safe, it is going to be there for me." (P3)

> [The [P-MPK] is my first choice as I always feel 100% in control. There is never any hesitation or a weird activity I find myself in. And if there is anything, then I am very aware of how to respond to that.] (P2)

Those who had previously used an A-MPK daily, reported the perceived level of control over that knee as one of the greatest differences compared to their current P-MPK. Despite gradually adjusting to the previous A-MPK, they felt it still required more effort to use than their P-MPK. However, when comparing the new unit with their previous A-MPK, two users reported increased levels of control and confidence.

> „The [P-MPK] follows you but you have to follow the [old A-MPK]. With experience I do not really feel that anymore [with the old A-MPK.] If I find out what it is doing, I can work with it. […] But my [P-MPK] is very reliable [....] It is going to support you no matter what you do. And it is not going to do anything on its own." (P3)

> [I felt that the previous [A-MPK] knee controlled me. If I [did] not step correctly or [did not do] the right things, the knee [did] not respond. So, I [needed] to adapt to the knee's routine for it to complete the correct actions, which is a very uncomfortable feeling. […] It [was] not natural.] (P2)

> [The [new A-MPK] is a lot more similar and almost completely the same as my preferred P-MPK, except it is motorized. It responds to everything I do.] (P2)

Levels of trust in participants' current knees varied under certain circumstances; Some reported a strong need to rely on quick reflexes and their sound side in response to environmental causes of instability while others utilize their prosthesis to a higher degree when preventing a loss of balance.

> {He would rather jump a little to make a safe step with the sound side} (P1)

> "[My P-MPK] has never let me down, to the point where I put weight on it and it […] buckled underneath me. It might let me down the other way, where I want it to bend and it stiffens up. But never in a dangerous way. So, I have never […] mistrusted that." (P3)

While safety functions contributed to satisfaction, they were also associated with feelings of restriction after reaching a certain level.

> "More safety is more limitation [so I don't want my knee to be safer than it already is.]" (P1)

> "This safety thing [in general is] very nice, and I understand that in most people's eyes it is like wearing a cycling helmet. […] I would never wear a cycling helmet because it would put me off. […] Maybe when it is 100% safe it is not quite as good" (P3)

5.18.1 Learning how to trust

Building trust was regarded as the most important aspect for becoming a fluent user and reap maximum benefits from a new prosthesis. Feelings of familiarity can promote trust while early mishaps can lead to anxiety that takes time to overcome.

> „[They] explained how fast the processor was, how the [knee] works, and I remember thinking, I [have] nothing to worry about. And then I started doing things like walking down the stairs without holding the rails because I knew I could trust it." (P3)

> [I felt so much more secure when I switched from a NMPK to a P-MPK because its breaks could support me and then I felt like I could walk unhindered.] (P2)

> "I think [the new A-MPK] is a little bit safer [than the previous A-MPK]. Part of it is [maybe] because I walked on [the old A-MPK] before. If I had not walked on it before, maybe I would be a bit

like ‘woah, it has a motor, it does its own thing every now and then.’ Whereas now it is like ‘oh yeah, it does that sometimes and it does this.’ But in my experience, […] it might not always do exactly what you expect it to do, but it is always going to work on the safe side rather than the unsafe side. So, I am never scared that I am going to fall over.” (P3)

“[The new A-MPK collapsed] five […] or six times [when I was taking my first steps with it]. And then you walk for 10 minutes and [the unease] does not disappear. You always have a little [anxiety.]” (P1)

Previous prosthetic experience can hamper adaptation due to habits not easily discarded. While such habits might be appropriate for NMPKs, they can prevent the user from experiencing some of the benefits provided by MPKs.

[I truly believe that people should get an MPK as their first knee so they can trust it and benefit from it as much as possible.] (P2)

[It is sometimes easier said than done to un-learn behavior that becomes obstructive when using an MPK, especially if you have experienced a fall with a mechanical knee. You do not want it to happen again. It is extremely difficult even though you have a knee that is supposed to prevent you from falling, because you do not want to fall.] (P2)

“Mechanical knees […] are a compromise for me. It is a beautiful piece of engineering. Fantastic. But it is a folding chair. It is a chair, and you can sit on it here, do not sit on it back there, do not try standing up on it and [using] it for something different, it is going to flap together. You have to be aware that this is a foldable [chair]. And it is not what you should have. It is just a cheap, easy solution before we had microprocessors.” (P3)

5.18.2 Modes & functions

All participants highlighted the importance of effortless and intuitive walking.

> “Just walking. That should be intuitive. I should be amputated, [receive] the knee, and kind of use what I already know to walk. And you can with this [P-MPK.]” (P3)

> “In the hotel last night, at one point I was just walking around and [thought] ‘okay, yeah, I am on the new A-MPK’. That would not have happened [with my old A-MPK where I would have thought] ‘okay, I am on the A-MPK so I have got to be aware of this, and I have got to be aware of that.’ I did not even think about it [with the new A-MPK.]” (P3)

> “I was willing to [train a lot] with the [previous A-MPK]. You really had to get into it. You could not just put it on […]. You [had] slightly more options [than with a P-MPK] which means you [had] to be more aware of where your body [was] so you would react in this way rather than that way. And it was frustrating at times.” (P3)

Different functions and support provided by MPKs and ankles during activities further affected user satisfaction. One example includes yielding, or the provision of limited initial knee flexion and resistance during stance which can assist people during walking, sitting down and navigating stairs.

> “When I walk with the [new A-MPK] I walk with the yielding I think 'oh yielding, this is nice'. With [my P-MPK] you do not use [it], it is not so easy. But with the [new A-MPK] it is so easy; You walk normally.” (P1)

> “[You create] shock absorption by having a little bit of flexion [in the knee] when you [place your foot on the ground]. It is quite nice [on my P-MPK], but on the [A-MPK] you just land on it, you do not have to time it, it locks and then it has got a little spring. […] I feel flexible.” (P3)

> “The [A-MPK] has a restrictor so it will always let you bend it and it will only let you bend it a certain amount and you know that you are not going to go too far over it or too little under it […] I

> like that, and I feel less shock in my body. Like a heel strike can feel [like a shock up] the whole body with [my P-MPK.]" (P3)

> "The only thing I do not like about prosthetics is that they are very dead. When the foot is flat on the floor [it is] dead [as opposed to bouncy when the heel or toe are on the floor.] That is when I feel mechanical and […] I cannot do my own little knee movement and bounce." (P3)

> „The NMPA suits me best due to the activities I partake in. I can jog [and] lift weights. The main idea is that there is a little bit of a rotation in the ankle. I use it when I play golf." (P2)

Energy expenditure was regarded as an important factor when users compared devices that they had previous experience with. Active motion was not only perceived as assistive, but also preventive for negative events such as tripping and falling.

> [The new A-MPK makes long walks much easier. It helps me during each step I take. I do not need to spend as much energy. In the long run, for level-ground walking, it is better than the P-MPK. But I am not walking enough on level ground that I need it. I can easily do that with a P-MPK. But if I have been walking for a long time […] I spend less energy.] (P2)

> "[My P-MPK is] more comfortable [than the NMPK]. It [is] easier for me to [walk] I [do not] need as much [energy] as before." (P4)

> "I really hate walking up hills, it gets so tiring. And I have just recently moved to somewhere with a lot of hills. So, I am excited about doing that [with the new A-MPK]. Going for a walk with my dog in different terrains and not worrying about it. [My dog] loves going down on the beach, but it is normally me who goes back before she wants to because I am just tired. And walking uphill in sand, it is just a nightmare. But the A-MPK […] plows through snow, grass, sand. [That takes] less energy, [..] I am going to feel that [with an A-MPK.]" (P3)

> {If he catches his toe in the woods, on a [branch] for example, he will fall either way with NMPKs and P-MPKs, but not with an A-MPK. That is why he does not feel safer [in some situations]

with his MPK than the NMPK he had before. But with the A-MPK he could feel if there was something [blocking] his foot that it would be kicked away or broken so he would not fall.} (P1)

Many MPK modes and functions the participants mentioned positively were related to spontaneity and relevance to their personal needs. The inclusion of a highly relevant function can be a make-or-break factor in preferences for one knee over another, even if there are other discernible functional differences between them.

> "The first problem is [I go on and off a bicycle a lot during the day]. And with the [A-MPK] it is not so easy. That is the first point [in why I would not use it], a big point." (P1)

> {He really likes that he can walk slowly and suddenly change the speed. If you must run for the bus for example.} (P5)

> "One of the things I like about [my P-MPK] is that you have to put it on and then you have to teach [it] who you are. And I like that I [cannot] take that off and put on someone else's ... It is my leg, it is programmed to me […] It is not just some technician that has done [it, the knee] has decided [the settings based on my walking.] It is me, not just a plastic thing on the end of my body. It is not just a prosthesis; it is my leg." (P3)

> {He likes being able to stand in a slope with a slightly bent knee, and if you stay like that for a certain time, it locks in that angle, even if he is doing exercises, which he likes.} (P5)

> {You could freeze his previous A-MPK in a slightly kneeled position. You could wash your hands, for example, without overloading the sound side. You could use the prosthetic leg, but with his P-MPK, it would just collapse.} (P1)

Despite frequently using other modes provided by their respective P-MPKs, none of the participants use stair ascension mode daily, regardless of their ability to do so. The bother of triggering coupled with a lack of assistance from the knee were regarded as the main contributing factors. Triggering can, for instance, require people to stop for a moment and produce a kicking motion with their prosthesis for mode activation. Participants saw the value of active motion although they stressed that they could compensate by taking alternate routes when possible or rely on the sound side.

> „I am never going to ever [trigger the stair mode with my P-MPK for one flight], because I have to stop and go ‘yes, you are [disabled], and now up you go ‘ rather than just get on with it [...] Maybe if I‘m at the Sacré-Cœur in France, and I want to do all those stairs, you know, lots of stairs. Then I would use it. But the minute I am holding something, it just [is not] practical.” (P3)

> {Triggering the stair function is annoying, so if it is only five steps to ascend, he would just jump up, but if it is one level of a building, he would rather take the elevator} (P1)

> {He is able to, and if he wants to, he can walk upstairs in an alternating manner with his P-MPK, but it is not the way you will do it normally because it is physically exhausting} (P5)

> [It is incredibly nice to walk upstairs with the new A-MPK. It is easy to trigger it, to stop in the middle of a step and then continue, which was difficult with the previous A-MPK.] (P2)

> “As amputees with the physios, they tell us 'okay, you stand like this, evenly, and then you clench your buttocks together' and I don‘t know what... And then you symmetrically go down and yield on the knee and da-da-da-da […] So it came into my mind, why not just completely protect the [intact] knee and just land on [the P-MPK.]” (P3)

People have varying levels of tolerance for the effort required to adapt to a prosthesis and utilize its functions.

> “I think it is okay to expect a certain level of investment if you want to be really good at it. But the basic functions of just walking [should be intuitive. But] if I wanted to run, if I wanted to be good at walking upstairs, if I wanted to do, whatever it was… Fair enough, then I need to work a little bit and have some instructions and training.” (P3)

> [At times I have opted for a knee that is easy to use rather than an unintuitive one with more functionality. But if there are

enough aspects that indicate it can improve my daily life, I will put in the effort.] (P2)

"[If I need to spend] one week [in intensive training to learn how to use a prosthesis], I must [be able to] fly and do everything [or it will not be worth it]." (P1)

Potential long-term benefits are not always sufficient motivation to adapt to a new device with increased functionality, especially if people are already satisfied and can compensate well physically.

{The active assistance makes it reasonable to change to a heavier, bulkier knee, but he says he would not want to switch from his P-MPK at the moment, because he is young and athletic and other knees provide what he needs. It might maybe be nice to have the support function when he is older, but if you ask him now, he will not choose it.} (P5)

"Let's say for example they told me: 'Now we have brought out a new knee and it's only [slightly different] but we know that if you use this, then in 10 years' time you're 50% less likely to get knee arthrosis I would think: 'Okay, well, maybe that is something I should be aware of now that I'm getting older'. I would not have thought that 10 years ago." (P3)

5.18.3 Other characteristics

While aesthetics ranked low on the list of participants' priorities, all expressed a preference for a "cool looking" prosthesis with a robotic- as opposed to "natural looking" appearance. However, it was important to them that when wearing trousers, the shape should match the intact limb without needing a cosmetic cover which emulates "natural" shape and appearance of the leg.

"I [do not] want people to [think] that I am something that I am not, [I have a prosthetic leg.] It has to look right. Because [it is] a part of my identity." (P3)

"[It] has to be cool. Because I do not wear cosmetic [covers] and I wear shorts in the summer […] I have […] small kids and they like [how my prosthesis looks.]" (P4)

{Artificial hair on a prosthesis would be the worst case.} (P1)

The noise accompanied by A-MPKs bothered some more than others, especially in social scenarios when wanting to avoid attention.

> “[I can see additional benefits in] something like [the A-MPK], then I can walk upstairs, but not with the noise. [My P-MPK is] perfect for me. I have all the functions I need. If I would have [health] problems [later where I needed assistance], the noise would not disturb [me.]” (P4)

> “[The noise provides] a little bit of security and I have gotten used to that, [I] have an audio signal and I know exactly where the leg is […] I would not want the [A-MPK] to be noisier, and there are certain situations where it would be a little bit [awkward as it is now]. In the middle of a lecture at the university or when you want to go to the toilet in the cinema, then you are conscious of it. Otherwise, people [think] 'who is that, what is that?' “(P3)

Volume and weight needed to be within a reasonable range for every participant, although perspectives differed depending on the individual and MPK in question. Some only found their MPKs weight noticeable when charging them, although none complained about the need to charge and found it comparable to charging their phones at night.

> {His P-MPK is heavy, he would like that improved.} (P5)

> {When he has the A-MPK on, then he does not feel the weight so much.} (P5)

> And I like the fact that [the new A-MPK is] still a bit heavy. [...] Because I am [tall] right? [When I had a microprocessor-controlled ankle], in the beginning I felt [the weight] but after a while I actually liked [it] because, for me, it gives a good pendulum effect. I have very long legs, so it is not difficult. I do find it slightly more challenging to walk a long distance fast because then I am having to work with the swing a bit and control that swing, a bit more... But otherwise, just normal everyday walking, I do not notice that.” (P3)

> “I do not feel [the weight of the new A-MPK] so much during walking. But [it could maybe] be a problem for longer walks [due to the weight of it when I swing my leg.]” (P4)

5.19 Discussion

Human factors are a very important consideration when it comes to making microprocessor-controlled knees (MPKs) and their functions accessible to people with transfemoral amputation (TFAs). Here we explored factors in human-machine interaction that may influence satisfaction, use and acceptance of MPKs, for both active (A-MPKs) and passive (P-MPK) knees. Although they are based on feedback from highly active individuals, our results can partially be applied to lower active TFAs; if highly active individuals find something challenging, it is probable that those less active will too, and likely even more so. Nevertheless, some challenges are unique to those with lower activity levels.

Satisfaction with MPKs was mainly associated with trust, perceived control over the prosthesis, feeling unrestricted by the prosthesis and being able to spontaneously partake in activities with the knee's support. While participants reported satisfaction with several functions, such as stair and incline descension, their feedback evoked several considerations; MPK functions must not only be made more accessible with more intuitive triggering methods but also that some P-MPK functions will not provide optimal benefits without the assistive power that A-MPKs can provide. Examples include stair ascension and transitioning between sitting and standing, although highly active users can compensate to some extent with physical abilities and altered behavior. The expected long-term benefits of active motion do not necessarily provide sufficient motivation for healthy and already satisfied P-MPK users to switch to an A-MPK. People adjust their expectations of MPKs to what they know is available and their own prosthetic history. If they have already adjusted their behavior to achieve their goals, they might not find it worth the effort to adapt to a new prosthesis unless it is likely to have significant benefits relevant for their daily lives. For instance, someone who seldomly hikes or finds them boring is less likely than those who frequently find themselves in challenging terrains, to invest in adaptation to an A-MPK if it requires time and effort to learn how to use it. Furthermore, those who frequently use a specific MPK function because of personal needs will not want a prosthesis without it, regardless of other potential benefits it could provide. In addition to training demands, prosthetic characteristics such as weight, noise and volume can affect satisfaction and MPK acceptance. Finally, high tech and sleek aesthetics can positively affect social interactions and self-image.

5.19.1 Limitations

While our study provides insight into users' MPK experiences, its qualitative nature limits generalizability, including for less active individuals, females, people with bilateral amputation, residual limb- or socket issues and NMPK users. Only one researcher was present during the interviews due to Covid-19 restrictions and the sample size was small. In addition to potential interviewer biases, in some instances, information might have been lost in translation or biased by interpreter characteristics.

5.20 Conclusions

We found that consistent and intuitive functions that allow people to spontaneously partake in daily activities are perceived as the greatest source of satisfaction in highly active K3-4 MPK users. Our results further indicate that acceptance of microprocessor-controlled knees is highly dependent on individual characteristics and needs, highlighting the necessity of taking human factors into account.

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Appendix I

*** The following is an English translation of the interview guide in Paper I

Daily life	
☐	What‘s a day in your life like? When do you don your prosthesis? Do you start your day before donning it?
	Probe keywords 1. Family life 2. Occupation
☐	What do you do in your spare time (e.g., weekends)? Do you do anything differently than during weekdays?
	Probe keywords 1. Hobbies

Mobility	
☐	As a person with a prosthesis, what do you feel matters the most for your mobility?
	Probe questions 1. Do you feel that having a prosthesis impacts you in any way? 2. What challenges do you face as a person with a prosthesis? 3. What does having a good day mean to you? 4. What does it mean for you to have a bad day? 5. What aspects of your life are impacted by your prosthesis? 6. Do you avoid any situations because of your prosthesis? 7. Do you think you do some things differently because of your prosthesis? 8. What changes when you switch between prostheses? 9. Are there any activities that you did before your amputation that you don‘t do today?

Pain	
☐	Do you experience any pain in your daily life?
	Probe keywords 1. Residual limb 2. Contralateral limb 3. Back 4. Muscle aches 5. Other…
☐	What do you think causes the pain? (If any)
	Probe keywords 1. Different scenarios 2. Prosthesis

Positions and spaces	
☐	How do you fare in general when bending down? What about when you need to lift something heavy? What about reaching to the sides? What about reaching high up?
	Examples of activities 1. Grabbing something from the back of the lowest cupboard in the kitchen? 2. Grabbing a cup from the coffee machine with a lot of people around you? 3. What about getting something from the highest kitchen cupboard? 4. If someone else is in the room, do you ask for help with such tasks?

Activities

*** To facilitate common understanding, participants were presented with images of people in certain positions and scenarios. Only the questions are presented in this appendix.

How easy or difficult do you find…

Lifting heavy objects?

Can't do it |——————————| No problem at all

How important is it for you to do so?

Not at all important |——————————| Very important

Squat down?

Can't do it |——————————| No problem at all

How important is it for you to do so?

Not at all important |——————————| Very important

Squat very far down?

Can't do it | | No problem at all

How important is it for you to do so?

Not at all important | | Very important

Crouching with both knees on ground?

Can't do it | | No problem at all

How important is it for you to do so?

Not at all important | | Very important

Crouching with right knee on ground?

Can't do it | | No problem at all

How important is it for you to do so?

Not at all important |———————| Very important

Crouching with left knee on ground?

Can't do it |———————| No problem at all

How important is it for you to do so?

Not at all important |———————| Very important

Crawling?

Can't do it |———————| No problem at all

How important is it for you to do so?

Not at all important |———————| Very important

How do you do in the following situations?

Airplane

Can't do it ——————————— No problem at all

Working on ground level (e.g., gardening)

Can't do it ——————————— No problem at all

Narrow restaurant booths

Can't do it ——————————— No problem at all

Crowded supermarket

Can't do it ——————————— No problem at all

If no experience with intent control

☐ Would you like to be able to control your prosthesis yourself?
Are there any scenarios where you would like to control functions yourself?

How important is it to you?

Not important at all	Rather unimportant	Neihter/ nor	Rather important	Very important

☐ If you could control the mode your prosthesis is in, do you think it could be useful?
What about annoying?

In what scenarios?

☐ What about a function that would only be used for plantarflexion or dorsiflexion?

☐ Do you think you would be willing to try such control?

Do you think you would trust your prosthesis more or less than you do now?

A lot less	Less	The same	More	A lot more

☐ How would you feel about being able to control your prosthesis with an app?

☐ Does your proshtesis ever do something it is not supposed to do?

How often?

Never	Rarely	Sometimes	Often	Very often

In what scenarios?
How does that affect you?

If experienced with intent control

☐ In what scenarios was the control most useful?

☐ What are it‘s greatest benefits?

☐ What are it‘s greatest downsides?

☐ If you could change how you controlled the prosthesis, what would you change?

☐ How mentally draining is using the control?

Not draining at all	A little draining	Fairly draining	Very draining

☐ How physically draining is using the control?

Not draining at all	A little draining	Fairly draining	Very draining

☐ Did the control allow you to do something you can‘t do without it?

☐ How difficult or easy is it to multitask with the control?

Very difficult	Rather difficult	Rather easy	Very easy

☐ Do you trust your prosthesis more or less when you have the control?

A lot less than before	Less than before	Same as before	More than before	A lot more than before

		Feedback
☐		Are you ever uncertain what you prosthesis is doing, where it is or what position it is in? Do you think it is important to know?
☐		Do you ever need to focus and look at your prosthesis to know what it is doing or where it is? What about when you are carrying something and can't look down?
☐		If you could choose to receive information from your prosthesis, do you think it would be useful to know: 1. What position it is in 2. Whether you are using it "correctly" 3. Whether you are using it "incorrectly" 4. How much weight you are placing on it 5. When your heel touches the ground 6. How high the toe is raised from the ground 7. Battery almost depleted

Appendix II

The following is an english translation of the interview guide used with expert participants in Paper I.

Focus group with engineers

1. What are the main users problems that we're focusing on?
2. Any problems that you'd like to be focusing on?
3. What are the main changes/development that will happen in the prosthetic industry the next year, 3 years, 5 years, 10 years?
4. Is there anything you'd want to look at during a contextual inquiry?

Focus groups with health care professionals

1. What are the difficult things your users deal with?
2. If you think about a microprocessor controlled knee and ankle (doesn't matter where it comes from) what would you say are their biggest drawbacks/problems and their biggest advantages?
3. When people loose their limb what is it that they're missing most or the biggest issues they see?
4. What are your thoughts on intent control and the technology?

Topics with individual experts

1. What are the main problems people with LLA face?
2. What factors weight the most during prescription for people of different activity levels?
3. What is the level of customization for people's prostheses?
4. How common are secondary prostheses?
5. What matters the most for reimbursement?
6. How are these factors evaluated?
7. What are the main challenges in evaluation?
8. What are your thoughts on intent control?
9. What about sensory feedback?

Aesthetics	
☐	Have you ever opted for a prosthesis because of how it looks? Even if it has less functionality than you are used to? How often?
☐	Would you ever sacrifice function for apperance
☐	If you could change one thing about the appearance of your prosthesis, what would it be?

Bathing and the beach	
☐	Do you prefer bathtubs or a showers?
☐	Do you have a shower leg?
☐	How often do you bathe/shower outside your home?
☐	Do you ever go to the pool?
☐	Do you ever go to the beach?

Heat and sweat	
☐	Does sweating affect you?
	Probe questions 1. When? 2. How do you deal with it?
☐	Does the prosthesis ever slip when you sweat? (If yes) In what scenarios?

Cold weather	
☐	How do you react to icy weather? Why? What about snow-heavy days?
	Probe examples 1. Getting stuck in snow 2. Difficult aspects (if any)
☐	Do you feel any different than usual when it is very cold?

Appendix III

Daily life		
☐		What is your day-to-day life like?
		Probe keywords 1) Occupation 2) Spare time 3) Differences in activities before/after amputation 4) Mentally/physically draining activities

Prosthetic history		
☐		What kind of knee are you currently using What kinds have you used before?
		Probe keywords 1) Current/previous ankles 2) Other prostheses (e.g., shower/running leg) 3) Switching between previous and current device 4) Training to use current device 5) Intuitiveness (need for thought)
☐		How satisfied are you with your current system? Are there any downsides or issues you can think of?
		Probe keywords 1) If difficult for participant, ask to name three things for each question
☐		Do you trust your prosthesis to maintain balance and catch you if you trip? Are there any particular scenarios that you do not?
		Probe keywords 1) Falling/tripping/balance with different knees
☐		Is there a function (of the knee) you like in particular?
		Probe keywords 1) Unused functions 2) Using a function vs. other means to achieve goals 3) Different functions
☐		Do you think some knees require more mental or physical effort to use?

		Probe keywords 1) Previous knees the participant has used

ONLY IF experience with powered knee and has not come up naturally		
☐		Have you tried a powered knee before?
		Probe keywords 1) When 2) Duration of use 3) Positive and negative aspects 4) Learning how to use 5) Noise 6) Weight 7) Bulk 8) Appearance 9) Motion 10) Intuitiveness 11) Other _____

Openness to experience		
☐		Generally speaking, how open are you to trying new things?
☐		Are you interested in new technology in general?
☐		How open are you to trying new prosthetic components?
☐		What influences your enthusiasm or lack thereof?
☐		Have you been dissapointed by prostheses you have tried/used before?
☐		Prope keywords 1) Do you think that influences your willingness to try new components?

Training		
☐		Does the length of a training program factor into your prosthetic preferences? What about a physically demanding program?
☐		Probe keywords 1) Falling/tripping during training 2) Training with complex vs. easy to use devices

Prosthetic characteristics		
☐		Have you ever chosen to use a smaller/lighter prostheses rather than a bulkier one (even though it had less functionality)?
☐		Do you mind having to charge your prosthesis?
☐		How much does noise factor into your preferences for a prosthesis?
☐		Have you ever chosen to use a prostheses based on how it looks rather than based on functionality?
☐		Can you rank the following aspects from the most important to the least important? - Noise ____ - Weight ____ - Bulk ___ - Physical apperance ____ - "Natural" aesthetic ____ - Fludity/naturalness of motion (kinsethetic cosmesis) ___ Which one are you least likely to sacrifice for improved prosthetic function?

Body		
☐		When do you don your prosthesis? Do you remove at some point during the day?
☐		Do you feel like the prostheses is a part of your own body? Does that change throughout the day? Does it ever feel like a tool to you?
☐		Do you think the physical apperance of your prosthesis influences other people's opinions of it?
		Probe keywords 1) Motions 2) Noise 3) Hiding prosthesis

New knee		
☐		How do you feel about the knee after testing?
☐		Was it intuitive to use?
☐		Did it require a lot of thought to use?
☐		How safe did you feel using it?
☐		Do you think you would like to use it in your daily life? Why/-not?
☐		Do you think it would allow you to do something you couldn’t before?
☐		Do you think it would make any activities more or less easy/ enjoyable?