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# TOWARDS A HOLISTIC ASSESSMENT OF WALKING WITH LOWER LIMB PROSTHESES IN REALISTIC CONDITIONS

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DISSERTATION SUBMITTED 2023

AALBORG UNIVERSITY
DENMARK

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Dissertation submitted

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# CV

Sabina Manz was born in Ulm, Germany in 1994. In 2016, she obtained a B.Sc. in Sportsmedical Engineering from the University of Applied Sciences Koblenz. Afterward, she obtained an M.Sc. in Kinesiology with a specialization in Biomechanics from the University of Calgary, Canada, focusing on running patterns in different running shoe conditions. Sabina began her industrial doctoral studies in the Department of Health Science and Technology at Aalborg University and Ottobock SE & Co. KGaA (Germany) in 2020. Her research focuses on the development of novel assessment methods for lower-limb prosthetic devices to be used outside of a laboratory.

"FOR ME, BECOMING ISN’T ABOUT ARRIVING SOMEWHERE OR ACHIEVING A CERTAIN AIM. I SEE IT INSTEAD AS FORWARD MOTION, A MEANS OF EVOLVING, A WAY TO REACH CONTINUOUSLY TOWARD A BETTER SELF. THE JOURNEY DOESN'T END."

- MICHELLE OBAMA -

# ENGLISH SUMMARY


Lower limb amputation is often a life-saving procedure and a life-changing event at the same time. Prostheses can be a critical contributor to this journey with the goal to gain back functionality, personal health, participation in society, and quality of life. An initial assessment of the patient determines the rehabilitation potential using performance-based outcome measures, clinical judgment, and self-reported measures that take place in a laboratory environment or clinical setting. This classification determines the type of prosthetic devices that are suitable for the patients. However, it has been demonstrated that the lab-based assessment does not correlate well with the performance in daily-life applications or with the user experience. Furthermore, clinical assessments do not consider measures of cognitive load, which is, however, a critical index because it has been shown that the use of a prosthetic device is associated with increased cognitive demands.

The aim of the present project was to bridge this gap by developing methods that would allow assessing the prosthesis outside of the lab. Specifically, the thesis compiled a collection of user needs expressed by lower limb prosthetic users, explored the use of the sensors embedded into mechatronic prostheses for clinical gait assessment, and tested the feasibility of using a mobile eye tracker to estimate cognitive load during walking with a prosthesis. Embedded sensor data were compared with the outcomes of conventional clinical gait analyses to show the potential of these sensors to record gait kinematics and kinetics. Eye tracking data was recorded to estimate visual attention (gazing) as well as cognitive activity (pupillometry) and was compared to the subjective perception of cognitive load while performing different motor tasks. The studies have demonstrated that sensors embedded into a prosthesis can be used to estimate relevant amputee gait parameters, while gaze data from a mobile eye tracker correlates with the perception of cognitive load. Importantly, these conclusions were obtained by conducting a comprehensive assessment that included walking in realistic conditions over slopes, stairs, and rough terrain, both in and outside the lab. The results of these studies pave the way toward an assessment outside of a laboratory, as well as the opportunity to provide a holistic assessment including estimates of cognitive load associated with prosthesis usage.

# DANSK RESUME

Benamputation er ofte både en livreddende og livsændrende hændelse. Brugen af benproteser kan være en substantiel medvirken i at genetablere funktionalitet, personlig sundhed, deltagelse i samfundet og livskvalitet. Rehabiliteringspotentialet afgøres ved hjælp af en indledende vurdering bestående af klinisk bedømmelse, præstationsbaserede resultatmål og selvrapporterede oplysninger, der finder sted i et laboratoriemiljø eller kliniske omgivelser. Resultatet af denne vurdering bestemmer den type protese, der er egnet til patienten. Vurderinger foretaget i kontrollerede kliniske omgivelser viser sig dog ikke at samstemme med funktionsevnen i dagligdagsaktiviteter eller med selve brugeroplevelsen. Desuden tager kliniske vurderinger ikke højde for kognitiv belastning ved protesebrug, som dog er en ellers betydningsfuld målestok, da brugen af en protese er forbundet med øgede kognitive anstrengelser.

Formålet med dette Ph.d.-projekt var derfor at udvikle metoder til at vurdere proteseanvendelsen uden for kliniske omgivelser. Mere specifikt blev der samlet en række brugerbehov direkte fra brugere af benproteser, udforsket brugen af sensorer indlejret i mekatroniske proteser til klinisk vurdering af gang og testet effekten af at bruge en mobil eyetracker til at estimere kognitiv belastning under gang med protese. Data fra de indlejrede sensorer blev sammenlignet med resultater fra konventionelle kliniske ganganalyser for at vise sensorernes potentiale i at registrere gangkinematik og -kinetik. Data fra eyetrackeren blev optaget for at estimere synsmæssig fokus (stirren) såvel som kognitiv aktivitet (pupillometri) og blev sammenlignet med den subjektive opfattelse af kognitiv belastning under udførelse af forskellige motoriske opgaver. Undersøgelserne viste, at sensorer indlejret i protesen kunne bruges til at estimere relevante gangparametre hos den amputerede, mens synsdata fra en mobil eyetracker korrelerede med opfattelsen af kognitiv belastning. Væsentligt for disse konklusioner var, at de blev fundet gennem en omfattende vurdering, der omfattede gang under realistiske forhold over skråninger, på trapper og i ujævnt terræn, både i og uden for laboratoriemiljø. Undersøgelserne udarbejdet i Ph.d.-projektet baner vejen for en mere holistisk vurdering uden for kliniske omgivelser, der indbefatter estimering af kognitiv belastning forbundet med benprotesebrug.

# ACKNOWLEDGEMENTS

It has been quite a journey, both literally as a PhD student in Denmark while residing in Germany for most of the time, all amidst the challenges of Covid lockdowns; and personally, as I have grown tremendously as both a researcher and as an individual. This path, however, wouldn't have been possible without the generous help and encouragement from numerous colleagues, friends, and family members.

I would like to start by expressing my gratitude to my supervisors, Jose and Strahinja. They have been an invaluable source of knowledge, support, and guidance over these past years. It's worth noting that they not only provided me with crucial scientific assistance but also proved to be wonderful people to have around on a personal level. Their combined expertise, both in industry and academia, was the perfect blend of skills I could have hoped for.

To my colleagues at the Global Research Hub Duderstadt and the Ganglabor Göttingen, you've made my time there truly memorable. Despite much of my PhD journey being spent working from home, I always cherished the moments in the office and the lab because of the wonderful people there. I wouldn't trade the interactions with this group, both inside and outside of work.

I wasn't on this journey alone — I was part of an incredibly intelligent group of PhD students, the SimBionics crew. A special shoutout to Fede, who was not only an exceptional colleague but also became a close friend through online workouts during lockdowns, our travels for summer schools and conferences, and the time spent together in between. I look forward to our continued friendship in the years to come.

To all my HST colleagues (past and present) whom I get to call my friends, you played a vital role in this journey, not only in the office but also in the many activities beyond work. You made my brief time in Aalborg even more special, perhaps even making it pass by a bit too quickly in the end. 😊

A heartfelt thanks goes out to those who have stood by me the longest: my family. You know me best, always having the right words of encouragement when things aren't going smoothly. You believe in me, even when I doubt myself. Completing this degree with your unwavering support means everything to me. Achieving this milestone fills me with immense pride, and I couldn't have done it without you. Danke schön!

Finally, I extend my thanks to all those who generously participated in my experiments, bringing this research project to life.

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# CHAPTER 1. INTRODUCTION

## 1.1. EFFECTS OF LOWER LIMB AMPUTATION & USER NEEDS

Lower limb amputation is a life-changing event for those that are affected by it [1–3]. After the amputation, the ultimate goal is to gain back quality of life to the level prior to the amputation [3–6]. Quality of life, however, is multifaceted and so are the effects resulting from an amputation.

Lower limb prosthetic users suffer from changes in balance or gait control [7–13], which can lead to an increase in metabolic energy consumption during gait [14–16]. Long-term effects of lower limb amputation can be low-back pain [17], osteoporosis and osteoarthritis [18]. But also, less obvious effects such as anxiety or depression [19–22], low self-esteem and frustration [23] can result from an amputation and the loss of independence. These psychological effects go hand in hand with a disturbed body image and fear of pain [24–28]. Furthermore, prosthetic users are at higher risk of falling compared to the general public and experience fear of falling because of the need to concentrate on every step they take [29, 30]. This risk can be partially attributed to the loss of somatosensory feedback and reduced lower-limb muscle strength, which leads to the inability to perform rapid gait adjustments to prevent falling [31–34]. As a result, people with lower limb loss report that they need to concentrate more on each step they take [35, 36], requiring additional processing capacities in the brain which are limited. This has been in return associated with an increased fear of falling in people with lower limb amputation [29] and the reduced ability to multitask [37]. Lastly, participation in leisure time activities and social interactions are reported to change or decrease after an amputation [38].

These detrimental effects are well reported in the literature, however, there is no comprehensive report on the actual requirements for prosthetic devices from the point of view of the users. These collections exist for upper limb amputees [39] and for subgroups of lower limb amputees focusing on certain amputation etiology [40] or certain aspects of everyday life (e.g., functional, psychological, etc.) [41–45]. Because every prosthetic user is different and can be described by age, etiology, social circumstances, functionality, and many other factors, there is a wide variability in this population. Each user has to be treated as an individual with individual needs. In order for a prosthetic device to match these individual needs and requirements, it is critical to collect these needs to be implemented into the development of new prosthetic devices.

## 1.2. PROSTHETIC KNEE JOINTS

Approximately 90% of all people living with an amputation are lower limb amputees [46]. This totals to an estimated number of 36 million people with lower limb amputation, of which one quarter are transfemoral amputees [47]. Transfemoral amputation intensifies the physical, psychological and social challenges due to limb loss, because of the loss of the natural knee joint compared to other, more distal, lower limb amputation levels [48]. This highlights the need to particularly research people living with transfemoral amputation.

The continuous development of prosthetic components aims to counteract the above-mentioned detrimental effects of lower limb loss. The prosthetic legs can generate, to some degree, real benefits to the users by gaining back quality of life, including functionality, personal health, and participation in society.

Generally, we can distinguish between three different kinds of prosthetic knee joints:

(1) passive, mechanical knee joints (passive knees),

(2) passive, mechatronic knee joints (MPKs), and

(3) active, mechatronic knee joints (active knees).

Passive knees are prosthetic components, that use mechanical or hydraulic properties to lock and release the joint and control flexion and extension of the knee. Examples for passive knees are the 3R85 (Ottobock Se & Co. KGaA, Duderstadt, Germany) (Figure 1 left) or the Mauch Knee (Össur, Reykjavik, Iceland). MPKs have a microprocessor embedded inside, which allows for a more controlled flexion and extension of the joint. Sensors are embedded in the devices to detect gait phases and situations like walking on stairs or ramps. This information is then used to modulate the resistance or damping for flexion and extension of the knee joint. To manage the amount of resistance against flexion and extension, magnetorheological fluids like in the Rheo Knee (Össur, Reykjavik, Iceland), or hydraulic cylinders like in the Genium X3 (Ottobock SE & Co. KGaA) (Figure 1 right) can be used. An active knee that is currently on the market is the Power Knee (Össur, Reykjavik, Iceland), which contains a motor and is therefore able to provide active assistance and power during walking.

MPKs have been shown to reduce the energy expenditure during walking, increase step length, walking velocity and symmetry, they overall provide a more stable gait with less stumbles and falls, and improve performance on stairs and leveled surfaces [4, 49–57]. Furthermore, they have been shown to reduce cortical brain activity during walking [58] and increase confidence, quality of life and overall satisfaction with the prosthesis [5, 6, 54, 55]. MPKs have shown great benefit over passive prosthetic knee joints and can be considered state of the art for transfemoral prosthetic components

[59]. Therefore, for the purpose of this work, we will focus on the Genium X3, a MPK representative of other MPKs on the market.


Figure 1 – Two different types of prosthetic knee joints from Ottobock SE & Co. KGaA: 3R85 (left), and Genium X3 (right).

## 1.3. ASSESSMENT AND OUTCOME MEASURES

There is a vast variety of assessment methods that are being used to determine the previously stated detrimental effects and improvements of prosthetic components, and therefore estimating quality of life. They range from (a) performance-based, to (b) subjective evaluations or patient-reported outcomes. Outcome measures are essential not only in the rehabilitation process but also with respect to the reimbursement of prosthetic devices by third parties [59].

(a) Performance-based outcomes

Performance-based outcomes are used to determine the physical abilities of a lower limb amputee on a specific task or group of tasks. The scoring can be compared across different users or within one user between sessions within a certain time frame. Performance-based outcomes for lower limb amputees include: Amputee mobility predictor (AMP) [60], Comprehensive high-activity mobility predictor (CHAMP)

[61], Timed up and go test [62], Six minute walk test [63], and biomechanical measures. The AMP is able to assess the current functionality of an amputee related to their ability to ambulate with a prosthesis. It can be administered with and without the prosthesis to help predict functional mobility after prosthetic fitting, and requires few equipment and little time. Items assessed in the AMP include sitting, standing balance, and transfers from sitting to standing, etc. [60]. The CHAMP focuses more on highly functional amputees, like service members for example. It includes items regarding balance, posture, upper body power, coordination, and endurance [61]. Biomechanical measures include kinetic, kinematic but also spatio-temporal parameters during ambulation in clinical settings. Examples include knee or hip joint moments and angles [64], or variables related to gait symmetry [65].

(b) Subjective evaluations/ patient-reported outcomes

Subjective evaluations directly reflect the users' opinions, preferences and perceptions as opposed to objective performance-based outcomes. Typically, domains such as satisfaction, function, health perception and quality of live are assessed. Patient-reported outcomes include: Amputee activity survey (AAS) [66], Prosthesis evaluation questionnaire (PEQ) [67], Prosthetic profile of the amputee (PPA) [68], Locomotor capabilities index (LCI) [69], Orthotic prosthetic user's survey (OPUS) [70], Trinity amputation and prosthesis experience scales (TAPES) [71], and Prosthetic limb users survey (PLUS) [72]. The AAS is asking for details about prosthesis use, employment status, social activity and walking habits, as well as use of other assistive devices [66]. Prosthesis related quality of life is assessed in the PEQ covering items related to mobility, prosthesis functioning, psychological experience and well-being [67]. The PPA focuses on frequency of prosthetic use and the level of function while ambulating with the prosthesis [68]. The LCI assesses the level of independence during ambulation for basic and advanced activities like getting up from a chair, walking inside and outside the house, or walking on stairs [69]. The OPUS consists of four components covering functionality, quality of life, satisfaction with the device itself and satisfaction with the service provided [70]. The TAPES takes into consideration physical and psychosocial aspects of adjusting to a prosthetic device and is also used to track changes in quality of life during the rehabilitation process [71]. Lastly, the PLUS is a collection of outcome measurements with different subsets, such as the PLUS-M which focuses on mobility with a prosthetic leg [72].

## 1.4. ASSESSMENT OF COGNITIVE LOAD

An important factor of everyday life is the cognitive load while walking. Often times walking is performed with a simultaneous task which demands the individual's attention. This can be the case when walking while talking on the phone for example. Because both tasks require attentional resources, the performance can be an estimate of the cognitive load [73]. However, this is not assessed by any of the afore-mentioned assessment methods. The closest they get to assess cognitive load is questions about experiencing difficulties concentrating or paying attention (OPUS), or whether they are able to walk while talking on the phone, or while looking up at the sky (PLUS-M). It is especially important to assess because the literature shows that the cognitive load of prosthetic users is higher compared to that of the general public [29], but also because there seems to be differences in the amount of cognitive effort depending on the prosthetic components [58]. Furthermore, there seems to be a relationship between the cognitive capacities and the ability to participate in activities of daily living or perform certain tasks, and cognitive impairments have been shown to be more prevalent in lower limb amputees [74]. To reduce the effects of this, and to not further increase the cognitive load on the patients, it is needed to further investigate the relationship between functional, psychological, and cognitive effects of prosthetic devices.

Lower limb amputation and the use of prosthetic devices can require an additional cognitive effort, due to the loss of the control of the limb, the lack of proprioception and an increased need for visual sampling, which in return might interfere with task performance, or a secondary task [12, 75, 76]. In summary, the increase in cognitive load, the dependency on the prosthetic components, and the ultimate effect of increased cognitive load on the execution and performance of everyday life activities highlights the value of this measure as it seems to be related to many aspects in the lifes of lower limb amputees.

There are several options to assess cognitive load in prosthetic users which have been reported in the literature. First of all, researchers have tried to simply ask the participants about their perception of cognitive load using custom made questionnaires [75] or the NASA Task Load Index which covers other aspects besides cognitive load as well [77, 78]. The perception of cognitive load has been able to distinguish between MPKs and non-MPK, showing a higher perceived cognitive load in non-MPKs [75]. Furthermore, high mental effort could be distinguished from lower effort using the NASA Task Load Index in two studies [77, 78]. The most frequently used measure of cognitive load, however, is the use of the dual-task paradigm [75, 77, 79–89]. Here, a secondary task is introduced, which can either be a purely cognitive task (e.g., computational), or an additional motor task (e.g., walking while carrying something). This would for example be the case when walking in a busy street, where many visual as well as auditive inputs from passing cars and other pedestrians exist. The amputee will then have to focus on all of these inputs, besides focusing on walking. If the cognitive load is sufficiently high in either one of the tasks, the performance in one or both tasks will decrease. In amputees, this has been shown to negatively affect gait and/or cognitive performance [77–79, 82–85, 88–90], and even show a difference between prosthetic components, where the performance using a non-MPK was affected more compared to the MPK [87]. More advanced techniques to assess the cognitive load using imaging devices such as EEG (electroencephalogram) or fNIRS (functional near-infrared spectroscopy) have only been used in the last five years [58, 77, 78, 86–89]. They have shown to be sensitive measures to distinguish levels of cognitive load between prosthetic components [58, 87, 89], amputation levels [78], whether feedback was provided or not [86], and between different activities such as walking versus sitting and walking on uneven versus even ground [77, 78, 88]. Lastly, a mobile eye tracker has been used in one pilot study to assess the cognitive load outside of a laboratory environment, showing an increased cognitive load in amputees compared to the general public [91].

While questionnaires are easy to administer, objective measures like eye-tracking, dual-task methodologies or measures of brain activity are highly desired. However, some instruments, especially brain activity measurements, require an extensive setup, as well as careful use and interpretation. In addition, they are heavily influenced by movement artifacts which need to be removed in order to draw conclusions about the cognitive load while performing a movement [92]. Furthermore, eye tracking measures like gaze tracking or pupillometry are advantageous over dual-task and subjective measures, as they can be measured in real time and therefore can be related to a certain instance in time instead of giving an overall estimation of cognitive load for a situation or a task [93].

## 1.5. LIMITATIONS OF OUTCOME MEASURES

The majority of measurement tools have been used to quantify mobility and functional limitations or quality of life of prosthetic users [94, 95]. These tools often only cover a single aspect of functional or psychological effects and fail to assess the impact of prosthetic devices in a holistic manner. Many of the performance-based outcome measures (e.g., Timed up and go test, Six minute walk test, AMP, biomechanical measures), but also some of the subjective ones, like the AAS as an example, purely focus on the functional aspects and the ability to ambulate, disregarding any other effects of prosthesis use. A holistic assessment would take into account the effects a prosthesis may have on any aspect of the users' lives, including functional, psychological or social, ergonmoic, and cognitive effects. The right combination of outcome measures could ultimately lead to a more comprehensive picture of the effects of the prosthesis on the users in their everyday lives.

Furthermore, while outcome measures have shown to be valid and reliable, it is unclear whether they are able to anticipate long-term impacts on functional abilities and prosthetic use, and therefore be able to predict which prosthetic component will be most beneficial for the user. This is also shown in the fact that between 11 to 22 % of lower limb amputees stop using their prescribed prosthetic device after one year, with transfemoral amputees being twice as likely to abandon their prosthetic device [96].

Self-reported outcomes often do not align with objective measures of function, underlining the importance to include both types of measures or using a more holistic approach [97, 98]. There appears to be a disparity between what people perceive to be capable of doing and what they actually achieved [97]. While prescription is primarily based on objectively measurable outcomes, the actual utilization of the prosthetic device depends on an individual’s feelings about their functional abilities. Consequently, future research should take into consideration both of these aspects.

Furthermore, there is limited information on the functional benefit of prostheses outside of a laboratory. As per the international classification of functioning, disability and health (ICF), assessing performance in the real-world environment of prosthetic users is an important aspect of functionality [99]. Most of the outcome measures are administered inside a laboratory or clinic under a strictly controlled environment, and the translation of the results into the real-world are not clear. This is because the use of a prosthetic device inside the laboratory or clinic might not necessarily reflect the usage outside in the everyday life of the users. The users may want to show their best performance while being observed, or they may feel uncomfortable because they are wearing few clothing during the tests, which might cause negative changes in performance as well. Furthermore, the tests are restricted to what is available in a clinic or laboratory environment, this can be limitations with regard to space, surfaces, etc. [100]. It is therefore often unclear how the results obtained in laboratory assessments translate or reflect prosthetic usage and the effects of the prosthetic devices in the real world.

Some clinical outcome measures were not specifically developed for the use with lower limb amputess, and therefore do not cover all aspects with regards to prosthetic usage, which is a complex interaction between human and machine. Moreover, some clinical measures need professional knowledge to be interpreted and may not correlate well with standardized measures [59].

## 1.6. THESIS GOAL AND STRUCTURE

For user-centered design of lower limb prosthetic devices, it is essential to take specific user needs into consideration. Because a collection of user needs only exits for upper limb amputees or a subgroup of lower limb amputees, the first study was to collect a comprehensive summary of lower limb user needs across all aspects of life: functional, psychological, ergonomics, etc.

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*Aim 1: Investigate the multifaceted needs and requirements for lower limb prosthetic devices, to be translated into the development process and investigate the existing assessment methods.*

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Identifying the needs as they are expressed by the users will define the areas of research for prosthetic device development. As a result, in order to determine the success of a newly developed device, there is a need for appropriate assessment methods, to show whether a prosthetic device has a real benefit for the user or not. The review therefore aimed to investigate whether the assessment methods could address those needs.

Typical assessments of lower limb amputees are performed inside a gait laboratory or a clinic. These approaches are unable to evaluate prosthesis usage outside, in the everyday lives of the users. As a result, it is unknown whether user needs are properly addressed. The goal of the second study was to develop novel assessment methods that contribute to the lack of evaluation methods that can be used outside of a conventional clinical gait laboratory. In the second study, sensors embedded in a prosthetic knee joint were compared to conventional clinical gait analyses during a variety of different motor tasks.

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*Aim 2: Assess if the prosthesis embedded sensors can be used for clinical gait analysis with the same precision as conventional gait analysis systems.*

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Besides the functional aspects, the literature shows a need to assess the cognitive demands of prosthesis usage as well. Higher cognitive demands compared to the general public, and differences between devices highlights the potential burden a lower limb amputee has to go through.

The visual sampling of the pathway can be related to a higher cognitive load, as the duration of visual sampling is generally associated with the time needed to process [101]. This effect could be even greater in an amputee population when taking into account that during a challenging task, such as stair climbing, the need for visual sampling is increased compared to healthy controls [91].

In the attempt of developing new assessment methods, a more holistic assessment including cognitive aspects will be taken into consideration. Current assessment methods either do not include the evaluation of cognitive load at all, are subjective, cumbersome to administer or to interpret, prone to be influenced by movement artifacts, or unable to measure cognitive load at any given moment. An objective, real-time measure of cognitive load in lower limb amputees, which can easily be used during movements even outside of a laboratory does not exist to date. As a result, the third study focused on using a mobile, wearable eye tracker to estimate the cognitive load during a variety of motor tasks. At the same time, gait parameters were investigated to observe a potential relationship between gait adjustments and a change in cognitive load.

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*Aim 3: Investigate if eye tracking can be used to estimate the cognitive load of lower limb amputees during different motor tasks and investigating the relationship of changes in cognitive load to gait parameters.*

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The thesis is based on the following three papers:

**Manz, S.**, Valette, R., Damonte, F. et al. A review of user needs to drive the development of lower limb prostheses. Journal of NeuroEngineering and Rehabilitation 19, 119 (2022).

**Manz, S.**, Seifert, D., Altenburg, B., Schmalz, T., Dosen, S., Gonzalez-Vargas, J. Using embedded prosthesis sensors for clinical gait analyses in people with lower limb amputation: A feasibility study. Clinical Biomechanics 106 (2023).

**Manz, S.**, Schmalz, T., Ernst, M., Köhler T., Gonzalez-Vargas, J., Dosen, S. Using a mobile eye tracker to estimate cognitive load in lower limb prosthesis users (submitted to Clinical Biomechanics).

# CHAPTER 2. METHODS

The following sections describe the methodologies used in studies two and three. Prosthesis embedded sensors have been used in study two only, while clinical gait analyses were used in studies two and three, and mobile eye tracking in study three only.

## 2.1. SENSORS EMBEDDED IN THE GENIUM X3

The Genium X3 (Figure 1 right) is a MPK which is able to respond to the needs of the users in real time, thanks to its embedded sensors. It has implemented the “Optimized Physiological Gait” technology [102] which enables a smooth walking pattern even on slopes, stairs, while changing walking speed, and in confined spaces. It is able to control the stance phase as well as the swing phase during walking, by changing the settings in the hydraulic unit based on a rule set identifying different gait phases, directly influencing the damping behavior of the joint. It is equipped with sensors to measure a variety of quantities. These measures include orientation of the knee joint, accelerations, angular velocities, joint angles and loads [64]. The sensors embedded in a Genium X3 include an axial encoder at the joint, two strain gauges of which one is in the hydraulics system and the other one is in the distal shank pylon, and a three degree of freedom IMU including a gyroscope and two accelerometers (Figure 2). The sensors sample the data at 100Hz and can then be streamed to a computer via Bluetooth where it can be recorded.

We recorded embedded sensors’ data to determine sagittal plane knee angle, knee moment, and thigh segment angle. Sagittal knee angle was measured using the axial encoder at the joint. The thigh segment angle was determined using the knee angle and the shank angle relative to the environment. To calculate the knee moment, the hydraulic force of the strain gauge in the hydraulics system and the internal moment arm were used.

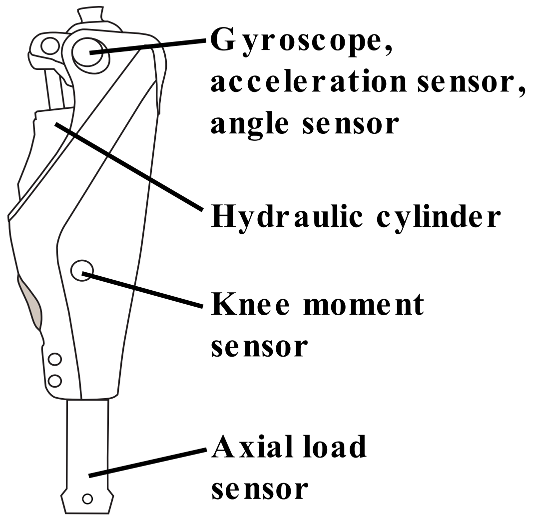


Figure 2 – Genium X3 with embedded sensors: gyroscope, acceleration sensor, angle sensor, hydraulic cylinder, knee moment sensor, and axial load sensor.

## 2.2. CLINICAL GAIT ANALYSES

Optoelectronic motion capture systems are considered the gold standard for clinical gait analyses. They consist of a number of infrared cameras, typically in combination with force measuring platforms. Within the scope of this PhD thesis the motion capture system consisted of twelve highspeed infrared cameras sampling at 200Hz (Vicon, Oxford, UK) and two force platforms sampling at 1000 Hz (Kistler, Winterthur, Switzerland). A marker set specifically developed for the use with lower limb prosthetic users, consisting of 34 retroreflective markers, was used to measure segment and joint trajectories. The marker placement has been published in [103] and can be seen in Figure 3. The markers have been placed on the following landmarks: 7th cervical vertebrae, 10th thoracic vertebrae, right and left shoulder, elbow and wrist, anterior superior iliac spine, posterior superior iliac spine, trochanter major, thigh, medial and lateral knee joint, medial and lateral ankle joint, 1st and 5th metatarsal heads, heel, and toe. Two additional markers were attached to the prosthesis shank tube, one on the medial side, and one on the lateral side (more proximal compared to the ankle markers).

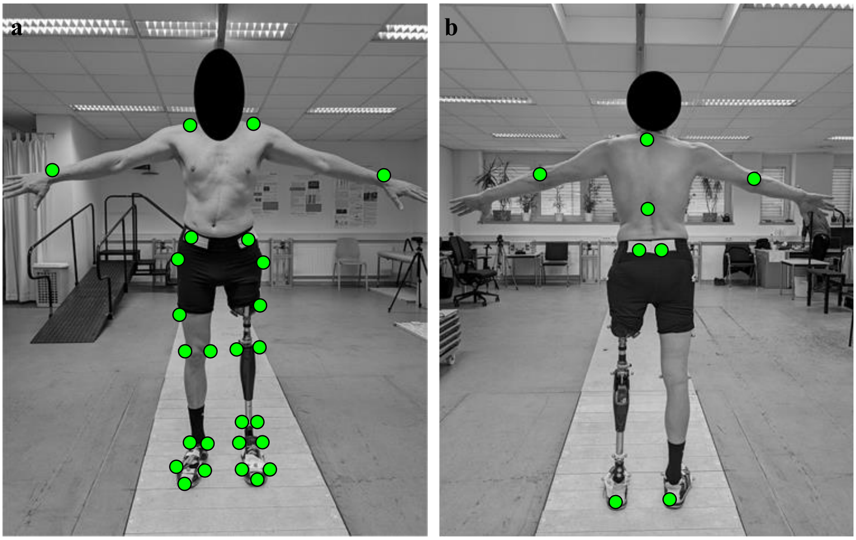


Figure 3 – Marker placement frontal view (a) and back view (b).

Forces and marker trajectories were down sampled to 100Hz to compare it to the embedded sensors data. Sagittal knee and thigh segment angles, as well as the knee moment were calculated. The knee moment was calculated using the ground reaction force vector technique, which is an accepted method especially at the knee and ankle [104, 105]. This method is beneficial over inverse dynamics calculations as it does not require an accurate model of the prosthesis and residual limb, however, only data during the stance phase can be calculated. The data analysis has been performed using MATLAB Release 2022b (The MathWorks, Inc., Natick, Massachusetts, United States).

Gait analyses inside the laboratory can include a variety of motor tasks. Typically, level walking as well as stairs and ramp ambulation are tested [50, 106–109]. The tasks included in this PhD project included level walking (in Study 2 at three different walking speeds), walking on uneven ground (Study 3 only), avoidance of obstacles at three predefined locations (Study 3 only), stair ambulation and ramp ambulation (in Study 2 at two different inclines of 10° and 15°), as well as some trials outside of the laboratory in the staircase of the building (Study 3 only). A schematic of all tasks can be seen in Figure 4 and photos of the setup can be seen in Figure 5.

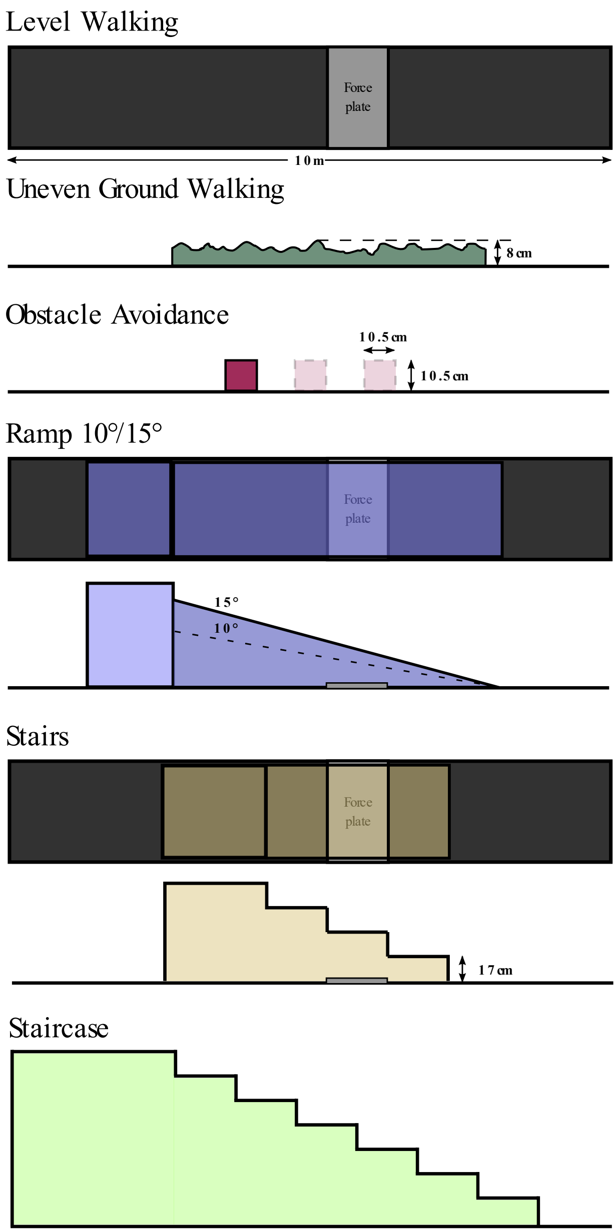


Figure 4 – Schematic setup from top to bottom: level walking (top view), uneven ground walking (side view), obstacle avoidance (side view), ramp at 10° and 15° inclines (top view and side view), stairs (top view and side view), and staircase (side view).

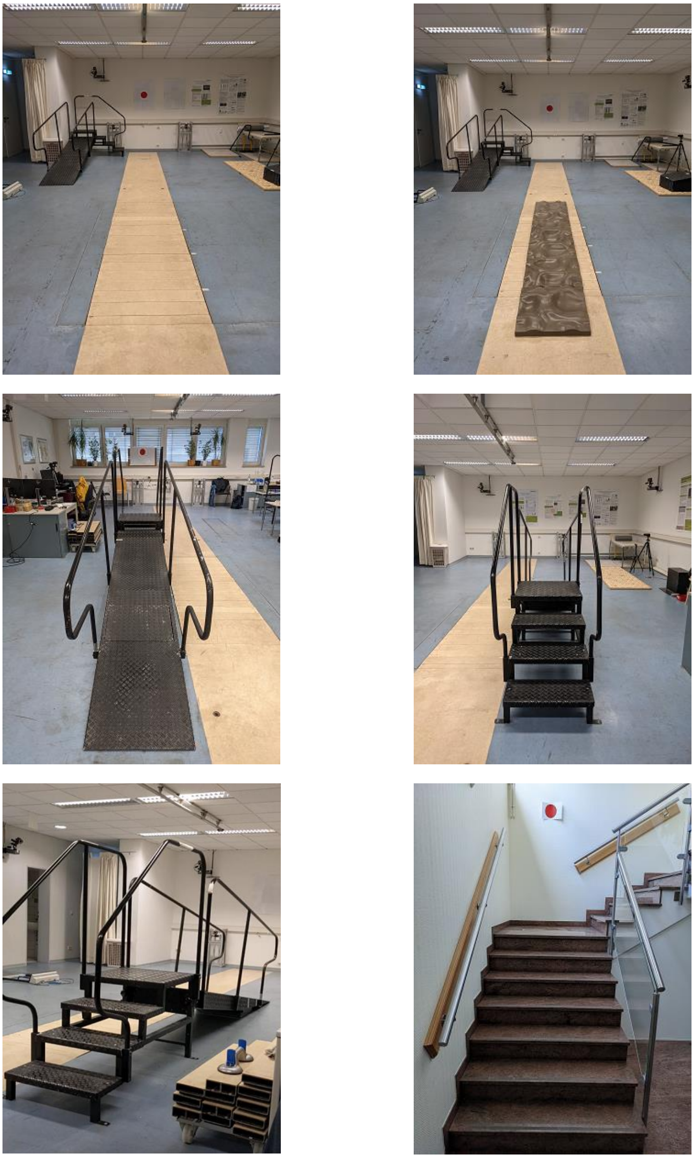

Figure 5 – Photos of the setup during the user testing inside the laboratory (top, middle, and bottom left), and in the staircase (bottom right).

## 2.3. MOBILE EYE TRACKING

Mobile eye tracking is typically done with a head-mounted eye tracker in the form of glasses. For the purpose of this work, the tobii Pro Glasses 3 (tobii, Stockholm, Sweden) were used (Figure 6). The glasses are able to record gaze as well as pupillometry through a world-view camera and two infrared cameras, one directed at each of the eyes. The eye tracking data was analyzed using tobii Pro Lab version 1.181 (tobii, Stockholm, Sweden). The gaze location in the world-view video stream, as determined by the eye tracker, was then mapped on a static image of the experimental setup (snapshot). A target area of interest (AOI) was defined around a target (red circle) on the wall at the end of the walkway. The participants were instructed to focus on this target for as long as possible throughout the tasks. It was then possible to determine the time spent fixating on the target during a specific motor task (target fixation time) and compare this across tasks. Similarly, the average pupil size (pupil diameter) from left and right eye while looking at the target was exported from the eye tracking software as a measure of cognitive load or mental activity [110]. Fixation times as well as pupil diameter can be used as measures of cognitive load, as they both respond to changes in task difficulty. Important areas for a specific task are fixated more and pupil diameter increases with an increase in cognitive load [93].


Figure 6 – Photo of the mobile eye tracker including the recording unit.

# CHAPTER 3. SUMMARY OF STUDIES

## 3.1. STUDY 1 - SYSTEMATIC REVIEW

### 3.1.1. PROTOCOL

A systematic search of the literature was performed to collect user needs of lower limb prosthetic users. User needs were defined as a requirement which has been directly expressed by a prosthetic user and reported in the literature. Two databases (PubMed and MEDLINE) have been used to collect a list of 7258 articles. After removing duplicates and scanning title, abstract and full-text for relevance, 7210 articles were excluded. The reference lists of the remaining 48 articles revealed an additional 8 relevant articles for the review [111].

### 3.1.2. RESULTS & DISCUSSION

A total of 31 user needs could be identified from the systematic search of the literature. The needs were divided into subgroups regarding functional, psychological and cognitive, ergonomic and other aspects. The five most frequently reported user needs were "Less pain", "Mobility", "Social integration", "Independence" and "Walk" (Figure 7) [111].

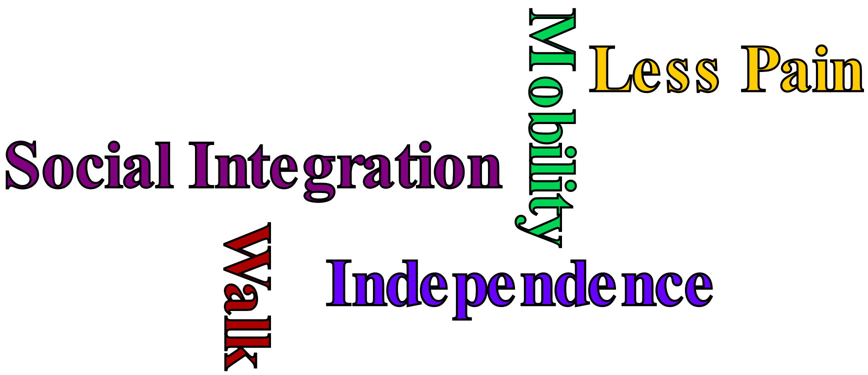


Figure 7 – Most frequently reported user needs: "Social integration", "Mobility", "Walk", "Independence", and "Less pain".

To this date, not all identified user needs are fully addressed with lower limb prosthetic devices that are currently available. The goal is that the needs will be translated into development guidelines for user-centered prosthetic devices in the future. There are, however, a few hurdles to consider. First, the user needs are multifaceted and interrelated. The user needs interact with each other within one category as well as with needs of different categories, which makes it difficult to act on only one. On the other hand, the fact that they are not independent from each other could make it possible to improve overall quality of live on several ends by acting on just one need. An example is the fact that the ergonomic need of socket fit directly affects comfort, which is within the same category [112]. However, the fit of a prosthesis has been shown to also influence the functioning of the amputees as for example their ability to walk [113]. Furthermore, generalizing the importance of user needs across different user groups is not always possible, as they can be dependent on mobility level, age, health, and gender. As an example, not feeling off-balance, the energy required to use the prosthesis, the ease of donning, and the ability to walk were aspects rated with higher importance in female users, compared to males [67, 114]. This all suggests that customization of prosthetic devices and the opportunity to adapt to the users' changing needs over time may be necessary.

The development of mechatronic prosthetic devices has shown improvements with regard to several user needs already, such as the perception of safety [115] or the cognitive demands of walking [75]. Nevertheless, there are areas with room for further improvement, such as the ability to walk and balance [116, 117], support especially during standing up from sitting which is directly acting on mobility and independence of the users [118], and increasing safety by reducing the number of falls and stumbles [115, 119].

In order for new developments to impact the quality of life of the users and act on the identified user needs, it is essential to be able to properly assess technological improvements quantitatively and qualitatively. Simply asking the users about their needs might not be sufficient, as they cannot think about ways to improve their devices because of a lack of awareness of the possibilities [67]. The techniques previously used to identify user needs include semi-structured interviews [23, 120–127] and multistakeholder workshops [128]. While semi-structured interviews can lead to a deeper understanding of the topic, there is a risk that they lack objectivity and generalizability due to small sample sizes [121].

In summary, a holistic, objective assessment of user needs is challenging. As self-reports may not correlate with objective metrics [75], and laboratory tests do not translate to actual prosthesis use in the real-world [100]. Current assessment methods in general may not be able to paint a comprehensive and representative picture of prosthetic use under real-world conditions [96, 100]. Being able to holistically assess lower limb prosthetics outside of the lab is the ultimate goal to measure the real-world usage and effect of the devices on the users. Using appropriate assessment methods to understand user needs and the development of prosthetic devices is, therefore, especially critical. It is important to be able to assess prosthesis function outside of a laboratory, which is currently not possible. Therefore, study two focused on developing an assessment method which can be used outside of a gait laboratory.

## 3.2. STUDY 2 - EMBEDDED SENSORS

The goal of this study was to assess if the prosthesis embedded sensors can be used for biomechanical gait analysis outside of a laboratory. Current assessment methods are unable to objectively evaluate prosthesis use outside a clinic or gait laboratory. The embedded sensors of a prosthetic knee joint have therefore been compared to a conventional gait analysis system.

### 3.2.1. PROTOCOL

Ten participants with unilateral transfemoral amputation participated in this study (Figure 8). A certified prosthetist fitted them with a Genium X3 (Ottobock SE & Co. KGaA, Duderstadt, Germany) for the duration of the tests. After familiarization with the device, the participants were prepared for motion capture analysis. A total of nine different tasks were performed while simultaneously recording motion capture and embedded sensors data. The tasks included in this study were level walking at three different self-selected speeds (slow, normal and fast), stair ascent and descent, and ramp ascent and descent on a 10° and 15° leveled walkway. The participants completed at least five valid trials for each of the tasks which were then used for the data analysis. The analysis included the comparison of sagittal knee angle, knee moment, and thigh segment angles. Pearson correlation coefficients, relative errors, and root mean square errors (RMSE) were calculated on the average data of five trails for each task and participant (with a few exceptions, where not enough valid data was available). In addition, discrete clinical variables were compared to determine the potential usage of embedded sensors for gait analyses outside of a laboratory.

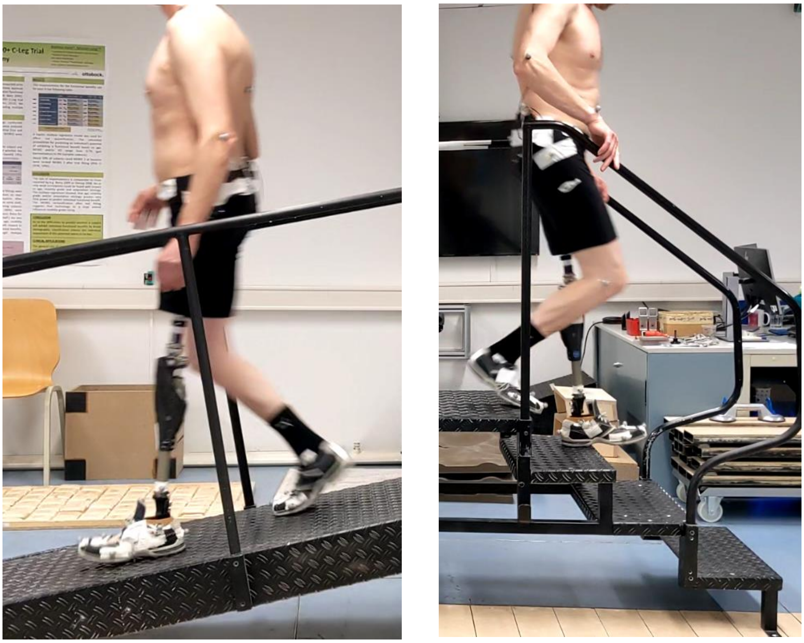

Figure 8 – Representative participant during ramp descent (left) and stair descent (right).

All statistical analyses were performed using IBM SPSS Statistics for Windows, version 27 (IBM Corp., Armonk, N.Y., United States). Shapiro-Wilk tests were used to test for normality of the data. Kruskal-Wallis tests with post-comparison and Bonferroni correction were performed to determine whether the average relative errors and correlation coefficients were significantly different between knee angle, thigh segment angle and knee moment. Wilcoxon signed-rank tests were used to test for differences between the knee angle and thigh segment angle RMSE. The clinical variables were compared between embedded sensors and motion capture data using paired t-tests and Wilcoxon signed-rank tests. The significance level for all tests was set to 0.05.

### 3.2.2. RESULTS & DISCUSSION

The profiles of the sagittal knee angle obtained from the motion capture data and the embedded sensors showed excellent agreements. However, some deviations between the profiles were visible in the sagittal knee moment and sagittal thigh segment angle, as can be seen in Figure 9.

The average results for RMSE, relative errors and correlation coefficients can be seen in Table 1, expressed as median and interquartile range (IQR). Significant differences were found between the RMSE of the knee angle and the thigh angle. Furthermore, significant differences were found for the relative errors and correlation coefficients between the knee angle and the thigh angle, and between the knee angle and knee moment.

Table 1 – Average results for RMSE, relative error and correlation coefficient between motion capture and embedded sensors data. Results are represented as median and IQR for sagittal knee angle, thigh angle and knee moment. *Significance: a: Significant differences between knee angle and thigh angle, b: significant differences between knee angle and knee moment.

| | **RMSE** | **Relative Error** | **Corr. Coefficient** |
|---|---|---|---|
| **Knee Angle** | 0.6° (0.3) | 0.75% (0.38) | 1.00 (0.00) |
| **Thigh Angle** | 5.3° (3.1) | 11.67% (8.25) | 0.97 (0.01) |
| **Knee Moment** | 0.08Nm/kg (0.01) | 9.66% (2.07) | 0.98 (0.01) |
| **Significance*** | a | a, b | a, b |

No significant differences were found in the peak knee flexion angles across all tasks. The embedded sensors significantly underestimated the peak thigh flexion angle at initial stance during walking at all three speeds, during ramp ascent at 10° and 15°, and during stair ascent and descent. Furthermore, the embedded sensors significantly overestimated the peak thigh extension angle during level walking at fast speeds. Lastly, significant differences between the peak knee flexion moment obtained by the motion capture and embedded sensors data were found during level walking at all three speeds, during ramp descent at 10°, and during stair descent (Table 2).

Overall, the performance of the embedded sensors in estimating the motion capture data depended on the variable of interest. The embedded sensors were highly accurate for the knee angle, but less accurate for the knee moment and thigh segment angle. Further, the embedded sensors were able to estimate peak knee flexion angle and peak thigh extension angles across tasks. The differences in the peak knee flexion moment were statistically significant, however, small in magnitude and likely of no clinical relevance. Larger differences were only found in the peak thigh flexion angle. These deviations could be due to inaccurate assumptions about the true hip joint center in the embedded sensors data. Furthermore, relative movement between the socket and the residual limb, which can neither be assessed with the embedded sensors nor with the motion capture system, could further contribute to the deviations between the two measurement systems. Lastly, an offset between the thigh segment angles obtained from the embedded sensors and the motion capture system could not fully be removed with the information from the static trials and could have affected the results in the dynamic trials as well, leading to an increase in the differences between the two measurement systems.

The magnitude of knee angle RMSE are well withing those reported in previous literature, when comparing wearable sensors or IMUs to motion capture systems [129–131]. The majority of previously published literature purely focused on level ground walking, while this study showed, that the embedded sensors are able to deliver good estimates across a variety of tasks. Similarly, the correlation coefficients and relative errors regarding the knee moment obtained in this study fall well within the range of previously published data [132], although a simplified approach was used to determine the moments using the ground reaction force vector technique, and therefore neglecting the inertia effects. At the same time, this technique prevented the analysis of the moments during the swing phase of walking.

The study results are limited in their generalizability, because of its sample size and because only male prosthetic users participated in this study. Furthermore, the analysis of variables was limited to the embedded sensor outputs, which were mostly in the sagittal plane. Future analyses could benefit from investigating the three dimensional orientation of the thigh [133], or ground reaction forces including the axial load in the prosthesis.

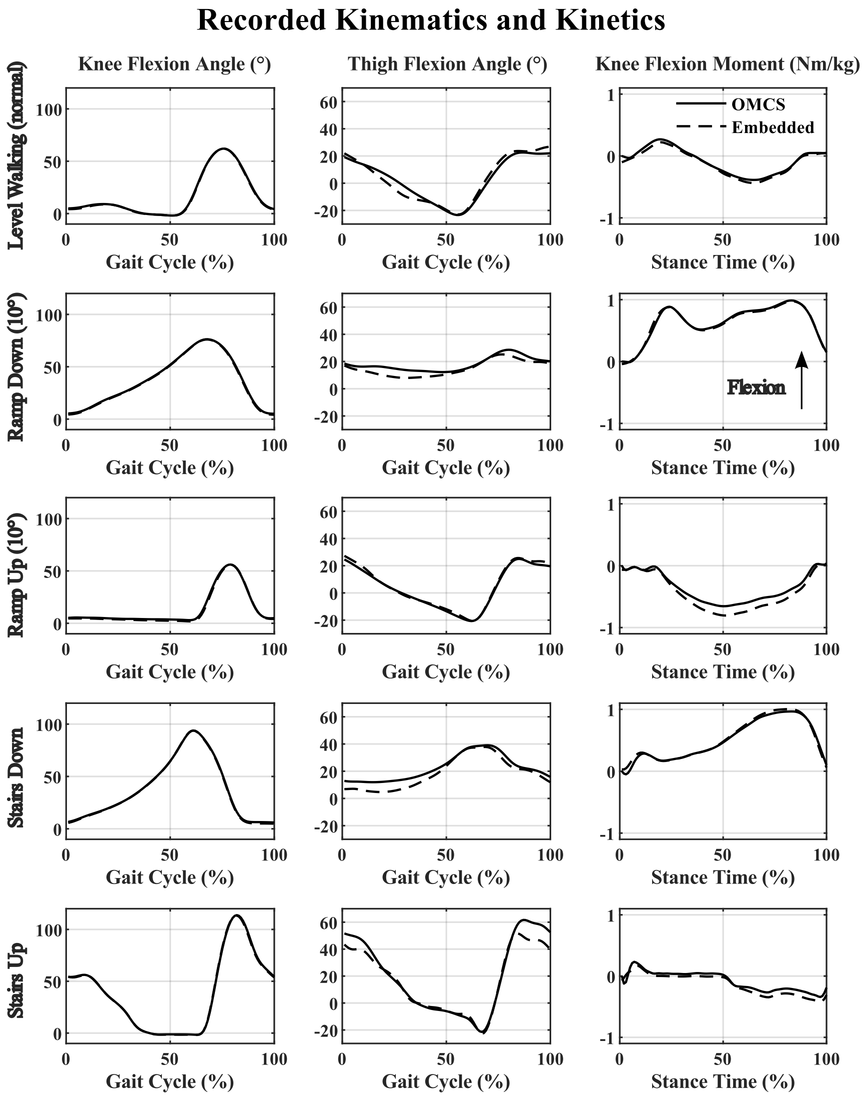


Figure 9 – Knee flexion angles (left), thigh flexion angles (middle), and knee flexion moments (right) for representative gait cycles of one participant. From top to bottom: Level walking at normal speed, ramp descent at 10°, ramp ascent at 10°, stair descent, and stair ascent. The solid and dashed lines represent the data recorded by the OMCS (optical motion capture system) and the embedded prosthesis sensors, respectively.

Table 2 – Differences in clinical outcome variables between motion capture and embedded sensors data across all tasks (*: motion capture data signifcantly higher than embedded sensors data (green), †: motion capture data significantly lower than embedded sensors data (green), n. s.: no significant differences (grey)). Variables not assessed in certain movements are shaded in white (-).

| | **Peak Knee Flexion Angle** | **Peak Thigh Flexion Angle** | **Peak Thigh Extension Angle** | **Peak Knee Flexion Moment** |
|---|---|---|---|---|
| **Level Walking Normal** | n. s. | * | n. s. | * |
| **Level Walking Fast** | n. s. | * | † | * |
| **Level Walking Slow** | n. s. | * | n. s. | * |
| **Ramp Ascent 10°** | n. s. | n .s. | n. s. | - |
| **Ramp Ascent 15°** | n. s. | n. s. | n. s. | - |
| **Ramp Descent 10°** | n. s. | * | - | * |
| **Ramp Descent 15°** | n. s. | * | - | n. s. |
| **Stair Descent** | n. s. | * | - | † |
| **Stair Ascent** | n. s. | * | n. s. | - |

In summary, the results showcase the potential of prosthesis embedded sensors to evaluate and assess gait parameters outside of a conventional gait laboratory and in the everyday lives of lower limb prosthetic users. Replacing conventional clinical gait analyses with embedded sensors would overcome many of the limitations of laboratory based tests. This could include tracking of changes in the gait pattern over time due to an intervention or during prosthetic training, complementing the information from self-report questionnaires. But also, short-term recordings would be feasible, drastically reducing the setup time compared to conventional gait analyses, because the sensors are embedded in the prosthetic device and the recording of gait data can start right away, anywhere, without having to attach reflective markers or being bound to any other piece of equipment. This approach could furthermore help orthopedic technicians with the dynamic alignment of prosthetic components without the need for an expensive and complicated setup.

## 3.3. STUDY 3 – EYE TRACKER

The aim of this study was to investigate if eye tracking can be used to estimate the cognitive load of lower limb amputees during different motor tasks and to investigate the relationship of changes in cognitive load to gait parameters. For this reason, we have used a new approach to measure cognitive load by challenging the participants to fixate on a target.

### 3.3.1. PROTOCOL

Five participants with unilateral transfemoral amputation participated in this study. A certified prosthetist fitted them with a Genium X3 (Ottobock SE & Co. KGaA, Duderstadt, Germany) at the beginning of the tests. In addition, eight able-bodied controls participated in this study. All participants were prepared for motion capture analysis and equipped with the mobile eye tracker (Figure 10). After familiarization with the wearable eye tracker and the MPK, a total of seven different tasks were performed. The tasks were level walking, walking over uneven terrain, obstacle avoidance, ramp ascent and stair descent, stair ascent and ramp descent, and staircase ascent and descent. During the tasks, the participants were asked to focus their gaze on a visual target (red circle) at the end of the walkway (Figure 11). The participants were instructed, that in the case that they needed to look somewhere else for safety reasons, that they could do so. After recording a sufficient number of trials for each of the tasks, the participants were asked to rate their perception of cognitive load on a scale from one to nine, where one represented very, very low cognitive load, and nine represented very, very high cognitive load [134] (Figure 12).

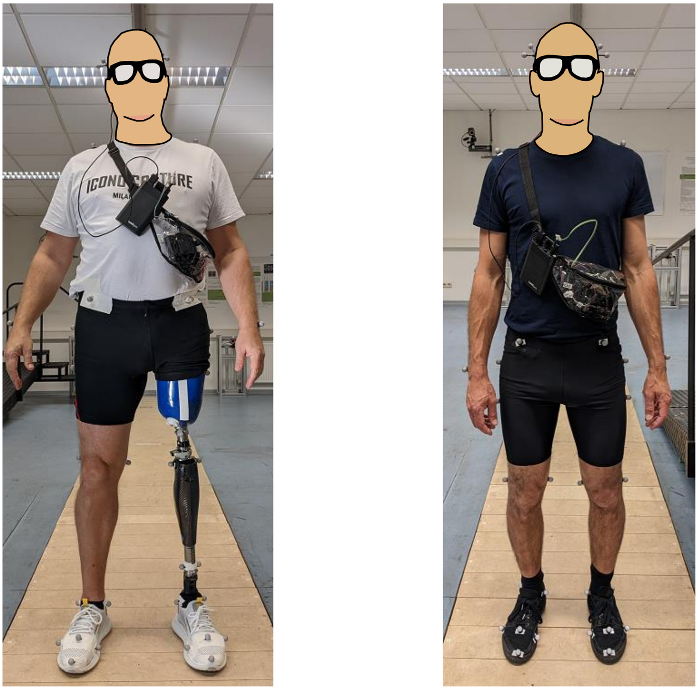

Figure 10 – Setup for motion capture and eye tracker recordings. Left: amputee participant. Right: able-bodied control participant.

Cognitive load was then correlated to the amount of time spent looking at the target, and to changes in pupil size using Spearman rank correlation coefficients. In addition, pairwise, between-subject correlations of the outcome measures target fixation time, pupil diameter, and subjective rating of cognitive load were calculated. Shapiro-Wilk tests were used to test for normality of the able-bodied control data. Kruskal-Wallis tests and one-way ANOVAs with post-comparison and Bonferroni correction were then performed to determine whether there were differences across tasks in the following outcome measures: subjective rating of cognitive load, target fixation time, and pupil size. The significance level for all tests was set to 0.05.

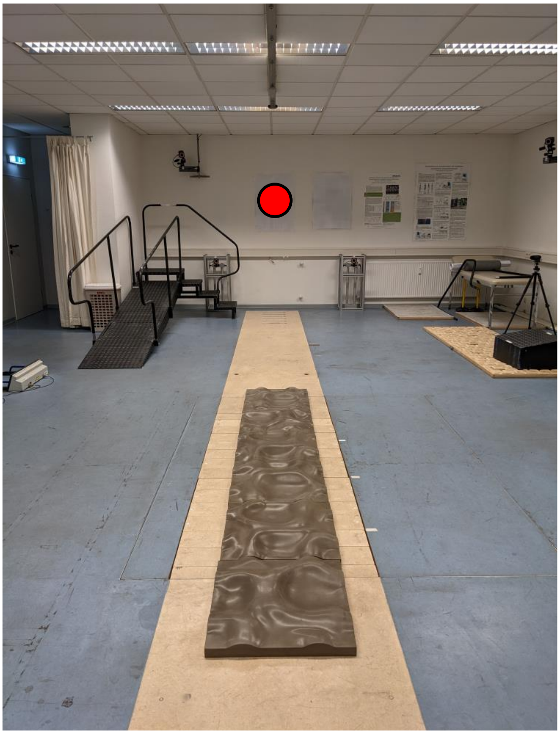

Figure 11 – Target (red circle) during walking on uneven ground.

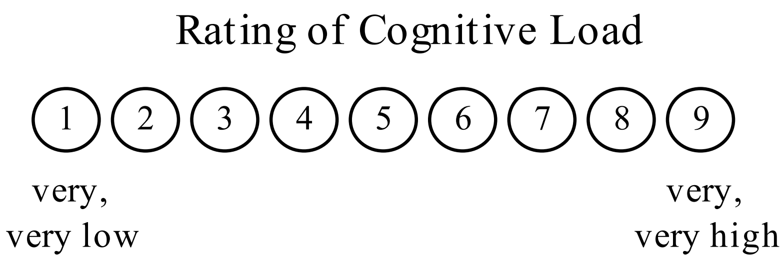


Figure 12 – Rating scale for the perception of cognitive load, from 1 (very, very low) to 9 (very, very high).

### 3.3.2. RESULTS & DISCUSSION

The prosthetic users rated the cognitive load of the motor tasks between one and five out of a nine point scale, similar to the able-bodied control participants who used ratings between one and seven. On average though, the able-bodied participants tended to rate the tasks as more cognitively demanding.

The eye tracking data revealed times where the participants looked at the target as instructed, and times that were spent looking away, for example on the pathway (Figure 13). Target fixation times as well as pupil diameter both changed as a response of the tasks included in this study (Figure 14). In the able-bodied participants, target fixation times significantly decreased during ramp up and stairs down, as well as during staircase ascent and descent, compared to level walking ($p < 0.05$). The amputee participants followed a similar trend on average, with an additional decrease in target fixation time during the obstacle avoidance task. Pupil diameter increased significantly during ramp up and stairs down, as well as during stairs up and ramp down, compared to level walking ($p < 0.05$) in the able-bodied participants. On average, the target fixation times showed strong, negative correlations to the subjective rating of cognitive load in both participant groups. Likewise, pupil diameter showed a strong positive correlation to the perception of cognitive load in the able-bodied participants, however, not in the amputees. The average correlation coefficients can be seen in Table 3. This means, that with an increase in the perceived cognitive load of a task, there was a decrease in target fixation time across all subjects and an increase in pupil diameter in the able-bodied participants. The median pairwise correlation coefficients for target fixation time, pupil diameter and the subjective rating of cognitive load were 0.48, 0.61, and 0.35, respectively.

Despite a change in cognitive load, step width did not change across tasks in the able-bodied participants ($p = 0.18$). The amputee data followed a similar trend, while step width was increased in the prosthetic users across all tasks compared to the able-bodied controls. Minimum toe clearance was higher during obstacle avoidance compared to level walking and walking on uneven ground in the able-bodied controls ($p < 0.01$), as well as in the amputee participants.

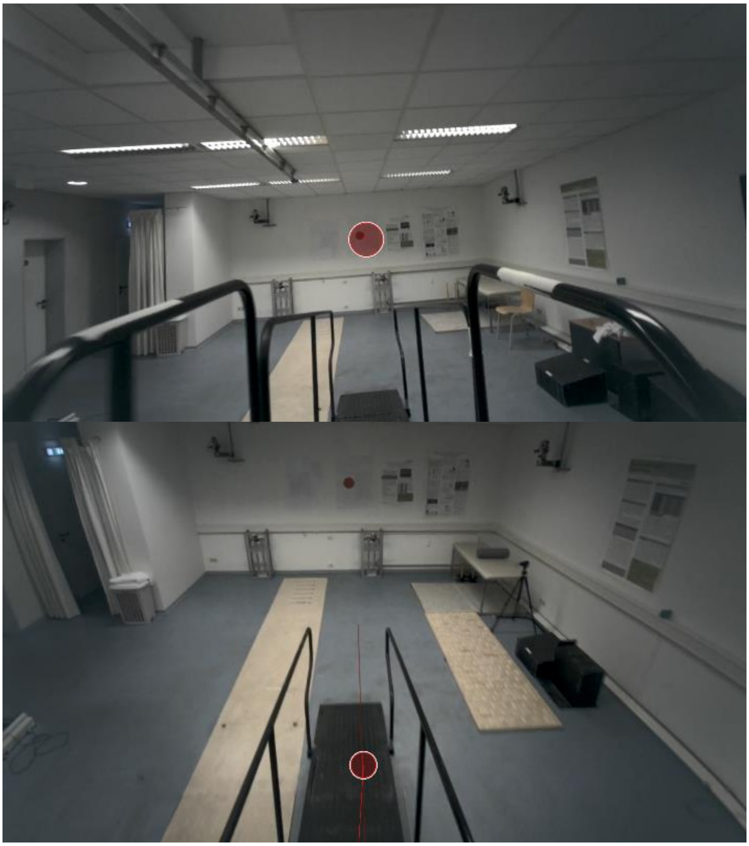

Figure 13 – Snapshots of times when the gaze (red circle) was on the target (top) and on the pathway (bottom).

While a strong negative correlation between the average subjective rating of cognitive load and target fixation time could be found, individual participant correlation coefficients revealed, that the approach did not succeed in all the participants. Two out of the five amputee participants showed weak correlations to cognitive load, and only two showed strong correlations. For one amputee participant, no correlation coefficient could be determined because the tasks were all rated on the same level of cognitive load. This might also be a reason, why two amputees were found with weak correlation coefficients. They rated the cognitive load of the tasks on a small range from one to two, while others used a range between one and five (Figure 15 and Figure 16). Six out of eight able-bodied participants showed strong correlations between target fixation times and the perception of cognitive load. Similar results were found for the correlations between pupil diameter and cognitive load. Seven out of eight able-bodied participants showed moderate to strong positive correlations, while this was the case in only two out of five amputees (Figure 15 and Figure 16). The median pairwise correlation coefficients of target fixation time, pupil diameter and the subjective rating of cognitive load showed that on average, the eye tracking measures had higher internal consistency across participants, compared to the subjective rating, as indicated by moderate to strong correlation coefficients.

Table 3 – Spearman rank correlation coefficients (corr. coef.) and p-values for the correlation between target fixation time and pupil diameter with the subjective rating of cognitive load.

| | **Prosthetic Users Corr. coef.** | **Able-bodied Corr. coef. (p-value)** |
|---|---|---|
| **Target Fixation** | -0.87 | -0.75 (0.05) |
| **Pupil Diameter** | 0.21 | 0.80 (0.10) |

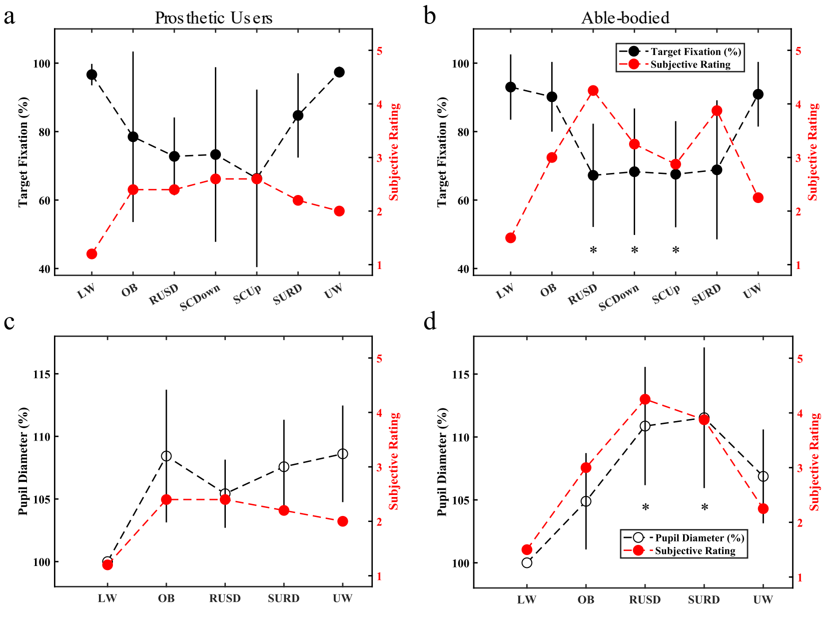


Figure 14 – Average results of subjective ratings, target fixation times in % (top, a and b), and pupil diameter in % relative to level walking (bottom, c and d) for prosthetic users (left) and control participants (right). Tasks included were: level walking (LW), obstacle avoidance (OB), ramp up and stairs down (RUSD), staircase down (SCDown), staircase up (SCUp), stairs up and ramp down (SURD), and uneven walking (UW). The asterisks indicate significant differences compared to LW, and the vertical black lines represent the standard deviation of target fixation times and pupil diameter.

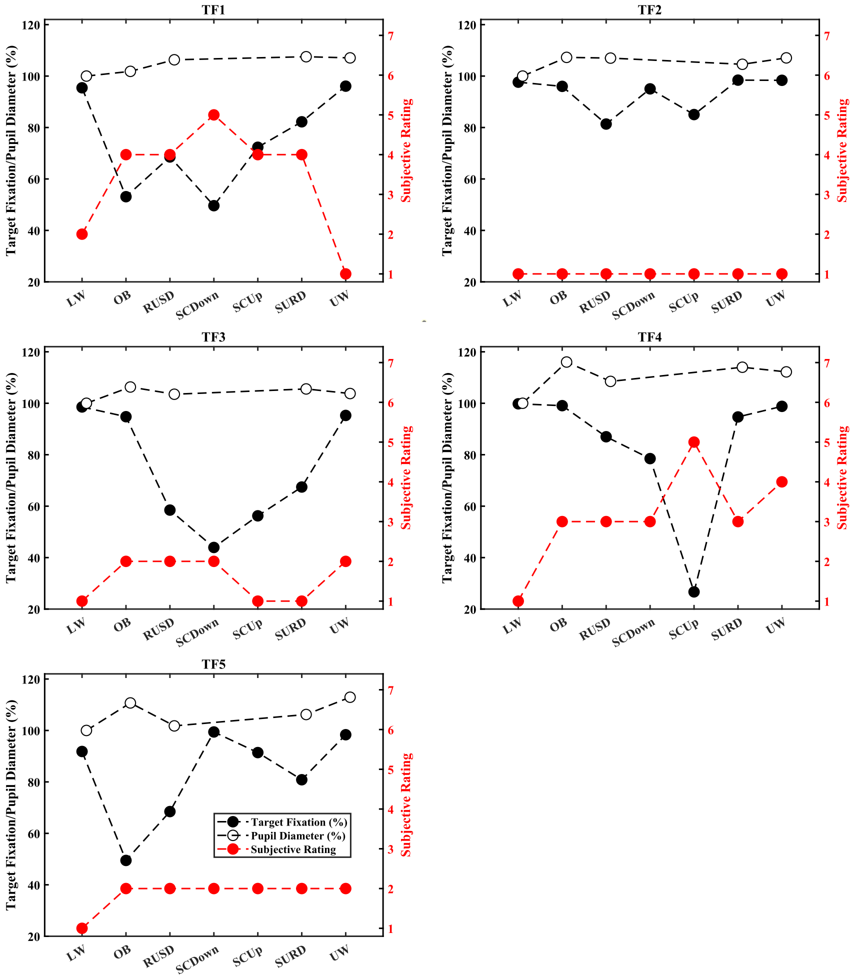


Figure 15 – Individual results of target fixation times in % (black), pupil diameter in % relative to level walking (white), and the subjective rating of cognitive load (red) for prosthetic users (TF1-TF5) Tasks included were: level walking (LW), obstacle avoidance (OB), ramp up and stairs down (RUSD), staircase down (SCDown), staircase up (SCUp), stairs up and ramp down (SURD), and uneven walking (UW).

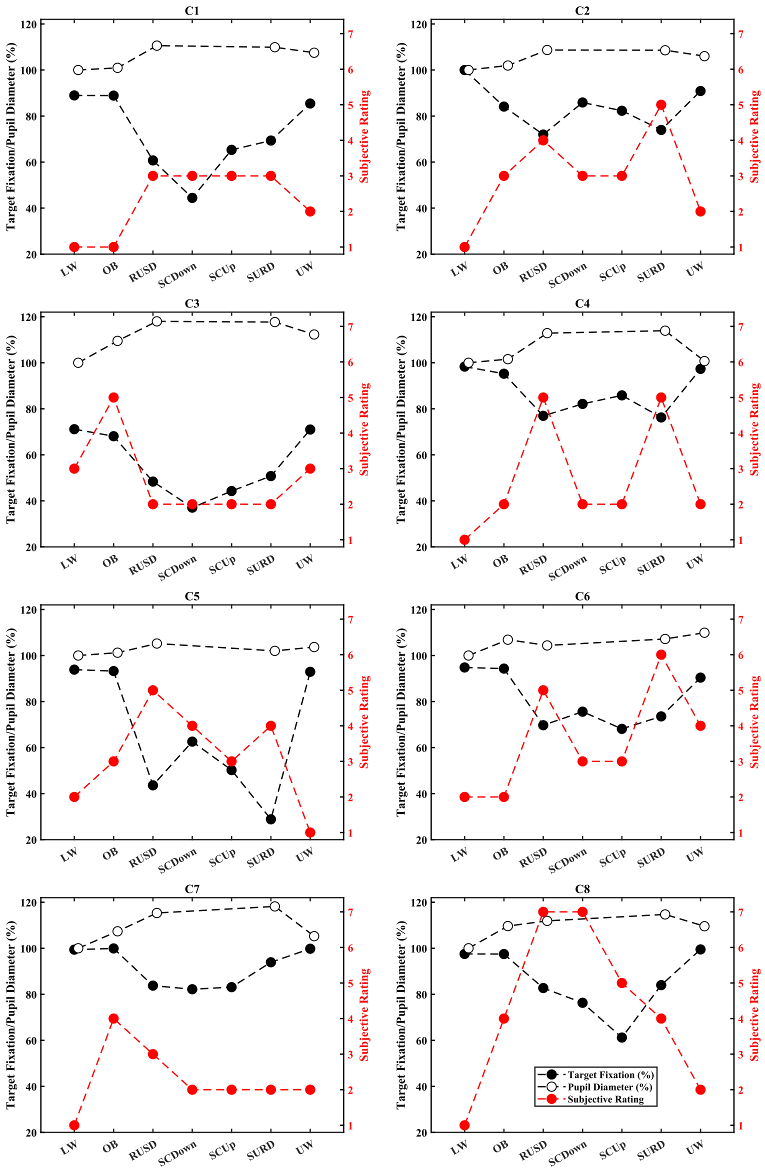


Figure 16 – Individual results of target fixation times in % (black), pupil diameter in % relative to level walking (white), and the subjective rating of cognitive load (red) for control participants (C1-C8). Tasks included were: level walking (LW), obstacle avoidance (OB), ramp up and stairs down (RUSD), staircase down (SCDown), staircase up (SCUp), stairs up and ramp down (SURD), and uneven walking (UW).

# CHAPTER 4. CONCLUSIONS

## 4.1. ADDRESSING THE THESIS GOALS

Lower limb amputation can be a traumatic life event which impacts quality of life substantially. Prosthetic devices are therefore essential for individuals with lower limb loss, enabling them to lead independent lives and participate in activities of daily living.

A prosthetic device, however, only gets used when the user accepts it and is satisfied with it. The ultimate goal of a successful lower limb prosthetic device is therefore to elevate acceptance and satisfaction rates, and ultimately increase the quality of life of lower limb prosthetic users.

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*Aim 1: Investigate the multifaceted needs and requirements for lower limb prosthetic devices, to be translated into the development process and investigate the existing assessment methods.*

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This work provides a collection of user needs, highlighting the fact that the needs are multifaceted, interrelated and that they cover different aspects of everyday living: functional, psychological, cognitive, ergonomic, and other needs. The identification of these user needs is a critical step in the development of prosthetic devices and can potentially assist in generating real benefits for prosthetic device users. Whether the improvements in technological developments transfer directly to an increase in quality of life of the users and higher satisfaction and acceptance with the device, needs to be assessed regardless. It has been shown that current assessment methods are not successful at measuring the real-life effect of prosthetic devices on the user and cognitive load is not part of the assessments. As a result, it is necessary to develop appropriate measures and assessment methods.

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*Aim 2: Assess if the prosthesis embedded sensors can be used for clinical gait analysis with the same precision as conventional gait analysis systems.*

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The prosthesis embedded sensors have demonstrated good estimations of kinematic and kinetic outcome variables frequently used in clinical gait analyses across a wide range of tasks. While significant differences were found between the embedded sensors and the motion capture system with respect to discrete outcome variables, the deviations were small in magnitude for the peak knee flexion moment. The larger deviations at the hip emphasize that further research is needed in order to improve this measurement before it can be used together with the other variables outside of a laboratory. This research could include a musculoskeletal model to better estimate the orientation of the residual limb and the movements relative to the socket. This could also help with the estimation of the hip joint center to be used by the embedded sensors. Finally, the alignment information of the prosthetic components in a static condition could potentially be used to further improve the estimation of the thigh segment angle.

The results showcase the potential of prosthesis embedded sensors for conducting gait analyses outside of a conventional gait laboratory across a wide range of tasks. Using these sensors will allow to measure meaningful lower limb prosthetic gait data, representative of everyday live scenarios.

This is promising for the potential usage of these sensors in assessing gait parameters during short- and long-term recordings. The sensors could potentially help overcome the limitations of costly and bulky equipment which can be found in a conventional gait laboratory. Furthermore, the recording would no longer be constrained by the available space or scenarios inside a laboratory. During a long-term recording, changes in the gait pattern over time could be tracked and used to objectively evaluate the accommodation process to a new device for example.

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*Aim 3: Investigate if eye tracking can be used to estimate the cognitive load of lower limb amputees during different motor tasks and investigating the relationship of changes in cognitive load to gait parameters.*

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Data from a mobile eye tracker seems to be able to estimate the cognitive load that is perceived by a prosthetic user during different motor tasks. While the average correlation coefficients showed strong correlations between the eye tracking data and the perception of cognitive load, the individual results differ from this average correlation. The individual results highlight the limitations of questionnaires to be used to assess cognitive load, as they were, in some cases, not sensitive enough to detect differences between motor tasks. It is possible, that amputees would not like to admit that certain tasks are more cognitively demanding, which could explain the overall trend of lower ratings and further presses the need for an objective measure.

The results from this study highlight the opportunity to rely on objective measurements of cognitive load using a mobile eye tracker, instead of asking the prosthetic users for their perception. A huge advantage of this measure is that the gaze information and pupil diameter is available in real-time, for any given moment in time, instead of an overall perception of cognitive load of a task. Furthermore, target fixation time can be used in a less controlled environment without the need of a gait laboratory or a clinic, and is easy to use compared to more cumbersome methods including brain imaging. In addition, it is not affected by a change in physical effort, as for example a measure of heart rate variability would be and can therefore be applied in many different motor tasks.

## 4.2. OVERALL CONCLUSIONS

This dissertation provides an additional piece of the puzzle to successfully assess lower limb prosthetic devices. The work reported here has tackled three important issues with respect to more meaningful assessment methods: identification of user needs and the state of the art in their assessment, a way to measure gait parameters outside the laboratory, and a way to measure attention as a measure of cognitive load. The advances in these three areas will likely generate real benefits in the future assessment of lower limb prosthetic devices as they counteract limitations of currently existing assessment methods.

The vision is that the use of embedded sensors data and a mobile eye tracker to measure cognitive load can be implemented together and lead to a more comprehensive assessment, which can be adapted and used outside of a laboratory. The manufacturer of the eye tracker, for instance, offers tinted lenses with infrared-blocking for use in outdoor environments. The data from the embedded sensors as well as the mobile eye tracker could in the future be directly uploaded to a cloud, where researchers can access, process and interpret the data (Figure 17). This has the potential to gain insights into real-life prosthetic use and associated attentional demands without constraining the assessment to the limitations of a gait laboratory.

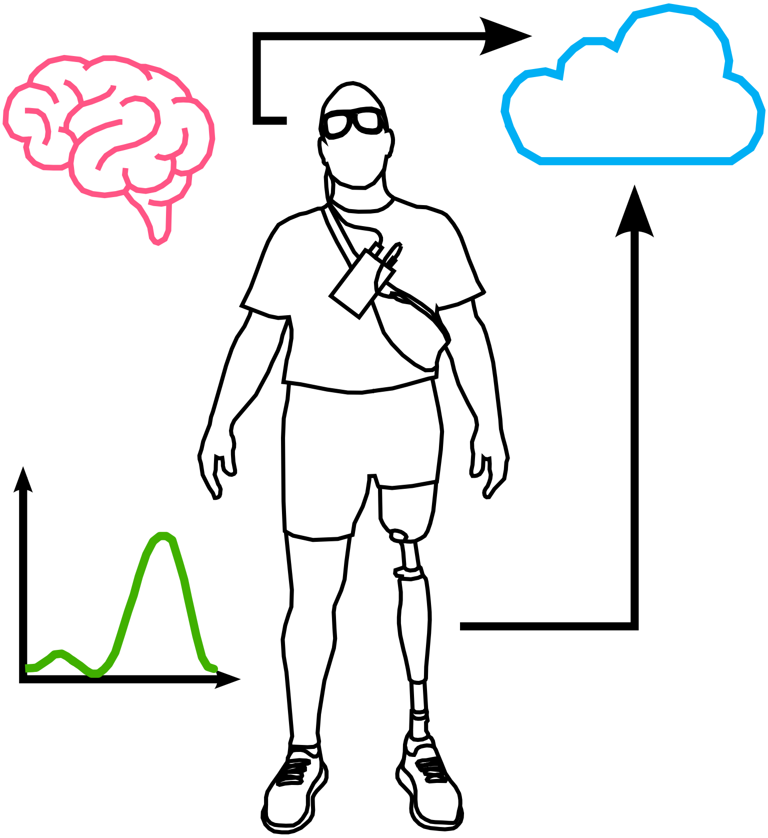

Figure 17 – Vision of newly developed assessment method outside of a laboratory, including cognitive load, prosthesis embedded sensors data, and the potential to be uploaded to a cloud.

## 4.3. FUTURE WORK

To further validate the presented results, it is critical to actually use the new tools in the everyday lives of prosthetic users. While the prosthesis embedded sensors can only extract kinematic and kinetic information about the prosthetic side, future work could focus on the integration of additional information. Inertial measurement sensors could be used to track the movement pattern of the intact limb. Another solution could be the integration of other additional sensors in the prosthesis which are able to collect information about the contralateral limb, as it has been explored in other research [135].

Future work could also include implementing a cloud solution where all the above-described data is collected and accessible for researchers and developers (see Figure 17). This will allow for fully remote user testing, perhaps including even long-term recordings, in the natural environment of the users. The information could be used to track the users during the rehabilitation process, or when switching to a different prosthetic device. The insights that could be gained from these measurements could be of invaluable importance for future prosthetic device development and the evaluation of usage, acceptance, and satisfaction with prosthetic devices.

For the integration of eye tracking data into the proposed approach, the method will need to be tested outside a laboratory, in a more realistic setting, including distractions by noises or passing people. The challenge here is that outside the laboratory, there are no targets which can be focused on. However, we can still define areas of interest that amputees naturally focus on while ambulating. These areas of interest could be defined as the pathway, the environment, or a secondary task. Additionally, a cognitive dual-task including having to pay attention to a phone screen for example could be introduced while walking, to represent a multitasking activity close to everyday live.

Gazing patterns on areas of interest during the walking course, such as the pathway, the environment or the phone screen, time to complete the walking task with and without the dual-task, and performance on the cognitive task could be compared between lower limb prosthetic users and the able-bodied population, or between different prosthetic devices. Through this, one could gain access to information about whether an additional cognitive task impacts prosthetic users in a similar way compared to healthy controls, or whether one prosthetic device is more beneficial for the users compared to another one.

This holistic assessment method could also be used to determine whether artificial sensory feedback which is being provided during gait can benefit the users. The goal of this approach would be to determine whether the added feedback system has an effect on the experienced cognitive load of the single- and dual-task walking in a realistic environment. An effect of the artificial sensory feedback could be seen in a change in the time spent focusing on certain areas of interest, and an effect on the performance of either the motor or the cognitive task, or both. Without training of what the feedback actually means, it could be possible that it can actually lead to an increase in cognitive load. This means the prosthetic users would be mentally more occupied with interpreting the feedback, which can be reflected as an increased time spent focusing on the pathway or the prosthetic leg, slower walking in general, or a worse performance in the cognitive task. Because the users are not used to the information they receive and are unsure what to do with it and how to process it, training the participants to interpret the feedback might be needed.

# CHAPTER 5. LITERATURE


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