

MASTER THESIS

Term paper submitted in partial fulfillment of the requirements for the degree of Master of Science in Engineering at the University of Applied Sciences Technikum Wien - Degree Program Healthcare and Rehabilitation Technology

The Impact of Power on the Gait of Transfemoral Amputees

By: Paula Stemmler, BSc
Student Number: 52004349

Supervisor 1: Dr. Johannes Martinek, FH-Prof. Dipl.-Ing.
Supervisor 2: Dr. Levi Hargrove, PhD

Vienna, September 2, 2022

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Nach Amputationen der unteren Gliedmaßen zeigen Oberschenkelamputierte beim Gehen verschiedene Gangabweichungen, die langfristig zu sekundären Komorbiditäten wie Schmerzen im unteren Rücken oder Kniearthrose führen können. Um diesen Effekten entgegenzuwirken, verspricht die Entwicklung von aktiv angetriebenen Knie- und Fußprothesen Fortschritte in der Optimierung des Gangbildes von transfemorale Amputierten. Es hat sich gezeigt, dass angetriebene Beinprothesen einerseits ein Höchstmaß an Mobilität für den Amputierten erreichen und andererseits die natürliche Gangkinematik und -kinetik sehr gut abbilden. Die Auswirkungen auf die kontralaterale Kinematik und Muskelaktivität, wenn entweder das Prothesenknie und/oder der Prothesenfuß aktiv angetrieben wird, wurden jedoch bislang nicht untersucht.

In dieser experimentellen Studie wird die Auswirkung von angetriebenen Prothesen, am Knie- und am Fußpassteil von Oberschenkelamputierten, auf die kontralaterale Gelenkinematik und die Aktivität der unteren Rückenmuskulatur untersucht. Zu diesem Zweck nahmen sechs Oberschenkelamputierte (5 Männer, 1 Frau, Altersdurchschnitt 49 Jahre, Altersspanne 32-73 Jahre) an dieser Studie teil.

Alle Probanden gingen unter vier verschiedenen Bedingungen ((A) verschriebener Prothese, (B) angetriebenes Prothesenknie und angetriebener Prothesenfuß, (C) angetriebenes Prothesenknie und passiver Prothesenfuß, (D) passives Prothesenknie und angetriebener Prothesenfuß), während die Kinematik der Beine und die Muskelaktivität des linken und rechten M. erector spinae aufgezeichnet wurden. Die Studie wurde mit einem hybriden Prothesen Kniegelenk und einem aktiv angetriebenen polyzentrischen Prothesenfuß durchgeführt. Dies sind zwei neuartigen Forschungsprodukte.

Die Ergebnisse zeigten keine eindeutigen Unterschiede zwischen den Bedingungen in Bezug auf Raum-Zeit. Die Tendenz zu einer verringerten Ganggeschwindigkeit wurde in der Bedingung B festgestellt. Darüber hinaus zeigten die vier Bedingungen keine klaren Unterschiede in der Kinematik im Durchschnitt aller Probanden. Es konnte festgestellt werden, dass einige Gangabnormalitäten bei einigen Probanden ausgeprägter waren, aber diese unterschieden sich nicht zwischen den Bedingungen. Die Ergebnisse der EMG-Datenanalyse des linken und rechten M. erector spinae stimmen überein und zeigen keine Veränderungen zwischen den Bedingungen.

Insgesamt, lässt sich sagen, dass keine klaren Unterschiede zwischen den vier Bedingungen festgestellt werden konnten. Dies lässt den Schluss zu, dass die Probanden in der Lage waren, sich innerhalb kürzester Zeit an verschiedene Protheseneinstellungen anzupassen, was auch darauf hindeutet, dass sich die individuellen Gangmuster nicht in einem kurzen Zeitraum ändern. Zusammenfassend ist festzuhalten, dass diese Studie eine Grundlage für künftige Forschungen bietet, um die Auswirkungen der Kraft bei anderen Fortbewegungsarten, wie zum Beispiel beim Auf- und Absteigen von Treppen und Rampen, weiter zu untersuchen.

Schlagwörter: aktiv angetriebene Prothesen, Kinematik, Elektromyographie, Ganganalyse, transfemorale Amputierte

Abstract

Individuals with a transfemoral amputation often show gait asymmetries and several compensatory movements during walking. These deviations in gait can lead to long term secondary comorbidities, such as lower back pain or knee osteoarthritis. To counteract these effects, the development of powered knee and ankle prostheses are a promising technology. Powered leg prostheses can potentially increase mobility for the user and mimic natural gait kinematics and kinetics very closely. However, the impact on contralateral kinematics and muscle activity, and how these signals change when power is delivered via the prosthetic knee and/or ankle, has not been systematically characterized.

In this experimental study, the effect of using powered prosthetic joints, at either the knee, the ankle, or both, on contralateral joint kinematics and lower back muscle activity is being investigated. Six transfemoral amputees (5 male, 1 female, age mean 49 years, age range 32-73 years) participated in this study. All subjects walked overground in four different conditions at a self-selected comfortable speed. The four conditions included walking with their prescribed home leg (a passive knee and passive ankle), walking with a powered knee and powered ankle, walking with a powered knee and passive ankle, as well as walking with a passive knee and powered ankle. These combinations of ankle and knee conditions were evaluated with regard to lower limb kinematics and lower back erector spinae muscle activity. This study was conducted with a hybrid powered knee and a powered polycentric ankle, two novel research devices. In preparation for this study, the two devices were configured and tuned to be able to carry out the study safely and reliably, using an impedance-based model.

Results have shown similar spatio-temporal parameters, such as step length, step width or percentage distribution of swing phase and stance phase across conditions. The tendency of a decreased gait speed was seen in the condition of both powered knee and ankle, possibly due to the short acclimation period provided to subjects across the three experimental conditions. Expected differences in prosthetic side kinematics were observed, including prosthesis side ankle plantarflexion during the conditions that included the powered ankle. Results demonstrated that during this study subjects did not change their walking strategy; if a subject presented with sound side vaulting or circumduction, they continued this pattern over all conditions. The results of the EMG data analysis of the left and right erector spinae muscle showed no changes between conditions. Overall, the results show no major differences between conditions in lower back EMG as well as sagittal lower limb joint angles. This leads to the conclusion that patients were able to adapt to different prosthetic settings within a short amount of time, which also suggests that individual gait patterns do not change very quickly. In summary, this study provides a basis for future research, to further investigate the impact of power in other ambulation modes, such as ascending and descending stairs and ramps.

Keywords: Powered prostheses, kinematics, electromyography, gait analysis, transfemoral amputees

Acknowledgements

Firstly, I would like to thank my supervisors, Dr. Levi Hargrove from the Shirley Ryan Ability Lab, who gave me the great opportunity to join his research lab, as well as Dr. Johannes Martinek of the University of Applied Sciences Technikum Wien, who supported my thesis project throughout the whole process as well. Through constant coaching they had been great mentors and inspiration to me.

I would also like to thank the entire project team of the Center of Bionic Medicine, especially Dr. Annie Simon, Andrea Ikeda and Suzanne Finucane, who stood by me every day to achieve my goals with this project. Regardless of this, I was continuously given the chance to ask fellow lab mates and collaborators for help and support, which I am very thankful of.

Additionally, I would like to express my gratitude to the Marshallplan Scholarship Foundation for the financial support for my stay in the USA and to give me the chance to contribute to such innovative research.

Last but not least, I would like to thank my family and friends, for their endless support, which I am deeply grateful for.

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1 Introduction

More than one million amputations occur worldwide every year. In the United States, approximately 150,000 people undergo lower limb amputations each year.[1] A lower limb amputation has severe impact on the individual's life and body, and especially on a person's gait. Due to an amputation, different gait abnormalities can occur, which are mainly asymmetries that cause abnormal loading of the body, often due to the fact that passive prosthesis joints are used to replace active biological joints. In particular, the sound side leg is usually affected and subjected to high levels of load.[2] For this reason, research is constantly being conducted to develop new prostheses that reduce these asymmetries and to maximize quality of the amputee's life. Novel research has shown how powered knee and ankle prosthetics can improve the ambulation symmetry of transfemoral amputees. Nevertheless, these new developments keep encountering barriers, such as usability or weight and size issues.[3] In previous research, the analysis of prostheses often focuses on the mechanical performance of the device and how much it can mimic natural movements. However, the research on the impact of power on the rest of the body has been limited, especially when it comes to investigating the difference where power is added, which for transfemoral amputees could be the ankle joint or the knee joint, or even both joints. This matter is being addressed in this thesis.

In this study, a novel research knee and ankle prosthesis is used to investigate the influence of prosthetic joint power on the gait pattern of transfemoral amputees and to what extent it affects the contralateral side kinematics and muscle activities during level walking.

For this purpose, a theoretical background is given in the first chapter. A brief insight into lower limb amputations and resulting gait abnormalities of transfemoral amputees will be presented in Chapter 1.2. and 1.3. An overview of different types of analyses of transfemoral gait, and which types of prostheses are used today will follow in Chapter 1.4 and 1.5. In Chapter 1.6 a detailed overview is given of the current research and development of powered prosthetic legs and their promising impact on the gait of transfemoral amputees. The first chapter thus ends with the motivation and objectives of this study (Chapter 1.7).

Next, the methods and materials of this study are presented. The mechanical functionalities of the ankle and knee prostheses that are used in this study are described, followed by a detailed illustration of the control system (Chapter 2.1) and its configuration (Chapter 2.2), which was performed as the basis for this study. Chapter 2.3 gives an overview of the study design and the study protocol (Chapter 2.3), followed by a description of the data acquisition (Chapter 2.4) and what data analysis was performed (Chapter 2.5).

The Results of this study are presented in Chapter 3 showing the effects of power in three different categories: Spatial parameters of the gait (Chapter 3.1), joint kinematics (Chapter 3.2) focusing especially on the sound side, as well as muscle activity of the lower back (Chapter 3.3).

The thesis ends with a critical discussion of the findings (Chapter 4), as well as a conclusion and limitations of this study, and gives an outlook into further research possibilities (Chapter 5).

1.1 Lower limb amputation

An amputation of a limb can occur for a variety of reasons. The etiology ranges from diabetic patients and infections to trauma patients from accidents or war injuries. The decision to remove a part of the body is always the last option to save a person's life, as it is related to major consequences on the life of the individual.

Amputations are distinguished by which part of the body they affect: upper limb or lower limb amputations (ULA/LLA) and henceforth differentiated based on the level of the amputation. An amputation above the knee is thereby described as a transfemoral (TF) amputation, whereas a transtibial (TT) amputation is an amputation below the knee.[4]

Vascular disease is the most common reason for a LLA. In particular, patients with peripheral arterial disease and diabetes mellitus have a high risk of LLA.[5] Notably, the number of people suffering from diabetes is continuously increasing.[6] Due to an increase in medical surgery treatments, especially in endovascular interventions, major amputations have decreased. Yet, there are still circumstances where LLA is the only and last option.[7] This is in part because a lot of patients around the world do not have access to advanced medical care.[8] Besides vascular diseases, a LLA can be caused by tumors, traumas, infections, injuries and gangrenes.[9]

After a lower limb amputation, a general goal for rehabilitation is the social reintegration of the patient and increasing the quality of life to a maximum possible extent.[10] However, the attainment of this goal can be affected by various factors. For example, the more proximal the amputation, the greater the loss of anatomical structures such as bones, ligaments, and especially muscles, which are crucial for a smooth and symmetric gait.[11] Furthermore, many patients suffer from comorbidities that negatively impact successful rehabilitation.[10] Common comorbidities are back pain or knee osteoarthritis, attributed to loading abnormalities in the patient's ambulation.[11]

In addition, residual limb health is often a critical factor for a successful rehabilitation. Residual limb problems, such as skin and wound issues, circulatory disorder, or even phantom limb pain can limit the load-bearing capacity of the residual limb, and can have a significant effect on activities of daily living (ADLs) and the patient's social life.[2], [12] In general, it can be said that patients with an active life before their LLA have a higher chance for a successful rehabilitation. Eventually, in order to achieve these goals of a successful rehabilitation and to eliminate the occurring problems as much as possible, individual and careful prosthetic care is indispensable, to be able to integrate it into the patient's everyday life.[10]

1.2 Amputee gait deviations

It is common to subdivide physical gait to help investigate it more accurately. The gait cycle contains one stride, designated by heel contact of one side to the following heel contact of the same side, which is normally divided into a stance phase and a swing phase. In a physiological gait of an able-bodied subject, the stance phase takes approximately 60% of the gait cycle and the swing phase requires 40%. The gait cycle can be divided into eight subphases which are characterized by spatial and temporal characteristics of ambulation [13]:

Phase 1: Initial contact (0%)

The Initial contact describes the beginning of the stance phase and is the moment in which the heel has its first contact to the ground.

Phase 2: Loading response (0 – 12%)

The loading response starts with the initial contact and ends as soon as the contralateral leg leaves the ground (Toe-off). This phase also marks the first double support, where both legs have contact to the ground. Important for this phase is the shock absorption and stability for weight transition.

Phase 3: Mid stance (12 – 31%)

The mid stance starts with the contralateral toe-off and ends as soon as the ipsilateral heel rises off the ground. In that moment the centre of mass (CoM) is vertical to the forefoot. Especially important for this phase is stability of the trunk.

Phase 4: Terminal stance (31 – 50%)

The heel rise initiates terminal stance and ends with the initial contact of the contralateral leg. With this phase the single support is completed, and the body is being moved over the supporting foot.

Phase 5: Pre-swing (50 – 62%)

Pre-swing starts with the initial contact of the contralateral leg and ends with toe-off. This phase is also described as the second double support phase and is characterised by preparing the leg for swing phase.

Phase 6: Initial swing (62 – 75%)

The initial swing starts with toe off and ends as soon as the foot crosses the contralateral leg in the sagittal plane. In this phase the leg is being moved forward.

Phase 7: Mid swing (75 – 87%)

The mid swing starts with the leg crossing the contralateral leg and ends with the tibia being vertical to the ground. Crucial for this phase is to provide enough clearance between the ground and the foot.

Phase 8: Terminal swing (87 – 100%)

Starting with the tibia being vertical to the ground, the terminal swing ends as soon as the foot touches the ground for the next initial contact. This phase is mainly about preparing the leg for the next stance phase.

After a transfemoral amputation, the amputees are fitted with a prosthesis to restore their ability to walk. However, this impacts gait resulting in different gait abnormalities. Firstly, it causes individual to walk more slowly. Studies have shown that the average walking speed of transtibial and transfemoral amputees varies around 1.32 m/s.[13] Whereas the speed of an abled-bodied person is at around 1.39 m/s for men and 1.41 m/s for women, for elderly subjects it slows down to 1.33 m/s for men and 1.39 m/s for women. Gait speed correlates with age, height and muscle strength.[14]

Other gait deviations often appear as asymmetries between the prosthesis side and the sound side, as measured by spatio-temporal parameters. This results in a smaller step length with the sound side compared to the prosthetic limb, likely caused by disbalance in muscle activity.[15], [16] Another reason for a shortened step length with the sound side is the missing forefoot-rocker-function on the prosthetic side, in terminal stance, due to missing metatarsophalangeal joints.[13] In addition, the duration of double support on both sides is longer compared to physiological gait, which is typically because prosthetic users are less stable while bearing weight through the prosthesis, so they consequently transfer weight off on both sides.[17] Furthermore, TF amputees often show a wider stride as well as decreased gait speed and cadence compared to normal gait patterns.[15], [18]

Another compensatory movement that causes gait asymmetries is vaulting. In the case of transfemoral amputees, vaulting occurs due to the loss of knee flexion control during prosthetic swing.[19] To prevent a fall or to trip, the TF amputee performs vaulting, which is a movement on the sound side ankle that performs an excessive plantarflexion during prosthetic swing, to increase clearance of the prosthetic foot and to therefore avoid tripping on their prosthetic leg.[20] This plantarflexion occurs at around 20-26% of the gait cycle.[18], [21] This pathological gait pattern differs between patients. Often the prosthetic user is able to adjust the extent of plantarflexion, depending on the environment.[22]

Individuals also show compensatory movements in the way of hip hiking, where the prosthetic user lifts their prosthetic side hip, or lateral trunk lean, both during prosthetic swing phase, which results in asymmetric trunk movements.[19] In a lateral trunk lean, the amputee leans

over to the sound side during prosthetic swing phase. One reason this occurs is to maintain balance by moving the centre of mass towards the sound side, to compensate for the muscle deficits of the hip abductors. Another reason for hip hiking is, similarly to vaulting, to increase clearance during prosthetic swing. This lateral trunk flexion has an effect on back muscle activity and this asymmetry can lead to lower back pain.[21], [23], [24] However, another way to compensate such a functional leg length discrepancy is circumduction, where the prosthetic leg swings outward during swing phase to increase clearance and to avoid collision with the ground.[19]

Diving deeper into the different phases of the gait cycle, it can be noted that the kinematics at several points also differ from those of a physiological gait. Due to the different step length, a greater hip flexion of the intact limb occurs at the prosthetic heel strike (at around 10% of the gait cycle). In contrast, a greater hip extension occurs in the residual limb at contralateral heel strike and therefore prosthetic toe-off.

The kinematics of the prosthetic limb depend on the prosthetic device that is prescribed to the patient. However, studies have shown that in some prosthetic devices the peak knee angles during swing are decreased compared to the sound side leg and healthy subjects.[25] Furthermore, the intact limb performs a knee flexion of about 25 degrees during loading response for shock absorption, whereas the prosthetic knee performs almost no knee flexion during swing, which is caused by the prosthetic design of most knee prostheses, that would turn unstable and collapse when the user allows a flexion of the prosthetic knee.[16], [26], [27]

Prosthetic feet allow different movements in the direction of plantarflexion and dorsiflexion. The focus is often on approaching the natural ankle movements of healthy people.[28] For abled-bodied subjects an average range of motion (ROM) of about 0 degrees in dorsiflexion and 20 degrees in plantarflexion are being used during level walking. At initial contact the ankle is in a neutral position, followed by a plantarflexion during loading response. The maximal ankle dorsiflexion is reached when the tibia progresses and the centre of mass moves forward and the ankle performs a dorsiflexion of about 10 degrees in terminal stance. From this dorsiflexed position, the ankle moves quickly into a plantarflexion of 15 to 20 degrees, as a push-off into swing phase. With a slightly dorsiflexed position the ankle provides toe clearance during swing.[13] These complex movements cannot be mimicked by most prosthetic feet. In particular, plantarflexion and the movement of the push-off are not available.[29]

In addition to the effects on spatio-temporal parameters, research has found that muscle activity of transfemoral amputees is significantly increased.[30] During walking, the hip and pelvis are in translational and rotational movement, which requires a complex balancing task from the trunk to keep stability, and due to the loss of a limb, even more for transfemoral subjects.[31] Consequently, many scientists have studied the muscle activity of back muscles during gait. Studies with abled-bodied subjects, investigating the activity of the lower back erector spinae (ES) muscle, have shown most ES activity during stance phase and right before

heel strike as well as contralateral heel strike (ipsilateral pre swing). To provide sufficient stability and balance when forces transfer through the body and during load transfer, the ES is especially active in loading response and with a second peak throughout double support.[32], [33] Studies with transfemoral amputees, as well as patients with lower back pain, have shown an overall larger percentage activation during the gait cycle. Furthermore, ES activation has increased amplitudes during sound side stance, compared to prosthetic stance, which leads to an overall asymmetric muscle activation of the left and right trunk muscles.[34] However, further investigations have shown that, firstly, with increased walking speed the amplitude peaks and duration of ES activity bursts increase, and secondly, the bursts become more discrete. Furthermore, it has been detected that peak amplitudes also increase with the age of subjects.[35]

Beyond that, asymmetric kinetics in the form of increased joint loads, especially on the sound side leg, occur in transfemoral gait. Due to missing active knee extension or ankle push-off the prosthetic leg has reduced vertical and horizontal propulsion.[29] Another study has shown that increased walking speed leads to increased load asymmetries, which increases spatio-temporal asymmetries in swing and stance time.[36] Furthermore, an increased load on the sound side can cause pain and secondary comorbidities such as osteoarthritis or lower back pain.[2]

1.3 Evaluation of transfemoral gait

To quantify the gait deviations described in Chapter 1.3 gait analyses are conducted. Different tools help to collect data about a patient's gait including kinematics, kinetics, spatio-temporal parameters, and muscle activities. Gait analyses are used for clinical assessments and to evaluate rehabilitation interventions by providing objective and detailed data about possible pathologies. [37] Before evaluating the gait of transfemoral amputees, target gait patterns such as stance time, flexion and extension angles, gait symmetries and trunk movements should be clarified for effective rehabilitation.[38]

One of the most commonly used methods for the interpretation of gait are three-dimensional (3D) motion capture systems to analyze kinematics and kinetics of the moving body. These analyses can be used for diagnosis of pathological gait or evaluation of a treatment, but notably for research purposes. The most widely used 3D motion capture system is Vicon (Vicon Motion Systems, Oxford, UK). To evaluate joint kinematics and kinetics, the system uses computer models. Reflective markers, which are attached to anatomical structures of the subject, are detected by a camera system that surrounds the area that is examined. Anatomical and biomechanical models are used to estimate joint centers, by the detection of the markers on the body. These systems assume three degrees of freedom for the knee and the hip (extension/flexion, abduction/adduction, inner-/outer rotation) and two for the ankle (extension/flexion, inversion/eversion). To further detect kinetic data, the camera system is

combined with force plates (e.g. Kistler force plates, Kistler Instrumente GmbH, Sindelfingen, Germany) using inverse dynamics to calculate ground reaction forces and joint moments.[39] To determine effects of interventions (e.g., different types of prostheses), knowledge of normal or physiological gait mechanics are used as a basis to then investigate changed mechanisms. Accordingly, 3D analysis has become a common method for scientific or clinical purposes to quantify gait abnormalities[37]. Sources of error for these systems are tissue artifacts causing the marker to move, resulting in incorrect assumptions of the marker's location.[39]

Although 3D motion capture tools have proven their validity and accuracy in several studies, these systems are expensive, and require intensive and time-consuming preparation, as well as a permanent research laboratory setting. Consequently, they are not available in many clinical settings.[40] For this purpose, several companies have worked on solutions for valid kinematic analyzing tools with increased usability. A common approach for such systems is mostly the development of wearable IMU (inertial measurement unit) based methods, as they do not require a limited space or a laboratory environment, (e.g. Xsens, Xsens Technologies B.V., Enschede, Netherlands).[41] Most IMUs contain accelerometers, gyroscopes, and magnetometers. Several tests have compared IMU gait data with visual motion capture systems data and came to the conclusion that most IMU systems have a high accuracy in the sagittal plane to determine flexion and extension angles, but a lower correlation in the direct comparison of values, such as maximum joint angles, whereas they are still valid and used for quantifying kinematic data and gait patterns.[42], [43], [44]

IMU based systems can also be used to identify spatio-temporal parameters of gait.[45] Spatio-temporal parameters include gait velocity, cadence, step length, step width, as well as swing and stance phase percentage of the whole gait cycle.[46] Especially for the evaluation of transfemoral gait, spatio-temporal parameters provide a comprehensive and basic understanding of the symmetries between the prosthetic and sound side.

Rather than using quantitative gait analyses, for relatively simple way and without any expenses, several outcome measurements can be used to indirectly assess gait, which are especially useful in a clinical environment. These include, for instance, the 2 minute walk (2MWT), the time up and go (TUG) or the 10 meter walk test (10MWT).[47], [48], [49] With slightly different approaches, all methods aim to inspect a patient's current state, and in case of repeated measurements, the progress of a therapy or, in transfemoral amputees, the fitting of the prosthesis, is evaluated.[48] This is primarily a question of the pace at which certain tasks are completed, and accordingly how this speed is changed by different supplies.[47] This offers a simple and inexpensive alternative to draw fast conclusions about a prosthetic device.

Electromyography (EMG) is an experimental measuring method to record and analyze myoelectrical signals that are generated by the action potential in the muscle fiber membrane. There are different types of electrodes to collect those signals. Non-invasive surface electrodes

are primarily used in gait analysis. To measure the muscle activity of one muscle, two surface electrodes are attached to the muscle, parallel to the direction of the muscle fibers. There are several external influencing factors that can distort results and therefore have to be taken into account when measuring surface EMG. One of the main disruptive factors can be the subcutaneous tissue between the muscle and the electrode, that can be either thicker or thinner and therefore change the amplitude and frequency of the EMG signals.[50] Motion artifacts are similar distribution factors that are difficult to control, especially when examining a moving subject, but that can be avoided as much as possible when securing the electrodes properly.[51]

Another common factor is the physiological cross-talk. Cross-talk indicates contamination of the measurement by the accidental measurement of a nearby muscle. Furthermore, external interfering voltages can manipulate the signal, and are noticeable by a continuous 50 or 60 Hz signal depending on the frequency of the electrical mains. To eliminate several distribution factors, an amplifier is connected to electrodes to, on the one hand filter signals (usually with a band-pass filter between 10 – 500 Hz) and, on the other hand to amplify the signals by about 500 – 1000 Hz. This setup can then be used to record muscle activity from a wide variety of muscles during gait. Different analyses can be carried out to determine whether or not a muscle is active, the timing of the muscle activation, how active a muscle is, or even when a muscle fatigues.[50], [51] Further, a rectification and calculation of the EMG integral, as well as the median frequency, can be executed.[52] When measuring EMG, no direct conclusions can be drawn about the muscle strength, rather only about how active a muscle is.[53]

1.4 State of the art prostheses for transfemoral amputees

Several hundred years ago, in 1579, the first types of prostheses were built to replace lost limbs, by the surgeon Ambrorise Paré.[54] A major growth in the world of prostheses then occurred, above all, as a result of the two world wars. A large number of injured soldiers had lost arms and legs due to battles, which then had to be treated with prostheses to restore as much lost functionality as possible.[55] Not only did the prosthetic devices develop, but surgical amputation techniques were also established to ensure a residual limb with less infections and sufficient blood supply after amputation. Thus, amputation no longer represented a high risk to life, but instead was recognized as a life-saving intervention in highly critical situations.[56] More prosthetic companies were founded throughout the years and the constant development of new technologies has increased, and is still growing today.

A wide variety of different prosthetic devices can be found on the market, which can be distinguished mainly by their functionalities. In the production and development of prostheses, the main objective is to increase the quality of the patient's life and his or her full social participation, as well as the reintegration to the maximum possible extent, by mimicking natural movements of the ankle and knee joint.[28]

The basic structure of a transfemoral prostheses, starting at the residual limb, consists of a socket that represents the connection between the prosthesis and the human being. It plays the decisive role in a patient's comfort with the prosthesis, or how well they are able to use it. There are many different design variants, however, it is crucial that the socket offers a high degree of suspension and remains comfortable. The socket is then connected to a knee joint via an adapter. The prosthetic knee should replace as many lost functions as possible while providing maximum safety. Further distal, the foot is assembled with the knee through a pylon, and therefore represents the connection to the ground as well as the support surface for the patient's body.[57]

Correct prosthetic fit is, on the one hand, crucial for amputees' comfort but, on the other hand, used to protect the rest of the body's structure from secondary complications and implications.[2]

As already noted, there are now many different types of prosthetic feet. To obtain an overview, they can be well divided into their construction characteristics, based on their energy source. A distinction is made between passive (mechanical) and active (microprocessor-controlled) prosthetic legs. A passive knee cannot produce any energy, whereas active knees can have the option to use external energy resources as actuators.[4]

In distinction of prosthetic feet, these two main categories can be observed as well, with on the one side mechanical prosthetic feet and, on the other side microprocessor controlled prosthetic feet. Among the mechanical feet, a distinction can be made between hinge-less and hinged devices. Hinge-less feet get their functionality from the deformation of materials, either from plastic materials or mostly carbon fibre. Due to the elasticity of the materials, the prosthetic foot deforms by the movement of the amputee and therefore provides a return of energy, which enables, for example, the rolling over the foot during walking. An example for these carbon fibre feet is the VariFlex (Össur, Reykjavik, Iceland) (Figure 1(b)) or the Triton (Ottobock, Duderstadt, Germany).



Figure 1: Echelon (Blatchford, Basingstoke, UK) hinged prosthetic foot (a) and LP VariFlex (Össur, Reykjavik, Iceland) carbon fiber prosthetic foot (b).

a: <https://www.blatchford.co.uk/products/echelon/> (last accessed: 08/25/2022),

b: <https://www.ossur.com/de-de/prothetik/fusse/lp-vari-flex/> (last accessed: 08/25/2022)

Hinged devices, such as the Echelon (Blatchford, Basingstoke, UK) (Figure 1(a)) have a carbon fibre spring as well and, in addition, an ankle joint, which is constructed with a hydraulic system to allow movement in plantar – and dorsiflexion. Mechanical hinged prosthetic feet are being used less frequently.



Figure 2: Empower (Ottobock, Duderstadt, Germany) powered prosthetic foot (a) and microprocessor controlled Proprio foot (Össur, Reykjavik, Iceland) (b)

a: <https://shop.ottobock.us/Prosthetics/Lower-Limb-Prosthetics/Feet---Microprocessor/Empower/p/1A1-2> (last accessed: 08/25/2022),

b: <https://www.ossur.com/de-de/prothetik/fusse/proprio-foot/> (last accessed: 08/25/2022)

Alternatively, there are the active prosthetic feet, such as the Proprio foot (Össur, Reykjavik, Iceland) (Figure 2(b)) or the Elan (Blatchford, Basingstoke, UK). Through different sensors, these feet detect which situation the user is in (level ground walking, walking on a ramp, standing, sitting) and therefore regulates, with an actuator, the desired resistance into plantarflexion or dorsiflexion electronically, by not providing positive energy.[28]

Besides these prosthetic feet there are also new developments in the field of powered microprocessor-controlled feet. Next to the ability to measure positions or angles of the foot, a powered prosthetic foot, has an integrated actuator which can provide positive net energy to perform ankle movements. Up to today there are only a few powered prosthetic feet on the market, such as the Empower (Ottobock, Duderstadt, Germany) (Figure 2(a)).[28]

Similar to prosthetic feet, there is also a range of different types of prosthetic knees which can be distinguished. Mechanical and passive prosthetic knees are relatively simple knees, but they already fulfil a large portion of the required functions for prosthetic knees. With different mechanical constructions, the user is able to bend the knee in swing phase and be stable in stance phase. In that case the user often performs unnatural movements to swing the knee, and to be stable and secure it in stance phase as well as standing. In addition, the user is limited in options on what movements can be performed with the prosthesis. Thus, some situations must be made with compensatory movements.[58] The 3R80 (Ottobock, Duderstadt, Germany) is, for example, an mechanical knee prosthesis, functioning with a rotational hydraulic (Figure 3(a)).



Figure 3: Mechanical knee (a), microprocessor controlled knee (b), powered knee (c)

a: <https://www.ottobock.com/de-de/product/3R80> (last accessed: 08/25/2022)

b: <https://www.ossur.com/en-us/prosthetics/knees/rheo-knee> (last accessed: 08/25/2022)

c: <https://www.ossur.com/de-de/prothetik/knie/power-knee> (last accessed: 08/25/2022)

The active category of prosthetic knees can be distinguished in the same way as the feet. There are several popular microprocessor-controlled knees on the market for different user types, such as the C-Leg 3R80 (Ottobock, Duderstadt, Germany) or the Rheo Knee (Össur, Reykjavik, Iceland) (Figure 3(b)). With the integrated sensors, the control of the knee is supported. Resistance parameters are regulated depending on the situation and positions the user and the leg are in. Furthermore, compared to the mechanical knees, more ambulation modes are made possible for the user. Such as alternating down a ramp or stairs, or even sitting down.[59]

To have the additional ability to go up the stairs, or to stand up without compensatory movements, the category of active and powered prosthetic devices is required. A commercially available powered knee is, for example, the Power Knee (Össur, Reykjavik, Iceland) (Figure 3(c)). Because those activities require net positive mechanical work, powered knees have an actuator that can generate active positive power, which allows users a great increase of possible activities that can be performed in their daily life.[60]

Even though the functionality of powered knees and ankles sounds promising, there exist some disadvantages, as well. Despite the fact that users with mechanical prosthetic devices are limited in their possibilities of different ambulation and movements, they benefit from the usability and robustness of those devices. Since they work purely mechanically, and no additional electronics or batteries are installed, the weight is significantly reduced.[61] An average mechanical knee weighs between 0.6kg – 1.2kg [61], whereas microprocessor-controlled knees have an average weight of 1.3kg.[62] With a weight of about 3kg, powered knees are by far the heaviest.[63] Even though the weight is still less than the weight of a healthy limb, studies have shown that the weight of a prosthesis feels comparatively heavier than its actual weight. The reason being that a healthy leg is connected to the rest of the body with bones, ligaments and muscles as part of the body, and therefore it is part of the full body mass. A prosthesis, however, is merely just attached to the body – specifically the residual limb - which must carry and tolerate the whole load of the prosthesis. For this reason, amputees often choose the most lightweight prosthesis and rather dispense additional functions.[64] Due to the comparatively simple design of mechanical prosthetic devices, they also require less maintenance and repair costs. In addition, the usability of those components is quite high, as they do not require regular charging.[65]

However, it can be said that the higher the functionality and freedom in different ambulation modes is, the heavier and more complicated the construction of the device gets. Thus, each of the different types of lower limb prostheses has its reason to be on the market and to meet the different needs of a large group of patients.

1.5 Research and development of powered prosthetic legs

Despite the many possibilities offered by the prosthetic market, functional and physical properties play a crucial role in the patient's satisfaction with a prosthesis. However, these properties are still not fulfilled.[66] Therefore, many research institutes around the world concentrate on further developments and new ideas on how to increase options to improve ambulation, especially in the field of powered prostheses. The reason why there are still few powered devices on the market, and being used by patients, is the hurdle of making such complex systems suitable for everyday use. The challenges of developing powered devices that are useful for daily living activities, often lie in controlling the leg in an environment outside of the lab.[3]

However, development concentrates on overcoming the disadvantages of powered devices by reducing the weight as well as its reliability in activities of daily living. For this reason, there are several powered devices in research, which have already been published in papers and promise a new era in the prosthetic world.

In the development of powered ankles, the main obstacle is to fit the weight and size similar to a human foot. Some researchers have developed powered prosthetic ankles that combine a parallel spring and a constrain controllable actuator.[67] Others designed semi-powered ankle devices with controlled damping and repositioning functionalities, which are even more lightweight than fully powered prostheses. In contrast to commercially available passive carbon fibre feet, they promise to reproduce healthy ankle behaviour.[68] In turn, the Massachusetts Institute of Technology has developed a powered ankle foot prosthesis that mimics human ankle kinetics and kinematics during gait.[69], [70]

The same issue occurs with powered knees, it is difficult to match the weight of passive prosthetic knees. Still, there are several attempts of robotic knees, that match those requirements and still provide suitable torque. This is done with the help of innovative systems such as an actively variable transmission control.[71]

Besides the development of either a knee or an ankle device, many research institutes have begun to focus on combined powered ankle-knee prosthetics. These prosthetics are often developed to conduct further research on controllers and actuator systems and not always necessarily to develop a finished product that fits all prosthetic requirements. For this purpose, the Open Source Leg (OSL) was developed, which is available to many groups, which will allow for better comparison across organizations.[72] Thus, these prostheses are used for laboratory testing and controller development.[73]

Different approaches in novel controlling and actuator systems have been proposed. A considerable number of papers focus on intuitive control with intent recognition algorithms. The main issue with these methods is a delay with which the system adapts to new modes or velocity changes and, therefore, a decrease in usability for ADLs.[74] Another innovative development is the control of the prosthetic leg with visual systems that can predict environmental changes and upcoming obstacles and thus, change the prosthesis into different ambulation modes. These approaches have been tested with powered prosthesis prototypes with actuators for knee and ankle, and a sensing system with depth cameras.[75]

Furthermore, advances to improve the weight of prosthesis, series elastic actuator or low-impedance actuators are being designed to create a lightweight version of actuators.[76],[77]

All these innovative developments have the goal to improve the biomechanics in gait of amputees. Strategies on neural control of powered knee and ankle prostheses have shown that intuitive control is possible and would be a great improvement for transfemoral

amputees.[78] Similar to this is the prosthetic control with EMG to predict intended ankle positions for intuitive control.[79]

Yet, only a few studies have examined the effect of powered leg prostheses on the contralateral limb. A recent paper that studied the impact on the contralateral limb with a commercial powered ankle prosthesis and a microprocessor controlled leg found out that subjects had no effect in their walking velocity, but experienced a significant reduction of knee frontal moments on the sound side, due to the powered ankle push-off.[80] The same effect was examined with transtibial subjects, with reduces load on the contralateral limb. This outcome results in reduced musculoskeletal stress due to powered prostheses mimicking natural ankle biomechanics.[81], [82]

Another often studied effect of powered lower limb prostheses is the significant reduction of metabolic costs by providing human like power at the leg, on level ground walking as well as uphill walking.[83], [70], [84]

In addition to these positive outcomes, recent research has shown that powered prosthetic devices could limit hip circumduction compensatory movements and therefore improve gait symmetries.[85] This can be seen, for example, on lower back muscle activity, where reduced asymmetries were examined in a comparison of a powered leg with a microprocessor controlled knee.[86] A very decisive role in this context is played by the timing of the powered ankle push-off for the improvement of gait, and the impact on the contralateral limb.[87]

Nevertheless, a study has shown no overall significant improvement of the user perspective or in the users' daily activities. However, strong variations between subjects were observed, which still shows the chances of powered devices improving everyday life of an amputee.[88]

1.6 Motivation and aim

It is apparent that a lot of research has been conducted on powered prosthetic legs, proving the advantages of powered prostheses (as shown in Chapter 1.6) with the assumption of increasing the quality of life of transfemoral amputees. However, the main focus of these studies is particularly on the improvement of the control and actuators of powered knee and ankle devices to demonstrate the impact on the biomechanics of transfemoral amputees. In consequence, little research has been conducted on the effects and differences when power is added at the prosthetic knee or prosthetic ankle alone.

Although, some studies have examined the impact of powered prostheses on the contralateral limb or muscle activities, they have been limited in investigating the impact of the joint location of power on the gait of transfemoral amputees. This study is intended to provide some clarity in this matter by examining general spatio-temporal parameters, contralateral lower limb kinematics as well as muscle activity of the lower back.

In order to achieve this goal, control was developed for a novel lightweight powered prosthesis such that both the knee and ankle joints could allow for comfortable and near-biomechanically correct ambulation for the subject in various combinations of passive and active modes and that the system could flexibly change between these powered conditions.

Following, the goal was to conduct a preliminary study to gain first insights into the effect of the location of powered device for transfemoral amputees in level walking, to create a general understanding and to give a basis for future studies in this matter. Results of the present study can shed light on the effects of powered prosthetic devices on the biomechanics of the user. In turn, these new insights can be used in clinical settings to reduce secondary comorbidities (such as gait abnormalities), possibly resulting in more individualized treatments contributing to a greater quality of life of the patient.

Accordingly, this study tries to answer the following research question:

How does power at the knee and/or ankle effect contralateral limb kinematics and lower back muscle activity in level walking of transfemoral amputees?

2 Materials and methods

2.1 Control system

Hybrid powered knee

This study is performed with a hybrid powered prosthetic knee, a novel development of a lightweight powered knee prosthesis (Figure 4).[89] This device is still a research prototype but has proven its functionality in several studies.[89], [90], [71] The main characteristic of the hybrid powered knee is, as the name indicates, its functionality to switch between a passive and active operation mode. A combination of a spring damper system with an electric motor and transmission system results in significant weight reduction.[90]

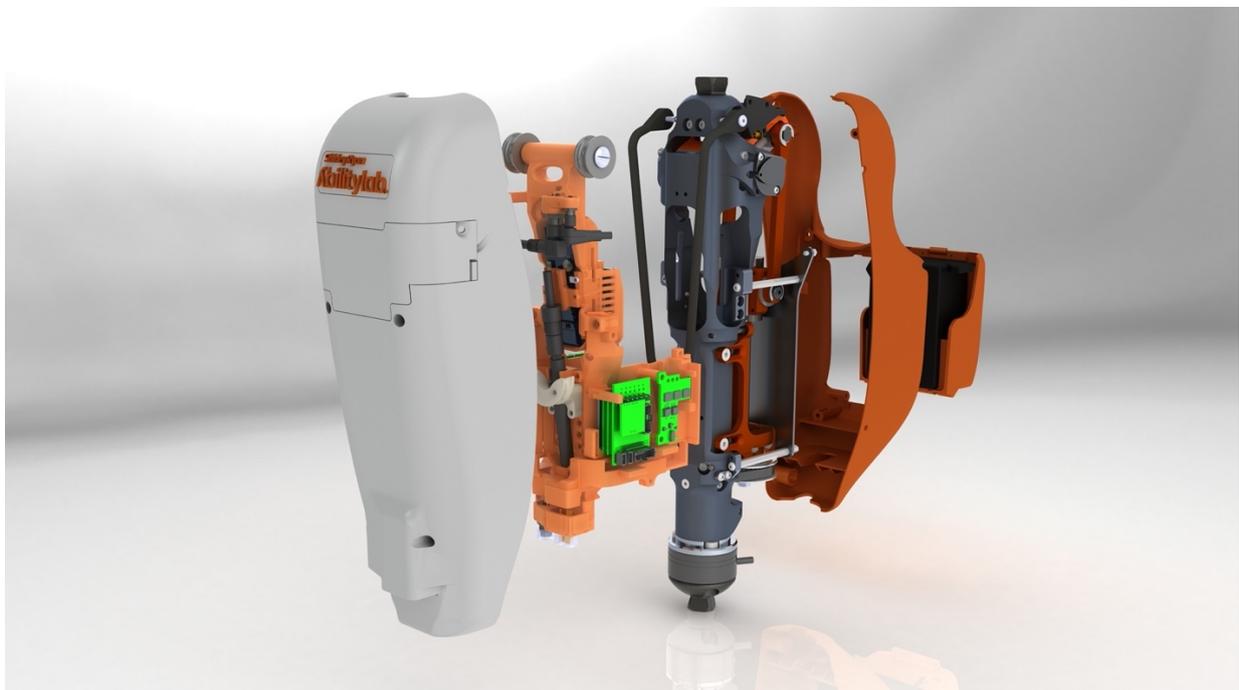


Figure 4: Render of the hybrid powered knee

The total weight of the knee is at 1.7 kg and is able to provide a repetitive torque of 125Nm. To selectively change between the active and passive mode the spring damper is permanently engaged and then a novel actively variable transmission (AVT), which allows a different transmission ratio for each ambulation, can be activated to enable the electric motor.[91] With this possibility to change between active and passive modes, power is only used in ambulation modes where it is needed, such as stair ascent or sit to stand movements, to provide the prosthesis with power to be able to perform those movements. Therefore, it has the effect of higher electrical efficiency as a smaller motor and transmission system is used, compared to a fixed transmission ratio across all activities. Furthermore, as the motor control and actuator is only needed for a short period of time, a smaller battery is needed.[89]

Even though this is the most energy efficient way of using the hybrid powered knee, it is still possible to use the active mode throughout all ambulation activities.

Powered polycentric ankle

In this study a powered polycentric ankle (Figure 5) is used, a novel development of a powered prosthetic device that is designed to be as lightweight as possible. The ankle has a weight of approximately 1kg, it can provide 125Nm of repetitive peak torque and has a range of motion (ROM) of about 44 degrees.[92] To achieve the goal of a lightweight foot prosthesis that still matches the requirements to act biomechanically accurate and provide enough power for common ambulation, this ankle has a unique polycentric mechanism.[93]

A polycentric design is known as a mechanism that represents a joint that rotates not only around one fixed centre of rotation (CR). The joint is constructed by moving four bar chain, which leads to the effect of having a moving centre of rotation, as opposed to an instantaneous centre of rotation (ICR). The ICR is moving on a curve, which describes a rotational and translational movement. [94] Therefore, the powered polycentric ankle has no physical ankle joint, thus the four bar polycentric mechanism and its ICR defines the position of the ankle between the foot and shank.[92]

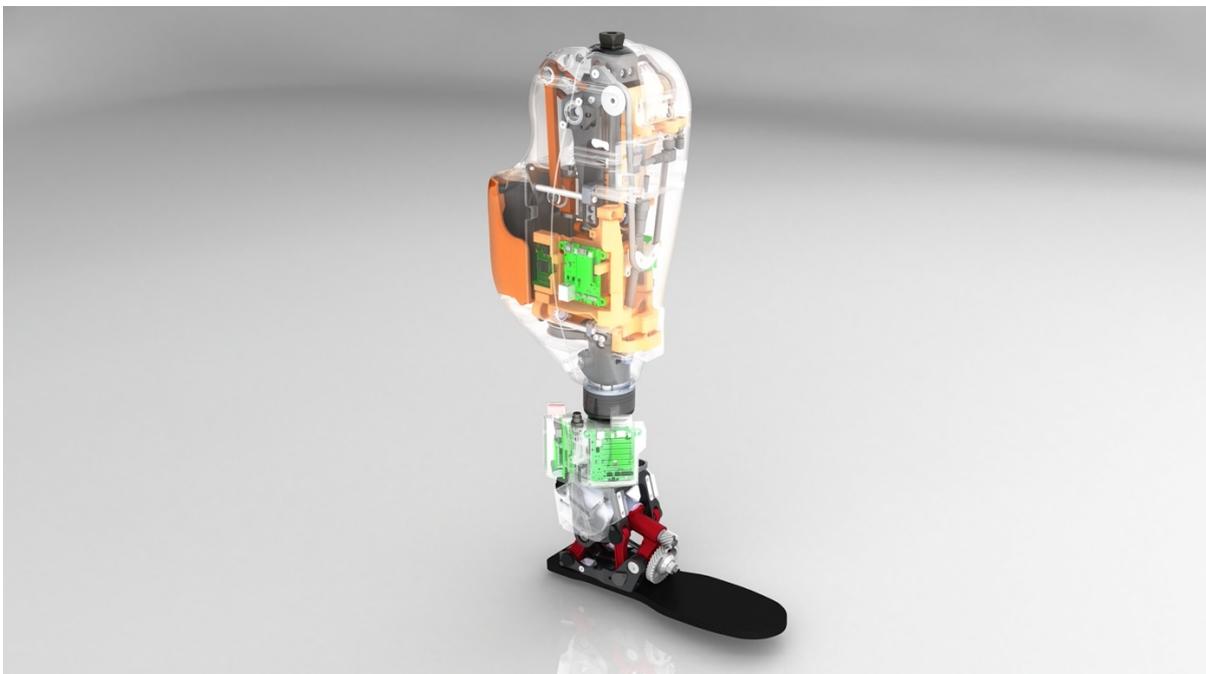


Figure 5: Render of the powered polycentric ankle assembled with the hybrid powered knee.

However, the ICR of the polycentric ankle has an effect on the ankle torque requirements, which depend on the moment arm and the value of ground reaction forces (GRF). Compared to a monocentric design, the ICR of the polycentric mechanism is anterior to the ankle joint location, which leads to lower plantarflexion torque and higher dorsiflexion torque. Gabert et al. study has shown that, with this shift of the centre of rotation and subsequent changed torque

requirements and moment arms the peak force of the linear actuator is decreased by 34.1% compared to conventional monocentric designs. Finally, this allows a lighter and more compact design.[93]

In contrast to the hybrid powered knee, the powered polycentric ankle is only able to operate in an active and powered mode and not in a passive mode.

Control system

There are numerous ways that a powered prosthetic leg can be controlled. In the case of this study with the hybrid knee and the polycentric ankle it is controlled by an impedance-based model, where the impedance parameters are switched using a finite-state-machine. The following equation (1) describes how torque (τ) commands for the knee and ankle joint (i) are generated withing each state (according to [95])

$$\tau_i = -k_i(\theta_i - \theta_{ei}) - b\dot{\theta}_i \quad (1)$$

The equation uses three impedance parameters, which are the equilibrium angle (θ_e), stiffness (k), and damping (b). The leg is equipped with several sensors to measure joint angular position (θ), and angular velocity ($\dot{\theta}$), which are used as inputs to the torque aquation. A six degree-of-freedom load cell, incorporated into the shank, measures loads and moments which are used as additional inputs to the control. When a subject starts walking, as it is being done in this study, the leg moves through different states and receives and output with different impedance parameters corresponding to the phase of the gait cycle. Figure 6 shows a schematic diagram of the four states that the leg goes through to complete one stride as a subject walks on it. Progression through the state-machine and the torque produced depend on the sensor data processed by the leg.

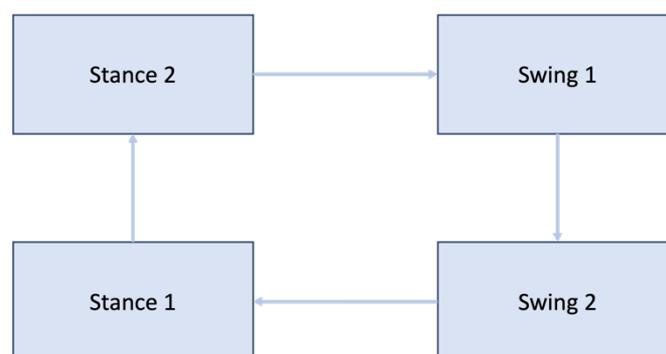


Figure 6: schematic overview of states during level walking

To control the leg, we segmented the gait cycle into four states: two states for the stance phase and another two for swing phase. Stance 1 as the beginning of stance until mid stance, stance

2 as terminal stance and pre swing. Swing 1 as the first half of swing phase and swing 2 as the second. In all states different impedance parameters are hand-tuned using a trial-and-error process such that the resulting movement matches a physiological gait cycle.

The arrows between the state represent triggers that are activated if certain requirements are true, for instance if the leg sensors are measuring a combination of angle and/or load values that are required to jump to the next state where new impedance parameters are sent. This way, the leg can be controlled, and the correct impedance parameters can be sent at the right times.

2.2 System configuration

To investigate the impact of prosthesis joint power on the gait of transfemoral amputees, the hybrid knee and polycentric ankle, described in Chapter 2.1, were used for this study. For this purpose, the leg is tested in different combinations of powered and passive combinations of the knee and the ankle.

Therefore, subjects walking in four different conditions will be examined:

Condition A: Prescribed home leg, control condition (passive knee and passive ankle)

Condition B: Powered knee and powered ankle (A1K1)

Condition C: Passive knee and powered ankle (A1K0)

Condition D: Powered knee and passive ankle (A0K1)

In condition B, the hybrid knee, as well as the polycentric ankle, are powered. In condition C, the hybrid knee is changed into the passive mode, but the the ankle remains powered. The other way around is in condition D, as the knee is powered again and the polycentric ankle is exchanged with a conventional carbon fibre foot (LP VariFlex, Össur, Reykjavik, Iceland). This choice was made because during preliminary testing we could not program the polycentric ankle to function appropriately as a passive foot.

To perform this study and thus these conditions, the configuration of the leg was developed first. For this purpose, an individual state machine, specifically for this study, was created in the control system (Figure 7).

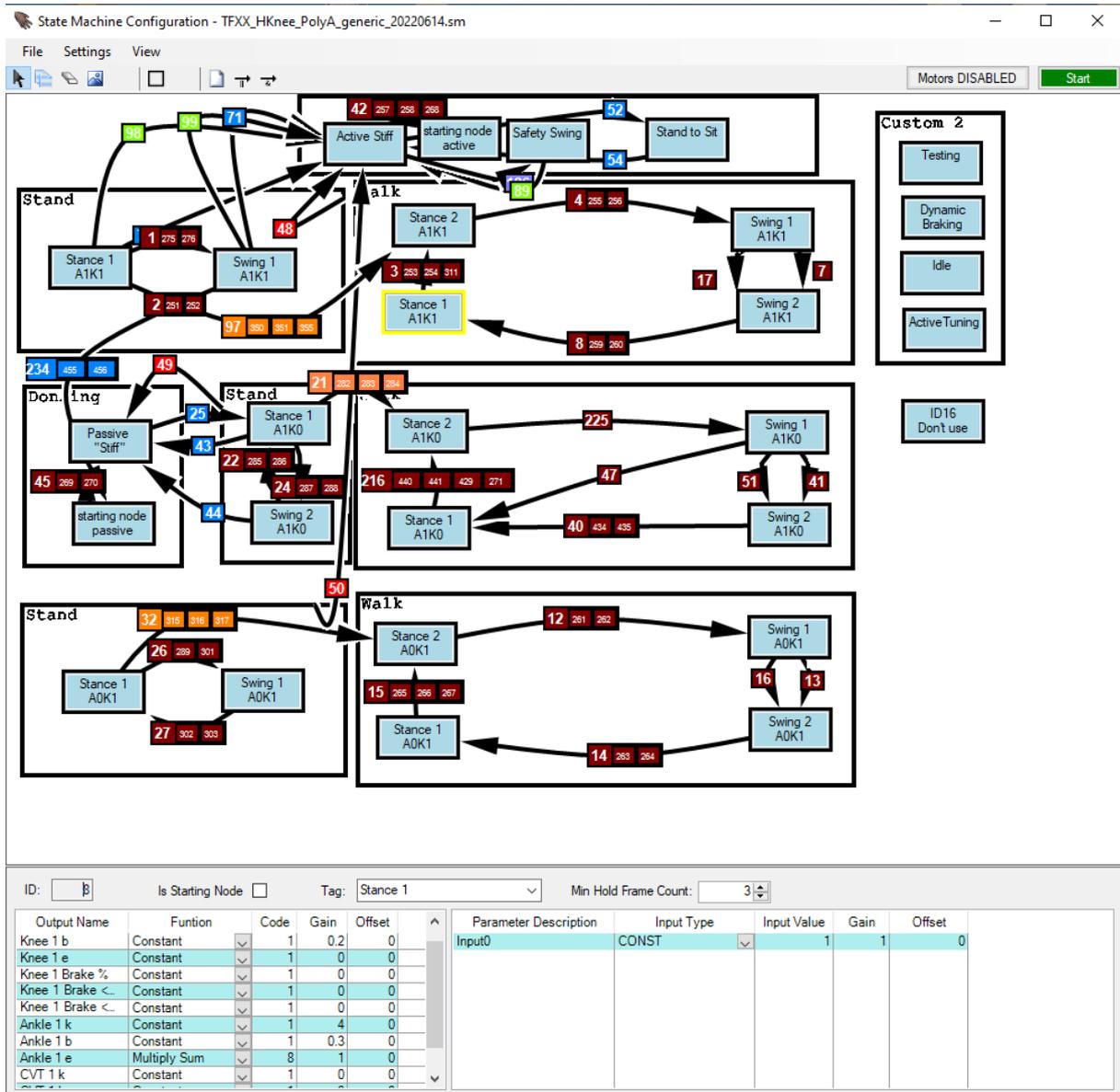


Figure 7: Screenshot of the developed state machine in the controlling tool for the hybrid powered knee and the polycentric ankle

In this state-diagram, the large, black-outlined boxes are the different modes and conditions the leg can be in. The small blue boxes are the individual states where different impedance parameters are configured. The arrows with different coloured numbers are state-machine transitions, also called triggers, that define the circumstances that have to be matched to transition from one state to another. These triggers depend on sensor outputs from the leg, for example if the subject is standing on the leg, it is in the state of “stance 1” and as soon as the leg is unloaded, measured by a reduction in the vertical axis of the load cell, the state changes through the trigger into “stance 2”.

Every row of boxes represents one condition (A1K1, A1K0, A0K1). The standing modes were mainly used for a smooth transition after donning or before walking on the prostheses, so the

subject can comfortably stand on the prostheses. All data was collected during walking, and therefore when the state machine was in the “walk” mode.

Impedance parameters were not constrained to be constant within individual states. Rather, they could be generated using equations, as described in prior work.[95] In the following, these functions are explained in more detail:

(1) Rate based function

Output Name	Function	Code	Gain	Offset	Parameter Description	Input Type	Input Value	Gain	Offset
Knee 1 k	Rate Based v2	11	1	0	Fz (Independent Variable)	Chan MV	3	1	0
Knee 1 b	Constant	1	0.05	0	Rate-change	CONST	1	1	0
Knee 1 e	Rate Based v2	11	1	0	Initial Dependent	Prev SM DOF ACT	1	1	0
Knee 1 Brake %	Constant	1	0	0	Final Dependent	CONST	60	1	0
Knee 1 Brake <	Constant	1	0	0	Fz (Initial Independent)	Chan MV St Entry	3	1	0
Knee 1 Brake <	Constant	1	0	0	Final Independent	CONST	0.2	1	0
Ankle 1 k	Constant	1	6	0	Min Limit	CONST	-120	1	0
Ankle 1 b	Constant	1	0.3	0	Max Limit	CONST	120	1	0
Ankle 1 e	Constant	1	0	0					

Figure 8: Rate based function in the state machine to control impedance parameters

The rate based function allowed for joint impedance to be modulated as a function of decreasing prosthesis load. For example, knee stiffness and knee equilibrium were modulated during late stance up to toe off as a function of axial load. As the individual transferred load off of the leg these parameters changed at a similar rate (e.g., the faster the subject transferred weight off of the leg the faster these parameters changed).

(2) Switch value

Output Name	Function	Code	Gain	Offset	Parameter Description	Input Type	Input Value	Gain	Offset
Knee k	Constant	1	0	0	Start Value	CONST	0.05	1	0
Knee b	Switch Value	6	1	0	Switch to Value	CONST	0.2	1	0
Knee e	Constant	1	0	0	Signal 1	Chan MV	1	65.534	0
Ankle k	Constant	1	0	0	< Threshold 1	CONST	15	1	0
Ankle b	Constant	1	0.3	0	AND Signal 2	Chan MV	2	1	0
Ankle e	Constant	1	0	0	< Threshold 2	CONST	0	1	0
					Min Limit	CONST	0	1	0
					Max Limit	CONST	1	1	0

Figure 9: Switch value function on the state machine to control impedance parameters

The switch value function allows change between one and the other value under certain specified conditions, while remaining in one state. Therefore, a start value and a target value (switch to value) are defined. The impedance parameter changes to the target value if one or two threshold values had been reached. The function value is limited between a minimum and maximum level.

(3) Multiply sum

Output Name	Function	Code	Gain	Offset	Parameter Description	Input Type	Input Value	Gain	Offset
Knee F/E	DOF Bypass	0	1	0	Multiplier	CONST	1	1	0
Ankle F/E	DOF Bypass	0	1	0	Addend 1	Prev SM DOF ACT	0	1	0
Knee k	Constant	1	1	0	Addend 2	DOF ACT	1	-0.03	0
Knee b	Constant	1	0.3	0	Min Limit	CONST	0	1	0
Knee e	Multiply Sum	8	1	0	Max Limit	CONST	90	1	0
Ankle k	Constant	1	2	0					
Ankle b	Constant	1	0.3	0					
Ankle e	Multiply Sum	8	1	0					

Figure 10: Multiply sum function in the state machine to control impedance parameters

The multiply sum function allows for several different linear relationships to be programmed into the controller as well as to set a minimum and maximum limit. In this study it was used to modify ankle equilibrium as a function of thigh angle for powered plantarflexion.

(4) Linear ramp

Output Name	Function	Code	Gain	Offset	Parameter Description	Input Type	Input Value	Gain	Offset
Knee k	Constant	1	3	0	Starting Value	CONST	0	1	0
Knee b	Constant	1	0.35	0	Target Value	CONST	-5	1	0
Knee e	State Chg Latch	5	1	0	Time (ms)	CONST	300	1	0
Ankle k	Constant	1	7	0					
Ankle b	Constant	1	0.25	0					
Ankle e	Linear Ramp	2	1	0					

Figure 11: Linear ramp function in the state machine to control impedance parameters

With the linear ramp function values can change linearly from one value to another, while remaining in one state. The impedance parameter value is a function of time (in milliseconds).

Table 1 shows the programmed impedance parameters for the knee and the ankle in each condition. For the A1K1 condition (knee and ankle powered), impedance parameters were configured for the knee and the ankle. For the A1K0 condition (powered ankle and passive knee) only the ankle was configured using impedance parameters, whereas the passive knee is regulated by different inputs for breaking, depending on the state, the leg is in. Breaking values could be modified using the knee angle and velocity to specify the amount of breaking percentage. For the A0K1 condition (passive ankle and powered knee) only the knee was configured using impedance parameters, as the powered polycentric foot was replaced with a passive carbon fibre foot.

Condition	State	Knee parameters			Ankle parameter		
		Stiffness k (Nm/deg)	Damping b (Ns/deg)	Equilibrium Angle θ_e (deg)	Stiffness k (Nm/deg)	Damping b (Ns/deg)	Equilibrium Angle θ_e (deg)
A1K1 (powered ankle and powered knee)	Stance 1	3	0.2	0	6	0.3	func. (3) (previous value to 8 - 12)
	Stance 2	func. (1) (previous value to 1 - 2)	0.05 - 0.1	func. (1) (previous value to 40 - 50)	func. (3) (previous value to 8 - 12)	0.3	func. (3) (previous value to 8 - 12)
	Swing 1	0.6	0.05	50	4	0.4	3
	Swing 2	1	func. (2) (0.05 - 0.1 to 0.15)	func. (4) (previous value to 0)	3	0.3	0
A1K0 (powered ankle and passive knee)	Stance 1		100% breaking		6	0.4	func. (3) (previous value to 8 - 12)
	Stance 2		0% breaking		func. (3) (previous value to 8 - 12)	0.6	func. (3) (previous value to 8 - 12)
	Swing 1		70% breaking, 10 / -40		5	0.3	3
	Swing 2		70% breaking, 10 / -40		3	0.3	0
A0K1 (passive ankle and powered knee)	Stance 1	3	0.2	0	-	-	-
	Stance 2	func. (1) (previous value to 1 - 2)	0.05	func. (1) (previous value to 40 - 50)	-	-	-
	Swing 1	1	0.05	60	-	-	-
	Swing 2	1	func. (2) (0.05 - 0.1 to 0.15)	func. (4) (previous value to 0)	-	-	-

Table 1: Configuration of impedance parameters for hybrid knee and polycentric ankle control. Bold text marks parameters that were tuned between subjects.

This state machine was tested as a preliminary evaluation in several sessions, to then define a configuration that was used as a starting point for all data collections in this study.

First step: T-handle testing (Figure 12)



The use of a t-handle is particularly suitable for initial testing. The functions can be tested by moving the device and applying load to the prosthesis. Thus, errors in functions or configurations of the state machine can be identified and corrected before someone walks on the prosthesis.

Figure 12: Picture of a t-handle, testing functionalities of the powered leg prosthesis

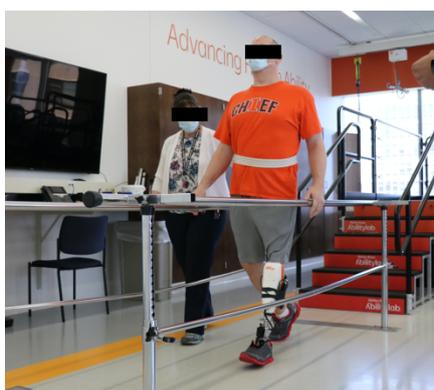
Second step: Bypass testing (Figure 13)



Bypass testing uses a construction through which even a healthy person can walk with a prosthesis and test the effects of it. This is particularly suitable when it has already been determined that there are no longer safety concerns, but the benefits and effects of new functions are to be tested, before a transfemoral amputee subject visits the laboratory for testing.

Figure 13: Bypass testing of the powered prosthesis

Third step: Subject testing (Figure 14)



In subject testing, the focus is on fine tuning of the prosthesis. It is particularly important for the evaluation of the prosthesis to ask for feedback from the subject and to be able to address individual concerns or improvement suggestions.

Figure 14: Subject testing of the powered prosthesis

Before every session a certified prosthetist carried out the individual bench alignment for each subject. In this process the prosthesis was customized to the correct height dimensions as well as the correct prosthetic alignment, such as socket rotation. Furthermore, the footplate of the polycentric ankle was matched to the subjects' shoe size. Despite the great dimensions of the polycentric ankle, it was ensured that the foot has a tight fit in the shoe.

After bench alignment the subject donned the prosthesis, and a stable position of the socket was assured and then followed by a static alignment examination. In the frontal plane the height of the prosthesis was tested again, the patient's comfort was queried and rotations in both the foot and the knee were checked. In the sagittal plane the anterior – posterior alignment of the prosthesis was verified. If necessary, adjustments were being made, otherwise if all requirements were correct, the subject was allowed to do their first steps.

During dynamic alignment the team of therapists, prosthetists, and the researcher work closely together to create a gait pattern that is as normal and symmetrical as possible. On the prosthetic side the alignment of the prosthesis was again being checked in both the frontal as well as the sagittal plane. If applicable, further prosthetic adjustments were made, such as external rotation of the foot or knee, as well as flexion or extension angles in the sagittal plane of the socket, knee, or ankle. Furthermore, the prosthesis control was also modified here.

As every subject had a different gait pattern or preferred to walk at different speeds, changes in the control of the prosthesis can be made, to match those specifications. The most frequently changed parameters are for example the knee flexion. The knee angle in swing can be increased if the subject itself or the therapist reports a deficit of foot clearance, which then results in a greater heel rise and reduces the risk of tripping over small obstacles. To support this setting even more, the ankle angle in swing 1 can be modified as well, to perform a greater dorsiflexion and therefore generate toe clearance as well.

With increased walking speed, subjects might also require the knee to move and swing faster, which is why stiffness and damping parameters can be modified to ensure correct timing of knee extension in terminal swing.

If in stance 1 the ankle is not allowing enough plantarflexion, but rather pulls the knee forward, damping parameters of the ankle can be reduced to ensure a soft and sufficient initial contact and loading response. At the end of stance 2, the ankle performs a plantarflexion to generate a push off movement. As this movement is a function of the thigh angle, the step length of a subject plays a crucial role. With increased step length, the thigh angle automatically increases as well. Therefore, to have the right timing for the push off, the plantarflexion of the ankle was controlled with a function at the individually correct thigh angle (see multiply sum function (3)).

2.3 Study design and protocol

Subjects were selected with the following inclusion and exclusion criteria:

Inclusion criteria:

- TF Amputation,
- at least 6 months since definitive prosthesis fitting,
- a minimum of MFCL K2-level limited community ambulators*,
- aged 18-85

Exclusion criteria:

- Skin lesion in residual limb that would prevent physical activity or fitting/use of a prosthesis,
- cognitive deficits that would impair ability to follow instructions during training or assessments,
- significant neuromuscular or musculoskeletal disorder or other comorbidity that would interfere with participation in the study.

* *The United States' Medicare Functional Classification Level (MFCL) was identified by a qualified therapist.*

Six healthy adults (5 male, 1 female, age mean 49 years, age range 32 – 73 years) with a transfemoral amputation participated in this study. (Table 2) The study was approved by the Northwestern University Institutional Review Board. The subjects were recruited through a database of subjects interested in performing research maintained by the Shirley Ryan AbilityLab. Informed written consent was obtained from each subject.

Subject number	Age (years)	Time since amputation (years)	Sex	Amputation side	Etiology	Weight with home leg (kg)	Prescribed prosthesis
1	73	46	Male	Right	Trauma	89	(microprocessor knee/ carbon fiber foot)
2	62	39	Female	Right	Blood Clot	70	(mechanical knee/ carbon fiber foot)
3	38	25	Male	Left	Sarcoma	100	(mechanical knee/ carbon fiber foot)
4	32	9	Male	Right	Sarcoma	62	(microprocessor knee/ carbon fiber foot)
5	36	18	Male	Left	Infection	111	(microprocessor knee/ carbon fiber foot)
6	51	48	Male	Left	Trauma	108	(mechanical knee/ carbon fiber foot)

Table 2: Subject demographics

Experimental conditions

After prosthetic fitting and initial parameter tuning, every subject performed the whole study on one day in an average of three hours. In total, the subject went through a process of walking in four different prosthetic settings, as briefly mentioned in Chapter 2.2.

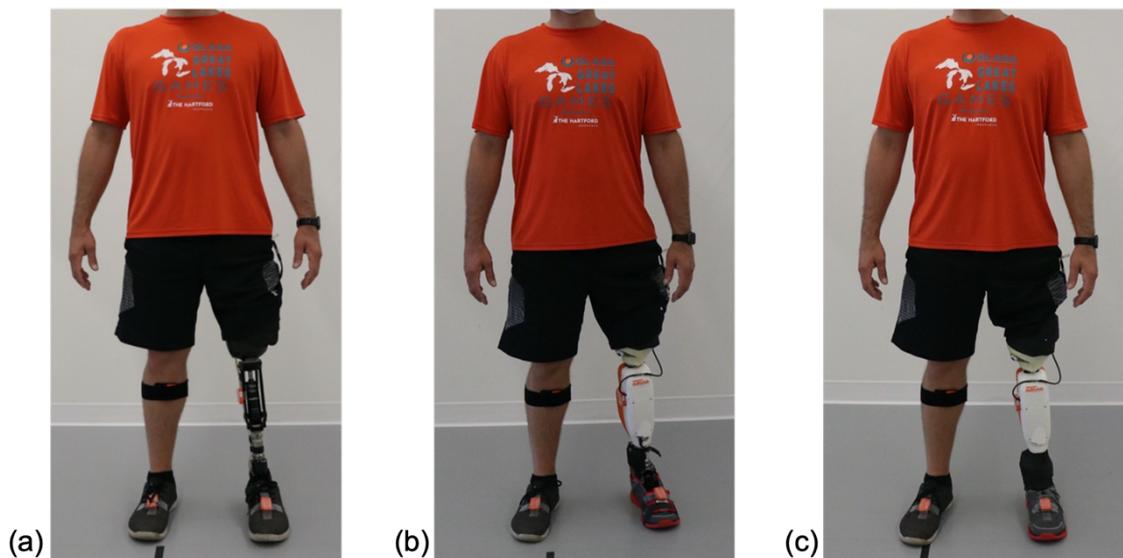


Figure 15: Prosthetic setting of four different conditions. Home leg condition (a), powered knee/powered ankle and passive knee/powered ankle condition (b), powered knee/passive ankle condition with additional weight (c).

Condition A: Prescribed home leg (passive knee and passive ankle)

The home leg condition (Figure 15(a)) served as the control condition to record the current status of the subject. Accordingly, it is used as a comparative variable when conclusions are drawn about the results.

Condition B: Powered knee and powered ankle (A1K1)

In contrast to condition A, condition B was recorded with the lightweight powered knee and the polycentric ankle, both in a fully powered mode (Figure 15(b)).

Condition C: Passive knee and powered ankle (A1K0)

In condition C the hybrid powered knee was changed into a passive mode, whereas the ankle is still in a fully powered mode (Figure 15(b)).

Condition D: Powered knee and passive ankle (A0K1)

To investigate the powered knee and passive ankle condition, the ankle was switched with a commercial carbon fibre ankle (LP VariFlex). To eliminate the influence of weight, the weight difference between the polycentric ankle and the LP VariFlex was added to the foot using sandbags (see Figure 15(c)). The average additional weight, depending on the height adapter between the ankle and the knee was at 810 grams across subjects.

For each subject, condition A was always the first condition, as walking with the home leg functions as the control condition to determine the prosthetic setting that they are used to. The order of conditions B to D were randomized for each subject to avoid limitations in accidental or selection bias.[96]

Procedure

At the beginning each subject was equipped with surface EMG electrodes on the back and the Xsens IMU based gait analysis system. After skin preparation, two EMG electrodes were placed on each left and right erector spinae (ES) and a ground electrode on the anterior superior iliac spinae (ASIS), according to SENIAM (Figure 16).[97]

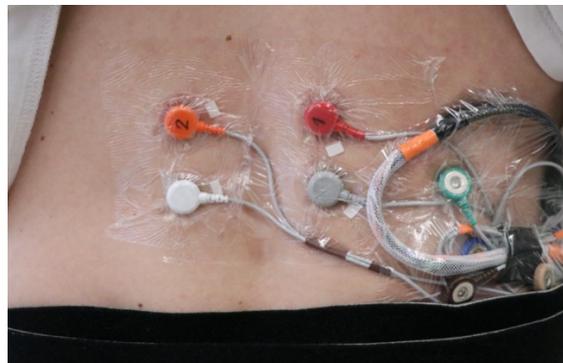


Figure 16: EMG placement of LES and RES.

After the set-up of the measuring equipment and making the subject familiar with the study protocol and their task, the subject started the first trial with their prescribed prostheses. After walking and completing the first condition the subject has a short break until it is ready to don the research prostheses. Every subject had their own research socket which was used for all three conditions. First a certified prosthetist adjusted and confirmed static and dynamic alignment. An acclimation time of approx. 10 minutes was given, where a certified therapist trained the subject with the prostheses in parallel bars. Furthermore, personalized tuning of certain impedance parameters was made during that acclimation time, by adjusting the control of the leg (Chapter 2.2). Those adjustments would for example effect toe clearance, knee flexion and extension during swing, or changes of dorsiflexion and plantarflexion angles. When the subject felt comfortable and safe walking with the prosthesis the same data collection procedure on the walkway was repeated. In between each condition the subjects had a break of around 10 to 15 minutes, including time for changing the prosthesis from one condition to the next condition.

In each condition subjects walked up and down a walkway in the laboratory of approx. 20 meters at their comfortable and self-selected speed. Meanwhile kinematic (Xsens) and EMG data was recorded. As illustrated in Figure 17 this procedure was repeated three times (six walkways).

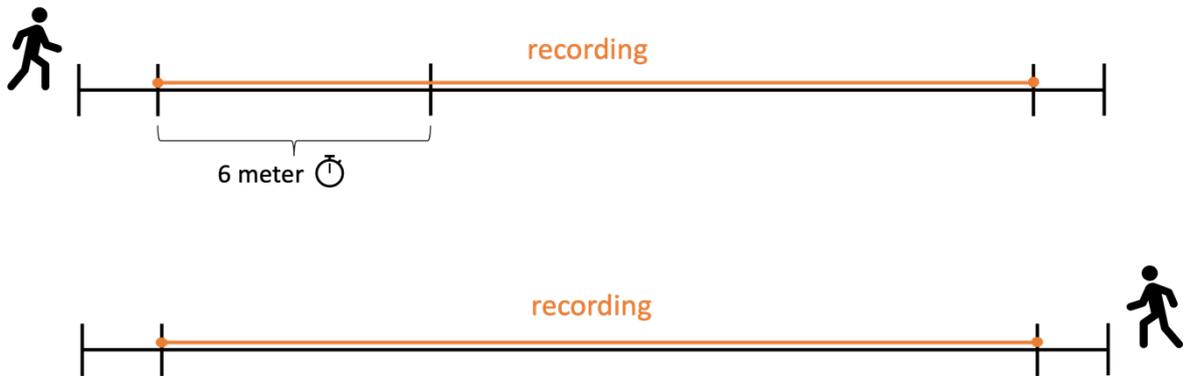


Figure 17: Outline of data collection situation when walking back and forth a straight line in four different conditions

As it is shown in Figure 17, the data recording of EMG and Xsens began after the subject started walking and ended after the subject stopped. This was done to avoid recording of gait cycles with acceleration and deceleration in the data set. To get the speed of the self-selected comfortable pace in every condition the 10 meter-walk test was performed. The 10MWT is a validated and common rehabilitation test to evaluate locomotor function and to examine the average speed of a walking subject.[48]

Subjects walk along a 10-meter line, while the middle 6 meters are recorded with a stopwatch (Figure 17). The first and the last two meters are neglected to exclude acceleration and deceleration.[98] Figure 18 (a&b) shows the laboratory setting during the study.

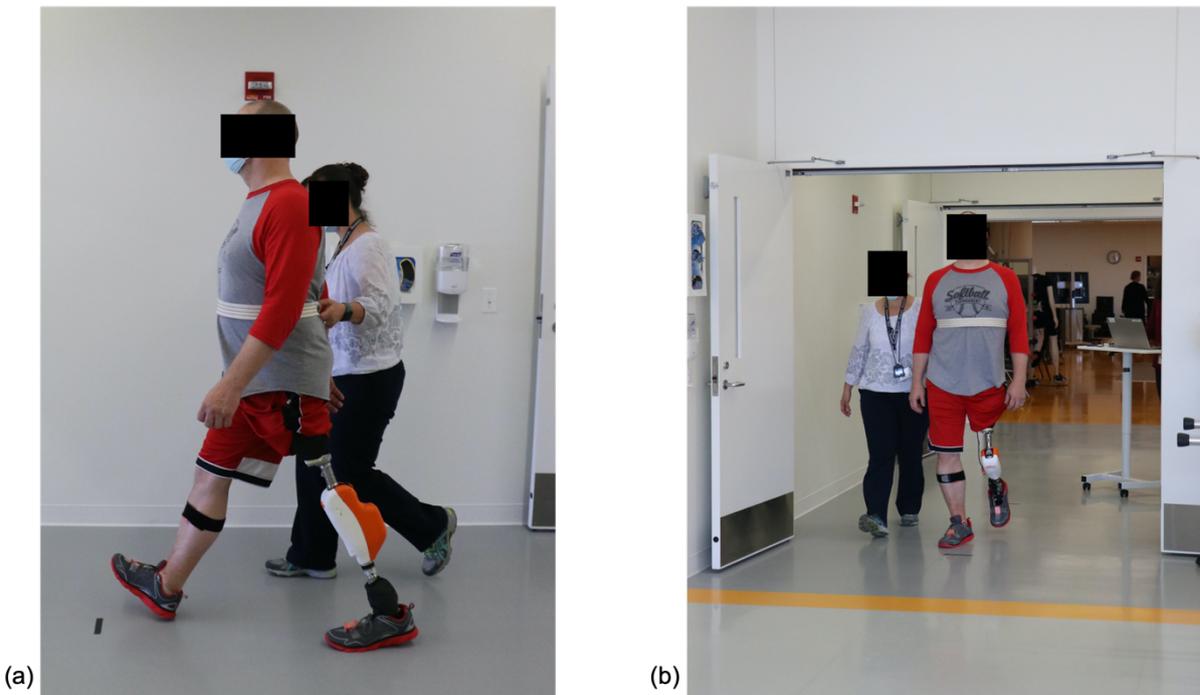


Figure 18: Sagittal (a) and frontal (b) view of a subject walking in the study setting.

2.4 Data acquisition

As already described in Chapter 2.3 data was collected during all waking trials. To examine the research aim and match the study protocol and design, different types of data collection tools were used.

To collect data of joint kinematics of the lower body the MVN Awinda system from Xsens was used (Xsens Technologies B.V., Enschede, the Netherlands) which is an inertial motion capture system consisting of hardware and software components. MVN Awinda is a completely wireless version with 17 motion trackers. Only 7 sensors for the lower body were used for this study. With 3D accelerometers, 3D magnetometers and 3D gyroscopes, the trackers are inertial and magnetic measuring units (IMUs), that are placed using body straps. The placement of the IMUs can be seen in Figure 16. One sensor is placed on each foot, the others on the sound side shank and thigh. On the prosthetic side the sensor is located on the medial surface of the knee and lateral on the upper third of the socket. Another sensor is placed on the pelvis.[99]

After placing the sensors and running the calibration an avatar of the subject can be observed in the Xsens MVN Awinda software (Figure 17). The software combines the IMU data with biomechanical models to identify segment orientation and position. The data is processed in real time and frame by frame. After recording the collected data is being HD reprocessed over a larger time window to optimize the estimation of the segment position and orientation. Depended on the environment and interaction with the floor, the HD reprocessing can be done with different scenarios: No level, multi-level or single level. For this study the single level scenario was used when reprocessing the data, as the subjects only walked on level ground and moreover the single level scenario gives information about heel and toe contact which is useful for further processing and dividing data into gait cycles.[99] In addition to joint kinematics main spatial-temporal parameters were recorded using the Xsens system as well.

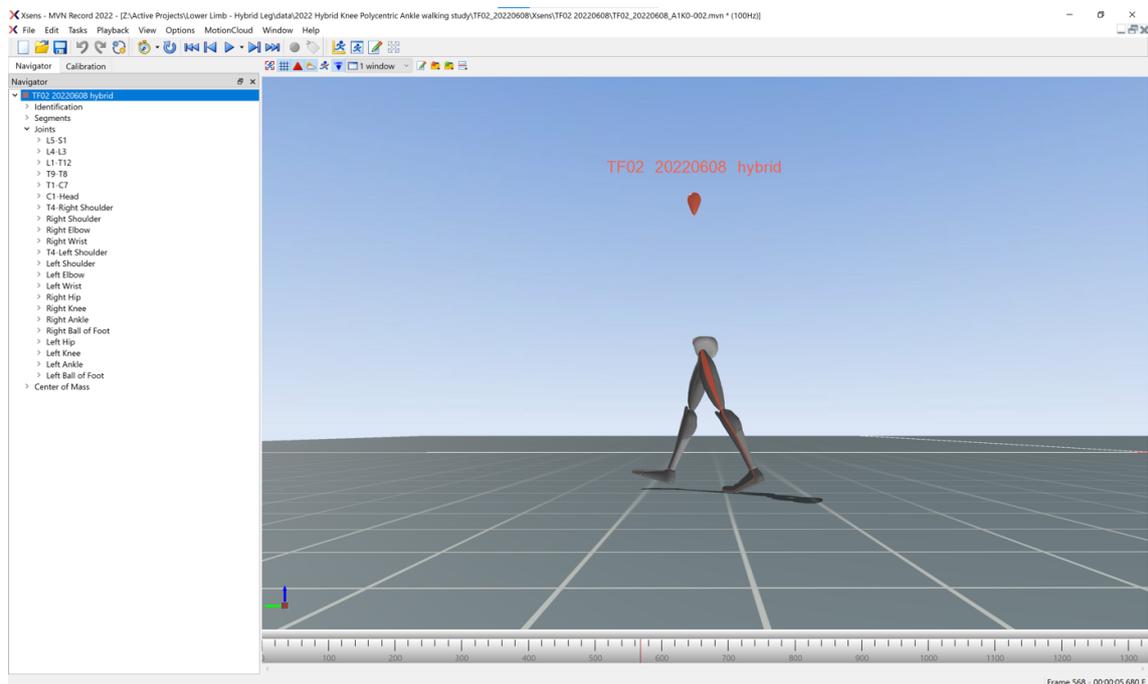


Figure 19: Screenshot of the Xsens Awinda Software after calibration.

As another outcome measurement tool muscle activity was recorded using surface electromyography (sEMG) electrodes. The electrodes were placed on the left and right M. erector spinae as described in chapter 2.3. All electrodes were wired to the hybrid leg via a converter, that bandpass filtered the data between 30 and 350 Hz. With the connection to the leg, EMG data was streamed together with all the other sensor data in the control system of the leg. In the home leg condition, the electrodes were connected to an external box that was attached to the subjects' socket to stream and record the data. Furthermore, an external IMU was placed on the subjects' socket when walking on their home leg to record acceleration and angle values, and to then be able to divide the EMG data into gait cycles.

Due to data saving issues, one subject is missing all EMG data and one subject is missing EMG data of condition B.

2.5 Data analysis

Spatial – temporal parameters

The self-selected comfortable speed of every subject was averaged between all three recorded times per condition. An average of subjects was calculated for each condition.

Step length, step width, swing and stance phase was extracted from the Xsens gait report and averaged between all walking trials, as well as then averaged for all subjects (total average of 25 +/- 4 gait cycles for each subject).

Kinematic data analysis

All kinematic data was post-processed using the cloud-based gait report, a supporting tool for gait analysis from Xsens, and then extracted to excel. A custom developed MATLAB (Mathworks, Natick, MA, version R2021a) script was used to further process the data. All recorded trials were divided into gait cycles and then normalized from 0 – 100%. An average of five trials, with each four to six gait cycles, were analysed (total average of 25 +/- 4 gait cycles for each subject). The averaged data was computed for all four conditions on the prosthetic and sound side separately. Furthermore, an average for each joint, on prosthetic and sound side was calculated for all subjects.

Initial testing of the study protocol has shown unusual peak values in Xsens data. In comparison with data collected from the prosthetic leg, it was examined that, besides peak values, curve patterns were similar, which led to the conclusion to include the data as a valid quantitative and qualitative analysis. The comparison of recorded Xsens data and the data collected from the prosthetic leg, is shown in two examples in Figure 18 and Figure 19.

Figure 18 shows sagittal kinematics of the knee and ankle in the active ankle and passive knee condition (A1K0). Xsens shows a peak knee flexion in swing phase of 68 degrees and the leg data measured 73 degrees.

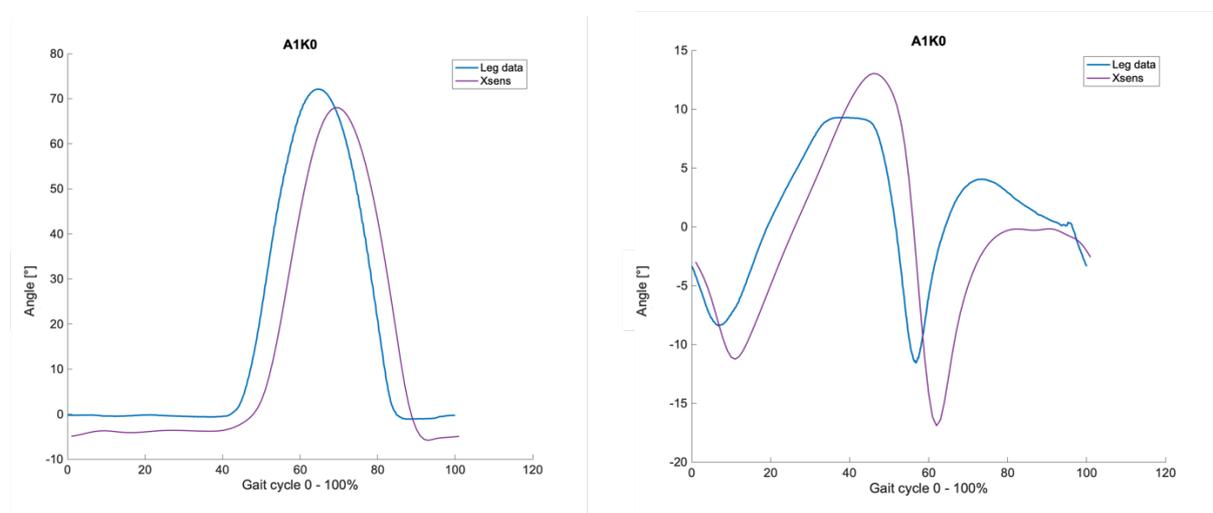


Figure 20: Comparison between Xsens and leg data of knee (left) and ankle (right) joint angles

The differences in ankle measurements seem more pronounced, with a maximum difference of about 8 degrees in plantarflexion and 5 degrees in dorsiflexion. (Figure 18)

Similar patterns were observed in the powered ankle and powered knee condition. Whereas the knee peak values are closer to each other (difference of 1-2 degrees), the ankle range of motion measured with the Xsens ranges from 13 degrees dorsiflexion to 17 degrees plantarflexion. In comparison the leg data measured a ROM of 8 degrees dorsiflexion to 12 degrees plantarflexion.

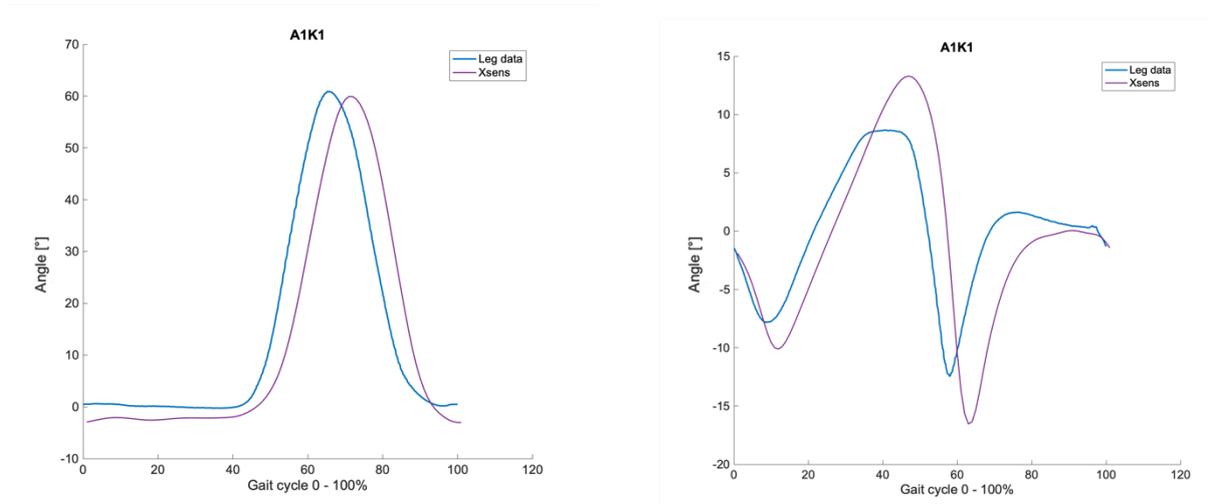


Figure 21: Comparison between Xsens and leg data of knee (left) and ankle (right) joint angles

EMG data analysis

The EMG data was analysed using custom developed MATLAB scripts (Mathworks, Natick, MA, version R2021a). The data was extracted from the leg and divided into gait cycles using the legs control system that indicates heel contact. All gait cycles were then normalized from 0 – 100%. EMG data was band pass filtered with a Butterworth filter with a band pass frequency of 80 – 350 Hz. The filtered EMG signals were then rectified, and low pass filtered, at a cut-off frequency of 25 Hz, to compute the linear envelope. The data was averaged between all walking trials for each subject to show the EMG activation profile of the LES and RES during gait cycle in each condition.

The same process was carried out with the EMG data that was recorded with the home leg. For the division into gait cycles, data of the IMU, that was attached to the subjects socket, was used. To confirm this division using the IMU, a test walking trial was recorded in combination with a foot switch, to identify heel contact.

Furthermore, the EMG data was normalized to the maximum peak value of the home leg condition, to allow direct comparison of each muscle between the four conditions.

4 Results

For a structured overview, the results are divided into spatio-temporal results, kinematic results, and EMG results.

4.1 Spatio-temporal parameters

Table 3 shows results of recorded spatio-temporal parameters as an average of all subjects including step length, step width, percentage of the gait cycle in swing phase and stance phase for the sound side and prosthetic side, as well as walking speed in the four different conditions.

Condition	Step length (cm)		Step Width (cm)		Swing phase (%)		Stance phase (%)		Velocity (m/s)
	Sound side	Prosthetic side	Sound Side	Prosthetic side	Sound side	Prosthetic side	Sound side	Prosthetic side	
Home leg	71.2 ± 2.14	75.8 ± 2.15	14.7 ± 2.75	14.7 ± 2.2	39.3 ± 1.36	44.4 ± 0.93	60.6 ± 1.15	55.6 ± 0.93	1.3 ± 0.05
A1K0	67.9 ± 1.94	73.5 ± 2.21	13.4 ± 1.93	13.7 ± 2.29	37.4 ± 1.27	44.5 ± 0.99	62.6 ± 1.1	55.5 ± 0.85	1.2 ± 0.05
A0K1	68.2 ± 1.95	72.9 ± 2.9	16.1 ± 1.97	16.8 ± 2.25	39.9 ± 1.11	43.0 ± 1.55	61.0 ± 1.05	57.1 ± 0.86	1.2 ± 0.07
A1K1	67.8 ± 2.04	71.9 ± 2.45	13.3 ± 1.72	13.3 ± 2.66	38.4 ± 0.72	43.6 ± 1.45	61.6 ± 0.7	56.4 ± 1.01	1.1 ± 0.03

Table 3: Average spatio-temporal parameters of six transfemoral subjects in four different prosthetic conditions: Home leg, A1K0 (powered ankle, passive knee), A0K1 (passive ankle, powered knee), A1K1 (powered ankle, powered knee). Values represent mean +/- standard deviation.

Data analysis of the spatio-temporal parameters revealed a slightly increased step length for the home leg condition on the sound side and prosthetic side. In every condition, steps have an increased length of around 3-6 cm with the prosthetic leg. The overall shortest step length occurred with the powered knee and powered ankle condition (A1K1).

No major differences can be seen in step width throughout all conditions. However, the widest step width took place with the passive ankle and powered knee condition (A0K1). Whereas the other two conditions caused the same step width and only a slight increase in the home leg condition.

Looking at the percentage distribution into stance phase and swing phase of the gait cycle, it can be seen that in general the prosthetic side has a longer swing phase than the sound side and therefore the other way around during stance phase, with a longer stance phase on the sound side. The sound side swing phase ranges between 37-40% percent of the gait cycle, the prosthetic side between 43-44%. The stance phase on the sound side is increased by

around 5% compared to the prosthetic side in all conditions. The greatest difference can be observed in the powered ankle and passive knee condition (A1K0).

Examinations of the walking speed show that subjects walked the fastest with their home leg, with a velocity of 1.3 m/s and slowest in the powered knee and powered ankle condition (A1K1) with a velocity of 1.1 m/s.

4.2 Lower limb Kinematics

For analysing the kinematic data from Xsens, all data for each subject was averaged across all level walking trials and then compared between conditions for each joint on the contralateral side and prosthetic side. As already explained in Chapter 2.5, Xsens data was not analysed by peak joint angle values in the different conditions. The following results refer to shape patterns and differences between conditions.

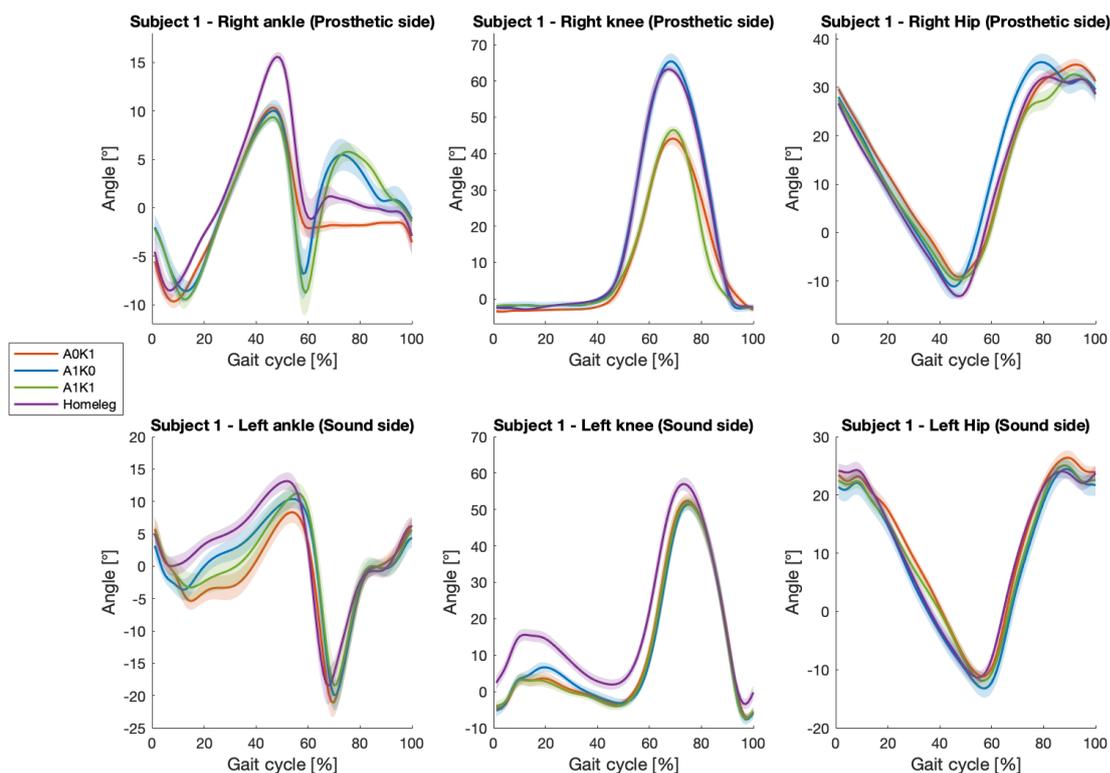


Figure 22: Average (25 +/- 4 gait cycles) joint kinematics of prosthetic and sound side of subject 1 in four different prosthetic conditions: Home leg, A1K0 (powered ankle, passive knee), A0K1 (passive ankle, powered knee), A1K1 (powered ankle, powered knee). The transparent areas show the corresponding standard deviation.

Walking with the home leg, subject 1 has an increased dorsiflexion during stance on the prosthetic side, and similar to the passive ankle and powered knee condition no plantarflexion during pre-swing or dorsiflexion in mid swing (Figure 22). In both powered knee conditions, the knee flexion angle during swing was controlled to about 45 degrees, whereas the home leg

and passive knee condition (A1K0) show a similar and increased knee flexion angle. On the sound side most dorsiflexion movement during stance phase was performed in the ankle of subject 1 when walking with the home leg, and the least in the passive ankle and powered knee condition (A0K1). The sound side knee of subject 1 performed a greater stance phase flexion with the home leg. The other conditions show similar knee angles. Furthermore, the sound side hip kinematics show a higher hip flexion angle at the beginning of the stance phase and at the end of the swing phase, when walking with the home leg.

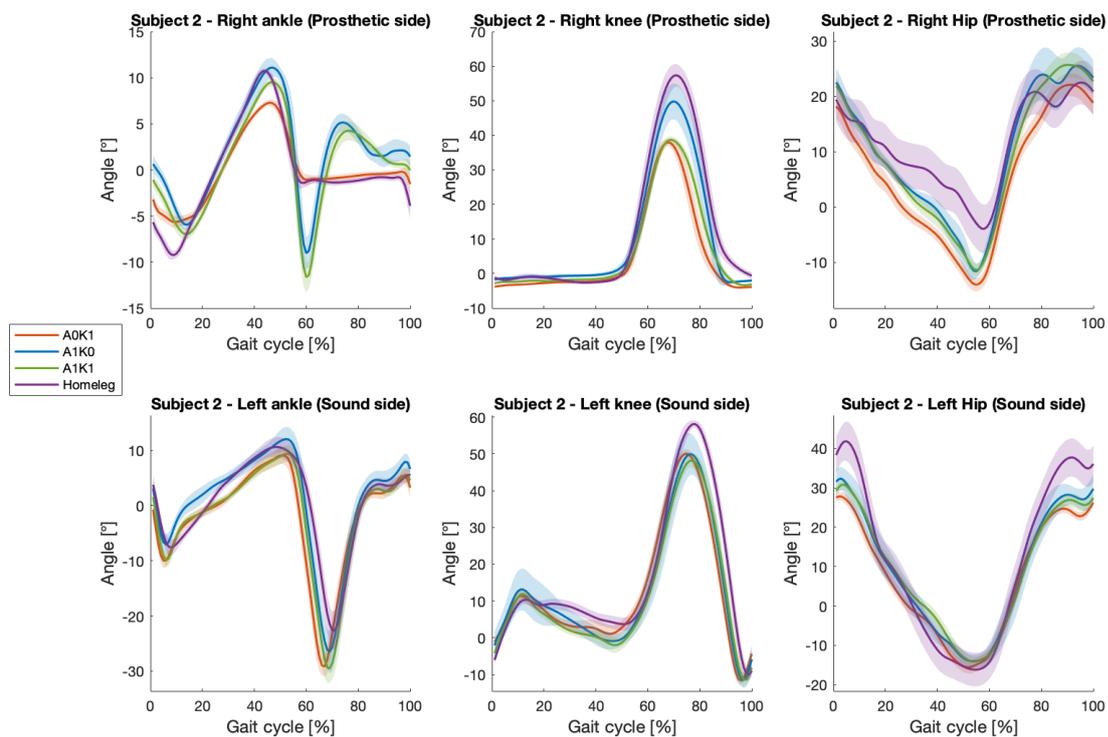


Figure 23: Average (25 +/- 4 gait cycles) joint kinematics of prosthetic and sound side of subject 2 in four different prosthetic conditions: Home leg, A1K0 (powered ankle, passive knee), A0K1 (passive ankle, powered knee), A1K1 (powered ankle, powered knee). The transparent areas show the corresponding standard deviation.

Subject 2 Figure 23 shows less hip extension on the prosthetic side with the home leg compared to the other three conditions. The sound side hip kinematics shows a similar range of motion into extension, but a higher hip flexion in the home leg condition.

Observing the prosthetic ankle and knee, it can be seen that both passive ankle conditions stay at a neutral ankle throughout swing phase. The passive ankle and powered knee condition (A0K1) shows less dorsiflexion in terminal stance, than the other three conditions. The sound side ankle show overall the same angles across conditions. Slightly increased hip flexion values can be observed on the sound side with the home leg condition.

The knee flexion angle of the prosthesis is the greatest when walking with the prescribed home leg and the least when walking in both powered knee conditions (A1K1 and A0K1). On the sound side knee similar kinematics can be observed across all conditions. However, in the home leg condition, an increased knee flexion during swing can be seen.

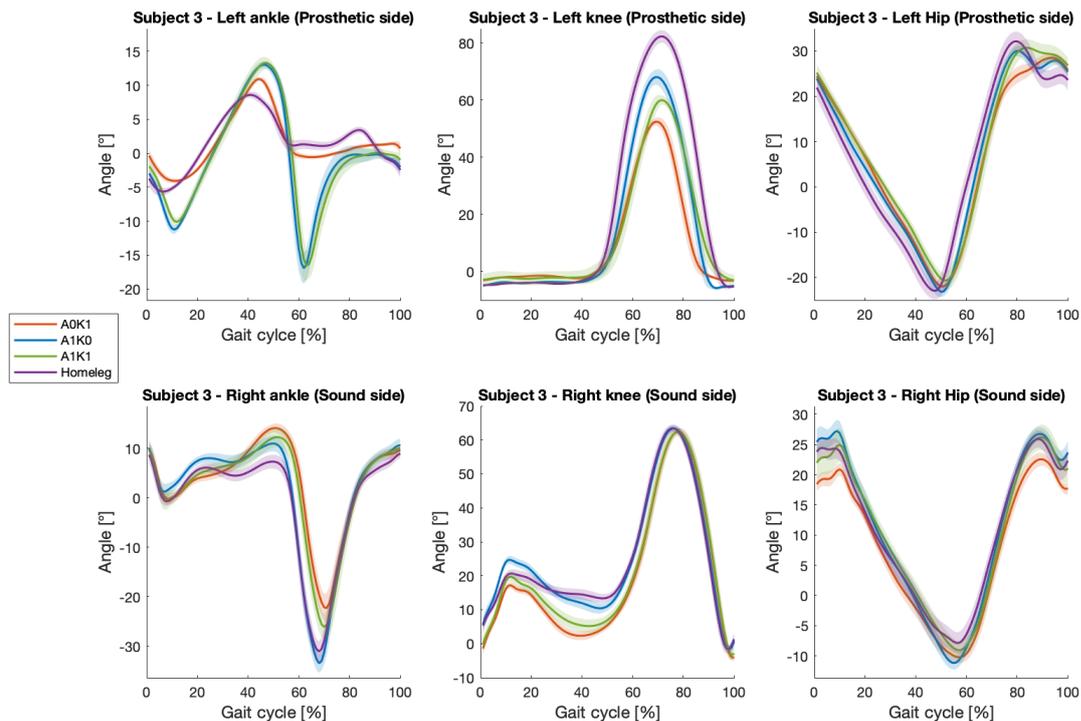


Figure 24: Average (25 +/- 4 gait cycles) joint kinematics of prosthetic and sound side subject 3 in four different prosthetic conditions: Home leg, A1K0 (powered ankle, passive knee), A0K1 (passive ankle, powered knee), A1K1 (powered ankle, powered knee). The transparent areas show the corresponding standard deviation.

Subject 3 (Figure 24) shows increased plantarflexion movements at loading response with the prosthetic ankle in the powered ankle conditions (A1K1 and A1K0) compared to the other two conditions. Further, both powered ankle conditions show a clear plantarflexion at the end of stance phase (60% of the gait cycle) and after that a neutral position for the remaining swing phase.

At about 30% of the gait cycle the sound side ankle shows a slight dorsiflexion and plantarflexion movements in the shape of a wave. During swing phase the sound side ankle shows an increased plantarflexion at the end of stance when walking in both passive knee conditions (home leg and A1K0), compared to the other two conditions.

With the sound side knee an increased knee extension movement can be observed during mid and terminal stance in the powered knee conditions (A0K1 and A1K1).

Both prosthetic and sound side hip angles show similar curve patterns across conditions. Besides the prosthetic side hip angle when walking with both passive knee conditions (A1K0 and home leg), that show an earlier hip extension (at 80% of the gait cycle) than the other two conditions.

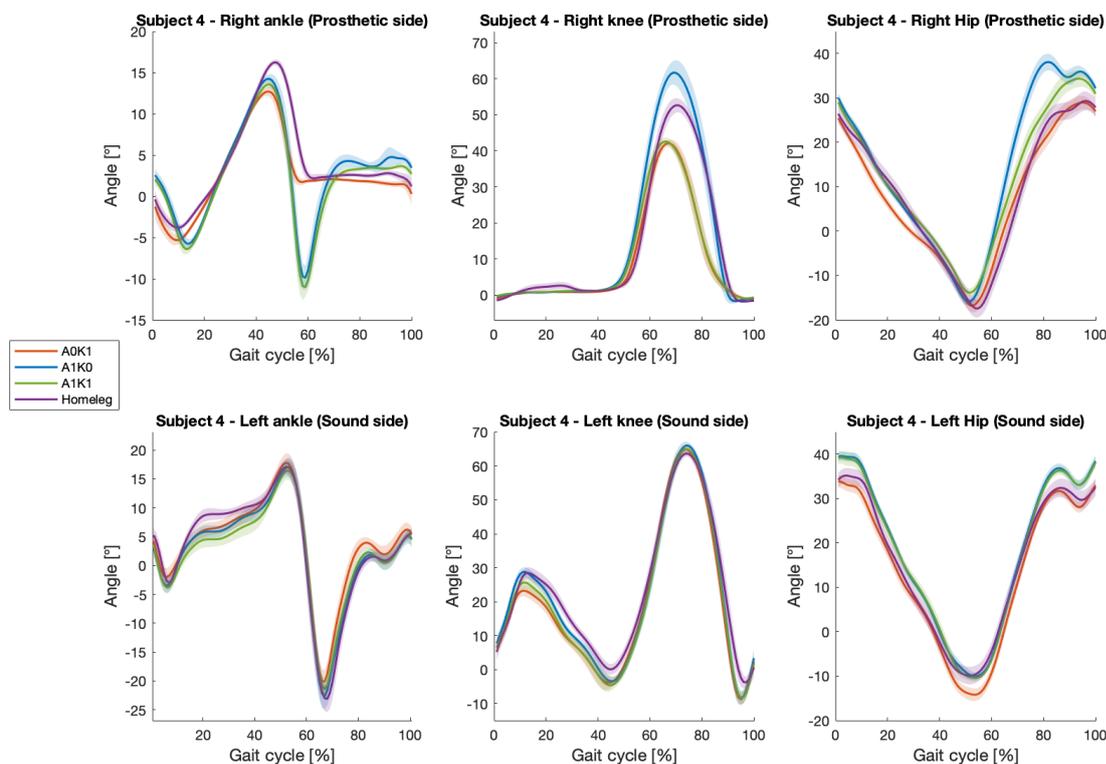


Figure 25: Average (25 +/- 4 gait cycles) joint kinematics of prosthetic and sound side subject 4 in four different prosthetic conditions: Home leg, A1K0 (powered ankle, passive knee), A0K1 (passive ankle, powered knee), A1K1 (powered ankle, powered knee). The transparent areas show the corresponding standard deviation.

Looking at the lower limb kinematics of subject 4 (Figure 25), it can be observed that the prosthetic side ankle in both powered ankle conditions (A1K1 and A1K0) performs a plantarflexion and then remains in a slightly dorsiflexed position throughout swing phase. Both passive ankle conditions show a neutral position during swing phase. The dorsiflexion movement in terminal stance phase shows no differences across all conditions.

The highest knee flexion angle on the prosthetic side is performed with the powered ankle and passive knee condition (A1K0), followed by the prescribed home leg. Both powered knee conditions (A1K1 and A0K1) have the same curve shape. The sound side knee shows the same movements throughout all conditions. The same applies for the sound side ankle. Nevertheless, it can be observed that the shape of the sound side ankle kinematics shows a plateau in a slightly dorsiflexed position during mid stance.

The prosthetic side hip joint shows the greatest and earliest hip extension at the end of swing when walking with the home leg, compared to the other conditions.

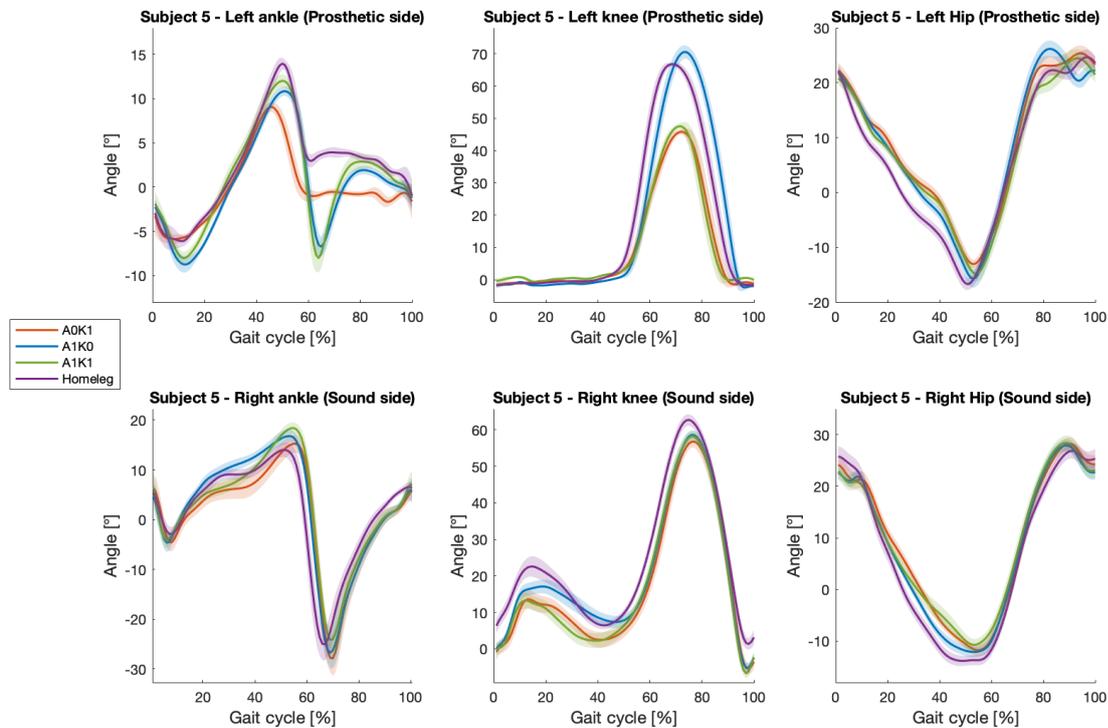


Figure 26: Average (25 +/- 4 gait cycles) joint kinematics of prosthetic and sound side of subject 5 in four different prosthetic conditions: Home leg, A1K0 (powered ankle, passive knee), A0K1 (passive ankle, powered knee), A1K1 (powered ankle, powered knee). The transparent areas show the corresponding standard deviation.

Subject 5 (Figure 26) shows smaller dorsiflexion angles with the passive ankle and powered knee condition during terminal stance on the prosthetic side. Both powered ankle conditions are controlled to perform a plantarflexion at the end of stance and a slight dorsiflexion during swing. When walking with the home leg a dorsiflexed position throughout swing occurs on the prosthetic side.

The prosthetic knee shows similar kinematics for both passive knee conditions (A1K0 and home leg) as well as similar kinematics for both powered knee conditions (A1K1 and A0K1). With the prosthetic side hip subject 5 shows a movement towards extension with the powered ankle and passive knee condition (A1K0), which cannot be observed for the other three conditions. For the sound side ankle and the sound side hip similar joint kinematics can be seen across all conditions. The sound side knee on the other hand shows an increased stance flexion when walking with the prescribed home leg.

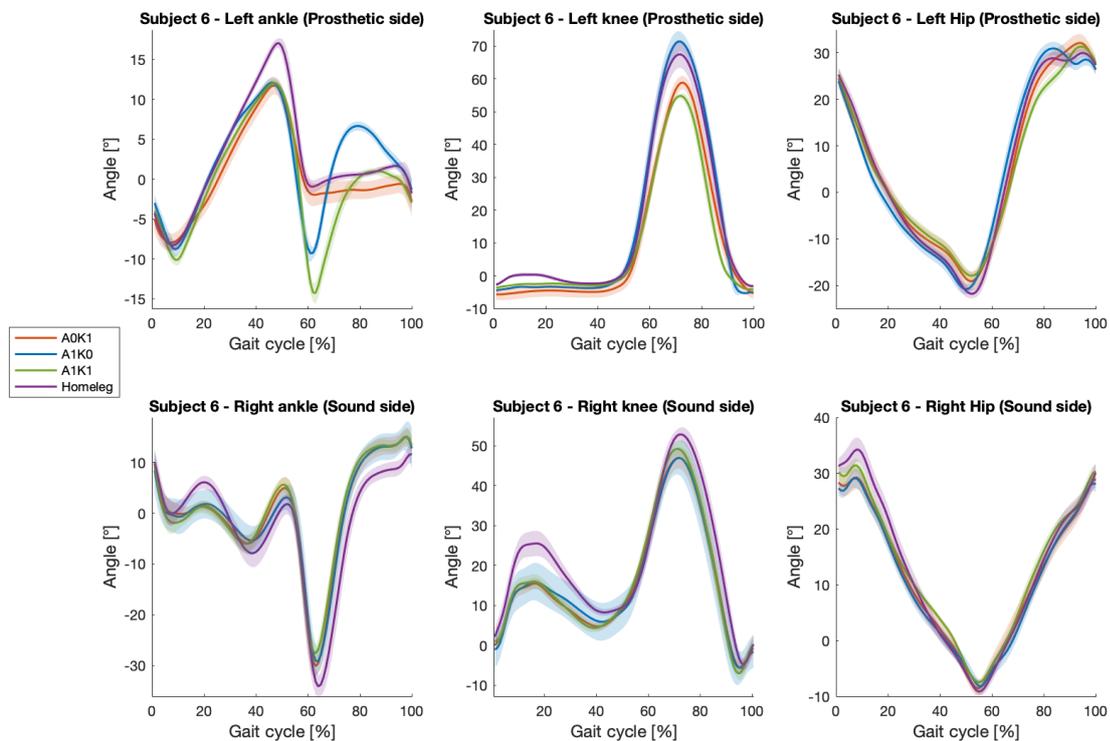


Figure 27: Average (25 +/- 4 gait cycles) joint kinematics of prosthetic and sound side of subject 6 in four different prosthetic conditions: Home leg, A1K0 (powered ankle, passive knee), A0K1 (passive ankle, powered knee), A1K1 (powered ankle, powered knee). The transparent areas show the corresponding standard deviation.

Walking with the home leg, subject 6 (Figure 27) shows an increased dorsiflexion during stance on the prosthetic side. With the powered ankle and passive knee (A1K0) condition less plantarflexion occurs in pre-swing and an increased dorsiflexion during mid-swing, compared to both powered joints condition (A1K1). The sound side ankle performs an excessive plantarflexion, in a shape of a wave, during stance throughout all conditions.

The prosthetic knee has a higher knee flexion in both passive knee conditions (A1K0 and home leg) compared to the powered knee conditions (A1K1 and A0K1).

Both the prosthetic and the sound side hip joints have similar curve patterns across all conditions.

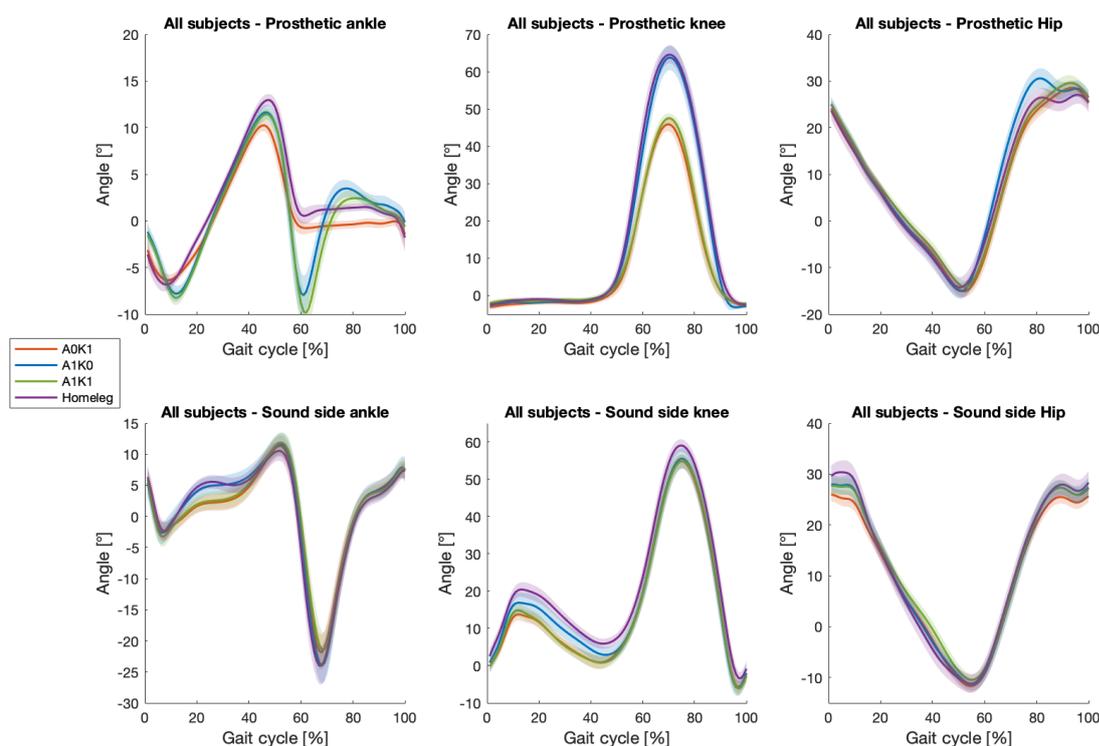


Figure 28: Average (25 +/- 4 gait cycles) joint kinematics of prosthetic and sound side of six transfemoral subjects in four different prosthetic conditions: Home leg, A1K0 (powered ankle, passive knee), A0K1 (passive ankle, powered knee), A1K1 (powered ankle, powered knee). The transparent areas show the corresponding standard deviation.

The average data of all subjects of all conditions (Figure 28), show a similar dorsiflexion movement in the prosthetic ankle during stance across all conditions. The passive ankle conditions (A0K1 and home leg) show no ankle movement on the prosthetic side, compared to the powered ankle conditions (A1K1 and A1K0) that perform a plantarflexion in pre-swing and a dorsiflexion in mid-swing. Averaged data of the knee show a greater knee flexion during swing with the passive prosthetic knee conditions (A1K0 and home leg) and a smaller angle with the powered knee conditions (A1K1 and A0K1).

Looking at the prosthetic side hip it is noticeable that the average of all subjects shows slightly higher and earlier hip flexion in terminal swing with the powered ankle and passive knee condition (A1K0), with a direct movement towards extension directly after.

All sound side joint angles show similar kinematic patterns. Nevertheless, it can be observed that walking with both passive knee conditions (A1K0 and home leg) a more pronounced plateau of the sound side ankle is caused during mid stance. Furthermore, the sound side knee kinematics when walking with the home leg condition show an increased stance phase flexion, compared to the other three conditions.

4.3 Left and Right Erector Spinae Muscle EMG

The following EMG results show activation profiles of the left and right ES during level walking for five subjects, as EMG is missing for one subject. The figures show averaged data of 25 +/- 4 gait cycles in each condition normalized to peak activation of the control condition (home leg) throughout a gait cycle (0-100%).

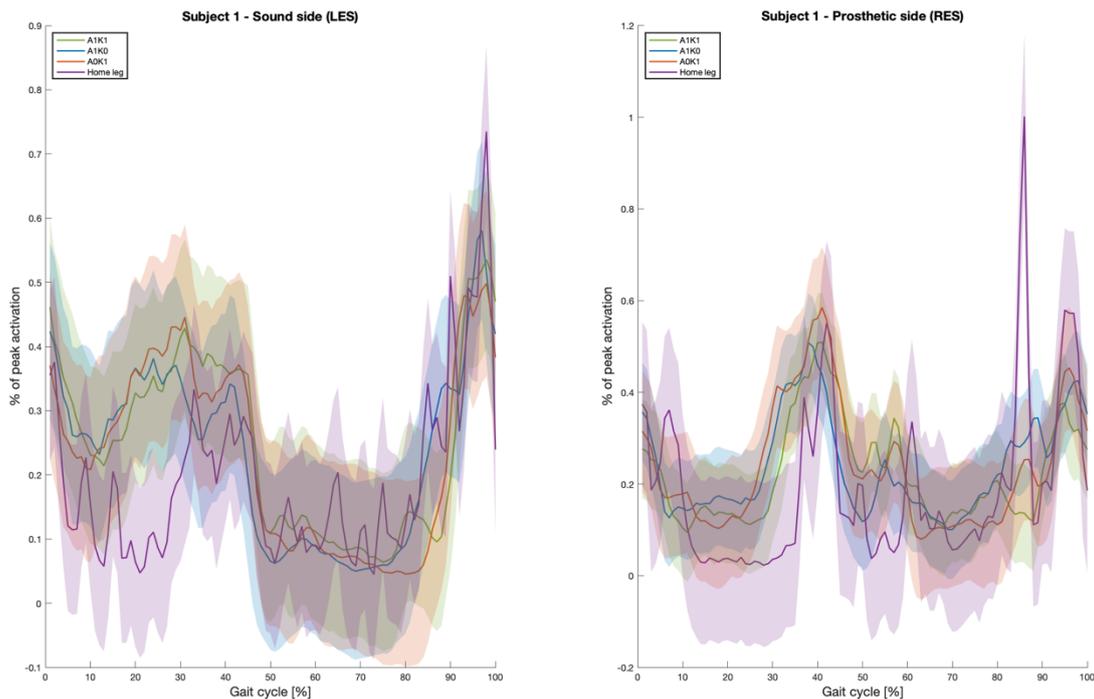


Figure 29: Average (25 +/- 4 gait cycles) ES activity in relation to peak activation percentage [%] of the control condition (peak activation = 1), of subject 1 in all four prosthetic conditions: Home leg (control), A1K0 (powered ankle, passive knee), A0K1 (passive ankle, powered knee), A1K1 (powered ankle, powered knee). The transparent areas show the corresponding standard deviation.

The activation pattern of subject 1 shows peak values of 40% activation throughout stance phase in all powered leg conditions on the contralateral ES. The home leg activation pattern shows two peaks during stance phase. The first at initial contact with about 40% activation, and the second between 35 and 50% of the gait cycle with a similar activation. In addition, all conditions show an increased activation of up to 70% of activation at the end of swing phase, and therefore just before initial contact. The activation profile of the prosthetic side ES shows no differences in activity between the powered leg conditions. They show a first smaller peak of 30% at initial contact, then a constant activation of 20% between 10 and 30% of the gait cycle, followed by a peak of 60% activation in terminal stance. Another peak can be observed at the end of stance phase (30% activation) as well as at the end of swing (40-60% activation) in all four conditions. Furthermore Subject 1 has a high peak of 100% activation in mid swing (Figure 29).

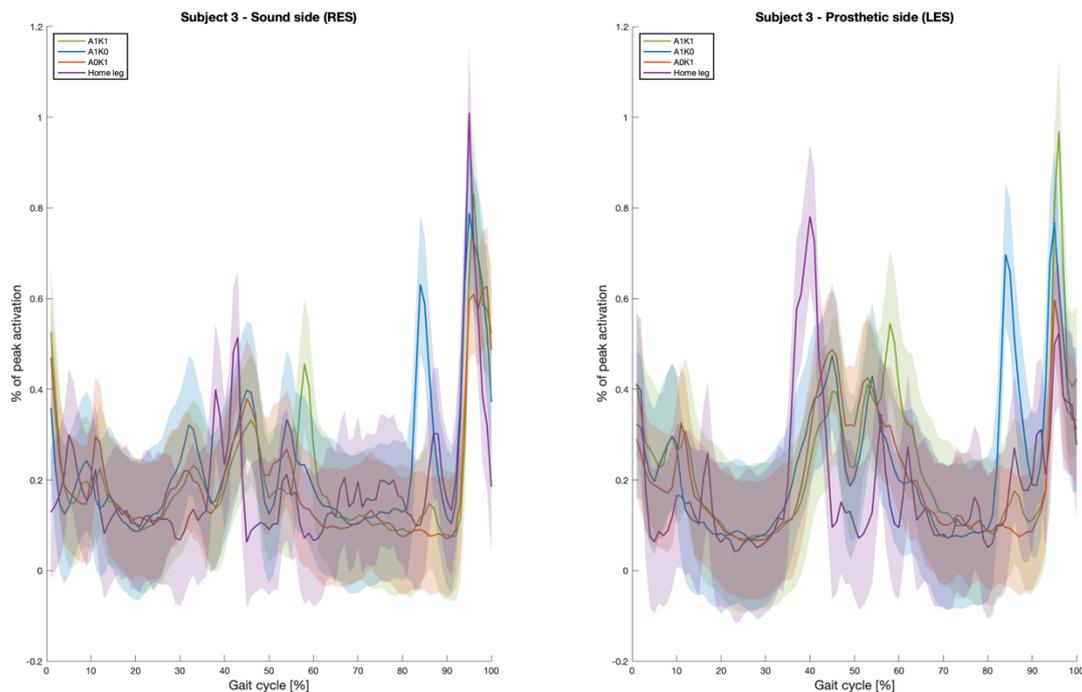


Figure 30: Average (25 +/- 4 gait cycles) ES activity in relation to peak activation [%] of the control condition, of subject 3 in all four prosthetic conditions: Home leg (control), A1K0 (powered ankle, passive knee), A0K1 (passive ankle, powered knee), A1K1 (powered ankle, powered knee). The transparent areas show the corresponding standard deviation.

Looking at the results of subject 3, the activation profile on the sound side ES shows activation peaks of 50% activation at 45% of the gait cycle when walking in the control condition. No differences can be observed across the three powered leg conditions with an activation peak of 30-40% at 48% of the gait cycle with the sound side ES. Also, on the sound side ES another peak occurs in the activation of the powered knee and powered ankle condition (A1K1) at the end of stance phase. On both the sound and the prosthetic side ES a peak activation of over 60% appears between 80 and 90% of the gait cycle, when subject 3 walked in the passive knee and powered ankle condition (A1K0). In all conditions, with up to 100% the highest ES activation appears at the end of swing, just before initial contact (Figure 30).

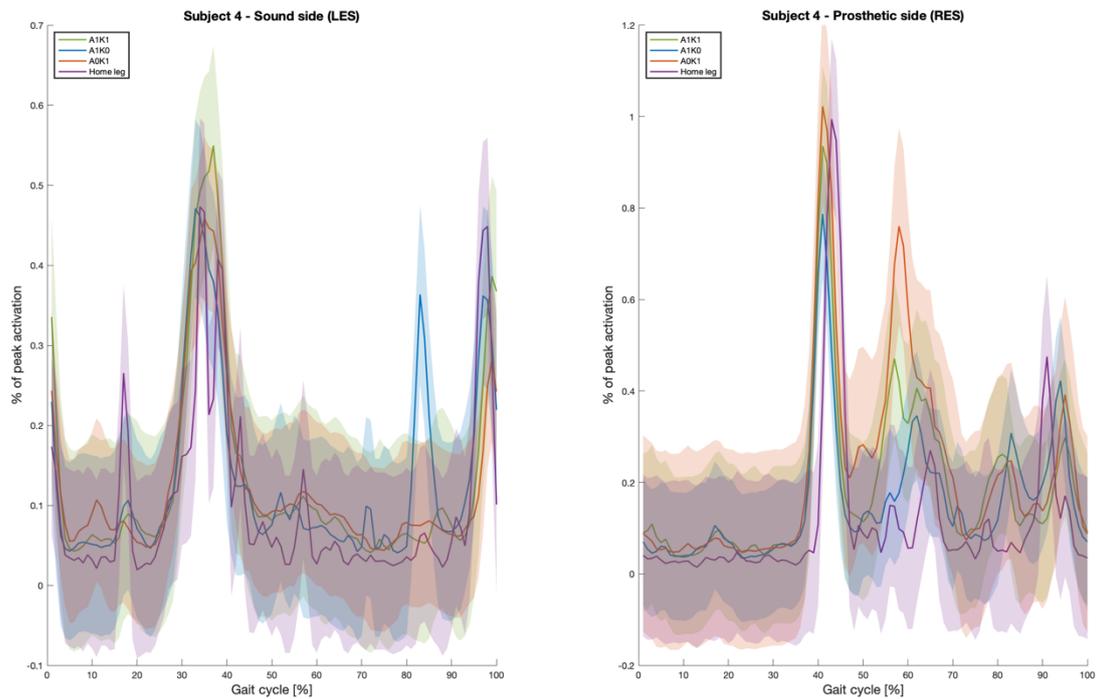


Figure 31: Average (25 +/- 4 gait cycles) ES activity in relation to peak activation [%] of the control condition, of subject 4 in all four prosthetic conditions: Home leg (control), A1K0 (powered ankle, passive knee), A0K1 (passive ankle, powered knee), A1K1 (powered ankle, powered knee). The transparent areas show the corresponding standard deviation.

Subject 4 shows no differences on the sound side ES between A1K1 and A0K1. In both activation profiles of the sound side ES, a first activation peak of about 45% can be seen between 30 and 40% of the gait cycle. A second peak occurs just before initial contact with an activation between 30 and 40% in both conditions. Walking with the home leg subject 4 generates a short activity of 25% after loading response with the sound side ES. In the passive knee and powered ankle condition, an activation of almost 40% occurs at 85% of the gait cycle.

Clearly higher activation occurs at 45% of the gait cycle on the prosthetic side ES in all four conditions with up to 100% of activation. This is followed by a peak activation of 80% in the powered knee and passive ankle condition (A0K1), whereas the other conditions show less activation. The prosthetic side ES shows 40% of activity at the end of swing in all four conditions for subject 4 (

Figure 31).

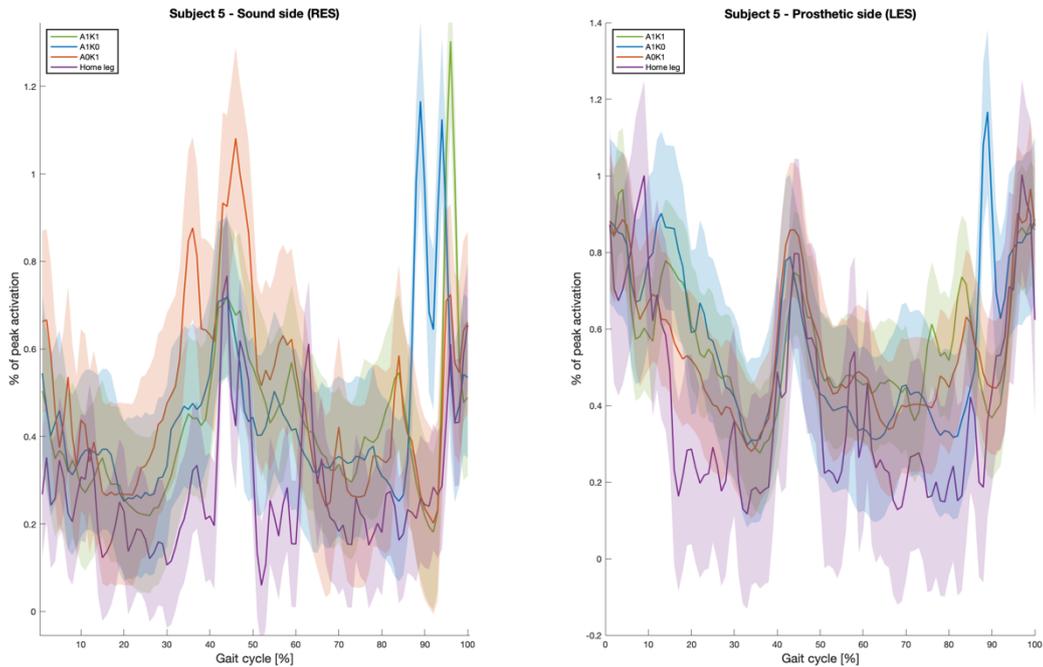


Figure 32: Average (25 +/- 4 gait cycles) ES activity in relation to peak activation [%] of the control condition, of subject 5 in all four prosthetic conditions: Home leg (control), A1K0 (powered ankle, passive knee), A0K1 (passive ankle, powered knee), A1K1 (powered ankle, powered knee). The transparent areas show the corresponding standard deviation.

Subject 5 shows an overall increased activity during stance with the sound side ES, with peak values of 110% in terminal stance, whereas with the other conditions the prosthetic side ES shows an activation of 60-70%. Furthermore, an activation of 115 – 130% appears in the A1K1 and A1K0 condition for the sound side ES at the end of swing.

On the prosthetic side ES subject 5 shows high activity (70-90% activation) in all conditions at initial contact and loading response. The activation with the home leg condition then decreases at 15% of the gait cycle and stays at an activation of about 20% until a second peak in terminal stance, that also occur in the other conditions. With peaks between 70 and 90% activation no differences can be observed at the prosthetic side ES. Walking with the powered ankle and passive knee condition (A1K0), an early peak activation of 120% appears on the prosthetic side ES in terminal swing (Figure 32).

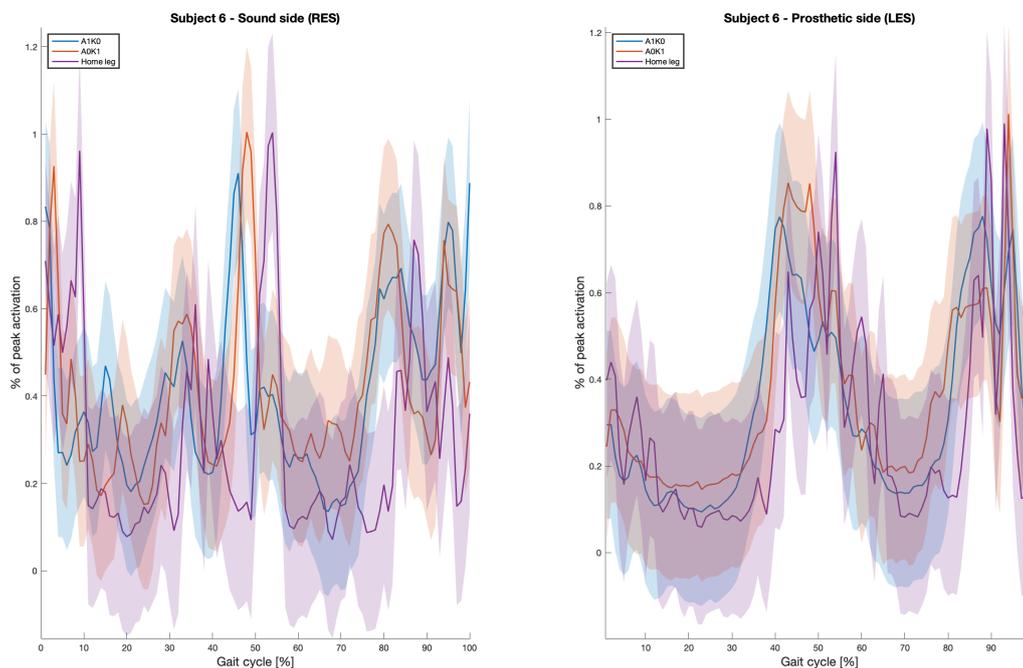


Figure 33: Average (25 +/- 4 gait cycles) ES activity in relation to peak activation [%] of the control condition, of subject 6 in all four prosthetic conditions: Home leg (control), A1K0 (powered ankle, passive knee), A0K1 (passive ankle, powered knee), A1K1 (powered ankle, powered knee). The transparent areas show the corresponding standard deviation.

The data set of subject 6 (Figure 33) only contained three out of the four conditions, where the powered knee and powered ankle condition is missing. Observing subject 6's data reveals a peak activation of 80 – 100% of the sound side ES in all conditions at loading response. Further, the sound side ES shows an activation (50%) throughout all conditions at 35% of the gait cycle. The activation profile of the prosthetic as well as the sound side ES show their highest peaks, with about 80% on the prosthetic side and almost 100% on the sound side at the end of stance phase (50% of the gait cycle). The prosthetic side ES show a smaller peak of 20-40% activation in all conditions during loading response

5 Discussion

This study aimed to investigate the effects on contralateral limb kinematics and lower back muscle activity in level walking of transfemoral amputees, when providing power at the knee and/or ankle. In the following the results of this study are discussed with regard to the current state of literature in order to draw conclusions afterwards.

Spatio-temporal parameters

The analysis of spatio-temporal parameters has shown a decreased step length when subjects walked on the study device compared to their home leg. This could be explained by the faster walking speed that was measured for subjects walking on their home leg. The general observation of a longer step length with the prosthetic leg is an often described gait pattern of transfemoral amputees, which is thought to be caused by a disbalance of muscle activity.[15] Furthermore a slight increased step width was revealed for both passive ankle conditions. This could be explained by the limited dorsiflexion of the prosthetic ankle during swing and therefore an increased circumduction to compensate a functional leg length discrepancy.[18]

Similar to the step length, a typical transfemoral gait deviation was observed concerning the distribution of percentage in swing phase and stance phase. The sound side swing phase is shorter than the prosthetic swing phase and the sound side stance phase is longer than the prosthetic stance phase. This analysis matches with observation in the literature, as a typical gait asymmetry of transfemoral amputees, and originates from a muscle disbalance and the metatarsophalangeal joints and therefore absent fore-foot-rocker.[13], [15]

Studies have investigated an average gait speed of about 1.33 m/s for healthy men and 1.39 m/s for healthy women. With an average of 1.3 m/s for subjects walking at their home leg, their self-selected speed matches the average comfortable speed of abled bodied. As average transfemoral subjects typically walk slower than abled-bodied subjects.[13] This highlights a highly active and functional group of transfemoral subjects that were tested in this study. With regard to the gait speed, conditions using the study device are all close, but slightly lower than the gait speed measured when ambulating with the home device.

Additionally, it should not be disregarded that different masses of the prosthesis could have an impact on these parameters. As only the weight in conditions with the hybrid powered knee were matched with each other, the home leg device had an in average lighter weight of about 1.2 kg.

Overall, the results of spatio-temporal parameters of this study indicate that there is no clear difference across conditions. This still provides an insight into the mechanisms of transfemoral amputees on how they can possibly quickly adapt to different prosthetic devices (with an acclimation time of around 10 minutes for each condition).

Joint kinematics of the prosthetic side hip and contralateral lower limb joints

As already explained in Chapter 2.5 the investigation of kinematic data was mainly conducted looking at curve shapes and patterns, due to irregularities in peak values for both the knee and ankle. An assumption for the reason of those irregularities could be made by movements between the footplate and the foot shell or the shoe. These movements could have been included in the Xsens IMU measurements and thus indicate falsified joint angles. No large standard deviations can be seen in the evaluation of the kinematic data, which shows that the kinematics throughout the examined gait cycles were relatively constant and less varying.

Primarily, the analysis of kinematics was used to investigate sagittal joint angles of the contralateral leg as well as the prosthetic side hip.

The averaged data of the prosthetic side hip, shows an overall similar curve pattern across conditions in all subjects. Looking isolated at some subjects' data, one kinematic pattern becomes noticeable. In the passive knee conditions (A1K0 and home leg), the hip has a greater hip angle at around 80% of the gait cycle and is then moving straight back in the direction of extension, and therefore has a small peak just at the end of stance (Figure 21). This curve pattern is not as pronounced with the powered knee conditions (A1K1 and A0K1). This could be explained by the movement of the hip trying to swing the passive prosthetic knee forward into full extension before initial contact. As the prosthetic knee swing flexion and extension is controlled in the powered knee conditions, the subjects do not have to perform this excessive hip movement, as they do with passive knee prostheses. Future research should further look into this since such effects can be clinically meaningful for an amputee.

Observing the sagittal angle of the contralateral hip the average data shows no differences in sound side hip kinematics between conditions. Further, the comparison between the prosthetic side and sound side hip kinematics shows that on the sound side extension peaks are at about 55% percent of the gait cycle, whereas the prosthetic side hip has its extension peak at about 45% of the gait cycle (Figure 28). The reason for this change is not clear.

Looking at individual subjects (e.g., subject 2, Figure 23) it can be seen that higher hip flexion angles at the beginning and at the end of the gait cycle are performed, when walking with the prescribed home leg. If this is taken into comparison with the spatio-temporal parameters, the increased hip flexion angles can be explained by a longer step length and faster walking speed, when subjects walked with their home leg. However, most subjects show similar curve patterns across all four conditions with their sound side hip (e.g., Figure 26)

For the sound side knee there are no clear differences in kinematics between conditions in the averaged data of all subjects (Figure 28). Looking into some subject data, it sticks out that several subjects performed a greater knee stance flexion, when walking with both passive knee conditions (home leg and A1K0). On the other hand, an increased extension during stance was examined right after stance flexion, possibly because of muscle activity.

Equally to the knee the average data of sound side ankle kinematics show no clear differences between the four conditions. However, in the individual analysis some gait deviations could be examined for some subjects. Hereby, it can be observed that compensatory movements in the way of vaulting is more pronounced in some subjects.[19] This can be detected by a plateau of a dorsiflexed ankle position that occurs in mid stance. This way the prosthetic user either stops the forward progression of the tibia to increase ipsilateral clearance or performs a movement into plantarflexion during stance to achieve the same effect of toe clearance. Nevertheless, this has not changed throughout the different conditions and could be seen as an automatic gait pattern of the subject, that does not adapt to new circumstances within a short period of time.

EMG data

Analysing the results of the recorded EMG data, general similar activation patterns, of the left and right erector spinae muscle can be observed across all subjects. Most subjects show two peaks during stance phase. The first peak occurs right at initial contact and slightly into the loading response. The second activation peak during stance phase appears at terminal stance and pre-swing. A third peak, which can be seen in all subjects, occurs at the end of swing. This analysis of the average activation characteristics of the ES is in line with the literature, that describes most ES activity during double support, as it is at initial contact as well as in pre-swing.[32], [33]

Nevertheless, the different subjects also show different muscle activities. Many subjects show an especially high activation of the ES at the end of prosthetic swing on the sound side as well as the prosthetic side. This could be either to provide a maximum of stability for the following initial contact and to balance the loads that are transferred through the body at that moment.[32] Another reason for such high activation pattern could be a motion artifact of the knee hitting the full extension of the prosthetic knee.

Furthermore, some subjects have shown another peak activation between 80 and 90% of the gait cycle, during mid and terminal swing with the left and right ES. These peaks can be observed with either the subjects walking with their prescribed home leg or in the powered ankle and passive knee condition (A1K0). As this activation occurs with both passive knee conditions, it could be explained by the fact that due to increased hip movements to control the prosthetic swing, more trunk stability is required and therefore the ES activity increases. Another ES activation pattern appears in some subjects, where the second peak during stance is followed by a smaller peak.

Overall, individual differences between conditions can be observed in some subjects. However, the EMG data of the left and right ES shows clear trends of asymmetries between the left and right or differences between conditions. A reason for these results could be that subjects walked only at a comfortable speed, that might have been too slow for the ES activity

to show clear activation profiles. It is stated in the literature, that especially with increased speed the activation of the ES shows repetitive activation profiles and more pronounced amplitudes.[100] Another reason for irregularities of the ES activation that could have been caused by the EMG data acquisition, could be the influence of EMG cross-talk as well as subcutaneous fat which has a high impact of EMG amplitudes.[50]

In addition, when comparing the results with the literature, it should be taken into account that the comparison of data between studies can be affected through different anatomical locations of the electrodes placed on the subjects body.[32]

Control system and strategy

As a basis for the study the control system of the hybrid powered knee and polycentric ankle were adjusted and a new control system was built for this study. The observed kinematic data gives an insight on what effect the control strategy had on the gait of transfemoral amputees. As both the knee as well as the ankle were configured to mimic ankle and knee movements as closely as possible and within the given time frame. For this purpose, the powered knee and powered ankle conditions are considered to give an understanding about the control of the leg. The kinematic data that was recorded with the Xsens system can be used to investigate the functionality of the control system and strategy by studying the kinematics of the prosthetic ankle and knee data.

During stance phase the polycentric ankle allows for controlled plantarflexion during loading response and as the leg is rolling over the foot the ankle moves into a dorsiflexion. In pre-swing the ankle carries out a plantarflexion to provide a push-off movement for forward propulsion. In swing the ankle goes back into a dorsiflexed position to provide clearance between the foot and the ground, to avoid tripping. This ankle movement throughout the gait cycle is similar to abled-bodied subject data from the literature.[13]

Evaluating the control of the knee, kinematic results show a neutral position (i.e., near full extension) during stance phase. Hence, the knee is not controlling stance phase flexion, which is a pattern that has been described before in intact-limb gait.[27] During swing an averaged knee flexion angle of 45 degrees is reached. This is 20 degrees less knee flexion during swing, when comparing it to passive prosthetic devices (home leg and A1K0) as well as abled bodied subjects.[25] The decreased knee flexion is due to the control of the leg. Different subject testing have shown that when increasing the knee flexion angle during swing, the leg turned out to be not fast enough back into full extension before initial contact, which leads to the effect of slowing the pace of a subject down, because they have to wait for the full extension of the leg in terminal swing, or to cause insecurity of the patient to perform the next stride with an unstable knee. Additionally, it remains unclear what impact the powered ankle has on the initial swing of the passive knee. Assumptions could be made, that due to the powered push off

movement from the ankle, the knee flexion of the passive knee is supported. To confirm this, further investigations would have to be conducted.

Further kinematics of the prosthetic leg can be explained by the functionality of the different prosthetic devices. As all prescribed prosthetic feet were carbon fibre spring feet, the initial plantarflexion movement of the foot is depending on the flexibility of the heel spring of the foot. The same circumstances determine the extent of dorsiflexion during mid stance and terminal stance, depending on how much deformation the prosthetic feet allow. Further, due to the construction of the passive prosthetic devices, passive ankle components cannot perform a dorsiflexion movement during swing, as it is visible in the kinematics and had been reported in literature.[29] Accordingly, the prosthetic knee angles of the home leg depended on the individual prescribed prosthesis of a subject. Because no subject had a prescribed powered prosthesis the knee is not controlled with impedance parameters to define a target angle value. The same case applies to the hybrid powered knee in its passive mode condition. This results in an increased knee flexion angle during swing compared to powered knee conditions. If able-bodied subjects are considered, the knee flexion with the unpowered devices is closer to the natural knee flexion than the knee flexion with the powered hybrid knee.[13]

Subjective feedback

Besides the effects on the kinematics and muscle activity, the subjects gave subjective feedback, after walking in the different conditions. Contrary to what the results suggest, the subjects noticed major changes between conditions. The first thing that was stated by everyone was the increased weight after changing from the home leg condition to the powered prosthesis, which was in average 1.2 kg. For most subjects, the additional weight felt heavy and dragging at first, but a majority then reported that they were getting used to the added weight quickly.

In the different conditions different effects were noticeable for the subjects. In both powered knee conditions (A1K1 and A0K1) subjects reported that the main difference, compared to a passive knee is, that they did not have to think about the way of how they would put weight on the leg or that they did not actively have to swing the knee during walking, because these mechanisms are controlled by the leg. However, some subjects reported that due to the controlled knee, it was sometimes not exactly following the intentions of the subject or adjusting to the walking speed, and therefore too slow in swing phase.

In the conditions, where the powered ankle was involved (A1K1 and A1K0), most subjects reported positively that they could feel the push-off from the ankle, which provided them with an additional forward propulsion, that they are usually missing with a passive foot prosthesis. For these reasons several subjects stated that they would prefer the A1K0 (powered ankle and passive knee) condition the most, because it would give them the push-off movement and still a freely swinging knee. This allows the assumption that the powered ankle could support the flexion of the knee in the swing phase, due to its push-off movement during pre-swing.

Limitations and conclusion

All in all, the results of the present study give further insights into the effect of powered prosthetic devices of transfemoral amputees. However, several limitations should be noted. Firstly, subjects were only given a short (~10 min) acclimation time for each condition. It is possible that it takes longer to acclimate to the device and that differences would only become apparent after much more walking. Secondly, it is possible that the control system was not ideally configured for the device. This is the first component of a much larger body of work which will examine several other gait activities. Consequently, the control system was configured to be safe, allow for spontaneous transitions to standing, and not optimized for steady-state walking. Thirdly, this study only examines sagittal kinematics and erector spinae muscle activity. Therefore, it remains open whether the different conditions could have a different effect on the other biomechanical parameters, such as sound side limb muscle activity, joint kinetics, or kinematics in the frontal and transversal plane.

Finally, as just noted, this work only considered walking. It is possible, and in fact likely, that joint power will be much more important for other activities such as stair climbing. Thus, future research should take the aforementioned limitations into account when investigating the effects of powered prosthetic devices.

To answer the research question of how power at the knee and/or ankle effects contralateral limb kinematics and lower back muscle activity in level walking of transfemoral amputees, kinematic and EMG data were analysed. To our knowledge, this is the first study that has investigated the effects of using a powered ankle with a passive knee for transfemoral amputees, and therefore this study provides some clarity in this matter.

Overall, the results show no differences throughout all conditions. Nevertheless, several conclusions can be drawn from these results, as they provide practical information. This is still an important finding, and several limitations (mentioned above) could have masked differences if they existed. The results not only show no differences between the four conditions, but they also show that walking on the powered prosthesis had no negative impact (e.g., due to additional weight) in the present study. Our finding that using these powered devices does not impair gait is important, as subjects will spend much of their time in this essential activity, underlining the importance of further investigating these mechanisms. Especially when the subjective feedback of the subjects, with the favoured powered ankle and passive knee condition (A1K0), is taken into consideration.

6 Outlook

This study serves as a first step for a larger body of work about the investigation of the impact of power on the gait of transfemoral amputees. As the focus of this work lays on the technology that was applied to the subjects, the configuration of the powered prosthesis and the investigations of lower back muscle activity and the kinematics of the contralateral leg, a solid basis for further studies could be established.

Future studies should include further ambulation modes such as ascending and descending stair and ramps. For this purpose, the control strategy should be further developed for subjects to perform these ambulation modes reliably and safely.

Furthermore, future studies should investigate the impact of power at the knee and/or ankle on contralateral leg muscle activity as well as sound side kinetics, to reduce transfemoral gait deviations and secondary comorbidities and therefore increase the quality of life of amputees.

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List of Abbreviations

10MWT	10-meter walk test
A0K1	passive ankle, powered knee
A1K0	powered ankle, passive knee
A1K1	powered ankle, powered knee
ADL	activities of daily living
ASIS	anterior superior iliac spinae
AVT	actively variable transmission
CR	centre of rotation
EMG	electromyography
ES	erector spinae muscle
ICR	initial centre of rotation
IMU	inertial measurement unit
LES	left erector spinae muscle
LLA	lower limb amputation
RES	right erector spinae muscle
TF	transfemoral
TT	transtibial