MSc thesis in Biomedical Engineering

Gait in transfemoral amputees using an osseointegrated prosthesis: Development of a biomechanical model and a measurement protocol

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Abstract

Introduction: A prosthesis can be used to regain function after an amputation of the lower limbs. Conventionally, the prosthesis is connected to the stump using a tight fitting socket. The socket often leads to sweating, skin problems or discomfort while sitting. A new way of prosthetic attachment is by osseointegration. During osseointegration surgery a titanium implant is fixed to the remainder of the femur. The prosthesis can be attached to the extracorporeal part of the implant called the abutment. In this way, socket related problems can be avoided. Qualitative analyses have reported improved walking ability, prosthetic use and a higher prosthesis related quality of life in patients using an osseointegrated prosthesis, but not much is known yet on quantitative improvements in gait measured in a clinical setting. Therefore this study mainly aims to compose and execute a measurement protocol for clinical quantitative gait analysis of unilateral transfemoral amputees using an osseointegrated prostheses. Furthermore, a biomechanical model will be created using OpenSim and will be validated using the data recorded using the clinical measurements.
Method: A measurement protocol for quantative gait analysis in a clinical setting was created and carried out by measuring one participant using an osseointegrated prosthesis. The participant walked at self selected walking speed across a runway with force plates built in and walked on the floor next to the runway with equal conditions around. The protocol also included measurements for stability and direction of attention during gait trials. A biomechanical model of a unilateral transfemoral amputee with an osseointegrated prosthesis was developed using OpenSim. Bones and muscles of one leg were replaced by prosthetic geometry and settings were altered. The model was used to analyse kinematics and kinetics.
Results: Spatiotemporal differences were found between the floor and runway condition. Kinematic comparison showed significantly different knee flexion for the intact leg for a small phase in the gait cycle. Despite the spatiotemporal differences were significant, these were mostly small. Together with the lack of kinematic differences, the difference between the two was not considered clinically relevant and only the runway condition was included in the results section. Kinematic and kinetic results were plotted against control values measured with healthy controls. Compared to these controls the prosthetic side showed a larger hip extension peak, no ankle plantairflexion peak, a larger hip flexion moment, absence of a characteristic knee flexion moment and a lower ankle plantairflexion moment. For the intact side the most noticeable differences were a knee flexion and ankle plantairflexion peak later in the gait cycle, lower hip extension moment and a higher knee flexion moment. Furthermore, prosthetic side Margin of Stability was higher, around 60% of the bodyweight was carried by the intact leg during standing up from and sitting down on a chair and the direction of attention was more focused downwards during the floor condition measurement.
Conclusion: The aim of that the development of a measurement protocol including a biomechanical model to measure and analyse the gait of a transfemoral amputee using an osseointegrated prosthesis is achieved. The results from several analyses were compareable to results found in literature, which served as a validation for the model developed in this study.

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Acronyms

AIM - Automatic Identification of Markers
AP - Anterior-posterior
BoS - Base Of Stability
BTK - Biomechanical Toolkit
BW - Bodyweight
CoM - Centre Of Mass
EMC - Erasmus Medical Centre
EMG - Electromyography
HREC - Human Research Ethics Committee
IC - Informed consent
ID - Inverse Dynamics
IK - Inverse Kinematics
ML - Medio-lateral
MOKKA - Motion Kinematic & Kinetic Analyzer
MoS - Margin Of Stability
MREC - Medical Research Ethics Committee
OI - Osseointegration
OIP - Osseointegrated Prosthesis
QTM - Qualisys Track Manager
SD - Standard Deviation
SP - Socket Prosthesis
SPM - Statistical Parametric Mapping
SPSS - Statistical Package for the Social Sciences
SSWS - Self Selected Walking Speed
TFA(s) - Transfemoral Amputee(s)
TUD - Delft University of Technology
X_{CoM} - Dynamic Centre of Mass

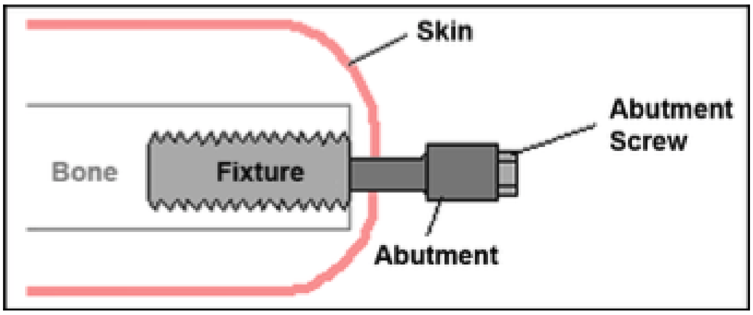
1. Introduction

In the Netherlands alone, annually around 3300 people undergo amputation of a part of their leg, or even legs [1]. Most amputations are needed due to blood vessel related problems possibly caused by diabetes mellitus, with other causes being a trauma or a tumor [1][2]. In the future, the amount of people suffering from blood vessel related problems and diabetes mellitus is expected to grow over time, because the growing and ageing population [3]. This suggests that prevalence of lower limb amputation is growing, and medical care and technology regarding lower limb amputations should as well.
Lower limb amputations are generally classified by the location of the amputation, distally starting with amputation of one or multiple toes, the whole foot, below the knee (transtibial), through the knee (knee disarticulation), above the knee (transfemoral) or through the hip (hip disarticulation). Logically, a higher amputation induces a larger impairment of the normal functioning and results in greater alterations to the gait pattern.
A prosthesis can be used to partially regain function. Attachment of the prosthesis to the stump, the remainder of the leg after an amputation, is conventionally done by a socket. This socket is personalised for each patient to create a tight fit around the stump in order to prevent movement from the leg in the socket or socket detachment from the leg. A downside to this snug fit is the problems it causes to the stump. One in three socket prosthesis (SP) users experience skin problems including sweating, itching, acne [4] [5] [6] or other conditions as blisters and open wounds are reported [7] [8] [9]. Besides the skin issues, transfemoral amputees (TFA(s)) experience discomfort while sitting due to the socket [10].

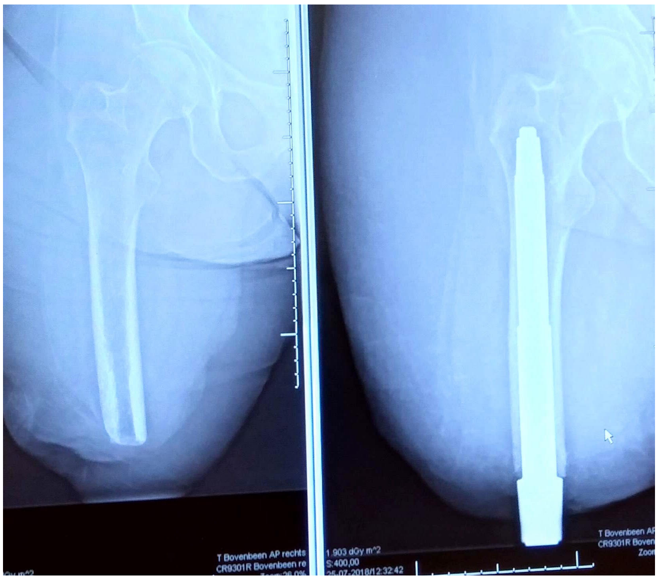
1.1. Osseointegration

A relatively new way of attaching a prosthesis to the stump is done by osseointegration (OI). The use of an osseointegrated prosthesis (OIP) was an already proven concept in dental implants and in the early 90's it was first used for lower limbs [9]. OI is a method of prosthesis fitting where a titanium part is surgically fixed into the remainder of the femur. On the other side this titanium part sticks out of the skin as an abutment, see figure 1.1. A prosthetic knee can be attached to this abutment with an allen key, a tool used to tighten or loosen bolts or screws.

A clear advantage is the needlessness of a socket and the socket related skin- and comfort problems. Patients using an OIP have shown significant improvements in prosthetic use, walking ability, a lower problem score and a higher prosthesis related quality of life [11] [12] [13] [14]. Qualitative analysis has shown that wearing an OIP leads to more than only improved functional ability. Patients reported they were less frustrated, more engaged in social activities and living with an OIP was describes as revolutionary [15]. On top of that, implant mediated sensory feedback, called osseoperception, is a result of the direct mechanical stimulation of the implant to the femur [16].
Nevertheless, OI related complications occur as well. Examples of these complications are



(a)



(b)

Figure 1.1.: The osseointegration fixture with (a) a schematic view , copied from [9] and (b) a radiograph of the femur before and after osseointegration surgery

failure of abutment, loosening of the implant and soft tissue infections and haematoma [17]. The first complication is a mechanical failure of the prosthesis, that could be caused by a faulty design of the prosthesis. The other complication are not merely caused by the prosthesis, but are a result of the interplay of prosthesis and human. The skin cannot fully close around the abutment, resulting in an open wound causing soft tissue infections. Thorough cleaning of the skin can help prevent infections and antibiotics are used to treat the majority of these infections, which are described as low-grade [11].

1.2. Gait and the value of clinical testing

Human gait is an intricate interplay of sensory- and musculoskeletal systems in your body providing the ability to walk. It depends on leg muscles to cooperate within a very strict timing. Many variables can be used to describe this complicated system and in this section the variables used in this report will be described shortly.

First of all, gait is an activity performed by repetitive gait cycles. A gait cycle is the period of time between one initial contact of the foot with the ground, called a heel-strike, until the following ipsilateral heel-strike. A graphical representation can be seen in figure 1.2. Variables related to foot placement, called spatiotemporal variables, are easiest to measure. These variables are based on either distance (spatio, e.g., step length), time (temporal, e.g., gait cycle duration) or a combination of both (e.g., walking speed). Measurements of spatiotemporal variables can be done using a stopwatch and a tape measure, so advanced technology is not necessary.

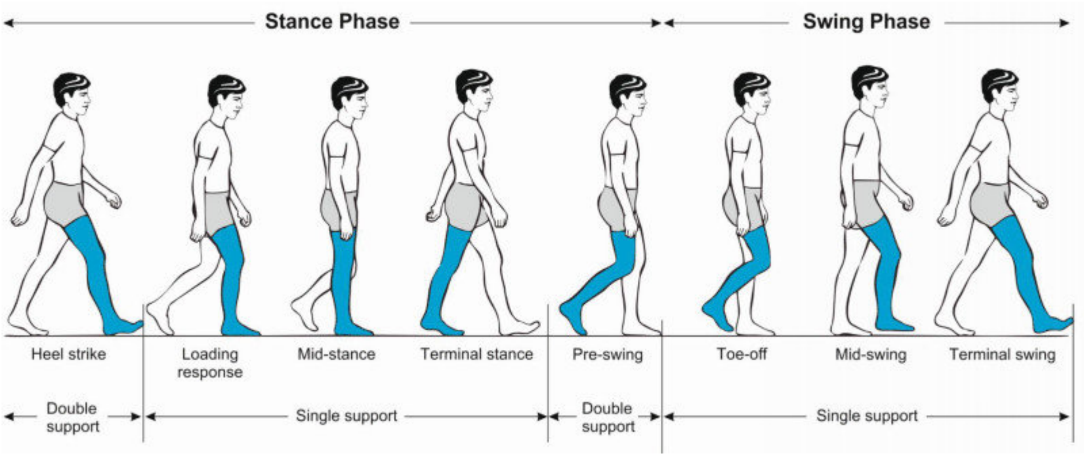


Figure 1.2.: Human gait cycle. Copied from [18]

How the skeletal system moves during the movement of a gait cycle is described by kinematics. Usually they describe rotations of a proximal segment relative to a distal segment around their axes or angles between these segments in intermediate joints. Examples of kinematic variables are hip- and knee flexion angles over time. These three dimensional orientations of the joint can be described using an angular decomposition in three anatomical planes, the first being the saggital plane, used in figure 1.2, the second one being the frontal plane and the third one being the coronal plane. Movements from the hip and the knee observed in the frontal plane are adduction and abduction and movements seen from the coronal plane are internal rotation and external rotation. These can be seen in figure 1.3.

Kinematic variables need a motion capture system to be able to look at measurement and perform calculations. Because kinematic measurements require a more advanced form of technology they are less feasible to implement.

The third category of variables measured in this research are kinetic variables. Kinetic variables describe the forces and moments associated to the mass distribution of the skeletal system when walking. These variables are used to assess the forces, e.g. ground reaction forces and muscle forces, experienced in joints during gait [20]. Ground reaction forces are

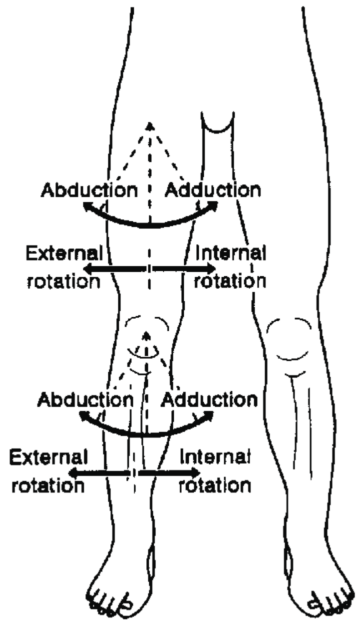


Figure 1.3.: Frontal and coronal movements of the knee and hip. Copied from [19]

used to calculate moments around the hip, knee and ankle. Ground reaction force measurement equipment is technologically advanced and therefore these variables are the least feasible to implement.

One can imagine the gait pattern changes drastically when a prosthetic device is used to replace a part of your leg after amputation. A broad variety of possible gait patterns are observed for patients with for example a different level of amputation or different type of prosthesis. The analysis of differences in gait patterns can result in insights in ambulation strategies or possible underlying pathologies or provide insight in possible mechanical failures and therefore gait comparisons can be clinically relevant.

Lastly, electromyography (EMG) is a diagnostic tool for measuring electrical activity of a muscle. EMG measurements can be valuable in prosthetic gait analysis, as they give insight in the muscle activation and the timing and pattern of these muscles and the differences between amputees using an OIP, socket prosthesis and healthy control subjects[21].

Besides variables describing the gait cycle other tests are used in the clinical setting to assess functional ability of a patient. These tests focus on other aspects of walking, such as stability or confidence. Stability is an important factor for functionality, because the lower the stability the higher the chance of falling over with possible injuries impairing the ability to walk. A way of measuring stability is by using a measure called the Margin of Stability (MoS) [22]. In MOS calculations the body is represented as an inverted pendulum. The location of the Centre of Mass (CoM) and the velocity of the CoM are used to assess a dynamic stability condition, by calculating the distance to the Base of Support (BoS).

Confidence is another aspect looked at in this study. Partly, this confidence is related to the prosthesis, because the patient needs to be confident in the prosthesis and trust on it to bear the load if load is applied onto the prosthetic leg. And partly, the patient needs to be confident in their ability to use the prosthesis to be able to walk. In consultation with the physician assistant from the Erasmus Medical Centre (EMC) the proposed measure to assess confidence is done by comparing the load application between both legs while standing up from a chair without using the arms to support. This method is based on the timed "up and go" test, previously established to highly correlate with walking speed, scores on the Berg Balance Scale and Barthel Index [23]. In this study the standing up part will be isolated from this test, because the gait is already measured and the task of sitting down is added. The more load a patient applies to the prosthetic leg, the more confident the patient will be in their prosthesis.
According to clinical observations by physician assistants from the EMC in Rotterdam patients using an OIP tend to look less downwards at their feet and more straight ahead while walking. This could be an indication of confidence in their own ability to walk across the terrain they are facing and therefore it is included in the measurements. Since the OIP is a relatively new concept, clinical proof of this observation has not been reported yet and therefore this remains an exploratory parameter.

In the beginning of this report a number of functional improvements were highlighted. The effect on the gait pattern is another important measure for the quality and effectiveness of a prosthesis.
Multiple studies have focused on a specific part of amputee gait by measuring a selection of the aforementioned gait variables, but a full biomechanical analyses has not been conducted in the same way as this research intents to. Mostly spatiotemporal values are reported in studies focusing on main topics other than biomechanical analysis, such as loading on the osseointegrated implant or the bone-implant interface [24] [25] [26] [27] [28]. Kinematic and kinetic analysis has been conducted in the same study, but angles and moments have not been reported for complete gait cyles, but only during the stance phase [29] [30]. The swing phase must be included to be able to analyse an entire gait cycle and strengthen the foundation for further research.
At the time of writing the report there is one other study with the same objective of designing an OpenSim model of a unilateral transfemoral amputee walking with an OIP [31]. The difference between the aim of both studies is the comparison between patients walking with an OIP and healthy controls. This study aims to fill the research gap described above, as can be read in the next section.

1.3. Aim of the study

The main objective of this study is to compose and execute a measurement protocol for a full biomechanical quantitative gait analysis of a transfemoral amputee using an OIP. Consequently, this study also aims to create a biomechanical model of a transfemoral amputee using an OIP based on the analysis. The measurement protocol and biomechanical model serve the purpose of creating a basic foundation for future researches on osseointegration to build on.
In this study a full biomechanical analysis is considered as an analysis where spatiotemporal, kinematic and kinetic variables can be successfully measured. This means the analysis

must at least include spatiotemporal variables, an inverse kinematics and an inverse dynamics analysis to measure joint angles and joint moments. The biomechanical model will be validated by comparing the results of all analyses to results found in literature. Furthermore, confidence and stability during walking and symmetry of loading between both legs will be included in this study.
Outcomes of the gait analysis could highlight certain aspects of the gait pattern to focus on during rehabilitation or changes in prosthetic design.

2. Methods

2.1. Preparations

Before the measurements approval by the the Medical Research Ethics Committee (MREC) from the EMC and the Human Research Ethics Committee (HREC) from the Delft University of Technology (TUD) had to be given. Both concluded the suggested measurements and methods of data storage and analysis were according to the regulations.
Potential participants were contacted by their treating trauma surgeon and physician assistant from EMC if all of the following inclusion criteria and none of the exclusion criteria were met:

Inclusion criteria	Exclusion criteria
18 years or older	Any balance disorder
Unilateral transfemoral amputation	Insufficient Dutch language proficiency
Using an osseointegrated prosthesis	
Finished full rehabilitation	
Able to walk for at least 2 minutes	

Table 2.1.: Inclusion and exclusion criteria for participants

After reading all information and agreeing to participate the participant was invited to the Gait Lab where Informed Consent (IC) was signed before the measurements could be conducted.

This process led to the inclusion of one participant for this study. Table 2.2 summarizes the participant demographics.

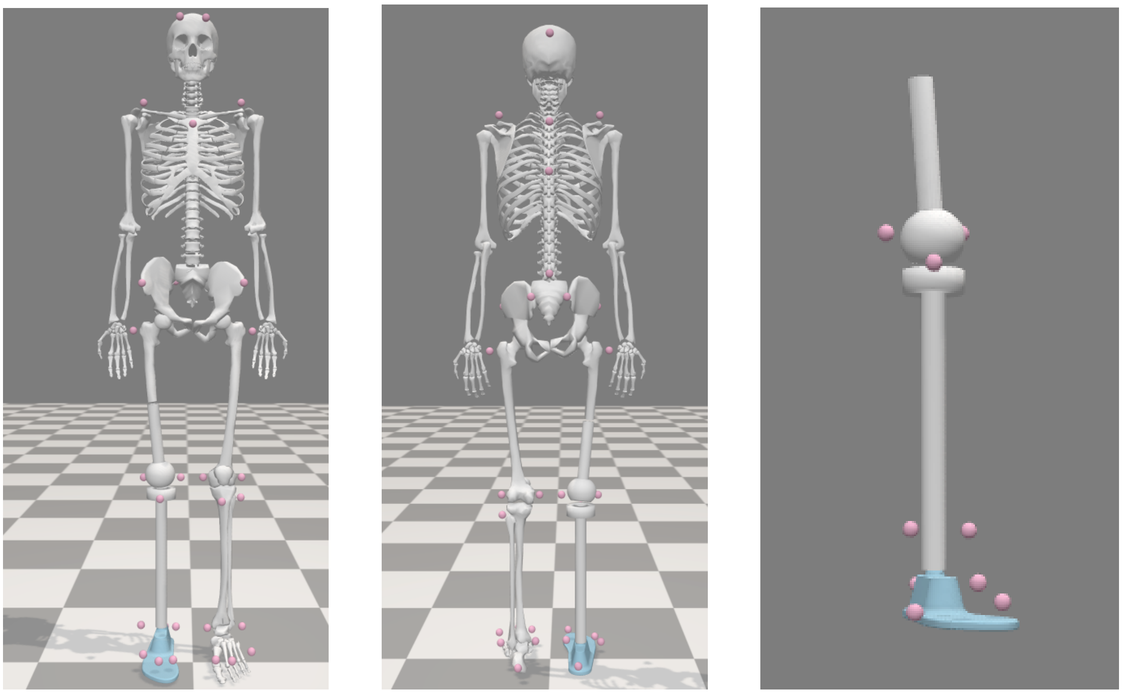
Demographic	Value
Age	65 years
Sex	Female
Weight	70 kg
Height	170 cm
Year of amputation	2001
Amputation side	Right
Type of amputation	Transfemoral
Year or OI surgery	2018
Usage of OIP	7 days a week up to 15 hours a day
Prosthesis type	OPL, type A (18x160)

Table 2.2.: Participant demographics

2.2. Biomechanical model

A model of a transfemoral amputee using a passive OIP was created in OpenSim. OpenSim is an open source software system for developing, modeling and analyzing musculoskeletal models.

The transfemoral amputated model is based on a healthy able bodied model by Rajagopal [32]. This model was edited to create a model with a transfemoral amputation and an OIP. Firstly the femur was unilaterally cut and all bones more distal to the femur were removed. The femur was cut at approximately halfway the femoral shaft and the weight was reduced by 41.5%, according to calculations based on relative mass of femoral parts [33]. Software used to adjust the geometry was Paraview 5.8.1 (Kitware, New York, the United States) and Meshlab version 2020.12 (Visual Computing Lab, Pisa, Italy). Basic geometry was added to replace the removed bones. A pylon was created and added to the upper leg and a shaft and a foot were copied from a transtibial model [34] and added to complete the prosthesis, as can be seen in figure 2.1.
Weights for the geometry were based on product information available in online catalogs, inertia was changed accordingly as well using the formula for the inertia of hollow cylinders and homogeneous material properties were assumed. A more detailed description of the inertia calculations and the placement of the CoM for the lower leg geometry can be found in appendix A.3.



(a) (b) (c)

Figure 2.1.: The OpenSim model of a unilateral transfemoral amputee with an OIP with (a) a front view with markers, (b) a back view with markers and (c) a close up of the prosthesis with markers

The pylon was joined to the femur by a WeldJoint. This is a joint where no relative motion is possible between the two bodies, as there is no relative motion between the femur and the titanium shaft after OI surgery in real life. The knee and ankle joints are modeled with the same degrees of freedom as the healthy opposite leg. For the knee this resulted in 1 degree of freedom in the knee allowing knee flexion and 2 degrees of freedom in the ankle allowing ankle dorsiflexion and ankle inversion[32].

Muscles and tendons are removed from the prosthetic side of the model, as there is high variability in muscle geometry in transfemoral amputees and therefore there is no general way of modeling the remaining upper leg muscles [35]. All muscles from the original healthy able bodied model with origo or insertion at the intact leg remain in the model. A list of these muscles can be found in Appendix A.2.

The markers implemented in this model in figure 2.1 (a), (b) and (c) are based on a marker model further elaborated on later in the report.

2.3. Measurement in the lab

2.3.1. Experimental setup

The measurements were all conducted in the Gait lab at the TUD. In this lab a level runway of 8 meter was put together with three portable Kistler force plates type 9260AA6 in the middle of the runway. Before and after these plates the runway was completed with plates equal to the force plates in height, width and color in order for the participant to get started and to end their walk so the gait cycles over the force plates are most like the normal gait cycles. The lab is equipped with a Qualisys motion capture system consisting of twelve infrared cameras able to locate passive markers in the room. The system is operated by Qualisys Track Manager (QTM) software.

The marker model used to measure the participant's gait is based on a modified version of the IOR Gait Full-Body Model [36]. It consists of 34 passive reflective markers. The marker model was modified by removing three markers on the spine, because these were so close to each other the QTM software would switch marker labels around and detailed measurements for the spine were outside of the scope of this research. The removed markers from the original were CV7, TV7 and LV1. Three markers were added on the head for measuring the gaze during gait. These can also be seen in figure 2.2

(a) (b)

Figure 2.2.: The participant with all markers attached to the body with (a) a front view and (b) a back view with markers.

This marker model was also implemented in the QTM software to create an automatic identification of markers (AIM) model, so markers were automatically detected and labeled. All anatomical marker locations can be found in table 2.3.

EMG measurements were supposed to be done using 4 Delsys Trigno Avanti surface EMG measurement devices, placed on the long head of the m. biceps femoris muscle and m. rectus femoris of both legs. These muscles were chosen as they are the main antagonists in the upper leg and were most common in other studies, for example measured by Wentink et al.[21], thus providing more literature for comparison. Unfortunately on the day of the measurement technical difficulties with the surface EMG devices led to exclusion of this measurement in this study, but it was not excluded from the measurement protocol.

Body part	Anatomical location
Foot	Calcaneus at the insertion of the Achilles tendon (L+R)
	Dorsal margin of metatarsal 1 (L+R)
	Dorsal aspect of metatarsal 2 (L+R)
	Dorsal margin of metatarsal 5 (L+R)
Tibia / prosthetic shank	Lateral prominence of the malleolus (L+R)
	Medial prominence of the malleolus (L+R)
	Anterior border of the tibial tuberosity (L+R)
	Fibula proximal tip (L)
Femur / prosthetic knee	Lateral prominence of the lateral epicondyle (L+R)
	Medial prominence of the medial epicondyle (L+R)
	Lateral prominence of the greater trochanter (L+R)
Pelvis	Anterior superior iliac spine (L+R)
	Posterior superior iliac spine (L+R)
Torso	Acromion (L+R)
	Thoracic vertebrae 2
	Deepest point of the incisura jugularis
	Most caudal point of Sternum
	Lumbar vertebrae 3
Head	Frontal bone (L+R)
	Back of the head

Table 2.3.: List of marker locations with the body part and more detailed anatomical location. (L=Left, R=Right)

2.3.2. Measurements

Model calibration

The measurements started with a recording of the participant standing still and with a recording where the patient made some random movements. These files were used for updating AIM model and the static file was also used for the scaling the OpenSim model to the subjects' geometry.

Gait

Gait measurements were conducted in two conditions. The participant was asked to walk at self selected walking speed (SSWS) during all measurements. For the first measurement the participant had to walk on the floor next to the runway. For the second gait measurement the participant had to walk across the runway described in the experimental setup. For both conditions the participant had to walk five times to one side and five times back.
By walking on the floor the conditions are most like conditions normally experienced during walking and gait is most like the person's gait and could therefore be considered as most normal.
The perceived gait patterns will be compared and this comparison aims to evaluate the differences between gait patterns on the floor and on the runway. If the gait patterns are similar in both scenarios, the gait measured on the force plates can be considered representative of normal gait and the results for the floor condition will not be relevant for further analysis.

Standing up from chair

For the last measurement the participant had to stand up from a chair placed on a level surface to the force platform and was asked to do this with both of their hands in front of them, without touching their knees or the chair. Both feet will be placed on different force plates to independently measure the load applied to each leg.

2.4. Analysis

2.4.1. Spatiotemporal variables

The analysis for spatiotemporal variables was done using MATLAB and Statistics Toolbox Release R2019b, 64-bit (The MathWorks Inc, Natick, Massachusetts, United States.) on c3d files exported from QTM. Gait events, in this case the heel strike or toe-off, were added to the recordings using open source Motion kinematic & kinetic analyzer (MOKKA) software, powered by the Biomechanical Toolkit (BTK)[37], an open source library. Walking speed was calculated by dividing the distance traveled by the heel markers between subsequent heel strikes and by the time needed to cover this distance. Cadence was calculated by the time needed for one step. The step length was calculated by finding the distance between both heel markers when the foot to whom they are attached had a consecutive heel strike. Step width was calculated by the orthogonal distance between the left foot and the right foot.

2.4.2. Stability

As described earlier the MoS is used to assess stability. For the MoS calculations the following equations used, based on other articles ([22][38]):

$$MoS = BoS - X_{CoM} \tag{2.1}$$

In this equation the Base of Support (BoS) is calculated by finding the maximum value for the boundary in the anterior-posterior (AP) and medio-lateral (ML) direction. For the AP direction this boundary was set by the distance between the second metatarsal marker and the pelvic CoM and for the ML direction this boundary was set by the lateral malleolus marker, see 2.3. In figure 2.3 the BoS is represented by the dotted lines, with the line through the toe marker the ap boundary and the dotted line through the lateral ankle marker.

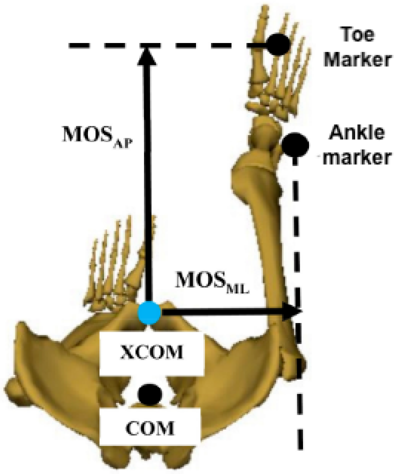


Figure 2.3.: Illustration of variables used in Margin of Stability calculations, copied from [38]

The MoS is eventually calculated by subtracting the velocity adjusted CoM (X_{CoM}) from the BoS. By comparing the dynamic CoM with the boundaries of the support base, an analysis of one's dynamic stability can be done. The X_{CoM} is calculated using the following equation:

$$X_{CoM} = CoM + \frac{v}{\omega_0} \tag{2.2}$$

In this equation CoM stands for the position of the CoM at a certain point. The CoM was calculated by averaging the location of the markers placed on the pelvis, as done by [38]. And v represents the velocity of the CoM in either the anterior-posterior (AP) or the medio-lateral (ML) direction, meaning the MoS will be calculated in both directions. In this equation the ω_0 is the eigenfrequentie of the lower body, represented as an inverted pendulum. It is calculated using the following equation:

$$\omega_0 = \sqrt{\frac{g}{l}} \tag{2.3}$$

In this equation g is the gravitational constant ($g = 9.81\ m/s^2$) and l is the length of the inverted pendulum. This length was calculated by finding the three dimensional distance between the left heel marker and the CoM at left heel strike.

2.4.3. Confidence

Symmetry of loading

The load placed on the prosthetic leg and intact leg will be measured while the participant performs the task of standing up from a chair. The symmetry of loading is calculated by dividing the force measured by each force plate by the bodyweight (BW) force. This will result in load on each leg described by a percentage of the BW during the course of

performing the task.
The start of the standing up and sitting down task was defined by the first frame a higher force was measured for either one of the legs. The task ended when the load on both legs was back to the original value and stable.

Direction of gaze

The direction of attention during gait was analysed by using the three markers placed on the head of the participant. A plane was drawn between these three markers and the angle of the plane relative to the x-axis was calculated. This was done during the static measurement, where the participant was asked to look straight ahead and during both the floor and runway condition. For the gait measurements, the mean of the angle was calculated during the trials and compared to the static measurement to find the direction of attention. A visual representation of the markers and the calculated angle can be seen in figure 2.4.

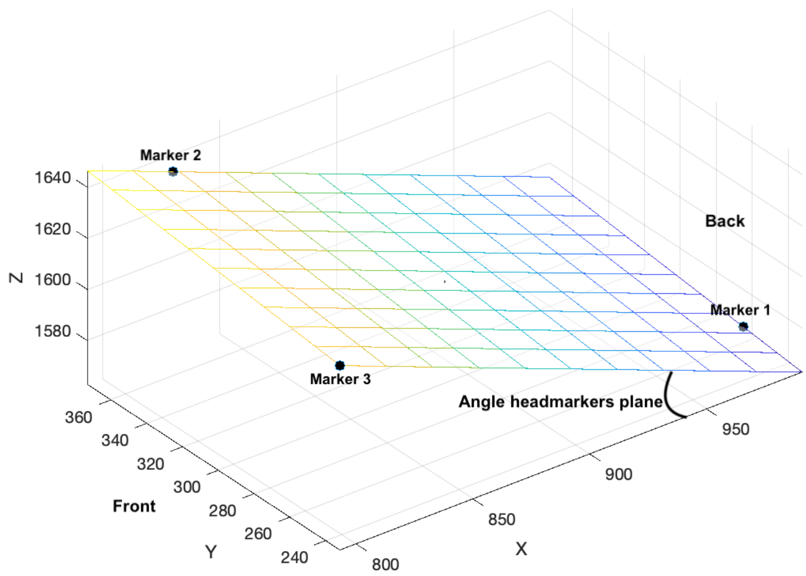


Figure 2.4.: The plane between three head markers and the angle calculated or the direction of attention

Scaling the model

Scaling the model was part of preprocessing the data, meaning this had to be done before further analysis could be done. The biomechanical model was scaled to match the anthropometrics of the participant by using a static measurement of the participant standing up. Scale factors were calculated for all bodies and applied and static pose weights were made higher for markers on bony landmarks and lower for markers on locations where marker location is more subject to movement, because they were placed on locations on top of looser skin or muscles. The scaling tool was ran and the marker error between the virtual model marker and the experimental marker was calculated. After that the locations of the virtual markers on the model and the weights were slightly altered to make sure marker error was minimized.

2.4.4. Kinematics

The inverse kinematics (IK) analysis was performed using tools provided by the OpenSim software on the aforementioned scaled biomechanical model. The IK tool goes through all frames step by step placing the model in a pose that best fits both the experimental values for markers and coordinates of the model. This match is defined as a ”weighted least squares problem”, the goal of which is to reduce both marker and coordinate error [39].

2.4.5. Kinetics

The inverse dynamics (ID) analysis was also performed using the tools provided by the OpenSim software. The ID tool uses the known motion of the model in solving the equations of motion and the additional unknown forces [40]. Coordinates were filtered by the ID tool and a value of 6Hz was chosen. Inverse dynamics data were filtered with a second-order Butterworth low pass filter with a cut off frequency of 6Hz in Matlab as well to ensure filtering of high frequency noise was done thoroughly.
Specific settings for the IK and ID tools will be included in the measurement and data analysis protocol provided with this thesis. This protocol can be found in appendix A.6.

2.4.6. Statistical analysis

Primary spatiotemporal outcomes will be reported by descriptive analysis using the mean and standard deviation (SD). These means, for the same participant walking on the floor or on the runway, will be compared by a paired two-sample t-test using aforementioned α to investigate statistically significant differences. Statistical analysis of all data, with the exception of curves, will be done using Statistical Package for the Social Sciences (SPSS) version 25.0 or higher (SPSS, Chicago, Ill., United States). The significance level α will be set at 0,05.
Statistical analysis on kinematic curves will be done with Statistical Parametric Mapping (SPM) a method suitable for statistical analysis of continuous curves [41]. This will be done using a matlab script called spm1d [42]. The SPM will be a paired sample T-test will be conducted when comparing two conditions, floor and runway, for the same participant. In this paired sample T-test kinematic values for the hip, knee and ankle joints will be separately compared for both legs. For comparing kinematic values for the participant with mean data for the average healthy able-bodied persons, retrieved from literature [43], the SPM will be a two-tailed t-test. All SPM statistical tests will be conducted using the same α of 0,05 as well.

3. Results

3.1. Gait

3.1.1. Spatiotemporal variables

For both gait conditions the spatiotemporal variables were calculated. These can be found in Table 3.1. For the floor walking condition a total of 43 steps were usable for this calculation and for the runway condition a total of 40 steps were usable for this calculation. This amount is the sum of steps taken with the prosthetic leg and the healthy leg.
When walking on the floor next to the runway the participant walked faster ($1,03$m/s versus $0,98$m/s), with shorter gait cycles ($1,13$s versus $1,17$s) mostly due to the shorter stance phases for the intact leg ($0,77$s versus $0,81$s) and the prosthetic leg ($0,64$s versus $0,67$s), and shorter step lengths for both the intact leg ($0,39$m versus $0,46$m) and the prosthetic leg ($0,45$m versus $0,50$m). Step width was found to be larger in the floor condition $18,77$cm versus $15,00$cm).
Even though statistical significance was found for almost all variables, differences between both conditions are relatively small for some those. Clinical relevance for these variables will be discussed later in this report.

	Floor	**Runway**
Walking speed*	1,03 m/s	0,98 m/s
Cadence*	53,11 steps/min	51,53 steps/min
Gait cycle duration*	1,13 s	1,17 s
Swing phase intact side	0,37 s	0,36 s
Stance phase intact side*	0,77 s	0,81 s
Step length intact side*	0,39 m	0,46 m
Swing phase prosthetic side	0,50 s	0,51 s
Stance phase prosthetic side*	0,64 s	0,67 s
Step length prosthetic side*	0,45 m	0,50 m
Step width*	18,77 cm	15,00 cm

Table 3.1.: Spatiotemporal variables during gait. Statistically significant differences between the two conditions are indicated by a (*)

3.1.2. Kinematics

For both gait conditions kinematics were calculated. For the prosthetic side a total of 4 steps were included for the floor and runway conditions and for the intact side a total of 3 steps were included for both conditions. For both conditions, all joint angles were calculated during one gait cycle and the mean angles for the hip, knee and ankle during a gait cycle can be seen in figures 3.1, 3.2 and 3.3. The period of the gait cycle where statistically significant differences were found in the SPM analysis are represented by the colored lines below the graph. All graphs resulting from the SPM analysis itself can be seen in Appendix A.5.1.

Comparison between floor and runway condition

First the comparison is made between the floor and runway condition.

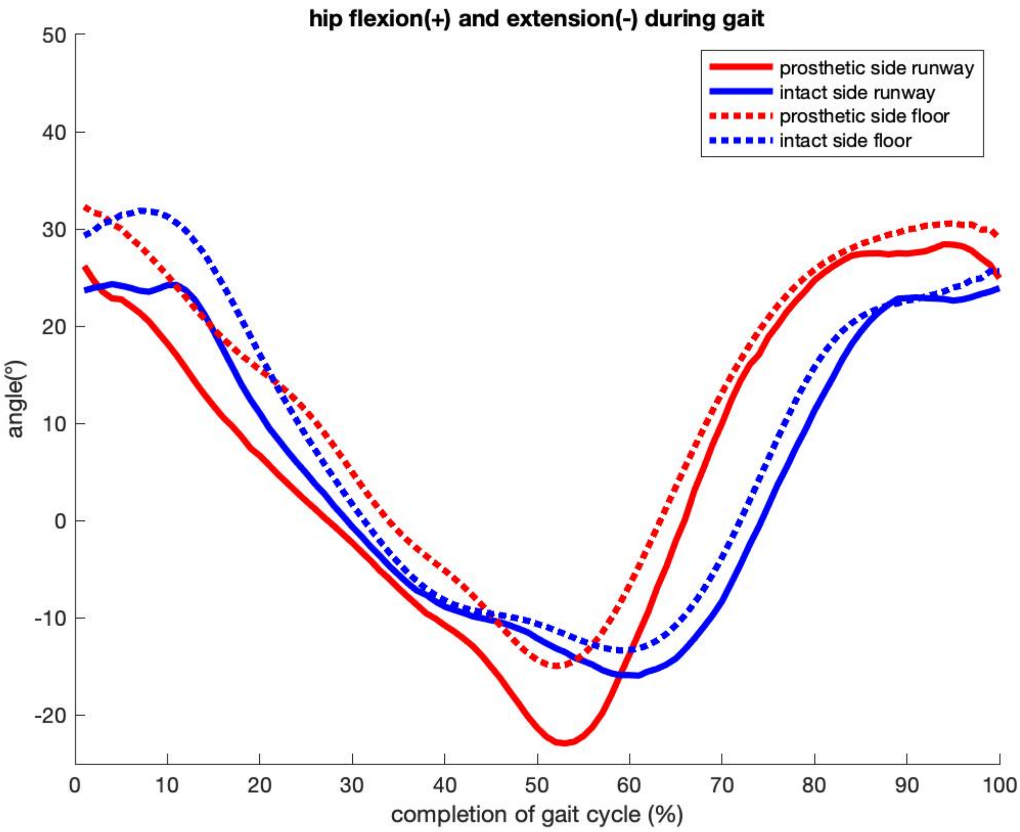


Figure 3.1.: Hip flexion and extension angles for the floor and runway condition

Hip flexion was slightly higher in the floor condition, as can be seen in 3.1. This effect is visible for both legs, but greater for the prosthetic leg. No statistical differences were found for hip flexion and hip extension between the floor condition and the runway condition for both the prosthetic side, see figure A.3a, and the intact side, see figure A.3b.

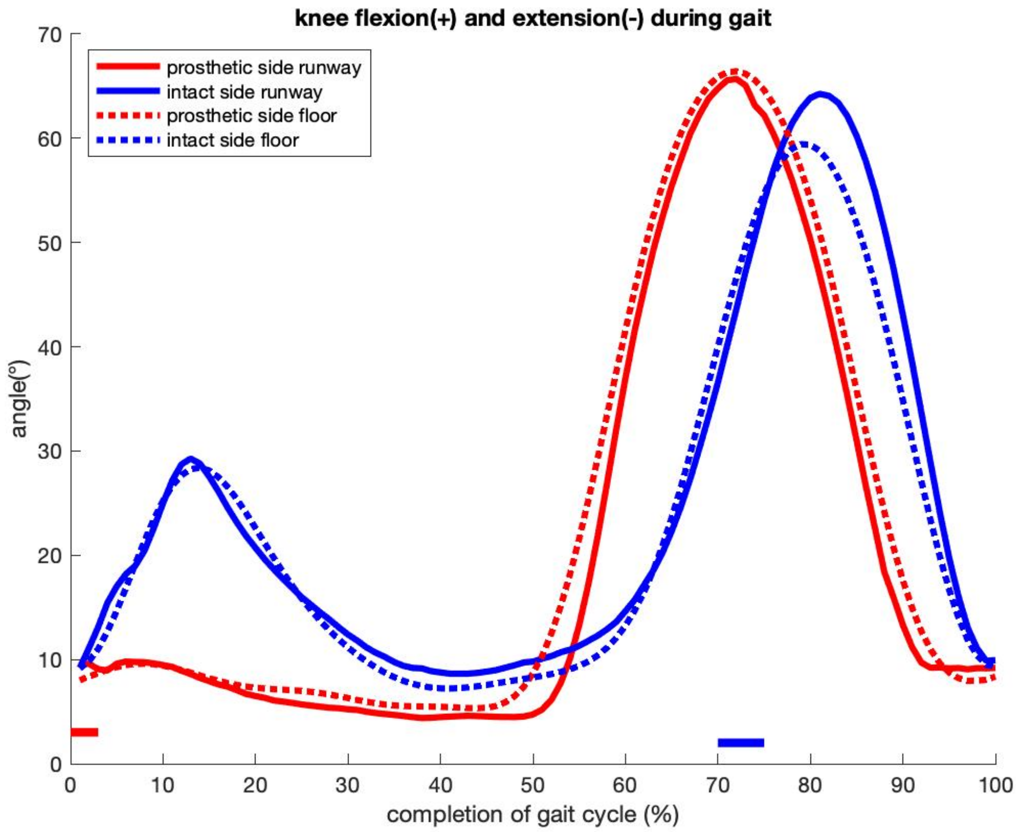


Figure 3.2.: Knee flexion and extension angles for the floor and runway condition

A statistically significant difference between both conditions was found for prosthetic knee flexion between 0% and 2% of the gait cycle as depicted bu the red line in figure 3.2. For the intact side a small but significant difference was found for knee flexion between 70% and 75% of the gait cycle, as can be seen by the blue line in figure 3.2. Both SPM graphs can also be found in the appendix, see figurefigure A.4a and figure A.4b.

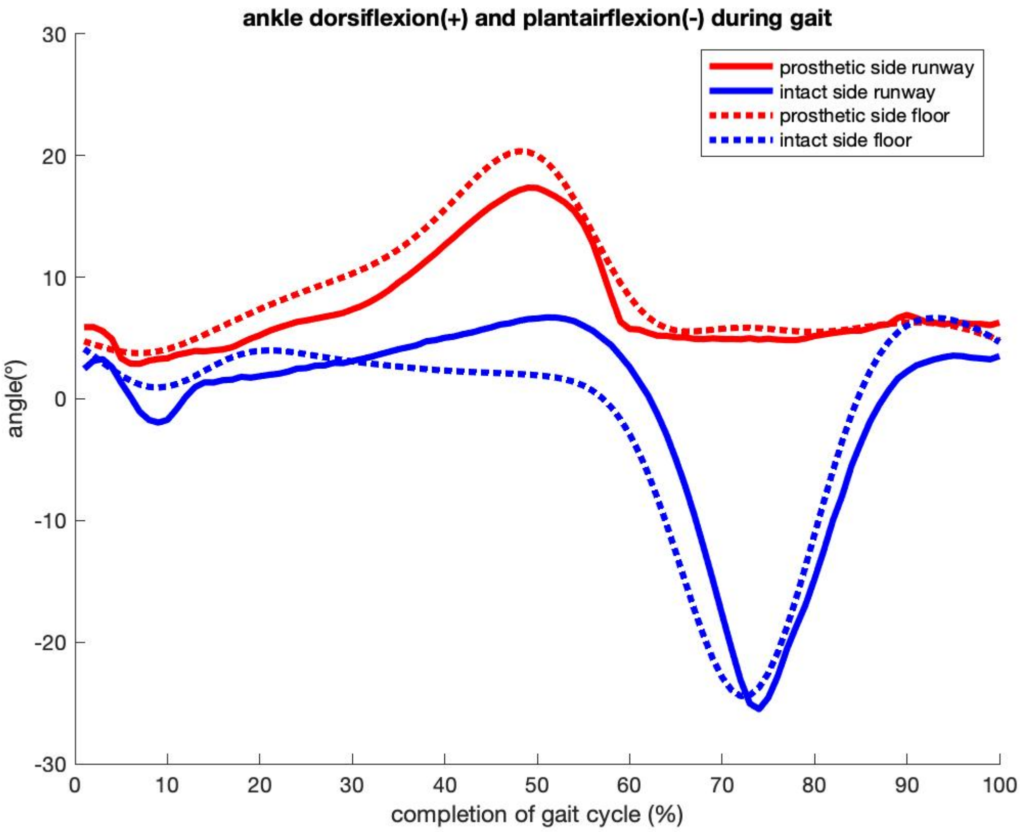


Figure 3.3.: Ankle dorsiflexion and plantairflexion angles for the floor and runway condition

No statistical differences were observed for ankle dorsiflexion and ankle plantairflexion between the floor condition and the runway condition for both the prosthetic side, see figure A.5a, and the intact side, see figure A.5b.

Comparison of prosthetic and intact legs for the runway condition

Since the curves between both conditions are only significantly different for a small percentage of the gait cycle, only the kinematic curves for the runway condition will be presented as can be seen in 3.4, 3.5 and 3.6. The gray area in the plot represents the mean joint angle for healthy able-bodied subjects walking with a walking speed between 0,8 m/s and 1,2 m/s, retrieved from [43]. These data will serve as the control values for further analysis.

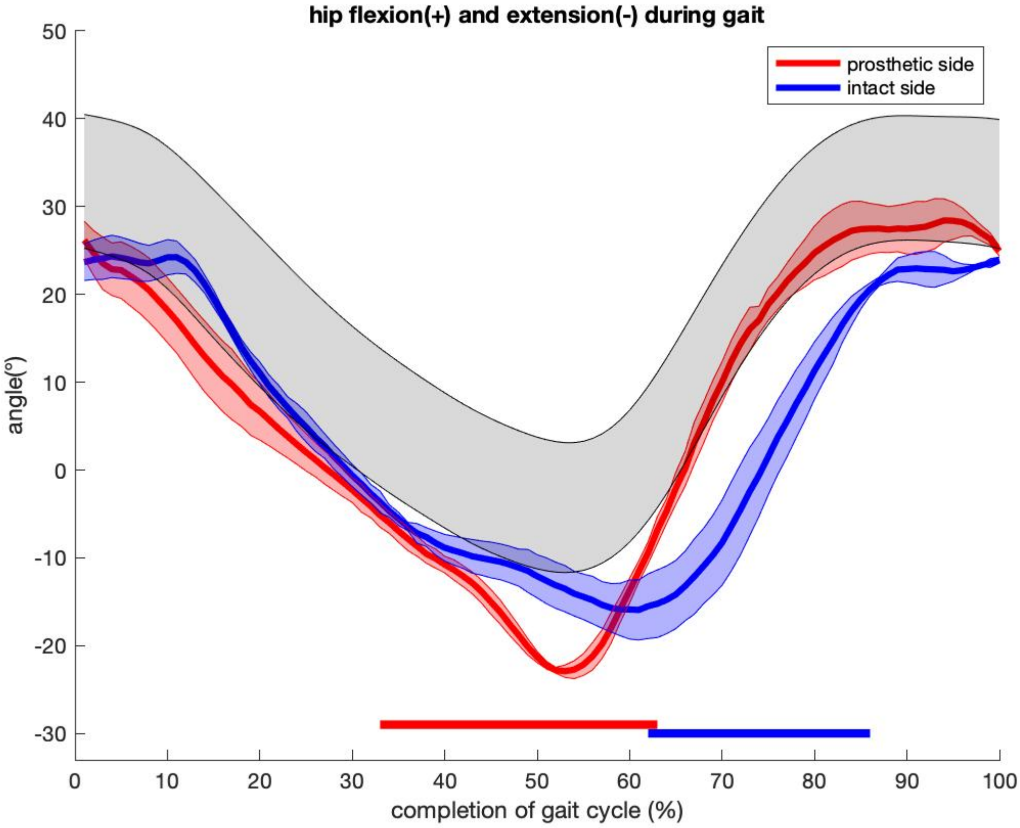


Figure 3.4.: Kinematic hip flexion and extension angles for the plate measurement. Control values are based on data retrieved from [43]

Prosthetic leg hip angle is slightly lower during the entire gait cycle and has a lower minimum value, meaning more hip extension is measured during the force plate trials compared to healthy subjects. This difference in prosthetic hip angle was found to be significantly different from the control value between 33 and 63%, see figure 3.4 and A.6a. Hip extension for the intact leg was found to be statistically different from the control value as well between 62 and 85%, see figure 3.4 and A.6b.

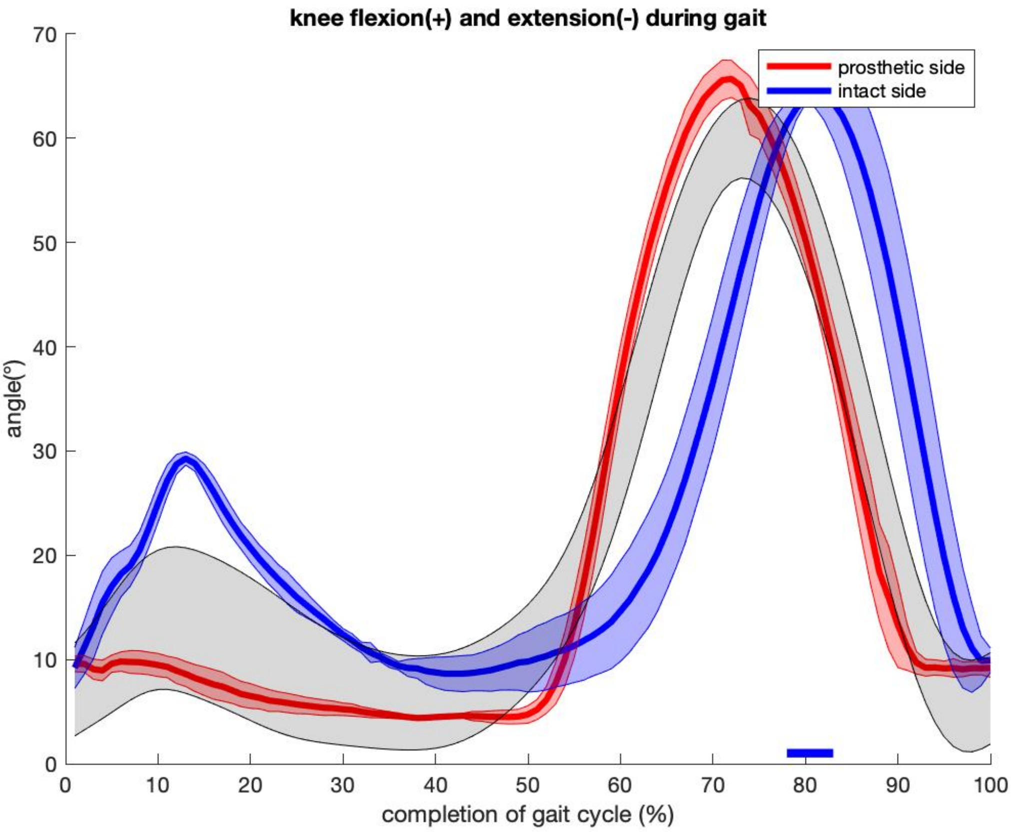


Figure 3.5.: Kinematic knee flexion and extension angles for the plate measurement. Control values are based on data retrieved from [43]

Prosthetic side knee flexion almost entirely lies within the healthy control range. In line with this finding, prosthetic side knee flexion was not significantly different from the control value, as can be seen in figure 3.5 and A.7a. Standard deviation was higher for the intact leg meaning the knee flexion and extension for this leg was less constant within the force plate measurement. Significant differences with these data and controls were found at around 82% of the gait cycle, see figure 3.5 and A.7b.

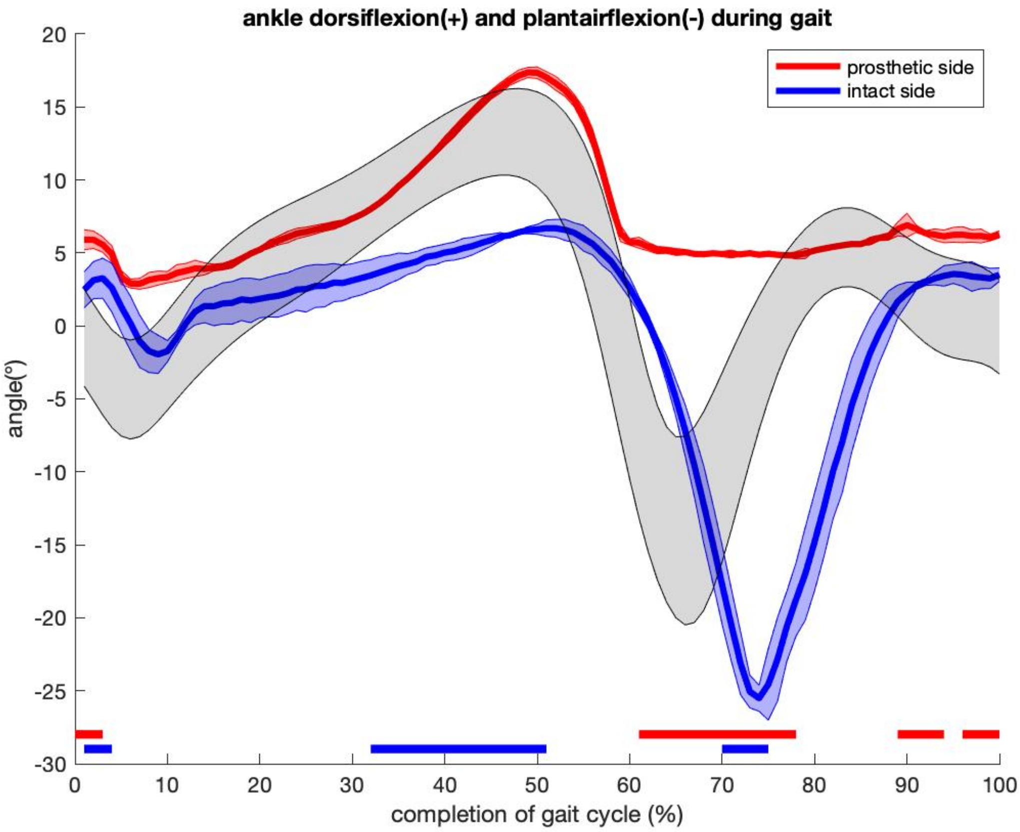


Figure 3.6.: Kinematic ankle dorsiflexion and plantairflexion angles for the plate measurement. Control values are based on data retrieved from [43]

Ankle dorsiflexion and plantairflexion values are most dissimilar to average healthy data. The prosthetic ankle is in dorsiflexion during the first 60% of the gait cycle, the stance phase, and has no plantairflexion during the last part of the gait cycle, the swing phase. Both of these differences were found to be significant, see figure 3.6 and A.8a. The intact leg ankle has less dorsiflexion than the average healthy control and has delayed and increased plantairflexion, which were found to be significantly different from control values, see figure 3.6 and A.8b.

3.1.3. Kinetics

As the inverse dynamic analysis requires ground reaction forces to calculate moments around joints this can only be done for the force plate condition. The mean moments with SD around the hip, knee and ankle can be seen in figure 3.7,3.8 and 3.9 respectively. The gray area represents the mean moment with standard deviation for able bodied healthy persons, retrieved from [44].

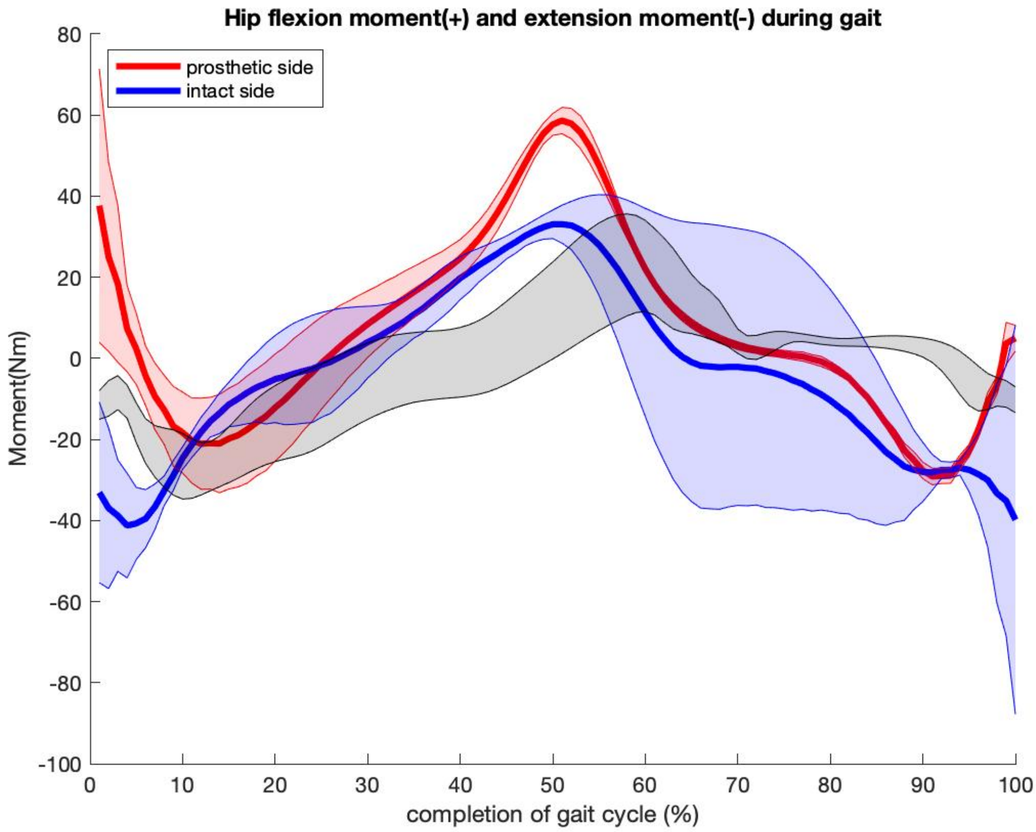


Figure 3.7.: Hip flexion and extension moment values for the force plate measurement. Control values are based on data retrieved from [44]

Hip flexion moment curves for both legs generally follow the same curvature, but the peak hip flexion moment is higher for the prosthetic leg compared to the intact leg and higher compared to healthy controls. Another noticeable difference between both legs is the higher starting value for prosthetic hip flexion moment. The same can be noticed for the intact leg, where a higher extension moment is measured at the start and end of the gait cycle. Furthermore a high variability can be seen for the intact leg hip flexion.

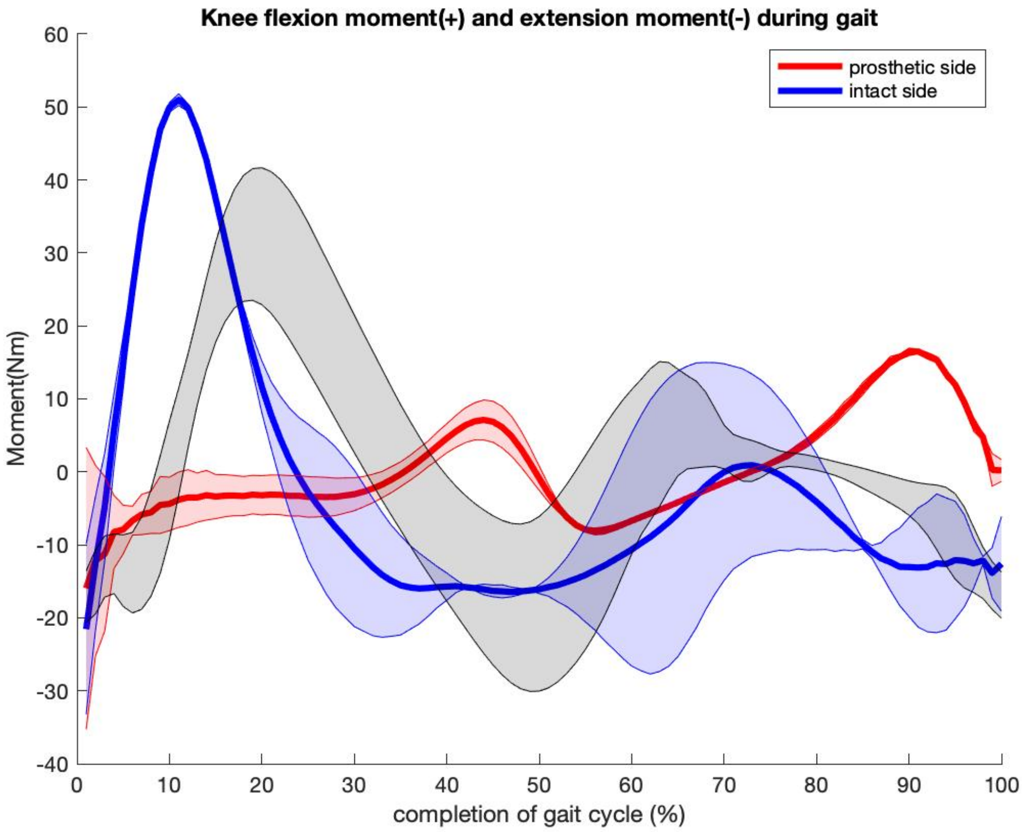


Figure 3.8.: Knee flexion and extension moment values for the force plate measurement. Control values are based on data retrieved from [44]

Intact knee flexion moment is largest right after heel strike. This is also observed in the healthy controls, but the flexion moment is not as large as measured in the intact leg of the participant in this study. A knee extension moment is observed halfway through the gait cycle and remains around the same value, with a small peak in the extension moment. Knee extension and flexion moments for the prosthetic knee are also plotted, but are not being compared to the intact leg or the healthy controls, as joints in the prosthetic leg are not moved by muscles forces and moments around these joints are therefore naturally different. These values could be useful when designing prosthetic components, because it is an indication of minimal forces it should withstand during gait, but that is outside of the scope for this research.
This does also apply to the ankle moments for the prosthetic side.

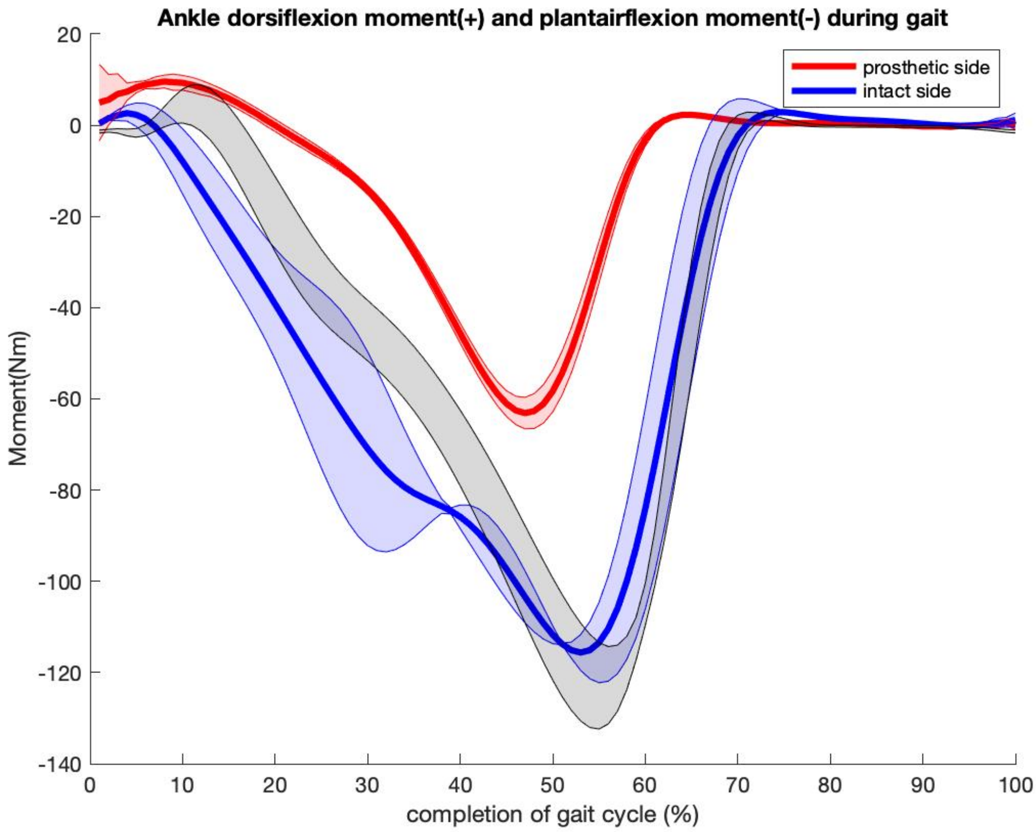


Figure 3.9.: Ankle dorsiflexion and plantairflexion moment values for the force plate measurement Control values are based on data retrieved from [44]

After heel strike a plantairflexion moment was observed for the intact ankle. This plantairflexion moment keeps increasing until almost 60% of the gait cycle after which it returns to zero during the swing phase. The healthy subject plantairflexion curve follows this curvature, with the addition of a small dorsiflexion moment before the plantairflexion moment. This was not observed in the participant in this study.

3.2. Margin of Stability

The number of steps included in this analysis was 3 for each leg. For the prosthetic leg, the mean MoS for the AP direction was $11,21 \pm 3,30$ centimeters for the prosthetic side and $6,08 \pm 1,80$ for the intact side. The MoS for the ML direction was $6,75 \pm 1,76$ centimeters for the prosthetic leg and $4,48 \pm 1,91$ for the intact leg.

3.3. Standing up

Loading on both legs was recorded during the tasks of standing up from and sitting down on a chair. This was measured three times and measurements were included in the analysis. The average loadings are represented in percentage of bodyweight for both legs and can be seen in figure 3.10.

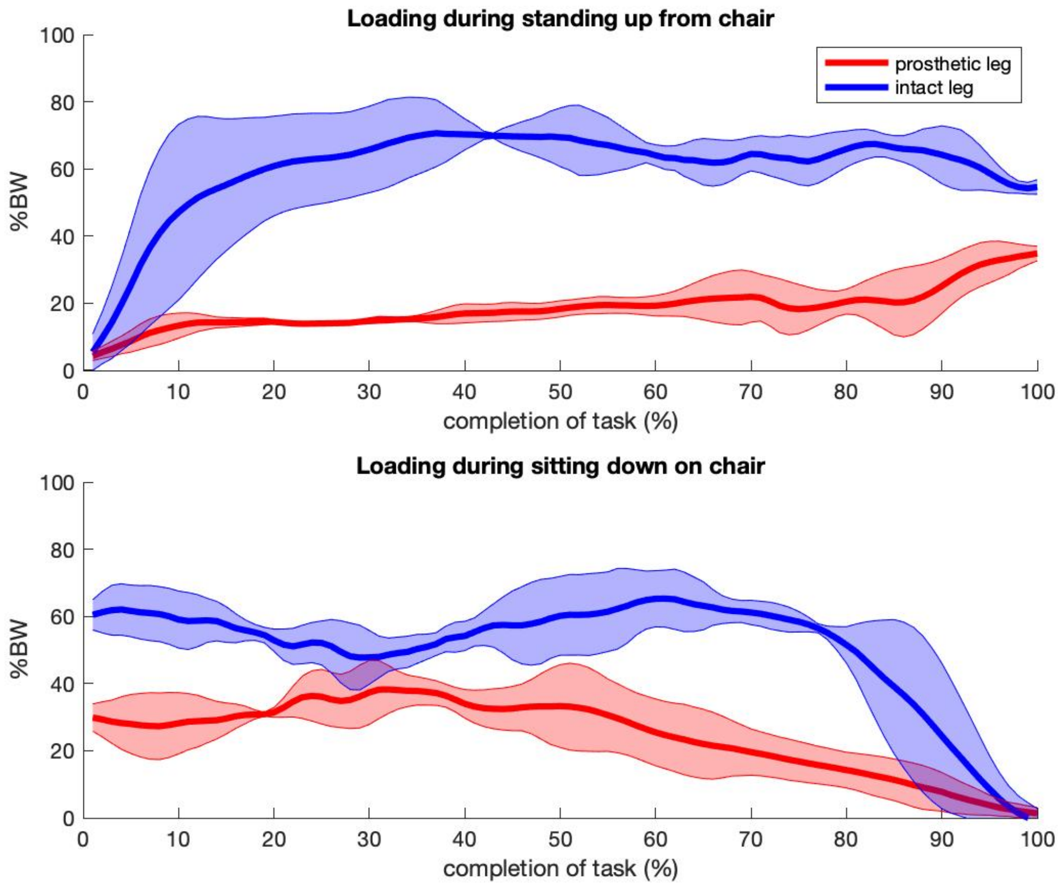


Figure 3.10.: Load distribution between both legs for (a) standing up from a chair and (b) and sitting down on a chair

It was observed most load was applied to the intact leg during the standing up task. When the initial increase in load is over, it can be observed the loading on the prosthetic leg is progressively increased as well, but the load on the prosthetic leg will not be equal to the load on the intact leg.
When sitting down the load is more equally distributed between both legs, but loading is higher for the intact leg in this condition as well.

3.4. Direction of attention

The angle between the plane through all three markers and the x-axis was calculated for the static trial ($N = 1$), the floor condition ($N = 3$) and the runway condition ($N = 4$). An angle of 25,15° was measured as a baseline value when the participant looked straight forward. During walking on the floor the head looked down with an angle of $3,80 \pm 8,52$ and for the runway condition this downwards angle was lower, with an angle of $-2,76 \pm 1,14$, meaning the head was more tilted forward, indicating a gaze more directed to the ground.

4. Discussion

A measurement protocol for a full biomechanical measurement of a transfemoral amputee using an OIP was created and used in a clinical setting. Besides that a biomechanical model was created in OpenSim that was used to analyse the data obtained during the measurements. The following section will be used to compare the results of this research to existing literature, interpret the results and findings of the comparison and elaborate on this study's limitations and implications or suggestions for future researches.

4.1. Interpretation of results

4.1.1. Kinematics

Measurements were conducted for two gait conditions. The first is a runway condition where the participant walked on top of the runway created by force plates with plates equal of color, height and width placed before and after the force plates. The second is a floor condition where the participant walked on the floor of the lab next to the runway. A significant difference was found for all spatiotemporal variables except for the swing phase time for the intact side in both legs. Among these differences, a significant difference ($p < 0,001$) was found for walking speed between two conditions. Walking speed has previously been reported as a confounding factor for kinematic differences [45] and kinetic differences [45] [46] between gait patterns.

This indicates an effect on the kinematic results between the floor and runway condition. The difference in walking speeds is less than 5%, so the clinical relevance is assumed to be low. This assumption is partly confirmed, because after statistical analysis it was found that only knee flexion between both conditions had significant differences for both the prosthetic as the intact leg. These differences were only significantly different for around 3% for the prosthetic leg and 1% for the intact leg. No statistically significant differences were found for the hip flexion and ankle dorsi- and plantairflexion.

The significant differences found for the knee flexion could be caused by the change in walking speed. This could also be caused by other variables, for example the difference between walking on the floor or the runway, so the difference can not entirely explained by the walking speed.

SPM analysis found significant differences for hip and knee flexion for the participant compared to the healthy able-bodied controls. for the hip flexion these differences were mainly found in the late stance phase for the prosthetic side and early swing phase for the intact side. Knee flexion was significantly different in the mid-swing for the intact side and not significantly different for the prosthetic side. This mostly indicates a compensatory hip movement during prosthetic stance phase and intact side swing phase, which is probably needed to ensure balance and prepare for the prosthetic leg's swing phase.

In the aim of the study is was stated that the biomechanical model will be validated by comparing the results of the analyses performed in this thesis with results found in literature. The results from this thesis presented significant differences between the TFA using an OIP and healthy controls for the prosthetic and intact hip flexion angles, intact knee flexion angles and prosthetic and intact ankle dorsiflexion and plantairflexion angles. The differences were also reported in an article by Sapin et al. [47]. In the results presented by Sapin et al. the same absence of a peak in prosthetic knee flexion quickly after heel strike and the plantairflexion for the prosthetic ankle were observed. The healthy controls measured by Sapin et al. show the same kinematic values as the controls used in this report. This shows the kinematic values measured in this study are representative for measurements done prior to this study.

The observed hip flexion during stance phase is similar to data previously reported on patients using an OIP by Harandi et al. [29] and Pantall et al. [30]. The knee flexion kinematic results by Pantall et al. also reported knee extension of around 20° during stance phase, but this was not found in this study. Ankle dorsiflexion and plantairflexion during the stance phase look similar to data reported by Pantall et al. and Harandi et al. as well.
Kinematics and kinetics for entire gait cycles were only reported for TFAs using a SP. Kinematics for hip flexion look similar to data from literature. The prosthetic kinematic curves for the knee and ankle are similar to the kinematics reported by Sapin et al. [47]. The only difference is a slightly higher ankle dorsiflexion and ankle plantairflexion. This is most likely related to prosthetic ankle design it is difficult to link it to the gait pattern. The prosthetic hip flexion and knee flexion reported in an article by Johansson et al. [48] are similar to the results found in this study. The absence of a small peak in prosthetic knee flexion quickly after heel strike is found in this study as well. The only difference between the kinematic curves from Johansson et al. and the kinematic curves in this report is that Johansson et al. report prosthetic ankle plantairflexion and this was not found in the results presented in this thesis.

Kinematic curves for the intact leg and prosthetic leg of transfemoral amputees using a SP were reported by Jarvis et al. [49] and by Harandi et al. [50]. Differences observed in the kinematic curves of the prosthetic leg and the intact leg by Jarvis et al. show a small intact leg knee flexion peak during early stance and a delay for the intact leg knee flexion peak compared to the prosthetic knee flexion peak and the absence of a plantairflexion peak for the prosthetic ankle. All of these differences between the prosthetic leg and intact leg can be seen in the kinematic curves reported in this thesis as well. This similarity adds to the validation of the measurement protocol and model presented in this study. More in depth comparison between patients using an OIP and patients using a SP needs to done in future research.

4.1.2. Kinetics

When comparing the kinetic curves with graphs reported in studies measuring unilateral transfemoral patients, albeit walking with socket prostheses, it can be seen that the general patterns have similar characteristics. Firstly, when comparing the data measured by Zhi et al. [51], it can be seen that during a gait cycle a hip extension moment is formed directly after heel strike, gradually changes into a hip flexion moment during the stance phase with peak hip flexion moment before toe-off and ending in a hip extension moment at the end of the swing phase.

Because the joints in the prosthetic leg are not moved by muscles forces and moments around these joints are therefore naturally different, the kinetic curves for the knee and ankle are only compared to the kinetic data for the intact leg. The knee flexion and extension measured by Zhi et al. [51] is also comparable to the knee flexion and extension measured in this article. A peak in the knee extension directly after heel strike is observed followed by knee flexion mid stance and a small knee flexion moment preparing for the subsequent heel strike. The ankle plantairflexion is easily comparable as a small dorsiflexion moment is followed by a large plantairflexion moment is built up during stance, followed by the absence of an ankle moment for the swing phase.

Additionally, the graphs measured by Johansson et al. [48] resemble the curves measured in this study. A difference with the data previously compared is the higher knee extension moment in the early stance phase, also reported in this study,

Few other differences between the intact limb curves can by found in an article by Segal et al.[52]. These differences are that in this study a hip extension moment was observed in both legs in the last 10% of the gait cycle and two knee extension moments, named K3 and K4 are not present in this study. Besides these differences similar graphs were also found in this article.

The kinetic curves measured in this study follow the general curves of the control group represented by the gray area, but with several noticeable differences. Knee extension peak earlier and higher: earlier also observed in Zhi and higher because of relatively higher loading at the intact limb for amputees, with able bodied persons have more equally distributed loading between both legs.

4.1.3. MoS

In a study conducted by Rodrigues et al MoS was measured for TFAs using a socket prosthesis. The MoS for the ML direction was $10,15 \pm 2,03$ cm and for the AP direction the MoS was $8,30 \pm 4,10$ cm [53]. The MoS in this thesis was higher for the prosthetic side in the AP direction and lower for the ML direction. These values are comparable, but the difference in a higher AP MoS and a lower ML MoS do not lead to a consistent conclusion.

4.1.4. Stability and confidence

It was observed that the direction of attention was more downwards during walking on the runway compared to the floor (-2,76° vs 3,80°), indicating the participant was less confident walking on the runway. Even though this means that with this measurement protocol the direction of attention during gait can be measured, no validation for this measure can be made for, as the measurement is specific for this research. protocol for this variable is specific for this research.
Besides that, the most load is applied to the intact limb during standing up from a chair. The difference is smaller when the participant was sitting down again on the chair. Even though no conclusion can be made on either of these two measurements, it is confirmed that using the proposed measurement protocol it is possible to measure the direction of attention and the differences in load applied to both legs during standing up.
The observations from the physician assistants at the EMC in which patients using a SP looked more downwards than patients using an OIP can not be confirmed nor denied,

because the data have only been measured for the participant walking with an OIP. The same can be said for the standing up from the chair.

4.2. Validation of biomechanical model

Because the patients walked at self selected walking speed during the measurements it can be compared to kinematic and kinetic results reported in literature. Spatiotemporal variables will not be compared for the model validation, as they were not calculated using OpenSim, but using Matlab.
The kinematic curves found in literature are generally very similar to the kinematic curves based on the data measured in this study. Even though they might not all be based on participants walking with the same SSWS, a validation of the biomechanical model for kinematic analysis can be established.
The same applies to the kinetic curves, where data found in multiple articles was comparable to the results measured in this report.

4.3. Limitations

4.3.1. limitations for method

A limitation for this research is that no TFAs walking with a SP and no healthy able-bodied controls were measured in the same lab using the same measurement protocol. This meant data comparisons between the OIP, the SP and the healthy controls were done using data presented in different studies. It can not be assured the measurements in other studies were conducted under the same circumstances.

4.3.2. limitations for results

Another limitation is the limited sample size for this research, because only one participant was measured in this research. Caution should be taken into consideration when taking conclusions based on the data presented in this study, as measurements were conducted for one participant, and this can therefore never be a representation of all people walking with an OIP.

4.4. Future research

Protocol based recommendation

Future researches should aim to measure TFAs using an OIP, TFAs using a SP and healthy able-bodied controls in one study. In this way differences in clinical conditions are minimised and comparisons will not be based on literature. EMG measurements could be added to the protocol to give an insight in muscle activation patterns of three participant

groups.
Furthermore, measurements for assessment of balance where the participant is asked to stand still with eyes open, eyes closed and while performing an interference task could be included in the measurement protocol. The possible differences for stability will be more elaborate if included.

Model based recommendation

Another way of getting insight in the muscle activation patterns is by adding the muscles for the prosthetic leg to the model. This could be based on the patient data of a single patient. In this way the muscles could be modeled based on this one patient, as it will be difficult to build a general musculoskeletal model fitting the muscular anatomy of all TFAs. The intact leg muscles were copied from the original biomechanical for healthy subjects. No changes are necessary, but combined with the EMG data that can be obtained by following the protocol further analysis of muscle activation patterns can be done with the model.

Another suggestion would be to implement more realistic prosthetic geometry for the knee and ankle prosthesis to get more insight in the distribution of loads between different prosthetic joints or between the prosthesis and the femur. This could be done by creating a more detailed mesh file or prosthetic components made up of several smaller components, to measure more specifically how the loads between these components are distributed over the joined surfaces.

Data based recommendation

Because further research based on this thesis will most likely include measurements for multiple persons, an optimization of the data analysis pipeline to easily analyse multiple datasets would be recommended. This also applies to generalisation of matlab code, because it is based on gait events for one file and code therefore cannot be applied to all datasets.

5. Conclusion

Looking back to the objective of this study, it can be concluded that the development of a measurement protocol including a biomechanical model to measure and analyse the gait of amputees is achieved. This conclusion is based on the fact that the gait of a unilateral transfemoral amputee on a runway and on the ground was successfully captured, converted into 3D marker paths readable by a biomechanical model and translatable into kinematic and kinetic values depicted in graphs.

In these final graphs the differences between walking on the ground and walking on the runway and between several variables for the prosthetic and intact limb can be detected, meaning the model is able to calculate these separately. The validation of the model was done by comparing the data to results previously reported in other studies. In this comparison the similarities observed between the graphs in this report and the graphs in literature led to the observation that generally, the results in this study are in line with previous studies. No definite conclusions can be made, but the results indicate an accurate model.

Acknowledgements

I would like to thank everyone who supported me throughout this journey, especially my supervisors, family, and friends. It was heartwarming to feel the support at times I thought finishing this project would be too much for me.

This study would not have been possible without the help and cooperation from the team at Erasmus Medical Centre.

I would also like to extend my gratitude to the participant, whose name I cannot mention. Your willingness to take part in the measurements, share pictures and information, and have a conversation about the impact of osseointegration surgery for her life and mobility was truly inspiring. Hearing about how engineering can positively affect lives outside the lab was a meaningful experience.

A. Appendices

A.1. Femoral mass

The femur was cut to mimic a transfemoral amputation. The geometry was changed using Meshlab Software. The weight of the femur had to be recalculated and the new weight of the femur had to be adjusted in OpenSim. The femur was cut at the halfway point of the shaft. This meant half of the shaft and both of the condyles were deleted from the femur. Relative masses for all femoral parts were found in literature [33] and these can be seen in table A.1. The removal of half the shaft (13,4%) and the condyles (28,10%) mean a total of 41,5% weight reduction.

Femoral part	**Relative mass**
Head	22.05%
Neck	23.05%
Shaft	26.80%
Condyles	28.10%
Total	100%

Table A.1.: Average femoral mass distribution, calculations based on data from [33]

A.2. Model geometry

A hollow cylinder was created in Meshlab to complete the models' upper leg. The geometry for the shank and the foot were copied from a transtibial OpenSim model [34]. The shank was lengthened and the weight and inertia were altered in OpenSim. The geometry of the parts forming the modeled prosthetic leg can be seen in figure A.1.

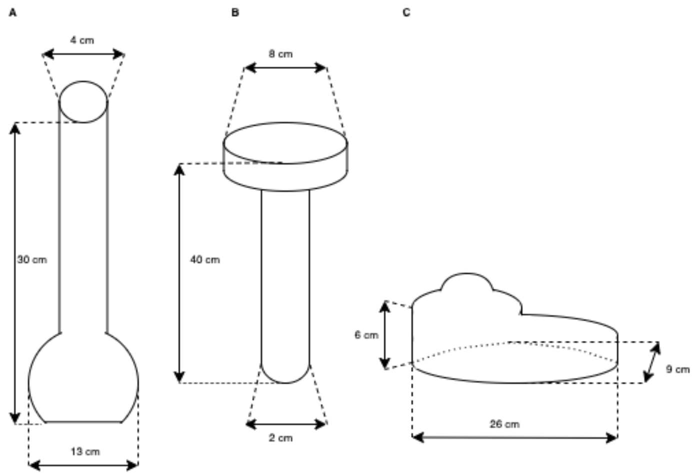


Figure A.1.: Dimensions for the prosthetic model parts

Inertia calculations are described more in depth in the next section of this appendix A.3. The geometry, weight and inertia were copied for the foot. The CoM was estimated visually and the locations were adjusted in OpenSim. The CoM's fot both lower limbs can be seen in figure A.2

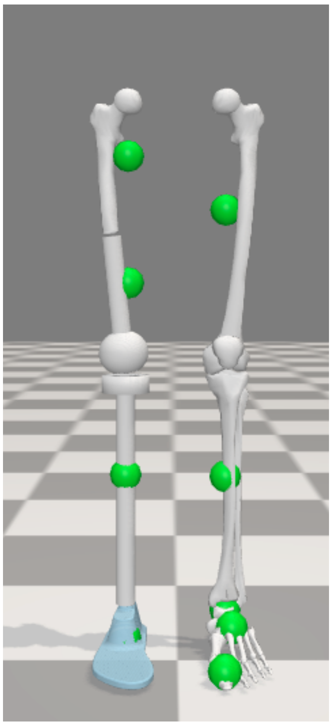


Figure A.2.: Location of CoM for the model geometry of both lower legs

A.3. Inertia calculations

Inertia for the x- and z- axis of the shank was adjusted for the length difference, since the previous geometry was used for a transtibial model and it remained equal for the y-axis. The equations used for inertia calculations are based on Steiner's Theorem. The following equations are used for inertia calculations for all three axes:

$$I_{ball_{x,y,z}} = \frac{2}{5} * m_b * (r_b^2) \tag{A.1}$$

$$I_{cylinder_{x,z}} = \frac{1}{12} * m_c * (L_c^2) \tag{A.2}$$

$$I_{cylinder_y} = m_c * (r_c^2) \tag{A.3}$$

A.4. Biomechanical model: intact leg muscles

The following table contains a list of the muscles modeled in the biomechanical model. The muscles were copied from [32].

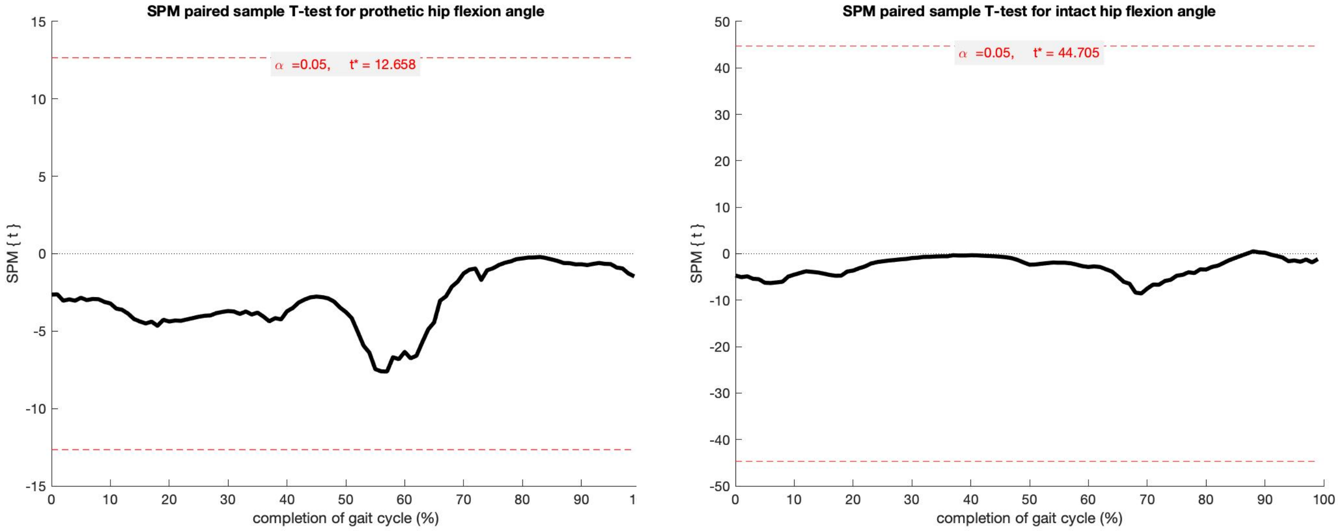
Muscle
Adductor brevis
Adductor longus
Adductor magnus (4 parts):
Adductor magnus (distal)
Adductor magnus (ischial)
Adductor magnus (middle)
Adductor magnus (proximal)
Biceps femoris long head
Biceps femoris short head
Extensor digitorum longus
Extensor hallucis longus
Flexor digitorum longus
Flexor hallucis longus
Gastrocnemius lateral head
Gastrocnemius medial head
Gluteus maximus (3 parts):
Gluteus maximus (superior)
Gluteus maximus (middle)
Gluteus maximus (inferior)
Gluteus medius (3 parts):
Gluteus medius (anterior)
Gluteus medius (middle)
Gluteus medius (posterior)
Gluteus minimus (3 parts):
Gluteus minimus (anterior)
Gluteus minimus (middle)
Gluteus minimus (posterior)
Gracilis
Iliacus
Peroneus brevis
Peroneus longus
Piriformis
Psoas
Rectus femoris
Sartorius
Semimembranosus
Semitendinosus
Soleus
Tensor fascia latae
Tibialis anterior
Tibialis posterior
Vastus intermedius
Vastus lateralis
Vastus mediali

Table A.2.: Muscles modeled for the intact leg

A.5. Statistical analysis SPM graphs

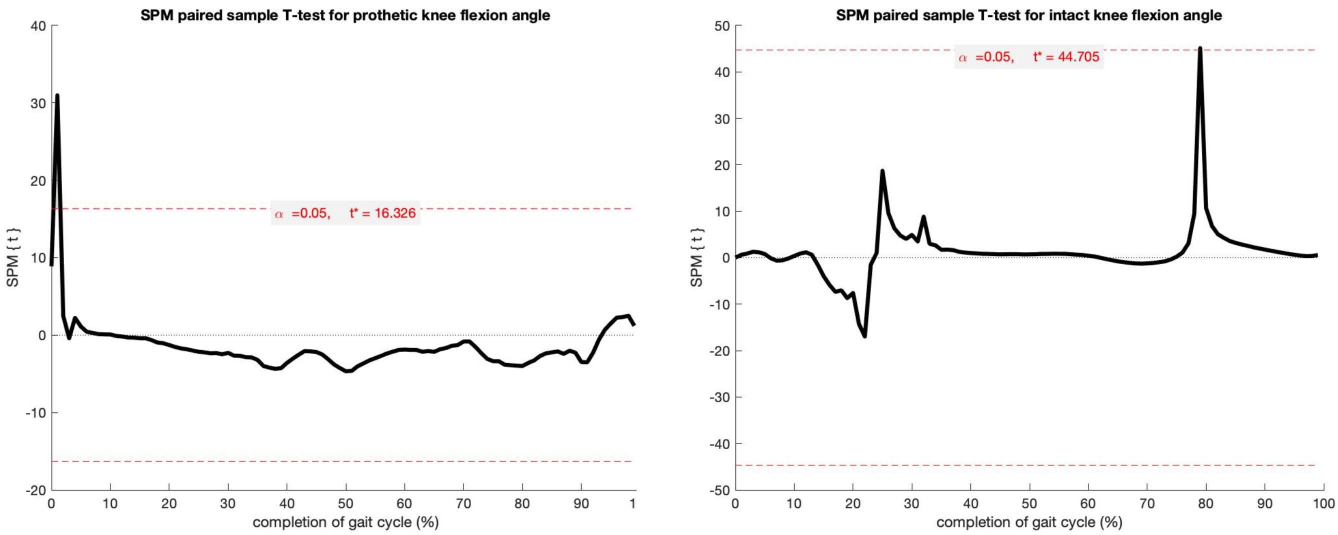
Below the SPM graphs for all comparisons mentioned in the results can be found. In this graph the dotted red line represents the critical t-value. If the SPM curve reaches values higher than the upper t-value or lower than the bottom value the variables in the comparison are significantly different for the period of time in which these t-values are crossed.

A.5.1. SPM paired sample t-test between the floor instance and the runway instance



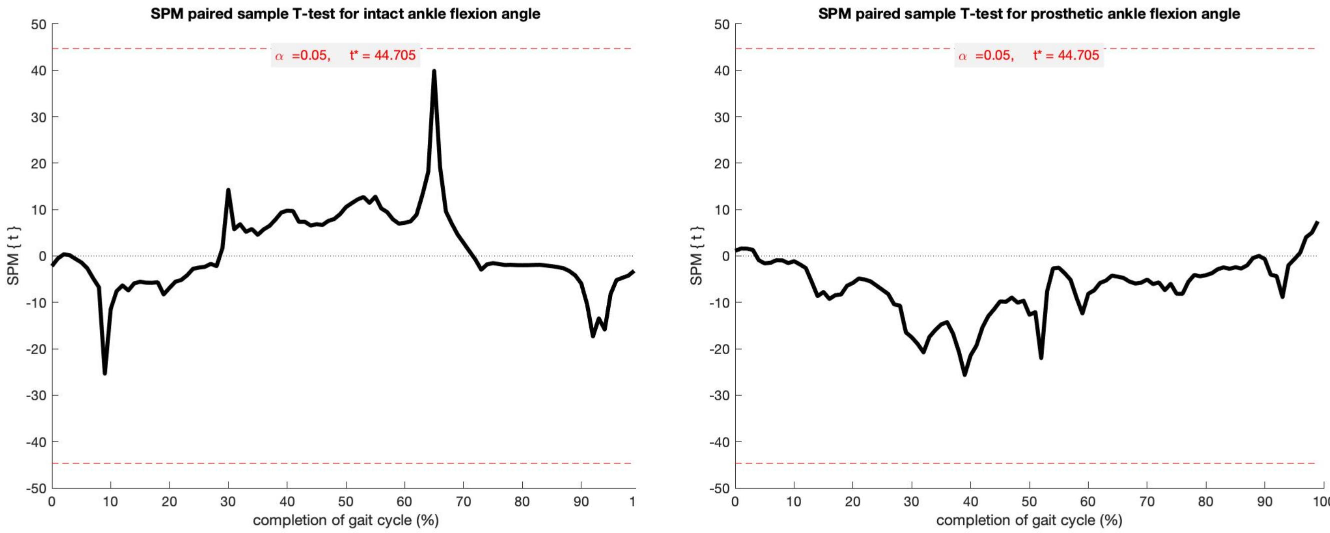
(a) (b)

Figure A.3.: Results of SPM analysis between the floor and runway instance for (a) hip flexion for the prosthetic leg and (b) hip flexion for the intact leg during gait



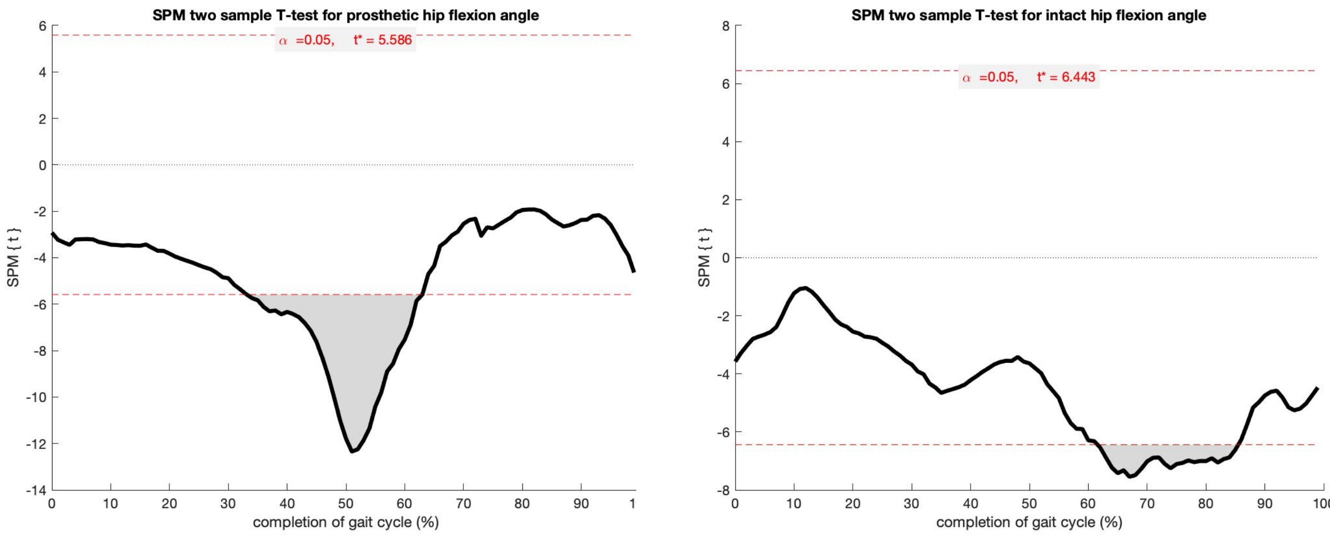
(a) (b)

Figure A.4.: Results of SPM analysis between the floor and runway instance for (a) knee flexion for the prosthetic leg and (b) knee flexion for the intact leg during gait



(a) (b)

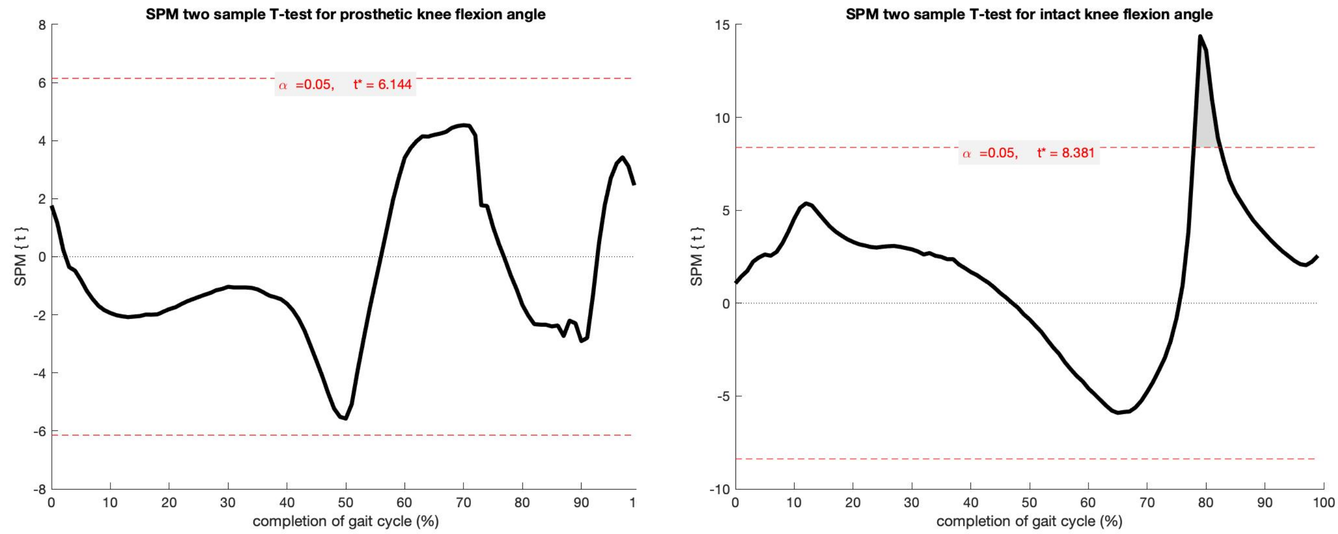
Figure A.5.: Results of SPM analysis between the floor and runway instance for (a) ankle dorsiflexion for the prosthetic leg and (b) ankle dorsiflexion for the intact leg during gait



(a) (b)

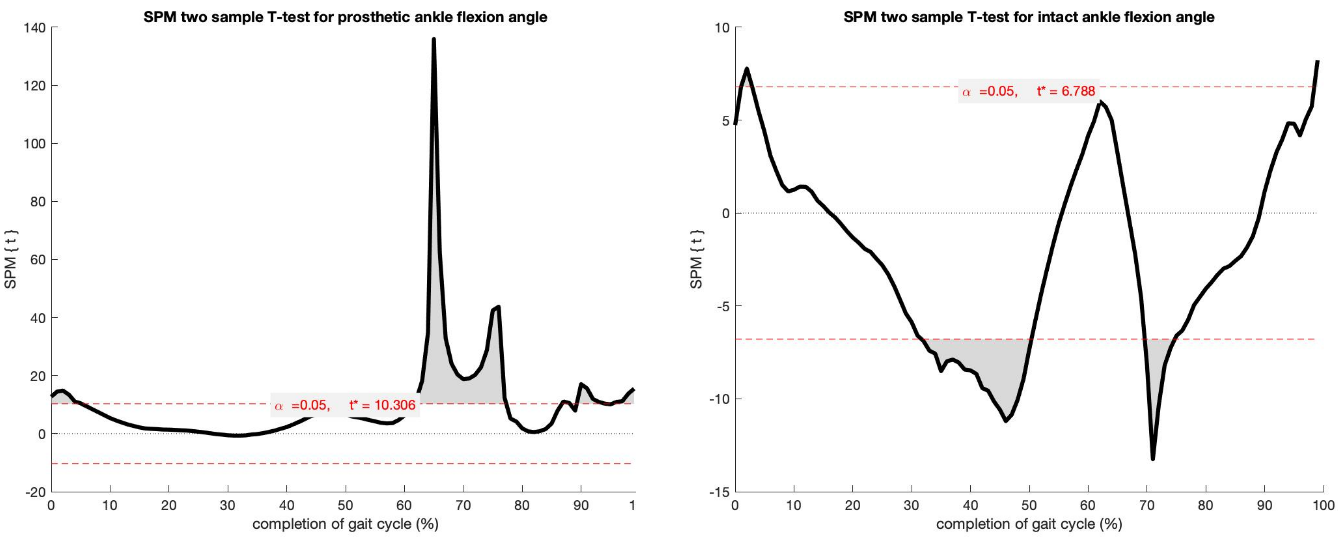
Figure A.6.: Results of SPM analysis between the runway instance and able-bodied mean for (a) hip flexion for the prosthetic side and (b) hip flexion for the intact side during gait

Knee flexion and extension angles



(a) (b)

Figure A.7.: Results of SPM analysis between the runway instance and able-bodied mean for (a) knee flexion of the prosthetic side and (b) knee flexion of the intact side during gait



(a) (b)

Figure A.8.: Results of SPM analysis between the runway instance and able-bodied mean for (a) ankle dorsiflexion of the prosthetic side and (b) ankle dorsiflexion of the intact side during gait

A.6. Measurement protocol

On the next page the measurement protocol can be found.

Protocol Lab measurement OI Gait Kamiel Leenen

Measurement

Participant:

Our aim is to measure and compare the biomechanics of gait in transfemoral amputees using an osseointegrated prosthesis (OIP) and healthy subjects to evaluate differences.

1. Equipment

The day before make sure the following things are prepared and ready to take to the lab

Print informed consent	
Print questionnaire	
Charge laptop	
Create patient ID and save it on the laptop	
Print marker placement list	
VVV voucher for participant	

Then finish this checklist to make sure everything that is needed is in the lab.

38 **normal** reflective markers and 4 marker plates (squares/triangles)	
4 EMG sensors (DELSYS)	
Tape to attach markers AND attach markers to it before participant arrives	
4 force plates	
Razor	
Alcohol wipes	
Harness for safety	
Printed informed consent forms	
Printed questionnaire about personal data	
Measuring tape and scale	
Check if there is enough storage space on computer	
Some coffee, water and food for the participant	

2. Start systems before participant arrives

1. Logged in as local administrator and ethernet 2 has to be selected
2. Open “Tringo Control Utility” → take out one IMU and push button (check which have bad battery on note at the computer)
3. Open QTM → create project: **YEAR-MM-DD-OIGAIT-Kamiel**
4. Settings → “input devices” → select “Delsys Trigno” and “Kistler”
5. Settings → Select “Force Data” and select all 4 force plates
6. Settings → Camera System → “locate system” → check 2 camera groups in 3D View → check each camera, remove white dots etc.
7. Calibration: place L-form wand on force plate (long arm = x-axis, short arm = y-axis). Long arm in direction of walking
8. Take T-form wand and click on “calibration ” → move wand for 2/3 minutes → check volume for each camera. Residual errors should be less than 1mm
9. Calibrate force plates: place specific corner markers on corners of each plate individually → record for 1 sec → drag markers to labelled section, check direction, write it down → go to “Force Data”, click on “generate” in the location section and check if the positive axes point to the same direction → Select “calculate force data” in the project options and check if the following symbols are visible: 

- Prepare 38 markers with tape for quicker application when the participant arrives

All steps above are done before participants arrive, then:

Ask participant to sign written consent	
Collect the length and weight of the participant and fill in on questionnaire	
Ask participant to fill in questionnaire	

3. Experimental set-up

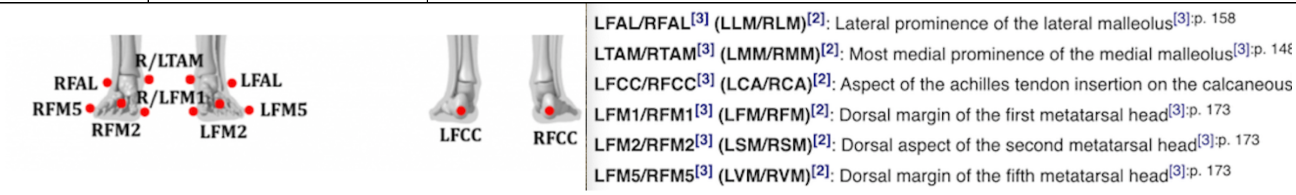
Participant changes into shorts and shirt is desired, nothing reflective.

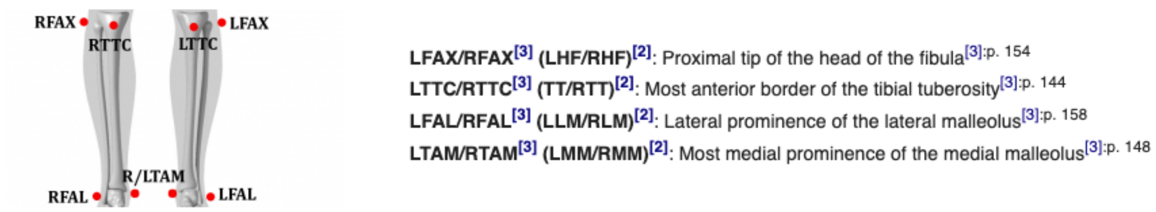
3.1. Marker placement

For the placement: 38 normal markers and 4 plates having 16 markers are placed on anatomical landmarks:

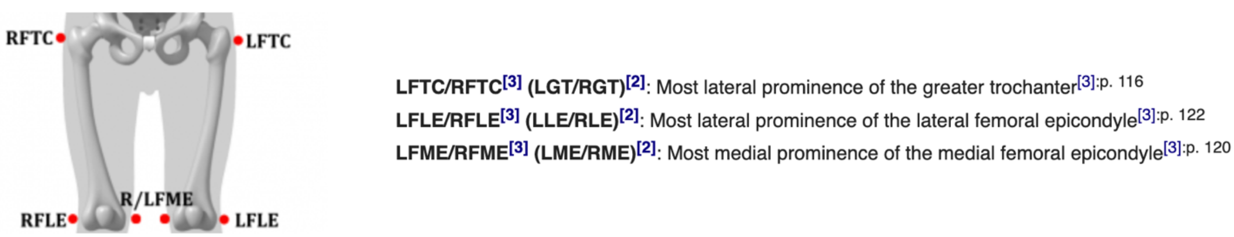
The markers in **bold and underlined** are anatomical markers and can be taken off after static measurement

Segment	Abbreviation	Landmark
Foot (8)	CAL	Calcaneus, insertion of Achilles tendon
	Mt1	Metatarsal 1
	Mt2	Metatarsal 2
	Mt5	Metatarsal 5
Shank (8)	LM	Lateral Malleolus
	MM	**Medial Malleolus**
	TTC	Tibial tuberosity
	FAX	Fibula proximal tip





Segment	Abbreviation	Landmark
Femur (6)	LEC	Lateral Epicondyle
	MEC	**Medial Epicondyle**
	TM	Greater trochanter

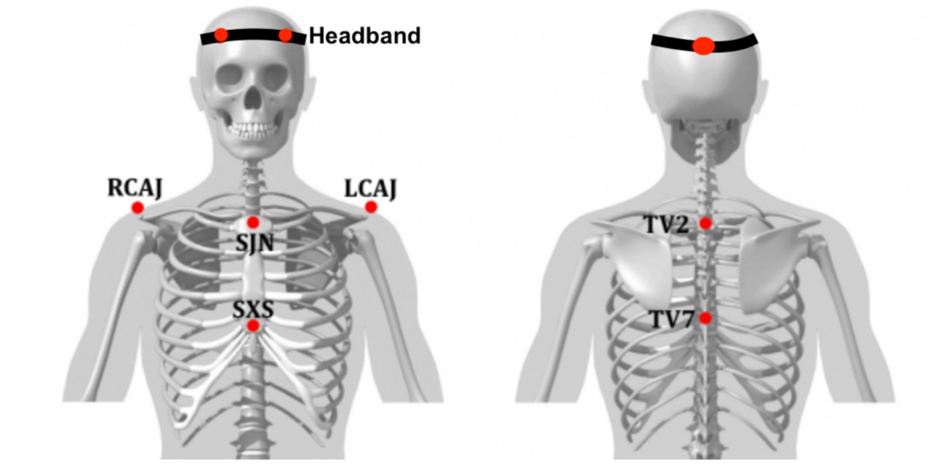


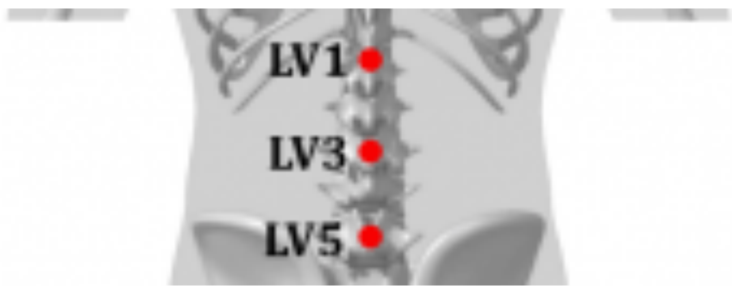
Segment	Abbreviation	Landmark
Pelvis (4)	ASIS	Anterior Superior Iliac Spine
	PSIS	Posterior Superior Iliac Spine

LIAS/RIAS[3] **(LASIS/RASIS)**[1]: Left/Right anterior superior iliac spine[3]:p. 106

LIPS/RIPS[3] **(LPSIS/RPSIS)**[1]: Left/Right posterior superior iliac spine[3]:p. 107

Torso (9)	L/R CAJ	Left / Right acromion
	TV2	Thoracic vertebrae 2
	TV7	Thoracic vertebrae 7
	SJN	Incisura jugularis
	SXS	Sternum most caudal point
	LV1	Lumbar vertebrae 1
	LV 3	Lumbar vertebrae 3
	LV 5	Lumbar vertebrae 5
Head (3)	Headback HeadLeftfront HeadRfront	Headband





Not all were used in the end, due to ‘pollution’ of markers on the lower back

Plates (4)		Thigh L+R Shank L+R

- Make frontal and sagittal photos and make a frontal and sagittal video of the person.

3.2. EMG

- Next, place the IMUs on the muscles of both legs (if applicable). Shave hair if needed.

Muscle name	**Abbreviation**	**Sensor number left**	**Sensor number right**
Biceps femoris (hamstring)	BF		
Rectus femoris	RF		

- Take pictures of the EMG locations

4. Measurements

When all markers and sensors are placed, the measurements start. The participant will do all motions. **First practice every motion before measurement starts.**

	Motion	
1	**Calibration**	
1.1	Static	10 seconds
1.2	Random motions	2 x 10 seconds
2	**Gait**	
2.1	Self selected pace	10 x walking over the platform
2.2	Normalized walking speed	10 x walking over the platform
3	**Balance**	
3.1	Eyes open	20 seconds
3.2	Eyes closed	20 seconds
3.3	Cognitive interference	20 seconds
4	**Standing up**	
4.1	Standing up	3 trials

1. Calibration

1.1. Static

The markers locations in this body position will function as the reference pose as the markers are placed while the participant is standing still and minimal skin motion artifacts are seen here.

Anatomical markers can now be taken of. These can be found in the marker placement list.

1.2. Dynamic motions

Ask the participant to make some random motions with their legs and torso. Check if the markers are labelled automatically and correctly. If not, label by hand and update the model by clicking on the  icon in the menu.

2. Gait measurements

First let the participant walk a couple of times across the path to the wall so they get used to the path and the width and get settled in their normal gait pattern.

2.1. Walking with self selected speed

The participant will be asked to walk 10 times from the beginning to the end over the force plates and 10 times back. So 20 times in total.

Instructions: tell the participant to walk towards the end of the path towards the cup of coffee as if they were to grab it. No instructions will be given about the pace they have to achieve.

2.2. *Walking with standardized normalized walking speed*

The participant will be asked to walk 10 times from the beginning to the end over the force plates and 10 times back. So 20 times in total. This time the time they take to walk this distance will be recorded and feedback about the desired pace will be given. This desired pace can be calculated with the length of the participants leg.

Instructions: tell the participant to walk towards the end of the path towards the cup of coffee as if they were to grab it. Feedback will be given about the pace they have to achieve based on the time it took them to walk the path.

3. Balance

3.1. Eyes open

The participant will be standing still with both feet on different force plate for 20 seconds, while the eyes are open.

Instructions: tell the participant to stand with their feet at shoulder width and next to each other and under their body (so not one foot in front of them and one foot more to the back). Then ask them to stand still with their eyes open.

3.2. Eyes closed

Standing still with both feet on different force plate for 20 seconds, while the eyes are closed.

Instructions: tell the participant to stand with their feet at shoulder width and next to each other and under their body (so not one foot in front of them and one foot more to the back). Then ask them to stand still with their eyes closed.

3.3. Interference task

Standing still with both feet on different force plate for 20 seconds while the eyes are closed. Count back from 100 to 0 with steps of 3.

Instructions: tell the participant to stand with their feet at shoulder width and next to each other and under their body (so not one foot in front of them and one foot more to the back). Then ask them to stand still, close their eyes and perform the interference task.

4. Standing up

In this test is participant will be asked to stand up from a chair with both their hands in front of them, without touching their knees or the chair. The chair will be placed on the blue walking path and will be level to the force plates.

4.1. Standing up

Participant will be asked to stand up from a chair with both their hands in front of them.

Instructions: tell the participant to stand up without their hand touching either the chair or their own legs.

5. After measurements

- Export data from local storage to “U: Project folder” by logging in with own NetID.
- Ask lab manager to make second backup → delete data from local disk → Save anonimysed version on own laptop
- Put everything back in its original place and clean the room
- Give participant voucher and ask their mail address in case they would like to receive the results of the measurements.

Analysis in OpenSim

Model preparation

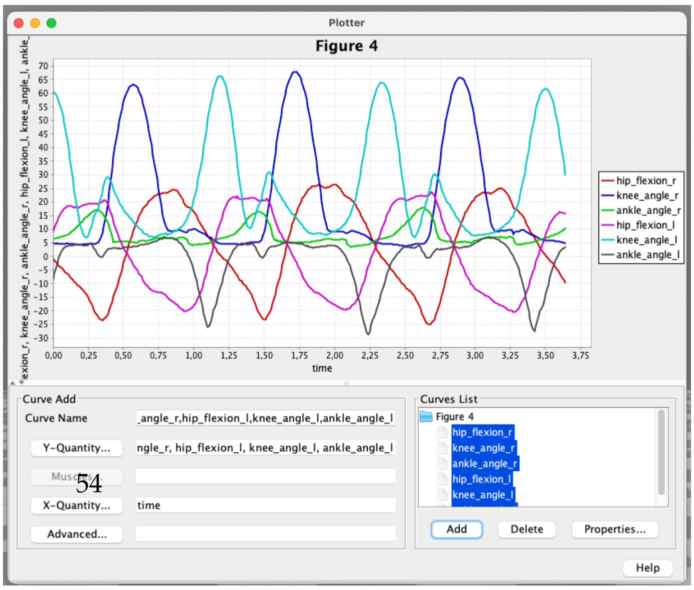
- Use the model from this research. The participant was a right amputee, so all the examples and screenshots are as well. Geometry for a left amputee is included in the package.
- Example: The model for this thesis is called Scaled_pelvis.osim. The word pelvis is in the name, because it is the model with least squared error after marker replacement of pelvic markers by trial and error

Scaling the model

- Open the scaling tool.
- Use a stationary measurement for scaling the model. Needs to be done using the wiki of the scale tool. If markers are placed in the same way as in the report. Otherwise move the markers in the model. Total squared error should be less than 0,02.
- Edit scale factors if it results in a lower squared error.
- Marker pairs have to be made for the following body part to set the length of the body part: foot, shank, upper leg, pelvis, shoulders.
- The marker data need to be in a .trc file. A program called MOKKA can be used for this.
- The data need to be rotated, to match the axes of the model. This can be done by selecting preview experimental data → drop down the menu for these data → right click on the trc file and select transform. The rotation parameters for this thesis were: X=-90 , Y=0 , Z=0.

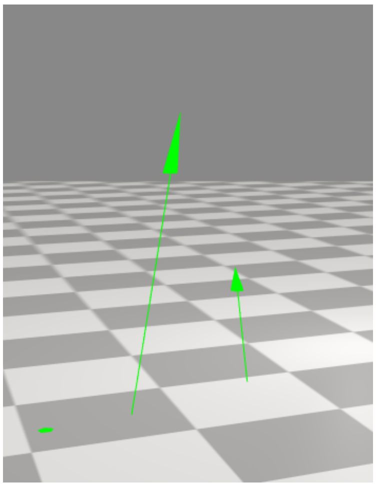
Inverse kinematics

- After inverse kinematics: trc file used is : plate_2_6sep_rotated.trc
- Specify weights for all markers. Higher weights should be given to markers placed on motion segments and lower values should be given to anatomical landmarks. These anatomical markers are helpful for scaling, but are influenced by movement of soft tissue and muscles. An example of a weights file used in my analysis is called 'Plate_1_IK_weights'
- Run the IK tool
- The result is a motion file (.mot file), necessary for the inverse dynamics tool.
- Plot to check the values:

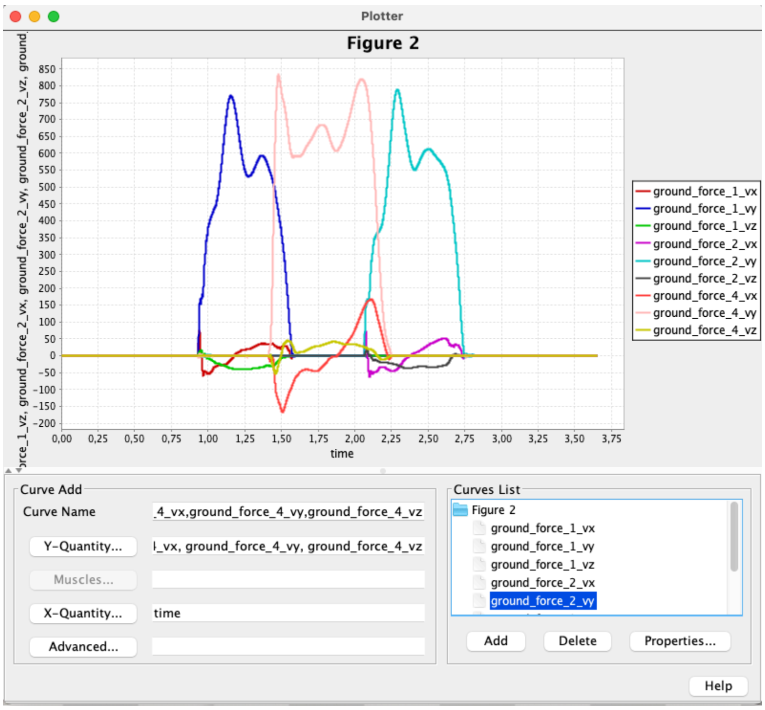


Inverse dynamics

- Use the IKresults file as input for the kinematics and use a separate motion file for the force plate data
- Filter the data with a 6 Hz filter.
- For obtaining the force data file use the matlab script c3dExport. This script can be used to substract and rewrite the forces in the c3d file exported from the gait lab computer
- To check if the force plate data are valid before the analysis, the following two methods can be used:
    - Choose Preview experimental data under 'File'



    - Plot force data against the time



- External loads are defined using a setup file to specify three point forces with torque for the corresponding steps. In my analysis the XML file was called 'Step2R.xml' for the second step with the right foot.

- Check what force plates correspond with the number of the ground force vectors and specify this in the setup file before saving the setupfile
- Define an external force for every step in the analysis. Name this force and select the part the force is applied to, for example the prosthetic foot or calcaneus.
- For each step define the force columns by selecting the vx, vy and vz value for the corresponding force plate
- Define the point column by selecting the px, py and pz value for the corresponding force plate
- Define the torque columns by selecting the moments for every column.
- Save all external load setup files.
- Export the Dynamics file as a .sto file. This file can be used in matlab to further analyse

Analysis in Matlab

All .sto files can be imported into Matlab. Matlab scripts for calculating spatiotemporal values and plotting kinematic values are provided. A separate matlab script for the force plate calculations is also provided. This is a separate file, because no force plate data are used in the other calculations.

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