EFFECTS OF PHYSICAL EXERTION AND ALIGNMENT ALTERATIONS ON TRANS-TIBIAL AMPUTEE GAIT, AND CONCURRENT VALIDITY OF PROSTHESIS-INTEGRATED MEASUREMENT OF GAIT KINETICS

by

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ABSTRACT
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Under the Supervision of Professor Brooke A Slavens

This study investigated the effects of slight changes in the alignment of the artificial limb of trans-tibial amputees on the walking pattern on the level of forces and moments, particularly when physical exertion levels increase. Two alignment conditions were assessed in ten trans-tibial amputees while walking with low and with "strong" levels of exertion. Two separate data collection methods were utilized simultaneously: a conventional motion analysis, and continuous recordings from prosthesis-integrated force sensors. While the former was used to compare bilateral leg symmetry across conditions, the latter allowed analyzing unilateral step variability within subjects. This paper presents both analyses in separate chapters. A third chapter addresses the question of concurrent validity of the utilized integrated-sensor-based gait data collection method.

Findings indicate that increased physical exertion and prosthesis ankle plantar-flexion angle was related to decreases in step length symmetry, maximal knee flexion angle, knee moment, and dorsi-flexion moment, but had no significant effect on an overall gait symmetry index. It was also shown, that effects were different among participants, with only three of them showing a significant change in parameters measured by the integrated sensor system. Integrated sensor measurements namely of axial force and joint moments were found to be closely correlated to conventional measurements, while pertaining to slightly different biomechanical quantities.

The detected effects of alignment perturbations and physical exertion were small in magnitude and inconsistent between participants of our sample population. The concept of a range of acceptable prosthesis alignments, within which no optimization is feasible, is supported. However, amputee gait pattern and responses to alignment perturbations seem to change with the level of exertion. This suggests a consideration of real life conditions for the individual optimization of prosthetic alignment. Provided the systematic limitations of the integrated sensor measurements are carefully considered, it appears possible to use this method for the assessment of individual effects of alignment changes.

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AAS	Amputee Activity Score
ANOVA	Analysis of Variance
ASIS	Anterior Superior Iliac Spine
BMI	Body Mass Index
BPM	Beats Per Minute
CGA	Conventional Gait Analysis
EMG	ElectroMyoGraphy
GRF	Ground Reaction Force
IPECS	Intelligent Prosthetic Endoskeletal Component System
MANOVA	Multivariate Analysis of Variance
PASW	Predictive Analytics SoftWare
PRE/NORM	Low exertion, normal prosthesis alignment
PRE/PF	Low exertion, 2 degrees increased plantar-flexion of the prosthetic ankle
POST/NORM	"Strong" exertion, normal prosthesis alignment
POST/PF	"Strong" exertion, 2 degrees increased plantar-flexion of the prosthetic ankle
RMANOVA	Repeated Measures Analysis of Variance
RMS	Root Mean Square
RPE (CR10)	Ratings of perceived exertion (Category Ratio 10)
SS	Single-Subject

ACKNOWLEDGEMENTS

I have been told that it is a common experience to look at one's own dissertation a few years later, and be utterly embarrassed about the naivety and ineptitude it had been written with. I can already relate to that feeling – all I need to do is glance over one of the earlier draft versions of this document. They are painful to read indeed. There is no denying that pretty much everything that is good in my dissertation is owed to the advice and help I received from other people. (Though, I am sure I managed to retain still enough naïve and inept components to trigger the above mentioned cringing a few years from now.) The one thing I am sure of today is that there are a big number of people who deserve to be acknowledged here:

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Dr. Brooke Slavens, besides being my advisor, hired me as a graduate assistant in late 2010, and I think it is safe to say that she is one of the best superiors one could wish for. There was never a day where I doubted her support for me and my work. I am grateful for having had the opportunity to finish my dissertation under her supervision.

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1 Introduction

1.1 Determining the alignment optimum of a prosthesis

The optimal alignment of an artificial limb – particularly, a lower limb – is an important aspect of the overall fitting quality. Like the prosthetic socket and the selection and adjustment of the mechanical components of the prosthesis, the alignment must be optimized for each patient individually. While it is a trivial fact that generally better alignment correlates with better prosthesis performance (Pinzur et al., 1995; Sanders, Reed, & Marks, 1993), it is debated in the scientific literature whether or not there is a specific optimal alignment for a given patient, or actually rather a range of acceptable alignments without distinction in quality (Blumentritt, 1997; Chow, Holmes, Lee, & Sin, 2006; Sin, Chow, & Cheng, 2001; Zahedi, 1986). A reason for some of the differences in the conclusions of different authors may be the fact that there is no universally applied quantitative method for the respective assessment of alignment quality: Typically, studies that have evaluated the influence of various interventions, such as change of prosthetic components, or change of prosthetic alignment, on prosthetic performance have selected either one or used combinations of different assessment criterions, as there are walking speed, metabolic efficiency, and inter-leg symmetry (Boonstra, Fidler, & Eisma, 1993; Nolan et al., 2003; Silverman et al., 2008).

1.2 Significance of alignment optimization

Irrespective of the actual nature of the alignment optimum, be it a discrete alignment setting (figure 1) or an acceptable range of settings, an approximation of this optimum (figure 2) is desirable to reduce the negative effects of misaligned prostheses (Sin et al., 2001), such as “abrasion and irritation at the interface of the socket and the stump” (Chow et al., 2006) or deficits in terms of “energy use, gait appearance, and walking comfort of the amputee with the prosthesis”(Jia, Wang, Zhang, & Lia, 2008). Many amputees are capable of compensating for

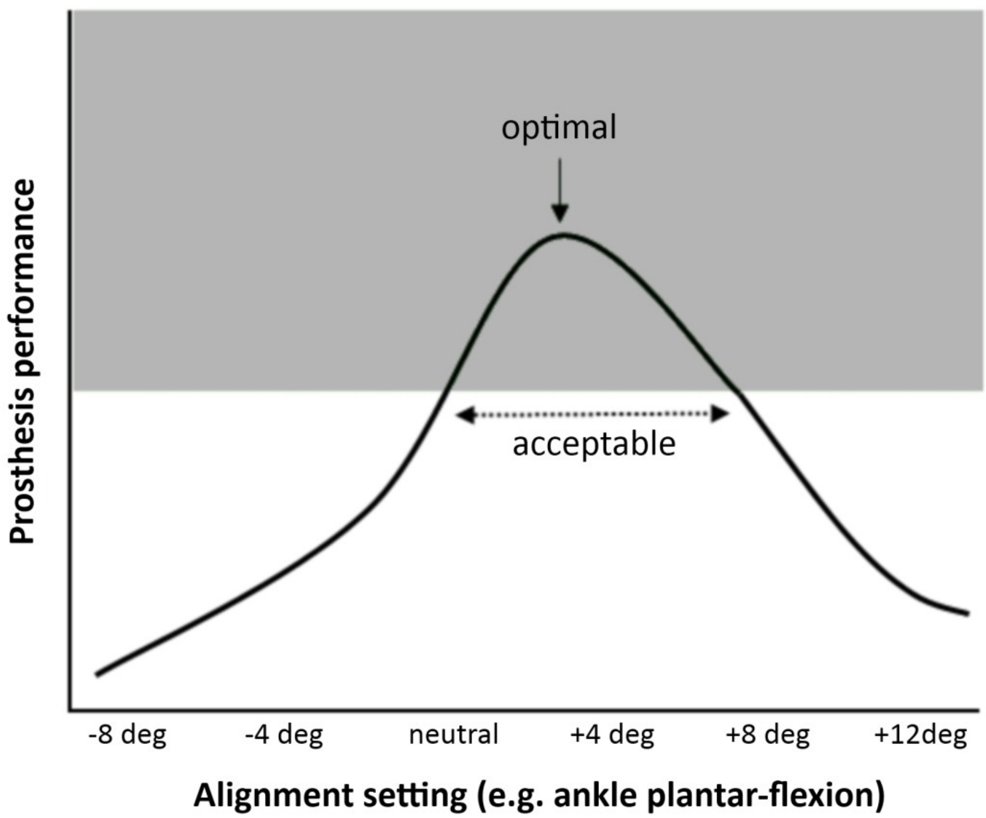

Figure 1: Illustration of alignment effects on prosthesis performance levels. Many assessment methods allow the identification of an acceptable level, but fail to answer the question for the (possible) optimum setting.

prosthesis alignment deficits (Beyaert, Grumillier, Martinet, Paysant, & André, 2008; Fridman, Ona, & Isakov, 2003; Grumilliera, Martineta, Paysanta, Andréa, & Beyaert, 2008; Jia et al., 2008; Van Velzen, Houdijk, Polomski, & Van Bennekom, 2005; Yang, Solomonidis, Spence, & Paul, 1991; Zahedi, 1986), which may mask the misalignment issue and lead to long-term side effects. Depending on the prosthetic components and the individual physical condition, those required compensation efforts may be more or less demanding (Jia et al., 2008; Schmalz, Blumentritt, & Jarasch, 2002). Yet any compensatory effort will always be a disadvantage from the point of energy efficiency, as the required muscle work and control capabilities will come at the expense of the available resources for locomotion. In consequence, the obtainable walking speed or walking distance may be reduced. This is a universally found result. For example, outside of the amputee population, it has also been observed in elderly populations (Ko, Ling, Winters, & Ferrucci, 2009), in patients coping with and recovering from motor disorders (Theo Mulder, Zijlstra, & Geurts, 2002), and in subjects using specific footwear (Perry, Radtke, McIlroy, Fernie, & Maki, 2007).

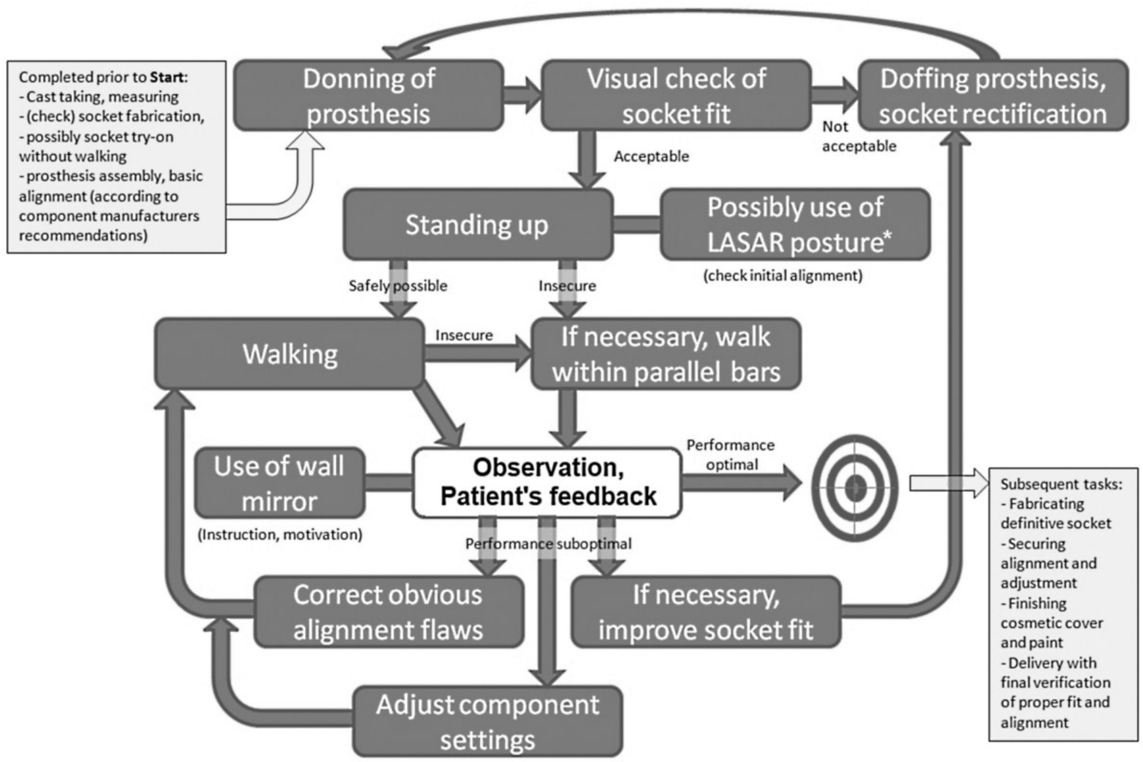

Figure 1:Schematic of the iterative alignment process in the clinic. Center piece is the assessment of gait, that depends on visual observation and patient's feedback. *Use of the LASAR posture device (Otto Bock, Duderstadt, GER) has been proposed by Blumentritt (1997)

1.3 Open Research Questions on Prosthetic Alignment

While there are many studies concerned with the optimal assessment of gait symmetry in amputees, some factors that may influence prosthesis performance have not been extensively discussed. Given that amputees regularly compensate alignment perturbations, it seems possible that observations obtained under experimental conditions inside a laboratory environment are not indicative of the prosthesis performance in situations that the patient encounters in everyday life (Neumann, 2009). Various parameters may be different, such as surface evenness, lighting, patient's fatigue, motivation, or distraction. Any of those factors may lead to a reduced level or success of compensatory efforts, which in turn would negatively affect the gait symmetry – particularly in the case of a misaligned prosthesis (Sin et al., 2001). If the notion is accepted that there is an optimum alignment (range) of the prosthesis (Chow et al., 2006), it can be concluded that even subtle alignment deviations from this optimum will have an adverse effect.

1.3.1 Typical alignment perturbations investigated in research studies

Alignment perturbations that have been frequently investigated in research studies. Often they included the realignment of the prosthetic ankle joint in the sagittal plane (e.g. foot plantar-flexion or dorsi-flexion). Beyond the popularity of that particular alignment in research, it also has significance in clinical practice. The easiest (although often improper[1]) way to increase the stance stability and perceived safety of a trans-tibial prosthesis is in many cases to increase the foot plantar flexion. That results in a higher knee extending moment, which prevents the knee from buckling during the early stance phase. As for research purposes, some authors have aimed the respective ankle angle alignment perturbations to most accurately match a predetermined ground reaction force (GRF) line (Blumentritt, 1997; Blumentritt, Schmalz, Jarasch, & Schneider, 1999), or an idealized 'roll-over' shape (A. H. Hansen, Meier, Sam, Childress, & Edwards, 2003). Others, who settled on a defined ankle angle change, choose misalignment ranges between 5 degrees (Rossi, Doyle, & Skinner, 1995), 10 degrees (Schmalz et al., 2002) and 15 degrees (Van Velzen et al., 2005); again others used a 5mm wedge under the

[1] The biomechanically more appropriate way to achieve static knee stability would be a parallel shift of the foot anteriorly with respect to the socket, which inhibits the roll-over motion less severely. However, this procedure is more complex and requires more work.

forefoot and heel respectively (Seelen, Anemaat, Janssen, & Deckers, 2003), or different shoes with heel height differences of 20 mm (Xiaobing, Xiaohong, Peng, & Lidan, 2005). The most subtle alignment changes with increments of 1 degree were reported by (Sin et al., 2001) and (Chow et al., 2006). In the last mentioned studies, an acceptable range of alignments was determined based on patient's feedback and the visual gait assessment by experienced prosthetists, leading to individually different ranges of acceptable alignments that were subsequently evaluated by instrumented gait analysis methods.

1.3.2 Measurement variables that have been evaluated in research studies

The published studies on amputee gait can be coarsely grouped according to the methods employed: In one group, authors considered kinematic parameters, such as joint angle symmetries during walking (Dingwell, Davis, & Frazier, 1996; Isakov, Burger, Krajnik, Gregoric, & Marincek, 1996). This most resembles the prosthetic gait assessment in clinical practice. The other group of studies included (solely or in addition to the kinematics parameters) kinetics parameters, for instance relative limb loading during ambulation (Bateni & Olney, 2002; Hong & Mun, 2005), and, alternatively, muscle activation patterns (Fey, Silverman, & Neptune, 2010). As this kind of measurements requires additional equipment, such as force plates or electromyography sensors, data collection for those studies is often constrained to the laboratory environment, a limitation that has been criticized to reduce the practical significance of the findings (Neumann, 2009). The reported walking interventions include different prosthetic components, different shoes, and different walking surfaces among others. It was found that the "acceptable alignment range for non-level walking [is] smaller than and fell within that for level walking" (Sin et al., 2001), suggesting that respective walking trials on uneven surfaces be included for alignment optimizations.

1.3.3 Contribution of the present study

There is a declared gap in knowledge on how prosthesis alignment perturbations affect amputee gait performance outside of the laboratory. Research is necessary to help understand the nature of the individual alignment optimum, and how to attain this optimum. The literature indicates that for a given patient, there is often a range of acceptable prosthesis alignments, within which no further optimization is possible. However, the range of acceptable alignments declines once the patient navigates uneven walking surfaces, which suggests that amputees compensate for slight alignment changes in the gait laboratory. An optimally aligned prosthesis would reduce the need for compensatory efforts to a minimum and thus increase the biodynamic efficiency of amputee gait.

Purpose of this study was to compare amputee-walking dynamics under different real life conditions, by including walking with a certain degree of physical exertion to the respective interventions. By investigating whether an interaction effect of subtle alignment perturbations and increased exertion levels could be detected, this study addressed the need to translate laboratory findings into practically relevant results. Based on this research, it may become possible to better define the individual range of acceptable alignments, and thereby develop a way to economically and efficiently improve the quality of lower limb prostheses. Assessing the concurrent validity of the mobile force sensor provided the prerequisite for this study as well as directions for future works.

1.4 Specific Aims and Hypotheses

Aim 1a: To investigate the effect of subtle alignment changes, physical exertion and their interaction on the gait symmetry in trans-tibial amputees.

Working hypothesis: Subtle changes of the prosthesis ankle alignment will have a significant effect on an overall index of gait kinematics when the amputee has reached a certain level of physical exertion.

Aim 1b: To investigate differences between kinematics and kinetics indices in reflecting the effects of alignment changes, exertion, and interaction. Rationale is to determine whether consideration of one quantity of variables is sufficient in clinical practice.

Working hypothesis: Subtle alignment changes will not have an immediate effect on gait kinematics, but on gait kinetics, specifically on knee moment and ankle moment. This would suggest monitoring kinetics variables during prosthesis fitting sessions.

Aim 2: To evaluate the concurrent validity of kinetics measurements based on prosthesis integrated sensors.

Working hypothesis: Measurement accuracy for ground reaction forces, ankle moments, knee moments, step duration, and step frequency is comparable to conventional gait analysis methods, as determined by correlation analysis.

Aim 3a: To investigate the effects of subtle alignment change and physical exertion on unilateral step kinetics within subjects.

Working hypothesis: Step variability between conditions is significantly higher than step variability within conditions.

Aim 3b: To investigate the linearity of effects with increasing exertion.

Working hypothesis: Effects will increase linearly when the amputee's level of physical exertion increases.

Aim 3c: To investigate the effect of subtle alignment changes and physical exertion on step-by-step variability.

Working hypothesis: Step-by-step variability will increase with exertion and misalignment.

1.5 A priori Limitations and Assumptions

With a sample population of active trans-tibial amputees, findings of this study may not be entirely transferable to subjects with other amputation levels or conditions.

1) There was no deliberate choice of prosthesis components or socket technology; instead the regular prostheses of participants were used. Conclusions pertaining to prosthesis components or technologies that were not represented may be limited.

2) It was assumed that the regular prostheses of study participants were well-fitting and optimally aligned.

3) It was assumed that participants gave truthful information in questionnaires and when reporting their perceived exertion levels.

4) It was assumed that the temporary modification of the prostheses by installing the integrated sensor did not alter the original alignment or the function of the prosthesis

1.6 Significance

Amputations of the lower extremity are comparably widespread. Trans-tibial amputation alone has an annual incidence rate of roughly 13 in 100,000 Americans (Dillingham, Pezzin, & MacKenzie, 2002). The main causes for such amputations are vascular conditions as are common in diabetes. With the expected higher prevalence rate of diabetes in the future, it is projected that the number of persons living with an amputation will double by the year 2050 (Ziegler-Graham, MacKenzie, Ephraim, Travison, & Brookmeyer, 2008). Artificial limbs that replace the lost structure below the knee are necessary to enable standing and ambulation without crutches, and to facilitate the prevention of secondary ailments. Since socket fit and static alignment of prostheses are customized to the individual user, standardized quality measures are difficult to define, and there is a high variability within the end products of prosthetist's efforts (Geil, 2002; Zahedi, 1986).

1.6.1 Scientific significance

The effect of subtle alignment changes on amputee gait in non-laboratory environments has not yet been extensively investigated. Physical exertion is a relevant factor to be analyzed in the context of gait pattern responses to alignment changes. Many previous findings, such as the "range of acceptable alignments" were based on study protocols where exertion was not an intervention variable. This work expands on the body of knowledge by including gait data from walking-with-"strong"-exertion trials, as well as by investigating the usefulness of mobile data collection methods for the analysis of amputee gait.

1.6.2 Clinical significance

The utilization of mobile gait analysis equipment (Intelligent Prosthetic Endoskeletal Component System "iPecs" Lab, College Park Industries, Fraser, MI) allowed a comparison of different environments in terms of inter-leg gait symmetry and step-to-step variability under different alignment conditions and exertion levels. The continuous and unobtrusive data collection method does not require any conscious collaboration from the subject, and allows thus to compare the walking kinetics of clinical test situations with those of situations where the subject is unaware of the gait monitoring. Results of this study may help optimize prosthetic fitting and alignment procedures in clinical practice when the provided evidence on the correlation of laboratory and real-life conditions is used to amend protocols and standards. The inclusion of extended walking sessions, as well as the use of mobile gait monitoring equipment, is among the conclusions supported by the findings. As such, the present study is a step towards future developments that will allow supplementing the current praxis of optimizing prosthesis alignments by respective assessment methods (figure 3), and eventually lead to a more effective and efficient alignment optimization process.

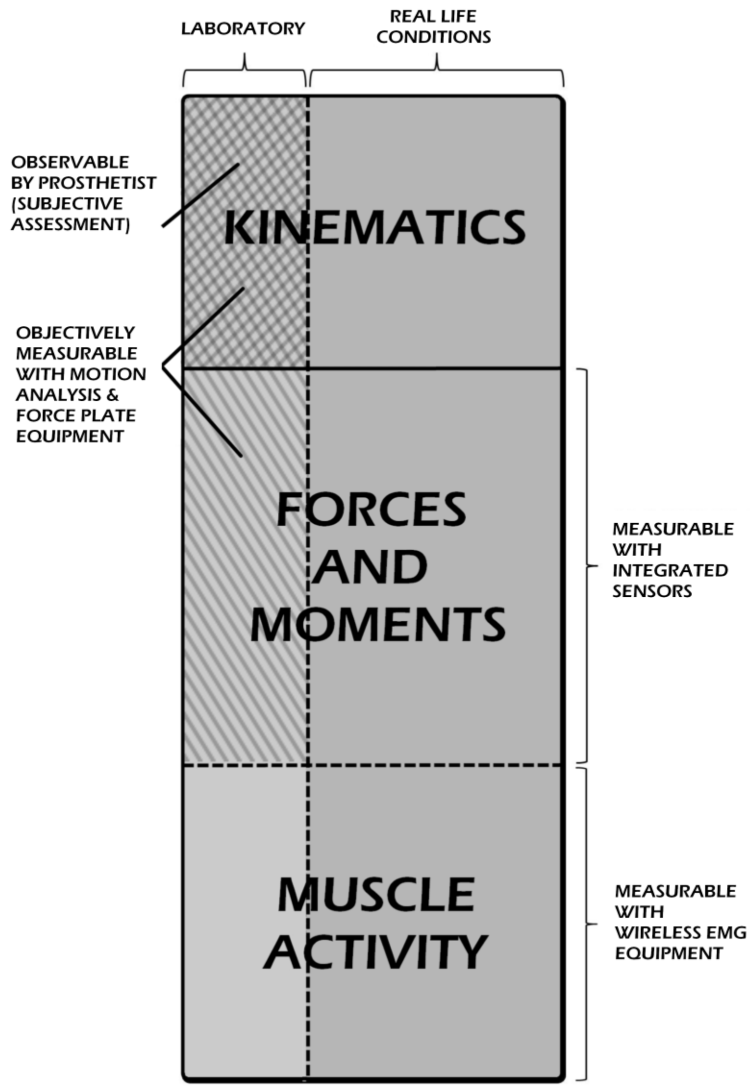

Figure 2: Currently, most of the alignment procedures in clinical prosthetics are based on visual gait assessment in the gait lab, which only covers a small part of the overall picture (upper left sector in the diagram). Extension of the test environment and inclusion of mobile sensors allows for a more comprehensive assessment of amputee gait as more contributing variables and boundary conditions can be considered.

1.6.3 Content presentation

In the following, the results of this study are presented in three chapters, anticipating their subsequent modification into a format for journal manuscript submission.

Chapter 2 is concerned with the effects of exertion and subtle alignment changes on gait, regarding main effects and interaction effect. Data was collected by conventional gait analysis (CGA). Dependent variables for this analysis are gait symmetry indices: one overall index, and two sub-indices for kinematics and kinetics parameters respectively. Also tested was the effect on unilateral gait variables. As such, this manuscript addresses aim 1.

Chapter 3 investigates the question of concurrent validity of integrated sensor measurements of amputee gait biomechanics. To that end, a correlation analysis was conducted of variables that can be measured simultaneously by CGA and by the iPecs integrated sensors. Those variables are the ankle moment and the ground reaction force on the prosthetic leg side. Aim 2 is being addressed.

In chapter 4, the initial analysis of exertion and misalignment effects is repeated based on variables from the integrated sensor that have been shown to be valid in chapter 3. In contrast to the analysis in the first chapter, the within-subject variability is assessed from multiple step samples, and is included in the computation of F-values. Repeated measurements over the course of the data collection session allow addressing aim 3.

All analyses are based on the same data set that has been collected by means of the previously described methods. A sample of 10 active trans-tibial amputees was recruited and participated in the data collection in the summer and fall of 2011. Anthropometric data are listed in table 1.

Table 1: Anthropometric information on study participants. All subjects were fitted with variations of patellar-tendon-bearing (PTB) socket designs, with elastic roll-on liners, and energy-storing-and-returning (ESAR) feet. *The Amputee Activity Score, proposed by Day (1981) is computed based on a questionnaire. Typical scores are in the Range of -70 to +40, although the scale is technically open-ended.

Subject number	Age (years)	Weight (kg)	Height (cm)	amputation side	Residual limb length (cm)	Time since fitting (years)	Amputee Activity Score*	measured preferred walking speed (m/s)	Heart rate at RPE 0	Heart rate at RPE 5
1	46	64	168	Right	14	0.5	25	1.45	75	111
2	29	81	179	Right	17	5	27	1.28	65	139
3	59	118	188	Left	22.5	2	7	1.13	71	102
4	61	84	170	bilateral	16.5 (both)	1	15	1.06	78	102
5	32	81	173	bilateral	15 (l), 16 (r)	4	21	1.13	100	140
6	55	82	187	Right	20	10	29	1.43	60	130
7	59	82	190	Left	18	5	17	1.42	75	134
8	60	91	173	Left	15	8	7	1.27	85	138
9	38	84	173	Left	23	2	-1	1.35	84	162
10	65	118	189	Right	23	3	19	1.52	88	141

2 Influence of physical exertion on the effect of subtle alignment changes in trans-tibial prosthesis walking

2.1 Introduction

The optimal static alignment of a leg prosthesis, that is the spatial orientation of the functional components of the prosthesis with respect to each other, is generally a compromise between dynamic efficiency and static stability, and is informed by a multitude of individually different factors that need to be considered during the alignment optimization process. As adjustment and alignment of an artificial leg remain constant, once set by the prosthetists, no adaptation to changes in walking surface, footwear, gait speed or other environmental factors is possible[2].

It has been suggested before, that there is a range of acceptable alignments in trans-tibial prosthetics within which no further optimization is possible (Blumentritt, 1997; Chow et al., 2006; Sin et al., 2001; Zahedi, 1986). This notion implies that continued alignment efforts are futile after a level of acceptability has been reached. However, it was noted that the range of acceptable alignments is smaller when walking on uneven ground (Sin et al., 2001), as well as that laboratory findings may not be sufficiently translatable into real-life conditions (Neumann, 2009). Observations in the gait laboratory may be biased by the idealized conditions, and by the selection of variables for analysis. An assessment that only considers kinematics but no kinetics – as common practice in prosthetics practice - may miss important information.

Various outcome measures have been used in the research literature, including walking speed (Boonstra et al., 1993; Fey et al., 2010; Isakov et al., 1996; Nolan et al., 2003; Silverman et al., 2008), balance and fall susceptibility (Nadollek, Brauer, & Isles, 2002; Perry et al., 2007;

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[2] That is true for the current state of prosthetic technology, based on passive components. Recent developments indicate that future generations of prosthetic feet will be capable of active motion, thus approximating able bodied biomechanics.

Summers, Morrison, & Cochrane, 1988; Vanicek, Strike, McNaughton, & Polman, 2009; Vickers, Palk, McIntosh, & Beatty, 2008), and user's content level (Legro et al., 1999; Miller & McCay, 2006; Pezzin, Dillingham, MacKenzie, Ephraim, & Rossbach, 2004). Gait symmetry has been widely used as an assessment variable (Cheung, Wall, & Zelin, 1983; Chow et al., 2006; Dingwell et al., 1996; Isakov et al., 1996; Nolan et al., 2003; Tura, Raggi, Rocchi, Cutti, & Chiari, 2010), presumably because it represents one of the major objectives in prosthetic intervention, namely the restoration of the unimpaired natural function and appearance. It is also comparably quickly assessed and therefore an important criterion for prosthetists and amputees alike.

Considering the reported finding of a "range of acceptable alignments", it could be reasoned that physically active lower limb amputees are capable of compensating unfavorable subtle alignment changes of their prostheses (Beyaert et al., 2008; Grumilliera et al., 2008; Jia et al., 2008; Sadeghi, Allard, & Duhaime, 2001; Silverman et al., 2008), and that therefore the gait pattern does not visibly change as the consequence of such an alignment change. With increasing physical exertion, those compensatory efforts should become less effective, and therefore the effect of subtle alignment changes would become measurable in amputee gait after a certain degree of exertion is reached.

The purpose of this research was to determine whether the assessment of kinematic gait symmetry under laboratory conditions is sufficient to facilitate optimal prosthesis alignment.

This study investigated the hypothesis that subtle prosthesis alignment changes, namely a by 2 degrees increased ankle plantar-flexion, have a different effect on trans-tibial amputee gait symmetry when the amputee is walking with different levels of physical exertion, those levels being 0 and 5 on the 11-point RPE scale (Borg, 1998). It was also investigated whether any changes in bilateral symmetry are consistent between kinematic and kinetic parameters.

2.2 Methods

A conventional gait analysis (CGA) was conducted with all ten subjects (demographic and anthropometric data are listed in table 1 in the previous chapter), wearing their respective original prostheses, and walking at a self-selected speed through the capture volume of the motion analysis laboratory (10 camera system (Cortex ®, Motion Analysis Corporation, Santa Rosa, CA, Sampling frequency 100 Hz), with 3 force plates (AMTI, Watertown, MA), Sampling frequency 1000 Hz). A modified Cleveland Clinic marker set was used, comprising of the customary leg and head markers (figure 4), but limiting the number of upper extremity and trunk markers to the three pelvis defining markers over the left and right anterior superior iliac spines (ASIS), and the Sacrum. Wireless electromyography (EMG) electrodes (Delsys, Inc., Boston, MA) were applied over the rectus femoris and over the hamstring muscles of both legs. EMG data collection rate was 2000 Hz.

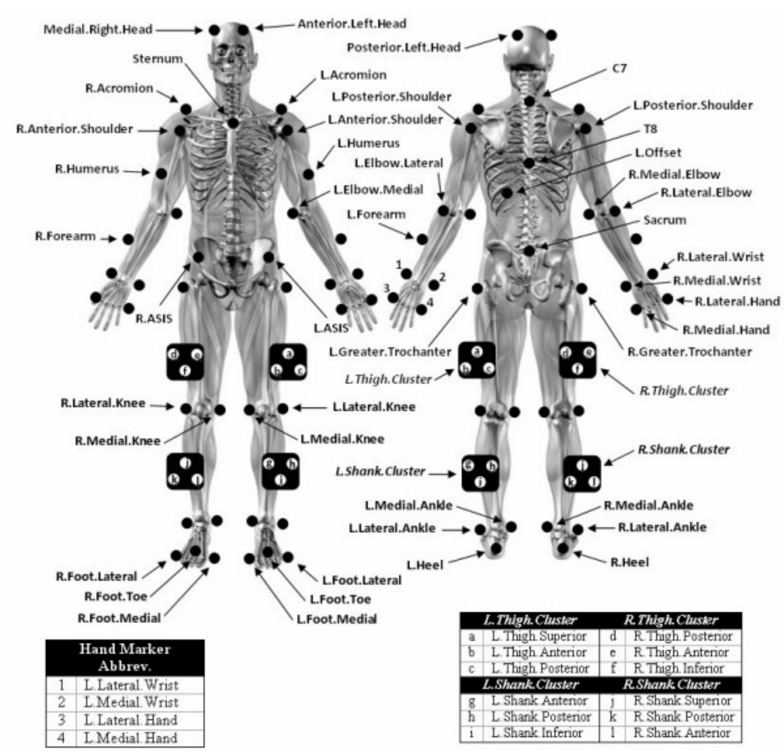

Figure 3: Complete Cleveland Clinic marker set, from KinTools RT for Cortex User's Manual (Motion analysis 2010)

Subjects were asked to walk back and forth on a specified path that led over the three force platforms installed flush with the ground. Initially, the force platforms were not pointed out to the subjects, in order to not compromise the walking pattern by attempts of aiming their steps at hitting the plates right. However, after subjects repeatedly failed to produce clean steps on the force plates, either by making only partial foot contact or multiple contacts on the same plate, they were oriented to the nature of the exercise, and asked to possibly hit the force plates in stride while maintaining a most natural walking pattern. This modification of standard practice has been shown to have acceptably small effects on the data (Grabiner, Feuerbach, Lundin, & Davis, 1995; Wearing, Urry, & Smeathers, 2000), and was motivated by the consideration of the fatiguing effect of multiple trials[3]. As fatigue, in the sense of exertion, was one of the independent variables of the study design, it was an objective to control it in the interest of having two clearly distinguishable exertion levels for comparison purposes. To minimize recovery effects and in light of the low rate of usable trials that could be recorded, generally only one trial per subject and condition was included in the post processing.

After the first set of trials had been recorded, the prosthetic ankle alignment was altered by increasing the foot plantar-flexion by 2 degrees. The magnitude of this deliberately subtle alignment change was determined based on previous studies that included perturbations between 1 and 15 degrees (Chow et al., 2006; Rossi et al., 1995; Schmalz et al., 2002; Seelen et al., 2003; Sin et al., 2001; Van Velzen et al., 2005; Xiaobing et al., 2005). Alignment changes were done without doffing the prosthesis, by replicating a respective adjustment that had been tested during the prosthesis preparation phase. Prior to the testing, the doffed prosthesis had

[3] At the level of low exertion, the physical demands of multiple repetitions would lead to an undesirable increase in exertion. Conversely, at the level of strong exertion, the time needed for multiple repetitions would allow for an undesirable recovery from the increased exertion level.

been placed in an alignment device, where the original position of socket and foot with respect to each other was documented. While in this alignment device (figure 5), the foot position was temporarily altered in the sense of increased plantar-flexion of two degrees, measured by a simple goniometer. The angle correlates with the position of the set screws in the pylon adapters, so that – once the number of screw twists for the desired alignment perturbation was determined – this perturbation could be replicated without the use of a goniometer.

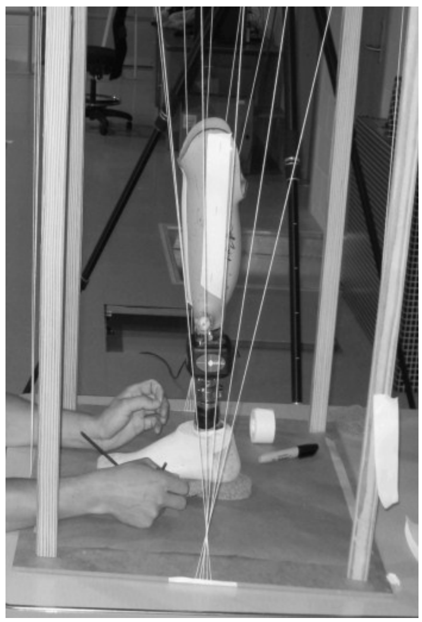

Figure 4: Preparation of prosthesis prior to data collection. The integrated sensor under the socket was used for additional data collection that is not reported in this chapter. Plumb lines on the socket allow maintenance and reconstitution of the ori

Following this subtle alignment change, the subject repeated the walking trials, captured by the motion analysis system. Next, the alignment was corrected to the original setting again, and the subject was asked to continue walking until the rated perceived exertion (RPE) would reach a “strong” level, as described by a level 5 of Borg’s “Category Ratio “10-point CR10 scale (Borg, 1998). Subjects were also wearing a heart rate monitor, which delivered the pulse rate as a backup measure of acute exertion, although the decision on when to continue with the data collection, that is when the desired exertion level was reached, remained solely with the subject.

Once the RPE level of 5 was reported – usually following a few repetitions of stair climbing – another set of walking trials in the gait laboratory was conducted. In the light of individual differences in recovery rates from exertion, it was attempted to conduct these data collection sessions in a swift manner with a minimum of repetitions. Again, trials were recorded with the original setting, as well as with the two degrees increased ankle plantar-flexion alignment.

In total, that resulted in motion analysis data of four different conditions:

(1) Normal alignment & low exertion (PRE/NORM),

(2) Altered alignment & low exertion (PRE/PF),

(3) Normal alignment & "strong" exertion (POST/NORM), and eventually

(4) Altered alignment & "strong" exertion (POST/PF).

Two of the participants had bilateral trans-tibial amputations. For those subjects (number 4 and 5), the data collection protocol was amended in that the alignment perturbation was performed for each leg separately, and gait trials were recorded for a total of eight conditions instead of four. (Added trials were "increased plantar-flexion in the second leg", and "increased plantar-flexion in both legs simultaneously" in each exertion level.)

A useable trial was selected for every condition and every subject for post processing. Marker position data was processed by filling gaps (Cortex ®, Motion Analysis Corporation, Santa Rosa, CA) and variables of interest were parameterized (OrthoTrack ®, Motion Analysis Corporation, Santa Rosa, CA). They included for both legs: step length[4], stance phase duration, knee flexion angle, ankle flexion angle, knee flexion moment, ankle flexion moment, ankle abduction moment, ankle rotation moment, pelvis tilt, pelvis obliquity, quadriceps activation

[4] Step lengths were measured between heel strike position of the contralateral leg, and heel strike position of the interesting leg along the line of progression. Several steps were averaged when possible in the respective captured trial.

and hamstring activation. Maxima and the time of maxima were found for the following variables: knee flexion angle, ankle flexion angle, knee flexion moment, ankle flexion moment, ankle abduction moment, ankle rotation moment, pelvis tilt, pelvis obliquity, quadriceps activation and hamstring activation. Figure 6 shows the definition of a subset of the data.

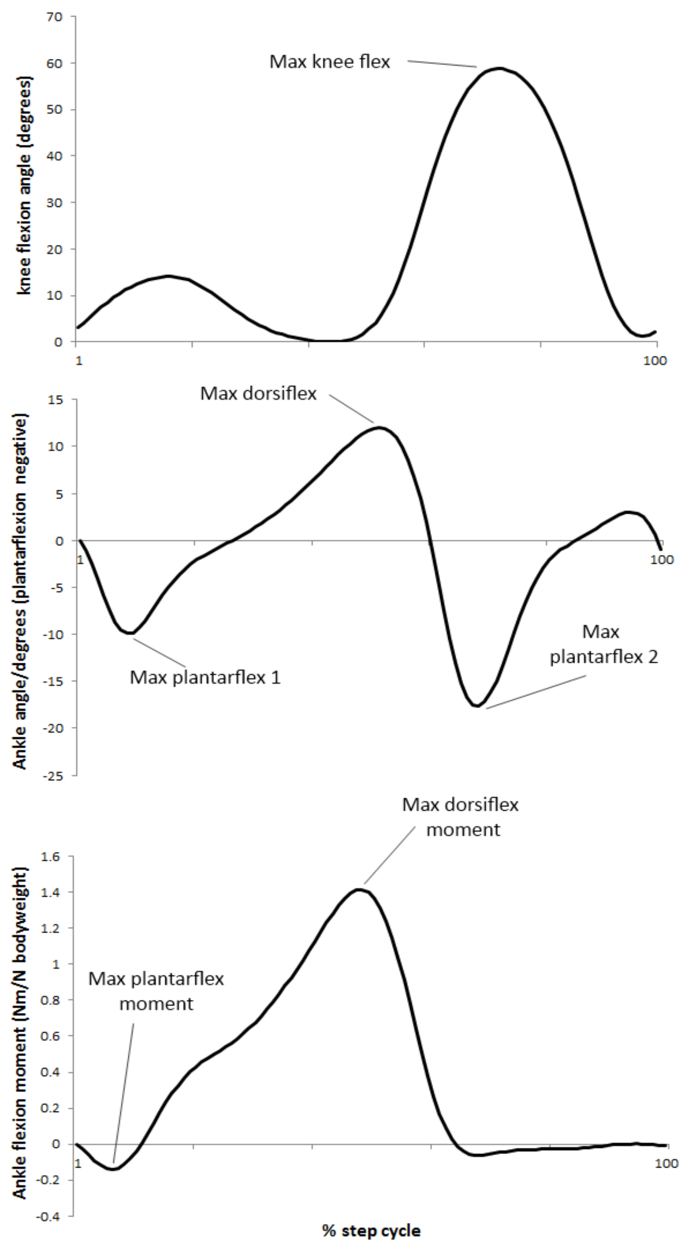

Figure 5: Illustration of landmark data points used for analysis of gait curves. Magnitude and timing of the marked peaks were evaluated

Based on those parameters, it was now investigated whether the subtle alignment change and the raised exertion level are correlated with any significant differences in bilateral asymmetry. In an effort to narrow the number of dependent variables, symmetry indices (Herzog, Nigg, Read, & Olsson, 1989) were devised following the study objective. In that sense, for each parameter the absolute bilateral difference was divided by the mean of both parameters in order to achieve a standardized positive index of symmetry. More correctly, this is an index of asymmetry as a value of 0 signifies perfect symmetry (Chow et al., 2006). The composition of the overall index, as well as the sub-indices for kinetics and kinematics parameters is depicted in table 2.

Table 2: Variables combined into the different asymmetry indices

overall asymmetry index	maximal knee flexion angle	kinematics index
	% time of maximal knee flexion angle	
	maximal dorsi-flexion angle	
	% time of maximal dorsi-flexion angle	
	maximal plantar-flexion angle 1	
	% time of maximal plantar-flexion angle 1	
	maximal plantar-flexion angle 2	
	% time of maximal plantar-flexion angle 2	
	Stance phase % of step cycle	
	step length	
	maximal knee flexion moment	kinetics index
	% time of maximal knee flexion moment	
	maximal dorsi-flexion moment	
	% time of maximal dorsi-flexion moment	
	maximal plantar-flexion moment	
	% time of maximal plantar-flexion moment	

Recording of the EMG signals was flawed by several factors, most notably the incompatibility of the rather voluminous wireless electrodes and the fact that subjects were using elastic liner technology for the suspension of their prostheses. Those liners cover large portions of the thigh and often disallowed the placement of EMG electrodes in the desirable locations over the muscle bellies. Although EMG data were collected for most of the subjects, they were not included in analysis as the low signal quality was deemed to considerably affect the level of confidence in possible conclusions.

Prior to statistical analyses of variances, the sample data was tested for the assumption of normality. In cases where the normality assumption could not be upheld, Friedman tests, and as appropriately respective non-parametric post-hoc tests were conduct, instead of the else applied Repeated-Measures Analysis of Variance (RMANOVA). Aside from the index-variables, tests were also conducted for variables describing the bilateral asymmetry based on isolated measures, to investigate possible trends in how those respond to the interventions.

Additionally to the bilateral symmetry, it was also investigated what leg-wise (prosthetic vs. sound leg) effect the interventions had on gait parameters. To that end, variables were compared across conditions within legs. Sample sizes were 8 for the sound legs, and 12 for the prosthetic legs, due to the fact that two of the subjects were bilateral amputees.

In a variation of the statistic calculation ran for the bilateral symmetry comparison above, two additional variables were selected (maximal pelvis obliquity, and maximal pelvis tilt), that could not be considered in the sense of bilateral symmetry. As before, the parameters maximal knee flexion angle, and time to maximum were included as well. All statistical evaluations were completed using the software IBM PASW (previously SPSS), version 19.

2.3 Results

The results show no indication that physical exertion has an influence on amputee gait symmetry measured by an overall symmetry index, or that there is a significant interaction effect of exertion and subtle alignment perturbation. It could not be shown that there are significant differences when evaluating gait symmetry based on only kinematics parameters and based on only kinetics parameters. The combined gait asymmetry indices (overall, kinematics, kinetics) met the normality assumption and where therefore analyzed by RMANOVA. For most of the isolated asymmetry variables, the normality assumption was found to be violated, and statistical tests were subsequently conducted using non-parametric methods, such as the Friedman test for repeated measures analysis, and the Wilcoxon Signed Ranks test for post-hoc comparisons of conditions. No adjustments were made to account for multiple comparisons.

Univariate comparisons suggest that asymmetry in the parameter “step length” was different across conditions (X^2 =7.8, p=0.05). Post hoc tests showed that a statistically significant difference existed between conditions PRE/NORM and PRE/PF (z= 1.960, p=0.050), with asymmetry being higher in the PRE/NORM condition. A statistically significant difference existed also between conditions PRE/PF and POST/PF (z= 2.380, p=0.017), with asymmetry being higher in the POST/PF condition (figure 7). This translates into the finding that asymmetry in step length improved initially after increasing the foot plantar-flexion, but decreased significantly when subjects had reached a higher level of exertion and were asked to walk with the same alignment of increased plantar-flexion.

Other differences in bilateral symmetry measured in isolated variables were not found to be significant at the 0.05 threshold.

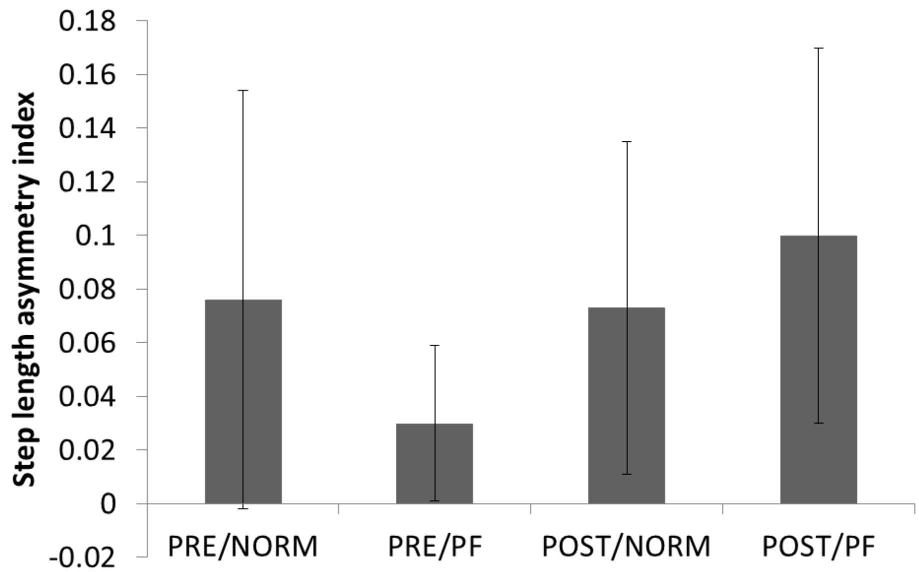

Figure 6: Step length asymmetry means and standard deviations over the four tested walking conditions. Differences between PRE/NORM and PRE/PF, as well as between PRE/PF and POST/PF are significant at the .05 level.

In comparing gait variables within the same leg across conditions, it was found that “maximal knee flexion” (X^2 =8.2, p=0.042), “maximal knee moment” (X^2 =9.0, p=0.029), and “maximal dorsiflexion moment” (X^2 =8.5, p=0.037) were significantly different.

Post hoc tests were conducted to determine the nature of those differences. The “maximal knee flexion” was significantly higher in condition POST/PF compared to PRE/PF (z=2.275, p=0.023). The “maximal knee moment” was higher in condition POST/NORM compared to PRE/NORM (z=2.511, p=0.012) and compared to PRE/PF (z=2.275, p=0.023). The “maximal dorsiflexion moment” was higher in condition PRE/NORM compared to POST/NORM (z=2.353, p=0.019).

Findings on the three investigated asymmetry indices, as well as on asymmetry in individual variables are listed in tables 3 and 4. Leg-wise effects of the interventions are listed in table 5 for the prosthetic legs, and table 6 for the respective sound legs.

Table 3: Effect sizes of exertion, increased ankle plantar-flexion, and interaction effects on indices of gait asymmetry. Asymmetry has been computed for each gait variable by dividing the bilateral differences with the bilateral mean. Combined indices were normally distributed over the sample of 8 unilateral amputees, and were statistically compared by RMANOVA. (PRE – low exertion, POST – strong exertion, NORM – initial alignment, PF – 2 deg plantar flexion)

Asymmetry					exertion		plantar-flexion		interaction	
indices	PRE/NORM	PRE/PF	POST/NORM	POST/PF	η_p^2	p	η_p^2	p	η_p^2	p
overall	0.373 ± 0.124	0.375 ± 0.123	0.377 ± 0.120	0.426 ± 0.157	0.021	0.709	0.001	0.923	0.029	0.663
kinematics	0.298 ± 0.071	0.325 ± 0.112	0.366 ± 0.185	0.417 ± 0.228	0.069	0.496	0.001	0.933	0.000	0.957
kinetics	0.498 ± 0.339	0.458 ± 0.302	0.395 ± 0.211	0.442 ± 0.175	0.018	0.731	0.001	0.948	0.082	0.454

Table 4: Group mean and standard deviation of asymmetry values for isolated gait variables. Asymmetry has been computed for each gait variable by dividing the bilateral differences with the bilateral mean. The majority of the asymmetry values were not normally distributed over the sample of 8 unilateral amputees. Shapiro-Wilk tests of normality were conducted, and respective p-values are reported (where p<0.05 indicates a violation of the normality assumption). For consistency, all variables were statistically compared by Friedman tests.

Asymmetry indices	PRE/NORM	PRE/PF	POST/NORM	POST/PF	$p_{Shapiro\text{-}Wilk}$	X^2	$p_{Friedmann}$
max knee flex	0.064 ± 0.053	0.062 ± 0.062	0.072 ± 0.047	0.061 ± 0.072	0.001	1.050	0.789
% time of max	0.037 ± 0.025	0.043 ± 0.033	0.037 ± 0.022	0.051 ± 0.046	0.156	1.720	0.632
max dorsiflex	0.352 ± 0.372	0.453 ± 0.451	0.377 ± 0.451	0.403 ± 0.349	0.001	3.750	0.290
% time of max	0.111 ± 0.173	0.101 ± 0.144	0.065 ± 0.074	0.109 ± 0.125	0.001	5.962	0.113
max plantarflex 1	0.541 ± 0.264	0.424 ± 0.349	0.524 ± 0.456	0.521 ± 0.379	0.055	1.350	0.717
% time of pflex 1	0.238 ± 0.137	0.139 ± 0.079	0.267 ± 0.189	0.415 ± 0.353	0.389	1.192	0.755
max pflex 2	1.481 ± 0.469	1.923 ± 0.927	2.119 ± 1.682	2.388 ± 2.317	0.093	1.950	0.583
% time to 2nd pflex	0.038 ± 0.026	0.038 ± 0.039	0.065 ± 0.064	0.070 ± 0.055	0.001	6.342	0.096
max knee moment	0.792 ± 0.599	0.786 ± 0.556	0.521 ± 0.458	0.660 ± 0.492	0.045	6.450	0.092
% time of max	0.794 ± 0.589	0.488 ± 0.514	0.276 ± 0.335	0.407 ± 0.476	0.014	1.709	0.635
max dflex moment	0.137 ± 0.129	0.264 ± 0.524	0.211 ± 0.196	0.471 ± 0.542	0.015	6.750	0.080
% time of max	0.178 ± 0.359	0.070 ± 0.037	0.128 ± 0.129	0.132 ± 0.166	0.314	0.237	0.971
max pflex moment	0.652 ± 0.598	0.691 ± 0.669	0.792 ± 0.776	0.761 ± 0.403	0.022	2.700	0.440
% time of max	0.437 ± 0.556	0.449 ± 0.507	0.440 ± 0.458	0.219 ± 0.320	0.014	2.042	0.564
STP % of cycle	0.041 ± 0.026	0.040 ± 0.042	0.064 ± 0.048	0.055 ± 0.046	0.018	0.150	0.985
step length	0.076 ± 0.078	0.030 ± 0.029	0.073 ± 0.062	0.100 ± 0.070	0.040	7.800	0.050*

Table 5: Group mean and standard deviation of unilateral variability values for isolated gait variables. Variables have been computed for every prosthetic leg and every condition. The majority of the values were not normally distributed over the sample of 12 prosthetic legs evaluated for this analysis. Shapiro-Wilk tests of normality were conducted, and respective p-values are reported (where p<0.05 indicates a violation of the normality assumption). For consistency, all variables were statistically compared by Friedman tests.

Gait variable	PRE/NORM	PRE/PF	POST/NORM	POST/PF	$p_{Shapiro-Wilk}$	X^2	$p_{Friedmann}$
max knee flex (deg)	65.079 ± 5.007	63.782 ± 7.495	66.688 ± 8.878	66.858 ± 8.045	0.021	8.200	0.042*
% time of max	72.333 ± 2.188	74.250 ± 3.019	72.750 ± 2.527	73.083 ± 3.728	0.036	2.235	0.525
max dorsiflex (deg)	15.172 ± 4.408	13.753 ± 4.552	15.418 ± 5.060	16.248 ± 6.248	0.333	5.700	0.127
% time of max	53.333 ± 6.415	53.667 ± 7.165	52.667 ± 7.177	53.833 ± 8.441	0.000	1.473	0.688
max plantarflex 1 (deg)	-7.060 ± 2.795	-8.645 ± 3.451	-8.436 ± 4.526	-7.562 ± 6.020	0.030	2.000	0.572
% time of pflex 1	8.167 ± 1.403	9.917 ± 1.379	8.333 ± 1.969	9.250 ± 3.621	0.187	7.619	0.055
max pflex 2 (deg)	-4.954 ± 9.675	-6.851 ± 9.909	-3.899 ± 9.274	-8.402 ± 18.089	0.012	3.900	0.272
% time to 2nd pflex	68.667 ± 3.257	70.000 ± 3.954	68.000 ± 2.730	71.083 ± 5.712	0.014	1.750	0.626
max knee moment (Nm)	0.966 ± 1.070	0.942 ± 0.989	1.502 ± 1.283	1.424 ± 1.301	0.005	9.000	0.029*
% time of max	41.750 ± 30.221	36.833 ± 23.288	31.917 ± 22.857	35.500 ± 28.315	0.003	4.282	0.233
max dflex moment (Nm)	1.623 ± 0.859	1.096 ± 0.468	0.902 ± 0.614	1.290 ± 1.233	0.000	8.500	0.037*
% time of max	52.083 ± 16.681	48.417 ± 5.744	44.167 ± 10.853	51.250 ± 14.536	0.000	1.964	0.580
max pflex moment (Nm)	-0.406 ± 0.512	-0.228 ± 0.135	-0.298 ± 0.248	-0.164 ± 0.124	0.000	2.500	0.475
% time of max	13.333 ± 17.510	21.083 ± 22.581	21.917 ± 25.486	34.417 ± 37.157	0.000	5.081	0.166
STP % of cycle	64.129 ± 2.285	65.304 ± 2.528	64.327 ± 4.033	64.604 ± 4.623	0.265	1.084	0.781
step length (cm)	70.568 ± 9.682	70.183 ± 8.003	74.816 ± 12.104	69.396 ± 12.117	0.001	1.800	0.615

Table 6: Group mean and standard deviation of unilateral variability values for isolated gait variables. Variables have been computed for the contralateral (sound) leg of all participating unilateral amputees for every condition. The majority of the values were not normally distributed over the sample of 8 sound legs evaluated for this analysis. Pelvis obliquity and pelvis tilt, although not attributable to one leg side or the other are included because these variables were evaluated for the same 8 subject sample of unilateral amputees. Shapiro-Wilk tests of normality were conducted, and respective p-values are reported (where p<0.05 indicates a violation of the normality assumption). For consistency, all variables were statistically compared by Friedman tests.

Gait variable	PRE/NORM	PRE/PF	POST/NORM	POST/PF	$p_{Shapiro-Wilk}$	X^2	$p_{Friedmann}$
max knee flex (deg)	66.692 ± 5.536	63.304 ± 3.803	63.482 ± 3.324	62.952 ± 4.203	0.075	5.100	0.165
% time of max	72.125 ± 1.553	72.625 ± 2.669	72.750 ± 2.053	71.750 ± 2.053	0.155	1.671	0.643
max dorsiflex (deg)	12.412 ± 5.327	11.621 ± 7.079	13.948 ± 6.360	14.441 ± 6.419	0.282	3.000	0.392
% time of max	49.000 ± 7.521	48.875 ± 6.010	50.875 ± 3.182	48.500 ± 4.106	0.001	1.303	0.729
max plantarflex 1 (deg)	-7.110 ± 3.212	-7.145 ± 3.290	-6.505 ± 2.392	-6.199 ± 2.187	0.088	0.450	0.930
% time of pflex 1	9.750 ± 1.389	10.375 ± 1.188	9.250 ± 1.982	8.750 ± 2.053	0.024	1.732	0.630
max pflex 2 (deg)	-11.462 ± 10.606	-12.047 ± 11.846	-11.261 ± 10.810	-9.913 ± 9.980	0.127	1.800	0.615
% time to 2nd pflex	67.500 ± 3.071	68.625 ± 1.598	69.125 ± 4.764	67.875 ± 2.100	0.014	4.027	0.259
max knee moment (Nm)	0.729 ± 0.626	0.725 ± 0.715	0.663 ± 0.521	0.835 ± 0.903	0.005	0.150	0.985
% time of max	27.875 ± 19.172	33.125 ± 21.027	27.250 ± 17.895	31.000 ± 18.974	0.001	3.164	0.367
max dflex moment (Nm)	1.374 ± 0.373	1.326 ± 0.315	1.351 ± 0.472	1.313 ± 0.413	0.360	2.850	0.415
% time of max	49.000 ± 2.390	49.125 ± 2.696	48.625 ± 2.264	47.125 ± 4.257	0.127	1.446	0.695
max pflex moment (Nm)	-0.315 ± 0.151	-0.312 ± 0.151	-0.285 ± 0.146	-0.256 ± 0.176	0.144	0.750	0.861
% time of max	10.500 ± 4.986	10.125 ± 5.617	14.250 ± 19.009	13.250 ± 15.782	0.000	2.015	0.569
STP % of cycle	63.490 ± 2.586	63.374 ± 2.481	62.821 ± 2.533	62.305 ± 1.353	0.021	2.468	0.481
step length (cm)	73.939 ± 6.719	73.348 ± 4.929	75.118 ± 7.380	73.921 ± 7.199	0.000	1.050	0.789
max pelvis obliquity (deg)	2.486 ± 3.820	2.308 ± 4.179	3.372 ± 3.824	3.676 ± 3.478	0.072	7.050	0.070
max pelvis tilt	22.534 ± 11.686	20.592 ± 10.086	20.808 ± 10.580	20.039 ± 10.837	0.282	0.150	0.985

A comparison on individual asymmetry indices is given in figure 8. The respective tables of extracted data are attached in Appendix B. Figure 9 visualizes the averaged asymmetry indices.

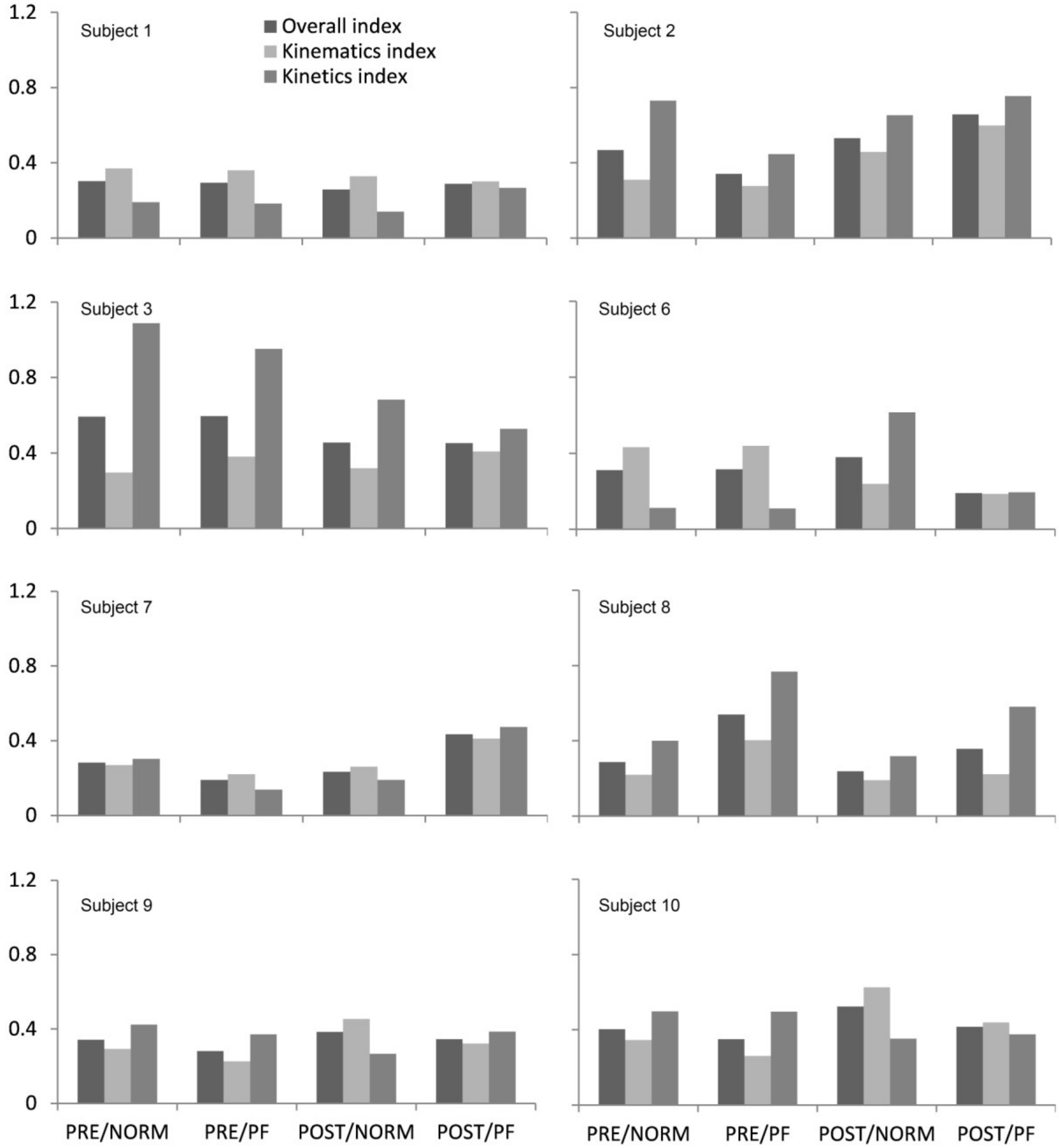

Figure 7: Individual asymmetry indices for all 8 subjects. Perfect bilateral symmetry would be represented by an index value of 0. Indices are comprised of gait variables as defined in table 2. One step per subject and condition was analyzed.

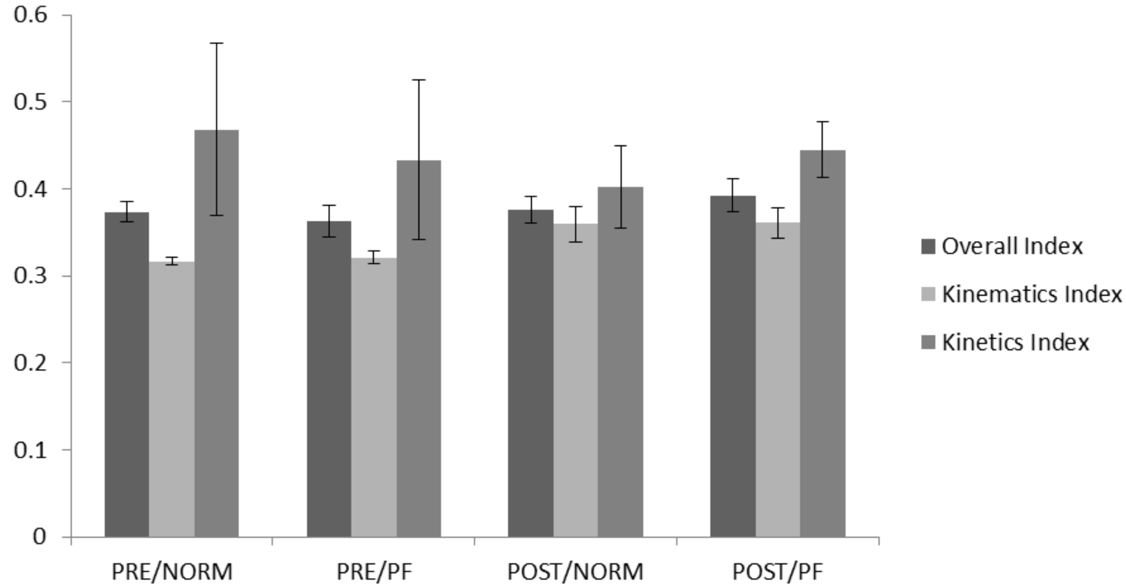

Figure 8: Comparison of asymmetry indices, averaged over all 8 subjects. Perfect bilateral symmetry would be represented by an index value of 0. Indices are comprised of gait variables as defined in table 7. Error bars illustrate the variance over the sample

Main contributor to the bilateral asymmetry in trans-tibial amputee gait were variables related to the ankle angle, with regard to the magnitude and time of the maximal plantar-flexion during the step cycle. Figure 10 shows the respective graphs pertaining to one subject. There is no ankle plantar-flexion in the prosthetic leg during the push-off phase. Instead, the maximal such ankle motion occurs at the beginning of the stance phase where the plantar flexion resembles that of the sound leg. As this curve is represented by two variables (maximal plantar-flexion 1 and maximal plantar-flexion 2), the different timing and magnitude of the absolute maxima of ankle plantar-flexion on prosthesis and sound leg is accounted for.

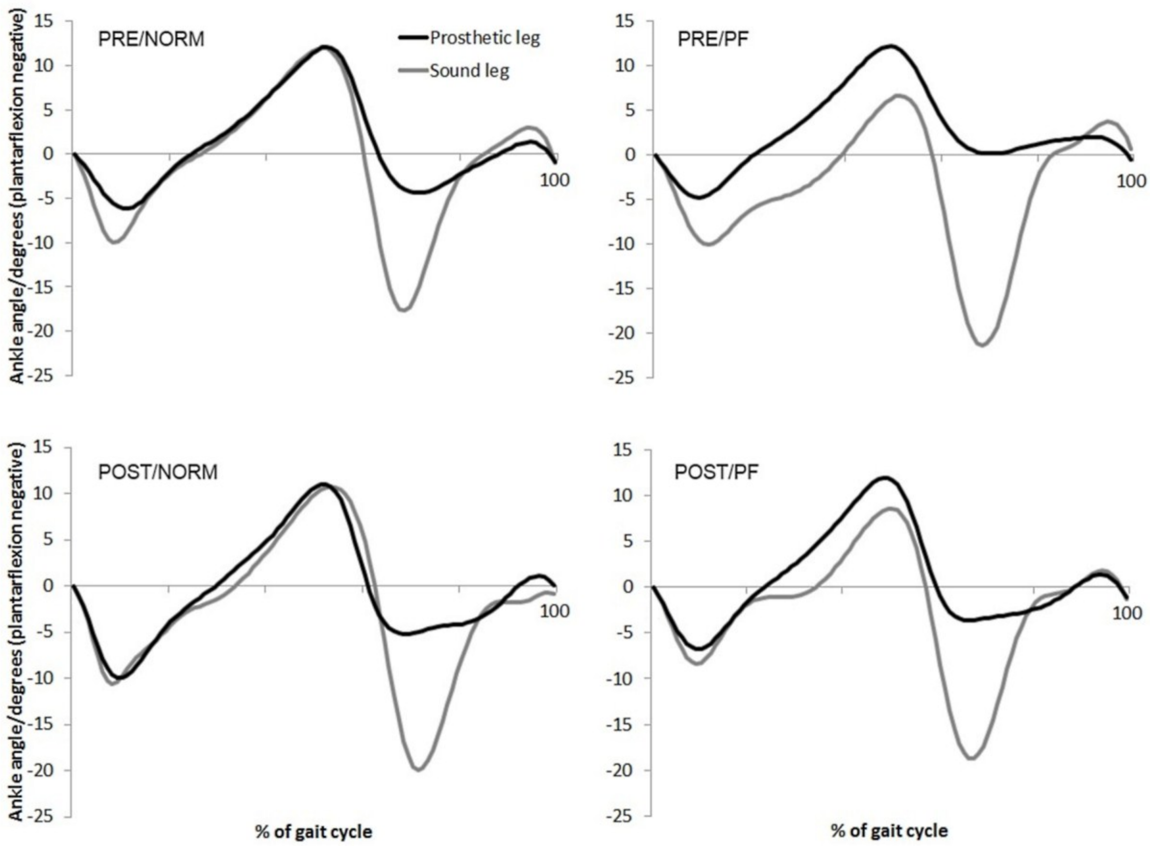

Figure 9: Ankle flexion angle curves for prosthetic and sound leg over one step cycle for one subject (number 8), measured by conventional gait analysis. Steps have been normalized to the step cycle duration and offset values corrected for comparability. To illustrate the 2x2 design matrix, the PRE condition of low exertion is displayed in the top row, POST condition of "strong" exertion below, normal alignment in the left column, altered alignment in the right.

2.4 Discussion

Although the combined indices of bilateral gait symmetry did not indicate any significant effects of the subtle alignment perturbation and the increased exertion on the gait pattern, the individual effects appeared to be considerable. This finding demonstrates how heterogeneous amputee gait responses to the interventions. Considering that individual trends within the sample were not only different in magnitude but even in orientation, it must be discussed whether it is justified to expect many findings that are generally applicable.

Previous studies have found that subtle alignment changes do not significantly affect gait symmetry as measured by an index similar to the one used here (Chow et al., 2006; Sin et al., 2001). While the composition of the indices was slightly different, this previous results were confirmed by our finding that neither the kinematics nor the kinetics symmetry index was significantly affected by the interventions.

It does not explain the found difference in the step length asymmetry. With respect to variables contributing to step length, it has often been reported that no significant effect of alignment perturbation could be identified. That was the case for variables such as walking speed (Beyaert et al., 2008; Burnfield et al., 1999; Chow et al., 2006; Fridman et al., 2003; Sanders, Bell, Okumura, & Dralle, 1998; Schmalz et al., 2002; Van Velzen et al., 2005), cadence (Beyaert et al., 2008; Burnfield et al., 1999; Sanders et al., 1998; Van Velzen et al., 2005), and bilateral ground reaction forces (Beyaert et al., 2008; Chow et al., 2006; Geil & Lay, 2004; Pinzur et al., 1995; Van Velzen et al., 2005). That the data contain no significant differences for the gait kinematics and gait kinetics indices respectively, and barely any for isolated gait variables seems to confirm the findings of previous studies, such as (Chow et al., 2006), who concluded that within the range of acceptable alignments, various gait parameters have differing optima over the continuum of alignment alterations.

While the initial hypothesis, that subtle alignment changes and physical exertion have an effect on amputee gait symmetry had to be rejected, clinical significance can be derived from individual symmetry comparisons (Figure 8). Those showed no consistent trend, but revealed that in some cases the asymmetry increased with the interventions (for instance in subject 2), and decreased in other cases (for instance in subject 3). A comparison of the two subjects may offer an explanation for this unexpected finding: Subject 2 is a young, very active prosthesis user (AAS of 27, Body-Mass-Index (BMI) of 25.3), who participated very diligently in the experimental protocol, raising his heart rate from 65 to 139 beats per minute (BPM) in the process. Subject 3 is 30 years older, less active (AAS of 7, BMI of 33.4), and a slower walker (preferred gait speed 1.13 m/s versus 1.28 m/s). He also appeared to not have exerted himself in the same manner over the course of the experiment, recording a maximal heart rate increase from 71 to 102 BPM. It is likely that different mechanisms were leading to the observed tendencies in symmetry change:

Subject 2 had initially an above-average level of asymmetry in his gait, particularly with respect to kinetics parameters. This may be attributed to a high sensitivity regarding the prosthesis modification, as well as the marker placement, safety harness and other preparations prior to the data collection. Age and activity level, paired with a long history of prosthesis experience make it likely that this subject developed very fine senses regarding slight changes of his artificial limb. After the plantar-flexion was increased, the asymmetry decreased. It is possible that this active patient had a very dynamic alignment to start with, meaning a low roll-over resistance to facilitate extensive and fast walking. The alignment change may have relieved the quadriceps temporarily, by facilitating a higher forefoot resistance, which stabilized the prosthesis in the stance phase and led to a better symmetry between legs. After the exertion protocol, the kinematics asymmetry was higher than before, while the kinetics asymmetry remained below the level of the initial condition. The former may be attributed to the exertion, whereas the latter is likely due to a training effect in walking under the conditions. At the level of strong exertion, the alignment change had the opposite effect on the asymmetry values than it had in the low exertion condition. This time, all asymmetry indices increased, which was much in accordance with the study hypothesis.

Subject 3 too came in with a very high level of bilateral asymmetry, especially regarding kinetic variables. In his case, this is attributed to a relative lack of practice in prosthesis use.

Being an amputee for 2 years at the time of the study, this patient was still in the process of becoming confident with his prosthesis. The fact, that his asymmetry indices declined over the entire session, almost irrespective of intervention, is possibly solely the result of a training effect. The test was conducted in the morning, and it is likely that it was the first time on that day, that this subject walked long distances. As a novice, he would be expected to need a longer accommodation time every time he puts on the prosthesis. In that context, subtle perturbations, such as the 2 degrees of increased plantar-flexion, are likely not to have any impact. The exertion, although perceived as “strong” after the exertion protocol, may in fact not have been all that high if the heart rate increase is any indication. There is no doubt that the subject was becoming tired of walking, but it may have been a different quality of tiredness, and less related to physical exhaustion than for instance in subject 2.

An interesting finding in subject 3, that he shares with subject 1, and to some extent with subjects 6, 9, and 10, was the fact that the kinematics index behaved disproportional to the kinetics index. In subjects 1 and 3, there is almost a constant level of kinematics asymmetry across conditions, while at the same time the kinetic asymmetry varies considerably. In subjects 6 and 8, low kinematic asymmetry is associated with high kinetic asymmetry and vice versa, leading to an almost constant combined index. In subject 10 both indices seem generally unrelated. This suggests the necessity to consider kinetic parameters in clinical practice, as the commonly applied and easily determined criterion of kinematic symmetry is not always indicative of kinematic symmetry.

Only two subjects (2 and 7) showed a sizeable decrease in bilateral symmetry as a result of the combined alignment perturbation and exertion. That the majority of subjects had no such effects was unexpected, based on the hypothesis that assumed that there would be generally a negative effect on gait symmetry when the alignment is made worse, and when the amputee gets too exhausted to activate compensation patterns. Four possible explanations for this unexpected finding are offered:

1) For one, the chosen alignment perturbation was indeed a subtle one, and one that is designed to stabilize the stance phase in the prosthetic leg by facilitating an earlier full foot contact in the step cycle. The undesirable effects of this kind of misalignment are that the initiation of swing phase is encumbered by the higher forefoot moment, that a shorter step length reduces walking speed, and that the ground clearance in the swing phase becomes smaller. In some participants of this study, the positive effects that subjects benefited from seemed to have outweighed those negative effects. In order to provoke a measureable effect, more severe perturbations would be required. However, as soon as perturbations fall out of the range of acceptable alignments, the purpose of the study to identify differences within that range would be abandoned.

2) Furthermore, there is a possibility that our alignment perturbation had not for every subject worsened the alignment after all, but had quite the opposite effect. Both the original and the altered alignment were within the acceptable range of alignments, which makes a distinction in alignment quality by traditional standards impossible. The assumption that the original alignment is the best possible one was based on the fact that this alignment had been the result of dedicated optimization efforts of the respective prosthetists for their patients. Besides, it would be the preferable of the two versions in the light of gait efficiency considerations. As discussed above, an increased plantar-flexion of the prosthetic foot can be understood as a “built-in uphill slope”. It suggests itself to have initial alignments standardized across the sample, in order to assure more homogenous effects. While this would help achieve statistical significance, it would jeopardize the practical relevance, considered that neither sample nor intervention would be representative of given facts in the field.

3) Another factor that might have not played its assumed role was the exertion. Again, the magnitude of the intervention was fairly subtle. Subjects were not entirely tired out to test the respective effect, but they were asked to report their perceived exertion level, and testing was concluded when this level was "strong". Much like the alignment change, there are two possible effects that have to be accounted for here. One is of course the desired physical and mental exhaustion that could lead to a less controlled and energetic gait pattern. The other is a training effect, or at least warming-up effect that could make the gait more fluent and confident. At the "strong" level of exertion, many subjects may have just had reached a state of "looseness" that actually benefited their gait symmetry. It is recommended to amend the protocol in the interest of provoking higher levels of exertion. This raises ethical questions, and increases the list of exclusion criteria, as it is unadvisable to subject some sub-populations to strenuous exertion protocols.

4) A systematic issue with the assessment of exertion may have further affected our measurements. It was fairly obvious that subjects had different ambitions when it came to reporting their exertion level. When the protocol had been explained during the informed consent procedure, it was pointed out that the decision about the cut-off point was to be made by the participant. They knew that this point was supposed to be the RPE level 5, and they were all alike oriented to the nature of the RPE scale. Yet, some of the subjects developed an almost competitive spirit to demonstrate how many repetitions of the walking loop or the stairs they could manage before that threshold was reached, while others were very comfortable with the option to call it a test-day as soon as they had provided a bare minimum of repetitions, and a slightly elevated heart rate to show for it. The testing protocol did not allow for a respective correction of the scores, but it might be worthwhile to account for sincerity of effort in future studies.

Six limitations of this study should be mentioned here, as they are to be kept in mind when interpreting the presented results. They may also inform the design and scope of follow-up studies:

1) The lack of significant findings with respect to the overall gait symmetry index disallows addressing of the sub-hypothesis that the alignment perturbation will have an effect on kinematics parameters only in combination with physical exertion, and that kinetic parameters will be affected immediately. There seems to be a trend, that certain kinematics parameters are indeed affected not by the alignment changes but by exertion. On the kinetics side, the magnitude of the dorsi-flexion moment in the prosthesis appeared to be immediately affected by the alignment change, especially at a low exertion level.

2) Another limitation was identified with the selected method of quantifying gait parameters, which in some cases is not sufficient for the detection of differences. That it may also be of relevance how a parameter curve behaves apart from its maximum and the time to maximum demonstrates the example of an the ankle flexion moment curve in figure 11, which shows the superimposed curves of the ankle moment in the prosthesis for conditions PRE/NORM and PRE/PF for one subject. The maxima, and their times of occurrence are essentially equal, yet the slopes of the ascending component are clearly different. This is likely to signify a practically relevant issue, as the smoothness of the foot rollover motion factors into the efficiency and appearance of amputee gait. The unsteady trajectory of the forefoot moment curve suggests a poor balance on the prosthetic foot, which may be caused by too stiff a foot design, or – as in the context of the here discussed study most likely – a misalignment of the ankle flexion position.

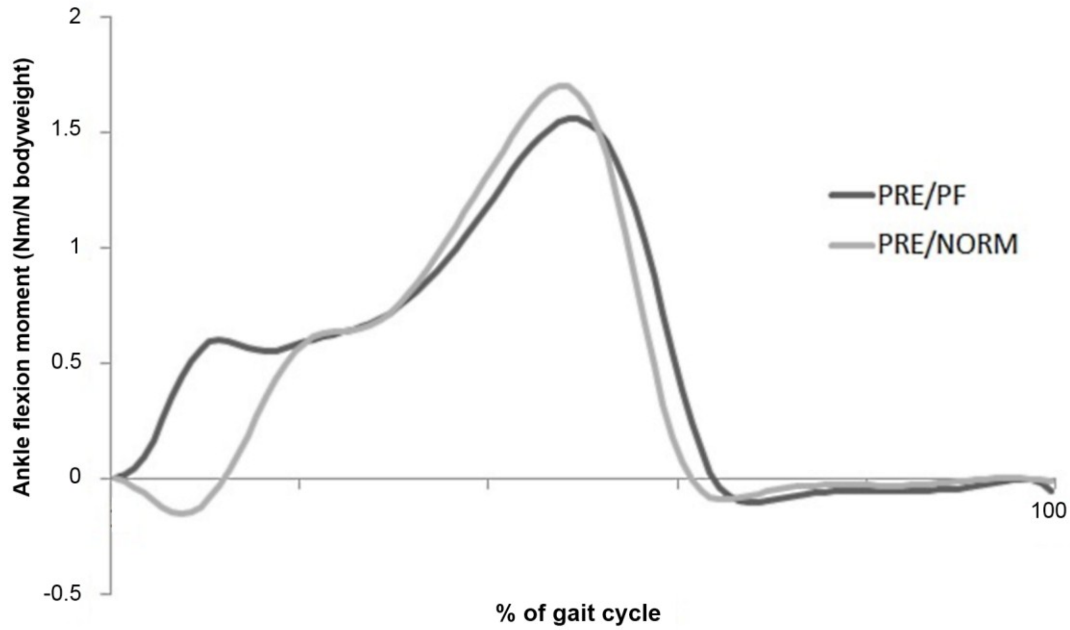

Figure 10: Prosthetic ankle moments measured with normal alignment, and with by two degrees increased plantar-flexion alignment (sample from subject 10). Although maximum, and time of maximum are almost identical, the shape of the curves is not the same.

3) A possible way of accounting for those differences in analysis is the computation of root mean square (RMS) errors between time-normalized parameter curves (see table 7). However, without the possibility of estimating within subject variability (see figure 12) it remains challenging to statistically analyze differences between groups (or repeated measures).

Table 7: Bilateral root mean square deviations of ankle moment curves

	Subject	1	2	3	6	7	8	9	10
Condition	PRE/NORM	0.0871	0.4075	0.2645	0.1066	0.3717	0.0663	0.1426	0.3170
	PRE/PF	0.0673	0.3349	0.3159	0.1026	0.2562	0.2734	0.0877	0.4663
	POST/NORM	0.0838	0.5371	0.2218	0.1484	0.2873	0.1872	0.1891	0.1988
	POST/PF	0.1548	0.5167	0.3187	0.0745	0.5343	0.1864	0.0885	0.3242

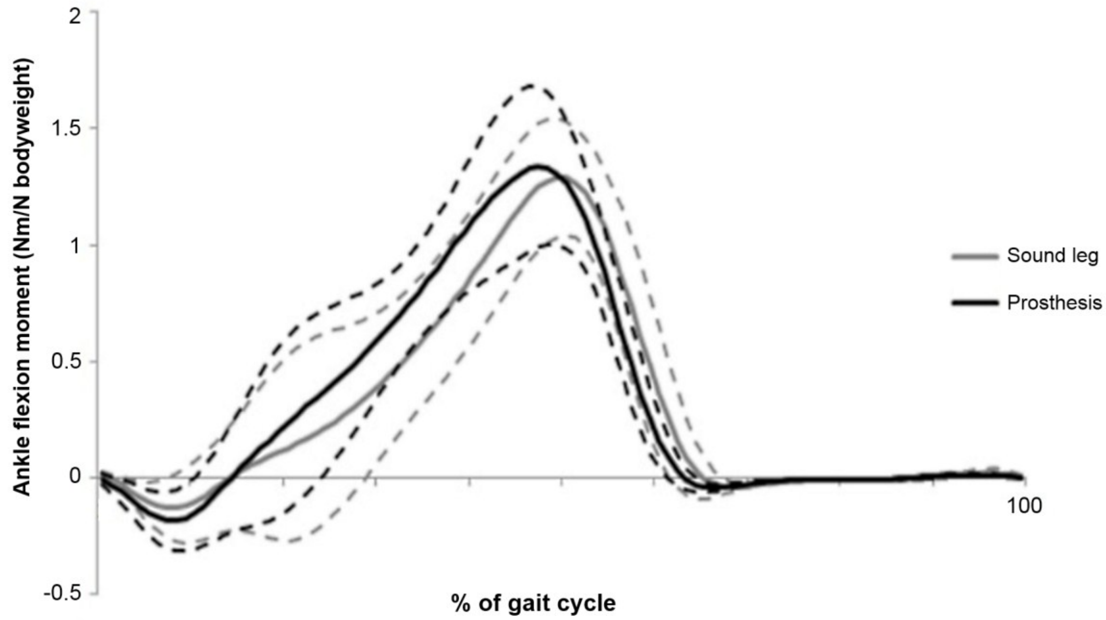

Figure 11: Visualization of bilateral ankle moment differences across all 8 subjects. Dotted lines mark the standard deviation envelope.

The same argument holds true for the previously applied method of extracting comparison variables from the curve shapes, as per subject and intervention only one trial could be included in the statistic. This is an area where the reliance on force plate measurements is a limitation.

4) Other possible limitations of this study design to be mentioned are the accuracy and reliability of the alignment changes, as well as the exertion measurements. Unlike in many previously published studies, the alignment modifications were realized without the subjects taking their prostheses off. While that disallows for a direct measurement of the ankle angle, it eliminates the possible inconsistencies in socket rotation and tissue compression that often come with the process of doffing and donning an artificial limb. Another constraint would have been the time requirement to do that, which would have aggravated another limitation: The exertion measurement had the limitation, aside from the subjectivity of the self-report scale, that there was an inevitable recovery phase in which the respective data collection fell. After the

subject had reported to have reached the desired level of perceived exertion, a few walking trials with normal alignment were recorded, upon which the alignment was changed, and the final walking trials were collected. The alignment change took at least 20 seconds, which for most subjects was enough time to lower their heart rate significantly, and it must be assumed that the actual exertion during the last trials was quite different than the one during the second-to-last trials. Due to the time required for the exertion protocol (as well as the subsequent recovery phase) no randomization of trials was possible.

5) Several questions arise from the inclusion of two bilateral amputees in the study sample. As it is likely that gait symmetry follows different mechanisms when there is not one sound leg to possibly compensate for deficits on the prosthetic side, these two subjects were not included in the respective analysis of bilateral symmetry. For the analysis of within-leg differences however, data from the bilateral amputees were included, following the reasoning that in this repeated-measures design every participant serves as their own control, and that a certain comparability of within-leg parameters is given across unilateral and bilateral amputees. For that it must be assumed that when their prosthesis alignments were modified only one side at a time, the respective other leg will remain a constant that does not interact with the intervention.

6) A similar justification exists for forgoing a homogenization of prosthetic technology and building principles for the purposes of this study. There are a tremendous number of variables that go into the performance capabilities of a prosthesis that it is practically impossible to control for all of them. Instead, it was conceded that different technology works best for different amputees, and it was assumed that the prosthesis they were walking on were built and aligned with that in mind. Again, the longitudinal study design allows the detection of relative differences within subjects irrespective of their initial within-differences.

2.5 Conclusion

It was shown that certain parameters of amputee gait symmetry, most notably step length difference, change with the level of exertion. Subtle alignment perturbations have not an immediate negative effect on step length symmetry but have a significant negative effect in interaction with an increased exertion. The results of this study suggest that various effects of exertion and alignment alteration are of a positive nature in some amputees, where the measured bilateral asymmetry became smaller with increasing exertion. While those cases contradict the initial hypothesis that the amputee gait pattern under real-life conditions would be worse than the one displayed during optimization sessions in the prosthetics lab, it remains a considerable fact that the gait pattern does change with exertion after all. In the clinical field, this could suggest having deliberately time allotted for the amputee to walk on a new prosthesis until being “strongly” exerted, even before the final alignment rectification is attempted. In many instances, this procedure is de-facto followed already, although it is usually involuntary and may be perceived as a nuisance caused by insufficient efforts sides the prosthetist or the amputee during the dedicated alignment session. Our results support the notion that there is good reason for multiple alignment sessions, and that a prosthesis alignment cannot be optimized within one session. It is also suggested to allow amputee’s exertion levels to increase during alignment sessions. Furthermore, kinetics parameters should be considered in the assessment of gait symmetry in amputees, as they are not always proportionally related to kinematics parameters.

The conclusions to be drawn also include the reaffirmed notion that lower limb amputees are too heterogeneous a population to allow very detailed generally applicable standards for prosthetic fit and alignment. Many of the gait parameters investigated for this study followed no consistent patterns across our sample population. This contributed to the lack of statistical significance found in the group differences. Regardless of that, there were difference between interventions that would be significant for the individual subject, which became clear from the verbal feedback that study participants provided. In several cases it was reported – unprompted – how the alignment perturbation changed the perception of the prosthetic function, or how the increasing exertion led to a different utilization of the sound leg during gait.

In the context of this research, it remains to conclude that amputee gait biomechanics need to be considered on an individual basis, and that future work should address the assessment of individual effects of prosthesis alignment changes. Following the latter objective, in the second part of this thesis, the described statistical procedures will be repeated with the data that were collected from the integrated sensors. This allows a consideration of within-trial variability by evaluating a number of consecutive steps, and might help receive more accurate estimations of variance between trials, e.g. intervention.

However, the data that can be obtained from integrated sensors are limited in scope to forces and moments, which reduces the number of parameters to be included in the analysis. Likewise, it is unsure to what extent integrated sensor data are comparable to conventional gait analysis data. In a first step, the concurrent validity of those measurements will therefore be investigated, thereby addressing the second aim of this study.

3 Concurrent validity of trans-tibial amputee gait analysis measures based on prosthesis integrated sensors

3.1 Introduction

Assessing human motion by means of wearable or elsewise attached measuring devices has long been of interest in applications where conventional gait analysis (CGA) methods have considerable limitations, as is for instance the case in outdoor applications. Devices such as wearable goniometers (Gibbs & Asada, 2005; Munro, Campbell, Wallace, & Steele, 2008), arrays of gyroscopes and accelerometers (Liu, Inoue, & Shibata, 2009; Lorincz et al., 2009) and instrumented shoe insoles (Bamberg, Benbasat, Scarborough, Krebs, & Paradiso, 2008; Morris & Paradiso, 2002) have been proposed and used for general activity monitoring (Mathie, Coster, Lovell, & Celler, 2004), classification (Parkka et al., 2006), and gait analysis purposes (Takeda et al., 2009). Many of those applications are also of interest in prosthesis research.

However, many concerns exist around wearable measurement equipment. One issue with such more or less loosely attached devices is their displacement relative to the body joint or other entity of interest, and the corresponding motion artifact. Beyond that, it must be considered that the measured variables are still not entirely congruent with the actual variable of interest, although obtained in close proximity to their origin. In order to, for example, obtain the flexion angle at the knee center of rotation, a computation is required that translates the data from the sensors on the surface of the leg to the knee center, much like the actual joint centers are routinely computed from the tracked location of skin surface markers in their vicinity. There is arguably some inaccuracy in deriving joint kinematics, and even more so, joint kinetics data from external measurements.

Accordingly, various approaches of directly implanting sensors have been reported. Widely noticed series of studies were conducted based on wireless force sensing equipment that had been adapted to be implanted during hip replacement surgery (Bergmann et al., 2001; Hodge et al., 1989). Previously, authors have used measuring devices that were temporarily anchored to the subject's tendons (Dennerlein, Diao, Mote Jr., & Rempel, 1999), inserted between the articulating compartments of the knee joint (Anderson et al., 2003; Harris, Morberg, Bruce, & Walsh, 1999) or have mounted motion capture markers on the bones (Manal, McClay Davis, Galinat, & Stanhope, 2003). Integrated force transducers were also used in animal studies (Holden et al., 1994) and cadaver studies (Rupp, Hopf, Hess, Seil, & Kohn, 1999). These examples illustrate the importance that has been assigned to this kind of data and that is reflected in the extraordinary efforts that are being made to obtain the desired information.

In many instances, the respective measurements were of an own quality, that made it difficult to compare them to conventional methods. This quality, after all, was the motivation for utilizing those new approaches. When, as in (Liu et al., 2009), a novel system was validated with CGA, correlations and root mean square errors were calculated to quantify the accuracy. In other cases, the question was reversed, and the integrated sensor measurements were instead used to validate computer simulations (Li et al., 2011; Papaioannou, Demetropoulos, & King, 2010). Among the most obvious disadvantages of implanted or integrated sensors is their intrusiveness, which makes it challenging to set up ethically justifiable in-vivo studies with human subjects. Essentially, potential subjects can only be patients who for medical reasons are scheduled to have a surgical procedure that happens to allow the implementation of the data collection equipment. This, in turn limits the sample population in that no subjects without prior history of medical problems can be included. Findings that have been derived from data collected by instrumented hip replacement prosthesis are therefore limited in their applicability to the majority of the general population who had not have hip replacement surgery. Other disadvantages are the considerable technical effort that has to go into designing, producing, installing and maintaining a research grade tool that must not interfere with its environment. That is, for instance an instrumented hip prosthesis cannot be less stable or more failure prone than its non-instrumented equivalent.

In amputee gait studies, the implementation of wearable sensors is much more straightforward, as the prosthetic structure that takes over the function of the lost limb is easily accessible and modifiable. Accordingly, there have been a number of instances where dedicated sensors were integrated into artificial legs for the purposes of gait analysis data collection. Most notably are probably the various installments of “intelligent” prostheses, where sensor technology is used to not only analyze the patient’s gait, but to make those analyses the base on which the likewise integrated microprocessor adapts the characteristics of the prosthesis to meet the respective requirements (Bellmann, Schmalz, & Blumentritt, 2010; Kirker, Keymer, Talbot, & Lachmann, 1996; Orendurff et al., 2006). Modern electronically controlled prosthetic knee joints have up to seven integrated sensors, including gyroscopes, goniometers, accelerometers, moment sensors and force cells (Blumentritt, Bellmann, Ludwigs, & Schmalz, 2012). Similar technology is integrated in many of the currently available or developed active ankle components (Au, Berniker, & Herr, 2008; A. Hansen, Gard, Childress, Ruhe, & Williams, 2007). The concept of integrated sensors as a stand-alone component in artificial legs is by comparison less popular, which may be explained with the unfavorable ratio of drawbacks and benefits. Aside from the cost aspect, such sensor units will also have a negative influence on weight, structural stability, and appearance of the prosthesis. Hence, the available sensor data must be considered valuable enough to be able to outweigh the downsides. Against that background, it may be asked which information is indeed that useful. Among the few prosthesis-integrated sensor units currently on the market, some are intended to provide an activity monitoring of sorts, such as the Endolite “Limb Activity Monitor” (Blatchford, 2012), and the

Orthocare “StepWatch Monitor” (Orendurff, Schoen, Bernatz, Segal, & Klute, 2008). Measuring amputee activity levels is an important objective, as this factor informs the prescription of prosthetic components, and may be used as an outcome measure as well. However, the mere assessment of step counts and general activity as measured by accelerometers does not necessarily require prosthesis-integrated sensors. In research studies, the higher accuracy of prosthesis-integrated accelerometer measurements (Ooi, Abu Osman, & Wan Abas, 2010), force transducers (Neumann, Yalamanchili, Brink, & Lee, 2012; Sanders, Miller, Berglund, & Zachariah, 1997), and load cells attached to osseointegrated prosthesis fixations (Frossard, Stevenson, Sullivan, Uden, & Pearcy, 2011) has been used to investigate biomechanical questions beyond simple activity measurement.

Recently, prosthesis integrated tools for the measurement of amputee gait parameters have become commercially available, such as the Orthocare Compass (Boone, 2005) and the College Park iPecs (Leydet, Harrington, Fedel, Link, & Street, 2007). Their intended use as a research tool raises questions on the comparability of the respectively obtained data with conventional gait analysis data. While those systems have been diligently tested with respect to their technical function and inherent measurement accuracy, it remains unclear how their usability in a clinical environment is. In other words: It may safely be assumed that the sensor technology within those systems is matured, that the manufacturer calibrated the systems well, and that on a test stand the accuracy and reliability of readings will justify all reasonable demands. Yet, that does not guarantee an automatic comparability of such obtained gait data with equivalent data that has been collected by other means. The differences in working principle between a conventional force plate and an integrated sensor may lead to unforeseen deviations that are important to be quantified.

In the context of research studies, integrated sensors may be used for the collection of prosthesis kinematics parameters over a large number of consecutive steps. As long as statistical comparisons are to be conducted only between data sets that were obtained by this method, the external validity may be negligible. However, in order to conduct multivariate analyses that include parameters not measurable by the integrated sensors, such as gait kinematics variables, it becomes necessary to evaluate the comparability of both systems. In a typical gait laboratory, the capture volume of the motion analysis system may be large enough to record about four or five complete step cycles, although only a subset of them will involve the force plates (e.g. one step cycle when two force plates are used). If one were to consider now the kinematic data of those five step cycles together with the kinetics measured by the integrated sensor, in order to increase the step sample size, it would be of importance to know how this data compares to the usually discussed force plate data. More generally, if findings that have been obtained by novel methods are to be reported, it must be considered to what extent they are comparable with more traditional methods. The purpose of this study was to validate the measurements of the prosthesis-integrated sensor system “iPecs”, in order to explore the usability of this tool for subsequent research studies.

3.2 Methods

A CGA was conducted with all ten subjects (demographic and anthropometric data are listed in table 1 in the introduction chapter), wearing their respective original prostheses, and walking at a self-selected speed through the capture volume of the motion analysis laboratory (10 camera system (Cortex ®, Motion Analysis Corporation, Santa Rosa, CA, Sampling frequency 100 Hz), with 3 force plates (AMTI, Watertown, MA), Sampling frequency 1000 Hz). A modified Cleveland Clinic marker set was used, comprising of the customary leg and head markers (figure 4), but limiting the number of upper extremity and trunk markers to the three pelvis defining markers over the left and right ASIS, and the Sacrum. The prostheses of all ten participants of this study were equipped with integrated sensors prior to any data collection. To that end, the initial alignment of the doffed prosthesis was documented, the prosthesis was disassembled and the sensor unit temporarily installed between the distal end of the socket and the proximal end of the foot component without changing the overall alignment or length of the prosthesis.

The ipecs sensor was installed in the original prosthesis, and programmed with the respective dimensions of the artificial leg for the online computation of joint moments in ankle and knee joint. To do so, the distance of the sensor's center to the adjacent leg joints was measured with a ruler and input into a respective interface in the sensor software on a laptop PC[5]. As most prosthetic feet do not feature a discrete ankle joint axis, the location of the ankle was estimated from the proportions of the foot, and the height of the malleoli on the contra-lateral leg. The knee axis was likewise approximated from the geometry of the socket, and placed about 2 cm proximal of the patella cutout vertically, and at the 60/40 division of the knee diameter sagittally (Nietert, 2008). (The same method was used for the placement of reflective markers for the motion analysis system.)

Following the marker placement, the sensors were zeroed to eliminate any baseline offset. Using the wireless transmission between sensor and computer, data collection at a sampling rate of 250 Hz was started at the beginning of the experiments, and was continued uninterrupted until the conclusion of all trials. The sampling rate is a compromise of high accuracy and low data volume, and was selected to be easily synchronized to measurement frequencies within the CGA system. The laptop computer had to be carried along when the

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[5] The iPecs software leaves the definition of moment axes to the user. Correctly denoted "proximal moment" and "distal moment" respectively, these variables will in the following be referred to as "knee moment" and "ankle moment" according to the location of the defined moment axes within the prosthesis structure.

subject left the gait laboratory in order to assure continued data streaming. On average, the data collection sessions lasted for about 30 minutes once all the preparations had been completed. A member of the research team was filming the prosthesis during the time of sensor data collection with a digital video camera. The video data was intended as a backup to the time coding information of the integrated sensors, to assure accurate identification of steps that were measured concurrently with force plate and integrated sensor.

For every subject and every of the four intervention, one such step cycle was identified and used for the calculation of concurrent validity of the sensor measurements.

Due to technical difficulties, only data of seven subjects could be used for that purpose (see discussion section). To identify steps on the force plate in the mobile sensor data, the video data was evaluated, using step counts beginning from an easily identifiable situation, such as "standing on both legs", until reaching the force plate (figure 13). In three cases, this method could not be applied, as the necessary walking steps were not clearly captured on video.

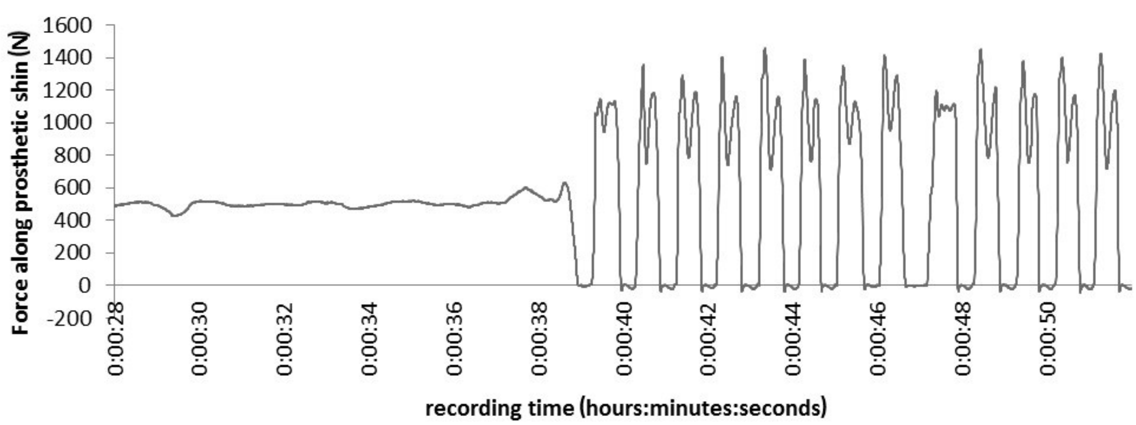

Figure 12: Sample data of the longitudinal force curve that was used to identify step cycles of interest. After standing on both legs for the first ten seconds of this sample, the subject started walking by lifting the prosthesis at about 0:00:39. The corresponding video data shows that the fifth step on the prosthesis side hit the force plate. This step cycle can be found by counting the intervals in the force graph. It is between 0:00:43 and 0:00:44.

Computed variables for each so identified step included the maximal knee flexion moment, ankle flexion moment, times to those maxima, stance phase percentage of stride time, and stride time itself. Collected CGA and iPecs data were normalized to 100 samples per step cycle in order to assure comparability between data sets.

Concurrent validity was estimated by linear correlation analysis in PAWS 19. This method is consistent with that used in previously reported comparable studies, such as (Chesnin, Selby-Silverstein, & Besser, 2000; Cutlip, Mancinelli, Huber, & DiPasquale, 2000; Raffin, Bonnet, & Giraux, 2012). Two different sets of variables were analyzed separately. A linear regression analysis was conducted for all 100 data points of the respective step time normalized curves from iPecs and CGA. Pearson coefficients were then averaged for all samples including one step each per condition and subject. This gave a sample size of 40 (10 subjects, 4 conditions) which was sufficient to achieve the desired statistical power. Secondly, the extracted variables of gait curve peaks and time-to-peaks were compared as well, using linear correlation over all included values.

3.3 Results

Joint moments and forces showed strong correlation between conventional gait analysis and integrated sensor data. In figure 14, the ankle moment as concurrently measured with both systems is plotted for visualization. A linear regression analysis including all 100 data points of either sample resulted in a correlation coefficient R of 0.978, confirming the notion of a high correlation between those measures of ankle moment. The same linear regression analysis was conducted for every of the seven subjects, leading to an overall Pearson coefficient R of 0.887 ($p < 0.001$).

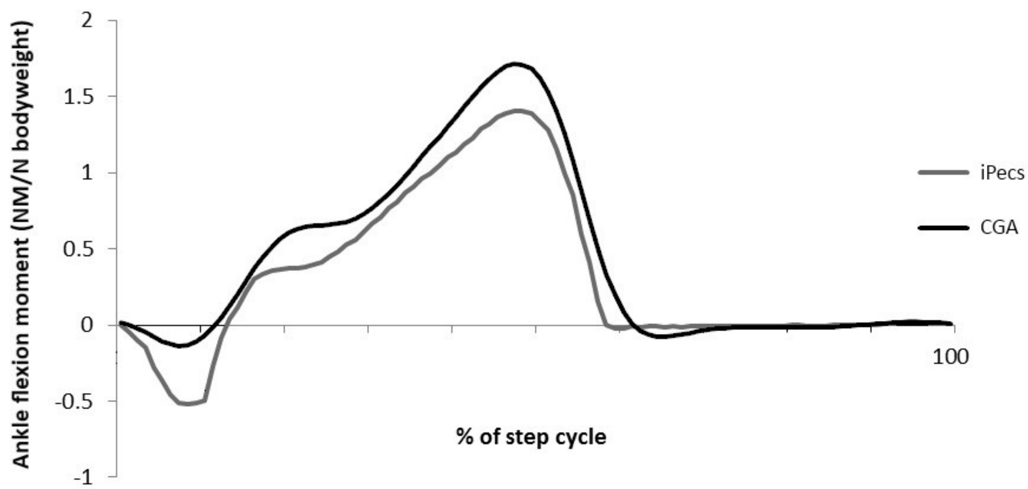

Figure 13: Ankle moment of a sample step, measured by conventional gait analysis (dark line) and prosthesis integrated sensor (light)

Correlation of force measurements was strong as well. Vertical forces measured concurrently by the force plate and the integrated sensors are plotted for one subject in figure 15. The correlation was even stronger than for the ankle moment, with R= 0.936 ($p < 0.001$) for the vertical force.

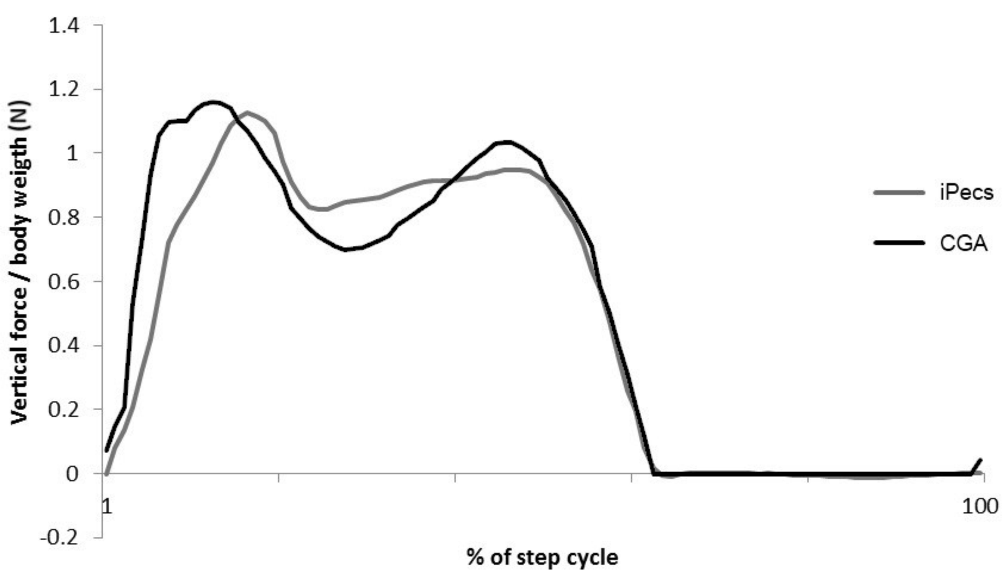

Figure 14: Concurrent measurement of vertical force (e.g. Fz) in the prosthetic leg of Subject 10 during walking with low exertion, increased plantar flexion

For the knee moment, which is calculated similarly to the ankle moment in the ipecs, no separate correlation analysis was conducted. Instead, an observed apparent deviation (figure 16) from the expected curve shape (figure 17) in some samples prompted a validation of the computation algorithm by comparing the results to manually calculated knee moments.

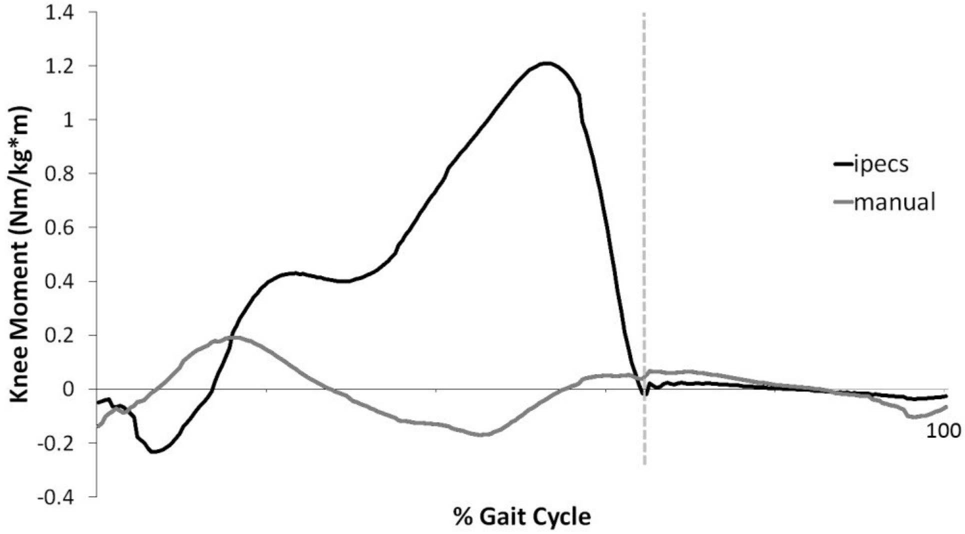

Figure 15: Sample comparison of knee moment curves as computed by the integrated sensor algorithm (light line), and calculated manually (dark line), based on the moments and forces measured at the center of the ipecs, and the vertical distance between the center of the ipecs and the knee axis.

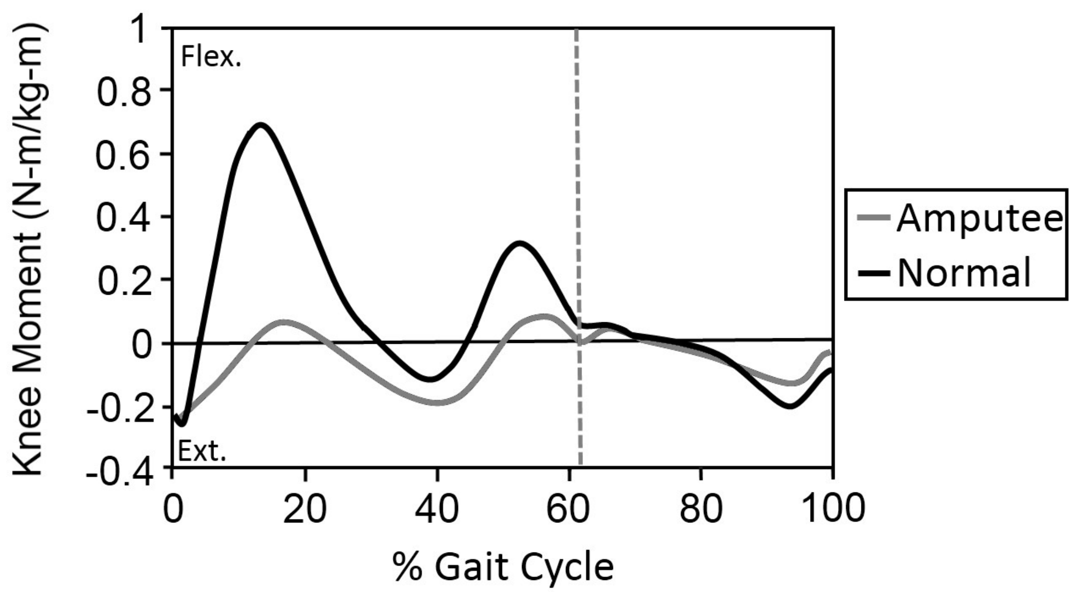

Figure 16: Normal gait knee flexion moment curve (from (Powers, Rao, & Perry, 1998) with permission). The vertical dashed line signifies the transition from stance to swing phase.

A visual comparison of the respective grey curves in figures 16 and 17 confirms that the direct computation of the knee moment based on ipecs raw data delivers a good approximation of the expected curve shape. The Pearson correlation coefficient for the manually calculated proximal knee moment data and the respective data concurrently obtained by CGA in this case was $R = 0.753$ ($p < 0.001$). Given the limitations of this computation method, and the fact that the knee moment as a variable is only of secondary concern in the context of this study, no further analyses pertaining to this variable were conducted.

The reliability of extracting maxima, minima, and occurrence times thereof within the gait cycle was also estimated (table 8). With respect to the ankle moments, those variables were again closely related to those derived from conventional measures. After eliminating two outliers, correlation coefficients were between 0.46 and 0.92 (table 9). Of the analyzed variables, the “% times of maxima” had the weakest correlations, even though the measured occurrence times differed by just 9% of the gait cycle at most. The average difference between measurement methods was 3.64% for the time plantar flexion moment maximum, 2.6% for time of dorsi-flexion moment maximum, and 0.04% for time of vertical force maximum. At stride durations of 1.05 s on average, those percentages translate to deviations of less than 40 ms, which seems acceptable.

Table 8: Extracted values for ankle moment and vertical force between CGA and ipecs data. Table is continued on the next page. Corresponding variables were included in correlation analysis. For a second analysis, two outliers were removed (stroked through: Subject 7 PRE/PF, and subject 10 PRE/PF). Moments and forces were normalized to body weight, to appear unit-less for correlation purposes.

subject	**Condition**	**Conventional Motion Analysis**						**Prosthesis Integrated Sensor**					
		max M_{ankle}	$\%_{max}$	min M_{ankle}	$\%_{min}$	max F_z	$\%_{max}$	max M_{ankle}	$\%_{max}$	min M_{ankle}	$\%_{min}$	max F_z	$\%_{max}$
1	PRE/NORM	1.313	46	-0.252	8	1.038	9	0.111	54	-0.039	9	1.079	10
	PRE/PF	1.259	49	-0.282	10	0.977	12	0.107	51	-0.035	10	1.006	12
	POST/NORM	1.169	48	-0.311	8	0.955	48	0.109	50	-0.030	9	0.982	48
	POST/PF	1.254	46	-0.246	8	0.941	47	0.110	48	-0.033	9	1.001	48
2	PRE/NORM	1.426	48	-0.095	6	1.018	19	0.128	50	-0.020	8	0.980	18
	PRE/PF	1.442	48	-0.109	8	1.026	19	0.122	52	-0.021	8	0.937	18
	POST/NORM	1.399	46	-0.090	5	1.131	16	0.129	49	-0.023	6	1.042	15
	POST/PF	1.156	46	-0.093	4	0.976	10	0.128	50	-0.022	9	0.970	19
3	PRE/NORM	0.877	49	-0.291	8	0.982	32	0.080	54	-0.027	11	1.048	24
	PRE/PF	0.995	49	-0.292	7	0.988	38	0.080	53	-0.023	3	1.096	16
	POST/NORM	0.952	52	-0.262	8	1.000	22	0.079	56	-0.023	13	1.069	25
	POST/PF	0.833	49	-0.252	8	1.069	22	0.078	54	-0.033	10	1.085	22
7	PRE/NORM	1.744	45	-0.412	10	1.091	45	0.155	50	-0.061	15	1.103	48
	PRE/PF	~~1.645~~	~~47~~	~~-0.433~~	~~9~~	~~1.112~~	~~16~~	~~0.073~~	~~27~~	~~-0.054~~	~~47~~	~~0.959~~	~~32~~
	POST/NORM	1.693	47	-0.512	9	1.037	47	0.146	47	-0.073	14	1.052	46
	POST/PF	1.651	47	-0.519	9	1.015	44	0.138	52	-0.058	12	1.046	22

subject	Condition	Conventional Motion Analysis						Prosthesis Integrated Sensor					
		max M_{ankle}	$\%_{max}$	min M_{ankle}	$\%_{min}$	max F_z	$\%_{max}$	max M_{ankle}	$\%_{max}$	min M_{ankle}	$\%_{min}$	max F_z	$\%_{max}$
8	PRE/NORM	1.516	47	-0.097	6	1.156	18	0.116	46	-0.031	6	1.134	15
	PRE/PF	1.448	45	-0.068	4	1.112	16	0.120	50	-0.036	9	1.148	16
	POST/NORM	1.367	47	-0.243	7	1.136	17	0.123	46	-0.045	9	1.144	16
	POST/PF	1.394	45	-0.139	6	1.174	15	0.120	47	-0.035	7	1.141	15
9	PRE/NORM	1.369	49	-0.246	9	1.069	17	0.123	53	-0.043	12	1.117	20
	PRE/PF	1.371	47	-0.210	9	1.259	12	0.119	51	-0.053	11	1.174	14
	POST/NORM	1.359	46	-0.332	7	1.200	13	0.124	54	-0.057	13	1.333	16
	POST/PF	1.314	47	-0.213	6	1.147	15	0.126	54	-0.044	13	1.198	18
10	PRE/NORM	1.715	47	-0.136	7	1.171	17	0.140	50	-0.052	10	1.204	14
	PRE/PF	~~1.596~~	~~48~~	~~-0.066~~	~~67~~	~~1.159~~	~~13~~	~~0.120~~	~~51~~	~~-0.046~~	~~9~~	~~1.128~~	~~17~~
	POST/NORM	1.674	45	-0.390	4	1.166	16	0.138	51	-0.073	7	1.294	8
	POST/PF	1.679	46	-0.269	6	1.170	15	0.135	54	-0.064	8	1.206	15

Table 9: Correlation coefficient R for CGA and ipecs

	max M_{ankle}	**$\%_{max}$**	**min M_{ankle}**	**$\%_{min}$**	**max F_z**	**$\%_{max}$**
all 7 subjects, 4 conditions	0.900814	0.444984	0.639149	0.016421	0.8186	0.958319
without trial 7/2 and 10/2	0.922775	0.461602	0.66005	0.535888	0.80863	0.851608

The used iPecs unit displayed inconsistencies with respect to the actual sampling frequency. That had been set to 250 Hz, but turned out to considerably deviate from that value. Comparison with video data suggests actual sampling rates between 172 and 250 Hz (table 10 and figure 17). The accuracy of the digital video camera that delivered the reference time base was subsequently tested by recording a clock for one hour, and comparing video time and clock time every 10 minutes. Deviations were below the detectable threshold of 1 second.

Table 10: Sampling frequency deviations, as observed in one data collection file. During the roughly 20 minutes of continuous data collection, several events occurred that allowed synchronization of the video and ipecs clocks (Standing, sitting, stair climbing, all leaves a typical pattern in the vertical force curve).

Video time/s	ipecs time/s	Gap/s	Expected frame count at 250 Hz	Actual frame count	Instantaneous frequency/Hz
28	28	0	7000	7000	250
42	39	3	10500	9750	196
123	110	13	30750	27500	219
188	165	23	47000	41250	212
239	200	39	59750	50000	172
367	299	68	91750	74750	193
516	419	97	129000	104750	201
611	508	103	152750	127000	234
715	603	112	178750	150750	228
750	637	113	187500	159250	243
837	718	119	209250	179500	233
897	770	127	224250	192500	217
1015	878	137	253750	219500	229
1110	960	150	277500	240000	216
1147	997	150	286750	249250	250
1192	1040	152	298000	260000	239

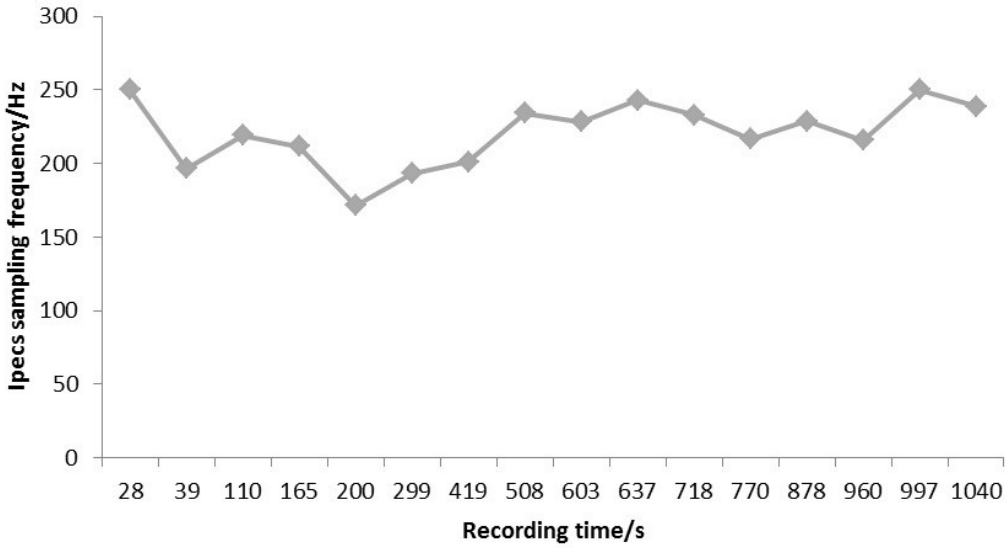

Figure 17: Graphical representation of changes in sampling frequency over the course of a continuous recording with the ipecs sensor

3.4 Discussion

Validity of the prosthesis-integrated measurement of kinetic variables is given for both the ground reaction force and ankle moment, which represent a close approximation of respective variables obtained from CGA. The proximal moment, if it is to be interpreted as knee moment, is best computed directly from the data measured at the center of the ipecs. Parameters that are based on time measurement could not be sufficiently determined, as the sampling frequency of the integrated sensor was subject to irregular fluctuations.

No previous peer-reviewed literature on the concurrent validity of the iPecs unit could be found. The manufacturer reports an accuracy of 1 to 1.5% and a non-linearity of less than 0.5% (CPI, 2011), although this refers to the actual measured forces and moments and likely not to the sampling frequency. Statements from (Papaioannou & Wood, 2011), as well as unpublished works (Dang, 2010; LeGare, 2009) give no indication of considerable problems with the reliability or validity of the data.

In validating ipecs measurements by correlating them to concurrent CGA measurements, a prerequisite for future use of the device in research and clinical practice is provided. This study showed that the results of integrated sensor measurements are comparable to conventional methods, but not entirely identical. While integrated sensors offer the advantage of continuous and direct capturing of kinetics parameters of prosthesis gait, it is important to carefully consider the systematic differences between CGA and for instance the ipecs device.

One such aspect is the different definition of the coordinate system within which vectors are described. Unlike gait laboratory coordinate systems that are generally aligned with the force plates, and thus fixed in space, the ipecs coordinate system originates at the center of the sensor unit, and moves with it. Only for the short instances in the gait cycle when both coordinate systems align, represent the respective F_z - vectors the same actual force. Irrespective of that, ipecs ankle moment and longitudinal force, although not to be used synonymously with ankle moment and vertical force measured by conventional methods, hold significant information on gait parameters, such as bilateral weight distribution, foot placement, and utilization of energy-storing-and-return capabilities of the component. It might even be argued, that the longitudinal force is of higher practical relevance than the vertical force that is reported with respect to a global coordinate system. When it, for instance, comes to estimating impact forces on the residual limb or on prosthetic components, it seems more appropriate to measure these variables directly, than deriving them cumbersomely from externally measured force and kinematics data. The appropriateness of describing joint moments and forces in different reference frames, even if that means that "…they represent subtly different biomechanical quantities" has been discussed before (Schache & Baker, 2007).

Explanations for discrepancies between measurements from CGA methods and those performed by integrated sensor equipment, with respect to joint moments, may be found in the different approaches and the respectively available database. Within the integrated sensor, joint moments are computed based on strain gauges measuring the bending moment at the center of the sensor unit, which is located in a known position between the axes of the adjacent joints of ankle and knee. Therefore, the information is limited to dimensions and internal moments of the shank segment. Segment mass and the inertial axes and angular velocity of the joints are not factored into the computation of the joint moments by the ipecs software, which leaves the so described quantity somewhat different from the conventionally calculated variable.

One interesting application of the ipecs “knee moment” measure could be the investigation of the swing phase in amputee gait, where the measured bending moment in the shank could clearly be attributed to the actual knee moment, which so could be measured accurately and directly. Interesting here is that, aside from being of comparably small magnitude, the knee moment in the swing phase has widely not been discussed as a variable of interest in amputee rehabilitation research. Open questions, such as on the muscle force employed during swing phase knee flexion and extension, cannot be answered by merely considering force plate data. A common method in able bodied research is the computer simulation of muscle forces (Piazza & Delp, 1996), often in combination with or addition to measurements of muscle activity, joint angle acceleration and angle velocity (Nene, Mayagoitia, & Veltink, 1999).

Several important limitations were noted while conducting this study:

1) The observed issue with the sampling frequency could not be anticipated, and caused thereby a reduction of the available sample size for analysis. The synchronization of mobile sensor and force plate data was supposed to be realized by maintaining a common time base. Both the Motion Analysis .cap file and the ipecs streaming file have a time stamp, which should make it easy to find representations of the same step in both systems. As the gait data can be

fragmented into discrete step cycles, a time resolution of about 1 second would be good enough for this method to work. The eventual accurate synchronization could then be based on the event of heel contact that leaves a clearly identifiable signature in both data sets. Due to the deviations in sampling frequency, it was impossible to apply this method, and the back-up method of analyzing video data had to be employed.

2) The choice of quantifying concurrent validity by calculating correlation coefficients between gait analysis curves discounts the possibility of a linear offset or factorial error from one measurement method to the other. Also, after time-normalizing steps for comparison, an important component of the data quality has already been corrected. Nonetheless, the issues relating to timing discrepancies were detected beforehand, and disallowed a direct comparison of step durations and other time-related variables between measurement methods.

3) Only one iPecs unit was used in this study. It could not be investigated whether the observed sampling fluctuation is the consequence of a malfunction of this particular unit. A detection of the sampling aberration earlier in the process would have prompted a timely replacement of the unit, and may have helped collect better data. The unit has been returned to the manufacturer, where the erroneous measurement could not yet be replicated. Further research is necessary to identify the origin of the observed frequency instabilities.

4) The integrated sensor was only used in wireless transmission mode. A radio frequency transmitter is included in the mobile unit that streams data to a receiver unit that is connected to the computer. Possibly, this wireless transmission was a factor in the observed sampling frequency fluctuations. There is a second operation mode in which data is stored on a micro-SD card within the mobile sensor unit. Using this option may have prevented the described problems, and is recommended for a follow-up study.

3.5 Conclusion

Despite some limitations, this method of prosthesis integrated gait data collection offers a quality of data that is not attainable by conventional methods. When restricted to the variables that have been shown to be valid, the integrated sensor measurements can be used to compare consecutive steps within the prosthetic leg, which is of scientific relevance in several ways. Firstly, the step-by-step variability can be interpreted as an indicator of gait stability. Since the sample size is much larger than in conventional force plate experiments, it can be expected that findings have a better accuracy and clinical significance. Secondly, the variance within a step sample can be used to compute variances between experimental interventions, which in turn would be useful for small-sample or even single-subject studies of prosthetic components, designs, or alignments.

The gait kinetics measurements with the Ipecs “mobile gait lab” are different than expected, as the measured variables have either no close equivalent in conventional gait analysis (which is the case for the “proximal moment”), or the respective equivalent variable is measured in a different (static) reference frame and therefore not continuously synchronous with the variable described in the local reference system of the prosthesis-integrated sensor unit (such as the “ankle flexion moment” and “vertical ground reaction force”). In some applications, consistency of the sampling frequency will be a concern. Storing data within the sensor unit is recommended in order to be able to base time calculations and time derivatives of measurement variables on this information.

Below, the application of integrated sensor measurements will be discussed in the third manuscript of this series.

4 Amputee step variance within and between conditions of different exertion levels and alignment perturbations in a single-subject study design

4.1 Introduction

A commonly encountered challenge in amputee gait studies is the small sample size (Neumann, 2009), leading to results of questionable statistical and practical significance. Beyond being comparably small, the amputee population is also widely heterogeneous (Highsmith, Schulz, Hart-Hughes, Latlief, & Phillips, 2010; Pasquina et al., 2008; Rogers, MacBride, Whylie, & Freeman, 1977-1978). The length of the residual limb can exemplify this. Depending on individual given facts, diagnosis and surgical technique, a trans-tibial amputation level may be anywhere within the diaphysis of the tibia bone. Obviously, limb length is an important factor in the biomechanics of prosthesis interface and control. Therefore, two trans-tibial amputees can be difficult to compare if they happen to have different residual limb lengths. This motivates the design of repeated measures studies, where subjects serve as their own controls.

In the previous research literature, such longitudinal study design has often been used for the investigation of long-term effects in leg amputees, ranging from the stability of phantom limb phenomena (J. Hunter, Katz, & Davis, 2008) over the improvement of weight bearing and walking velocity (Jones, Bashford, & Bliokas, 2001) to the 6-month survival rate based on physical independence (Stineman et al., 2009). While especially such studies that are based on comparably easy to obtain data from questionnaires or hospital records may have sample sizes in the hundreds or even thousands, it is much more challenging to recruit a sufficient number of subjects for more elaborate intervention studies. Accordingly, there is an uncountable number of case studies, only a few of which shall be referenced here, that for instance are trying to address the effects of experimental surgical procedures (Kuiken et al., 2007; Yoho, Wilson, Gerres, & Freschi, 2008), socket designs (Kahle, 2002; Mitchell & Versluis, 1990; Söderberg, Ryd, & Persson, 2003), prosthetic components (Highsmith, Kahle, et al., 2010; Stevens & Carson, 2007), weight loss (Sanders, Fergason, Zachariah, & Jacobsen, 2002), and even alignment interventions (Andres & Stimmel, 1990; Jia et al., 2008). The viability of single-subject studies has been discussed by (Bates, 1996), who argued that the assumptions of normality and independence are justified even in cases where samples are taken from the same subjects. He also advises "to combine group and SS [single-subject] designs to gain additional insight about the problem(s) of interest when the research question is appropriate."(Bates, 1996)

In this light, the here discussed study compared the effects of subtle alignment perturbations and physical exertion on gait parameters within trans-tibial amputees. Prosthesis-integrated sensors were used for data collection, as they – within the range of their limitations - can help assess the variance of amputee gait, and can thus provide a basis for statistical interpretation of differences between experimental interventions. While conventional gait analysis is arguably the gold standard of investigating gait biomechanics, it is a limitation of this method that subjects have to walk through the capture volume, and over the force plates. Even in the ideal case that subjects hit the force plates cleanly every time, the number of repetitions, and therefore the number of steps that can be sampled is limited by the available time, as well as the endurance of the subjects. In amputee populations, both the issue of hitting the force plates and the problem of limited physical capacity are even more pronounced, which may lead to the circumstance that only one valid trial per subject has to be deemed sufficient for the conventional data collection (as was the case in the study described in chapter 2). Neither a desirable averaging of steps, nor an estimation of step variance is possible that way.

The purpose of this study was to compare the experimental conditions by using within subject step-variance in variables such as "peak moments" and "peak forces", "times to peak", and “overall curve variability” as a factor for the ANOVA. Research hypothesis was that subtle alignment changes of the prosthetic ankle within the acceptable range of alignments have a greater effect on step variance when the subject is walking at a “strong” level of physical exertion as opposed to a low level of physical exertion. Furthermore, it was hypothesized that those effects would increase linearly with the exertion.

4.2 Methods

Ten subjects (demographic and anthropometric data are listed in table 1 in the introduction chapter), wearing their respective original prostheses, modified by the temporary installation of an iPecs mobile gait lab (College Park Industries, Fraser, MI) performed walking trials under four different experimental conditions: 1) low exertion, normal alignment (PRE/NORM), 2) Low exertion, two degrees increased ankle plantar-flexion (PRE/PF), 3) “Strong” exertion, normal alignment (POST/NORM), and 4) “Strong” exertion, two degrees increased ankle plantar-flexion (POST/PF). IPecs data of internal tri-axial prosthesis forces and moments were recorded at a sampling rate of 250 Hz continuously during the data collection sessions, and wirelessly transmitted to a laptop computer, thus making a multitude of step cycles available for statistical evaluation. Subjects were walking for a minimum of 10 steps in the conditions that included alignment perturbation of the prosthesis (once rested, once with “strong” exertion), and for even more steps on their originally aligned prosthesis (starting with low exertion, and until a level of “strong” exertion was reached). Walking speeds were self-selected on a looped path that included uneven surfaces, slopes and stairs. For evaluation purposes, samples of 10 level-ground-steps per subject and condition were extracted and processed.

In a first post-processing step, step duration was measured, based on the sample count between heel contact events. Then step lengths were normalized to 100 samples per step cycle. Vertical force and ankle moments were averaged across all 10 sampled steps for every percentile of the step duration and were plotted. Standard deviations between steps were computed in the same manner. Eventually, measuring variables such as ankle flexion moment maxima and minima, time of maxima, longitudinal force maximum, and time of maximum were extracted from the curves and used for repeated measures ANOVA of the four experimental conditions.

The so computed within group variance was applied into the equation for the F-statistic (F= between-group variability/within-group variability), in an attempt to estimate the significance of the previously observed RMS deviations in gait analysis graphs of different experimental interventions. Respective computations were conducted using the algorithm for Multivariate ANOVA in PAWS. For that, values at every percentile of the step cycle were treated as a separate variable, in an extension of the previously applied concept of extracting discrete point data from curve peaks only. In post-hoc tests, multivariate differences between groups were computed as well. As MANOVA does not account for repeated measures, six such group pairings had to be evaluated for every subject. No adjustment for multiple comparisons was applied. Figure 19 illustrates the data extraction and statistical methods applied.

The averages and standard deviations of force and ankle moment measures over 10 time-normalized steps were regarded for every subject separately for the computation of F-statistics. A sample is illustrated in figures 20 and 21, where ankle flexion moment curves for subject 6 are displayed for all four experimental conditions.

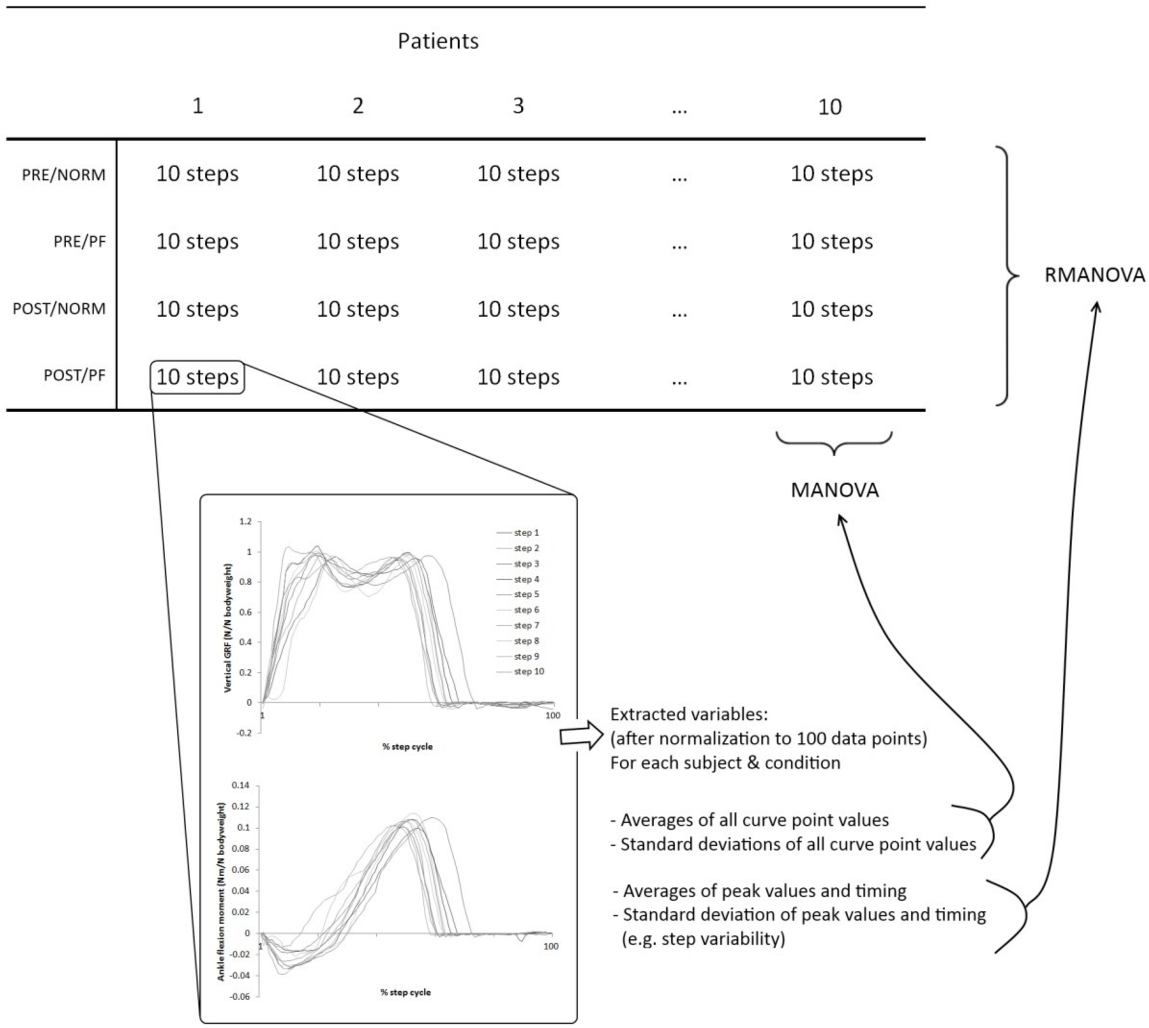

Figure 18: Illustration of statistical analyses conducted for this study.

4.3 Results

Data from eight subjects were included in the analysis. Subjects 4 and 5 as bilateral amputees could not be properly categorized with respect to the prosthetic alignment intervention, and were excluded.

Computed effect sizes and p-values for the selected variables over the four experimental conditions, as resulting from the RMANOVA are listed in table 11.

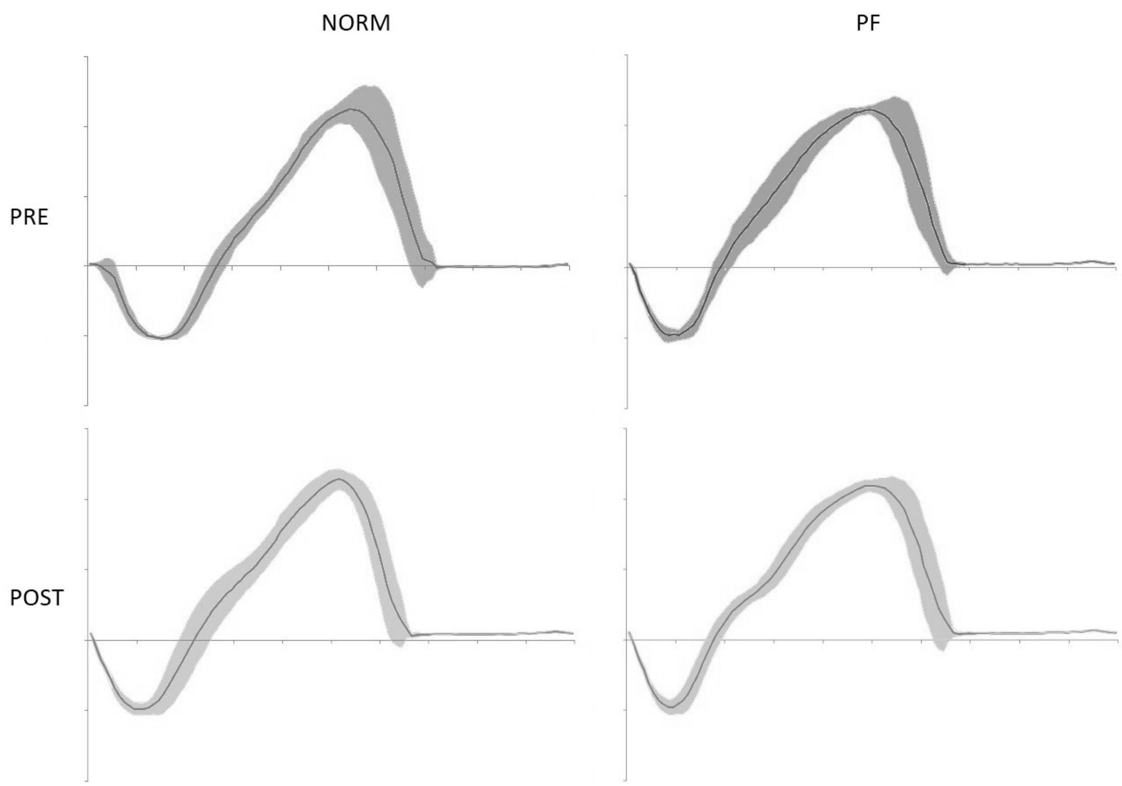

Figure 19: Graphical representation of ankle flexion moments in one subject. 10 steps of each condition have been time normalized to compute averages and standard deviations at every point in time. The solid line in any one curve represents the average, and the lighter area above and below the standard deviation. NORM stands for normal alignment, PF for increased plantar-flexion. PRE denotes the low exertion level, POST the strong exertion level

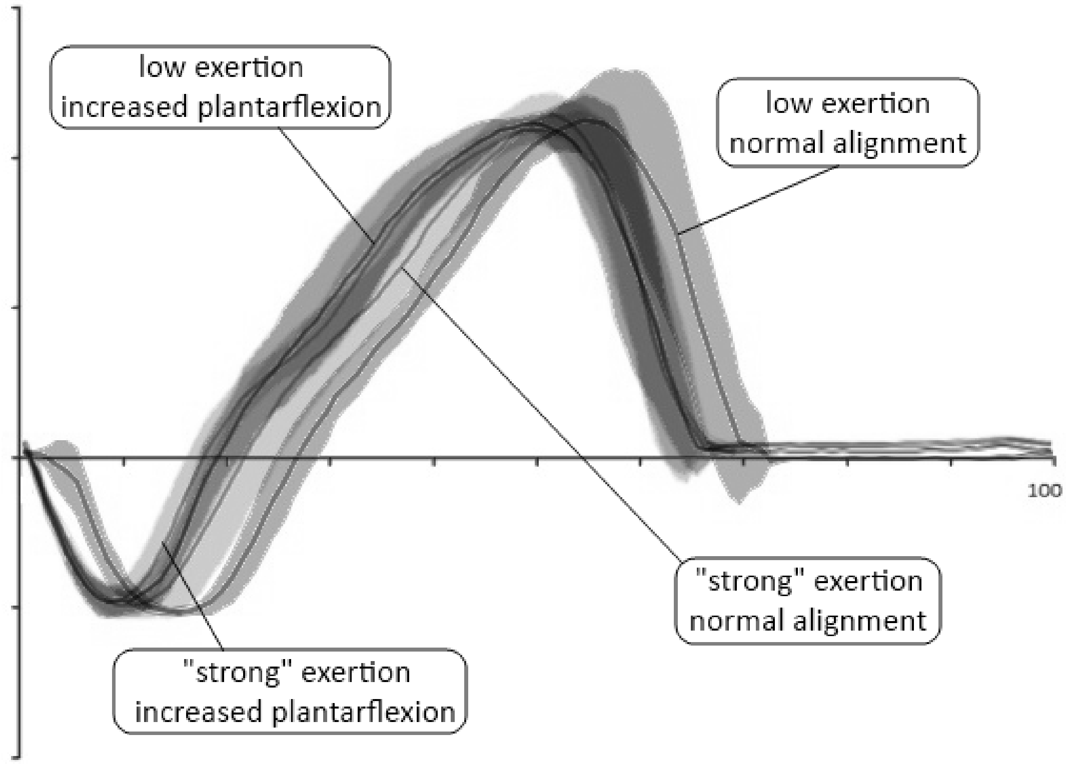

Figure 20: Superposition of the ankle moment curves from figure 20.

Table 11: Effects of exertion and increased plantar flexion on amputee gait parameters based on integrated sensor data. (*) denotes significance at the .05 level. Moments and forces are normalized to body weight.

Variable	**p-value**			η_p^2		
	Increased exertion	Increased plantar flexion	Increased exertion & plantar flexion	Increased exertion	Increased plantar flexion	Increased exertion & plantar flexion
Minimal M_{ankle} (=plantar-flexion moment) (Nm/N)	0.402	0.340	0.682	0.102	0.130	0.025
% time of min Mankle	0.307	0.008*	0.088	0.148	0.655	0.360
Stdev. of min M_{ankle} (Nm/N)	0.887	0.208	0.312	0.003	0.216	0.145
Maximal M_{ankle} (= dorsi-flexion moment) (Nm/N)	0.703	0.126	0.273	0.022	0.301	0.168
% time of max M_{ankle}	1.000	<.001*	0.026*	0.000	0.851	0.529
Stdev. of max M_{ankle} (Nm/N)	0.449	0.164	0.083	0.084	0.257	0.368
Maximal longitudinal shin force F_z (N/N)	0.431	0.393	0.135	0.091	0.106	0.290
% time of max F_z	0.061	0.002*	0.028*	0.415	0.765	0.523
Stdev. of max F_z (N/N)	0.511	0.447	0.350	0.064	0.085	0.125

F-statistics were computed for every subject separately. With respect to the variable ankle flexion moment, only one, subject 6, had statistically significant differences between experimental conditions, $F(108,3.9)=8.462$, $p=0.026$. In the longitudinal shin force several subjects had significant differences across conditions: Subject 6 ($F(108,3.9)=51.010$, $p=0.001$), subject 7 ($F(108,3.9)=5.904$, $p=0.049$), and subject 8 ($F(108,3.9)=10.852$, $p=0.017$). Pairwise post-hoc comparisons showed that the main differences were in two cases between the conditions PRE/PF and POST/PF (subject 6 and 8), and in one case between PRE/NORM and POST/NORM (subject 7). The respective plots in figures 22-25 show the nature of the differences.

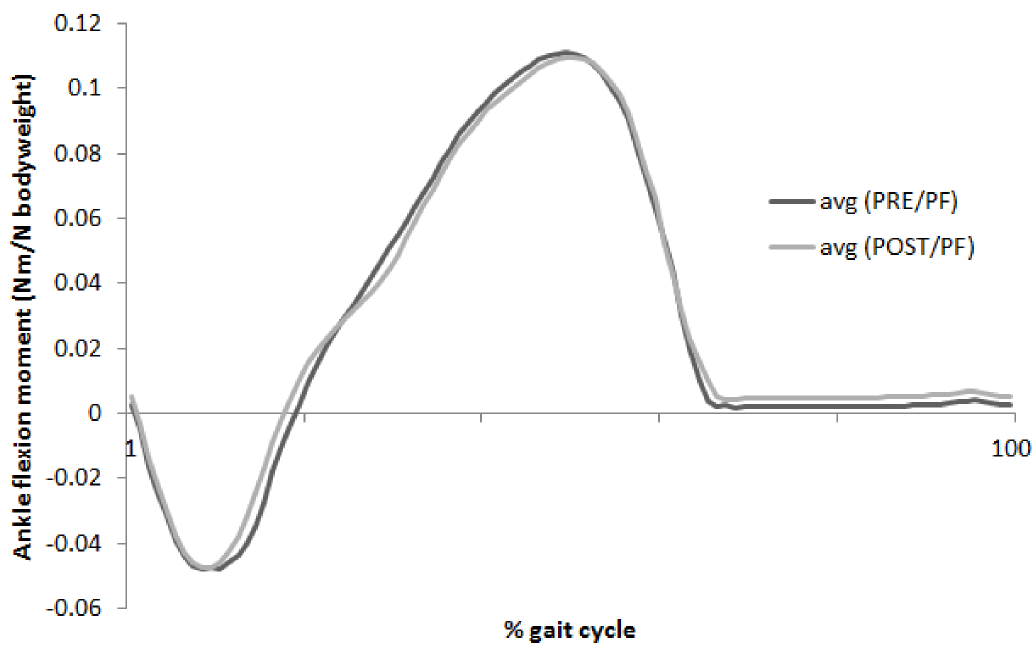

Figure 21: Ankle moment comparison in subject 6. Averages of 10 steps with the misaligned prosthesis are plotted, once before the exertion protocol, and once after.

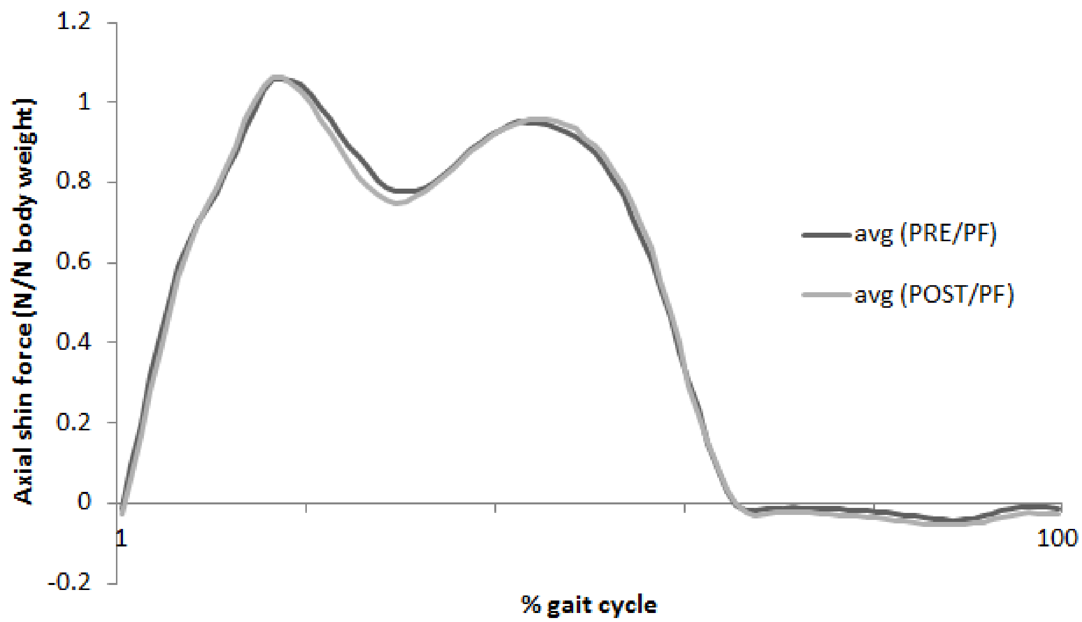

Figure 22: Longitudinal shin force in subject 6, compared between conditions PRE/PF and POST/PF. 10 steps each were normalized to 100 samples and averaged.

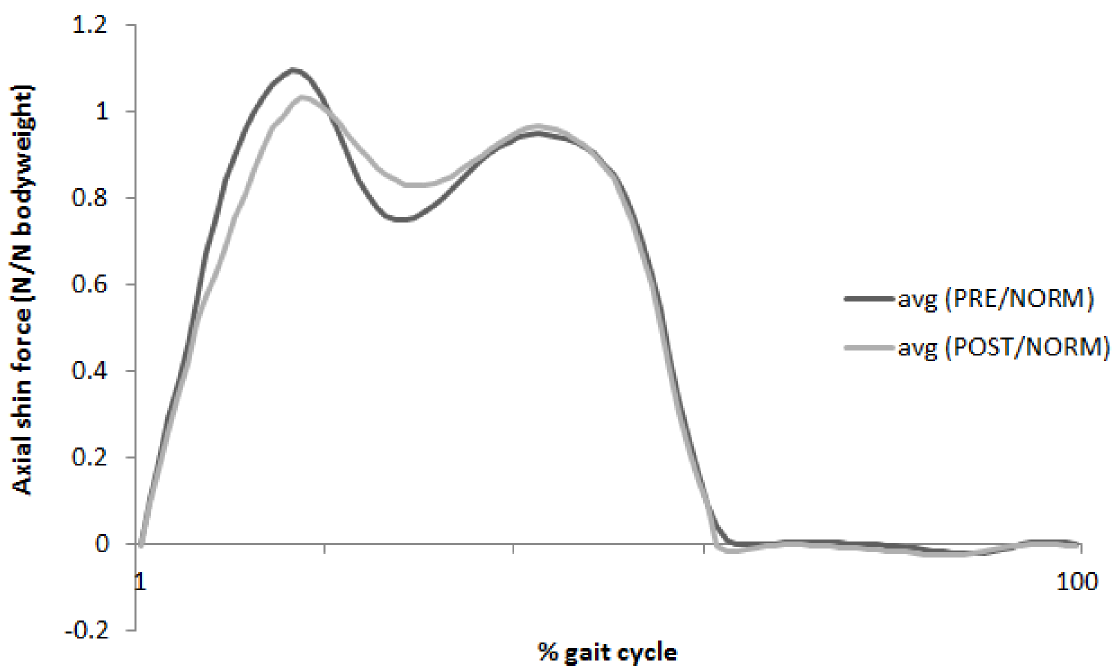

Figure 23: Longitudinal shin force in subject 7, compared between conditions PRE/PF and POST/PF. 10 steps each were normalized to 100 samples and averaged.

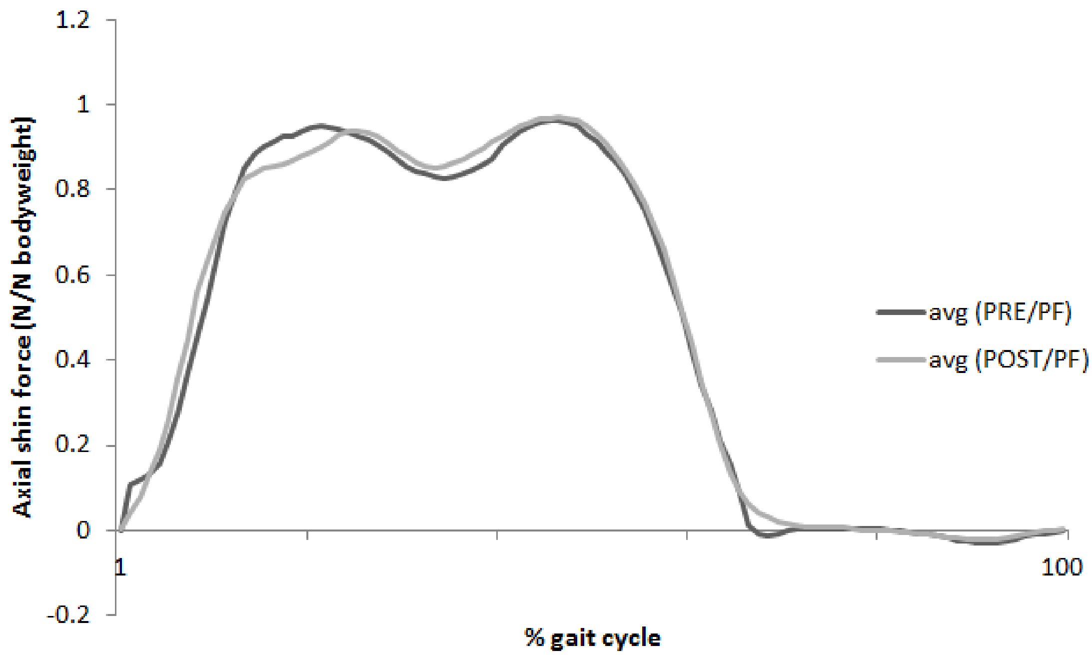

Figure 24: Longitudinal shin force in subject 8, compared between conditions PRE/PF and POST/PF. 10 steps each were normalized to 100 samples and averaged.

A similar comparison of gait curves was conducted with normal alignment and gradually increasing exertion. Figures 26 and 27 visualize the respective differences in one subject by displaying the curves for average ankle moment and longitudinal force during four points in time during the data collection. “Start” denotes the initial walking trial; this and the subsequent measures “after 1 lap, 2 laps, 3 laps” are separated by approximately 3 minutes and 210 meters walking distance each.

A multivariate comparison over conditions revealed no significant differences for the ankle moment curves, but a difference in longitudinal force curves ($F(108, 3.9)=28.678$, $p<0.001$). Subsequent group-wise comparisons showed significant differences to have occurred only between conditions “start” and “after 1 lap” ($F(18,1)=726.587$, $p=0.029$). Comparison between other measurement points in time yielded no significant differences at the 0.05 level.

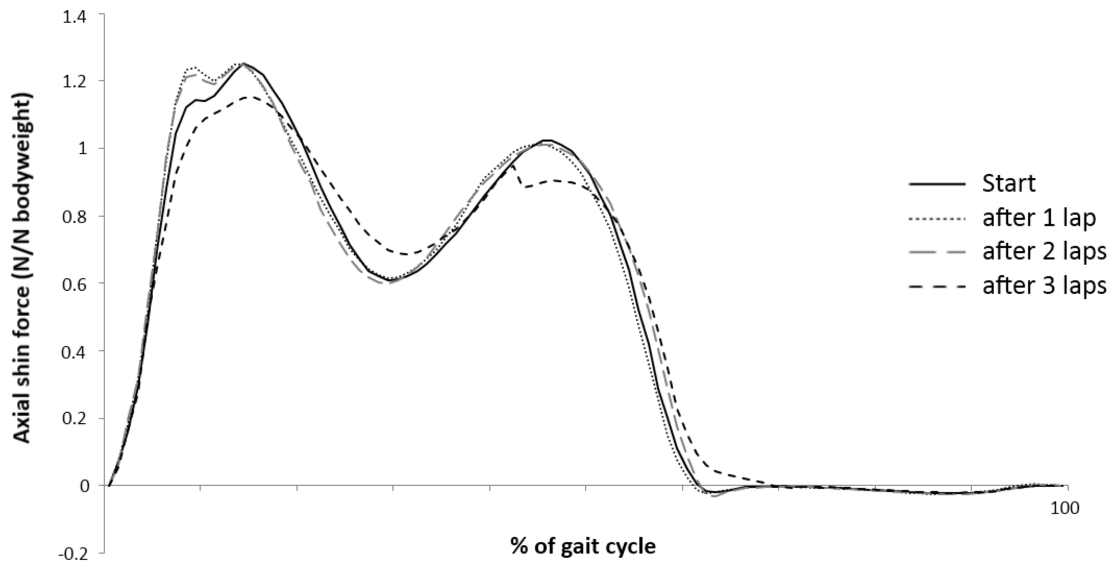

Figure 25: Comparison of longitudinal shin force over the step cycle at different levels of exertion for one subject (Subject 10). Curves are each averaged over samples of 10 consecutive time normalized steps.

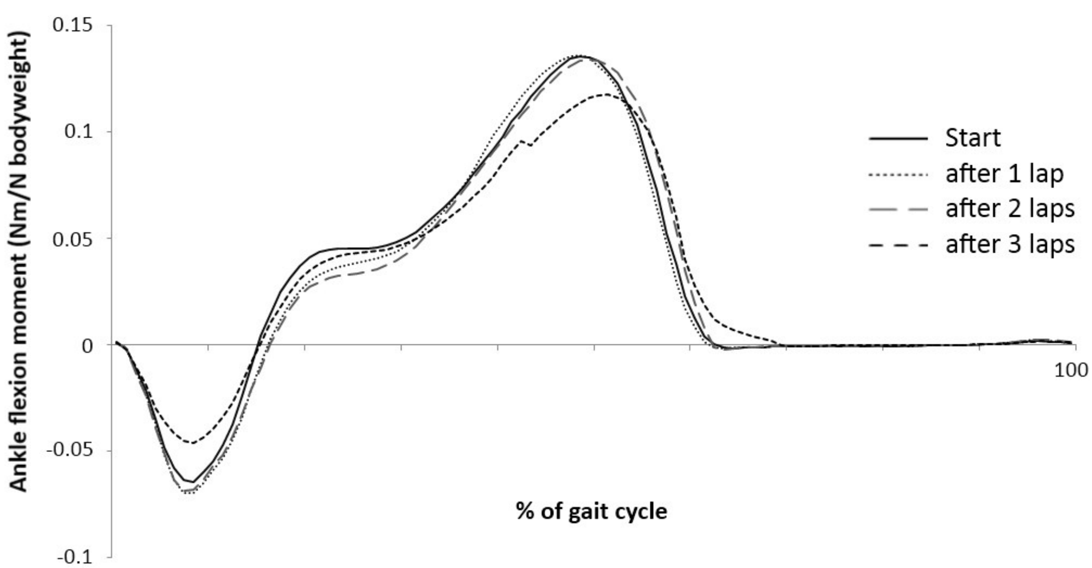

Figure 26: Comparison of ankle flexion moments over the step cycle at different levels of exertion for one subject (Subject 10). Curves are each averaged over samples of 10 consecutive time normalized steps.

Regarding the subjects whose gait was found to show significant effects of exertion, it was investigated whether the actual level of exertion was a factor in that. Subject 6 happens to be the subject with the highest relative gap between PRE exertion heart rate (60) and POST exertion heart rate (130). Subjects 7 (75 vs. 134) and 8 (85 vs. 138) had above average increases in heart rate as well. However, neither in subject 2 (65 vs. 139), nor in subject 9 (84 vs. 162) could significant effects be detected, although their heart rate increased above average between PRE and POST condition. A visualization of the possible correlation is given in figure 28. Findings were not conclusive, as the correlation coefficient R^2 of about 0.3 is relatively small, and even assumed a value of 0 when one outlier was removed from the equation.

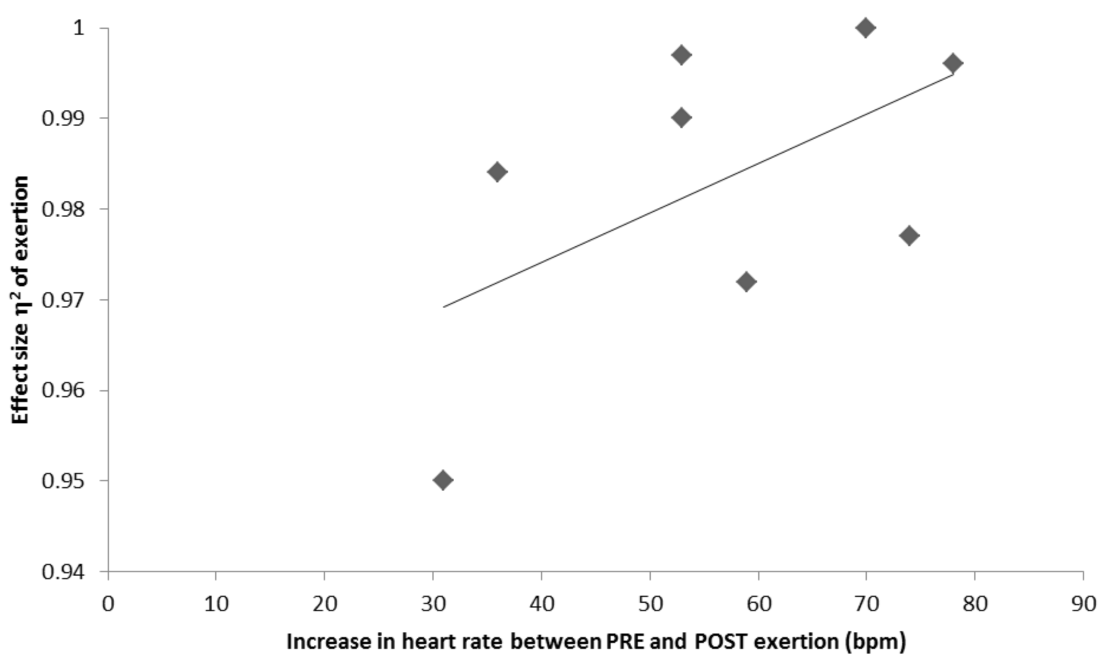

Figure 27: MANOVA effect sizes of exertion in the condition PF (increased plantar-flexion). The variable "absolute increase in heart rate" shows a weak linear correlation to the effect size of exertion on ankle moment (R^2 = .3156)

4.4 Discussion

Multivariate comparison of ipecs variables revealed significant effects of both the increased plantar-flexion and the interaction of increased exertion and increased plantar-flexion, affecting the timing of peaks in the force curves and moment curves of a step cycle. Those findings indicate that there are measureable effects of subtle alignment perturbation even within the acceptable range of alignments for each subject. That challenges the belief that no differences in alignment quality exist within this range.

Within-subject comparisons showed significant effects of the interventions for three of the subjects, but not for the others. A post-hoc correlation of absolute increases in heart rate during the exertion protocol and observed effect sizes of exertion suggested that those factors are proportionally related by trend. While this in itself would be an expected correlation, it shows the divergence in self-assessment of exertion levels among the subjects of this study, and again the generally limited comparability of individuals with amputation.

In the three cases, significant differences could be found for one pairwise comparison out of six in each case. As this may indicate individually differences in strategies, employed by those subjects to cope with the respective interventions, it supports the finding that a great homogeneity in biomechanics of amputee gait cannot be assumed. The observed individual differences in step-by-step variability change across interventions can be interpreted in the same sense.

It was shown, that the utilized data collection method by prosthesis integrated sensor is appropriate to detect individual gait changes. By increasing the step sample size, this method also improves measurement accuracy and facilitates statistical analyses even of small sample size studies.

The selected approach of comparing gait curves over 100 data points across conditions is an extension of the widely used method to quantify variability in gait, based on extracted discrete values, such as peak moments or timing of peaks. It was deemed sufficient for the purposes of this study, but may be extended upon in future analyzes. Possible evaluation methods could include such simple procedures as measuring the standard deviation of step parameters as a variable (Brach, Perera, Studenski, & Newman, 2008), calculating the coefficient of variation (Sosnoff, Sandroff, & Motl, 2012; Svoboda, Janura, Cabell, & Elfmark, 2012), or deriving the Minimal Detectable Change (MDC) for those gait variables (Kesar, Binder-Macleod, Hicks, & Reisman, 2011). More elaborate is the application of principal component analysis (Deluzio & Astephen, 2007), that has been "characterized by the assumption that a few dominant forms of variation can characterize most sets of data." (Wrigley, Albert, Deluzio, & Stevenson, 2006), and has been used for investigations in sports biomechanics (O'Connor & Bottum, 2009), gait changes after diseases (Yamamoto et al., 1983) and recently also for amputee gait studies (Kark, Vickers, McIntosh, & Simmons, 2012). In another effort to adapt mathematical approaches for amputee research, computation of the largest Lyapunov exponent (LyE) has been proposed, "which, in simple words, is a measure of how fast the waveform shape of a time series changes from step cycle to step cycle." (Federolf, Tecante, & Nigg, 2012). This method has also been used "for analyzing the temporal structure of variability in amputee gait" (Wurdeman, Myers, Jacobsen, & Stergiou, 2012). However, this method can be criticized for the fact that, in order for it to yield reliable results, the collected data have to meet high requirements regarding the resolution, "a conservative rule of thumb [suggesting] a minimum of 8 meaningful bits of precision be used for exponent calculations."(Wolf, Swift, Swinney, & Vastano, 1985). Realistically, such a resolution is not attainable without introducing systematic measurement errors, especially in gait analysis applications.

Irrespective of the eventually applied method for quantifying gait variability, the approach of considering within-step variability for the statistical evaluation of within-test variability appears to be an interesting option that is supported by the mobile sensor technology. Although this study could not find any significant differences in step variability between interventions, the computed effect sizes (table 11) indicate that the variable "step variability" is indeed affected by changes in alignment and exertion. A within-subject comparison of the variable "step variability" (figure 28) reveals again substantial individual differences in how this variable is affected by the interventions. In some subjects (e.g. subject 1 or 6), the step variability decreased over time, possibly hinting at an increased level of gait stability. In other subjects (3 or 7), this trend seemed reversed, again others (2 or 10) did not show any linear trends of step variability changes in response to the interventions.

More significant have been the findings of analyses of changes within the same subject. Between-group variability in gait variables (that is, across different interventions), as well as within-group variability (that is, across a sample of consecutive walking steps) can be calculated within a single subject. This allows statistical comparisons by means of F-statistics, such as in the here-utilized MANOVA procedure, without requiring a large patient cohort. In fact, the results of our respective analyses support the argumentation that the effects of prosthesis interventions can rarely be meaningfully compared across different amputees. Three of our subjects had a significant change in the shape of the longitudinal force curve over the step cycle, when subjected to our different experimental interventions; the others did not. A likely explanation for the lack of significance in the latter cases is that step variability in those subjects was generally on a relatively high level, so that the variability that was caused by the actual interventions could not be detected. Two conclusions could be drawn from that: firstly, the sample size could be increased in future studies – something that seems easy enough to do by simply collecting data over 100 instead of 10 consecutive walking steps; and secondly, the sample size that has been available from the conventional gait analysis is too small for meaningful comparisons within the trans-tibial amputee population.

Limitations: Comparing ankle moment and force curves over normalized step cycles by means of a multivariate ANOVA is not without limitations.

1) Based on previously discussed findings, caution is required in interpreting variables that inherently rely on proper time measurement, as the integrated sensor appears to have sizeable fluctuations in its clock rate. Although, it may be the case that those random effects are averaged out over our sample of 10 subjects, the results lack a desirable level of confidence.

2) When interpreting the results, it must be considered that the detected differences refer to the magnitude of the respective value at a given gait cycle percentile. In that sense, a higher or lower peak force in one of the conditions could yield the same results, as would a delayed peak force of unchanged magnitude. An error in properly defining the time of stance phase initiation can therefore skew the entire analysis. This possible error has been mitigated by the fact that 10 steps per sample were averaged, as was the case in this analysis.

3) Likewise unexpected results yielded the analysis of vertical force curves measured at different times during the exertion protocol (figures 26 and 27). MANOVA indicated that only the first and second measurement (solid and dotted curves) were significantly different, whereas the last measurement (dashed) was not found to be significantly different from any other curve, which contradicts the notion from visual assessment that this curve has the biggest deviation from the respective others. This raises the

question whether the selected analysis method is appropriate to detect interesting differences. A principal component analysis is recommended for future studies of that data.

4.5 Conclusion

This study expanded on the results of our initial comparison of the effects of prosthesis alignment and physical exertion on amputee gait, that have been based on conventional gait analysis data, and yielded no significant difference (in gait symmetry), by investigating unilateral gait variables. Analysis of prosthesis ankle moments and longitudinal shin measured by ipecs equipment detected gait changes across interventions that – unlike the results from CGA – were statistically significant in some parameters. The measurement method was also used to analyze within subject step-by-step variability, and on this basis evaluate individual responses to alignment changes and exertion. In the clinical application, this capability should be a relevant one, as it may be used to evaluate and optimize prosthetic fittings on a single case basis.

Possible applications of this technology include studies on amputee gait kinetics in different real life conditions, such as on stairs and inclines, over prolonged periods of walking, with different alignments, and prosthetic components. The specific capabilities of the integrated sensors also allow investigating leg laterality in bilateral amputees, gait stability in amputee gait, and long term outcomes of prosthetic use. Some of those questions have been discussed in a series of abstracts that were based on preliminary data of this study, (Fiedler & Slavens, 2011; Fiedler, Slavens, Briggs, & Fedel, 2012; Fiedler, Slavens, & Smith, 2012a, 2012b, 2012c), and that are attached in Appendix D.

5 Overall Summary and Conclusions

This research confirmed previously stated notions that prosthesis fitting and alignment follows individually different mechanisms, which makes it difficult to find generally applicable principles. Investigating differences in gait symmetry based on conventional motion analysis did not yield many significant results. Aside from the small effect size of the tested interventions, the inconsistency of effects across the ten subjects of the sample population was identified as a limitation of this approach. For some subjects, interventions had the opposite effect than for others. While this obviously reduces the statistical significance of group-wise effect sizes, it may obscure possible considerable effects for individual subjects.

This problem can be addressed by using within-subject variability for the statistical comparison of conditions. With that objective, the usability and validity of an integrated sensor module was tested. Although the quantity of accurately measurable variables is somewhat limited in comparison to CGA, it was found that the used sensor provides reliable patient specific data on ankle moments and forces.

Step parameters measured by prosthesis integrated sensors were compared across interventions, factoring in the step variability within trials for the computation of F-statistics in a SS design. According to the results, several of the tested subjects experienced significant effects from the interventions, which were differently among the sample.

5.1 Notes on protocol and data collection issues

While testing the study hypotheses, several unanticipated aspects presented themselves that are worth mentioning, as they may motivate future studies and inform their respective study design.

Measuring exertion, muscle activity, and step timing parameters proved to be challenging with the utilized protocol and equipment. It is recommended to apply a more accurate method of assessing physical exertion than the here used self-report scale. In the sense of limiting recovery effects, it would also be worthwhile to devise a system that makes alignment changes quicker, or even entirely unobtrusive, for instance by using active ankle adapters (Eilenberg, Geyer, & Herr, 2010; Fradet, Alimusaj, Braatz, & Wolf, 2010). By being able to change the ankle alignment for instance by remote control or by a randomized protocol during the walking trials, the probability could be reduced that results are affected by timing, training, and expectation effects.

Muscle activity was hypothesized to change significantly across testing conditions, yet a measuring accuracy that would allow the respective analyses could not be realized. Despite the technical advantages of the used wireless EMG sensor system, including the capability of transmitting signals directly to the base unit, and the correction for motion artifacts by integrated accelerometers, it seems recommendable to use different equipment instead. Mainly the size and the attachment mode of the wireless sensor units presented problems when using them in our population. Placing them under the elastic liner sleeve or the knee brace was problematic due to the discomfort to the patient, as well as a loss in adhesion between skin and sleeve. Placing them proximal of the upper sleeve end caused the EMG signal to be weak and noisy, aside from issues with properly keeping the sensors in place over the length of the trials. A patient-worn EMG monitor that is connected to thin sensors by wires, but transmits data wirelessly to the computer (GreatLakesNeurotechnologies, 2011) would be a better option in this population.

Future work is required to address the sampling frequency inconsistencies in the iPecs sensor in order to achieve more reliable measures on timing based gait parameters. Assuming that the observed issue is not a general one, it is recommended to verify the sampling frequency prior to testing, and if necessary replace the faulty unit. In the case that the frequency deviations are caused by the wireless transmission procedure, a feasible remedy might be the adaptation of the protocol to include data collection in the on-unit memory storage instead of the wireless transmission.

5.2 Discussion on the applicability of integrated sensor measurements

Although it did not succeed in this study to identify many gait variables, that are dependent on subtle prosthetic alignment changes, clearly measurable and generally applicable to a wide population, the applied method may hold the potential of addressing the common problems in amputee studies, namely a small sample size, and high within-subjects variability. If it is accepted that many alignment interventions have individually different effects on the gait biomechanics in (trans-tibial) amputees, it becomes very reasonable to conduct SS studies, e.g. to consider studies with sample sizes greater than one as a series of case studies.

Particularly with respect to studies on gait pattern, gait symmetry, and gait variability, the dependent variables can often be extracted from a small step sample. Depending on the number of available force plates in CGA, this sample may be as small as one step cycle (as was the case in our here discussed study). Comparing this one step across different experimental conditions or interventions is obviously limited in its statistical significance. The desirable increase in step samples would necessitate a greater number of captured repetitions, which is not only time consuming, but may also bear problems regarding the clear definition of the intervention condition. Multiple repetitions of walking trials in a gait lab can have several undesired and difficult to quantify side effects on the subject, such as a warm-up or training effect, or eventually a fatigue effect. This would limit the validity of the assumption that all sampled steps are part of the same group.

If for instance, one were to investigate the effect of physical therapy on the gait symmetry in amputees, the two intervention groups would likely be “Before PT” and “After PT”. In order to collect a reasonable sample of for instance 10 steps in the “Before PT” condition, the subject would have to be asked to complete repeated walking trials until those 10 steps, meaning 10 clean strikes of the force plate with the interesting leg, have been recorded. For every step on the force plate, there may be 10 more per trial occurring before and after the force plate. Depending on the step length and gait variability of the subject, the total number of repetitions may become much larger than 10, if the subjects fails to cleanly strike the force plate. It is a conservative estimate that only 20% of trials in amputee gait studies can be used for data extraction. Stochastic deliberations suggest that even of non-impaired subjects “only about 25% … will, on average require 3 or less trials for every successful test …, only 43% will require 5 or less …, and almost 42% will not be able to have valid trials at all.” (Oggero, Pagnacco, Morr, Simon, & Berme, 1997). In our case, an average subject would have to perform about 50 repetitions of 10 steps each in order to provide a sample of 10 steps. Those up to 500 steps of walking between the first and the final sample step could be compared to a session of physical therapy already, so that it would be misleading to categorize both step samples in the same group “Before PT”. In fact, the first step may be “Before PT” whereas the last one should be labeled as “After 1 PT session”.

Another limitation of the CGA in this context is the impossibility of analyzing consecutive steps. Such an analysis reveals interesting information, such as the within-steps variability (Hausdorff, 2007; Maki, 1997) that can be interpreted as a measure of gait stability. One approach of obtaining respective data is the use of instrumented treadmills (Bagesteiro, Gould, & Ewins, 2011; Draper, 2000) or wearable sensors (Aminian, Najafi, Büla, Leyvraz, & Robert, 2002; Nolan et al., 2003). Both techniques have their own limitations, mainly in the comparability of treadmill gait with solid ground gait (Alton, Baldey, Caplan, & Morrissey, 1998; Zeni Jr. & Higginson, 2010), and in the susceptibility to measurement errors caused by motion artifacts and sensor displacement (Leardini, Chiari, Della Croce, & Cappozzo, 2005; Reinschmidt et al., 1997).

By installing the sensor in the prosthesis structure, much of those systematic shortcomings can be addressed. The integrated sensor measures step data continuously – a sample of 10 steps can be collected while the subject is walking 10 steps. In order to compare the previously mentioned conditions “Before and After PT”, essentially only 10 steps of gait on either side of the PT session need to be recorded, which can be done in a matter of seconds. For the statistical comparison, for instance by student’s t-test, a simple F-statistic can be computed based on the variability within the groups and between the groups respectively. The results would have to be interpreted as only valid for this particular subject, which is an inherent limitation of single-case studies. Nonetheless, the relatively low technical complexity and time intensity of this data collection and analysis could make it an interesting outcome assessment method in the clinic.

The quality of gait data delivered by the iPecs device is in some respects different from CGA standards. Where this affects the comparability and meaningful interpretation, as discussed in chapter 3, these differences are clearly a drawback and they limited the feasibility of our initially intended investigations. On the other hand, it may be worthwhile to consider the specific capabilities of this technology to utilize them for the investigation of slightly different questions. Mobile sensors do not necessary measure quantities that would else be unattainable, but they may do so more directly, and less error-prone (for instance in the light of marker motion artifacts, and the inevitable approximations concerning segment masses and centers of gravity in CGA). Three examples may illustrate this.

1) Being within the structure of the prosthesis, the force cell of the mobile sensor detects forces over the entire spectrum of the gait cycle, which cannot be said for force plate based kinetics analysis methods. Especially in the swing phase, it so becomes possible to quantify the forces that work on the prosthesis, and eventually on the residual limb. In the light of the perennial debates about socket suspension systems (Hagberg & Brånemark, 2009; Klute et al., 2011; Narita, Yokogushi, Shii, Kakizawa, & Nosaka, 1997) and energy returning foot components (Gitter, Czerniecki, & DeGroot, 1991; BJ Hafner, Sanders, Czerniecki, & Fergason, 2002; Postema, Hermens, de Vries, Koopman, & Eisma, 1997; Versluys et al., 2009), this particular information may help shed some light on the respective relationships and correlations. For example, it has been claimed that the comparably high weight of novel powered ankle systems, capable of active plantar-flexion at the initiation of the swing phase, has none of the negative effects usually associated with higher prosthesis weight (HM Herr & Grabowski, 2012). Measuring the longitudinal force component in the prosthesis pylon could be one easy way to investigate that claim.

2) Another consequence of collecting kinetics data during the swing phase is the availability of directly measured internal prosthesis moments. As already discussed in chapter 3, this internal moment in the stance phase resembles much the ankle moment that can be measured by CGA. Given the changed nature of the observed system in the swing phase (from a closed kinematic chain to an open chain), it could be reasoned that the then measured internal moment is closer related to the moment in the proximal joint, which would be the knee in trans-tibial amputees. Measuring internal knee moments in the swing phase of amputee gait directly, other than deriving it from the computed external moments, would possibly hold some interesting information in the context of questions on muscle utilization, prosthesis weight balance, and socket efficiency.

3) Finally, the fact that forces and moments are directly available in a local coordinate system that moves with the prosthesis may ease some of the analyses that are directed at investigating socket forces or internal moments of the residual limb. Those quantities have their probably most relevant effects on the residual limb itself, and would therefore best be described in a reference frame that is established right in that system.

5.3 Possible future directions

It is a perennial issue in prosthetics how to properly prescribe (and bill for) prosthetic components; and with every new piece of available technology it has to be determined whether or not it is worth its price tag, and for whom its use is indicated. Manufacturers and prosthetists have naturally a different bias on that question than have insurances and other payers, which regularly causes disagreement. An individual assessment of the new part's effect on gait biomechanics could help decide this debate on a case-by-case basis.

This work (in chapter 4) discussed one application of that concept in investigating the hypothesis that exertion and subtle alignment changes have an effect on amputee gait kinetics. In future studies, this approach could be extended in several ways.

1) More variables could be compared. Although it was determined, that the proximal moment computed by the iPecs has no useful equivalent in CGA, there are still various valid variables that may hold interesting information on amputee gait kinetics. For the analysis in chapter 4, only ankle flexion moment and longitudinal internal force were considered, because those variables are most commonly discussed in the literature, and are also most likely to be affected by the particular interventions of this study. Yet, those quantities are available in three degrees of freedom, and in a different study it may be indicated to include ankle pronation moment, ankle rotation moment, transversal force, and shin torsion force in the analysis.

2) More steps could be regarded. Increasing the step sample size requires close to no additional time and effort, as merely an additional few seconds of walking need to be included in the data set. This can help achieve the desired statistical power and detect small effect sizes in comparison studies.

3) More interventions could be compared. Beyond the question of how exertion and increased ankle plantar-flexion affects amputee gait, it may also be of interest what effect, if any, different walking surfaces, environmental conditions, prosthetic components, or e.g. shoe designs have in this context. Data on some of those possible interventions have in fact already been collected as a byproduct of the exertion protocol in this study. When subjects walked along the looped path along the hallways, down and up the stairs, through dimly lit corridors, and across the outdoor parking lot, the iPecs sensor was continuously collecting data. Those may well be the preliminary data for a respectively proposed study.

4) More amputation levels could be included. Trans-tibial amputation is the most prevalent among several common leg amputations. Gait biomechanics with a trans-femoral prosthesis are obviously subject to different constrains and prosthetic interventions, but could be investigated in a similar fashion as in trans-tibial prosthetics by integrated sensors. A comparable case of including a different sub-population of amputees would be the study of bilateral amputee gait mechanics. The data of the actual study already yielded one such abstract that can be found in the appendix.

5) Step-by-step variability, derived for instance from the standard deviation of gait parameters over the step cycle, may be used as a dependent variable to compare interventions. Step variability is often discussed as an indicator for gait stability, and could therefore be an important outcome measure in amputee gait studies. Preliminary data is displayed in figure 29 that shows step variability data that has been collected for the subject sample of this study.

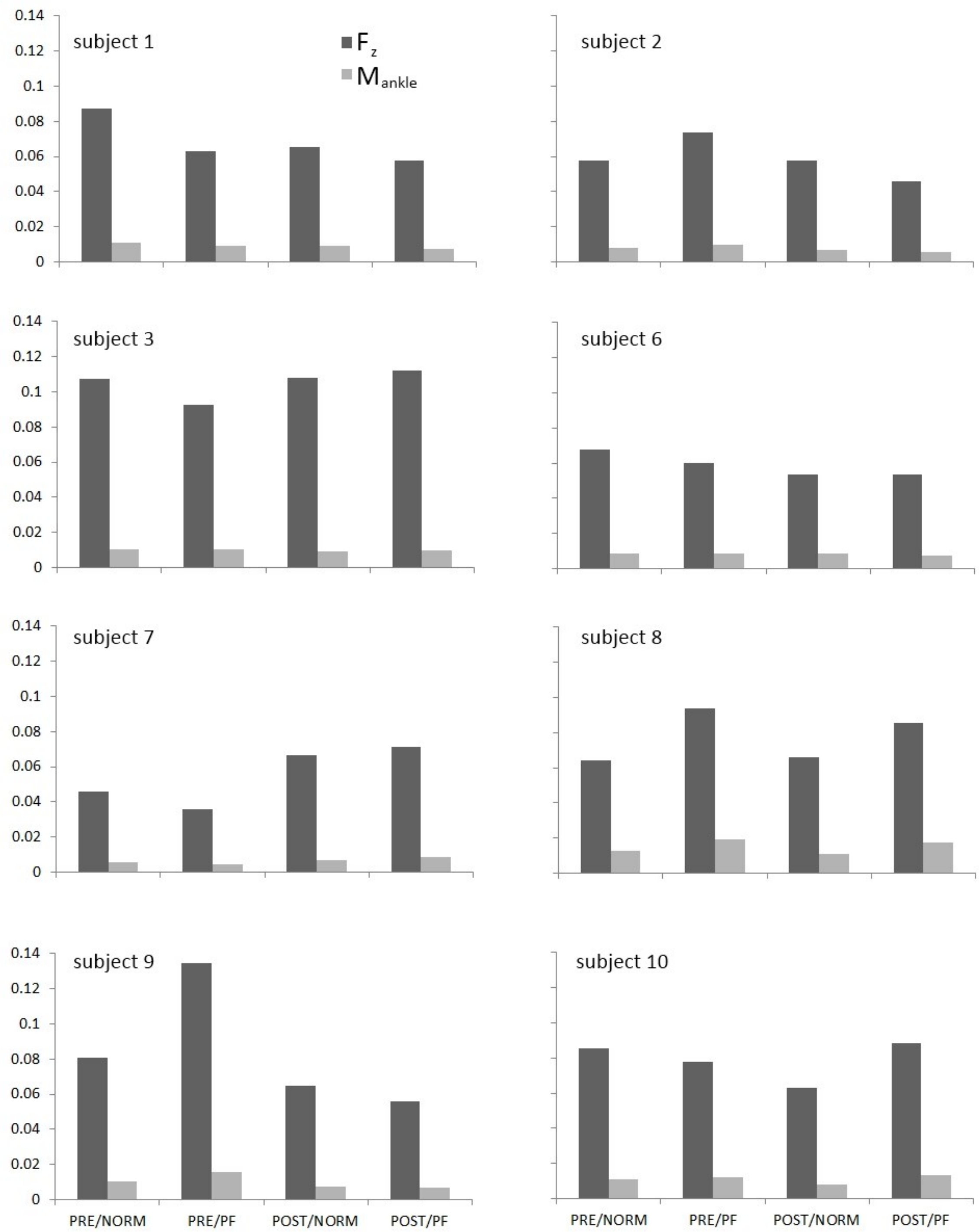

Figure 28: Average standard deviations of vertical force F_z (in N) and ankle flexion moment M_{ankle} (in Nm) curve points in a 10-step sample, as a measure of in step variability in each subject over the intervention conditions.

Beyond the adoption of the protocol for extended gait analysis studies, it is also conceivable to use the sensor technology in the sense of outcome assessment. With respect to practical significance, this kind of research is probably even more interesting than pure biomechanics observations. Assessment of patient activity may be more accurate if the sensor is installed in the prosthetic structure and not worn comparably loosely on the belt or strapped to the skin, as is common in accelerometry measures. Depending on the amount of relative displacement between residual limb and prosthesis, it may be feasible to reduce the noise artifacts to an extent that allows even the detection of gait events on the non-instrumented contralateral side.

In any event, it is foreseeable that prosthesis integrated sensors become more versatile and accurate, smaller, lighter, and most of all more affordable in the coming years. Increasing complexity of prosthetic technology and the likewise increasing necessity to balance amputee's entitlement to the best available treatment with an economically sound prescription practice may soon make the by-default equipment of artificial limbs with integrated activity monitors a standard practice.

References

Alton, F., Baldey, L., Caplan, S., & Morrissey, M. (1998). A kinematic comparison of overground and treadmill walking. *Clinical Biomechanics, 13*(6), 434-440.

Amann, M., & Dempsey, J. A. (2008). Locomotor muscle fatigue modifies central motor drive in healthy humans and imposes a limitation to exercise performance. *J Physiol, 586(Pt 1)*, 161-173.

Aminian, K., Najafi, B., Büla, C., Leyvraz, P.-F., & Robert, P. (2002). Spatio-temporal parameters of gait measured by an ambulatory system using miniature gyroscopes. *Journal of Biomechanics, 35*(5), 689-699.

Anderson, I. A., MacDiarmid, A. A., Harris, M. L., Gillies, R. M., Phelps, R., & Walsh, W. R. (2003). A novel method for measuring medial compartment pressures within the knee joint in-vivo. *Journal of Biomechanics, 36*(9), 1391-1395.

Andres, R., & Stimmel, S. (1990). Prosthetic alignment effects on gait symmetry: a case study. *Clinical Biomechanics, 5*(2), 88-96.

Andrews, K. (1996). Rehabilitation in limb deficiency. 3. The geriatric amputee. *Arch Phys Med Rehabil, 77*(3 Suppl), S14-17.

Au, S., Berniker, M., & Herr, H. (2008). Powered ankle-foot prosthesis to assist level-ground and stair-descent gaits. *Neural Netw, 21*(4), 654-666.

Bach, T., Barnes, L., Evans, O., & Robinson, I. (1994). *Optimization of inertial characteristics of transfemoral limb prostheses: tests of predictions of a computer simulation.* Paper presented at the Canadian Society for Biomechanics Eighth Biennial Conference, Calgary, Canada.

Bagesteiro, L. B., Gould, D., & Ewins, D. J. (2011). A vertical ground reaction force-measuring treadmill for the analysis of prosthetic limbs. *Brazilian Journal of Biomedical Engineering, 27*(1), 3-11.

Baker, P., & Hewison, S. (1990). Gait recovery pattern of unilateral lower limb amputees during rehabilitation. *Prosthetics and Orthotics International, 14*, 80-84.

Baker, R., McGinley, J. L., Schwartz, M. H., Beynon, S., Rozumalski, A., Graham, H. K., & Tirosh, O. (2009). The Gait Profile Score and Movement Analysis Profile. *Gait & Posture, 30*(3), 265-269.

Bakshi, R. (2003). Fatigue associated with multiple sclerosis: diagnosis, impact and management. *Mult Scler, 9*(3), 219-227.

Balogh, A. (2008). The Effect Of Prosthesis Suspension On Residual Limb Pistoning. *MSPO Student Presentations* Atlanta, GA: Georgia Institute of Technology.

Bamberg, S. J. M., Benbasat, A. Y., Scarborough, D. M., Krebs, D. E., & Paradiso, J. A. (2008). Gait Analysis Using a Shoe-Integrated Wireless Sensor System. *IEEE TRANSACTIONS ON INFORMATION TECHNOLOGY IN BIOMEDICINE, 12*(4), 413-423.

Barth, D., Schumacher, L., & Thomas, S. S. (1992). Gait Analysis and Energy Cost of Below-Knee Amputees Wearing Six Different Prosthetic Feet. *JPO Journal of Prosthetics & Orthotics, 4*(2), 63-75.

Bateni, H., & Olney, S. J. (2002). Kinematic and Kinetic Variations of Below-Knee Amputee Gait. *Journal of Prosthetics & Orthotics, 14*(1), 2-10.

Bates, B. T. (1996). Single-subject methodology: an alternative approach. *Medicine & Science in Sports & Exercise, 28*(5), 631-638.

Bellmann, M., Schmalz, T., & Blumentritt, S. (2010). Comparative Biomechanical Analysis of Current Microprocessor-Controlled Prosthetic Knee Joints. *Archives of Physical Medicine and Rehabilitation, 91*(4), 644-652.

Berge, J., Czerniecki, J., & Klute, G. (2005). Efficacy of shock-absorbing versus rigid pylons for impact reduction in transtibial amputees based on laboratory, field, and outcome metrics. *J Rehabil Res Dev, 42*(6), 795-808.

Bergmann, G., Deuretzbacher, G., Heller, M., Graichen, F., Rohlmann, A., Strauss, J., & Duda, G. (2001). Hip contact forces and gait patterns from routine activities. *J Biomech, 34*(7), 859-871.

Beschorner, K., & Cham, R. (2008). Impact of joint torques on heel acceleration at heel contact, a contributor to slips and falls. *Ergonomics, 51*(12), 1799-1813.

Beyaert, C., Grumillier, C., Martinet, N., Paysant, J., & André, J.-M. (2008). Compensatory mechanism involving the knee joint of the intact limb during gait in unilateral below-knee amputees. *Gait & Posture, 28*(2), 278-284.

Bilodeau, S., Hébert, R., & Desrosiers, J. (1999). Questionnaire on the satisfaction of persons with lower-limb amputations towards their prosthesis: development and validation. *Can J Occup Ther, 66*(1), 23-32.

Bilodeau, S., Hébert, R., & Desrosiers, J. (2000). Lower limb prosthesis utilisation by elderly amputees. *Prosthetics and Orthotics International, 24*(2), 126-132.

Blatchford. (2012). Endolite - get busy living Retrieved 06/21, 2012, from http://www.endolite.co.uk/products/intro/intro.html

Blumentritt, S. (1997). A new biomechanical method for determination of static prosthetic alignment *Prosthetics and Orthotics International, 21*, 107-113

Blumentritt, S., Schmalz, T., Jarasch, R., & Schneider, M. (1999). Effects of sagittal plane prosthetic alignment on standing trans-tibial amputee knee loads. *Prosthetics and Orthotics International, 23*(3), 231-238.

Board, W., Street, G., & Caspers, C. (2001). A comparison of trans-tibial amputee suction and vacuum socket conditions. *Prosthetics and Orthotics International, 25*, 202-209.

Bolgla, L. A., & Uhl, T. L. (2007). Reliability of electromyographic normalization methods for evaluating the hip musculature. *Journal of Electromyography and Kinesiology 17*, 102-111.

Bontrager, E. L. (1998). Instrumented Gait Analysis Systems. In J. A. DeLisa & C. K. Kerrigan (Eds.), *RRDS Gait Analysis in the Science of Rehabilitation* (pp. 11-32). Baltimore, MD: Scientific and Technical Publications Section, Rehabilitation Research and Development Service.

Boone, D. A. (2005). *Investigation of socket reactions from transtibial prosthesis malalignment.* PhD, Hong Kong Polytechnic Uuniversity, Hong Kong.

Boonstra, A., Fidler, V., & Eisma, W. (1993). Walking speed of normal subjects and amputees: aspects of validity of gait analysis. *Prosthet Orthot Int, 17*(2), 78-82.

Borg, G. (1970). Perceived exertion as an indicator of somatic stress. *Scand J Rehabil Med Suppl, 2*(2), 92-98.

Borg, G. (1982). Psychophysical bases of perceived exertion. *Med Sci Sports Exerc, 14*(5), 377-381.

Borg, G. (1998). *Perceived exertion and pain scales*. Champaign, IL: Human Kinetics.

Brach, J. S., Perera, S., Studenski, S., & Newman, A. B. (2008). The Reliability and Validity of Measures of GaitVariability in Community-Dwelling Older Adults *Archives of Physical Medicine and Rehabilitation, 89*(12), 2293-2296.

Breakey, J. (1976). Gait of unilateral below-knee amputees. *Journal of Orthotics and Prosthetics, 30*(2), 17-24.

Breakey, J. (1998). Theory of integrated balance: the lower limb amputee. *Journal of Prosthetics & Orthotics, 10*, 42-44.

Buckley, J. (1999). Sprint kinematics of athletes with lower-limb amputations. *Arch Phys Med Rehabil, 80*(5), 501-508.

Buckley, J., Jones, S., & Birch, K. (2002). Oxygen consumption during ambulation: comparison of using a prosthesis fitted with and without a tele-torsion device. *Arch Phys Med Rehabil., 83*(4), 576-580.

Burkett, B., Smeathers, J., & Barker, T. (2001). Optimising the trans-femoral prosthetic alignment for running, by lowering the knee joint. *Prosthetics and Orthotics International, 25*(3), 210-219.

Burnfield, J., Bontrager, M., Boyd, L., Rao, S., Mulroy, S., Gronley, J., & Perry, J. (1999). Effect of prosthetic malalignment on EMG and intra-socket pressures in an individual with a transtibial amputation. *Gait Posture, 9*(2), 137-138.

Cappozzo, A. (1984). Gait analysis methodology. *Human Movement Science, 3*(1-2), 27-50.

Chaffin, D. B. (1973). Localized Muscle Fatigue - Definition and Measurement. *Journal of Occupational Medicine, 15*, 346-352.

Chen, M. J., Fan, X., & Moe, S. T. (2002). Criterion-related validity of the Borg ratings of perceived exertion scale in healthy individuals: a meta-analysis. *Journal of Sports Sciences, 20*(11), 873 - 899.

Chesnin, K. J., Selby-Silverstein, L., & Besser, M. P. (2000). Comparison of an in-shoe pressure measurement device to a force plate: concurrent validity of center of pressure measurements. *Gait & Posture, 12*(2), 128-133.

Cheung, C., Wall, J., & Zelin, S. (1983). A microcomputer based system for measuring temporal asymmetry in amputee gait. *Prosthetics and Orthotics International, 7*, 131-140.

Chow, D. H. K., Holmes, A. D., Lee, C. K. L., & Sin, S. W. (2006). The effect of prosthesis alignment on the symmetry of gait in subjects with unilateral transtibial amputation. *30*(2), 114-128.

Cifrek, M., Medved, V., Tonkovic, S., & Ostojic, S. (2009). Surface EMG based muscle fatigue evaluation in biomechanics. *Clinical Biomechanics 24*, 327-340.

Cortés, A., Viosca, E., Hoyos, J., Prat, J., & Sánchez-Lacuesta, J. (1997). Optimisation of the prescription for trans-tibial (TT) amputees. *Prosthetics and Orthotics International, 21*(3), 168-174.

Coventry, E., O'Connor, K., Hart, B., Earl, J., & Ebersole, K. (2006). The effect of lower extremity fatigue on shock attenuation during single-leg landing. *Clin Biomech (Bristol, Avon), 21*(10), 1090-1097.

CPI, C. P. I. (2011). ipecs LAB wireless gait lab, product specifications, from http://www.college-park.com/images/pdf/cpi-specs-ipecslab.pdf

Cutlip, R. G., Mancinelli, C., Huber, F., & DiPasquale, J. (2000). Evaluation of an instrumented walkway for measurement of the kinematic parameters of gait. *Gait & Posture, 12*(2), 134-138.

Czerniecki, J., Gitter, A., & Munro, C. (1991). Joint moment and muscle power output characteristics of below knee amputees during running: the influence of energy storing prosthetic feet. *J Biomech, 24*(1), 63-75.

Dang, V. (2010). *Data Analysis for Amputee Gait Analysis*. Project paper. Marquette University. Milwaukee.

Davidson, J. (2002). A survey of the satisfaction of upper limb amputees with their prostheses, their lifestyles, and their abilities. *J Hand Ther, 15*(1), 62-70.

Davis, B., Kuznicki, J., Praveen, S., & Sferra, J. (2004). Lower-extremity amputations in patients with diabetes: pre- and post-surgical decisions related to successful rehabilitation. *Diabetes Metab Res Rev, 20*(Suppl 1), S45-50.

Day, H. J. B. (1981). The assessment and description of amputee activity. *Prosthetics and Orthotics International, 5*, 23-28.

De Luca, C. J., Gilmore, L. D., Kuznetsov, M., & Roy, S. H. (2010). Filtering the surface EMG signal: Movement artifact and baseline noise contamination. *Journal of Biomechanics, 43*, 1573-1579.

Deluzio, K., & Astephen, J. (2007). Biomechanical features of gait waveform data associated with knee osteoarthritis An application of principal component analysis. *Gait & Posture* (25), 86-93.

Dennerlein, J. T., Diao, E., Mote Jr., C. D., & Rempel, D. M. (1999). In vivo finger flexor tendon force while tapping on a keyswitch. *Journal of Orthopaedic Research, 17*(2), 178-184.

Dillingham, T., Pezzin, L., & MacKenzie, E. (2002). Limb Amputation and Limb Deficiency: Epidemiology and Recent Trends in the United States. *Southern Medical Journal, 95*(8), 875-883.

Dillingham, T., Pezzin, L., MacKenzie, E., & Burgess, A. (2001). Use and Satisfaction with Prosthetic Devices Among Persons with Trauma-Related Amputations: A Long-Term Outcome Study. *American Journal of Physical Medicine & Rehabilitation, 80*(8), 563-571.

Dingwell, J., Davis, B., & Frazier, D. (1996). Use of an instrumented treadmill for real-time gait symmetry evaluation and feedback in normal and trans-tibial amputee subjects. *Prosthetics and Orthotics International, 20*(2), 101-110.

Draper, E. R. (2000). A treadmill-based system for measuring symmetry of gait. *Medical Engineering & Physics, 22*(3), 215-222.

Edyburn, D. L., & Smith, R. O. (2004). Creating anAssistive Technology Outcomes Measurement System: Validating the Components. *Assistive Technology Outcomes and Benefits, 1*(1), 8-15.

Eilenberg, M., Geyer, H., & Herr, H. (2010). Control of a powered ankle-foot prosthesis based on a neuromuscular model. *IEEE Trans Neural Syst Rehabil Eng, 18*(2), 164-173.

Ephraim, P., Dillingham, T., Sector, M., Pezzin, L., & MacKenzie, E. (2003). Epidemiology of limb loss and congenital limb deficiency: a review of the literature. *Arch Phys Med Rehabil, 84*(5), 747-761.

Esquenazi, A., & DiGiacomo, R. (2001). Rehabilitation after amputation. *J Am Podiatr Med Assoc, 91*(1), 13-22.

Exell, T. (2010). *Lower-limb biomechanical asymmetry in maximal velocity sprint running.* PhD, University of Wales Institute, Cardiff, Wales.

Fang, L., Jia, X., & Wang, R. (2007). Modeling and simulation of muscle forces of trans-tibial amputee to study effect of prosthetic alignment. *Clinical Biomechanics 22*, 1125-1131.

Federolf, P., Tecante, K., & Nigg, B. (2012). A holistic approach to study the temporal variability in gait. *Journal of Biomechanics, 45*(7), 1127-1132.

Fey, N. P., Silverman, A. K., & Neptune, R. R. (2010). The influence of increasing steady-state walking speed on muscle activity in below-knee amputees. *Journal of Electromyography and Kinesiology, 20* 155-161.

Fiedler, G., & Slavens, B. A. (2011). *Integrated Sensor Systems for Assessment of Rehabilitation in Lower Extremity Amputees*. Paper presented at the Third International Symposium on Quality of Life Technology Toronto, CAN.

Fiedler, G., Slavens, B. A., Briggs, D. W., & Fedel, F. (2012). *Leg Laterality in Bilateral Trans-Tibial Amputees, A Case Study using Prosthesis-Integrated Sensors.* Paper presented at the Annual Conference of the Rehabilitation Engineering And Assistive Technology Society of North America (RESNA), Baltimore, MA.

Fiedler, G., Slavens, B. A., & Smith, R. O. (2012a, May 9-12). *Evaluation of an Integrated Sensor System for Assessment of Prosthesis Ankle Alignment in Lower Extremity Amputees.* Paper presented at the Gait and Clinical Movement Analysis Society (GCMAS) Conference, Grand Rapids, MI.

Fiedler, G., Slavens, B. A., & Smith, R. O. (2012b, March 23-24). *Gait stability measured by prosthesis-integrated sensors as an outcome measure in persons with prostheses for the lower extremity.* Paper presented at the 25th Annual Dean's Research Day, Kalamazoo, MI.

Fiedler, G., Slavens, B. A., & Smith, R. O. (2012c, March 11-13). *Influence of Handrail Use on Stair Walking Stability in Trans-Tibial Amputees.* Paper presented at the 1st Occupational Science Summit, St. Louis, MO.

Fitts, R. (1994). Cellular mechanisms of muscle fatigue. *Physiol Rev, 74*(1), 49-94.

Foort, J. (1965). The patellar-tendon-bearing prosthesis for below-knee amputees, a review of technique and Criteria. *Artif. Limbs, 9*(1), 4-13.

Fradet, L., Alimusaj, M., Braatz, F., & Wolf, S. (2010). Biomechanical analysis of ramp ambulation of transtibial amputees with an adaptive ankle foot system. *Gait Posture, 32*(2), 191-198.

Fridman, A., Ona, I., & Isakov, E. (2003). The influence of prosthetic foot alignment on trans-tibial amputee gait. *Prosthetics and Orthotics International, 27*(1), 17-22.

Frossard, L., Stevenson, N., Sullivan, J., Uden, M., & Pearcy, M. (2011). Categorization of Activities of Daily Living of Lower Limb Amputees During Short-Term Use of a Portable Kinetic Recording System: A Preliminary Study. *Journal of Prosthetics & Orthotics, 23*(1), 2-11.

Gallagher, P., & Maclachlan, M. (2001). Adjustment to an Artificial Limb: A Qualitative Perspective. *Journal of Health Psychology, 6*(1), 85-100.

Gandevia, S. (1992). Some central and peripheral factors affecting human motoneuronal output in neuromuscular fatigue. *Sports Med, 13*(2), 93-98.

Gard, S., & Konz, R. (2003). The effect of a shock-absorbing pylon on the gait of persons with unilateral transtibial amputation. *J Rehabil Res Dev, 40*(2), 109-124.

Geil, M., & Lay, A. (2004). Plantar foot pressure responses to changes during dynamic trans-tibial prosthetic alignment in a clinical setting. *Prosthet Orthot Int 28*, 105-114.

Geil, M. D. (2002). Variability among Practitioners in Dynamic Observational Alignment of a Transfemoral Prosthesis. *Journal of Prosthetics & Orthotics, 14*(4), 159-164.

Geil, M. D. (2009). Assessing the state of clinically applicable research for evidence-based practice in prosthetics and orthotics. *J Rehabil Res Dev, 46*(3), 305-314.

Gibbs, P., & Asada, H. (2005). Wearable Conductive Fiber Sensors for Multi-Axis Human Joint Angle Measurements. *J Neuroeng Rehabil, 2*(1), 7.

Gitter, A., Czerniecki, J., & DeGroot, D. (1991). Biomechanical analysis of the influence of prosthetic feet on below-knee amputee walking. *Am J Phys Med Rehabil, 70*(3), 142-148.

Grabiner, M., Feuerbach, J., Lundin, T., & Davis, B. (1995). Visual guidance to force plates does not influence ground reaction force variability. *Journal of Biomechanics, 28*(9), 1115-1117.

Graham, L., Datta, D., Heller, B., Howitt, J., & Pros, D. (2007). A comparative study of conventional and energy-storing prosthetic feet in high-functioning transfemoral amputees. *Arch Phys Med Rehabil, 88*(6), 801-806.

GreatLakesNeurotechnologies. (2011). BioCapture: Acquiring EMG data. In G. L. Neurotechnologies (Ed.). Cleveland, OH.

Grumilliera, C., Martineta, N., Paysanta, J., Andréa, J.-M., & Beyaert, C. (2008). Compensatory mechanism involving the hip joint of the intact limb during gait in unilateral trans-tibial amputees. *Journal of Biomechanics, 41*(14), 2926-2931.

Hafner, B., Sanders, J., Czerniecki, J., & Fergason, J. (2002). Energy storage and return prostheses: does patient perception correlate with biomechanical analysis? *Clin Biomech (Bristol, Avon), 17*(5), 325-344.

Hafner, B., Willingham, L., Buell, N., Allyn, K., & Smith, D. (2007). Evaluation of Function, Performance, and Preference as Transfemoral Amputees Transition From Mechanical to Microprocessor Control of the Prosthetic Knee. *Archives of Physical Medicine and Rehabilitation, 88*(2), 207-217.

Hagberg, K., & Brånemark, R. (2009). One hundred patients treated with osseointegrated transfemoral amputation prostheses--rehabilitation perspective. *J Rehabil Res Dev, 46*(3), 331-344.

Hansen, A., Childress, D., & Knox, E. (2000). Prosthetic foot roll-over shapes with implications for alignment of trans-tibial prostheses. *Prosthetics and Orthotics International, 24*(3), 205-215.

Hansen, A., Gard, S., Childress, D., Ruhe, B., & Williams, R. (2007). *Automatically-Adapting Ankle-Foot Prosthesis Concept.* Paper presented at the 12th World Congress of the International Society for Prosthetics and Orthotics, Vancouver, Canada.

Hansen, A. H., Meier, M. R., Sam, M., Childress, D. S., & Edwards, M. L. (2003). Alignment of trans−tibial prostheses based on roll−over shape principles. *Prosthet Orthot Int 27*, 89-99.

Harris, M., Morberg, P., Bruce, W., & Walsh, W. (1999). An improved method for measuring tibiofemoral contact areas in total knee arthroplasty: a comparison of K-scan sensor and Fuji film. *J Biomech, 32*(9), 951-958.

Hausdorff, J. M. (2007). Gait dynamics, fractals and falls: Finding meaning in the stride-to-stride fluctuations of human walking. *Human Movement Science, 26*(4), 555-589.

Herr, H., & Grabowski, A. (2012). Bionic ankle-foot prosthesis normalizes walking gait for persons with leg amputation. *Proc Biol Sci, 279*(1728), 457-464.

Herr, H., & Wilkenfeld, A. (2003). User-adaptive control of a magnetorheological prosthetic knee. *Industrial Robot, 30*(1), 42-55.

Herzog, W., Nigg, B., Read, L., & Olsson, E. (1989). Asymmetries in ground reaction force patterns in normal human gait. *Med Sci Sports Exerc, 21*(1), 110-114.

Highsmith, M. J., Kahle, J. T., Carey, S. L., Lura, D. J., Dubey, R. V., & Quillen, W. S. (2010). Kinetic Differences Using a Power Knee and C-Leg While Sitting Down and Standing Up: A Case Report. *Journal of Prosthetics & Orthotics, 22*(4), 237-243.

Highsmith, M. J., Schulz, B. W., Hart-Hughes, S., Latlief, G. A., & Phillips, S. L. (2010). Differences in the Spatiotemporal Parameters of Transtibial and Transfemoral Amputee Gait. *Journal of Prosthetics & Orthotics, 22*(1), 26-30.

Hillery, S. C., & Wallace, E. S. (2000). Trans-tibial amputee gait adaptations as a result of prosthetic inertial manipulation. *Disability and Rehabilitation, 22*(8), 383-386.

Hodge, W., Carlson, K., Fijan, R., Burgess, R., Riley, P., Harris, W., & Mann, R. (1989). Contact pressures from an instrumented hip endoprosthesis. *The Journal of Bone and Joint Surgery. American Volume, 71*(9), 1378-1386.

Holden, J. P., Grood, E. S., Korvick, D. L., Cummings, J. F., Butler, D. L., & Bylski-Austrow, D. I. (1994). In vivo forces in the anterior cruciate ligament: Direct measurements during walking and trotting in a quadruped. *Journal of Biomechanics, 27*(5), 517-519, 521-526.

Hong, J., & Mun, M. (2005). Relationship between socket pressure and EMG of two muscles in trans-femoral stumps during gait. *Prosthet Orthot Int, 29*(1), 59-72.

Houghton, A., Taylor, P., Thurlow, S., Rootes, E., & McColl, I. (1992). Success rates for rehabilitation of vascular amputees: implications for preoperative assessment and amputation level. *Br J Surg, 79*(8), 753-755.

Hunter, D., Smith Cole, E., Murray, J., & Murray, T. (1995). Energy expenditure of below-knee amputees during harness-supported treadmill ambulation. *J Orthop Sports Phys Ther, 21*(5), 268-276.

Hunter, J., Katz, J., & Davis, K. (2008). Stability of phantom limb phenomena after upper limb amputation: A longitudinalstudy. *Neuroscience, 156*(4), 939-949.

Hurley, G., McKenney, R., Robinson, M., Zadravec, M., & Pierrynowski, M. (1990). The role of the contralateral limb in below-knee amputee gait. *Prosthetics and Orthotics International, 14*(1), 33-42.

Isakov, E., Burger, H., Krajnik, J., Gregoric, M., & Marincek, C. (1996). Influence of speed on gait parameters and on symmetry in trans-tibial amputees. *Prosthetics and Orthotics International, 20*(3), 153-158.

Isakov, E., Burger, H., Krajnik, J., Gregoric, M., & Marincek, C. (2001). Knee muscle activity during ambulation of trans-tibial amputees. *J Rehabil Med, 33*(5), 196-199.

Isakov, E., Keren, O., & Benjuya, N. (2000). Trans-tibial amputee gait: time-distance parameters and EMG activity. *Prosthetics and Orthotics International, 24*(3), 216-220.

Janura, M., Svoboda, Z., & Elfmark, M. (2006). The variability assessment of the dynamic gait parameters of persons with unilateral trans-tibial amputation. *Acta Univ. Palacki. Olomuc., Gymn., 36*(4), 19-24.

Jepson, F., Datta, D., Harris, I., Heller, B., Howitt, J., & McLean, J. (2008). A comparative evaluation of the Adaptive knee and Catech knee joints: a preliminary study. *Prosthetics and Orthotics International, 32*(1), 84-92.

Jia, X., Wang, R., Zhang, M., & Lia, X. (2008). Influence of Prosthetic Sagittal Alignment on Trans-Tibial Amputee Gait and Compensating Pattern: A Case Study. *Tsinghua Science & Technology, 13*(5), 581-586.

Jones, M., Bashford, G., & Bliokas, V. (2001). Weight-bearing, pain and walking velocity during primary transtibial amputee rehabilitation. *Clin Rehabil, 15*(2), 172-176.

Kahle, J. T. (2002). A Case Study Using Fluoroscope to Determine the Vital Elements of Transfemoral Interface Design. *Journal of Prosthetics & Orthotics, 14*(3), 121-126.

Kark, L., Vickers, D., McIntosh, A., & Simmons, A. (2012). Use of gait summary measures with lower limb amputees. *Gait & Posture, 35*(2), 238-243.

Kark, L., Vickers, D., Simmons, A., & McIntosh, A. (2009). Using the movement analysis profile with lower limb amputees. *Gait & Posture, 30*(Supplement 2), S42-S43.

Kegel, B., Carpenter, M., & Burgess, E. (1977). A survey of lower-limb amputees: prostheses, phantom sensations, and psychosocial aspects. *Bull Prosthet Res, 10*(27), 43-60.

Kendell, C., Lemaire, E., Dudek, N., & Kofman, J. (2010). Indicators of dynamic stability in transtibial prosthesis users. *Gait & Posture, 31*(3), 375-379.

Kesar, T. M., Binder-Macleod, S. A., Hicks, G. E., & Reisman, D. S. (2011). Minimal detectable change for gait variables collected during treadmill walking in individuals post-stroke. *Gait & Posture, 33*(2), 314-317.

Kirby, R. L., Brown, B. A., Connolly, C. M., McRae, S., & Phillips, P. L. (2009). Handling Stairs in the Seated Position for People With Unilateral Lower-Limb Amputations *Archives of Physical Medicine and Rehabilitation, 90*(7), 1250-1253

Kirker, S., Keymer, S., Talbot, J., & Lachmann, S. (1996). An assessment of the intelligent knee prosthesis. *Clinical Rehabilitation, 10*, 267-273.

Kitayama, I., Hada, S., Kawauchi, T., Yokota, H., & Hamada, T. (2010). *Development of a Portable Device for Gait Analysis, and Gait Analysis on Stairs and Uneven Terrain.* Paper presented at the 6th World Congress of Biomechanics (WCB 2010), Singapore.

Klute, G., Berge, J., Biggs, W., Pongnumkul, S., Popovic, Z., & Curless, B. (2011). Vacuum-assisted socket suspension compared with pin suspension for lower extremity amputees: effect on fit, activity, and limb volume. *Arch Phys Med Rehabil, 92*(10), 1570-1575.

Ko, S. u., Ling, S. M., Winters, J., & Ferrucci, L. (2009). Age-related mechanical work expenditure during normal walking: The Baltimore Longitudinal Study of Aging. *Journal of Biomechanics, 42*(12), 1834-1839.

Kram, R., Griffin, T., Donelan, J., & Chang, Y. (1998). Force treadmill for measuring vertical and horizontal ground reaction forces. *J Appl Physiol., 85*(2), 764-769.

Kuiken, T. A., Miller, L. A., Lipschutz, R. D., Lock, B. A., Stubblefield, K., Marasco, P. D., . . . Dumanian, G. A. (2007). Targeted reinnervation for enhanced prosthetic arm function in a woman with a proximal amputation: a case study. *369*(9559), 371-380.

Leardini, A., Chiari, L., Della Croce, U., & Cappozzo, A. (2005). Human movement analysis using stereophotogrammetry: Part 3. Soft tissue artifact assessment and compensation. *Gait & Posture, 21*(2), 212-225.

LeGare, S. (2009). Clinical Reliability of a Device for Measuring Forces and Moments in Amputee Gait. *MSPO Research Presentation*.

Legro, M., Reiber, G., del Aguila, M., Ajax, M., Boone, D., Larsen, J., . . . Sangeorzan, B. (1999). Issues of importance reported by persons with lower limb amputations and prostheses. *J Rehabil Res Dev, 36*(3), 155-163.

Leydet, M. G. (2011, May 13, 2011). [iPecs design and working principles].

Leydet, M. G., Harrington, R. H., Fedel, F. J., Link, M., & Street, J. J. (2007). USA Patent No. 20070255424.

Li, L., Patil, S., Steklov, N., Bae, W., Temple-Wong, M., D'Lima, D. D., . . . Fregly, B. J. (2011). Computational wear simulation of patellofemoral articular cartilage during in vitro testing. *Journal of Biomechanics, 44*(8), 1507-1513.

Lindström, L., Kadefors, R., & Petersén, I. (1977). An electromyographic index for localized muscle fatigue. *J Appl Physiol., 43*(4), 750-754.

Liu, T., Inoue, Y., & Shibata, K. (2009). Development of a wearable sensor system for quantitative gait analysis. *Measurement, 42*(7), 978-988.

Lorincz, K., Chen, B.-r., Challen, G. W., Chowdhury, A. R., Patel, S., Bonato, P., & Welsh, M. (2009). Mercury: A wearable sensor network platform for high-fidelity motion analysis. *Proceedings of the 7th ACM Conference on Embedded Networked Sensor Systems*, 183-196.

Macomber, B., Boone, D. A., & Beck, J. (2011). US Patent Patent No. 7886618.

Maki, B. (1997). Gait changes in older adults: predictors of falls or indicators of fear. *J Am Geriatr Soc, 45*(3), 313-320.

Manal, K., McClay Davis, I., Galinat, B., & Stanhope, S. (2003). The accuracy of estimating proximal tibial translation during natural cadence walking: bone vs. skin mounted targets. *Clinical Biomechanics, 18*(2), 126-131.

Mathie, M., Coster, A., Lovell, N., & Celler, B. (2004). Accelerometry: providing an integrated, practical method for long-term, ambulatory monitoring of human movement. *Physiol Meas, 25*(2), R1-20.

Matsen, S., Malchow, D., & Matsen, F. (2000). Correlations with Patients' Perspectives of the Result of Lower-Extremity Amputation. *The Journal of Bone and Joint Surgery, 82*, 1089-1095.

Merletti, R., Lo Conte, L., & Orizio, C. (1991). Indices of muscle fatigue. *J Electromyogr Kinesiol, 1*(1), 20-33.

Michael, J. (1999). Modern prosthetic knee mechanisms. *Clin Orthop Relat Res, 361*, 39-47.

Miller, L. A., & McCay, J. A. (2006). Summary and Conclusions From the Academy's Sixth State-of-the-Science Conference on Lower Limb Prosthetic Outcome Measures. *Journal of Prosthetics & Orthotics, 18*(6), P2-P7.

Mitchell, C., & Versluis, T. (1990). Management of an above-knee amputee with complex medical problems using the CAT-CAM prosthesis. *Phys Ther, 70*(6), 389-393.

Moirenfeld, I., Ayalon, M., Ben-Sira, D., & Isakov, E. (2000). Isokinetic strength and endurance of the knee extensors and flexors in trans-tibial amputees. *Prosthetics and Orthotics International, 24*(3), 221-225.

Morris, S., & Paradiso, J. (2002). *Shoe-integrated sensor system for wireless gait analysis and real-time feedback.* Paper presented at the Engineering in Medicine and Biology, 2002. 24th Annual Conference and the Annual Fall Meeting of the Biomedical Engineering Society EMBS/BMES Conference, 2002. Proceedings of the Second Joint.

Mulder, T., Nienhuis, B., & Pauwels, J. (1998). Clinical gait analysis in a rehabilitation context: some controversial issues. *Clin Rehabil, 12*(2), 99-106.

Mulder, T., Zijlstra, W., & Geurts, A. (2002). Assessment of motor recovery and decline. *Gait & Posture, 16*(2), 198-210.

Munro, B. J., Campbell, T. E., Wallace, G. G., & Steele, J. R. (2008). The intelligent knee sleeve: A wearable biofeedback device. *Sensors and Actuators B: Chemical, 131*(2), 541-547.

Murley, G. S., Menz, H. B., Landorf, K. B., & Bird, A. R. (2010). Reliability of lower limb electromyography during overground walking: A comparison of maximal- and sub-maximal normalisation techniques. *Journal of Biomechanics, 43*, 749-756.

Murray, C., & Fox, J. (2002). Body image and prosthesis satisfaction in the lower limb amputee. *Disabil Rehabil, 24*(17), 925-931.

Nadollek, H., Brauer, S., & Isles, R. (2002). Outcomes after trans-tibial amputation: the relationship between quiet stance ability, strength of hip abductor muscles and gait. *Physiother Res Int, 7*(4), 203-214.

Naeder, M., & Naeder, H.-G. (Eds.). (2000). *Prothesen-Kompendium, Untere Extremitaet* (3 ed.). Berlin: Schiele & Schoen.

Narita, H., Yokogushi, K., Shii, S., Kakizawa, M., & Nosaka, T. (1997). Suspension effect and dynamic evaluation of the total surface bearing (TSB) trans-tibial prosthesis: a comparison with the patellar tendon bearing (PTB) trans-tibial prosthesis. *Prosthet Orthot Int, 21*(3), 175-178.

Narita, H., Yokogushi, K., Ship, S., Kakizawa, M., & Nosaka, T. (1997). Suspension effect and dynamic evaluation of the total surface bearing (TSB) trans-tibial prosthesis: a comparison with the patellar tendon bearing (PTB) trans-tibial prosthesis. *Prosthetics and Orthotics International, 21*, 175-178.

Neal, M., Neptune, R. R., & Gitter, A. (2003). *Neuromotor Adaptations used by Unilateral Transtibial Amputees during normal Walking.* Paper presented at the 27th Annual Meeting of the American Society of Biomechanics, Toledo. OH.

Nene, A., Mayagoitia, R., & Veltink, P. (1999). Assessment of rectus femoris function during initial swing phase. *Gait & Posture, 9*(1), 1-9.

Neumann, E. S. (2009). State-of-the-Science Review of Transtibial Prosthesis Alignment Perturbation. *Journal of Prosthetics & Orthotics, 21*(4), 175-193.

Neumann, E. S., Yalamanchili, K., Brink, J., & Lee, J. S. (2012). Transducer-based comparisons of the prosthetic feet used by transtibial amputees for different walking activities: a pilot study. *Prosthetics and Orthotics International, 36*(2), 203-216.

Nielsen, C., Psonak, R., & Kalter, T. (1989). Factors Affecting the Use of Prosthetic Services. *Journal of Prosthetics & Orthotics, 1*(4), 242-249.

Nielsen, D., Shurr, D., Golden, J., & Meier, K. (1988). Comparison of Energy Cost and Gait Efficiency During Ambulation in Below-Knee Amputees Using Different Prosthetic Feet - A Preliminary Report. *JPO Journal of Prosthetics & Orthotics, 1*(1), 24-31.

Nietert, M. (2008). *The Compromise Pivot Axis of the Knee Joint: Studies of the Kinematics of the Human Knee Joint in Regard to Their Approximation in Prosthetics (Berichte Aus Der Medizin)*. Aachen, Germany: Shaker.

Nolan, L., Wit, A., Dudziñski, K., Lees, A., Lake, M., & Wychowañski, M. (2003). Adjustments in gait symmetry with walking speed in trans-femoral and trans-tibial amputees. *Gait & Posture, 17*(2), 142-151.

O'Connor, K., & Bottum, M. (2009). Differences in cutting knee mechanics based on principal components analysis. *Med Sci Sports Exerc, 41*(4), 867-878.

Oggero, E., Pagnacco, G., Morr, D., Simon, S., & Berme, N. (1997). Probability of valid gait data acquisition using currently available force plates. *Biomed Sci Instrum, 34*, 392-397.

Ooi, S., Abu Osman, N., & Wan Abas, W. (2010). *Ambulatory Function Monitor of the Amputees with Their Prosthesis.* Paper presented at the 6th World Congress of Biomechanics (WCB 2010) Singapore.

Orendurff, M., Schoen, J., Bernatz, G., Segal, A., & Klute, G. (2008). How humans walk: bout duration, steps per bout, and rest duration. *J Rehabil Res Dev, 45*(7), 1077-1089.

Orendurff, M., Segal, A., Klute, G., McDowell, M., Pecoraro, J., & Czerniecki, J. (2006). Gait efficiency using the C-Leg. *J Rehabil Res Dev, 43*(2), 239-246.

Papaioannou, G., Demetropoulos, C. K., & King, Y. H. (2010). Predicting the effects of knee focal articular surface injury with a patient-specific finite element model. *The Knee, 17*(1), 61-68.

Papaioannou, G., Mitrogiannis, C., Nianios, G., & Fiedler, G. (2010). Assessment of amputee socketstump-residual bone kinematics during strenuous activities using Dynamic Roentgen Stereogrammetric Analysis. *Journal of Biomechanics, 22*(43(5)), 871-878.

Papaioannou, G., & Wood, J. R. (2011, March 16-19, 2011). *Transtibial Prosthetic Kinetics During Prolonged Strenuous Activities of Daily Living Measures by Internal Gait Analysis Instrumentation.* Paper presented at the 37th Annual Meeting of the AAOP, Orlando, FL.

Parkka, J., Ermes, M., Korpipaa, P., Mantyjarvi, J., Peltola, J., & Korhonen, I. (2006). Activity classification using realistic data from wearable sensors. *Information Technology in Biomedicine, IEEE Transactions on, 10*(1), 119-128

Pasquina, P. F., Tsao, J. W., Collins, D. M., Chan, B. L., Charrow, A., Karmarkar, A. M., & Cooper, R. A. (2008). Quality of medical care provided to service members with combatrelated limb amputations: Report of patient satisfaction. *Journal of Rehabilitation Research & Development, 45*(7), 953-960.

Perry, S. D., Radtke, A., McIlroy, W. E., Fernie, G. R., & Maki, B. E. (2007). Efficacy and Effectiveness of a Balance-Enhancing Insole. *The Journals of Gerontology: Series A, 63*(6), 595-602.

Pezzin, L., Dillingham, T., MacKenzie, E., Ephraim, P., & Rossbach, P. (2004). Use and satisfaction with prosthetic limb devices and related services. *Archives of Physical Medicine and Rehabilitation, 85*(5), 723-729.

Piazza, S. J., & Delp, S. L. (1996). The influence of muscles on knee flexion during the swing phase of gait. *Journal of Biomechanics, 29*(6), 723-733.

Pinzur, M., Cox, W., Kaiser, J., Morris, T., Patwardhan, A., & Vrbos, L. (1995). The effect of prosthetic alignment on relative limb loading in persons with trans-tibial amputation: a preliminary report. *J Rehabil Res Dev, 32*(4), 373-377.

Postema, K., Hermens, H., de Vries, J., Koopman, H., & Eisma, W. (1997). Energy storage and release of prosthetic feet. Part 2: Subjective ratings of 2 energy storing and 2 conventional feet, user choice of foot and deciding factor. *Prosthet Orthot Int, 21*(1), 28-34.

Powers, C., Boyd, L., Torburn, L., & Perry, J. (1997). Stair ambulation in persons with transtibial amputation: an analysis of the Seattle LightFoot. *J Rehabil Res Dev, 34*(1), 9-18.

Powers, C. M., Rao, S., & Perry, J. (1998). Knee kinetics in trans-tibial amputee gait. *Gait & Posture, 8*(1), 1-7.

Radcliffe, C. (1994). Four-bar linkage prosthetic knee mechanisms: kinematics, alignment and prescription criteria. *Prosthetics and Orthotics International, 18*(3), 159-173.

Raffin, E., Bonnet, S., & Giraux, P. (2012). Concurrent validation of a magnetometer-based step counter in various walking surfaces. *Gait & Posture, 35*(1), 18-22.

Reinschmidt, C., van den Bogert, A., Lundberg, A., Nigg, B., Murphy, N., Stacoff, A., & Stano, A. (1997). Tibiofemoral and tibiocalcaneal motion during walking: external vs. skeletal markers. *Gait & Posture, 6*(2), 98-109.

Renström, P., Grimby, G., Morelli, B., & Palmertz, B. (1983). Thigh muscle atrophy in below-knee amputees. *Scand J Rehabil Med Suppl, 9*, 150-162.

Rice, J., & Seeley, M. K. (2010). An Investigation of Lower-extremity Functional Asymmetry For Non-preferred Able-bodied Walking Speeds. *International Journal of Exercise Science, 3*(4).

Rogers, J., MacBride, A., Whylie, B., & Freeman, S. (1977-1978). The use of groups in the rehabilitation of amputees. *Int J Psychiatry Med, 8*(3), 243-255.

Rossi, S., Doyle, W., & Skinner, H. (1995). Gait initiation of persons with below-knee amputation: the characterization and comparison of force profiles. *J Rehabil Res Dev, 32*(2), 120-127.

Rupp, S., Hopf, T., Hess, T., Seil, R., & Kohn, D. M. (1999). Resulting Tensile Forces in the Human Bone-Patellar Tendon-Bone Graft: Direct Force Measurement In Vitro. *Arthroscopy: The Journal of Arthroscopic & Related Surgery, 15*(2), 179-184.

S. Blumentritt, M. B., E. Ludwigs, T. Schmalz. (2012). [Zur Biomechanik des mikroprozessorgesteuerten Prothesenkniegelenks Genium] Biomechanics of the Microprocessor-controlled Prosthetic Knee Joint Genium. *Orthopädie-Technik* (1), 24-35.

Sachs, M., Bojunga, J., & Encke, A. (1999). Historical Evolution of Limb Amputation. *World Journal of Surgery, 23*, 1088-1093.

Sadeghi, H., Allard, P., & Duhaime, P. (2001). Muscle power compensatory mechanisms in below-knee amputee gait. *Am J Phys Med Rehabil, 80*(1), 25-32.

Sadeghi, H., Allard, P., Prince, F., & Labelle, H. (2000). Symmetry and limb dominance in able-bodied gait: a review. *Gait & Posture, 12*(1), 34-45.

Sanders, J., Bell, D., Okumura, R., & Dralle, A. (1998). Effects of alignment changes on stance phase pressures and shear stresses on transtibial amputees: measurements from 13 transducer sites. *IEEE Trans Rehabil Eng, 6*(1), 21-31.

Sanders, J., & Daly, C. (1999). Interface pressures and shear stresses: sagittal plane angular alignment effects in three trans-tibial amputee case studies. *Prosthetics and Orthotics International, 23*(1), 21-29.

Sanders, J., Fergason, J., Zachariah, S., & Jacobsen, A. (2002). Interface pressure and shear stress changes with amputee weight loss: case studies from two trans-tibial amputee subjects. *Prosthet Orthot Int, 26*(3), 243-250.

Sanders, J., Miller, R., Berglund, D., & Zachariah, S. (1997). A modular six-directional force sensor for prosthetic assessment: a technical note. *The Journal of Rehabilitation Research and Development, 34*(2), 195-202.

Sanders, J., Reed, R., & Marks, R. (1993). Computer-aided prosthetic alignment for lower-limb amputees. *Engineering in Medicine and Biology Society, . Proceedings of the 15th Annual International Conference of the IEEE* 1282 - 1283.

Sanders, J., Zachariah, S., Baker, A., Greve, J., & Clinton, C. (2000). Effects of changes in cadence, prosthetic componentry, and time on interface pressures and shear stresses of three trans-tibial amputees. *Clin Biomech (Bristol, Avon), 15*(9), 684-694.

Sanderson, D. J., & Martin, P. E. (1996). Joint kinetics in unilateral below-knee amputee patients during running. *Archives of Physical Medicine and Rehabilitation, 77*(12), 1279-1285.

Schache, A., & Baker, R. (2007). On the expression of joint moments during gait. *Gait & Posture, 25*(3), 440-452.

Schmalz, T., Blumentritt, S., & Jarasch, R. (2002). Energy expenditure and biomechanical characteristics of lower limb amputee gait: the influence of prosthetic alignment and different prosthetic components. *Gait Posture, 16*(3), 255-263.

Schmalz, T., Blumentritt, S., & Marx, B. (2007). Biomechanical analysis of stair ambulation in lower limb amputees. *Gait & Posture, 25*(2), 267-278.

Schmalz, T., Blumentritt, S., & Reimers, C. (2001). Selective thigh muscle atrophy in trans-tibial amputees: an ultrasonographic study. *Arch Orthop Trauma Surg, 121*, 307-312.

Seelen, H., Anemaat, S., Janssen, H., & Deckers, J. (2003). Effects of prosthesis alignment on pressure distribution at the stump/socket interface in transtibial amputees during unsupported stance and gait. *Clin Rehabil, 17*(7), 787-796.

Segal, A., Orendurff, M., Czerniecki, J., Shofer, J., & Klute, G. (2009). Transtibial amputee joint rotation moments during straight-line walking and a common turning task with and without a torsion adapter. *J Rehabil Res Dev, 46*(3), 375-383.

Segal, A., Orendurff, M., Klute, G., McDowell, M., Pecoraro, J., Shofer, J., & Czerniecki, J. (2006). Kinematic and kinetic comparisons of transfemoral amputee gait using C-Leg and Mauch SNS prosthetic knees. *J Rehabil Res Dev, 43*(7), 857-870.

Seliktar, R., & Mizrahi, J. (1986). Some gait characteristics of below-knee amputees and their reflection on the ground reaction forces. *Eng Med, 15*, 27-34.

Selles, R., Bussmann, J., Klip, L., Speet, B., Van Soest, A., & Stam, H. (2004). Adaptations to mass perturbations in transtibial amputees: kinetic or kinematic invariance? *Arch Phys Med Rehabil, 85*(12), 2046-2052.

Silverman, A., Fey, N., Portillo, A., Walden, J., Bosker, G., & Neptune, R. (2008). Compensatory mechanisms in below-knee amputee gait in response to increasing steady-state walking speeds. *Gait & Posture, 28*(4), 602-609.

Sin, S., Chow, D., & Cheng, J. (2001). Significance of non-level walking on transtibial prosthesis fitting with particular reference to the effects of anterior-posterior alignment. *J Rehabil Res Dev, 38*(1), 1-6.

Sjödahl, C., Jarnlo, G., & Persson, B. (2001). Gait improvement in unilateral transfemoral amputees by a combined psychological and physiotherapeutic treatment. *J Rehabil Med, 33*(3), 114-118.

Skinner, H., & Effeney, D. (1985). Gait analysis in amputees. *American Journal of Physical Medicine & Rehabilitation, 64*(2), 82-89.

Slavens, B., Sturm, P., Bajournaite, R., & Harris, G. (2009). Upper extremity dynamics during Lofstrand crutch-assisted gait in children with myelomeningocele. *Gait & Posture, 4*(30), 511-517.

Smets, E., Garssen, B., Bonke, B., & De Haes, J. (1995). The Multidimensional Fatigue Inventory (MFI) psychometric qualities of an instrument to assess fatigue. *J Psychosom Res, 39*(3), 315-325.

Smith, R. (1996). Measuring the outcomes of assistive technology: challenge and innovation. *Assist Technol., 8*(2), 71-81.

Snyder, R., Powers, C., Fontaine, C., & Perry, J. (1995). The effect of five prosthetic feet on the gait and loading of the sound limb in dysvascular below-knee amputees. *J Rehabil Res Dev, 32*(4), 309-315.

Soares, A. S. O. d. C., Yamaguti, E. Y., Mochizuki, L., Amadio, A. C., & Serrão, J. C. (2009). Biomechanical parameters of gait among transtibial amputees: a review. *Sao Paulo Med J, 127*(5), 302-309.

Söderberg, B., Ryd, L., & Persson, B. M. (2003). Roentgen Stereophotogrammetric Analysis of Motion between the Bone and the Socket in a Transtibial Amputation Prosthesis: A Case Study. *Journal of Prosthetics & Orthotics, 15*(3), 95-99.

Sosnoff, J. J., Sandroff, B. M., & Motl, R. W. (2012). Quantifying gait abnormalities in persons with multiple sclerosis with minimal disability. *Gait & Posture, 36*(1), 154-156.

Stauffer, R., Chao, E., & Brewster, R. (1977). Force and motion analysis of the normal, diseased, and prosthetic ankle joint. *Clin Orthop Relat Res, 127*, 189-196.

Stevens, P. M., & Carson, R. (2007). Case Report: Using the Activities-Specific Balance Confidence Scale to Quantify the Impact of Prosthetic Knee Choice on Balance Confidence. *Journal of Prosthetics & Orthotics, 19*(4), 114-116.

Stineman, M. G., Kurichi, J. E., Kwong, P. L., Maislin, G., Reker, D. M., Vogel, W. B., . . . Bates, B. E. (2009). Survival Analysis in Amputees Based on Physical Independence Grade Achievement. *Arch Surg, 144*(6), 543-552.

Street, G. (2006). Vacuum Suspension and its Effects on the Limb. *Orthopädie-Technik Quarterly, English edition, IV*, 1-7.

Summers, G., Morrison, J., & Cochrane, G. (1988). Amputee walking training: a preliminary study of biomechanical measurements of stance and balance. *Int Disabil Stud, 10*(1), 1-5.

Svoboda, Z., Janura, M., Cabell, L., & Elfmark, M. (2012). Variability of kinetic variables during gait in unilateral transtibial amputees. *Prosthetics and Orthotics International, 36*(2), 225-230.

Takeda, R., Tadano, S., Todoh, M., Morikawa, M., Nakayasu, M., & Yoshinari, S. (2009). Gaitanalysis using gravitational acceleration measured by wearable sensors. *Journal of Biomechanics, 42*(3), 223-233.

Taylor, M., Clark, E., Offord, E., & Baxter, C. (1996). A comparison of energy expenditure by a high level trans-femoral amputee using the Intelligent Prosthesis and conventionally damped prosthetic limbs. *Prosthetics and Orthotics International, 20*(2), 116-121.

Tesio, L., Lanzi, D., & Detrembleur, C. (1998). The 3-D motion of the centre of gravity of the human body during level walking. II. Lower limb amputees. *Clin Biomech (Bristol, Avon), 13*(2), 83-90.

Thompson, B. (1991). A primer on the logic and use of canonical correlation analysis. *Measurement & Evaluation in Counseling & Development, 24*(2), 80-96.

Torburn, L., Perry, J., Ayyappa, E., & Shanfield, S. (1990). Below-knee amputee gait with dynamic elastic response prosthetic feet: a pilot study. *J Rehabil Res Dev, 27*(4), 369-384.

Torburn, L., Powers, C., Guiterrez, R., & Perry, J. (1995). Energy expenditure during ambulation in dysvascular and traumatic below-knee amputees: a comparison of five prosthetic feet. *J Rehabil Res Dev, 32*(2), 111-119.

Torburn, L., Schweiger, G., Perry, J., & Powers, C. (1994). Below-knee amputee gait in stair ambulation. A comparison of stride characteristics using five different prosthetic feet. *Clin Orthop Relat Res, 303*, 185-192.

Tura, A., Raggi, M., Rocchi, L., Cutti, A. G., & Chiari, L. (2010). Gait symmetry and regularity in transfemoral amputees assessed by trunk accelerations. *J Neuroeng Rehabil, 7*(4).

Vagenas, G., & Hoshizaki, B. (1992). A multivariable Analysis of lower extremity kinematic asymmetry in running. *International Journal of Sports Biomechanics, 8*(1), 11-29.

van der Linde, H., Hofstad, C., Geurts, A., Postema, K., Geertzen, J., & van Limbeek, J. (2004). A systematic literature review of the effect of different prosthetic components on human functioning with a lower-limb prosthesis. *Journal of Rehabilitation Research and Development, 41*(4), 555-570.

Van Velzen, J., Houdijk, H., Polomski, W., & Van Bennekom, C. (2005). Usability of gait analysis in the alignment of trans-tibial prostheses: a clinical study. *Prosthetics and Orthotics International, 29*(3), 255-267.

Vanicek, N., Strike, S., McNaughton, L., & Polman, R. (2009). Gait patterns in transtibial amputee fallers vs. non-fallers: biomechanical differences during level walking. *Gait & Posture, 29*(3), 415-420.

Versluys, R., Beyl, P., Van Damme, M., Desomer, A., Van Ham, R., & Lefeber, D. (2009). Prosthetic feet: state-of-the-art review and the importance of mimicking human ankle-foot biomechanics. *Disabil Rehabil Assist Technol, 4*(2), 65-75.

Vickers, D., Palk, C., McIntosh, A., & Beatty, K. (2008). Elderly unilateral transtibial amputee gait on an inclined walkway: a biomechanical analysis. *Gait & Posture, 27*(3), 518-529.

Waters, R., Perry, J., Antonelli, D., & Hislop, H. (1976). Energy cost of walking of amputees: the influence of level of amputation. *The Journal of Bone and Joint Surgery, 58*(1), 42-46.

Wearing, S. C., Urry, S. R., & Smeathers, J. E. (2000). The effect of visual targeting on ground reaction force and temporospatial parameters of gait. *Clinical Biomechanics, 15*(8), 583-591.

White, S., Yack, H., Tucker, C., & Lin, H. (1998). Comparison of vertical ground reaction forces during overground and treadmill walking. *Med Sci Sports Exerc, 30*(10), 1537-1542.

Wilson, J., Asfour, S., Abdelrahman, K., & Gailey, R. (2009). A new methodology to measure the running biomechanics of amputees. *Prosthetics and Orthotics International, 33*(3), 218-229.

Winter, D. A., & Sienko, S. E. (1988). Biomechanics of Below-Knee Amputee Gait. *Journal of Biomechanics, 21*(5), 361-367.

Wolf, A., Swift, J. B., Swinney, H. L., & Vastano, J. A. (1985). Determining Lyapunov exponents from a time series. *Physica D: Nonlinear Phenomena, 16*(3), 285-317.

Worrell, T., & Perrin, D. (1992). Hamstring muscle injury: the influence of strength, flexibility, warm-up, and fatigue. *J Orthop Sports Phys Ther, 16*(1), 12-18.

Wrigley, A. T., Albert, W. J., Deluzio, K. J., & Stevenson, J. M. (2006). Principal component analysis of lifting waveforms. *Clinical Biomechanics 21*, 567-578.

Wurdeman, S. R., Myers, S. A., Jacobsen, A. L., & Stergiou, N. (2012). *Amputee Prosthesis Preference is Related to the Nonlinear Dynamics.* Paper presented at the Gait and Clinical Movement Analysis Society (GCMAS) Conference, Grand Rapids, MI.

Xiaobing, L., Xiaohong, J., Peng, D., & Lidan, F. (2005). Influence of Shoe-heel Height of the Trans-tibial Prosthesis on Static Standing Biomechanics. *Conf Proc IEEE Eng Med Biol Soc, 5*, 5227-5229.

Yamamoto, S., Suto, Y., Kawamura, H., Hashizume, T., Kakurai, S., & Sugahara, S. (1983). Quantitative gait evaluation of hip diseases using principal component analysis. *J Biomech, 16*(9), 717-726.

Yang, L., Solomonidis, S. E., Spence, W. D., & Paul, J. P. (1991). The influence of limb alignment on the gait of above-knee amputees. *Journal of Biomechanics, 24*(11), 981-997.

Yoho, R. M., Wilson, P. K., Gerres, J. A., & Freschi, S. (2008). Chopart's Amputation: A 10-Year Case Study. *The Journal of Foot and Ankle Surgery, 47*(4), 326-331.

Zahedi, M. (1986). Alignment of lower-limb prosthesis. *Journal of Rehabilitation Research and Development, 23*(2), 2-19.

Zahedi, M., Spence, W., Solomomidis, S., & Paul, J. (1987). Repeatability of kinetic and kinematic measurements in gait studies of the lower limb amputee. *Prosthetics and Orthotics International, 11*, 55-64.

Zeni Jr., J. A., & Higginson, J. S. (2010). Gait parameters and stride-to-stride variability during familiarization to walking on a split-belt treadmill. *Clinical Biomechanics, 25*(4), 383-386.

Ziegler-Graham, K., MacKenzie, E., Ephraim, P., Travison, T., & Brookmeyer, R. (2008). Estimating the prevalence of limb loss in the United States: 2005 to 2050. *Arch Phys Med Rehabil, 89*(3), 422-429.

Zmitrewicz, R., Neptune, R., Walden, J., Rogers, W., & Bosker, G. (2006). The effect of foot and ankle prosthetic components on braking and propulsive impulses during transtibial amputee gait. *Arch Phys Med Rehabil, 87*(10), 1334-1339.

Zmitrewicz, R. J., Neptune, R. R., & Sasaki, K. (2007). Mechanical energetic contributions from individual muscles and elastic prosthetic feet during symmetric unilateral transtibial amputee walking: A theoretical study. *Journal of Biomechanics 40*, 1824-1831.

6 Appendix A: Literature Review

6.1 Introduction and State of the Arts

6.1.1 Significance of prosthetics

Limb loss is obviously a severe medical condition that has potentially life changing consequences for the respective patient. The literature on the topic offers divergent information on the exact prevalence of amputation. A study from 2002 (Dillingham et al., 2002) addressed the question by analyzing a large number of hospital discharge records, encompassing about 20% of the respective documents issued in the United States between the years of 1988 and 1996. According to this study, the average annual number of limb-loss-related hospital discharges is 133,325 nationwide, and the corrected increase is approximately 3% every year. Corrected for population effects, the total number of amputations increased by 27% during the period of the study. As for the explanation, the authors refer to "[increased] prevalences of diabetes, smoking, hypertension, and hypercholesterolemia [that may] be contributing to the increasing rates of dysvascular amputations." (Dillingham et al., 2002)

Epidemiology of Limb Loss and Congenital Limb Deficiency in a global scope was investigated later by an extensive literature review of the same research group (Ephraim, Dillingham, Sector, Pezzin, & MacKenzie, 2003). In the general category of lower limb amputations, incidence rates varied between 0.1/10,000 for Japanese women and 4.4/10,000 for male inhabitants of the Navajo region of the United States. On average, the incidence rate in the U.S. appears to be comparable to other countries, such as the United Kingdom, with 1.9/10,000 for men and 1.3/10,000 for women. Amputation rates are by trend increasing, which is especially true for diabetes and vascular disease related causes.

Those epidemiologic data allow for estimates of the total prevalence of amputations at a given time (Ziegler-Graham et al., 2008). "[Using] age-, sex-, and race-specific incidence rates for amputation combined with age-, sex-, and race-specific assumptions about mortality" the authors computed the estimated actual number of amputees living in the United States, as well as the predicted number for the years through 2050. Results of the study indicate that about 1.6 million Americans are living with limb loss today (that is the year 2005), and that this number will reach 3.6 million by the year 2050

Continuous research was conducted to answer the question, how well prostheses are perceived by their respective users (Pezzin et al., 2004). By means of structured telephone interviews, the authors collected data from 1538 persons with amputation of the lower or upper extremity. Of the participants 94.5% had prosthesis and used it extensively. However, only 75.7% were overall satisfied with their prosthesis, where the socket fit was least acceptable (75.5%) behind appearance (80.4%) and weight (77.1%). The level of content could be related to the time span that went by between surgery and the receiving of the first prosthesis, as "those who were fitted later in the rehabilitation process—most notably, those waiting more than 60 days to first prosthesis fitting—were less likely to be satisfied with the prosthesis fit … and overall performance" (Pezzin et al., 2004).

6.1.2 Prosthetics in historical and medical context

Technological progress in prosthetics is a matter of several levels. The first area of intervention is the amputation surgery itself. Steady modification of the initially used amputation technique, in which the leg with a single Pitch of the surgical knife was cut to the bone, begun already in the 18th Century (Sachs, Bojunga, & Encke, 1999). At the beginning of the 20th Century, the first myoplastic techniques were applied, where the antagonistic muscle groups on the bone end were stitched together to improve soft tissue coverage, improved strength and agility of the stump. Following the amputation, it is the rehabilitation regimen that influences the physical abilities of the amputee. (Esquenazi & DiGiacomo, 2001) summarize the measures that should be applied in order to avoid depression, joint contraction and post-surgical pain, while promoting wound healing, cardiovascular condition, muscle strength, and balance prior and during the early stages of prosthetic training.

Beyond the amputation technique, the efficiency of a prosthetic leg fitting is a function of socket design and the prosthesis technology. In trans-tibial prosthetics, different socket designs have been successfully implemented, including the still popular Patellar Tendon Bearing (PTB), and the Total Surface Bearing (TSB) socket (Foort, 1965; Narita, Yokogushi, Ship, Kakizawa, & Nosaka, 1997). In the field of functional exo-prosthetic parts, such as knee joints, shock absorbers, rotational adapters, or feet, extended research and development has been done over the years (Gitter et al., 1991; B Hafner, Willingham, Buell, Allyn, & Smith, 2007; H Herr & Wilkenfeld, 2003; Michael, 1999; Radcliffe, 1994; van der Linde et al., 2004)(to name a few). However, those functional components are considered only a minor part of the overall prosthetic performance, as even the best hardware will not have a benefit for the user as long as the socket does not fit properly. Accordingly, the socket fit is considered the decisive factor (Legro et al., 1999; Miller & McCay, 2006).

In a wider sense, this includes prosthetic alignment. Also a very important factor for the overall performance of the prosthesis, it is determined usually based on rather coarse and subjective gait evaluation data. Even more so than a poorly fitting socket, a flawed static alignment might be compensated by conscious or subconscious efforts sides the amputee during locomotion (Neal, Neptune, & Gitter, 2003). This further complicates the visual assessment, but may also suggest that there is a certain acceptable range of variability of prosthetic alignment. Respective studies came to the conclusion that a “prosthetist could not repeat a given alignment at will. In fact a number of alignments were acceptable to the patient and prosthetist. Different prosthetists produced different ranges on any one patient, and these ranges varied on AP and ML views with different prosthetists" (Zahedi, 1986; Zahedi, Spence, Solomomidis, & Paul, 1987).

6.1.3 Previous research on amputee gait

With above annotations in mind, the following review is intended to illustrate the various aspects of amputee gait that have been addressed by researchers so far. Starting with the basic research that has helped understand the biomechanical characteristics of amputee locomotion, and the diverse gait analysis tools and methods that have been used to that end, our discussion will subsequently focus in on the issue of gait symmetry, as this is a critical variable in our proposed study. In the same sense, the emphasis of the review is put on trans-tibial prostheses. Their alignment poses a comparably straightforward challenge, as they come with fewer degrees of freedom than trans-femoral or other higher level leg prostheses, yet there are many questions still unanswered or at least debated in the literature. While introducing selected publications on the topic, it will be attempted to draw connections to the proposed work, whenever there is a relevant aspect to be considered in our context. Likewise, established data collection methods will be introduced towards the end of this chapter in order to support the study design that will be explained in detail within subchapter 6.2.

6.1.4 Biomechanical specifics in trans-tibial prosthetics

Investigating the gait biomechanics that are specific to below-knee-prosthesis walking, (Winter & Sienko, 1988) conducted a gait study with eight unilateral transtibial amputees, wearing prostheses with different foot components (SACH and Greissinger). Conventional motion capturing and force plate measurements were combined with surface electromyography of several residual leg muscles. Upon normalizing the obtained forces and moments to body mass, the respective curves were compared to baseline curves of a non-amputee population. The authors came to the conclusion that amputees display a modified motor pattern in walking, although without being able to tell whether those modifications are optimal in the individual case.

Generally, this paper has delivered the groundwork for many subsequent studies, and has been referenced extensively in the literature since. The used systematic segmentation and description of the amputee gait cycle has introduced a scientific approach to gait assessment, and has helped clarify the specific conditions during ambulation on an artificial limb. Although, the amount of collected data was considerable, as were the computed moments and forces, the study could not conclusively answer whether the observed differences of amputee subjects walking to the familiar pattern of normal gait are undesirable deviations from the ideal, or rather inevitable results of efficient adaptations to the specific situation of this condition.

Trans-tibial amputee gait is by now very well understood in terms of typical joint force and moment curves (Cappozzo, 1984; Stauffer, Chao, & Brewster, 1977), on level ground, stairs and uneven surfaces (Torburn, Schweiger, Perry, & Powers, 1994; Vickers et al., 2008). Studies have been conducted investigating the influence of different socket designs and prosthesis components (Board, Street, & Caspers, 2001; Czerniecki, Gitter, & Munro, 1991; Taylor, Clark, Offord, & Baxter, 1996; Torburn, Perry, Ayyappa, & Shanfield, 1990), residual limb length, activity level, and diagnosis (Andrews, 1996; Davis, Kuznicki, Praveen, & Sferra, 2004; Sadeghi et al., 2001; Waters, Perry, Antonelli, & Hislop, 1976). The questions of gait efficiency, dynamic and safety have been scrutinized (Barth, Schumacher, & Thomas, 1992; Schmalz et al., 2002; Vanicek et al., 2009), and recommendations for surgery, rehabilitation therapy, and prosthetic prescription have been issued (Cortés, Viosca, Hoyos, Prat, & Sánchez-Lacuesta, 1997; Houghton, Taylor, Thurlow, Rootes, & McColl, 1992; Segal et al., 2006; Sjödahl, Jarnlo, &

Persson, 2001; Summers et al., 1988). Much of the research work in the field is still based to big parts or even entirely on motion analysis and force plate measurements.

6.1.4.1 Reliability of gait assessment

Given the popularity of force plate equipment among researchers, the reliability of such amputee gait assessment is an important factor to quantify. Studies on the "variability of the basic dynamic gait parameters of physically active persons with unilateral trans-tibial amputation" include one by Janura et al [69], where variability between subjects as well as within subjects was evaluated and compared. Hereby it was found that the "inter-individual variability … is higher [than] the intraindividual variability", and that "the coefficients of reliability … exceeded for measured parameters (time, force, force impulse) … the value 0.976" (Janura, Svoboda, & Elfmark, 2006). It was noted that those coefficients depended on individual given facts of the respective subjects. The study design suggests meaningful comparisons of sound leg and prosthesis based on the measured ground reaction forces. This is an interesting approach that supports the premise of inline assembly of force sensors for gait analysis purposes, as it was undertaken in this dissertation work. However, kinematic data and joint moments, which are relevant in gait analysis as well, have not been regarded or discussed in Janura's article. Hence, it could be argued that the quantity of measured variables was not sufficient to justify generally applicable conclusions on amputee gait.

6.1.4.2 Muscle force and muscle activity measurements

Something that cannot be directly measured by kinetic gait analysis is the muscle activity that facilitates the walking pattern. Due to the severely changed structure of the affected limb after an amputation, the effective muscle strength is likely reduced when compared to the sound limb. (Nadollek et al., 2002) published a respective study that was investigating this hypothesis.

23 unilateral trans-tibial amputee participated in the data collection by standing “on two adjacent forceplates whilst the weight distribution and standard deviation (SD) of the … centre of pressure excursion (COPE) under each limb was recorded…”A simple gait analysis was conducted as well, to obtain correlation variables. Despite some bilateral differences in CPOE, no “differences in muscle strength or gait measures between limbs were demonstrated. However, strong hip abductor muscles were correlated with increased weight-bearing on the amputated limb, improved gait parameters and reduced medio-lateral COPE under the amputated limb” (Nadollek et al., 2002). In conclusion, it was recommended to strengthen the hip abductor muscles by appropriate training efforts.

After Winter & Sienko already had included electromyography measurements in their studies of amputee gait, this method has been a mainstay of related research. EMG captures the electrical potential changes on the skin surface that occur as a result of the activation of the underlying muscles. Muscle force is a function of the muscle dimensions (physiologic cross-sectional area) and the frequency in which electrical stimuli (action potentials) are applied (the phenomenon of muscle fatigue factors in as well, but will be discussed at a later point). Since muscle composition and dimensions are usually constant over time, the obtained EMG signals can be closely correlated with the actual muscle force. (Bolgla & Uhl, 2007) published the results of a study that “was to determine the reliability of three normalization methods for analyzing hip abductor activation during rehabilitation exercises.” A more recent study (Murley, Menz, Landorf, & Bird, 2010) was investigating the reliability of EMG measurements with respect to successive data collection sessions, which was also related to the used normalization technique. While the results somewhat contradict the Bolgla study above, the information that time-of-peak amplitude is the most reliable evaluation parameter in walking trials stands uncontested and can be used for respective experiments, such as the here proposed one.

The issue of noise filtering was addressed in an article by (De Luca, Gilmore, Kuznetsov, & Roy, 2010), who had noted that typical recommendations for filter bandwidths are often based merely on literature reviews rather than empirical studies. The findings “indicate that the 10 Hz filter does not fully remove the artifact; and the 30 Hz filter, while successfully attenuating the artifact, also removes a portion of the lower frequency components of the sEMG signal” (De Luca et al., 2010). In conclusion, there is no optimal cutoff frequency for general EMG measurements. Instead the selected bandwidth of the filter is a compromise that “may be determined by considering the percentage of movement artifact and the percentage of EMG signal loss as a function of frequency increment”. For instance, when measuring “muscle groups which have lower frequency distribution than those tested in this study, such as the … quadriceps muscles … a 20 Hz corner frequency is still appropriate” according to the authors.

6.1.4.3 EMG methodology and findings in TT amputees

EMG characteristics of amputee walking were investigated by (Isakov, Keren, & Benjuya, 2000), who analyzed “14 traumatic TT amputees, walking at a mean speed of 74.96 m/min...” placing “Surface electrodes … over the quadriceps (vastus medialis-VM) and hamstrings (biceps femoris-BF) of both the amputated and non-amputated thighs”. Among the results was the finding that the “biceps femoris/vastus medialis ratio in the amputated leg, during the first half of stance phase, was significantly higher when compared to the same muscle ratio in the sound leg. This difference was due to the higher activity of the biceps femoris, almost four times higher than the vastus medialis in the amputated leg.” The authors discuss the implied gait asymmetry which agrees with findings of previous studies, and may be explained with the above normal knee flexor moment in trans-tibial amputee walking due to the rigid ankle and the static alignment of the socket with respect to the foot. Strength training has been proposed to increase the symmetry of walking, as well as the development of advanced prosthetic components. Beyond that, the method suggests itself for the investigation of alignment perturbations, and is thus relevant for our study design.

More recently, (Fey et al., 2010) compared EMG activity between sound and residual limb in amputee walking, with the objective to “identify changes in muscle activity in below-knee amputees in response to increasing steady-state walking speeds.” Generally, they concluded, that “[most] amputee EMG patterns were similar between legs and increased in magnitude with speed. Differences occurred in the residual leg biceps femoris long head, vastus lateralis and rectus femoris, which increased in magnitude during braking compared to the intact leg.” On the question of compensatory activity in sound legs of amputees, only the gluteus medius at a higher walking speed had a different pattern in amputees. Overall, the results can be interpreted that a comparison across subjects will not necessarily be helpful in identifying compensatory mechanisms, as those – if they occur at all – are not represented by typical EMG signals for isolated muscles.

6.1.4.4 Computer modeling of alignment changes

(Fang, Jia, & Wang, 2007) noted the insufficiency of moment and force calculations from motion analysis data and EMG measurements, thus making the case for a computer model to predict changes in muscle forces in response to alignment adjustments of the prostheses: ”The musculoskeletal modeling proves to be useful in a wide field of human biomechanics, and is mostly used to be predicting muscle forces, ligaments and articular loading ...”. Based on typical segment dimensions and masses that have been reported in the literature, a two dimensional model of the amputated leg together with the prosthesis was developed. Seven independent muscle groups were included, and the prosthesis socket was assumed “to attach to the stump firmly without any slippage or rotation”. The known characteristics and contraction statuses of the muscles were inserted in a static optimization algorithm that had the objective to minimize total muscle fatigue as the performance criterion. With the several muscles involved, this optimum would be a combination of different fatigue levels in response to simulated prosthesis alignment changes. Also, the solution is time variant and was hence computed over 100 time points during the step cycle.

In conclusion, it was found that the temporal distribution of predicted muscle forces remains widely unaffected by alignment perturbations. However, peak forces were shown to be significantly affected by the described alignment changes.

(R. J. Zmitrewicz, Neptune, & Sasaki, 2007) used a musculoskeletal model to investigate the question of energy contribution from individual muscles. A standard SIMM leg model was modified to include the artificial foot, which was chosen to be an “Energy Storage And Return” (ESAR) foot type. The results of this theoretical study indicated that with such feet a symmetrical gait pattern can be achieved, albeit not without compensatory work by both the residual and the contra-lateral intact leg.

A criticism of this study approach could be that no slip or similar interaction between prosthesis and residual limb was factored in. Against the background of the considerable extent of those relative motions, as has been shown in various studies on stump-socket interaction (Balogh, 2008; Papaioannou, Mitrogiannis, Nianios, & Fiedler, 2010; Street, 2006), it remains questionable whether a model as the described one is sufficiently representing real life conditions. In conclusion, there is a legit demand for actual intervention studies to determine the effects of prosthesis settings on walking.

6.1.4.5 Measuring muscle dimensions

An indirect method to determine muscle force was applied by (Schmalz, Blumentritt, & Reimers, 2001), who investigated the atrophy of residual leg muscles and nerves in amputees by ultra-sonography. Muscle thickness and cross sectional area were then compared between amputated and unaffected leg. Differences were significant for five of the eight examined muscles, especially the rectus femoris and sartorius muscles that were reduced in thickness and cross sectional area.

While following a convincing premise, the here discussed method is obviously not applicable for clinical use in the actual alignment optimization of prosthesis, as the observed muscle atrophies are a long term result of prosthesis use. It does however demonstrate the physiological changes inherent to prosthetic walking. Muscle cross sectional area changes in response to their utilization frequency and magnitude. The reported atrophies hint at either a more effective walking pattern in amputees, or – more likely – an adaptation of the gait style that favors the remaining muscles at the expense of natural appearance.

6.1.5 Common limitations and standards in research on artificial limbs

The so far discussed amputee studies demonstrate a fairly wide spectrum of scientific activity, as well as the appropriate utilization of sound principles in terms of experimental design and statistical evaluation. However, those examples might not be representative of the typical research that has been published in the field: For one, many studies do not bridge the gap between basic and applied research and thus lack practical significance (Theo Mulder, Nienhuis, & Pauwels, 1998)]. Then again, in cases where actual interventions have been investigated, the scientific value and validity is often debatable.

Prosthetics and Orthotics (P&O) is traditionally a trade that depends widely on the practitioner's personal professional experience. Accordingly, the consistent quality of prosthetic fittings can be questioned, which was done in a study by (Geil, 2002) who "determined the outcomes of the alignment of five different prosthetic practitioners given the same subject and components using kinematic and kinetic gait analysis. Differences in static alignment were quantified through instrumented gait analysis…" He found that "however, these differences were relatively small [which might suggest] that automated alignment is probably feasible". The results of this study somewhat contradict the findings of (Zahedi et al., 1987) that are discussed above.

Geil himself, in a later work (Geil, 2009), deliberates on the validity of studies with a limited sample size, as they are very commonly found in the field of prosthetics and orthotics: "research in P&O relies on basic research from other disciplines if it relies on basic research at all. While this phenomenon is partly due to the relative youth of sophisticated P&O research, the applied nature of the field also lends itself to applied research" (Geil, 2009). On the issue of P&O research, Geil goes on to lament "the dearth of randomized controlled trials, low numbers of subjects, difficulties in blinding subjects, variability in subject populations, threats to validity … and a host of other challenges. … Because P&O components are external and widely variable in appearance and function and because they are only suitable for certain individuals, randomized controlled trials are often impossible for component studies."

6.1.5.1 Criticism of studies on prosthetic alignment and gait performance

There have been several studies investigating amputee gait, and comparing results between different alignment settings. Neumann (Neumann, 2009) in a recent review of the literature lists 34 articles, sorted by type of perturbation and measured outcome. Among the included studies, most involved the measurement of ground reaction forces, as well as perturbations in the sagittal plane. Almost all studies utilized a longitudinal design, where each subject serves as their own control, and measurements are conducted at different levels or types of intervention. Notable is also, that more than half of the studies were done with five or fewer subjects, while the largest number of participants in any of the studies was 18. Accordingly, the level of confidence in the results of individual studies that could be assigned by the reviewers was often low. On the question of external validity, findings were compared across studies when possible. The result was that of 113 evidence statements overall, only "two were rated at a high level of confidence, 41 at a moderate level of confidence, and the remaining 70 as having insufficient evidence to support the statement."

The two statements that rated high on the confidence scale were "A range of socket flexion-extension angular alignments and a range of foot anterior-posterior translations seem to be acceptable to the amputee, with interactions between the two alignment variables limiting acceptable conditions", which was a finding in 6 different studies, and "Walking speed exhibits no significant change with perturbation of socket angular alignment, foot linear position, or foot transverse angular position", which was supported by a total of 7 studies. However, it is noted that contradicting observations were also reported, albeit mainly in studies with a low internal validity rating. Moreover, the fact that the reviewed studies were usually conducted with experienced prosthesis users and inside a gait laboratory raised the concern that the results might not be automatically transferable "to new amputees or to nonlaboratory conditions".

Considering the apparent range of alignments that is acceptable, it is concluded that "the subjective acceptability to the amputees of the initial alignment and subsequent alignment resulting from perturbations" should be measured in order to assure repeatability of the experiments. In the same sense, initial alignment settings should be described quantitatively.

Both issues call for the development of objective measuring methods and tools to facilitate a respective comparability and repeatability of prosthesis studies. Furthermore, it was concluded that many of the studies did not present “conclusions that were useful for alignment. As a result, few of the studies produced findings, which could be applied directly in the clinic.”

The verdict on the question of optimal alignment is that “as a whole, there is insufficient evidence to make statements about the existence of measurable variables that define an optimal alignment” (Neumann, 2009). Statements with high confidence only confirm that certain parameters do not indicate misalignment. While some studies suggest that parameters exist that are correlated with alignment quality, those belong to the group of studies with low or insufficient confidence rating.

6.1.5.2 Reviewing research relating to gait parameters, and typical interventions within

Less critical reviews exist, and a selection shall be discussed here to help illustrate the various aspects of amputee gait research, as well as some more or less well established findings.

A total of 115 publications on “biomechanical parameters of gait among trans-tibial amputees” have been reviewed and summarized in a review article by (Soares, Yamaguti, Mochizuki, Amadio, & Serrão, 2009). Some of the reviewed studies were addressing gait velocity as an outcome measure. Here, it was found that prosthetic components play a minor role. Instead, the physical abilities of the patient are determining factors.

Interesting in our context are the conclusions that are stated on the question of gait symmetry: “With regard to inter-limb symmetry, Dingwell et al ... presented an important discussion on this subject. There have been several studies on symmetry as a measurement index for the efficiency of walk among amputees… According to Winter and Sienko … structural asymmetry in amputees creates adaptations to the musculoskeletal and nervous systems that consequently lead to an asymmetric pattern. These authors therefore rejected the presumption that efficiency of walk among unilateral transtibial amputees is linked to symmetry.” On the other hand, the review identified statements that support a contrary view: “Prior use of GRF to analyze inter-limb symmetry is an important indicator of mechanical overload imposed on the lower limbs… Chronic abnormalities of gait, as occur in cases of lower-limb amputation, may lead to degenerative problems such as meniscus lesions…” (Soares et al., 2009). In summary, standardized assessment methods are rarely established or even applied, mostly due to the fact that the subject population is highly heterogeneous, and that there is a large number of possible outcome measures that suggest themselves for evaluation. Furthermore, the findings and interpretations thereof of different studies in the field are not always consistent. Especially with regard to the validity of inter-limb symmetry as an outcome criterion, authors have published various conclusions, which in consequence leave this question unanswered. Further discussion of this problem follows later in this chapter.

Aside from exchanging prosthetic components such as feet (Barth et al., 1992; A. Hansen, Childress, & Knox, 2000; D. Nielsen, Shurr, Golden, & Meier, 1988; Snyder, Powers, Fontaine, & Perry, 1995; R. Zmitrewicz, Neptune, Walden, Rogers, & Bosker, 2006), or adding adapters, such as torsion adapter or vertical damping units (Berge, Czerniecki, & Klute, 2005; Gard & Konz, 2003; Segal, Orendurff, Czerniecki, Shofer, & Klute, 2009), it was mainly the static alignment of the artificial limb that was altered as an experimental intervention (Fridman et al., 2003; Sanders et al., 1998; Schmalz et al., 2002).

Very little is known on the effects of fatigue on the walking pattern. In fact, generally efforts have been made to design study protocols so that fatigue would not occur and thus skew the findings (Buckley, Jones, & Birch, 2002; Sanders, Zachariah, Baker, Greve, & Clinton, 2000;

Torburn, Powers, Guiterrez, & Perry, 1995). In cases where fatigue was discussed as a relevant factor, its extent was not quantified. Instead, statements such as “Three of the amputees did not perform the … condition because of general fatigue caused by the walking” (Selles et al., 2004) or acknowledgement of the mere fact that subjects were experiencing fatigue were included. While there is an extensive body of literature on the question of fatigue in able-bodied subjects, it remains unclear how applicable the respective methods and findings are to an amputee population.

6.1.6 Fatigue as a variable in amputee research

Generally, fatigue is a very broad concept that can be applied to any kind of physical or mental exhaustion, usually after a respectively tiring activity. With respect to the muscular strength, “[fatigue] may be defined as a reduction in the maximal force-generating capacity of a muscle.” (Gandevia, 1992). Countless studies have been conducted to investigate the mechanisms that cause muscle fatigue (Fitts, 1994), to identify how fatigue affects physical performance (Amann & Dempsey, 2008), describe how it alters joint mechanics and injury risk (Coventry, O'Connor, Hart, Earl, & Ebersole, 2006; Worrell & Perrin, 1992), and to develop diagnostics and treatment methods for underlying conditions (Bakshi, 2003), to name just a few of the related research questions.

In the context of the proposed study, determining the level of fatigue -or exhaustion- is of interest to investigate the question if prosthesis performance is depending on the user’s muscle fatigue, and eventually, if the alignment that appears optimal for a rested user turns out to be less than optimal once fatigue sets in. The fatigue that is logically associated with ambulation is more of the systemic kind since multiple muscles are involved to varying degrees, and factors such as cardiovascular endurance as well as pain sensation are likely to influence the overall level of exhaustion. Since the fatigue from walking is not limited in location, as the case in localized muscle fatigue that has been described by (Chaffin, 1973), it is difficult to simulate the effects in the laboratory without actually having the subject walk until tired.

6.1.6.1 Role of specific muscle groups in amputee gait

Previous studies investigated which muscles – in both legs – experience the highest work load in trans-tibial amputees (Isakov, Burger, Krajnik, Gregoric, & Marincek, 2001; Isakov et al., 2000; Moirenfeld, Ayalon, Ben-Sira, & Isakov, 2000; Renström, Grimby, Morelli, & Palmertz, 1983; Schmalz et al., 2001; Winter & Sienko, 1988; R. J. Zmitrewicz et al., 2007). In summary, it seem to be mostly the hip flexor and extensor muscles of the thigh that carry the workload of walking with a trans-tibial prosthesis. Their contribution is even more pronounced for the biarticular muscles that also affect the knee joint.

While it is undeniable that muscles contribute differently to the gait pattern in amputees than in able-bodied subjects, it remains unclear to what extent muscle fatigue influences the outcome with respect to gait symmetry. (Moirenfeld et al., 2000) discussed the implied safety and overall performance deficits, and it seems logical to assume that walking symmetry is affected in a similar sense. A literature search does not bring up any publications on this assumed interrelation.

One option for assessing muscle fatigue is the derivation from EMG readings. Respective algorithms have been proposed and refined for many decades (Cifrek, Medved, Tonkovic, & Ostojic, 2009; Lindström, Kadefors, & Petersén, 1977; Merletti, Lo Conte, & Orizio, 1991). Another way of measuring actual fatigue would be by means of self-assessment questionnaires. (Berge et al., 2005) in their prosthesis walking study utilized a quite complex questionnaire, the Multidimensional Fatigue Inventory (Smets, Garssen, Bonke, & De Haes, 1995), to that end, which is a rather time consuming procedure that may not be most appropriate for many studies. An alternative, rather simple, subjective scale measures the RPE - "Ratings of Perceived Exertion". It was developed over several decades of the last century by Swedish psychologist Gunnar Borg (Borg, 1970, 1998), and has been widely used in different subject fields. The RPE scale (table 12) considers the observed power function of stimulus intensity (S) and response (R):

$$R = a + c(S - b)^n$$

[Equation 1]

(with
a, b = constants determining starting point of function,
c = proportionality constant,
n = exponent)

Table 12: CR10 scale for perceived exertion (from Borg 1998). Instructions ask the subject to imagine Level 10 as the strongest perception of exertion ever experienced. Because it may be conceivable that an even stronger level exists, the scale does not end there. When grading the level of exertion, muscle fatigue, breathlessness and aches are to be considered.

Score	Exertion level
0	Nothing at all
0.3	
0.5	Extremely weak
1	Very weak
1.5	
2	Weak
2.5	
3	Moderate
4	
5	Strong
6	
7	Very strong
8	
9	
10	Extremely strong
11	
~•	Absolute maximum

The author (Borg, 1982) noted that in "many studies, correlations of ratings and heart rates ranging from 0.80-0.90 have been found, but high correlations with other physiological variables … have also been found." A more recent meta-analysis for the purpose of validity estimations (Chen, Fan, & Moe, 2002) found a somewhat limited validity of the subjective scale compared to the more objectively quantifiable assessment criteria. Nonetheless, there is a correlation that has also been reported for research involving amputees. (D. Hunter, Smith Cole, Murray, & Murray, 1995) found the results from the RPE scale in their treadmill-walking study to confirm additional measures as they "identified significantly lower ratings of perceived exertion, heart rates, and VO2s for able-bodied subjects vs. below-knee amputees for all trials." (Kirby, Brown, Connolly, McRae, & Phillips, 2009) were using RPE in a study on stair negotiating efficiency of amputees. However, their small sample size of 8 precluded any statistically significant statement.

Despite the acknowledged limitations in validity, it can be summarized that questionnaires are a legit tool for the estimation of overall fatigue, or exertion level. Especially, in the case of the RPE scale they are uncomplicated to handle in terms of both data collection and evaluation. Although the nature of such questionnaires suggest them to be used for observational rather than interventional studies, particularly when the level of exertion is supposed to be one of the independent variables (as in our case), it should be possible to design an experimental setup that accommodates this method. The intra-subject validity of the rating scale can be quantified by repeated assessment of the same exertive activity. Subject's exertion can be assessed at different times of the ordinary test protocol, and the respective readings can be factored into the subsequent data processing and statistical evaluation. In the proposed study, walking would ideally be the way to induce the exertion; if that is not sufficient (e.g. in well-conditioned active participants), an additional workout on an exercise machine would be used to provoke an exertion level that differs from the initially determined baseline.

6.1.7 Research on amputee gait symmetry

Following the short excursion on gait symmetry above, this chapter introduces some of the respective studies in more detail, in an effort to identify proven experimental methods, find an appropriate definition of gait symmetry, and help estimate the variables that influence the latter.

6.1.7.1 Methods of assessing gait symmetry

Most of the investigations on how to quantify and explain gait asymmetry in amputees during normal walking have been published in the 1980's and 90's. More recently, the attention seems to have shifted towards performance optimization questions and the respective tools and interventions to be used in that sense. Dingwell et al in 1996 published a paper that proposed the use of an instrumented treadmill for the purpose of obtaining consistent gait symmetry data (Dingwell et al., 1996), as well as a review on the available literature. At this time, the commonly described asymmetries were shortened stance phase durations (P. Baker & Hewison, 1990; J Breakey, 1976; Cheung et al., 1983; Seliktar & Mizrahi, 1986; Skinner & Effeney, 1985) as well as reduced ground reaction forces (P. Baker & Hewison, 1990; Seliktar & Mizrahi, 1986; Skinner & Effeney, 1985) of the prosthesis compared to the contra lateral limb. The description of gait asymmetries was usually merely qualitative (Skinner & Effeney, 1985). Quantitative evaluations were based on raw differences (P. Baker & Hewison, 1990; J Breakey, 1976; Cheung et al., 1983; Skinner & Effeney, 1985), or left-right limb ratios of observed variables (Seliktar & Mizrahi, 1986). Lack of normal ankle motion due to missing active plantar flexion, has been cited as the primary cause of asymmetrical gait timing, knee joint motions, and increased muscle activities in both limbs (J Breakey, 1976; Winter & Sienko, 1988). The loss of normal neuromuscular control and proprioceptive feedback leads to the increased variability in gait timing that has been observed between normal and amputee subjects (Zahedi et al., 1987).

Dingwell et al. assumed the position that the goal of any intervention should be the optimization of walking symmetry. The used treadmill technology had the claimed "advantages … that it allows the rapid collection and comparison of temporal and kinetic parameters of gait for multiple successive strides, at a constant known speed, without forcing subjects to target their footsteps" (Dingwell et al., 1996), and has since been used for several related studies not limited to amputee walking (Kram, Griffin, Donelan, & Chang, 1998; White, Yack, Tucker, & Lin, 1998).

6.1.7.2 Defining gait symmetry from kinematic and kinetic measurements

There is no uniformly applied way of quantifying gait symmetry. According to a review article by (Sadeghi, Allard, Prince, & Labelle, 2000), among the several equations that have been used, are the Symmetry Index (SI) first introduced by Herzog (Herzog et al., 1989)

$$SI = \frac{X_{sound} - X_{prosthetic}}{0.5(X_{sound} + X_{prosthetic})} \cdot 100\%,$$

[Equation 2]

the ratio index, and derivations thereof, such as the "new ratio" proposed by Vagenas & Hoshizaki (Vagenas & Hoshizaki, 1992):

$$Ia = \frac{L - R}{max(L, R)} \cdot 100,$$

[Equation 3]

along with “statistical approaches to determine similarities… between the lower limbs [that] might eliminate the main limitations of using the ratio index… Analyses have included correlation coefficients …, coefficients of variation…, and variance ratios…” The authors point out, that due to the complexity of the phenomenon of gait asymmetry, sophisticated statistical methods are called for, most notably multivariate data analysis. Principal component analysis is a recommended method, “to characterize the large number of variables calculated…” (Sadeghi et al., 2000). While those analyses have been successfully used in studies on healthy subjects, as well as on hemiplegic and stroke patients, many amputee studies have utilized some form of index measure.

So was for instance inter-leg symmetry at high running speeds investigated by (Wilson, Asfour, Abdelrahman, & Gailey, 2009), who studied amputee sprinters by using treadmill, motion analysis and EMG data. “The symmetry index was computed by taking the individual values of X_{sound} and $X_{prosthetic}$ for each complete gait cycle” (Wilson et al., 2009). While the selected X-variable in this paper was the spring stiffness of the sprint foot, it can be conceivably replaced by most any measured variable of the motion analysis protocol.

An experimental design similar to ours was proposed in a study by (Chow et al., 2006), where “symmetry of various gait parameters in subjects with unilateral trans-tibial amputation [were investigated] over a range of acceptable anteroposterior translational and tilt alignments”. The gait of seven subjects was observed while walking on different surfaces and with stepwise altered prosthesis settings. “A total of 15 kinetic and kinematic parameters were” measured and averaged over five steps, and normalized by the body weight, including “Knee flexion at loading response”, “Maximum knee flexion during swing”, “Knee range of motion”, “Time to knee flexion loading”, “Time to maximum knee flexion”, “First vertical ground reaction force peak”, “Through of vertical ground reaction force”, “Second vertical ground reaction force peak”, “Peak

AP [anterio-posterior] braking”, “Deceleration impulse”, “Acceleration impulse”, “Peak AP propulsion”, and “Stance duration”.

After calculating the absolute asymmetry index (AAI) for each of the 15 parameters separately, they were ordered according to their weight in the overall mean AAI. Subsequently, the less influential parameters were removed to obtain a simplified table, leaving the six parameters with the highest average symmetry.

Hereby it was remarkable, “that some parameters show consistently higher symmetries, particularly the vertical ground reaction force parameters ...”, and that some alignment settings seemed to influence gait parameters in contrarian fashion. According to this, no alignment setting was found that optimizes symmetry for all considered gait parameters simultaneously. The authors suggest several explanations for “Asymmetry in a particular parameter …:

> (1) Simply the fact that this parameter is not relevant to healthy prosthetic gait;
>
> (2) That the parameter is relevant to healthy prosthetic gait, but the asymmetry is a reflection of the biomechanical difference between the prosthetic and contralateral sides; or,
>
> (3) That symmetry in this parameter is relevant to healthy gait, but can only be achieved at the expense of a certain level of symmetry in another parameter.”

On the merit of gait symmetry as an alignment assessment criterion, they state the possibility that “… optimum symmetry in these six parameters is not an adequate method of determining the optimum alignment, or simply that an optimum alignment does not exist” (Chow et al., 2006).

The usability of gait analysis has been investigated in a clinical study by (Van Velzen et al., 2005). Accordingly, the motion analysis system’s use for the purpose of identifying misaligned prosthetic settings was questioned. Instead the variables ground reaction force and ankle joint moment appeared as possible indicators of alignment alterations. (Tesio, Lanzi, & Detrembleur, 1998) had come to a similar conclusion when comparing kinematic data with the time variant position of the center of gravity and the calculated external work provided by either leg: “it has been shown that in unilateral lower limb amputee gait, the motion of the [center of gravity] can be more asymmetric than might be suspected from kinematic analysis...” (Tesio et al., 1998). Again, this work supports the notion that force and moment measurements are more significant in determining gait symmetry than mere kinematic assessment.

6.1.7.3 Influence of walking speed on compensatory mechanisms

Compensatory muscle activation was discussed in a study on amputee gait in different walking speeds (Silverman et al., 2008). Statistical analysis showed that, while the sound leg contributes a greater part of the overall propulsion work, the respective ratio between the legs did not change with the walking speed. Aside from the finding, that the prosthetic foot design was of no significant influence, it was the conclusion regarding gait speed and symmetry that is of interesting in our context: “the amputees did not display greater GRF asymmetry as walking speed increased… In addition, it appears loading symmetry is not likely a reason amputees have a slower self-selected walking speed compared to control subjects, as asymmetry was not influenced by walking speed” (Silverman et al., 2008). According to those findings, it appears to be expendable to control the variables foot selection and walking speed in comparable studies.

6.1.7.4 Inter-limb symmetry in running

The question of gait symmetry is not merely if interest in the field of disability and rehabilitation. An area where even slight deviations from the perfect left-right symmetry can have significant implications is sports biomechanics. The objective to optimize training methods and competitive performance includes in many cases respective considerations. Most obvious is the requirement of perfect symmetry probably in sports such as weightlifting or rowing. It must not be discounted in running and sprinting though, as (Exell, 2010) points out: “Many biomechanical studies of sprint running have collected spatio-temporal data unilaterally due to constraints on data collection... [However, in] the event of a large amount of asymmetry being present for an athlete during sprint running, a unilateral analysis could provide an incomplete description of technique and important kinematic and kinetic factors could be overlooked if they occurred in the limb that was not chosen for analysis” (Exell, 2010) pp 42 ff.

Regarding running asymmetry in amputee athletes, the motivation for such assessment can even be extended “due to the physiological asymmetry of such athletes. Investigations of unilateral amputees allow direct comparison between an affected and intact limb within a subject (Hillery & Wallace, 2000) so that the effects of the prosthesis on technique can be compared to the intact limb.”

The related literature includes a study by (Sanderson & Martin, 1996) who compared running at two defined speeds between able bodied and trans-tibial amputee subjects, and a quite similar study by (Buckley, 1999), who had recruited “five of the world's best unilateral amputee sprinters” and used kinematic analysis based on digital video data. In the Wilson study, the main intervention was a change in prosthesis height, which affected the overall stiffness of the artificial limb during running and the peak forces. Interestingly, those patterns were entirely different between the two participants of the study. The authors recommend for future studies that “[the] number of amputee subjects analyzed should be increased for future research…” (Buckley, 1999).

6.1.7.5 Symmetry in trans-femoral amputees

Even more so than in trans-tibial amputees, achieving a high degree of gait symmetry is a challenge for patients with higher level amputations. For trans-femoral amputees where the knee joint is lost, the resulting necessary compensation mechanisms exceed those that are applied by users of trans-tibial prostheses. Many studies are concerned with the influence of prosthetic components on the gait pattern (Graham, Datta, Heller, Howitt, & Pros, 2007; Jepson et al., 2008)(to name a few), which is legitimate due to the crucial role that prosthetic knee or foot parts play in this population. A commonly used evaluation criterion here is indeed the gait symmetry, as this is generally conceived as a direct function of the prosthesis components' performance. The swiftness with which a chip controlled knee joint, for instance, adapts the hydraulic flexion resistance to changing walking speeds determines how comfortable, safe, and eventually symmetric the gait will be. Obviously, trans-tibial and trans-femoral amputation levels are hardly comparable with respect to realistically expectable outcomes. Yet, some considerations that are of relevance in our context are discussed in the respective literature.

(Tura et al., 2010) conducted a study "to evaluate a method based on a single accelerometer for the assessment of gait symmetry" in trans-femoral amputees. The authors conclude that this simple method "is adequate for the assessment of gait symmetry and regularity in trans-femoral amputees" (Tura et al., 2010). While the objective of this study was somewhat similar to the one for our proposed work, it appears that the introduced technique has some shortcomings. Defining gait symmetry merely by comparing readings from in-shoe force transducers disregards most of the kinematic and kinetic parameters that have been discussed to determine gait symmetry. Furthermore, the binary distinction between "good" and "bad" symmetry, based on a somewhat arbitrarily selected parting line, is rather coarse and probably insufficient for most practical purposes. There is a good chance that a similar assessment could be made entirely without instrumentation, just by observing the subject walk. Another study that was looking at inter-leg symmetry and how it is influenced by alignment changes, evaluated trans-femoral runners (Burkett, Smeathers, & Barker, 2001). It came to the conclusion "… that for all four [trans-femoral] subjects, who used the same prosthetic components, lowering the prosthetic knee joint centre improved their interlimb symmetry, and subsequently their running velocity by an average of 26%." (Burkett et al., 2001) This work is listed here for the sake of completeness, although its practical significance is likely limited. Running is usually not a recommended activity for trans-femoral amputees, and at least for recreational purposes it is practiced by very few. However, we do find support for the general point, that improved symmetry enables a higher level of performance.

6.1.8 Discussion on the value of gait symmetry

A common feature of publications on amputee gait assessment is a discussion on the validity of gait symmetry as a "gold standard", or alternatively a stated or implied assumption that said validity is indeed given. Some of the articles that will be discussed in the following are dedicated to this question entirely, albeit without providing a conclusive answer.

The issue is not limited to the field of prosthetics, as (Sadeghi et al., 2000) points out in a review of the literature. According to this, questions that are controversial in the assessment of able bodied gait include"(a) whether or not the lower limbs behave symmetrically during able-bodied gait; and (b) how limb dominance affects the symmetrical or asymmetrical behavior of the lower extremities." As a result of the literature review it was found "that gait symmetry has often been assumed, to simplify data collection and analysis." Other studies that investigated "asymmetrical behavior of the lower limbs during able-bodied ambulation [suggested that this corresponds to] natural functional differences between the lower extremities … probably related to the contribution of each limb in … propulsion and control during able-bodied walking.” A popular explanation claims that laterality is responsible “for the existence of functional differences between the lower extremities, although … [further] investigation is needed to demonstrate functional gait asymmetry and its relationship to laterality...” (Sadeghi et al., 2000).

Along those lines, the concept of functional asymmetry has been postulated since. It is described by (Rice & Seeley, 2010): “Functional asymmetry is an idea that is often used to explain documented bilateral asymmetries during able-bodied gait. Within this context, this idea suggests that the non-dominant and dominant legs, considered as whole entities, contribute asymmetrically to support and propulsion during walking.” The authors conducted a study that determined the dependence of functional asymmetry upon walking speed. To that end, “[bilateral] ground reaction forces (GRF) were measured for 20 healthy subjects who walked at nine different speeds… support and propulsion impulse were quantified in order to determine the contribution of each leg to support and propulsion” (Rice & Seeley, 2010).

Concepts like laterality and functional asymmetry could conceivably be applied to (unilateral) amputee studies as well, if one would assume that the non-amputated leg is the dominant one. Consequently, a certain asymmetry would have to be considered as normal, maybe even desirable in the interest of achieving a natural gait pattern. The objective of prosthetic optimization would then be to facilitate an asymmetry that falls well in the commonly observed range of asymmetry in able-bodied walkers. However, it should be noted that the used methods of establishing gait symmetry parameters in above mentioned studies take only part of the available variables into account.

(Wilson et al., 2009) remarked: “It is not clear whether improved symmetry of kinematic and kinetic biomechanics provides an advantage or disadvantage to amputee gait…” Among the publications that support this ambiguous notion is (Fridman et al., 2003), who observed kinematic parameters in prosthesis walking with suboptimal foot rotation angles, finding that “Speed of gait remained almost constant … [however, stance] and swing time, as well as step length, significantly changed when 36 degrees were added to the optimal foot angle.” Despite the inter-leg symmetry, their subjects managed to offset the misalignment “…by internal rotation of the limb at the hip joint level. It is concluded that TT [trans-tibial] amputees can maintain an efficient speed of gait even when the prosthetic foot is malpositioned in excessive external rotation. Although such a malalignment significantly influences other gait parameters during walking, amputees are able to adapt themselves by internal rotation of the hip joint in the amputated leg” (Fridman et al., 2003).

(Hurley, McKenney, Robinson, Zadravec, & Pierrynowski, 1990) in an earlier study found that “amputees demonstrated a lesser degree of lower limb symmetry than … non-amputees.” Despite this apparent misbalance and need for compensatory activity, they computed “…forces acting across the joints of the contralateral limb [that] were not significantly higher than that of the non-amputee. This suggests that … there will not be increased forces across the joints of the contralateral limb and consequently no predisposition for the long-term wearer to develop premature degenerative arthritis.” While those results seem to downgrade the importance of walking symmetry in amputees, other authors have come to different conclusions.

According to the reasoning of (Isakov et al., 1996), who were investigating that the “speed of gait in trans-tibial amputees significantly affected the symmetry of all temporal and distance parameters as well as the symmetry of knee angles during load response and toe-off”, it is still a crucial objective to facilitate a natural gait pattern by prosthetic alignment: “Gait inter-leg symmetry is considered to be perfect when all measured gait parameters in both lower limbs are equal. Symmetry between legs indicates a normality of gait, and therefore prosthetic rehabilitation aims at fitting amputees with an artificial limb which will reproduce as closely as possible the performances of a normal leg…" (Isakov et al., 1996).

A direct contradiction to Hurley's conclusion is found in (Nolan et al., 2003), who conducted a similar study as Fridman: "With increasing walking speed, temporal gait variables reduced in duration, particularly on the prosthetic limb, while vertical ground reaction force … increased in magnitude, particularly on the intact limb… The greater force on the intact limb may reflect the method by which the amputees achieve greater temporal symmetry in order to walk fast, and could possibly account for greater instances of joint degeneration in the intact limb ..." (Nolan et al., 2003).

A contribution to the discussion on practical significance of gait symmetry is the work of (Bach, Barnes, Evans, & Robinson, 1994) who, by means of a computer simulation, adjusted inertial loading and mass distributions in trans-femoral prostheses with the objective to maximize swing phase symmetry. Tests with five amputee subjects that were wearing the symmetry optimized prostheses, resulted in significantly greater swing phase symmetry, while oxygen consumption was reduced, and subjective ratings were improved. Dingwell states that this obviously "support[s] the idea that improved gait symmetry … is related to reduced energy expenditure, and is therefore an appropriate goal in rehabilitation" (Dingwell et al., 1996).

6.1.9 Mobile force transducers and alternative or similar assessment tools

The sensor unit "iPecs" that is intended to be used in our study was introduced by the manufacturer (College Park Industries, Fraser, MI) in 2009, initially as a research device, but with the declared objective to make it a clinical tool for the practitioner. Research literature at this time is rare, and essentially concerned with the validation of the obtained measures (LeGare, 2009), or the somewhat unreflecting utilization as a “mobile gait lab” (Papaioannou & Wood, 2011). No work has been reported that could be interpreted in the sense of letting the findings become directly useful for prosthetic alignment optimization. However, alternative approaches to providing technical tools for the alignment task, as well as for a mobile gait assessment method, are well documented.

Blumentritt noted that “prostheses aligned during one session in the traditional subjective manner seem to lack any recognizable biomechanical systematic” and proposed a method that utilizes a single force plate. The center of pressure was determined while subjects were standing with one leg on, and one leg next to the force plate, leading to a recommendation on how to objectively verify a proper alignment: “Initial results suggest the knee centre should be 10 to 30mm behind the load line, depending on patient's weight. This knee position is independent on the type of the prosthetic foot” (Blumentritt, 1997). The findings have been essentially confirmed and recommendations extended to include the position of the foot in the frontal plane (Blumentritt et al., 1999; JW Breakey, 1998).

For dynamic assessment, instrumented footwear is available. Bontrager, in a book chapter (1998) describes “Force measuring sandals [as capable of] record[ing] vertical force data from portable transducers attached to the bottom of the feet” (Bontrager, 1998). Similar systems have been proposed by other authors (Kitayama, Hada, Kawauchi, Yokota, & Hamada, 2010), who suggest their usability in prosthesis research. Also have wearable pressure sensors been used to investigate dynamic stability of amputee walking (Kendell, Lemaire, Dudek, & Kofman, 2010), in an effort to investigate their “potential for falls and the dynamic stability measures”. Various parameters were found to be different between amputees and able bodied subjects, suggesting that fall risks in prosthesis users need to be investigated separately. It should be mentioned that many studies on fall mechanics do not use wearable sensors, but force plate equipment instead (Beschorner & Cham, 2008). A shortcoming of such wearable sensors is probably the lacking rigidity in connecting to the weight bearing structure. Every relative motion, however small, causes shear forces that cannot be sufficiently interpreted by traditional force transducers.

Accordingly, there have been attempts to include load cells directly in line with the weight bearing structure. In non-amputee subjects, that is not an option, although studies have been reported with wireless sensors that were integrated in hip endo-prostheses (Hodge et al., 1989), as well as with instrumented crutches (Slavens, Sturm, Bajournaite, & Harris, 2009). Boone reported findings of measurements with an integral force transducer for artificial limbs, similar to the iPecs that is to be used in the proposed study. “The Prosthesis Alignment Instrument, (PAI) was used to measure and affect sagittal and coronal changes in angular (±3° and ±6°) and translational (±5mm and ±10mm) alignment. [It] measured axial force, sagittal moment and coronal moment.” Based on subjective perception of the participating prosthesis users, the effects of alignment perturbations were specified. Computational methods (“Discrete non-linear algebraic modeling’) allowed the prediction of alignment changes from the measured data with errors of about “1.13° of angulation and 1.96 mm of translation” (Boone, 2005). The PAI has been patented (Macomber, Boone, & Beck, 2011) and is now commercially available under the name “compass” (OrthoCare Innovations, Oklahoma City, OK).

6.1.10 Questionnaires

The overall satisfaction of an amputee with the prosthetic fit has been topic of research from various fields, including Psychology and Occupational Therapy (Bilodeau, Hébert, & Desrosiers, 1999, 2000; Davidson, 2002; Dillingham, Pezzin, MacKenzie, & Burgess, 2001; Gallagher &

Maclachlan, 2001; Kegel, Carpenter, & Burgess, 1977; Matsen, Malchow, & Matsen, 2000; Murray & Fox, 2002; C. Nielsen, Psonak, & Kalter, 1989; Pezzin et al., 2004).

The Amputee Activity Score (AAS) as an outcome measure was proposed by (Day, 1981). The paper based assessment method is claimed to take “about 15 minutes and [uses] the minimum of observer judgement.” Unlike extensive physiological testing, accelerometer monitoring or clinical judgment by an observer, this scoring method is intended to be “unrelated to age, sex, gait and other disability … quick and simple to apply...” This is accomplished by the standardized interview form, which requires no observer judgment other than “asking the patient to reconsider his answers if they appear unlikely” (Day, 1981). The completed form can be easily evaluated by means of a marking aid, which delivers a numerical activity score between -70 and +50. The AAS was validated by correlating results with clinical assessment results, and with annual step count. Likewise, the repeatability was determined by comparing repeated measures over a several months long span. The findings indicate the feasibility of this method for uncomplicated assessment of amputee activity, and it has since experienced widespread use in respective research studies. Although it has been slightly modified in recent years, it is still a paper based test. Efforts of transcribing the questionnaire into a computer program that would allow collection of the information by completing a virtual form e.g. on a touch screen device are probably not put forth as the traditional method is deemed straightforward and efficient enough for most purposes. However, such computer based methods have been proposed and successfully implemented in outcome measures of assistive technology (Edyburn & Smith, 2004; Smith, 1996) and might be realized at a future stage also for tools like the AAS.

6.2 Study Design and Selection of Methods

Purpose of this subchapter is to convey detailed information on the utilized method while avoiding extensive redundancy. It addresses the aspects of methodology and study design that have been consistent over all the three parts of the study in chapters 2 through 4.

6.2.1 Overview of utilized methodology

Major objective of this work was to compare trans-tibial amputee gait kinematics and kinetics under different conditions regarding the ankle alignment and the physical exertion of the amputee. Data collection utilized conventional gait analysis equipment, as well as wearable and prosthesis-integrated devices that delivered additional measurements. Force and moment data were obtained with an “iPecs” sensor device, as well as - for those steps that happened inside the laboratory - by force plate measurements. The effect of two different interventions was investigated: Change of the prosthetic ankle alignment, and change in exertion level. This setup allowed the comparison of 4 conditions in a 2 x 2 repeated measures analysis of variance (table 13) based on the conventional gait analysis. Dependent variables were typical gait analysis parameters that were considered individually, or combined in indices of kinematic and kinetic parameters for different sections of the analysis, as detailed in chapter 2.

Table 13: Study design

	low exertion	”strong” exertion
normal alignment		
2 deg plantar flexion		

Concurrent measurements by conventional gait analysis method and integrated sensor method were used to validate the mobile sensor data, which was a prerequisite for using this continuous data for steady monitoring of the variables over the course of the entire test session. Gait data of all subjects over all interventions was used for correlation analysis (table 14).

Table 14: Study design for kinetics comparison

	Conventional Gait Analysis Data		Mobile Sensors Data	
	low exertion	”strong” exertion	low exertion	”strong” exertion
normal alignment				
2 deg plantar flexion				

Instrumented gait analysis is an established method in amputee research, and was adopted for this study. The same is the case for EMG measurements, which - in a small scale - were implemented as well. A novelty is the prosthesis-integrated sensor unit, which is capable of collecting somewhat unusual data. Correlating those data to established measures is necessary to answer the study questions.

In the following, components of the methodology are explained, related to the literature, and their appropriateness is justified.

6.2.2 Prosthesis technology

No standardization of prosthesis design has been attempted for this study. While many studies controlled for this factor by manufacturing new prostheses after a consistent method for the use during the data collection (Chow et al., 2006; Sanders & Daly, 1999), this effort was not indicated for our purposes. Instead, the fit of the prosthesis was assessed prior to data collection, based on the reports by the user and the judgment of an experienced prosthetist (Fridman et al., 2003).

Considered how individualized the fit of prostheses usually is, it seems reasonable to standardize the requirements with respect to outcomes rather than to the employed manufacturing technique and technology. The concept of a well-fitting prosthesis may mean completely different things for different patients. One user may walk best with a silicone liner suspension, while another one prefers the softer and usually thicker polyurethane solution. In the lengthy process of optimizing the prosthetic care, those preferences have been identified and accommodated. In the result, both patients can display the same level of comfort and activity with their respective artificial legs – provided their physiological given facts are comparable. If we now would standardize the fitting technology to one material or the other, we would likely reduce this comfort (and activity) level for one subject but not the other. Essentially the same is true for the question of socket designs and functional components. Even though there are large differences between mechanical characteristics of available feet components, it has been shown that in fact the walking speed influences the ground reaction forces much more than the foot type (Silverman et al., 2008).

6.2.3 Gait velocity

Instead of controlling for the walking speed, participants were asked to walk in a self-selected speed. Speed has not been selected as an intervention variable, as the requirement to collect steps in a predefined range of walking velocities would potentially increase the number of repetitions and tire the amputee subject out before the desired amount of walking samples has been collected. Setting the margin of speed definition too wide may reduce the number of necessary repetitions, but will affect the significance of the results. The alternative use of a treadmill to standardize walking speeds (Dingwell et al., 1996) was not considered, in order to provide comparability across trials on different surfaces. Gait velocity was measured and used as a comparison criterion within different trials of the same subject.

6.2.4 Interventions

Apart from walking on the level surface of the gait lab floor, subjects were asked to absolve a circular walking path on some irregular walking surfaces as well. A foldable 10-yard gravel path had been set up so that it can be used within the regular laboratory capture volume. The principle is similar to a custom made irregular surface that has been used for a recently published study on amputee gait (Curtze, Hof, Postema, & Otten, 2011). The main advantage of having the gravel path cover the force plates is that subjects could use the safety harness that is connected to a rail on the ceiling. Force plate data were not deemed dependable, due to the irregular size and distribution of stones.

After the gravel path, subjects were asked to walk along the hallway and to climb a flight of stairs, in order to reach the outdoor parking lot, cross the parking lot, and return to the lab on a different route through the building (figure 31). While those walking trials were mainly intended to serve as a fatiguing exercise to reach the desired level of exertion, they also yielded data that promise to be interesting for subsequent analysis in possible follow-up studies[6].

Stair walking has been investigated before, mostly to describe the functionality of the used prosthetic components (Powers, Boyd, Torburn, & Perry, 1997; Schmalz, Blumentritt, & Marx, 2007), or develop better ones (Au et al., 2008). Experimental setups may feature a small stair that can be climbed in the gait lab while using one of the floor force plates to capture the kinetics of one foot during landing from the step or pushing up to climb the step. More elaborate structures have instrumented steps integrated in the stairs, which allows a more

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[6] Although members of the research team accompanied the subjects while doing so, this condition could be considered walking in a real-life environment. Data was solely collected by means of the mobile iPecs systems, and could be used to compare walking in and outside the lab. A more diverse selection of walking surfaces might seem desirable in order to provoke more significant differences in the data. However, it may be already a considerably different condition to just walk outside of the controlled confinements of the laboratory, away from the critically observing eyes of the technician, and on the way to a destination (for instance the stairwell) instead of just “aimlessly” walking up and down.

natural motion pattern during ascend and descent alike. A setup like this, although desirable, did not fit in the scope of our study at this time. Stair ambulation mechanics are too complex for an in-depth investigation in our context. Instead, the iPecs readings could be used to merely compare step-by-step and inter-leg symmetry, similarly than for all other interventions (see manuscripts in Appendix D).

With respect to prosthetic alignment, two levels of perturbation have been included: Optimal alignment, which we assumed to be the original alignment that was found when the subject arrives, and a by 2 degrees increased ankle plantar flexion, which was considered a subtle misalignment. This was easily realized by adjusting the setscrews of the standard modular adapters in the prostheses (figure 30). Connections between prosthetic components in the standard modular system (Naeder & Naeder, 2000) are realized by adapters with a four faced inverted pyramid structure on a spherical base (male adapter), and respectively with four set screws around an opening that accommodates the pyramid structure (female adapter). The magnitude of alignment changes followed respective examples from the literature. A range of six degrees of socket tilt in anterior-posterior direction has been reported to be on the brink of acceptability for most amputees (Chow et al., 2006). Three and six degrees respectively have been used as typical perturbations to demonstrate changed kinetics (Boone, 2005). Even a ten degree change as an intervention has been used before (Pinzur et al., 1995), which indicates that our selected perturbation is indeed subtle in comparison.

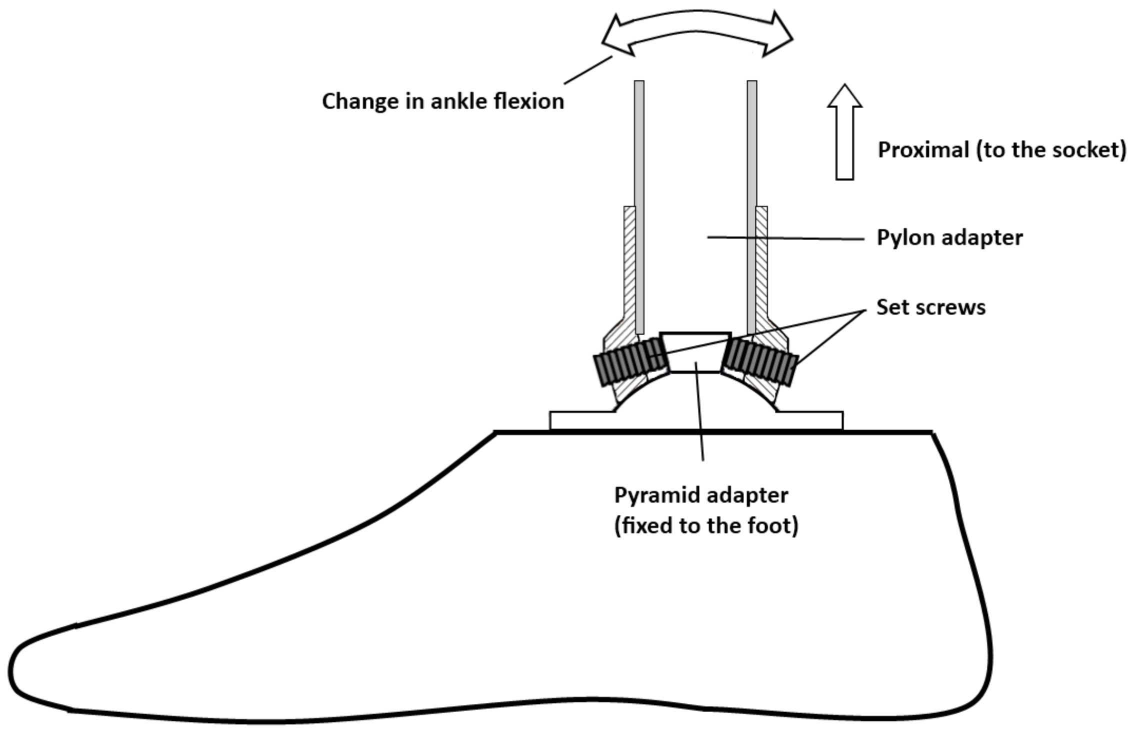

Figure 29: Alignment mechanism of prosthesis modular adapter

In order to simulate the real-life occurrence of the prosthesis user being fatigued, a respective intervention was included. As already discussed in the respective paragraphs of the literature review section earlier, the definition of an appropriate fatigue protocol is not trivial. The most influential muscle group for trans-tibial gait seems to be the hip-extensors. However, an exercise that targets fatiguing of those particular muscles will require the prosthesis be worn for leverage or support, which in turn increases the risk of friction-induced skin breakdown and further inconvenience. Unilateral fatiguing of the sound leg would result in a condition too far off of the actually expected situation that is supposed to be simulated. Instead of applying a standardized fatigue protocol, the fatigue level was monitored as an uncontrolled variable. After the first two walking trials in the lab (one with the original alignment, one with the increased ankle plantar flexion), subjects were asked to continuously walk along the path (figure 31) while frequently reporting their perceived exertion on the Borg RPE scale (Borg, 1998). The data captured during the repetition where the perceived exertion reached 5 on the CR10 scale was used for the evaluation. Immediately following, the ankle alignment was returned to its misaligned state, and subjects were asked to complete one last walking trial, during which data was captured as well.

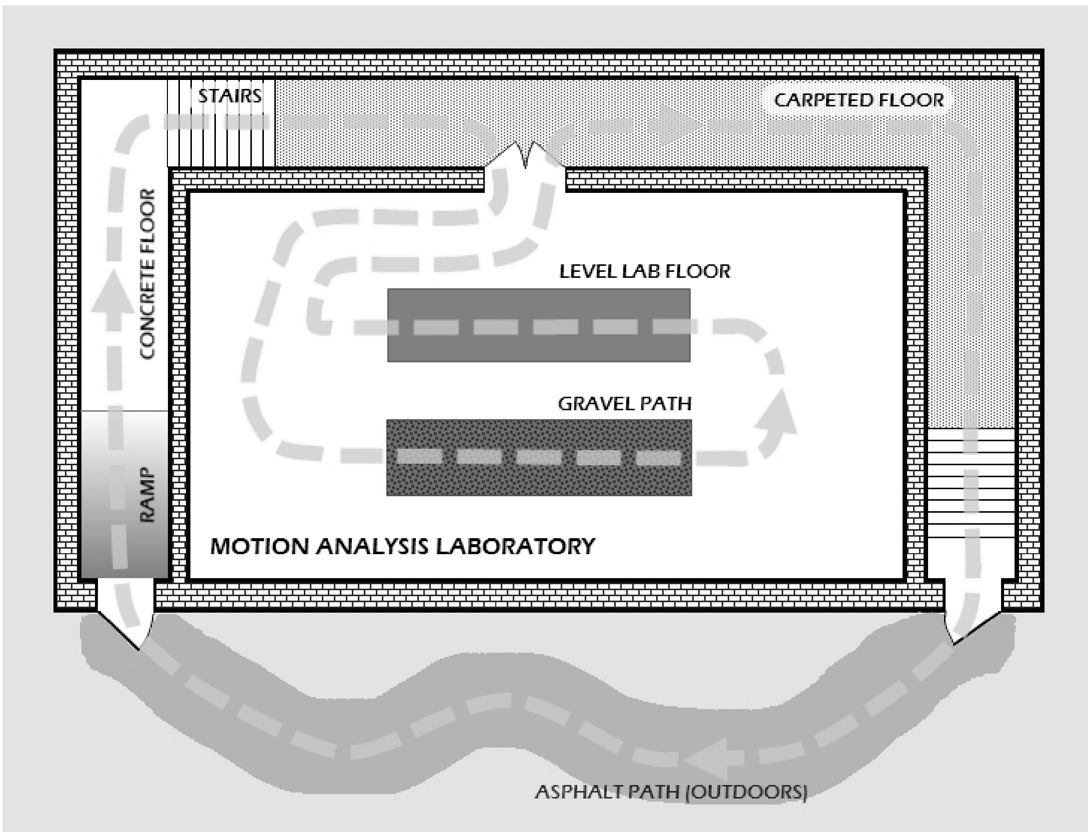

Figure 30: Schematic of the walking path in and outside the laboratory building. Total length of the loop is 210 meters, 40 of which are outdoors

6.2.5 Population and Sample

Irrespective of the heterogeneity that is typical for the amputee population, broad inclusion criteria were defined. This had mainly practical reasons, knowing that subject recruitment is generally an issue in comparable studies. Since many amputee studies used heterogeneous samples, e.g. subjects with traumatic amputations together with diabetics, comparability of the results would be given within the limitations of significance due to sample size problems. The effect size of the proposed interventions could hardly be estimated. Particularly, the expected effect was minimal for the 2 degrees of additional plantar flexion. As the conditions would be compared within subjects, this effect size would have to be related to the standard deviation of gait parameters within this particular subject. As we assumed that subjects are proficient in prosthesis walking, this standard deviation might indeed be smaller than the effect size of the alignment perturbation. (Sin et al., 2001) and (Chow et al., 2006) who used similarly subtle alignment changes had sample sizes of six and seven amputees respectively. On the other hand, the effect of the exertion was expected to be more pronounced. No comparable intervention studies could be identified, but those amputee studies that investigated different exertion levels had sample sizes of eight and seven (D. Hunter et al., 1995; Kirby et al., 2009).

Our study had a sample size of 10. This is admittedly well below any sufficient sample size for a conservatively expected small effect size, but so would have been a sample of 18, which is the biggest of the sample sizes in prosthesis alignment studies (Neumann, 2009).

Subjects were recruited by distributing flyers in local prosthetist offices, at amputee support group meetings, and by posting search ads in online platforms, as well as by direct contact. Persons from 18 to 80 years of age with trans-tibial amputations who use prosthesis built in modular technique, and are able to walk at least 30 minutes per day pain-free and without assistive devices could participate in this study. Persons whose prosthesis did not provide enough space between socket and foot module to fit the mobile measuring unit (about 2 inches), or persons who were physically or mentally unable to perform the required tasks could not participate in this study. An initial screening to assure eligibility was conducted a few weeks prior to the data collection session. In accordance with usual IRB requirements, informed consent was obtained in person.

6.2.6 Hardware

A 10 camera (Raptor-4 digital) motion analysis system (Motion Analysis, Santa Rosa, CA) in combination with 3 force plates (BP400600, AMTI, Watertown, MA) was used. The marker protocol followed the Cleveland Clinic Convention, as this was considered versatile and efficient for our purposes. Combined data acquisition used NI DAQ equipment (National Instruments, Austin, TX). The primary processing software was Cortex (Motion Analysis, Santa Rosa, CA) running on a Windows-PC.

Four channels of a wireless EMG system ("Trigno", Delsys, Boston, MA) were used to continuously capture EMG signals from the biceps femoris and quadriceps femoris muscles of both legs. The system has integrated accelerometers that help reduce motion artifacts, a sampling rate of 2000 or 4000 Hz, and a wireless transmission range of up to 40 meters.

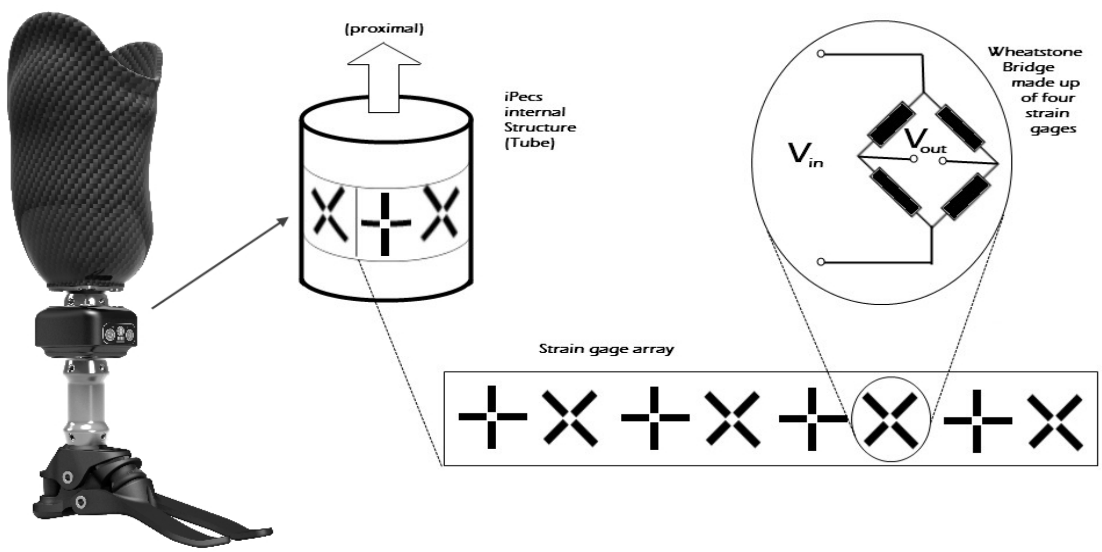

Figure 31: Principle of strain gage assembly in iPecs

The "iPecs" (College Park Industries, Fraser, MI) is a research grade measuring tool that essentially consists of multiple arrays of strain gages, housed in a shell of 1.8" x 2.8" x 3.2". The gages, four at a time, are connected in Wheatstone bridge circuits which are aligned in varying orientations within the structure. Based on a calibration matrix, the readings of those units are combined to output force and moment data. A total of eight such Wheatstone bridges are assorted around the central pylon (figure 32). A user interface allows the definition of knee and ankle joint axis with respect to the center of the iPecs device, upon which the respective moments at those points are derived by means of respective transformation matrices (Leydet, 2011). The assumption of a rigid body between those points is justified by the stiffness of the prosthesis structure, and the necessary good connection between residual limb and socket. Data can be streamed wirelessly via a radio transmitter to a personal computer, or alternatively stored on a micro SD card within the unit. Sampling rates can be defined to be between 30 and 1000 Hz.

To facilitate a repeatable and accurate misalignment and eventually reconstitution of the original alignment, a double-plumb-line frame was used (Figure 33). The doffed prosthesis could be placed in the center of the lower platform, where the foot position was marked by pencil outline. Plumb lines were marked on the socket while the parallel threads of the frame helped prevent parallax errors. Besides the perpendicular lines, there are lines spanned in a 2 degree angle for easy alignment position changes. The origin of this angle is at the ankle joint at 7 cm over the ground, as this is roughly the height of most prosthesis feet ankles.

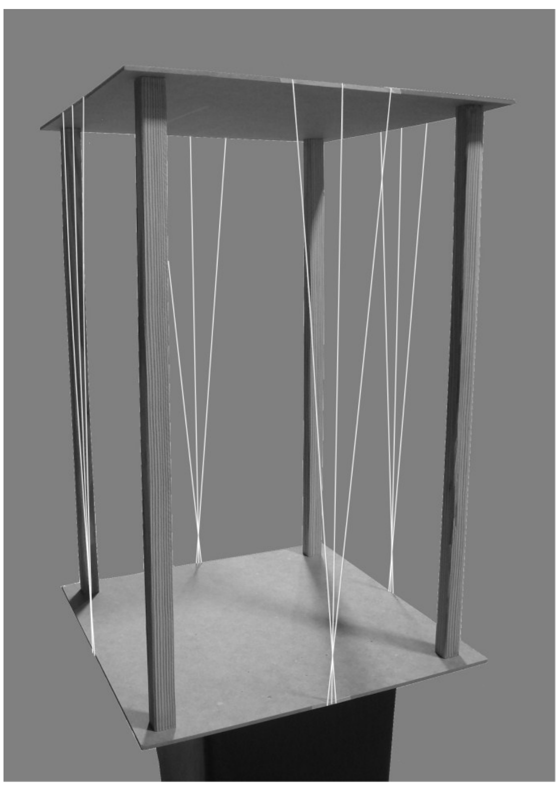

Figure 33: Prosthesis alignment aid

6.2.7 Data synchronization and validation

Camera, force plate and EMG data are routinely synchronized within the motion analysis system software, which was used to collect and process those data. The sampling rate of the iPecs unit was determined so that the collected data had a time base compatible with the gait laboratory data. Synchronization was then supposed to be based on a significant event within the gait cycle, namely the instant of heel contact, which is marked by a typical increase in vertical ground reaction force in both measuring entities.

One of the objectives of this work was to determine the concurrent validity of the integrated sensor data, which requires the statistical comparison of the novel data with simultaneously measured data from a validated system, in this case the conventional motion analysis and force plate system. Several approaches are documented for this, such as the identification of gait curve landmarks and subsequent error calculation based on those discrete values (Bamberg et al., 2008), the quantification of deviations by a dedicated index (R. Baker et al., 2009; Kark, Vickers, Simmons, & McIntosh, 2009), and eventually some variation of correlation analysis (Cutlip et al., 2000; Thompson, 1991). As the here applied data collection method provided time-variable continuous gait curves, both a comparison of landmark values, as an overall correlation of curves could be conducted.

6.2.8 Data collection

At the beginning of the session, the Ratings of Perceived Exertion table (Borg, 1998) was explained to the participant, and perceived exertion before the start of the test was noted. The subject was asked to again report perceived exertion repeatedly throughout the test session in order to be able to monitor this parameter.

In preparation of the data collection, the existing prosthesis of the subject was then modified for this study; by the student PI who is trained as a prosthetist. Modifications included the replacement of the tube adapter above the foot module with the iPecs integral sensor unit, and if necessary a respectively shorter tube adapter to maintain the overall length and alignment of the prosthesis. In the gait lab, the subject donned the modified prosthesis. Reflective markers were placed by double-sided adhesive tape on the skin of the subject. Likewise, two EMG sensors were placed on each leg at the quadriceps and biceps femoris muscles, and secured with coban. A wearable heart rate monitor was strapped to the subject's chest. Anthropometric data, such as limb dimensions, subject height and body mass were measured. The Amputee Activity Score sheet was completed based on subject's self-report.

The motion analysis system was used to capture data. Continuous iPecs and EMG measurements were conducted while subjects are performing these tasks in subsequent order, interrupted regularly by breaks to rest, and have the procedures explained:

1) Perform a set of maximal voluntary contractions of the thigh muscles (3 times for 4 seconds for each quadriceps and biceps femoris)
2) Walk in their preferred speed through the capture volume of the gait lab (until at least one valid trial had been collected),
3) Have the prosthetic ankle position adjusted to 2 degrees increased plantar flexion
4) Repeat step 2, after which the normal alignment was reconstituted
5) Accompanied by the PI and a staff member, walk along the hallway outside the gait lab, walk down the stairs to the 1st floor and out the building door, cross the parking lot, use the main entrance to come back in, climb up the stairs, and return to the lab
6) Walk through a 10 feet long sand box filled with gravel, while
7) Report perceived exertion
8) Repeat steps 5) and 6) until perceived exertion at level 5 (CR10 scale)
9) Repeat steps 2) through 4)

Effective performance time over the test session (without the breaks) was regularly less than 2 hours (table 15). Data collection could have been interrupted or ended prematurely, at any point in time in case that subjects experience discomfort, pain or tiredness. In cases that subjects needed to test glucose levels and take their personal medication, this could have been easily accommodated as well. Exhaustion was assessed according to the RPE scale. In the case that a test would have to be aborted, the data that had been collected up to this point would have been included in the analysis. Participants were compensated with US$ 100.

Table 5: Timeline of data collection session

Protocol steps	Subject	Time/min
1	Read and sign consent form	10
2	Report RPE (0-10)	5
3	Doff Prosthesis	5
4	Complete AAS, while prosthesis is modified	60
5	Don prosthesis	5
6	Put on HR watch, markers and EMG sensors	30
7	Maximal Voluntary Contractions	10
8	Marker calibration	5
9	Walk in lab, Gait data collection by MA system and ipecs	10
10	Prosthesis adjustment (+2 deg plantarflexion)	5
11	Walk in lab, data collection	10
12	Prosthesis adjustment (back to neutral)	5
13	Walk loop until RPE = 5 (data collection)	60
14	Prosthesis adjustment (+2 deg plantarflexion)	5
15	Walk in lab (data collection)	10
16	Doff Prosthesis, remove markers, EMG, HR watch	20
17	Don prosthesis, after re-modification to original	5
18	Receive compensation	
	Total time in minutes:	260

6.3 References

Alton, F., Baldey, L., Caplan, S., & Morrissey, M. (1998). A kinematic comparison of overground and treadmill walking. *Clinical Biomechanics, 13*(6), 434-440.

Amann, M., & Dempsey, J. A. (2008). Locomotor muscle fatigue modifies central motor drive in healthy humans and imposes a limitation to exercise performance. *J Physiol, 586(Pt 1)*, 161-173.

Aminian, K., Najafi, B., Büla, C., Leyvraz, P.-F., & Robert, P. (2002). Spatio-temporal parameters of gait measured by an ambulatory system using miniature gyroscopes. *Journal of Biomechanics, 35*(5), 689-699.

Anderson, I. A., MacDiarmid, A. A., Harris, M. L., Gillies, R. M., Phelps, R., & Walsh, W. R. (2003). A novel method for measuring medial compartment pressures within the knee joint in-vivo. *Journal of Biomechanics, 36*(9), 1391-1395.

Andres, R., & Stimmel, S. (1990). Prosthetic alignment effects on gait symmetry: a case study. *Clinical Biomechanics, 5*(2), 88-96.

Andrews, K. (1996). Rehabilitation in limb deficiency. 3. The geriatric amputee. *Arch Phys Med Rehabil, 77*(3 Suppl), S14-17.

Au, S., Berniker, M., & Herr, H. (2008). Powered ankle-foot prosthesis to assist level-ground and stair-descent gaits. *Neural Netw, 21*(4), 654-666.

Bach, T., Barnes, L., Evans, O., & Robinson, I. (1994). *Optimization of inertial characteristics of transfemoral limb prostheses: tests of predictions of a computer simulation.* Paper presented at the Canadian Society for Biomechanics Eighth Biennial Conference, Calgary, Canada.

Bagesteiro, L. B., Gould, D., & Ewins, D. J. (2011). A vertical ground reaction force-measuring treadmill for the analysis of prosthetic limbs. *Brazilian Journal of Biomedical Engineering, 27*(1), 3-11.

Baker, P., & Hewison, S. (1990). Gait recovery pattern of unilateral lower limb amputees during rehabilitation. *Prosthetics and Orthotics International, 14*, 80-84.

Baker, R., McGinley, J. L., Schwartz, M. H., Beynon, S., Rozumalski, A., Graham, H. K., & Tirosh, O. (2009). The Gait Profile Score and Movement Analysis Profile. *Gait & Posture, 30*(3), 265-269.

Bakshi, R. (2003). Fatigue associated with multiple sclerosis: diagnosis, impact and management. *Mult Scler, 9*(3), 219-227.

Balogh, A. (2008). The Effect Of Prosthesis Suspension On Residual Limb Pistoning. *MSPO Student Presentations* Atlanta, GA: Georgia Institute of Technology.

Bamberg, S. J. M., Benbasat, A. Y., Scarborough, D. M., Krebs, D. E., & Paradiso, J. A. (2008). Gait Analysis Using a Shoe-Integrated Wireless Sensor System. *IEEE TRANSACTIONS ON INFORMATION TECHNOLOGY IN BIOMEDICINE, 12*(4), 413-423.

Barth, D., Schumacher, L., & Thomas, S. S. (1992). Gait Analysis and Energy Cost of Below-Knee Amputees Wearing Six Different Prosthetic Feet. *JPO Journal of Prosthetics & Orthotics, 4*(2), 63-75.

Bateni, H., & Olney, S. J. (2002). Kinematic and Kinetic Variations of Below-Knee Amputee Gait. *Journal of Prosthetics & Orthotics, 14*(1), 2-10.

Bates, B. T. (1996). Single-subject methodology: an alternative approach. *Medicine & Science in Sports & Exercise, 28*(5), 631-638.

Bellmann, M., Schmalz, T., & Blumentritt, S. (2010). Comparative Biomechanical Analysis of Current Microprocessor-Controlled Prosthetic Knee Joints. *Archives of Physical Medicine and Rehabilitation, 91*(4), 644-652.

Berge, J., Czerniecki, J., & Klute, G. (2005). Efficacy of shock-absorbing versus rigid pylons for impact reduction in transtibial amputees based on laboratory, field, and outcome metrics. *J Rehabil Res Dev, 42*(6), 795-808.

Bergmann, G., Deuretzbacher, G., Heller, M., Graichen, F., Rohlmann, A., Strauss, J., & Duda, G. (2001). Hip contact forces and gait patterns from routine activities. *J Biomech, 34*(7), 859-871.

Beschorner, K., & Cham, R. (2008). Impact of joint torques on heel acceleration at heel contact, a contributor to slips and falls. *Ergonomics, 51*(12), 1799-1813.

Beyaert, C., Grumillier, C., Martinet, N., Paysant, J., & André, J.-M. (2008). Compensatory mechanism involving the knee joint of the intact limb during gait in unilateral below-knee amputees. *Gait & Posture, 28*(2), 278-284.

Bilodeau, S., Hébert, R., & Desrosiers, J. (1999). Questionnaire on the satisfaction of persons with lower-limb amputations towards their prosthesis: development and validation. *Can J Occup Ther, 66*(1), 23-32.

Bilodeau, S., Hébert, R., & Desrosiers, J. (2000). Lower limb prosthesis utilisation by elderly amputees. *Prosthetics and Orthotics International, 24*(2), 126-132.

Blatchford. (2012). Endolite - get busy living Retrieved 06/21, 2012, from http://www.endolite.co.uk/products/intro/intro.html

Blumentritt, S. (1997). A new biomechanical method for determination of static prosthetic alignment *Prosthetics and Orthotics International, 21*, 107-113

Blumentritt, S., Bellmann, M., Ludwigs, E., & Schmalz, T. (2012). [Zur Biomechanik des mikroprozessorgesteuerten Prothesenkniegelenks Genium] Biomechanics of the Microprocessor-controlled Prosthetic Knee Joint Genium. *Orthopädie-Technik* (1), 24-35.

Blumentritt, S., Schmalz, T., Jarasch, R., & Schneider, M. (1999). Effects of sagittal plane prosthetic alignment on standing trans-tibial amputee knee loads. *Prosthetics and Orthotics International, 23*(3), 231-238.

Board, W., Street, G., & Caspers, C. (2001). A comparison of trans-tibial amputee suction and vacuum socket conditions. *Prosthetics and Orthotics International, 25*, 202-209.

Bolgla, L. A., & Uhl, T. L. (2007). Reliability of electromyographic normalization methods for evaluating the hip musculature. *Journal of Electromyography and Kinesiology 17*, 102-111.

Bontrager, E. L. (1998). Instrumented Gait Analysis Systems. In J. A. DeLisa & C. K. Kerrigan (Eds.), *RRDS Gait Analysis in the Science of Rehabilitation* (pp. 11-32). Baltimore, MD: Scientific and Technical Publications Section, Rehabilitation Research and Development Service.

Boone, D. A. (2005). *Investigation of socket reactions from transtibial prosthesis malalignment.* PhD, Hong Kong Polytechnic Uuniversity, Hong Kong.

Boonstra, A., Fidler, V., & Eisma, W. (1993). Walking speed of normal subjects and amputees: aspects of validity of gait analysis. *Prosthet Orthot Int, 17*(2), 78-82.

Borg, G. (1970). Perceived exertion as an indicator of somatic stress. *Scand J Rehabil Med Suppl, 2*(2), 92-98.

Borg, G. (1982). Psychophysical bases of perceived exertion. *Med Sci Sports Exerc, 14*(5), 377-381.

Borg, G. (1998). *Perceived exertion and pain scales*. Champaign, IL: Human Kinetics.

Brach, J. S., Perera, S., Studenski, S., & Newman, A. B. (2008). The Reliability and Validity of Measures of GaitVariability in Community-Dwelling Older Adults *Archives of Physical Medicine and Rehabilitation, 89*(12), 2293-2296.

Breakey, J. (1976). Gait of unilateral below-knee amputees. *Journal of Orthotics and Prosthetics, 30*(2), 17-24.

Breakey, J. (1998). Theory of integrated balance: the lower limb amputee. *Journal of Prosthetics & Orthotics, 10*, 42-44.

Buckley, J. (1999). Sprint kinematics of athletes with lower-limb amputations. *Arch Phys Med Rehabil, 80*(5), 501-508.

Buckley, J., Jones, S., & Birch, K. (2002). Oxygen consumption during ambulation: comparison of using a prosthesis fitted with and without a tele-torsion device. *Arch Phys Med Rehabil., 83*(4), 576-580.

Burkett, B., Smeathers, J., & Barker, T. (2001). Optimising the trans-femoral prosthetic alignment for running, by lowering the knee joint. *Prosthetics and Orthotics International, 25*(3), 210-219.

Burnfield, J., Bontrager, M., Boyd, L., Rao, S., Mulroy, S., Gronley, J., & Perry, J. (1999). Effect of prosthetic malalignment on EMG and intra-socket pressures in an individual with a transtibial amputation. *Gait Posture, 9*(2), 137-138.

Cappozzo, A. (1984). Gait analysis methodology. *Human Movement Science, 3*(1-2), 27-50.

Chaffin, D. B. (1973). Localized Muscle Fatigue - Definition and Measurement. *Journal of Occupational Medicine, 15*, 346-352.

Chen, M. J., Fan, X., & Moe, S. T. (2002). Criterion-related validity of the Borg ratings of perceived exertion scale in healthy individuals: a meta-analysis. *Journal of Sports Sciences, 20*(11), 873 - 899.

Chesnin, K. J., Selby-Silverstein, L., & Besser, M. P. (2000). Comparison of an in-shoe pressure measurement device to a force plate: concurrent validity of center of pressure measurements. *Gait & Posture, 12*(2), 128-133.

Cheung, C., Wall, J., & Zelin, S. (1983). A microcomputer based system for measuring temporal asymmetry in amputee gait. *Prosthetics and Orthotics International, 7*, 131-140.

Chow, D. H. K., Holmes, A. D., Lee, C. K. L., & Sin, S. W. (2006). The effect of prosthesis alignment on the symmetry of gait in subjects with unilateral transtibial amputation. *30*(2), 114-128.

Cifrek, M., Medved, V., Tonkovic, S., & Ostojic, S. (2009). Surface EMG based muscle fatigue evaluation in biomechanics. *Clinical Biomechanics 24*, 327-340.

Cortés, A., Viosca, E., Hoyos, J., Prat, J., & Sánchez-Lacuesta, J. (1997). Optimisation of the prescription for trans-tibial (TT) amputees. *Prosthetics and Orthotics International, 21*(3), 168-174.

Coventry, E., O'Connor, K., Hart, B., Earl, J., & Ebersole, K. (2006). The effect of lower extremity fatigue on shock attenuation during single-leg landing. *Clin Biomech (Bristol, Avon), 21*(10), 1090-1097.

CPI, C. P. I. (2011). ipecs LAB wireless gait lab, product specifications, from http://www.college-park.com/images/pdf/cpi-specs-ipecslab.pdf

Curtze, C., Hof, A. L., Postema, K., & Otten, B. (2011). Over rough and smooth: Amputee gait on an irregular surface. *Gait & Posture, 33*(2), 292-296.

Cutlip, R. G., Mancinelli, C., Huber, F., & DiPasquale, J. (2000). Evaluation of an instrumented walkway for measurement of the kinematic parameters of gait. *Gait & Posture, 12*(2), 134-138.

Czerniecki, J., Gitter, A., & Munro, C. (1991). Joint moment and muscle power output characteristics of below knee amputees during running: the influence of energy storing prosthetic feet. *J Biomech, 24*(1), 63-75.

Dang, V. (2010). *Data Analysis for Amputee Gait Analysis*. Project paper. Marquette University. Milwaukee.

Davidson, J. (2002). A survey of the satisfaction of upper limb amputees with their prostheses, their lifestyles, and their abilities. *J Hand Ther, 15*(1), 62-70.

Davis, B., Kuznicki, J., Praveen, S., & Sferra, J. (2004). Lower-extremity amputations in patients with diabetes: pre- and post-surgical decisions related to successful rehabilitation. *Diabetes Metab Res Rev, 20*(Suppl 1), S45-50.

Day, H. J. B. (1981). The assessment and description of amputee activity. *Prosthetics and Orthotics International, 5*, 23-28.

De Luca, C. J., Gilmore, L. D., Kuznetsov, M., & Roy, S. H. (2010). Filtering the surface EMG signal: Movement artifact and baseline noise contamination. *Journal of Biomechanics, 43*, 1573-1579.

Deluzio, K., & Astephen, J. (2007). Biomechanical features of gait waveform data associated with knee osteoarthritis An application of principal component analysis. *Gait & Posture* (25), 86-93.

Dennerlein, J. T., Diao, E., Mote Jr., C. D., & Rempel, D. M. (1999). In vivo finger flexor tendon force while tapping on a keyswitch. *Journal of Orthopaedic Research, 17*(2), 178-184.

Dillingham, T., Pezzin, L., & MacKenzie, E. (2002). Limb Amputation and Limb Deficiency: Epidemiology and Recent Trends in the United States. *Southern Medical Journal, 95*(8), 875-883.

Dillingham, T., Pezzin, L., MacKenzie, E., & Burgess, A. (2001). Use and Satisfaction with Prosthetic Devices Among Persons with Trauma-Related Amputations: A Long-Term Outcome Study. *American Journal of Physical Medicine & Rehabilitation, 80*(8), 563-571.

Dingwell, J., Davis, B., & Frazier, D. (1996). Use of an instrumented treadmill for real-time gait symmetry evaluation and feedback in normal and trans-tibial amputee subjects. *Prosthetics and Orthotics International, 20*(2), 101-110.

Draper, E. R. (2000). A treadmill-based system for measuring symmetry of gait. *Medical Engineering & Physics, 22*(3), 215-222.

Edyburn, D. L., & Smith, R. O. (2004). Creating anAssistive Technology Outcomes Measurement System: Validating the Components. *Assistive Technology Outcomes and Benefits, 1*(1), 8-15.

Eilenberg, M., Geyer, H., & Herr, H. (2010). Control of a powered ankle-foot prosthesis based on a neuromuscular model. *IEEE Trans Neural Syst Rehabil Eng, 18*(2), 164-173.

Ephraim, P., Dillingham, T., Sector, M., Pezzin, L., & MacKenzie, E. (2003). Epidemiology of limb loss and congenital limb deficiency: a review of the literature. *Arch Phys Med Rehabil, 84*(5), 747-761.

Esquenazi, A., & DiGiacomo, R. (2001). Rehabilitation after amputation. *J Am Podiatr Med Assoc, 91*(1), 13-22.

Exell, T. (2010). *Lower-limb biomechanical asymmetry in maximal velocity sprint running.* PhD, University of Wales Institute, Cardiff, Wales.

Fang, L., Jia, X., & Wang, R. (2007). Modeling and simulation of muscle forces of trans-tibial amputee to study effect of prosthetic alignment. *Clinical Biomechanics 22*, 1125-1131.

Federolf, P., Tecante, K., & Nigg, B. (2012). A holistic approach to study the temporal variability in gait. *Journal of Biomechanics, 45*(7), 1127-1132.

Fey, N. P., Silverman, A. K., & Neptune, R. R. (2010). The influence of increasing steady-state walking speed on muscle activity in below-knee amputees. *Journal of Electromyography and Kinesiology, 20* 155-161.

Fiedler, G., & Slavens, B. A. (2011). *Integrated Sensor Systems for Assessment of Rehabilitation in Lower Extremity Amputees*. Paper presented at the Third International Symposium on Quality of Life Technology Toronto, CAN.

Fiedler, G., Slavens, B. A., Briggs, D. W., & Fedel, F. (2012). *Leg Laterality in Bilateral Trans-Tibial Amputees, A Case Study using Prosthesis-Integrated Sensors.* Paper presented at the Annual Conference of the Rehabilitation Engineering And Assistive Technology Society of North America (RESNA), Baltimore, MA.

Fiedler, G., Slavens, B. A., & Smith, R. O. (2012a, May 9-12). *Evaluation of an Integrated Sensor System for Assessment of Prosthesis Ankle Alignment in Lower Extremity Amputees.* Paper presented at the Gait and Clinical Movement Analysis Society (GCMAS) Conference, Grand Rapids, MI.

Fiedler, G., Slavens, B. A., & Smith, R. O. (2012b, March 23-24). *Gait stability measured by prosthesis-integrated sensors as an outcome measure in persons with prostheses for the lower extremity.* Paper presented at the 25th Annual Dean's Research Day, Kalamazoo, MI.

Fiedler, G., Slavens, B. A., & Smith, R. O. (2012c, March 11-13). *Influence of Handrail Use on Stair Walking Stability in Trans-Tibial Amputees.* Paper presented at the 1st Occupational Science Summit, St. Louis, MO.

Fitts, R. (1994). Cellular mechanisms of muscle fatigue. *Physiol Rev, 74*(1), 49-94.

Foort, J. (1965). The patellar-tendon-bearing prosthesis for below-knee amputees, a review of technique and Criteria. *Artif. Limbs, 9*(1), 4-13.

Fradet, L., Alimusaj, M., Braatz, F., & Wolf, S. (2010). Biomechanical analysis of ramp ambulation of transtibial amputees with an adaptive ankle foot system. *Gait Posture, 32*(2), 191-198.

Fridman, A., Ona, I., & Isakov, E. (2003). The influence of prosthetic foot alignment on trans-tibial amputee gait. *Prosthetics and Orthotics International, 27*(1), 17-22.

Frossard, L., Stevenson, N., Sullivan, J., Uden, M., & Pearcy, M. (2011). Categorization of Activities of Daily Living of Lower Limb Amputees During Short-Term Use of a Portable Kinetic Recording System: A Preliminary Study. *Journal of Prosthetics & Orthotics, 23*(1), 2-11.

Gallagher, P., & Maclachlan, M. (2001). Adjustment to an Artificial Limb: A Qualitative Perspective. *Journal of Health Psychology, 6*(1), 85-100.

Gandevia, S. (1992). Some central and peripheral factors affecting human motoneuronal output in neuromuscular fatigue. *Sports Med, 13*(2), 93-98.

Gard, S., & Konz, R. (2003). The effect of a shock-absorbing pylon on the gait of persons with unilateral transtibial amputation. *J Rehabil Res Dev, 40*(2), 109-124.

Geil, M. D. (2002). Variability among Practitioners in Dynamic Observational Alignment of a Transfemoral Prosthesis. *Journal of Prosthetics & Orthotics, 14*(4), 159-164.

Geil, M. D. (2009). Assessing the state of clinically applicable research for evidence-based practice in prosthetics and orthotics. *J Rehabil Res Dev, 46*(3), 305-314.

Geil, M. D., & Lay, A. (2004). Plantar foot pressure responses to changes during dynamic trans-tibial prosthetic alignment in a clinical setting. *Prosthet Orthot Int 28*, 105-114.

Gibbs, P., & Asada, H. (2005). Wearable Conductive Fiber Sensors for Multi-Axis Human Joint Angle Measurements. *J Neuroeng Rehabil, 2*(1), 7.

Gitter, A., Czerniecki, J., & DeGroot, D. (1991). Biomechanical analysis of the influence of prosthetic feet on below-knee amputee walking. *Am J Phys Med Rehabil, 70*(3), 142-148.

Grabiner, M., Feuerbach, J., Lundin, T., & Davis, B. (1995). Visual guidance to force plates does not influence ground reaction force variability. *Journal of Biomechanics, 28*(9), 1115-1117.

Graham, L., Datta, D., Heller, B., Howitt, J., & Pros, D. (2007). A comparative study of conventional and energy-storing prosthetic feet in high-functioning transfemoral amputees. *Arch Phys Med Rehabil, 88*(6), 801-806.

GreatLakesNeurotechnologies. (2011). BioCapture: Acquiring EMG data. In G. L. Neurotechnologies (Ed.). Cleveland, OH.

Grumilliera, C., Martineta, N., Paysanta, J., Andréa, J.-M., & Beyaert, C. (2008). Compensatory mechanism involving the hip joint of the intact limb during gait in unilateral trans-tibial amputees. *Journal of Biomechanics, 41*(14), 2926-2931.

Hafner, B., Sanders, J., Czerniecki, J., & Fergason, J. (2002). Energy storage and return prostheses: does patient perception correlate with biomechanical analysis? *Clin Biomech (Bristol, Avon), 17*(5), 325-344.

Hafner, B., Willingham, L., Buell, N., Allyn, K., & Smith, D. (2007). Evaluation of Function, Performance, and Preference as Transfemoral Amputees Transition From Mechanical to Microprocessor Control of the Prosthetic Knee. *Archives of Physical Medicine and Rehabilitation, 88*(2), 207-217.

Hagberg, K., & Brånemark, R. (2009). One hundred patients treated with osseointegrated transfemoral amputation prostheses--rehabilitation perspective. *J Rehabil Res Dev, 46*(3), 331-344.

Hansen, A., Childress, D., & Knox, E. (2000). Prosthetic foot roll-over shapes with implications for alignment of trans-tibial prostheses. *Prosthetics and Orthotics International, 24*(3), 205-215.

Hansen, A., Gard, S., Childress, D., Ruhe, B., & Williams, R. (2007). *Automatically-Adapting Ankle-Foot Prosthesis Concept.* Paper presented at the 12th World Congress of the International Society for Prosthetics and Orthotics, Vancouver, Canada.

Hansen, A. H., Meier, M. R., Sam, M., Childress, D. S., & Edwards, M. L. (2003). Alignment of trans−tibial prostheses based on roll−over shape principles. *Prosthet Orthot Int 27*, 89-99.

Harris, M., Morberg, P., Bruce, W., & Walsh, W. (1999). An improved method for measuring tibiofemoral contact areas in total knee arthroplasty: a comparison of K-scan sensor and Fuji film. *J Biomech, 32*(9), 951-958.

Hausdorff, J. M. (2007). Gait dynamics, fractals and falls: Finding meaning in the stride-to-stride fluctuations of human walking. *Human Movement Science, 26*(4), 555-589.

Herr, H., & Grabowski, A. (2012). Bionic ankle-foot prosthesis normalizes walking gait for persons with leg amputation. *Proc Biol Sci, 279*(1728), 457-464.

Herr, H., & Wilkenfeld, A. (2003). User-adaptive control of a magnetorheological prosthetic knee. *Industrial Robot, 30*(1), 42-55.

Herzog, W., Nigg, B., Read, L., & Olsson, E. (1989). Asymmetries in ground reaction force patterns in normal human gait. *Med Sci Sports Exerc, 21*(1), 110-114.

Highsmith, M. J., Kahle, J. T., Carey, S. L., Lura, D. J., Dubey, R. V., & Quillen, W. S. (2010). Kinetic Differences Using a Power Knee and C-Leg While Sitting Down and Standing Up: A Case Report. *Journal of Prosthetics & Orthotics, 22*(4), 237-243.

Highsmith, M. J., Schulz, B. W., Hart-Hughes, S., Latlief, G. A., & Phillips, S. L. (2010). Differences in the Spatiotemporal Parameters of Transtibial and Transfemoral Amputee Gait. *Journal of Prosthetics & Orthotics, 22*(1), 26-30.

Hillery, S. C., & Wallace, E. S. (2000). Trans-tibial amputee gait adaptations as a result of prosthetic inertial manipulation. *Disability and Rehabilitation, 22*(8), 383-386.

Hodge, W., Carlson, K., Fijan, R., Burgess, R., Riley, P., Harris, W., & Mann, R. (1989). Contact pressures from an instrumented hip endoprosthesis. *The Journal of Bone and Joint Surgery. American Volume, 71*(9), 1378-1386.

Holden, J. P., Grood, E. S., Korvick, D. L., Cummings, J. F., Butler, D. L., & Bylski-Austrow, D. I. (1994). In vivo forces in the anterior cruciate ligament: Direct measurements during walking and trotting in a quadruped. *Journal of Biomechanics, 27*(5), 517-519, 521-526.

Hong, J., & Mun, M. (2005). Relationship between socket pressure and EMG of two muscles in trans-femoral stumps during gait. *Prosthet Orthot Int, 29*(1), 59-72.

Houghton, A., Taylor, P., Thurlow, S., Rootes, E., & McColl, I. (1992). Success rates for rehabilitation of vascular amputees: implications for preoperative assessment and amputation level. *Br J Surg, 79*(8), 753-755.

Hunter, D., Smith Cole, E., Murray, J., & Murray, T. (1995). Energy expenditure of below-knee amputees during harness-supported treadmill ambulation. *J Orthop Sports Phys Ther, 21*(5), 268-276.

Hunter, J., Katz, J., & Davis, K. (2008). Stability of phantom limb phenomena after upper limb amputation: A longitudinalstudy. *Neuroscience, 156*(4), 939-949.

Hurley, G., McKenney, R., Robinson, M., Zadravec, M., & Pierrynowski, M. (1990). The role of the contralateral limb in below-knee amputee gait. *Prosthetics and Orthotics International, 14*(1), 33-42.

Isakov, E., Burger, H., Krajnik, J., Gregoric, M., & Marincek, C. (1996). Influence of speed on gait parameters and on symmetry in trans-tibial amputees. *Prosthetics and Orthotics International, 20*(3), 153-158.

Isakov, E., Burger, H., Krajnik, J., Gregoric, M., & Marincek, C. (2001). Knee muscle activity during ambulation of trans-tibial amputees. *J Rehabil Med, 33*(5), 196-199.

Isakov, E., Keren, O., & Benjuya, N. (2000). Trans-tibial amputee gait: time-distance parameters and EMG activity. *Prosthetics and Orthotics International, 24*(3), 216-220.

Janura, M., Svoboda, Z., & Elfmark, M. (2006). The variability assessment of the dynamic gait parameters of persons with unilateral trans-tibial amputation. *Acta Univ. Palacki. Olomuc., Gymn., 36*(4), 19-24.

Jepson, F., Datta, D., Harris, I., Heller, B., Howitt, J., & McLean, J. (2008). A comparative evaluation of the Adaptive knee and Catech knee joints: a preliminary study. *Prosthetics and Orthotics International, 32*(1), 84-92.

Jia, X., Wang, R., Zhang, M., & Lia, X. (2008). Influence of Prosthetic Sagittal Alignment on Trans-Tibial Amputee Gait and Compensating Pattern: A Case Study. *Tsinghua Science & Technology, 13*(5), 581-586.

Jones, M., Bashford, G., & Bliokas, V. (2001). Weight-bearing, pain and walking velocity during primary transtibial amputee rehabilitation. *Clin Rehabil, 15*(2), 172-176.

Kahle, J. T. (2002). A Case Study Using Fluoroscope to Determine the Vital Elements of Transfemoral Interface Design. *Journal of Prosthetics & Orthotics, 14*(3), 121-126.

Kark, L., Vickers, D., McIntosh, A., & Simmons, A. (2012). Use of gait summary measures with lower limb amputees. *Gait & Posture, 35*(2), 238-243.

Kark, L., Vickers, D., Simmons, A., & McIntosh, A. (2009). Using the movement analysis profile with lower limb amputees. *Gait & Posture, 30*(Supplement 2), S42-S43.

Kegel, B., Carpenter, M., & Burgess, E. (1977). A survey of lower-limb amputees: prostheses, phantom sensations, and psychosocial aspects. *Bull Prosthet Res, 10*(27), 43-60.

Kendell, C., Lemaire, E., Dudek, N., & Kofman, J. (2010). Indicators of dynamic stability in transtibial prosthesis users. *Gait & Posture, 31*(3), 375-379.

Kesar, T. M., Binder-Macleod, S. A., Hicks, G. E., & Reisman, D. S. (2011). Minimal detectable change for gait variables collected during treadmill walking in individuals post-stroke. *Gait & Posture, 33*(2), 314-317.

Kirby, R. L., Brown, B. A., Connolly, C. M., McRae, S., & Phillips, P. L. (2009). Handling Stairs in the Seated Position for People With Unilateral Lower-Limb Amputations *Archives of Physical Medicine and Rehabilitation, 90*(7), 1250-1253

Kirker, S., Keymer, S., Talbot, J., & Lachmann, S. (1996). An assessment of the intelligent knee prosthesis. *Clinical Rehabilitation, 10*, 267-273.

Kitayama, I., Hada, S., Kawauchi, T., Yokota, H., & Hamada, T. (2010). *Development of a Portable Device for Gait Analysis, and Gait Analysis on Stairs and Uneven Terrain.* Paper presented at the 6th World Congress of Biomechanics (WCB 2010), Singapore.

Klute, G., Berge, J., Biggs, W., Pongnumkul, S., Popovic, Z., & Curless, B. (2011). Vacuum-assisted socket suspension compared with pin suspension for lower extremity amputees: effect on fit, activity, and limb volume. *Arch Phys Med Rehabil, 92*(10), 1570-1575.

Ko, S. u., Ling, S. M., Winters, J., & Ferrucci, L. (2009). Age-related mechanical work expenditure during normal walking: The Baltimore Longitudinal Study of Aging. *Journal of Biomechanics, 42*(12), 1834-1839.

Kram, R., Griffin, T., Donelan, J., & Chang, Y. (1998). Force treadmill for measuring vertical and horizontal ground reaction forces. *J Appl Physiol., 85*(2), 764-769.

Kuiken, T. A., Miller, L. A., Lipschutz, R. D., Lock, B. A., Stubblefield, K., Marasco, P. D., . . . Dumanian, G. A. (2007). Targeted reinnervation for enhanced prosthetic arm function in a woman with a proximal amputation: a case study. *369*(9559), 371-380.

Leardini, A., Chiari, L., Della Croce, U., & Cappozzo, A. (2005). Human movement analysis using stereophotogrammetry: Part 3. Soft tissue artifact assessment and compensation. *Gait & Posture, 21*(2), 212-225.

LeGare, S. (2009). Clinical Reliability of a Device for Measuring Forces and Moments in Amputee Gait. *MSPO Research Presentation*.

Legro, M., Reiber, G., del Aguila, M., Ajax, M., Boone, D., Larsen, J., . . . Sangeorzan, B. (1999). Issues of importance reported by persons with lower limb amputations and prostheses. *J Rehabil Res Dev, 36*(3), 155-163.

Leydet, M. G. (2011, May 13, 2011). [iPecs design and working principles].

Leydet, M. G., Harrington, R. H., Fedel, F. J., Link, M., & Street, J. J. (2007). USA Patent No. 20070255424.

Li, L., Patil, S., Steklov, N., Bae, W., Temple-Wong, M., D'Lima, D. D., . . . Fregly, B. J. (2011). Computational wear simulation of patellofemoral articular cartilage during in vitro testing. *Journal of Biomechanics, 44*(8), 1507-1513.

Lindström, L., Kadefors, R., & Petersén, I. (1977). An electromyographic index for localized muscle fatigue. *J Appl Physiol., 43*(4), 750-754.

Liu, T., Inoue, Y., & Shibata, K. (2009). Development of a wearable sensor system for quantitative gait analysis. *Measurement, 42*(7), 978-988.

Lorincz, K., Chen, B.-r., Challen, G. W., Chowdhury, A. R., Patel, S., Bonato, P., & Welsh, M. (2009). Mercury: A wearable sensor network platform for high-fidelity motion analysis. *Proceedings of the 7th ACM Conference on Embedded Networked Sensor Systems*, 183-196.

Macomber, B., Boone, D. A., & Beck, J. (2011). US Patent Patent No. 7886618.

Maki, B. (1997). Gait changes in older adults: predictors of falls or indicators of fear. *J Am Geriatr Soc, 45*(3), 313-320.
Manal, K., McClay Davis, I., Galinat, B., & Stanhope, S. (2003). The accuracy of estimating proximal tibial translation during natural cadence walking: bone vs. skin mounted targets. *Clinical Biomechanics, 18*(2), 126-131.
Mathie, M., Coster, A., Lovell, N., & Celler, B. (2004). Accelerometry: providing an integrated, practical method for long-term, ambulatory monitoring of human movement. *Physiol Meas, 25*(2), R1-20.
Matsen, S., Malchow, D., & Matsen, F. (2000). Correlations with Patients' Perspectives of the Result of Lower-Extremity Amputation. *The Journal of Bone and Joint Surgery, 82*, 1089-1095.
Merletti, R., Lo Conte, L., & Orizio, C. (1991). Indices of muscle fatigue. *J Electromyogr Kinesiol, 1*(1), 20-33.
Michael, J. (1999). Modern prosthetic knee mechanisms. *Clin Orthop Relat Res, 361*, 39-47.
Miller, L. A., & McCay, J. A. (2006). Summary and Conclusions From the Academy's Sixth State-of-the-Science Conference on Lower Limb Prosthetic Outcome Measures. *Journal of Prosthetics & Orthotics, 18*(6), P2-P7.
Mitchell, C., & Versluis, T. (1990). Management of an above-knee amputee with complex medical problems using the CAT-CAM prosthesis. *Phys Ther, 70*(6), 389-393.
Moirenfeld, I., Ayalon, M., Ben-Sira, D., & Isakov, E. (2000). Isokinetic strength and endurance of the knee extensors and flexors in trans-tibial amputees. *Prosthetics and Orthotics International, 24*(3), 221-225.
Morris, S., & Paradiso, J. (2002). *Shoe-integrated sensor system for wireless gait analysis and real-time feedback.* Paper presented at the Engineering in Medicine and Biology, 2002. 24th Annual Conference and the Annual Fall Meeting of the Biomedical Engineering Society EMBS/BMES Conference, 2002. Proceedings of the Second Joint.
Mulder, T., Nienhuis, B., & Pauwels, J. (1998). Clinical gait analysis in a rehabilitation context: some controversial issues. *Clin Rehabil, 12*(2), 99-106.
Mulder, T., Zijlstra, W., & Geurts, A. (2002). Assessment of motor recovery and decline. *Gait & Posture, 16*(2), 198-210.
Munro, B. J., Campbell, T. E., Wallace, G. G., & Steele, J. R. (2008). The intelligent knee sleeve: A wearable biofeedback device. *Sensors and Actuators B: Chemical, 131*(2), 541-547.
Murley, G. S., Menz, H. B., Landorf, K. B., & Bird, A. R. (2010). Reliability of lower limb electromyography during overground walking: A comparison of maximal- and sub-maximal normalisation techniques. *Journal of Biomechanics, 43*, 749-756.
Murray, C., & Fox, J. (2002). Body image and prosthesis satisfaction in the lower limb amputee. *Disabil Rehabil, 24*(17), 925-931.
Nadollek, H., Brauer, S., & Isles, R. (2002). Outcomes after trans-tibial amputation: the relationship between quiet stance ability, strength of hip abductor muscles and gait. *Physiother Res Int, 7*(4), 203-214.
Naeder, M., & Naeder, H.-G. (Eds.). (2000). *Prothesen-Kompendium, Untere Extremitaet* (3 ed.). Berlin: Schiele & Schoen.
Narita, H., Yokogushi, K., Shii, S., Kakizawa, M., & Nosaka, T. (1997). Suspension effect and dynamic evaluation of the total surface bearing (TSB) trans-tibial prosthesis: a comparison with the patellar tendon bearing (PTB) trans-tibial prosthesis. *Prosthet Orthot Int, 21*(3), 175-178.
Narita, H., Yokogushi, K., Ship, S., Kakizawa, M., & Nosaka, T. (1997). Suspension effect and dynamic evaluation of the total surface bearing (TSB) trans-tibial prosthesis: a

comparison with the patellar tendon bearing (PTB) trans-tibial prosthesis. *Prosthetics and Orthotics International, 21*, 175-178.

Neal, M., Neptune, R. R., & Gitter, A. (2003). *Neuromotor Adaptations used by Unilateral Transtibial Amputees during normal Walking.* Paper presented at the 27th Annual Meeting of the American Society of Biomechanics, Toledo. OH.

Nene, A., Mayagoitia, R., & Veltink, P. (1999). Assessment of rectus femoris function during initial swing phase. *Gait & Posture, 9*(1), 1-9.

Neumann, E. S. (2009). State-of-the-Science Review of Transtibial Prosthesis Alignment Perturbation. *Journal of Prosthetics & Orthotics, 21*(4), 175-193.

Neumann, E. S., Yalamanchili, K., Brink, J., & Lee, J. S. (2012). Transducer-based comparisons of the prosthetic feet used by transtibial amputees for different walking activities: a pilot study. *Prosthetics and Orthotics International, 36*(2), 203-216.

Nielsen, C., Psonak, R., & Kalter, T. (1989). Factors Affecting the Use of Prosthetic Services. *Journal of Prosthetics & Orthotics, 1*(4), 242-249.

Nielsen, D., Shurr, D., Golden, J., & Meier, K. (1988). Comparison of Energy Cost and Gait Efficiency During Ambulation in Below-Knee Amputees Using Different Prosthetic Feet - A Preliminary Report. *JPO Journal of Prosthetics & Orthotics, 1*(1), 24-31.

Nietert, M. (2008). *The Compromise Pivot Axis of the Knee Joint: Studies of the Kinematics of the Human Knee Joint in Regard to Their Approximation in Prosthetics (Berichte Aus Der Medizin)*. Aachen, Germany: Shaker.

Nolan, L., Wit, A., Dudziñski, K., Lees, A., Lake, M., & Wychowañski, M. (2003). Adjustments in gait symmetry with walking speed in trans-femoral and trans-tibial amputees. *Gait & Posture, 17*(2), 142-151.

O'Connor, K., & Bottum, M. (2009). Differences in cutting knee mechanics based on principal components analysis. *Med Sci Sports Exerc, 41*(4), 867-878.

Oggero, E., Pagnacco, G., Morr, D., Simon, S., & Berme, N. (1997). Probability of valid gait data acquisition using currently available force plates. *Biomed Sci Instrum, 34*, 392-397.

Ooi, S., Abu Osman, N., & Wan Abas, W. (2010). *Ambulatory Function Monitor of the Amputees with Their Prosthesis.* Paper presented at the 6th World Congress of Biomechanics (WCB 2010) Singapore.

Orendurff, M., Schoen, J., Bernatz, G., Segal, A., & Klute, G. (2008). How humans walk: bout duration, steps per bout, and rest duration. *J Rehabil Res Dev, 45*(7), 1077-1089.

Orendurff, M., Segal, A., Klute, G., McDowell, M., Pecoraro, J., & Czerniecki, J. (2006). Gait efficiency using the C-Leg. *J Rehabil Res Dev, 43*(2), 239-246.

Papaioannou, G., Demetropoulos, C. K., & King, Y. H. (2010). Predicting the effects of knee focal articular surface injury with a patient-specific finite element model. *The Knee, 17*(1), 61-68.

Papaioannou, G., Mitrogiannis, C., Nianios, G., & Fiedler, G. (2010). Assessment of amputee socketstump-residual bone kinematics during strenuous activities using Dynamic Roentgen Stereogrammetric Analysis. *Journal of Biomechanics, 22*(43(5)), 871-878.

Papaioannou, G., & Wood, J. R. (2011, March 16-19, 2011). *Transtibial Prosthetic Kinetics During Prolonged Strenuous Activities of Daily Living Measures by Internal Gait Analysis Instrumentation.* Paper presented at the 37th Annual Meeting of the AAOP, Orlando, FL.

Parkka, J., Ermes, M., Korpipaa, P., Mantyjarvi, J., Peltola, J., & Korhonen, I. (2006). Activity classification using realistic data from wearable sensors. *Information Technology in Biomedicine, IEEE Transactions on, 10*(1), 119-128

Pasquina, P. F., Tsao, J. W., Collins, D. M., Chan, B. L., Charrow, A., Karmarkar, A. M., & Cooper, R. A. (2008). Quality of medical care provided to service members with combatrelated

limb amputations: Report of patient satisfaction. *Journal of Rehabilitation Research & Development, 45*(7), 953-960.
Perry, S. D., Radtke, A., McIlroy, W. E., Fernie, G. R., & Maki, B. E. (2007). Efficacy and Effectiveness of a Balance-Enhancing Insole. *The Journals of Gerontology: Series A, 63*(6), 595-602.
Pezzin, L., Dillingham, T., MacKenzie, E., Ephraim, P., & Rossbach, P. (2004). Use and satisfaction with prosthetic limb devices and related services. *Archives of Physical Medicine and Rehabilitation, 85*(5), 723-729.
Piazza, S. J., & Delp, S. L. (1996). The influence of muscles on knee flexion during the swing phase of gait. *Journal of Biomechanics, 29*(6), 723-733.
Pinzur, M., Cox, W., Kaiser, J., Morris, T., Patwardhan, A., & Vrbos, L. (1995). The effect of prosthetic alignment on relative limb loading in persons with trans-tibial amputation: a preliminary report. *J Rehabil Res Dev, 32*(4), 373-377.
Postema, K., Hermens, H., de Vries, J., Koopman, H., & Eisma, W. (1997). Energy storage and release of prosthetic feet. Part 2: Subjective ratings of 2 energy storing and 2 conventional feet, user choice of foot and deciding factor. *Prosthet Orthot Int, 21*(1), 28-34.
Powers, C. M., Boyd, L., Torburn, L., & Perry, J. (1997). Stair ambulation in persons with transtibial amputation: an analysis of the Seattle LightFoot. *J Rehabil Res Dev, 34*(1), 9-18.
Powers, C. M., Rao, S., & Perry, J. (1998). Knee kinetics in trans-tibial amputee gait. *Gait & Posture, 8*(1), 1-7.
Radcliffe, C. (1994). Four-bar linkage prosthetic knee mechanisms: kinematics, alignment and prescription criteria. *Prosthetics and Orthotics International, 18*(3), 159-173.
Raffin, E., Bonnet, S., & Giraux, P. (2012). Concurrent validation of a magnetometer-based step counter in various walking surfaces. *Gait & Posture, 35*(1), 18-22.
Reinschmidt, C., van den Bogert, A., Lundberg, A., Nigg, B., Murphy, N., Stacoff, A., & Stano, A. (1997). Tibiofemoral and tibiocalcaneal motion during walking: external vs. skeletal markers. *Gait & Posture, 6*(2), 98-109.
Renström, P., Grimby, G., Morelli, B., & Palmertz, B. (1983). Thigh muscle atrophy in below-knee amputees. *Scand J Rehabil Med Suppl, 9*, 150-162.
Rice, J., & Seeley, M. K. (2010). An Investigation of Lower-extremity Functional Asymmetry For Non-preferred Able-bodied Walking Speeds. *International Journal of Exercise Science, 3*(4).
Rogers, J., MacBride, A., Whylie, B., & Freeman, S. (1977-1978). The use of groups in the rehabilitation of amputees. *Int J Psychiatry Med, 8*(3), 243-255.
Rossi, S., Doyle, W., & Skinner, H. (1995). Gait initiation of persons with below-knee amputation: the characterization and comparison of force profiles. *J Rehabil Res Dev, 32*(2), 120-127.
Rupp, S., Hopf, T., Hess, T., Seil, R., & Kohn, D. M. (1999). Resulting Tensile Forces in the Human Bone-Patellar Tendon-Bone Graft: Direct Force Measurement In Vitro. *Arthroscopy: The Journal of Arthroscopic & Related Surgery, 15*(2), 179-184.
Sachs, M., Bojunga, J., & Encke, A. (1999). Historical Evolution of Limb Amputation. *World Journal of Surgery, 23*, 1088-1093.
Sadeghi, H., Allard, P., & Duhaime, P. (2001). Muscle power compensatory mechanisms in below-knee amputee gait. *Am J Phys Med Rehabil, 80*(1), 25-32.
Sadeghi, H., Allard, P., Prince, F., & Labelle, H. (2000). Symmetry and limb dominance in able-bodied gait: a review. *Gait & Posture, 12*(1), 34-45.

Sanders, J., Bell, D., Okumura, R., & Dralle, A. (1998). Effects of alignment changes on stance phase pressures and shear stresses on transtibial amputees: measurements from 13 transducer sites. *IEEE Trans Rehabil Eng, 6*(1), 21-31.

Sanders, J., & Daly, C. (1999). Interface pressures and shear stresses: sagittal plane angular alignment effects in three trans-tibial amputee case studies. *Prosthetics and Orthotics International, 23*(1), 21-29.

Sanders, J., Fergason, J., Zachariah, S., & Jacobsen, A. (2002). Interface pressure and shear stress changes with amputee weight loss: case studies from two trans-tibial amputee subjects. *Prosthet Orthot Int, 26*(3), 243-250.

Sanders, J., Miller, R., Berglund, D., & Zachariah, S. (1997). A modular six-directional force sensor for prosthetic assessment: a technical note. *The Journal of Rehabilitation Research and Development, 34*(2), 195-202.

Sanders, J., Reed, R., & Marks, R. (1993). Computer-aided prosthetic alignment for lower-limb amputees. *Engineering in Medicine and Biology Society, . Proceedings of the 15th Annual International Conference of the IEEE* 1282 - 1283.

Sanders, J., Zachariah, S., Baker, A., Greve, J., & Clinton, C. (2000). Effects of changes in cadence, prosthetic componentry, and time on interface pressures and shear stresses of three trans-tibial amputees. *Clin Biomech (Bristol, Avon), 15*(9), 684-694.

Sanderson, D. J., & Martin, P. E. (1996). Joint kinetics in unilateral below-knee amputee patients during running. *Archives of Physical Medicine and Rehabilitation, 77*(12), 1279-1285.

Schache, A., & Baker, R. (2007). On the expression of joint moments during gait. *Gait & Posture, 25*(3), 440-452.

Schmalz, T., Blumentritt, S., & Jarasch, R. (2002). Energy expenditure and biomechanical characteristics of lower limb amputee gait: the influence of prosthetic alignment and different prosthetic components. *Gait Posture, 16*(3), 255-263.

Schmalz, T., Blumentritt, S., & Marx, B. (2007). Biomechanical analysis of stair ambulation in lower limb amputees. *Gait & Posture, 25*(2), 267-278.

Schmalz, T., Blumentritt, S., & Reimers, C. (2001). Selective thigh muscle atrophy in trans-tibial amputees: an ultrasonographic study. *Arch Orthop Trauma Surg, 121*, 307-312.

Seelen, H., Anemaat, S., Janssen, H., & Deckers, J. (2003). Effects of prosthesis alignment on pressure distribution at the stump/socket interface in transtibial amputees during unsupported stance and gait. *Clin Rehabil, 17*(7), 787-796.

Segal, A., Orendurff, M., Czerniecki, J., Shofer, J., & Klute, G. (2009). Transtibial amputee joint rotation moments during straight-line walking and a common turning task with and without a torsion adapter. *J Rehabil Res Dev, 46*(3), 375-383.

Segal, A., Orendurff, M., Klute, G., McDowell, M., Pecoraro, J., Shofer, J., & Czerniecki, J. (2006). Kinematic and kinetic comparisons of transfemoral amputee gait using C-Leg and Mauch SNS prosthetic knees. *J Rehabil Res Dev, 43*(7), 857-870.

Seliktar, R., & Mizrahi, J. (1986). Some gait characteristics of below-knee amputees and their reflection on the ground reaction forces. *Eng Med, 15*, 27-34.

Selles, R., Bussmann, J., Klip, L., Speet, B., Van Soest, A., & Stam, H. (2004). Adaptations to mass perturbations in transtibial amputees: kinetic or kinematic invariance? *Arch Phys Med Rehabil, 85*(12), 2046-2052.

Silverman, A., Fey, N., Portillo, A., Walden, J., Bosker, G., & Neptune, R. (2008). Compensatory mechanisms in below-knee amputee gait in response to increasing steady-state walking speeds. *Gait & Posture, 28*(4), 602-609.

Sin, S., Chow, D., & Cheng, J. (2001). Significance of non-level walking on transtibial prosthesis fitting with particular reference to the effects of anterior-posterior alignment. *J Rehabil Res Dev, 38*(1), 1-6.

Sjödahl, C., Jarnlo, G., & Persson, B. (2001). Gait improvement in unilateral transfemoral amputees by a combined psychological and physiotherapeutic treatment. *J Rehabil Med, 33*(3), 114-118.

Skinner, H., & Effeney, D. (1985). Gait analysis in amputees. *American Journal of Physical Medicine & Rehabilitation, 64*(2), 82-89.

Slavens, B., Sturm, P., Bajournaite, R., & Harris, G. (2009). Upper extremity dynamics during Lofstrand crutch-assisted gait in children with myelomeningocele. *Gait & Posture, 4*(30), 511-517.

Smets, E., Garssen, B., Bonke, B., & De Haes, J. (1995). The Multidimensional Fatigue Inventory (MFI) psychometric qualities of an instrument to assess fatigue. *J Psychosom Res, 39*(3), 315-325.

Smith, R. (1996). Measuring the outcomes of assistive technology: challenge and innovation. *Assist Technol., 8*(2), 71-81.

Snyder, R., Powers, C. M., Fontaine, C., & Perry, J. (1995). The effect of five prosthetic feet on the gait and loading of the sound limb in dysvascular below-knee amputees. *J Rehabil Res Dev, 32*(4), 309-315.

Soares, A. S. O. d. C., Yamaguti, E. Y., Mochizuki, L., Amadio, A. C., & Serrão, J. C. (2009). Biomechanical parameters of gait among transtibial amputees: a review. *Sao Paulo Med J, 127*(5), 302-309.

Söderberg, B., Ryd, L., & Persson, B. M. (2003). Roentgen Stereophotogrammetric Analysis of Motion between the Bone and the Socket in a Transtibial Amputation Prosthesis: A Case Study. *Journal of Prosthetics & Orthotics, 15*(3), 95-99.

Sosnoff, J. J., Sandroff, B. M., & Motl, R. W. (2012). Quantifying gait abnormalities in persons with multiple sclerosis with minimal disability. *Gait & Posture, 36*(1), 154-156.

Stauffer, R., Chao, E., & Brewster, R. (1977). Force and motion analysis of the normal, diseased, and prosthetic ankle joint. *Clin Orthop Relat Res, 127*, 189-196.

Stevens, P. M., & Carson, R. (2007). Case Report: Using the Activities-Specific Balance Confidence Scale to Quantify the Impact of Prosthetic Knee Choice on Balance Confidence. *Journal of Prosthetics & Orthotics, 19*(4), 114-116.

Stineman, M. G., Kurichi, J. E., Kwong, P. L., Maislin, G., Reker, D. M., Vogel, W. B., . . . Bates, B. E. (2009). Survival Analysis in Amputees Based on Physical Independence Grade Achievement. *Arch Surg, 144*(6), 543-552.

Street, G. (2006). Vacuum Suspension and its Effects on the Limb. *Orthopädie-Technik Quarterly, English edition, IV*, 1-7.

Summers, G., Morrison, J., & Cochrane, G. (1988). Amputee walking training: a preliminary study of biomechanical measurements of stance and balance. *Int Disabil Stud, 10*(1), 1-5.

Svoboda, Z., Janura, M., Cabell, L., & Elfmark, M. (2012). Variability of kinetic variables during gait in unilateral transtibial amputees. *Prosthetics and Orthotics International, 36*(2), 225-230.

Takeda, R., Tadano, S., Todoh, M., Morikawa, M., Nakayasu, M., & Yoshinari, S. (2009). Gaitanalysis using gravitational acceleration measured by wearable sensors. *Journal of Biomechanics, 42*(3), 223-233.

Taylor, M., Clark, E., Offord, E., & Baxter, C. (1996). A comparison of energy expenditure by a high level trans-femoral amputee using the Intelligent Prosthesis and conventionally damped prosthetic limbs. *Prosthetics and Orthotics International, 20*(2), 116-121.

Tesio, L., Lanzi, D., & Detrembleur, C. (1998). The 3-D motion of the centre of gravity of the human body during level walking. II. Lower limb amputees. *Clin Biomech (Bristol, Avon), 13*(2), 83-90.

Thompson, B. (1991). A primer on the logic and use of canonical correlation analysis. *Measurement & Evaluation in Counseling & Development, 24*(2), 80-96.

Torburn, L., Perry, J., Ayyappa, E., & Shanfield, S. (1990). Below-knee amputee gait with dynamic elastic response prosthetic feet: a pilot study. *J Rehabil Res Dev, 27*(4), 369-384.

Torburn, L., Powers, C. M., Guiterrez, R., & Perry, J. (1995). Energy expenditure during ambulation in dysvascular and traumatic below-knee amputees: a comparison of five prosthetic feet. *J Rehabil Res Dev, 32*(2), 111-119.

Torburn, L., Schweiger, G., Perry, J., & Powers, C. M. (1994). Below-knee amputee gait in stair ambulation. A comparison of stride characteristics using five different prosthetic feet. *Clin Orthop Relat Res, 303*, 185-192.

Tura, A., Raggi, M., Rocchi, L., Cutti, A. G., & Chiari, L. (2010). Gait symmetry and regularity in transfemoral amputees assessed by trunk accelerations. *J Neuroeng Rehabil, 7*(4).

Vagenas, G., & Hoshizaki, B. (1992). A multivariable Analysis of lower extremity kinematic asymmetry in running. *International Journal of Sports Biomechanics, 8*(1), 11-29.

van der Linde, H., Hofstad, C., Geurts, A., Postema, K., Geertzen, J., & van Limbeek, J. (2004). A systematic literature review of the effect of different prosthetic components on human functioning with a lower-limb prosthesis. *Journal of Rehabilitation Research and Development, 41*(4), 555-570.

Van Velzen, J., Houdijk, H., Polomski, W., & Van Bennekom, C. (2005). Usability of gait analysis in the alignment of trans-tibial prostheses: a clinical study. *Prosthetics and Orthotics International, 29*(3), 255-267.

Vanicek, N., Strike, S., McNaughton, L., & Polman, R. (2009). Gait patterns in transtibial amputee fallers vs. non-fallers: biomechanical differences during level walking. *Gait & Posture, 29*(3), 415-420.

Versluys, R., Beyl, P., Van Damme, M., Desomer, A., Van Ham, R., & Lefeber, D. (2009). Prosthetic feet: state-of-the-art review and the importance of mimicking human ankle-foot biomechanics. *Disabil Rehabil Assist Technol, 4*(2), 65-75.

Vickers, D., Palk, C., McIntosh, A., & Beatty, K. (2008). Elderly unilateral transtibial amputee gait on an inclined walkway: a biomechanical analysis. *Gait & Posture, 27*(3), 518-529.

Waters, R., Perry, J., Antonelli, D., & Hislop, H. (1976). Energy cost of walking of amputees: the influence of level of amputation. *The Journal of Bone and Joint Surgery, 58*(1), 42-46.

Wearing, S. C., Urry, S. R., & Smeathers, J. E. (2000). The effect of visual targeting on ground reaction force and temporospatial parameters of gait. *Clinical Biomechanics, 15*(8), 583-591.

White, S., Yack, H., Tucker, C., & Lin, H. (1998). Comparison of vertical ground reaction forces during overground and treadmill walking. *Med Sci Sports Exerc, 30*(10), 1537-1542.

Wilson, J., Asfour, S., Abdelrahman, K., & Gailey, R. (2009). A new methodology to measure the running biomechanics of amputees. *Prosthetics and Orthotics International, 33*(3), 218-229.

Winter, D. A., & Sienko, S. E. (1988). Biomechanics of Below-Knee Amputee Gait. *Journal of Biomechanics, 21*(5), 361-367.

Wolf, A., Swift, J. B., Swinney, H. L., & Vastano, J. A. (1985). Determining Lyapunov exponents from a time series. *Physica D: Nonlinear Phenomena, 16*(3), 285-317.

Worrell, T., & Perrin, D. (1992). Hamstring muscle injury: the influence of strength, flexibility, warm-up, and fatigue. *J Orthop Sports Phys Ther, 16*(1), 12-18.

Wrigley, A. T., Albert, W. J., Deluzio, K. J., & Stevenson, J. M. (2006). Principal component analysis of lifting waveforms. *Clinical Biomechanics 21*, 567-578.

Wurdeman, S. R., Myers, S. A., Jacobsen, A. L., & Stergiou, N. (2012). *Amputee Prosthesis Preference is Related to the Nonlinear Dynamics.* Paper presented at the Gait and Clinical Movement Analysis Society (GCMAS) Conference, Grand Rapids, MI.

Xiaobing, L., Xiaohong, J., Peng, D., & Lidan, F. (2005). Influence of Shoe-heel Height of the Trans-tibial Prosthesis on Static Standing Biomechanics. *Conf Proc IEEE Eng Med Biol Soc, 5*, 5227-5229.

Yamamoto, S., Suto, Y., Kawamura, H., Hashizume, T., Kakurai, S., & Sugahara, S. (1983). Quantitative gait evaluation of hip diseases using principal component analysis. *J Biomech, 16*(9), 717-726.

Yang, L., Solomonidis, S. E., Spence, W. D., & Paul, J. P. (1991). The influence of limb alignment on the gait of above-knee amputees. *Journal of Biomechanics, 24*(11), 981-997.

Yoho, R. M., Wilson, P. K., Gerres, J. A., & Freschi, S. (2008). Chopart's Amputation: A 10-Year Case Study. *The Journal of Foot and Ankle Surgery, 47*(4), 326-331.

Zahedi, M. (1986). Alignment of lower-limb prosthesis. *Journal of Rehabilitation Research and Development, 23*(2), 2-19.

Zahedi, M., Spence, W., Solomomidis, S., & Paul, J. (1987). Repeatability of kinetic and kinematic measurements in gait studies of the lower limb amputee. *Prosthetics and Orthotics International, 11*, 55-64.

Zeni Jr., J. A., & Higginson, J. S. (2010). Gait parameters and stride-to-stride variability during familiarization to walking on a split-belt treadmill. *Clinical Biomechanics, 25*(4), 383-386.

Ziegler-Graham, K., MacKenzie, E., Ephraim, P., Travison, T., & Brookmeyer, R. (2008). Estimating the prevalence of limb loss in the United States: 2005 to 2050. *Arch Phys Med Rehabil, 89*(3), 422-429.

Zmitrewicz, R., Neptune, R., Walden, J., Rogers, W., & Bosker, G. (2006). The effect of foot and ankle prosthetic components on braking and propulsive impulses during transtibial amputee gait. *Arch Phys Med Rehabil, 87*(10), 1334-1339.

Zmitrewicz, R. J., Neptune, R. R., & Sasaki, K. (2007). Mechanical energetic contributions from individual muscles and elastic prosthetic feet during symmetric unilateral transtibial amputee walking: A theoretical study. *Journal of Biomechanics 40*, 1824-1831.

7 Appendix B: Data tables

Extracted gait analysis curve parameters for all 10 subjects are listed in the following tables. Data were collected during one step cycle in every condition. Units are degrees for angles, Nm for moments and cm for step length. Timing of the peaks is normalized to percent of the overall gait cycle from heel contact to subsequent heel contact. The combined indices contain kinematics and kinetics data respectively, as defined in table 2.

Tables 16-25: Extracted gait analysis data and computed asymmetry indices for all subjects

subject 1	Prosthesis right				sound leg left				Asymmetry			
	PRE/ NORM	PRE/PF	POST/ NORM	POST/PF	PRE/ NORM	PRE/PF	POST/ NORM	POST/PF	PRE/ NORM	PRE/PF	POST/ NORM	POST/PF
max knee flex	71.395	69.866	68.299	70.888	70.105	66.006	69.970	68.676	0.018	0.057	0.024	0.032
% time of max	71	75	72	71	73	77	74	75	0.028	0.026	0.027	0.055
max dorsiflex	10.034	9.361	10.823	10.524	8.26	6.589	9.846	8.576	0.194	0.348	0.095	0.204
% time of max	50	52	52	53	49	50	51	47	0.020	0.039	0.019	0.120
max plantarflex1	-8.579	-7.701	-5.333	-10.701	-3.017	-3.809	-3.993	-6.244	0.959	0.676	0.287	0.526
% time of pflex1	9	12	8	16	9	11	8	9	0	0.087	0	0.560
max plantarflex2	0.803	0.989	2.566	-3.784	-18.798	-19.433	-17.684	-19.421	2.178	2.214	2.679	1.348
% time of pflex2	66	71	70	69	64	68	66	66	0.031	0.043	0.059	0.044
max knee moment	0.442	0.331	0.471	0.253	0.755	0.788	0.688	0.693	0.523	0.817	0.374	0.930
% time of max	15	17	15	14	16	16	14	14	0.065	0.061	0.069	0
max dorsiflex moment	1.314	1.238	1.206	1.279	1.301	1.273	1.353	1.281	0.010	0.028	0.115	0.002
% time of max	46	49	48	46	48	50	48	50	0.043	0.020	0.000	0.083
max plantarflex moment	-0.251	-0.303	-0.274	-0.221	-0.303	-0.327	-0.324	-0.355	0.188	0.076	0.167	0.465
% time of max	8	10	8	8	11	11	9	9	0.316	0.095	0.118	0.118
STP % of cycle	60.000	62.857	60.952	63.462	61.321	64.423	61.905	63.462	0.022	0.025	0.016	0.000
step length	80.400	75.317	75.839	75.635	63.011	68.901	70.687	67.454	0.243	0.089	0.070	0.114

combined index (avg)	0.302	0.294	0.257	0.288
combined kinematics	0.369	0.360	0.328	0.300
combined kinetics	0.191	0.183	0.141	0.266

subject 2	**Prosthesis right**				**sound leg left**				**Asymmetry**			
	PRE/ NORM	PRE/PF	POST/ NORM	POST/PF	PRE/ NORM	PRE/PF	POST/ NORM	POST/PF	PRE/ NORM	PRE/PF	POST/ NORM	POST/PF
max knee flex	68.816	68.582	73.900	80.429	69.523	67.267	65.674	64.102	0.010	0.019	0.118	0.226
% time of max	71	72	70	69	73	75	75	73	0.028	0.041	0.069	0.056
max dorsiflex	17.512	17.164	21.768	29.241	8.782	7.474	2.964	5.828	0.664	0.787	1.521	1.335
% time of max	53	52	50	49	52	52	53	53	0.019	0	0.058	0.078
max plantarflex1	-10.254	-10.958	-9.059	-8.616	-6.78	-8.461	-9.547	-9.336	0.408	0.257	0.052	0.080
% time of pflex1	8	10	7	5	10	11	12	13	0.222	0.095	0.526	0.889
max plantarflex2	-1.904	-3.501	0.383	5.699	-21.364	-25.506	-32.110	-27.850	1.673	1.517	2.048	3.029
% time of pflex2	69	69	66	80	67	69	69	67	0.029	0	0.044	0.177
max knee moment	0.131	0.163	0.245	0.183	0.847	0.989	1.220	1.119	1.464	1.434	1.331	1.438
% time of max	60	19	16	16	17	16	16	16	1.117	0.171	0	0
max dorsiflex moment	1.426	1.435	1.421	1.186	1.532	1.585	1.901	1.862	0.072	0.099	0.289	0.444
% time of max	48	48	46	46	52	52	52	52	0.080	0.080	0.122	0.122
max plantarflex moment	-0.095	-0.116	-0.068	-0.063	-0.309	-0.303	-0.486	-0.551	1.059	0.893	1.509	1.590
% time of max	6	8	5	4	11	8	10	11	0.588	0	0.667	0.933
STP % of cycle	64.463	64.167	58.929	59.292	66.393	66.957	66.667	64.286	0.029	0.043	0.123	0.081
step length	68.281	74.328	75.117	77.924	69.255	75.233	73.724	80.820	0.014	0.012	0.019	0.036

combined index (avg)	0.467	0.341	0.531	0.657
combined kinematics	0.310	0.277	0.458	0.599
combined kinetics	0.730	0.446	0.653	0.754

subject 3	**Prosthesis left**				**sound leg right**				**Asymmetry**			
	PRE/ NORM	PRE/PF	POST/ NORM	POST/PF	PRE/ NORM	PRE/PF	POST/ NORM	POST/PF	PRE/ NORM	PRE/PF	POST/ NORM	POST/PF
max knee flex	64.985	59.901	61.959	60.133	65.654	58.671	62.531	60.51	0.010	0.021	0.009	0.006
% time of max	76	79	72	78	73	71	75	69	0.040	0.107	0.041	0.122
max dorsiflex	18.953	20.414	22.125	18.036	21.007	25.647	23.226	22.118	0.103	0.227	0.049	0.203
% time of max	73	75	73	78	54	52	57	53	0.299	0.362	0.246	0.382
max plantarflex1	-10.328	-15.649	-18.14	-10.585	-6.815	-4.73	-5.14	-4.19	0.410	1.072	1.117	0.866
% time of pflex1	7	8	6	7	10	9	11	10	0.353	0.118	0.588	0.353
max plantarflex2	-18.953	-20.414	-1.839	-18.036	-2.111	-1.799	-3.679	-1.102	1.599	1.676	0.667	1.770
% time of pflex2	73	75	63	78	71	69	80	69	0.028	0.083	0.238	0.122
max knee moment	0.057	0.084	0.345	0.472	0.426	0.354	0.276	0.309	1.528	1.233	0.222	0.417
% time of max	76	66	18	12	18	17	27	20	1.234	1.181	0.400	0.500
max dorsiflex moment	1.324	1.259	1.079	1.188	0.888	1.02	0.969	0.857	0.394	0.210	0.107	0.324
% time of max	54	56	51	57	49	49	52	49	0.097	0.133	0.019	0.151
max plantarflex moment	0.005	0.01	0.009	-0.065	-0.28	-0.267	-0.245	-0.228	2.073	2.156	2.153	1.113
% time of max	2	3	2	4	8	7	8	8	1.200	0.800	1.200	0.667
STP % of cycle	67.391	70.629	64.138	70.769	64.706	62.162	66.923	62.687	0.041	0.128	0.042	0.121
step length	64.419	70.961	77.135	55.113	69.552	69.648	63.549	62.791	0.077	0.019	0.193	0.130

	PRE/ NORM	PRE/PF	POST/ NORM	POST/PF
combined index (avg)	0.593	0.595	0.456	0.453
combined kinematics	0.296	0.381	0.319	0.408
combined kinetics	1.088	0.952	0.684	0.529

subject 4	**Prosthesis right**				**Prosthesis left**				**Asymmetry**			
	PRE/ NORM	PRE/PF	POST/ NORM	POST/PF	PRE/ NORM	PRE/PF	POST/ NORM	POST/PF	PRE/ NORM	PRE/PF	POST/ NORM	POST/PF
max knee flex	64.255	59.585	53.891	61.923	58.847	55.981	59.617	60.050	0.088	0.062	0.101	0.031
% time of max	69	73	73	67	75	74	78	77	0.083	0.014	0.066	0.139
max dorsiflex	19.622	18.355	16.057	24.202	20.374	18.64	16.769	22.080	0.038	0.015	0.043	0.092
% time of max	52	54	51	48	54	54	58	56	0.038	0	0.128	0.154
max plantarflex1	-6.743	-8.111	-6.564	-0.876	-4.713	-7.699	-9.028	-3.200	0.354	0.052	0.316	1.140
% time of pflex1	9	12	9	4	6	10	10	13	0.400	0.182	0.105	1.059
max plantarflex2	2.123	0.466	2.258	6.277	5.104	2.288	2.477	7.524	0.825	1.323	0.093	0.181
% time of pflex2	65	69	69	63	68	69	72	72	0.045	0	0.043	0.133
max knee moment	0.573	0.529	2.661	2.561	0.614	0.147	3.566	4.009	0.069	1.130	0.291	0.441
% time of max	57	59	67	64	23	29	75	91	0.850	0.682	0.113	0.348
max dorsiflex moment	1.202	1.221	0.593	0.409	1.045	0.093	0.276	4.905	0.140	1.717	0.730	1.692
% time of max	52	54	39	52	55	51	61	95	0.056	0.057	0.440	0.585
max plantarflex moment	-0.354	-0.455	-0.256	-0.283	-0.412	-0.138	-0.494	-0.417	0.151	1.069	0.635	0.383
% time of max	11	14	90	66	10	10	27	61	0.095	0.333	1.077	0.079
STP % of cycle	65.693	65.957	63.816	60.000	66.165	64.964	73.203	68.276	0.007	0.015	0.137	0.129
step length	59.558	59.070	56.221	55.466	60.904	58.963	53.041	57.884	0.022	0.002	0.058	0.043

combined index (avg)	0.204	0.416	0.273	0.414
combined kinematics	0.190	0.167	0.109	0.310
combined kinetics	0.227	0.831	0.547	0.588

subject 5	Prosthesis right				Prosthesis left				Asymmetry			
	PRE/ NORM	PRE/PF	POST/ NORM	POST/PF	PRE/ NORM	PRE/PF	POST/ NORM	POST/PF	PRE/ NORM	PRE/PF	POST/ NORM	POST/PF
max knee flex	66.917	78.338	80.466	82.920	74.233	74.737	82.854	71.673	0.104	0.047	0.029	0.146
% time of max	72	73	71	77	74	75	73	78	0.027	0.027	0.028	0.013
max dorsiflex	19.437	16.805	22.504	17.804	15.633	13.753	16.112	12.957	0.217	0.200	0.331	0.315
% time of max	50	55	48	58	53	54	51	57	0.058	0.018	0.061	0.017
max plantarflex1	-2.378	-5.252	-5.854	-7.045	-4.545	-6.463	-8.43	-7.824	0.626	0.207	0.361	0.105
% time of pflex1	6	9	8	9	9	10	11	12	0.400	0.105	0.316	0.286
max plantarflex2	4.247	4.256	6.020	4.481	1.372	-1.609	-2.815	-2.778	1.023	4.431	5.513	8.525
% time of pflex2	73	80	65	80	74	71	70	74	0.014	0.119	0.074	0.078
max knee moment	2.219	2.189	2.629	2.02	3.306	2.749	3.061	2.560	0.393	0.227	0.152	0.236
% time of max	99	65	43	59	9	64	48	65	1.667	0.016	0.110	0.097
max dorsiflex moment	3.653	0.737	0.009	0.632	3.114	0.489	0.01	0.399	0.159	0.405	0.105	0.452
% time of max	99	39	22	47	25	36	27	41	1.194	0.080	0.204	0.136
max plantarflex moment	-1.938	-0.195	-0.824	-0.004	-0.624	-0.196	-0.564	-0.002	1.026	0.005	0.375	0.667
% time of max	67	68	37	96	7	24	42	95	1.622	0.957	0.127	0.010
STP % of cycle	66.667	67.521	63.107	70.175	62.879	68.033	66.000	71.818	0.058	0.008	0.045	0.023
step length	64.816	60.975	79.763	53.907	63.823	60.738	81.011	68.471	0.015	0.004	0.016	0.238

combined index (avg)	0.538	0.428	0.490	0.709
combined kinematics	0.254	0.517	0.677	0.975
combined kinetics	1.010	0.281	0.179	0.266

subject 6	**Prosthesis right**				**sound leg left**				**Asymmetry**			
	PRE/ NORM	PRE/PF	POST/ NORM	POST/PF	PRE/ NORM	PRE/PF	POST/ NORM	POST/PF	PRE/ NORM	PRE/PF	POST/ NORM	POST/PF
max knee flex	65.537	62.141	65.226	61.493	60.473	58.530	59.968	56.941	0.080	0.060	0.084	0.077
% time of max	70	70	70	71	71	72	70	71	0.014	0.028	0	0
max dorsiflex	16.217	14.145	16.778	14.048	4.409	1.806	13.544	10.004	1.145	1.547	0.213	0.336
% time of max	50	51	48	48	49	50	48	48	0.020	0.020	0	0
max plantarflex1	-4.296	-5.360	-3.211	-3.801	-11.107	-11.961	-5.770	-4.652	0.884	0.762	0.570	0.201
% time of pflex1	7	9	6	9	9	12	7	8	0.250	0.286	0.154	0.118
max plantarflex2	-1.306	-2.885	-4.622	-4.869	-29.793	-29.708	-17.899	-16.012	1.832	1.646	1.179	1.067
% time of pflex2	64	66	66	68	66	67	65	66	0.031	0.015	0.015	0.030
max knee moment	2.448	2.624	2.642	2.811	2.132	2.354	1.678	2.932	0.138	0.108	0.446	0.042
% time of max	59	60	46	50	59	61	57	46	0	0.017	0.214	0.083
max dorsiflex moment	0.780	0.764	0.467	0.446	0.793	0.735	0.410	0.607	0.017	0.039	0.130	0.306
% time of max	52	53	40	39	50	50	49	38	0.039	0.058	0.202	0.026
max plantarflex moment	-0.403	-0.406	-0.005	-0.188	-0.623	-0.604	-0.184	-0.091	0.429	0.392	1.894	0.695
% time of max	21	24	26	53	22	23	61	52	0.047	0.043	0.805	0.019
STP % of cycle	63.793	65.873	67.308	63.793	66.087	64.754	62.376	61.818	0.035	0.017	0.076	0.031
step length	77.948	75.413	82.828	75.097	76.025	74.256	75.631	75.487	0.025	0.015	0.091	0.005

combined index (avg)	0.312	0.316	0.380	0.190
combined kinematics	0.432	0.440	0.238	0.187
combined kinetics	0.112	0.109	0.615	0.195

subject 7	Prosthesis left				sound leg right				Asymmetry			
	PRE/ NORM	PRE/PF	POST/ NORM	POST/PF	PRE/ NORM	PRE/PF	POST/ NORM	POST/PF	PRE/ NORM	PRE/PF	POST/ NORM	POST/PF
max knee flex	63.118	62.461	68.209	62.677	74.503	61.623	59.622	60.131	0.165	0.014	0.134	0.041
% time of max	74	73	75	74	69	73	74	73	0.070	0	0.013	0.014
max dorsiflex	14.671	11.406	9.445	14.519	14.167	12.015	16.183	20.588	0.035	0.052	0.526	0.346
% time of max	54	51	54	52	31	35	50	40	0.541	0.372	0.077	0.261
max plantarflex1	-10.318	-9.032	-9.035	-23.498	-5.115	-7.092	-7.783	-8.171	0.674	0.241	0.149	0.968
% time of pflex1	10	8	9	13	11	9	11	7	0.095	0.118	0.200	0.600
max plantarflex2	-10.879	-19.424	-16.397	-55.361	-4.363	-3.740	-3.062	-3.964	0.855	1.354	1.371	1.733
% time of pflex2	70	67	69	69	63	66	67	72	0.105	0.015	0.029	0.043
max knee moment	0.366	0.55	0.654	0.572	0.759	0.478	0.377	0.741	0.699	0.140	0.537	0.257
% time of max	16	16	17	16	25	23	18	22	0.439	0.359	0.057	0.316
max dorsiflex moment	1.260	1.586	1.334	0.455	1.762	1.691	1.710	1.718	0.332	0.064	0.247	1.162
% time of max	51	49	51	49	45	47	47	47	0.125	0.042	0.082	0.042
max plantarflex moment	-0.348	-0.346	-0.448	-0.138	-0.394	-0.387	-0.495	-0.452	0.124	0.112	0.100	1.064
% time of max	9	8	8	9	10	9	9	9	0.105	0.118	0.118	0
STP % of cycle	65.000	63.492	65.185	63.566	58.779	62.500	61.314	62.500	0.101	0.016	0.061	0.017
step length	76.001	80.611	92.366	84.142	81.150	82.740	87.537	75.908	0.066	0.026	0.054	0.103
						combined index (avg)			0.283	0.190	0.235	0.435
						combined kinematics			0.271	0.221	0.261	0.412
						combined kinetics			0.304	0.139	0.190	0.474

subject 8	**Prosthesis left**				**sound leg right**				**Asymmetry**			
	PRE/ NORM	PRE/PF	POST/ NORM	POST/PF	PRE/ NORM	PRE/PF	POST/ NORM	POST/PF	PRE/ NORM	PRE/PF	POST/ NORM	POST/PF
max knee flex	55.876	54.022	62.599	59.525	58.841	66.318	64.099	60.071	0.052	0.204	0.024	0.009
% time of max	73	73	76	72	72	69	72	70	0.014	0.056	0.054	0.028
max dorsiflex	11.988	6.680	10.777	8.567	12.121	12.206	11.041	11.911	0.011	0.585	0.024	0.327
% time of max	51	51	53	50	52	49	52	48	0.019	0.040	0.019	0.041
max plantarflex1	-9.937	-10.072	-10.562	-8.403	-6.164	-4.794	-9.944	-6.745	0.469	0.710	0.060	0.219
% time of pflex1	8	11	8	9	11	9	10	9	0.316	0.200	0.222	0
max plantarflex2	-17.663	-21.410	-19.928	-18.719	-4.379	0.146	-5.153	-3.624	1.205	2.027	1.178	1.351
% time of pflex2	68	68	71	67	71	70	68	66	0.043	0.029	0.043	0.015
max knee moment	0.832	0.869	1.000	0.828	0.065	0.102	0.188	0.127	1.710	1.580	1.367	1.468
% time of max	13	14	13	13	15	57	16	58	0.143	1.211	0.207	1.268
max dorsiflex moment	1.414	1.407	1.320	1.533	1.523	1.451	1.377	1.402	0.074	0.031	0.042	0.089
% time of max	48	50	51	49	47	45	47	45	0.021	0.105	0.082	0.085
max plantarflex moment	-0.143	-0.199	-0.288	-0.237	-0.090	-0.065	-0.233	-0.131	0.455	1.015	0.211	0.576
% time of max	6	8	7	6	6	4	7	6	0	0.667	0	0
STP % of cycle	64.486	65.455	68.317	63.810	62.264	58.879	60.952	59.804	0.035	0.106	0.114	0.065
step length	85.075	73.284	62.646	67.027	83.304	68.198	73.592	79.478	0.021	0.072	0.161	0.170

combined index (avg)	0.287	0.540	0.238	0.357
combined kinematics	0.219	0.403	0.190	0.222
combined kinetics	0.401	0.768	0.318	0.581

subject 9	Prosthesis left				sound leg right				Asymmetry			
	PRE/ NORM	PRE/PF	POST/ NORM	POST/PF	PRE/ NORM	PRE/PF	POST/ NORM	POST/PF	PRE/ NORM	PRE/PF	POST/ NORM	POST/PF
max knee flex	62.662	60.965	56.491	63.123	63.223	60.763	63.842	65.063	0.009	0.003	0.122	0.030
% time of max	73	73	73	73	72	70	70	70	0.014	0.042	0.042	0.042
max dorsiflex	6.589	8.752	7.545	10.465	12.961	11.788	14.056	14.510	0.652	0.296	0.603	0.324
% time of max	49	46	46	48	51	48	47	49	0.040	0.043	0.022	0.021
max plantarflex1	-5.532	-3.966	-14.254	-1.394	-5.219	-4.531	-3.574	-2.812	0.058	0.133	1.198	0.674
% time of pflex1	10	11	12	6	11	11	8	7	0.095	0	0.400	0.154
max plantarflex2	-21.857	-18.335	-18.951	-22.584	-1.027	-1.771	0.397	-0.733	1.820	1.648	2.086	1.874
% time of pflex2	67	67	66	67	70	71	71	69	0.044	0.058	0.073	0.029
max knee moment	0.42	0.753	0.459	0.636	0.282	0.299	0.427	0.345	0.393	0.863	0.072	0.593
% time of max	14	16	15	13	58	57	54	56	1.222	1.123	1.130	1.246
max dorsiflex moment	1.238	1.369	1.188	1.337	1.377	1.349	1.445	1.388	0.106	0.015	0.195	0.037
% time of max	48	48	49	48	49	47	46	47	0.021	0.021	0.063	0.021
max plantarflex moment	-0.159	-0.286	-0.214	-0.11	-0.238	-0.232	-0.246	-0.139	0.398	0.208	0.139	0.233
% time of max	6	9	7	5	9	9	7	6	0.400	0	0	0.182
STP % of cycle	61.905	61.765	60.396	62.105	63.551	62.136	60.396	61.386	0.026	0.006	0	0.012
step length	60.674	73.331	72.921	70.912	72.316	71.000	73.053	67.269	0.175	0.032	0.002	0.053

combined index (avg)	0.342	0.281	0.384	0.345
combined kinematics	0.293	0.226	0.455	0.321
combined kinetics	0.423	0.372	0.267	0.385

subject 10	Prosthesis right				sound leg left				Asymmetry			
	PRE/ NORM	PRE/PF	POST/ NORM	POST/PF	PRE/ NORM	PRE/PF	POST/ NORM	POST/PF	PRE/ NORM	PRE/PF	POST/ NORM	POST/PF
max knee flex	64.305	58.808	66.740	67.465	71.211	67.252	62.151	68.124	0.102	0.134	0.071	0.010
% time of max	70	81	70	70	74	74	72	73	0.056	0.090	0.028	0.042
max dorsiflex	11.035	9.56245	14.312	12.528	17.589	15.446	20.726	21.991	0.458	0.471	0.366	0.548
% time of max	51	49	48	49	54	55	49	50	0.057	0.115	0.021	0.020
max plantarflex1	-7.098	-13.4776	-1.756	-4.804	-12.662	-11.782	-6.289	-7.444	0.563	0.134	1.127	0.431
% time of pflex1	9	9	6	8	7	11	7	7	0.250	0.200	0.154	0.133
max plantarflex2	-0.529	-2.6326	4.060	1.321	-9.864	-14.561	-10.901	-6.601	1.796	1.388	4.374	3.001
% time of pflex2	67	68	69	66	68	69	67	68	0.015	0.015	0.029	0.030
max knee moment	0.187	0.314	0.294	0.181	0.565	0.435	0.447	0.412	1.005	0.323	0.413	0.779
% time of max	60	17	10	13	15	18	16	16	1.200	0.057	0.462	0.207
max dorsiflex moment	1.700	1.556	1.919	1.706	1.817	1.5	1.645	1.392	0.067	0.037	0.154	0.203
% time of max	47	48	45	46	52	53	48	49	0.101	0.099	0.065	0.063
max plantarflex moment	-0.151	-0.106	-0.145	-0.242	-0.285	-0.312	-0.067	-0.101	0.615	0.986	0.736	0.822
% time of max	7	67	4	6	7	10	3	5	0	1.481	0.286	0.182
STP % of cycle	61.111	62.931	60.577	58.182	64.815	65.179	62.037	62.500	0.059	0.035	0.024	0.072
step length	84.916	79.204	88.900	91.170	76.900	76.806	83.167	82.162	0.099	0.031	0.067	0.104

combined index (avg)	0.403	0.350	0.523	0.415
combined kinematics	0.345	0.261	0.626	0.439
combined kinetics	0.498	0.497	0.352	0.376

8 Appendix C: Equivalent text descriptions

In an effort to make documents universally accessible, written descriptions of graphic elements are included. The intention is to accommodate the requirements of individuals with vision impairments, with cognitive or perceptual limitations, non-native English speakers, or generally of readers who have difficulties in completely understanding the purpose of a graphic or picture.

Figure 1 (page 2): "Illustration of alignment effects on prosthesis performance levels. Many assessment methods allow the identification of an acceptable level, but fail to answer the question for the (possible) optimum setting."

The figure shows a coordinate system with one bell shaped graph. The horizontal axis is labeled "Alignment setting (e.g. ankle plantar-flexion)" and has units from "-8deg" to "+12 deg". The vertical axis is labeled "Prosthesis performance" and has no units. The upper half of the graph area – equivalent with high prosthesis performance is shaded in a different color than the lower part. The bell curve is within this upper area for values of approximately 0 to +8 deg. An arrow signifies this range as "acceptable". Another arrow points at the pinnacle of the bell curve which is at an Alignment setting value of about +3 deg

Figure 2 (page 3): "Schematic of the iterative alignment process in the clinic. Center piece is the assessment of gait that depends on visual observation and patient's feedback."

The figure shows a rather busy flow-chart, that illustrates the complexity and subjectivity of the task of prosthetic alignment. A flow-chart with 14 boxes is shown. The initial field contains information on the state of a prosthesis prior to alignment optimization: It has been produced to measure and assembled according to default recommendations. The alignment optimization procedure starts with "Donning of the prosthesis", followed by "Visual check of socket fit". If acceptable “Standing up” follows”, as well as the (possible)”Use of LASAR posture” to check the initial alignment. If standing is safe, “walking” commences, if unsafe “Walking in parallel bars”. Either is accompanied by “Observation” and Solicitation of “Patient’s feedback”. If the thus determined performance is optimal, the goal is accomplished and the prosthesis is being finished. In the case of unsufficient performance, Steps that include “Correct obvious alignment flaws”, “adjust component settings”, and “if necessary, improve socket fit” are required. The latter results in “Doffing of prosthesis, socket rectification”, which is also called for when at the initial donning no acceptable socket fit was determined.

Figure 3 (page 10): “Extension of the test environment and inclusion of mobile sensors allows for a more comprehensive assessment of amputee gait than the traditional way of observing gait patterns in the laboratory.”

A cake diagram in rectangular shape consists of three major blocks pertaining to the different components of gait analysis: 1) Kinematics, 2) Forces and Moments, and 3) Muscle Activity. Another division splits the three blocks into subsections at approximately a 1 to 2 ratio: “Laboratory” and “Real Life Conditions”. This makes a total of 6 sections (2 per block), some of which are labeled. According to that, Kinematics in the Laboratory are “observable by prosthetist (subjective assessment)”, and both Kinematics and Forces & Moments in the Laboratory are “objectively measurable with Motion Analysis and Force plate equipment”. Forces and Moments in both laboratory and real life conditions are “measurable with integrated sensors”, as is muscle activity with “wireless EMG equipment”.

Figure 4 (page 15): “Complete Cleveland Clinic marker set, from KinTools RT for Cortex User's Manual (Motion analysis 2010).”

The image shows two views of a skeleton and muscle model of a male adolescent in upright standing position holding the arms on the sides, palms facing forward. On the left is a front view and on the right a back view. Black dots mark the points where reflective markers for gait analysis purposes are to be placed according to the Cleveland clinic protocol. All the points are labeled with the respective name of the marker, usually pertaining to the position, such as “R.Foot.Lateral” or “L. Anterior.Shoulder”.

Figure 5 (page 17): “Preparation of prosthesis prior to data collection. The integrated sensor under the socket was used for additional data collection that is not reported in this paper. Plumb lines on the socket allow maintenance and reconstitution of the original alignment setting.”

This photo was taken during the static assembly procedure of a prosthesis. A trans-tibial prosthesis is seen set up in the alignment frame from figure 7 in a side-view. The plumb lines are marked on the prosthetic socket by pencil lines. This demonstrates the principle of using the parallel strings on opposite sides of the alignment device for the avoidance of parallaxes errors.

Figure 6 (page 19): “Illustration of landmark data points used for analysis of gait curves. Magnitude and timing of the marked peaks were evaluated”

Three graphs are displayed in vertical order. The horizontal axes are marked “% of step cycle” and range from values of 0 to 100. The vertical axes are labeled “knee flexion angle (degrees)”, “Ankle angle/degrees (plantarflexion negative)”, and “Ankle flexion moment (Nm/N bodyweight)” respectively. Each graph shows a typical curve for the respective variable. All curves start and end at zero values. The upper curve has a local maximum of about 15 degrees at 20% gait cycle, a local minimum of 0 at 45%, and a global maximum of 60 degrees at 75% gait cycle. The latter is marked with “Max knee flex”. The second curve has a maximum of 12 degrees at 50% gait cycle, labeled “Max dorsiflex”, and two minima of -10 degrees and -17 degrees at 10% and 75% of the gait cycle respectively. Those are labeled “Max plantarflex 1” and “Max plantarflex 2”. There is another local maximum of about 3 degrees at the 95% mark that is not labeled. The last curve has a minimum of -0.1 at 5% and a maximum of 1.4 at 50% gait cycle, after which the curve reaches zero value at about 65% and remains there. The extrema are labeled “Max plantarflex moment” and “Max dorsiflex moment”

Figure 7 (page 23): “Step length asymmetry means and standard deviations over the four tested walking conditions. Differences between PRE/NORM and PRE/PF, as well as between PRE/PF and POST/PF are significant at the .05 level.”

A bar graph with four vertical bars is shown. Error bars show the standard deviations. On the horizontal axis the four conditions “PRE/NORM”, “PRE/PF”, “POST/NORM”, and “POST/PF” are listed. The vertical axis shows step length asymmetry as a unit-less index, ranging from 0 to 0.18. The bars for PRE/NORM and POST/NORM are almost identical with a value of 0.08. The bar PRE/PF between them is clearly shorter with a value of 0.03, and the bar POST/PF on the right is longer with a value of about 1.0. Standard deviations are generally of the same magnitude as the value represented by the respective bar.

Figure 8 (page 27): “Individual asymmetry indices for all 8 subjects. Perfect bilateral symmetry would be represented by an index value of 0. Indices are comprised of gait variables as defined in table 2. One step per subject and condition was analyzed.”

This figure shows an assembly of eight bar graphs, each of which showing four groups of three bars. The eight graphs represent the eight subjects that were tested, the four groups are the four conditions, and the three bars are the three asymmetry indices, being “overall index”, “kinematics index” and “kinetics index”. There is no consistent trend recognizable, neither is a consistent magnitude of the indices. Some subjects have rather low overall asymmetry, barely reaching levels of .4, whereas others' exceed values of 1. Some subjects have big differences between conditions or between kinematics and kinetics indices, and some have not. Overall, the figure conveys the notion that the subject population was very heterogeneous.

Figure 9 (page 28): "Comparison of asymmetry indices, averaged over all 8 subjects. Perfect bilateral symmetry would be represented by an index value of 0. Indices are comprised of gait variables as defined in table 7. Error bars illustrate the variance over the sample."

This bar chart lists the four experimental conditions next to each other on the horizontal axis. The bilateral asymmetry index is represented by the vertical axis, ranging from 0 to 0.6. The overall asymmetry index is roughly constant over all four conditions "PRE/NORM", "PRE/PF", "POST/NORM", and "POST/PF" at a value of about .4 and a small standard error bar in both directions. The kinematics index is slightly lower than the overall index. It is almost identical for the two "PRE" conditions at about .3, and is about .35 for both "POST" conditions. Error bars are small as well. The kinematics index is higher than the others at about .45. In the "PRE/NORM" condition it is slightly higher than that, and in the "POST/NORM" condition slightly lower. Its error bars are considerably greater than for the other indices, spanning a range of .2 in the first and .08 in the last condition

Figure 10 (page 29): "Ankle flexion angle curves for prosthetic and sound leg over one step cycle for one subject (number 8), measured by conventional gait analysis. Steps have been normalized to the step cycle duration and offset values corrected for comparability. To illustrate the 2x2 design matrix, the PRE condition of low exertion is displayed in the top row, POST condition of "strong" exertion below, normal alignment in the left column, altered alignment in the right."

Four diagrams represent the four experiemental conditions “PRE/NORM”, “PRE/PF”, “POST/NORM”, and “POST/PF”, are showing “% of gait cycle” on the horizontal axis, ranging from 0 to 100, and “Ankle angle/degrees (plantarflexion negative)” on the vertical axis, ranging from -15 to +25.In each diagram, two function graphs are visible, one for the sound leg, and one for the prosthetic leg. They run parallel for about the first 30 % of the gait cycle, where they show a local minimum of about 3 degrees before climbing up to 13 degrees. The prosthetic curve keeps climbing after that, and reaches its global maximum of 20 degrees at about 50% of the gait cycle. The sound leg curve reaches only about 15 degrees at that point. Between 50 and 70 % both curves point downward, the prosthetic leg reaching a plateau at 12 degrees, and the sound leg reaching its global minimum at -12 degrees. After that point, the curves inlines rapidly, reaches + 5 degrees at the 80% mark and goes on to end on the same level of 7 degrees as the prosthesis curve. Between conditions there are slight deviations of the curve shapes, but the general fact, that the prosthetic ankle is very limited in its dorsi-flexion during the push-off phase is visible throughout.

Figure 11 (page 36): “Prosthetic ankle moments measured with normal alignment, and with by two degrees increased plantar-flexion alignment (sample from subject 10). Although maxima and times of maximum are almost identical, the shape of the curves is not the same.”

This diagram shows the “% of gait cycle” on the horizontal axis, ranging from 0 to 100, and “Ankle moment in NM/lbs body weight (plantar flexing moment is negative)” on the vertical axis, ranging from -.5 to +2. Two curves are displayed, one for “normal alignment”, and one for “increased plantar flexion”. The are for the most part almost identical, but have an obvious deviation from each other in the first 20% of the gait cycle. The normal alignment curve points downward after starting at 0, and reaches about -.2 at 7% before climbing up rapidly and reaching +.6 at the 20% mark. The increased plantar flexion curve, also starting at 0, points upward immediately und reaches +.6 already at the 10% mark.

Figure 12 (page 37): "Visualization of bilateral ankle moment differences across all 8 subjects. Dotted lines mark the standard deviation envelope."

This diagram shows the "% of gait cycle" on the horizontal axis, ranging from 0 to 100, and "Ankle moment in NM/lbs body weight (negative = plantar flexing)" on the vertical axis, ranging from -.5 to +2. Two curves are displayed, one for "normal alignment", and one for "increased plantar flexion", each together with its standard deviation. The average curves are mostly identical, apart from the increasing compartment between 15% and 50%, where the sound leg' values are by .2 units lower than the prosthesis' values. Standard deviations are in the range of about .4 units for large stretches, enveloping the average curve of the respective other condition consistently.

Figure 13 (page 47): "Sample data of the longitudinal force curve that was used to identify step cycles of interest. After standing on both legs for the first ten seconds of this sample, the subject started walking by lifting the prosthesis at about 0:00:39. The corresponding video data shows that the fifth step on the prosthesis side hit the force plate. This step cycle can be found by counting the intervals in the force graph. It is between 0:00:43 and 0:00:44."

This graphs shows the "recording time" on the horizontal axis, ranging from 0:00:28 to about 0:00:52. The horizontal axis represents the "Force aling the prosthetic shin (N)", ranging from -200 to +1600. The function graph starts at a value of 500, which it maintains with some slight fluctuations until the 0:00:39 mark. There it rapidly decreases to 0, before climbing up to about 1200, and after a double peak there recedes to 0 again, all within about 1 second. This one-second pattern continues with slight deviations until the end of the recording, totaling in 13 such curves.

Figure 14 (page 49): "Ankle moment of a sample step, measured by conventional gait analysis (dark line) and prosthesis integrated sensor (light)"

This diagram shows the "% of step cycle" on the horizontal axis, ranging from 0 to 100, and "Ankle flexion moment normalized to body weight" on the vertical axis, ranging from -1 to +2. Two curves are displayed, one for "ipecs", and one for "forceplate" measurement. They are essentially identical, with a slight offset during the stance phase. The curves have minima of -.1 and -.5 respectively at about 10%, and maxima of 1.7 and 1.4 respectively at 50%. They both reach 0 at close to 60% and remain there for the rest of the step cycle.

Figure 15 (page 49): "Concurrent measurement of vertical force (e.g. F_z) in the prosthetic leg of Subject 10 during walking with low exertion, increased plantar flexion"

This diagram shows the "% of step cycle" on the horizontal axis, ranging from 0 to 100, and "Vertical force/ body weight" on the vertical axis, ranging from -.2 to +1.4. Two curves are displayed, one for "ipecs", and one for "forceplate" measurement. They are essentially identical, with a slight deviation during the first 50%. The curves each have two maxima of 1.2 and 1 at about 15%, and at 45%, and a local minimum of .8 in between. The ipecs curve reaches the first maximum slightly later, has a higher local minimum and a lower second maximum.

Figure 16 (page 50): "Sample comparison of knee moment curves as computed by the integrated sensor algorithm (light line), and calculated manually (dark line), based on the moments and forces measured at the center of the ipecs, and the vertical distance between the center of the ipecs and the knee axis"

This diagram shows the “% of step cycle” on the horizontal axis, ranging from 0 to 100, and “Knee flexion moment normalized to body weight” on the vertical axis, ranging from -1 to +3. Two curves are displayed, one for “ipecs”, and one for “forceplate” measurement. They are entirely different for most of the stance phase, where the forceplate curve describes a low double peak curve between values of -.3 and +.2, wheras the ipecs curve has peaks of +1 and +2.5.

Figure 17 (page 50): “Normal gait knee flexion moment curve (from (C. M. Powers, Rao, & Perry, 1998) with permission). The vertical dashed line signifies the transition from stance to swing phase.”

This diagram shows the “Percent (stride)” on the horizontal axis, ranging from 0 to 100, and Knee flexion moment on the vertical axis, ranging from -200 to +200 with no units. The displayed curve has local minima of -30 at about 5%, 45% and 90%. Local maxima are 100 at 20% and 30 at 60%.

Figure 18 (page 55): “Graphical representation of changes in sampling frequency over the course of a continuous recording with the iPecs sensor.”

This graph has “Recording time/s” on the horizontal axis, ranging from 0 to 1040 and “Ipecs sampling frequency/Hz” on the vertical axis, ranging from 0 to 300. There are 16 discrete data points, connected by straight lines. The resulting plot shows an irregular trajectory including values between 250 and about 160.

Figure 19 (page 64): “Illustration of statistical analyses conducted for this study”

This illustration tries to visualize the data extraction and analysis method. A table shows that for each subject ten step samples (of vertical force and ankle flexion moment) were collected for each of the four conditions “PRE/NORM”, “PRE/PF”, “POST/NORM”, and “POST/PF”. Each of those samples was normalized to 100 data points. Then landmark variables were extracted, and within group standard deviations computed. Two different statistics were employed to compare those variables: A MANOVA to compare condition differences within individual subjects, and RMANOVA to compare conditions across subjects. Small data plots illustrate the nature and multitude of data sets. Arrows and brackets are used to connect the statistical methods with the respective raw data in the table.

Figure 20 (page 65): "Graphical representation of ankle flexion moments in one subject. 10 steps of each condition have been time normalized to compute averages and standard deviations at every point in time. The solid line in any one curve represents the average, and the lighter area above and below the standard deviation."

This diagram shows four ankle moment curves in a 2 by 2 array, each representing a different condition. From left to right and up to down they are "Low exertion/normal alignment", "Low exertion/increased plantar flexion", "Strong exertion/normal alignment", and "Strong exertion/increased plantar flexion". The curves all have similar shapes but appear to have some deviations from each other.

Figure 21 (page 66): "Superposition of the ankle moment curves from figure 20."

In this diagram, all four ankle moment curves and their respective standard deviation envelopes are displayed in the same coordinate system. It can be seen, that they are not identical, as there seems to be a temporal shift between some of them.

Figure 22 (page 68): Ankle moment comparison in subject 6. Averages of 10 steps with the misaligned prosthesis are plotted, once before the exertion protocol, and once after.

The figure shows a diagram with "% gait cycle" on the horizontal axis, ranging from 0 to 100, and "Ankle flexion moment (Nm/N bodyweight)" on the vertical axis ranging from -0.06 to +0.12.

There are two curves plotted, one labeled “avg (PRE/PF), the other labeled “avg (POST/PF)”. Both curves are widely similar, starting at 0, having a global minimum of about -0.05 at 10% gait cycle, a global maximum of about 0.11 at 50% gait cycle, and a plateau at the level of 0 between 65% und 100% gait cycle, thus looking much like typical ankle moment curves. The slight differences between the curves occur on the inclining aspect of the curve, where the “POST” curve is initially ahead of the “PRE” curve by 1 or 2 % gait cycle, before it crosses over at the level of +0.03, and stays behind the PRE curve by 1 or 2 % gait cycle for the rest of the incline.

Figure 23 (page 69): Longitudinal shin force in subject 6, compared between conditions PRE/PF and POST/PF. 10 steps each were normalized to 100 samples and averaged.

The figure shows a diagram with “% gait cycle” on the horizontal axis, ranging from 0 to 100, and “Axial shin force (N/N bodyweight)” on the vertical axis ranging from -0.2 to +1.2. There are two curves plotted, one labeled “avg (PRE/PF), the other labeled “avg (POST/PF)”. Both curves are widely similar, starting at 0, having a global maximum of about 1.1 at 15% gait cycle, a local minimum of 0.8 at 30% gait cycle, a local maximum of about 1.0 at 50% gait cycle, and a plateau at the level of 0 between 65% und 100% gait cycle, thus looking much like typical vertical force gait curves. The slight differences between the curves occur between the first maximum and the subsequent minimum, where the “POST” curve is ahead of the “PRE” curve by 1 or 2 % gait cycle.

Figure 24 (page 69): Longitudinal shin force in subject 7, compared between conditions PRE/PF and POST/PF. 10 steps each were normalized to 100 samples and averaged.

This figure shows the same gait curves as figure 22 for a different subject. In this case the “POST” curve deviates from the “PRE” curve by having a less steep incline after the 5% gait cycle mark, thus reaching a lower first maximum with a value of 1.0 as opposed to 1.1 for the “PRE” curve. It subsequently has also a less steep decline, resulting in a crossing over of the “PRE” curve and a local minimum of 0.8 as opposed to 0.7 for the “PRE” curve. The “POST” curve then inclines less steep than the “PRE” curve again, joining it at the second maximum value of roughly 0.95. For the last 50% gait cycle both curves are basically identical.

Figure 25 (page 70): Longitudinal shin force in subject 8, compared between conditions PRE/PF and POST/PF. 10 steps each were normalized to 100 samples and averaged.

This figure shows the same gait curves as figure 22 for a different subject. In this case the “POST” curve deviates from the “PRE” curve by having a less steep incline after the 10% gait cycle mark, thus reaching the first maximum with a value of 0.95 about 5% later in the gait cycle than the “PRE” curve. It also has a slightly higher local minimum of 0.85 as opposed to 0.8 for the “PRE” curve. The “POST” curve joins the “PRE” curve again at the second maximum (value of roughly 0.95). For the last 50% gait cycle both curves are basically identical.

Figure 26 (page 71): “Comparison of longitudinal shin force over the step cycle at different levels of exertion for one subject (Subject 10). Curves are each averaged over samples of 10 consecutive time normalized steps.”

This diagram shows the “% of step cycle” on the horizontal axis, ranging from 0 to 100, and “longitudinal shin force normalized to body weight” on the vertical axis, ranging from -.2 to +1.4. Four curves are displayed, one for “start”, and one each for “after 1 lap”, “after 2 laps”, and “after 3 laps” respectively. They are essentially identical, with only slight deviations between 10% and 70%. The curves each have two maxima of 1.2 and 1 at about 15%, and at 45%, and a local minimum of .7 in between. The curve “after 3 laps” appears to have the greatest deviations from the other curves, ranging in magnitude at about .1 units.

Figure 27 (page 71): "Comparison of ankle flexion moments over the step cycle at different levels of exertion for one subject (Subject 10). Curves are each averaged over samples of 10 consecutive time normalized steps."

This diagram shows the "% of step cycle" on the horizontal axis, ranging from 0 to 100, and "Ankle flexion moment (Nm/N body weight)" on the vertical axis, ranging from -.1 to +.15. Four curves are displayed, one for "start", and one each for "after 1 lap", "after 2 laps", and "after 3 laps" respectively. They are essentially identical, with only slight deviations between 10% and 70%. The curves each have a minimum of about -.05 at 8% and a maximum of +.14 at about 50%. The curve "after 3 laps" appears to have the greatest deviations from the other curves, ranging in magnitude at about .02 units, with a less pronounced minima and maxima values.

Figure 28 (page 72): "MANOVA effect sizes of exertion in the condition PF (increased plantar-flexion). The variable "absolute increase in heart rate" shows a weak linear correlation to the effect size of exertion on ankle moment (R^2 = .3156)"

This figure shows a scatterplot. The horizontal axis reads "Increase in heart rate between PRE and POST exertion (bpm) and ranges from 0 to 90. The vertical axis is labeled Effect size eta squared of exertion and ranges from0.94 to 1. There are 8 points plotted with a linear trend line that inclines at an angle of about 30 degrees. 5 points are on the upper side of the trend line, 3 on the lower side and in greater distance to it. The greatest distance to the line and the other points is the point at about (30; 0.95) that is referred to as "outlier" in the text.

Figure 29 (page 86): "Average standard deviations of vertical force Fz (in N) and ankle flexion moment Mankle (in Nm) curve points in a 10-step sample, as a measure of in step variability in each subject over the intervention conditions"

An array of eight bar diagrams is shown, each representing on subject. In each diagram, four pairs of bars are displayed, color coded as "F_z" and "M_{ankle}". The four conditions are marked as "PRE/NORM", "PRE/PF", "POST/NORM", and "POST/PF" respectively. The vertical axis shows the standard deviation over 10 steps, and ranges from 0 to 0.14. The magnitude of the F_z standard deviation is approximately 10 times greater than for the M_{ankle} standard deviation. There appears to be some proportionality between both measures. Subjects vary in magnitude (ranging for F_z standard deviation from 0.04 in subject 7 to 0.13 in subject 9) and pattern of the bars. Subject 1 and subject 6 had the highest variability in condition one, and the lowest in condition 4. Subject 2 and 9 had their highest step variability in condition 2, and lowest in condition 4. This pattern is reversed in subjects 3 and 7. Subject 8 and subject 10 had the lowest variability in condition 3, and highest in either condition 2 (subject 8) or condition 4 (subject 10).

Figure 30 (page 147): "Alignment mechanism of prosthesis modular adapter."

This figure shows the side view of the prosthetic foot and ankle assembly, partly sectioned. It can be seen how the adjustment of setscrews in the upper component of the assembly changes the angular orientation of the pylon adapter that connects the foot with the socket. Setscrews on opposite sides fixate the foot adapter that looks like the top part of an inverted pyramid. Simultaneously turning the screws in the same sense will not change the distance between them, but will move the pylon in which their thread is guided. This happens on a spherical support base, leading to an angular rather than translational change.

Figure 31 (page 148): "Schematic of the walking path in and outside the laboratory building. Total length of the loop is 210 meters, 40 of which are outdoors."

A floor plan of the gait lab and the surrounding corridors and outdoor environments is shown. The rectangular gait lab features a stretch of "gravel path" and else "level lab floor". The lab is on three sides adjoined by a hallway that can be reached through a door from the lab. The hallway floor is partly carpeted and partly concrete. Two stairwells connect to the lower level, which also contains a sloped ramp. Exit doors on both ends of the corridor open up to an "asphalt path (outdoors)" that connects both doors on the fourth side of the gait lab. A dashed arrow marks the typical walking path to be absolved by the participants, including in a loop all the different surfaces and obstacles.

Figure 32 (page 150): "Principle of strain gage assembly in iPecs."

This illustration reveals the inner structure of the integrated sensor. On the left is a photograph of a below knee prosthesis with the ipecs unit, a black cubic component approximately 2 inches square by 1.5 inches high, installed underneath the prosthetic socket. An arrow points from there to the center of the image, to a drawing of the internal structure, a short tube in vertical orientation, with a band of cross like patterns wrapped around it. This band is depicted rolled up underneath, which shows the assembly of strain gages in 8 groups of four, placed next to each other in alternating + and x orientation. One of those groups is enlarged at the right side of the figure, revealing a Wheatstone bridge wiring between them.

Figure 33 (page 151): "Prosthesis alignment aid."

A structure made out of wood and strings is depicted. It consists of a rectangular base plate and a similar top plate, about 20 x 20 inches in dimension. They are connected by four upright bars of about 40 inches length in the corners. Strings are spanned in the centers of the open sides of the structure, three in each plane: one vertically, and two more in V-shaped fashion.

9 Appendix D: Short papers based on data collected for this work

9.1 Gait Stability Measured by Prosthesis-Integrated Sensors as an Outcome Measure in Persons with Prostheses for the Lower Extremity

Goeran Fiedler, Dipl. Ing (FH), CPO-D, Brooke A. Slavens, PhD, and Roger O. Smith, PhD, OT

Department of Occupational Science and Technology Rehabilitation Research Design and Disability (R2D2) Center

(Presented at the 25th Annual Dean's Research Day. 2012. Kalamazoo, MI)

9.1.1 Abstract

Some of the major concerns in leg amputee rehabilitation are falls [1] or similar accidents attributed to impaired gait stability. Thus, the achieved gait stability is of great interest in assessing the functional outcome of a prosthetic fitting. Determining step-by-step variability, which has been used as a measure of gait stability [2,3], is usually restricted to few steps within the capture volume of a gait laboratory, posing limits to the available sample size. Artificial legs allow the integration of dedicated sensors directly into the weight bearing structure of the locomotor apparatus, enabling the capturing of specific information on step cadence, bilateral weight distribution, knee moments, and ankle moments continuously over long periods of time. Based on extensive data that we collected in the context of a larger study on amputee gait dynamics, we introduce first findings, propose methods of identifying and comparing distinct gait sequences, and discuss the limitations of this method.

9.1.2 Background

Limb amputation is among the most drastic and irreversible conditions that affect a patient's physical integrity. In many cases, amputations become necessary due to vascular conditions, such as those resulting from diabetes. The reported annual incidence rate of trans-tibial amputation is about 13 in 100,000 Americans [4], and as the prevalence of diabetes and similar lifestyle diseases is expected to rise in the future, estimations project the number of persons living with an amputation to double by the year 2050 [5]. Particularly in the therapy of lower extremity amputees, the necessity of artificial limbs is imperative. Sufficiently replacing the lost structure below the knee enables standing and ambulation without crutches, and furthermore facilitates the prevention of secondary ailments.

For a variety of reasons, it is desirable to assess the effectiveness of a prosthetic device and the corresponding gait training in an accurate and practically applicable way. Among the tools that have been used to assess the quality of prosthetic fit and performance capabilities are questionnaires, pedometers, accelerometers, and motion analysis methods. Being limited to either subjective recollection, variables unspecific for gait performance, or reduced samples, all of those methods must fail to answer the questions that are most relevant for long-term outcomes.

For many amputees, safety is the primary concern when it comes to ambulation on prostheses. Falls, or even the fear of falls, are known to severely affect the gait efficiency of prosthesis users. In order to prevent the undesirable consequences of accidental falls, an assessment method that predicts fall susceptibility before the falls actually happen is required. Another typical problem is overuse of the contra-lateral extremity due to pain or discomfort, which bears the risk of promoting comorbidities such as premature joint degeneration, muscle contractures, and spinal malpositions. Uneven weight distribution between legs would be a reasonable indicator of over-use. Among the relevant outcome criteria is also the ambulation speed, as this determines a patient’s capacity to move about in an efficient manner comparable to non-amputees. Detailed questions could address the walking speed in non-optimal situations, when for instance the surface is uneven, the lighting is insufficient, or the subject is preoccupied or distracted.

Recently, a new generation of integrated sensor units has become available, providing precise and extensive mobile data that – while initially intended to help investigate prosthetic hardware and alignment specifications - may well be useful in assessing these rehabilitation outcomes for amputees.

9.1.3 Methods

The “iPecs” (College Park Industries, Fraser, MI) is a research grade measuring tool that essentially consists of multiple arrays of strain gages, housed in a shell of 1.8” x 2.8” x 3.2”. The gages, four at a time, are connected in Wheatstone bridge circuits which are aligned in varying orientations within the structure. Based on a calibration matrix, the readings of those units are combined to output force and moment data. Knee and ankle joint moments are derived from the known location of the respective axes with respect to the center of the iPecs device, using transformation matrices [6]. Data is streamed wirelessly to a personal computer, or alternatively stored on a micro SD card within the unit. As long as the unit’s dimensions allow, it can be installed within the existing structure of most modular leg prostheses. In our studies, that procedure took up between 10 minutes and one hour per prosthesis. The additional weight is assumed to be no significant factor in the gait pattern, which was confirmed by the feedback our subjects voiced. In the context of our studies that investigated differences in gait biomechanics depending on the alignment of the prosthesis, as well as force and moment characteristics of prosthesis stair walking, and in two cases leg symmetry in bilateral amputee gait, subjects were asked to walk for about 20 minutes while data were continuously collected.

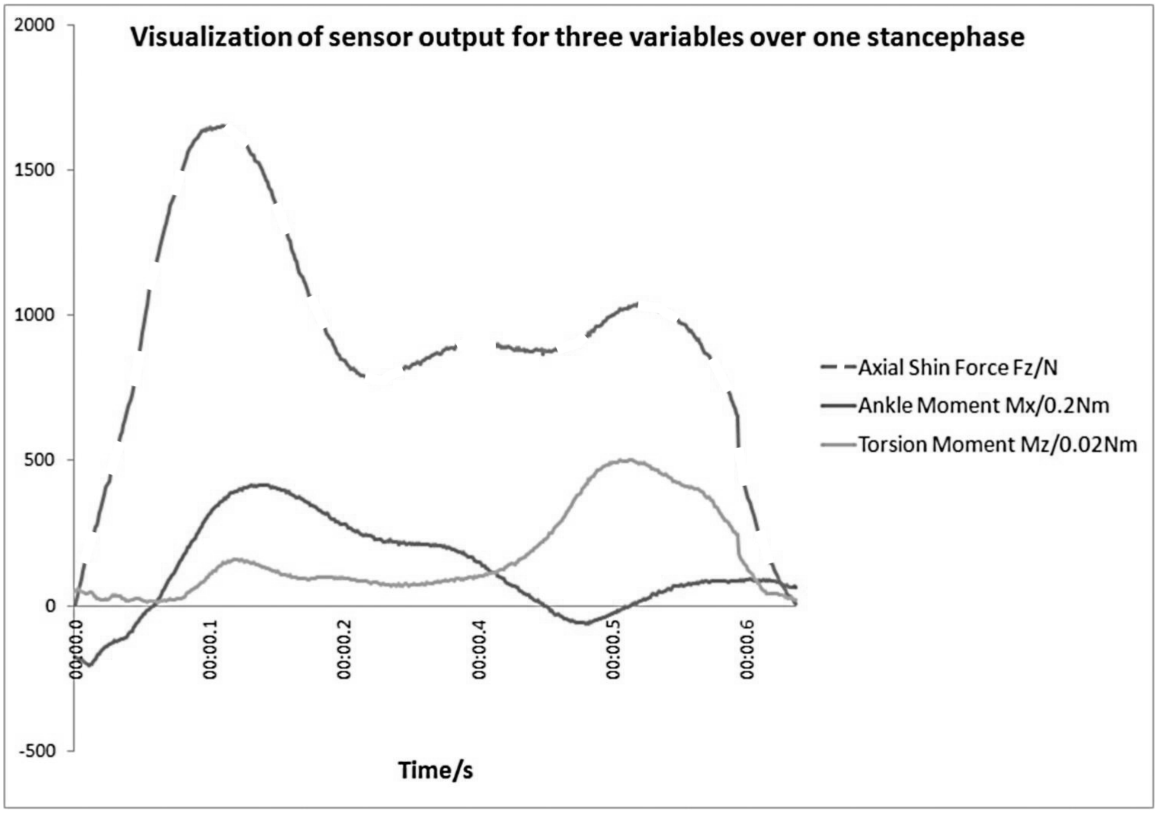

Figure 32: Illustration of iPecs measurements. Time base is one stance phase from heel contact to toe off during level walking at 1.69 m/s.

Outputting tri-axial forces and moments within the sensor unit, as well as the derived joint moments, at sampling rates of up to 850 Hz, there is obviously a wealth of data available that needs to be reduced in order to extract the relevant information. Figure 34 shows a selection of three variables over the duration of one stance phase as measured by the integrated sensor.

9.1.4 Preliminary results

Scrutinizing the various gait curves available reveals some simple conclusions that can be drawn, and that can inform the above mentioned outcome assessment. Figure 35 shows a 1-minute-sample of the Fz data, that is the axial force longitudinal to the shin, for one subject. This variable is especially well utilizable for the detection of gait events. It is easily recognizable, when the subject was sitting (when Fz is close to zero), walking (repeated typical vertical force curve), and standing (Fz at about 50% of maximum value). During the walking stage, steps can be counted, step frequency, and consistency can be derived; the shape of the curve even indicates stair walking and the direction thereof. Subsequent evaluation of the stair walk curves can show whether the subject was performing an alternating technique, was placing the prosthetic foot right (the ankle moment can be interpreted to show the forefoot resistance applied by the stair step), used a handrail (peak forces are considerably higher without handrail use), and whether there were critical situations (e.g. large step-by-step variability).

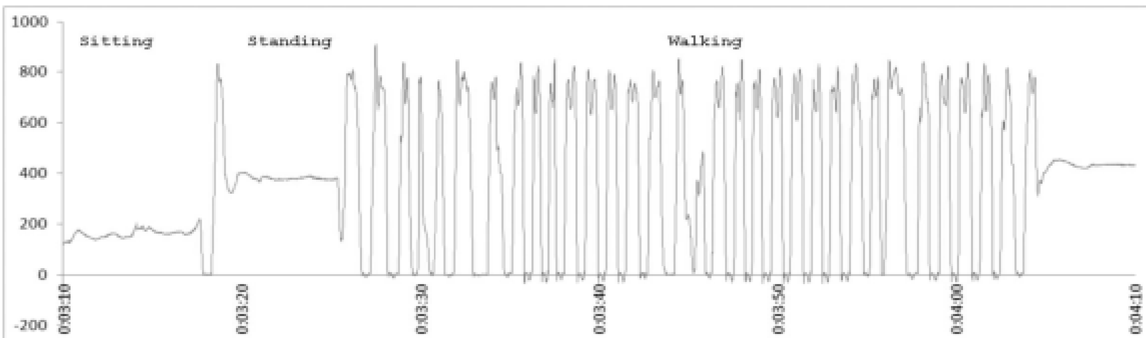

Figure 33: Sample of axial shin force (Fz) over one minute of data collection. The 26 steps between time stamps 3:30 and 4:00 correspond to a step frequency of 52/minute. The distance between consecutive peaks can be used to compute gait accelerations respective decelerations, and – together with other variables – step variability.

While the Fz information helps identify specific gait situations, evaluation of stability can take into account other parameters as well. Figure 36 shows the step-by-step variability in different variables during up-stair walking, depending on handrail use. This data suggests that especially the deviation in knee moment increases when the handrail on the opposite side of the prosthesis is used. A possible explanation is the inconsistency in lateral foot placement that is possible only on the wall-averted side of the stairs.

9.1.5 Discussion

Internal sensor systems for prosthetic gait assessment add new options to the field of amputee rehabilitation outcomes measurement. In order to fully utilize the capabilities of this technology, efficient algorithms must be developed to reduce and analyze the considerable amount of information, and to translate it into useful quantitative metrics for clinical and rehabilitation assessment of lower extremity amputees. A limitation is given by the fact that only data from the prosthesis side can be collected. This delivers only half of the information of conventional gait analyses, while the other half has to be deducted by appropriate calculations and assumptions, and respective additional measures. Body weight distribution for instance can be derived from one legged data as long as the total body weight is known. An interesting variable that can be measured directly is step-by-step variability as an indicator of gait instability. This may be used to inform prosthetic prescription as well as training and therapy with the goal of reducing fall accidents, and overall improving gait efficiency and confidence in prosthesis users.

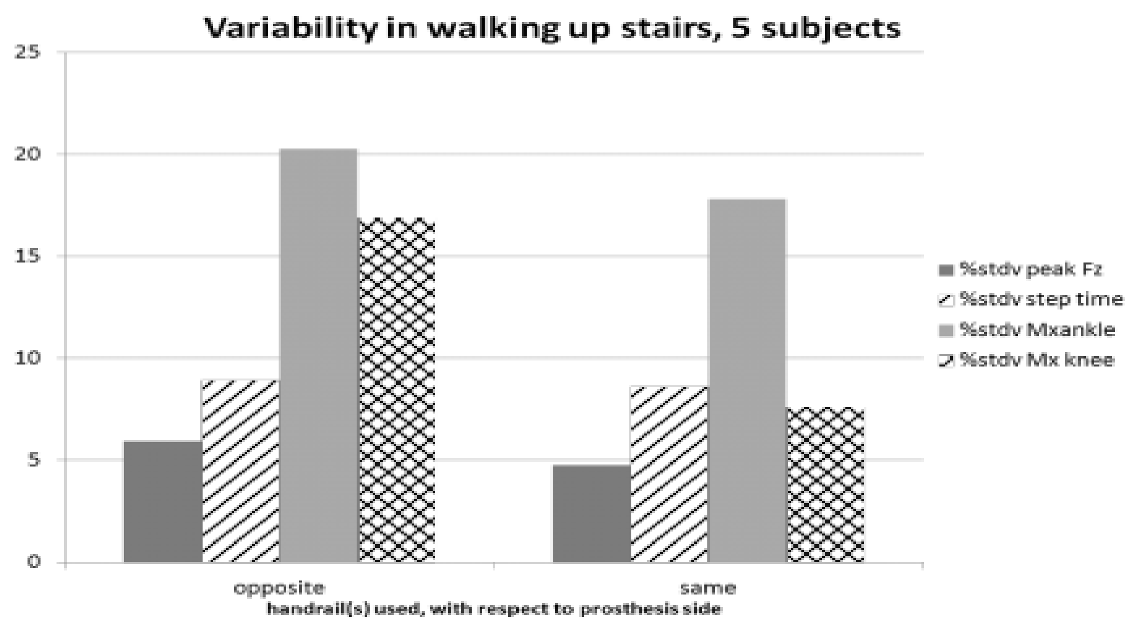

Figure 34: Stair walking step-by-step variability in selected gait variables, depending on handrail side.

Acknowledgements

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References

[1] W. C. Miller, M. Speechley, and B. Deathe, "The prevalence and risk factors of falling and fear of falling among lower extremity amputees," Archives of Physical Medicine and Rehabilitation, vol. 82, pp. 1031-1037, 2001.

[2] D. A. Winter, "Kinematic and kinetic patterns in human gait: Variability and compensating effects," Human Movement Science, vol. 3, pp. 51-76, 1984.

[3] J. Hausdorff, D. Rios, and H. Edelberg, "Gait variability and fall risk in community-living older adults: a 1-year prospective study," Archives of Physical Medicine and Rehabilitation, vol. 82, pp. 1050-1056, 2001.

[4] T. Dillingham, et al., "Limb amputation & limb deficiency: epidemiology & recent trends in the United States," *Southern Medical Journal*, vol. 95, pp. 875-83, 2002.

[5] K. Ziegler-Graham, et al., "Estimating the prevalence of limb loss in United States: 2005 to 2050," *Archives of Physical Medicine and Rehabilitation*, vol. 89, pp. 422-9, 2008.

[6] M. G. Leydet, "iPecs design and working principles." Fraser, MI, 2011, Personal communication.

9.2 Influence of Handrail Use on Stair Walking Stability in Trans-Tibial Amputees

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(Presented at the 1st Occupational Science Summit. 2012. St. Louis, MO.)

9.2.1 Abstract

This paper presents preliminary findings on stair walking kinetics in trans-tibial amputees, as part of a larger, ongoing study of lower extremity kinetics of amputee gait.

9.2.2 Introduction

The ability to walk on stairs is an important skill, as stairs belong to the typical obstacles that can be widely found in most every environment. Various disabilities are known to reduce the stair walking efficiency in patients, which not only limits their range of mobility, but can also become a safety issue due to the high injury probability of stair accidents. Accordingly, the biomechanics of stair ascent and descent have been investigated to great extent [1]. Previous studies that were conducted on different populations, including elderly people [2], patients having undergone ACL reconstruction [3], and amputees [4-6] used force plates that were integrated in one or more steps of the stairs. This setup reduced the number of steps available for evaluation and limited information on step-to-step variability, a variable that indicates walking stability [2]. Artificial limbs offer the opportunity to install sensors to directly measure forces and moments in the weight bearing structure of the locomotor apparatus, which allows continuous data collection over entire flights of stairs.

9.2.3 Methods

Ten subjects were recruited for this IRB approved study. Upon installation of the mobile sensor (iPecs, College Park Industries, Fraser, MI) in their respective original prosthesis, participants were asked to walk down and up a 13-step stair with handrails conveniently located on both sides. Walking speed and technique were self-selected. Knee and ankle moments were compared within subjects over the intermediary 11 steps of their stair walk trials, separately for descent and ascent. Averages and standard deviations in stance duration, maximal longitudinal shin compression force, maximal ankle moment and maximal knee moment were compared between subjects who used no handrail, one handrail and both handrails.

9.2.4 Results

Preliminary findings indicate that use of one handrail in stair descent reduces the bodyweight normalized, maximal compressive force on the shin segment by almost 50% as compared to freehanded walking. When the same person was using different handrails, the average peak force was increased slightly by 5% when using the non-preferred handrail down, but reduced by 2% upstairs. With both handrails, the force was reduced by 39% (down) and 8% (up).

Variability between steps was considerable, with standard deviations of 10 to 20% for step time, maximal longitudinal force, and ankle flexion moments throughout. Stability, as expressed in deviation of peak force, step time, peak ankle moment, and peak knee moment was best with use of the preferred handrail, and worst with both handrails. However, step time decreased when both handrails were used.

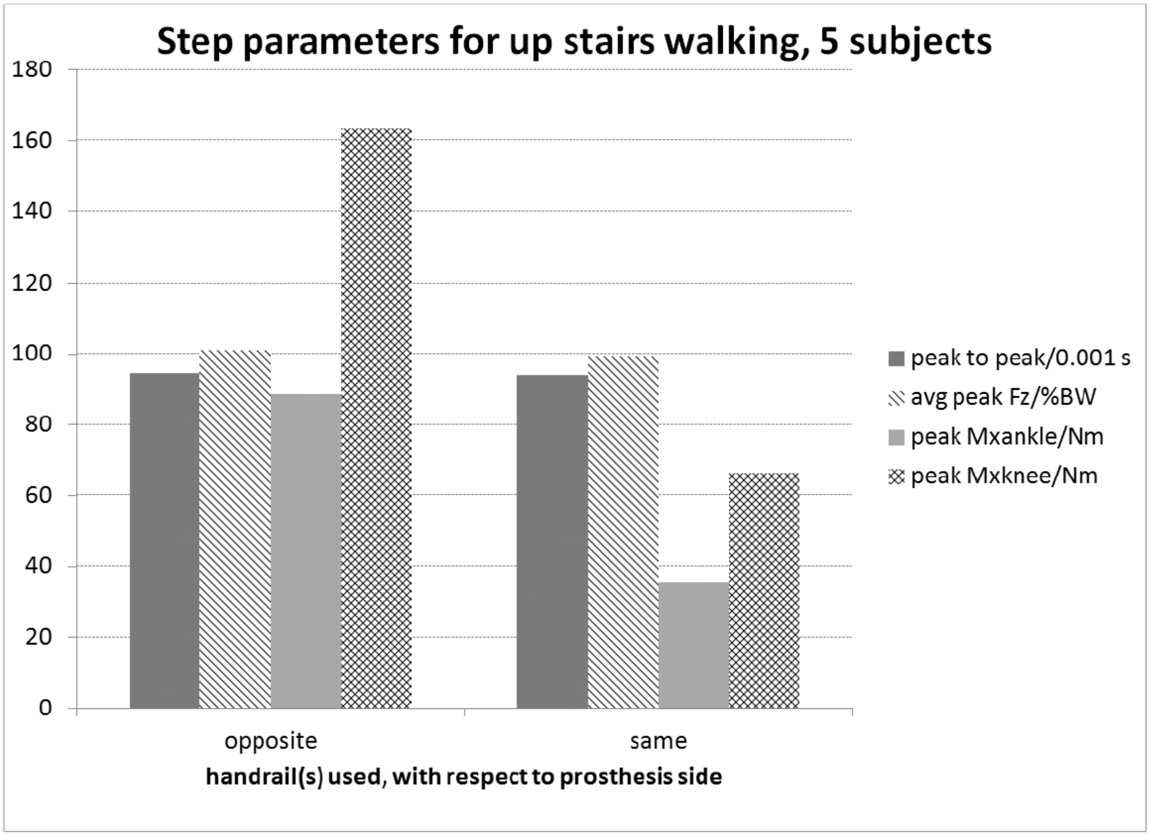

Figure 37: Effect of handrail selection on selected gait parameters during up stairs walking

9.2.5 Discussion

Only two of the subjects elected not to use a handrail for normal speeds, and two others used both handrails. Of those who used one handrail, four preferred the one on the side opposite of the prosthesis, and two preferred the same sided handrail. Stability measures did not show big differences between subjects who preferred the handrail on the same side of the prosthesis and those who preferred the opposite side handrail.

Given the fact, that the majority of subjects used the respective right handrail, it can be suspected that the preferred hand seems to be more important than the preferred leg. In absolute measures, preference of the opposite handrail seemed to decrease the stair climbing velocity, especially down stairs, and it clearly increased the measured knee and ankle flexion moments during up stairs climbing. Step-by-step variability within the selected kinetics parameters does not seem significantly influenced by the use of handrail(s); however, this finding may be attributed to the fact that subjects were free to decide which handrail to use. We suspect that other factors, such as prosthetic socket fit or the componentry design determine the level of stair walking stability in amputees.

Acknowledgements

This work is supported by an UWM Chancellors Award. We would also like to thank Doug Briggs, PhD, Caitlin Moore, and Stacy van Dyke for their help.

References

[1] T. Andriacchi, G. Andersson, R. Fermier, D. Stern, and J. Galante, "A study of lower-limb mechanics during stair-climbing," J Bone Joint Surg Am, vol. 62, pp. 749-57, 1980.

[2] A. Stacoff, C. Diezi, G. Luder, E. Stüssi, and I. Kramers-de Quervain, "Ground reaction forces on stairs: effects of stair inclination and age," Gait Posture, vol. 21, pp. 24-38, 2005.

[3] S. Ristanis, G. Giakas, C. Papageorgiou, T. Moraiti, N. Stergiou, and A. Georgoulis, "The effects of anterior cruciate ligament reconstruction on tibial rotation during pivoting after descending stairs," Knee Surg Sports Traumatol Arthrosc, vol. 11, pp. 360-5, 2003.

[4] C. Powers, L. Boyd, L. Torburn, and J. Perry, "Stair ambulation in persons with transtibial amputation: an analysis of the Seattle LightFoot," J Rehabil Res Dev, vol. 34, pp. 9-18, 1997.

[5] T. Schmalz, S. Blumentritt, and B. Marx, "Biomechanical analysis of stair ambulation in lower limb amputees," Gait Posture, vol. 25, pp. 267-78, 2007.

[6] M. Alimusaj, L. Fradet, F. Braatz, H. Gerner, and S. Wolf, "Kinematics and kinetics with an adaptive ankle foot system during stair ambulation of transtibial amputees," Gait Posture, vol. 30, pp. 356-63, 2009

9.3 Evaluation of an Integrated Sensor System for Assessment of Prosthesis Ankle Alignment in Lower Extremity Amputees

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(Presented at Gait and Clinical Movement Analysis Society (GCMAS) Conference. 2012. Grand Rapids, MI)

9.3.1 Introduction

Prosthesis integrated sensors allow the continuous measurement of forces and moments directly within the weight bearing structure of the locomotor system. This possibility is unique for amputee subjects, as comparable measurements in normal subjects would always necessitate the use of an external gait analysis system, or the surgical implantation of respective sensor units [1, 2]. Intended applications of prosthesis integrated sensors include the assessment of amputee gait in clinical and non-clinical environments, and efficient optimization and outcome assessment of prosthetic fittings without the need for conventional gait analysis [3]. These applications are based on the assumption that the integrated sensor delivers valid information. Beyond that, it remains to be determined whether three-dimensional force and moment data in the prosthetic leg is sufficient to accomplish those objectives. This study presents preliminary evaluation of the iPecs integrated sensor for quantitative assessment of prosthesis alignment.

9.3.2 Clinical significance

Optimal prosthesis fitting and alignment is a prerequisite to efficient and symmetrical amputee gait. In the clinic, the respective assessment is usually based on visual observation and feedback that the patient voices [4, 5]. A more objective and reliable method would be based on conventional gait analysis that, indeed, is commonly used as a research tool. However, relevance is lacking to everyday clinical practice, due to the significant time, space, and effort that the operation of such systems require. The emergence of easy to use, quantitative tools for objective assessment of amputee gait has the potential for improving prosthesis fit and alignment.

9.3.3 Methods

A total of 10 trans-tibial amputees were recruited for participation in this IRB-approved study. Subjects who were pain free and able to walk comfortably for at least 30 minutes were included in the sample. Amputees whose residual limb length prevented the accommodation of the sensor unit in the prosthesis had to be excluded. Participants' prostheses were modified to install the sensor unit (iPecs, CPI, Fraser, MI). Subjects then performed walking trials with different ankle alignment settings, each deviating 2 degrees from their normal position in the sagittal plane. Between walking trials, subjects were asked to stand normally, with feet placed on adjacent force plates (AMTI, Watertown, MA). Ankle and knee moments were computed from Motion Analysis Data (Motion Analysis, Santa Rosa, CA), as well as from the iPecs data. Intermethod reliability of moment averages and maxima was estimated for each intervention using a 2 x 3 ANOVA.

Figure 35: Prosthesis with iPecs sensor below the socket

9.3.4 Demonstration

Figure 38 shows the experimental setup with the integrated sensor mounted in the prosthesis and the subject wearing markers for the motion analysis. Figure 39 illustrates the differences in vertical force and ankle torsion moments during walking trials, as measured with both methods for one representative subject.

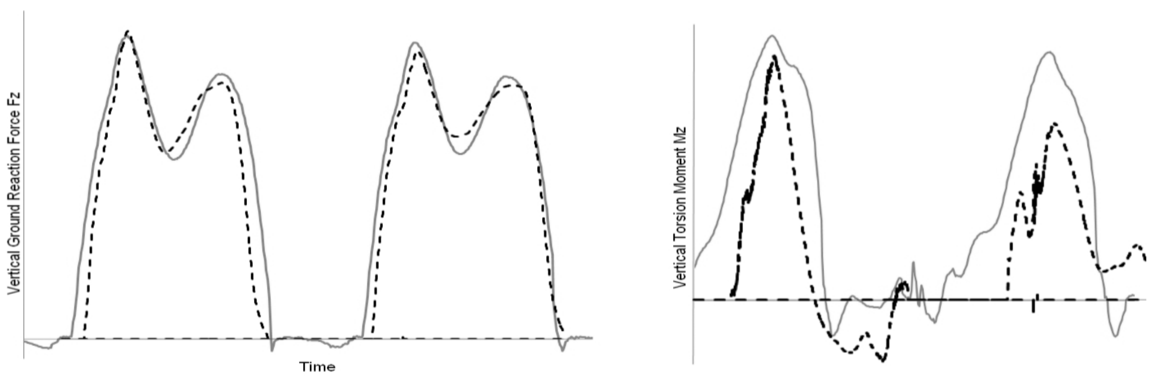

Figure 39: Superposition of force and moment data of two consecutive steps obtained by integrated sensors (orange) and by force plates (black dotted).

9.3.5 Summary

Our study investigated whether the forces and moments within trans-tibial prostheses can be accurately measured using integrated sensors. Changes in the alignment of the prosthetic ankle joint should be reliably represented in the respective changes of the joint moment(s) regardless of the measurement method. If differences in alignment can be successfully detected using the iPecs, integrated sensors may be used alternatively to conventional gait analysis. For the static optimization of the ankle flexion, which is of relevance for the safety and efficiency of amputee gait, this seems to be the case. Typical limitations of this tool, such as delivering information only on one leg, and without any kinematic data, are not of concern for this application, but should be considered in more extensive observations that include locomotion. This evaluation serves as the foundation for further investigation of improving prosthetic alignment and overall assessment through the use of integrated sensors.

References

[1] Harris, M. et al. (1999) *J Biomech*, 32: 951-958.

[2] Bergmann, G. et al. (2001) *J Biomech*, 34: 859-871.

[3] Fedel, F. et al. (2008) *Proceedings of the AAOP Annual Meeting, Orlando, FL*, 31.

[4] Zahedi, M. (1986) *Journal of Rehabilitation Research and Development*, 23: 2-19.

[5] Geil, M. D. (2002) *Journal of Prosthetics & Orthotics*, 14: 159-164.

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This work was supported by the UWM College of Health Sciences, Department of Occupational Science and Technology, and the Rehabilitation Research Design and Disability (R_2D_2) Center. We would also like to thank Doug Briggs, PhD and Caitlin Moore for their help with this work.

Disclosure Statement

The authors have no conflict of interest to disclose.

9.4 Integrated Sensor Systems for Assessment of Rehabilitation in Lower Extremity Amputees

By Goeran Fiedler, Dipl. Ing (FH), CPO-D and Brooke A. Slavens, PhD

(Presented at isQoLT 2011, Toronto)

9.4.1 Abstract

The emergence of internal sensor systems for prosthetic gait assessment brings new perspective in the field of amputee rehabilitation outcomes measurement. Existing methods for determining the quality of prosthetic fit are limited. New technology using integrated sensor systems, such as the “iPecs”, may provide useful quantitative metrics for clinical and rehabilitation assessment of lower extremity amputees. These systems may prove essential for mobile monitoring and biomechanical evaluation.

9.4.2 Background

Amputations of the lower extremity are comparably widespread. Trans-tibial amputation alone has an annual incidence rate of roughly 13 in 100,000 Americans [1]. The main causes for such amputations are vascular conditions, such as those resulting from diabetes. With the expected higher prevalence rate of diabetes in the future, it is projected that the number of persons living with an amputation will double by the year 2050 [2]. Artificial limbs that replace the lost structure below the knee are necessary to enable standing and ambulation without crutches, and to facilitate the prevention of secondary ailments. Since socket fit and static alignment of prostheses are customized to the individual user, standardized quality measures are difficult to define and often result in high variability within the end products of prosthetist’s efforts.

The tools that have been used to assess the quality of prosthetic fit and performance capabilities include questionnaires, pedometers, accelerometers, and motion analysis. While each of these methods has a unique scope, all have some shortcomings with respect to subjectivity and reliability of long-term evaluation of outcomes. A new generation of integrated sensor units promises to provide precise and extensive mobile data that may be very useful in quantifying the relevant factors for amputees.

9.4.3 State of the Art

Prosthetics and Orthotics (P&O) is traditionally a trade that depends widely on the practitioner's personal professional experience. While much of the manual labor that goes into building and fitting a prosthesis has been replaced by standardized solutions over the last decades, the crucial task of optimizing socket shape and static alignment of the prosthesis remains a domain of the prosthetist's expertise and keen eye.

Accordingly, the consistent quality of prosthetic fittings can be questioned [3], especially in regions where skilled labor is scarce. In low income countries, for instance, as estimated by the World Health Organization (WHO), approximately 20,000 orthopedic technicians was needed in 2010, whereas only 300 technicians graduate annually from training centers [4]. Efficient methods to consistently achieve a proper alignment of the prosthesis are required to increase the quantity and quality of prosthetic provisions.

The consequent application of evidence based practice principles in the field has been hampered by the inevitably narrow bandwidth of research, leading to a lack of basic science. According to Geil et al. (2009), research in P&O relies on basic research from other disciplines if it relies on basic research at all. While this phenomenon is partly due to the relative youth of sophisticated P&O research, the applied nature of the field also lends itself to applied research [5].

One aspect is also the availability of dedicated tools for static alignment. Replacing some traditional analogous measuring devices with modern computer aided scanners and laser plumb lines has contributed to a reduction of the error variance [6], without however addressing the basic problem of obtaining objective information on the quality of fit during the rectification and optimization process. Promising methods to standardize prosthetic alignment algorithms based on accurate data collection have been proposed [7], but have not gained widespread popularity.

Similarly, the usefulness of motion analysis for the optimization of prosthetic gait pattern is evident, yet in everyday practice almost irrelevant due to the extensive equipment and time demands that cannot usually be accommodated (figure 1). Recently, the adaptation of miniaturized sensors for P&O purposes has changed this situation. Ayyappa et al. [8] states that current technology provides onboard gait laboratories as components of the prosthesis, which may allow practitioners to more intimately meet the needs of their patients.

9.4.4 The Future of integrated Gait Analysis

The option of integrating a sensor unit directly into the weight bearing structure is unique to the field of prosthetics, as any sensor that a non-amputated subject would be equipped with can merely be attached to the surface of the body, and is thus susceptible to various measurement errors. The onset of commercially available computer controlled prosthesis knee joints in the 1990s brought about the first miniaturized sensors that were required in order to deliver the input for the respective swing phase control or stance phase safety. The Otto Bock C-Leg features a set of strain gages inside the modular shin tube adapter and uses the obtained moment information during the ground contact phase to determine the actual segment of the gait cycle.

Based on essentially the same technology, various modular components have been introduced by different manufacturers. Initially, these devices were intended to be temporarily mounted into the prosthesis, and deliver gait data to help optimize the alignment. Considerations on weight and cost of these early generation sensor units did not suggest their permanence in the prosthesis.

The prospect of measuring online gait data independent of a gait laboratory is not without inherent difficulties. Apart from the question on validity of the data collection [9], it is most of all important to decide what exactly should be measured, and how this information can be useful for clinical purposes. The iPecs (Intelligent Prosthetic Endoskeletal Component System) by College Park Industries [10], for instance, is capable of measuring forces and moments in six degrees of freedom (figures 2, 3), most of which the practitioner may be challenged to use.

First studies that utilized this tool [11] restrained themselves to longitudinal comparisons of selected output values measured in different situations of prosthesis use. Arguably, these findings require additional information on how the parameters in question relate to practically relevant factors. Values which are correlated to desirable outcomes should be identified, as else the data remains useless in practice.

There exists a need for a reliable, objective assessment method to serve as the gold standard to compare outcomes from the iPecs or other integrated sensor systems. Conventional gait analysis may be suggested as the standard for comparison of data with these systems. This approach offers the possibility to identify significant parameters characteristic of amputee gait. Once these factors are known, integrated sensor systems may be used to assess prosthetic gait in various environments which utilizes its mobile capabilities.

9.4.5 Discussion

Current force and moment sensor technology and their application in prosthetics offers unique insight to prosthetic gait by allowing the collection of objective data over extended periods of time, independent of the laboratory environment. Caution is recommended when interpreting the raw data without a well-defined reference, in order to avoid merely having shifted the guessing to a more technical and costly level.

Provided that the available technology is capable of identifying clinical deviations in gait patterns, it can be projected that the hardware will be subsequently optimized to become lighter, less bulky, and more affordable. It is conceivable in the future that every prosthesis will be equipped with such a mobile gait lab, improving prosthetic fit and rehabilitation assessment of lower extremity amputees.

References

[1] T. Dillingham, et al., "Limb amputation & limb deficiency: epidemiology & recent trends in the United States," *Southern Medical Journal*, vol. 95, pp. 875-83, 2002.

[2] K. Ziegler-Graham, et al., "Estimating the prevalence of limb loss in United States: 2005 to 2050," *Archives of Physical Medicine and Rehabilitation*, vol. 89, pp. 422-9, 2008.

[3] M. D. Geil, "Variability among Practitioners in Dynamic Observational Alignment of a Transfemoral Prosthesis," *Journal of Prosthetics and Orthotics*, vol. 14, pp. 159-164, 2002.

[4] J. Pearlman, et al., "Lower-limb prostheses & wheelchairs in low-income countries," *IEEE Engineering in Medicine and Biology Magazine*, vol. 27, pp. 12-22, 2008.

[5] M. D. Geil, "Assessing the state of clinically applicable research for evidence based practice in posthetics and orthotics," *Journal of Rehabilitation Research and Development*, vol. 46, pp. 305-314, 2009.

[6] M. D. Geil, "Consistency & accuracy of measurement of lower-limb amputee anthropometrics," *Journal of Rehabilitation Research and Development*, vol. 42, pp. 131-40, 2005.

[7] S. Blumentritt, "A new biomechanical method for determination of static prosthetic alignment " *Prosthetics and Orthotics International*, vol. 21, pp. 107-113,1997.

[8] E. Ayyappa, et al., "Infusing Cutting Edge Technology Into Everyday O&P Clinical Care," *Journal of Prosthetics and Orthotics*, vol. 22, pp. 2-10, 2010.

[9] S. LeGare, "Clinical Reliability of a Device for Measuring Forces & Moments in Ampute Gait,“ *MSPO Research Presentation.*, Atlanta, GA, 2009.

[10] M. G. Leydet, et al., "Prosthetic Sensing System & Methods," US patent, Publication No. 20070255424, 2007.

[11] G. Papaioannou et al., "Transtibial Prosthetic Kinetics During Prolonged Strenuous Activities of Daily Living Measures by Internal Gait Analysis Instrumentation," presented at 37th Annual Meeting of the American Academy of Orthotists and Prosthetists, Orlando, FL, 2011.

Acknowledgements

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9.5 Leg Laterality in Bilateral Trans-Tibial Amputees, A Case Study using Prosthesis-Integrated Sensors

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[1]*University of Wisconsin Milwaukee,* [2] *Eastern Michigan University*

(Presented at the Annual Conference of the Rehabilitation Engineering And Assistive Technology Society of North America (RESNA). 2012. Baltimore, MD)

9.5.1 Abstract

Bilateral leg amputation is obviously a severe detriment of physical integrity. However, at least in the case of bilateral trans-tibial amputation, rehabilitation efforts are often promising, and many patients succeed in learning to use prostheses. Due to the relatively small population size, literature on gait biomechanics for these patients is scarce, and prosthetic fitting practice is based on tradition and empiric rules of thumb. One question that is frequently encountered during fitting is whether there is a disparity in leg strength and controllability, and if so, which one of the legs is the favored one. This may have implications for the selection and adjustment of prosthetic parts, as well as for the prescription of physical therapy, and possibly recommended assistive devices. Prosthesis-integrated sensors suggest themselves as efficient assessment tools, as they can be installed in both legs, and thus allow continuous and un-obstructive data collection during various activities (Fiedler & Slavens, 2011). Simple pair-wise comparison of parameters between legs can then help answer the research question.

9.5.2 Introduction

Among the many millions of people world-wide who live with limb loss, the fraction of bilateral trans-tibial amputees is considerable, and includes an estimated 11,400 individuals in the US alone (Su, Gard, Lipschutz, & Kuiken, 2007). Many of the main causes of amputation, such as cardiovascular disease, trauma, and congenital defects are usually not limited to a single limb or side. The rehabilitation of these patients can be challenging due to having to replace several limbs by prostheses. However, in many cases an efficient verticalization can be achieved, enabling the amputee to walk with little or even entirely without crutch support. The success rate in using prostheses for bilateral trans-tibial amputees has been reported to be as high as 60-90% (De Fretes, Boonstra, & Vos, 1994). Their gait has been found to be characterized by lower speeds, cadences, ankle moments and knee moments, compared to able bodied controls, which might be attributed to a deficit in available prosthetic componentry (Su, Gard, Lipschutz, & Kuiken, 2007).

One issue in the prosthetic fitting process is the decision about socket technology and functional part selection in cases where the residual limbs display different capabilities in terms of weight bearing, and prosthesis control. This is usually assumed when there is a large gap in limb length, and/or additional impairments such as large scars, muscular deficits or joint ailments affecting one side more than the other. Consequently, optimal selection and adjustment of the prosthetic foot components may be different for both legs. Prosthetic feet characteristics can generally be described as a continuum between stiffness and flexibility. While the former allows energy storage and return in the interest of a dynamic and efficient gait pattern, the latter secures stable ground contact, accommodation of uneven surfaces, and reduction of ankle moments, which is conducive to the stance stability and thus the (perceived) safety of the amputee (Su, Gard, Lipschutz, & Kuiken, 2010).

Knowledge on the preferred leg of bilateral trans-tibial amputees can inform the prescription of prosthetic feet and other functional parts such as torsion adapters or shock absorbers. Beyond that, it becomes possible to customize a physical therapy regimen that considers the respective different capabilities of both legs, so as to include strengthening and balance, and to practice individualized strategies for stair walking and other demanding tasks of everyday life.

9.5.3 Methods

IRB approval for this study was granted. Persons from 18 to 80 years of age with bilateral trans-tibial amputations who use prostheses built in modular technique, and were able to walk at least 30 minutes per day pain-free and without assistive devices were recruited for this study. Patients whose prostheses did not provide enough space between socket and foot module to fit the mobile measuring unit could not participate in this study. An initial screening was conducted to assure eligibility. Two male subjects (A: 61 years, 5’7”, 185 lbs, and B: 32 years, 5’8”, 178 lbs) participated in this study. Informed consent was obtained prior to the data collection.

In preparation of the data collection, the existing prostheses of the subject were modified by replacing the tube adapters above the foot modules with the iPecs integral sensor units (College Park Industries, Fraser, MI), and tube adapter in respectively shorter or longer lengths while maintaining the overall static alignment of the prostheses. In the gait lab, the subjects donned the modified prostheses in the usual fashion. In addition to measuring anthropometric data, such as limb dimensions, subject height and body mass, the Amputee Activity Score sheet was completed based on the subject’s self-report (Day, 1981).

Continuous iPecs measurements were conducted while subjects performed the following tasks in subsequent order:

- Walked in their preferred speed along the hallway (level surface, concrete floor),
- Walked down the stairs to the 1st floor (15 steps, concrete),
- Walked across a parking lot outside of the building (slightly uneven, asphalt and concrete sidewalk),
- Walked up a different set of stairs (13 steps), and
- While secured with a safety harness, walked through a 10 ft long sand box filled with gravel.

Gait analysis parameters such as step stance duration, knee-, and ankle moment, axial shin compression force, all delivered by the iPecs device were normalized to body weight and averaged over the trials of each task group (baseline gait inside the lab, stair gait, gait outdoors). A bilateral comparison was conducted by means of MANOVA, using the statistical package IBM SPSS 20. For every task, the mean difference of the parameters was calculated based on the available sample of steps.

9.5.4 Results

Both participants were comparably active prosthesis users with several years of experience. Subject A has been a bilateral amputee for 17 years and scored 15 on the Amputee Activity Score. Both of his residual limbs had about the same dimensions with a length of 16.5 cm. Subject B lost his legs 4 years prior, and had an Amputee Activity Score of 21. His residual limbs measured 16.5 cm (right) and 15 cm (left) in length. Both participants were fitted with patellar tendon bearing sockets with silicon liners and energy storing carbon feet.

Figure 40: Average values in peak vertical force (Fz), stance phase duration, Ankle flexion moment, Knee flexion moment, and stride duration for 17 steps of walking on level ground for Subject A. All values are normalized to lbs body weight.

Participant A preferred a slower walking speed, and used a cane with his right hand. His time on the 210 m long circuit path (including the stairs) was 5:55 minutes, equaling an average velocity of about 0.59 m/s. Participant B walked without assistive devices and averaged a lap time of 3:53 minutes (0.90 m/s). Both participants climbed up stairs employing an alternating pattern and using handrails. For the task of walking down stairs, Subject A preferred to step forward always with his right foot before placing the left foot on the respective same stair step, whereas Subject B displayed an alternating foot placement.

As a result, 13 steps of down stair walking have been recorded for both legs of Subject A (not counting the respective first and last steps), and seven, respectively six steps for the two legs of Subject B. Walking up the stairs, both subjects had five or six valid steps of each leg. Level ground walking involved 17 steps (A) and 15 steps (B), while outdoor walking was evaluated over 27 steps (A) and 31 steps (B) respectively. No useable data could be collected for Subject A walking on the gravel path, and only 4 steps were evaluated for Subject B performing this task.

Figure 40 illustrates the bilateral differences between legs during level ground walking in Subject A. All comparisons are summarized in tables 26 and 27.

Table 26: Bilateral comparison of step parameters during different walking activities. Listed are the absolute values for Subject A. * marks significant bilateral differences at the .05 level.

Subject A	level walk				down stairs			
	left	**right**	**difference**	**p-value**	**left**	**right**	**difference**	**p-value**
F_z (N)	956.925	956.848	0.077	0.991	822.622	922.951	100.329	<0.001*
Stp durat. (s)	0.868	0.996	0.128	<0.001*	1.217	1.174	0.043	0.266
M_y knee (Nm)	126.676	133.938	7.262	0.004*	111.284	65.505	45.779	<0.001*
M_y ankle (Nm)	-0.173	9.853	10.026	<0.001*	0.209	2.331	2.123	0.003*
Stride dur. (s)	1.351	1.528	0.177	<0.001*	1.771	1.887	.116	0.019*
	outdoors				upstairs			
F_z (N)	980.777	936.442	44.336	<0.001*	817.541	890.423	72.882	0.168
Stp durat. (s)	0.928	0.968	0.039	0.118	1.787	2.219	0.432	0.122
M_y knee (Nm)	122.74	127.276	4.536	0.181	74.761	56.045	18.717	0.082
M_y ankle (Nm)	-0.489	6.595	7.085	<0.001*	2.342	10.479	8.138	0.011*
Stride dur. (s)	1.46	1.476	0.016	0.605	2.851	3.55	.699	0.039*

Table 27: Bilateral comparison of step parameters during different walking activities. Listed are the absolute values for Subject B. * marks significant bilateral differences at the .05 level.

Subject B	level walk				down stairs			
	left	**right**	**difference**	**p-value**	**left**	**right**	**difference**	**p-value**
F_z (N)	1186.65	933.629	253.022	<0.001*	1381.38	1293.76	87.62	0.511
Stp durat. (s)	0.838	0.721	0.116	<0.001*	0.891	0.829	0.062	0.135
M_y knee (Nm)	135.300	164.681	29.381	<0.001*	163.565	192.233	28.669	0.003*
M_y ankle (Nm)	4.477	2.308	2.170	0.002*	6.45	4.111	2.338	0.258
Stride dur. (s)	1.145	1.109	0.035	0.080	1.423	1.465	0.043	0.589
	outdoors				upstairs			
F_z (N)	1164.585	918.434	246.151	<0.001*	1176.017	914.486	261.532	<0.001*
Stp durat. (s)	0.859	0.725	.135	<0.001*	0.916	0.925	0.009	0.940
M_y knee (Nm)	127.691	159.29	31.598	<0.001*	142.968	186.247	43.280	0.021*
M_y ankle (Nm)	4.887	3.372	1.515	0.015*	3.942	5.23	1.288	0.276
Stride dur. (s)	1.224	1.097	.127	0.001*	1.621	1.398	0.222	0.181

9.5.5 Discussion

The bilateral differences of walking parameters can be interpreted as an indicator of gait symmetry. According to the data we collected, bilateral amputee walking seems to be characterized by a considerable asymmetry in gait parameters. The parameters that display those asymmetries appear to be individually different. Subject A had very symmetrical weight distribution (judged by the peak vertical forces) during level walking, but significant bilateral differences in stance phase duration, knee moment and ankle moment. When walking on less smooth ground outdoors, the vertical forces became less balanced, but differences in knee moment and stance phase duration diminished. The only consistent pattern over all four walking tasks was that the ankle moment in the right foot was greater than in the left foot. The bilateral differences in Subject B were overall more consistent. Most notably was the knee moment that in all situations was higher in the right leg than in the left. The subject reported that he often depends more on his left leg, which seems to be confirmed by the peak forces that are mostly higher for this side. The fact that greater moments were measured in the right knee might be related to this residual limb being longer than the left one.

Our chosen data evaluation method based on discrete variables has been used in previous studies (Chow, Holmes, Lee, & Sin, 2006), but has its limitations in that it cannot entirely describe the kinetics parameters of the step cycle. Judged by the data plots, the measured differences may appear even greater when assessed more elaborately. In this context, however, it could be discussed what level of difference is indeed of clinical significance. Does the discrepancy of 10 Nm in ankle moment warrant a change of the used prosthetic foot component, or is such a small aberration an individual peculiarity that does not call for an intervention? A more extensive study, both in sample size, and assessment period, may be required to answer this question.

Acknowledgements

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References

Chow, D. H. K., Holmes, A. D., Lee, C. K. L., & Sin, S. W. (2006). The effect of prosthesis alignment on the symmetry of gait in subjects with unilateral transtibial amputation. *30*(2), 114-128.

Day, H. J. B. (1981). The assessment and description of amputee activity. *Prosthetics and Orthotics International, 5*, 23-28.

De Fretes, A., Boonstra, A., & Vos, L. (1994). Functional outcome of rehabilitated bilateral lower limb amputees. *Prosthet Orthot Int., 18*(1), 18-24.

Fiedler, G., & Slavens, B. A. (2011). *Integrated Sensor Systems for Assessment of Rehabilitation in Lower Extremity Amputees*. Paper presented at the Conference Name|. Retrieved Access Date|. from URL|.

Su, P.-F., Gard, S. A., Lipschutz, R. D., & Kuiken, T. A. (2007). Gait characteristics of persons with bilateral transtibial amputations. *Journal Of Rehabilitation Research And Development, 44*(4), 491-501.

Su, P., Gard, S., Lipschutz, R., & Kuiken, T. (2010). The effects of increased prosthetic ankle motions on the gait of persons with bilateral transtibial amputations. *Am J Phys Med Rehabil, 89*(1), 34-47.

10 Appendix F: Informed Consent form

UNIVERSITY OF WISCONSIN – MILWAUKEE

CONSENT TO PARTICIPATE IN RESEARCH

THIS CONSENT FORM HAS BEEN APPROVED BY THE IRB FOR A ONE YEAR PERIOD

1. General Information

Study title: Biomechanical Assessment of Gait in Lower-Extremity-Amputees

Person in Charge of Study (Principal Investigator):

- The principal investigator for this study is Brooke Slavens, PhD.
- Dr. Slavens is an assistant professor at the College of Health Sciences at UWMilwaukee
- Goeran Fiedler is the student-PI for this study. He is a PhD student at the College of Health Sciences.

2. Study Description

You are being asked to participate in a research study. Your participation is completely voluntary. You do not have to participate if you do not want to.

Study description:

The purpose of this study is to investigate the symmetry of gait; that is how the motion patterns of your left and right leg differ when walking with prosthesis.

- This study is being done to find out how the gait pattern is linked to the setting of the prosthesis. This information can help improve the quality of prosthetic fittings.
- Specific goals of the study are to investigate how gait symmetry changes on different surfaces, with different prosthetic alignments, and at different levels of muscle fatigue. Also, we will temporarily install a small sensor unit in your prosthesis, and see whether this can be used to measure your gait symmetry.
- The study is being done at the UWM University Research and Services Building, 115 East Reindl Way, Milwaukee, WI 53212.
- Up to 20 subjects will participate in this study.
- All data collection will take a maximum of five hours per subject, and will be done on the same day. In order to assure that your prosthesis can be modified as planned, a short (10 minute) technical check-up will be conducted prior to the appointment.

3. Study Procedures

What will I be asked to do if I participate in the study?

If you agree to participate you will be asked to

- Come to the UWM University Research and Services Building, 115 East Reindl Way, Milwaukee, WI 53212.
- Doff your prosthesis, so that we can install a small sensor unit. Depending on technical circumstances this may take up to one hour to do.
- In the meantime, complete a short standardized interview on your activity level (the Amputee Activity Score).
- Don the prosthesis again and have reflective markers placed on your skin and garment. Those are required for the motion capturing. Also we will place sensors that measure your muscle activity on the skin of your thighs. It is possible that we will need to shave off some hair where the sensors are to be placed. We will take measurements of your foot size, height and body weight. You will put on a safety harness that will be required towards the end of the testing. Overall, those preparations will be concluded within 30 minutes.
- Following this, perform a number of walking trials in the gait lab. This is used to synchronize the readings from the sensor unit with the data from the motion analysis system and will take 5 minutes at most.
- Next, walk along the hallway outside the lab and down a flight of stairs, and return the same way, walk through a box of gravel while being secured by the safety harness. This delivers measurement data that we can compare with the data from the gait lab. Depending on your preferred walking speed, this will require between 5 and 10 minutes.
- Take a break while we make slight adjustments to the static alignment of your prosthesis. Those include a total of 6 different interventions, such as lowering the forefoot, or increasing the outward rotation. With each of the 6 different settings you will be asked to walk a few minutes. Again, this gives us data that we can use for comparison purposes, and will take about one half hour overall.
- Eventually, walk on a looped path along the hallway, down the stairs, out the backdoor, across the parking lot, through the front door, up the stairs and back to the laboratory. You will be accompanied at all times by members of the research team. This exercise will cause a certain degree of overall exertion, which we will assess according to your feedback. Depending on your fitness level, this walking exercise will take anywhere from 10 minutes to 60 minutes.
- With your harness connected to a safety rope, perform another set of walking trials in the lab. The data will allow us to determine the effect of fatigue on your walking pattern. This last test will take no longer than 5 minutes.
- Doff your prosthesis and have the sensor removed and the original state restored. Depending on technical conditions, this will require up to 30 minutes.

You can take a break at any point in time. Much of the estimated time between the test procedures, will be needed for technical preparations, and can be used to rest. In fact, the actual performance time will sum up to less than 2 hours total. Your gait will be recorded by a multi-camera motion capture system. However, those cameras only record the reflective markers, so that your face will not be recognizable. We may ask for permission to take some photos for documentation purposes. If published, it will be masked in a way to make you unidentifiable. If you do not want to have your picture taken, you can still participate in the study.

4. Risks and Minimizing Risks

What risks will I face by participating in this study?

- Foreseeable risks and discomforts include skin irritation from the markers and EMG sensors. Those are attached by means of adhesive tape, which is somewhat likely to cause pain at removal. In the case that we need to shave off some hair, this might cause some inconvenience too. Risks, such as pressure pain and falls, are related to walking with prosthesis, especially on stairs and uneven ground, but their likelihood won't increase by the temporary modifications. The fatiguing workout on the exercise machine can cause muscle weakness and overall exhaustion. We will use a visual analogue scale to monitor your pain level. If you experience uncommon pain or discomfort, the data collection can be interrupted or discontinued at any point in time.
- During the tests with a modified prosthesis, two members of the research staff will accompany you at all times for assistance. To reduce the falling risk on the gravel path and after the fatigue protocol you will be using the safety harness for the remaining trials. In the case that you are injured because of this study, the cost of medical care for your injuries will be billed to you or to your insurance company. Insurance companies may not pay for medical care to treat injuries you receive while participating in this study. If you think that you have suffered a research-related injury, let the study PI know right away. By signing this form, you do not give up your right to seek compensation for injuries you receive while participating in this study.

5. Benefits

Will I receive any benefit from my participation in this study?

- There are no benefits to you other than to further research.

6. Study Costs and Compensation

Will I be charged anything for participating in this study?

- You will be responsible for your transportation to and from the USR facilities. Parking at the USR facilities is free. We will not charge you anything for taking part in this research study.

Are subjects paid or given anything for being in the study?

- Upon conclusion of the tests you will receive a cash compensation of US$ 100.-

7. Confidentiality

What happens to the information collected?

All information collected about you during the course of this study will be kept confidential to the extent permitted by law. We may decide to present what we find to others, or publish our results in scientific journals or at scientific conferences. Information that identifies you personally will not be released without your written permission. Only the PI and personnel directly related to data collection and evaluation for this study will have access to the information. However, the Institutional Review Board at UW-Milwaukee or appropriate federal agencies like the Office for Human Research Protections may review this study's records.

- Your information will be recorded and stored under an anonymous identifier, which prevents linking your data to your personal information without the paper records.
- Your personal information and the key to the identifier will be stored in a locked cabinet that only authorized staff has access to.
- The data collected for this study will be stored in a locked cabinet at the laboratory for 10 years for future use.

8. Alternatives

Are there alternatives to participating in the study?

- There are no known alternatives available to you other than not taking part in this study.

9. Voluntary Participation and Withdrawal

What happens if I decide not to be in this study?

Your participation in this study is entirely voluntary. You may choose not to take part in this study. If you decide to take part, you can change your mind later and withdraw from the study. You are free to not answer any questions or withdraw at any time. Your decision will not change any present or future relationships with the University of Wisconsin Milwaukee.

- In the case that you withdraw or are withdrawn early, we will use the information collected to that point.

10. Questions

Who do I contact for questions about this study?

For more information about the study or the study procedures or treatments, or to withdraw from the study, contact:

Goeran Fiedler (Student PI)
Department of Occupational Science & Technology
University of Wisconsin-Milwaukee
PO Box 413
Enderis Hall 135G
Milwaukee, WI 53201-0413
Phone: (414) 229-6803 / Fax: (414) 229-6843

Who do I contact for questions about my rights or complaints towards my treatment as a research subject?

The Institutional Review Board may ask your name, but all complaints are kept in confidence.

Institutional Review Board
Human Research Protection Program
Department of University Safety and Assurances
University of Wisconsin – Milwaukee
P.O. Box 413
Milwaukee, WI 53201
(414) 229-3173

11. Signatures

Research Subject's Consent to Participate in Research:

To voluntarily agree to take part in this study, you must sign on the line below. If you choose to take part in this study, you may withdraw at any time. You are not giving up any of your legal rights by signing this form. Your signature below indicates that you have read or had read to you this entire consent form, including the risks and benefits, and have had all of your questions answered, and that you are 18 years of age or older.

____

Printed Name of Subject/ Legally Authorized Representative

____

Signature of Subject/Legally Authorized Representative Date

Research Subject's Consent to Audio/Video/Photo Recording:

It is okay to photograph me while I am in this study and use my photographed data in the research.

Please initial: ____Yes ____No

Principal Investigator (or Designee)

I have given this research subject information on the study that is accurate and sufficient for the subject to fully understand the nature, risks and benefits of the study.

_______________________________ _______________________________

Printed Name of Person Obtaining Consent Study Role

____

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12 Curriculum Vitae

Goeran Fiedler

Place of birth: Mittweida, SA, Germany

Education/training

Bachelor of crafts (Prosthetics/orthotics), Chamber of Crafts of Thuringia, Gera, GER, January 1994

Master of crafts (Prosthetics/orthotics), Chamber of Crafts of Lower Bavaria/Upper Palatinate, Regensburg, GER, October 1998

M.S. [Dipl. Ing. (FH)] (Clinical engineering, Biomechanics), University of Applied Sciences, Giessen, GER, March 2008

Dissertation Title: Effects of physical exertion and alignment alterations on trans-tibial amputee gait, and concurrent validity of prosthesis-integrated measurement of gait kinetics

Positions and Honors

1990-1995	Prosthetist/Orthotist, Orthopaedietechnik Duesedau, Gera, GER
1995-1999	Prosthetist/Orthotist ,OTE Gera, GER
1999-2002	Certified Prosthetist/Orthotist, Otto Bock Health Care, Duderstadt, GER
2008-2010	Research Assistant UWM, MOVE Center, Milwaukee, WI
2010-2012	Project Assistant UWM, R2D2 Center, Milwaukee, WI
2012-2013	Postdoctoral Fellow, UW, Seattle, WA

2006	Selected for Hesse-Wisconsin Exchange (app. $8,000 in tuition remission)
2006	Fulbright Travel Grant (app. $6,000 for travel, housing, tuition)
2011	UWM Chancellor’s Award ($13,000)
2011	UWM College of Health Sciences Student Research Grant ($2,000)
2012	Force and Motion Foundation, Travel Grant ($500)

Other Experience and Professional Memberships

2005- present: Member: VDI (Society of German Engineers)

2009- present: Member: AAOP (American Association of Orthotists and Prosthetists)

2005- present: Member: TOB (Technical Orthopeadics and Biomechanics)

2012-present: Member: GCMAS (Gait and Clinical Movement Analysis Society)

Reviewer: Journal of Rehabilitation Research & Development (2010)

Publications and conference presentations

[1] Fiedler, G., B.A. Slavens, D.W. Briggs, F. Fedel, and R.O. Smith (2012). “Leg Laterality in Bilateral Trans-Tibial Amputees, A Case Study using Prosthesis-Integrated Sensors”, Annual Conference of the Rehabilitation Engineering And Assistive Technology Society of North America (RESNA) 2012. Baltimore, MA, June 27-July 2

[2] Fiedler, G., B.A. Slavens, and R.O. Smith (2012). “Evaluation of an Integrated Sensor System for Assessment of Prosthesis Ankle Alignment in Lower Extremity Amputees”, presented at the Annual Conference of the Gait and Clinical Movement Analysis Society (GCMAS) 2012. Grand Rapids, MI, May 9-12

[3] Fiedler, G., B.A. Slavens, and R.O. Smith (2012). “Gait stability measured by prosthesis-integrated sensors as an outcome measure in persons with prostheses for the lower extremity”, presented at the 25th Annual Dean's Research Day 2012. Kalamazoo, MI, March 23-24

[4] Fiedler, G., B.A. Slavens, and R.O. Smith (2012). “Influence of Handrail Use on Stair Walking Stability in Trans-Tibial Amputees”, presented at the 1st Occupational Science Summit 2012. St. Louis, MO, March 11-13

[5] Fiedler, G. and Slavens, B. (2011). “Integrated Sensor Systems for Assessement of Rehabilitation in Lower Extremity Amputees”, presented at the Festival of International Conferences on Caregiving, Disability, Aging and Technology - FICCDAT 2011, Toronto, Canada, June 5-8

[6] Papaioannou, G., Wood, J. R., Fiedler, G., Mitrogiannis, C., Nianios, G., Kanellos, T. G. and Tsiokos, D. (2011). "Cardiopulmonary and Biomechanics of Three Daily Activity Tasks - Comparison between Two Prosthetic Socket Designs," presented at the 37th Annual AAOP Meeting and Scientific Symposium, Orlando, FL, March 16-19

[7] Papaioannou, G., Wood, J. R., Mitrogiannis, C., Fiedler, G., Nianios, G., Kanellos, T. G. and Tsiokos, D. (2011). "Amputee Stair Ascending and Descending: Direct Measurement of Prosthesis Kinetics," presented at the 37th Annual AAOP Meeting and Scientific Symposium, Orlando, FL, March 16-19

[8] Papaioannou, G., Wood, J. R., Mitrogiannis, C., Tsiokos, D., Fiedler, G., Nianios, G. (2011). "Transtibial Prosthetic Kinetics during Prolonged Strenuous Activities of Daily Living

Measures by Internal Gait Analysis Instrumentation," presented at the 37th Annual AAOP Meeting and Scientific Symposium, Orlando, FL, March 16-19

[9] Wood, J. R., Papaioannou, G., Fiedler, G., Mitrogiannis, C., Nianios, G. and McKinney, R. (2011). "Effect of Elevated Vacuum Sockets on Residual Limb-Socket Motion in Prolonged Strenuous Activities," presented at the 37th Annual AAOP Meeting and Scientific Symposium, Orlando, FL, March 16-19

[10] Fiedler, G. and Günther, M. (2011). “ Der Milwaukee-Schaft - wissenschaftliche Ergebnisse als Grundlage für ein verbessertes transfemorales Schaftdesgin. [The Milwaukee Socket - an improved trans-femoral socket design based on scientific findings]”, Orthopädie-Technik, 2/11

[11] Papaioannou, G., Mitrogiannis, C., Nianios, G. and Fiedler, G. (2010). "Assessment of amputee socketstump-residual bone kinematics during strenuous activities using Dynamic Roentgen Stereogrammetric Analysis". Journal of Biomechanics, 22; 43(5), pp.871-8.

[12] Papaioannou, G., Nianios, G., Mitrogiannis, C. and Fiedler, G. (2010). "Assessment of internal and external prosthesis kinematics during strenuous activities using Dynamic Roentgen Stereophotogrammetric Analysis". Journal of Prosthetics and Orthotics, 22 (2), pp. 91-105.

[13] Günther, M. and Fiedler, G. (2010). “Schnittstelle Mensch-Prothese: Ansätze zur Schaftoptimierung [Humanprosthesis interface: approaches for socket optimization]”, Orthopädie-Technik, 7/10, 524-528

[14] Papaioannou, G., Mitrogiannis, C., Nianios, G. and Fiedler, G. (2010). "Internal and external prosthesis kinematics assessment using Dynamic Radiography ". Proceedings of the 56th Annual Meeting Orthopaedic Research Society New Orleans, LA, March 6-9.

[15] Papaioannou, G., Mitrogiannis, C., Nianios, G. and Fiedler, G. (2010). "Bilateral below knee amputee socket-stump kinematics using Biplane Dynamic Roentgen Stereophotogrammetric Analysis ". Proceedings of the 56th Annual Meeting Orthopaedic Research Society New Orleans, LA, March 6-9.

[16] Papaioannou, G., Mitrogiannis, C., Nianios, G. and Fiedler, G. (2010). "Quantitative assessment of dynamic radiography data for lower limb amputees". Proceedings of the 56th Annual Meeting Orthopaedic Research Society New Orleans, LA, March 6-9.

[17] Papaioannou, G., Kanellos, T.G., Pleros, N., Mitrogiannis, C., Nianios, G. and Fiedler, G. (2010). "Validation of a new Optical Fiber Sensor for novel amputee socket designs". Proceedings of the 56th Annual Meeting Orthopaedic Research Society New Orleans, LA, March 6-9.

[18] Papaioannou, G., Mitrogiannis, C., Nianios, G., Fiedler, G. and Wood, J. (2010). "Effects of assisted vacuum TT socket design on the relative motion at the stump/socket interface". Proceedings of the 56th Annual Meeting Orthopaedic Research Society New Orleans, LA, March 6-9.

[19] Papaioannou, G., Mitrogiannis, C., Nianios, G., Fiedler, G. and Baradaki, V. (2010). "Validation of a novel Adaptive Smart Surface bed with Integrated Decubitus Prophylaxis Sensors". Proceedings of the 56th Annual Meeting Orthopaedic Research Society, New Orleans, LA, March 6-9.

[20] Papaioannou, G., Mitrogiannis, C., Nianios, G. and Fiedler, G. (2010). "Towards a novel “SMARTsocket” design for lower extremity amputees". Proceedings of the Human Factors & Medicine SYMPOSIUM on «Use of Advanced Technologies and new Procedures in Medical Field Operations», Essen, Germany, 19-21 April.

[21] Papaioannou, G., Kanellos, G.T., Pleros, N., Mitrogiannis, C., Nianios, G. and Fiedler, G. (2010). "Flexible strain sensing surface based on fiber optic sensors for application in orthopedic biomechanics and rehabilitation". Proceedings of the Human Factor & Medicine SYMPOSIUM on «Use of Advanced Technologies and new Procedures in Medical Field Operations», Essen, Germany, 19-21 April.

[22] Papaioannou, G., Mitrogiannis, C., Nianios, G. and Fiedler, G. (2009). "Tracking high speed arthrokinematics using a new and high resolution Biplane Dynamic Roentgen Stereogrammetric method". International Journal of Imaging, 2(Number A09), pp. 66-85.

[23] Papaioannou, G., Mitrogiannis, C., Nianios, G. and Fiedler, G., (2009). "A new method for assessing residual limb skin-tissue strain during above-knee amputee high-speed movement". Proceedings of the Orthopaedic Research Society, Las Vegas, NV, February 22-25.

[24] Papaioannou, G., Mitrogiannis, C., Nianios, G. and Fiedler, G. (2009). "A new Improved Tracking Technique for assessment of high Resolution Dynamic Radiography Skeletal kinematics". Proceedings of the Orthpadic Research Society, Las Vegas, NV, February 22-25.

[25] Papaioannou, G., Mitrogiannis, C., Nianios, G. and Fiedler, G. (2009). "Assessing Residual Bone-StumpSkin-Socket interface kinematics of Above Knee Amputees with High Accuracy Biplane Dynamic Roentgen Stereogrammetric Analysis". Proceedings of the ORS, Las Vegas, NV, February 22-25.

[26] Papaioannou, G., Mitrogiannis, C., Nianios, G. and Fiedler, G. (2009). "Assessment of internal and external prosthesis kinematics during strenuous activities using high speed Dynamic Roentgen Stereogrammetric Analysis". Proceedings of the Radiological Society of North America (RSNA), Chicago, IL, 29 Nov - 4 Dec.

[27] Papaioannou, G., Mitrogiannis, C., Fiedler, G., Hostens, I. and Spaepen, A. (2009). "Comparison of several seating solutions designed for prolonged sitting and car driving with transportation-oriented wheelchairs". Brazilian Journal of Biomotricity, 3(2), pp. 194-207.

[28] Papaioannou, G., Fiedler, G., Mitrogiannis, C. and Nianios, G. (2009). "Using high accuracy Biplane Dynamic Roentgen Stereogrammetric Analysis to assess interface proximity residual bone-stump-skin-socket kinematics of above knee amputees during strenuous activities ". Proceedings of the International Society of Biomechanics, XIIth International Symposium on Computer Simulation in Biomechanics, Cape Town, South Africa, 5-9 July.

[29] Papaioannou, G., Mitrogiannis, C., Fiedler, G. and Nianios, G. (2009). "Assessment of Vacuum-assisted trans-tibial amputee socket dynamics". Proceedings of the 9th International Conference on Information Technology and Applications in Biomedicine, Larnaca, Cyprus, November 5-7.

[30] Mitrogiannis, C., Fiedler, G., Papadopoulos, C., Nianios, G. and Papaioannou, G. (2009). "Validation of 3D fluoroscopy image distortion correction and calibration algorithms".

Proceedings of the 9th International Conference on Information Technology and Applications in Biomedicine, Larnaca, Cyprus, November 5-7.

[31] Fiedler, G., Papaioannou, G., Mitrogiannis, C. and Nianios, G. (2009). "Development of a new Bed System With Improved Decubitus Prophylaxis For Bed-Ridden Patients". Proceedings of the 9th International Conference on Information Technology and Applications in Biomedicine, Larnaca, Cyprus, November 5-7.

[32] Papaioannou, G., Mitrogiannis, C., Nianios, G. and Fiedler, G. (2008). "The use of Dynamic Biplane Roentgen Stereophotogrammetric Analysis (DRSA) as a new diagnostic paradigm in orthopedics". Proceedings of the Fifth International Conference on Health Care Systems, Milwaukee, WI, October 13-15.

[33] Papaioannou, G., Fiedler, G., Nianios, G. and Mitrogiannis, C. (2008). "Integration of a series of wound diagnosis, prevention and treatment devices into an expert system for skin wound management". Proceedings of the Fifth International Conference on Health Care Systems, Doubletree Milwaukee City Center, Milwaukee, WI, October 13-15.

[34] Mitrogiannis, C., Papaioannou, G., Fiedler, G. and Nianios, G. (2008). "A new tracking technique for assessment of above-knee amputee socket-stump kinematics from high speed-high resolution dynamic radiography data". Proceedings of the Fifth International Conference on Health Care Systems, Doubletree Milwaukee City Center, Milwaukee, WI, October 13-15.

[35] Fiedler, G., Papaioannou, G., Mitrogiannis, C. and Nianios, G. (2008). "Control of variable pneumatic pressure in an anti-decubitus seat cushion". Proceedings of the Fifth International Conference on Health Care Systems, Doubletree Milwaukee City Center, Milwaukee, WI, October 13-15.

[36] Papaioannou, G., Fiedler, G., Nianios, G. and Mitrogiannis, C. (2008). "Using a direct digital radiography CCD imaging sensor in place of image intensifiers in human joint imaging." Proceedings of the 54th Annual ORS Meeting, Moscone W Convention Center San Francisco, CA, 2, pp. 145-156, March 2-5.

[37] Papaioannou, G., Bottum, M., and Fiedler, G. (2007). “Menisci Displacement under Joint Load”. Paper presented at the XXI Congress of International Society of Biomechanics, Taipei, Taiwan, July 1 – 5