Evaluation of Dynamic Prosthetic Alignment Techniques for Individuals with Transtibial Amputation

by

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Abstract

Although dynamic prosthetic alignment is an important process for the rehabilitation of transtibial amputees, such alignment technique is subjective and inconsistent. Using biomechanical variables and questionnaire assessments, this study compared an instrument-assisted dynamic alignment technique using the Compas™ system and conventional alignment techniques on nine adults with unilateral transtibial amputation. A focus group discussion was conducted with six prosthetists to understand clinical practice of dynamic alignment and their perception of the Compas™ system. Results found that Compas™ produced more anterior weight line displacement and greater varus moment on the prosthesis than conventional alignment techniques. Alignment changes did not affect pelvic acceleration, and the instrument-assisted alignment technique produced certain biomechanical changes but not necessarily better alignments. Although the current version of the Compas™ system is not clinically feasible, it can be used as a teaching/justification tool. Further investigation with larger sample size and ankle alignment or moment measures is needed.

Acknowledgments

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Chapter 1

Introduction and Motivation

The conventional prosthetic alignment is performed by prosthetists subjectively through an iterative process. As evidence-based practice is encouraged and increased in clinical settings, the need for a quantitative measure has become more pertinent to help objectively assess the outcomes of alignment techniques. The Compas™ system is a prosthesis alignment technology that provides alignment recommendations based on kinetic data. Its accuracy and validity, however, have not been clinically evaluated. Research questions for this project will help address this gap by comparing the biomechanics and functional outcomes between conventional and instrument-assisted dynamic alignment techniques. The outcomes from this study are important not only to demonstrate how alignment technique can best aid prosthetists in properly fitting and aligning a transtibial prosthesis to an individual, but also for the development of a clinically objective and repeatable alignment protocol. In a broader scope, it is expected that the results can shed light on what is needed in future endeavors to continue improving prosthetic alignment techniques. This will allow individuals living with amputation to benefit from a simple and reliable prosthetic alignment technique adapted to current clinical practice in the field of prosthetics.

Chapter 2

Background and Literature Review

1. Incidence and Prevalence of Extremity Amputations

Approximately 1.7 million people in the United States, or almost six in every 1,000 individuals, are currently living with upper and lower limb loss (Kathryn *et al*. 2008). Roughly, 185,000 amputation-related hospital discharges occur in the United States each year (Amputation, 2008). About 86% of these are lower limb amputations (Saunders, 2003). The lower limb amputations are distributed into five level-groups: foot exclusive of toes, transtibial, through-knee, transfemoral, and through-hip (Ebskov, 1992). According to the United States' National Health Interview Survey, there were 42,000 transtibial amputations performed in 1996, accounted for 50% of the total lower limb amputations (Torres, 1994 and Saunders, 2003). The main causes for transtibial amputations are due to tumors, congenital reasons, traumas, or vascular diseases. According to statistics collected by the Canadian Association of Wound Care, vascular diseases such as diabetes are the leading cause. People with diabetes often suffer from poor blood circulation and sensory nerve problems in the foot. These conditions eventually develop into non-healing foot ulcers requiring transtibial amputation (O'Carroll *et al*, 2008, Gailey, 2010, and Amputation, 2008).

2. Amputee Rehabilitation

Amputation rehabilitation for transtibial amputees plays a critical role in helping them regain functional locomotion, achieve independent life styles and return into previous social environment (Burger, 1997). A typical amputee rehabilitation process involves amputation surgery, physiotherapy, the provision of prostheses, as well as gait training (Esquenazi, 2004).

For any amputee to acquire a new prosthesis, multiple clinical visits are required to complete the process. Clinical visits include casting, fabrication and fitting of the socket, as well as alignment and acclimatization of the prosthesis. A transtibial prosthesis usually consists of a custom-fitting socket, a suspension mechanism, a pylon, and a prosthetic foot. The socket is made according to the topographical shape and biomechanical characteristics of the amputee's residual limb. The types of socket suspension and prosthetic foot are prescribed based on the functional needs of the individual amputees, and can maximize the allowable range of motion (Esquenazi, 2004). The suspension mechanism can be a simple calf sleeve or a more sophisticated locking pin. The prosthetic foot can be a standard solid-ankle-cushion-heel (SACH) foot with a rigid ankle or an energy-storing flex foot with a more flexible ankle (Torburn *et al*, 1990 and Klodd, 2010). The success of the provision of a transtibial prosthesis involves both the socket fitting and the prosthetic alignment. There is a substantial need to recognize the importance of an adequate prosthetic alignment, a factor which significantly affects the quality of life of transtibial amputees (O'Neill, 2008).

3. Prosthetic Alignments

In general, prosthetic alignment of a transtibial prosthesis is performed following the spatial three-dimensional (3D) orientation of the prosthetic components with respect to one another. For a transfemoral prosthesis this includes aligning the foot, knee joint and socket. For a transtibial prosthesis, however, the process is simpler and concerned with only the orientation of the socket with respect to the prosthetic foot. Alignment is performed in the three orthogonal planes of the Cartesian system commonly referred to as the anterior/posterior (AP), medial/lateral (ML), and transverse (horizontal) planes, as shown in Figure 1.

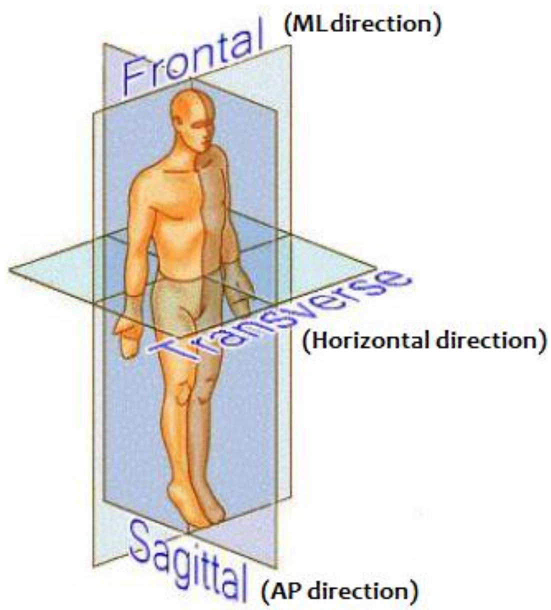

Figure 1: Cartesian orthogonal system

The process of aligning a prosthesis typically involves three stages, referred to as bench alignment, static alignment and dynamic alignment, as shown in Figure 2 (Chow *et al*, 2006).

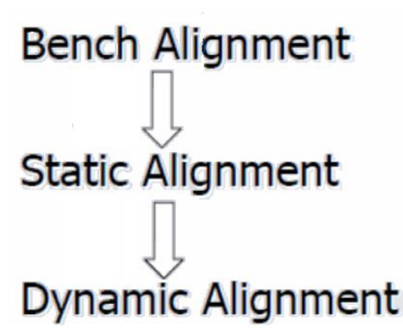

Figure 2: Alignment processes flow

At a clinical fitting of a transtibial prosthesis, both static and dynamic alignments usually involve either a tilt (rotation) or a shift (translation) of the socket or the prosthetic foot in the AP or ML directions. Figure 3 illustrates an alignment change example. In the AP direction, a posterior socket tilt of 5° can correct a rotational misalignment, or a posterior socket shift of 38 mm can correct a translation with respect to the prosthetic foot. Similarly, a lateral translational misalignment of 13 mm can be corrected by shifting the socket medially, or a rotation of 5° can be corrected by tilting the socket in the medial direction. Two additional adjustable parameters involved are the height of the socket and the orientation of the prosthetic foot in the transverse plane with respect to the line of progression, which represents the direction of motion (Zahedi *et al*. 1986).

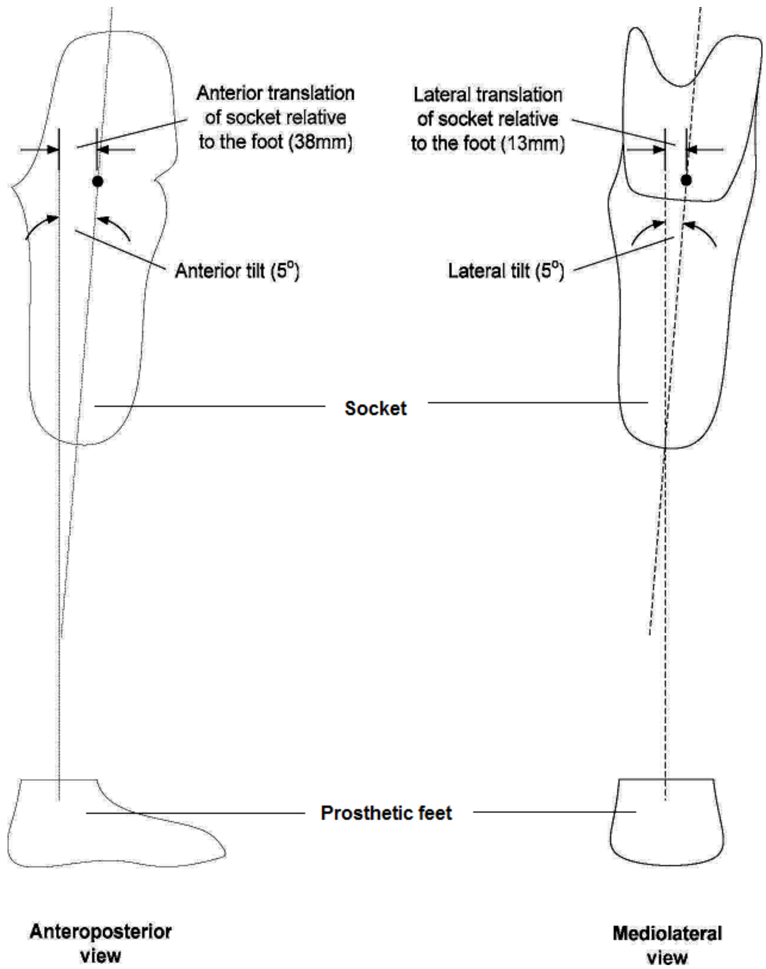

Figure 3: Example of alignment change of a transtibial prosthesis (Chow *et al*. 2006)

The following subsections will describe each alignment process and examine the current clinical practice for each.

3.1 Bench alignment

A bench alignment provides an initial assessment on the fabrication of the prosthesis and is typically performed by a prosthetic technician fitting the prosthesis onto the individual. It is done often on a mechanical jig to ensure that the socket and all prescribed components are aligned according to specific manufacture guidelines (Chow *et al*. 2006 and Neumann 2009), as shown in Figure 4.

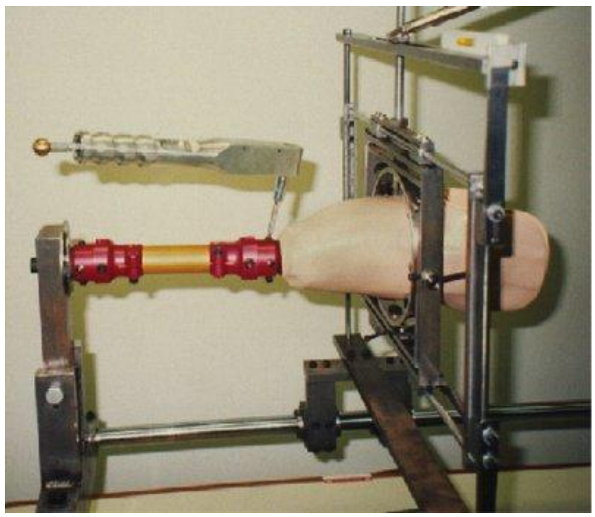

Figure 4: Bench alignment of prosthetic components on a mechanical jig (Sin, 2001)

3.2 Static alignment

Static alignment is performed once an amputee is wearing the prosthesis while standing. Stance stability is achieved with balanced foot leverage and equal foot contact during standing. Prosthetists observe the amputees' standing posture to determine if they are off balance. For example, the amputee is working hard not to fall backwards, the foot may be too plantarflexed or the socket too posteriorly titled. Prosthetists also observe if the pelvis is level in the frontal plane and adjust the length of the prosthesis as needed. In some cases, prosthetists have access to instruments such as the Laser Assisted Static Alignment Reference system (LASAR), which is intended to aid the statistic alignment process by quantifying the standing balance of the amputee in terms of variables such as the centre of pressure (COP) or the weight line (Blumentritt *et al*. 1997 and 1999). This instrument is described in detail in Chapter 4, Section 4.1.

Although static alignment sets a reference position of various prosthetic component parts under stable conditions, it does not give any prediction of the person's gait characteristics during locomotion. This can be achieved through dynamic alignment.

3.3 Dynamic alignment

Dynamic alignment is performed on the amputee's prosthesis during locomotion. A variety of gait characteristics are examined through both the prosthetists' and physical therapists' observation of the amputees' gait as well as the amputees' feedback. Some common indicators of dynamic misalignment are presented in detail in Section 4.2 of this chapter. The aim is to meet the amputees' biomechanical needs and produce a safe and effective gait pattern by adjusting and offsetting the various prosthetic components from static alignment position without compromising standing stability. Apart from achieving a correct and effective gait pattern, dynamic alignment also aims to reduce sensational discomfort and energy expenditure during walking (Schmalz, 2002), and to improve cosmetic appearance ("Transtibial", 2009). For these reasons, dynamic alignment appears to be the most imperative alignment stage, since it is the final step of the alignment process and determines the final position of the prosthetic components. It affects not only the amputees' locomotion but also their static posture. For this reason, this study focused on dynamic alignment.

When it comes to evaluating this alignment process, several studies have explored techniques to aid prosthetists in achieving more effective alignments. In 1986, Mizrahi *et al* conducted a study to assess successful fitting through a combination of gait analysis, a 10-meter walk test and camera recordings. This study found that alignment decisions were based on a combination of factors, including the participants' preferences and the prosthetists' subjective judgments; therefore, a wide range of alignment variations were obtained. Subsequently, a neural network aided system was developed to acquire force/moment data and to recognize patterns of misalignment automatically (Reed *et al*. 1995). However, since the device was tested on only one subject, its outcomes were susceptible to subject-dependency and the need of prolonged training. A decade later, Geil *et al*. (2004) examined a device called planar pedoarography, where the centre of pressure was traced from foot pressure measured by an in-shoe pressure sensor. They concluded that foot pressure distribution exhibited significant changes with alignment modifications and that good alignment changes could increase prosthesis support during gait if given sufficient adaptation time (*e.g.* seven to ten steps minimal). Nonetheless, this device was very expensive and difficult to set-up for measuring the direction of locomotion, the starting point, and the number of steps per trial. In short, there exists a need for a dynamic alignment instrument that is less expensive and can produce more objective and consistent alignment results.

More recently, Neumann (2009) conducted a thorough review of transtibial prosthetic alignment studies done over 35 years (from 1973 to 2008) and found 34 articles with 43 outcome measures. Neumann evaluated each outcome measure and gave a confidence level to each. Almost all studies were done with experienced amputees (over 1 year after amputation) in a controlled environment, which means that the range of acceptable alignments would likely decrease if other walking surfaces were considered. Only three out of the 34 studies recruited more than ten participants, and no indication of randomizing trials to avoid learning effects was reported. The author of this review accorded only moderate confidence in most of the results from these studies. The mechanism of the contralateral knee (*e.g.* maximum knee flexion) was identified as a potential indicator of misalignment; however, this parameter cannot be easily measured clinically. More research is needed to identify new kinetic and kinematic variables as good indicators of misalignment.

4. Effects of a Prosthetic Misalignment

4.1 Physiological and biomechanical effects

Dynamic alignment of a transtibial prosthesis is one of the key factors to ensure effective amputee locomotion. Prosthetic misalignment leads to asymmetric gait and uneven weight-bearing between sound limb and prosthesis. Typically amputees already have slower gait compared to the healthy population, this lack of stability due to misalignment may lead to even slower cadence, and hence amputee's loss of confidence to use the prosthesis (Ford *et al*. 1995). As a result, rehabilitation outcomes are compromised, restricting an individual's ability to perform activities of daily living and also adding an increased burden to their care-givers.

If a prosthesis is misaligned, it also adversely results in skin abrasion and uneven forces acting on the residual limb within the socket, which could lead to discomfort, pain, and even more serious skin and joint trauma such as infection and musculoskeletal complications (Zahedi *et al*, 1986). Moreover, individuals are more likely to under-utilize the prosthesis if it is misaligned, consequently placing more weight on their sound limb, or causing them to entirely abandon the use of their prosthesis (Pinzur, 1995 and Schmaltz *et al*, 2002). Even when the amputee is able to tolerate a misaligned prosthesis, the abnormally large forces acting on the residual limb can lead to long-term negative effects on the underlying tissues and ligaments (Pearson *et al*. 1973). Having good prosthetic fit and proper alignment has been shown to decrease the overloading of the sound limb, thereby, avoiding potential degenerative changes and complications such as osteoarthritis (Grumillier *et al*. 2008, Beyeart *et al*. 2008, and Gailey *et al*. 2008).

4.2 Gait deviation effects

The typical gait cycle of a healthy person is depicted in Figure 5. The cycle begins at heel-strike and ends at the subsequent heel-strike of the same limb. A gait cycle is composed of two parts: a) stance phase and b) swing phase. The stance phase is the period when the limb touches the ground and supports the body. The swing phase is the latter half of the gait cycle where the limb is in the air not bearing any weight (Winter, 1990 and Fang *et al*. 2009). A gait deviation, defined as any walking pattern that departures from a smooth and natural gait, may be expected in the case of a prosthetic misalignment.

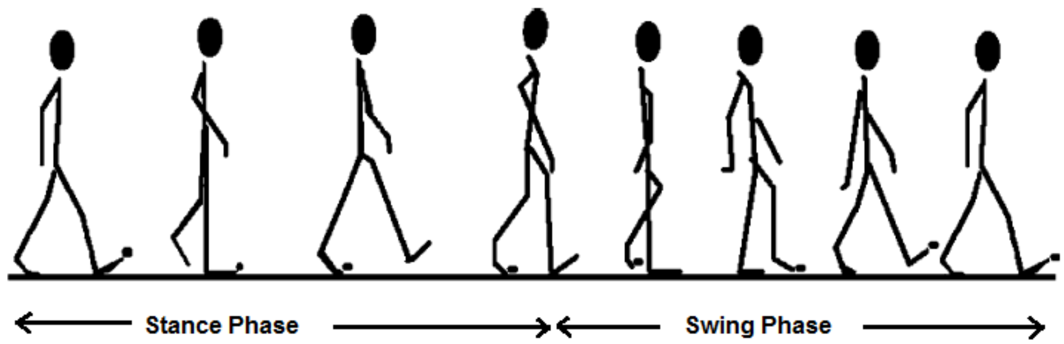

Figure 5: A typical gait cycle (Plotnik *et al*, 2006)

Prosthetic gait is complex. Reasons leading to transtibial gait deviations can be caused by intrinsic or extrinsic factors. Intrinsic factors are the individuals' medical or psychological states and/or their locomotor adaptations. Extrinsic factors may include socket fit, comfort, prosthetic alignment settings and/or environmental conditions. Transtibial alignment settings refer mainly to the positions of the socket in relation to the prosthetic foot. Some examples of transtibial prosthesis misalignments and the dominant gait deviation that each could cause are presented in Table 1 (Mensch, 1986 and Grumillier, 2008).

Table 1: Transtibial prosthetic settings and possible resulted gait deviations

Transtibial prosthetic settings	**Dominant gait deviation**	**Compensatory postural adaptations**
Socket placed too anterior in relation to the foot, or foot set too posterior - in excessive dorsiflexion.	Gait is accelerated during stance phase, causing excessive or early knee flexion from heel-strike to midstance or prior to toe-off.	Like walking downhill, greater heel strike impact causing pelvic drop and shoulder drop on the prosthetic side to recover balance.
Socket placed too posterior in relation to the foot, or foot set too anterior - in excessive plantarflexion.	Gait is slowed at the end of stance phase, causing insufficient or delayed knee flexion from heel-strike to midstance and from midstance to toe-off.	Like walking uphill, greater forefoot push required causing hip abduction on the prosthetic side and vaulting on the sound side to reduced spinal rotation.
Socket placed too far lateral in relation to the foot, or foot set too far medially - in excessive eversion	Excessive varus or medial moment.	Pelvic drop or shift laterally on the sound side to centre the weight over the socket.
Socket placed too far medially in relation to the foot, or foot set too far laterally - in excessive inversion	Excessive valgus or lateral moment and knock knees effect.	Residual limb drawn toward midline or pelvic bend laterally toward the prosthetic side to avoid discomfort.

5. Limitations of Conventional Alignment Techniques

When prosthetists try to produce an optimal static or dynamic alignment, they strive to ensure the following aspects: equilibrium of opposite torques on the residual limb (Mensch, 1986), equal limb length, level hip and even weight bearing between sound limb and prosthesis (Neumann 2009). Studies have shown that conventional practice produces a number of acceptable alignments but not necessarily the best outcome (Zahedi *et al*. 1986 and Geil 2002). There are many amputee-related factors that indirectly affect the outcomes of prosthetic alignment such as level of amputation, residual limb strength, joint range of motion and coordination, as well as any preexisting postural and habitual problems of the amputee (Mensch, 1986). As individuals' tolerance of pain and weight-bearing ability vary, so do their acceptable range for alignments. Thus the definition of an "optimal" alignment becomes relative to each person, adding variability to alignment outcomes.

A conventional alignment technique requires the iterative interaction between the prosthetists and amputees based on their visual judgement and verbal feedback. Prosthetists largely rely on their own experiences and the feedback from the amputees (Blumentritt *et al*., 1997 and 1999). However, in the case of a misalignment, pressure differences and discomfort may not be felt immediately; in such cases, feedback from the amputee may be unreliable (Saleh, 1988).

Conclusions were drawn by Ford *et al*. (1995) stating that no specific and systematic observational methods were used by prosthetists for gait analysis, so exchange of information between prosthetists and amputees is subject to inconsistency. Each alignment outcome is different and there is no systematic way of recording the exact position of prosthetic components in relation to one another. Therefore, if prosthetists want to reproduce particular alignments they can only do so based on what they remember. Thus, differences in training, clinical practices and orders of performance would make clinical repeatability a challenge between prosthetists, and even between alignments performed by the same prosthetist on separate occasions (Zahedi *et al*., 1986).

As a result, current alignment techniques are often subjective, time-consuming, and inconsistent if they are performed by prosthetists without specialized tools. On account of these factors, there exists the need to evaluate more objective alignment instruments and more quantifiable biomechanical parameters for assessing a dynamic alignment.

6. Prosthetic Outcome Measures for Dynamic Alignment

Various factors can be utilized to assess dynamic alignment, such as knee joint flexion (Neumann, 2009), socket interface pressure (Geil *et al*, 2004) and symmetry of limb loading and movement during gait (Chow *et al*, 2006 and "Transtibial", 2009). A dynamic alignment of a transtibial prosthesis often involves gait analysis (Velzen *et al*, 2005), which includes assessing measurable biomechanical parameters during the gait cycle. Some of these parameters from gait analysis have been used in literature as outcome measures to assess alignment, such as: the vertical ground reaction force (Chow *et al*, 2006), the weight line projection displacement to knee centre (Blumentritt *et al*, 1997 and 1999), knee and ankle moment of the prosthesis and of the sound limb (Reed *et al*. 1995 and Torburn *et al*, 1990), spatiotemporal parameters such as stance duration, stride length, speed, stance and swing phase duration (Zijlstra, 2003), foot angle with respect to line of progression and inclination (Klodd, 2010), and pelvic acceleration (Tura *et al*, 2010 and Menz *et al*, 2003).

Several articles published between 1998 and 2010 examined the validity of pelvic acceleration as a measure of gait stability between amputee groups and normal groups. Lumbar 3 (L3) was recognized to be the "global measure of walking balance" (Kavanagh *et al*. 2008). The root-mean-square (RMS) value of the L3 accelerations was a statistical measure used to assess the magnitude of varying quantities of pelvic sway and was identified as the parameter closely associated with walking speed and acceleration variability (Menz *et al*. 2003). Lower RMS values were proportional to a decrease in pelvic sway, which could be minimized as the individuals selected a comfortable walking speed.

In addition, qualitative assessments, such as questionnaires (Condie *et al,* 2006) and observations of gait through video camera recording (Mizrahi *et al,* 1986 and Velzen *et al*, 2005), were used to provide additional measures to help better understand amputees' subjective feedback in more organized manner and evaluate the prosthetic rehabilitation outcomes in more systematic ways. These measures have been used in the field of prosthetics for decades, and their validity and reliability have been internationally accepted (Gauthier-Gagnon, 2006 and Boone, 2009).

7. Transtibial Prosthesis Model

7.1 Locations for alignment change

It is important to note that when prosthetists make alignment adjustments, screws could be turned at two locations along the vertical alignment axis: the below-socket or the ankle level. They would either perform a rotation/tilt by adjusting screws at only one location as shown in Figure 6 (b), or a translation/shift by adjusting screws at both locations as shown in Figure 6 (c), where foot is always flat on the ground.

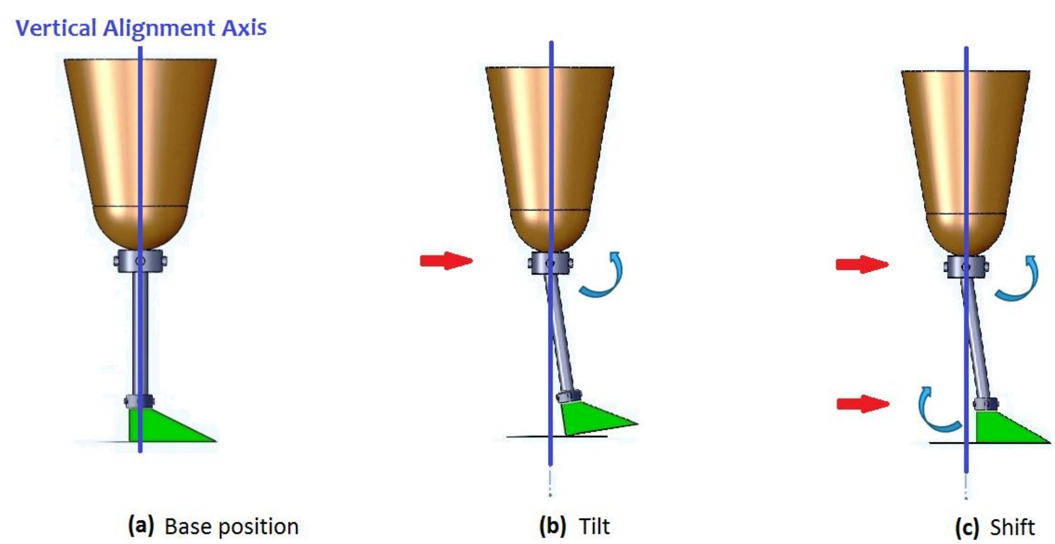

Figure 6: Screw adjusting locations for tilt or shift alignment change

(a) Base position of a neutral alignment; (b) A tilt: one angular change done at the below-socket location; (c) A shift: one angular change done at the below-socket location and an opposite angular change done at the ankle location. The foot is always flat on the ground.

8. Summary

Dynamic prosthetic alignment is an essential process for gait rehabilitation of individuals with transtibial amputations. Conventionally, a dynamic prosthetic alignment is performed by prosthetists and is primarily based on the prosthetists' experiences and subjective assessments of the amputees' gait patterns and feedback. Scarce instruments exist today to quantify and improve this alignment process. Instruments such as the Compas™ system could provide real-time biomechanical measures and potentially serve as an objective aiding tool for prosthetists conducting the dynamic alignment of a transtibial prosthesis. To date, no studies have assessed the benefits or performance outcomes of the Compas™ system. Would the Compas™ system produce sufficiently better alignment results compared to the conventional technique used by prosthetists? This is the primary focus of this research project.

Chapter 3

Objectives and Research Questions

The main goal of the study was to evaluate an instrument-assisted alignment technique using the Compas™ system by comparing it to the conventional alignment techniques. Briefly, the types of comparisons used to achieve this goal included the fundamental biomechanical changes (*i.e*. static weight line displacement to the anatomical knee centre and moments of the prosthesis during locomotion), gross changes in gait (*i.e*. the root-mean-squared values of pelvic acceleration and walking speed) and prosthetists' and amputees' perceptions (*i.e*. questionnaires and focus group discussions).

The two dynamic alignment techniques compared in this study are defined as follows:

1. **Conventional dynamic alignment technique** – the alignment of a transtibial prosthesis done by prosthetists based on their expertise and subjective observation of the amputees' gait and verbal feedback.

2. **Instrument-assisted dynamic alignment technique** – the alignment of the same prosthesis done by prosthetists with the help of real-time moment information provided by the Compas™ system.

1. Primary Research Question

Objective 1: The two prosthetic dynamic alignment techniques described above were evaluated and compared according to how they optimize biomechanics, mobility, and amputee satisfaction. Data from both biomechanical parameters and questionnaires was compared to address this primary research question: Does an instrument-assisted dynamic alignment technique improve amputee's locomotion outcomes (*i.e.* better mobility function, gait characteristics, and amputee satisfaction) compared to the conventional alignment technique?

2. Secondary Research Questions

Objective 2: Each biomechanical parameter was compared to alignment changes between techniques to address the second research question: How does an alignment change affect the biomechanical and gait characteristics of a transtibial amputee?

Objective 3: With a subset of participants, a specific prosthetic alignment setup was maintained over a period of one week and re-assessed upon returning to the clinic to address the third research question: Does an amputee become acclimatized to the same alignment setup over time?

3. Tertiary Research Questions

Objective 4: The focus group discussion was designed to understand clinical perspectives on dynamic alignment and the instrument-assisted technique. Specifically, it was conducted to address three main goals:

1. To qualitatively assess what defines an "optimal" alignment and how to achieve it;
2. To understand how prosthetists perform dynamic alignment clinically and their concerns and perspectives on the alignment process in general; and
3. To hear prosthetists' perceptions of the Compas™ system and gather a list of limitations and additional features for the technology that could shape future directions of transtibial alignment research.

Chapter 4

Methods

1. Clinical Setting

This study required involvement of a multi-disciplinary team including engineers, certified prosthetists, and a physical therapist. The research methods involved two clinical assessments with each transtibial amputee and his/her prosthetist that performed the alignments, as well as a focus group discussion with all prosthetists at the Sunnybrook Centre of Independent Living (SCIL). All clinical assessments were conducted indoors.

2. Targeted Population and Recruitment

The participant inclusion criteria were developed according to clinical advice given by the prosthetists, taking into account a number of factors: the availability of amputee patients, their mobility function, and the SCIL prosthetists' clinical schedule. Upper age limit and minimum years of amputation were not included in the criteria because of the challenges in getting the suitable participants.

Inclusion criteria:

Participants

1) Had an unilateral transtibial amputation;
2) Were at least 18 years old;
3) Lived in the community and were able to walk without mobility aids;

4) Were accustomed to wearing a transtibial prosthesis since amputation. New amputees were not considered because their unstable conditions (*i.e.* shrinking residual limb size and shape after an amputation, emotional unsteadiness, and participants being un-customized to wearing a definitive prosthesis, *etc*.) which would confound data.

Upon ethical approval, certified prosthetists at SCIL assisted with the recruitment of participants in the study. During the recruitment process, eligible participants were identified by a certified prosthetist and/or a physical therapist using clinical records from SCIL. Among those meeting the inclusion criteria, patients who needed new prostheses made and had finished socket fittings were invited to participate in this study. If the patient agreed to participate in the study, verbal permission was obtained; the researcher explained the study in detail and answered any questions that the participant had. If the participant was still interested, clinical visits were scheduled and a formal consent form was provided on the day of the first visit.

3. Experimental Protocol

Each participant was asked to come for two clinic visits, each being about two to three hours long in duration. For each visit, participants were asked to carry out a list of tests (Table 2) after each alignment setup performed by their own prosthetist.
For the following chapters, the terminology of the two alignment techniques is simplified to:

1. Conventional (for Conventional dynamic alignment technique);
2. Compas (for Instrument-assisted dynamic alignment technique).

Table 2: Tests during clinical visits and corresponding outcome measures

Tests for each alignment techniques	Instruments for outcome measures	Parameters measured or calculated	Specific variables
Static posture measure	LASAR*	Weight line displacement (mm)	AP limb (single foot) AP total (double feet) ML limb (single foot)
Standard 10-meter walk	Compas™	Screw turns at below-socket level (1 screw turn = 4.55° socket tilt)	Alignment change (degrees)
		Below-socket peak moment of the prosthetic limb (Nm)	AP forefoot AP heel ML medial/varus ML lateral/valgus
	Shimmer™	Pelvic acceleration RMS (g)	Vertical AP ML
		Cadence (steps/min)	Self-selected speed Fast speed
Questionnaire	Given to both participants and prosthetists	Alignment technique rating	A score of 1 or 0

**LASAR: Laser Assisted Static Alignment Reference*

3.1 Visit 1

Before participants arrived at the clinic, prosthetists prepared the new prosthesis such that it was bench aligned and the smart pyramid of the Compas™ system was incorporated below the socket of the new prosthesis. The researcher ensured that the Compas™ adaptor and the Shimmer accelerometer's batteries were fully charged.

At the beginning of Visit 1, the participant's profile/information questionnaire and an LCI evaluation were completed (Appendices A1 and B). Then the Compas™ adaptor was plugged into the pyramid of the new prosthesis, and the following steps were followed:

1. The prosthesis was aligned using the Conventional alignment technique;
2. The participant was given five minutes to walk around and get familiarized with the new prosthesis;

3. Data collection tests were performed (Table 2, column 1):
    a. Static weight lines were measured using LASAR
    b. 10-meter walk tests were conducted using self-selected and fast speeds (two trials each):
        i. Below-socket moment recording using Compas™
        ii. L3 pelvic acceleration recording using Shimmer™
4. Data collection forms were completed during the process (Appendix C);
5. Both participant and prosthetist rated the alignment technique (Appendices A2 and A3), and comments were documented;
6. The prosthesis was aligned using the Compas technique. Data collection tests were repeated (steps #2 - #5) for the second technique, and specific alignment changes at below-socket location were recorded in units of screw turns and later converted to degrees;
7. For some participants (if the participant's condition and ability permitted), the prosthesis was misaligned by one or two screw turns in the AP direction. Steps #2 - #5 were repeated.

    A study by Fang et al, 2007, showed that muscle forces and external moment on the knee were increased significantly at ± 6° of misalignment in the AP direction. Based on experimental measure, one screw turn was equivalent to 4.55° of socket tilt. Therefore this misalignment setup of ±1 to ±2 screw turns was added in the AP direction as a reliability check to see sensitivity in the moment measures. However, because some participants' conditions did not allow them to tolerate such misalignment, it was not applied to all participants.

After all the assessments, the new prosthesis was realigned to the preferred alignment setup. The Compas™ adaptor was removed and the pyramid was replaced by a generic component without changing the alignment positions. The participant was asked to take the new prosthesis home for acclimation and return to SCIL after one week for Visit 2. The participant was reminded to wear shorts and the same shoes for the next visit.

3.2 Visit 2

The smart pyramid of the Compas™ system was incorporated below the socket of the new prosthesis when the participant arrived at the clinic. Then the Compas™ adaptor was plugged into the pyramid of the new prosthesis, and the following steps were followed:

1. Data collection tests were performed for the alignment setup the participant initially took home from Visit 1 (Table 2, column 1):
    a. Static weight lines were measured using LASAR
    b. 10-meter walk tests were conducted using self-selected and fast speeds (two trials each):
        i. Below-socket moment recording using Compas™
        ii. L3 pelvic acceleration recording using Shimmer™
2. Data collection forms were completed during the process (Appendix C);
3. Both participant and prosthetist rated the alignment technique (Appendices A2 and A3), and comments were documented;
4. The prosthesis was aligned using the other technique. Data collection tests were repeated for the second technique, and specific alignment changes at below-socket location were recorded.

At the end of Visit 2, the Compas™ adaptor was removed, the pyramid was replaced by a generic unit, and the new prosthesis was reset to the preferred alignment setup for the participant to take home.

4. Instruments

In this study, three tools were used during clinical testing to acquire variables as outcome measures, as listed in Table 2, column 2: the LASAR system, the Compas™

system, and the Shimmer™ tri-axial accelerometer. The Compas™ system was also used as part of the instrument-assisted alignment technique in aligning the prosthesis. Each instrument is discussed in detail in this section.

4.1 LASAR system

Currently, very few technologies exist commercially to evaluate static posture from an alignment. The Laser Assisted Static Alignment Reference system (LASAR), developed by Otto Bock (Minneapolis) in 2000, is a commercial system used in this study as an instrument for outcome measures. It consists of a weight-sensitive platform, a laser beam, and a display showing the person's weight and the position of the weight line with respect to the anatomical knee centre. Figure 7 shows the device platform.

Figure 7: The LASAR system

A laser beam projecting from the force platform onto the participant indicates the location of the weight line. When the participant is standing with both feet on the platform, it is called the total weight line. When only the prosthesis was placed on the platform and the sound foot was placed on a leveling plate beside, the laser beam represents the limb weight line (Willingham, *et al*. 2004 and Winter, 1990). The position of the anatomical knee centre is marked as the midpoint of the tibia in the AP and ML directions (Mensch, 1986). The horizontal distance of the weight line to the anatomical knee centre point was measured for each alignment setup. Based on validation studies by Blumentritt *et al* (1997, 1999), weight line displacement measures were taken in both

AP and ML directions (refer to Figure 1), then the results were compared to see if static position of the prosthesis was affected by the dynamic alignment techniques.

Weight line displacement measurements were taken for: AP limb weight line (AP limb), AP total weight line (AP total), and ML limb weight line (ML limb). Figure 8 illustrated each scenario and how to determine each respectively. According to Breakey (1998), the closer the weight line is to the anatomical knee centre point or the less the displacement, the more optimal the person's balance. The recommended alignment position should give an AP limb weight line approximately 15 mm anterior to the knee centre of the prosthesis for the most efficient transtibial gait (Blumentritt, 1999). The ML limb weight line is recommended to be about 10 mm lateral to the knee centre of the prosthesis to maintain a normal base support and allow more loading in the pressure-tolerant medial residual area, rather than the fibular head region (Seymour, 2002).

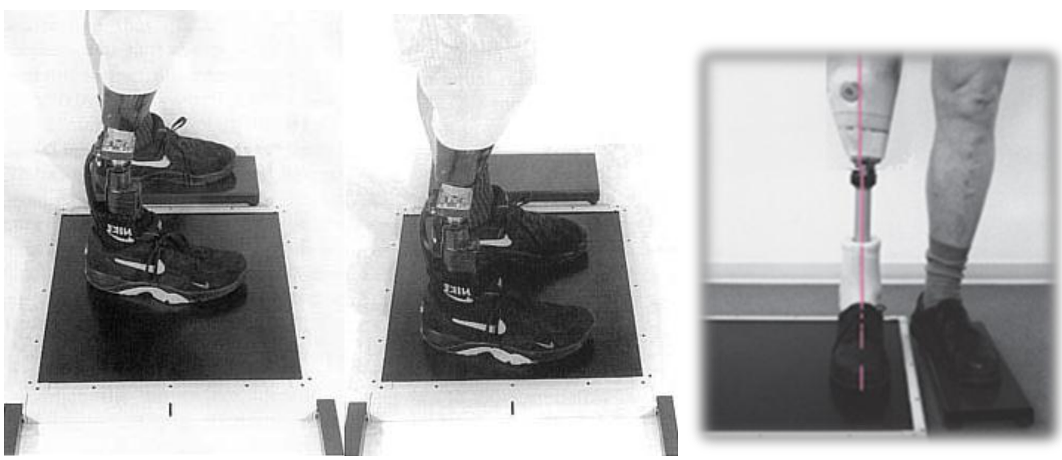

Figure 8: Determining AP limb weight line (left), AP total weight line (middle) and ML limb weight line displacement to knee centre (right) (Breakey, 1998)

4.2 Compas™ system

The Compas™ system was introduced in early 2009 as an innovative prosthetic alignment technology. In this study, it was used as an assistive tool in one of the dynamic alignment techniques and also as an instrument for acquiring below-socket moments on the prosthesis as one of the outcome measures. It consists of a smart pyramid with a built-in load cell measuring vertical forces as well as moments in the AP and ML planes, an adaptor for transmitting the data from the pyramid to the computer via a Bluetooth connection, and software displaying a graphical representation of real-time moment profiles as well as providing alignment analysis suggestions (Orthocare, 2009). The smart pyramid was fitted into participants' new prosthesis at the distal end of the socket in replacement of a generic pyramid (Figure 9).

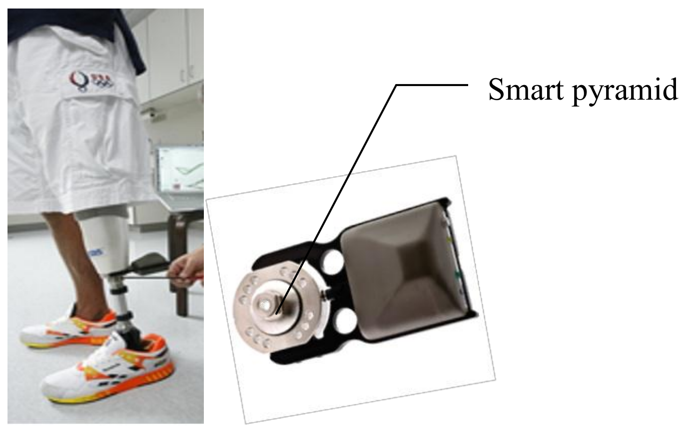

Figure 9: Compas™ system (Orthocare Innovations, 2009)

An example of the graphical moment profile plots is shown in Figure 10. For each alignment technique performed on a participant, two trials of the knee moment profiles of the prosthesis were recorded at 100 Hz through the Compas™ system for self-selected and fast speeds. Each gait trial records the moment profile of six complete gait cycles. Then these moment profiles were overlaid onto a single plot, averaged immediately after recording, and compared to a database of similar amputee profiles (shown as the green shaded region in Figure 10).

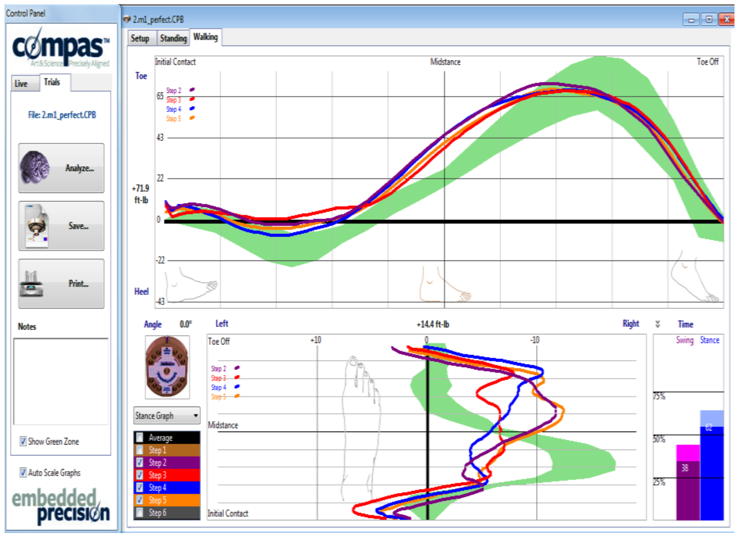

Figure 10: Compas™ system trial analysis plot

From the literature, the shape of the below-socket moment recorded by the Compas™ system is similar to the shape of the external moment or torque profile of the ankle (Klodd *et al*, 2010). Figure 11 is one example of such moment profile in the AP direction. The minimum peak represents the heel strike moment and occurs approximately at 25% stance phase, and the maximum peak corresponds to the toe-off or forefoot moment and occurs at about 80% stance phase.

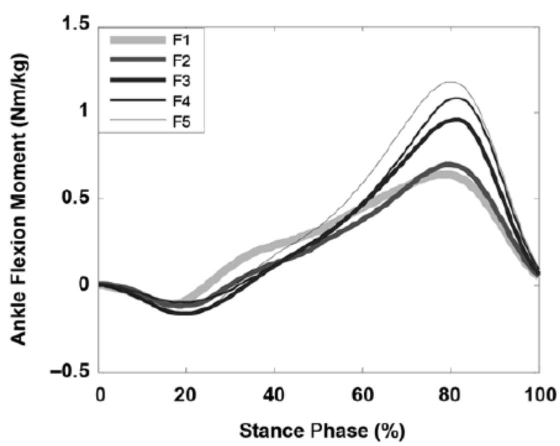

Figure 11: External ankle moments of the prosthetic limb of an unilateral transtibial prosthetic user from literature (Klodd *et al,* 2010)

The Compas™ system also provides suggestions to the prosthetist based on an algorithm that matches the amputee's moment profile to a database of "normal" moment profiles established by the researchers at Orthocare Innovations. An example of the alignment suggestions provided by the Compas™ system after each analysis is shown in Figure 12, given for both AP and ML directions. On the left is an outcome window given to a good or adequate alignment. Green check mark icons indicate where no further adjustment is needed for both directions. On the right is a suggestion window for a less adequate alignment. The source of the misalignment was described in terms of the relationship of the prosthetic foot relative to the socket. Recommendations are given as how to loosen or tighten the pyramid's screws in the AP and ML directions, so that alignment change was recorded in the number of screw turns at the below-socket location of the prosthesis.

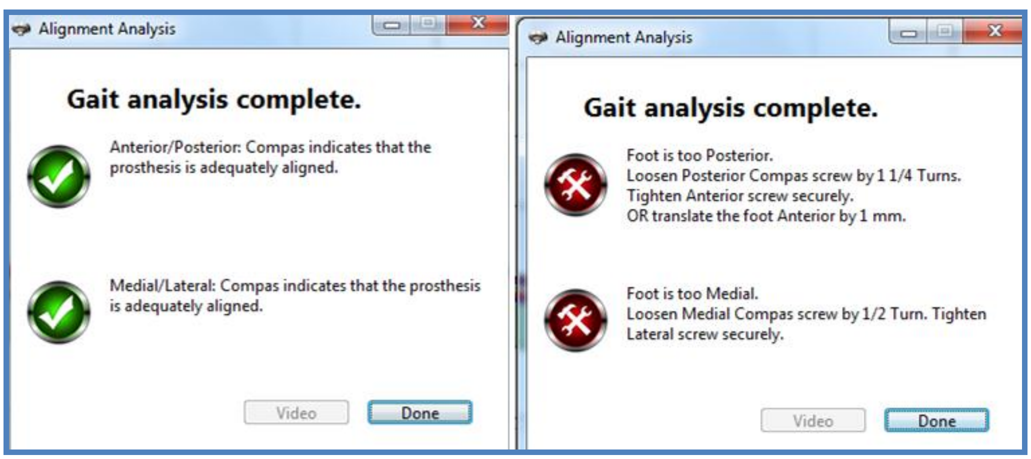

Figure 12: Compas™ system analysis suggestions

(left: good alignment; right: inadequate alignment)

To reiterate, in this study the Compas™ system was used not only to assist in performing the alignment for the instrument-assisted technique, but also to provide kinetic data as one of the outcome measures in terms of AP and ML lower-limb moments.

4.3 Shimmer™ tri-axial accelerometer

The Shimmer™ Tri-axial Accelerometer (Figure 13) was the instrument used to record pelvic accelerations. It consists of a power button to turn the device on/off and a light-emitting diode (LED) to reflect the device modes. It utilizes a wearable wireless sensor platform capable of high-speed data transfer via a Bluetooth connection (Shimmer, 2011). It is small in size (53 mm x 32 mm x 25 mm) and weighs about 22 grams with casing. The accelerometer has a built-in battery that could last for about 10 hours running data collection and is rechargeable with a base charger which can also update its firmware.

Figure 13: Shimmer™ accelerometer (Shimmer, 2011)

Literature suggested that the pelvic acceleration variation is a good indicator of misalignment, principally between-subject variation in pelvic sway during walking in the ML accelerations, because more force than normal is required to lift a misaligned prosthesis (Neumann, 2009 and Zijlstra, 2003). A number of studies comparing acceleration measured among Lumbar 3 (L3), Cervical 7 (C7), and head locations concluded that accelerations generated by walking were attenuated largely as the recording position became closer to the head (Moe-Nilssen *et al*. 2005 and Lamoth *et al*. 2010). In general, an amputee would take priority to stabilizing his/her head during walking; therefore, accelerations at the head are less affected by how a person walks. This intentional stabilization of the head maybe assisted by increasing acceleration at the pelvis, thus allowing L3 movement pattern to mimic more body sway. Acceleration at C7 is less sensitive to changes in walking stability compared to L3. As one would compromise the stability of the pelvis to stabilize the head, it is a general consent that acceleration measured at L3 would be used as "a global measure of walking balance" (Menz *et al*. 2003 and Moe-Nilssen. 1998).

The accelerometer was strapped to the back of the person at L3 during the 10-meter walk test and real-time acceleration data were recorded and transferred via Bluetooth to the computer after each trial. For each alignment technique, two trials of the L3 pelvic acceleration data was collected at self-selected and fast speeds at a sampling frequency of 100Hz from the Shimmer™ accelerometer. A range of ± 1.5g was chosen to ensure adequate sensitivity of the accelerometer sensor to capture the pelvic acceleration. Each sensor was calibrated according to the user manual (Shimmer, 2011) prior to clinical visits.

5. Alignment Changes and Expected Outcomes using Model

For easier illustration of different parameters with respect to alignment change, a biomechanical model (refer to Figure 14) was developed. The alignment changes depicted in this model were shifts of the prosthetic foot in relation to the socket. In fact, the alignment changes recorded in this study were either a foot shift (adjusting screws at both locations) or a foot tilt (adjusting screws at only below-socket location) with respect to the socket. For simplicity, they were referred to as an "alignment change" in the AP or ML direction. For illustration purpose of all alignment changes, the foot was always flat on the ground. The expected outcomes of each alignment change were based on the compensative mechanisms described in the literature (Mensch, 1986, Grumillier, 2008, and Perry, 1992).

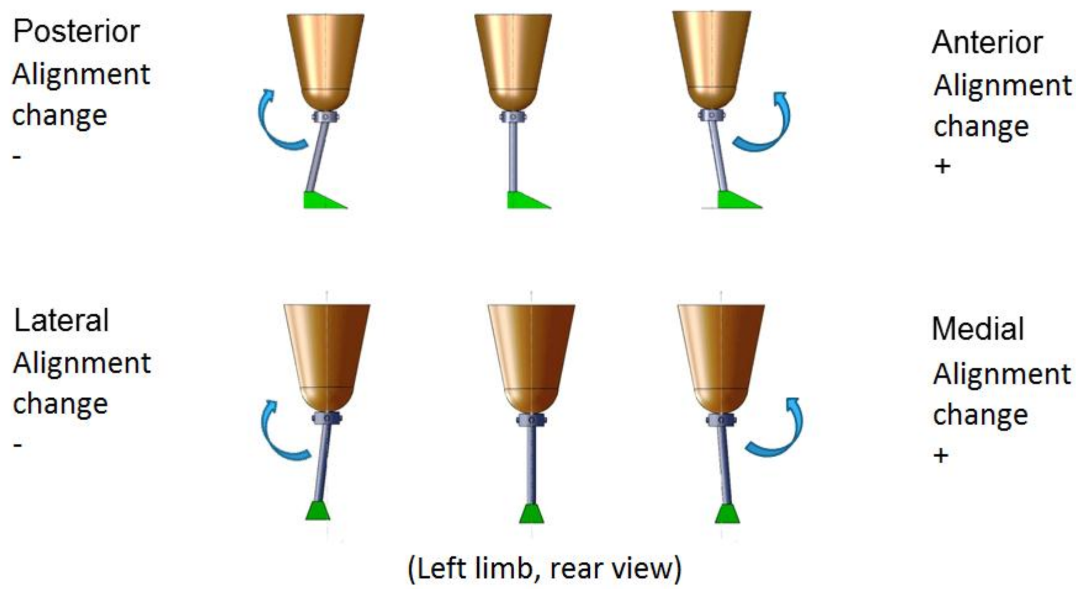

Figure 14: Biomechanical model of a transtibial prosthesis with alignment changes

In the AP direction, an anterior alignment change is defined as positive in the data and a posterior alignment change as negative. In the ML direction, through unifying the data to a left-prosthesis at the rear view, convention is defined such that a medial alignment change is positive and a lateral alignment change is negative. The expected direction of change of the outcome parameters was based on the compensative mechanisms described in the literature (Mensch, 1986, Grumillier, 2008, and Perry, 1992) and also confirmed clinically with prosthetists from SCIL.

5.1 Expected weight line displacement

In the AP direction, an anterior alignment change was expected to cause the AP weight line to shift anteriorly from the anatomical knee centre, whereas a posterior alignment change would cause the AP weight line to shift posteriorly, as depicted in the model (Figure 15). In this direction more variations are expected due to alignment changes because of more involvement of the knee and ankle muscles.

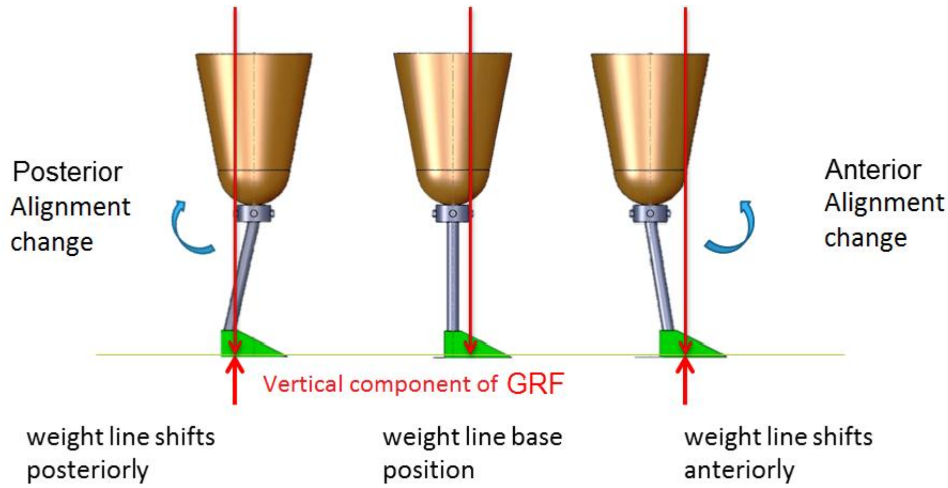

Figure 15: AP alignment change and expected weight line displacement

In the ML direction, alignment perturbations could be hidden by utilizing more hip muscles to maintain an upright posture. Small effects were still expected such that a medial alignment change would correspond to the weight line displacement shifting medially and vice versa laterally, as shown in the model (Figure 16).

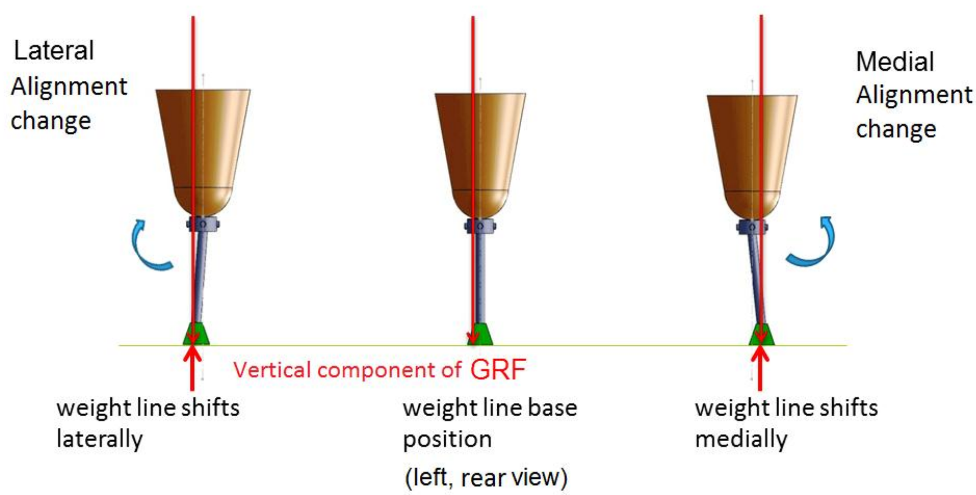

Figure 16: ML alignment change and expected weight line displacement

5.2 Expected peak moment change

In the AP direction, the model was developed based on possible alignment positions and corresponding gait deviations described in Table 1. Peak moment changes in the AP direction are harder to predict because knee muscles exert more control, so the body can fake the right gait posture to hide perturbations to a certain degree. This model (Figure 17) expects that:

- An anterior alignment change would lead to a greater forefoot moment. The amputees would feel as if they are walking uphill and would need to push over a greater toe moment;
- A posterior alignment change would put the foot back, like walking downhill, leading to accelerated gait during stance phase and greater heel strike impact, or larger heel moment.

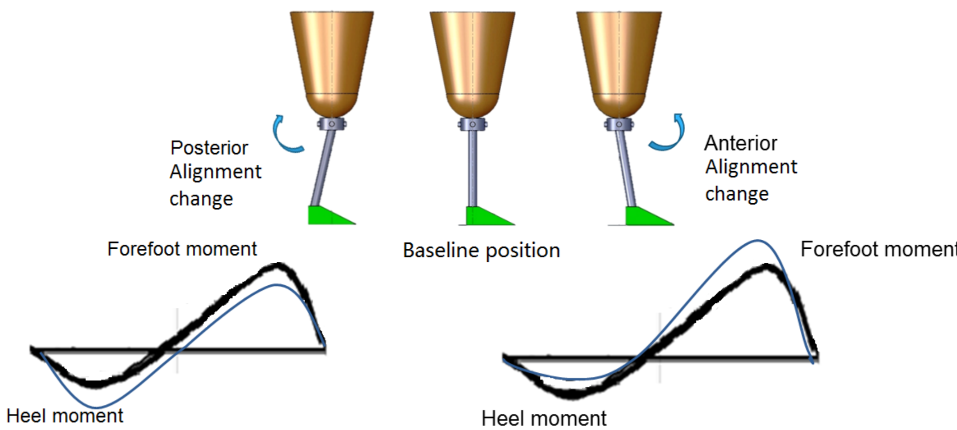

Figure 17: AP alignment change and expected peak moment change

In the ML direction, the peak valgus/lateral and varus/medial moment values were considered. In this direction, knee muscles have little control over gait posture, and thus a small alignment change would be expected to cause a larger shift in moment. According to the Compas™ system's User Guide (Orthocare, 2010):

- With a medial alignment change, if the foot is placed too far medial, it would create a second peak and increase varus moment;
- With a lateral alignment change, if the foot is positioned too far lateral, it would create a knock-knee effect, and the moment profile would shift more laterally (Figure 18).

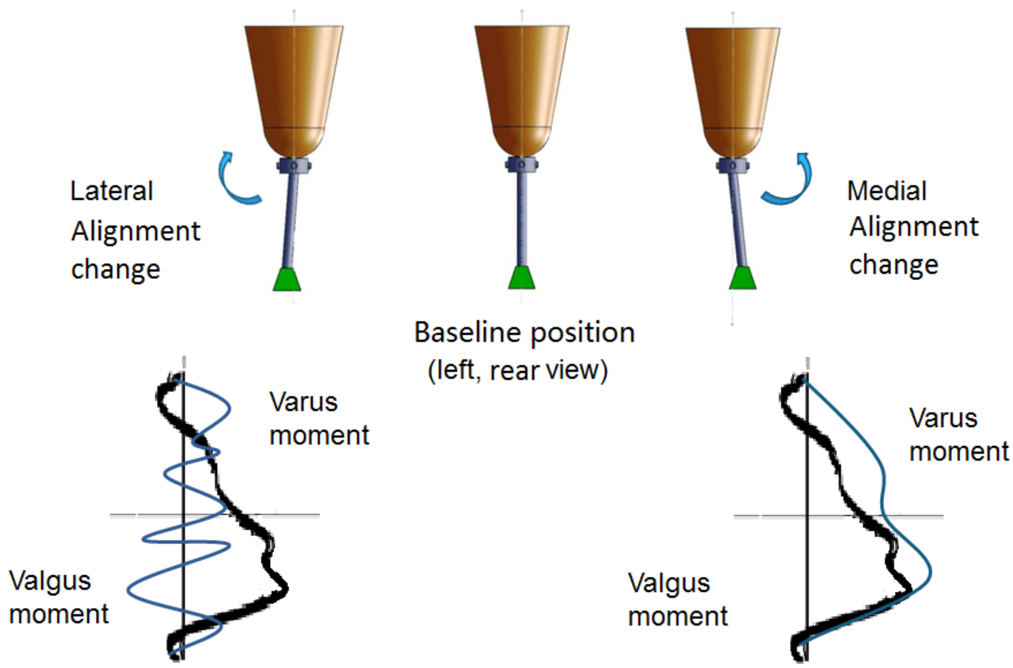

Figure 18: ML alignment change and expected peak moment change

6. Outcome Measures

For outcome measures in this study, both quantitative and qualitative parameters were used. The biomechanical variables and questionnaire ratings were used to address the specific research questions, whereas the characteristics assessments were recorded to gain information about participants' characteristics.

6.1 Quantitative biomechanical variables

Several biomechanical variables were measured or extracted from the three instruments used in this study:

1) Total and limb weight line displacement (or the horizontal distance of the weight line) to the anatomical knee centre of the prosthesis measured for each alignment technique by the LASAR system;

2) Below-socket peak moments of the participants' prosthesis at self-selected and fast speeds in both AP and ML directions obtained by the Compas™ system for each alignment technique;

3) RMS of the L3 pelvic acceleration recorded by the Shimmer™ device at self-selected and fast speeds in all three axes (vertical, AP, and ML) calculated for both techniques;

4) Cadence extracted from the acceleration data (Shimmer™) for self-selected and fast walking trials, compared within participants to test for the validity of the acceleration data.

Table 3 describes how each biomechanical variable was used to address the research objectives and the expected results based on the literature and model discussed in Chapter 2.

Table 3: Research objectives and expected outcome measures

<table>
<tr><th>Research objectives</th><th>Parameters and variables calculation</th><th>Expected results</th></tr>
<tr><td rowspan="6">1. Comparing alignment techniques</td><td colspan="2">Compared Conventional vs. Compas values for all variables graphically and statistically:</td></tr>
<tr><td>• Weight line displacement (mm): AP limb, AP total, ML limb</td><td>Smaller absolute displacement values mean closer to knee centre and better alignment. Literature-recommended value for AP limb is 15 mm anterior, for ML limb is 10 mm lateral (Blumentritt, 1999 and Seymour, 2002).</td></tr>
<tr><td>• Below-socket peak moment of the prosthetic limb (Nm): AP forefoot, AP heel, ML varus, ML valgus</td><td>Optimal peak values indicate less unequal torques on the residual limb and hence better alignment (esp. in ML direction due to less knee muscle interference; Mensch, 1986 and Grumillier, 2008).</td></tr>
<tr><td>• Pelvic acceleration RMS (g): vertical, AP, ML</td><td>Smaller RMS values indicate less pelvic sway and hence better gait stability and alignment (esp. in ML direction; Menz et al. 2003).</td></tr>
<tr><td>• Cadence (steps/min): self-selected speed, fast speed</td><td>Larger values indicate better alignment (Zijlstra, 2003).</td></tr>
<tr><td>• Subjective questionnaire rating: participants and prosthetists</td><td>Higher the rating means better alignment</td></tr>
<tr><td>2. Effect of alignment changes on outcomes</td><td colspan="2">Alignment changes (Compas minus Conventional tehcnques settings) were calculated as independent values of the y-axis. Differences of all variables (Compas minus Conventional) were calculated as defendant values of the x-axis for all correlation figures, where a positive trend line indicates a positive relationship between the direction of alignment change and the magnitude of that variable, and a negative change indicates a negative relationship.
Correlated alignment change (degrees) and the <u>differences</u> of all variables from Conventional to Compas, using scatter plots and linear regression:</td></tr>
</table>

Table 3 (continued): Research objectives and expected outcome measures

Research objectives	Parameters and variables calculation	Expected results
2. Effect of alignment changes on outcomes (continued)	• AP alignment change vs. AP weight line displacement difference (with/without misalignment values) • ML alignment change vs. ML weight line displacement difference	Anterior alignment change should shift weight line anteriorly, vice versa for posterior change. Medial alignment change should shift weight line medially, vice versa for lateral change (Figure 15 and Figure 16).
	• AP alignment change vs. forefoot and heel moment difference (with/without misalignment values) • ML alignment change vs. varus and valgus moment difference	Anterior alignment change should increase forefoot moment and decrease heel moment, vice versa for posterior change. Medial alignment change should increase varus moment and decrease valgus moment, vice versa for lateral change (Figure 17 and Figure 18).
	• AP alignment change vs. AP and vertical acceleration RMS difference (with/without misalignment values) • ML alignment change vs. ML and vertical acceleration RMS difference	AP alignment change should cause an increase in AP and vertical acceleration variation. ML alignment change should also increase ML and vertical acceleration variation (Menz *et al*. 2003, Mensch, 1986 and Perry, 1992).
3. Acclimation effects over time	Compared graphically Visit 1 vs. Visit 2 values for all variables of the same alignment setup that the participants took home from Visit 1:	
	• Weight line displacement (mm): AP limb, AP total, ML limb	Qualitative analysis through visual inspection, refer to **Expected results** for research objective 1
	• Below-socket peak moment of the prosthetic limb (Nm): AP forefoot, AP heel, ML varus, ML valgus	
	• Pelvic acceleration RMS (g): vertical, AP, ML	
	• Cadence (steps/min): self-selected speed, fast speed	

6.2 Characteristics assessments

Several functional mobility and demographic characteristics of the participants were collected to provide background information of the sample population and could be useful in understanding results and explaining outliers in data. The following assessments were chosen:

1) BMI score of participants calculated from their weights and heights;

2) The Locomotor Capabilities Index (LCI) completed by the participants at the beginning of Visit 1 to assess their ability to perform basic and advanced activities with their regular prosthesis (Appendix B). The LCI computes a score for both basic and advanced locomotor skills and assesses the participant's level of independence (Gauthier-Gagnon 2006, Larsson *et al*. 2009);

3) The participant's basic information, such as gender, age, years and cause of amputation, residual limb condition and length, years of prosthesis experience, and how often the prosthesis was worn during the week, was also recorded to provide additional evidence when interpreting outliers in the outcome data (Appendix A1).

6.3 Subjective questionnaires ratings

Lastly, questionnaires were given to both participants and prosthetists at the end of each visit to subjectively rate the two alignment techniques (Appendices A2 and A3) to address research objectives 1 and 3 (described in Table 3). All existing questionnaires found in the field of prosthetics were for evaluating prosthesis, functional and mobility outcomes, and quality of life (Condie *et al,* 2006 and Boone *et al*, 2006). Since none of these questionnaires were conducted specifically for evaluating prosthetic alignment, the questionnaires used in this study were developed clinically with prosthetists from SCIL. A Likart scale was used originally; however, a binary rating scale was generated from the questionnaire results for clearer comparison of the perceptions of the two alignment techniques. A score of 1 meant that the prosthetist or the participant liked the alignment setup, whereas a score of 0 meant that they were dissatisfied with the alignment. This subjective evaluation was included as an additional verification measure to help interpreting discrepancies with other quantitative results.

7. Data Analysis

All quantitative biomechanical variables were exported and process in MATLAB (Mathworks, Inc.; Massachusetts) and Microsoft Excel (Microsoft Corporation; Redmond, Washington). Next, the data were compared between the two dynamic alignment techniques to address the primary research question. These results would indicate whether the changes produced from one alignment technique to another caused differences in weight bearing while standing, below-socket peak moment magnitude, pelvic sway variability, and perception of satisfaction. If so, these results would reveal whether these differences between the Conventional and Compas techniques were significant. Details of these comparisons are described in Table 3.

Defining relative alignment change from one alignment technique to the other was done by recording the numbers of screw turns at below-socket location and converting that to angular change in degrees (Figure 6). Then to address the second research question, each biomechanical variable from Visit 1 was scatter-plotted as a function of alignment change to observe any correlations. Pelvic acceleration data was also plotted as a function of cadence to validate whether the data was sensitive to speed. Next, data for the same alignment technique that was carried over from Visit 1 to Visit 2 were compared to test for acclimation effects of the third research question. Table 2 summarizes the specific variables and Table 3 describes the details of the thesis analysis.

7.1 Weight line displacement data

Three weight line displacement values were manually recorded for each alignment technique through the LASAR system, as described in Section 4.1. Raw data and averages among participants were compared between the two techniques and with literature recommended values. Expected results for each research objectives are described in Table 3.

7.2 Peak below-socket moment data

For each trial, six steps of the moment profiles were recorded. Data from the first and the last steps was omitted due to transients at the beginning and the end. Then four absolute peak moment values were extracted from the remaining steps: forefoot (maximum) and heel (minimum) peak moment in the AP direction (Figure 19), varus (maximum medial) and valgus (maximum lateral) in the ML direction (Figure 20). For consistency, a medial/lateral naming system was used instead of using left/right for the variables, thus avoiding confusion with the side of transtibial prosthesis. Finally, the values were averaged across three steps and between the two trials for each speed. Again, expected results for each research objective are described in Table 3.

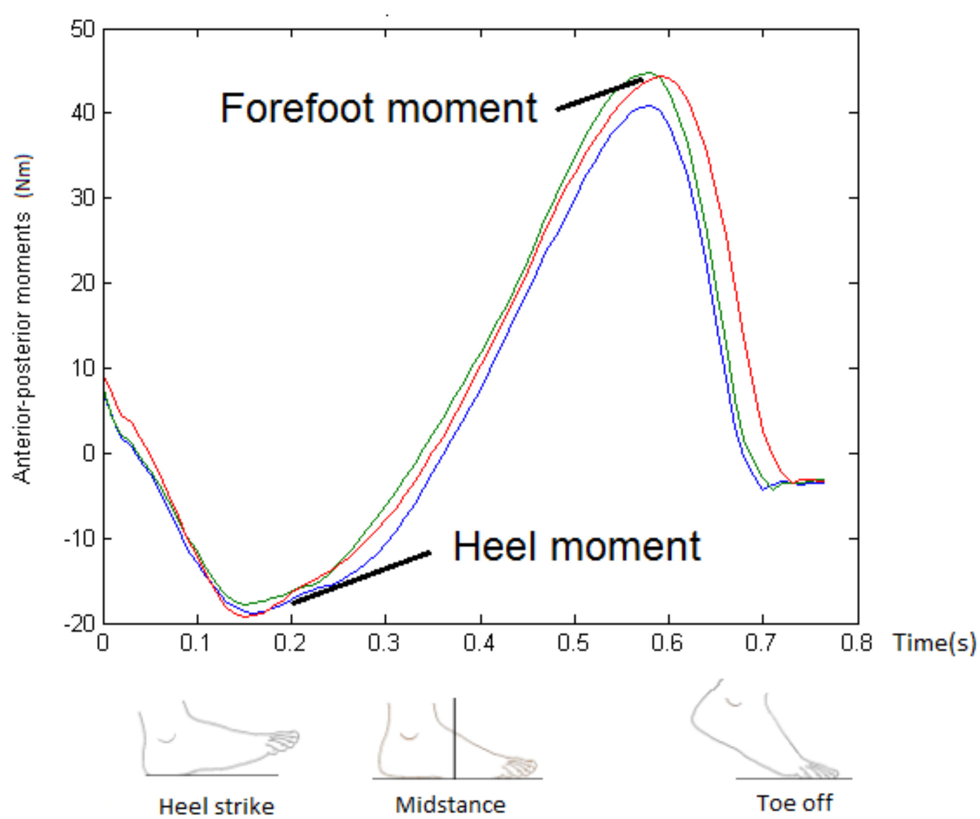

Figure 19: Forefoot and heel peak moment (Nm) vs. time (s) in the AP direction (MATLAB)

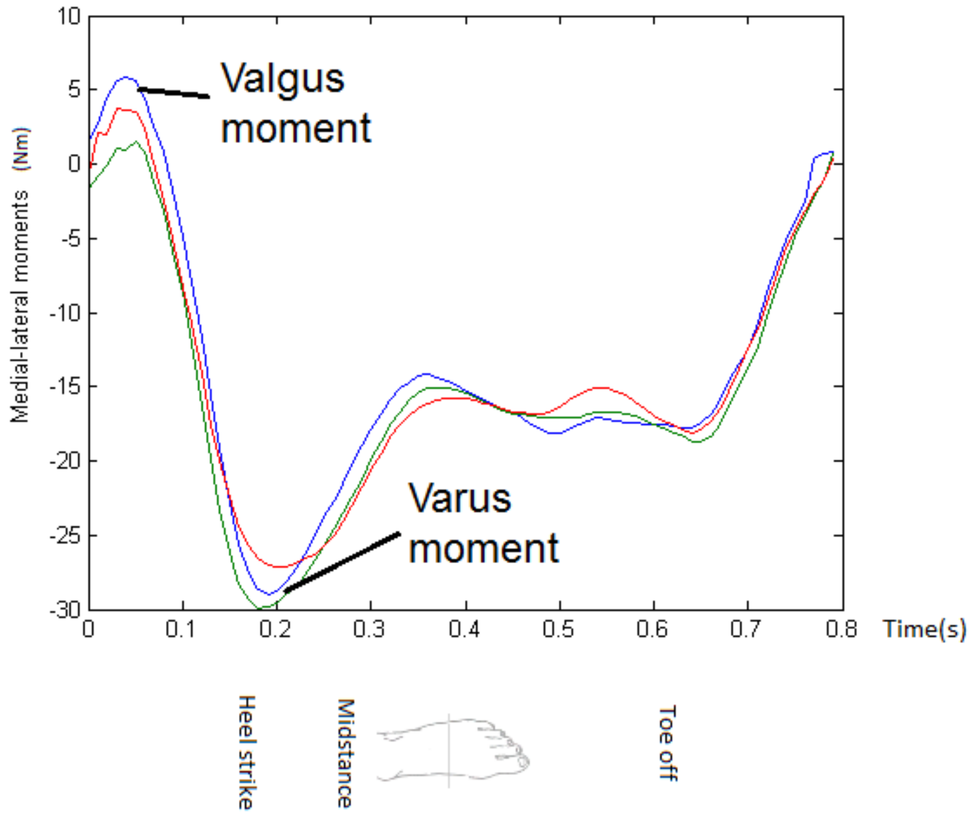

Figure 20: Varus and valgus peak moment (Nm) vs. time (s) in the ML direction (MATLAB)

7.3 Pelvic acceleration RMS data

For each trial, data from all three axes (vertical, AP and ML) was first filtered with a 3rd order Low-pass Butterworth bi-directional filter, with a cut-off frequency of 20Hz (*Lamoth et al, 2010*). Under the consideration that the sensor could be fixed onto the pelvis at an angle or its orientation could be altered during walking, data was offset back to the same static baseline. The baseline values used to offset for all axes were obtained through collecting three to five seconds of acceleration data while the participants were standing still, based on the method recommended by the manufacturer (Shimmer, 2011). These baseline values were then subtracted from the walking trials to obtain the clean data. With the clean data, approximately five to six seconds of relative consistent walking data were extracted RMS calculation.

Finally, the RMS values of the pelvic acceleration, given by the square-root of the average of the individual values squared, were calculated according to equation (1) and averaged over the two trials for each speed. In the case of a set of *n* values x_1, x_2, … x_n, the RMS is (Menz *et al*, 2003):

$$x_{\mathrm{rms}} = \sqrt{\frac{1}{n}\left(x_1{}^2 + x_2{}^2 + \cdots + x_n{}^2\right)} \qquad (1)$$

7.4 Statistics

Statistical tests were used to infer potential differences of the data between alignment techniques to determine if the Compas alignment technique produced improvements upon the Conventional technique in achieving better mobility and stable gait characteristics. All statistical tests were performed using SPSS 16.0 (SPSS, Inc.; IBM, New York).

To address the primary research question, a comparison between the alignment techniques was made for each variable with non-parametric Wilcoxon Signed Rank Test (the equivalent of the parametric paired t-test, two-tailed) to detect significant differences. Non-parametric tests were used after variables were checked for normal distribution and did not fit a pre-determined form (Field, 2009). The significant level was set at $p < 0.05$ (Chan, 2003) in order to assess whether an outcome variable was significantly different between the Conventional and the Compas techniques.

For the second research question, two values were used to determine if a correlation was significant or not:

1) The correlation coefficient squared, known as the coefficient of determination, R-Squared (R^2), was calculated in Microsoft Excel (Microsoft Corporation; Redmond, Washington) through its linear regression analysis function. It is a measure of the amount of variability in one variable that is shared by the other, and determines the goodness of fit of the trend line to the data (Field, 2009). The R^2 value ranges from 1 to 0, where a value of 1 indicates that all of the data points agree to a perfect positive or

negative correlation, and where a value of 0 means no correlation (Cameron *et al*. 1997). For this study, due to the small sample size, a R^2 value of less than 0.5 was considered to have a weak correlation because it meant more than 50% of the data could not be accounted for the trend line (Field, 2009, p.166-223).

2) The p-value from the same Wilcoxon Signed Rank Test was used to test for the significance of the correlation between alignment change and each variable. Significance was set to $p < 0.05$.

For the third research question, repeated measures from Visit 1 and 2 for each participant were compared for the same alignment technique. Due to the small sample size from Visit 2 (four participants) and missing data due to technical difficulty, the data was underpowered for any statistical analysis and the results were only compared qualitatively.

8. Focus Group Protocol

A focus group was held to understand the process of transtibial prosthetic alignment and identify differences between alignments performed using the Conventional technique and the Compas technique from a clinical perspective. The participants of this focus group included six SCIL prosthetists who have had limited experience using the Compas™ system. The focus group approach is a recommended methodology because it provides a non-discriminated platform for participants who are either too reluctant to be interviewed on their own or feel they have nothing to say (Kitzinger, 1995).

Prior to the group discussion, a list of questions relevant to using the Compas™ system and to general alignment approaches was generated (Appendix D). Then during the focus group, participants took turns to address each question and explored potential solutions. Discussion questions were designed to be open-ended in order to evoke ideas and suggestions from participants for improving the alignment processes and the alignment technology (Klute, 2009).

8.1 Roundtable discussion session

The focus group discussion was conducted as an one-hour luncheon style meeting with people sitting around a table (Klute, 2009). Notes were taken and the session was recorded to be transcribed at a later time. After the researcher explained the focus group goals, participants were encouraged to answer questions and to talk to one another. Dialogues around inconsistencies both between the participants and within their own thinking were encouraged. At the end of the session, an additional questionnaire (Appendix D) was given to all participants so help them summarize and write down their own thoughts from the discussion.

8.2 Analysis

Discussion answers and questionnaire results were grouped into categories based on the three focus group objectives found in Chapter 3, Section **Error! Reference source not found.**. Several topics surrounding the objectives were identified, and specific points were counted by the frequency of their mentioning. A summary of findings was generated to distinguish between individual opinions and group consensus. The details of this summary can be found in Chapter 5, Section 7.2.

Chapter 5

Results

1. Participants Characteristics

A total of nine individuals with unilateral transtibial amputation participated in the study and the evaluations took place at the SCIL. The nine participants were patients of six different prosthetists, who performed alignments on their own patients in the clinical visits for this study.

The participants consisted of eight males and one female between the ages of 21 and 81, with an average age of 45 (SD=18). All participants have been using transtibial prostheses for at least one year, with years of amputation ranging from one to 34 years (mean=14 years, SD=12 years). Six of them had lost their limbs due to trauma such as motor vehicle accidents. The other three owed the cause to circulatory disorders such as diabetes gangrene or aneurysm. Four participants had left side amputation and five had right side.

Table 4 presents the details of the participants' demographics, including residual limb length, foot and socket suspension types of their new prostheses. All nine participants volunteered to be evaluated under the study protocol for Visit 1; however, due to their availability, health and family reasons, only four completed Visit 2.

Table 5 presents the participants' BMI and LCI scores. The average weight with prosthesis was 94.9 (SD=22.6) kg, with BMI scores ranging between 23.2 and 43.2. Out of the nine participants, two were within the normal category, four were overweight, and three were at the risk of obesity. In terms of LCI assessment, all participants had perfect scores for the basic activities category (21/21), but only three had a perfect score for the advanced activities. Most required supervision or assistance to walk outside in inclement weather (*e.g.* snow, rain, ice conditions). Participants' scores average 18.1 (SD=4.1) out of 21 for advanced activities and 38.7 (SD=4.0) out of 42 for total LCI score.

Table 4: Participants' demographics

Participants	Age (years)	Gender	Amputation time (years)	Residual limb length (mm)	Amputation etiology	Foot type	Socket & Suspension type
1	28	M	3	18	Trauma	Energy-storing flex	TSB*, liner sleeve
2	81	M	18	15	Surgery complication	College park	Calf sleeve
3*	21	M	1	11	Trauma	Reflex rotate	Pin with liner
4*	45	M	1	10	Diabetic gangrene	SACH+	TSB*, waist strap
5*	57	M	10	11	Surgery complication	SACH+	Superacondula, pelite liner
6*	52	M	34	9	Trauma	Energy-storing flex	Suction
7	32	M	25	21	Trauma	Energy-storing flex	Calf sleeve
8	37	F	13	17	Trauma	College park	Superacondula, thermal liner
9	52	M	22	22	Trauma	SACH+	Pin with liner
Mean(SD)	**45 (18)**	**--**	**14 (12)**	**15 (5)**	**+SACH = solid ankle cushion heel *TSB = total surface bearing**		

***Participants who came for Visit 2.**

Table 5: Participants' BMI and LCI scores

Participants	Weight with prosthesis (kg)	Height (m)	BMI	LCI advanced activities score /21	LCI total score /42
1	93	1.83	27.7	20	41
2	89	1.78	28.3	17	38
3	78	1.83	23.2	21	42
4	139	1.83	41.7	20	41
5	78	1.77	24.7	9	30
6	106	1.88	30.0	20	41
7	119	1.66	43.2	21	38
8	71	1.68	25.2	21	42
9	82	1.80	25.2	14	35
Mean(SD)	94.9 (22.6)	1.78 (0.07)	29.9 (7.4)	18.1 (4.1)	38.7 (4.0)

2. Results from LASAR Weight Line Displacement Data

2.1 Results for primary research question

Three weight line variables were compared between two alignment techniques performed from Visit 1: AP limb (single foot), AP total (double feet), and ML limb (single foot). The LASAR data of participant #6 was not recorded due to device malfunction.

In the AP direction, the average limb weight line displacement was 14.0 (SD=12.7) mm for the Conventional technique and 16.4 (SD=16.7) mm for the Compas technique, as shown in Figure 21. The values were not statistically significant ($p=0.735$, Wilcoxon Signed Ranks Test).

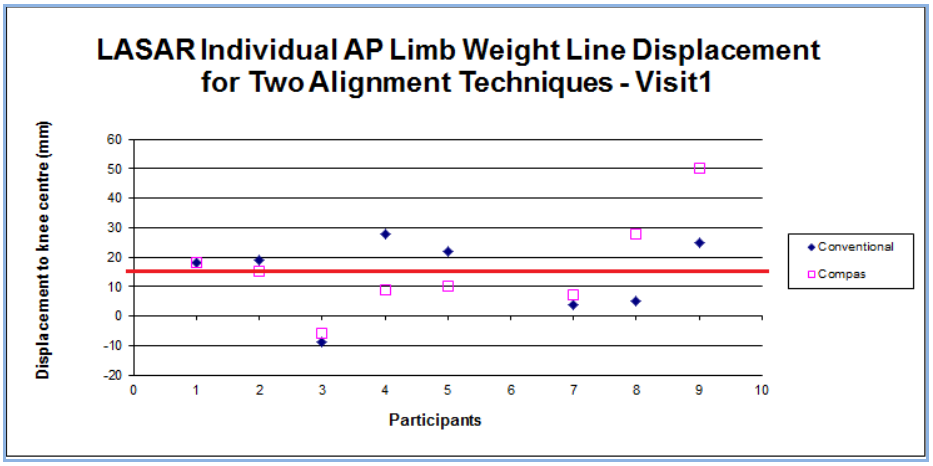

Figure 21: AP limb weight line displacement for two alignment techniques; Red line: literature recommended value of 15 mm (Breakey, 1998)

The average total weight line displacement in the AP direction was -0.1 (SD=27.9) mm for the Conventional technique and 12.3 (SD=22.2) mm for the Compas technique, as shown in Figure 22. Statistically, the Compas values (median=6.0 mm) were significantly more anterior than the Conventional values (median=0.0 mm), p=0.027 (Wilcoxon Signed Ranks Test). Both values were close to the desired outcome value of 15 mm.

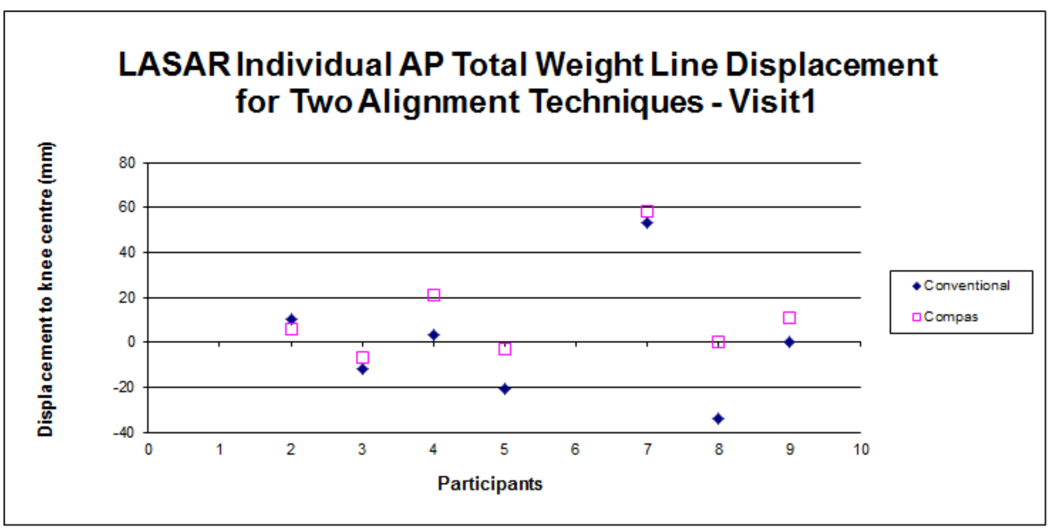

Figure 22: AP total weight line displacement for two alignment techniques

In the ML direction, the average limb weight line displacement was -28.5 (SD=24.4) mm for the Conventional technique and -19.4 (SD=27.2) mm for the Compas technique, as shown in Figure 23. The Compas values (median=-26.5 mm) were significantly more medial than the Conventional values (median=-32.5 mm), (p=0.043, Wilcoxon Signed Ranks Test) and closer to the literature recommended value of -10 mm.

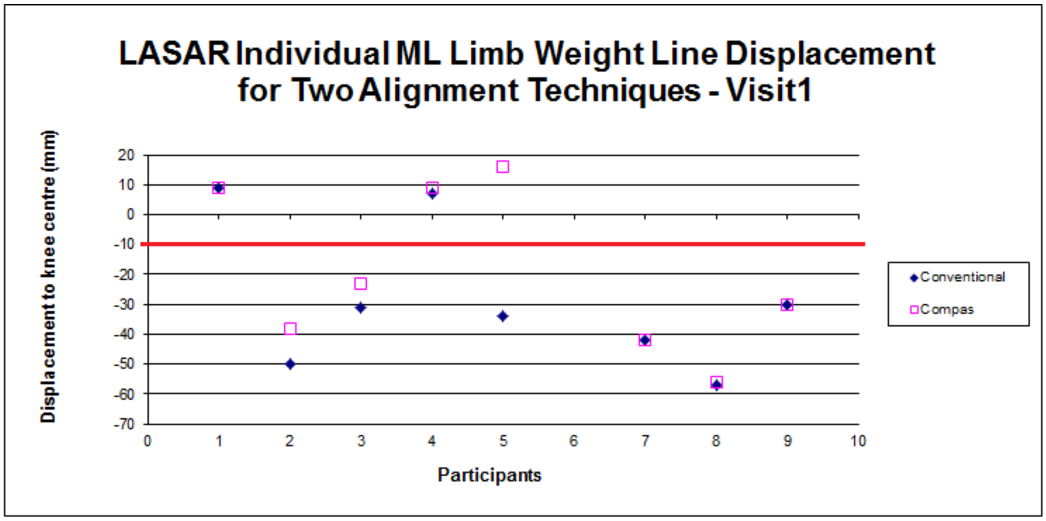

Figure 23: ML limb weight line displacement for two alignment techniques; Red line: literature recommended value of -10 mm (Seymour, 2002)

2.2 Results for second research question

Three variables were plotted against alignment change to look for correlations between weight line displacement and alignment change. For the correlation graphs, the y-axis represents the dependent variables, or the differences obtained from values of the Conventional technique to that of the Compas technique (*i.e*. Compas minus Conventional) for either the AP or ML direction. The x-axis represents the independent variable, the alignment change in the same direction. The alignment change data was not obtained from participant #1 because the study protocol was refined for the subsequent clinical visits.

Results showed that the AP limb weight line (with single foot on the platform) did not demonstrate a significant relationship with alignment change, as shown in Figure 24

(R^2=0.161, linear regression analysis; p=0.735, Wilcoxon Signed Rank Test). Whereas the AP total weight line (with double feet on the platform) did result in a moderately positive correlation with AP alignment change (R^2=0.632, linear regression analysis; p=0.028, Wilcoxon Signed Rank Test), as shown in Figure 25.

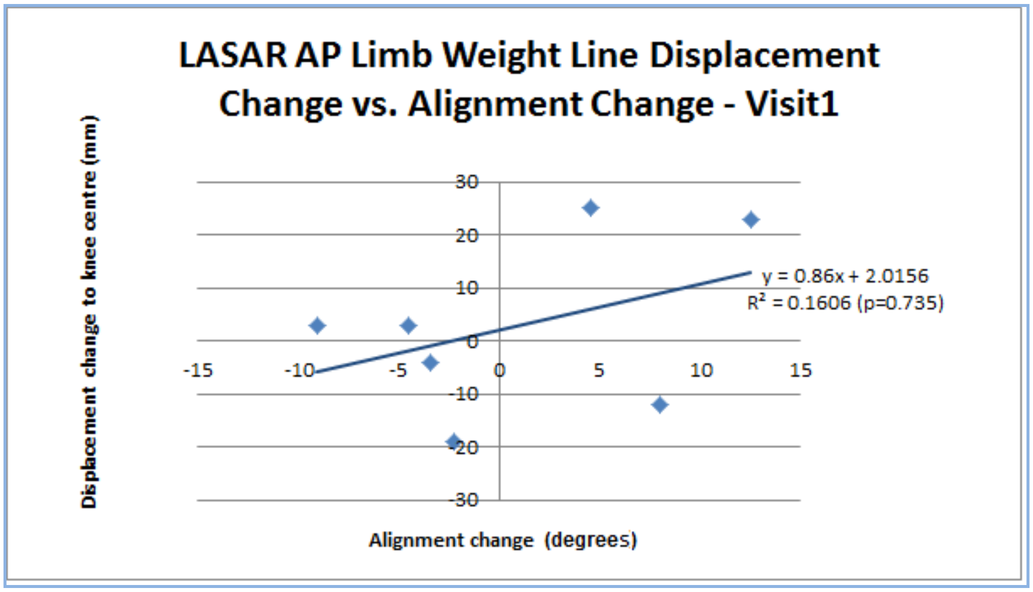

Figure 24: AP limb weight line difference and alignment change

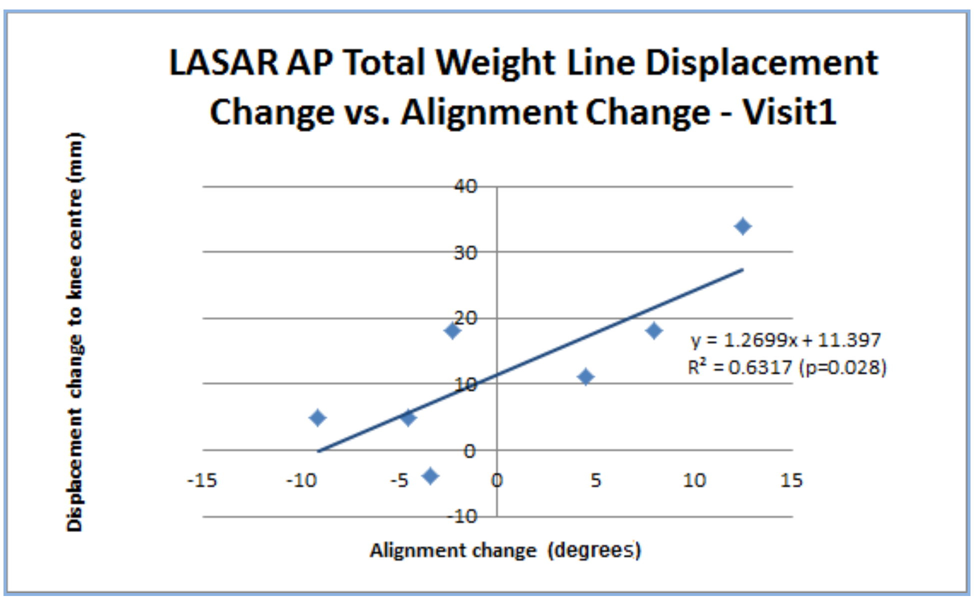

Figure 25: AP total weight line difference and alignment change

In addition, five participants were able to tolerate a misalignment setup in the AP direction, so the data from these misaligned positions was also added into the comparison, as described in Chapter 4, Section 3.1. Figure 26 and Figure 27 show the individual AP limb and total weight line changes with respect to alignment changes. For each participant, two data points were plotted. The first value was the Compas technique minus the Conventional tehcnque, and the second value was the misalignment minus the Compas technique. Alignment changes differences were independent values of the y-axis, and the weight line displacement differences were defendant values of the x-axis. A positive trend line indicates a positive relationship between the direction of alignment change and the direction of the weight line displacement, and a negative change indicates a negative relationship (Table 3, #2). In both cases (AP limb and total weight line), there were no consistent trends between the direction of the weight line displacement with the direction of the alignment change among participants.

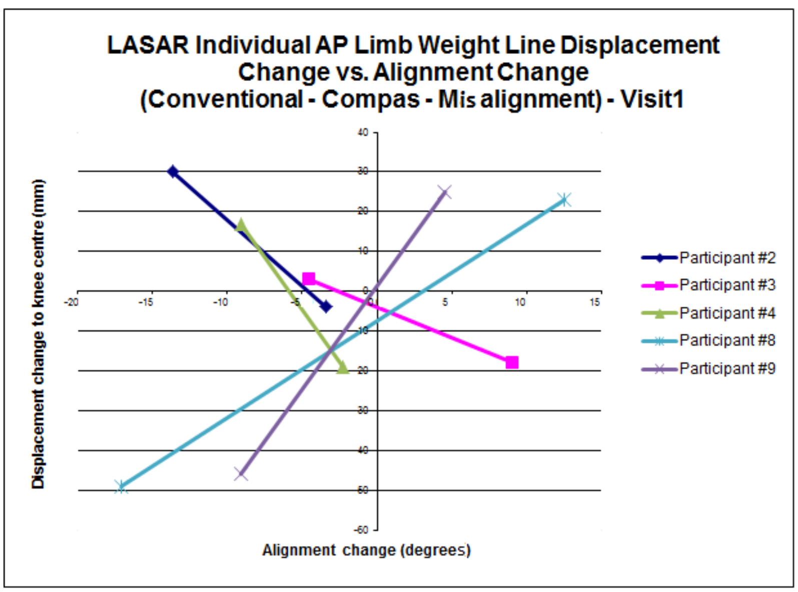

Figure 26: Individual AP limb weight line differences and alignment changes

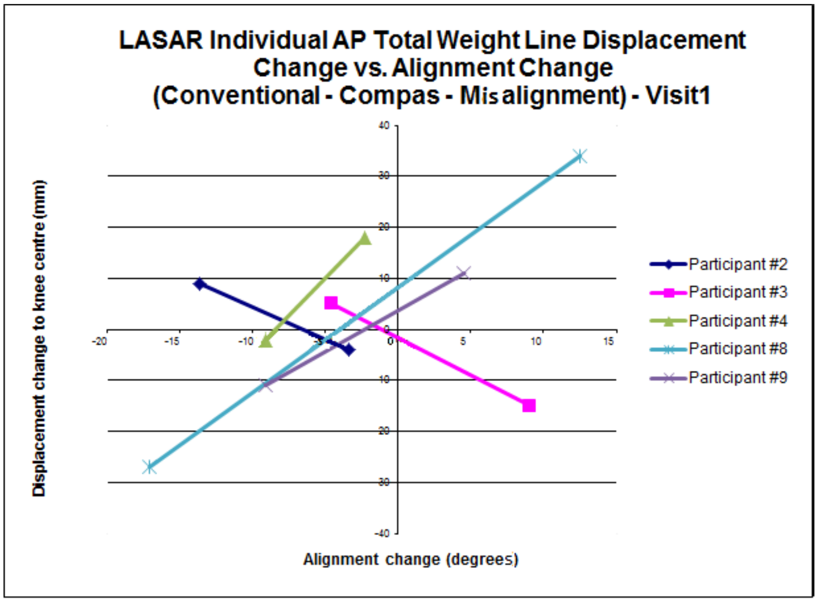

Figure 27: Individual AP total weight line differences and alignment changes

In the ML direction, the limb weight line difference vs. alignment change graph (Figure 28) demonstrated a weak correlation with only marginal significance (R^2=0.033, linear regression analysis; p=0.051, Wilcoxon Signed Rank Test).

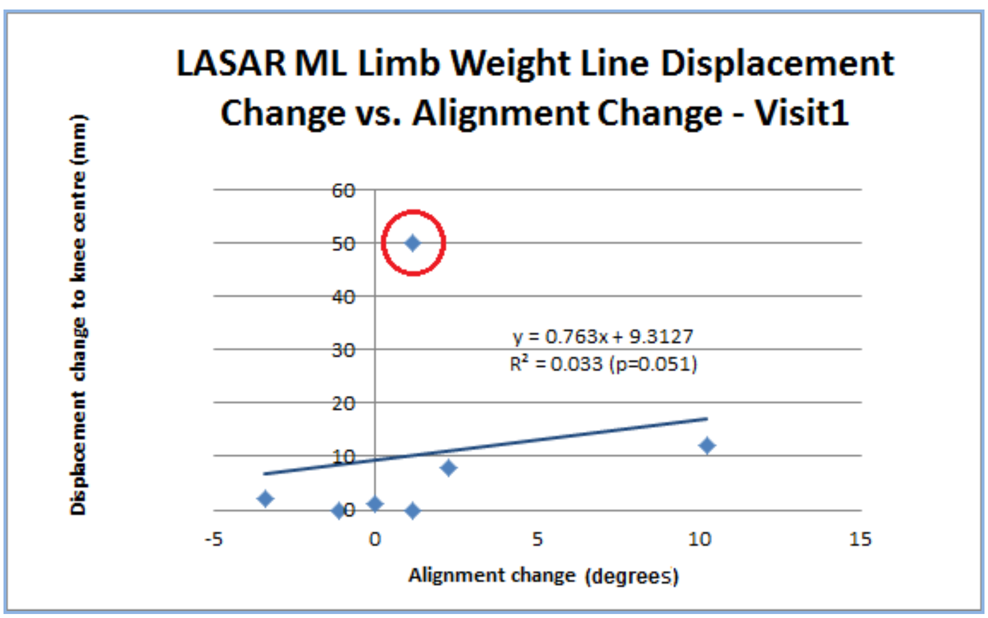

Figure 28: ML limb weight line difference and alignment change

Red circle: A suspected outlier were noted

2.3 Results for third research question

To find the effect of acclimation, the same alignment setup that the participant took home was compared from Visit 1 to Visit 2. Only four participants had Visit 2 data, and the alignment setups they each took home are shown in Table 6. Due to LASAR device malfunction for participant #6, only three data points were compared. All three participants compared took the Compas alignment setup home from Visit 1 to acclimatize over a week period.

Table 6: Alignment setup brought home by participants from Visit 1

Participants	Alignment setup brought home from Visit 1	Prosthetists
3	Compas	3
4	Compas	4
5	Compas	2
6	Conventional	1

All Visit 2 values shifted anteriorly compared to that of Visit 1 for both AP limb weight line (Figure 29) and AP total weight line (Figure 30) displacement, whereas the ML limb weight line values shifted laterally from Visit 1 to Visit 2 over time (Figure 31).

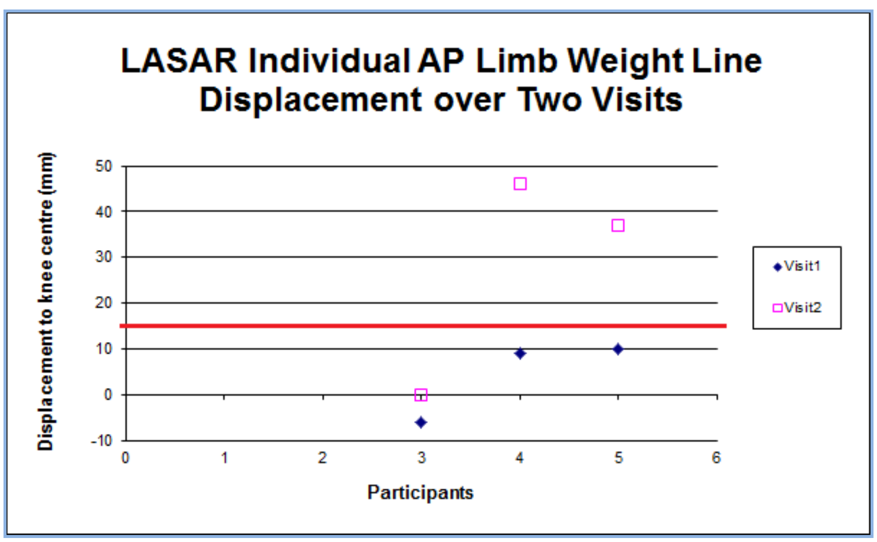

Figure 29: AP limb weight line values between visits;

Red line: literature recommended value (Breakey, 1998)

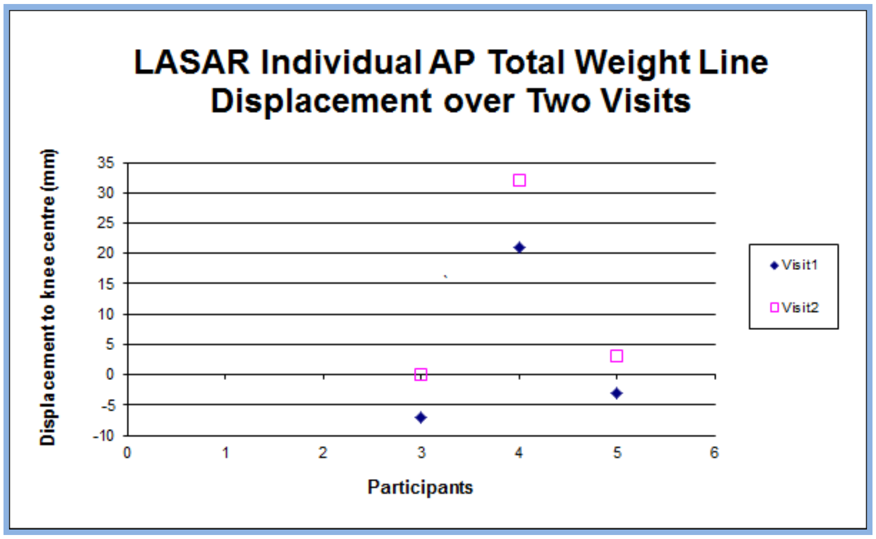

Figure 30: AP total weight line values between visits

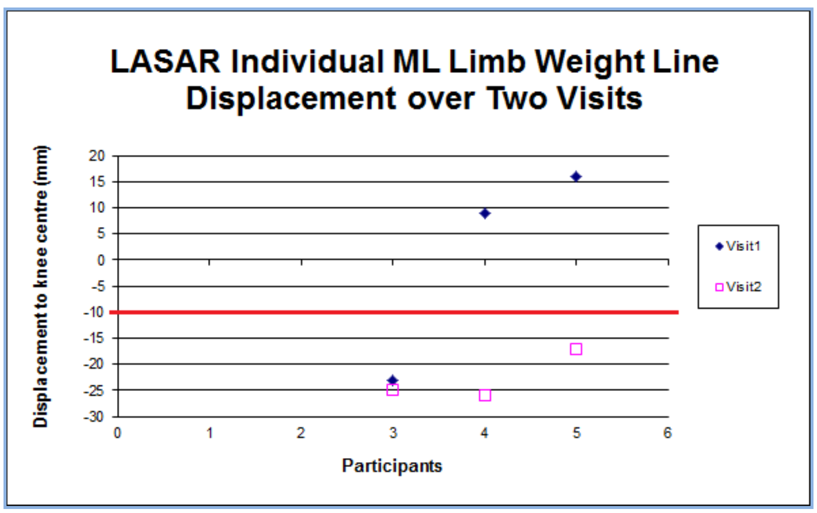

Figure 31: ML limb weight line values between visits;

Red line: literature recommended value (Seymour, 2002)

3. Results from Below-Socket Peak Moment Data

Despite alignment changes made between the two techniques, with the exception of participant #1 and participant #7, all participants were able to walk at both self-selected and fast speeds without great difficulty. In the case of participant #1, this amputee did not have fast speed walk trials because these were added to the study protocol for the subsequent clinical visits beginning with participant #2. In the case of participant #7, this amputee was not able to tolerate misalignment settings due to excessive pain experienced wearing the new prosthesis.

3.1 Results for primary research question

Four below-socket peak moment variables, as depicted in Figure 19 and Figure 20, were compared between the two alignment techniques performed from Visit 1 for both self-selected and fast walking speed trials: AP forefoot, AP heel, ML varus, and ML valgus. The average values and statistical test results are summarized in Table 7. Only the average varus moment at the self-selected speed demonstrated significant difference (p=0.038, Wilcoxon Signed Ranks Test) between the alignment techniques, indicating that the Compas varus moment values (median=12.63 Nm) were significantly higher than the Conventional (median=10.48 Nm). When examining individual varus peak moment values as shown in Figure 32, all participants had higher Compas values except for participant #2 who showed the opposite trend.

Table 7: Average peak moment variables and statistical test results

Peak Moment Variables (Nm)	Trials	Conventional		Compas		Wilcoxon Signed Ranks Test
		Mean	SD	Mean	SD	P-value
AP Forefoot	Self-selected	65.61	18.51	68.76	16.90	0.139
	Fast	64.11	20.16	67.27	17.93	0.161
AP Heel	Self-selected	14.26	7.19	15.13	10.27	0.374
	Fast	14.71	6.57	13.56	8.73	0.484
ML Varus	Self-selected	11.00	4.71	13.30	5.27	0.038
	Fast	12.75	6.61	13.91	5.16	0.237
ML Valgus	Self-selected	3.83	2.29	3.54	2.60	0.553
	Fast	3.99	2.73	3.46	3.11	0.262

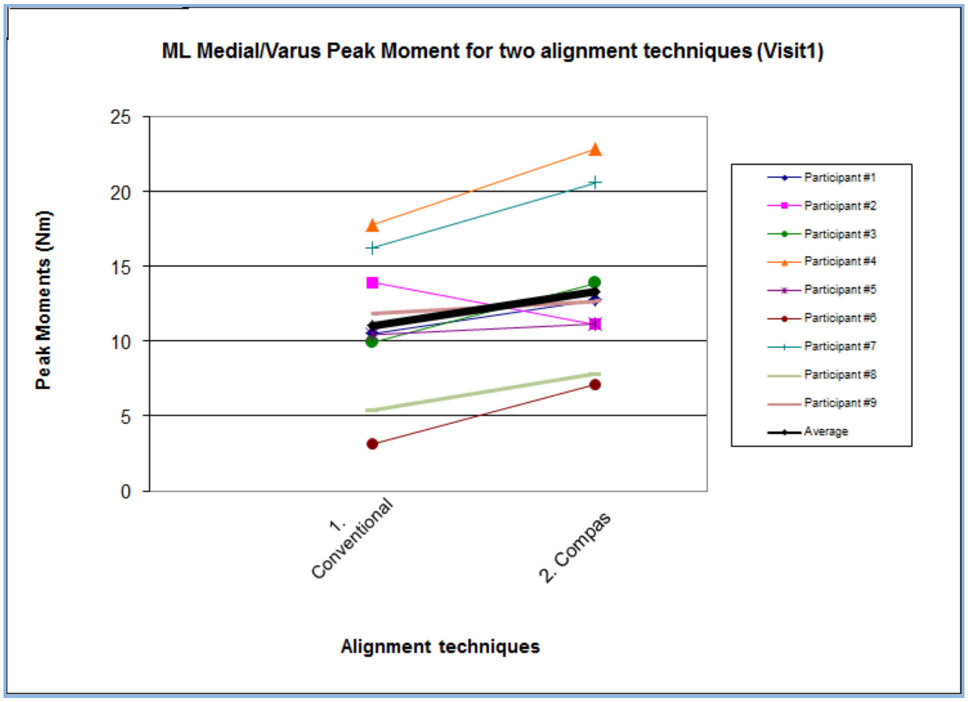

Figure 32: Individual varus peak moment between two alignment techniques

The average values were also normalized with individual weights and compared again through the same statistical test. Results are summarized in Table 8 and show the same conclusion that only the average peak varus moments at the self-selected speed were significant different (p=0.028, Wilcoxon Signed Ranks Test) between the Conventional and Compas alignment techniques.

Table 8: Average normalized peak moment variables and statistical test results

Normalized Peak Moment Variables (Nm/kg)	Trials	Conventional		Compas		Wilcoxon Signed Ranks Test
		Mean	SD	Mean	SD	P-value
AP Forefoot	Self-selected	0.69	0.16	0.73	0.13	0.214
	Fast	0.67	0.15	0.71	0.13	0.123
AP Heel	Self-selected	0.15	0.08	0.16	0.11	0.374
	Fast	0.16	0.07	0.14	0.09	0.401
ML Varus	Self-selected	0.12	0.04	0.14	0.03	0.028
	Fast	0.13	0.05	0.15	0.04	0.176
ML Valgus	Self-selected	0.01	0.04	0.01	0.04	0.066
	Fast	0.01	0.04	0.01	0.04	0.263

3.2 Results for second research question

Four below-socket peak moment variables were plotted against alignment change to look for correlations. Figure 33 and Figure 34 show the forefoot and heel peak moment differences between alignment techniques as a function of alignment change for both self-selected and fast speeds. Using linear regression analysis, in general correlations were weak and not significant.

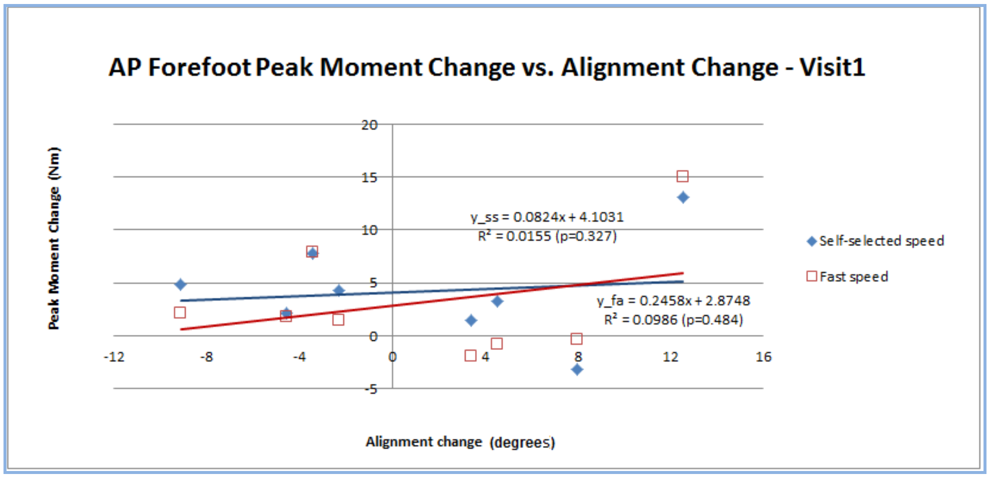

Figure 33: AP forefoot peak moment difference and alignment change

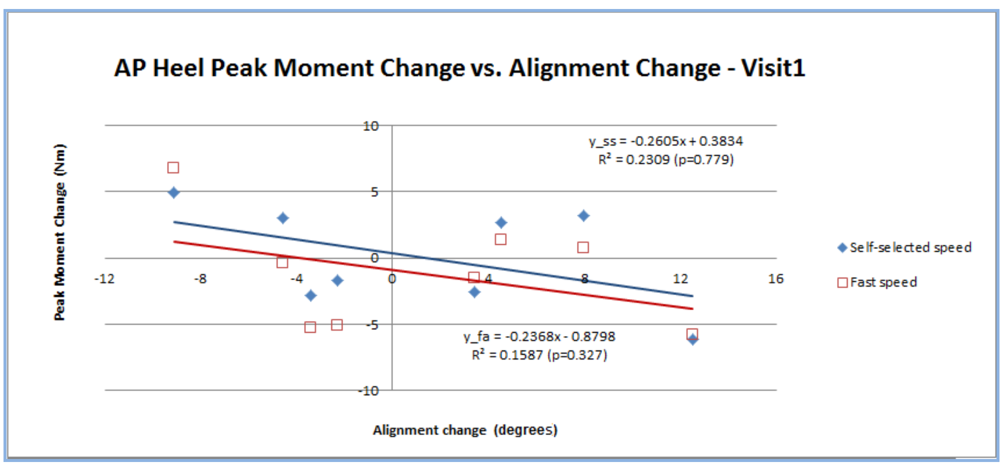

Figure 34: AP heel peak moment difference and alignment change

Figure 35 and Figure 36 show individual participants' forefoot peak moments with misaligned position for both self-selected and fast speeds, respectively. Two data points for each participant were plotted: the alignment changes from the Conventional technique to the Compas technique and from the Compas technique to misalignment. Alignment changes differences were independent values of the y-axis, and the peak moment differences were defendant values of the x-axis. A positive trend line indicates a positive relationship between the direction of alignment change and the magnitude change of peak moments, and a negative change indicates a negative relationship (Table 3, #2). Both graphs depict a positive direction of change for the majority of participants with the exception of participants #3 and #5 (Table 3, #2).

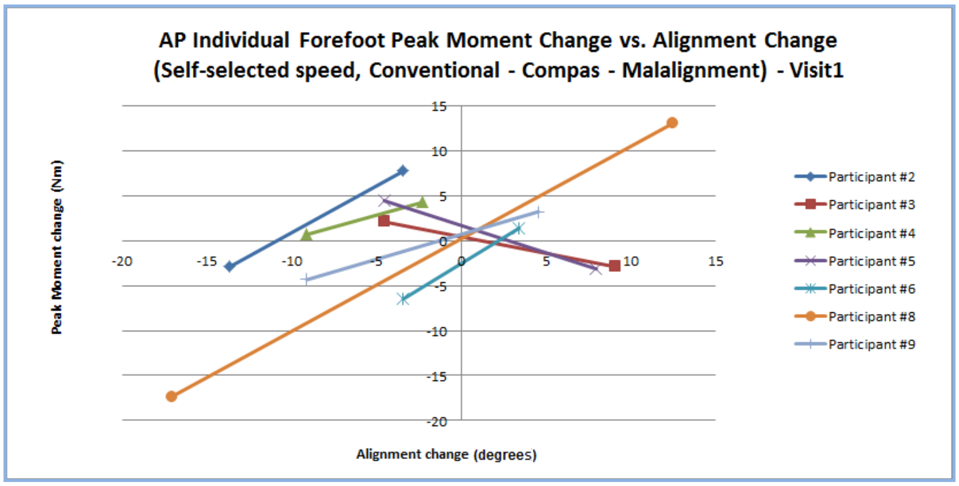

Figure 35: Individual forefoot peak moment differences and alignment changes (self-selected)

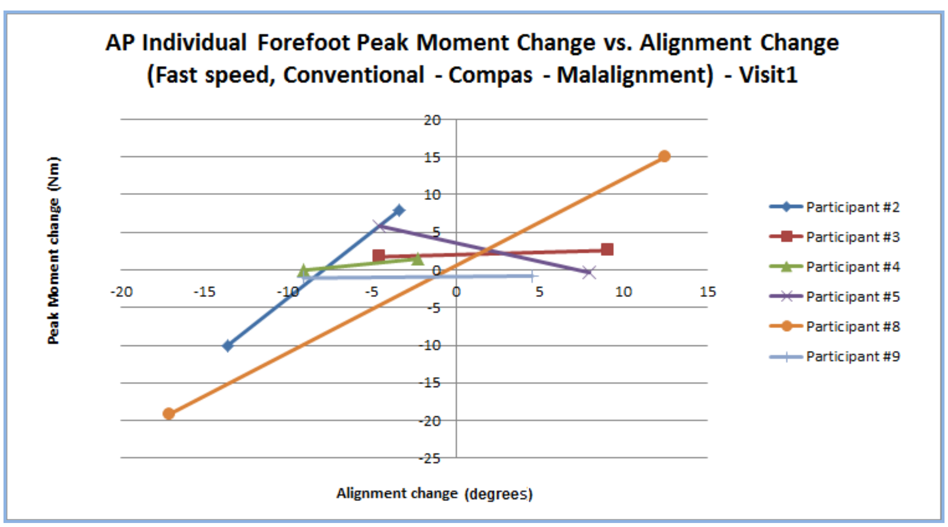

Figure 36: Individual forefoot peak moment differences and alignment changes (fast)

For peak heel moment, two data points were also plotted representing the difference values calculated from the Conventional technique to the Compas technique, and from the Compas technique to misalignment for each participant. For these cases, self-selected speed trials showed inconsistent directions of change when a misaligned condition was added (Figure 37). Fast speed trials were more consistent with a negative direction of change except for participant #5 (Figure 38).

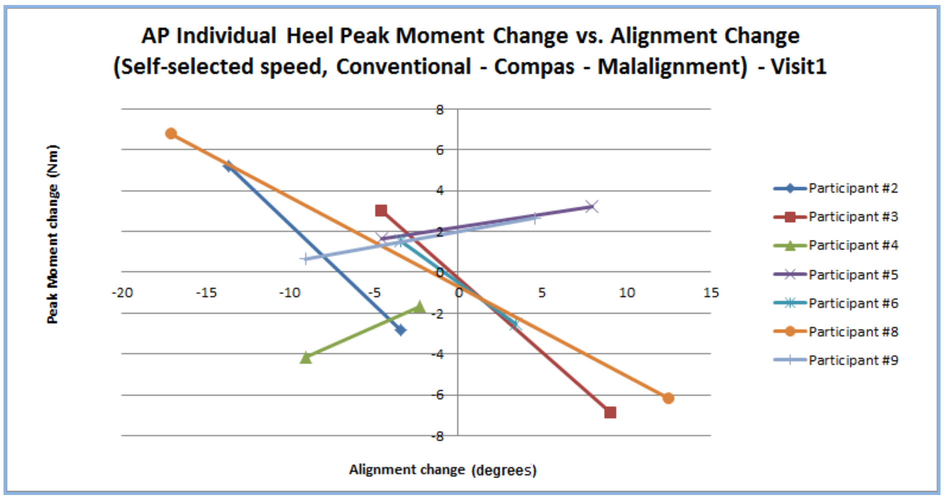

Figure 37: Individual heel peak moment differences and alignment changes (self-selected)

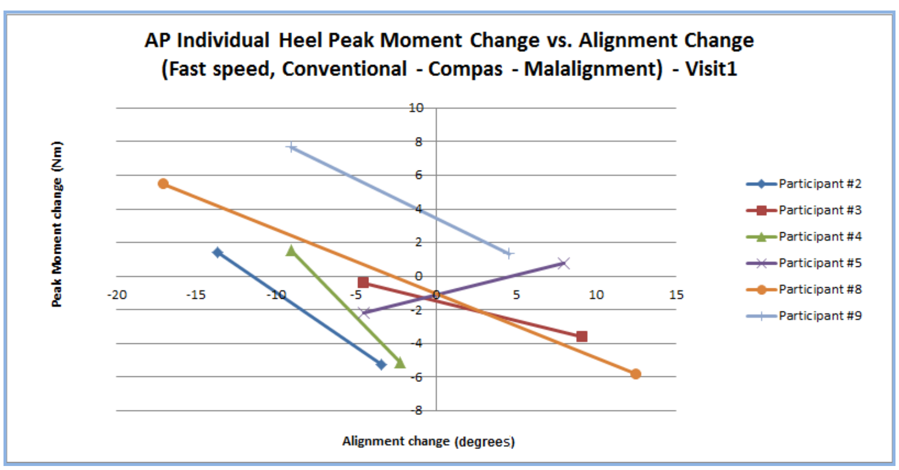

Figure 38: Individual heel peak moment differences and alignment changes (fast)

Figure 39 and Figure 40 show the valgus and varus peak moment differences between alignment techniques as a function of alignment change for both self-selected and fast speed. Linear regression analysis revealed a weak correlation and no statistical significance. All peak varus moment values at fast speed increased from the Conventional to the Compas techniques with the exception of participant #2 (Figure 40, red circle).

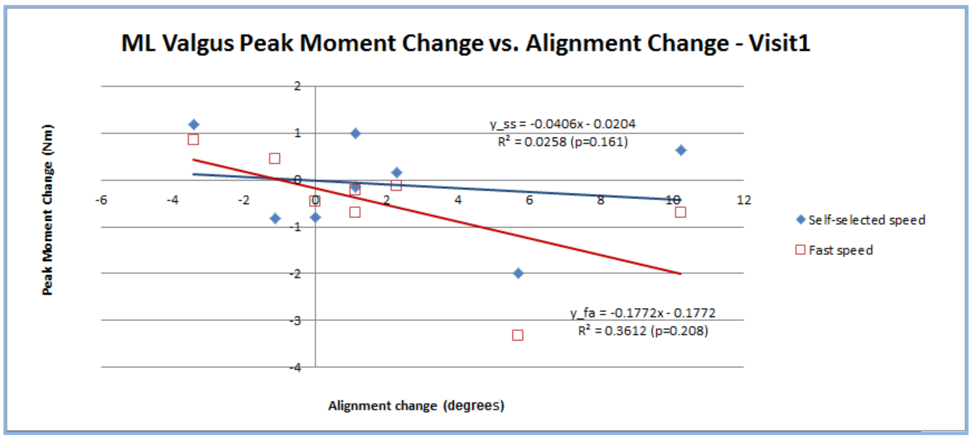

Figure 39: ML valgus peak moment difference and alignment change

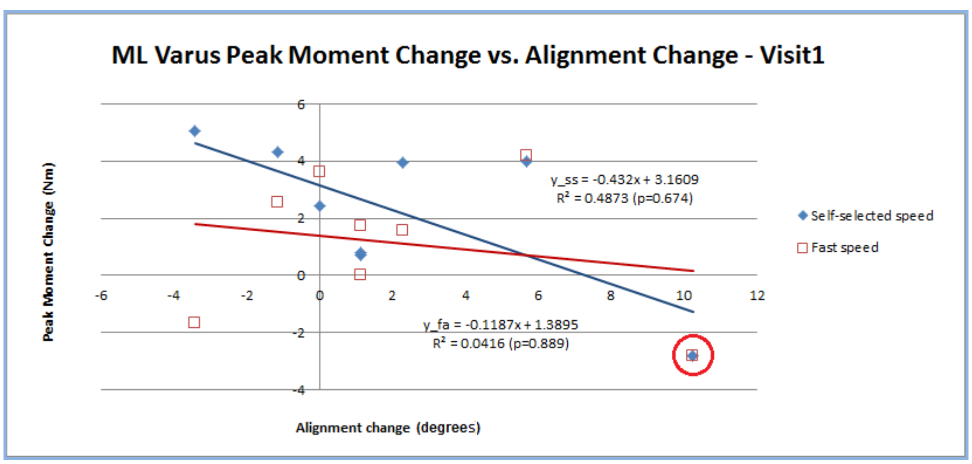

Figure 40: ML varus peak moment difference and alignment change

Red circle: A suspected outlier were noted

3.3 Results for third research question

Four participants' data was compared between Visit 1 and Visit 2 for assessing acclimation effects. Three participants took the Compas alignment setup home to acclimatize over a one-week period, and one participant took the Conventional alignment setup home from Visit 1 (Table 6).

The four figures show the results at both self-selected and fast speeds for each participant. A positive value represents an increase and a negative value represents a decrease in peak moment magnitude from Visit 1 to Visit 2 (Visit 2 minus Visit 1). In the AP direction, Visit 2 peak forefoot moment values decreased compared to that of Visit 1 except for participant #3 at fast speed (Figure 41). Through visual inspection, three out of four peak heel moments increased over time (Figure 42). In the ML direction, peak valgus moment showed no consistent directional change (Figure 43), whereas peak varus moments increased over time in fast speed trials except in the case of participant #3 (Figure 44).

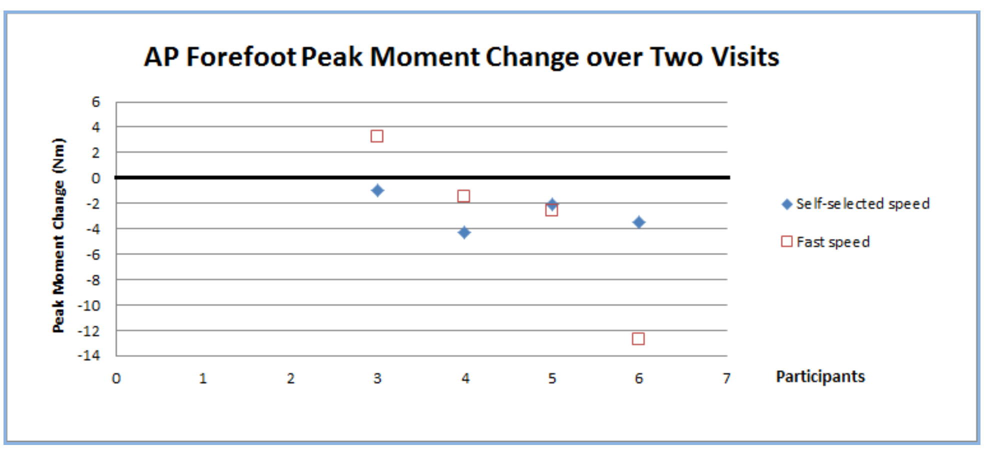

Figure 41: AP forefoot peak moment values between visits

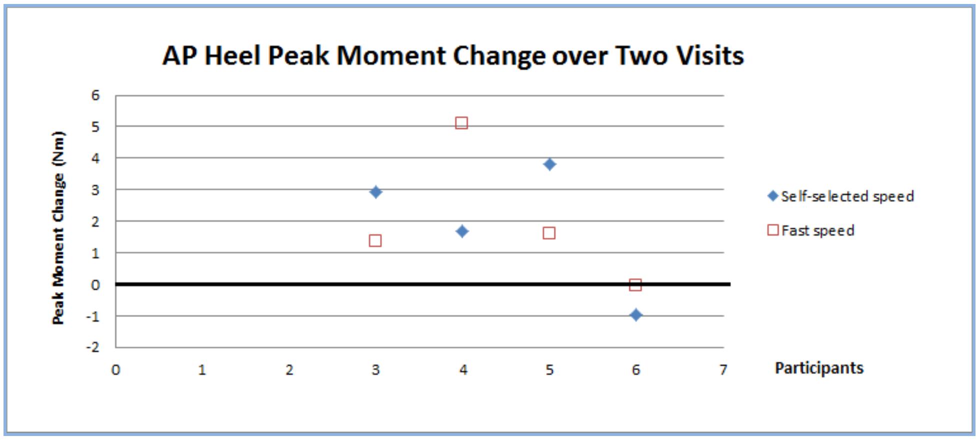

Figure 42: AP heel peak moment values between visits

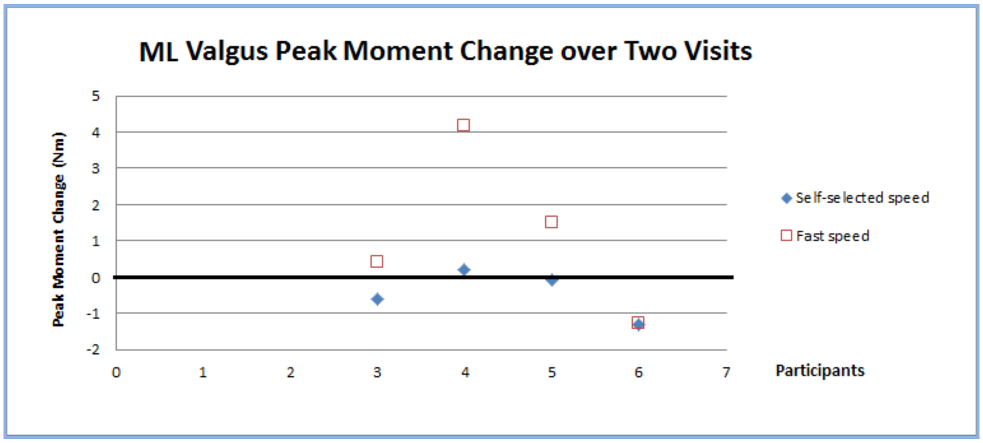

Figure 43: ML valgus peak moment values between visits

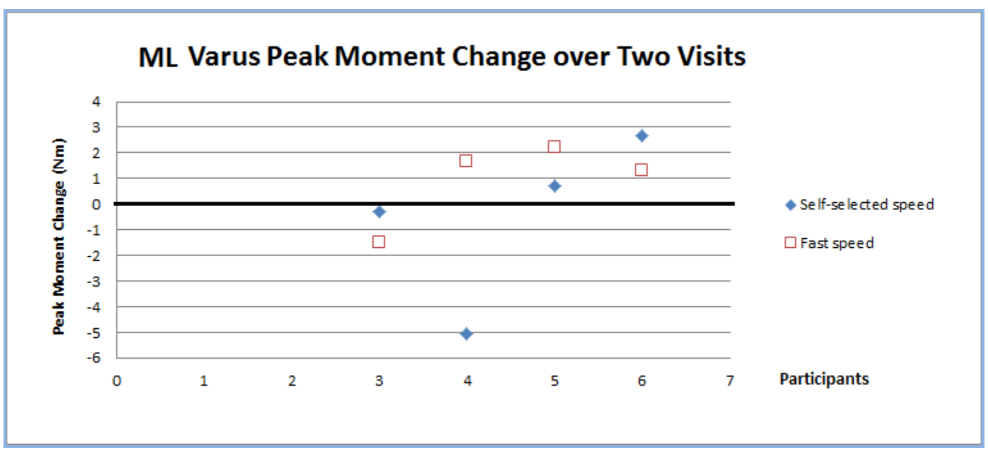

Figure 44: ML varus peak moment values between visits

4. Results from RMS Values of Pelvic Acceleration Data

The root mean square (RMS) values of the pelvic acceleration in all three axes (vertical, ML, and AP directions) were recorded for each alignment technique as a measure of gait stability. Figure 45 depicts a typical example of one participant's five-second acceleration profile during a 10-meter walk. The thick black lines across each acceleration profile represent the calculated RMS values. Data was missing from participant #3 due to the Shimmer™ device malfunction. Fast walking trials and alignment change data for participant #1 were not collected because the study protocol was refined after the first pilot trial.

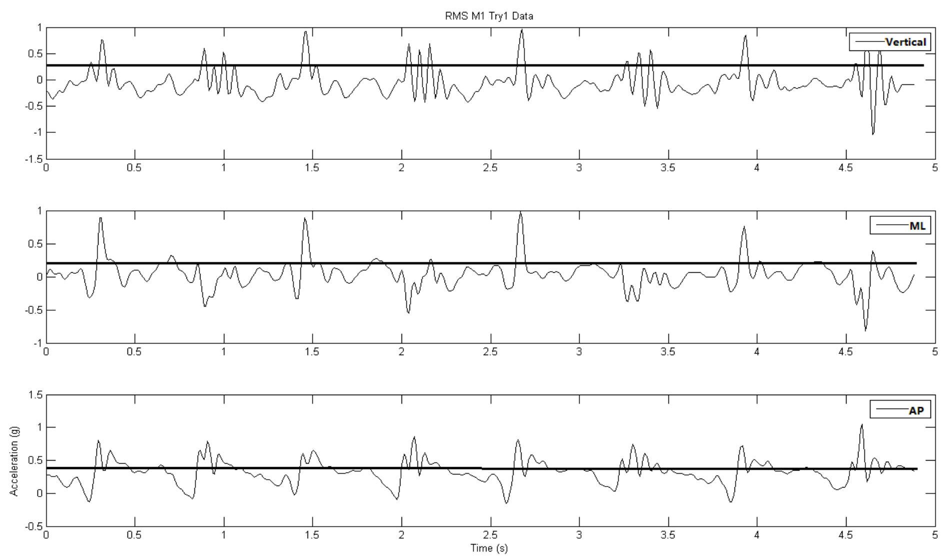

Figure 45: L3 Pelvic acceleration (thin line) and RMS values (thick line) in vertical (top), ML(middle), and AP (bottom) directions

4.1 Results for primary research question

Three pelvic acceleration RMS variables were compared between the two alignment techniques performed from Visit 1. As shown in Table 9, the average RMS values among participants ranged from 0.06 g to 0.38 g, and the differences in magnitude between techniques were very small. Statistically, no differences were observed.

Table 9: Average RMS of pelvic acceleration variables and statistical test results

RMS Pelvic Acceleration Variables (g)	Trials	Conventional		Compas		Wilcoxon Signed Ranks Test
		Mean	SD	Mean	SD	P-value
Vertical	Self-selected	0.26	0.09	0.30	0.13	0.327
	Fast	0.38	0.18	0.34	0.14	0.345
ML	Self-selected	0.20	0.05	0.23	0.08	0.208
	Fast	0.30	0.12	0.28	0.07	0.249
AP	Self-selected	0.21	0.09	0.20	0.06	0.575
	Fast	0.28	0.12	0.25	0.10	0.249

4.2 Results for second research question

Three RMS variables were plotted against alignment change to look for correlations between pelvic acceleration and alignment change. As shown in Figure 46, Figure 47, Figure 48 and Figure 49, linear regression analysis demonstrated no statistical or graphical significant relationships.

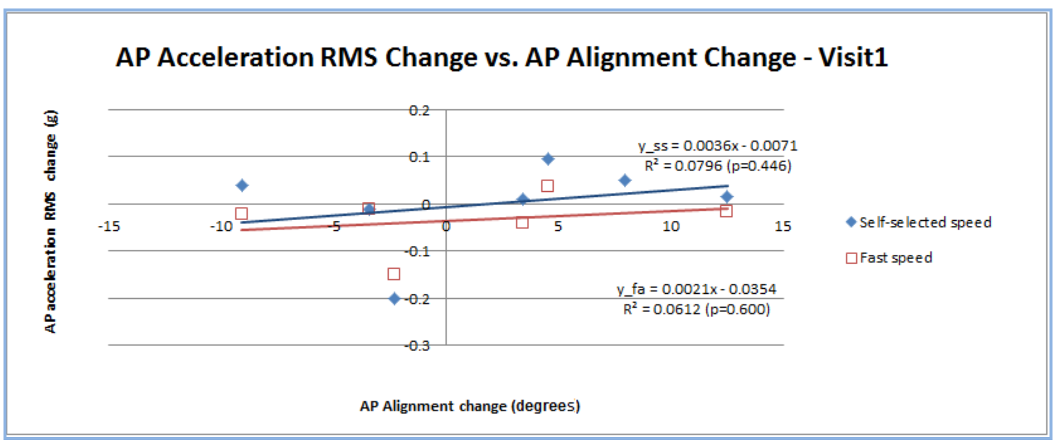

Figure 46: AP pelvic acceleration change with AP alignment change

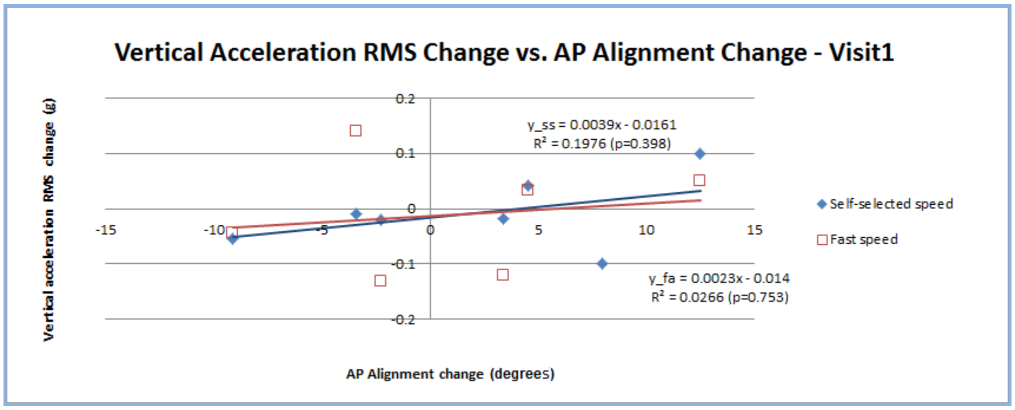

Figure 47: Vertical pelvic acceleration change with AP alignment change

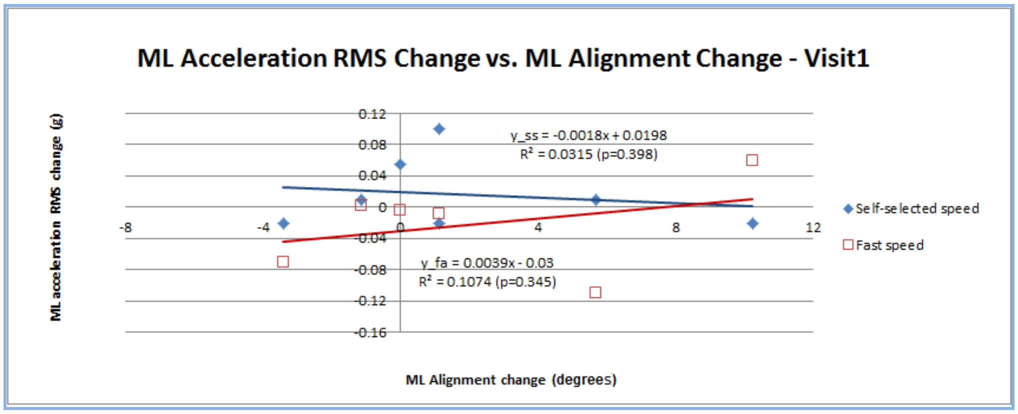

Figure 48: ML pelvic acceleration change with ML alignment change

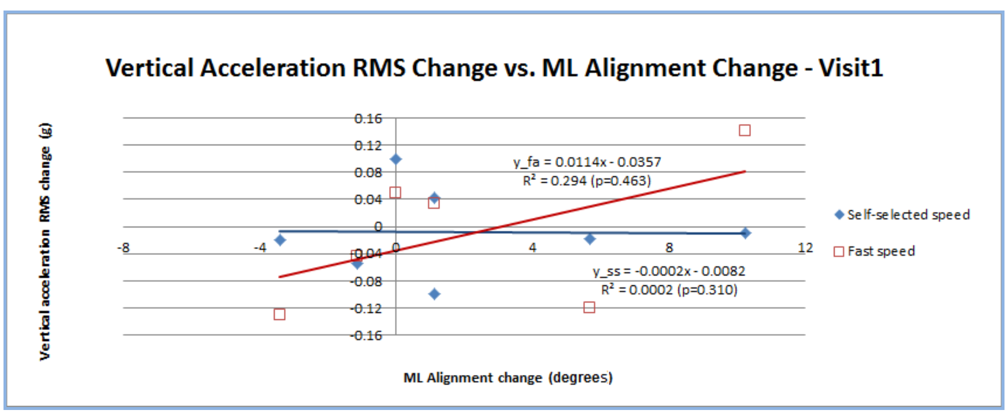

Figure 49: Vertical pelvic acceleration change with ML alignment change

4.3 Results for third research question

For acclimation effects, acceleration data was acquired for only three out of four participants who came for Visit 2, due to the Shimmer™ device malfunction for participant #3. Two participants took the Compas alignment setup home to acclimatize over a week period, and one participant took the Conventional alignment setup home from Visit 1 (Table 6). The following three figures present the results for vertical (Figure 50), ML (Figure 51), and AP (Figure 52) directions. No trends could be observed from the data.

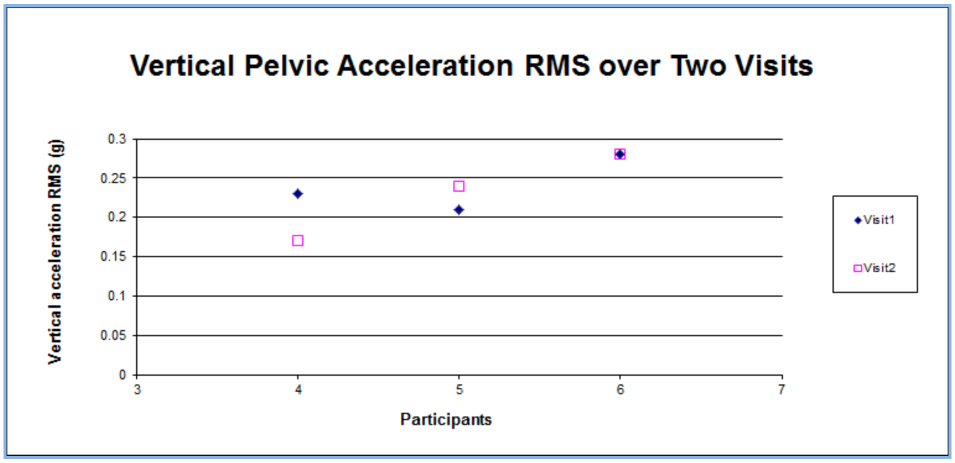

Figure 50: Vertical RMS pelvic acceleration values between visits

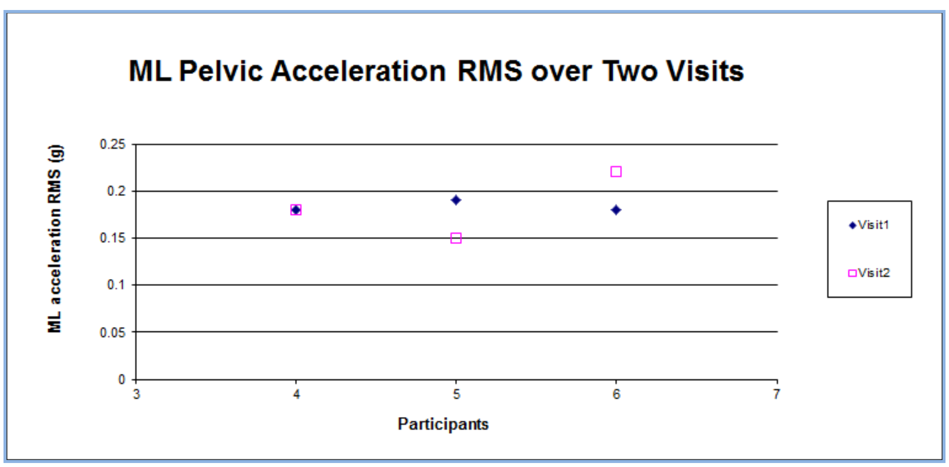

Figure 51: ML RMS pelvic acceleration values between visits

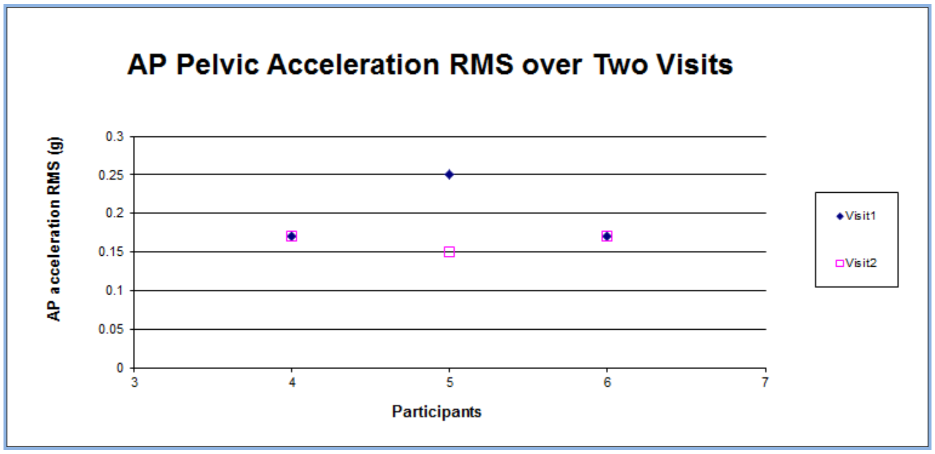

Figure 52: AP RMS pelvic acceleration values between visits

5. Results from Cadence Data

5.1 Results for primary research question

Cadence was extracted from the acceleration data of both visits and compared between the two alignment techniques. For self-selected speed trials in Visit 1, participants' average cadence was 98 (SD=8) steps/min in the Conventional technique and 99 (SD=9) steps/min in the Compas technique (p=0.785, Wilcoxon Signed Ranks Test). The averages for fast speed trials in Visit 1 were 114 (SD=12) steps/min and 111 (SD=16) steps/min, for the Conventional and Compas techniques respectively (p=0.343, Wilcoxon Signed Ranks Test). Depicted in Figure 53 and Figure 54, both visits showed that the Conventional and the Compas techniques had very similar cadence for both walking speeds.

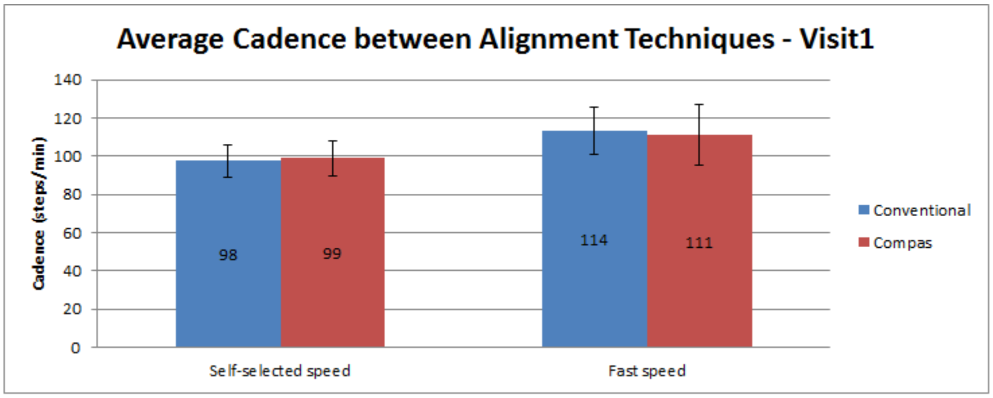

Figure 53: Average cadence between alignment techniques for Visit 1

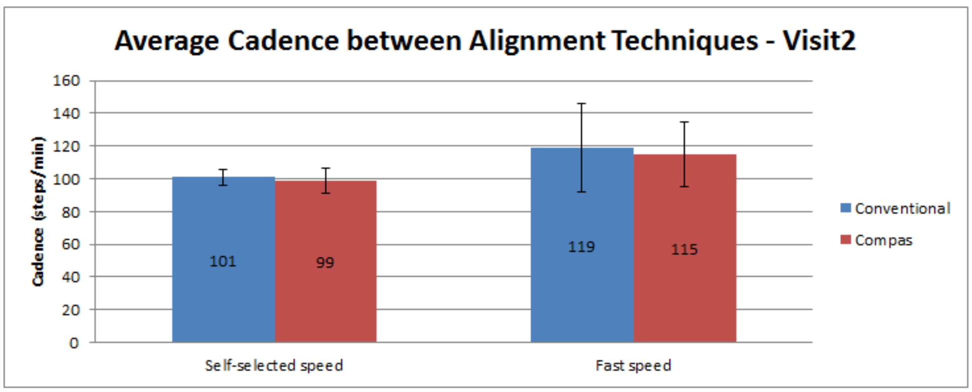

Figure 54: Average cadence between alignment techniques for Visit 2

5.2 Results for third research question

When comparing cadence between visits for the three participants who acquired acceleration data in Visit 2, the results were very similar between Visit 1 and Visit 2, as shown in Figure 55. No acclimation effects could be concluded for cadence.

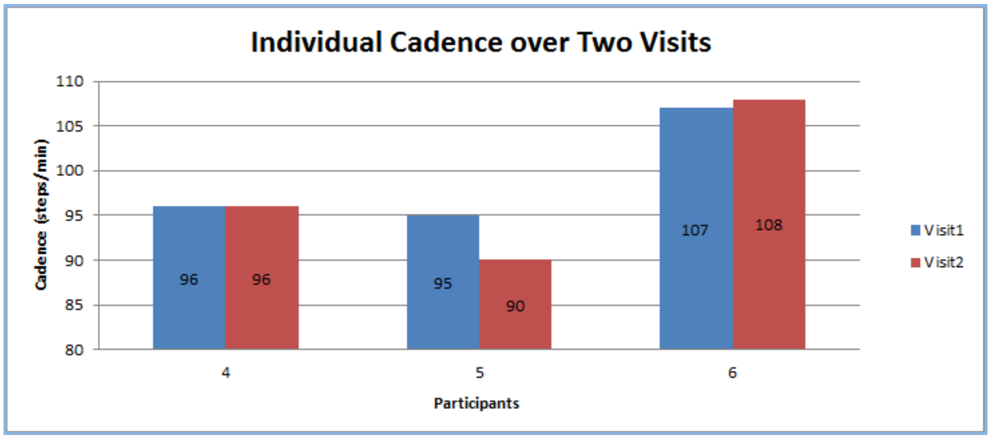

Figure 55: Individual cadence between visits

5.3 Results for validating acceleration data

Since results from the previous section demonstrated that the pelvic acceleration data was not a sensitive measure to alignment change or alignment techniques, in order to examine for its sensitivity, it was assessed with cadence to see whether it was responsive to speed changes.

Cadence of fast speed trials was significantly larger than that of self-selected speed trials (p=0.027, Wilcoxon Signed Ranks Test) for both alignment techniques (Figure 53). Figure 56, Figure 57, and Figure 58 are plots of individual pelvic acceleration RMS values as a function of cadence with data from Visit 1 in vertical, ML, and AP directions. Four conditions for each direction, namely: the Conventional technique with self-selected speed, the Compas technique with self-selected speed, the Conventional technique with fast speed, and the Compas technique with fast speed, were plotted onto the same graph for easier comparison. All RMS values showed a significant positive correlation with speed for both self-selected and fast speed trials (p=0.012 and p=0.028, respectively, Wilcoxon Signed Ranks Test).

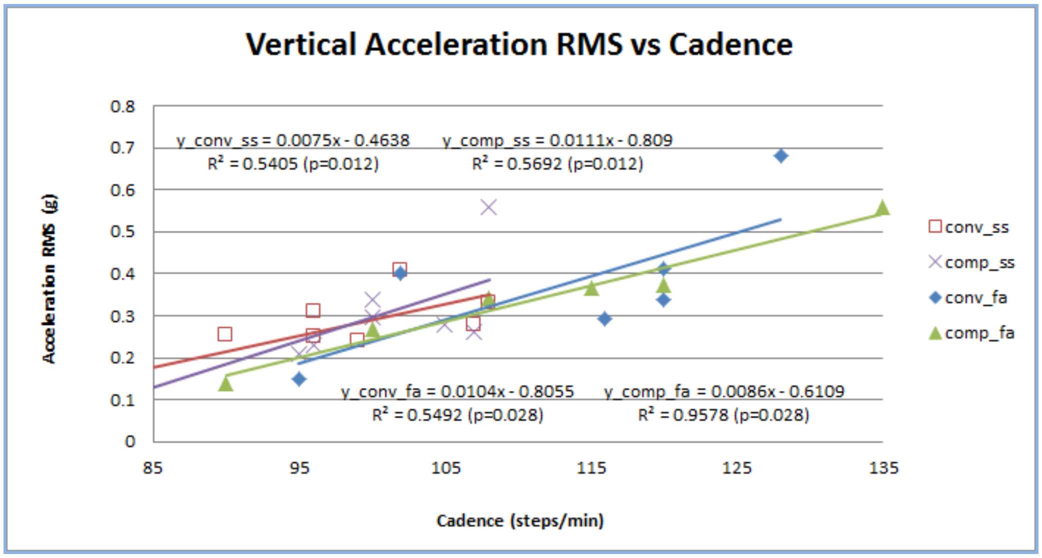

Figure 56: Vertical pelvic acceleration RMS and cadence

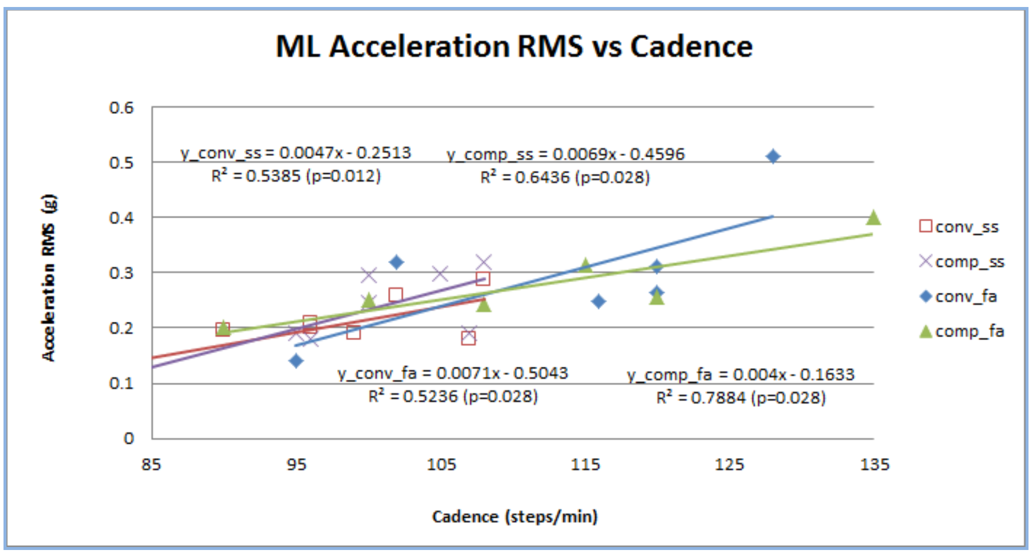

Figure 57: ML pelvic acceleration RMS and cadence

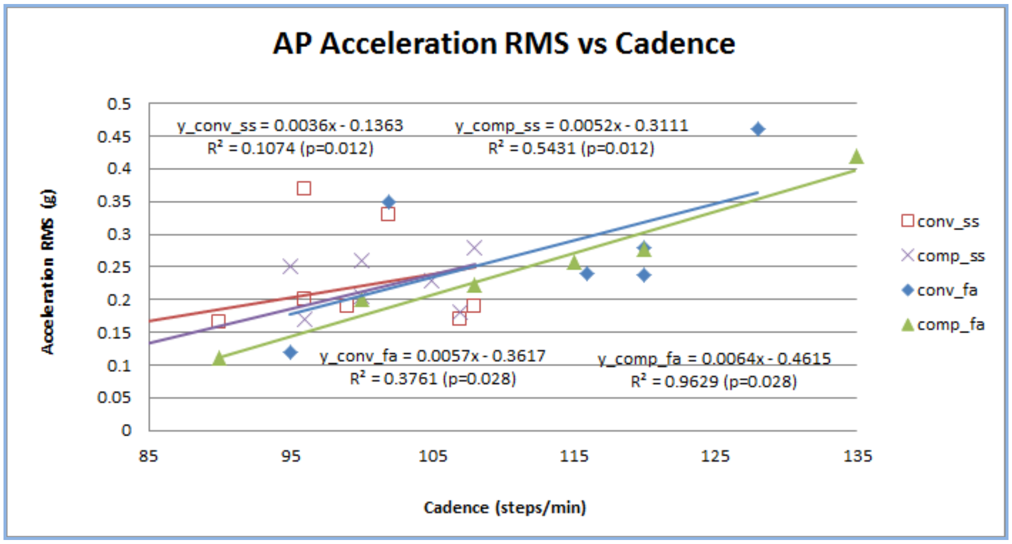

Figure 58: AP pelvic acceleration RMS and cadence

6. Results from Subjective Questionnaire Ratings

Table 10 summarizes individual alignment technique preferences from subjective questionnaires given to both participants and prosthetists. Six out of the nine participants in Visit 1 and three out of the four in Visit 2 could not detect differences made from one alignment setup to another. For the three participants in Visit 1 and the one in Visit 2 who did express a preference, all indicated that they preferred the Conventional alignment setup over the Compas setup. Unlike participants, prosthetists were more aware of the alignment techniques they were using during the clinical visits. Four out of six prosthetists involved in the study claimed to prefer the Conventional alignment technique over the Compas technique.

Table 10: Preferred alignment setup for both visits by participants and prosthetists

Participants	Visit #1 preference		Visit #2 preference		Prosthetists
	Participant	Prosthetist	Participant	Prosthetist	
1	Same	Conventional	--	--	1
2	Same	Compas	--	--	2
3	Same	Compas	Same	Conventional	3
4	Conventional	Conventional	Same	Conventional	4
5	Same	Same	Same	No change	2
6	Same	Conventional	Conventional	Conventional	1
7	Same	Conventional	--	--	5
8	Conventional	Conventional	--	--	6
9	Conventional	Compas	--	--	2

An alignment technique was assigned a numeric value of 1 each time it was mentioned as "preferred" or "the same", otherwise a value of 0 was given. The rating results showed that for both visits, participants and prosthetists alike preferred the Conventional technique to the Compas technique (Figure 59 and Figure 60).

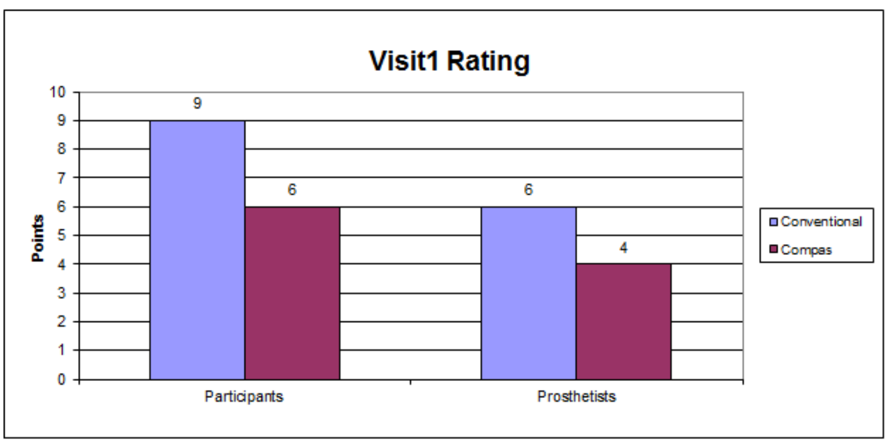

Figure 59: Subjective ratings for alignment techniques in Visit 1

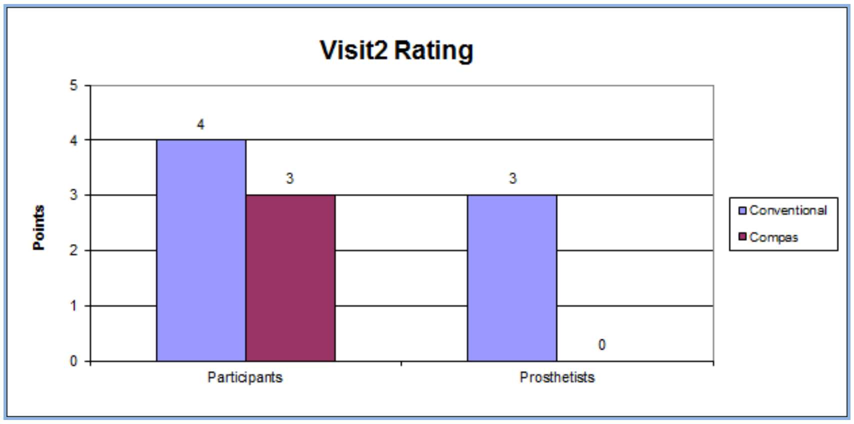

Figure 60: Subjective ratings for alignment techniques in Visit 2

Additional comments collected from these questionnaires (Appendices A2 and A3) are summarized into reasons expressed by the prosthetists for their preferred techniques. Those prosthetists preferred the conventional alignment technique because of two major reasons:

1. The Conventional alignment technique was the one that they were most familiar with, using their personal expertise and professional experience. Therefore, they were more comfortable making adjustments through observing the participants' gait patterns and listening to their feedback. This contrasts with them not being familiar to the Compas technique and following suggestions based on scientific calculations.

2. The Conventional alignment technique allows them to fine-tune each alignment at both the below-socket and ankle locations, rather than just turning screws at the Compas™ pyramid location. They were able to adjust the foot position with translation, eversion/inversion, or dorsiflexion/plantarflexion, to compensate for the changes made at the higher level and to ensure that the foot was always flat on the ground. For both functional and cosmetic reasons, they felt that the Conventional technique produced more appearance-aware outcomes and also minimized the effects on stability and balance. This contrasts with the Compas

technique which only gave alignment change suggestions at the below-socket level because it was limited by the location of the measure taken at the pyramid.

For the prosthetists who indicated that they preferred the Compas alignment technique, two prominent reasons were expressed:

1. The Compas-assisted technique provided a graphical representation of the real-time below-socket moment profile of the participants' prosthesis, as well as the "green zone" of the similar amputee population. This was a useful visual cue in comparing gait pattern and making alignment adjustments.

2. By following through the alignment analysis suggestions one direction at a time, one prosthetist discovered that alignments in the AP and ML planes were not independent. Changing alignment in the AP plane would affect the alignment in the ML plane, and vice versa. This would especially be the case when the pylon was rotated to adjust the direction of progression in the prosthetic foot, where the AP and ML screws were no longer aligned the same as the bench-aligned positions. Therefore, when following the alignment suggestions produced by the Compas™ system, an AP screw turn could no longer be a pure change in the AP direction. Thus alignment suggestions provided by the Compas™ system should be addressed one direction at a time. Initially, the prosthetist should address the ML direction suggestions to make an adjustment because the knee muscles have less control medial-laterally. This is followed by letting the Compas™ recalculate the moment profile and re-analyze the alignment. Once the ML direction was adequately aligned, the prosthetist could proceed to follow the AP screw adjustment suggestions.

7. Results from Focus Group Discussion

7.1 Focus group participants' information

All participants were prosthetists at Sunnybrook Centre for Independent Living (SCIL). A total of six prosthetists contributed through an in-person discussion session and questionnaires. The average number of professional experience years as certified prosthetists was 13 (SD=8) years.

Only four of the six prosthetists had experiences using the Compas™ system at the time of the discussion. They had used it only on a limited basis for the purpose of this study but not on a day-to-day basis as part of their regular clinical practice.

7.2 Focus group findings summary

After gathering and analyzing answers from the discussion session and questionnaires, the following seven topics were identified. This section details the findings for each topic.

1. Definition of an "optimal" alignment and how to achieve it:

   Most prosthetists agreed that an optimal alignment is primarily characterized by an amputee's own perceived satisfaction level. For new and inexperienced amputees, it is generally determined by the professional experience and expertise of the prosthetists. One clinician mentioned that a good goal was to help amputees reach pre-amputation function and mobility level, or the level they would want themselves to be at. However, the outcomes vary from individual to individual and are very much dependent on multiple intrinsic and extrinsic factors. Examples of intrinsic factors are age, gender, comorbidities, injury severity, functional level, athletic ability, health, and mental state. Extrinsic factors could include environmental conditions such as uneven ground, slippery floors due to ice or rain, and other safety concerns.

Biomechanically, “optimal” means attaining equilibrium of socket torque and moments acting on the prosthesis. It can also refer to the minimizing of pain, discomfort, and unusual or high pressure, acting on both the residual limb and the components. Unwanted pressure on the residual limb would lead to stress on the ligaments and joints causing secondary health complications. Unwanted pressure on the prosthesis components would lead to device deterioration and breakdown over time. An optimal alignment also refers to achieving as close as possible to a “normal” gait.

Performing an “optimal” alignment depends on a number of criteria. A prosthetist needs to:

- Reduce areas of high socket pressure
- Check foot placement
- Inspect for skin redness and abrasion
- Observe gait characteristics through gait analysis
- Listen to amputees’ verbal feedback and act accordingly

One important note was the amount of clinical time the prosthetists used to achieve good socket fit and alignment. Most prosthetists agreed that alignment and socket fit were equally important in producing an “optimal” alignment, but that they would typically devote more clinical time to socket fitting. Especially during fine-tuning at the end, it became more difficult to separate issues due to socket fit and alignment. It was also noted that alignment would lose its purpose if the socket was problematic.

2. Challenges in alignment:

When asked to identify the biggest challenge prosthetists found in performing an alignment, the following three points were mentioned most frequently:

a) Running out of room to assemble all the prosthesis components. Prosthetists need to assemble all parts of the prosthesis to fit within the required limb length. This process needs a lot of design and fabrication skills from the prosthetists, especially for prostheses that require specialized components, such as the Compas™ pyramid;
b) Amputee's general health state. If an amputee has diminished sensations due to medication or other factors, verbal feedback becomes less reliable or it may be difficult for them to express how they actually feel;
c) Language barriers.

For point b) above, oftentimes prosthetists need to interpret discrepancies between visual and verbal feedback. This occurs especially when an amputee expresses some discomfort or opinions which cannot be verified through visually inspection. Their verbal feedback might not necessarily be accurate to what is really going on with their prosthesis.

Interestingly, none of them considered the lack of quantifiable technology as a challenge, as they were quite confident relying on their own expertise.

3. Understanding clinical dynamic alignment process:

During dynamic alignment, whether using the Conventional technique or with the Compas™ system, prosthetists often perform either a "translation/shift" or a "rotation/tilt". For transtibial amputees, these adjustments can be done in two areas: below-socket and at the ankle (Figure 6).

When asked which location they would adjust more often, all expressed that both proximal and distal screw adjustments were needed because both must be used to complete a shift. However, the order in which they perform the entire alignment was different due to differences in training and habits.

Three of the six prosthetists would adjust the foot during bench alignment and focus on socket adjustment during dynamic alignment. In their view, the ankle alignment should not be altered too much in order to maintain a straight relation between the socket and the foot. Due to the length of the pylon, adjustment below the socket has the greater ability to move the foot. Also, some foot designs do not allow very much change and have certain flexibilities to allow energy storing and shock absorption. The distal ankle screws are only altered to ensure that the foot remains flat on the ground to compensate for the changes made below the socket.

The other three prosthetists first adjusted the ankle level at the start of the dynamic alignment according to heel height and levels of incline. Then they would check weight bearing and adjust the socket.

When using the Compas technique during clinical visits, prosthetists still followed their preferred practice. Due to conflicting suggestions provided by the Compas™ system and lack of clear instructions in the study protocol, half of the prosthetists also adjusted at the ankle level in addition to the below-socket level. The other half did not adjust the ankle level at all during clinical visits. In addition, since the Compas™ System could not infer adjustment made at the ankle level unless it affected below-socket moment, screw turns at the ankle were not recorded during the clinical visits.

4. Experience and perceptions with the Compas™ system:

   a) When asked how easy it was to understand how to use the Compas™ system, they expressed that it was easy to connect and read suggestions. However, it was difficult to interpret and follow those suggestions given by the Compas. Assembling the pyramid into the prosthesis was the most difficult. The term "time-consuming" was mentioned several times by the majority of the prosthetists and this seemed to be the prominent limiting factor.

b) When asked what they liked and disliked about the Compas, the following points were summarized:

Table 11: Prosthetists' perceptions with the Compas system

Positives	Negatives
• Component was small and portable. • It allowed automated monitoring of functional/biomechanical outcomes.	• Not enough information was provided. • The amount of time required for assembly and setup was too long.

5. Limitations of the Compas™ technology:

a) Below-socket moment is an important variable used by the Compas™ system in assessing dynamic alignment, but variables such as weight line displacement or observational gait characteristics need to also be considered. This technology should be used always in combination with the prosthetists' experience.

b) Both the assembly and connection processes of the system are time-consuming because prosthetists ran into issues with build height when fitting the pyramid into the prosthesis as well as issues with Bluetooth connection when setting up the software. Whether a process takes too long cannot be quantified, but rather measured by clinical efficiency and patient/clinician satisfaction.

c) Overall, the system seems to provide inconsistent data and inaccurate suggestions. Based on prosthetists' comments and consultation with the manufacturer, the current software of the Compas™ system (version 1.2.8 Build 34, Orthocare Innovations, 2009) is not sensitive enough to the finer alignment adjustments. Many prosthetists have had the experience of being given repeatedly the same suggestions even though the alignment changes had already been made. It was reported that when an alignment was closer to adequate, the system would suddenly jump to a two-turn alignment suggestion rather than the usual ¼ or ½ screw turn suggestions and it stayed with this same suggestion regardless of further changes. A 2-turn alignment change was considered to be a big change by prosthetists. Therefore, they were often confused and unwilling to follow such instructions.

d) Fitting the Compas™ pyramid into a prosthesis always affects the overall build height restriction. For someone with a dynamic pylon built into the foot, using the system would necessitate the cutting of the pylon, hence destroying the component. This factor limited the number of amputees who could use the system and reduced the motivation for prosthetists to use it. It would be impractical and financially unrealistic to change the overall build height each time they brought in a new prosthesis for their amputees.

6. Additional features suggestions:

    a) When asked what would help the Compas™ system to become more clinically desirable, prosthetists listed a number of features:

        - Easier fabrication process that does not affect the build height, or provide an increase in funding for custom prosthesis without interfering with clinical resources;
        - More clinically accurate and quantifiable information than it currently provides;
        - More user-friendly (*i.e.* fully setup and ready to go with the press of a button);
        - Able to measure torque equilibrium at various stages of gait;
        - Able to monitor the alignment changes made at the ankle and corresponding changes in ankle moments, in addition to below-socket moments.

b) When asked how the current version of the Compas™ system can be better utilized, two prosthetists affirmed that it was a good pilot device for measuring alignment and could potentially be improved and incorporated into clinical guidelines, fostering evidence-based practice. However, with the limitations explained above, none of the prosthetists would use the Compas™ system as part of their daily clinical routine.

At the current stage, the Compas™ system is suitable for:

- Performing alignment adjustments for unusual cases;
- A new prosthetist who is unsure of the correct action to take;
- Amputee education or documentation to justify an alignment;
- Prosthetic students as a visual teaching tool.

c) When asked about what other tools and parameters would help improve the prosthesis alignment process in general, prosthetists identified the following:

- They would like to more comprehensively measure the amputees' feel before and after each alignment to help interpret areas of discomfort. This would be more than a questionnaire rating;
- They would like to measure real-time high pressure points all around within the socket while standing or walking (as a helpful tool for socket fitting);
- They would like a tool to compare a prosthesis' height to the contralateral limb;
- They would like to obtain smoother transitions at various stages of a gait cycle (*i.e*. from heel-strike to midstance, from midstance to toe-off, and from toe-off to the next heel-strike)

7. Comments about the LASAR System:

   All prosthetists have had some experience using the LASAR System. They would tend to use it mostly for transfemoral amputees during static alignment of the knee components. Since transtibial amputees have their own knee and hence the ability to control knee muscles, it is less useful for this group.

Chapter 6

Discussions and Limitations

1. Discussions

According to expected values described in Table 3, results were compared with the literature to infer findings and corresponding clinical implications for each of the three research objectives.

1.1 Findings for primary research question and clinical implications

First, the LASAR results showed that both Conventional and Compas techniques produced similar AP limb weight line displacements (Figure 21), which were (on average) consistent with the literature recommended value of 15 mm anterior to the anatomical knee centre (Blumentritt, 1999 and Breakey, 1998). Conventionally, prosthetists often tried to match weight lines to the anatomical knee centre point, because the less the displacement, the more optimal the person's balance (Mensch, 1986 and Perry, 1992).

From the same result, participants #4, #8, and #9, had a larger AP limb weight line difference between the Compas and the Conventional values. Interestingly, these three participants were the only ones who expressed preference in the subjective questionnaire. All three preferred the Conventional technique to the Compas alignment technique, whereas the other participants did not have any preference (Table 10). This could imply a correlation between larger weight line displacement and detectable perception to alignment change. On average, amputees could be pleased with a range of alignment setups in an intra-rater test retest scenario and the acceptable range could expand up to 10 mm socket shift and/or 10° tilt for a transtibial prosthesis (Zahedi *et al*., 1986 and Geil 2002). From Figure 24, it can be observed that the majority of AP alignment changes were within ±5.0 degrees. Therefore, when the difference made between alignments was small it was not enough to be noticed by amputees.

Second, the Compas alignment technique produced significantly more anterior total weight line displacement in the AP direction. There was no literature recommended values for the total weight line displacement. However, by adding the weight-bearing effect of the sound limb (double feet on the LASAR weight platform), participants could utilize the other knee and ankle to maintain the right posture in many uncontrolled ways, so individual values varied more as observed graphically in Figure 22. The average values for Conventional alignment technique were very close to zero, which demonstrated that conventionally, prosthetists tried to align the prosthesis to match the AP total weight line to the anatomical knee centre. A more anterior total weight line displacement (Figure 61) produced by the Compas technique could mean that the transtibial amputees utilized fewer upper leg muscles (such as the quadriceps) to stand upright. This result could be clinically beneficial because the amputees tend to stand in a more natural and comfortable position with this posture. They can experience more external extension of the knees and do not need to work their muscles as hard to remain upright (Mensch, 1986 and Perry, 1992).

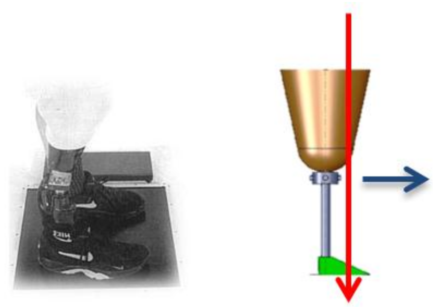

Figure 61: Direction of AP total weight line displacement by Compas technique (sagittal view)

Thirdly, the average values of ML limb weight line for both alignment techniques were not close to the literature recommended value of 10 mm lateral to the anatomical knee centre (Seymour, 2002). The differences between Compas values and Conventional values were statistically significant, indicating that the Compas technique produced a more medial limb weight line displacement (Figure 62), which would increase the external varus knee moment on the prosthesis (Mensch, 1986 and Perry, 1992).

Although the sample size was too small to account for outlier effects (Cousineau, 2010 and Field, 2009), through visual inspection, a data point was found to be largely different from others, *i.e*. participant #5's data (Figure 23). Also, due to large standard deviations in data between the Compas and Conventional alignment techniques (24.4 mm and 27.2 mm respectively), the statistical significance of this result was debatable. When examined more closely, participant #5 had the lowest LCI scores (Table 5) and was noted to have low pain tolerance, which could account for the unpredicted exception in data. In this case, more hip muscles were utilized in the ML direction in achieving external hip abduction/adduction to maintain the upright posture (Orthocare, 2009). With the exception of participant #5, most participants exhibited no change in weight line displacement. Clinically, this result was also not significant.

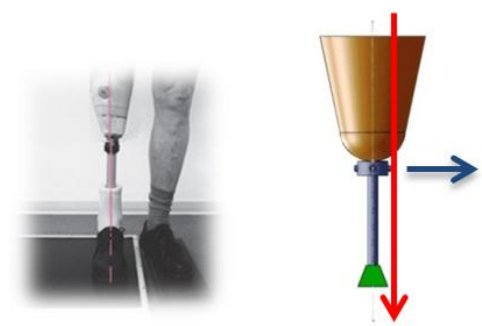

Figure 62: Direction of ML limb weight line displacement by Compas technique (front view, right limb)

The shape of the below-socket moment profiles in the AP direction were similar to the ankle torque and moment graphs from the literature (Klodd *et al*, 2010 and Torburn *et al*, 1990), which confirmed the way each peak moment value was defined. The Compas alignment technique produced significantly greater varus moment (as shown in Figure 63) for all participants at self-selected walking speed except for participant #2 (Figure 32). This person underwent the largest ML alignment change. Depicted more clearly in Figure 40, all peak varus moment values increased from the Conventional technique to the Compas technique with the exception of participant #2 (red circle). While the majority of the ML alignment changes for other participants were within ±3.0 degrees, participant #2 experienced an alignment change of 10.2 degrees (recorded at the below-socket level) in the medial direction. One possible explanation for this exception was that with such a large alignment change, the person was too uncomfortable and used the prosthesis much less than others, which could cause the uncontrolled compensation or perturbations and hence unusual moments in the ML direction.

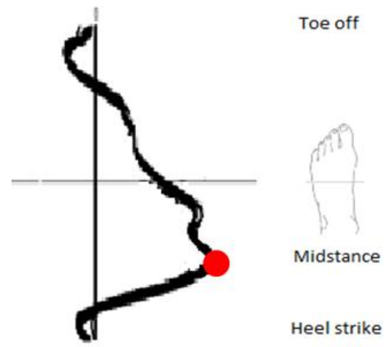

Figure 63: Peak varus moment of a left prosthesis

ML direction alignment changes should have effects over the moment more directly because knee muscles in this case have less control over the gait posture than in the AP direction (Orthocare, 2009). This could be the reason for seeing the significant change in peak varus moments, as the moment profile was more sensitive to changes in the medial direction. However, one needs to realize that statistical significance does not always imply a clinical significance. Excessive medial and lateral moments were not desired clinically, especially when it caused the forces and torques exerted on both sides (valgus and varus) to be unbalanced (Mensch, 1986 and Perry, 1992). Recall the definition of an "optimal" alignment gathered from the focus group discussion in Chapter 5, Section 7.2, in which minimizing high pressures and maintaining equilibrium of moments was one of the goals in producing a good alignment. Therefore, the clinical validity of this result needs further examination.

Lastly, pelvic acceleration RMS values and cadence were not sensitive to alignment changes between techniques. Since pelvic sway was sensitive to speed (cadence) in all vertical, AP, ML directions, it could be concluded that either this result was valid to show there was no significant difference between alignment techniques, or this outcome measure was not a good indicator to evaluate alignments. Although literature suggested that higher pelvic variability might be an indication of ML misalignment (Neumann, 2009), it was not observed with this group of participants. Further research is needed with a larger sample size in the future.

1.2 Findings for secondary research questions and clinical implications

First, the AP total weight line demonstrated a statistically significant correlation with AP alignment change as shown in Figure 25. An anterior alignment change led to a weight line displacement in the anterior direction, and vice versa. This result matched with what was expected in the model in Figure 15.

In the ML direction, perturbations could be hidden by utilizing more hip muscles to maintain an upright posture (Orthocare, 2009). Small effects were still expected such that a medial alignment change would correspond to the ML limb weight line to shift medially and vice versa for a lateral alignment change, as shown in the model in Figure 16. This result might be due to an exceptionally large data point like participant #5 (circled in red, Figure 26), who as mentioned before had the lowest LCI scores and a low pain tolerance. Thus for this individual, even a small alignment change could lead to a large shift in ML limb weight line displacement between alignment techniques. Without this data point, the trend line could have been almost flat.

Peak moment changes were harder to predict in the AP direction because knee muscles exert more control, therefore the body could compensate to hide perturbations to a certain degree (Orthocare, 2009). Based on the model (Figure 17 and Figure 64), an anterior alignment change may increase forefoot moment, and posterior alignment change may increase heel moment (Mensch, 1986 and Perry, 1992). Results from data showed that correlations were weak and not statistically significant (Figure 33 and Figure 34). However, graphically, the directions of change agreed with what was expected from the model.

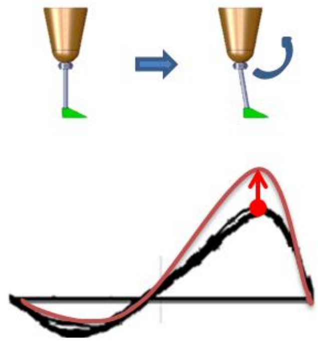

Figure 64: Anterior alignment change causes forefoot moment increases

When adding the misalignment data into the comparison, for both self-selected (Figure 35) and fast speed (Figure 36 and Figure 38), five out of seven participants' data demonstrated that an anterior alignment change leads to an increase in peak forefoot moment, and a posterior alignment change would lead to greater heel moment. This agreed with what was expected from the model. Participants #3 and #5 showed the opposite. Again, participant #5 had pain-tolerance issues and low LCI scores, which could account for unpredictable gait compensations. For participant #3, one possible explanation for the exception is the different type of prosthetic foot and socket suspension used. Although the majority of the participants had a SACH or flexed energy-storing foot and most suspensions were just socket sleeve and liner, participant #3 had a pin suspension and a reflex rotate prosthetic foot on his new prosthesis. Biomechanically, this suspension type would allow more shock absorption and this foot type more degree of freedom at the ankle, thus reducing the energy cost and flexion moments (Torburn *et al*, 1990). It is anticipated that with a larger sample size, these effects might become more apparent.

In terms of pelvic accelerations, according to the gait deviations described due to alignment changes and the corresponding postural compensations (Table 1), an anterior alignment change in the model would lead to more knee super-extension and hip-hiking and vaulting on the sound side to push off the prosthetic foot. A posterior alignment change would need more pelvic thrust and even shoulder movement to bring over the prosthetic foot. Thus in both cases, an alignment change in the AP direction would expect to affect or increase the AP and vertical pelvic variability (Mensch, 1986 and Perry, 1992). However, these relationships were not observed (Figure 46 and Figure 47). Possible explanations could be that participants compensated the pelvic sway with other gait postures such as forward/backward upper trunk leaning or that the alignment changes were not large enough to cause these expected differences.

In the ML direction, a medial alignment change would cause pelvic thrust laterally on the sound side to return the centre of mass to recover balance; whereas a lateral alignment change would cause the trunk to bend laterally towards the prosthetic side to avoid discomfort. For these cases, alignment changes in the ML direction would also expect to increase pelvic movement as an effort for balance (Mensch, 1986 and Perry, 1992). Literature also suggested that alignment changes would be more sensitive to excess pelvic sway in the ML direction during walking because of more utilization of the hip for stability (Neumann, 2009). Data in both Figure 48 and Figure 49 did not show any significant relationship. Again, the alignment changes may not have caused large enough differences, or the compensative mechanisms during gait such as medial/lateral shoulder thrust could be another reason for the discrepancy between the result and the expected trend.

Lastly, data was underpowered to conclude for acclimation effects. Due to the small sample size and technical issues, only three or four data points were compared. The LASAR weight line showed anterior (Figure 29 and Figure 30) and lateral (Figure 31) directional shifts over time for all four participants, and three out of four participants had a decrease in forefoot moments (Figure 41) and an increase in heel moments (Figure 42) over time. These results demonstrated that participants may be adjusting to the new alignment via certain bodily compensations, and the magnitudes of these changes over time were comparable to those due to alignment changes. Also, the lack of stability of the data might be also due to that fact that some participants forgot to wear the same pair of shoes for Visit 2, and that the toe-in/toe-out positions of the prosthetic foot could have been different from Visit 1. A study by English *et al.* (1995) that examined the effect of amputee acclimation period on biomechanical variables recommended an acclimation time of at least three weeks. One week period was chosen for this study based mainly on prosthetists' expertise and clinical feasibility. However, due to lack of scientific evidence whether it was sufficient for stabilization of kinetic and gait parameters was unknown. If the overall biomechanics of the "body/prosthesis system" were still changing throughout the provision of the new prosthesis, then it was important to reassess alignment after several weeks and to make necessary adjustments according to individual needs.

2. Limitations of Study Design

1. Ankle alignment changes not recorded

As learned from the focus group results, to complete an alignment change, both adjusting screws at the below-socket and ankle locations were needed, as shown in Figure 6. As noted earlier, for some participants, ankle screw adjustments were made during the study, but they were not recorded. This was one of the biggest limitations in the study design for two reasons. Firstly, the Compas™ system only recorded moment and gave screw-turning suggestions at the below-socket level, yet the suggestions were vague and conflicting in that both a tilt and a shift were recommended to correct one single misalignment. Secondly, clinical visits lacked instructions to specify where the alignment changes should be made. Consequently, prosthetists were unclear about how to follow the instructions to make alignment changes during the clinical assessments. Half of the prosthetists followed the Compas™ suggestions strictly and only adjusted below-socket screws to complete a tilt, and the other half used their own interpretation of a shift and adjusted screws at both locations. This issue due to different clinical practice only became apparent at the later stage of the study through analyzing the focus group discussion results. Consequently, the study protocol was not changed, and the alignment changes recorded could in fact be either a tilt (if screws at only one location were adjusted) or a shift (if screws at both locations were adjusted). The assumptions and predictions from the model in weight line displacement and moment peak magnitude would be different depending whether they were postulated from a shift or a tilt. Thus, this would add complexity in interpreting correlations between the numbers and locations of screw turns and the outcome measures of each alignment adjustments.

2. Prosthetists-related effects

In this study, there were six prosthetists involved giving the alignments and nine participants receiving the alignments. The study protocol had no controls for the inter-person variations existed among different prosthetists or for their level of experiences. Although these effects would add noise to the data because prosthetists' clinical practice and training varied, in reality, even within-person practice had variations. One alignment produced by a prosthetist was not exactly the same as another alignment produced by the same person on separate occasions (Zahedi *et al*. 1986). In fact, this "noise" could also be advantageous because it added variation to the data and prevented the results from being biased, which could be the case if there were only one prosthetist performing the alignment with the same order and practice.

3. No randomization for alignment techniques performed

The study protocol was designed to place the Conventional alignment technique before the Compas technique because in this way, prosthetists would not be influenced by the Compas™ suggestions when performing the Conventional alignment technique. Since the order of the alignment techniques was not randomized, order and learning effects were potentially introduced to the data with this protocol, but were very difficult to be accounted for in the outcome measures. Also, the participants' subjective ratings were not affected in that they were blinded in knowing which alignment technique was being tested.

4. Limited to below-socket moment measures

The moment profiles of the prosthetic foot could be measured in a number a locations for transtibial prosthetic users. However, the below-socket location was used arbitrarily because of the requirement for the Compas™ pyramid to be placed at the bottom of the socket. Therefore, it was difficult to compare the resulting profiles to the literature because most measures were taken at anatomical locations such as the ankle, knee, and hip locations. Although the forefoot/heel moments were similar to the ankle torque/moment profiles in the AP direction (Klodd *et al*, 2010 and Torburn *et al*, 1990), the comparison was not exact. The only comparison provided by the Compas™ system was against the "green zone" database of "normal" data. However, the manufacturer did not provide any details to the precise origins of these data (Orthocare, 2009). Nonetheless, the analysis performed in this study used within-person comparisons of alignment techniques, so this limitation did not hinder achieving the research objectives.

Alternatively, according to the focus group discussion outcomes, other variables were identified by prosthetists as being important in prosthetic alignment, such as measuring ankle moments, pressure inside the socket, and how moments could be reduced during various stages of gait.

5. Participants' characteristic effects on alignment

There were a number of participants' characteristic factors not taken into consideration when assessing alignment outcomes. These factors were foot and suspension types, toe-in/toe-out positions of the prosthetic foot, shoe designs, participants' weights, and residual limb lengths. The Compas™ system asked to record this information, but it was not clear how these factors would affect the moment profiles it measured. There were other potential confounding factors. Participant #7 was not able to perform fast walk trials due to excessive pain felt inside the new socket and due to fatigue from trying out the new prosthesis, and participant #5 had pain intolerance issues which affected the alignment outcomes. Individual medical and psychological health conditions were also important considerations when assessing prosthetic alignment. Thus, in future studies, efforts should be directed also to quantify these factors and to understand how they affect alignment outcomes.

6. Small sample size

This study experienced a fair amount of difficulty in recruitment of unilateral transtibial amputees. Originally 16 individuals comprised the proposed number. However, due to a lack of suitable patients and various unpredictable reasons in the clinic, only nine were recruited for Visit 1 and only four for Visit 2. Considering the nature of this field, this was still a reasonable sample size compared to past studies where only three of 34 alignment studies over the past 35 years recruited more than 10 amputee participants (Neumann, 2009).

7. Subjective measures

In this study, several subjective outcome measures were used, such as focus group discussion, questionnaires, and how each alignment was performed by individual prosthetist. However, the field of prosthetics does rely heavily on subjective results and it has been using these measures successfully for many years (Condie et al, 2006 and

Boone et al, 2006). Ultimately, the optimality of an alignment still links tightly to the patients’ satisfaction with their prosthesis. There will always be variations in the outcome, as each patient demands individual alignments to achieve personalized improvements.

Chapter 7

Conclusion and Future Work

In conclusion, the instrument-assisted alignment technique using the Compas™ system resulted in more anterior AP total weight line displacement and greater varus moment on the prosthesis. A more anterior weight line displacement would promote more knee extension while putting less stress on quadriceps muscles, which could be clinically beneficial by improving amputees' standing stability. However, a greater varus moment would not be clinically desired because equalizing unbalanced torques/moments on the prosthesis was identified through the focus group as one of the criteria for optimal alignments. Alignment changes did not affect pelvic acceleration but did cause certain biomechanical changes. Although the instrument-assisted alignment technique did not produce better alignment, this study presents pilot results in understanding the effects of alignment changes to biomechanical outcome measures.

The current version of the Compas™ system is not clinically feasible as prosthetists would not use it due to lack of clinical time and difficulty with assembly and setup. This system was designed to assist prosthetists to adjust and measure dynamic alignments based on objective evidence without having to have a full gait lab or specially trained staff. However, at the present stage, it can only serve as an evidence-based teaching or justification tool to amputees or prosthetic students.

Lastly, a list of limitations and additional features were gathered from the focus group discussion to help improve the Compas™ system. Further research with a larger sample size and additional ankle moment or alignment change recordings is needed to verify the findings.

The contributions of this study are as follows:

1. The process of evaluating and learning prosthetic alignment techniques could help researchers and clinicians to develop a deeper appreciation and acknowledgement of the complexity of the problem. The success of the outcomes of an alignment could never be determined merely by a single quantitative biomechanical measure or solely through the subjective feedback of the individual. Rather, it is a comprehensive process which can be best achieved using the combination of scientific justification, prosthetists' expertise, and amputees' satisfaction level.

2. A thorough understanding of the current clinical practice of transtibial prosthetic alignments could help future endeavours to develop more effective outcome measures in addition to the outcome measures used in this study. Some examples of such outcome measures are ankle alignment changes, within-socket pressure, toe-in/toe-out effects, and prosthetic foot types.

3. There still exists a great need of usability studies to examine the accuracy and validity of innovative technologies such as the Compas™ system in the field of prosthetics. For any alignment technology to be clinically feasible, researchers and developers should work alongside prosthetists in the clinic to really understand their needs and expectations. It is important for the technology not only to provide adequate and accurate scientific evidence, but also to fit nicely into the current clinical workflow.

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Appendix A1
Questionnaire – Participant Information

Client ID: **PAGE __**
Date: ___________________________

PROSTHETICS QUESTIONNAIRE – Participant Information (Visit 1)
Sunnybrook Health Sciences Centre
Holland Bloorview Kids Rehab

Gender M F

Date of birth ____________________________ ____ years

Time since amputation ____________________________ ____ years

Amputation cause ________________________

Name of primary prosthetist ________________________

No. of years with this prosthetist ________________________

Time with current prosthesis ____________________________ ____ years

Condition of residual limb: ______________________________ Side: L / R

Measure:

Residual limb length: _______________ (PTV to end of tissue)

Prosthesis length: ________________ (PTV to bottom of foot)

Socket and Suspension Type: __________________________________

(Belt, suction etc.)

Foot type: ____

(SACH, Seattle, energy storing, etc.)

How many days did you wear your prosthesis in the last week? ______________

How many hours per day? ____________________

Client's weight (to be measured with prosthesis) ___________________ lbs. kg

Client's height (to be measured) ___________________ inches cm

BMI ____________________

Appendix A2
Questionnaire for Participants

Client ID: **PAGE __**
Date: ________________________

PROSTHETICS QUESTIONNAIRE for participants

– Alignment Evaluation (Visit___)
Sunnybrook Health Sciences Centre
Holland Bloorview Kids Rehab

Circle one response for each item (Alignment technique _________)

* Make sure client's responses are based on the immediate prosthetic setup

1) Are you satisfied with the comfort of this prosthetic setup when you stand?

Not at all A little Somewhat A lot Very much

2) Are you satisfied with the comfort of this prosthetic setup when you walk?

Not at all A little Somewhat A lot Very much

3) How satisfied are you with how this prosthesis feels when you stand?

Not at all A little Somewhat A lot Very much

4) How satisfied are you with how the prosthesis feels when you walk?

Not at all A little Somewhat A lot Very much

5) Is it difficult to walk with this prosthesis?

Not at all A little Somewhat A lot Very much

6) Overall, how satisfied are you with the current alignment of your prosthesis?

Not at all A little Somewhat A lot Very much

Do you prefer this alignment and why:

____

Appendix A3
Questionnaire for Prosthetists

Client ID: **PAGE __**

Date: ________________________

PROSTHETICS QUESTIONNAIRE for Prosthetists

– Alignment Evaluation (Visit ___)
Sunnybrook Health Sciences Centre
Holland Bloorview Kids Rehab

1) Which alignment setup did you prefer the most and why: **(first, or this one)**

____

EXAMINER TO PROVIDE THIS INFO:

A) Order of testing: **____ Conventional**

____ Compas

B) Alignment taken home for one-week acclimation:

____ Conventional

____ Compas

Appendix B
Locomotor Capabilities Index

Client ID: **PAGE __**

At the present time, would you say that your patient is
“able” to do the following activities WITH HIS PROTHESIS ON?
(Observation)

Scale descriptors: 0 = no 1 = yes with help 2 = yes with supervision 3 = yes alone
(Circle one number for each item)

ITEM	SCALE			
1. Get up from a chair	0	1	2	3
2. Walk in the house	0	1	2	3
3. Walk outside on even ground	0	1	2	3
4. Go up the stairs with a handrail	0	1	2	3
5. Go down the stairs with a handrail	0	1	2	3
6. Step up a sidewalk curb	0	1	2	3
7. Step down a sidewalk curb	0	1	2	3
Basic activities score	__/21			
1. Pick up an object from the floor (when you are standing up with your prosthesis)	0	1	2	3
2. Get up from the floor (*e.g.* if you fell)	0	1	2	3
3. Walk outside on uneven ground (*e.g.* grass, gravel, slope)	0	1	2	3
4. Walk outside in inclement weather (*e.g.* snow, rain, ice)	0	1	2	3
5. Go up a few steps (stairs) without a handrail	0	1	2	3
6. Go down a few steps (stairs) without a handrail	0	1	2	3
7. Walk while carrying an object	0	1	2	3
Advanced activities score	__/21			
Total score	__/42			

Appendix C
Data Collection Sheet and Checklist

Client ID: **PAGE __**

Date: ________________________

Data Collection Sheet & Checklist (Visit ___)

Consent form signed ☐

Prosthetist: ____

Compas

Compas direction: facing up / down

Floor to bottom of pyramid: _________________________ cm

(Enter into Compas set up: + 0.5cm)

Check if completed:

Info Sheet (Visit 1 only) ☐

LCI (Visit 1 only) ☐

BORG score (if applicable) ☐

3 Questionnaires (for participant, 1 for each alignment / misalignment) ☐

Questionnaires (for prosthetist) ☐

Second appointement date? ____

Client ID: **PAGE __**

Date: _________________________

(Visit ___)

Alignment method used: (Conv, Compas, Mis) **#_____________**

LASAR

*Sign convention for left prosthesis:
+ Anterior - Posterior
+ Medial - Lateral

AP weight line displacement to knee centre: ______________ mm (single foot on platform)

______________ mm (double feet)

ML weight line displacement to knee centre: ______________ mm

10-m walk test

File names:

Compas™: __________________________________fast:______________________________

Shimmer™: _________________________________fast:______________________________

L3 Pelvic sensor #_____________ (Bluetooth connection COM port #____)

Alignment set screw turn recording:

Conventional to Compas	Compas to misalignment

Appendix D
Focus Group Discussion Questions

1. From your experience, how do you define an optimal transtibial prosthetic alignment? How do you best achieve this?

2. From your experience, what is the biggest challenge when you perform a transtibial alignment? Why?

   (*i.e*. expertise, patient's psychological and general health state, lack of technology, etc.)

Two alignment techniques are used in this study:
3. Conventional (subjective, or how a prosthetist would normally align) 4. Compas (use the Compas™ System to make alignment changes)

3. When you align conventionally, do you adjust screws between socket and pylon, or at ankle level, or both? What's the purpose of ankle adjustment?

4. Under what condition do you perform a 'translation/shift'? a 'rotation/tilt'?

5. Was it easy to figure out how to use the Compas™?

6. When you align with Compas, do you adjust screws at ankle level? If you do, why do you think it's necessary?

7. What did you like about the Compas™ system in your clinical practice?

8. What didn't you like about the Compas™ system in your clinical practice?

9. In your opinion, what are the limitations of the Compas™ system, if any?

   (*i.e*. missing ankle moment information, confusing suggestion box comments, time required to apply, *etc*.)

10. What additional features would you like to see in the Compas™ system that would help improve the prosthesis alignment process and hence become more clinically useful? (*i.e.* to simplify or speed up the alignment, or to produce better alignment results, such as more stable and normal gait, more even weight distribution, less discomfort, etc.)

11. How and when would you use the LASAR system as you perform an alignment? Explain.

Focus group questionnaire

1. What are your years of experience as a prosthetist? ________________________
2. How many times have you used the Compas for prosthesis alignment? _________

   On how many clients? _________

3. Would you use the Compas system in the clinic? If yes how and when would you use it as you perform an alignment? As a visual assistive tool? If not why not? Explain.

____

____

4. What additional features proposed from question #9 above about the Compas system you like the most?

____

____

5. How many times have you used the LASAR system? ____________

6. In your opinion, can the LASAR system help improve alignment?

7. Can you think of other tools/technology that could help you make better alignment?

____

____

8. Do you have anything else you would like to share? It would be great if you do!

____

____