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The Effects of Prosthetic Alignment over Uneven Terrain

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The Effects of Prosthesis Alignment over Uneven Terrain

A THESIS

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Abstract

The purpose of this study was to analyze kinetic and kinematic data of individuals with unilateral transtibial limb loss and the effect different alignments have on the individual's gait while they walk over uneven terrain. Individuals with lower limb loss are currently having their prostheses dynamically aligned to ensure a satisfactory walking gait on level ground with smooth surfaces, usually in the clinician's office or hallway. This study was looking to determine whether or not current prosthesis alignment procedures are adequate for determining a satisfactory walking gait on non-level and non-smooth terrains as well level smooth surfaces. An effective and efficient walking pattern is necessary to prevent degenerative conditions within the bones, muscles or other tissues of the body, due to compensations of the gait pattern. Sometimes, individuals are able to mask any compensations if their safety is unaffected by their surroundings and they are able to maintain a gait that appears normal or optimal. However, if terrains used on a daily basis present a sense of insecurity, gait compensations could be more problematic to the individual and they need to be addressed and corrected as best they can. This study determined that while there were some changes in gait on the uneven surface, due to the number of subjects it is unclear whether the changes are significant. The individuals showed a decrease in walking speed and step length and an increase in step width. There were also changes in the peak axial force.

I. Introduction

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Individuals with unilateral transtibial limb loss sacrifice comfort, stability, and mobile efficiency due to the mechanical nature of their prosthesis and its interaction with their residual limb. Sometimes individuals with unilateral transtibial limb loss are able to mask any compensations and/or adaptations they may have when walking on level surfaces with their prosthesis not aligned optimally. With the additional element of uneven terrains, individuals may be unable to continue masking the compensations, making them observable to the clinician. The purpose of this study was to determine if the individual's optimized alignment while walking on even ground was also sufficient for walking on uneven terrains. If it was insufficient, additional methods of aligning prostheses are necessary in order to ensure comfort, stability, and efficiency on a daily basis, and on multiple kinds of surfaces.

This study determined there was a decrease in step length and walking speed, and an increase in step width when an individual with unilateral transtibial limb loss walked over uneven terrain. At the same time, we also looked to see if there were changes in the peak axial force for each step. We recruited apparently healthy adults who were at least one year post amputation and who could walk comfortably and unassisted for at least 50 meters. The individuals were asked to walk on both even and uneven surfaces; the uneven surface consisted of loosely packed pebbles of varying size. There were four alignment changes done to each individual's prosthesis. These changes were 4° and 8° of external rotation and 4° and 8° of internal rotation. The two levels of degrees were used to determine if there was a threshold angle where the compensations were no longer able to be masked. Each subject had their self-selected optimized alignment identified as 0°, or neutral, and each of the changes in rotation were done in relation to it. Overall, there were five conditions observed and compared. The two changes in each direction help to ensure the results were more clinically relevant by potentially identifying a threshold angle in which compensations were no longer able to be

successfully masked. The uneven surfaces may have unmasked any gait compensations the individual might have used successfully on even surfaces in order to get through the uneven terrain as safely and comfortably as possible.

Statement of Question

Does a change in prosthesis alignment from an optimized state to that of a non-optimized state in individuals with unilateral transtibial limb loss cause a change in any gait compensations they may adopt while walking through loosely packed pebbles of varying size, as compared to the same misaligned prostheses while walking on even terrain?

Rationale

In order to better understand the transtibial prosthesis alignment process on outdoor surfaces, it is necessary to measure and observe gait on such surfaces. Since we are unable to take our equipment outside, we brought one of many outdoor surfaces into the laboratory. We used a quarter ton of various sized pebbles arranged into a path. Using gait analysis technology to study prosthetics allows for better insight and knowledge about different compensation strategies individuals develop in order to walk as safely as possible in their prosthesis. Therefore, these insights can help give us information for more effective gait training programs and also provide new knowledge for the development of new prosthetic components (J. Rietman, K. Postema and J. Geertzen, 2002). Currently, the dynamic alignment process consists of a prosthetist relying on clinical training in observational gait analysis and experience performing alignment changes producing a satisfactory gait. However, this is subjective and variable process (M. Geil and A. Lay, 2004). In addition to the process being subjective and variable, there are also the manufacturers' alignment recommendations to take

into consideration in order to achieve an optimized alignment. This results in a multitude of information to consider for a safe and comfortable walking pattern.

Realistically, most, if not all, of the surfaces being used to walk on are neither level nor smooth; there are inclines, declines, steps, loose rocks, gravel, sand, and other navigational distractors that need to be taken into consideration. With the conclusion of this study we stand to benefit from additional knowledge of the alignment procedure that can improve current clinical alignment processes by learning that it is not necessarily enough to achieve a satisfactory gait on even walking surfaces, but that walking satisfactorily on uneven surfaces needs to be achieved as well. Sometimes, individuals with unilateral transtibial limb loss are able to mask their gait compensations while walking over level terrain because they do not have insecurities about the surfaces they are walking on, and if the individual is required to concentrate on what they are walking on to ensure security, then any gait adaptations that could have otherwise been masked, may be brought to the forefront and observed (Geil, 2002).

Hypothesis

When individuals with unilateral transtibial limb loss walk through loosely packed pebbles of varying size after the alignment of their prosthesis has been re-aligned by 4 and 8 degrees of internal rotation and 4 and 8 degrees of external rotation, the individual will compensate by decreasing walking speed and step length, and increasing step width.

There will also be changes in peak axial force caused by the changes in alignment when an individual with unilateral transtibial limb loss walks through loosely packed pebbles of varying size.

Delimitations and limitations

The results of this study may be generalized to apparently healthy adult unilateral transtibial amputees between the ages of 18 and 65, whose prosthesis pylon is of an adequate

length to contain the iPecs prosthetic force transducer unit, and who are also able to comfortably walk a distance greater than 50 meters and have had their prosthesis for longer than one year. The results do not necessarily apply to individuals with unilateral transtibial limb loss who currently experience pain associated with wearing their prosthesis or have any other orthopedic impediments, nor do they necessarily apply to individuals with other levels of amputation, such as trans-femoral.

We recognize there are different reasons for amputation and time frames associated with limb loss, limited funds and sample size, as well as equipment issues. Also, the conclusions of this study are observations of the subjects used and must not be generalized to the rest of the population. Therefore, this study has inherent limitations associated with it.

Definitions

Unilateral Trans-Tibial Limb Loss: an amputation occurring only on one leg and below
      the knee.

Contralateral Limb: limb without the amputation, intact limb.

Step Length: the distance one foot moves ahead of the other foot during the gait cycle.

Step Width: also walking base or base of support; the side-to-side distance between the
      line of two feet, usually measured at the midpoint of the back of the heel.

Walking Speed: the distance covered by the whole body in a given time, measured in
      meters per second.

Medial: towards the midline of the body.

Lateral: away from the midline of the body.

Peak Axial Force: the upward force applied by the ground to the foot, in response to the
      downward force applied by the foot to the ground.

II. Background

There have been a number of studies performed pertaining to prostheses giving us the current knowledge we have about the ideal transtibial prosthesis alignment and how it varies among individuals and that optimal alignment allows the individual to go about life in a more secure, comfortable, and efficient manner. However, many of them consider the individual and their prosthesis in either a stationary manner or walking on level ground. The amount of knowledge currently available involving the individual's prosthetic alignment, and in particular, while the individual is walking over uneven terrain, is not quite as vast. Being so, it is necessary to study individuals with limb loss and how uneven terrains influence the alignment of their prosthesis. Achieving this will help us understand how clinicians can ensure comfort, stability, and efficiency; not only on the ipsilateral side, but also on the contralateral side and throughout the rest of the body.

If we first look at normal human locomotion with lower limbs intact, a better understanding of what this study is attempting to accomplish can be achieved. Walking coordinates multiple systems simultaneously, specifically the neurological, sensorimotor, musculoskeletal, and visual–vestibular systems. Therefore, normal gait profiles can be used as a reference point for disability assessment, intervention, and treatment (M. Chiu and M. Wang, 2007). Previous studies found that when individuals without limb loss walk on inclines they tend to have a slower cadence and longer strides, and while they walk on downhill sloped surfaces, they tend to use shorter stride lengths and a faster cadence (K. Kawamura, A. Tokuhiro, and H. Takechi 1991; J. Sun, M. Walters, N. Svensson, and D. Lloyd, 1996). Leroux *et al.* (2002) investigated postural adaptations when walking on smooth but non level surfaces, such as inclines, declines, and stairs. They found that while standing, individuals shift the pelvis and

trunk within their base of support in order to maintain a balanced center of gravity; however, during walking, the trunk is shifted slightly ahead of the center of gravity in order to assist in forward motion propulsion. They also explain that lower limb deficits have the potential to cause more pronounced adaptations at the trunk and pelvis in order to maintain balance while walking uphill and downhill. At the conclusion of their study, they clarify how "postural adaptations are task-specific and the control requirements are different between standing and walking conditions on an inclined surface." With this being said, it is reasonable to also suggest that walking on uneven terrains would require another task-specific postural adaptation since it also has different control requirements. Normal walking requires the individual to use his or her systems together in order to maintain a sense of security. Individuals with limb loss have some of their systems deficient in both efferent and afferent messaging and therefore have to adapt and compensate for those deficiencies first and then for the rest of the information being sent throughout the rest of the body.

Before any dynamic alignments can be done, it is necessary for individuals with trans-tibial limb loss to first have the prosthesis fitted adequately to the residual limb, including both the alignment and tissue contact, in order to maintain both stability and walking flexibility (H. Seelen, S. Anemaat, H. Janssen, and J. Deckers, 2003). Blumentritt *et al.* (1999) mentions that prosthetic alignment has very little effect on muscle activity of the contralateral lower limb during static standing. However, prosthetic alignment has a significant influence on the amputee's ipsilateral knee joint. In addition to methods of measuring static alignment, methods for clinically measuring angular alignment are also necessary. These methods have been explained as "shifts and tilts without a defined reference system" by Zahedi *et al.* (1986) after the original method was developed at University of Strathclyde in 1978 that included an identified socket system (N. Berme, C. Purdey, and S. Solomonidis, 1978). Since then, an

angular alignment measurement system has been developed by way of a protractor that is "light, simple to attach, easy to use and capable of accurately measuring angular alignment changes" (G. Kerr, M. Saleh, and M. Jarrett, 1984). However, these methods are conducted while the individual with limb loss is standing still, sitting or when the individual is not wearing the prosthesis at all. After the prosthesis is properly fitted, the next step would be to align it dynamically. This process involves the prosthetist watching the individual walk and using feedback from the individual and his or her own subjective findings and determining the best alignment. There are many methods for aligning prostheses in this manner, and for the most part it depends on the preference of the prosthetist. As such, it is the job of the prosthetist to be able to perceive what optimal alignment is during observation of the individual's gait. They then interpret the individual's feedback and adjust the prosthesis as necessary (M. Zahedi, W. Spence, S. Solomonidis, and J. Paul, 1986).

During dynamic aligning sessions, it has been found that when individuals with intact limbs and individuals with prostheses were compared to each other after they walked over level and uneven ground, ascended and descended stairs, and ascended and descended ramps, the individuals with unilateral trans-tibial limb loss produced stability parameter values that were higher, or less stable, on the contralateral side and lower values, or more stable, on the ipsilateral side (C. Kendell, E. Lemaire, N. Dudek, J. Kofman, 2010). In other words, the limb with the prosthesis was more stable than the limb that was still intact. Kendell *et al.* concluded by stating "the prosthetic limb had consistently lower outcomes, indicating a gait strategy that optimizes dynamic stability on the prosthetic limb and adaptation by the intact limb." There is agreement that the body compensates for the lack of the lower limb throughout the rest of the body, both muscularly and skeletally. And that this possibly has degenerative effects on the lumbar spine and knees, as well as fatigue and injury to the muscles due to long term muscle

imbalances, and disturbances in the musculoskeletal, neuromuscular, and sensorimotor systems (D. Sanderson and P. Martin, 1996; L. Fang, X. Jia, and R. Wang, 2007; R. Andres and S. Stimmel, 1990). For these reasons, it is important to learn what is happening throughout the rest of the body during movement over uneven terrain since it is probable that uneven surfaces could be used more frequently than even terrains, depending on the individual's lifestyle.

What could complicate these ideas further is that while the individuals with limb loss walk on slopes, upstairs, and non-flat surface roads, pressures at the socket interface are neither uniformly distributed nor proportionately applied (P. Dou, X. Jia, S. Suo, R. Wang, and M. Zhang, 2006). This may be dependent on the type of non-level surfaces used; for example, a non-level but stable surface, like asphalt or grass, versus a surface that is not only uneven but also gives way, like sand or gravel. We are still learning about how uneven surfaces affect individuals with limb loss and with this study, we are attempting to build on what is already known by adding the element of an uneven surface so that we can potentially provide helpful alignment information to the prosthetist on achieving a satisfactory gait on both level and uneven surfaces.

III. Method

Subjects

3 volunteer adults with unilateral transtibial limb loss between the ages of 18 and 65, with adequate pylon length, who can walk comfortably and unassisted for at least 50 meters and have no apparent health issues were recruited for this study. The amputation must have occurred at least twelve months prior to study. Volunteers who have other orthopedic impediments or current pain associated with wearing their prosthesis were excluded. All volunteer subjects signed an informed consent (Appendix A), filled out a PAR-Q health

questionnaire (Appendix B), an activity questionnaire (Appendix C), and were compensated for their time with $40.

Instrumentation

Kinematic data of the lower body was collected via the lower body marker system with Plug-in-Gait by the Vicon Workstation and Nexus system (Oxford Metrics, Oxford, England). Passive reflective markers were used on the lower body and were located on the left and right posterior superior iliac spine, left and right anterior superior iliac spine, both thighs on the lateral side, both knees on the lateral side at the axis of rotation, both tibias on the lateral side, each lateral malleolus, heel of each foot, and the second metatarsal head of each foot. Kinetic data were collected with an iPecs prosthetic force transducer unit (College Park Industries, Fraser, Michigan) which was inserted into the pylon of each subject's prosthesis. The equipment in the Human Movement Lab at Georgia Tech included six Vicon M2 cameras with 1.3 Megapixel resolution at a capture rate of 120 Hz. The data were processed and analyzed using Vicon Nexus Plug in Gait version 1.7.1 and Polygon version 4.0.

Procedures

The subjects and their prosthesis were examined by Robert Kistenberg, Licensed and Certified Prosthetist, and their personally defined optimized alignment was marked as 0, or neutral. All alignment changes were based on an alignment consistency plan of using two rotation increments and four rotation increments of the pylon adapter away from the neutral mark both internally and externally for 4 and 8, respectively. The subjects also stood with their heels lined up against a level board and had the inside line of their shoe traced onto a large piece of paper. After the subject moved from the paper, a straight line was drawn using a ruler connecting the two inside curves. There was a neutral line and then four more lines for

each of the alignment changes, five lines total. We then measured the angle of the neutral line and the first or second lines to ensure the angles were 4 and 8 degrees.

We began with the subjects walking normally with their prosthesis at their optimized alignment along the even pathway (Figure 1) and then the uneven pathway (Figures 2 and 3) second; both pathways were 3.66 meters long. The rest of the eight alignment changes were tested in random order. There were five trials per condition, after the first and fifth trials the subject was asked to give a level of comfort associated with the condition; the rating was based on a scale from 0 to 10, with zero being "worst possible" and 10 being "best ever" (Appendix D). After all the trials were completed, the individuals' original prosthesis alignments were restored and the iPecs unit was removed from their prosthesis pylons.

Figure 1: Even surface pathway taped off and bordering the built in tan colored walkway.

Figure 2: Various sized pebbles used for the uneven surface pathway.

Figure 3: Uneven surface pathway.

Analysis

A descriptive analysis was done rather than a statistical analysis due to the size constraints necessary for the statistical analysis. The variables analyzed were step length, step width, walking speed, and the peak axial force of each step. There were three subjects with five condition changes (4 and 8 degrees of external rotation, 4 and 8 degrees of internal rotation, and self-selected neutral) per subject, five trials per condition, and five steps per trial. We used the average of all five steps per trial and all five trials per subject. Each graph consisted of only one subject and comparisons were made among the five conditions first and between the subjects second.

The following outcome measures were analyzed using bar graphs:

- Step width, measured as the distance between the heel markers on each foot.

- Step Length, the right step length was measured from the toe off of the left foot to the initial contact of the right foot and left step length was measured from the toe off of the right foot to the initial contact of the left foot.

- Walking speed, calculated from the time it took the individuals to walk the distance of 3.66 meters.

- Peak axial force, representing the maximum value from the iPecs transducer for each step.

Each variable was averaged across all 25 steps for each condition.

IV. Results

This was a descriptive study of three subjects (n=3, 1 female, 2 male) with unilateral transtibial limb loss between the ages of 18 and 65 participated in this study (Table 1). All subjects had different prosthesis suspensions and feet and have had their prostheses for more than one year (Table 2). The variability of the conditions was representative of the differences among all the trial conditions, not each individual condition; and the changes in each of the four variables, step length, walking speed, step width, and peak axial force, were described as the uneven terrain with relation to the even terrain.

Table 1: Subject Information						
Subject	Gender	Age	Height, cm	Weight, kg	BMI	Side of Prosthesis
1	Male	61	180.34	100.45	30.9	Left
2	Female	47	170.18	90.91	31.4	Left
3	Male	42	177.8	94.09	29.8	Right

Table 2: Prosthesis Information				
Subject	Suspension Type	Type of Foot	Cause of Amputation	Year of Amputation
1	Pin with 9mm iceross dermoliner	Freedom Innovations Renegade	Trauma	1989
2	Sleeve with 1-way valve, total surface bearing	Otto Bock 1D35	Trauma	2003
3	Elevated vacuum	Endolite Elite 2	Trauma	2001

Subject 1:

Kinematics

On the prosthesis side, there was a decrease in step length on the uneven surface among all five alignment condition changes with the average step length being 0.70m ± 0.01, compared to the average step length on the even surface which was 0.77m ± 0.04 (Figure 4). The contralateral side also had a decreased average step length, 0.64m ± 0.03, on the uneven surface, compared to the average even surface step length of 0.70m ± 0.02 (Figure 5).
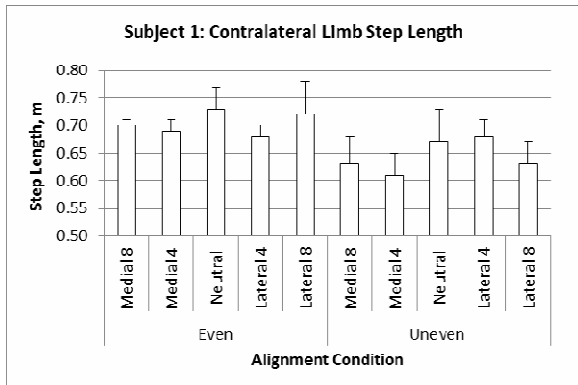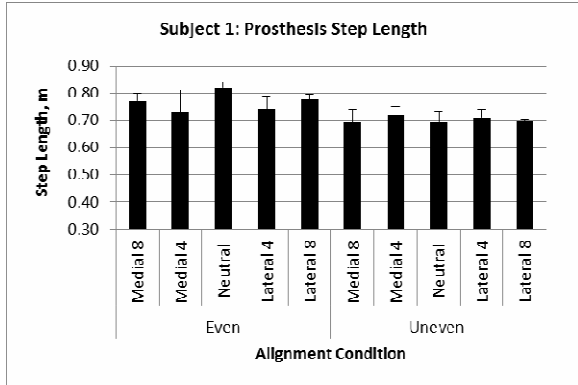
Figure 4: Subject 1, Average Prosthesis Step Length.   Figure 5: Subject 1, Average Contralateral Step Length.

Average walking speed was maintained at the same pace on both the uneven surface and the even surface, however, the speed was more consistent on the uneven surface, 1.06m/s ± .11 and 1.06m/s ± 0.19, respectively (Figure 6).
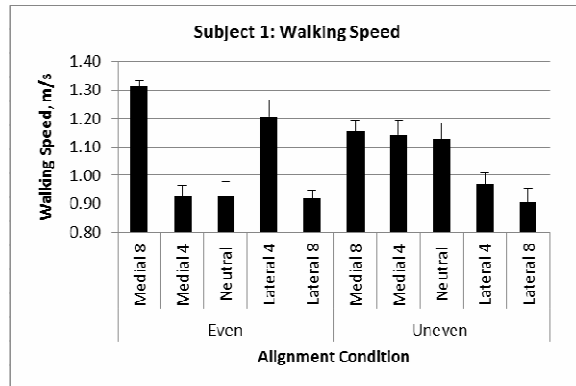
Figure 6: Subject 1, Average Walking Speed.

Both the prosthesis and the contralateral average step widths did not distinctly increase on either the even or the uneven surfaces. Instead, there tended to be an overall increase from the medial alignment changes to the lateral alignment changes on both the even and the uneven surfaces. The average prosthesis step width on the even surface was 0.19m ± 0.02 and on the uneven surface was 0.18m ± 0.04 (Figure 7). The average contralateral step width on the even surface was 0.18m ± 0.03 and was 0.19m ± 0.02 on the uneven surface (Figure 8).
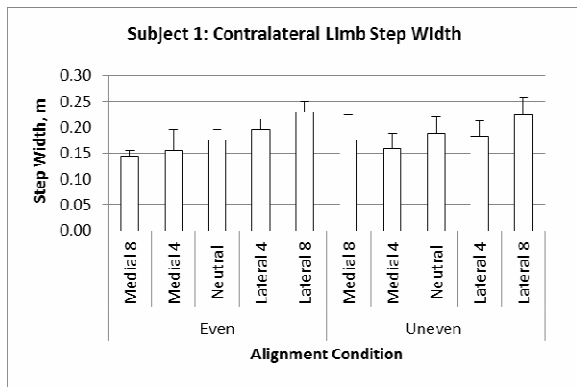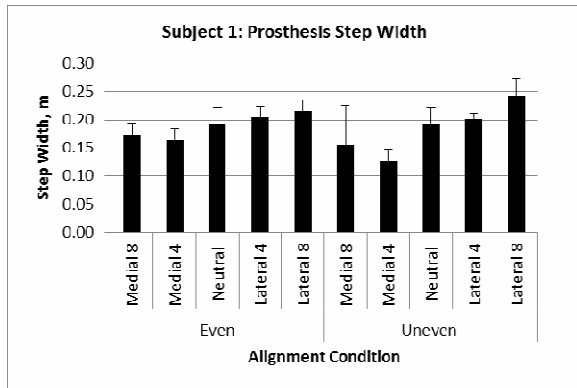
Figure 7: Subject 1, Average Prosthesis Step Width.

Figure 8: Subject 1, Average Contralateral Limb Step Width.

Kinetics

Peak Axial Force decreased and stayed more consistent on the uneven surface than on the even surface, where the average neutral alignment and lateral 8 alignments both brought higher values, 1271.93 N and 1195.88 N, respectively. The average neutral alignment on the even surface was the highest value at 1272.93 N, and the average neutral alignment on the uneven surface was the lowest at 968.84 N. Overall, the average force for the even surface is 1136.48 N ± 93.72, and for the uneven surface is 1043.88 N ± 44.67 (Figure 9).
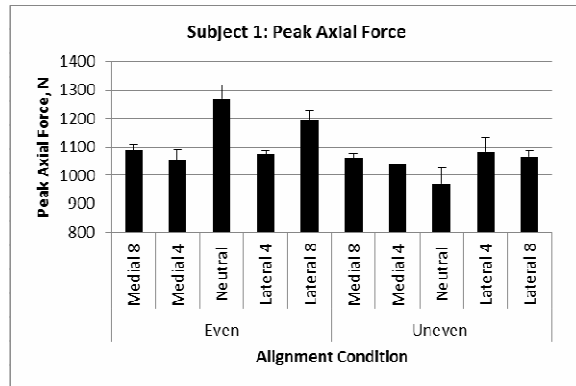
Figure 9: Subject 1, Average of the Peak Axial Force of
all the steps for each condition.

Subject 2:

Kinematics

Both the prosthesis and the contralateral average step length decreased while walking on the uneven surface. The prosthesis average was 0.94m ± 0.09 on the uneven surface and 1.11m ± 0.05 on the even surface (Figure 10). The contralateral average was 0.91m ± 0.07 on the uneven surface and 1.14m ± 0.06 on the even surface (Figure 11).
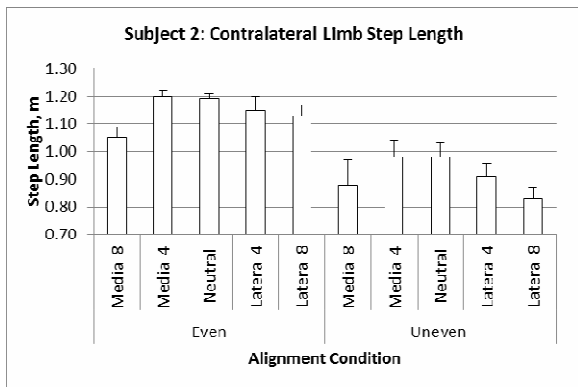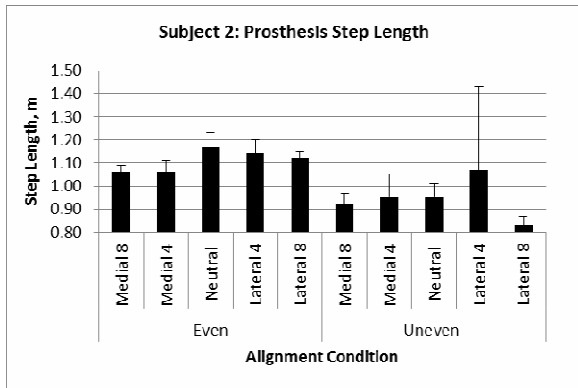
Figure 10: Subject 2, Prosthesis Step Length.   Figure 11: Subject 2, Contralateral Limb Step
                                                                 Length.

Average walking speed decreased to 0.72m/s ± 0.07 on the uneven surface from .99m/s
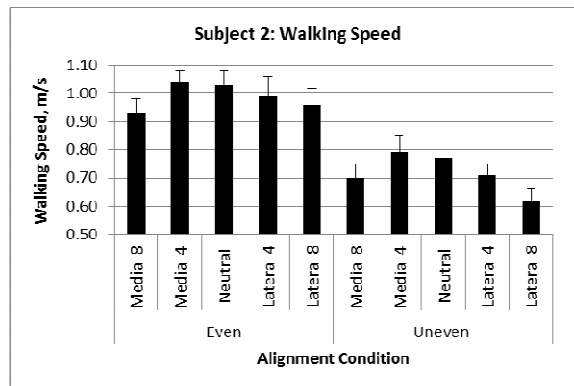
± .05 on the even surface (Figure 12).

Figure 12: Subject 2, Walking Speed.

On the even surface, average step width gradually increased with each alignment change; neutral alignment was the narrowest and the 8° medial and lateral changes brought the largest widths. Prosthesis step width on the even surface started with neutral at 0.26m, increased to 0.27m ± 0.01 with the 4° alignment changes, and increased again to 0.30m ± 0.02 with the 8° alignment change. On the uneven surface, there was a gradual increase in width from the medial 8° alignment to the lateral 8° alignment; the average was 0.26m ± 0.04 (Figure 13). The contralateral side follows the same trends on both the even and uneven surfaces. On the even surface, average step width started with neutral at 0.23m, increased to 0.26m ± 0.01 at the 4° alignment change, and increased again to 0.29m ± 0.03 at the 8° alignment change. The uneven surface brought a gradual increase in width beginning with the medial 8° alignment and moving towards the lateral 8° alignment; the average was 0.26m ± 0.03 (Figure 14). Both the prosthesis and the contralateral average step widths follow the same trends, the contralateral side has the same width for both the even and the uneven surface, 0.26m ± 0.03. The prosthesis side was slightly higher on the even surface than on the uneven surface, 0.28m ± 0.02 and 0.26m ± 0.04, respectively.
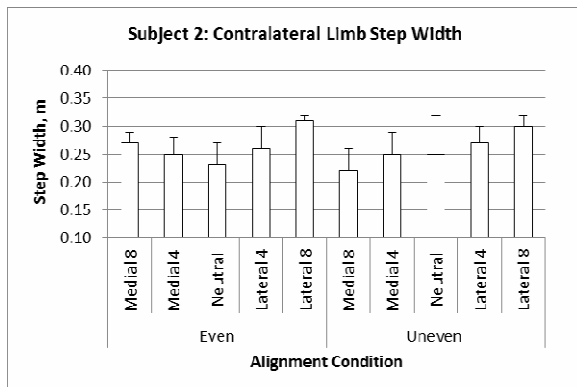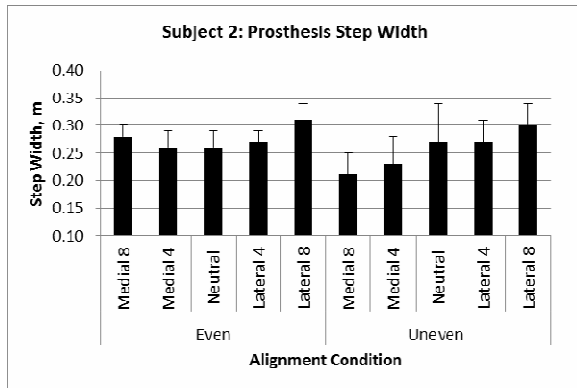
Figure 13: Subject 2, Prosthesis Step Width.

Figure 14: Subject 2, Contralateral Limb Step Width.

Kinetics

The average peak axial force for all the steps for each trial condition gradually increased on the even surface from the medial 8   alignment at 893.47 N ± 36.81 to the lateral 8 alignment at 972.13 N ± 27.73. The alignment conditions on the uneven surface followed a similar trend, though there was a smaller range in values and with the exception of the medial 4   alignment value, which was 859.28 N ± 68.28; medial 8   alignment was 920.9 N ± 75.49 and the lateral 8   alignment was 968.39 N ± 33.99 (Figure 15).
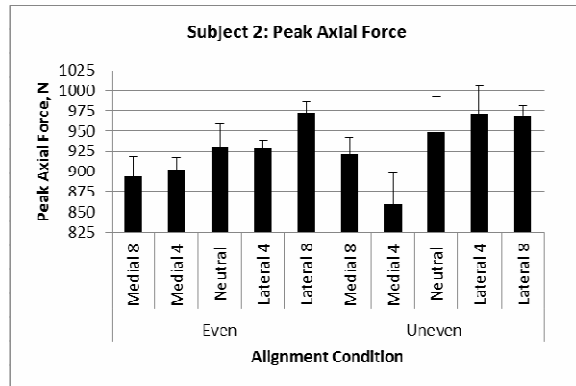
Figure 15: Subject 2, Average Peak Axial Force
of all steps per condition.

Subject 3:

Kinematics

Average prosthesis step length on the even surface was higher than the average step length on the uneven surface, 1.32m ± 0.05 and 1.19m ± 0.07, respectively. On the uneven surface, step length decreased gradually from the neutral alignment to the medial and lateral 8 alignments; starting with neutral at 1.28m, decreased to 1.20m ± 0.05 at the 4 alignment change, and decreased again to 1.14m ± 0.04 at the 8 alignment change (Figure 16). The contralateral side stays relatively consistent on the even surface with an average of 1.33m ± 0.04, and then follows the same trend as the prosthesis side on the uneven surface. The average neutral alignment step length was 1.28m; it decreased to 1.16m ± 0.06 at the 4 alignment change, and decreased again to 1.0m ± 0.0 at the 8 alignment change (Figure 17).
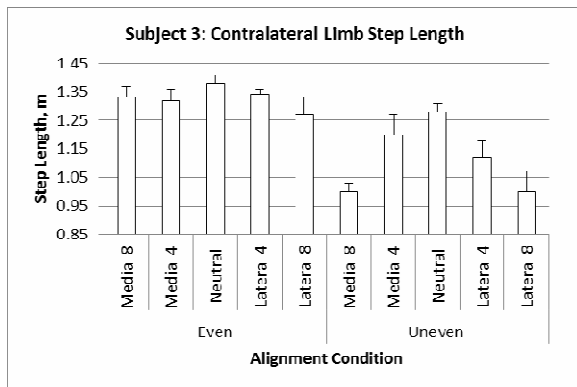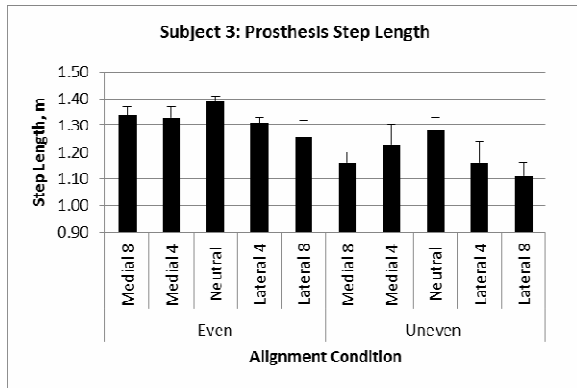
Figure 16: Subject 3, Prosthesis Step Length.

Figure 17: Subject 3, Contralateral Limb Step Length.

Average walking speed decreased from the even surface to the uneven surface, 1.21m/s ± 0.03 and 0.94m/s ± 0.11, respectively. The speed was more consistent on the even surface and the trend on the uneven surface decreased gradually from neutral, 1.08m/s, to 0.98m/s ± 0.04 on the 4° alignments, and to 0.84m/s ± 0.05 on the 8° alignments (Figure 18).
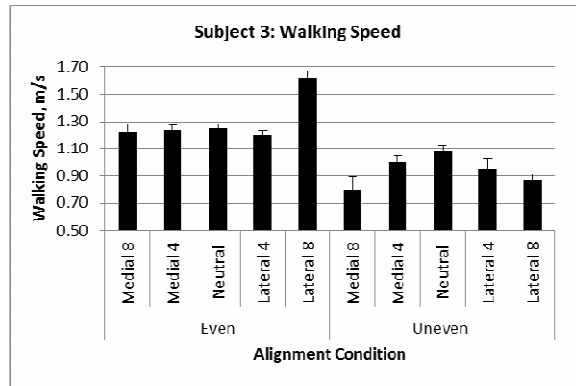
Figure 18: Subject 3, Walking Speed.

Average step width was maintained more consistently on the even surface for both the prosthesis and contralateral sides, with both averaging 0.21m ± 0.01. The prosthesis side on the uneven surface gradually increased from neutral at 0.19m, to 0.22m ± 0.02 at the 4 alignment, and to 0.26m ± 0.01 at the 8   alignment (Figure 19). The trend continued on the contralateral side where neutral started at 0.19m, increased to 0.23m ± 0.02 for the 4 alignments, and increased again to 0.25m ± 0.0 for the 8   alignments (Figure 20). Overall step width average was the same on the even surface for both the prosthesis and the contralateral sides, 0.21m ± 0.01; and it was also the same on the uneven surface for both the prosthesis and the contralateral sides, 0.23m ± 0.03.
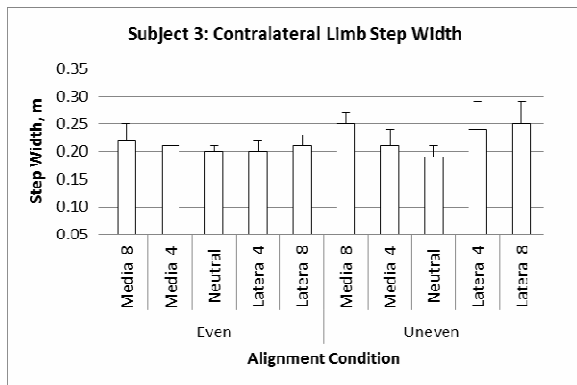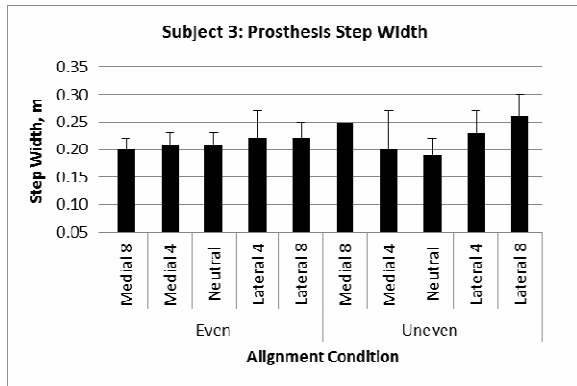
Figure 19: Subject 3, Prosthesis Step Width.

Figure 20: Subject 3, Contralateral Limb Step Length.

Kinetics

The average peak axial force for all the steps in each condition gradually decreased in force on the even surface from the medial 8   alignment, 1408.44 N ± 59.62, to the lateral 8 alignment, 1047.61 N ± 42.85. The uneven surface condition forces produced ranged from 1051.91 N ± 68.68 to 1307 N ± 43.9, with the exception of the lateral 4   alignment which produced a force of 230.43 N ± 84.87 (Figure 21).

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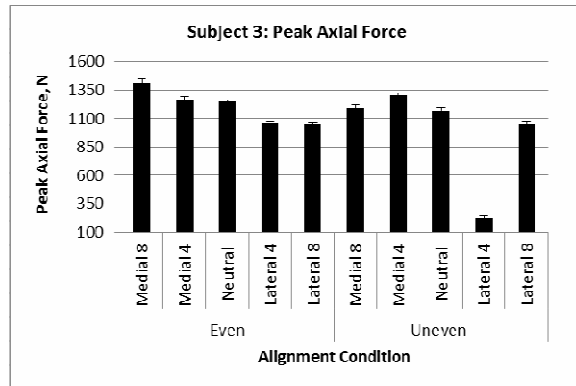
Figure 21: Subject 3, Average Peak Axial Force
of all Steps per Condition

Comparison amongst All Subjects

Kinematics

When all three subjects were compared, the average walking speed was higher on the

even surface and decreased on the uneven surface (Figure 22).

Figure 22: All Subjects, Average walking speed
for separated even and uneven surfaces.

Average prosthesis step width ranged from 0.21m to 0.24m on the even surface and

from 0.19m to 0.27m on the uneven surface (Figure 23). The contralateral limb step width

stayed more consistent on both the even and uneven surfaces with the even surface range

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being from 0.2m to 0.25m and the uneven surface range being from 0.21m to 0.26m (Figure 24).
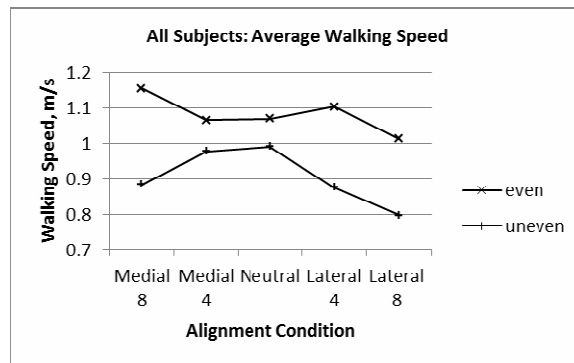

Figure 23: All Subjects, Prosthesis Step Width
separated for even and uneven surfaces.

Figure 24: All Subjects, Contralateral Limb Step Width
separated for even and uneven surfaces.

Average prosthesis step length decreased on the uneven surface with a range of 0.88m to 0.98m compared to 1.04m to 1.13m on the even surface (Figure 25). The average contralateral limb step length also decreased on the uneven surface with a range of 0.82m to 0.98m compared to the even surface values of 1.03m to 1.1m (Figure 26).
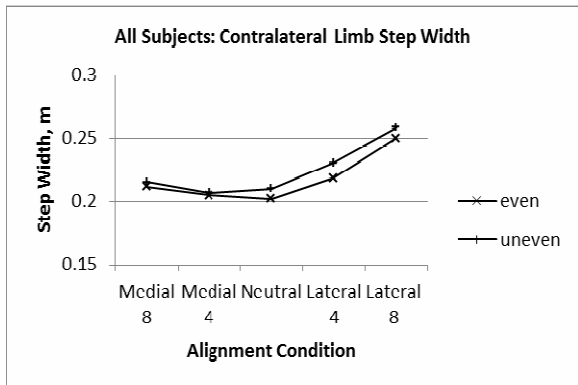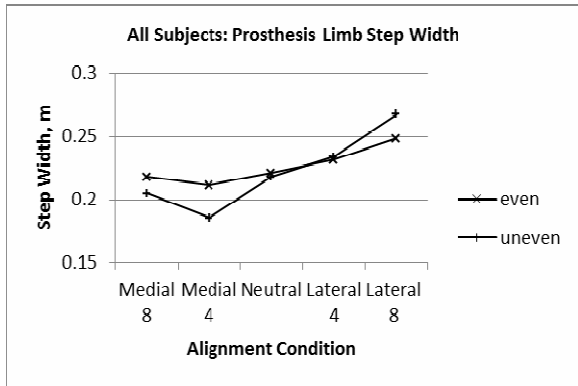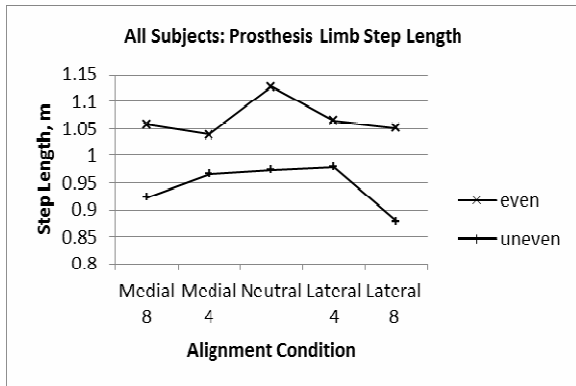
Figure 25: All Subjects, Prosthesis Step Length separated for even and uneven surfaces.
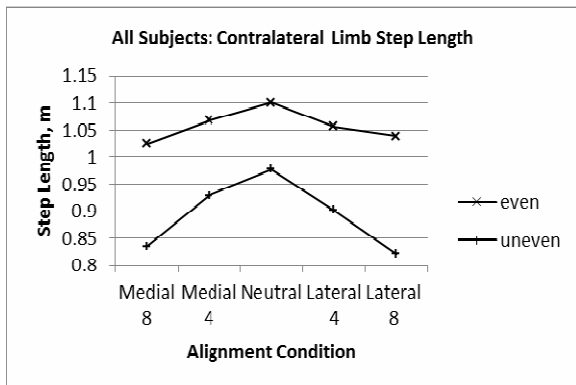
Figure 26: All Subjects: All Subjects, Contralateral Limb step length separated for even and uneven surfaces.

Kinetics

The average peak axial force followed opposite trends during the medial 8° and medial 4° alignments, and then followed similar trends during the neutral, lateral 4° and lateral 8° alignments for both surfaces. The range for the even surface was 1020.82 N to 1149.26 N, and for the uneven surface was 761.75 N to 1068.91 N (Figure 27).
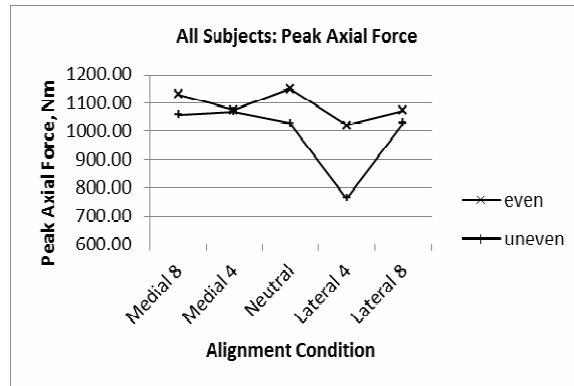
Figure 27: All Subjects, Average Peak Axial Force.
Dorsiflexion moment of the foot.

Rate of Comfort

Subject 1 had a rate of comfort range of five to ten, Subject 2's range was four to ten, and Subject 3's was one to ten (Table 3).

Table 3: Rate of Comfort						
	Subject 1		Subject 2		Subject 3	
Alignment	After		After		After	
Condition	Trial 1	Trial 5	Trial 1	Trial 5	Trial 1	Trial 5
EVM8	9	9	4	4	6	6
EVM4	9	9	10	10	8	8
EV00	10	10	10	10	10	10
EVL4	9	9	6	6	6	7
EVL8	9	9	5	5	4	6
UNM8	7	6	7	7	3	3
UNM4	7	7	10	9	6	6
UN00	5	6	10	10	7	7
UNL4	8	8	7	7	5	4
UNL8	7	7	4	4	2	1

Daily Activity

None of the subjects led sedentary lifestyles; they were all active throughout the week to some degree (Table 4).

Table 4: Physical Activity Questionnaire			
Subject	Types of Activity	Frequency	Duration, min/occurrence
1	bike riding, minimal walking, gardening	5-6x/week	60
2	walking, agility trials with dog	2x/day	30
3	running, cycling	1-3x/week	60

X. Discussion

All subjects were given little time to adjust to their new alignments to ensure any compensation was collected in the data. The only chances they had to become adjusted were walking from the chair where their alignment was changed to one of the paths, and then when there was a change in the surface. The surfaces and alignments were intentionally randomly selected so as to ensure acute responses, similar to a dynamic alignment session at a prosthetist's office. They were all very relaxed throughout the data collection and followed the directions very well.

Subject 1

A male who weighed 100.45kg, had a height of 180.43cm, and had a left limb prosthesis.

Subject 1 decreased his step length on the uneven surface with both the prosthesis and the contralateral limb. In this instance, both medial and lateral alignment changes resulted in the expected pattern. The 8° alignments were expected to and did result in shorter step lengths and the 4° alignments were expected to have longer step lengths, which they also did. However, the neutral alignment had a step length closer to those of the 8° alignments, rather

than the 4   alignments, which was unexpected and interesting since the uneven surface neutral alignment trial occurred immediately after the even surface neutral alignment trial and they were the first two trials completed. Walking speed did not decrease when the subject walked on the uneven surface; it actually stayed the same as the walking speed on the even surface. In fact, the speed on the uneven surface was maintained more consistently than the speed on the even surface, which was also unexpected. The increased consistency on the uneven surface might have been expected as a sign of a safer, more cautious gait, however, without an overall slower walking speed as well, it does not make sense. Step width stayed about the same among all the alignment changes and both surfaces. There was not the expected increase on the uneven surface. Instead, on the prosthesis side, the average step width was 0.19m on the even surface and 0.18m on the uneven surface. The contralateral limb was the opposite with .18m on the even surface and 0.19m on the uneven surface. The two levels degree changes for the medial and lateral alignments did not seem to have an effect on the step width for this subject. Peak axial force was more consistent on the uneven surface than on the even surface where both the lateral alignments brought the higher forces.

He reported the highest overall scores on the rate of comfort scale and interestingly, his lowest scores on the scale were associated with the neutral alignment on the uneven surface. It could be possible his alignment was not optimal and we only learned of it by his walking on the uneven surface. Subject 1 was the only one who did not have the highest values at neutral on the uneven surface. He was also fairly active in his daily life, taking care of the house and yard, and looking after his grandson.

Subject 2

 A female who weighed 90.91kg, had a height of 170.18cm, and had a left limb prosthesis.

The graphs show the same basic shape for the uneven versus even surfaces on all three kinematic variables. Step length did decrease for both the prosthesis and the contralateral limb on the uneven surface. Step width decreased on the uneven surface as well. On the contralateral limb the width ultimately stays the same for both surfaces. This was interesting since the widths on the even surface followed the expected pattern and the widths on the uneven surface gradually increased from medial 8° to lateral 8°. The prosthesis side step width was larger on the even surface, but more variable on the uneven surface, which might show how adjustments are necessary to work with the alignment and then to also navigate uneven surfaces more safely. The uneven surface peak axial force was more variable than the forces produced on the even surface, which potentially showed the adjustments to the pebbles

She reported the lowest scores on the rate of comfort scale for the even medial 8° and the uneven lateral 8° alignments. Her highest scores were recorded for both the even surface neutral alignment and the even surface medial 4° alignment. She stays moderately active by practicing agility trials with her dog.

Subject 3

A male who weighed 94.09kg, had a height of 177.8cm, and had a right limb prosthesis.

Step length did decrease on the uneven surfaces for both the prosthesis side and the contralateral limb. The contralateral limb produced results that were more expected than the prosthesis did, which changed very little. Step width increased on the uneven surfaces in the expected manner and was also more variable than the even surface. Walking speed decreased on the uneven surface and showed the expected results between the neutral, 4° and 8° alignments. Peak axial force was more variable on the uneven surface, especially with the lateral 4° alignment. The data was checked to ensure the correct numbers were used and there

is no video recorded of the trials, so I was unable to go back and look to see if something happened.

This was the only subject whose results produced what was expected. On even terrain he was able to maintain step length, walking speed, and step width consistently, but when the uneven terrain was factor, the different alignments caused him to compensate by reducing step length and walking speed and increasing step width.

Subject 3 reported the lowest scores on the rate of comfort scale at the uneven lateral 8   alignment. His highest scores were recorded on the even surface neutral alignment. While his activities were less frequent than the other two subjects, they were more intense.

All Subjects

The variability within each condition produced no patterns. We are unable to determine if there was a particular condition was more consistent or less consistent both in the overall results and individually.

The lack of symmetry, between the even and the uneven surfaces could have been caused by the compensations the individuals used to navigate the uneven surface. In the instance of Subject 2, where the even and the uneven surfaces where symmetrical in shape, but the uneven surface results were overall lower than the even surface results, the symmetry could have been caused by an overall compensation to the uneven surface; not the graduated compensations expected, as in Subject 3's results.

With only three subjects it's difficult to determine whether pattern was evident and if threshold between the 4   and 8   alignments were there.   Also, the one female may have skewed the data since females tend to have slightly different parameters than males. I think interesting future studies would be to have a larger number of participants to determine if a

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pattern and threshold are achieved, to do the same study with individuals with intact lower limbs, and the same study again with individuals with transfemoral prostheses. There could have been different factors that affected the results of this study; for instance, the age, physical fitness, body mass index, and outdoor activities the individuals were familiar with. Compared to subjects 1 and 2, subject 3 was the youngest and had the lowest body mass index. This may have accounted for the results he produced.

Conclusion

The use of the two levels of alignment changes, 4° and 8°, was expected to help distinguish a threshold angle in which the compensations were no longer able to be masked. The pattern being the neutral alignment would be the highest value for step length and walking speed. Then the 4° changes would bring similar, but slightly lower values to the neutral alignment, and the 8° changes would bring the lowest values of all the alignments. The opposite would be the pattern for step width. Individually, this pattern occurred with subject 3 on step length, step width, and walking speed and subject 2 on the contralateral step length. Overall, the data supported this pattern for the average of all the subjects for the step length, both on the prosthesis side and the contralateral limb. Step width and walking speed did not follow the same pattern.

Qualitatively, the hypotheses was supported for the step length, step width, and walking speed for all the subjects with the exception of subject 1's walking speed, where the speed

remained the same for both the even and the uneven surfaces. The hypothesis was also

supported for peak axial force. However, a larger number of subjects would be needed to

determine if the changes were in fact significant. I would not recommend anything changing in

the current alignment process until a more thorough similar study has been conducted.

Acknowledgments

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Appendix A

Georgia State University
Department of Kinesiology

Georgia Institute of Technology School
of Applied Physiology

Informed Consent

Title: *Prosthetic alignment over uneven terrain*

Principal Investigators:

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(404) 413-8379

Robert Kistenberg @ GT
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Atlanta, GA
(404) 894 6269

Student Investigator: Linda Meurer

Purpose:

You are invited to participate in a research collaboration between the Georgia Institute of Technology and Georgia State University. The purpose of the study is to investigate how you walk with your prosthesis alignment changed a little bit. We will watch you walk walking on a flat surface and then over different sized pebbles. You are invited to participate because you are an adult missing your lower limb. A total of 5 participants will be recruited for this study. Participation will require 2 hours of your time on one day.

Inclusion/Exclusion Criteria:

We will be recruiting apparently healthy adults ages 18 - 65 with unilateral transtibial (below the knee) amputations who are at least one year post amputation and who can walk comfortably and unassisted for at least 50 meters, have no apparent health issues, have no other orthopedic impediments, and have no current pain associated with wearing their prosthesis

Procedures:

If you decide to participate, the prosthetists at Georgia Tech will attach a small box to your prosthesis to measure force. We will attach small shiny markers to some spots on your legs with tape and make some measurements. Then two types of cameras will record you. One special camera is going to record the shiny markers attached to you while you walk. With this camera, only the markers will be seen, not your face or body. The other camera will be a regular video camera. It will record your face and body while you walk. We will use this video of you in case we need to double check the way you walk. If we use the video of you with your face for research or educational purposes, your identity will be protected or disguised by being blacked out or blurred. You will be asked to walk along a path of level ground five times. Each time you walk the path your prosthesis will have a different alignment. Then you will walk along another path that has different sized pebbles on it. You will walk along this path five times as well.

During the study, your prosthesis will be changed from its most comfortable alignment in two ways. We will turn the toe in a little bit and then turn the toe out a little bit. Each time we change the way your toe is pointing, you will be asked to walk along the path again. At the end we will put the prosthesis back the way it was, torqued and set to manufacturers specifications.

Before we start the study you will be asked to fill out an activity questionnaire. Please answer the questions to the best of your ability. You will also be asked about your comfort while walking along the path. Please identify your comfort level on a scale from one to ten. One would be very uncomfortable, can't get up. Ten would be very comfortable, can walk all day.

You will be compensated $40 for being in this study. If you withdraw yourself and your data early from this study, for

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any reason, your compensation will be pro-rated at $10 per half hour but not more than $40 total.

U.S. Tax Law requires a mandatory withholding of 30% for nonresident alien payments of any type. Your address and citizenship/visa status may be collected for compensation purposes only. This information will be shared only with the Georgia Tech department that issues compensation, if any, for your participation.

Risks:

This study involves minimal risk. It includes walking across a level, even floor, and through different sized pebbles. There is a minimal risk of stumbling or falling, though no greater than that faced in normal daily activities like walking on a regular floor or on a gravel road.

There could also be risks involved with taking part in this study that are not known to researchers at this time.

Benefits:

Participation in this study may not help you personally. Overall, we hope to gain information about prosthetic alignment over uneven terrain that could possibly lead to more efficient and effect prosthetic alignment processes.

Costs to You:

There is no cost to you to participate in this study apart from your time.

Voluntary Participation and Withdrawal:

Participation in research is voluntary. You do not have to be in this study. If you decide to be in the study and change your mind, you have the right to drop out at any time. You may stop participating at any time. Your decisions will not change any present or future relationship with Georgia State University, Georgia Institute of Technology or their affiliates.

Confidentiality:

All information collected about you during the course of this study will be kept confidential to the extent permitted by law. Information may also be shared with those who make sure the study is done correctly (GSU Institutional Review Board, Georgia Institute of Technology Institutional Review Board,] the Office for Human Research Protection (OHRP) and/or the Food and Drug Administration (FDA). You will be identified in the research records by a code name or number. However, the researcher and his/her committee may review your case. Your name and other facts that might point to you will not appear when we present this study or publish its results. The results of the study will be reported in a case study form; however, you will not be personally identifiable. If photos or video are utilized in the case study or a subsequent presentation, all identifiable aspects of the subjects will be masked or blurred so as to protect your identity.

When the results of this research are published or discussed in conferences, no information will be included that would reveal your identity. The study involves use of video- or audio-taping of participants, the principal investigator, co-investigator and student investigators will have access to the tapes, and they will be stored in the GSU Biomechanics Lab under lock and key. The video will only be used for internal reference in the case a trial has data that does not seem to fit and when the study has finished the data will be deleted. If videos of you will be used for research or educational purposes, your identity will be protected or disguised. You have the right to review the tapes in order to allow their use in a conference.

Disclaimer:

If you have any question about this study, or believe you have suffered any injury because of participation in the study, you may contact Mark Geil at (404) 413-8379 or Rob Kistenberg at (404) 894 6269. The Principal Investigator, Co-

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[APPROVED] Consent Form Approved by Georgia Tech IRB: February 01, 2012 - January 31, 2013

GSU IRB
Approved
From 9-15-2011 To 9-14-2012

Investigator, Georgia State University, and Georgia Institute of Technology have made no provision for payment of costs associated with any injury resulting from being in this study.

Participant Rights:

Your participation in this study is voluntary. You do not have to be in this study if you don't want to be. You have the right to change your mind and leave the study at any time without giving any reason and without penalty. If you decide not to finish the study, you have the right to withdraw any data collected about you. Any hard copy data collected prior to your withdrawal will be shredded and any data files stored on the password protected folder on the project flash drive will be destroyed. Any new information that may make you change your mind about being in this study will be given to you. You will be given a copy of this consent form to keep. You do not waive any of your legal rights by signing this consent form.

Contact Persons:

Contact Mark Geil at (404) 413-8379, or mgeil@gsu.edu, Linda Meurer at lmeurer1@student.gsu.edu or Rob Kistenberg (404) 894-6269) at rober@gatedu.edu if you have questions about this study. None of the researchers have a conflict of interest with regards to this study.

If you have questions or concerns about your rights as a participant in this research study, you may contact Susan Vogtner in the GSU Office of Research Integrity at 404-413-3513 (svogtner1@gsu.edu) or Kelly Winn at the GT Office of Research Compliance at 404-385-2175 (Kelly.Winn@grrs.gatech.edu).

If you are willing to volunteer for this research and he video recorded, please sign below.

_____   _____
Participant   Date

_____   _____
Principal Investigator   or Researcher Obtaining Consent   Date

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Physical Activity Readiness Questionnaire (PAR-Q) and You

Regular physical activity is fun and healthy, and increasingly more people are starting to become more active every day. Being more active is very safe for most people. However, some people should check with their doctor before they start becoming much more physically active.

If you are planning to become much more physically active than you are now, start by answering the seven questions in the box below. If you are between the ages of 15 and 69, the PAR-Q will tell you if you should check with your doctor before you start. If you are over 69 years of age, and you are not used to being very active, check with your doctor.

Common sense is your best guide when you answer these questions. Please read the questions carefully and answer each one honestly:

YES	NO		
☐	☐	1.	Has your doctor ever said that you have a heart condition and that you should only do physical activity recommended by a doctor?
☐	☐	2.	Do you feel pain in your chest when you do physical activity?
☐	☐	3.	In the past month, have you had chest pain when you were not doing physical activity?
☐	☐	4.	Do you lose your balance because of dizziness or do you ever lose consciousness?
☐	☐	5.	Do you have a bone or joint problem that could be made worse by a change in your physical activity?
☐	☐	6.	Is your doctor currently prescribing drugs (for example, water pills) for your blood pressure or heart condition?
☐	☐	7.	Do you know of any other reason why you should not do physical activity?

	YES to one or more questions
If you answered:	Talk to your doctor by phone or in person BEFORE you start becoming much more physically active or BEFORE you have a fitness appraisal. Tell your doctor about the PAR-Q and which questions you answered YES. • You may be able to do any activity you want – as long as you start slowly and build up gradually. Or, you may need to restrict your activities to those which are safe for you. Talk with your doctor about the kinds of activities you wish to participate in and follow his/her advice. • Find out which community programs are safe and helpful for you.

NO to all questions	**Delay becoming much more active:**
If you answered NO honestly to all PAR-Q questions, you can be reasonably sure that you can: • Start becoming much more physically active – begin slowly and build up gradually. This is the safest and easiest way to go. • Take part in a fitness appraisal – this is an excellent way to determine your basic fitness so that you can plan the best way for you to live actively.	• If you are not feeling well because of a temporary illness such as a cold or a fever – wait until you feel better; or • If you are or may be pregnant – talk to your doctor before you start becoming more active. Please note: If your health changes so that you then answer YES to any of the above questions, tell your fitness or health professional. Ask whether you should change your physical activity plan.

Informed use of the PAR-Q. Reprinted from ACSM's Health/Fitness Facility Standards and Guidelines, 1997 by American College of Sports Medicine

Appendix C

figure 5.1

Physical Activity Questionnaire

Name _____ Date _____

Please complete this questionnaire, which will help you and your physician understand your physical activity patterns.

1. What types of physical activities do you enjoy?
   _____
   _____
   _____
   _____

2. How often do you participate in these activities?
   _____

3. What exercises do you do regularly? _____
   _____
   _____
   _____
   _____

4. How often, and for how long each time, do you do these activities? _____
   _____
   _____
   _____

5. What gets in the way of you consistently engaging in physical activity/exercise? _____
   _____
   _____
   _____
   _____

6. How many hours of television do you watch every day?
   _____

7. How many hours are you at a computer/desk everyday?
   _____

8. What types of exercise equipment or exercise tapes do you have at home? _____
   _____
   _____
   _____
   _____

9. Do you belong to a health club or attend classes?
   ☐ Yes   ☐ No

10. How often do you attend? _____
    _____

11. Would you like to change your physical activity/ exercise habits?
    ☐ Yes   ☐ No

12. Which habits would you like to begin to change?
    _____
    _____
    _____
    _____
    _____
    _____
    _____
    _____
    _____

Figure 5.3

Physical Activity Time Study

Record your activities for each of the time slots indicated below on at least one weekday and one weekend day. Use your step counter to keep track of the number of steps you take during each time period. Try to keep this sheet with you and write down your activity as you go. For each time slot, determine the amount of time you were physically active and the amount of time you were not active. At the end of the day, total the number of minutes you were active and inactive and your number of steps. You may make copies of this worksheet to record information daily.

Date / /	Day of the week	Physically active?		
Time slot	Tasks/activities	Yes	No	Steps
Midnight to 4 am				
4:01 to 8 am				
8:01 am to noon				
12:01 to 4 pm				
4:01 to 8 pm				
8:01 pm to midnight				
	Total number of minutes and steps			

Example

For each 4-hour block of time describe how you spend your time and record your number of steps using your step counter. Try to record your activities at least every 1 to 2 hours so you can be as accurate as possible. Add up the minutes you were physically active and record in the Yes column. Subtract the minutes of activities from the total number of minutes in the 4-hour block of time, which is 240 minutes. Record the total number of minutes and steps at the bottom of the sheet.

Date 10 / 5 / 02	Day of the week Wednesday	Physically active?		
Time slot	Tasks/activities	Yes	No	Steps
8:01 am to noon	desk work, 75 minutes; meetings, 120 minutes; walk to and from car at lunch, 7 minutes; walk to vending machine, 3 minutes; walk to meeting, 4 minutes; talk with co-workers (standing), 31 minutes	14 min	226 min	1,145

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Figure 5.4

Physical Activity Barriers

What keeps you from being more physically active? Maybe you are too busy at work. Or perhaps your kids or other loved ones need you and they come first. Brainstorm all the reasons you are not more physically active and write down what comes to mind. Nothing is too big or too small. Some examples include: "Not enough time," "Don't like to sweat," and "Too out of shape."

A. Physical activity barriers

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

B. Prioritize your barriers from the biggest to the smallest.

1. _____

2. _____

3. _____

4. _____

5. _____

6. _____

7. _____

8. _____

9. _____

10. _____

11. _____

12. _____

C. Pick one barrier and come up with a way to get around it. Be creative! List you ideas below.

_____

_____

_____

_____

Now pick one of your ideas and try it for a week. If after a week it didn't work, try another strategy. Keep trying new ideas until you find some that help you overcome your barriers.

Figure 5.6

Benefits of Physical Activity

Post this list in a place where you will see it often, such as a bathroom mirror, bulletin board, or refrigerator door.

There are many possible benefits to becoming more physically active. Read through this list and check the benefits that are important to you.

Potential benefits

[ ] Increase stamina

[ ] Stimulate weight loss

[ ] Lower blood cholesterol

[ ] Lower blood pressure

[ ] Improve self-image

[ ] Improve mood

[ ] Enhance quality of life

[ ] Sleep better

[ ] Strengthen heart and lungs

[ ] Decrease stress

[ ] Increase energy

[ ] Maintain appropriate weight

[ ] Lower triglycerides

[ ] Control blood sugar levels/diabetes

[ ] Feel better

[ ] Reduce feelings of depression and anxiety

[ ] Improve productivity

[ ] Build and maintain healthy bones, muscles, and joints

[ ] Increase muscle tone

[ ] Reduce risk of dying prematurely

What other ways do you think you could benefit from being physically active?

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

Figure 5.2

Physical Activity Calendar

Write in the month and the corresponding dates in the spaces provided. Then record your minutes, steps, and miles for each day. You may make copies of this sheet to record information monthly.

American Medical Association
Physicians dedicated to the health of America

Month _____ Year _____

Monthly goals

Minutes	Steps	Miles

	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Weekly total
Weekly goal ___ Minutes ___ Steps ___ Miles								___ Minutes ___ Steps ___ Miles
___ Minutes ___ Steps ___ Miles								___ Minutes ___ Steps ___ Miles
___ Minutes ___ Steps ___ Miles								___ Minutes ___ Steps ___ Miles
___ Minutes ___ Steps ___ Miles								___ Minutes ___ Steps ___ Miles
___ Minutes ___ Steps ___ Miles								___ Minutes ___ Steps ___ Miles

Monthly totals

Minutes	Steps	Miles

47

On a scale of 0 to 10, please rate your level of walking comfort for this trial

0 = can't get up/move

10 = I can do this all day

0	1	2	3	4	5	6	7	8	9	10

Worst Possible

Best Ever