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THE USE OF A PYLON MOUNTED TRANSDUCER FOR INVESTIGATING THE GAIT OF TRANSTIBIAL AMPUTEES

By

Justin Robert Brink, EI

Bachelor of Science in Kinesiological Science
University of Nevada, Las Vegas
2003

A thesis submitted in partial fulfillment
of the requirements for the

Master of Science Degree in Biomedical Engineering

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University of Nevada, Las Vegas
May 2012

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THE GRADUATE COLLEGE

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ABSTRACT

The Use of a Pylon Mounted Transducer for Investigating the Gait of Transtibial Amputees

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Two areas of research interest in the design and use of lower limb prosthetic devices are how foot performance varies with design and how prosthesis alignment affects gait. The current study addressed both of these areas through the use of the JR3 triaxial transducer mounted at the base of the socket. The transducer is an innovative form of instrumentation that measures forces and moments at the end of the socket. Traditional measurement of gait uses a force plate buried in the floor of a gait laboratory. The study established that the transducer offers a viable means of instrumentation for amputee gait. It provides insight into performance differences between energy storing and release feet (ESAR) and SACH (solid ankle cushioned heel) feet with respect to gait kinematics and kinetics. The effects of variations in the anterior-posterior alignment of the foot in the sagittal plane also were examined.

The prostheses of four unilateral transtibial amputee subjects were instrumented with the transducer by mounting it where the socket is attached to the pylon. The instrument setup was designed to wirelessly transmit data from the transducer to a laptop. This eliminated the need to have subjects tethered to stationary instruments and allowed for data collection of consecutive steps in a range of walking environments. For this study, subjects were instructed to walk on a level surface at a self-selected comfortable speed. Data were recorded to obtain 10 consecutive steps while using both the SACH and an ESAR foot. The walking trial was repeated for several of the feet at three differing alignments: neutral (initial alignment), a shift of the foot +5mm anterior from neutral, and a shift of the foot -5mm posterior from neutral. Effects from varying foot type as well as alignment were examined with respect to stride characteristics, maximum resultant forces and moments, and the maximum moment arm of the resultant force from the center of the transducer; this moment arm was termed the Effective Moment Arm (EMA).

The different design characteristics of SACH versus ESAR feet led to hypotheses that stride characteristics as well as peak resultant forces, moments, and EMA's would vary between foot types. These hypotheses were examined using transducer data. T-test computations revealed statistically significant differences in all trials. The peak EMA was found to be larger during toe loading for the ESAR feet, and the time spent in stance and the overall gait cycle times were shorter when using the SACH foot.

It also was hypothesized that variations in alignment would lead to statistically significant differences in stride characteristics, peak resultant forces, peak resultant moments, and EMA's. ANOVA analysis revealed statistically significant differences in the data for all trials. Using statistical analyses, it was found that neutral alignment led to shorter times spent in stance and shorter gait cycle time. With posterior shifts in alignment the

moment in the sagittal plane increased during heel loading and, with anterior shifts in alignment, the moment in the sagittal plane increased during toe loading.

The study established the feasibility of using a triaxial transducer to analyze some of the characteristics of the gait of transtibial amputees. The transducer appeared to be a useful alternative for investigations that typically use force plates in a gait laboratory. Patterns found in the data indicate statistically significant differences between the ways transtibial amputees respond to feet featuring ESAR design versus feet featuring SACH design. Patterns also indicate statistically significant differences when the sagittal plane alignment of the foot is varied in an anterior-posterior direction. Both sets of findings warrant further investigation.

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CHAPTER 1

INTRODUCTION AND BACKGROUND

1.1 Objectives

The objective of the study was to assess the feasibility of using a triaxial transducer for transtibial amputee gait analyses. A triaxial transducer measures forces and moments along three orthogonal axes, and when attached rigidly between a lower limb prosthetic socket and a pylon it measures the forces and moments transmitted to the socket where they produce pressure on the residual limb contained in the socket. Unlike methodology which utilizes a force plate, the transducer can record kinetic data from several consecutive steps as opposed to one step. Additionally, transducer data could be recorded in a variety of environments as opposed to being limited to a gait laboratory. Furthermore, mounting the transducer at the end of the socket allows for the acquisition of the forces and moments at that location rather than deriving them from data recorded at the interface between the ground and the foot.

The feasibility of using a transducer to measure certain aspects of gait was explored by mounting the transducer at the socket/pylon interface and recording the 3-dimensional forces and moments while the subjects walked at a self-selected comfortable speed on a level surface. Each subject performed a walking trial with a SACH foot and an ESAR foot. Trials were repeated for several of the feet at three different alignments: neutral (initial alignment), a shift of the foot +5mm anterior from neutral, and a shift of the foot -5mm posterior from neutral. Effects from varying foot type as well as the alignment of the prosthesis were examined with respect to stride characteristics, maximum resultant forces and moments, and the maximum moment arm of the resultant force from the center of the transducer. Results compared to existing studies which explored the same outcome measures but from data collected with a force plate facilitated the exploration of the feasibility of the transducer.

1.2 Background

A goal when developing prosthetic feet is to restore gait patterns acceptable to the amputee while not compromising comfort of the residual limb. Outcome measures of prosthesis performance and comfort have commonly been explored utilizing data recorded in gait laboratories with a force plate. Findings have been limited to collecting data from one step contacting the force plate while walking or running on a level surface. Generally, force plates must be mounted flush with the laboratory's floor. Research is then limited to hypotheses which can be examined by having the subject attempt to naturally contact the force plate during activities such as level walking or running. To obtain sample sizes sufficiently large for statistical analysis, multiple trials must be conducted with measurements taken during only one or a limited number of steps. Fatigue from repetitive trials, as well as the need to take strides intentionally aimed at the force plate, can lead to unnatural gait which can result in misrepresentative ground reaction force data.

Use of the JR3 triaxial transducer for amputee gait studies could overcome many of the environmental constraints of a gait lab. Prosthetic users frequently are exposed to a variety of environments in addition to level walking. During the common activities of daily living, a person may ascend and descend stairs, ascend and descend sloped surfaces, walk across slopes, and be required to make left and right turning movements. A triaxial transducer provides a means for collecting data while an amputee ambulates in varied environments. The data which are collected can then be analyzed to investigate prosthesis performance in more typical everyday environments. This could lead to advances in prosthetic component development as well as provide insight to the clinician, who must select components, set up the bench alignment of the components, and align the prosthesis to produce a gait acceptable to the amputee.

In addition to allowing for data acquisition during ambulation in varied environments, use of the transducer could reveal previously undetected performance differences in foot types. For example, previous studies have not found consistent patterns of statistically significant differences in performance between energy storing and release (ESAR) feet made of carbon-fiber composites that produce spring-like properties on the heel and forefoot during gait and older-style feet featuring solid ankles and foam heels that do not store and release energy, such as the SACH foot. Also, the biomechanical goals of alignment have not yet been identified. This may be due to the limitations of conventional gait labs. If an investigator is interested in kinetic consequences of alignment or foot-type at the socket, data collected with a force plate may not provide a full description. By mounting the triaxial transducer at the socket/pylon junction, complete information can be obtained about the forces and moments that are transmitted from the foot to the socket.

1.3 Hypotheses

Working hypotheses were developed to address how foot performance varies with design and how prosthesis alignment affects aspects of gait that can be measured using a transducer. It was hypothesized that foot design and alignment interventions would lead to significant differences in: the magnitudes of the moment arm from the center of the transducer to the resultant force; the magnitudes of the resultant forces, and the magnitudes of moments in the sagittal plane; and the times spent in the stance phase, swing phase, and overall gait cycle. The basis for the foot performance hypotheses were the ESAR foot's capability to store and release energy since the SACH cannot, and findings published by Lehmann, Price, Boswell-Bessette, Dralle, and Questad (1993) noting significant increases in dorsiflexion when using an ESAR foot versus the SACH (6). The basis for the alignment effects hypotheses reflect the possibility of the toe lever arm increasing with anterior translations of the foot and the heel lever increasing with posterior translations.

CHAPTER 2

LITERATURE REVIEW

Content of this chapter summarizes literature relevant to the working hypotheses of the study. Inclusion criteria required the publications to address hypotheses rooted in two areas of interest: comparisons of the SACH vs. ESAR feet, and effects from perturbing the alignment in the sagittal plane. The literature was required to report on at least one of the following: subjective feedback; vertical ground reaction force peak characteristics; or gait parameters: velocity, cadence, gait cycle duration, stance duration, swing duration, and the percentage of time spent in the swing phase.

Considering that the current study analyzed differences in gait due to foot type and alignment, the question of whether or not the transducer itself alters gait was an important question. A review of literature focused on the mass implications of the transducer was conducted and is summarized in section 2.3. This review assessed literature addressing mass, cataloged the outcome measures, and established levels of confidence in experimental results.

2.1 ESAR Feet vs. SACH

2.1.1 Subjective

Hafner *et al.* (2002) conducted a review of literature addressing usage perceptions between ESAR feet and traditional feet. They stated that the users predominately preferred ESAR feet which were typically attributed to a perceived increase in velocity and stability as well as a reduction in pain (1).

Torburn *et al.* (1990) compared the gait of five subjects when using ESAR feet (Flex-Foot, Carbon Copy II, SEATTLE, STEN) and SACH. Each subject was analyzed using an ESAR foot and a SACH while walking at a self-selected free speed and at a fast-paced speed. All of the

subjects preferred the foot which gave them the greatest velocity at the self-selected speed. Every instance involved an ESAR foot (3).

Lehmann *et al.* (1993) compared gait kinetics and biomechanics of two ESAR feet (Flex-Foot and Seattle Foot) with the SACH. Nine subjects were instructed to walk at a self-selected walking speed. All of the subjects preferred the ESAR feet; one specified the Seattle Foot and the others the Flex-Foot (7).

Macfarlane *et al.* (1991) investigated the perception of walking difficulty using the SACH compared to the Flex-Foot. Seven subjects walked at a self-selected comfortable speed on a level surface, 8.5° decline, and an 8.5° incline. The authors reported that a significant difference in difficulty was perceived by the subjects. The Flex-Foot was deemed less difficult to walk with across all grades. Additionally, subjects found walking on a level surface to be easiest while walking up an incline to be the hardest (13).

Kinnunen *et al.* (1991) examined the subjective feedback of subjects using the SACH foot compared to the Flex-Foot. Feedback from thirty-one subjects was analyzed for 10 items of walking: indoors, upstairs, downstairs, even street, uneven ground (sand, snow), forest, street uphill, street downhill, swift walking, and running. The Flex-Foot was deemed to allow for walking with less difficulty for all 10 items. The greatest differences were reported when walking upstairs and walking uphill (14).

2.1.2 Kinetics

Torburn *et al.* (1990) compared the gait of five subjects when using ESAR feet (Flex-Foot, Carbon Copy II, SEATTLE, STEN) and SACH. Each subject was analyzed using an ESAR foot and a SACH while walking at a self-selected free speed and at a fast-paced speed. Data collected with a Kistler piezoelectric force plate yielded vertical ground reaction forces that were analyzed for differences in maxima and minima. No significant differences were reported. A 97.6 ± 8.3 %

body weight toward the end of terminal stance (2nd peak in the bimodal Gait Cycle vs. VGRF plot) was reported for the Flex-Foot, and 99.5 ± 4.9 % body weight for the SACH (3).

Barr *et al.* (1992) compared the vertical ground reaction force peaks between the Carbon Copy II and the SACH. One subject was used and was directed to walk at a self-selected speed for ten trials per foot. Two force plates (AMTI) were used to collect the VGRF data No significant differences were reported in the peak magnitudes. However, it was noted that the 1st peak in terminal stance was greater for the SACH while the 2nd peak was nearly identical (5).

Lehmann *et al.* (1993) investigated the changes in kinetics when using a Seattle Ankle/Lite Foot versus a SACH. Ten subjects were recorded with a three-dimensional motion capture system (VICON) and Kistler force plate. Maximum dorsiflexion was significantly greater when using the ESAR foot. When maximum dorsiflexion occurred, the VGRF was not significantly different. However, the moment arm at the ankle was. Moment maxima about the knee were not significantly different as well as the ground reaction forces and moment arms at those times. No significant differences in the VGRF peaks were reported (6).

Lehmann *et al.* (1993) compared gait kinetics of two ESAR feet (Flex-Foot and Seattle Foot) with the SACH. Nine subjects were instructed to walk at a self-selected walking speed. No significant differences were reported for the resultant force producing maximum knee flexion. However, significant differences were reported for the moment arm at max knee flexion. Differences were listed for the vertical force peak transfer and the ankle moment arm. However, no significant difference was found in the ground reaction forces (7).

Menard *et al.* (1992) investigated gait asymmetry in eight transtibial amputees when waking on a level surface at a self-selected comfortable speed using the Seattle Foot and the Flex-Foot. Vertical ground reaction forces were measured by the use of a force plate. The authors reported that the subjects demonstrated weaker propulsion on the amputated side and stronger propulsion

on the sound side when using both feet. However, slightly less symmetry was observed when using the Seattle Foot. Also, the 2nd peak in the VGRF, the propulsive force, was much lower when using the Seattle Foot (8).

Snyder *et al.* (1995) examined gait characteristics of seven subjects walking at a self-selected free walking speed. The vertical ground reaction forces were measured with a Kistler force plate for the usage of five different feet: SACH, Flex-Foot, Carbon Copy II, Seattle Foot, and Quantum. Significant differences between feet were reported for the 1st peak of the bimodal VGRF peak. The magnitudes of the initial peaks in descending order are: Flex-Foot, SACH, Seattle, Carbon Copy II, and Quantam (9).

Perry *et al.* (1993) observed the effects on gait of seventeen subjects using the SACH in comparison to four dynamic elastic response feet: Seattle Foot, Flex-Foot, Carbon Copy II, and Sten. Ground reaction forces were measured via a force plate while the subjects walked at a self-selected speed on a level surface. No significant differences were reported in the values (10).

Powers *et al.* (1994) investigated differences in gait of ten subjects when using different feet: SACH, Flex-Foot, Carbon Copy II, Seattle Foot, and Quantum. Data were collected through the use of a Stride Analyzer System, VICON motion capture system, and Kistler piezoelectric force plate. Subjects walked along a level surface at a self-selected speed. The only significant difference in the vertical ground reaction force occurred between the SACH and the Quantum, the difference in the magnitude of the initial peak. The SACH had the largest initial peak in comparison to all the other feet (12).

Murray *et al.* (1988) observed vertical ground reaction force characteristics when using the SACH and compared it to usage of the Seattle Foot. One subject was measured walking across a force plate. Significant differences were not reported. However, the authors stated that the SACH lead to a larger initial peak and smaller 2nd peak (15).

2.1.3 Gait Parameters

Nielsen *et al.* (1989) observed the self-selected walking speeds of seven subjects. Each subject was instructed to walk at a comfortable speed on a level surface while using the Flex-Foot and the SACH. Walking velocities were measured using an electronic timer. Results showed increases of about 7-9% when using the Flex-Foot. Average values listed were: Flex-Foot (85.8 m/min) and SACH (80.5 m/min) (2).

Torburn *et al.* (1990) compared the gait of five subjects when using ESAR feet (Flex-Foot, Carbon Copy II, SEATTLE, STEN) and SACH. Each subject was analyzed using an ESAR foot and a SACH while walking at a self-selected free speed and at a fast-paced speed. Stride characteristics (velocity, cadence, stride length, gait cycle duration; for both limbs: initial and terminal double-limb support as a percentage of gait cycle, single-limb support as a percentage of gait cycle, stance as a percentage of gait cycle, duration of heel only contact as a percentage of gait cycle, and time of heel off as a percentage of gait cycle) were measured with a Stride Analyzer that consisted of compression-closing footswitches taped to the soles of the subject's shoes. No significant differences were found at the fast pace. Only cadence and gait cycle duration yielded significant differences at the self-selected speed (3).

Wagner *et al.* (1987) investigated differences in gait for three subjects when using the Flex-Foot and the SACH. Subjects were directed to walk at a self-selected comfortable speed. Differences in velocity, cadence, % of single limb stance spent on the prosthesis, and % of single limb stance spent on the sound limb were observed. No significant differences were reported (4).

Barr *et al.* (1992) compared the prosthetic side single limb support time, swing period, cadence, and velocity when using the Carbon Copy II versus the SACH. One subject was used and was directed to walk at a self-selected speed for ten trials per foot. A three-dimensional motion

capture system (VICON) was utilized to acquired kinematic data. No significant differences were reported (5).

Lehmann *et al.* (1993) investigated the changes in gait biomechanics when using a Seattle Ankle/Lite Foot versus a SACH. Ten subjects were recorded with a three-dimensional motion capture system (VICON). The midstance phase and push-off phases were significantly shorter when using the Seattle Ankle/Lite Foot. There were no significant differences in the velocities (6).

Lehmann *et al.* (1993) compared gait biomechanics of two ESAR feet (Flex-Foot and Seattle Foot) with the SACH. Nine subjects were instructed to walk at a self-selected walking speed. No significant difference was observed in velocity. However, significant differences were reported for midstance duration and push-off duration (7).

Snyder *et al.* (1995) examined gait characteristics of seven subjects walking at a self-selected free walking speed. Velocity, stride length, and cadence were measured with a Stride Analyzer System and Vicon motion capture. Five different feet were used: SACH, Flex-Foot, Carbon Copy II, Seattle Foot, and Quantum. Significant differences were found in velocity between the SACH and the Flex-Foot; the Flex-Foot being greater. Also, the stride length with the Flex-Foot was significantly longer than the SACH, Carbon Copy II, and Seattle. No significant differences were found in cadence (9).

Perry *et al.* (1993) observed the effects on gait of seventeen subjects using the SACH in comparison to four dynamic elastic response feet: Seattle Foot, Flex-Foot, Carbon Copy II, and Sten. Stride characteristics were measured via footswitches and a Vicon motion analysis system while the subjects walked at a self-selected speed on a level surface, up and down a 10% grade ramp, and up and down stairs. No significant differences were found in free-walking velocity.

The Flex-foot and Carbon Copy II foot provided a more symmetrical gait during stair ascent and descent (10).

Powers *et al.* (1994) investigated differences in gait of ten subjects when using different feet: SACH, Flex-Foot, Carbon Copy II, Seattle Foot, and Quantum. Data were collected through the use of a Stride Analyzer System, VICON motion capture system, and Kistler piezoelectric force plate. Subjects walked along a level surface at a self-selected speed. Of the three gait characteristics measured; velocity, stride length, and cadence, a significant difference was only detected in stride length (12).

2.2 Alignment Perturbations

Hansen *et al.* (2003) studied the relationship of alignment with foot roll-over shapes. Seven subjects were acquired and feet with three different roll-over shapes were used. Different alignment methods were used and compared. The methods involved a computational alignment method designed to establish an "ideal" roll-over shape, alignments made by prosthetists, and no alignment. "Ideal" roll-over shape involved a specific center of pressure position on the foot. Data were acquired with three-dimensional motion capture and a force plate which then was used to establish the COP. Alignments were adjusted by translating the pylon forward or backward and/or adjusting the plantarflexion and dorsiflexion of the foot. Results supported that alignment should match the roll-over shape however; no significant differences were found in the alignment methods. Additionally, they concluded that once the prosthesis is aligned to produce an "ideal" roll-over shape, the alignment can be perturbed anteriorly and posteriorly in limited amounts and still be considered acceptable (17).

Blumentritt *et al.* (1997) investigated a biomechanical method for establishing optimal alignment. This method involved statically aligning the prosthesis based off of the horizontal distance in the sagittal plane from the knee center to the ankle. Eighteen subjects were acquired and the Otto

Bock Laser Assisted Static Alignment Reference Posture (L.A.S.A.R.) system was used. As different feet were introduced, no alignment consistency was observed. The authors hypothesized that longer adjustment periods would lead to changes in alignment. They also stated that the short accommodation periods did not allow the subjects sufficient time to evaluate the quality of the alignment (18).

Reisinger *et al.* (2007) utilized three different alignment methods; the anatomically-based alignment (ABA)-standing system, the ABA-supine system, and the vertical alignment axis (VAA) approach with five subjects. Subjects were asked to rate the alignments. The alignments most often chosen were those made with the ABA-standing and VAA systems. The best alignments occurred when the ankle bolts were 25-30mm posterior to the socket centers (19).

Sanders *et al.* (1998) examined the effects of alignment variations on socket pressures, vertical ground reaction forces, and gait kinematics. Two subjects were acquired. The prosthetic foot for one subject was translated anteriorly 19.7, 9.5, and 22.9mm and posteriorly 8.3mm. The second subject's foot was translated anteriorly 7.6 and 8.3mm and posteriorly 8.9mm. A statistically significant difference in walking velocity was only found for one subject and only at the 7.6mm perturbation. The authors commented that there were no drastic differences in cadence. The average gait cycle durations had statistically significant differences for half of the alignment perturbations for one of the subjects. Of those that were significantly different, 40% resulted in longer gait cycle durations. For one subject, the perturbations in the sagittal plane resulted in significantly different timing for the 1st peak in the bimodal ground reaction force. Also reported was the occurrence of a larger impact on pressures on the anterior regions of the limb from the perturbations (20).

Chow *et al.* (2006) studied the effects of alignment perturbations on gait symmetry. Six subjects were examined with anterior-posterior alignment variations of 5mm. They were instructed to

walk at a self-selected comfortable speed on level ground. Data were collected with force plates and a motion analysis system (VICON). All alignments were considered to be acceptable alignments. No significant difference was found in walking velocity. They reported the stance duration between the prosthetic side and contralateral side to be "highly symmetric". Both bimodal peaks in the vertical ground reaction force were examined. Although no tests of statistical significance were reported, they stated that consistent symmetry did exist (21).

Schmalz *et al.* (2002) investigated biomechanical characteristics of gait with varying alignments. Fifteen subjects were studied while walking on level ground at a self-selected comfortable speed. Alignment perturbations consisted of anterior-posterior translations of ±2cm. Biomechanical gait parameters were recorded with Kistler force plates and an optoelectronic camera system. No significant differences were found in velocity. Tendencies toward increases in knee flexion external moments occurred with a posterior shift, and tendencies toward increases in knee extension external moments occurred with an anterior shift (22).

Pearson *et al.* (1973) studied socket pressures with anterior-posterior alignment perturbations of ±5mm and ±10mm. Eight subjects were observed while walking at a self-selected comfortable speed on level ground. Pressures were recorded through the use of transducers (Kulite Semiconductors Products Corp.) taped to the subjects' residual limbs. Regions measured were the patellar tendon, distal anterior tibia, lateral tibial condyle, and medial tibial condyle. The distal anterior tibia was observed to have the highest pressures which decreased as the foot was translated in a posterior to anterior direction. The patella tendon and lateral tibial condyle had smaller pressure magnitudes which also would decrease with anterior translation but at a slower rate. The medial tibial condyle experienced the lowest amount of pressure and was decreased the least with anterior translation (23).

Hannah *et al.* (1984) studied the effect on gait symmetry from varied alignment. Four unilateral transtibial amputees were utilized. They were instrumented with electrogoniometers at their hips and knees and allowed to walk at a self-selected comfortable speed. 180 indices were established from the combinations of alignment changes, joint motion pairs, and subjects. 22% of the indices indicated asymmetry in the time domain, and 47% in the frequency domain. The authors stated that optimal or neutral alignment "tended to minimize asymmetry of gait at the hips and knees for persons with below-knee amputations" (24).

Andres *et al.* (1990) examined the effects on gait symmetry from alignment variations. One subject was observed at a comfortable walking speed with varied alignments consisting of ±0.64cm, ±1.28cm, and ±1.92cm. Movements in the sagittal plane were recorded with two high speed 16mm cameras. The asymmetry ratio, AR, (prosthetic limb value divided by contralateral limb value) was significantly different. Step time asymmetry increased as the foot moved anteriorly from the posterior 2cm alignment. This indicated an increase in step time. Swing time asymmetry increased as the foot moved posteriorly as well as anteriorly from an acceptable alignment. This indicated an increase in swing time. No statistically significant difference in stride length was found (25).

Sin *et al.* (2001) investigated the acceptable anterior-posterior alignment ranges for level and non-level walking. Six unilateral transtibial amputee subjects were observed walking on a level surface, up and down a flight of stairs, and up and down a 10% slope ramp. The range of acceptable alignments for non-level walking was found to be significantly less than that of level walking. The range for level walking was +35mm to -15mm and +20mm to -10mm for non-level (26).

Lin *et al.* (2000) examined whether or not the Radcliffe and Foort bench alignment technique provided an acceptable dynamic alignment. Sixteen subjects received new prostheses with a

bench alignment using this technique. Prosthetists examined the gait of the subjects. Properly fitted prostheses were compared to improperly fitted prostheses based on the location of the center of the sockets on the outlines of the shoes. No statistically significant difference was observed between the anterior-posterior locations of socket centers (27).

2.3 Mass Perturbations

Review of literature was systematically performed by following the American Academy of Orthotists & Prosthetists (AAOP) State-of-the-Science Evidence Report Guidelines.

Initially, "does mass influence unilateral transtibial gait?" was defined as the question to research. Multiple database searches were performed using relevant key words and phrases (Table 2.3.1). Inclusion/exclusion criteria were developed to filter the resulting literature. Articles to be included in a detailed review needed to be written in English, published in a refereed journal, utilize human subjects; include transtibial amputees, examine perturbations of the mass of the prosthesis during the experiment, and quantitatively measure characteristics associated with gait. After applying this set of criteria to the search results, ten journals qualified for inclusion. Their demographics were tabulated and can be reviewed in Table 2.3.2.

After obtaining the included articles, internal and external validity rankings were established (Table 2.3.3, Table 2.3.4, and Table 2.3.5). Internal validity deals with the ability to establish a cause-and-effect relationship among the experiment's conditions. External validity relates to the generalization of the experiment's cause-and-effect to populations outside of the study. Assessments of the articles were based on expanded internal and external validity criteria (Appendix A) used by the American Academy of Orthotists and Prosthetists. If an article failed to list calculated p-values, it was automatically excluded from high internal and external validity rankings. Furthermore, in addition to p-values, rest intervals between trials needed to be discussed for consideration of a high internal validity ranking. Similarly, studies needed to have five

subjects or more in addition to listing p-values to be considered for a high external validity ranking.

The outcomes measured in each study are listed in Table 2.3.6. Effects from mass perturbations were classified under three main categories: Metabolic Effects, Kinematic Effects, and Kinetic Effects. Moreover, the locations on the prostheses where the masses were varied are tabulated in Table 2.3.6. Specifying these locations was necessary to facilitate a determination of which studies were similar. The identification of similar studies which could be compared also required categorizing studies by the magnitude of mass alterations. Table 2.3.7 indicates mass loads used in the experiments.

Table 2.3.8 and Table 2.3.9 show whether mass perturbation was found to have a statistically significant effect on each outcome measure. Approximately one-third of the outcome measures were examined by only a single study. Also, effects on VO2 was the only measure to be examined by more than one study that received a high validity ranking

When developing evidence statements based on the ten articles that were reviewed in detail, studies with low validity rankings were essentially ignored. After ignoring these studies, Kinetic Effects was the only one of the three categories of outcomes not to have conflicting findings among the studies. Among three studies involving a total of 21 subjects, variations in mass from 0kg to magnitudes greater than 2kg were found to significantly affect joint torque and joint power. However, this occurred when the mass was perturbed distally on the prosthetic. Studies of Metabolic and Kinematic outcomes obtained conflicting results. Effects being insignificant from mass variations were favored by studies of higher validity rankings. Conflicting metabolic and kinematic outcomes with stronger validity rankings on the “no significant difference” side were: VO2, stride length, stride frequency, and velocity over a force plate (walking speed). Conclusive results yielding no significant kinematic and metabolic effects

were: heart rate, exercise intensity, cadence, hip angle, and knee angle. Strong support for distal mass variations having significant effects can be made for: gait symmetry, and swing limb support and swing periods.

While there were some conflicting results, some generalized conclusions could be made. Prosthetic mass perturbations can significantly affect gait. However, the location of the addition/subtraction of mass was critical. When mass was altered more distal from the prosthetic/residual limb's center of mass, a significant effect on gait was observed.

Causes of conflicting results could be directly influenced by experimental protocol. Studies by Lin-Chan, Nielsen, Yack, Hsu, and Shurr (2003) and Selles RW *et al.* (2004) both were deemed to have high rankings in internal and external validity (31, 33). Yet, they found conflicting results for the same kinematic outcome measures. Both studies perturbed mass of approximately the same magnitude and at the COM. Also, subjects were of approximately the same demographics. Subjects studied by Selles RW *et al.* (2004) were instructed to walk at a self-selected speed (31). The speed among subjects was averaged and found to be 73.2m/min. While subjects studied by Lin-Chan SJ *et al.* (2003) walked at prescribed speeds, the speeds varied from 54-107m/min and were evenly spaced apart over five intervals (33). Essentially, subjects across both studies were observed while walking at approximately the same speed.

Despite little variation between these two studies, the accommodation period between conditions (mass variations) were different. Lin-Chan SJ *et al.* (2003) gave subjects a 3-hour acclimation period, while Selles RW *et al.* (2004) allowed a 5-minute minimum adaptation period that lasted until the subject indicated they were used to the new condition (31, 33). Adaptation periods of different durations could be a variation in experimental protocol that led to inconsistent results.

Based on the literature review, it is inferred that the transducer would not significantly alter gait. Much of the studies examined similar kinematic and kinetic characteristics of gait as the current study. The trend of significant differences was associated with kinetic characteristics and when the mass was perturbed toward the distal end of the prosthesis. Also, these mass perturbations reached magnitudes up to 2kg. The transducer is approximately 0.8kg. Additionally, locating it at the proximal end of the prosthesis reduces the probability of it significantly influencing gait.

		Data Bases					
		PubMed*	CINAHL	Cochrane	Medline**	RECAL Legacy	ScienceDirect
Key Word	"prosthesis mass gait"	106	44322	1	52	16	1299
	prosthesis AND mass AND gait	106	22	4	52	15	1299
	"prosthesis symmetry gait"	54	13442	6	44	17	391
	prosthesis AND symmetry AND gait	54	21	6	44	17	391
	"prosthesis contralateral ipsilateral gait"	15	15863	0	12	0	236
	prosthesis AND contralateral AND ipsilateral AND gait	15	2	0	12	0	236

*PubMed-indexed for MEDLINE

**Medline via Web-of-knowledge

Mapped prosthesis to "Artificial Limb"
(Topic=(prosthesis) OR MeSH Heading:exp=(Artificial Limbs)) AND Topic=(mass) AND(Topic=(gait) OR MeSH Heading:exp=(Gait))
((Topic=(prosthesis) OR MeSH Heading:exp=(Artificial Limbs)) AND Topic=(mass)) AND(Topic=(gait) OR MeSH Heading:exp=(Gait))

Table 2.3.1 Mass Perturbation Search Results

Demographics of Articles Reviewed in Detail:

Number of Articles by Type	
Controlled Before-and-After Trial	6
Single Subject Experimental Trial	2
Controlled Trial - (Quasi)Experimental Trial	1
Systematic Review	1
Number of Articles by Year of Publications:	
1980-1989	1
1990-1999	4
2000-2009	5
Number of Articles by Journal:	
Archives of Physical Medicine and Rehabilitation	5
Prosthetics and Orthotics International	3
Disability and Rehabilitation	2

Table 2.3.2 Demographics of Mass Perturbation References

Number of Articles Reviewed by Validity Ranking

Ranking	Internal Validity	External Validity
High	3	4
Moderate	4	3
Low	2	2

Table 2.3.3 Validity Rankings of Mass Perturbation References

Classifications from Quality Assessment (AAOP)	
High	Indicates that the reviewer has strong confidence in the design (when reviewing internal validity) or applicability (when reviewing external validity) of the reviewed article and that bias introduced by threats to validity identified in the quality evaluation does not compromise this confidence.
Moderate	Designates that the reviewer has confidence in the design/applicability of the reviewed article, but that bias introduced by threats to validity identified in the quality evaluation may limit the confidence in the study design and/or results.introduced by threats to validity identified in the quality evaluation does not compromise this confidence.
Low	Denotes that the reviewer has little-to-no confidence in the design/applicability of the reviewed article due to strong bias introduced by the threats to validity identified in the quality evaluation.

Table 2.3.4 Mass Perturbation Article Assessment

Articles Reviewed in Detail

Type=study design; Subjects=the number of subjects

Ref. #	Authors	Title	Journal	Type Subjects	Validity: Internal External
28	Gailey RS *et al.*	The effects of prosthesis mass on metabolic cost of ambulation in non-vascular trans-tibial amputees.	*Prosthetics and Orthotics International*	E_2; 10	High High
29	Hillery SC *et al.*	The effect of changing the inertia of a trans-tibial dynamic elastic response prosthesis on the kinematics and ground reaction force patterns.	*Prosthetics and Orthotics International*	E_4; 1	Moderate Low
30	Donn JM *et al.*	The effect of footwear mass on the gait patterns of unilateral below-knee amputees.	*Prosthetics and Orthotics International*	E_5; 10	Low Moderate
31	Selles RW *et al.*	Adaptations to mass perturbations in transtibial amputees: kinetic or kinematic invariance?	*Archives of Physical Medicine and Rehabilitation*	E_5; 10	High High
32	Lehman JF *et al.*	Mass and mass distribution of below-knee prostheses: effect on gait efficacy and self-selected walking speed.	*Archives of Physical Medicine and Rehabilitation*	E_5; 15	Low Moderate
33	Lin-Chan SJ *et al.*	The effects of added prosthetic mass on physiologic responses and stride frequency during multiple speeds of walking in persons with transtibial amputation.	*Archives of Physical Medicine and Rehabilitation*	E_5; 8	High High
34	Hillery SC *et al.*	Trans-tibial amputee gait adaptations as a result of prosthetic inertial manipulation.	*Disability and Rehabilitation*	E_4; 1	Moderate Low
35	Selles RW *et al.*	Effects of prosthetic mass and mass distribution on kinematics and energetics of prosthetic gait: a systematic review.	*Archives of Physical Medicine and Rehabilitation*	S_2	NA
36	Selles RW *et al.*	The effect of prosthetic mass properties on the gait of transtibial amputees – a mathematical model.	*Disability and Rehabilitation*	E_5; 10	Moderate Moderate
37	Mattes SJ *et al.*	Walking symmetry and energy cost in persons with unilateral transtibial amputations: matching prosthetic and intact limb inertial properties.	*Archives of Physical Medicine and Rehabilitation*	E_5; 6	Moderate High

Table 2.3.5 Details of Mass Perturbation Articles

Articles Classified by Outcome Measures & Location of Mass Perturbation

Outcome Measures	At Prosthetic Center of Mass (COM)	Distal from COM	Proximal from COM	Evenly Distributed Over Shank	Moment of Inertia Matched Intact Limb
Metabolic:					
A. Heart Rate (Hr)				28	
B. VO2	32, 33, 35	32	32	28	37
C. Exercise Intensity	33				
Kinematics:					
A. Gait Symmetry		30, 34			
B. Cadence		29, 34			
C. Stride Length	31, 37	29, 31, 35	31		37
D. Stride Frequency	31, 33, 37	31, 35	31		
E. Swing Limb Support & Swing Periods		29			37
F. Hip Angle	31	29, 30, 31	31		
G. Knee Angle	31	29, 30, 31	31		
H. Ankle Angle	31, 36	29, 31, 36	31, 36		
I. Velocity Over Force Plate (Walking Speed)	31, 32	29, 31, 32, 34, 35	31, 32		
Kinetics:					
A. Ground Reaction Force (GRF) Patterns		29			
B. Joint Torques	31, 36	31, 36	31, 36		
C. Joint Work		32	32		
D. Joint Power		34			

Numbers listed in cells coincide with their associated Reference number. Reference #35 was a systematic review, locations of mass perturbations were not given for every study. Those not given, or weren't clearly stated, are not included in the matrix.

Table 2.3.6 Outcome Measures and Location of Mass Perturbation

Articles Reviewed by Loading

Ref. #	Title	Mass Conditions and Added Masses (kg)										
		1	2	3	4	5	6	7	8	9	10	11
28	The effects of prosthesis…	*+0*	*+0.454*	*+.907*								
29	The effect of changing…	*+0*	*+0.530*	*+1.460*								
30	The effect of footwear…	*+0*	*+0.05*	*+0.1*	*+0.15*	*+0.2*						
31	Adaptations to mass…	*+0*	*+1.0*	*+1.0**	*+1.0**	*+2.0*						
32	Mass and mass dist…	*+2.02‡*	*+3.00‡*	*+3.50‡*	*+2.02*‡*	*+3.00*‡*	*+3.50*‡*					
33	The effects of added…	*+0.3‡*	*+1.31‡*	*+2.31‡*								
34	Trans-tibial amputee…	*+0.118*	*+0.53*	*+1.46*								
35†	Effects of prosthetic…											
36 €	The effect of prosthetic…	*-2.5*	*-2.0*	*-1.5*	*-1.0*	*-0.5*	*+0*	*+0.5*	*+1.0*	*+1.5*	*+2.0*	*+2.5*
37	Walking symmetry…	*+0*	*+0.85‡*	*+1.7‡*								

*=Same mass load as prior condition, but applied at a different location

‡=Average mass value added. Mass additions were based off of a % of the prosthetic and residual limb mass.

†=S_2 Study. Results are discussed in body of paper.

€=VariedMass location was varied in 12 locations.

Table 2.3.7 Mass Perturbation Articles Reviewed by Loading

Outcome Measures Results

Internal Validity

Outcome Measures	Significant Differences Level of Mass Loading (kg)				No Significant Difference Level of Mass Loading (kg)			
	m≤0	**0<m<1**	**1<m<2**	**2≤m**	**m≤0**	**0<m<1**	**1<m<2**	**2≤m**
Metabolic:								
A. Heart Rate (Hr)					**28**	**28**		
B. VO2			35, 37	35	**28**	**28**, **33,** 35, 37	**33**, 35	32, **33,** 35
C. Exercise Intensity						**33**	**33**	**33**
Kinematics:								
A. Gait Symmetry		30, 34	34					
B. Cadence		29	29		29	29, 34	29, 34	
C. Stride Length	37	29, 37	29, 37		29, **31**	29, **31**, 35	29, **31**, 35	**31,** 35
D. Stride Frequency		**33**	**33**	**33**	31	**31**, 35	**31**, 35	**31**, 35
E. Swing Limb Support & Swing Periods	37	29, 37	29, 37		29			
F. Hip Angle					29, **31**, 36	29, **31**, 36	29, **31**, 36	**31**, 36
G. Knee Angle					29, **31**, 36	29, **31**, 36	29, **31**, 36	**31**, 36
H. Velocity Over Force Plate (Walking Speed)		29, 34	29, 34		29, **31**	29, **31**	29, **31**, 35	**31**, 32, 35
Kinetics:								
A. Ground Reaction Force (GRF) Patterns		29	29		29			
B. Joint Torques	**31**	**31**	**31**	**31**	36	36	36	36
C. Joint Work								32
D. Joint Power		34	34					

Numbers listed in cells coincide with their associated Reference number. High Validity is in bold type.

Table 2.3.8 Outcome Measures Internal Validity

External Validity

Outcome Measures	Significant Differences Level of Mass Loading (kg)				No Significant Difference Level of Mass Loading (kg)			
	m≤0	**0<m<1**	**1<m<2**	**2≤m**	**m≤0**	**0<m<1**	**1<m<2**	**2≤m**
Metabolic:								
A. Heart Rate (Hr)					**28**	**28**		
B. VO2			35, 37	35	**28**	**28**, **33,** 35, **37**	**33**, 35	32, **33,** 35
C. Exercise Intensity				**33**		**33**	**33**	**33**
Kinematics:								
A. Gait Symmetry		30						
B. Cadence		29	29		29	29, 34	29, 34	
C. Stride Length		29	29		29, **31**, **37**	29, **31**, **37**	29, **31**, **37**	**31**
D. Stride Frequency		**33**	**33**	**33**	**31**	**31**	**31**	**31**
E. Swing Limb Support & Swing Periods	**37**	29, **37**, 34	29, **37**, 34		29	34	34	
F. Hip Angle					29	29	29	
G. Knee Angle					29	29	29	
H. Velocity Over Force Plate (Walking Speed)		29, 34	29, 34		29, **31**	29, **31**	29, **31**, 35	**31**, 32, 35
Kinetics:								
A. Ground Reaction Force (GRF) Patterns		29	29		29			
B. Joint Torques	**31**	**31**	**31**	**31**	36	36	36	36
C. Joint Work								32
D. Joint Power		34	34					

Numbers listed in cells coincide with their associated Reference number. High Validity is in bold type.

Table 2.3.9 Outcome Measures External Validity

CHAPTER 3

TRANSDUCER MEASUREMENTS CONCEPTS

3.1 Analysis Using Real-Time versus Normalized-Time

The transducer collected kinetic data at 100 Hz. This frequency was appropriate for collecting data at walking velocities and was the default value for the JR3 and the highest stable capture rate. Magnitudes of moments about 3-axes and magnitudes of forces in 3-dimensions were tabulated with a row spacing of 0.01s. The primary areas of interest in the current study were narrowed down to those within the sagittal plane; analyses were completed using transducer variables My, Fx, and Fz, and the computed resultant force in the sagittal plane, Rxz. Refer to Figures 3.1.1-3.1.4 below for examples of moment and force data. This raw data was then either directly analyzed or normalized for other analyses.

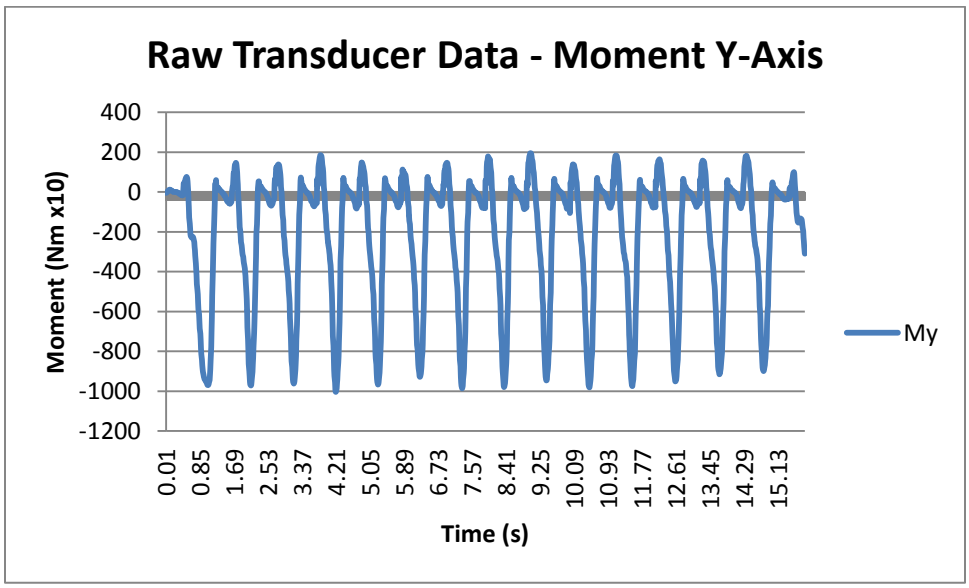


Figure 3.1.1 Raw transducer data of moment about y-axis

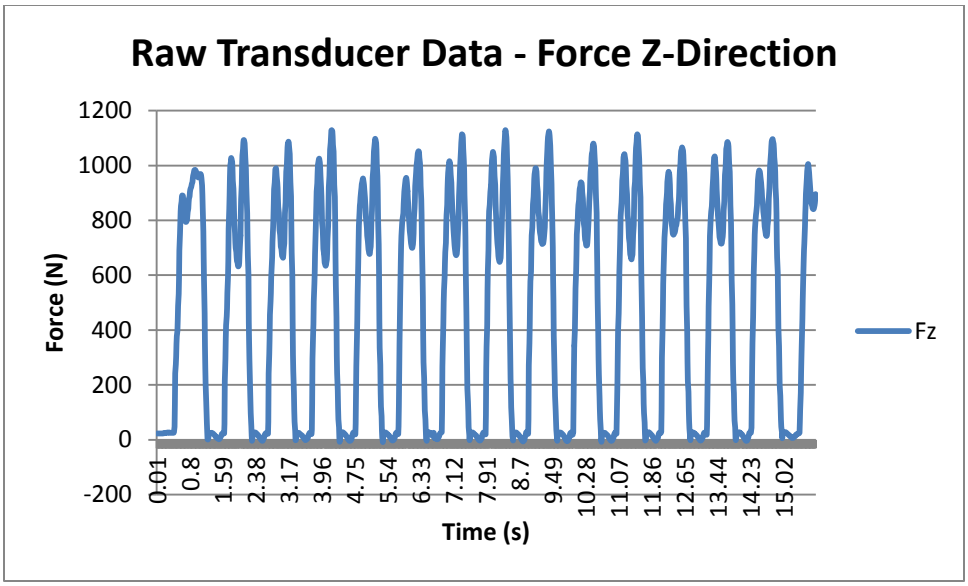


Figure 3.1.2 Raw transducer data of force in the z-direction

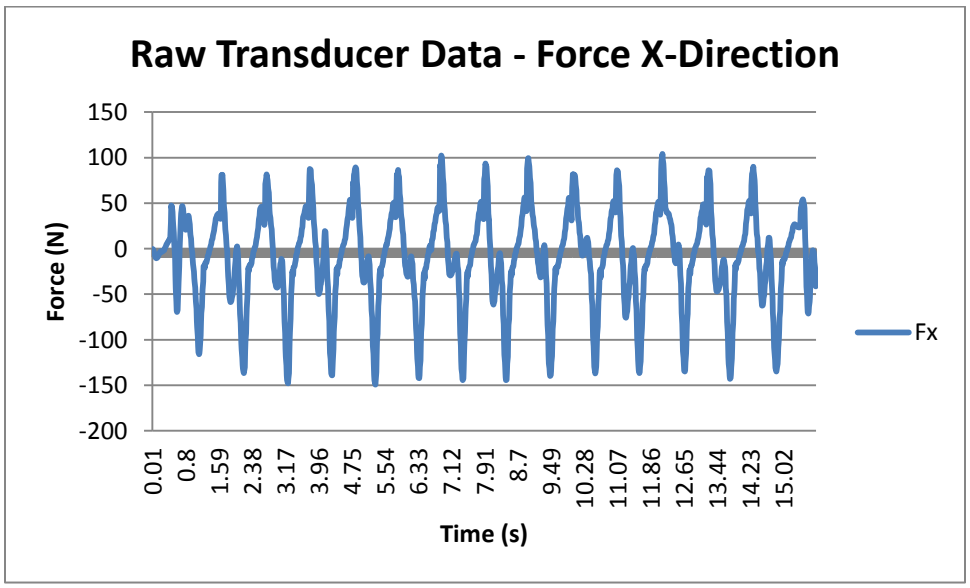


Figure 3.1.3 Raw transducer data of force in the x-direction

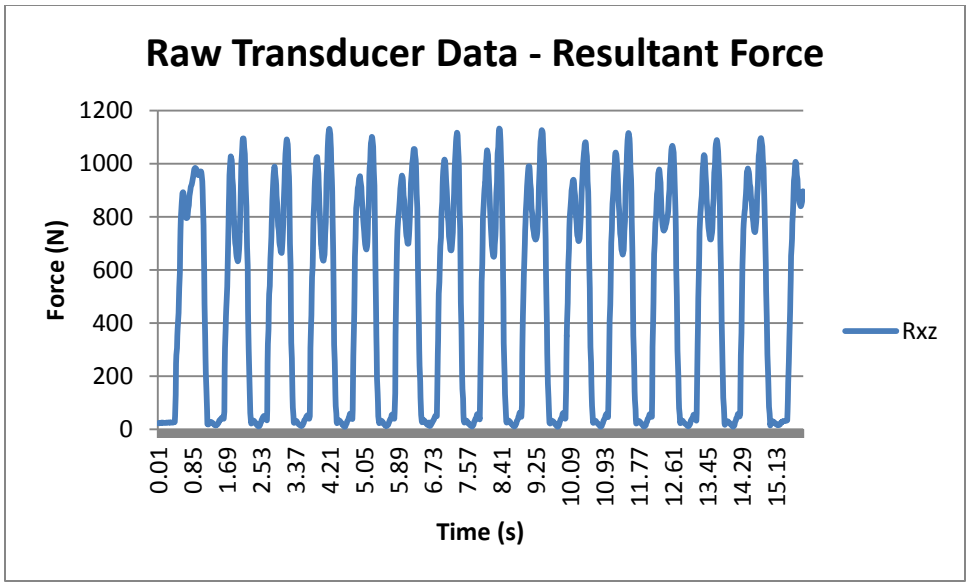


Figure 3.1.4 Raw transducer data of the resultant force in the sagittal plane

The analyses conducted required comparisons of the mean values for ten consecutive steps. Since the gait cycle times varied slightly with each stride, a method of normalizing gait was required. The stance phase was the portion of the gait cycle of most interest, and the phase targeted for normalizing. Normalization was accomplished by dividing the stance phase into 50 intervals of equal duration. Each interval comprised 2% of stance. Figures 3.1.5-3.1.8 below display normalized data for My, Fz, Fx, and Rxz averaged over 10 steps. Since all six transducer variables were disaggregated into 50 intervals having the same starting and ending times, data could be synchronized.

Gait parameters, as opposed to kinetic, did not require normalizing. The analyses undertaken with the raw data focused on temporal gait characteristics. Stance and swing phases were isolated through visual inspection of the data recorded by the transducer along the z-axis (refer to CH 4.4 for methods for identifying stance initiation and termination). Identifying the initiation and termination of phases allowed the time durations spent in stance and swing to be tabulated. Real-time differences were evaluated using EXCEL.

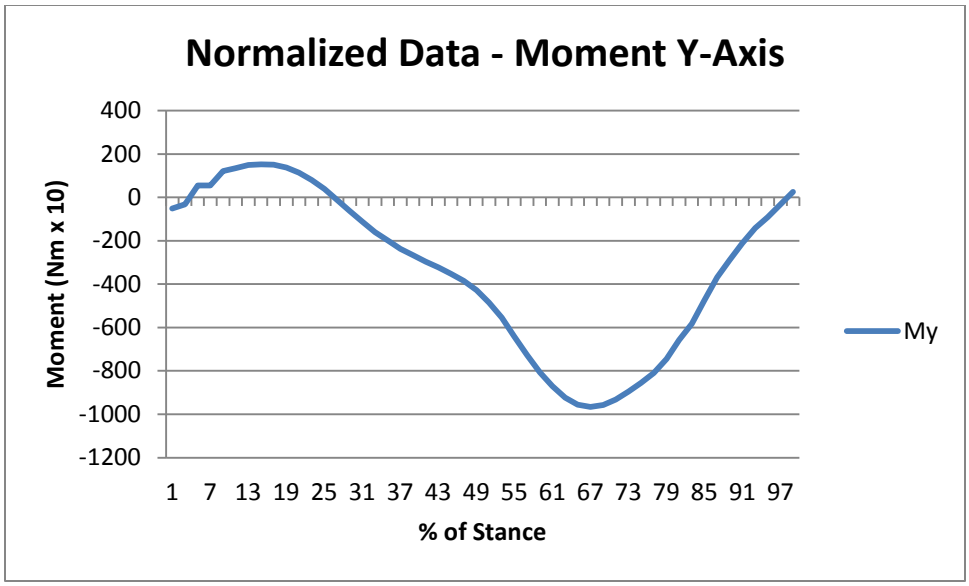


Figure 3.1.5 Normalized transducer data –moment about y-axis – mean of 10 steps

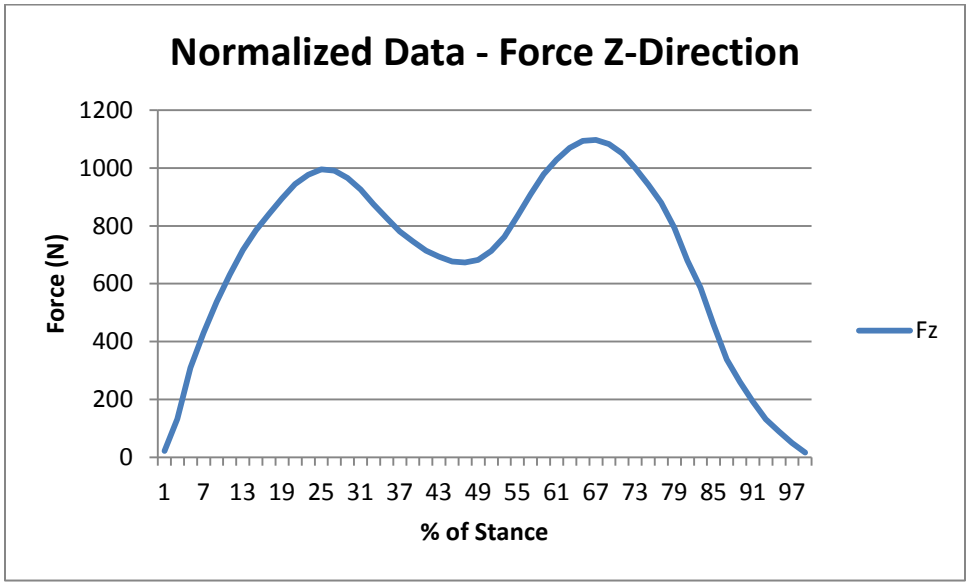


Figure 3.1.6 Normalized transducer data – force in the z-direction – mean of 10 steps

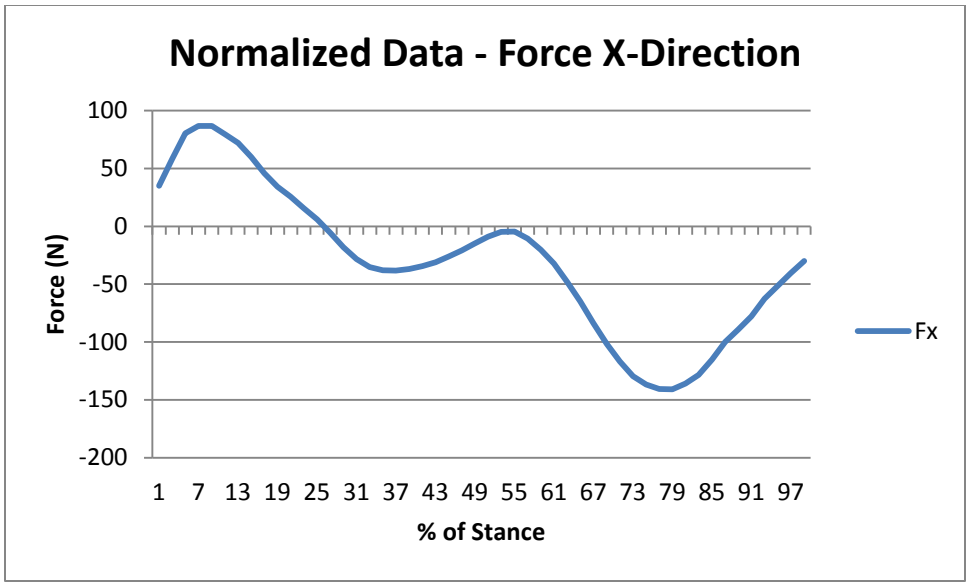


Figure 3.1.7 Normalized transducer data – force in the x-direction – mean of 10 steps

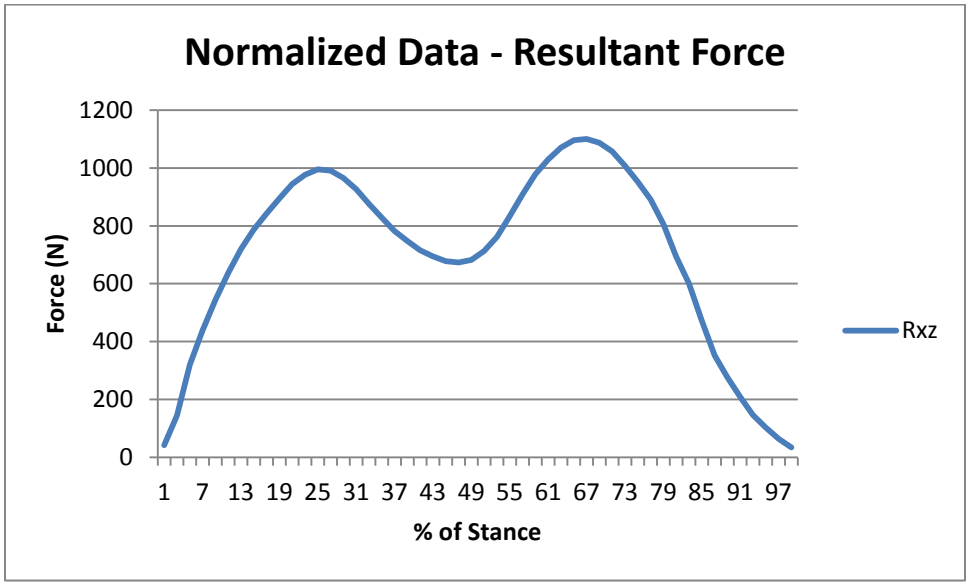


Figure 3.1.8 Normalized transducer data – resultant force in the sagittal plane – mean of 10 steps

3.2 Relationship Between Transducer Measurements and Ground Reaction Force Measurements

The relationship between the transducer measurements and the actual ground reaction force can be visualized in Figure 3.2.1 for the sagittal plane. The transducer's positive x-axis is directed toward the left side of the page, the positive y-axis is directed outward toward the

viewer, and the positive z-axis is directed toward the top of the page. Moments measured by the transducer are recorded as being positive when occurring in a counter-clockwise direction, negative for moments that are clockwise (Figure 3.2.2). The 3-component forces measured by the transducer comprise a resultant force; its magnitude can be computed as: $R_{xyz}=\sqrt{(F_x^2+F_y^2+F_z^2)}$. The ground reaction force resolved into its components in the sagittal plane is shown in Figure 3.2.1. Fz is directed parallel to the pylon, while Fx is perpendicular (positive during heel loading and negative during forefoot loading). The resultant force in the sagittal plane was computed as $R_{xz}=\sqrt{(F_x^2+F_z^2)}$ which was used in the analyses.

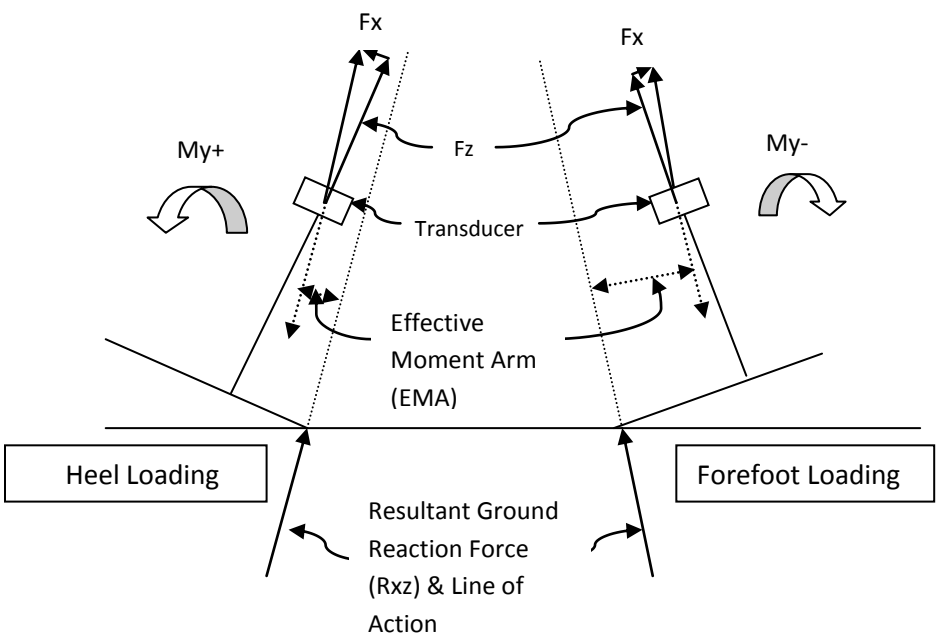


Figure 3.2.1 Transducer/Ground Reaction Force Measurements

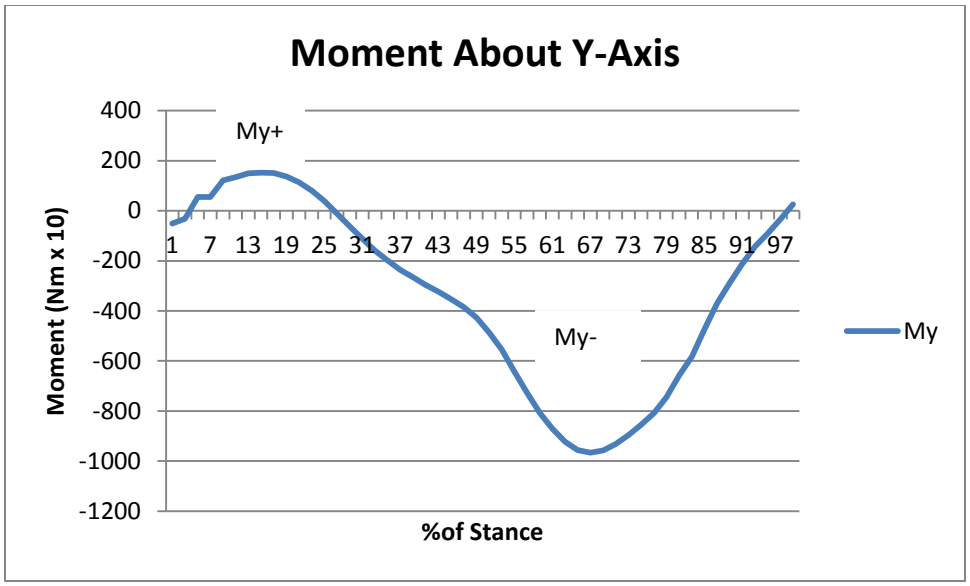


Figure 3.2.2 Positive and negative moments about y-axis – mean of 10 steps

3.3 Concept of Effective Moment Arm

Understanding that a moment is a function of a force and moment arm (**My**=**EMA** x **Rxz**), the moment arm was computed by dividing the magnitudes of the moments about the y-axis by the magnitudes of the resultant forces. The respective moment arms were termed "effective moment arms" (EMA) as shown in figure 3.2.1. The EMA is the perpendicular distance from the line of action of the resultant ground reaction force to the center of the transducer.

The primary areas of interest in the current study were narrowed down to those within the sagittal plane. Forces directed in the sagittal plane, x-direction and z-direction, create these moments of interest. Therefore, analyses were conducted utilizing the moments about the transducer's y-axis, My, and the resultant force in the sagittal plane, Rxz (see Figure 3.3.1).

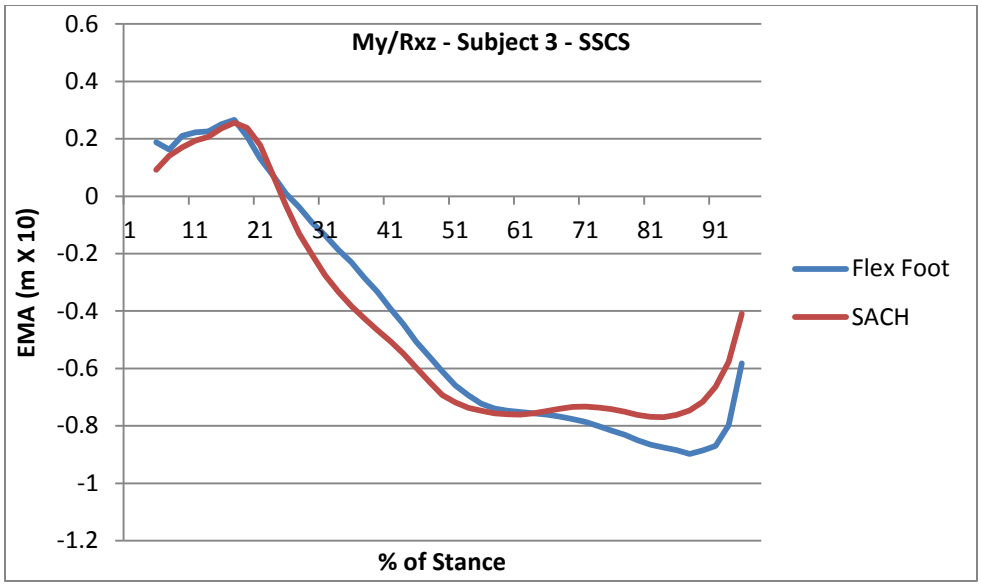


Figure 3.3.1 Effective moment arm – moment about the y-axis/resultant force – mean of 10 steps

3.4 Effects of Alignment Perturbations

Proper prosthetic alignment is critical to maximizing the performance of the prosthesis without generating adverse effects on the user's comfort and the residual limb. This can be challenging for the prosthetist due to the subjectivity of comfort. Additionally, the sensory feedback in the residual limb may vary significantly between subjects and/or regions of the residual limb. Regions may have reduced sensory perception which then fails to relay excessive socket pressures to the user. This can lead to infections and negative effects on the morphology of the limb.

The anterior and posterior portions of the limb warrant investigations because these areas bear high and fluctuating socket pressures throughout gait. The anterior area can be subcategorized into the notch and distal tibia regions, and the posterior into the popliteal and gastrocnemius regions. Socket pressures can be viewed as functions of the forces occurring at the base of the socket which result from ground reaction forces produced in the sagittal plane as a function of the heel and toe levers of the prosthetic foot. The heel and toe levers can be directly

manipulated by perturbing the prosthesis alignment through adjustments within the sagittal plane. The foot can be translated anterior or posterior. Moving the foot backward would increase the length of the heel lever arm, and moving the foot forward would increase the length of the toe lever arm.

Theoretically, alignment variations should increase socket pressures in specific regions of the limb while causing a decrease in others. While it is important to ensure excessive pressures aren't occurring which can damage the residual limb, a level of pressure is necessary to provide the perception of stability to the user. This fine line of tradeoff between the two is not easily defined.

3.5 Analysis Rationale of Gait Parameters and Effective Moment Arm

Existing literature reports patterns for less time spent in stance and swing phases and faster self-selected walking velocities when subjects used feet of ESAR design compared to the SACH (2, 3, 6, 7, 9, 12). Findings were based on data acquired from one or more of the following: an electronic timer, Stride Analyzer, three-dimensional motion capture, or force plate. The real-time data recorded by the transducer were divided into stance and swing phases (Section 4.4 describes methods) for comparing stance durations, swing durations, overall gait cycle times, and the percentage of time spent in stance. It was hypothesized that significant differences could be observed between trials completed with the SACH VS a foot of ESAR design. Results obtained from the transducer were compared to results in the published literature for stance, swing, and gait cycle times.

Another reported difference between ESAR feet and the SACH is the allowable range of flexion of the prosthesis in the sagittal plane during heel and toe loading. Wagner, Sienko, Supan, and Barth (1987) reported an increased range of motion during dorsiflexion and plantar flexion when using the Flex Foot compared to the SACH (4). The SACH (Solid Ankle Cushioned Heel)

design is around 50 years old and does not feature energy storage and release; it is low-cost and has been used in many research studies. It was hypothesized that increases in dorsiflexion and plantar flexion would result in increases of the effective moment arm computed from the transducer data. The peak EMA's during heel and toe loading with the SACH and ESAR feet were computed and compared. Figure 3.3.1 illustrates the effective moment arms computed for the stance phases of the SACH VS the FlexFoot.

Analyses of the effective moment arm also were performed to investigate effects from alignment interventions in the sagittal plane. Schmalz, Blumentritt, and Jarasch (2002) reported tendencies toward increases in knee flexion external moments occurring with posterior shifts of the prosthesis in the sagittal plane, and tendencies toward increases in knee extension moments occurring with anterior shifts (22). It was hypothesized that the moment in the sagittal plane recorded by the transducer (at the end of the socket) could be significantly different between alignment perturbations. Below, Figure 3.5.1 illustrates the moments about the y-axis for the SACH VS the Carbon Copy 2. It was also hypothesized that variations in moment magnitudes could be the result of variations in EMA magnitudes. Therefore, significant differences could also be observed in the EMA's. Refer to Figure 3.5.2 below for plots of the effective moment arm for the SACH at the three different alignment perturbations.

Methods for the statistical analyses performed to test the hypotheses and the study's experimental design are explained in the subsequent chapter.

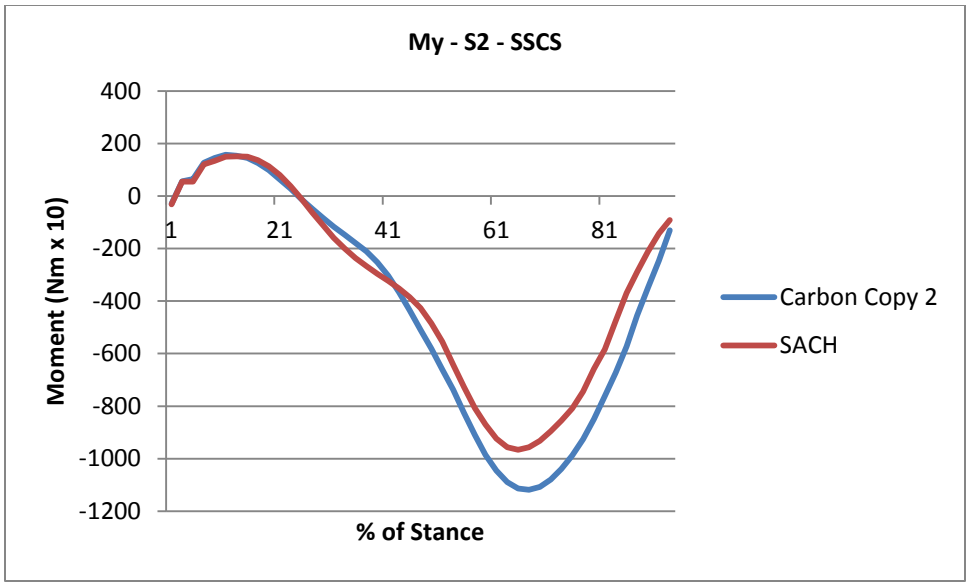


Figure 3.5.1 Moment about the y-axis – SACH VS ESAR – mean of 10 steps

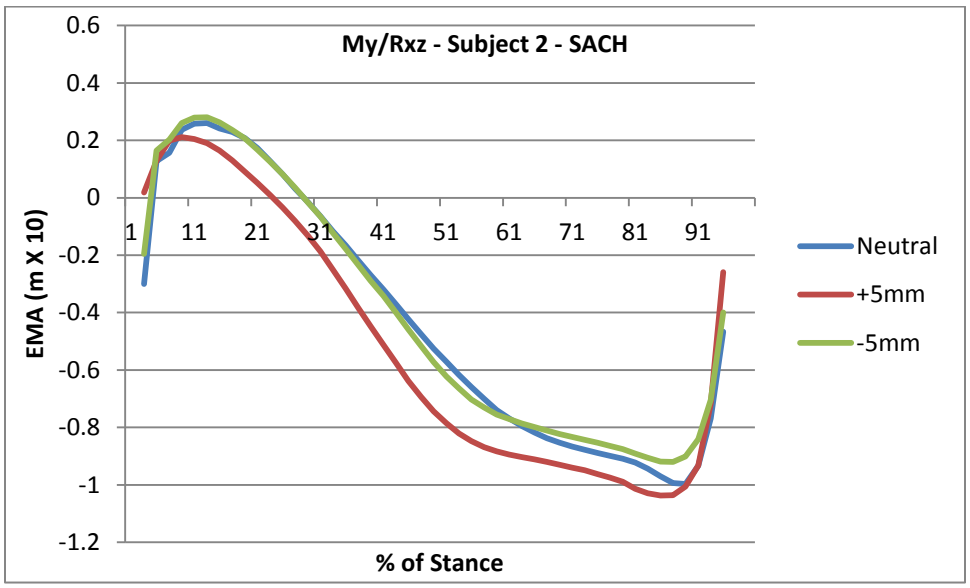


Figure 3.5.2 Effective moment arm – alignment comparisons – mean of 10 steps

CHAPTER 4

DESIGN OF EXPERIMENT

4.1 Transducer Instrumentation

The transducer used in the current study was a JR3 tri-axial transducer model OTESTSENSOR 45E15A4 1000N125 featuring digital output with a reported error of ±0.25% of measured range. It is capable of recording viable data for subjects undergoing activities that involve forces along the prosthesis pylon (mounting location) of up to approximately 2224 N. The limitations and accuracies of the tri-axial transducer, published by JR3, are displayed in Table 4.1.1.

Diameter	11.43 cm
Thickness	3.81 cm
Material	AL 2024
Mass	0.79 kg
Nominal Accuracy, all axes	± 0.25 % of measuring range
Operating Temperature Range, non-condensing	-40 to 65.56 C
Fx, Fy	
Standard Measurement Range	± 1112 N
Standard Resolution	0.138 N
Stiffness	6.41e8 N/m
Single-axis Overload	6894.4 N
Fz	
Standard Measurement Range	± 2224 N
Standard Resolution	0.280 N
Stiffness	4.96e8 N/m
Single-axis Overload	21350.4 N
Mx, My	
Standard Measurement Range	±127.1 N·m
Standard Resolution	1.58e-2 N·m
Stiffness	5.41e5 N·m/rad
Single-axis Overload	497.1 N·m
Mz	
Standard Measurement Range	±127.1 N·m
Standard Resolution	1.58e-2 N·m
Stiffness	1.68e5 N·m/rad
Single-axis Overload	423.7 N·m

Table 4.1.1. Transducer Limitations and Accuracy

To verify the load limits would not be exceeded in this study, the following equations were used to calculate multi-axis overloads:

$Fx/a + Fy/b + Fz/c + My/d + Mz/e \leq 1$, and

$Fx/b + Fy/a + Fz/c + My/d + Mz/e \leq 1$ where

a=7561.6 N

b=6894.4 N

c=21350.4 N

d=497.1 N·m

e=423.7 N·m

The activities performed in this study would not exceed these limits. To verify loads would not be excessive, data recorded for a subject walking down steps was entered into the equations above. Figures 4.1.1-4.1.2 display the results and confirm that the loads are largely below the transducer's limitations.

The transducer was machined by JR3 to allow it to be mounted to the prosthesis. Four bolt holes on the top and bottom of the transducer were fabricated to comply with standard prosthetic adaptors. Figure 4.1.3 shows the transducer equipped with the standard adaptors, and Figure 4.1.4 displays the addition of the Hosmer Spectrum Alignment System (used for varying the prosthesis alignment by 1mm for each complete revolution of the adjusting screw). The transducer was mounted between the socket and pylon. Figure 4.1.5 shows the mounted transducer and the orientation of its axes on a left-sided prosthesis. This orientation remained consistent throughout data collection. The y-axis was positive in the lateral direction for a left-sided amputee and was positive in the medial direction for a right-sided amputee. The x-axis was always positive pointing in the anterior direction (toward the toes).

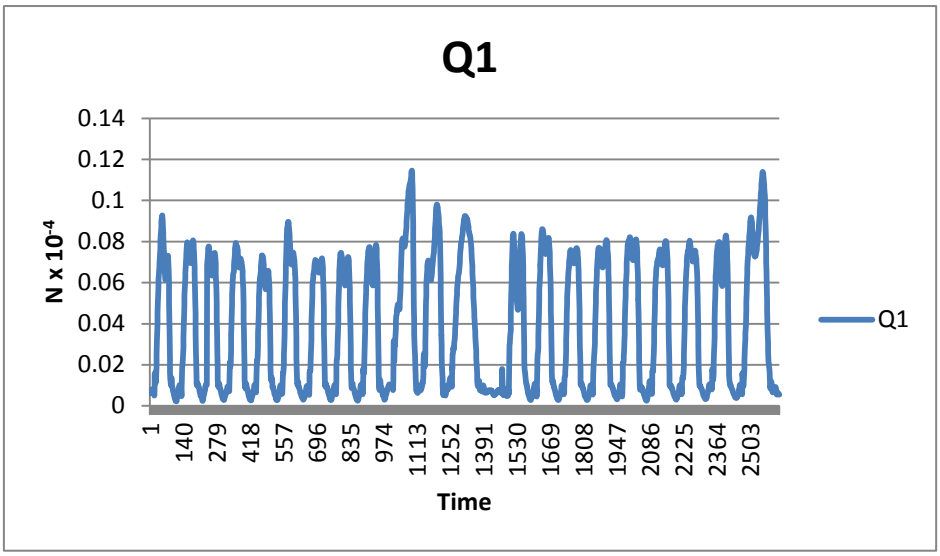


Figure 4.1.1. Values Obtained by Applying the First Overload Equation to Going Down Steps.

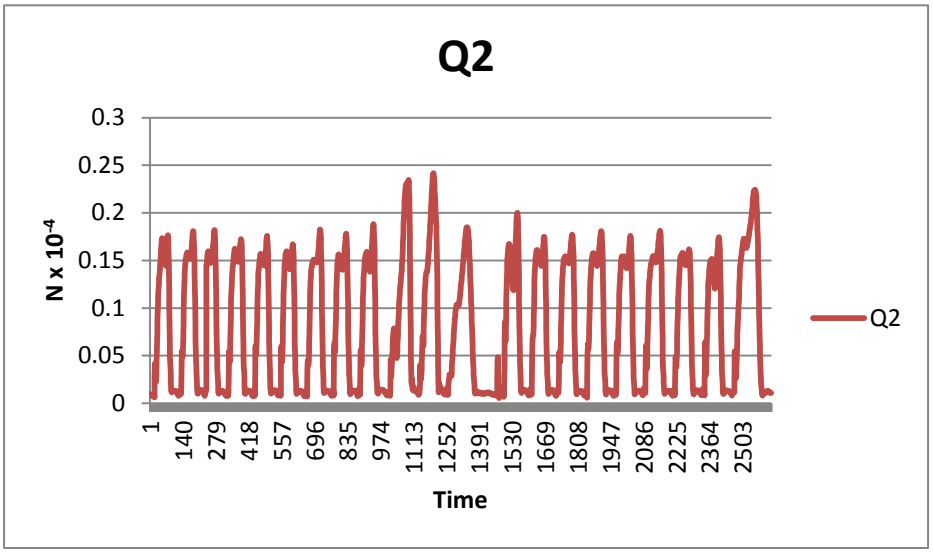


Figure 4.1.2. Values Obtained by Applying the Second Overload Equation to Going Down Steps.

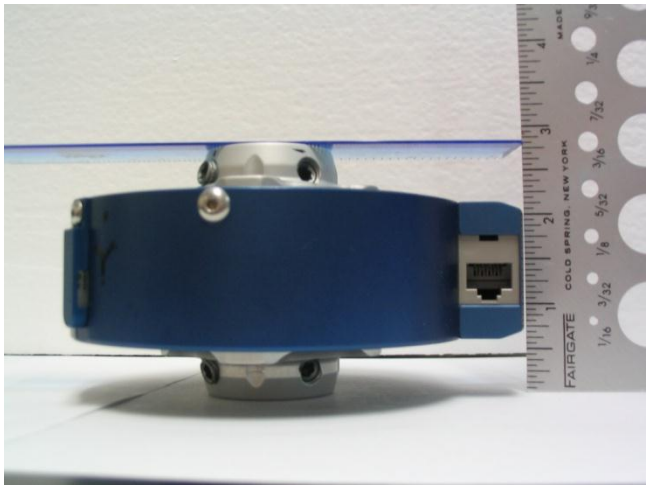


Figure 4.1.3. Transducer with Standard Components attached

Figure 4.1.4. Transducer with Hosmer Spectrum Alignment System Attached

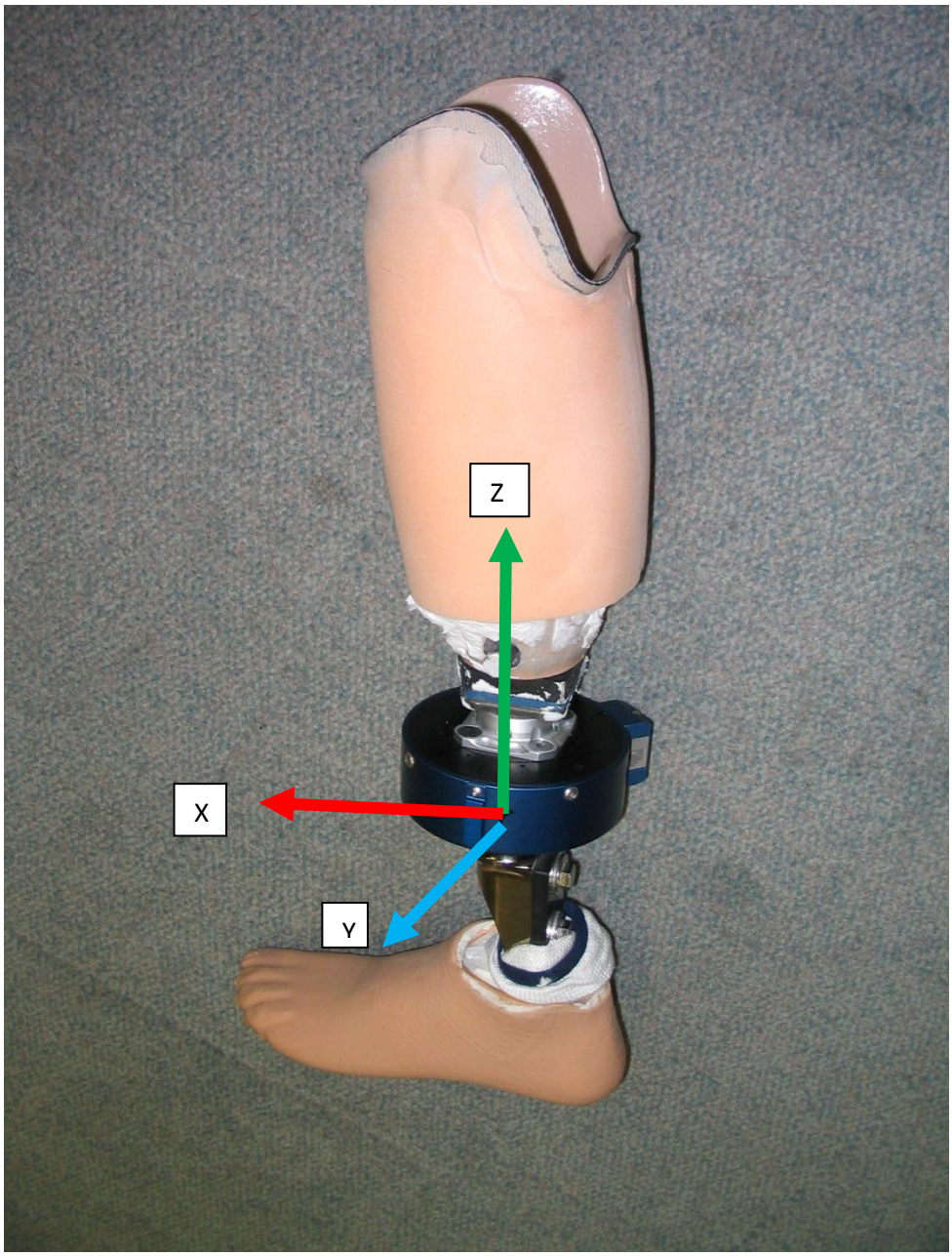


Figure 4.1.5. Mounting and Orientation of the Transducer

Data collection allowed the subjects to undertake the activities independently without being tethered to a cable. To undertake wireless data collection, the following components were acquired: a data processing board and related electronic instrumentation, a PC104/Plus bus-based compact system (WindSystems model PPM-GX-ST) with Wi-Fi wireless access, and a battery power supply (14.8 V 4400 mAh). This bus-based system was a 32bit AMD single board

computer with Windows XP (Microsoft) as the embedded operating system. Force sensor system software was developed and installed on a lap top computer for wireless data recording. Figure 4.1.6 displays the force sensor system block diagram. The system is displayed in Figure 4.1.7 and its specifications are presented in Table 4.1.2.

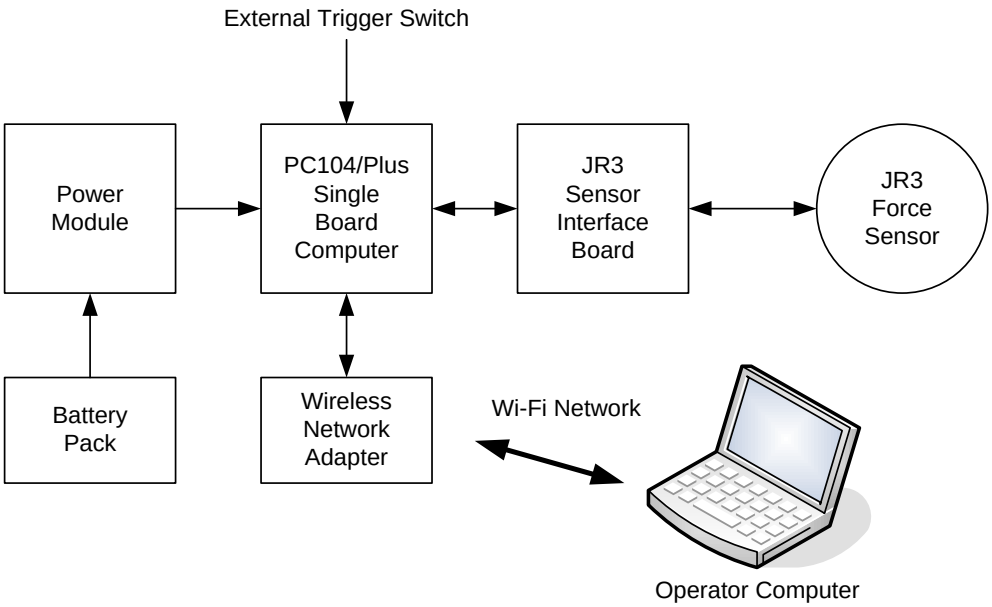


Figure 4.1.6. Force Sensor System Block Diagram

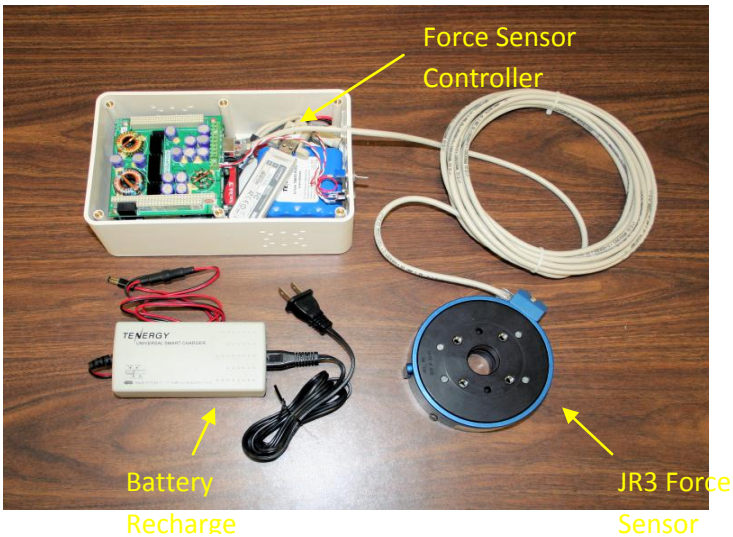


Figure 4.1.7. Picture of Force Sensor System

Item	Specification
Size	20.96 x 12.70 x 7.62 cm
Power Battery	14.8V 4400mAh
Computer	Industrial PC/104 Single Board Computer
SBC Operating System	Windows XP Embedded
Wi-Fi Network	Wireless-G with Speed Booster
Operator Computer	Windows XP with Remote Desktop Connection
Force Sensor	JR3 1000N125
Operating Time	above 60 min after complete charge
Minimum Sampling Time	10msec

Table 4.1.2. Force Sensor System Specification

With a high speed interface cable, the JR3 force sensor was connected to the sensor controller (single board computer and DSP processing interface board). The force sensor controller, along with its power supply, was secured in a Swiss Gear backpack that was worn by the subject while performing the activities (Figure 4.1.8). Using a Linksys router allowing a data transfer speed up to 50Mbytes, the force sensor controller was remotely operated from the lap top (operator computer). Real time force and moment data was relayed back to the operator computer and displayed in the Windows dialog box shown in Figure 4.1.9. Every 10 milliseconds the force and moment data were saved to the single board computer in the form of a data file.

Figure 4.1.8. Computer, Battery Pack, and Backpack

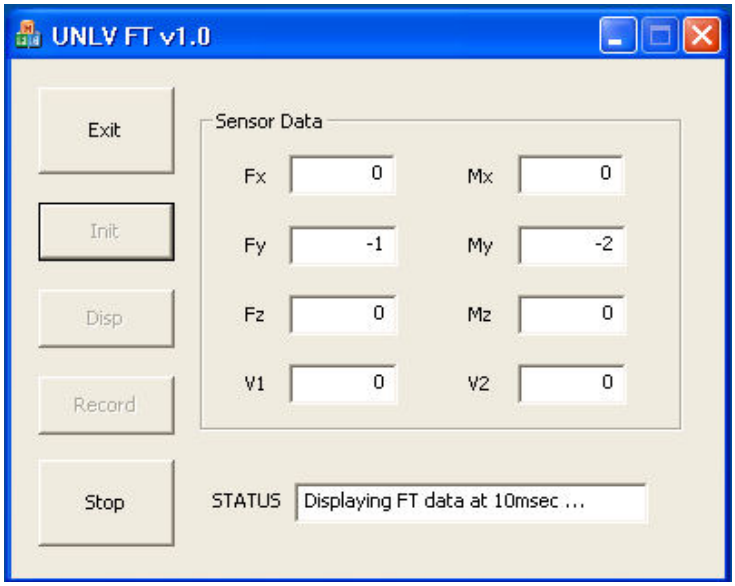


Figure 4.1.9. Dialog Box of Windows Program

4.2 Experimental Methods and Data Collection

The research protocol was submitted to the IRB at UNLV on November 20, 2007, and was then approved on April 22, 2008. A convenience sample of four subjects was recruited. Their demographics and characteristics are listed in Table 4.2.1. Inclusion criteria required the subjects to be able to walk without a loss of balance or an unsteady gait, the ability to function at a K3 or K4 level, and a good fitting socket. Exclusion criteria included residual limb pain, open sores, infections, preparatory prostheses, and new amputees. Two subjects were recruited through the Las Vegas Hanger Prosthetics & Orthotics, Inc. clinic. Through word-of-mouth, a third subject became aware of the study and volunteered to participate. The fourth subject was acquired through BioQuest, Inc. The latter subject utilized two feet of different design, manufactured by BioQuest, Inc. (PerfectStride and BioStride), on which BioQuest wished to receive performance data. All subjects read and signed a Letter of Informed Consent which described the research protocol. Data collection began in December of 2009 and was completed at the end of March, 2010.

	Subject 1	**Subject 2**	**Subject 3**	**Subject 4**
Age	30	38	29	63
Sex	M	M	F	M
Weight, kg	93	95.3	70.8	94.4
Height, cm	170	183	170	180
Reason for Amputation	Trauma	Trauma	Cancer	Trauma
Side of Amputation	Left	Left	Left	Right
Years Since Amputation	5 yrs 6 mos	14 yrs 7 mos	9 yrs 5 mos	40 yrs
Foot Size	27 cm	27 cm	24 cm	27 cm
Feet Compared	TrueStep Renegade	SACH Carbon Copy 2	SACH FlexFoot	SACH PerfectStride BioStride
K Level	4	4	4	4
Suspension	Gel Liner & Sleeve	Gel Liner & Pin Lock	Gel Liner & Pin Lock	Pelite Liner, Socks & Cuff
Residual Limb Length, cm	15.2	19.1	14.3	9.8

Table 4.2.1. Subject Demographics and Characteristics

Data were collected in the Thomas Beam Engineering Building on the main campus of the University of Nevada, Las Vegas. Two feet were used for three of the subjects, and three feet used by the fourth subject. For each subject except the first, one foot was chosen by the principle investigator and the other feet were those that the subjects were using or had used. Table 4.2.1 specifies the feet used by each subject. Shortened pylons were supplied by the principle investigator to allow for the transducer to be mounted at the end of the socket. The subjects wore their preferred shoes. The shortened pylon was connected to the prosthetic foot and the transducer, which was then connected to the socket. The prosthesis was aligned by the principle investigator who was a Certified Prosthetist. A high speed interface cable connected to the female port of the transducer ran up to the backpack worn by the subject where it was connected to the force sensor controller. The wireless router was plugged into an electrical outlet and placed within transmission range of the force sensor controller and operator computer. The transducer was powered-on and initialized by having the subject bear all of their weight on their anatomically intact side to remove all force from the transducer except the weight of the transducer and prosthesis. This initialized the transducer to have a zero load so that during stance all the body weight of the subject would be reported. The Windows dialog box on the operator computer displaying real time measurements was observed to show values of approximately zero while the transducer was initialized. Then the subject was instructed to walk on a level surface at a self-selected comfortable speed (SSCS). Each trial was performed to produce at least fifteen good steps. The location where the trials were conducted (a hallway in the TBE A building) provided sufficient length that the subject did not have to reverse direction to complete fifteen good steps. As a subject completed a trial, the transducer measurements were transmitted back to the lap top and stored. Each file was saved and named according to the subject. After the subject completed three trials (neutral, +5mm, and -5mm alignments), the principle investigator switched prosthetic feet for the subject, realigned the prosthesis, and the trials were then performed with

the different foot. Perturbations were undertaken for only one foot except for Subject 4. Subject 4 involved perturbations of 3 feet.

Data were collected for each subject using two different foot designs with the exception of Subject 4 whom used three. Subject 1 provided a TrueStep and Renegade (College Park, Inc., Fraser, MI; and Freedom Innovations, Inc., Irvine, CA); Subject 3 provided a FlexFoot (Ossur, Inc., Foothills Ranch, CA); and Subject 4 provided a PerfectStride and BioStride (BioQuest, Inc., Bakersfield, CA). Subject 2 was provided with an ESAR foot, Carbon Copy 2 (Ohio Willow Wood, Mt. Sterling, OH). Subjects 2, 3, and 4 were provided with SACH feet obtained new from the same manufacturer and featured identical designs (Ohio Willow Wood, Mt. Sterling, OH). All subjects had prior experience with the feet they used with two exceptions: Subject 2 had no prior experience with the Carbon Copy 2 and Subject 3 had no prior experience the SACH.

Each subject provided their own socket. Subject 1 brought a spare socket and foot, neither of which caused comfort problems. Subject 2 brought a spare socket no longer frequently used, but found it to be acceptable for data collection. Subject 3 brought a socket used for athletic activities; it was suitable for data collection as well as long term use. Subject 4 brought the socket he typically used in daily activities. It also was suitable for data collection as well as long term use.

4.3 Processing of Transducer Data

4.3.1 GUI Design

A GUI (graphical user interface) was used for displaying and analyzing force and moment data collected from the tri-axial transducer as well as preparing data to be exported and processed in EXCEL and SPSS. The software allowed for comparisons of steps of slightly different durations by normalizing gait cycles. Each step was subdivided into 50 discrete time intervals; each representing 2% of the gait cycle. The mean and standard deviation of the 50

normalized intervals for the entire trial were computed, displayed, and copied into an EXCEL file.

The GUI's design required the selection of ten good steps from the continuous stream of data collected from the subject while walking continuously. Experimental protocol called for collecting approximately fifteen steps in a trial. This was done so non-representative steps such as those at the beginning and end of the trial, as well as any that may have occurred in the middle could be discarded. A sample of ten good steps was sufficient to compute means and standard deviations which could be used in tests of significance. The GUI design also allowed for the starting and stopping points for all ten steps to be selected in one window. The display of more than ten steps would have been quite cumbersome in the GUI (38).

4.3.2 GUI Output

After specifying which data file was to be analyzed with the GUI, the screen illustrated in Figure 4.3.1 was displayed.

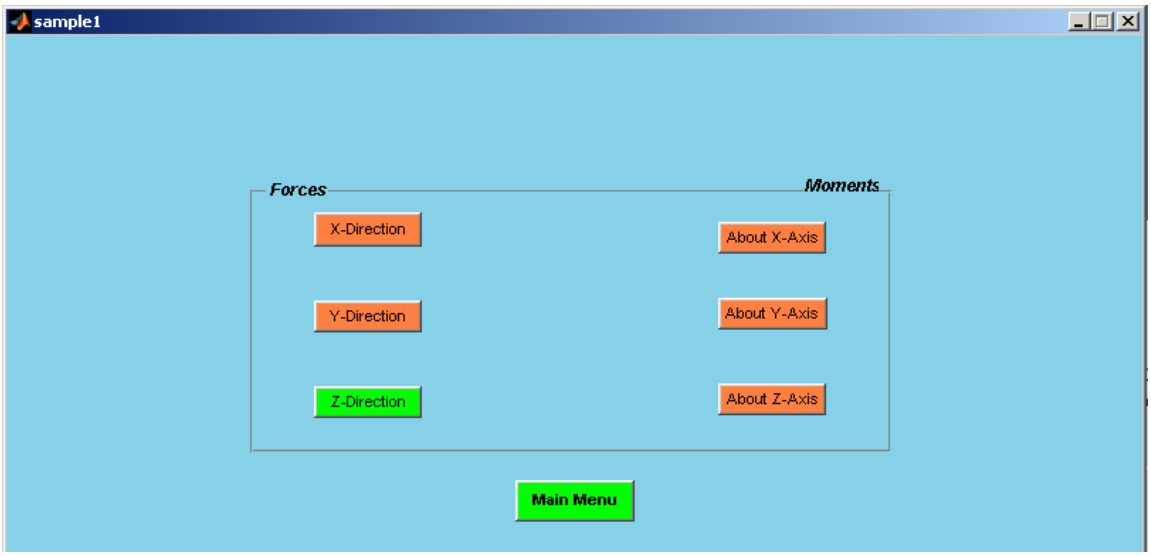


Figure 4.3.1 GUI display of transducer variables to be analyzed

The force in the z-direction was required to be analyzed first. Ten good steps in the z-direction were first selected (refer to CH. 4.4 for the methods), and then the same starting and stopping points were applied to the other variables.

Figure 4.3.2 illustrates the trial's continuous stream of data. In this window the ten good steps for measurement were identified.

The data plot could be zoomed in on to better identify the good steps. After determining the starting and stopping points of the steps (refer to CH. 4.4 for the methods), the time positioning was entered into the GUI (see Figure 4.3.3). The software then divided data for each individual step into 50 segments and computed the means and standard deviations over 10 steps (see Figure 4.3.4).

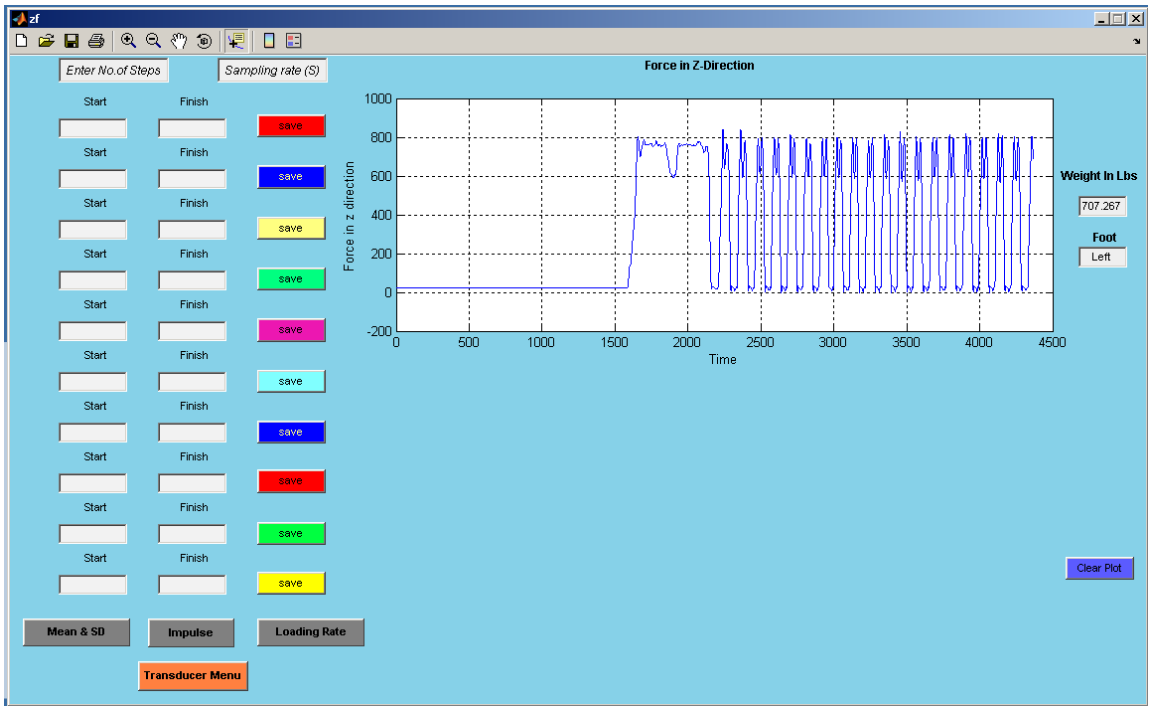


Figure 4.3.2 GUI display of continuous stream of trial data

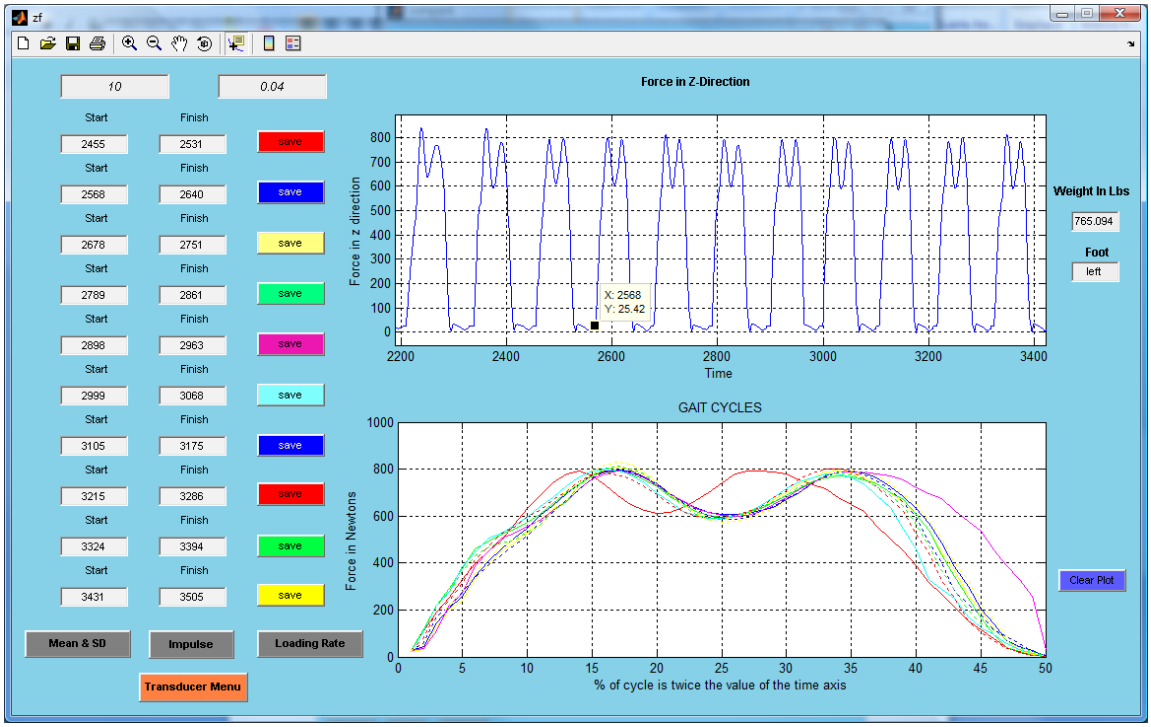


Figure 4.3.3 GUI display of selection of ten good steps

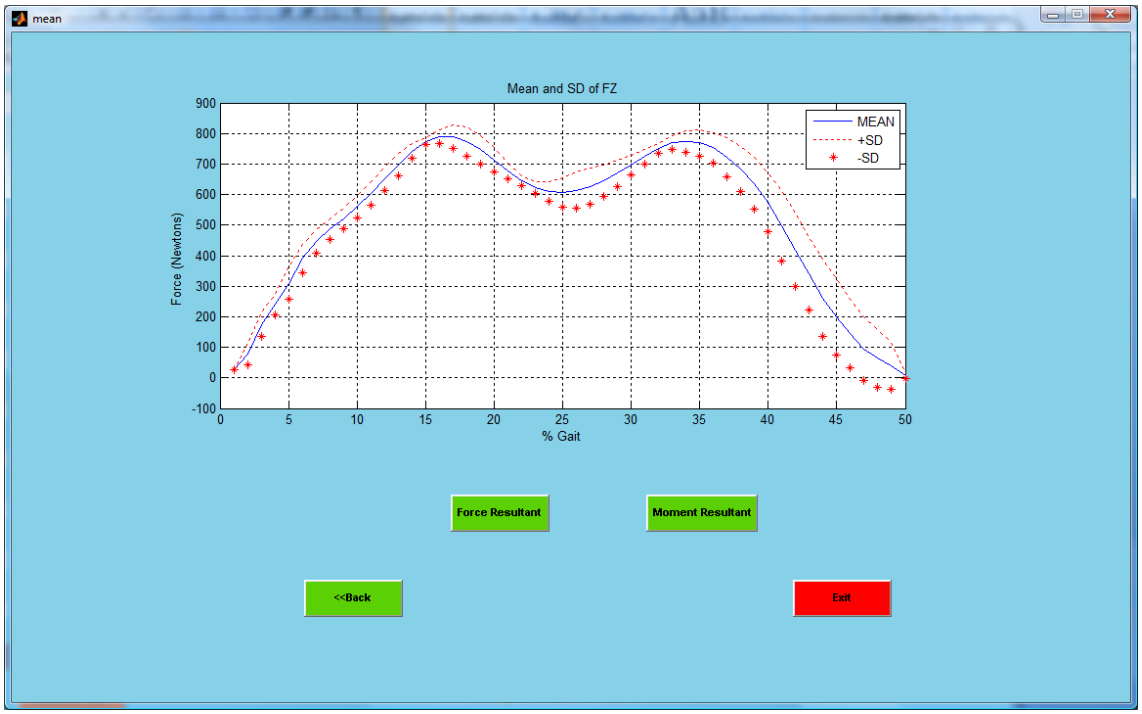


Figure 4.3.4 GUI display of the means and standard deviations

The data collected for the moments about the x, y, and z-axes were processed in the same manner as the forces. The starting and stopping points were automatically entered in for the moment windows. Figure 4.3.5 illustrates the moment about the y-axis window.

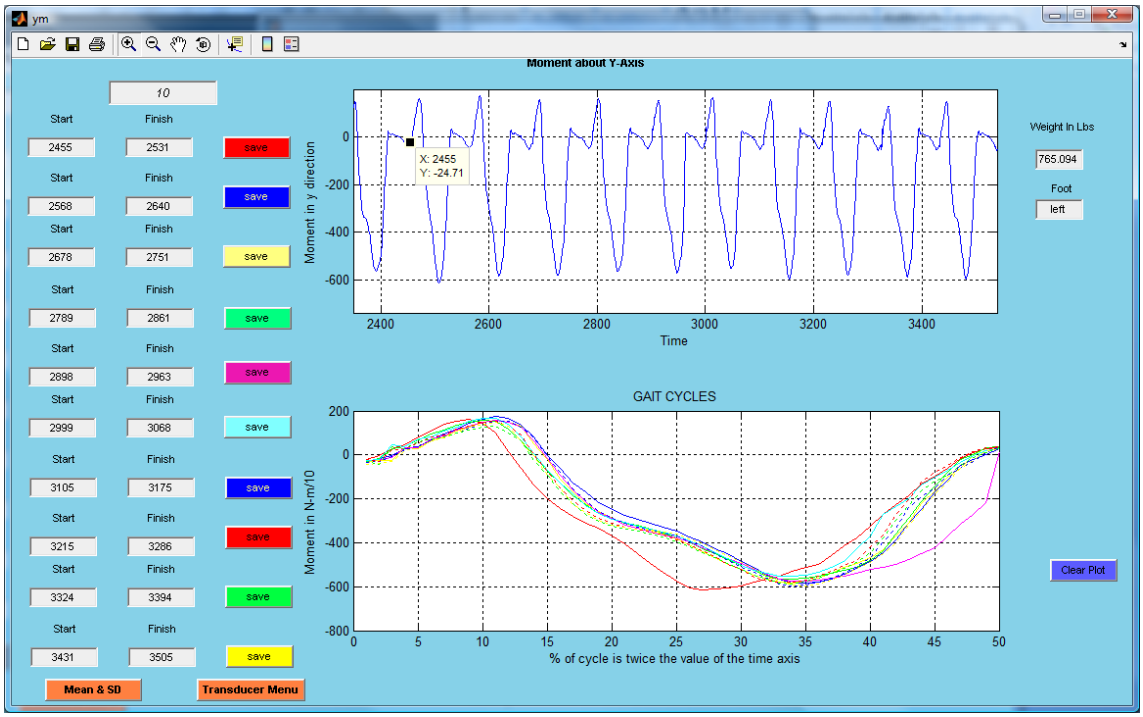


Figure 4.3.5 GUI display of the moment about the y-axis

4.4 Steps Selections in the GUI

1. The Fz data recorded for each trial was observed in the GUI to determine which steps were to be used (Figure 4.4.1). The ten steps selected were those displaying the most consistent vertical ground reaction force profiles. Profile consistency and quality were derived from visually inspecting the Fz Force vs. Time plot in the GUI. Steps displaying similar maxima and minima values in force during midstance were chosen.

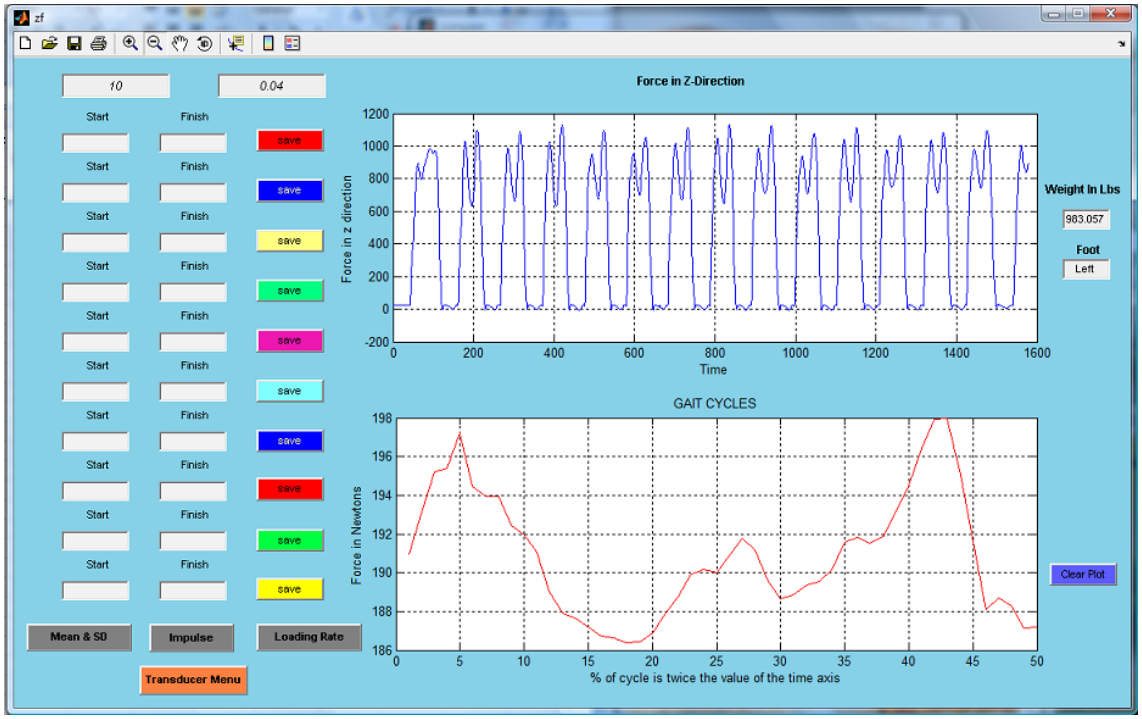


Figure 4.4.1. Appearance of GUI as Used to Select Steps Based on Maximum and Minimum Values Associated with Midstance

2. After identifying the first step, the zoom feature in the GUI was used to maximize the profiles for two steps within the Fz Force vs. Time plot window (Figure 4.4.2). This sufficiently exposed the plot characteristics to allow them to be visually examined for stance initiation and termination.

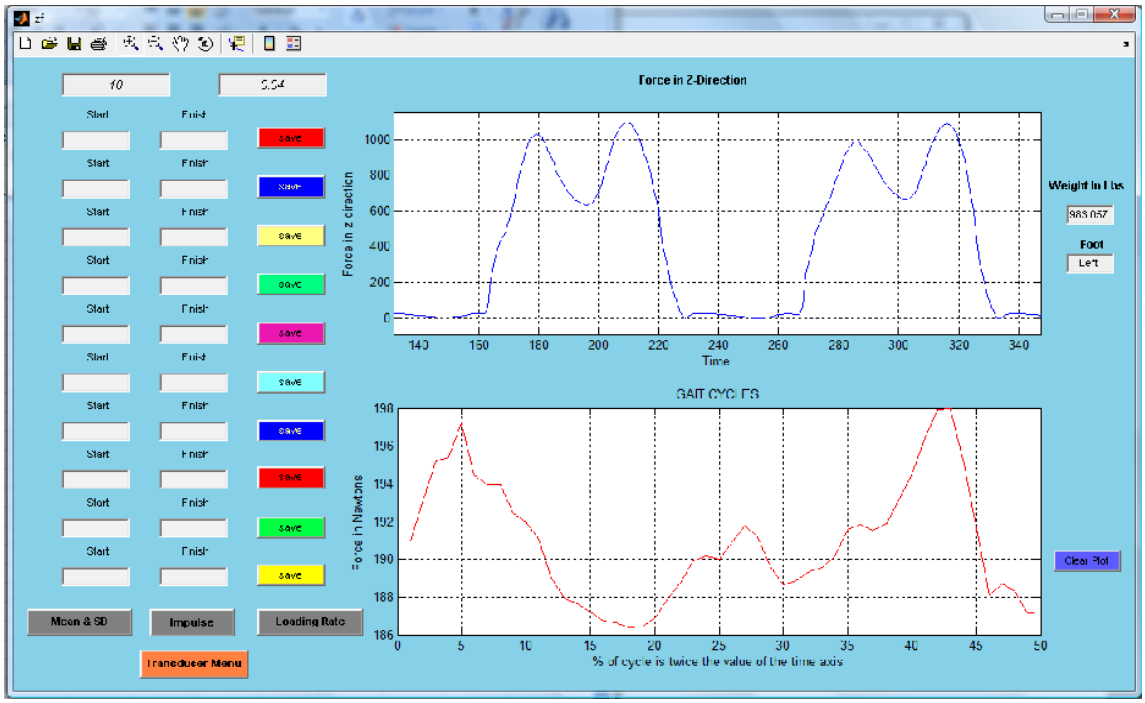


Figure 4.4.2. Magnification of Individual Steps in the GUI

3. The loading portion of stance was easily identified by the positive slope from approximately zero Newtons of force to the first maxima of the bimodal curve. The low point of the bimodal curve occurred close to midstance. The second maxima preceded a negative slope terminating at approximately zero Newtons of force which represented unloading prior to toe-off. Between stance, the swing phase was represented by a nearly flat line with values of approximately zero Newtons.

4. Toward the end of the swing-phase, the subject's leg would decelerate in preparation for stance. Consequently, the transducer would record a drop in magnitude approximately a fraction of a Newton. This created a "U" in the plot consisting of three data points. Having the first data point in the swing phase and the third in the loading of stance, the middle value was identified as heel strike. Using the GUI's data cursor and toggling between adjacent points, this lowest value in the "U" (heel strike) was indentified, and its position in time was recorded (Figure 4.4.3).

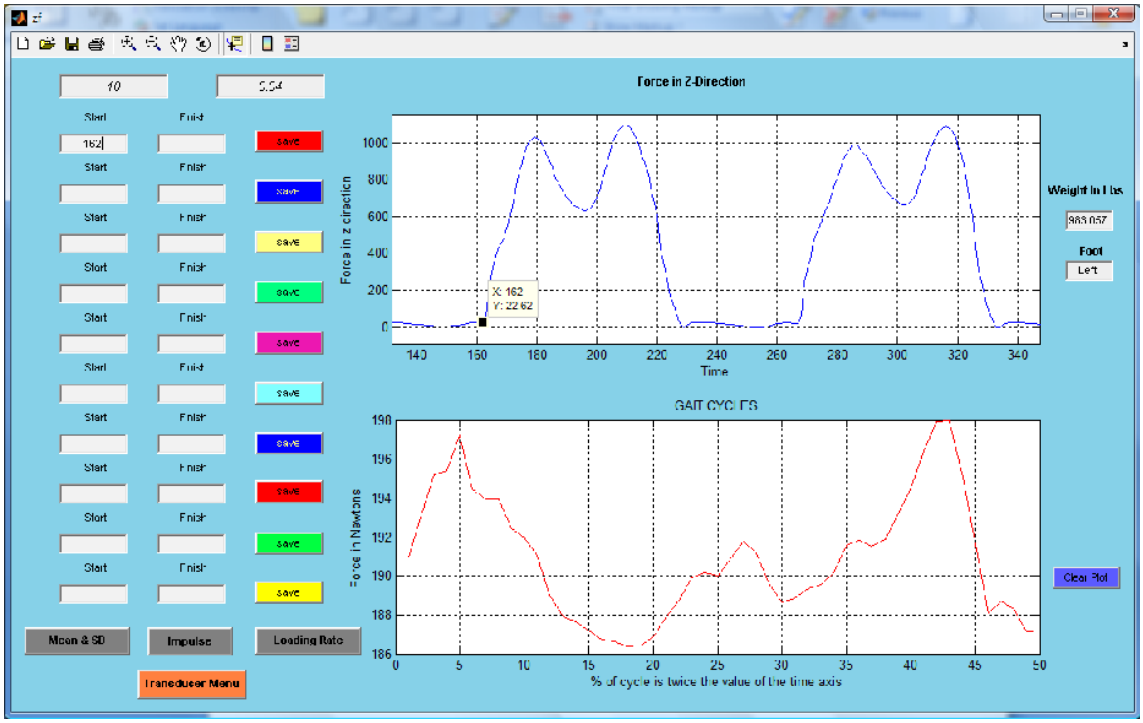


Figure 4.4.3. Identification of Points Representing Heel Strike

Similar to the initiation of stance, the transition from stance termination into swing delivered a three point "U" shape in the plot. Like the selection for heel strike, toe-off was termed as the lowest force value of the three points (Figure 4.4.4).

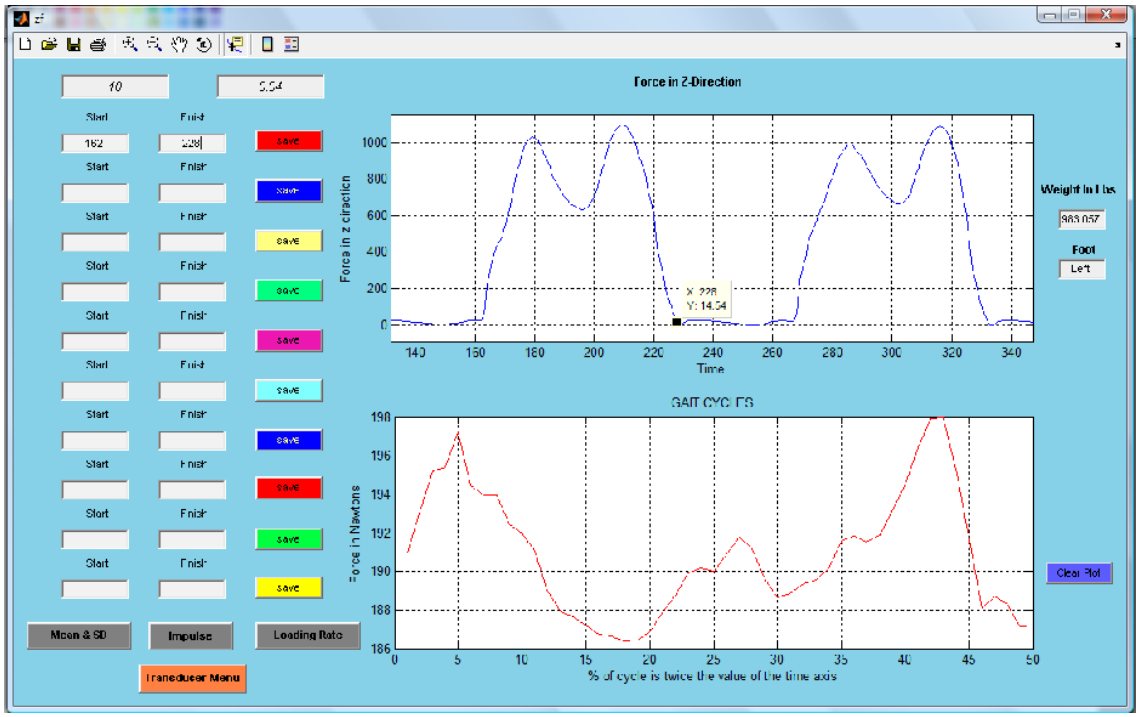


Figure 4.4.4. Selection of Points Representing Toe-Off

* Some exceptions in data characteristics required some alterations to Step 4. See below for Step 4 Alternative Approaches.

Steps 4 and 5 were repeated for the remaining 9 steps. All starting and stopping points for each step were recorded. The time positions found in the Fz plot were then used to define the starting and ending times for Fx, Fy, Mx, My, and Mz.

5. Step 4 Alternative Approaches: In cases where more than three points comprised the "U" portions before and/or after stance (two mid-point values of equal magnitude), the middle "U" value closest to the start or stop of stance was chosen. Occasionally a distinct "U" could not be identified before and/or after stance. In these cases, the data cursor was positioned

toward the end of swing. It was then toggled toward stance until it reached the first point on the loading slope that was much greater than the previous point; approximately 200% larger. The cursor was then toggled back to the previous position and marked as the “Start” of the step. The selection of the “Stop” position was found in the same way except substituting the unloading slope for the loading. Due to the centrifugal force of the prosthesis during swing, there were instances when the transducer recorded a relatively small negative Fz force. When this occurred, the start/stop of the step was identified as the first point on the loading/unloading slope with a positive force magnitude adjacent to a negative magnitude.

* It should be noted, that when one step required an alternative approach to start/stop selection the other nine steps typically required the same approach. Therefore, there was consistency in point selection throughout the activity.

4.5 Analysis of Transducer Data

Working hypotheses are structured under two main objectives: addressing how foot performance varies with design, and how prosthesis alignment affects aspects of gait. Table 4.5.1 below summarizes the transducer measurements that were investigated to test the hypotheses (refer to CH 1.3 for hypotheses details).

The effects of foot design on performance were investigated by comparing transducer measurements recorded for each subject using feet of two different designs with the exception of Subject 4 whom used three. Each analysis compared the SACH, or one of similar traditional design, to an ESAR foot; an additional comparison was made of the two ESAR feet used by Subject 4. Prosthesis alignment affects on aspects of gait were investigated utilizing one foot for each subject at three different alignments with the exception of Subject 4 whom used three different foot designs. Table 4.5.2 summarizes the foot designs used by each subject for the analyses.

Transducer Measurements Compared Between Feet and Between Alignments		
	Foot Comparisons	**Alignment Comparisons**
Gait Parameters		
Stance Duration	✓	✓
Swing Duration	✓	✓
Gait Cycle	✓	✓
% Stance	✓	✓
Effective Moment Arm		
Interval in Stance When Equal to Zero		✓
Peaks at Heel and Toe Loading	✓	✓
Interval in Stance of Peaks		✓
Alignment Perturbations		
Maximum Resultant Force (Rxz) at Heel and Toe Loading		✓
Interval in Stance of Maximum Resultant Force (Rxz) Magnitudes		✓
Effective Moment Arm Magnitude Coinciding With Maximum Resultant Force (Rxz)		✓
Maximum My Magnitudes		✓

Table 4.5.1 Summary of comparisons of transducer data

Feet Used For Foot Design Comparisons and Analyses of Effects From Alignment				
	S1	**S2**	**S3**	**S4**
Feet Compared	TrueStep Renegade	SACH Carbon Copy 2	SACH FlexFoot	SACH PerfectStride BioStride
Feet Evaluated at Varied Alignments	TrueStep	SACH	SACH	SACH PerfectStride BioStride

Table 4.5.2 Summary of included foot designs, grouped by Subject

Statistical tests were computed for comparisons of feet and comparisons of alignment. T-tests (EXCEL) were used for comparing two feet while a one-way ANOVA (SPSS) was used for

comparing three alignments. Differences in gait parameters, EMA peaks, Rxz peaks and My peaks were investigated.

Statistical tests for significant differences in gait parameters were computed utilizing raw (non-normalized) transducer data of ten steps. Stance durations were obtained by subtracting heel strike time values from toe-off. Time values were obtained from the GUI during step selection (refer to values preceded by "y:" in Figure 4.4.3 and Figure 4.4.4 for examples). Swing durations were computed by subtracting the y-value at toe-off from the y-value of the following heel strike. Gait cycle durations were obtained by computing the time differential between consecutive heel strikes. The percentage of stance was computed by dividing stance times by gait cycle durations.

Effective moment arms were obtained for ten steps using data normalized to fifty equal intervals representing 2% of stance. The moments about the y-axis (My) recorded by the transducer were divided by the resultant forces (Figure 4.5.1 and Figure 4.5.2 below). Rxz (resultant force) was derived from the Fz and Fx values recorded by the transducer, $R_{xz}=\sqrt{(F_x^2+F_z^2)}$. Statistical tests were calculated for the peak EMA's during heel loading and toe loading. Positive EMA values occurred during heel loading and negative values during toe loading. Tests of statistical significance were also computed for the interval in stance at which peak EMA's occurred.

Tests for statistically significant differences in transducer measurements affected by alignment perturbations were performed for: peak resultant forces (Rxz) at heel and toe loading (Figure 4.5.3 and Figure 4.5.4), the interval in stance that peak resultant forces occurred, the EMA magnitudes coinciding with peak Rxz's, and peak values for the moment about the y-axis during heel and toe loading (Figure 4.5.5 and Figure 4.5.6). Data for ten steps, normalized to fifty equal intervals, were used.

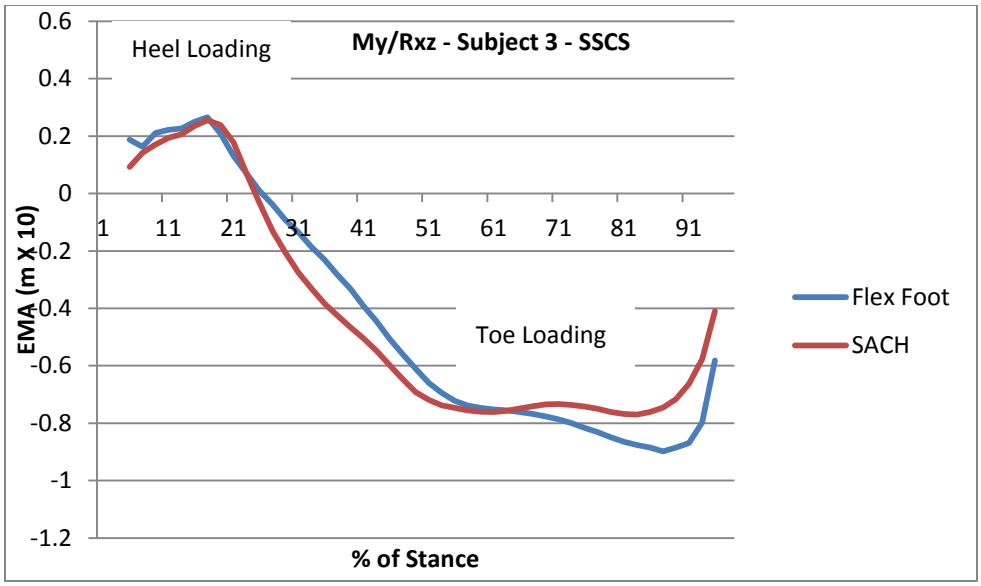


Figure 4.5.1 Effective moment arm - mean of 10 steps – foot comparisons

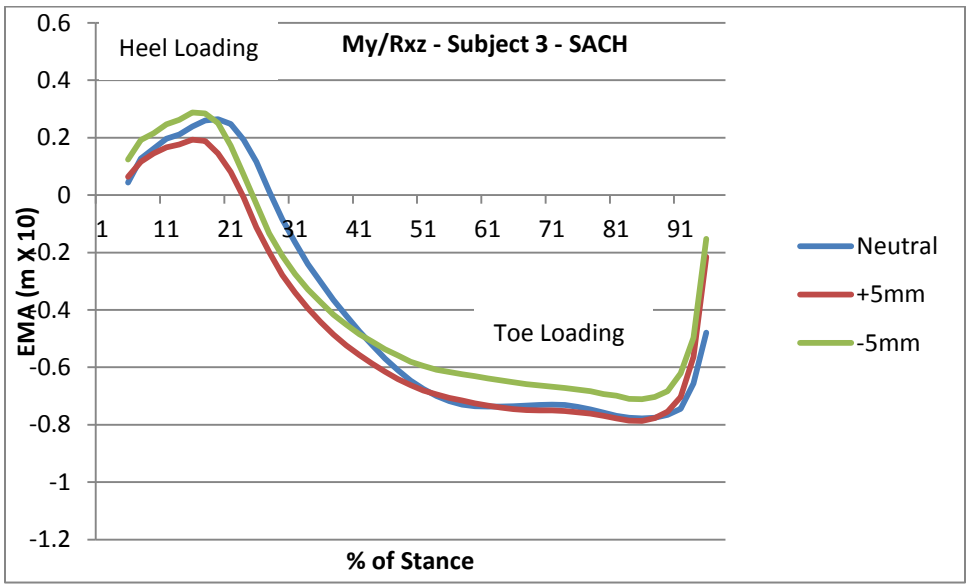


Figure 4.5.2 Effective moment arm – mean of 10 steps – alignment comparisons

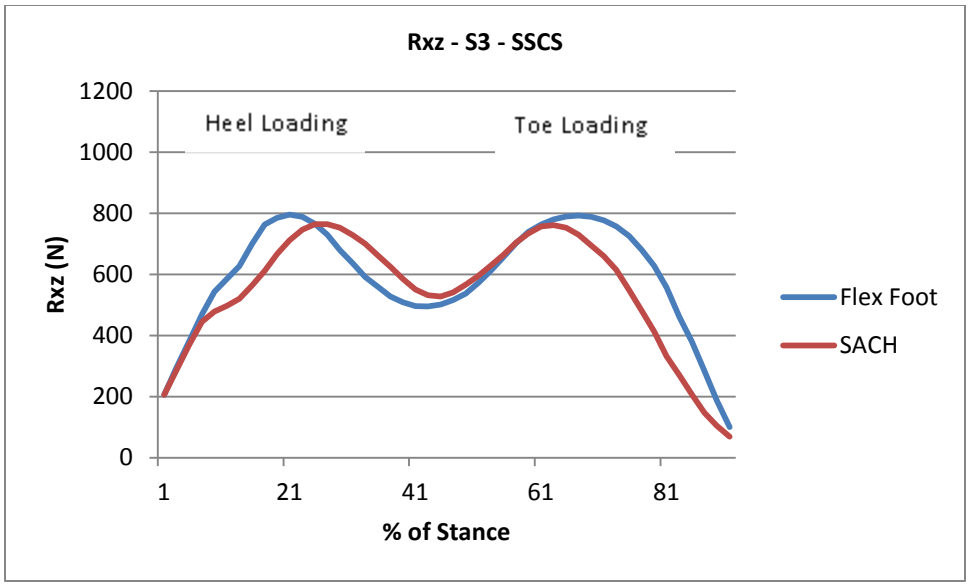


Figure 4.5.3 Resultant force – mean of 10 steps – foot comparisons

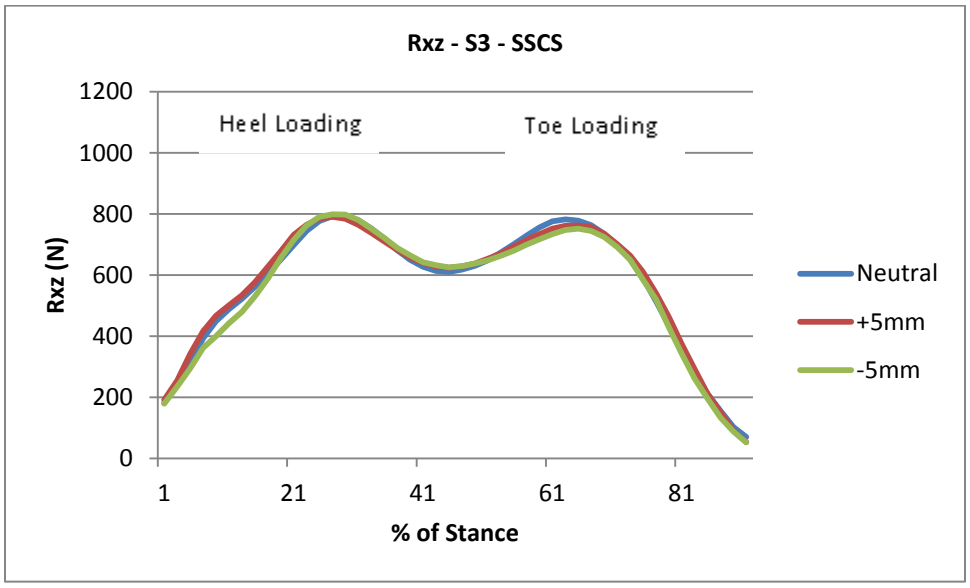


Figure 4.5.4 Resultant force – mean of 10 steps – alignment comparisons

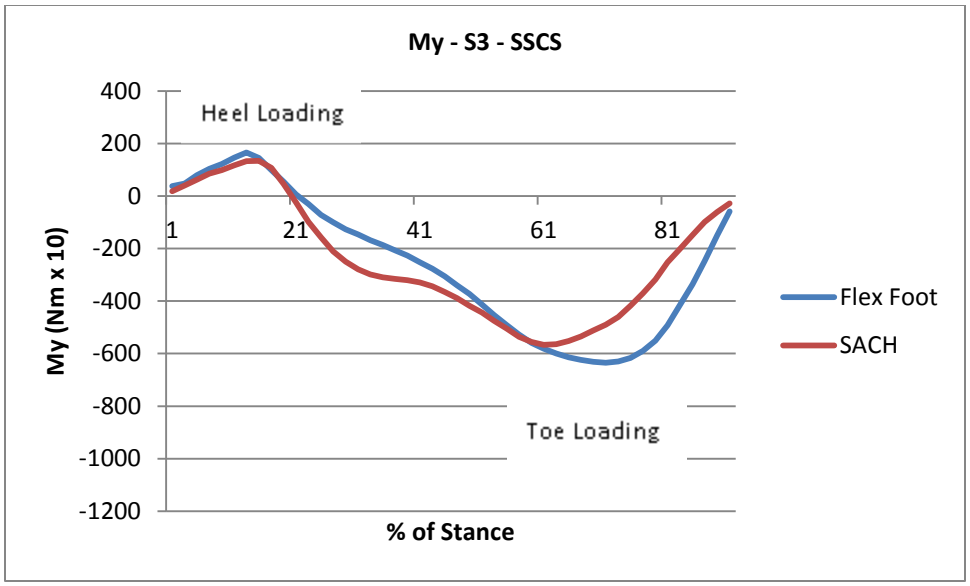


Figure 4.5.5 Moment about y-axis – mean of 10 steps – foot comparisons

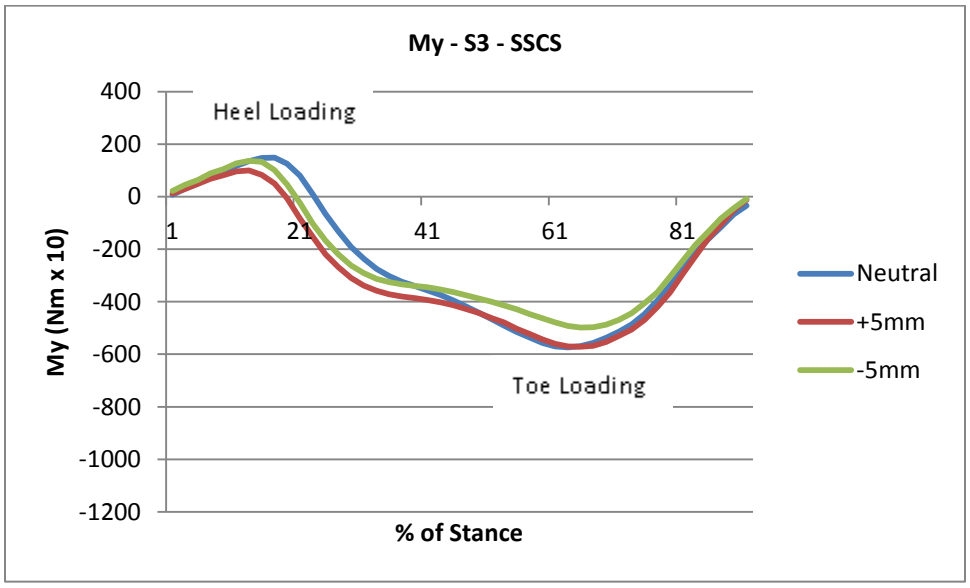


Figure 4.5.6 Moment about y-axis – mean of 10 steps – alignment comparisons

CHAPTER 5

RESULTS

This chapter presents the results of the statistical analyses. Appendix B contains tables arranging the results of the statistical tests (p-values) for comparisons of feet and analysis of alignment effects according to the transducer variables being compared. Tables 5.1.1, 5.1.2, 5.2.1, 5.2.2, 5.3.1, and 5.3.2 below summarize the means and standard deviations. Significant differences resulted in some of the analyses with patterns being identified across feet. The subsequent sections summarize the patterns.

5.1 Gait Parameters

T-tests and one-way ANOVA's were calculated to examine the hypotheses that stance and swing times, gait cycle duration, and the percentage of time spent in stance would vary with foot design as well as prosthesis alignment in the sagittal plane. Table 5.1 below summarizes the design of analysis (the feet used, the transducer variables compared, and the type of statistical test performed).

5.1.1 Differences between feet

Six within subject foot comparisons were made utilizing nine different feet involving seven different designs (Table 5.1 and Table 5.1.1). Results of the t-tests are shown in Table 9.1.1 in Appendix B. Of the four comparisons involving the SACH foot, all exhibited significantly different stance times with p-values ranging from 1.78E-06 to 0.0448. Three resulted in less time being spent on the SACH and one the Flex Foot. Three of the four SACH comparisons resulted in significantly less time spent in the gait cycle when using the SACH ($p<7.60E-05$ to 0.0215), the fourth was the Flex Foot. No patterns were observed when comparing swing duration and the percentage of time spent in stance.

Gait Parameters Compared Between Feet and Between Alignments							
						Foot Comparisons	**Alignment Comparisons**
Transducer Measurements							
	Stance Duration					✓	✓
	Swing Duration					✓	✓
	Gait Cycle					✓	✓
	% Stance					✓	✓
	Comparison						
	1	2	3	4	5	6	
	Subject						
	S1	**S2**	**S3**	**S4**	**S4**	**S4**	**Statistical Test**
Feet Compared	TrueStep Renegade	SACH Carbon Copy 2	SACH FlexFoot	SACH PerfectStride	SACH BioStride	PerfectStride BioStride	**T-Test**
Feet Evaluated at Varied Alignments	TrueStep	SACH	SACH	SACH	BioStride	PerfectStride	**One-Way ANOVA**

Table 5.1 Summary of gait parameter comparisons.

Results of Gait Parameter Comparisons Between Foot Designs									
		Stance (s)		Swing (s)		Gait Cycle (s)		% of Time in Stance	
Subject	**Foot**	**Mean**	**Std Dev**	**Mean**	**Std Dev**	**Mean**	**Std Dev**	**Mean**	**Std Dev**
S1	**Renegade**	0.705	0.0222	0.428	0.0128	1.258	0.0316	62.3	0.7
	TruStep	0.724	0.0250	0.425	0.0120	1.146	0.0325	62.9	1.0
S2	**Carbon Copy 2**	**0.686**	0.0267	**0.392**	0.0097	**1.071**	0.0209	63.4	0.6
	SACH	**0.665**	0.0135	**0.381**	0.0078	**1.044**	0.0142	63.5	0.7
S3	**Flex Foot**	**0.625**	0.0172	0.387	0.0087	**1.009**	0.0203	**61.7**	0.7
	SACH	**0.677**	0.0164	0.396	0.0113	**1.073**	0.0218	**63.1**	0.8
S4	**SACH**	**0.703**	0.0241	**0.458**	0.0083	**1.158**	0.0268	**60.4**	0.8
	BioStride	**0.749**	0.0173	**0.429**	0.0093	**1.174**	0.0174	**63.5**	0.7
	PerfectStride	0.733	0.0306	0.441	0.0285	**1.176**	0.0375	62.5	2.1

* Sample Sizes: N=9; except for Stance: N=10. Significant differences are in bold type.

Table 5.1.1 Summary of differences in Gait Parameters between foot designs

Results of Gait Parameter Comparisons Due to Alignment Interventions									
		Stance (s)		Swing (s)		Gait Cycle (s)		% of Time in Stance	
Subject	**Align**	**Mean**	**Std Dev**	**Mean**	**Std Dev**	**Mean**	**Std Dev**	**Mean**	**Std Dev**
S1 TruStep	**Neutral**	0.737	0.0221	0.402	0.0254	**1.133**	0.0308	64.5	1.2
	+5mm	0.753	0.0211	0.041	0.0088	1.156	0.0240	64.9	0.7
	-5mm	0.764	0.0350	0.414	0.0113	**1.178**	0.0396	64.8	1.3
S2 SACH	**Neutral**	**0.728**	0.0148	0.370	0.0381	**1.097**	0.0424	66.3	2.4
	+5mm	**0.771**	0.0292	0.389	0.0318	**1.158**	0.0540	66.5	1.6
	-5mm	0.751	0.0384	0.383	0.0132	1.129	0.0362	66.0	1.5
S3 SACH	**Neutral**	**0.712**	0.0301	0.376	0.0113	**1.084**	0.0347	65.4	1.0
	+5mm	**0.738**	0.0114	0.389	0.0190	**1.127**	0.0265	65.5	1.0
	-5mm	0.731	0.0213	0.382	0.0130	1.117	0.0261	65.8	1.1
S4 SACH	**Neutral**	**0.712**	0.0204	**0.444**	0.0101	**1.151**	0.0176	**61.4**	0.6
	+5mm	**0.677**	0.0195	0.436	0.0235	**1.112**	0.0367	60.9	1.3
	-5mm	**0.683**	0.0298	**0.459**	0.0117	1.139	0.0366	**59.7**	1.0
S4 BioStride	**Neutral**	0.746	0.0320	0.429	0.0117	1.168	0.0323	63.3	0.7
	+5mm	0.772	0.0123	0.428	0.0383	1.199	0.0428	**64.4**	2.2
	-5mm	0.745	0.0280	0.441	0.0145	1.183	0.0374	**62.7**	0.9
S4 PerfectStride	**Neutral**	**0.689**	0.0202	0.441	0.0127	**1.131**	0.0242	**61.0**	1.0
	+5mm	**0.725**	0.0268	0.450	0.0150	**1.174**	0.0260	**61.7**	1.4
	-5mm	**0.776**	0.0250	0.448	0.0249	**1.228**	0.0349	**63.5**	1.4

* Sample Sizes: N=9; except for Stance: N=10. Significant differences are in bold type.

Table 5.1.2 Summary of differences in Gait Parameters from alignment variations

5.1.2 Differences between alignments

Six within subject alignment comparisons were made at three alignment settings (Neutral, +5mm, -5mm) with four different foot designs (Table 5.1 and Table 5.1.2). Results of the ANOVA's are shown in Table 9.1.2-9.1.4 in Appendix B. Two of the three SACH feet were observed to spend significantly less time in stance and the overall gait cycle at the Neutral alignment VS +5mm ($p<0.007$ to 0.038); the third SACH was observed to have significantly shorter stance and gait cycle times at +5mm. No patterns were observed in: swing times and the percentage of time spent in stance, comparisons of Neutral VS -5mm and +5mm VS -5mm, and comparisons for the BioStride and PerfectStride.

5.2 Effective Moment Arm

T-tests and one-way ANOVA's were calculated to examine the hypotheses that the interval in stance when the EMA equals zero, EMA peaks at heel and toe loading, and the interval in stance coinciding with EMA peaks would vary with foot design as well as prosthesis alignment in the sagittal plane. Table 5.2 below summarizes the design of analysis (the feet used, the transducer variables compared, and the type of statistical test performed).

5.2.1 X-Axis Crossover Time – Comparison of Alignments

Theoretically, the moment arm should cross the x-axis (EMA=0) in the order from earliest in stance to last: +5mm, Neutral, -5mm. This is due to the heel-lever arm being increased with anterior to posterior prosthesis translations in the sagittal plane, and the toe-lever arm being increased with posterior to anterior translations. Results are consistent with this theory (Table 9.2.1 in Appendix B). Figure 5.2.1.1 below illustrates the effective moment arms computed for all feet. Plots and normalized data were visually inspected to identify the percentage of stance when the EMA crossed the x-axis (or equaled zero) for each alignment.

Effective Moment Arm Compared Between Feet and Between Alignments							
						Foot Comparisons	**Alignment Comparisons**
Transducer Measurements							
	Interval in Stance When Equal to Zero					☐	✓
	Peaks at Heel and Toe Loading					✓	✓
	Interval in Stance of Peaks					☐	✓
	Comparison						
	1	2	3	4	5	6	
	Subject						
	S1	**S2**	**S3**	**S4**	**S4**	**S4**	**Statistical Test**
Feet Compared	TrueStep Renegade	SACH Carbon Copy 2	SACH FlexFoot	SACH PerfectStride	SACH BioStride	PerfectStride BioStride	**T-Test**
Feet Evaluated at Varied Alignments	TrueStep	SACH	SACH	SACH	BioStride	PerfectStride	**One-Way ANOVA**

Table 5.2 Summary of effective moment arm comparisons.

Results of Effective Moment Arm Comparisons Between Foot Designs					
		Peak EMA (m x 10)			
		Heel Loading		Toe Loading	
Subject	**Foot**	**Mean**	**Std Dev**	**Mean**	**Std Dev**
S1	**Renegade**	**0.304**	0.0226	**-0.921**	0.0101
	TruStep	**0.246**	0.0229	**-0.949**	0.0200
S2	**Carbon Copy 2**	0.22	0.0142	**-1.155**	0.0372
	SACH	0.223	0.0276	**-1.046**	0.0166
S3	**Flex Foot**	0.266	0.0187	**-0.898**	0.0164
	SACH	0.256	0.0363	**-0.770**	0.0162
S4	**SACH**	**0.360**	0.0239	**-0.669**	0.0255
	BioStride	**0.047**	0.0195	**-0.665**	0.0353
	PerfectStride	**0.187**	0.0189	**-0.714**	0.0304

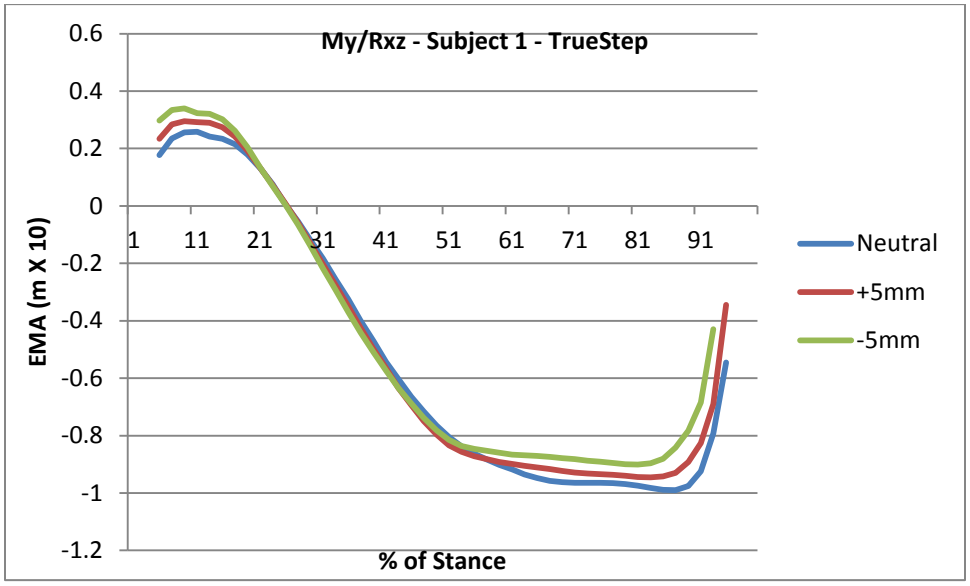
* Sample Sizes: N=10. Significant differences are in bold type.

Table 5.2.1 Summary of differences in Effective Moment Arm (My/Rxz) between foot designs

Results of Effective Moment Arm Comparisons Due to Alignment Interventions											
		% of Stance When EMA=0		Peak EMA (m x 10)				% of Stance at Peak EMA			
				Heel Loading		Toe Loading		Heel Loading		Toe Loading	
Subject	**Align**	**Mean**	**Std Dev**	**Mean**	**Std Dev**	**Mean**	**Std Dev**	**Mean**	**Std Dev**	**Mean**	**Std Dev**
S1 TruStep	**Neutral**	27.4	2.7	**0.267**	0.020	**-0.996**	0.015	11.0	1.1	**86.6**	3.3
	+5mm	27.4	3.4	**0.302**	0.007	**-0.954**	0.017	10.8	1.7	84.4	2.8
	-5mm	27.0	1.9	**0.342**	0.013	**-0.903**	0.021	9.6	1.3	**81.8**	1.8
S2 SACH	**Neutral**	**32.0**	3.3	0.298	0.131	**-1.007**	0.021	**13.6**	1.3	**89.2**	1.0
	+5mm	**25.8**	2.4	0.219	0.020	**-1.057**	0.017	**10.2**	2.0	**85.0**	2.9
	-5mm	**29.8**	2.9	0.285	0.024	**-0.937**	0.024	**13.0**	1.1	**86.2**	2.7
S3 SACH	**Neutral**	**29.2**	1.0	**0.268**	0.016	**-0.787**	0.016	**20.4**	0.8	87.0	4.4
	+5mm	**25.6**	2.3	**0.216**	0.014	**-0.793**	0.015	18.4	2.1	86.0	1.9
	-5mm	**26.6**	3.1	**0.302**	0.015	**-0.718**	0.013	**18.2**	2.6	85.6	2.3
S4 SACH	**Neutral**	38.8	2.7	**0.391**	0.016	**-0.679**	0.018	21.8	2.2	81.6	3.1
	+5mm	**36.4**	1.8	**0.333**	0.013	**-0.713**	0.007	21.0	1.9	80.2	4.7
	-5mm	**40.0**	1.6	**0.423**	0.022	**-0.626**	0.019	22.4	0.8	82.4	1.8
S4 BioStride	**Neutral**	**35.2**	3.4	**0.122**	0.032	**-0.616**	0.019	**16.4**	3.1	**60.6**	6.3
	+5mm	**30.8**	1.7	**0.099**	0.022	**-0.665**	0.027	**12.4**	1.6	**54.0**	1.6
	-5mm	33.2	3.6	**0.163**	0.025	**-0.572**	0.045	15.6	4.1	56.2	5.5
S4 PerfectStride	**Neutral**	**32.4**	1.8	**0.162**	0.018	**-0.757**	0.033	**18.4**	2.3	**67.4**	3.9
	+5mm	**32.8**	1.0	**0.137**	0.023	**-0.765**	0.029	**19.2**	1.4	**66.2**	1.5
	-5mm	**30.0**	1.9	**0.190**	0.025	**-0.703**	0.035	**15.0**	2.4	**59.8**	5.7

* Sample Sizes: N=10. Significant differences are shown in bold type.

Table 5.2.2 Summary of differences in Effective Moment Arm (My/Rxz) from alignment variations



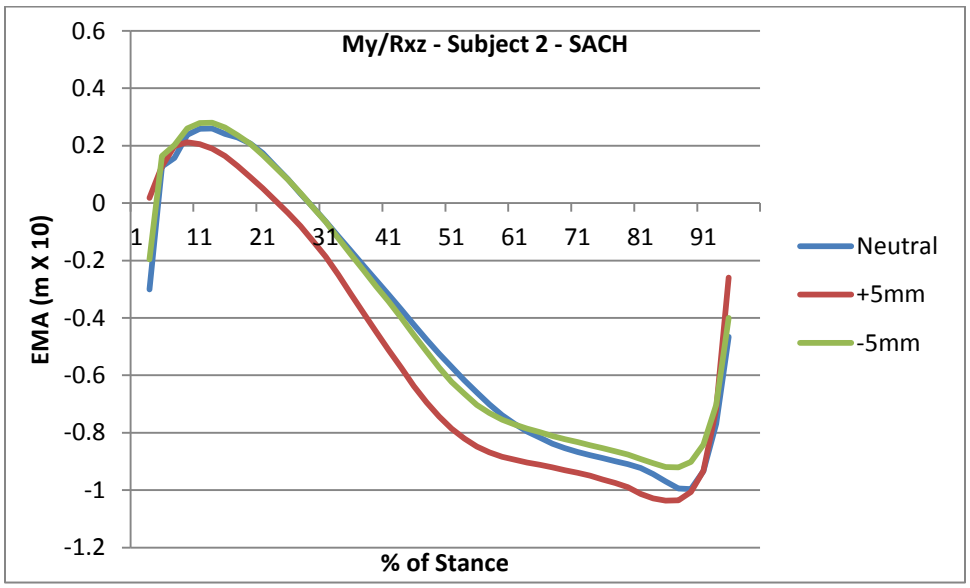
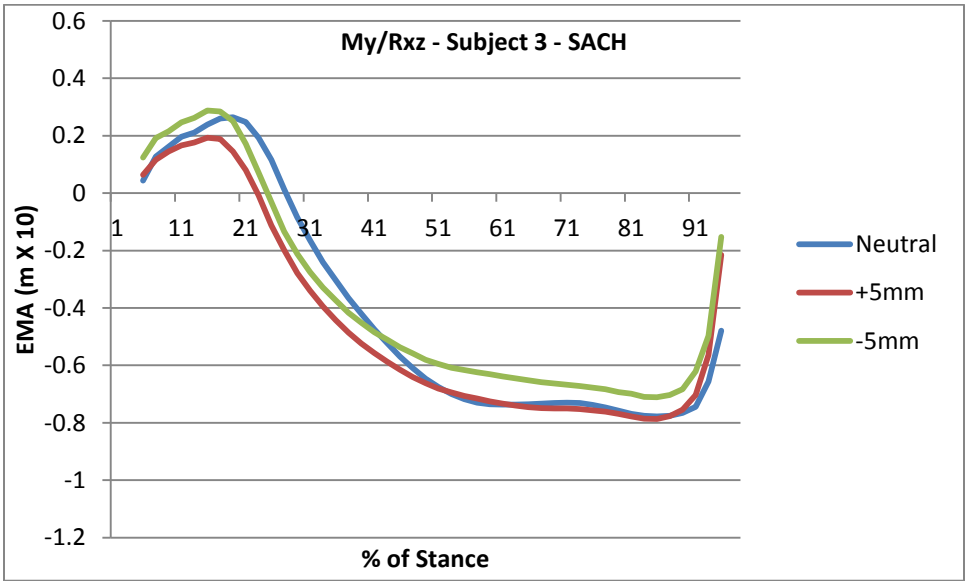


Figure 5.2.1.1 Effective moment arms – alignment comparisons – mean of 10 steps



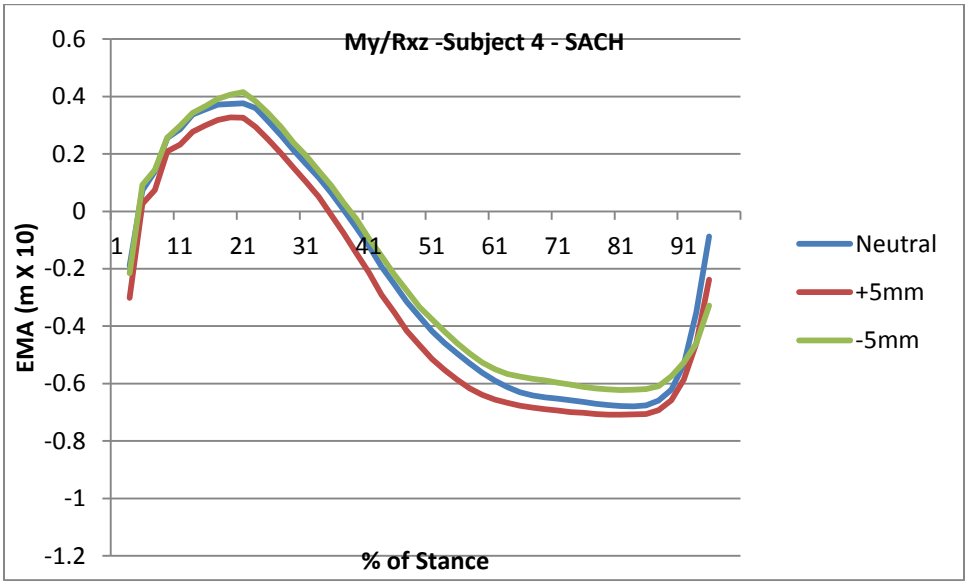
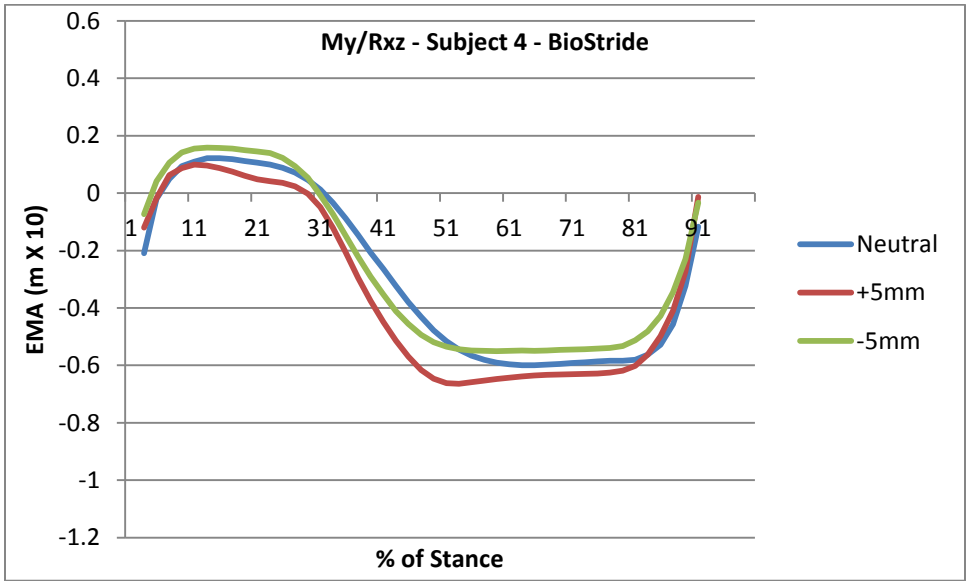


Figure 5.2.1.1 Effective moment arms – alignment comparisons – mean of 10 steps - continued



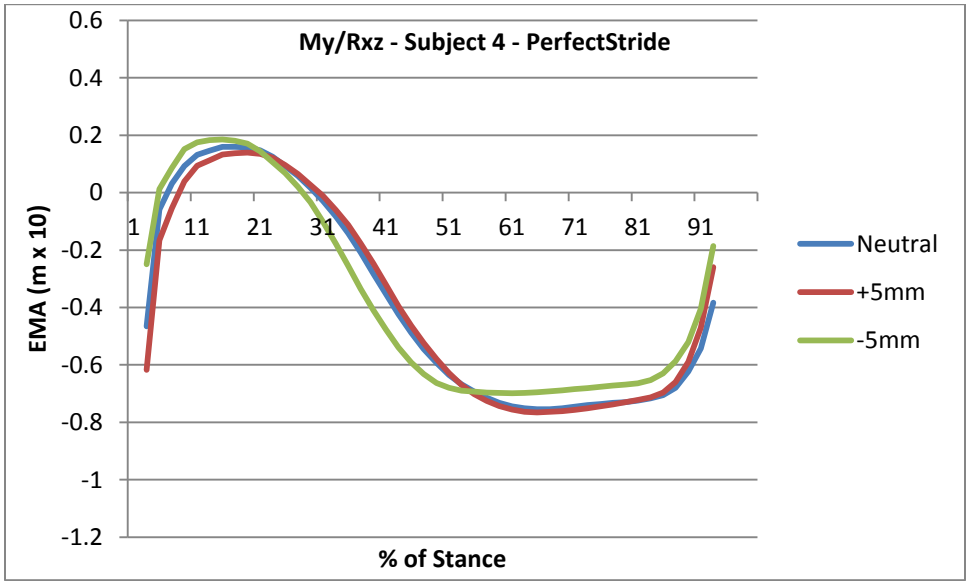


Figure 5.2.1.1 Effective moment arms – alignment comparisons – mean of 10 steps - continued

All three SACH feet and the BioStride were observed to have an EMA equal to zero earliest in stance at the +5mm alignment (Tab le 9.2.1 in Appendix B). The PerfectStride had an EMA equal to zero earliest in stance at the -5mm alignment. The TrueStep was observed to have an EMA equal to zero at the same interval in stance for all three alignments. No patterns were observed for the alignments having an EMA equal to zero later in stance.

Within subjects one-way ANOVA's were computed comparing the percentage in stance when the effective moment arm changed signs or was equal to zero. Table 9.2.2 in Appendix B summarizes the results. Two of three SACH feet and the BioStride were observed to have an EMA equal to zero significantly earlier in stance at the +5mm alignment when compared to the Neutral alignment ($p<0.000$ to 0.008); the fourth SACH was observed to have a p-value of 0.053. A pattern was observed for the PerfectStride to have an EMA equal to zero significantly earlier in stance with anterior to posterior translations of the prosthesis. No patterns were observed for the Neutral VS -5mm and the +5mm VS -5mm comparisons.

5.2.2 Maximum Effective Moment Arm (My/Rxz) Values

5.2.2.1 Max EMA – Differences between feet

Six within subject foot comparisons were made utilizing nine different feet involving seven different designs (Table 5.2 and 5.2.1). Results of the t-tests are shown in Table 9.2.3 (Appendix B). Two of the four SACH vs. ESAR feet comparisons resulted in a larger peak EMA's during heel loading when using the SACH ($p<7.49E-17$ to 2.02E-05); the other two were observed to have no significant difference. The peak EMA during toe loading was significantly larger for ESAR feet in three of the four comparisons with the SACH ($p<8.42E-13$ to 0.004); the fifth was observed to have no significant difference.

5.2.2.2 Max EMA – Differences between alignments

Six within subject alignment comparisons were made at three alignment settings (Neutral, +5mm, -5mm) with four different foot designs (Table 5.2 and Table 5.2.2). Results of the ANOVA's are shown in Table 9.2.4 (Appendix B). When comparing Neutral VS +5mm as well as +5mm VS -5mm, significantly larger peak EMA's were observed during heel loading for all comparisons ($p<0.000$ to 0.022) except for Subject 2 (SACH) which had no significant differences. Every peak EMA comparison during toe loading for Neutral VS +5mm as well as +5mm VS -5mm resulted in a significantly larger peak when the alignment was perturbed posterior to anterior ($p<0.000$ to 0.015). No patterns were observed for the Neutral VS +5mm comparisons.

5.2.2.3 Timing of Max EMA – Differences between alignments

Six within subject alignment comparisons were made at three alignment settings (Neutral, +5mm, -5mm) with four different foot designs (Table 5.2 and Table 5.2.2). Results of the ANOVA's are shown in Table 9.2.5 (Appendix B). Approximately one-third of the comparisons were observed to have significant differences in the interval in stance for peak EMA's during heel and toe loading. Comparisons that were significantly different were observed to have a pattern for peak EMA's to occur sooner in stance during toe loading with anterior to posterior translations.

5.3 Alignment Perturbations

Within subject one-way ANOVA's were calculated to examine the hypotheses that the maximum resultant force (Rxz) during heel and toe loading, the interval in stance for peak Rxz's, the EMA coinciding with peak Rxz's, and the peak moments about the y-axis during heel and toe loading would vary with foot design as well as prosthesis alignment in the sagittal plane. Table 5.3 below summarizes the design of analysis (the feet used, the transducer variables compared, and the type of statistical test performed).

Alignment Perturbations							
Transducer Measurements							
	Maximum Resultant Force (Rxz) at Heel and Toe Loading						
	Interval in Stance of Maximum Resultant Force (Rxz) Magnitudes						
	Effective Moment Arm Magnitude Coinciding With Maximum Resultant Force (Rxz)						
	Maximum My Magnitudes						
	Comparison						
	1	2	3	4	5	6	
	Subject						
	S1	**S2**	**S3**	**S4**	**S4**	**S4**	**Statistical Test**
Feet Evaluated at Varied Alignments	TrueStep	SACH	SACH	SACH	BioStride	PerfectStride	**One-Way ANOVA**

Table 5.3 Summary of alignment perturbation comparisons.

Results of Resultant Force (Rxz) Comparisons Due to Alignment Interventions													
		Normalized Peak Rxz (N/N)				% of Stance at Peak Rxz				Normalized EMA at Peak Rxz (m/m x 10)			
		Heel Loading		Toe Loading		Heel Loading		Toe Loading		Heel Loading		Toe Loading	
Subject	**Align**	**Mean**	**Std Dev**	**Mean**	**Std Dev**	**Mean**	**Std Dev**	**Mean**	**Std Dev**	**Mean**	**Std Dev**	**Mean**	**Std Dev**
S1 TruStep	**Neutral**	**1.18**	0.043	**1.16**	0.020	21.6	4.0	**73.2**	6.5	0.497	0.328	**-3.48**	0.032
	+5mm	**1.14**	0.023	**1.19**	0.023	22.4	4.0	**66.6**	7.1	0.452	0.280	**-3.32**	0.038
	-5mm	1.14	0.030	1.18	0.031	22.4	0.8	**61.0**	1.9	0.433	0.185	**-3.14**	0.032
S2 SACH	**Neutral**	0.98	0.037	**1.06**	0.027	**28.0**	3.0	**68.4**	6.2	0.123	0.571	**-3.05**	0.125
	+5mm	0.97	0.027	**1.03**	0.008	**23.0**	2.5	**59.0**	6.9	0.111	0.191	**-3.21**	0.115
	-5mm	0.99	0.027	**1.07**	0.015	**27.2**	3.4	63.0	8.1	0.231	0.162	**-2.84**	0.116
S3 SACH	**Neutral**	**1.06**	0.019	1.05	0.011	33.0	1.9	67.6	5.0	**-0.840**	0.166	**-2.99**	0.082
	+5mm	**1.09**	0.014	1.05	0.021	31.6	3.6	68.0	6.5	**-1.387**	0.132	**-3.05**	0.113
	-5mm	**1.10**	0.025	1.04	0.013	32.6	4.0	68.4	6.6	**-1.225**	0.118	**-2.69**	0.114
S4 SACH	**Neutral**	**1.10**	0.028	**1.02**	0.019	28.0	1.9	72.0	5.2	0.961	0.149	**-2.37**	0.097
	+5mm	**1.16**	0.042	**0.99**	0.015	26.0	2.7	68.2	2.9	0.905	0.120	**-2.48**	0.074
	-5mm	**1.11**	0.032	**1.02**	0.027	28.4	2.1	72.6	4.2	1.031	0.151	**-2.17**	0.099
S4 BioStride	**Neutral**	**0.99**	0.015	**0.98**	0.025	**26.4**	2.5	**64.0**	5.1	**0.315**	0.124	**-2.20**	0.080
	+5mm	**0.96**	0.020	1.00	0.015	**20.8**	2.5	**58.2**	1.5	**0.215**	0.102	**-2.37**	0.090
	-5mm	**0.99**	0.017	**1.00**	0.022	23.4	3.1	**58.6**	5.8	**0.514**	0.128	**-2.04**	0.187
S4 PerfectStride	**Neutral**	**1.09**	0.038	1.00	0.036	25.4	3.4	**67.8**	2.7	0.352	0.174	**-2.74**	0.111
	+5mm	**1.08**	0.027	1.00	0.017	27.0	4.4	**68.2**	3.6	0.255	0.190	**-2.77**	0.110
	-5mm	**1.03**	0.024	1.03	0.033	26.0	2.5	**59.0**	5.8	0.257	0.137	**-2.52**	0.153

* Sample Sizes: N=10. Resultant force is normalized by body weight. EMA is normalized by foot length (Moment about y-axis for calcualting EMA is normalized by body mass). Significant differences are shown in bold type.

Table 5.3.1 Summary of differences in Resultant Force (Rxz) from alignment variations

Results of Moment About Y-axis (My) Comparisons Due to Alignment Interventions					
		Normalized My (m^2/s^2 x 10)			
		Heel Loading		Toe Loading	
Subject	**Alignment**	**Mean**	**Std Dev**	**Mean**	**Std Dev**
S1 TruStep	**Neutral**	**0.261**	0.0217	**-1.09**	0.0169
	+5mm	**0.292**	0.0134	**-1.07**	0.0222
	-5mm	**0.303**	0.0156	**-0.999**	0.0304
S2 SACH	**Neutral**	**0.186**	0.0330	**-0.890**	0.0240
	+5mm	**0.151**	0.0231	**-0.899**	0.0258
	-5mm	**0.200**	0.0208	**-0.841**	0.0218
S3 SACH	**Neutral**	**0.202**	0.0151	**-0.755**	0.0226
	+5mm	**0.151**	0.0116	**-0.766**	0.0360
	-5mm	**0.197**	0.0155	**-0.670**	0.0329
S4 SACH	**Neutral**	0.379	0.0211	**-0.656**	0.0275
	+5mm	**0.352**	0.0244	**-0.669**	0.0224
	-5mm	**0.405**	0.0512	**-0.602**	0.0267
S4 BioStride	**Neutral**	**0.107**	0.0301	**-0.582**	0.0290
	+5mm	**0.087**	0.0210	**-0.642**	0.0281
	-5mm	**0.148**	0.0272	**-0.552**	0.0557
S4 PerfectStride	**Neutral**	0.168	0.0329	-0.742	0.0514
	+5mm	0.138	0.0315	-0.752	0.0349
	-5mm	0.155	0.0313	-0.701	0.0609

* Sample Sizes: N=10. Moment is normalized by body mass. Significant differences in bold type.

Table 5.3.2 Summary of differences in moment about y-axis (My) from alignment variations

5.3.1 Maximum Resultant Force (Rxz)

Table 9.3.1 in Appendix B summarizes the ANOVA results for the peak resultant force comparisons. Approximately 42% of the comparisons resulted in significant differences. Of those, a pattern for larger heel loading occurred at +5mm when the SACH was used and at a neutral alignment when an ESAR foot was used ($p<0.000$ to 0.042).

5.3.2 Interval in Stance of Max Resultant Force

Table 9.3.2 in Appendix B summarizes the ANOVA results for comparisons of the interval in stance when peak resultant forces occurred. All feet except for Subject 3-SACH experienced some significant difference in the timing of Rxz peaks. The majority of significant differences occurred during toe-loading. For every comparison of Neutral vs. +5mm which resulted in a significant difference, the peaks occurred later in the gait cycle at a neutral alignment ($p<0.000$ to 0.023). The same pattern occurred for the significant differences in Neutral vs. -5mm ($p<0.000$ to 0.030).

5.3.3 EMA Coinciding with Max Resultant Force

Results for the ANOVA comparisons of the EMA coinciding with the heel and toe loading Rxz peaks are shown in Table 9.3.3 in Appendix B. Of the comparisons involving the +5mm alignment, 75% resulted in a significantly larger EMA's during toe loading with the +5mm alignment ($p<0.000$ to 0.023). Three of six Neutral VS +5mm comparisons resulted in significantly larger effective moment arms during toe loading at the +5mm alignment ($p<0.016$ to 0.023). All six +5mm VS -5mm comparisons resulted in significantly larger EMA's at +5mm during toe loading ($p<0.000$). Five of six Neutral VS -5mm comparisons resulted in significantly larger EMA's at a Neutral alignment during toe loading ($p<0.000$ to 0.030).

5.3.4 Max Moment about Y-Axis

Results for the ANOVA comparisons of the peak moments about the y-axis during heel and toe loading are shown in Table 9.3.4 in Appendix B. Two of three comparisons using the SACH at Neutral VS +5mm resulted in larger peaks during heel loading at a neutral alignment ($p<0.000$ to 0.018). Four of the six comparisons for Neutral vs. -5mm resulted in larger My maxima during toe loading with a neutral alignment ($p<0.000$). Five of the six tests for +5mm VS -5mm resulted in significantly larger peaks during toe loading with a +5mm alignment ($p<0.000$).

Observable patterns in the results of the study when comparing feet were: less time was spent in stance and the overall gait cycle time was shorter when using the SACH; and max EMA peaks increased when using an ESAR foot. For comparisons in alignment, the patterns identified were: there was less time spent in stance and the overall gait cycle was shorter at a neutral alignment; the max EMA increased during heel loading with posterior shifts and during toe loading with anterior shifts; the EMA coinciding with peak Rxz's occurred earlier in stance with anterior shifts; and the max My during toe loading increased with anterior shifts. The following chapter discusses implications of the results, relates them to the present literature, and discusses aspects of the study.

CHAPTER 6

DISCUSSION

While differences in foot performance or effects from alignment could not be proven from transducer measurements, patterns in the data demonstrated the viability of the transducer for amputee gait analyses. The remainder of this chapter discusses their significance.

6.1 Gait Parameters

It was hypothesized that significant differences in gait parameters would be observed when using the SACH versus an ESAR foot. Previous publications have reported the SACH to decrease dorsiflexion and plantar flexion, comfort and stability, and gait velocity (1-4, 6). The result is a gait pattern in which less time is spent on the SACH foot. The current study's comparisons of stance and gait cycle times were consistent with this hypothesis; 75% resulted in a shorter gait cycle with less time spent in stance when using the SACH.

6.2 Effective Moment Arm

Wagner *et al.* (1987) reported an increased range of motion during dorsiflexion and plantar flexion when using the Flex Foot compared to the SACH (4). It was hypothesized that the ESAR feet used in the current study would function in the same way and that this would directly influence the magnitude of the EMA. The hypothesis was that peak EMA's would be larger when using an ESAR foot. Patterns in the data led to tentatively accepting this hypothesis.

Another hypothesis was that peak EMA's would be significantly different between alignment variations. Schmalz *et al.* (2002) reported differences in moment arm magnitudes when the alignment was perturbed ±2cm, which is a very large perturbation (22). Patterns in the current study's data were supportive; significant differences in peak EMA values were computed

between alignments. Experimental design called for perturbations of ±5mm in contrast to ±2cm which would be considered drastic in a clinic.

6.3 Alignment Perturbations

It was hypothesized that changes in alignment would lead to differences in the length of the heel/toe levers arms, or EMA's, which would increase the peak moments about the y-axis. The My analyses resulted in patterns consistent across subjects. Approximately 78% of the heel loading comparisons, first peaks of the bimodal plots, resulting in significant differences yielded larger My values with an anterior to posterior shift in alignment. Similarly, 100% of the toe loading comparisons, second peaks, resulting in significant differences yielded larger My values with a posterior to anterior shift in alignment. These results were consistent with lever theory as well as findings published by Schmalz *et al.* (2002) (22).

Different patterns were also present for the EMA analyses. Peak EMA values increased during heel loading with posterior shifts and during toe loading with anterior shifts. Also, the EMA values coinciding with peak Rxz values increased during toe loading with anterior shifts. These patterns also remained consistent with the theory of increasing and decreasing heel and toe levers.

Conclusions on differences in foot performance and effects of alignment were limited by three shortcomings: sample size, adaptation period, and the differences in foot masses. The sample size (n=4) lowered the statistical power. Lack of an adaptation period allowed the possibility of measuring the subject acclimating to changes in foot type or alignment rather than measuring performance differences in foot design or effects from alignment interventions. It is not known whether a longer adaptation time for the SACH foot would have resulted in changes in the gait parameters, forces, moments, and EMA's that would have reduced the dissimilarity of the SACH feet to the ESAR feet, or perhaps increased dissimilarity. Altering the mass distally has

been observed to significantly alter gait symmetry, stance time, swing time, and ground reaction force patterns (29, 30, 34, 37). The current study did not account for variations in foot mass and therefore cannot rule out recorded differences resulting from changes in mass. However, the literature review did not identify any concerns with the experimental design.

Further validation of the transducer could be achieved by repeating the study's experimental design with the addition of simultaneous force plate data collection. A relationship could be observed between the ground reaction forces and the forces at the end of the socket which could clarify patterns in the transducer data of variations in foot design and effects from alignment interventions.

Future studies could be conducted analyzing transducer data recorded in a variety of environments frequently encountered by K4 amputees. Macfarlane, Nielsen, Shurr, and Meier (1991) reported the perception of difficulty while ascending and descending an 8.5°-sloped surface to be significantly less when using the Flex Foot VS the SACH (13). Alaranta, Kinnunen, Karkkainen, Pohjolainen, and Heliovaara (1991) reported perceptions of the Flex Foot to be less difficult VS the SACH when walking: indoors, upstairs, downstairs, even street, uneven ground (sand, snow), forest, street uphill, street downhill, swift walking, and running (14). It could be hypothesized that the Flex Foot is perceived to be less difficult to use in these environments due to increased dorsiflexion and plantar flexion capabilities. Investigations of the effective moment arm computed from transducer recorded data could help form conclusions about the influence of foot design on difficulty perception.

The transducer is an innovative form of instrumentation that measures forces and moments at the end of the socket. The study demonstrated the feasibility of using a transducer to measure certain aspects of gait by mounting it at the socket/pylon interface and recording the 3-

dimensional forces and moments while the subjects walked at a self-selected comfortable speed on a level surface. The subsequent chapter summarizes the findings and conclusions.

CHAPTER 7

CONCLUSIONS

The pilot study demonstrated that the triaxial transducer can be used in transtibial amputee gait studies to examine some characteristics of gait. Patterns in the data obtained during a pilot study led to the acceptance of the hypothesis that magnitudes of forces and moments recorded at the end of the socket, and the associated computed effective moment arm, vary during level walking when using an ESAR foot versus the SACH as well as from sagittal plane alignment perturbations. It was observed that: less time was spent in stance and overall gait when using the SACH as well as when the prosthesis was at the initial (neutral) alignment, peak EMA's increased when using an ESAR foot during heel loading with posterior shifts and during toe loading with anterior shifts, EMA magnitudes at the time of peak resultant force (Rxz) magnitudes increased during toe loading with anterior shifts, and My increased during toe loading with anterior shifts.

Observing these differences aid both design engineers and clinicians. Observing how different feet perform leads to more refined design concepts. Showing varying effects from alignment aid in effectiveness of evaluating alignment interventions. This may help achieve improved functioning and comfort while minimizing adverse effects on the residual limb.

Future studies should establish experimental design protocol to account for challenges associated with the current study's design as well as affects from the size of the transducer. It was concluded that the transducer's mass of 0.8kg would not significantly affect gait however, reductions in mass would improve confidence in the outcome measures. Reduction in the size of the transducer could also allow for data recording with subjects having residual limbs longer than 19.1 cm; mounting the transducer at the end of subject 2's socket (residual limb of 19.1 cm) left minimal space for the prosthesis to be attached. Appropriate adaptation periods to changes in

conditions like foot design and alignment perturbations need to be implemented; the study did not specify adaptation periods which limited conclusions on the outcome measures.

Further research is recommended to examine effects on amputee gait from varying adaptation periods. Via the transducer, data could be recorded at intervals (i.e. 0 mins, 15 mins, 1 day, 1 week, and 1 month) after altering the subject's foot or alignment. Examination of patterns in the peak forces, moments, and EMA's would reveal effects from varying adaptation periods. Additionally, simultaneous data acquisition from a motion capture system would be beneficial. Ankle, knee, and hip kinematics would be recorded and observations in how the subject adapts could be made. The relationship between how the prosthesis performs and how the subject utilizes it could then be established.

Strengths of utilizing the transducer for data collection in transtibial amputee gait analyses were revealed in the study and should be considered for future investigations. Literature details investigations on the influence of foot designs and sagittal plane alignments on resultant reaction forces and gait parameters (stance, swing, and gait cycle times) with data collected from force plates; the study examined the same outcome measures but with transducer data. Compared to a force plate, the transducer is significantly less expensive, capable of recording several consecutive steps, and adept to collect data in a multitude of diverse environments.

APPENDIX A

Internal and External Validity Threats

(Source: American Academy of Orthotists & Prosthetists (AAOP), State-of-the-Science Evidence Report Guidelines)

Internal Validity – Expanded Criteria

IV-1. Comparison or control group used

a) Not applicable

b) Other

IV-2. Groups formed by random assignment

a) Not applicable

b) Other

IV-3. Groups comparable at baseline

a) Not applicable

b) Other

IV-4. Groups handled the same way

a) Not applicable

b) Other

IV-5. Control/comparison group not appropriate

a) Not applicable

b) Dissimilar demographics

IV-6. Intervention(s) not blinded

a) blinding not mentioned

b) subjects not blinded

c) other

IV-7. Inclusion criteria not appropriate

a) Criteria not mentioned

b) Criteria mentioned but were very broad

c) Insufficient information on the subjects' ages, sex, reasons for amputations, experience with prosthetic use, activity levels, and stump lengths.

IV-8. Exclusion criteria not appropriate

a) Criteria not mentioned

b) Residual limb length not mentioned

c) Socket fit not mentioned

d) Other

IV-9. Protocol does not address fatigue and learning

a) Relevant protocol not mentioned

b) Fatigue likely to occur during experiment

c) Learning likely to occur during experiment

d) Rest periods between mass perturbations were not mentioned

IV-10. Protocol does not address accommodation and washout

a) Relevant protocol not mentioned

b) No accommodation period prior to experiment

c) No accommodation periods prior to mass perturbations

IV-11. Attrition reported

a) Attrition greater than 20%

b) Other

IV-12. Attrition between groups

a) Not mentioned

b) Attrition differs between groups

c) Other

IV-13. Outcome measures are not reliable

a) Experiment cannot be replicated

b) Measurements and observations involve subjective interpretations

c) No mention of an experienced prosthetist fitting the subjects

d) Other

IV-14. Statistical analysis not appropriate

a) Low sample size

b) Low number of trials

c) Mathematics

i. Requires several calculations that leads to compounding errors

ii. Uncommon methodology used

d) Relative masses were not mentioned for between-subjects comparisons

IV-15. Effect size not reported

a) None mentioned

b) R-Values not given

c) Other

IV-16. Statistical significance not reported

a) None mentioned

b) P-values and/or R-values not given

c) Other

IV-17. Statistical power inadequate

a) Not mentioned

b) α-value and/or β-value not given

c) Other

IV-18. Potential conflicts of interest

External Validity – Expanded Criteria

EV-1. Sample characteristics not adequately described

a) Insufficient information on the subjects' ages, sex, reasons for amputations, experience with prosthetic use, activity levels, and stump lengths.

EV-2. Sample not representative of the target population

a) Experience level with prosthetic is less than one year

b) Out-dated prosthetic and socket type

EV-3. Outcome measures not adequately described

a) Results are not compared to expected values

b) Results rely on subjective interpretation

EV-4. Outcome measures not valid for this study

a) Subjects walked at prescribed pace other than self-selected

b) Fatigue was a concern

EV-5. Intervention not adequately described

a) Absolute and/or relative prosthetic mass prior to experiment, and post intervention not stated

b) Location on prosthetic of mass adjustment not described

c) Reasons for selected masses used in perturbances not mentioned

EV-6. Findings not clinically significant/relevant

a) Lack of discussion

EV-7. Conclusions not placed in context of existing literature

a) Minimal mention of similar studies

EV-8. Conclusions not supported by findings

Negative results are not reported along with positive results

APPENDIX B

Feet Which Exhibited Significant Differences in Stride Characteristics - Grouped by Subject ($p \leq 0.05$)						
	S1 (Renegade vs. TruStep)	**S2 (SACH vs. Carbon Copy 2)**	**S3 (SACH vs. Flex Foot)**	**S4 (SACH vs. PerfectStride)**	**S4 (SACH vs. BioStride)**	**S4 (PerfectStride vs. BioStride)**
Stance	-	0.0448 (SACH)	1.78E-06 (Flex Foot)	0.026 (SACH)	1.48E-04 (SACH)	-
Swing	-	0.0172 (SACH)	-	-	3.49E-06 (BioStride)	-
Gait Cycle	-	0.00682 (SACH)	7.58E-06 (Flex Foot)	7.60E-05 (SACH)	0.0215 (SACH)	0.0192 (BioStride)
% Stance	-	-	7.45-E04 (Flex Foot)	0.0196 (SACH)	2.42E-07 (SACH)	-

Feet listed in parentheses are those with significantly shorter Stance/Swing/Gait Cycle/%Stance times

Table 9.1.1. Summary of Significant Differences between Feet Grouped by Subject

Significant Differences in Stride Characteristics Due To Alignment Perturbations - Grouped by Subject ($p \leq 0.05$)												
	S1 (TruStep)		**S2 (SACH)**		**S3 (SACH)**		**S4 (SACH)**		**S4 (BioStride)**		**S4 (PerfectStride)**	
	Stance	**Swing**	**Stance**	**Swing**	**Stance**	**Swing**	**Stance**	**Swing**	**Stance**	**Swing**	**Stance**	**Swing**
Neutral vs. +5mm	-	-	0.007 (Neutral)	-	0.038 (Neutral)	-	0.007 (+5mm)	-	-	-	0.007 (Neutral)	-
Neutral vs. -5mm	-	-	-	-	-	-	0.028 (-5mm)	-	-	-	< 0.000 (Neutral)	-
+5mm vs. -5mm	-	-	-	-	-	-	-	0.015 (+5mm)	-	-	< 0.000 (+5mm)	-

Alignments listed in parentheses are those with significantly shorter Stance/Swing times

Table 9.1.2. Summary of Significant Differences between Alignments Grouped by Subject.

Significant Differences in Gait Cycle Due To Alignment Perturbations - Grouped by Subject ($p \leq 0.05$)						
	S1 (TruStep)	**S2 (SACH)**	**S3 (SACH)**	**S4 (SACH)**	**S4 (BioStride)**	**S4 (PerfectStride)**
Neutral vs. +5mm	-	0.021 (Neutral)	0.010 (Neutral)	0.039 (+5mm)	-	0.010 (Neutral)
Neutral vs. -5mm	0.019 (Neutral)	-	-	-	-	< 0.000 (Neutral)
+5mm vs. -5mm	-	-	-	-	-	0.002 (+5mm)

Alignment listed in parentheses are those with significantly shorter Gait Cycle times

Table 9.1.3. Summary of Significant Differences between Alignments Grouped by Subject

Significant Differences in % of Time in Stance Due To Alignment Perturbations - Grouped by Subject ($p \leq 0.05$)						
	S1 (TruStep)	**S2 (SACH)**	**S3 (SACH)**	**S4 (SACH)**	**S4 (BioStride)**	**S4 (PerfectStride)**
Neutral vs. +5mm	-	-	-	-	-	-
Neutral vs. -5mm	-	-	-	0.004 (-5mm)	-	0.001 (Neutral)
+5mm vs. -5mm	-	-	-	-	0.046 (-5mm)	0.015 (+5mm)

Alignment listed in parentheses are those with significantly shorter % Stance times

Table 9.1.4. Summary of Significant Differences between Alignments Grouped by Subject

Order (My/Rxz) Effective Moment Arms Changing Signs - Grouped by Alignment (% of Stance)						
	S1	**S2**	**S3**	**S4**	**S4**	**S4**
	Trustep	**SACH**	**SACH**	**SACH**	**BioStride**	**PerfectStride**
1st	-	+5 (23)	+5 (21)	+5 (33)	+5 (27)	-5(27)
2nd	-	-	-5 (23)	-	-5 (29)	-
3rd	-	-	Neutral (27)	-	Neutral (31)	-

*S1, all alignments changed signs at the same % of Stance; 25%.
*S2, Neutral and -5mm changed signs at the same % of Stance; 27%.
*S4 SACH, Neutral and -5mm changed signs at the same % of Stance; 37%.
*S4 PerfectStride, Neutral and +5mm changed signs at the same % of Stance; 29%.
Table 9.2.1. Order (My/Rxz) Changes Signs - Varies with Alignments

Alignments Which Exhibited Significantly Different Timing In Stance When (My/Rxz) Effective Moment Arm Changed Signs - Grouped by Subject (p≤0.05)						
	S1 (TruStep)	**S2 (SACH)**	**S3 (SACH)**	**S4 (SACH)**	**S4 (BioStride)**	**S4 (PerfectStride)**
Neutral vs. +5mm	-	< 0.000 (+5mm)	0.005 (+5mm)	-	0.008 (+5mm)	-
Neutral vs. -5mm	-	-	0.046 (-5mm)	-	-	0.008 (-5mm)
+5mm vs. -5mm	-	0.012 (+5mm)	-	0.002 (+5mm)	-	0.002 (-5mm)

Alignment listed in parentheses are those which changed My/Rxz values significantly sooner in stance

Table 9.2.2. Summary of Significant Differences between Alignments Grouped by Subject

Feet Which Exhibited Significantly Greater (My/Rxz) Effective Moment Arm - Grouped by Subject (p≤0.05)						
	S1 (Renegade vs. TruStep)	**S2 (SACH vs. Carbon Copy 2)**	**S3 (SACH vs. Flex Foot)**	**S4 (SACH vs. PerfectStride)**	**S4 (SACH vs. BioStride)**	**S4 (PerfectStride vs. BioStride)**
1st Peak	Renegade (2.02E-5)	-	-	SACH (1.65E-12)	SACH (7.49E-17)	PerfectStride (3.22E-12)
2nd Peak	TruStep (0.001)	Carbon Copy 2 (1.79E-6)	Flex Foot (8.42E-13)	PerfectStride (0.002)	-	PerfectStride (0.004)

Table 9.2.3. Summary of Significant Differences between Feet Grouped by Subject

Alignments Which Exhibited Significantly Greater (My/Rxz) Effective Moment Arm - Grouped by Subject ($p \leq 0.05$)												
	S1 (TruStep)		**S2 (SACH)**		**S3 (SACH)**		**S4 (SACH)**		**S4 (BioStride)**		**S4 (PerfectStride)**	
	1st Peak	**2nd Peak**	**1st Peak**	**2nd Peak**	**1st Peak**	**2nd Peak**	**1st Peak**	**2nd Peak**	**1st Peak**	**2nd Peak**	**1st Peak**	**2nd Peak**
Neutral vs. +5mm	< 0.000 (+5mm)	< 0.000 (Neutral)	-	< 0.000 (+5mm)	< 0.000 (Neutral)	-	< 0.000 (Neutral)	< 0.000 (+5mm)	-	0.006 (+5mm)	0.048 (Neutral)	-
Neutral vs. -5mm	< 0.000 (-5mm)	< 0.000 (Neutral)	-	< 0.000 (Neutral)	< 0.000 (-5mm)	< 0.000 (Neutral)	0.001 (-5mm)	< 0.000 (Neutral)	0.004 (-5mm)	0.015 (Neutral)	0.022 (-5mm)	0.003 (Neutral)
+5mm vs. -5mm	< 0.000 (-5mm)	< 0.000 (+5mm)	-	< 0.000 (+5mm)	< 0.000 (-5mm)	< 0.000 (+5mm)	< 0.000 (-5mm)	< 0.000 (+5mm)	< 0.000 (-5mm)	< 0.000 (+5mm)	< 0.000 (-5mm)	0.001 (+5mm)

Alignments listed in parentheses are those with significantly larger My/Rxz values

Table 9.2.4. Summary of Significant Differences between Alignments Grouped by Subject.

Alignments Which Exhibited Significantly Different Timing In (My/Rxz) Effective Moment Arm Peaks - Grouped by Subject ($p \leq 0.05$)												
	S1 (TruStep)		**S2 (SACH)**		**S3 (SACH)**		**S4 (SACH)**		**S4 (BioStride)**		**S4 (PerfectStride)**	
	1st Peak	**2nd Peak**	**1st Peak**	**2nd Peak**	**1st Peak**	**2nd Peak**	**1st Peak**	**2nd Peak**	**1st Peak**	**2nd Peak**	**1st Peak**	**2nd Peak**
Neutral vs. +5mm	-	-	< 0.000 (+5mm)	0.001 (+5mm)	-	-	-	-	0.020 (+5mm)	0.015 (+5mm)	-	-
Neutral vs. -5mm	-	0.001 (-5mm)	-	0.023 (-5mm)	0.048 (-5mm)	-	-	-	-	-	0.003 (-5mm)	0.001 (-5mm)
+5mm vs. -5mm	-	-	0.001 (+5mm)	-	-	-	-	-	-	-	< 0.000 (-5mm)	0.004 (-5mm)

Alignments listed in parentheses are those with peak My/Rxz values significantly sooner in stance

Table 9.2.5. Summary of Significant Differences between Alignments Grouped by Subject.

Alignments Which Exhibited Significantly Greater Rxz Peaks – Grouped by Subject (Normalized by body weight) ($p \leq 0.05$)												
	S1 (TruStep)		**S2 (SACH)**		**S3 (SACH)**		**S4 (SACH)**		**S4 (BioStride)**		**S4 (PerfectStride)**	
	1st Peak	**2nd Peak**	**1st Peak**	**2nd Peak**	**1st Peak**	**2nd Peak**	**1st Peak**	**2nd Peak**	**1st Peak**	**2nd Peak**	**1st Peak**	**2nd Peak**
Neutral vs. +5mm	0.042 (Neutral)	0.007 (+5mm)	-	0.001 (Neutral)	0.039 (+5mm)	-	0.003 (+5mm)	0.016 (Neutral)	0.003 (Neutral)	-	-	-
Neutral vs. -5mm	-	-	-	-	< 0.000 (-5mm)	-	-	-	-	0.046 (-5mm)	0.001 (Neutral)	-
+5mm vs. -5mm	-	-	-	< 0.000 (-5mm)	-	-	0.015 (+5mm)	0.036 (-5mm)	0.019 (-5mm)	-	0.008 (+5mm)	-

Alignments listed in parentheses are those with significantly larger Rxz values

Table 9.3.1. Summary of Rxz Peak Differences between Alignments Grouped by Subject.

Alignments Which Exhibited Significantly Different Timing In Rxz Peaks - Grouped by Subject (Normalized by body weight) ($p \leq 0.05$)												
	S1 (TruStep)		**S2 (SACH)**		**S3 (SACH)**		**S4 (SACH)**		**S4 (BioStride)**		**S4 (PerfectStride)**	
	1st Peak	**2nd Peak**	**1st Peak**	**2nd Peak**	**1st Peak**	**2nd Peak**	**1st Peak**	**2nd Peak**	**1st Peak**	**2nd Peak**	**1st Peak**	**2nd Peak**
Neutral vs. +5mm	-	0.039 (+5mm)	0.003 (+5mm)	0.017 (+5mm)	-	-	-	-	< 0.000 (+5mm)	0.021 (+5mm)	-	-
Neutral vs. -5mm	-	< 0.000 (-5mm)	-	-	-	-	-	-	-	0.034 (-5mm)	-	< 0.000 (-5mm)
+5mm vs. -5mm	-	-	0.011 (+5mm)	-	-	-	-	-	-	-	-	< 0.000 (-5mm)

Alignments listed in parentheses are those with peak Rxz values significantly sooner in stance

Table 9.3.2. Summary of Rxz Peak Timing Differences between Alignments Grouped by Subject.

Alignments Which Exhibited Significantly Greater (My/Rxz) Effective Moment Arm During Rxz Peaks in VGRF- Grouped by Subject (p≤0.05)												
	S1 (TruStep)		**S2 (SACH)**		**S3 (SACH)**		**S4 (SACH)**		**S4 (BioStride)**		**S4 (PerfectStride)**	
	1st Peak	**2nd Peak**	**1st Peak**	**2nd Peak**	**1st Peak**	**2nd Peak**	**1st Peak**	**2nd Peak**	**1st Peak**	**2nd Peak**	**1st Peak**	**2nd Peak**
Neutral vs. +5mm	-	< 0.000 (Neutral)	-	0.015 (+5mm)	< 0.000 (+5mm)	-	-	0.023 (+5mm)	-	0.013 (+5mm)	-	-
Neutral vs. -5mm	-	< 0.000 (Neutral)	-	0.002 (Neutral)	< 0.000 (-5mm)	< 0.000 (Neutral)	-	< 0.000 (Neutral)	0.002 (-5mm)	0.030 (Neutral)	-	0.002 (-5mm)
+5mm vs. -5mm	-	< 0.000 (+5mm)	-	< 0.000 (+5mm)	0.039 (+5mm)	< 0.000 (+5mm)	-	< 0.000 (+5mm)	< 0.000 (-5mm)	< 0.000 (+5mm)	-	< 0.000 (+5mm)

Alignments listed in parentheses are those with significantly larger My/Rxz values

Table 9.3.3. Summary of Effective Moment Arm Differences between Alignments Grouped by Subject.

Alignments Which Exhibited Significantly Greater My Peaks - Grouped by Subject (Normalized by body mass) ($p \leq 0.05$)												
	S1 (TruStep)		**S2 (SACH)**		**S3 (SACH)**		**S4 (SACH)**		**S4 (BioStride)**		**S4 (PerfectStride)**	
	1st Peak	**2nd Peak**	**1st Peak**	**2nd Peak**	**1st Peak**	**2nd Peak**	**1st Peak**	**2nd Peak**	**1st Peak**	**2nd Peak**	**1st Peak**	**2nd Peak**
Neutral vs. +5mm	0.002 (+5mm)	-	0.018 (Neutral)	-	< 0.000 (Neutral)	-	-	-	-	0.006 (+5mm)	-	-
Neutral vs. -5mm	< 0.000 (-5mm)	< 0.000 (Neutral)	-	< 0.000 (Neutral)	-	< 0.000 (Neutral)	-	< 0.000 (Neutral)	0.005 (-5mm)	-	-	-
+5mm vs. -5mm	-	< 0.000 (+5mm)	0.001 (-5mm)	< 0.000 (+5mm)	< 0.000 (+5mm)	< 0.000 (+5mm)	0.006 (-5mm)	< 0.000 (+5mm)	< 0.000 (-5mm)	< 0.000 (+5mm)	-	-

Alignments listed in parentheses are those with significantly larger My values

Table 9.3.4. Summary of My Peak Differences between Alignments Grouped by Subject.

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