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Biomechanical Analysis of Gait Kinetics Resulting From Use of a Vacuum Socket on a Transtibial Prosthesis

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BIOMECHANICAL ANALYSIS OF GAIT KINETICS RESULTING FROM USE OF A VACUUM SOCKET ON A TRANSTIBIAL PROSTHESIS

By

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PREFACE

The research aspect of my project began long before enrolling in HON 498, the first semester of the honors thesis course. I have been interested in mechatronics and bionics for the better part of my childhood, mostly influenced by sci-fi movies and cartoons, but there was something much bigger that intrigued me. What intrigued me the most was a human being's willingness and strength to push forward even in the event of losing a body part. Instead of claiming defeat, humans have looked for ways to keep somebody moving forward through the creation of prostheses. I had never had a course in anatomy or biomechanics when I chose this project but my drive to learn eventually led me to contact the CEO of Precision Orthotics and Prosthetics (POP's), a local clinic. Something in my eyes must have indicated that I was willing to learn anything and everything about prostheses and I was immediately set up with a shadowing position. I became the new intern, a position created solely for me, where I was able to follow Kevin Bidwell, a certified prosthetist, as he measured newly amputated to matured patients' limbs, uniquely crafted their prosthetic sockets, and adjusted their various prosthetic components to ensure proper gait. I spent a few days every week at the clinic, following Kevin during outside patient visits, scrambling with him to eat something during a 10 minute break we found between patients, and getting to know the lives of the patients in front of us. My first-hand acquired knowledge enabled me to learn new vocabulary terms, such as unilateral/bilateral, transfemoral/transtibial, disarticulation, double-wall suspension, negative pressure, and so forth. Without this knowledge, searching through the hundreds of prosthesis articles in the UNLV database would have been quite an undertaking.

Once I had established my general area of interest, I was able to find an advisor who had a similar passion for learning more about prosthetic devices. Dr. Edward Neumann was willing to take me on as a student, even though he had just retired, to undertake a more sophisticated way of measuring forces and moments produced from a prosthetic device than what was currently being used. He directed me to several journals to begin learning more about load cells and the most current research being published on prosthetic devices. Two theses were instrumental in my background knowledge of load cells and analyzing data acquired with a load cell; they belonged to Dr. Neumann's former graduate students who first began analyzing forces and moments with a load cell. Reading two master's theses helped hone my own research strategies and helped me to identify the appropriate key words related to my scholarly work. I was also able to recognize the importance of proper formatting to clearly demonstrate the methodology and results section. Even though an undergraduate honors thesis has no specific formatting requirements and is mostly intended to be a scholarly learning process for the student, I wanted my work to parallel that of a master's thesis. I intend to continue my research with Dr. Neumann and Kevin Bidwell to delve even deeper into the many capabilities of incorporating a load cell to measure forces and moments on amputees. I hope that my work can help establish clinical use for load cells to gather tangible data for clinicians to relay to insurance companies and prosthetic companies.

ACKNOWLEDGEMENTS

Many individuals were involved in the creation of this thesis. I would like to thank Jimmy Colson, the CEO of Precision Orthotics and Prosthetics for opening his facility's doors to me and for allowing me to test my research patients at his facility. Everyone at Precision has been friendly and helped answer any questions I had during my shadowing experience. I would especially like to thank Kevin Bidwell. Subject acquisition and testing would not have been possible without his selfless dedication to his profession. He took me under his wing and went above and beyond when helping me recruit and test patients. There were a few long mornings and nights testing patients, one even staying until 10 pm, in order to make sure everything we measured came out right. I would also like to thank all the patients at Precision for allowing me to observe as they were fitted with new sockets and adjusted, and for always answering my questions about their prostheses.

I would also like to thank everyone on my committee. I would like to thank Dr. David Lee for contributing to my fascination of biological beings when I took his Biorobotics course and for agreeing to be part of this project. I would also like to thank Dr. Andrew Hanson, the Associate Dean for the Honors College, who found the time to dedicate to my entire thesis review process from the beginning concept to the final revisions even though he was also juggling around 50 other students and their individual theses. Finally, I would like to thank my third committee member, and main advisor, Dr. Edward Neumann, who was instrumental to my learning process when it came to honing my research question, acquiring data, converting and analyzing the load cell data, and for pushing me to realize my potential in this topic. He encouraged me to never give up and to stay true to my passions.

I would also like to thank Dr. Neumann's former graduate students, Justin Brink and Kartheek Yalamanchili. Their master's work helped me analyze and interpret my results and also helped me format my honors thesis in a way that could parallel master's level work.

Finally, I would like to thank those I love. My best friend and other half was with me through every step of the writing process and even before I began my thesis work. No matter how frustrated I became or how close to tossing my laptop out of a window I came, he was always there to keep me calm and to encourage me, reminding me that nothing that is worth doing comes easy. I would also like to thank my mom and my older sister who have helped make me the person I am today and have always driven me to excel. It is because of their selflessness that I have been able to accomplish as much as I have in my entire school career. I know they will be with me as I continue my scholarly journey, sharing my frustrations, my nervousness, and my happiness, because my achievements are, and will always be, theirs as well.

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ABSTRACT

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The technology and design of lower limb prosthetics have evolved greatly since their introduction. The current study proposed to compare the effects of a conventional pin socket attachment and a vacuum socket attachment for a transtibial amputee. Whereas traditional measurements of gait utilize force plates and camera systems, this study made use of a small tri-axial load cell located at the base of the socket to measure the forces and moments exerted during a regular gait cycle. The hypothesis tested stated that a vacuum pump socket attachment, when compared to a non-vacuum (pin) socket, will have a significant effect on the forces and moments developed during gait.

The forces and moments load the residual limb and it is generally believed that a vacuum socket will produce a more favorable loading than a conventional pin attachment socket. If changes in forces or moments can be measured, this may provide clinical evidence supporting the use of vacuum pumps on prostheses. The hypothesis was tested using a Student-t -test which compared the maximum resultant force and moments during heel strike and toe-off between the vacuum and pin systems. Two subjects, S1 and S2, were tested with both vacuum and pin attachment sockets. S1 exhibited a statistically significant effect on toe-off when wearing the vacuum socket. The rest of the variables showed no statistical significance due to the vacuum socket. S2 did not exhibit a statistical significance due to the vacuum socket during heel-strike or toe-off.

The beneficial effects were not established by the results alone, but the literature review and subject assessment of a vacuum pump prosthesis offered support for the general conclusion that vacuum pump sockets produce beneficial gait outcomes.

Further analysis is needed to examine the effects on the forces and moments that occur on the sagittal, frontal, and transverse anatomical planes to determine whether use of a vacuum socket results in more or less force and moment when walking. Also needing further examination is whether a vacuum socket helps to stabilize the gait of a transtibial amputee.

CHAPTER 1: INTRODUCTION AND BACKGROUND

1.1 Purpose

This study tested one hypothesis and examined a belief generally held by prosthetists. The hypothesis tested was whether a vacuum socket produces different forces and moments at the base of the socket than a pin socket. The belief examined was that beneficial gait outcomes result from using a vacuum socket rather than a pin socket. A tri-axial transducer (hereinafter referred to as a “load cell”) was used to measure the forces and moments acting on the base of a socket. The load cell was attached to the pylon of the prosthetic leg, directly below the socket, to measure the loads as close to the distal end of the residual limb as possible. Data acquisition was conducted in a clinical setting to determine the feasibility of clinician use.

1.2 Background

1.2.1 Growing Market

The human body is an extraordinary architectural feat. It can withstand large forces, heal broken bones to withstand more impact, and in cases of trauma, calculate how much blood flow to route to the most essential organs. In cases of amputation, the human body can adapt to using prosthetic devices. Currently, the market for prosthetic devices is growing and becoming more sophisticated every year. In recent years, more advanced knee and foot prosthetics have been produced to improve range of motion and step propulsion. The main problem with the fast-changing market is a prosthetist’s inability to write a prescription knowing exactly what prosthesis will best benefit the patient before the patient has been fitted and tested with the prosthetic device. A patient can have either unilateral or bilateral transfemoral or transtibial amputations; he or she could be missing a toe, half a foot, or not have an amputation at all but instead, a partially developed lower limb. It is only after the patient has been custom fitted with a prosthesis that gait analysis can be performed. The information gathered from a gait analysis can be relayed to prosthesis designers to better improve their products. The more information prosthesis designers have, the better a patient's case is taken into account when designing the limbs and preventing future complications for patients.

1.2.2 Force Plates

Gait analysis is typically done in a gait lab setting which houses a force plate on the ground and usually also houses a state-of-the-art camera system to track a patient's movements. Neither the gait lab or state-of-the-art camera system is practical to use in the typical clinic setting due to their cost, the expertise required to collect and interpret data, and space requirements. In the case of gathering data with a force plate, the patient is instructed to walk with the aim of striking the force plate with his or her left or right foot in order to read a measurement. This may produce an exaggerated gait or even a hesitant step before hitting the force plate. Force plates can usually record only one or two steps while the patient walks. This can cause data acquisition to be lengthy and for the patient to develop an awkward gait in order to make sure he or she strikes the force plate. The main disadvantage to gathering measurements with a force plate is its immobility. Force plates are usually set up in a gait laboratory, which can cause the patient unwanted travel time and be costly to reserve for experiments. Another disadvantage to using force plates is their positioning. Force plates cannot be used in varying environments as they are usually bolted flush with the floor. This diminishes the acquisition of force readings in any other type of walk than level walking. Unlike unnatural gait caused by aiming at a force plate, the patient would walk normally, at a self-selected pace. The load cell would record data itself while the clinician can subjectively analyze the patient to ensure correct alignment and walking pattern.

1.2.3 Inverse Dynamics

Once data have been recorded from the force plate, it must be analyzed to provide useful information about different limbs and joints. Force plates only record ground reaction forces as the foot lands at heel-strike, rolls over, and leaves the plate at toe-off. In order to get useful data for the rest of the limbs, assumptions about the patient must be made. A mathematical model is used and the results are assumed to be close to precise. Whereas readings from a force plate use estimation to calculate different aspects of an amputee's gait, a load cell attached to the prosthesis close to the site of interest may give more accurate force and moment readings without inserting force sensors inside the socket.

1.3 Hypothesis

Vacuum pump attachments are frequently used on a transtibial prosthesis socket to improve the fit between the socket and the residual limb, but their effect on gait has never been measured using a load cell directly attached to the prosthesis. The positioning of the load cell right below the socket may give an indication of the forces posed on the distal end of the residual limb. Unlike force plate readings which only read ground reaction forces, the load cell readings will not need additional assumptions and computations to estimate the forces at the end of the socket in terms of limb measurements or joint velocities. This study specifically analyzed a transtibial amputee's gait by means of a load cell to determine how much the force and moment that can be generated by an amputee during normal gait was influenced by a vacuum pump. The hypothesis was as follows:

> A vacuum pump socket attachment will cause a significantly different force and moment on the residual limb than a conventional pin attachment during a self-selected walking pace.

CHAPTER 2: LITERATURE REVIEW

2.1 Causes and Types of Amputations

Amputations in the modern age are more common than they were in the war era of the early 1900's. According to the Amputee Coalition, Limb Loss Resource Center statistics, there are nearly 2 million amputees in the United States. Every year, around 185,000 amputations are performed in the United States (1). NetWellness, an online community service that gathers information from its partner university faculty, reports up to 90% of amputations are caused by vascular disease, which includes people with diabetes and non-diabetic smokers (2). The Amputee Coalition reports up to 55% of amputees with "diabetes who have a lower extremity amputation…will require amputation of the second leg within 2-3 years" and "nearly half of the individuals who have an amputation due to vascular disease will die within 5 years" (1).

There are various types of amputations, depending on which limb was amputated. Focusing on the lower half of the body, the various types of amputations include hip disarticulation, transfemoral amputation (also referred to as above knee), knee disarticulation, transtibial amputation (also referred to as below knee), ankle disarticulation (known as Syme's amputation), and partial foot and toe amputations. A unilateral amputation refers to one amputation, whereas a bilateral amputation refers to two amputations. May (1996) found in her case study of amputations and prosthetics that the "transtibial amputation is the most common level of extremity amputation necessitated by peripheral vascular disease" (3). The growing number of amputations is or high concern, not only to medical practitioners, but to prosthetists who must keep up with the high demand of patients.

2.2 Pin and Vacuum Pump Prosthetic Attachments

Various methods of residual limb attachments exist for prosthetic legs. One of the most common is a pin attachment. With a pin socket, the patient wears a liner over the residual limb with a locking pin attached to the distal end. The pin tries to rotate in the socket as the patient walks but is corrected with a properly fitting socket. Richard Krosin (2005), a prosthetics resident at Hanger Prosthetics & Orthotics, summarized several advantages and disadvantages to using a pin lock as compared to a total surface weight bearing socket. The advantages of a pin system are listed as follows (4):

1) Secure and simple
2) No need for suspension sleeve
3) Donning and doffing, putting on and taking off, the prosthesis is quick and easy
4) The pin lock produces audible feedback when engaging the lock mechanism

Figure 2.2.1 Liner with Distal Locking Pin (12)

Some of the disadvantages of the pin system are as follows (4):

1) The distal tissue experiences a stretching, or “milking,” effect. This stretching can permanently elongate the distal tissue and can lead to pain and, in some cases, eventually cause a reopening of the suture line.
2) Some patients have trouble aligning the pin with the plunger pin hole. This can cause some patients to repeatedly jam the end of the liner into the socket and could cause the pin to rip through the liner, injuring the residual limb.
3) Locking pin liners usually contain a hard umbrella for attaching the pin. This hard umbrella can cause pain on the distal end of the residual limb and can also prevent the limb from completely contacting the socket.

Although a locking pin mechanism may be more convenient to manufacture into a socket than a vacuum pump, a vacuum pump prosthesis ensures total contact of the residual limb with the socket. Street (2007) defines vacuum suspension as "the removal of air molecules from the sealed air space in a valve suspension system" (5).

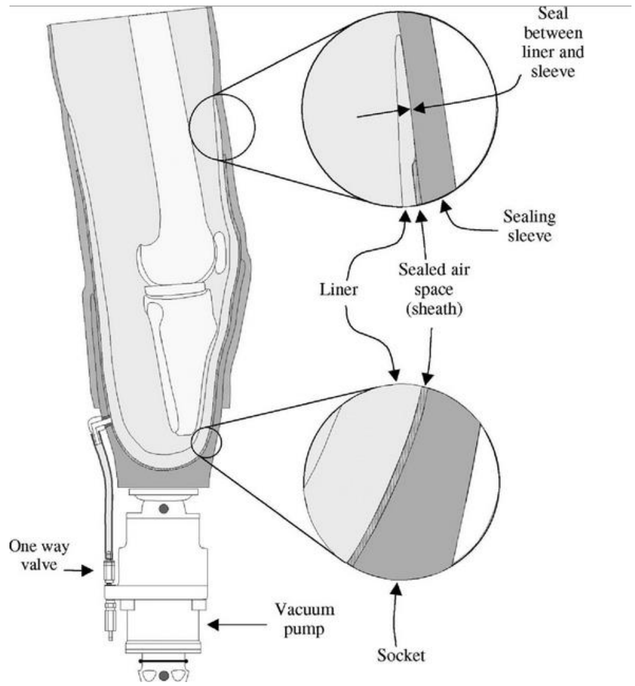

Figure 2.2.2 Vacuum Suspension System (13)

Krosin lists various advantages and disadvantages of a pump system. Some of the disadvantages of a vacuum system are as follows (4):

1) Vacuum prosthesis sockets require the use of a suspension sleeve to keep the air from going into the socket. Suspension sleeves often bunch-up, inhibiting knee flexion, especially when sitting.

Figure 2.2.3 Suspension Sleeve on Prosthesis (14)

2) Donning and doffing requires more time and effort because of additional sleeves or other methods.
3) Prosthetist manufacturing can be time consuming, especially when trying to find a leak in the system.

The advantages, though, far outweigh the disadvantages of a vacuum pump prosthesis. Street (2007) analyzed the effects of vacuum suspension on the limb. The residual limb fluctuates in volume daily as activities change. Various advantages of a vacuum system are examined as follows (5):

1) Vacuum suspension prevents fluctuation of the residual limb, keeping it at a constant volume which improves residual limb health.
2) The patient feels a more intimate connection with the prosthetic limb. This increases a patient's spatial awareness as any movement of the residual limb is followed by an immediate following of the prosthetic leg.
3) Many patients feel a vacuum limb to be lighter than a conventional pin attachment limb even though many are actually heavier than other prostheses.

Whereas the pin liner rotates as the patient walks, the vacuum socket is rigidly attached to the residual limb. A patient's ability to maneuver more confidently increases in a vacuum prosthesis. The increased hydration of the residual limb keeps the patient's overall health from diminishing as well.

2.3 Financial Cost of Pin and Vacuum Prostheses

A financial analysis is also relevant for the patient and prosthetist in making the final decision of whether to choose a pin attachment socket or vacuum pump socket. The following information was produced with the help of Precision Orthotics and Prosthetics and the 2014 Medicare fee schedule:

Using a Flex Foot (standard K3 level foot) code for pricing included the $4758 cost of the prosthetic foot in the financial analysis. A standard endoskeletal transtibial prosthesis with a silicone locking liner suspension costs $12,160, including the prosthetic foot. At Precision Orthotics and Prosthetics, this comes with a liner, an annual allotment of multi-ply socks, and three suspension sleeves. A double wall vacuum suspended socket costs $17,550, which includes the inner socket and vacuum pump. The sleeves for this type of system last an average of four months. A single wall vacuum suspended socket costs $16,920 and the patient will need an average of one new sleeve a month. Suspension sleeves cost a minimum of $118 and go up to an initial cost of $1,213 for a custom-fabricated liner (for either vacuum or pin sockets). A second liner produced from the custom liner will cost the patient $613 whereas an off-the-shelf locking liner will cost $736 liners. Medicare usually covers 80% of the cost and then the patient is liable for the rest unless they have secondary insurances that can help cover the remaining costs.

There is about a $5000 difference in the initial cost of the pin and vacuum socket. Although the vacuum socket may be more expensive initially, the patient may improve the health of his or her residual limb while using a vacuum socket. Pin sockets may lead to deterioration of the residual limb which could increase a patient's future medical costs.

2.4 Load Cells

Previous clinical studies have included the use of a load cell to capture gait data. One such study was conducted by Neumann *et al.,* (2012) in which the forces and moments on a transtibial residual limb were measured using a load cell. The study found varying load cell readings depending on the alignment of the prosthetic foot. Another study also found that the load cell, when attached to the distal end of the socket, provided a strong indication of pressures produced at the distal tibia (9). This study not only made use of a load cell for capturing gait data but also provided useful measurements of the pressures exerted on the residual limb during a gait cycle.

Another study conducted by Neumann *et al.,* (2012) made use of a load cell to capture gait data and analyze the effects of alignment on foot roll-over kinetics. The study focused on measuring forces and moments on a transtibial amputee for various alignments. Analysis was conducted by plotting forces with moments in the sagittal plane, which according to the study is "the plane of most importance to forward progression" (10).

Use of a load cell has also been implemented in measuring forces and moments of a transfemoral amputee, such as in the study conducted by Frossard *et al.,* (2013). The multi-axial transducer was mounted between the residuum and the prosthetic knee. Two different types of prosthetic knees were used to measure the intra-socket pressures produced during activities of daily living (ADLs). This study also confirmed the varying intra-socket pressures produced from different prosthetic components (11).

Making use of a load cell to analyze the forces and moments produced during a gait cycle can give insight to the various pressures produced inside the socket without having to alter the socket or wedge force sensors inside to touch the residual limb. Load cells are not intrusive and do not require any more modification to attach than the pylon already used in the prosthetic leg.

CHAPTER 3: EXPERIMENTAL METHODOLOGY

3.1 Subjects

Subject recruitment was facilitated by Kevin Bidwell, a certified prosthetist at Precision Orthotics and Prosthetics. All patients were administered a letter of informed consent, as approved by the University of Nevada, Las Vegas Institutional Review Board. A facility authorization letter from Precision Orthotics and Prosthetics enabled the data collection to be acquired at the facility. The research protocol was submitted to the IRB on January 15, 2014 and approved February 21, 2014. Data collection began March 14, 2014. The inclusion/exclusion criteria for patient selection were as follows:

Inclusion	**Exclusion**
Adult unilateral transtibial amputee	Bilateral amputee
At least six months since amputation	Less than six months since amputation
Absence of balance or gait problems	Unstable gait or apparent difficulty with balance
Absence of open sores or infections on residual limb	Infections or open sores on the residual limb
Correct socket fit	Poor or loose socket fit
Sufficient pylon length to incorporate load cell	Insufficient pylon length

Table 3.1.1 Subject inclusion/exclusion criteria

Subject 1 and 2 information is tabulated in Table 3.1.2.

Subject	1	2
Age of Patient	70 years	69 years
Sex	Male	Male
Date of Amputation	8/2013	6/ 2007
Reason for Amputation	Diabetes related	Mrsa virus
Self-reported Weight (lbs)	198	209
Scale Weight (lbs)	225	197
Load Cell Weight (lbs)	223	192
Height (ft)	6	6
K Level[1]	K2	K3
MPT to Floor (shoe off) (in)	19 5/8	20 1/8
Foot Size (cm)	28	25
Tibial Length (in)	5 5/8	4 ¾
Shape of Residual Limb	Fleshy but no redundant tissue. Not conical yet. Slightly bulbous but closer to cylindrical.	Cylindrical
Type of Liner or Suspension	Pin: silicone Vacuum: low durometer silicone	Vacuum: urethane Pin: silicone
Type of Prosthetic Foot	Össur K2 Sensation	Freedom Innovations Sierra
Miscellaneous Info	Vacuum test socket (20 mmHg). Wearing silicone liner on the vacuum and 7 ply socks for pin.	

Table 3.1.2 Subject Information

3.2 Load Cell Instrumentation

The load cell used in this experiment was a JR3 35E15A4 load cell with external electronics. The specifications are listed in table 3.2.1.

[1] Refer to Appendix C for K Level definitions

Sensor Model: **Mechanical Load Rating:**	**35E15S4** **250 lb**
Diameter (in)	3.5
Thickness (in)	1.50
Material	SS 15-5PH
Weight (lb)	2.60
Nominal Accuracy, all axes (% measuring range)	±0.25
Operating Temp. Range, non-condensing (°F)	-40 to + 150
Fx, Fy	
Standard Measurement Range (lb)	±250
Digital Resolution (lb)	0.031
Stiffness (lb/in)	0.290e6
Single-axis Overload (lb)	1450
Multi-axis Overload Coefficient, a (lb)	1450
Multi-axis Overload Coefficient, b (lb)	2700
Fz	
Standard Measurement Range (lb)	±500
Digital Resolution (lb)	0.063
Stiffness (lb/in)	3.16e6
Single-axis Overload (lb)	5780
Multi-axis Overload Coefficient, c (lb)	5780
Mx, My	
Standard Measurement Range (in-lb)	±875
Digital Resolution (in-lb)	0.11
Stiffness (in-lb/rad)	3.18e6
Single-axis Overload (in-lb)	4100
Multi-axis Overload Coefficient, d (in-lb)	4100
Mz	
Standard Measurement Range (in-lb)	±875
Digital Resolution (in-lb)	0.11
Stiffness (in-lb/rad)	1.00e6
Single-axis Overload (in-lb)	3520
Multi-axis Overload Coefficient, e (in-lb)	3520

Table 3.2.1 JR3 Multi-Axis Force-Torque Sensor Technical Specifications

Figure 3.2.1 JR3 Load Cell Model 35E15A4

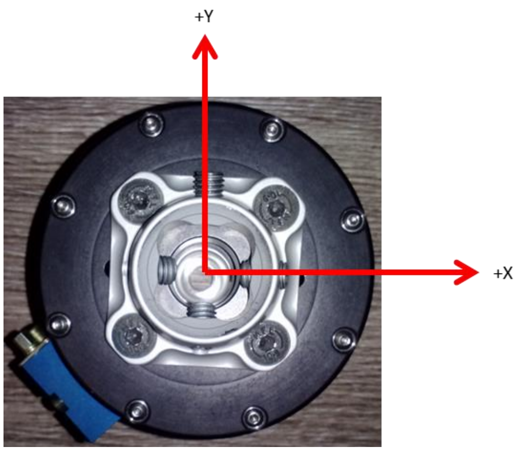

Figure 3.2.2 Load Cell Robot View

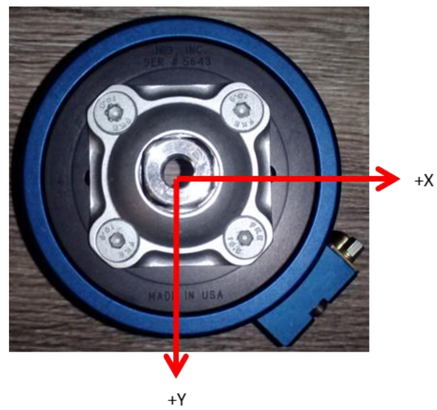

Figure 3.2.3 Load Cell Tool View

(Photos by M. Ramos, 2014)

The load cell connects to a computer, along with its power supply, via cable. A 30 foot cable was used in the experiment to allow a 60 foot range maximum for the patient to produce around 10 steps with the prosthetic limb. Data were recorded wirelessly through the router and displayed on a remote desktop that is accessed by a laptop connected to the router.

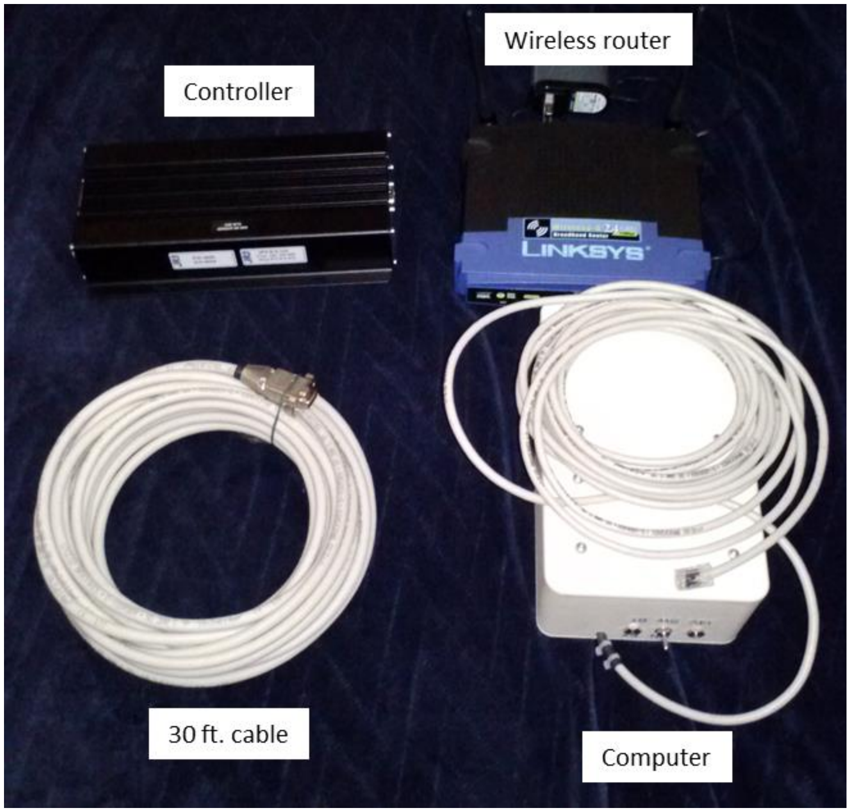

Figure 3.2.4 Load Cell Controller, Wireless Router, 30 ft. Cable, and Computer
(Photo by M. Ramos, 2014)

3.3 Clinical Set-up

The clinic hallway at Precision Orthotics and Prosthetics was used as the runway for the patients. The hallway measured about 35 feet in length with the patient being able to walk around 10 steps with his prosthetic limb. Both subjects' pylons were modified to include the load cell right beneath the socket. Alignment and height were checked and verified by a certified prosthetist before the beginning of data collection.

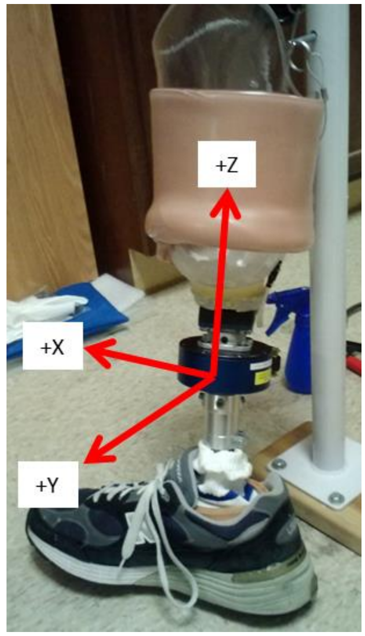

Figure 3.3.1 Subject 1 Vacuum Socket with Suspension Sleeve and Load Cell
(Photo by M. Ramos, 2014)

Figure 3.3.1 shows the mounting orientation of the load cell. Both subjects were right transtibial amputees. The load cell was mounted with a positive X oriented forward, a positive Y oriented to the subject's medial direction, and a positive Z pointing upwards. A positive Z pointing upwards helped distinguish positive values of Z when the patient was putting his weight on the prosthesis.

Figure 3.3.2 Subject 1 Silicon Sleeve **Figure 3.3.3** Subject 1 Manual Pump
(Photos by M. Ramos, 2014)

Subject 1 was fitted with a low durometer silicon sleeve to ensure suction of vacuum and total contact inside the socket. A suspension sleeve was put around the socket and the residual limb to prevent any loss of vacuum. Due to the limited time and budget of the project, subject 1 was fitted with a clear test socket. Final fabrication of a vacuum socket includes a constant source of vacuum suction facilitated by an electronic vacuum pump. The vacuum was pumped to -20 mmHg.

Figure 3.3.4 Subject 2 Load Cell and Cable Setup
(Photo by M. Ramos, 2014)

Figure 3.3.4 shows Subject 2 instrumented for data collection. A 30 foot span was marked to record subject velocity for every trial. Subjects were instructed to walk at a self-selected comfortable speed (SSCS) and to pass the markings on the ground. They were also instructed to keep walking at their selected pace and not slow down too much when about to reach the finish line. This helped to prevent any awkward steps at the end of the data trial.

3.4 Data Recording

The load cell computer was remotely connected by a router to a laptop. Before data collection began, the subjects' prosthetic limb was suspended horizontally so as not to cause pressure readings in the Z direction. Calibration was completed when the display showed forces and moments near zero.

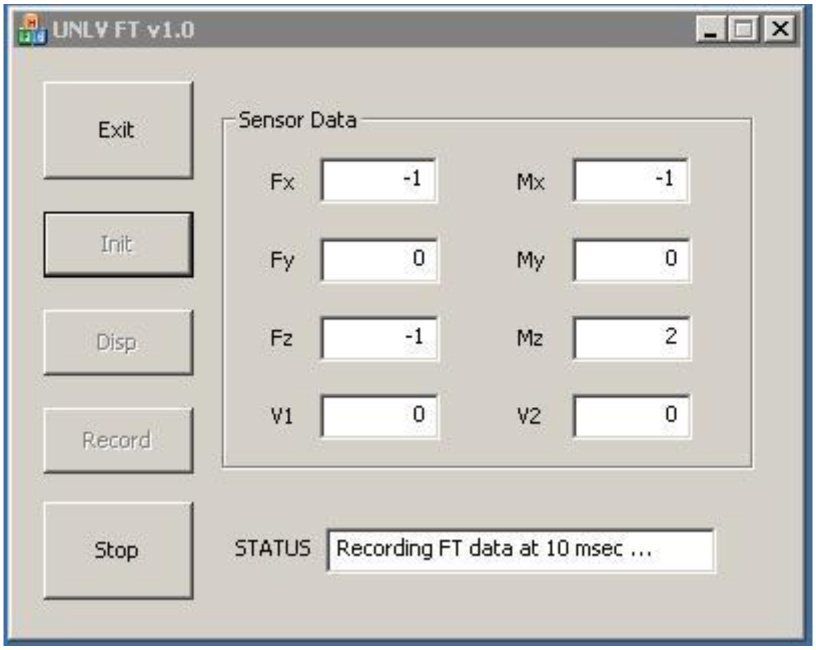

Figure 3.4.1 Calibration of the Load Cell

The subjects were instructed to walk at an SSCS. The load cell recorded the various pressure readings in all three axes. A stopwatch was used to measure the speed of the subject for a 30 foot distance during each trial. The subject began walking as soon as data recording began and ended once the end of the runway was reached. Five to six trials were recorded for each socket type and around ten steps were produced during each trial. SSCS and subject socket type were recorded as follows:

	Subject 1		Subject 2	
	Vacuum (m/s)	Pin (m/s)	Vacuum (m/s)	Pin (m/s)
Trial 1	0.621	0.728	0.904	0.878
Trial 2	0.631	0.806	0.953	0.935
Trial 3	0.653	0.863	0.950	0.941
Trial 4	0.705	0.829	0.998	0.945
Trial 5	0.795	0.833	0.947	0.982
Trial 6	N/A	0.835	0.897	0.966
Average	0.681	0.816	0.941	0.941

Table 3.4.1 Subject Self-Selected Comfortable Speeds

3.5 Data Processing

A Graphical User Interface (GUI) was used for displaying and analyzing force and moment data collected from the load cell. The GUI can analyze up to ten steps. At least eight steps are needed for statistical analysis. All the acquired trials were analyzed with the GUI. A complete list of steps for processing the data with the GUI can be found in Appendix A. The GUI software divides each step into 50 discrete time intervals, each of which represents 2% of the gait cycle. The GUI was developed by Dr. Neumann's former graduate student, Kartheek Yalamanchili. Reference to his thesis can be found in the bibliography for further explanation.

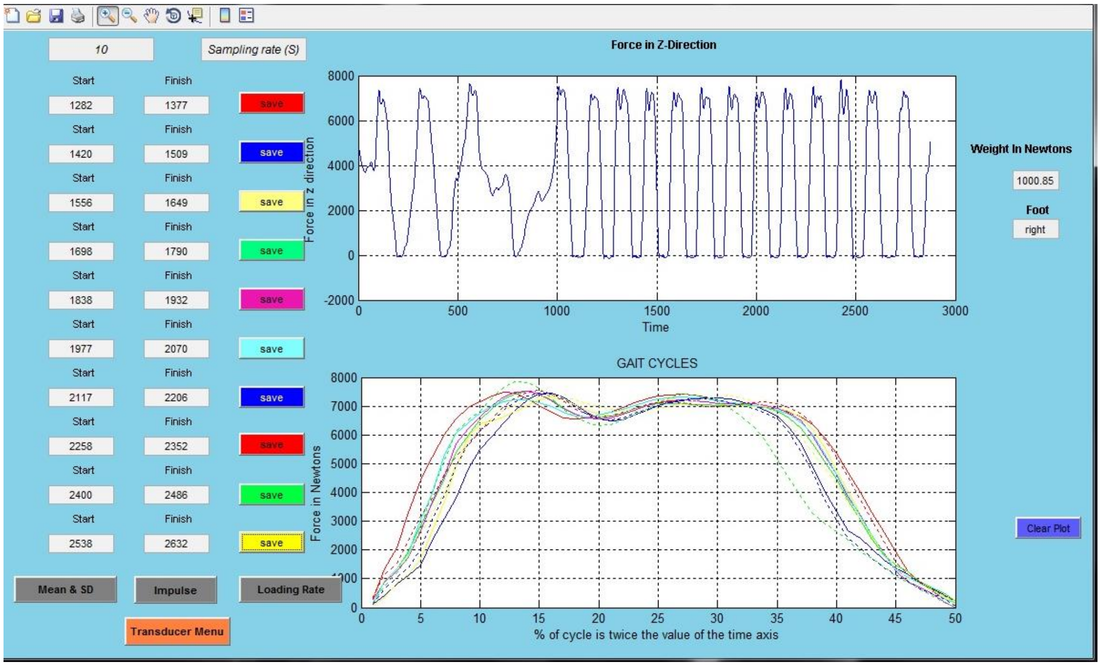

Figure 3.4.1 GUI Display and Step Selection for Force in Z-Direction

Figure 3.4.1 represents a typical display of steps. The GUI allows for zooming into specific intervals of data to choose the appropriate start and end sections of each step. Once the step start and end intervals have been input into the columns, the GUI displays the selected steps in the GAIT CYCLES. The same start and end intervals are transferred to analyze the forces in the X and Y directions as well as the moments in the X, Y, and Z directions. Steps from the beginning of the trial and the end of the trial were excluded from analysis to avoid variation involving hesitant starts, rushed stops, and anything else that can occur when beginning to walk and stopping.

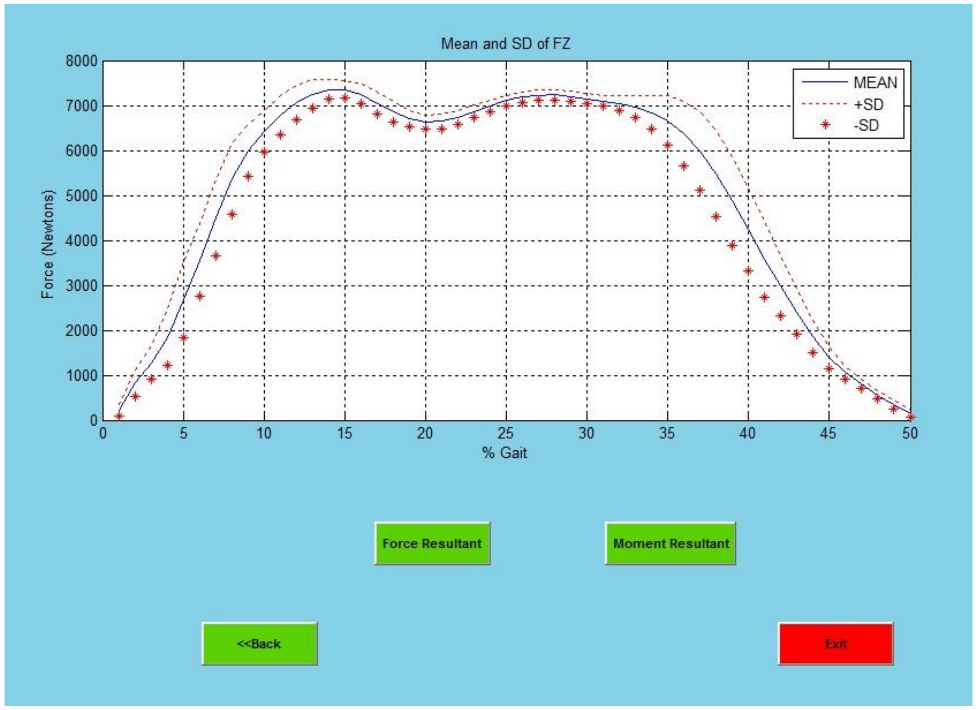

Figure 3.4.2 Example of GUI Display for Mean and SD of Force in Z-Direction

Figure 3.4.2 represents the mean and standard deviation for the steps selected for analysis. The GUI calculates mean and SD for all forces and moments.

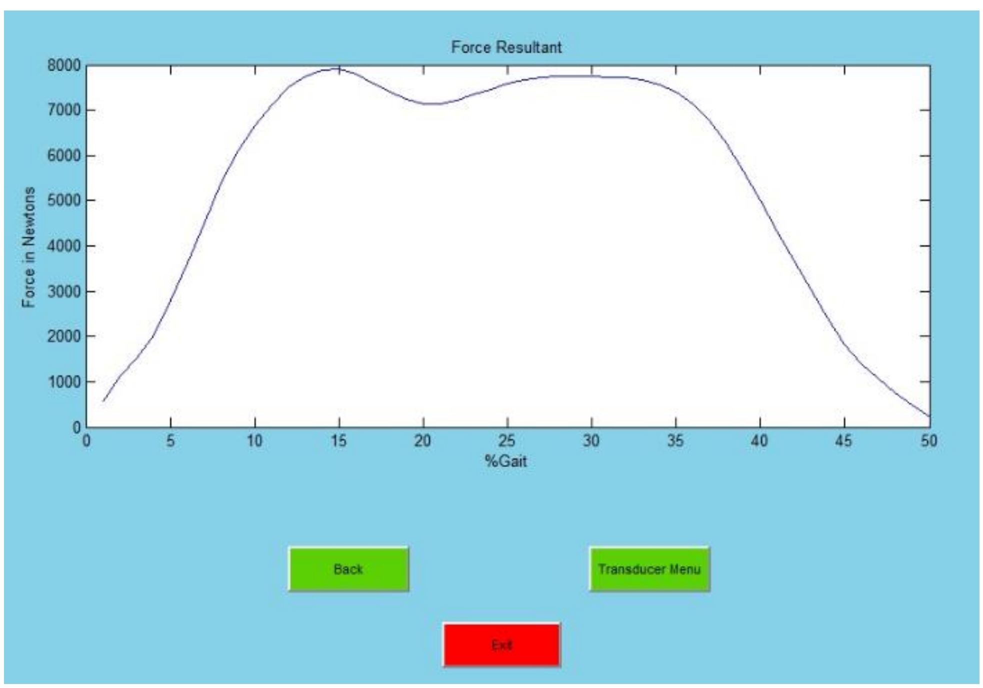

Figure 3.4.3 Example of GUI Display for Force Resultant

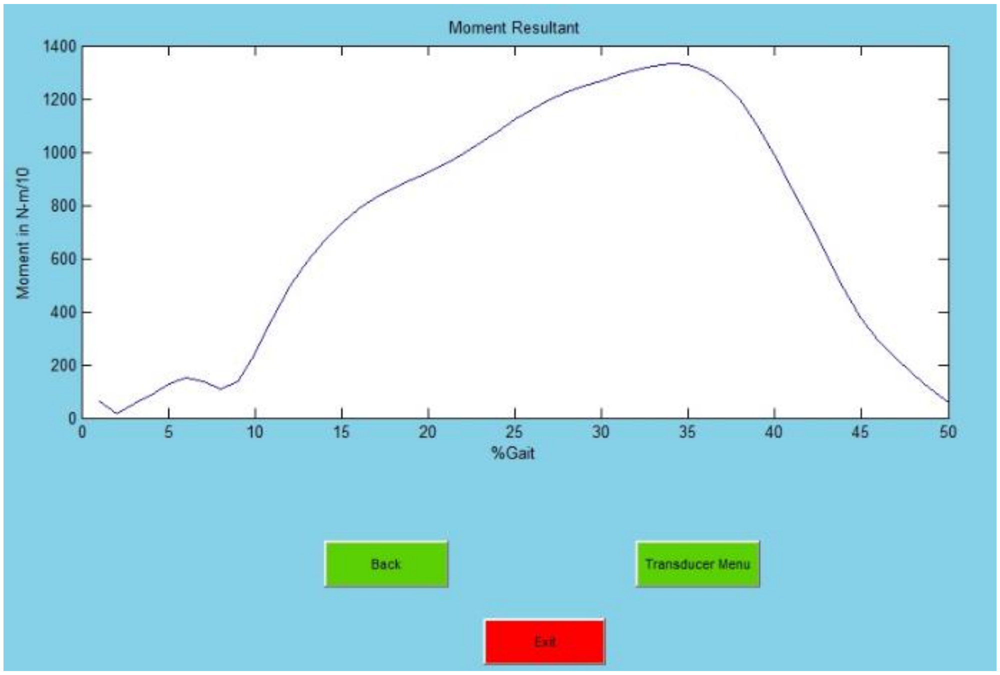

Figure 3.4.4 Example of GUI Display for Moment Resultant

Figures 3.4.3 and 3.4.4 are the final force and moment resultants for the load cell data in the X, Y, and Z directions. Once the GUI is done processing the data, three files are output labeled "Transducer Rawdata," "Transducer Data in Newtons," and "Gait Cycles."

3.6 Data Analysis

The "Gait Cycles" Excel file displayed the readings in Newtons for the forces in the X, Y and Z directions. The moments about the X, Y, and Z axes were displayed in Newton-meters. Each step is displayed at its 2% interval, producing 50 intervals per step. The data for each of the three forces and moments were displayed in six matrices of size 50x10 cells. Each matrix contained 50 rows (intervals) and up to 10 columns of data for the recorded steps. The mean and SD were also displayed for every interval. The load cell produces values on a full scale of 16384. All values must be converted to a percentage of full scale by dividing the number by 16384. The force in the X and Y directions were then multiplied by 250 to produce the values in pounds. The force in the

Z direction was multiplied by 500 to produce its value in pounds. The moments were output in Newton-decimeters. After multiplying all the values by 10, the values were divided by the full scale value of 16384 and multiplied by 875 to convert to inch-pounds. All values were then converted to their respective Newtons or Newton-meters.

A complete analysis was done for the fourth trial of the pin and vacuum sockets. Justification for choosing the fourth trial stemmed in having the patients adjust to walking at their SSCS and becoming familiarized with starting and stopping at the indicated locations. Five to six trials were recorded for each subject and respective socket, with the exception of Subject 1, producing only five trials with the vacuum socket. The last two trials were also excluded from complete analysis due to having the patients mentally aware that the trials were almost completed, possibly causing steps to be rushed or overcompensated from fatigue.

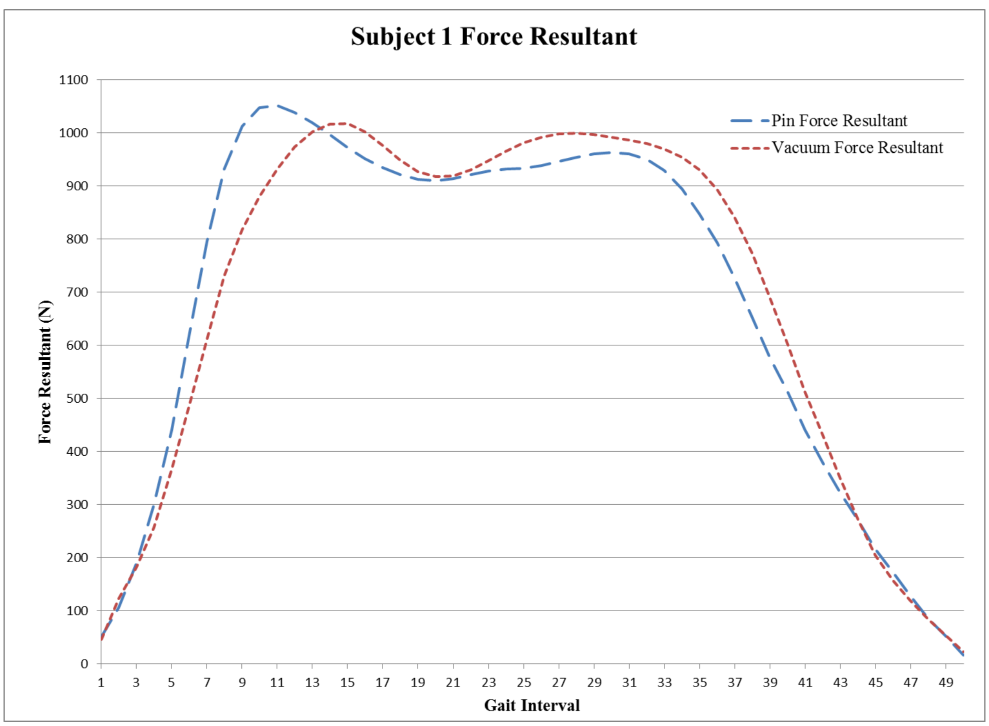

Figure 3.6.1 Force Resultant Graph

In order to visually analyze the data, the force resultant was plotted with the force in Newtons on the vertical axis and the normalized gait interval on the horizontal axis as shown in Figure 3.6.1 for S1. The percent of stance is equal to twice the interval minus one. Plotting the force resultant eliminates the orientation of the mounted load cell from causing any differences from socket to socket. Both socket types (pin and vacuum) were plotted on the same graph for the individual subjects to visually spot any differences.

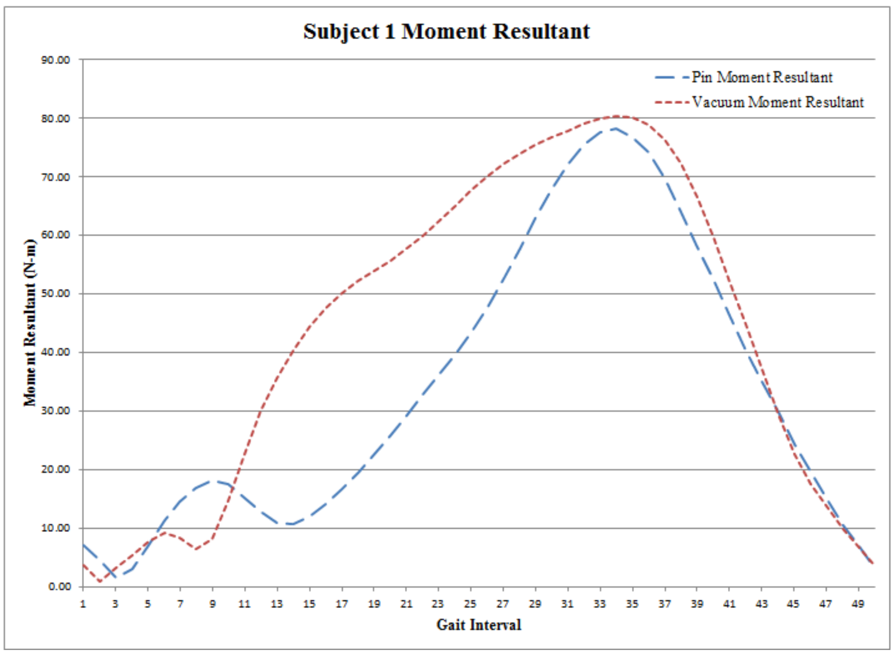

Figure 3.6.2 Moment Resultant Graph

The moment resultant was plotted with the moment in Newton-meters on the vertical axis and the gait cycle percentage on the horizontal axis. Again, both socket types were plotted on the same graph to visually display any differences. Resultant moments for S1 are shown above.

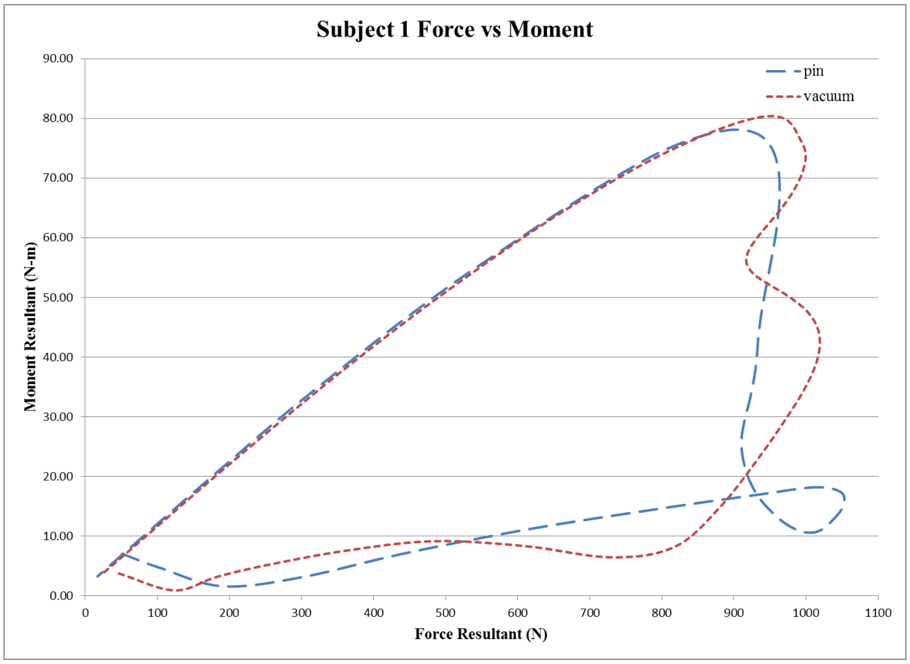

Figure 3.6.3 Force vs. Moment Graph

Finally, the force and moment curves for the vacuum and pin sockets were plotted for each individual subject as shown in Figure 3.6.3 for S1. The moment lies on the vertical axis in Newton-meters and the force lies on the horizontal axis in Newtons. The length of the moment arm is proportional to the slope of a line connecting the origin with a point. The two curves can be compared to determine which socket condition involves a longer moment arm.

Statistical analysis was facilitated by an Excel Student-t test. The t-test displays the statistical probability that the compared samples came from the same two underlying populations. The first maximum in the force resultant, caused by the subject during heel strike or loading response, for the pin was compared with the first maximum in the force resultant for the vacuum socket. Likewise, the second maximum in the force resultant, caused during toe-off or propulsion, for the pin was compared with the second maximum in the force resultant for the vacuum socket. The moment resultant curve produced one maximum for each of the two force maximums, which was compared for the pin and vacuum sockets. The maximum during loading response was less than the overall maximum, which occurred during propulsion.

CHAPTER 4: RESULTS

This chapter presents the results of the fourth trial for both the pin attachment and vacuum attachment sockets of each subject. Statistical analysis was conducted through an Excel t-test to determine the probability of the force resultant and moment resultant values coming from the same distribution for each subject.

4.1 Forces

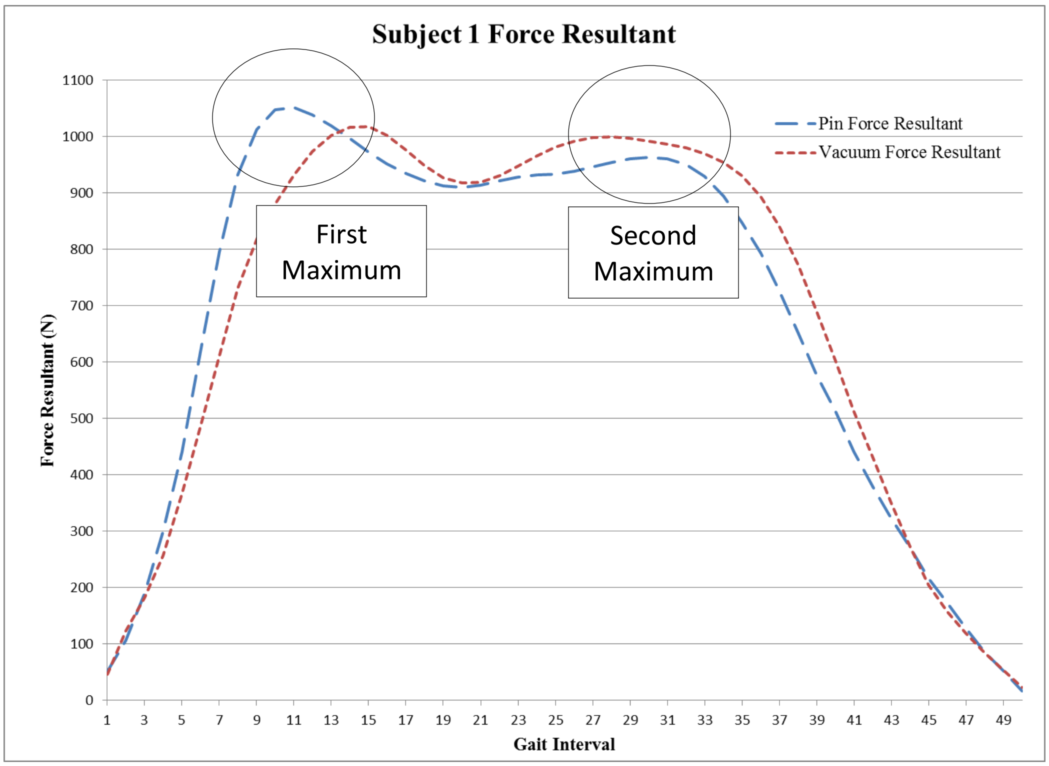

Figure 4.1.1 Subject 1 Pin and Vacuum Socket Force Resultants

Figure 4.1.1 represents the force resultants of the gait cycle for subject 1. The pin and vacuum sockets produced two maxima at heel strike and at toe-off. Stance occurs between the two maxima. The first maximum for the pin socket occurred at the 11th interval of the gait cycle with a resultant force of 1052.02 Newtons. The second maximum occurred at the 30th interval of the gait cycle with a resultant force of 963.34 Newtons. The vacuum socket produced its first maximum at a later interval than the pin socket. The first maximum was produced at the 15th interval with a resultant force of 1017.55 Newtons and the second maximum occurred at the 28th interval with a resultant force of 999.48 Newtons.

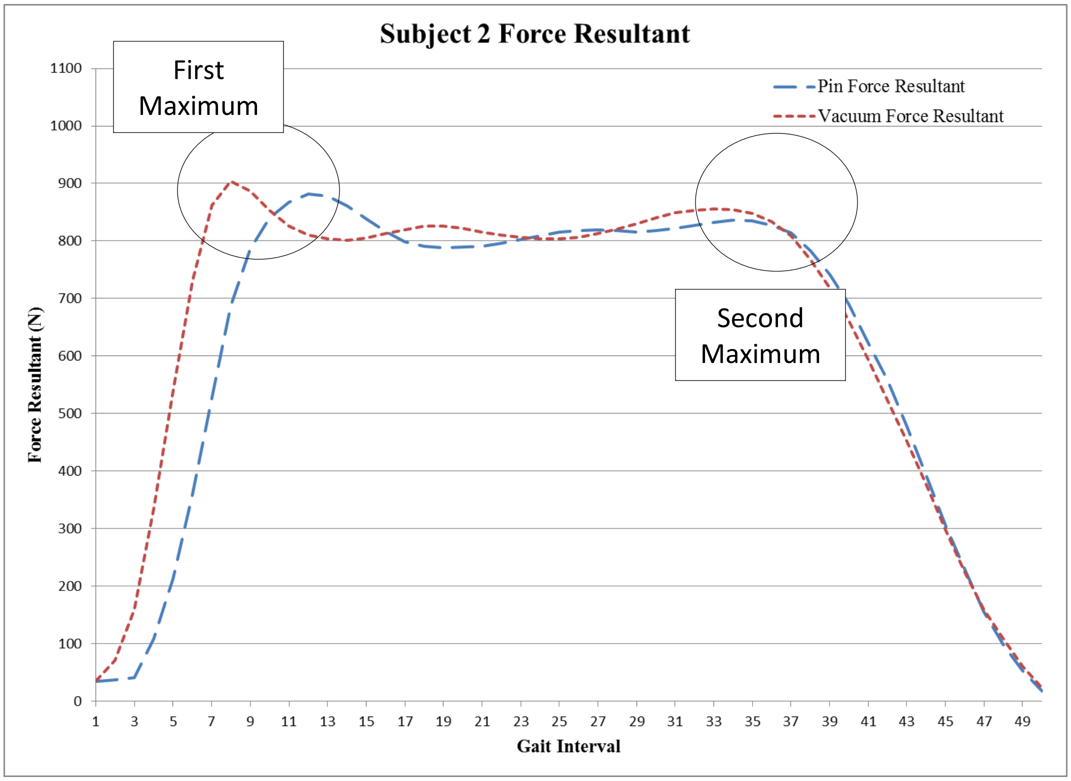

Figure 4.1.2 Subject 2 Pin and Vacuum Socket Force Resultants

Figure 4.1.1 represents the force resultants of the gait cycle for subject 1. The first maximum for the pin socket occurred at the 12th interval of the gait cycle with a resultant force of 881.64 Newtons. The second maximum occurred at the 34th interval of the gait cycle with a resultant force of 836.47 Newtons. Unlike subject 1, the vacuum socket produced its first maximum at an earlier interval than the pin socket. The first maximum was produced at the 8th interval with a resultant force of 903.86 Newtons and the second maximum occurred at the 33rd interval with a resultant force of 855.91 Newtons.

The following table summarizes the findings of the force resultants for each subject:

Subject	Socket	Interval	First Max (N)	Interval	Second Max (N)
1	Pin	11	1052.02	30	963.34
1	Vacuum	15	1017.55	28	999.48
2	Pin	12	881.64	34	836.47
2	Vacuum	8	903.86	33	855.91

Table 4.1.1 Force Resultant Maxima

4.2 Moments

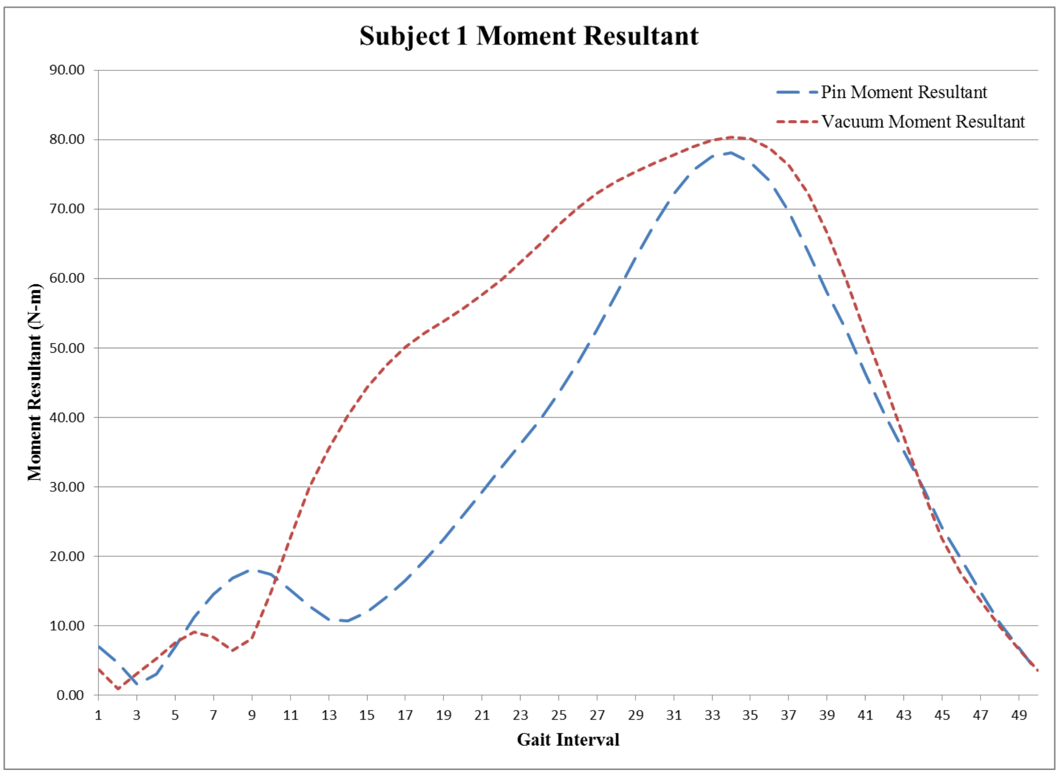

Figure 4.2.1 Subject 1 Pin and Vacuum Socket Moment Resultants

Figure 4.2.1 represents the moment resultants of the gait cycle for subject 1. The pin and vacuum sockets produced one maximum. The maximum for the pin socket occurred at the 34th interval of the gait cycle with a resultant moment of 78.07 Newton-meters. The vacuum socket also produced its maximum at the 34th interval with a resultant moment of 80.38 Newton-meters.

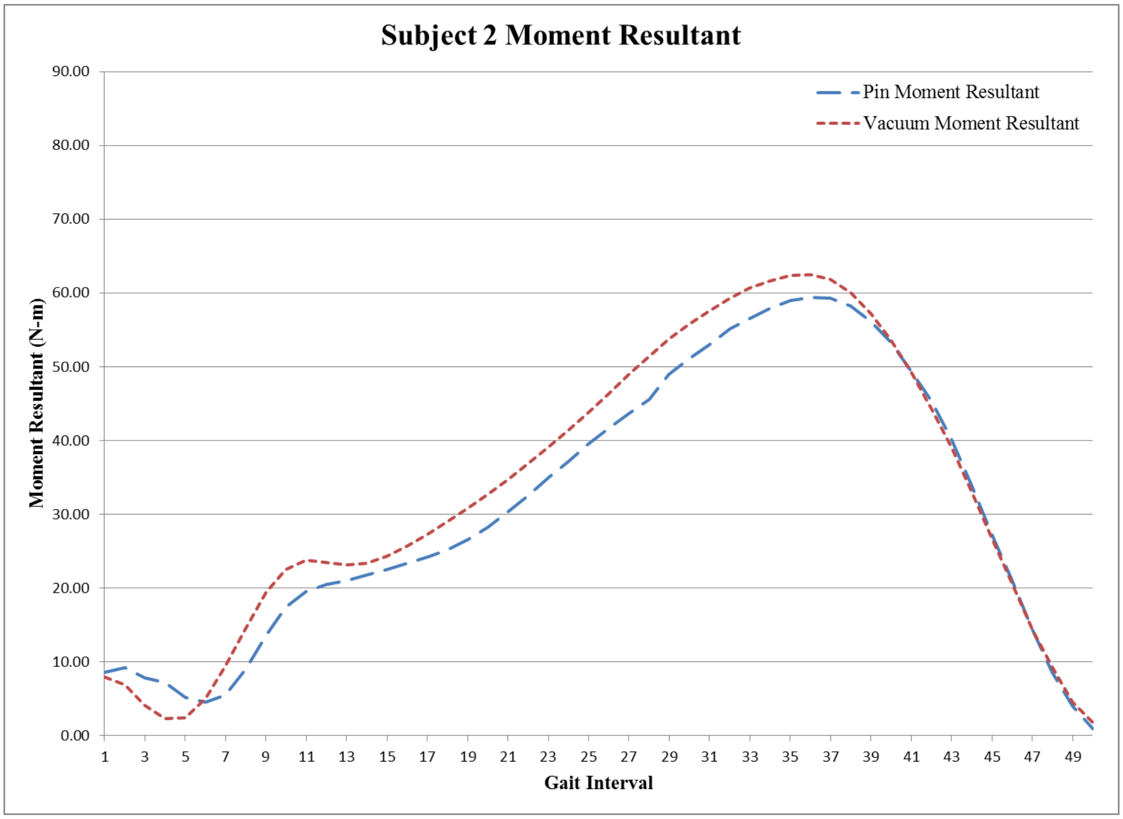

Figure 4.2.2 Subject 2 Pin and Vacuum Socket Moment Resultants

Figure 4.2.2 represents the moment resultants of the gait cycle for subject 2. The pin and vacuum sockets produced one maximum. The maximum for the pin socket occurred at the 36^{th} interval of the gait cycle with a resultant moment of 59.40 Newton-meters. The vacuum socket also produced its maximum at the 36^{th} interval with a resultant moment of 62.50 Newton-meters.

The following table summarizes the findings of the moment resultants for each subject:

Subject	Socket	Interval	Max (N-m)
1	Pin	34	78.07
1	Vacuum	34	80.38
2	Pin	36	59.4
2	Vacuum	36	62.5

Table 4.2.1 Moment Resultant Maxima

4.3 Force vs. Moment

In order to understand the relationship between the forces and moments produced during a gait cycle, the moment resultant was plotted on the vertical axis and the force resultant was plotted on the horizontal axis.

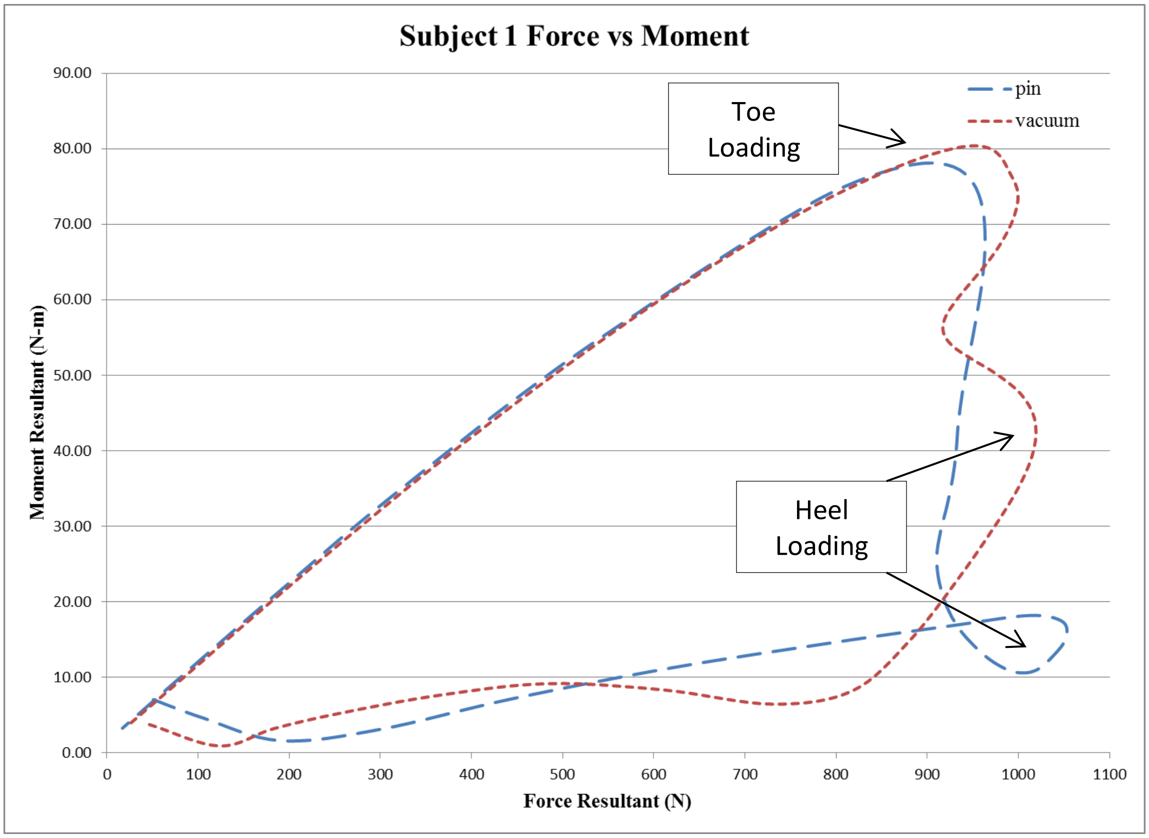

Figure 4.3.1 Subject 1 Force vs. Moment Curves

Figure 4.3.1 represents the force and moment produced at various stages of the gait cycle for subject 1. Starting from the lower left-hand side of the graph and moving to the lower right-hand side, the subject begins the cycle by loading force on the heel. Maximum load on the heel occurs at the position labeled “heel loading.” Subject 1 heel loading occurs at different stages of the gait cycle for the pin and vacuum sockets. Maximum toe loading, or push-off, occurs around the same interval of the gait cycle for both the pin and vacuum sockets at the top right-hand side of the graph. The subject then releases the load on the prosthetic limb and both forces and moments go back to zero at the lower left-hand side of the graph.

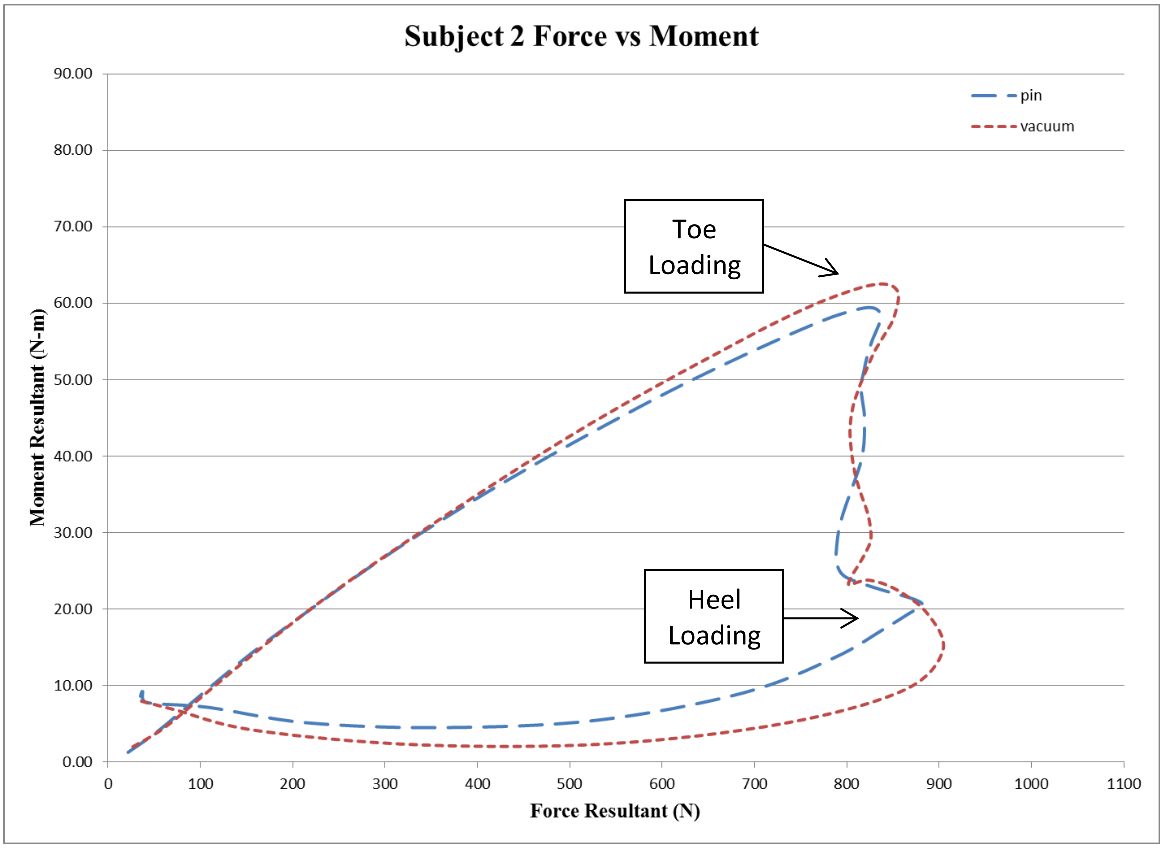

Figure 4.3.2 Subject 2 Force vs. Moment Curves

Figure 4.3.2 represents the force and moment produced at various stages of the gait cycle for subject 2. Starting from the lower left-hand side of the graph and moving to the lower right-hand side, the subject begins the cycle by loading force on the heel. Maximum load on the heel occurs at the position labeled "heel loading." Subject 2 heel loading occurs around the same interval of the gait cycle for the pin and vacuum sockets. Maximum toe loading, or push-off, also occurs around the same interval of the gait cycle for both the pin and vacuum sockets at the top right-hand side of the graph. The subject then releases the load on the prosthetic limb and both forces and moments go back to zero at the lower left-hand side of the graph.

4.4 Statistical Analysis

A two-tailed t-test statistical analysis with unequal variance was used to interpret the effect of the two sockets. An alpha value of 0.05 was used to determine the significance of the effects of the vacuum socket. A value larger than 0.05 indicated that the vacuum socket and pin attachment socket produced similar values in force or moment, suggesting there was no effect caused from using the vacuum socket. A value less than 0.05 indicated that the vacuum socket did produce a difference in the forces or moments being produced. The analysis was focused on the resultant forces and moments, reducing the chances of the load cell alignment to cause variability from socket to socket. The forces and moments in the X, Y, and Z-directions for every step were taken and converted to Newtons and Newton-meters, respectively. Statistical significance increases with the number of steps analyzed. The target was 10 steps but due to various circumstances, 9 or 8 good steps may have been produced for analysis.

4.4.1 Subject 1

The following statistical analysis was conducted for subject 1 at the maxima of the force and moment resultants. The two-tailed t-test was conducted with the respective maximum resultants of the pin and vacuum sockets. Tables containing the t-test data for S1 are displayed in Appendix C.

T-test analysis for the first maximum of the vacuum and pin socket resultant forces was 0.133. T-test analysis for the second maximum of the vacuum and pin socket resultant forces was 0.00246. Finally, t-test analysis for the maximum of the vacuum and pin socket resultant moments was 0.34701.

The following table summarizes the T-test values for the three maxima:

S1	t-test probability
Force Resultant 1st Max	0.133
Force Resultant 2nd Max	0.00246
Moment Resultant Max	0.347

Table 4.4.1.1 Subject 1 Pin and Vacuum Resultant T-test Values

4.4.2 Subject 2

The following statistical analysis was conducted for subject 2 at the maxima of the force and moment resultants. The two-tailed T-test was conducted with the respective maximum resultants of the pin and vacuum sockets. Tables containing the t-test data for S2 are displayed in Appendix C.

T-test analysis for the first maximum of the vacuum and pin socket resultant forces was 0.341. T-test analysis for the second maximum of the vacuum and pin socket resultant forces was 0.169. T-test analysis for the maximum of the vacuum and pin socket resultant moments was 0.249.

The following table summarizes the T-test values for the three maxima:

S2	t-test probability
Force Resultant 1st Max	0.341
Force Resultant 2nd Max	0.169
Moment Resultant Max	0.249

Table 4.4.2.1 Subject 2 Pin and Vacuum Resultant T-test Values

CHAPTER 5: DISCUSSION

Subject 1 and 2 SSCS from Table 3.4.1 indicate varying speeds depending on the type of socket worn. S1 walked with a higher average speed in the pin socket than in the vacuum socket whereas S1 walked with the same average speed with both sockets. S1 started with a slower speed in the vacuum socket and ended with a higher speed. The trend is similar for the pin socket. S1 also began with a slower speed in both the pin and vacuum sockets but increased his SSCS near the end of the trials, only slowing down for the final trial.

Subject 1 and 2 force, moment, and statistical results were different for both the pin and vacuum sockets. The force resultant graph for Subject 1 shown in Figure 4.1.1 depicts a two-humped bimodal curve. The first maximum represents the full weight of the subject at heel strike. As the foot makes full contact with the ground, the force on the socket lessens and rises again as the foot pushes off the ground. The second maximum occurs because the body is accelerated upward as one walks and must be pushed to propel the body forward. In the case of a non-amputee, the second hump is usually higher to propel the body forward.

The data for Subject 1 in the pin socket produced a heel strike maximum of 1052.02 Newtons and push-off maximum of 963.34 Newtons resulting in a difference of 88.68 Newtons from heel strike to push-off. The lower force caused during push-off may signify that the socket was not comfortable, but other explanations may account for this. A consideration for subject 1 is the relatively short time since amputation and K2 ambulation level. The vacuum socket exhibited less of a difference between heel strike and push-off with a difference of 18.07 Newtons resulting from a heel strike maximum of

1017.55 Newtons and push-off maximum of 999.48 Newtons. Heel strike values differed for the pin and vacuum sockets. The pin socket was associated with a higher force during heel strike than the vacuum socket, with a difference of 34.47 Newtons. The vacuum socket was associated with a higher force during propulsion than the pin socket, with a difference of 36.14 Newtons. Subject 1 was able to absorb more force and push off with more force with the vacuum socket during the gait cycle. Although the patient did not have time to adapt to the vacuum socket before the trials, the lessened force difference may indicate a higher stability while walking with the vacuum socket than with the pin socket.

Subject 2 also exhibited a difference in forces between the two peaks of force during heel strike and push-off. The difference between heel strike and push-off for the pin socket was 45.17 Newtons, resulting from a heel strike maximum of 881.64 Newtons and a push-off maximum of 836.47 Newtons. Subject 2, like Subject 1, also displayed a lower push-off force in the pin socket. The difference between heel strike and push-off for the vacuum socket was 47.95 Newtons, resulting from a heel strike maximum of 903.86 Newtons and push-off maximum of 855.91 Newtons. Subject 2 primarily wears a vacuum socket and has seven years of experience with prostheses, ambulating at a K3 level. There was less difference between the forces produced during heel strike and toe-off between both sockets. There was only a difference of 22.22 Newtons during heel strike and 19.44 Newtons during toe-off between the pin and vacuum sockets. The subject was able to push off with more force with the vacuum socket but also required a higher braking force at heel strike with the vacuum socket. Subject 2 verbally communicated he preferred the vacuum socket as it produced less pain than the pin socket. According to the results, he walks with similar forces on either socket.

The moment resultants for both subjects were primarily influenced by the moment about the Y-axis, the large values of which tend to dominate the resultant. Subject 1 exerted a maximum moment during the same interval for both the pin and vacuum sockets. Subject 2 also exerted a maximum moment during the same interval for both the pin and vacuum sockets. Subject 1 produced a much higher moment during the majority of the gait cycle in the vacuum socket. This could be due to the fact that the subject was wearing a vacuum socket for the first time and did not have time to adjust. It could also indicate a more loosely fitting vacuum socket since the prosthetist did not have time to modify the fit. The forces he exerted seemed to be close to the pylon as he walked and their line of action did not appear to cross the heel region of the foot nor extend far onto the forefoot . The trajectory of the moment curve with the vacuum socket varies greatly for subject 1 but the peak moment occurs during an interval that is similar for the pin socket. The difference between the peak moments for the two types of sockets was 2.31 Newton-meters. Subject 2 exerted more control in both the vacuum and pin sockets, as shown in Figure 4.2.2 with the plotted analysis matching closely between the pin and vacuum sockets. Like Subject 1, Subject 2 exerted a higher moment with the vacuum socket at the peak of the curve than the pin socket but the difference was only 3.1 Newton-meters and was not significant.

The force and moment curves plotted together show the relationship between the moment and force during the gait cycle. Subject 1's gait cycle produced a loop during heel loading in the pin socket. The moment and force both increased during loading response to a local maximum but the moment suddenly dropped as stance continued. Toe loading was similar for both the pin and vacuum socket. Subject 1 appeared to reach heel strike sooner in the pin socket than the vacuum socket during the gait cycle. Subject 2 produced more consistent results for both moments and forces. He reached heel strike and toe-off around the same interval during both gait cycles.

The statistical analysis served to refute the first hypothesis which states that a vacuum pump socket attachment will cause less force on the residual limb than a conventional pin attachment during a self-selected walking pace. An alpha value of 0.05 was used to determine effectiveness of the test. Subject 1 produced a T-test result of 0.133 for the comparison of heel strike forces with the vacuum and pin sockets. This means there is a 13.3% chance that the distribution was the same for the pin and vacuum. There is no clear effect caused by the vacuum socket. The T-test produced a result of 0.00246 for the force resultant during toe-off in the pin and vacuum sockets. This indicates that the vacuum socket did produce an effect on the subject's gait. Finally, the moment resultant maximum produced a statistical value of 0.347, indicating there was no effect by using a vacuum socket rather than a pin socket. All of subject 2's results were over 0.05, indicating there was no clear effect from using a vacuum socket instead of a pin socket. Thus, there was no significant effect produced on the forces and moments due to the vacuum socket.

5.1 Shortcomings

There were a few shortcomings during the experiment that may have influenced the results. First, the goal was to recruit subjects who were transitioning from a pin to a vacuum socket. The original intent of the experimental design was to first measure a subject who was using a pin socket prior to the initial fitting of the vacuum socket. Two weeks after the vacuum socket had been fitted, measurements would be taken with the vacuum socket. This would allow two weeks for adaptation to the vacuum socket to occur, which would help ensure that the subject had adjusted to wearing a vacuum socket prosthesis. The results of the repeated experiment would be examined to determine whether the patient was exerting less or greater force and moment due to the vacuum socket. Adaptation time was not feasible for S1. Subject 1 was a relatively recent amputee and still adjusting to wearing a pin socket; he had only a K2 mobility level. The vacuum socket he used during the trials was the first vacuum socket he had ever worn. Proper alignment was ensured during all trials but the lack of time to adjust to a vacuum socket may have been the cause of the moment resultant curve not matching the form of the pin moment resultant curve.

Subject 2 was an experienced prosthesis user and accustomed to walking with a vacuum socket. The pin socket he used for the trials was an older socket that may have no longer fit as well as it should have. Visually, the gait was not forced or uneven for both sockets and the results did not indicate a major difference in the use of both for subject 2.

A longer runway at both clinic locations where measurements were taken would have served better to produce more than 10 steps. This could be a limiting factor for other clinics that do not have long hallways. At least 10 good steps would have provided a stronger statistical analysis but usually the first and last steps are discarded as they are non-representative of the entire trial.

Another major shortcoming came from the limited time available to process, analyze, and interpret data. The ideal complete analysis would involve analyzing all the trials, not just trial 4, and looking at the differences in the sagittal, transverse, and coronal planes to help distinguish the varying forces exerted in all directions of the gait cycle.

CHAPTER 6: CONCLUSIONS

The use of a load cell can quickly produce quantitative results for a prosthetist to relay to insurance companies and medical physicians. With the increasing demand from insurance companies for proper documentation and justification for producing new sockets, prosthetists have a difficult time justifying the production of a new socket for a patient who may not be comfortable in his or her socket even though he or she may benefit from having a new or different type of socket. The expected lifetime for a socket is 5 years, which insurance companies take into consideration when approving or denying the billing of a new socket. Patients change physically and emotionally during those 5 years and will become increasingly more confident walking with their prosthesis. They can realize the benefits from a more sophisticated socket design. They may also be experiencing painful sensations as they walk due to "milking" effects of a pin vacuum and could benefit from switching to the more expensive-to-produce vacuum socket. This could be researched with load cell data by examining the force and moment being created during the gait cycle.

This experiment measured the forces and moments produced during the entire gait cycle. The pin and vacuum sockets produced different results between the maximum force at heel strike and maximum force at toe-off. A small load cell, such as the one used in this experiment, would be a valuable asset to a prosthetist's tool box when fitting a patient with a new socket. Further research is needed to fine tune the data gathering and data analysis portions of the experiment. Future examination would require an analysis of normalized data, inspection of the forces produced in the different anatomical planes, and a larger pool subject to produce an improved statistical analysis.

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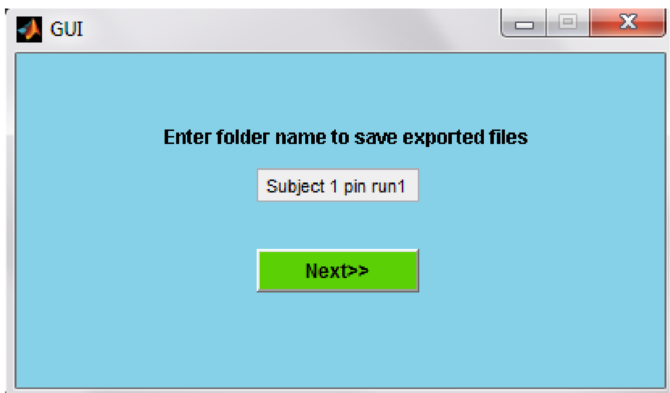
APPENDIX A

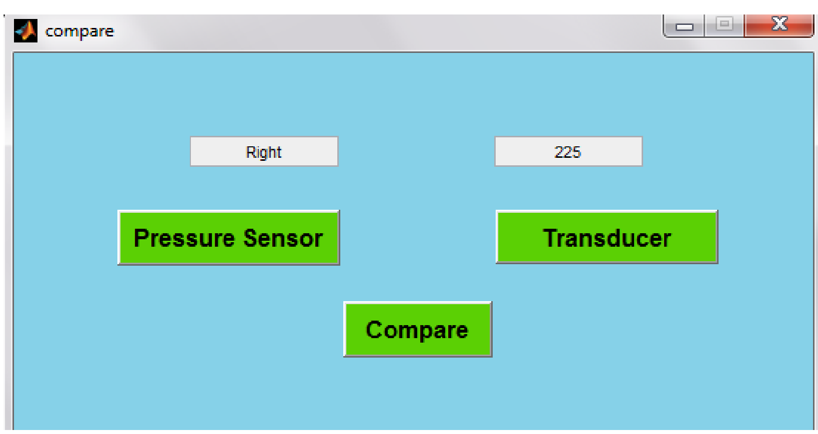
GUI Interface

The following steps were taken to process the raw data collected by the load cell. The load cell file first needed to be opened through Microsoft Excel in order for the GUI to read the data. The GUI output file was saved as a gait cycle Excel file. Various calculations were needed to convert the raw load cell data from the GUI to values in the correct SI units. The average time needed to analyze one trial from loading into the GUI to the export of gait analysis in Excel format without the necessary conversion factors was approximately 20 to 30 minutes. Subjects 1 and 2 had 25 trials altogether, with a minimum estimated processing time of 500 minutes.

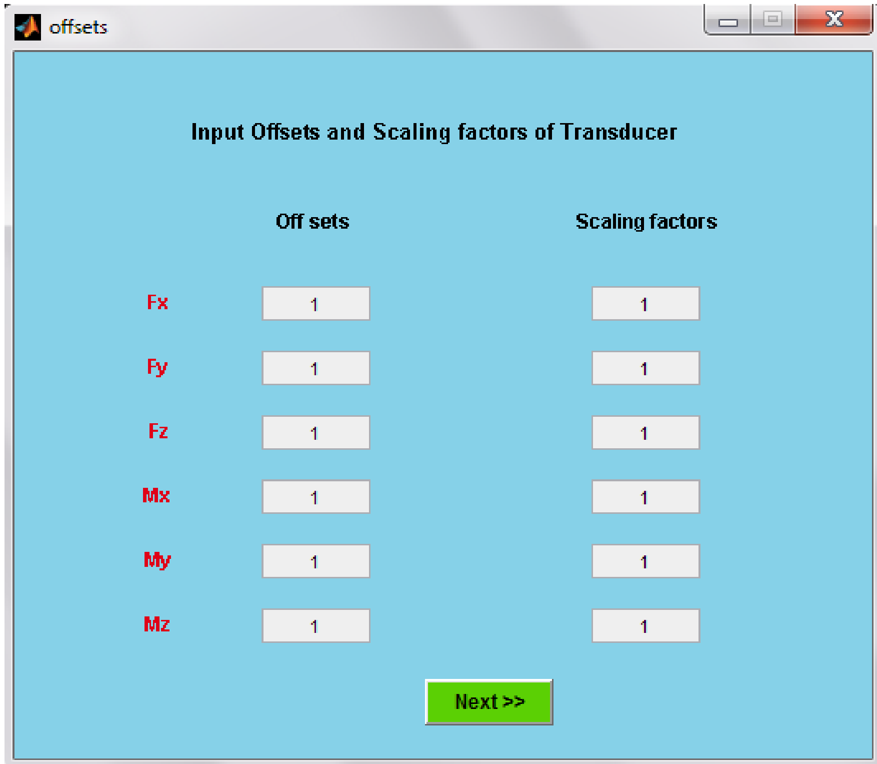
1. Installation and Initialization of GUI. Folder is created after clicking "Next"



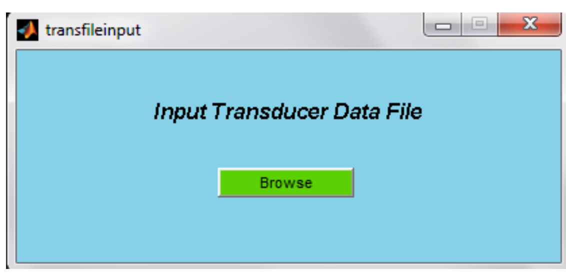
2. Enter foot to be analyzed and weight of subject in pounds



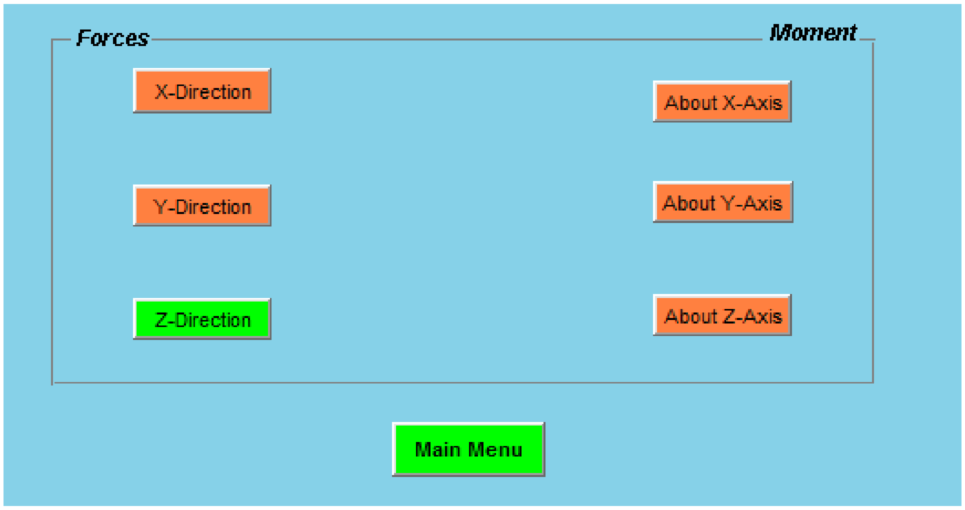
3. Input the offsets and scaling factors. In this experiment, all were 1.



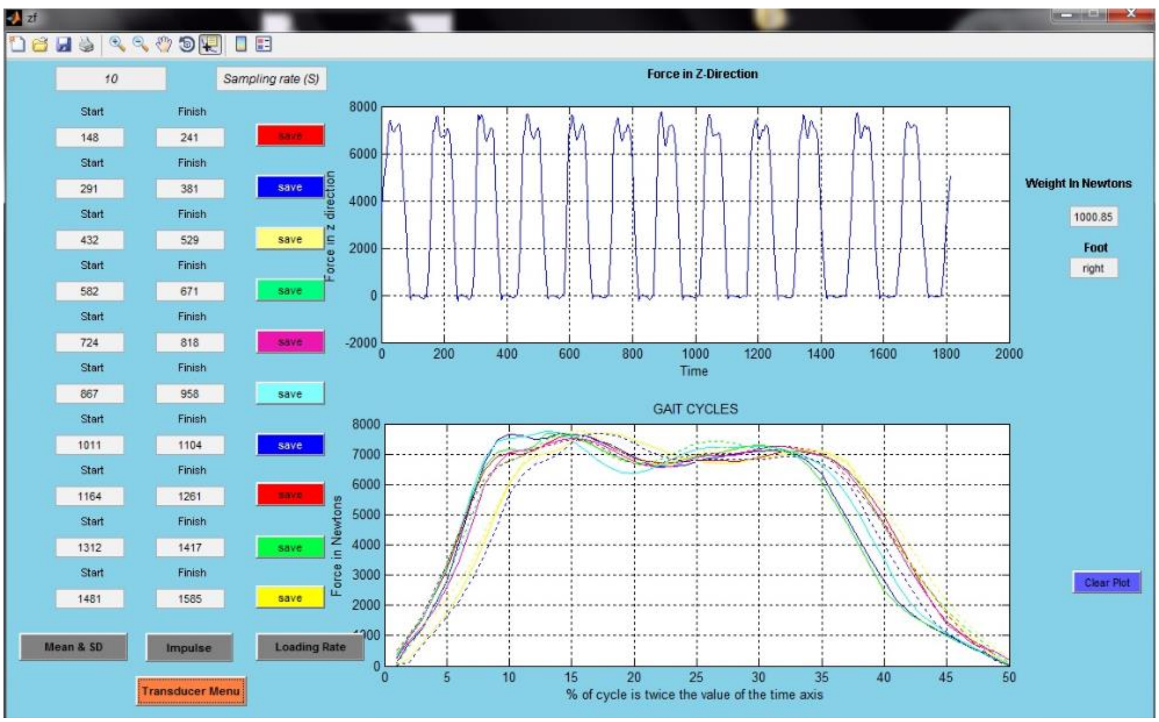
4. Select the load cell Excel file to be analyzed. Must be in the same folder as the GUI initialization application.



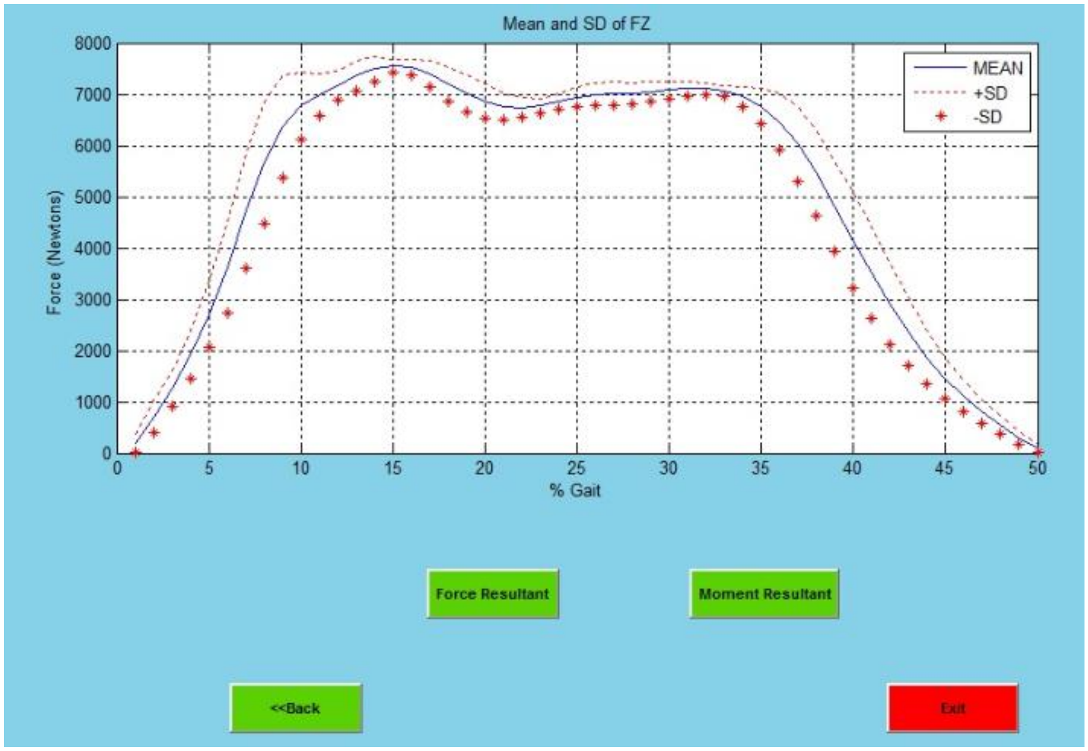
5. The forces in the Z-direction must be analyzed first



6. Input the coordinates for steps to be analyzed. The zoom function can be used to select the positive starting and ending points of the gait cycle. Exclusion of any non-representative steps either in the beginning, middle, or end of the trial may be necessary to produce accurate results.

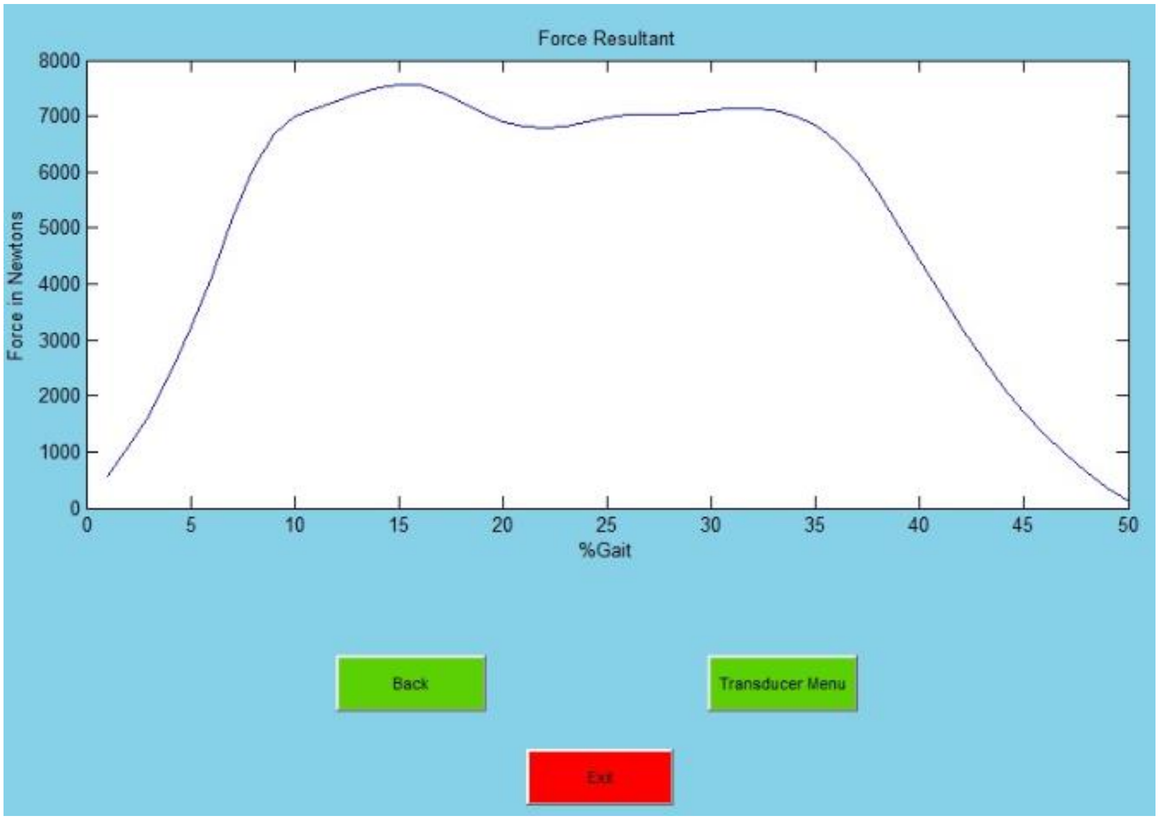


7. Select “Mean & SD.” The following plots are produced:

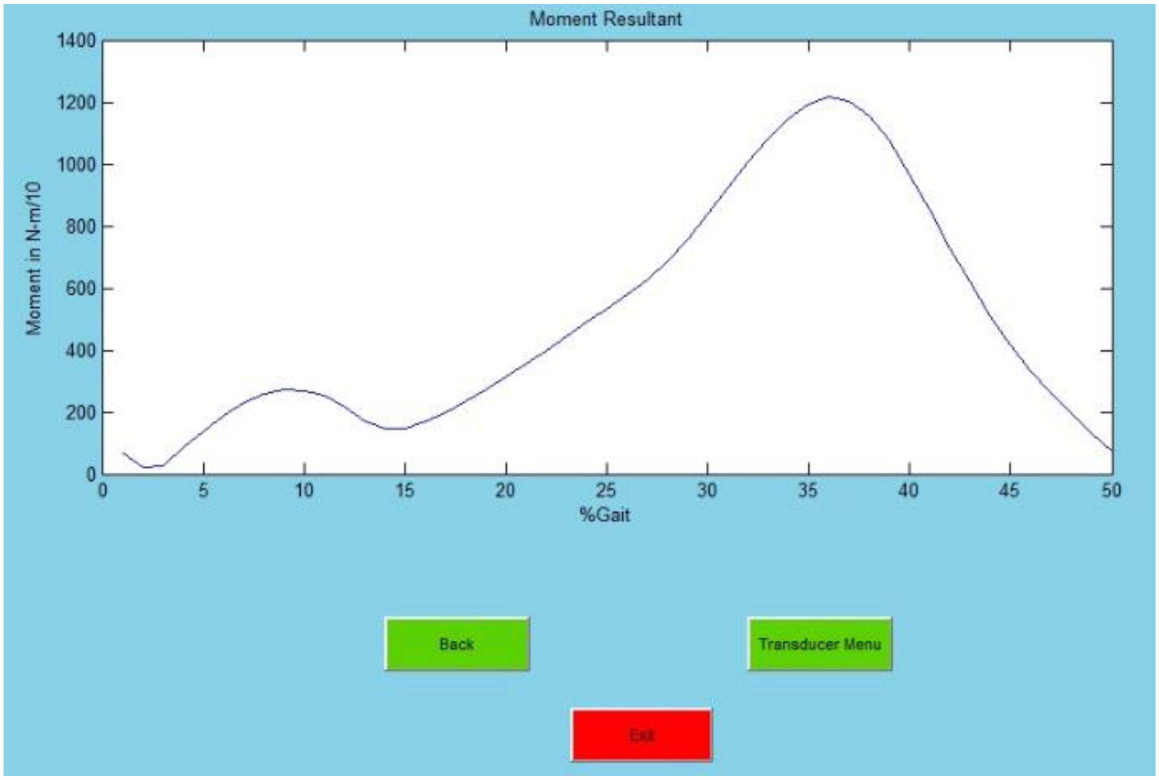


8. Close the window by pressing "Back." The window in step 6 is restored. Go back to "Transducer Menu" and all forces and moments will be green. Select forces in the X-direction and follow steps 6 and 7. Do the same for forces in the Y-direction.

9. After analyzing forces, mean and SD in the Y-direction as well, select "Force Resultant." This analyzes the resultant of the three forces and produces a resultant curve and resultant angles. Only the curve is necessary for experimental analysis.



10. Close by pressing “Back.” If “Transducer Menu” or “Exit” are pressed, the program will shut down and processing must start over.
11. Repeat steps 6 – 10 for the moments about the X, Y, and Z-axes. Produce the moment resultant plot.



12. Close by pressing “Back.” Go back to the beginning and exit at the very end.

13. Three files are produced inside the folder:

    a. Gait cycles

    b. Transducer Data in Newtons

    c. Transducer Rawdata

14. “Gait cycles” will be used for the analysis portion of the experiment.

APPENDIX B

K Level Definitions

K-levels are defined by Medicare based on an individual's ability or potential to ambulate and navigate their environment. Once it is determined in which K-level an individual resides, it can be determined which prosthetic components are covered by Medicare (8).

K-Level	Description	Foot/Ankle Assemblies	Knee Units
K0	This patient does not have the ability or potential to ambulate or transfer safely with or without assistance and a prosthesis does not enhance their quality of life or mobility.	Not eligible for prosthesis	Not eligible for prosthesis
K1	This patient has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence - a typical limited or unlimited household ambulator.	External keel, SACH feet or single axis ankle/feet	Single-axis, constant friction knee
K2	This patient has the ability or potential for ambulation with the ability to traverse low-level environmental barriers such as curbs, stairs, or uneven surfaces - a typical community ambulator.	Flexible-keel feet and multi-axial ankle/feet	Single-axis, constant friction knee
K3	The patient has the ability or potential for ambulation with variable cadence - a typical community ambulator with the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic use beyond simple locomotion.	Flex foot and flex-walk systems, energy storing feet, multi-axial ankle/feet, or dynamic response feet	Fluid and pneumatic control knees
K4	The patient has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels - typical of the prosthetic demands of the child, active adult, or athlete.	Any ankle foot system appropriate	Any ankle knee system appropriate

APPENDIX C

Statistical Analysis

The following tables were produced when examining the statistical significance of the forces and moments produced for S1 and S2 in the pin and vacuum socket. The interval was chosen based on the percent of stance which produced the maximum force or moment resultant. The percent of stance is equal to twice the interval minus one. The t-test compared the final column displaying the resultant force or moment in Newtons or Newton-meters of the pin and vacuum sockets.

Subject 1

1st max	inverval 11						
pin Fx	**lb**	**pin Fy**	**lb**	**pin Fz**	**lb**	**resultant (lb)**	**resultant (N)**
1781.00	27.18	-624.00	-9.52	7551.50	230.45	232.25	1033.08
885.00	13.50	93.50	1.43	8101.00	247.22	247.60	1101.36
-46.00	-0.70	502.50	7.67	8101.00	247.22	247.34	1100.24
353.00	5.39	436.50	6.66	7978.00	243.47	243.62	1083.67
874.00	13.34	372.00	5.68	7492.00	228.64	229.10	1019.07
1739.50	26.54	-602.50	-9.19	7987.00	243.74	245.36	1091.40
-63.50	-0.97	380.50	5.81	8119.00	247.77	247.84	1102.46
1837.50	28.04	-293.00	-4.47	7487.50	228.50	230.26	1024.24
1388.50	21.19	-212.50	-3.24	6793.50	207.32	208.43	927.13

Table C.1 Subject 1 Pin Force Resultant First Maximum [9 Steps]

1st max	interval 15						
vacuum Fx	**lb**	**vacuum Fy**	**lb**	**vacuum Fz**	**lb**	**resultant (lb)**	**resultant (N)**
-2092.00	-31.92	1329.50	20.29	7026.50	214.43	217.74	968.56
-2407.00	-36.73	1430.50	21.83	7419.00	226.41	230.41	1024.90
-2543.50	-38.81	1444.50	22.04	7205.00	219.88	224.36	998.02
-2701.00	-41.21	1591.50	24.28	7408.00	226.07	231.08	1027.89
-2494.50	-38.06	1601.50	24.44	7416.50	226.33	230.81	1026.69
-2011.00	-30.69	1456.00	22.22	7127.00	217.50	220.77	982.05
-2483.00	-37.89	1507.00	22.99	7454.50	227.49	231.77	1030.96
-2599.00	-39.66	1541.00	23.51	7562.00	230.77	235.33	1046.82
-2924.50	-44.62	1357.00	20.71	7625.50	232.71	237.85	1058.03

Table C.2 Subject 1 Vacuum Force Resultant First Maximum [9 Steps]

2nd max	inverval 30						
pin Fx	lb	pin Fy	lb	pin Fz	lb	resultant (lb)	resultant (N)
-600.00	-9.16	265.50	4.05	7047.00	215.06	215.29	957.66
-870.00	-13.28	367.00	5.60	7238.50	220.90	221.37	984.71
-1290.50	-19.69	308.50	4.71	7093.00	216.46	217.41	967.07
-903.00	-13.78	323.50	4.94	7305.00	222.93	223.41	993.78
-666.50	-10.17	657.00	10.03	7238.50	220.90	221.36	984.67
12.50	0.19	232.00	3.54	7012.00	213.99	214.02	952.00
-1064.00	-16.24	238.00	3.63	6965.00	212.55	213.21	948.38
-321.00	-4.90	142.50	2.17	7180.00	219.12	219.18	974.97
-603.00	-9.20	661.00	10.09	6691.50	204.21	204.66	910.39

Table C.3 Subject 1 Pin Force Resultant Second Maximum [9 Steps]

2nd max	interval 28						
vacuum Fx	lb	vacuum Fy	lb	vacuum Fz	lb	resultant (lb)	resultant (N)
-2562.00	-39.09	1533.50	23.40	7390.00	225.52	230.08	1023.45
-2037.50	-31.09	1474.50	22.50	7265.50	221.73	225.02	1000.95
-2365.50	-36.09	1483.00	22.63	7182.50	219.19	223.29	993.26
-2522.50	-38.49	1566.00	23.90	7070.00	215.76	220.46	980.67
-2291.00	-34.96	1455.00	22.20	7191.50	219.47	223.34	993.47
-2360.00	-36.01	1510.00	23.04	7300.50	222.79	226.86	1009.12
-2047.50	-31.24	1397.00	21.32	7268.50	221.82	225.02	1000.93
-2750.50	-41.97	1476.50	22.53	7068.00	215.70	220.90	982.59
-2403.00	-36.67	1349.00	20.58	7399.50	225.81	229.70	1021.74

Table C.4 Subject 1 Vacuum Force Resultant Second Maximum [9 Steps]

max	interval 34						
pin Mx	lb-in	pin My	lb-in	pin Mz	lb-in	resultant (lb-in)	resultant (N-m)
-221.75	-118.43	-1350.75	-721.38	70.30	37.54	732.00	82.70
-229.55	-122.59	-1436.25	-767.04	64.10	34.23	777.53	87.85
-214.10	-114.34	-1346.50	-719.11	66.50	35.51	729.01	82.37
-228.65	-122.11	-1372.30	-732.89	78.35	41.84	744.17	84.08
-197.30	-105.37	-1330.15	-710.38	71.30	38.08	719.16	81.25
-122.70	-65.53	-1266.25	-676.25	36.35	19.41	679.70	76.80
-174.00	-92.93	-1222.45	-652.86	59.75	31.91	660.21	74.59
-151.65	-80.99	-1170.30	-625.01	27.95	14.93	630.41	71.23
-131.50	-70.23	-1013.25	-541.13	95.65	51.08	548.06	61.92

Table C.5 Subject 1 Pin Moment Resultant Maximum [9 Steps]

max	interval 34						
vacuum Mx	lb-in	vacuum My	lb-in	vacuum Mz	lb-in	resultant (lb-in)	resultant (N-m)
-125.65	-67.10	-1407.35	-751.61	156.35	83.50	759.20	85.78
-41.85	-22.35	-1359.75	-726.18	138.60	74.02	730.29	82.51
-56.30	-30.07	-1298.45	-693.45	139.25	74.37	698.07	78.87
-60.30	-32.20	-1323.65	-706.91	154.70	82.62	712.45	80.50
-92.10	-49.19	-1322.95	-706.53	137.45	73.41	712.04	80.45
-75.95	-40.56	-1378.75	-736.33	154.25	82.38	742.04	83.84
-52.45	-28.01	-1308.10	-698.60	135.60	72.42	702.90	79.42
-106.70	-56.98	-1371.20	-732.30	138.45	73.94	738.23	83.41
-40.50	-21.63	-1211.90	-647.22	135.55	72.39	651.62	73.62

C.6 Subject 1 Vacuum Moment Resultant Maximum [9 Steps]

The following table summarizes the T-test values for the three maxima:

S1	t-test probability
Force Resultant 1st Max	0.133
Force Resultant 2nd Max	0.00246
Moment Resultant Max	0.347

Table 4.4.1.1 Subject 1 Pin and Vacuum Resultant T-test Values

Subject 2

1st max	interval 12						
pin Fx	lb	pin Fy	lb	pin Fz	lb	resultant (lb)	resultant (N)
840.00	12.82	1144.50	17.46	6861.00	209.38	210.50	936.34
287.50	4.39	1336.00	20.39	6706.50	204.67	205.73	915.11
232.00	3.54	1287.00	19.64	6558.00	200.13	201.13	894.66
382.50	5.84	1248.50	19.05	6371.50	194.44	195.46	869.45
744.00	11.35	1280.50	19.54	6624.50	202.16	203.42	904.87
585.00	8.93	1191.50	18.18	6439.50	196.52	197.56	878.79
728.00	11.11	1087.50	16.59	6246.50	190.63	191.67	852.60
729.00	11.12	1035.00	15.79	5877.50	179.37	180.40	802.48

Table C.7 Subject 2 Pin Force Resultant First Maximum [8 Steps]

1st max	interval 8						
vacuum Fx	lb	vacuum Fy	lb	vacuum Fz	lb	resultant (lb)	resultant (N)
1252.00	19.10	450.50	6.87	6939.50	211.78	212.75	946.35
1311.00	20.00	1608.50	24.54	6811.00	207.86	210.25	935.25
1039.50	15.86	1209.00	18.45	6589.00	201.08	202.55	900.97
1401.50	21.39	849.00	12.95	7003.00	213.71	215.17	957.13
1547.00	23.61	488.50	7.45	6578.00	200.74	202.27	899.72
1427.50	21.78	234.00	3.57	6307.50	192.49	193.75	861.85
1275.00	19.45	296.50	4.52	6799.00	207.49	208.45	927.22
1108.50	16.91	918.50	14.02	5900.50	180.07	181.40	806.92

Table C.8 Subject 2 Vacuum Force Resultant First Maximum [8 Steps]

2nd max	interval 34						
pin Fx	lb	pin Fy	lb	pin Fz	lb	resultant (lb)	resultant (N)
-2053.50	-31.33	745.00	11.37	5878.50	179.40	182.47	811.66
-2483.50	-37.90	970.50	14.81	6266.50	191.24	195.52	869.71
-2496.00	-38.09	817.00	12.47	5910.00	180.36	184.76	821.84
-2482.00	-37.87	1083.50	16.53	6235.00	190.28	194.71	866.12
-2378.00	-36.29	866.00	13.21	6179.00	188.57	192.48	856.20
-2322.00	-35.43	884.00	13.49	5940.00	181.27	185.20	823.79
-2365.00	-36.09	1026.00	15.66	6154.00	187.81	191.88	853.53
-2069.00	-31.57	996.00	15.20	5701.00	173.98	177.47	789.44

Table C.9 Subject 2 Pin Force Resultant Second Maximum [8 Steps]

2nd max	interval 33						
vacuum Fx	lb	vacuum Fy	lb	vacuum Fz	lb	resultant (lb)	resultant (N)
-2140.00	-32.65	1070.00	16.33	5933.00	181.06	184.70	821.61
-2227.00	-33.98	1298.00	19.81	6012.00	183.47	187.64	834.67
-2361.00	-36.03	1201.00	18.33	6274.00	191.47	195.69	870.46
-2050.00	-31.28	1102.00	16.82	6165.00	188.14	191.46	851.67
-2156.00	-32.90	1060.00	16.17	6106.00	186.34	189.91	844.77
-2035.00	-31.05	1033.00	15.76	6230.00	190.12	193.29	859.78
-1737.00	-26.50	1344.00	20.51	6240.50	190.44	193.37	860.16
-635.50	-9.70	1395.00	21.29	6666.50	203.45	204.79	910.93

Table C.10 Subject 2 Vacuum Force Resultant Second Maximum [8 Steps]

max	interval 36						
pin Mx	lb-in	pin My	lb-in	pin Mz	lb-in	resultant (lb-in)	resultant (N-m)
245.35	13.10	-946.75	-50.56	93.80	5.01	52.47	5.93
282.60	15.09	-967.70	-51.68	133.60	7.14	54.31	6.14
243.70	13.01	-968.10	-51.70	123.60	6.60	53.72	6.07
294.50	15.73	-983.40	-52.52	130.60	6.97	55.27	6.24
278.30	14.86	-1005.00	-53.67	110.20	5.89	56.00	6.33
282.90	15.11	-923.30	-49.31	126.00	6.73	52.01	5.88
292.90	15.64	-951.70	-50.83	136.95	7.31	53.68	6.06
236.60	12.64	-764.80	-40.84	122.10	6.52	43.25	4.89

Table C.11 Subject 2 Pin Moment Resultant Maximum [8 Steps]

max	interval 36						
vacuum Mx	lb-in	vacuum My	lb-in	vacuum Mz	lb-in	resultant (lb-in)	resultant (N-m)
305.00	16.29	-1030.50	-55.03	141.60	7.56	57.89	6.54
285.10	15.23	-1027.20	-54.86	181.40	9.69	57.75	6.52
280.00	14.95	-1046.70	-55.90	195.80	10.46	58.80	6.64
294.60	15.73	-990.50	-52.90	139.60	7.46	55.69	6.29
290.90	15.54	-1034.40	-55.24	158.20	8.45	58.00	6.55
272.20	14.54	-995.20	-53.15	160.40	8.57	55.76	6.30
343.45	18.34	-974.85	-52.06	162.85	8.70	55.88	6.31
292.30	15.61	-742.90	-39.68	112.40	6.00	43.06	4.86

Table 4.4.2.6 Subject 2 Vacuum Moment Resultant Maximum [8 Steps]

The following table summarizes the T-test values for the three maxima:

S2	t-test probability
Force Resultant 1st Max	0.341
Force Resultant 2nd Max	0.169
Moment Resultant Max	0.249

Table 4.4.2.1 Subject 2 Pin and Vacuum Resultant T-test Values