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The Effect of Socket Tightness in Femur Stability in a HiFi Socket

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THE EFFECT OF SOCKET TIGHTNESS IN FEMUR STABILITY IN A HIFI SOCKET

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School of Medicine & Health Sciences

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Doctor of Physical Therapy

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This Scholarly Project, submitted by Mary Bachman, Alicia, Beckel, and Amanda Belyaks in partial fulfillment of the requirements for the Degree of Doctor of Physical Therapy from the University of North Dakota, has been read by the Advisor and Chairperson of Physical Therapy under whom the work has been done and is hereby approved.

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Title
THE EFFECT OF SOCKET TIGHTNESS IN FEMUR STABILITY IN A HIFI SOCKET

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Signature: Clara Kumar

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Date: 12/10/2017
# TABLE OF CONTENTS

LIST OF FIGURES ............................................................................................................................................ vi

LIST OF TABLES ................................................................................................................................................ vii

ACKNOWLEDGEMENTS ........................................................................................................................................ viii

ABSTRACT ............................................................................................................................................................. ix

CHAPTER I Background and Purpose .................................................................................................................. 1
  I. Gait of Persons with Amputations ..................................................................................................................... 3
  II. High Fidelity Socket ........................................................................................................................................... 5
  III. Subject Demographics ..................................................................................................................................... 7

CHAPTER II Methods .............................................................................................................................................. 9
  I. Subjects ............................................................................................................................................................... 9
  II. Informed Consent .............................................................................................................................................. 9
  III. Measurements/Instruments ............................................................................................................................. 10
    A. Vicon ............................................................................................................................................................ 10
    B. HiFi Socket .................................................................................................................................................. 11
    C. Marker Placement ....................................................................................................................................... 11
    D. Data Analysis ............................................................................................................................................... 13

CHAPTER III Results .............................................................................................................................................. 15

CHAPTER IV Discussion and Conclusions ............................................................................................................. 20
  I. Limitations ....................................................................................................................................................... 21
  II. Future Research .............................................................................................................................................. 22
  III. Biases ............................................................................................................................................................. 22
  IV. Conclusion ...................................................................................................................................................... 22
LIST OF FIGURES

Figure 1. Examples of trans-femoral sockets ............................................................. 5
Figure 2. HiFi socket system .................................................................................. 6
Figure 3. Marker placement ............................................................................... 12
Figure 4. Mathematical calculations used for data analysis ........................................... 14
Figure 5. Marker numbering and data set numbering ................................................... 15
Figure 6. Averages from data set 1 and 2 ................................................................. 17
Figure 7. Averages from data sets 3-7 ................................................................... 17
Figure 8. Average distances (in millimeters) for set 8.................................................... 18
Figure 9. Average distances (in millimeters) for set 9................................................. 19
Figure 10. Average distances (in millimeters) for set 10............................................... 19
Figure 11. Average distances (in millimeters) for set 11............................................... 19
LIST OF TABLES

Table 1. Data collection .................................................................12
Table 2. Data set and motions measured ........................................16
Table 3. Average heights for marker points in relation to the ground ........18
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ABSTRACT

Background and Purpose: The introduction of the High-Fidelity (HiFi) interface was developed to help increase the intimacy of the prosthetic interface by using a series of alternating zones of tissue compression and release. The purpose of this study was to utilize motion analysis to measure the stability of the femur in individuals with trans-femoral amputation that utilize the HiFi socket for ambulation.

Methods: The subject was a 62 year old Caucasian female. She had a trans-femoral amputation 35 years prior due to a diagnosis of cancer located in the bone of her femur. Data collection was done with the Vicon motion analysis system. The Vicon system utilizes reflective anatomical markers, which were placed at the junction of the HiFi Prosthetic Socket and at other significant anatomical landmarks, to allow the Vicon system to track and quantify the motion of these markers. Nine walking trials were completed utilizing each of the three pressure conditions, low tightness, medium tightness, high tightness, for a total of twenty eight walking trials for the participant.

Results: Data was gathered through analysis of the peaks and valleys representing movement collected by the Vicon system, and trigonometry was used to interpret the results and movement in a three-dimensional space. The results demonstrated that increasing HiFi socket tightness, increases femur stability, and decreases movement of the femur on the prosthetic for this subject.
Discussion/Conclusion: The results of this study suggest that increased stability and tightness of the socket around the femur are advantages provided by the HiFi socket to improve gait mechanics and requires less compensation than a looser fitted socket, but further research is needed.
CHAPTER I

BACKGROUND AND PURPOSE

Normal gait can be interrupted by many different pathologies including amputation. Prosthetic devices have been used over many years to help people with amputations maintain their quality of life and independence in ambulation. The earliest report of the use of a prosthesis is in the Rig-Veda period between 3500-1800 BC. Since then, many advances have been made to make prosthetic devices more similar to normal functioning body parts. Trans-femoral prosthetics have focused on knee function during stance and swing phases of gait. The 1990s had the introduction of the rotary hydraulic knee which offered a load dependent hydraulic stance stability and hydraulic swing phase mechanism. The introduction of computers and microprocessor knees has allowed for more energy efficient gait velocities in people with amputations. The development of the C-leg by Otto Bock provided a variable hydraulic stance phase control with multiple sensors to adjust the knee to the desired gait velocity. For more proximal levels of amputations or bilateral amputations, the introduction of custom-made sockets and frames which allow heat and air to pass through allowed for independent motion of the corset within the frame and accommodated for volume fluctuation and contour change. The creation of internal suction sockets allowed the elimination of external strapping systems. While the internal suction sockets allowed for a less bulky prosthetic and reduction in the amount of piston action, some weaknesses to the suction socket included limited space, additional weight, disproportionate distal residual limb shrinkage, and increased complexity.¹
In order to know what a deviation from normal gait is, examination of normal gait needs to be done. Perry's list of priorities of normal gait include:

1. Stability of the weight bearing limb throughout the stance phase
2. Clearance of the non-weight bearing foot during the swing phase
3. Appropriate prepositioning (during terminal swing) of the foot for the next gait cycle
4. Adequate step length

Proper alignment of the weight bearing lower extremities reduces the chance of strain and injury by reducing joint friction and tension, it improves the stability of the weight-bearing limb and the balance of the trunk and proper alignment reduces excess energy expenditure. Gait is the displacement of body weight in a wanted direction, using coordinated movement between the trunk, the extremities and the muscles that control or initiate these motions. Any pathology that alters proper alignment may result in a disturbance of the normal gait pattern. The results from a meta-analysis, of gait mechanics in young and older adults, support the suggestion that gait deviation can contribute to a decline in mobility, energy expenditure and performance of activities of daily living. Reduced mobility is an independent risk factor for morbidity, disability, and mortality.

Energy efficiency in the gait of patients with trans-femoral amputations is thought to vary depending on the level of amputation and the orientation of the residual bone. A study done by Bell et al compared residual limb length and orientation in patients and hypothesized that in patients with a shorter residual limb and/or a more abnormal the residual limb would have a higher energy efficiency requirement. An abnormal limb was qualified as one that was lacking musculature and had misoriented lever arms. Patients with longer residual limbs walked 0.17 m/s
faster for their self-selected walking velocity in this study however, the angle of abduction and the other metabolic variable tested showed no statistically significant findings.

Another study done by Waters et al.,\textsuperscript{5} compared and analyzed gait of patients with varying levels of amputations with both vascular and traumatic amputations. Patients with trans-femoral amputations due to vascular problems had a slower velocity, cadence, and stride length than the patients with a traumatic trans-femoral amputation. Interestingly the patients used approximately the same rate of oxygen uptake (12.6ml/kg-min for vascular and 12.9ml/kg-min for traumatic). Also calculated in this study was the relative energy cost and it was stated to be a mean of 38 percent for the control subjects however this does vary with age. Patients with a vascular trans-femoral amputation required a relative energy cost of 63 percent indicating they are working 25 percent harder than their cohort. Patients with a traumatic trans-femoral amputation had a relative energy cost of 37 percent which is approximately the same as for controls in their cohort. Overall, energy efficiency varies depending on the type of injury and may be influenced by the length of the residual limb.

Gait of Persons with Amputations

The gait of a person with an amputation can vary across the spectrum. Gait mechanics can vary based on a number of things such as cause of amputation, the amount of years without the limb, and the length of the residual limb. While great strides in prosthetic research have been made, the analysis of gait in a patient with a trans-femoral amputation has not been well researched.

With all of the therapy and training a person with an amputation goes through in order to properly walk with a prosthesis, there are still some common compensations that are seen in
patients with trans-femoral amputations. O'Sullivan\(^6\) states some common adaptations used by patients with trans-femoral amputations and also differentiates between a prosthetic or anatomical cause. The most commonly seen adaptations of patients with trans-femoral amputations are abduction of the residual limb in stance or swing phase, lateral trunk shift towards the affected side, and uneven step length. Anatomically the abduction can be because of a contracture, weak abductors, instability, or pain. The prosthetic cause of this gait could be a long prostheses, inadequate lateral wall adduction, sharp or high medial wall, small socket, or a loose socket. A lateral trunk lean anatomically can come from abduction contractures, weak abductors, hip pain, instability, or a short amputation limb. Prosthetic issues such as inadequate lateral wall adduction, a sharp, or high medial wall can cause a lateral trunk lean as well. A study done by Devan et al\(^7\) looked at movement of the lumbar spine and hip joint in those with amputations versus their intact leg and also normal control subjects. The researchers found an increased transverse plane motion and increased lumbar extension in those with amputations compared to the control group. The hip showed limited extension during heel strike when compared to the intact leg.

The reason for gait adaptations can be from kinematic issues, prosthetic fit or even pain. Fatone et al\(^8\) states in their research that gait adaptations are used to minimize discomfort a patient feels with ambulation. Both the intact limb and the residual limb can have different movement patterns leading to asymmetry\(^8\). This asymmetry can cause abnormal tissue loading and deformations in some of the musculoskeletal structures.\(^7\) Along with abnormal loading, patients that have a poor prosthetic fit can have gait compensations. According to Fatone et al\(^8\), when a socket moves laterally to a residual limb it can create impingement of the soft tissue of the medial leg causing the person discomfort. The bone end can also come in contact with the
wall of the socket during ambulation which can cause pain. Pain cannot only affect how a person
ambulates but can also increase the amount of energy that is required to ambulate.

High Fidelity Socket

A few decades ago there was a shift in trans-femoral interface design from quadrilateral
trans-femoral socket to ischial containment sockets allowing for improved function, such as
improved comfort and increased range of motion. From there, ischial containment sockets have
begun to move towards a brimless design at the turn of the millennium further increasing range
of motion and comfort.

Figure 1. Examples of trans-femoral sockets

Examples of transfemoral sockets: (a) Ischial Containment and (b) Sub-ischial.
The more recent innovations have focused on user controlled adjustment systems and tissue compression and release method of indirect-skeletal prosthetic anchoring. The introduction of the High-Fidelity (HiFi) interface was brought about to help increase the intimacy of the prosthetic interface by using a series of alternating zones of tissue compression and release. Unlike traditional socket designs that focus on tissue containment and uniform tissue loading, the HiFi uses selective loading of pressure-tolerant areas.

The HiFi began as an upper-limb application but now is used regularly with persons with trans-femoral and knee-disarticulation amputations along with most recently, trans-tibial amputations. By using indirect skeletal anchoring, the HiFi allows for benefits such as increased proprioception, or osseoperception, which is caused by vibrations sent through soft tissue to the skeletal system improving proprioceptor and mechanoreceptor activity.
A study from 2017 compared the ischial containment socket to the HiFi socket for people with trans-femoral amputations using gait analysis and found that the HiFi socket presents some biomechanical advantages compared to the ischial containment socket. The HiFi allows for reduced trimlines allowing for increased comfort with sitting, improved hip range of motion, and improved function. The HiFi is also reported to increase prosthetic control and balance due to increased adduction angle of the femur. These results were determined through 3D motion analysis using the Vicon system and the Oswestry v2.0.\textsuperscript{10}

Subject Demographics

There’s an estimated 185,000 amputations of upper and lower limbs each year in the United States. The last NHIS survey completed in 1996 stated there were 1.2 million people living with the loss of a limb. In 2005, it was estimated that number was 1.6 million people. Of the etiological cause of the limb loss, 56% were due to dysvascular disease, with two thirds of those from diabetes. Forty five% was due to trauma, and the remaining less than 2% due to cancer. Forty two% of those living with loss of limb are 65 or older. Sixty five% are men and 42% are nonwhite. Sixty five% of those with loss of limb are lower limb amputations.\textsuperscript{11}

The subject for this study was a 62 year old Caucasian female. She had a trans-femoral amputation 35 years prior due to a diagnosis of cancer located in the bone of her femur. She has been ambulating with an ischial containment socket however for data collection she utilized a HiFi socket designed for her by the prosthetist.

Purpose

The purpose of this study was to utilize motion analysis to measure the stability of the femur in individuals with trans-femoral amputation that utilize the HiFi socket for ambulation.
The researchers hypothesized that the higher the pressure within the HiFi containment socket there will be increased stability of the femur. Better control of the femur has the potential to provide for improved efficiency of gait and a decrease in energy expenditure. The results will be beneficial to the health care providers (i.e. prosthethists, physical therapists, even surgeons) to be able to best inform patients in the future on the benefit (or lack of benefit, depending on the results) of the use of the HiFi socket. For the research participants, the personal benefit will be less, it will be in a 'pay it forward' manner. The knowledge gained from the study will benefit people in the future that wear this type of prosthesis.
CHAPTER II

METHODS

The following chapter includes information on how this study was organized and carried out and it includes: information on the subject and how she was recruited, informed consent, and measurements and instruments used.

Subjects

The subject was recruited by a local prosthetist, who currently works with the patient population and was willing to participate in the study. The subject completed a one-time 45-60 minute obligation. The University of North Dakota researchers did not meet the subject until the day of the study. Inclusion criteria include: subject older than 18 years of age, an individual with a trans-femoral amputation, and able to wear any trans-femoral socket and is functional in ambulation. Exclusion criteria included subjects that do not have a trans-femoral amputation, cannot ambulate more than 10 meters, and under 18 years of age. For data collection, the participant wore a HiFi socket.

Informed Consent

Prior to data collection, the research participant was asked to read and sign the informed consent form (see Appendix B). This indicated that she understood the study and its purpose. She was given a copy of the consent form to take with her, for use if there were further questions or concerns. Data collected was not linked to the consent forms; all data was reported in aggregate. The subject was labeled as “subject one” for data collection and for identity protection. Results
and consent forms are kept in a locked, storage area in the Department of Physical Therapy at the University of North Dakota. Records from the study will be destroyed using a paper shredder three years following the conclusion of this study. Participants and researchers were not compensated for this study.

Measurements and Instruments

Vicon Motion Analysis System

Data collection was done with the Vicon motion analysis system with the assistance of a professor with a PhD in pedagogical kinesiology and a master's degree in biomechanics. The Vicon system utilizes reflective anatomical markers which allow the Vicon system to track and quantify the motion of these markers. The participant had these markers placed at the junction of the HiFi Prosthetic Socket and the participant's upper hip as well as other significant anatomical landmarks as described in the marker placement section further on in this paper. The Vicon internally stores data from ten, wall mounted infrared cameras which is stored on a centrally located, password protected computer. Digital data will be disposed of after a period of five years via deletion, followed by overwrite.

To calibrate the Vicon system, reflective markers were moved about the area where the cameras capture data until 5,000 frames were collected on each camera. The center frame origin was then set by placing reflective markers at the center of the data field. Patient calibration was done with static frame at the center of the data collection field prior to walking trials. The Vicon capture system has a positioning error slightly larger than 1 mm positioning variability is less than 1.5 mm. Accuracy is expected to be around 1 mm given reference. A study found the mean error to be between 0.15 to 0.58 mm with a standard deviation of 0.05 to 0.46 mm. Faster displacements (movement of the markers versus static) were found to lead to lower errors.12
HiFi Socket Tightness

Nine walking trials were completed utilizing each of the three pressure conditions, low tightness, medium tightness, high tightness, for a total of twenty eight walking trials for the participant. Medium tightness for this study was defined as a normal, comfortable pressure for the participant. The participant then loosened the HiFi socket by releasing the pressure of the socket and then tightened it to below the level of her medium tightness but tight enough that she could still ambulate safely. For the third set of trials the patient tightened the socket to a pressure that is above her medium tightness but not at a level of pain. The risk was minimal for the participant as she was walking in a clear, even, unobstructed path in the laboratory. The amount of walking required for the study was 180 meters; 6 meters per trial.

Marker Placement

A series of reflective markers were placed on the participant at the junction of the HiFi Prosthetic Socket and the participant’s upper hip. This allowed for kinematic data relating to the prosthetic junction to be collected by the Vicon system. Markers one through three provided data on anterior and posterior movement of the femur in relation to prosthesis. Markers four through six yielded data on lateral and medial movement of the femur in relation to the prosthesis. The final markers, six through twelve, gave values on rotation movement of the femur in relation of the prosthetic. Markers were placed as shown in Figure 3 and described in Table 1.
Above-Knee Amputation

Figure 3. Marker placement.

Table 1. Marker placement

<table>
<thead>
<tr>
<th>Marker Number</th>
<th>Placement</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Anterior Femur in line with Greater Trochanter</td>
</tr>
<tr>
<td>2</td>
<td>Anterior Femur placed on prosthetic where bone ends</td>
</tr>
<tr>
<td>3</td>
<td>Anterior knee joint on prosthetic in line with anterior femur</td>
</tr>
<tr>
<td>4</td>
<td>Lateral knee joint on prosthetic in line with lateral femur</td>
</tr>
<tr>
<td>5</td>
<td>Lateral Femur placed on prosthetic where bone ends</td>
</tr>
<tr>
<td>6</td>
<td>Greater Trochanter on lateral femur</td>
</tr>
<tr>
<td>7</td>
<td>Posterolateral thigh above rim of prosthetic</td>
</tr>
<tr>
<td>8</td>
<td>Posterolateral thigh below rim of prosthetic</td>
</tr>
<tr>
<td>9</td>
<td>Anterolateral thigh above rim of prosthetic</td>
</tr>
<tr>
<td>10</td>
<td>Anterolateral thigh below rim of prosthetic</td>
</tr>
<tr>
<td>11</td>
<td>Anteromedial thigh above rim of prosthetic</td>
</tr>
<tr>
<td>12</td>
<td>Anteromedial thigh below rim of prosthetic</td>
</tr>
</tbody>
</table>
Data Analysis

Results were derived from the distance between markers and angle between markers. Data for each trial was taken from the markers at a peak and at the valley of a step. Numbers given at the two peaks and valleys were used for each set to represent two steps. To quantify the differences between the two points seen in the peaks and valley, calculations were done. Because the two markers exist in 3D space, calculations were done to represent a 3D environment rather than a 2D space usually used in trigonometry. This was done by calculating the distances of a 3D triangle using the 2 markers. The equations for part one are seen in figure 4. Part one consists of correcting the points in a 3D space by calculating the Hypotenuse of the blue triangle seen in figure 4. This helps capture volume. The rest of the equations in part one subtracts the X’s and Y’s for points A and B to provide the distance of ADJ II and OPP II. These distances allow us to calculate HYP II using the Pythagorean Theorem. From finding HYP II, ADJ I is also found. The second part of the equations is seen in Figure 4. Using these equations the distance of OPP I by subtracting the Z’s for points A and B is calculated. Now that OPP I and ADJ I are known, the angle point the A and B make with the horizontal plane can be calculated using the Tangent function. These equations were plugged into Excel to automatically calculate and input the numbers seen in the results section. Two values were taken for each of the nine walking trials for each of the three tightness conditions.
Figure 4. Mathematical calculations used for data analysis
CHAPTER III

RESULTS

Eleven total data sets were derived from the Vicon reflective marker placement during the walking trials. Figure 5 labels the markers used for the study and the data sets created from the markers. Table 2 states the marker points and their relationships for the data sets.

Figure 5. Marker numbering and data set numbering
Table 2. Data set and motions measured

<table>
<thead>
<tr>
<th>Data Set</th>
<th>Marker Numbers</th>
<th>Marker Relationship</th>
<th>Motion Measured</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1, 2, 3</td>
<td>The angle between</td>
<td>Sagittal Plane Flexion/Extension</td>
</tr>
<tr>
<td>2</td>
<td>4, 5, 6</td>
<td>The angle between</td>
<td>Frontal Plane Flexion/Extension</td>
</tr>
<tr>
<td>3</td>
<td>7, 8</td>
<td>The distance between</td>
<td>Prosthetic Stability Anteromedial</td>
</tr>
<tr>
<td>4</td>
<td>8, 9</td>
<td>The distance between</td>
<td>Prosthetic Rotation Around Thigh</td>
</tr>
<tr>
<td>5</td>
<td>9, 10</td>
<td>The distance between</td>
<td>Prosthetic Stability Anterolateral</td>
</tr>
<tr>
<td>6</td>
<td>10, 11</td>
<td>The distance between</td>
<td>Prosthetic Rotation Around Thigh</td>
</tr>
<tr>
<td>7</td>
<td>11, 12</td>
<td>The distance between</td>
<td>Prosthetic Stability Posterolateral</td>
</tr>
<tr>
<td>8</td>
<td>2, ground</td>
<td>The distance between</td>
<td>Prosthetic Swing Phase Height</td>
</tr>
<tr>
<td>9</td>
<td>3, ground</td>
<td>The distance between</td>
<td>Prosthetic Swing Phase Height</td>
</tr>
<tr>
<td>10</td>
<td>4, ground</td>
<td>The distance between</td>
<td>Prosthetic Swing Phase Height</td>
</tr>
<tr>
<td>11</td>
<td>5, ground</td>
<td>The distance between</td>
<td>Prosthetic Swing Phase Height</td>
</tr>
</tbody>
</table>

Data in each set was recorded for each of the 9 walking trials at each of the three socket tightness levels and then an average was found for each level to compare. Outlying data for trials were removed to allow more accurate results. The graphs in Figures 6 and 7 show the average for each data set for each of the socket tightnesses. For data set one and two (shown in Figure 6) there was no significant change in flexion and extension motion when socket tightnesses are compared. The data sets of three and seven were thrown out because they did not show a trend with increasing socket tightness.
Figure 6. Averages from Data Set 1 and 2

Figure 7. Averages from Data Sets 3-7
Data set four showed a decreasing trend for the distances between anterolateral and posterolateral thigh above the prosthetic as the socket tightness increased. The averages for data set five showed a smaller distance between markers nine and ten, anterolateral thigh above and below the prosthetic, as the socket was tightened. As socket tightness increased the distance between markers ten and eleven increased. Data sets eight, nine, ten, and eleven all show a decreasing distance of the prosthetic to the ground as the socket is tightened.

Markers two, three, four, and five were further evaluated. The height from the marker to the floor was measured in the Vicon system. Average heights for the points and standard deviations can be found on Table 3. The averages between these data points show consistency throughout the trails and show a trend of less movement as the HiFi socket tightened.

Table 3. Average heights for marker points in relation to the ground (in millimeters)

<table>
<thead>
<tr>
<th>Marker Number</th>
<th>Set Number</th>
<th>Loose</th>
<th>Comfortable</th>
<th>Tight</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>8</td>
<td>694.8</td>
<td>694.3</td>
<td>692.7</td>
</tr>
<tr>
<td>3</td>
<td>9</td>
<td>634.7</td>
<td>634.2</td>
<td>632.6</td>
</tr>
<tr>
<td>4</td>
<td>10</td>
<td>605.6</td>
<td>604.0</td>
<td>604.0</td>
</tr>
<tr>
<td>5</td>
<td>11</td>
<td>663.9</td>
<td>662.2</td>
<td>662.8</td>
</tr>
</tbody>
</table>

Figure 8. Average distances (in millimeters) for set 8
Figure 9. Average distances (in millimeters) for set 9

Figure 10. Average distances (in millimeters) for set 10

Figure 11. Average distances (in millimeters) for set 11
CHAPTER IV
DISCUSSION AND CONCLUSIONS

The researchers hypothesized that the tighter the HiFi containment socket is, there will be increased stability of the femur. By increasing the stability of the femur the amount of energy required for gait can be decreased. Decreasing the energy requirement for gait can improve function in patients with trans-femoral amputations. Finding the proper level of tightness for the socket not only could increase the efficiency of gait but could also help reduce the amount of patients with back pain, hip flexor tightness, and skin complications from a poor prosthetic fit. Our data shows that the participant needed to flex her hip more to clear the floor when the socket was looser than was comfortable for her. This repeated movement can create strain on the lower back, cause overuse injuries of the hip flexors and tighten them down and cause an asymmetric gait pattern.

The results demonstrated that increasing HiFi socket tightness, increases femur stability, and decreases movement of the femur on the prosthetic for this subject. The researchers used data sets eight through eleven to explain the trends found in data sets four, five, and six. When in swing phase the leg is hanging inward causing data sets four and five, which are markers on the lateral thigh, to lengthen and data from set 6, medial thigh markers, to shorten in distance due to pinching. For data sets eight, nine, ten, and eleven all show a decreasing distance of the prosthetic to the ground as the socket is tightened, this shows that the subject decreased the height of her step as the socket tightness increased.
Data sets seven and three were thrown out because they did not show a trend with increasing socket tightness. The markers for these data sets specifically marker seven which keep falling off and marker 12 which kept disappearing from camera sight due to its placement on the anteromedial thigh on the prosthetic. There was no significant change in flexion and extension motion, which are represented by data sets one and two. For the loose and the comfortable conditions we excluded some trials due to the data being outliers. All walking trials, for all data sets for the tight conditions were included in data extraction.

In a previous study done by Kelnow et al, the researchers analyzed biomechanical indicators of gait between a HiFi socket and Ischial Ramus Containment (IRC) socket and perceived disability using an 8-camera Vicon system. Results found that self-selected gait velocity increased significantly with the HiFi versus the IRC socket along with sound side-step length. Improved symmetry of step length, width, center of mass deviation was also noted. The researchers concluded that the HiFi socket may present some biomechanical advantages when compared to traditional IRC sockets which may allow for increased stability.

Limitations

A limitation of this study was the use of one subject rather than a larger sample size. This limits the generalizability of our results. Due to the HiFi technology being relatively new, recruiting a large amount of subjects was finite. The study was limited in there being only a small specific type of patient available in the area. The subject recruited was not a Hi-Fi socket wearer prior to the study. As the walking trials progresses the participated reported that ambulation felt “better as it got tighter”. Since she had no previous practice with the HiFi socket this could be a limitation that could have resulted in a change in biomechanics due to the socket being new rather than the socket itself. Another limitation was the lack of Vicon knowledge prior
to the beginning of this study, so there was a learning curve for the researchers. Help and guidance from the professor with a PhD in pedagogical kinesiology was given where knowledge of the system and its computerized data may have been lacking by the researchers.

Further research

Additional research with a larger population is recommended to confirm and expand upon the results of this study. More research could be done to find if tight and comfortable are the same, if there is a zone of diminishing returns, where comfortable is close to the best you can get before you have adverse effects like skin irritation.

Biases

Subject was recruited by a local prosthetist who has worked with the subject prior to this research study.

Conclusion

This current study found that increased tightness of the HiFi socket did result in less movement between markers and decreased lifting of the leg to compensate for a looser socket resulting in better biomechanics. This suggests that increased stability and tightness of the socket around the femur are advantages provided by the HiFi socket to improve gait mechanics and requires less compensation than a looser fitted socket, but further research is needed.
University of North Dakota Human Subjects Review Form
January 2015 Version

All research with human participants conducted by faculty, staff, and students associated with the University of North Dakota, must be reviewed and approved as prescribed by the University’s policies and procedures governing the use of human subjects. It is the intent of the University of North Dakota (UND), through the Institutional Review Board (IRB) and Research Development and Compliance (RD&C), to assist investigators engaged in human subject research to conduct their research along ethical guidelines reflecting professional as well as community standards. The University has an obligation to ensure that all research involving human subjects meets regulations established by the United States Code of Federal Regulations (CFR). When completing the Human Subjects Review Form, use the “IRB Checklist” for additional guidance.

Please provide the information requested below. Handwritten forms are not accepted – responses must be typed on the form.

**Principal Investigator:** Cindy Flom-Meland

- **Telephone:** 701-777-4130
- **E-mail Address:** cindy.flom.meland@med.und.edu

**Complete Mailing Address:** 1301 No. Columbia Road stop 9037, Department of PT suite 321

**School/College:** School of Medicine & Health Sciences  
**Department:** Physical Therapy

**Student Advisor (if applicable):**

- **Telephone:**
- **E-mail Address:**

**Address or Box #:**

- **School/College:**
- **Department:**

***All IRB applications must include a Key Personnel Listing.***

**Project Title:** The Effect of Socket Tightness on Femur Stability in a HiFi Socket

**Proposed Project Dates:**
- **Beginning Date:** May 2017
- **Completion Date:** December 2017
  (Including data analysis)

**Funding agencies supporting this research:**

N/A

**Did the grant proposal with the funding entity go through UND Grants & Contracts Admin.?** □ YES or □ NO

Attach a copy of the grant proposal. Do not include any budgetary information. The IRB will not be able to review the study without a copy of the grant proposal submitted to the funding agency.

- □ YES or □ NO Does any researcher associated with this project have an economic interest in the research, or act as an officer or a director of any outside entity whose financial interests would reasonably appear to be affected by the research? If yes, submit on a separate piece of paper an additional explanation of the financial interest. The Principal Investigator and any researcher associated with this project should have a Financial Interests Disclosure Document on file with their department.

- □ YES or □ NO Will any research participants be obtained from another organization outside the University of North Dakota (e.g., hospitals, schools, public agencies, American Indian tribes/reservations)?

- □ YES or □ NO Will any data be collected at or obtained from another organization outside the University of North Dakota?

If yes to either of the previous two questions, list all organizations:

Altru Health System

Revised 1/9/15
Letters from each organization must accompany this proposal. Each letter must illustrate that the organization understands its involvement and agrees to participate in the study. Letters must include the name and title of the individual signing the letter and should be printed on organizational letterhead.

Does any external site where the research will be conducted have its own IRB? ☒ YES ☐ NO ☐ N/A

If yes, does the external site plan to rely on UND’s IRB for approval of this study? ☒ YES ☐ NO ☐ N/A
(If yes, contact the UND IRB at 701 777-4279 for additional requirements)

If your project has been or will be submitted to other IRBs, list those Boards below, along with the status of each proposal.

Altru Health System Date submitted: 5-30-2017 Status: ☐ Approved ☒ Pending

Type of Project: Check “Yes” or “No” for each of the following.

☒ YES or ☐ NO New Project ☐ YES or ☒ NO Dissertation/Thesis/Independent Study
☐ YES or ☒ NO Continuation/Renewal ☒ YES or ☐ NO Student Research Project
☐ YES or ☒ NO Is this a Protocol Change for previously approved project? If yes, submit a signed Protocol Change Form, along with a signed copy of this form with the changes bolded or highlighted.
☐ YES or ☒ NO Does your project involve abstracting medical record information? If yes, complete the HIPAA Compliance Application and submit it with this form.
☐ YES or ☒ NO Does your project include Genetic Research?

Subject Classification: This study will involve subjects who are in the following special populations: Check all that apply.

☐ Children (< 18 years) ☐ UND Students ☐ Pregnant Women/Fetuses
☐ Prisoners ☐ Cognitively impaired persons or persons unable to consent
☐ Other ☐ Other

Please use appropriate checklist when children, prisoners, pregnant women, or people who are unable to consent will be involved in the research.

This study will involve: Check all that apply.

☐ Deception (Attach Waiver or Alteration of Informed Consent Requirements)
☐ Radiation
☐ New Drugs (IND) IND # _______ Attach Approval
☐ Investigational Device Exemption (IDE) # _______ Attach Approval
☐ Non-approved Use of Drug(s)
☒ None of the above will be involved in this study

I. Project Overview
Please provide a brief explanation (limit to 200 words or less) of the rationale and purpose of the study, introduction of any sponsor(s) of the study, and justification for use of human subjects and/or special populations (e.g., vulnerable populations such as children, prisoners, pregnant women/fetuses).

The advancement of prosthetic design has continued to progress over several hundreds of years. Surges in advancements tend to follow war times. One of the latest developments in prosthetics for individuals with transfemoral amputations is the HiFi socket. This socket design provides for more stability of the residual limb than the more traditional ischial containment socket or the older quadrilateral socket designs. There are longitudinal struts that apply pressure to the residual limb in select areas and windows between the struts allow for management of the soft tissue. It is felt that this design provides for better control of the femur within the socket.

Revised 1/9/15 2
The purpose of this study is to utilize motion analysis to measure the stability of the femur in individuals with transfemoral amputation that utilize the HiFi socket for ambulation. Better control of the femur has the potential to provide for improved efficiency of gait and a decrease in energy expenditure. Human subjects with transfemoral amputations are required for this study, as it cannot be simulated in a laboratory or with individuals without amputation. There are no sponsors for this study.

II. Protocol Description
Please provide a thorough description of the procedures to be used by addressing the instructions under each of the following categories.

1. Subject Selection.
   a) Describe recruitment procedures (i.e., how subjects will be recruited, who will recruit them, where and when they will be recruited and for how long) and include copies of any advertisements, fliers, etc., that will be used to recruit subjects. Subjects will be recruited by prosthetist, Paul Edman, from Altru Health System. This will be completed by Paul calling potential subjects. Each subject will complete a one-time 45-60 minute obligation. The subjects' names and contact information will be not be shared with the researchers from UND. The UND researchers will not meet the subjects until the day of the study. There will be 5-10 subjects that are recruited.
   b) Describe your subject selection procedures and criteria, paying special attention to the rationale for including subjects from any of the categories listed in the “Subject Classification” section above. Subjects will be >18 years of age, an individual with a transfemoral amputation, and current HiFi socket wearer.
   c) Describe your exclusionary criteria and provide a rationale for excluding subject categories. Subjects that do not have a transfemoral amputation and HiFi transfemoral socket.
   d) Describe the estimated number of subjects that will participate and the rationale for using that number of subjects. We anticipate 5-10 subjects; this socket design is relatively new and there is a limited potential subject pool in the local area.
   e) Specify the potential for valid results. If you have used a power analysis to determine the number of subjects, describe your method. We are not using a power analysis as we are doing a pilot study.

2. Description of Methodology.
   a) Describe the procedures used to obtain informed consent. Prior to data collection, research participants will be issued the informed consent form (see attached form). Each research participant will be asked to read and sign the informed consent form. This will indicate that they understand the study and its purpose. They will be given a copy of the consent form to take with them, for us if further questions or concerns come up.
   b) Describe where the research will be conducted. Document the resources and facilities to be used to carry out the proposed research. Please note staffing, funding, and space available to conduct this research. The data will be collected in the BiPed laboratory in the Hyslop building on UND's campus. No funding has been received for this research study. Dr. Jesse Rhoades will lead the data collection with the Vicon motion analysis system. Dr. Cindy Flom-Meland, Paul Edman, and 3 physical therapy students, Mary Bachman, Alicia Beckel, and Amanda Belyaks will assist.
   c) Indicate who will carry out the research procedures. The research procedures will be led by Cindy Flom-Meland and assisted by Jesse Rhoades, both UND faculty members; the following physical therapy students: Mary Bachman, Alicia Beckel, and Amanda Belyaks; Paul Edman, prosthetist from Altru Health Systems will also be assisting.
d) Briefly describe the procedures and techniques to be used and the amount of time that is required by the subjects to complete them.

During this study participants will be asked to walk utilizing their own transfemoral prosthesis which has the HiFi socket design. This device will be utilized to apply differentiated socket pressure for a series of walking trials. Essentially, the pressure within the device will be increased in an effort to reduce non-gait associated motion at the socket junction. The pressure will be measured with use of pressure film that will be placed on the inside of the HiFi socket. Ten walking trials will be completed utilizing each of the three pressure conditions, low tightness, medium tightness, high tightness, for a total of thirty walking trials for each participant. Trials will be filmed utilizing a Vicon infrared camera system. A series of reflective markers will be placed on the participants. Markers will be placed at the junction of the HiFi Prosthetic Socket and the participant’s upper hip. This will allow for kinematic data relating to the prosthetic junction to be collected by the Vicon system. Overall, between participant preparation and data collection, roughly forty five minutes will be necessary for these procedures, for each participant.

e) Describe audio/visual procedures and proper disposal of tapes.

Video data will be collected utilizing the Vicon motion analysis system. The Vicon system utilizes reflective anatomical markers which allow the Vicon system to track and quantify the motion of these markers. Participants will have these markers placed at the junction of the HiFi Prosthetic Socket and the participant’s upper hip. The Vicon internally stores digitally infrared camera data. These data are stored on a centrally located, password protected computer. Digital data will be disposed of after a period of five years via deletion, followed by overwrite.

f) Describe the qualifications of the individuals conducting all procedures used in the study.

Dr. Jesse Rhoades, holds a Ph.D. in pedagogical kinesiology as well as a master’s degree in biomechanics. These qualifications are within the specific skill set required to perform motion analysis with the Vicon system. Dr. Cindy Flom-Meland, associate professor in physical therapy, has 25+ years of experience working with individuals with amputations / prostheses. Paul Edman, Prosthetist, has 18+ years of experience with individuals with amputation and prosthetic limb fabrication. The three physical therapy students will be working under the direct supervision and guidance of Dr. Rhoades, Dr. Flom-Meland, and Paul Edman. The have received instruction in motion analysis and will function as research assistants.

g) Describe compensation procedures (payment or class credit for the subjects, etc.).

Subjects and students will not receive compensation for this study.

Attachments Necessary: Copies of all instruments (such as survey/interview questions, data collection forms completed by subjects, etc.) must be attached to this proposal.


a) Clearly describe the anticipated risks to the subject/others including any physical, emotional, and financial risks that might result from this study.

There will be minimal risk to the research participants. They will be walking in a clear, even, unobstructed path in the laboratory. The amount of walking required for the study is 180 meters; 6 meters per trial. It is not anticipated that fatigue will be an issue; however, if needed the participants will be allowed to rest. No emotional or financial risks are anticipated.

b) Indicate whether there will be a way to link subject responses and/or data sheets to consent forms, and if so, what the justification is for having that link.

Data collected will not be linked to the consent forms; all data will be reported in aggregate.

c) Provide a description of the data monitoring plan for all research that involves greater than minimal risk.

Not applicable.
d) If the PI will be the lead-investigator for a multi-center study, or if the PI's organization will be the lead site in a multi-center study, include information about the management of information obtained in multi-site research that might be relevant to the protection of research participants, such as unanticipated problems involving risks to participants or others, interim results, or protocol modifications.
Not applicable.

4. Subject Protection.

a) Describe precautions you will take to minimize potential risks to the subjects (e.g., sterile conditions, informing subjects that some individuals may have strong emotional reactions to the procedures, debriefing, etc.).

The procedures will be clearly explained to each research participant, they will be instructed to request time to rest at any time during the data collection process if needed.

b) Describe procedures you will implement to protect confidentiality and privacy of participants (such as coding subject data, removing identifying information, reporting data in aggregate form, not violating a participants space, not intruding where one is not welcome or trusted, not observing or recording what people expect not to be public, etc.). If participants who are likely to be vulnerable to coercion and undue influence are to be included in the research, define provisions to protect the privacy and interests of these participants and additional safeguards implemented to protect the rights and welfare of these participants.

Research participant data will be coded (i.e. via a number), this will not be connected to participant's name or informed consent form; reporting will be done in aggregate.

c) Indicate that the subject will be provided with a copy of the consent form and how this will be done.

Prior to beginning the set-up and any data collection, the subjects will be asked to read the consent form and sign if they are willing to participate; a copy of this form will be provided to them upon signing.

d) Describe the protocol regarding record retention. Please indicate that research data from this study and consent forms will both be retained in separate locked locations for a minimum of three years following the completion of the study.

Describe: 1) the storage location of the research data (separate from consent forms and subject personal data)
2) who will have access to the data
3) how the data will be destroyed
4) the storage location of consent forms and personal data (separate from research data)
5) how the consent forms will be destroyed

Results and consent forms will be kept in a locked, storage area in the Department of Physical Therapy at the University of North Dakota. Records from the study will be destroyed using a paper shredder three years following the conclusion of this study. The Vicon internally stores digitally infrared camera data. These data are stored on a centrally located, password protected computer. Digital data will be disposed of after a period of five years via deletion, followed by overwrite. The only individuals with access to the information will be the people who audit IRB procedures, the three student researchers, Dr. Cindy Flom-Meland and Dr. Jesse Rhoades.

e) Describe procedures to deal with adverse reactions (referrals to helping agencies, procedures for dealing with trauma, etc.).

If injury should occur during the study, medical treatment will be available as it would be for any member of the community. The participant and their third party payer will be responsible for paying for such treatment.

f) Include an explanation of medical treatment available if injury or adverse reaction occurs and responsibility for costs involved.

If injury should occur during the study, medical treatment will be available as it would be for any member of the community. The participant and their third party payer will be responsible for paying for such treatment.

III. Benefits of the Study
Clearly describe the benefits to the subject and to society resulting from this study (such as learning experiences, services received, etc.). Please note: extra credit and/or payment are not benefits and should be listed in the Protocol Description section.
The purpose of this study is to utilize motion analysis to measure the stability of the femur in individuals with transfemoral amputation that utilize the HiFi socket for ambulation. Better control of the femur has the potential to provide for improved efficiency of gait and a decrease in energy expenditure. The results will be beneficial to the healthcare providers (i.e. prosthetists, physical therapists, even surgeons) to be able to best inform patients in the future on the benefit (or lack of benefit, depending on the results) of the use of the HiFi socket. For the research participants, the personal benefit will be less, it will be in a 'pay it forward' manner. The knowledge gained from the study this will benefit people in the future that wear this type of prosthesis.

IV. Consent Form
Clearly describe the consent process below and be sure to include the following information in your description (Note: Simply stating 'see attached consent form' is not sufficient. The items listed below must be addressed on this form.):
1) The person who will conduct the consent interview
2) The person who will provide consent or permission
3) Any waiting period between informing the prospective participant and obtaining consent
4) Steps taken to minimize the possibility of coercion or undue influence
5) The language (English, French, German, etc.) to be used by those obtaining consent
6) The language (English, French, German, etc.) understood by the prospective participant or the legally authorized representative
7) The information to be communicated to the prospective participant or the legally authorized representative

Please see attached informed consent form.

1). The student researchers will conduct the consent interview.
2). The prospective participant will provide consent.
3). The will be minimal to no waiting time between informing the prospective participant and obtaining consent; time for the participant to read the form.
4). The prospective research participant will be encouraged to ask any/all questions prior to making an informed decision of whether to or not to participate in the study. Those conducting the consent interview will answer questions directly without imparting undue influence.
5). English.
6). English.
7). The prospective participant will be made aware of all of the risks and benefits of the study.

A copy of the consent form must be attached to this proposal. If no consent form is to be used, document the procedures to be used to protect human subjects, and complete the Application for Waiver or Alteration of Informed Consent Requirements. Refer to form IC 701-A, Informed Consent Checklist, and make sure that all the required elements are included. Please note: All records attained must be retained for a period of time sufficient to meet federal, state, and local regulations, sponsor requirements, and organizational policies. The consent form must be written in language that can easily be read by the subject population and any use of jargon or technical language should be avoided. The consent form should be written at no higher than an 8th grade reading level and must be written in the second person (please see the example on the RD&C website). A two inch by two inch blank space must be left on the bottom of each page of the consent form for the IRB approval stamp.

Necessary attachments:

☐ Signed Student Consent to Release of Educational Record Form (students and medical residents only);
☐ Investigator Letter of Assurance of Compliance; (all researchers)
☐ Consent form, or Waiver or Alteration of Informed Consent Requirements (Form IC 702-B)
☐ Key Personnel Listing
☐ Surveys, interview questions, etc. (if applicable);
☐ Printed web screens (if survey is over the Internet); and
☐ Advertisements (flyer, social media postings, email/letters, etc.).

By signing below, you are verifying that the information provided in the Human Subjects Review Form and attached information is accurate and that the project will be completed as indicated.
Signatures:

(Principal Investigator) Date:

(Student Advisor) Date:

**All students and medical residents must list a faculty member as a student advisor on the first page of the application and must have that person sign the application.**

Requirements for submitting proposals:

Additional information can be found on the IRB website at: [http://und.edu/research/resources/human-subjects/index.cfm](http://und.edu/research/resources/human-subjects/index.cfm)

Original, signed proposals and all attachments, along with the necessary number of copies (see below), should be submitted to: Institutional Review Board, 264 Centennial Drive Stop 7134, Grand Forks, ND 58202-7134, or brought to Room 106, Twamley Hall.

Required Number of Copies:

- Expedited Review: Submit the signed original and 1 copy of the entire proposal.
- Full Board Review: Submit the signed original and 22 copies of the entire proposal by the deadline listed on the IRB website: [http://und.edu/research/resources/human-subjects/meeting-schedule.cfm](http://und.edu/research/resources/human-subjects/meeting-schedule.cfm)
- Clinical Medical Subcommittee and Full Board Review: Submit the signed original and 24 copies of the entire proposal by the deadline listed on the IRB website: [http://und.edu/research/resources/human-subjects/meeting-schedule.cfm](http://und.edu/research/resources/human-subjects/meeting-schedule.cfm)

Prior to receiving IRB approval, researchers must complete the required IRB human subjects' education. Please go to: [http://und.edu/research/resources/human-subjects/human-subject-education.cfm](http://und.edu/research/resources/human-subjects/human-subject-education.cfm)

The criteria for determining what category your proposal will be reviewed under is listed on page 3 of the IRB Checklist. Your reviewer will assign a review category to your proposal. Should your protocol require full Board review, you will need to provide additional copies. Further information can be found on the IRB website regarding required copies and IRB review categories, or you may call the IRB office at 701 777-4279.

In cases where the proposed work is part of a proposal to a potential funding source, one copy of the completed proposal to the funding agency (agreement/contract if there is no proposal) must be attached to the completed Human Subjects Review Form if the proposal is non-clinical; 5 copies if the proposal is clinical-medical. If the proposed work is being conducted for a pharmaceutical company, 5 copies of the company’s protocol must be provided.
INVESTIGATOR LETTER OF ASSURANCE OF COMPLIANCE
WITH ALL APPLICABLE FEDERAL REGULATIONS FOR THE
PROTECTION OF THE RIGHTS OF HUMAN SUBJECTS

I ____________________________________________
(Name of Investigator)

agree that, in conducting research under the approval of the University of North Dakota Institutional Review Board, I will fully comply and assume responsibility for the enforcement of compliance with all applicable federal regulations and University policies for the protection of the rights of human subjects engaged in research. Specific regulations include the Federal Common Rule for Protection of the Rights of Human Subjects 45 CFR 46. I will also assure compliance to the ethical principles set forth in the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research document, The Belmont Report.

I understand the University's policies concerning research involving human subjects and agree to the following:

1. Should I wish to make changes in the approved protocol for this project, I will submit them for review PRIOR to initiating the changes. (A proposal may be changed without prior IRB approval where necessary to eliminate apparent immediate hazards to the subjects or others. However, the IRB must be notified in writing within 72 hours of any change, and IRB review is required at the next regularly scheduled meeting of the full IRB.)

2. If any problems involving human subjects occur, I will immediately notify the Chair of the IRB, or the IRB Coordinator.

3. I will cooperate with the UND IRB by submitting Research Project Review and Progress Reports in a timely manner.

I understand the failure to do so may result in the suspension or termination of proposed research and possible reporting to federal agencies.

Investigator Signature ___________________________ Date ___________________
STUDENT RESEARCHERS: As of June 4, 1997 (based on the recommendation of UND Legal Counsel) the University of North Dakota IRB is unable to approve your project unless the following "Student Consent to Release of Educational Record" is signed and included with your IRB application.

STUDENT CONSENT TO RELEASE OF EDUCATIONAL RECORD

Pursuant to the Family Educational Rights and Privacy Act of 1974, I hereby consent to the Institutional Review Board's access to those portions of my educational record which involve research that I wish to conduct under the Board's auspices. I understand that the Board may need to review my study data based on a question from a participant or under a random audit. The title of the study to which this release pertains is ____________________________

________________________________________________________________________

I understand that such information concerning my educational record will not be released except on the condition that the Institutional Review Board will not permit any other party to have access to such information without my written consent. I also understand that this policy will be explained to those persons requesting any educational information and that this release will be kept with the study documentation.

ID #                                      Printed Name

Date                                      Signature of Student Researcher

1Consent required by 20 U.S.C. 1232g.
THE UNIVERSITY OF NORTH DAKOTA
CONSENT TO PARTICIPATE IN RESEARCH

TITLE:  
*The Effect of Socket Tightness on Femur Stability in a HiFi Socket*

PROJECT DIRECTOR:  
Cindy Flom-Meland

PHONE #:  
701-777-4130

DEPARTMENT:  
Department of Physical Therapy

A person who is to participate in the research must give his or her informed consent to such participation. This consent must be based on an understanding of the nature and risks of the research. This document provides information that is important for this understanding. Research projects include only subjects who choose to take part. Please take your time in making your decision as to whether to participate. If you have questions at any time, please ask.

You are invited to be in a research study about determining the effect of tightness of a HiFi socket on upper leg stability during walking because you a wearer of a HiFi socket.

The purpose of this research study is to determine which amount of socket tightness provides for the greatest amount of lower extremity stability during walking. The researchers anticipate that the tighter the socket (while maintaining comfort, no pain) will provide the greatest amount of stability to the lower extremity for each participant during walking. This information will be beneficial to prosthetists that build this type of socket for individuals with above the knee limb loss and for other healthcare professionals that provide education to individuals with limb loss in the leg.

Approximately 5-10 people will take part in this study at the University of North Dakota.

Your participation in the study will last one day. You will need to visit the BiPed laboratory in Hyslop one time. The visit will take about 45 minutes.

During this study you will be asked to walk while wearing your prosthesis which has the HiFi socket. This device will be utilized to apply differentiated socket pressure for a series of walking trials. You will complete ten walking trials will be completed utilizing each of the three pressure conditions, low tightness, medium tightness, high tightness, for a total of thirty walking trials for each participant. Trials will be filmed using an infrared camera system. A series of reflective markers will be placed on your prosthesis and your upper hip.

There may be some risk from being in this study, each participant will be asked to walk in a clear, flat walkway in a laboratory room that spans 20 feet; you will be asked to walk a total of
600 feet. Each walking bout will be for 20 feet. This may make you feel tired; however, you may request to rest at any time.

You may not benefit personally from being in this study. However, we hope in the future other people might benefit from this study because the information learned will be used to better inform professionals that work with individuals that wear the HiFi socket.

You will not have any costs for being in this research study, nor will you be paid for being in this research study.

The University of North Dakota and the research team are receiving no payments from other agencies, organizations, or companies to conduct this research study.

The records of this study will be kept private to the extent permitted by law. In any report about this study that might be published, you will not be identified. Your study record may be reviewed by Government agencies and the University of North Dakota Institutional Review Board.

Any information that is obtained in this study and that can be identified with you will remain confidential and will be disclosed only with your permission or as required by law. Confidentiality will be maintained by means of coding of data, meaning no name will be linked to any of the data collected. Any information collected will be kept in a locked storage room in the Department of Physical Therapy and will be destroyed three years following the completion of the study.

If we write a report or article about this study, we will describe the study results in a summarized manner so that you cannot be identified.

Your participation is voluntary. You may choose not to participate or you may discontinue your participation at any time without penalty or loss of benefits to which you are otherwise entitled. Your decision whether or not to participate will not affect your current or future relations with the University of North Dakota.

The researcher conducting this study is Dr. Cindy Flom-Meland and Dr. Jesse Rhoades. You may ask any questions you have now. If you later have questions, concerns, or complaints about the research please contact Dr. Cindy Flom-Meland at 701-777-4130 during the day and at 218-779-4141.

If you have questions regarding your rights as a research subject, you may contact The University of North Dakota Institutional Review Board at (701) 777-4279 or UND.irb@research.UND.edu or Altru Institutional Review Board at (701)780-6161.
- You may also call this number about any problems, complaints, or concerns you have about this research study.
- You may also call this number if you cannot reach research staff, or you wish to talk with someone who is independent of the research team.
- General information about being a research subject can be found by clicking "Information for Research Participants" on the web site: http://und.edu/research/resources/human-subjects/research-participants.cfm

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Subjects Name: _______________________

____________________________________  Date
Signature of Subject

I have discussed the above points with the subject or, where appropriate, with the subject’s legally authorized representative.

____________________________________  Date
Signature of Person Who Obtained Consent

Date: __________
Subject Initials: __________
REFERENCES


25


