PERCUTANEOUS, OSSEOINTEGRATED IMPLANTS:
A METHOD TO EVALUATE LIMB COMPENSATION
IN AN OVINE MODEL

by

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This thesis has been read by each member of the following supervisory committee and by majority vote has been found to be satisfactory.
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ABSTRACT

Socket prosthetics are currently used to restore function to individuals with limb loss. However, there are several complications associated with these docking systems, especially in patients with limited residual limb lengths. Percutaneous, osseointegrated prosthetics are presently being investigated to overcome these problems. To help develop these prosthetics, an ovine model was used in which the right metacarpal III bone was surgically amputated and restored with an osseointegrated implant with an exoprosthetic. The purposes of this study were to develop a method to quantify and to compare limb function before and following amputation.

A commercially available force sensitive mat (Tekscan HR Mat, Tekscan, Inc., Boston, MA) was used in conjunction with a custom oval walkway to measure the limb function from the ovine model. Limb loads, stride length, and stance phase as a percent gait cycle were collected from each limb before amputation and then compared to postamputation data.

To date, 17 animals have been amputated and implanted with a percutaneous, osseointegrated implant and fit with an exoprosthetic. On average, the prosthesis was loaded 82.5% ± 5.3% (N=17) of the preamputation load 1 month after surgery and improved to 86.9% ± 9.9% (N=3) at 6 months following surgery. The kinematic data of the stance phase as a percent gait cycle and stride length of the amputated limb were not significantly different from the contralateral, nonamputated limb following the opera-
Based upon these findings, it was concluded that the prosthetic limb of the animals was loaded by the subjects, albeit less than the preamputation loads. However, based upon the kinematic data obtained, the subjects were not limping. This method may help to establish a rehabilitation timeline for patients with percutaneous, osseointegrated implants with an exoprosthetic in the future and an objective method to compare new treatments for amputees.
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CHAPTER 1

INTRODUCTION

Loosing a limb can be detrimental to an individual's physical lifestyle and emotional well-being. For over 3,000 years, prosthetics have been used to restore function to these individuals. There are evidences of prosthetics being used by the Egyptians [1, 2] and stories of individuals using prosthetics from Greece [3, 4], India [3], and others throughout the Middle Ages and the Renaissance [3-5]. These early prosthetics were crude and usually consisted of a wooden core attached to the residual limb using leather sockets and straps.

In the 1500s, Ambroise Paré, a French surgeon who is now considered the father of modern prosthetic design [1, 3, 5], introduced new amputation techniques and began designing prosthetics using scientific methods. Throughout the past centuries, prosthetics have been developed that included mechanical locks and moving joints to help restore function to patients [6]. Continued advancements occurred after World War II with Verne Inman, a surgeon, studying the biomechanics of locomotion in patients with prosthetics, enabling prosthetists to create better prostheses and to help improve the quality of life for patients with limb loss [7, 8]. Despite the changes in materials used to improve mobility and comfort for patients with limb loss, the overall concept of prosthetics have not changed.
Socket Prosthetics

Socket prosthetics generally consist of three main parts: a soft insert, a socket, and an exoprosthetic. The soft insert sits between the socket and the residual limb. It is usually made of a silicone material and is positioned in the socket to absorb load and to increase comfort and stability. The fit of the prosthesis can be improved by adhering the inserts directly to the residual limb and socket casing [9]. The socket sits over the residual limb and are typically made of a durable plastic cast molding that fits closely to the residual limb to ensure the prosthetic remains attached to the limb. The exoprosthetic attaches directly to the socket and distributes the loads of the limb to prevent high pressure areas and skin sores [9].

There are many advances that have been made with socket prosthetics over the years but there are still limitations. For example, socket prosthetics are not adequate for amputees with heterotopic bone formation (HBF). HBF is characterized by bone growing in nonosseous tissue [10, 11], and is common in military amputees, due to high velocity bullets or blast injuries. This causes problems for amputees as the socket prosthesis applies a load to the bone formation, damaging tissue and frequently causing pain and soft-tissue damage [9]. However, HBF is not the only problem with socket prosthetics.

The physical characteristics of some amputations can also be a limitation. In order for a socket prosthesis to be effective there must be enough of the residual limb for proper attachment. With some patients with limb loss, there is not sufficient enough residual limb for a socket prosthesis to be used, or if used, it would dig into the proximal region of the limb creating skin irritation. One more issue with socket prosthetics is the
fit of the prosthetic. If the socket does not fit properly it causes some sliding of the socket, leading to excessive skin irritation and pressure and causing pain for the patients with limb loss [9, 12, 13].

Another major concern with socket prosthetics is the pain associated with them. A survey of 255 lower-limb amputees was conducted [14]; in this survey, subjects were asked to rate their residual limb pain on a scale from 0 to 10 (0 being no pain and 10 being as bad as it could be). Their findings revealed that 74% of the subjects had residual limb pain and that 38% reported an average residual limb pain between 7 and 10. According to the survey, residual limb pain was rated as the worst pain problem for amputees at 33%, followed by phantom pain at 24%. This survey also reveals that pain can occur in the back, neck, shoulders, hips, and the nonamputated leg and foot. This is suggested to be due to changes in gait due to living with the amputation [14]. These findings have been supported in other studies [15, 16]. The residual limb pain has been attributed to the loading of the soft-tissue of the residual limb, causing soft tissue breakdown [13]. However, it has been suggested that retraining an amputee in gait and back posture shortly after amputation may prevent the development of some of these problems [17, 18].

In short, socket prosthetics are a valuable device for amputees in helping them to ambulate without the use of crutches; however, most amputees are not satisfied with the comfort of their prosthetic, in fact less than half (only 43%) are completely satisfied with the comfort [15]. This dissatisfaction can be attributed to many different things such as poor design, fit of the prosthetic, or pain in the amputated limb or other loca-
Osseointegrated Implants

The term osseointegration was introduced by Per-Ingvar Bränemark as a means of describing the attachment of titanium to bone in dental implants [19-21]. Titanium implants have been used in dentistry since the 1950s. Osseointegration has been used in other applications such as facial prosthetics, hearing aids, and finger prosthetics [19, 22]. More recently, percutaneous, osseointegrated prosthetics have been investigated for their use in treating patients with limb loss.

Osseointegrated prosthetics have several potential benefits over socket prosthetics. It has been reported that patients with osseointegrated interphalangeal joint prostheses reported a greater range of motion and hand function, better pain relief, an increase in grip strength, and were also more satisfied with its appearance [23]. However, the strength of the implant depends largely upon the quality of bone attachment to the implant [19].

Another potential benefit of osseointegrated implants is the potential for osseoperception, which is defined as: “(i) the sensation arising from mechanical stimulation of a bone-anchored prosthesis, transduced by mechanoreceptors that may include those located in muscle, joint, mucosal, cutaneous and periosteal tissues: together with (ii) a change in central neural processing in maintaining sensorimotor function” [24]. In fact, it has been suggested that patients with osseointegrated implants could, in part, have some of their sensory feedback pathway restored as the prosthetic is directly attached to the bone. This feedback system is critical while walking and can help prevent overload-
ing the prosthesis [25, 26]. However, despite these benefits, there are some risks involved with this technology and operation procedure.

The biggest risk associated with osseointegrated implant treatments is the risk of infection as the implant penetrates the skin and attaches to the bone. If the skin does not seal around the implant, the risk of infection can be great. The infection can then migrate along the implant interface and cause a biofilm layer which could lead to the necessary removal of the implant, and in turn, require a higher amputation to prevent the systemic infection and chronic antibiotic therapy. Fortunately, there have been advances in materials and antimicrobials that encourage ingrowth of both the bone and skin, creating an infection barrier [27-30]. Successful bone and skin integration has been reported with percutaneous prosthetics [27, 28, 31, 32]. Another potential problem is the proper transfer of the load from the bone to the implant, which could lead to bone loosening, osteopenia; however, there have been no reports of this yet in the literature.

**Experimental Model**

As a means of testing the design of the osseointegrated implant, an *in vivo* model needed to be established in order to test the implant pertaining to questions regarding bone remodeling, the skin infection barrier, and overall effectiveness of the osseointegrated implant concept could not be answered by use of a computer model. A small animal model, such as rabbits or mice, would have provided valuable information regarding the infection barrier and the bone remodeling [27, 28]; however, the weight and size of these subjects would not have provided the adequate information for a translational model.

To translate the *in vivo* model to human application, a large animal model was
chosen, specifically an ovine model, to determine the effectiveness of these osseointegrated implants [33, 34]. This ovine model was chosen as it has been documented that these subjects show promise for testing of bone implant materials [35-37]. The sheep have a body weight that is more similar to humans and also have bones that are appropriate for testing human implants, due to bone size and structure [38]. It has also been concluded that the ovine model would provide an understanding of the bone remodeling rate for humans [36]. Specifically, it was determined that the forelimbs of these subjects would “provide appropriate approximations of anatomical and biomechanical factors associated with human limb prostheses” [36].

In order to test the effectiveness of osseointegrated prosthetics, many areas of analysis should be explored. One area being studied is histology; to determine infection at the skin-implant barrier and bone ingrowth at the bone-implant interface. Biomechanical data are also being used to study the strength of the bone-implant interface and an additional means of determining bone ingrowth. Finally, another area being examined is the loading of the prosthetic limb in vivo. It has been documented that this can be a valuable tool to confirm loading, determine the effectiveness of a prosthesis, create rehabilitation timelines [7, 8], and encourage bone ingrowth [39].

**Purpose of Study**

The purpose of this study is to measure vertical ground reaction forces (GRFs) in percutaneous, osseointegrated prosthetics in an ovine model to help with osseointegrated implant evaluation and to help provide information regarding the recovery pattern for rehabilitation purposes. Measuring the GRFs will also confirm the load bearing of the implants. In addition to GRFs, various kinematic data will be recorded, mainly stance
phase as a percent gait cycle and stride length. The reason for analyzing these values is to help determine the lameness of the subjects. For instance, a limp is characterized by a shorter stride length and a shorter amount of time spent on the injured limb. By comparing these values, it will give insight into how much discomfort the amputated limb is causing the subjects.
CHAPTER 2

SENSOR SELECTION

Comparing the gait of subjects before and after can lead to understanding the effectiveness of osseointegrated implants. Several different methods can be used to assess gait. One method that could be used is by visual observation. For this method, a subject is observed while walking and given a lameness score while several different kinematic and temporal parameters are observed [40]. These scores can then be compared between trials. This method is beneficial because it does not require equipment and can be done while the subject is performing a variety of gaits such as walking, running, going up or down an incline, or any other task. However, the drawback to this method is that it does not provide quantitative data and can be difficult to compare between trials. This becomes a larger problem when using quadrupeds since they can mask their limping better than bipeds by distributing weight to the other three limbs. This led to investigating a method that would provide quantitative force data for quadrupeds.

The most common method used for gait analysis is using a full motion analysis lab. In these labs, a gait analysis is performed by collecting kinetic, joint kinematics, electromyography (EMG), and foot pressures [41]. These data can be used for diagnosis and assessment or to predict the results of an intervention for certain conditions [42]. The kinetic data are measured by using a force plate. The force plate provides very ac-
curate GRFs acting in all three directions (the vertical, mediolateral, and craniocaudal directions) and also provides a moment reading to determine center of pressure. Force plates are normally used in conjunction with skin markers and multiple cameras to perform inverse dynamics [41]. This can lead to understanding the forces acting on the joints, which can be very valuable for determining the effectiveness of a prosthetic device. Not only can performing a full gait analysis provide accurate force data but it can also provide kinematic data for a better understanding of the gait cycle [7]. This additional information is beneficial as changes of time in stance phase or limb length can be used to assess patient recovery from surgeries or evaluate their prosthetic devices.

Although this method is considered the ‘gold standard’ there are still disadvantages. For instance, for a full motion analysis, more equipment is needed (such as multiple cameras, skin markers, and a force plate) as well as a large area for a walkway to record data while the subject is ambulating. For the force plate to provide accurate data, there must be a clean strike, meaning that only one foot can be in contact with a force plate at a time and that it must strike squarely on the force plate. This can become a problem with animals because it becomes difficult to control the location of the contact of the limbs [43]. This makes using a force plate a very time consuming process for quadrupeds, taking sometimes 40 passes to collect sufficient data [44]. Fortunately, there are other methods available to minimize the data collection time.

One of those methods is to use a treadmill. The treadmill method can be beneficial as velocity correlates directly to GRFs; however, with a treadmill the velocity of the subjects can be maintained, making for easier comparison between foot strikes [45]. Initially, when treadmills were used in conjunction with force plates, a rigid treadmill
was fastened directly to the force plate; however, this provided noisy data as multiple foot strikes occurred on the force plate. To help with this an instrumented treadmills have been developed consisting of two belts, a belt for the right side and a belt for the left side, with each belt corresponding to a force plate [45, 46]. However, there are some consequences of using a force treadmill. The largest problem arises when using animals, especially animals that are not domesticated, as the subjects must be trained to walk on the treadmills. This is a process that could take months to do properly to ensure that the animals do not injure themselves.

Extensive training of animals can be avoided by using a method that employs sensors that attach directly to the limbs. One way of accomplishing this is to use force sensing insoles. These insoles consist of pressure sensors, which can be attached to a shoe insole to record forces in the vertical direction. Gyroscopes and accelerometers can also be incorporated with the sensors in the insoles to provide some kinematic data such as velocity and acceleration [47]. These sensors are capable of measuring subtle changes in weight distribution and as such can be used to assess an individual's health and can be used for individuals with maladies, such as Parkinson's, as a means of assessing treatment [48]. The benefit of this method is that the patient can walk around and perform a variety of tasks while force data are collected, minimizing the amount of time necessary for training of subjects. Because of this benefit, this method was investigated further.

A pilot study was performed in which force sensing insoles were created that could be used with sheep. To do so, force sensing resistors (Interlink Electronics Inc., Camarillo, CA) were used for the sensor. These sensors are resistors that consist of a
three layer sensor area. One layer is a flexible semiconducting layer, while the middle layer is a nonconducting spacer, and the third layer consists of imprinted electrodes. As a force is applied to the sensor, the resistance decreases. The force applied to the sensor can be determined by developing a calibration equation between force and voltage output. By incorporating several force sensing resistors (FSRs) in an insole, more accurate results can be obtained.

For the sheep pilot study, insoles were made by embedding three FSRs in silicone (Smooth-On Inc., Easton, PA) to form an insole. These insoles were then put in a Mediboot (Davis Manufacturing, Brandon, WI), commonly used to treat hoof injuries in sheep. Subjects could then wear the boots while force data were recorded from each of the sensors. Despite the several potential advantages of this method, there were disadvantages as well.

The biggest deterrent to this method was the several wires associated with the sensors. This meant the animals could not walk around freely as they could become entangled in the wires. To prevent entanglement, telemetry could be used; however, this method is still being developed. Another problem with this approach is that each sensor in an insole would need to be calibrated to provide accurate data, a process that would be time consuming when considering insoles would have to be created for each limb. There is also a problem with the accuracy considering only three sensors could be incorporated in the insoles (due to the small hoof size). This means that spot loading would be performed as not all of the load bearing surface of the hoof would be covered, underestimating the actual loads.
Another method that was evaluated is the use of a load cell. The load cell could be placed at the base of the transcutaneous post of the implant where it meets the exoprosthesis; in this manner, the vertical GRFs could easily be measured postoperatively. However, forces also need to be measured preoperatively, rendering the load cell method problematic; although, there have been studies done in which a load cell has been used to measure forces in vivo [49], this was deemed to be too invasive. There is also the problem with having wires associated with this method in the same manner as using the force sensing insoles. Given the methods that are commonly used in measuring GRFs, a design criterion was established for the sensor.

Sensor Requirements

As observed, there are many methods that can be used in gait analysis. Each method has certain benefits and limitations based on its application. From studying these various methods, a design criterion was established for the requirements of the sensor for this particular study. First, the sensor needed to be portable to allow for easy transportation to the site where subjects are housed and be easy to set-up and disassembly for each data recording session. Second, the sensor also needed to be able to record a full gait cycle as the subjects walked about. This was important as data are easily compared between limbs when using one gait cycle, when using multiple gait cycles, there is variation between kinetic and kinematic data due to changes in subjects’ velocity. To record a full gait cycle from each limb, it was determined that the sensor needed to record data for at least 1.5 times the stride length. Based on literature values of stride length in ovine subjects, the minimum recording distance was 1.3 m [50].
A third requirement for the sensor was that the sensor had to be able to measure GRFs before and after amputation to assess prosthetic limb function. The fourth requirement was that there needed to be little to no training of the subjects. It was decided that training needed to take less than two weeks due to the large number of subjects that would undergo surgery in the 12-month study. This sensor requirement would minimize the time before surgery for each subject. Coinciding with this requirement was the fifth, which was that the subjects needed to walk on it easily so data could be recorded from all four limbs without making the subjects make several passes for data from one limb.

The final requirement was that the sensor needed to provide quantitative accurate data within 5%. Based upon this design criterion, a sensor was found that appeared to meet the established requirements, that sensor was a Tekscan High Resolution (HR) Mat (Tekscan, Inc., Boston, MA). A comparison of requirements and possible sensors is found in Table 1.

**Tekscan HR Mat**

The Tekscan HR Mat is a pressure walkway system. The walkway system itself is made of three sensors that can either work together, or can be used to work independently. Each of the sensors is made of individual sensels, which are the sensing elements for the HR mat. These sensels are arranged in a grid pattern giving a resolution of 3.9 sensels per square-centimeter. Each sensel is portrayed by the software in a real-time window, indicating the force applied to that sensel.

The HR Mat is made of two thin flexible polyester sheets with electrically conductive electrodes (traces of silver) placed on the surfaces. The sheets are overlain so
Table 1—Established design criterion for the sensor to record limb forces and possible methods of assessing prosthetic limb loading. This table compares the methods used to measure limb loads and which of the design criteria that method fulfills.

<table>
<thead>
<tr>
<th></th>
<th>Observation</th>
<th>Force Plate</th>
<th>Force Treadmill</th>
<th>Force Sensing Insole</th>
<th>Load Cell</th>
<th>Tekscan HR Mat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Portable</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Record full gait cycle</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Record preamputation &amp; postamputation</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Little to no training of subjects</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Subjects easily walk on it</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Quantitative accurate data</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

one of the sheets forms rows and the other sheet forms columns, creating the sensels. Between the two layers, is placed an adhesive and dielectric, to prevent the conductive electrodes from shorting each other, as well as a semiconductive material. As a load is applied to the sensels, the two conductive layers get closer together, causing the resistance to decrease. By measuring the voltage output, a relationship between force and voltage can be determined. The sensing area of the HR Mat used is approximately 1.5 m in length and 0.45 m in width and is only 10 mm thick. It should be experimentally determined, however, that this sensor fulfills the established design criteria.

Fulfillment of Design Criteria

The first criterion stated that the sensor needed to be portable. The Tekscan HR Mat weighs less than 10 kgs and can easily be transported in a vehicle and carried by one person. The HR Mat can be assembled without difficulty to record the data and dis-
assembled quickly afterwards. Each sensor has two ports, which connect to a hub, meaning that each sensor has one hub. Each of these hubs connects to a computer with the Tekscan software installed via a USB connection to be used. In this sense, the pressure mat is easily portable and can be quickly assembled and disassembled for each use.

The second established criterion was that the sensor needed to record a full gait cycle, and to do so, the sensor needed to record at least 1.3 m. This would provide force data for each of the four limbs as the subject walked across the mat. The length of the HR Mat was 1.5, which was greater than the minimum 1.3 m. This allowed force data to be obtained from each of the four limbs for each pass or to record static data with the subject standing on the mat. In addition, a second limb strike could be obtained, which allows for calculation of stride length and the time for a gait cycle.

The third requirement was that the sensor needed to be able to record force data before and after amputation. This is accomplished without difficulty as it can be assembled for use before and amputation without any limitations, allowing for an easy comparison.

The fourth requirement for the sensor was the need for little to no training of the animals while the fifth was that the subjects needed to easily walk on it. These two requirements were necessary to minimize the amount of time needed to train the animals before amputation, and also to reduce the amount of time for each trial recording. The HR Mat is thin, allowing the animals to ambulate freely across the sensor without any changes in their gait. However, there was an issue with the surface of the sensor being too smooth, which could have been potentially harmful to the subjects if they slipped on it. As well, there needed to be a way of protecting the sensors from getting wet or torn
from the hooves of the subjects. To accomplish this, a thin outdoor carpet was placed over the sensor. This prevented the sheep from slipping and protected the sensors from damage, while not hindering the resolution of the Tekscan HR Mat system, as seen when discussing the accuracy of the sensor. Although, this helped the sheep to walk across it easily without changing their gait, there needed to be a way of forcing the animals to walk on the mat without much training.

This was accomplished by developing an enclosure for the animals to walk through (Figure 1). This encouraged the sheep to walk on the mat and continue around the enclosure. The first design was a hexagonal shape made of a PVC frame with walls
made of shade cloth. The HR mat was then placed along one of the longer sections of the enclosure to measure GRFs. However, this design proved to be insufficient as it was too light and not robust enough and would not hold up throughout the course of the study. More durable designs were then explored and an elliptical metal walkway was made. This walkway was approximately 4 m in width and 10 m in length, and 1 m in height, while the path in the enclosure was 0.6 m in width. The length of the walkway allowed the sheep to ambulate at a comfortable pace with full stride lengths while the narrowness of the path forced the subjects to walk in one direction without being able to turn around. The mat was then placed at the end of one the long sections of the enclosure.

The final requirement was that the sensor needed to provide quantitative accurate data with an average error less than 5%. It has been stated that there are force differences between force plates and pressure sensing walkways (PSW); however, the PSWs are consistent and could be used to compare forces overtime with subjects [51]. To test the accuracy, it was determined that the HR Mat should be tested against a force plate, the standard for ground reaction force testing. The HR Mat was placed on top of a force plate at the Movement Analysis Lab at Shriners Hospital, Salt Lake City (Figure 2).

The HR Mat was calibrated using a standing calibration, where an individual uses their body weight for calibration and stands on one limb on the sensor. An individual first stood on the force plate and the body weight was measured. This force was the value that was used for the calibration of the Tekscan system, with each sensor in the HR Mat being calibrated individually to balance the mat. The individual then walked across the HR Mat/force plate combination while data were collected from both. The
Figure 2—Diagram of the Tekscan HR Mat lain on top of the force plate at the Movement Analysis Lab at Shriners Hospital (Salt Lake City) to test the accuracy for the peak vertical force (PVF) of the HR Mat to the force plate.

The force plate recorded at 100 Hz while the Tekscan recorded at 30 Hz, the frequency to be used in the study. The peak vertical force (PVF) data were then compared between the two devices for a total of 10 foot strikes.

A graphical representation between the HR Mat and force plate for one foot strike is seen in Figure 3. Notice the linear relationship between the two ($R^2 = 0.979$). The average PVF error was determined by calculating the percent difference between the PVF from the Tekscan and the PVF from the force plate for all ten foot strikes, yielding the average error as $1.53\% \pm 5.1\%$ (95% Confidence Interval). Only the vertical forces were compared as the HR Mat records forces only in the vertical direction, unlike the force plate that measures forces in all three directions. However, this was not deemed to be a disadvantage for the HR Mat as vertical forces are the most studied [7], while the craniocaudal and mediolateral forces are rarely studied or reported in veteri-
Figure 3—Plot demonstrating the linear relationship between the vertical forces of the force plate and the Tekscan HR Mat for one foot strike. The $R^2$ value equal to 0.979, meaning that there is a very good correlation between the two.

nary research [51]. However, the percent difference for all three directions was also considered to justify only using the vertical direction.

The forces in all three directions from the force plate were summed together giving the magnitude of the force vector at each time when the PVF was obtained per foot strike. The percent difference was then determined by comparing the Tekscan PVF with the magnitude of the force vector, doing so gave a percent difference of $0.97\% \pm 5.02\%$, which was more accurate than just comparing the PVFs. The HR Mat was therefore deemed to provide accurate quantitative data, meaning that the HR Mat fulfilled all of the necessary design criteria that were established, providing an average error less than 5%, established in the design criteria.
In addition to fulfillment of the design criteria, Tekscan’s pressure sensitive walkways have been used with several animal models, such as cats [52], dogs [51], cows [53], and horses [54], indicating that the mat would be able to withstand the forces from the animals throughout the course of the study. This makes the Tekscan HR Mat more appealing for use in the percutaneous, osseointegrated ovine model. As well, the HR Mat can be used in conjunction with a digital camcorder, synchronizing the pressure mapping data from the pressure mat with video images of the subjects. This is a valuable tool in data collection as it can help differentiate which limb strike on the HR Mat corresponds to which limb of the subject, ensuring that data are analyzed correctly.

Another benefit is that any area of the mat can be analyzed individually without analyzing the whole mat. This means that individual foot strikes can be evaluated, minimizing the amount of times the sheep have to walk across the mat. The HR Mat also has a benefit in allowing for length to be measured at different points of the mat. This means that parameters such as stride length could be measured by only using the pressure mat. Time spent on the limb and time for a gait cycle can also be determined as each video recording is timed. Both the stride length and the time of different phases of the gait cycle can provide valuable information in assessing an individual’s gait cycle. However, one drawback to the HR Mat is that each video must be analyzed individually, meaning that analyzing data can be time consuming [51].

Calibration Methods

According to the user manual of the Tekscan HR Mat, three different methods can be used for calibration: a walking calibration, two-point calibration, and a step calibration. Each has benefits for different applications. The calibration is based on pres-
sures and as such, it is recommended that an area similar to that to be used in actual trial be used, meaning for this application, an area similar to that of a sheep's hoof should be used. However, with all three calibration methods, it is assumed that each sensel behaves in the same manner as the ones used in calibrating. The walking calibration is recommended for human subjects who will be walking across the mat. This method is performed by entering the subject's weight into the computer and walking across the mat during the calibration process. This method was not used as it is not beneficial for quadrupeds as different weights are applied to the forelimbs than the hindlimbs.

The second method, the two-point, calibration method is recommended for research applications as it uses two points to determine a polynomial fit to the data, ensuring greater accuracy than the other methods. However, this method is not practical in most applications, as an individual must stand on one limb with one force and then with a force three to four times that, which cannot be achieved since the sheep could not be trained to perform such a task.

The third method, the step calibration, was selected to use. This method is performed by entering an individual's weight into the computer and standing on a sensor for a few seconds. By standing on one foot, the area of the applied force is reduced and mimics more the actual trials, a procedure which has been recommended to increase accuracy [35]. The accuracy can be improved by performing the calibration procedure for each of the three sensors in the Tekscan HR Mat, balancing the walkway system.
CHAPTER 3

METHODS

Percutaneous, osseointegrated implants for patients with limb loss generally consist of a bone implant portion, a transcutaneous portion, and a Morse taper for exoprosthetic attachment. The bone implant portion inserts into the bone and encourages bone ingrowth, helping to transfer the load from the implant to the bone. The transcutaneous portion consists of a post coming through the skin, which transfers the load from the exoprosthetic to the bone implant portion. The transcutaneous portion is porous coated to help prevent infection by providing a seal. The post is connected to the bone implant portion by means of a porous coated subcutaneous collar. The exoprosthetic attaches by means of the Morse taper and is designed to support the weight applied to the residual limb and provide traction.

Prosthetic Design

The design of the implant is vital for the function of the implant as it will help to ensure infection prevention and proper bone integration, which helps with the transfer of the load from the bone to the implant [21]. An important part of the implant design is the materials used. Recent advances in antimicrobial strategies and materials used in implants allow for skin and bone ingrowth [37]. The implants used in this experiment were made of a pure titanium alloy and designed to be implanted into the intramedullary
canal of the third metacarpal of the ovine subjects. Commercially pure titanium was selected for its biocompatibility [37, 55]. A porous coating was used on the distal surface of the implant to allow skin and bone ingrowth (Figure 4).

Connected to the distal end of the implant is a Morse taper post. This post goes through the skin and threads into the exoprosthetic by means of a titanium connecting adapter. To restore limb length, the hoof piece height can be adjusted by means of metal washer spacers, which thread into the exoprosthetic hoof piece.

**Exoprosthesis Development**

The exoprosthetic hoof consists of a Delrin® core surrounded by polyurethane (PMC-870, Smooth-On, Inc., Easton, Pennsylvania). The Delrin®, or polyoxymethylene, was selected as it lightweight and commonly serves as a metal substitute due to its...
mechanical properties [56]. The use of Delrin® was important because the weight of
the final exoprosthesis was not to exceed 200 g. The polyurethane had a Shore A hard-
ess of 70, which was the desired criterion as it is the same Shore as most shoe soles.

The final exoprosthesis prototype is approximately 5.7 cm in length, accounting
for both the Delrin® core and the polyurethane and weighs approximately 80 g. The
final weight of the exoprosthetic with the adapter and washers was about 130 g, less
than the 200 g limit. The Delrin® core is threaded at the proximal end for 3 cm to allow
for height adjustment depending on the subject, and is about 3.8 cm in diameter and 4.5
cm in length with rounded edges at the distal end. The core also consists of oval inden-
tations 3 mm in depth, 12 mm in height, and 5 mm in width to allow for better attach-
ment of the polyurethane. The polyurethane starts 1.5 cm from the proximal portion of
the Delrin® core and is 4 mm in thickness around the core except at the distal end where
the polyurethane is approximately 1.2 cm in thickness with circular treads that are 3 mm
wide and 5 mm deep to allow for traction similar to that found on a crutch tip.

The original prototype consisted of a Delrin® core similar in design, but was 1.5
cm longer and was not rounded at the distal end, whereas the polyurethane was only 2
mm in thickness around the Delrin® core and did not consist or round treads. However,
this design failed as the Delrin® core cut through the polyurethane on the distal end.
This problem combined with the lack of treads on the distal end led to the subject slip-
ning. Another problem with this design was that the exoprosthesis was too long for
most subjects.

To mitigate these problems, another prototype was designed that consisted of
shaping the Delrin® core to allow a crutch tip to be inserted onto the distal end. A tread
design on the bottom of the crutch tip helped to provide traction, and hence prevented slipping, however, this design failed as the Delrin® core tore through the crutch tip, leaving the subjects walking on the slippery surface of the Delrin® core. Also, this design was too long for most of the subjects. This prototype was abandoned and the first prototype was modified.

To prevent the Delrin® core from cutting through the polyurethane, the thickness of the urethane was doubled and the distal edge of the Delrin® core was rounded. Then to provide traction, rounded treads were added to the polyurethane so that it would behave more like the crutch tip. The prototype was finalized by shortening the design by 1.5 cm.

Exoprosthesis Manufacturing

Once the design of the prototype was finalized, the exoprostheses were manufactured. To do this, a mold was created using a rapid prototype to make the exoprosthetics interchangeable. The mold had two holes on the outside to allow two mold attachments to lock into the mold. These pieces then fit into the indentations on the Delrin® core. This allowed for a uniform depth for each of the Delrin® cores, meaning the thickness of the polyurethane on the distal end of each exoprosthesis would be the same.

The first step in manufacturing the exoprosthetics was to spray the mold with a mold release (Universal Mold Release, Smooth-On Inc., Easton, PA). The polyurethane was prepared (Smooth-On Inc., Easton, PA) by mixing two portions of part A with one portion of part B. To make one exoprosthetic, 30 g of part A was mixed with 15 g of part B. The two portions were mixed together using smooth strokes to reduce bubbles, for 2-3 minutes, according to manufacturing specifications. The polyurethane was then
poured into the mold and the Delrin® core was inserted into the polyurethane. The mold attachments were then locked into the mold as well as the inserts in the Delrin® core. A bubble level was placed on top to ensure that the Delrin® core was completely vertical and to maintain a uniform polyurethane thickness.

**Amputation Procedure**

Prior to surgery, subjects went through a screening process to ensure they were healthy for surgery and also to ensure the third metacarpal, the target bone for implantation, would be large enough to accept one of the sizes of implants, done by radiograph. Once this was done, kinetic and some kinematic data (an explanation of how these data were obtained will be provided later) were obtained for all four limbs, providing a pre-operative reading, assumed to be normal gait for sheep.

At the time of surgery, the subjects were prepped and anesthetized. A skin flap was made on the anterior side of the right forelimb, taking care to preserve the blood supply of the skin. The third metacarpal was then removed at the distal end of the metaphyseal flare of the third metacarpal. The medullary canal was then reamed and the implant was pressed and tapped into place. Following this, a radiograph was taken of the implant to ensure proper positioning (Figure 5). The skin flap was put back in position and the exoprosthetic was attached (Figures 6 and 7).

Subjects were allowed to recover from anesthesia and bear weight on their amputated limb. The subjects were housed inside for 3 weeks following surgery with other subjects and then moved to an outside pen. Throughout the recovery process the wound was examined for infection, bandages changed, and radiographs taken to observe the bone-implant interface.
Figure 5— X-ray taken before surgery showing the 3rd metacarpal, dew claw, and phalanges of the hoof of the right forelimb (left) and an X-ray immediately after surgery of the 3rd metacarpal with the implant and exoprosthesis attached (right).

Figure 6— Image during the surgery showing the implantation of the titanium implant in the 3rd metacarpal.

Figure 7— Image 3 months after surgery showing the percutaneous post and attachment to the exoprosthesis.
In total 17 Columbus female sheep underwent amputation in anticipation that vertical GRFs and kinematic data would be measured for a total of 12 months. Thus far, forces have been measured 1 month, 2 months, 3 months, and 6 months following surgery.

Gait Measurements

Before each trial, the HR Mat was placed at the end of a straight section of the elliptical walkway to allow the subjects to ambulate using full gait cycles. After the HR Mat was in place, it was calibrated using the standing calibration method explained earlier. Upon completion of the calibration, the acquisition parameters were then set. The sensor was set at a sampling rate of 30 Hz. This frequency was chosen as it corresponded to the sampling rate of the digital camcorder, ensuring that one frame from the HR Mat matched one frame from the video recording, making sure that each limb strike was properly analyzed. There was a concern that measuring at 30 Hz was too low; however, subjects were walking through the enclosure, not running. As well, multiple passes are done for each subject, mitigating the possible error from the sampling rate.

Following the completion of these steps, a subject was brought into the walkway and encouraged to walk around the enclosure while video data were collected. Subjects walked around the walkway several times providing 4-7 good trials. After this, the subject was led out of the walkway and both the Tekscan video and digital video were saved for analysis later on. Video recordings were then obtained for other subjects.

Once video recordings were obtained, the data of interest were acquired. The data of interest were the peak vertical forces (PVFs), stride length, and stance phase as a percent gait cycle. To explain how the data were collected, some definitions should be
Peak vertical force (PVF) – is the highest ground reaction force in the vertical direction during a limb strike.

Stride length – is the distance between two successive hoof strikes from the same limb.

Stance phase – is the time from when the hoof first touches the ground to the time that the hoof pushes off, in other words, the time the hoof is on the ground.

Gait cycle – defined from when one hoof touches the ground to when that same hoof touches the ground again. A gait cycle is composed of two phases: stance phase and swing phase.

The PVF was obtained by going through each subject’s video. Once a limb strikes the Tekscan mat, that area of the mat can be selected by forming a box around that area (Figure 8). Then, going frame-by-frame, the forces can be analyzed until the peak force was found for each foot strike. An example of this analysis is provided in Table 2, in this example the force in frame 7 would be recorded as the PVF for that limb, a force of 600.3 Newtons.

Stride length was determined by using the line method of the Tekscan software. This allowed for one point of the line to be placed anywhere on the mat and the other end of the line to be placed at another location, the software then provides the distance of the line. Knowing this, the stride length was obtained by placing one end of the line where the heel of one limb first touches the mat while the other end of the line was placed where the heel of the same limb touches the mat for the second time. A pictorial display of this analysis is seen in Figure 9, the length recorded for this sample was 0.895 meters.

The stance phase as a percent gait cycle was determined by first recording the time when a limb first touches the ground, defined as T1. The time is provided by the
Figure 8—Graphical display of the Tekscan interface displaying three limb strikes and the graph of the forces for each limb strike. The arrows indicate where the time and forces are displayed.

Table 2—Table displaying how the PVF was determined for one hoof strike. A pictorial display of one hoof strike from the Tekscan mat (red indicates areas of higher pressure while blue indicates areas of lower pressure), the frame for the hoof strike, time during the video, and the force displayed from the Tekscan interface.

<table>
<thead>
<tr>
<th>Pictoral Display</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>5</th>
<th>7</th>
<th>9</th>
<th>11</th>
<th>13</th>
<th>14</th>
<th>15</th>
</tr>
</thead>
<tbody>
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<td>Frame</td>
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<td>30.99</td>
<td>31.03</td>
<td>31.09</td>
<td>31.16</td>
<td>31.23</td>
<td>31.29</td>
<td>31.36</td>
<td>31.39</td>
<td>31.43</td>
</tr>
<tr>
<td>Time (sec)</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Force (N)</td>
<td>14.2</td>
<td>216.8</td>
<td>421.7</td>
<td>549.6</td>
<td>600.3</td>
<td>532.6</td>
<td>437.1</td>
<td>250.3</td>
<td>101.7</td>
<td>0</td>
</tr>
</tbody>
</table>
Figure 9—Tekscan software display showing how stride length was determined. The top frame shows the first limb strike for the right forelimb while the bottom frame shows the second limb strike. A line can be drawn from any two points, giving the length. The length recorded for this limb would be 0.895 meters.

Tekscan software for each frame, much like the force data (Figure 8, previous page). The video was analyzed frame-by-frame until the limb came off the ground (defined as T2), starting the swing phase, this time was then recorded providing the time for stance phase by subtracting T1 from T2. Finally, a third time (T3) was recorded once the limb touches the ground a second time, allowing for the time of the gait cycle to be obtained by subtracting T1 from T3. The stance phase as a percent gait cycle was then obtained by dividing the time in stance phase by the time spent for a gait cycle.
**Reporting Peak Vertical Forces**

PVFs can be reported in several ways. One such way of reporting the data is simply to record the raw force data as read from the Tekscan software. However, in using the method, there would be a large variation between subjects due to the varying weights, making it hard to compare data between subjects. To make the data more comparable, a normalization method was used to report the data as a force per body weight, which was used initially for the preoperation data (Figure 10). To do this, the body weight was determined from the HR Mat during a static pass by the subject, when the subject was standing on the mat with all four limbs, the force from each limb was summed together to give the body weight.

With this normalization method, there was a large variation between the sub-

![Figure 10](image-url)

**Figure 10**—Graphical representation of the preoperation data for the four limbs, normalized using the subjects' body weight. This demonstrates there was no statistical difference between the forelimbs and the hindlimbs ($P = 0.253$, two-tailed Paired t-Test).
jects. This made it difficult to distinguish any difference between the forelimbs and hindlimbs (p-value of 0.253, based upon a two-tailed Paired t-Test). This large variation meant that decreases or increases in loading of the right forelimb would be difficult to determine following amputation and throughout the course of the study. However, other methods of recording PVFs have been used. Another method of recording force data was obtained, known as a peak vertical force ratio (PVF ratio). The PVF ratio is defined as the PVF of one limb in a gait cycle divided by the sum of the PVFs from all four limbs in a complete gait cycle. In equation form, this is:

\[
PVF\text{ Ratio } = \frac{PVF \text{ of limb of interest in one gait cycle}}{\text{Sum of the PVF from all 4 limbs in one gait cycle}}
\]

(1)

In an effort to create a database of kinetic and kinematic data for sheep, Kim et al. used this method and found that approximately 30% of the PVFs were on each forelimb and 20% on each hindlimb. Kim et al. also reported that these values were similar to those found in dogs and horses [50]. This PVF ratio was then applied to the preoperative data and provided a smaller deviation, making comparison between the forelimbs and hindlimbs more manageable (Figure 11). These data were comparable to the findings by Kim et al., giving a p-value of 0.989 between the two studies based upon a two-tailed Student t-Test.

**Reporting Data**

The stance phase as a percent gait cycle, stride length, and PVF ratio were obtained for each of the four limbs both pre- and postamputation. Preoperation data were analyzed first to determine any differences between the forelimbs and any differences between the hindlimbs. The postoperative data for stance phase as a percent gait cycle
and the stride length were analyzed to help determine how the subjects were compensating for the prosthetic limb. First, the postoperative data were compared to the preoperation condition; and then, the amputated limb (right forelimb) was compared to the left forelimb as a means of looking at a symmetrical gait.

The PVF ratio was used to calculate a percent difference from the postoperation data to the preoperation data. The right forelimb (the limb of interest) data are presented first followed by the other three limbs. A Noninferiority Test was also used for each limb to test for equivalency to the preoperation condition as a means of testing if the limb returned to preamputation conditions. The $A$ value used to characterize the preamputation condition was defined as the standard deviation from the preoperation PVF.
data. The rationale for using one standard deviation is that subjects within one standard deviation from the mean PVF data preamputation would be assumed to be normal, comprising 67% of the subjects if assumed to be Gaussian distributed.

For all comparisons between limbs before and after surgery, a Paired t-Test (parametric), a Wilcoxon Signed-Rank Test (nonparametric), and a Hochberg Multiple Comparison Test were used to determine differences between the limbs. A nonparametric test was explored as the sample size was small in this study (which is generally the case in orthopedics) while the Hochberg Multiple Comparison Test was investigated as multiple postoperative readings were compared to preoperative readings. Only the p-values from the Paired t-Test are included in the results as there was no difference between the tests regarding when data were significantly different. As well, the Paired t-Test was also more strict than the unparametric test. A two-tailed t-Test was used in all cases except for force data comparisons to preoperation conditions for the right and left forelimbs as it was assumed that the amputated limb would be loaded less following surgery while the left forelimb would be loaded more. Data are displayed in means and 95% confidence intervals.
CHAPTER 4

RESULTS

To date, a total of seventeen subjects have received preoperation data recordings, undergone surgery, and have 1-month postoperative readings. There are currently 14 subjects at the 2-month postoperative mark, 8 at the 3-month mark, and 3 at the 6-month mark. Data for one subject were not collected at the 3-month mark as the subject was sacrificed due to a problem with the skin flap, due to a decreased blood supply, and the subject was 'three-legged lame,' meaning that amputated limb with the prosthetic never made contact with the ground.

Stance Phase as a Percent Gait Cycle

Preoperatively, the stance phase for each limb was between 54-60% of the total gait cycle (Figure 12). There was a statistical difference between the forelimbs (p = 0.012) but not for the hindlimbs (p = 0.951). Following surgery, the stance phase as a percent gait cycle gradually increased by 22% at the 6-month recording for the amputated limb (Figure 13). A statistical difference was noted for the 3- and 6-month recordings. This increase in stance phase as a percent gait cycle was not subject to only the right forelimb but was also observed in the other three limbs (Figure 14). Following surgery, there was no difference between the forelimbs at any postoperative time point (Figure 15).
Figure 12—Stance phase as a percent gait cycle for all four limbs for the preoperation data (N=17). There was a statistical difference between the forelimbs (P = 0.012, two-tailed Paired t-Test) but not between the hindlimbs (P = 0.951, two-tailed Paired t-Test).

Figure 13—Graphical representation of the stance phase as a percent gait cycle for the amputated limb. This graph demonstrates that throughout the study, the time in stance phase of the amputated limb increased. P-values are based upon a two-tailed Paired t-Test.
Figure 14—This chart displays the general trend of increasing time in stance for all four limbs throughout the study.

Figure 15—Chart revealing the symmetry of the gait postoperatively for the percent of time spent in stance phase for the left and right forelimb. There was no statistical difference between the forelimbs postoperatively. P-values are based upon a two-tailed Paired t-Test.
**Stride Length**

The stride length was approximately 1 m for all four limbs preoperatively (Figure 16). There was no statistical difference between the forelimbs ($p = 0.788$) or hindlimbs ($p = 0.931$) preoperatively. For the amputated limb, the stride length decreased by approximately 6% at 6 months following surgery (Figure 17). The stride length was statistically significant for the third month following amputation. This decreased stride length was not subject to the amputated limb alone. The stride length of the other three limbs followed the same trend as the amputated limb (Figure 18). There was no difference between the forelimbs at any point (Figure 19).

![Graph showing stride length](image)

**Figure 16**—This figure displays the similarity in stride length between the two forelimbs and between the two hindlimbs preoperatively ($N = 17$). P-values are based upon a two-tailed Paired t-Test.
Figure 17—Graphical representation of the stride length for the amputated limb. The general trend is a decreased stride length throughout the study. P-values are based upon a two-tailed Paired t-Test.

Figure 18—This chart displays the decrease in stride length for all four limbs throughout the 6-month study.
Figure 19—This graph demonstrates the symmetry in gait between the left and right forelimb for the preoperation data and 1, 2, 3, and 6 months following amputation. There was no statistical difference between the two forelimbs for any time point (based upon a two-tailed Paired t-Test).

**Peak Vertical Force**

**Preoperatively**

The first data set to be analyzed was the preoperation data. Based upon the PVF ratio, the forelimb were loaded about 33% more than the hindlimbs (Figure 20). There was no statistical difference between the two forelimbs (p = 0.733) or the two hindlimbs (p = 0.152).

**Amputated Limb**

At 1 month following amputation, the prosthesis was loaded an average of 82.5% of the preoperative value, and remained near that value for the second month fol-
Figure 20—PVF ratios for all four limbs preoperatively (N = 17). This demonstrates that both forelimbs are loaded with similar loads and that both hindlimbs are loaded with similar loads. P-values based upon a two-tailed Paired t-Test.

Following surgery, the limb loading improved gradually to nearly 87% of normal, the preoperative condition (Figure 21). The first 3 months were found to be statistically significant with a p-value less than 0.001, based upon a one-tailed Paired t-Test. However, the p-value for the 6 month data was 0.075, indicating that the data might be significant. A Noninferiority Test further verified this as the first 3 months were inferior to the preoperation value while the 6-month reading was inconclusive (Figure 22).

Other Limbs

The left forelimb was loaded an average of 10% more for the first 3 months following surgery (Figure 23). At 6 months, the left forelimb was loaded approximately
Figure 21—Force on the right forelimb (amputated limb) as a percent difference of the preoperation condition. This shows that the amputated limb was loaded less after surgery for all time points except the 6-month mark. P-values represent a one-tailed (it was assumed the amputated limb would be loaded less following surgery) Paired t-Test.

Figure 22—Noninferiority plot for the right forelimb (amputated limb) for postoperative readings. The first three months the right forelimb was loaded less while at 6 months the data are inconclusive. The \( \Delta \) values are defined as the standard deviation of the preoperative data for the right forelimb. If at 1 year the lower bound of the 95% confidence interval is greater than \(-\Delta\), the noninferiority will be demonstrated at \( \alpha=0.05 \) level.
Figure 23—Force on the left forelimb as a percent difference of the preoperation condition. This plot shows the left forelimb was loaded more following surgery. P-values represent a one-tailed (it was assumed that the left forelimb would be loaded more following amputation) Paired t-Test.

20% of the preoperation value. All of the postoperation readings were significantly different. The Noninferiority Test indicates that the first 3 months were inconclusive, whereas at 6 months, the left forelimb was loaded more than the preoperation reading (Figure 24).

The left hindlimb was loaded an average of 10-15% more for the first 3 months after amputation and about 2% at 6 months (Figure 25). The first 2 months were statistically significant while months 3 and 6 were not. For the left hindlimb, the Noninferiority Test was inconclusive for all of the postoperation readings (Figure 26).

The right hindlimb was loaded about 2% more for the first 3 months following amputation and was loaded about 9% less at the 6-month recording with no statistical
Figure 24—Noninferiority plot for the left forelimb for the postoperative readings. The first three months are inconclusive while the 6-month mark demonstrates that the left forelimb is being loaded more. The $\Delta$ values are defined as the standard deviation of the preoperative data for the left forelimb. If at 1 year the upper bound of the 95% confidence interval is less than $+\Delta$, the noninferiority will be demonstrated at $\alpha=0.05$ level.

Figure 25—Force on the left hindlimb as a percent difference of the preoperation condition. The first 2 months there was a statistical difference while for 3-month and 6-month mark, there was no statistical difference when compared to preamputation loading. P-values represent a two-tailed Paired t-Test.
Figure 26—Noninferiority plot for the left hindlimb for the postoperative readings. This plot shows that the data are inconclusive for all time points. The Δ values are defined as the standard deviation of the preoperative data for the left hindlimb. If at 1 year the upper bound of the 95% confidence interval is less than +Δ, the noninferiority will be demonstrated at α=0.05 level.

difference for any postoperative reading (Figure 27). The Noninferiority Test demonstrated that there was no difference for the first 3 months following surgery while the 6-month recording is inconclusive (Figure 28).
Figure 27—Force on the right hindlimb as a percent difference of the preoperation condition. This plot demonstrates that there was no difference in loading from preamputation conditions for the right hindlimb. P-values represent a two-tailed Paired t-Test.

Figure 28—Noninferiority plot for the right hindlimb for the postoperative readings. This figure shows that there was no difference in loading for the first 3 months while the data are inconclusive for the 6-month time point. The $\Delta$ values are defined as the standard deviation of the preoperative data for the right hindlimb. If at 1 year the upper bound of the 95% confidence interval is less than $+\Delta$, the noninferiority will be demonstrated at $\alpha=0.05$ level.
 CHAPTER 5

DISCUSSION

Socket docking prosthetics are very useful in helping to restore amputees to pre-amputation conditions. Despite their benefits, there are limitations associated with them, mainly the fit of the prosthetic, residual limb length, residual limb pain, and skin sores [9, 12]. Often, these prosthetics can lead to pain in other locations as patients attempt to compensate for their amputated limb and, as such, gait analysis is often used to help amputees learn to walk with a more normal gait [7, 8, 17]. One possible alternative to socket prosthetics is osseointegrated implants.

Osseointegration has been in practice for several decades, originating with dental implants. Since that time, osseointegration has been used with facial prosthetics, hearing aids, and finger prosthetics [19]. Since the 1990s, osseointegrated prosthetics have been investigated for their use in upper and lower extremity prosthetics. These prosthetics would potentially alleviate some problems associated with socket prosthetics as the implant would directly load the bone, and prevent the loading and breakdown of residual soft-tissue, which contributes to some of the residual limb pain in amputees [13].

To help with the development of these prosthetics, an ovine model has been established to understand how these prosthetics would function in humans [33]. Ovine subjects were used as they are close to the same bodyweight as humans and also have bone structure that is favorable to implantation because of its similarities to humans [35-
38]. As a part of this study, histology and biomechanical data will be collected as will the limb loading. The loading of a limb can be an effective tool in evaluating the effectiveness of a prosthetic and can also help in creating a timetable for rehabilitation [7].

Therefore, the purpose of this study was to develop a system to measure limb loads in ovine subjects before and after amputation so that it could be used to evaluate the osseointegrated prosthetics. In addition to measuring limb loads, it was investigated whether recording stance phase as a percent gait cycle and stride length could also be used in prosthetic evaluation as these decreases in both of these parameters would be an indication of a limp.

**Tekscan HR Mat**

To measure these limb loads, several different methods were investigated, such as visual observation, a motion analysis set-up involving force plates, force treadmills, force sensing insoles, and load cells. Each of these methods has various advantages and disadvantages, and it became evident that the sensor must be selected carefully based on the intended purpose of the sensor. A design criterion was thus established based upon the intended ovine model.

The sensor selected was a pressure sensitive walkway (Tekscan HR Mat). This walkway was portable and could be set-up quickly before use and taken down easily after use. The mat could also record a full gait cycle of the subjects, which would reduce the amount of passes required for each subject and thus reduce the amount of time spent for recording and also provide forces from all four limbs during one gait cycle, making comparison between limbs easier. Also, the mat could record ground reaction forces before and after amputation, a necessary requirement to compare the prosthesis to
preamputation conditions. The mat was also used in conjunction with a metal elliptical walkway, ensuring the subjects would walk on the sensor, and would not have to be trained to walk on the mat, reducing the amount of time to collect the data.

The final requirement for the sensor was accuracy. Based on the comparison of the HR Mat to a force plate, the HR Mat was deemed to be accurate within 2%, which was better than the 5% established for the design criteria; however, the HR Mats accuracy is based on pressure. This validation ensured that data obtained from the hooves and exoprostheses were accurate.

The HR Mat also allowed for some kinematic data to be determined for each limb strike. The time spent on the limb could easily be obtained in addition to the time for one gait cycle. This made it possible to calculate the stance phase as a percent gait cycle. As well, the distance between two points on the mat was easily obtained making it possible to measure stride length. Both of these variables can give insight into whether a subject is limping or not.

**Measuring Limb Loads and Kinematic Variables**

To date, 17 ovine subjects were walked across the HR Mat in the metal walkway while forces and kinematic data were obtained from each of the limbs. These subjects then had their right forelimbs amputated and were fit with a titanium implant in their third metacarpal [33]. The data were then recorded 1 month, 2 months, 3 months, and 6 months following amputation.

Based on a PVF ratio, it was determined that each forelimb of the subjects had approximately 30% of the total PVF from a gait cycle while the hindlimbs had approximately 20% each. This was consistent to what has been recorded in the literature [50].
One month after surgery, the right forelimb was loaded at approximately 82.5% of the preoperative value. Over the next several months, this value rose to approximately 87% of normal. Based upon the Noninferiority Test, the first 3 months were loaded less than the preoperation value while the 6-month mark was inconclusive. The subjects compensated for the amputated limb by distributing more load to the other limbs, primarily the left forelimb and left hindlimb.

For stance phase as a percent gait cycle, there was a statistical difference between the forelimbs but not for the hindlimbs preoperatively. However, there was no difference for stride length before surgery for either the forelimb or hindlimb. Following surgery, the stance phase as a percent gait cycle increased every month while the stride length decreased every month; however, this was not observed for the amputated limb only, this same trend was seen in all of the limbs. A limp is characterized by a decrease in stride length and an increase in stance phase as a percent gait cycle. The stride length decreased with time, indicating a limp; however, the increase in stance phase as a percent gait cycle is not characteristic of a limp.

For this reason, the two forelimbs were compared together to determine if a limp was present, as it can be assumed with a limp for the right forelimb, the subject would be compensating with the left forelimb, and as such, there would be a difference between the stance phase as a percent gait cycle and stride length between the two forelimbs. Doing this comparison, it was determined that there was no difference between the forelimbs at any of the postoperative readings for the stance phase as a percent gait cycle or stride length, meaning that the forelimbs were behaving in the same manner. As such, the amputated limb was not affecting the subjects enough to change their kine-
matic parameters with their nonamputated limb to compensate for pain or discomfort. However, this does not explain the increase in stance phase as a percent gait cycle and decrease in stride length observed over the 6 months following surgery.

One possible explanation for this is the subjects became more use to the procedure of measuring gait parameters and were walking with a more ‘relaxed’ or slower gait cycle. Subjects had spent the majority of their life in the field, and therefore were not use to human contact. This could have attributed to the subjects being more anxious during the preoperation reading, which would make the subjects ambulate with an increased pace. This means the subjects would take longer strides and would spend less time on their limb. This anxious gait could also explain the statistical difference for the stance phase as a percent gait cycle between the left and right forelimb before surgery. This could be verified by having nonamputated sheep undergo the same gait analysis procedure at the same time intervals as the amputated sheep. If this is the case, it would be recommended that subjects be given more time to adjust to their environment before gait data are recorded.

There is also the explanation of a small sample size for stance phase as a percent gait cycle and stride length. These variables could only be obtained about half of the passes for each limb. Meaning that if six passes were performed, stance phase as a percent gait cycle and stride length could be obtained three times for the left limbs and three times for the right limbs.

Conclusions

Based on these results the selected system is deemed to be able to measure limb loads to evaluate the prosthetic and can be used to establish a rehabilitation timeline for
subjects with osseointegrated prosthetics to determine when amputees return to preamputation conditions. The stance phase as a percent gait cycle and stride length can also be used to assess prosthetic performance if the amputated limb is compared to the contralateral limb at each time point. However, if the amputated limb is compared to its preoperative value it is unclear as to whether a limp is observed as stance phase as a percent gait cycle increases and stride length decreases. In either case, the Tekscan HR Mat was used primarily for its ability to measure forces, not kinematic variables. More investigation should be done regarding the accuracy of the stride length and the time from the mat.

The findings of this study indicate that the force data can be a valuable tool in evaluating a prostheses. The force data can also be used with various exoprosthetics that can increase or decrease the load on the implant, giving an indication as to what forces provide for optimal bone ingrowth. This information is not only valuable to osseointegrated prosthetics but for total joint replacements as well. This experimental setup could be used to determine lameness in quadrupeds that could not be determined by visual observation. As well, this method can be applied to other surgical protocols to evaluate surgical outcomes and formulate rehabilitation timelines.

The rehabilitation timeline established by measuring forces and kinematic data in the 12-month ovine study may help to evaluate the effectiveness of the prosthesis. As well, the timeline established may help indicate lameness in subjects and possible problems with the implant. This, combined with the biomechanical testing and histology can provide valuable insight as to what might be expected in a human model for subjects with percutaneous, osseointegrated prosthetics.
REFERENCES


