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A study of the parameters and stipulations involved in the design of prosthetic limb socket liners

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ABSTRACT

A STUDY OF THE PARAMETERS AND STIPULATIONS INVOLVED IN THE DESIGN OF PROSTHETIC LIMB SOCKET LINERS

by
Sally F. Shady

The objective of this thesis is to illustrate the parameters that define and characterize the elements necessary for an optimal prosthetic socket interface design. Previous studies have revealed that the industry is manufacturing materials that are causing irregularities in gait patterns and causing major discomfort for transtibial amputees. As a result, chances for recovery and rehabilitation of many patients have been greatly reduced.

This study has indicated that the success of a socket liner depends on quantitative and qualitative factors that assess the overall efficacy of an artificial limb. Quantitative analysis is observed through calculations and deviations in gait cycles, and therefore distortions in patterns will determine the overall performance of the prosthesis numerically. The qualitative aspect covers the significance of the residual limb. Based on these two fundamental criteria, it has been concluded that socket interface materials must contain the following characteristics: excellent mechanical properties (to withstand the various impacts and loads), flexibility (to adjust to variations in motion), biocompatibility (for prevention of reactions), porosity (to reduce irritations and sores), and functionality (to maintain normality in the amputees gait cycle). Furthermore, additional research was conducted to present and prove polyvinyl chloride (PVC) foam is a material that possesses such requirements.

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A STUDY OF THE PARAMETERS AND STIPULATIONS INVOLVED IN THE DESIGN OF PROSTHETIC LIMB SOCKET LINERS

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This thesis is dedicated to my loving and supportive parents
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CHAPTER 1

INTRODUCTION

Being afflicted with an amputation can be one of the most traumatizing experiences a person will ever have to endure. The emotional and physical pain is incomprehensible but is existent upon three million amputees currently living in the United States. Nearly three thousand amputations (http://www.prs-research.org/PRS_Web/links/gam/gam.html, p 2) are performed each week and once the actual procedure is completed, amputees are faced with several frustrating dilemmas. They must first be able to accept the fact that they have permanently lost an integral part of their body and later must become accustomed to living with an artificial replacement. Part of the challenge of being an amputee is the entire rehabilitation process and the ability to resume a normal and healthy life. By observing and researching the amputee population in greater depths, the need for better prosthetic limb reconstruction has become of extreme importance. Patients must learn to utilize a new mechanism into their daily active lives but the industry is manufacturing limbs that are lacking important qualities. With transtibial amputees, poor prosthetic development has caused alterations within walking patterns. Observing such findings has opted the need for in depth research of factors that make successful prosthetics.

In order to begin the actual examination process, it is essential to explore the most popular prosthetics available amongst the current market. Evaluating and identifying a common disadvantage existing between each limb can propose an enhancement to the prosthesis. In the next section, literature reviews are presented to illustrate some of the basic components involved in the assembly of prosthetics and the more minute areas that need better enhancements. In this study, the socket liner material has proven to be the most vital and integral part of the entire prosthesis. It is the portion of the design that actually interacts closely with the body because it is faced with the task of dispersing bodily forces uniformly without imposing on the comfort of the amputee. Transmission of frictional and shear forces are critical in the ability to produce minimal deviating gait patterns. This is the minimal requirement for the legitimate efficiency of any liner material, and studies have indicated that current products are not up to par. Assessing the quality of these materials heightens the need for an alternative. However, before such an innovation can be presented, the quantitative and qualitative measurements of an optimal socket liner must be introduced.

The quantitative measurements of prosthetic socket liners are basically determined through gait analysis. Measurements of gait cycles determine the exact area where an amputee may be witnessing any discrepancies or alterations in their ability to acquire smooth mobility and energy expenditure. Analysis of stride dimensions and other kinematical parameters allow researchers to compare with normalized data of non-amputees. Certain factors such as the person's age, height and weight are considered when evaluating existing deviations in gait patterns. Gait analysis allows numerical calculations to be drawn about the model, but does not cover the qualitative aspects that may exist.

Examination of quality encompasses a wide spectrum of areas that must be addressed to pinpoint significant areas such as the wound site. The health of the residual limb is one of the major problems being faced during the actual recovery process of the patient. Wound healing is of extreme importance due to the possibilities of infections and skin irritations. Once the healing process after surgery is complete, the stump is still prone to irritability during the actual usage of the artificial limb. Forces from the thigh corset, the weight of the body and minute areas of spacing are directed and pressed toward the residual limb, in turn causing incidents of pain and discomfort.

Cosmesis is another characteristic that lacks eminence and is currently a major problem for many transtibial and tranfemoral amputees (See Appendix). Poor cosmetic design has influenced the functionality and psychology of many patients. When cosmesis is portrayed through unreliable materials, instances of failure can occur, therefore, causing loose components that interfere with other parts of the prosthesis. Additionally, cases of sores, rashes and skin ulcers are being presented as a result of such insufficient mechanical construction.

Within the next few sections, the current market will be thoroughly to provide the basis and proof that successful prosthetics can be produced if certain factors are kept in mind. A basic overview of the available limbs is introduced along with some of the existing disadvantages. Analysis of a study regarding current prosthetics used by most patients has led to several conclusions. First, socket designs should be a major concern for any given prosthetic limb. The socket has proven to be a vital area that withstands and distributes weight to establish sufficient mobility. Secondly by reaching such a conclusion, further investigation into the socket industry assess the fact that socket-lining materials are constantly being replaced. Poor materials are not only causing mechanical breakdown but skin abrasions as well. As a result, patients will have difficulty walking and delay the entire recovery process. Before introducing enhancements to alleviate such problems, it is essential to identify these concerns and produce standards for ideal characteristics.

1.1 Literature Review: Available Prosthetic Limbs and Their Components

The main objective of this section is to introduce the basic prosthetic limbs that are available to amputees in the current market. The industry manufactures several types of limbs with variations in strength, activity and overall performance. By discussing the advantages and disadvantages of these products, an area of re-design can be applied to ameliorate some of the existing problems.

After enduring a traumatic amputation, patients are faced with the dilemma of deciding which prosthesis would best suit their needs. There are many prosthetic limbs available on the market and the purchasing process can sometimes prove to be very overwhelming. For the elderly, such an experience can be extremely difficult due to their existing health status. One of the decisions that must be established when purchasing a prosthetic foot is whether the foot falls in the category of non-articulated or articulated. The major difference between the two is the non-articulated foot does not allow movement of the ankle, while the articulated foot allows rotational mobility.

Currently, many non-articulated feet exist within the market. For instance, there is the Sach Foot, Seattle Foot, Carbon Copy II, and Flex Foot. The Sach Foot is a molded heel cushion made of high-density foam rubber, which forms the foot and ankle into one, component. It offers the following advantages: lightweight, good absorption of ground reaction forces, no moving parts (thus no maintenance), no noise during regular activity, and more stability than articulated assemblies. However, some disadvantages are: no adjustment of plantar flexion/dorsiflexion, compression of the heel making inclines difficult, breakage of heel due to lack of wear resistance, and very limited energy storage.

The Seattle Foot is the first prosthetic to provide increased push-off capabilities. The heel is composed of energy storing plastic, which deflects during mid-stance to terminal-stance, thus, storing energy to provide "spring" during toe-off. Some of the advantages of the Seattle Foot is more dynamic response, more cosmetic, and is available in a lighter model (Seattle Lite). The disadvantages include increased cost, width, and prone to breakage in highly active amputees.

The Carbon Copy II is a solid non-articulated ankle with heel cushion that stimulates plantar flexion. The heel, in this case, is composed of a rigid block heel made of reinforced Kevlar and flexible anterior deflection plates made of carbon. Upon walking, energy return is provided by the thin primary deflection plate, which also simulates addition push-off for activities such as running. Advantages of this model are narrow shape, lightweight, and are cosmetic but not as detailed as the Seattle Foot. Although there lie many benefits in this design, the cost and availability only in adult sizes limit its use.

The final type of non-articulated foot is the Flex Foot. It is a lightweight graphite composite foot originally hand made from a computer-generated design specific to individual amputees. This is very useful because it has the greatest energy return of all dynamic response feet. Very little maintenance is required, it is lightweight, and is available in several variations for a wider variety of activities for specified amputee needs. Cost and cosmesis are its primary disadvantages.

Articulated prosthetics are subdivided into two categories: single axis and multiple axis. The single axis foot allows dorsiflexion and plantar flexion. In contrast, multiple axes permits lateral and rotary movement. There are several types of single axis models present. All allow 5-7 degrees of dorsiflexion and 15 degrees of plantar flexion. Due to the limitations of motion, no eversion or inversion is accepted. The basic advantages are that it allows for a greater response of movement than Sach, adjustable PF/DF, and may allow adjustment of heel height. While the benefits offered seem attractive at first, the single axis has many disadvantages. These include no mediolateral or transverse rotary motion, the moving parts may be noisy, wear of rubber bumpers can occur, heavier weight, less cosmetics than the Sach Foot, and it is only available in adult sizes.

Foot assemblies for the multiple axis models offer lateral and rotary movement for the uneven terrain as well as an adjustable plantarflexion. Mediolateral and torsion forces are reduced which allows for activities such as golf. Again, many disadvantages exist, which comprise the following: older models can be bulky, maintenance and adjustments are frequent, moving parts can become noisy, more expensive, they tend to be more heavier and are not as cosmetic as the single axis or Sach foot.

A general description of the available prosthetic feet indicates limitations and problems with these limbs. Researchers are constantly experiencing patients that are in constant need of re-fitting and re-alignment to produce better mobility with their prosthesis. Studies have been presented to designate that one significant area that must be considered is the actual weight acceptance capacity (Perry, 283).

1.1.1 Case Study: Comparison of Prosthetic Weight Acceptance in Transtibial Amputees Wearing the Single Axis, Seattle Lightfoot and the Flex Foot

As previously indicated, each prosthetic foot has unique characteristics that distinguish its capabilities. Some feet are more desirable because of their ability to produce better comfort, mobility, or cosmetic inclinations. Researchers tend to focus more attention on weight acceptance capacity in correlation with walking patterns. It is during the gait cycle, that the loading response challenges the stability of the patient's residual limb. This situation creates demands for a prosthesis that accepts the rapidly moving body weight in a manner that absorbs the shock off the floor contact and creates solidity for the patient to advance. When analyzing different scenarios, such as transtibial amputees, the knee and hip extensor muscles will only support stability during heel support. In addition, transtibial amputees have a greater usage of energy. In a study previously conducted by a research team, the mechanical causes of instability were analyzed in the Single Axis, Seattle Lightfoot and Flex Foot of transtibial amputees (Perry, 285).

In order to observe and measure the differences in each of these prosthetic feet, it was essential to conduct a specified experiment. The study included 10 male transtibial amputees (mean age = 62.4 range = 49 – 72) and 10 individuals (5 males and 5 females with a mean age = 51.1 and range = 34 – 67) without transtibial amputation. Each subject wore each foot for approximately one month prior to testing to become accustomed to the design.

The actual measuring procedure that was used to acquire the data involved several techniques. First, the gait cycle was recorded over a 10-meter walkway with six meters marked for data collection by photoelectric cells and each patient was analyzed over two trails. Secondly, the stride of the participants was measured using the Stride Analyzer

System, which was taped to the bottoms of each shoe. Next, the motion analysis was performed with a six-camera VICON system. Infrared strobe light and retro-reflective markers recorded motion about each joint in the lower extremity. Finally, the angular velocity of the foot, shank, and thigh segments were determined.

Once all of the data was obtained, it was necessary to analyze and draw relative conclusions. By observing the information closely, it was evident that the mechanics of each prosthetic foot dictated the stability available at the knee. For example, when amputees used the Single Axis Foot, they experienced tibial instability such that knee joint compliance was five times higher than normal. In the case of the Seattle Lightfoot and the Flex Foot, they tended to prolong the heel support. This caused instability and delayed forefoot contact, which resulted in reduced forward progression during the weight acceptance period of the stance phase. Perry concluded by stating that patients with transtibial amputations, need the "stability of timely foot flat support with limited knee flexion, a greater arc of functionally restrained plantar flexion would be required and a means of stimulating shank advancement to preserve forward momentum" (Perry, 288). This basically states that some of these prosthetic limbs are not measuring up with the ability to produce stable gait patterns. Therefore, it indicates a great deal of prosthetic failures occur at the region where weight acceptance is occurring the most, which is evident at the socket interface.

By arriving at this critical piece of information, further research in the socket liners was conducted. Consequently, it has been found that liners are typically composed of a compressible material, which moderates and allows the transmission of impact and shear forces from the prosthesis to the tissues of the patient's limb (http://www.oandp.com/organiza/aaop/jpo/12/1292.htm, p.1). These forces are of extreme importance because they initiate even distribution of pressure from the prosthesis to the residual limb as well as producing comfort to the patient.

> Achieving appropriate distribution of pressures at the residual limb-socket interface is critical for successful prosthetic fitting for, and rehabilitation of, transtibial amputees. Pressures placed on a residual limb in a prosthetic socket can contribute to tissue breakdown, discomfort, adventitious bursae, and poor function in transtibial amputees. Prolonged static pressure and shear, for example, are known causes of blood flow occlusion. (http://www.oandpnet.com/LINER.html, p. 2)

Additional findings have discovered that the socket liner will minimize shear forces experienced by the skin if a close fit is established, which will obtain limited knee flexion. Furthermore, incidences of re-fitting have occurred when patients gain or lose weight. The liners capability to adjust to fluctuating residual limb volume is key in interface design. Experience has shown that patients are much more comfortable and fitting problems are minimized when distal support is provided in the sockets. The actual material or liner being placed in the entire socket can achieve this type of advantage (http://www.adbiomech.com/pa92-2.html, p. 3)

Such research has indicated that the designing process will have to utilize this information and produce the most effective prosthesis possible. To be able to present an idea to enhance the weight acceptance, close fit and stability of amputees, further research will have to be assessed. The socket of the prosthesis has proven to be of great magnitude in force distribution, comfort and overall dynamic mobility. Evaluation of the interface being utilized by prosthetics manufacturers of the Seattle Foot, Sach Foot and Flex Foot, provides the ability to understand that this particular portion of the socket effects performance, which in turn, will allow enhanced functionality of the entire artificial limb during daily usage. This section has indicated the immense vitality of socket materials and in the following section explorations of interfaces used by the industry and the problems that have been witnessed will be discussed.

1.2 Available Socket Interfaces

The primary setback with the prosthetic socket liners currently available is the detrimental effect on the health of the residual limb and the inferior mechanical properties. The limb is being afflicted with sores, pimples and skin abrasions that are a result of the socket's material. In one type of liner, the material allows optimal fit but during daily practice, will produce wear on the residual limb. With other interfaces, the material will eventually be replaced due to poor mechanical properties.

In addition to selecting the foot that will provide stability, energy expenditure and lightweight, the patient must also be aware of the main issue of comfort. Comfort lies between the interface of the socket and the residual limb. Currently, the market manufactures three popular socket interfaces: the silicon suction socket (3S), the Pe-Lite and the TEC liner.

Socket design first began with the simplest type of components and applications. The open-end plug historically originated from carved wood, which was suspended by a leather thigh corset. The socket was open at the end, which does not provide total contact with the end of the stump. These are rarely used because the residual limb becomes exposed to distal edema due to the lack of distal contact. The 3S liner was fabricated over a mold (individually taken and modified) with silicone resins and reinforced nylon. This revolutionized socket interface is currently being used in various types of limbs and is favorable amongst many amputees for several reasons. In the next section a study was initiated to display the preference of transtibial amputees for the silicone suction socket (3S) verses the Pe-Lite liner (http://www.oandp.com/organzia/aaop/jpo/12/1292.htm, p 1). From this study and other sources, the silicone liner tends to obtain the most intimate and closest fit to the prosthesis. As a result, patients have established more control and proficiency with their prosthesis. In addition, to producing a better alignment, silicone's properties generally allow less perspiration to occur. However, excessive fit has caused detrimental effects on the health of the residual limb. Due to the tight fit of the prosthesis, patients are spending a long time putting on and taking off the limb. Consequently, the stump becomes highly irritated, therefore initiating discomfort during ambulation.

The next type of interface is composed of polyethylene closed-cell foam, known as Pelite, which fits between the residual limb and the socket. Many amputees also prefer this liner because of its comfort and cushioning. However, the main discrepancy with this type of liner is the lack of wear resistance. Many prosthetists have stated that the material will eventually have to be replaced within a year of usage. This is primarily from the shear and frictional forces that are produced by the prosthesis on the residual limb. It is this material that must endure and protect the stump from such high impacts. In chapter 3, the health of the wound site is emphasized due to its tremendous role in rehabilitation and prosthetic limb performance. With a material such as Pe-Lite, the mechanical properties are not sufficient enough to protect and withstand such great impacts. In chapter 4, a comparative analysis of the properties is explored in greater depths to illustrate the need for enhancements. In addition, to poor mechanical properties, the Pe-Lite insert has proved to be problematic in fitting the prosthesis with the residual limb (http://www.oandp.com/organzia/aaop/jpo/12/1292.htm, p 3). We have found that two layers of Pe-Lite are necessary for the distal end cap; otherwise, the distal end becomes extremely thin after the copolymer is formed over the insert (www.oandpnet.com/LINER.html, p. 1).

Next, the TEC liner is a thick polyurethane sleeve, which rolls on the residual limb. This particular liner provides better absorption of forces, therefore reducing skin breakdown. The stump does not experience the type of injury that the silicone suction socket presents due to the materials cushioning factor. With the TEC liner, the health of the residual limb is maintained. However, this only occurs if the material is durable and mechanically stable. The main disadvantage associated with TEC liners is again poor mechanical properties. Some liners have failed when the material is at excessive elongation, which primarily occurs if the socket is not properly aligned. Many amputees have reported their TEC liners as incompetent due to visible tearing. Most of these liners last about 6-8 months before having to be replaced. An amputee in rehabilitation will have to distinguish and identify whether it is their incapability or simply the material. Manufactures of the TEC liner have stated that the reason for these tears is the lack of distal contact being achieved by the residual limb. On the contrary, patients that have returned their liners due to tearing have witnessed bubbles where the cracks have initiated and began to propagate. The TEC liner is not the best selection for a liner due to its limitations on strength. Manufactures of this particular interface are working on improving the properties of material to decrease the number of complaints.

If sockets are not providing stability or comfort during mobility, then they are not meeting the demands of desired functionality. Functionality basically defines the ability to resume full activity and when analyzing issues such as the gait cycle, the need to enhance the socket becomes of extreme importance. Cases where gait patterns are distorted due to the lack of comfort and agility demonstrates the urge for new improvements within this area. For instance, observations of gait deviations are witnessed in:

- Decreased stance time caused by pain in the actual socket.
- Excessive lateral bending toward the prosthetic side during the stance phase occurs due to an abducted socket. Additionally, the lateral socket wall does not support the femur, therefore causing such a strain.
- Abducted Gait: prosthesis is held in abduction away from the midline throughout the gait cycle. This occurs due to the socket being aligned in abduction, which results in a wide base of support.
- Circumduction: Prosthesis is swung laterally in a wide arc during the swing phase. When the socket is inadequately suspended and aligned in abduction this type of deviation is likely to occur.
- Vaulting: Amputee rises on the toe of the stable foot during the swing phase due to inadequate socket suspension.
- Excessive Trunk Extension During Stance Phase: Exaggerated lumbar lordosis when the prosthesis is in the stance phase, trunk leans posteriorly, often seen in running, which is due to insufficient support from the anterior brim causing

anterior rotation of the pelvis

(http://www.prs_research.org/PRS_Web/links/gam/gam.html, p5).

Introducing the most popular liners being used by the Seattle Foot, Sach and Flex Foot, general disadvantages of these materials are presented as a primary concern. If these materials are posing as a threat to the ambulation of the patient, then this must be considered in designing a better socket interface. The socket interface of the prosthesis is hindering gait patterns and by observing this component in greater depths, the need for a better material becomes mandatory.

The current liners being utilized by the industry have presented us with the two disadvantages: hindrance to the residual limb and lack of mechanical strength. These two factors are the cause of irregularity in gait patterns, which greatly afflicts the amputees' ability to rehabilitate and resume daily activities. The main advantage of the 3S liner is the ability to provide superior fitting and comfort for the patient during usage. With the Pe-Lite foam, the cushioning factor of the material was admirable however, did not provide adequate durability. If a material can possess excellent cushioning for comfort and flexibility to establish proper fitting, while maintaining strengths at various loading, then optimality will be achieved. Within the next section, a study is presented to examine preferences of one type of liner over another.

1.2.1 Silicone Suction Socket (3S) verses Supracondylar Patellar Tendon Bearing (PTB) Socket with Pe-Lite Liner

In many literature reviews experiments were conducted to understand the differences in the quality of various types of sockets. In an experiment conducted by the Prosthetic

Research Study (PRS) the main objective was to obtain transtibial patients with severe skin breakdown and observe the comfort level of the Silicone Suction Socket (3S) verses the Pe-Lite Liners (http://www.oandp.com/organiza/aaop/jpo/83/8396.htm). In order to obtain this type of information, the study acquired 8 participants with a mean age of 41 years and a range of 24-62 years old. Six participants were male and two were female. The mean residual limb length measured from the proximal end of the tibia to the distal end of the tibia was 12.5 cm (range 11-15 cm). Many of the causes for amputation include: trauma (five patients), malignant tumor removals (two patients) and amputation secondary to congenital deformity (one patient). The study only included patients with sores or folliculitis and it was mandated that the skin problems had to be present for at least two months. The aim of the study was to obtain patients with severe skin breakdown and observe the comfort level of the silicone verses the Pe-Lite interface.

During the actual procedure four patients were randomly chosen to walk first with the 3S socket and the remaining four with the PTB socket. The subjects used each type of prosthesis for a duration of approximately 8 weeks. After using both prostheses, each amputee was asked to answer a questionnaire. The subjects were asked 11 questions about ambulation, eight about comfort of the residual limb during walking and standing, one about standing, cycling, bending the knee, five about walking on the stairs, hills grass, etc., one question about donning and doffing, perspiration, noise, two about sports and leisure, one pertaining to housekeeping and work. Once the data was collected, an assessment of the sockets was initiated.

From these questionnaires, the authors concluded that the silicone liner causes less perspiration but Pe-Liner was much more comfortable to the skin. Silicone has great incentives over other products for many obvious reasons. The actual composition of the material allows more patient comfort and sustained stability with their prosthesis. The silicone liner creates a negative atmospheric pressure and an adhesive bond to the skin so that it moves with the tissue. The amputee will generally feel that the socket is closely related to the actual limb. Additionally, the silicone liner has been documented to reduce friction, shear forces and perspiration at the residual limb. Although silicone has been widely accepted, it must be replaced for several reasons. Some amputees feel greater damage to the residual limb is exhibited during regular activities such as donning and doffing. Although the 3S socket liner is very comfortable to the skin during ambulation, the simple task of putting on and taking off the prosthesis becomes very difficult. The amputee is obtaining a close fit with the socket, which is ideal for alignment and mobility, but an extreme hindrance when trying to don or doff. Secondly, the Pe-Lite liner felt more comfortable to the skin than 3S, which is critical in maintenance of a healthy residual limb. If a particular liner is reproducing discomfort to the wound site, then some degree of immobility will be present. This study is illustrating that one of the most highly recommended liners being used by many patients is causing discomfort and skin breakdown to the residual limb. These two factors cannot be ignored because as a result, deviations in gait are produced from such cases.

Overall socket development is a complex and tedious process. However, can the successes of a prosthesis be obtained by evaluating quantitative and qualitative measurements within the socket? The answer to this question becomes very obvious and clear. The industry is manufacturing sockets that are not measuring up to certain standards. They are generating deviations in gait patterns, and causing some level of skin breakdown, which eventually takes a toll on the psychological well being of the individual. Interface construction is the key to developing more comfort and rapid rehabilitation rates for the typical amputee. It must be extracted from the advantages of the current products and redesigned to produce the best possible model. The main objective of any socket design should be attaining a material that will encompass better mechanical properties that eliminates failure and reduces residual limb deterioration. Exploring these products thoroughly has set forth certain standards that these materials must possess. It is evident that liners require greater compressive and tensile strengths to be able to withstand daily usage and decrease the number of failures being produced by these other materials each day. In addition to this particular quality, materials should demonstrate other provisions further discussed in the next section.

1.3 Objective

The main purpose of this thesis is to evaluate the steps that are involved in the assessment of developing an innovative socket liner material and present polyvinyl chloride as an alternative. Presently, the industry is producing several types of prosthetic limbs that are available for transtibial amputees. There is a wide selection of limbs presented to the consumer with various types of capabilities. Every prosthesis demonstrates a unique enhanced quality that may seem appealing to different lifestyles. Prosthetic limbs tend to encompass one of three types of liners: silicone, polyurethane or polyethylene. The problem with these liners is they are not durable enough for any type of patient. Whether the patient is highly active or practically immobile, the liner material will eventually be replaced.

By identifying the factors involved in what actually defines a successful prosthesis, optimization of current socket liner materials can be achieved. Once these quantitative and qualitative parameters are explored, a material known as polyvinyl chloride foam will be presented with the following stipulations:

A) Functionality. The socket interface should allow the amputee to demonstrate support, control, suspension and alignment. In turn, deviations in gait patterns will be minimized, therefore fulfilling quantitative expectancies.

B) Mechanical Properties. Transmission of shear, and friction forces throughout the residual limb. Must exhibit optimal endurance and low fatigue responses. This will establish minimal irritations that are produced from weak materials that deteriorate the condition of the residual limb. Economically, amputees will not have to replace their liners due to incidences of tear and wearability.

C) Biocompatibility. The point of contact between the skin and the socket must illustrate low immune responses to the material.

D) Porosity. The biomaterial will absorb moisture in closed and confined environments.

E) Flexibility. Adjusts to fluctuating volume changes. Patients are constantly gaining and losing weight, which must be accounted for. Additionally, a flexible material will provide excellent fit and cushioning.

1.4 Summary

In this particular chapter, the general prosthetic limbs currently utilized by the market were introduced and evaluated to understand some of the basic problems that are existent amongst the amputee population. As a result, many studies were developed to explore issues of abnormal gait patterns, discomfort and lack of rehabilitation. In an experiment conducted by Perry, it was concluded that weight acceptance was a major cause of distorted gait cycles, which are produced at a particular area. This specified region is the socket of the prosthesis, which is the primary interacting component between the wound and artificial limb. By identifying this integral element, further investigation of the socket led to several findings. First, many of the sockets presently used by patients are directly related to the deterioration in residual limb health, mechanical failure, and improper fitting of the entire prosthesis. Secondly, by having such disadvantages, amputees are less likely to walk properly, therefore decreasing chances of full recovery. By acquiring such information, it is essential to pinpoint what actually defines an optimal socket, present set requirements for socket designs and present an alternate material.

CHAPTER 2

THE QUANTITATIVE MEASUREMENT OF AN OPTIMAL SOCKET LINER

2.1 Introduction

As previously mentioned, the design of a socket liner can be one of the most tedious and difficult projects to endure. Almost every dynamic aspect must be taken into account when putting forth an idea. The most descriptive illustration of a prosthetic limb is obtained from understanding the fundamentals of the gait cycle. This cycle describes the elements that are involved in the actual manner or pattern of walking. In the process of modeling a socket design, gait analysis is one of the first criteria that will determine the success or failure of the material. If a transtibial amputee's gait pattern is disturbed due to poor design implementations, prosthetists and orthotists must return to the drawing board. Obtaining the most optimal gait pattern is the main goal in any enhanced prosthetic design and it is essential to understand what actually composes this entire process. Therefore, this chapter provides general background information of the gait cycle and the methodologies used to acquire such significant values.

2.2 Fundamentals of Gait Cycles: A Basic Overview

The gait cycle can be simply explained and defined as human walking. Human walking is a process of locomotion in which the erect moving body is supported first by one leg and then the other. As the moving body passes over the supporting leg, the other leg is swinging forward in preparation for its next support phase. The left or right foot is always on the ground and during that period, when the support of the body is transferred from the trailing to the leading leg, there is a brief period when both feet are on the ground. If a person walks faster, these periods of support become smaller and smaller.

A number of different disciplines use gait cycle analysis in their evaluations. The importance of gait is particularly essential in medical professions that deal with cerebral palsy, degenerative joint disease, amputation, poliomyelitis, multiple sclerosis, etc. By examining the pattern of walking, practitioners are able to pinpoint areas that need further augmentation. To assemble pertinent information, it is necessary to understand the components involved in the whole process. To discuss the gait cycle in more technical terms, the fundamental phases that make up the entire process must be described in greater depths.

2.2.1 Phases of Walking

The gait cycle is generally divided into two distinct phases (see Figure 1). The first phase is the stance phase. The stance phase is defined from the moment the heel contacts the floor to the time the toe pushes off. This particular sub-division of the gait cycle occupies more than half the duration of the entire cycle. It is the time period when both feet are in contact with the ground and when body support is being transferred from one foot to the other. During the swing phase, the foot is basically in the air and it is in the transition back to the stance phase. This stage only encompasses these general characteristics.

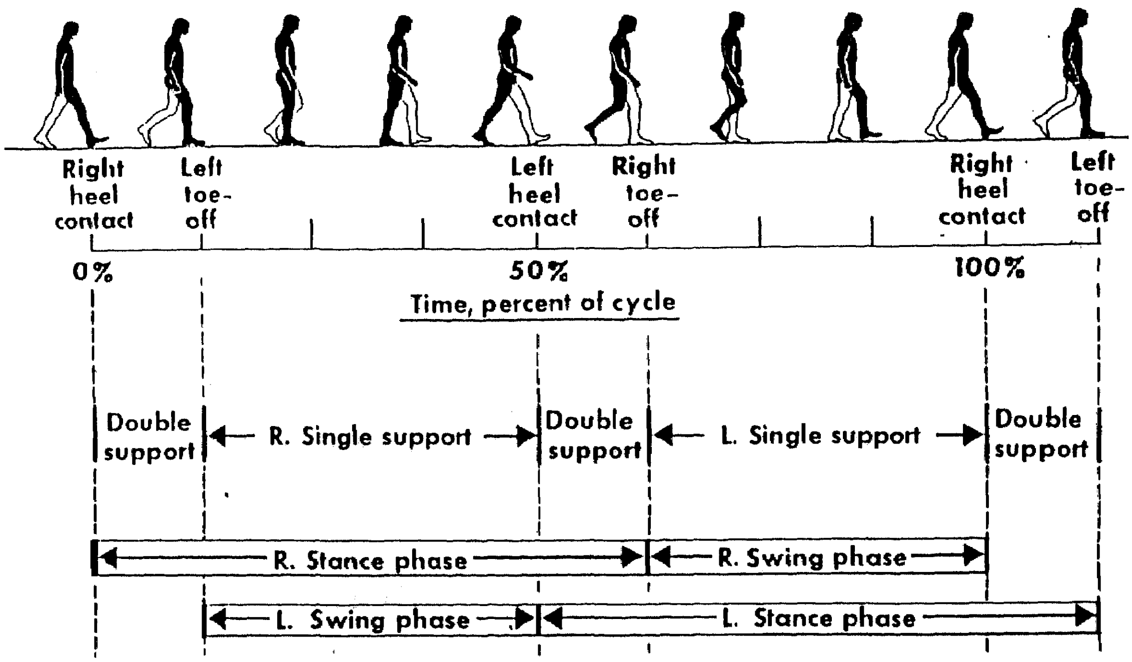

Figure 1: Gait Cycle Phases.
Source: Inman, Verne T., Henry J. Ralston, and Frank Todd. Human Walking. (Maryland: Waverly Press, Inc., 1982) p 28

2.3 Measurement Parameters

The gait cycle is "the period of time from the point of initial contact of the subject's foot with ground to next point of initial contact for that same limb". In order to measure the gait cycle in a more detailed manner, certain data must be acquired. Scientists are interested in these particular parameters to interpret the cycle descriptively and adequately. Such data includes:

- Static physical examination measures, such as passive joint range of motion, muscle strength and tone, and the presence and degree of bony deformity.
- Stride and temporal parameters, such as step length and walking velocity

- Segment and joint angular displacements commonly referred to as kinematics
- The forces and torque applied to the subject's foot by the ground, or ground reaction forces
- The reactive joint moments produced about the lower extremity joints by active and passive soft tissue forces as well as the associated mechanical power of the joint moment, collectively referred to as kinetics
- Indications of muscle activity during gait, i.e., voltage potentials produced by contracting muscles, known as dynamic electromyography (EMG)
- A videotape of the individual's gait trial for qualitative review and quality control purposes (Bronzino, p 528).

Before any of this data can be collected, certain testing protocols must be followed. Obtaining particular pieces of information, require steps that are administered prior and during the actual examination process (See Appendix A). Each parameter is acquired using various types of experimental approaches and systems. First, timing of the entire gait cycle starts from the initial contact and toe off phase. In order for this measurement to take place, the stride and temporal quantities must be computed. Foot switches are placed on the plantar aspect of the subject's foot over the bony prominences of the heel and in a specified configuration (depending on the information desired) on the metatarsals. The placement of the foot switches can be a challenging process because of the variability in foot deformities. To avoid this problem, many use video cameras to determine the timing of initial contact and toe-off events.

The second parameter that is measured is the motion measurement. This is the assessment of the body's spatial orientation. Motion can be analyzed by utilizing electrogoniometry, high-speed photography (cinefilm), accelerometry, and video-based digitizers.

Electrogoniometry: This device typically consists of a rotary potentiameter with fixed arms to the shaft and base for attachment to the extremity across the joint of interest. The advantages for using such a machine is the minute measurements of single-joint information can be collected. However, they are limited to the measurement of relative angles and can become somewhat cumbersome.

Cinefilm: This technique basically uses high-speed photography to measure a subjects' specified motion. It is not a very useful method for motion measurement because it requires digitizing each component individually, which can become very time consuming.

Accelerometry: Multiple transducers are placed on the area of interest. Multiaxis accelerometers can be used to measure linear and angular accelerations. Once this is obtained, the velocity and position can be derived.

Video-based digitizers: External markers are placed on the patient's body segments and aligned with a specific bony landmark. The trajectories produced by the subject's ambulation through a specific measurement volume are then monitored by a system of cameras (around two to seven). Stereophotogrammetric methods are then used to produce instantaneous three-dimensional coordinates of each marker.

These methods are used to assess motion relative to a certain portion of the body. Using force platforms, foot pressure distributions, and Dynamic Electromyography (EMG) ground reaction measurements can be calculated.

Force Platforms: They consist of force plates that are placed in the walkway of the subject with several strain gauges or piezoelectric sensor arrays that are rigidly mounted together. They provide significant information, which include: ground reaction forces, vertical torque, and the center of pressure force.

Foot Pressure Distributions: They use a flat two-dimensional array of piezoresisitive sensors. They are used to measure the dynamic distributed load that corresponds to the vertical ground reaction force.

Dynamic Electromyography (EMG): Voltage potentials are measured as the specified muscle contracts. Electrodes are placed the skin and small wires are inserted into the muscles. The EMG basically conveys the level activity of the muscle and the degree of intensity that is being exerted.

2.4 Normalization of Kinematical Dimensions

Individuals are depicted distinctively by their own specific stride pattern. Stride dimensions are typically altered and fluctuated based upon the person's particular leg length or body height. It is a cycle within itself that involves the right and left steps exhibited during walking. If each step dimension for both legs is equal, the gait sequence is defined as being symmetrical. Symmetry in this case, displays that each step induced by one is equivalent to the step taken by the other. The stride length portrays the amount of displacement exhibited during each gait cycle. Stride frequency defines the total amount of time used to travel this distance. Once obtaining these two parameters, the speed of walking can be determined. In other words, by means of basic physics, the $d = vt$ kinematics equation can be utilized.

The analysis of gait involves measurement and thorough assessment of these dimensions. However, once these parameters are readily obtained, the validity of the data becomes questioned based on relativity. When designing and modeling a prosthesis, researchers must have normalized data to compare the significance of the their output. To acquire a normalized method to establish information regarding an individuals gait pattern, a study was conducted. The experiment involved 20 subjects, which consisted of 2 women and 18 men. The aim of the study was to measure the relationship between stride length and step rate. The stride length was divided by the body height of each individual. This would inhibit any variations that occur from different human characteristics. Secondly, a recording of the step frequency was ensued to measure the rate of each step taken by the subjects. The results were then plotted and a straight line was fitted (see Figure 2).

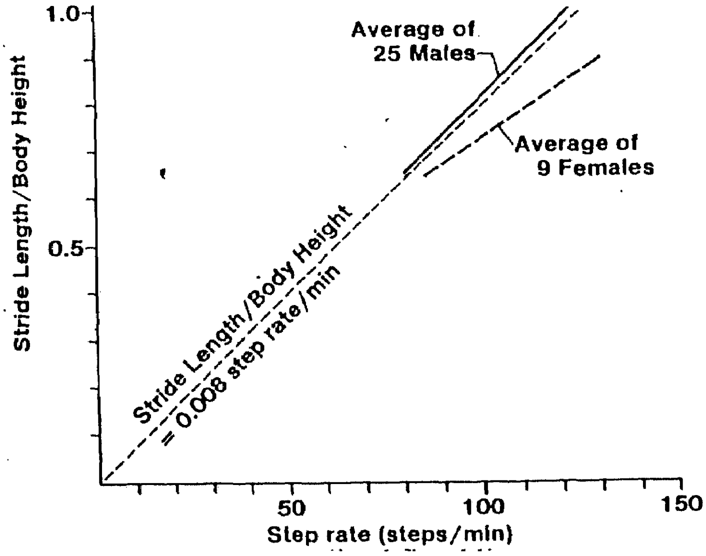

Figure 2: Normalized fitted line.
Source: Inman, Verne T., Henry J. Ralston, and Frank Todd. Human Walking. (Maryland: Waverly Press, Inc., 1982) p 34

From this data, an equation was derived which depicted the linear relationship between stride length and step frequency.

$$\frac{\text{Stride length / body height}}{\text{Step frequency / min}} = 0.008$$

This formula can be applied only as a reference point for male individuals because the subjects, contained in the study, were mostly men. Additionally, women typically tend to possess a shorter stride length, which would therefore make the slope of the graph less steep.

By conducting such an experiment, we will have a clearer picture of the certain goals that the design must meet. For instance, when implementing an innovative socket interface liner, gait analysis must be thoroughly investigated. Amputees are required to illustrate stride lengths and frequencies within these specified limits.

2.5 Innovations to Aid in Analysis

To eliminate the experimental factors that may produce illegitimate data, PRS has developed a Step Watch Gait Activity Monitor and the Portable Prosthesis Force Transducer. This device will measure the mobility of a patient outside of the laboratory. It is a small and lightweight mechanism that will record the steps a person takes each and every minute for up to a month. The data is then downloaded to a computer for interpretation and graphical representation. Figure 3 illustrates an example of typical patient data that was acquired by the Step Watch Gait Activity Monitor.

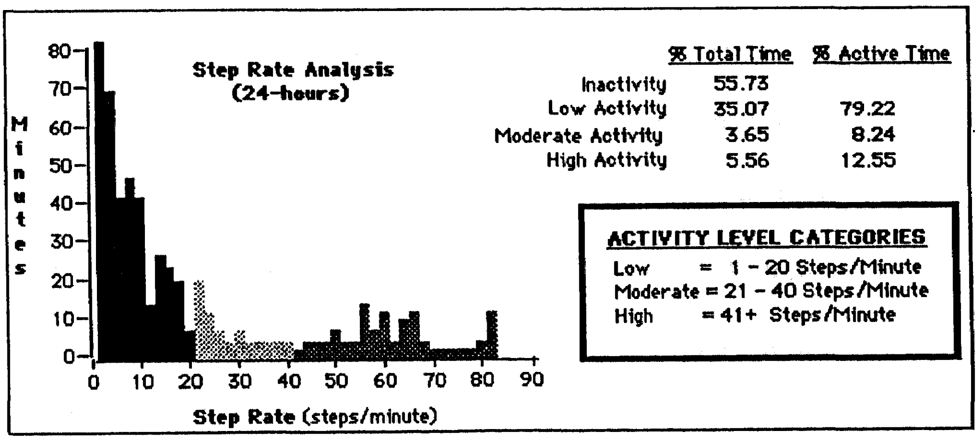

Figure 3: Graphical Data of the Step Watch Gait Activity Monitor.
Source: http://www.weber.u.washington.edu:80/~prs/links/ref/areas.research.html, p3

The Portable Prosthesis Force Transducer measures the forces between the shank and the socket of an endoskeletal lower limb prosthesis. This device has dimensions of (3 ¼ width x 3 ¼ length x ¾ thickness) and attaches to the shank and socket using a 4-bolt. The force measurements are transmitted by a radio link to a laptop computer for later analysis. The Portable Prosthesis Force Transducer is ideal because it provides more dimensional information than the traditional gait lab. The greatest advantage of this mechanism is that it is portable which allows measurements to be extracted in any location and terrain presented to the patient. These two devices are spectacular innovations that will allow further clinical research to take place.

2.6 Limitations in Gait Analysis

With all of the technological advancements being used to measure the physiological phenomena, precision is an important factor that may be overlooked. Error can arise from sources such as soft tissue displacements relative to bone and wrong estimated of other locations on the body. Additionally, errors can also be witnessed during the data collection procedure itself. For example, improperly placed makers on specified limbs can alter results and calculations that are to be developed. With this in mind, researchers must be aware that gait parameters must specify a limited numerical range for mistakes that can be made in future clinical trials.

2.7 Summary

This chapter has basically described all of the components that are involved in the assessment of an amputees gait cycle. By analyzing this element thoroughly, the practitioner is able to determine whether the patient is displaying complete functionality with their artificial limb. Normalized data demonstrates the range and degree of stability being achieved by the user. Static and dynamic evaluations allow a complete picture to be drawn about the progress of the amputee.

When introducing new materials for socket interfaces, such as polyvinyl chloride foam, the testing procedures discussed within this chapter will be applied to ensure functionality and efficacy has been achieved. Gait is part of the entire process of patient rehabilitation, because once a patient is able to walk properly, they can finally resume a happy and healthy life. Although gait analysis is of extreme importance, the next design parameter involved in socket lining optimality that must also be emphasized is the residual limb.

CHAPTER 3

THE QUALITATIVE MEASUREMENT OF AN OPTIMAL SOCKET LINER

3.1 What Makes a Prosthesis Successful?

When trying to improve the stature and general design components of a prosthesis, engineers, orthotists and prosthestist often focus their attention on energy storage, improving gait patterns or simply using materials with better mechanical properties. They neglect to consider other factors that affect the patient directly, emotionally or even cosmetically. The answer to a better invention may be in the most practical elements of the entire process. It is extremely vital to understand what actually happens to an amputee the day before and after surgery. If these professionals can actually map the life of such patients, they will be provided with an extremely different picture. They will be able to understand that there are other components that can realistically ameliorate the design and rehabilitate the patient more rapidly. Analyzing certain aspects such as: medical complications and healing rates of the residual limb, the psychological condition of the patient, and the general cosmesis of the prosthesis with its physical limitations, can open the door to new ideas. This thesis places great emphasis on the residual limb because it is the main component that is interacting with the prosthesis and by understanding all of the complications involved, the socket interface material can be further enhanced.

The first important element that must be addressed is the actual preparation of the wound site and the healing process that transpires. Wound healing is a very broad and complex process. It initially begins with the actual surgical procedure. The region that the surgeon decides to amputate is the most crucial part of the whole wound healing process.

It determines the amount of success that the patient will undergo six months to a year after surgery. For instance, the doctor is required to save as much of the knee as possible. If an amputation takes place below the knee relative to above the knee, the chances for that particular patient to rehabilitate is much more higher. Another significant area that is taken into account is the amount of post-surgical complications that can be witnessed. Preventative measures must be demonstrated to eliminate skin breakages, ulcers, pimples, and sores while the prosthesis is being utilized. Some patients do not exhibit proper recovery at the incision site or experience other difficulties. The next important aspect of wound healing is the actual rate of healing. The sooner a patient recovers, and is ready for fitting of their prosthesis, the faster they can start rehabilitation.

3.2 Stump Health

Why is wound healing of the stump of critical importance? The basic answer to this question is that it is the major interacting point with the socket liner itself. It is the driving force behind the success or failure of the entire systems utility. The residual limb must be prioriterized as the sole motivation behind a winning prosthesis.

The process of development first begins by monitoring the wound site from the day of surgery. Physicians use the most preventative measures to save as much of the limb as possible. This is of high importance because the recovery of the patient is greatly dependent on such an issue. Transtibial amputees have an overall greater advantage than transfemoral amputees in many areas. They demonstrate greater gait cycle velocities, use less energy and rehabilitate much quicker. New techniques are currently being developed to save as much of the knee as possible and prepare the stump for adequate healing. Dr. Burgess, a member of the Prosthetic Research Study, recently developed a system known as posterior flap surgery, which has been accepted worldwide. The main objective behind this method is to provide a functional residual limb muscle to acquire maximal stabilization during rehabilitation. This type of technique has increased the ease of prosthetic fitting and has allowed the patient to witness less pain. However, it is important to note, that this particular methodology of protecting the wound site does not completely prevent skin irritations once the prosthesis is put into daily practice.

Once the actual healing process begins, the skin at the wound site may be subjected to certain complications. The next few days after surgery, the residual limb does not remain the same. It shrinks, swells, experiences pimples, sores, infection, muscle cramps, and other skin afflictions. Recent techniques are being proposed to fight these specific problems. The most basic suggested procedure for combating such events is through medical contribution. Physicians have recommended keeping the skin clean and using an antibacterial regimental hygiene. For skin irritations and infection, Phisohex is prescribed to keep the skin at low bacterial counts. To decrease the pressure from the prosthesis a product called Second Skin is suggested. Second Skin is a thin (1/16 inch) piece of perforated silicone gel. It applies directly to the skin and adheres by its own viscosity. It eliminates the skin friction that results from usage of the prosthesis. Additionally, it allows the skin to breath and can actually promote healing at the stump site. These methods are idealistic for temporary relief, but do not diminish the problem from ever arising. Patients should not have to constantly pay for these medications and repeatedly be concerned about the progress of their residual wound site.

The second element of defense used to maintain the health of the stump involves enhancing the fit of the prosthesis itself. Practitioners feel that if they obtain the closest possible fit, less skin irritations will occur. They believe by reducing the amount of friction (between the stump and the prosthesis), which results in skin wear; the amputee will be in less discomfort. To fit the prosthesis to the patient, a prosthetist typically takes a plaster cast mold of the surface of the residual limb. The successful fit of a prosthesis is often dependent upon the experience of the prosthetist. If the prosthesis doesn't fit well, the artificial limb may cause discomfort or pain. Ultimately, the patient may refuse to wear the prosthesis, leading to a limitation in activities and the ability to perform activities of daily living. With this in mind, researchers at Washington University in St. Louis are using an imaging system, which may help improve the fitting of the artificial limb. CT scans are taken to obtain three-dimensional images of the patient's bones, muscles, and fat while the prosthesis is in a particular position. By using computer modeling techniques, investigators are able to observe how the prosthesis fits with the entire body. This is not the answer to reconstructing and implementing a better design. The prosthesis can illustrate excellent fit on the computer screen, but in reality be a complete disaster. The technological advancements of computer simulation cannot emulate the mundane activities each individual encounters daily.

Bioengineers have established the Controlled Environment Treatment (CET), which is another technique developed to improve residual limb health. This type of treatment aims at assisting and restoring soft tissue healing. CET measures the volume and edema alterations in the limb and actually controls the temperature and air in the atmosphere. By monitoring conditions of the air, the wound site will be able to heal at a quicker rate and bacterial growth will not be induced. This is just a few of the many studies conducted to provide researchers with information about wound healing rates. Although this procedure may seem appealing, it still does not restore or prevent skin irritations at the residual limb. This is the main element that is hindering the wound healing process. It is the actual complications that occur from the frictional forces that are being generated on the stump, as a result of a forceful material or a non-biological fragment. In order to examine this aspect more closely, it is essential to understand what is actually occurring at this particular location.

3.2.1 Stump vs. Socket

When an amputee uses their prosthesis, the stump ensures that transmission of body weight and prosthetic control is exhibited. Overstraining of the ligamentous structures of the knee by hyperextension under load can occur. To protect these ligaments, it is essential to maintain the forces and moments about the knee within safe limits. The factors that affect the contact pressures between the stump and the socket of a transtibial amputee are the fit of the socket and the alignment of the prosthesis itself. By obtaining these two important elements, the amputee should be able to: (1) control of knee-flexion from the time of heel contact until the foot reaches a stable position flat on the floor, (2) control of knee flexion extension during roll-over and (3) control of knee-flexion during the push-off phase as an aid in accelerating the prosthesis forward in the swing phase.

3.2.1.1 Forces Acting Upon Transtibial System In order to obtain the best possible picture of the relationship between the stump and the socket of the prosthesis, the physics must be thoroughly explored. The magnitudes of the forces that are exhibited are of extreme importance because they provide the amputee with maximal restoration of function and minimal gate deviation. If they can be calculated and accurately controlled, patients will be at a greater advantage.

Before actually determining the range of reasonable forces acting between the residual limb and the socket, it is critical to understand the entire phenomena. Figure 4 displays a transtibial amputee in the midstance phase. The directional forces show that left forces are forces on the amputee and the right forces are on the prosthesis.

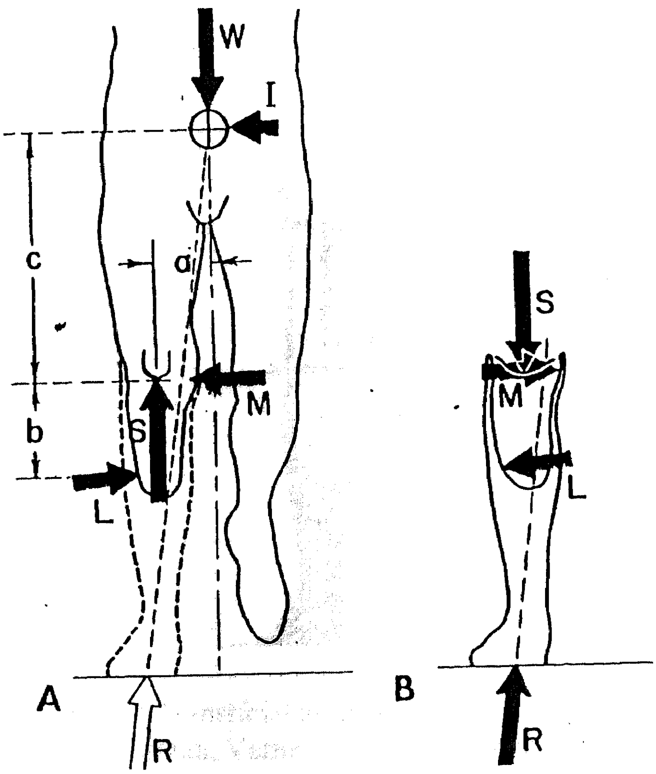

Figure 4: Forces being produced by the body and the prosthesis.
Source: Inman, Verne T., Henry J. Ralston, and Frank Todd. Human Walking. (Maryland: Waverly Press, Inc., 1982, p 134)

3.2.1.2 Derivation of Equations The prosthesis is considered to be a means of supporting the body both vertically and medialaterally. All of vertical forces displayed by the surface of the socket on the stump are a represented by S. The socket also places lateral forces L, while the floor exerts a normal force R with a medial inclination, which presents:

$$L\,b = W\,a \qquad (3.1)$$

However, this equation must be taken further. As indicated by Figure 5, the body is producing a horizontal acceleration, which in turn is opposed by a lateral inertia force.

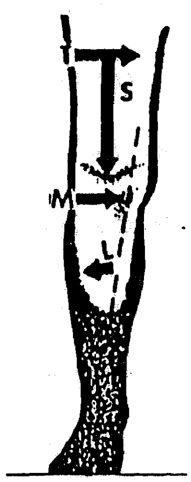

Figure 5: Transtibial amputee during midstance phase.
Source: Inman, Verne T., Henry J. Ralston, and Frank Todd. Human Walking. (Maryland: Waverly Press, Inc., 1982, p 134)

The inertial force must be considered when balancing moments about the point of support, therefore:

$$L = \frac{W\,a - I\,c}{b} \qquad (3.2)$$

Equation 3.2 demonstrates that L is a balancing force and can be reduced in two ways. First, by increasing the horizontal inertia force or increasing the lever arm b. To increase the inertial forces the foot should be moved laterally to increase the medial inclination R.

When observing the effect of the foot inset-outset on the mediolateral forces, the lateral stabilization force L is eliminated. This is the case because the weight and inertia are observed to be in balance:

$$W\,a = I\,c \qquad (3.3)$$

Figure 5 illustrates the effects of the thigh corset and sidebars on the pressures between the stump and socket. If the sidebars are stiff enough, it is possible to develop a thigh force T. This force acts in conjunction with the laterodistal socket force L to provide mediolateral stabilization. With the proper prosthetic fit, this force can be minimized. By properly adjusting the thigh corset, sidebars and other components, modification and control of the general pattern of forces between the stump and prosthesis can be achieved. Although alteration of the prosthetic fit seems to be the answer, the integral component lies in the material that is being utilized at that particular compartment.

3.3 Summary

Amputees encounter many problems at their wound site. The residual limb experiences incidences of skin irritations, lack of socket adjustability, and inadequate distribution of forces. A material that will provide the necessary requirements can improve these important aspects. For instance, many skin irritations are caused by the materials' inability to absorb moisture at high degrees of perspiration. This can only be obtained if the material contains the appropriate size and sufficient number of pores. Secondly, some materials are highly flexible when combined with the right type of resins. Flexibility will allow the residual limb to be able to fit into place with the entire prosthesis and establish uniformly distributed forces. Examining the significance of the stump has amplified the need for a material that possesses all of these qualities. As a result, such findings have led to investigating alternate materials. In chapter 4, polyvinyl chloride (PVC) foams have been proposed as materials that can fulfill these stipulations over any of the liners currently being manufactured.

CHAPTER 4:

PROPOSAL OF POLYVINYL CHLORIDE (PVC) FOAM AS A SOCKET LINER

4.1 Introduction

In prosthetic rehabilitation for the transtibial amputees, no consideration is more important than the socket, the vital interface between the human anatomy and artificial limb. (http://www.adbiomech.com/ps92-2.html, p 1) The socket is a key determinant of an amputee success at adapting to a prosthetic system. For optimal prosthetic performances and patient compliance, the socket must provide stability and facilitate motion, which cannot be achieved without a permissible interface liner.

The interface component illustrates its vitality in many instances. It is the force behind patient discomfort. Patients are not adapting to their sockets and, as a result, will experience failure in two of the factors that influence the prevalence of a particular material. Initially, discomfort is produced by mechanical failure of the material being used. Once the individual is not able to adjust to their limb, gait patterns are deviated and the stump begins to experience greater distress. The wound site constantly experiences trauma to such high extents that further breakdown becomes incomprehensible. If an amputee is witnessing discomfort from their prosthesis, chances of rehabilitation and acceptance of their newly replaced limb is very slim.

The market currently manufactures sockets that are hindering the rehabilitation process for the general amputee population. Common liners are designed from materials such as silicone, polyurethane and polyethylene. However, they are not the most favorable materials due to poor mechanical properties and irritation to the residual limb.

As a result, irregular gait cycle movements will inhibit patients from maintaining a legitimate source of mobility. If patients are demonstrating restricted patterns in their gait cycle they may be at high risks for injury. Some may experience fractures at other sites due to abnormal variations in their stance phase. These are important functional parameters that cannot be ignored. The industry is producing liners that are not reasonable for any type of patient. Silicone and polyethylene are demonstrating fatigue during excessive activities or daily common usage. These materials are not efficient enough both mechanically or biologically to withstand any amount of impact. Despite the obvious need for mechanical reconstruction, other characteristics are also mandatory for liners to achieve maximal acceptance. Absorption of moisture must clearly be witnessed in the interface liners due to variations in temperature and high degrees of perspiration. Factors such as flexibility and biocompatibility are also presented as integral elements necessary for a liner. It is essential to note that these are brief and general properties explored for this particular material. In order for a biomaterial to be presented to the Food Drug Administration, screening tests are first administered. These include the procedures mentioned in the next few sections, which portray general characteristics of the interface. Once the liner has passed such requirements, application tests are set forth to determine the overall validity and performance of the material.

4.2 Analysis of Pe-Lite Foam Liner (Polyethylene)

Before encountering the dilemma of obtaining a better material for socket lining, it is essential to study and investigate the materials that are currently being used most frequently. Manufacturers are presently distributing sockets that are composed of silicone and polyethylene. Other mixtures are also being utilized but the greatest demands are placed on these two materials. These liners possess certain characteristics that are vital for basic prosthetic function. It is of extreme importance to identify these qualities and try to enhance these properties by searching for a more optimal material. The main property that we are searching for is one that contains enhanced strength. Additionally, the material chosen must achieve other requirements that include functionality, flexibility, porosity, and biocompatibility. Before this is assessed, the disadvantages of current materials must be explored. The disadvantage of the silicone suction socket (3S) is the irritability produced by donning and doffing. Mechanical properties are not an issue with this particular liner. However, the Pe-Lite foam is more comfortable to the skin but displays weak mechanical strengths. Therefore, investigation of the polyethylene material must be explored and improvements should be presented.

Evaluating the mechanical capabilities of polyethylene foams, again it is evident that durability of the ideal material is not exhibited. Typically, this material is used in many liners because it contains outstanding impact absorption and compressibility, making it suitable for cushioning and padding. Polyethylene also provides impressive water absorption capabilities, which is necessary for maintaining a healthy residual limb in moist atmospheres. However, it lacks high compressive strengths, therefore declining optimal strength needed for loading that is placed during prosthetic application. As depicted by Table 1, the load deflection and tensile strength of the Pe-Lite foam is relatively low. These strengths are not sufficient enough to withstand shear frictional forces and should be greater to induce less incidences of failure.

Table 1: Mechanical Properties of Polyethylene Foams

Property	Value
Density, pcf	2.0 – 2.6
Load deflection, psi	
At 25% deflection	3 – 10
Tensile strength, psi	20 – 30
Water Absorption % by volume	0.5
Heat resistance, °F	160 –180

Source: Rosato, D.V. Plastic Foams: The Physics and Chemistry of Product Performance and Process Technology. (New York: John Wiley & Sons, Inc., 1969, p 335)

The Pe-Lite insert has proven to contain unique qualities that have been beneficial to the socket interface industry. Polyethylene foams possess excellent absorption properties while maintaining comfort for the residual limb. However, they are still lacking an appropriate amount of strength due to many incidences of failure caused by simple daily activities. Cases of fatigue have been presented as a costly obstacle both economically and functionally. Patients constantly have to replace their torn liner for a newly replaced one. As a result, some amputees must endure an actual refitting process to ensure they can maneuver properly. This is an issue that cannot be ignored and a material with superior mechanical properties such as polyvinyl chloride must be considered.

4.3 PVC Foam Socket Liner: A Proposed Idea

As previously mentioned all of the current liner materials being utilized lack mechanical durability or maintenance of stump health. The Pe-Lite liner fails to demonstrate optimal strength during excessive usage of the prosthesis. If this is not present in the material being used, then the quantitative and qualitative measurements of optimality will be hindered. In other words, liners that are not strong enough to withstand daily activity desynchronize any given patients gait cycle and deteriorate the agility of the residual limb. The question now becomes what makes any foam an optimal material? The answer is a material that is flexible, durable, porous, and able to portray chemical resistance in any given environment.

By assessing the advantages and disadvantages of silicone and polyethylene, polyvinyl chloride (PVC) foams seem to be a more advanced idea. They are unique with their ability to display better qualities than the conventional materials being manufactured. The silicone suction socket and the Pe-Lite foam liner are the two best possible sources for amputees to utilize as socket liners. Silicones are beneficial because they provide the best possible fit to the prosthesis, while polyethylenes are more comfortable to the skin.

With this in mind, polyvinyl chloride (PVC) foam is presented as an application for socket lining encompassing both of these characteristics, while diminishing the existing problems. The reason why a foam material was implemented is because one special feature exhibited by foams is the force-deflective behavior. They have the ability to produce comfort cushioning reactively. This phenomenon is demonstrated in any foam cushion, which can either be eliminated or minimized by the chemistry of the foam polymer and the foam density. For example, if the foam density were low, i.e. 0.04 kg m^{-3} or lower, the cushioning factor would be diminished. Indentation Force Deflection (IFD) or stress-strain curves are used to show the relationship of force (load) verses indentation deflection). As the force increases, the indentation also increases as a result of the load pressing further into the cushion or foam. By observing the IFD curve of a typical cellular polymer (See Figure 6), a force applied to this particular polymer illustrates a plateau between 25-75% deflection. Figure 6 would be indicative of a foam cushion that would be rated low in comfort.

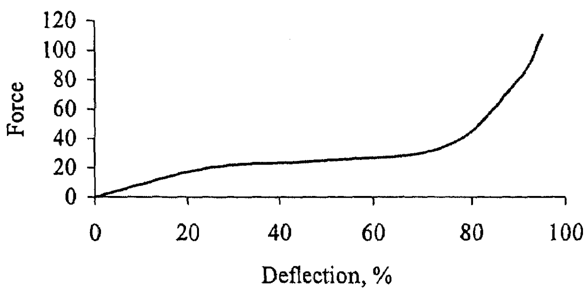

Figure 6: Indentation force deflection (IFD) curve of a typical foam with an attenuated plateau that signifies lack of comfort in the material.

The longer the plateau within an IFD curve, the less flexibility the material contains in response to loading mechanisms. At the 75% deflection mark, there is a steep rise in the curve that displays the reactive forces being stimulated. In prosthetic limb systems, polyesters are used for absorbing energy during impact and polyvinyl chloride exhibits this property. By observing this graph closely, the cushioning properties of the material can be acquired, which is critical for prosthetic fitting.

Although the cushioning factor is an extreme benefit, PVC foams generally express the following advantages:

1) Low density.
2) Corrosion resistance.
3) Inertness to water and most acids, bases, and other chemicals.
4) Wide range of resilience.
5) Good heat insulating properties.
6) High compressive, tensile and shear strengths (Rosato, 369).

PVC foams contain all of the elements that initiate and propel a socket to be at its finest and to prove this theory, the stipulations of an optimal socket liner must be explored in the mechanical properties, biocompatibility, porosity, flexibility, and overall functionality of the material.

4.4 Mechanical Properties of PVC Foams

In the previous section, the mechanical properties of the Pe-Lite foam insert were briefly discussed. It displayed reasonable amounts of strength numerically, but when amputees actually utilize this liner in daily practice, the numbers were less impressive. Mechanical properties are of extreme importance because many materials are failing due to regulatory actions such as donning and doffing the artificial limb. Repetitive stresses of such activities, as well as ambulation alone, give higher probabilities of fatigue. Liners must be able to express superior compressive strengths mechanically and structurally.

Compressive strengths are of interest because the weight of the body will be placing a tremendous amount of stress on the liner being placed in the socket. By observing the loading capabilities of the material, the point of buckling and eventual failure will be able to be determined. This illustrates what is occurring to the material in conditions of stress verses strain. It exhibits how the material will behave in response to load and how far it will be able to endure any type of deformation. Before comparing the actual compressive strength of the Pe-Lite material verses PVC foams, it is essential to note that the mechanical properties of each material will differ based upon the technique that is used to produce the material. For example, polyvinyl chlorides can be manufactured by methods such as: mixing, molding, or expansion. The manner in which the material behaves mechanically depends upon the basic mode of processing.

In chapter 3, the forces occurring between the stump and the socket proved to be of great importance. It is these forces that are affecting the overall health of the wound site. The main objective behind designing or even proposing a new material is to reduce these forces in any possible way. Figure 7 demonstrates the forces that are involved between the stump and socket.

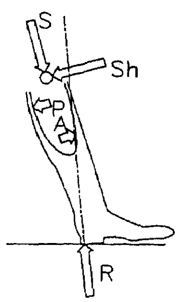

Figure 7: Forces being placed on residual limb by prosthesis. If the socket liner can absorb some of these forces, optimality can be achieved. Source: Inman, Verne T., Henry J. Ralston, and Frank Todd. Human Walking. (Maryland: Waverly Press, Inc., 1982, p 135).

It is apparent that vertical components of force are applied against the surfaces of the stump, but for purposes of simplified analysis the combined effect of all of these forces is shown as the single support force S (Inman, p 137). It is this cumulative force, S, that must be reduced by application of a new socket interface liner. In chapter 3, equations were presented to emphasize what was actually occurring at this intimate area. The force S is considered to be the point of support or balance and formulas concerning the lateral forces were derived. However, the main concern of the PVC foam is for it to be able to withstand and exhibit compressive stability. The reactive force, S, must be reduced by the material's cushioning factor. PVC's ability to absorb the forces and reproduce minimal reactive magnitudes will be the most integral part of the design, which is highlighted in the up coming sections. To prove this unique characteristic, the mechanical properties have to be thoroughly evaluated.

As observed by Table 2, the mechanical properties of polyvinyl chloride foams are more impressive than the typical properties of the other liners. It is evident that as the materials' density increases, the compressive strength of the material will also increase. This is critical to the flexibility and cushioning phenomena previously mentioned. Given the general knowledge of foams, the mechanical durability of the material is enhanced as the density is augmented. Observing the basic properties of PVC foams illustrates the greater qualities that this material possesses.

Table 2: Mechanical Properties of PVC Foam at Various Densities

Property	Density, (pcf)		
	2	4	6
Compressive strength, ult. (psi)			
At 70 °F	55	140	230 – 320
At 175 °F	45	112	190 – 230
At 212 °F	40	93	140 – 190
Compressive modulus (psi)			
At 70 °F	2020	6400	7900 – 10000
At 175 °F	1780	5000	6400 – 9000
At 212 °F	1565	3600	5000 – 6400
Flexural strength, psi at 70°F	50	280	355 – 500
Flexural modulus, psi, at 70°F	2400	7000 – 8500	10000 - 13000
Dimensional stability Remaining volume, (% after 100 hr, dry heat)			
At 175 °F	97	99	99
At 212 °F	94	97 – 98	98
Water absorption (% by vol.)	1.9		

Source: Source: Rosato, D.V. Plastic Foams: The Physics and Chemistry of Product Performance and Process Technology. (New York: John Wiley & Sons, Inc., 1969, p 419)

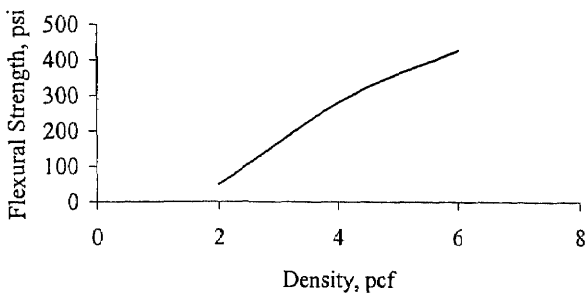

Figure 8: Flexural strength verses density of PVC foams illustrates the directly proportional relationship.

If these general mechanical properties are compared with polyethylene, it is evident that PVC will be able to withstand more weight than the Pe-Lite liner. If the appropriate density is accurately increased or even at low levels, the compressive and tensile strengths are more efficient with the PVC foam. If analyzing a more durable material than polyethylene such as polyurethane, PVC foams still surpass (See Table 3).

Table 3: PVC vs. Polyurethane

Property	PVC	Polyurethane
Density	2.0	2.0
Compressive Strength (psi) 5%deformation	52	26
Water absorption (% by vol.)	1.9	3.0

Source: Rosato, D.V. Plastic Foams: The Physics and Chemistry of Product Performance and Process Technology. (New York: John Wiley & Sons, Inc., 1969, p 419)

A 2.0 lb/cu ft of grafted PVC displays a 55psi compressive strength, while polyurethane expresses 30psi. Additionally, in shear strength, PVC foams exhibited 40psi and polyurethane only 22psi, which proves mechanically that PVC, is at a greater advantage than the most durable traditional socket liners.

It is evident that the compressive capabilities of PVC are much more remarkable than any of the other materials available on the market. This is an extremely important factor, due to the simple fact that the socket liner experiences tremendous amounts of impact from the total weight of the body alone. As a result, the socket produces a reactive force back on the residual limb.

The next important mechanical property that PVC foams possess is excellent chemical resistance. Skin has the tendency to demonstrate certain properties such as:

- High concentration of salts and amino acids (from sweat).
- High concentrations of fatty acids (from sebum).
- Low pH (from amino acids and fatty acids).
- Low availability of water (due to evaporation from surface).

With all of these chemicals, hydrolysis of the material must be analyzed. Fortunately, in this case, PVC foams tend to show little to no reactions to such inert environments. With polyurethane and polyethylene, high humidity causes a slow hydrolysis rate with increased temperature. If this is occurring, the socket will be in danger of experiencing mechanical failure.

In order for the mechanical properties of these materials to be attested, it is essential to follow several testing procedures. Certain testing specifications stress the fact that the size and shape of the test specimen must be considered when determining the actual properties.

4.4.1 Testing Protocol to Measure Mechanical Properties

The mechanical tests that will be performed on the PVC foam material will include measurements of: Young's modulus, tensile and compressive strengths.

Protocol 1: Measurement of Young's Modulus.

1) Normalize testing machine to appropriate reading (e.g.. gauge length, load range, cross-head speed).

2) Measure thickness and width of specimen.

3) Attach strain gauge to the test piece.

4) Place specimen in fixtures of testing machine.

5) Connect an extensometer (can only be used if the strain gauge is not being used).

6) Set the strain gauge or extensometer according to the appropriate values.

7) Initiate the cross head to deform the specimen in tension.

8) The test will be complete when the material fracture or strain limit is exceeded.

9) Calculate Young's modulus using:

$$E= (F / x) / BW$$

Where, L is the gauge length of the strain gauge or extensometer, B is the specimen thickness and W is the width.

Protocol 2: Measurement of Tensile Strength

1) Normalize testing machine to appropriate reading (e.g. gauge length, load range, cross-head speed).

2) measure the width and thickness of the test piece in the central and parallel region.

3) Place specimen in fixtures of testing machine.

4) Initiate the cross head to deform the specimen in tension.

5) Stop the cross-head one the specimen has fractured completely.

6) If fracture occurs near occurs near the grips near the grips, reject the specimen.

7) Calculate the tensile strength using:

tensile strength = peak load / (breadth X width)

4.5 Biocompatibility of PVC Foams

When introducing a new material into the physiological environment, the harms that can be produced from interaction of a foreign surface must be explored. The skin has specific surface properties that must be taken into account when developing an idea for biomechanical usage. Skin has the primary function of protecting the body against foreign invaders, injury, dehydration, and regulation of temperature. It possesses certain qualities that must be acknowledged when introducing a new material. The point of contact between the stump and the socket is at this outer covering. Issues such as toxicity and immuniological responses must be addressed to ensure that the foam will not hinder the health of the residual limb. Amputees are already being afflicted with pimples and skin breakage at the wound site; additional reactivity would be a tremendous setback for patient recovery.

PVC foams do not have any toxicity that would harm the residual limb. However, if PVC is combined with certain plasticizers, they can be extracted or absorbed by the body. Plasticizers do not demonstrate harmful toxins. This can occur when the material is being utilized internally. In this case, the foam will be used externally, which will not produce any toxic chemicals. Simultaneously, the skin exhibits little allergic reactions to the foam material. To test the biocompatibility of PVC foams, cytotoxicity tests are used.

4.5.1 Testing Protocol to Measure Biocompatibility

A toxic material is defined as one that releases a chemical in sufficient quantities to kill cells either directly or indirectly (Moghe). The main purpose of any type of toxicity test is to evaluate the relevant harm that the biomaterial can have on the body. The most common types of tests used are the Direct Contact Test, Agar Diffusion Test and the Elution Test. With the PVC foam, the best method would be the Direct Contact Test. This type of test is the best choice for our material because it accurately examines the exposure of the material with the residual limb in cases where an open wound might occur.

The Direct Contact Test is an in vitro process that requires several preparation techniques. Sterilization, procurement and storage methods of cells have to be evaluated. Once all of these parameters have been addressed, the actual experimentation takes place. With the Direct Contact Test, a confluent monolayer of L-929 mammalian fibroblast cells are placed in a 35 mm diameter cell culture plate along with a media and the PVC foam. Next, the culture is incubated for one hour at 37 degrees Celsius (approximated according to body temperature) in a humidified incubator. Once the time is completed, the culture media is removed, the cells are stained (with Trypsan blue) and are analyzed. Any cell that was invaded with the dye is considered to be a dead cell. This is partly because the cell lost its membranes integrity and if such occurs, the material is ruled as being toxic to the body.

The next method that should be used for further analysis involves thin sections of the material being placed in a dish with cells being stained using Paragon. This particular dye allows visibility of cellular structures under the microscope and if it present within the nuclei, then the material is concluded as being toxic. Similarly, cells are also placed in a dish and observed for any discrepancies to test its immune response.

4.6 Porosity of PVC Foams

Porosity is one of the most important factors in socket liner design. This is a fundamental objective in any type of interface material being developed. It is vital to the patient because in this intricate compartment, high degrees of humidity are witnessed. Amputees, especially in the summer, are exposed to high temperatures that allow great amounts of perspiration to be produced. It is this element that affects the entire health and status of the wound healing process. Added moisture inhibits hygiene, comfort, and stability at the wound site. Such a component becomes an important focus of the entire socket interface design. The liners porosity factor lies in the cellular structure of the actual material. Controlling the pore size of the material affects the mechanical properties, which means special attention should be placed on the actual manufacturing processes.

The polyvinyl chloride (PVC) foam is decent for water absorption properties. It contains water absorption rates that are low in comparison with polyurethane and polyethylene (See Table 4). Silicone is the only material that is more desirable in the water absorbing property. It has specific capabilities of absorbing high concentrations of water at relatively low densities.

Table 4: Comparison of Water Absorption Property

	Silicone	Polyurethane	Polyethylene Foam	Polyvinyl chloride
Density (lb/cu ft)	3.5	2.1	2.0	2.2
Water Absorption (lb/sq ft)	0.284	0.04	0.04	0.01

Source: Landrock, Arthur H. Polyurethane Foams: Technology, properties and Applications. (New Jersey: Plastics Technical Evaluation Center, 1969, p 165).

4.6.1 Testing Protocol to Measure Porosity

Testing procedures utilized to determine the porosity objective are accomplished by observing the cell morphology. Surface roughness and pore sizes are the key components used to determine if there are adequate water absorption properties. Additionally, test experiments mapped by placing test specimens in water and calculating the rate of water suction. Other methods used are by immersing the socket in water for 24 hours and later weighing the material. The dried weight of the socket is subtracted from the weight of the socket when it is wet which indicates the materials ability to retain water.

4.7 Flexibility of PVC Foams

The amount of flexibility that is required of the socket liner is of great importance. This property goes hand in hand with the compressive strength previously observed. Flexibility is essential because the material is often exposed to fluctuating volumes. Patients are constantly gaining and losing weight during their lifetime and the material must be able to endure these events. Prosthetic limb users are in need of a socket that will be able to exhibit this particular quality. Many patients have to be refit as a result of gaining or losing weight. By focusing attention on this particular issue, a tremendous amount of expenses will be reduced.

A materials flexibility factor is determined by observations of stress-strain diagrams or cushioning factors. Elasticity is the property of a material, which enables it to regain its original configuration after having been deformed (Shigley, p 91). Foams are highly desirable because they possess such a characteristic. With PVC foams currently being developed, flexural properties are very minimal. However, the degree of flexibility can always achieved by using different additives and various techniques to manufacture the material. Silicone offers great adaptability to changes in residual limb volume but little durability.

Alteration of the PVC foam properties can obtain the most desired specifications. Observing Figure 6, will establish the appropriate cushioning factors permissible for any liner. While manufacturers are developing this material, the best possible combination must be achieved to reduce the plateau that illustrates low comfort. The main goal of any liner is produce excellent padding properties, which are essential for residual limb comfort, fitting and absorption of the forces previously mentioned.

4.7.1 Testing Protocol to Measure Flexibility

To measure the flexibility of the material, calculation of the flexural strengths have to be achieved. To obtain such information, the material must experience the following testing procedure:

1) Normalize testing machine to appropriate reading (e.g. gauge length, load range, cross-head speed).

2) Measure the width and thickness of the beam and the distance of the bendable material.

3) Position the suture on the bending equipment.

4) Initiate the cross-head to deform the suture in bending.

5) Stop the cross-head beam once the suture has fractured completely .

6) Accept results only when the fracture surface of the suture is approximately normal to the edges of the suture.

7) Calculate the flexural strength using:

flexural strength= 3Pmax S/ 2BD

where, Pmax is the maximum load at failure.

4.8 Functionality Exhibited by PVC Foams

Functionality is the primary concern and priority of any innovative design. The aim of the entire model is to exhibit the most optimal type of performance. The overall success of the prosthesis depends on the degree of efficiency that is being displayed. In this case, the interface liner must allow proper support, control, suspension and alignment for the residual limb, in turn producing excellent gait patterns.

The socket must be able to support the stress and strain mechanisms that will be placed on the actual material. "A primary measure of a socket's effectiveness is its ability to distribute efficiently among the residual limb tissues the substantial forces transmitted by the prosthetic during the stance and swing phases. A well-designed socket is carefully shaped to channel the heaviest pressures to the tissues best able to withstand to them. Soft materials built into the socket can provide added protection for bony prominences and particularly tender tissues." (http://www.adbiomech.com/ps92-2.html, p 1) In order for the PVC foam to be successful, it is mandatory for it to be able to support the weight and forces that are being exerted by the residual limb. To examine such a quality, it is essential to develop testing protocols that can mimic daily activities. However, by observing the mechanical properties of the material directly, it is obvious that material will experience little fatigue.

The next important factor that must be witnessed is the actual control of the prosthesis. This basically occurs by the entire ability of the socket. The interface liner will only be responsible for dispersion of forces on the socket and limb. Intimate socket fit is integral to an amputee's ability to use the prosthesis effectively. The PVC foam is flexible and is able to bend and adjust to give the best possible fit. Concurrently, the material will be able to provide close suction fit between the residual limb and the socket wall. By achieving such a phenomena, the prosthesis will be aligned both angularly and linearly, to maintain the residual limb in proper biomechanical relationship with the prosthesis. Alignment is first addressed during the initial stages of socket fabrication, but later refined dynamically when the amputee actually begins usage of the limb.

The functionality factor is evaluated by observing the gait pattern of the patient while wearing the PVC foam insulation. In chapter 2, a detailed discussion of the methods and tools used in such analysis were mentioned. The amputee would have to place special markers on various parts of their limb and several recordings would be taken. Once all of the data is obtained, a comparative study is initiated. Results are validated according to normalized figures and conclusions are drawn based upon the fit and overall pattern of the patient's locomotion.

4.9 Quality Assurance

In order to ensure that the PVC foam liner is serving its purpose appropriately as an optimal socket material for the typical amputee, a survey must be distributed to acquire patient feedback. Questions about the patient as well as level of activity should be observed to evaluate the effect of the interface on the performance of the entire prosthesis (See Appendix F).

4.10 Limitations and Problems

Polyvinyl chloride is presently being applied in various other markets. The main applications for foamable polyvinyl chloride are as carpet underlays, the backing for floor tiles, protective metal coatings or decorative sheetings. Although polyvinyl chloride foams contain high tensile and compressive strengths, some disadvantages are also present. It is evident that water absorption property of the Pe-Lite insert foam is much higher than the PVC foam. The factor of porosity is a key element in the basic requirements of any type of liner. It is key for residual limb health to be maintained. If a socket liner is not absorbing moisture being produced by the stump, ulcers and soars will initiate, which will defeat the purpose of even proposing a new material.

The next disadvantage of this material is the actual cost issue. Typically, PVC with a density of approximately 3 pcf will cost about $1.00. The manufacturing cost of making PVC foam into a socket interface is highly questionable. Since this is new application, further research should be administered within this area.

4.11 Solutions

While utilizing such a material is of high cost, the magnitude of quality is irreplaceable. The emphasis that is being placed on the value of this material is its compressive capabilities. It has demonstrated superiority amongst its competitors due to the simple fact that it is stronger. Compressive strengths are of great importance for the socket liner industry. Amputees are repetitively placing incomprehensible strains on their socket and it is essential for them to have a material that will be able to withstand such forces without deformation.

Technological processing techniques should be evaluated to create the most optimal combination of resins, additives, or plasticizers to obtain the best formulation of PVC foams. If researchers consider this material to be of significance in the socket interface market, methods will be developed to produce this enhanced version. By acquiring the appropriate methodology of constructing the PVC foam material to the desired socket interface properties, the issue of porosity and cost can be minimized.

4.11.1 Suggested Manufacturing Process

The majority of flexible PVC foams is made from liquid plastisols and may be divided on the basis of open- or closed- cell structure (Benning, p. 348). The role of the plasticizer is to produce a degree of viscosity among the properties of the foam. However, the manufacturing process used to produce the PVC foam will alter the mechanical properties of the material. For instance, methods for the expansion of flexible PVC foam can be developed using mechanical or chemical techniques. The chemical methods involve the use of blowing agents that liberate gas on heating. The mechanical expansion processes involve either air entertainment or dissolution of gas (Benning, p. 355).

For the PVC foam socket liner, a method used to develop the material using mechanical expansion is the Vanderbilt process. The Vanderbilt process involves the mechanical whipping of air into a plastisol containing proprietary surfactants. A key element in the Vanderbilt PVC process is the use of the proprietary surfactant, Fomade. Fomade enhances foam stability sufficiently to allow the foam to be poured, spread, and finally gelled with a minimum change in cell structure or density. The air is then added by the mixing action of an Oakes foamer or Hobart type batch whip. The stable froth resulting from the mixing is spread or molded in its final form and subsequently gelled and fused under controlled heat. The fused product has a very uniform, small, open-cell structure with density in the range of 12-50 pcf and surface characteristics that are soft and porous.

In Table 5, the physical properties of the Vanderbilt process are compared with a chemically blown technique. It is evident that the Vanderbilt foam will posses better properties for the socket liner being produced.

Table 5: Comparison of Physical Properties Using Two Expansion Processes

Property	Vanderbilt foam	Chemically blown foam
Density, pcf	12.6	12.8
Tensile strength, psi	57.1	25.4
Elongation, %	220	140
Compression, psi	9.1	10.1
Rebound resilience, %	26	14

Source: Rosato, D.V. Plastic Foams: The Physics and Chemistry of Product Performance and Process Technology. New York: John Wiley & Sons, Inc., 1969, p 358)

CHAPTER 5

CONCLUSION

The aim of this study was to highlight the importance that must be placed on the interface liners being utilized by prosthetic limb sockets. Recent studies have indicated the vitality of such a component calls upon the need for great enhancements. However, before assessing and proposing a new material, the disadvantages of the current market are explored. Evaluations of present liners, such as the 3S and Pe-Lite liner, have revealed that gait deviations were being developed from poor interface construction. Gait cycles were being hindered as a result of liners causing irritations during donning and doffing the prosthesis or simply breaking down mechanically due to low compressive strengths. Therefore, obtaining such information has led to investigations in what actually defines an optimal socket liner.

First, the quantitative measurement of optimality was discussed to highlight the importance of the gait cycle. Gait is the process of human locomotion. If a prosthesis is not able to provide the best possible pattern, then the entire functionality of the limb can not be achieved. The qualitative measurement of an ideal socket liner entails residual limb health. Proposing an idea to improve the comfort of the wound site is ideal for any prosthetic design.

Observing the current market and understanding the stipulations of a progressive socket liner have led to the proposal of polyvinyl chloride foam as an alternate material. Screening the material has been presented within this thesis, to provide general information regarding the capabilities of this particular material. PVC foams are ideal socket liners because they are biocompatible, durable, flexible and efficient. However, they do not provide the highest water absorption properties given by the silicone or polyethylene interfaces presently being manufactured. Additionally, the costs of this material are also presented as a problem. These two factors can be minimized by the manufacturing techniques that will be developed to process PVC.

An element as minute as the liner of the socket, can alleviate major problems being experienced by millions of prosthetic wearers today. Amputees will be able to achieve rapid recovery rates and decrease the costs of constantly replacing a torn liner. By examining mechanical properties and studies of current interface liners, it is evident that an alternative is necessary. If PVC foams can be modified to obtain the specified design objective being proposed, the solution may be a step away.

APPENDIX A

TESTING PROTOCOLS FOR GAIT CYCLE DATA COLLECTION

The steps involved in the gathering of the data for the interpretation of gait pathologies usually include a complete physical examination, biplanar videotaping, and multiple walks of the instrumented subject along a walkway that is commonly both level and smooth. The time to complete these steps can range from three to five hours. Although the standard for analysis is farefoot gait, subjects are tested in other conditions as well, e.g., lower extremity orthoses and crutches. Requirements and constraints associated with clinical gait data include the following:

Table 6: Gait Data Collection Protocol

Test Component	Estimated Time (Minutes)
Pretest tasks: test explanation to the subject	10
Videotaping: Brace, barefoot, close-up, standing	15 – 25
Clinical examination: Range of motion, muscle strength, etc.	30 – 45
Motion Marker placement	15 – 20
Motion data collection: Subject calibration and multiple walks per condition (barefoot, orthoses)	30 – 60
Electromyography	20 – 60
Data Reduction of all trials	30 – 90
Data interpretation	20 – 30
Report dictation, generation, distribution	120 – 180

Source: Bronzino, Joseph D. The Biomedical Engineering Handbook. (New York: CRC Press, Inc., 1995).

APPENDIX B

SPECIAL FEATURES OF THE MOST POPULAR PROSTHETICS AVAILABLE

Seattle Limb Systems

A. Seattle Natural Foot

Features:

- Compliant keel for excellent rollover during walking
- Slim, sculpted, natural looking cosmesis
- 3/8" heel rise
- Appropriately designed for the low to medium active patient
- Available in various skin colors

B. Seattle Lightfoot

Features:

- Slim, sculpted, natural cosmesis
- 3/4" keel
- Delrin II dynamic response keel
- Lightweight design

C. Kingsley SACH feet

Features:

- Eastern Hard-Rock Maple Keel
- Single composite 3 density medathane

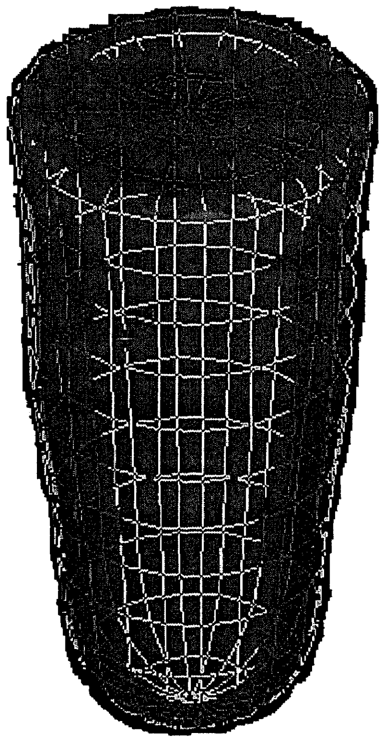

Figure 9: Prosthetic Socket Interface Liner

APPENDIX C

NEW TECHNOLOGICAL ADVANCEMENTS IN SOCKET LINERS

Recently, there has been a more high-tech approach to limb protection known as Silosheath. The actual socket liner is impregnated with a certain gel that provides extra protection for facilitation of the socket suction and total surface contact. Silosheath is formulated with medical grade mineral oil, which softens, soothes and protects the skin from impact, perspiration and itching, which frequently results from prolonged socket wear. The disadvantage of this particular type of interface is the limited life expectancy, which ranges from two to eight months.

APPENDIX D

OTHER IMPORTANT FACTORS INVOLVED IN MAKING A PROSTHESIS SUCCESSFUL

Special emphasis being placed on the progress of the wound site is of extreme importance. However, the psychological well being of the patient must also be analyzed. By understanding the patient's particular lifestyle and overall emotional status, certain prosthetics can be more beneficial than others. Elderly amputees may already express depression, anxiety and disturbances and have different requirements for their device. In comparison, younger patients, such as adolescents, may presently be experiencing peer pressure and also want a particular type of prosthesis that will meet their individual needs. The amputees' personal needs should be addressed and understood when prescribing a particular limb.

The next aspect that must be considered is the cosmesis of the entire limb. Researchers and insurance companies often neglect the significance of this specific area. They feel that functionality should be the main concern of the amputee. On the contrary, cosmesis places an integral part of the whole recovery process. It is the key component involved in closely replacing the amputated limb. Allowing the patient to be comfortable with their physical appearance is irreplaceable. Additionally, poor cosmesis has contributed to the failure of many prosthetics. It is one of the most disregarded areas of the design process and should be drastically improved.

D.1 Cosmesis

Cosmesis, the external appearance of a prosthetic system, is the integral ingredient of restored wholeness for a typical amputee. For the average amputee, a basic level of cosmetic finishing will surface based on their particular lifestyle. Some may require advanced shaping, pigmentation or extra detailing of the surface. Why is cosmesis not taken so seriously? The importance of cosmesis is often overlooked as the least important aspect. The reason for this outlook is because of the cost issue. Medicare or any other types of insurance companies do not cover the expenses for cosmetic enhancement. Prosthetists fail to see that it may serve as a key component in the success and stability of the entire design. Significant factors, such as texture, color and shape, are extraordinarily detrimental to the recovery and rehabilitation of the patient. By restructurizing the cosmetic characteristics of the prosthesis, they will be able to eliminate some of the problems that may arise as a result of poor cosmesis.

The human body is the most difficult specimen to replicate. It is protected by the outer covering known to all of us as skin. Skin has many important roles in the body and is not easily replaced. When trying to redesign an individual's prosthetic limb, researchers fail to take this into account. Currently, in order to duplicate skin, foot shells and spray-ons are completing this task. How can the vitality of skin be so easily overlooked? The industry is presently manufacturing limbs that lack one important characteristic; durability. Many patients are revisiting their prosthetist for refitting due to total lack of satisfaction. The main problem with cosmetically inclined prosthetic feet is the need for constant reconstruction. For example, if some patients need a certain component of their prosthesis to be fixed, the prosthetist must tear or destroy the exterior "skin" or sleeve. Components of the skin come apart and are affecting the overall performance. In most cases, failure in cosmetic production, such as weak adhesives, hinder the function of the prosthesis.

To alleviate this recent problem, researchers have developed the One Step Ahead skin sleeves. They are basically sleeves that are produced from a more durable and thicker material than traditional cosmetic wraps. The product is available in 18 different skin pigments and 13 standard sizes to accommodate pediatric patients and both transtibial and transfemoral amputees. Additionally, One Step Ahead can be ordered with the appearance of hair for male patients. This type of cosmetic phenomena also provides patients with waterproof characteristics. Patients are able to restore most of their daily activities without fear of destroying their limb. However, the only disadvantage to this product is it is not skin and certain precautions must be taken. For example, wearers are advised not to walk barefoot or wear tight or loose fitting shoes. How is this close to replicating the amputees lost limb? Limitations are being placed on the patient's life and are not rectifying the cosmetic crisis that exists within the prosthetic limb industry today.

In order to improve the existing horrors, it is crucial to focus on the components of the skin. Skin has certain types of texture, shape and pigmentation that differ from person to person. General shaping of the limb involves the way the muscles are situated in the calf, the actual position of the ankles and Achilles tendons, and toes of the foot. By applying these three elements to innovative ideas, a better design will be produced and patients will experience the first step towards complete rehabilitation. Re-selecting or even formulating a new material may lead the way to further development. In addition to examining the cosmetic importance in prosthetic design, the psychology of the patient is assessed to also present its significance.

D.2 Psychology of the Patient

"No one thanks a surgeon for cutting off an arm or leg." Losing a portion of your body can be one of the most traumatic experiences an individual will ever undergo. Most of us are born as whole human beings and cannot imagine ourselves otherwise. The emotional health of the patient is another vital characteristic that must be emphasized. It is the means to physical recovery for both rehabilitation and resuming a normal healthy life. So what actually affects the psychological well being of an amputee? There are many answers to that particular question. It can be their particular lifestyle, age or family background. Or maybe the answer to better physiological and psychological recovery lies in the stump and cosmesis of the prosthetic limb. Focusing our attention on producing a material that will both prevent residual limb breakdown and enhance cosmetic finishing, the psychology of the patient be of minimal severity. If this factor is taken into account, rehabilitation can be greatly facilitated.

APPENDIX E

PHYSICAL PROPERTIES OF OTHER LINER MATERIALS

The silicon suction socket (3S) was incorporated into the mainstream of prosthetic designs due to its tremendous amount of evolutionarily development. In the initial steps of its production material known as Surlyn was initially used. Surlyn is highly compliant in thin cross sections but does not respond appropriately to changes in volume. When patients lose or gain weight dramatically, problems with cracks and tears were encountered. The repetitious stress of donning and doffing on the socket caused eventual failure of the material. The next approach was to use the Icelandic Roll-On Suction Socket (ICEROSS). ICEROSS compromises thin walls, is highly compliant and basically is composed of silicone. With this particular socket, the idea of using a liner was a better idea. The liners were made of compressible materials that were used to moderate the transmission of impact and shear forces from the prosthesis to the tissues of the patient's limb. However, problems still persisted and reports of failure were still exhibited. Using a very thin walled layer of silicone with little reinforcement contributed to overall poor performance. This is the point where the actual development of the Silicone Suction Socket (3S) was introduced. Analysis of the silicone liner would be presented through comprehension of the basic properties and characteristics of the material. However, for prosthetic liner application, the property of concern is the basic strength of the material.

Silicone has many advantages as a socket liner because of its thermal capabilities. No other material is currently available that will withstand continuous exposure at 650 °F. Additionally, it absorbs moisture in great quantities. Water absorption is a key characteristic for constructing any type of liner. It is necessary for the suction of perspiration and will eliminate irritation of the skin at this intimate part. With this particular material, the water absorption property seems to be reasonable high compared to other materials. Although it possesses ideal characteristics at high temperatures and absorbs moisture in greater quantities, the main disadvantage of silicone is its poor mechanical properties and high cost. As illustrated by Table 1 silicone requires high densities to provide a legitimate source of durability. At a density of 3.5 lb/cu ft, compressive strengths were as low as 6.2 psi. It does not possess the reliability and lifespan needed to endure typical activities such as donning and doffing the prosthesis. In order for it to be able to withstand daily practices, more material must be used which includes exceeding economical limitations.

Table 7: Typical Properties of Two Types of Silicone Materials

	Type 1: R-7002	Type 2: R-7003
Density (lb / cu ft)	14	16
Compressive Strength (psi)		
At 77 °F	200	325
At 77 °F, after 200 hrs at 500 °F	190	210
At 500 °F, after 1/2 hr at 500 °F	25	70
At 500 °F, after 200 hrs at 500 °F	45	80
Water absorption (% by tw after 24 hr immersion)	2.3	2.1

Source: Rosato, D.V. *Plastic Foams: The Physics and Chemistry of Product Performance and Process Technology*. New York: John Wiley & Sons, Inc., 1969.

Polyurethane foams acquire properties that are more impressive mechanically. The advantage of using polyurethane foams is the ability to alter and tailor the chemical resistance, electrical performance and overall mechanical properties. Urethanes are currently, manufactured as three types: (a) Flexible foams, which are based on propylene oxide, adducted of glycerol. The desired properties of these types of foams are the low density and high-load bearing ability. (b) Rigid foams are made by both prepolymer and one-shot processes. The one-shot process is more promising, since it produces lower-cost, high-performance foams. (Rosato, p. 142) (c) Semirigid foams are used chiefly in the automotive industry. It must be noted the processes used to make these types of foams will greatly alter the physical properties and progress of the material. Typically, mechanical properties for socket liners made of polyurethane foam contain the following qualities: (See Table 8)

Table 8: Mechanical Properties of Polyester Polyurethane Foams.

Property	Range
Density (lb/ cu in)	1.6 - 2.0
Tensile Strength (psi)	25 – 33
Ultimate Elongation (%)	250 – 500
Tear Strength (lb/ linear in)	23 – 42
Compression Deflection (psi)	
At 25% compression	0.46 - 0.48
At 50% compression	0.56 - 0.80
At 75% compression	1.29 - 2.90

Source: Landrock, Arthur H. Polyurethane Foams: Technology, properties and Applications. (New Jersey: Plastics Technical Evaluation Center, 1969.)

For flexible polyurethane foams, Figure 4.1 illustrates that these types of foam contain a pronounced plateau in their IFD or stress strain curves, which have been controlled by adding reinforcing fillers. This indicates that polyurethane foams are flexible, which is a very important characteristic needed to maintain a healthy residual limb. However, polyurethane foams still express wear at minimal strains that eventually portray the material as being mechanically weak.

APPENDIX F

QUESTIONNAIRE FOR STATISTICAL ANALYSIS

1) What led to your amputation? Please choose one or more of the following categories.

Peripheral vascular disease ____
Diabetes mellitus ____
Trauma (from an injury) ____
Congenital (condition at birth) ____
Tumor ____

Other, please describe ____

2) How long is your stump? ____ Short ____ Medium _____ Long

3) What is the condition of the skin on your stump? Check one or more if applicable.

Irritation _____
Contact dermatitis _____
Soreness _____
Heat rash _____
Ulcer _____
No Problems _____

Other, please specify ____

4) How satisfied are you with your prosthesis?

5) How satisfied are you with life in general?

6) How satisfied are you with leisure activities?

7) How satisfied are you with your ability to participate in sports?

8) On an average day, how long do you wear your prosthesis?

9) Do you limit the time you wear your prosthesis for any of the following reasons?

Pain _____
Discomfort _____
Noise _____

Appearance _____
Weight of Prosthesis _____
Instability _____
Fear of falling _____
Cardiopulmonary problems _____
Fatigue _____

Other, please specify ____

10) On an average, how far can you walk without resting?

11) Please respond to the following statements:

A. My walking ability and overall performance while wearing my prosthesis is limited because of pain in my stump.

Never _____ Often _____

Sometimes _____ Not applicable _____

B. My walking ability and overall performance while wearing my prosthesis is limited because I try to avoid pain.

Never _____ Often ______

Sometimes _____ Not applicable ______

12) How often do you have stump pain?

13) At what point in is the pain the most intense?

14) Does the pain increase when you stand longer than usual?

15) When you walk faster do you have more stump pain?

16) How would you evaluate your pain in the proximal sites of your stump (closest to the brim of the socket)?

17) How would you evaluate your pain in the distal sites of the stump (furthest from the socket)?

18) Is running more painful than walking?

19) Does pain increase when you walk a greater distance?

20) Do experience loosening of your socket when you wear your prosthesis during the day?

21) What type of prosthetic foot do you wear?

Not sure ____
Uniaxial ____
Greisinger ____
College Park ____
C2E ____
Cirrus ____
SACH foot ____
SAFE foot ____
Seattle foot ____
Quantum ____
Flex-Walk ____
Flex-foot ____
Carbon Copy II ____
Endolite ____

Other, please specify ____

22) What is your age?

23) Are you:

Male ____ Female ____

24) What is your height?

25) What is your weight?

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