GUIDELINES FOR DESIGNING ORTHOPEDIC DEVICES

RELATED TO ATHLETIC INJURIES

Benjamin Lee Nowland

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THESIS ABSTRACT

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Athletes constantly put their bodies at risk and often sustain major injuries from participating in their sport of choice. The purpose of this thesis is to create guiding principles for the construction of orthopedic devices that relate particularly to sport injuries. The guidelines will encompass input from orthopedic doctors, athletic trainers, designers, and athletes. The majority of sport related injuries occur to the lower extremities of the athlete. The following thesis will focus on collegiate athletes and more specifically lower leg injuries. The need for this study is to assist, through research, in the making of better products in a timely fashion, which will allow the student-athlete to function normally while injured. Athletes typically require special devices for rehabilitation enabling them to return to a peek state of fitness and performance. The following study will provide information to make the design process of orthopedic devices more comprehensive and specialized.

ACKNOWLEDGEMENTS

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Style Manual or Journal used:	American Psychological Association
Computer software used:	Microsoft Word Adobe Illustrator Adobe Photoshop Rhino 3D

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CHAPTER 1: INTRODUCTION

1.1 PROBLEM STATEMENT

In collegiate sports athletes are consistently debilitated by lower leg injuries. These injuries range from stress fractures in the meta-tarcels, tibia, and fibula to ankle sprains and Achilles tears. Injuries such as these lead to the athletes becoming dependent upon crutches to regain ambulatory function. Crutches may provide mobility for the athlete, but it also creates an additional handicap. Crutches require the use of the athlete's hands. From 2003-2005, 15,000 lower leg injuries have occurred in collegiate sports (NCAA.org). These injuries vary in severity, but they almost always result in the need for crutches. The average injury requires an athlete to use crutches for 2-8 weeks. During this 2-8 week time period, the athlete's quality of life is significantly lowered. Crutches make it extremely difficult to function normally. The athlete's rehabilitation can be more rigorous and faster than that of a non-athlete due to the elevated health and fitness levels as well as the need to return to the playing field.

An athlete's academic progress can also be affected by the use of crutches. Campus becomes harder to navigate and the athlete begins to miss class. Crutches are essential for the mobility of injured athletes; however, because the design for crutches dates back 4,836 years and advances have only been made to the production materials, crutches remain extremely limiting (www.emedicinehealth.com). Athletes are in need of a more technologically advanced product, which will allow more normal, everyday functionality. In order to create this product, a new process of communication between orthopedists, trainers, and designers needs to be developed that could radically change the way orthopedic products are built, look, and function; thus, minimizing the need for crutches.

1.2 NEED FOR STUDY

The need for the study is to create a product for athletes who suffer from lower leg injuries that will restore regular mobility and allow them to sustain the quality of life they are used to without causing further discomfort and dependency.

This study will also create a better, more comprehensive methodology of designing orthopedic products that restore functionality to the user. This method would include direct input from orthopedic surgeons, athletic trainers, and the product designer. The communication and expertise of these individuals should bring about a solid platform to build better products.

1.3 OBJECTIVES FOR STUDY

- Identify and create a set of guiding principles for the design and development of orthopedic products related to sport injuries
- Study injuries; types, causes, time lost due to injury, capabilities, limitations of the injured
- Study current products specific to providing motion for the injured i.e. crutches, canes, and walkers

- Define the problem of existing products and design processes for those products
- Create guidelines for designing a product, which rectifies the problems created by current products
- Construct a product, which applies the guidelines set by the documentation that demonstrates the validity of the study

1.4 DEFINITION OF KEY TERMS (Shannon, 2002)

Accident - An occurrence in a sequence of events that produces unintended injury, death, or property damage. Accident refers to the event, not the result of the event (see unintentional injury).

Acute - An illness or injury that lasts for a short time and may be intense.

Arthroscopy - The doctor manipulates a small, lighted optic tube (arthroscope) that has been inserted into the joint through a small incision typically in the knee, shoulder, or ankle. Images of the inside of the joint are projected onto a monitor. While the arthroscope is inside the joint, removal of loose pieces of bone or cartilage or the repair of torn ligaments is possible.

Aesthetic - A guiding principle in matters of artistic beauty and taste; artistic sensibility.

Approach - The method used in dealing with or accomplishing.

Bone Scan (radionuclide scanning) - A very small amount of radioactive material is injected into the user's bloodstream and detected by a scanner. This detects blood flow to the bone and cell activity within the bone and can show abnormalities in these processes that may aid diagnosis.

Bruise - Bleeding under the skin.

Capabilities -

1. The quality of being capable; ability.
2. A talent or ability that has potential for development or use.
3. The capacity to be used, treated, or developed for a specific purpose.

Chronic - An illness or injury that lasts for a long time.

Computer Axial Tomography (CAT scan) - X-rays lasting a fraction of a second are passed through the body at different angles, detected by a scanner, and analyzed by a computer. This produces a series of clear cross-sectional images (slices) of the tissues on a computer screen. CAT scan images show soft tissue such as ligaments or muscles more clearly than conventional x-rays. The computer can combine individual images to give a three dimensional view.

Criteria - A standard, rule, or test on which a judgment or decision is made.

Direct Sport Injury - Those injuries that resulted directly from participation in the skills of a specific sport.

Disabling Injury - An injury causing death, permanent disability, or any degree of temporary total disability beyond the day of the injury.

Extension - Takes place between the anklebone (talus) and the lower leg bones (tibia and fibula) pulling the toes upward (Wirhed, 1997).

Femur - The upper leg or thighbone, which extends into the hip socket at its upper end and down to the knee at its lower end.

Fibula - The thin, outer bone of the leg that forms part of the ankle joint at its lower end.

Flexion - Takes place between the anklebone (talus) and the lower leg bones (tibia and fibula) pointing the toes downward (Wirhed, 1997).

Functional -

1. Of or relating to a function.
2. Designed for or adapted to a particular function or use.
3. Capable of performing; operative.

Gait - Pattern of walking or running.

Human Potential - The inherent ability or capacity for growth, development, or coming into being.

Indirect Sport Injury - Those injuries that were caused by systemic failure as a result of exertion while participating in a sport activity or by a complication that was secondary to a non-fatal injury.

Inflammation - A characteristic reaction of tissues to disease or injury. It is marked by four signs: swelling, redness, heat, and pain.

Injury - A physical harm or damage to the body resulting from an exchange, usually acute, of mechanical, chemical, thermal, or other environmental energy that exceeds the body's tolerance.

Joint - A junction where two bones meet.

Ligament - A band of tough, fibrous tissue that connects two or more bones at a joint and prevents excessive movement of the joint.

Limitations -

1. The point, edge, or line beyond which something cannot or may not proceed.
2. The boundary surrounding a specific area; bounds.
3. A confining or restricting object, agent, or influence.

Magnetic Resonance Imaging (MRI) - Energy from a powerful magnet (rather than x-rays) stimulates tissue to produce signals that are detected by a scanner and are analyzed by a computer. This creates a series of cross-sectional images of a certain part of the body. A MRI is particularly useful for detecting soft tissue damage or disease. Like a CAT scan, a computer is used to create three-dimensional views during a MRI.

Metatarsus - Bones that make up the foot (Wirhed, 1997).

Muscle - Tissue composed of bundles of specialized cells that contract and produce movement when stimulated by nerve impulses.

Musculoskeletal System - The body's muscles, bones, tendons, and ligaments.

Occupational Injury - Any such injury such as a cut, fracture, sprain, amputation, etc., which results from a work accident or from a single instantaneous exposure in the work environment.

Orthopedic Surgeons - Doctors who treat disorders of the bones, muscles, and related structures.

Orthotics - Inserts that are placed in shoes to correct bad alignment between the foot and lower leg.

Permanent Disability (or permanent impairment) - Includes any degree of permanent nonfatal injury. It includes any injury that results in the loss, or complete loss of use, of any part of the body or any permanent impairment of functions of the body or part thereof.

Phalanges - Toes (Wirhed, 1997).

Physical Activity - Movement created by skeletal muscle contractions, resulting in energy expenditure.

Physical Fitness - Can be categorized into five health-related components: a) cardio respiratory endurance (aerobic fitness), b) muscle endurance, c) strength, d) flexibility, and e) body composition.

Physical Therapy - Is used to increase the range of motion and strength after an injury. Physical therapy includes various exercise and physical fitness programs that can be customized to meet each user's needs.

Physical Training - An organized exercise intended to enhance fitness. The terms exercise and physical training are used interchangeably

Pronation - Takes place between the ankle bone (talus) and the lower leg bones (tibia and fibula) rolling the foot inward such that the big toe is down to the inside (Wirhed, 1997).

Range-of-motion - The arc of movement of a joint from one extreme position to the other; range-of-motion exercises help increase or maintain flexibility and movement in muscles, tendons, ligaments, and joints.

Repetitive Motion Injuries- Painful injuries such as stress fractures (where the ligament pulls off small pieces of bone) and tendonitis (inflammation of a tendon) can occur from over use of muscles and tendons.

RICE- Rest, Ice, Compression, and Elevation:

1. **Rest -** Reduce or stop using the injured area for 48 hours.
2. **Ice -** Put an ice pack on the injured area for 20 minutes at a time, 4 to 8 times per day. Use a cold pack, ice bag, or a plastic bag filled with crushed ice that has been wrapped in a towel.

3. **Compression -** Compression may help reduce the swelling. Compress the area with bandages, such as an elastic wrap, to help stabilize the shoulder.
4. **Elevation -** Keep the injured area elevated above the level of the heart. Use a pillow to help elevate the injury.

Sport - Physical activity that is governed by a set of rules or customs and often engaged in competitively.

Sprain - An injury to a ligament-a stretching or a tearing. One or more ligaments can be injured during a sprain.

Strain- An injury to either a muscle or a tendon.

Stress Fracture - Micro cracks formed in the bone due to the body not being able to replace the bone lost during vigorous activity.

Supination - Takes place between the ankle bone (talus) and the lower leg bones (tibia and fibula) rotating the foot outward such that the big to is up (Wirhed, 1997).

Tarsus - Ankle bone (Wirhed, 1997)

Technology -

1. The application of science, especially to industrial or commercial objectives.
2. The scientific method and material used to achieve a commercial or industrial objective.

Temporary Total Disability - An injury that does not result in death or permanent disability, but that renders the injured person unable to perform regular duties or activities on one or more full calendar days after the day of injury.

Tendons - Tough, fibrous cords of tissue that connect muscle to bone.

Tibia- The thick, long bone of the lower leg (also called the shin bone) that forms part of the knee joint at its upper end and the ankle joint at its lower end.

Unintentional Injury- The preferred term for accidental injury in the public health community. It refers to the result of an accident.

X-ray (radiography) - An x-ray beam is passed through the body to produce a two-dimensional picture of the bones.

1.5 LITERATURE REVIEW

1.5.1 Overview

According to the Sports Injuries Handbook, it is estimated that 2.6 million visits to hospital emergency rooms are a result of sport related injuries sustained by persons five to twenty four years of age. This group's cost for medical treatment is around $500 million annually. In terms of percentage, athletic related injuries are accountable for 25% of all emergency room visits. Visit rates for males are twice as high as that of females. These sport related injuries are most commonly to the head or skull, or are a fracture, sprain, or tear, which require the immediate attention of an orthopedic surgeon (Shannon, 2002).

The sports that account for the most injuries vary per age group. For ages five to twenty four, the leading sport is basketball with 447,000 injuries per year. Football, baseball/softball, gymnastics/cheerleading, and wrestling round out the top five with 271,000 injuries, 245,000 injuries, 146,000 injuries, and 61,000 injuries respectively (Shannon, 2002). Focusing more on young adults and team sports, football accounts for more injuries than any other sport at the collegiate level. Around 1.35 million men played college football from 1982 to 2000 averaging about 75,000 participants yearly (Shannon 2002). From 1986 to 1994, there were 3.7 to 4.4 injuries per 1000 exposures. The rate for injury per 1000 exposures increased tremendously when going from practice (4.1) to games (36.3). The most common injuries were to the knees, ankles, and shoulders due to football's physicality. Knee injuries account for 19% of all injuries while ankle and shoulder injuries account for 14% and 13% respectively (Shelton, 1997).

Focusing on injuries sustained to the lower extremities, which often leave an athlete non-weight bearing for various amounts of time, the use of crutches becomes a necessity. Injuries that commonly result in the use of crutches are as follows: stress fractures or factures to the bones in the foot or lower leg (tibia and fibula); sprains to the ligaments in the ankles or knees; and strains to the tendons or muscles of the lower leg (Achilles tendon ruptures). All of the above mentioned injuries will require the use of crutches. Depending on the severity of the injury, the time of crutch use will vary most commonly from 2-12 weeks.

Crutches are used as extensions of the upper extremities to assist in the weight bearing of the body when suffering from a leg injury (www.emedicine.com). There are eight conditions where the use of crutches are essential: 1) to protect the injured area, 2) to rest the injured area, 3) to defer from causing pain, 4) to allow healing of the injured area, if non or partial weight bearing, 5) to prevent limping, 6) when muscular endurance, power, and strength are decreased, 7) when swelling is present, 8) when the range of motion is restricted by the injury (Subotnick, 1999).

There are several disadvantages of crutches. Some of the main disadvantages are as follows: they are unattractive, noisy, rattle, cause discomfort underarms, strain the shoulders and back, may cause nerve impingement, wear out fast, and take away the use of hands (www.hphdhelp.org). They also require a great deal of upper body strength and balance as well as muscular endurance. Essentially, the user does a push up with every step, which expends a great deal of energy. The gait is also unnatural due to the injured person's center of gravity being raised and lowered while walking (www.oandp.org). In addition to the aforementioned disadvantages of crutches, the user must learn special techniques required to maneuver in everyday society. These techniques help the user to stand up and sit down, go up and down stairs, learn which gait pattern is best for the specific injury, and how to go in and out of doors. As stated on the Post Graduate Medicine website in their advice to people on crutches, "If you get tired, sit and rest, do not rest your arms on the crutches. Prolonged pressure on the armpits can pinch nerves and cause pain and numbness in your arms" (www.postgradmed.com).

Crutches are not the athlete's only option in today's sports injury market. Several other ambulatory products are available, but they have been found to have similar flaws. Walking canes are not supportive enough considering they only supporting 15-20% of the injured bodyweight (www.geriatricsyllabus.com). Forearm crutches or non-auxiliary crutches are smaller, lighter, and more maneuverable, yet still cause many of the same problems as crutches. Nerve and joint damage are still present with extended use. They also have the disadvantage of not being hands free (www.hphdhelp.org).

Designing orthopedic products is a time consuming and detailed process. The process starts with need. Following the need for a new design come research, conceptual design, engineering, product design, rapid prototyping, testing, and manufacturing. Each of these steps is essential in the product design process; however, if some of these steps could be consolidated, the product could be created faster and at a higher quality. This would benefit the manufacturer, the orthopedist, and the injured athletes.

The market is saturated with different types of ambulatory products from crutches to canes to walkers, yet none of these products are hands free. A hands free ambulation aid is an untapped market. If standards are set and a design process is put in motion, a quality product that solves this problem will be the outcome.

1.5.2 Printed Research Material

The printed material contains mainly information on sport related injuries, and the use of crutches through the rehab process. It also contains a significant amount of statistics on injuries including types of injuries, frequency of injury, and sport specific data as well as information on anthropometrics, which is the study of human proportions used in the designing of products.

1.5.3 Internet Research Material

Internet information on this subject is abundant. There were a few lengthy design processes, but none that incorporated the input of all parties necessary. Statistical information on sports related issues as well as some pros and cons of crutch use were readily available; however, information containing input from athletic trainers in designing products related to sports injuries was unavailable with the exception of clinical studies.

1.6 ASSUMPTIONS OF STUDY

It is assumed that the sources used in this documentation are valid, true, and proven. The method of medical products specific to sports related injuries is vast and complicated. The documentation in this thesis is scaled and pertains specifically to injuries sustained to the lower extremities and the development of products used to restore regular ambulatory function.

1.7 SCOPE AND LIMITS OF STUDY

The focus group is comprised of NCAA Division 1 athletes that compete in football, basketball (men's and women's), baseball, softball, gymnastics, and wrestling. In this study there is only a revision to current design methodology as it pertains to the design of orthopedic products that restore ambulatory function and are created for lower leg injuries.

1.8 PROCEDURES AND METHODS

The procedures and methods used in this thesis are comprised of three main categories:

- Research:

  -Sport injuries: Specifically to the lower extremities in NCAA Division 1 athletes; length of recovery, type of injury, diagnostics required, orthopedic products required, quality of life

  -Current orthopedic products: Ambulatory products such as crutches, canes, walkers, wheelchairs, etc.; What is the problem with current ambulatory products? How can they can be improved or replaced?

-Current design processes for orthopedics; Need, concept, design, testing, manufacturing, marketing: Are there problems with the current design process? Are orthopedic doctors and athletic trainers incorporated into the design process? Should they be? What are the benefits of having their insight?

- Development:

  -Concepts: Idea sketches, product renderings, computer aided designs, mechanical models, prototypes, and a final model

  -Production: Documentation of the process of the production of a product through all the phases in the design process

- Communication:

  -Analyze: To certify that the process was completed accurately

  -Finalize: Document the entire design process

1.9 ANTICIPATED OUTCOME

The anticipated outcome for this study is the development of a conceptual orthopedic product that eliminates the use of crutches, restoring normal activity to a temporarily injured athlete. The product will be the main outcome of this study through which a new design methodology specific to lower leg injuries is tested.

Additionally, a communication network between the orthopedic surgeon, the athletic trainer, and the designer, which enables the construction of a better product, will be implemented. It will encompass the methodology, which is established throughout this thesis.

CHAPTER 2: DESIGN RESEARCH

2.1 OVERVIEW

In Chapter 2 further research will be covered providing more insight into the disadvantages of using crutches. The injuries that cause the use of crutches will be reviewed as well as the length of use. Athletic trainers' and orthopedic surgeons' opinions and views will be collected and analyzed to give a better understanding of their thought process from evaluating an injury to the rehabilitation process post surgery. Existing products such as crutches, canes, forearm crutches, platform crutches, wheelchairs, and walkers will be compared and evaluated. Finally, early concepts for a product that may replace crutches for select injuries will be derived and illustrated.

2.2 PHYSIOLOGY OF THE LOWER LEG

This section will cover the types of injuries an athlete may suffer to the lower leg, the surgery (if needed), and the rehabilitation that follows the injury. The lower leg contains bones, tendons, ligaments, blood vessels, nerves, and skin. The two main bones of the lower leg are the tibia and fibula. The tibia and fibula are held together by ligaments at the knee and ankle along with muscle throughout the leg. The foot is comprised of many smaller bones and ligaments as illustrated in Figure 2.1 through Figure 2.3 (Dekornfeld, 1990). The primary ligaments in the knee are the medial collateral (MCL), lateral collateral (LCL), anterior cruciate (ACL), and posterior cruciate (PCL) ligaments. These ligaments connect the lower leg to the upper leg or femur. The ligaments in the ankle are as follows: medial ligament (Deltoid), posterior talofibular ligament, anterior talofibular ligament, syndesmotic ligament (posterior and anterior tibiofibular ligaments), and calcaneofibular ligament. These ligaments hold the tibia and fibula together and also secure the foot to the lower leg creating the ankle joint (Fu, 1994). Refer to Figure 2.7-9

Figure 2.1

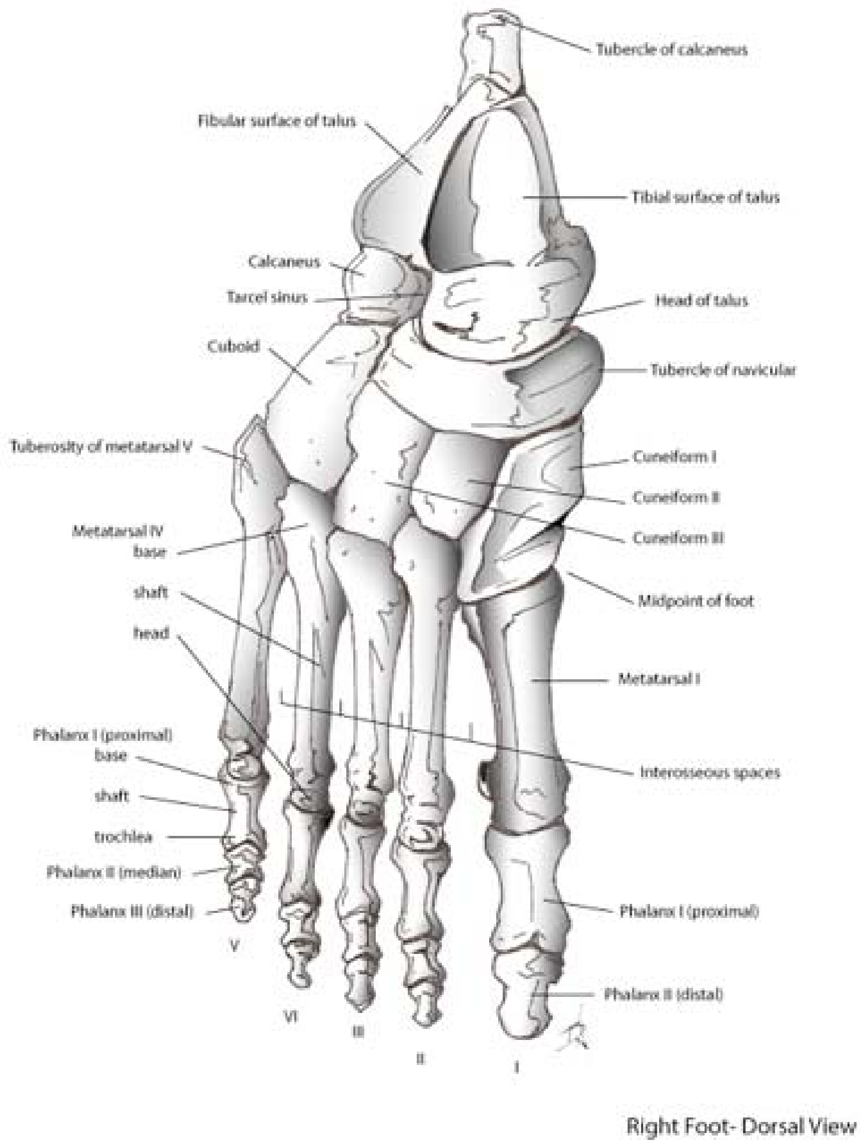

Figure 2.1 is an illustration of the bones found in the foot.

Figure 2.2

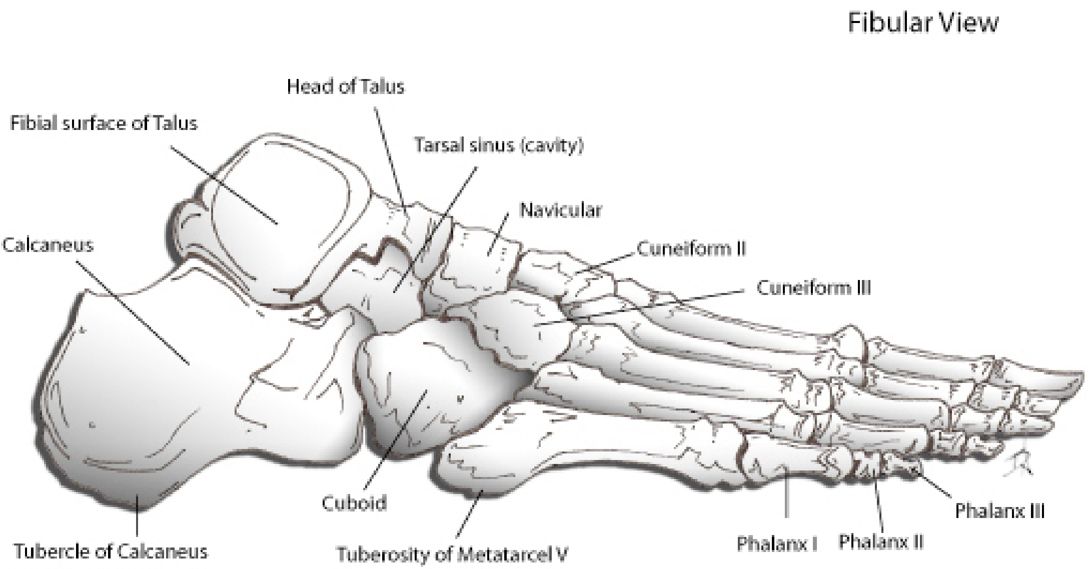

Figure 2.2 is an illustration of the fibular view of the right foot.

Figure 2.3

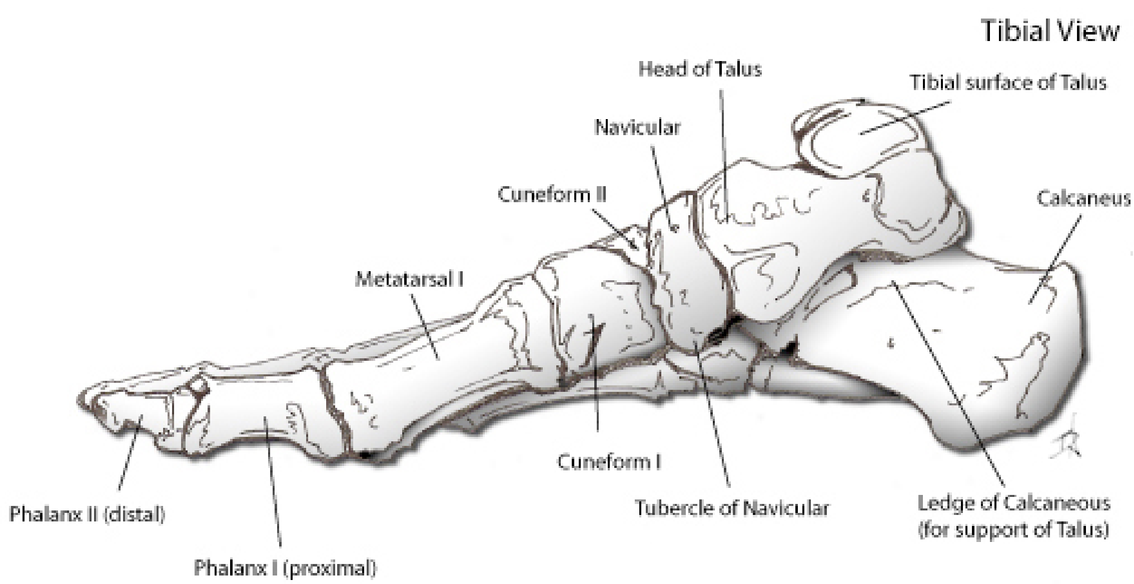

Figure 2.3 is an illustration of the tibial view of the right foot.

Figure 2.4

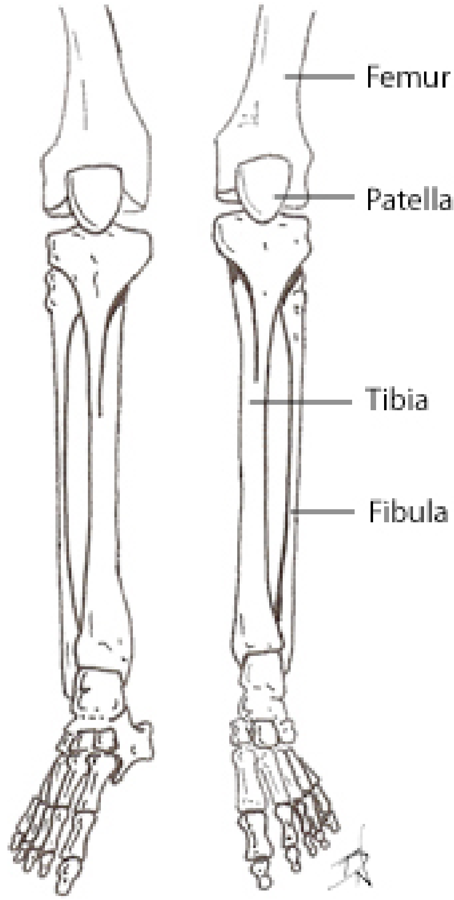

Figure 2.4 is an illustration of the main bones in the leg.

Figure 2.5

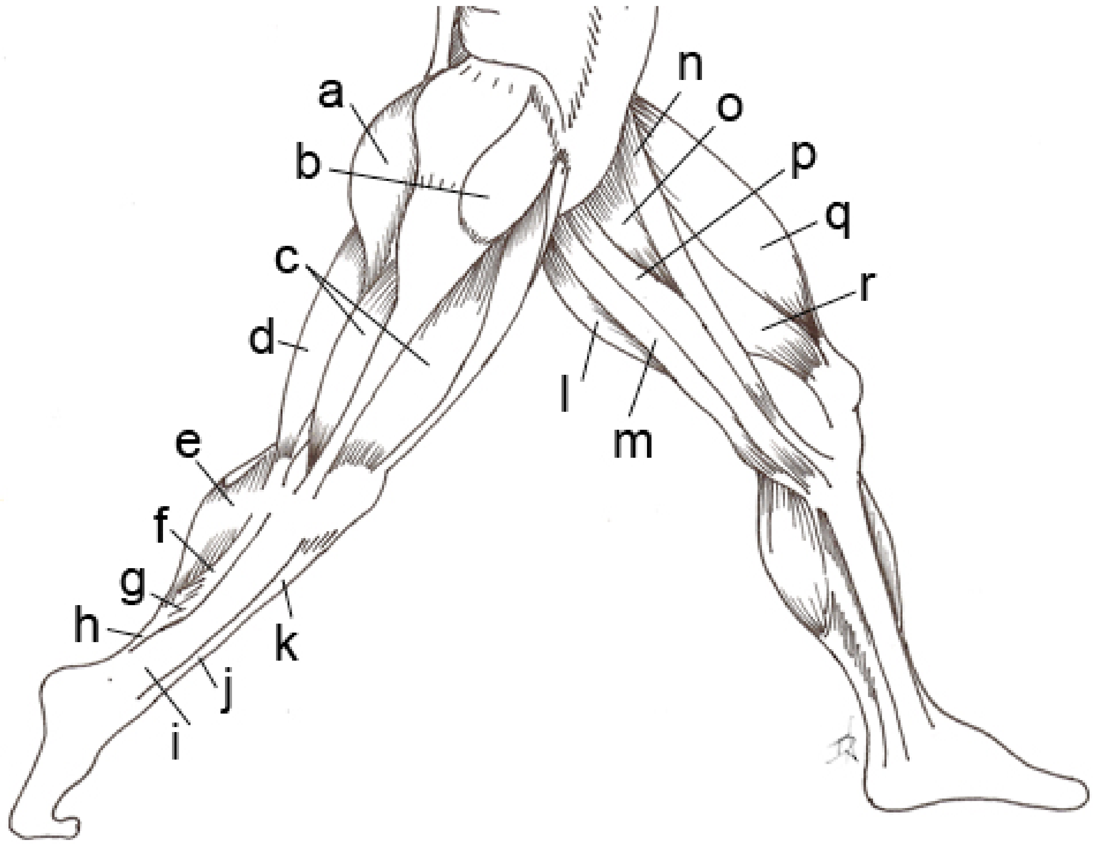

Figure 2.5 is an illustration of the muscles in the legs.

a. Gluteus maximus, b. Tensor fascia latae, c. Vastus lateralis, d. Biceps femoris, e. Gastocnemius, f. Soleus, g. Peroneus longus, h. Peroneus brevis, i. Extensor digitorum longus, j. Extensor hallucis longus, k. Tibialis anterior, l. Rectus femoris, m. Semintendinosus, n. Sartorius, o. Adductor longus, p. Gracilis, q. Rectus femoris, r. Vastus medialis

2.2.1 Injury

According to the National Collegiate Athletic Association's website, during the 2003-2004 football season, thousands of injuries occurred resulting in the need for an athlete to use orthopedic products such as crutches. Injuries to the lower leg account for 23% of all injuries that occurred during practice. Lower leg injuries include the ankle, the heel/Achilles tendon, the foot and toes, and the tibia and fibula. When knee injuries are included the percentage goes up to 37%. The rate at which these injuries occur during practice are .99 per 1000 exposures without the knee and 1.63 per 1000 exposures including the knee. That means in practice a lower leg injury occurs 1 in every 1000 plays. The rate and percentage increases significantly when games are considered. In the same season lower leg injuries made up 26% of all injuries during games and 46% when the knee is included in that group. The rate is also higher as the exposures are extremely lower than that of practice. The rate goes from .99 per 1000 exposures in practice to 10.9 in games and 19 per 1000 exposures when including the knee (www.NCAA.org).

Injuries suffered to the lower extremities are quite common. According to the NCAA injury surveillance database, the most common injuries that occur are sprains and strains. A sprain relates to a ligament and is most common to the ankles and knees. Ankle sprains account for 20% to 30% of all sports related injuries nationwide (drgreene.mediwire.com). A strain is a tear to a tendon or muscle and can also be referred to as a pull. There are partial tears and complete tears. Surgery is not always required for sprains except in extreme cases where there is a complete tear and surgery is primarily the only way to make a full recovery. Complete tears requiring surgery are most typically knee injuries, primarily ACL's (Anterior Cruciate Ligament). Severe fractures and tendon ruptures also require surgery. Injuries to the knee can come from an outside force making contact to the joint forcing it out of position or from the body of the athlete rotating over the joint when the foot is in a fixed position. The same is true for the ankle (www.NCAA.org).

There are four main ligaments that are in and around the knee and three main tendons. The main ligaments are called cruciates. They are the medial collateral, lateral collateral, anterior, and posterior cruciate ligaments. The main tendons are the patellar, hamstring, and quadriceps tendons. The cartilage in the knee is called the meniscus and can also be injured by an impact or twisting motion. When an athlete suffers the "triad" or "the big-three," this normally means that the ACL, MCL, and meniscus have all been injured. Surgery is required along with extensive rehabilitation to repair this injury (Delforge, 2002). Refer to figure 2.6.

Figure 2.6

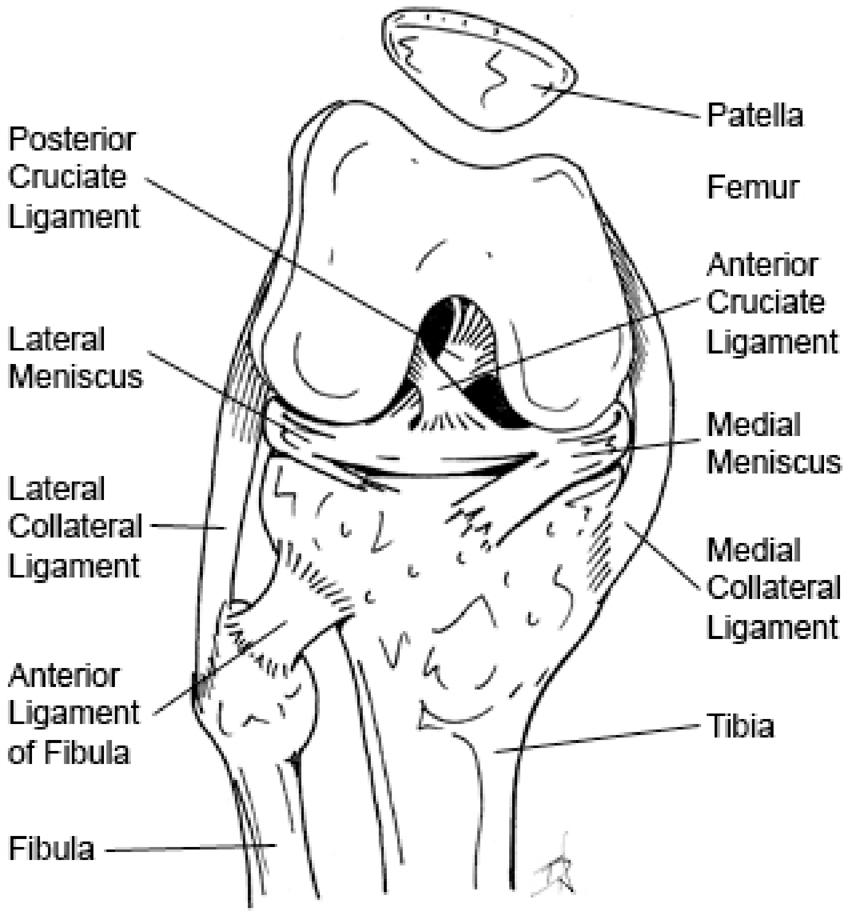

Figure 2.6 is an illustration of the ligaments in the knee joint

The ankle is also made up of many ligaments, tendons, and bones. The main ligaments found in the ankle are as follows: medial ligament (Deltoid), syndesmotic ligament, and calcaneofibular ligament. Sprains to the ankle are the most common ankle injury and depending on severity can take from one week to a full year to recover. According to the NCAA injury surveillance system the rate per 1,000 exposures for ankle injuries is .57. A sprain occurs when the ankle joint is forced out of its natural position. When this happens the ligaments are put under unnatural forces and start to tear, thus creating the sprain. There are two types of sprains inversion and eversion, inversion being the most common. The most common sprain is the plantar-flexion inversion sprain. It accounts for 15% of all reported sports injuries and occurs when the anterior talofibular ligament is isolated and stretched or ruptured (Subotnick, 1999). The Achilles tendon or heel tendon (figure 2.9) attaches the calf muscle to the heel and is not injured as often as a knee or ankle, yet when ruptured it is one of the most devastating injuries in sports. When the tendon is torn all flexion is lost. A complete tear will require surgery. The speed to which surgery is undergone determines whether a full recovery can be made. The reason a speedy surgery is required for this particular injury is that the muscle is no longer attached to the bone and cannot be used thus it begins to atrophy. Atrophy is the deterioration of the muscle due to lack of use. The average recovery time from an Achilles injury is a one complete year (ajs.sagepub.com).

Figure 2.7

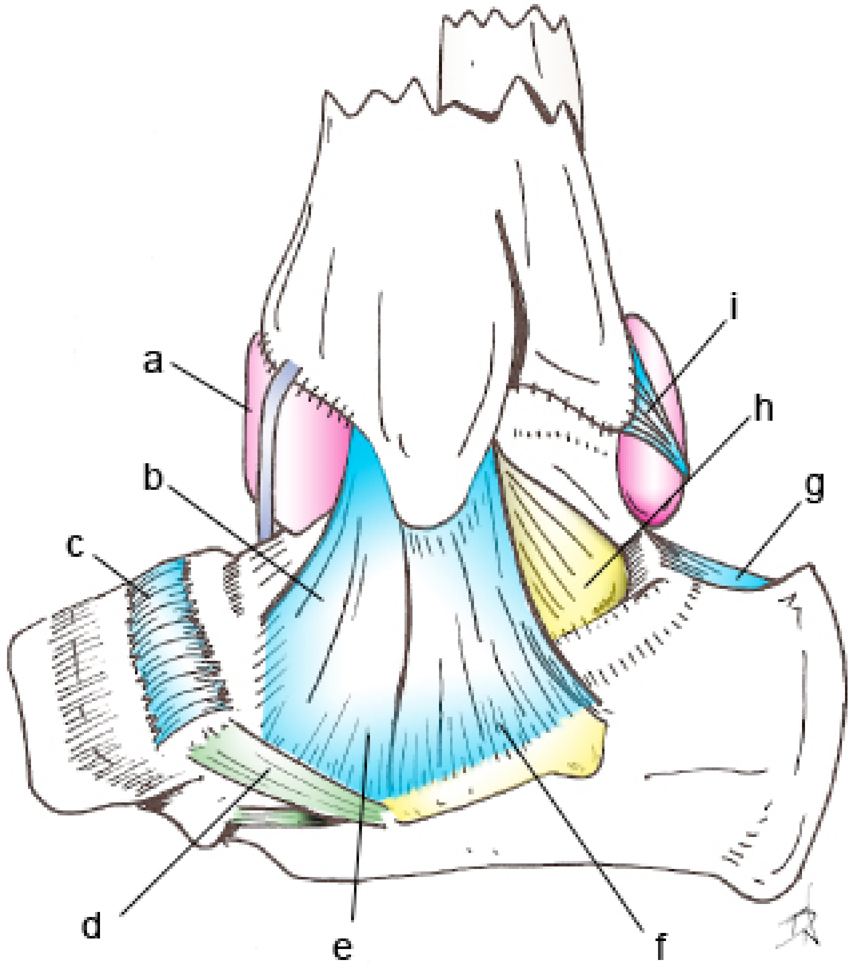

Figure 2.7 shows the tibial view of the ankle.

Figure 2.8

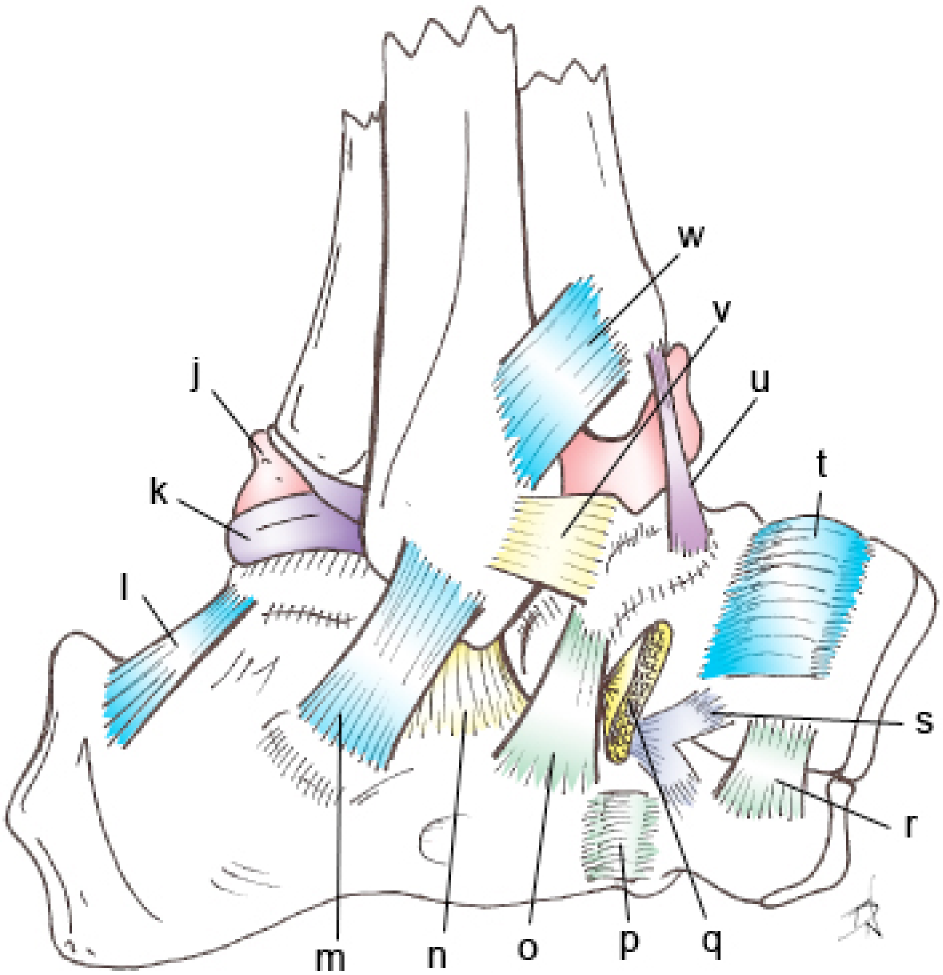

Figure 2.8 shows the fibular view of the ankle.

Figure 2.9

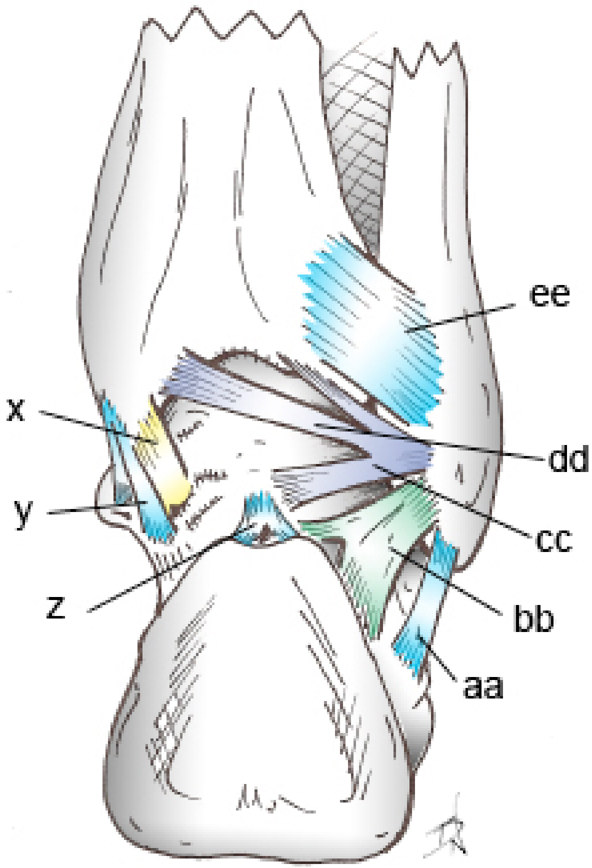

Figure 2.9 shows the rear view of the ankle.

List of ligaments for figures 2.6-2.8

a. anterior oblique capsular support

b. medial ligament, superficial tibiotalar portion

c. talonavicular ligament

d. deep portion of spring ligament

e. medial ligament, superficial portion attached to spring ligament

f. medial ligament, superficial tibiocalcaneal portion

g. posterior talocalcaneal ligament
h. medial ligament, deep component
i. posterior intermalleolar ligament
j. posterior intermoalleolar ligament
k. posterior talofibular ligament
l. posterior talocalcaneal ligament
m. calcaneofibular ligament
n. lateral talocalcaneal ligament
o. cervical ligament
p. dorsal calcaneocuboid ligament
q. extensor digitorum brevis
r. dorsal cuboideonavicular ligament
s. bifurcate ligament
t. talonavicular ligament
u. anterior oblique capsular reinforcement
v. anterior talofibular ligament
w. anterior inferior tibiofibular ligament
x. deep tibiotalar portion of medial ligament
y. superficial portion of medial ligament
z. posterior taocalcaneal ligament
aa. calcaneofibular ligament
bb. fibulotalocalcaneal ligament
cc. posterior talofibular ligament

dd. posterior intermalleolar ligament

ee. posterior inferior tibiofibular ligament

Figure 2.10

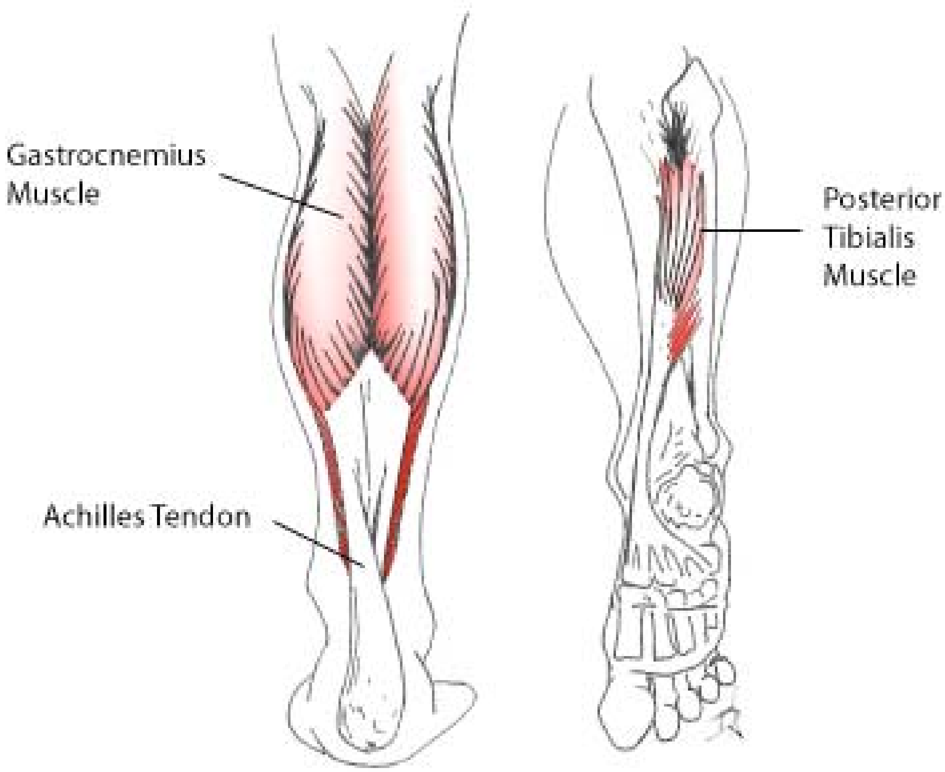

Figure 2.10 is an illustration of the main muscles and tendon in the lower leg.

Other common sport injuries to the lower extremities are sustained to the bones of the athlete. These injuries are called fractures or breaks. There are different types and severities of fractures. When dealing with fractures there are two main classes. An open fracture means the bone has broken the skin, and a closed fracture means the bone has not broken the skin. There are also several different ways to describe the type of fractures. The seven main types of fractures found in athletes are (Figure 2.10):

1) transverse- bone is broken perpendicular to the length of the bone
2) oblique- bone is broken at an angle
3) spiral- the bone is twisted when broken
4) comminuted- bone is broken into three or more pieces
5) avulsion- a piece of bone is pulled off by a ligament or tendon
6) open- the bone breaks the skin
7) incomplete- the bone is partially broken, not complete (The Team Physician handbook, 1997).

The injury rate for fractures in football is .22 per 1,000 exposures. Like sprains, breaks can occur through contact with another person, object, or ground or from twisting the body over a limb that is in a fixed position. Like an Achilles injury, fractures are less common, yet are more severe and result in a greater amount of time required to heal.

Figure 2.11

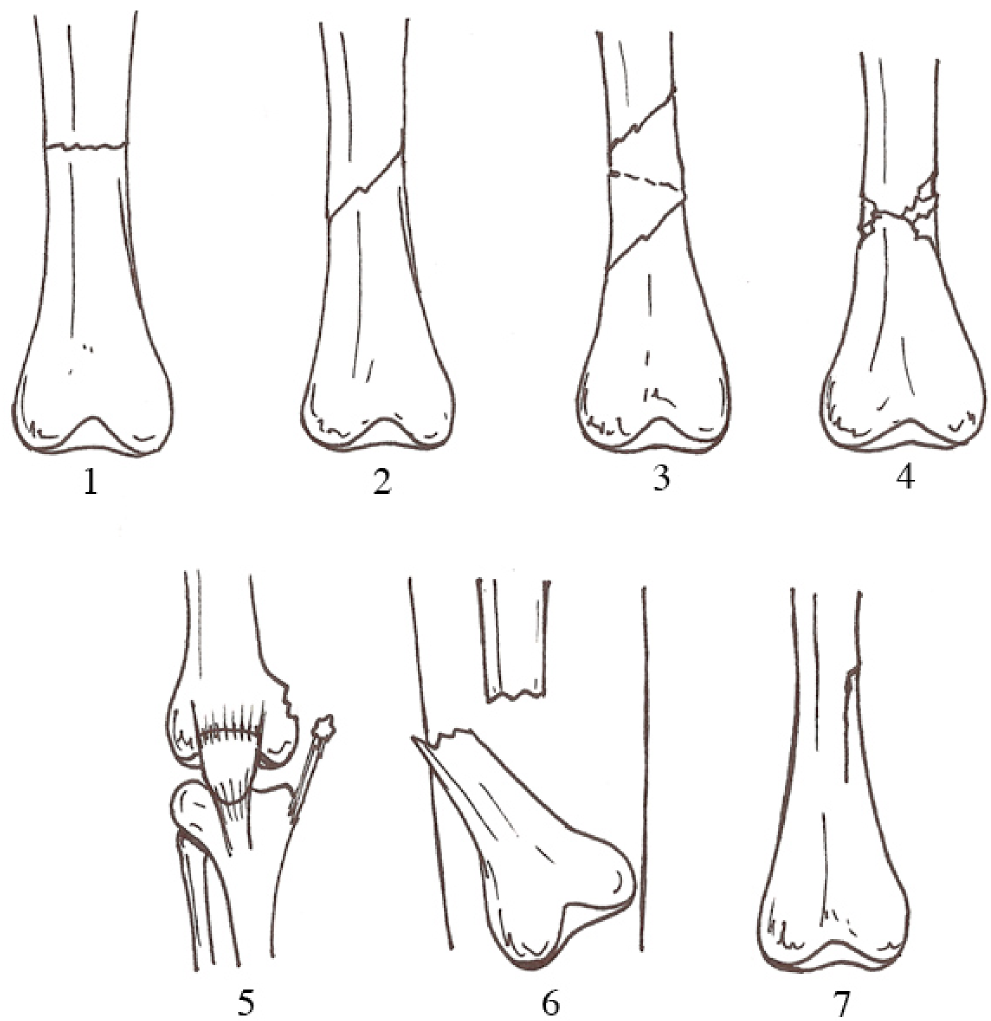

Figure 2.11 illustrates the different types of breaks common in lower leg injuries.

The one thing lower leg injuries have in common is the need to use crutches. Immediately following an injury the athlete will be given crutches to use for at least a day. The more severe the injury the longer the need for crutches. There are many other injuries that can occur to the lower leg; however, the previously mentioned injuries are the most common and severe (www.NCAA.org).

2.2.2 Surgery (Repair)

There are many steps the injured athlete must go through before surgery is deemed necessary. The first is an on field diagnosis done by a team trainer and/or physician. Next, the athlete goes to the hospital for further review, if needed. Once at the hospital, the athlete meets with an orthopedic surgeon who evaluates the injury and calls for further examinations usually consisting of x-rays, MRI's, CT scans, or bone scans. From that point a full diagnosis of the injury and the recommendation for how to proceed with treatment can be made. It is not uncommon in athletic related injuries for a few days to pass before performing surgery to allow the swelling to reduce; however, emergency surgery may be required depending on the severity of the injury. Refer to table 2.1 for statistical data on the surgery rate for Division 1 athletics.

After surgery the athlete starts the rehabilitation process. Depending on the surgery, very low intensity exercises can be done to reduce the amount of atrophy. More intense exercises may begin after the wound has healed and sutures/staples have been removed. The most common types of surgeries performed on the lower extremity are arthroscopic (key-hole), reconstructive, internal/external fixation, open/closed reduction, loose body removal, and ligament/tendon repair (Subotnick, 1999).

Table 2.1:

Injuries resulting in 7+ days missed:

Sport	Practice Rate per 1,000 exp	Game Rate per 1,000 exp
Football	3.8	13.7
Wrestling	2.1	13.3
Women's Gymnastics	1.9	9.8
Men's Basketball	1.2	2.6
Women's Basketball	1.3	3.0
Baseball	0.7	2.2

Injuries resulting in surgery:

Sport	Practice Rate per 1,000 exp	Game Rate per 1,000 exp
Football	1.2	2.3
Wrestling	0.4	3.2
Women's Gymnastics	0.6	3.5
Men's Basketball	0.3	0.3
Women's Basketball	0.4	0.7
Baseball	0.2	0.7

(www.NCAA.org)

2.2.3 Rehabilitation

The most vital time once an injury has occurred is thought to be the first 48 hours. In that time the body will react to the trauma inflicted upon it. The common practice used to treat a new injury is referred to as R.I.C.E., which means rest, ice, compression, and elevation (Shannon, 2002). The body is given a chance to swell. Swelling is a reaction designed by the body to protect itself. This time is also given to let the body start the healing process. For example, if it is a ligament injury known as a sprain, the ligament will heal itself by scarring over the partially torn portion. It also allows some of the swelling to subside, so that an accurate assessment of the injury can be made. The ice, compression, and elevation are all used in an effort to reduce swelling. Ice is widely used throughout sports medicine for every sort of injury. Cold reduces swelling in an injured area by constricting the blood vessels and preventing any excess fluid from being delivered. Compression, such as ace wraps and stockings, is used in combination with elevation of the injured limb to help move the swelling out of the injured area. This is vital. Swelling causes restricted motion in and around a joint as well as discomfort and pain. Excess fluid is an unwanted presence in the injury site. Reducing the swelling in an injured area not only alleviates discomfort, but also allows for a more comprehensive and accurate evaluation. For example, when getting an MRI or other computer image diagnostic done, the less swelling that is present in an injury site the better the image will be. If the picture is clear, without excess fluid being present, the injury is easier to assess. Making a more accurate diagnosis is key to what procedures are to be pursued (Mike Fink, personal communication, August 20,2006).

One of the first steps in rehabbing the athlete post injury/surgery is getting weight off of the injured area. For lower leg injuries the most common way to do that is to prescribe the user crutches. Depending on the severity of the injury, crutches may become a vital part of an athlete's life. Crutches are used for everything from mild ankle sprains (first 48 and rest) to ruptured Achilles tendons and compound fractures that may require their use for 8-12 weeks (drgreene.mediwire.com). The longer crutches are used the more problems the athlete will encounter. Some of these problems include crutch palsy, which is numbness in the arms and hands from the improper use of crutches, to losing the function of the hands from the general use of crutches (www.gpnotebook.co.uk).

Not all lower leg injuries require the use of crutches, for example in some cases with mild knee sprains where a knee immobilizer is used crutches are not given. This is done to help reduce the atrophy that would occur in the leg from being non-weight bearing. Atrophy can increase the recovery time due to the loss of muscle that must be rebuilt before returning to play (Mike Fink, personal communication, August 20,2006).

In cases that do require prolonged use of crutches, doctors limit their use. An example of this is Thomas Fetterman, a polio victim and crutch user for 40+ years, who stated “I developed shoulder pain. My doctor said it was caused by the pounding resulting from years of crutch use and recommended that I take aspirin and limit my activity.” Fetterman is an extreme example of the additional injuries that can occur due to prolonged crutch use, but he is a testament to the need for a better product (www.fetterman-crutches.com).

Dr. Bill Dickerson agrees with Fetterman that something needs to be done to make crutches better or possibly eliminate them all together in certain situations. In an interview Dr. Dickerson stated that crutches are a tool that breeds instability and inefficiency because of the way they are designed. Dr. Dickerson argued that "it's simply basic physics. You use about 78 percent more energy than a regular walk" (www.crutches.net).

The rehabilitation process for athletes will steadily become more physical as the injury heals. The portion under review refers only to that portion where crutches are needed. It is the quality of life that is in question while depending on crutches for mobility and if a product that eliminates the need for crutches would create a higher quality of life.

2.3 MARKET OVERVIEW: EXISTING AMBULATORYAIDS

This section is a comparison of existing ambulatory aids that include crutches, canes, walkers, wheelchairs, forearm crutches, and platform crutches. It compares price, ease of use, length of use, how the product is used, if hands are required, the comfort of the product while in use, and who primarily uses the product.

2.3.1 Comparative Product Chart

Table 2.2

	Price	Length of Use in weeks	Mobility (good, limited, extremely limited)	Comfort (good, moderate, bad)	Ease of Use	Is it Hands Free
Canes	$10-$50	1-indefinite	limited	Good	Good	No
Forearm Crutches	$80-$300	1-12	Extremely limited	Moderate	Moderate	No
Aluminum Crutches	$30-$50	1-12	Extremely limited	Bad	Moderate	No
Platform Crutches	$80-$200	1-12	Extremely limited	Moderate	Bad	No
Titanium Crutches	$800-$1,000	1-12	Extremely limited	Bad	Moderate	No
Walkers	$45-$225	1-indefinite	Extremely limited	Moderate	Good	No
Wheeled walkers	$100-$300	1-indefinite	Extremely limited	Moderate	Good	No
Heel Sling	$85	1-12	Extremely limited	Bad	Moderate	No
Wheelchair	$180-$500	1-indefinite	Good, limited access	Good	Moderate	No
Power Wheelchair	$450-$5,000	Indefinite	Good, limited access	Good	Good	No
Electric Scooter	$900-$3,500	Intermittent	Good, limited access	Good	Good	No
I-Bot Wheelchair	$5,000-$10,000	Indefinite	Good, limited access	Good	Moderate	No

Table 2.2- Comparative Product Chart

Table 2.2 illustrates the problems with the current ambulatory aids available on today's market. The problem with the current products is that they all require the use of the hands in some aspect of their function regardless of the time they are needed. Even wheelchairs require the users' hands to provide motion, whether it is pushing the wheels or holding a lever. Mobility is very limited with all the available forms of crutches. Though it is faster and easier to be mobile in a wheelchair, the user is extremely limited in how accessible certain areas of the world are. It is very evident that a new product is needed to address the problem of the current products.

2.3.2 Kobayashi Chart

Table 2.3

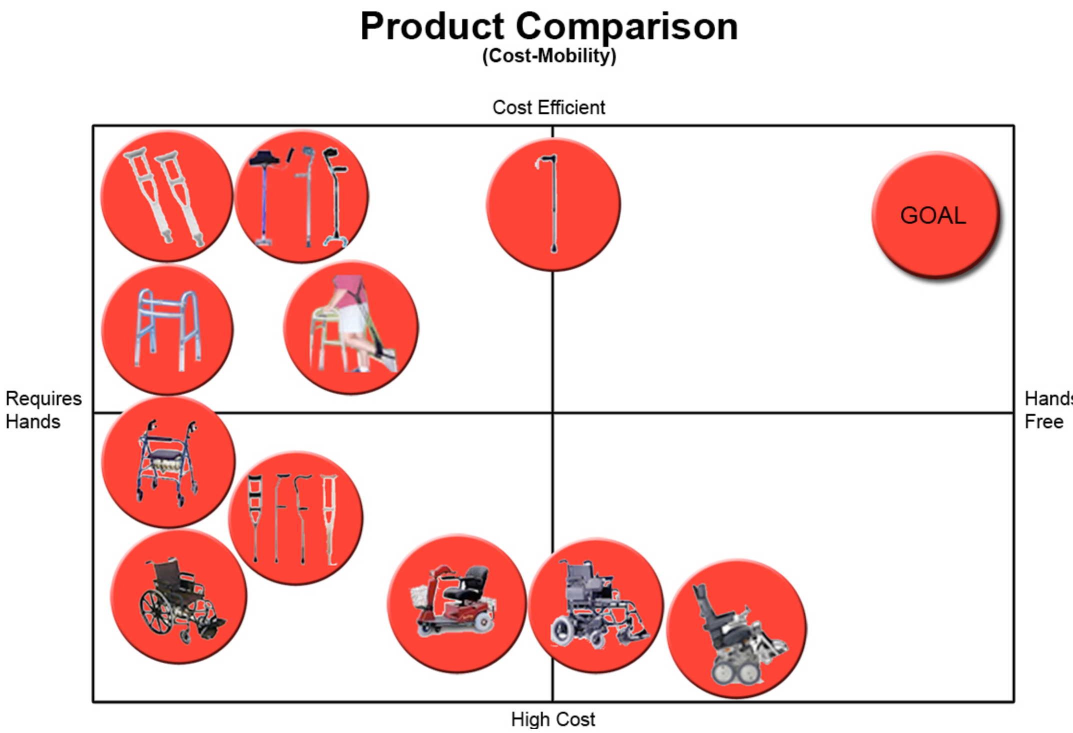

Table 2.3- Kobayashi Chart: Product Comparison

The Kobayashi chart compares cost and mobility using quadrants to visually separate the products. The requirements are that the product is inexpensive and does not require the user's hands to provide mobility. The upper right quadrant is the target quadrant being the most mobile product as well as the least expensive. Crutches, canes, and walkers are the cheapest products on the chart, so they are positioned high; however, since they require the user's hands to provide mobility, they are positioned to the far left. Though they are inexpensive, they do not provide a sufficient amount of mobility. Wheelchairs and powered scooters provide a great amount of mobility, but are they are the most expensive items on the graph. Few products are available that meet both requirements.

2.4 SIZING THE PRODUCT- Anthropometric Data

The human form comes in a multitude of sizes. The study of anthropometry takes into consideration every dimension of the human body and breaks down the population by percentiles. The 50th percentile person has the most common measurements and accounts for the largest group of people. The scale is in the shape of a bell curve with the x-axis being the measurements starting at 0 on the left side and increasing from there. The y-axis represents the number of people with that measurement. The 50th percentile person is at the height of the curve due to having the largest amount of people with that measurement (Tilley, 2002). See Table 2.4 for an example of the scale.

Table 2.4

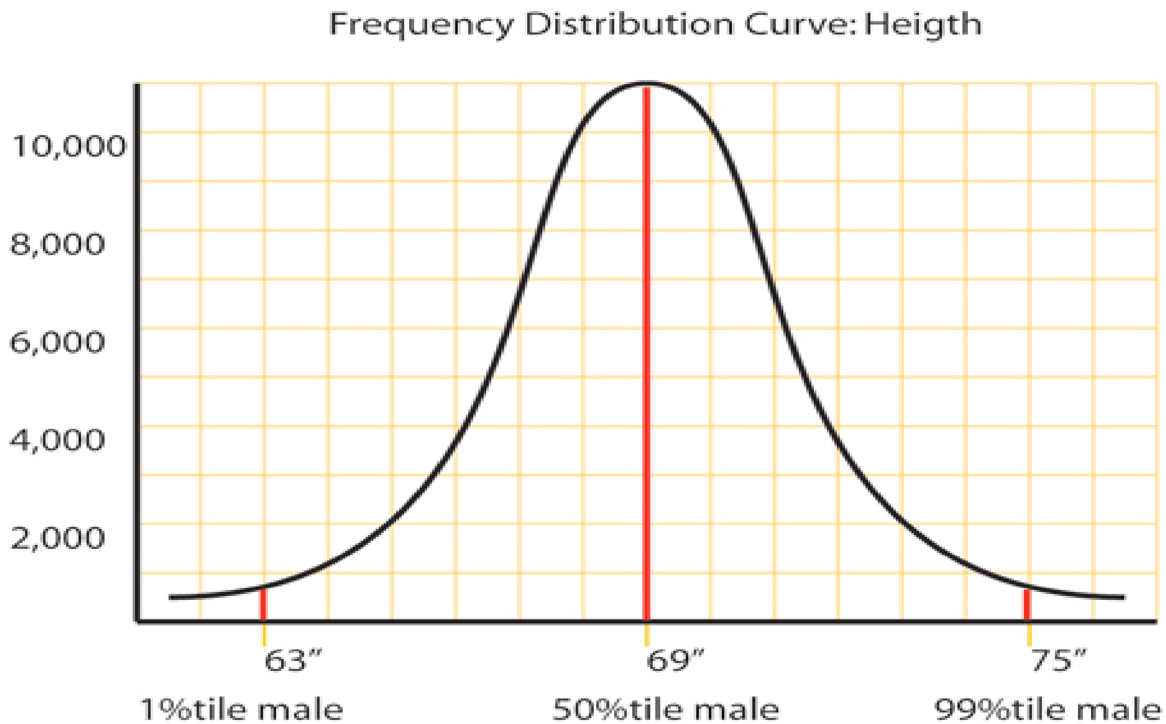

Table 2.4- Frequency Distribution Curve: Male Height

When designing a product it is common to build the product to accommodate a large portion of the population. Designers typically design for 98% of the population, which includes the 1st percentile person to the 99th percentile. It is believed that the other two percent of the population's measurements are so extreme that the product would end up being too large to accommodate the rest of the population. The military takes this a step further and designs goods to accommodate only 90% of the population and uses the 5th percentile through the 95th percentile persons' measurements (Tilley, 2002). (See figures 2.12 & 2.13 for male and female measurements)

Figure 2.12

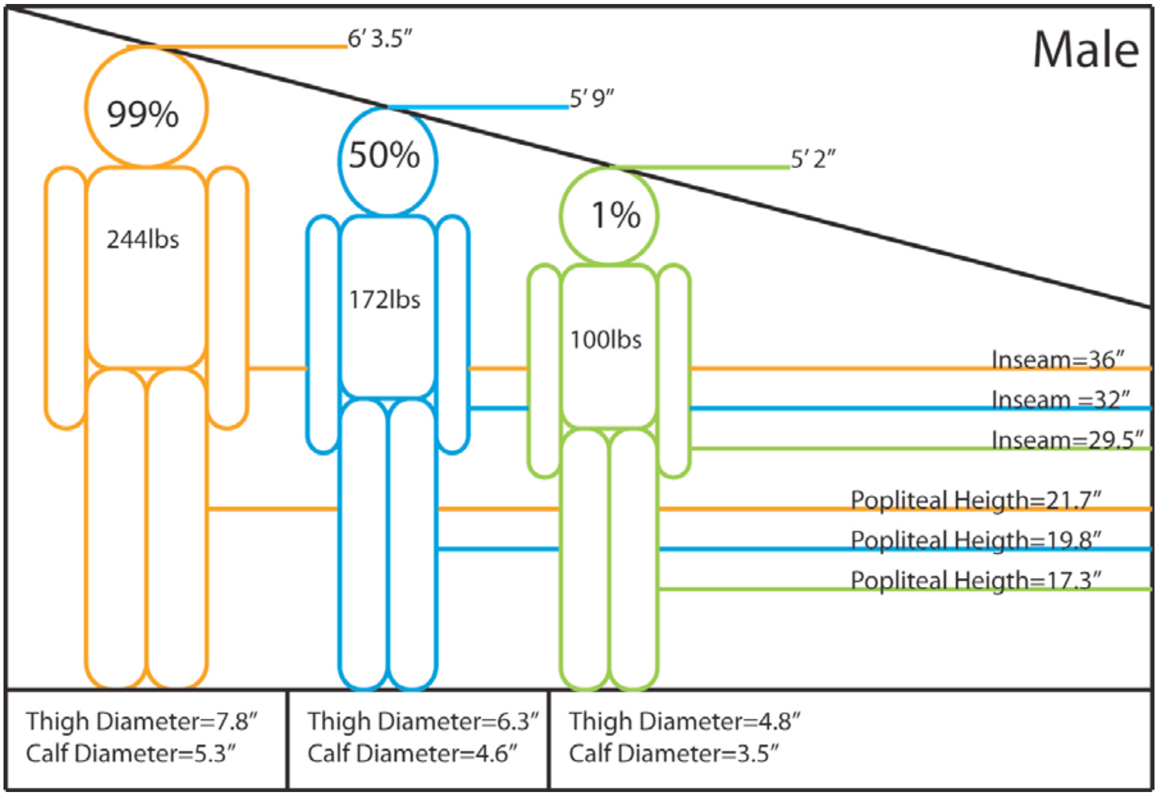

Figure 2.12- Male Measurements

When designing a product for the lower extremity anthropometrics play a key role. Data taken from certain age groups, sexes, and race play a significant role. The age group used in this study ranges from 19-65 years old. Data for both sexes is also included. When dealing with race or ethnicity there are formulas for finding measurements using the standard mean. For example, to find the total leg height (inseam) of a Japanese male you take the mean of the scale and subtract 3.6 inches.

If you want to find an African-American male's leg height, you add 1.5 inches to the mean. Another measurement to take into account is shoe height. According to Human

Factors in Design, the industry average is 1.2 inches. This measurement shows that a product must account for an addition 1.2 inches on the tallest individual designed for.

Figure 2.13

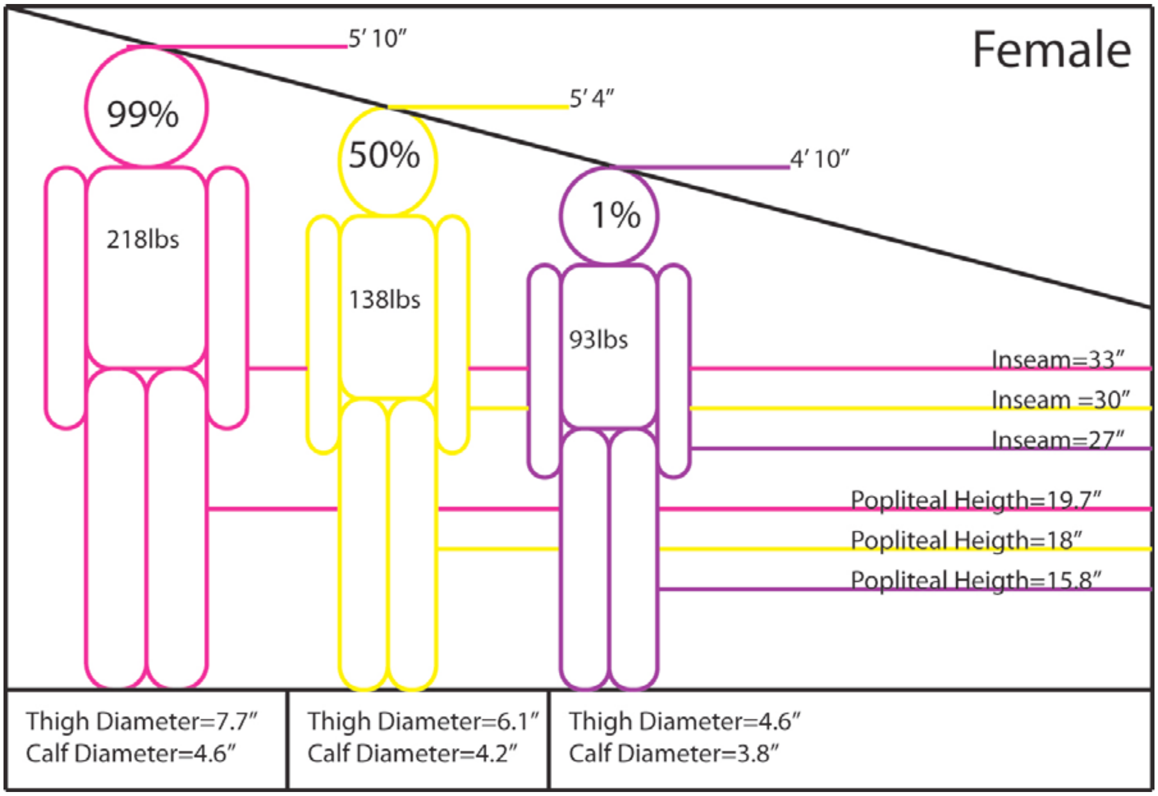

Figure 2.13- Female Measurements

The product design will depend greatly on the sizing charts used. If the product is a one size fits all, it will have to be able to accommodate 98% of the population from very small women to very large men meaning the product will have to be highly adjustable. It will have to take into account the calf and thigh diameter of the smallest person to the largest as well as the popliteal leg height and total leg height. The popliteal leg height is the distance from the base of the knee to the ground (Tilley, 2002). Other methods would include making a men's and women's version of the product accommodating the whole by designing specifically to sex. A sizing method could be employed as well. Small, medium, and large sizes could easily be made to accommodate the majority of the population. This would simplify the design by making specific products for certain ranges of people, but it would increase production cost. The final way to accommodate the population is to design or fit each product specifically to the user. Custom products are common in the orthopedic field. Custom products would be the most expensive route, but would guarantee the best fit for the user.

2.5 OUTCOME: Performance Criteria

Performance criteria are used as a tool to create a product that fills a specific need. A list of functions, specifications, and features are created to be used as guidelines for designing and constructing the best possible product. The human, technical, and production functions are all considered. From how the product looks to how it will be marketed all have parameters set in the performance criteria. In the latter part of the design stage the performance criteria will be used to create an evaluation checklist to insure all goals/criteria are met and function as they should.

The performance criteria for the replacement product will include the following elements categorized into functions, parameters, and criteria:

- Must eliminate the need for crutches
- Must be hands free
- Must be easy to use

- Must be inexpensive ($100-$250) to compete with crutches
- Must be structurally sound: supporting a body weight of up to 400 lbs.
- Must be comfortable for long term use
- Must be lightweight: under 5lbs
- Must be sturdy and durable: environmentally resistant
- Must provide better mobility than crutches
- Must enable user more functionality than crutches
- Safety: non-slip tread
- Must aesthetically appeal to athletes
- Must visually communicate function

These criteria are broken down from parameters, which are parts of the functions system. The Human function has three categories Social Economic, Cultural Aesthetic, and Practical Physiological. The Technical and Production functions both have two categories. The Technical categories are Direct and Indirect Technical. The Production categories are Planning and Manufacturing. Once the criteria are set, the design development can begin. Table 2.5 is the Required Performance Criteria for this thesis project.

Table 2.5

REQUIRED PERFORMANCE CRITERIA			
		Parameters	Performance Criteria
Human Function	Social Economic	Est. Retail Price	$100.00-$250.00
		Est. Product Life	Length of Injury (Shelf 10 yrs)
		Sport	Any
		Injury	Lower Leg/ Below the knee
		Product Availability	Perscription
	Culteral Aesthetic	Style	Sporting
		Color of Metal Support Stucture	Black/Grey
		Color of Plastic Support Structure	Assorted
		Color of Straps	Black/Grey
		Color of Padding	Assorted
		Color of Tread	Black
	Practical Physical	Weight of Product	Approx 5lbs.
		Height of Product Collapsed	24" or less
		Height of Product Extended	36"
		Width of Product	8" or less
		Length of Foot	6" or less
		Width of Foot	4" or less
		Ease of Use	Understandable interface
		Width of Straps	2" or less
Technical Function	Direct Technical	Material for Metal Support Structure	Aluminum
		Material for Plastic Support Structure	ABS plastic
		Material for Padding	High-Density Poly-urathane Foam
		Materrial for Padding Covers	Neoprene
		Material for Straps	Nylon Velcro
		Material for Foot	ABS plastic/Aliuminum
		Material for Tread	Non-slip urethane
		Paint for Metal Structure	Powder-coat
	Indirect Tech.	Safety Features	Non-slip Tread Secure Fasteners
		Environmental Resistance	Powder Coated Metal Neoprene Covered Padding
Production Function	Plan.	Distribution	Mail-order, clinics, and medical supply stores
		Packaging	Cardboard, styrofoam, and plastic
		Advertizing	Print and Internet
	Manufacturing	Material for Metal Support Structure	Aluminum
		Material for Plastic Support Structure	ABS plastic
		Material for Padding	High-Density Poly-urathane Foam
		Materrial for Padding Covers	Neoprene
		Material for Straps	Nylon Velcro
		Material for Foot	ABS plastic/Aliuminum
		Material for Tread	Non-slip urethane
		Paint for Metal Structure	Powder-coat
		Assembly	Automated & Manual

Table 2.5 Required Performance Criteria for a crutch replacement

2.6 SUMMARY OF CHAPTER

Chapter 2 illustrates the composition of the lower leg as well as injuries that occur during practice and game situations. This information provides the basis for understanding the frequency with which lower leg injuries occur and the need for orthopedic products such as crutches. It also illustrated the need to replace crutches when possible due to the additional problems they cause. The need for a hands free ambulation product is highly evident in college athletics.

A study of the market was done, and the current products were compared and evaluated. The conclusion that was reached shows ample space and need for a product that eliminates the use of crutches for severe lower leg injuries. Crutches not only cause a lack of mobility and the loss of function and dependability, but can also cause more serious problems as well. Crutch palsy, which is numbness in the hands from extended crutch use, can be eliminated, if a new product is created.

Sizing the human body was also discussed in this chapter and many solutions where concluded. A one-size-fits-all approach will cut down on manufacturing costs and help make the final product more affordable. With it being a niche market, any effort to keep the product inexpensive should be considered.

CHAPTER 3: DESIGN DEVELOPMENT

3.1 OVERVIEW

Chapter 3 will cover the design development process of this thesis. Preliminary sketches, refined concepts, and mechanical models will makeup the majority of this chapter. The performance criteria from the previous chapter will be used to create an evaluation checklist. The design will be modified after evaluation and the best solution will be determined.

3.2 CONCEPTS: Preliminary Sketches

This section contains the early ideas and sketches of a product replacement for crutches. The sketches are of a product that is designed to support the lower leg (injured area) while transferring the weight of the person to a support beam. The support beam acts as an extension of the injured person's femur so that all the weight is removed from the lower leg. In essence, the product is a prosthesis for a fully able bodied person during the time of injury.

Figure 3.1

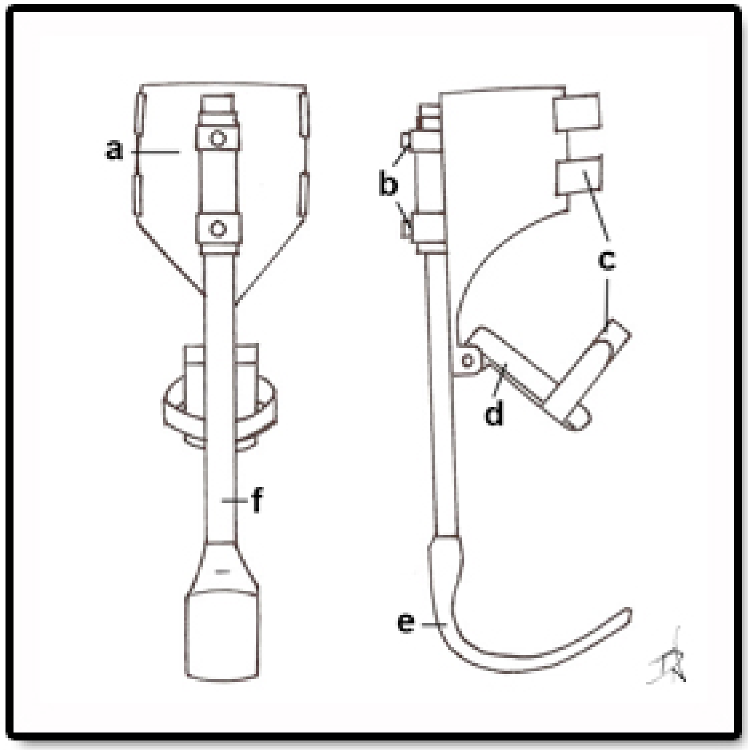

Figure 3.1- Concept 1

Concept 1 is comprised of the following components:

a) Plastic thigh support

b) Adjustable height controls

c) Velcro straps

d) Adjustable angled lower leg support

e) Curved foot

f) Support beam

Concept 1 has an adjustable support beam (b, d) to fit a broad range of people. The lower leg support (d) can be locked at three varying angles to allow for comfort. It has a curved foot (e) to allow for a more realistic gait. Concept 1 attaches to the leg with adjustable Velcro straps (c) for a fast, easy, and comfortable fit.

Figure 3.2

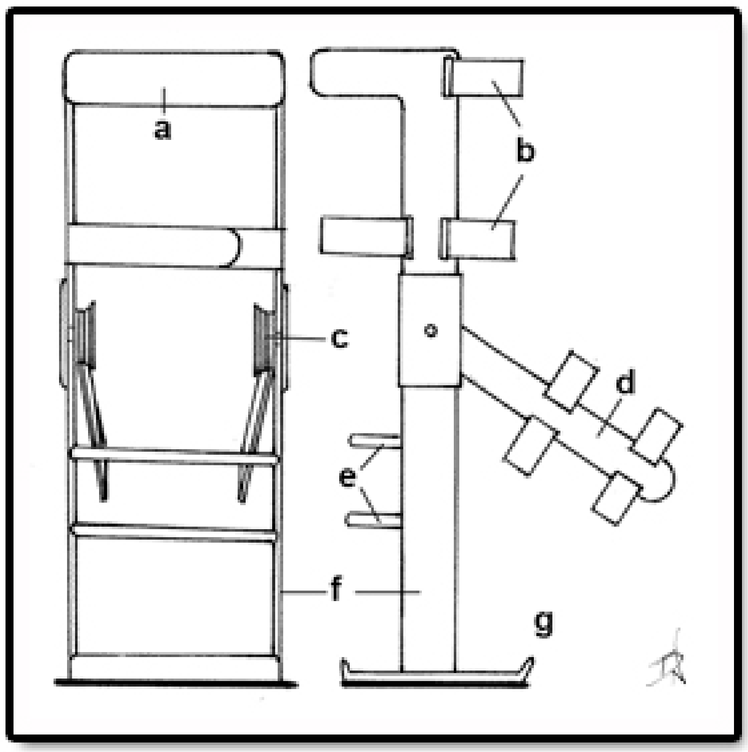

Figure 3.2- Concept 2

Concept 2 is comprised of the following components:

a) Thigh support

b) Velcro straps

c) Hinge knee pads

d) Swing arm lower leg support

e) Shin guard support structures

f) Support beams

g) foot

The main feature of Concept 2 is a swing arm (d) contained inside the support structure (f). The idea behind this concept is to take the weight of the injured lower leg and let it swing weightless in the structure. The lower leg may also be locked at a certain angle depending on comfort for the user. Adjustable Velcro straps (b) are used to attach the product to the user.

Figure 3.3

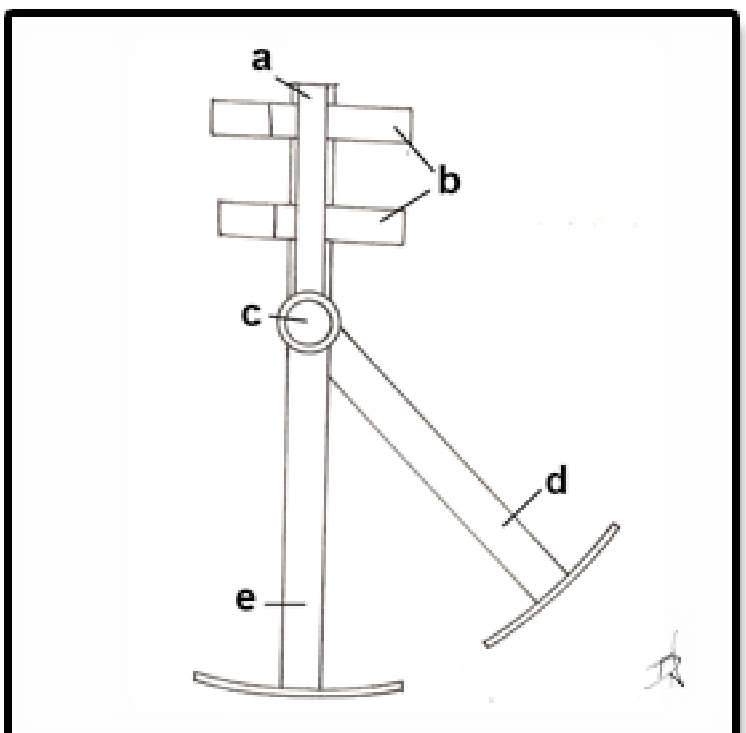

Figure 3.3- Concept 3

Concept 3 is comprised of the following components:

a) Thigh support

b) Velcro straps

c) Hinge

d) Swing arm lower leg support

e) Support beam

Concept 3 is similar to Concept 2 in that they both have a swing arm (d). The swing arm in this concept is not strapped to the lower leg as it is in the previous concept. In this concept the injured extremity rests on the base of the swing arm while friction does the work. Like the previous concept, this product has adjustable angles so (c) the leg can be locked at for comfort while walking. Adjustable Velcro straps (b) attach the product to the injured thigh.

Figure 3.4

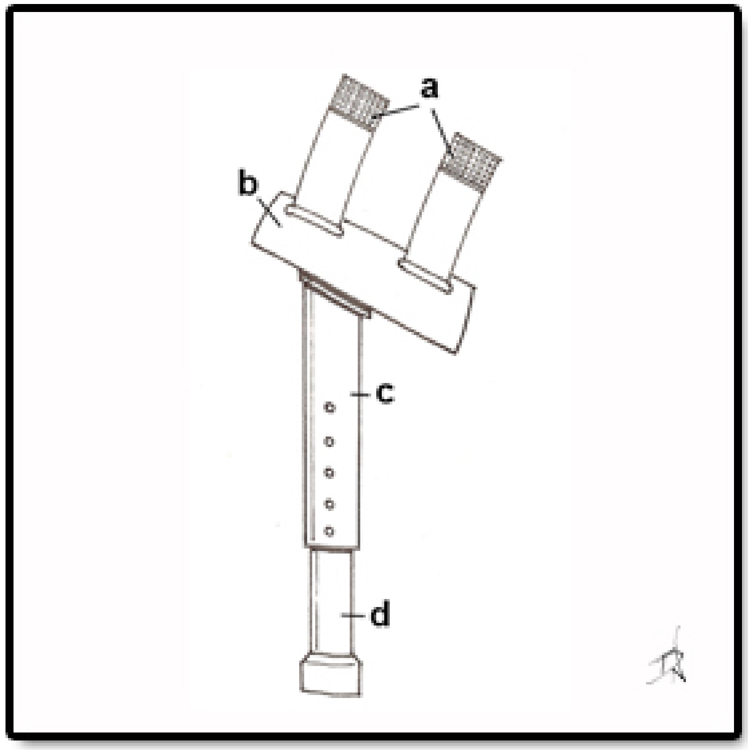

Figure 3.4- Concept 4

Concept 4 is comprised of the following components:

a) Velcro straps

b) Lower leg support

c) Upper support beam

d) Lower support beam

Concept 4 is a simple concept. Designed for ease of use and comfort, the user would be standing still and observing rather than moving around with this concept. Its primary function would be to support the injured extremity while freeing up the hands. This product has adjustable height and straps (a, c, d) to custom fit the user.

Figure 3.5

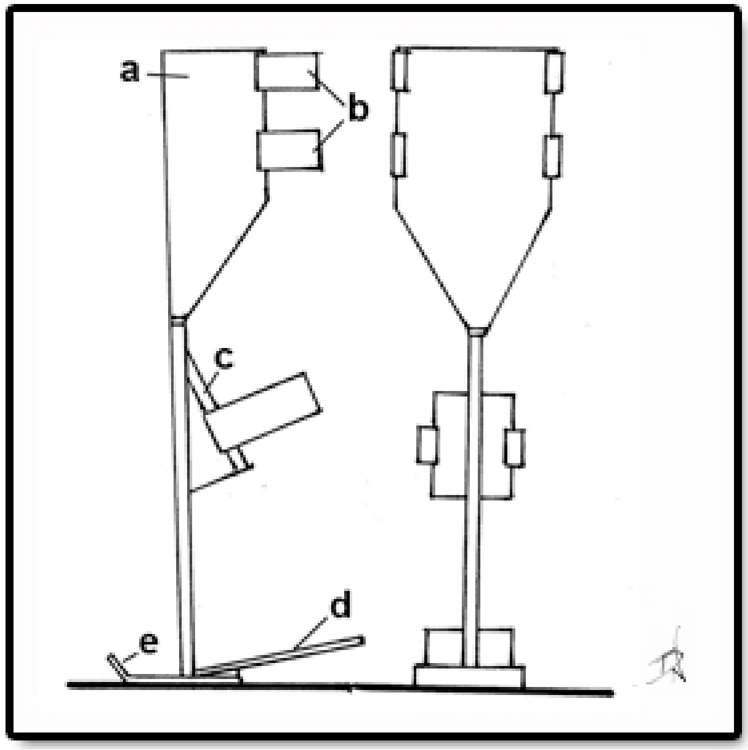

Figure 3.5- Concept 5

Concept 5 is comprised of the following components:

a) Thigh support

b) Velcro straps

c) Lower leg support

d) Footrest

e) Foot

Concept 5 supports the leg at a slight angle (c) to take the weight off of the injured limb. It has a footrest (d) for the injured leg and is attached using adjustable Velcro straps (b). The lower leg support is padded to add comfort for long-term use.

Figure 3.6

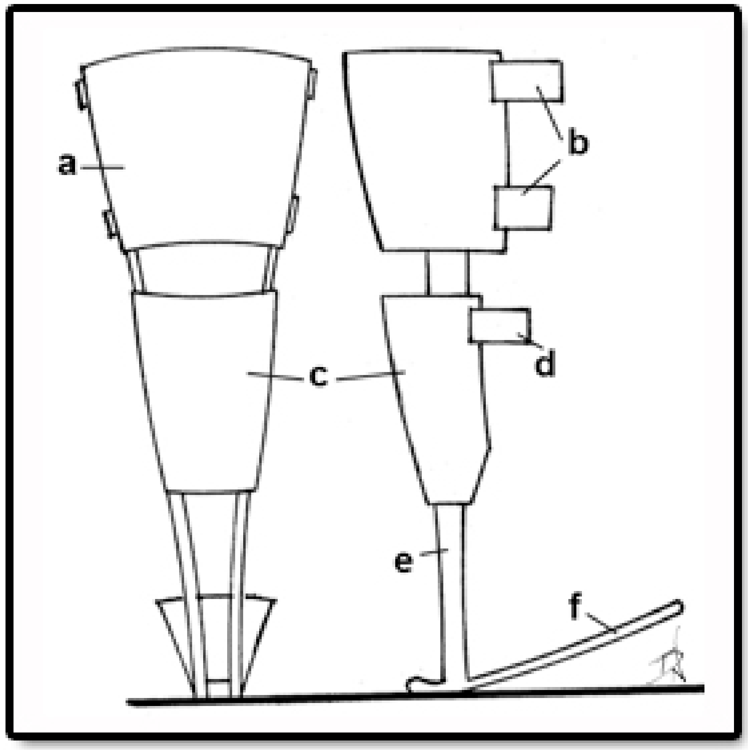

Figure 3.6- Concept 6

Concept 6 is comprised of the following components:

a) Thigh support
b) Velcro straps
c) Shin rest/ lower leg support
d) Velcro straps
e) Support beam
f) Foot/ footrest

Concept 6 is similar to Concept 5 with the footrest (f) and the fixed angle of the lower leg. It transfers the weight of the body to the femur through the support beams (e). This concept uses a carbon fiber shell (a,c) for stringency and strength. It is also held to the leg with adjustable Velcro straps (b). Concept 6 is a custom product and would have to be fitted specifically for the user.

3.3 KINEMATIC/MECHANICAL MODELS

This section will show the development of the idea through mechanical and kinematical models. The building of these models is used to test the idea of a crutch-less product to see if it is possible to have a supportive structure that can be worn and provide a more normal mobility than that of crutches. These models will show whether or not a product like this is feasible and also show what principles work and do not work. The following photos are of the mechanical and kinematical models being created and tested.

3.3.1 Model 1

Model 1 is a variation on Concept 4, which is the simplest design. This model was built to test the idea of the thesis. Model 1 was used to see if the injured area could be elevated while still allowing the user mobility.

Figure 3.7

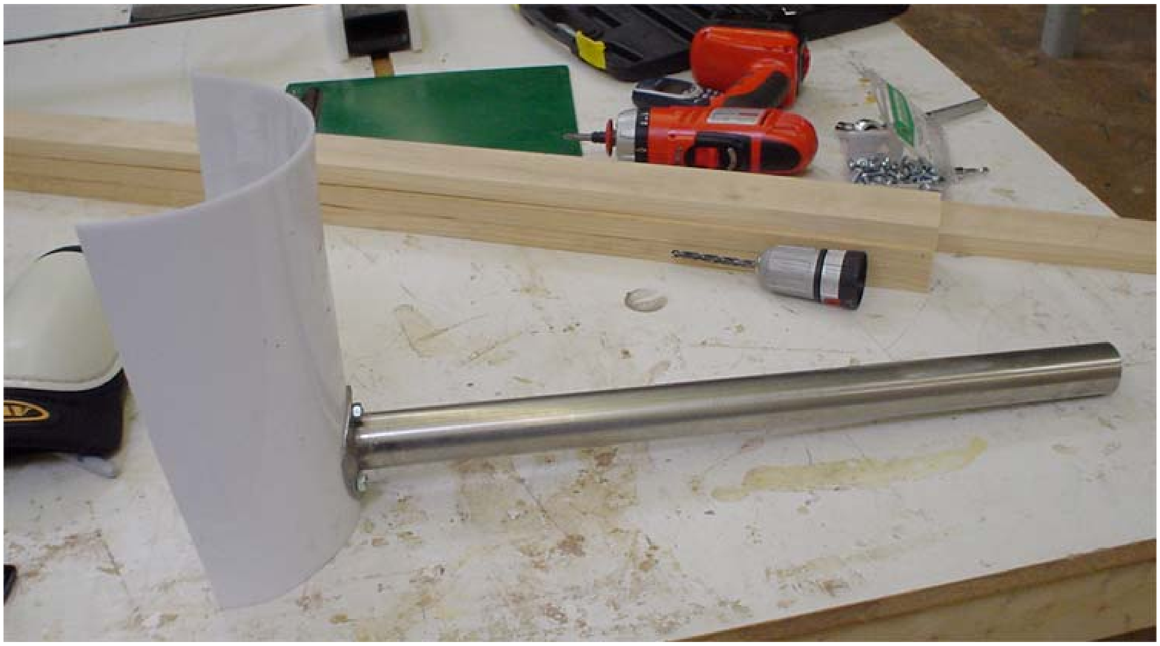

Figure 3.7- Model 1

Model 1 used PVC plastic that was heated and molded into a lower leg support platform. This platform is used to elevate and lock the lower leg at a 90-degree angle. An aluminum pipe was cut to length and affixed to the lower leg support creating the support structure. The metal piping will act as the user's lower leg. The weight of the user will be transferred through the support beam to the femur.

Figure 3.8

Figure 3.8- Connection Detail

Figure 3.8 is a detail view of the connection between the lower leg support and the support beam. The plastic lower leg support was fixed to the support beam by three quarter inch bolts. The support beam is affixed to the front of the lower leg support for weight transfer issues. The support beam is positioned directly under the femur for maximum support and comfort.

Figure 3.9

Figure 3.9- Model 1 in use

Figure 3.9 is the first finished model. The product is attached to the user's leg by adjustable straps. The injured lower extremity is elevated eliminating it from bearing weight. The support beam is used to transfer the user's weight from femur to the floor. The product is used as an artificial limb. This model proved that the concept is valid and that a support structure could be created that would eliminate the need for crutches.

3.3.2 Model 2

This model is a variation on Concept 5. It differs from Model 1 in that it has an upper leg support, which is used to add stability to the product as well as to better stabilize the injured area. It also uses an angled lower leg support and footrest to limit the amount the injured area protrudes out from behind the user. They are used in combination to lessen the chances of hitting the injured limb on objects around the user.

Figure 3.10

Figure 3.10- Model 2 lower leg support

Figure 3.10 is a detail shot of the angled lower leg support. Again, this model was built to test this idea to see if it is possible to rest the leg at an angle other than 90 degrees and have enough support to be mobile. Another idea behind the angled support is to allow the hamstring to rest and not be flexed the entire time the product is being used.

Figure 3.11

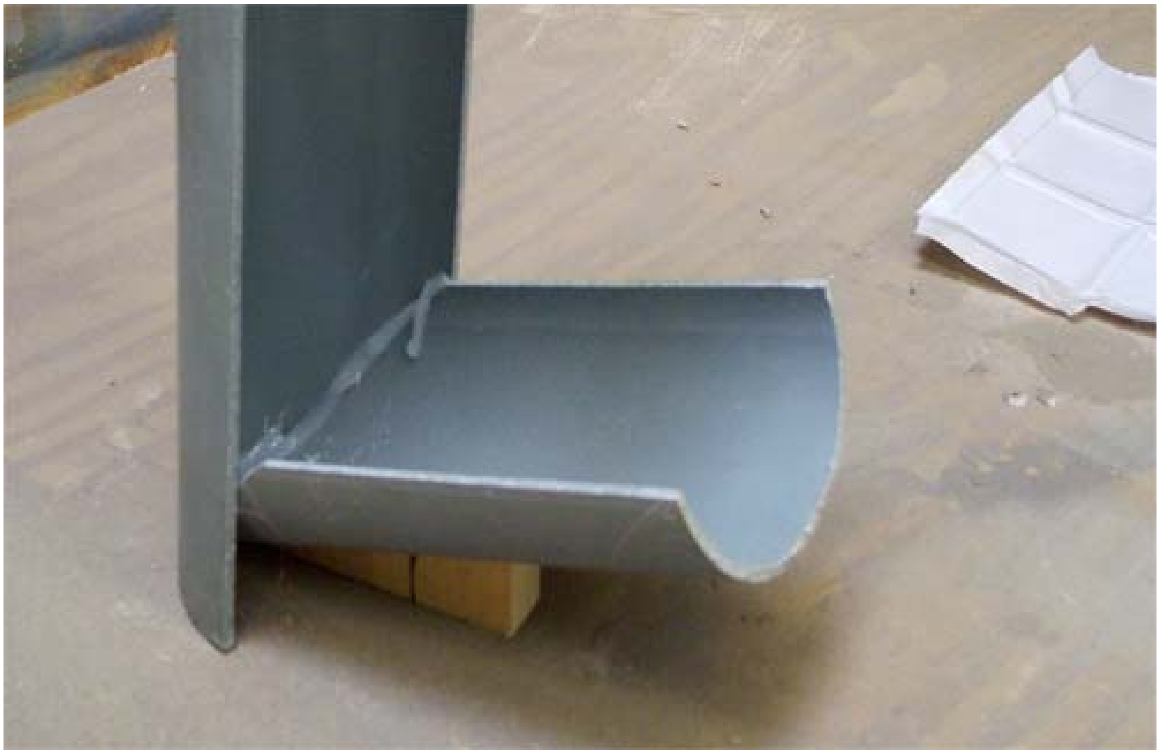

Figure 3.11 Model 2 footrest

Figure 3.11 is a detailed picture of the footrest component of Model 2. This concept was used to further eliminate the possibility of hitting the injured limb on objects that may be in the user's way. This model also tested to see if the footrest is necessary and provide an adequate weight removal from the injured area. If the footrest puts any force on the injured limb, then it is counter productive to the healing process.

Figure 3.12

Figure 3.12- Model 2

The finished second model was constructed from PVC pipe and wood. The footrest was found to be unusable. If it were to be used, it would have to be much longer and act like a foot in itself. Adding a longer footrest would create a larger surface area for walking on. The angled lower leg support added enough support to be mobile.

3.3.3 Model 3

Model 3 is a variation of Model 2. It expands on the footrest to see if the idea is salvageable or necessary. Model 3 also expands on the support of the leg. The product is more efficient when securely fastened to the leg. This model is taken through a few variations from having a footrest to having just a foot, which provides a base for walking. This is done to evaluate the best method for ambulation and comfort.

Figure 3.13

Figure 3.13- PVC Pipe

Figure 3.14

Figure 3.14- PVC cut to length

Step one was cutting the PVC to height and then in half to create the support structure.

Figure 3.15

Figure 3.5- PVC cut to be adjustable

Next, a cut was made to allow the upper leg support to flex to fit the users thigh width.

Figure 3.16

Figure 3.16- Holes made for straps

Holes were created for the Velcro straps that are used to attach the product to the user's leg. The Velcro straps fits around the upper and lower thigh to provide an adequate amount of support for the user.

Figure 3.17

Figure 3.17- Lower leg support

The angled lower leg support was attached to the support structure. There is a rounded out area on the lower leg support to alleviate the pressure put on the kneecap. Eliminating the pressure on the user's kneecap makes the product more comfortable. The more comfortable the product is the longer it may be worn.

Figure 3.18

Figure 3.18- Lower leg support padding

Padding was added for further comfort.

Figure 3.19

Figure 3.19- Lower leg support

A groove in the lower leg support was made to accommodate the Velcro strap.

Figure 3.20

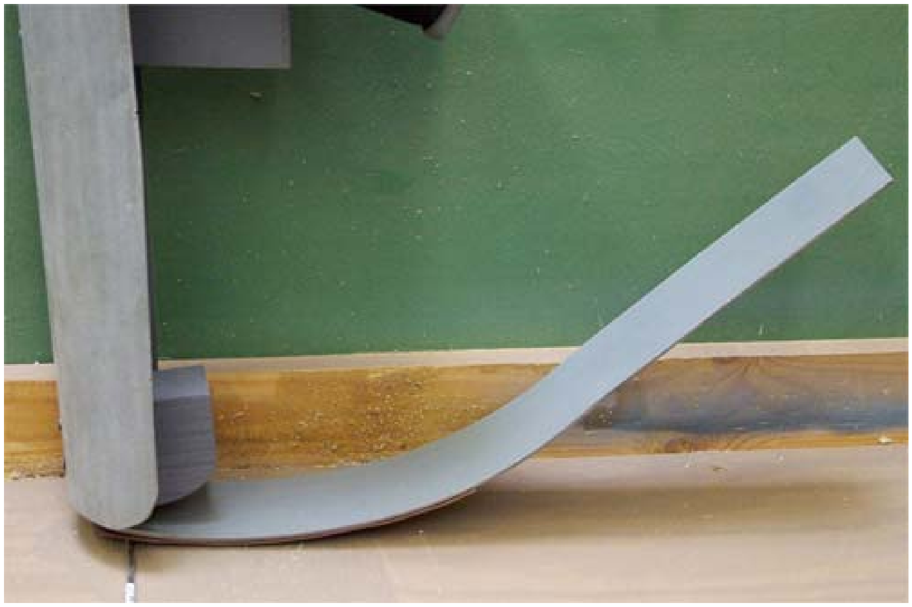

Figure 3.20- Footrest

The footrest was added and tested further.

Figure 3.21

Figure 3.21- Non-slip Tread

The footrest also acted as a walking surface. A rubber grip was added to provide a stable contact area and prevent slippage. The footrest was arched to help create a normal walking motion while in use. The arch also helps the product reach the foot providing it with a platform to rest on. In final production the footrest would have to be made from a much stronger material than PVC plastic. Aluminum or another light weight yet durable metal would be used.

Figure 3.22

Figure 3.22- Model 3 attached to user

Model 3 worked better than the previous models. It had adequate support and was easily joined to the leg. The lower leg support was found to need more padding. The padding was needed more on the lower portion of the leg closer to the shin rather than the knee.

Figure 3.23

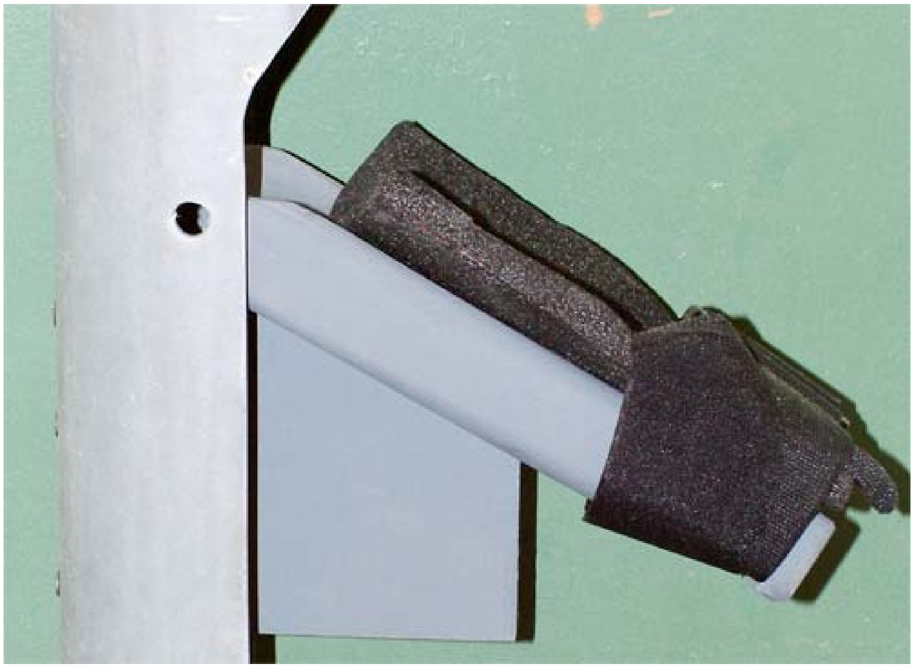

Figure 3.23 Padding

The padding was moved down on the lower leg support to add more comfort and cushion where it was needed. The portion of the shin that hangs over the edge of the lower leg support needs the most padding. With the limb hanging off of the support, it creates more pressure on the shin, thus keeping weight off of the injured area.

Figure 3.24

Figure 3.24- Model 3

Model 3, when completed, was found to provide ample support for the leg. It attached sturdily and provided a very stable ambulation product. The footrest was still found to be unnecessary and bulky when extended to a usable size.

3.3.4 Variations to Model 3

Model 3 was a successful mechanical model and demonstrated only a few flaws in the design. One of the biggest flaws was the footrest. That design element was eliminated and an adequate replacement was made. A sturdy foot was added to the design and gave the user a large contact area with the ground to provide secure footing.

Figure 3.25

Figure 3.25 Model 3 modified

An additional variation was the lower leg support. Taking data from Model 1 and Model 3, it was found that a 90-degree angle is best for walking, but the 120-degree angle was more comfortable while at rest. A hinged lower leg support would be able to provide both the 90-degree walking angle and the 120-degree rest angle. When in use the leg will naturally bend raising it up from the resting position to the walking position. When the user comes to rest the leg will lower taking the stress off of the hamstring muscle. This solution should provide the most comfort to the user.

3.4 MODEL EVALUATION CHECKLIST

Table 3.1

Model Evaluation Checklist				
		MODEL 1	MODEL 2	MODEL 3
Injury	Lower Leg: Does the model lift and protect injury	yes	yes	yes
Weight	5lbs. Or less	yes	yes	yes
Support	Does the model have an upper thigh support	no	yes	yes
	Does the model have straps to secure the brace	yes	no	yes
	Does the model have a secure base (foot)	no	yes	yes
	Does the model support the weight of the user	yes	no	yes
	Is the user mobile while using the model	yes	no	yes
	Does the Model eliminate the need for crutches	yes	no	yes
	Is the model hands free	yes	yes	yes
	Lower leg support angle of 90 degrees	yes	no	no
	Lower leg support 120 degrees	no	yes	yes
	Does the Model have a foot rest	no	yes	yes
Score		8	7	11
Materials	Nylon straps	yes	no	yes
	Wood foot	no	yes	yes
	Metal support beam	yes	no	no
	Plastic support beam	no	yes	yes
	Plastic Upper thigh support	no	yes	yes
	Plastic foot	no	yes	yes
	Metal foot	yes	no	no
	Plastic Lower leg support	yes	yes	no
	Wood lower leg support	no	no	yes
	Padded lower leg support	no	no	yes

Table 3.1 is an evaluation checklist of the mechanical models.

The evaluation checklist analyzes the functions and materials of the models. This evaluation checklist is simplified and does not take into account the materials, colors, and features that will be present in the final production model. The checklist does evaluate the principle of the design and validate the premise of this thesis. The next step is to refine the design and construct a pre-prototype.

3.5 DESIGN AND PERFORMANCE MODIFICATIONS

The modifications that will be made to the design of the product will greatly increase its performance capabilities. The previous part of this chapter tested the principle of the initial product idea using PVC pipe. It was determined that the concept is workable. Building from the initial product design was the next step that was carried out to complete this chapter. The modifications will not only change the appearance of the model, but also the materials. The new materials will consist of metal, polyurethane foam, Velcro straps, neoprene, and plastic.

3.6 REFINED CONCEPTS

Figure 3.26

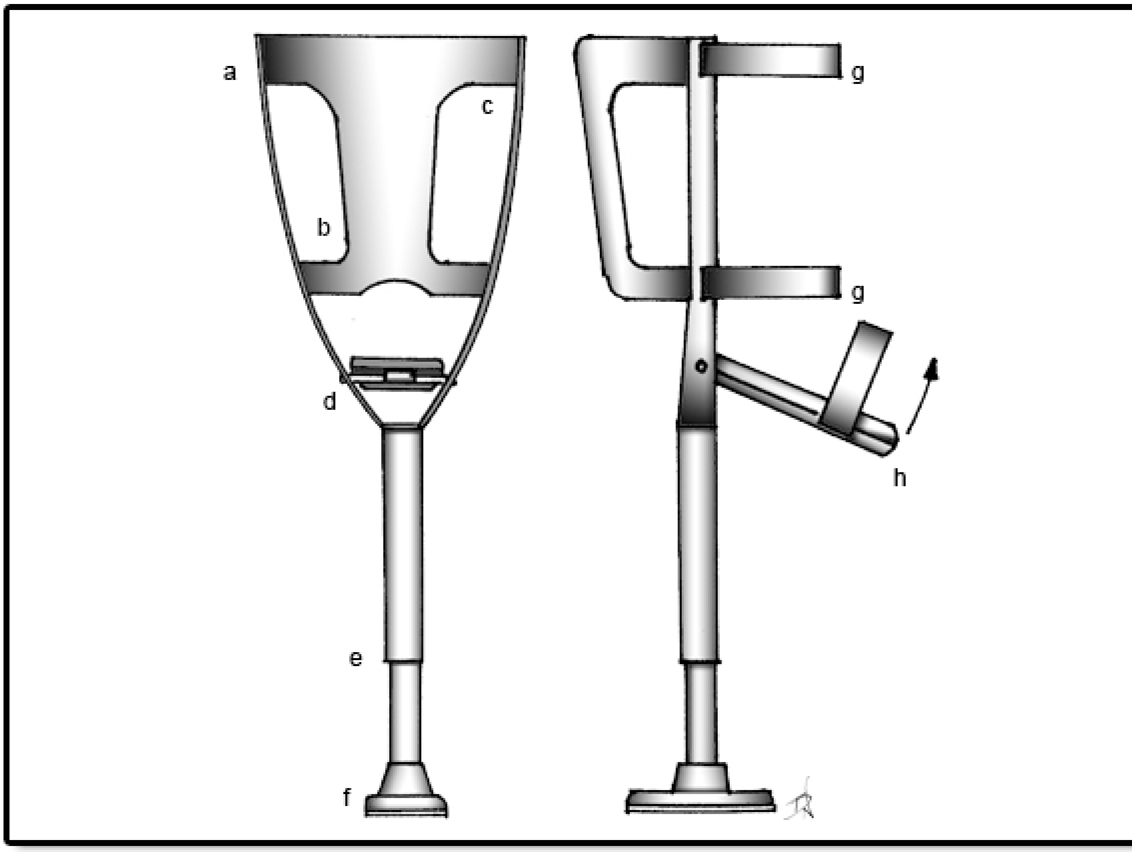

Figure 3.26- Refined Concept 1

Refined Concept 1 is comprised of the following components:

a) Metal side thigh supports

b) Plastic front thigh support

c) Vents

d) Hinge

e) Adjustable height support beam

f) Foot

g) Velcro straps

h) Lower leg support

Refined Concept 1 uses the best features from the previous designs and mechanical models. The footrest was eliminated. The hinged lower leg support is still incorporated and provides the user with the most comfort. It can also be detached from the structural component for convenience when putting on and taking off the product. Vents in the front thigh support will add to the user's comfort level by allowing the limb to get air and not over heat. The adjustable height allows for the product to fit a diverse range of people. The foot component provides a non-slip contact area with the floor to increase the safety and stability of the user.

Figure 3.27

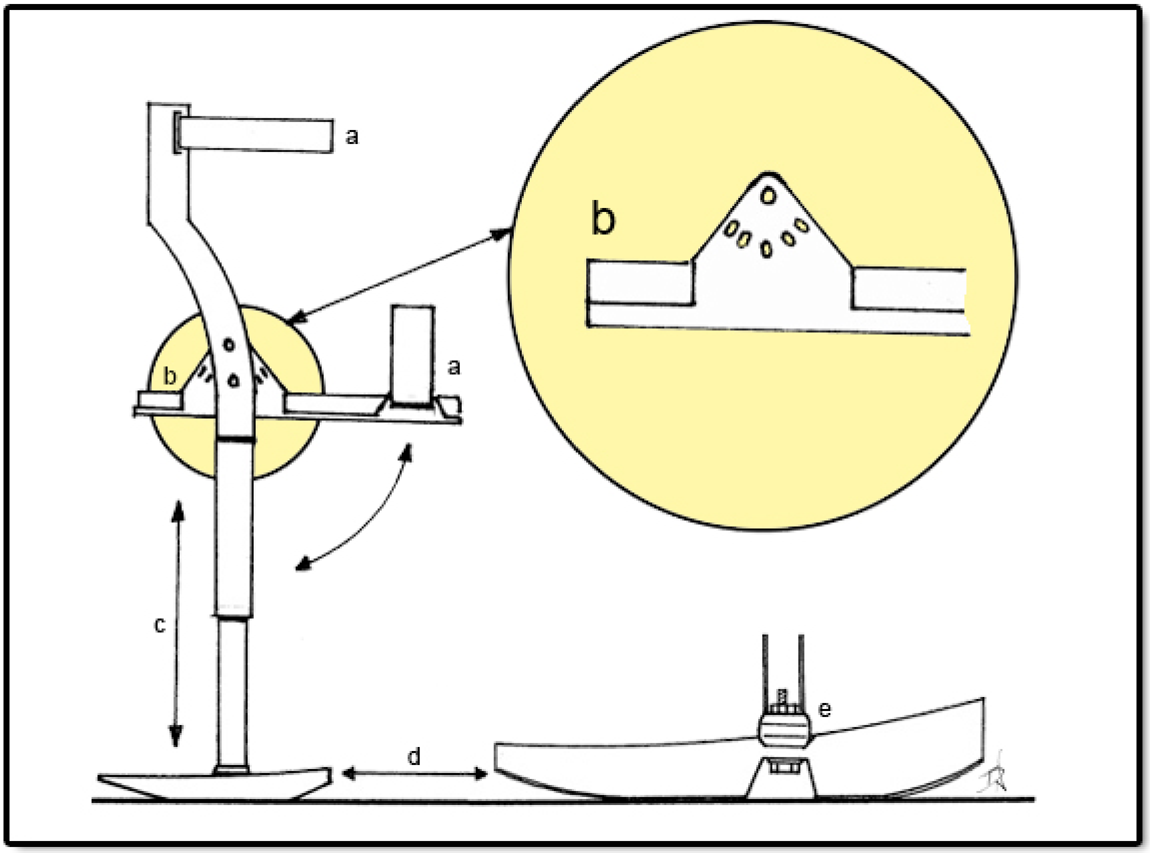

Figure 3.27- Refined Concept 2

Refined Concept 2 is comprised of the following components:

a) Velcro straps

b) Adjustable angle lower leg support

c) Adjustable height support beam

d) Foot

e) Rubber bushing

Refined Concept 2 uses an adjustable lower leg support that can be fixed at certain angles to allow the user a fully customized fit. The lower leg support is hinged and uses a pin to secure the leg at the desired angle. The foot is different from the previous concept in that it incorporates a rubber bushing to allow a limited range of motion in the foot. The previous concept and all other models used a fixed foot. With each person being different, this feature will allow for more secure contact to be made between the product and the floor. The better the contact the more stable the user will be, adding additional safety and comfort.

3.7 BEST SOLUTION

Refined Concept 1 is the best design for the product. Concept 1 is made of a sturdy metal and is designed to attach securely to the user. It provides the most convenience to the user by offering a quick release mechanism of the lower leg support from the structural component of the product. This allows the user to rapidly remove the structural component to perform an activity that the product would hinder. For example, if the user was getting in and out of a vehicle or sitting for a long period of time in the classroom or home, he/she could simply remove the structural component by unhinging the lower leg support. It also allows for quick attachment when the user is on the go. The lower leg support stays free to swing while in use allowing the leg to move naturally from the walking position to the resting position and vise-versa. The vented plastic thigh support is also an added feature that provides the most comfort to the user while injured. The adjustable height and Velcro straps make the product fully customizable to the user allowing for a broad range of people to be able to use the product.

3.8 SUMMARY OF CHAPTER

Chapter 3 was the second phase of the design process. After the research phase, the creative phase began. The process started with idea sketches that incorporate a variety of different solutions to the problem. These idea sketches were used as a basis for mechanical models to test the main principles behind the solution.

The models were constructed of PVC pipe, metal tubing, and wood. All materials are readily available to anyone. They were constructed to test the principles of the concepts and are not intended to represent a final production piece. These models proved that mechanically it is feasible to have a support system that eliminates the need for crutches. These concepts where evaluated using the evaluation checklist comprised of the performance criteria from the previous chapter. The best features of each were then refined into two concepts from which a final solution was chosen to further develop.

CHAPTER 4: DESIGN SOLUTIONS

4.1 OVERVIEW

Chapter 4 reviews the pre-prototype construction. The pre-prototype is a result of the culmination of information gathered throughout the research and design phase. The following chapter includes photographs of the pre-prototype design as well as explains how the product solves the problems that are caused by crutch use. Additionally, this chapter also contains a Sequence of Use Chart that describes how to correctly and effectively use the product.

4.2 CONSTRUCTION OF PRE-PROTOTYPE

4.2.1 Workspace

The workspace is the area where the pre-prototype was constructed and assembled.

Figure 4.1

Figure 4.1- Workspace

4.2.2 Materials

The materials used in the construction of the pre-prototype consist primarily of steel, plastic, and high-density foam. In the final production of the product a lighter metal should be used. Steel was the most readily available metal to obtain for constructing the pre-prototype for design testing purposes. The plastic portions of the product are located in the upper thigh support, lower leg support, and the foot. The High-density foam was used in the lower leg support to provide added comfort. All of the materials used in the pre-prototype include: 4- 1/4" x 1/2" bolts, 3- 1/4" x 1 1/2" bolts, 6- 1/4" nuts, 1- 1/4" wing-nut, 1- 1" x 1/8" x 30" steel bar, 1- 1" x 10" square pipe, 1- 1 1/4" x 12" square pipe, 4- nylon Velcro straps, 1- 12" x 4" x 1/2" foam padding, Rubber, PVC plastic, Bondo, epoxy.

4.2.3 Tools

The tools used to construct the pre-prototype were comprised mostly of metal working tools. A metal miter saw was used to cut the steel tubing to length. Welding instruments were used to fix the main support beam to the main thigh structure as well as the foot to the lower support beam. A vacuum-forming machine was used to create the upper thigh support. The plastic was heated and pulled over a mold to create the final shape. A band saw was used to remove the excess plastic. A drill press was used to drill holes in the plastic and metal thigh support to allow for them to be connected. A sander and grinder were used to smooth the edges and welds of both the plastic and metal pieces.

Figure 4.2

Figure 4.2- Metal Miter Saw

Figure 4.2 shows a miter saw, which was one of the many tools used in the construction of the pre-prototype. This particular miter saw is made primarily for cutting metal.

4.2.4 Construction

The construction of the pre-prototype took approximately 3 weeks to complete from raw materials to final product. The following images consist of a partially complete product through the construction phase.

Figure 4.3

Figure 4.3- Construction phase

Figure 4.3 shows the primed main frame of the support structure with an unpadded lower leg support. The upper Velcro strap is attached to the main support structure to get an idea of fit and dimensions. The lower support beam and foot are unfinished.

Figure 4.4

Figure 4.4- Pre-prototype construction phase

Figure 4.4 shows the unpainted upper thigh support. In this image the plastic thigh support is being fit into the metal thigh support to create the final shape of the upper support portion of the product. The lower angled stop is also visible in the picture. The metal portion of the product is primed and waiting for its final glossy coat of paint.

Figure 4.5

Figure 4.5- Pre-prototype construction phase

Figure 4.5 illustrates the fitting process between the thigh support pieces and how that portion of the product interacts with the hinged lower leg support. The lower leg support is still unfinished and uncovered. The plastic upper thigh support is also not complete.

Figure 4.6

Figure 4.6- Lower leg support

Figure 4.6 shows a detailed picture of the lower leg support illustrating how the angled stop is used to prevent the lower leg support from going below a 120-degree angle. The angled stop is connected to the lower support structure with two 1 1/4" x 1/4" bolts.

Figure 4.7

Figure 4.7- Foot

Figure 4.7 is a detailed view of the foot portion of the pre-prototype. The foot is constructed from steel, plastic, and a non-slip rubber sole. The steel upper plate is welded to the lower support beam. The plastic foot is attached to the metal portion using epoxy. The imperfections in the plastic were covered using Bondo. The foot was later primed and painted.

4.3 TESTING THE PRE-PROTOTYPE

4.3.1 Assembly

Figure 4.8

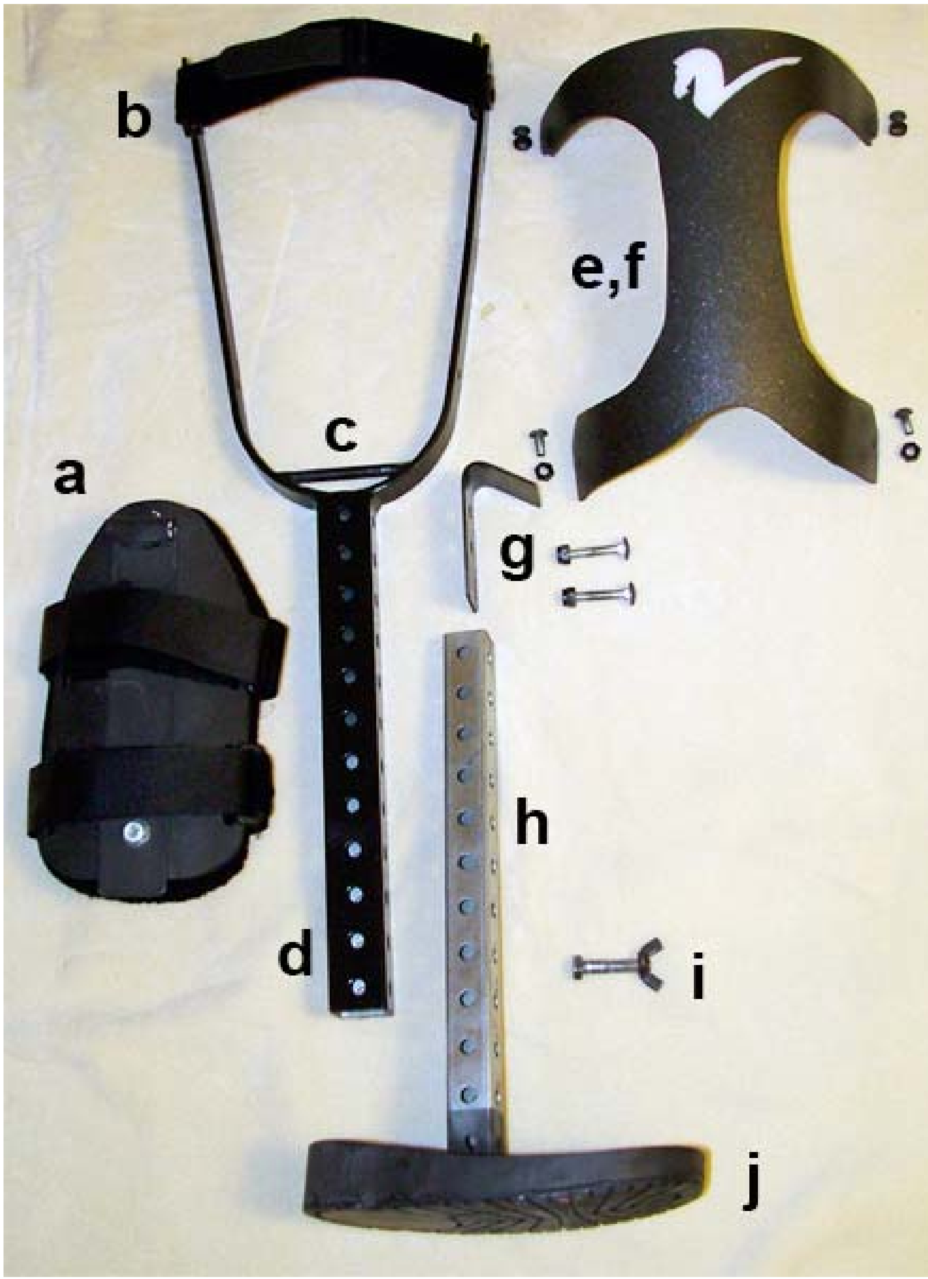

Figure 4.8 Components of the pre-prototype

In figure 4.8 the pieces of the pre-prototype are separated and labeled. The following parts are assembled to form the pre-prototype:

a. Lower leg support complete with Velcro straps, high density foam padding, Neoprene cover, hinge mechanism, and plastic support platform
b. Upper thigh support with attached Velcro straps
c. Axis of hinge mechanism
d. Lower support beam
e. Plastic thigh support with foam liner
f. Bolts to connect the two thigh supports
g. Angled stop to prevent the foot from touching the ground
h. Lower support beam
i. Bolt that is used in the height adjustment
j. Foot

4.3.2 Fitting the Product

The pre-prototype is fully adjustable and can accommodate 90% of the population. It fits everyone from the 5th percentile woman to the 95th percentile man. The height is adjustable from fourteen inches to twenty-four inches. The thigh support and lower leg both have adjustable Velcro straps to fit comfortably to the user regardless of size. When the user first receives the product he/she needs to adjust the height of the support beam to allow for the most normal gait while walking. Once the height is adjusted, the product is ready to use. The Velcro straps need to be adjusted to the user's comfort every time the product is used. No permanent adjustments can be made to the straps. The lower leg support is self-adjusting while in motion. The body naturally flexes the hamstring raising the foot and creating a 90-degree angle. While at rest the hamstring will relax and the leg will lower resting on the angled stop. The angled stop will prevent the injured limb from touching the ground and keep the leg at a comfortable angle of 120-degrees while at rest.

4.3.3 Mobility

The pre-prototype provides the user with the ability to function more normally than with crutches and other ambulatory aids. The pre-prototype does not require the use of the user's hands to create motion, which enables him/her to be more mobile and have everyday capabilities.

4.3.4 Sequence of Use

The following section employs images to illustrate how the pre-prototype is used. These images will demonstrate how the user will adjust the product to height and affix it to his/her leg enabling the user to perform everyday activities.

Figure 4.9

Figure 4.9- Step 1

Figure 4.9 illustrates a user completing the first step of using the product by adjusting the height to fit her needs. The height is adjusted by removing a bolt and moving the lower support beam up or down to lengthen or shorten the total height of the product. Once the desired height is reached, the bolt is simply put back through both beams to hold them securely in place.

Figure 4.10

Figure 4.10- Step 2

Figure 4.10 shows a user completing step two in the pre-prototype use sequence. The user is attaching the lower leg support by using the adjustable Velcro straps. The lower leg support is placed on the upper shin just below the knee and affixed with the straps.

Figure 4.11

Figure 4.11- Step 3

Figure 4.11 demonstrates the next step in using the product. Once the height has been adjusted and the lower leg support is attached, the two parts can be combined. The lower leg support has a hook that acts as a hinge when attached to the upper thigh support. The crossbeam acts as an axis for the joint when the lower leg support is attached.

Figure 4.12

Figure 4.12- Step 4

Figure 4.12 shows the final step in attaching the product. After the lower leg support is attached, the leg can be locked in using the adjustable Velcro straps on the upper thigh support. Once the leg is locked in place, the product is secure and ready for motion.

Figure 4.13

Figure 4.13- Step 5

Figure 4.13 illustrates the product being used in the home. The user is in the resting position, so the leg hangs at a 120-degree angle. When in use, the product allows the user the freedom to perform everyday activities by keeping the hands free.

4.3.5 Interaction Matrix

The Interaction Matrix is used to rate the interaction between two individual parts of a product and the interaction of one part to the rest of the parts of the product. The left column is identical to the top row. The Totals column is the total sum of that part's interaction with all the other parts. The higher the total the more that part interacts. The interaction is rated on a 2 point scale; 0=no interaction, 1=mild interaction, 2=frequent interaction. The information gained from an interaction matrix helps the designer see how parts relate to each other.

Table 4.1

Parts	1	2	3	4	5	6	7	8	9	10	11	12	Totals
1. Upper Support Structure		2	1	2	0	2	2	0	0	2	2	0	13
2. Plastic Thigh Support	2		2	1	0	0	0	0	0	0	0	0	5
3. Thigh Padding	1	2		0	0	0	0	0	0	0	0	0	3
4. Plastic Buckles	2	1	0		2	0	0	0	0	0	0	0	5
5. Velcro Straps (upper)	0	0	0	2		0	0	0	0	0	0	0	2
6. Hinge Axis	2	0	0	0	0		2	0	0	2	0	0	6
7. Lower Leg Support	2	0	0	0	0	2		2	2	2	0	0	10
8. Lower leg Padding	0	0	0	0	0	0	2		1	0	0	0	3
9. Velcro Straps (lower)	0	0	0	0	0	0	2	1		0	0	0	3
10. Hinge Hook	2	0	0	0	0	2	2	0	0		0	0	6
11. Lower Support Beam	2	0	0	0	0	0	0	0	0	0		2	4
12. Foot/Base	0	0	0	0	0	0	0	0	0	0	2		2

Table 4.1 illustrates the interaction of the products components.

The Interaction Matrix for the pre-prototype shows that the upper support structure interacts the most with other components of the product, which is understood since most of the components attach directly to it. With the heavy interaction, this piece should be made of a durable material. The lower leg support is second behind the upper support structure. The lower leg support has many components as well.

4.3.6 Interaction Tables

The Interaction Table works the same way as the Interaction Matrix with the exception that only the table scores the components of the product with environmental elements and the user's body parts. These tables illustrate how often each component will be affected by such things as rain, dirt, and humidity. The tables also help the designer gauge how to protect the product from wear and tear through contact areas with the user. The designer can take friction, moisture, and slippage into account and design the product to withstand the elements.

Table 4.2

Parts	Hands/Arms	Thigh	Shin	Foot	Score
1. Upper Support Structure	0	2	0	0	2
2. Plastic Thigh Support	0	2	0	0	2
3. Thigh Padding	0	2	0	0	2
4. Plastic Buckles	1	2	0	0	3
5. Velcro Straps (upper)	1	2	0	0	3
6. Hinge Axis	0	0	1	0	1
7. Lower Leg Support	1	0	2	0	3
8. Lower leg Padding	0	0	2	0	2
9. Velcro Straps (lower)	1	0	2	0	3
10. Hinge Hook	0	0	1	0	1
11. Lower Support Beam	1	0	0	0	1
12. Foot/Base	0	0	0	0	0

Table 4.2 illustrates the product's interaction with the user.

Table 4.3

Parts	Rain/Water	Dirt/Dust	Light/Sun	Humidity	Temperature	Score
1. Upper Support Structure	2	2	2	2	2	10
2. Plastic Thigh Support	2	2	2	2	2	10
3. Thigh Padding	1	1	0	1	2	5
4. Plastic Buckles	2	2	2	2	2	10
5. Velcro Straps (upper)	2	2	2	2	2	10
6. Hinge Axis	2	1	1	1	1	6
7. Lower Leg Support	2	2	2	2	2	10
8. Lower leg Padding	1	1	0	2	2	6
9. Velcro Straps (lower)	2	2	2	2	2	10
10. Hinge Hook	2	1	1	1	1	6
11. Lower Support Beam	2	2	2	2	2	10
12. Foot/Base	2	2	2	2	2	10

Table 4.3 illustrates the product's interaction with environmental factors.

4.3.7 Hierarchical Tree Structure

The Hierarchical Tree Structure (HTS) illustrates how the product breaks down into components, parts, and materials. The HTS also shows how the concept will work as a product. The chart shows how the components of the design are placed into sub-systems and break down into materials. When the chart is placed into a super-system it shows how the product interacts in the market. For example, this thesis product's (crutch free support system) super-system would be ambulatory aids such as crutches and walkers. Table 4.4 on the following page illustrates what the thesis product's HTS looks like.

Table 4.4

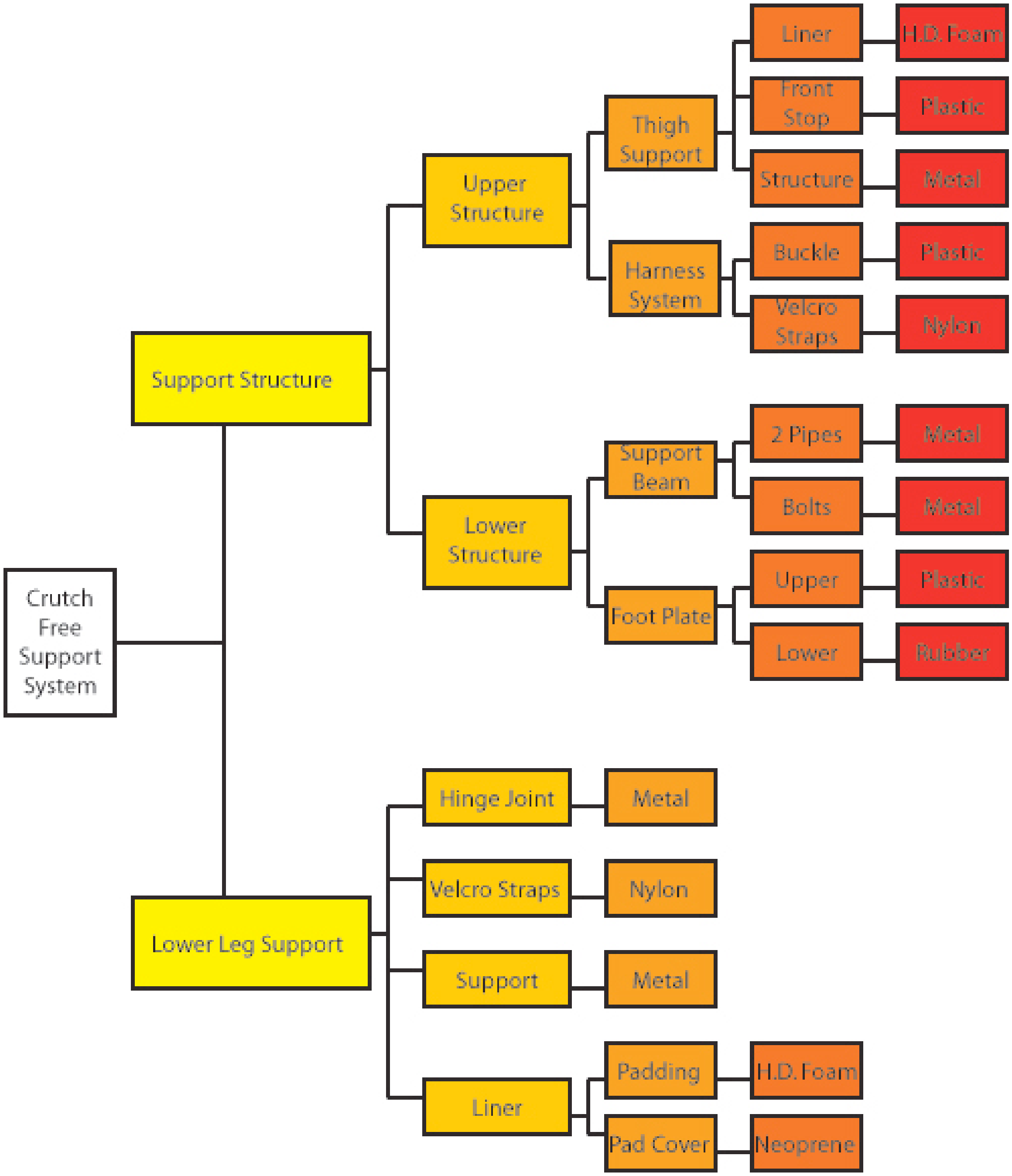

Table 4.4 shows how the product is broken down into sub-systems, components, and materials.

4.4 BRANDING

When dealing with a niche market product, finding an identity is key. The product needs to be appealing to both male and female athletes. The design of the product needs to be sporty and functional. The aesthetics of the product needs to communicate its function while at the same time look appealing. A product that is not aesthetically pleasing will not sell regardless of how functional it is. Also, with this design, it needs to have more personality and be more of an accessory that is worn rather than something medical that must be used. Crutches have no personality and visually communicate that the user is injured. This product will up lift the athlete by allowing them to be more functional and mobile.

4.4.1 Finding a Name

In order to brand a product a unique name needs to be identified. The name must correspond to the product and illustrate what it is. In the medical industry the name tells exactly what the product does. There are walkers, wheelchairs, knee immobilizers, ankle products, etc. The initial thought was to get away from those boring medical names and create something fun that would still communicate its function. Some of the first names include single name words to complete sentences. The following are a few of the names The Peg Leg, The Peg Leg 4000, The Hands Free Support System, The Crutch-less Support System, and The Crutch Alternative. The design is a system that frees the user from needing crutches, which in turn makes the user more functional and mobile. The design is a prosthesis for a fully able bodied person. In that aspect an ancient form of prosthetic came to mind, a wooden leg or a peg leg. Carrying the idea further, the product helps the user. Help can also be viewed as assistance. From these thoughts a product name was finally established. The name is a combination of how the product looks and what the product does. It looks like a peg leg that assists the user, thus the Peg-Asyst was born. Asyst is intentionally spelled incorrectly to accommodate and illustrate the words assist and system. It is also a play on words and lends a helping hand with logo development. The mythical winged horse Pegasus is the inspiration for the logo development. The Name "Peg-Asyst" becomes the brand.

4.4.2 Logo Development

Once a name was established, the logo development phase began. With the name Peg-Asyst it was obvious that a winged horse would be incorporated into the logo design. For a sporty look the logo would have to be highly stylized and simple. It would have to be something that a brand could be built around. The following images are samples of a few ideas followed by the final logo, which is on the pre-prototype.

Figure 4.14

Figure 4.14 is an example of existing logos.

Figure 4.15

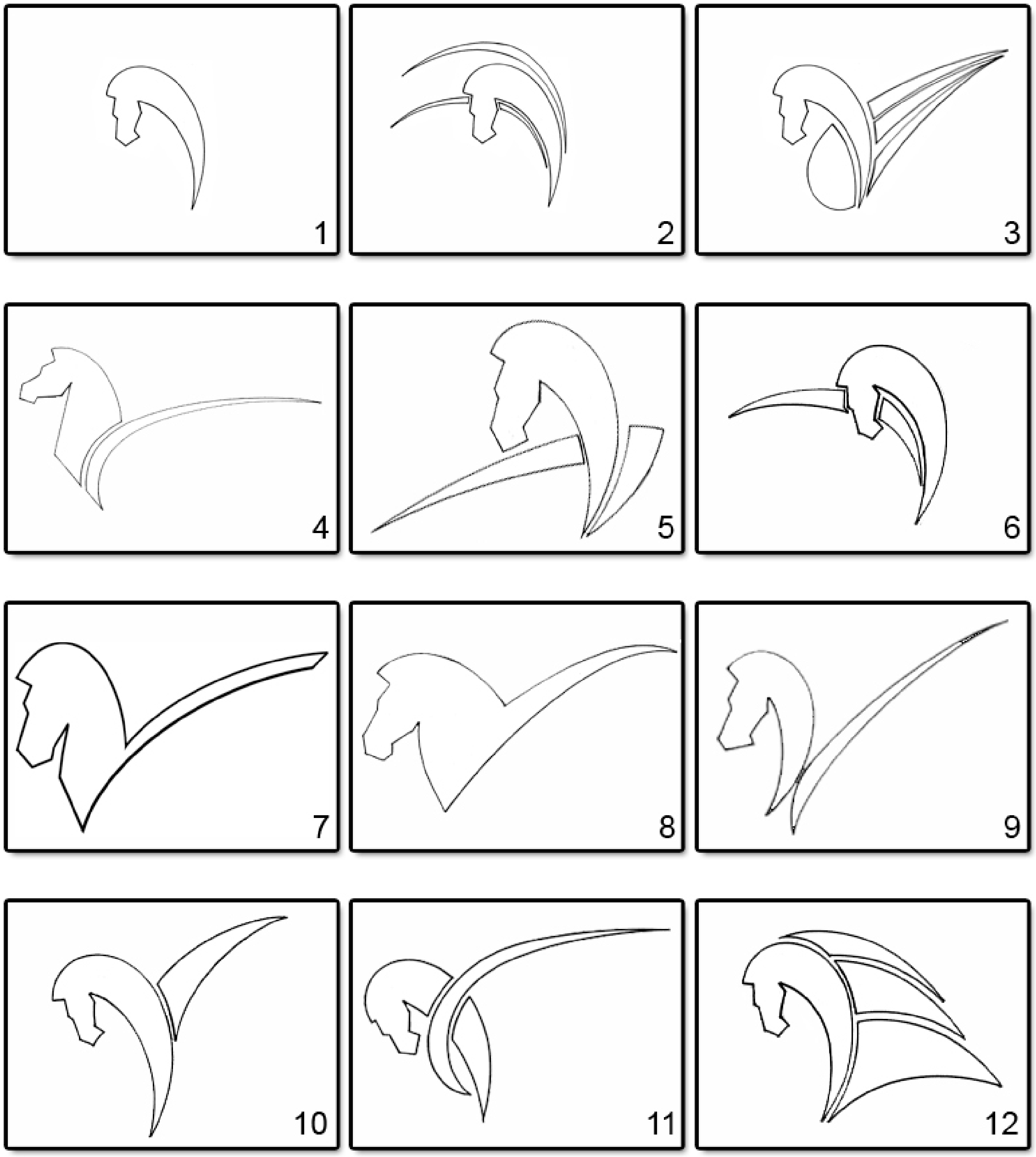

Figure 4.15 illustrates concept development in the logo design phase.

Figure 4.16

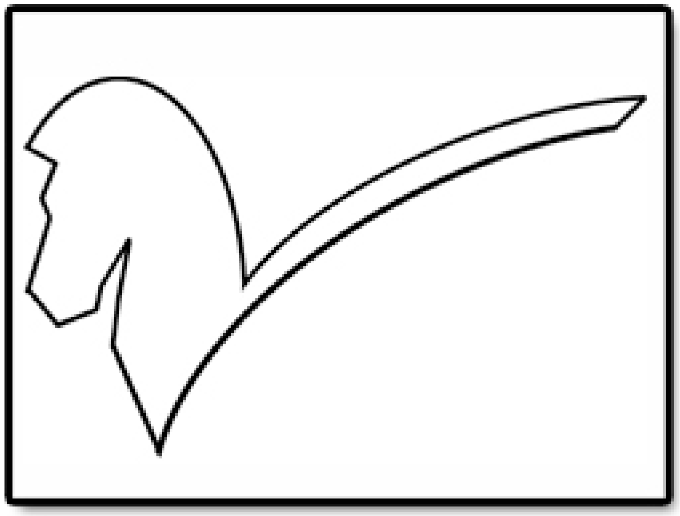

Figure 4.16- Final Logo: Concept 7

Figure 4.17

Figure 4.17 illustrates the final logo on the pre-prototype.

4.5 FINAL DESIGN

4.5.1 Evaluation Checklist for Pre-Prototype

EVALUATION CHECKLIST

		Parameters	Performance Criteria	Pre-prototype (Specs)	Score (1-5)	Average
Human Function	Social Economic	Est. Retail Price	$100.00-$250.00	$250	1	
		Est. Product Life	Length of Injury (Shelf 10 yrs)	10 years	5	
		Sport	Any	Any	5	
		Injury	Lower Leg/ Below the knee	Lower leg	5	
		Product Availability	Prescription	Prescription	5	
					Total=21	Avg=4.2
	Cultural Aesthetic	Style	Sporting	Sporting	3	
		Color of Metal Support Structure	Black/Grey	Black	5	
		Color of Plastic Support Structure	Assorted	Black	2	
		Color of Straps	Black/Grey	Black	5	
		Color of Padding	Assorted	Black	2	
		Color of Tread	Black	Black	5	
					Total=22	Avg=3.7
	Practical Physical	Weight of Product	Approx 5lbs.	12lbs.	1	
		Height of Product Collapsed	24" or less	25"	1	
		Height of Product Extended	36"	38"	2	
		Width of Product	8" or less	7.5"	5	
		Length of Foot	6" or less	8.5"	1	
		Width of Foot	4" or less	4.5"	1	
		Ease of Use	Understandable interface	Understandable	4	
		Width of Straps	2" or less	1.25"	4	
					Total=19	Avg=2.4

Technical Function	Direct Technical	Material for Metal Support Structure	Aluminum	Steel	1	
		Material for Plastic Support Structure	ABS plastic	PVC plastic	3	
		Material for Padding	High-Density Poly-urethane Foam	HD Foam	5	
		Material for Padding Covers	Neoprene	Neoprene/Cotton	4	
		Material for Straps	Nylon Velcro	Nylon Velcro	5	
		Material for Foot	ABS plastic/Aluminum	Plastic & Metal	1	
		Material for Tread	Non-slip urethane	Rubber	4	
		Paint for Metal Structure	Powder-coat	Primed, base, and Gloss coat	3	
					Total=26	Avg=3.3
	Indirect Tech.	Safety Features	Non-slip Tread	Non-slip Tread	5	
			Secure Fasteners	Velcro fasteners	5	
		Environmental Resistance	Powder Coated Metal	Primed, base, and Gloss coat	3	
			Neoprene Covered Padding	Neoprene/Cotton	3	
					Total=16	Avg=4
Production Function	Plan	Distribution	Mail-order, clinics, and medical supply stores	All of available	5	
		Packaging	Cardboard, Styrofoam, and plastic	Cardboard, Styrofoam, and plastic	4	
		Advertising	Print and Internet	Print and Internet	5	
					Total=14	Avg=4.7
	Manufacturing	Material for Metal Support Structure	Aluminum	Steel	1	
		Material for Plastic Support Structure	ABS plastic	PVC plastic	3	
		Material for Padding	High-Density Poly-urethane Foam	HD Foam	5	
		Material for Padding Covers	Neoprene	Neoprene/Cotton	4	
		Material for Straps	Nylon Velcro	Nylon Velcro	5	
		Material for Foot	ABS plastic/Aluminum	Plastic & Metal	1	
		Material for Tread	Non-slip urethane	Rubber	4	
		Paint for Metal Structure	Powder-coat	Primed, base, and Gloss coat	3	
		Assembly	Automated & Manual	Manual	2	
					Total=26	Avg=3.3
Totals					Grand T=144	Total Avg=3.7

Table 4.5- Evaluation Checklist

The Evaluation checklist, like before, is used to measure the product's ability to meet the performance criteria. The Human, Technical, and Production Functions are broken down into categories with each category containing parameters the product must meet to be successful. The pre-prototype was evaluated and scored on a 5-point scale, 5 points being a perfect score. The pre-prototype's average score was 3.7 indicating there is room for improvements to be made. The strongest category was Planning with a score of 4.7, and the weakest category was Practical Physiological with a score of 2.4. The Practical Physiological category is vital to the success of the product. It determines the product's usability. In order to be successful changes will be made to the product to better perform in the Practical Physiological portion of the human function. In the social economic and cultural aesthetic categories the product graded a 4.2 and 3.7 respectively, which shows little need for improvement in those areas. The remaining scores indicated the same result.

4.5.2 Problems with the Pre-Prototype

Once the pre-prototype was completed and tested, a few problems were discovered. One of the problems is with the upper thigh support portion of the design. Initially, it was thought that the pre-prototype would be able to accommodate the 5th percentile female to the 95th percentile male. The current design does not. The thigh support structure is too large to accommodate a smaller female user.

The second problem discovered in testing the pre-prototype was the angle at which the foot made contact with the ground. Humans are unique and each user's walking pattern differs, so the angle that the foot comes into contact with the ground will vary.

The third problem discovered was with the hinge that connects the lower leg support to the main support structure. The hinge works very well, but it is an open hinge and does not provide enough stability to the user. All of these problems are easily remedied with simple design changes. The overall design of the product was successful and the testing of the pre-prototype showed flaws that once corrected will make the design even more successful.

4.5.3 Solutions

In testing the pre-prototype some problems in the design were found. Those problems can be remedied with a few simple changes. One of the issues was with the design's ability to accommodate a large portion of the population with a single model. A change in the design can be made to fix the sizing flaw. Rather than having a support structure that encompasses half of the user's leg with steel bars on both sides, a support structure that is on the front of the leg can be made.

The second problem was with the foot and how it made contact with the ground. This part of the design is essential because it takes the safety of the user into consideration. The product's design is to keep the injured area elevated and out of harm's way while still allowing the user to remain fully functional in daily activities. The foot needs to make solid contact with the ground to provide the most stability possible. A design modification that would fix the problem is a simple one. Instead of being in a fixed position the new foot design will be hinged. The hinge of the foot will provide the user the safest design possible. The hinge will use a high-density rubber bushing to act as a pivot point for the foot where it connects with the lower portion of the support beam. The bushing will give according to the user's natural walking gait. This concept allows the foot to move more realistically by providing extension, flexion, pronation, and supination. The bushing will also act as a buffer providing the user with more comfort.

The final problem addressed is with the hinge portion of the lower leg support. In the pre-prototype phase of the design process the user attached the lower leg support and then attached the main support structure by hooking the lower leg support to an axle built into the frame. This design was made as a convenience to the user and allowed for the main portion of the product to be put on or taken off quickly. Though convenient, the design failed to provide adequate stability. The lower leg support slid around on the axle and sometime disconnected. Rather than having a removable lower leg support for convenience, the design will now have a fixed lower leg support that not only functions better, but is also safer to use. The lower leg support will remain hinged to provide comfort to the user and will also be able to be locked into position. Both angles will remain the same as in the original design, a 90-degree walking angle and 120 degree resting angle.

The pre-prototype testing exposed weaknesses in the design, but once remedied, these will make the design stronger and safer. The main objectives are to provide the user with more functionality and mobility than crutches, while remaining safe and comfortable. Testing the design allows for changes to be made that create a better product.

4.5.4 Final Design and Styling

The final design will incorporate the changes made through the testing of the pre-prototype and a more sport oriented aesthetic. The final design will be modeled in Rhino, which is a 3-D modeling software. The styling of the design needs to exhibit how the product is to be used, while still appealing to athletes.

Figure 4.18

Figure 4.18 shows the Peg-Asyst final design.

The final design uses a rigid plastic front thigh support enabling the product to accommodate a larger range of users. The thigh support will be attached to the user's leg by heavy duty adjustable Velcro straps. The lower leg support will be attached in the same manner. The over all design/styling of the product is sleeker than that of the pre-prototype. The new design is friendlier to the eye and should be more appealing to the user.

Figure 4.19

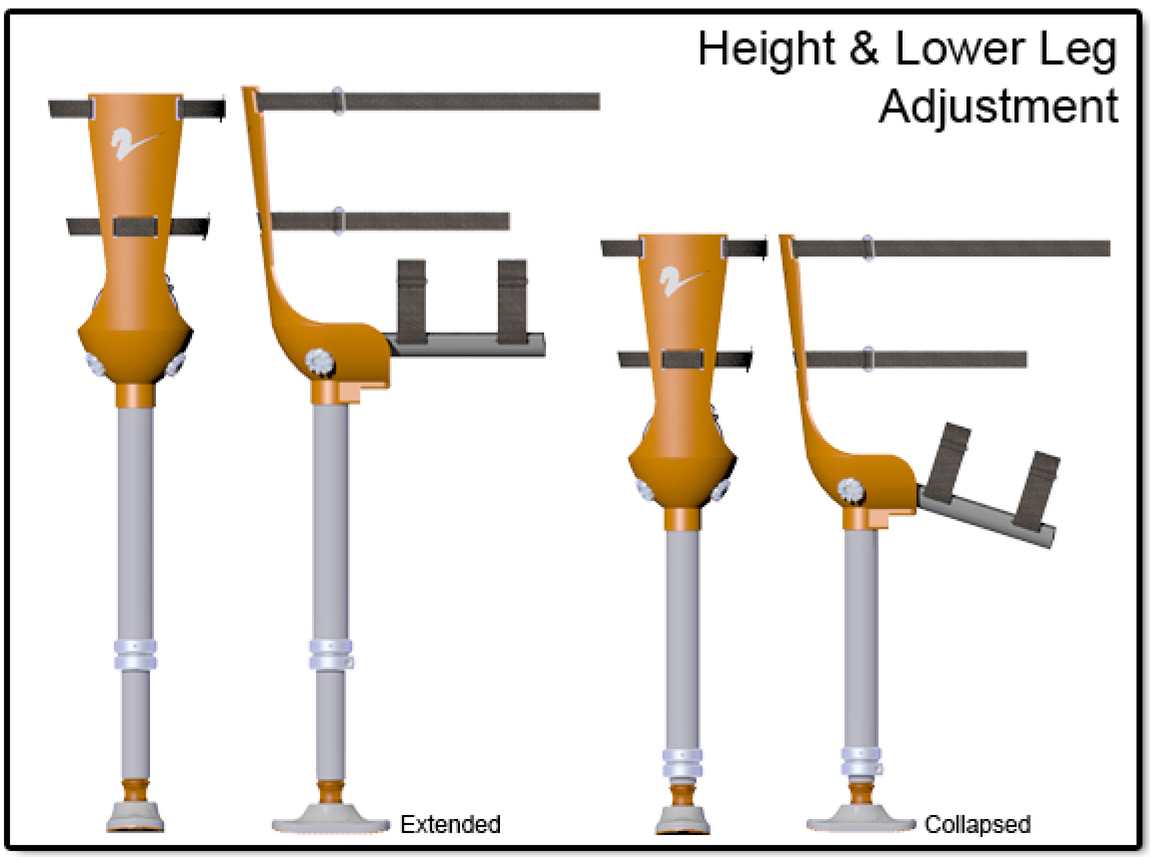

Figure 4.19 is a front and side view of the Peg-Asyst final design.

The Peg-Asyst can also be adjusted to fit a wider range of users through the use of a fully adjustable support beam. To adjust the height the patient simply turns the lower portion of the support beam to unlock it. Then, the patient slides the support beam up or down to the desired height twisting it back to lock it in place.

Figure 4.23

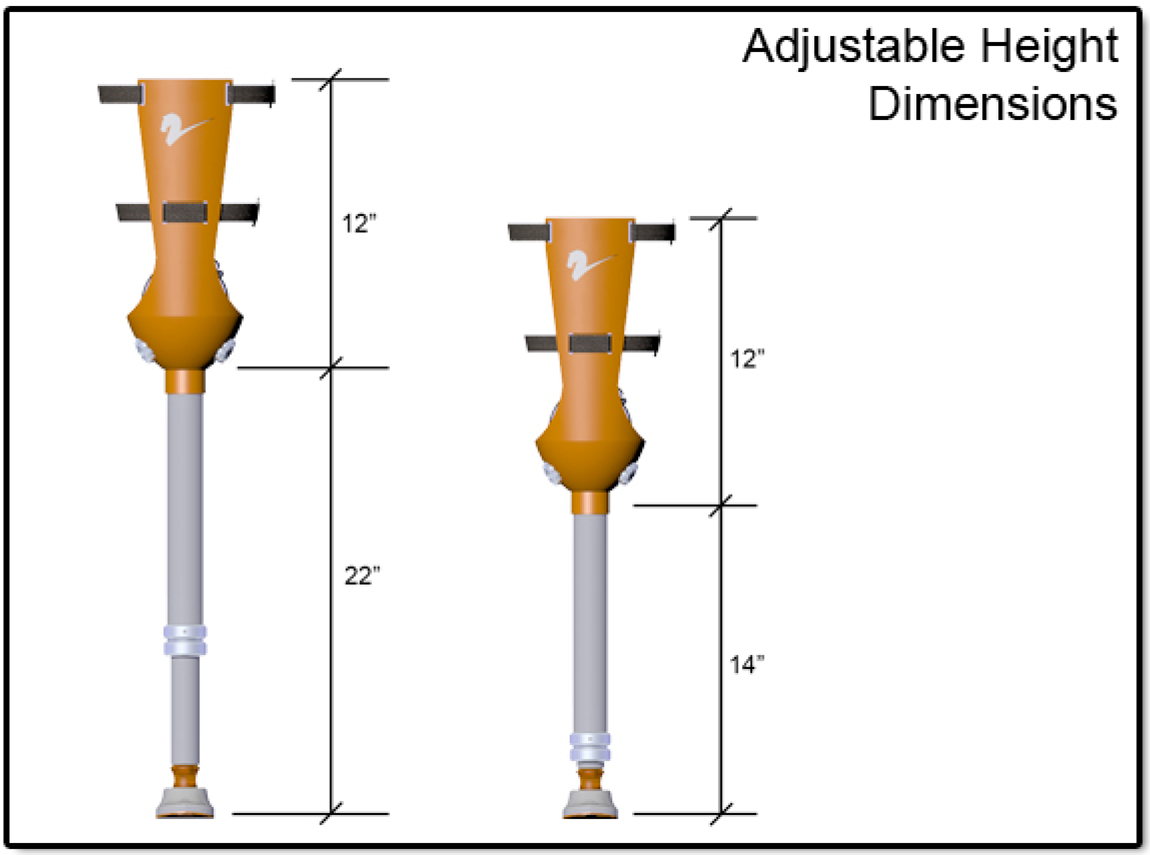

Figure 4.23- Height adjustments variable between 14”-22”

The Peg-Asyst has an adjustable height between 14 and 22 inches. The adjustable height allows the Peg-Asyst to accommodate both the 5th percentile woman and the 95th percentile male.

Figure 4.20

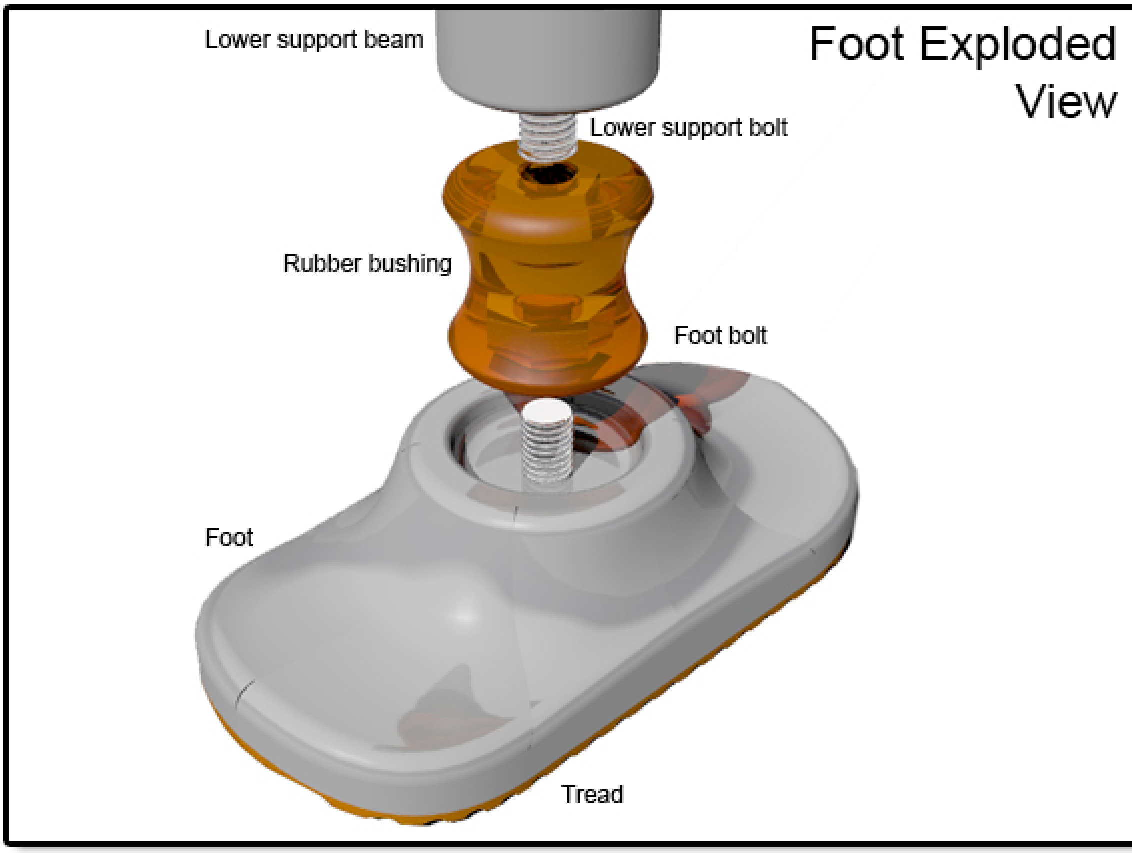

Figure 4.20 is an exploded view of the foot component of the Peg-Asyst.

The foot has been significantly changed from the pre-prototype version of the design. The new foot will incorporate a rubber bushing that will act as a shock absorber as well as enable the foot to always be flush with the ground. The bushing will be rigid enough to give the user a stable base, yet pliable enough to accommodate their unique walking pattern. If the bushing wears out it is easily replaced. Simply remove the bushing and insert a new bushing. The bolt is threaded into the lower portion of the support beam and locked in place with a lock washer to prevent it from loosening while in use.

Figure 4.21

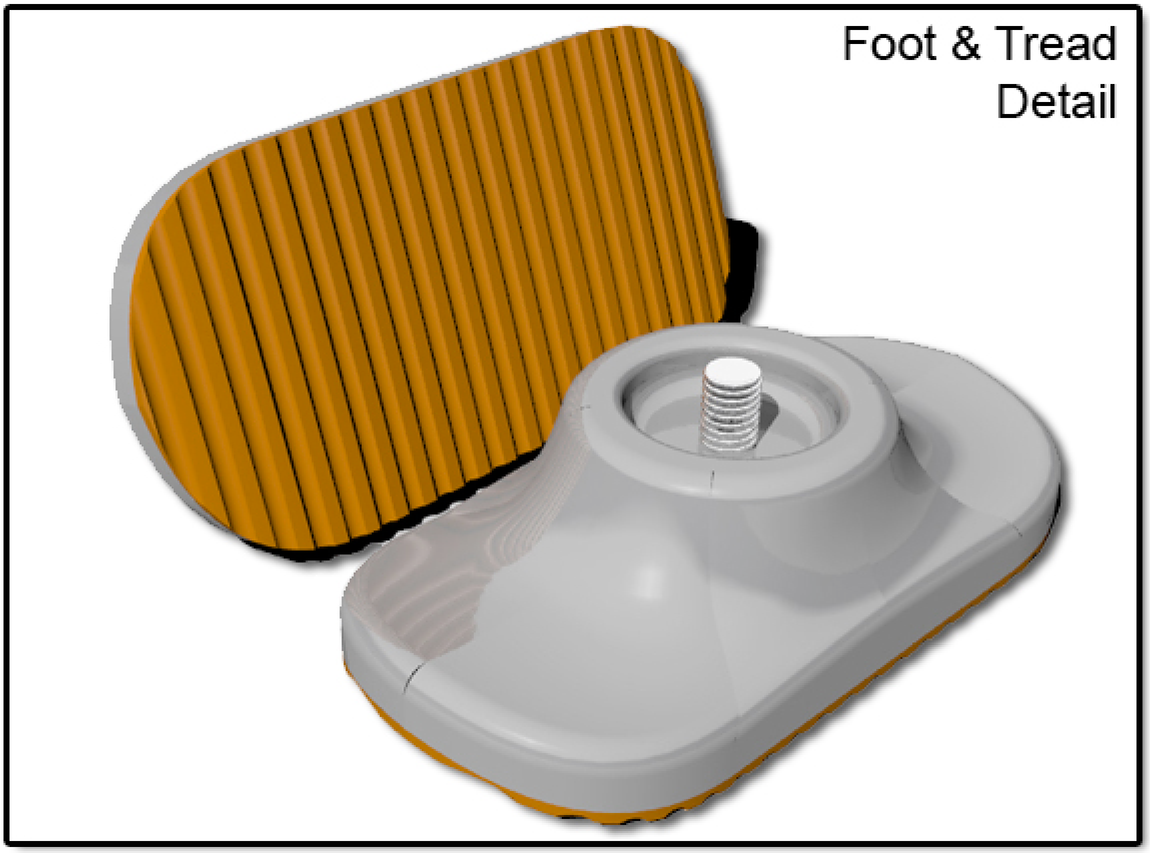

Figure 4.21 illustrates the final design of the foot and tread.

The foot is made of a high-density injection molded plastic. The foot has a recessed area on both the top and bottom to provide a place to securely affix the bushing and lower support beam. The foot will provide the user with a base that is wide and covered with a non-slip tread that enables the user to go almost anywhere. The styling of the foot is also a sleeker design than that of the pre-prototypes. The streamlined design gives a more modern appeal to the product.

Figure 4.22

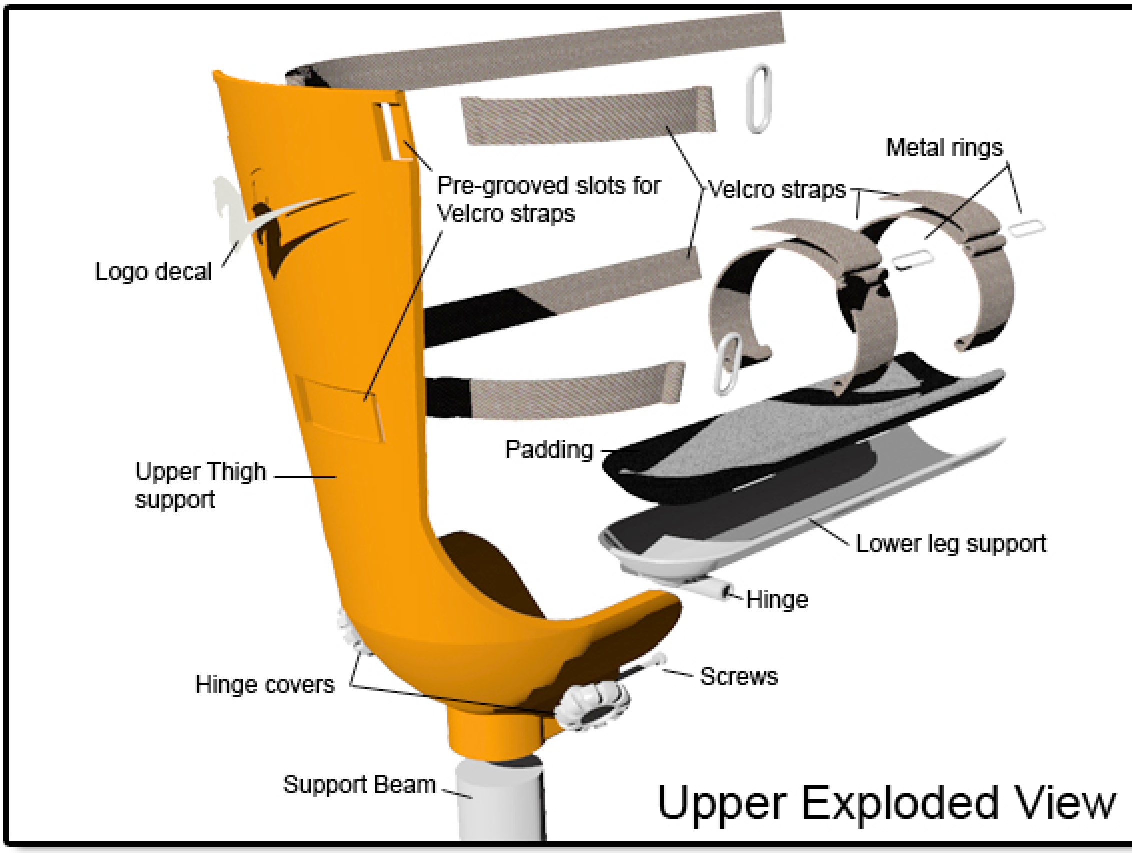

Figure 4.22 shows the components that make up the upper portion of the Peg-Asyst.

The Peg-Asyst is a simple design solution and is comprised of very few parts. The upper portion of the product is made up of nine main components. The thigh support, lower leg support, padding, screws, Velcro straps, hinge, hinge covers, support beam, and a decal. The simpler the design the cheaper the product is to produce and sell. A lower sale price will allow the product to compete more competitively with crutches. The simplified design will also make the Peg-Asyst more user friendly. The Peg-Asysts use is implicit in its design. The product visually communicates its function to the user.

Figure 4.23

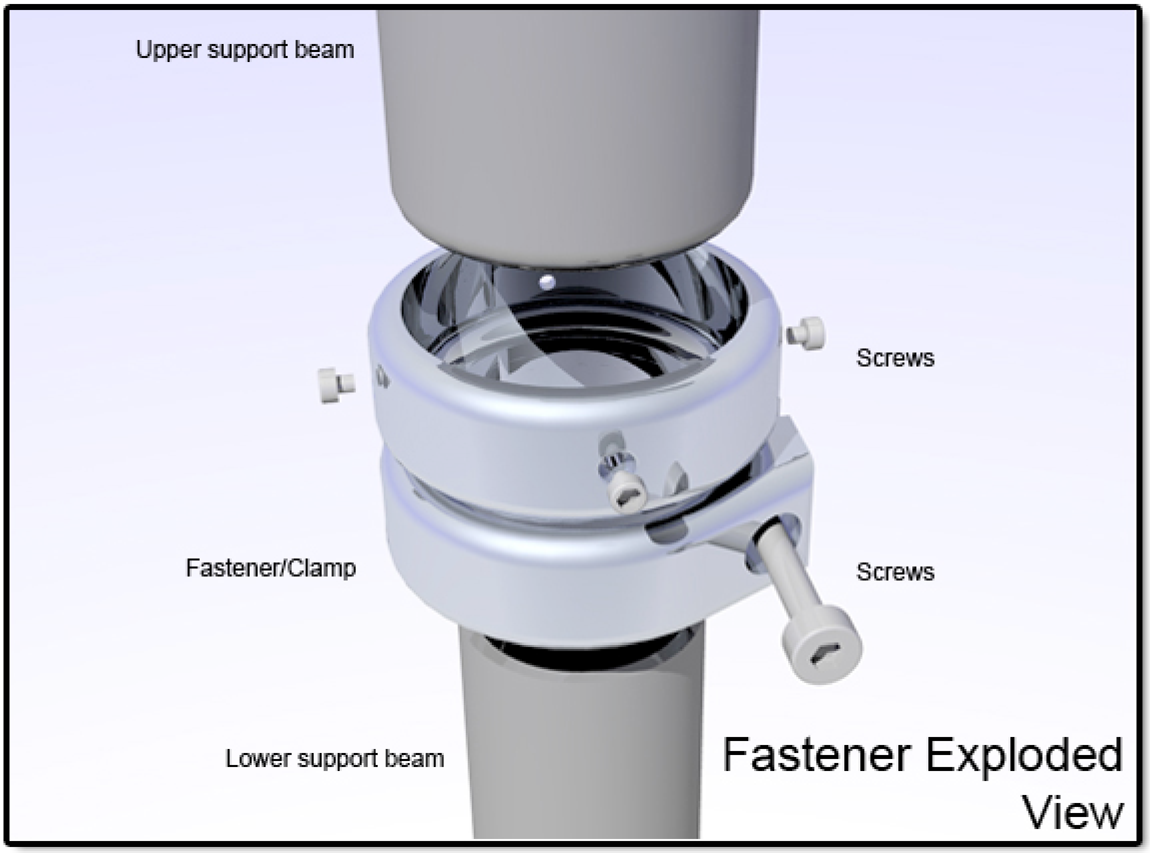

Figure 4.23- Exploded view of the fastener mechanism

Figure 4.24

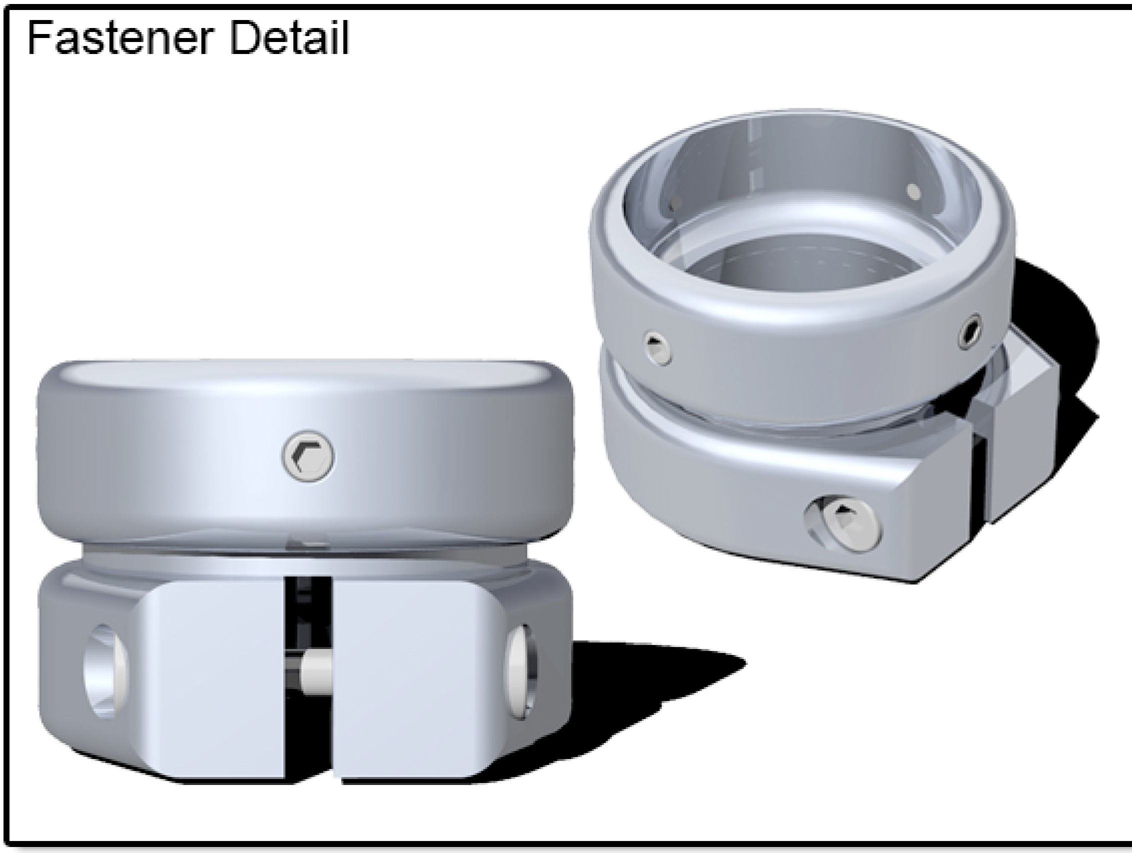

Figure 4.24- Detail view of fastener mechanism

Figure 4.25

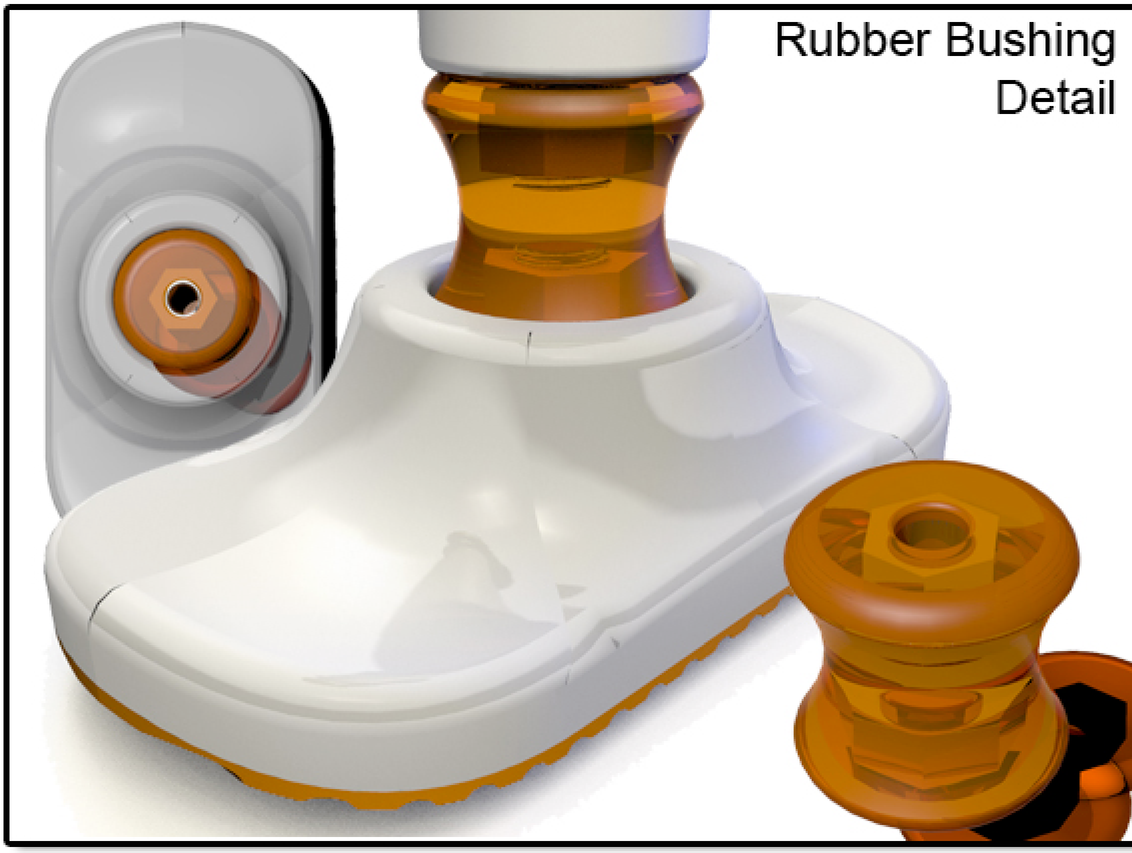

Figure 4.25- Detail of the rubber-bushing component

Figure 4.26

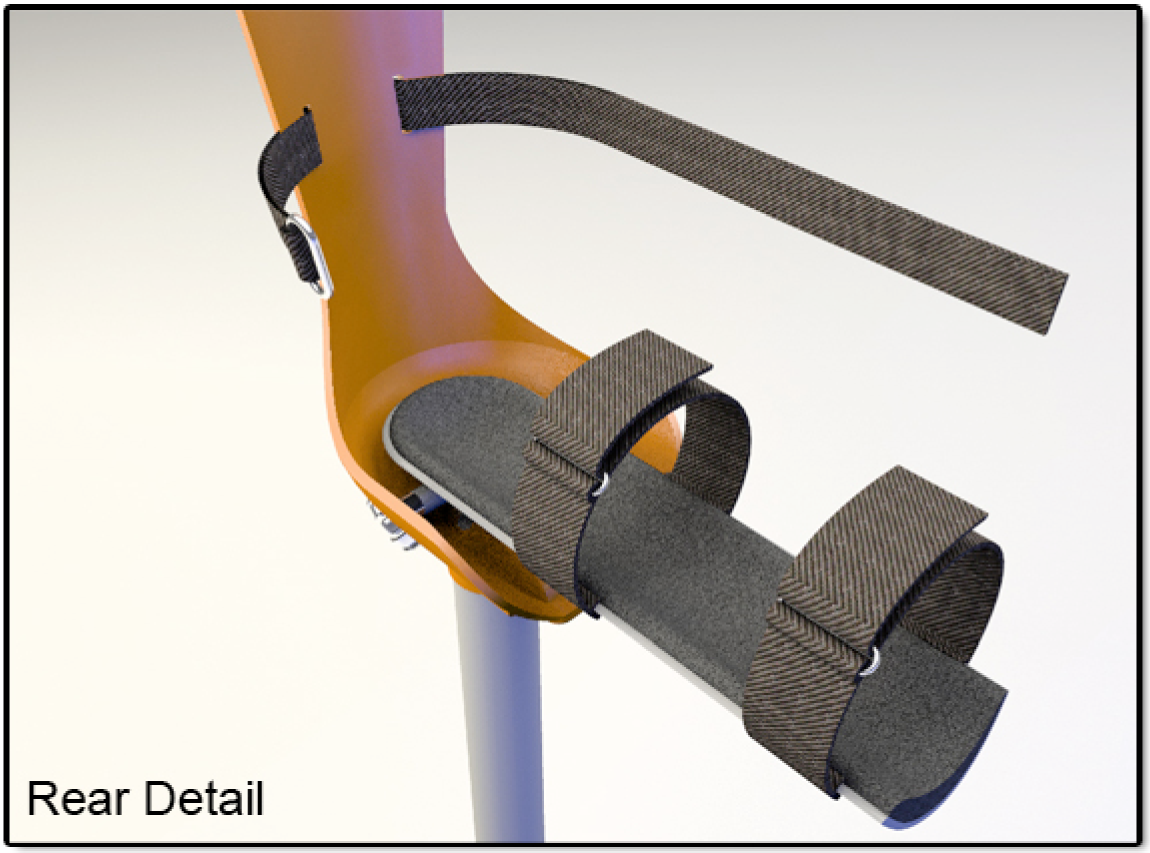

Figure 4.26 is a rear perspective picture of the Peg-Asyst.

Figure 4.27

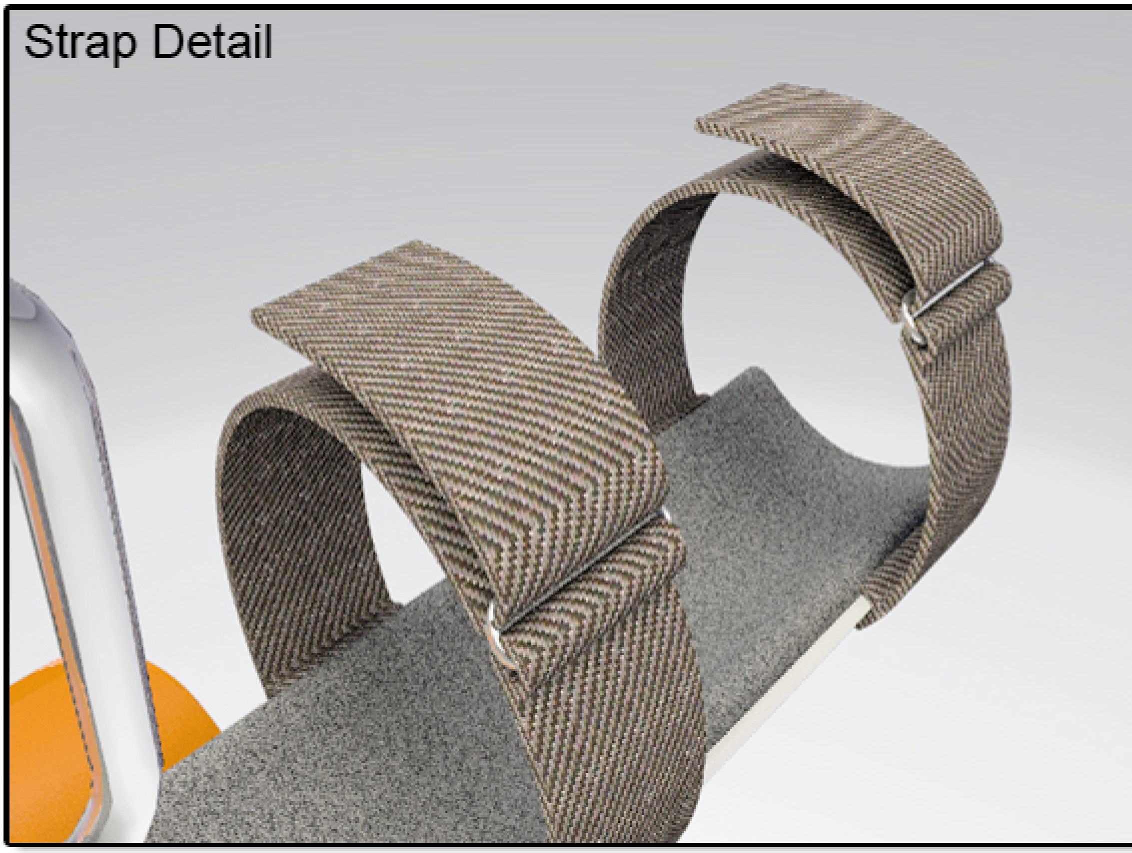

Figure 4.27 is a detailed picture of the straps located on the lower leg support.

4.6 SUMMARY OF CHAPTER

Chapter 4 covers the production of the pre-prototype from the construction phase through the refinement phase. The design was evaluated and tested to determine possible flaws. After being tested, the product was redesigned to eliminate those flaws. A refined model was constructed using Rhino 3-D Modeling software. This chapter also covered product identity including branding the product and logo development.

The pre-prototype was constructed and evaluated in many ways. This was done primarily by the evaluation checklist, which is the guidelines set by the performance criteria. All of the parameters set early in Chapter 3 of this thesis were used as a grading system for the design. All the functions of the pre-prototype were tested and scored. From this evaluation process the problems with the pre-prototype could be isolated and corrected followed by further design changes. The pre-prototype's interaction with the user, environment, and itself was also scored and analyzed. This form of testing lets the designer find points of the product that will encounter high wear patterns and over exposure to the elements. The data is used to correct potential weaknesses in the product and extend the life of the product.

The product identity was concluded in this chapter. The target market was found to be athletes, so the product's name, brand, styling, and logo are all influenced by that fact. A sporty look was adapted to the design process. By making the product look less medical, it appeals more to the target market. The name Peg-Asyst was chosen and a stylized winged horse will be used as the logo.

The final design of the Peg-Asyst incorporated the changes that needed to be made to the pre-prototype. The new design is now able to accommodate the population from the 5th percentile female to the 95th percentile male. The foot was also changed to allow for a more stable walking surface to be established adding to the safety of the user. The overall design is now more functional and more visually appealing to the target market.

CHAPTER 5: CONCLUSIONS

5.1 SUMMARY OF STUDY

This study began with a problem and ended with a product. The Peg-Asyst was the end result of a complex research and design process, which was outlined in this documentation. The documentation of this process was presented in an instructional manner so that it may be used as a template for future design projects. Each step was discussed and explained as to why it was performed. The steps are also captured through figures and photographs to help illustrate the process.

Chapter One lays out the guidelines for the study. It labels the problem, the need, and the objectives of this thesis. The problem is the loss of functionality due to using crutches while injured and the need is for a device that can take the place of crutches. The first chapter is also the beginning of the research phase of the study. The literature review illustrates the need for the study by supporting the problem through facts.

Chapter Two begins the design process with design research. The initial step in designing a solution for a problem is research. The chapter analyzes, in depth, the anatomy of the lower leg, injuries sustained to the leg, existing products in the market, the flaws with those products, and anthropometric data used to size the new product. The anatomy and injuries sustained to the lower leg are used to set parameters for the new product. The study of the existing products and their flaws help illustrate where the areas of improvement are needed and how they can be resolved. The anthropometric data is used to find the best possible means for sizing the new product. The research, done in this chapter further supports the need for the study and the development of a replacement product.

In Chapter Three the second phase of the design process begins. Design development is the beginning of the creative part of the process. In this chapter the concept or identity of the product is born. The solution is approached through multiple ideas that attempt to solve the problem and fit the need. The process begins with concept sketches and mechanical models. After proving that the concept is valid through testing the mechanical models, the next step is creating guidelines and parameters that the design must fulfill. Once the parameters have been set, new concepts are created that complete the requirements. The designs are graded and the best possible solution is selected for further development.

Chapter Four takes the best solution and further develops the idea. In this chapter the production of a pre-prototype takes place and the product's identity is created through selecting a target market. Once the market is selected, the name/brand of the product is developed and a logo is established. Also in this chapter, the pre-prototype is tested and graded using the performance criteria set in chapter three. The design is then given final adjustments and changes before being finalized. The final design is now ready to become a prototype.

5.2 RECOMMENDATIONS FOR FURTHER STUDIES

Because I was unable to test the outcome of the full benefits of the Peg-Asyst a follow up study is necessary to test the medical benefits of the product. Further testing could be used to evaluate the rate at which athletes who use the product heal, as well as, assess the role mobility plays in the healing process. Another test could look at the mental benefits of using the product. The question, "does allowing a more normal functionality than that of crutches reduce the stress of the patient?" should be asked. It would be interesting to see if there is a difference in the cross over effect from the non-injured leg to the injured leg between crutch users and Peg-Asyst users. The cross over would be measured in how slow the injured leg atrophied while using the product compared to the atrophy seen in the injured limb of the crutch user. Clinical tests of the product would be the best means of conducting these studies.

Due to a lack of professional equipment, I believe that the product could further be enhanced through the use of technology that is capable of producing a customized fit for the individual patient. The use of three dimensional scanners and rapid prototyping/fabrication machines may be able to produce a product that is custom fit to the patient allowing for same day availability. The rapid fabrication could be done in office and may only add a slight price increase.

5.3 SYNOPSIS

The main purpose of this thesis was to develop guidelines to create an orthopedic device that could assist in the restoring of functionality and mobility to an injured athlete. I believe that this thesis was successful in that aspect. Parameters were set and information was gathered that could be used in the design of a multitude of orthopedic devices. The outcome of this documentation was ultimately the production of an orthopedic device that accomplished the aforementioned tasks.

The Peg-Asyst, as named in Chapter Four, is the product of this thesis and replaces the need for crutches. The product completes all eight of the functions that crutches are intended to do as outlined in the literature review and more. By eliminating the need for crutches and freeing the hands, the quality of life is dramatically improved. The most important side effect that is avoided by using the Peg-Asyst is crutch palsy. Crutch palsy is numbness in the hands and arms caused by excessive or improper use of crutches. Another advantage of the Peg-Asyst over crutches is the amount of energy it requires to be ambulatory. The Peg-Asyst only requires the normal amount of energy it takes to walk where as crutches require the athlete to support the weight of his/her body causing the athlete to expend much more energy. In the end, the study proves that crutches are becoming a product of the past, and the Peg-Asyst could be the product of the near future.

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