An Approach For The Development of Low Cost Prosthetic Limbs With 3D Printing Technology

by

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Abstract

After limb amputation, the stump muscle needs to define its shape for at least three to six months during atrophy to allow permanent prosthesis installation, but to some degree, there exist amyotrophy after the artificial limb installation, which causes economic and spiritual burdens to the patient. Meanwhile the stump cannot receive appropriate physical therapy.

Traditional prostheses cannot meet different users' requirement types. Modern prosthesis parts and components are expensive, and prosthesis parts and components are limited. Also different types of parts and components have the deficiency of inadequate interchangeability.

Amputees need comfortable prosthetics in order to use and accept the new technology on their limbs. In this case, it becomes important to help the disabled people to get comfortable, with reduced or eliminated more pain, which will make their lives easier.

The topic of the thesis aims to combine technology and human body with multi-material 3D printing, from the perspectives of physiological status or requirements of human body, and psychological status of the disabled, especially the needs of physiological parts. This means using scientific knowledge, combined with three-dimensional-printing technology, will make possible building products for the disabled so that amputees will feel more comfortable and greater convenience when using prosthetics.

The improvement developed in this study will focus on developing low-cost prosthetic limbs with 3D printing technology, which based on human requirement, because 3D printing has customization advantages. We will then conclude with several design guidelines for the

development of products to improve the experience of using prosthetics for amputees.

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List of Abbreviations

CAD	Computer-Aid Design
CAM	Computer-Aid Manufacturing
MCSC	Multi Cross Section Contour
NS	Neo-Strength

Chapter 1

Introduction

1.1 Problem Statement

After limb amputation, the stump muscle requires at least three to six months to get into shape, while the muscle atrophies to allow permanent prosthesis installation, but to some degree, there exists amyotrophy after the artificial limb installation, which may cause economic and spiritual burdens to the patient. Meanwhile the stump cannot obtain necessary and appropriate physical therapy.

Prosthetic limbs are not mass-produced to be sold in stores, but similar to dental prosthesis procurement, prosthetic limbs are prescribed by a medical doctor. Then the patient needs to negotiate with prosthetics specialists to create a prosthetic limb plan. After a series of processes, the patient can obtain the finished prosthetic limbs. These process are energy draining and time-consuming, Prostheses made according to the traditional process are very costly. The amputee requires a prosthetic limb that will need to be replaced over a lifetime. Most amputees are satisfied with their prosthetics, but some of them need repair or renewal. Prosthetics can be expensive, and the patient may not be able to afford replacement every three to five years after wear and tear for the patient's lifetime.

In the prosthesis market, there are two types of prostheses, traditional and modern, both of which have some issues. Though widely used, traditional prostheses have several disadvantages. The first problem is because of the lack of understanding of biomechanical principles, according to the traditional production process, the outcome does not meet the criteria of bio mechanicals. In addition, traditional prosthesis components and parts are limited, so the usage of parts in a traditional prosthesis, whether in types or functions, is much weaker than that of the modern prosthesis with its functionally rich technology. Therefore, the traditional prostheses cannot meet different users' requirement types. However, though modern prostheses are superior to traditional ones in several ways, the modern ones have their disadvantages, too. The disadvantages for modern prosthesis are as follows. The prices of prosthesis parts and components are expensive. In addition, for manual laborers or overweight patients, prosthesis parts and components have a limited lifespan. Also, different types of parts and components have the deficiency of inadequate interchangeability.

Both types of prostheses have some manufacturing and usage issues, as well. Currently, sockets are made of carbon fiber, which requires an expensive custom fabrication process due to the typical structural design of prosthesis. Each prosthetic limbs must be custom made to fit to each individual amputees. Depending on what kind of prosthetic components the patient needs, the cost could vary considerably. Once the amputee’s prosthetic limb is dressed, the patient needs to participate in rehabilitative training for weeks or months. In addition, when an amputee uses the prosthesis, he or she probably experiences discomfort where the prosthesis connects to the body. This discomfort is caused by the lower limb socket, which can be very painful, and this is one of the crucial reasons some people stop wearing their prosthetics. The need to get a new prosthetic at this point would be more expensive, time-consuming for the patient.

1.2 Need for study

A good prosthesis can be worn for as much time as a patient desires. The most critical part of the prosthesis is the socket, which is the combination point between the upper or lower limb and the amputee’s skin. It is the key point where the prosthesis touches the patient’s body. However, many people will stop wearing their prosthetics because of discomfort or pain at the point of connection..

The most common reasons that most amputees experience pain within their prosthetic sockets is because their limb shapes are different, their limbs change over time, and the sockets have been crudely designed. When a limb shrinks, its shape changes relative to the original mold obtained during the casting process, which allows pressures inside the socket to move from tolerant areas to intolerant areas resulting in blisters and pressure sores, with the amputee's life being negatively impacted.

The purpose of this thesis is to propose an approach for the development of low cost prosthetic limbs with 3D printing technology. One must first understand the need for the prosthesis, and its relation to the development of stump pain and skin issues. Understanding anthropometric design is the first consideration. The designer must also consider the anatomy and physiology of human bones and muscles, types of amputations, and prosthetic component design principles, while using multi-material 3D printing or other machines and devices on amputee limbs in order to develop comfortable extensions of limbs, either to replace lost functionality caused by injury or illness, or merely to overcome human inadequacies.

From the study of these aspects, the designer will develop new concepts to design. The goal of this thesis is that by using scientific knowledge combined with three-dimensional printing technology, the designer will develop a better application for amputees.

1.3 Objective of Study

- To research existing design methods pertaining to the design of prosthetic limbs
- To research existing prosthetic limbs and their effectiveness
- To study the physiology of human bones and muscles
- To study bone anatomy
- To study types of amputations
- To study stump pain and skin issues
- To study anthropometrics
- To study the use of technology and innovation to connect the human limb to a device comfortably.
- To research anthropometric design considerations
- To study 3D printing
- To research current prostheses in the assistive field
- To organize these materials
- To develop a process for prosthesis design
- To illustrate the process with an application of the process

1.4 Definition of Key Terms

Above elbow amputation (transhumeral) - The removal of the arm above the elbow.

Above knee amputation (transfemoral) - An amputation of the leg above the knee joint.

Amputation - Removal of a body extremity by trauma, prolonged constriction, or surgery.

Approach – The method used in dealing with or accomplishing a goal.

Ankle disarticulation - An amputation of the foot at the ankle.

Anthropometry - The scientific study of the measurements and proportions of the human body.

Below elbow amputation (transradial) - Removal of the forearm below the elbow joint.

Below knee amputations (transtibial) - An amputation of the leg below the knee that retains the use of the knee joint.

Bone – The hard tissue that provides structural support to the body. It is primarily composed of hydroxyapatite crystals and collagen. Individual bones may be classed as long, short, or flat.

Bones of the arm – Support the upper limb and providing attachment points for the muscles that move the upper limb.

Bones of the foot - Tarsals, metatarsals and phalanges.

Bones of the hand - Carpals, Metacarpals and Phalanges

Bones of the leg - Part of the appendicular skeleton that supports the many muscles of the lower limbs.

Bones of the lower limb - The femur, the tibia, and the fibula

Bones of the upper limb - The scapula, the clavicle, the humerus, the radius, and the ulna.

CAD – Computer-aided design.

CAM – Computer-aided manufacturing.

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

Elbow disarticulation - The amputation of the forearm at the elbow.

Flexion – Takes place between the anklebone (talus) and the lower leg bones (tibia and fibula) pointing the toes downward (Hitzmann S, 2003)

Functional – relating to a function. Designed for or adapted to a particular function or use, Capable of performing; operative.

Gait – A manner of walking or moving on foot.

Hemipelvectomy (transpelvic) - The removal of the entire limb and the partial removal of the pelvis.

Hip disarticulation - The removal of the entire limb up to and including the femur.

Joints of the lower limb - The knee joint, the ankle joint and the hip joint.

Joints of the upper limb - The shoulder joint, the strernoclavicular joint, the wrist joint and the elbow joint.

Lower limb amputation - Lower limb amputations vary from the partial removal of a toe to the loss of the entire leg and part of the pelvis.

Lower limb prosthetics – Devices designed to replace the function or appearance of the missing lower limb as much as possible.

Metacarpal Amputation - Removal of the entire hand with the wrist still intact.

Muscles of the upper limb - Muscles of the pectoral region, muscles of the arm, muscles of the shoulder region, and muscles in the anterior compartment of the forearm.

Partial foot amputation - This commonly involves the removal of one or more toes.

Partial hand amputation - The amputation of fingertips and parts of the fingers.

Prosthesis - An artificial device that replaces a missing body part, which may be lost through trauma, disease, or congenital conditions.

Shoulder disarticulation and forequarter amputation - The removal of the entire arm including the shoulder blade and collarbone.

Stump pain - After amputation is acute stump pain. Infection or wound dehiscence may prolong postoperative pain in some cases.

Through the knee amputations - The removal of the lower leg and knee joint.

Types of anthropometrics - Strength, posture, sensation, and weight

Upper limb amputations - From the partial removal of a finger to the loss of the entire arm and part of the shoulder.

Upper limb prosthetics - Designed to replace, as much as possible, the function or appearance of a missing upper limb.

Wrist disarticulation - Removal of the hand and the wrist joint

1.5 Assumptions of Study

This study is based on the following assumptions: In the new age of 3D printing, prosthetic design is receiving more and more attention all over the world, and the prosthetic uses a 3D-printed covering that can be personalized to individual user requirements. Once designed, prosthetics can be personalized even further with the use of graphics and patterns. These products are shaped by human needs and enhanced by individuality. The developed prosthetics will provide amputees with a unique way to recreate their body, and also showcase their individuality and style.

From the point of rehabilitation, redesign of the prosthetic limb has a better impact on amputees, compared to the standard prosthesis; the prosthetic could therefore be designed differently which can express amputee's personality. 3D printed prosthetic limbs realized people's imagination as art work, which may captures people's minds. This gives the impression of the prosthetic limb itself being special and unique. In addition, the 3D printed prosthetic limbs opens up a conversation space that helps people to understand each other, especially the topic of disability, which is not easy to discuss. For example: if someone wants to discuss a patient's prosthetics, the patient can take this opportunity to explain the prosthetics themselves, or someone may be interested to look closely at those prosthetics.

1.6 Scope and Limitations

This research will focus on a prosthetic design incorporating human factors and adapting these principles to an industrial design process. The approach created in this study will be applied in a 3D printing process of a prosthetic design. Some limitations of the collected research are that most of the research will be from books and web materials. Some areas of the 3D printing process may not yet be usable with types of materials and technology discussed in this project. One of the limitations of 3D printing is the range of materials that can be used; 3D printers are currently using a single material, usually a plastic. Also, 3D printing production time is slow. While it is much quicker than crafting and assembling an object piece by piece, 3D printing does still take time. With a 3D printing project, the larger the piece, the longer the printing time. Small items might take an hour or two, but larger ones take much more time. Therefore, at this time, the process described in this study may not be feasible for large-scale production. Finally, the study will be limited in types of prostheses, and only one prosthetic, a lower limb prosthetic, will be produced during this research, as a demonstration of the application of the developed approach.

1.7 Procedures and Methods

Step 1

Study anatomy.

Methodology

- Collect information from different sources: library and internet
- Gather useful information from these materials
- Derive the relationship between prosthetics and anatomy.

Step 2

Study amputation

Methodology

- Collect information from different sources: library and internet
- Gather useful information from these materials
- Derive the relationship between prosthetics and upper limb/ lower limb amputation

Step 3

Study existing prosthetics and research limitations

Methodology

- Collect information from different sources: library and internet
- Gather useful information that help amputees from these materials
- Derive the relationship between prosthetics and amputees stump pain and skin issues
- Classify existing products
- Identify the gap of current products.

Step 4

Study anthropometrics

Methodology

- Collect information from different sources: library and internet
- Gather useful information of anthropometric study from these materials
- Derive the relationship between prosthetics and amputees' stump pain and skin issues, and establish need for more ergonomically designed prosthetics.

Step 5

Study anthropometric design considerations

Methodology

- Collect information from different sources: library and internet
- Gather useful information of anthropometric study from these materials
- Derive the relationship between user requirements and prosthetics

Step 6

Develop the design approach

Methodology

- Collect information from different sources: library and internet
- Gather useful information to develop a process for design prosthetic from these materials
- Define criteria

Step 7

Demonstration of the approach

Methodology

- Gather all information from studied materials to develop a process for prosthetics design
- Implement the guidelines into the prosthetics design process
- Document the outcome of product development

Step 8

Finish the thesis

Methodology

- Gather the materials during the whole research process
- Organize these materials in a good order
- Review the thesis
- Revise written problems and refine the whole thesis
- Finish the thesis

1.8 Anticipated Outcomes

The primary outcome of this study will be an approach for the development of low cost prosthetic limbs with 3D printing technology. Once designed, prosthetics can be personalized even further with the use of graphics and patterns through 3D Printing. These products are shaped by human needs, enhanced by individuality, and are developed to provide leg amputees with a unique way to recreate their bodies, and also to showcase their individuality and style. This enables the construction of a better product, which could encompass the methodology established throughout this thesis.

Chapter 2

Literature Review

2.1 Overview

The purpose of this thesis is to propose an approach to designing a specific prosthesis for amputees. To do so, the designer must consider a number of things. First, a designer must consider the anatomy and physiology of human bones and muscles, types of amputations, and prosthetic component design principles, discussed in the following section. Next, one must understand the need for the prosthesis, which will include an anthropometric study and its relation to the development of stump pain and skin issues, with an anthropometric design being a primary consideration in this section. Then, this review will discuss the use of multi-material 3D printing on amputee limbs to develop a comfortable extension of a limb as a machine or another device, either to replace lost functionality caused by injury or illness, or merely to overcome human inadequacies.

Another issue, covered last in this review, is that of the process of producing a prosthetic. Prosthetic limbs are not mass-produced to be sold in stores, but similar to dental prosthesis procurement, prosthetic limbs are prescribed by a medical doctor. Then the patient needs to negotiate with prosthetics specialists to create a prosthetic limb plan. After a series of processes, the patient can obtain the finished prosthetic limbs. These process are energy draining and time-consuming, Prostheses made according to the traditional process are very costly. From the study of these aspects, designers must consider reducing unnecessary steps in manufacturing the prosthesis and simplifying the components. The goal is that using scientific knowledge, combined with three-dimensional printing technology, will allow development of a better application for amputees.

2.2 Bone Anatomy

Bones are of vital importance, serve many roles that the body could not function without, and, arguably, the greatest importance lies in providing the body with both structure and movement. Bone anatomy, relative to this thesis, is the study of the physiology of human upper and lower limbs and their relation to prosthetic movement and functions.

2.2.1 Bones of The Upper Limb

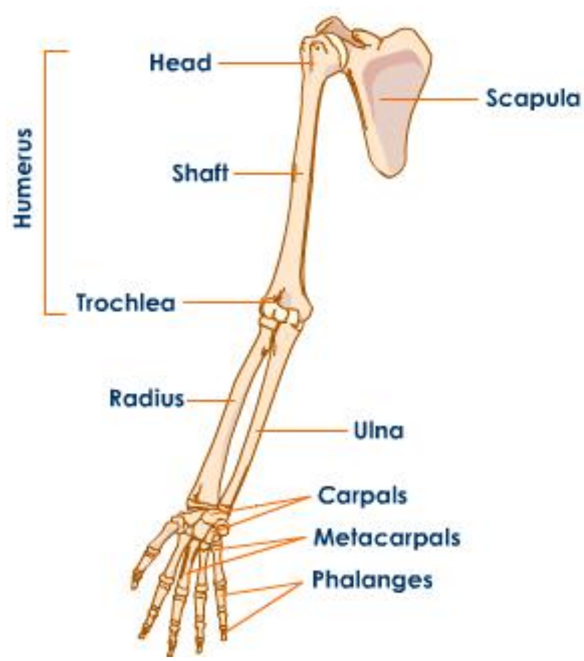


Figure 1: Bones of the upper limb (limb bones, 2014)

The upper limb is made up primarily of the arm, the forearm and the hand. The arm bone is called the humerus, which is the largest and longest bone of the upper limb. The forearm has two parallel long bones called the radius and the ulna. The hand contains 8 wrist bones called carpals. These bones articulate with the radius and the ulna, 5 hand bones or metacarpals, and 14 finger bones or phalanges. The purpose of the study of bones of upper limb is to understand upper limb structures, and provide a foundation for the future study of prosthetic upper limb structure and function, production process and prosthetic parts.

2.2.2 Bones of The Lower Limb

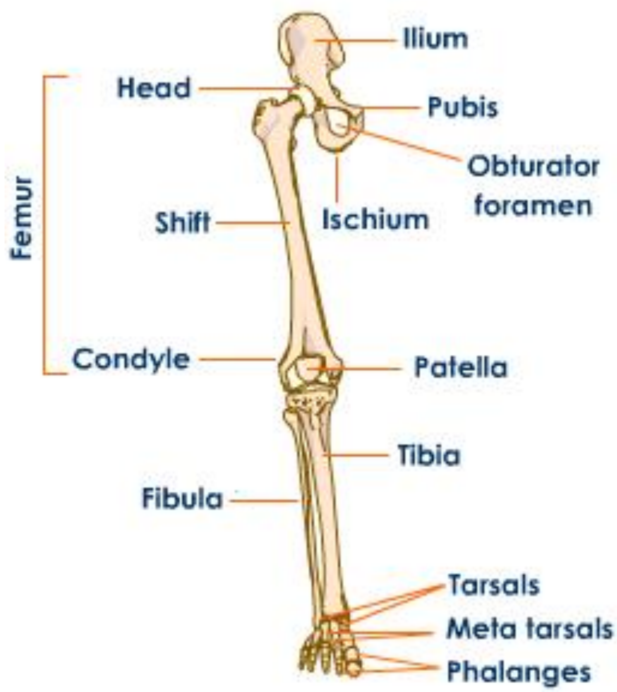


Figure 2: Bones of the lower limb (limb bones, 2014)

The bones of the lower limb include the femur, the patella, the tibia and the fibula. The femur is the single bone of the thigh, and is the largest, longest, and strongest bone in the body. The patella is a triangular shaped sesamoid bone encased in the patellar tendon. The tibia, the bone on the medial side of the lower leg, is the weight bearing bone of the lower leg, and the fibula is the slender bone on the lateral side of the lower leg.

The bones of the foot are part of the lower limb which is made up primarily of the ankle, the ball and the toes. The bones of the ankle are tarsals, and the bones of the ball of the human foot are called metatarsals which are between the tarsals and the toes. The bones of the human toes are called phalanges. A joint is the key connection between two bones which holds the bones together, but permits movement and activities. Joint study will help the designer understand types of joints, because he /she must consider the study of movements in order to develop prosthetic motions for amputees.

2.3 Limb Joints

"A need for strength makes the bones rigid, but if the skeleton consisted of only one solid bone, movement would be impossible. Nature has solved this problem by dividing the skeleton into many bones and creating joints where the bones intersect" (Taylor, n.d.). Joints are strong connections that join the bones of human body to one another; each joint has a different shape and structural component, in order to control the range of motions between the connection parts, because different structural components of the joints have different functions.

In this section, upper lower limb joints will be discussed, in order to help the designer understand basic joints structures and the different function of each joint. The designer must consider joints' range of motion in prosthetic design.

2.3.1 Lower Limb Joints

Lower limb joints have three major components that include the hip joint, knee joint and ankle joint. “The hip joint is an articulation between the hemispherical head of the femur and the cup-shaped acetabulum of the hipbone” (Norman, 1999). The hip joint is one of the most important joints in the human body. It allows human lower limbs to walk, run and jump. Also, it bears the human body’s weight and the force of the strong muscles of the hip and leg. In addition, the hip joint is one of the most flexible joints and allows a greater range of motion than all other joints in the body except for the shoulder. The movements at the hip joint are lower limb flexion, extension, adduction, lateral rotation and medial rotation.

“The knee joint is an articulation between the condyles of the femur and of the tibia as well as the lower end of the femur and the patella” (Norman, 1999). The knee joint is one of the most important and strongest joints in the human body; it allows the lower limb to move the thigh while supporting the body's weight. The knee joint is essential to many daily activities, include walking, running and standing. The main movement at the knee joint is flexion and extension.

“The ankle joint is an articulation between the tibia, fibula and talus. It is a synovial hinge joint with only two movements possible, dorsiflexion (extension) or plantar flexion (flexion)” (Norman, 1999). Functionally, it is a hinge joint. These three bones are flexible on the foot, and these are responsible for propulsion, balance and support of the human body's weight during different activity levels, such as walking and standing.

2.3.2 Upper Limb Joints

Upper limb joints have three major components that include shoulder joints, elbow joints and wrist joints. "Shoulder joint is formed by the union of the humerus, the scapula (or shoulder blade), and the clavicle (or collarbone). Commonly thought of as a single joint, the shoulder is actually made up of two separate joints - the glenohumeral and acromioclavicular joints. These two joints work together to allow the arm both to circumduction in a large circle and to rotate around its axis at the shoulder" (Taylor, n.d.). The shoulder joint is the one of the most mobile and flexible joints in the entire human body. At the cost of joint stability, it is a ball socket joint and it can do multiaxial flexible movements, and allows a wider range of motion than lower limb hip joint. It allows the upper limb flexion and extension, abduction and adduction, medial rotation and lateral rotation, and circumduction. But it lacks stability. The designer needs to consider this factor of permitted movement in prosthetic design.

"The elbow joint is a complex hinge joint formed between the distal end of the humerus in the upper arm and the proximal ends of the ulna and radius in the forearm" (Taylor, n.d.). The elbow joint allows the forearm flexion and extension, in addition, it allows the forearm and wrist rotation.

"The wrist is a complex joint that bridges the hand to the forearm. It is actually a collection of multiple bones and joints. The bones comprising the wrist include the distal ends of the radius and ulna, 8 carpal bones, and the proximal portions of the 5 metacarpal bones" (Phillips & Schmidt, n.d.). The wrist joint marks the area of transition between the forearm and the hand. It is an ellipsoid type synovial joint, allowing flexion and extension, abduction and adduction, and rotation, but the extension has less range of motion than flexion.

2.4 Amputation

2.4.1. Amputation Cause

An amputation is the surgical removal of part of the body such as an arm or leg. There are many reasons an amputation may be necessary. "The most common ones are vascular disease and diabetes. Vascular disease limits the circulation to the extremities. Diabetes, which affects blood sugar, can decrease the body's ability to heal itself" (Causes of Amputation, 2012). Most amputations are unavoidable operations to help save or prolong amputees' lives. In addition, other causes for amputation may include trauma, "Trauma resulting in amputation is most frequently related to motor vehicle accidents and industrial accidents" (Causes of amputation, 2012), or malformations, "Congenital malformation or birth defects can result in either the person having no limb or a very short limb that is treated as an amputation, for which a prosthetic device is made" (Causes of amputation, 2012). Therefore, amputations should be considered in this case, as well. Tumors, referring to tumors of the bone or limb, can cause extensive damage and can sometimes be treated by amputation of the limb.

2.4.2 The Purpose of Amputations

Amputations are not medical failures, but are the result of a medical decision to save or prolong a patient's life. They are done to produce functional stumps and preserve limb strength, sensation, and proprioception. As long as the amputation procedure is carefully planned and executed, there are new opportunities for the limbs. There will be reduction or elimination of suffering and loss of function. Fit with an appropriate prosthesis, the patient could gain relief from pain and experience support of limb function. Amputations are somewhat common in the US, with "Approximately 185,000 amputations occur in the United States each year" (DeFrances., Lucas, C., Buie, V., & Golosinskiy, A. 2008) and "The most common reason for amputation is a loss of blood supply to the affected limb (critical ischaemia), which accounts for 70% of lower limb amputations. Trauma is the most common reason for upper limb amputation, which accounts for 57%" (Amputation Details, Causes, Symptoms, Treatment - Patient Memoirs. n.d.). Amputation is the surgical removal of all or part of a limb or extremity such as an arm, leg, foot, hand, toe or finger. Upper limb amputations and lower limb amputations are the most common types of amputation procedures performed.

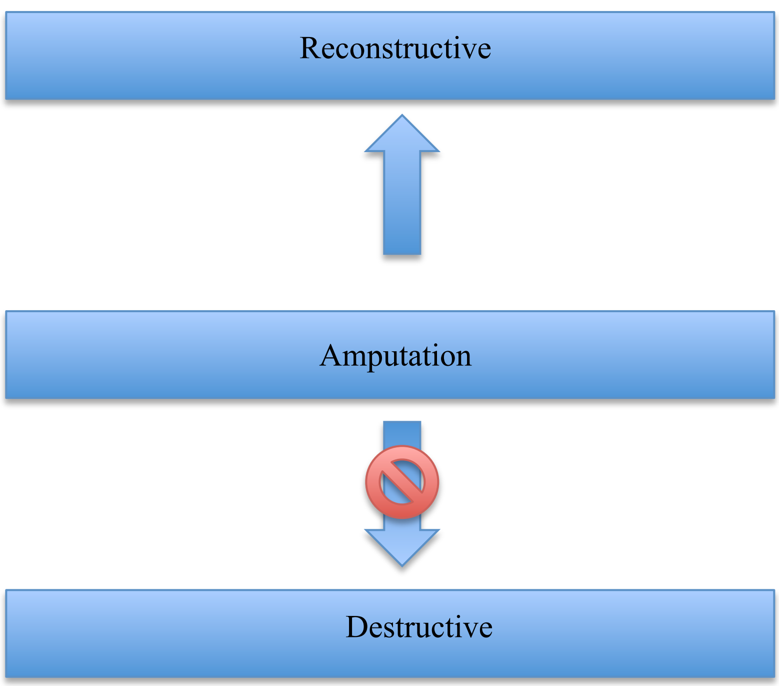


Figure 3: The purpose of amputation

2.4.3 Upper Limb Amputations

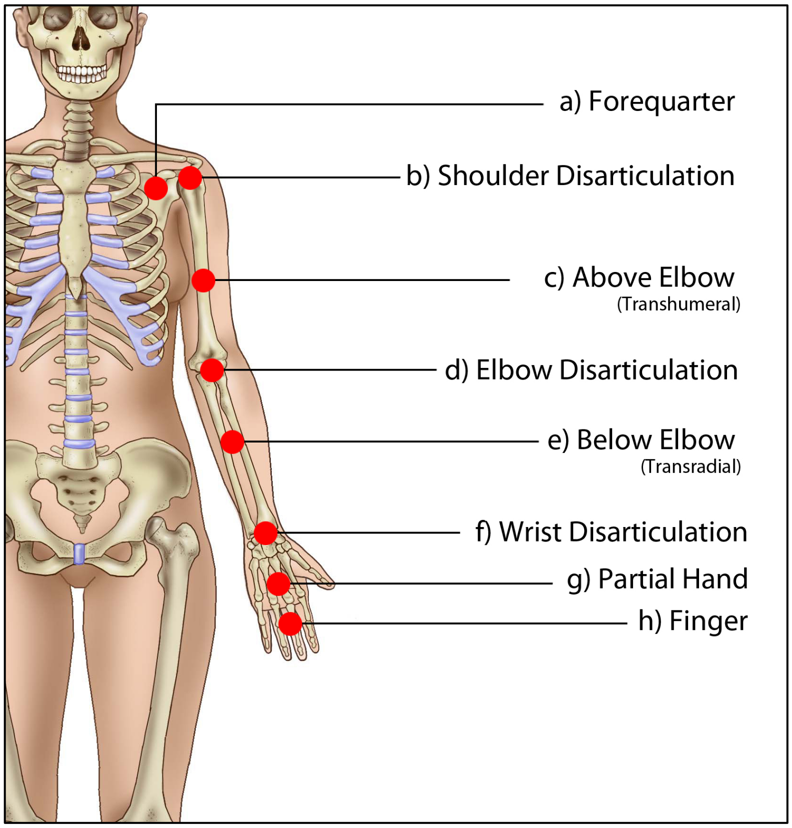


Figure 4: Upper limb amputation levels (Bogdan, 2015)

There are several different types of upper limb amputations that can occur including: a) Forequarter amputation, the removal of entire shoulder girdle, b) Shoulder disarticulation, performed where the upper arm bone (humerus) meets the rest of the shoulder (clavicle and scapula), through the shoulder joint, c) Above-elbow (transhumeral), occurring through the upper arm bone, d) Elbow disartoculation, e) Below-elbow (transradial), the amputation occurs through the radius and ulna of the lower arm, f) Wrist disarticulation, occurring through the radius and the metacarpal bones, which involves the removal of the hand and the wrist joint, g) Partial hand (transcarpal) and h) Fingers amputation (transphalangeal).

2.4.4 Lower Limb Amputations

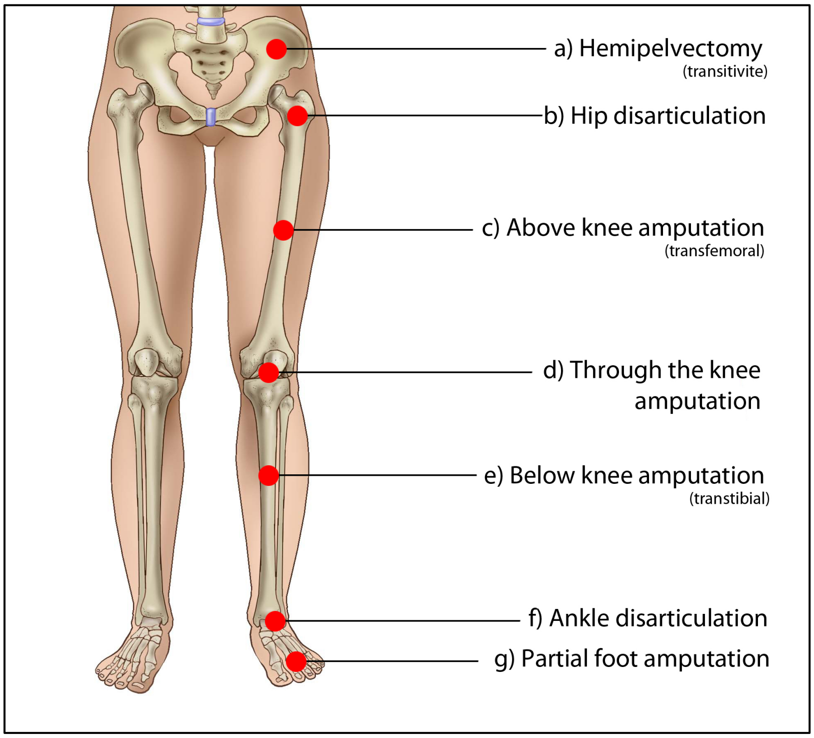


Figure 5: Lower limb amputation levels (Bogdan, 2015)

Lower limb amputations that can occur include: a) Hemipelvectomy, the amputation of half of the pelvis and the leg on that side, and is the rarest of lower limb extremity amputations, b) Hip disarticulation, c) Above knee amputation (AKA), the amputation of the leg above knee joint usually occurring at the middle of the thighbone, d) Through the knee amputation, e) Below knee amputation (BKA), the amputation of the leg below the knee joint, usually occurring if the limb has been severely damaged or is diseased, f) ankle disarticulation, the amputation of the foot at the ankle, g) Partial foot amputation, the amputation of one or more toes.

The term amputation level is used to describe the location at which the body part is amputated. Patients have different prosthetic options depending on their level of amputation. In addition to other factors, the amputation level also affects the respective suitable prosthesis. The purpose of amputation is removing infected, injured or non-functional extremity. Techniques for building inexpensive, rapidly fabricated 3D printed prosthetic limbs, can increase the patient's function and quality of life.

2.5 Prosthetics

2.5.1 Overview

Prosthetic limbs are mechanical replacements for missing limbs including both upper limbs and lower limbs. Prosthetic limbs, to a certain degree, help amputees get back to their basic functional movement systems, and to help amputees develop better mobility and operate freely without depending on others. Depending on the types of specific needs of the patient, prosthetics will be one of two categories. “Artificial limbs are of two types- Exoskeletal or Crustacean and Endoskeleton or modular. The Exoskeletal variety has a hard and rigid shell because the walls of the artificial limbs are responsible for the shape as well as the weight transmission” (Medindia, n.d.).

After an amputation, there are different types of limb prosthetics depending on the level of the amputation. For example, there are two types of lower limb prostheses: one for an above the knee and below the knee which include a partial foot prosthesis and for a hemipelvectomy prosthesis. Also, the upper limb prostheses include an above and below the elbow prosthesis, a shoulder prosthesis, a partial hand prosthesis and a wrist prosthesis.

In the existing market, there are three main types of functional prosthetics which include a passive prosthetic, which is a mechanical replacement for missing limbs providing basic functional movements. Aesthetic prosthetics could be provided and customized for completely different lifestyles or as fashion objects and represent uniqueness of life. Powered prosthetics use electrical signals generated by the wearer's muscles or nerves in order to control the functions of the prosthetic.

Today, many modern prosthetics as designed are heavy, complex, and cumbersome. Most amputees develop pain within their prosthetic sockets because the socket design is very crude. The user's skin often becomes uncomfortable, resulting in blisters and pressure sores with the amputee's lifestyle being impacted. If the condition permits, the prosthetic limbs need to be more lightweight with a substantial increase in stability and ease of use. Also the prosthetic limb could be more quickly repaired and adjusted than is currently the case.

In this chapter, the approach for using 3D print technology to design prostheses will be discussed, for the purpose of creating an approach to help designers understand design research and methods, laying a foundation for a future of products development.

2.5.2 Upper Limb Prosthetic

2.5.2.1. Overview

Losing any part of the upper limb causes amputees difficulties in daily life, work, and mind, but loss of the hands are especially difficult. Human hands are perceptive, usually well-coordinated with complex function. For this reason, any flexible and constitutional mechanical structure is no comparison with a normal hand.

2.5.2.2 Types of Upper Limb Prosthetics

"Basically there are three types of arm prostheses" (Ottobock, n. d.) in the existing market. They are a passive prosthesis, a mechanical (body powered) prosthesis and myoelectric (externally powered) prosthesis.

The passive prosthesis can be used for all levels of upper limb amputation. It is mainly used to replace the body part that is missing. This prosthetic has a realistic exterior, and is comfortable, lightweight and easy to operatic. The mechanical (body powered) prosthesis can be used on above elbow amputations. It is connected to the body through the use of a cable and harness system. The movement happens through the amputees' stump using the shoulder strap support control system to perform actions. The myoelectric prosthesis is an externally powered prosthesis. The working principal is that the stump muscle is sent a myoelectric signal through muscle contractions, and the signal will be used to control functional activities. In this instance, the amputee alone should control relevant muscle groups and generate enough contraction for the muscles to move.

2.5.3 Lower Limb Prosthetics

2.5.3.1 Introduction

Lower limb prosthetics are made of prosthetic foot, ankle joints, calf, knee joint, thigh, socket, suspension system, or any combination of these parts. There are different styles or designs of prosthesis based on amputation levels. Also prostheses are designed for patient's height, weight, and level of activity. This section focuses on working principles of each part of prosthetics.

2.5.3.2 Types of Lower Limb Prosthetics

There are three types of leg prosthetics in the existing market. They are foot or partial foot prosthesis, below-the-knee prosthesis, and above-the-knee prosthesis. “The foot or partial foot prosthesis replaces the part of the patient's foot that was amputated, and the ankle part maybe bendable to help him/her move easier” (Lower Limb Prosthesis, n.d.). “The below-the-knee prosthesis has a lightweight metal tube with a socket on the top to connect the patient's stump; it connects to artificial foot and ankle at the bottom” (Lower Limb Prosthesis, n.d.). “The above-the-knee prosthesis is made with a thigh, knee, shin, ankle and foot” (Lower Limb Prosthesis, n.d.). This prosthesis has a lightweight metal tube with a socket on the top to connect to the stump; the knee part is bendable for walking and sitting.

2.5.4 The Purpose of Assembling Prosthesis Limbs

A prosthetic limb is a device that is designed to replace, as much possible, the function or appearance of a missing limb such as an upper or lower limb. When a person becomes a limb amputee, the patient is faced with economic pressures and lifestyle changes. Requiring a prosthetic limb becomes a life-long series of events because the amputee must replace the prosthetic every few years.

“The characteristics of a successful prosthetic are that it is comfortable to wear, light weight, durable, cosmetically pleasing and mechanically functional” (Lower Limb Prosthetics, n.d.). Finally, amputees need comfortable prosthetics in order to use and accept the new technology on their lost limbs. In this case, it becomes important to help the disabled to become comfortable with their new prosthetic, with reduced pain, which will make their lives easier.

When designing a prosthetic limb that is part of a design system, such as a 3D printed prosthetic limb, the designer must understand the design system structure, then look at the design system as whole to avoid the designing of a product that does not meet the criteria of the design system. After defining and understanding these functions, the designer can now begin researching the new product how to meet functional requirements. The purpose is creating a 3D printed prosthetic limb with functions that can make up for the defects in current prosthetic limbs. Investigating and identifying the users individual needs will help designers to create a strongly innovative, functional product.

2.5.5 Prosthetic Sockets

2.5.5.1 Overview

"The socket is the most critical component of your prosthesis. If it doesn't fit correctly, you can experience pain, sores and blisters, and the prosthesis will feel heavy and cumbersome. Your mobility may be compromised, or the prosthesis may even end up in the back of your closet" (Sabolih, 2006). The socket is the foundation of the prosthesis, as designed a connection carrier between a patient's stump and his/her prosthesis, the main functions are to hold and protect the stump, and transfer forces from the stump throughout the patient's daily activities. The socket must fit well to provide comfort and function and it needs to be durable and lightweight. In this section, prosthetic limb sockets and types will be discussed in order to understand the current manual process for fabrication of prosthesis sockets.

2.5.5.2 Types of Sockets

In recent years, with the development of science and technology, new technologies, new materials and new technology applications are seemingly endless. The manufacture method for the prosthesis has been increasingly improved, especially the prosthetic socket, which has changed from the traditional socket and open-ended style change to a closed and full-bearing contact socket. The upper limb socket includes the below elbow (transradial) socket, transhumeral socket and shoulder disarticulation socket. The lower limb socket development has undergone several phases, from a traditional plug fitting socket, to a pre quad socket, quadrilateral socket and finally ischial containment. Today, the types of socket design are based on two major factors. One is art form and the other one is weight distribution.

Concerning art form, "Fitting a socket is an art form that continues to evolve." (Sabolich, 2006). In earlier designs, the socket was created with soft material, but now the socket is designed for as much stability and comfort as possible. For weight distribution, “Where weight is carried within the socket can be a critical issue...The use of socks and padding can be explained with this nautical analogy. Think of the residual limb as the rudder of a ship. The water can be thought of as socks. If the water level gets too low, the rudder will drag the bottom; as water is added, the ship will rise, freeing the rudder” (Sabolich, 2006). If he/she is using a prosthetic limb and it is too loose, the prosthetic limb will not have a good connection with the socket and it will not work well or at all. The designer must consider the socket balance of some issues within a range that is flexible and comfortable for the amputee.

2.5.5.3 Summary of Socket

The socket's basic tasks include fitting the stump and containing the soft tissue. The socket is a connection carrier between a patient's stump and his/her prosthesis: the main functions are to hold and protect the stump. The socket passes the force of the human stump to the far-end of the prosthetic to achieve control by the human stump, standing stability of the prosthetic, and flexible function of walking. Through different structural shapes, sockets serve as the connection between the stump and prosthesis. Through different shapes, the socket can bear reasonable weight based on human anatomy and human body biomechanics. The connection between socket and stump provides amputee's stump and prosthetic to have good function. The socket must fit well to provide comfort and function. The prosthesis should feel and move likes an extension of patient's body. It has to be fairly snug; otherwise, when patient moves his/her limb, it will just move inside the prosthesis and not move the prosthesis itself. In this case, he/she expends energy without a full response from the prosthesis, and it is very inefficient. A loose connection also results in rubbing of the skin and can create soreness and skin problems.

2.6 Process of Prosthesis

Prosthetic limbs are not mass-produced to be sold in stores. Similar to dental prosthesis procurement, prosthetic limbs are prescribed by a medical doctors. Then the patient needs to negotiate with prosthetics specialists to create a prosthetic limb plan.

After a series of processes. the patient can obtain the finished prosthetic limbs. These processes are energy-draining and time-consuming.

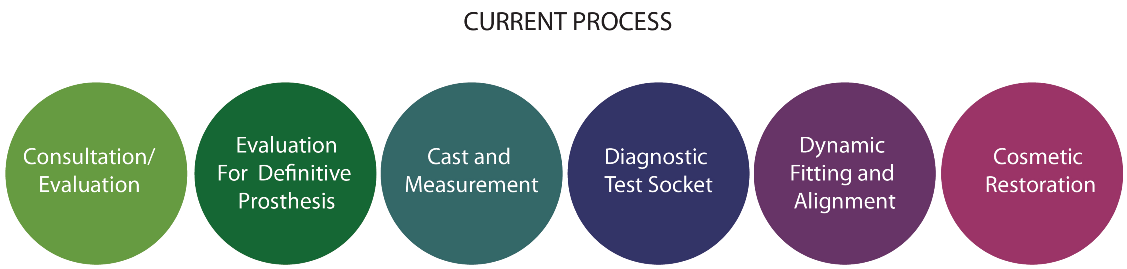


Figure 6: Current process of prosthesis (Copeland, 2001)

According to the "First Step – A guide for adapting to limb loss", during the last 20 years, the science and fine art of prosthetic rehabilitation has taken great strides. There has been a great evolution in the design and comfort of prostheses. The first main step is consultation/evaluation. The patient needs pre-amputation consultation, which is important to seek prior to the surgery to obtain information. This consultation directly relates to the patient's stump getting into shaped and being dressed for the prosthesis. The second step is evaluation for a definitive prosthesis. Once the patient stump is healed, the prosthetist performs an evaluation. "This is the beginning process of designing and fabricating your new prosthesis" (Copeland, 2001) where questionnaires are given to survey the patient. "Different issues will be discussed and agreed upon, including socket design, materials, componentry, and how long the whole process should take." (Copeland, 2001). Currently, sockets are made of carbon fiber, which requires an expensive custom fabrication process due to the typical structural design of prosthesis. Each prosthetic limbs must be custom made to fit to each individual amputees. Depending on what kind of prosthetic components the patient needs, the cost could vary considerably. The third step is cast and measurenment. "Once the cast is taken, it is filled with plaster, and then modified to enhance comfort and weight-bearing areas" (Copeland, 2001). During the assessment, a plaster impression and measurement data of the stump is recorded, which are used for the fabrication of the patient's socket. The fourth step is a diagnostic test of the socket. "Most practitioners will use a diagnostic test socket for the 'definitive prosthesis' to ensure a satisfactory comfort level…This is a critical part of the process and for the hard-to-fit amputee, there may be a need for more than one test socket to ensure a proper fit" (Copeland, 2001). However, this would produce additional cost. The fifth step is dynamic fitting and alignment. "At this stage of the process, the prosthesis will be tested for comfort and function. The prosthetist will make the necessary adjustments in the office before letting you try it on for a one- or two-week test run" (Copeland, 2001), Once the amputee's prosthetic limb is dressed, the patient needs to participate in rehabilitative training for weeks or months. In addition, when an amputee uses the prosthesis, he or she probably experiences discomfort where the prosthesis connects to the body. This discomfort is caused by the lower limb socket, which can be very painful, and this is one of the crucial reasons some people stop wearing their prosthetics. The need to get a new prosthetic at this point would be more expensive, time-consuming for the patient. The sixth step is cosmetic restoration. "The final stage can be very exciting for amputees, especially for those who are more cosmetically conscious. Most amputees want their prosthesis to look and work as naturally as possible" (Copeland, 2001). However, even though the prosthesis is fitted with the patient to "look and work as naturally as possible," with no personality, the prosthesis is inadequate. It could be designed differently which can express the amputee's personality which may capture people's minds, giving the impression of the prosthetic limb itself being special and unique.

2.7 Upper Limb Motions Analysis

2.7.1 Introduction

Upper limb motions are very important for human daily activities, such as eating, drinking, grasping and lifting objects. The functional capacity of the upper limb is determined by the shoulder complex, elbow, wrist, and hand developing multiple integrated spheres of action. In this section, shoulder complex, elbow, wrist functions will be discussed. In order to analyze human upper limb motions and its range, several factors should be considered in designing a prosthetic upper limb, including upper limb flexion and extension, abduction and adduction, and internal/external (or medial/lateral) rotation. The designer needs to understand the impact of upper limb motions on prosthetic limb design.

2.7.2 Upper Limb Motions Analysis

The first discussion is shoulder motions. The shoulder joint itself known as the glenohumeral Joint, which is the primary joint of the shoulder and most mobile joint in the human body. The most common type of motions include flexion, extension, abduction and adduction. The glenohumeral joint has two very different functions that can often be contradictory: 1) it must allow a great amount of movement potential for arm motion and therefore be very flexible; and 2) it must provide a strong, stable socket for actions such as lifting or pushing resistance (Hitzman, 2004). Secondly is elbow motion. The elbow is a free moving synovial joint, allowing shortened and lengthened arm movements and rotation of the forearm. In the motions of extension and flexion, the elbow joins the wrist and shoulder joints to allow complex movements of the shoulder girdle down to the fingertips (Chai, 2002). The elbow is an extension of the shoulder joint. It allows smooth, controlled motion. In the motion of supination and pronation, the elbow rotating the forearm outward and upward is supination, while rotating the forearm inward and downward is pronation (McNulty, 1994). These rotating actions allow the shoulder girdle, the upper and lower arms, and the wrist and hands free and smooth movements. In the motion of pronated flexion, since the shoulder, elbow and wrist provide support to the entire shoulder girdle, the elbow can lift weights in excess of a person's own body weight (Movements of the elbow joint, n.d.). This motion allows the forearm to roll inward and downward and the elbow to bend and straighten. Thirdly is wrist motion. The wrist acts as a universal joint; this is a key joint with regard to the functional activities of the hand, and it is one of the smaller joints in your body, but it is made up of multiple bones. The wrist flexes, extends, deviates laterally, and participates minimally in pronation-supination. The motion of wrist bending, including forward bending or flexion, always happens in daily activities such as writing and lifting objects. The other situation is backward bending or extension; the wrist is necessary for opening the door, pushing a door closed the basic activities. Although there have been studies involving upper limb motion, they are few in number. In contrast to the cyclic and often predictable motion of normal lower extremity tasks such as gait and running, upper limb tasks are varied and difficult to analyze.

2.8 Lower Limb Motions Analysis

2.8.1 Introduction

In this section, the gait cycle will be discussed. It could be divided into two stages: stance phase and swing stance. These factors should be analyzed and considered in designing a prosthetic lower limb. The designer should find key points in order to design comfortable and attractive prosthetic lower limbs.

2.8.2 Gait Cycle Analysis

"Gait is the medical term to describe human locomotion, or the way that we walk" (Inverarity, 2014). Human gait is the whole body muscle movement, include weight shift, pelvic tilt and pelvic rotation, hip joint, knee joint, ankle joint stretching and flexing. This is a complex voluntary movement. Internal rotation and external rotation cause body displacement.

"Walking is the rhythmic repetition of the gait cycle" (Fishwick, 2013). There are two separate phases that must defined in gait cycle, one being "the stance phase defined as the interval in which the foot is on the ground, 60% of the gait cycle" (Loudon, J., & Bell, S. 2008). The other is "the swing phase defined as the interval in which the foot is not in contract with the ground. It is 40% of the gait cycle" (Loudon, J., & Bell, S. 2008). In the gait cycle, the stance phase is divided into four phases: "heel strike to foot flat, foot flat through mid-stance, and then heel off to toe off" ((Loudon, J., & Bell, S. 2008). The swing phase is divided into two phases: "acceleration to mid-swing and mid-swing to deceleration" (Loudon, J., & Bell, S. 2008). By study of each individual phase of the gait cycle, the designer obtains clues to specific aspects that will lead to a more efficient gait pattern of the prosthetic limb, resulting in less energy expenditure, greater functional independence, and improved lower limb balance.

2.9 What Patients Needs

"Due to the increasing rate of amputations, there is an ever-growing demand for prosthetic limbs. Next to an immediate need for a person's initial prosthetic limb, multiple replacement limbs and repairs are necessary over a lifetime. For children, a prosthetic replacement is needed typically every 6-12 months. Adults need such a replacement every 3-5 years. This means that youngsters may need around 25 limbs throughout the course of their life, whilst adults will use up to 20 limbs" (Mathews, D., Pye, R., & Burgess, E. 2005). Prosthetics can be expensive, and the patient may not be able to afford replacement every three to five years after wear and tear for the patient's lifetime. Therefore, the patient needs low cost prosthetic limbs. The exact cost depends on the level of amputation, physical ability and functional needs, so each prosthetic limb will be somewhat different. Secondly, the patient needs to learn to use prosthetic limbs, which is a tough job that takes time, great effort, strength, patience and perseverance. Also the patients need to learn how to handle the new device, which may include skills such as learning how to use a computer. The patients need guidance on how to accept and investigate new things he/she maybe uncertain of, such as walking or other activities (involving the prosthetic lower limb), or the motion of picking up, grasping, reaching and lifting (involving the prosthetic upper limb). Daily activities are performed inside and outside, at home and elsewhere, and basic prosthetic lower limb functions, such as walking on different types of surfaces / grounds like stairs and uneven terrain, and basic prosthetic upper limb functions, such as picking up, grasping, reaching and lifting of different types of objects / shapes.

2.10 What Patients Wants

Affordable and readily available prosthetic limbs are vital for amputees that need them. Also important is reducing the cost of replacements and maintenance. In addition, proper fit of the socket and good alignment will ensure that the prosthetic is useful to amputees. Also, the patient wants prosthetic limbs that look more personal, that are designed differently to express the amputee's personality.

2.11 Conclusion

A prosthetic limb is a device that is designed to replaced, as much possible, the function or appearance of a missing limb such as an upper or lower limb. When a person becomes a limb amputee, the patient is faced with economic pressures and lifestyle changes. The amputee requires a prosthetic limb that will need to be replaced over a lifetime. Most amputees are satisfied with their prosthetics, but some of them need repair or renewal. In the field of prosthetics, prostheses made according to the traditional process are very costly.

The purpose of this thesis is to propose an approach to develop low cost prosthesis for amputees. One must first understand the need for the prosthesis, which includes an anthropometric study as well as bone anatomy, upper limb motions and lower limb gait cycle, and existing prosthetic manufacture process analyses, to develop low-cost 3D printed prosthetic limbs for amputees, and understanding the reason and user requirements for design is essential. Low-cost and affordability are key factors; the characteristics of a low- cost prosthetic limb are new construction, lightweight and affordability. Finally, the patient needs an affordable prosthetic limb in order to use and accept the 3D printing technology on their lost limbs. In this case, it becomes important to help the disabled to get low-cost, lightweight with a newly constructed prosthetic limb that will make their lives easier.

Also designers must consider reducing unnecessary steps in manufacturing the prosthesis and simplifying the components in order to propose a new approach to developing a low-cost prosthetic limb with 3D printing technology. The goal is that in using scientific knowledge, combined with three-dimensional printing technology, the designer will develop a superior application for amputees, which is both affordable and functional.

Chapter 3

An Approach for The Development of Low Cost Prosthetic Limb With 3D Printing Technology

3.1 Overview

In this chapter, the design approach described is intended to provide a detailed approach on how to design low-cost prosthetic limbs with 3D printing technology better than currently represented by current prosthetic limbs. Patient consultations and methods of sizing the limbs will be introduced in this chapter. The purpose is to create an approach to help designers better understand design research methods and possible solutions.

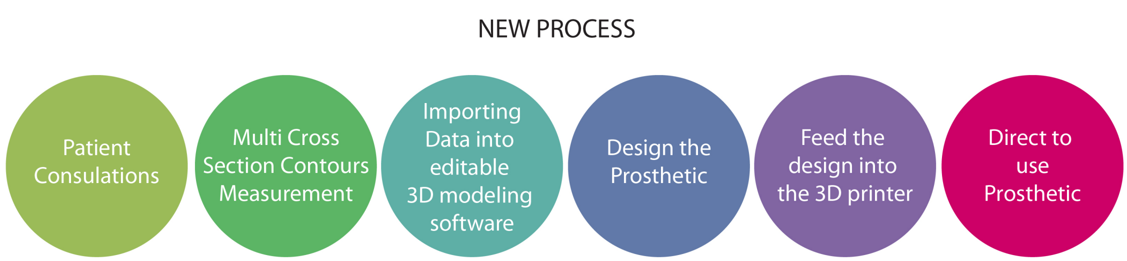


Figure 7: The new approach of prosthetics design

The approach of development of low cost prosthetic limbs with 3D printing technology is shown in Figure 7. Firstly, the designer needs make an evaluation of the patient in order to identify basic information, and what kind of prosthetic components the patient needs. This is the beginning of the process of designing and fabricating the patient's new prosthetic limb. Secondly, data for the prostheses are acquired with a specialized tool. Once captured, the datasets are used to generate a 3D model by a 3D modeling software such as SolidWorks, Subsequently, the 3D model is converted into STL file, which can then be read by a desktop 3D printer.

3.2 Introduction

When a person becomes a limb amputee, the patient is faced with economic pressures and lifestyle changes. The amputee requires a prosthetic limb, the upkeep and replacement of which becomes a life-long event. A prosthetic limb is a device that is designed to replaced, as much possible, the function or appearance of a missing limb such as an upper or lower limb. The characteristics of a low- cost prosthetic limb are new construction, lightweight and affordable. Finally, the patient needs an affordable prosthetic limb in order to use and accept the 3D printing technology on their lost limbs. In this case, it becomes important to help the disabled people to obtain low-cost, lightweight prosthetic limb with a new kind of construction that will make their lives easier.

When designing a low-cost prosthetic limb that is part of a design system, such as a 3D printed prosthetic limb, the designer must understand the design system structure, then look at the design system as whole to avoid the designing of a product that does not meet the criteria of the design system. After defining and understanding these factors, the designer can now begin researching the new product in order to meet functional requirements. The purpose is to create a low cost 3D printed prosthetic limb with functions that can make up for the defects in current prosthetic limbs. Investigating and identifying the user's individual needs would help designer create a new functional product with strong innovative characteristics.

3.3 Patient Consultations

After amputation, and after the stump gets into shape, if the patient wants to get a new prosthetic limb, or the patient needs to replace an existing prosthetic limb, the patient may need to get a new inexpensive prosthetic limb that he/she can afford.

The first step is the designer needs to evaluate the patient in order to identify the patients' basic information, and what kind of prosthetic components the patient needs. This is the beginning process of designing and fabricating patient's new prosthetic limb. In a design process, the designer must keep in mind for whom he or she is designing. In this case, there are two research objects that must be defined: one is the patient and the other is the prosthetic limb. The use of this background information can be very helpful, in order to avoid problems that designer developers may encounter fitting prosthetic limbs fitting onto the patient's stump. After targeting the patient group, then the designer can develop an extensive and in-depth understanding of patient characteristics.

When the designer has made decisions regarding the design procedures, the designer can realize how the prosthetic limbs are guided by patient characteristics. Identified characteristics will fall into three major categories: General patient parameters, Stump parameters and Stump measurements. In the following a description will be provided: General patient parameters, including 1) Gender: the patient's gender, male or female. 2) Age: the patient's age in years. 3) Weight: the patient's body weight. 4) Height:

the patient's body height. 5) Amputee cause: the reasons for amputation. 6) Amputation level: the location at which the patient's body part is amputated. 7) Lifestyle: Gathered through the questionnaire method for patient's lifestyle (see Table 1); includes the physical conditions, activity level and adaption level.

PHYSICAL CONDITIONS
1. How are your general physical conditions?
2. How is your general muscle activation?
3. How is your muscle coordination?
ACTIVITY LEVEL
UPPER LIMB
4. Do you lift / reach / grab /hold only at home or outside?
5. Can you lift / grab / hold only for few pounds?
6. Do you lift / reach / grab / hold with some limitations?
7. Do you lift /reach /grab /hold at different weight?
8. Do you lift / grab / hold for more than 5 lbs.?
LOWER LIMB
9. Do you walk only at home or outside?
10. Can you walk only for few miles?
11. What are some limitation you may face?
12. Do you walk at different speeds?
ADAPTATION LEVEL

UPPER LIMB
13. Do you lift / reach / grab / hold from ground or any level?
14. Can you lift / reach / grab / hold only for few pounds without outside strength.
15. Can you lift / reach / grab / hold different shape objects?
16. Can you do only a few pounds of a object?
17. Can you lift / reach / grab / hold on irregularly shaped object and overcome tough obstacles?
18. Can you lift / reach / grab / hold varying object size?
LOWER LIMB
19. Do you walk only on flat ground?
20. Can you go over only small obstacles such as edges or irregular ground?
21. Can you do only a few steps of a stair?

Table 1 - Questionnaire methods for patient's lifestyle

Stump parameters include 1) Amputation type: upper or lower limb amputation, 2) Amputation side: the left, the right or both sides of limbs, 3) Stump shape: the shape of the residual limb, which usually will be conical or cylindrical, and 4) Stump skin: the sensitivity of the stump skin, scars or scratches on the stump.

The stump measurements are general measurements of patient's body, including 1) Weight: Patient weight, 2) Height: patient height, 3) Amputation stump length, and 4) Amputation stump girth. In addition, in particular situations, such as dual limb amputations, the designer must identify patient height before the amputation. The purpose of these three factors is ensuring the prosthetic limb's configuration meets that of amputated stumps.

3.4 Measurements and The Fabrications Process

3.4.1 Overview

Once the patient consultation has been completed, the patient needs to be measured for the stump limb. The patient's measurement is the first step in fabricating the prosthetics. It is important that correct measurements are taken by the stump measurement tools. In this section, the amputee's stump measurement methods will be discussed, including traditional methods, CAM/CAD methods and multi cross-section contours (MCSC) methods. By a comparative analytical method, a method that provides the best low cost measurement methods will be chosen.

3.4.2 Traditional Measurement Methods

After the illness or accident that caused the need for amputation, the patient ultimately needs to receive a prosthetic limb installation in order to restore physical and mental health. Once the patient consultation has been completed, the patient needs to be measured for the stump limbs. The patient's measurement is the first step in fabricating the prosthetics. It is important that correct measurements are taken by the stump measurement tools (Figure 8). There are four tools that assess linear dimensions: AP (Anterior-Posterior) diameter, ML (Medial-Lateral) diameter, and length, and three assessed circumferences. The measured data are recorded in the measurement data form (Figure - 9). The measurements will be used to create a plaster-filled model.

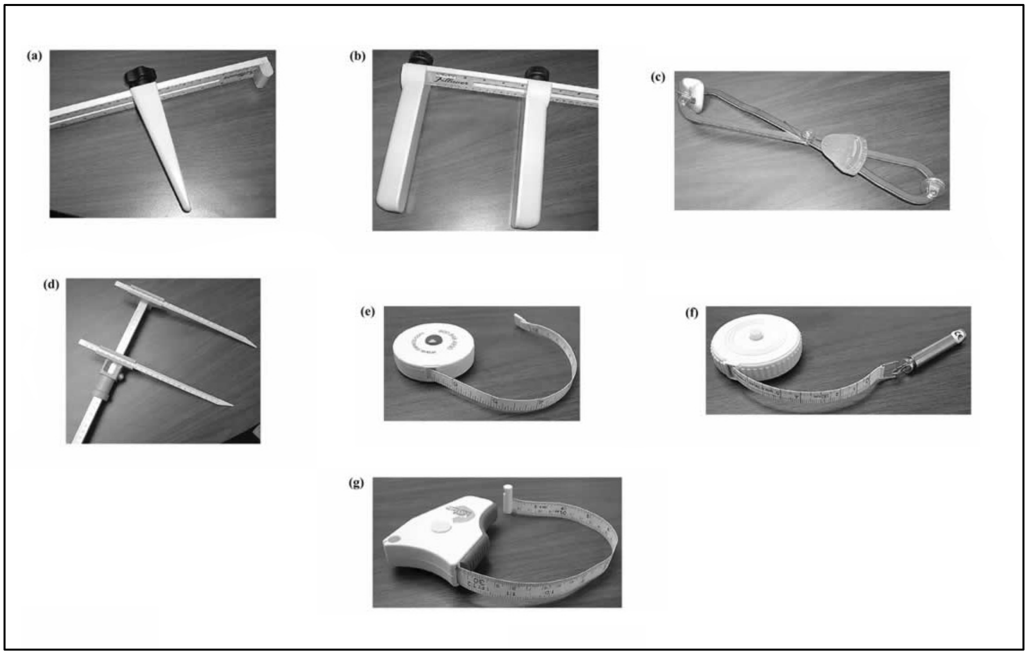
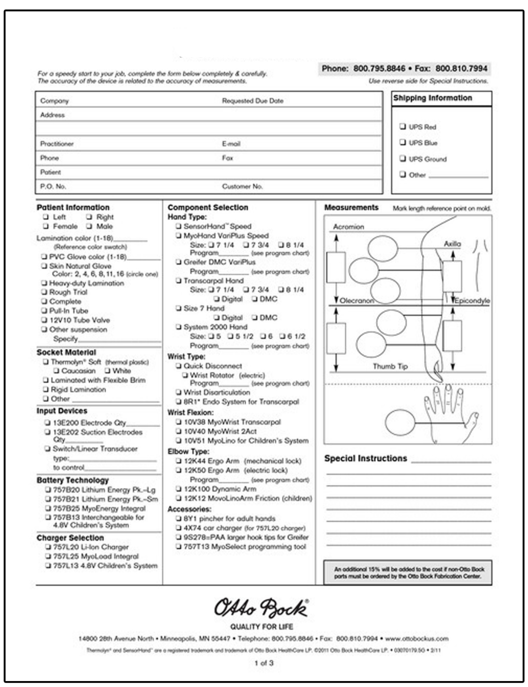


Figure 8: Measurement devices: (a) transtibial length caliper, (b) GPM anthropometer, (c) universal anterior-posterior-medial-lateral caliper, (d) VAPC caliper, (e) standard tape, (f) spring tape and (g) circumferential tape.



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For a speedy start to your job, complete the form below completely & carefully. The accuracy of the device is related to the accuracy of measurements.

Use reverse side for Special Instructions.

Company	Requested Due Date
Address	
Practitioner	E-mail
Phone	Fax
Patient	
P.O. No.	Customer No.

Shipping Information
- ❑ UPS Red
- ❑ UPS Blue
- ❑ UPS Ground
- ❑ Other ________

Patient Information
- ❑ Left ❑ Right
- ❑ Female ❑ Male

Lamination color (1-18)________ (Reference color swatch)
- ❑ PVC Glove color (1-18)________
- ❑ Skin Natural Glove Color: 2, 4, 6, 8, 11, 16 (circle one)
- ❑ Heavy-duty Lamination
- ❑ Rough Trial
- ❑ Complete
- ❑ Pull-In Tube
- ❑ 12V10 Tube Valve
- ❑ Other suspension Specify________

Socket Material
- ❑ Thermolyn® Soft (thermal plastic)
  - ❑ Caucasian ❑ White
- ❑ Laminated with Flexible Brim
- ❑ Rigid Lamination
- ❑ Other ________

Input Devices
- ❑ 13E200 Electrode Qty________
- ❑ 13E202 Suction Electrodes Qty________
- ❑ Switch/Linear Transducer type:________ to control________

Battery Technology
- ❑ 757B20 Lithium Energy Pk.–Lg
- ❑ 757B21 Lithium Energy Pk.–Sm
- ❑ 757B25 MyoEnergy Integral
- ❑ 757B13 Interchangeable for 4.8V Children's System

Charger Selection
- ❑ 757L20 Li-Ion Charger
- ❑ 757L25 MyoLoad Integral
- ❑ 757L13 4.8V Children's System

Component Selection

Hand Type:
- ❑ SensorHand™ Speed
- ❑ MyoHand VariPlus Speed
  - Size: ❑ 7 1/4 ❑ 7 3/4 ❑ 8 1/4
  - Program________ (see program chart)
- ❑ Greifer DMC VariPlus
  - Program________ (see program chart)
- ❑ Transcarpal Hand
  - Size: ❑ 7 1/4 ❑ 7 3/4 ❑ 8 1/4
  - ❑ Digital ❑ DMC
- ❑ Size 7 Hand
  - ❑ Digital ❑ DMC
- ❑ System 2000 Hand
  - Size: ❑ 5 ❑ 5 1/2 ❑ 6 ❑ 6 1/2
  - Program________ (see program chart)

Wrist Type:
- ❑ Quick Disconnect
  - ❑ Wrist Rotator (electric)
  - Program________ (see program chart)
- ❑ Wrist Disarticulation
- ❑ 8R1* Endo System for Transcarpal

Wrist Flexion:
- ❑ 10V38 MyoWrist Transcarpal
- ❑ 10V40 MyoWrist 2Act
- ❑ 10V51 MyoLino for Children's System

Elbow Type:
- ❑ 12K44 Ergo Arm (mechanical lock)
- ❑ 12K50 Ergo Arm (electric lock)
  - Program________ (see program chart)
- ❑ 12K100 Dynamic Arm
- ❑ 12K12 MovoLinoArm Friction (children)

Accessories:
- ❑ 8Y1 pincher for adult hands
- ❑ 4X74 car charger (for 757L20 charger)
- ❑ 9S278=PAA larger hook tips for Greifer
- ❑ 757T13 MyoSelect programming tool

Measurements Mark length reference point on mold.

Special Instructions ________

An additional 15% will be added to the cost if non-Otto Bock parts must be ordered by the Otto Bock Fabrication Center.

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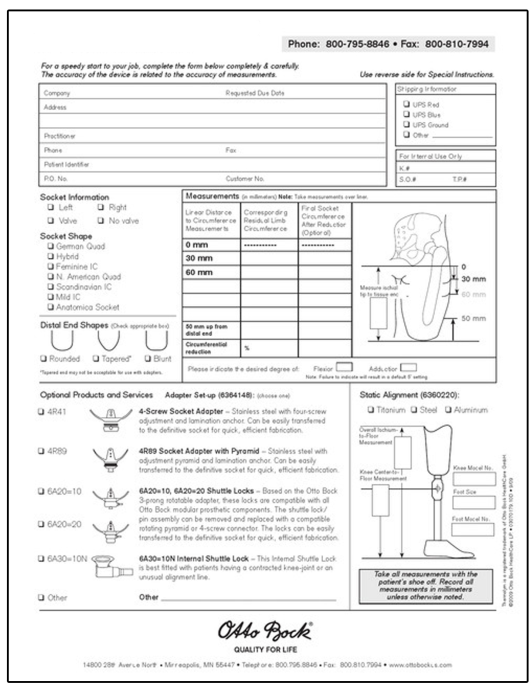

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Company	Requested Due Date
Address	
Practitioner	
Phone	Fax
Patient Identifier	
P.O. No.	Customer No.

Shipping Information
- ❑ UPS Red
- ❑ UPS Blue
- ❑ UPS Ground
- ❑ Other ________

For Internal Use Only

K.#

S.O.# T.P.#

Socket Information
- ❑ Left ❑ Right
- ❑ Valve ❑ No valve

Socket Shape
- ❑ German Quad
- ❑ Hybrid
- ❑ Feminine IC
- ❑ N. American Quad
- ❑ Scandinavian IC
- ❑ Mild IC
- ❑ Anatomica Socket

Distal End Shapes (Check appropriate box)
- ❑ Rounded ❑ Tapered* ❑ Blunt

*Tapered end may not be acceptable for use with adapters.

Measurements (in millimeters) **Note:** Take measurements over liner.

Linear Distance to Circumference Measurements	Corresponding Residual Limb Circumference	Final Socket Circumference After Reduction (Optional)
0 mm	-----------	-----------
30 mm		
60 mm		
50 mm up from distal end		
Circumferential reduction	%	

Please indicate the desired degree of: Flexion ☐ Adduction ☐

Note: Failure to indicate will result in a default 5° setting

Optional Products and Services **Adapter Set-up (6364148):** (choose one)

❑ 4R41 — **4-Screw Socket Adapter** – Stainless steel with four-screw adjustment and lamination anchor. Can be easily transferred to the definitive socket for quick, efficient fabrication.

❑ 4R89 — **4R89 Socket Adapter with Pyramid** – Stainless steel with adjustment pyramid and lamination anchor. Can be easily transferred to the definitive socket for quick, efficient fabrication.

❑ 6A20=10 / ❑ 6A20=20 — **6A20=10, 6A20=20 Shuttle Locks** – Based on the Otto Bock 3-prong rotatable adapter, these locks are compatible with all Otto Bock modular prosthetic components. The shuttle lock/pin assembly can be removed and replaced with a compatible rotating pyramid or 4-screw connector. The locks can be easily transferred to the definitive socket for quick, efficient fabrication.

❑ 6A30=10N — **6A30=10N Internal Shuttle Lock** – This Internal Shuttle Lock is best fitted with patients having a contracted knee-joint or an unusual alignment line.

❑ Other — Other ________

Static Alignment (6360220):
- ❑ Titanium ❑ Steel ❑ Aluminum

Take all measurements with the patient's shoe off. Record all measurements in millimeters unless otherwise noted.

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Figure 9: Prosthetic upper limb and prosthetic lower limb order (Ottobock, 2014)

Once measurements are obtained, "The prosthetics then makes a plaster cast of the stump. This is most commonly made of plaster of paris, because it dries fast and yields a detailed impression. From the plaster cast, a positive model—an exact duplicate—of the stump is created" (Artificial/ Prosthetic Limb. n.d.). After a plaster mold of the amputee's stump is made, then the vacuum-forming process is used to get a test socket. In this process, the plaster mold is placed in the vacuum-forming workspace. The air is pumped out, the heated plastic sheet surrounds the plaster mold, and the plastic sheet adheres to the plaster mold and gets into the desired shape. After cooling, the socket will be formed for patient's upper limb or lower limb, which can be used to prepare a new prosthetic limb.

The traditional methods are labor intensive and use measuring tapes to measure the limb stump. In addition to measuring the length of limb, the designer also has to measure the circumference of the limb in order to get molded plaster impressions gain data from the stump limb size and shape. Then a plaster mold is used as a replica of the limb. The traditional process is also time-consuming because of the trial-and-error method that even the most experienced prosthetics developers must use. The plaster mold needs considerable adjustment before a final prosthetic limb is available to the patient.

3.4.3 CAM/CAD Measurement Methods

The second measurement method is using CAM/CAD technology to measure the patient stump. "CAD/CAM (computer-aided design and computer-aided manufacturing) refers to computer software that is used to both design and manufacture products" (CAD/CAM, n.d.). The CAM/CAD system is composed of a digital scanning device, a computer, and a milling machine; this technology uses a digital scan device to scan a patient's body and then translates the scan to an editable 3D image and import that to the computer that contains all of the patient's measurements. This process is very accurate; "CAD-CAM templates are precise to within 1 mm" (CAD-CAM Modeling for Craniofacial Surgery. n.d.). Once the digital representation of the residual limb is obtained, software is used to add the modifications that transform the digital shape from an exact mold of the amputated limb, to the shape of a functioning prosthetic socket. Once the digital measurement data and patient's stump 3D model is complete, the 3D model is carved by a milling machine, and a prosthetic part fabricated over this model.

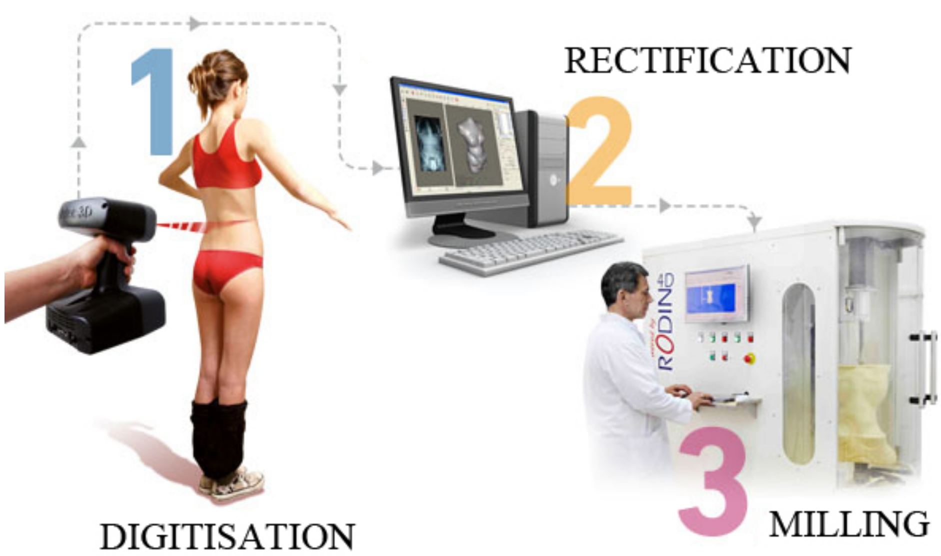


Figure 10: CAM/CAD Technology process

The carved model can be used in order to prepare to shape a new prosthetic. Compared with traditional measurement methods, the advantages of CAM/CAD are increased productivity and reduced overall production time. Data can be saved and edited, which makes it easier to modify the design and saves time. The process also allows for quick carving of models and fabrication of prosthetic sockets. Compared to all these advantages, the only disadvantage of CAD/CAM technique is high cost. "Cost may be an impediment to using these tools in the field. Significant investment in software and hardware is needed, which is not reimbursable."(Sanders, & Wynne, 2012). It is a part of an added expense for the technologies in the process of making the prosthesis, because the patient looks at scanning as a cost instead of a profit or way to save money. Also, the operator needs to be trained how to use the CAD/CAM system, which adds to costs.

3.4.4 Multi Cross Section Contour Methods

3.4.4.1 Background

After the illness or accident causes amputation, the patient ultimately needs to go through prosthetic limb installation in order to restore physical and mental health. During the installation, the key technique problem is the stump socket. The traditional method is using a measuring tape to measure the limb stump. In addition to measuring the length of limb, the designer also has to measure the circumference of the limb, but this method is not very accurate. Then a plaster mold used as a replica of the limb needs considerable adjustment to the plaster mold before a final prosthetic limb is available to the patient. But this method is soon-to-be-outdated, and it is time consuming and costly. In recent years, a new method, CT scanning, has been developed, but this method is expensive, and the patient's measurements are not easy to obtain accurately.

3.4.4.2 Overview

The objective of this study is to introduce and assess a new method for capturing and measuring limb stump at different amputation levels. This method will be used to design and develop a low cost prosthesis with 3D print technology. Because of the disadvantages of other methods discussed previously, in this section an adapted a method of MCSC will be discussed. The goal is to create a capture and measurement method that will be helpful in determining the optimal prosthetic fit. The MCSC method could be used to manufacture prosthetic limbs, so that the prosthetic limb can be uniquely matched to the patient's limb stump. In addition, limb stump measurement should require as short a time as possible to complete, with reduced equipment cost, so that patient can be measured inexpensively and relatively quickly. In this section, the new method improves on the prior technique, and provides a cost and time effective method to accurately measure the stump limb.

3.4.4.3 Specialized Tool Development

The method of MCSC requires a specialized tool to capture the limb stump. The method is as follows:

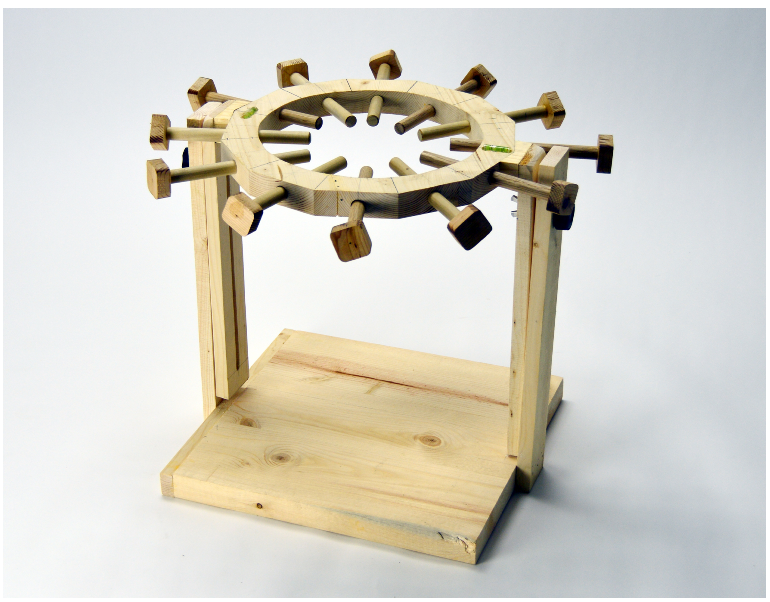


Figure 11: MCSC tool: measure and capture tool and the stand base.

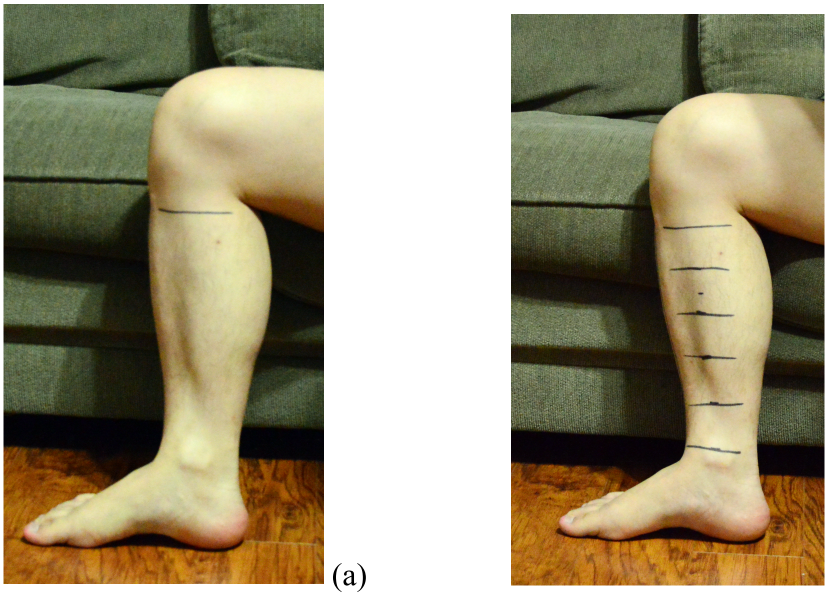
Figure 12: A) Measure and Capture tool B) The Stand Base

Shown in Figure 11 and 12a, the measurement and capture tool size is 16 inches wide, 14 inches long, and 17.5 inches high. It is made up of a polygon with 12 edges; each edge has 1 stick, 7.5 inches long, with a total of twelve sticks. The two arms of MCSC tool can moved up and moved down in order to measure and capture at different stump heights.

Shown in Figure 12b, the stand base is made up of the stand base and two support arms. Each support arm has one knob to fix the adjustable support arms.

3.4.4.4 Multi Cross Section Contour Methods

For the method of MCSC, the first step is preparatory work. The method is as follows: 1) the patient should be a state of relaxation with the MCSC tool ready. 2) Depending on the patient's amputation level, a starting point should be marked and the stump length measured (Figure 13a). 3) From the starting point, other new points should be marked with horizontal lines every two or three inches (Figure 13b).



(a) (b)

Figure 13: preparatory work

The second step is capturing the stump cross-section contours. The method is as follows: 1) Amputee must be hold firm, with the limb stump placed into the MCSC tool, with the capture tool and the first horizontal mark at same level, 2) As shown in Figure 14, twelve sticks are inserted into the drilled holes until each stick front end contacts the stump's skin, 3) As shown in Figure 15, all sticks are fixed at the drill holes to capture the stump shape.

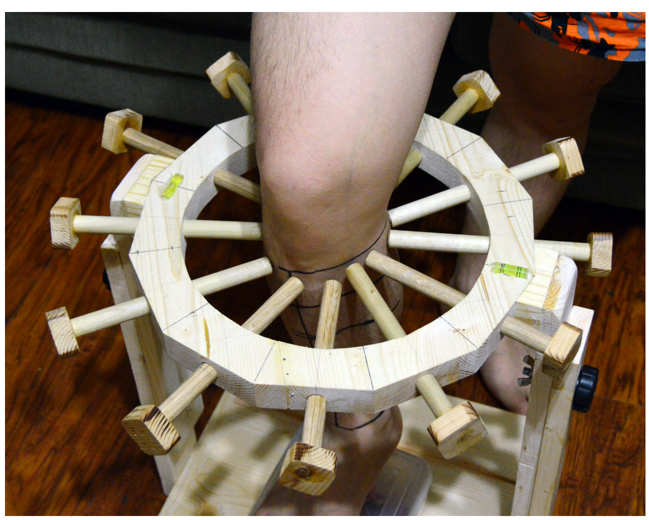


Figure 14: Twelve sticks contract with limb stump skin

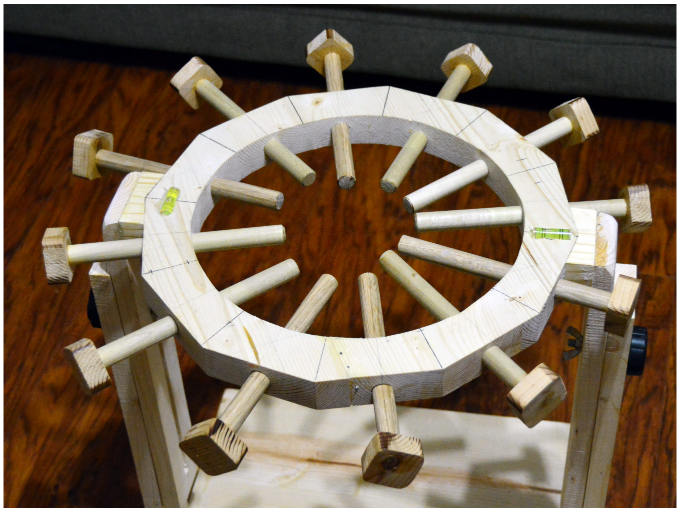


Figure 15: Capturing the stump cross-section contours

4) Shown in Figure 16, the limb stump is removed from of MCSC tool. Then a blank paper is placed under the captured stump contour, 5) Shown in Figure 17, all the points from inner sticks front ends are linked to get cross section contours, and the paper is marked number one, 6) After adjusting MCSC tool height even with the next horizontal line, other stump cross section contours are captured, 7) The same method is repeated for the next point and level until the end of stump, and each page is marked by number (see Figure 18).

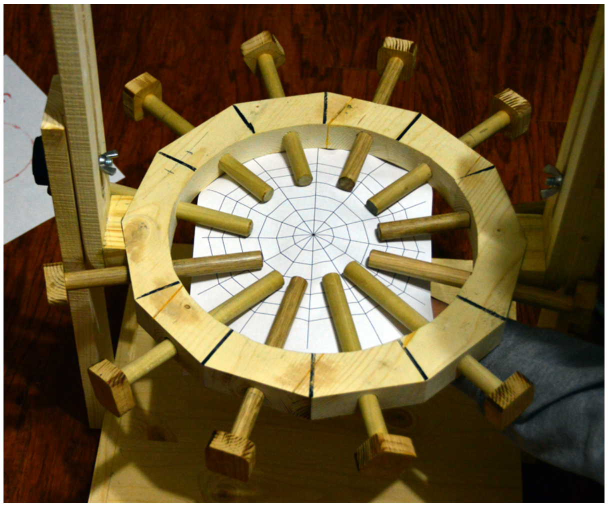


Figure 16: Capturing the contour

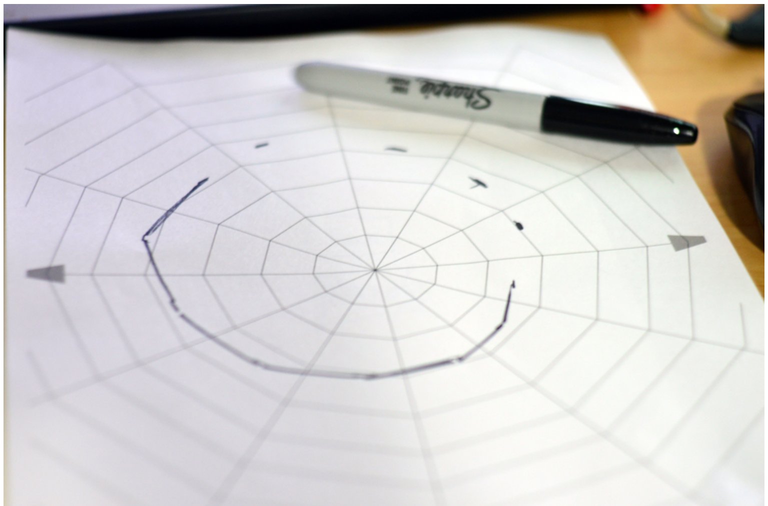


Figure 17: Link all captured dots

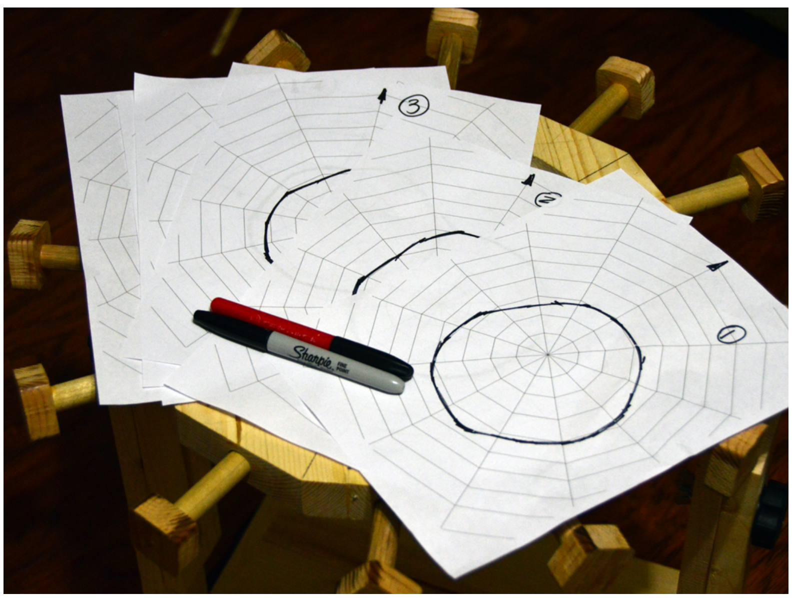


Figure 18: Obtain the contours

3.4.4.5 Capturing Limb Contour

The method of capturing limb contours is related to which patient stump limb is being measured. The limb contour is captured at two different photographing positions with at least two images. Based on these images, with the lower limb as the reference, the contour line is determined. This includes front side and right side contours, according to the reference image and contour line segment. The images are imported to 3D model building software, and finally the outer surface of the limb portion is determined.

For the method of "capturing limb contour," the first step is preparatory work. The method is as follows: 1) On the flat ground, mark a point as a center point, and draw a circle. Then from the center point, draw two straight lines A (horizontal) and line B (perpendicular). The length is four or five feet, and the angle is ninety degrees. 2) Cameras are placed at the fronts ends of lines A and line B.

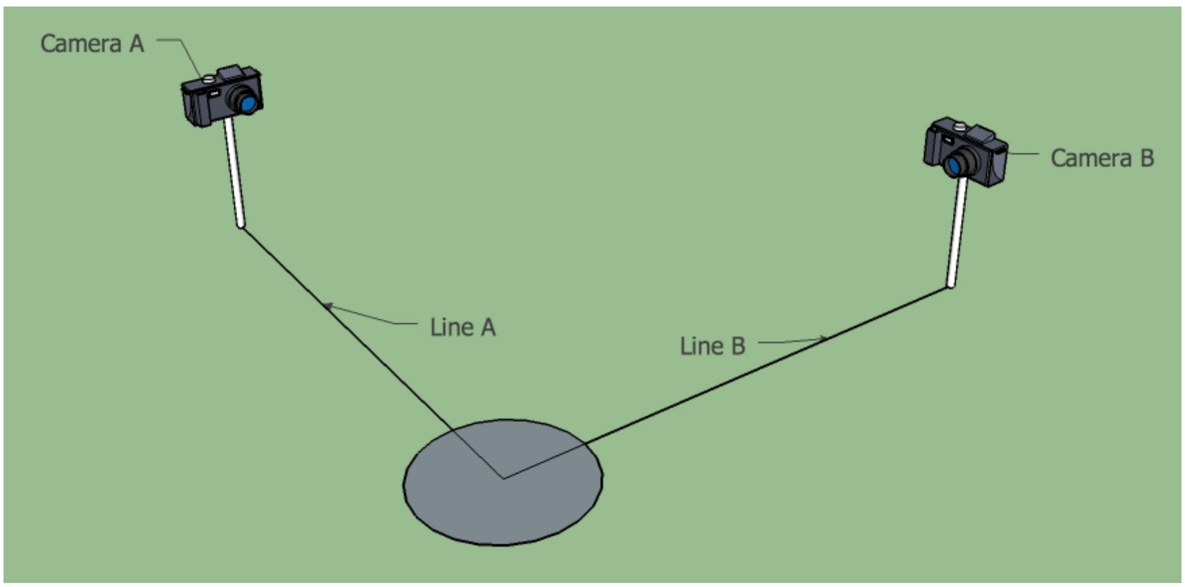


Figure 19: Preparatory work

The second step is capturing limb contours (see Figure 20 to 23). The method is as follows: 1) The patient stands on line B in the circle, and makes sure the lower limbs face camera A on the coronal plane, 2) Camera A's height is adjusted; the patient's limb is made sure to be in the range of capturing by looking through the viewfinder, and 3) When the patient stands in the appropriate place at least two captured images are taken. Based on these images, the front side of contour line is determined. 4) Adjust camera B's height; the patient's limb should be in range of capturing. 5) When the patient stands in the appropriate place at least two captured images are taken. Based on these images, the right side of the contour line is determined.

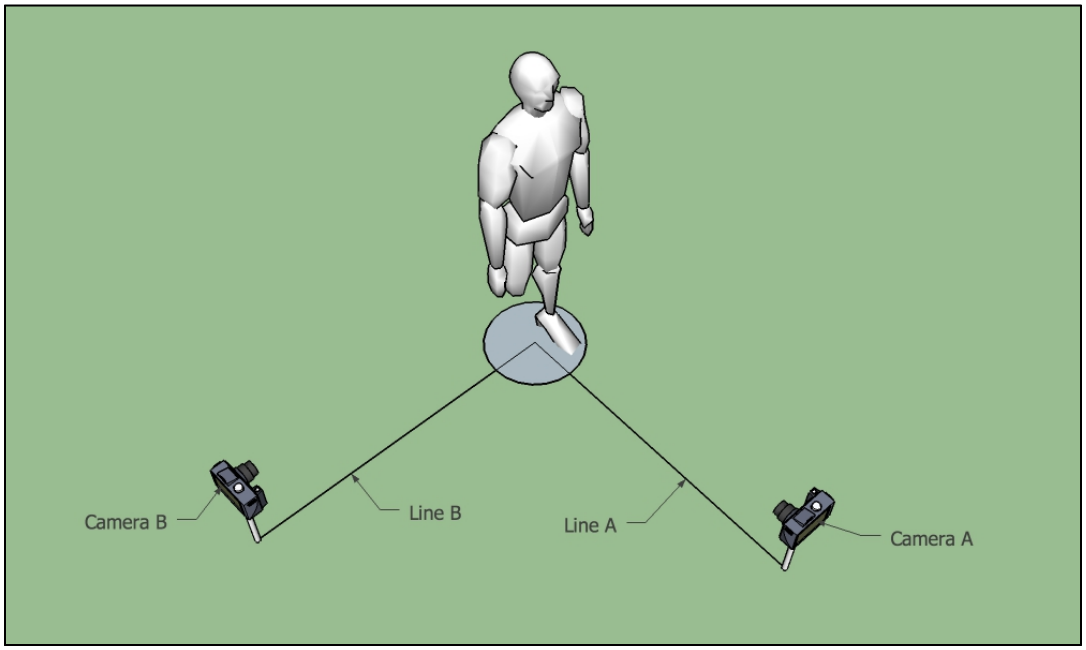


Figure 20: Capturing limb work (Top view)

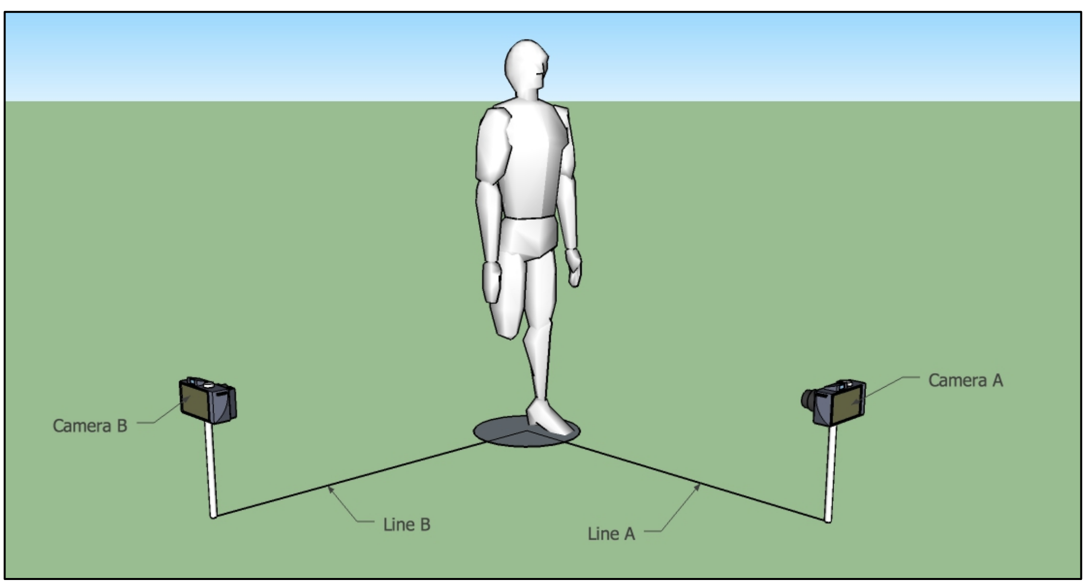


Figure 21: Capturing limb work (Front view)

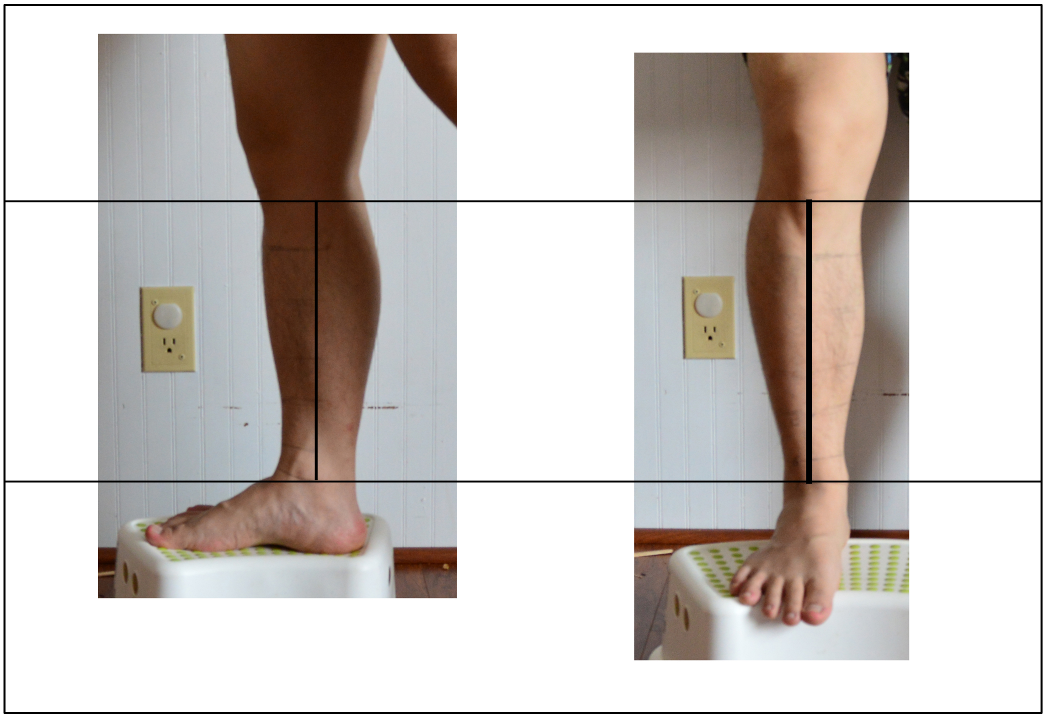


Figure 22: Captured limb contours

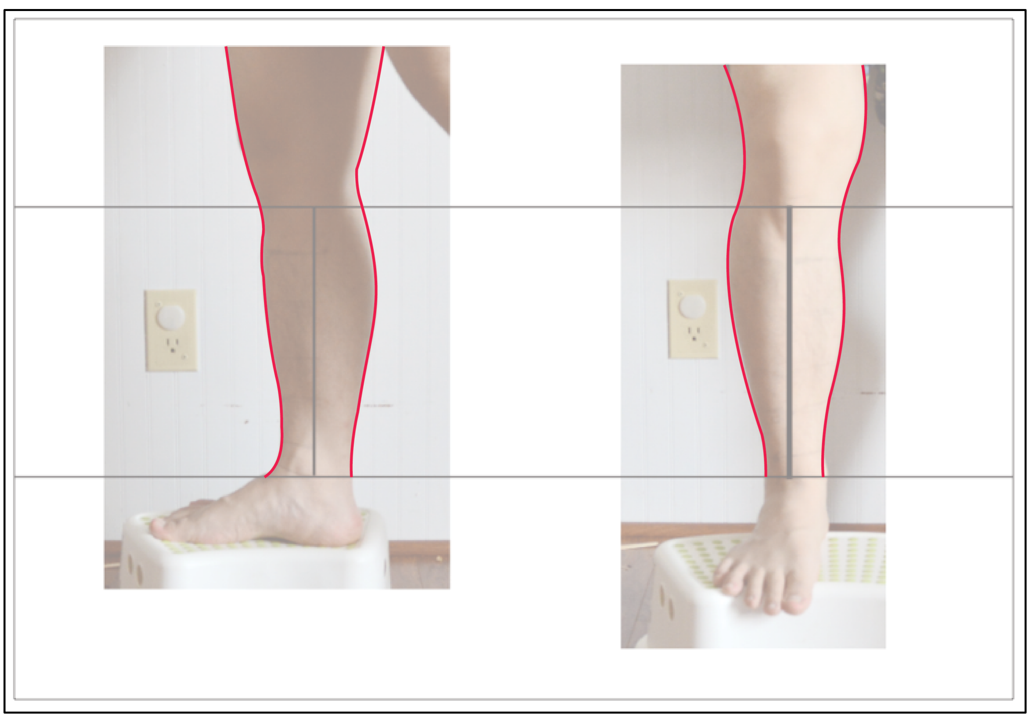


Figure 23: Captured contours

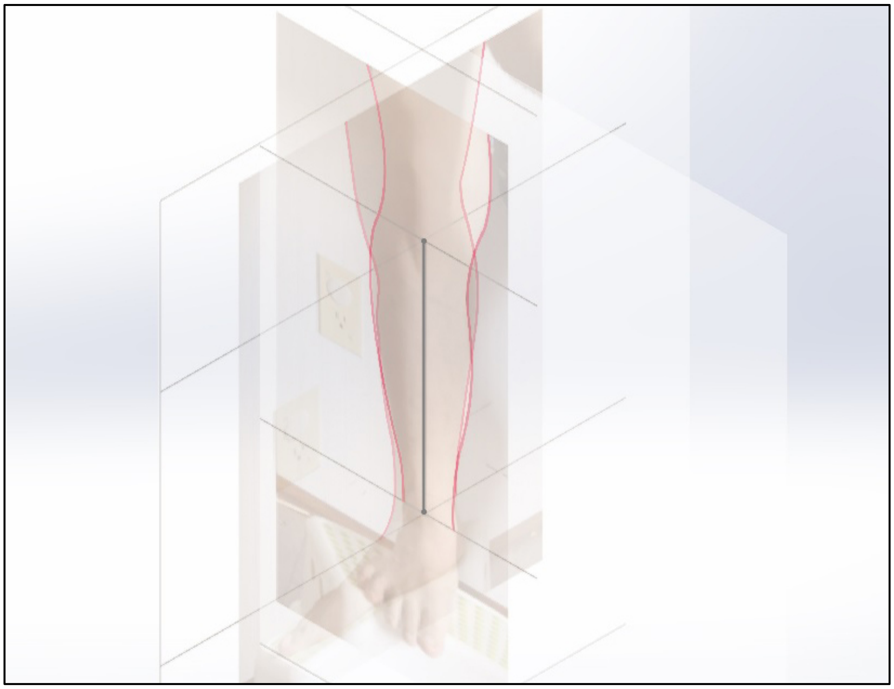


Figure 24: Importing to 3D building software.

After this work, data is gathered in order to get ready to build a low cost 3D model.

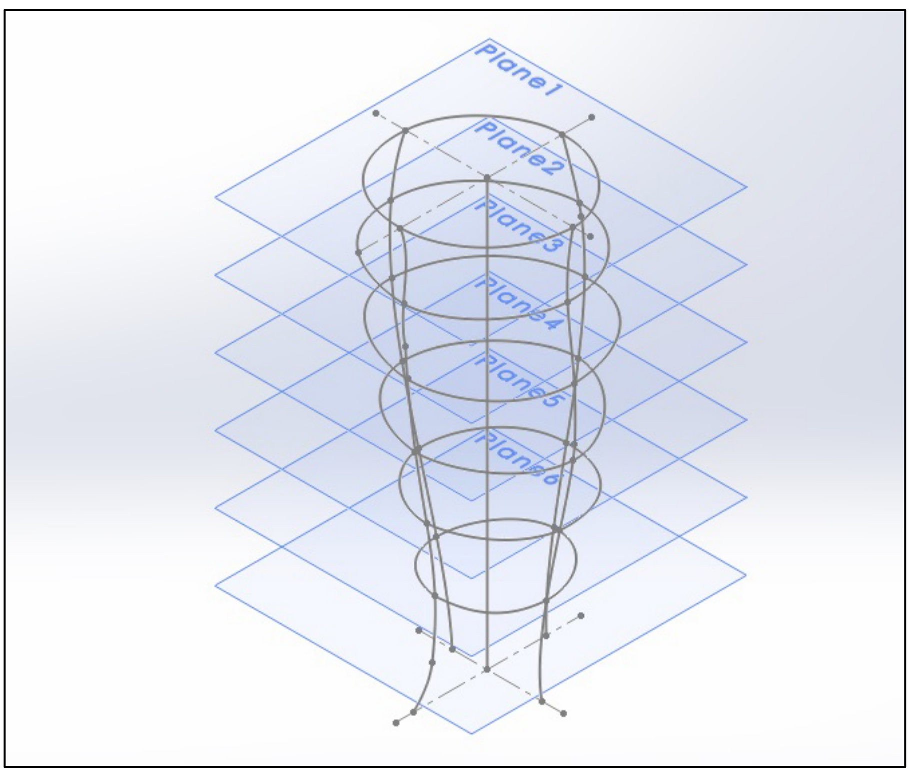


Figure 25 – MCSC in 3D building software

The MCSC method offers a possible approach, which is a combination method between CAD and traditional methods. This methods presents a low-cost, reusable, and time-effective way to carry out accurate stump limb measurement.

3.5 Approaches for Developing Prosthetic Limbs

3.5.1 Overview

In this section, an approach for developing prosthetic limbs with 3D Printing technology analysis will be discussed, including 3D printers analysis. This will be done by comparing industrial-grade 3D printers and desktop 3D printers in order to find the low cost solution. 3D printing material cost analysis will be conducted by comparing mainstream filaments in the market in order to provide for the most cost-effective

3.5.2 3D Printer Analysis

3.5.2.1 3D Printers

The prosthetic traditional manufacturing process is particularly lengthy, as it includes several steps: impression, plaster mold, mold fabrication, curing and extrinsic finishing. This process consumes considerable time, energy, and materials. 3D printing technology provides an effective way to help speed up the prosthesis fabrication process and reduce its cost. The primary material used in prosthesis, either Acrylonitrile butadiene styrene (ABS) or Polylactic acid (PLA), minimizes time and cost more.

There are two types of 3D printers used in the market: the industrial-grade 3D printer, and desktop 3D printer. The industrial-grade 3D printer is expensive, and the cost of the final product is still high, which has hindered the wide use of 3D printing for the fabrication of body parts. For example, according to Boboltz (2013), “Silicone ears and noses might cost $4,000 each, constructed by taking an impression of the injured area, sculpting the body part out of wax as it should appear, and then casting that shape in silicone.”

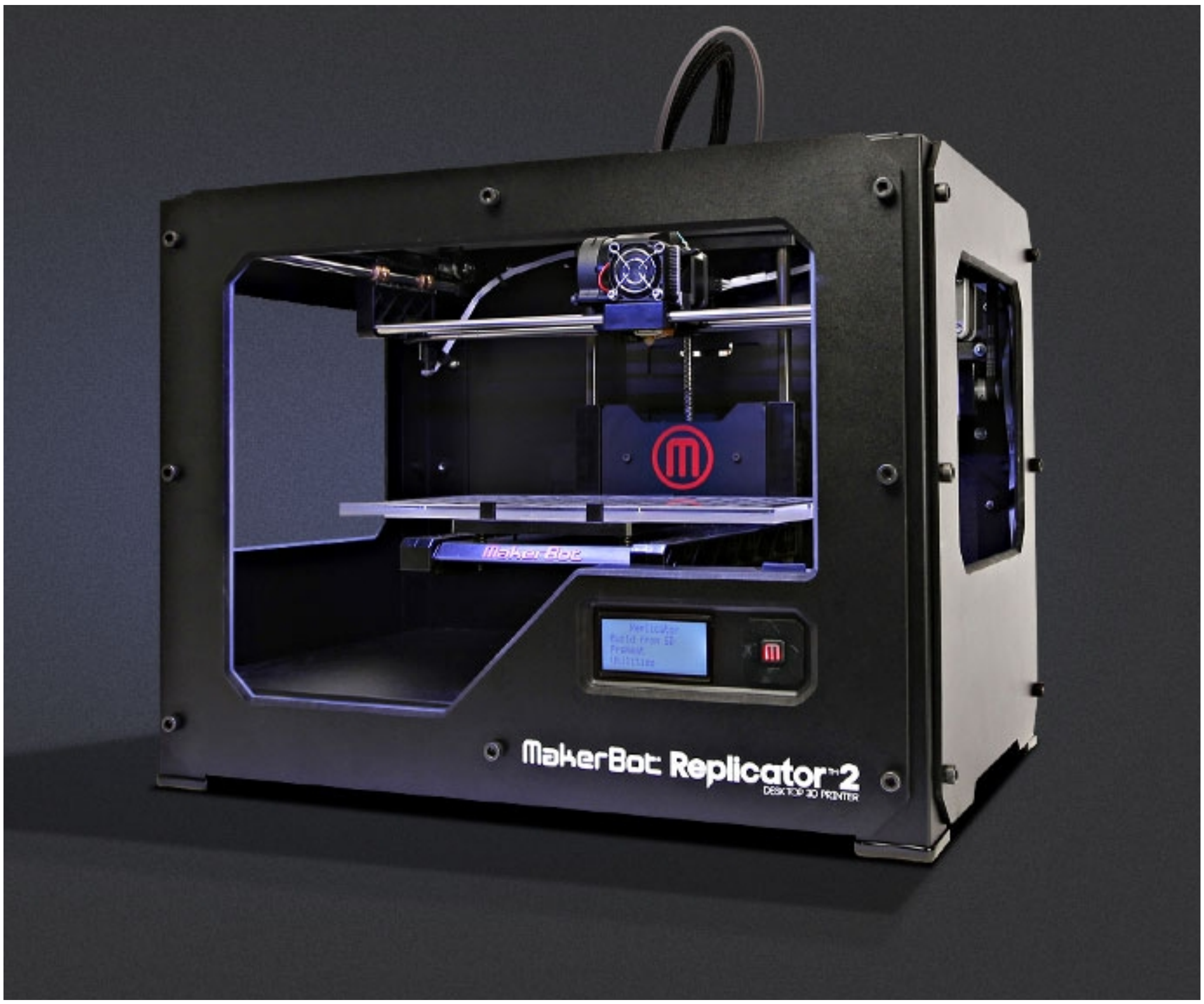


Figure 26: MakerBot Rplicator 2X 3D printer

The desktop 3D printer is very popular. The advantages of desktop 3D printer include low cost and as a result, many people can afford a 3D printer. Use of the desktop 3D printer also means extremely low to zero toxicity and waste. Therefore, the 3D desktop printer is used to directly manufacture prosthetic limbs for this study. In the current market, the MarkerBot 3D printer is widely used and is considered a de facto standard. The MakerBot Replicator 2X provides reliability and cost efficiency that meets each patient's unique needs. Also the MakerBot Replicator 2X is the simplest, most efficient and affordable machine that prints professional quality models.

3.5.2.2 Cost Analysis

The biggest advantage of this approach for development of 3D prosthetic limb is its low cost. Thus the model making cost could be negligible, because it is printed by the 3D printer. In addition, the materials used in prosthetic limb printing are inexpensive and easily available.

3D printing giant MakerBot has launched a range of plastic filament material that can be used in the MakerBot Replicator 2X. The two dominant plastics are Polylactic Acid (PLA) and Acrylonitrile Butadiene Styrene (ABS). Material performance and cost are two key factors that can directly impact customers' satisfaction with designer's solution, so these need to be considered. In this section, shown in the comparison charts below, based on MakerBot's website, the cost of the two filaments are discussed.

PLA filament

	Small	Large	Comment
Weight	0.22 kg (0.5lb)	0.90 kg (2.00 lb.)	
Color / Cost optional	12 True colors / $18	$48	
	15 Specialty colors / #25	$65	Grows in the dark Small: $50 Large: $130
	7 limited colors / $18	$48	Photo chromatic Small: $25, Large: $65

Table 2: PLA filament compare chart

ABS filament

		Comment
Weight	1 kg (2.20lb)	
Color / Cost optional	10 True colors / $48	Natural $43

Table 3: ABS filament compare chart

After comparing PLA and ABS filament above, accurate costs based on 3D print industry standard can be determined. The standard unit is cubic inch, so the cost in dollar per cubic inch needs to be calculated. According to the 3D printing filament standard, the following of reference parameters are listed below:

PLA

Density: 1.25 g/cm$^{\wedge 3}$

Volume: 0.80 cm$^{\wedge 3}$/g or 800 cm$^{\wedge 3}$/kg

1.75 mm filament length for 1 kg spool: ~ 330 meters / ~ 1080 feet

3.00 mm filament length for 1 kg spool: ~ 110 meters / ~ 360 feet

ABS

Density: 1.04 g/cm$^{\wedge 3}$

Volume: 0.96 cm$^{\wedge}$3/g or 960 cm$^{\wedge 3}$/kg

1.75 mm filament length for 1 kg spool: ~ 400 meters / ~ 1310 feet

3.00 mm filament length for 1 kg spool: ~ 130 meters / ~ 430 feet

At roughly $48/kg, ABS is less expensive at roughly $0.05/cm$^{\wedge 3}$, while PLA is $0.06/cm$^{\wedge 3}$. Also the ABS filament has good quality and durability. For these reasons, ABS filaments were chosen for this study.

3.6 Summary of Chapter

Chapter 3 introduces the process patients might go through before they receive their prosthetic limbs. This process includes patient consultation, measurement methods and cost analysis. In the consultation process, it is assumed that there are some parameters decided responsibly by prosthetic professionals: what parameters' values can be changed or cannot be changed. A study of the evaluation of developing a low cost prosthetic limb identifies key points in design. This chapter also breaks down the previous measurements and cost methods, an important part of the thesis. It is important to know the cost of measurement devices, cost of product manufacturing and the cost of materials because these factors influencing patients' choice of the prosthetics. A list of performance criteria (see Table 4) was developed to define the characteristics that need to be evident in the design of the low cost prosthetics.

		PARAMETERS	CRITERIA
HUMAN FUNCTION	SOCIAL ECONOMIC	Price	$150 or less
		Gender	Any
		Age range	18-65
		Activity level	Basic upper limb / lower limb function
		Amputation	Varies (Depend on amputation level)
		Location of use	Indoor/Outdoor
	CULTURE AESTHETIC	Style	Custom, the product must aesthetically appeal to user
		Color for product	Custom, the product must aesthetically appeal to user
		Color of Filament	Custom, the product must aesthetically appeal to user
	PRACTICAL PHYSICAL	Weight	10 lbs. or less
		Size	Varies (Custom, Depend on patient's amputation level)
		Easy of use	Product must be easy to operation, it enable user more functionality and provide better mobility.

		PARAMETERS	CRITERIA
TECHNICAL FUNCTION	DIRECT TECH.	Material for upper limb	ABS Filaments
		Material for lower limb	ABS Filaments
	INDIRECT TECHN.	Environment interaction	All material must work well with indoor/outdoor elements
		User Interaction	Product must be easy to use and provide better mobility

		PARAMETERS	CRITERIA
PRODUCTION FUNCTION	PLANNING	Distribution	Prosthetic store shipping, clinics and medical supply stores
		Marketing	Medical supply stores and catalog or website.
	MANUFACTURING	Custom or Prefabricated	Custom
		Method of manufacture	3D printing

Table 4 – Performance criteria

Chapter 4

Application of The Developed Approach

4.1 Overview

This chapter will focus on the design and development of low-cost prosthetic limbs with 3D printing technology, the decisions made in each step will result in the best outcome to product an effective low-cost prosthetic limb. Sketches, branding, renderings and prototypes will be used to come up with a final solution. Each step is given an explanation and in most cases will be illustrated with either a drawing or photograph.

4.2 Brainstorming

"The most common reason for amputation is a loss of blood supply to the affected limb (critical ischemia), which accounts for 70% of lower limb amputations. Trauma is the most common reason for upper limb amputation, which accounts for 57%" (Amputation Details, Causes, Symptoms, Treatment - Patient Memoirs. n.d.). For this reason, I chose the lower stump limb in order to focus on the development of low-cost 3D printing technology for the purpose of this thesis. After defining the specific group of users, with the intention of creating a unique way to recreate their lost limbs, and also showcase their individuality and style. I began brainstorming to create ways to achieve and broaden potential.

As outlined in the previous chapter, several criteria should be considered and kept in mind, so sketching some ideas during brainstorming and producing prosthetic product is to be achieved step by step, including patient parameters and prosthetic aesthetics, 3D printing direct tech and user interaction, product manufacturing and planning.

4.3 Design Brief

Since the goals of the low-cost prosthetic limb have been outlined, the development of the prosthetic limb can begin. The development begins with five preliminary sketches. The sketches explore the different options in terms of form and function. Simplifying components is one of the goals of this study. The purpose of this project is to develop a low cost limb prosthetic: the ideal prosthetic limb must have simplified parts, lightweight, flexible, and easily adaptable to the user to permit easy movement. It should also be strong enough to support the body's weight. Prosthetic limbs basically need to be functional, personalized, stable to a great degree, and also the patient accepting the new technology on their bodies. In this case, the prosthetic will help disabled people to gain more confidence and easier lives.

In addition, the prosthetic must be affordable and available. 3D printing has brought about a change in how prosthetic limbs are made and customized. Once designed, prosthetics can be personalized even further with the use of graphics and patterns so that it aesthetically appeals to the user. A good prosthesis must be sturdy and durable, a key concern for environment resistance. Simplified parts could be help the prosthetic limb to be quickly assembled which will reduce the manufacturing cost.

4.4 Concepts

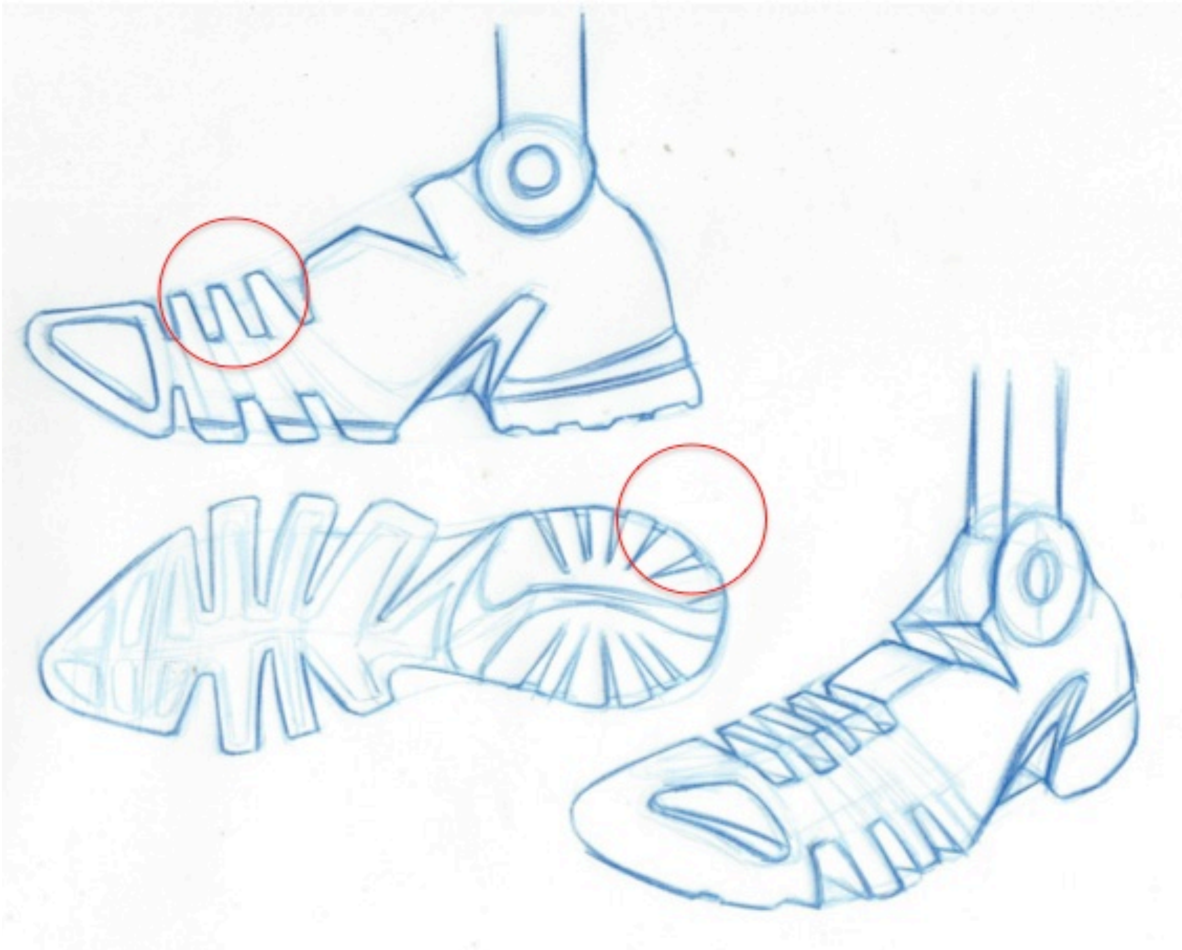


Figure 27: Concept 1

In concept 1, shown in Figure 27, the product has a flexible foot sole, and the flex grooves into the outsole, allowing the device to bend and be parallel to the ground while the user walks. This product offers flexibility and cushioning for comfort while walking. The joint swings back and forth to allow for a more realistic gait.

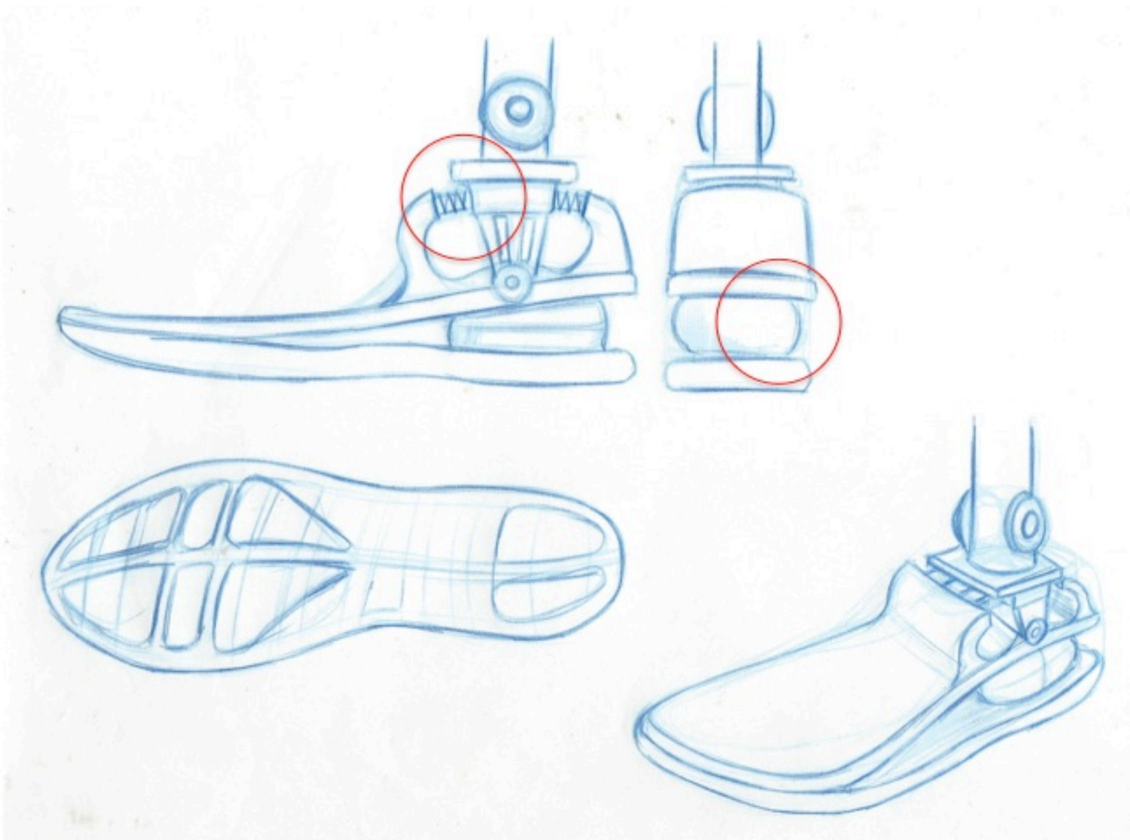


Figure 28: Concept 2

In concept 2, shown in Figure 28, the main structures of foot are made of two plates. The bottom plate is designed in the shape of shoe soles, and the foot sole relates to a full rubber anti-skidding sole with mold pressed patterns. There is a half elliptically shaped part in the end of the top plate, which allows the ankle joint to swing forward and backward across the springs, which allows for a more realistic gait.

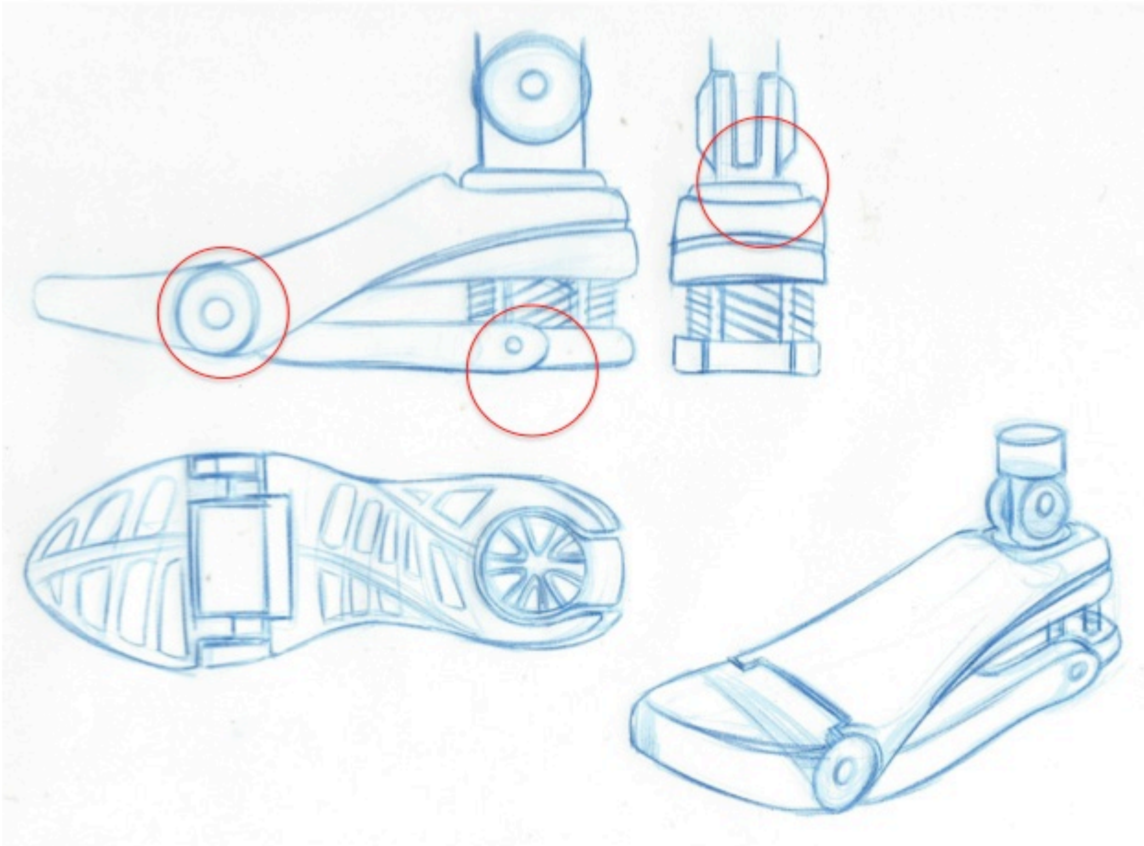


Figure 29: Concept 3

In concept 3, shown in Figure 29, there are three main types of joints in the prosthetic foot: the toe joint, end of heel joint and ankle joint. The toe joint and end of heel joint are flexible, allowing the device to bend and be parallel to the ground while the user walks. The end of the heel helps cushion steps when the end of the heel lands on the ground. This product offers flexibility and delivers cushioning for comfort when walking. The foot sole relates to a full rubber anti-skidding sole with mold pressed patterns.

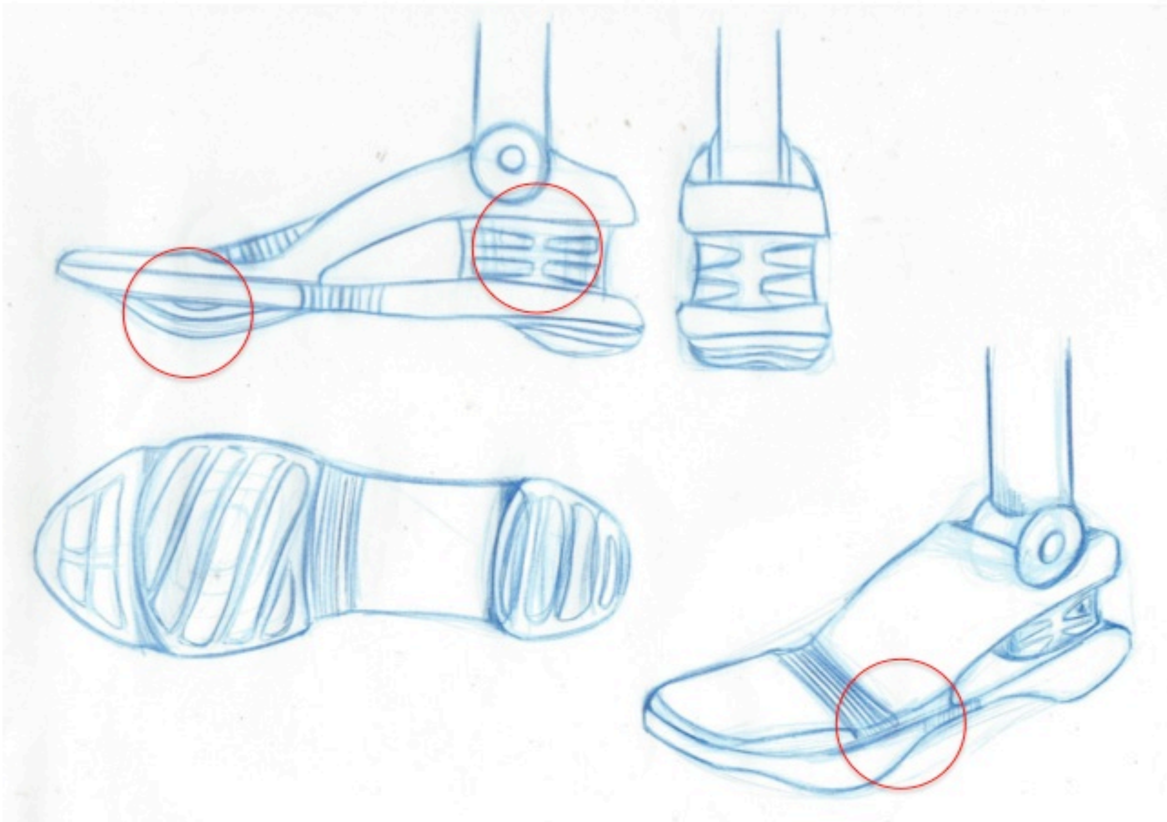


Figure 30: Concept 4

Concept 4, shown in Figure 30, has a spin spot in the front and back ends, located under the anti-split sole; the spin spots help increase control and balance. The perforated Achilles part allows for ventilation and breathability, and offers strength and elasticity on the footplate. The lower case supports weight.

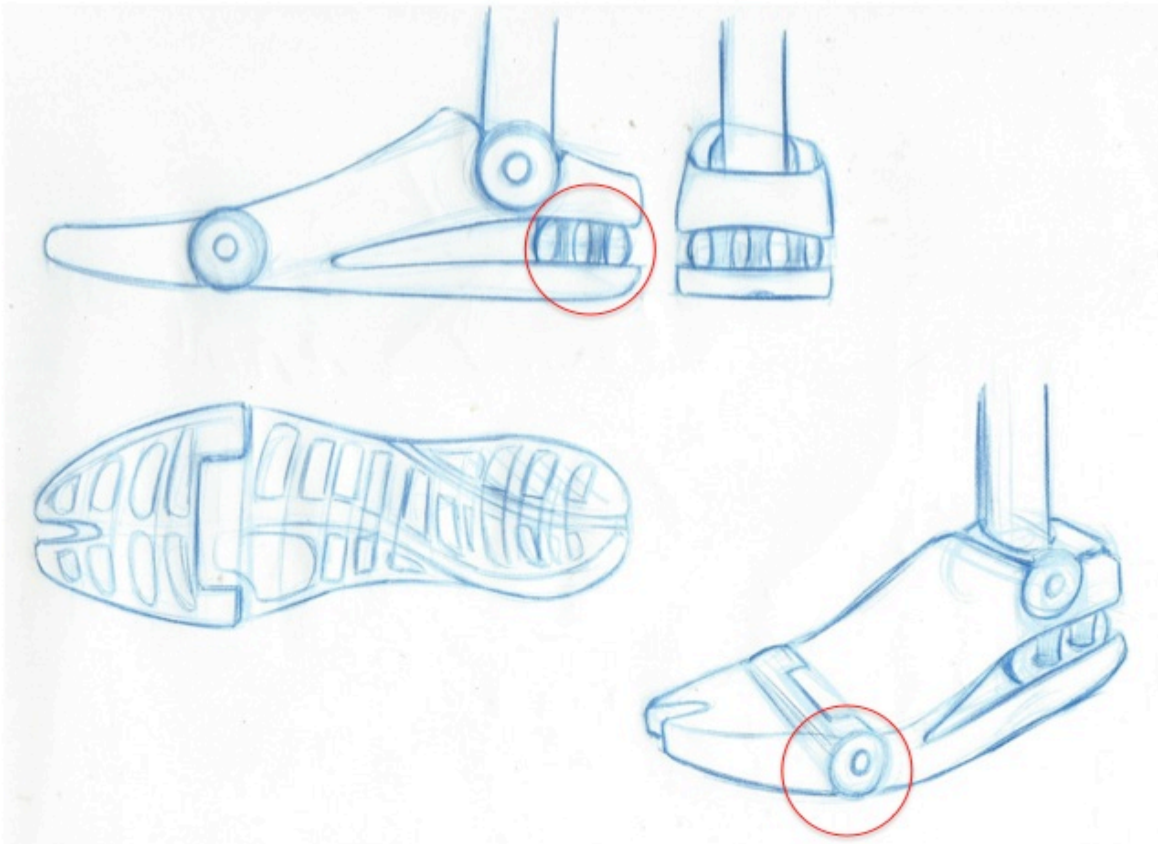


Figure 31: Concept 5

In concept 5, shown in Figure 31, the toe-plate moves with the motion of the gait cycle, bending and returning to its original position. The full volume design of the foot is functional, ergonomic, and durable; the ankle allows pivoting, flexing, and rotation.

4.5 Branding

4.5.1 Product Name

Essentially, brands should be easy to remember, which can greatly enhance memorability among consumers. In order to create a unique brand, one should consider three elements: brief and forceful to create strong associations, easy to pronounce and read, and unique and new.

The brand name itself should build a unique position, so the lower limb prosthetic brand name develops a unique position in the field of assistive technology, such as walking aids and assistive devices, prosthetic limbs products, etc. The initial idea was to use combination of letters, or acronyms: PSNC (Previous Strength and New Competence), NF (New Force) or NS (New Strength). Later I found a term "Neo" from "Neo-plasma", which comes from new plasma and new person to become a new tissue. And the term of Neo, which means new "neonate", and a new or revived form of, is a key point of 3D printed prosthetic limbs for amputees, who will be more likely to accept new generation of prosthetic limbs. I use the term "strength" because the user relies on their own efforts overcome all the difficulties. The term of strength refers to physical strength that someone has to lift or move things, and a supply of physical power that you have for doing things that need physical effort. From these key points a product name was finally established. The name “Neo-Strength” became the brand.

4.5.2 Logo Design

Once the brand name phase was complete, then the logo design phase is entered. The brand name "Neo-Strength" will use combination of letters for logo design. The logo should be the most effective, impressionable, concise, intuitive and clear, then give a clear explanation of product features. This would all bring strength and courage to the user. Logo design concepts are shown in Figure 32. The final design is shown in Figure 33 and 34.

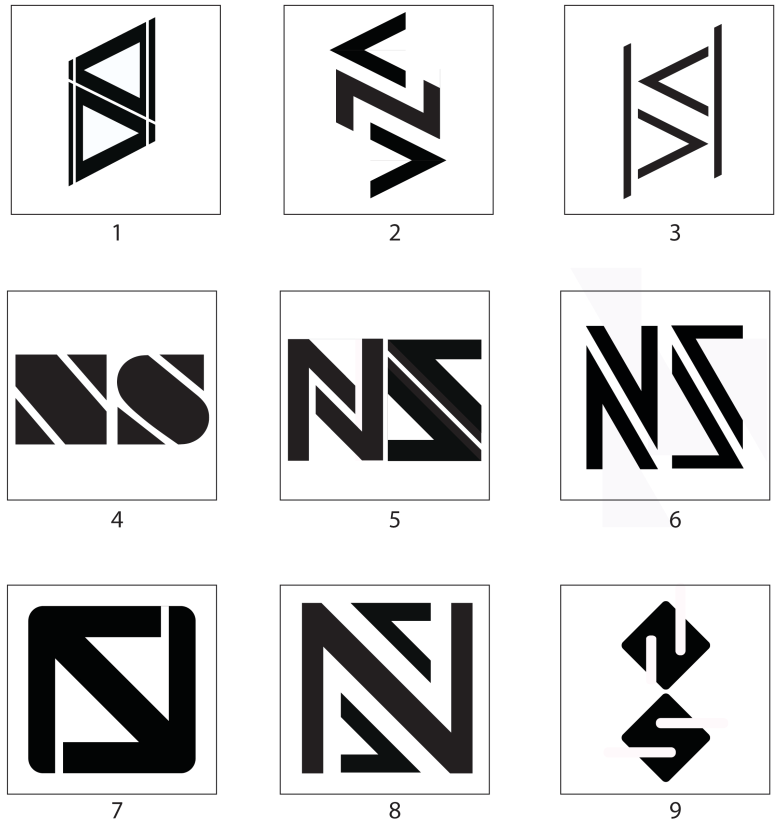


Figure 32: From Sketching and Conceptualizing. During this phase, I develop the logo design concepts around the brief and research.

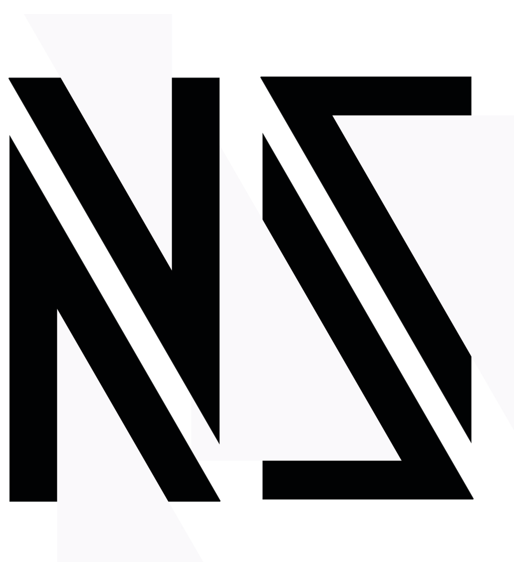


Figure 33: Final Logo: Concept

Figure 34: Image effect of final logo design

4.6 Fabricating the Neo-Strength

4.6.1 Overview

This section illustrates the process of building the Neo-Strength prosthetic for the lower limb. The fabrication of the lower leg prosthetic will be conducted in 3D molding software SolidWorks and 3D printer Makerbot Replicator 2X. The fabrication of the lower leg prosthetic will be different due to difference certain variables such as the 3D print material instability. The final outcome will be a final model of the design solution proposed in Chapter 4.

4.6.2 Measurement

This step of the process is to measure and capture the patient's lower leg stump, and produce the 3D print file of the prosthetic limb; this step will use "multi cross-section contours" methods and "capture contours" methods. These methods will be conducted in the same manner as the methods described in Chapter Three.

Figure 35 illustrates the full process of using the "MCSC" tool. The "MCSC" tool works by placing the patient's stump multiple times into the "MCSC" tool, and uses twelve sticks whose front ends contact with the stump skin until capturing the stump contour. A contour is produced by measuring until the end of the stump, producing multiple layers of contours. The "capture limb contour" method works by ascertaining the limb contour at two different photographing positions through least two captured images. Based on these images, and with the lower limb as the reference, the contour line is determined, including the front side and right side contours. The reference image and contour line segments are imported to 3D model building software, and finally the outer surface of the limb portion is determined. This process is reviewed in Figures 35 and 36.

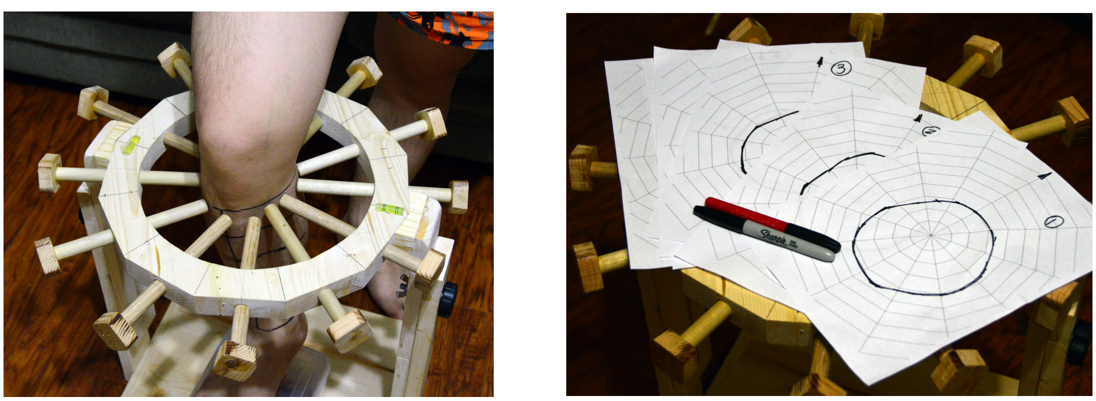


Figure 35 - process of Multi Cross Section Contours Method and Multi layers of contours

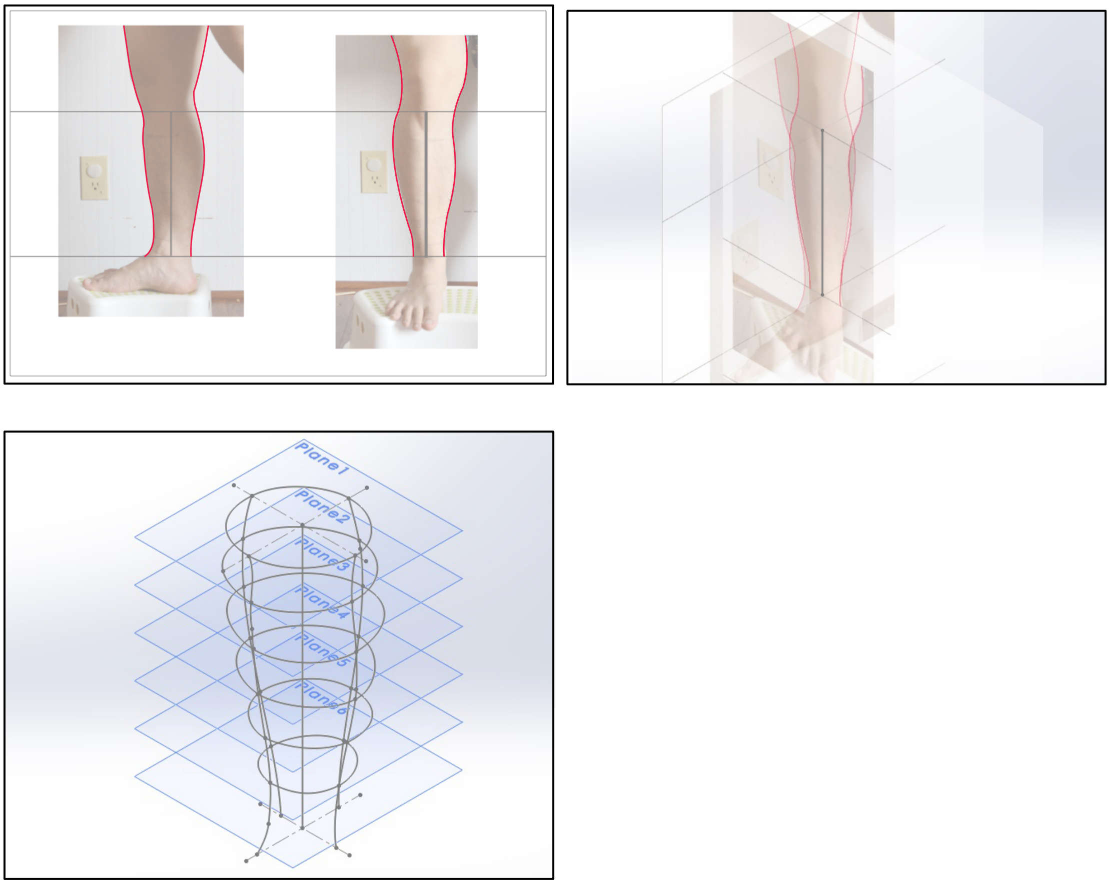


Figure 36 - Capture process of limb contour method: different photographing positions captured images, imported to the SolidWorks, build 3D model.

4.6.3 Fabricating 3D Prosthetic Lower Leg Model

The next step is to fabricate the 3D prosthetic lower leg model in SolidWorks before 3D printing. It will take time to build models but this is an important step because it will affect prosthetic lower leg installation on the patient's stump. The prosthetic lower leg model is divided into three sections: socket, lower leg support and foot.

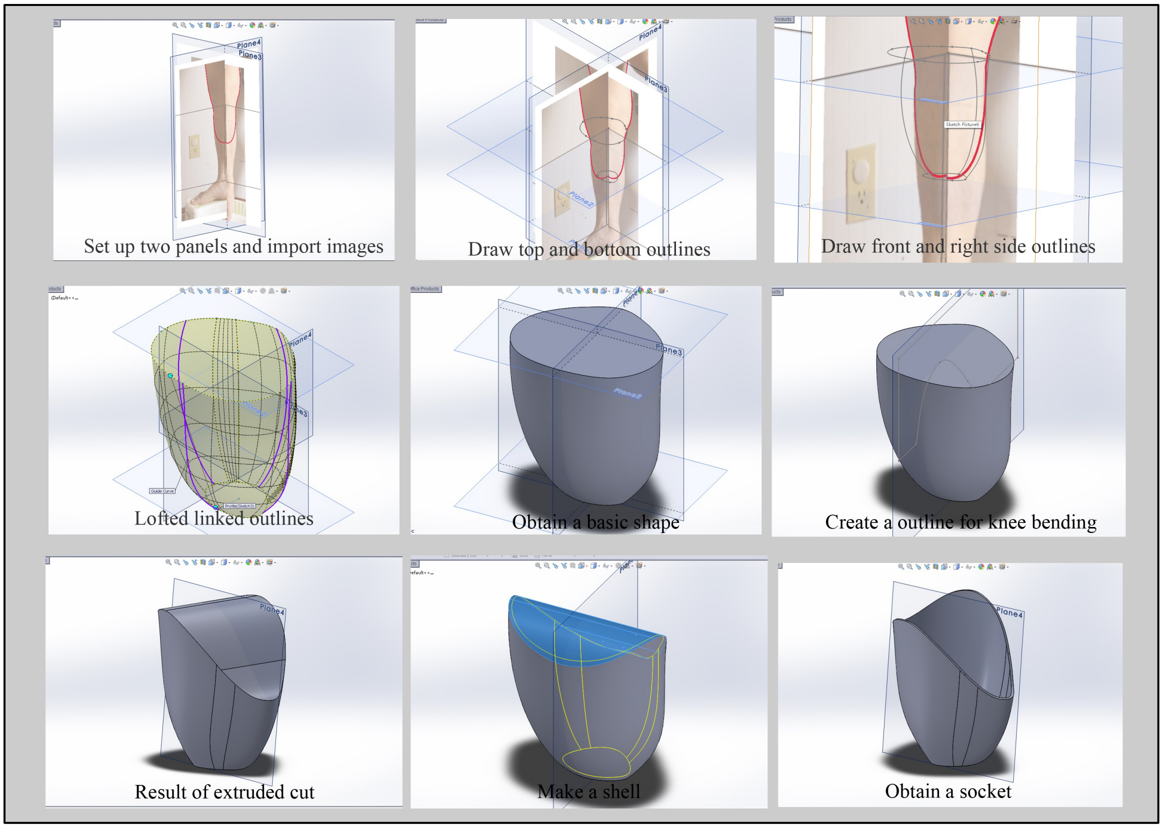


Figure 37 – Building prosthetic leg socket

The first component is the socket. In SolidWorks, four panels are set up as front and right, top and bottom panels, with the front and right panels' height the same as the stump's length. Then the captured images which correspond to each side panels are imported. Consistent size and position should be ensured. Outlines of the stump on each panels are drawn using 'spline,' and are aligned. In these conditions, the base shape is completed. Then an outline is created to extrude. The Shape should be cut so that this portion can be used for knee bending. Last is to make a shell of a socket in order to place the amputee's stump into the socket. Figure 36 is a visual representation of the aforementioned process. The socket will be used for the one of components for the low-cost prosthetic limb.

Figure 38 - Building prosthetic lower leg support

The second component is the lower leg support; the same methods as before are used to set up two panels, and then draw four outlines based on captured contours in SolidWorks. Secondly, multiple equidistant layers are set up in order to create a lower leg shape similar to the patient's other limb. In this process, outlines and contours must be aligned, then lofted on the base shape. Thirdly, a base under the lower leg shape is create to be used for prosthetic foot connection. Fourthly, the shape is turned into a shell. It will be used for setting up the "ribs" of the prosthetic structures inside the shell. Fifthly, superfluous parts at the ribs are eliminated. Then using the lofted cut method a base for the socket is created, and a logo on the lower leg support is added. The last method is aligning the model shape with captured images. Figure 37 is a visual representation of the aforementioned process. The lower leg support will be used for a custom design, so the user can express him or herself.

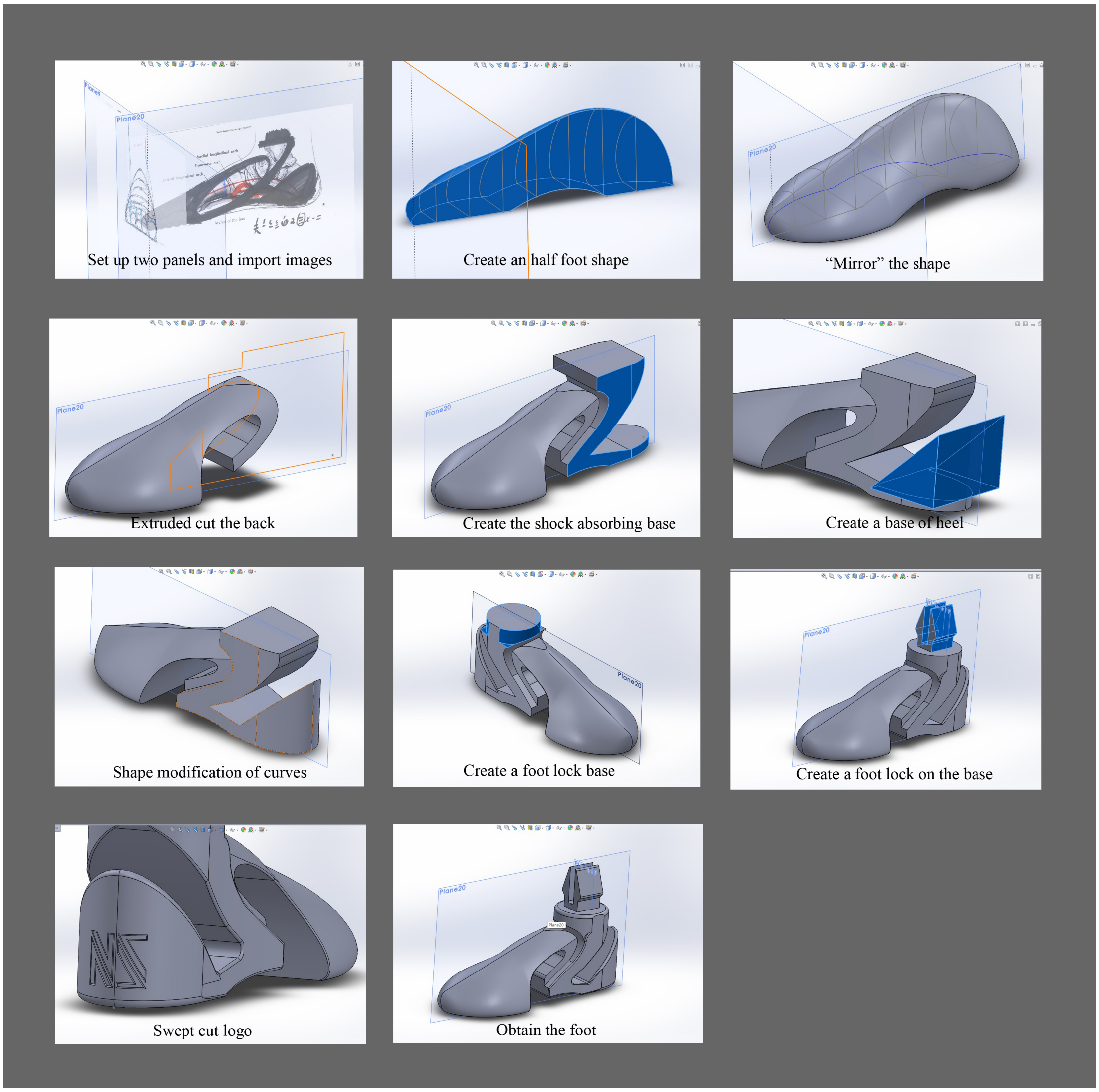


Figure 39 - Building the foot

The third component is the foot. Using the same methods to set up two panels in the beginning, captured images are imported and basic outlines of a human foot are drawn to create an basic foot shape. Secondly, the back of foot is extruded and cut in order to create a flexible base that helps cushion steps when the end of the heel lands on the ground. On the top of the base, there needs to be a foot lock that will be used to connect with lower leg support. Figure 39 is a visual representation of the aforementioned process.

4.6.4 MakerBot Desktop

MakerBot Desktop is a straightforward and user-friendly, yet powerful and full-featured program that enables control of a MakerBot Replicator 2X. The program allows one to easily move, rotate and scale 3D models. It is a powerful algorithm that slices the digital file into very thin layers to prepare it for 3D printing.

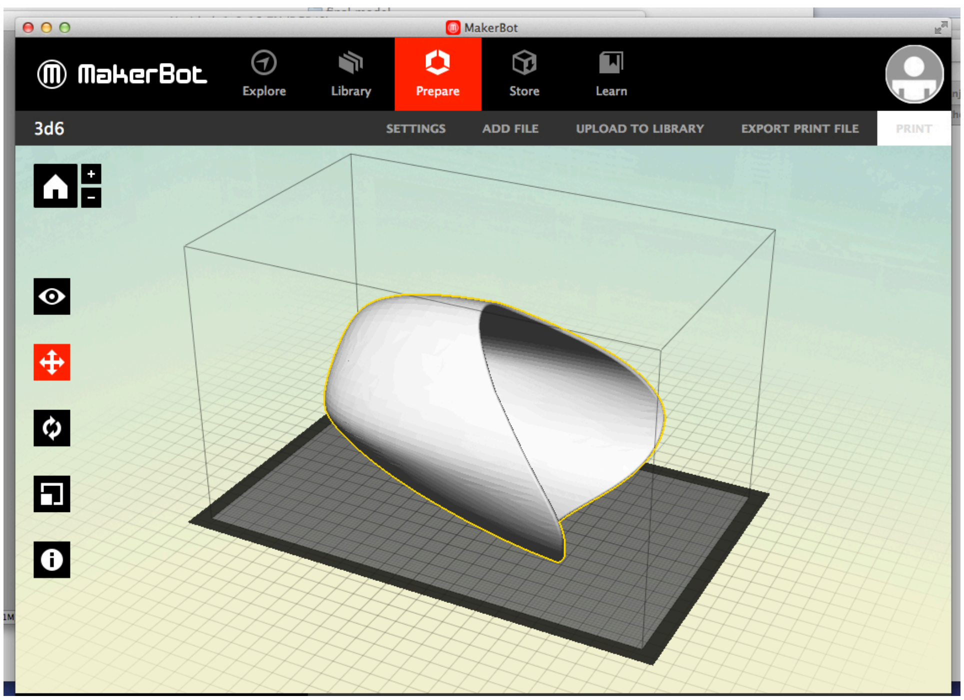


Figure 40 – Prosthetic limb socket in MakerBot Desktop software

Launching the MakerBot Desktop on Windows or Mac reveals a full-screen representation of the printer's build area. At the top of the screen are Add, Make, and Save buttons. Add allows import of a 3D file in STL format.

4.6.5 Slicing

Once the 3D model is designed and imported to the MakerBot Desktop, the first thing to occur is that the MakerBot slicing engine cuts the 3D model into thin horizontal layers, turning a 3D model into a toolpath for MakerBot Replicator 2X. Slicing allows MakerBot Desk to calibrate printer settings for extrusion speed (rotations/minute), head speed and temperature. In addition, Makerbot Desk allows wall thickness and fill patterns to be defined.

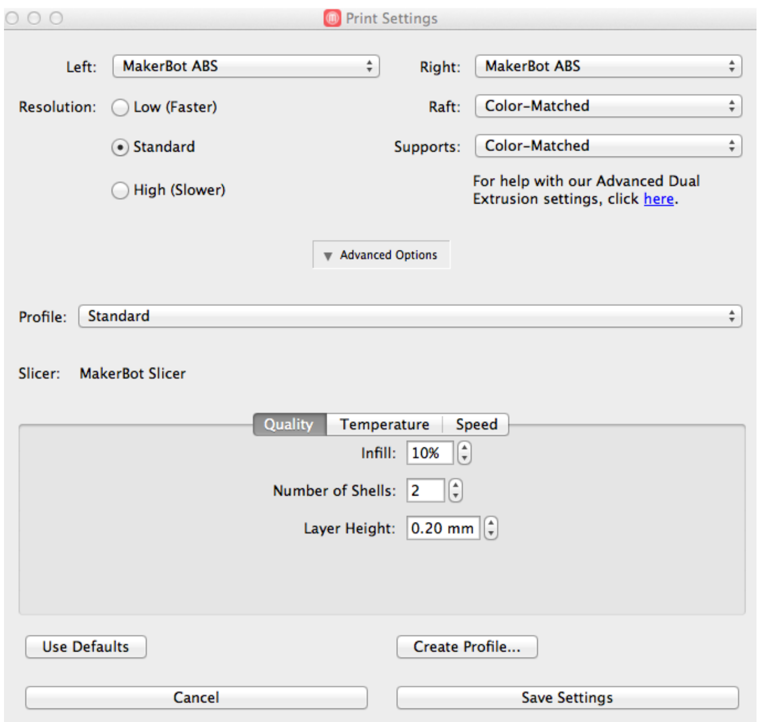


Figure 41 – MakerBot Desk Printing Settings

4.6.6 Structure

There are only three repeating infill patterns that can be used in a 3D printer: square, equilateral triangle and hexagon. At different densities, each pattern has a tradeoff between weight, strength, print time, and decorative properties.

The MakerBot Desktop is set to use hexagonal infill as default; it could be as simple as an arbitrary choice. Due to the mechanical properties of the material and printing method, which save print time, and materials, it's more cost effective to choose the setting that reduces the fabrication time for printing models. Due to the mechanical properties of the material and printing method, the hexagon is optimal for both strength and economy.

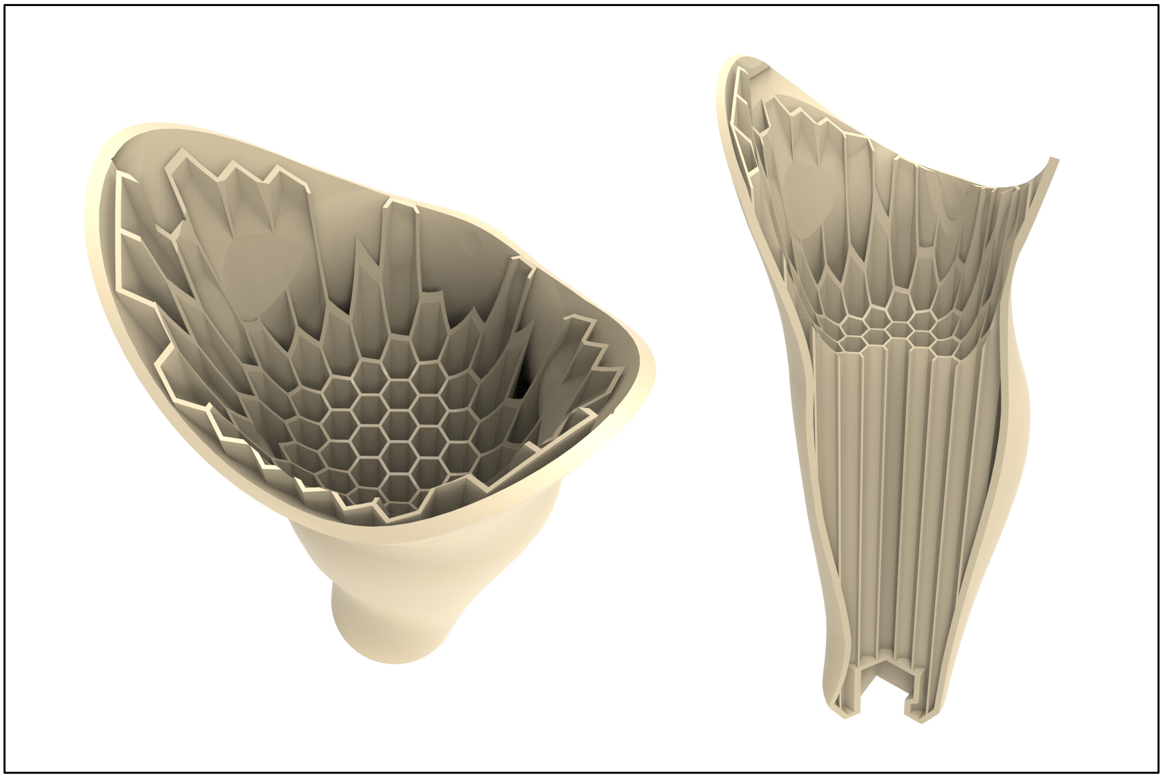


Figure 42 - Neo-Strength Lower leg support structure

4.6.7 Printing

Once the print setting is launched, the design parts will be printed in the heated platform. Considering the prosthetic leg is full size at 24.6 L X 15.2 W X 15.5 H CM (9.7 X 6.0 X 6.1 IN), but the MakerBot Replicator 2X print range is limited, the prosthetic leg must be divided into parts. The maximum dimension of the printer is 8 inches, so I divided prosthetic leg into three parts and the foot into two parts, which fit in the 3D printer print range. During printing the printing process and part quality must be checked to prevent ABS filament from cracking. After printing, the printed part must be tested and the print quality checked again. If nothing requires a change, then the printed part is confirmed for the finalized design.

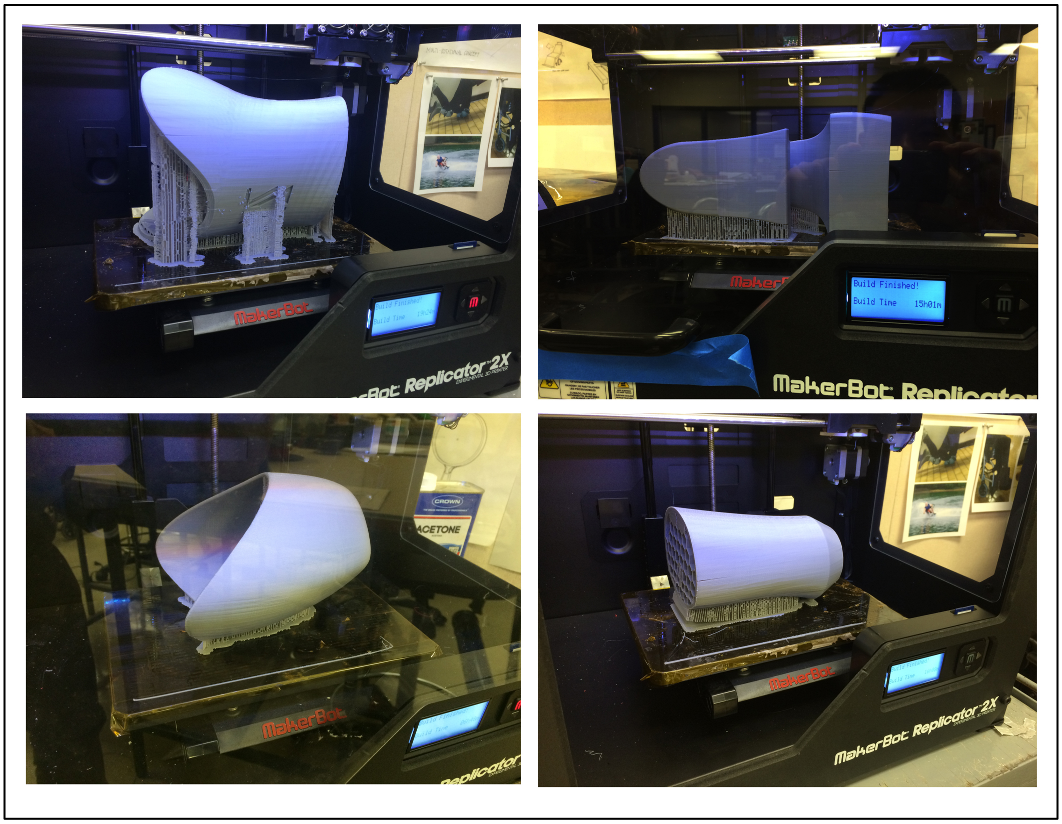


Figure 43 – 3D printed Prosthetic limb parts with ABS filament

4.6.8 Control Drawing

Once the design for the product was finalized, I began determining this product's its overall dimensions. The final design will be modeled in SolidWorks, As well as showing size and dimension, the following control drawings (Figure 44 to 57) include exploded views to show how the final product would be assembled, while still appealing to amputees.

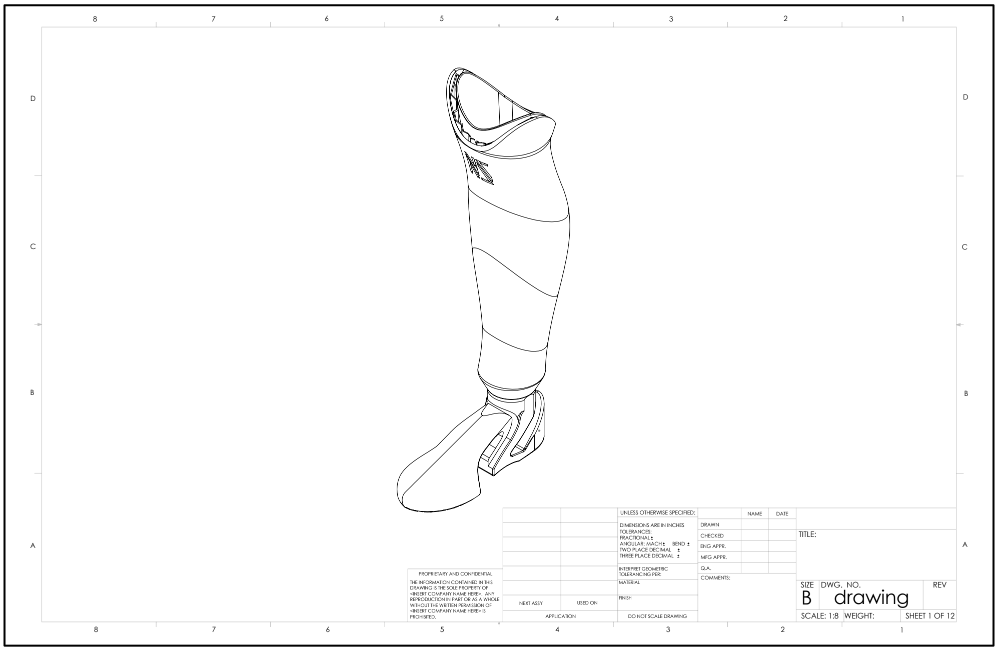


Figure 44 – Neo-Strength Combination

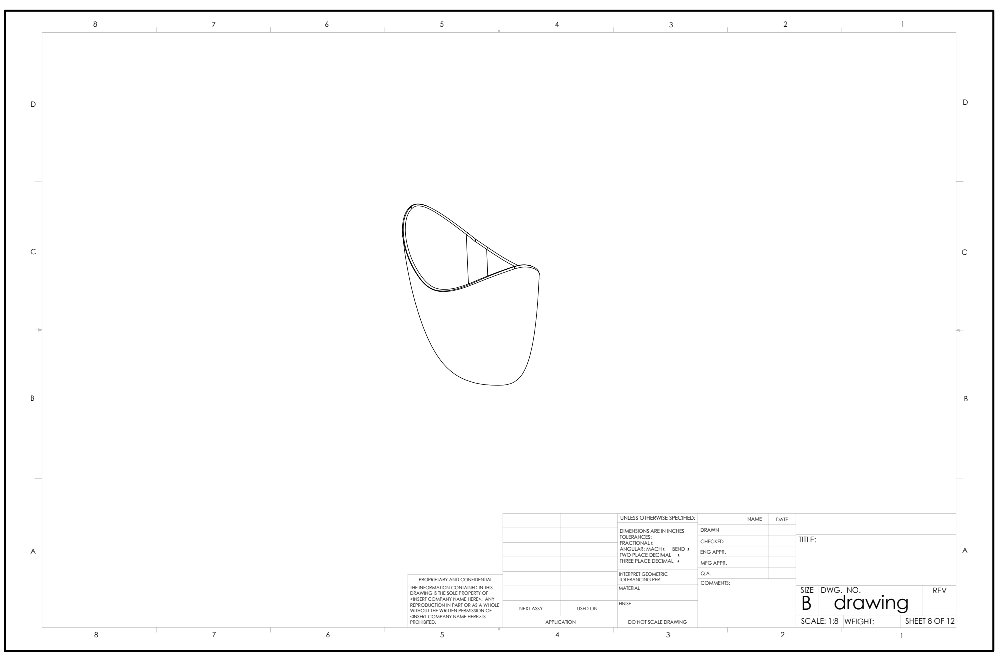


Figure 45 - Neo-Strength Socket

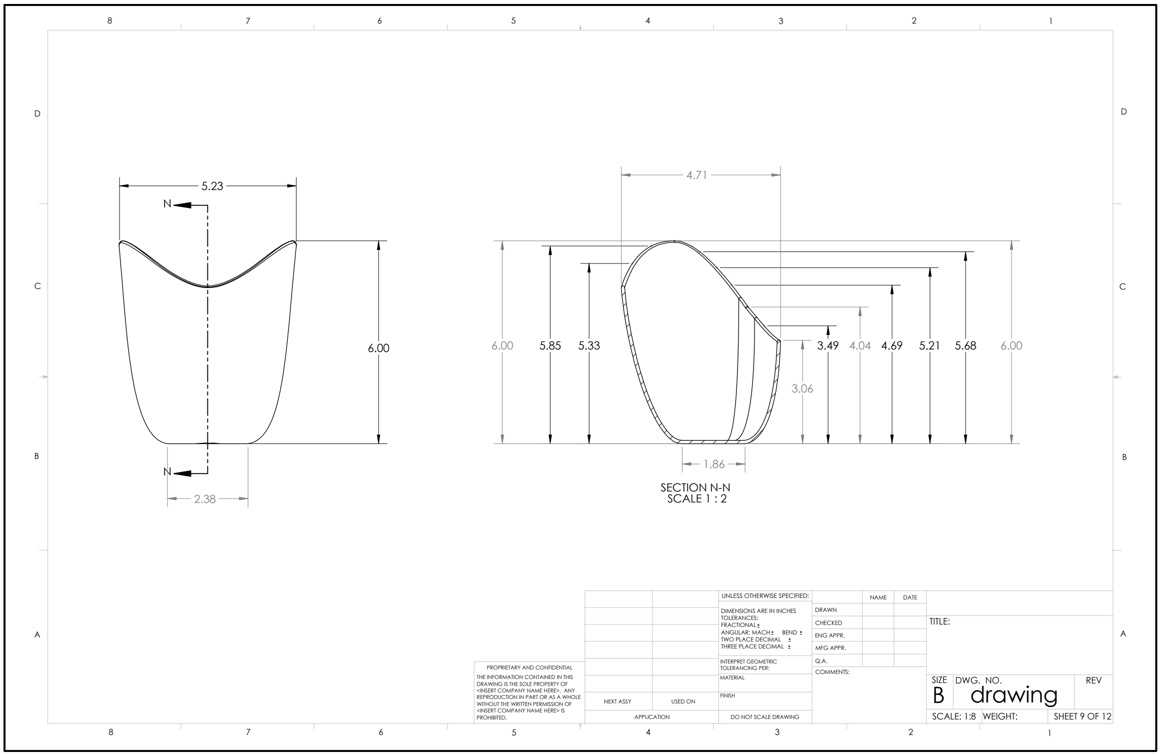


Figure 46 - Neo-Strength Socket Front and Side View

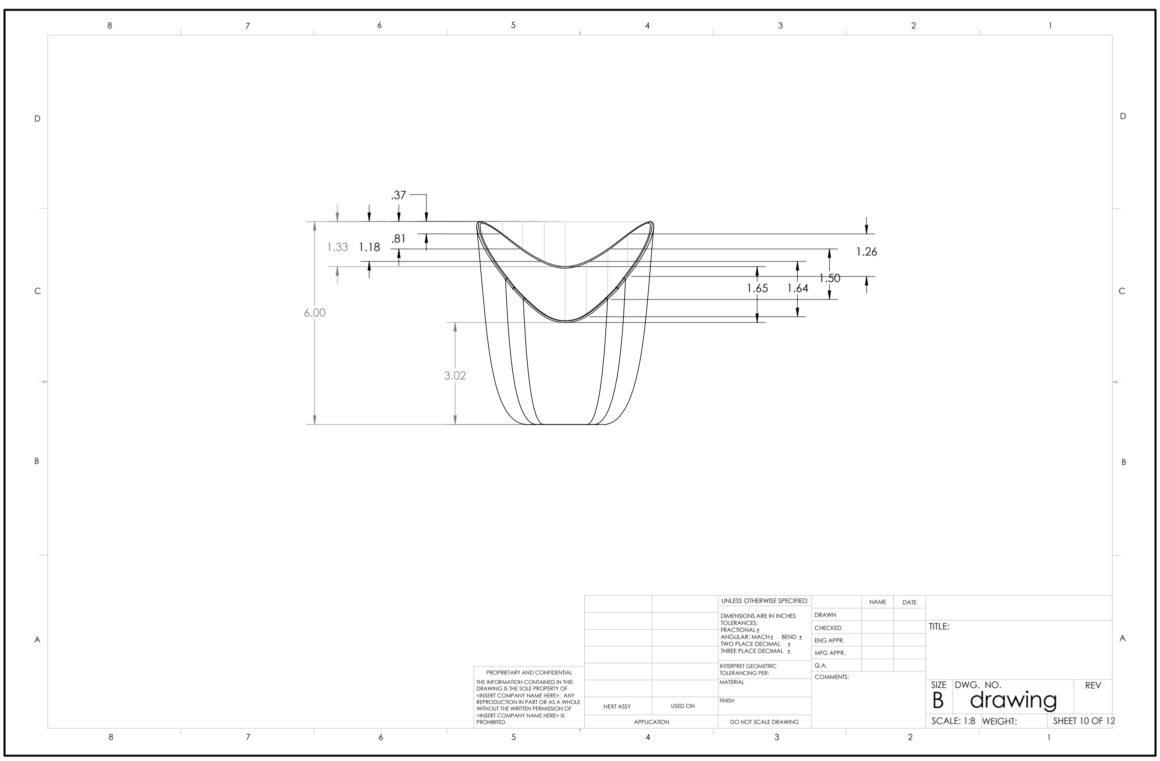


Figure 47 - Neo-Strength Socket back View

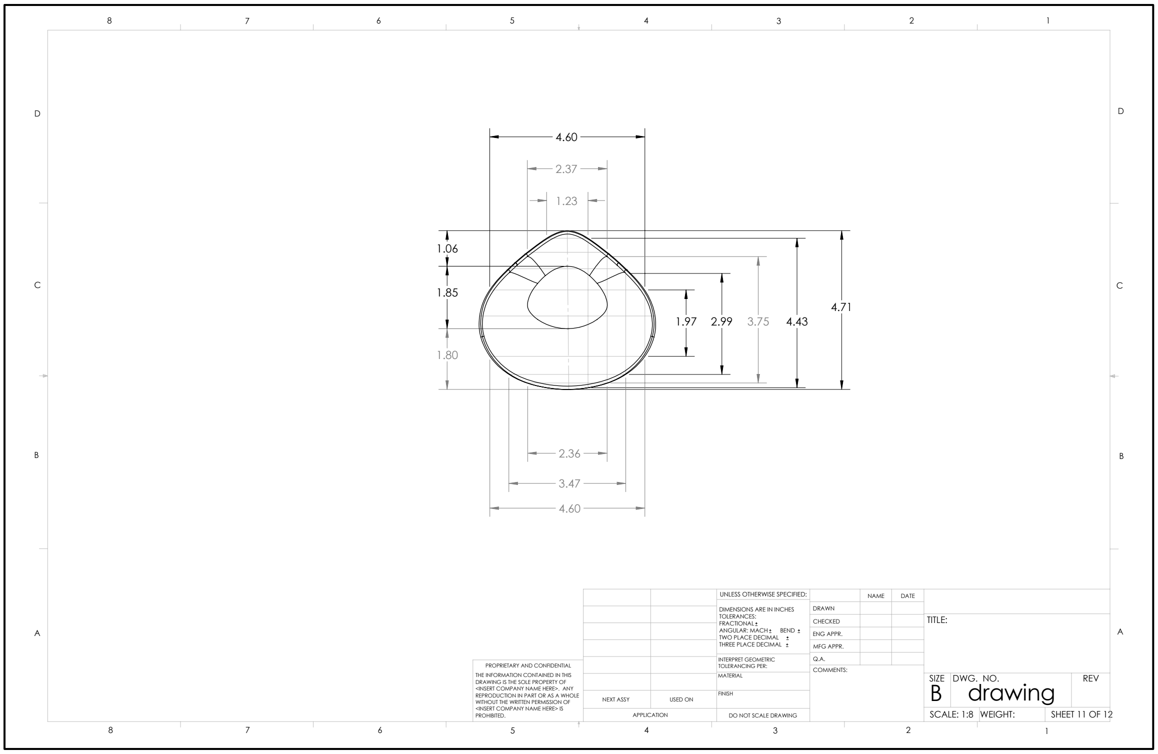


Figure 48 - Neo-Strength Socket Top View

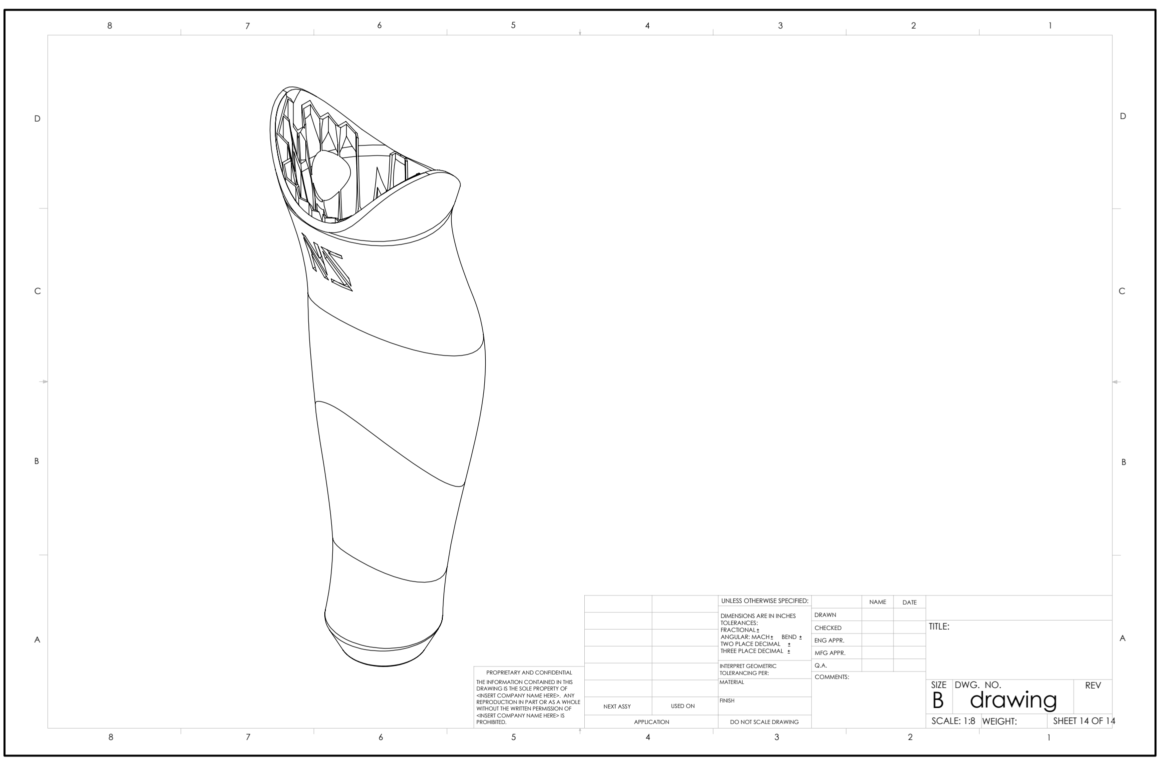


Figure 49 - Neo-Strength Lower Leg Support

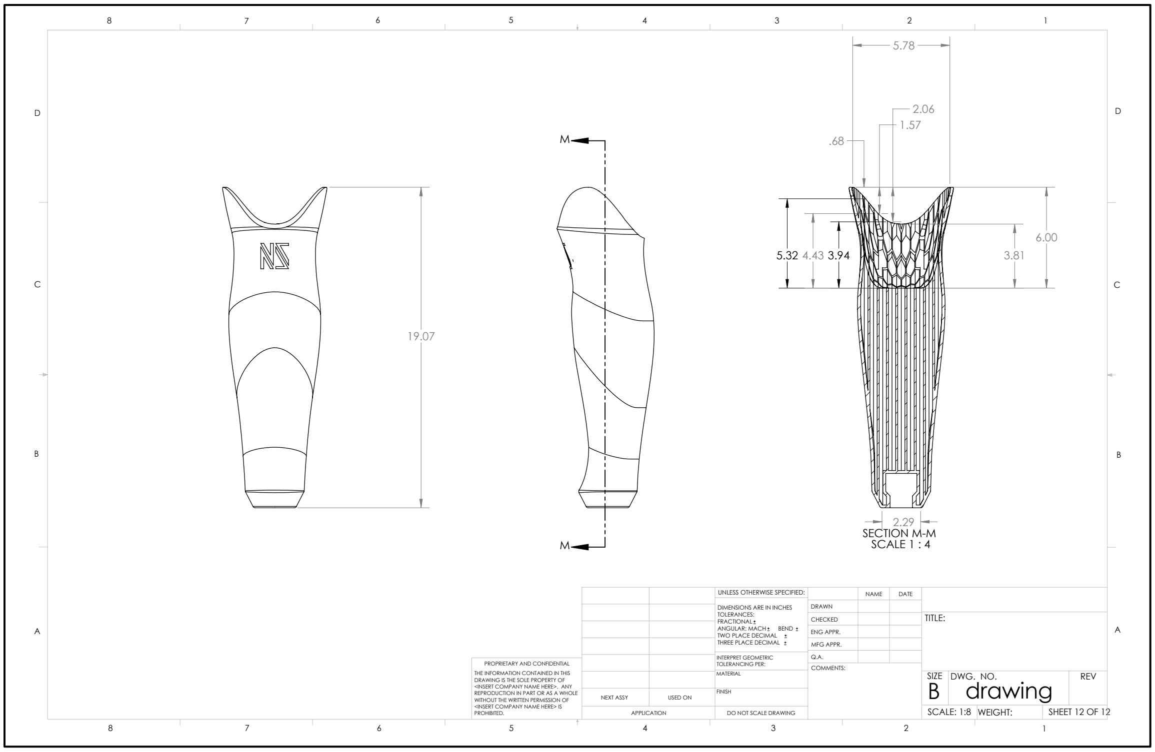


Figure 50 - Neo-Strength Lower Leg Support Control Drawings

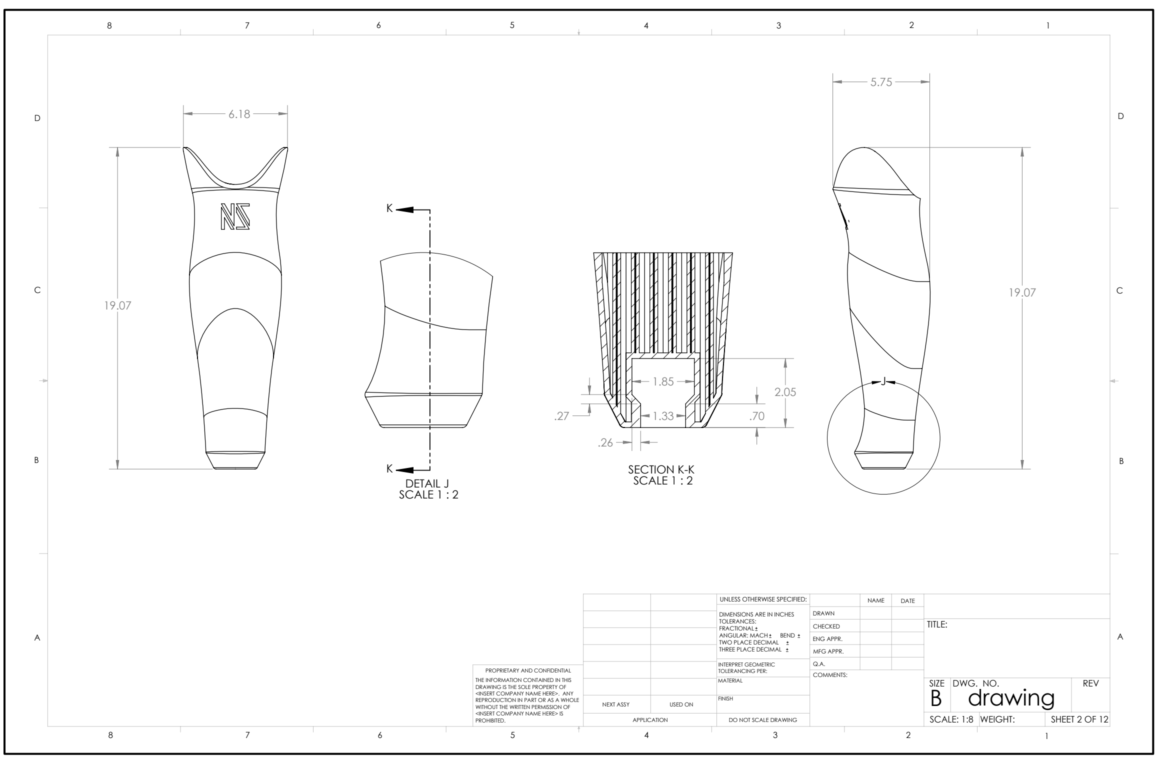


Figure 51 - Neo-Strength Lower leg front view, and section view

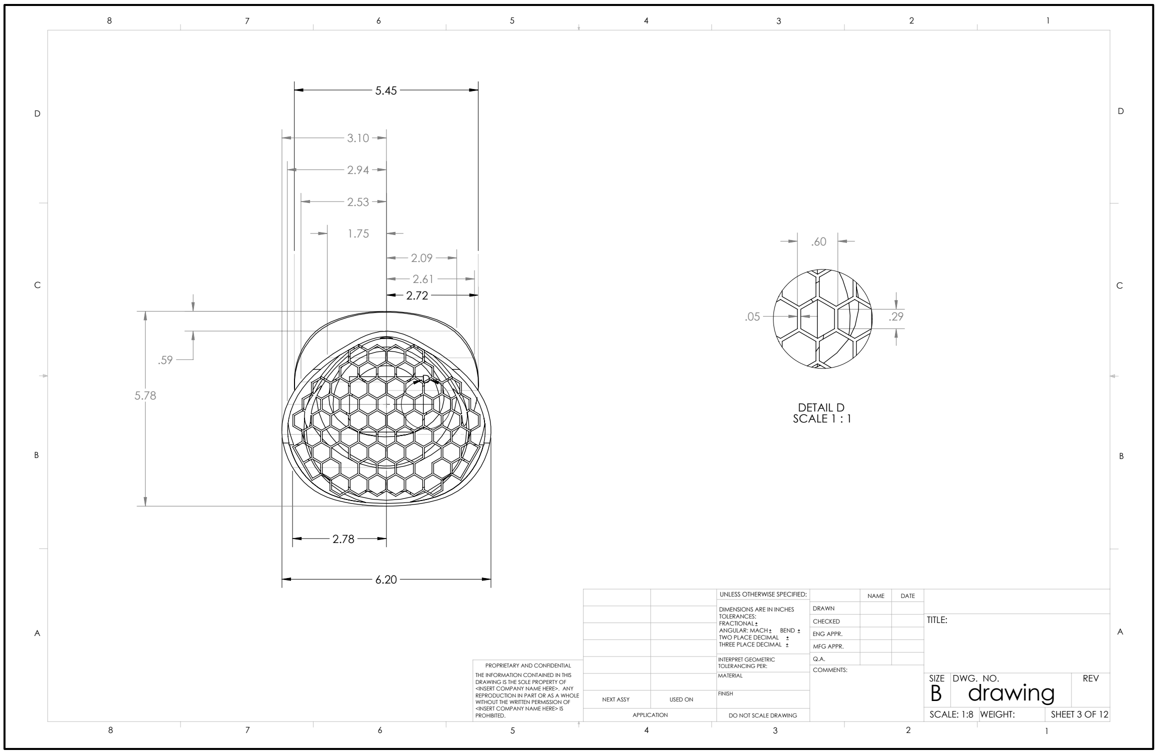


Figure 52 - Neo-Strength Lower Leg Support Top View and Details.

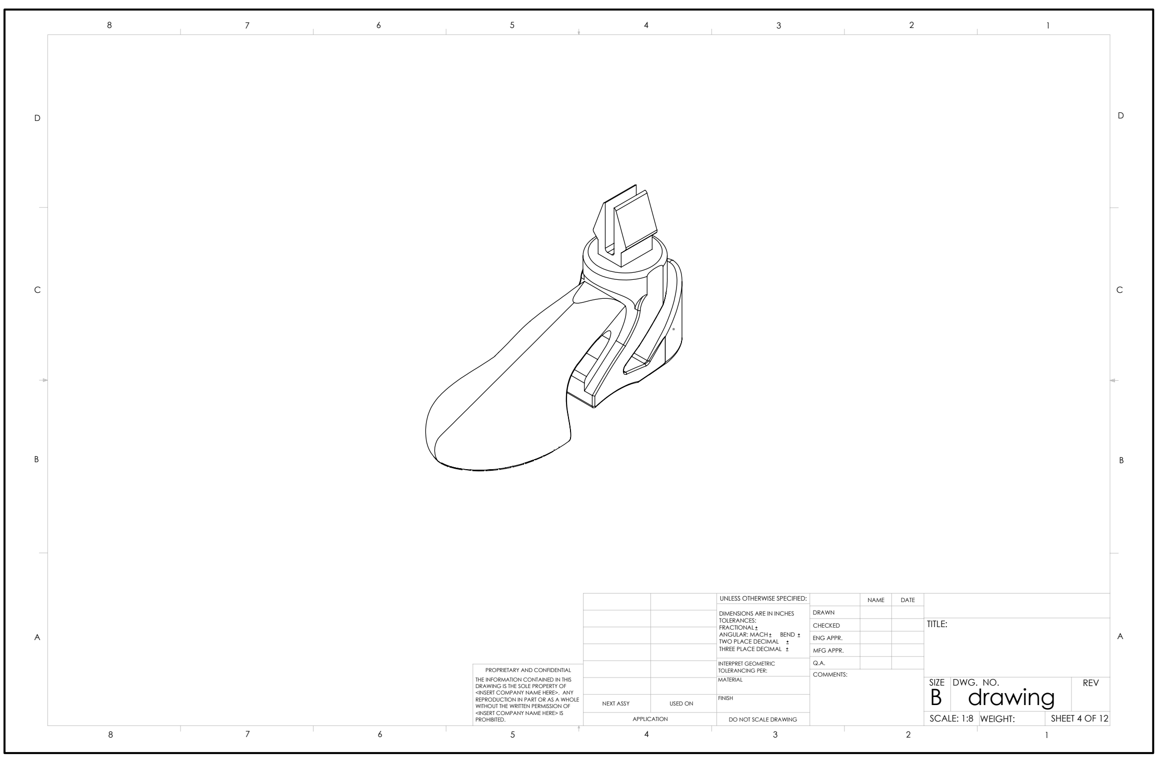


Figure 53 - Neo-Strength Foot Control Drawings.

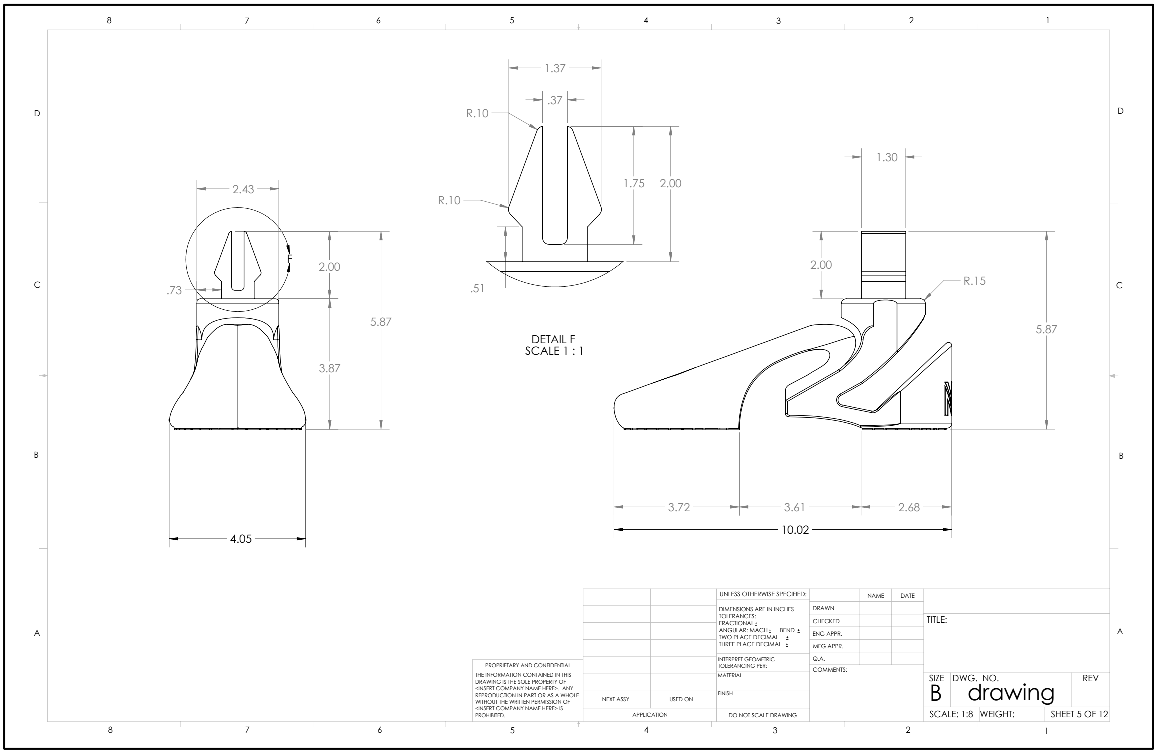


Figure 54: Neo-Strength Foot Back and Side View.

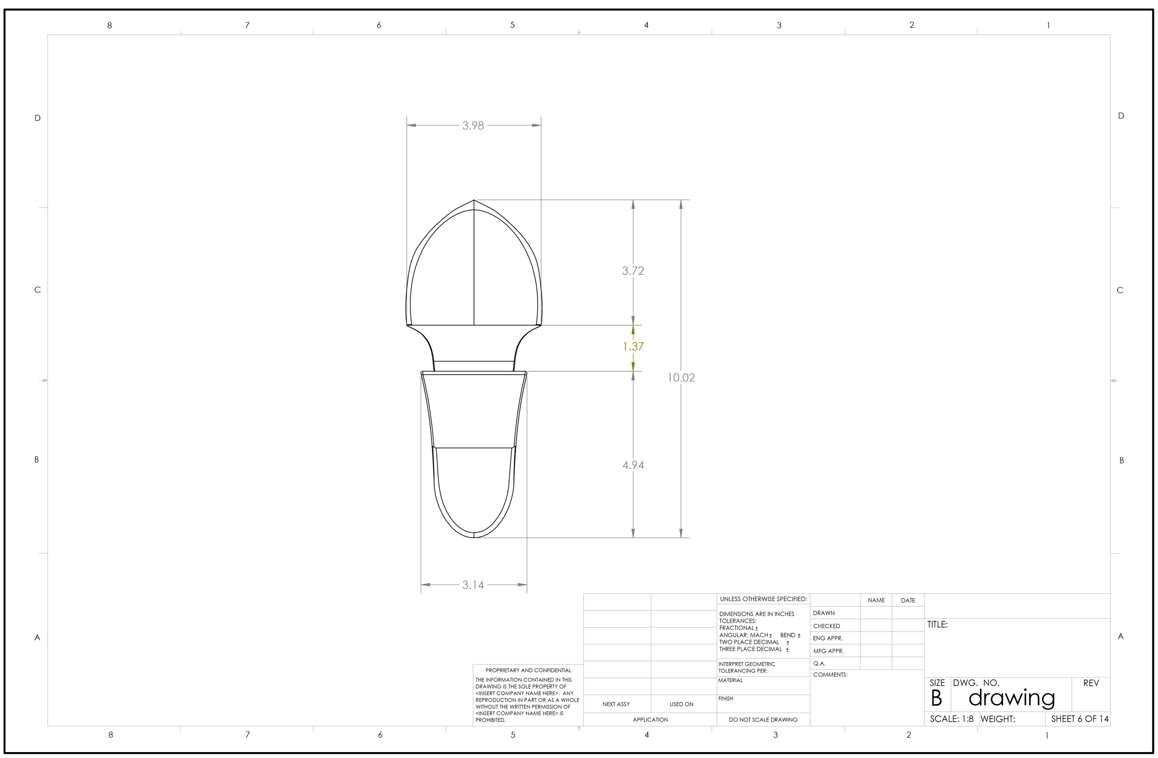


Figure 55 - Neo-Strength Foot Button View Control Drawings.

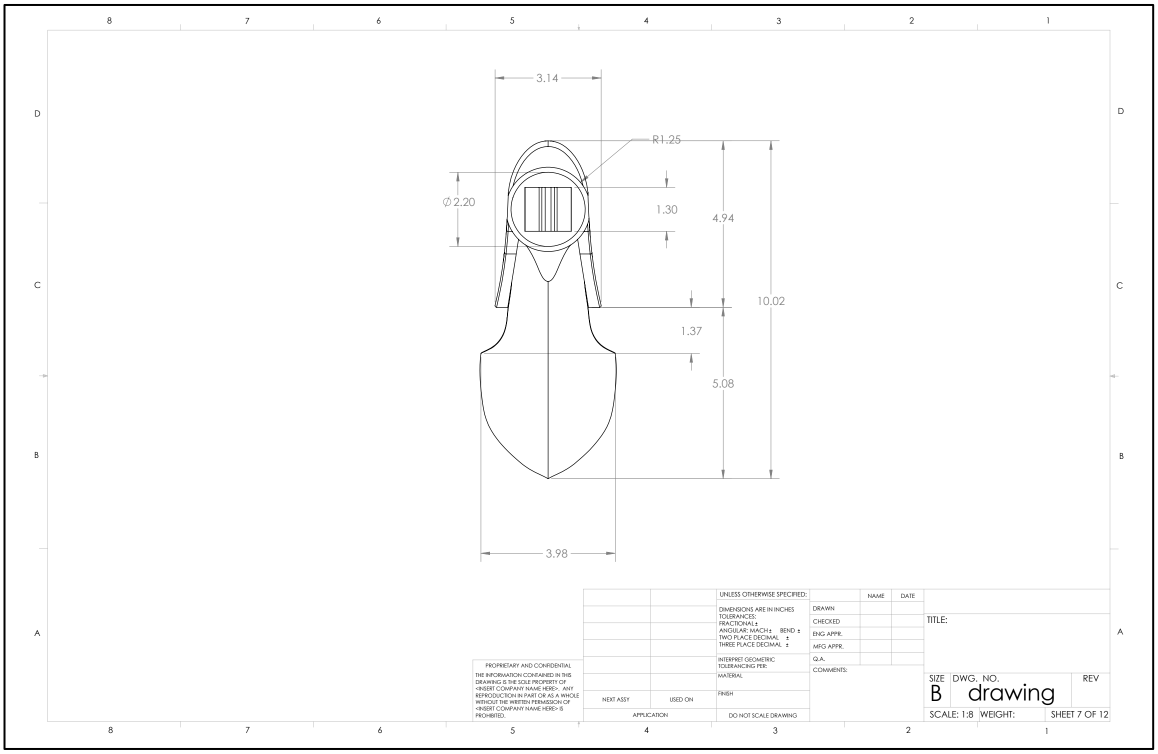


Figure 56 - Neo-Strength Foot Top View Control Drawings.

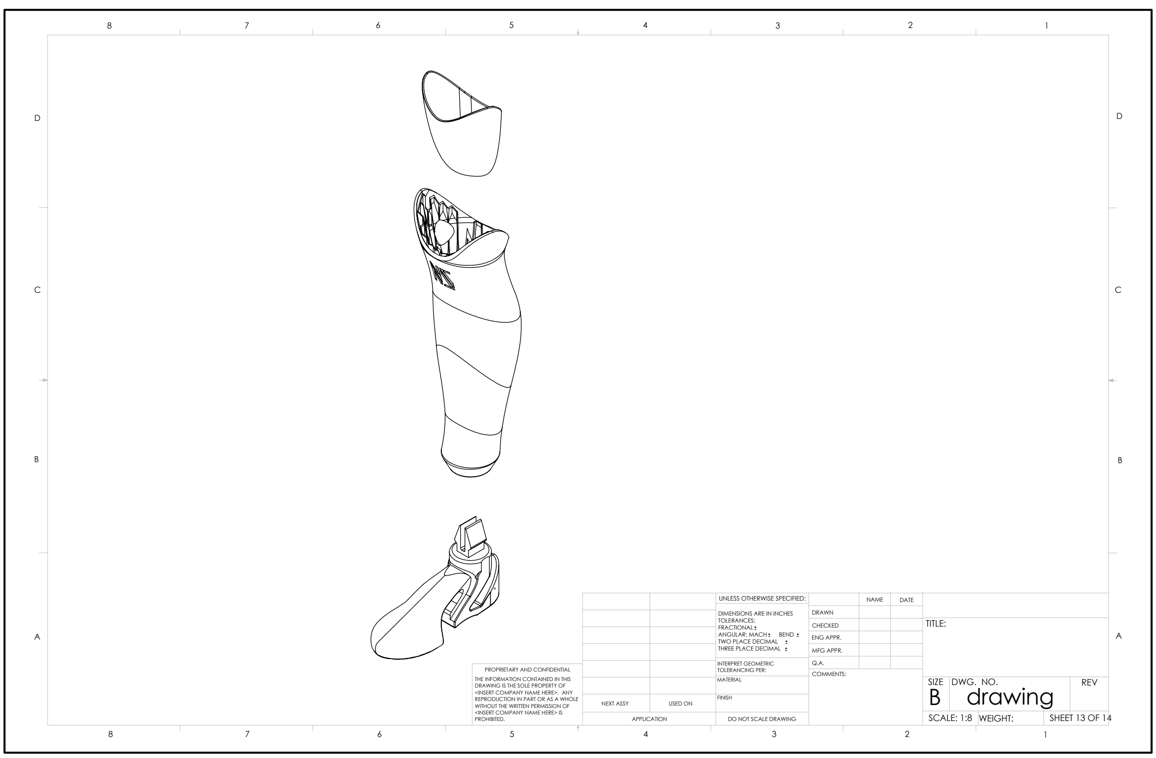


Figure 57 - Neo-Strength Lower Leg Prosthetic Explored View Control Drawings

4.7 Final Design and Styling

The final design was created at full scale and presented in a way that shows how it would be assembled for amputees. The styling of the design needs to exhibit how the product is to be used, while still appealing to amputees.

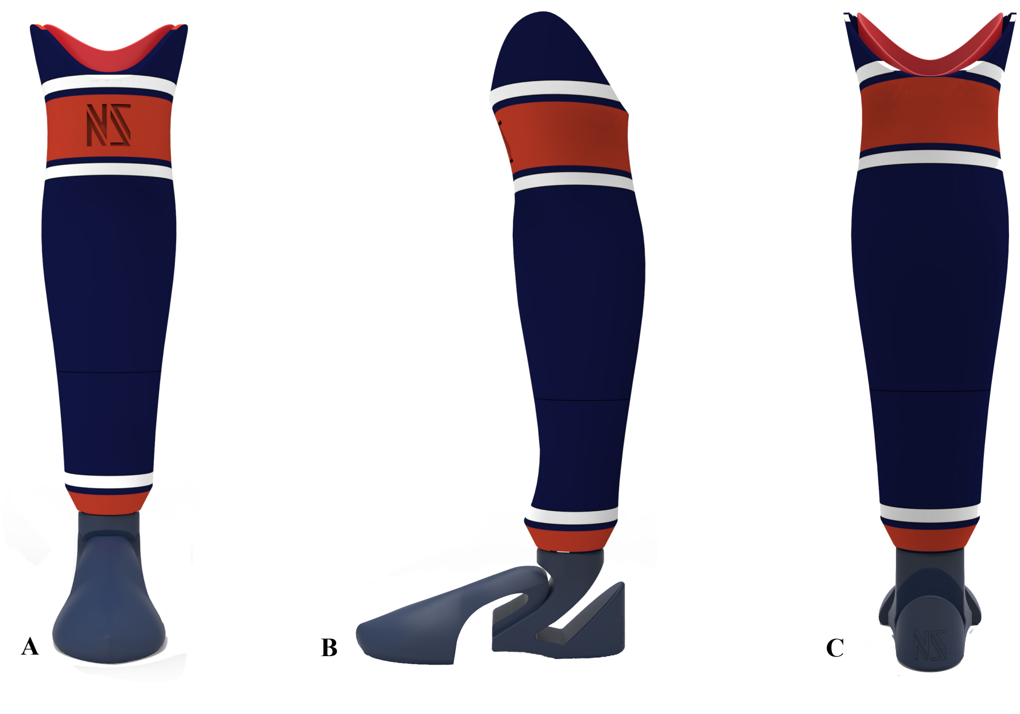


Figure 58 – Views A: front, B: right, C: back view of the final design

The final design overall uses ABS filament. The flexible, durable 3D printed durable socket will be attached to the users below the knee stump. The 3D printed lower leg support will be attached in the same manner; the 3D printed foot support will be attached to the 3D printed lower leg. The over all design and styling of the product is more rounded than the pre-prototype; the new design is friendlier, and more colorful with more pattern options and should be more appealing to the user.

The final model uses the well-known college football team theme, which is designed for college football fans. Therefore, he or she can take this opportunity to explain the prosthetics himself/herself, or someone may be interested to look closely at this prosthetic.

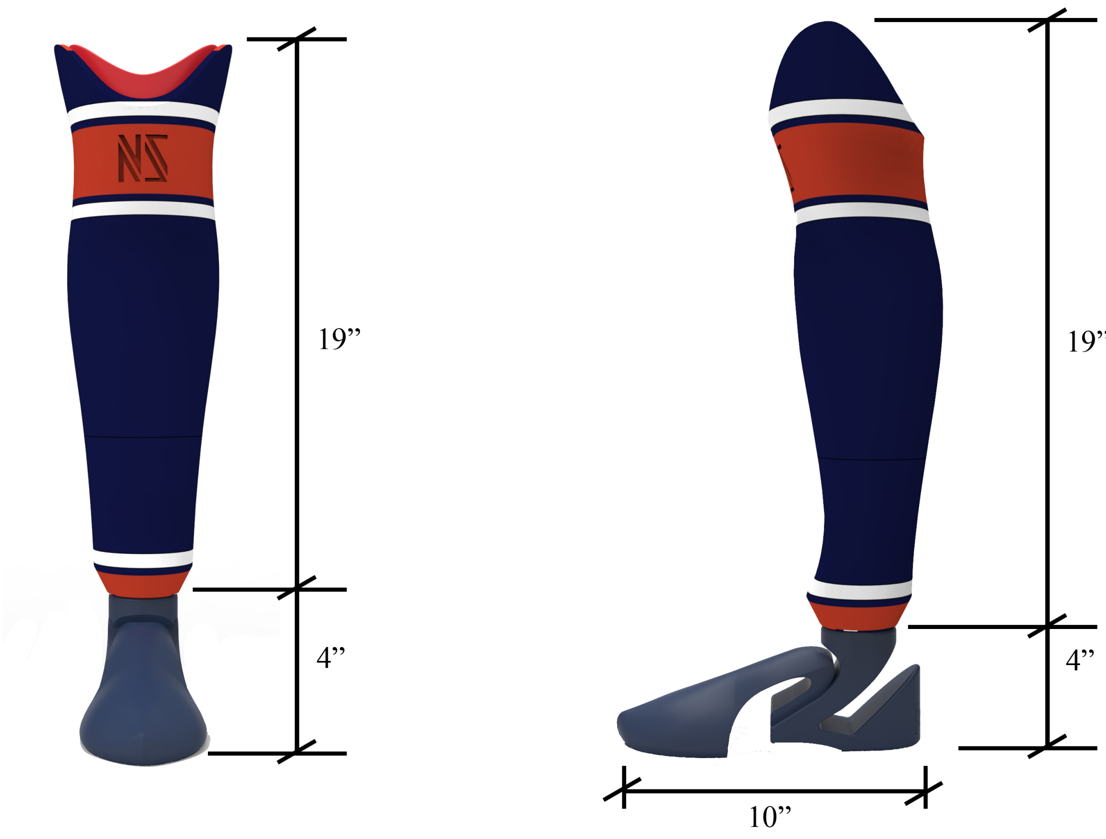


Figure 59 – Height Dimensions

The Neo-Strength height is 23 inches total. The lower leg height is 19 inches, the foot height is 4 inches, and length is 10 inches.

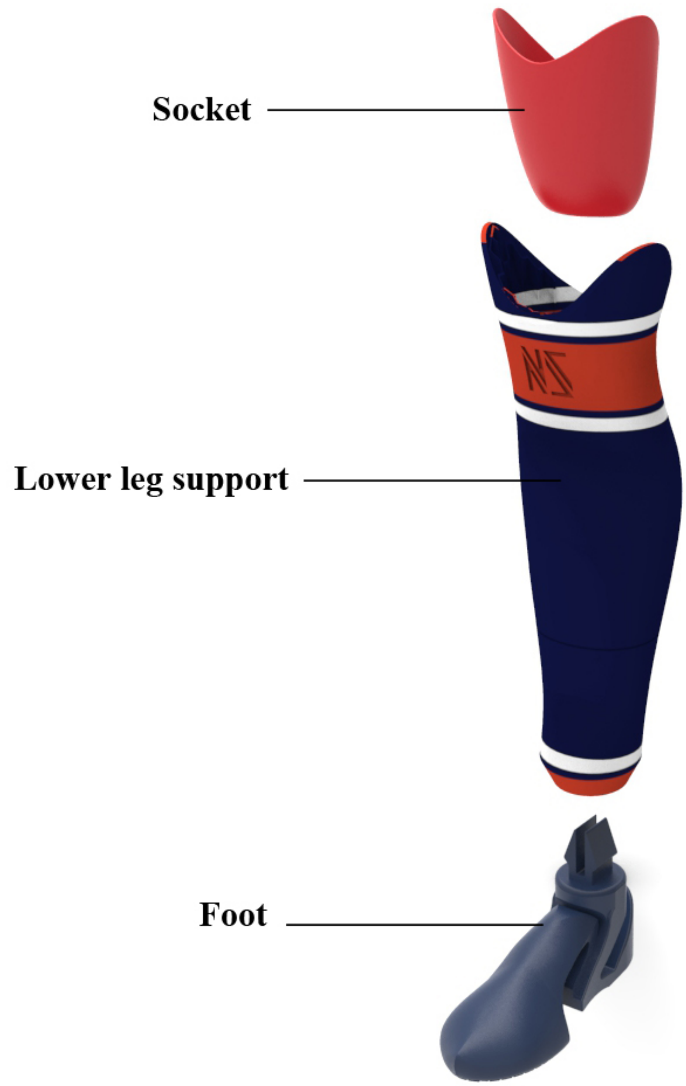


Figure 60 – Exploded view

The Neo-Strength is a simple design solution, and it is composed of very few parts. The prosthetic is made up of three components, the socket, lower leg support and foot. Due to the fewer number of parts than the traditional prosthetic creation process, as well as the measurement, design, and printing processes explained in this thesis, the prosthetic designed here is simpler, more affordable, and more user-friendly than traditional prosthetics.

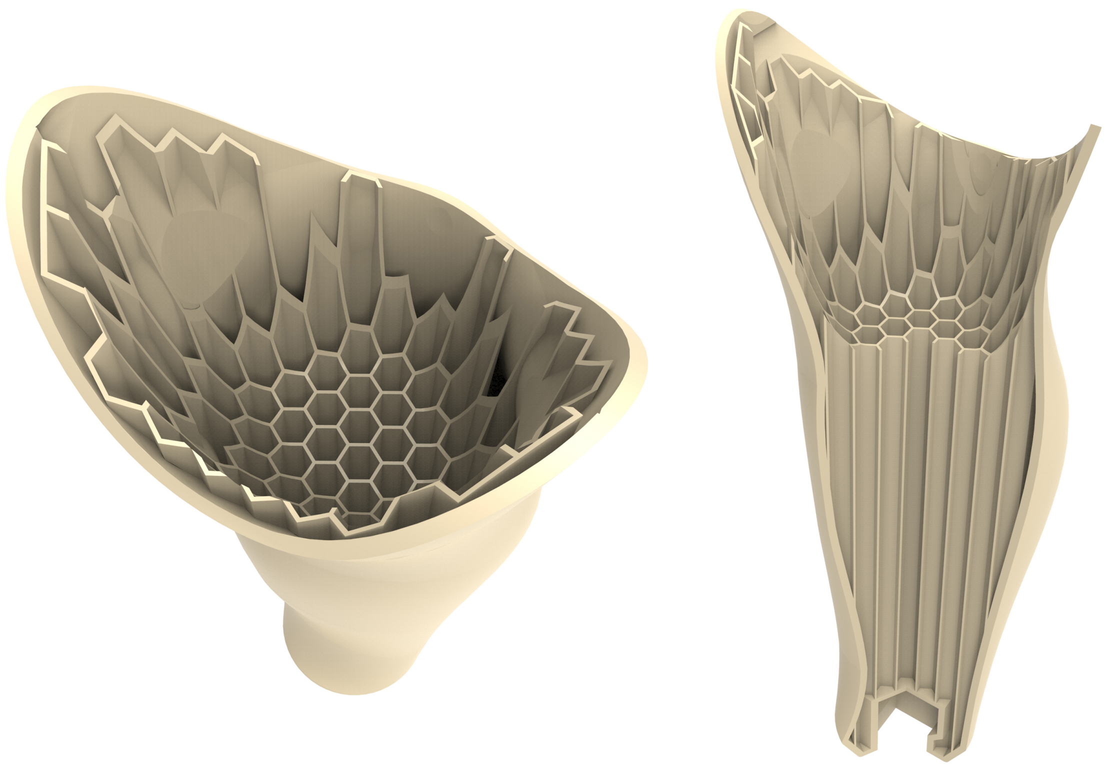


Figure 61 – Hexagon strength

The lower leg support strength comes from using a hexagonal infill. The hexagon is optimal for both strength and economy. It is stronger due to the properties of a hexagon, and it is more cost effective because it reduces the fabrication time for printing models.

The foot is made of 3D printing material ABS filament. The foot structure has a simple beautiful appearance, and is strong for use and bearing weight. The top of the foot secured to the lower leg, and it is easy to assemble, so it will not fall off from the lower leg. The toe is designed to disperse weight, and the heel designed to provide stability to the foot, both of which enable the user to go almost anywhere. The foot's streamlined design gives a more modern appeal to the product

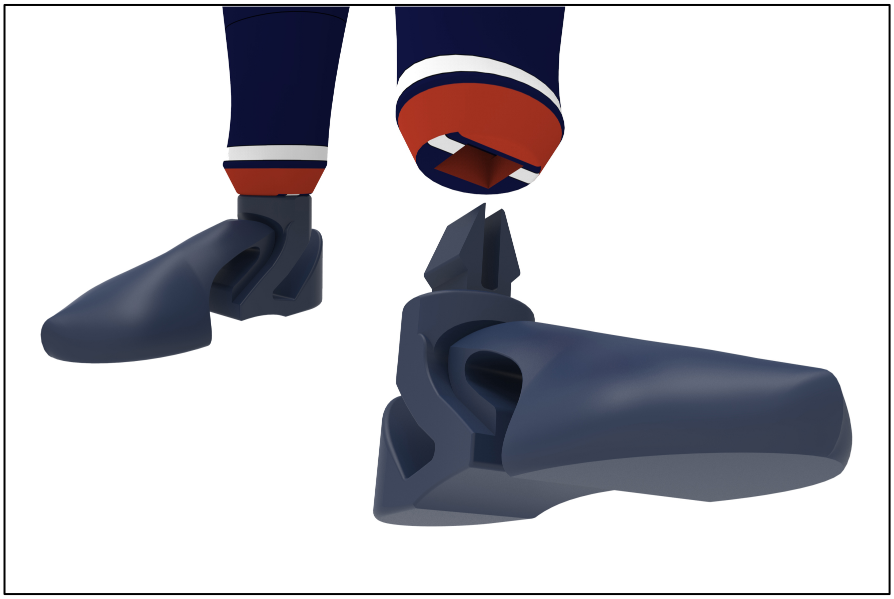


Figure 62 – Illustration of the final design of the foot lock

In Figure 63, shows gait motions of the Neo-Strength: A) Heel touching the ground, B) Foot flat, loading response phase, C) Middle stance phase, D) Terminal stance phase (heel off the ground, E) Pre-swing phase (toe off the ground).

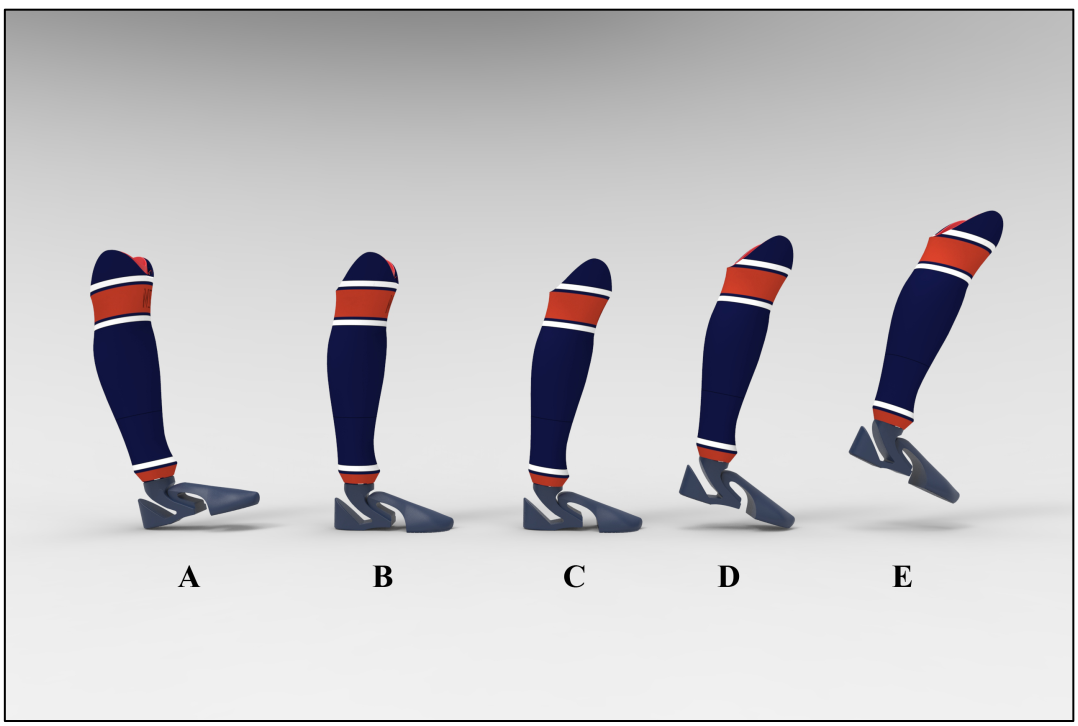


Figure 63 – Neo-Strength Gait motions

In Figure 63, shows gait motions of the Neo-Strength: A) Heel touching the ground, B) Foot flat, loading response phase, C) Middle stance phase, D) Terminal stance phase (heel off the ground, E) Pre-swing phase (toe off the ground).

Figure 64 - More theme options, and there could be more

Figure 64 shows a number of theme options for the prosthetic. From left to right in the first row is the well-known college football brand theme, with main colors including navy blue, orange, and white. From left to right in the second row, the Sport

Line theme includes stick and curved lines. From left to right in the third row is the America Spirit theme, which includes white stars, red and white classic colors.

Figure 65 – Other theme options

Figure 65 shows some more options. From left to right, the options are named Hawaii Feeling, Auburn Spirit, America Spirit and Sport Line.

Chapter 5

Conclusions

5.1 Summary of Study

Chapter One gives an introduction to prosthetic limbs design problems. Based on the problem statement and study, it then leads into the preliminary research in order to set up the research framework which includes the object of study, assumptions of study, scope and limitations, procedures and methods. In the end, Chapter One concludes with the anticipated outcome.

Chapter Two is the literature review. In this chapter is introduced bone anatomies and limb joints, types of prosthetic limbs and location of amputations. Relationships between prosthetic and limbs are discussed, in order to seek a breakthrough point in the existing work to direct the current project. New research methods and the better science evidence of customizing and 3D printing are studied. Both are an important component of the thesis.

Chapter Three is development of the approach. It describes an approach for developing of low-cost prosthetic limb with 3D printing technology. After analysis and research in patient consultations, two main measurement and the fabrication processes between traditional and CAD/CAM are compared. At this point, all gathered information is used to create a new approach to assist designers in the prosthetic limbs industry field.

Chapter Four is the new approach applied theoretically to development of low-cost prosthetic limbs with 3D printing technology. In this chapter, the reader can follow each step in design and production of creating 3D printed prosthetic limbs in an order analogous to industrial design methods.

5.2 Recommendations

The purpose of this project was to design a new approach for developing a low cost 3D printed prosthetic limbs with functions that can make up for defects in current prosthetic limbs. The MCSC method offers a possible approach, which is a combination method between CAD and traditional methods. This methods presents a low-cost, reusable, and time-effective way to carry out accurate stump limb measurement. It reducing unnecessary steps in manufacturing the prosthesis and simplifying the components. The goal is that in using scientific knowledge, combined with 3D printing technology, the designer will develop a superior application for amputees, which is both affordable and functional. The characteristics of a low- cost prosthetic limb are new construction, lightweight and affordability. In this case, it becomes important to help the disabled to get low-cost, lightweight with a newly constructed prosthetic limb that will make their lives easier. Investigating and identifying the user's individual needs would help the designer create a new functional product with strong innovative characteristics. For this reason, I chose it for my study. By redesigning the structure of prosthesis to mimic the strong and lightweight natural internal structure of bones, through customer-oriented design, the 3D printed prosthetic limb looks more personal and more artistic. This approach could be used in either the medical support or prosthetic industry.

5.3 Synopsis

This approach can aid a designer to create prosthetic limbs that meet customer needs with prosthetic limbs that are more personal and more artistic while improving, cost, and fit, make the prosthetic more comfortable and functional. Also 3D printed prosthetics can express amputee's aspirations. In the thesis, the approach could be used as a reference guide to designers in medical support or prosthetic industry.

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