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Performance of Rapid Tooling Molds for Thermoformed Sockets

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by

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of the requirements for the degree of
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Dedication

This thesis is dedicated to my parents who have supported and encouraged me from the beginning of this path. Especially, I hope to inspire my brother and sister who have been a tremendous source of motivation to continue moving forward during difficult times. I look at this achievement as a family effort rather than an individual triumph.

Also, this thesis is dedicated to Yisset who believed in my dreams and never abandoned me.

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I want to thank all my family members who reside in the US that were tremendously supportive. Finally, warm gratitude is devoted to Silvia Blanco and her family for their encouragement and support.

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Jairo Chimento

ABSTRACT

Traditional prosthetic socket fabrication is a laborious and time consuming process that involves physical measurements, plaster wrapping of the stump, plaster casting for positive mold preparation, and a thermoforming process. During the mold preparation stage, significant modifications are performed subjectively based on the prosthetist's experience to transmit an optimum load to the residual limb through the socket. Rapid Prototyping techniques have advanced rapidly during the recent decades emerging as a computer aided socket design alternative which promises a potential reduction in the fabrication time, and a more systematic design approach. In addition, 3-D scanning provides accurate and fast virtual replica of the stump which can be imported in CAD environments. Within 3-D CAD software, prosthetists are able to perform modifications precisely and store files indefinitely. This work examines the potential use of ZCorp 3-D printers to directly manufacture the thermoforming mold required for prosthetic socket manufacture. This work analyses the performance of Rapid Tooling molds for thermoformed socket based on three main parameters: pneumatic permeability, flexural strength and wear rate. The traditional material for mold casting, Plaster of Paris, is compared to materials used for three dimensional printing by Zcorp printers: zp130 and zp140 untreated as well as using them with custom and novel post treatments. To obtain the flexural strength of the different materials, three point bend tests were performed in a universal test machine using ASTM Standard D790-03 requirements. In addition, pneumatic permeability tests were performed to cylindrical specimens of the different materials following ASTM Standard D6539-00.

Thermoforming tests confirm that Zcorp 3-D printed parts can serve as effective molds for thermoforming of prosthetic socket.

Chapter 1: Introduction

1.1. Thesis Statement

The overall goal of this thesis is to evaluate the suitability of a modified commercial 3-D printing process to produce socket molds. The socket manufacturing process is analyzed based on material comparison between standard and alternative materials used in rapid tooling versus traditional materials and processes in prosthetics. Currently, Zcorp three dimensional printers offer the lowest cost and higher speeds available in the market. This work addresses the integration of 3-D scanning and rapid prototyping techniques, 3-D printing in this case, in prosthetic sockets molds manufacturing as an alternative to potentially reduce fabrication time and increase accuracy in molds shape. To evaluate suitability, the key properties of standard and modified materials are measured. The main parameters analyzed are pneumatic permeability and flexural strength due to their relevance in the vacuum process and applied loads involved in the thermoforming process of the socket. In addition, other properties were tested such as surface wear rate and volumetric stability to assess part accuracy and ease of modifications. Time, costs, and process implications of the proposed approach are also examined.

This chapter will review the overall concept of prosthesis on residual limbs, terminology and basic components, socket fitting issues and the motivation for considering new techniques in socket design and manufacturing.

1.2. Background

1.2.1. Prosthesis for Residual Limbs

Approximately 1.6 million people in the United States currently live with limb loss. There are approximately 135,000 new amputees each year. Amputation statistical incidents show: 53% of amputations are of the leg below the knee, 33% are of the leg above the knee, 2% are of the arm above the elbow and 4% are of the arm below the elbow. Lower limb amputations are caused due to several reasons such as disease (70%), trauma (22%), birth defects (4%) and tumors (4%). Following amputation, there are several aspects that may diminish the recovering and rehabilitation of the patient including inactivity, lack of physical and counseling therapy, improper gait and socket fitting. Secondary conditions may further impede amputee recovery. Moreover, these conditions may include lack of body temperature control, obesity, retention of liquids and lack of flexibility. As a result, an increasing necessity to provide comfort and rehabilitation to the amputees creates the space for continuous research in the prosthetic field [1, 2].

Prosthesis is a device emulating a missing part of the body connected to residual limbs which are remaining extremities that have suffered amputation. The prosthetic socket is the cavity of the prosthesis where the residual limb is inserted. In addition, prosthetic sockets are needed in order to align, stabilize and support prosthesis in the residual limb. Researchers and prosthetists have agreed that appropriate socket fitting is the most important element in the rehabilitation of an amputee [3, 4]. An individual can recover the ability to function normally if the prosthetic socket fits well with the stump. For example, if a lower limb amputee’s prosthetic socket fits correctly, the individual will develop a near normal-gait, providing the ability to continue daily activities with independence [3]. However, if the prosthetic socket fits improperly, unnatural conditions result from the frictional interaction between the soft tissue of the residual limb and the prosthetic socket. These conditions lead the amputee to suffer pain, blisters, edema, pressure ulcers, and sometimes flap necrosis and osteomyelitis [5, 6].

Various improvement opportunities in the design and manufacturing of prosthetic sockets have motivated different investigations in the prosthetic field. The majority are related to the analysis of the stump-socket surface interface using finite element analysis (FEA) to find the regions where the normal and shear stresses could affect the patient's comfort [7, 8]. Other studies have been devoted to implement three dimensional reconstruction of the residual limb using MRI and CT images[3, 4, 9]. Moreover, Rapid prototyping, a new manufacturing technology, has been used to aid in the prosthetic socket design and manufacturing [9-11]. One particular study described the process of digitalization of the positive mold using 3-D scanning technology followed by modeling of the socket using computer aided design (CAD) software, and the further Computer Aided Manufacturing software/machine interfaces. The technology used for fabricating the socket was fused deposition modeling (FDM).

1.2.1.1. Terminology and Basic Components

Prosthetic terminology will be used throughout this work. A brief explanation of some components and specific terms are described next.

- Amputation: Partial or complete removal of a limb.
- Residual limb: Portion of the extremity remaining after amputation.
- Upper limb amputee: Individual that has lost any segment of the arm(s) by accident or due to a surgery.
- Lower limb amputee: Individual that has lost any segment of his/her leg(s) by accident or due to a surgery.
- Transhumeral amputation (TH): Above the elbow amputation (AE).
- Transradial amputation (TR): Below the elbow amputation (BE).
- Transfemoral amputation (TF): Above the knee amputation (AK).
- Transtibial amputation (TT): Below the knee amputation (BK).

- Socket: Cavity that fits around the residual limb which works as an interconnecting device between patient's stump and prosthesis.
- Shank: Leg section between knee and ankle.
- Suspension systems: System that holds the prosthesis onto residual limbs.

Terminal devices, sockets, shanks, suspension systems are the common basic components of a prosthesis. Moreover, devices simulating joint motions are used depending on the level of amputation on the residual limb.Figure 1 illustrates the levels of amputation on lower limb amputees. Figure 2 illustrates the levels of amputation on upper limb amputees.

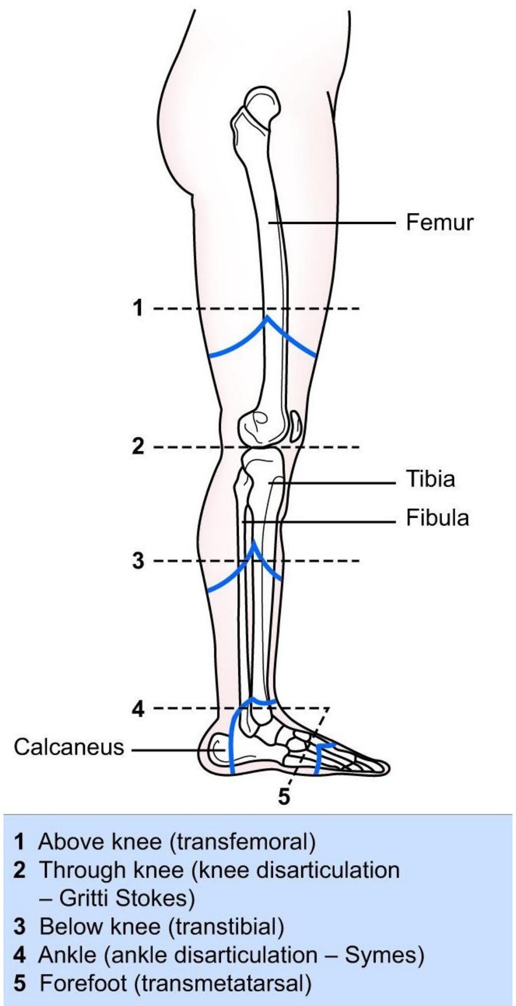

Figure 1: Lower extremity level of amputation [12].

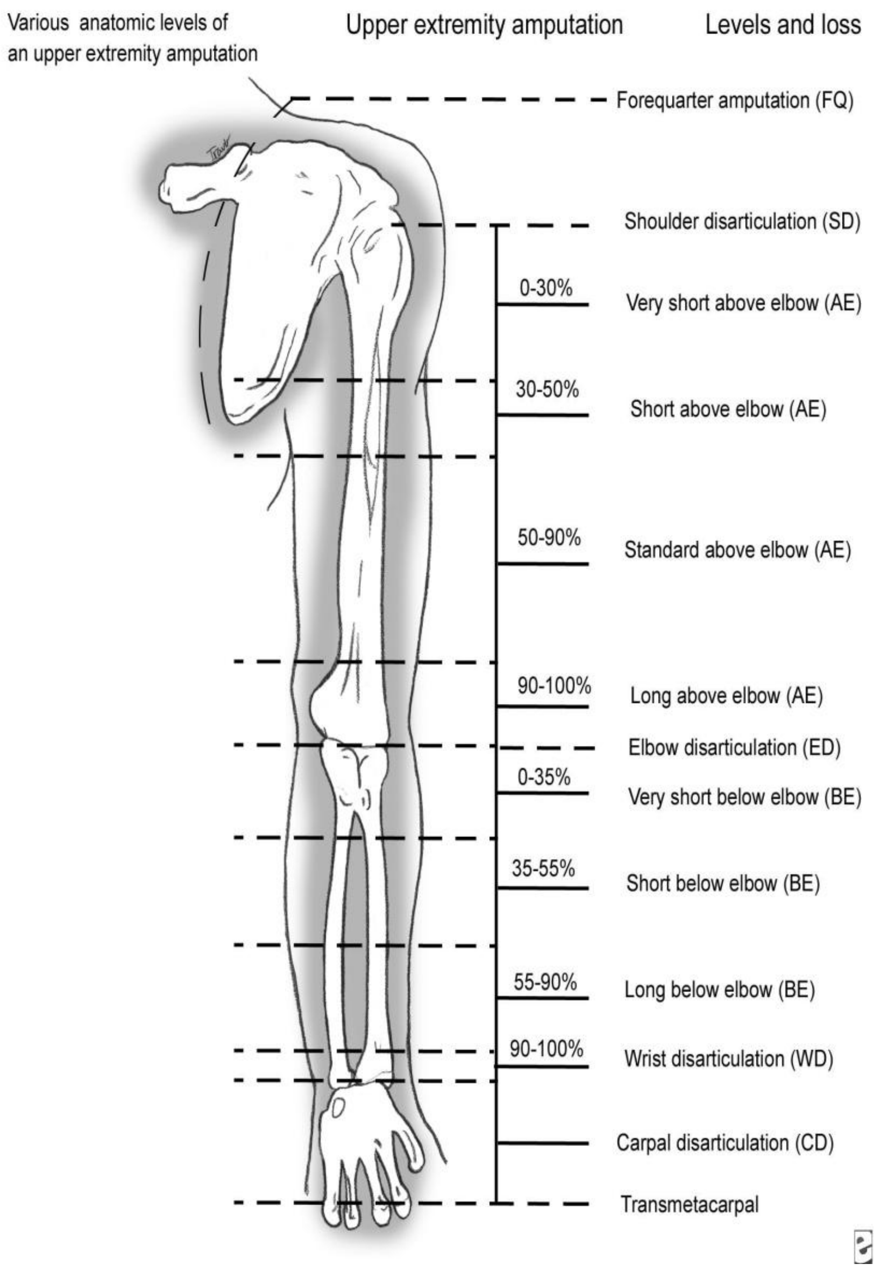

Figure 2: Upper extremity levels of amputation [13].

In fact, prostheses for transtibial (below the knee) amputees should include: a socket, foot ankle assembly, and a shank. Prostheses for transfemoral (above the knee) amputees should include the components listed above in addition a thigh and a prosthetic knee. The following two images illustrate the basic components of lower limb prostheses.

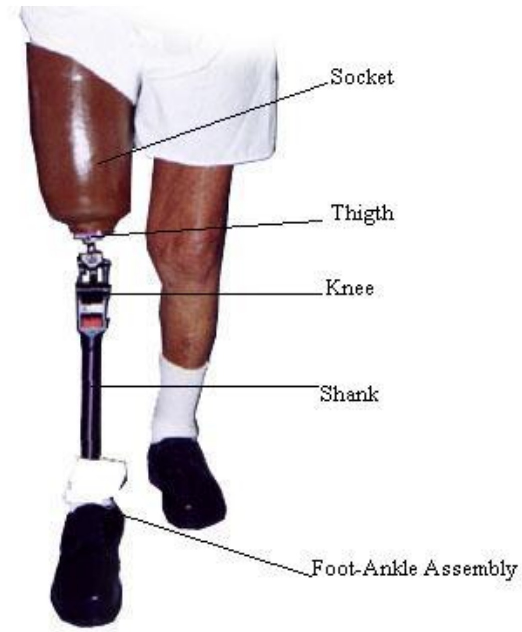

Figure 3: Above the knee prosthesis [14].

Figure 4: Below the knee prosthesis [14].

In the case of upper limb prostheses, the most common prostheses are fabricated for transhumeral (above the elbow) and transradial (below the elbow) amputees. The components of a below the elbow prostheses are: socket, suspension, control-cable system and a terminal device such as a mechanical hand or a hook. Prostheses for transhumeral amputees should include the previously mentioned components in addition to a prosthetic elbow.

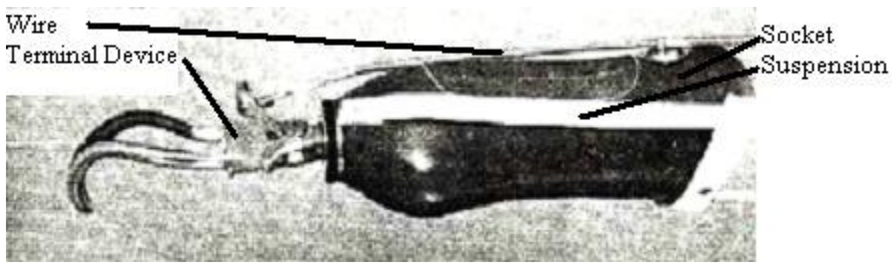

Figure 5: Below the elbow prosthesis [15].

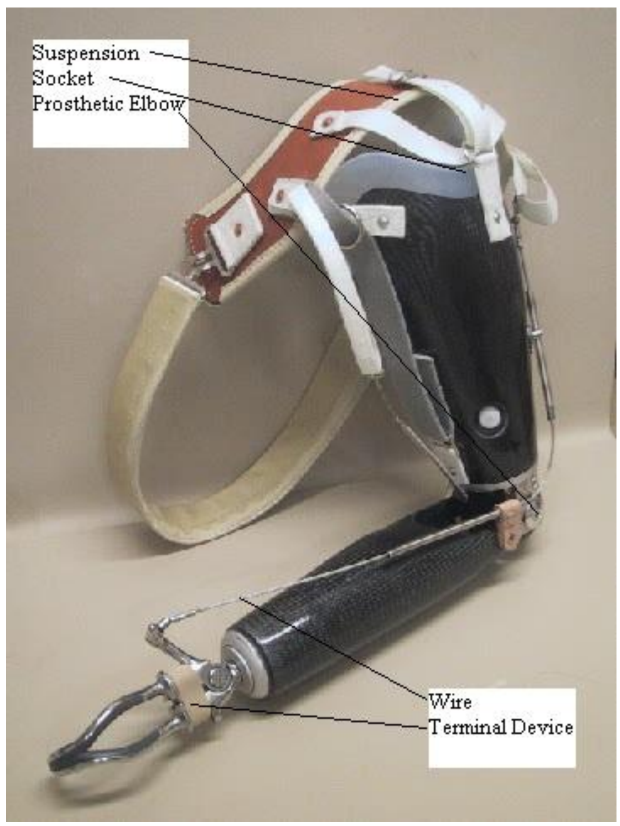

Figure 6: Above the elbow prosthesis [14].

1.2.2. Socket

The socket fits around the patient's stump and serves as an interconnecting component between the residual limb and the prosthesis. The main objectives of the socket are to hold the prosthesis at the residual limb and distribute the pressure due to the forces generated when standing or walking in the case of lower limb prosthesis at the socket-residual limb interface. An optimal socket should deliver alignment, stability and comfort.

1.2.2.1. Importance of Socket Fit

Socket fitting plays a key role in the rehabilitation and normal recovery of activities developed by the patients. The interface between the socket and the residual limb is an area exposed to normal and shear stresses that can affect patients' comfort with painful symptoms. The socket design should aim to decrease the pressure along intolerant areas and promote higher stresses at more tolerant areas. In addition, the socket should stay in place to provide the alignment needed to operate in a natural fashion [16].

1.2.2.2. Problems in the Socket Wearing

The major drawback of the socket fitting is the skin traumas that it generates. In fact, skin ruptures and irritation are caused by large shear loads and friction respectively. Large normal and shear loads blocks the natural blood circulation at the residual limb area contributing to skin traumas. Also, tightness of the socket fit produces a perspiration increment at certain areas causing humid environments which lead to discomfort and skin damage. A tighter-fit socket will prevent the socket from slipping off the residual limb. Looser-fit sockets will cause it to slip off easier. Finally, regardless of the load transfer of the socket to the residual limb efficiency, the socket will not be used if it generates pain or any discomfort on the patient [7, 17].

1.2.2.3. Traditional Socket Manufacturing

In prosthetics, the aim when designing a socket is creating a comfortable weight-bearing socket that enables the soft tissue of the stump to be compressed at pressure tolerant areas, and relieved at pressure intolerant areas. The following principles should be addressed in the production of the socket: accurate measurement of the stump geometry, close fitting of the prosthesis to the stump, good response to forces and mechanical stress, safety, and minimal impact on blood circulation [4]. As a result, generating sockets is high-skill process. The socket fabrication follows several stages: wrapping, casting, modifying, thermoforming, and assembly. The first stage consists in recording physical information of the residual limb and casting a negative mold using plaster wraps (Figure 7a, Figure 7 b). The second stage implies the generation of a positive mold by pouring a mixture of plaster of Paris, vermiculite if needed and water into the previous cast (Figure 7c). Before pouring the mixture, a steel pipe is placed at the center of the negative mold 1 inch from the bottom. This tube will connect the mold to the vacuum system. The positive mold is then modified by adding or removing material from the mold. These adjustments are based on the physiology of the patient's residual limb and subjective decisions based on the prosthetist's experience (Figure 7d). Finally, a flat thermoplastic sheet is heated and deformed onto the positive mold connected to a vacuum line that helps the heated sheet reproduce the mold's shape (Figure 7e). The vacuum is used to prevent the formation of air cavities in the interface between the thermoformed plastic and the plaster mold. The desired shape of the socket is acquired by removing the excess of thermoformed material attached to the plaster mold (Figure 7f). After the socket is generated, the socket is assembled to the other elements of the prosthesis (Figure 7g). Finally, the patient tries and evaluates the fitting of the socket in the residual limb (Figure 7h). If the socket is rejected, the physician modifies the plaster mold by adding or removing material depending on the patient's feedback until the socket is acceptable. Later, the final socket is thermoformed again. Other components of the artificial limb are assembled to the socket to provide functionality and cosmetic appearance [10].

Figure 7: Traditional prosthetic socket manufacturing stages [9, 18, 19].

1.2.2.4. Socket Fitting Process

The following chart describes the sequence flow of the processes undertaken during the socket manufacturing and fitting.

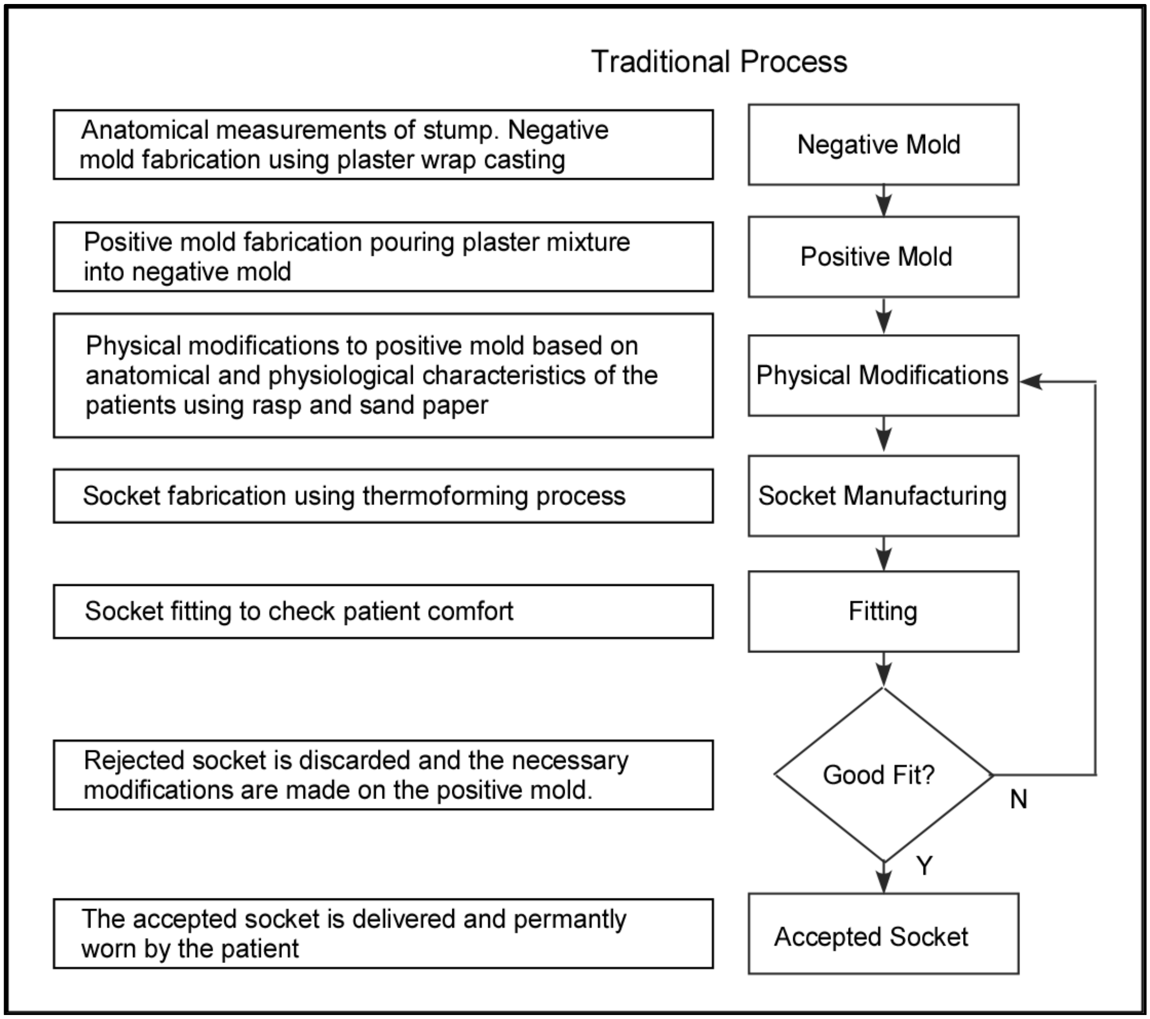

Figure 8: Traditional socket fitting process.

1.2.2.5. Computer Aided Socket Design and Manufacturing

Computer aided design (CAD) and computer aided manufacturing (CAM) technology is well known to help in the automation and the precision of a manufacturing process resulting in a substantial increase in final product quality and a reduction of fabrication process time. The CAD software will help to generate and visualize a three-dimensional (3-D) model that enables rapid virtual modifications of the products. The CAM software/hardware interface will generate the codes that control the automated machines. CAD/CAM technology has been widely used in many applications where a CNC machine is needed. However, the increasing influence of this technology has penetrated in the medical field. A new research field of computer aided socket design (CASD) and computer aided socket manufacturing was subsequently born. The aim of this research field is to shorten and automate the traditional and laborious fabrication process of the prosthetic socket manufacturing [9].

1.2.2.6. Rapid Manufacturing Methods

Liou describes rapid prototyping as “the physical modeling of a design using a special class of machine technology. It involves adding and bonding materials in layers to form objects, and thus is also called ‘‘layered manufacturing’’ or ‘‘solid freeform fabrication.’’ The advantages of RP include the fact that objects can be formed with any geometric complexity or intricacy, reducing the construction of complex objects to a manageable, straightforward, and relatively fast process.”[20]

Hopkinson et al defines rapid manufacturing as “the use of a computer aided design (CAD)-based automated additive manufacturing process to construct parts that are used directly as finished products or components.”[21] However, it is wise to mention that some references define the fabrication of molds using rapid prototyping techniques as rapid manufacturing. On the other hand, Cooper refers to rapid tooling as “mold cavities that are either directly or indirectly fabricated using rapid prototyping techniques.”[22]

Another approach available in the market is fabricating the molds using foam blank CNC milling machines. These are computer numerically controlled machines which are capable to produce complex geometries on a foam block with high accuracy. However, molds produced by this technique do not tolerate high temperatures similar to those applied in thermoforming processes ().

Rapid prototyping and rapid manufacturing of sockets have been done previously. This work is focused on rapid tooling as a new alternative to facilitate prosthetic socket fabrication ().

1.2.2.7. Potential for New Approaches

Three dimensional scanning is a new technique that collects data from the surface of physical objects and generates a 3-D model file compatible to CAD software. Under the CAD environment, prosthetists have the opportunity to precisely modify the geometry of the model to create the appropriate fit between the socket and residual limb. When the model is finished, STL file is generated to be printed using any rapid prototyping technique depending on the application. Rapid Prototyping (RP) is a technology that enables to automatically produce a 3-D physical object from a virtual CAD model. 3-D scanning and RP have the potential to substantially decrease the time spent by the prosthetists and technicians to fabricate the mold of the sockets for prosthetic applications. Figure 9 describes the socket manufacturing process using rapid tooling. Moreover, the CAD models of residual limbs can be annexed to patient’s medical history file and can be reprinted at any time if the socket fitting is appropriate. The 3-D printing mold can be modified and reprinted after the original mold is destroyed saving storage space in prosthetists clinics. In addition, an electronic medical record of the patient can keep track of all the changes made from the original residual limb scanned mold. The resulting history will enable improved fitting methods. Scheduled scans could provide important information to prosthetists to analyze precisely the chronological changes on the residual limb therefore preventive modifications can be made on the thermoforming mold to ensure a better fit and better patient care. More complete discussion of the potential benefits of using rapid tooling for prosthetic socket mold manufacturing is presented on Chapter 2.

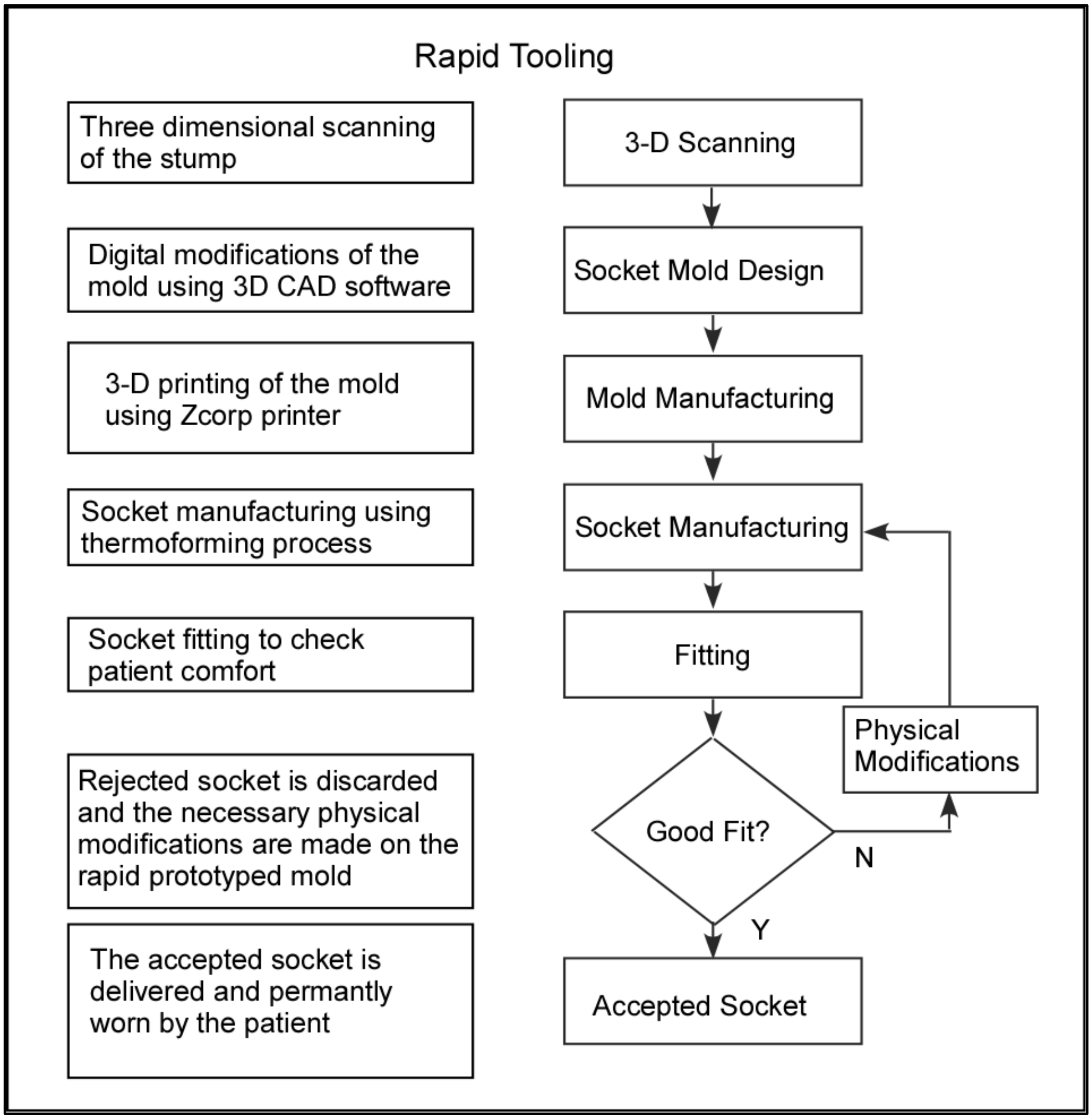

Figure 9: Potential for new approaches in socket manufacturing.

1.3. Thesis Outline

The thesis proceeds as described next. Chapter 1 introduced the importance of prosthesis for residual limbs, terminology and basic components in prosthetics, the concept of computer aided socket design and manufacturing. Chapter 2 reviews research efforts in the different socket modeling approaches, available socket manufacturing techniques, material properties required in socket performance, and the value of three dimensional printing of rapid tooling molds for thermoforming of prosthetic sockets. Chapter 3 describes the tests and specimens fabrication by which the materials were characterized to analyze their performance. Chapter 4 presents and evaluates alternative materials with different post-treatments for rapid tooling mold fabrication. Chapter 5 recommends future research areas of study.

Chapter 2: Literature Review

This section will describe the current alternatives on socket modeling and manufacturing. It will also provide theoretical background regarding to the rapid prototyping techniques and material properties involved in the mold fabrication and socket thermoforming.

2.1. Socket Modeling

Several studies have focused their attention on the improvement of the comfort, fabrication time, and appearance of prosthetic sockets. This section provides an insight of relevant works conducted in the socket design and fabrication process.

2.1.1. FEA Simulation Based

Finite element analysis (FEA) has been used to achieve better understanding of the behavior of the socket-stump interface, internal loads, shear and normal stresses at skin tissues. FEA usually approximate complex engineering problems, and its accuracy to predict relevant results will depend on the determination of the material properties, boundary conditions and simplifications of the model.[23] During the last decades, many research efforts have been devoted to create three dimensional residual limbs models to be analyzed using FEA.

One challenge is gathering residual limb data. Colombo et al [4] proposed the acquisition of stump morphology using a combination of Magnetic Resonance Images (MRI), Computer Tomography (CT) and Laser Scanner techniques. MRI and CT provide information of the internal structure including bones, muscles, fat tissue and skin. A noncontact laser acquires the data of the external geometry of the residual limb providing a high accuracy three dimensional representation of the stump anatomical shape. Then the three different models are assembled to generate a definite model. Indentation tests are performed for material characterization of the soft tissue. Finally, the 3-D model is used for donning and gait simulation that aims to verify wear rate and analyze the biomechanical behavior of the socket limb interface respectively. Stereolithography (SLA) rapid prototyping technique was chosen to create the model of the socket. However, SLA material properties are inferior to traditional socket manufacturing methods.

Winson et al [24] illustrates the use of computational analysis to predict prosthetic socket fit based on the pressure distribution during single support stand. An indenter was used to record the load tolerance of pain from patient's stump. In addition, MRI technique is used to build a residual FE model. Its simulation reveals the pressure distribution on the residual limb at the surface underlying the indenter. The socket fabrication is carried out by replicating the residual limb mold using foam carving machine. The prosthetic socket is thermoformed over the liner using a plastic material. As a result, a prosthetic socket was made that induced no pain in the amputee subject.

Shuxian et al [3] proposes an innovative reverse engineering application for 3-D reconstruction of residual limb. The process starts with CT scanning of the residual limb. The contours of skin and bones are achieved through image processing. The drawback form this approach is the elevated costs. However, it can provide higher accuracy, visible bony structure and less laborious work for the physician.

Lee et al [25] proposed the modeling of the contact interface including the friction/slip conditions and pre-stresses applied on the limb within a rectified socket. The residual limb and socket were modeled as two separate. It was found that peak normal and shear stresses over the regions where socket undercuts were made reduced.

Faustini et al [23] analyzed a patellar tendon bearing prosthetic sockets with integrated compliant features designed to relieve contact pressure between the residual limb and socket.

The quasi-static FEM model was composed of a socket, liner and residual limb and. The geometry of the residual limb, liner and socket were acquired from computed tomography (CT) data of a transtibial amputee. The compliant mechanism consisted of thin-wall sections and two variations of spiral slots integrated within the socket wall. The results suggest that the integration of local compliant features is an effective method to reduce local contact pressure and improve the functional performance of prosthetic sockets.

2.1.2. 3-D Scanning Based

Francis et al [9] described a CASD/CASM method for prosthetic socket. The proposed method uses a laser scanner to digitalize a positive mold of the patient’s stump. The stump is rotated and several data points are acquired horizontally by the sensor. The data collection will generate a CAD model subject to modifications under any CAD software environment and conversion to an STL file for CAM convenience. After further transformations, an SML file, which contains a list of instructions for the head movements and material flow rate, is generated to begin the fabrication stage supported in a Rapid Prototyping technique. Fused Deposition Modeling (FDM) provided good appearance and merely acceptable material properties to the fabricated socket. The major drawback of the method relies on the manufacturing time (about 30 hrs) which was not considered to be cost-effective. The method considered here improves on this by manufacturing a mold that admits to rapid modifications.

Cheng et al [26] presented an approach that combines scanning technology, computer aided design and Rapid Prototyping. Residual limb casts from transtibial amputees are scanned using a 3-D laser digitalizer. After the CAD data is generated, modifications are performed prior fabrication using FDM technique.

2.2. Socket Manufacturing Technologies

2.2.1. Thermoforming

Thermoforming is a well known manufacturing process in which a thermoplastic sheet is exposed to elevated temperature and then deformed onto the desired mold shape. The process starts heating the thermoforming material by radiant electric heaters located on both sides of the plastic surface sheet. The duration of the heating cycle will depend on the polymer, its thickness, and color. Then, the softened plastic is placed onto the molds. In which negative pressure (vacuum generated) is used to draw a preheated sheet into the mold cavity. Normally, thermoforming molds have holes, so the vacuum line can apply a negative pressure. In prosthetic thermoformed socket the molds are inherently porous since they are plaster based [27].

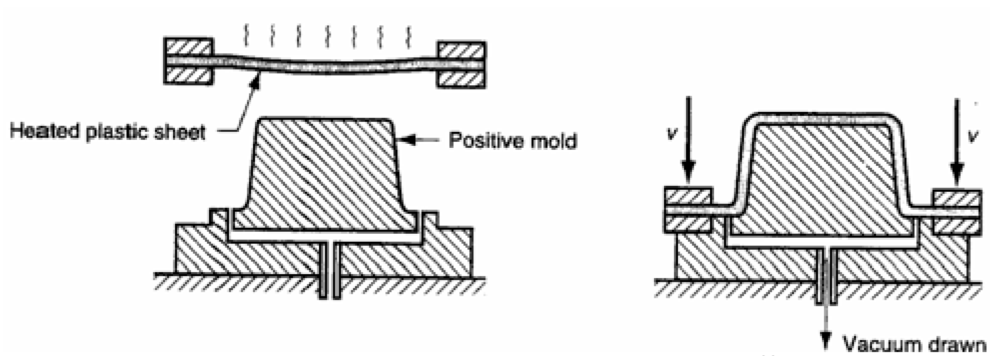

Figure 10: Thermoforming process schematic [28].

2.3. Why 3-D Printing for Rapid Tooling in Prosthetics?

Three dimensional printing provides a great alternative for RP applications in prosthetics because is the fastest, lowest cost of all RP methods, and it produces inherently porous prototypes. This technique is ideal to emulate the plaster based molds that are used for thermoforming sockets due to the following reasons.

- Plaster and the Zcorp powder have are both gypsum based

- Both 3-D Printing and plaster casting produce porous parts.
- 3-DP is an inexpensive high speed rapid prototyping process with an average build time of one vertical inch per hour, even a part several inches tall can be built within a normal work day.
- 3-D printed molds can be thermoformed and vacuumed using the traditional approach that has been performed by prosthetists for many years.
- In the case the mold needs to be slightly modified, regular plaster mixture can be adhered to the mold surface therefore the mold does not have to be reprinted.
- Current rapid prototyping technology cannot replicate the mechanical properties of a traditionally manufactured socket. Given the critical load bearing role of the socket, it is easier to generate rapid tooling of the molds than the socket itself.

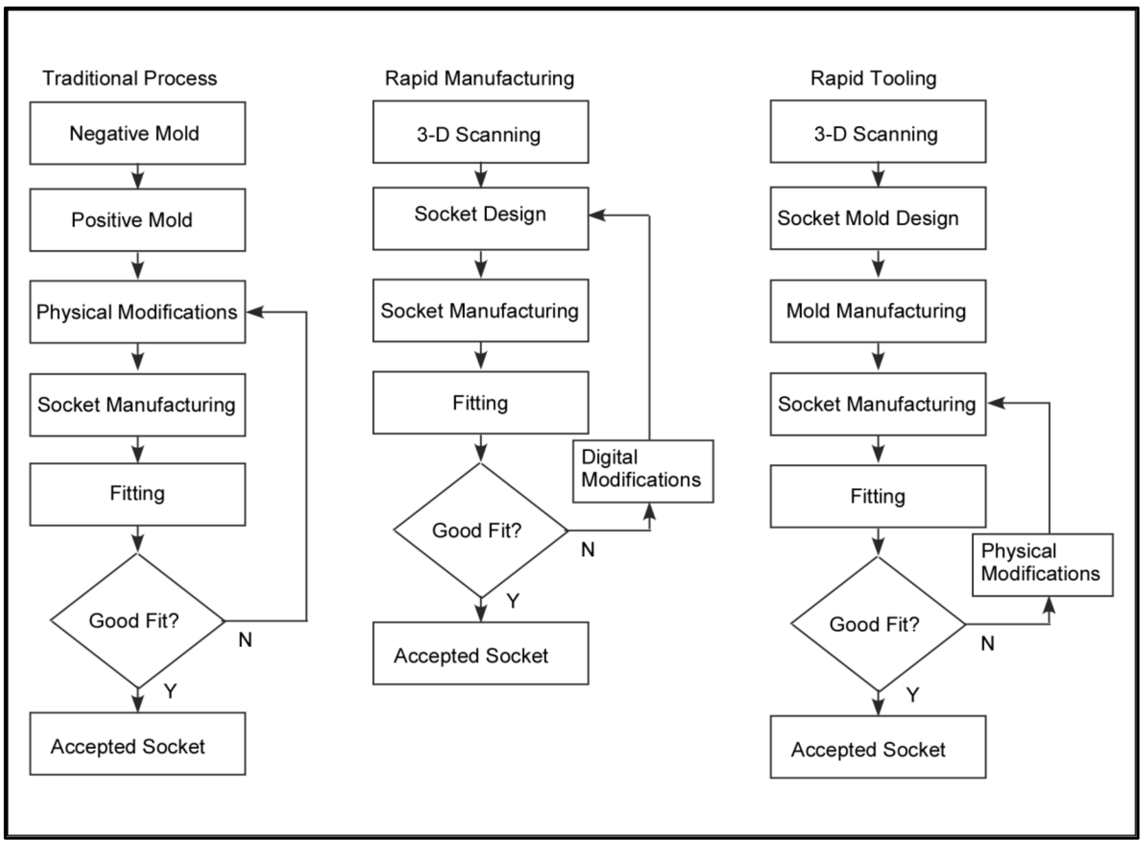

Figure 11: Rapid tooling, rapid manufacturing and traditional socket manufacturing comparison.

The rapid manufacturing of a socket is the generation of an end user element that is going to be permanently worn by the patient. The material properties of the current RP methods are not good enough to overcome the performance of the thermoformed polymer sockets. The rapid tooling of the molds is the reproduction of the residual limb being printed in a porous material that has properties similar to the traditional plaster based molds. Due to normal physical changes, residual limb shape tends to change slightly with time. Therefore, socket fabrication becomes an iterative process aiming to find the most comfortable fitting for the patient. The main advantages of rapid tooling over rapid manufacturing processes are not only that RT has the fastest fabrication speed but also the flexibility to make modifications faster. In order to make these modifications 3-D printed molds can be physically modified in the traditional way that plaster casted molds are modified. This affects new sockets fabricated via thermoforming using these molds. On the other hand, rapid manufactured sockets cannot be modified at all after fabrication. The modifications have to be done digitally to the CAD design and the socket has to be remanufactured increasing the fabrication time due to slow rates of this rapid prototyping technique.

2.3.1. Rapid Prototyping

Kenneth Cooper states that Rapid Prototyping (RP) refers to the layer by-layer fabrication of three-dimensional physical models directly from a computer-aided design (CAD). This additive manufacturing process provides designers and engineers the capability to literally print out their ideas in three dimensions. The RP processes provide a fast and inexpensive alternative for producing prototypes and functional models as compared to the conventional routes for part production [22].

“Dr. Frank Liou, professor in the mechanical engineering department at the University of Missouri-Rolla, considers RP is based on layered manufacturing, which builds a part in a layered fashion—typically from the bottom-up. It makes use of an old technology—printing. A layer of material is printed or laid down on a substrate with careful control. When various layers are stacked together, it forms a 3-D object. Conceptually, it is like stacking many tailored pieces of cardboard on top of one another. Part geometry needs to be sliced, and the geometry of each slice determined. It is computer controlled and fully automated. Therefore, it is fully compatible with the CAD/CAM system for concurrent product development."[20]

Rapid Prototyping (RP) is a technology that enables to automatically reproduce a 3-D physical object from CAD data. It consists of a 3-D printer that constructs the physical prototype commanded by the CAD data. The applications of RP are endless such as in the automotive, aerospace, medical, and consumer products industries. For instance, it can be used to test shape, size or strength of designs, produce complicated geometry shapes and fabricate end user products. RP decreases the time spent in manufacturing processes allowing the manufacturers to commercialize their products faster and cheaper.

Even though RP can be performed through various techniques, a common process is taken in this technology. First, a 3-D model is generated using a Computer Aided Design software package such as Solid Edge, Solid Works or PROEngineer. Next, the model is converted to a STL file which is a file format commonly used in the RP industry. This format represents three dimensional models as an assembly of triangles. Then, the STL files are sliced into layers that will be 3-D printed in an automated fashion. Post processing may be needed to improve the product quality.

Rapid prototyping can be used to generate parts directly. This technique is called rapid manufacturing and has been previously used in prosthetics. Previous research efforts have used fused deposition manufacturing for socket fabrication. Other approach of rapid prototyping is rapid tooling which is the fabrication of the tooling for the further manufacturing of the final part. This work considers rapid tooling of the molds because it offers several advantages in the process fabrication. These include improved material properties of final socket, ease to perform modifications, lower costs and faster fabrication times. Next are described the most common RP techniques.

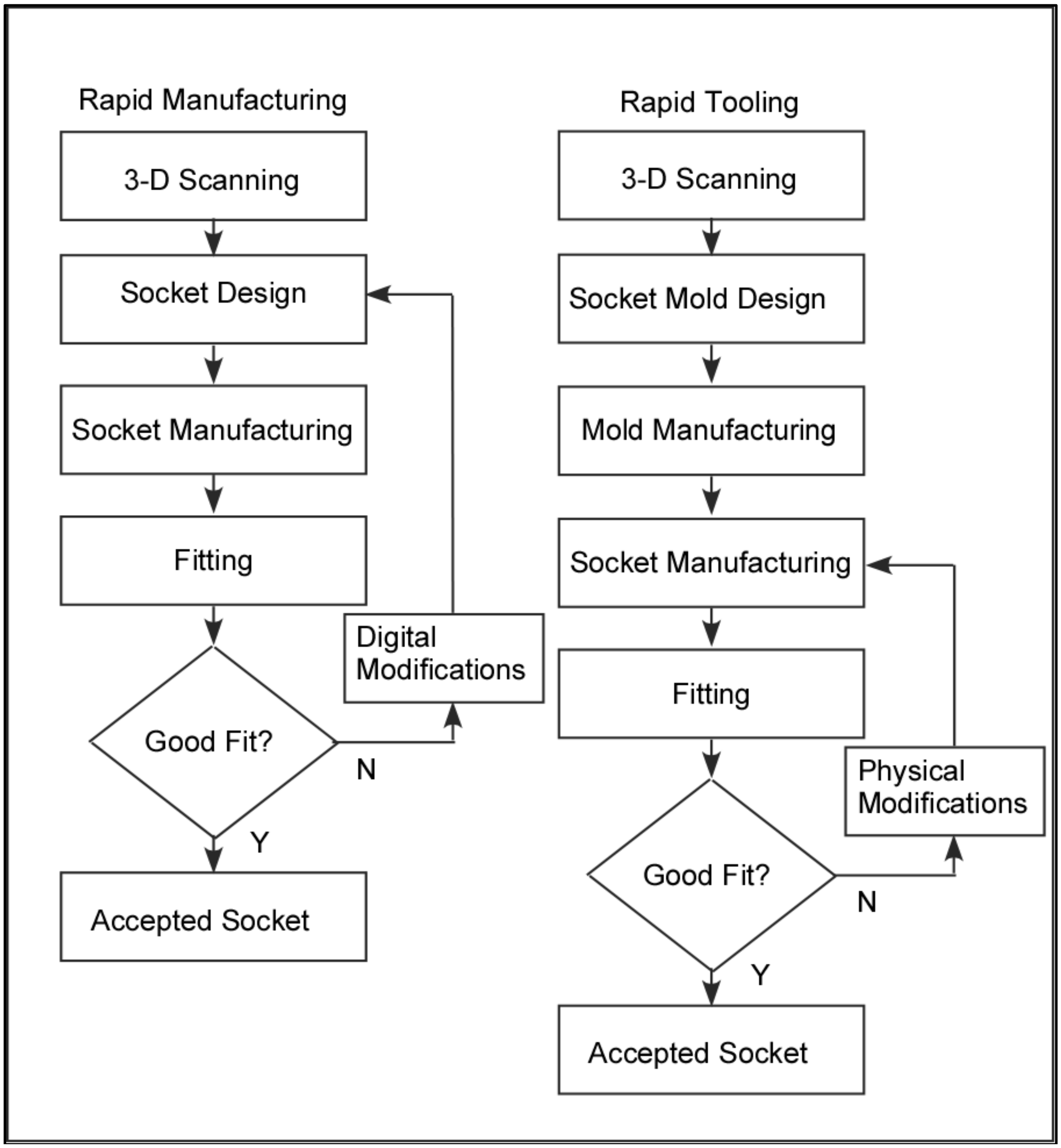

Figure 12: Comparison between rapid tooling and rapid manufacturing.

Figure 12 shows the schematic comparison between rapid tooling and rapid manufacturing. This thesis considers rapid tooling of molds as the best option of rapid prototyping for sockets manufacturing in prosthetics due to the following reasons. Current fused deposition modeling materials do not meet the requirements needed in a prosthetic socket in terms of strength and comfort. In addition, Rapid tooling of the molds creates a more flexible process which is ideal for such an iterative process as socket manufacturing. This method provides the opportunity to physically modify the 3-D printed mold or digitally modify the mold and reprint it. Finally, Rapid tooling offers lower costs and faster fabrication rates than rapid manufacturing preserving the mechanical properties of traditional methods.

2.3.1.1. Three Dimensional Printing

Three Dimensional Printing (3-DP) technology was originally developed at Massachusetts Institute of Technology (MIT) in 1993 and now commercialized by ZCorporation. The process starts with a bin filled of powder in a platform. An ink jet head prints a liquid binder material over desired regions to be transformed as solid parts. Additional powder layers are applied and selectively printed after the platform has been lowered. The process is repeated until the part geometry is obtained. In other words, this technique prints 2-D images per layer on the powder bed from bottom to top. Recently, a new gypsum based material and a new binder system have replaced the initial starch based powder and the water based binder.

It is important to state 3-D printing produces weak parts initially when removed from the powder bed, but the porosity characteristic of the material enables the improvement of the mechanical properties. The final porous prototype is post-treated to improve strength, surface finish, durability and overall quality. Post processing consists of removing excess of unbound powder with pressurized air and infiltrating the parts using wax, epoxy, Cyanoacrylate (CA) or other sealants. The main advantage of using inkjet printing technology is that the process is able to operate at high speeds with minimal costs.

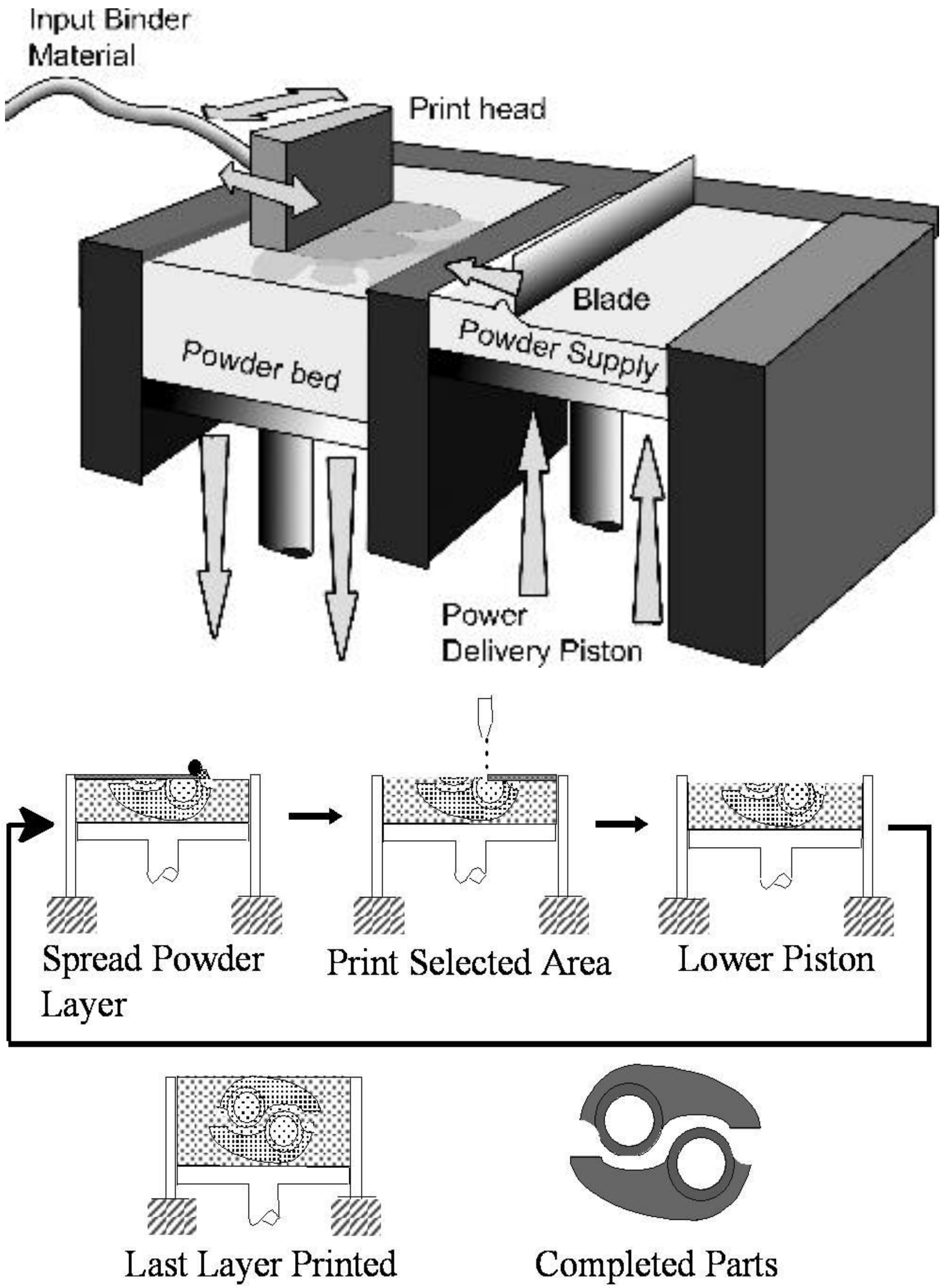

Figure 13: 3-D ink jet printing apparatus schematic and process [21].

Current Zcorp printers available in the market are described in the following table.

Table 1: Technical specifications of Zcorp printers [29].

	ZPrinter® 310 Plus	ZPrinter® 450	ZPrinter® 650
Application	Most Affordable, Great Parts	Most Affordable Color, Easy to Use, Office Friendly	Premium Color, Easy to Use, Largest Build Size, Office Friendly
Multicolor		✓	✓
Automated		✓	✓
Build Speed	2-4 Layers per Minute	2-4 Layers per Minute	2-4 Layers per Minute
Build Size	8 x 10 x 8 inches (203 x 254 x 203 mm)	8 x 10 x 8 inches (203 x 254 x 203 mm)	10 x 15 x 8 inches (254 x 381 x 203 mm)
Material Options	High Performance Composite, Direct Casting, Elastomeric, Investment Casting	High Performance Composite	High Performance Composite
Layer Thickness	0.0035 - 0.008 inches (0.089 - 0.203 mm)	0.0035 - 0.004 inches (0.089 - 0.102 mm)	0.0035 - 0.004 inches (0.089 - 0.102 mm)
Resolution	300 x 450 dpi	300 x 450 dpi	600 x 540 dpi
Number of Print Heads	1	2	5
Number of Jets	304	604	1520
File Formats for Printing	STL, VRML, PLY, 3DS, ZPR	STL, VRML, PLY, 3DS, ZPR	STL, VRML, PLY, 3DS, ZPR
Equipment Dimensions	29 x 34 x 43 inches (74 x 86 x 109 cm)	48 x 31 x 55 inches (122 x 79 x 140 cm)	74 x 29 x 57 inches (188 x 74 x 145 cm)
Equipment Weight	255 lbs (115 kg)	425 lbs (193 kg)	750 lbs (340 kg)
Power Requirements	90-110V ~ 50-60Hz 5.3A 100-120V ~ 50-60Hz 4.3A 200-240V ~ 50-60Hz 2.4A	100-240V ~ 50-60Hz 15-7.5A	100-240V ~ 50-60Hz 15-7.5A
Network Connectivity	TCP/IP 100/10 base T	TCP/IP 100/10 base T	TCP/IP 100/10 base T
Workstation Compatibility	Windows® XP Professional and Windows Vista® Business / Ultimate	Windows® XP Professional and Windows Vista® Business / Ultimate	Windows® XP Professional and Windows Vista® Business / Ultimate
Regulatory Compliance	CE, CSA	CE, CSA	CE, CSA
Special Facility Requirements	None	None	None

2.3.1.2. Fused Deposition Modeling

Fused deposition modeling (FDM) is a layer by layer extrusion based rapid prototyping process. This process extrudes a previously liquefied thermoplastic polymer through a controlled nozzle that travels throughout the XY plane. The nozzle deposits small quantities of the polymer tracing the cross sectional boundary layer and subsequently fills it with parallel filaments of the thermoplastic. The material deposited is used to create the part itself and supports where required. Recently, water soluble supports have been developed for complex geometries. The lower platform is maintained at a lower temperature to promote the polymer solidification. Then the platform lowers to initiate the deposition process again over the previous layer. This technique uses a wide variety of materials including polycarbonate, polyphenylsulfone (PPSF) and, most commonly acrylonitrate butadiene styrene (ABS) [21].

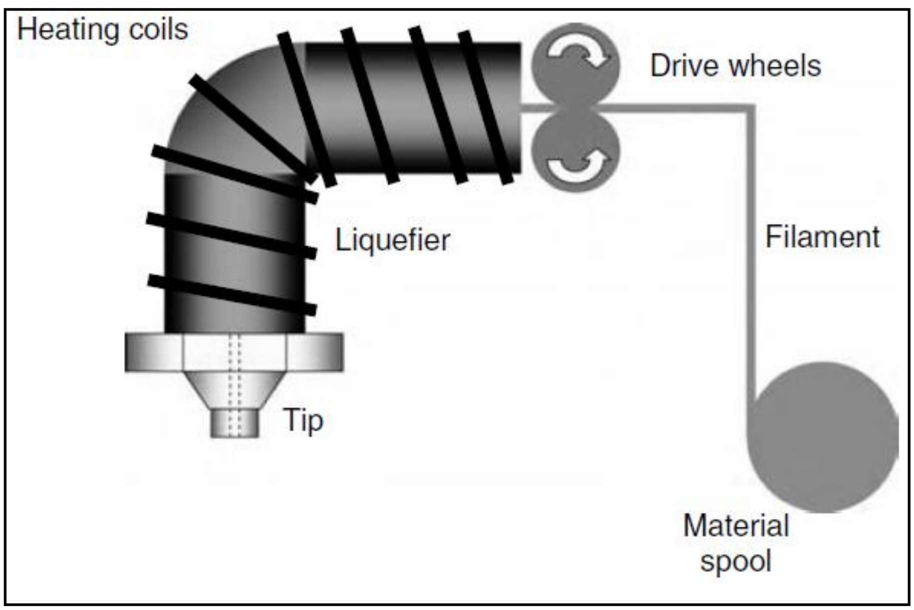

Figure 14: Fused deposition manufacturing apparatus [20].

2.4. Material Property Requirements of Socket Molds

This thesis examines potential replacement mold materials suitable for rapid prototyping of the thermoforming molds. The next sections will be devoted to overview the different material properties taken into account for the material characterization of the different materials and post-treatments available for the rapid tooling molds.

2.4.1. Flow through Porous Media

Porous medium presents a rigid or microscopic deformable solid matrix with interconnected voids in the inner structure. Conventionally, the pore size is much smaller than the length of the specimen. Laboratory samples of porous medium are generally homogeneous, in the sense of the irregular pore structure reproduces itself in the various portions of the sample [30]. Fluids fill the voids and find their way through the channeled interior structure suffering a significant pressure drop, due to the narrow passages, but reaching a stable flow rate.

Flow through porous media phenomena is important in traditional prosthetic socket manufacturing. The molds used for thermoforming the plastic sheet are connected to vacuum lines, and air has to travel through the micro channels of the material. Measurements and results related to the flow through porous media will be discussed in chapter 3 and 4.

2.4.2. Mechanical Strength

Mechanical properties are usually calculated from a stress-strain curve obtained by measuring the response of the material under specific loads. For ductile materials, the mechanical properties are obtained from a tensile test. The curve typically goes through an elastic region, which its maximum point is called yield strength, and a plastic region, which its maximum point is called tensile strength, followed by a breaking point or failure.

For brittle materials, the tensile test is not suitable since the material usually cracks when is placed in the grips of the tensile test machine. Instead, a bend test is more appropriate to test brittle materials where a stress-deflection curve can be obtained to calculate the mechanical properties of the material. The material strength is described by the flexural strength and the modulus of elasticity by the flexural modulus [31].

Porous materials can be classified as brittle due to their mechanical behavior. In these materials, the yield strength, flexural strength and breaking strength are all the same. Porous materials usually have a better performance under compression loads than tensile loads. In fact, in the three points bending test the fracture of the specimen starts on the side exposed to tensile stress.

Since plaster of Paris and Zcorp materials are brittle, three point bending tests will be used to assess flexural strength as described in chapter 3 and 4.

2.4.3. Wear Rate

During the modification stage of the mold manufacturing, prosthetists remove material from the molds using sand paper and rasp. Adding vermiculite to the plaster of Paris mixture is a common practice when generating the mold. In addition, this material adds enhanced pneumatical permeability, reduces the overall weight of the mold and increases the wear rate of the mold. However, the mold cannot wear to easily or it would not survive the necessary handling without undesired changes.

Wear rate measures the ability to remove material from the outer surface of a component. This process can be achieved by mechanical attack of solids or liquids. Wear is known as the surface damage or removal of material form one or both of two solid surfaces in a sliding, rolling, or impact motion relative to one another [32]. In the case of the rapid tooling molds, the wear obtained can be defined as abrasive wear. This type of wear occurs when material is removed from a surface by contact with hard particles.

2.5. Conclusions

Throughout this chapter the state of the art on the socket modeling and manufacturing were described. In addition, the most important material properties involved during the thermoforming process were analyzed. Finally, several reasons were stated to demonstrate the potential suitability of 3-D printing technique for rapid tooling mold manufacturing.

Chapter 3: Material Characterization

One objective of this work was to analyze the performance of the different materials available for socket molds manufacturing on the Zcorp printer. This chapter illustrates the material characterization process including specimen fabrication, apparatus configuration and testing methods. It also documents the results of plaster of Paris-based specimens.

3.1. Introduction

The aim of material characterization in this work is to provide a quantitative comparison of the materials properties relevant in the socket manufacturing. For this matter, tests have been selected to obtain the necessary data from the candidate materials.

3.2. Materials and Preparation Methods

Plaster of Paris is a powder obtained from heating gypsum to 150°C. It is used for the molding application to its particular characteristics that when mixed with water forms a paste which liberates heat and hardens[33].

Vermiculite is a natural mineral that has the property to expand in the presence of heat creating a process called exfoliation. Vermiculite is the mineralogical name given to hydrated laminar magnesium-aluminum-ironsilicate which resembles mica in appearance[34].

For preliminary tests, the main material used was a solidified mixture of plaster of Paris, water and vermiculate when appropriate. The mixture recipe proposes 1.7 grams of plaster per milliliter of water in the case of 100 % plaster concentration. Vermiculate is added to water-plaster mixtures to decrease the weight of the socket molds due to its incredibly low specific weight. Moreover, the inclusion of vermiculate facilitates the manual removal of material that is performed manually by the prosthetists when performing mold modifications. In this study, different concentrations of plaster-water-vermiculate were tested. The first material analyzed was plaster of Paris since it is the material traditionally used by prosthetists for mold manufacturing.

3.3. Determination of Pneumatic Permeability

The determination of the pneumatic permeability provides information concerning to the air flow through the porous media. This is relevant to the socket manufacturing since the thermoforming process includes vacuum pumping of the mold.

3.3.1. Darcy's Model

The physical model that best defines the pneumatic permeability is Darcy's Model. In this model, the pneumatic permeability is obtained as the coefficient of various components such as average flow of air trough the material, differential pressure across the material, length and area of the specimen to be tested.

Darcy's law is the model that describes the flow of homogeneous fluids in porous media. A schematic of the classical experiment setup is shown in Figure 15. It consist of a filter bed of height h bounded by horizontal plane areas of equal size A. If open manometer tubes are attached at the upper and lower boundaries of the filter bed, the liquid rises to the heights h_2 and h_1 respectively from an arbitrary datum level.

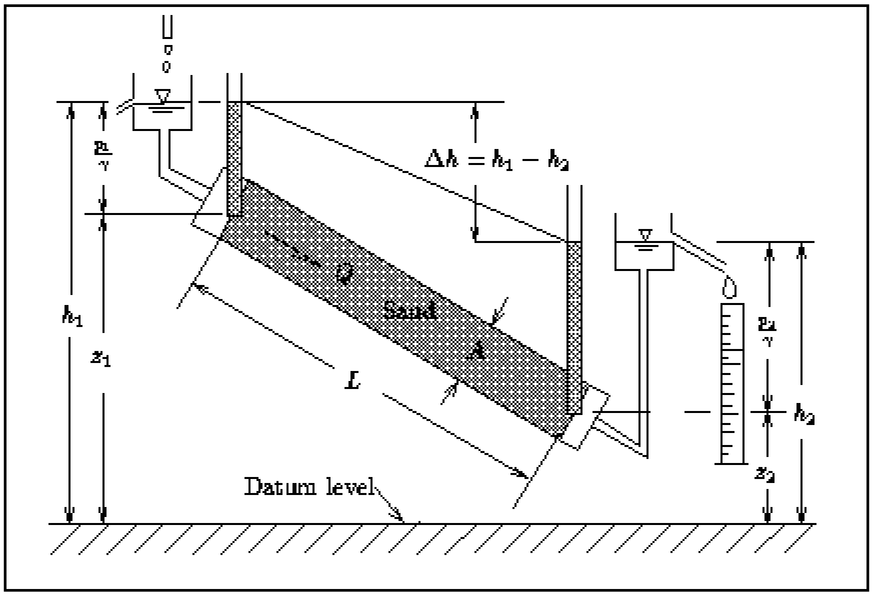

Figure 15: Darcy's experiment [35].

Darcy's findings show the relationship between the volumetric flow, area, elevation, pressure and a constant of proportionality

$$Q=Ak\,\Delta[(p/\rho g+z)]/L \qquad (1)$$

where, Q is the volumetric flow rate [m^3/s or ft^3/s], A is the flow area perpendicular to L [m^2 or ft^2], k is the permeability [m/s or ft/s], L is the specimen length [m or ft], p is the fluid pressure [Pa or psi], g is gravity [m/s^2 or ft/s^2] and, z is the elevation [m or ft].

3.3.1.1. Pneumatic Permeability

Pneumatic permeability is the capacity of a porous medium to conduct gas in the presence of a gas pressure gradient measured as the ratio of volumetric flow through a specimen to the resultant pressure drop across it. It is also known as pneumatic conductivity or permeability to air. Generally, Pneumatic permeability is calculated from experimental data obtained from a permeameter which is an apparatus that emulates Darcy's classical experimental set up.

3.3.2. ASTM Standard for Pneumatic Permeability Measurements

The apparatus set up, specimen preparation, measurements and testing procedures were supported from ASTM Standard D6539-00: Test Method for Measurement of Pneumatic Permeability of Partially Saturated Porous Materials by Flowing Air. The following formulae are provided by the Standard.

$$Q_{av} = Q \frac{P_B}{\left(P_I + P_B - \frac{\Delta P}{2}\right)} \quad (2)$$

where, Q_{av} is the volumetric flow at specimen average pressure and test temperature [m^3/s], Q is the flow of air out of specimen [m^3/s], P_B is the test barometric pressure [Pa], P_I is the specimen inlet gage pressure [Pa], and ΔP is the specimen pressure drop [Pa].

$$K_p = \frac{Q_{av}}{\Delta P}\frac{L}{A}\mu \cdot 1.013 \times 10^{12} \quad (3)$$

where, K_p is the pneumatic permeability, [darcy], Q_{av} is the volumetric flow at specimen average pressure and test temperature [m^3/s], ΔP is the specimen pressure drop [Pa], L is the specimen length [m], A is the specimen cross-sectional area [m^2], and µ is the viscosity of air at the test temperature [Pa·s].

3.3.2.1. Specimen Fabrication

A 2’’ (diameter) x 3’’ (length) cylindrical specimen fulfills the ASTM requirements. After several experimentations, the test specimens are obtained from pouring the desired mixture of Plaster-water-vermiculate into a PVC pipe with the previously mentioned dimensions. After at least 2 days of curing time at room temperature, the specimens can be tested.

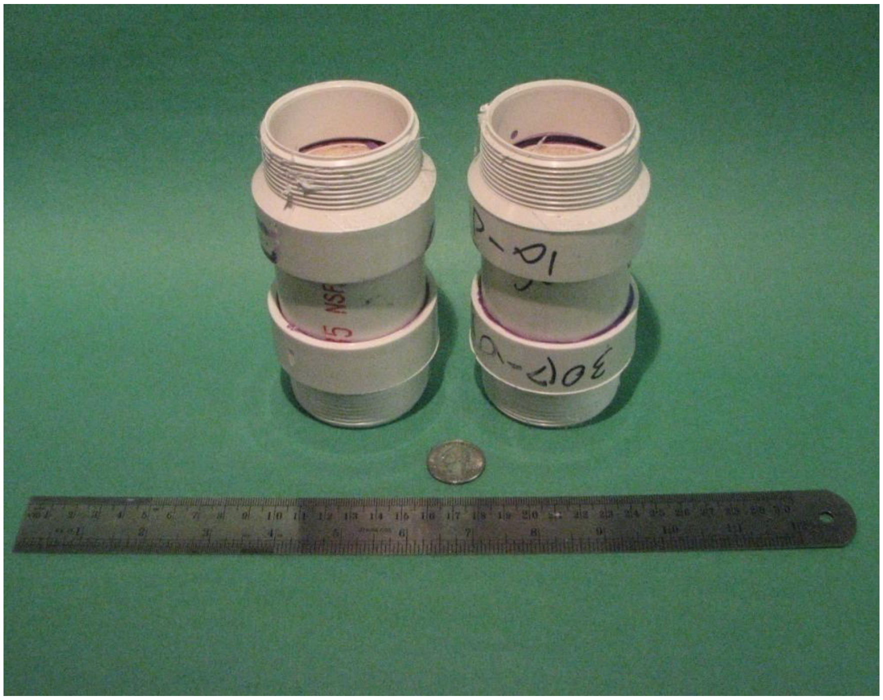

Figure 16: Plaster of Paris based specimens in PVC pipes.

The rapid prototyped parts are printed in the 3-D printer Zcorp using an STL file extension. The prototype is modeled using any CAD software and saving the file in the STL extension. In this case the specimens were designed using Solid Edge.

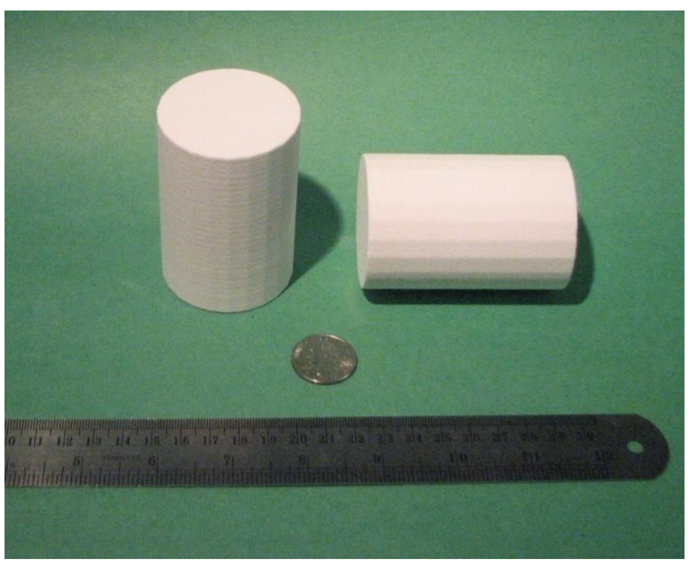

Figure 17: Rapid prototyped specimen for pneumatic permeability test.

After the rapid prototyped specimens were cleaned and post treated if needed, they were dip coated in rubber coating. This treatment was applied to ensure the air is going to flow through the specimens and not through the clearance between the specimen and the PVC pipe. Masking tape was applied to the ends to avoid the coating clogging the pores where the air was going to flow. After one day of drying at room temperature, one end of a 2 in diameter 3 in length PVC pipe was covered with masking tape and partially filled with rubber coating. The already sealed specimen was immersed into the pipe and placed in the center of the pipe. The excess of the rubber coating that overflows after the specimen was embedded was cleaned. The specimens were cured overnight and the proper fittings were attached to both ends of the PVC pipes that enable the connection to the pneumatic permeability apparatus. Finally, the perimeter of the specimen was sealed using silicone to ensure the air flow through the specimen's micro channels.

3.3.3. Apparatus Configuration

This experimental apparatus was designed using 1.5'' diameter PVC pipes connected through several fittings to achieve amplifications from the air line to the specimens and reductions from the specimens to the outlet. A differential pressure gage was installed to acquire the pressure drop along the specimens. The differential pressure sensor provides an output voltage proportional to the pressure being applied. For this set up, the sensor used was the PX26-030DV from omega with a range of 0-30 psid. The most important measurements in this experiment were pressure and volumetric flow rate. The data acquisition for these two parameters is described next.

The pressure sensor was used to measure the pressure gradient and pressure at the inlet of the specimens. The pressure sensor generates an output voltage proportional to the pressure applied. The excitation voltage for the sensor was 5 Volts DC. The voltage was measured using a voltmeter that has the capability to measure DC voltage in millivolts.

The volumetric flow rate was calculated using a bubble meter technique. This technique uses a container with a fixed volumetric capacity and a stopwatch. For this experiment, the time recorded was the time needed to replace one litter of water with the air that went through the specimens. The stopwatch was able to record data with a resolution of tenths of seconds.

Figure 18: Pneumatic permeability set up.

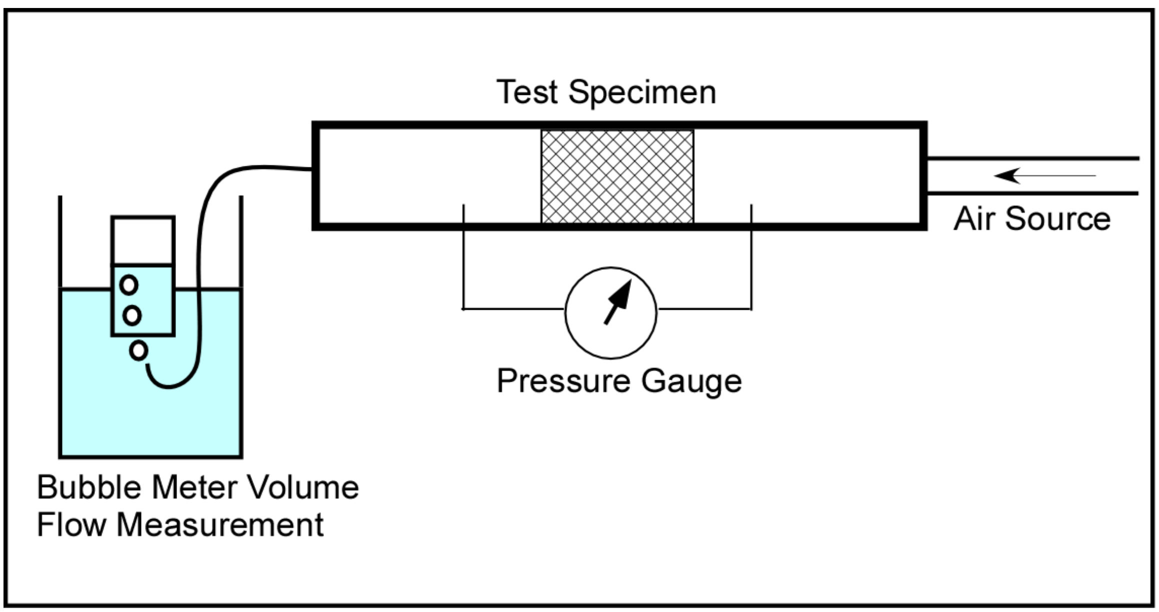

Figure 19: Pneumatic permeability schematic apparatus.

To verify that the pneumatic permeability set up was perfectly sealed preliminary steps had to be undertaken. Initially, the complete set up was immersed in water to identify any leakage while the air was flowing across the apparatus. If a leakage was found in a permanent connection, silicone was applied to the connection. However, if the leakage was found in an interchangeable connection Teflon tape was applied to the internal threads of the connections. Finally, the set up was run using identical specimens expecting to obtain similar readings in the pressure differences and flow rate.

After the apparatus was calibrated, the specimen to be tested was coupled to the system. After the air line was open Three to five minutes were need by the system to become stable and record the voltage output and time. Next, the pressure was slightly increased and the process is repeated until 4 readings are recorded for each specimen.

3.3.4. Results

The following table is a typical table of results from the data obtained in the pneumatic permeability tests. The first column labeled V1 is the reading from the output of the differential pressure placed at the ends of the specimens in millivolts. The second column labeled ΔP is the conversion from millivolts to units of pressure using the PX 26 differential pressure transducer specifications of output range. The third column displays the amount of time spent to fill one liter of air using bubble meter technique. The next column is the air flow rate across the specimens. The column labeled as V2 displays information of the absolute pressure obtained from the transducer. The next column is the conversion from millivolts to pressure units using the sensor specifications. The last two columns display the results using the average flow rate and the pneumatic permeability using the formulas form the ASTM standard.

Table 2: Typical data obtained from pneumatic permeability test.

V1 (mv)	ΔP (Pa)	time (s)	flow (m^3/s)	V2 (mv)	inlet press (Pa)	AVG FLOW (m^3/s)	K (darcy)
2.50	5171	40.63	2.46E-05	2.74	5667	2.38E-05	0.807
2.03	4198	50.35	1.98E-05	2.25	4653	1.93E-05	0.806
1.50	3102	68.80	1.45E-05	1.70	3516	1.42E-05	0.803
1.28	2647	81.09	1.23E-05	1.48	3061	1.21E-05	0.800

3.4. Determination of Flexural Strength

In the three-point bending test a load is applied at three points causing the bending of the specimen followed by the final failure of the specimen. In this arrangement, the load is applied by a loading nose at midspan of the two supports. The curve obtained from a bending test is commonly plotted showing the relationship between stress and deflection.

The apparatus set up, specimen preparation, measurements and testing procedures were supported from ASTM Standard D790-03: Test Method for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials. The following formulas are provided by the Standard

$$\sigma_f = \frac{3PL}{2bd^2} \quad (4)$$

where, σ is the stress in the outer fiber at midpoint, [psi], P is the load at a given point on the load-deflection curve, [lbf], L is the support span, [in.],b and d are the width and depth of beam tested, [in.].

Specimen preparation, measurements and testing procedures were supported from ASTM Standard D790-03: Test Method for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials. The most important characteristics of the test are

- Specimen Geometry: 6 in x 1.5 in x 0.35 in.
- Rate of crosshead motion: 0.0125 in/s.
- Support span: 5.25 in.

3.4.1. Specimen Fabrication

Plaster mixture specimens were fabricated using the following sequence. A negative silicone mold is previously sprayed with a mold release agent and filled with the appropriate mixture of plaster and vermiculate. The excess of material is removed carefully so a horizontal surface is obtained. The curing time for the plaster mixture is about 3 hours before the specimen can be released from the mold. The specimen can be tested after 2 days.

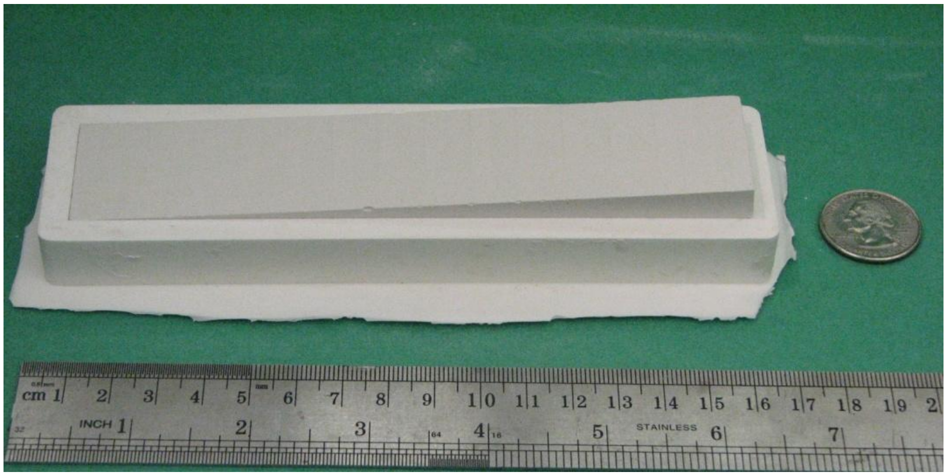

Figure 20: Molded plaster specimen.

The rapid prototyped specimens were printed in a standard ZCorp printer using STL files with the appropriate dimensions. Both rapid prototyped and molded specimens are prismatic bars with 6'' long, 1.25'' wide and 0.35'' thick.

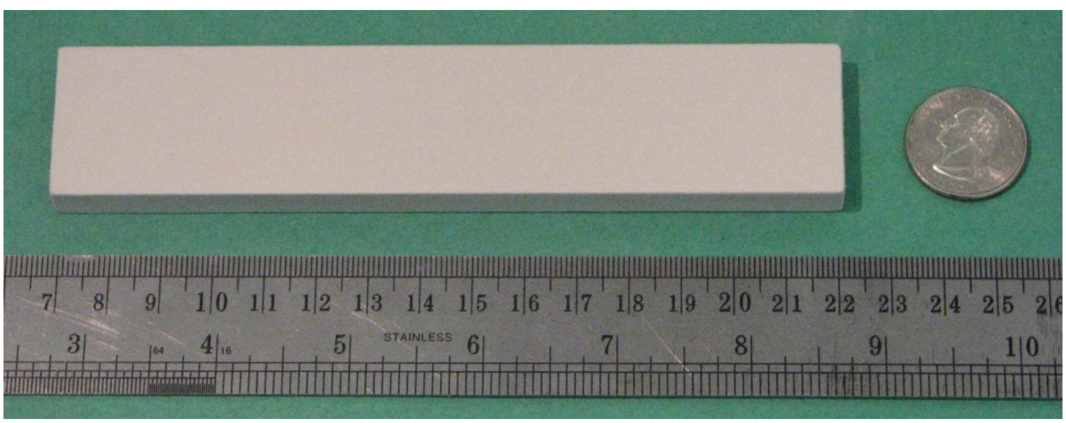

Figure 21: Zcorp printed specimen for three point bending test.

3.4.2. Apparatus Configuration

MTS Universal Testing Machine was the equipment used for the execution of the three point bending test. An external low force sensor, LC101 stainless steel “S” beam load cell purchased in omega, was added to the system in order to obtain more accurate readings at lower forces. The bending fixtures were installed onto the testing machine with a span of 5.25 in. on the lower supports. The crosshead motion rate was fixed to be 0.00125 inches per seconds.

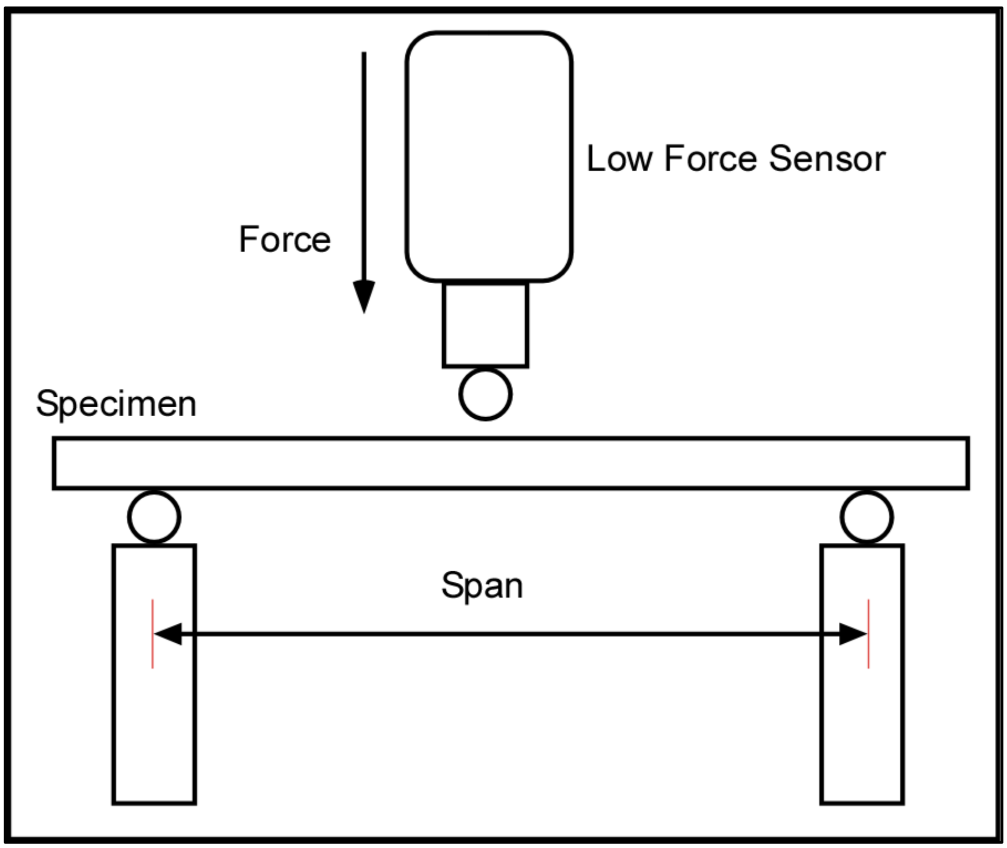

Figure 22: Three point bend test schematic apparatus.

Figure 23: MTS universal testing machine with bending fixtures and low force sensor.

The data recorded using the MTS data acquisition software. The software writes a .txt file with the information of the displacement and force applied during the test. This data can be easily imported in excel software spreadsheet to perform calculations. In addition, each specimen's dimensions was measured with a caliper to be used in the stress calculations. The following graph displays the information obtained from a three point bend test of a specimen.

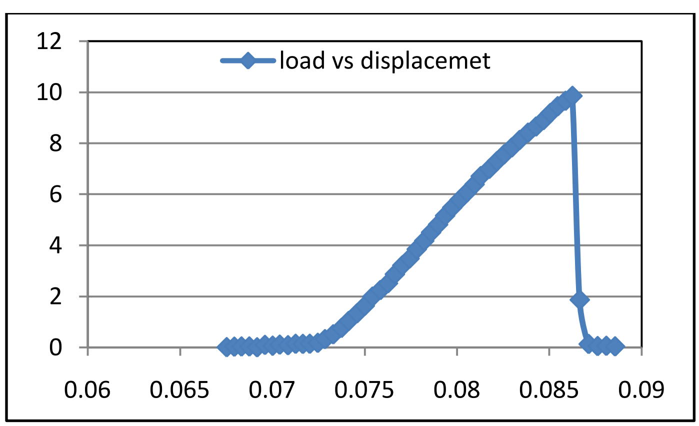

Figure 24: Typical load vs. displacement graph from three point bend test.

In this load vs displacement graph, it can be observed the brittle behavior of the porous samples since no plastic deformation ocurred during the test.

3.5. Wear Testing

Traditionally, vermiculate was added to the plaster of Paris mixture to facilitate the removal of material from the porous material molds. In order to improve socket fit this material property has a key role in the socket manufacturing since reshaping is fundamental in the final stages of the socket mold fabrication. The three point bending test specimens were used to directly measure the wear rate of the different materials and post-treated materials. The following figure shows in detail the apparatus and experimental set up that was used during the tests.

Figure 25: Wear test set up.

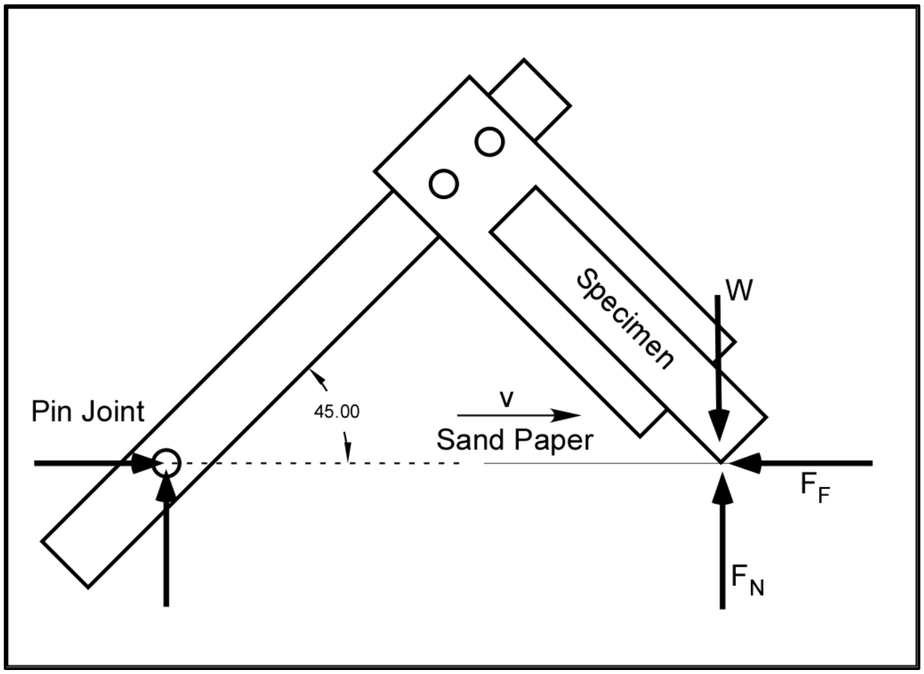

Figure 26: Free body diagram of wear test setup.

From the summation of moments at the pin joint, it can be found that F_N = W only if F_F acts through the pin line of action. Therefore this distance was minimized in the wear test setup to maintain constant normal forces over the specimen and avoid moment due to friction force.

The motion rate of the specimens over the sand paper was 2 in/sec and the wear rate was obtained only in one direction covering 8 inches over the sand paper. Each pass of the specimen was done using fresh sand paper. The specimen rests in a 45 angle which minimizes frictional forces that tend to elevate the specimen form the sanding surface. The specimens are sanded over 3M coarse grain sand paper with reference 332U 60 made of aluminum oxide.

Five specimens were tested for each available material. To quantify the wear obtained on the specimens, the resulting worn surface area was scanned. The area of each specimen was obtained from each scanned image using a dimension tool in Canvas software.

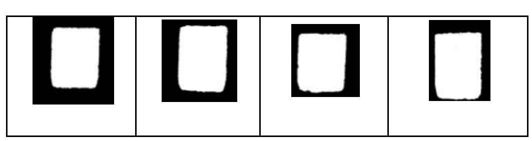

Figure 27: Scanned images of exposed areas after wear rate test.

The following graph illustrates the substantial difference in the wear rate of the specimens using pure plaster of Paris and the mixture using 30% of vermiculite in volume. These two materials were analyzed due to their importance in real life prosthetic application.

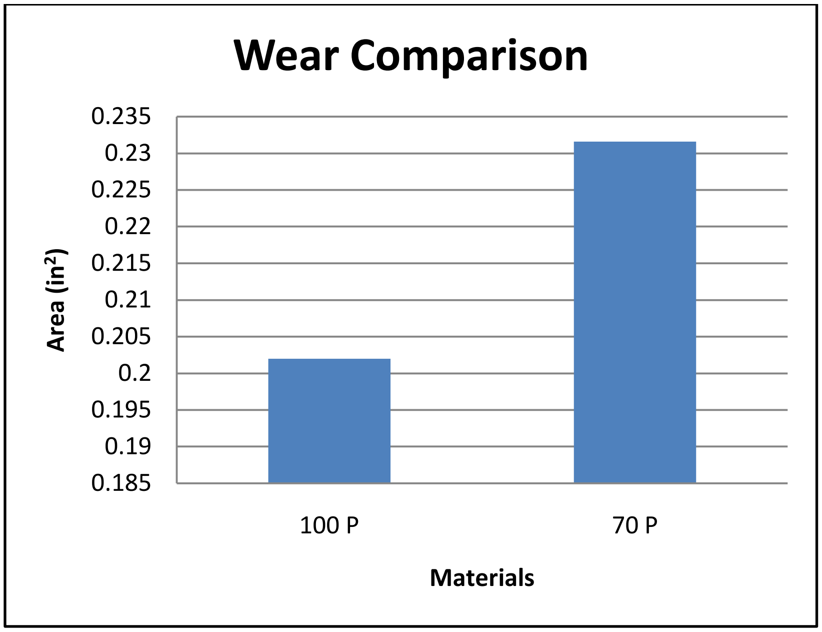

Figure 28: Wear comparison of traditional materials.

The results illustrated in the graphs are the measured area exposed at the corner where the specimens were sanded. Needless to say the amount of area exposed is proportional to the wear rate of the material. It can be observed that including vermiculate in the plaster-water mixtures increases the wear rate of the hardened material.

Chapter 4: Evaluation of Alternative Materials

4.1. 3-D Printing Powder

Two different powder were analyzed during this work. The basic information and advantages of each powder are mentioned next.

Zp 130 is the traditional powder used by the three dimensional printers commercialized by Zcorp. The main advantages from this material are the high feature and color definition, excellent dimension accuracy and great strength if infiltrated. The prototypes printed with this powder do not stand water because in presence of water they disintegrate.

Zp 140 is a material that produces high definition three dimensional parts with the possibility of water curing. Another outstanding property of zp 140 is its brightness. In fact, zp 140 prototypes are 180% whiter than zp 130 prototypes [36]

The water curing can be performed using two techniques that include dipping or misting. However, this powder is not widely used

4.1.1. List of Materials and Post-treatments

Cyanoacrylate is a high strength adhesive used to bond surfaces and is commonly named as CA. Generally, CA is an acrylic resin which rapidly polymerizes in the presence of water forming long, strong chains, joining the bonded surfaces together[37]. CA is commercialized as super glue or krazy glue. The infiltration of the specimens used in this work was done using the commercially distributed Cyanoacrylate from Zcorp called ZBond which has a special slow cure formula.

Another traditional infiltrant used in 3-D printed parts is epoxy. However, using epoxy as a post treatment for this mold rapid tooling is not convenient. The post treated layer will become significantly strong making it harder for further modifications. Also, the epoxy will completely seal the pores of the material making impossible the flow through the molds which is undesirable in this application.

4.1.2. Zp 130

Different post-treatments were applied to the rapid prototyped specimens. For the zp130 specimens two approaches were used. Using different mixture ratios of acetone and Cyanoacrylate, 4:1 and 8:1, the specimens were infiltrated. The idea of these mixtures is to infiltrate the porous material with the Cyanoacrylate but leaving some of the pores open, so the air can travel through the micro-channels inside the material. Experimental data has proven that specimens treated with pure Cyanoacrylate performed poorly in the pneumatical permeability test since all the pores were clogged and no flow was obtained through the specimens.

The 3-D printed specimens were cleaned and slightly sanded without affecting the original dimensions. The infiltrant mixture was applied slowly over the surface using a pipette providing sufficient time to penetrate the material. Infiltrant over saturation of the specimen was avoided by applying small amounts of infiltrant and removing it after the material was unable to absorb it.

The additional post-treatment applied to the zp 130 specimens was steaming the surface using a steam generator commercially used to remove wrinkles from clothing. This procedure was performed in a closed container for 2-3 minutes to allow the vapor to treat the surface. A special care has to be taken to avoid condensate water get in contact with the printed parts. Zp 130 printed parts will disintegrate if water is directly applied to them.

4.1.3. Zp 140

Water was applied by two different ways to the zp 140 prototyped specimens. Dipping the specimens in water for a short period until no bubbles came out from inside and misting the surface using a regular spray bottle. Since the specimens were small, only 30-45 minutes drying time was required after dipped. The drying time for the sprayed specimens was 10-15 minutes.

The following list shows the available materials and their proper post-treatments that were used to fabricate the testing specimens.

Table 3: Available material with different post-treatments.

Material	Post-treatment	Reference
Plaster of Paris	None	100% Plaster
Plaster of Paris 30% Vermiculate	None	70% Plaster
Plaster of Paris 50% Vermiculate	None	50% Plaster
Plaster of Paris 70% Vermiculate	None	30% Plaster
zp 130	None	zp 130 untreated
zp 130	Infiltrated with pure CA	zp 130-CA
zp 130	infiltrated with Acetone:CA (4:1 ratio)	zp 130-CA (4:1)
zp 130	infiltrated with Acetone:CA (8:1 ratio)	zp 130-CA (8:1)
zp 130	Steamed surface	zp 130-V
zp 140	None	zp 140 untreated
zp 140	Misted with water	zp 140-M
zp 140	Dipped in water	zp 140-D

4.2. Measurements of Performance

The performance of the Zcorp materials were analyzed and compared to traditional plaster- based materials in the areas of flexural strength, permeability, and wear rate using the methods described in chapter 3. The results are summarized in the following sections.

4.2.1. Strength

The following graph was obtained from the three point bending tests applied to different materials with different post treatments.

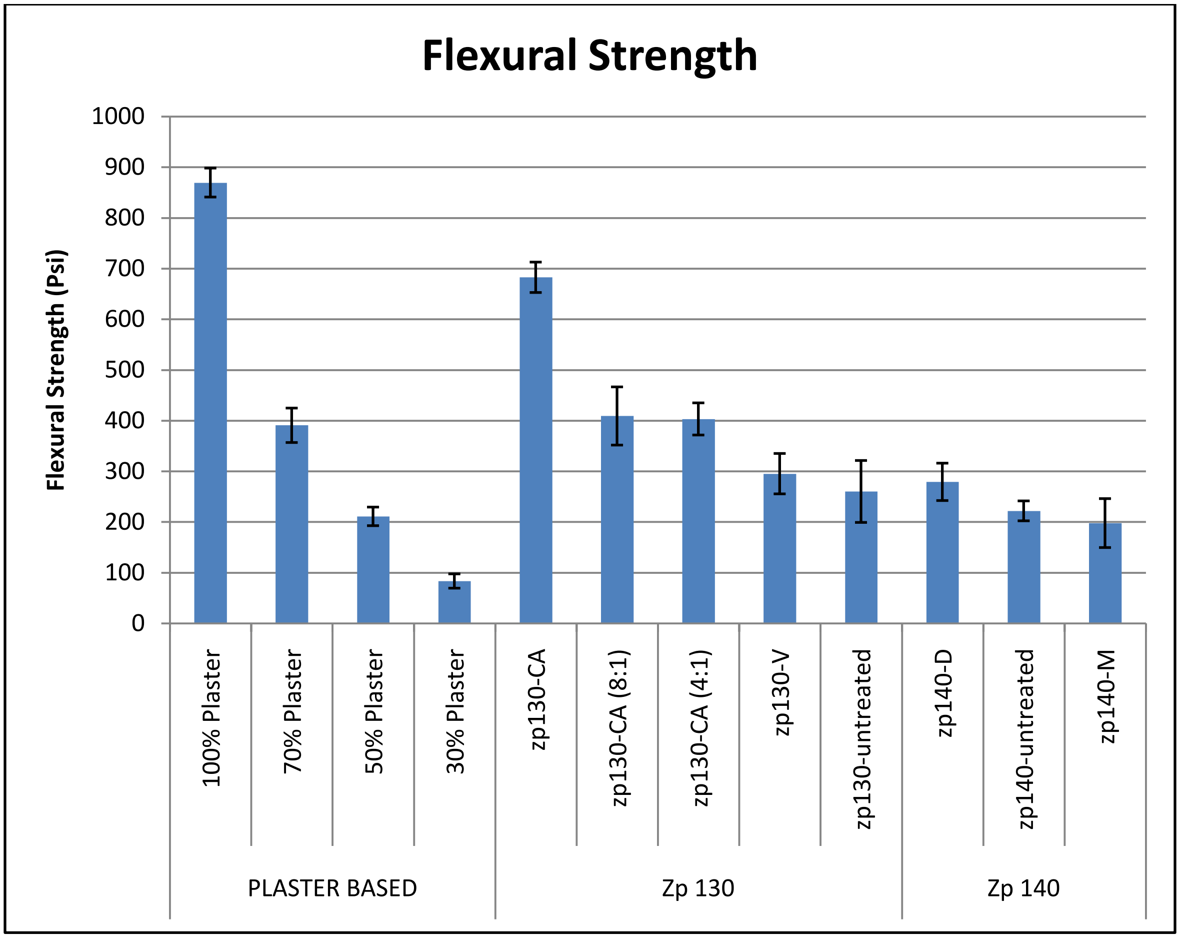

Figure 29: Flexural strength of the different material configurations.

The results show that the post treated material flexural strength was increased compared to untreated Zcorp materials. The most important information that can be observed in this chart is that the post-treated Zcorp materials are in the same range of traditional plaster-based materials. This means that 3-D printing materials after being post treated have acceptable strengths for the socket thermoforming application. Zp 130 infiltrated with pure Cyanoacrylate has the highest flexural strength over all the RP materials, but is left out of the analysis since it has no pneumatic permeability. However, the parts infiltrated with mixtures of Cyanoacrylate and Acetone performed better than other Zcorp materials and do have flow of air through them.

4.2.2. Permeability

The following graph was obtained from the pneumatic permeability tests applied to different materials with different post treatments. It is clear that the rapid prototyping materials, zp 130 and zp 140, exhibit the highest pneumatic permeability characteristics. Depending on the different post-treatment and the corresponding material, the rapid prototyping materials can approach the performance of the traditional plaster of Paris-vermiculate mixtures. Thus, the traditional socket thermoforming process will not be affected by using rapid tooling molds.

For the pneumatical permeability tests, zp 130-CA and 50% plaster were not tested. The 130-CA specimens showed no permeability and 50% plaster is not clinically used in mold casting. Zp 30% was used in this test only for reference to see the effects of vermiculate addition to the pneumatic permeability.

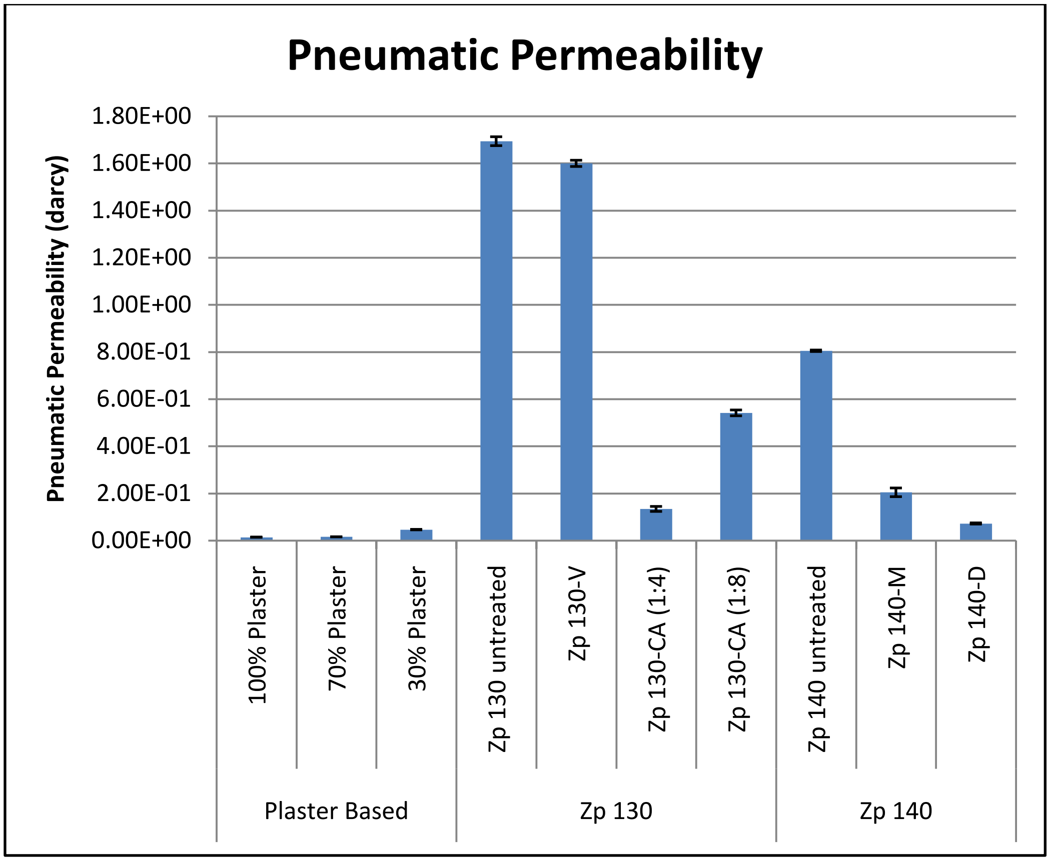

Figure 30: Pneumatic permeability of different material configurations.

4.2.3. Wear

The specimens used for the wear test were the same specimens used for three points bend test. The test performed on these specimens was described in the previous chapters. The following chart shows the wear rate of the different materials and post treatments. 50% and 30 % plaster were not included in the experiment because they have no clinical application in the socket thermoforming process. Also, zp 130-CA was excluded from the test due to the fact that it does not have pneumatic permeability. The results are promising due to the fact that all the materials exhibit a similar wear rate to the traditional plaster-based materials. The final mold for thermoforming the sockets should not be too soft because it will loss dimensional accuracy, but it cannot be to hard that will prevent to make modifications at the surface of the mold.

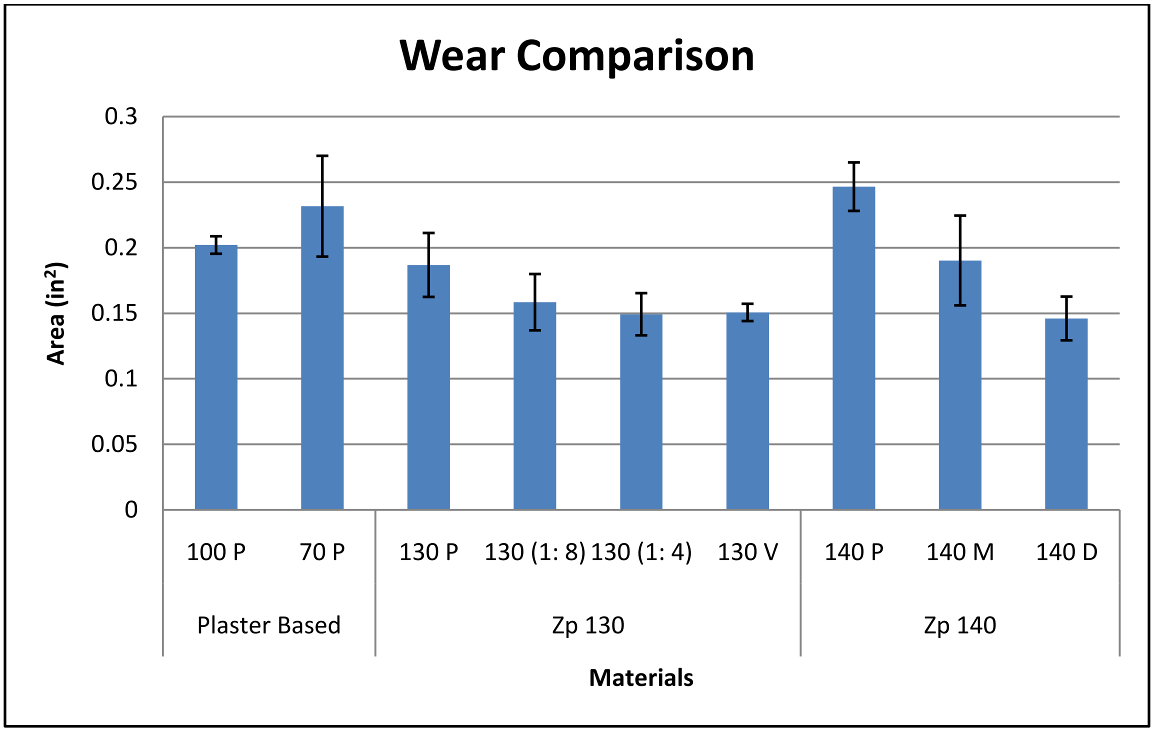

Figure 31: Wear test results from the different material configurations.

4.2.4. Dimensional Stability

After the bars for three point bend testing were printed and post treated, measurement of the thickness and width were taken to compare the dimensional stability after post treatment. It is highly important to conserve the original dimensions of the printed parts in terms of accuracy. The following table shows calculated values from the obtained data, attached in the appendix, where it can be observer that no significant change in dimensions has occurred after post treatment for the two different materials.

Table 4: Relative error of thickness and width with respect of nominal dimensions.

Material	Thickness		Width	
	Avg.Error (%)	Stdev Error (%)	Avg.Error (%)	Stdev Error (%)
zp-130	-1.26	0.12	0.13	0.26
zp-130 CA	-0.63	0.63	0.26	0.23
zp-130 CA (4:1)	-0.83	0.16	0.54	0.43
zp-130 CA (8:1)	0.71	0.46	1.87	0.41
zp-130 V	-1.75	0.81	0.35	0.36
zp-140	1.09	0.37	1.51	0.15
zp-140 D	1.26	1.04	1.38	0.15
zp-140 M	0.46	0.38	1.49	0.20

4.3. Build-Up Test

Additional flexural strength analysis was devoted in this work to Zcorp printed specimens reinforced with plaster. The interest of this analysis is to observe the behavior of failure and compare the maximum strengths of the reinforced specimens. The specimens are reinforced with a thick layer of plaster of Paris on one side to emulate the interface of a hollow mold backfilled with plaster. The specimens have the same dimensions and were tested using the same parameters employed on the three point bend test to obtain the flexural strength proposed by the ASTM Standard D790-03. Additional plaster was added to one side of the specimens after post treated.

Figure 32: Reinforced specimen for flexural strength test.

The following graph shows the comparison between the tested specimens and non reinforced specimens.

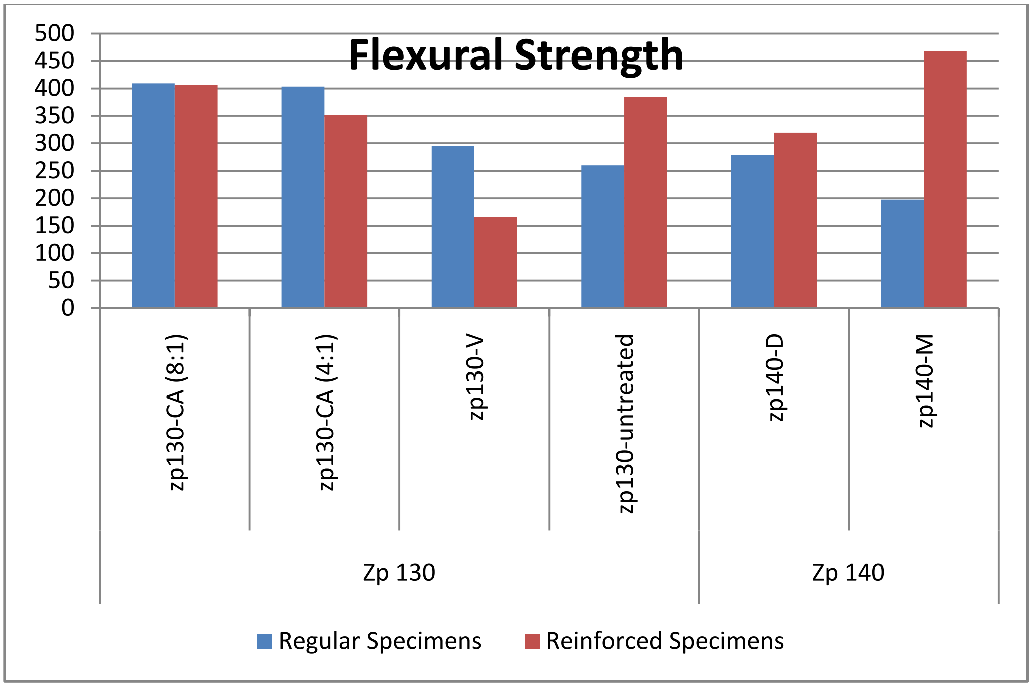

Figure 33: Flexural strength comparison between regular and reinforced specimens.

Unexpectedly some of the reinforced specimens showed lower strength. This could be due to the fact of poor adhesion between the plaster and the specimen. Another reason could be the moisture from the plaster mixture may have affected the internal structure of the rapid prototyped parts. Specimens that performed better were the zp 140 series since they can be post treated using water.

4.4. Comparison to Traditional Materials

3-D printed prototypes using powder-based materials can be post treated to improve different mechanical properties. For the socket thermoforming manufacturing process, the traditional socket mold has medium-high flexural strength, low pneumatic permeability and medium-high wear rate. The following table will summarize the performance of the different materials in terms of those three characteristics.

Table 5: Comparison of performance of different materials.

Material	Flexural Strength	Pneumatic Permeability	Wear rate
100% plaster	High	Low	Medium
70% plaster	Medium	Low	High
30% plaster	Low	Low	High
zp 130- untreated	Medium	High	Medium
zp 130-CA	High	None	Low
zp 130-CA(4:1)	Medium	Low	Medium
zp 130-CA(8:1)	Medium	Medium	Medium
zp 130-V	Medium	High	Medium
zp140 untreated	Medium	Medium	High
zp 140-D	Medium	Low	Medium
zp 140-M	Medium	Low	Medium

From the analysis of this table, it can be observed that the post treatments applied to the different materials approximate the behavior of the 3-D printed molds to plaster casted molds. From the variety of combinations of treatments on the Zcorp materials, zp 130-V, zp 130-CA(4:1) and zp 130-CA(8:1) should be a great alternative because of their good flexural strength, wear rate, low cost and repeatability.

4.5. Thermoforming Tests Using Rapid Tooling Molds

Since the enormous difference in the pneumatic permeability between plaster based mixtures and the pure zp 130, two thermoforming molds were tested to analyze if the rapid prototyping material could be thermoformed when most permeable before post treatment.

Mold was produced by 3-D printing in zp 130 powder, with approximate dimensions to an forearm without a wrist. After the mold was printed, no post treatment was applied to it. The mold was thermoformed by an experienced prosthetist. The prosthetist suggested that no noticeable difference in the process was observed comparing it from thermoforming with a plaster-based thermoforming process.

The resulting socket from the rapid tooling mold was normal in shape appearance and thickness of the plastic layer. The experienced prosthetist performing the thermoforming did not detect any problems due to the increased permeability.

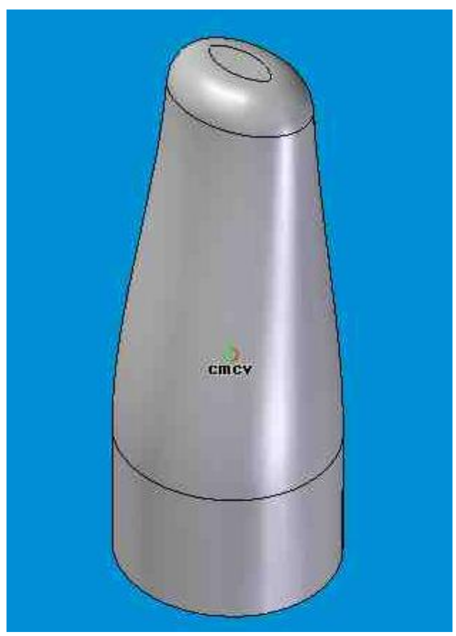

Figure 34: CAD image of the preliminary mold tested.

Figure 35: Preliminary thermoformed socket using 3-D printed mold.

Figure 36: CAD image of the preliminary mold tested.

Figure 37: Preliminary thermoformed socket using 3-D printed mold.

4.6. Ease of Integration into Current Processes

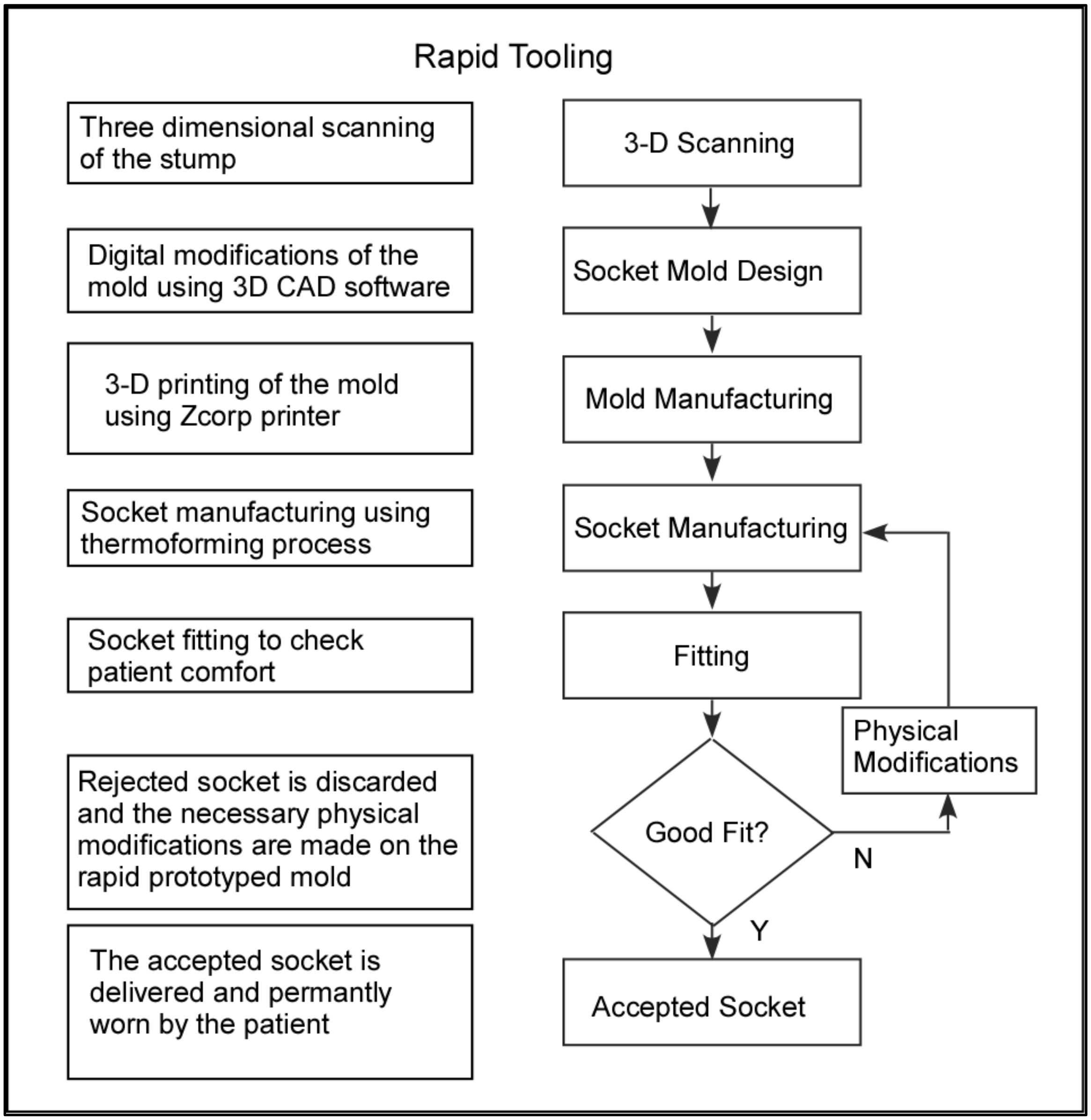

Figure 38: Schematic process of rapid tooling of molds.

Ease of integration into the traditional process is the great advantage of 3-D printing technique over other rapid prototyping techniques on socket manufacturing application. Prosthetists traditionally make the negative mold using plaster wraps. After the mold is manufactured, prosthetists reduce in about 4% the volume of the plaster based mold. However, this process can be performed in an easier and more accurate fashion using a CAD software tool. With the proposed method, the prosthetist will manually scan the residual limb with a hand held optical device. After that step, the prosthetist will give the cast to technicians to reproduce the positive mold. Using the 3-D printing method, the prosthetist would open the file and create a solid CAD version of the scanned image and then send it to the Zcorp printer. If further modifications are required after printing, the mold can be easily reshaped using traditional processes including removal of material using a rasp, sanding the surface or adding material using plaster of Paris. When the desired shape is obtained the 3-D printed mold can be thermoformed as well as a plaster casted mold. The final part can be 3-D scanned again to record the geometry in medical patient files. This will facilitate future adjustments of the socket.

4.6.1. Discussion

This chapter provided meaningful data to compare the different materials and post treatments available for 3-D powder based printing technique. As well as thermoforming test that demonstrated the suitability to integrate the rapid tooling molds into the traditional thermoforming process of socket manufacturing in prosthetics applications. The zp 130-V, zp 130-CA(4:1), zp 130-CA(8:1) and zp 140 dipped show promising performance in the properties analyzed.

Chapter 5: Conclusion and Future Work

Throughout this thesis the suitability and integration of 3-D printing technique for molds manufacturing has been discussed and demonstrated. Different characterization methods were employed to analyze the performance of the different materials and available post treatments to enhance specific properties. Flexural strength, pneumatic permeability and wear rate were evaluated in this thesis to compare the combinations of materials and post treatments.

The use of the 3-D printing for the fabrication of molds for thermoformed sockets can bring several advantages including higher accuracy in the acquisition of the anatomical geometry of the stump due to the 3-D scanning process. In addition, an electronic file of the scanned residual limb can be attached to the patient medical history. This file can be reprinted at any time using the Zcorp printer.

The following section will discuss some of the potential issues that can have a negative impact on the proposed method.

5.1. Size Issues

The biggest Zcorp printer available has a printing area capability of 10 in x 15 in. With this limitation, some of the mold might not be able to be printed as one solid piece. To overcome this disadvantage, the molds are printed in multiple pieces that can be assembled together to produce an integral mold with the original shape. This process can bring alignment issues on the surface and also on the longitudinal axis. To integrate multiple pieces plaster of Paris can be used or glue type substances. However, special care needs to be dedicated to the joint lines to avoid ridges that can be reflected in the final thermoformed socket and can create high stress lines at the residual limb.

It is suggested to analyze in the future different design solutions for the alignment fixtures. This is a key point to ensure the rapid prototyping molds are acceptable to be used for thermoforming sockets. It is imperative to not lose the precision obtained by the 3-D printing technique due to rotational or longitudinal misalignments.

5.2. Solid/Hollow Parts Designs

To be able to thermoform a plastic sheet onto a 3-D printed mold, the mold need to have inserted an air line pipe at the base. Hence, during the design stage at the CAD environment a 1.5 in diameter whole needs to be created from the base of the mold. This space will allow clearance for the pipe to be inserted freely, and the void filled with plaster to support the pipe that will be connected to the vacuum line.

With this inevitable step in the process, an alternative for low cost mold production appears. The production of hollow designed molds could substantially reduce the cost of printing, but conserving the high accuracy of 3-D printing technique. The final properties of the mold will be more similar to plaster casted molds since the volume occupied by the plaster of Paris will be dominant. Again, future research should investigate the effects of backfilling the rapid prototyped shells with plaster. Initial observations showed no noticeable changes in the volume or surface of the molds. However, more investigation should be focused on effects of this alternative.

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Appendices

Appendix A

Table 6: Measured dimensions of specimens.

#	Material	Thickness (inches)	Width (inches)
1	zp130-pure	0.345	1.251
2	zp130-pure	0.3455	1.253
3	zp130-pure	0.3455	1.255
4	zp130-pure	0.346	1.2525
5	zp130-pure	0.346	1.2465
1	zp130-4:1	0.347	1.255
2	zp130-4:1	0.3475	1.253
3	zp130-4:1	0.3485	1.2495
4	zp130-4:1	0.345	1.252
5	zp130-4:1	0.351	1.257
1	zp130-8:1	0.347	1.261
2	zp130-8:1	0.348	1.251
3	zp130-8:1	0.347	1.259
4	zp130-8:1	0.3465	1.251
5	zp130-8:1	0.347	1.262
1	zp130-CA	0.354	1.277
2	zp130-CA	0.3545	1.279
3	zp130-CA	0.3515	1.268
4	zp130-CA	0.351	1.268
5	zp130-CA	0.3515	1.275
1	zp130-V	0.3473	1.251
2	zp130-V	0.3425	1.257
3	zp130-V	0.3415	1.261
4	zp130-V	0.3465	1.251
5	zp130-V	0.3415	1.252
1	zp140-pure	0.352	1.271
2	zp140-pure	0.355	1.269
3	zp140-pure	0.355	1.267
4	zp140-pure	0.354	1.267
5	zp140-pure	0.353	1.2705
1	zp140-M	0.353	1.268
2	zp140-M	0.356	1.269
3	zp140-M	0.36	1.264
4	zp140-M	0.351	1.268
5	zp140-M	0.352	1.267
1	zp140-D	0.353	1.273
2	zp140-D	0.35	1.268
3	zp140-D	0.351	1.267
4	zp140-D	0.353	1.267
5	zp140-D	0.351	1.268