Advanced Prototyping of Variable Impedance Prosthetic Sockets for Trans-tibial Amputees: Polyjet Matrix 3D Printing of Comfortable Prosthetic Sockets Using Digital Anatomical Data

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Submitted to the Program in Media Arts and Sciences, School of Architecture and Planning, in partial fulfillment of the requirements for the degree of

Master of Science in Media Arts and Sciences

at the

Massachusetts Institute of Technology

June 2012

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Abstract

This work, supported by the Media Lab Consortium, evaluates the design of a Variable Impedance Prosthetic (VIPr) socket for a transtibial amputee using computer-aided design and manufacturing (CAD/CAM). Compliant features are seamlessly integrated into a 3D printed socket to achieve lower interface peak pressures over bony protuberances by using anthropomorphic data acquired through surface scanning and magnetic resonance imaging techniques. An inverse linear mathematical transformation spatially maps quantitative measurements (bone tissue depth) of the human residual limb to the corresponding socket shape and impedance characteristics. The CAD/CAM VIPr socket is compared to a state-of-the-art prosthetic socket of similar internal geometry and shape, designed by a prosthetist using conventional methods. An active, bilateral transtibial male amputee of weight 70 kg walks on a force plate-loaded 5-meter walkway, at self-selected speeds while synchronized ground reaction forces, motion capture data and socket residual limb interface pressures are measured for the evaluated sockets. We anticipated a decreased average interface pressure (measured using the Teksan F-Socket™ pressure sensors) in the VIPr socket, especially over stiff anatomical landmarks including the fibula head, the tibia, lateral and medial femoral condyles and medial tibial flare. Contact interface pressure recorded during stance of a complete gait cycle indicated a 15% and 17% reduction at toe-off and heel-strike respectively at the fibula head while the subject uses a VIPr socket in comparison to a conventional socket of similar internal shape. A corresponding 7% and 8% reduction in pressure is observed along the tibia. Similar trends of high-pressure reductions are observed during stair ascent trials with the VIPr socket.

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Acknowledgments

I would like to thank Hugh Herr for being a wonderful adviser, mentor and friend. Discussing every stage of this project with him was an opportunity to learn, grow and understand how to ask the toughest questions. I appreciate the feedback and support from Neri Oxman and Ed Boyden, who were my thesis readers and research advisers.

My sincere appreciation goes to Nicholas Negroponte for being my adviser, my friend and someone who I could bounce ideas off. Introducing me to the Media Lab was one of the best things to have happened to me. I could not be happier doing anything else. To my Media Lab friends: Linda Peterson, Alex Olwal, David Mellis, Nadya Peek, Joost Bonsen, Eyal Shahar, Nan-wei Gong, Nan Zhao, Micah Eckhardt and many more, thank you for making me not count the hours I spend at the lab. Thanks to Tom Lutz and John Difrancesco for teaching me how to make almost anything. Everyone else who continues to stand my chatter, thank you.

Many thanks to Sarah Hunter and the Biomechatronics Group, especially David Hill, Jared Markowitz, Andrew Marecki and Bob Emerson who played a very important role in ensuring I finished this project. Steve Shannon, Sheeba Anterapper, and Christina Triantafyllou at the McGovern Institute were instrumental in helping me get wonderful MRI data.

To the undergraduate students from MIT and Harvard (Daniel Fourie, Tyler Clites, Isabella Tromba, Pauline Varley and other UROPS) thank you for the many hours you put into the different phases of the project. I would also like to thank Gerald Berberian and Object Geometries Inc. for being wonderful collaborators.

Other people who played important roles in ensuring that this project was completed at one stage or the other include Justin Grinstead, Lindsey Brinton, and my housemates who constantly had to entertain some of my brainstorming sessions. Finally, this is to everyone else whose name should be here, I have not forgotten about you, especially my close friends and family.
Dedicated To:

This thesis is dedicated to my lovely mother Elizabeth Mamala Sengeh (Ngo Lizzy) who continues to teach me how to love, and to all my loved ones who give me the opportunity to practice that love. Peace.
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Chapter 1:

**Introduction**

**1.1 Overview**

It was estimated in 2005 that 1.7 million Americans live with a limb loss and that number was expected to double by the year 2050 [1]. The lack of prosthetic socket comfort continues to be the most important challenge faced by both prosthetists and amputees. The quality and comfort of a prosthetic socket can determine whether patients use their artificial limbs and can prevent further pathological outcomes for amputees. There exist commercially available complex passive and robotic knees, and ankle-foot prostheses [2][3]. However, reproducible comfortable prosthetic sockets, either passive or active, remain elusive.

Presently, *comfortable* prosthetic socket design is mostly an art, based primarily on the experience of the prosthetist. Even with advances in computer-aided design and computer-aided manufacturing (CAD/CAM), prosthetists often have to modify a socket using many man-hours. Furthermore, prosthetists seldom integrate comprehensive quantitative anthropomorphic data and material properties into the design process or use CAD/CAM processes to fully design and manufacture the final socket for amputees [4]. This means that two prosthetic sockets made by the same prosthetist are most likely different in shape. Certainly, prosthetic sockets made for one specific patient by two prosthetists will be different in shape, have different socket-residual limb interface pressure distributions and thus different overall comfort as experienced by the patient.

There are a number of tools that can be used to transform the art of socket design and manufacturing into a fundamentally scientific process. Surface scanning of the residual limb coupled with a detailed map of the underlying anatomical internal tissue distribution of the limb can produce a blueprint for comfortable socket design. Furthermore, technologies exist that can provide biomechatronical material properties including stress and strain of the major tissue components (bone and muscle) in a limb while advanced rapid prototyping tools can produce solid objects with varying material properties. Utilizing these different tools together in the design of prosthetic sockets for amputees will save time and money through central fabrication
and economies of scale, and provide comfortable user experiences for amputees by reducing interface pressure over bony protuberances of the residual limb during dynamic activities.

1.2 Previous Work

1.2.1 Conventional Socket Design

There are two main kinds of prosthetic sockets: a Total Surface Bearing (TSB) socket, and a Patella Tendon Bearing (PTB) socket. It has been observed that the type of prosthetic socket used by an amputee affects the physical and biomechanical conditions of the residual limb, and that patient preference for a type of socket is generally towards a TSB socket (including hydrostatic sockets) [5]. The PTB socket loads significantly at the patella tendon and other anatomy that can accommodate increased pressure for weight bearing while the TSB uses an even distribution of pressure along the entire residual limb–socket interface.

State-of-the-art socket manufacturing has its limitations. To produce a socket, the prosthetist has to capture the 3D shape of the residual limb by wrapping a cast around it while the residual limb is either loaded or unloaded, depending on the preference of the prosthetist. A positive mold of the residual limb is then acquired from the negative mold. Modifications can be done on the negative mold before a positive mold is made from it. However, rectifications are usually made to the positive mold. That significantly affects the final outcome of the socket. The anatomical points of interest are identified on the positive mold and extra material is either added to relieve pressure at sensitive regions, or removed, to increase pressure at specific load bearing locations [6]. A test socket is formed from the modified positive mold to be tried by a patient before a final socket is manufactured. This process is repeated and could last several weeks or months until manageable comfort is achieved as experienced by the amputee.

Even with this complex and time-consuming methodology used to design prosthetic sockets, it is estimated that nearly 100% of amputees experience socket discomfort. The primary aim of the prosthetist is to produce a structurally sound prosthetic socket with compliance over anatomical landmarks. Compliance in prosthetic sockets over anatomical landmarks reduces socket interface pressure, which is a major reason for sores, pain and discomfort in sockets.
The present approach to creating compliance through material addition and removal on the positive and negative mold of the residual limb is inadequate in ensuring socket comfort.

1.2.2 Computer-Aided Design and Computer-Aided Manufacturing

Computer-aided design and manufacturing (CAD/CAM) has been used to improve prosthetic sockets for many decades now. As both mechanical design and manufacturing technology have evolved in the medical field, so has the integration of CAD/CAM into prosthetic design. The surface shape of residual limbs of amputees is acquired by directly scanning the limb or the generated positive mold of the limb. That data is modified to produce sockets using computer-aided manufacturing and rapid prototyping technologies. Some CAD/CAM processes used in socket design and fabrication include Computer Numerical Controlled (CNC) milling of a positive mold, Stereolithography (SL), Selective Laser Sintering (SLS), Fused Deposition Modeling (FDM), Laminated Object Manufacturing (LOM), and Inkjet printing techniques for the fabrication of the final socket.

Results on the impact of CAD/CAM prostheses in comparison to conventional approaches have not been unanimous. There is a reported preferential indifference among patients who used a socket that was made using CAD/CAM and sockets made from conventional methodologies, though reports indicate reduced interface pressure over anatomical landmarks for amputees in CAD/CAM sockets. There are known approaches to relieving unwanted pressure at specific locations on the residual limb using CAD/CAM. Compliance over bony protrusions, a means to relieving pressure, can be achieved by changing socket wall thickness or by adding mechanical features to the designed socket to increase compliance.

1.2.3 Acquisition and Use of Anthropomorphic Data in CAD/CAM Socket Design

Conventional state-of-the-art techniques use externally acquired anthropomorphic data to create prosthetic sockets through a laborious, experience-based artisan skill. Present advanced technologies provide new opportunities for a complete integration of the anatomy of the residual limb into the design of prosthetic socket. Digitizers are used to effectively measure small
differences in the shape of a negative cast used to generate positive molds of a residual limb and the final prosthetic sockets [18]. Ultrasound has been used to capture the internal and surface shape of a residual limb for use in socket design [19][20][21]. MRI and Computed Tomography (CT) are other imaging tools that have been integrated in CAD/CAM socket design [22][23][24]. Even though advanced imaging tools have been used to acquire surface and internal tissue distribution of residual limbs, limited progress has been made towards a manufactured socket whose properties are fundamentally determined by the underlying anatomical dataset acquired. The 3D shape and material of the final prosthetic socket is not informed by these biomechanical and viscoelastic data acquired from the adjacent 3D shape and anatomical material property of the residual limb.

1.3 Thesis Statement

This thesis presents a CAD/CAM approach to producing a seamless, variable impedance prosthetic socket for transtibial amputees using quantitative anthropomorphic data from advanced surface scanning and magnetic resonance imaging technology. An inverse transformation is used to establish the relationship between the estimated residual limb stiffness and the adjacent socket material. The fundamental goal of a comfortable socket design is to maintain reduced socket interface pressure on anatomical landmarks including the fibula head, tibia, medial tibial flare, lateral femoral condyle and the medial femoral condyle. Increasing compliance over these locations while maintaining structural integrity for dynamic walking activities is crucial. Unlike previous works, this project will use the most advanced CAM technology available – Polyjet matrix 3D printing technology – to seamlessly integrate compliant features into the socket design by changing material properties to match the anatomy of the limb.

1.4 Hypothesis

A CAD/CAM fabricated variable impedance socket with compliant features designed using a transformational mapping generated from the quantitative 3D anthropomorphic data of a residual limb will maintain reduced socket – residual limb interface peak contact pressures for an amputee during dynamic walking activities. With improved comfort from lower peak
pressures, we anticipate an increase in the self-selected walking speed of the amputee while using a variable impedance socket over a conventional or a single impedance socket.

1.5 Thesis Roadmap

This thesis is divided into six chapters. Chapter 1: Introduction gives an introduction to the design of prosthetic sockets and an overview of the state-of-the-art methodologies used by prosthetists before concluding with a Hypothesis derived from the Thesis Statement. Chapter 2: Volumetric Data Acquisition of Residual Limb is used to describe the multiple ways by which the surface geometry and the internal anatomy of the residual limb of the amputee are captured. Using that acquired data in Chapter 3: Computer-Aided Design and Manufacture of Transtibial Prosthetic Sockets, an account of how the transtibial prosthetic socket is designed using CAD platforms is presented. Compliant features are integrated into the socket design based on the specific anatomy of the residual limb. In Chapter 4: Finite Element Analyses of CAD Socket, a methodology for analysis is presented to test the structural integrity of the designed socket after the integration of compliant features into the design. To test the hypotheses of this thesis, socket interface pressures, subject gait and metabolic cost are analyzed in Chapter 5: Evaluation of Interface Pressure, Gait and Metabolic Cost while the subject performs dynamic activities including walking, stepping up and down stairs, and standing on one leg. The thesis ends with Chapter 6: Conclusion, which ties the whole document together while projecting the trajectory of the future work. Following the final chapter is a list of references and an appendix.
Chapter 2

Volumetric Data Acquisition of a Residual Limb for a transtibial amputee

2.1 Overview

The comfort of a prosthetic socket is, in part, dependent on the quality of the volumetric data acquired of the residual limb. The fit of the socket is dependent on how accurately the surface contours of the residual limb are captured. Methodologies that have been used to capture the shape of the residual limb include plaster casting, surface scanning and more advanced imaging techniques including Computerized Tomography (CT) and Magnetic Resonance Imaging (MRI). In this thesis, a combination of data acquisition techniques have been employed to optimize socket comfort, as measured primarily by reduced peak socket-residual limb interface pressures. The internal socket shape of the amputee’s conventional socket is captured by surface scanning a positive mold made from the socket while an MRI is used to capture the quantitative anthropomorphic internal geometry of the residual limb.

The amputee participant is a 47-year-old male of mass 70 kg. The participant is a double transtibial amputee who lost his legs from trauma at the age of 17. He is very active and lacks any other pathological conditions other than the amputation. The participant does not have any metal pins in his body and could undergo magnetic resonance imaging safely.

2.2 Methodology for Capturing Data

2.2.1 Surface Geometry Capture

A positive mold of the participant’s conventional socket is formed using alginate at the prosthetist’s shop. No modifications are made to the internal shape of the patient’s conventional socket prior to creating the positive mold.
Figure 1: External view of the final carbon transtibial socket on the left, and an internal view of the same socket (right), depicting internal craft modifications performed by a prosthetist to optimize comfort. Tape is wrapped around the top of the socket so that the cut lines can be accurately captured.

Figure 2: Tape wrapped around prosthetic socket to capture socket cut lines
Once the tape is wound around the socket, the alginate mixture is poured into the socket. A metal rod is inserted into the center of the mixture to facilitate easy removal once the mold dries up.

**Figure 3:** Smooth-On Alja-Safe™ alginate used to make positive mold from sockets

The solidified mold is removed with visible trim lines as seen in the images in Figure 4.
A knife is used to trace the cut lines and remove the excess material. This is necessary to facilitate easy recognition of the trim lines once the male plug is scanned.

**Figure 4:** Positive plug of the prosthetic socket

**Figure 5:** FastSCAN™ system (image acquired from the website of Polhemus)
The positive mold is stabilized on a table for scanning. The FastSCAN™ system manufactured and supplied by Polhemus (40 Hercules Dr, Colchester, VT 05446, USA, T: 800-357-4777) is used to capture the surface shape of the positive mold. This system is used because of its convenience and accuracy. Setup and scan time is about five minutes and the scanning tool is easy to use. The system is lightweight and connected to a computer monitor making it ideal to see the results in real time. Multiple scans are recorded of the mold and compared to each other to ensure accuracy from the scanning. Images are exported from the FastSCAN™ software and converted to STL files.

![Image of STL files](image)

**Figure 6:** STL files exported from the scanning software trimmed to match the original cut lines of the socket.

Other tools can be used to capture the internal shape of the socket including digitizers. Though commercially available digitizers exist, Sanders *et al.* developed a mechanical digitizer specifically for use in prosthetic socket research [18]. The commercial Provel d2 Digitizer™ is made specifically to capture the internal shape of a prosthetic socket. The Provel d2 exports files in the AOP format used by most prosthetists and these files can be converted to STL formats and other CAD file formats using third party software.
2.2.2 Internal Geometry Capture

Magnetic Resonance Imaging (MRI)

Magnetic Resonance Imaging (MRI) uses Nuclear Magnetic Resonance (NMR) to spatially map the distribution of hydrogen atoms in a body. It is a non-invasive imaging technique that relies on the magnetic properties of the nucleus in hydrogen atoms. A three-Tesla MRI machine uses the high magnetic field to align the magnetic particles in the hydrogen atoms within water molecules in the body. Radio waves of known frequencies are then applied to the body causing the magnetic particles within the nuclei of the hydrogen atoms to change their orientation from the direction of the magnetic field applied by the magnet in the scanner. The spin of the hydrogen nuclei is detected by a sensitive radio and this information is processed to generate a magnetic resonance image.
MRI is used mostly to image the brain. However, it has been used for imaging other parts of the body and also for diagnosing various diseases and conditions. Researchers have reported the use of MRI in prosthetic socket design as a means of studying the shape and volume of prosthetic sockets [22] as well as the atrophy experienced by a residual limb [23]. This project uses the MRI data as a means of estimating and mapping body stiffness and anatomical landmarks directly to prosthetic socket design. As such, MRI is used to generate 2D and 3D reconstructions of the different tissues found in the residual limb of the amputee. Furthermore, the surface geometry image generated by MRI is comparable to the surface image captured using other scanners. Estimations of quantitative properties like localized body stiffness, the distance between the surface of the skin and the bones in a specific plane, and the percentage deformation allowed at that location could be analyzed.

As such, MRI is used to generate 2D and 3D reconstructions of the different tissues found in the biological limb of interest. Furthermore, the surface geometry image generated by MRI may be used to supplement, or replace, surface images captured using other scanners.

Figure 8: A 3T Siemens Tim Trio 60 cm whole-body MRI
Figure 9: MRI images of a transtibial-amputee residual limb showing different tissues. Visible anatomy in the left image includes tibia, gastrocnemius muscle, femor, and patella.

MRI Sequence

The quality of the image developed depends on the type of sequences run on the MRI machine. The pulse sequence is the computer program that affects how and what signal frequencies are emitted to and captured from the body by controlling the hardware of the MRI system. A pulse sequence consists of a predefined gradient of radio frequencies used during a scan.

MRI Coil Used

An MRI coil is made of conductive material looped around the core of the coil. The coil serves a dual function: creating and detecting magnetic fields around a specific area that is being imaged. There are different types of coils depending on the type of body part or object to be imaged. For the residual limbs of amputees, extremity coils are favorable. Specific coils for knees are usually long enough and have a large enough field of measurement to capture the full length of a transtibial residual limb (See Figure 10). Furthermore the inner diameter of the coil is large enough to hold the residual limb while being small enough to allow for good quality images.
Figure 10: 3T 15 Channel Knee Coil (Weight: 6.6 kg Dimensions: 256 mm x 360 mm x 310 mm (L x W x H), Inner diameter ≥ 154 mm

MRI Data Processing and Export

MRI data consist of hundreds of images that are generated based on the spatial distribution of the frequency and phase of proton magnetization. The sequences used in this project generated about 192 images for each residual limb imaged with and without a liner. The primary format for all MRI files is the Digital Imaging and Communications in Medicine (DICOM), standard for distributing and viewing medical images. DICOM images can be opened and modified in various image-processing platforms. These DICOM images can be converted to STL formats, which could be opened in other software platforms (e.g SolidWorks, Matlab) for further computer-aided design and manufacture.
Chapter 3:

**Computer-Aided Design and Manufacturing of Transtibial Prosthetic Sockets**

### 3.1 Overview

Computer-Aided Design and Manufacturing (CAD/CAM) of prosthetic sockets have seen an evolutionary progression towards smarter and more comfortable prostheses. Though the use of CAD /CAM processes varies widely from a limited use to a more extensive approach, it has advantages over conventional and traditional processes at various stages. CAD/CAM used in prosthetics allows for repeatability and a more quantitative approach to socket design. The following stages are generally followed in using CAD/CAM to design prosthetic sockets:

i. Image Acquisition
ii. CAD Socket Design from Anthropomorphic Data of Residual Limb
iii. Production/Manufacture of Product

**Image Acquisition**

For socket comfort, acquiring a near perfect volumetric shape of a residual limb either under a loaded or unloaded state is highly important. For this thesis, surface scanning technologies have been used to generate the internal shape of designed prosthetic sockets. MRI data is used to capture and locate internal anatomical landmarks as discussed in Chapter 2 of this thesis. Images are acquired in various formats supported by the different hardware used but they are exported as STL file types to be integrated in further design steps.

**CAD Socket Design**

3D images of the residual limb and the internal shape of the amputee’s conventional prosthetic socket are imported into SolidWorks (Dassault Systèmes SolidWorks Corporation, 175 Wyman Street, Waltham, MA 02451, USA, T: 1-800-693-9000). The STL mesh files are transformed into surfaces in SolidWorks and thickened. The cut lines of the designed socket are kept as close as possible to those outlined by the prosthetist. Compliant regions are integrated
into the design based on the mapping obtained from the surface scans and the MRI data. A distal support block for the pyramid is designed such that any standard pyramid could be attached at the bottom of the socket.

3.2 Mapping Anthropomorphic Data of Residual Limb to Stiffness of Interfacing Material

3.2.1 Introduction and Overview

The human anatomy is complex and consists of multiple materials of different properties. A residual limb of a below-knee amputee typically consists of bones (femur, tibia, fibula, and the patella), muscles (tibialis, gastrocnemius, peroneus longus) and other anatomical landmarks including the tibial tuberosity, medial femoral condyle, lateral femoral condyle and the medial tibial flare. Since these vital anthropomorphic points all consist of varying material properties, using current conventional sockets leads to unwanted high pressures over several of these points.

This thesis presents the hypothesis that there exist several relationships between anatomical body stiffness and the adjacent material stiffness of the prosthetic socket, which yield an optimal prosthetic socket-residual limb interface with reduced average pressure. Once the surface geometry and anatomy of the patient is imaged, a grid of known resolution of average (2 x 2) inches$^2$ is established on the CAD socket, where a node of known variables is created around each grid or averaged for a defined grid. Each node vector V(i) has known properties including body impedance features: 3D location, stiffness K, damping B, external shape of limb, the sensitivity of skin influenced by anatomy and physiology of the imaged body, and spatial deformation %S – calculated from the distance between the surface of the skin to a centrally defined axis – both under load and without load.

However, this thesis specifically uses an inverse relationship between the stiffness of the socket material and the stiffness of the adjacent interfacing area on the residual limb. The stiffness of the residual limb is approximated to be directly proportional to the distance between the surface of the skin and the anatomical bone tissue at each location. Though an inverse linear mapping algorithm is used here, there could exist a nonlinear mapping, including but not limited to parabolic, hyperbolic, trigonometric, exponential functions, and differential equations that will...
create unique spatial material composition for each prosthetic socket. The tools to automatically measure body stiffness for a residual limb are presently limited.

Figure 11 shows a series of curves representing the quantitative relationship between a mechanical interfacing material stiffness, or durometer, and body stiffness represented as the percentage of soft tissue depth. Here the horizontal axis is the soft tissue depth, D, normalized by the maximal soft tissue depth, D_{max}, multiplied by 100. Both linear and non-linear curves are presented showing the possible variation in the relationship between interface durometer and corresponding soft tissue depth. Generally, as soft tissue depth decreases, and body stiffness increases, the adjacent interface becomes increasingly soft. Where there are bony protuberances, the adjacent interface will be soft and compliant, but where the body is soft with a large soft tissue depth, the adjacent interface is designed to be more rigid.

Figure 11: A graph showing linear and non-linear relationships between the body’s viscoelastic properties as estimated from soft tissue depth plotted horizontally, and the corresponding durometer of the mechanical interface plotted vertically.
3.2.2 Estimation of Residual Limb Soft Tissue Depth

From the MRI data, one can approximate the stiffness of each location on the residual limb from the distances between the bone and the surface of the skin on each plane. Though there exist various image processing toolboxes and software, this project used the Mimics Innovation Suite ® (v. 13.0, Materialise, Leuven, Belgium) to analyze the MRI data. The Mimics ® toolbox can be used to represent a 3D soft tissue depth analysis while providing depth information (distance between the nearest bone surface and the surface of the skin) at each unique location. In Figure 12 below, the left image represents multiple views of the residual limb being analyzed while the right image is a representation of the tissue depth measurement. The green regions represent where the bones are closest to the skin while red represents the regions that are furthest away from the surface of the skin.

For our analyses, the patella tendon is removed from the 3D soft tissue regeneration from the MRI data for two reasons. Firstly, since our design was based on a Patella Tendon Bearing prosthetic socket where most of the loading takes place, it was necessary for the material that interfaced with the patella tendon area to be stiff. Secondly, because the patient had been loading at the patella tendon for many years, the tissue was very densely packed and much closer to the skin. This would affect the color gradient seen in Figure 12, which is used in the design of the socket.
Figure 12: Multiple views of the right residual limb from MRI data (Left). A bone tissue depth representation: red implies farthest surface from a bone and green mean skin closet to the bone (Right).

Figure 13 is a reconstructed image of the right residual limb of the amputee participant in multiple orientations. Again, the patella tendon is removed from this analysis for reasons already discussed.
**Figure 13:** Left-Right Orientation: Posterior, Lateral, Medial and Posterior. Row 1: MRI image of Right Residual Limb; Row 2: depth of bone from skin surface

<table>
<thead>
<tr>
<th>Bone Tissue Depth from Skin Surface (mm)</th>
<th>Color Representation</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 – 9</td>
<td><img src="Image" alt="Green Color" /></td>
</tr>
<tr>
<td>9 – 13</td>
<td><img src="Image" alt="Yellow Color" /></td>
</tr>
<tr>
<td>13 – 16</td>
<td><img src="Image" alt="Orange Color" /></td>
</tr>
<tr>
<td>16 – 20</td>
<td><img src="Image" alt="Red Color" /></td>
</tr>
<tr>
<td>20 – 50</td>
<td><img src="Image" alt="Orange Color" /></td>
</tr>
</tbody>
</table>

**Table 1:** Color mapping of bone tissue depth of residual limb acquired from the Mimics®
3.3 Variable Impedance Features

Various methods have been suggested to relieve pressure over bony protrusions and other anatomical landmarks in passive prosthetic sockets. In conventional approaches, different materials have been bonded together to relieve pressure on anatomical protrusions. Other CAD/CAM methodologies introduced in Chapter 1 include the use of double walls, variable thickness walls and most recently, the creation of mechanical compliant features.

The design described here uses variable impedance seamlessly integrated into socket production using advanced 3D printing technology. This thesis will use the most advanced CAM technology on the market to seamlessly integrate compliance into the socket design by changing material properties to match the anatomy of the limb over multiple locations. Polyjet matrix 3D printing technology allows the integration of different materials with variable stiffness into the same socket. The final socket will be designed in a CAD environment and printed using the Objet Connex 500™ printer.

Figure 14: Connex 500™ 3D Printer from Objet
3.4 Inverse Linear Map Between Soft Tissue Depth and Socket Material Stiffness

The Objet Connex 500™ printer can print objects of varying properties from a library of materials with modulus of elasticity values ranging from 0.5 GPa to 3 GPa. The tensile strength of the materials is within the range of 1 MPa to 65 MPa. The Digital Materials that give the most variability in material properties is a combination of VeroWhitePlus™ and TangoBlackPlus™. See Appendix 3 for a list of material and their properties. VeroWhitePlus™ has a modulus of elasticity range of $2—3$ GPa and tensile strength range of $50—65$ MPa. TangoBlackPlus™ has a tensile strength range of $0.8—1.5$ MPa.

An inverse linear equation is employed to map bone tissue depth to material stiffness properties. Using the Mimics® software, a text file can be generated which outputs the magnitude of the soft tissue depth at each location on the residual limb. The minimum depth was identified from the soft tissue depth while the minimum modulus of elasticity employed was 1.1 GPa. The maximum tissue thickness (depth) defined by the threshold value used to create the color map is 50 mm while the maximum modulus is 3 GPa.

<table>
<thead>
<tr>
<th></th>
<th>Minimum Thickness (mm)</th>
<th>Maximum Thickness (mm)</th>
<th>Minimum Modulus of Elasticity (GPa)</th>
<th>Maximum Modulus of Elasticity (GPa)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Left Leg</td>
<td>0.5766</td>
<td>50.0000</td>
<td>1.1000</td>
<td>3.0000</td>
</tr>
<tr>
<td>Right Leg</td>
<td>0.3076</td>
<td>50.0000</td>
<td>1.1000</td>
<td>3.0000</td>
</tr>
</tbody>
</table>

Table 2: Parameters used to create mapping between soft tissue depth (body stiffness) and the stiffness of the socket interface material.

The equations generated from the above values are:

\[ Y = 0.0382 \times X + 1.0882 \text{ (Right Leg)} \]

\[ Y = 0.0384 \times X + 1.0778 \text{ (Left Leg)} \]

$Y$ is the Young’s Modulus of printing material while $X$ is the range of soft tissue depth.
From the established mapping between the anatomical body and the socket material stiffness, the final design of the prosthetic socket is split into half-inch squares, which are eventually grouped to represent the distribution seen for the adjacent soft tissue depth. In Figure 16, a color-coded representation of the CAD socket is shown in the second row. This aspect of socket design, how the underlying anatomy of the residual limb is used to quantitatively determine the final continuously varying interfacing socket material, is novel and unique to this project to the best of the author’s knowledge. Though the shape of the designed socket is acquired from conventional methods, it is conceivable to design a comfortable socket using only data quantitatively acquired from MRI and other imaging technology.
Figure 16: In rows 1 and 2 are shown the MRI image of the right residual limb of a transtibial amputee, soft tissue depth, and the 3D design of a variable viscoelastic socket, respectively. Orientation from left to right for all images are anterior, lateral, medial and posterior, respectively.

3.5 Exporting Files for 3D Printer

From the different CAD environments, the completed socket designs are exported or saved as STL file formats. The STL files are saved with the following properties: a deviation of 0.0005 inches and a 5-degree angle. For the 3D printer to print the files, each one must be a watertight closed solid. Furthermore, since there are multiple materials with different material properties in the design (see Figure 17), each file corresponding to a different material type must be saved as a unique file. That is, all materials of the same durometer are saved together in different files before exporting them as STL files. Where the STL files (meshes) need repair or
contain inverted normals for the different parts of a file, third-party software could be used to make the files printer-ready.

Figure 17: Different socket files saved for printing for the right leg. The first five files can be combined to form the final socket.

3.6 3D Printing of Variable Impedance Socket

3D printing has been used in the design of medical technologies for a couple of decades. However, the methodologies and capabilities of the machines have continued to evolve. Objet Geometries Inc. (North America, 5 Fortune Drive, Billerica, MA 01821,USA, T: +1-877-489-944) produces an advanced 3D printer, which uses their PolyJet Matrix™ Technology. This technology enables two different material types to be simultaneously jetted in the production of the same model using the Connex™ printer with build tray size of 500mm x 400mm x 200mm. With a16 micron, high-resolution print layer, high dots-per-inch in both X and Y resolution and an easy-to-remove support material property, this technology is ideal for the development of multi-material prosthetic sockets.
There is a relatively large library of standard materials used by the Connex family of 3D printers. In addition, composite materials can be created to produce Digital Materials™ to give a wide range of material properties, which is a desirable feature in a prosthetic socket design mapped from calculated residual limb stiffness. The materials have been used in various medical fields and are reported as biocompatible. Printing properties for the right and leg are as follows can be found in the Appendix 4.

A mass of 1,434.3 g and 1,372.3 g is recorded for the modified right and left socket respectively (the weight recorded includes that of the casting tape, the metal base within casting tape and a 4-hole male pyramid).

Figure 18: In rows 1 and 2 are the 3D design of a variable viscoelastic socket, and the 3D printed sockets respectively. Orientation from left to right for all images are anterior, lateral, medial and posterior, respectively.
The 3D printed sockets are post processed by a prosthetist while keeping the internal socket shape untouched. A metal base is glued to the bottom of the socket with some Coyote Design Quick Adhesive CD4150. Multiple rolls of Techform Premium Casting Tape™ of appropriate length are used in the anteroposterior and the mediolateral direction to enclose the metal base.
Chapter 4:

**Finite Element Analyses (FEA) of CAD Socket**

### 4.1 FEA at Stance Phase of the Gait Cycle

Finite Element Analysis (FEA) is essential in mechanical design. The importance in prosthetic design is even more apparent because the failure of a product can affect the amputee’s rehabilitation both physically and mentally. Even though this project combines multiple materials into one socket through 3D printing based on anatomical information, the final prosthetic socket has to be structurally sound to accommodate dynamic walking activities of an amputee. It is assumed that materials that are not as stiff as the hardest material in the socket have negligible effects on the structural integrity of the socket and are thus removed from the part to be analyzed. Since the socket to be analyzed is reduced to only one material, the SolidWorks SimulationXpress™ package on the SolidWorks™ 3D CAD Software is sufficient for the evaluation. As observed in Figure 19, a supporting truss is utilized for the final design because with this feature the socket was more structurally sound.

![Figure 19: Comparison of completed sockets without a supporting truss and one with a truss. The right image is the solid part (representing the red parts in the middle image) that is analyzed.](image)
It is assumed that the pressure exerted on the socket wall is uniformly distributed across the whole socket during stance or while a user is standing. This assumption is accurate for both a total surface-bearing socket (TSB) and a patella tendon-based socket (PTB), though our design is modeled off the latter. PTB sockets are so designed because the patella tendon can load increased pressures thereby relieving pressure at other locations. Since the goal of this design is to reduce peak pressures in the socket across the entire surface of the residual limb, it is appropriate to assume a uniform pressure distribution in the entire socket.

Uniform pressure \( P = \frac{\text{Force}}{\text{Area}} \), measured in units of Pascal (Pa). To calculate the Area \( A \), a simplified circle is extracted from the sketch that forms a planar circumference around the fibula head and the proximal end of the tibia. The calculated Diameter \( D \) is 3.75 inches or 0.09525 meters. Thus, \( A \) at that plane is \( \pi(D/2)^2 = 7.1 \times 10^{-3} \text{ m}^2 \).

The mass of the patient recorded is 70 kg and with the constant acceleration to gravity \( g \) 9.8 m/s\(^2\), Weight \( W = (70 \times 9.8) \text{ N} = 686 \text{ N} \). To test for structural integrity, we use \( 3W = 2058 \text{ N} \) as the applied weight of the user. Thus, uniform pressure within the socket, \( P = \frac{2058/(7.1 \times 10^{-3})}{7.1 \times 10^{-3}} = 289859.2 \text{ Pa} = 290 \text{ kPa} \). The properties of the material used for the 3D printed material analyzed are presented in Table 3.

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elastic Modulus in X</td>
<td>( 2 \times 10^9 )</td>
<td>N/m(^2)</td>
</tr>
<tr>
<td>Poisson’s Ration in XY</td>
<td>0.394</td>
<td></td>
</tr>
<tr>
<td>Shear Modulus in XY</td>
<td>( 3189 \times 10^5 )</td>
<td>N/m(^2)</td>
</tr>
<tr>
<td>Tensile Strength in X</td>
<td>( 3 \times 10^7 )</td>
<td>N/m(^2)</td>
</tr>
<tr>
<td>Yield Strength</td>
<td>( 5 \times 10^7 )</td>
<td>N/m(^2)</td>
</tr>
<tr>
<td>Izod Notched Impact</td>
<td>25</td>
<td>J/m</td>
</tr>
</tbody>
</table>

Table 3: Material properties used for FEA

A standard 4-hole male pyramid is used for the connection between the 3D printed prosthetic socket, adapter and a prosthetic foot. The pyramids are often made from aluminum, stainless steel or platinum. The screws used with the pyramids are M4 with a 4mm diameter thickness.
Both the right and left designed prosthetic sockets of thickness 0.5 inches are evaluated. The FOS for the right and left socket models is 1.91849 and 2.05294 respectively when the pressure of 290 kPa is applied uniformly on each face within the socket. The socket is fixed at the base in a similar manner in which it is attached to the participant. Even though our goal is to use a standard of at least 290 kPa for all sockets used in this project, it must be noted that the average maximum pressure values recorded in a conventional socket for a patient during dynamic walking activities is lesser than 290 kPa [25][26].

As shown in Figure 21, the model is fixed at the base without affecting the compliant features of the design. The green arrows indicate the regions that are fixed. In the physical prototype, this is achieved by wrapping a casting tape around the base of the prosthetic socket and the base metal to which the positive pyramid is connected. The red arrows in Figure 21 indicate the direction of the applied uniform pressure. The black circles in Figure 22 show areas that experience the most deflection and stress during stance.

Figure 20: A standard 4-hole male pyramid for connections to a supplied prosthetic foot.
Figure 21: A representation of fixture position (green arrows) and applied pressure (red arrows) during FEA.

Figure 22: The black circles represents regions with the most displacement (left) and highest stress (right).

There are many design approaches to increasing the FOS to higher values. The obvious approach is to increase the thickness of the socket wall, to add fillets in the design and to have the cast be more uniform with no sharp edges. Adding more trusses in the proximo-distal axis will decrease the displacement values observed in the above designs. Figure 23 summarizes the results of the FEA for Factor of Safety, Static Displacement, and Static Nodal Stress under
uniform pressure of 290 kPa. FEA results indicate that the 3D printed socket is structurally sound for evaluation while the amputee is standing. Applied pressures and forces are well beyond those reported in literature that amputees feel within their socket during gait studies.

Figure 23: In rows 1, 2 and 3 are the images for the Factor of Safety representation (Red < FOS = 1 < Blue), Static Displacement under force 3W, and Static Nodal Stress, respectively. Orientation from left to right for all images are anterior, lateral, medial and posterior, respectively.
Figure 24: The Von Mises Stress distribution (Left) and displacement (Right) for finite element analyses shown in Figure 23.

4.1 FEA at toe-off:

Pressure distributions within the prosthetic socket vary at the different stages of the gait cycle. Furthermore, there are different forces and moments experienced in the socket interface especially at the patella tendon bar at toe-off. An approximation of this force (F) is $F = 3W \cos(\theta)$, where $\theta$ is assumed to be approximately equal to the angle between the shank of the residual limb and the surface on which the participant walks. For the FEA at toe-off, an additional force of 1.455 kN is applied at the patella tendon region to account for the additional torque in addition the uniform pressure of 290 kPa already applied as shown in Figure 25. At heel-strike, the forces experienced on the posterior end of the socket are distributed along the entire surface of the socket wall.
Because the rest of the socket is made up of flexible rubber-like materials in the anterior region, when the new force is applied at the patella tendon bar, the original socket model fails. Furthermore, on an uneven terrain, the direction of the force will vary, and that change in torque will have a major impact on the structural integrity of the socket. As seen in Figure 26, when the entire posterior side of the socket is bound together to the base and the truss to avoid relative movement between the 3 regions, the results show an improved Factor of Safety for uniform pressures experienced at stance phase or standing, and the socket model can withstand the forces applied at toe-off. The FOS at stance for uniform applied pressure within the entire socket surface is $12.8164$ while the FOS observed at toe-off was $2.61671$ (Figure 26).

To effectively bind the 3 regions in the physical model to prevent relative movement, especially the movement in the proximo-distal axis between the truss and the distal end of the socket, one can use materials of high tensile strength along that axis. For dynamic walking tests conducted with an amputee, the 3D printed sockets were bound using reinforced tapes with high tensile strength along the truss and the posterior wall of the socket (Figure 27).
Figure 26: (Left) FEA showing locations in red on a socket where FOS < 1 when only base and posterior end are bound. (Right) Stress representation of a completely bound socket with FOS 2.61671.

Figure 27: Prosthetic socket wrapped with tape with high tensile-strength properties.
Chapter 5:

Evaluation of Interface Pressure

5.1: Overview

The Committee On the Use of Humans as Experimental Subjects (COUHES) at MIT approved the protocol used in this project. The COUHES protocol number is 1101004280. The sockets evaluated for this project include a conventional carbon fiber socket and a compliant variable impedance 3D printed socket. The properties of the two sockets are summarized in Table 4. The weight of the sockets is different, even though the internal geometry is similar. The alignment of the sockets is similar across the trials. The subject walks using the sockets until they feel like they have a comfortable normal gait. Sockets are held firmly on the subject during these activities using a standard suspension sleeve.

<table>
<thead>
<tr>
<th>Property</th>
<th>Conventional Socket</th>
<th>Multivariable 3D printed socket</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mass (kg)</td>
<td>0.4811</td>
<td>≈1.4</td>
</tr>
<tr>
<td>Internal Geometry</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td>External Geometry</td>
<td>Different</td>
<td>Different</td>
</tr>
<tr>
<td>Material</td>
<td>Carbon fiber</td>
<td>Object Digital Materials&lt;sup&gt;1&lt;/sup&gt;</td>
</tr>
<tr>
<td>Compliance</td>
<td>None</td>
<td>Yes</td>
</tr>
<tr>
<td>Socket Alignment</td>
<td>Prosthetist A</td>
<td>Prosthetist A</td>
</tr>
</tbody>
</table>

Table 4: Properties of evaluated sockets

5.2 Interface Pressure Measurement

The interface pressure between the socket and the residual limb is evaluated in the entire socket with special attention to anatomical features including the tibia, medial tibial flare, femoral head, medial and lateral femoral condyles for specific dynamic activities. The

<sup>1</sup> See Appendix for a material list provided by Objet Inc.
anatomical points indicated here usually have high interface pressure measurements and often lead to discomfort as experienced by amputees. Pressure is measured using the *F-Socket Pressure System* provided by Tekscan, Inc. (307 West First Street. South Boston, MA 02127-1309, USA T: 800.248.3669) at 100 Hz while the participant does the activities listed below.

1) Stands on both legs
2) Loads one leg by standing on it while lifting the other
3) Steps up a stair using one leg
4) Steps up a stair using other leg
5) Walks ten times at self-selected speed on a force plate loaded walkway while motion capture data is recorded

The pressure sensors are attached to the residual limb of the participant using double-sided tape to prevent displacement during tests (Figure 28). The flexibility, thickness and other properties of the sensor are specifically optimized for measuring pressure in prosthetic sockets.

**Figure 28:** Pressure sensors are taped on to the liner to cover the entire residual limb (Left), the limb is then inserted into the socket (Center), and a sleeve is rolled up on the limb for suspension (Right).
Figure 29 shows markers placed on the evaluated limb before the gait studies take place as the amputee walked at self-selected speeds on a walkway that was loaded with force plates. The markers help with the analysis of the motion capture data. The pressure readings were synchronized with the motion capture thus allowing for accurate determination of the different phases of the gait cycle.

![Figure 29: A full body marker set for motion capture is put on the participant’s protheses and entire body](image)

### 5.3 Result Analyses

Contact pressure follows a cyclic pattern during a complete gait cycle. The highest pressures recorded are during stance phase of the gait cycle while pressure values observed in swing phase are often negligible in comparison. During stance phase, two peaks are observed (Figure 30 and 31): the first peak happens at heel strike while the second, and often, higher peak happens right before toe-off. In the figures below, the average contact pressures are higher in the conventional socket at all stages in stance phase over ten gait trails at self-selected speeds.
Figure 30: Comparison of average contact pressure over ten gait cycles for the variable impedance socket and the conventional socket for the fibula head.

Figure 31: Comparison of average contact pressure over ten gait cycles for the variable impedance socket and the conventional socket for the tibia.
Figure 32: Comparison of average contact pressure over ten gait cycles for the variable impedance socket and the conventional socket for the medial condyle.

Figure 33: Comparison of average contact pressure over ten gait cycles for the variable impedance socket and the conventional socket for the lateral condyle.

Closer evaluation at stance show a 15% and 17% reduction in contact pressure at toe-off and heel-strike respectively at the fibula head while the subject uses a VIPr socket in comparison to a conventional socket of similar internal shape. A corresponding 7% and 8% reduction in contact pressure is observed along the tibia. The average walking speeds of the participant are 0.84 and 0.72 m/s while using the VIPr and conventional socket respectively.
At the fibula head and the tibia, the VIPr socket achieves lower interface pressures during dynamic activities like going up a stair and standing on one leg. Because the participant is a bilateral transtibial amputee, in Figure 34, Figure 35 and Table 5, Leg 1 represents the leg with the sockets being evaluated. It contains the pressure sensors. Leg 2 contains no pressure sensors and the prosthetic socket used by the participant is consistent across both trials.

![Graph of Contact Pressure at Fibula Head](image)

- **Leg 1**: Leg with sockets fitted with pressure sensors for evaluation.
- **Leg 2**: Leg with a conventional socket that is not evaluated. No pressure sensors attached.

**Figure 34**: Peak contact pressure measured at fibula head during various dynamic activities.
Figure 35: Peak contact pressure measured along length of tibia during various dynamic activities.

<table>
<thead>
<tr>
<th>Activity</th>
<th>% Reduction of Contact Pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Fibula Head</td>
</tr>
<tr>
<td>Standing on Leg 1 and Leg 2</td>
<td>26%</td>
</tr>
<tr>
<td>Standing on Leg 1</td>
<td>8%</td>
</tr>
<tr>
<td>Stair Ascent: Leg 1 lead</td>
<td>33%</td>
</tr>
<tr>
<td>Stair Ascent: Leg 2 lead</td>
<td>44%</td>
</tr>
</tbody>
</table>

Table 5: Percentage reduction of contact pressure at fibula head and tibia achieved by use of the V1Pr over a conventional socket for various dynamic activities.
From Table 5, it can be observed that the variable impedance socket can achieve significantly lower contact pressures on the fibula head and tibia when the participant ascends a stair 6 inches high. The percentage pressure reductions are highest on both the fibula head and tibia when the evaluated leg is used for support while the amputee goes up the stair on the opposite leg. As the amputee lifts one leg to ascend up a stair, the standing leg then supports most of his body weight, which is when pressures are highest in the socket. The CAD/CAM socket’s compliant features allows the bony protuberances of the fibula head and the tibia to be displaced a minimal amount allowing for the 44% and 36% reduction of contact pressure over the fibula head and tibia respectively.

Though the VIPr socket is about three times heavier than the conventional socket, the subject stated that they did not notice the weight during the trials. The participant noticed the added comfort in the socket at the compliant features mapped directly from the MRI of the patient. The present weight of the socket is a characteristic of the materials used in the design needed for structural integrity. As the library of 3D printing materials grow to contain materials of higher Young’s Modulus and higher tensile strengths, the weight of the design (thickness of the walls) can be further reduced.
Chapter 6:

**Conclusion**

**6.1 Summary**

Nearly all amputees experience discomfort within their prosthetic sockets due to unevenly high pressures over anatomical points. This thesis project is an amalgamation of multiple academic disciplines with an aim to design comfortable interfaces between a human body and a mechanical device. The previous chapters have been segmented to demonstrate this integration of techniques and tools for the design, manufacturing and evaluation of prosthetic sockets for transtibial amputees. The thesis presents ways of acquiring both surface data of a transtibial residual limb and the underlining anatomical data for analyses. These anatomical data, captured through digital imagining techniques, are then mapped to material properties of digital materials available for 3D printing.

The materials with properties determined to be optimal for a spatial distribution over an imaged residual limb are overlaid on a computer-aided design (CAD) model of a prosthetic socket. The internal shape of the CAD socket is an exact copy of the participant’s comfortable residual limb. The external features of the socket are designed to keep the weight of socket minimal without sacrificing the structural integrity of the socket. Furthermore, the design allows for an easy connection with standard male pyramids and each vector in the 3D design can be spatially and independently assigned a material property as determined from the anatomical data.

Once a CAD socket is designed, finite element analyses (FEA) are conducted on the model to understand the load distributions, stress and strain on the actual physical embodiment during dynamic walking. From the model studies, it was necessary to build trusses to connect the patella tendon bar to the rest of the stiffest regions in the socket. Although, the trusses provide structure to withstand a uniform pressure of approximately 260 kPa of a standing participant of weight 70 kg, they do not offer the integrity needed to contain the high torque experienced at toe-off in the patella tendon region. However, when materials of high tensile strength that prevent relative movement between the trusses and the posterior wall of the socket are used, the factor of safety is much improved. Under a 260 kPa uniform pressure and a 1,455 N
force applied at the patella tendon bar for a socket that is fixed at the distal end, the posterior wall and the trusses connecting the patella tendon bar to the posterior wall, the factor of safety for stance phase and toe-off are 12.8164 and 2.61671 respectively.

Each of the designs that are evaluated to be structurally able is then produced using an advanced 3D printer (Connex™). The computer-aided machining (CAM) technique employed in this work allows for a seamless integration of multiple materials of varying material properties. Each socket takes about 33 hours to be manufactured layer by layer as the different materials (one hard ABS-like material and another that is rubber-like) are combined to produce the varying impedances achieved. The finished CAD/CAM 3D printed sockets are then post processed by adding materials of high tensile strength along the trusses, and the base is fitted with standard pyramids used in prostheses for connection with the ankle-foot prostheses.

Contact pressure data over anatomical landmarks show significant decreases in the 3D printed variable impedance prosthetic socket in comparison to conventional sockets of similar internal shape used by participants. Furthermore, there was a slight increase in self-selected speed of the participant while walking in the 3D printed material. This observation was interesting especially because the 3D printed socket is more than two times heavier in mass.

6.2 Future Work

As the first project to actually use quantified anatomical data that is then mapped unto a structural CAD/CAM prosthetic socket of total variable impedance, the results are encouraging. We have learnt from various steps already taken by the dozens of CAD/CAM related work in prosthetic design and from the use of digital anatomical data to acquire shape of a CAD socket. Quite often, critics of this work note cost and time of production as an issue. Though this is of concern, it takes on average many months for a prosthetist to design and fit an amputee with a comfortable prosthetic socket. Hence the 33 hours needed to 3D print a socket is a major improvement. Furthermore, an average 3D printed socket will cost about US$ 3,000 in material cost when multiple materials are used. Again, it is not uncommon for a socket to cost upwards of US$5,000 when produced by a prosthetist. However, the longevity of the 3D printed sockets is yet to be evaluated.
A significant part of this thesis evolved around getting an accurate set of digital data. The internal surface shape of the CAD socket was acquired from surface scans of the male plug of a socket designed by a prosthetist while the material properties of the socket were determined from a mapping acquired from Magnetic Resonance Imaging (MRI). Though there are benefits of repeatable imaging, since MRI lacks issues of radiation experienced by other imaging techniques like X-rays and CT scans, the costs of getting MRI scans can be limiting. Hence, an interesting area of research will involve the design of a comfortable multivariable prosthetic socket from only known surface points from which the underlying body impedances are calculated.

Furthermore, an interesting study we are looking forward to carrying out is the design of a comfortable prosthetic socket that uses no input from a prosthetist. The shape of the CAD socket will be determined through a combination of images and surface scans of the residual limb, and the residual limb in a liner. The ultimate test will involve the design of a comfortable socket that has no input from a prosthetist and also no requirement for an MRI scan. Certainly, one would hope that structural integrity could be achieved through digital fabrication. Otherwise, another interesting area of research will explore the manufacturing of the ideal comfortable prosthetic socket.
Appendices

Appendix 1: Pre-scan Check-Off List for Subjects Using Magnetic Resonance Imaging

**PRE-SCAN CHECK-OFF LIST**

<table>
<thead>
<tr>
<th>BEFORE SUBJECT ENTERS THE MAGNET ROOM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prep magnet room for your subject</td>
</tr>
<tr>
<td>Prep control room for your equipment</td>
</tr>
<tr>
<td>Look at completed screening form</td>
</tr>
<tr>
<td>Ask questions regarding any red flags</td>
</tr>
<tr>
<td>Make sure that the consent form is completed</td>
</tr>
<tr>
<td>Make sure that the subject is briefed about the experiment</td>
</tr>
<tr>
<td>Check with the subject if glasses are required</td>
</tr>
<tr>
<td>Make sure that the subject has changed to scanning attire and whether they need to use the restroom</td>
</tr>
<tr>
<td>Metal screen subject with hand held wand</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>BEFORE SUBJECT GETS ON THE TABLE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Give Subject Earplugs / Ear protection</td>
</tr>
<tr>
<td>Explain the importance of not moving at all during the session</td>
</tr>
<tr>
<td>Have subject lie down ensuring they do not hit the coil edges</td>
</tr>
<tr>
<td>Give the subject the emergency squeeze ball and explain what it is for</td>
</tr>
<tr>
<td>Give the subject the button boxes and explain what they are for</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ENSURE SUBJECT IS COMFORTABLE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ask the subject if they would like a cushion under the knees and a blanket</td>
</tr>
<tr>
<td>Place the top part of the head coil (moving it over the head from back to front ensuring that the plug does not hit the subject)</td>
</tr>
<tr>
<td>Attach the mirror to the head coil and ask the subject to make adjustments if necessary to see the entire visual display</td>
</tr>
<tr>
<td>Place head restraints or padding to help prevent patient motion</td>
</tr>
<tr>
<td>Tell the subject that the table will move and move the table to the approximate landmark position</td>
</tr>
<tr>
<td>Tell the subject to close their eyes and keep them closed until you instruct them to, and landmark the subject via the laser light</td>
</tr>
<tr>
<td>Give your subject the final instructions and send them to isocenter ensuring all cables and sheets do not get caught by the moving table</td>
</tr>
<tr>
<td>Ask the subject if all is okay and tell them you are going to speak to them via the control room</td>
</tr>
<tr>
<td>Set up I-SCAN Eye tracker to have eye in focus if applicable</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>BEFORE SCANNING</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ask the subject to press the button boxes</td>
</tr>
<tr>
<td>Ask the subject if they can see the entire FOV on the screen via the mirror</td>
</tr>
<tr>
<td>Test Audio equipment and make sure subject is comfortable (if applicable)</td>
</tr>
<tr>
<td>Instruct the subject that a first series will be starting and if all is okay to press the squeeze ball</td>
</tr>
<tr>
<td>Speak with the subject between each run to ensure subject is okay</td>
</tr>
</tbody>
</table>
Appendix 2: Certified to Scan List Check-Off List for Patients Using Magnetic Resonance Imaging

Athinoula A. Martinos Imaging Center
Subject / Volunteer Screening Form
(This form is to be used for imaging only)

Name: ___________________________ Date: ______________

Date of Birth: _________________ Weight: _______________

Race/Ethnicity: _______________ Gender: ________________

Type of Exam: _______________ Principal Investigator: __________

<table>
<thead>
<tr>
<th>I have / had / am</th>
<th>YES</th>
<th>NO</th>
<th>IF YES, Please Explain</th>
</tr>
</thead>
<tbody>
<tr>
<td>History of Head Trauma / Surgery</td>
<td>___</td>
<td>___</td>
<td>______________________</td>
</tr>
<tr>
<td>Surgical Aneurysm Clips</td>
<td>___</td>
<td>___</td>
<td>______________________</td>
</tr>
<tr>
<td>Cardiac Pacemaker</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prosthetic Heart Valve</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neurostimulator</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Implanted Pumps</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cochlear Implants</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Metal rods, Plates, Screws</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Previous Surgery</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intrauterine Device (IUD)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hearing Aid, Dentures</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Injury to eye (metal?)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pregnant</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Body Piercings</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Meniere’s Disease</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tattoos</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nicotine Patch (or other foil backed patch)</td>
<td>___</td>
<td>___</td>
<td>______________________</td>
</tr>
<tr>
<td>Dental Implants / Braces</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

I have received a copy of the informed consent document(s) for this study: ______ (initial)

All subjects MUST wear either ear plugs or headphones during any imaging.

I hereby agree to have a nuclear magnetic resonance study.

Signature: ___________________________ Date: ______________

Witnessed by: ___________________________ Date: ______________

To be filled out by investigator:
IRB Protocol #: ______________ IRB Expiration Date: ___________ Rescan ___

2011, Athinoula A. Martinos Imaging Center at McGovern Institute
Appendix 3: Objet™ Digital Materials™ Data Sheets
**Appendix 4: Left Socket Material Consumption, Printing Costs and Printing Time**

![Print Quoting Tool](image)

<table>
<thead>
<tr>
<th>Machine Type:</th>
<th>Material 1:</th>
<th>Material 2:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Connex500</td>
<td>VeroWhite</td>
<td>TangoBlackPlus</td>
</tr>
<tr>
<td></td>
<td>3.6 kg</td>
<td>3-Pack</td>
</tr>
<tr>
<td>Cartridge Size:</td>
<td>M1 3-Pack Cost:</td>
<td>$2,916</td>
</tr>
<tr>
<td>Cartridge Pricing:</td>
<td>M2 3-Pack Cost:</td>
<td>$3,456</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Grams Consumed</th>
<th>Grams per Container</th>
<th>Cost Per Container</th>
<th>Consumption Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Model Material 1:</td>
<td>1860</td>
<td>3600</td>
<td>$972</td>
</tr>
<tr>
<td>Model Material 2:</td>
<td>678</td>
<td>3600</td>
<td>$1,152</td>
</tr>
<tr>
<td>Support Material:</td>
<td>1922</td>
<td>3600</td>
<td>$450</td>
</tr>
</tbody>
</table>

Build Time (HH:MM): 33:30

Subtotal Cost: $959.41

Quantity: 1

Total Cost: $959.41

*default cost per container is generated from lowest cost per gram pricing*
Appendix 5: Right Socket Material Consumption, Printing Costs and Printing Time

**Objet Print Quoting Tool**

- **Machine Type**: Connex500
- **Material 1**: VeroWhite
- **Material 2**: TangoBlackPlus

<table>
<thead>
<tr>
<th>Material Type</th>
<th>Model Material 1</th>
<th>Model Material 2</th>
<th>Support Material</th>
<th>Cost Per Container</th>
<th>Consumption Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1910</td>
<td>642</td>
<td>1661</td>
<td>$972</td>
<td>$515.70</td>
</tr>
<tr>
<td></td>
<td>3600</td>
<td>3800</td>
<td>3600</td>
<td>$1,152</td>
<td>$205.44</td>
</tr>
<tr>
<td></td>
<td>$450</td>
<td>$1,152</td>
<td>$207.63</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Cartridge Size**: 3.6 kg
**Cartridge Pricing**: 3-Pack

**Build Time (HH:MM)**: 31:10

*Default cost per container is generated from lowest cost per gram pricing*
References


