Dynamic Prosthetic Socket

A Major Qualifying Project Report
submitted to the Faculty of
WORCESTER POLYTECHNIC INSTITUTE
in partial fulfillment of the requirements for the
Degree of Bachelor of Science
by

Michael Chan
Alexander Fitzgerald
James Honicker

Report submitted to:
Professor Gregory Fischer, Advisor, WPI

Acknowledgements

We would like to thank the following individuals, organizations and institutes for aiding us in this project and providing us with the support and knowledge necessary for the completion of this MQP.

- Professor Gregory Fischer for his expertise and guidance throughout the entire course of this project.
- Christopher Nycz and Paulo Carvalho for their aid and advice on the project.
- Worcester Polytechnic Institute and the AIM lab for sponsoring this project and providing us with the workspace and the means to make this project.
- James Loiselle for aiding us in the machining of the parts we required.
- Liberating Technologies Inc. for their extremely helpful input in the design portion of the project.

Table of Authorship

The table below outlines all of the topics covered in this MQP report. The author's last name is given for each section to indicate who wrote that section.

Section	Author
Acknowledgements	Chan
Executive Summary	Chan/Honicker
1 Introduction	Chan/Fitzgerald
2 Literature Review	Honicker
2.1 Health Problems Caused by Improper Socket Size	Honicker
2.1.1. Epidemiology	Honicker
2.1.2. Pain and Discomfort	Honicker
2.1.3. Skin Problems	Honicker
2.1.4. Vascular and Lymphatic Problems	Honicker
2.1.5. Overall Health	Honicker
2.2. Current Socket Technology	Fitzgerald
2.2.1. Mechanical Adjusting Sockets	Fitzgerald
2.2.2. Vacuum Suspension Socket (VSS)	Fitzgerald
2.2.3. Smart Variable Geometry Socket (SVG)	Fitzgerald
2.2.4. Compression/Release Stabilized Socket (CRS)	Fitzgerald
2.2.5. Dynamic Adjustable Prosthetic Socket (DAPS)	Fitzgerald
2.2.5.1. Electrical System	Honicker
2.2.5.2. Control Algorithm	Chan
2.2.5.3. Mechanical Attributes	Fitzgerald
2.3. Biometrics	Chan
2.3.1. Leg Characteristics (shank length, volume, shrinkage, etc.)?	Honicker

2.3.2. Detecting the User's State	Chan
2.4. Electrical System	Chan
2.4.1. EMG Noise	Chan
2.4.2. Hardware Filtering	Chan
2.4.3. Signal Processing Methods	Chan
2.4.4. Electrodes	Chan
2.4.5. Hall Effect Sensors	Chan
2.4.6. Control and Processing Interface	Chan
2.5. Control Algorithms	Chan
2.5.1. Bang-Bang Control	Chan
2.5.2. Proportional Integral Derivative Control	Chan
2.6. Mechanical Factors	Fitzgerald
2.6.1. Strength	Fitzgerald
2.6.2. Weight	Fitzgerald
2.6.3. Motor Strength	Fitzgerald
3 Project Strategy	Chan
3.1. Project Approach	Chan
3.2. Design Requirements	Chan
3.2.1. Technical	Chan
4 Design Justification / Process	Fitzgerald
4.1 Brief overview of the DPS design	Chan/Fitzgerald
4.2. The Prosthetic Socket	Honicker
4.2.1. Socket	Honicker
4.2.2. Knee and Foot	Honicker
4.2.3. Shank	Honicker
4.3. Bladders	Fitzgerald

4.4. Actuation Mechanism	Fitzgerald
4.4.1. Hydraulic cylinder	Fitzgerald
4.4.2. Motor	Fitzgerald
4.4.3. Attaching the Motor to the Hydraulic Cylinder	Fitzgerald
4.5. Valves	Honicker
4.5.1. Two way gate valves	Honicker
4.5.2. Pinch valves	Honicker
4.6. EMG sensors	Chan
4.7. Battery	Honicker
4.8. Tubing	Honicker
4.9. Pressure sensor	Chan
4.10. Hall Effect Sensors	Chan
4.11. Electrical System Integration	Honicker
4.12. Rejected Designs	Fitzgerald
4.12.1. Design A	Fitzgerald
4.12.2. Design B	Fitzgerald
4.12.3. Design C	Fitzgerald
5 Design Validation (testing, measurements, results, etc.)	Chan
5.1. Hall effect calibration	Chan
5.2. EMG calibration (muscle spasm and twitch test)	Chan
5.3. Response time test	Chan
5.4. System weight	Chan/Fitzgerald
5.5. Compactness	Fitzgerald
5.6. Duration and power efficiency	Honicker
5.8. Electrical integration	Honicker
5.9. Validation of the overall Dynamic Prosthetic Socket system	Chan

6 Discussion (discussion of the test results/measurements obtained in chapter 5, topics ordered by items on priority list from most to least important)	Fitzgerald
6.1. Reliability	Chan
6.2. Response time	Chan
6.3. Power efficiency	Honicker
6.4. Safety	Honicker/Chan
6.5. Strength	Fitzgerald
6.6. Weight	Fitzgerald
6.7. Comfort	Honicker
6.8. Aesthetics	Fitzgerald
6.9. Size	Fitzgerald
7 Conclusion and Recommendations	Chan
Bibliography	Honicker/Chan

Contents

1. Introduction **13**

2. Literature Review **15**

2.1. Health Problems Caused by Socket Use 15

2.1.1 Epidemiology 15

2.1.2 Pain and Discomfort 16

2.1.3 Skin Problems 16

2.1.4 Vascular and Lymphatic Problems 17

2.1.5 Overall Health 17

2.2. Current Socket Technology 18

2.2.1. Mechanical Adjusting Socket 18

2.2.2. Vacuum Suspension Socket (VSS) 19

2.2.3. Smart Variable Geometry Socket (SVG) 20

2.2.4. Compression/Released Stabilized Socket (CRS) 21

2.2.5. Dynamic Adjustable Prosthetic Socket (DAPS) 22

2.2.5.1 Electrical System 22

2.2.5.2 Control Algorithms 23

2.2.5.3. Mechanical Attributes 23

2.3. Biometrics 24

2.3.1. Leg Characteristics 24

2.3.2. Detecting The User's State 25

2.3.2.1 Electromyographic Sensors 25

2.4 Electrical System 26

2.4.1 EMG Noise 26

2.4.2 Hardware Filtering 26

2.4.3 Signal Processing Methods 26

2.4.3.1 Rectify and digital low pass filter 26

2.4.3.2 Root mean square filters 26

2.4.4 Electrodes 27

2.5 Control Algorithms 27

2.5.1 Bang Bang Control 27

2.5.2 PID Control 27

2.6. Mechanical Factors 28

2.6.1. Strength 28

2.6.2. Weight 29

2.6.3. Motor Strength 29

3. Project Strategy **30**

3.1. Project Approach 30
3.2. Design Requirements 31
3.2.1. Technical 31
3.2.1.1 Functionality 31
3.2.1.2 Constraints 31

4. Design Justification / Design Process 33
4.1 Brief Overview of the DPS Design 33
4.1.1 Coding 35
4.2. The Prosthetic Socket 35
4.2.1 Socket 36
4.2.2 Knee and Ankle 36
4.2.3 Shank 36
4.3. Bladders 37
4.4. Actuation Mechanism 38
4.4.1. Hydraulic Cylinder 39
4.4.2. Motor 40
4.4.3. Attaching the Motor to the Hydraulic Cylinder 41
4.5 Valves 42
4.5.1 Two Way Gate Valves 42
4.5.2 Pinch Valves 42
4.6. EMG Sensors 43
4.7 Battery 44
4.8 Tubing 44
4.9. Pressure Sensor 46
4.10. Hall Effect Sensor 46
4.11 Electrical System Integration 47
4.12. Rejected Designs 51
4.12.1. Design A 51
4.12.2. Design B 52
4.12.3. Design C 53

5. Design Validation 54
5.1 Hall effect calibration 54
5.2 EMG calibration 54
5.3 Response Time Test 55
5.4 System weight 56
5.5 Compactness 56
5.6 Duration and power efficiency 57
5.7 Electrical Integration 57

5.8 Validation of the overall Dynamic Prosthetic Socket system 58

6. Discussion **59**

6.1 Reliability 59

6.2 Response time 59

6.3 Power efficiency 59

6.4 Safety 59

6.5 Strength 60

6.6 Weight 61

6.7 Comfort 61

6.8 Aesthetics 61

6.9 Size 61

7. Conclusion and Recommendations **63**

7.1 Recommendations 63

7.1.1 Reduce length of shaft 63

7.1.2 Reduce weight of system 63

7.1.3 Embedded Processor 64

7.1.4 Clinical Trials 64

7.1.5 Alternate Pumping System 64

8. Bibliography **65**

Executive Summary

In the United States alone, there are approximately 2 million cases of citizens currently living with limb loss [1]. Out of the 2 million, about 18.5% of the patients are transfemoral amputees, patients who have had their amputation above the knee[1]. This loss of such a critical limb leads to a greatly diminished quality of life and while current prostheses can restore a person to pre-amputation levels of mobility, the prostheses create several challenges themselves. With the majority of amputations being due to health reasons, such as diabetes and peripheral vascular disease[2], the number of cases are only expected to rise as time goes on[1]. As such, the challenges that amputees face on a day to day basis with their prosthetics need to be addressed.

The greatest cause of distress for transfemoral amputees is ill-fitting sockets[10]. As such, the necessity for a socket that can consistently fit well throughout the day, as well as account for the changes that their residual limb undergoes throughout time is extremely high. In an attempt to satisfy this need, last year's Dynamic Adjustable Prosthetic Socket team combined elements from current prosthetic technologies such as the Smart Variable Geometry (SVG) socket and the Compression/Release Stabilized (CRS) socket. This resulted in an impressive proof of concept design that utilized hydraulic bladders to fit the patient's limb, as well as EMG sensors to predict a patient's activity.

The main goal for the project was to improve upon last year's design, making it faster and more efficient, while remaining safe and reliable for the user. With last year's design, there was quite a lot of room for improvement for both the hardware and software components. By redesigning both of these aspects, it is possible to create a prototype that can be much more responsive, efficient, and aesthetically pleasing than the projects previous iterations.

The socket can adjust the fit on a user's residual limb based on their activity level as well as the current volume of their limb. Dynamic calibration allows for the system to be based off of pressure exerted onto the patient. When the patient dawns the system the bladders in the socket begin to fill. The filling is performed by a Firgelli Linear actuator driving a hydraulic piston within the shank of the limb. This piston pushes water into all bladders that have their valves open. Each bladder receives a small amount of water through the solenoid pinch valve system. Each valve opens momentarily to allow water to pass before being shut. This process cycles through all of the valves filling each bladder slowly one at a time. The periodic filling continues until all of the bladders hit their calibration points. These calibration points are determined by a pressure spikes registered by the pressure sensor located within the shank. The pressure spikes occurs when the bladders presses against the side of the user and can not inflate further.

When a pressure spike is registered, a calibration point is set by the hall sensor respective of the bladder with the pressure spike. Each bladder has a hall sensor and magnet mounted on opposite face in parallel. Together they can measure how inflated the center of the bladder has become. The readings taken by each sensor are used for future referencing when inflating and deflating the bladders based on the user state.

User state is determined by EMG sensors mounted on the thigh of the patient. The raw analog readings are passed through a series of filters and algorithms to help generate a smooth and consistent state reading. When the user moves or tries to stand the system is sent into active state. When in active state the system will inflate the bladders till they fill within a tolerable distance of the same inflation level set through initial calibration. Unlike in calibration, all bladders can be filled simultaneously. When a bladder reaches its set position it will close its respective valve, forcing additional water from the motor driven reservoir into the bladders that are still filling. When in active state the system will attempt to maintain relative pressure and inflation of the bladders. If pressure is consistently to high and the system

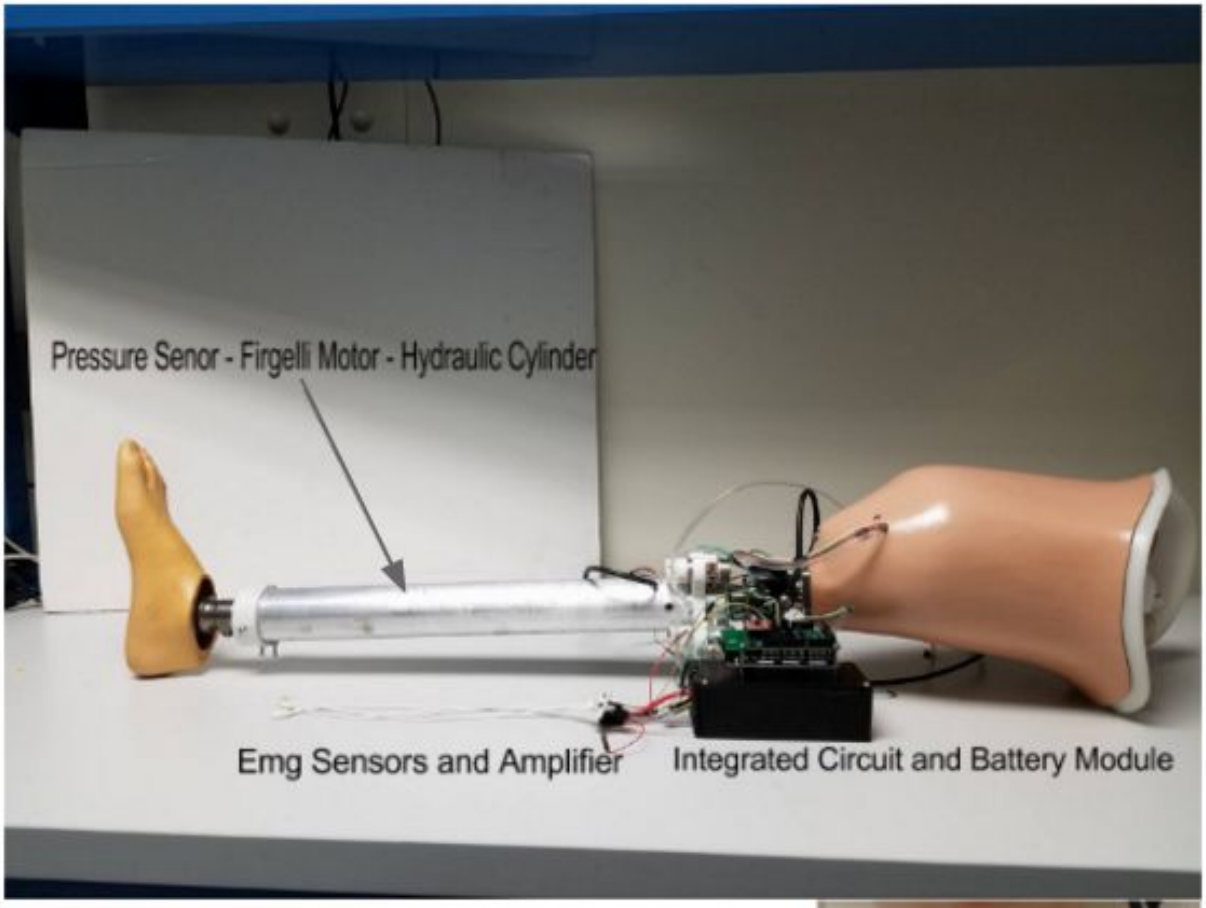
can remove some waters from the valves to lighten up the squeeze on the limb. Otherwise the system attempts to keep all of the bladder near the initial fill readings.

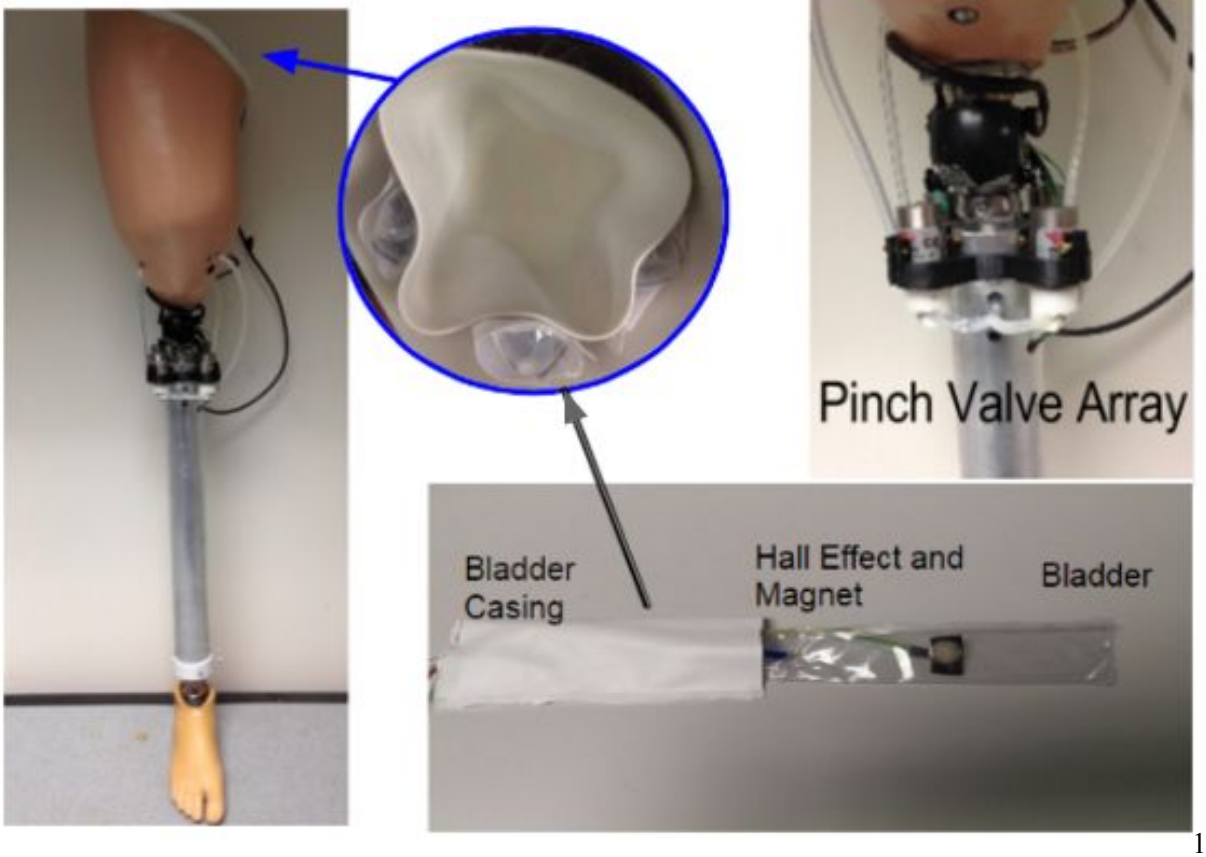
When the user becomes passive,such as sitting down, the system will go through a series of brief checks to ensure the user is indeed passive. The system defaults to active state so as to never accidently cause the leg to loosen on someone who is actively using the prosthetic. If passive state is entered the bladders within the socket will begin to drain until their hall sensors read a predetermined value related to the initial calibration settings. Once this drain inflation is reached, or is within tolerable margins the system goes into waiting. As soon as a single active reading is registered by the EMG algorithm the system springs back to life and inflates all of the bladders to their active state levels. If the user ever feels like the system calibration is off, they can reset the system to trigger the initial calibration filling again. The system will recalibrate every time it is powered on.

Through the complete overhaul of the previous project's design, it was possible to reduce the overall system and contain the major mechanical parts within a singular aluminum shaft. This results in a much more sleek and simplistic design of the leg that is more aesthetically pleasing than previous designs. However, the resulting system ended up averaging around 13.5 lbs total, which is heavier than what was initially expected. This can be improved further upon through better material selection and fabrication.

Through extensive testing, it was found that the implemented EMG signal processing algorithm resulted in a successful twitch detection rate of 96%. Coupled with the relatively small response time the system has towards state transitions (around ¼ of a second) and the fact that the whole system is completely autonomous, it can safely be said that the system's control scheme has become sufficiently robust. For more intense control purposes, machine learning algorithms can be implemented to determine what types of movement patients are exhibiting rather than sensing only muscle twitches.

In conclusion, this project succeeded in nearly all of its objectives and was therefore largely successful. It is also a strong platform for future work and clinical trials.


Pressure Senor - Firgelli Motor - Hydraulic Cylinder
Emg Sensors and Amplifier
Integrated Circuit and Battery Module


Pinch Valve Array
Bladder Casing
Hall Effect and Magnet
Bladder

1. Introduction

Every year, around 185,000 amputations happen in the United States [1]. The need for these amputations is largely the result of vascular diseases such as diabetes, tumors, or infection [2]. This fast rate brings the total to around two million people living with limb loss in the United States today and that number will continue to grow. Just under a fifth of those people have a transfemoral or above knee amputation in particular [3]. This lower leg amputation severely impedes one's ability to stand, walk, or run - many transfemoral amputees resort to wheelchairs if they feel disconcerted with learning how to move with a prosthetic device. Transfemoral amputees need and deserve a reliable prosthetic socket device to compensate for their missing lower leg.

A transfemoral amputee's residual limb can bring about challenges that a prosthetic socket should overcome - including volume fluctuations and skin sensitivity. When a person begins living with lower limb loss, the thigh muscles for that leg begin to atrophy. An amputee's residual limb experiences significant decrease in size for the first 12-18 months. However, even when this period of time has ended, the limb volume continues to change. It experiences small daily fluctuations due to multiple circulatory mechanisms: vasodilation, interstitial fluid volume alterations, and blood pooling. Furthermore, a user will experience limb shrinkage when they stand up or begin moving around because of the subsequent increase in interstitial fluid pressure [4].

The sensitivity of the residual limb skin can also allow for serious skin conditions if the amputee is not careful. The prosthetic socket will trap limb perspiration, thus creating a risk of pathologic conditions for the limb skin. Furthermore, the skin can be damaged when experiencing the stress of the weight that the residual limb has to bear. Skin strength varies for different people, but the residual limb skin is generally sensitive enough to experience compression under just a small amount of force. The repetitive stretching of skin and constant rubbing against the contact points of the socket can harm the residual limb to the point that the prosthesis can no longer be worn by the amputee. Furthermore, the residual limb is subjected to negative pressure in vacuum suspension systems. Even if the socket's shape is a near-perfect match for the user's leg, the residual limb must still be treated with special care [34].

Current socket technologies have attempted to account for the residual limb volume fluctuations and skin sensitivity, however, they all seem to lack convenience or comfort. Mechanical adjusting sockets (Section 2.2.1), for example, are less convenient because they are not dynamically adjustable. They require the user to manually tighten or loosen the grip on their residual limb throughout the day - and if they over-tighten the socket, then they risk blocking circulation. Furthermore, the Compression/Released Stabilized (CRS) socket (Section 2.2.4) can become uncomfortable because it applies the same compressive force to the residual limb throughout the day - regardless of if the user is walking or not. This can lead to discoloration as well as block circulation.

The Dynamic Adjustable Prosthetic Socket (DAPS) project (Section 2.2.5) aimed to combine the dynamically adjustable nature of the Smart Variable Geometry (SVG) socket (Section 2.2.3) with the compression/released grip mechanism of the CRS socket to ensure a comfortable *and* tight connection for the user. Last year (2015-16), the DAPS team developed a 'smart' device that could sense when the patient was moving and apply more pressure by utilizing syringes and inflatable bladders. The DAPS project was a successful proof of concept.

The purpose of this project is to improve upon the DAPS system. The Dynamic Prosthetic Socket (DPS) system could more accurately predict patient movement and determine which state to move into in real time by implementing a robust EMG signal processing algorithm. The appropriate hydraulic pressure can then be applied to the residual limb with a faster response time, based on the determined state. Furthermore, the mechanical design could become more compact and aesthetically appealing to the patient. The main goal of this project is to develop a more practical and efficient system, which can serve as a platform for clinical trials.

2. Literature Review

Prosthetics have been in use for nearly 3000 years, dating back to the ancient Egyptians. The first famously noted use of prosthetics was a Roman General named Marcus Sergius. Sergius had a prosthetic hand created that allowed him to hold a shield. He went on to fight in many additional wars in his long military career, using his hand prosthetic. Since then, till the American Civil war prosthetic technology remained fairly stagnant. Basic improvements in comfort and functionality were made but advancement was very limited. Following the civil war and the turn of the 20th century prosthetics saw a boom in development. New connection techniques, such as the vacuum fit were developed as well as well as bendable parts and multi joint attachments.[8]

In the last decade in particular socket technology has improved substantially. New moulding techniques and attachment methods have allowed a variety of prosthetic technologies to take hold in the marketplace that offer the users options for comfort and functionality. However, although the technology has improved there are still many problems associated with long term socket use. Socket fit is incredibly important for proper device use, but is a challenge given that the limb can fluctuate within approximately 10% of its volume throughout the course of the day.[9] Additionally weight fluctuations can affect the total volume of the limb causing an improper fit as well as a plethora of other bodily functions or conditions that cause swelling or shrinkage. These fluctuations can cause a great deal of discomfort and loss of functionality, as well as some serious medical problems.[10] This issue is very prevalent as there are approximately 1 million residents within the united states with a lower limb amputation. [11] The majority of the amputations being necessary as a result of vascular disease. [12]

2.1. Health Problems Caused by Socket Use

Among the users of prosthetics there are a plethora of shared issues and concerns in regards to the overall comfort, health, and safety of their residual limbs. In surveys conducted across the industry the majority of users reported that comfort or function was the most important aspect of a prosthetic socket.[10] However, in a second survey, the majority of the users reported that fit was the single most important factor. The second survey was targeted more specifically at those who suffered lower limb amputations[22]. With these primary concerns from patients in mind, the design of the socket will focus on maintaining the health of the limb while also trying to be as functional, comfortable, and fit as well as possible.

2.1.1 Epidemiology

In the United States there are approximately 185,000 amputations performed annually. The primary cause of these amputations are peripheral vascular disease and diabetes, accounting for 70-82%, with trauma being the second leading cause [13] [14]. 97% of dysvascular, having a defective blood supply, amputations were lower-limb with 25.8% transfemoral [15]. The number of individuals living with amputations is expected to continue to rise for the foreseeable future and the health issues plaguing individuals as a result of amputation will continue to grow in number[11].

2.1.2 Pain and Discomfort

Medical advancements in socket technology are primarily focused on improving the health of the residual limb. One of the main symptoms of a limb suffering from a health issue is pain and discomfort. A patient with a prosthetic,suffering pain on the augmented limb is a great indicator of medical problems caused by the socket [9]. The pain is a natural reaction to excessive forces and tissue damage. However, pain is sometimes difficult to quantify, especially between individuals. Certain individuals with limb loss, such as those resulting from diabetic issues, may feel decreased pain due to neuropathy [10]. Because of the discrepancies between individuals, other forms of observing residual limb health are needed and are identified below.

2.1.3 Skin Problems

After an amputation the skin of the new residual limb is prone to a plethora of problems. Because the soft tissues of the limb are now exposed to additional shear and friction forces from the prosthetic socket, skin diseases, abrasions and other skin related concerns are very prone to occur. A few examples of common skin problems associated with prosthetic use are as follows. Ingrown hairs and rashes, a commonly associated problem of wearing gel sleeves, a popular component of suspension sockets [17]. Skin irritation can occur from sweat on the skin compounded by a lack of airflow [16]. Additionally sweat contributes to prosthetic odor, which was identified as important to avoid in the survey of lower-limb amputees [10]. Another major component to the skin problems associated with prosthetic use is the continuous friction and rubbing that goes along with socket use. Friction is a contributor to skin complaints such as erythema (see Figure 2.1.3.1), blisters, and skin thickening [18]. When friction force is relatively small but sustained for a long time, it creates skin thickening. However, an increase in the friction force applied of time can result in the formation of blisters [19].

One of the single most important factor in reducing skin damage and preserving limb health is maintaining a good fit of the prosthetic socket. There is a direct correlation between socket slippage and friction felt by the prosthetic user. Research conducted on a series of prosthetic users determined the following with regards to allowed range of slipping motion. Well-fitting sockets had slip of 2 mm to 6 mm [20]. Slip substantially greater than that causes user distrust of the prosthetic limb, abnormal gait, and severe friction on the limb causing the aforementioned frictional skin problems. Slip measuring less than 2mm - 6mm puts extra pressure on the limb causing issues such as pressure sores and ulcers. The intensity of the load on the leg and the duration the force applied is inversely proportional to the amount of ulcers observed [16]. Additionally sockets that were too tight and allowed little slippage led to increased skin temperature, contributing to sweat production in the socket [16].

Many types of skin problems such as these can deter amputees from using socket devices as even the most mild problems can cause discomfort and can lead to infection or ulcers if not treated correctly. It is estimated that 75% of lower-limb amputees will experience skin issues [21].

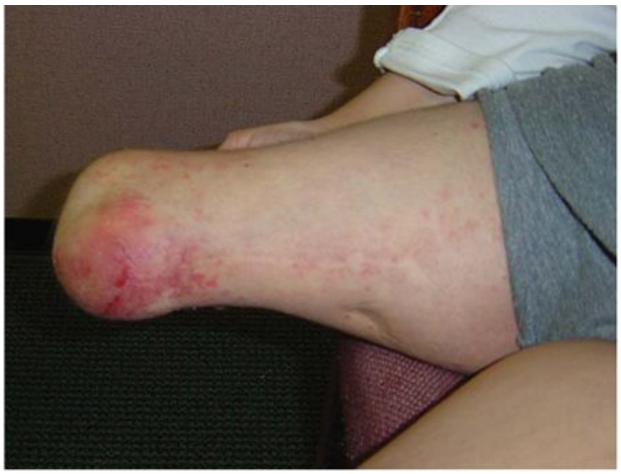


Figure 2.1.3: Acute erythema and edema on the distal end of the thigh on a transfemoral amputee[18]

2.1.4 Vascular and Lymphatic Problems

In addition to surface level skin problems caused by prosthetics there are a series of vascular and lymphatic problems associated with the use or misuse more specifically of prosthetic sockets. Ischemic injury, restriction of blood flow, of the limb can cause pressure sores and localized malnutrition. Epidermal forces, that is forces applied to the outer layer of the skin, are a major factor in the formation of a microvascular response. Decreased blood flow occurs with increased application of either normal or shear forces [16]. Similarly, the prosthetic device affects the lymphatic system. Lymphatic function is associated with skin health in the form of tissue edema [16]. Accumulation of lymphatic waste could occur if external forces hindered the flow of lymph fluids. In layman's terms, the prosthetic limb can not be too tight on a patient's limb for too long. If the limb causes too much external pressure on the leg, the reduction in blood flow and lymphatic fluid buildup can be extremely detrimental the the limbs overall health.

2.1.5 Overall Health

Looking beyond just the health of the residual limb, the overall health of the patient can be affected by improper fitting of a lower limb prosthetic. An abnormal gait caused by a poor fitting socket can lead to significant back and hip problems after prolonged used. Additionally the mental toll of losing the ability to perform even some everyday actions such as climbing stairs or riding a bike without experiencing pain can weigh in on an individual. Lastly any stigmas of appearance or lack of acceptance from family or significant others can have a physiological effect on a user of a prosthetic, should they feel unaccepted for having a augmented limb.[10]

2.2. Current Socket Technology

There are a variety of prosthetic socket devices that have found success in the real world. They enable amputees to walk again by utilizing multiple different attachment methods. However, they each have weaknesses that need to be considered in order to develop a more practical system. This section focuses on mechanically adjusting sockets, vacuum suspension sockets, smart variable geometry sockets, compression/released stabilized sockets, and the Dynamic Adjustable Prosthetic Socket (DAPS).

2.2.1. Mechanical Adjusting Socket

Mechanical adjusting sockets allow the user to manually tighten the socket's grip on their residual limb. The RevoFit™ socket system and the LIM Infinite Socket™ are two examples of mechanical adjusting sockets that utilize a tension dial and ratcheting straps, respectively. The RevoFit™ socket system is manufactured by Click Medical [23] and the LIM Infinite Socket™ system is manufactured by LIM Innovations [24]. Both systems give the user the ability to completely control how tight the prosthetic socket connection is. Unfortunately, that means that the user is also required to constantly be making adjustments to the compressive forces on their residual limb because the volume is always fluctuating. Furthermore, this system introduces the risk of human error. If the patient tightens the socket device too much or if they apply a reasonable tightness and then the limb swells, the prosthetic device could restrict blood flow through the limb.

Figure 2.2.1: RevoFit™ Socket System

2.2.2. Vacuum Suspension Socket (VSS)

Vacuum Suspension Sockets (VSS) rely on a suction effect to attach to a patient's residual limb. An amputee can don the socket by first putting a liner on their residual limb and then putting their residual limb in the socket - the device removes the air separating the liner from the socket wall, causing the liner and socket to make complete contact with each other. Figure 2.2.2 illustrates this sealing process. This firm connection is strong enough that the socket will not slip off from any of the forces it would experience during a typical day. The fit is strong enough that the user can experience greater control - satisfied users have described the leg as feeling lighter than alternative socket devices because it is so well connected to the residual limb - forces felt on the residual limb have been minimized.

The sealing mechanism of the VSS socket also appears to prevent the residual limb volume from shrinking both during the day and in the long run. Tests demonstrated that, after some users went for a walk while wearing the VSS socket, the limb volume actually increased slightly. Furthermore, an increase in blood flow through the residual limb was also observed. This boost in blood flow and this prevention of limb volume loss both seem to be beneficial for the health of the patient's residual limb.

The VSS socket provides an optimal environment for the user's residual limb, however, problems can emerge if the prosthetist and user are not careful. Firstly, if the socket is not a perfect fit for the user's limb, then skin damage can occur when suction occurs and/or the user can feel more pressure on the limb than they are supposed to. Furthermore, just like for other socket devices, the inside of a VSS socket can encourage bacterial growth due to the heat and sweat that enters.

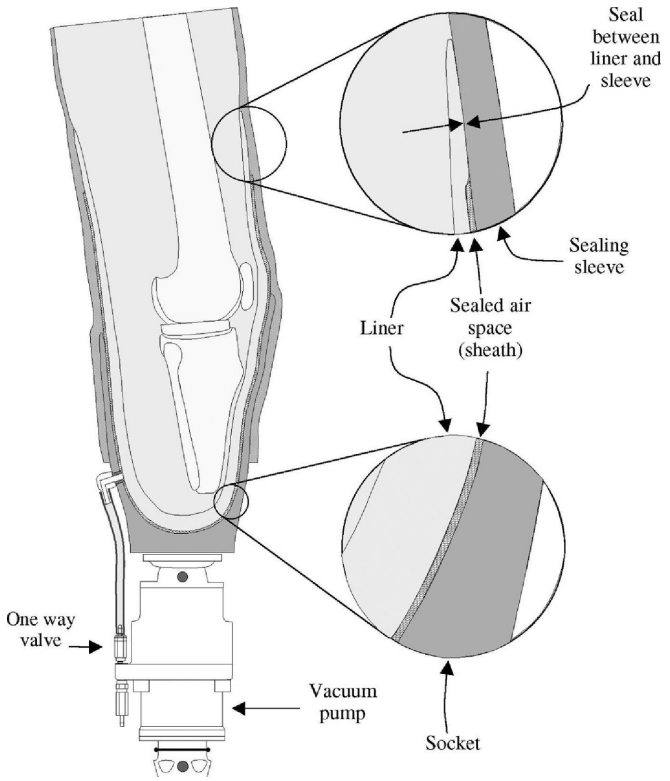


Figure 2.2.2: Vacuum Suspension Socket Sealing Mechanism

2.2.3. Smart Variable Geometry Socket (SVG)

The Smart Variable Geometry (SVG) Socket was designed as a more reliable and secure device for transfemoral and transtibial amputees to wear. Without the SVG socket, users would be required to manually don or doff socks and padding in order to compensate for the daily fluctuations in residual limb volume. The leg may also be subjected to high pressures if the socks and padding are not removed frequently enough. The SVG socket continuously adjusts the amount of space inside the socket in order to account for the changes in limb volume. Users can find comfort, convenience, and safety with the socket fit adjusting on its own: according to the person's needs. The SVG socket works by applying hydraulic pressure to the amputee's residual limb through inflatable bladders. A reservoir beneath the socket contains the fluid, which is pumped through a series of tubes and valves up into the bladders, which are mounted inside the socket. These system components are shown above in Figure 2.2.3. Furthermore, the pumping action is driven by the patient's gait cycle.

The SVG socket offers greater comfort, convenience, and safety to the user. A prosthetist specifically chooses the quantity, distribution, and dimensions of the bladders according to the size and shape of the residual limb. He or she also decides the maximum pressure that the bladders would exert on the user's residual limb, ensuring that they remain comfortable wearing it for long periods of time. The dynamically adjusting nature of the system also saves amputees the time that they would otherwise spend donning or doffing each day. Furthermore, the system ensures that the socket fit does not constrict the limb's blood flow too much. Unfortunately, this system does not control individual bladders - this is a slight limitation on the device's ability to provide comfort to the patient. Finally, the SVG socket has difficulty allowing the person to transition from sitting to walking; it requires them to take a few steps before the necessary pressure is applied and this can create a risk of discomfort or loose fit.

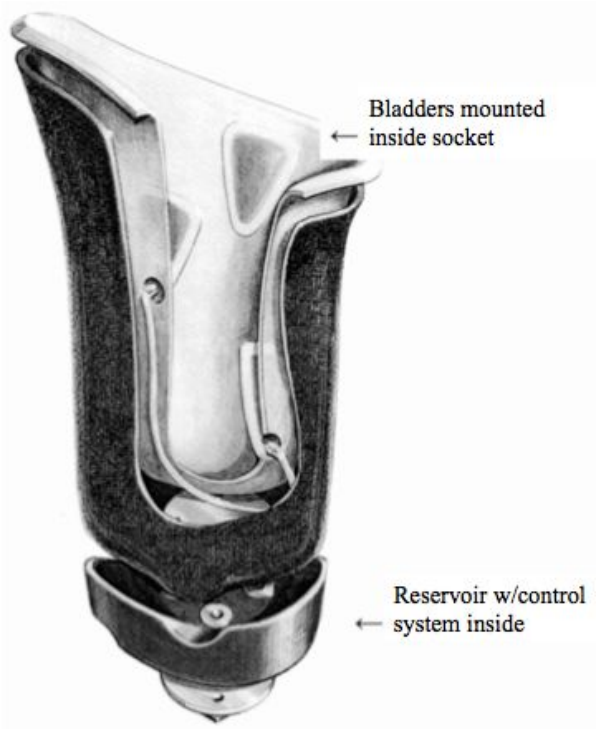


Figure 2.2.3: Smart variable geometry socket (SVG)

2.2.4. Compression/Released Stabilized Socket (CRS)

The Compression/Released Stabilized (CRS) socket was developed as a more energy efficient and controlled prosthetic socket device for amputees in comparison to the traditional prosthetic socket systems; the frame-interface for a CRS socket can be seen in Figure 2.2.4b. CRS sockets can be used for both arm and leg amputations; they apply a tight grip to the residual limb by applying pressure at three or four points around the circumference of the limb with areas of relief in between. This idea of applying compressive force at specific points and release in between is illustrated in Figure 2.2.4a, which displays cross-sectional images of CRS sockets with (a) two, (b) three, and (c) four areas of compression. A convenience of this system is that users do not have to spend the time/energy donning or doffing because the CRS socket device compresses the tissue on its own. Furthermore, the biggest advantage of the CRS system is that it applies enough compression such that the user has better control than they would for traditional prosthetic sockets. This tightness or lack of wiggle room within the socket makes it easier for the user to apply forces to the leg. The CRS fit features higher energy efficiency (for energy transfer from the residual limb to socket), less slipping, improved mobility, and enhanced stability/strength.

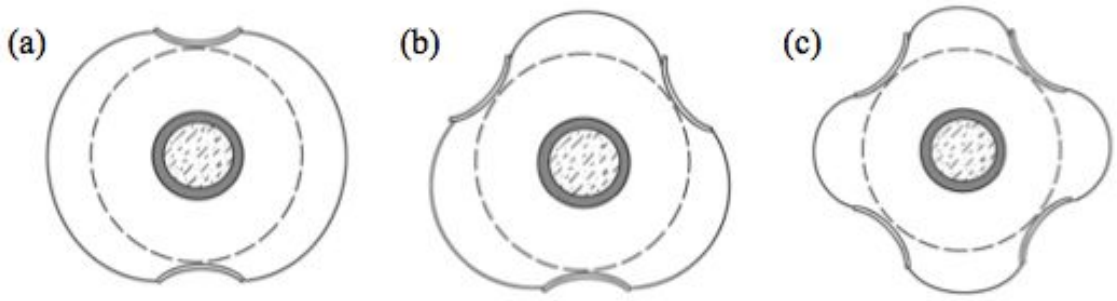


Figure 2.2.4a: Cross-sectional diagrams for the tissue compression of a CRS socket

The tightness of the CRS socket device provides a variety of advantages, however, it also has potential to cause problems for the user because the same tightness is maintained throughout the amputee's day. If the fit on the residual limb is stronger, then the system could be less comfortable for the patient and it may become more difficult for them to attach the device to their residual limb. This generally requires amputees to visit their prosthetist more often until the fit is 'right'. However, even when the fit feels appropriate, there is still a risk of the socket affecting circulation throughout the limb - especially problematic for patients with heart disease or diabetes. Furthermore, the firm grasp on the residual limb can result in discoloration. It is normal for a patient's residual limb skin to experience redness for the first hour after doffing, however this redness period can last three or four hours for tighter socket devices. More research regarding pressure is necessary before the CRS socket can become a reliable option for users.

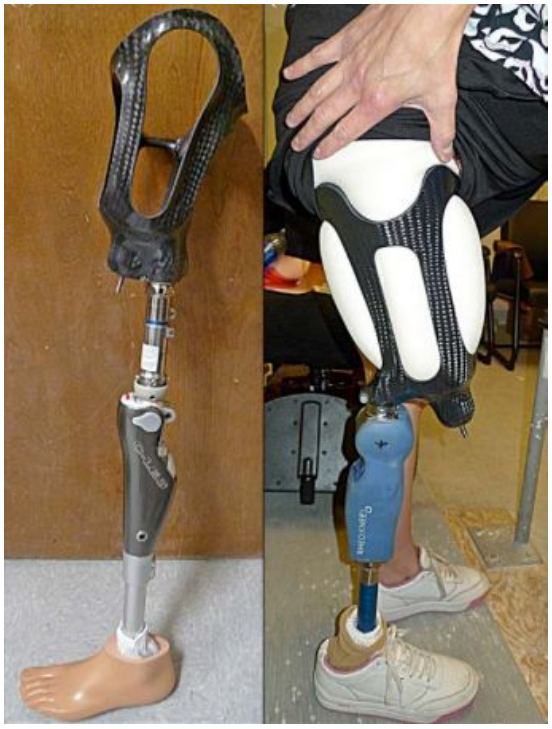


Figure 2.2.4b: Frame-interface for a compression/release stabilized (CRS) socket

2.2.5. Dynamic Adjustable Prosthetic Socket (DAPS)

The Dynamic Adjustable Prosthetic Socket (DAPS) was an MQP designed last year (2015-2016). The system combines the volume adjustment features of the SVG socket with the alternating areas of compression/relief, as exhibited by the CRS socket. This section briefly describes the electrical system, control algorithms, and mechanical attributes of the DAPS system.

2.2.5.1 Electrical System

Last years electrical system followed a pretty traditional design. It contained a 14 volt Lipo battery with the necessary voltage regulators to subvert the required voltages to the control board, peripheral sensors, and motor controller. From the microcontroller signal lines were fed to a motor controller that powered two Firgelli linear actuators. The linear actuators required 12 volts DC and had a stall current of approximately 1 Amp. The mbed also provided the power for the sensory system which included 2 sets of bitalino EMG modules and two hardware filters for the Emgs. Additionally there was a pressure sensor included on the system and power straight from the battery. This sensor was used primarily for safety concerns. The total current pull on the 14 volt battery can be measured by summing the max currents of its components at their running voltage. This can be assumed since the excess voltage is burned off in the power regulators. The main power consumption comes from the two motors, the microcontroller and the peripherals, totaling a worse case power draw of 2-2.4 amp hours at 14 volts. During passive periods only approximately .3 amps would be drawn and during active non stall periods approximately 1.6 amps are drawn.

2.2.5.2 Control Algorithms

On the control aspect, last year's team implemented simple Bang-Bang control to determine whether or not the bladders had reached their filling set point. This setpoint was based on the volume of water being pushed into the bladders overall, which meant that while all of the bladders were receiving water, it was not necessarily being distributed evenly. This was a rather rudimentary method, but it was an effective one, as it allowed the system to accurately reach the stable filling point each time. However, the fact that their set point for filling was an arbitrary value within the code was something that raised an issue. Given a normal patient, whose leg can fluctuate over several months, (leg volume can change up to ±10%) one arbitrarily set point to fill the bladders to could result in a poor fit for the patient.

Along with this, the EMG signal processing algorithm that they used for detecting movement was rudimentary at best. According to their paper, a modified double threshold detector (mDTD) was implemented to a degree of success, but overall, there was a large delay and inconsistency of the signal. On average, their best case scenario was a 68.2% detection rate for muscle actuations, meaning that their algorithm was detecting muscle spasms, even when the user was stationary. This is obviously a problem due to the fact that this allows for unnecessary filling and deflating of the system while the user is either moving or standing still. These inconsistent readings for such an important part of the control scheme could lead to the patient's leg deflating and falling off during movement, or inflating and causing discomfort while a user is standing still.

With these two parts of the control system outlined, the general flow of the entire control scheme can be seen. Essentially with the way the system has been set up, it is a binary system, when the EMG algorithm notices movement the system fills to the set point, when it doesn't detect movement, it turns off and deflates the bladders.

2.2.5.3. Mechanical Attributes

The DAPS system (shown in Figure 2.2.5) applied hydraulic pressure to the residual limb by utilizing syringes, linear actuators, and bladders. The system applies enough compressive force such that the user has appropriate control over the socket and efficient energy transfer from the limb to the device. However, the actuation system allows the pressure on the limb to vary in order for the patient to experience more comfort when they are sitting down.

To be more specific, the actuation system uses four 100-mL syringes that are filled with water. It also implements two Firgelli linear actuators, each of which actuates two of the 100-mL syringes to push water up through the tubing and into the bladders (located inside the socket). The bladders are made of vinyl - they inflate when filled with water, thus applying force upon the patient's residual limb. Furthermore, the leg has a pylon length of 17 inches which means it could have a realistic knee height. In addition, the weight of the system is 4.24 kg (9.34 lb). However, the hydraulics rig exhibits a widest dimension of 5.75 inches (14.6 cm) along most of the leg's height, which is wide enough to create slight difficulty for the user when they are putting on pants. Finally, the device's knee was 3D printed and may not have a reliable strength when the user is putting their weight on the system.

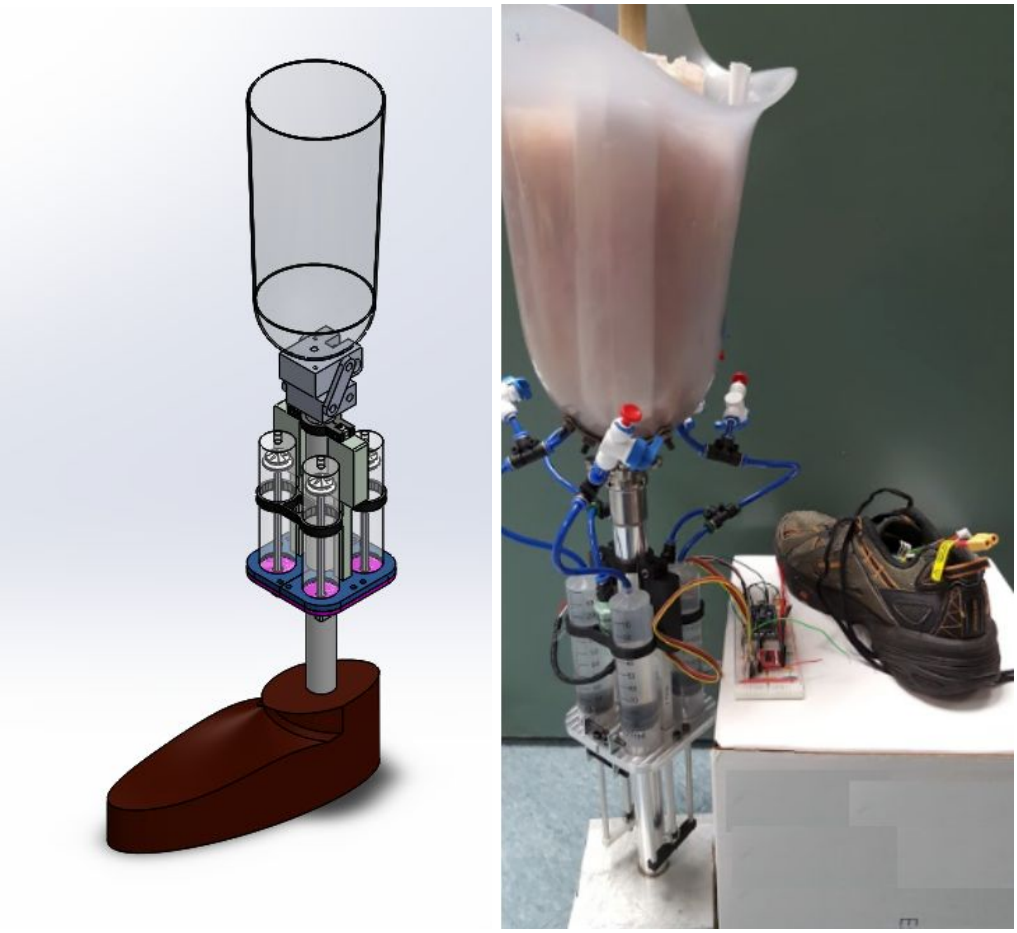


Figure 2.2.5: Dynamic Adjustable Prosthetic Socket (DAPS) system

2.3. Biometrics

Biometrics is the measurement of the physiological signals output by humans. Through the measurement of this, it is possible to determine things such as the movement of the human, their brain waves, as well as their overall health.

2.3.1. Leg Characteristics

To be able to construct a prosthetic system that could be seen as one day clinically viable, the system needs to be approximately the same size as traditional human limbs. For an above knee amputation the important sizes that need to be observed are knee height tibial length and thigh volume. In addition to total volume of socket, observing the potential volume fluctuations over specific time periods is equally important for the systems fluid manipulation requirements.

According to a study performed for designing ergonomic work spaces, the average tibial length for an adult male is 18 inches. This means for a prosthetic system to be viable the shank, the piece connecting the thigh socket and knee to the foot, needs to be designed around 18 plus or minus 2 inches

for the 5th to 95th percentiles of height. The knee height was also found to reside at approximately 20 inches, plus or minus 2 inches for the 5th through 95th percentile.
[32]

The average socket volume for transfemoral prosthetics is between 1200 and 1800 ccs. The average volume of a thigh for a male is around 4000 ccs however, usually the entire limb is not encased by the prosthetic. Reports of volume swings of 10% have been observed usually within the first few months after surgery. Shrinkage is usually very common and more aggressive than what is expected of a mature limbs volume fluctuations after the settling period. On an observed 20 day period, a user with a mature prosthetic limb within a 1500 ml socket saw 40 ml changes on average. Taking the standard of 1500 ml as was the case in Greenwald's study, that would require a system capable of storing 150 ml of fluid to account for volume changes. However, excluding the drastic changes that come with limb volume following amputation only approximately 80 ml of volume change are needed to account for daily fluctuations.
[33][34]

2.3.2. Detecting The User's State

2.3.2.1 Electromyographic Sensors

EMG sensors are sensors that measure the electric potential generated by muscle activation. This allows for an accurate prediction of a patient's movement before the actual muscle actuation occurs. This ability to predict movement rather than react to it makes EMG sensors an extremely useful tool in the biomedical world.

There are two types of EMG sensors currently used in the field. Surface EMGs and intramuscular EMGs. For this project, we focused solely on surface EMG sensors. This is due to the fact that intramuscular EMGs are needle tipped sensors, made to be inserted into the patient's muscle itself. While this results in more specific and accurate readings, for the sake of testing surface EMGs were more desirable.

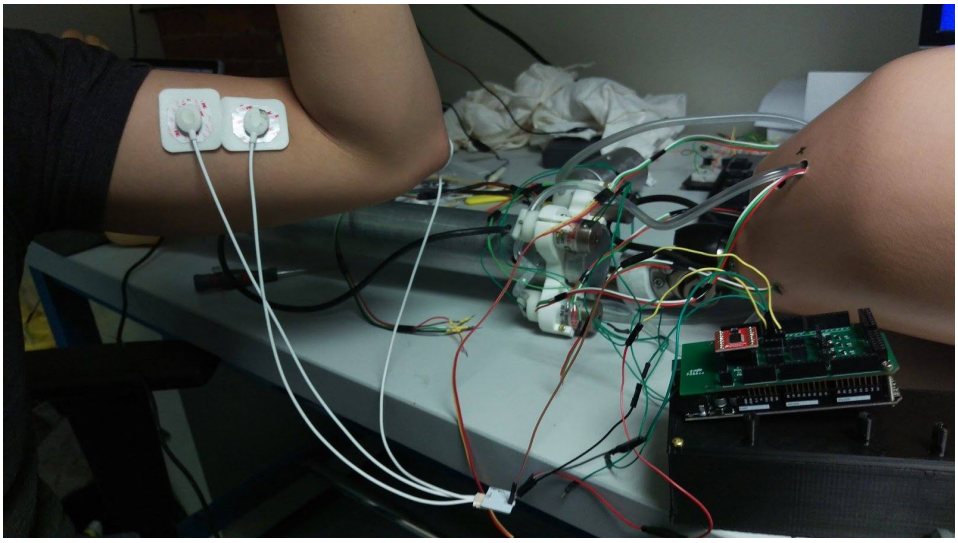


Figure 2.3.2.1a Surface EMG sensors on a User's arm.

2.4 Electrical System

2.4.1 EMG Noise

EMG signals, while useful are quite noisy, with the raw signal from the sensors fluctuating between 10-350Hz. With such a large range of readings, filtering is normally implemented to gather more useful readings. This inherent noise comes from various different sources, such as external electrical noise, motion artifact, cross-talk contamination, clipping, and physiological noise.

2.4.2 Hardware Filtering

Generally, hardware filters can be used to smooth out the raw EMG signals received from the sensors. Last year, the team implemented a hardware filter to filter out the inherent noise that they were getting. However, the Bitalino sensors that the team is using has a built in hardware filter already that works to filter out some of the noise generated from external sources.

2.4.3 Signal Processing Methods

In addition to using hardware to aid in getting relevant data from the sensors, software signal processing algorithms can be used as well. These different types of methods are things such as full wave rectifiers and Root mean square filters, etc. These types of algorithms will be detailed below in sections 2.4.3.1 and 2.4.3.2.

2.4.3.1 Rectify and digital low pass filter

Also known as full wave rectification, this filter first rectifies the signal then passes it through a low pass filter. The rectification of the wave is the most important step in this filter as without it, one would only be low-passing a raw signal. This doesn't work well due to the fact that EMG signals are naturally mean zero, swinging quickly between positive and negative. As such, applying a low pass signal to it in hopes of smoothing the signal is not very useful. However, by rectifying the signal first, one turns the negative swings into a positive swings, thus getting the envelope or shape of the signal and a viable candidate for low-passing. Examples of this filter are things such as finite impulse response (FIR) filter, and a infinite impulse response (IIR) filter. [1]

2.4.3.2 Root mean square filters

Root mean square filters (RMS filters) are essentially a running average taken over a set period of time. By discretizing the system, and finding the average value within each window, it is possible to get an accurate sense of the readings despite ambient noise in the readings. The more samples in your time window, the greater the accuracy of the filter. The general equation of the RMS filter can be seen below.

$$X_{rms} = \sqrt{\frac{1}{n}({x_1}^2 + {x_2}^2 + ... + {x_n}^2)}$$

2.4.4 Electrodes

Electrodes are used in conjunction with the EMG sensors in order to get relevant signals. The electrodes are adhesive patches that connect to the sensors that are placed on the muscles of the areas that are being measured. Generally, there are three electrodes placed on the muscle area, these are the positive and negative reference, which are placed directly on the muscle, and the ground reference, which is normally placed on a bony area of the body.

2.5 Control Algorithms

When dealing with complex systems, there are several different control schemes that can be utilized to control the robot. Two of the most general and widely used ones are detailed below.

2.5.1 Bang Bang Control

Bang Bang control is a very simplistic control scheme for controlling systems. In essence there are three states that Bang-bang control switches through: forward, reverse, and off. Unlike PID or other control schemes, Bang-bang controllers do not have transition states, instead, having a deadband zone as a targeted area, and then driving fully towards that zone and then switching between forward and reverse until the sensors read that they are within the deadband zone. An example of this is a standard heating system. The thermostat has a reading that it is set to. Reading the temperature of the room it is at currently, it then either turns on the heater, to heat the room, or the air conditioner, to cool it. It moves between heating and cooling the room until the temperature of the room is within a deadband zone around the set temperature. Once it has hit that deadband zone, the thermostat then turns off both the air conditioning system and the heating system until the sensors read that the temperature of the room has left the deadband zone, where it will then turn on again to correct it.

2.5.2 PID Control

Proportional Integral Derivative (PID) control is one of the most widely used control schemes, being one of the more easy to implement control schemes that still retains its transition states. Using the error that is read from the sensors, PID control allows the system to ramp up or ramp down to the desired set point. The larger the error, the faster the system corrects, the lower the error, the slower it corrects. As such, if the error starts off high, it will drive the system faster, and then slow down as the error decreases at the system gets close to its goal. The general equation of PID is shown below in equation 2.1.

$$u(t) = u_p * u_i * u_d \tag{2.1}$$

The output of PID control is determined from three different gains. Proportional, Integral, and Derivative. These three gains are constants that are tuned for the system, all working off of the current error being read from the system. This error is defined below in equation 2.2.

$$e(t) = x^d(t) - x(t) \tag{2.2}$$

Where x^d is the desired point of the function and $x(t)$ is the current position of the system. The equations that each gain utilizes to calculate its part of the input variable is shown below.

The proportional response is the first term of the PID control, and has the greatest effect on the controller. The gain k_p is directly multiplied to the system error e which results in a term directly proportional to the speed with which the system will try to correct the error, i.e the system's response to error. This calculation for the proportional response can be seen in equation 2.3.

$$u_p = k_p * e(t) \tag{2.3}$$

The integral response is the second term of the system. This term takes the summation of all the collected error over the time period and multiplies it by the integral gain k_i. Essentially, what the integral term does is reduce the steady state error, allowing the overall PID controller to reach stability. The equation for the integral response is shown in equation 2.4.

$$u_i = k_i * \int_0^{tf} e \, ds \tag{2.4}$$

Finally, the third response is the derivative response. For this term, the difference in error is calculated between time steps and multiplied by the gain k_d. This term helps aids in reducing the overshoot of the system due to the proportional gain and works to help settle the system to a steady state faster. The calculation for the derivative response is shown in equation 2.5.

$$u_d = k_d * \frac{de}{dt} \tag{2.5}$$

2.6. Mechanical Factors

This section describes the various mechanical considerations that were made prior to designing and building the Dynamic Prosthetic Socket system. These mechanical factors include the prosthetic leg's mechanical strength, the device's weight, and the strength of the system's linear actuator.

2.6.1. Strength

The prosthetic socket device should be strong enough to support the weight of the user. When the user is walking or running, they are repeatedly putting all of their weight on their prosthetic leg. Furthermore, when the patient jumps, he or she can exert a significantly greater force on the device. A prosthetic socket should enable users to make these motions throughout the day. The Dynamic Prosthetic Socket team aimed to develop a system that could support a person that weighs 100 kg (220 lb) or less. According to the Ohio Willow Wood Company, an orthotics and prosthetics service company, a mass of

100 kg (220 lb) can be associated with a maximum force of up to roughly 4,000N. For that reason, the Dynamic Prosthetic Socket system should be designed to withstand a force of up to 4,000N which is roughly four times the magnitude of the user's weight.

2.6.2. Weight

The Dynamic Prosthetic Socket team asked Liberating Technologies Inc. if the weight of the prosthetic leg should be close to the weight of a regular leg or if it should be as light as possible. It turns out that the weight should be as light as possible, because the amputee is missing lower leg muscles that would otherwise help them support the weight of the leg [37]. For comparison, the weight of the full DAPS system was 4.24 kg (9.34 lbs). The Dynamic Prosthetic Socket system should be as light as possible and lighter than the DAPS system, if possible.

2.6.3. Motor Strength

There are multiple forces that resist the linear actuator when it is pushing the hydraulic cylinder piston. These resistive forces include gravity, friction, viscosity, and the force of the user's weight on the bladders. Furthermore, the linear actuator also needs to supply enough force to give fluid the kinetic energy to move upward into the bladders. The force needed to supply kinetic energy and to overcome viscosity are both negligible due to the low volume of fluid, the slow speed of fluid movement, and the low pressures involved in the system. The required strength of the linear actuator is primarily needed to counter gravity, friction, and the force of the user's weight.

Assuming that the amount of fluid in the system is at most 200 mL, then the weight of the fluid or the gravitational force that the linear actuator must overcome is roughly equivalent to 2 Newtons. Furthermore, the frictional force on the fluid is greatest within the tubing because of its significantly more-narrow diameter. The estimated frictional force was ~16 Newtons after applying the Head Loss Darcy Weisbach Equation to calculate the head loss. Finally, the linear actuator is estimated to require a maximum force of ~46 Newtons in order to overcome the weight of the user on the bladders. This value was calculated by first assuming a maximum pressure on the bladders of 5 psi (34,500 Pa) [37] and then adding pressure for the weight of the water above the hydraulic cylinder and multiplying this total pressure by the cross-sectional area of the hydraulic cylinder. This brings the total force up to approximately 64 Newtons. The linear actuator should be capable of driving more than 64 Newtons.

3. Project Strategy

When approaching the project, the team first had to lay out an idea of how complete each step of the project, from the initial idea to the building of the system to the different tests run, all of the different components of the system required thorough planning and strategy beforehand.

3.1. Project Approach

Beginning this project, there were several different ideas of how to go about actually improving upon the project from last year's DAPS team. While the previous team had created a strong proof of concept idea, there were many fields in which it could be improved upon. As such, the a weekly meeting was set up where the team, along with advisors, would meet and discuss the different ideas that could be pursued. From these meetings and brainstorming, it was found that a more in-depth idea of the entire prosthetics process from a patient and provider viewpoint was needed, rather than looking at the problem from the perception of researchers. As such, it was decided that the team would get in contact with Liberating Technologies Inc. a local prosthetics company located in Holliston, MA. Having an interview with this company would broaden the team's understanding of the project to the more business side of the prosthetics world, and it gave several key insights to the desires of the patient that were not as obvious to the team coming from an engineering standpoint of things. Taking these key points that was gathered from the interview, the team then moved to synthesize what was learned into a priorities pyramid, which the team would refer to when making any future design decision.

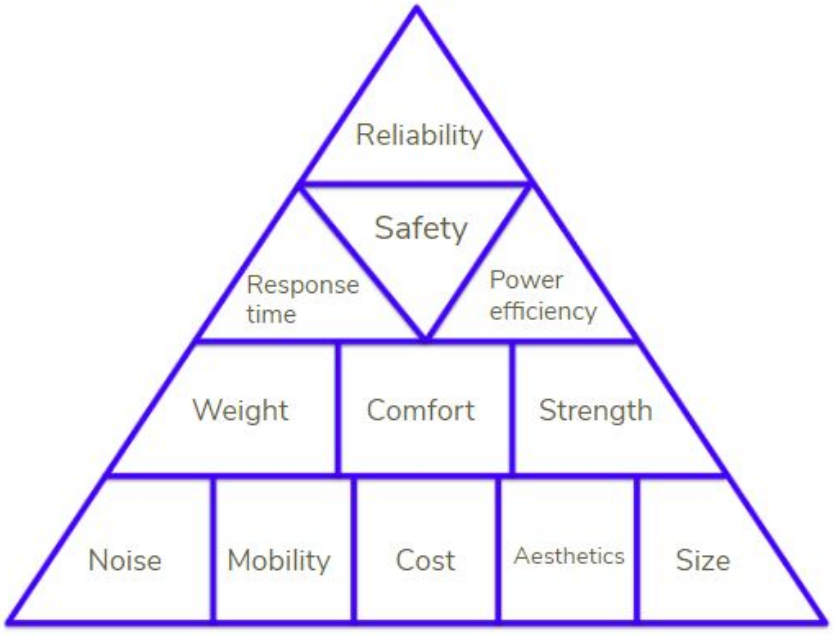


Figure 3.1a: The Team's Priority Pyramid

As it can be seen, things like reliability played a large role in the design decisions that were made, while things such as size, noise, and cost played a lesser role in decisions. In the end, thanks to the

interview with LTI, main project goals were able to be more rigidly set, these are listed below along with the team's reach goals [37].

Main Project Goals

1. Develop a prosthetic socket technology that is more efficient, comfortable, and less harmful than those currently in the market.
2. Improve upon the control scheme of last years DAPS project to make the system more dynamic.
3. Reduce the size of the system to a much more compact and aesthetically pleasing size.
4. Optimize the system to have a fast, accurate, and precise response to user motion

Reach Goals

1. Have the system adjust dynamically throughout the gait cycle.
2. Begin testing on real patients with IRB approval

3.2. Design Requirements

With the priority pyramid in mind, the team was able to move forward with the designing of our system. Due to the interview with LTI, we now knew what to avoid when designing prosthetics, as well as what rules to adhere to and what functionality the system needed to be able to accomplish.

3.2.1. Technical

3.2.1.1 Functionality

From our interview, several necessary functionalities that the device needed were outlined. These were things such as how the system had to account for the maximum change in patient limb volume change on a day to day basis. The system also had to dynamically calibrate the fit of the socket to account for the patient's current limb volume. Thirdly, the system had to be able to change with the activity level of the user, tight when the user was moving, and loose when the patient was standing still or sitting.

3.2.1.2 Constraints

From LTI, it was stated that there were several different constraints that had to be kept in mind when designing new systems such as this. For one, the area of the leg is very small relatively. In addition to the fact that human skin is very sensitive to pressure changes, the team had to keep to pressure being exerted onto the patient's leg to a minimum. The range given was around 0 to 5 psi, as any more would cause discomfort and perhaps even harm the user.

Another constraint given was battery life. Last year, an arbitrary length of time was set for the system, the device had to last for "the length of one grocery trip". For this year's team, it was gathered that from other powered prosthetics, the desired battery length for other products on the market was

around 6 hours at least. Any less, and it could actually be a deterrent for the more active patients, who would not necessarily have the time needed to continuously keep charging their prosthetic.

Finally, a third constraint that was given which was weight. While not a hard constraint in the least, LTI suggested that the team strive to reduce the weight of the system as much as possible. Most prosthetic manufacturers make their products as light as possible, so as to be as little hassle for the user as possible. This meant that many of the current prosthetics on the market were made out of extremely light yet strong material, such as carbon fiber.

4. Design Justification / Design Process

This chapter describes the Dynamic Prosthetic Socket design in full detail. Details have been provided for the original prosthetic socket device that the team purchased, the actuation mechanism, the implemented sensors, and the controls system. Justification is provided for all of the design decisions that were made. The final section describes all of the designs that were considered before the final design was created and why these 'rejected designs' are inferior to the design that the team chose to pursue instead.

4.1 Brief Overview of the DPS Design

Figure 4.1a displays the system that the Dynamic Prosthetic Socket team designed and built. The device still utilizes inflatable bladders on the inside of the socket. However, the actuation mechanism is now hidden inside the shank with the number of components reduced to one hydraulic cylinder and one linear actuator. Furthermore, the team has also attached four pinch valves at the top of the shank, as shown in Figure 4.1a, which allow for independent control of each bladder.

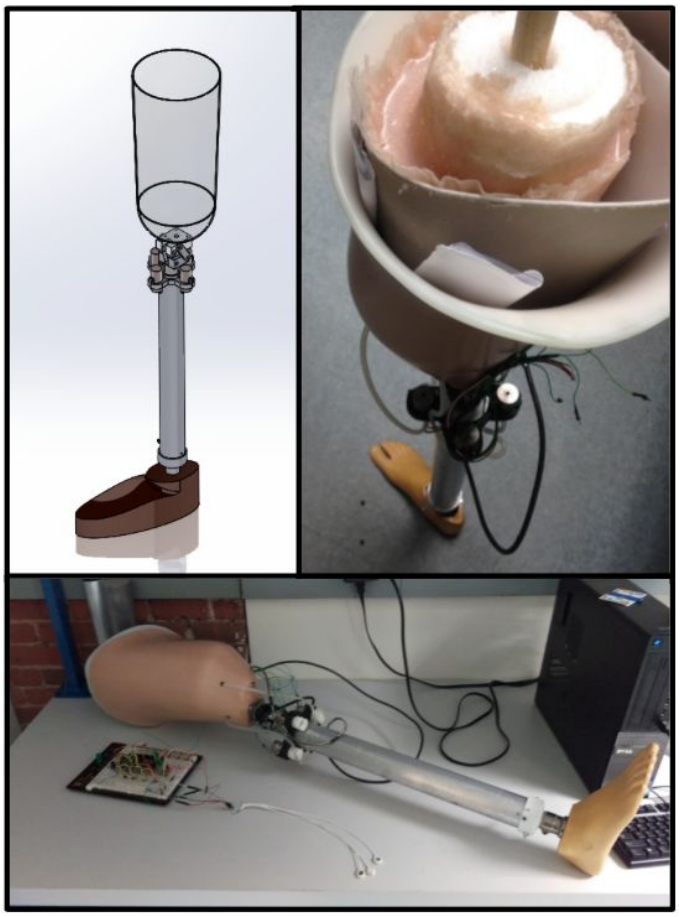


Figure 4.1a: The Dynamic Prosthetic Socket system

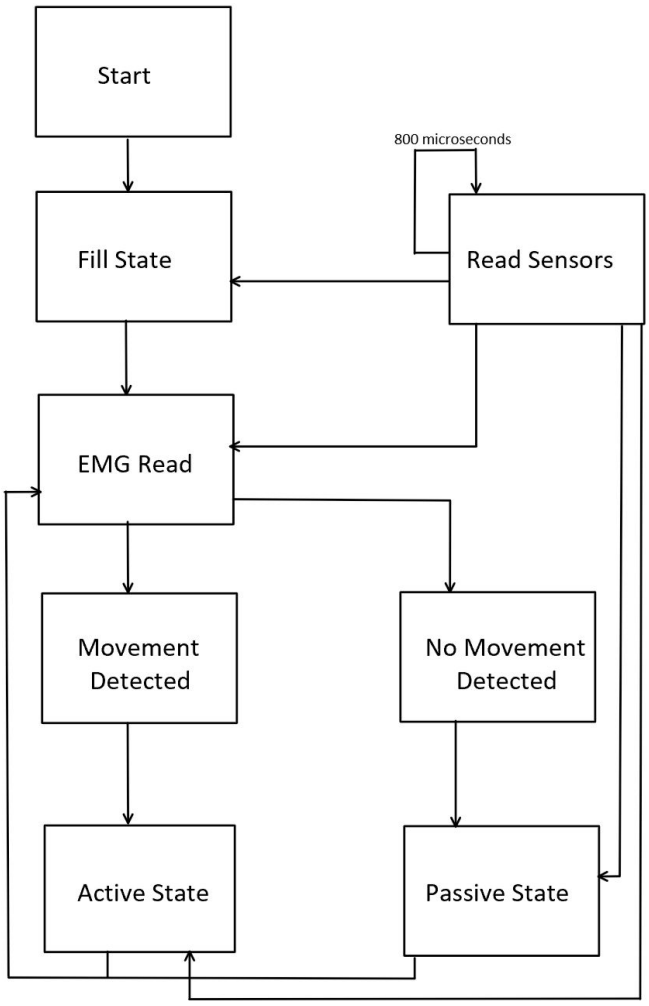


Figure 4.1b: DPS Control Design

In setting up the system architecture of the project, we decided on Figure 4.1b as our control design. As the system starts up, it enters the fill state. In this state, the socket uses the various hall effect sensors and pressure sensor to calibrate the bladders, filling each one with a small amount of water in a counterclockwise pattern. Once a bladder has filled and presses against the patient's leg, the next time the system tries to fill that bladder, due to it's inability to expand any further, a pressure spike will result. Once the system has read the spike in pressure, then it will take the current hall effect readings of that bladder and set that as its calibration point.

Once all of the bladders have been filled and calibration points set, then the system then moves into the EMG read state. In this state, the system simply polls the EMG sensors to detect whether or not the patient is moving or not. If the system does detect movement, then it will move into active state. If it does not detect any movement, then it moves into passive state.

In active state, the prosthetic tries to keep the bladders filled to the setpoint, constantly reading the hall sensors to see whether or not there is any change in the bladder's deformation. If there is any

detected, then the system fills the bladder until the hall effect readings move back into the correct range. If all of the bladders are within an acceptable range of the calibration point, then the system moves back into the EMG read state.

In passive state, the system deflates the bladders to a percentage of the calibration point. This is because since no motion was detected, it would mean that the patient has either stopped moving, or is in a situation where they do not require the prosthetic to be tightly adhered to their leg. As such, the bladders release their hold on the patient by a small amount, not completely emptying the system of water, but loosening the fit on the patient enough so that the patient can be comfortable. Once all of the bladders have been deflated to this point, then the system will move back into EMG read state, checking once more for movement.

4.1.1 Coding

When we initially began coding, we had decided to code using an MSP432 due to it being an extremely low level board which allowed the user a high degree of control. For our system, where power efficiency and response time is a large priority, an embedded system would have been ideal. However, after initial dealings with the MSP432, we as a team decided to move forward with an Arduino Mega, which while much less powerful of a platform, was something that we were all extremely familiar with. As such, when coding the system, we as a team worked to keep the processes that we were running as small and computationally efficient as possible.

4.2. The Prosthetic Socket

Figure 4.2: Pre Existing Prosthetic Limb used for Basic Parts

In order to properly experiment with the socket design in relationship to the other components,a pre existing prosthetic was purchased. The system was necessary for experimentation due to the limitations of space and structure of other components. The Dynamic Prosthetic Socket and its components needed to all fit within or around the preexisting components of a prosthetic system in order to be deemed viable. Additionally, the purchase of the preexisting system allowed experimentation with forces and comfort that a standalone test bench, or socket, would not allow for. The project looks to augment the standard static system with new electrical and mechanical components to make it dynamic.

4.2.1 Socket

By purchasing a prosthetic with a transfemoral socket already in place, the general shape and size of socket could be used as reference for the integration of the bladders into the system. By using a socket that is already on a preexisting system, and maintaining it in such a way that there are no issues mounting the socket or its inner lining, it can be inferred that that system could be retrofitted into existing sockets. However, the main purpose of using this socket is for a simple reference to work with when designing and implementing the dynamic aspect to a previously static system.

4.2.2 Knee and Ankle

The knee is usually a complicated component and it was felt that using a prefabricated knee was in the best interest of the research. By not having to design a knee and using an already basic and compact mechanical knee, the focus of the project could be shifted into modifying the socket and shank to contain and drive the dynamic system. For this reason a prosthetic system with a prefabricated knee was chosen as the base model that would be modified. Additionally the ankle and foot will remain untouched, simply as a balance and mounting point to help complete the prosthetic. No modification is necessary or desired for this component. Because the system was designed around standard prefabricated knee and ankle systems, it can be integrated with other existing knees and ankles.

4.2.3 Shank

The shank, or tibial section of the prosthetic system is one of the main areas that will be modified from this system. The connectors allowing for connection to the foot and knee will be maintained but the original metal shank will be replaced with a component of our own design. This component will house all of the necessary mechatronics to actuate and regulate the fluid within the bladders in the socket.

4.3. Bladders

The Dynamic Prosthetic Socket utilizes four inflatable bladders to apply the compressive forces to the residual limb when they (the bladders) fill up with water as exhibited by CRS socket technology. As shown in Figure 4.3, the bladders are located inside the socket and they are evenly spread out along the circumference of the inner space. The DPS bladders are made up of the same material as the DAPS bladders: vinyl. Vinyl is still an appropriate material for this application because it is waterproof and easily sealable. Furthermore, the material is flexible enough that the size will easily inflate when the bladders fill with water.

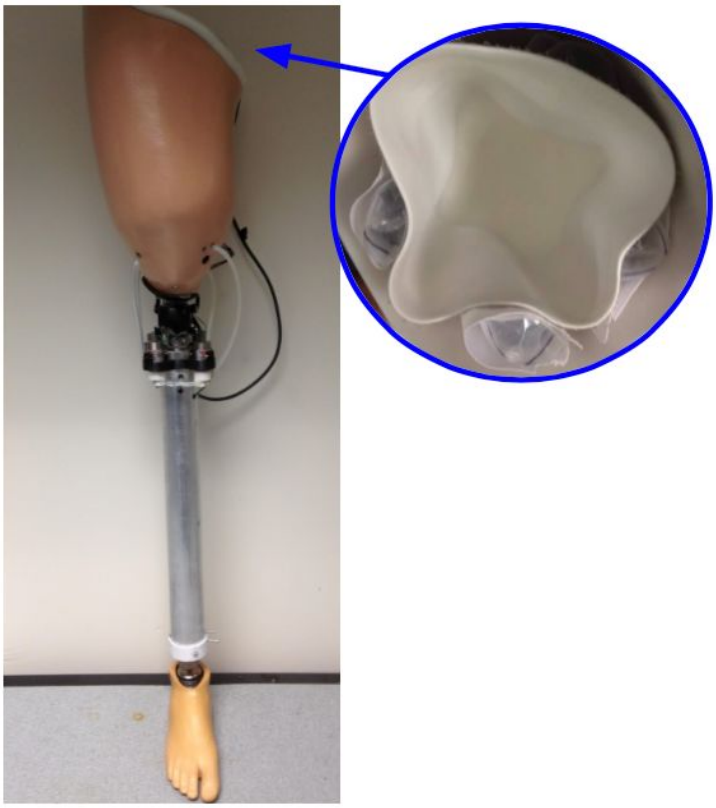


Figure 4.3: Bladders

4.4. Actuation Mechanism

Figure 4.4a compares the actuation mechanism of the DPS with that of the DAPS system. The number of components has been reduced to just one hydraulic cylinder and one linear actuator, with the linear actuator below the hydraulic cylinder. Both components are now concealed. The subsections below provide more detail and justification for the hydraulic cylinder and the linear actuator implemented.

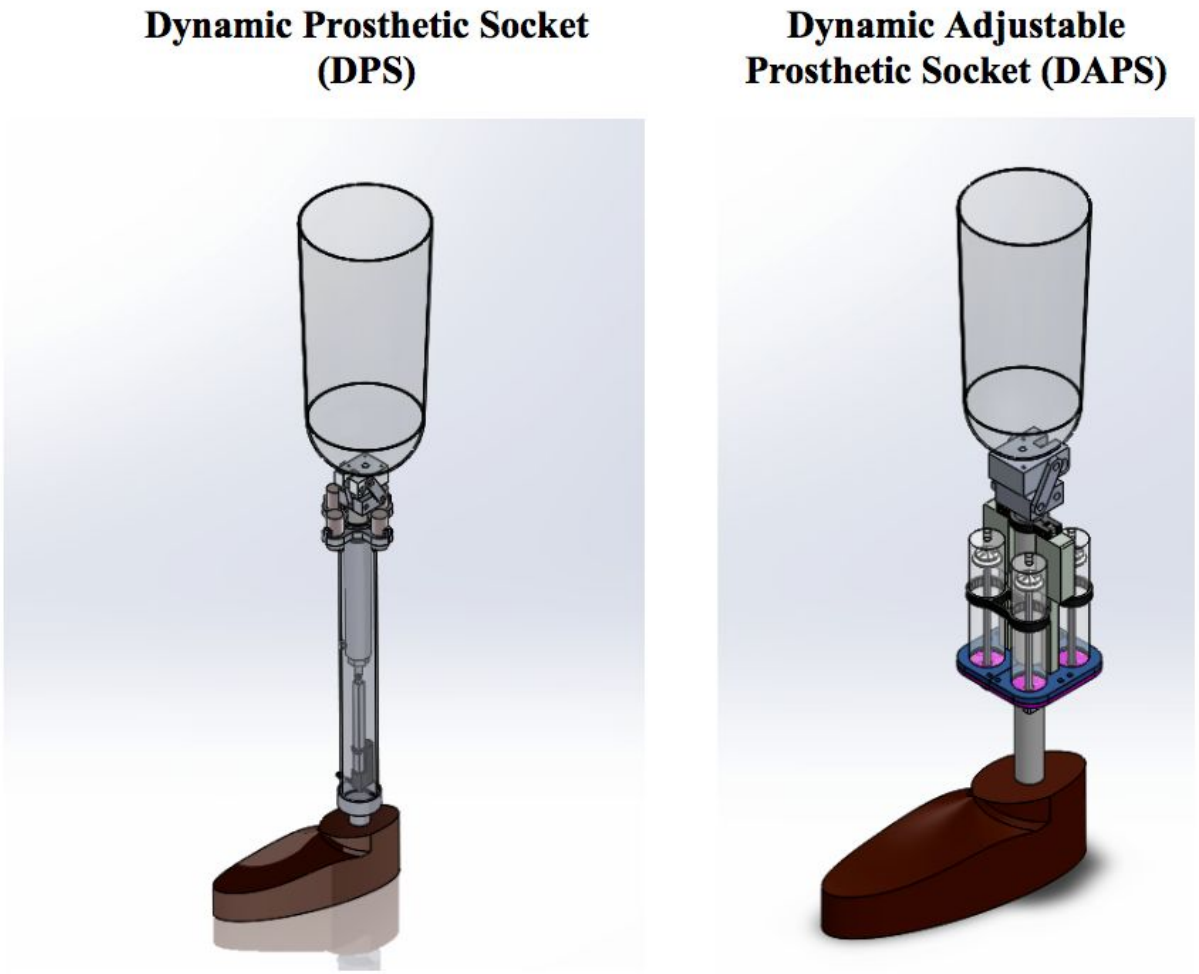


Figure 4.4a: DPS and DAPS Actuation Mechanisms

4.4.1. Hydraulic Cylinder

The Dynamic Prosthetic Socket system uses a Parker Fluidpower hydraulic cylinder (see Figure 4.4b). The cylinder itself is 8.56 inches (21.7 cm) tall and has an outer diameter of 1.57 inches (3.99 cm). The piston inside of the cylinder has an outer diameter of 0.4375 inches (11.11 mm) and is capable of smoothly moving a distance of 6.00 inches (15.2 cm), which means the volume of water that the cylinder can contain/push is approximately 175 mL, which is more than the desired value of 150 mL (Section 2.3.1).

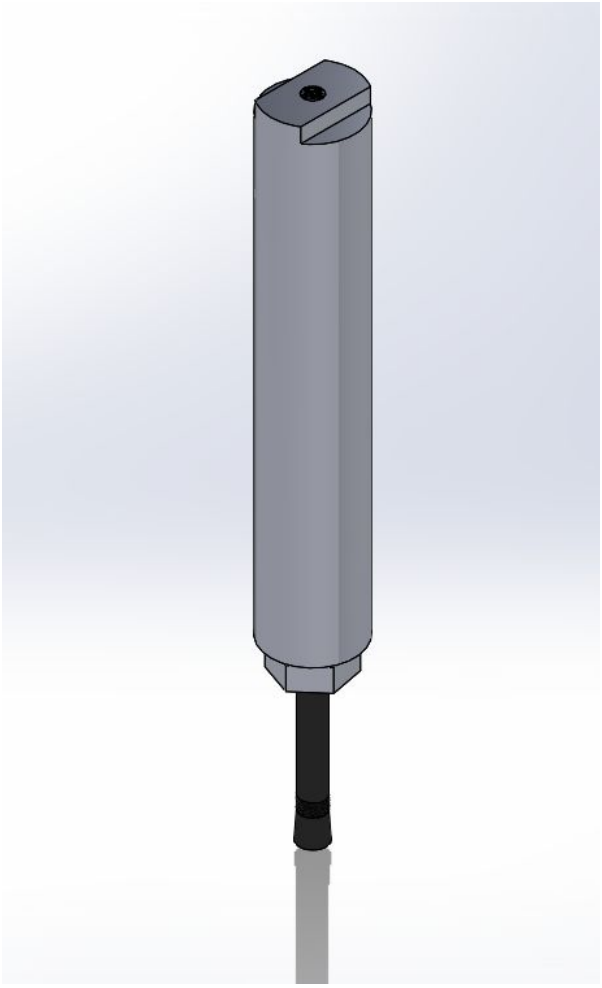


Figure 4.4b: Hydraulic cylinder

Building a hydraulic cylinder was a consideration, however, an off the shelf cylinder was desired, instead, to avoid having to 'reinvent the wheel'. An off the shelf hydraulic cylinder offers more reliability because it removes the risk of leaking and already allows for smooth piston movement. Furthermore, the Parker Fluidpower cylinder was supplied for no cost - saving $200-300. The cylinder is a few inches longer than preferred, however, cost is a factor that was prioritized over size (see section 3.1 for more information about the project priorities list).

4.4.2. Motor

The Dynamic Prosthetic Socket system uses a Firgelli linear actuator (see Figure 4.4c). The motor itself has a height of approximately 20 centimeters (7.9 inches) with a stroke length of 15.0 centimeters (5.91 inches). The moving cylinder on the inside has an outer diameter of 8.9 mm (0.35 inches). Furthermore, the Firgelli linear actuator has a back drive force of 75N.

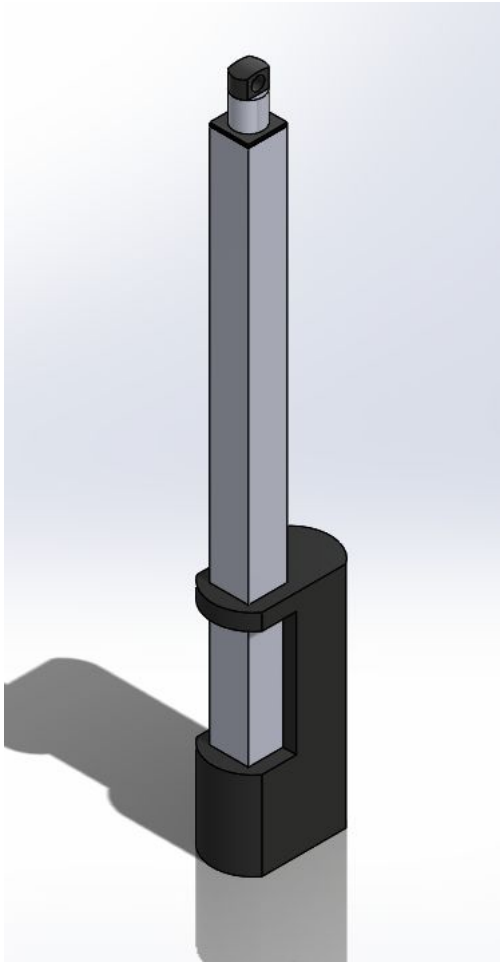


Figure 4.4c: Firgelli Linear Actuator

Purchasing another linear actuator was a consideration, however, the Firgelli linear actuator built into the Dynamic Prosthetic Socket was supplied for no cost. Both the Firgelli linear actuator and the Parker Fluidpower hydraulic cylinder share a stroke length of about 6 inches - so the motor is not limiting the volume that the system can push. Furthermore, the diameter of the motor's moving cylinder is smaller than the piston's outer diameter, which means that the moving cylinder can enter the hydraulic cylinder. Finally, the Firgelli linear actuator has a driving force of 75N which is more than the required driving force of 64N found in Section 2.6.3.

4.4.3. Attaching the Motor to the Hydraulic Cylinder

Figure 4.4d displays the connection between the Firgelli linear actuator and the hydraulic cylinder. In order to reduce the height of the overall prosthetic device, most of the hydraulic cylinder's piston length was removed. A hole was then drilled in the end of the remaining piston in the axial direction, creating enough space for the head of the Firgelli linear actuator to enter inside of it. Another small hole was drilled through the side of the hydraulic cylinder piston and a pin (with epoxy) was used to secure the attachment. Now the linear actuator can easily push the piston by moving in and out of the hydraulic cylinder.

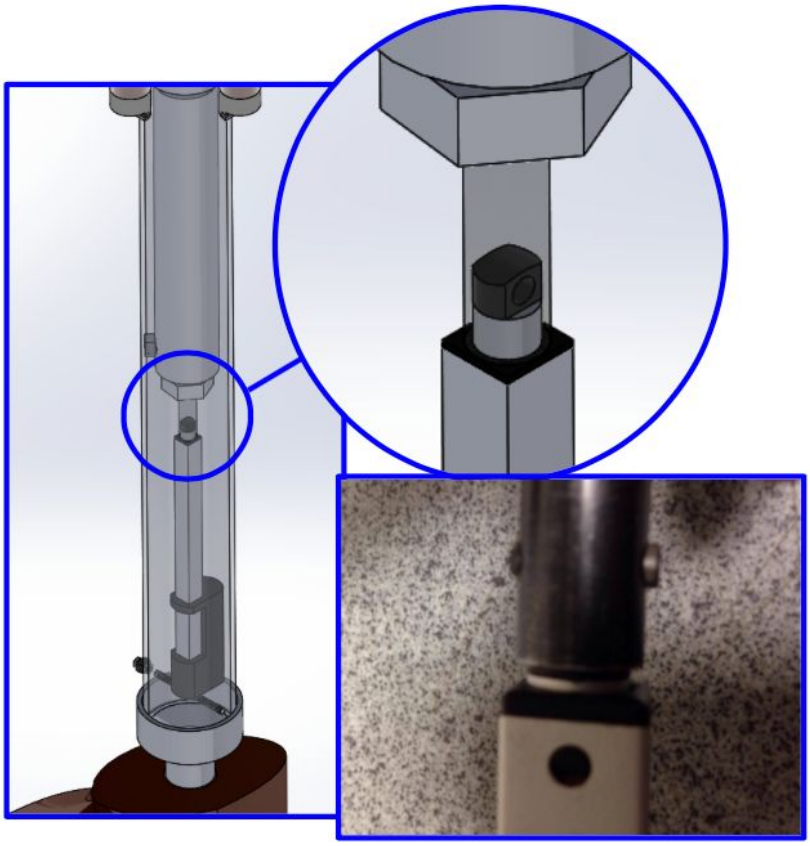


Figure 4.4d: Attaching the Firgelli Linear Actuator to the Hydraulic Cylinder

4.5 Valves

The system called for the use of at 4 valves to direct the flow of fluid from one source into 4 individual bladders. The challenge being having to extract the fluid back out of the bladders through the same flow controllers. For this reason two way valves seemed like the answer to the dilemma at hand.

4.5.1 Two Way Gate Valves

After some preliminary research it was notated that most two way valves had slight leaking tendencies or did not function very well at very low PSI. Our system functions completely under 5 PSI and most valves called for at least 10 to 20 PSI and functioned up to 100 PSI. The cheaper valves within our budget did not fall within our functional range, while the more expensive bidirectional, low pressure, fluid tight valves ranged upwards of a hundred dollars per valve. These valves were directed at high precision gas management, something outside of the scope or requirements for our system.

4.5.2 Pinch Valves

Looking deeper into the medical and science fields, bio-chem pinch valves were discovered. These valves do not contact the fluid itself but pinch the tubing it is transported in. They function only at sub 20 PSI and with soft, flexible tubing. Both requirements being ideal in our system. These pinch valves were purchased and configured as seen below. They work incredibly well for allowing bi-directional flow but still supply enough stopping power to regulate which bladders the fluid is able to flow in and out of when driven by the motor. The valves are driven by a NPN-switching circuit, which can direct 12 volts to the solenoids controlling the valves when a signal is given to the NPN transistor by the microcontroller.

The valves are normally closed, resulting in minimal power consumption, as the majority of the time they remain unpowered and closed. The only times the valves need to be open and powered is for making modifications to the volume of the system. Additionally by being normally closed, if power is lost for whatever reason the leg will remain firm on the user, if they were in the active state. Rending the leg still useful for a time after power failure. This is not cause for any serious safety concern as the leg is not tight enough to cause immediate harm to the user if remaining for a reasonable amount of time. Additionally there are safety drain stoppers under the first layer of the socket that can be pulled to dump the bladders.

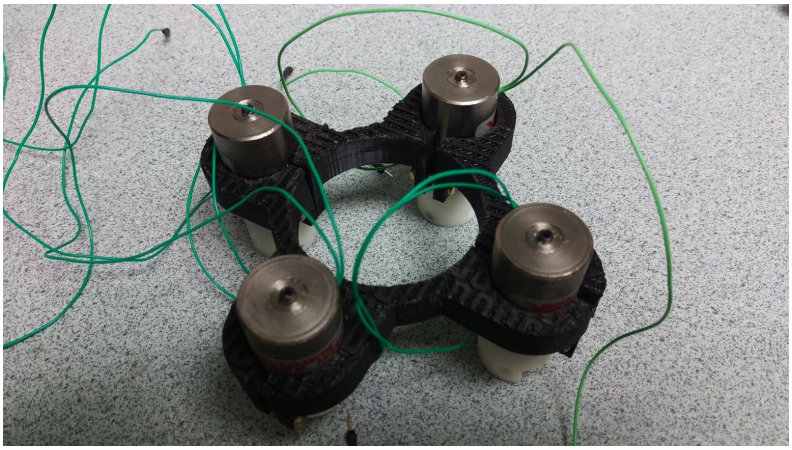


Figure 4.5.2.A: Mounting configuration of Bio-Chem bidirectional pinch valves

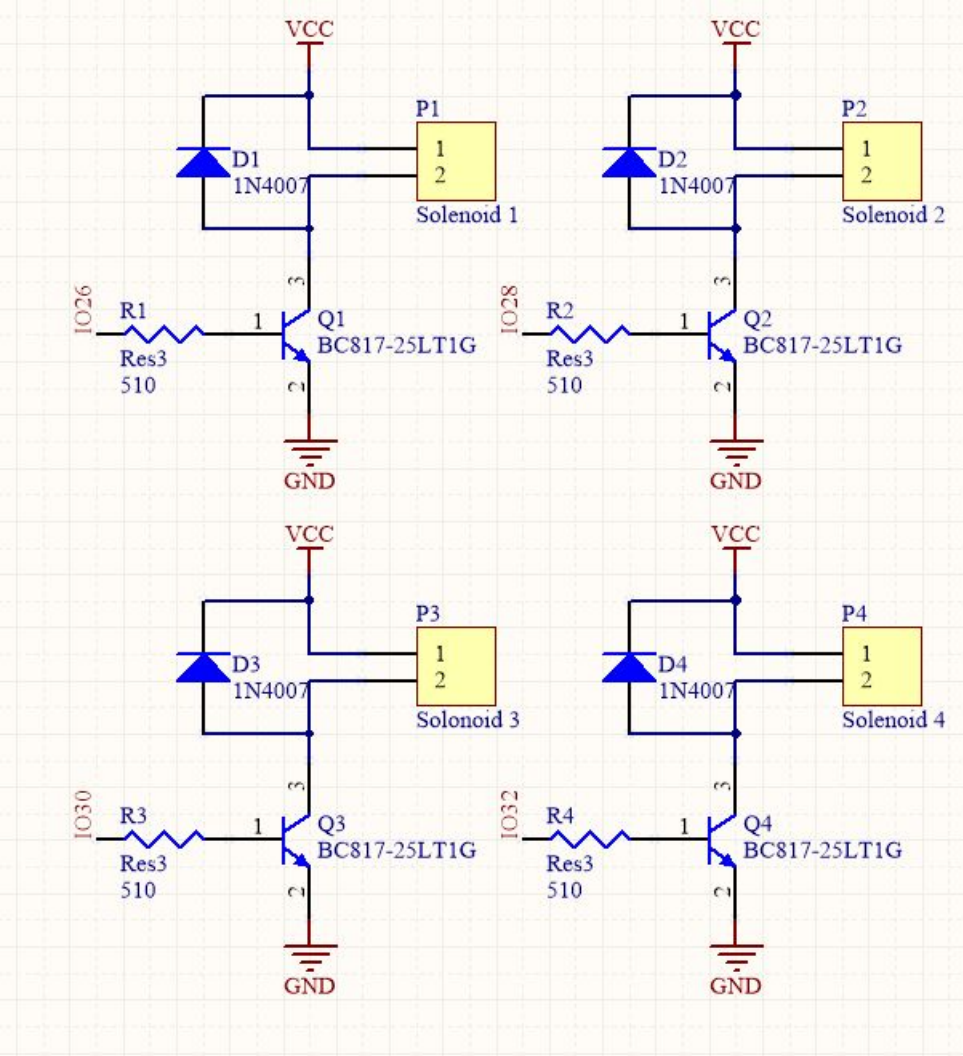


Figure 4.5.2.B: Control Circuit for Valves, Protects From Back EMF and Current into the Arduino.

4.6. EMG Sensors

Last year, sensors were bought from the company Bitalino, a european based company that specializes in selling biomedical boards. Due to the fact that last year's team utilized these boards to a certain degree of success, our group decided to continue on with the sensors from last year.

The DAPs group utilized several sensors to determine and predict the patient's movements, however, in our design phase, we realized that this was a bit excessive. Due to the fact that the system is only detecting whether or not the patient is moving, rather than detecting the types of movement the patient is making, only one sensor was needed. As such, we reduced the amount of EMG sensors used from two to one, and improved the signal processing algorithm used to obtain movement data.

To accomplish this task, we implemented a root mean square filter that would take a running average of the EMG readings, thus helping to reject any disturbances and smooth out our readings. The system took clumps of 64 analog readings, digitized them to a threshold of high and low and summed the resulting series of binary. Digital 0 represented movement and 1 represented no movement. In a perfect

system, during periods of no movement, the sum of the cluster readings will all read 64. Likewise, during periods of movement, all clusters should be reading 0. However, in the real system there are transition times and intermittent readings that occur while muscles change from active to relaxed. Random noise and sporadic muscle firings essentially ensure the active periods never read 0. Taking this into account a threshold summation of 50 was established as the baseline for the sum of a cluster to be considered active. The system was designed to engage active mode at even the slightest notion of movement. For this reason, a threshold close to the no movement maximum cluster summation was chosen. Noise and imperfections in readings rarely drove the system into cases of false transitions. After testing, which can be found in section 5.2, the system was able to maintain a reliability of 96 percent in accurate state determination and switching.

The next order of business was to implement a failsafe to ensure that our system would not move into passive state while the patient was actively moving. This edge case would happen in situations during various stages of the gait cycle, such as when the patient has raised their leg to the max or when the patient has finished pushing off on their leg. To solve this we implemented a counter that would only allow the system to enter passive state if the system read 10 passive readings in a row with no active state readings in between. If there was an active reading, the counter would reset and the system would move into active state. This basically set the system up so that for any active readings, the system would enter active state, but would only enter passive state if it was sure the patient was done moving.

4.7 Battery

The power supply unit for the system is a single 12 volt, 6400mA hour LiPo battery. The battery needs no step down regulators or any other modifications. Two lines are spliced from the batteries lead. One is attached into the Arduino Mega, and the other goes into the PCB that connects to the rest of the electrical system. Every component on the prosthetic can function off of 12 volts or a reference voltage supplied by the Arduino so no power is loss to additional step down circuits. Based on average case and worse case power draw, the system has an expected life of 4 to 6.5 hours.

4.8 Tubing

The tubing that was selected for the system was chosen around the premise of being soft enough for the Pinch Valves to properly seal off, while also being flexible enough to bend into all of the tight cavities within the socket and shank. The ideal tube that was chose was an ultra-soft tygon PVC tube from Mcmaster, part number 5894K32 . The tube was designed to be used with food and beverage and was made with non toxic materials. This was important in case the fluid in the system ever leaked, no dangerous contaminant would be exposed to the user. The official specs on the tune are as follows:

For Use With	Beverage, Food
Hardness Rating	Soft
Hardness	Durometer 40A
Clarity	Clear
Material	PVC Plastic
ID	1/8"
OD	1/4"
Wall Thickness	1/16"
Flexibility	Very Flexible
Bend Radius	3/8"
Temperature Range	-60° to 120° F
Maximum Pressure	15 psi @ 72° F
Maximum Vacuum	Not Rated
Compatible Tube Fittings	Barbed
For Use With Metering Pumps	Yes
Sterilize With	Gas
Brand	Tygon
Formulation	E-1000
Specifications Met	Made of FDA Listed Materials
Color	Clear
Chemical Resistance	
Excellent	Acetic Acid (10% in Water), Deionized Water, Hydrochloric Acid (10% in Water), Hydrogen Peroxide (10% in Water), Hydrogen Peroxide (30% in Water), Phosphoric Acid (25% in Water), Phosphoric Acid (85% in Water), Sodium Hypochlorite (Bleach) (1-10% Concentration), Sulfuric Acid (10% in Water), Sulfuric Acid (30% in Water)
Moderate	Acetic Acid (30% in Water), Hydrochloric Acid (30% in Water)
Not Recommended	Acetone, Isopropyl Alcohol, Methanol (Methyl Alcohol), Methyl Ethyl Ketone (MEK), Mineral Oil, Sodium Hydroxide (Caustic Soda) (10% in Water), Sodium Hydroxide (Caustic Soda) (30% in Water), Vegetable Oil
Note	Chemical compatibility must be determined by the customer based on the conditions in which the product is being used, including the presence of other chemicals, temperature, and consistency.
Additional Specifications	SDS

Figure 4.8.1: Tubing specifications from McMaster-Carr

To secure all of the tubing connections, 1/8th inch barbed connectors were used. This applied for all splitters, connectors or anything that went into this tube. Because of how soft it was, the barbed connections were necessary to ensure a tight seal and prevent any leaks.

4.9. Pressure Sensor

From the interview that we had with Liberating Technologies we learned that we had to keep the amount of pressure that we exerted onto the leg to an extremely small amount of psi. This is due to the fact that over such a small area, a small change in pressure can have a huge effect on the comfort level of the patient. As such, in our design decisions, we tried to keep our maximum pressure change to the range of 0-5 psi.

As such, when looking for a pressure sensor, we had to find one that fit within the our operational range. Luckily for us, within our workspace, we were able to find an Omega PX309-030G5v.

Figure 4.9a: Omega Pressure Sensor

This sensor was already in the lab at the time as it had been used before for a previous project, and once it was determined that the sensor was within our operational range, we decided to move forward with it.

The pressure sensor allows us to determine when the bladders have filled up to the maximum point, which is the point when the bladders are pushed up against the patient's leg and cannot move any further. This creates a pressure spike due to water being an incompressible fluid and the bladders not being able to fill anymore. Once the pressure sensor detects this spike, the system then is able to determine that the current point of filling is enough for the bladder, and in turns sets the current hall effect sensor readings as the current max reading, which is further covered in section 4.10. This setpoint is used in later stages of the system such as active state and passive state.

4.10. Hall Effect Sensor

Hall effect sensors were used in conjunction with magnets as a means to determine how filled the bladders were and the deformation on them due to the patient's leg. By placing the bladder in between the hall effect sensor and the bladder, the hall sensor could read when the bladder was filled and the readings would get lower the farther away the magnet got due to the bladder's inflation. As the bladder was deflated, the magnet would move closer to the sensor, thus making the sensor readings increase.

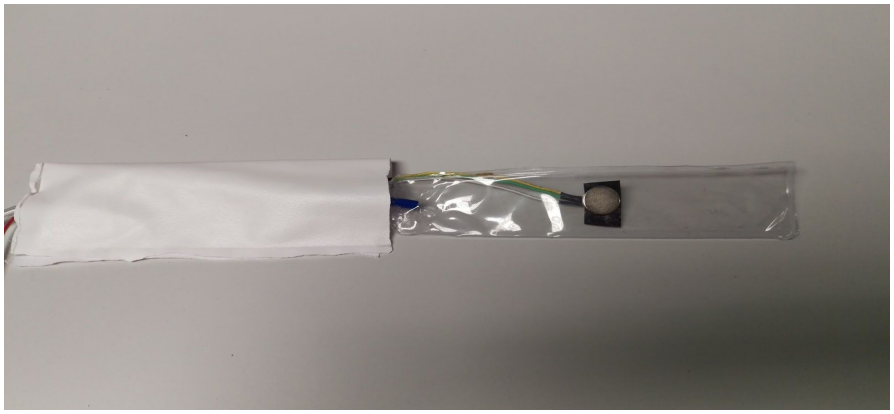


Figure 4.10a: Hall Effect sensor and magnet with bladder

Using this in conjunction with the pressure sensor allowed us to accomplish the state transitions as stated above.When the pressure sensor would spike, that would mean that the bladders had inflated to the point where they could not anymore, the system would then read the hall effect readings, and then use those readings as the calibration setpoint for the system.

When in the stages after calibration, these setpoints are used as the backbone of the system. In active state, the system tries to keep the bladders filled within a deadband zone centered around the calibration point.

In passive state the system drains the bladders to a percentage of the setpoint, making the fit on the patient less tight, but not completely loose.

4.11 Electrical System Integration

Below can be seen what the original test bench looked like with all of the components and wires coming in and out of the microcontroller. This was not acceptable to be mounted on a portable system and had to be redesigned to be more compact and transportable

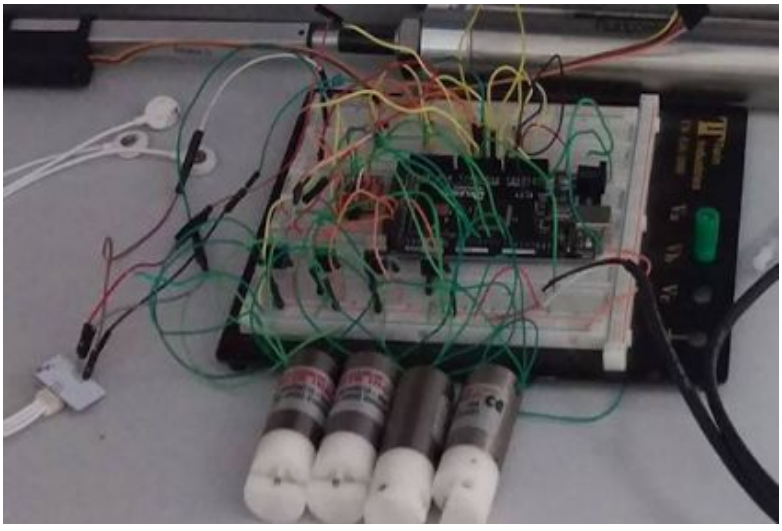


Figure 4.11.A: Test Bench Wiring Configuration

The main components of this electrical system are a series of NPN transistors to control the solenoids, as well as a handful of resistors and diodes for amperage regulation and back emf protection. The rest of the circuit is mostly tieing grounds together, providing reference voltages and the dozen or so I/O and other miscellaneous connections needed to run all of the components and the motor controller on the prosthetic.

The first step in reducing the electrical system was to properly draw up all the components in one conscience schematic. From there all of the necessary grounds and reference voltages can be tied together and intraconnected within one power line. Surface mount version of all of the transistors, diodes, and resistors were selected based on the desired performance for each component. The complete schematic can be seen below, displaying the components and summarizing everything is wired together.

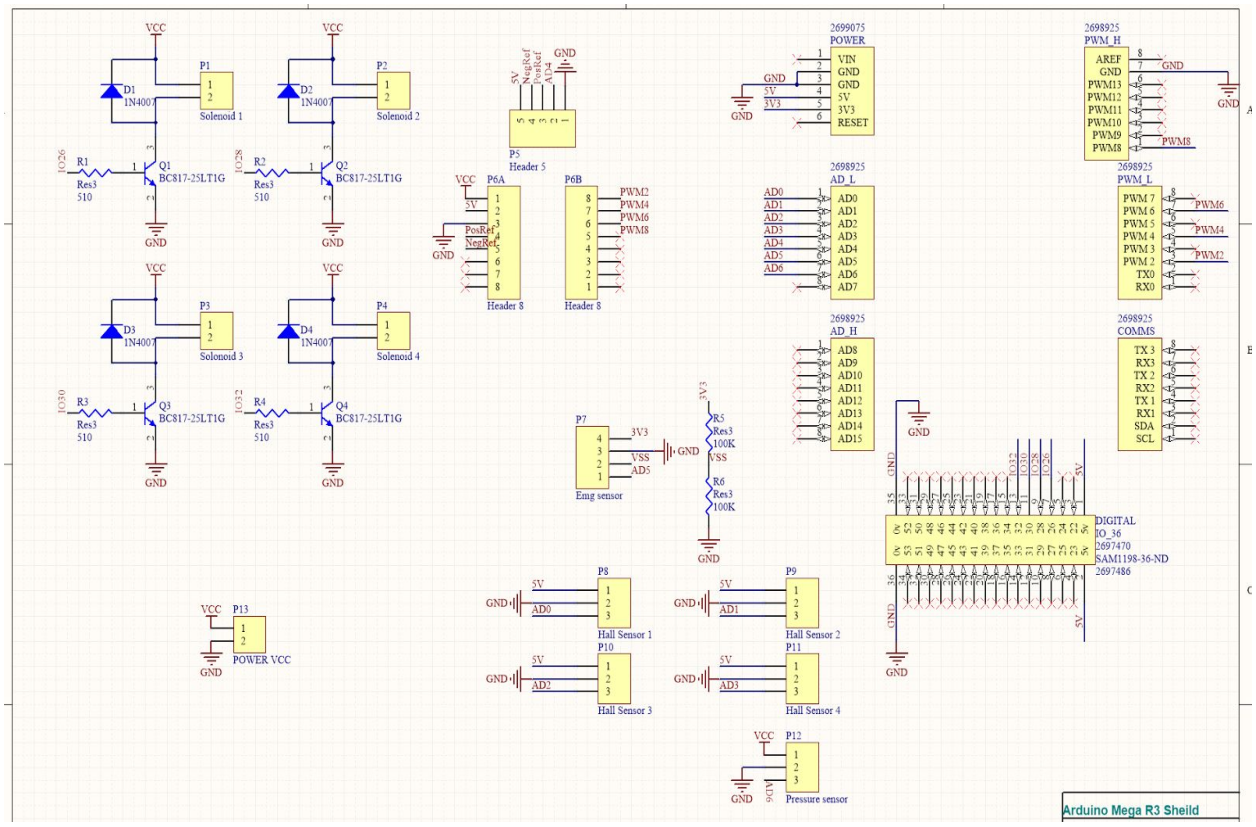


Figure 4.11.B: Complete Altium Schematic for DPS Electrical System.

Following the completion of the schematic and selection of components a PCB board was designed and ordered to be directly mounted on top of the existing microcontroller. The final pin layout and surface mount configuration are displayed below:

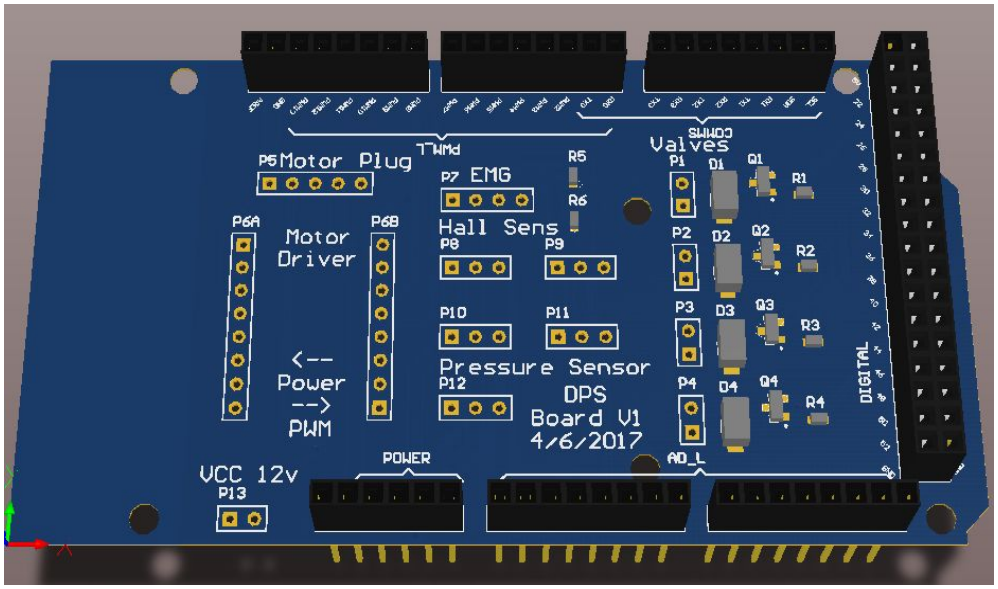


Figure 4.11.C: Final Pin layout and SMD on PCB board for DPS system.

The circuit board was ordered from Advanced Circuits and integrated into the final system design. In order to further add to the portability of the system a custom mount was created that would attach directly to the microcontroller and the new PCB shield. The mount encases the battery and has a snap on lid. The lid has a hole that allows the battery wires to escape and plug directly into the microcontroller and PCB. The board sits up on a standoff to prevent any potential shorts from conductive material touching the solder points on the bottom of the microcontroller. The completed module can be seen below:

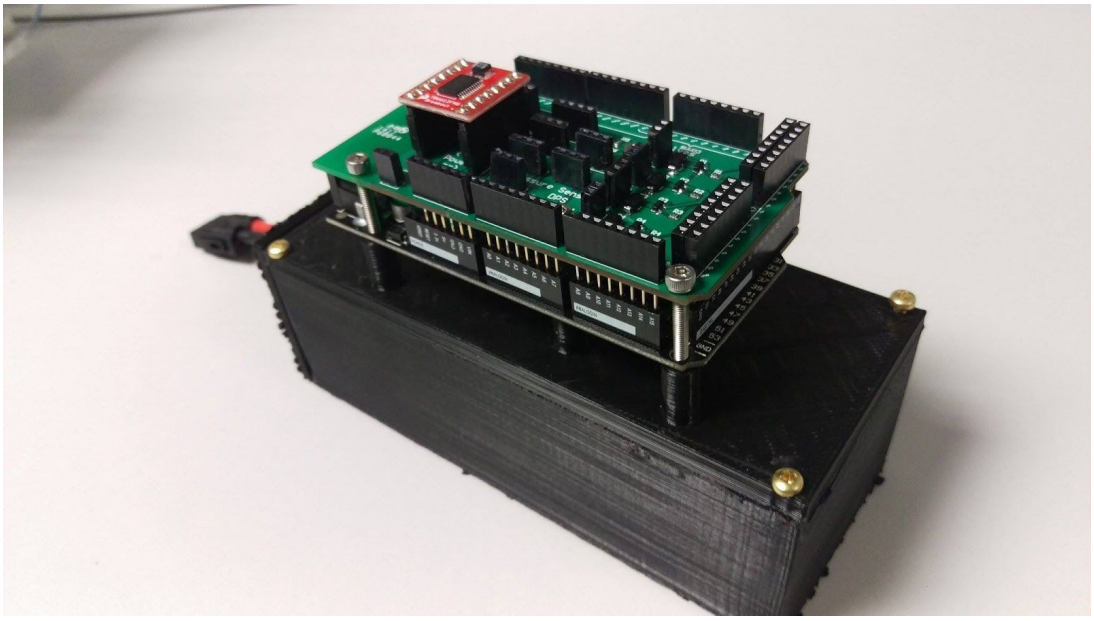


Figure 4.11.D: Side view of Final Module for DPS system

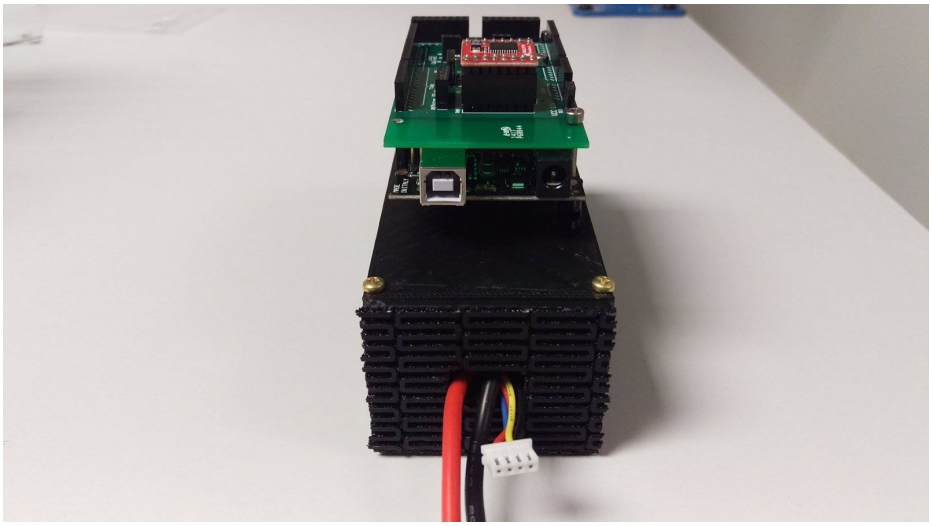


Figure 4.11.E: Front view of Final Module for DPS system

4.12. Rejected Designs

This section describes the various designs that were considered prior to creating the final design that the team eventually pursued. Each subsection describes a specific design, its advantages, and its weaknesses. The designs are listed in the order that they were invented. Design A is very similar to the DAPS system and each subsequent design becomes closer to resembling the final DPS system.

4.12.1. Design A

The Dynamic Prosthetic Socket team initially sought to simplify the mechanical design of the system by reducing the number of components from four 100-mL syringes and two Firgelli linear actuators down to one 400-mL syringe and one Firgelli linear actuator. The syringe and linear actuator are attached to the side of a metal pylon, just as they are in the DAPS system. While this idea slightly simplifies the system by removing components, it appears to be *too similar* to the DAPS system. The team intended to develop a prosthetic device that was more aesthetically appealing than the DAPS system, however, Design A is bulky and asymmetric. Furthermore, the volume of 400 mL of water is unnecessarily too much according to Section 2.3.1.

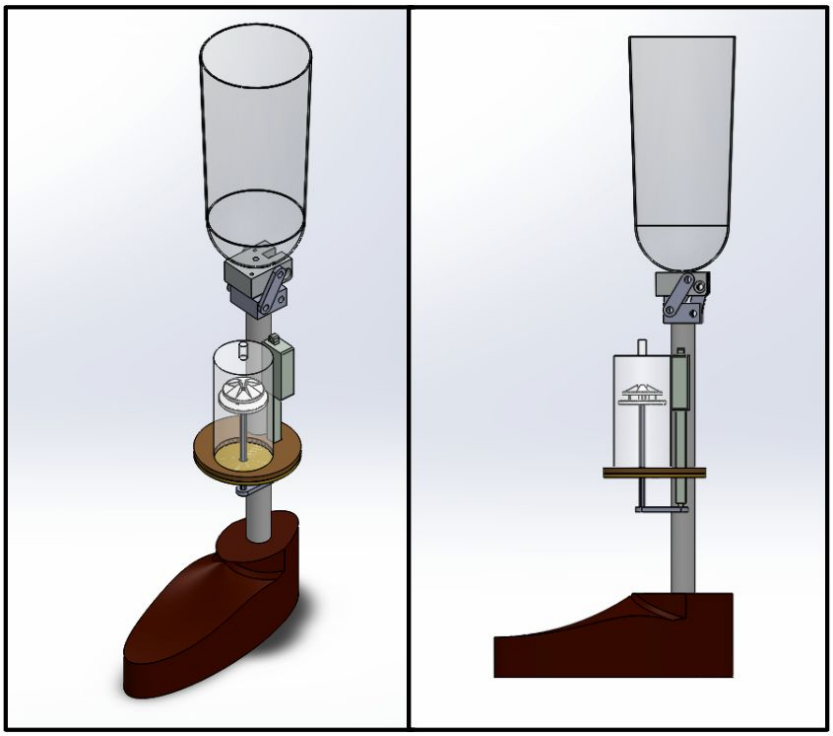


Figure 4.12a: Design A, Isometric and Side Views

4.12.2. Design B

Design B maintains the one-motor, one-syringe setup. However, it replaces the pylon with a larger tube that surrounds the actuation system. This tube bears the weight of the user and conceals the inner components. Unfortunately, this design appears to be an inefficient use of space. There is a fair amount of empty space beneath the hydraulics rig and the surrounding tube is fairly wide. Once again, the volume of 400 mL of water is still more water than the system actually requires.

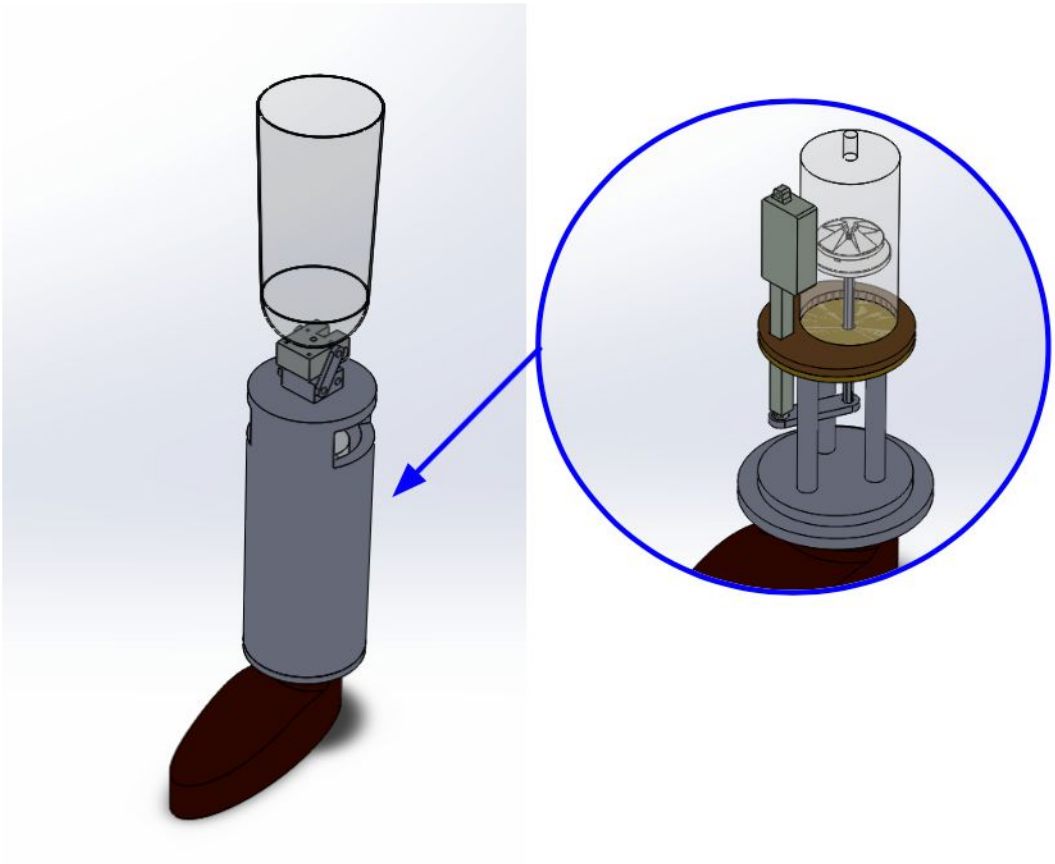


Figure 4.12b: Design B, Isometric and Inside View

4.12.3. Design C

The team developed Design C as a more compact system. The volume of fluid has been reduced to 200 mL and the syringe itself has actually become part of the leg's shank - meaning it is now bearing weight. The Firgelli linear actuator is attached to the side of the syringe and it is connected to the syringe piston by a small rod. Furthermore, a slot has been cut in the side of the pylon beneath the syringe so that this rod can move up and down. Unfortunately this large hole could lead to a mechanical failure of the system if the device experiences any powerful forces. In addition, the connecting rod, itself, may be susceptible to mechanical failure because of its cantilever nature.

Note that the final design removes both the hole in the side of the shank and the cantilever rod by repositioning the Firgelli linear actuator beneath the syringe and inside of the shank.

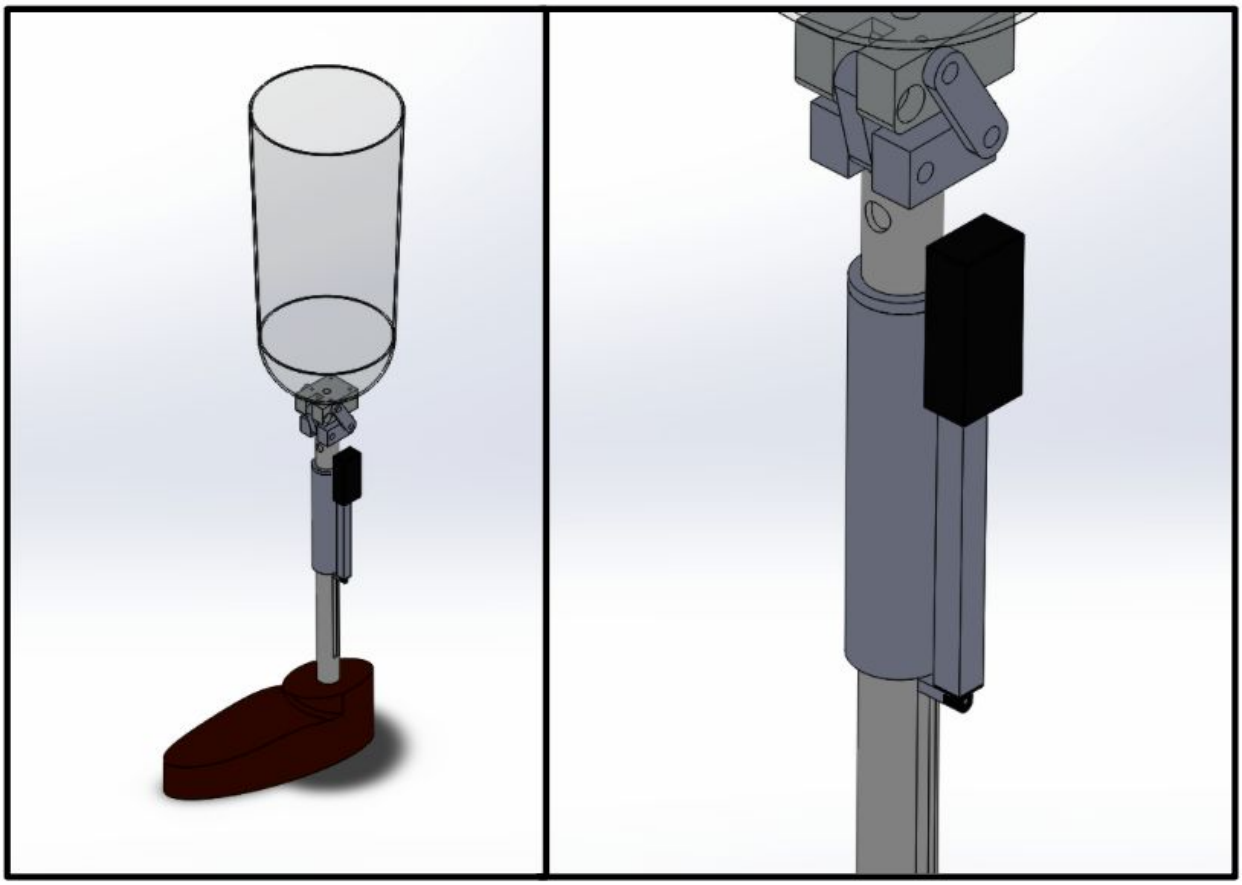


Figure 4.12c: Design C, Isometric and Close-up Views

5. Design Validation

Once the system architecture had been established, it was necessary to calibrate and test the sensors. This was done through a series of tests, all to ensure that our sensors were working as intended and to calibrate.

5.1 Hall effect calibration

When calibrating the hall effect sensors, the team set up a test where a magnet was placed on a mountable calibration table. This table was an extremely precise measuring tool, able to change the distance from the magnet to hall sensor by hundredths of a millimeter. By taking individual readings at every single interval, slowly moving the magnet farther away and then back, the team was able to accurately graph the response of the hall sensor.

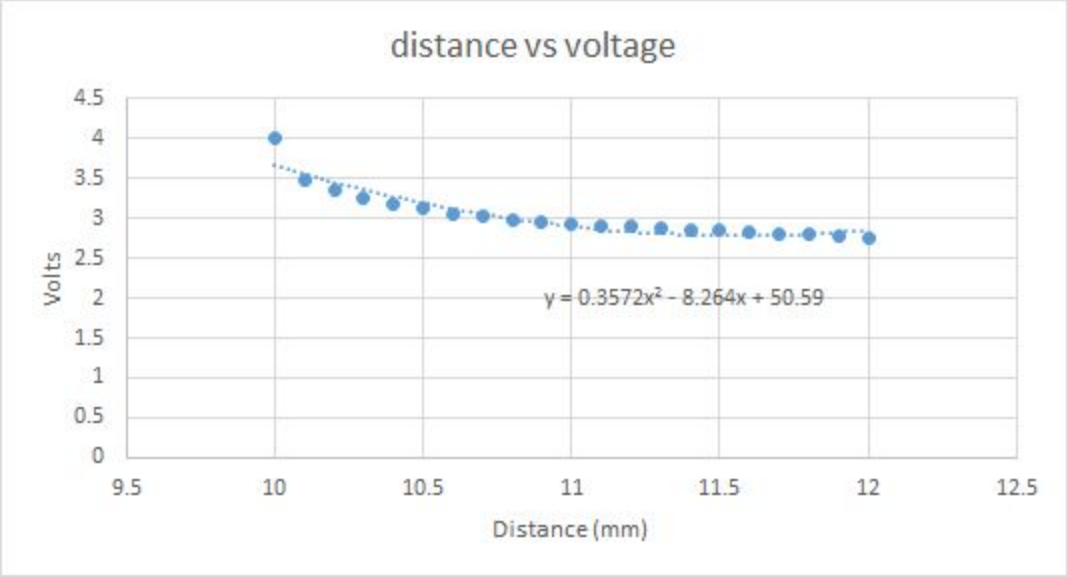


Figure 5.1a: Hall Effect Distance vs. Voltage

Once all of the necessary data points were gathered, it was possible to generate a polynomial that would best fit the range of data points recorded. This would allow for the change of readings gathered from the hall sensors from voltage readings to distance readings. This allows for an accurate calculation of the difference in distance between the hall effect and the magnet (around 22mm), thus showing how far the bladder has expanded. These distance values allow for a much easier time debugging and reading than the raw ADC values.

5.2 EMG calibration

When calibrating the EMG sensors, an RMS filter was implemented that was detailed in section 4.6. With the control architecture that was implemented for the EMG sensors, the system allowed for the detection of patient movement to a high degree of accuracy. A fairly simple method of testing the muscle twitch detection accuracy was used. Over the course of 5 minutes, team members would go through the

movements of remaining still for a period of time, then a quick period of active bursts, with random intermittent pauses in between. The user would try their hardest to find any weaknesses within the system, attempting to tense their muscle at random intervals while announcing their intentions when they were doing so. The graph showing our results can be seen in figure 5.2a.

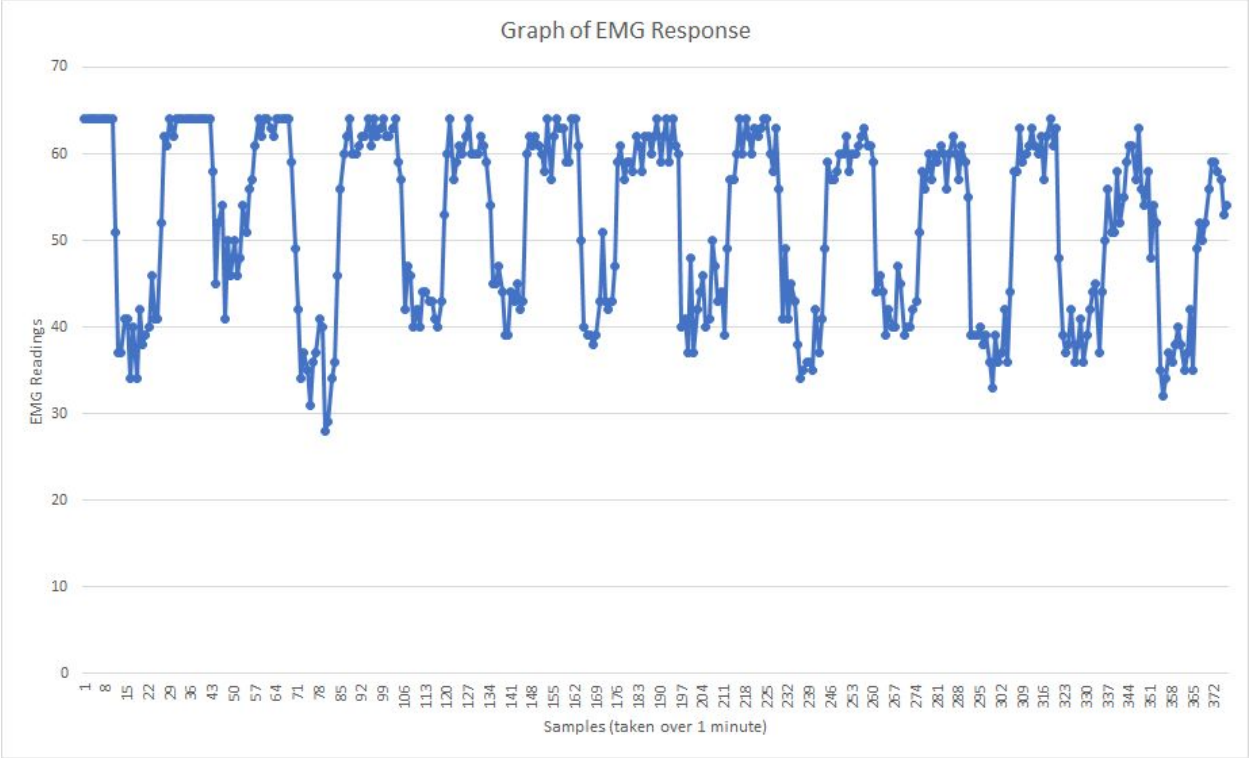


Figure 5.2a: Graph of EMG response

From the graph, it can be seen that at low periods of movement, the EMG readings move back to around 64, which is the number of high readings in each cluster of 64 samples. As seen in the graph, during a minute of movement, there is only one case where the group of active readings pass the threshold that was discussed in section 4.6, thus moving into the passive region, resulting in a false positive. Since the set has 25 transitions from passive to active, this means that only 1 out of 25 or 4% of our transitions resulted in false readings. Thus, we can safely say that our system is 96% efficient at determining periods of activity and periods of no activity.

5.3 Response Time Test

At the same time as the EMG calibration tests were occurring, another teammate would be standing by, attempting to measure the time between the announced muscle spasm and the response of the system. This was much harder to accurately determine to the fact that the response time was in milliseconds, making it difficult to record.

However, by providing further analysis on Figure 5.2a, it is possible to calculate a rough estimate of the system's response time to state transitions. From the graph, it takes about it takes about 2 sample readings for the system to transition fully from passive reading, to active reading. Taking into account the

setup time, the amount of time spent actually recording sample clusters was 50 seconds. Thus, 50 seconds over 372 clusters, results in one cluster sample taken every 0.1344 seconds or 7.44 samples per second. And with 2 samples being the time of transition, this can now be calculated to a response time of about 0.26s.

Due to the robustness of the code, and the various different software filters that the sensor readings went through, the team found that the system was extremely accurate, being able to detect and respond to the spastic readings with great response time and accuracy.

5.4 System weight

Once the entire system had been built, a scale was procured and zeroed before placing the full system onto it. By this point, the device was complete with a battery and a hydraulic cylinder filled with water. The total weight of the system is approximately 13.5 pounds (6.12 kg).

5.5 Compactness

The pinch valve holder (shown in Figure 5.5) features the widest dimension along the height of the aluminum tube with an outer diameter of 5.30 inches (13.5 cm). However, this component is located near the top of the shank - directly beneath the prosthetic socket and knee - which means it probably would not make it difficult for the user to put pants on over it. The majority of the prosthetic socket height is provided by the aluminum tube which contains the hydraulic cylinder and the Firgelli linear actuator. The aluminum tube has an outer diameter of 2.25 inches (5.715 cm) which is a significant reduction from the DAPS design, which has a widest dimension of 5.75 inches (14.6 cm) along most of its height.

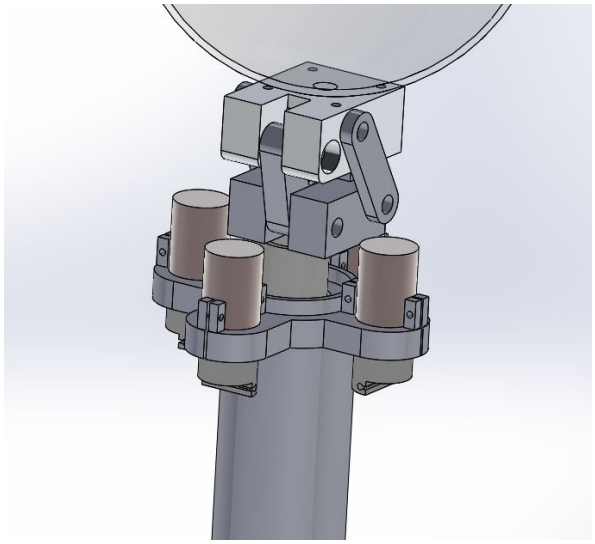


Figure 5.5: DPS Widest Component

5.6 Duration and power efficiency

When tested the system draws an average of 200-300 mA when nothing is engaged except the sensors and Arduino. When the motor and solenoids are firing during intermittent corrections in pressure and volume the average current pull is about 1-1.2 amps. When the motor is driving its full stroke length and all of the solenoids are firing the max pull was observed to flicker between 1.7 to 1.8 amp draw. That means the system has an average expected battery life between 4 and 7 hours approximately depending on what the user is doing. If the user does not move at all and the system stays passive, the system would be powered for nearly 20 hours, but that is highly unlikely. Or if the user is standing and sitting constantly so that the states keep changing, the battery will die in as little as 4 hours. The expected duration for the battery is somewhere near six ish hours. This time frame is within the minimal requirements set by the LTI advice given during the interview. The benchmark being enough power to go to the grocery store and get back on a single charge.

5.7 Electrical Integration

Once we had received our custom PCB shield that we had ordered to replace our test bench circuit, it was only a matter of plugging in the correct circuit components into the board. Upon doing this, we realized that in the electrical diagram, due to a fault in the auto routing feature in Altium, the digital pins were one pin off from their original destination. As such, what used to be pin 26, was now 27, and so on so forth. To fix this, we simply changed the variable within the code to the new pins and the rest of the board worked as intended. After this minor correction the circuit worked perfectly and functioned as designed. The electrical system had been reduced from a space covering three break out boards to a single surface the size of an arduino. Additionally by creating the battery mount package to hold the two stacked boards the entire power and control system fit into an area the size of the batteries top face.

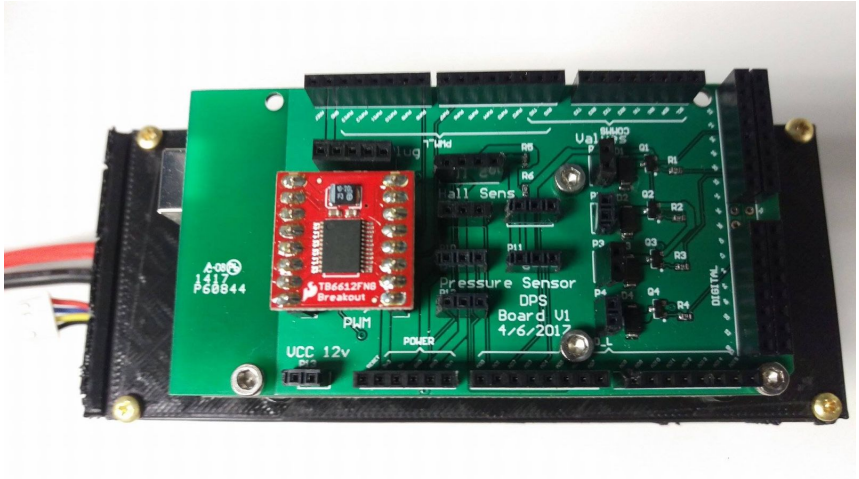


Figure: 5.7.A: Top down view of Electrical Module

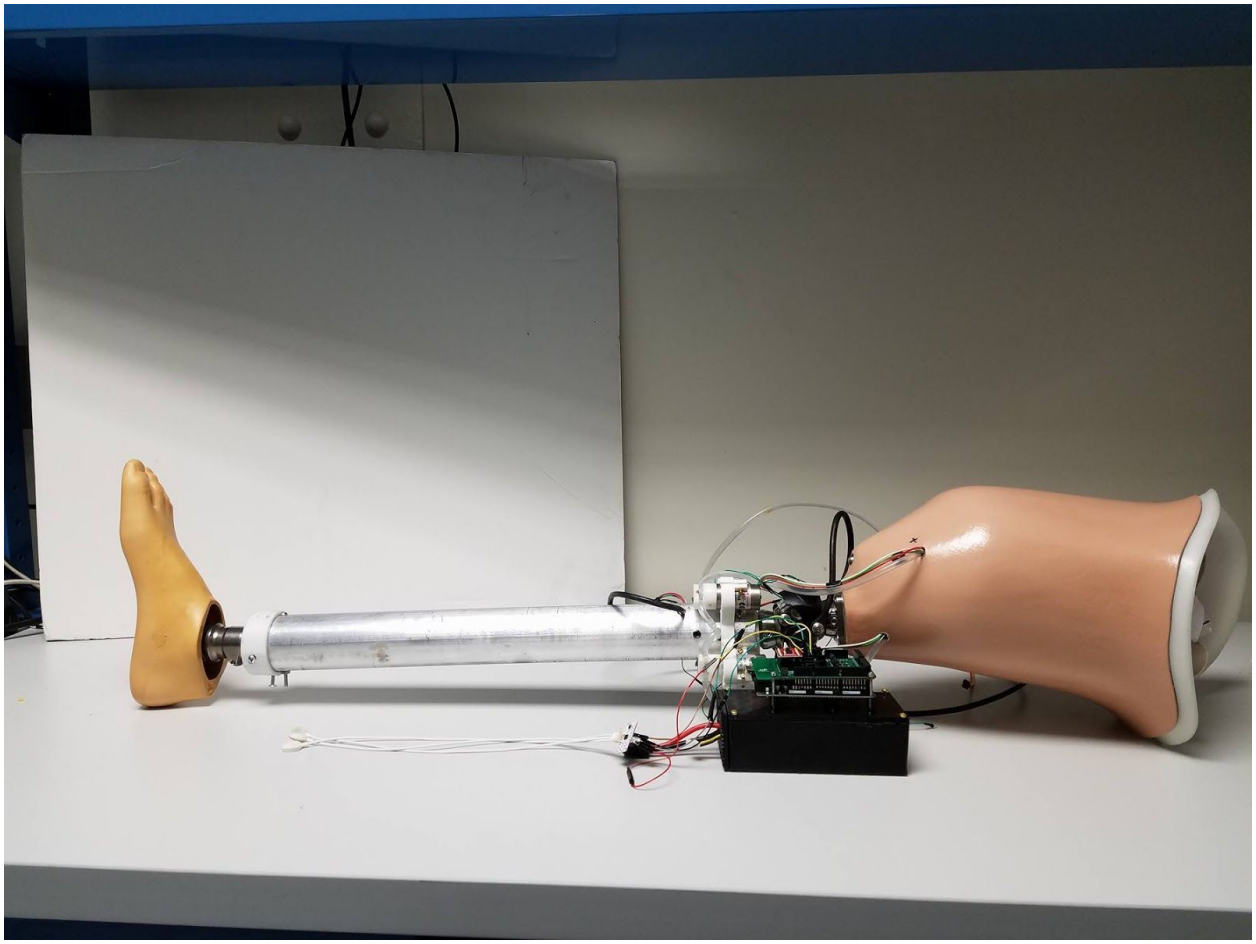


Figure 5.7.B: Electrical Module Hooked up with Respect to the Whole Leg

5.8 Validation of the overall Dynamic Prosthetic Socket system

Overall, after testing each individual system on the prosthetic and validating that it was working as intended, the whole system was run altogether. The result was a system that, after running through it's initial calibration state, would smoothly transition through states in response to a user's muscle activity. When movement was detected, the system would fill with water to the setpoint previously calibrated, when the user relaxed and no movement was detected, then the system would drain to a percentage of the setpoint.

6. Discussion

This chapter reflects upon the pros and cons of the Dynamic Prosthetic Socket system. In particular, this chapter analyzes the following characteristics of the device: reliability, response time, power efficiency, safety, strength, weight, comfort, aesthetics, and size.

6.1 Reliability

In terms of reliability, the system is quite good, in which it can accurately detect muscle twitches to a high degree of success. Rarely if ever does the system move into a state when the user does not want it to. However, the firgelli motor that is used does have a hard time driving the system when it is filled with water, and sometimes fails on calibrating as it cannot push hard enough to generate the necessary pressure spike. However, this could also be due to the fact that the residual limb mold that we are using to simulate a patient's amputation was not made for this socket, and as such, leaves quite a bit of room in the socket itself.

6.2 Response time

The response time of the system is incredibly good, as the team kept optimality of code in mind while coding. This resulted in very fast state transitions that allows the system to move from passive state to active state in almost no delay time at all.

6.3 Power efficiency

The system has a very similar power draw as the previous Dynamic Socket MQP, however the DPS model has added many additional sensors and increased the functionality. In terms of being efficient with the power, this rendition of the leg seems to well within practical bounds. By removing one motor and only periodically having to power the solenoids there is not a large current draw on the system most of the time. When the user is passive or no adjustment is needed in active state, the system maintains. Drawing only a few hundred milliamps for sensor readings. Both the mBed and Arduino Mega have similar 200 mA min active pull for when they are not in standby. The removal of a motor and replacement with 4 solenoids is comparable when the majority of the solenoids need to be driven. However, whenever the previous MQP made any adjustment they had to drive 2 motors while the DPS model only has to fire one solenoid and one motor. This means on the average, when making adjustments to user state the DPS model will draw less power since the solenoids draw less current on an individual basis than the Firgelli motor.

6.4 Safety

Overall, the safety of the system is hard to quantify, due to the fact that the system was not tested on an actual patient. However, it can be inferred that due to the fact that steps were taken to separate the different systems as much as possible, that DPS system is indeed as safe as it can be. There are pressure regulations in place as well to ensure no more than a set PSI can ever be applied to the bladders and the user. Additionally there are failsafe release ports on all of the bladders incase the solenoids or motor ever fail and the bladders can not be drained automatically.

6.5 Strength

The prosthetic leg shank needs to be strong enough to support a maximum weight of approximately 4,000 Newtons, as calculated in Section 2.6.1. Specifically, the shank needs to withstand the compressive force acting on it in addition to the bending/buckling action that may result. The compressive stress is equivalent to:

$$\sigma = \frac{F}{A}$$

where σ is the compressive stress, F is the force acting on the cylinder, and A is the cross sectional area of the cylinder. The cylinder has an outer diameter of 2.25 inches (5.715 cm) and an inner diameter of 2.00 inches (5.08 cm), so the cross sectional area is equivalent to 0.834 square inches or 5.38 x 10^{-4} square meters.

$$\sigma = \frac{F}{A} = \frac{4000N}{5.38 \times 10^{-4} m^2} = 7.43\ MPa$$

The material of the shank is Aluminum 6061-T6, which has a bearing yield strength of 386 MPa - significantly greater than the compressive stress of 7.43 MPa. Furthermore, the critical buckling load can be calculated using the equation below:

$$P_{CR} = \frac{\pi^2 EI}{(KL)^2}$$

where P_{CR} is the critical buckling load, E is the material's elastic modulus, I is the moment of inertia about the axis through the center of the cylinder, K is the effective length factor, and L is the unsupported height of the aluminum cylinder. The mass of the tube, as given in Section 6.6, is 0.738 kg (1.63 pounds) and the length of the tube is 50.8 cm (20 inches).

$$P_{CR} = \frac{\pi^2 EI}{(KL)^2} = \frac{\pi^2 (68.9\ GPa)(0.5MR^2)}{(0.5 \times 0.508\ m)} = 802\ MPa$$

So the actual stress acting on the cylinder is also significantly smaller than the critical buckling stress. This means that the aluminum shank is strong enough to reliably support the weight of the user.

6.6 Weight

The weight of the Dynamic Prosthetic Socket is approximately 13.5 pounds. This is around half the weight of a typical leg, however, it is heavier than the DAPS system's weight of 9.34 pounds. A future prosthetic device could improve upon the DPS system by reducing the weight by a few pounds - because the leg should be as light as possible for user satisfaction. The leg's weight can be reduced by

implementing lighter components. In particular, aluminum is lighter than other structural metals, but it is heavier than a material like carbon-fiber. The leg's aluminum shank weighs 1.63 pounds (0.738 kg), but could be reduced to 0.97 pounds (0.44 kg) if the material was replaced by carbon fiber. Furthermore, the weight of the aluminum shank could be lowered by reducing the length of it - this would also improve upon the system size.

6.7 Comfort

The system is pressure regulated to tighten just enough around the user. This ensures that the squeeze on the leg is ideal and can be adjusted on a per user basis if they feel the default pressure trigger is too high or low. Additionally when the user is inactive, the leg releases some of the pressure from the socket, bringing relief to the leg and allowing the leg to recover from the continuous application of force. By regulating the two states the system drives for optimal comfort and health with respect to the users residual limb.

6.8 Aesthetics

Aesthetic appeal is an important factor for prosthetic socket devices. Even if the device is physically comfortable, the patient should also be mentally comfortable with wearing it around other people. If the prosthetic socket closely resembles a leg then the user will not be as conscious of its difference in appearance (relative to an actual leg). The DAPS system consisted of four syringes and two Firgelli linear actuators attached to the outside of a pylon - this bulky mechanism was not concealed in any way. The Dynamic Prosthetic Socket has improved upon the DAPS system aesthetically by hiding the actuation system (the hydraulic cylinder and the Firgelli linear actuator) inside of the aluminum tube.

6.9 Size

The Dynamic Prosthetic Socket system has a disproportional appearance because of its great shank length. The knee height for the device is approximately 26 inches (66 cm) which is roughly half a foot greater than a typical/average knee height. This presents a problem because very few people exist with a knee height of 26 inches - the system could be improved by developing a smaller version that is more reasonable for a normal human being. More specifically, the device could be made shorter by utilizing a hydraulic cylinder that contains less fluid or that is wider and shorter than the Parker Fluidpower hydraulic cylinder implemented in the DPS system. Furthermore, this adjustment could be followed by replacing the Firgelli linear actuator with another linear actuator that features a shorter stroke length. These alterations would allow for a reduction in the length of the shank.

7. Conclusion and Recommendations

This project aimed to adapt last year's proof of concept dynamically adjusting prosthetic socket into a much more dynamic socket, capable of more rigorous control as well as streamline the design of the system, making it more compact and aesthetically pleasing. The objective that was set out to be accomplished was the eventual creation of a prosthetic, ready for clinical trials with actual patients once IRB approval has been established. As such, the design goals of the system was a compact and lightweight system, that would minimize any discomfort or awkwardness while in use by a patient. This project also set out to improve upon the EMG signal analysis algorithm that last year's team used to a partial degree of success for use in state transitions of the prosthetic.

All in all, the team was able to successfully create a dynamic prosthetic socket, able to continuously fit and adjust itself to the patient's leg. The system is able to autonomously move through its states, based solely on the external readings from the EMG sensors, which,
due to an improvement on the EMG signal processing algorithm,are able to accurately and quickly respond to nearly all muscle twitches. This allows the system to accurately predict a patient's movement and change states before the user's muscle actuation.

Dynamic fitting of the socket was also successfully implemented in which the system can now fill and calibrate each individual bladder to a setpoint determined by the user's current residual limb volume as opposed to the arbitrarily set fill values of last year's project.

The team was also successfully able to reduce the system down into a compact design where the majority of the parts were hidden within a single aluminum tube, thus rendering the outward appearance of the prosthetic unassuming and aesthetically pleasing.

In addition to this, battery life calculations place the overall battery life of the system to well within the predetermined set time of 6 hours.

In conclusion, this project met nearly all of its tasks that it was set out to accomplish, and therefore can be labeled a large success. The result is a dynamic prosthetic system capable of dynamically fitting and adjust to account for times when the patient is moving, and when the patient is not.

7.1 Recommendations

The team's recommendations for further work on this project are detailed below.

7.1.1 Reduce length of shaft

Currently, the system is only using about half of the firgelli motor's travel length. This means that the length of the shaft could be cut to accommodate for a lesser stroke length, which would put the length of the shaft into a more realistic length of a human tibia. This is useful as it offers some variability for potential users as it means that there is room for customization of the shaft length on a user to user basis.

7.1.2 Reduce weight of system

The weight of the system is more than we anticipated, around 13.5lbs or about half the weight of an average adult male's leg. This weight can be greatly reduced by changing the material of the shaft

itself. Something like carbon fiber would be ideal as that would retain the current strength of the shaft, while greatly reducing the weight of it.

7.1.3 Embedded Processor

Currently, the system runs off of an Arduino Mega 2560. While the system's response time and power efficiency are satisfactory, an embedded processor that is dedicated for this task could improve the overall quality of the project even moreso.

7.1.4 Clinical Trials

While IRB approvals were obtained to perform trials on actual subjects, actual clinical trials were never run. Having a future team carry out clinical trials with an amputee patient to test the system would provide invaluable data.

7.1.5 Alternate Pumping System

There are some experimental attempts at combining an electric and passive system together that regulated the flow of water into the bladders through intra socket pressure differences. These differences are caused by the gait of the person wearing the prosthetic. The studies show some potential and may be worth looking deeper into for a future project, or modification of the DPS socket. [45]

8. Bibliography

[1] Ziegler-Graham K, MacKenzie EJ, Ephraim PL, Travison TG, Brookmeyer R. Estimating the Prevalence of Limb Loss in the United States: 2005 to 2050. Archives of Physical Medicine and Rehabilitation 2008;89(3):422-9.

[2] "Amputation Overview." *WebMD*. WebMD, n.d. Web. 25 Apr. 2017.

[3] Smith, Douglas G., M.D. "Amputee Coalition." *Resources and News for Amputees, Amputation, Limb Loss, Caregivers and Healthcare Providers*. Amputee Coalition, n.d. Web. 25 Apr. 2017.

[4] Sanders, JE, and S Fatone. "RESIDUAL LIMB VOLUME CHANGE: SYSTEMATIC REVIEW OF MEASUREMENT AND MANAGEMENT." *Journal of rehabilitation research and development* 48.8 (2011): 949–986. Print.

[5] Levy, William S., M.D. "Journal of Rehabilitation Research & Development (JRRD)." *Strength Evaluation of Prosthetic Check Sockets, Copolymer Sockets, and Definitive Laminated Sockets*. Atlas of Limb Prosthetics: Surgical, Prosthetic, and Rehabilitation Principles, n.d. Web. 25 Apr. 2017.

[6] Sanders, JE et al. "Clinical Utility of in-Socket Residual Limb Volume Change Measurement: Case Study Results." *Prosthetics and orthotics international* 33.4 (2009): 378–390. *PMC*. Web. 25 Apr. 2017.

[7] Hiatt, Meagan, Joshua Friscia, Mollie Myers, and Jacob Zizmor. *Dynamic Adjusting Prosthetic Socket*. Tech. no. 1. Worcester: Worcester Polytechnic Institute, 2016. Print.

[8] "The History of Prosthetics." *UNYQ*. N.p., 23 Sept. 2015. Web. 25 Apr. 2017.

[9] Greenwald R, Dean R, Board W. Volume management: Smart Variable Geometry Socket (SVGS) technology for lower-limb prostheses. J Prosthet Orthot. 2003;15:107–112.

[10] M. W. Legro, G. Reiber, M. del Aguila, M. J. Ajax, D. A. Boone, J. A. Larsen, D. G. Smith, and B. Sangeorzan, "Issues of importance reported by persons with lower limb amputations and prostheses," *J. Rehabil. Res. Dev.*, vol. 36, no. 3, pp. 155–163, Jul. 1999.

[11] K. Ziegler-Graham, E. J. MacKenzie, P. L. Ephraim, T. G. Travison, and R. Brookmeyer, "Estimating the Prevalence of Limb Loss in the United States: 2005 to 2050," *Arch. Phys. Med. Rehabil.*, vol. 89, no. 3, pp. 422–429, Mar. 2008.

[12] Owings M, Kozak L. Ambulatory and inpatient procedures in the United States, 1996. National Center for Health Statistics. Vital Health Stat. 1998;13(139)

[13] G. McGimpsey and T. C. Bradford, "Limb Prosthetics Services and Devices Critical Unmet Need: Market Analysis," Bioengineering Institute Center for Neuroprosthetics Worcester Polytechnic Institution, White Paper.

[14] C. C. Nielsen, *Issues Affecting the Future Demand for Orthotists and Prosthetists: Update 2002 : a Study Updated for the National Commission on Orthotic and Prosthetic Education*. National Commission on Orthotic and Prosthetic Education, 2002.

[15] T. R. Dillingham, L. E. Pezzin, and E. J. MacKenzie, "Limb amputation and limb deficiency: epidemiology and recent trends in the United States," *Southern Medical Journal*, vol. 95, no. 8, p. 875+, Aug-2002.

[16] A. F. T. Mak, M. Zhang, and D. A. Boone, "State-of-the-art research in lower-limb prosthetic biomechanics- socket interface: A review," *J. Rehabil. Res. Dev.*, vol. 38, no. 2, pp. 161–174, Apr. 2001.

[17] M. T. Maguire and J. Boldt, "Prosthetic Rehabilitation Manual: Transfemoral (Above Knee) Amputation." Advanced Prosthetics Center, 2013.

[18] J. T. Highsmith and M. J. Highsmith, "Common skin pathology in LE prosthesis users," *JAAPA Off. J. Am. Acad. Physician Assist.*, vol. 20, no. 11, pp. 33–36, 47, Nov. 2007.

[19] P. F. D. Naylor, "Experimental Friction Blisters.," *Br. J. Dermatol.*, vol. 67, no. 10, pp. 327–342, Oct. 1955.

[20] P. K. Commean, K. E. Smith, and M. W. Vannier, "Lower extremity residual limb slippage within the prosthesis," *Arch. Phys. Med. Rehabil.*, vol. 78, no. 5, pp. 476–485, May 1997.

[21] M. J. Highsmith, J. Highsmith, and J. Kahle, "Identifying and managing skin issues with lower-limb prosthetic use," *ResearchGate*, vol. 21, pp. 41–43.

[22] J. P. Seaman, "Survey of Individuals Wearing Lower Limb Prostheses," *J. Prosthet. Orthot.*, vol. 22, no. 4, pp. 257–265, 2010.

[23] "RevoFit Solutions." *Click Medical*, www.clickmedical.co/store/revofit/revo/. Accessed 26 Apr. 2017.

[24] "Infinite Socket TF." *LIM Innovations*, www.liminnovations.com/products/infinite-socket/. Accessed 26 Apr. 2017.

[35] Vacuum-Assisted Socket Suspension Compared With Pin Suspension for Lower Extremity Amputees: Effect on Fit, Activity, and Limb Volume Klute, Glenn K. et al.

[36] Archives of Physical Medicine and Rehabilitation , Volume 92 , Issue 10 , 1570 - 1575

[37] Street, Gt. "Vacuum suspension and its effects on the limb." *Orthopadie Technik* 4 (2006): 1-7.

[38] Hardin, Shanon. "Transtibial Case Study." *Shanonhardinprosthetics*. N.p., 28 Jan. 2012. Web. 25 Apr. 2017.

[39] Greenwald, Richard M., Robert C. Dean, and Wayne J. Board. "Volume Management: Smart Variable Geometry Socket (SVGS) Technology for Lower‐Limb Prostheses." *JPO: Journal of Prosthetics and Orthotics* 15.3 (2003): 107-112.

[40] T Walley Williams III, M. A., and David E. Altobelli. "Prosthetic sockets stabilized by alternating areas of tissue compression and release." *Journal of rehabilitation research and development* 48.6 (2011): 679.

[41] Resnik, Linda, et al. "Comparison of transhumeral socket designs utilizing patient assessment and in vivo skeletal and socket motion tracking: a case study." *Disability and Rehabilitation: Assistive Technology* 11.5 (2016): 423-432.

[42] *Anthropometric Data*. Rolling Meadows, IL: Graphic Products, 1986. *Ohio Bureau of Workers Compensation*. Web. 24 Apr. 2017. <https://www.bwc.ohio.gov/downloads/blankpdf/ErgoAnthropometricData.pdf>.

[43] Greenwald R, Dean R, Board W. Volume management: Smart Variable Geometry Socket (SVGS) technology for lower-limb prostheses. J Prosthet Orthot. 2003;15:107–112.

[44] Sanders, Joan E., and Stefania Fatone. "Residual limb volume change: Systematic review of measurement and management." *Journal of rehabilitation research and development* 48.8 (2011): 949.

[45] Rose, William. "Electromyogram Analysis." *Mathematics and Signal Processing for Biomechanics*. University Of Delaware, 23 July 2014. Web. 25 Apr. 2017. <https://www1.udel.edu/biology/rosewc/kaap686/notes/EMG%20analysis.pdf+>

[46] Gerschutz, Maria J., et al. "Strength evaluation of prosthetic check sockets, copolymer sockets, and definitive laminated sockets." *Journal of rehabilitation research and development* 49.3 (2012): 405.

[47] Chan, Michael, et al. “Interview with Liberating Technologies Inc. .” 29 Sept. 2016.

[48] Metals Handbook, Vol.2 - Properties and Selection: Nonferrous Alloys and Special-Purpose Materials, ASM International 10th Ed. 1990.

[49] Metals Handbook, Howard E. Boyer and Timothy L. Gall, Eds., American Society for Metals, Materials Park, OH, 1985.

[50] Structural Alloys Handbook, 1996 edition, John M. (Tim) Holt, Technical Ed; C. Y. Ho, Ed., CINDAS/Purdue University, West Lafayette, IN, 1996.

[51] Information provided by The Aluminum Association, Inc. from Aluminum Standards and Data 2000 and/or International Alloy Designations and Chemical Composition Limits for Wrought Aluminum and Wrought Aluminum Alloys (Revised 2001).

[52] “Matweb Is Currently Undergoing Maintenance.” *MatWeb*, www.matweb.com/search/datasheet_print.aspx?matguid=1b8c06d0ca7c456694c7777d9e10be5b. Accessed 26 Apr. 2017.

[53] Varam, A., Dr. "Compression Member Design." *CE 405: Design of Steel Structures*(n.d.): n. pag. *CE 405: Design of Steel Structures*. University Of Michigan. Web. 24 Apr. 2017. <https://www.egr.msu.edu/~harichan/classes/ce405/chap3.pdf>.

[54] Greenwald, Richard M. "Volume Management: Smart Variable Geometry Socket (SVGS) Tec... : JPO: Journal of Prosthetics and Orthotics." *LWW*. JPO Journal of Prosthetics & Orthotics, July 2003. Web. 26 Apr. 2017. <http://mobile.journals.lww.com/jpojournal/Fulltext/2003/07000/Volume_Management__Smart_Variable_Geometry_Socket.11.aspx>.