WPI

University of Massachusetts Medical School

Transforming Physical Therapy: A Wearable Device for Skeletal Muscle Mechano-therapy

A Major Qualifying Project
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Abstract

Volumetric muscle loss is a life-altering, traumatically- or surgically-induced loss of skeletal muscle with extremely high incidence in military personnel. Muscle atrophy, the shrinkage of skeletal muscle caused by prolonged periods of inactivity and age, affects the general population and among 25-90% of Intensive Care Unit patients. The purpose of this project is to create a wearable device that conducts passive skeletal muscle mechano-therapy for these patients. Currently, there are no available devices that accomplish these goals. Alternate treatment tools require significant time and effort from the patient and are not universally accessible. The team pursued two pneumatic systems and one mechanical system to apply cyclic compression therapy to the calf. The devices are comfortable, non-invasive, and execute mechanical compressions on the affected area to promote proper proliferation of skeletal muscle cells. By assessing these criteria through testing, the pneumatic device with a hard backing ranked the highest overall. However, the other devices accomplish cyclic compression and outranked this device in certain applications. These devices are to be used alongside traditional treatment methods, such as physical therapy, to passively stimulate skeletal muscle and improve treatment outcomes.

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Chapter 1: Introduction

Proper muscle function is an important component in comfortably and confidently performing activities of daily living. Although there are a wide variety of factors that may hinder muscle function, muscle atrophy is a particularly prominent cause. Muscle atrophy refers to the wasting or thinning of muscle tissue and is caused primarily by extended periods of inactivity. Specifically, between 25-90% of Intensive Care Unit (ICU) patients experience muscle atrophy as a result of prolonged bed rest [1]. Furthermore, approximately 26.9% of patients admitted to hospitals in the US are admitted to the ICU at some point during their hospitalization [2]. In addition to muscle atrophy, volumetric muscle loss (VML) of skeletal muscle through surgery or traumatic injury seriously affects muscle functionality. Though less common than muscle atrophy, VML can often affect military personnel through combat-related injuries [3]. In both cases, physical therapy (PT) is the primary treatment used to regain muscle function and size. PT is an advanced field of medicine where practitioners are trained to adapt to individual needs and abilities. However, participating in PT is a time intensive task with many at-home exercises required to regain full muscle functionality.

Achieving full physical rehabilitation after hospitalization is a long process. Outpatient physical therapy programs on average last from 6 months to a year [4, 5]. Along with that, full rehabilitation is often significantly delayed by a lack of adherence to prescribed rehabilitation tasks [6-8]. Due to the extensive time and effort commitments placed on individuals recovering from muscle atrophy and volumetric muscle loss, there is a need for an effective passive form of therapy that expedites the recovery process while minimizing the burden on the patient. Such a device should be applicable in hospital, rehab, and home settings. Electrical stimulation therapy is commonly used in PT settings to passively activate muscles and aid in regaining strength and functionality. This technique has proven very effective, but has several practical drawbacks. In particular, electrical stimulation can be uncomfortable, cause skin abrasions, and requires the patient to be sedentary while being applied. Furthermore, it is not universally applicable as patients with pacemakers and other electronic implants cannot use electrical stimulation [9]. Researchers continue to search for alternative methods to stimulate muscle growth.

Information on the effects of compressive therapy on VML and atrophied muscle is relatively limited, but has gained traction in recent years. In 2015, researchers at Harvard

University published their findings on the use of compressive therapy to stimulate muscle growth after induction of VML in rabbits [10]. The results demonstrated compressive therapy to be a promising method for improving skeletal muscle regeneration. A separate form of cyclic massage therapy was investigated in 2018 for atrophied limbs in mice. This study reported a significant increase in muscle recovery not only on the treated limb, but also on the contralateral, non-treated limb, indicating the potential for valuable clinical applications [11]. This team's collaborator, Dr. Giorgio Giatsidis, is researching the effects of non-invasive compression on skeletal muscle regeneration with the goal of adapting this technique to assist patients suffering from VML and muscle atrophy. Currently, no device exists in research or clinical settings that provides cyclic, compressive therapy to humans.

This project designed a device that applies comfortable, customizable, and easy-to-use compressive therapy to the calf muscle. Because of the wide range of muscle shapes and atrophy or injury severities, particular care was dedicated to designing a highly customizable device that can be fine-tuned by medical professionals to meet patients' individual needs. Additionally, as this is a form of passive therapy that will be used between PT sessions, ease of use was of high importance. While atrophy and VML can occur on nearly all muscles, this project targeted the gastrocnemius and surrounding muscles in the calf as it is a common location of atrophy induced by prolonged bed rest [12]. Since no research has been published regarding the effects of compressive therapy in humans, the purpose of this project was to provide the team's collaborator with several design options from which to choose the one that best suits his research needs. Thus, while this report includes a single recommended final product, three primary designs are presented with pros and cons. Specifically, one mechanical and two pneumatic devices were finalized, tested, and compared.

This project encompassed the entire design process to analyze and address the problem in a comprehensive manner. Creative ideation led to many possible designs, which each member of the team compared against one another using an array of project-specific metrics. Three designs were chosen to progress to the prototyping stage. The team performed material testing and experimentation for the pneumatic designs to improve prototypes. The group created a control system in Arduino that was used with separately purchased pumps and motors. Once in working form, the three devices were tested against each other and ranked both quantitatively and

qualitatively. After identifying the primary shortcomings of each design through testing, the team made improvements to finalize prototypes. The group put an emphasis on comfort in this phase.

The following chapters provide a fully detailed account of the design process. Chapter 2 consists of a literature review spanning muscle loss, regeneration, therapy techniques, and prior arts. Chapter 3 details the client statement and design requirements. Chapter 4 explains all design concepts in detail, the comparison tests done to identify the designs for prototyping, and the prototyping process itself. Chapter 5 describes the tests performed on the prototypes and their results. Chapter 6 discusses the final recommended design as well as potential large-scale impacts of this work. Chapters 7 and 8 elaborate on the field of compressive therapy and medical devices and provide recommendations for future work.

Chapter 2: Literature Review

2.1 Muscle Atrophy

Muscle atrophy is a decrease in mass of tissues or organs as a result of cellular shrinkage, which can result from a loss of organelles, cytoplasm, and cellular proteins. Such cellular behavior may occur due to aging, inactivity, injury, and disease [13]. Prolonged bed rest, a frequent experience for patients admitted to the ICU, is a common cause of muscle atrophy. Immobilization leads to catabolism in the muscles and a decreased synthesis of muscle proteins [1]. Similarly, in the presence of serious medical conditions such as cancer, sepsis, heart failure, and more, catabolic periods are induced where muscles serve as an alternative source of amino acids, and thus, a source of energy production [13]. This proteolytic process causes muscle atrophy.

Often, muscle atrophy is associated with the ubiquitin-proteasome system [13]. Ubiquitin is a protein commonly found in cellular tissues of eukaryotes that acts to regulate other protein processes. While ubiquitin is instrumental in apoptosis, it is also influential in cell division and multiplication, as well as the degeneration of neurons and muscular cells. For this reason, ubiquitin is of particular interest in the field of muscular regeneration [14, 15].

Ubiquitin research is also present in the study of atrophy-related genes, or “atrogenes.” These genes encode two muscle-specific ubiquitin ligases, Atrogin-1 (i.e. muscle atrophy F-box or “MAFbx”) and MuRF1, which in turn affect the ubiquitin-related processes previously mentioned [13]. The overexpression of these genes may result in atrophy by excessively targeting and marking molecules for ubiquitin-dependent degradation [16]. Knockdown experiments of MAFbx indicate its important role in the cellular processes of muscle atrophy [13].

2.2 Volumetric Muscle Loss

Volumetric muscle loss (VML) is not universally defined, but it is generally considered to be the traumatic or surgical loss of skeletal muscle that results in a functional impairment. Combat related injuries, in particular, are a leading cause of VML [2]. VML can be subdivided

into two categories: partial compartment loss or total compartment loss. Total compartment loss includes the loss of a nerve that supplies an involved compartment, making it more difficult to treat than partial compartment loss. Current muscle regeneration methods involving extracellular matrix scaffolds require the presence of nerve and adjacent muscles in a compartment, limiting this treatment to partial compartment loss [17].

Scientists continue to research potential treatments by investigating the biological processes and responses following a VML. After undergoing a VML, the body experiences a rush of tissue macrophages to the site of injury. The sub-categories of macrophages are categorized as classically activated M1-like macrophages or alternatively activated M2-like macrophages, the latter of which act as mediators for pro-regenerative responses, resulting in fibrotic tissue. This proinflammatory macrophage response directs the body from a more favorable pro-myogenic response to a less favorable profibrotic response, which causes functionally-limiting fibrosis instead of muscular regeneration. A prominent goal of regenerative medicine for VML is to minimize the accumulation of fibrotic tissue at the injury site [18, 19]. Regenerative medicine for VML is not yet a common clinical practice, but remains of high interest in the research field [20].

2.3 Muscle Cell Regeneration

Skeletal muscle regeneration is an intricate process that requires the presence of a variety of cell types to achieve the most complete healing at a damaged tissue site. Satellite cells (SCs) are skeletal muscle stem cells that facilitate the growth, maintenance, and healing of skeletal muscle tissue. Fibro-adipogenic precursors (FAPs), fibroblasts, endothelial cells, pericytes, and other immune cells work alongside satellite cells to play regulatory roles during skeletal muscle regeneration. In mature resting muscles, SCs are dormant, but upon injury or damage, these satellite cells activate and enter the cell cycle to repair the injured area [21]. Scar tissue formation occurs when there is an absence of the necessary signaling cues, causing fibroblasts to flood the damaged tissue with collagen and form excessive scar tissue [22].

Muscle growth after a decrease in volume due to atrophy or VML is, in general, a similar process between the two causes. However, the physiological difference in each situation induces a slightly different set of responses. Reloading a muscle after atrophy causes multiple signaling pathways for both protein synthesis and degradation to take effect. The elimination of damaged

proteins is a necessary step in the early stages of regrowth before beginning synthesis of new muscle [23]. In VML, skeletal muscle regeneration can be broken into three distinct phases. The destruction/inflammatory phase first involves the necrosis of damaged myofibers by M1 macrophages, which are eventually replaced with M2 macrophages. M2 macrophages increase myoblast proliferation leading to the repair phase. The repair phase primarily consists of recruitment and proliferation of SCs, and their differentiation into mature muscle tissue [22]. However, as VML is such a destructive occurrence to the muscle, the signaling to promote SC migration and proliferation that occurs in regeneration from muscle atrophy is often lost. This lack of signaling results in the third phase, remodeling, to be dominated by fibroblasts and the creation of scar tissue, limiting functionality of the muscle [22].

2.3.1 Quantification of Skeletal Muscle

The ability to reliably measure the volume of skeletal muscle in a specific area of the human body interests medical professionals working with individuals in or recently released from ICUs. As described in section 2.1, muscle atrophy occurs during extended periods of inactivity, such as those experienced by ICU patients. Atrophy-induced muscle weakness can lead to clinical outcomes such as mortality, ventilator-dependent time, and length of hospital stay [24]. Measurement of skeletal muscle mass is also of interest in healthy populations to identify sarcopenia, the loss of skeletal muscle mass and function associated with aging. The muscles of interest and the methods of quantification vary depending on the clinical purpose. When evaluating for sarcopenia, clinicians typically measure vertebral muscle [25], while ICU atrophy markers are primarily found in the quadriceps muscles [24]. Direct measurement methods include dual-energy X-ray absorptiometry, computed tomography, magnetic resonance imaging (MRI), and ultrasound technology, each with its own specific applications. The most robust of these methods is MRI, which can provide highly accurate and reliable measurements, but can be time consuming [26]. Ultrasound methods allow for skeletal muscle quantification with similar accuracies to MRI techniques and are less time-intensive [24, 27]. Both MRI and ultrasound have difficulties accurately measuring muscle volume in individuals with fibrous and fatty infiltration, and these techniques are not well-studied in pathological muscles [26].

2.4 Therapy Techniques

2.4.1 Physical Therapy

Physical therapy (PT) is the primary form of treatment following most joint reconstruction surgeries [28, 29]. Around 7 million Americans have either a hip or knee replacement as of 2015 [30], all of whom have completed some degree of PT to maintain daily abilities. PT is necessary after procedures such as total knee arthroplasty or anterior cruciate ligament reconstruction due to the significant atrophy that occurs particularly in the quadriceps and surrounding muscles [31-33]. To restore joint range of motion and leg muscle strength, patients on average attend PT sessions twice a week for 6 months, during which they perform a variety of strength and neuromuscular training programs [5]. Though limited clinical data exists related to the efficacy of PT after VML due to the condition's severity and relatively low occurrence compared to muscle atrophy, there is evidence to support positive effects of PT on muscle quality in VML recovery [34, 35]. While PT is a broad term and some treatment techniques work better than others, doctors prescribe it as the primary and most reliable method to restore muscle function to pre-injury levels.

A critical part of PT rehabilitation is the completion of home exercise programs. Adherence to these programs shows significant functional improvement in follow-up sessions [6,7]. However, physical therapists experience many barriers in patient compliance with at-home programs, resulting in approximately 50% non-adherence. In particular, the number and complexity of exercises, as well as contributing physical and psychological factors such as pain and self-efficacy, have been linked to non-adherence [6, 8]. For these reasons, devices that passively stimulate skeletal muscles have become widely used in outpatient settings.

While current methods of passive muscular therapy exist, patients find them unappealing due to their inconvenience, discomfort, or invasiveness. The types of therapy discussed in the following sections are non-invasive and work to promote muscle mass regeneration.

2.4.2 Electrical Stimulation Therapy

Electrical stimulation therapy is a well-researched treatment with high success rates when coupled with physical therapy. This type of therapy delivers a low electric current through electrodes to a specific muscle or muscle group. The stimulation causes the muscle to contract in

a manner similar to during exercise, thus deeming the treatment active rather than passive. Placement of the electrodes as well as the level of current and pattern of stimulation are important factors that allow physicians or physical therapists to customize the device for patients and their unique muscular statuses, as seen in Fig. 2.4.2. Additionally, patients can utilize different levels of electric stimulation for slightly different purposes. A transcutaneous electrical nerve stimulation (TENS) unit typically produces lower levels of current and is advantageous for pain management, while neuromuscular electrical stimulation (NMES) is efficient at strengthening muscles and preserving muscle mass [36]. Alongside these results, patients see an increase in recruitment of surrounding muscles, range of motion, and overall functionality [37]. Electrical stimulation therapy is an excellent method for treating patients with loss of muscle control due to stroke or other afflictions, repair and recovery of orthopedic injuries and/or resulting conditions, and progressive chronic illnesses that may leave the patient in a less active state resulting in low endurance or low muscle strength [37].

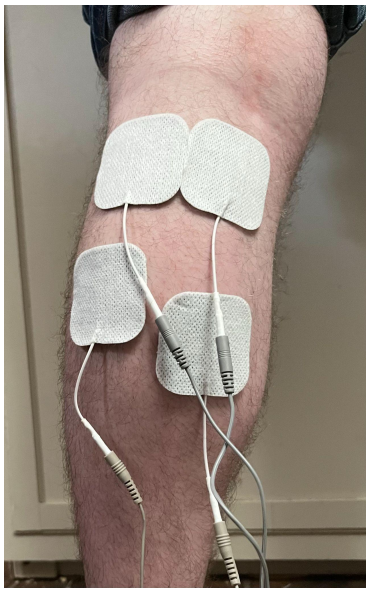


Fig. 2.4.2. Recommended electrode placement for calf muscle [38].

An advanced NMES unit designed to increase muscle strength and minimize muscle loss can carry a current of over 80 milliampere through large electrodes, approximately 10 centimeters by 13 centimeters [37]. There are many patterns the stimulations can follow such as constant, alternating, or simultaneous. Constant stimulation refers to a non-stop delivery of

current to the muscle through a single electrode. Simultaneous stimulation utilizes two or more electrodes sending current at the same time to different areas of the targeted muscle or muscle group. Alternating stimulation uses two or more electrodes allowing current one after another. The electrodes are placed in different areas of the muscle, and the alternating electrodes allow one area of the muscle to rest while the other is at work [37]. Another important factor of the stimulation is the ratio of how long the stimulation is being delivered to how long it is shut off for the muscle to rest. A typical ratio is around 1:3; that is, one unit of stimulation and three units of rest. Smaller ratios result in less rest time and fatigue the muscle much faster [37]. There are several different electrode types to minimize allergic reactions from patients and maximize the conduction of the electrical current. The most popular electrodes are self-adhesive and packaged with the appropriate gel pre-applied, followed by carbon rubber electrodes that must be taped down and use carbon as a conductor. Extra electrode gel or sponges help increase conductivity, especially when treating larger muscle groups [37].

Although NMES is well researched and proven to increase muscle strength and decrease muscle loss, there are restrictions to this method of therapy. Patients with nerve damage and loss of feeling can not decipher if the current is too strong, which could cause damage or fatigue to the muscles. In addition, irritation or even abrasions to the skin can occur from allergic reactions to the electrodes, and chemical or electrical burns can result from too high amplitudes through too small electrodes. More seriously, patients with pacemakers or other electronic implants can not use TENS or NMES units, as they will interfere with the functions of the implants and result in unpredictable shock results [9]. Finally, as this treatment causes the targeted muscles to contract, it is a physically tiring procedure, which limits its possible frequency of use.

2.4.3 Ultrasound Therapy

Therapeutic ultrasound enhances the speed of tissue repair in muscle injuries. This treatment technique uses heat generated by ultrasound waves to promote blood flow in the tissue and relax the muscles. Research on rats regarding the effects of ultrasound therapy for restoring muscle strength and mass showed improved mechanical properties after five-minute daily sessions for six continuous days. However, the study also showed that this therapy caused the treated muscles to be 38% stiffer than the control muscles, making this method of therapy less desirable for skeletal muscle [39]. Although ultrasound therapy has been clinically available for

decades, its efficacy is still heavily debated and quantitatively unclear [40]. Additionally, this treatment method must be administered by a medical professional, with treatment parameters and specifications varying widely [40, 41].

2.4.4 Compression Therapy For Blood Flow

Compression therapy is a common treatment used to reduce the symptoms of many afflictions. Compression therapy is not currently used clinically to promote skeletal muscle regeneration. Rather, pressure associated with compression therapy can manage swelling, blood clots, venous insufficiency, varicose veins, and ulcers. It also helps remove lymphatic fluid and promotes blood flow, which benefits injury and athletic recovery [42]. The increased pressure prevents veins from overfilling and back-flowing, as well as deterring fluid buildup in the area [43]. This process is shown in Fig. 2.4.3, which is adapted from Ref. [43].

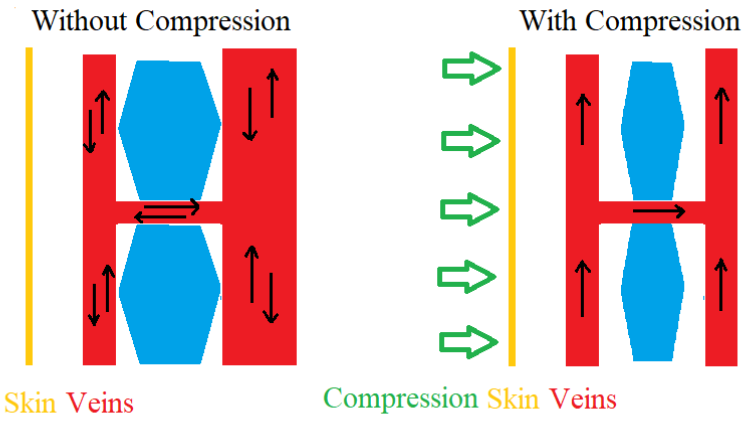


Fig. 2.4.3. Compression stocking mechanisms.

Important factors in compression therapy are the level of compression and the duration of use. There are three classifications of compression tightness: low compression, medium compression, and high compression [43]. The values associated with these classes are shown in Table 2.4.1. The variables affecting these values are the material of the compression bandage, the size or shape of the targeted muscle or muscle group, and any movement performed while wearing the bandage.

Table 2.4.1: Compression Classification

Classification	Measurement
Low Compression	< 20 mmHg
Medium Compression	20-30 mmHg
High Compression	> 30 mmHg

Compression therapy bandages contain many different materials. One classification of materials are low-elasticity bandages. These bandages have low stretch percentages, with some materials even having 0% stretch. Because of this, they are stiff, have low resting pressures, and high working pressures. These characteristics result in the need for regular bandage replacement as the pressure applied by the bandage fluctuates easily with different swelling levels. On the other hand, high-elasticity bandages can have up to 200% stretch, which results in the resting pressures being about equal to working pressures. Most patients find these bandages very uncomfortable, since there is a large amount of pressure from the bandage even while resting. Since neither low- nor high-elasticity bandages are entirely ideal, the most utilized system is a multicomponent bandage system, or a system that utilizes both high and low-elasticity bandages [43].

2.4.5 Compression Therapy For Muscle Growth

Though there is no clinical application of compression therapy for muscle growth, there is promising research in this area. A 2015 study investigated the effects of cyclic compression therapy after inducing a VML. Researchers performed the therapy through both an injection of magnetic ferrogel, which was stimulated with a magnet outside of the skin, and a pneumatic cuff that fully enveloped the injury site. Researchers concluded that cyclic compressions reduced both fibrous capsule formation around the implant and fibrosis in the injured muscle, increasing functionality of the rabbits' muscles [10]. A 2018 study investigated muscle response to cyclic compression therapy in mice after inducing muscle atrophy. This study demonstrated significant improvement in muscle recovery for the "massaged" limbs and a greater presence of SCs. Furthermore, mice who received compressive therapy in only one limb showed substantially

improved muscle recovery in their non-treated limbs compared to the control [11]. While this field of research is relatively new, available publications show highly promising results. These experiments demonstrate the potential for clinical applications of targeted, cyclic, compressive mechano-therapy to promote muscle cell regeneration after VML or muscle atrophy.

2.5 Prior Arts

The current method to treat muscle atrophy is moderate to intense aerobic exercises or physical activities 3-5 times a week for at least 30 minutes to activate the muscles and circulate blood flow. The major disadvantage of this method is that patients with reduced muscle mass can not always perform these exercises to the extent necessary to promote muscle growth until they build up the muscles needed to move sufficiently [44]. This method requires patient dedication to perform these activities each week in order to gain skeletal muscle.

To treat volumetric muscle loss, surgeons clean the patient's wound and prescribe physical therapy to build strength and functionality in the affected area. However, patients must continue the prescribed therapy exercises by themselves at home to gain back the strength and motion they once had. This method must take into account that patients need time to heal from the surgery before they start this therapy, causing them to lose additional muscle mass to that lost from the original injury [21, 45]. The goal of this project is to develop a passive method of therapy that improves muscle regeneration to minimize the difficulties and delays associated with PT. Cyclic compression is the therapeutic technique chosen for this project, the motivation for which is described in section 2.4.4.

In the current market, there are few options using cyclic compression therapy. The Normatec Compression Therapy device is a sleeve that ices a patient's extremities and cycles compressive forces through different sections, as seen in Fig. 2.5.1. Currently, the most popular model of this technology by Normatec is the lower extremity pants, but there are hip and arm attachment options as well. The coldness and cyclic rhythm of the pulsing pressure promote blood flow, increase flexibility, and reduce swelling in patients' extremities, fostering recovery after sports training or injuries. While the Normatec device is widely used especially in sports recovery scenarios, it is not explicitly designed for rehabilitation after atrophy or VML. In particular, it is not designed to be individually customized to a patients' injury, the compression area is very broad, and patients cannot carry out daily tasks or activities while wearing it [46].

Fig. 2.5.1. The Normatec Pulse therapy device in use.

A similar device is the Kendall SCD comfort sleeves. Doctors prescribe the Kendall device to patients on bed rest to increase blood flow and prevent deep vein thrombosis and pulmonary embolism. The device uses compression therapy on the leg and foot of the patient and automatically adjusts the amount of compression and cycle time based on the patient's needs by measuring the venous refill time to customize the cycles [47]. It is portable and flexible, which benefits its ease of use. However, the device is designed for use while in a bed and is not easily portable for continuing treatment during daily activities. Furthermore, though the purpose of the compression is to prevent medical complications related to poor blood flow during bed rest, not to affect muscle healing. While the Kendall SCD functions similarly in principle to the goal of this project, its portability and specificity, and design intent make it unsuitable for passive skeletal muscle mechanotherapy.

The device that has a monopoly on the NMES market is the TENS units and muscle stimulators. As discussed in section 2.4.1, the TENS units work by stimulating the muscles to relieve pain and rehabilitate the injured muscle. Many stores and online distributors offer this device because patients can learn how to use this device from their physical therapist or doctor due to its simplicity and ease of use. Since patients can carry out this therapy on their own time and at home, it allows for patients to use the machine more often; this leads to a faster recovery time compared to solely clinically administered treatments [37]. This treatment, however, is primarily useful in preventing atrophy, rather than promoting muscle synthesis after loss.

Chapter 3: Project Strategy

3.1 Initial Client Statement

The team will design a novel, effective, inexpensive, passive mechano-therapy that could be delivered through a non-invasive, wearable device to be used on patients suffering from volumetric muscle loss or muscle atrophy.

3.2 Technical Design Requirements

3.2.1 Concept Mapping

A concept map demonstrates the possible routes to solve a problem. As seen in the concept map in Fig. 3.2.1, the central problem was to find a way to regenerate skeletal muscle. Through research, the team determined that mechanical and fluid compression were two routes to achieve this. There are three mechanical compression systems that the team continued with after the brainstorming phase: the roller, piston, and reel. These three systems mechanically compress the muscles through rolling, pushing, and tightening into the muscles. For fluid compression, the team focused on hydraulics and pneumatics. These fluids distribute pressure evenly, which leads to complete compression of the muscle at once, and through a tube and sensor the pressure adjusts to obtain the required pressure. As discussed above, these five systems produce a force on the muscles to stimulate blood flow to the region and initiate muscle growth.

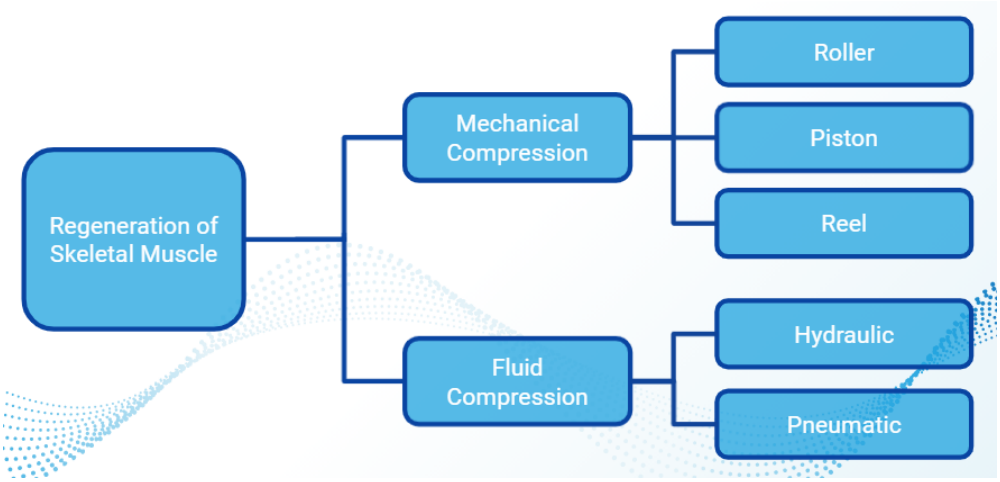


Fig. 3.2.1. Concept map diagram of initial brainstorming ideas.

3.2.2 Concept Evaluation

The initial functionalities deemed essential to the device were ease of use, limb versatility, comfort, portability, programmability, adjustability, wearability, and the ability to compress. Upon reconsideration of the scope of the project, the team decided to remove limb versatility as an essential function and chose to focus primarily on the gastrocnemius (calf) and surrounding muscles. The team chose the calf as it is a common site of muscle atrophy due to bed rest [12]. The team chose ease of use for patients that have difficulties moving around so they can use the device. Additionally, the comfort of the device is important since the patients need to wear it for a long time. Portability is to make sure patients can move around and carry on with their daily activities while wearing it. Wearability and adjustability go hand in hand to make sure the device works well for each patient's specific needs. Lastly, for the device to rebuild muscle with mechano-therapy, the device needs to be able to compress to the designated pressure.

3.3 Design Requirements Standards

The design requirements discussed in this section include determining testing methods via standards set by the International Organization for Standardization (ISO) or non-standard methods found through researching similar studies that test designs in methods not adhering to ISO standards.

3.3.1 Standard

Using the list of critical functions necessary for the device, the team researched the International Organization for Standardization's testing methods to evaluate the effectiveness of individual components. One element that is key in the design of the device is the fabric and tubing used to store the compressed air. These materials must not be irritating to the skin, and even more importantly, these materials need to withstand the amount of tension from the pressure of the air in the device. The ISO-13934-1 standard for the tensile strength of fabrics helps determine the maximum tensile strength of the fabrics and materials to ensure it is strong enough. This test measures maximum force until failure in both the warp and weft directions as well as the maximum elongation. The collected data allows the team to better understand the mechanical properties of these materials and select the best-suited material for the device [48].

Another critical function is for the device to create compression through a pneumatic system. The compression needs to be uniform throughout increasing and decreasing so the inlet volume of air is constant. The ISO standard 6953-3 refers to testing the pneumatic fluid power specifically in compressed air pressure regulators and filter-regulators. This testing is standard for compressed air pressure regulators and electro-pneumatic pressure control valves, both of which could become the source of compression in the device. This testing standard also ensures the inlet pressure for the device remains constant, as it visualizes any undershoot or overshoot and identifies any large variation in inlet pressure [49].

3.3.2 Non-standard

Though the standard testing methods cover critical functions of the device, there are features of the device that the team cannot analyze through official standards. Though some features may appear trivial to assess, it is nevertheless important to follow a validated testing method to avoid unexpected oversights. Patients use the device throughout their recovery period, which often takes a minimum of 6 months. The device must therefore maintain pressure without leakage over that period of time. A simple test of this concept is to follow the "Differential Pressure Leak Test Cycles" test from Cincinnati Test Systems [50]. In this test, the researchers fill the device to a prescribed pressure, with the input and output sealed, and a differential pressure transducer attached to both the device and a control with the same volume. The

researchers take a measurement of the difference in pressure over a set amount of time. A successful test would show no difference between the two systems.

Another critical aspect of the device that is not available in an official standard is assessing comfort. Comfort relates to both the overall comfort of wearing the device and the possibility of skin irritation over time. A simple questionnaire is sufficient to gauge users' comfort wearing the device [50]. This method is well validated, and patients can answer comfortability questions on a scale of 1-10. This comfort test is done before finishing the final product by using a non-functional model of similar weight, material, and size to help guide the details of the final product. Given the repeated inflation and deflation, as well as the possibility of movement of the device throughout the wear period, skin abrasion is also an important comfort benchmark to assess. To do so, precedence drawn from airbag testing, wherein a piece of porcine skin is laid flat, and the airbag material is propelled across the surface at a known velocity to measure possible abrasions [51]. The team can perform a similar test with the chosen device material. Though forces will be nowhere near that of an airbag, the team can adjust the test to more realistic values and provide a wide tolerance range.

3.4 Revised Client Statement

After going over the design requirements and deciding what aspects are the most important, the team decided on this revised client statement:

Develop a novel, effective, inexpensive, passive mechano-therapy that can be delivered through a non-invasive wearable device for patients with skeletal muscle loss through trauma or atrophy. The device should be able to treat skeletal muscle damage on the gastrocnemius without limiting the mobility of the client.

Chapter 4: Design Process

4.1 Needs Analysis

Using the client statement mentioned in Section 3.4 the team was able to generate a list of criteria in order to better understand the needs for the device. As opposed to similar products currently available, this device should not limit the mobility of the patient, while also being lightweight and inexpensive. After brainstorming and discussion, the team decided on a list of eight criteria that will fulfill the desired device's needs. Each team member then gave the individual criteria a score between 1 and 5 based on how they ranked its importance, with 1 being the lowest importance and 5 being the most important. The group took the average for each criteria and used it in the weighting during the selection process of designs. Table 4.1.1 below displays each of the final eight criteria and their corresponding weighting.

Table 4.1.1. Weighted Criteria for Device Needs

	Criteria	**Weight**
Needs	Ease of Use	1.8
	Programmable	4.4
	Adjustable	4.6
	Compressive (at least 100mmHg)	5.0
	Wearability	5.0
Wants	Comfort	3.8
	Portable	3.9
	Limb Versatility	3.2

4.1.1 Means Table Analysis

A means table is a visual of the functions that the designed device should carry out with four means to achieve each one. The functions listed in Table 4.1.2 are not in any order of importance. The first function is to secure the device to the site of the injury by using Velcro,

buckles, bands, or a non-slip sleeve. All of these means work well with any body shape, since there is no restriction to a single length. Function two is to compress the skeletal muscle. To achieve this, the device can utilize a pneumatic system, air compressor, strong compressive material, or a manual pump. These means can pump air into the device to tighten around the muscle and cause compression. The third function is biocompatibility by making the device hypoallergenic, non-irritating, soft, or non-invasive. Biocompatibility is important as it ensures that the device will not initiate an immune response when patients wear it. The next function is maintaining pneumatic volume by using an air pump, high tensile strength tubing, sealed material, or a valve system. Making sure the device can hold air is critical, because if not, it will not fill up the material or compress the muscle. The final functionality is the ability to control pressure, which incorporates the use of a programmable system, pressure sensors, real-time adjustability, or a fine adjustment reel. If the pressure output by the device can not change, the device may not provide adequate stimulation to induce skeletal muscle growth. Table 4.1.2 helps to guide the design process by organizing the means by which important functions can occur.

Table 4.1.2. Functions and Means of Achievement

Functions	**Means**			
Secures to Injury Site	Velcro	Buckles	Bands	Non-slip Sleeve
Compresses Muscle	Pneumatic System	Compressor	Strong Compressive Material	Manual Pump
Biocompatible	Hypoallergenic	Non-irritating	Soft	Non-invasive
Maintain Pneumatic Volume	Air Pump	High Tensile Strength Tubing	Sealed Material	Valve System
Pressure Control	Programmable System	Pressure Sensors	Real-time Adjustability	Fine-Adjustment Reel

4.2 Conceptualizations, Prototyping, and Feasibility

During initial brainstorming, the most important factors were the ability of the device to compress and be worn by a variety of patients. The design systems that stood out during the brainstorming sessions were the roller, piston, reel, hydraulic, pneumatic, and mechanical systems.

4.2.1 Roller Compression System

The first design idea is a neoprene non-slip sleeve with massage rollers integrated in between the fabric. These rollers are programmable and customizable to allow for a wide variety of treatment/massage options. The rollers are on a vertical track system allowing the rollers to travel the length of the muscle fibers providing compression in the form of a kneading massage.

This roller system allows for various massage patterns and customizability in the form of treatment. The neoprene sleeve prevents any slipping of the sleeve at the site of the injury, allowing the rollers to consistently work on any damaged muscle. The compressive roller sleeve design is wearable and portable, allowing clients treatment anywhere and at any time. Although this design allows for comfort, effectiveness, and the variety of provable treatments, this roller design also has flaws. The rollers moving along a track system causes muscle displacement in that the roller pushes one side of the muscle, but there would not be an equal force pushing on the opposite side of the muscle, therefore creating uneven pressure and thus inconsistent compression. This would impact the effectiveness of the device in its primary function of stimulating muscle regeneration. This design also does not provide the versatility desired for the device, since it is not able to be utilized on any limb and does not allow for use at any point of injury recovery. The muscle surface area covered by the rollers varies based on the part of the body that needs treatment. For example, if the patient wears the device on his quadriceps, the rollers spread farther apart than if they were used on the arm, where rollers would gather closer together. Although a comfortable and customizable option, the massage roller system proved to be less functional and effective than other designs.

4.2.2 Piston Compression System

The second concept was a piston-driven compression system. Fig. 4.2.1 illustrates the design concept.

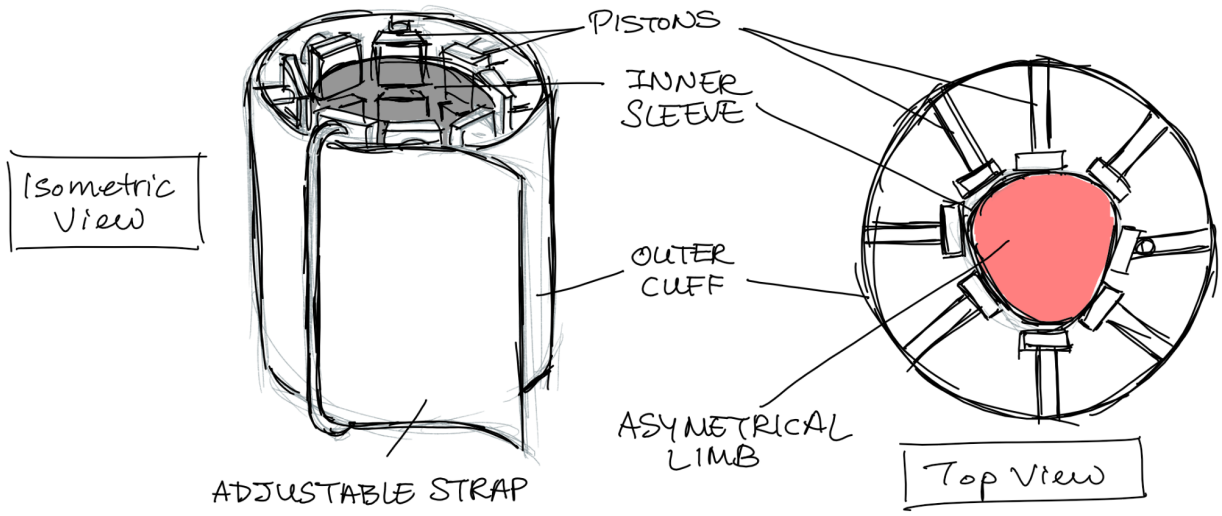


Fig. 4.2.1. Isometric (left) and top (right) view of the piston-driven design concept for muscular compression.

The piston-driven compression system involves using several mechanical pistons attached to a cuff. The pistons detach to allow for an overlap on the cuff, which attaches to itself via Velcro, providing size customizability. An inner sleeve provides a barrier between the limb and the piston system, not only protecting the mechanism, but also increasing comfort and a more even pressure distribution for the client. An outer cuff is made of a pliable material with low elasticity, allowing the user to wrap the cuff around their limb while still providing the pistons with enough rigidity to apply pressure to the muscle.

On the face of each piston, a pressure sensor detects the local pressure; the system receives the pressure reading as an input for each piston on the system. Using this feedback, pistons extend or retract to different lengths, allowing each piston to apply uniform pressure even if the limb cross-section is asymmetrical or a different size than that of other users.

While this system exhibits great customizability, team brainstorming developed various drawbacks that make the piston system unideal. While patients can remove the pistons, the spacing between pistons is still finite. As a result, nodes of spacing between pistons do not provide complete compression of the entire surface area and may even pose a threat to catching skin or tissue between pistons. Compared to other concepts explored, it is highly probable this design would also be heavier than other options to operate the mechanism, limiting the wearability and comfort of the device.

4.2.3 Reel System

The third concept design is the reel system, which involves a padded sleeve that constricts the limb by twisting a reel to tighten a network of strings, as seen in Fig. 4.2.2.

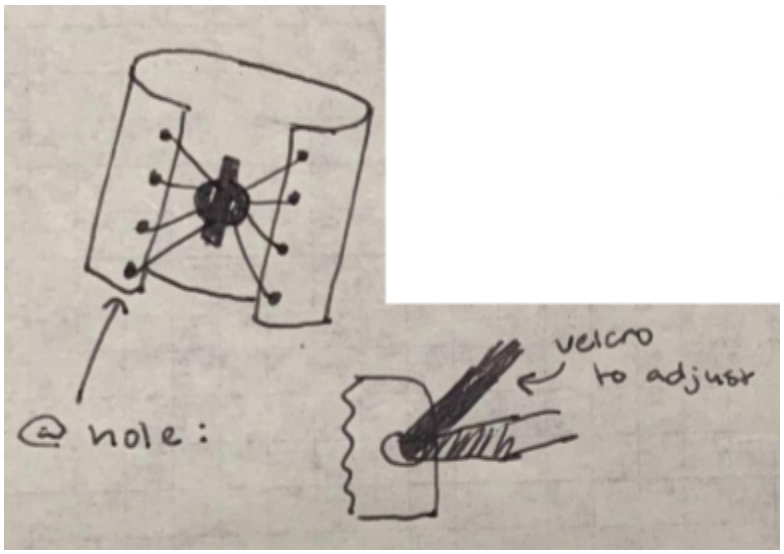


Fig. 4.2.2. Brainstorm drawing of the reel system.

A timer set to pre-designated intervals tightens and relaxes the reel periodically to provide cyclic compression. Additionally, this design has a sleeve on the inside to protect the skin from the twisting motion of the reel and the friction from the strings.

Benefits of this design include incorporating a Velcro strap, strings, and pads. The Velcro strap holds the design at a user-secured pressure to keep the device on the muscle comfortably before tightening the strings. With the Velcro and the reel for the strings, patients can adjust the device to fit around any muscle and control the compression to apply specific pressure levels based on their unique needs.

Downsides to the design also deem this concept unideal. Firstly, the point where the reel sits on the patient's extremity experiences more pressure than other points on the sleeve. This does not guarantee uniform compression. Next, it is unclear how comfortable the design is where the reel and strings are due to the plastic reel and the twisting motion. Since there are more pitfalls with this design, the team decided to pursue a different device.

4.2.4 Hydraulic System

The next design involves hydraulics, using water and a pressure difference to provide cyclic compression. A patient uses the device while sitting on a chair or lying in a bed. An inflatable cuff resembling a blood pressure cuff uses Velcro to tighten around the patient's affected limb. A tube coming from this cuff attached to a bag filled with water connects to a large post that has the mechanics to move the bag up and down the post. Figure 4.2.3 shows the mechanisms of the device.

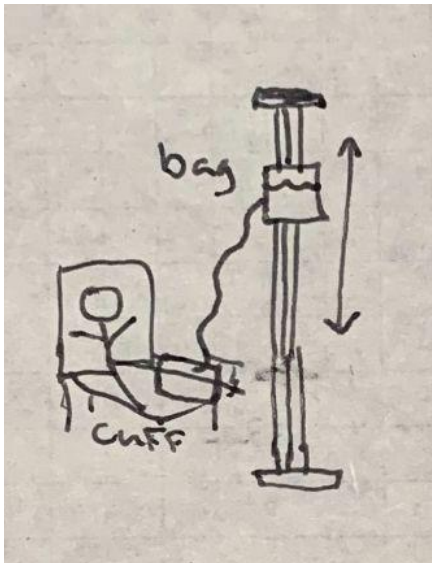


Fig. 4.2.3. Brainstorm drawing of the hydraulic system.

This change in position creates a pressure difference; when the bag is higher than the cuff, water will feed down the tube into the cuff, and when the bag is lower, the water will drain back out. This design allows for a personalized treatment as the bag movement and speed are adjustable. It also allows for hot or cold therapy with different temperature water used in the insulated bag. The cuff adjusts to any limb and works for patients of different sizes. Some drawbacks to this design are that the device restricts the patient's mobility during use. Additionally, if the patient pierces or jams the bag, tube, or cuff, the device does not work. Finally, this device would not be comfortable enough for patients to use for an extended period of time.

4.2.5 Modular Pneumatic System

The modular pneumatic system features two components that serve the device's compressive and customization capabilities. This device consists of a plastic, inflatable cuff that secures to the affected limb akin to a blood pressure monitor and an air generating mechanism, which generates pneumatic pressure in the cuff through an input valve. Air inflates the device to the desired pressure, determined by selective pressure sensors in the lining of the cuff, and releases it through a separate valve on the cuff to perform the desired cyclic therapy. Taking advantage of the input and output valves on the cuff, the device can have multiple modules of varying lengths. Each module connects to the next through the valves, propagating the airflow and maintaining an even pressure between modules, as seen in Fig. 4.2.4.

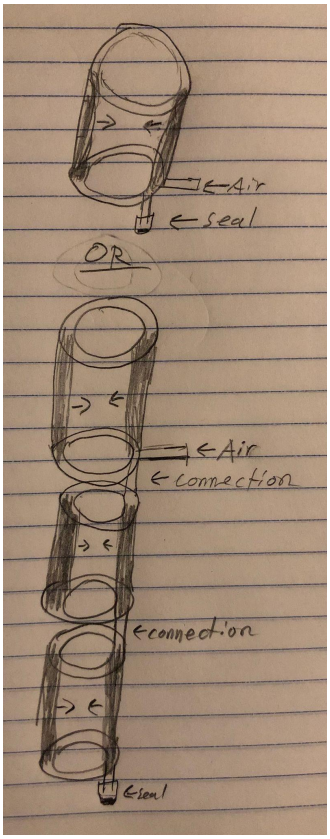


Fig. 4.2.4. Brainstorm drawing of modular pneumatic system.

The selection of cuff lengths allows for the client to create a compressive tool that fits the length of the affected limb. For example, a client who is recovering from reconstructive knee surgery may experience atrophy in both their calf and thigh muscles. A single large sleeve may

suffice to properly cover the calf muscle, but an additional module may be needed to span the length of the thigh and effectively treat the quadriceps. While the connection system provides an important level of customizability, the mechanism may cause slight gaps along the length of the treatment area.

4.2.6 Rack and Pinion System

The team expects mechanical systems to have finer control of compressive strength as well as greater long-term durability. In addition to not being subject to puncture, a mechanical system involves distinct parts. This allows interchangeability, making the mechanism system easier to fix and maintain if parts of the system fail.

To execute mechanical compression, the team chose to implement a stepper motor. This motor allows for controlled rotation to specific angles, making this motor advantageous for finer compressive control. This design utilizes a stepper motor as a pinion to use rotational movement to translate a toothed rack that pushes a hard plate into and out of the muscle. A rack and pinion system allows the motor to be perpendicular to the translating movement of the rack. A stationary track system mounted on the frame directs the rack to ensure the movement is uniaxial, and the motor remains static. The basics of this design are shown in Fig. 4.2.5.

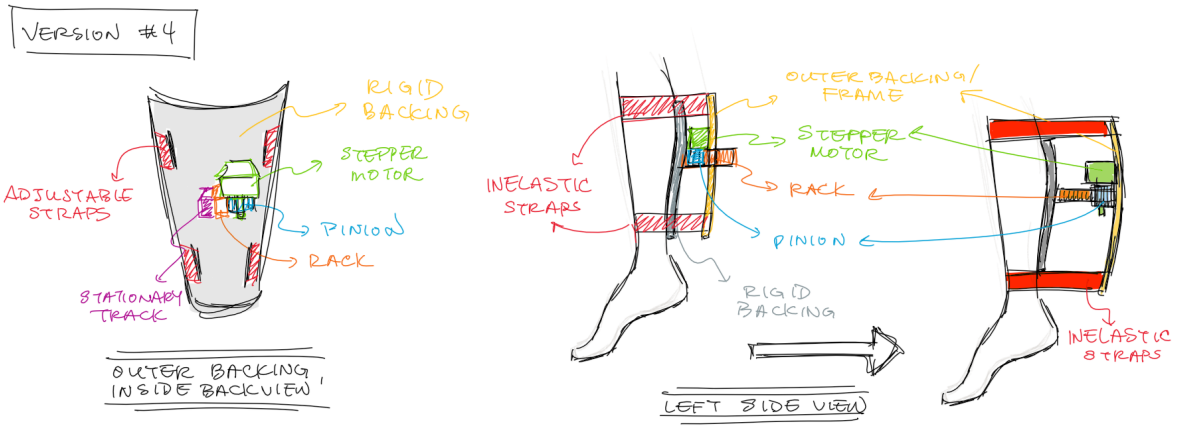


Fig. 4.2.5. Rack and Pinion design using stepper motor.

This design involves a hard plate to distribute the compressive force across a larger area. The plate directs the compression to a specific muscle, causing only specific parts of the leg to receive compression therapy. This design also utilizes a frame to level mechanical forces and

straps to mount the frame to the extremity as well as customizes the fit to prevent distal or proximal movement of the system along the limb.

This version involves a direct translation of the motor's rotational movement to the linear translation necessary to execute compression. However, this system requires the stepper motor to translate in synchrony with the translating rack, making it difficult to support or mount to the system properly, which prevents the motor itself from rotating. To improve this mechanical system of compression the team designed a new system that used a central gear rotating on a motor, driving two other gears that are attached to threaded flanges and causing lead screws to translate through the outer gears. This "screw system" can be seen in more detail in section 4.3.3.

4.2.7 Pugh Decision Matrix

Using a scale from 1-5, where one is the least important and five is the most important to the project, the team rated each functionality as an average of each team member's ranking. Ease of use ranked 1.8/5 because although it is important for a patient to put the device on easily, this is a process that the patient can learn. Limb versatility ranked 3.5/5 because the device should function on either a leg or an arm, accomplished by producing different sizes of the device. Comfort ranked 3.8/5 as patients need to wear the device for long durations of time, especially for patients with high amounts of atrophy or VML. A large advantage to any medical device is the patient's ability to perform their day-to-day activities while receiving treatment; because of this, portability ranked 3.9/5. Programmability ranked 4.4/5 as compressive pressure, as well as timing intervals, may need to vary for each patient. Adjustability ranked 4.6/5 since the device must fit on different patients' muscles. Wearability and the ability to compress both ranked 5/5 because these are essential to the viability of the device and the client statement.

A Pugh Analysis helped the team evaluate these functionalities and their ranks, shown in Table 4.2.1, to determine which design objectively meets the needs of the device. Each member of the team ranked the device's ability to complete the criteria on a scale of -1, 0, or 1; with -1 meaning it is not met, 0 meaning it is just barely met, and 1 meaning it is easily met.

Table 4.2.1. Pugh Selection Matrix of Brainstormed Ideas

Criteria	Weight	Piston Mech.	Water ΔP	Reel System	Massage Roller	Modular Pneumatic	Rack and Pinion
Ease of Use	1.8	0	-1	1	0	0	0
Limb Versatility	3.2	-1	1	1	0	1	0
Comfort	3.8	-1	0	-1	1	1	1
Portable	3.9	0	-1	1	0	1	0
Programmable	4.4	1	0	0	0	1	1
Adjustable	4.6	-1	1	1	0	1	1
Wearability	5.0	-1	-1	1	-1	1	0
Compressive	5.0	0	0	0	0	1	1
	Score:	**-12**	**-3.0**	**16**	**-1.0**	**28**	**18**

Next, the value in the resultant cell was multiplied by the weighted criteria column of that row and added together the total score for each device. The Pugh Analysis objectively shows that the pneumatic device best meets the needs of the device determined from the client statement, with the mechanical rack and pinion design as a close second. These designs were prioritized moving forward in the design process. Second iterations of these concepts were also designed, highlighted in section 4.3.

4.3 Final Designs

Early brainstorm ideas were weighed in a Pugh Selection Matrix which allowed the team to decide which designs were the most beneficial to move forward with. These ideas led to second iterations which were selected to be final designs that went through the testing phases.

4.3.1 Pneumatic Cuff System

This section describes the pneumatic cuff system including the pump, cuff design, code, and accessories.

4.3.1.1 Programmable Air

For the pump system, the team decided to take advantage of an open-source hardware kit called Programmable Air, developed by Amitabh Shrivastava [52]. This kit is typically utilized for soft-robotics projects as it is Arduino-based, however, the team saw the potential in using it to deliver cyclic compression. The components of the built kit are shown in Fig. 4.3.1.

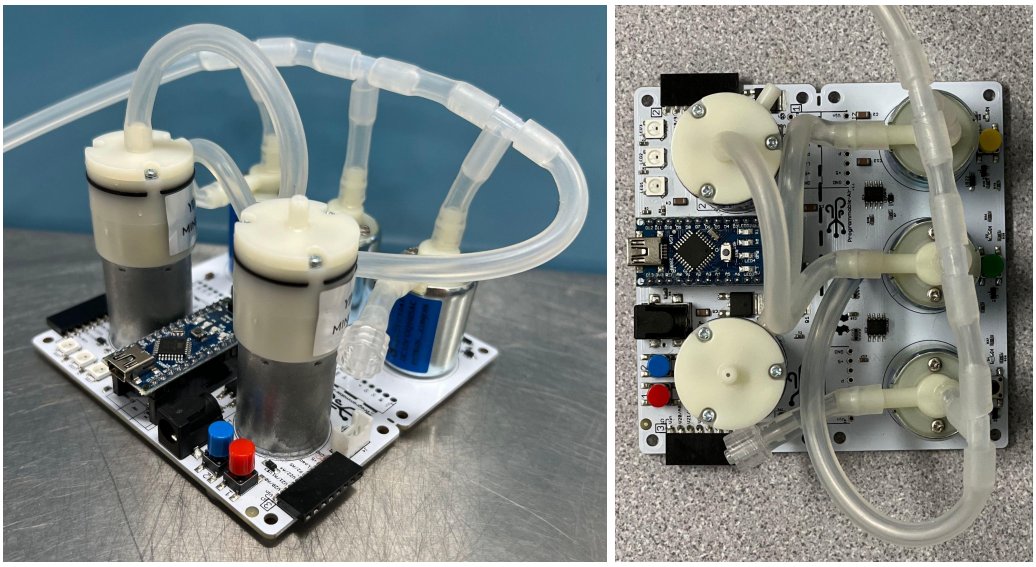


Fig. 4.3.1. Programmable Air device used to power pneumatic systems.

The Programmable Air kit utilizes two compressor/vacuum pumps and three pneumatic valves to accomplish inflating and deflating abilities. Arduino Nano allows for programming abilities, which the team utilized to code the device to deliver cyclic compression, put into more detail below. A pressure sensor is an important feature for the device to give readings on the amount of pressure the device is receiving. Since compression treatment for muscle atrophy and VML requires a specific pressure, and higher pressures are dangerous to the user, this feature is a key part of the device design. Other aspects of the Programmable Air include a power source, LEDs as indicators, user buttons for manual control, and an expansion port to connect multiple devices together.

4.3.1.2 Cuff Design

This design consists of an inflatable bladder, which rests inside a cuff that wraps around the limb, adjustable by Velcro strapping, with pneumatic tubing to fill the cuff with air. A control system will allow the inputs for the electrical components of the device. The Programmable Air set-up will connect to the pneumatic tubing and provide the means for inflating and deflating the cuff. A schematic of the design is shown in Fig. 4.3.2. This design differs from a standard blood pressure cuff in the size of the bladder, the length of the cuff, and the ability to provide cyclic compression.

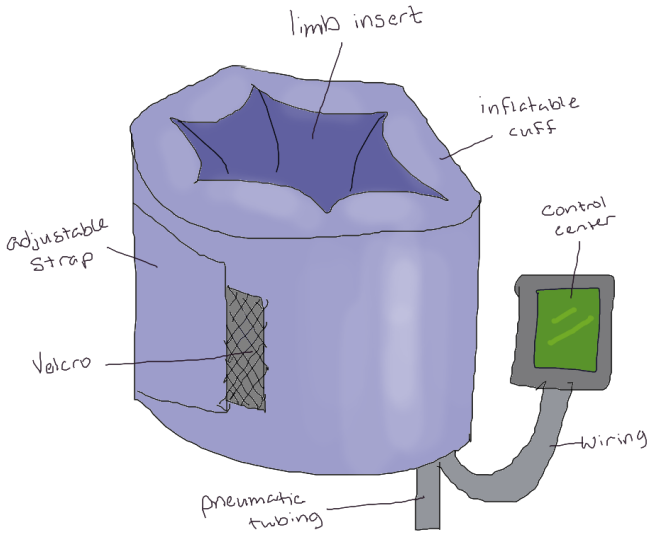


Fig. 4.3.2. Cuff design schematic sketch.

For the cuff design, it is necessary to choose a material that can hold the bladder, resist the outward force from the inflating air, and can adjust to the patient's limb. The material used for commercial blood pressure cuffs is nylon since it is strong, sewable, and will not stretch with outwards pressure. This section is sewn by attaching two pieces of nylon fabric, about one foot by two feet each, around both short ends and one long end. The remaining long end is reserved to sew Velcro in order to allow for the opening and closing of the nylon pouch. Additionally, a Velcro strapping system can attach to the nylon by sewing it on, allowing for a more personalized fit to the patient's body. The Velcro mechanism integrated into this design includes six thin Velcro straps to allow the user to pull the top, middle, and bottom sections of the cuff flush against the muscle. Each strap has soft Velcro on the outward facing surface as well,

allowing the straps to overlap if necessary. This is especially helpful in muscles with a large taper, such as the calves, which is demonstrated in Fig. 4.3.3a.

The bladder material must be durable, sealable, and non-elastic. The bladder size and insertion are shown in Fig. 4.3.3b. A bladder pocket can be sewn into the main figure by sewing two vertical lines that outline the bladder. A material suited for the bladder design is PVC sheets. These sheets are durable and do not stretch when the bladder is inflated. Additionally, the sheets seal together well with a heat; this is particularly advantageous for creating bladders of different sizes and treatment techniques. The process followed for the scope of this project included using a small iron to melt the edges of the plastic bladder together as well as using hot glue as an extra measure to prevent air leakage during bladder-tubing interfaces.

A programmable air pump connected to an Arduino controls the inflation of the bladder. Through programming the pump in response to a pressure sensor on the Arduino, the pump can inflate to a specific pressure and deflate accordingly within the desired cycle.

Fig. 4.3.3a. Cuff design highlighting overlap of Velcro strap mechanism for tapered muscles.

Fig. 4.3.3b. Cuff design highlighting bladder that inserts into the sleeve.

The following process flow diagram, shown in Fig. 4.3.4, illustrates the steps needed to use the device. First the user must use the Velcro straps to attach the cuff flush to the affected limb. If more than one cuff is needed to apply treatment, such as in an instance where the user needs one cuff for the calf and one cuff for the thigh, any additional cuffs should be attached and connected using the modular tubing mechanism. Then the electronic inputs are selected with the handheld controller. These inputs determine the cycle rate, pressure, compression duration, and treatment duration. With these inputs, the device will push air into the bladder of the cuff, inflating to the determined pressure and remaining in the bladder for the determined duration. Next, the air will be vacuumed out of the cuff, with the speed of which fulfilling the determined cycle rate. If the unit is set to continue, it will repeat these two steps until the desired treatment duration is reached. If the user does not want to continue, or if the treatment is finished, the user will disconnect any modular tubing and un-Velcro the device from the limb. The treatment is finished, and the device is ready to be put away.

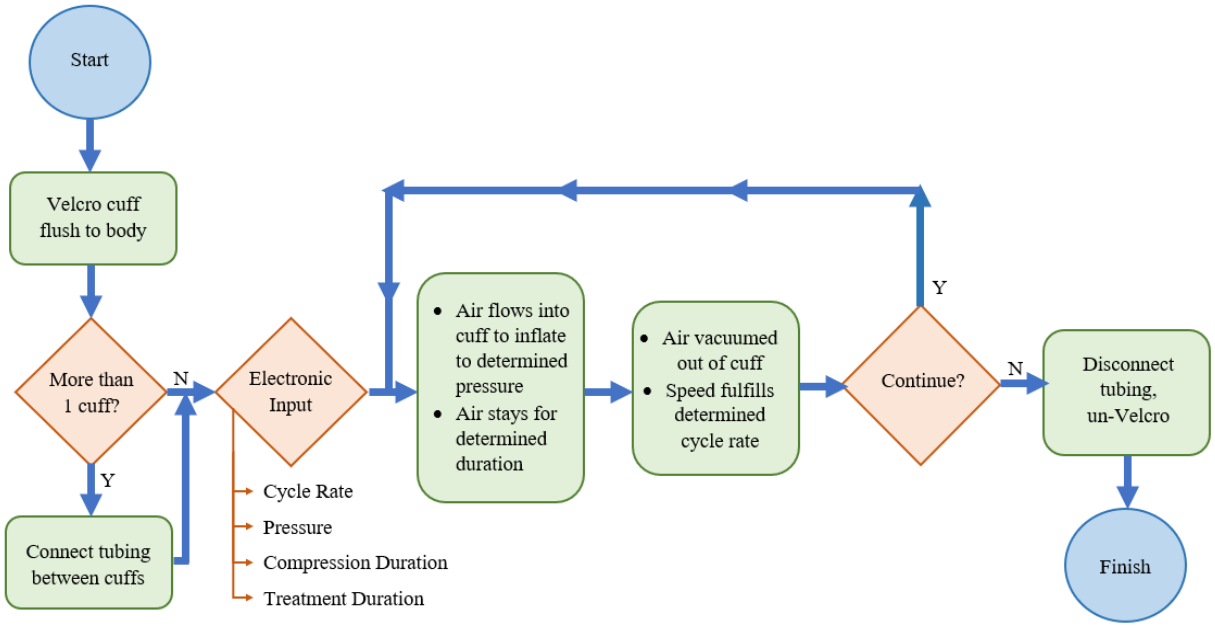


Fig. 4.3.4. Process flow diagram explaining the mechanisms of the cuff device in use.

4.3.1.3 Code

The control system for the Programmable Air pump was coded and implemented via Arduino Nano. Though the final, marketable product will allow the prescriber to control the treatment parameters prior to patient use, the method by which they will be inputted to the device is not yet clear. For example, direct Arduino control is plausible, but a more user-friendly, physical interface or a separate app are also reasonable methods. Regardless, to simulate the customizable parameters in the prototype, a user-input setup stage was implemented. Using the Arduino serial monitor, default options for maximum pressure, minimum pressure, inflation, and deflation intervals are displayed. The user is able to accept or modify these parameters within the serial monitor. The final parameters are then used throughout the rest of the code.

Once the treatment parameters are set (i.e., the setup function is completed), the Arduino enters a loop function. This loop function uses a case structure with three possible states: a waiting state, a pumping state, and a vacuuming state. A series of flags and "if" statements control movement between the cases, which each cause a different pumping action. The nature of an Arduino loop function is to repeat indefinitely, so a counter is used to indicate when the desired number of cycles has been reached and end the treatment process. The general structure of the system is shown in Fig. 4.3.5. To initiate the treatment in the prototype model, the user presses the blue button on the Programmable Air system (see Fig. 4.3.1). To stop the treatment at any point in the cycle, the user can press the red button on the Programmable Air system (see Fig. 4.3.1), which will ensure the cuff is deflated and set the state back to the initial waiting state. See Appendix C.1 for the complete script.

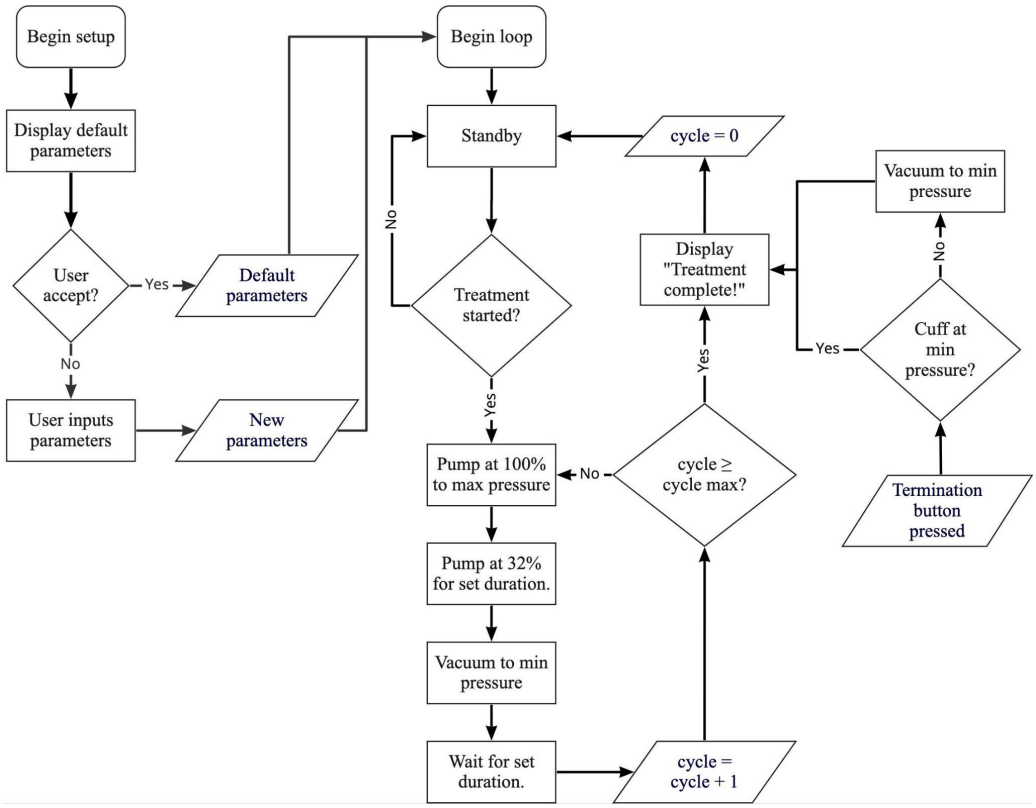


Fig. 4.3.5. Descriptive flowchart of the code for the pneumatic models.

4.3.1.4 Accessories

A Computer-Aided Design (CAD) casting was created and 3-D printed in PLA to hold the Programmable Air set-up. The design intentions include a low level of sound-proofing the compressors, as well as protection and aiding in ease of use. The less the user has to interact with the Arduino Nano and related mechanisms of the Programmable Air, the easier it will be for average users. Instead, there will be controls outside of the PLA encasing that the user will interact with. This case design is shown in Fig. 4.3.6.

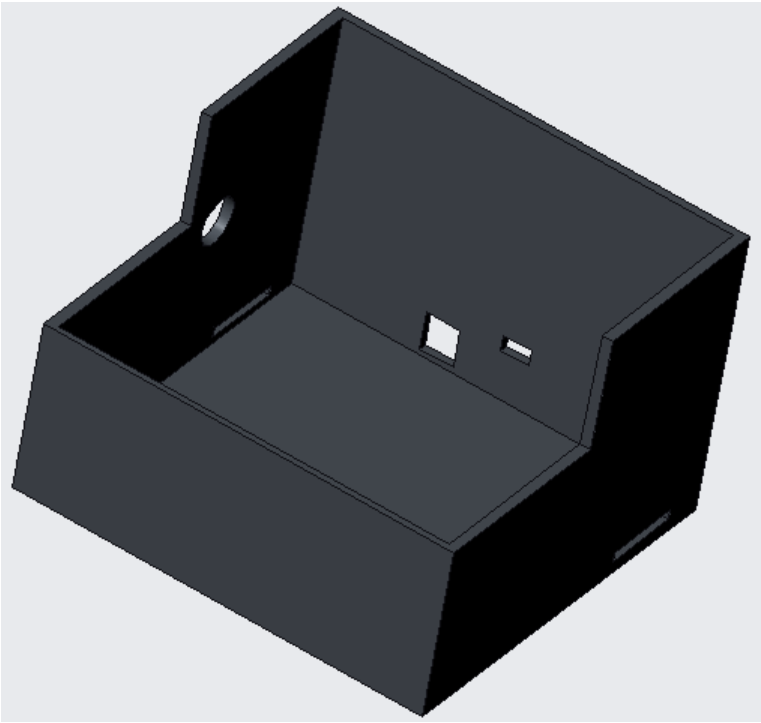


Fig. 4.3.6. Isometric view of the casing model in CAD software.

In addition, the user needs a way to hold this PLA casing on their person without being inhibited in day-to-day activity. For this purpose, a fanny pack or belt bag will be utilized. This will allow the Programmable Air set-up to remain close to the cuff without being a significant load to the user.

4.3.2 Pneumatic Backing System

The designing of the pneumatic cuff system led to a second iteration of this system utilizing a hard backing rather than an inelastic cuff. The idea was that this plate would save energy and prevent more wasted airflow than with the cuff.

Fig. 4.3.7. Preliminary prototype of pneumatic system with backing.

The initial rendition of the pneumatic system with a hard backing uses the calf section of an ankle Aircast as the needed hard backing and Velcro to secure it to the muscle. The PVC bladder was designed to fit the shape of both the calf and the hard backing and was then heat sealed closed. By customizing the bladder shape rather than using a generic rectangle, the device is better suited to the gastrocnemius muscle. This system functions identically to the pneumatic cuff system in how the Programmable Air controls the inflation and deflation of the bladder with Arduino code and a connecting hose. As can be seen in Fig. 4.3.7, the backing is a similar shape to the calf for a comfortable feel, increasing wearability and allowing for movement. This allows treatment to occur seamlessly and not impede on the patients' daily tasks. This system also differs from the cuff system above in how it contains a hard backing. The hard backing is a rigid element that contains the inflation of the bladder and directs it towards the muscle. It also allows the bladder to fill faster and therefore creates an opportunity for more cycles to occur in the same amount of time.

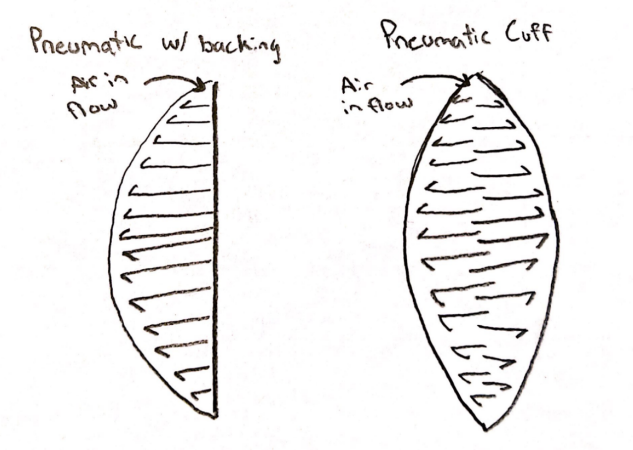


Fig. 4.3.8. Diagram displaying the effects of a hard backing vs the cuff securement system. The hard backing helps direct the compression more towards the gastrocnemius muscle specifically and the hard backing reduces the time needed to reach desired compression allowing for more cycles and more cycle variance.

A second iteration of this device was built with better material use in mind, shown in Fig. 4.3.8. The materials necessary to build this device are a backing, frame, and bladder. The bladder has the same material as the pneumatic with cuff system due to the PVC sheets achieving the requirements of the bladder material. The shaped bladder is formed in a similar method as mentioned earlier, by cutting the PVC shapes to size and heat sealing the edges with a flat iron.

The material for the backing needs to be rigid to stop the outwards force of the bladder, but it also needs to be flexible and adjustable to adapt to each patient. Acrylic works well as it is flexible to hold the muscle better but it is strong enough to provide the necessary support for stabilization. The quarter inch acrylic was cut to shape using a jigsaw, and then bent to fit the contour of the calf using a heat gun. By heating the acrylic and using clamps and straps to hold it in shape, the acrylic bends to the desired curve as it cools.

To fill the bladder, the pump used in the pneumatic cuff system is also used for this system due to the ability to inflate to a desired pressure.

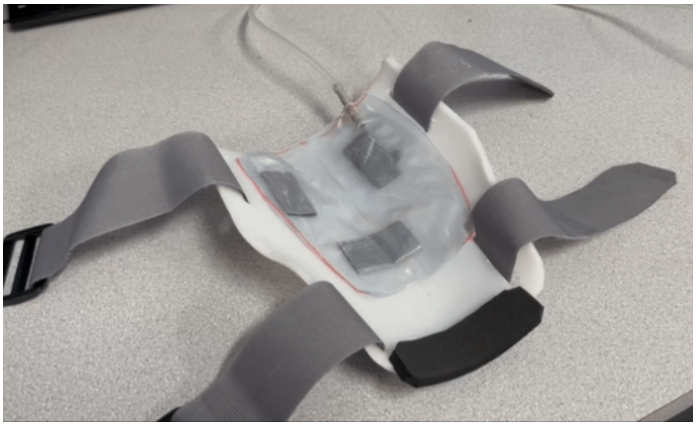
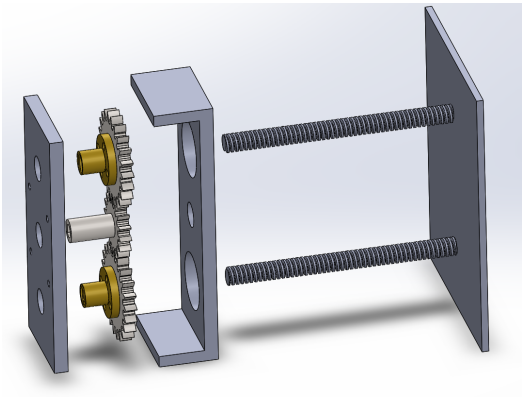


Fig. 4.3.9. Final prototype of pneumatic system with backing.

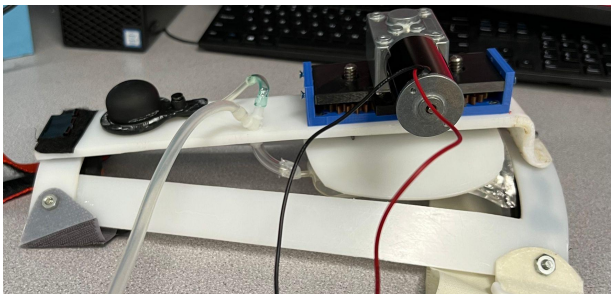
4.3.3 Mechanical System

The mechanical system is a derivation of the rack and pinion mechanical system described in Fig. 4.2.7 and is considered a second iteration of this concept. Similar to the rack and pinion system, the mechanical system uses a motor and translates rotational motion to linear motion to compress the customizable back plate.

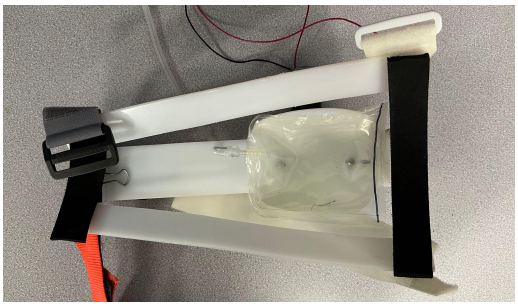
In contrast to the rack and pinion system, the mechanical system offers two-point loading on the back plate, which distributes the force more evenly across the extremity and prevents the need for a higher, single point force. This is a more adaptable design, as the single point force used in the rack and pinion may not provide even pressure across varying backplate sizes. The mechanical system also provides greater creative control than the pneumatic systems; the ratio of gear diameters and number of teeth can be manipulated for speed, rotational precision, torque, and much more. The overall system is shown in Fig. 4.3.10a.



(a)



(b)



(c)

Fig. 4.3.10. Design drawing of mechanical system, where gears translate rotational movement of a motor to linear movement of lead screw. (a) Exploded view of components involved in the gear system. (b) Side view of assembled mechanical system prototype with 3D printed parts. (c) Inner view of mechanical system with air cushion.

The initial design involved distributed pressure sensors throughout the customizable backing to detect when the desired compression level is achieved. However, due to the large surface area over which the pressure was distributed, the pressure sensors proved unsuitable for this application and were unable to detect the pressure. It was initially assembled with a stepper motor for finer rotational control. However, the stepper motors used in preliminary prototypes did not supply enough torque to overcome the resiliency of the calf muscle, and a high-torque DC motor still provides effective and accurate compression. Therefore, the system implemented a BRINGSMART 12V 160rpm DC worm gear motor (70 kg*cm) in place of the stepper motor, and an air cushion was used in place of the pressure sensor.

The bladder attached to the inner surface of the customizable backing acts primarily as a pressure feedback system, as well as an air cushion for comfort and better fit to the limb. An initial volume is achieved through a small button pump, as shown in Fig. 4.3.10b, and the bladder can best be seen in Fig. 4.3.10c. Snug-fitting tubing attaches the bladder to an air pressure reader integrated into the same Arduino circuit used to control the DC motor driving this mechanism, which allows the bladder to function as a pressure sensor. This air pressure reader is used to detect and tare the initial pressure after inflation, and changes in this pressure due to compression are read by the Arduino, which then used to start and stop cycles at the desired level of compression.

The major advantage of this mechanical system is the utilization of screws instead of a rack and pinion. The screws use threads to apply a linear force onto the backing with a rotation movement about its central axis using a lead screw and flange nut system. In the rack and pinion system, a disadvantage of the system was the potential counter-force applied by the muscle's resilience creating a counter-torque that must be overcome by the motor's holding torque. However, this counter force would be applied along the axis of rotation in the screw system, eliminating the need for holding torque and requiring little to no power from the motor to hold compression against a muscle. The functional components of this system are illustrated in Fig. 4.3.11.

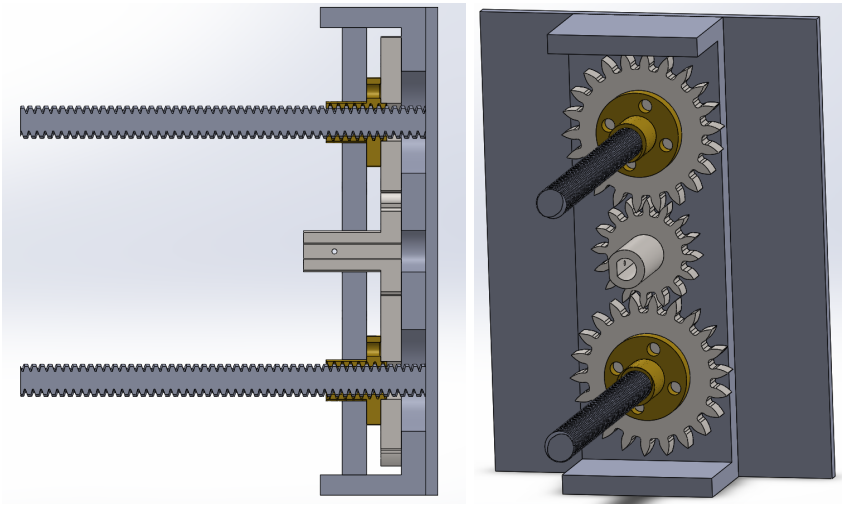


Fig. 4.3.11. SolidWorks model of gear system closely resembling the functional components of the physical prototype. The left image shows a midway section view to illustrate the screw mechanism. The right image shows the model with the backplate removed to show the gear connection.

The frame of the mechanical system was molded using 0.25” acrylic. The outer frame is a 14”x9” rectangle of acrylic (with 1” of width around the entirety of the frame) that was heat molded using a heat gun to provide the desired contour of the gastrocnemius muscle and surrounding limb. Velcro straps were then attached using a small machine nut and bolt in the corners of the rectangular frame. A “rib” was attached across the middle of the back of the frame to hold the screw compression system. Two 0.5” holes were later put into the “rib” to provide spots for the lead screw to translate through. To gain a better visual of the frame of the mechanical screw system view figure 4.3.10.b. The screw compression system was built around two 100 mm high power lead screws and precision ACME flanges with 2 mm of travel per turn. The remainder of the gearbox was created using 3D printed parts designed on SolidWorks, all printed with an infill density of 40% to ensure they could tolerate the stresses applied to the system. The gears were designed with an outer to inner gear ratio of 22:16 to maximize teeth within the desired diameter. The outer gears then had the flanges embedded in them and secured by the four hole screw pattern on the flanges so that the gear rotated the flange as well. The central gear was attached directly to the motor shaft and secured by a set screw to keep it in place. The outer gears, with flanges attached, were lined up with the corresponding holes in the printed casing and the rib on the back of the device frame. An assembly of the gearbox can be seen in figure 4.3.11. The compression plate driven by the lead screws was attached by machining slots into the lead screws and cutting vertical slots in the backing for the lead screws to sit in. The lead screws were then held in place by using a set screw into a machined hole at the end of the lead screw. The two halves of the casing of the gearbox were secured using four 0.5” machine screws.

4.3.3.1 Arduino circuit and code.

Unlike the Programmable Air system that came with all of the necessary functionalities for the pneumatic systems included, a new Arduino circuit was created to operate the mechanical system. In addition to the Arduino Uno microcontroller, the control system utilized four components: An Adafruit MPRLS Ported Pressure Sensor Breakout for reading feedback pressure, an L298N Dual H Bridge motor driver for transmitting speed, directional control, and power to the DC motor, and two pushbuttons for start, stop, and rewind control. Each component was integrated according to its setup guide. The pressure sensor was wired to ground, 5V, the

SLC port to the A5 pin on the Arduino, and the SDA port to the A4 Arduino pin. The start and stop pushbuttons were powered with 5V and wired through ground and a 10kΩ resistor then into Arduino digital pins 8 and 9. A 12V battery pack was connected to the Arduino ground and the motor driver 12V input power supply. The motor driver Enable A, Input 1, and Input 2 pins were wired into the Arduino digital 3, 2, and 4 pins, respectively. The driver connected to the Arduino 5V and ground pins. Lastly, the Vcc and ground of the DC motor were wired to the driver outputs 1 and 2, respectively. An enclosure was 3D printed to hold the Arduino Uno, a mini breadboard with sensor and buttons on top, and the L298N motor driver. Holes were made to accommodate the necessary wires and usage of the device. Figure 4.3.12 shows the SolidWorks rendering.

While each component is effectively integrated into the hardware system separately, their effects combine in the code to produce the desired functionality. On a high level, the code that operates the mechanical system is similar to that of the pneumatic systems shown in Fig. 4.3.5. The main differences between the types of systems are in the details of how the compression is administered, the pressure is read, and controls are implemented. For example, a different unit conversion and method of reading data is necessary for pressure control. Additionally, the motor is powered to cause compression and decompression in a different manner than the pneumatic systems. The full Arduino code for the mechanical system can be seen in Appendix C.2.

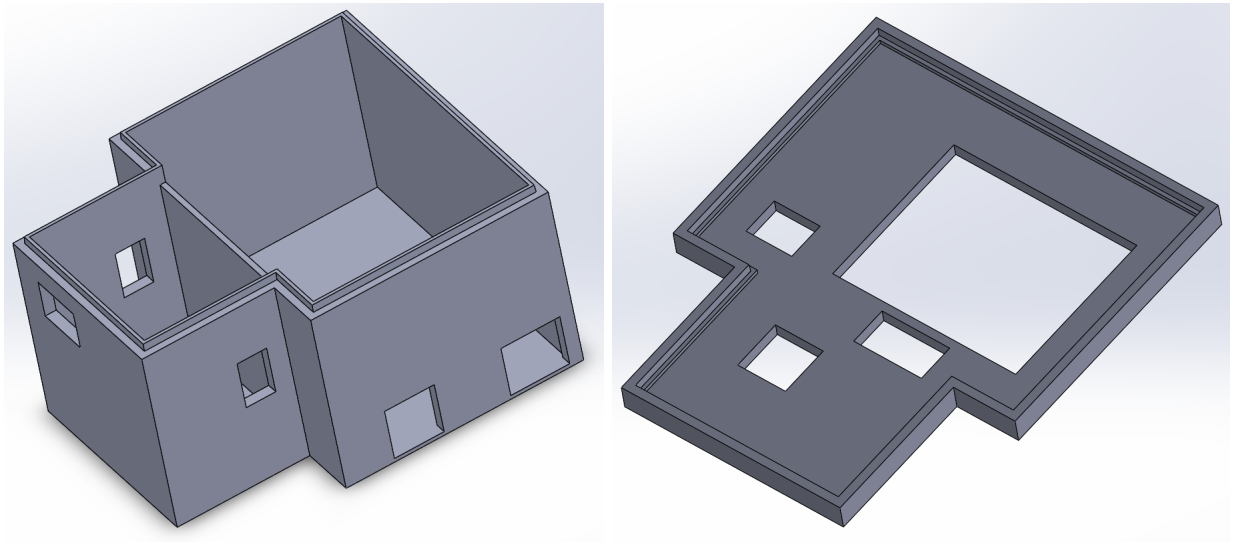


Fig. 4.3.12. SolidWorks image of the Arduino casing body and lid.

Chapter 5: Design Verification

5.1 Testing Outline

This section describes the results of the testing methods outlined in Appendix A. These testing methods were used to determine the best device by testing for:

- Slipping
- Fit
- Comfort (sitting, elevated leg, and walking)
- Weight
- Ease of Use
- Speed

The tests provide data about how each device performs for each objective of the client statement. The slipping test determined how far down the leg the device slipped while the subject walked about one hundred yards. The fit test determined how well a device fit the calf and if the surface area of compression was sufficient for the muscle. As comfort is important to persuade the patients to wear the device for long periods of time, the devices were tested for comfortability while the subjects sat, rested with the leg up, and walked around. The weight test measured the relative weight of each device according to each user. The ease of use test determined which device is the most intuitive for patients to strap on and take off as well as turn on and off the compression system. Lastly, the speed test was a comparison between the two pneumatic devices to determine the effectiveness of using a hard acrylic backing over the nylon cuff.

The test subjects were chosen to be the group members of this project as they were available throughout the testing period and offered a large range of testing parameters as calf sizes differed. Each subject carried out the tests on each of the three devices; the subject scores were then averaged to determine a raw data score. Once the raw data was obtained, those values were multiplied by a predetermined weight to obtain the final score. The weight value for each test was determined on a scale of 1-5 based on importance, with 5 being the most important. The group individually weighted each test and then averaged the score as shown in Table 5.5.1. This

weight helped accurately determine the best design to pursue after testing as some tests were valued more than others. Lastly, the final scores for each test were added up for each device to ascertain which device performed the best overall.

5.2 Testing Results

The results of testing are shown in Table 5.5.1. The first column describes the testing method, while the first row of columns two through four list the designs. The subjects ranked each device on a scale of one through five based on how well the device performed during the test. A score of five indicates optimal design performance, while a score of one refers to poor performance. As mentioned previously, each score was then multiplied by a predetermined weight, where greater weight values indicate greater team-determined importance. Columns six through eight show the final scores of each tested design, which was used to determine the design with best overall performance.

The design that outperformed the others in both weighted and unweighted scoring was the pneumatic backing design. For the slipping test, there was a tie between the mechanical system and the pneumatic backing as those devices did not slip on the subject's leg while walking, giving both of these devices a score of two. The leading device for the fit test was the pneumatic backing, as the backing was molded to fit a calf and the straps pulled the sides in to provide extra compression around the muscle. The pneumatic backing also ranked the highest out of the three designs for the ease of use test as it only had two straps, unlike the pneumatic cuff with multiple straps, and was light enough to hold by only the straps, unlike the mechanical system. The pneumatic cuff ranked the highest for the leg-up and sitting comfort test as it had the slimmest profile and did not contain a hard backing. The mechanical system ranked the highest for walking comfort as it had straps at the top and bottom of the calf to provide support.

Comparing the results of both the raw data and the final scores, the pneumatic backing ranked highest in more tests than the other two designs. In addition to the tests outlined in Table 5.5.1, inflation and deflation speed was measured according to the methodology found in Appendix A. The results from the average inflation and deflation speed for the two systems using the pneumatic air technology is shown in Fig. 5.5.1, with the pneumatic backing being faster for both inflation and deflation speed.

Table 5.5.1. Ranking, Weight, and Final Scores of Each Device

	Ranking			Weight	Final Scores		
	Pneumatic Cuff	**Pneumatic Backing**	**Mechanical System**	*** by weight**	**Pneumatic Cuff**	**Pneumatic Backing**	**Mechanical System**
Slipping	1	2	2	**4.2**	4.2	8.4	8.4
Fit	3.40	4.00	3.00	**4.2**	14.28	16.80	12.60
Weight	5.00	5.00	3.50	**3.7**	18.50	18.50	12.95
Ease of Use	2.50	4.60	3.60	**3.6**	9.00	16.56	12.96
Sitting Comfort	4.50	4.25	3.70	**4.4**	19.80	18.70	16.28
Leg up Comfort	4.70	4.35	3.20	**2.9**	13.63	12.62	9.28
Walking Comfort	3.80	3.80	4.00	**3.8**	14.44	14.44	15.20
Sum	24.9	28	21	**-**	***91.65***	***106.015***	***87.67***

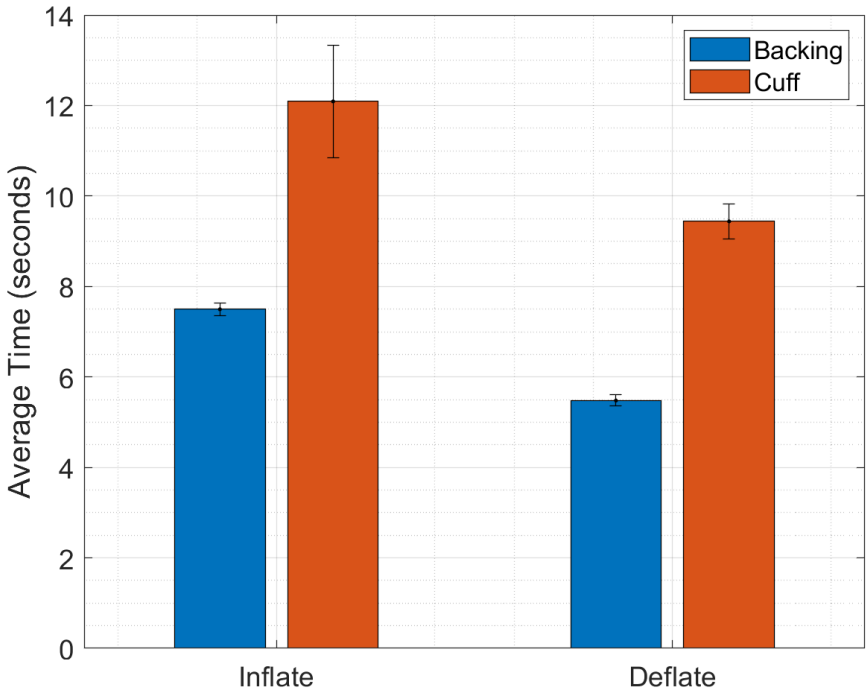


Fig. 5.5.1. Average speed to inflate to 100 mmHg and deflate to 0 mmHg over four cycles with both pneumatic designs. Error bars represent ± one standard deviation.

Chapter 6: Final Design Implications

The goal of this project was to offer a leading wearable device for skeletal mechano-therapy in an effort to offer a more effective solution to muscular recovery and regeneration. Preliminary design ideas were assessed as shown in Table 4.2.1, where brainstorm-developed design options were compared to pre-established wants and needs for an acceptable minimum viable product. This was created to ensure the designs, at minimum, perform the therapy necessary to be an effective, valuable product to the user. These designs were then compared to pre-established wants and needs for the mechano-therapy device and tested for viability and performance. Finally, with the testing results as objective data determining which designs held up best in relevant categories, it was determined that the design that performed the best was the pneumatic backing. This chapter discusses the possible implications of creating and producing the three final designs.

6.1 Economics

The results of this project would not influence the economy of everyday living as the target audience is not the majority of the population. The target audience for this device is people that have muscle atrophy or volumetric muscle loss. Since this is a medical device, however, it will economically impact the medical field. The four external factors that economically impact medical devices are: (1) the regulatory framework, (2) the medical device industry structure, (3) the short product life-cycle, and (4) the early market diffusion of medical devices [53]. The device is to be used in a lab for testing the validity of cyclic compression for muscle growth allowing the team to disregard these external factors. The device will not be available on the market. The device-level factors are more relevant to the scope of this project. These factors include: (1) constraints to study design, (2) procedural integration, (3) reusability, and (4) dynamics of effectiveness and resource use [53]. For the first device-level factor, the team needed a fair study that measures the device's effectiveness, which the team's customer at UMass Medical achieved. The integration procedure will not incur a large cost as UMass Medical has many patients and researchers who can facilitate introduction of the device into the market. One of the design constraints kept in consideration for the device was that it needs to be reusable,

which will cut down on single-use production costs. Finally, the customer will determine the effectiveness of the design by testing it in the labs.

6.2 Environmental Impact

The designed devices were created with environmental impact in mind. The designs have been engineered to be reusable, mostly recyclable, and are customizable. The reusable nature of the designs increases their sustainability. Furthermore, the bulk of the device can be reused between patients, with only changes in the customized backing. The 12V power supply used to run the device is relatively small and does not necessitate batteries that are environmentally damaging to manufacture and dispose of. The pneumatic device uses easily disposable materials while the mechanical device is composed of easily replaceable parts allowing much of the device to be reused.

6.3 Societal Influence

This device will impact a relatively small subset of the global population but will be widely applicable within extended care medical situations. However, muscle regeneration from compression is a new concept which has the potential to increase the popularity of this device. Additionally, since the primary customer, UMass Medical, is a well-known figure in the medical field, the device will be seen by many people in the medical community and may spark novel research interests and patient care techniques.

This product will influence the global market in a positive way as it is the first device to offer compressive therapy for muscle regeneration. This product will not have any effect on the global market and cultures since it does not change how the individual functions. The only effect that it could have is that it might be more expensive in countries other than the United States of America since the technology was developed and tested there.

6.4 Ethical Concerns

The intention of this device is to assist in healing patients who suffer from muscle atrophy and volumetric muscle loss, which directly improves quality of life. Ethical concerns that need to be addressed when designing are: (1) safety of the user, (2) clinical trials, and (3)

confidentiality of patients. The device either meets or will meet these three criteria to be ethically correct and released for patient use [54]. The review board at UMass Medical, where the device will be tested in clinical trials will ensure research is conducted safely, ethically, and confidentially. Ethical considerations that affect the final device primarily relate to cost and accessibility. This device should be available to all who need it, but medical expenses may be high and harmful discrimination exists even within medical care. These issues are critical to address in the later stages of product development, but do not directly apply to this MQP.

An issue that the group decided to take into account was the testing of each device as they were tested on the group members. This caused testing bias due to favorability of one device over another and rating the devices higher to make sure they fit the requirement. Although the team tried to handle the testing as professionally as possible, there is no way that it can be completely unbiased. Additionally, since the devices were not tested on patients with volumetric muscle loss or muscle atrophy, there is no way of knowing how the patients will react to the devices.

Overall, the group tried to follow the ethical guidelines while completing this project. Ideally, these devices will help people with muscle atrophy and volumetric muscle loss live a normal life by experiencing the same opportunities and having similar muscular levels. The team hope these devices close the gap between people by promoting proper muscular regeneration in an ethical way.

6.5 Health and Safety Issues

This device has no impact on the health and personal safety of people other than the user. The patient will be safe while using this device and their health will improve as their muscle regenerates. Potential for injury is only present in the case of a device malfunction. Specifically, injury may occur if the device applies too much pressure or does not release pressure after the designated compression period. Every design presented in this paper includes a stop option that will override the current task and release all pressure. More detail of potential health and safety issues can be found in Appendix B, which includes Failure Modes and Effects Analyses (FMEAs).

6.6 Manufacturability

Each design is easily manufactured, but due to the option of customizability for comfort, those devices will not be mass produced. The pneumatic designs rely on simple parts, mainly made of easily moldable acrylic. Since the comfort of the wearer is a priority, the backings should be customized to their legs, but it is not required for the device to function. Therefore, the devices can be mass produced with backing sizes such as small, medium, and large. The Programmable Air pump that powers the system is available for purchase online and consists of a printed circuit board and several pumps, none of which are prohibitively difficult to acquire. Additionally, the code for each device is adjustable to inflate and deflate to a customized pressure and length of time for the required therapy of each patient. For the mechanical system, all parts are standard and regularly manufactured items with the code also being just as adjustable as the pneumatic systems. Lastly, the notes and descriptions of all assembly and design techniques used in this project are available for reference to aid in reproduction.

Chapter 7: Discussion

Since the suitability of a mechano-therapy device differs slightly with unique applications, the team pursued three separate designs for prototyping. These designs were then evaluated on desirable criteria after completing a series of verification and validation testing. All designs sufficiently met and exceeded expectations for these criteria, so the criteria were then primarily used to identify optimal solutions, subject to independent user wants and needs, which is discussed in greater detail in Chapter 8. After each design was assigned a value based on its performance in each test, each test criteria was assigned a weight based on importance. This combination allowed the team to not only ensure each design's ability to fulfill desirable and necessary criteria, but it also accounts for the varying levels of importance that each criteria holds. These results were summarized in Table 5.5.1, illustrating that for generalized application, the pneumatic with backing system had the most effective overall performance. However, the weights assigned to each characteristic are subjective based on the priorities of each application. Therefore, each design may outperform the remaining designs given circumstances unique to each user, and for this reason, all three prototypes are recommended.

To better and establish the unique advantages of each system relative to one another, additional criteria were established and outlined in this report. Figure 5.5.1 illustrates the comparative speed of the two pneumatic systems and shows that the pneumatic system with the hard, customizable backing achieves the target pressure of 100 mmHg faster than the pneumatic cuff system. This makes the pneumatic with backing system suitable for applications favoring speed, and since less inflation is necessary, for greater energy efficiency as well.

Meanwhile, the cuff system does not require the unique customization necessary for the hard backing in the opposing pneumatic system, making the cuff system more suited for those who have wide-spread manufacturability in mind or limited access to resources to shape the acrylic backing. With the cuff fully encompassing the circumference of the extremity, this design also best minimizes muscular displacement that could lessen the efficiency of compression. Bladders can easily be extended and incorporated into this design, making it easier to accommodate for large-scale mechano-therapy that may encompass more of the extremity. As seen in Table 5.5.1, this design also features the best overall performance in comfort, besting the

other two systems in sitting and leg-up comfort, and matching the pneumatic with backing system's walking comfort score.

Lastly, the mechanical system features interchangeable parts, a gear system, and motor control, which makes this system easier to maintain long-term than the pneumatic devices due to the easy replacement of interchangeable parts. This system and its customizability also make it more robust compared to pneumatic tubing and bladders. The mechanical make-up of the system also allows the user to have finer motor control of compressibility through manipulation of gear mechanic; by changing factors such as gear ratios and number of teeth, gears can alter speed of compression, fine control of compression, torque/power necessary to achieve pressure, and programmable degrees of motor rotation. While the team still considers this system a lightweight, comfortable, and efficient solution for muscle mechanotherapy, this system is outperformed by the pneumatic systems in system weight, efficiency lost to muscle displacement, and leg-up comfort. These distinctions better equip users with the knowledge necessary to choose the best proposed solution to compressive mechano-therapy for their individual priorities.

The systems proposed in this report offer a skeletal muscle-mechanotherapy that outperforms previous solutions or offers new solutions to problems in current solutions. Physical therapy is time-consuming and requires high levels of human adherence to therapy regimens, which may be unattainable due to patient strength, to be effective. Solutions such as electrical stimulation create a disparity through its inapplicability to patients with electrical implants and do not have the ability to regenerate muscle at an efficient rate. Compressive therapy offers promising results to promote muscle regeneration. Other compressive systems have not yet been used to target muscular regeneration and prohibit patients from being mobile during usage. The three proposed systems address and overcome all such disadvantages of therapeutic precedence.

Chapter 8: Conclusions and Recommendations

As a new method for treating VML and muscle atrophy, compression therapy techniques are limited and not widely available to the public. The designs outlined in this paper work to encompass many different engineering principles to provide a comprehensive range of final recommendations. Two pneumatic designs of different styles, as well as a mechanical design are presented to allow for customization of the necessary components for each user. The design that outperformed the other two devices in testing is the pneumatic backing.

Although the pneumatic with backing device scored the highest during preliminary testing, further testing is needed to provide a conclusive recommendation of one system over another. The group determined this as each design has its own unique properties and all prototypes accomplish the client statement successfully. In addition, there are a few recommendations to be made for each design to make them more adaptable for a large consumer base.

The pneumatic cuff is long and difficult to Velcro on with the many straps. A future suggestion would be to standardize small, medium, and large sizes for different patients. This would also allow the device to be used for muscle groups other than the calf.

The pneumatic with backing design has a noticeable flaw in that the Velcro buckles can align on the shin which causes great discomfort to the user. In addition, the rigid backing can cause discomfort and requires more padding in the compressive area. A more comprehensive method for creating and molding the hard backings is necessary to allow for easy manipulation and customization by medical professionals prescribing this device.

For the purposes of this project, the Programmable Air pump system worked very well. In future iterations, however, the pump system would benefit from optimization in size and power. Designing a pump system specifically for pneumatically powered compression therapy is a worthwhile task if the pneumatic backing or pneumatic cuff designs are pursued further.

The mechanical system was difficult to use during testing as it was too large for a number of the subjects. Having only one sized prototype was a great drawback in this area; therefore it is recommended to develop standardized sizes in small, medium, and large or add an adjustable component for the length of the device. Furthermore, implementing a system for adjusting the compressive plate for customizability is encouraged. In general, it is recommended to work on

minimizing the overall size and weight of the system. Since this system has two points of contact with a customizable back piece, the two screws may need to be at different starting positions to ensure even application of force across the back plate, since the circumference of the extremity (and ultimately, the distance the screw must travel to apply force on the back plate) changes throughout the limb. Therefore, a specific recommendation for the mechanical system includes introducing a spring mechanism that allows the central gear to disengage from the outer gears, and the screws can then be individually adjusted to a starting position as flush with the back plate as possible. The sketch seen in Fig. 8.1 illustrates the proposed mechanism.

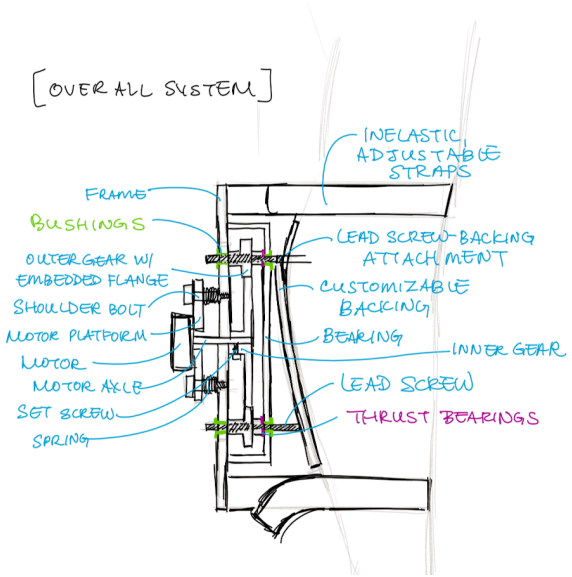


Fig. 8.1. Proposed spring-loaded gear disengagement mechanism for future iterations of the mechanical compression system.

Although each design has its flaws, all prototypes are excellent proof-of-concept models and performed at a very high level during testing. These three designs offer a versatile treatment for different users in need of compression therapy. After reviewing the results of testing, it is shown that the designs outperformed each other in separate categories. Therefore, although the pneumatic backing device ranked the highest out of all three designs during testing, the recommendation for a certain device over the others can be based on the testing, financial situation, customizability, or the variation of specific patient's needs.

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Appendix A: Testing Methods

Slipping Test

The device was secured to the subject's calf as intended by each design. A piece of tape was placed on the subject's leg at the top and bottom of the device. The subject then completed five walking laps around the lab, with the device delivering pressure as intended by the design. The displacement of the device was then recorded in millimeters. This test was repeated for each design on five different subjects.

Fit Test

The device was secured to the subject as intended by each design. The subject then rated the fit of the device on their calf on a scale of one through five while sitting, with the device delivering pressure as intended by the design. A score of one referred to a poor fit, a score of three to a satisfactory fit, and a score of five to a very secure fit. This test was repeated for each design on five different subjects.

Speed Test

The device was secured to the subject's calf as intended by the design. A pressure of 100 mmHg was applied to the subject's calf, with the time needed to reach this determined pressure recorded. This test was repeated three times for each design.

Weight Test

The device was secured to the subject's calf as intended by the design. The subject then rated the weight of the device on their calf on a scale of one through five while standing. A score of one referred to the device being very heavy, a score of three to a satisfactory weight, and a score of five to a very light weight. This test was repeated for each design on five different subjects.

Ease of Use Test

The subject was asked to secure the device to their leg. The subject then rated the ease of use for the design on a scale of one through five. A score of one referred to the subject having a difficult experience securing the device, a three referring to a satisfactory experience, and a five referring to a very easy experience. This test was repeated with each device three times on five different test subjects.

Sitting Comfort Test

The device was secured to the subject's calf as intended by the design, with the device delivering pressure. While sitting, the subject then rated the comfort of the device on their calf on a scale of one through five, with a score of one referring to a very uncomfortable fit, a score of three being satisfactory, and a score of five being very comfortable. This test was repeated for each design on five different test subjects.

Leg Up Comfort Test

The device was secured to the subject's calf as intended by the design, with the device delivering pressure. With the leg resting up on a chair, the subject then rated the comfort of the device on their calf on a scale of one through five, with a score of one referring to a very uncomfortable fit, a score of three being satisfactory, and a score of five being very comfortable. This test was repeated for each design on five different test subjects.

Walking Comfort Test

The device was secured to the subject's calf as intended by the design, with the device delivering pressure. After walking a lap around the lab, the subject then rated the comfort of the device on their calf on a scale of one through five, with a score of one referring to a very uncomfortable fit, a score of three being satisfactory, and a score of five being very comfortable. This test was repeated for each design on five different test subjects.

Appendix B: Failure Modes and Effects Analyses

Failure modes and effects analysis (FMEA) is a method of anticipating and preparing solutions for situations and conditions in which the device does not function properly, resulting in minimal results for the user, or at worst, risks to user health or well-being. Considering the minimum viable product for this project, the device is most simply designed to execute muscular compression with a pneumatic system. Therefore, the failure modes anticipated by the team are primarily based on the failure of the pneumatic and pressure moderation system. Two such possibilities are explored in the FMEAs in Tables B.1 and B.2.

Table B.1 describes the FMEA for potentially defective pressure sensors. Poor device handling or using the device prior to proper calibration could skew pressure readings and result in inaccurate pressure control, affecting the device's overarching functionality to control pressure within the system. Faulty or poorly calibrated pressure sensors could cause over- or under-estimations of pressure being applied by the device, resulting in insufficient or over-compression respectively. Insufficient compression compromises the device's core functionality, decreasing its value as a system that stimulates muscular regeneration, increasing the severity of this product failure, although it does not lead to adverse effects for the patient with this mode of failure. However, the alternative over-compression of the muscle in the device region is more dangerous for the patient or user, because over-compression could hinder blood flow or may result in forces greater than the muscular region can handle, reopening wounds or causing user discomfort. Nevertheless, it is unlikely either of these conditions cause serious or irreparable damage.

Preventative measures for this defect involve conducting proper calibration or performing regular device inspection, both of which a medical professional prescribing the device, or the user, can do: professionals can be trained to calibrate the sensor or perform inspections at the commencement of treatment, and including a user guide with the device can train users, which mitigates the need for users to return the devices to medical professional for regular inspection. Overall, these conditions led to the device receiving a severity rating of 6, occurrence rating of 3, and detectability rating of 3, resulting in a risk priority number (RPN) of 54. The team deemed this FMEA as critical, because it compromises the device's primary functionality and has potential to harm the user if unaddressed.

Table B.1. FMEA for potentially damaged or uncalibrated pressure sensors.

Function	Pressure Control
Failure Mode:	Damaged or uncalibrated pressure sensor
Effects:	Insufficient compression, over-compression
Severity (S):	6
Causes:	Poor device handling, using device before calibration
Occurrence (O):	3
Current Controls:	Calibration and regular device inspection
Detectability (D):	3
CRIT:	Yes
Risk Priority Number (RPN):	6x3x3 = 54
Recommended Actions:	Regular inspection, user training
Responsibility:	(TBD at time of FMEA)
Target Completion Date:	(TBD at time of FMEA)
Action Taken:	(TBD at time of FMEA)

A second FMEA is outlined in Table B.2. As seen in Table B.2, a risk of using a pneumatic system involves the inability to retain the air volume necessary for compression. Poor environmental conditions such as drastic temperature change or sharp objects can lead to puncture or rupture of the air pouch, preventing inflation. Small occurrences with low detectability could still allow some inflation of the device, but would hinder the effectiveness, thus never reaching sufficient pressure for muscular therapy. Current controls set in place include establishing an effective sealing method and careful material consideration when designing this

device to have optimum mechanical properties able to withstand the aforementioned, potentially-damaging conditions. After device production, preventative measures include regularly checking the inflatable portion of the pneumatic system for air leaks, such as through audible observation, pressure comparison methods mentioned in the non-standard methods, or by simple methods such as bubble testing, where the team submerges the pouch in water which they observe for visible bubbles. Overall, these conditions lead to a severity rating of 3 (does not pose a great danger to the patient but compromises the core functionality of the device), an occurrence rating of 2, and a detectability rating of 2, leading to an RPN of 12. The team deemed this FMEA critical, because this dysfunction would make the device's sole function negligible, despite the device having no negative impact on the user.

Table B.2. FMEA for potentially punctured or ruptured pneumatic systems.

Function	Compression Controls
Failure Mode:	Loss of air pressure
Effects:	Insufficient compression
Severity (S):	3
Causes:	Device puncture or rupture
Occurrence (O):	2
Current Controls:	Sealing mechanisms, strong material design consideration
Detectability (D):	2
CRIT:	Yes
Risk Priority Number (RPN):	3x2x2 = 12
Recommended Actions:	Periodically checking material and points of sealing
Responsibility:	(TBD at time of FMEA)

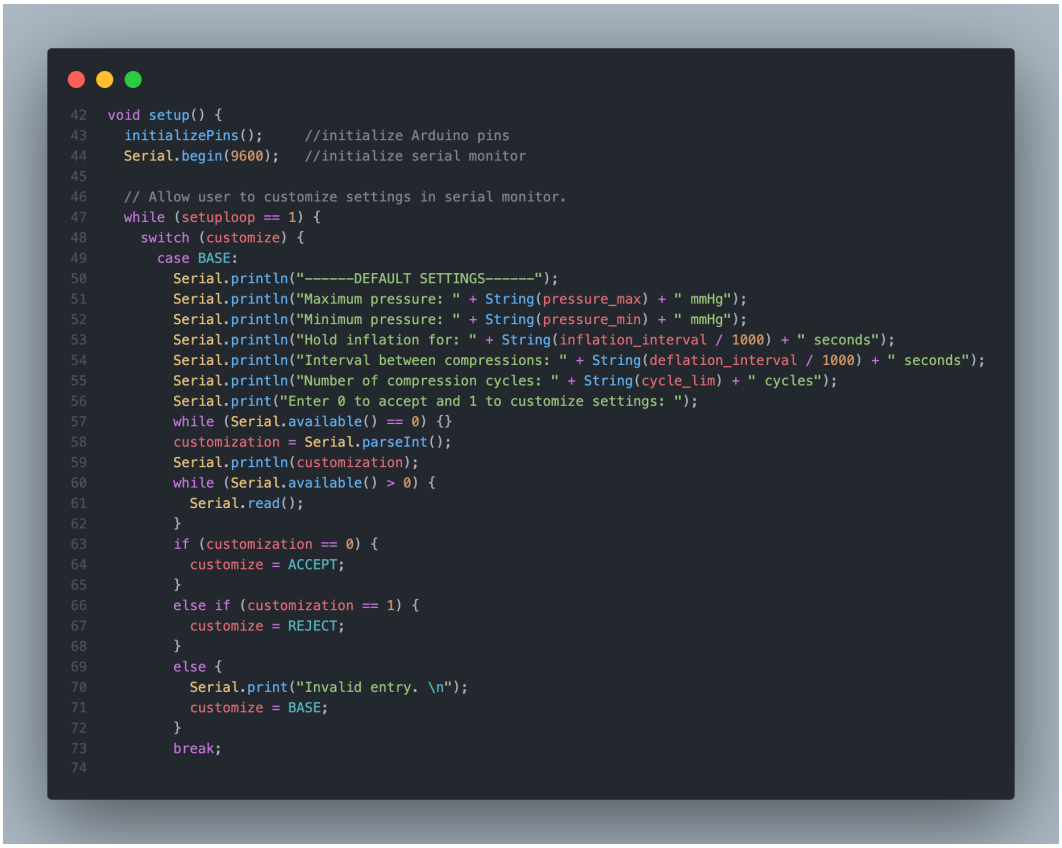
Target Completion Date:	(TBD at time of FMEA)
Action Taken:	(TBD at time of FMEA)

Appendix C: Arduino Code

Appendix C.1 Pneumatic cuff and pneumatic backing

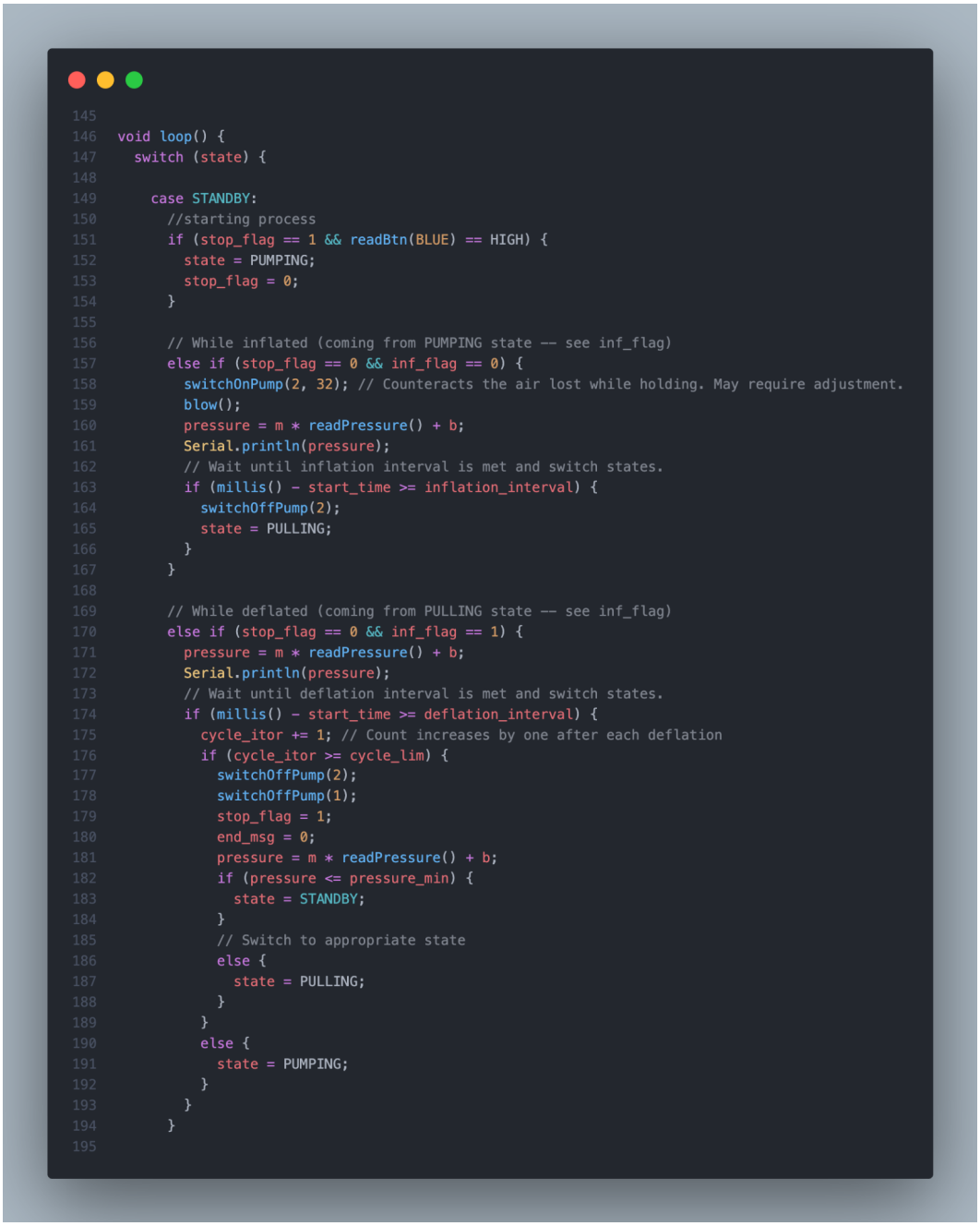
Below is the final Arduino code for the Programmable Air pump system used in the pneumatic cuff and pneumatic backing designs.

```
#include "programmable_air.h"
#include <Adafruit_NeoPixel.h>
#define DEBUG 1

// Case structure setup
// First three for loop, next three for customization.
enum state_type {
    STANDBY,
    COMP,
    DECOMP,
    BASE,
    ACCEPT,
    REJECT,
};
state_type state = STANDBY;
state_type customize = BASE;

// Flags
int stop_flag = 1; // Used to terminate treatment
int inf_flag = 1; // 0 is inflated state, 1 is deflated (not inflated)
int end_msg = 1; // Used to terminate treatment

// User customization
int customization = 1;
int setuploop = 1;

// Treatment variables
int pressure = 0;
int pressure_max = 100; //set upper pressure limit, default 100
int pressure_min = 0; //set lower pressure limit, default 0
int deflation_interval = 3000; //set duration of deflation (ms), default 3 s
int inflation_interval = 3000; //set duration of inflation (ms), default 3 s
int cycle_itor = 0; //number of cycles that have passed
int cycle_lim = 3;  //number of cycles desired

// Linear equation variables for calibrating pressure
float m = 1.363; //slope
float b = -681.363; //intercept

unsigned long start_time;

```

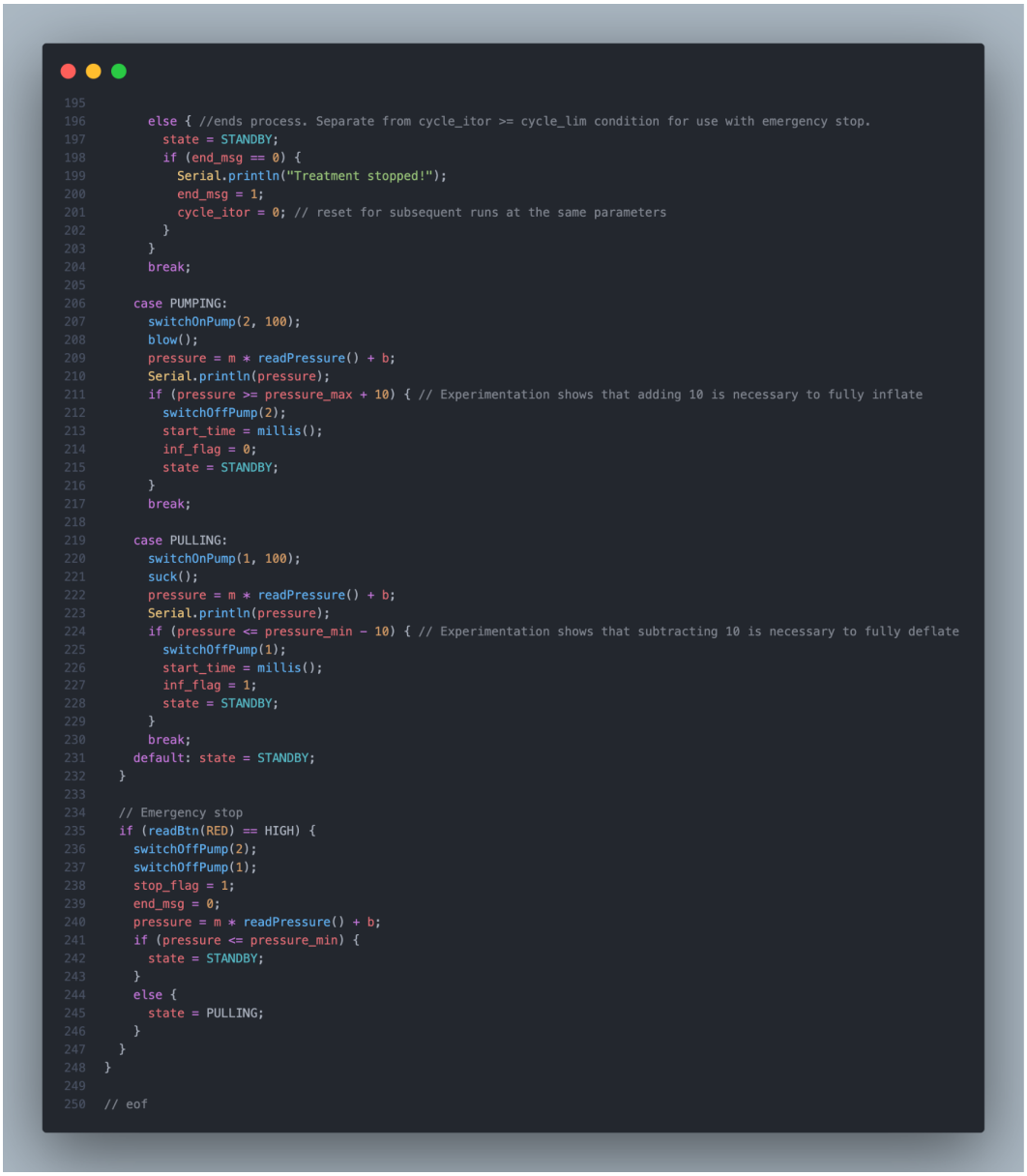


```
void setup() {
  initializePins();     //initialize Arduino pins
  Serial.begin(9600);   //initialize serial monitor

  // Allow user to customize settings in serial monitor.
  while (setuploop == 1) {
    switch (customize) {
      case BASE:
        Serial.println("------DEFAULT SETTINGS------");
        Serial.println("Maximum pressure: " + String(pressure_max) + " mmHg");
        Serial.println("Minimum pressure: " + String(pressure_min) + " mmHg");
        Serial.println("Hold inflation for: " + String(inflation_interval / 1000) + " seconds");
        Serial.println("Interval between compressions: " + String(deflation_interval / 1000) + " seconds");
        Serial.println("Number of compression cycles: " + String(cycle_lim) + " cycles");
        Serial.print("Enter 0 to accept and 1 to customize settings: ");
        while (Serial.available() == 0) {}
        customization = Serial.parseInt();
        Serial.println(customization);
        while (Serial.available() > 0) {
          Serial.read();
        }
        if (customization == 0) {
          customize = ACCEPT;
        }
        else if (customization == 1) {
          customize = REJECT;
        }
        else {
          Serial.print("Invalid entry. \n");
          customize = BASE;
        }
        break;

```

```
      case ACCEPT:
        state = STANDBY;
        setuploop = 0;
        Serial.println("Ready to start! Press the blue button to start and the red button to stop!");
        break;

       case REJECT:
        Serial.print("Enter the desired maximum pressure: ");
        while (Serial.available() == 0) {}
        pressure_max = Serial.parseInt();
        Serial.println(pressure_max);
        while (Serial.available() > 0) {
          Serial.read();
        }
        Serial.print("Enter the desired minimum pressure: ");
        while (Serial.available() == 0) {}
        pressure_min = Serial.parseInt();
        Serial.println(pressure_min);
        while (Serial.available() > 0) {
          Serial.read();
        }
        Serial.print("Enter the interval between compressions in seconds: ");
        while (Serial.available() == 0) {}
        deflation_interval = Serial.parseInt() * 1000;
        Serial.println(deflation_interval / 1000);
        while (Serial.available() > 0) {
          Serial.read();
        }
        Serial.print("Enter the compression duration in seconds: ");
        while (Serial.available() == 0) {}
        inflation_interval = Serial.parseInt() * 1000;
        Serial.println(inflation_interval / 1000);
        while (Serial.available() > 0) {
          Serial.read();
        }
        Serial.print("Enter the desired number of cycles: ");
        while (Serial.available() == 0) {}
        cycle_lim = Serial.parseInt();
        Serial.println(cycle_lim);
        while (Serial.available() > 0) {
          Serial.read();
        }
        Serial.println("------CONFIRMING DETAILS------");
        Serial.println("MAXIMUM PRESSURE: " + String(pressure_max) + " mmHg");
        Serial.println("MINIMUM PRESSURE: " + String(pressure_min) + " mmHg");
        Serial.println("INTERVAL BETWEEN COMPRESSIONS: " + String(deflation_interval / 1000) + " seconds");
        Serial.println("DURATION AT COMPRESSION: " + String(inflation_interval / 1000) + " seconds");
        Serial.println("NUMBER OF CYCLES: " + String(cycle_lim));
        Serial.print("Enter 0 to accept and 1 to re-customize settings: ");
        while (Serial.available() == 0) {}
        customization = Serial.parseInt();
        Serial.println(customization);
        while (Serial.available() > 0) {
          Serial.read();
        }
        if (customization == 0) {
          customize = ACCEPT;
        }
        else if (customization == 1) {
          customize = REJECT;
        }
        else {
          Serial.print("Invalid entry. \n");
          customize = BASE;
        }
        break;
       default: customize = BASE;
      }
    }
  }
```



```
145
146  void loop() {
147    switch (state) {
148
149      case STANDBY:
150        //starting process
151        if (stop_flag == 1 && readBtn(BLUE) == HIGH) {
152          state = PUMPING;
153          stop_flag = 0;
154        }
155
156        // While inflated (coming from PUMPING state -- see inf_flag)
157        else if (stop_flag == 0 && inf_flag == 0) {
158          switchOnPump(2, 32); // Counteracts the air lost while holding. May require adjustment.
159          blow();
160          pressure = m * readPressure() + b;
161          Serial.println(pressure);
162          // Wait until inflation interval is met and switch states.
163          if (millis() - start_time >= inflation_interval) {
164            switchOffPump(2);
165            state = PULLING;
166          }
167        }
168
169        // While deflated (coming from PULLING state -- see inf_flag)
170        else if (stop_flag == 0 && inf_flag == 1) {
171          pressure = m * readPressure() + b;
172          Serial.println(pressure);
173          // Wait until deflation interval is met and switch states.
174          if (millis() - start_time >= deflation_interval) {
175            cycle_itor += 1; // Count increases by one after each deflation
176            if (cycle_itor >= cycle_lim) {
177              switchOffPump(2);
178              switchOffPump(1);
179              stop_flag = 1;
180              end_msg = 0;
181              pressure = m * readPressure() + b;
182              if (pressure <= pressure_min) {
183                state = STANDBY;
184              }
185              // Switch to appropriate state
186              else {
187                state = PULLING;
188              }
189            }
190            else {
191              state = PUMPING;
192            }
193          }
194        }
195
```



```
195
196         else { //ends process. Separate from cycle_itor >= cycle_lim condition for use with emergency stop.
197           state = STANDBY;
198           if (end_msg == 0) {
199             Serial.println("Treatment stopped!");
200             end_msg = 1;
201             cycle_itor = 0; // reset for subsequent runs at the same parameters
202           }
203         }
204         break;
205
206       case PUMPING:
207         switchOnPump(2, 100);
208         blow();
209         pressure = m * readPressure() + b;
210         Serial.println(pressure);
211         if (pressure >= pressure_max + 10) { // Experimentation shows that adding 10 is necessary to fully inflate
212           switchOffPump(2);
213           start_time = millis();
214           inf_flag = 0;
215           state = STANDBY;
216         }
217         break;
218
219       case PULLING:
220         switchOnPump(1, 100);
221         suck();
222         pressure = m * readPressure() + b;
223         Serial.println(pressure);
224         if (pressure <= pressure_min - 10) { // Experimentation shows that subtracting 10 is necessary to fully deflate
225           switchOffPump(1);
226           start_time = millis();
227           inf_flag = 1;
228           state = STANDBY;
229         }
230         break;
231       default: state = STANDBY;
232     }
233
234     // Emergency stop
235     if (readBtn(RED) == HIGH) {
236       switchOffPump(2);
237       switchOffPump(1);
238       stop_flag = 1;
239       end_msg = 0;
240       pressure = m * readPressure() + b;
241       if (pressure <= pressure_min) {
242         state = STANDBY;
243       }
244       else {
245         state = PULLING;
246       }
247     }
248   }
249
250   // eof
```

Appendix C.2 Mechanical system

Below is the Arduino code used to run the mechanical system. It is very similar in structure to the pneumatic cuff and pneumatic backing code, but differs in its details.

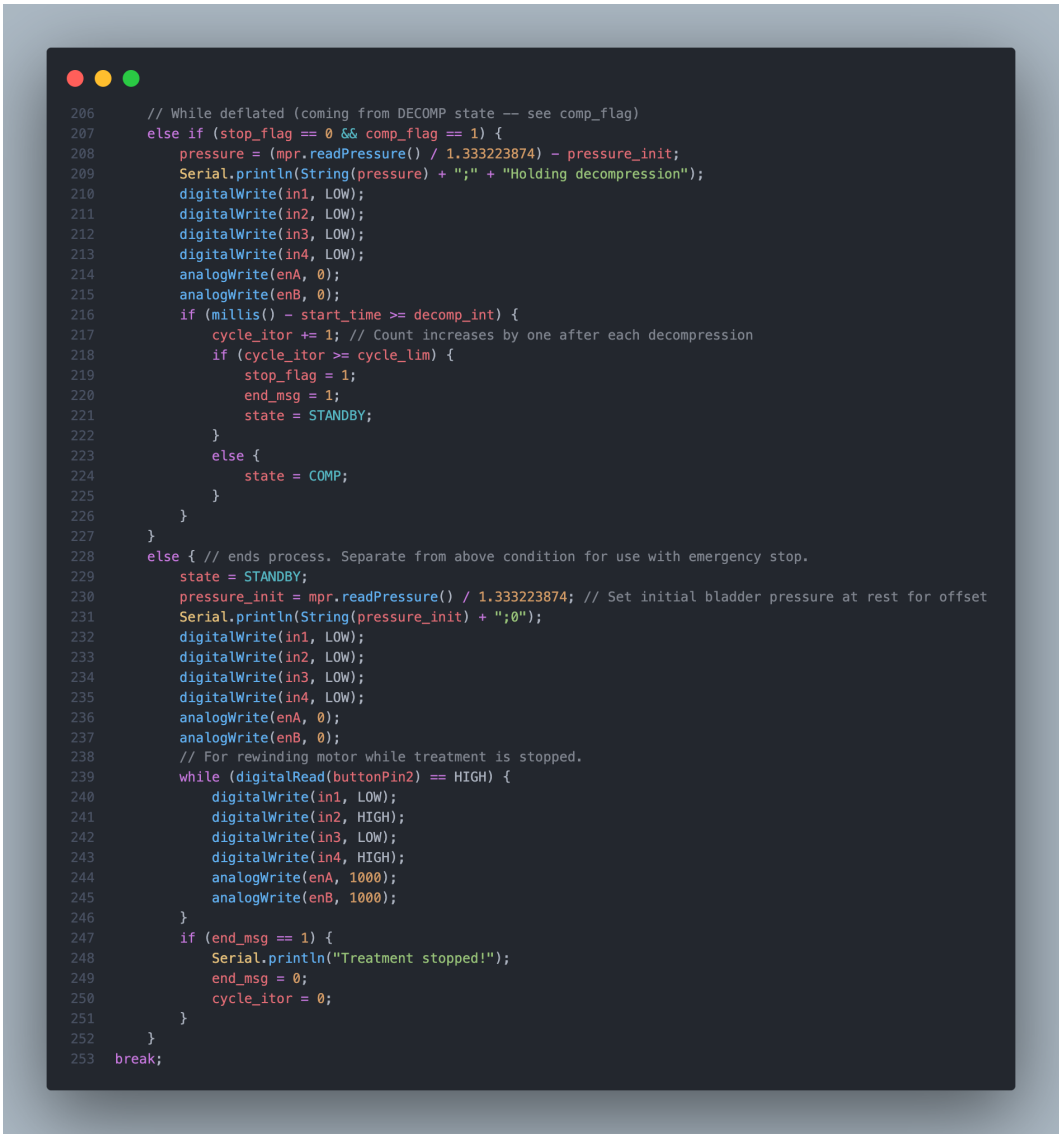
```
// Sensor
#include <Wire.h>
#include "Adafruit_MPRLS.h"
#define RESET_PIN  -1  // set to any GPIO pin # to hard-reset on begin()
#define EOC_PIN    -1  // set to any GPIO pin to read end-of-conversion by pin
Adafruit_MPRLS mpr = Adafruit_MPRLS(RESET_PIN, EOC_PIN);

// Motor pins
int in1 = 2;
int in2 = 4;
int enA = 3;

int in3 = 5;
int in4 = 7;
int enB = 6;

// Case structure setup
// First three for loop, next three for customization.
enum state_type {
    STANDBY,
    COMP,
    DECOMP,
    BASE,
    ACCEPT,
    REJECT,
};
state_type state = STANDBY;
state_type customize = BASE;

// Case variables and flags
int stop_flag = 1;
int comp_flag = 1; // 0 is compressed, 1 is decompressed
int end_msg = 0;
unsigned long start_time;

// User customization
int customization = 1;
int setuploop = 1;

// Settings
int cycle_itor = 0; //variable for number of cycles that have passed
int cycle_lim = 3;  //total number of cycles desired
int pressure_max = 100; // mmHg
int pressure_min = 1;
int comp_int = 3000; //compression interval in ms
int decomp_int = 3000; //decompression interval in ms

// Sensor
float pressure_init;
float pressure;

// Button
const int buttonPin1 = 8; // Start button
const int buttonPin2 = 9; // Rewind button

```

```
void setup() {

    Serial.begin(115200);

    // Motor pins
    pinMode(enA, OUTPUT);
    pinMode(in1, OUTPUT);
    pinMode(in2, OUTPUT);
    pinMode(enB, OUTPUT);
    pinMode(in3, OUTPUT);
    pinMode(in4, OUTPUT);

    // Button pins
    pinMode(buttonPin1, INPUT);
    pinMode(buttonPin2, INPUT);

    // Check pressure sensor is reading
    if (! mpr.begin()) {
        Serial.println("Failed to communicate with MPRLS sensor, check wiring?");
        while (1) {
            delay(10);
        }
    }

```

```
// Allow user to customize settings in serial monitor.
 while (setuploop == 1) {
     switch (customize) {
         case BASE:
             Serial.println("------DEFAULT SETTINGS------");
             Serial.println("Maximum pressure: " + String(pressure_max) + " mmHg");
             Serial.println("Minimum pressure: " + String(pressure_min) + " mmHg");
             Serial.println("Hold inflation for: " + String(comp_int / 1000) + " seconds");
             Serial.println("Interval between compressions: " + String(decomp_int / 1000) + " seconds");
             Serial.println("Number of compression cycles: " + String(cycle_lim) + " cycles");
             Serial.print("Enter 0 to accept and 1 to customize settings: ");
             while (Serial.available() == 0) {}
             customization = Serial.parseInt();
             Serial.println(customization);
             while (Serial.available() > 0) {
                 Serial.read();
             }
             if (customization == 0) {
                 customize = ACCEPT;
             }
             else if (customization == 1) {
                 customize = REJECT;
             }
             else {
             Serial.print("Invalid entry. \n");
                 customize = BASE;
             }
             break;

```

```
            case ACCEPT:
                state = STANDBY;
                setuploop = 0;
                Serial.println("Ready to start! Press the blue button to start and the red button to stop!");
                break;

            case REJECT:
                Serial.print("Enter the desired maximum pressure: ");
                while (Serial.available() == 0) {}
                pressure_max = Serial.parseInt();
                Serial.println(pressure_max);
                while (Serial.available() > 0) {
                    Serial.read();
                }
                Serial.print("Enter the desired minimum pressure: ");
                while (Serial.available() == 0) {}
                pressure_min = Serial.parseInt();
                Serial.println(pressure_min);
                while (Serial.available() > 0) {
                    Serial.read();
                }
                Serial.print("Enter the interval between compressions in seconds: ");
                while (Serial.available() == 0) {}
                decomp_int = Serial.parseInt() * 1000;
                Serial.println(decomp_int / 1000);
                while (Serial.available() > 0) {
                    Serial.read();
                }
                Serial.print("Enter the compression duration in seconds: ");
                while (Serial.available() == 0) {}
                comp_int = Serial.parseInt() * 1000;
                Serial.println(comp_int / 1000);
                while (Serial.available() > 0) {
                    Serial.read();
                }
                Serial.print("Enter the desired number of cycles: ");
                while (Serial.available() == 0) {}
                cycle_lim = Serial.parseInt();
                Serial.println(cycle_lim);
                while (Serial.available() > 0) {
                    Serial.read();
                }
                Serial.println("------CONFIRMING DETAILS------");
                Serial.println("MAXIMUM PRESSURE: " + String(pressure_max) + " mmHg");
                Serial.println("MINIMUM PRESSURE: " + String(pressure_min) + " mmHg");
                Serial.println("INTERVAL BETWEEN COMPRESSIONS: " + String(decomp_int / 1000) + " seconds");
                Serial.println("DURATION AT COMPRESSION: " + String(comp_int / 1000) + " seconds");
                Serial.println("NUMBER OF CYCLES: " + String(cycle_lim));
                Serial.print("Enter 0 to accept and 1 to re-customize settings: ");
                while (Serial.available() == 0) {}
                customization = Serial.parseInt();
                Serial.println(customization);
                while (Serial.available() > 0) {
                    Serial.read();
                }
                if (customization == 0) {
                    customize = ACCEPT;
                }
                else if (customization == 1) {
                    customize = REJECT;
                }
                else {
                Serial.print("Invalid entry. \n");
                    customize = BASE;
                }
                break;
            default: customize = BASE;
        }
    }
}
```

```
179
180 void loop() {
181     switch (state) {
182         case STANDBY:
183             //starting process
184             if (stop_flag == 1 && digitalRead(buttonPin1) == HIGH) {
185                 while (digitalRead(buttonPin1) == HIGH) {}
186                 state = COMP;
187                 stop_flag = 0;
188             }
189             // While compressed (coming from COMP state -- see comp_flag)
190             else if (stop_flag == 0 && comp_flag == 0) {
191                 // sensor reads in hPa (hextopascal). Convert to mmHg, offset with init.
192                 pressure = (mpr.readPressure() / 1.333223874) - pressure_init;
193                 Serial.println(String(pressure) + ";" + "Holding compression");
194                 // Turn motor off
195                 digitalWrite(in1, LOW);
196                 digitalWrite(in2, LOW);
197                 digitalWrite(in3, LOW);
198                 digitalWrite(in4, LOW);
199                 analogWrite(enA, 0);
200                 analogWrite(enB, 0);
201                 // Wait until compression interval is met and switch states.
202                 if (millis() - start_time >= comp_int) {
203                     state = DECOMP;
204                 }
205             }
```



```
    // While deflated (coming from DECOMP state -- see comp_flag)
    else if (stop_flag == 0 && comp_flag == 1) {
        pressure = (mpr.readPressure() / 1.333223874) - pressure_init;
        Serial.println(String(pressure) + ";" + "Holding decompression");
        digitalWrite(in1, LOW);
        digitalWrite(in2, LOW);
        digitalWrite(in3, LOW);
        digitalWrite(in4, LOW);
        analogWrite(enA, 0);
        analogWrite(enB, 0);
        if (millis() - start_time >= decomp_int) {
            cycle_itor += 1; // Count increases by one after each decompression
            if (cycle_itor >= cycle_lim) {
                stop_flag = 1;
                end_msg = 1;
                state = STANDBY;
            }
            else {
                state = COMP;
            }
        }
    }
    else { // ends process. Separate from above condition for use with emergency stop.
        state = STANDBY;
        pressure_init = mpr.readPressure() / 1.333223874; // Set initial bladder pressure at rest for offset
        Serial.println(String(pressure_init) + ";0");
        digitalWrite(in1, LOW);
        digitalWrite(in2, LOW);
        digitalWrite(in3, LOW);
        digitalWrite(in4, LOW);
        analogWrite(enA, 0);
        analogWrite(enB, 0);
        // For rewinding motor while treatment is stopped.
        while (digitalRead(buttonPin2) == HIGH) {
            digitalWrite(in1, LOW);
            digitalWrite(in2, HIGH);
            digitalWrite(in3, LOW);
            digitalWrite(in4, HIGH);
            analogWrite(enA, 1000);
            analogWrite(enB, 1000);
        }
        if (end_msg == 1) {
            Serial.println("Treatment stopped!");
            end_msg = 0;
            cycle_itor = 0;
        }
    }
break;
```

```
        case COMP:
            digitalWrite(in1, HIGH);
            digitalWrite(in2, LOW);
            digitalWrite(in3, HIGH);
            digitalWrite(in4, LOW);
            analogWrite(enA, 1000);
            analogWrite(enB, 1000);
            pressure = (mpr.readPressure() / 1.333223874) - pressure_init;
            Serial.println(String(pressure) + ";0");
            if (pressure >= pressure_max) {
                start_time = millis();
                comp_flag = 0;
                state = STANDBY;
            }
        break;
        case DECOMP:
            digitalWrite(in1, LOW);
            digitalWrite(in2, HIGH);
            digitalWrite(in3, LOW);
            digitalWrite(in4, HIGH);
            analogWrite(enA, 1000);
            analogWrite(enB, 1000);
            pressure = (mpr.readPressure() / 1.333223874) - pressure_init;
            Serial.println(String(pressure) + ";0");
            if (pressure <= pressure_min) {
                start_time = millis();
                comp_flag = 1;
                state = STANDBY;
            }
            break;
        default: state = STANDBY;
    }

    // Emergency stop
    if (stop_flag == 0 && digitalRead(buttonPin1) == HIGH) {
        while (digitalRead(buttonPin1) == HIGH) {
            digitalWrite(in1, LOW);
            digitalWrite(in2, LOW);
            digitalWrite(in3, LOW);
            digitalWrite(in4, LOW);
            analogWrite(enA, 0);
            analogWrite(enB, 0);
        }
        cycle_itor = cycle_lim;
        pressure = (mpr.readPressure() / 1.333223874) - pressure_init;
        if (pressure <= pressure_min) {
            state = STANDBY;
        }
        else {
            state = DECOMP;
        }
    }
}

// eof
```