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Designing Non-Pneumatic Anti-Shock Trousers

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Submitted by:

Catherine Blejwas

Megan Heinle

Anne Hughes

Colleen O'Malley

Date: May 6th, 2021

Professor Jeannine M. Coburn, Ph.D., Advisor

Department of Biomedical Engineering

This report represents the work of one or more WPI undergraduate students submitted to the faculty as evidence of completion of a degree requirement. WPI routinely publishes these reports on the web without editorial or peer review.

Abstract

Hemorrhagic shock is a significant cause of death for trauma patients. Current treatment methods face a variety of shortcomings and limitations. The team conducted research and testing which informed the design and prototyping of a device to combat hemorrhagic shock by shunting blood from the lower extremities to the core of the body. The team decided to create a fully functional segment of the device to study proof of concept and create a baseline for the future of the design. Verification testing showed that the device does not obstruct the cutaneous view. Furthermore, the team found the device can be applied within the identified time window of less than five minutes. It was measured that the device can apply 30-50 mmHg which is in the desired range of pressure to meet the device objectives.

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The team is grateful to all who contributed to the completion of this project.

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All team members contributed to the report. However, the team identified two roles for each section: primary author and primary editor. The primary authors are members who created the initial draft of the section. The primary editors are members who made major edits to that section of the report. Both contributed significantly to the completion of the report.

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1.0 Introduction

Trauma is the fourth leading cause of death worldwide. Furthermore, trauma due to unintentional injuries is the leading cause of death for people under the age of 45. Following a traumatic injury, patients frequently experience shock. Shock is defined as a failure in the cardiovascular system that results in decreased blood perfusion throughout the body [1]. The type of shock linked to traumatic injuries with resultant bleeding is referred to as hemorrhagic shock. In fact, hemorrhagic shock is the most frequent cause of death due to traumatic injury [2]. Hemorrhagic shock is cited as the cause of death for more than 80% of trauma patients in the operating room.

1.1 Current Treatment

Hemorrhagic shock results in hypovolemia, or low blood pressure. The most common course of treatment in the Intensive Care Unit (ICU) for this condition is to use intravenous (IV) fluids and blood products including platelets, fresh frozen plasma, and packed red blood cells. This treatment method allows the patient to regain sufficient bodily fluid, consequently increasing the patient's fluid circulation and blood pressure. Compression is an alternative treatment strategy that is occasionally used independently or in tandem with IV fluid stabilization [3]. In this treatment, compression is applied to the peripheral limbs to increase the blood flow in the central circulatory region and create hemodynamic stabilizing effects. In pneumatic compression, the device includes an external compressor element to create the effect, while non-pneumatic compression does not utilize an air-compressor; instead, relying on the device directly applying the desired pressure.

One example of a pneumatic compression device is military anti-shock trousers (MAST). They were once a common emergency medicine treatment strategy, but they have fallen out of use due to several shortcomings. MAST have three sections, a compartment for each leg and one for the abdominal section that contain inflatable air bladders [4]. The non-pneumatic anti shock garment (NASG) is a device intended for stabilizing post-partum hemorrhage patients. This compression suit has five neoprene sections that are secured tightly with Velcro and in the abdominal section there is a detachable foam ball for additional pressure. Both these devices were designed to be used in medical settings with limitations or for use while transporting patients to maintain stability until they can be treated [5].

1.2 Shortcomings

There are a number of problems and limitations with the existing solutions and treatment strategies. Regarding blood products, there is a chronic shortage of resources. As a result, blood products are very expensive, with the average price being between $130-150 per unit. The most severe trauma cases can receive 10 units of blood in 24 hours [6]. The price increases in rural areas, due to decreased availability. Furthermore, extensive coordination is required for this

treatment. The resources must be immediately available, administered in a sustained fashion, and the blood products must be an appropriate blood type for the patient [2]. Even if all these challenges are overcome, there are still several risks associated with blood products including blood borne illnesses and immune reactions [7].

Similarly, existing compressive strategies have several downfalls. MAST had numerous issues associated with it which consequently resulted in them no longer being used. They were cumbersome and bulky, had an extensive application time, and were too expensive. Additionally, the removal process was slow as they needed to be deflated in a highly controlled manner which did not often occur once patients arrived at the hospital and were moved to the operating room. NASGs also have a few downfalls. The efficacy of this device relies on the patient's BMI and the strength of the clinician applying the device for sufficient pressure to be created. Furthermore, their lack of a pressure sensor means that the pressure being applied at any section of the device is unknown and consequently continuous, thorough patient monitoring is required. Both devices raise concerns about potentially leading to pressure sores and causing the patient more harm than pursuing other stabilizing methodologies for treating shock.

1.3 Project Procedure

The purpose of this project was to design and develop a device that could be used to effectively combat hemorrhagic shock for adult patients in the ICU. Objectives of this project were initially outlined by the team's clients, Dr. Ulises Torres Cordero and Dr. Landon Guntman from UMASS Memorial Medical Center. The client stressed that the device should be an accessible price and transparent. To be successful, the device had to mechanically reduce intravascular space and circumvent the complications and consequences of shock. It was imperative to the client that the device maintained visibility to ensure for continuous patient monitoring on the cutaneous level.

The team followed the design process to create a solution that would address these needs and requirements. First, the team performed extensive research and interviewed stakeholders. The information gained in this process guided the team as they conducted a material search. They identified several potential materials that were then subjected to a series of tests. These tests provided insight on the strength and mechanical properties of the materials. The samples were subjected to a series of transparency testing including testing the material over a range of skin tones to ensure adequate visibility for all patients. These trials showed 20-gauge PVC (20 G PVC) to be the most advantageous material for the team's needs. Additionally, this material has the added benefit of being readily available and commonly used in the hospital setting. Next, the team used the material they selected from testing to create multiple prototypes. Following material selection, the team considered various closure and tightening techniques. For closure, the team considered hook and eyes, zippers, Velcro, and adhesive strips. To tighten, the team considered the use of daisy chain loops with hooks, a dial fastener system, various lacing patterns, and a tourniquet rod that is twisted then locked into place. Ultimately Velcro and a bungee lacing system attached to a tourniquet rod were chosen as fastening and tightening mechanisms, respectively. After completing the selection process, the team decided to focus on

creating a flushed out, fully functional prototype of a single section rather than create a full garment.

1.4 Future Recommendations and Plan

After completing several design iterations, the team determined their final design. The primary component is a PVC segment that, at the start of the application process, is threaded through a two slotted buckle. Then, the segment is held in place with translucent Velcro attaching the excess PVC to the PVC that is pressed directly against the patient's limb. Next, the device is tightened with bungee cord tighteners connected to elastic bungees; the elastic bungee is laced through the buckle's six holes and through the grommets on the loose end of the PVC. Finally, a tourniquet rod is twisted, then locked into place when slid under the hooks attached to the buckle. The team conducted a series of tests to validate that the device applies enough pressure to be effective. A force sensitive resistor was utilized throughout testing and would ideally be incorporated into the device and the output will be correlated to the applied pressure. Additionally, the team conducted a series of time trials to ensure that device application is within the optimal time window. Finally, user studies were conducted with potential future users to generate feedback on ease of application and obtain suggestions and ideas for future iterations.

Future teams should investigate expanding the uses of the device as well as developing sizing for a broad range of patients. Additionally, they should investigate implementing sensors for monitoring biometrics such as temperature, blood pressure, and heart rate. Once a full suit has been made, the team should conduct additional feasibility and user studies to confirm it meets the client statement while avoiding pressure injuries. In order to support the continued work and testing required, future teams should apply for grants as detailed further in this report.

2.0 Literature Review

2.1 Definition of Shock

2.1.1 *Introduction to Shock*

Shock is characterized as a failure within the cardiovascular system that leads to an inadequate level of blood circulation. Blood circulation is responsible for carrying and delivering oxygen and nutrients throughout the body. Thus, as a result of the inadequate blood flow due to shock, the body's critical needs are not met. Cells use oxygen and nutrients to create energy and maintain metabolic function. In a healthy body, perfusion is defined as the adequate circulation of blood within organs and tissues which meet the cells' required levels of oxygen, nutrients, and waste removal function. The baseline amount of blood required varies between patients and is largely dependent on size and weight. When a patient actively experiences shock, they are in a hypoperfusion state. Hypoperfusion is characterized by the body not receiving the required baseline amount of blood circulation. As a result of this disease state, oxygen and nutrient levels

are too low within individual cells, tissues, and organ systems [8]. When the body begins to experience shock, it redirects blood flow from the organs that can temporarily withstand a low blood flow, such as the skin and intestines, to organs that are unable to tolerate low blood flow, such as the brain and lungs [9].

When organs are actively deprived of nutrients and oxygen for an extended period, there can be life threatening consequences. This time period is highly variable between patients and is dependent on the extent of their injury, illness, or condition. The progression of shock can lead to an increasingly intense decline and an eventual block of blood flow. When poor blood circulation persists for too long, it is called ischemia which can cause the cells to necrose—cellular death caused by external factors [1]. Different tissues can survive in a state of low oxygen, or hypoxia, for various lengths of time. For example, skeletal and smooth muscles are highly adaptable to a lack of oxygen. Similarly, cells in the liver can withstand over two and a half hours of ischemia before irreversible damage occurs. However, other tissues are very intolerant to a lack of oxygen, namely the brain which suffers permanent damage after five minutes without adequate blood supply [10]. As cells begin to die, large sections of organ tissue die off, causing organ failure which can progress to multiple organ dysfunction syndrome (MODS) and could result in the death of the patient [1]. MODS, as a result of shock, can have a variable timetable of progression, however, the respiratory system is often the first to fail after 72 hours. Subsequently liver failure may occur within five to seven days, followed by the gastrointestinal system after 10 to 15 days and finally the kidneys after 11 to 17 days [11].

Shock is a complex and dynamic state. A patient can shift between different stages of shock throughout the course of their illness. The three main stages of shock are nonprogressive, progressive, and irreversible. Nonprogressive, also known as compensated, is the mildest stage of shock. In this stage, the patient can recover on their own strictly through natural compensatory mechanisms of the body, which means no outside help is needed. However, if a patient's condition worsens, they can advance into a more severe stage of shock. The progressive stage is when the patient’s vital signs become noticeably abnormal. This stage marks the start of organ dysfunction as the lack of adequate blood flow to tissues begins to cause bodily repercussions. Here, the body is unable to compensate for the insufficient perfusion, if the patient does not receive medical intervention, shock will become increasingly severe leading to death [1]. The final, and most severe stage of shock is irreversible shock. As its name suggests, once the patient enters this stage, there is no chance of recovery. There is no way to determine when a patient has reached this final stage of shock [8]. At this point, shock has progressed beyond a recoverable threshold and there is no known form of intervention or therapy that will effectively save the patient. As there is no quantitative way to determine when the patient has passed into irreversible shock, the only effective indicator is that there is no response to any method of treatment [1].

2.1.2 *Types of Shock*

Shock can have many different causes, but there are two main types of shock that can be differentiated into four classes [12]. **Table 1** provides the definitions of each type of shock and their corresponding classes.

Table 1: Types of Shock and Corresponding Classes

Type of shock	**Definition**	**Classes**	**Etiology**
Vasodilative	Due to the dilation of the blood vessels, the body experiences shock	Disruptive	Anaphylaxis, spinal injury, bacterial infection
Vasoconstrictive	When the cardiovascular system is impaired, and the body attempts to regain homeostasis through the narrowing of blood vessels	Cardiogenic	Disease of or injury to heart muscle or electrical system
		Obstructive	Mechanical obstruction of the circulatory system
		Hypovolemic	Acute loss of fluid or blood

The classification of the types of shock are differentiated based on the size of the blood vessel. The difference in the cross section of blood vessels is depicted in **Fig. 1**. **Fig. 1a** depicts a normal cross section of a blood vessel. **Fig. 1b** depicts the cross section of a blood vessel experiencing vasodilation, or the widening of the intravenous space. **Fig. 1c** depicts a blood vessel experiencing vasoconstriction or narrowing of the intravenous space.

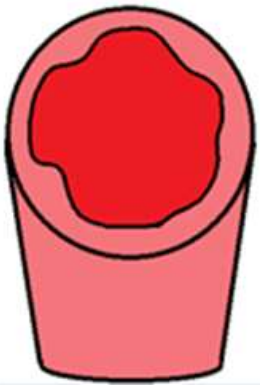
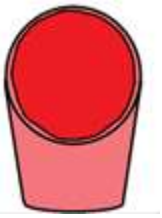
	Type of Shock	Class
(a) Normal Blood Vessel 	(b) Vasodilative 	Disruptive
	(c) Vasoconstrictive 	Cardiogenic
		Obstructive
		Hypovolemic

Figure 1(a-c): (a) Normal, healthy cross section. (b) Vasodilative. (c) Vasoconstriction

2.1.2.1 Disruptive Shock

Vasodilative shock, or disruptive shock, is the result of widespread dilation of areoles and venules, which leads to a decrease in the systemic vascular resistances. This results in a buildup of blood in vascular beds thus decreasing tissue perfusion. As the dilation sets in, blood pressure begins to drop which makes it much more difficult for the heart to pump blood [13]. The most common types of disruptive shock are septic shock, anaphylactic shock, and neurogenic shock. Septic shock is the result of an infection. The infectious bacteria damage the blood vessels causing them to leak, preventing contraction. This leads to insufficient blood volume and a large volume of the plasma leaks out into the third space, which is the interstitial space between cells. As fluid moves into the non-functional third space, the patient experiences hypovolemia, or low circulatory blood volume. The leaking fluid can collect in the respiratory system and decreases oxygenation of the blood. Anaphylactic shock results from a violent immune reaction to a foreign substance. The body reacts by causing widespread vasodilation, or high permeability of blood vessels, and contraction of the airways. This results in poor oxygenation of the blood along with poor perfusion of the blood which further amplifies the negative consequences of shock. Neurogenic shock is the result of "high spinal cord injuries, brain condition, tumors, pressure on spine, [or] spina bifida" [8]. The muscles in charge of dilating the blood vessels are blocked from receiving signals from the brain that are trying to make them contract. The blood vessels dilate causing blood to pool. Even when appropriate levels of blood are present, the blood is unable to meet the body's need in a dilated circulation system. The perfusion of oxygen and nutrients to tissue are too far below the necessary levels and shock occurs [8].

2.1.2.2 Cardiogenic Shock

Cardiogenic shock is characterized as a dysfunction of the cardiac system which results in a critical reduction of the heart's pumping capacity, consequently causing inadequate blood supply to the organs. Cardiogenic shock is not the result of hypovolemia, hypoxia, or any other correctable reasons; it typically stems from inflammation or injury to the heart muscle. Cardiogenic shock creates and perpetuates a vicious cycle. Ischemia of the cardiac tissue causes destruction of the myocardial tissue, which in turn exacerbates myocardial ischemia [9]. A healthy heart continuously and forcefully pumps blood. However, when the heart sustains elevated levels of damage, such as after a heart attack, it is unable to support its proper level of functioning; as a result, the needs of the body are not met, and shock begins to set in [8].

2.1.2.3 Obstructive Shock

Obstructive flow is a type of shock that results from an obstruction that prevents the normal and healthy volume of blood from entering the heart. Since less blood travels through the heart, less blood pumps out of the heart and into bodily tissue. There are multiple different etiologies that lead to this type of shock. Cardiac tamponade is caused by hemorrhaging around the heart. Blood pools into the pericardial space surrounding the heart, causing an increase in pressure making it difficult for the heart to pump blood. Tension pneumothorax is when damaged lungs allow air to escape in the chest cavity, compressing the heart and blood vessels. The elevated level of compression will decrease blood flow to and from the heart. Finally, pulmonary embolism is when a blood clot forms in the pulmonary circulatory system, blocking the flow of blood from the right side of the heart to the left. This results in reduced blood flow from the right ventricle to the rest of the body which can lead to complete pump failure [8].

2.1.2.4 Hypovolemic Shock

Hypovolemic shock is the result of severe loss of intravascular volume, either blood or fluid, preventing the heart from pumping an adequate volume of blood to the body. As a result, tissue and organ systems in the body are not receiving the nutrients or oxygen they need to function properly and survive. Hypovolemic shock can result from extreme dehydration or blood loss [14]. Dehydration is when severe loss of water and fluid leads to a decrease in the volume of blood available for perfusion of blood into tissue. There is an insufficient volume of fluid within the vessels which supplies tissues of the organs with the necessary oxygen and nutrients [8]. Hypovolemic shock is broken into four stages based on fluid loss. **Table 2** provides more information on each of these stages and their characteristics. Stages 1 and 2 typically correspond with the nonprogressive stage of shock, stage 3 corresponds to the progressive stage of shock and stage 4 corresponds to irreversible shock. There is considerable variance between the metrics in any given patient, but the information in **Table 2** provides a baseline [15].

Table 2: Stages of Shock, Corresponding Biometrics, & Symptoms

	Stage 1	Stage 2	Stage 3	Stage 4
Blood Loss by %	<15%	15-30%	30-40%	>40%
Blood Pressure	Normal	Elevated diastolic pressure	Systolic pressure <100 mmHg	Systolic pressure <70 mmHg
Heart Rate	Normal	>100 bpm Slight tachycardia	>120 bpm Tachycardia	>140 Extreme tachycardia
Appearance	Slightly pale	Pale, cool, clammy	Increased perspiration	Excessive perspiration, occasional blotches on skin
Capillary Refill	Normal	Delayed	Delayed	No refill
Urine Output	Normal	20-30 mL/h	5-15 mL/h	Negligible
Mental Status	Normal	Anxious	Confused	Lethargic, coma

Hemorrhagic shock is the most common type of hypovolemic shock and is the most common shock seen in the ICU. This shock is most often due to trauma. One study found that 62.2% of massive blood transfusions at a level one trauma center were related to traumatic injury [11]. Hemorrhagic shock results from an acute hemorrhage, with or without major tissue injury. When major tissue injury is present in the patient, the shock is further differentiated as traumatic hemorrhagic shock [16]. The common characteristic of this type of shock is bleeding, triggering a critical drop in the blood available for circulation. The body attempts to compensate by increasing heart rate and initiating vasoconstriction. As this continues, the diastolic blood pressure rises, and the pulse pressure, the difference between systolic and diastolic pressure, narrows. As the body continues to lose blood, systolic blood pressure drops and oxygen delivery to the organs drops with it. Due to the low oxygen delivery to the cell, they are forced to switch to anaerobic metabolism, producing lactic acid, in an attempt to meet the energy requirements of cells. Blood flow is redirected away from organs to maintain adequate blood flow to the brain and heart. This results in tissue ischemia and progressively worsens lactic acidosis and, if left untreated, results in death. The time frame for death to set in is dependent on the patient and the extent of their injuries [17].

2.1.3 *Blood Pressure*

Blood pressure is defined as the force exerted on the arterial walls by blood that is circulating throughout the body and is measured in millimeters of mercury (mmHg) [18]. Various bodily systems control blood pressure such as the respiratory and the nervous system. If a large amount of blood is lost, the endocrine system becomes stimulated via the release of an antidiuretic in order to maintain adequate levels of sodium and water within the blood. The juxtaglomerular apparatus also becomes activated which ultimately leads to the formation of angiotensin II, which causes vasoconstriction and leads to the release of aldosterone [6].

A multicomponent device, known as a sphygmomanometer, which consists of a pressure cuff attached to a manometer, a rubber pump, and a stethoscope, is often used to measure and monitor blood pressure [19]. When measuring blood pressure, a clinician squeezes the rubber pump which fills the cuff with air and raises the pressure surrounding the brachial artery. This momentarily cuts off the blood flow in the patient's arm and the air is then gradually released from the cuff. The clinician places the stethoscope on the patient's antecubital region, or area on the opposite side of the elbow inside the joint bend, to listen for a soft ticking. The soft tick is the auditory indicator of turbulent flow through the blood vessels, also known as Korotkoff sounds [19]. The recorded pressure is transcribed as one number over another. Systolic blood pressure is the first number of a blood pressure reading which signifies the amount of pressure the blood is exerting on the arterial walls while the heart beats. Diastolic blood pressure, the second number of a blood pressure reading, signifies the amount of pressure the blood is exerting on the arterial walls while the heart is at rest between heart beats [18]. Overtime, plaque can build-up within the arteries and increase the risk of cardiac and vascular diseases; for this reason, systolic pressure is often monitored much more closely than diastolic pressure. Additionally, high systolic or high diastolic blood pressure can indicate high blood pressure which requires appropriate attention and intervention such as medication or lifestyle changes in order to maintain the well-being of the patient.

Low blood pressure, also known as hypotension, is when the force exerted on the arterial walls by circulating blood is lower than necessary [20]. Hypotension can be induced by internal or external bleeding, dehydration, pregnancy, diabetes, or general aging. The elderly population is at an increased risk of experiencing symptoms related to low blood pressure which may include fainting, falling, or dizziness; they are also likely to develop low blood pressure, especially if they are taking medicine to control high blood pressure. A wider range of hypotension symptoms include light-headedness, confusion, fatigue, blurred vision, headache, neck or back pain, nausea, and heart palpitations. Medical professionals can easily test for low blood pressure through blood samples, urine samples, imaging, and/or a tilt table test for those who are highly susceptible to fainting [20]. To treat hypotension, patients are often encouraged to consume an increased quantity of fluids such as water. Additionally, medication may be adjusted or prescribed if needed, and moderate lifestyle changes may be recommended and encouraged. It's important that hypotension is addressed in a timely fashion and treated with the utmost urgency. If blood pressure drops too low for an extended period, vital organs are

continuously deprived of essential oxygen and nutrients which can ultimately lead to shock [21]. Symptoms of shock include but are not limited to cold and sweaty skin, rapid breathing, blue skin tone, and weak or rapid pulse.

2.1.3.1 Hypovolemia

When a patient is experiencing hypotension, it may be a direct result of hypovolemia. Hypovolemia, also known as low blood volume, can be caused by excessive bleeding, dehydration, vomiting, severe burns, and even medications used to treat hypertension. An individual may not experience symptoms of hypovolemia until 10-20% of their blood volume has already been lost [21]. Treatment of low blood volume consists of intravenous fluid replacements and rest. On the contrary, hypervolemia, excessive fluid volume, can be caused by retention of water and sodium. Treatment of hypervolemia consists of restoring homeostasis within the patient's body and counteracting the condition that triggered the increase in blood volume in the first place [21].

2.2 Current Treatment Strategies

To combat the circulatory distress associated with shock, treatment options build on the concepts of compression and intravenous fluid stabilization to maintain the patient's central blood pressure. The general treatment strategies fall under two categories intravenous (IV) fluid stabilization and compression. The compressive devices include Military Anti-Shock Trousers (MAST), Non-Pneumatic Anti-Shock Garment (NASG), and Auto-Transfusion Tourniquet. Additionally, devices for athletic applications were noted for further design ideas including inflatable compression pants with differential pressurization and shock blankets.

2.2.1 *Intravenous (IV) Fluid Stabilization*

Shock causes hypovolemia which is defined as a decrease in blood volume and loss of intravascular content. Generally, patients are provided approximately 1L of IV fluids to increase fluid circulation [3]. Fluid resuscitation, vasopressors, and blood transfusions are used to maintain the oxygen delivery to tissues [3]. By increasing the volume of fluid in the intravenous space, the global blood flow is increased. The goal of increasing the volume is to improve the flow of the microcirculation, consequently increasing the oxygen availability for the tissues. Currently there is a shift in the classification of shock [3]. It has been defined by the static model of identifying a percentage of blood volume loss. Whereas the dynamic model, that is on the rise as the classification tool, focuses on monitoring the response to the initial IV fluid resuscitation. IV fluid stabilization is used independently or in conjunction with compression as a treatment strategy for shock as well as to replace fluid while waiting on blood products.

2.2.2 *Blood Products*

For patients suffering from traumatic bleeding, the preferred resuscitation strategy often focuses on the transfusion of blood products to not only increase fluid volume but maintain the appropriate levels of the corresponding blood products [2]. Both whole blood and blood products are used to stabilize patients and promote hemodynamic stabilizing effects. There are various types of blood products that are used; however, whole blood transfusion is the most common form of resuscitation [2, 7]. The secondary method consists of using a 1:1:1 ratio of red blood cells (RBCs), plasma, and platelets which attempts to recreate the component composition of whole blood [7].

2.2.2.1 Types of Blood Products

2.2.2.1.1 Whole Blood

Whole blood is collected from donors that are considered safe; however, whole blood is often scarce as only about 8% of the United States population are universal donors with an O- blood type [7]. Additionally, this treatment strategy is simpler during the transfusion process, when the patient is given units of whole blood, as clinicians do not need to balance the appropriate ratio of the various blood components [7].

2.2.2.1.2 Packed RBCs (PRBCs)

Packed red blood cells are the most utilized blood product in the treatment of trauma patients [2]. However, this strategy lacks platelets and coagulation factors, so it does not replenish all that the trauma patient is actively losing [2]. Preservative solutions are added but the quality declines with storage time [7].

2.2.2.1.3 Fresh Frozen Plasma (FFP)

One of the most commonly used plasma-based products is fresh frozen plasma (FFP). It can be prepared from a single unit of whole blood or via apheresis, where only a specific component of the blood is harvested while everything else is returned to the donor [7]. The plasma is frozen within eight hours of collection and can remain frozen up to one year [7].

2.2.2.1.4 Liquid Plasma

This form of plasma is collected from a whole blood donation within five days of the whole blood expiration date and then stored for a maximum of 20 days [7]. There is a chronic shortage of liquid plasma, the universal donor type is AB blood, as it lacks anti-A and anti-B antibodies, which only constitutes 4% of the global population [7]. Some studies have associated liquid plasma with transfusion-related acute lung injury (TRALI) which is the most common cause of transfusion related death [7].

2.2.2.1.5 Platelets

Platelets can be isolated from donated whole blood or obtained by apheresis [7]. Platelets have the shortest shelf life of all the blood products with only five days before expiration [2, 7]. Platelet donation can come from single-donor apheresis or random-donor apheresis which pools from multiple donors [7].

2.2.2.2 Shortcomings

Although blood transfusion is one of the current treatment strategies for patients suffering from traumatic bleeding, it requires immediate coordination, availability and accessibility of the necessary resources, and evaluation of the inherent risks. Additionally, the patient must be treated as soon as possible and in a sustained fashion [2]. Often, it can be difficult to determine who requires blood products and even more challenging to match the necessary blood products to the patient's needs [2]. Blood products are a precious commodity with limited availability that is dependent on volunteer blood donors and proper storage conditions [2, 7]. With the transfusion of blood and blood products, there is an inherent risk of pathogens which are vectors of blood borne illnesses [2, 7]. Additionally, patients can have negative immune reactions which can occur acutely or even weeks later [7].

2.2.3 *Compression*

Compression applied to the peripheral limbs can increase the blood flow in the central circulatory region and create hemodynamic stabilizing effects. By compressing the extremities, the fluid remains in the central region ensuring that the organs receive the necessary fluids to stabilize the patient experiencing shock. For patients who are actively bleeding, compression as a wound management strategy helps to diminish blood loss, consequently, preventing the progression of hemorrhagic shock. There are two common types of compressive devices: pneumatic and non-pneumatic. Pneumatic garments include pressurized compartments filled by an external pressure compressor whereas non-pneumatic use a tight, constrictive application.

2.2.3.1 Military Anti-Shock Trousers (MAST)

2.2.3.1.1 How it Works

The military anti-shock trousers (MAST) were first described in 1903 [4]. This device is a pneumatic suit used to decrease the postural hypotension, defined as blood pressure less than or equal to 90 mmHg, in trauma patients during transport to the hospital [22]. The device applies pressure to the lower extremities to "shift the patient's blood volume from the abdomen, pelvis, and lower extremities to the upper body and central circulation" [23]. This suit is composed of one abdominal compartment and two leg compartments made of urethane and synthetic, inflatable air bladders which are held together by Velcro as shown in **Fig. 2**[4]. The air bladders are attached to an inflation unit which makes this a self-contained treatment option for shock. Originally used for soldiers experiencing traumatic hemorrhagic shock with injuries previously

considered fatal, with the use of MAST, patients were able to survive the 30 to 60-minute airlifts for further treatment. In the 1970s, MAST was included in the civilian Emergency Medical Services (EMS) listed as an essential device to be carried on all ambulances [4]. This decision was made after establishing that it was beneficial in ruptured abdominal aortic aneurysms (AAA) which lead to hemorrhagic shock [22]. Additionally, some studies suggest that it was possibly beneficial for relieving hypotension due to pelvic fracture, anaphylactic shock refractory to standard therapy, uncontrollable lower extremity hemorrhage, and severe traumatic hypotension—palpable pulse with no blood pressure [4, 22].

Figure 2: Military Anti-Shock Trousers [24]

2.2.3.1.2 Methods of Use

Compression is used to stabilize the hemodynamic state improving cardiac output and mean arterial pressure [4]. Depending on the type of shock and type of injury, there are various methodologies to use the anti-shock trousers as outlined in **Table 3** [4]. Overall, the goal of the compressive garment is to reverse hypotension by increasing peripheral vascular resistance. This is achieved by creating a tamponade effect on intra-abdominal bleeding, and by auto-transfusion of blood from the lower extremities and abdomen to the head and upper trunk area which contain vital organs. When deploying the MAST garment, the leg compartments must be inflated prior to the abdominal compartment to push the blood from the peripherals to the central region. The compartments are then filled with air until systolic blood pressure increases back to a normal amount, around 100 mmHg, or until the Velcro or urethane begins to pull apart [4].

Table 3: MAST Methods of Use

Method	Use
Trouser Method	The MAST is put on like a pair of pants and cannot be used for potential spinal injuries.
Log-roll Method	The patient is log-rolled onto a backboard with the MAST covering them. Each portion is wrapped around and inflated accordingly.
Diaper Method	Used for pelvic and hip injuries, the MAST is slipped under the patient in the same manner as a sheet would be placed. After, the inner edges and front part of the abdominal section are rolled toward the center.

Due to legal constrictions and updated findings regarding the risks associated with the anti-shock trousers, the Indications for Use have changed. Although the original Indication of Use was for hypovolemic shock it is no longer recommended for this clinical state. The two current Indications for Use include: splinting and control of pelvic fractures with continuing hemorrhage and hypotension, and intra-abdominal trauma with severe hypovolemia in patients who are en route to the operating room or another facility [22]. MASTs are still in use in more rural settings, however due to the changes for the Indications of Use their popularity has decreased since the 1970s when they were first introduced to the market.

2.2.3.1.3 Shortcomings of MAST

The Indications of Use is based on the specific state and county regulations. It is apparent that for specific scenarios MAST has worked effectively and has saved lives. However, based on the intended use on an ambulance it was noted that it took up valuable storage space in addition to its expensive price—ranging from $900 to $1,400 per pair. When transporting patients in a helicopter, due to the changes in pressure, complications arise during ascent and descent [25]. Additionally, in emergency situations the time required to apply the pants is about 4.7 minutes and leads to pre-hospital delays [4]. Once at the hospital, removal of the garment requires an experienced physician to ensure that the device is deflated in a controlled manner. This controlled deflation and removal process needs to be performed cautiously to avoid the equivalent effects of losing a significant volume of blood in just a few seconds. The extensive duration of the removal process may delay necessary trauma surgeries or essential care.

2.2.3.2 Non-Pneumatic Anti-Shock Garment (NASG)

2.2.3.2.1 How It Works

The Non-Pneumatic Anti-Shock Garment (NASG) is intended for severe postpartum hemorrhaging to temporarily regain hemodynamic stability allowing for patient transfer or treatment. Like the MAST, it is a compression suit composed of five neoprene segments which

are closed with Velcro along the legs, pelvis, and abdomen, as shown in **Fig. 3**. In the abdominal section, there is a foam ball which increases the targeted compression by exerting pressure on the surrounding vasculature to decrease blood flow to the pelvis [5]. The device "shunts blood from the lower extremities and abdominal area to the essential core organs: heart, lungs, and brain" [26]. This is achieved by an increase in the resistive index of the internal iliac artery [27]. The device features controllable segments designed to allow access for examinations and surgeries. The lifespan of the device is approximately 40 uses with proper laundering and decontamination between patients [27].

Figure 3: Non-Pneumatic Anti-Shock Garment (NASG) [28]

2.2.3.2.2 Shortcomings

The NASG efficacy and side effects for the patient are dependent on two main factors: the applier's strength and the patient's BMI [23]. These sources of variation are a limiting factor for the device as the device does not include any pressure gauge or sensor to indicate the pressure that is being applied to ensure that it is within the appropriate range [23]. Compared to the Pneumatic Anti-shock Garment (PASG), the blood flow to the legs is not diminished as much as with the NASG. This is a limitation of the current design based on efficacy; however, it may also be considered a benefit as lower extremity ischemia and compartment syndrome have not been reported with this device [23]. Although the lifespan of the device is approximately 40 uses, concerns about adequate cleaning procedures and the loss of compressibility are noted as difficulties for ensuring a safe re-use [24]. The NASG has strong qualifications for use in medical settings with constraints including limited blood products and definitive treatment available, however, careful monitoring and evaluation is critical to ensure the pressure applied is assisting the patient.

2.2.3.3 Auto-Transfusion Tourniquet (ATT)

2.2.3.3.1 How It Works

The auto-transfusion tourniquet, such as the HemaClear[R] ATT, is rolled onto each leg up to the upper thigh **(Fig. 4)**. The goal of the device is to compress blood out of the leg to

maintain the core circulation and perfuse the vital organs. As each adult male leg has approximately 500 cc, or one unit of blood per leg, when the device is applied it equates to an auto-transfusion of one liter of whole blood. While eliminating the legs, the perfusion demand of about 40% of the cardiac output is being removed minimizing the pressure on the cardiovascular system. First, clinicians elevate the leg before applying the tourniquet to drain some of the venous blood into the core circulation. Then, using the pull strap and silicone ring wrapped in a stockinette sleeve the sock is rolled up to the femoral artery [29]. Being a single-use device, the ATT can be cut off to allow visibility of injuries. When appropriately functioning, the tourniquet stops the arterial blood flow to the extremity. However, if applied at a lower pressure it can instead stop the venous flow trapping the blood in the leg which results in clotting. In a case study, a patient had their systolic blood pressure increase from 60 mmHg to 100 mmHg when ATTs were worn on both legs [29]. The risk associated is minimal when worn for less than two hours

Figure 4: AutoTransfusion Tourniquet [30]

2.2.3.3.2 Shortcomings

When the device is worn for a prolonged duration, there is increased incidences of nerve injuries and compartment syndrome. This is caused by increased pressure that diminishes circulatory and neuromuscular function [31]. To prevent complications, alternating legs every two hours permits a longer duration of use is recommended [29]. Similar to the aforementioned devices that utilize compression, including the MAST and NASG, it is imperative that the device is removed gradually. If removed all at once, the body will experience the equivalent effects of removing one liter of blood as the blood travels back to the extremities [29].

2.2.4 *Other Potential Devices to Treat Shock*

2.2.4.1 Inflatable Compression Pants with Differential Pressurization

Used as a recovery system after exercise, inflatable compression garments offer circulatory benefits specifically intended for athletes. Using five chambers for the legs and arms, the device inflates to 50-130 mmHg—normal human blood pressure is 120 mmHg systolic to 80 mmHg diastolic [32]. These devices fall between $500 to $1,000 depending on the quality and technology [32]. One brand, NormaTec, is on the higher end of the spectrum and offers "pulsing, gradients, and distal release" [33]. Requiring a pre-utilization set up and adequate space, these devices are used in athletic training facilities and for at-home recovery, as seen in **Fig. 5**.

Figure 5: NormaTec Compression Pants (NormaTec: By Hyperice, 2018)

2.2.4.2 Shock Blanket

A shock blanket, also known as a first aid blanket or safety blanket, is used to prevent hypothermia for patients experiencing hemorrhagic shock. It is essential that shivering is suppressed as the muscle contractions that produce shivering require energy creating increased demands for oxygen which can be damaging [34]. In trauma patients, hypothermia negatively impacts wound healing and recovery while increasing morbidity and mortality rates [35].

2.3 Complication Consideration for Lack of Blood Flow

When applying pressure to effectively shunt blood centrally from the periphery, it is critical to consider the possible complications based on the diminished blood flow. When pressure is applied, pressure sores can occur at various points on the skin and progress through stages that may ultimately lead to cell death. However, pressure sores can be prevented which is an aspect of device design that must be considered.

2.3.1 *Pressure Sores*

Pressure sores, also known as bed sores, are sections of the skin that become irritated and damaged. They often occur following the lack of physical movement, for example, an individual remaining in a single position for an extended period of time. Pressure sores are most common in elderly patients and those living in nursing homes as they often spend hours sitting or lying down in a singular position without physical adjustment [36]. However, those at risk of pressure sores are not only the elderly, but anyone who may be bedridden or unable to alter their physical position for an extended period.

2.3.2 *Sites for Pressure Sores*

There are many different bodily locations where a patient may suffer from pressure sores which differ in risk of severity based on the position of the patient [36]. Pressure sores commonly occur in areas of the body where bones are more directly in contact with the skin. These locations are commonly referred to as bony landmarks. For instance, upper areas of the body such as the backside of the head, shoulders, full back, elbows, as well as lower areas, such as the hips, heels, and ankles, are all susceptible to pressure sores [36]. This is because these bony landmarks prevent easy access of blood to the region as there is a reduced amount of fat and other tissue to cushion the compression of the bone on the skin.

2.3.3 *Stages of Pressure Sores*

Pressure sores may start out minimal but could result in serious infections, which ultimately can become life-threatening. When blood supply to the skin is cut off for more than two to three hours, the skin begins to deteriorate and die. As the skin dies, the affected area will physically appear red and the patient may experience painful irritation, burning sensations, or itchiness. Eventually the skin will begin to turn purple, and if the area is left untreated, the skin can blister or scrape and break open, increasing the risk of infection in the area [37]. The broken skin can have a physical crater-like appearance which signifies a degree of damage that extends deeper than what can be seen superficially.

2.3.4 *Necrosis*

Necrosis is an irreversible condition and often results from severe pressure sores that go untreated for an extended period [37]. Necrosis is defined as the death of cells within an organ that can result from injury, disease, or lack of blood supply. This type of cell death is not due to natural causes such as apoptosis, the death of cells which occurs normally throughout growth and development, or autophagy, a way that the body cleans out damaged cells in order to make room for newer and healthier cells. Necrosis is dangerous and undesired cell death. It often results in the loss of a limb or organ failure, which could ultimately lead to patient death if not immediately cared for [38].

2.3.5 *Treatment and Prevention*

Pressure sores can have a negative physical impact on the human body that can take days, months, or even years to heal depending on the severity of the wound, as they can easily spread to muscle and bone if not cared for properly and urgently. The treatment of less severe pressure sores includes removing pressure from the affected area by rotating the bodily position of the patient or applying additional pillows and cushions in order to alleviate the force of the body's weight on the affected area. Other methods of treatment to maintain a healthy and stable patient include protecting the wound with gauze, cleaning the wound, applying, or ingesting medicine, and negative pressure wound therapy. In more severe cases of pressure sores, where necrosis occurs, treatment of the patient may require skin graft surgery or even limb amputation [36]. However, the cause of necrosis must be cured prior to the treatment and removal of the damaged or dead cells to prevent the spread of the disease. Pressure sores can be prevented by keeping the skin clean and dry, regularly inspecting the skin for areas of redness, altering the patient position as often as possible and *at least* every two hours, and utilizing pillows and cushions in wheelchairs and other medical equipment to relieve pressure on bony areas of the body [36].

3.0 Project Strategy

3.1 Initial Client Statement

The initial client statement was provided to the team by the client at the beginning of the project:

"Develop an ergonomic full-body compression suit that will effectively combat shock and circumvent its consequences by mechanically reducing both the intravascular space and the 'third space.'"

3.2 Design Requirements

3.2.1 *Objectives*

From the client statement, interviews with the client as well as other clinicians, and literature review the team identified a list of objectives for the device to meet. The following objectives, ordered based on importance, must be met to adequately address the clinical need:

1. Effectively shunt blood centrally from the periphery
2. Transparent material for cutaneous wound monitoring
3. Segmented to create accessibility for patient assessment and treatment
4. Easily applied and removed to meet the application time frame
5. Lightweight and compact for efficient storage
6. Cost efficient design and materials for accessible pricing of the device

3.2.2 *Constraints*

The team also identified constraints that would impact the progress and outcome of the project. The constraints were identified based on limitations of time, resources, and experience.

3.2.2.1 University Project Constraints—Project Duration and Budget

Due to the nature of the project, the team was allocated one academic year to adequately develop a design, assemble a prototype, and complete a formal report that documented and detailed each step of the design process. Additionally, the team was provided with a budget of $250 per student, for a total allotment of $1,000 to complete the project.

3.2.2.2 Knowledge Constraints

The team consisted of four undergraduate Biomedical Engineering students with mixed backgrounds in Biomechanics and Biomaterials & Tissue Engineering. Although the team had a strong academic background, none of the team members were medical professionals, consequently, they needed to conduct extensive research and consult with professionals in the clinical field.

3.2.2.3 Clinical Constraints

The device should be able to be applied by two or less medical professionals due to limited personnel available to treat a given patient in an ICU setting. Furthermore, the application of the device should not require such extensive force that it would put medical professionals at risk of injury. The device should also take less than 10 minutes to put on the patient.

3.2.3 *Design Requirements – Functions, Means & Specifications*

3.2.3.1 Functions, Means, & Specifications Table

Table 4 lists the functions that the device must achieve in order to be considered successful, the means used to accomplish them, and the specific criteria that must be met by the device.

Table 4: Functions, Means, & Specifications

Functions	Means	Specifications
Applying pressure to move fluid from the third space	Clasps, straps, & fasteners for tightening a non-pneumatic device	Apply 30-50 mmHg
Biocompatibility	Breathable & non-toxic material Ex. PVC[1], nylon, spandex, neoprene	ISO 10993-10
Applied by two or less medical professionals	Light weight, fasteners to amplify force applied, 4 or less parts required to secure at a time	<35 pounds OSHA 2014-04-09
Customizable	Flaps that create sections for isolating key segments of lower body, various sizing, straps and fasteners to adjust sizing	5 leg segments per leg, 1 waist, and 1 abdomen segment, 2 socks
Transparent	Translucent material, windows of clear material Ex. Clear vinyl, EVA, PVC[1]	ISO 14782: 1999
Measure Pressure Applied	Wearable tactile pressure sensor, piezoresistive textile pressure sensor, force sensitive resistor	ASTM F2070-00(2017)

[1] Polyvinyl Chloride

3.2.3.2 Pressure Application

The device must apply an adequate amount of pressure to the patient's lower limbs and abdomen in order to increase their blood pressure. This must be done carefully and without cutting off the patient's circulation, which could subsequently put them at risk for further

physiological damage. If this was to be prevented, the pressure applied by an external force must not exceed the patient's diastolic arterial pressure. To achieve this desired function, a buckle system with a tourniquet style tightening mechanism was utilized in order to modify the amount of pressure applied.

3.2.3.3 Customizable

The device must be customizable to fit a range of patients regardless of their age, sex, and body size. In order to achieve this, the device should come in a range of sizes and be easily adjustable. For this iteration, the team focused on a single size that would fit a small female patient due to easy access of test subjects who fall into that category. Future iterations should investigate developing the sizes for other users.

Additionally, the device must be customizable to isolate select sections of the body. The flaps allowed for the device to isolate regions of the leg for easy access whilst others are still able to maintain a compressive state. This feature allows for easy wound management, access for imaging and observation, and progressive detachment of the device. While the device design included five sections for the legs, two for the abdomen, and a compression stocking for the foot, the team decided to focus on developing a single, flushed out, fully functional prototype of a single section rather than create a full garment.

3.2.3.4 Biocompatibility

The device must not cause skin sensitization. This device is classified as a medical device that is in contact with intact skin, and based on the indicated use, it would be used in a prolonged exposure setting, somewhere between 24 hours and 30 days. Considering the risk of pressure sores, the device would need to be removed, then reapplied every two hours to avoid additional injuries. To test for sensitization such as delayed-type hypersensitivity which can lead to allergic reactions, the team recommends conducting testing on the device based on ISO 10993-10. To achieve biocompatibility, the material must not allow for bacteria growth; the team selected an antimicrobial 20-gauge polyvinyl chloride (20 G PVC) to account for this.

3.2.3.5 Transparent

Due to the range of traumatic injuries that may result in hemorrhagic shock, the properties of the device must accommodate the need for patients and clinicians to monitor the patient's body while the device is in use. In scenarios such as laceration injuries or external traumatic bleeding, it is of particular importance that the patient's injury is visible for condition monitoring. To achieve transparency, 20 G PVC, a translucent material was utilized to allow for skin visibility. The transparency and haze of the materials under various conditions were tested in accordance with ISO 14782:1999, the standard for determination of haze of transparent materials.

3.2.3.6 Measure Pressure Applied

Compression, as a treatment option, achieves a significant improvement in blood pressure to vital organs by addressing shock through the shunting of blood from the lower limbs. The material of this device needs to be strong enough to withstand the pressure from the compressive wrapping, while successfully shunting the blood flow to centralize the circulatory flow. In order to measure the pressure applied mechanically, pressure sensors will allow for real time analysis of pressure applied. A wearable tactile pressure sensor would allow for measurement of the compression on the patient's skin, and a piezo resistive textile pressure sensor could be incorporated into the material of the device to analyze the force applied by the segments of the garment. The value of the force applied could be cross referenced with the value of the force endured by the patient. A force sensitive resistor achieves the same goal by correlating bit value and pressure using a standard to calibrate the sensor. This system must be developed in accordance with ASTM F2070 - 00(2017), which outlines the standard specifications for transducers for pressure applied and pressure differential.

3.2.3.7 Application by Two or Less Medical Professionals

The suit must be able to be applied by two or less medical professionals. To avoid occupational injuries, there is 35-pound safe lift limit for nurses. Translated to a force, the required force to apply the device needs to be less than or equal to 155.69 N. To test this, the device will be assessed through user studies. By incorporating fasteners or other mechanical fixtures, the device can provide an assistive application in order to amplify the force applied. Maintenance of a light-weight device will ensure it can be lifted and easily put on the patient. Finally, based on having four hands available to secure the device, the device will have less than four parts that need to be held simultaneously.

3.3 Design Requirements (Standards)

3.3.1 *Biocompatibility*

In the future, the final device should be assessed for skin sensitization in terms of the chemical toxicity and physical characteristics. The ISO 10933-1 standard, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process" describes the standards for both *in vivo* and *in vitro* biological safety experiments that are used for the biological evaluation for medical assessment. The standard describes the standard biocompatibility assays that should be as well as animal studies which should be used. These tests are outlined using a risk matrix. Specific tests should be completed to analyze the biological response resulting from device mechanical failure based on the geometric and/or physicochemical properties as they are released from the device. The endpoint assessment should be on the final design of the device.

3.3.2 *Nursing Care Plan*

In order to ensure a patient is receiving the attention they need to remain stable and make positive strides in their recovery, it is important for clinicians to follow a care plan. These plans are documented standards for nurses to reference guiding the monitoring and interventions required. A patient experiencing shock requires thorough evaluation and associated treatment strategies; therefore, a nursing care plan for such a patient consists of cardiac rhythm observation, monitoring of their hemodynamic parameters, fluid status, and the adjustment of medications and treatment therapies as needed [39].

As shock begins to set in, a patient may experience changes in respiration rate as a result of low oxygen intake. Hypoxia can become a more severe threat as shock continues to progress which may lead to hyperventilation and respiratory failure from respiratory muscle fatigue. The patient may exhibit changes in their consciousness or complain of headaches or become restless which are also indicators of hypoxia. Therefore, a clinician must include in their care plan the assessment of the patient's respiration in terms of rate, rhythm, and depth, and keep an eye out for changes in the patient's level of consciousness.

Overall blood pressure will begin to decrease along with the patient's heart rate as shock progresses which could also lead to dysrhythmias of the heart [39]. Assessments of the patient's heart rate and blood pressure are vital and require continuous monitoring.

3.3.3 *Ethical Standards*

For medical treatments to be considered ethical, they must meet the four tenets of ethical medicine: non-maleficence, beneficence, autonomy, and justice. As mentioned earlier, the device does pose a potential risk for creating hospital acquired conditions (HACs e.g., pressure sores, moisture injuries, and shear injuries). Consequently, the clinician must only use the device when its implementation will clearly benefit the patient. The patient should be experiencing shock that is severe enough to result in further damage that can be averted with the use of this device. If the device is implanted on the patient, significant care must be put in to ensure that the risk of the previously mentioned HACs is reduced as much as possible. Furthermore, before the device is applied to the patient, they should have given informed consent for treatment. It is the clinician's responsibility to ensure that their patient is as aware as possible about the course of action that will be taken. Finally, the device must not create inequity between groups. The material of the device allows for clear viewing of the skin independent of skin tone.

3.3.4 *Revised Client Statement*

Following an assessment of the objectives, constraints, and goals of this project, a revised client statement was generated:

Develop a *transparent and cost-efficient* lower-body compression suit *for adult patients in the Intensive Care Unit (ICU)* that will *effectively combat the plateau stage of hemorrhagic shock* and circumvent its consequences by mechanically reducing the intravascular space *as well as maintaining visibility for cutaneous patient monitoring*.

3.4 Project Approach

3.4.1 *Technical Approach*

After revising the project objectives and completing background research, the team began outlining steps for executing the design process which included designing, testing, and evaluating the anti-shock suit. Utilizing the design objectives and constraints, the team referenced a prioritization matrix to create a preliminary ranking of the desired characteristics of the device. The team then conducted a series of interviews with medical professionals who would be likely to use the device when implemented in a hospital setting. In these meetings, the clinicians were given a randomized list of established objectives. They were then asked to separate each item into 'needs', 'wants', and 'not beneficial'. The items were then prioritized and ranked within the category. Afterwards, the team analyzed, then finalized the categorization of these objectives as either 'needs' or 'wants.' This step informed the team which design features can be left out of the initial device design and could potentially be incorporated into future product iterations. The team utilized their findings to prioritize their design objectives. For each defined objective, there was a corresponding function with associated specifications.

The team then entered the ideation phase which included brainstorming, discussing, and describing the conceptual device designs. Each idea was documented and then expanded upon for further design and analysis. The enumeration phase was another critical step in the design process in order to ensure that innovation and creativity remained unbound while staying separate from the decision-making process. The team completed preliminary evaluations to understand the benefits and shortcomings of each of the proposed designs; this process included feasibility experimentation to understand the properties of each material and design.

Mechanical testing was conducted to measure the tensile strength that the material can withstand before rupture. Testing was completed to measure the elastic deformation properties as well as the fatigue limits to ensure the device can be adjusted several times. Additionally, the team studied the transparency and visibility characteristics of each material using optical testing techniques as well as considering the impacts of moisture.

At this point in the design process, the team utilized componential prototypes to understand how the different parts function. Next, using a ranking system which included the design requirements and preliminary designs, the team determined which solution to proceed with. The team then developed computational modeling techniques to demonstrate how the design will effectively combat the disease state and employ this modeling to collect preliminary data on the proposed design.

Testing continued throughout the remainder of the project which expanded upon preliminary experimentation. Functional engineering standards were referenced when testing potential materials which allowed the team to make informed design decisions. The prototype and testing phase became cyclic as the team continued to learn more about the efficacy of the design. The resultant testing data then underwent a quantitative analysis to assist the team in understanding the validity of the characteristics. Finally, the team holistically evaluated the

proposed anti-shock suit. Each step of the design process, limitations of the design, and recommendations for future improvements were compiled into a detailed and formalized written report.

3.4.2 *Financial Approach*

Each team member was allocated $250 from the Biomedical Engineering Department, collectively providing the group with a maximum total budget of $1,000. As is defined by the project goal, the team created iterative prototype designs with a summative design that was presented at the conclusion of the academic year. The funds were spent on purchasing materials to create these prototypes that assisted in the formulation of the final design. The actual purchase history is detailed in **Table 5**.

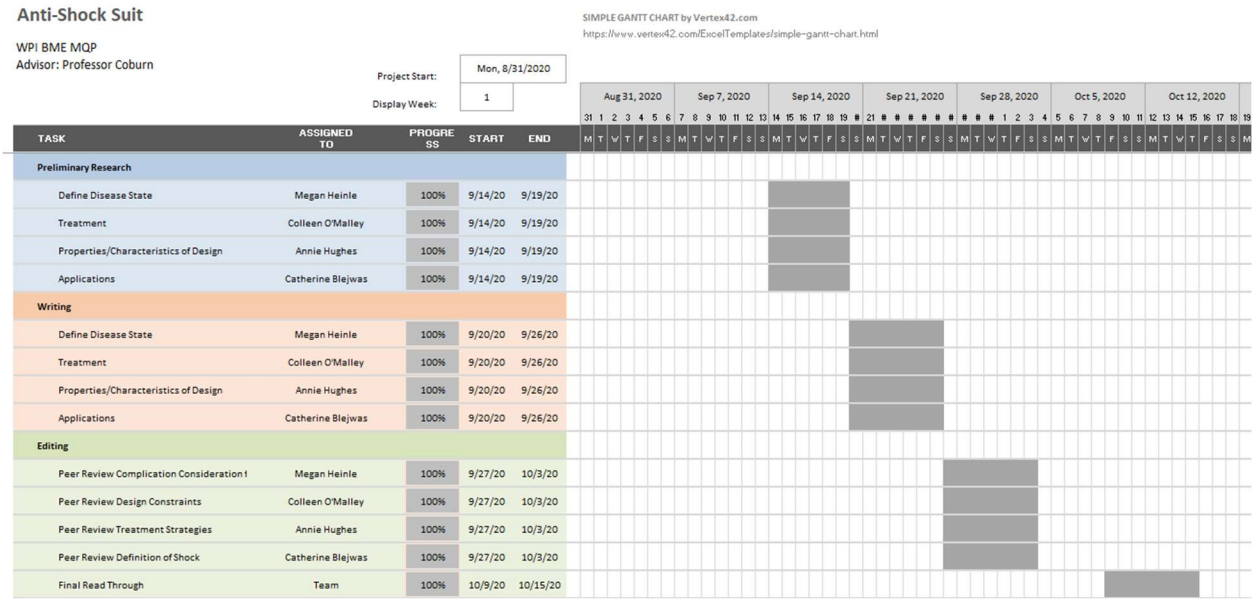
Table 5: Itemized List of Purchased Items

Item	Cost (USD)
AmazonBasics Shower Curtain Liner	12.31
mDesign Shower Curtain Liner	9.99
Compression Socks	10.95
Hydrapack Water Bladder	75.90
Neoprene	14.8
Collapsible Water Container	11.99
16-Gauge Vinyl from JoAnns	16.78
Water- and Chemical-Resistant PEEK Film	11.80
Clear Moisture-Resistant Polyester Film	13.65
Home Depot Adhesive Purchase	65.64
AmazonBasics Shower Curtain Liner	23.76
FOSER Daisy Chains	25.18
GRLIFE Daisy Chain Rope	19.98
Soft Loop Tie Down Straps	19.90
Teflon Sewing Foot	5.99
Polyester Sewing Thread	14.99
SINGER Sewing Machine Needles	4.99
Strings for Harp	13.99
Bungee Shock Cord	6.99
Single Hole Spring Toggle Stopper Cord Stops	4.49
Double Hole Spring Stopper Fastener Slider Toggles End	7.38
3M Dual Lock Reclosable Fastener	30.69
Female Plastic Thigh High Mannequin Leg	40
Pangda Grommet Tool Kit	9.99
3D Printed Components (buckle & rod)	negligible
Total	**472.13**

3.4.3 *Management Approach*

The team used a Gantt chart as shown in **Fig. 6**, which displays the timeline and distribution of tasks throughout the academic year. The team utilized a flat and informal structure to promote collaboration, creativity, and innovation. To ensure that the team maintained high

levels of productivity and accountability, rotating chair and secretary roles were assigned for all meetings.



Anti-Shock Suit

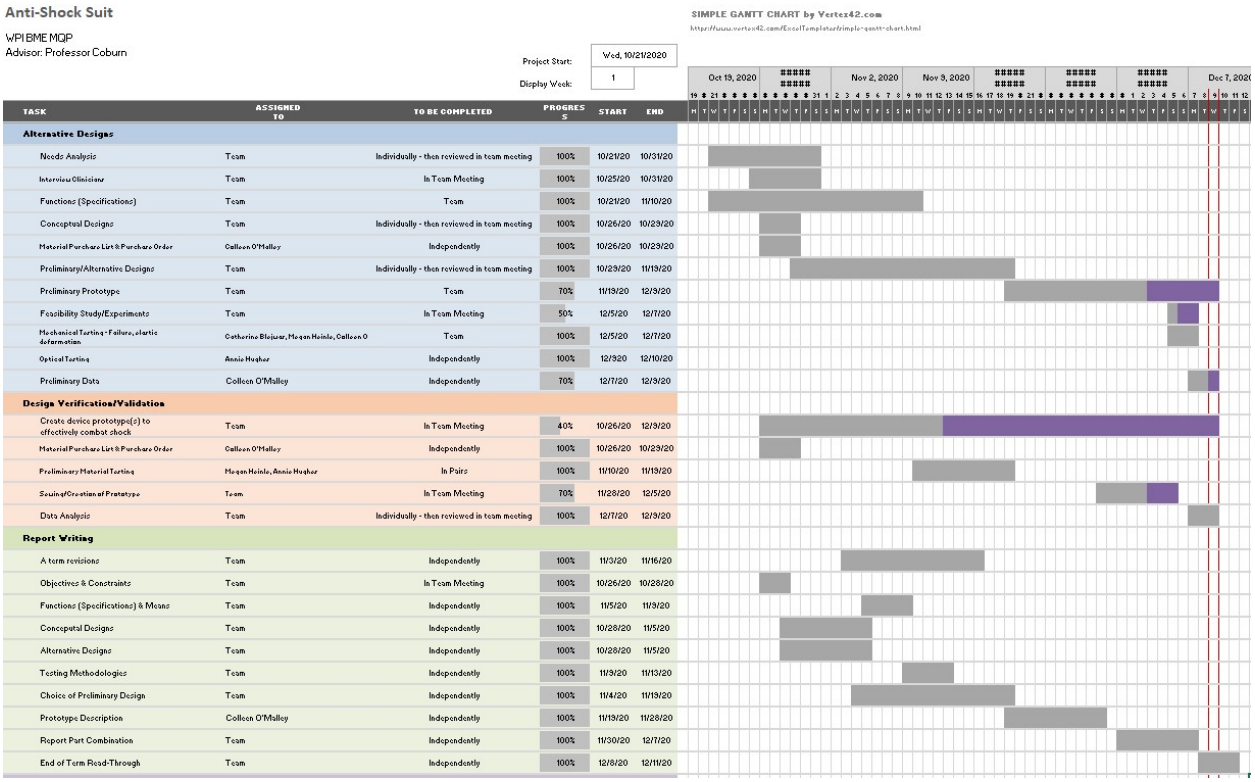
WPI BME MQP
Advisor: Professor Coburn

SIMPLE GANTT CHART by Vertex42.com
https://www.vertex42.com/ExcelTemplates/simple-gantt-chart.html

Project Start: Mon, 8/31/2020
Display Week: 1

TASK	ASSIGNED TO	PROGRESS	START	END
Preliminary Research				
Define Disease State	Megan Heinle	100%	9/14/20	9/19/20
Treatment	Colleen O'Malley	100%	9/14/20	9/19/20
Properties/Characteristics of Design	Annie Hughes	100%	9/14/20	9/19/20
Applications	Catherine Blejwas	100%	9/14/20	9/19/20
Writing				
Define Disease State	Megan Heinle	100%	9/20/20	9/26/20
Treatment	Colleen O'Malley	100%	9/20/20	9/26/20
Properties/Characteristics of Design	Annie Hughes	100%	9/20/20	9/26/20
Applications	Catherine Blejwas	100%	9/20/20	9/26/20
Editing				
Peer Review Complication Consideration t	Megan Heinle	100%	9/27/20	10/3/20
Peer Review Design Constraints	Colleen O'Malley	100%	9/27/20	10/3/20
Peer Review Treatment Strategies	Annie Hughes	100%	9/27/20	10/3/20
Peer Review Definition of Shock	Catherine Blejwas	100%	9/27/20	10/3/20
Final Read Through	Team	100%	10/9/20	10/15/20

Figure 6(a): Gantt Chart A Term



Anti-Shock Suit

WPI BME MQP
Advisor: Professor Coburn

SIMPLE GANTT CHART by Vertex42.com

Project Start: Wed, 10/21/2020
Display Week: 1

TASK	ASSIGNED TO	TO BE COMPLETED	PROGRESS	START	END
Alternative Designs					
Needs Analysis	Team	Individually - then reviewed in team meeting	100%	10/21/20	10/31/20
Interview Clinicians	Team	In Team Meeting	100%	10/25/20	10/31/20
Functions (Specifications)	Team	Team	100%	10/21/20	11/10/20
Conceptual Designs	Team	Individually - then reviewed in team meeting	100%	10/26/20	10/29/20
Material Purchase List & Purchase Order	Colleen O'Malley	Independently	100%	10/26/20	10/29/20
Preliminary/Alternative Designs	Team	Individually - then reviewed in team meeting	100%	10/29/20	11/19/20
Preliminary Prototype	Team	Team	70%	11/19/20	12/9/20
Feasibility Study/Experiments	Team	In Team Meeting	50%	12/5/20	12/7/20
Mechanical Testing - Failure, elastic deformation	Catherine Blejwas, Megan Heinle, Colleen O	Team	100%	12/5/20	12/7/20
Optical Testing	Annie Hughes	Independently	100%	12/3/20	12/10/20
Preliminary Data	Colleen O'Malley	Independently	70%	12/7/20	12/9/20
Design Verification/Validation					
Create device prototype(s) to effectively combat shock	Team	In Team Meeting	40%	10/26/20	12/9/20
Material Purchase List & Purchase Order	Colleen O'Malley	Independently	100%	10/26/20	10/29/20
Preliminary Material Testing	Megan Heinle, Annie Hughes	In Pairs	100%	11/10/20	11/19/20
Sewing/Creation of Prototype	Team	In Team Meeting	70%	11/28/20	12/5/20
Data Analysis	Team	Individually - then reviewed in team meeting	100%	12/7/20	12/9/20
Report Writing					
A term revisions	Team	Independently	100%	11/3/20	11/16/20
Objectives & Constraints	Team	In Team Meeting	100%	10/26/20	10/28/20
Functions (Specifications) & Means	Team	Independently	100%	11/5/20	11/9/20
Conceptual Designs	Team	Independently	100%	10/28/20	11/5/20
Alternative Designs	Team	Independently	100%	10/28/20	11/5/20
Testing Methodologies	Team	Independently	100%	11/9/20	11/13/20
Choice of Preliminary Design	Team	Independently	100%	11/4/20	11/19/20
Prototype Description	Colleen O'Malley	Independently	100%	11/19/20	11/28/20
Report Part Combination	Team	Independently	100%	11/30/20	12/7/20
End of Term Read-Through	Team	Independently	100%	12/8/20	12/11/20

Figure 6(b): Gantt Chart B Term

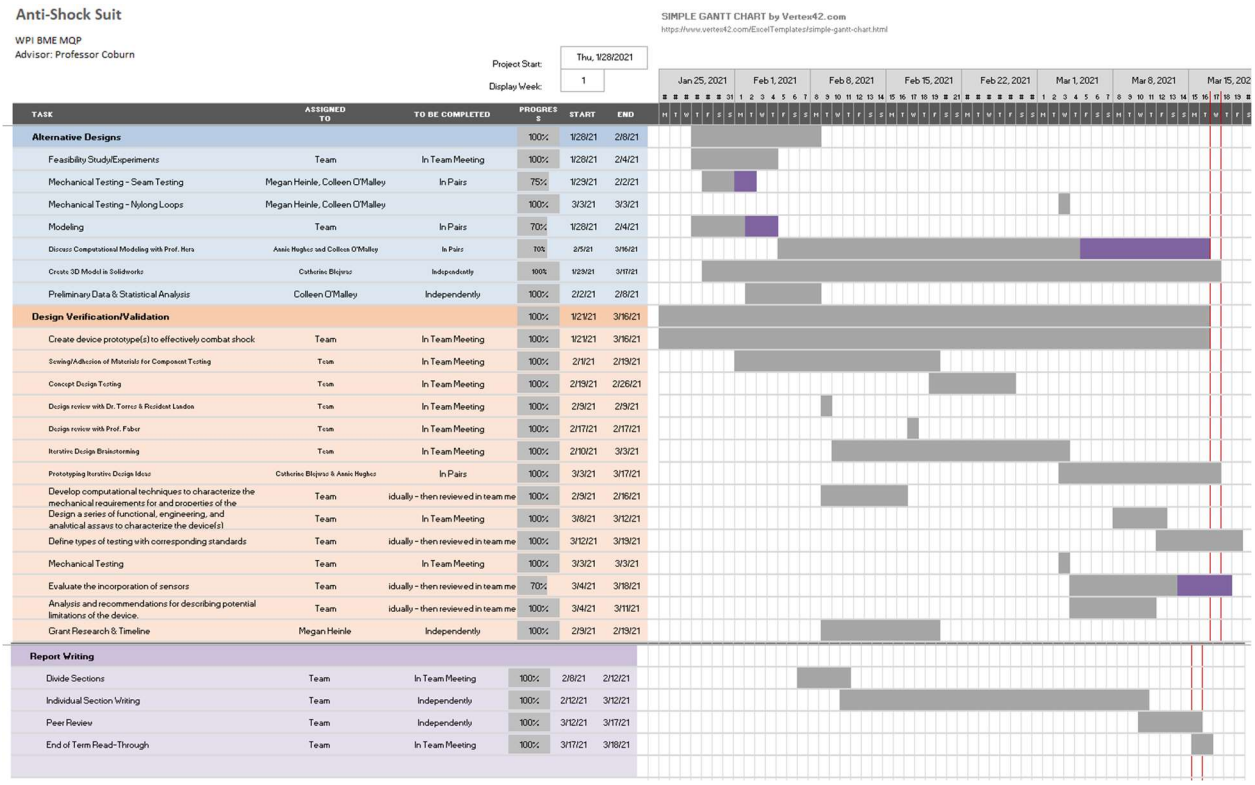


Figure 6(c): Gantt Chart C Term

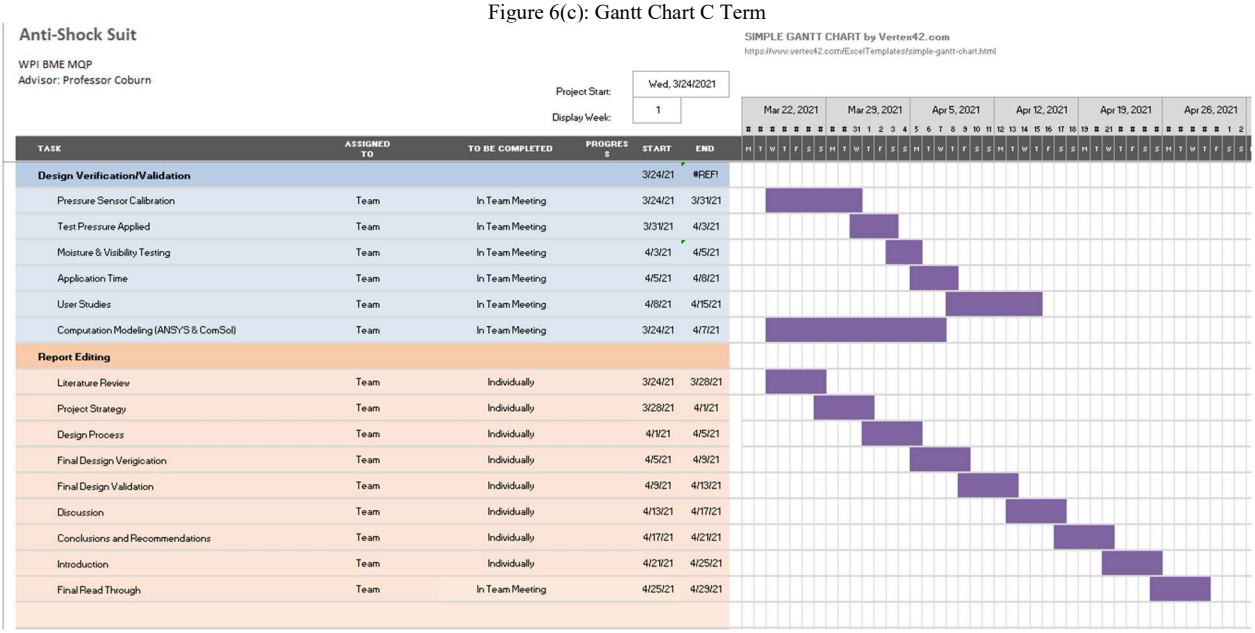


Figure 6(d): Gantt Chart D Term

4.0 Design Process

4.1 Needs Analysis

A needs analysis was completed in phases to determine the categorization of various characteristics of the anti-shock trousers as needs versus wants, shown in **Table 6**. The team held a discussion to set a baseline and then documented this protocol to be implemented during clinician interviews.

Table 6: Needs & Wants

Needs	Wants
Accessibility for intervention	Cost Efficient
Visibility for wound monitoring and patient assessment	Lightweight
Treat hemorrhagic shock	Cut apart in emergent situations
Easily applied and removed	Non-toxic, breathable materials for perspiration and/or condensation
Progressive and gradual application and removal	Imaging Compatibility –ultrasounds
Causes no skin sensitization (irritation)	Temperature regulated

Effectively shunt blood centrally from the periphery without causing direct pressure injuries - avoid pressure wounds	• Sensors
	  ○ Blood Pressure
	  ○ Body Temperature
	  ○ Heart Rate
	  ○ Respiration Rate
	  ○ Pulse Oximetry
	  ▪ Pulse Rate
	  ▪ Blood Oxygenation Saturation

Quantifying/monitoring pressure applied by device on body	Ergonomic design

The needs column consisted of criteria such as accessibility for intervention, which allows the patient to receive treatment and be easily monitored by the medical team. This requires each of the segments to be individually adjusted and detachable so that specific areas of the lower body can be excluded based on injury. Likewise, visibility for wound monitoring and patient assessment is essential to track progress of blunt trauma injuries and ensure that the skin is protected from pressure sores. Additionally, the device needs to be able to be easily applied and removed so that it can be applied by medical professionals in under ten minutes. The progressive and gradual application and removal of the device is classified as a need to ensure that a change of applied pressure does not negatively impact the clinical state of the patient. As the device may be contacting blood due to its use for hemorrhagic shock, it must be made of a material that does not cause any type of skin sensitization. This includes ensuring that it is hypoallergenic and inhibits the growth of bacteria within the environment. Producing a cost-efficient product is a need as this will allow the device to be more accessible for use in hospitals, independent of financial status. Finally, to achieve the desired goal of an anti-shock device, it needs to effectively shunt blood from the periphery without causing direct pressure injuries. With this, the device or an additional feature will need to quantify and monitor the pressure that the device applies to the patient's body.

Wants were identified as characteristics to consider but would not be implemented until future design iterations. The device is intended to be lightweight, and in emergent situations, the material should be able to be cut apart. This is classified as a want, not a need, as it is not a design priority as the team understands that cutting the device minimizes the reusability. Material selection was based on various criteria, however, finding a non-toxic breathable material to diminish perspiration or condensation that may arise on the surface of the device will require further evaluation. At this stage of the project, visibility was prioritized over breathable material. Since shock decreases circulation, the device should be compatible with medical equipment used for imaging, specifically ultrasound compatibility to check for blood clots. The implementation of a segmented design will achieve this. Considering the intended use, future iterations would benefit from the incorporation of sensors that would allow for remote and continuous patient monitoring. Patient vitals to consider monitoring include blood pressure, body temperature, heart rate, respiration rate, and pulse oximetry to record the pulse rate and blood oxygenation saturation.

4.1.1 *Clinical Interviews*

Interviews with clinicians were conducted to better understand the current treatment strategies for shock. The Clinical Interview Questions and Protocol are noted in **Appendix A**. The interview started by asking the interviewee about their experience as a medical professional. The clinician was then prompted to share their personal encounters with patients experiencing shock including symptoms, treatment strategies, and any complications that arose. These questions were posed again, in specific reference to hemorrhagic shock; asking what treatment strategies were used, patient compliance in terms of the treatment process, and any potential

areas of improvement for treatment. Lastly, the team directly asked the interviewee if they had ever used any type of anti-shock device and if so, share the advantages of it as well as any challenges they may have faced. Afterwards, the interviewee was provided with a list of design objectives and asked to separate them into three categories: needs, wants, and not beneficial. The clinicians were then asked to identify their top five needs. This activity provided the team with an understanding of what objectives should be prioritized; thus, differentiating those from others that could be tabled for future design iterations.

Nursing Student A is currently a senior at Boston College and shared her experience working as a patient care assistant (PCA). Working as a PCA for the past two years, Nursing Student A discussed the last time she encountered a patient in shock as well as the treatment strategies covered in her educational career. During her time at Mass General working on the labor and delivery floor, she assisted with treatment of a patient experiencing postpartum hemorrhaging. This occurred 10 hours after the patient's delivery of a single child. Nursing Student A shared that the current treatment strategy is to administer blood products including packed red blood cells, frozen, fresh plasma, and platelets in a one to one-to-one ratio. While waiting on blood products, crystalloid 0.9% saline is used as a fluid replacement.

Although Nursing Student A's clinical experience is limited thus far, she noted the ideas of esophageal varices which utilizes a treatment strategy that inflates balloons in order to physically hold pressure on the site. A concern that was raised with the current treatment strategy of general fluid volume replacement is risk of organ damage specifically prerenal acute kidney injury. Nursing Student A noted that compression as well as early indication of shock would improve the treatment process. The results of this classification are shown in **Table 7**.

Table 7: Nursing Student A's Needs, Wants, & Not Beneficial Rankings

Needs	Wants	Not Beneficial
Treat hemorrhagic shock	Transparent for easy viewing	Anti-perspirant
Easily applied and removed	Lightweight device	
Customizable	Ergonomic design	
Biocompatibility	Imaging compatibility	
Cost efficient	Temperature regulated	
	Hypoallergenic	
	Effectively shunt blood	

Emergency Medicine Physician B offered insight from her perspective of delivering care in an emergency room setting. As an Attending Physician she encounters patients in shock almost every shift in the level 1 trauma ER. She described the physical symptoms that would require emergency treatment for shock as low blood pressure, an altered mental state, cool extremities, and a diminished ejection fraction as identified in a heart echocardiogram.

Specifically, for septic shock, she noted that she observes fever, sweating, and warm extremities. In Medicine Physician B's experience working in the emergency room, she noted that she had never used an anti-shock device, due to the abundant access to blood products for other types of treatment such as massive transfusion protocols. The treatment process in a trauma setting typically includes fluids, pressers, and antibiotics. Another alternative to the compressive treatment suit that she mentioned was the use of a Resuscitative Balloon Occlusion of the Aorta (REBOA) which clamps off the aorta to control bleeding and maintain blood pressure after shock. Due to her lack of experience with these devices Medicine Physician B did not identify her preferred device criteria, but her insight into alternative trauma treatment options was valuable.

Medical professional C, a board-certified and fellowship-trained specialist in critical care medicine, provided the team with more insight on the treatment of shock in an ICU setting. During the interview, he expressed that almost one out of every four patients he sees in a day expresses some form of shock. The most common type that he reports seeing is hemorrhagic shock. When hemorrhagic shock patients are brought into the ICU the first goal is to restore blood volume. This is typically accomplished through the administration of IV fluid and 30 mL of blood per 1 kg of body weight. Directly after this, the team addresses the source of shock. They do this to ensure that it does not progress and so the symptoms do not worsen. Next, any possible organ damage or other complications are addressed. Medical professional C did not sort the device criteria, but he did provide input regarding the steps taken for treatment of a patient in shock when they are admitted to the ICU.

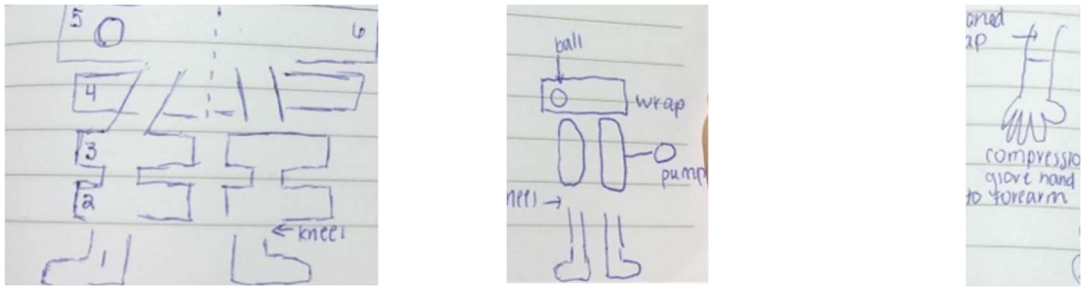
4.2 Conceptual Designs

Prior to coming together to determine a preliminary design, team members independently brainstormed and sketched individual design ideas.

The first design, shown in **Fig. 7a**, uses compression socks covering the area of the leg from the toes to the knees. This section would be made of stockinette and applied with a ring to ensure that it is tight around the lower leg. From the knee to the hip, there would be a non-pneumatic segmented wrap design with three sections around the thighs. Around the abdomen there would be a wrapped design that includes a foam ball for increased pressure.

The second design, displayed in **Fig. 7b**, uses compression socks covering the area of the leg from the toes to the knee, with the same conceptual idea as the first design. From the knee to the hip, there would be a pneumatic component around the thighs with an external pump. Finally, there would be a non-pneumatic section wrapped around the abdomen including a foam ball for increased centralized pressure.

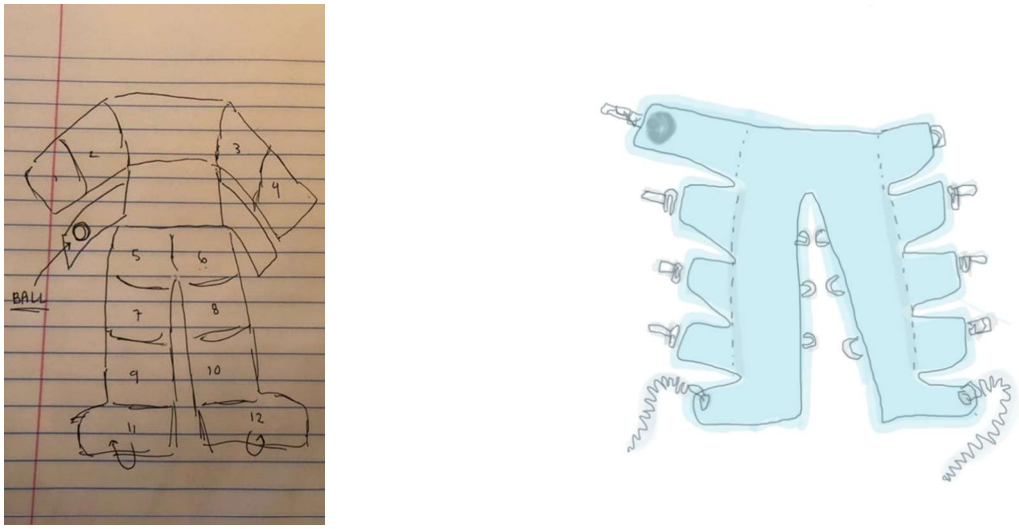
Both designs consider an additional segment for the arms shown in **Fig. 7c**. Starting with a compression glove that starts at the fingers and goes to the elbow. Around the upper arm, there would be two non-pneumatic wrap sections.



(a) (b) (c)

Figure 7(a-c): Conceptual Design 1

The design displayed in **Fig. 8a-b** includes wrap features which allow for mechanical compression and visibility. All segments would be made from transparent non deforming plastic, with pressure sensors in each segment. The pressure sensors would allow for confirmation that enough pressure was being applied and indicate whether the closure mechanism was properly secured. The torso section would have a removable foam ball to apply to the uterus region for additional centralized pressure in female patients, to be utilized in post-partum hemorrhaging scenarios. The foot section would be inflatable by pneumatic pressure distributed by an external tank system.



(a) (b)

Figure 8(a-b): Conceptual Design 2

4.3 Alternative Designs

As shown in **Fig. 9**, an alternative design relies on a chemical reaction to inflate and simultaneously apply pressure to the patient's body. It consists of one large multilayer sheet with segregated compartments containing various amounts of baking soda. Pre-attached rubber tubes consisting of one-way valves allow for a mixture of water and citric acid to be inserted via syringe and induce a chemical reaction to form carbon dioxide gas. The design also consists of multi-segmented layers of plastic clasps to ensure that the device can be securely wrapped around the patient and adjusted based on their physiological needs. A fallback of this design is the inability to reverse the chemical reaction and simultaneously decrease the applied pressure. The suit may be gradually loosened, but the chemical reaction cannot be undone and therefore the utilization of this design would require great precision which may become time consuming and delay patient treatment. Additionally, the device may not be reused.

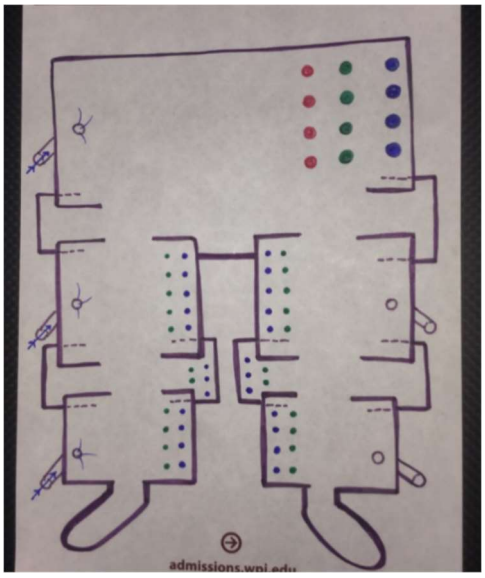


Figure 9: Alternative Design 1

Another alternative design that the team considered is shown in **Fig. 10.** This design has two primary components—a pair of pants which also enclose the feet and a belt around the waist. The pants would be made from a transparent, ductile plastic with Ziplock technology along the sides for easy access to the limbs and to allow for easy implementation and removal of the device. The belt at the waist ensures that a tight seal can be made and prevents any air from entering. The vacuum port allows for the air within the pants to be sucked out once the pants have been put on the patient. When implementing this device, it is important that the legs would be elevated as this device cannot be applied in sections. If blood is trapped in the lower section of the extremities, compartmentalization syndrome could set in. A pressure sensor would be incorporated into the device to measure the pressure being applied to the patient by the device.

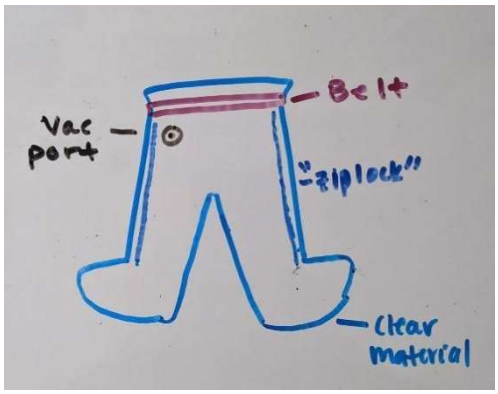


Figure 10: Alternative Design 2

4.4 Final Design Selection

The preliminary design idea was based on a compression sock to be worn from the toes to the knee. From there, a non-pneumatic wrap design made of a transparent material was selected. The team chose a non-pneumatic design over an inflatable design because a pneumatic device would require an external compressor to inflate each section of the suit, which ultimately would become cumbersome in an ICU setting. A non-pneumatic approach ensures a clear, unobscured visibility of the patient's legs which allows for monitoring of wounds and the prevention of potential pressure injuries. There was also a concern raised that a pneumatic suit may allow for buildup of condensation within air pockets, ultimately reducing visibility of the patient's skin. Whereas a non-pneumatic design allows for the application of a precise pressure that can be gradually applied then removed. Additionally, pneumatic devices require more physical space for storage and during use, as an external air compressor is required to inflate the device. For inflation, the device requires that the air pocket has a seal that will not permit leakage. As is true with blood pressure cuffs, the device would begin to deflate over time which also concerned the team. The material choices that were considered for the device include thermoplastic polyurethane, clear vinyl, low- and high-density polyethylene, and polyvinyl chloride. Overlapping segmented flaps were included in the initial design to ensure that no skin was excluded from the compression to prevent compartmentalization. The abdomen section also included a detachable foam ball to be used if needed, ultimately dependent upon the injury triggering the hemorrhagic shock.

4.4.1 *Prototype Process*

The dimensions of the prototype were based on the physical measurements of a 21-year-old female team member to ensure that the team could efficiently evaluate the device fit. **Table 8** displays the measured dimensions utilized for the prototype.

Table 8: Preliminary Prototype Dimensions

Body Part	Circumference [cm]	Flap Length (per side) [cm]
ankle	21.5	10.75
mid-calf	26.5	13.25
knee	36	18
quarter thigh	45	22.5
mid-thigh	49.5	24.75
¾ thigh	53	26.5
hips	85.5	42.75
abdomen	74.5	37.25

As shown in **Fig. 11**, an outline of the team member's lower body was traced on paper. Then, for each body part, the above dimensions were used, and the flap length for each side of the leg was determined to be equal to half of the circumference. The width of the leg was then added to these values to ensure there was ample fabric to wrap around the body. The length of the inner flaps was originally constrained by the width of the inner legs. Therefore, the outer flaps were made longer to compensate for the shorter inner flaps. This did not allow for an ideal connection point, as the underside of the leg is not easily accessible. For the next design iteration, the team's intention was to make the inner and outer flaps more even to ensure that the connection point would be located either on the top or outer edge of the leg for ease of access. To accomplish this, a centerline was drawn down the outline of both legs and was used as the starting point for measurements.

(a) (b) (c)

Figure 11(a-c): (a) Traced Outline on Paper. (b) Traced Outline on 20 G PVC (c) Assembled and Tacked Prototype

This design consisted of one sheet of material that was made from the outline of the legs, where three out of the seven flaps extended from the main segment. The other four flaps were overlap flaps that attached to the main segment to ensure that there were no gaps between sections that could leave part of the leg exposed and potentially cause compartmentalization. Theoretically, these three segments would be connected to the main segment by a layer of shoe glue along a centerline on the posterior of the leg.

4.4.2 *Initial Design Iteration Improvements*

The next step in the design process was to finalize the material selection. The first prototype iteration was made of 20-gauge PVC. The team made plans to conduct tensile testing on different material options and utilize the CES EduPack database to determine other viable options. Additionally, the team considered angling the segmented flaps, as shown in **Fig. 12**, to create constant constriction around the body despite the gradient circumference of the leg. In order to accomplish this, the team would need to find a model of the human body with corresponding dimensions to ensure an accurate fit. To finalize the method of connection and securing of the device segments, the team made plans to further analyze various types of adhesion and sewing patterns as potential options.

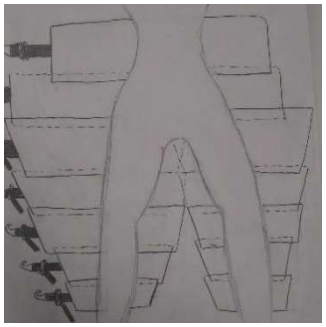


Figure 12: Anti-shock Suit with Angled Segmented Flaps

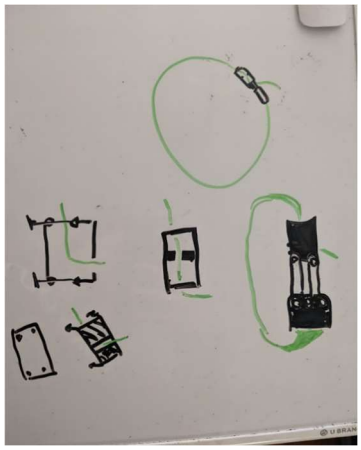
4.4.3 *Updates to Initial Design Iteration*

Mid-project, the team met with project client, Dr. Torres, accompanied by the medical resident that initially presented the idea, Dr. Landon Guntman, and discussed the design displayed in **Fig. 12**. This design consisted of a nylon strap connected to the PVC segment that would wrap around the entire leg and be secured with a hook onto a belt-style daisy chain. Both doctors expressed concerns about the idea due to the risk of potentially inducing HACs. The belt-style securing system would create concentrated areas of pressure which could create high-risk scenarios for pressure injuries. Additionally, HACs have been a critical factor in treatment management for clinicians as they need to ensure that the device does not cross the threshold of doing more harm than good. The team requested feedback regarding the anticipated application time for the daisy chain loop and incremental tightening method. The clinicians noted that the total application process would take longer than desired. The initial goal time of 4.7

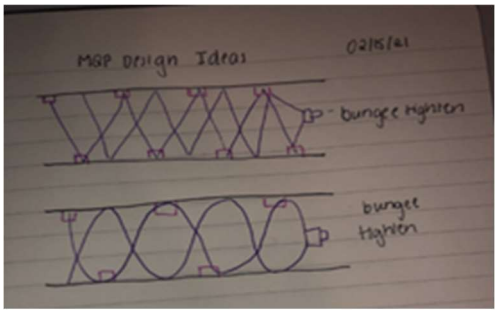
minutes was determined as part of an effort to combat a documented limitation of the MAST, its extensive donning time. However, Dr. Torres clarified that the application time does not need to be so stringent, as the intended use is for patients in the plateau stage of shock as opposed to emergent situations. Therefore, there would be a slightly larger time buffer in which device application could take place. The discussion pivoted to discuss alternative techniques for securing the device. Dr. Torres introduced the traumatic pelvic orthotic device (TPOD) used for pelvic stabilization. This device uses a back brace and is tightened with circumferential wires and Velcro. Additionally, the team considered Boa® Fit dials, a tightening technology that uses a dial, lace, and guide that is incorporated into various sports apparel as well as medical equipment.

Dr. Torres also commented on the prevalence and reliability of Jobst stockings, which have been a staple for medical professionals as they are highly effective. Jobst stockings come in varying pressure application ranges with the maximum applied pressure reaching 30 to 40 mmHg. In terms of pressure application, it was noted that from the toes to the leg, there must be a crescendo of pressure—largest pressure being applied at the feet, slowly decreasing pressure in each section up to the hips—to protect against any potential compartmentalization issues. In a follow up message after the conclusion of the meeting, Dr. Guntman shared that he had imagined that the product would be discarded after each patient; therefore, a single-use device.

After this meeting and subsequent team discussions, the team decided to focus on a singular segment of the anti-shock trousers. Team members brainstormed additional design ideas that specifically focused on the securing and tightening techniques. One idea, shown in **Fig. 13a**, displays a buckle with an open and closed setting. The PVC segment can be threaded through the buckle and when closed, would latch into place holding the device tight. The other end of the PVC would be attached to a TPOD tightening mechanism which would then connect to the buckle. Another team member shared the concept of using a bungee cord, threaded through a series of loops on both sides of the opening, and a bungee tightener to pull the edges of the segment together as displayed in **Fig. 13b**. An alternative design, shown in **Fig. 13c,** included a hook and eye to secure the device around the patient's limb with another opening to tighten the segment and apply the desired pressure via Boa® Technology. Similarly, this design idea can incorporate a buckle, as shown in **Fig. 13d**, to provide some mechanical advantage, and then utilize Velcro to secure the segment. Lastly, in **Fig. 13e**, a zipper was considered for the closure technique in conjunction with the Boa for tightening, as well as an underlap flap to ensure the skin would not be pinched or compartmentalized as the device was tightened.



(a)



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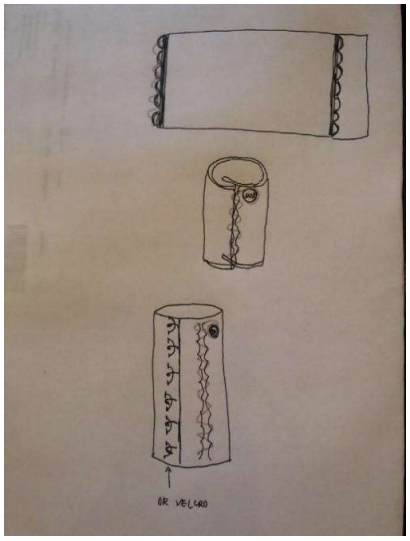
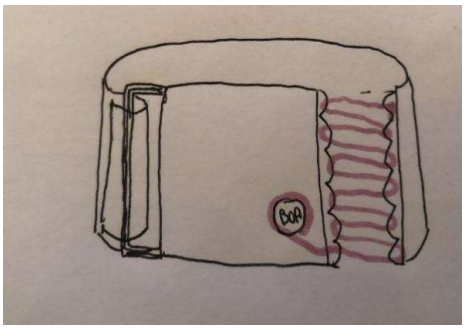
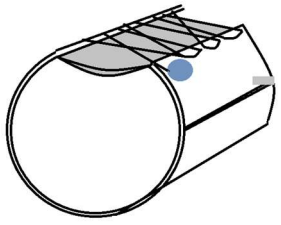


(c)



(d)



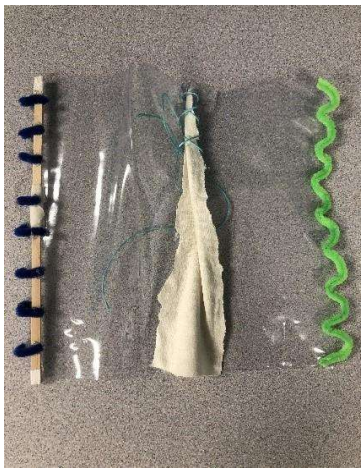
(e)

Figure 13(a-f): (a) Buckle. (b) Bungee. (c) Hook & Eye with Boa. (d) Buckle with Boa. (e) Zipper with Boa and underlap flap.

During the design process, the team met with a WPI professor, Professor A, who is also a practicing paramedic. He provided the team with valuable insight and recommendations to consider for future iterations. He raised a concern regarding the reusability of the device. He stated that it would be very difficult to clean blood out of the intricacies of the device—specifically noting the crevices of Velcro, zippers, and any other closure technique. The device should not include any elements that may be too difficult for those with less dexterous hands to use, and even in outdoor settings with varying weather conditions. Based on the device's objective to effectively shunt blood, Professor A recommended that the team further investigate and analyze the workings of a tourniquet. A tourniquet uses a strap that is threaded through a buckle then secured with Velcro tightly around the patient's extremity. The rod of the tourniquet includes the strap looped through and is twisted to further tighten and effectively cut off blood flow. There are clasps and an additional Velcro strap that secure the rod into its locked position. The rod of a tourniquet provides a mechanical advantage by increasing the torque involved when twisting the device.

The team considered various techniques for the closure of the device and preliminary securing methods. Visibility was a key factor to be considered, especially since the device needs to be adjustable to correspond to the size of the patient. As the device is tightened, the components that are involved can become a source of visible obstruction. Likewise, this is a potential point of failure due to the mechanical stress applied in such a concentrated area. Velcro was considered because of its mechanical strength and the availability of various types of Velcro, such as transparent Velcro, that would minimize view obstruction. Additionally, the incorporation of a zipper was considered, then discarded, based on the concern that if combined with a tightening fixture, the teeth of the zipper would pull apart. Thus, resulting in pinching of the skin. Lastly, for a single-use device, the team considered using an adhesive strip that would have a peel and stick design to permanently secure the device prior to tightening.

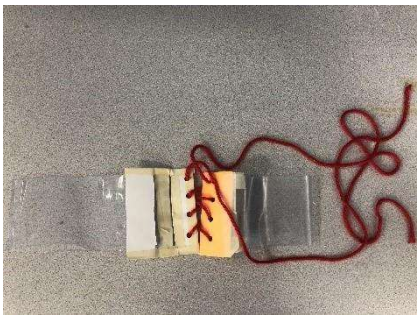
The team completed a prototyping session to visualize the proposed designs and collaboratively brainstorm. The first design shown in **Fig. 14a-c** displays the hooks and eye method to secure the device. The hooks were attached to a rod so only a single motion would be required for application. The silk material would fit underneath the lacing to ensure there was a constant force distributed circumferentially around the leg. In **Fig. 14d-e**, the prototype consisted of a buckle with two openings through which the segment can be threaded. This buckle would provide a mechanical advantage and increase the force acting on the PVC strap to secure the excess material. Lacing was used as the secondary method to tighten the device and reach the desired pressure. In the third design, shown in **Fig. 14f**, lacing was used to attach a piece of material to the underside to maintain the consistent circumferential pressure. Finally, in **Fig. 14g-h**, tape serves as a representation of a strip of Velcro to secure the device, and the pipe cleaner would be threaded through additional holes, like the Boa, and the lacing would then be twisted to tighten the segment.



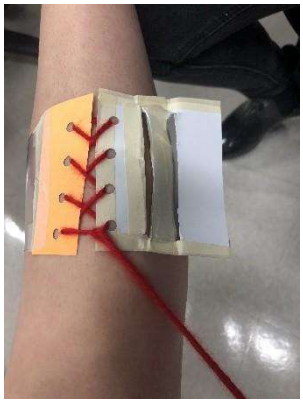
(a)

(b)

(c)

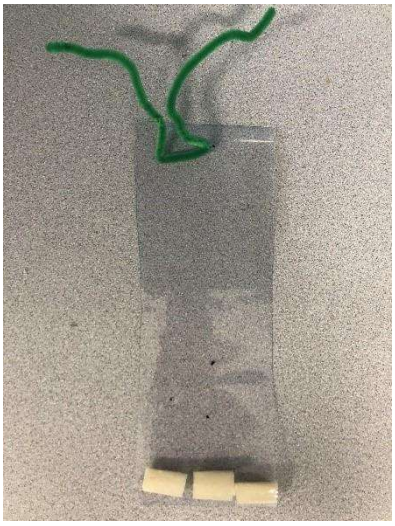


(d)



(e)

(f)



(g)

(h)

Figure 14(a-h): (a-c) Hooks with Rod. (d-e) Buckle with Lacing. (f) Lacing. (g-h) Tape and Pipe Cleaner Twist.

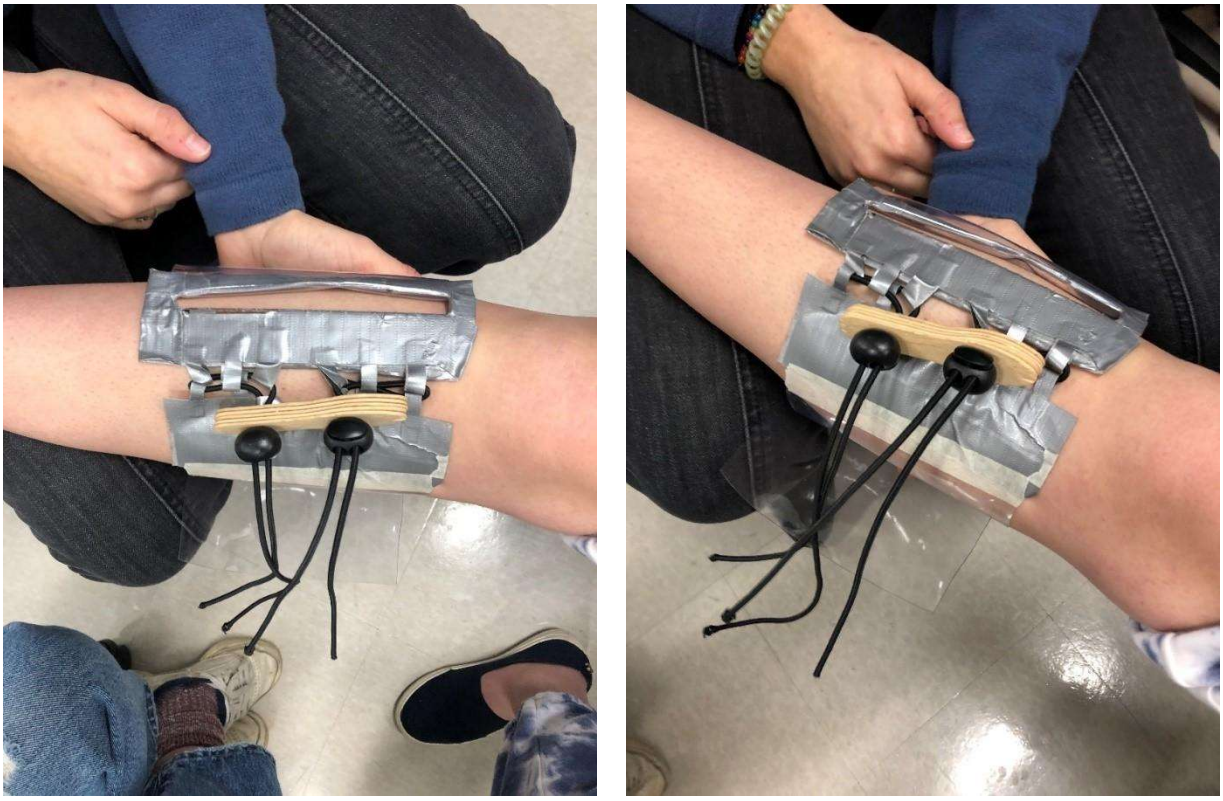
Based on the designs that resulted from the prototyping session, the team conducted further research to understand the various possible elements. The tourniquet rod would provide mechanical advantage by increasing the distance of the applied force from the midpoint and thus, increasing the moment. The ridges on the end of the rod would act as grips and provide friction for the user. The elastic and frictional properties were considered for the laces, as they need to be able to slide through the loops with ease and be pulled tight enough and stay in place in order to apply the required mechanical force. The team considered flat versus cylindrical laces and deemed that the latter would be more effective for the intended design due to their decreased friction. Round laces are considered much more durable than flat laces and their cylindrical design allows them to withstand a stronger applied pressure than that of flat laces [40]. The team then considered grommets, also known as eyelet holes or hooks, to lace through. The team explored different types of Velcro for securing the excess strap. Various types were analyzed including pre-cut strips, a roll, and dots.

The different methods of securing and fastening the segment have various mechanical strengths and visual properties. A buckle the width of the section could be incorporated to meet the appropriate fit for the patient. This feature would provide a mechanical advantage for initial securing as the user would feed it through the opening and then pull it across the buckle with additional mechanical support. The buckle should ideally have appropriate rounding to match the curvature of the leg. There are various types of buckles including ratchet strap buckles and cam lock buckles.

The application for this specific design iteration would be to thread the segment through the buckle then secure it with the Velcro as tightly as possible. Then, the bungee lacing would be tightened. Lastly, the rod should be twisted to apply additional force and then secured in place with a clasp. The concerns and limitations at this point in the design process were that the Velcro might obstruct visibility and would not be flush against the skin. Additionally, the lacing must be strong enough to be pulled tight in order to apply an evenly distributed force to the material across the device segment; ultimately avoiding patient discomfort, concentrated pressure, and the possibility of pressure sores.

This prototype, shown in **Fig. 15**, is representative of an early iteration of the team's final design. The buckle is modeled out of cardboard and reinforced with duct tape. The Velcro is intended to fall on the interior of the leg, rather than the underside of the leg, both for accessibility and to avoid pressure wounds for patients. The buckle and lacing should be located on the outer side of the leg to allow for ease of access for the clinicians when they are securing and tightening the device. Loops, represented by duct tape, were used to lace the bungee through. One set of loops were attached to one edge of the buckle, while the other were attached directly to the flap of PVC. Two bungees were strung towards the center: one from either end of the loops. The two ends of each bungee were then strung through the holes in the rod, modeled with layered popsicle sticks. On the outer side of the rod, the ends of the bungee were threaded through a plastic bungee toggle to be tightened. This is the same for both bungee laces.

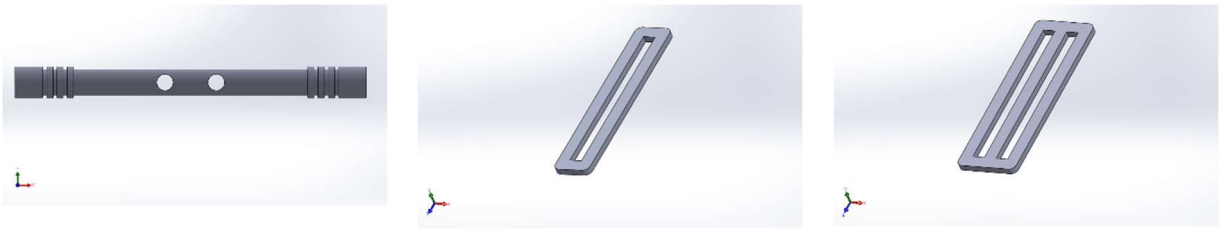
First, the device should be secured as tight as possible with the Velcro. The bungees should then be tightened for increased compression. Finally, the rod should be twisted approximately two turns and then locked into place. In this iteration, the team observed pinching of the skin as a result of the lacing pulling the buckle and PVC together. For this reason, an underlap flap was extended from the buckle, in the opposite direction the segment is worn, to ultimately mimic the tongue of a shoe and minimize the pinching effect.



(a) (b)

Figure 15(a-b): (a) Side View of Prototype. (b) Top View of Prototype.

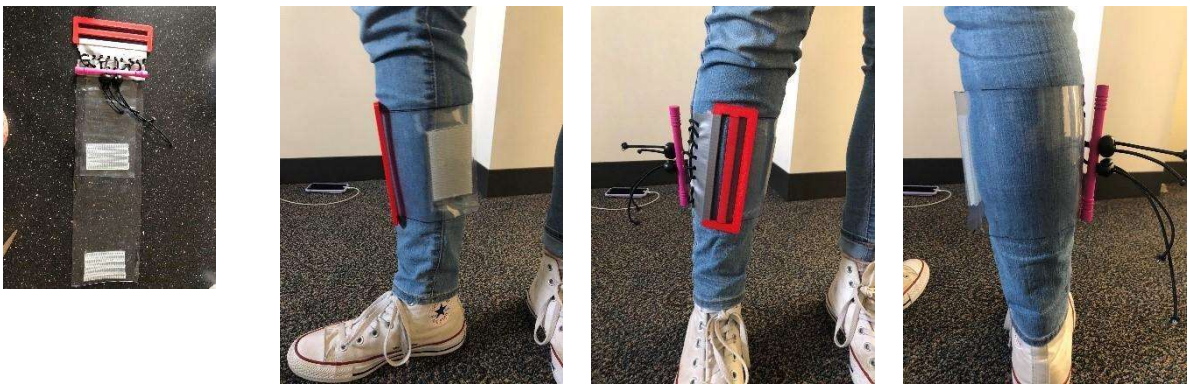
Based on this prototype, the team utilized SolidWorks to model various components of the design and 3D print them. The rod, shown in **Fig. 16a**, was modeled to be approximately the same length as the width of the segment, with ridges on each end for an improved grip. The buckle was modeled with both one slot and two slots, as shown in **Fig. 16b** and **Fig. 16c**, respectively. The reason behind the two-slotted buckle was to mimic that of a belt buckle, which would ideally hold the flap in place more securely. With both 3D printed buckles, the team decided that the two-slotted buckle was preferable as it allowed for a more intuitive application and successfully held the flap in place.



(a) (b) (c)

Figure 16(a-c): (a) Rod. (b) One-Holed Buckle. (c) Two-Holed Buckle.

At this point the team's prototype consisted of a strip of PVC covered in duct tape with punctured holes for lacing, and a 3D printed rod and two-slotted buckle, as well as a strip of transparent Velcro, as displayed in **Fig. 17**. The loose end of the PVC segment was reinforced with duct tape and had pre-punctured holes for the lacing to thread through. After testing, there was some deformation observed at the edge connected to the buckle as well as the loose end.



(a) (b) (c) (d)

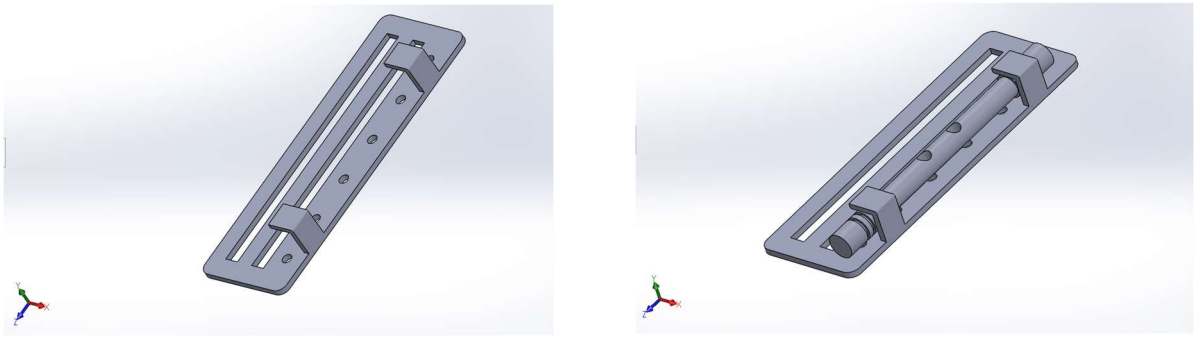
Figure 17(a-d): (a) Flat View. (b) Interior of Leg. (c) Exterior of Leg. (d) Posterior View.

To overcome these challenges, the buckle was then adapted to have six holes along one side, as shown in **Fig. 18a**. For the loose end of the segment, the team purchased and installed grommets to reinforce the punctured holes and prevent further deformation. Another challenge faced was how to successfully secure the rod into place once it was turned and tightened. Hooks, approximately the size of the radius of the rod, were added to the 3D printed buckle to secure the rod and lock it into place, as modeled in **Fig. 18b**.

(a) (b)

Figure 18(a-b): (a) Two-Slotted Buckle with Six Extruded Holes. (b) Two-Slotted Buckle with Six Extruded Holes and Hooks for Rod.

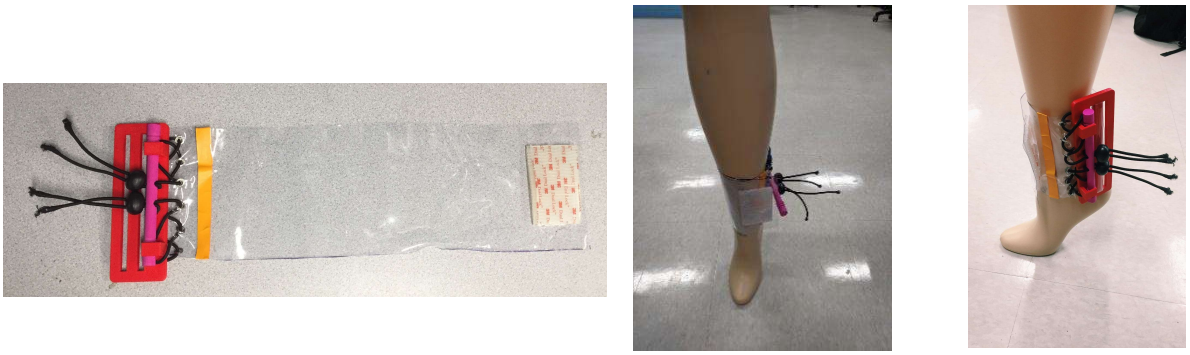
The team encountered difficulty when attempting to 3D print this model. The base of the hooks was not thick enough to support their own weight given the curved architecture of the design, ultimately causing the 3D printed part to fail. From there, the team discussed additional options such as 3D printing the hook component of the model in a different material, considering a different rod lock mechanism, and redesigning the shape of the hooks. Ultimately, the buckle was redesigned to have rectangular hooks, as shown in **Fig. 19**. Additionally, the number of hooks was reduced from three to two to minimize interference with the lacing and twisting of the rod. The thickness of the buckle was reduced from 0.5 cm to 0.3 cm to reduce unnecessary bulkiness with the intention of increasing patient comfort.



(a) (b)

Figure 19(a-b): (a) Two-Slotted Buckle with Rectangular Hooks. (b) Two-Slotted Buckle with Rectangular Hooks for Rod

The final design for a single segment of the anti-shock trousers is shown in **Fig. 20**. The tightening methods were adequate to meet the client's requests as outlined in the client statement. The intention is for future project groups to incorporate this design into a full set of anti-shock trousers and make additional design updates, as necessary.



(a) (b) (c)

Figure 20(a-c): (a) Flat View. (b) Front View. (c) Side View.

4.4.4 *Indications of Use*

This anti-shock garment is designed to shunt blood from the legs to the core of a patient's body. The device is intended for use exclusively on adults in the plateau phase of hemorrhagic shock. Indications that the patient is in hemorrhagic shock include blue lips, low urinary output, low blood pressure, increased sweating, weak or elevated pulse, and confusion, as shown in **Fig. 21**. Common causes of hemorrhagic shock include severe or widespread burns, deep wounds or cuts, trauma, and internal bleeding. A clinician should diagnose the patient with hemorrhagic shock before this device is donned on the patient [1].

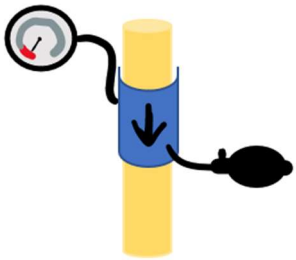
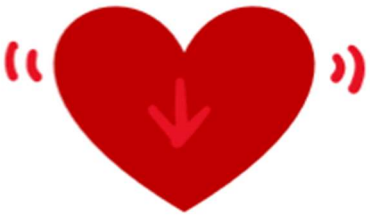
Blue lips	Low urinary output	Low blood pressure
		
Increased sweating	**Weak or elevated pulse**	**Confusion**
		

Figure 21: Signs of shock

4.4.5 *Application*

If the patient meets the conditions for device use, then the application process can begin. The entire device should start in the open configuration as indicated by **Fig. 22**. While the patient is lying down, the suit should be slid underneath their body, one leg at a time. Tightening of the device should occur from the most distal end to the most proximal end, i.e., from the feet to hips, and the pressure applied to each section should gradually lessen so that the feet receive the most pressure and the hips receive the least. Further research is required to determine the ideal pressure setting for each section. Using a pressure sensor, as well as blood pressure measurements from a blood pressure cuff, will guide the application. Additionally, the device contains markings that can be used to determine the girth of the wrapped section. This value can be used to determine the change of volume and thus the amount of blood shunted.

Figure 22: Open Configuration of Flap

4.4.6 *General Patient Use*

After the device has been applied, the clinician should ensure that the patient has a hospital gown that can easily cover their body. This will provide the patient with privacy and a sense of comfort, but the gown can also be easily removed if patient evaluation is required. The patient should be inspected hourly for pressure sores. The device needs to be taken off every two hours in the reverse order of application; starting at the hips and down to the feet and should remain off for at least five minutes to reestablish temporary blood flow and stretch out the restricted muscles and tendons. In order to avoid a rapid shift of blood, which would disrupt the stability of the patient, the removal of the garment must be gradual. If the two-hour time limit has not been reached but a section of the body appears to be at risk, then the individual section covering that body part, as well as those proximal, should be removed and then reapplied once concerns are addressed.

4.4.7 *Cleaning and Inspection*

As this device is single-use, there will be no need for complete sterilization of the device after it has been utilized. However, if there is ever a buildup of blood, other bodily fluids, or other elements that results in obstruction of the clinicians' view of the patient's body, then a brief cleaning may be necessary. More research is required to determine the ideal cleaning method. The current recommendation is to use soap and water due to its safety and efficacy. Before application, the device should be inspected for any punctures, tears, or separated seams. While the patient is wearing the device, it should be periodically inspected for mechanical or device malfunctions such as the failure of a given section to reach the required level of applied pressure, patient skin poking through a tear or rip in the device, or separation of the device at the seams.

4.4.8 *Contraindications of Use*

The device should not be used on a patient who is experiencing any of the following: congestive heart failure, myocardial infarction, stroke, pregnancy, thoracic hemorrhage, diaphragmatic injury, head injuries, adnominal injury with evisceration, impaled object, or uncontrolled bleeding.

4.5 Feasibility Studies

Feasibility studies were conducted to understand how various components of the design would meet the specified function. First, the tensile strength of the material was tested to determine mechanical properties. This testing was performed on the Instron 5544 as outlined in the Tensile Testing Protocol included in **Appendix B**. The materials tested were the 20-gauge polyvinyl chloride (20 G PVC), 16-gauge polyvinyl chloride (16 G PVC), clear moisture resistant polyester film, and neoprene.

Next, various seam patterns and connection strategies underwent tensile testing to determine the strength of this connection method. This testing allowed the team to better

understand whether the connection would be the failure point of the device in order to determine the ideal connection method. Since the device is intended to be reusable, fatigue testing was completed as outlined in **Appendix C**.

In order to adequately monitor the patient throughout their treatment, the skin must be visible to the clinician. The transparency of each material was quantitatively measured with a UV-Visible Spectrophotometer to perform the Transparency Testing Protocol as detailed in **Appendix D**.

4.6 Modeling

4.6.1 *Physical Modeling*

The team created an initial prototype based on the physical dimensions of an average adult female, as shown in **Table 8**. In order to fully realize the team's vision prior to creating further prototype iterations, the team conducted 3D modeling through the utilization of SolidWorks, a Computer Aided Design (CAD) software. This 3D model assisted the team in their consideration of various design aspects such as the shape and size of different components. A rough 3D model of the device was created with a main, segmented base, and overlap segments. Once these parts were completed separately, the dimensions from **Table 8** were applied. An assembly, as shown in **Fig. 23**, was then created. With this information, the team determined which aspects of the design needed further consideration and which worked well.

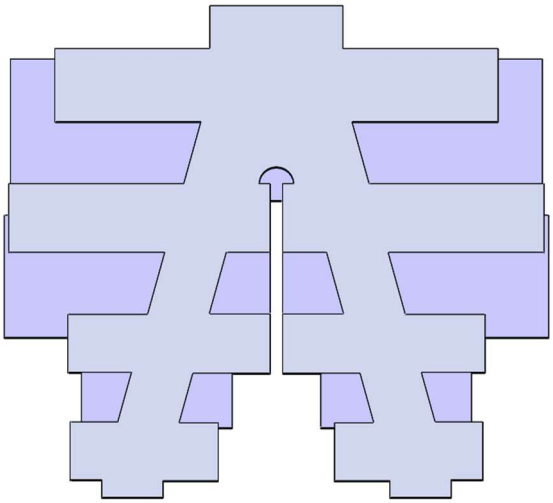


Figure 23: Initial 3D Model of the Anti-Shock Trousers

4.6.2 *Computational Modeling*

The team also utilized additional computer-based software to gain insight on material properties, mechanical properties of the design, and perform simulations. The CES EduPack resource provided a materials database that allowed the team to find out more about the current material selections and identify areas, such as elasticity properties, Young's modulus, density,

and relative cost per unit volume where alternative materials would be more useful. The Ashby Charts allowed for the display and comparison of these material properties, with each property on one axis and the ranges of values depicted by bubble shapes.

The ANSYS software allows for simulation, visualization, and mechanical exploration. Fatigue testing is a capability of ANSYS allowed for material simulation and mechanical analysis. The computational modeling showed the force distribution based on the dimensions of the body and the force applied to wrap the compressive device. This software granted the opportunity to assess deformation, points of failure, and to simulate cycles to failure or wear. In the future, hemodynamic testing could be utilized to conduct fluid-structure interaction modeling to assess the compressive forces will have on blood flow and circulation.

4.7 Preliminary Data

4.7.1 *Tensile Testing*

Tensile testing, conducted as detailed in **Appendix B**, consisted of various materials including 20 G PVC, 16 G PVC, clear moisture resistant polyester film, and neoprene produced the results summarized in **Fig. 24**. The team utilized GraphPad Prism 8 to perform statistical analysis. Normality was verified with the Shapiro-Wilks test for maximum load and tensile stress at maximum load for these samples. The 20 G PVC and neoprene were not normal, so a Kruskal-Wallis test was conducted, and it was determined that the medians do not vary significantly. This data is shown on the following bar graph displaying the average Tensile Strength at Maximum Load in **Fig. 24**. The error bars represent the standard deviation.

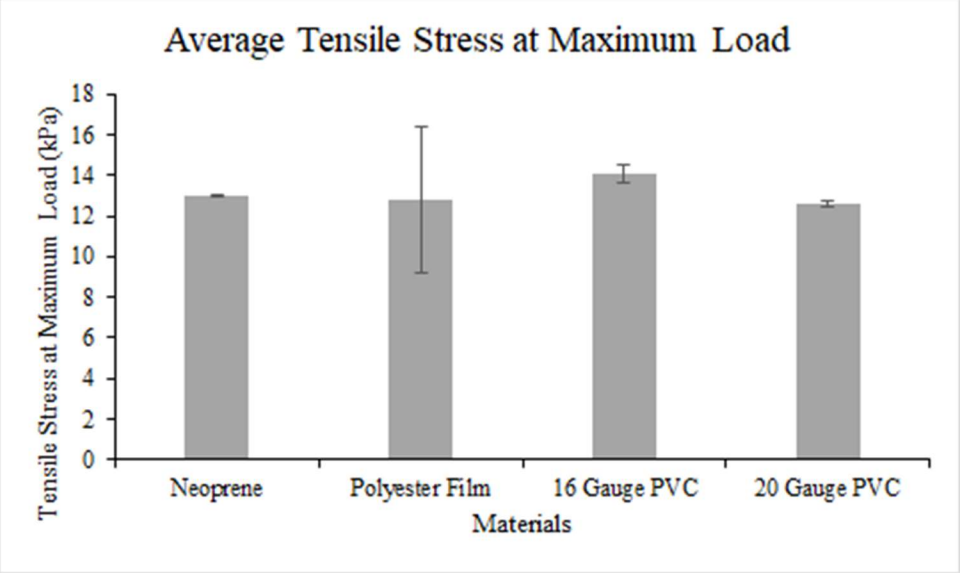


Figure 24: Average Tensile Stress at Maximum Load for Each Material

4.7.2 *Transparency Testing*

Transparency testing on various materials was completed using a UV-Visible Spectrophotometer according to the methodology detailed in **Appendix D**. The Polyester Film and 16 G PVC had the highest average light transmittance after air, which was the control in this test. The dark notebook was comparable to the predicted results of the neoprene material, with an average percent light transmittance of zero.

This UV-vis spectrum transmittance data, with values collected for wavelengths between 400 to 700 nm, is depicted in **Fig. 25**, noting the controls of air and the Dark Notebook, with 100% and 0% transmittance, respectively. The dark notebook exhibited a transmittance of 0%, as no light passed through the solid cardboard cover. The KimTech wipe results show a transmittance of 2%, as this material is slightly thinner than a standard tissue, with significant opacity. The scotch tape was affixed directly onto the measurement apparatus and resulted in a 10-20% light transmittance It can be noted that the results for the polyester film show significant oscillations. This can likely be attributed to the iridescent shine on the film and nano-features impacting the light transmittance through the material. The 20 G PVC reached a steady transmittance of 85%, which likely was due to the slightly reflective nature of the material. The Air was the positive control, with a transmittance of 100% as the light passed directly through. The 16 G PVC normalized at approximately 87% transmittance, as it was one of the thicker materials.

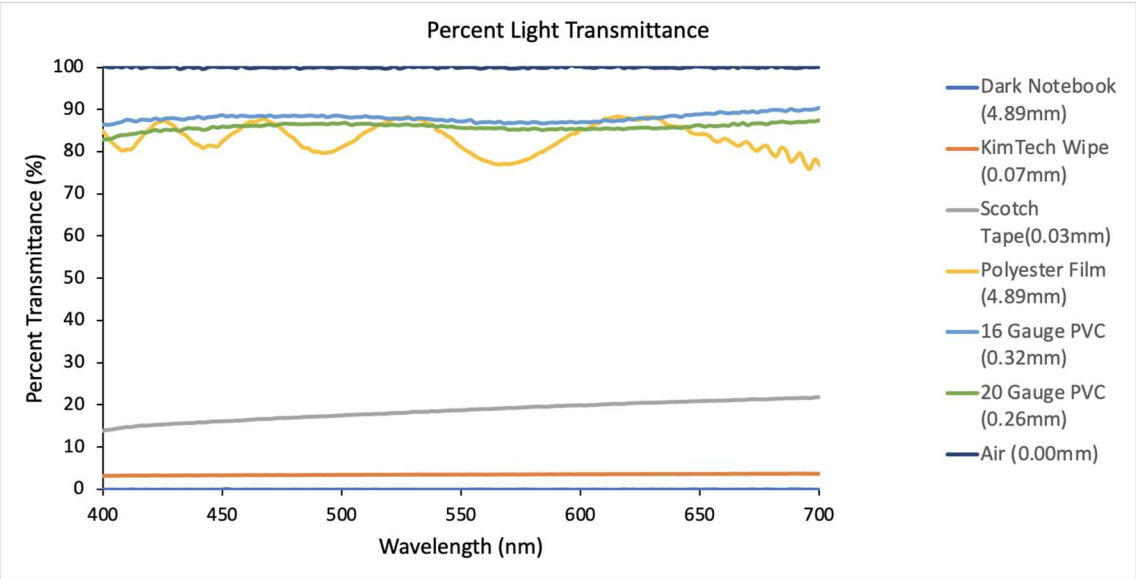


Figure 25: Percent Light Transmittance on the UV-vis Spectrum

4.7.3 *Connection Method Tensile Testing*

4.7.3.1 Connection Method Descriptions

4.7.3.1.1 Tested Connection Strategies

In order to determine the best strategy for assembling and implementing the device, a variety of connection strategies were researched and observed. Information was collected on both permanent connection techniques for the assembly of the device, and removable techniques that can be used in donning and doffing the device. A variety of factors were considered such as tensile strength, durability, and obstruction of visibility. The following section details the connection strategies considered, summarizing the information provided from the manufacturers. Tensile testing results can be found in Chapter 4.7.3.2.

4.7.3.1.1.1 *Roberts Double-Sided Carpet Seam Tape*

This adhesive strategy, primarily used in construction applications, creates a seam between two segments of material preventing the carpet seam from peaking [41]. The tape strip has a top surface coated with a hot melt adhesive (HMA), thermoplastic resins that liquify when heated, and a bottom surface with a heat activated contact adhesive, and a chemical substance that has adhesive properties that can only be activated at elevated temperatures [42, 43]. Roberts Double-Sided Carpet Seam tape does not require ironing and is used to adhere carpet to the subfloor [44].

4.7.3.1.1.2 *Carpet Shield® Self-Adhesive Film*

This sheet roll is made of low-density polyethylene and is used to temporarily protect carpet during construction projects [45]. To achieve its intended use, it is highly resistant to tears and punctures so that it may persistently adhere to the carpet. The tensile strength of the material is 3,000 psi and has an adhesion level of 17-25 oz/in according to the manufacturer. The film attaches to the carpet and is thin and flexible, easily wrapping around the edges to create a protective covering around the carpet.

4.7.3.1.1.3 *Roberts MAX GRIP® Vinyl Tape*

This product is specifically designed for the installation of vinyl sheet flooring adhering to any clean and dry subflooring [46]. The tape itself is made of an acrylic adhesive that has reinforced fabric webbing, creating additional strength. The tape instantly creates an adhesive bond, and no heat treatment is required. Similar to the other flooring adhesives, it is a thin tape that will remain flat.

4.7.3.1.1.4 *Eclectic E6000*

E6000 is a clear, perchloroethylene adhesive that can be used on a variety of materials including wood, metal, rubber, leather, vinyl, and many plastics [47]. The product has a tensile strength of 3,500 psi and elongation of 900%. When connected to PVC, according

to the ASTM D 903 standard for 180° Peel Strength Test, the average maximum load measured was 38 pounds per linear inch [48].

4.7.3.1.1.5 *Roberts 7500 Vinyl Seam Sealer*

This strong and durable adhesive product is used for sealing seams in sheet flooring [49]. The glue has an opaque white color when dry and is intended for interior use only including vinyl-backed sheet flooring. Suggested bead size is a 1/8” that is tacked then rolled with a hand roller creating a thin, uniform layer of adhesion.

4.7.3.1.1.6 *Roberts 8015 Universal Carpet Seam Sealer*

This carpet seam sealer is used for seaming most types of carpet, including vinyl backed [50]. One of the features specifically noted is the antimicrobial product protection. The suggested bead size is 1/8” with smoothing out once applied to the backing. The adhesive is a white color.

4.7.3.1.1.7 *Loctite® Shoe Glue*

Shoe glue is a gap-filling adhesive that bonds, seals, and repairs many types of materials including vinyl [51]. It creates a flexible and durable bond that can withstand moisture, impact, and vibration because of its strong adhesion and high initial grab [51]. The glue dries clear and is resistant to high temperatures.

4.7.3.1.1.8 *Sewing*

Sewing the polyvinyl required the implementation of a specific technique to ensure a clean and effective seam interface. Factors to consider included the needle size, needle type, thread type, foot type, stitch size, and programmed tension of the needle. The team’s first attempt at sewing the material resulted in bird nesting. A bird nest is when the thread bunches up underneath the needle plate; this is caused by unbalanced tension between the top and bottom threads [52]. This unbalance can be due to the bobbin being too loose, the top thread bypassing the thread take up lever, or the lack of top tension [52]. Through experimentation, it was discovered that the premiere method of sewing includes the use of a Teflon foot, polyester thread, 2-inch stitch size, and 110/18 heavy duty needle.

4.7.3.1.2 Other Considered Connection Strategies

4.7.3.1.2.1 *Ultrasonic Welding*

Ultrasonic welding is one of the most popular methods for joining plastic and uses ultrasonic energy at high frequencies to produce low amplitude mechanical vibrations [53, 54]. This welding strategy is commonly used in the medical device industry and packaging industry. At the joint interface of the pre-welded parts, the vibrations generate heat and result in the melting of the thermoplastic materials and once cooled the weld is formed [53]. Ultrasonic welding for PVC to PVC is considered compatible [53]. The equipment required for this

technique is either an integrated ultrasonic welding machine or a handheld ultrasonic welding system [53].

4.7.3.1.2.2 *Velcro®*

Velcro is a fastener composed of tiny loops and hooks that is apparent in many facets of daily life including medical solutions and apparel [55, 56]. Based on the requirements of the specific application, there are various types of adhesive options and hook and loop designs.

4.7.3.1.2.3 *Boa® Fit*

Boa® Fit is a company that uses a dial to customize the fit and configuration of various types of apparel and footwear, as shown in **Fig. 26** [57]. The company makes equipment for cycling, golf, hiking, snowboarding, and medical equipment. The medical equipment made includes braces for the ankles, knees, wrists, and back. The technology has three components including the dial, lace, and guide. The low friction lace guides are what the lace is looped through in a crisscross pattern with a dial at one end. The dials are turned to adjust the tightness, and depending on the type, are either twisted to loosen, or pulled for a quick release. They have four series of dials that can are tailored for a variety of needs including thick, stiffer applications, durability to withstand force and impact, meticulous adjustment and adaptability, as well as being lightweight for precise adjustment zonal fit.

(a) (b) (c)

Figure 26(a-c): (a) Skates with Boa® Dial. (b) Front View of Boa® Dial. (c) Side View of Boa® Dial.

4.7.3.1.2.4 *Breakaway Zippers*

Breakaway zippers can be found in sport pants and gear for firefighters. The technology uses right and left side zippers that do not have catch mechanisms [58]. The connectors on either side hold the material together to prevent the zippers from unzipping. Additionally, the zipper

pull tab includes a friction enhancing material that catches on the connectors to ensure that the pants are not inadvertently unzipped. When the connectors are not engaged, the zippers easily unzip permitting a rapid removal of the garment.

4.7.3.1.2.5 *FIDLOCK® Magnetic*

FIDLOCK® combines magnetic forces and a mechanical latching closure [59]. The technology is used for locking systems for bike accessories such as mounting a water bottle onto the bike. Combining a base, connector, and the module of choice, for example a water bottle or bag, the magnetic force attracts the base to the connector and then secures it in place with mechanical locking. To disconnect the two, a simple twist or push is required depending on the specific design.

4.7.3.2 Connection Method Tensile Testing Results for Vinyl to Vinyl Samples

Tensile testing, conducted as detailed in **Appendix C**, of numerous connection strategies including carpet tapes and different types of adhesives produced the results shown in **Fig. 27**. With testing, the goal was to find a connection strategy that would be able to withstand the same force applied as the material is able to. This way, the limiting factor of the design would be the material and not the seams. As these strategies were compared, the thickness and flexibility were considered to understand how the seams could bend when wrapped around the leg. An adhesive strategy that would be flush to the leg was critical to the prevention of pressure wounds.

The team utilized GraphPad Prism 8 to perform statistical analysis. Normality was verified with the Shapiro-Wilks test for Shoe Glue, E6000, 7500 Vinyl Seam Sealer, 8015 Universal Carpet Seam Sealer, Max Grip Vinyl Tape, Double-Sided Carpet Seam Tape, and Carpet-Shield Self-Adhesive. The Carpet Shield Self-Adhesive was not normal for tensile stress at maximum load as indicated on the graph with a hashtag. The Carpet Shield Self-Adhesive was no longer considered for the design because it had the lowest strength properties and was not further analyzed. The remaining samples, Shoe Glue, E6000, 7500 Vinyl Seam Sealer, 8015 Universal Carpet Seam Sealer, Max Grip Vinyl Tape, and Double-Sided Carpet Seam Tape, were then analyzed through ANOVA followed by Tukey post-hoc test and it was determined that there was a significant difference among the means. This data is shown on the following bar graph displaying the average tensile stress at maximum load in **Fig. 27.** The error bars represent the standard deviation.

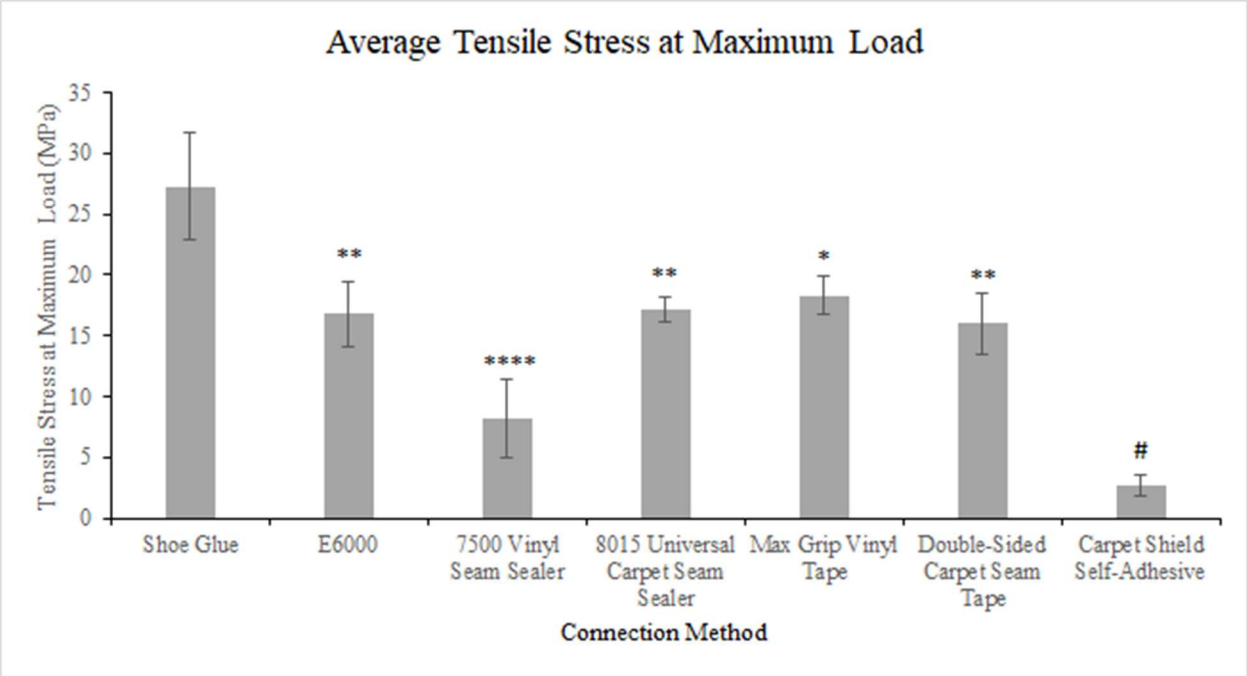


Figure 27: Average Tensile Stress at Maximum Load for Various Connection Methods Between Vinyl and Vinyl. Data is represented as mean ± standard deviation. # indicates non-normal data. Significance level when comparing Shoe Glue to other adhesives l is indicated as: * represents 0.05, ** represents 0.01, *** represents 0.001, **** represents <0.001.

Based on this preliminary data, the team performed additional testing on samples connecting two pieces of 20 G PVC with shoe glue. The tensile testing produced the results shown in **Table 9.**

Table 9: Instron Connection Method Testing Results Vinyl to Vinyl

Sample	Length (mm)	Width (mm)	Thickness (mm)	Extension (mm)	Max. Load (N)	Tensile Stress at Max. Load (MPa)	Modulus (Automatic) (MPa)
Shoe Glue							
Average ± Standard Deviation	106.2 ± 4.8	71.08 ± 2.02	0.82 ± 0.08	73.9 ± 10.7	303.5 ± 16.4	30.4 ± 1.6	104.9 ± 10.9

The team also considered varying stitch lengths to determine which sewing method would be most effective. No statistical analysis was conducted as there was only one sample of each stitch length. This data is shown on the following bar graph displaying the average tensile stress at maximum load in **Fig. 28.**

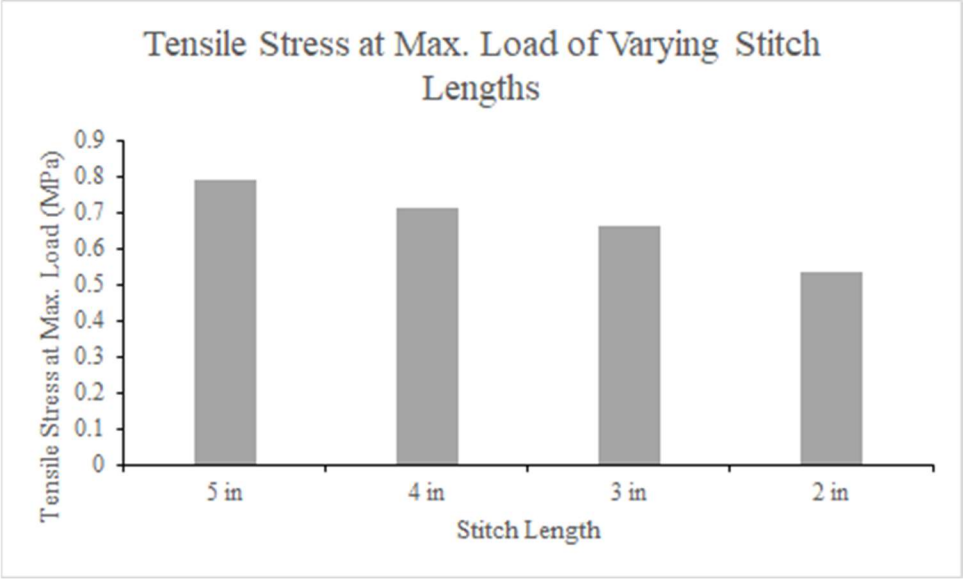


Figure 28: Average Tensile Stress at Maximum Load for Varying Stitch Lengths

4.7.3.3 Connection Method Tensile Testing Vinyl to Nylon

To determine the best connection strategy for attaching nylon straps to the 20 G PVC, the team performed tensile testing, as detailed in **Appendix C**, to determine the superior option.

The team utilized GraphPad Prism 8 to perform statistical analysis. Normality was tested with the Shapiro-Wilks test and all samples were determined to be normal. An unpaired student t-test was then conducted and the difference between the Shoe Glue versus the E6000 was determined that the means did not vary significantly. This data is shown on the following bar graph displaying the average tensile stress at maximum load in **Fig. 29.** The error bars represent the standard deviation.

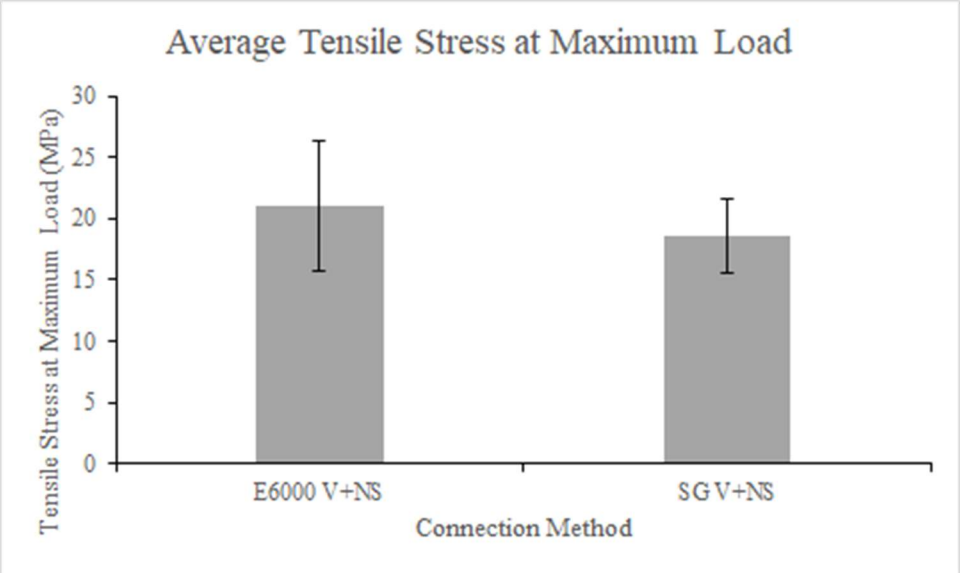


Figure 29: Average Tensile Stress at Maximum Load for Various Connection Methods Between Vinyl and Nylon Strap

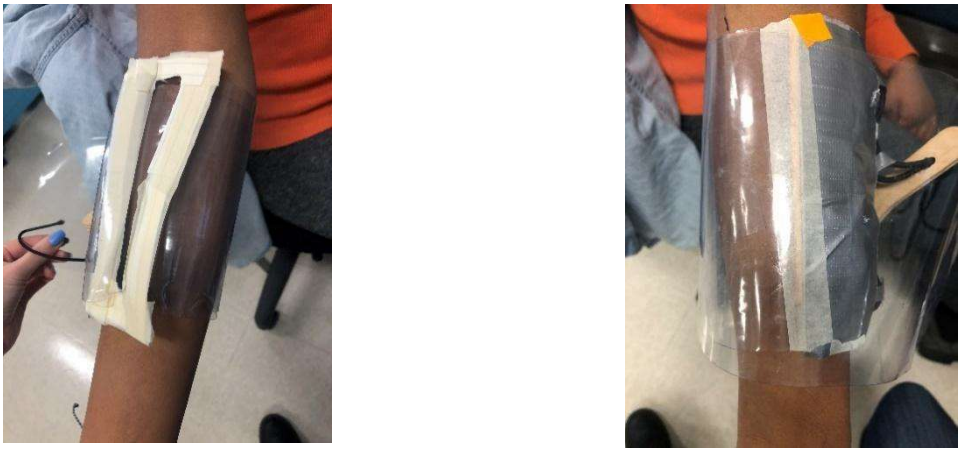
5.0 Final Design Verification

5.1 Measure Pressure Applied

Utilizing the final prototype, testing was performed to verify and validate the proposed design. To evaluate the effectiveness of shunting the blood from the peripherals, the pressure applied was measured using a wearable force-resistive sensor. This type of sensor measures the relationship between the resistance within the circuit and the amount of force applied to the sensor face. The force measurement was translated to pressure applied and correlated to change in blood pressure, as well as changes in interstitial volume. The sensor system used an Arduino Uno, a device that supports open-source software and hardware. The force-resistive sensor was included in the circuit and using a liquid-crystal display (LCD), the open-source code was adapted to output varying text warnings such as, inadequate pressure applied, adequate amount of pressure, and too much pressure [60]. These direct indications proved to the team the efficacy of the device design and could be permanently incorporated into future design iterations. This would ideally output directly to the clinician to demonstrate changes needed and be incorporated near areas that are more susceptible to pressure injuries. During the sensor calibration, an applied force using the Instron 5544 machine was mapped to the resistance by creating a characteristic plot. The code that was adapted based on the use for this project is shown in **Appendix F**.

5.2 Visibility on Varying Skin Tones

The team also examined visibility based on varying skin tones. This was a critical ethical consideration to align with the design objective for cutaneous patient monitoring. The resultant images are shown in **Fig. 30** and success was achieved with the material choice. Reduction of the buckle and Velcro strip size was further explored to maximize visibility while maintaining adequate pressure applied.



(a) (b)

Figure 30(a-b): (a) Top View. (b) Side View.

5.3 Application Time Testing

In order to estimate the approximate donning time for the trousers, the team conducted application time testing. The application time test group was made up of the four team members and the device utilized was the latest prototype iteration shown in **Fig. 31.**

Figure 31: Prototype Utilized for Application Time Testing

The team recorded the amount of time it took each individual member to apply the segment as detailed in **Table 10**. Two application trials were completed by each of the four team members and the average application time was determined by calculating the mean of all eight trials; this data is displayed in **Table 10**.

Table 10: Application Time Raw Data

Team Member	Trial #1	Trial #2	Average Application Time
Teammate #1	28 seconds	33 seconds	42 seconds
Teammate #2	50 seconds	63 seconds	
Teammate #3	24 seconds	26 seconds	
Teammate #4	56 seconds	59 seconds	

The team acknowledged that this testing only consisted of one segment, and theoretically, the device would be made up of a total of 12 segments (5 for each leg, and 2 on the abdomen). These 12 segments would ideally be applied by two medical professionals simultaneously. Therefore, the team multiplied the average application time by 12 and then divided that value by two, based on the two applicators. As shown in **Table 11**, the approximate donning time for the anti-shock trousers was four minutes and 14 seconds, which is comfortably within our target range of 0 to 10 minutes. Even if the team considered the number of available clinicians as a limitation, and only one applicator was present, the approximate donning time is still less than 10 minutes. These trials proved that the segment meets the design objective “easily applied and removed to meet the application time frame.”

Table 11: Approximate Donning Time

Number of Segments	Number of Applicators (Medical Professionals)	Approximate Donning Time
1	1	42.33 seconds ≈ 42 seconds
12	1	507.96 seconds ≈ 8 minutes 28 seconds
12	2	253.98 seconds ≈ 4 minutes 14 seconds

5.4 User Studies

The team recruited peers who were EMT certified to participate in user studies to evaluate ease of application and solicit feedback. Four participants were included in the study as outlined in the User Study Protocol in **Appendix H**. This study consisted of training the user, presenting them with demonstrated instructions, and having them repeat back the process while narrating the steps taken. This was followed by a 30-minute decay period, a gap between training and testing used to mimic memory loss that would occur when the device is introduced to clinicians. Then, testing was conducted to evaluate their donning of the segment and concluded with a discussion.

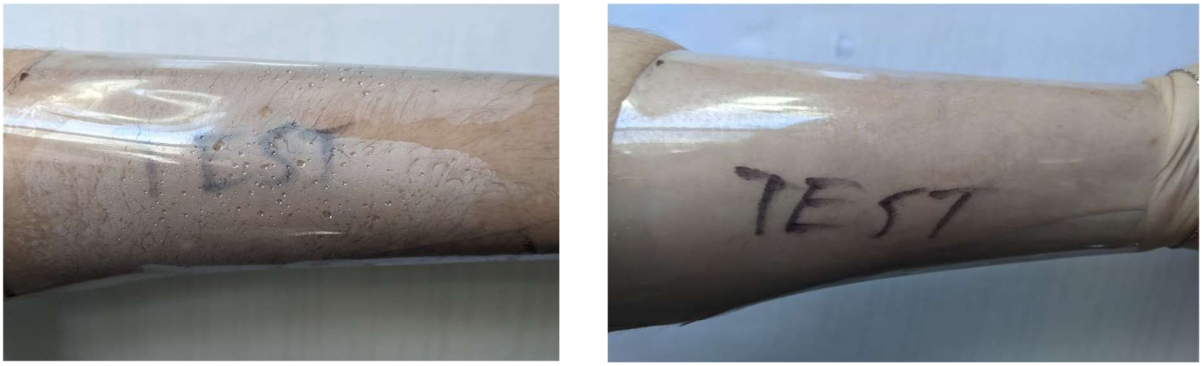
Overall, the device was described as intuitive, compact, and easy to use. One user recommended a "This Side Up" label as it was difficult to determine the appropriate orientation for the open configuration. The underlap flap that is meant to protect the skin and apply uniform pressure ended up getting stuck in the first slot of the buckle, which made it a bit difficult to tighten. The material choice was another concern, as it required adjustment and did not have a natural stretch. The bungee tightening was noted to be the most complicated step, as it required dexterity to tighten the bungee cord through each of the holes and would be simplified if there was only one motion required. The tightening techniques were comparable to other devices used for emergency care. For example, the over, under, pull technique of the buckle was compared to traction splinting, a common technique used for upper leg breaks, and the rod matched the tourniquet practice. Users found that the proposed device design aligned with current practices and was viewed as a new opportunity for treatment with the aforementioned areas of improvement.

5.5 Moisture Transparency Studies

Moisture testing was performed to determine how visibility was maintained when moisture was present on the device. In the test, water was applied to the device in an even layer using a spray bottle, the device was then applied to the patient and observed over a period of one hour. The protocol for this test is detailed further in **Appendix E**.

The team found that when there was an air pocket, as seen in **Fig. 32 (a)**, condensation formed in the open space and obscured the view. However, the test mark was still visible. This indicates that even in the presence of condensation, wound monitoring is still possible.

Additionally, when no air pocket was present, as seen in **Fig. 32 (b)**, cutaneous visibility was maintained at an optimal level throughout the course of the test.



(a) (b)

Figure 32(a-b): Moisture Test Results (a) Air Pocket Present. (b) No Air Pocket Present.

5.6 Weight & Dimensions

To confirm that the segment was scalable to a full set of light and compact trousers, to allow for easy storage, the measurements for one segment were completed. The mass of the segment was 85.0 g with the associated dimensions: 135.94 mm width, 490 mm length with the underlap flap extended, and 30.88 mm thickness folded up.

6.0 Final Design Validation

6.1 Economics

Introducing a new medical device to the market influences the economy based on phasing out prior solutions, production costs, and purchasing costs. In the healthcare industry, it takes compelling evidence to phase out a preexisting treatment option for a new one. Furthermore, when a new technique or device is introduced, significant training must occur to ensure that all clinicians involved with the implantation of the device are fully capable of using it in a safe and effective manner. If the proposed device were implemented, hospitals would no longer be using IV fluid and blood products as the primary treatment strategy for patients in shock, resulting in a reduced need for both. Upon introduction, the anti-shock suit will be a lower cost solution but require an additional cost to acquire for the hospitals, while IV fluid and blood products are common readily available commodities used for many other treatments in a hospital setting.

6.2 Environmental Impact

PVC is the primary material of this device and an environmentally damaging plastic. The disposal of this single-use device in large quantities has the potential to negatively impact the natural environment. The entire lifecycle of this material—production, use, and disposal—releases toxic chemicals into the air which can build up over time in water and air. To mitigate this, the design and future iterations of the design will incorporate sections that can be removed, reused, or reapplied to a future suit. Future device designs should include portions that can be recycled, at the very least, separate from the sections that will need to be disposed of in hazardous waste. These recommendations would result in material reuse and address concerns about toxic impacts on the natural environment from the plastic during late stages in the lifecycle of the device.

6.3 Societal Influence

This device has the potential for a strong, positive societal influence. It will provide a revolutionary alternative to treating patients experiencing shock. Since the device increases the available blood volume to vital organs during shock, the need for blood products and IV treatments will be greatly reduced.

6.4 Political Ramifications

A successful device would influence the global market in a variety of ways. This anti-shock suit is beneficial for rural areas or developing countries as it addresses a current crisis in a large part of the world based on availability of blood products. The United States this past year suffered a national blood shortage largely due to the consequences of the COVID-19. A reduction in the reliance on blood products could prove very beneficial for trauma care, especially in places where access to IV treatment and blood products are scarce. Furthermore, some individuals are uncomfortable with the use of blood products as part of their treatment based on religious or personal reasons, this would provide a potential alternative for such patients. Independent of the socioeconomic status of residents and cultural perspectives, this device presents a simple, effective manner of treating shock that is comparable to everyday wearables and basic, commonly accepted medical devices.

6.5 Ethical Concerns

Ethical concerns surrounding this device are established primarily in regard to patient safety and experience. The anti-shock suit must be biocompatible and safe for human use. Considering that this will be an alternative to pre-established treatment options, it must be confirmed through data that this device is comparable to or more effective than current treatments. The transparency of the device to monitor cutaneous changes in skin appearance must be efficacious for all skin tones. Additionally, the patient’s comfort level must be

acknowledged regarding the transparency of the pants in the hospital environment, and additional gown or dressing options should be offered. The pressure sensor must be accurate in order to adequately provide data that directs patient care. Moreover, the patient's care should not cause pressure wounds or additional HACs as this device is intended to treat and prevent the progression of shock while avoiding further harm.

6.6 Health and Safety Issues

This prototype provides a preliminary design of an anti-shock garment and sets the stage for future research and projects. The device aims to shunt blood from the lower extremities to the core of the body with the goal of increasing the blood supply available to the vital organs. In order to ensure the safety and efficacy of the device, animal trials will need to be completed prior to human trials, submitted to the appropriate regulatory bodies, and then finally brought to market. The device must be biocompatible, not cause injury, and be safe for use on humans achieving the intended goal of effectively treating hemorrhagic shock. Patient monitoring is necessary to ensure prevention of HACs. Common HACs include pressure wounds, shear injuries, and moisture injuries.

6.7 Manufacturability

The device is designed to be single-use for one treated patient throughout the extent of their treatment, and then discarded. As the device is disposable, and will likely be in high demand, production will require large scale manufacturing. The materials and parts that make up the device are inexpensive and easily obtained through purchase from appropriate bulk vendors. For the buckle and tourniquet rod, the current parts for the prototype were 3D printed and they could ultimately be injection molded. Adhesion and fabrication techniques can be incorporated into mass production and assembly lines. Large scale manufacturing will decrease the cost of production per unit, allowing the device to be sold at an accessible price.

6.8 Sustainability

The manufacturing of the anti-shock suit would require significant energy, specifically for the preparation and adherence stages of production. The environmental impact of this product would be limited by the large volume manufacturing, and minimal toxic products and processes used in the preparation of the device. PVC plastic is a widely produced polymer, however it does contaminate the environment. To lessen the negative impact of PVC, some segments could be reused and become new source material through mechanical recycling. Considering that this device will be discarded after each patient’s use, the resultant waste would not be ecologically ideal, but prioritizing renewable energy-based manufacturing processes, in addition to recycling procedures, will minimize the harmful impacts of this device.

7.0 Discussion

7.1 Limitations

The team faced limitations throughout the completion of this project that impacted the design process. Due to the COVID-19 pandemic, the team was prohibited from any off-campus travel. Therefore, the team was unable to utilize UMass Memorial Medical Center simulation lab. This resource would have aided the team in understanding how the device might fit the patient's legs as well as the impact the device would have on blood flow and blood pressure.

7.2 Limitations of Data

7.2.1 *Sensor Testing*

The team utilized a force-resistive sensor and conducted testing to measure the amount of pressure applied to the patient by the device. These measurements were recorded in resistance then, correlated to force and used to better inform the team of the different ranges of pressure that can be applied. The force-resistive sensor was used to demonstrate proof-of-concept and a more precise measurement tool would be required to meet the intended need.

7.2.2 *Test Subjects*

The team continuously tested the device design on team members as Covid-19 restrictions resulted in a lack of accessibility to other test subjects or simulation tools. The team consists of four young adult females of average height and weight. Therefore, this pool of test subjects is not representative of the entire population for which the device would be used. As a result, it is difficult to predict how the device may react across varying physiologies. In order to adequately test the device, the team would need a much larger and more diverse sample pool to use for human testing.

7.2.3 *Mechanical Testing*

The team conducted material and tensile testing on three to four samples of each material per test, which ultimately limited the power of the statistical analysis. The small size of the material testing trials was mostly due to time and budget constraints, but the team was able to make design decisions despite the limited data collection. This testing focused on the strength of various materials as well as adhesion methods. Another form of testing that the team might have considered could have been multilateral testing, to test the material strength in varying directions along with burst strength testing, which would apply force to the material in a different and more applicable way.

7.2.4 *Accurate Application of the Device*

Data collection was further limited by the lack of accessibility to a patient in the targeted disease state and the inability to safely test the device design on a patient in shock. This prevented the team from making more informed design decisions due to the lack of first-hand clinical experience regarding difficulties encountered with device application and utilization within the designated setting.

7.2.5 *Transparency Testing*

The team conducted visibility testing using a UV-Visible Spectrophotometer to determine the average light transmittance at varying wavelengths and to better understand factors that could negatively impact visibility. However, the team was unable to conduct additional and more extensive testing that would simulate what a trauma patient experiencing hemorrhagic shock might experience. For example, if a patient had an uncontrolled, external bleed, their blood may pool within the device and cause visibility issues. Additionally, the patient may begin to perspire while wearing the device which could also create condensation within the suit impact cutaneous visibility.

7.2.6 *Longevity Testing*

Due to the nature of the project, the team was unable to conduct longevity testing to understand how the device would function and sustain durability throughout its lifecycle. Since the device is currently designed for single-use, the team did not conduct extensive testing on the reusability of the device. To better understand this, the team might have considered cyclic testing to determine how the components of the device might fatigue or how the material may fail after readjustment throughout use by one patient. Additionally, the team may have considered determining the expected shelf life of the device.

7.2.7 *Reliability Testing*

The data presented on the strength of the material did not account for potential tears or punctures of any kind. Therefore, the data may not be entirely representative of the device in a clinical setting, as tear or puncture damage could occur and impact its reliability and efficacy.

8.0 Conclusions and Recommendations

8.1 Conclusion

The device outlined in the client statement was anticipated as a cost efficient and transparent lower-body compression suit for use on adult patients in the ICU that would effectively combat the plateau stage of hemorrhagic shock. The final design of this MQP was an easy to apply segment of the suit, with securing and customizable compression technology which

can be applied to each of the segments. The combination of the buckle with securing Velcro and the tourniquet style compression method is easy to apply in three steps per segment. Furthermore, the final design utilizes PVC material which offers continuous cutaneous visibility for monitoring of surface level wounds or sores. At the approximated total cost of $94.79 and a cost for production of 23.15, this is a reasonable option for a single-use transparent compression suit for patients in shock.

In order to be successful, the anti-shock suit was expected to effectively combat hemorrhagic shock by reducing intravascular space and the third space, while maintaining visibility for cutaneous patient monitoring. The team's design applies between 30 and 50 mmHg of pressure to the leg region. This is accomplished by increasing the mechanical advantage applied by the user to the segmented flaps through the buckle application and tourniquet rod as a tightening mechanism. With minimal obstructions in the design, the transparent material acts as a window for clinicians to view the state of the patients' legs throughout the course of treatment while having the mechanical strength to withstand force to apply sufficient pressure. The segmented design allows for easy access to any portion of the leg, without sacrificing the centralization of the circulatory flow.

The data thus far indicates that our material choice and securing methods allow for maintained visibility for cutaneous monitoring. The tightening method creates mechanical advantage to optimize the pressure applied. The buckle and Velcro securing method offers the ability to customize section size as well as the pressure applied to the patient while allowing for simple device removal and application. Additional testing confirmed that the pressure applied fell within the desired range of 30 to 50 mmHg, and an average application time of 4 minutes and 14 seconds offers data to support these design objectives.

This is a viable proposed design option that incorporates the various objectives set forth in the client statement. The tourniquet-style compression method with the use of the rod utilizes a technology already in use by clinicians, which avoids a learning curve with a new compression technique. The single-use aspect of this device eliminates the need for cleaning. Furthermore, the non-pneumatic design allows for controllable, gradual application and removal, enabling a decrescendo of applied pressure from the feet to the hips. Future iterations could improve upon accommodating more sizes, incorporating a component for female obstetric postpartum hemorrhaging, and durability for repeated use and disinfection. Our device was targeted at use in the ICU, but based on its single-use nature, it could easily be adapted to other settings and applications including implementation in treatment of shock in a prehospital setting, such as on an ambulance.

The results of our validation testing indicate that this device is an effective strategy to shunt blood using non-pneumatic compression. The team developed a successful securing and tightening technology to be applied to a pair of transparent and cost-efficient anti-shock trousers.

8.2 Recommendations

8.2.1 *Modification for Use in Various Types of Shock*

The current intended use of the anti-shock suit is for patients who are experiencing hemorrhagic shock resulting from physical trauma. Transparency of the suit for ease of access in terms of patient and wound monitoring is helpful in this type of medical situation. The team recommends that the device be modified in order to be successfully utilized in the treatment of other forms of shock such as septic shock or more specifically post-partum hemorrhaging.

8.2.2 *Modify for Use in Emergent Situations*

The device is not designed to be utilized in emergent situations; it is intended for use in the ICU once the patient's condition has been managed, but they still require critical medical support. However, the device can be adapted so that it can be successfully utilized in an emergent situation. In order to adapt the device for such use, the team recommends conducting additional testing that takes into consideration the effect that blood accumulation, severe temperatures, and a critical timeline may have on the application and lifecycle of the device as well as the medical professional or user applying it. In an emergent care setting, time is vital, and conditions can be suboptimal. Thus, the donning time for device application must be less than five minutes to ensure that the patient can be transported as quickly as possible. Currently, device application is estimated to be around four minutes in a controlled environment. Design modifications may consider how the tightening method could be altered to reduce the level of dexterity required so that the device is more suitable for emergent situations. Additional research should be conducted in order to more fully understand the progression of shock and the physical symptoms that are more prevalent in emergent situations.

8.2.3 *Create Various Sizes*

Ideally the device would be adapted so that it may be utilized to treat a variety of patients experiencing shock regardless of their sex, age, or body size. However, due to the limitations the team faced in terms of test subject accessibility, team members were used for modeling and testing. Therefore, the current device measurements were intended to fit an average sized adult female patient. Additionally, the device should be modified in order to be effective in the treatment of pediatric and geriatric patients. The fragile skin and limited mobility of geriatric patients present challenges when considering how to apply adequate pressure without causing HACs. Similarly, the variation in size of pediatric patients creates difficulty in selecting an effective size of the device. Therefore, these adaptations would require additional research in order to account for the decrease in the amount of physical pressure that geriatric patients can withstand prior to the infliction of pressure wounds, and the average size of pediatric patients in different age groups.

8.2.4 *Production Process*

Due to the nature of the current design, the life cycle of the anti-shock suit is single-use only. As previously stated in *Chapter 6: Final Design Validation*, the life cycle of the device has many social, economic, and environmental impacts. The team recommends that future MQP groups conduct research and take into consideration the incorporation of recyclable materials to decrease the negative environmental impact and increase the sustainability of the device. Another recommendation would be to make each portion of the design replaceable. This would ensure that, if segmental failure were to occur, the clinician could simply remove a segment and easily replace it without the need to use a completely new device; thus, reducing the overall waste. Future teams may consider making the device reusable, taking into consideration how the product would be disinfected between uses and exploring how complete sterilization could be achieved. Additionally, the team recommends minimizing the manufacturing and production costs which would in turn allow the device to be as widely accessible as possible. This may be accomplished by seeking out suppliers for the different components of the device and using an assembly line for compilation of the final product. Specific emphasis on diminishing waste to promote efficiency and cost awareness should guide the manufacturing process. Additionally, future teams should take into consideration alternative adhesive methods, such as ultrasonic welding or a method similar to the sealing of IV bags. This would ensure that the adhesion method is safe and reliable, meets medical grade biocompatibility, and is expandable for mass manufacturing.

8.2.5 *Feasibility Studies*

In order to further evaluate the design, the team recommends conducting feasibility studies and utilizing professional resources to identify additional areas for design improvement. One available resource is the UMass Memorial Medical Center simulation lab. Additionally, the team recommends that once the device is ready for living system testing, that animal studies are conducted to provide evidence of device safety, how the device performs when applied to a living system, and the biological response that a living system may have towards the device. At this time, the team has specifically identified moisture injury studies as well as pressure wound studies as the most important studies to prevent additional physical injury caused by the anti-shock suit. Animal studies should be completed in full compliance with the General Considerations for Animal Studies for Medical Devices FDA guidance document.

8.2.6 *User Studies*

It is vital that the intended use of the anti-shock suit and application of the device are intuitive and can be successfully completed with minimal training. Clinicians undergo various training sessions in order to properly utilize medical equipment safely and accurately, but often if the intended use does not align with the simplest method of application, the device may be misused which can result in patient safety concerns. Conducting user studies and developing evaluation criteria to assess the intuitiveness and ease of application and utilization of the

device will assist in the identification of user errors. These user studies may be completed in conjunction with clinical staff members at UMass Memorial Medical Center, as these medical professionals have extensive prior knowledge of and experience with medical device function and performance. The results from these studies would allow for the modification of the device so that it becomes intuitive and incorporates application techniques to which medical professionals are already accustomed.

8.2.7 *Incorporation of Sensors*

Sensors allow for continuous and remote patient monitoring which is an essential element when it comes to caring for patients who are experiencing shock. The need for continuous and remote monitoring has increased significantly for inpatient care throughout the Covid-19 pandemic. Pressure sensors should be incorporated into the device design to ideally allow clinicians to monitor the pressure applied to the skin applied by each segment of the device, as well as prevent the development of pressure wounds as much as possible. These pressure sensors should be located near high-risk areas such as bony landmarks that are susceptible to pressure wounds. This would alert clinicians if a specific segment of the body is receiving too much applied pressure, or if the patient has not moved recently, which may also present problems. Other vitals that may be beneficial to monitor with the inclusion of additional sensors are the patient's body temperature, heart rate, respiration rate, and pulse oximetry. These measurements are representative of the patient's overall health. As the length of time that the patient is wearing the anti-shock suit increases, their vital signs should begin to stabilize. If complications were to arise, the data collected from these sensors would serve as an indication to clinicians that they may need to reconsider the patient's care plan.

8.2.8 *Apply for Grants*

The inclusion of sensors and access to medical materials for research and development can become rather costly. In order to supplement this cost, the team recommends that future MQP groups seek out additional funding and consider applying for grants. The team has included various resources that may serve as a guide for future MQP groups so that they may be fully prepared for and begin the grant application process as soon as possible. These resources include: where to search for available grants, a list of possible grants along with their required application materials, a calendar that provides a timeline of when to begin the grant application process, a drafted letter of intent which consists of the basic description as to why the grant is needed, the project proposal, as well as the objectives and goals of the MQP project, and a complete breakdown of all the anticipated costs that may arise throughout the course of the project. In order to successfully navigate the grant application process, the team suggests that one person monitors the provided calendar and ensures all desired grant applications are completed and deadlines are properly met. All this information can be found in **Appendix I**.

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10.0 Appendices

10.1 Appendix A – Clinical Interview Questions and Protocol

Personal Introduction

1. What is your official job title/ job description? (Briefly describe the clinical setting or healthcare system in which the interviewee works.)
    a. How long have you been working as a ___job title____?

Shock

2. How frequently do you encounter a patient in shock?
    a. Tell me about the last time you encountered a patient in shock?
    b. What physical symptoms do patients display indicating that they would require emergency treatment for shock?
    c. What physical symptoms do patients continue to display during treatment for shock?
    d. What have you observed about the interface between the patient and anti-shock treatment?
3. What are the treatment strategies you use most frequently for patients experiencing shock?
4. What are other complications that patients in shock most often experience?

Hemorrhagic Shock

5. What is the process for treating a patient that is experiencing hemorrhagic shock?
6. Do your patients have any complaints/concerns about this treatment process? If so, what are they?
7. What are alternatives to address similar physical symptoms?
    a. How are new treatment strategies implemented at this facility?
8. If you can change anything about the treatment process, what would it be and why?

Anti-Shock Devices

9. Have you ever treated a patient with an anti-shock suit such as a LifeWrap, Military Anti-Shock Trousers (MAST), or other compression devices used for treatment of shock?
    a. What are the advantages of using this process?
    b. What issues (if any) have you experienced when using these devices?

Conclusion

10. Do you have any other connections/recommendations for interviewees?

Client statement: Develop an ergonomic and cost-efficient full-body compression suit for adult patients that will effectively combat hemorrhagic shock and circumvent its consequences by mechanically reducing both the intravascular space and the “third space” to be used in the Intensive Care Unit (ICU).

Need vs. Want Activity

1. Separate the below design objectives into the three categories (needs, wants, not beneficial) using **Table 12**.
2. Identify your top five needs

Table 12: Needs, Wants, & Not Beneficial Activity

Needs	Wants	Not Beneficial

Design Objectives

- Cost efficient
- Ergonomic design
- Accessibility and visibility for wound monitoring and assessment of the patient
- Treat hemorrhagic shock
- Easily applied and removed
- Lightweight device
- Customizable
    - Detached in sections to expose or exclude desired areas of the body, yet maintain the tensile strength
    - Adjustable compressive capability
    - Cut apart in emergent situations
    - Progressive and gradual application and removal
- Transparent for ease of viewing
    - Anti-fog material as the patient will be sweating
- Anti-perspirant
- Biocompatibility
    - Skin sensitization
    - Blood-contacting material
    - Breeding ground for bacteria
- Imaging compatibility
    - Need to be able to do an ultrasound to check for blood clots
- Temperature regulated
- Hypoallergenic
- Effectively shunt blood centrally from the periphery without causing direct pressure injuries
    - Avoid pressure wounds
- Sensors

- Blood Pressure
- Pressure applied by device
- Body Temperature
- Heart Rate
- Respiration Rate
- Pulse Oximetry
    - Pulse Rate
    - Blood Oxygenation Saturation

10.2 Appendix B – Material Tensile Testing

Purpose: The purpose of this experiment is to determine the maximum force that each of the materials can withstand in comparison to Neoprene, a commonly used material in anti-shock suits. This test will inform the team as to which material is most dependable and may ultimately be utilized in the final design.

Materials:

- Instron 5544 with a load cell accuracy of 0.25% and range of 2000N
- Bluehill Software
- Mitutoyo digital caliper with an accuracy of 0.01 mm
- Material samples:
    - neoprene
    - 20 G PVC
    - 16 G PVC
    - polyester film

Hypothesis: Out of the materials tested, all will fail prior to the application of 200 N of force, and neoprene will yield the highest tensile strain due its thickness and elasticity in comparison to the other materials.

Methods:

1. Clean the caliper, computer, and Instron control panel with 70% ethanol prior to use
2. Prepare three 152mm x 152mm samples of each test material
3. With the Mitutoyo digital caliper, measure and record the thickness of the test sample and enter that value into the Bluehill software
4. Load the proper equipment for a tensile test onto the Instron
5. Load the test sample onto the Instron
6. Set the sampling rate for each material as follows:
   *sampling rates differ in order to minimize the amount of time spent testing – the Polyester film and the Neoprene are outliers that require unique sampling rates due to their material properties.
    a. Neoprene: 250 mm/min
    b. 20 G PVC: 200 mm/min
    c. 16 G PVC: 200 mm/min
    d. Polyester film: 150 mm/min
7. Apply a 2N tare load to the sample and zero the extension
8. Select ‘Start’ and allow the test to run until the material reaches a failure point
9. Repeat 3x for each test material

Analysis:

1. The maximum modulus, E, is calculated as the maximum slope of the σ-ε curve as $E= \Delta\sigma/\Delta\varepsilon$.
2. Ultimate tensile strength (UTS) calculated as the maximum force divided by the initial area, $UTS = F_{max}/A$
3. Calculate the average and standard deviation for the three samples.
4. Use the Shapiro-Wilks test to confirm normality. Then, if the data sets were normal, determine if the statistical difference between the means of the samples is significant

using an ANOVA. If the data sets were not normal, use a Kruskal-Wallis test to determine if the statistical difference between the medians is significant.

Results:

Table 13: Instron Testing Results

Sample	Length (mm)	Width (mm)	Thickness (mm)	Extension (mm)	Max. Load (N)	Tensile Stress at Max. Load (MPa)	Modulus (Automatic) (MPa)
20 G PVC							
Average ± Standard Deviation	154 ± 1	152 ± 2	0.28 ± 0.00	37.8 ± 65.3	1.41 ± 0.89	0.009 ± 0.006	4.61 ± 0.23
16 G PVC							
Average ± Standard Deviation	154 ± 2	150 ± 2	0.33 ± 0.00	0.01 ± 0.00	2.14 ± 0.07	0.014 ± 0.000	7.98 ± 1.40
Polyester Film							
Average ± Standard Deviation	151 ± 3	149 ± 2	0.04 ± 0.01	15.6 ± 22.1	1.94 ± 0.55	0.013 ± 0.004	78.3 ±5.95
Neoprene							
Average ± Standard Deviation	156 ± 1	154 ± 1	3.48 ± 0.00	0.03 ± 0.03	3.16 ± 2.04	0.021 ± 0.013	0.93 ± 0.11

10.3 Appendix C – Connection Method Tensile Testing

Purpose: Once completed, the device may utilize a combination of materials with various connection methods. The purpose of this test is to understand the potential failure points and ultimate tensile strength of each connection method. Additionally, fatigue testing will be conducted to estimate material longevity.

Hypothesis: If the tensile strength of each of the three stitch patterns shown in **Fig. 33** are tested, then stitch pattern 43 will yield the highest tensile strength as it covers the most surface area.
*Welding is an alternative connection method. However, due to equipment limitations, the team was unable to test this connection method.

Figure 33: Control (1), Primary Stitch Pattern (43), Secondary Stitch Pattern (29)

Materials:

- Instron 5544 with a load cell accuracy of 0.25% and range of 2000N
- Bluehill Software
- Mitutoyo digital caliper
- Stitch samples:
    - 3 x 20 G PVC connected with stitch pattern 1
    - 3 x 20 G PVC connected with stitch pattern 43
    - 3 x 20 G PVC connected with stitch pattern 29

Failure Testing on the Seams

Methods:

1. Clean the caliper, computer, and Instron control panel with 70% ethanol before use
2. Measure and record the dimensions of each material component
3. Measure and record the overlap length that creates the seam
4. Mount the specimen onto the screw-action grips with grip faces on the Instron
5. Load the specimen with a 2N tare load and measure the grip-to grip length
6. Using the Instron and Bluehill software, determine the ultimate tensile strength (UTS) for when the combination product fails
7. Repeat with each of the three stitch samples

Analysis:

1. The maximum modulus, E, is calculated as the maximum slope of the σ-ε curve as $E= \Delta\sigma/\Delta\varepsilon$.
2. Ultimate tensile strength (UTS) calculated as the maximum force divided by the initial area, $UTS = F\_max/A$
3. Calculate the average and standard deviation for the three samples

4. Use the Shapiro-Wilks test to confirm normality. Then if the data sets were normal determine if the statistical difference between the means of the samples is significant using an ANOVA. If the data sets were not normal, use a Kruskal-Wallis test to determine if the statistical difference between the medians is significant.

Fatigue Testing on the Seams

Methods:

1. Clean the caliper, computer, and Instron control panel with 70% ethanol before use
2. Measure and record the dimensions of each material component
3. Measure and record the overlap that creates the seam
4. Mount the specimen onto the screw-action grips with grip faces on the Instron
5. Using the software set the applied stress as below the UTS value recorded from the failure testing N/m^2 based on the UTS
6. Perform fatigue testing using the predetermined test stress then unload to zero load repeating until the sample fails
7. Repeat each of the three stitch samples

Analysis:

1. The number of samples signifies the number of uses the material can be used for under the stress value
2. Calculate the average and standard deviation for the three samples
3. Use the Shapiro-Wilks test to confirm normality. Then if the data sets were normal determine if the statistical difference between the means of the samples is significant using an ANOVA. If the data sets were not normal, use a Kruskal-Wallis test to determine if the statistical difference between the medians is significant.

Results:

Table 14: Instron Connection Method Testing Results Vinyl to Vinyl

Sample	Length (mm)	Width (mm)	Thickness (mm)	Extension (mm)	Max. Load (N)	Tensile Stress at Max. Load (MPa)	Modulus (Automatic) (MPa)
Shoe Glue							
Average ± Standard Deviation	124.2 ± 12.8	60.35 ± 6.24	1.07 ± 0.29	117.0 ± 8.3	272.9 ± 43.7	27.3 ± 4.4	60.3 ± 13.3
E6000							
Average ± Standard Deviation	109.9 ± 10.3	49.77 ± 4.29	1.01 ± 0.21	45.5 ± 12.5	167.9 ± 26.9	16.8 ± 2.7	103.7 ± 11.6
7500 Vinyl Seam Sealer							
Average ± Standard Deviation	123.0 ± 11.4	61.45 ± 2.11	1.19 ± 0.52	15.0 ± 18.8	81.2 ± 32.2	8.1 ± 3.2	222.4 ± 71.0
8015 Universal Carpet Seam Sealer							
Average ± Standard Deviation	126.2 ± 4.0	54.44 ± 1.94	1.00 ± 0.18	47.8 ± 24.2	171.3 ± 10.7	17.1 ± 1.1	104.1 ± 28.1
Max Grip Vinyl Tape							
Average ± Standard Deviation	98.1 ± 8.0	52.02 ± 0.46	0.76 ± 0.03	78.1 ± 18.4	183.1 ± 15.8	18.3 ± 1.6	74.7 ± 18.8
Double-Sided Carpet Seam Tape							
Average ± Standard Deviation	105.3 ± 12.5	57.86 ± 6.95	1.32 ± 0.06	51.8 ± 29.47	162.0 ± 27.5	16.0 ± 2.5	82.2 ± 25.7
Carpet Shield Self-Adhesive							
Average ± Standard Deviation	102.6 ± 6.2	49.35 ± 1.81	0.86 ± 0.19	13.8 ± 13.09	27.0 ± 8.7	2.7 ± 0.9	124.5 ± 46.8

Table 15: Connection Method Vinyl to Nylon Testing Results

Sample	Length (mm)	Width (mm)	Thickness (mm)	Extension (mm)	Max. Load (N)	Tensile Stress at Max. Load (MPa)	Modulus (Automatic) (MPa)
E6000							
Average ± Standard Deviation	83.9 ± 3.2	26.42 ± 0.33	1.90 ± 0.13	73.9 ± 10.7	210.5 ± 53.3	21.1 ± 5.3	208.1 ± 60.5
Shoe Glue							
Average ± Standard Deviation	93.29 ± 1.5	26.14 ± 0.91	1.62 ± 0.10	24.5 ± 6.9	185.4 ± 30.4	18.5 ± 3.0	206.6 ± 41.2

Table 16: Instron Stitch Length Testing Results

Sample	Length (mm)	Width (mm)	Thickness (mm)	Extension (mm)	Max. Load (N)	Tensile Stress at Max. Load (MPa)	Modulus (Automatic) (MPa)
5 in.	292.1	137.44	0.9	256.5	340.7	0.8	105.7
4 in.	132.8	153.0	0.9	18.8	284.2	0.7	65.8
3 in.	131.9	154.0	0.8	66.0	266.3	0.7	67.9
2 in.	144.3	138.5	0.7	54.0	234.6	0.5	69.2

10.4 Appendix D – Transparency Testing Protocol

Purpose: The purpose of this experiment is to determine the transparency of the different materials in an effort to identify which has the highest visibility. This test will inform the team as to which material is most transparent and may ultimately be utilized in the final design.

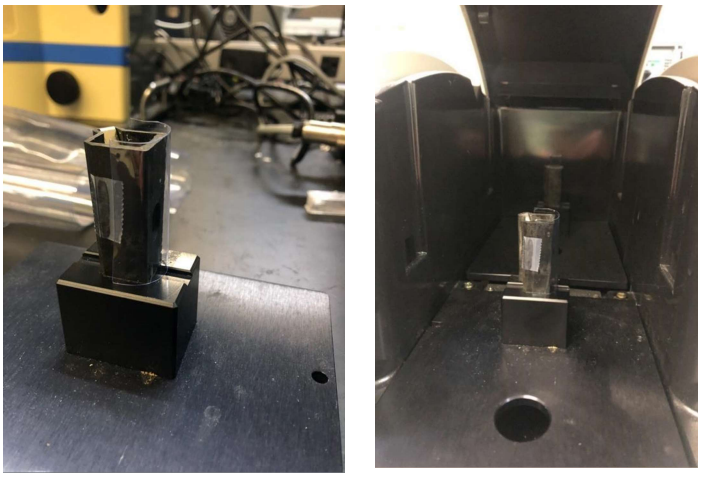
Hypothesis: The team's hypothesis for this experiment is that out of the materials tested, the 16 G PVC and 20 G PVC will have the highest and most similar light transmittance values. The air will have a transmittance of 100% and the dark notebook will have a transmittance of 0%.

Materials:

- UV-Visible Spectrophotometer
- Scissors
- Scotch Tape
- Material samples:
  - 20 G PVC
  - 16 G PVC
  - Polyester Film
  - KimTech Wipe
  - Scotch Tape
  - Dark cardboard notebook cover

Methods:

1. Remove the cuvette sample holder from the UV-Vis Spectrophotometer
2. Cut a 3x4 inch piece of material and affix with tape to the cuvette sample holder, ensuring that the material is covering the slot on the right side as indicated in **Fig. 34a**
3. Carefully place the sample tray back in the machine as indicated in **Fig. 34b** and close the cover
4. Proceed with the testing protocol in the software



(a) (b)

Figure 34(a-b): (a) Material Fastened to a Sample Holder with Tape. (b) Sample Holder in the Spectrophotometer.

Analysis:

1. The data output consists of percent transmittance values for each wavelength in the assigned range at the indicated interval
2. Graph the percent transmittance values for each material on the same graph to compare transparencies
3. Calculate the average transmittance value for each material for each trial, and an overall average value for each material sample

Results:

Table 17: Transparency Testing Results

Material	Transmittance Trial 1 Average	Transmittance Trial 2 Average	Average % Light Transmittance
Air	99.99	99.99	99.99
20 G PVC	79.18	78.34	78.76
16 G Vinyl	77.84	76.74	77.29
Polyester Film	79.53	78.54	79.03
Scotch Tape	18.09	17.59	17.84
KimTech Wipe	3.49	3.09	3.29
Dark Notebook	0.00	0.00	0.00

10.5 Appendix E - Moisture Transparency

Purpose: The purpose of this experiment is to determine the transparency of the selected material when moisture is present between the device and the surface of the patient's skin.

Hypothesis: The transparency of the material will be maintained within a responsible level even under conditions of moisture. Here the team defined “reasonable level” as still being able to see substantial marks on the patient’s skin.

Materials:

- Segment of 20 G PVC
- Test Subject
- Camera
- Spray bottle filled with water
- Permanent marker
- Tape
- Paper towel

Methods:

1. Write “TEST” on the anterior and posterior of the subject’s forearm with the marker
2. Spray the segment of 20 G PVC with a thin evenly distributed layer of water
3. Wrap the segment of 20 G PVC around the test subject’s arm and secure it with tape
4. Photograph the anterior and posterior of the test subject’s arm and record the results
5. Remove the segment of 20 G PVC and dry it with a paper towel
6. Spray the patient’s arm with a thin evenly distributed layer of water
7. Wrap the segment of 20 G PVC around the test subject’s arm and secure it with tape
8. Photograph the anterior and posterior of the test subject’s arm and record the results
   *Note: Experiment was performed at room temperature

Analysis:

1. Observe the results
2. Record the results with photos
3. Evaluate the results

10.6 Appendix F – Methodology for Calibrating Force Sensitive Resistor

Purpose: The purpose of this methodology is to calibrate a force-resistive sensor and set the boundary conditions for adequate pressure applied; ultimately providing the user with a text output.

Materials:

- Prototyped segment of anti-shock trousers
- Arduino Uno
- Force-resistive sensor
- Breadboard
- Liquid crystal display (LCD)
- Male to female jumper wires
- Arduino IDE software
- Leads
- USB Cable to Arduino Uno
- Resistors (one 2.2 kΩ & one 10 kΩ)
- Blood pressure cuff

Methods:

1. Set up the circuit according to the Makerguide as shown in **Fig. 35**
2. To determine the boundary conditions for the "Adequate Pressure Applied" range, use a blood pressure cuff and calculate the mean value following 10 trials. This number will represent the bit value for the pressure applied at 30 mmHg and 50 mmHg
   *Determined to be 170 and 330, respectively.
3. Code the values below the 30 mmHg to output on the serial monitor and LCD "No Pressure Detected"
4. Code the values above the 50 mmHg to output on the serial monitor and LCD "Too Much Pressure Applied"

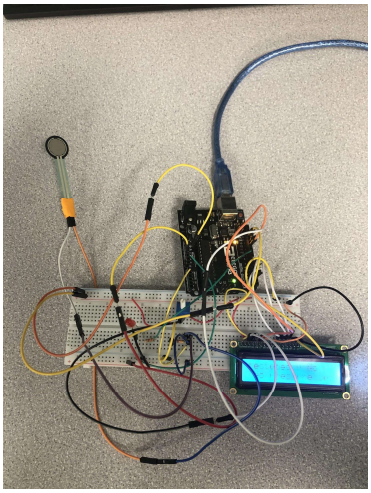


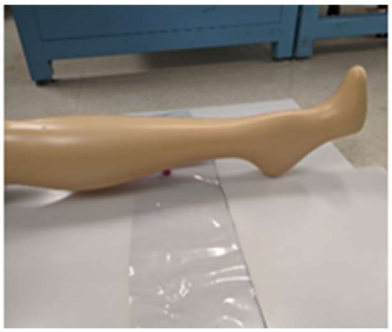
Figure 35: Force Sensitive Resistor with Arduino and LCD Display Circuit

The following code was adopted from the open source supported by Makerguides [58].

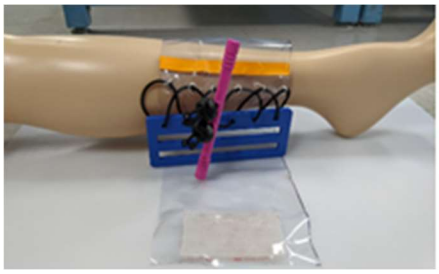
```
/* Simple example code for Force Sensitive Resistor (FSR) with Arduino. More info:
https://www.makerguides.com */

#include <LiquidCrystal.h>

LiquidCrystal lcd(12,11,5,4,3,2);

int fsrPin = 0;
int fsrReading;
int LEDpin = 9;
int LEDbrightness;

void setup(void) {
  Serial.begin(9600);
  pinMode(LEDpin,OUTPUT);
  lcd.begin(16, 2);
  lcd.print("MQP");

}

void loop(void) {
  fsrReading = analogRead(fsrPin);

  Serial.print("Analog reading = ");
  Serial.print(fsrReading);
  LEDbrightness = map(fsrReading,0,1023,0,255);
  analogWrite(LEDpin,LEDbrightness);

  if ((fsrReading < 330)&&(fsrReading > 170))  {
    lcd.println(" - Adequate Pressure Applied");
    Serial.println(" - Adequate Pressure Applied");
  }
  if ((fsrReading < 1023)&&(fsrReading > 330))  {
    lcd.println(" - Too Much Pressure Applied");
    Serial.println(" - Too Much Pressure Applied");
     }
  else {
    lcd.println(" - No Pressure Detected");
    Serial.println(" - No Pressure Detected");
    }
```

10.7 Appendix G – Prototype Application Instructions

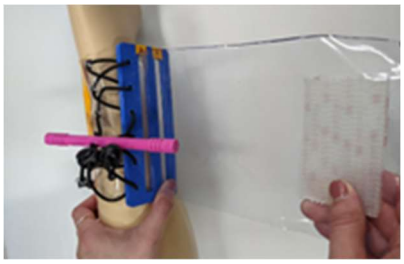
1. Lift the patient's leg and slide the open device underneath.

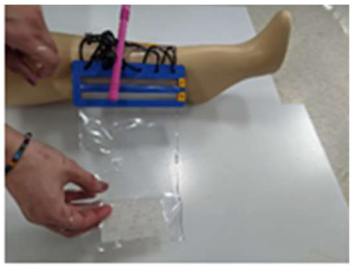

2. Wrap the device around the leg with the buckle situated on the outside of the leg. Ensure that the underlap flap is situated flat under the buckle and lacing.



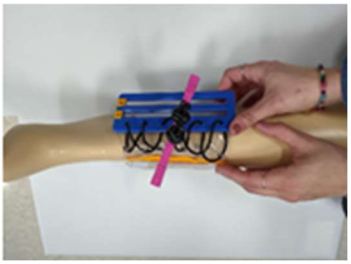
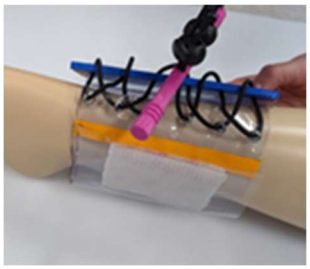

3. Thread the flap up through the buckle slot labeled with "1", the flap should be pulled through the buckle so that the segment is as tight as possible and the buckle rests flush against the patient's leg.



4. Thread the flap down through the buckle slot labeled "2."

5. Remove the paper backing from the adhesive side of the Velcro and secure.

6. Pull the excess bungee through each of the two-hole clamps.
7. Tighten the segment by rotating the tourniquet rod to achieve the desired pressure.
8. Lock the tourniquet rod into place using the hooks on the buckle.

10.8 Appendix H – User Study Protocol

1. Train User
    a. Present with Instructions (**Appendix G**) and while reading through, demonstrate to the trainee
    b. Instruct Trainee to repeat steps while narrating the actions they will be taking, tell them what to do if they forget
        i. Ensure that they go slowly and act as if it is a real patient
        ii. Continuously ask questions, “What are you doing now?”
2. Decay Period (30 minutes)
3. Testing
    a. Have them apply the device
        *Note: Do not intervene
    b. Make note of any mistakes
4. Questions
    a. What was the hardest part?
    b. Were there any confusion or misleading steps in the instructions?
    c. Do you have any suggestions for improvement?

10.9 Appendix I – Grant Application Materials

10.9.1 *Appendix I.1 - Timeline of Potential Grants*

The timeline of potential grants based on the company, qualification, source, application requirements, and deadline are outlined in **Table 18**.

Table 18: Timeline of Potential Grants

Company	Qualify?	Website	Application requirements	Deadline
United Engineering Foundation	Yes	https://www.uefoundation.org/uef-grants-program/	Online, proposal, need to meet 501(c)(3) status	May 1
Alstom Foundation	maybe	https://www.foundation.alstom.com/submit-project	Application with employee and NGO	June
Eversource	maybe	https://www.eversource.com/content/nh/about/community/supporting-the-community/charitable-contributions-volunteerism	Online	Nov
L.L. Bean	Yes	https://www.llbean.com/llb/shop/516899?nav=C2t516899-516898	Emailed proposal	Rolling
NCEES	yes	https://ncees.org/education/engineering-award/enter-the-competition/	Poster board with engineering project details	Spring
Cornell Douglas Foundation	maybe	http://www.cornelldouglas.org/apply	Letter and project introduction, 990 form for current year	Rolling
Awesome Grant	yes	https://www.awesomefoundation.org/en/submissions/new	Online application	Rolling
PepsiCo	maybe	http://www.pepsico.com/sustainability/Philanthropy/strategic-grants	Online application	Rolling
3M	maybe	https://www.3m.com/3M/en_US/gives-us/	May need to apply from in country location/ send a letter to plant manager	Rolling
Pentair Foundation	maybe	http://www.pentair.com/en/about-us/corporate-social-responsibility/pentair-foundation	Email pentaircsr@pentair.com	Rolling
GM Foundation	maybe	http://www.gm.com/company/giving-back/about.html	Letter of inquiry	Rolling

10.9.2 *Appendix I.2 - Search Engines*

Free:

- http://www.hmheducation.com/grantsfunding/search.php
- www.grants.gov
- http://dir.yahoo.com/Society_and_Culture/Issues_and_Causes/Philanthropy/Organizations/Grant_Making_Foundations

Payment Required:

- Foundation directory online (http://fconline.foundationcenter.org/ipl.php)

10.9.3 *Appendix I.3 - Grant Information*

Working Title: Designing Non-Pneumatic Anti-Shock Trousers

Proposing entity and participating entities: Worcester Polytechnic Institute and UMASS Memorial

Funding requested and budget: To be determined by future groups

Period of performance: To be determined by future groups

Abstract/Project Description:

Abstract

Hemorrhagic shock is a significant cause of death for trauma patients. Current treatment methods face a variety of shortcomings and limitations. The team conducted research and testing which informed the design and prototyping of a device to combat hemorrhagic shock to shunt blood from the lower extremities to the core of the body while maintaining a clear, unobstructed view of the patient's skin for wound and injury monitoring. The team created a fully functional segment of the device in order to perform proof of concept testing and create a baseline for the future of the design. Verification testing showed that the device does not obstruct the cutaneous view. Furthermore, extrapolating from the data collected on a single segment, the team estimated that the device can be applied by two applicators within the identified time window of five to ten minutes. The device can apply 30-50 mmHg which is in the desired range of pressure to meet the device objectives to sufficiently shunt blood to the core of the body.

Explanation of shock

Shock is characterized as a failure within the cardiovascular system that leads to a decrease in blood circulation throughout the human body. As blood is responsible for carrying oxygen throughout the body, when its supply diminishes, the body's needs are not met. When the baseline amount of blood is decreased, oxygen and nutrient levels are too low within individual

cells, tissues, and organ systems. This will result in the body going into shock. If the blood flow in the body remains inadequate, the patient can progress further into shock and eventually die. There are many types of shock, one that is most common in the ICU is hypovolemic, which is characterized by excessive loss of fluid or blood.

Shock in the ICU is predominantly treated with intravenous fluids (IV) to regain sufficient bodily fluid increasing the fluid circulation and blood pressure. This increase in bodily fluid is used for microcirculation improvement transporting oxygen throughout the body and maintaining oxygen availability for tissues. As an alternative or in conjunction with IV fluid stabilization, compression is applied to the peripheral limbs to increase the blood flow in the central circulatory region and create hemodynamic stabilizing effects. Compressive devices fall into two categories: pneumatic and non-pneumatic depending on whether an external compressor element is required.

Military anti-shock trousers (MAST) were a common emergency medicine treatment strategy of the past that have fallen out of use due to several shortcomings. MAST have three sections, a compartment for each leg and one for the abdominal section, that each contain inflatable air bladders. These are then pumped up until the blood pressure increases back to about 100 mmHg or until the Velcro or urethane begins to pull apart. Non-pneumatic anti shock garments (NASG) is a device intended for stabilizing post-partum hemorrhage patients. The compression suit has five neoprene sections that are secured tightly with Velcro and in the abdominal section there is a detachable foam ball for additional pressure. Both these devices were designed to be used in medical settings with constraints and when transporting the patients to maintain stability until they can be treated.

Our proposed device design will be differentiated as it will be used in the ICU when patients are in the plateau stage of shock making the intended duration of use longer as the objective is to improve patient stability. With this goal in mind, the device will be transparent to permit continuous patient monitoring.

Summary of Concepts:

Project description

This project seeks to design an anti-shock garment that will effectively shunt blood from the peripheral limbs to the patient's core and in doing so, combat hemorrhagic shock, which is commonly found in ICU patients. This design differs from previous designs by incorporating transparent materials for unobstructed patient monitoring and pressure injury prevention. Additionally, this device is lightweight, easily applied, and cost-efficient. With the redesign, this device can overcome the failures of past anti-shock garments and allow for a more effective treatment for patients.

Collaboration of faculty, students, and licensed professional engineers

This project seeks cross-disciplinary collaboration between engineering students, medical students, engineering professionals, and medical professionals. The engineering students take the lead on design and research with close guidance, support, and feedback from the professionals and medical students. Professor Coburn of WPI, (Assistant Professor Biomedical Engineering, PhD Chemical and Biomolecular Engineering, and Postdoc Biomedical Engineering), advises the team. Dr. Torres of UMASS Memorial provides invaluable insight from the clinical perspective. Working with graduate nursing students, the team approaches the problem to protect the user-experience for nurses and technicians who will be responsible for donning, monitoring, and doffing the device. Additionally, informational interviews with professionals from the medical and other industries have been interviewed to provide a diverse take on the project.

Knowledge or skills gained

To be determined by future groups.

Proposal

Detailed schedule, business plan, and any reporting (To be determined by future groups).