GRADO EN INGENIERÍA EN TECNOLOGÍAS INDUSTRIALES

TRABAJO FIN DE GRADO

SOFT ROBOTICS FOR AUTOMATIC FEMORAL ARTERY CLOSURE

Autor: Elena Villanueva Nieto

Director: Enrique Gutierrez Wing

Madrid

Declaro, bajo mi responsabilidad, que el Proyecto presentado con el título

Soft Robotics for Femoral Artery Closure

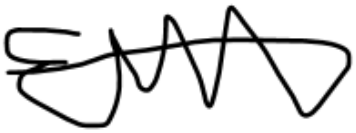
en la ETS de Ingeniería - ICAI de la Universidad Pontificia Comillas en el

curso académico 2021/22 es de mi autoría, original e inédito y

no ha sido presentado con anterioridad a otros efectos.

El Proyecto no es plagio de otro, ni total ni parcialmente y la información que ha sido

tomada de otros documentos está debidamente referenciada.



Fdo.: Elena Villanueva Nieto Fecha: 11/07/2022

Autorizada la entrega del proyecto

EL DIRECTOR DEL PROYECTO

Fdo.: Dr. Enrique S. Gutierrez Wing Fecha: 14/ JUL / 2022

GRADO EN INGENIERÍA EN TECNOLOGÍAS INDUSTRIALES

TRABAJO FIN DE GRADO

SOFT ROBOTICS FOR AUTOMATIC FEMORAL ARTERY CLOSURE

Autor: Elena Villanueva Nieto

Director: Enrique Gutierrez Wing

Madrid

Acknowledgments

Professor E. G-Wing: helped the team brainstorm with guidance. Gave the team the steel bar, the shaft connectors and the motors. Helped the team with the code. Helped the team to calibrate the pressure sensors and lent the Push / Pull Force Gauge.

Professor S. Russo: guided the team through the project.

TA Jessica: helped the team with the code for the motors.

EPIC: helped the team with the slit in the bar and printed base plate.

RÓBOTICA PARA CIERRE DE ARTERIA FEMORAL

Autor: Villanueva Nieto, Elena.
Director: Gutierrez Wing, Enrique.
Entidad Colaboradora: Boston University

RESUMEN DEL PROYECTO

Gracias a los avances tecnológicos, el siglo XXI representa una época en la que los dispositivos médicos pueden ser tan fiables como los médicos y las enfermeras. Durante los últimos 200 años, los procedimientos relativos a la arteria femoral se realizaban mediante compresión manual hasta la aparición de los dispositivos intravasculares y extravasculares que eliminan la presencia de un humano para la realización del procedimiento. El reto consistía en diseñar un dispositivo médico que combinara la tecnología de la compresión manual y de los dispositivos extravasculares para cerrar la perforación de la arteria femoral después de los procedimientos de cateterismos para evitar la pérdida de sangre. El dispositivo creado aplica una presión cíclica de diferentes intervalos de tiempo en el lugar de la perforación para lograr la hemostasis de forma rápida, fácil y cómoda con una tela que se envuelve alrededor de una barra que gira para proporcionar presión en la superficie de la tela mientras su radio disminuye. La validación y el éxito del dispositivo se comprobaron mediante la lectura de la presión aplicada con un sensor de presión y la detención de una fuga de agua en un sistema de tuberías presurizadas que representaban una pierna.

Palabras clave: Cateterismo, Arteria Femoral, Tela, Sangre, Hemostasis, Presión, Motores, Conectores, Barra de acero, Sensor de presión, Vendaje de Presión, Cables.

1. Introducción

Tras los procedimientos de cateterismos, la arteria femoral tiene un tamaño de acceso por el que el paciente puede perder mucha sangre. El principal procedimiento utilizado para lograr la hemostasis es la compresión manual, pero como ésta puede ser muy agotadora para el médico e incómoda para el paciente, se han investigado nuevos enfoques, como los dispositivos extravasculares e intravasculares. Este tipo de dispositivos utilizan elementos como materiales coagulantes, tapones de colágeno, geles o clips para cerrar el lugar de la incisión y evitar la salida de sangre. Los dispositivos intravasculares requieren muchas veces que una pequeña parte del dispositivo

permanezca en la arteria y no se han realizado suficientes estudios para demostrar que no dañan la arteria a largo plazo. Por eso se necesita un dispositivo que combine las tecnologías de la compresión manual (major método para lograr la hemostasis) y de los dispositivos extravasculares (automatización de un dispositivo): "Un dispositivo que pueda seguir el método y los tiempos de la compresión manual y que no necesite que una persona haga el trabajo necesario.

El método que se ha encontrado para conseguir la hemostasis con la compresión manual, que se muestra en la ilustración 1, consiste en aplicar una presión de 60-80 mmHg durante un minuto y luego retirarla. A continuación, se aplica una presión de 100 mmHg durante 3 minutos. A continuación, la enfermera aplica 80 mmHg de presión durante 15 minutos. A continuación, la enfermera disminuye la presión en 20 mmHg en incrementos de tiempo de 2 minutos hasta que la presión llega a cero.

El objetivo principal es aplicar suficiente presión, por lo que se necesitan al menos 100 mmHg. Otros requisitos son que debe ser ponible, intuitivo, rápido y reutilizable.

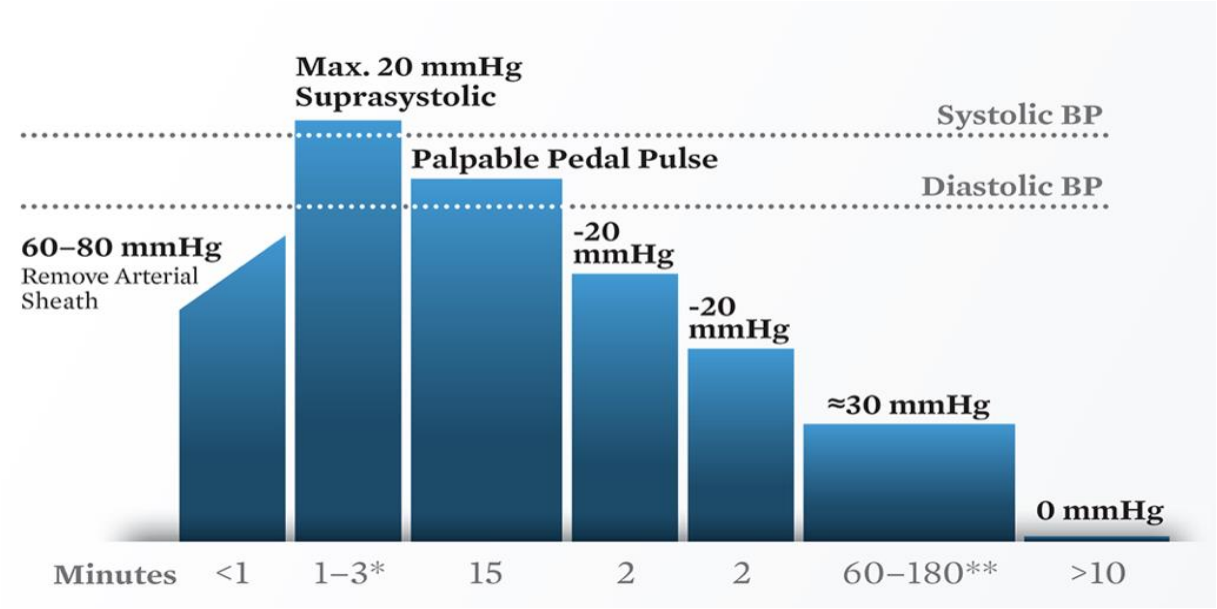


Ilustración 1. Método para llegar a la hemostasis [1]

2. Descripción del modelo/sistema/herramienta

El dispositivo creado aplica una presión mecánica cíclica durante diferentes intervalos de tiempo para lograr la hemostasis. Mediante una serie de tomas de datos en el lugar de la perforación, el dispositivo ajusta la presión que se consigue en el lugar del acceso y en la pierna mediante un sistema de retroalimentación. Consta de tres partes principales: actuador, sensor y placa base.

El actuador tiene dos motores conectados con conectores de eje a una barra de acero que gira con los motores. Esta barra tiene una hendidura en el centro y una tela (capa exterior) que la atraviesa. La tela tiene un velcro que conecta sus dos extremos para que se pueda fijar fácilmente a la pierna. Los motores giran en diferentes direcciones y se controlan con una placa Arduino y un código.

La placa base está impresa en 3D y es lo que mantiene todo en su sitio y respecto a la pierna. Es redondeada como la forma de la pierna para que se adapte a ella y pueda ir encima. También tiene tiras de velcro en ambos extremos para asegurar el dispositivo a la pierna para que no se deslice en caso de movimiento y para que aplique la presión en el lugar correcto.

El sensor utilizado es un FSR (Force Sensitive Resistor) cuya parte principal es redonda y pequeña. Esta parte se coloca en la parte superior del lugar de la incisión para que pueda proporcionar información sobre la presión que se está aplicando.

Por último, también hay una capa interior o vendaje de presión que se coloca justo encima del lugar de la perforación para protegerlo y evitar que el dispositivo toque la herida y que la sangre se extienda por todo el dispositivo. Se cambia con cada paciente para que el dispositivo sea reutilizable.

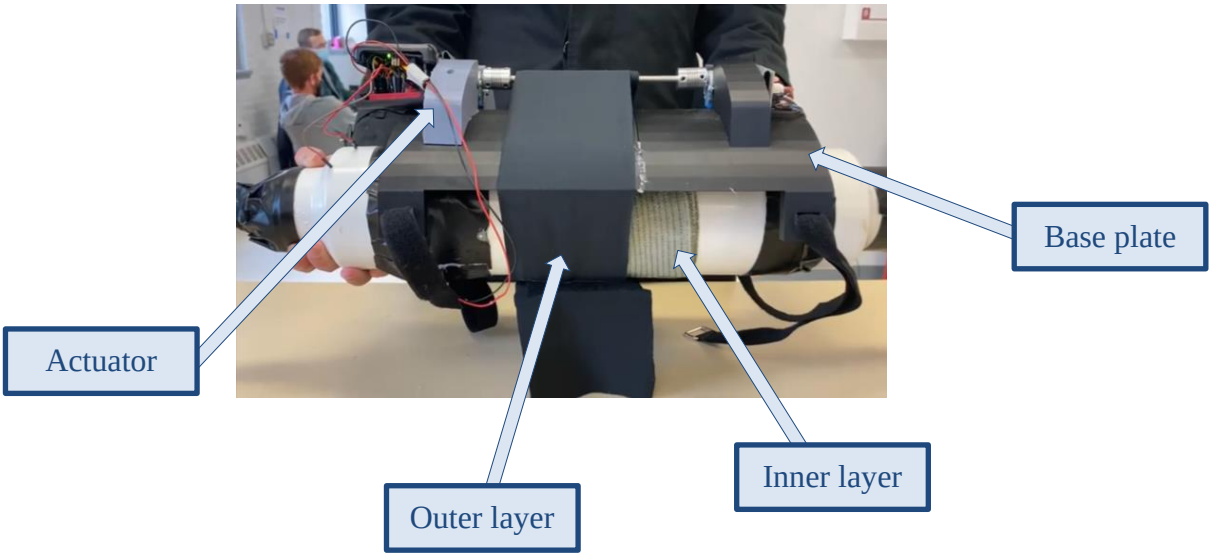


Ilustración 2. Partes del dispositivo

3. Resultados

Para validar el dispositivo, se realizaron dos pruebas.

La primera fue la prueba del sensor. Para esta prueba, lo primero que había que hacer era calcular la fuerza máxima que debía aplicar el dispositivo para lograr la hemostasis. A partir de la investigación, se encontró que la presión máxima necesaria en todos los ciclos es de 100 mmHg. La fuerza depende del área y como es el sensor de presión el que va a dar ese valor, era necesario calcular la fuerza con esa presión y el área del sensor utilizado.

$$Max\ presión\ necesaria\ \cong 13.000\ Pa$$

$$Sensor\ 1\ area = \frac{\pi}{4} \times 0{,}01905^2$$

$$P = \frac{F}{A} \rightarrow F = P\ \times A$$

$$Fuerza\ con\ sensor\ 1 = 3{,}705\ N$$

La fuerza objetivo es de 3.705 N, así que se empezó a hacer funcionar el dispositivo y a leer la presión con el Arduino hasta que se leyese esa fuerza. Los resultados son:

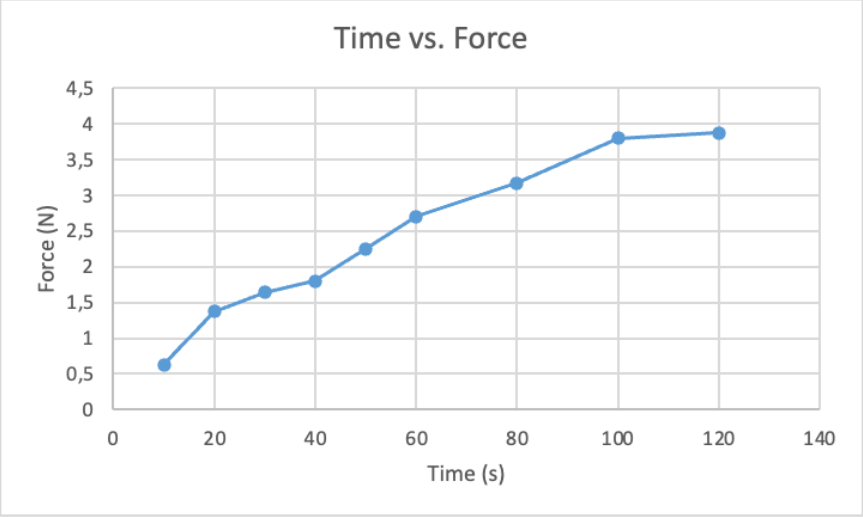


Ilustración 3. Resultados test de sensor

Dado que se alcanza la fuerza objetivo, la primera prueba se considera un éxito.

La segunda prueba fue la prueba de presión y lo que se quería era ver si el dispositivo podía detener una fuga en un sistema presurizado que imitaba una pierna.

El montaje se hizo con tuberías que estaban conectadas y tenían un tubo de PVC en el medio que es lo que representaba la pierna. También había dos lectores de presión de agua en ambos extremos de la tubería para leer la presión del agua que iba de un extremo a otro gracias a una bomba de agua.

Cuando no había fugas se leyó la presión antes y después de la tubería y era la misma en ambos lugares. Luego se hizo un agujero en la tubería y se volvió a leer la presión. Como era de esperar, se produjo un descenso significativo de la presión después de la fuga. Para terminar, se puso en marcha el dispositivo y se leyó la presión por última vez. Lo que se pudo observar después de un tiempo, fue que la presión volvió a subir a sus niveles iniciales y volvió a ser la misma en ambos extremos. Esto demostró que el dispositivo tiene la capacidad de detener la fuga y devolver el sistema a su estado inicial, por lo que la segunda prueba también se consideró un éxito.

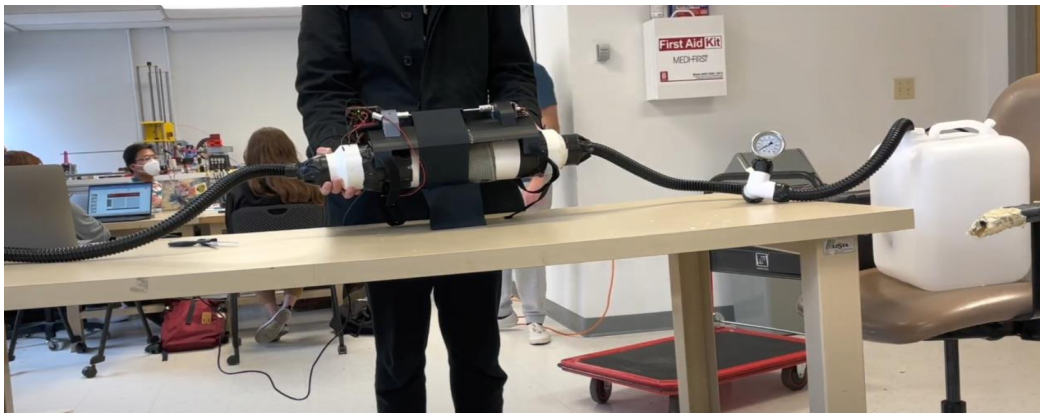


Ilustración 4. Montaje del sensor de presión

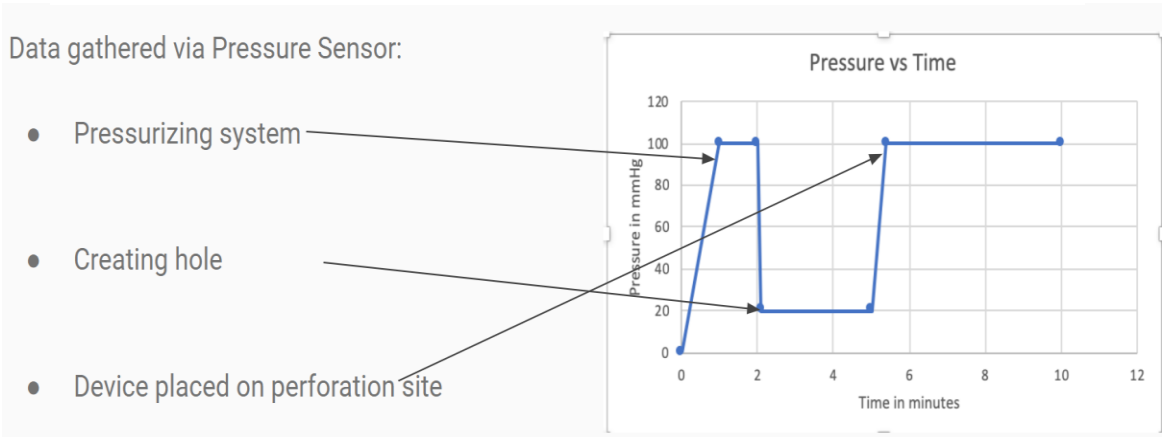


Ilustración 5. Resultados del test de presión

4. Conclusiones

La principal conclusión es que el dispositivo cumple con su principal requisito y propósito aunque todavía tiene mejoras que hacer para cumplir con todos los requisitos y ser óptimo. Es necesario añadir elementos como un interruptor o una batería y se debería imprimir en 3D una placa base más pequeña ya que esta primera tiene material extra que hace que el dispositivo sea un poco demasiado grande. Por último, para que el dispositivo sea óptimo, necesita una mejor carcasa (caja donde van todos los controles y se pega a la placa base para que no estorbe).

Tabla 1. Conclusiones y recomendaciones

REQUERIMIENTOS	PROTOTIPO ACTUAL	RECOMENDACIONES FUTURAS
PRESIÓN	SÍ	Sistema de retroalimentación (LCD)
PONIBLE - TAMAÑO - PESO	- NO - SÍ	- Placa base impresa en 3D más pequeña - Batería - Soldar
INTUITIVO	SÍ	Añadir interruptor
REUTILIZABLE	SÍ	Vendaje de presión más corto
VELOCIDAD	SÍ. Podría ser mejorada	Mejores motores

5. Referencias

[1] *Home | Abbott U.S.* (2020). Abbott Laboratories. https://www.abbott.com/

[2] *DEFINE_ME*. (2019). Journal of Vascular Surgery.

https://secure.jbs.elsevierhealth.com/action/cookieAbsent

SOFT ROBOTICS FOR FEMORAL ARTERY CLOSURE

Author: Villanueva Nieto, Elena
Supervisor: Gutierrez Wing, Enrique.
Collaborating Entity: Boston University

ABSTRACT

Due to the progress in technology, the 21st century represents an age where medical devices can be as reliable as doctors and nurses. For the last 200 years, procedures regarding the femoral artery were done by manual compression until the emergence of intravascular and extravascular devices which eliminates the presence of a human for the completion of the procedure. The challenge was to design a medical device that combined the technology of both manual compression and extravascular devices to close the perforation of the femoral artery after catheterization procedures to prevent blood loss. The device created applies cyclical pressure of different time intervals at the perforation site to achieve hemostasis in a fast, easy and comfortable manner with a textile that wraps around a rotating bar to provide pressure at the surface of the textile when its radius dereases. The validation and success of the device was tested by reading the pressure applied with a pressure sensor and by stoping a leak in a pressurized piping system which mimicked a leg.

Keywords: Catherization, Femoral Artery, Textile, Blood, Hemostasis, Pressure, Motors, Shaft Connectors, Steel Bar, Pressure Sensor, Pressure Bandage, Wires.

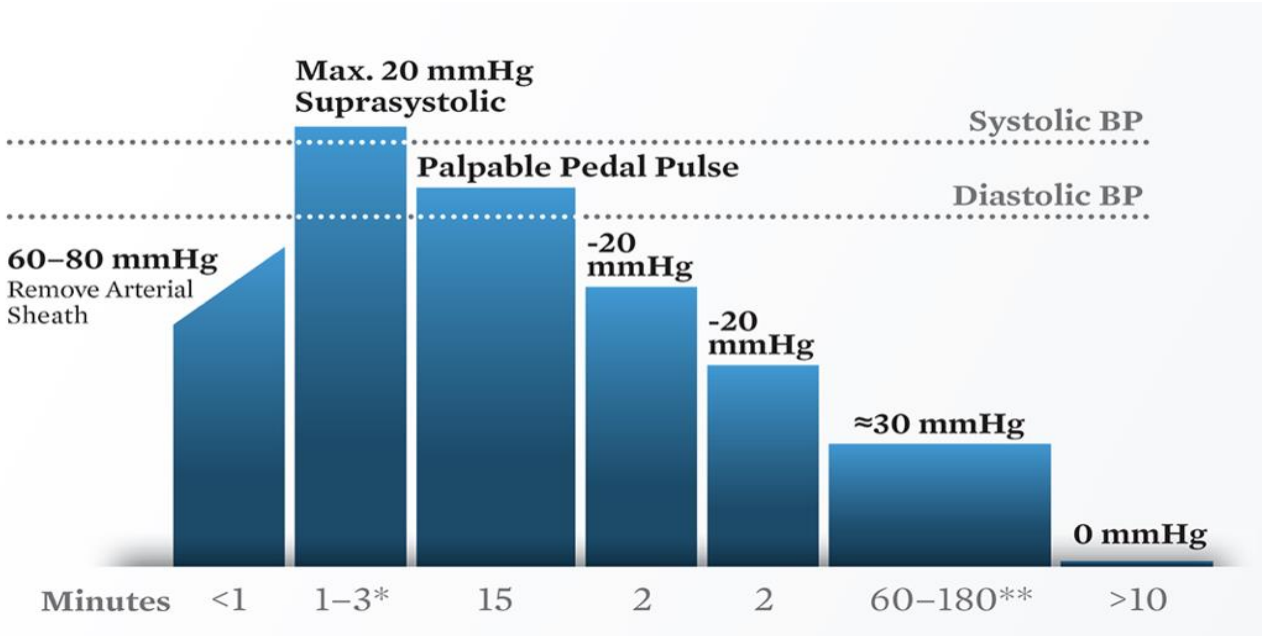
1. Introduction

After catheteriazation procedures, the femoral artery has an access size from which the patient can loose a lot of blood. The main procedure used to achieve hemostasis is manual compression but as this can be very tiring for the medical practitioner and uncomfortable for the patient, new approaches have been researched such us extravascular and intravascular devices. These kind of devices use elements such as coagulant materials, sutures, collagen plugs, gels or clips to close the incision site and prevent blood from coming out. Intravascular devices many times requires a small part of the device to stay in the artery and not enought studies have been conducted to prove that they do not harm the artery in the long run. This is the reason why a device that combines the techonologies of both manual compression (goal standard to achieve hemostasis) and extravascular

devices (automatization of a device) is needed: “A device that can follow the method, the times and the oressure appliance of manual compression and that does not need a person to do the work that is needed.

The method found to achieve hemostasis with manual compression, shown in illustration 1, consists of applying pressure of 60-80 mmHg for a minute and then removing the sheath. Then applying 100mmHg of pressure for 3 minutes. After that, the nurse applies 80 mmHg of pressure for 15 minutes. Then the nurse decreases the pressure by 20 mmHg in time increments of 2 minutes until the pressure reaches zero.

The main goal is to apply enough pressure so at least 100 mmHg are needed. Other requirements are that it needs to be wearable, intuitive, fast and reusable.



Ilustration 1. Method to achieve hemostasis [1]

2. Design description

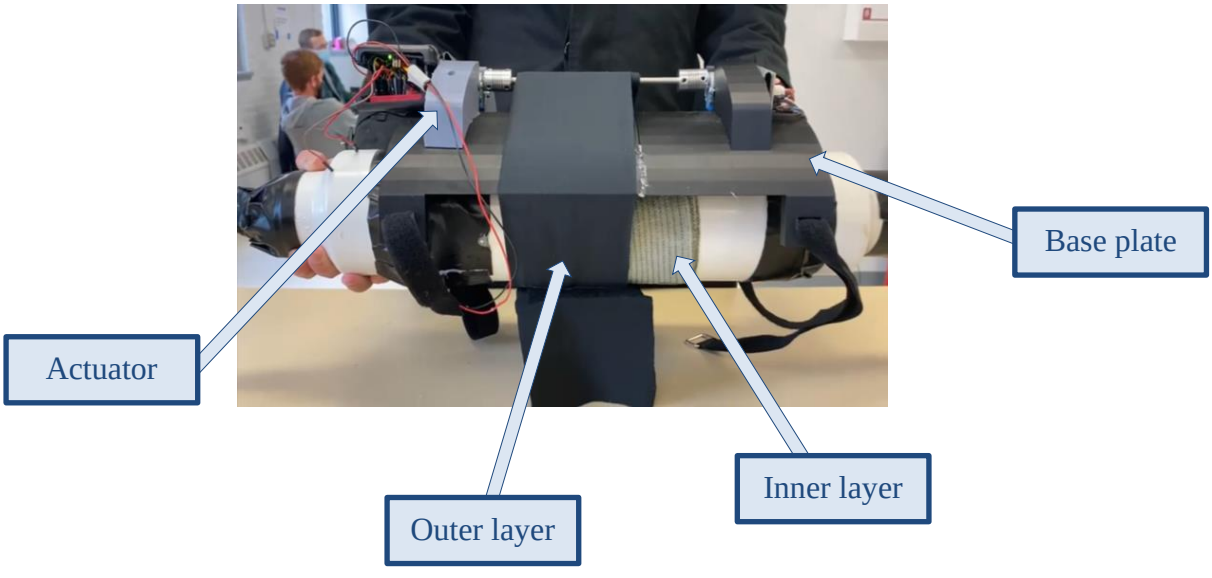
The device created is a compression sleeve that applies cyclical mechanical pressure during different time intervals to achieve hemostasis. Through a series of data gathering at the perforation site, the compression sleeve adjusts the pressure that is achieved at the site and on the leg via a feedback system. It has three main parts: actuator, sensor and base plate.

The actuator has two motors connected with shaft connectors to a steel bar which rotates with the motors. This bar has a slit through the middle and a textile (outer layer) goes through it. The textile has Velcro which connects its both ends so it can be easily attached to the leg. The motors rotate in different directions and are controlled with an Arduino board and a code.

The base plate is 3D printed and its what holds everything in place and respect to the leg. It is rounded like the shape of the leg so it adapts to it and can go on top of it. It also has Velcro strips at both ends to secure the device to the leg so it does not slip in case of movement and so that it applies pressure at the correct place.

The sensor used is a FSR (Force Sensitive Resistor) which main part is round and small. This part goes op top of the incision site so that it can provide feedback on the pressure that is being applied to it.

Lastly, there is also an inner layer or pressure bandage which is worn right on top of the perforation site for protection and to prevent the device from touching the wound and the blood from getting all over the device. It changes with every patient to make the device reusable.



Ilustration 2. Parts of the design

3. Results

To validate the device, two tests were conducted.

The first one was the Sensor Test. For this test the first thing needed was to calculate de maximum force the device needed to apply in order to achieve hemostasis. From the research, it was found that the maximum pressure needed in all cycles is 100 mmHg. The force depends on the area and as it is the pressure sensor what is going to give that value, it was needed to calculate the force with that pressure and the area of the sensor uses.

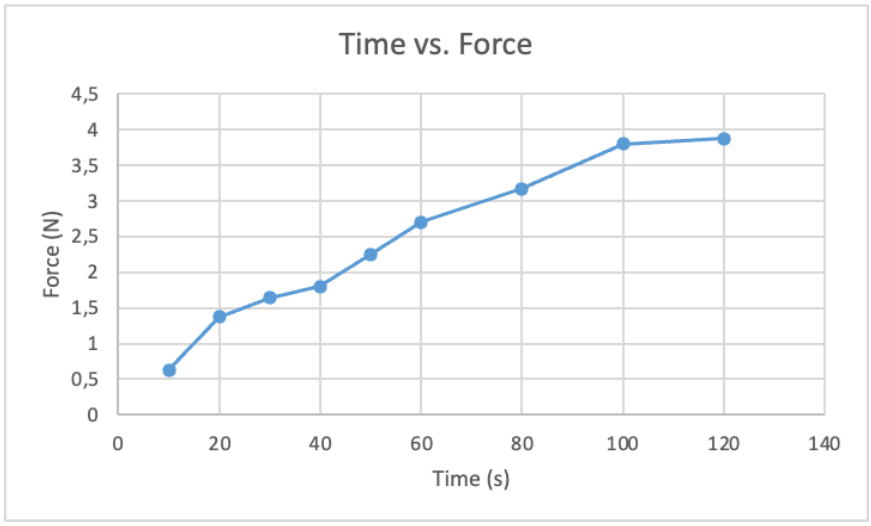
$$Max\ pressure\ applied\ \cong 13.000\ Pa$$

$$Sensor\ 1\ area = \frac{\pi}{4} \times 0{,}01905^2$$

$$P = \frac{F}{A} \rightarrow F = P\ \times A$$

$$Force\ sensor\ 1 = 3{,}705\ N$$

The target force is 3,705 N so we start to function the device and read the pressure with the Arduino until that force is read. The results are:



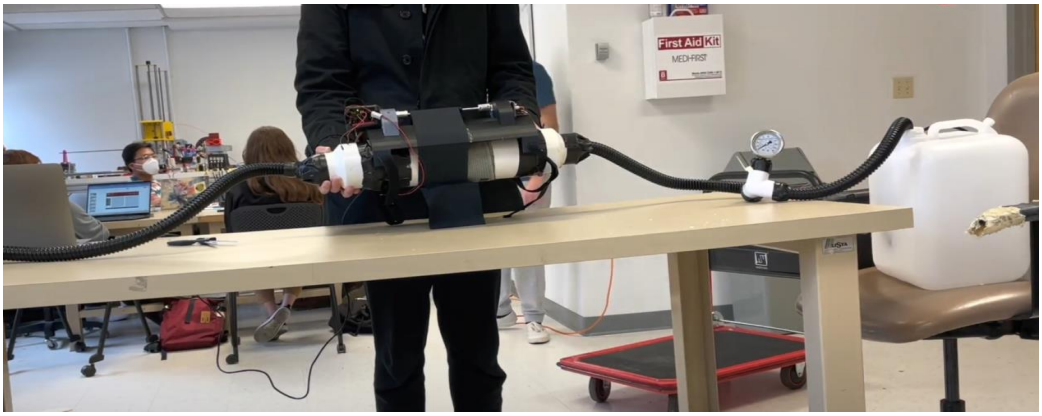
Ilustration 3. Pressure test results

Since the target force is achieved, the first test is considered a success.

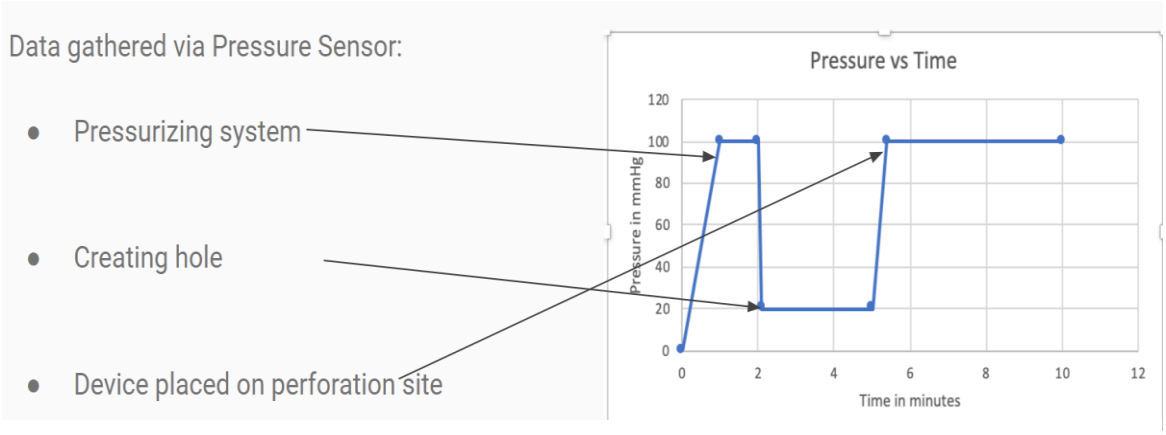
The second test was the Pressure test and what was wanted was to see if the device could stop a leak in a pressurized system that mimicked a leg.

The set up was done with pipes that were connected and had a PVC pipe in the middle which is what represented the leg. There were also two water pressure readers at both ends of the pipe to read the pressure of the water that went from one end to another thanks to a water pump.

When there were no leaks the pressure was read before and after the pipe and it was the same in both places. Then a hole was created at the pipe and the pressure was read again. There was a significant drop in the pressure after the leak, as expected. To finish, the device was put into action and the pressure was read one last time. What could be observed after some time, was that the pressure went back up to its initial levels and it was again the same at both ends. This showed that the device has the ability to stop the leaking and turn the system back to its initial condition and thus the second test was also considered a success.



Ilustration 4. Pressure test set up



Ilustration 5. Pressure test results

4. Conclusions

The main conclusion is that the device meets its main requirement and purpose even though it still has improvements to make to meet every requirement and to be optimal.

Elements such as a switch or a battery need to be added and a smaller base plate should be 3D printed as this first one has extra material which makes the device a little bit to big. Lastly, to make the device optimal, it needs a better housing (box where all the controls go and is glued to the base plate so it is out of the way).

REQUIREMENTS	ACTUAL PROTOTYPE	FUTURE RECOMMENDATIONS
PRESSURE	YES	Feedback system (LCD)
WEARABLE - SIZE - WEIGHT	 - NO - YES	 - Smaller 3D printed base plate - Battery - Soldering
INTUITIVE	YES	Add switch
REUSABLE	YES	Shorter pressure bandage
SPEED	YES. Could be improved	Better motors

5. References

[1] *Home | Abbott U.S.* (2020). Abbott Laboratories. https://www.abbott.com/

[2] *DEFINE_ME*. (2019). Journal of Vascular Surgery. https://secure.jbs.elsevierhealth.com/action/cookieAbsent

Index

Figure Index

Table index

Chapter 1. PROJECT DEFINITION

1.1 INTRODUCTION AND MOTIVATION

My client Prof Sheila Russo, who works at Boston University, presented a problem to the class Senior Design Project and we started looking for a viable solution to it.

In the medical space, catheterization procedures are becoming more common as the development of the catheter is improving. A catheterization is a procedure that requires the doctor to insert a catheter into the femoral artery so it can have access to the vascular system. When the catheter is removed there is a rapid blood loss from the femoral artery, so the incision site must be blocked by applying pressure to the leg. Usually, this bleeding is stopped by a nurse who places a hand on the leg, above the access, applying a certain pressure for a long time. If this is wrongly done, it can result in an increase of the time necessary for the wound to heal and can be very painful for the patient as well as fatiguing to the nurse.

The problem in case is that current methods to stop bleeding after some procedures such as femoral artery catheterization can be very painful for the patient and very tiring for the medical practitioner.

More people are tending to use this method to overcome complicated heart problems like placing a valve in the heart to regulate blood pressure or just to assist blood pumping during dangerous procedures especially with older people. With that said, people are investigating the best and most effective ways to achieve hemostasis after the removal of the catheter from the main artery which is usually accessed through the leg. When the catheter is removed from the leg, there is a high blood loss at a very high rate due to a high blood pressure inside the artery. Our goal is to stop the bleeding by achieving hemostasis which could only be done by applying pressure at the perforation site or closing the perforation site through the skin with the help of a medical device.

To solve this, a soft robotic device that can provide the necessary pressure to the leg at the incision site in a simple, automated, and repeatable manner will need to be developed.

A prototype will need to be designed and, with different materials and resources, fabricated and tested to see if the goals have been achieved.

1.2 IMPORTANT TERMONOLOGY

- **Catherization**: it is a medical procedure used to diagnose certain heart conditions in which a thin tube called catheter is entered through a heart vessel which goes to the heart. This procedure usually uses the Femoral Artery to enter the catheter and thus the interest in closing an incision site in that location.
- **Hemostasis**: it is the way our bodies have to stop our blood vessels from bleeding when we have an injury. It is a natural process but with certain injuries the body needs local compression to achieve it.

1.3 BACKGROUND RESEARCH

Catheterization procedures are becoming more appealing to the patients as it is very non-invasive. Catheters are used in many heart surgeries, as they contribute to improving the outcome and the safety of the surgery. This is the main reason why many people are investigating better and more effective ways to achieve hemostasis in the artery's incision site of the catheter. This artery is usually the femoral artery.

Hemostasis can be achieved either by applying pressure at the perforation site or by closing the access through the skin with the help of a medical device. The main methods to achieve this are: manual compression, extravascular devices and intravascular devices.

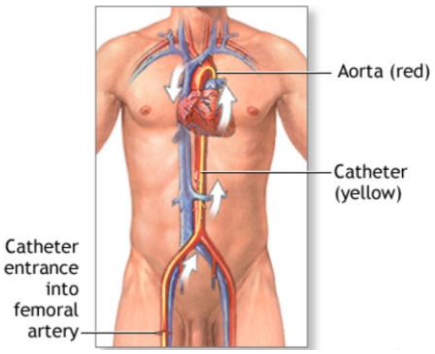


Figure 1. Cardiac catherization [7]

Manual Compression has been around since the early 1950s and is the gold standard of achieving hemostasis but as pressure must be applied during long periods of time, it can be very tiring for the nurse or doctor. There can also be inconsistencies with the pressure applied which can be very uncomfortable for the patient and painful.

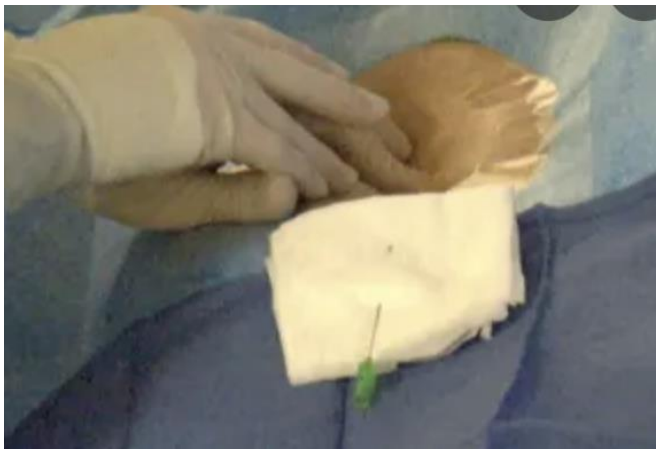


Figure 2. Manual compression [14]

Intravascular or passive devices are an alternative to manual compression since the early 2000s. They enter through the skin and close the perforation site in a matter of minutes instead of half an hour. They stop the bleeding by closing the wound with suture devices, collagen plugs or clips. This requires that a small part of the device must stay in the artery holding the wound closed which many times leads to different complications like infections, but this device also achieves hemostasis in less time which allows the patient to move before. New devices that can dissolve themselves once the bleeding has stopped and they are not needed anymore are being researched by many companies. Other types of intravascular devices use sealing materials like gels to stop the blood from coming out.

Extravascular or active devices came around in the 1990s and they reduced the time it takes for a patient to stop bleeding which keeps them more comfortable. They are a help to manual compression. They apply external pressure along the sides of the leg and specially at the perforation site so that the nurse does not need to apply as much pressure to achieve hemostasis as they have a complementary help. Other types of extravascular devices use pads impregnated with coagulant materials to form blood clots and it is also used as a complementary help to the manual compression for patients who are on certain medication such as anticoagulants.

Some examples of devices that are in the market are:

-The passive closure device Angio-seal which uses a collagen plug that helps blood clot in less time with the help of an intraluminal anchor.

-The active closure device StarClose SE (Abbott) which uses a nitinol clip to close the puncture.

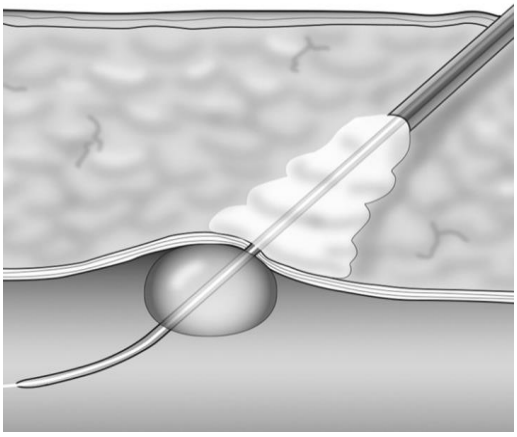


Figure 3. Intravascular device [3]

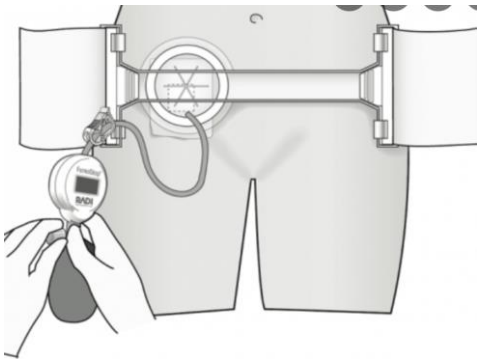


Figure 4. Extravascular device [13]

Even though intravascular devices offer advantages over extravascular devices in terms of time and efficiency, not enough studies have been conducted to fully conclude that intravascular devices do not harm the artery in the long run. Thus, the interest in extravascular devices and how to optimize a specific device.

1.4 GOALS

The main goal is to design and build an extravascular device that generates mechanical pressure around the leg and at the perforation to achieve homeostasis.

The main requirement is:

- **Enough pressure**: for the device to be useful to close a site access in the femoral artery it needs to apply different values of pressure and for certain amounts of different times so the device needs to apply at least the maximum value of pressure needed and it needs to be able to change the pressures applied.

Other requirements are:

- **Wearable**: anyone should be able to carry around the device and wear it on them. It should not be something that can only be in hospitals, whoever wants it should be able to acquire it. This means that it should have an adequate size and weight, small and light enough to be carried around.

- **Intuitive**: the person who uses it should not need medical training; it should be an intuitive device that anyone can use. This device is focused on femoral artery closure after procedures such as catheterization but, with certain modifications, someone should also be able to use it in an accident to close a wound for example so, for someone who is around to help and probably does not have medical training, it should be intuitive.

- **Fast**: it should close the wound before a lot of blood has been lost so the device has to be fast and easy enough to put on the patient and to apply the pressure needed.

- **Reusable**: the prototype needs a textile or a certain type of bandage to go over the actual wound so that the device does not touch it and so that it can be used with different patients without having to change the device but by only

changing the inner layer. This layer should also apply a small pressure so that the blood loss can be minimized in the time needed to make the device start working.

1.5 JUSTIFICATION

The main reason for this project is to achieve a device that can combine both the advantages of manual compression and extravascular devices.

As it was said before, manual compression is the gold standard of achieving hemostasis, but it can be very tiring, so the goal is to automatize it. A device that can follow the method, the times and the pressure appliance of manual compression and that does not need a person to do the work is needed.

The objective is to combine manual compression with extravascular devices because even tough intravascular devices offer advantages over extravascular devices in terms of time and efficiency (it makes the patient achieve hemostasis faster and better), not enough studies have been done to conclude that these types of devices do not harm the artery in the long run.

1.6 RESOURCES

To manufacture the device, Boston University provided the following resources:

A budget of $500 in this case which was used to purchase any materials needed to manufacture the device or the test set up.

Another source of resources available for the projects are the laboratories and workshop. The main one used for the project was the Engineering Product Innovation Center (EPIC) where machines tools can be used under the supervision of staff and teaching assistants (TAs). From the many machines available, the 3D printer was used for the base

plate, the laser cutter and the shearing machine for the steel bar and the wire EDM to solder the wires to the Arduino board.

It was also used textile for the prototype and Velcro to close it. For the inner layer, a pressure bandage will be used.

Lastly, the professor also gives, in the weekly meetings, resources available in the lab used for this class such us glue guns, motors, steel bars, wires and Arduino boards

1.7 METHODOLOGY

As a methodology, the steps of the engineering design process were followed.

First the problem definition was stated, then the work was organized in a Gantt chart and then the design started.

In this design phase, the first step was to think of a conceptual design that later on would turn into a first proof of concept. A preliminary design was then manufactured and many improvements were made until reached a detailed design which had to be tested.

In the testing phase, changes have to made after seeing the results in order to achieve the optimal funcional design.

1.8 PLANIFICATION

To solve this problem and to build a functional prototype, the first thing to do is to research on how the problem is solved and this is, on how a person can achieve homeostasis.

Then, research engineering and medical papers about existing devices in the market and how they work as innovation from that is needed so there had to be learning about them to apply it to the own device.

After the research is done, ideas for a device will start to be developed to then start building it and testing it.

As I am taking a class called Senior Design Project in Boston University, to achieve every one of these steps and to build a successful and functional prototype, there are different types of meetings. First of all, team meetings where brainstorming happen and where manual work to build the device is done (electronics included). There are also meetings with the project's director who guides during the project, helps with the brainstorming and supervises what is done. And the last types of meetings are with the customer, who needs to be updated every couple of weeks, and she gives feedback on what she requires and how she wants it. During the first semester she gave three main deadlines and meeting were set with her after every deadline to report. In the first one she asked to talk about the findings from the research, in the second one she requires a potential design and a list of the materials needed and the last one was a first proof of concept of a device, a first prototype.

FEMORAL ARTERY CLOSURE DEVICE
Grantt Chart

Project Start: 1/10/21

TASK DESCRIPTION	PLAN START	PLAN END	TYPE
1st SEMESTER	1/10/21	14/12/21	
1. Research papers and write why they could be useful	1/10/21	15/10/21	G
2. Potential design ideas	15/10/21	30/10/21	G
3. List of materials	15/10/21	30/10/21	G
4. Buy different textiles	30/10/21	9/11/21	G
5. Manufacture base plate with polyester plastic	30/10/21	9/11/21	G
6. Slit in steel bar	30/10/21	9/11/21	G
7. Design a code for two motors	9/11/21	21/11/21	G
8. Assemble motors with bar and textile	21/11/21	6/12/21	G
9. Calibrate pressure sensor	21/11/21	1/12/21	G
10. Code for pressure sensor	1/12/21	4/12/21	G
11. Assemble a first prototype and report	4/12/21	14/12/21	G
2nd SEMESTER	20/1/22	9/5/22	
1. Improve pressure sensor and calibrate new one	20/1/22	9/2/22	G
2. Design CAD for the base plate	20/1/22	9/2/22	B
3. Print base plate	9/2/22	6/3/22	B
4. Research and design possible pressure test	20/1/22	9/2/22	B
5. Leak test	9/2/22	6/3/22	B
6. Housing plan	6/3/22	21/3/22	B
7. Assembly pressure sensor	6/3/22	21/3/22	B
8. Assembly prototype	21/3/22	10/4/22	B
9. Improve code	21/3/22	10/4/22	B
10. Pressure test	10/4/22	23/4/22	B

Figure 5: Gantt chart

Chapter 2. FINAL DESIGN DESCRIPTION

The device created, named CloZe, was first designed as a compression sleeve that applies cyclical mechanical pressure during different time intervals to achieve hemostasis. Through a series of data gathering at the perforation site, the compression sleeve is able to adjust the pressure that is achieved at the site and on the leg via a feedback system.

The device has three main parts which are actuation, sensors and controls and they are all linked and depend on each other. The actuation system in the device is able to apply pressure all around the leg with a textile for comfortability and pressure range. Two 28BY-J stepper motors actuate the system by rotating a steel shaft which makes the textile wrap around the bar and decrease its radius (fig 6). The bar has a slit through part of its length, made by a drill press, so that the textile could be inserted. There are also two shaft connectors with set screws that connect both motors and the steel bar in order to make the bar move along with the motors.

Figure 6. Actuator

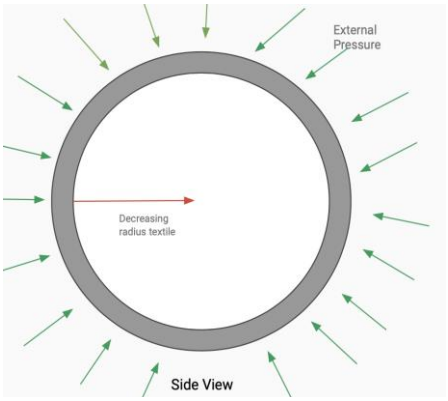


Figure 7. Compression of the textile

As the motors rotate and the textile starts to wrap itself around the bar, the radius of the textile around the leg decreases (videos 1 and 2) so the compression of the textile around increases and thus the external pressure achieved at the perforation site increases as well (fig 7).

The Arduino controls the actuation of the system as it undergoes pressurized cycles. The actuation is a time dependent cycle that applies pressure over 30 minutes to achieve hemostasis. As the code is time dependent, most of the operations revolve around long delays on the Arduino.

In terms of sensors, the pressure sensor used is a Force Sensitive Resistor (FSR). It is also connected to the Arduino and programmed to read the outputs of the force applied at the perforation site. Two different pressure sensors were tested on the device after calibration which will be discussed later. When the pressure increases, active elements touch the semiconductor so the resistance goes down, which gives an output in the Arduino. Every output represents a certain force and that equivalence is what was obtained with the calibration. The FSR is put between the outer layer and the inner layer (pressure bandage) where it reads the pressure the device generates.

Figure 8. Pressure sensor (FSR) [5]

In terms of controls, the Arduino Uno is responsible for applying the mechanical pressure exerted by the sleeve by the rotation of the motors, monitoring the pressure at the perforation site and finally providing feedback to the system. First, it is important to note that the code is a time dependent cycle and undergoes cyclical pressure of different time intervals to achieve hemostasis over 30 minutes.

In order to write the code, the first thing needed is to research how a person achieves hemostasis (how much pressure is needed and during how much time).

The method found (figure 9) to achieve homeostasis with manual compression consists of applying a pressure of 60-80 mmHg for a minute and

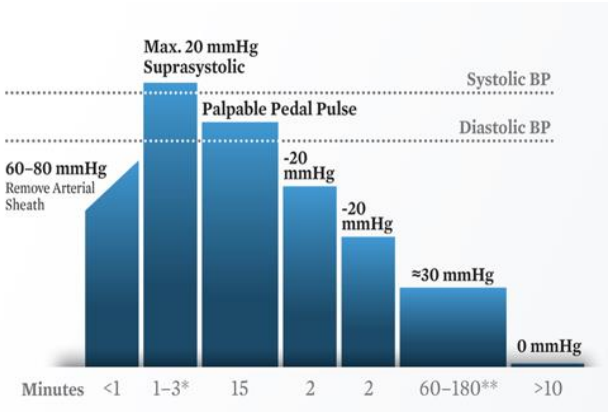


Figure 9. Method to achieve hemostasis [1]

then removing the sheath. Then the nurse applies 100mmHg of pressure for 3 minutes. After that, the nurse applies 80 mmHg of pressure for 15 minutes. Then the nurse decreases the pressure by 20 mmHg in time increments of 2 minutes until the pressure reaches zero.

Looking at figure 10, the device starts at 0 minute and the motors begin to turn when the device is placed on the leg until the pressure sensor reads a value of 80 mmHg. The motors are held at this position for 3 minutes and then turned again until the pressure reaches the maximum pressure which is 100 mmHg (this is called the suprasystolic phase). The motors are held at this position for 3 minutes as the textile is exerting its maximum pressure and then the motors turn in reverse direction for the first time decreasing the pressure to 80 mmHg and held at this position for approximately 15 minutes. This is the most important phase of the cycle which is called the palpable pedal pulse phase. Finally, when the quarter of an hour has passed, the system is ready to undergo the final stage of cyclical pressure. The motors turn in reverse direction until the pressure reaches 60 mmHg and hold for 2 minutes. The motors will turn in decrement of 20 mmHg for 2 minutes until the pressure reaches 20 mmHg and hold for 7 minutes or until the perforation site on the leg stops leaking.

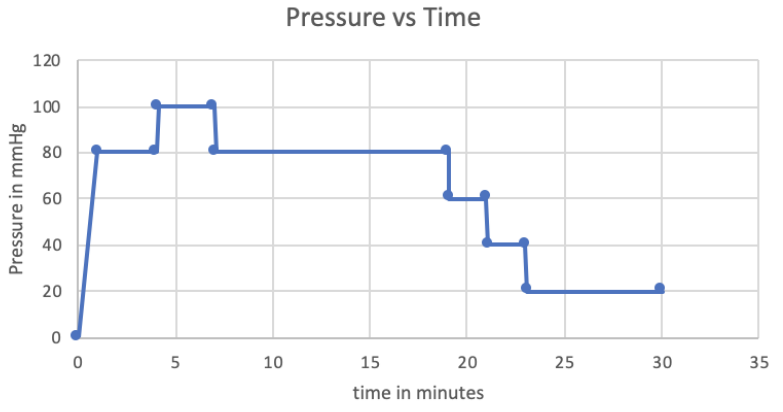


Figure 10. Pressure vs. time to achieve hemostasis

Moreover, the pressure sensor offers a feedback system to the motors and actuation system to prevent errors in pressure felt at the site since the main requirement of the device is to be able to apply a specific amount of pressure over a period of time. Figure 11 shows the feedback schematic in CloZe and starts by having a desired pressure reading P(t) and having the motors turn until the pressure reaches that value. Every five seconds, the pressure

sensor reads the FSR reading into an analog output value which is translated into a pressure/force reading to compare with P(t). Depending on the value of the FSR the motors adjust their position until the FSR reading matches the desired pressure.

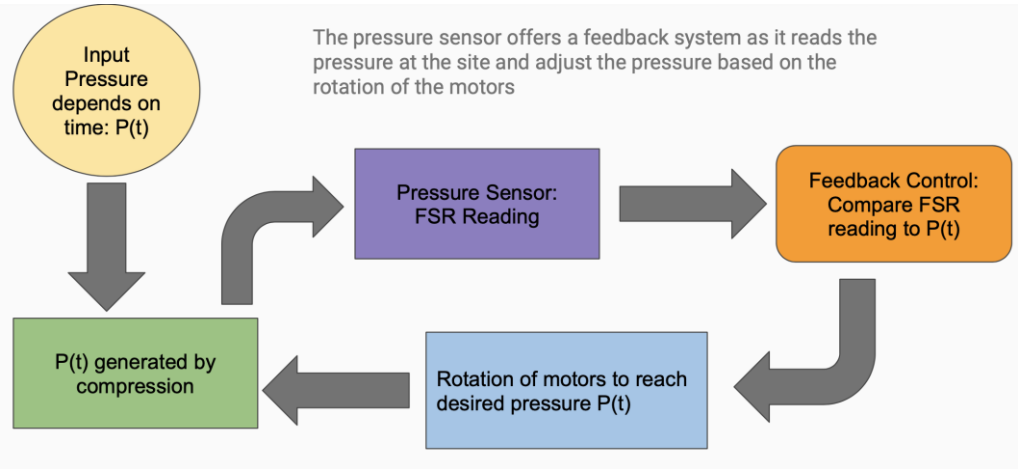


Figure 11. Feedback schematic

CloZe has 5 main components: the inner layer, the outer layer, the 3D printed base plate, the design of the pressure sensor and the textile actuator with the controls (figure 16).

- The **inner layer** (Fig 12) is worn on the leg and is the first fabric that is put between the leg and the device. It is a pressure bandage which has a patch in the middle to secure the blood from getting all over the device and changes with each patient. This fabric is elastic, so it is easy to put around the leg and its main purpose is comfort and skin protection, so the device is not in direct contact with the leg and the perforation site to avoid infections among other things.

Figure 12. Inner layer (pressure bandage)

- The **outer layer** is made out of a single layer fabric, and it is what generates the force to the leg by wrapping around it. The outer layer is adjustable to fit the patient's leg perfectly and to accommodate all sizes by the use of Velcro.

- On the other hand, the **base plate** (Fig 13) is fabricated using 3D printing with a material of TPE black. The main purpose of the base plate is to hold the actuation system in place and bring all the components together. The base plate is attached to the leg by the use of Velcro strips from both sides of the plate so it is fully fixed around the leg.

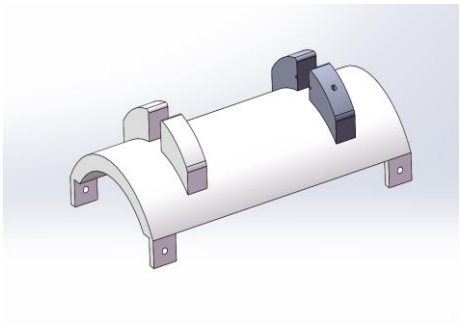


Figure 13. Base plate

Figure 14. FSR

- The **pressure sensor** (fig 14) is designed to have some rigidity while still being flexible and easy to handle. The sensor is wrapped between a piece of cardboard and textile to ensure an optimized reading of the values at the FSR.

- The **textile actuator,** shown before in figure 15, goes on top of the base plate and is composed by two 28BYJ motors with a 5V power supply and the steel bar with the two shaft connectors. The electrical components are the Arduino board, the motors, two stepper drivers, the power supply and a resistor hooked to the FSR pressure sensor.

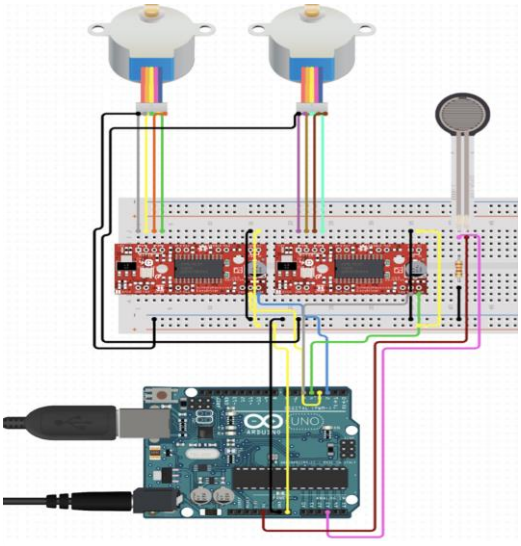


Figure 15. Electrical componets for actuator

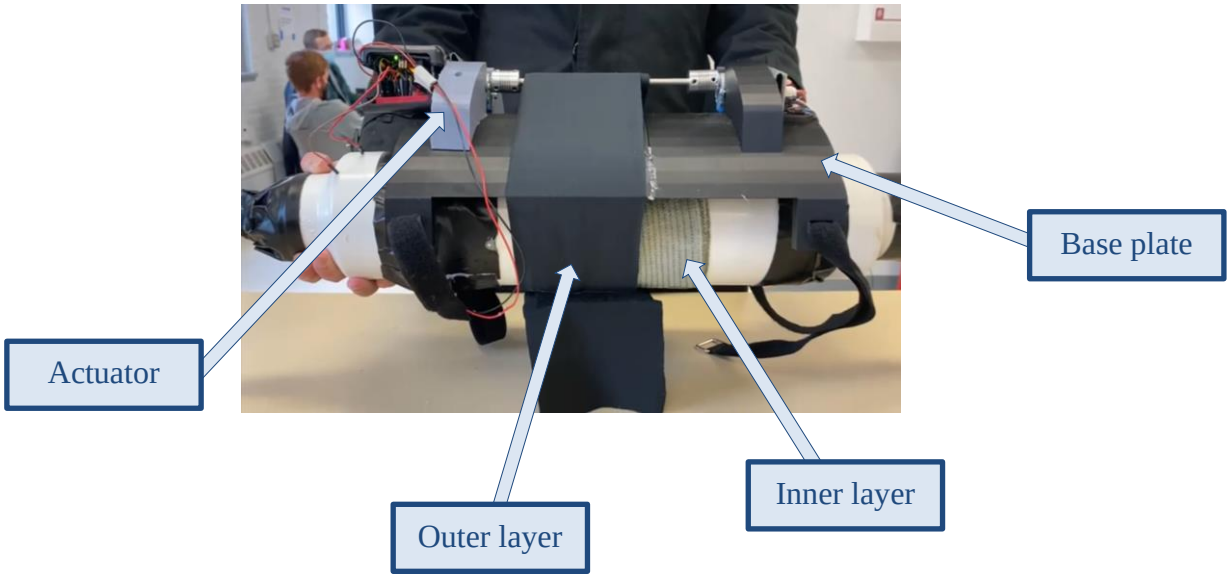


Figure 16. Parts of the design

Finally, as CloZe is a multi-component device, it is important to note the steps of wearing the device to get the highest accuracy possible in terms of pressure generated at the site. The pressure bandage is worn first securing the perforation on the patch and tightened to the maximum to prevent any leakage. Next, the pressure sensor is placed on top of the bandage and then the base plate on top of all the components. It is very important to secure the plate with the Velcro around the leg because the device is placed on the leg so a minimum movement can cause the device to slip or not apply pressure in a proper manner.

2.1 VIDEOS

Video 1. Reduction of the textile's radius and compression of the outer layer
https://drive.google.com/file/d/1Z0OXLPXmHjYrjiXE8trNiRdHtj89j7zO/view?usp=sharing /
https://drive.google.com/file/d/1dGepP6CAzL7oXGuKBZSHI9UReKlItuED/view?usp=sharing

Video 2. Compression of the textile to the leg:
https://drive.google.com/file/d/1VkmeyVpxMnCFAbDdoAgmNPN__AvHs_r4/view?usp=sharing

Chapter 3. DESIGN DECISIONS

Before settling on the final design, many actuation systems, sensors design, and controls were put to the test and finally compared against the main requirements of the prototype to assess the best way to go.

3.1 DESIGN OPTION 1

The first design that was thought about is based on combining several soft robot components in terms of actuators, sensors, controls, modeling and manufacturing from the website which the client referred to and advised to use. It is called “softroboticstoolkit.com” and offers methods and ideas for the design of soft robots. The total design of the device that was envisioned is a combination of a knit textile bending actuator which is controlled by an electro - pneumatic circuit. The actuator would provide a compression force in a form of bending around the leg and thus offering pressure at the compression site. The compression force from the actuator is generated by locking air at high pressure inside a balloon which presses on the site.

3.1.1 ACTUATION

The actuation of this design is based on a pneumatic textile actuator. The basis of this design utilizes different materials with different stretching properties and a balloon that could be pressurized to produce a motion such as bending. The concept of producing a force by the device is by increasing the mass of the air in the balloon thus increasing the volume of the balloon. When the volume of the balloon reaches its maximum, an increase in air mass results in an increase in pressure on the walls of the balloon. Consequently, having the balloon placed and constrained between two materials with different stretching properties produces a motion of bending and compression when air is being released and compressed in the balloon (Fig 17). When air is released, fabric 1 stretches more than fabric 2. In order for the actuator

to maintain equilibrium, it must adopt an arc shape and thus apply pressure on the leg in an arc form

Figure 17. Pneumatic actuator design [3]

3.1.2 CONTROLS

Design 1 offers an electro-pneumatic circuit to control the inflation and deflation of the balloon and thus the pressure applied at the perforation site. The main advantage of the utilization of this system is that the circuit also offers a built-in pressure sensor to control the amount of air being released in the balloon. The main function of the circuit would be to perform pressurized cycles of compression for extravascular devices (FDA approved) to achieve hemostasis. This circuit could produce input pressures of up to 60 kPa which is more than enough for having a maximum pressure of 1332 Pa for the maximum pressurized cycle and is also low-cost compared to other control systems. The Integration of solenoid valves in the design results in the communication between the pneumatic circuit and an electric circuit powered by Arduino. When the solenoid valve is on, an electric current will flow through the coil. The iron armature inside the solenoid is attracted by magnetism and thus air released and transported to the balloon. To put the pneumatic circuit in place, there will used two solenoid valves, an air pump, and tubes running through the components to transport the air as desired. A simple schematic of the pneumatic circuit is shown below (Fig 18).

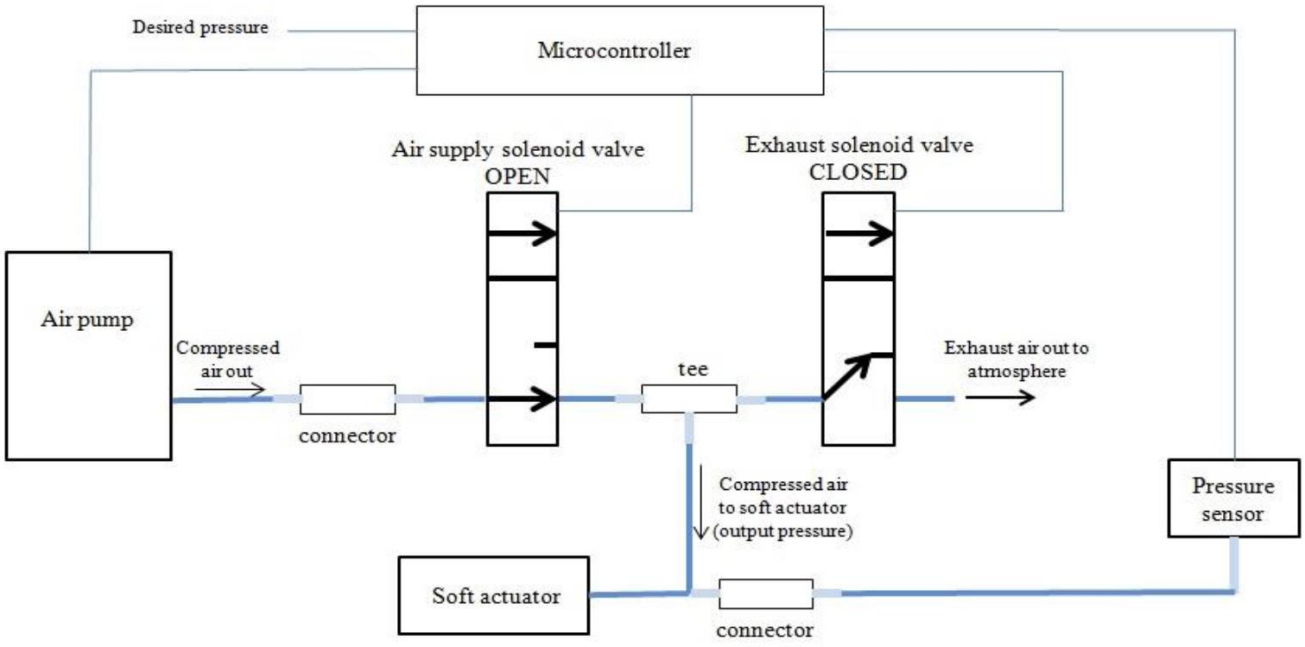


Figure 18. Pneumatic circuit [3]

The main concern with this design and implementation of the circuit is the size, its weight and the extensive documentation that is provided. It was desired to implement a design that is creative with own ideas manifesting throughout the prototype. And that is why braimstorming started again and got to the second design option.

3.2 DESIGN OPTION 2

The second design (Fig 19) contains all the components mentioned in the final design description with a different actuation system, a wire actuator system. The wire actuating system uses a motor to spin and pull the wires that are connected to two supporting bars. The wires will then pull the textile which wraps around the leg to apply pressure (video 3).

Figure 19. Design 2

3.2.1 ACTUATION

The wire actuating system is the core component of the design that generates compression force. Our design uses a 6V motor, as shown in figure 23, to provide torque. A 3D printed shaft connector is connected to the end of the shaft on the motor. The connector works as a pulley and is fixed to the motor shaft using a set screw so that it rotates with the shaft (Fig 22). Wires go through the 3 holes on the shaft connector and are pulled when the motor spins. Two supporting bars are designed to connect the wires with the textiles (Fig 21). The main challenge with this type of actuation system is the force that is generated does not fit the pressured range required by the device to achieve hemostasis. Moreover, the wires get entangled and could be very messy if the device gets transported or constantly moved.

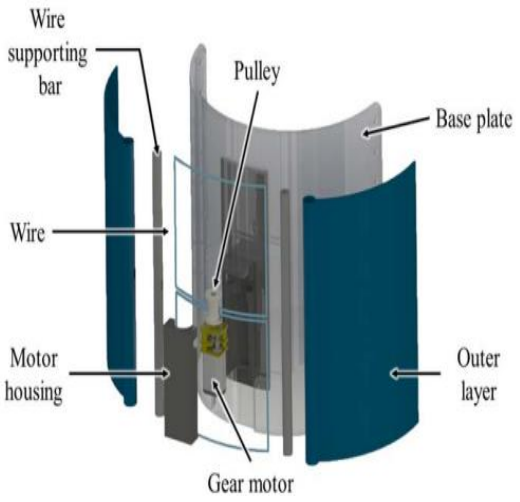


Figure 20. Wire actuator [4]

Figure 23. Motor for design 2 [12]

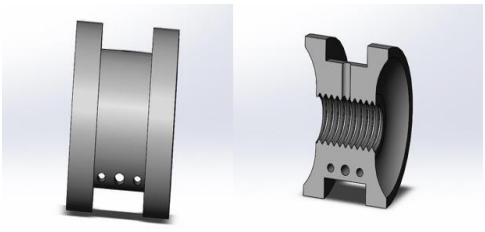


Figure 22. Shaft connectors

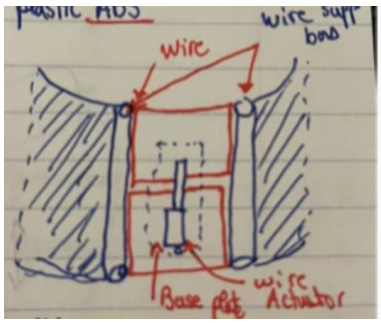


Figure 21. Wire actuator

3.2.2 CONTROLS

The controls for design 2 and the final design are very similar with the only difference being the number of motors to control in each design. The code is simple which is just turning the motors to a specific position until the desired pressure is reached. The feedback system is accurate via a pressure sensor which eliminates any potential errors in terms of the force generated at the site. The electrical components for the first design are an Arduino Uno, a pressure sensor, a L298D motor driver and a 5V power source (Fig 24).

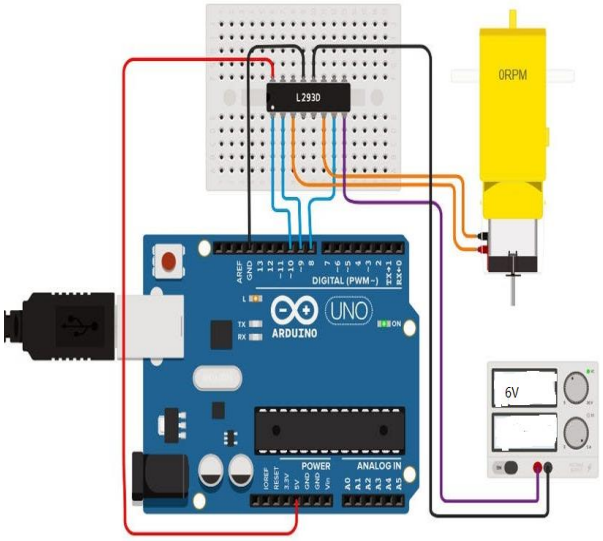


Figure 24. Controls for design 2

3.3 DESIGN OPTION 3

After having several problems with the wires there was a need to think of a way to eliminate them but still have the textile create a force around the leg.

A bar had been 3D printed for the actuator and it has been messed up the dimensions so it was very thick. When brainstorming with the professor, the idea of connecting the textile directly to the bar came up and after thinking of ways the bar could pull the textile without wires, the idea of putting the textile through the middle of the bar came up. So it was decided to try it out with the 3D printed bar, as it was rather thick. With the appropriate tools, a slit was done through the bar and it was connected to a motor with anything there was available next to us such as tape. The design was tried out (video 4). Conceptually, that preliminary design worked as the

textile wrapped around the bar reducing its radius just like it was wanted. And that is why it was decided to work from there, manufacture that same thing with the proper materials and tools until a final design and a first proof of concept was reached. That design had to tested to see if this would be the final design. And that is how CloZe was created.

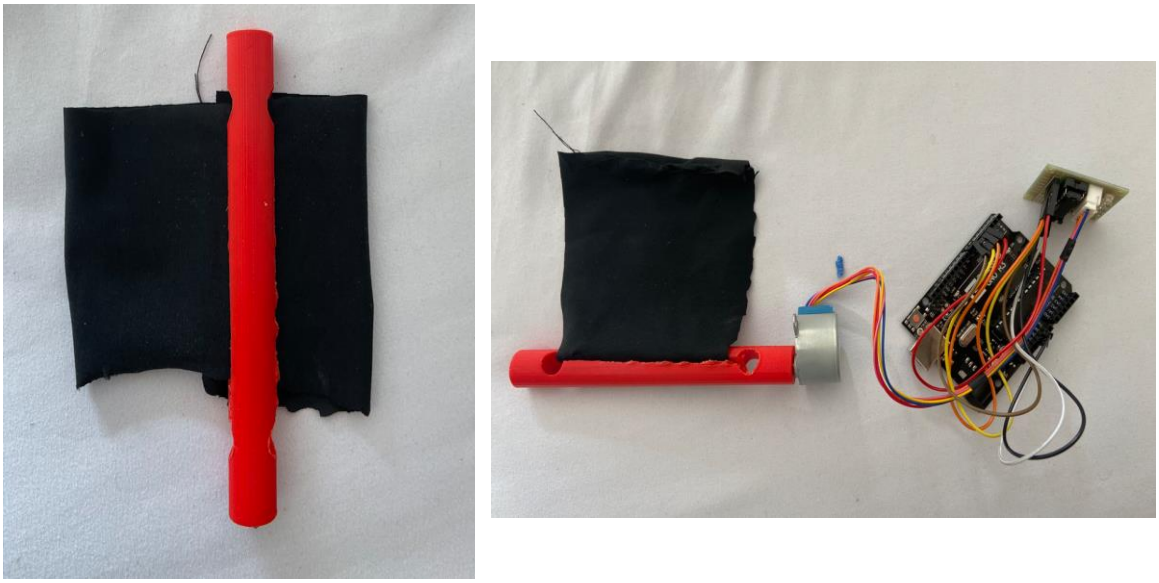


Figure 25. Preliminary design

3.4 DECISIONS

After having all this ideas, all of them were compared to the requirements of CloZe, and it was chosen to pursue the third design. The Pugh chart helped decide and classify the best designs as it is shown below (Table 1).

The actuation system of design 1 is better than design 2 in terms of the requirements of the prototype for response time and pressure range but not in terms of size and weight as the air pump is heavy.

X X	Importance	Design 1: Wire Actuator	Design 2: Pneumatic Actuator	Design 3: Textile Actuator
Requirements	X X	XX	XX	XX
Response time	3	1	2	2
Pressure Range	3	1	2	2
Comfortableness	2	2	1	2
Easy to wear	2	1	1	2
Weight/Size	1	2	1	1
Total	X X	14	17	19

Table 1. Comparison of designs

3.5 DESIGN EVOLUTION

As you can see in section 3.3. the first protoype was a proof of concept but not a functional design so once it was decided that idea should be the one pursued with, an actual protoype had to start being developed. As said in chapter 2 (Design Description), the prototype has many components: inner layer, outer layer, pressure sensor, textile actuator and base plate. mMany diferente steps were taken before reaching what now are the final components.

Textile actuator

The first step for the actuator was to collect the elements necessary to create it: two stepper motors with two shaft connectors, a steel bar, and elements for a circuit such as wires and an Arduino board were acquired.

In EPIC they helped with the steel bar and did a slit through it's lenght and, as the diameter was slightly bigger than the one of the shaft connector, they also helped enlarge the hole of the shaft until the bar fit inside but at the same time it was tight enough so the bar moved with the motors.

Once the actuator was done, the next step was to make the motors move so circuits with those type of motors and with an Arduino board, wires and a stepper driver were researched, and then the proper circuit was built and the code to make a motor turn clockwise was written.

As there was one motor at each end of the bar, to make the bar turn, the code had to turn both motors at the same time but one had to go clockwise and the other motor had to one anticlockwise.

Once both motors turned like it was needed, every component of the actuator were put together, a piece of textile which was put through the slit of the bar was cut and then both ends of the textile were sewed together.

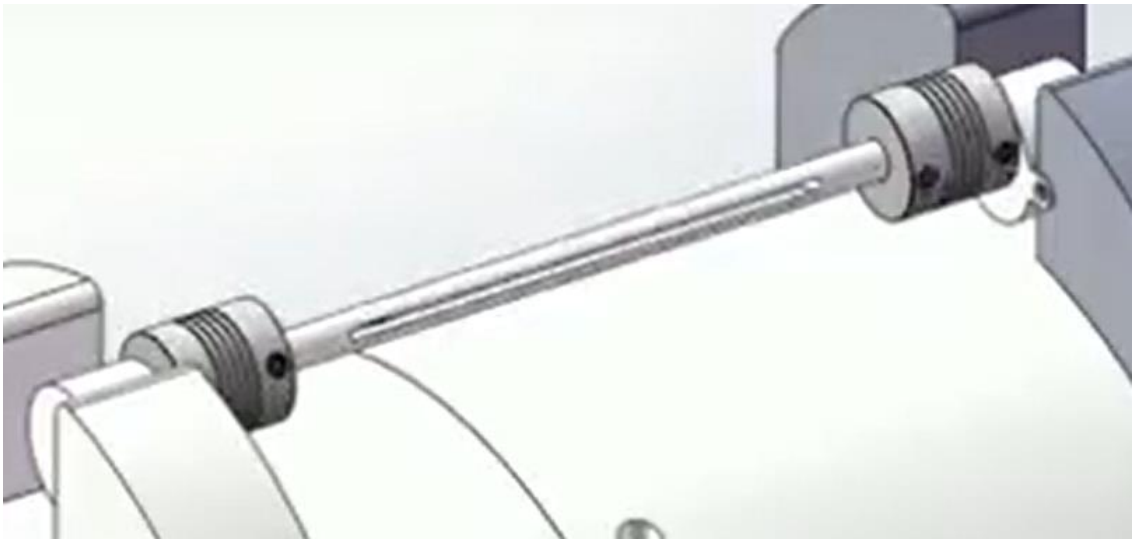


Figure 26. Textile actuator

Base plate

Then it was realized that eventhough there was a working device, there was no way to attach it comfortably to the patient´s leg so a base plate was created to hold every component in place when used and when placed on top of the leg. The first base plate was done with polyester thermoplastic like shown in figure 27.

Figure 27. Thermoplastic polyester base plate

Sensor

Eventhough the actuator was done and there was a way to put it on top of the leg without compromising it, there was still no way to know how much pressure it was applying so for pressure sensors had to be added and researched.

Two pressure sensors with different areas where chose to be investigated and assessed to choose which would suit best for the design.

They are both FSR sensors which detect the physical pressure from squeezing and applying weight. When the pressure increases, active elements touch the semiconductor so the resistance goes down and an Analog Reading value is read from the Arduino output. The pressure sensors have different areas.

When calibrating both devices it was realized that with the larger pressure sensor it was more difficult to read the pressure applied by the device because for the FSR to give

outputs in the Arduino you could only apply the pressure in the middle of the device and it read the pressure applied in its whole length, so it gives an overview of what the total pressure being applied is. Because of how the base plate is designed, the textile only applies pressure at one half of the leg and the larger pressure sensor reads the pressure applied to every point of the leg because it wraps around it so it would not make a lot of sense to compare the pressure applied in the whole leg with the pressure that needs to be applied just on top of the wound.

That is why it was decided to use the smaller area sensor as it gives the pressure applied exactly on top of the wound, and it is more important to know the pressure obtained exactly on top of the access site where the 13,000 Pa need to be applied and it is not important if slightly less pressure is applied in other areas of the leg.

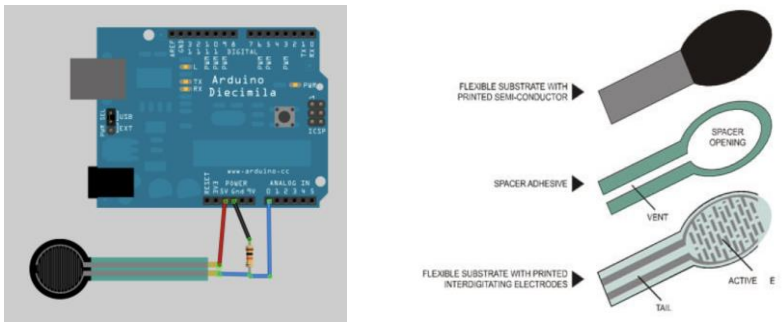


Figure 28. Smaller pressure sensor [11]

Figure 29. Larger pressure sensor [10]

Improvements

Now, a protoype was fully done now but many improvements had to be made. Before this, a first test was done on the device, the sensor test (explained in section 4.2.1. later on).

Once this test was a success, different improvements were implemented.

First of all, it was decided to **3D print the base plate**. same shape as what had been done with the thermoplastic and a section to hold the motors in place. This was the first design:

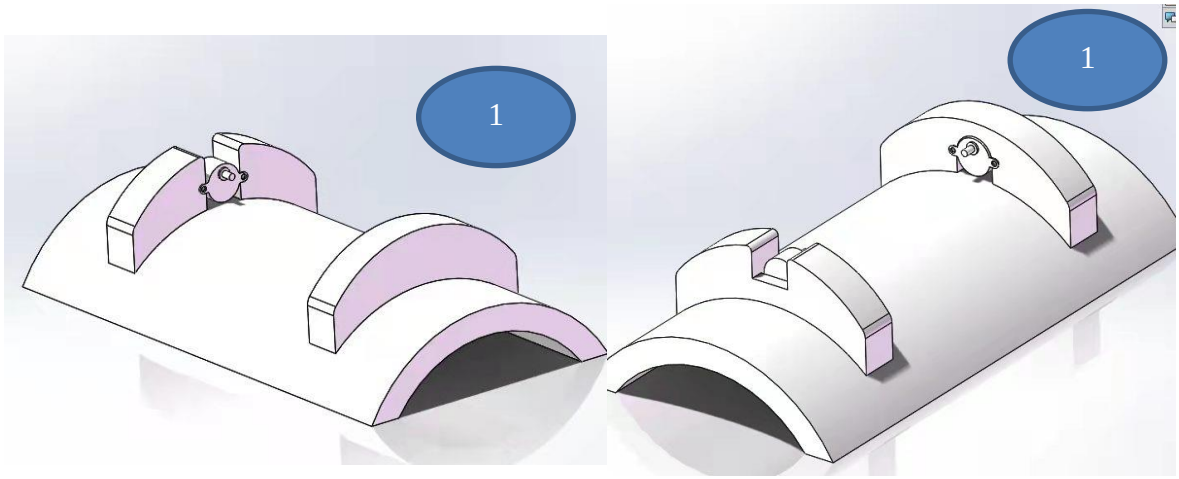


Figure 30. Base plate design 1

Then as the motors and the bar were already attached, they could not be fit so onde side had to be made attachable and disattchable so it could be set after placing the actuator. That is how design 2 was reached.

In this design two extra components were also added at the bottom so that another improvement could be implemented**: velcro strips** to hold tight the base plate on top of the leg without moving.

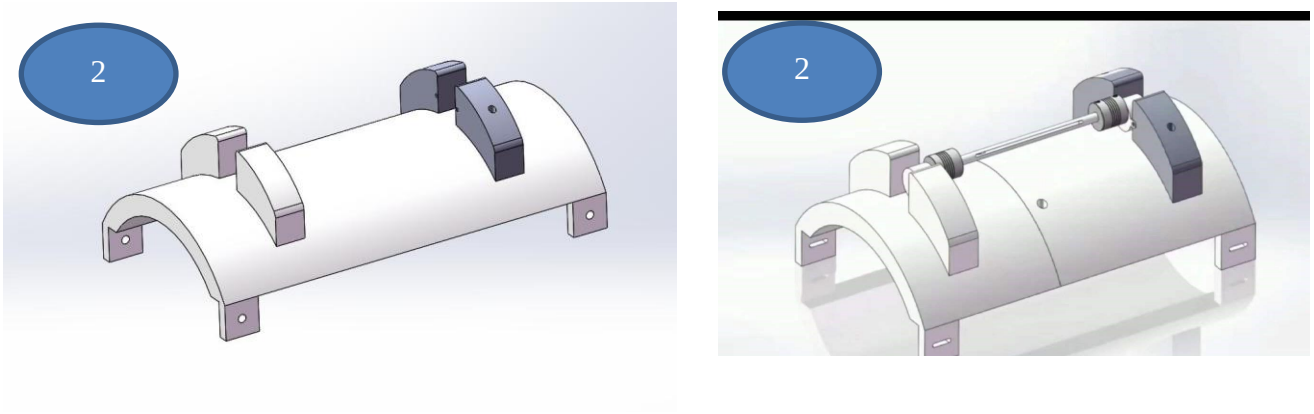


Figure 31. Base plate design 2

When the CAD file was sent to print, they said that the printer could not work with sizes that big so the last design is the same as the seond one but split into two parts that can be attached after printing them.

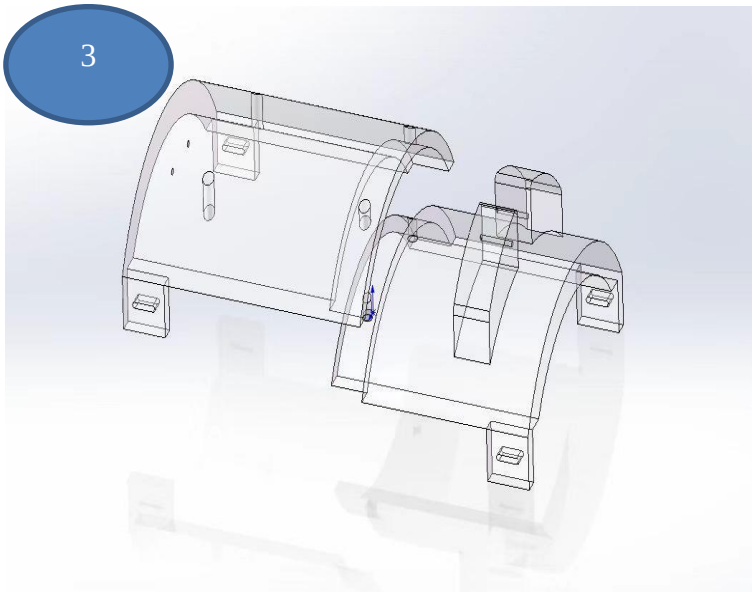


Figure 32. Base plate design 3

Another improvement was to put **velcro at both ends of the outer layer** instead of having it sewn so it is easier to put on and take off the leg.

All of the electric components were put in a **box** which was then glued to the base plate so that the wires and the Arduino could be secured and out of the way.

Figure 33. Box for electronics

And lastly, the pressure sensor was between two textiles and then velcro was glued at both ends so it could be easily attached to the leg underneath the device.

Figure 34. Pressure sensor design

3.6 VIDEOS

Video 3. Conceptual textile actuator:
https://drive.google.com/file/d/1ATCPo_IQVVhjDhfx5OtCuoEHIfXysJ7a/view?usp=sharing

Video 4. Preliminary design of final prototype:
https://drive.google.com/file/d/1MJRf1OJ5LhUjGS7Ia9Fl6Txh2zfRsBl-/view?usp=sharing

Chapter 4. DESIGN EVALUATIONS

After catheterization procedures, the catheter is removed from the leg which leads to blood loss at a very high rate. The natural way to achieve hemostasis and stop the bleeding is by applying cyclical mechanical pressures at different time intervals. External pressure is the most important factor to achieve hemostasis. Thus, achieving the maximum pressure desired for all cycles is the target pressure set to find in this test. The location of the pressure site should also be noted as the pressure is different along the outer layer of the device. Finally, the success of the device also depends on a test where a pressurized pipe is leaking and test the ability of the device to hold the leakage and pressure in place over 30 minutes. Two critical tests are going to be conducted to validate the prototype Cloze:

4.1 CALCULATION OF THE FORCE

At the beginning of the project, it was researched how a person achieves hemostasis and it was found that the maximum pressure in all cycles is 13.000 Pa. So brainstorming started as well as the manufacturing of the device and now it needs to be tested. The first thing there is to test is if the device reaches, at least, that pressure of 13.000 Pa a person needs to achieve hemostasis as if it were being done with manual compression. The FSR reads the Force that the device is applying to the leg so in order to do this first test to see if the desired pressure is achieved, the equivalent force to that pressure needs to be calculated:

$$Max\ pressure\ applied\ \cong 13.000\ Pa$$

$$Sensor\ 1\ area = \frac{\pi}{4} \times 0{,}01905^2 \qquad Sensor\ 2\ area = \ 0{,}004191\ m^2$$

$$P = \frac{F}{A} \rightarrow F = P\ \times A$$

$$Force\ sensor\ 1 = 3{,}705\ N$$

$$Force\ sensor\ 2 = 55\ N$$

The target force which corresponds to the maximum pressure is 3.705 N with the sensor with the smaller area, which is the one that was chosen.

4.2 TESTS

4.2.1 SENSORS TEST

In order to test the device it has to be put it into operation with the pressure sensor on top of the inner layer or pressure bandage at the incision site and read the values of force obtained to see if enough pressure was applied to reach hemostasis. It was needed to test if those 3,75 N that had been calculated were obtained.

4.2.1.1 Calibration

The analog readings from the Arduino change with the resistance and thus the voltage at the sensor is the equation: **Vo = Vcc (R / (R + FSR)).** Vcc stands for voltage input which is 5V in this case, R is the resistor value which is 10KOhm and the FSR value is 250Ohm. Since the analog reading values could be accurate with an error percentage of +- 10%, force values should not be generated by the Arduino but calibrate the FSR and record weight vs analog readings on the serial monitor of the Arduino.

The sensors were calibrated using a Push / Pull Force Gauge and different weights. With the second sensor, as it has a larger area, a slightly tall wooden bar had to put on top of it to distribute the weight evenly throughout all the sensor. The weights were changed and recorded and the analog values read. With all that data, a chart Arduino Reading vs. Force was made so that when using the prototype, an analog value from the Arduino is read and then with the chart it is obtained how much force that reading is equivalent to.

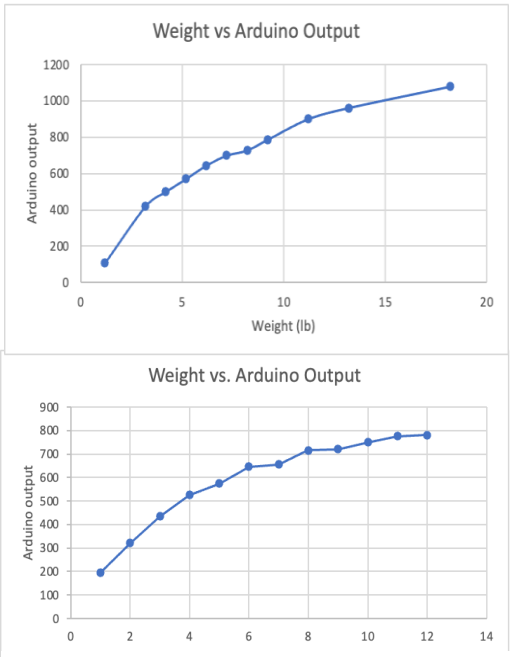


Figure 35. Calibration of the sensors

4.2.1.2 Results

After calibrating the sensors and choosing to use the one with the smaller area, the prototype was tested and the values of force the FSR gave were read to see if the pressure needed was obtained. The force obtained was recorded until the target force was reached.

The results of the Force vs time graph is shown below in figures 36, 37 and table 2.

Since the target force is 3.705 N and the maximum force achieved by the device is 3.87N, the device is able to reach the target pressure of 13332 Pa and thus the success of the hypothesis and the first test.

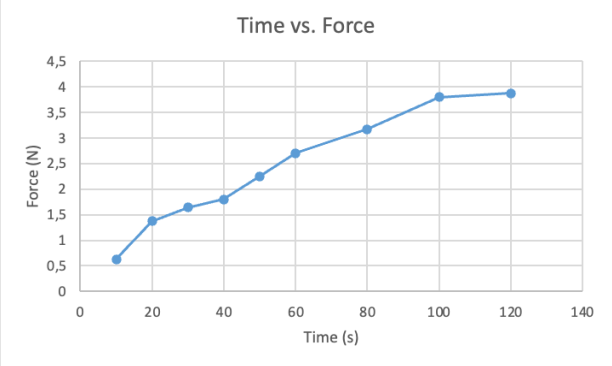


Figure 36. Graph time vs. Force

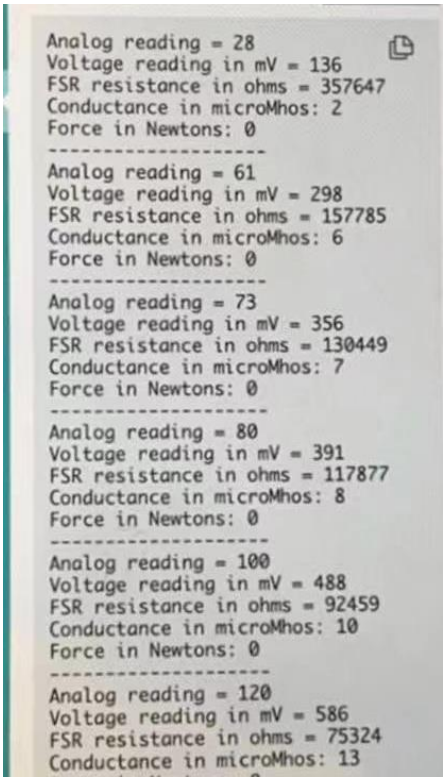


Figure 37. Analog readings Arduino

Time(s)	Analog reading	Force readings (N)
10	28	0.63
20	61	1.37
30	73	1.64
40	80	1.80
50	100	2.25
60	120	2.70
80	141	3.17
100	169	**3.80**
120	174	**3.87**

Table 2. Test results

4.2.2 PRESSURE TEST

In the second test, the objective was to prove if the device can actually provide enough pressure to stop the bleeding and maintain the pressure, so a pressure test was designed to validate the protype. The test had a pressurizing system which was constructed with pipes and it also has a water pump and two water pressure sensors.

4.2.2.1 Set Up

To construct this test, a pressurized system had to be manufactured. This system had a PVC pipe that mimicked the leg and it was connected to two smaller pipes which had two pressure gauges in the middle. At one end of the system there was a water bucket and a water pump (figure 38) which made the water flow from one end to the other with pressure. At the other end there was another empty bucket where the water went to leave the system. The first thing that was done before testing the device was a leak test. After gluing everything together there were a lot of leaks, so the water was moved through the pipe to detect those leaks so they could be closed. When every leak was closed, the pressure of the water was the same at both water pressure sensors and the test was ready to take place.

Figure 38. Water pump [9]

Figure 39. Water pipes and pressure gauges

The pressure was read at the pipes without any leaks and holes and then a hole was created in the pipe that mimicked the leg, the water was started and the pressure read after the hole again.

Then, the pressure bandage (inner layer) was put and then the device was put on top and it was turned on. After the textile was creating its maximum pressure on top of the hole created, the pressure was read again.

Figure 40. Pressure test set up

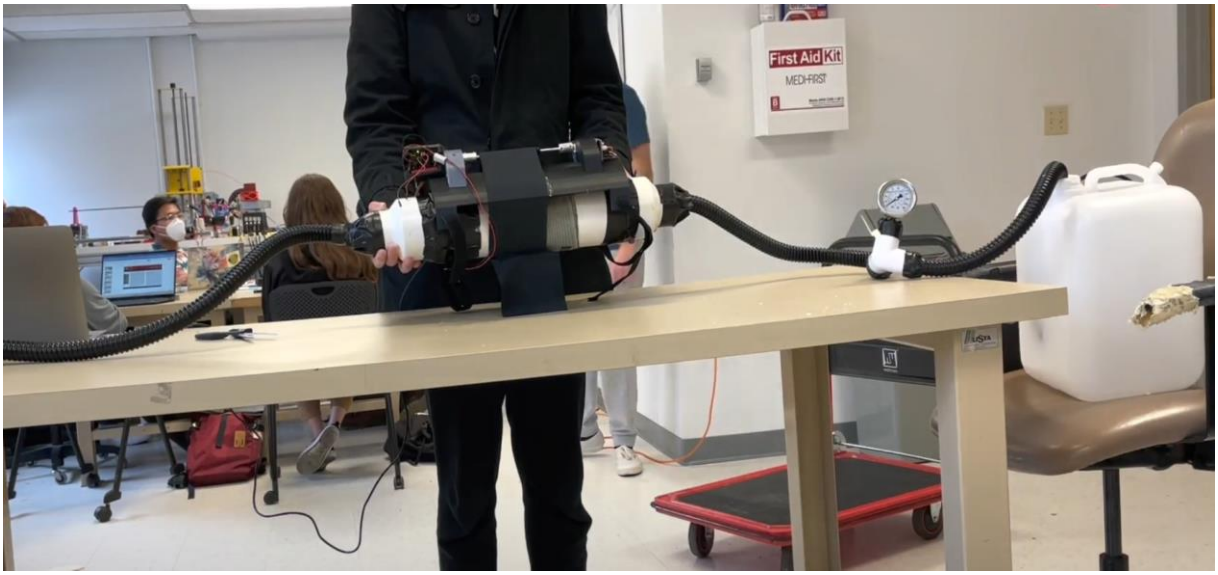


Figure 41. Pressure test with device

4.2.2.2 Results

Data gathered through pressure sensor is shown on the plot below (Figure 42):

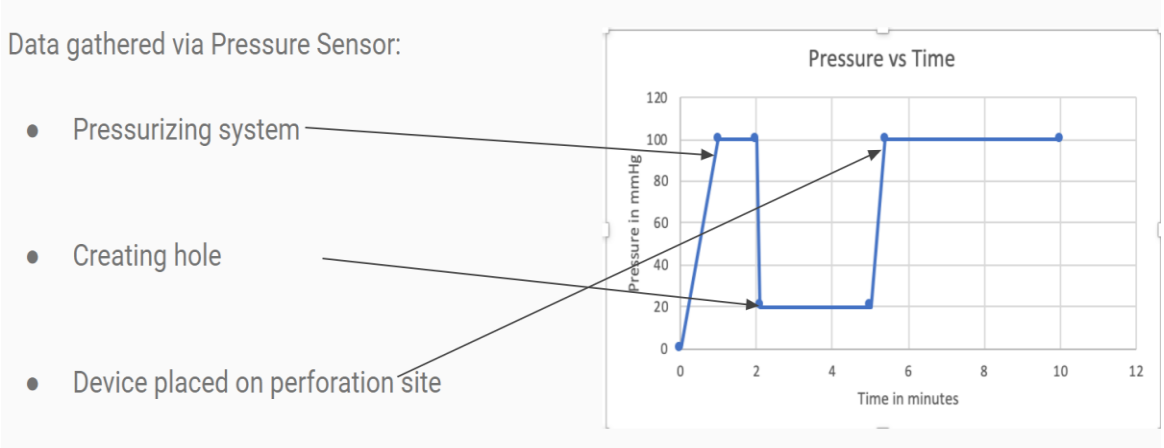


Figure 42. Data gathered in test

Data gathered through the sensor shows that the pressure reaches 100 mmHg at the initial set-up, and then goes to 20mmHg when leaking. After placing the device to stop the leak, the pressure goes back to the initial 100mmHg and maintained for more than 4 minutes. This result shows that the device has the ability to stop the leaking, turn the system back to its original condition and maintain the pressure for a quite sufficient amount of time.

4.3 VIDEOS

Video 5. Putting pressure bandage: https://drive.google.com/file/d/1R-NzcFJLl4j0b0qZIiwWwyeqaTOviomA/view?usp=sharing / https://drive.google.com/file/d/1Aop5H4N3PNcoqbIuupA6bwd5ki_iVgqG/view?usp=sharing

Video 6. Pressure test with working device and no leaks seen: https://drive.google.com/file/d/1txbi8fD7pmRJ5mTVFCrL1bdFjIsNbvIP/view?usp=sharing / https://drive.google.com/file/d/1_3AInC-2-dy1bO7xq-uPCV2WSUFgyL_k/view?usp=sharing

Chapter 5. MARKET COST ANALYSIS

Our estimated total cost of the prototype is 92 dollars, with 12 dollars laying on Inner Layer, 10 dollars on Outer layer, 27 dollars on Base Plate and 43 dollars on Electronic components. A chart is shown below.

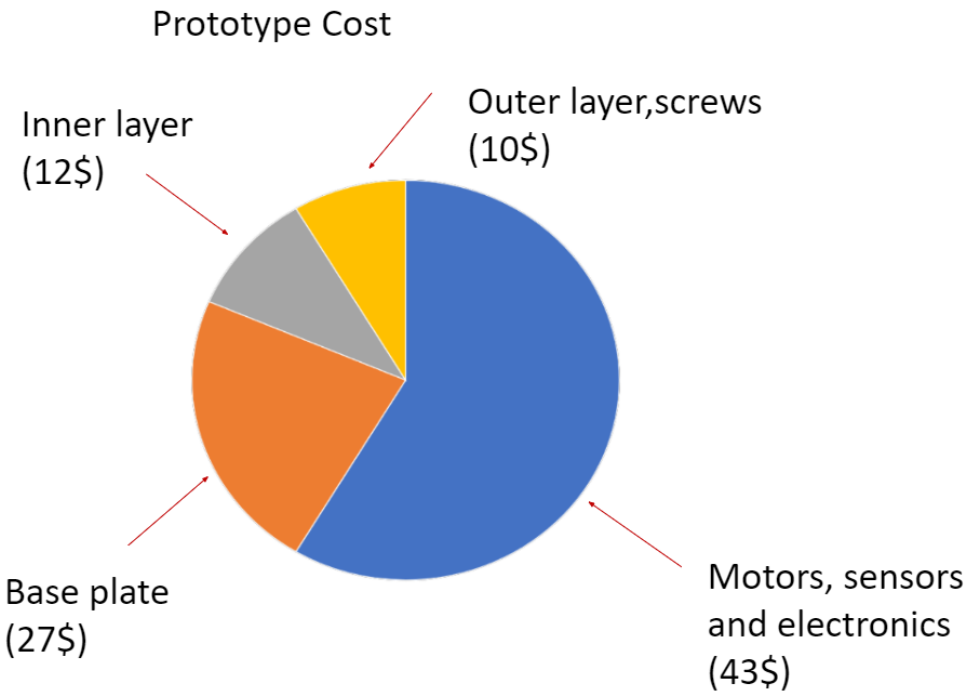


Figure 43.Cost analysis

For Inner Layer, Double Vaccum was used as Sealed material, and for outer layer a Single Layer Mesh Fabric. The material costs are listed above. For the base plate, it is 3D printed using PLA Black and Grey. The cost of 3D printing may cost more than 27 dollars, but for future mass production, the manufacturing cost would be a lost less than the prototype's cost is estimate it to be 27 dollars. The 2 stepper motors, Arduino Uno board and wires cost around 43 dollars according to the Amazon buyer's account.

Chapter 6. CONCLUSIONS AND FUTURE RECOMMENDATIONS

Our final prototype met the main requirements from the client but not all of them.

The most important thing was that it should apply **enough pressure** and that was achieved. The device had to apply at least 13.000 Pa of pressure and after doing the needed calculations such as the force equivalent to that pressure with the area of the pressure sensor, the device was tested with the sensor and proved that the pressure was achieved.

On the other hand, the device is not fully **wearable**. It is a device that you can easily move and take to other places but is not a device you could carry with you everywhere you went. It has met the requirements for its weight as it is not heavy at all but it is still too big for someone to wear. Having said this, there was no time to print another base plate but this problem is easily fixable by changing the dimensions of the base plate with the same model.

The device is **intuitive**, anyone could use it without any medical training and it has an inner layer to go on top of the wound so it can be **reusable** to any patient. And although with a better motor the **speed** could be improved, as a first prototype is fast enough to achieve homeostasis in the indicated time.

For the future there are many improvements and recommendations:

- Switch: a switch must be added to the circuit to turn the device on and off so that when it is wearable anyone could use it just by putting it on top of the desired wound and turning on / off the switch.
- Battery: a battery should also be added to the circuit so that the device is fully transportable and wearable. It has been tested by powering it with the computer or with an external power supply. By adding a small 5V battery the device is easier to transport and to carry.

- Soldering: the wires right now can easily disconnect when the device is being moved so to make the device more durable another improvement is soldering all the wires and components to a solderable Arduino and bread board.
- Housing: after adding the switch and battery and after soldering everything, it would be known the actual size of everything that needs to be in a box and glued to the side of the base plate. It would be in the same place as it is now but a more suitable box.
- Feedback system: an LCD should also be added to the circuit and it should display the pressure being read by the smaller pressure sensor. With the code, the motors should turn on and off depending on the phase of achieving hemostasis and the pressure being read.
- Smaller 3D printed base plate: the base plate has extra material and it could be printed again in a smaller size and it could also have smaller dimensions with a shorter steel bar and a shorter slit in the middle of it.

Here is a table summarizing everything stated above:

REQUIREMENTS	ACTUAL PROTOTYPE	FUTURE RECOMMENDATIONS
PRESSURE	YES	Feedback system
WEARABLE - SIZE - WEIGHT	 - NO - YES	 - Smaller 3D printed base plate - Battery - Soldering
INTUITIVE	YES	Add switch
REUSABLE	YES	Shorter pressure bandage
SPEED	YES. Could be improved	Better motors

Table 3. Results and future recomendations

Chapter 7. REFERENCES

[1] *Home | Abbott U.S.* (2020). Abbott Laboratories. https://www.abbott.com/

[2] *NCBI* (2018). National Library of medicine. https://www.ncbi.nlm.nih.gov/books/NBK557472/

[3] *Soft Robotics Toolkit*. (2021). Soft Robotics Tool Kits. https://softroboticstoolkit.com/

[4] *ShieldSquare Captcha*. (2021). IOP Science. https://validate.perfdrive.com/?ssa=7e0e717b-c02f-4e60-8ebf-a0b5e6d461a4&ssb=61643223260&ssc=https%3A%2F%2Fiopscience.iop.org%2Farticle%2F10.1088%2F1361-665X%2Fab3f56%2Fmeta%3Fcasa_token%3DNpy6zPCa4Q4AAAAA%3AaflfTnKJRDjo_tuFEWvZkHFHWH0I0yd_v2zJfK8YUkfSehCuNxQMTNSonIPCv8hpGDnAJRJJzJZGuTDZjWg&ssi=a7264d1e-8427-4644-ae1d-ffbaa93619f0&ssk=support@shieldsquare.com&ssm=49550873831813409109785803958292&ssn=7e9fe5fd71b7d54851b62905cf546651acf0babaddfb-9b63-44a3-a56fe7&sso=122b178b-949c80c3c9a42262a3b700c8461aac3387603896353e835e&ssp=69684070821658185004165812306119252&ssq=13971029117028955036491170735558381201697&ssr=ODMuOTYuMjQ1LjIyMQ==&sst=&ssv=&ssw=&ssx=W10=

[5] *Sensor de presión MD30-60 de 0 a 30 kg, 30 mm de diámetro, resistencia de detección de fuerza : Amazon.es: Industria, empresas y ciencia*. (2021). Amazon. https://www.amazon.es/Fuerza-sensible-resistencia-pel%C3%ADcula-presi%C3%B3n/dp/B07PY443HS/ref=asc_df_B07PY443HS/?tag=googshopes-21&linkCode=df0&hvadid=372996847332&hvpos=&hvnetw=g&hvrand=9153241001418404864&hvpone=&hvptwo=&hvqmt=&hvdev=c&hvdvcmdl=&hvlocint=&hvlocphy=1005424&hvtargid=pla-790261382095&psc=1

[6] *Coronary artery balloon angioplasty - series—Procedure, part 1*. (2016). Medlineplus. https://medlineplus.gov/ency/presentations/100160_3.htm

[7] HeartPlace. (2018). *Comprehensive Cardiovascular Care for North Texas.* https://www.heartplace.com/services-cardiac-cath

[8] *DEFINE_ME*. (2019). Journal of Vascular Surgery. https://secure.jbs.elsevierhealth.com/action/cookieAbsent

[9] Amazon.com: VIVOSUN Bomba sumergible de 800 GPH (3000 L/H, 24 W), bomba de agua ultra silenciosa con elevación de 10 pies, bomba de fuente con cable de alimentación de 6.5 pies, 3 boquillas para pecera, estanque, acuario, estatuaria, hidroponía : Productos para Animales. (2021). Amazon. https://www.amazon.com/-/es/sumergible-silenciosa-alimentaci%C3%B3n-estatuaria-hidropon%C3%ADa/dp/B07L54HB83

[10] SF15-600 Sensor de presi¨®n 10 kg Sensor de fuerza de pel¨ªcula delgada tipo resistencia : Amazon.es: Industria, empresas y ciencia. (2021). Amazon. https://www.amazon.es/dp/B07Q4TN3T9/ref=sspa_dk_detail_2?psc=1&pd_rd_i=B07Q4TN3T9&pd_rd_w=z924F&content-id=amzn1.sym.1831d79b-677b-428e-990a-c04cdbe213a7&pf_rd_p=1831d79b-677b-428e-990a-c04cdbe213a7&pf_rd_r=QARKXPZ7JBYNVXQ3FKE5&pd_rd_wg=hhWol&pd_rd_r=55c970b3-8fa1-46a7-a461-c34b5d74654b&s=industrial&spLa=ZW5jcnlwdGVkUXVhbGlmaWVyPUEyQzRDT0dJTkpETEhPJmVuY3J5cHRlZElkPUEwNjg3ODI0MllGT1I5WTdOMFMwSCZlbmNyeXB0ZWRBZElkPUEwNTUyNTQ4MktZWkc4WVExOFJBRiZ3aWRnZXROYW1lPXNwX2RldGFpbCZhY3Rpb249Y2xpY2tSZWRpcmVjdCZkb05vdExvZ0NsaWNrPXRydWU=

[11] *Force Sensitive Resistor*. (2018). flexkpd. https://www.flexkpd.com/force-sensing-resistor-0-43.html

[12] DC 6v 30/60/100/150/200/300/300/400 / 500RPM Motor de Engranaje de Reducción de Velocidad, con M3 * 55MM Eje de Salida(6V 30RPM) : Amazon.es: Bricolaje y herramientas. (2021). Amazon. https://www.amazon.es/500RPM-Engranaje-Reducci%C3%B3n-Velocidad-Salida/dp/B07HKGKHD6/ref=asc_df_B07HKGKHD6/?tag=&linkCode=df0&hvadid=420397508147&hvpos=&hvnetw=g&hvrand=9651403869273281233&hvpone=&hvptwo=&hvqmt=&hvdev=c&hvdvcmdl=&hvlocint=&hvlocphy=9061036&hvtargid=pla-833619220499&ref=&adgrpid=96502138712&th=1

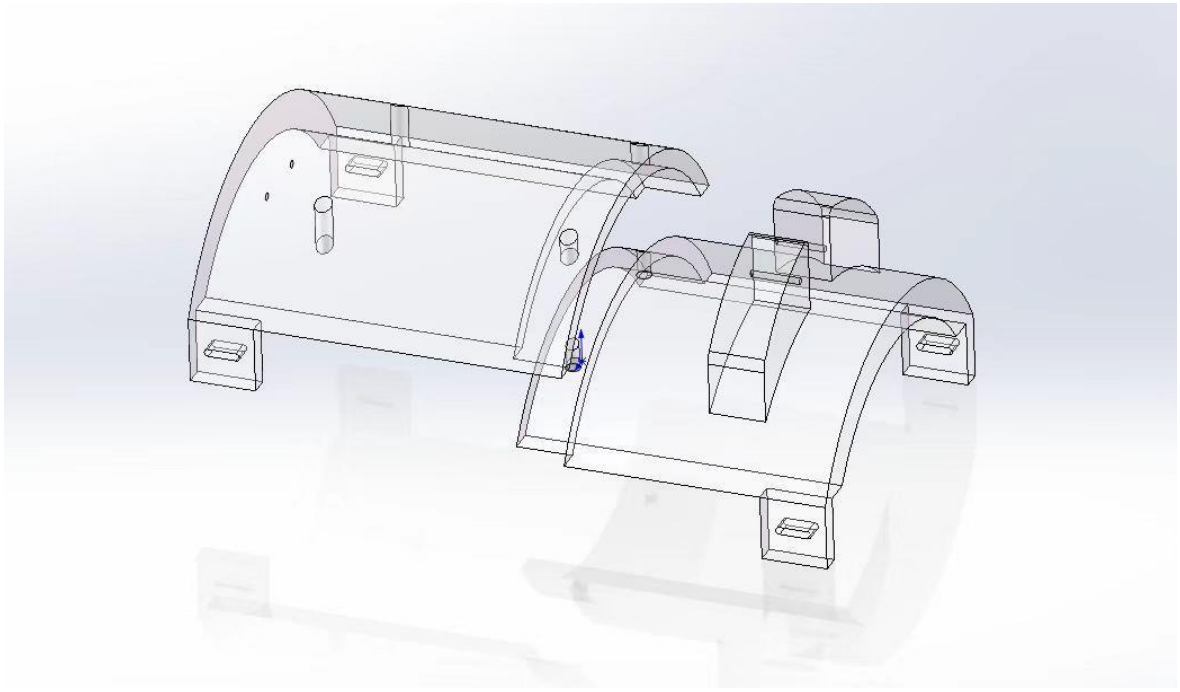
[13] https://www.hmpgloballearningnetwork.com/site/cathlab/articles/review-vascular-closure-devices

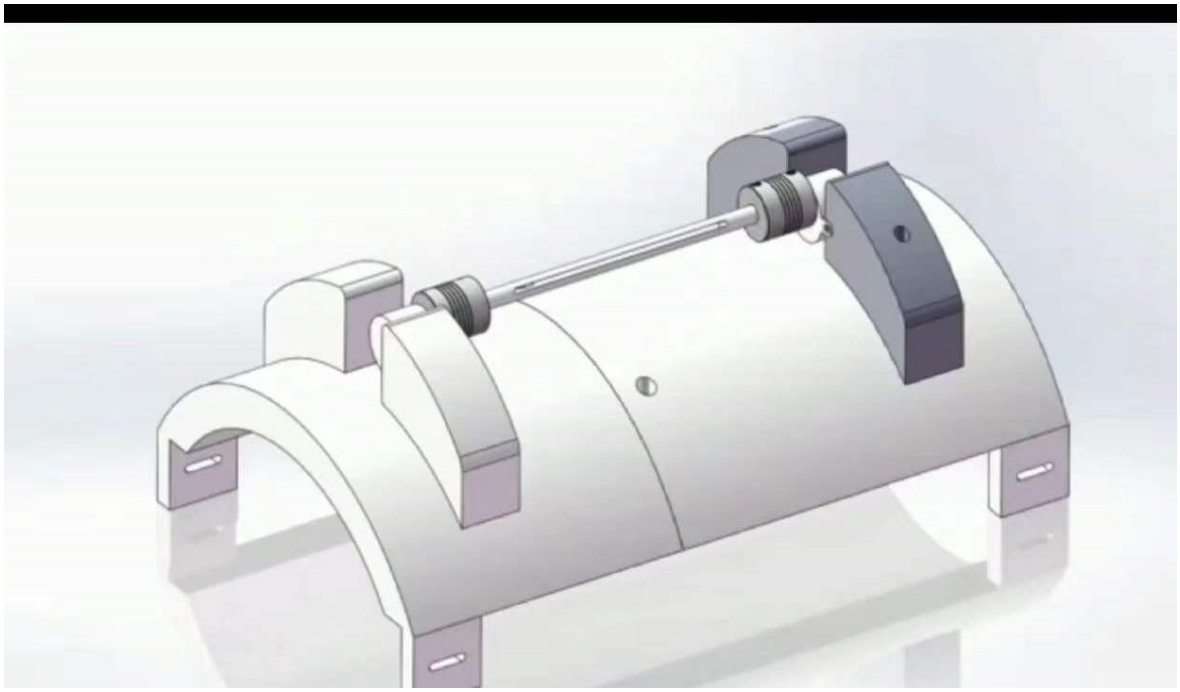
[14] *Vascular*. (2019). Albo Medical Mexico. https://www.albomedical.com/nuestros-productos

APPENDIX I: BILL OF MATERIALS

	Components	Description	Material	Quantity
Inner Layer	Inner Layer	Pressure bandage	spun silk fabric	1
Outer Layer	Compression sleeve	Textile layer	single layer mesh fabric	1
	DC Motor	Textile Actuator	Metal/ Copper	2
	Shaft	Textile Actuator	Metal/ Copper	1
	Base Plate	Connects all components	TPU	1
	Screws	To put base plate in place	Metal/ Copper	6
	Housing box	6$	ABS	1
Electronics	Soft Pressure Sensor	FSR pressure sensor	x	1
	Ardunio UNO	microcontroller	x	1
	L298N Motor Driver	Driver for the motors	x	2

APPENDIX II: WORKING DRAWINGS





APPENDIX III: CODE

```
Code For Testing:

/*

*/

#define pinA1 4
#define pinA2 6
#define pinB1 5
#define pinB2 7
#define pinC1 8
#define pinC2 10
#define pinD1 9
#define pinD2 11

void setup(
  pinMode(pinA1,OUTPUT);
  pinMode(pinA2,OUTPUT);
  pinMode(pinB1,OUTPUT);
  pinMode(pinB2,OUTPUT);
  pinMode(pinC1,OUTPUT);
  pinMode(pinC2,OUTPUT);
  pinMode(pinD1,OUTPUT);
  pinMode(pinD2,OUTPUT);
  Serial.begin(9600);
}

int d=5;
int x=0;

void loop() {


   for (int ct=1;ct<512;ct++){
     x++
     ;digitalWrite(pinA1,HIGH);
     digitalWrite(pinA2,LOW);
     digitalWrite(pinB1,LOW);
     digitalWrite(pinB2,LOW);
     digitalWrite(pinC1,LOW);
     digitalWrite(pinC2,LOW);
```

```
  digitalWrite(pinD1,LOW);
  digitalWrite(pinD2,HIGH);
  delay(d);

  digitalWrite(pinA1,LOW);
  digitalWrite(pinA2,LOW);
  digitalWrite(pinB1,HIGH);
  digitalWrite(pinB2,LOW);
  digitalWrite(pinC1,LOW);
  digitalWrite(pinC2,HIGH);
  digitalWrite(pinD1,LOW);
  digitalWrite(pinD2,LOW);

  delay(d);

  digitalWrite(pinA1,LOW);
  digitalWrite(pinA2,HIGH);
  digitalWrite(pinB1,LOW);
  digitalWrite(pinB2,LOW);
  digitalWrite(pinC1,LOW);
  digitalWrite(pinC2,LOW);
  digitalWrite(pinD1,HIGH);
  digitalWrite(pinD2,LOW);
  delay(d);

  digitalWrite(pinA1,LOW);
  digitalWrite(pinA2,LOW);
  digitalWrite(pinB1,LOW);
  digitalWrite(pinB2,HIGH);
  digitalWrite(pinC1,HIGH);
  digitalWrite(pinC2,LOW);
  digitalWrite(pinD1,LOW);
  digitalWrite(pinD2,LOW);
  delay(d);
}
```

Code of the device undergoing pressure cycles for 30 minutes:

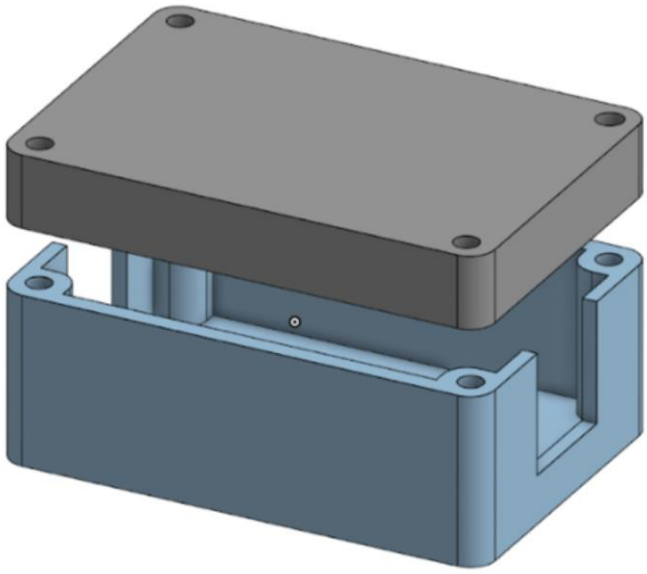
APPENDIX IV: ALLINGMENT WITH SUSTAINABLE DEVELOPMENT GOALS

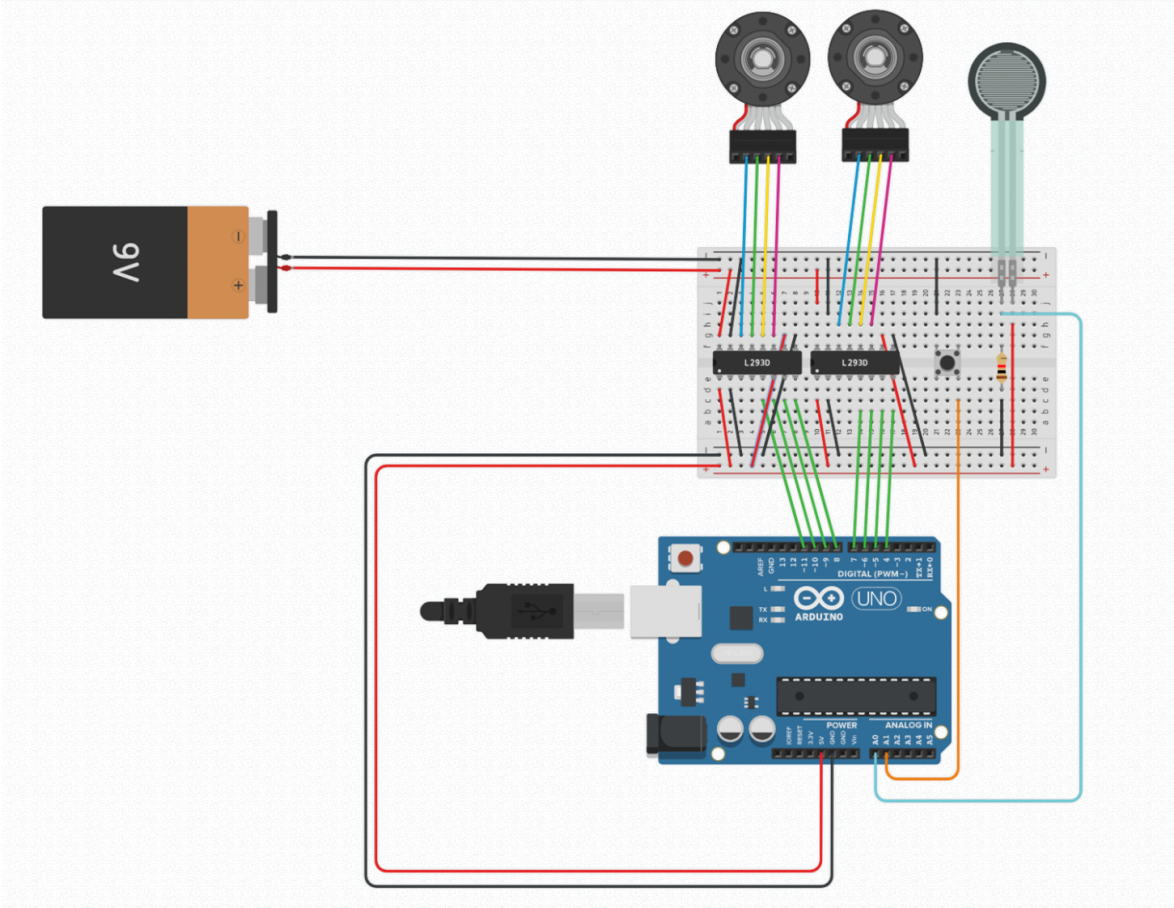
- **GOAL 3 – GOOD HEALTH AND WELL BEING** ("Ensuring healthy lives and promoting the well-being for all at all ages is essential to sustainable development"). Our device wants to provide a better and safer recovery to patients who have just had complicated and most likely dangerous surgery. This could help with their health and can reduced complications, pain and discomforts so it can improve their well-being.

- **GOAL 10 – REDUCED INEQUALITIES** ("To reduce inequalities, policies should be universal in principle, paying attention to the needs of disadvantage and marginalized populations"). As it was stated in point number 3, Motivation, one of the reasons to create this device is that it is much cheaper than intravascular or extravascular devices which are in the market nowadays so that everyone could afford it. This will reduce many inequalities from the society that many times manifest in healthcare. Many people cannot afford a good healthcare system which can affect their health, this could be one of the many changes needed for a just healthcare system for everyone.

- **GOAL 13 – CLIMATE ACTION** ("Climate change is a global challenge that affects everyone, everywhere"). This device can be re-used in many patients by only changing a bandage so it is not a use and waste device which will help climate change.

APPENDIX V: IMPROVEMENTS





```
#define pinA1 4
#define pinA2 6
#define pinB1 5
#define pinB2 7
#define pinC1 8
#define pinC2 10
#define pinD1 9
#define pinD2 11

#define fsrPin A0

#define onoff A1

int d=5;
int x=0;

int fsrReading=0;
int fsrVoltage=0;
unsigned long fsrResistance=0;
unsigned long fsrConductance=0;
long fsrForce=0;

void setup() {
  Serial.begin(9600);
  pinMode(pinA1,OUTPUT);
  pinMode(pinA2,OUTPUT);
  pinMode(pinB1,OUTPUT);
  pinMode(pinB2,OUTPUT);
  pinMode(pinC1,OUTPUT);
  pinMode(pinC2,OUTPUT);
  pinMode(pinD1,OUTPUT);
  pinMode(pinD2,OUTPUT);

  pinMode(onoff, INPUT_PULLUP);

  pinMode(fsrPin,INPUT);

  Serial.begin(9600);

}

void loop() {

  if(digitalRead (onoff) == 0){

      delay(100);
      fsrReading = analogRead(fsrPin);
      Serial.print("Analog reading = ");
      Serial.println(fsrReading);
      fsrVoltage = map(fsrReading, 0, 1023, 0, 500);
      Serial.print("Voltage reading in mV = ");
      Serial.println(fsrVoltage);
      delay(500);
```

```
for (int ct=1;ct<512;ct++){

    x++
    ;digitalWrite(pinA1,HIGH);
    digitalWrite(pinA2,LOW);
    digitalWrite(pinB1,LOW);
    digitalWrite(pinB2,LOW);
    digitalWrite(pinC1,LOW);
    digitalWrite(pinC2,LOW);
    digitalWrite(pinD1,LOW);
    digitalWrite(pinD2,HIGH);
    delay(d);

    digitalWrite(pinA1,LOW);
    digitalWrite(pinA2,LOW);
    digitalWrite(pinB1,HIGH);
    digitalWrite(pinB2,LOW);
    digitalWrite(pinC1,LOW);
    digitalWrite(pinC2,HIGH);
    digitalWrite(pinD1,LOW);
    digitalWrite(pinD2,LOW);

    delay(d);

    digitalWrite(pinA1,LOW);
    digitalWrite(pinA2,HIGH);
    digitalWrite(pinB1,LOW);
    digitalWrite(pinB2,LOW);
    digitalWrite(pinC1,LOW);
    digitalWrite(pinC2,LOW);
    digitalWrite(pinD1,HIGH);
    digitalWrite(pinD2,LOW);
    delay(d);

    digitalWrite(pinA1,LOW);
    digitalWrite(pinA2,LOW);
    digitalWrite(pinB1,LOW);
    digitalWrite(pinB2,HIGH);
    digitalWrite(pinC1,HIGH);
    digitalWrite(pinC2,LOW);
    digitalWrite(pinD1,LOW);
    digitalWrite(pinD2,LOW);
    delay(d);

    if(digitalRead(fsrVoltage)>= 135){
      ct=512;
    }

}

if(digitalRead(fsrVoltage) >= 135) {
  delay(60000);
```

```
      }
      for (int ct=1;ct<512;ct++){
          x++
          ;digitalWrite(pinA1,HIGH);
          digitalWrite(pinA2,LOW);
          digitalWrite(pinB1,LOW);
          digitalWrite(pinB2,LOW);
          digitalWrite(pinC1,LOW);
          digitalWrite(pinC2,LOW);
          digitalWrite(pinD1,LOW);
          digitalWrite(pinD2,HIGH);
          delay(d);

          digitalWrite(pinA1,LOW);
          digitalWrite(pinA2,LOW);
          digitalWrite(pinB1,HIGH);
          digitalWrite(pinB2,LOW);
          digitalWrite(pinC1,LOW);
          digitalWrite(pinC2,HIGH);
          digitalWrite(pinD1,LOW);
          digitalWrite(pinD2,LOW);

          delay(d);

          digitalWrite(pinA1,LOW);
          digitalWrite(pinA2,HIGH);
          digitalWrite(pinB1,LOW);
          digitalWrite(pinB2,LOW);
          digitalWrite(pinC1,LOW);
          digitalWrite(pinC2,LOW);
          digitalWrite(pinD1,HIGH);
          digitalWrite(pinD2,LOW);
          delay(d);

          digitalWrite(pinA1,LOW);
          digitalWrite(pinA2,LOW);
          digitalWrite(pinB1,LOW);
          digitalWrite(pinB2,HIGH);
          digitalWrite(pinC1,HIGH);
          digitalWrite(pinC2,LOW);
          digitalWrite(pinD1,LOW);
          digitalWrite(pinD2,LOW);
          delay(d);

          if(digitalRead(fsrVoltage)>=169){
            ct=512;
          }
      }
      if(digitalRead(fsrVoltage)>=169){
        delay(180000);
      }
  }
}
```