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MÁSTER UNIVERSITARIO EN INGENIERÍA BIOMÉDICA

MASTER THESIS

DESIGN AND IMPLEMENTATION OF A BLEEDING TRAUMA LEG FOR CLINICAL SIMULATION

AURORA FERNANDA PÉREZ JIMÉNEZ

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Resumen

La práctica es un elemento importante para alcanzar el éxito en distintas profesiones. Los equipos de fútbol practican estrategias una y otra vez para memorizarlas. Los actores practican sus guiones hasta conseguir aprenderselo de memoria. Esto mismo debería suceder en las profesiones del ámbito clínico, donde la práctica es igual de necesaria para aprender las técnicas que se llevan a cabo con pacientes, evitando de esta forma poner en riesgo su salud.

La progresión en el ámbito clínico se debe a la reevaluación permanente de los conceptos utilizados durante el desarrollo de la medicina lo cual genera cambios que hacen posible un mejor ejercicio de esta. Esto provoca que surjan nuevos métodos de aprendizaje. Así aparece la simulación clínica, una herramienta de enseñanza y aprendizaje que permite recrear escenarios reales para realizar acciones clínicas en pacientes virtuales. Esto permite poner en práctica las técnicas adquiridas teóricamente y evaluarlas objetivamente. Además, el uso de emuladores durante la simulación clínica hace posible la recreación de escenarios más realistas para practicar distintos casos clínicos. Teniendo en cuenta que el trauma hemorrágico es una de las principales causas de muerte en el mundo, es de gran importancia que los médicos conozcan las técnicas utilizadas para controlar estas situaciones. Una de las mejores maneras de conseguirlo es utilizando la simulación clínica, puesto que permite su aprendizaje sin generar riesgos. Ahí es donde nace la importancia de este proyecto.

Este trabajo de Fín de Máster se enfoca en diseñar y desarrollar una pierna capaz de reproducir diferentes escenarios de trauma hemorrágico. Este emulador será capaz recrear una lesión vascular sin fractura para que se practiquen las técnicas necesarias y que a su vez, se pueda realizar una evaluación objetiva de la actuación durante la simulación.

Este objetivo se ha logrado mediante la fabricación mecánica de un muslo humano de tamaño estándar que cumple con las características requeridas. Para ello, ha sido necesario identificar los principales componentes de la pierna: el hueso, los vasos sanguíneos, los músculos y la piel, para poder simularlos correctamente mediante el uso de materiales sintéticos. Además, se han identificado diferentes escenarios posibles que tienen lugar cuando se sufre un trauma hemorrágico, los cuales serán simulados para comprobrar el funcionamiento del emulador. Se reproducirán diferentes sangrados que se detendrán automáticamente mediante la realización de dos técnicas: presión directa sobre la herida o colocación de un torniquete.

El emulador de la extremidad inferior será fabricado con el objetivo de proporcionar a los clínicos una solución que les permita aprender a realizar un correcto control de escenarios de traumas hemorrágicos.

Palabras clave: Simulación, trauma, shock hemorrágico, extremidad inferior, emulador, sangrado.

Abstract

Practice is an important element to achieve success in different professions. A football team practice strategies over and over again to memorize them. An actor practices its role until it is fully retained. Therefore, there is no difference when talking about medical healthcare professionals where practice is necessary to learn techniques and not put patients' health at risk.

The progress in healthcare professionals follows an objective and permanent reevaluation of concepts that allow clinicians to better acquire skills and capabilities as they are being continually updated. Therefore, new learning methods in this area have been developed. This is how the clinical simulation appeared, a learning tool which allows to recreate real scenarios to perform clinical actions in virtual patients. This allows to practice required skills and evaluate it objectively. Moreover, the main objective of an emulator is to recreate an scenario as realistic as possible to practice clinical cases. Taking into account that the hemorrhagic trauma is one of the most causes of death in the world, the clinicians need practice the techniques to control this situations using clinical simulations scenarios. That is where the importance of this project is born.

This Master Thesis focuses on developing a leg capable of generating different hemorrhagic trauma scenarios. This emulator will be able to recreate a vascular lesion without fracture scenarios for clinician to practice and also, allows the professional to make an objective evaluation to the people who rehearse with the emulator.

This goal has been achieved through the mechanical design of a human thigh with standard size that meets the required characteristics. For that, it has been necessary to identify the main components of the leg: the bone, the blood vessels, the muscles and the skin, in order to simulate it correctly using synthetic materials. Moreover, different scenarios have been identified when a hemorrhagic trauma takes place. This scenarios will be simulated to check the functionality of the lower limb emulator. Therefore, some bleeding will be reproduce stopping automatically when different techniques are applied: pressure on the wound or placement of a tourniquet.

The lower limb trauma emulator will be manufactured in order to provide the clinicians the solution to learn to lead a correct control of hemorrhage trauma scenarios.

Keywords: Simulations, trauma, shock hemorrhagic, lower limb, emulator, bleeding.

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Contents

List of Figures

List of Tables

List of Acronyms

UPM: Universidad Politécnica de Madrid.

HULP: Hospital Universitario La Paz.

CASE: Comprehensive Anesthesia Simulation Environment.

ATLS: Advanced Trauma Life Support.

BP: Blood Pressure.

PLA: Poli- Lactic Acid.

PSI: Pounds-force per Square Inch

IDE: Integrated Development Environment

FSR: Force Sensor Resistant

Chapter 1

Introduction

This Master Thesis has been done in collaboration with the Hospital Universitario La Paz (HULP), in particular with the Advanced Clinical Training and Simulation Center. This Project has been proposed in order to develop an emulator of the leg capable of generating different hemorrhagic trauma scenarios. This will allow clinicians to practice the necessary techniques to control the bleeding in different trauma scenarios during clinical simulation sessions.

1.1. Motivation

Simulation is a learning tool which allows to replicate different real scenarios in order to obtain the skills needed to face those scenarios. It allows the interaction between knowledge, skills and human factors in order to provide an effective learning method. This technique allows professionals who use it to achieve higher performance. There are many professional areas that have used simulation as it is really useful and effective in certain specific activities. For instance, the military field has an important experience in using emulators to practice their maneuvers [1].

The progress in healthcare professionals follows an objective and permanent reevaluation of concepts that allow clinicians to better acquire skills and capabilities as they are being continually updated. Therefore, new learning methods in this area have been developed [2]. The clinical simulation born in order to cover clinical needs and it is a learning tool which has awaken interest in the last years as it offers many advantages [3]. Clinical simulation is the recreation of a scenario which represents a real clinical situation in order to train, practice, assess and acquire skills [4]. Using clinical simulation can speed up the acquisition of technical knowledge boosting the clinical performance as the skills acquired through the simulation can be easily transferable to reality. Simulation can reduce the stress suffered by clinicians in the real environment as they will be more trained and their confidence will increase [2]. Moreover, they can get a higher level of management of different situations without risking any life and taking into account that the trainee can repeat the scenarios as many times he or she needs [3].

The type of simulation determines the knowledge acquired by the students as the more realistic the simulation is, the more useful the knowledge gained from it will be. Therefore, the tools used to recreate scenarios have a lot of influence on this. One of the main components in simulation are emulators. Emulators are devices which try to model the system accurately and in such a way that they work as if using the original system. Usually, clinical emulators model different parts of the human organism in order to get an appearance and functionality as real as possible. They allow the reproduction of sensations that, in reality, are not happening. There are different types of emulators that are used in many areas of medical training.

The main goal of this Master Thesis has been to design and implement an emulator. This has been developed in order to cover a need in trauma area. Trauma is one of the most complex diseases to face as the multiple causes which can produce this disease is still challenge. The human body suffers a trauma when the threshold of the physiological tolerance is exceeded compromising its functionality [5]. Trauma is a disease that generates a serious social impact due to the fact that it represents the third cause of death for all social groups and the first cause of death for people between 1 to 45 years old. It is the cause of death of 80% of the teenagers, 60% of the childhood deaths and it is an important cause of death in the elderly people. Trauma is considered as an epidemic disease as it affects mainly to the young people and economically active people. Furthermore, it generates high sequelae and a difficult reintegration into work or school [6]. For all these reasons, it is imperative that the clinical world focuses on teaching how to better treat patients that suffer from these type of injuries in order to reduce this impact.

One of the leading causes of death after injury in traumatic patients is the hemorrhagic shock. In these situations, the main body system affected is the cardiovascular system and the bleeding produced must be controlled really fast. The bleeding can be different depending on the blood vessels affected; therefore, recognizing the situations, being trained to face them and control them, is essential to do it properly. Moreover, different protocols are being set in order to treat trauma injuries. Clinicians must learn and train those protocols to control the different trauma scenarios as effectively as possible to avoid more physiological complications. The medical treatment can extremely modify the evolution of the hemorrhagic shock stopping the bleeding.

In the hemorrhagic injury, early control of significant external hemorrhage is the most important intervention. According to the severity of the situation, different techniques can be applied: direct pressure over the wound when there are one or a few blood vessels affected and tourniquet when the situations is really complicated. Each technique has different requirements which must be controlled by the clinicians. During the **direct pressure** technique, clinicians need to check the pressure applied over the wound in the extremities in order to know what is the exact value needed to stop the bleeding. However, when a **tourniquet** is required apart from the pressure, it is important measuring where this tourniquet is placed and also, how long it stays in place. The place where it must be located is established between 5 to 10 cm and the duration of the tourniquet should be around 20 or 30 minutes [7].

Usually clinicians apply over the injuries the maximum pressure to stop the bleeding. However, this application could generate important consequences in the extremities and the solution may become the problem. Moreover, stress is an important aspect to consider in these simulations as in poli-traumatic patients, decisions must be done fast and quick. Training clinicians in charge of these scenarios is necessary to optimize the healthcare services. Therefore, the use of emulators have become a worthwhile experience and a useful tool in the development of self-confidence skills to apply the two main techniques, direct pressure or tourniquet placement in a correct way to avoid other complications [8]. Therefore, the main motivation during this Master Thesis has been to design a lower limb emulator which is able to train the control of different hemorrhages. This emulator must present an appearance as real as possible using different synthetic materials to create more realistic the simulated scenarios.

Due to the progress in clinical simulation some hospital areas which involve circulatory dysfunctions such as trauma and burn treatment units, demand bleeding trauma modules to support them to reproduce hemorrhagic real cases. Taking this into account, the HULP and the UPM have seen an opportunity to develop an emulator to train the maneuvers and skills needed to treat serious trauma situations. The designed and developed emulator during this project will cover this medical need, producing different hemorrhagic bleeding scenarios on the lower limb and allowing clinicians to train mechanical techniques such as manual pressure or tourniquet placement to stop the bleeding.

1.2. Project scope and objectives

The simulation center of HULP works on the creation of emulators in order to cover medical needs in different clinical specialities. Also, emulators help them to make clinical training scenarios more realistic. Therefore, a bleeding lower limb trauma emulator will be developed with the following characteristics:

- **Design:** The emulator has to be shaped as a real human person's thigh. It must have a texture as close as possible to the skin so that the clinicians could feel a real lower limb. In addition, the emulator will be made of different synthetic materials which have to recreate all the biological components such as muscles, bones and blood vessels.
- **Functionality:** The bleeding action is performed through an electronic system. The lower limb should be able to reproduce all type of bleeding scenarios taking into account the type of vessel damaged. It should be able to provide also feedback on the actions taken by the trainee. This will be achieved due to the

use of sensors placed along the emulator. The bleeding trauma should have an automatic control in order to get a robust structure for clinical applications.

- **Adaptability:** The emulator has a standard size of a human thigh. For this reason, it should be able to reproduce hemorrhages of different groups of patients, such as adults men or women. The lower limb emulator is prepared to add more materials in the mechanical design in order to recreate different human anatomies. Moreover, the emulator is able to recreate different bleedings: arterial and venous in different blood vessels which irrigate the lower limb. These situations can create a light bleeding or a massive hemorrhagic depending on the amount of the affected blood vessels. According to the type of hemorrhage to apply direct pressure over the wound or placement a tourniquet will be required. The mechanical design of the emulator allows to replace the materials once they are damaged without the need to renew the entire emulator.

- **Repeatability:** Once the bleeding has been controlled, the emulator can immediately be prepared for another simulation. For this reason, the clinicians can repeat the simulations as many times as they may consider necessary.

- **Educational:** The design of the emulator allows to obtain a feedback when the techniques are applied correctly. This makes it a very practical device for the educational setting because it allows doctors to learn techniques through repeated use of this emulator. They will know when they do something right or when they do it wrong, so they can correct their mistakes. Therefore, many data collected from the recreation of the simulation can be stored in order to check the evolution of the clinicians along many simulation in order to train and to improve the least developed areas.

In order to fulfill these characteristics, an electromechanical device will be developed for simulating different scenarios of bleeding trauma in the lower limb.

1.3. Document layout

This manuscript has been structured in four different sections.

Chapter 2 shows the two main topics related with this project. The first section is an introduction to clinical simulation presenting a review of its history and focusing on it as a learning and teaching tool. Moreover, taking into account the objectives to achieve, one of the main components during the simulation, emulators, will be presented and also, some materials used to manufacture them will be explained. The second section of this Chapter will be focused on trauma, specifically on bleeding trauma. Within this section, the main system affected during these injuries, the cardiovascular system, will be studied. Different protocols which must be followed in limbs trauma scenarios will be provided in order to understand how to act in hemorrhagic shock situations. Furthermore, to focus on the specific case of the emulator created during this project, the currents lower limbs trauma emulator present in the market are shown.

Chapter 3 presents the process followed to develop the emulator design. The process used have been divided into mechanical and electronic design. First of all, the mechanical design will be presented being the main part of this work. This includes a description of the selected biological elements which will be part of the emulator in order to know their features and the necessary requirements to simulate each of them. The synthetic materials used to represent each of these biological elements and their manufacturing process will be presented. Finally, the integration of all the components will be explained. The second part presents the electronic design which includes the different elements used to assembly the electronic circuit. Besides, a brief explanation of the system created to activate the different types of bleeding is provided.

Chapter 4 shows the results obtained from the manufacturing process of the mechanical and the electronic design. In addition, the prototype testing is provided where different hemorrhage scenarios will be simulated in order to check the correct functioning of the emulator. Moreover, the different scenarios where the two main techniques can be practised are presented.

Chapter 5 presents the main conclusions of this project and the future developments. In this Chapter, the assessment of the project taking into account the objectives established and the results obtained is provided. Besides, taking into account the situations in which this Master Thesis has been developed many ideas could not be developed and their implementation in future studies could be a good improvement of this lower limb emulator.

Chapter 2

State of the Art

2.1. Clinical Simulation

The clinical simulation born in order to cover clinical needs and it is a learning tool which has awaken interest in the last years as it offers many advantages [3]. Clinical simulation is the recreation of a scenario which represents a real clinical situation in order to train, practice, assess and acquire skills [4]. Simulation supports training for those scenarios as technical and non-technical skills could be practiced. Using clinical simulation can speed up the acquisition of technical knowledge which can be easily transferable to reality. Simulation can reduce the stress suffered by clinicians in real environments as they will be more trained and their confidence will increase [2]. Moreover, they can get a higher level of management of different situations without risking any life [3].

2.1.1. Background

Simulation for teaching and learning has a long history. It is a learning tool which has been used in different professional fields for a long time. Some of these fields are; astronaut training, computer simulations for economics or simulated games used in the field of human resources by companies. With the evolution of the technology and the use of computers, simulation has evolved along the years incorporating the latest technologies. The simulation concept as we know it nowadays, was born in 1929 when the first flight simulator was developed by Edwin Link and it was called Link Trainer, shown in Figure 2.1 [4] [9]. Flight emulators are known as training devices which allow the pilot to train so that they can acquire navigation skills, maneuvering and maintenance of the systems. In 1943, the first flight emulator was made for one airline company and in 1960, with the arrival of digital computers, more sophisticated emulators were developed to manage critical situations [9] [10].

Figure 2.1: First flight simulator, Link Trainer [11].

In the medical field, simulation find its origins in the old days in which a human patient was made using mud and stone. Nonetheless, it is not until the 20th century, thanks to development in aviation simulation, that the clinical simulation gives a boost [12]. Created in the early 60s, the mannequin Resusci-Anne, shown in Figure 2.2, was designed by Asmund Laerdal together with a toy factory, being a tool for training mouth to mouth resuscitation. In that moment, another emulator, shown in Figure 2.3, was created. It was called Sim One and it was developed by the University of Southern California. The Sim One emulator was a remarkably lifelike mannequin controlled by a hybrid digital and analogue computer. This emulator had many high fidelity features such as the chest was anatomically shaped and moved while breathing, the eyes blinked, the pupils' response changed and the jaw opened and closed. It was used for training anaesthesia residents in the skills of endotracheal intubation. [13].

Figure 2.2: Asmund Laerdal with Resusci-Anne, in 1970 [13]

Figure 2.3: Sim One in the late 1960s [13]

In 1968, the mannequin Harvey, shown in Figure 2.4, was first demonstrated. It is a full mannequin which simulates 27 cardiac conditions. This emulator displays various physical conditions, being able to simulate a spectrum of cardiac diseases by varying blood pressure, breathing pulses, normal heart sounds, and murmurs. In 1987, a study showed that the students who had trained with it during their formation performed significantly better than their peer who interacted only with patients. [13].

Figure 2.4: Harvey in the early 1970s [13]

The development of mathematical models of the physiology and pharmacology of drugs have been an important contribution to the development of realistic mannequin simulators. This allowed to create a computer based simulation for instructing anaesthesia residents in managing intraopreative events [13]. In 1986, two teams of anesthesiologists created a life-size emulator to combine different technical skills in order to help specialists such as: anesthesiologists, emergenciologists, intensicits and cardiologists [4]. Researchers of the Standford University and Florida created the known CASE (Comprehensive Anaesthesia Simulation Enviroment) which was the pioneer of a generation of mannequins. They were used to investigate various aspects of human performance in anaesthesia and related domains [13].

Clinical simulation started focusing on critical situations in the operating room, but then it has been expanded to other settings and specialists such as emergency physicians, intensive care physicians, surgeons or orthopedists. This is supported by a global education reform which has, as one of its pillar, the research for new teaching methods applying new technology. This allows to learn and train not only clinical skills but also communication and stress management abilities. Moreover, simulation allows to train as many times as needed [12].

2.1.2. Learning-teaching process

During the learning-teaching process, simulation is a good method to improve the diagnosis techniques, the treatment and troubleshooting but also, it allows to improve human relations skills compared to those acquired using traditional teaching methods. Simulation allows to show what the students have accomplished and how they have reacted to a specific situation. Therefore, simulation is a good training tool to face clinical challenges ensuring safety and training to avoid critical mistakes which could have an important impact on patients [2].

According to [12], the learning starts with an experience, and after the experience, it is necessary to think about what happened. This reflection about the experience of the process allows to detect the mistakes made and to consider different possible actions. Therefore, in [12] it is explained that the action itself is not enough for the students to generate an adequate learning experience and that reflection on what happened during the action is required. This explains why clinical simulation has three phases [14]:

1. **Clinical Diagnosis:** This phase is the first one. It focuses on adapting the simulation to the students' characteristics and to the learning environment. Then, the simulation has to be organized in order to show the reality as much as possible. Once this is done, an explanation about how the simulation will be, its goals and the roles involved is provided. During this phase, the students have to get used to instructions and materials. If the situation is complex, this phase can be long. Sometimes a previous test is necessary to fully understand the case to accomplish in the simulation.

2. **Intervention:** This phase is the basis of the experimental learning. The students have to show all their theoretical knowledge and their skills in order to do the best performance they can. They must be involved with the simulation. Students could perform simulations individually or in groups and several iterations could be done.

3. **Reflection or De-briefing:** This is the key element in simulation and it is the main difference with other clinical learning tools. This is the phase in which success or failure is discussed and estimated, as well as the quality of the simulation. The evaluation is done by a person who has not participated, but each participant must carry out a self-evaluation. The last step will be the reflection about the experience of the process, allowing the trainees to detect the mistakes made which probably they will not repeat again in other similar situation.

Usually, when a simulation is carried out it is usually done in two different rooms. One of them, the *control room* where the director is watching the simulation, outside the student's visual field. An the other of one, the *simulation room* where clinicians are training the recreated situation. This distribution contributes to a general environment closer the reality [8] and it also allows a correct application of real clinical scenarios in simulation [1].

2.1.3. Emulators

The type of simulation can greatly determines the knowledge acquired by the students, as the more realistic the simulation is, the more useful the knowledge acquired from it will be. Therefore, the tools used to recreate scenarios, emulators, are one of the main components in simulation. Emulators are devices which try to model the system accurately and in such a way that they work as if using the original one. Usually, clinical emulators model different parts of the human organism in order to get an appearance and functionality as real as possible. In [15], a classification of the emulators in five categories:

1. **Part task emulator:** They are models which only replicate a part of the organism. Therefore, they only allow the development of basic psychomotor skills.

2. **Simulated patients:** These are actors trained to act as patients. They are used to train skills in obtaining a medical history, performing a physical examination and communication techniques with the patients.

3. **On-screen virtual emulators:** They are computer programs that allow to simulate several situations, mainly in areas such as physiology, pharmacology or similar. They allow the training and evaluation of knowledge and decision making. Allowing to interact with students.

4. **Complex task emulators:** These are electronic, computational and mechanical devices. Having auditory, visual and tactile functionalities that a three-dimensional representation of an anatomical space is achieved. These emulators are usually combined with part task emulators in order to combine physical interaction with the virtual environment. They have been used in endoscopic procedures allowing the development of manual skills and three-dimensional orientation.

5. **Full patient emulators:** They are life-size mannequins which are computationally managed and simulate anatomical and physiological aspects. Moreover, they allow to manage complex situations and to develop group work skills.

Another important aspect in simulation is the concept of fidelity of the emulator. This concept is used to define the level of realism of the models and the scenarios in which they are used [16]. There are three levels:

1. **Low fidelity emulators:** They use models which simulate scenarios to acquire basic specific skills in a simple process. For example, emulators to practice how to insert an intravenous catheter, as we can see in Figure 2.5.

Figure 2.5: Low fidelity emulator [16]

2. **Medium fidelity emulators:** They combine the anatomical parts with simple computational programs which allow the instructor to manage several variables. For example, devices to train how to perform the cardiopulmonary reanimation or how to properly ventilate and resuscitate a baby as shown in Figure 2.6.

Figure 2.6: Medium fidelity emulators [16]

3. **High fidelity emulators:** They have a lot of physiological variables to train advanced techniques. High fidelity emulators can integrate different respiratory sounds, heart rhythms, pulses in different parts of the body or pupil dilation among many other variables. They are used to manage a critical situation in the clinical environment. In Figure 2.7 it can see one of the most complete emulators.

Figure 2.7: High fidelity emulators [16]

It is important that the fidelity term is not confused with the complexity used as they are not proportional. As an example, when a scenario in which a medical examination is performed and also, in the simulated situation the patient requires a review of the dilation of the pupils, the simulation is high fidelity as the situation is close to reality. However, the recreated scenario in this simulation require low complexity because the task is not really difficult to simulate. Therefore, these two concepts are different [15].

2.1.4. Materials used in clinical simulation

Along the history of the emulators, there have been many ways to design and develop them. The selection of materials used to design an emulator is one of the most complex process during their manufacturing as they have to provide a real appearance and similar functionality to the real one. Different studies show some synthetic materials used to simulate biological materials. Within this Subsection a review of some of them are shown below.

A study presented in [17], considers different materials to manufacture several emulators: head and neck emulators to provide a complete assessment of image acquisition will be manufactured using adjustable thermoplastic hardened with resin. Also, male mannequin to place thermoluminescent dosimeters to measure the dose-organ ratio during radiological examinations will be manufactured using soft plastics to simulate soft tissue and epoxy to simulate bones.

In addition, the improvement of 3D printing technology has been a great progress in the development of clinical emulators. The aforementioned technology is capable of printing all kinds of plastic parts using polymers. There are printers capable of using many types of polymers in the same impression, mixing dosages of each polymer to form skin, subcutaneous tissues and bones generating shapes, texture, flexibility and consistency very close to the real ones [18].

It is important to take into account that one of the main goals of the manufacturing process in an emulator is getting an appearance as real as possible; therefore, the skin is one of the most important elements to recreate as it is the external layer. Human skin has complex properties and functions. It is in a continuous change due to different factors such as: environmental, biochemical and psychological. As a result of this complexity, assigning exact numeric values for the properties to simulate it using non-biological materials is really difficult. Studies as [19] present different skin models to simulate it with different materials. Some of them consisting of liquid suspensions, gelatinous substances, elastomers, resins, metals and textiles incorporating nano and micro-fibres.

The arguments provided for the use of elastomers to simulate skin in [19], which will be presented in Section 3.1, has been one of the motive to manufacture the emulator in this project using silicones. This decision is not only backed by the aforementioned studies but also, by other studies as [20] and [21] where artificial muscles made using silicones-rubbers for a novel emulator to spine surgery are presented and where the good correlation between the properties of silicones and soft tissues is shown.

2.2. Bleeding Trauma

Trauma is an injury which produces a damage to the body caused by an external force. In this Section, trauma scenarios that the lower limb could suffer will be presented. In trauma situations, the main system affected is the cardiovascular system.

2.2.1. Cardiovascular system

This system can be thought of as the transport system of the body and is formed of three components: the heart, the blood and the blood vessels. It transports approximately 5 liters of blood around the human body providing the cells in the body with the oxygen and nutrients they need to survive [22].

The circulatory system can be divided in two parts: the pulmonary circulation and the systemic circulation. The pulmonary circulation, between the heart and lungs, transports deoxygenated blood to the lungs to get oxygen, and then back to the heart. The systemic circulation carries oxygenated blood from the heart to the tissues and cells, and then this blood goes back to the heart. In this way, all the body cells receive blood and oxygen [23]. All of this is possible due to the action performed by the main components of the system.

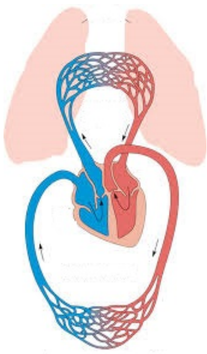

Figure 2.8: Cardiovascular system [24]

In order to understand the functioning of the cardiovascular system, its main components must be defined:

- **Blood:** The blood is a body fluid that circulates through the blood vessels. The blood is responsible to carry oxygen and nutrients around the body and also carries away carbon dioxide and waste products that the body does not need. It has other functions such as helping the body to keep its temperature, carrying hormones to the body cells and distributing antibodies to fight infection. When an important amount of blood is lost due to larger wounds, it has to be replaced through a blood transfusion. Depending on the amount of oxygen that the blood has, it has different colours from bright red when the blood has lot of oxygen to dark red when the blood does not have so much oxygen [22].

- **The heart:** It is the main component of this system as it is the muscle responsible to pump blood to different parts of the body. The heart has four chambers. The two upper chambers are known as left and right atria and lower chambers are known as left and right ventricle. The blood is introduced in the heart following an orderly flow which progresses through the heart to the lungs, where it receives oxygen; then goes back to the heart and then out to the rest of body. The heart alternately contracts and relaxes the pressure in the arteries rising and falling with each beat producing the heart rate. It is regulated by the autonomic nervous system; therefore, there is no voluntary control over the beating of the heart. [25] [23].

- **Blood vessels:** Blood vessels are the tubes which carry the blood. Three different types of vessels can be distinguised: arteries, veins and capillaries. The walls of arteries are usually much thicker than the walls of veins. This structural difference is related to the function they perform in the body [25]. In Figure 2.9 the veins and arteries of the human body are represented.

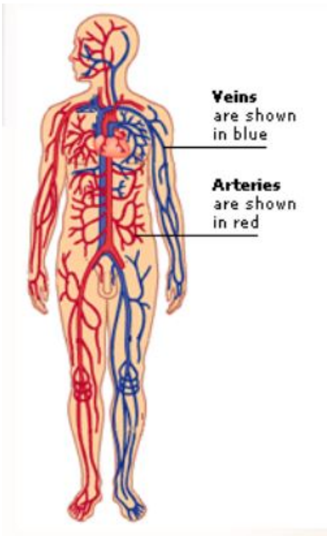

Figure 2.9: Blood vessel [25]

  * **Arteries** They are blood vessels which carry blood from the heart to the body. They are much closer to the pumping action of the heart, so their walls must be strong enough to support the continuous changes in pressure. The flow in these vessels is intermittent because during the ventricular systole, there is an arterial pressure peak while the blood ejection, so the blood flow is high. This pressure is known as the systolic pressure. Just before the blood ejection, the diastolic pressure takes place which is the minimum arterial blood pressure between heartbeats and the blood flow

decreases. The smallest arteries are called the arterioles and their diameter varies from 10 μm to 0.3 mm.

* **Veins:** These vessels are responsible to carry blood from the body back to the heart. They are far from the heart in the circulatory pathway, so the pressure within them tends to be low. All the veins except the pulmonary one move blood to the heart and carry deoxygenated blood. The diameter of the veins is around 0.5 mm. They are usually referred to as the capacitance vessels due to their ability to expand and store blood. To support the venous return, the veins contain valves which prevent back-flow. Unlike arterial flow, venous flow is constant and not intermittent as they do not feel the pressure changes.

* **Capillaries:** They are microscopic blood vessels which produce the exchange of water and other substances between blood and tissues. The diameter of the capillaries is around 8-10 μm. The capillaries have a higher resistance to make blood flow slow and to allow for maximal gas and nutrient exchange. The micro-circulation through the tissue is generated by the capillaries [26].

Blood pressure (BP) is a measurement of the force exerted by the blood against the wall of a blood vessel, and it is the force that keeps the blood circulating continuously, even between heartbeats [23]. This blood pressure is affected by different characteristics of the blood and the blood vessels such as the elasticity and the diameter of the blood vessels or the viscosity of the blood. The pressure has its highest value in the aorta and continues to drop throughout the circulatory system, reaching zero or negative pressure values at the cava vein, as shown the Figure 2.10. Blood flows from regions of higher to lower pressure: from the aorta with values around 100 mmHg to the other vessels decreasing the pressure progressively until it reaches 35-40 mmHg in the capillaries and around 15 mmHg at the exit of the capillaries. It becomes 0 mmHg when the blood enters the right ventricle.

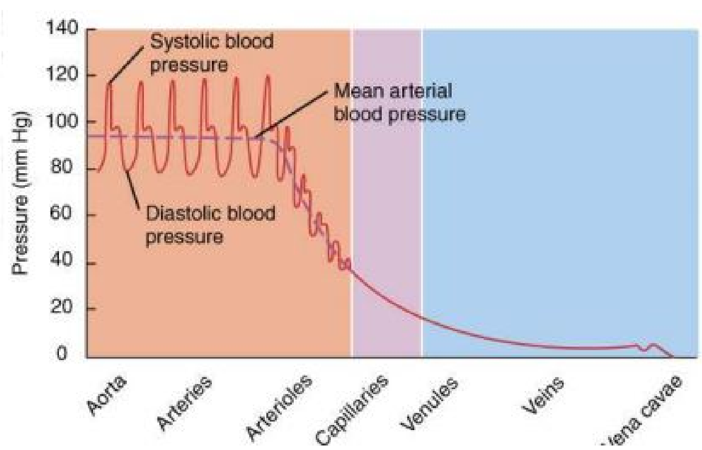

Figure 2.10: Pressure in the Cardiovascular System [25]

This concept is really important as the pressure applied in the techniques to stop a bleeding injury will depend on the values of the internal blood flow pressure.

2.2.1.1. Lower limb cardiovascular system

As the focus of this Mater Thesis is to develop a lower limb emulator, the lower limb of the leg anatomy will be described in order to understand the behaviour of the system and to know the main blood vessels that irrigate this body part. When an injury occurs, it is important to know in which part of the leg occurs in order to identify the blood vessels affected. Therefore, the venous and arterial system of the lower limbs will be explained.

Venous system in the lower limbs:
In this system we have to highlight two systems: the deep venous system and the superficial venous system.

- **Superficial Venous System:** It is formed by veins which are placed between the skin and the muscles. The two main veins in this system are the lesser and the greater saphenous, shown in Figure 2.11.

  Lesser saphenous vein starts in the foot and it goes up through the inner front of the thigh until it reaches the groin where it leads into the femoral vein. It is in contact with different collateral veins such as circumflex iliac, abdominal subcutaneous and the external pudendal vein.

  Greater saphenous vein goes up through the posterior front of the leg and it leads into the popliteal vein. It is also in contact with the colateral veins.The main function of greater saphenous veins are to take the venous blood from the skin and subcutaneous cellular tissue to the deep venous system. This communication between deep and superficial system is done by the perforates veins.

- **Deep venous system:** It is the system placed between different muscles. The main veins in this system are the tibial, femoral and illiac veins, as shown in Figure 2.11. The tibial veins are double (anterior and posterior) and they come together forming the popliteal vein which crosses the abductor muscle and changes the name to the superficial femoral vein. Then, the femoral vein becomes the external iliac vein. This system is the main responsible for taking the venous blood to the heart [27] [28].

Arterial System in the lower limbs:
It carries the oxygenated blood from the heart into the limbs. The arterial system in the leg is mainly formed by the femoral artery, the popiliteal artery and the anterior and posterior tibial arteries, shown in Figure 2.12.

- **Femoral Artery:** It is known as commom femoral artery which is the biggest artery in the thigh and it is created as a continuation of the external illiac artery; this junction usually occurs near the femur head. The common artery is divided and generates the deep femoral artery and the superficial femoral artery. The superficial femoral artery makes its route across the leg's surface and then goes through the front of the thigh following the femur.
- **Popliteal artery:** It is the femoral artery prolongation which distributes arterial blood to the knee.
- **Tibial arteries:** They are distributing arterial blood to the leg, the ankle and the foot [29][30].

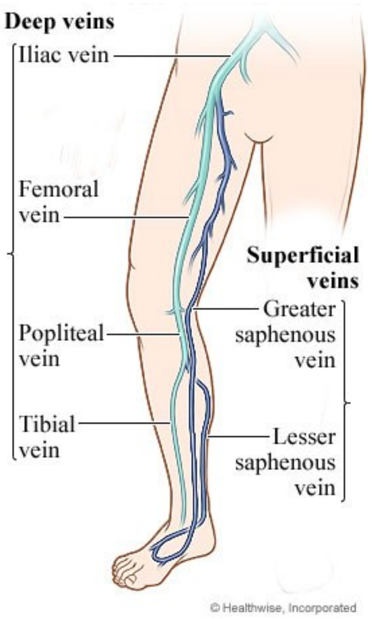

Figure 2.11: Venous system in the lower limbs [31].

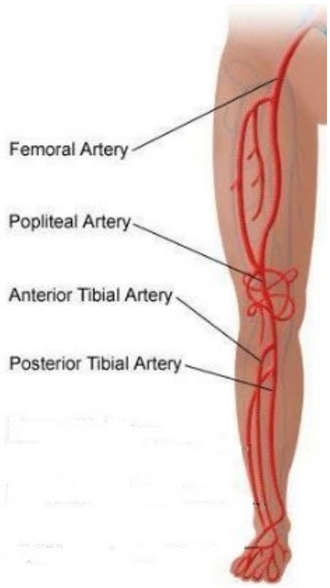

Figure 2.12: Arterial system in the lower limb [32].

2.2.2. Trauma

Trauma is one of the leading causes of death in the world. Therefore, clinicians must be prepared to face these situations in order to reduce the number of deaths. To achieve this purpose, a lower limb emulator has been designed to reproduce different hemorrhagic trauma scenarios [6].

Trauma can be defined as several intentional or unintentional injuries at organic level, which results from an acute exposure to a high amount of energy by agents external to our body [6] [33]. As it has been explained in the Chapter 1, the human body suffers trauma when the threshold of physiological tolerance is exceeded compromising their functionality [5]. Therefore, trauma is not considered as an event but it is considered as a wound that mainly affects the cardiovascular system, which generates repercussions that can have an impact on the lives of people who suffer them [34]. The social impact generated by the trauma disease is so serious, therefore clinical world must focus on teaching how to better treat patients that suffer from these type of injuries [6].

There are many different **types of traumatic injuries** and they can be classified depending on the traumatic agent which creates it: physical, chemical and psychical [35]. Besides, they may be also categorized depending on the injury produced as closed or penetrating injuries. It is considered a closed injury when the trauma happens inside the body. They are normally related to car accidents and falls. For instance, a traumatic brain injury can be developed due to a blunt force trauma to the head or a traumatic pelvis injury can be suffered in a car accident. On the other hand, it is considered as a penetrating trauma the one which origin comes from an external agent such as a stab wound with a knife or scissors.

Trauma deaths have been described as having a trimodal distribution, as shown in Figure 2.13. The peaks shown in the graphic correspond to the types of interventions that would be most effective in reducing mortality. The first peak, the immediate deaths, represents patients who die before reaching the hospital. These injuries include major brain or spinal cord trauma and those resulting in rapid exsanguination. Almost 60% of these deaths occur at the same time as the injury. The second peak, the early deaths, are those that occur within the first few hours after the injury. Half of them are caused by internal hemorrhages, and the other half, due to central nervous system injuries. In most cases, it requires a hospital where immediate resuscitation, identification of injuries, and access to a ready operating room 24 hours a day can be provided. Development of well-organized trauma systems with rapid transport and a protocol-driven care, can reduce the mortality by 30%. The third peak, the late deaths, refers to patients who die days or weeks after injury. Mortality for this period has usually been attributed to refractory intracranial hypertension following severe head injuries. From 10% to 20% of all trauma deaths occur during this period [36].

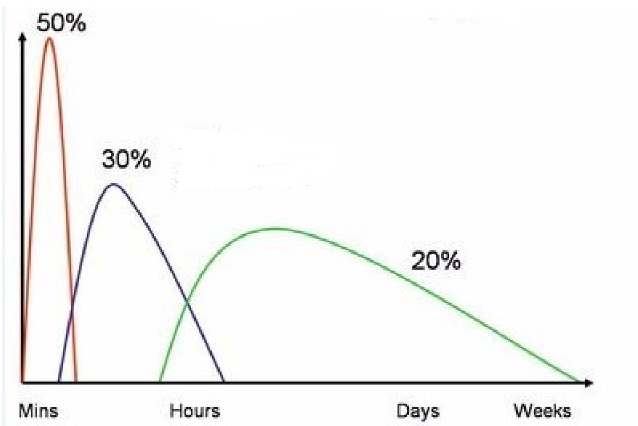

Figure 2.13: Trauma deaths' distribution [37]

As already explained, in every traumatic injury, the cardiovascular system is affected. When this occurs, a blood loss is produced which could cause further complications such as complications in the recovery process, surgery or damage in different organs. When a massive loss of blood is produced, it is known as hemorrhagic shock.

2.2.2.1. Hemorrhagic shock

The most severe phenomenon that accompanies major bleeding is the considerable loss of intravascular volume, that further leads to hypovolemic shock, also known as hemorrhagic shock [38]. Hemorrhagic shock is the leading cause of death after injury in traumatic patients and the major cause of potentially preventable deaths. Massive hemorrhage may lead to hemodynamic instability, decreased tissue perfusion, organ damage, and death. The main goals of resuscitation are two: restoring circulating blood volume and stopping the source of the hemorrhage [39]. In order to decrease the number of deaths, clinicians must be able to rapidly identify and manage internal and external hemorrhages. Recognizing the type of bleeding is needed to apply the appropriate hemorrhage control techniques, understand the risks associated with the different types of hemorrhage, and understand how to estimate blood loss. The blood can escape from all vessels; arteries, veins or capillaries. Depending on where this loss takes place, three types of hemorrhages can be distinguished:

- **Arterial:** The arterial bleeding presents a bright red blood due to the fact that it carries hemoglobin, blood rich in oxygen. Moreover, the bleeding happens in a pulsating way showing the intermittent heart rate.
- **Venous:** The venous bleeding presents a dark red color as the blood has a low amount of oxygen. The venous flow blood is slower than the arterial one and it is homogeneous.
- **Capillary:** These vessels are smaller than venous or arteries. Therefore, the blood loss will happen slower than for venous or for arterial bleeding. It is the most common bleeding and the least dangerous.

The bleeding depends on its localization. When some of these vessels are bleeding, it may be appreciated outside of the body, known as external bleeding, but in other situations it may occurs inside some cavity of the organism, known as internal bleeding [40]. Moreover, a classification of hemorrhage could be made taking into account the amount of blood loss:

- **Mild:** They are hemorrhages that do not exceed 15% of the total blood volume in the body, Class I.
- **Serious:** These refer to the hemorrhages which loss represents between 15% and 30% of the total blood volume, known as Class II.
- **Very serious:** When the hemorrhage exceeds 30% of the total blood volume but it remains below 40%, Class III.

- **Lethal:** The volume of blood loss is above 40% which corresponds with the hemorrhagic Class IV.

The speed at which blood loss occurs worsens the situation [41]. It is possible to make a differentiation between the degrees of the shock according to the amount of blood loss, shown in Table 2.1.

	Class I	Class II	Class III	Class IV
Blood loss (mL)	<750	750-1500	1500-2000	>2000
Blood loss (% total)	15%	15-30%	30-40%	40%
Pulse rate (lpm)	<100	>100	>120	>140
Blood Pressure (mm Hg)	Normal	Normal	↓	↓↓
Pulse Pressure	Normal	↓	↓↓	↓↓↓
Respiration Rate (rpm)	14-20	20-30	30-35	35-40
Urine Output (mL/hr)	>30	20-30	5-15	Negligible
Mental Status	Slight anxiety	Mild anxiety	Anxious/confused	Confused/lethargic
Fluid used	Crystalloids	Crystalloids	Crystalloids + colloids	Crystalloids + colloids

Table 2.1: Degrees of hemorrhagic shock [42]

When there are a hemorrhages with high intensity, the human body reacts generating a pathophysiological response which is shown in different ways: pale and cold skin, sticky sweating, tachypnea, yawning, thirst, fast and soft pulse. Due to the loss of blood pressure, dizziness and even disturbances of consciousness can occur. Therefore, it is necessary to learn how to control hemorrhages. In the first place, a diagnosis of existence is necessary to know if there is or not an hemorrhage in somewhere in the body. In the second place, a diagnosis of the location of the bleeding is important in order to find the specific location, specially important if there is an internal hemorrhage. Once the hemorrhage has been localized, the treatment starts and there are different manners to stop an hemorrhage:

- **Mechanical methods:** The application of force in the vessel would support a collapse and therefore, the hemorrhage could be stopped. The common way of doing this is applying a direct compression on the wound. In addition, it is possible to do a compression using a tourniquet. Moreover, it is possible to throttle the vessel by using hemostat forceps, ligatures or metal clips. Depending on which vessel is affected, the pressure to apply on the wound might be different, being higher to stop the bleeding in the arteries than in the veins. Direct compression and tourniquet will be trained in the emulator developed in this project.

- **Thermal methods:** Two options could be considered: the first one would be to apply heat in the wound to create a scab and the second one would be to apply cold to generate vasoconstriction.

- **Electrical methods:** The electricity would go across the body through a scalpel until it reaches the damaged tissue in order to coagulate the blood and stop the bleeding.

- **Chemical methods:** There are different chemical ways to control an hemorrhage and all of this with the purpose to create fibrin which is a protein that will allow the creation of a clot.

Whereas massive hemorrhage continues to be a major cause of mortality, it is often reversible, and it can be appropriately managed by an early identification of these patients and the source of their bleeding, approaching them with protocols and treatment to stop the bleeding.

2.2.2.2. Limbs trauma protocol

The medical treatment provided to a patient can extremely modify the evolution of a trauma case. If the medical attention happens early and it is fast and organized, the life of the patient can be saved and more complications could be avoided. In order to do so, there are different trauma protocols to provide a guidance on how to proceed with trauma patients [43].

The proper organization of trauma care is still pending in our healthcare system. However, the situation has improved in recent years, as some autonomous communities have implemented trauma system. A trauma system is a continual and coordinated action which offers an early attention when the injury occurs The implementation of a trauma system reduces the mortality rate by 10-20 % and reduces avoidable deaths by 50 % [43]. In trauma systems, there is a trauma code which is defined as a set of actions to identify major trauma in a fast and effective way and to support the clinical professional involved in trauma management. When a patient is detected with a serious injury, the activation of this code must be done, launching the whole process. The ideal triage system would be one that is capable of assigning to each patient the priority level that corresponds according to the severity of the injuries that they present [44].The assessment and initial care of these patients should be carried out by priority, for which the guidelines proposed by the American College of Surgeons in their ATLS (Advanced Trauma Life Support) courses are very useful. These courses consist in the fundamental concept of initial care for the poli-trauma patients that is: treating life-threatening injuries first [43] [7].

In general, musculoskeletal system's injuries do not endanger the patient's life and, therefore, they will be treated once the hemodynamic stabilization is achieved. However, certain injuries can generate significant blood losses which must be controlled to avoid shock. On the other hand, there are injuries which do not entail a vital risk but they can produce a high risk of limb viability or serious functional physical damages [43]. Injuries which can threaten the life of the patients known as vital injuries are:

- Unilateral or bilateral femoral fractures, open or closed.
- Vascular injuries with or without associated fractures, proximal to the knee or elbow.
- Traumatic amputations of arms or legs.

This project will be focused on recreating the vascular lesions in the lower limbs without associated fractures. They can be ischemic or hemorrhagic injuries. The isquemic injury is a tearing of the intimate tunic can lead to thrombosis of the vessel, causing distal limb ischemia that, if not treated early, will cause necrosis and loss of the limb. The hemorrhagic injury is the loss of the integrity of the vessel with active bleeding, which will be more or less profuse depending on the affected vessel. This last type will be simulated in this project.

The actions which can be done in order to repair hemorrhagic injuries on the limb are to control the bleeding and to replace the loss blood volume. During this evaluation, clinicians should look for external bleedings and assess vital functions in order to monitor them. When bleeding is observed, it must be controlled by direct pressure or a tourniquet.

Direct pressure applied over a bleeding site, is the initial technique used to control external hemorrhage for non life-threatening bleeding. Most external hemorrhages are controlled by direct pressure at the bleeding site. Performing direct pressure technique correctly requires two hands pushing against the wound, while the patient is lying on a flat and hard surface for counter pressure. The ideal direct pressure is to use any clean tissue found to pressure on the wound, as shown in Figure 2.14. If the wound is deep and extensive enough, the gauze or tissue will be inserted so that the entire wound is filled. In the case of not having clothing or any other tissue, direct pressure only with hands at the bleeding point is enough [45]. If direct pressure fails to control extremity hemorrhage, the next step is to use a tourniquet [46].

Figure 2.14: Direct pressure applied over the wound [45]

Tourniquets as the one shown in Figure 2.15, are used to decrease blood loss. Despite the benefits of surgical tourniquets, and despite many advances in tourniquet technology, their use is not without risk and complications still occur. Usually high pressures are applied on the limb under a tourniquet cuff when are required which can cause nerve, muscle, and skin injury. Establishing a cuff pressure more precise should minimize these risks. The question of how to minimize cuff pressure, and thereby reduce the risk of injury, is of interest to all medical personnel involved in tourniquet use [47]. Tourniquets have the potential to induce serious consequences, the use of correct tourniquet width for the patient's size, minimizing the application time and applying the lowest effective pressure for an individual patient is required.

Figure 2.15: Tourniquet [48]

The site that the tourniquet is to be applied should be inspected and ascertained to be outside the zone of operation and injury, between 5 to 10 cm above the wound. Do not apply a tourniquet to a site where a nerve crosses a bone as this increases the likelihood of nerve damage [49] [47].

The time duration of the tourniquet inflation is related with one of the major cause of tourniquet complications which is ischemia. The incidence of post-tourniquet pain increase during periods of prolonged tourniquet inflation [50]. A tourniquet should be inflated at the last possible moment to ensure that the minimum tourniquet time is required. The ischaemia tolerance of tissues varies from patient to patient, so that the time what is acceptable in the fit young person may well not be so in the elderly patient, in a diabetic or in an arteriopathic patient [49]. Nerve conduction abnormalities may be observed 5-10 minutes after tourniquet inflation. Complete conduction block does not occur until 30-50 minutes after inflation. Additionally, tourniquet pain can develop 30-60 minutes after inflation and is often relieved by immediate deflation. The maximum safe duration for lower limb tourniquets was determined to be 90-120 minutes in some studies. However, many researchers have argued that tourniquets should be inflated for less than 1 hour, while others have advocated up to 3 hours [50]. In [43] is suggested that the time the tourniquet is kept on must be controlled. Therefore, the time the tourniquet has been placed should be recorded and loosened every 20-30 minutes, noting the time of each performances again.

The pressure to which the cuff should be inflated is dependent on a number of variables, including the patient's age, blood pressure, and the shape and size of the extremity in question, as well as the dimensions of the cuff [51] [50]. In [52], suggests that a fixed pressure maximum of 550 mmHg in the leg is necessary to compensate for the padding effect of muscle and fat. However, one should be wary of using pressure higher than 350 mmHg unless necessary [47]. A properly functioning tourniquet applies a compression tissue pressure higher than the patient's systolic arterial pressure. A commonly used tourniquet application pressure is 100 mmHg above the systolic pressure which is enough to compensate for tissue set in the human body. If the anatomy of the patients changes as obesity, this will usually need to be higher adding 50 mmHg. High pressure can predispose to increased pain, soft tissue damage and neurovascular injury. In case where the higher pressure are required, the tourniquet time should be minimized [47].

2.2.2.3. Lower limbs hemorrhagic trauma simulation

Patients who suffer from poli-traumatic events can trigger different clinical situations due to the possible side effects of the lesions and the combination of them. This generates a challenge to develop clinical scenarios of traumatic patients in simulation [8]. Due to the progress in clinical simulation some hospital areas which involve circulatory dysfunctions such as trauma and burn treatment units, demand bleeding trauma modules to support them to reproduce hemorrhagic real cases [53]. Usually, the full patient emulators are which provide the ability of producing a bleeding automatically. In the current market, the majority of the emulators which simulate the limbs are considered specific and low technology emulator as they are mechanically manufactured which only replicate a part of the organism. Nevertheless, they offer the possibility of being completed with trauma modules allowing trainees to practice appropriate treatments for hemorrhagic situations. Figures 2.16 and 2.17 show this situation.

Lower Limb Hemorrhagic Emulator: It is suitable to improve technical skills for trauma contusion in the lower limb, as it is shown in Figure 2.16. The simulation represents a significant tissue loss that is expected in an aggressive assault environment that will require rapid rescue intervention. The emulator can be used with dressings or related products to treat large irregular wounds and the risks associated with large blood loss. It is not as real as the high fidelity emulators, however it is valid for specific trauma cases.

Figure 2.16: Higher Limb Bleeding Simulator [54]

Individual bleeding trauma module: It is capable to suit in any type of emulator as it is flexible and has a simple design. In Figure 2.17, a module emulator is shown. It can be used with an emulator or with an actor who simulates a patient. It tends to have a fluid tank that serves as blood flow to supply blood and tubes which can simulate blood vessels. Some of the disadvantages of these emulators are the mechanisms of manual operation and the lack of realism.

Figure 2.17: Individual bleeding trauma module [55]

However, there are other emulator which can offer the complete bleeding training kit, as shown in Figure 2.18. It is designed with everything necessary to demonstrate and to train in advanced wound packaging techniques with the use of advanced hemostat gauze. Blood is pumped using the attached compression bottle.

Figure 2.18: Bleeding training kit [56]

In addition, there are emulators with better features and more improvements than the other shown above. The emulator shown in Figure 2.19 can provide a real-time PSI measurement of the force applied to the source of the bleed.

Figure 2.19: Bleeding training kit with biofeedback [57]

However, the design of these devices can be improved including an automatically control upon the bleeding . In that way, the emulator designed and developed during this Master Thesis is able to stop the bleeding automatically when the applied pressure is enough to collapse the blood vessels. This features provides a feedback to the clinicians in order to learn how to control an hemorrhage, so far not provided by most bleeding emulators.

Chapter 3

Emulator Design

The design is a key part in the development of an emulator as its components have a direct impact on the applications and functions of any clinical emulator.

The development of this emulator differentiates two parts with respect to its design: the mechanical and the electronic design. Both designs must be complementary parts in order to create an emulator as useful and complex as possible. On the one hand, a realistic physical appearance is necessary to feel that it is a real lower limb and this will be taken into consideration within the mechanical design. On the other hand, the practice and complex functionality are important to learn the needed skills to treat an hemorrhagic trauma. This fact is going to provided in the electronic design section.

3.1. Mechanical Design

The main goal of the mechanical design has been to create a realistic emulator. The identification of the components involved in an hemorrhage on the lower limb is necessary. The design takes into account the following main components: the bone, the muscles, the blood vessels and the skin. Each of the components has its specific functionality.

- **The bones:** One of the main functions of the bones is to support the soft tissues, and the fulcrum of most skeletal muscles. They are in charge of supporting the human body structure. Superficially, the bone is formed by a compact, smooth and very hard outer layer. Nevertheless, the bones internally are not completely solid, as they have many spaces. They have a porous structure formed by trabeculae [58]. The femur is the main bone in the thigh, as shown in Figure 3.10, and it is the largest bone in the human body. It must be the base of the emulator and therefore, it must be resistant enough to support the actions that will be performed on the emulator without deforming. The femur has been 3D printed using a polymer material which will be explained in Subsection 3.1.1.

Figure 3.1: Femur bone [59]

- **The muscles:** They are between 35% and 45% of the total weight of the body. The mechanical behavior of the muscles can be described through a basic model that involves elastic and contractile elements. In addition, they have a protective function of the bones [60]. In Figure 3.2, the muscles of the thigh are shown in red. They are in charge of making the emulator's form and to generate a firm structure. The material chosen to make the muscles has been silicone as its properties that will be explained in the Subsection 3.1.1.

Figure 3.2: The muscles of the thigh [61]

- **The blood vessels:** The walls of the blood vessels are in charge of supporting the pressure exerted by the blood when it travels through them, as shown in Figure 3.3. They are in charge of conducting the blood in order to reproduce the different bleeding scenarios. There are many vessels in the thigh, as it has been explained in Chapter 2, but only the main veins and arteries will be considered in this emulator: the deep and superficial femoral artery, the femoral vein and the greater saphenous vein. Moreover, they must be located in the exact and precise place in the thigh to create a correct simulation. Plastic tubes has been used to simulate the blood vessels.

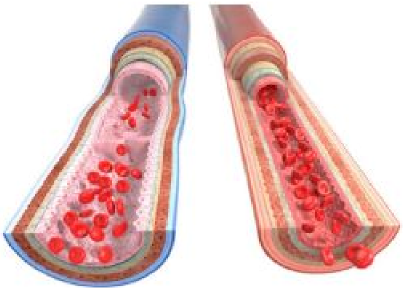

Figure 3.3: Blood Vessels [62]

- **The skin:** It is the largest organ of the human body with a dimension from $1.5m^2$ to $2m^2$ and a weight from 3kg to 4kg. Its structure is made of multiple layers, which makes its deformation behavior complex. The main functions of the skin are protection, reparation and adaptation. It has three superimposed layers: *Epidermis* is the most superficial and thin layer of the skin. It is joined to the following layer, the dermis, through a basement membrane to which it is firmly attached and which provides the smooth appearance and texture of the skin. *The dermis* provides resistance and elasticity to the skin. It is the thickest layer of the skin and it is like a soft netting. Finally, the *hypodermis* layer is placed behind the dermis. All of them can be seen in Figure 3.4. Creating a skin as real as possible has been one of the main goals in the mechanical design. It is the superficial layer of the emulator and the real appearance of this layer is an important aspect as clinicians are in direct contact with it. For this reason, the touch should be very similar to the real skin. This has been achieved with the use of silicons of different densities.

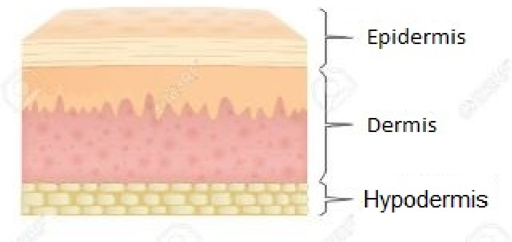

Figure 3.4: Skin [63]

3.1.1. Materials selection

In this Subsection, the synthetic materials chosen to recreate each of the components of the emulator will be presented. For that purpose, the properties and features desired from each biological part should be considered.

The synthetic materials chosen to simulate each of the biological components are explained below:

Polymer: As previously mentioned, the bone is in charge of providing support as the structure of the emulator. Therefore, the chosen material must have the functionality to be resistant enough. The material used is a biodegradable polymer derived from lactic acid, shown in Figure 3.5, called polylactic acid or PLA, whose mechanical characteristics are sufficiently appropriate to achieve the required functionality [64]. On the one hand, this polymer has a glass transition temperature of 60°C. This temperature allows to have a wide range of working temperatures in which the material maintains its stiffness. Furthermore, this material has a suitable melting temperature of 160°C for its formation process since excessive heating is not necessary; this allows energy savings. On the other hand, PLA is a biodegradable thermoplastic derived from renewable resources, which makes it a more environmentally friendly solution than other petrochemical-based plastics. In this way, bone made from PLA fulfills the required structural support function [65].

Figure 3.5: Polymer Poli- Lactic Acid [66]

Silicons: The muscles and the skin have been manufactured using platinum silicons: PlatSil Gel-25 and PlatSil Gel-0030 as shown in Figure 3.6. The main advantages of silicone based models are related to the broad range of properties that can be simulated, easy manipulation, non-toxicity during and after preparation and long-term stability [19]. Besides, models manufactured using silicons are durable and can be moulded to obtain various shapes; from simple geometries to anatomical shapes. On the one hand, Plastil Gel-25 has been chosen to simulate muscles because it is a silicone with appropriate hardness. Taking into account that the muscles in this emulator have the goal to support the skin, it is a good option. In addition, it cures quickly, only within 4 hours, which allows to work with it quite fast. On the other hand, PlatSil Gel-0030 has been chosen to simulate the skin taking into account that their properties need to be similar to the human skin. Having this appropriate properties is directly related to having a glass transition temperature below the room temperature [19]. Moreover, the study [67] shows an experiment that silicons with the same properties as PlatSil Gel-0030 offers similar mechanical characteristics as the skin. Finally, this silicone has been used to simulate skin in numerous applications such as tactile assessments, which is one of the most important features of the emulator. The skin has three different layers and they have different densities. *Slacker* is a tactile alterator, shown in Figure 3.6 that allows modifying the densities of the silicons to be able to manufacture different layers that give the emulator a proper touch. For this reason, Platsil Gel-0030 has been mixed with Slacker to reproduce the look, feel and move of the living tissue.

(a) Platsil Gel 0030

(b) Platsil Gel 25

(c) Slacker

Figure 3.6: Silicons Used [68]

Plastic tubes: Blood vessels will be represented by intravenous lines used in hospitals. These are flexible plastic tubes that allow fluids to be transported through them.

Figure 3.7: Plastic tubs

3.1.2. Manufacturing process

The manufacturing process followed to build and shape all the parts of the emulator has required the use of different techniques which will be presented hereafter.

3D printing: The manufacturing of the bone with polylactic acid polymer is done by 3D printing. For this purpose the Prusa i3 hephestos shown in Figure 3.8 has been used. This manufacturing system has provided the bone with the desired morphology. 3D printing is a process by which 3D solid objects of any shape or geometry can be manufactured from a digital file. The creation is achieved by laying down successive layers of a specific material until the entire object is created. The process of 3D printing consists on transforming a digital file into a solid object through a stepper motor which is a electromagnetic device that converts digital pulses into mechanical shaft rotation. This system has been selected because the manufacturing complexity is free and it can make many shapes. Moreover, it can fabricate objects as large as its printing bed and also, uses exactly the necessary material without generating waste. This fact allows to increase the efficiency [69].

Figure 3.8: 3D printer

Molding: The soft parts made using silicons will be shaped using different molds. This technique will allow to create different complex morphologies. The use of molds to create silicone objects is one of the modern manufacturing techniques to construct parts that are used directly as finished products in which the post-processing is not necessary. The system is low-cost as specific machines are not required and moreover, the molds can be reused. The molds used have been made of paperboard but, in this process a wide range of materials could be used such as plastic, wood, or cork among others. [70].

The process that has been carried out to develop the mechanical part of the emulator will be detail step by step below.

The femur has been the first component manufactured as it has to support the rest of the materials. It is the longest bone in the human body and it was necessary to take into account that, in an adult, it can measure around 500 mm, concretely in this case 440 mm. This was a problem to print all of it in a single piece as the used 3D printers had a working area dimension of 22 cm^2. For this reason, three different pieces were manufactured. The 3D design of the femur has been done in a multi-platform computer program especially dedicated to modeling, lighting, animation, and creating 3D graphics called Blender [71]. This aforementioned program allows to modify the design of the bone in order to cut it in three sections, as shown in Figure 3.9.

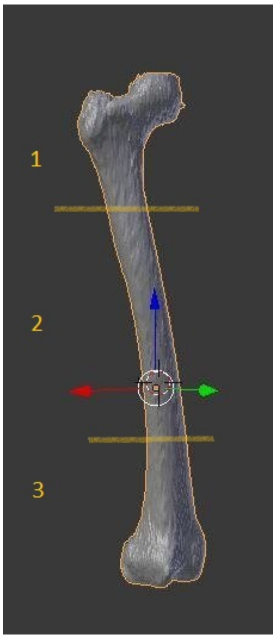

Figure 3.9: Parts of femur designed in Blender

In addition, Blender generates .STL files compatible with the program called Cura [72] which allows to adjust and prepare the image for printing. Once, the three sections have been printed, they have been bonded together using a powerful glue and obtaining the complete femur, as shown in Figure 3.10.

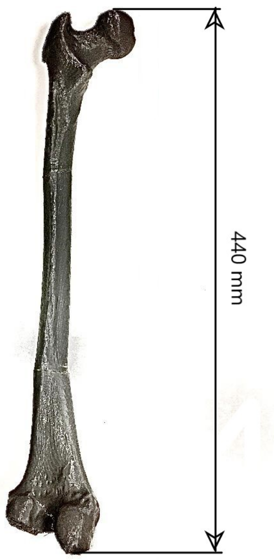

Figure 3.10: Femur printed in 3D

Once the structure of the bone has been finished, the following step was to create the muscles and the skin. The use of molds has been necessary to obtain a cylindrical shape, as a real thigh. The molds have been manufactured by paperboard and their dimensions are conditioned by the amount of silicone available. This amount has to be enough to create a standard size thigh and the dimensions of layers have to be close to reality, but taking into account the current situations created by COVID-19 the amount of silicone has been limited.

On the one hand, the amount of silicone available has been two canisters of 450 gr for each type of silicone. Each type of silicone consists of two parts, A and B, which must be always mixed in equals parts in order to get a perfect mixture. In addition, one canister of 450 gr of slacker. On the other hand, the thigh has been approximated to a filled hollow cylinder in order to facilitate the manufacturing. The hollow cylinder is formed by the muscles and the skin with a size of 340 mm long and in the center of the cylinder the bone measuring 440 mm long is placed. Due to the shortage of material, the amount is not enough to manufacture a complete emulator with silicone; therefore, the muscle layer will be built using silicones and foam.

The dimensions of the muscles and the skin require to calculate the possible size of the layers to manufacture the molds. Knowing the exact volume of each canister is essential to calculate the dimensions of each layer which will have a hollow cylinder shape. The data sheet of the silicone indicates that the specific volume of each canister is 26 in^3/lb and 25 in^3/lb for PlatSil Gel 0030 and PlatSil Gel 25 respectively [73]. This value is the inverse of the density, so as the mass is known, 450 gr, the volume can be calculated using the equation 3.1. Each canister of PlatSil Gel 25 has a volume of 406504.06 mm^3, in total 813008.13 mm^3 to use for the muscles layer. Instead, each canister of PlatSil Gel 0030 has a volume of 424528.31 mm^3, in total 849056.61 mm^3 to do the layer of skin.

$$Density = \frac{Mass}{Volume} \tag{3.1}$$

The amount of the silicone used to make the skin has to be divided in order to create three different layers: the hipodermis, the dermis and the epidermis. This division has been done taking into account that the slacker will be mixed with the PlatSil Gel 0030 in order to obtain layers with different densities. The Slacker must be mixed with the silicones measuring the amount of each product by volume or by mass, that is, if there are 450 gr of silicone in the mixture, there will be 450 gr of the slacker too, or if there are 50 mL of silicone, there will be 50 mL of the slacker as well. Depending on the application and desired level of stickiness, the mixture will vary. In Table 3.1 the different mixtures to obtain different results are shown:

Mixture	Results
1 Part A + 1 Part B + 1 Part Slacker	Tacky
1 Part A + 1 Part B + 2 Part Slacker	Very Tacky
1 Part A + 1 Part B + 3 Part Slacker	Extremely Tacky or Gel-like
1 Part A + 1 Part B + 4 Part Slacker	Super Soft Tacky Silicone Gel

Table 3.1: Measuring of the Slacker [74]

In order to mix the components appropriately, the dimensions and the properties of the layers of the skin have to be considered. The most elastic and thick layer is the dermis. Moreover, taking into account that the hypodermic and the epidermic do not need more elasticity than the one obtained using of PlatSil Gel 0030 alone, all amount of the Slacker has been used to make this layer. The desired effect for the dermis layer would be very tacky. Therefore, considering the Table 3.1, the proportion of the silicone used must be 1 Part A + 1 Part B + 2 Part Slacker. The mixture has been done measuring the amount of each component in grams and taking into account that all the amount of slacker should be used for not wasting. For this reason, the proportion made has been 450 gr of Slacker together with 225 gr for Part A and 225 gr for Part B. The rest of PlatSil Gel 0030, 450 gr, has been used to make the epidermic and hypodermic layers. Due to the fact that the epidermic layer is really thin, the total amount of silicone used to make this layer has been 100 gr. Therefore, the hypodermic layer has been made using the 350 gr remaining. Using the Equation 3.1, the volume corresponds to each layer could be calculated. However, in order to calculate the volume of the dermis layer the density of the slacker must be taken into account. This data is not provided by the manufacturer, for this reason, it has been considered that the density is the same as PlastSil Gel 0030. This approximation has been done taking into account that the canister of the slacker and the PlastSil Gel 0030 weighted the same and have similar dimension.

Layers	Material	Mass (gr)	Volume (mm^3)
Muscle	PlatSil Gel 25	900	813008.13
Hypodermic	PlatSil Gel 0030	350	330188.68
Dermis	PlatSil Gel 0030	450	849056.61
	Slacker	450	
Epidermis	PlatSil Gel 0030	100	94339.62

Table 3.2: Amounts of the layers of the emulator

Once the volumes of the silicones are known, the radius of each layer can be calculated using the equation 3.2. This equation corresponds to the calculation of the volume of a cylinder, since the layers will have a cylindrical final shape.

$$Volume = Length\pi(Radius_{ext}^2 - Radius_{int}^2) \qquad (3.2)$$

Although the dimensions of each layer have been calculated taking into account that the final form is cylindrical, the molds will be rectangular in order to facilitate the spill of the silicones. The dimensions of the rectangular molds have been approximated with the external radius, that is, the external radius of each cylindrical layer is one side of the rectangular dimension of the mold and the other side corresponds to the length of the thigh, this is 340 mm. To do the first mold which corresponds to the muscle layer, the internal radius has been established. The chosen value has been 450 mm taking into account that the silicone available has been enough to achieve a thigh with real dimensions. Once the internal radius has been set as a starting point, the unknown dimension is the external radius of the muscle layer. This external radius can be calculated using the equation 3.2. Therefore, the dimensions of the first rectangular mold shown in Figure 3.11 to pour the silicone Platsil Gel 25 have been approximately 340 mm which corresponds to the length, and 332 mm which corresponds with the perimeter of the external radius.

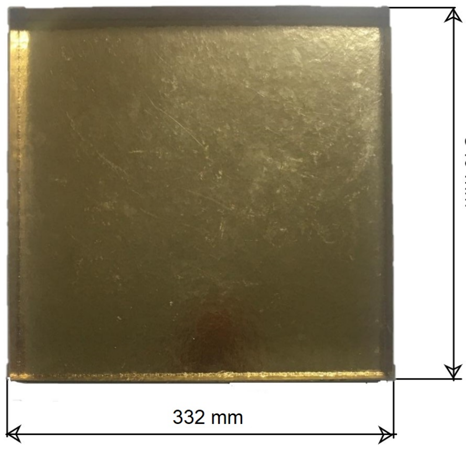

Figure 3.11: Mold for the muscles layer

The rest of the molds have been created in the same manner taking into account that the internal radius of each layer will have the same value as the external radius of the previous layer. For this reason, the external radius has been always the unknown which must be calculated using the equation 3.2. The value of the perimeter of the external radius used to make the rectangular molds has been rounded to higher values in order to ensure the layer obtained could create a hollow cylinder with the internal radius needed in order to cover the previous layer. Additionaly, the density of the slacker was unknown, hence the volume of the silicone used to make the dermis layers could not be determined. Therefore, in dermis case, the overestimation of the perimeter of the external radius has been even higher. For this reason, the final thickness of each layer has been smaller when compared to the calculations, as the final dimensions of the molds has been larger than the ones calculated previously. In Table 3.3 the dimensions of the layers are shown: the internal radius, the external radius, the thickness and the external perimeter calculated, the perimeter used to make the rectangle molds and the final thickness achieved using the rectangle molds. As example, the muscle layer has been calculated with an internal radius of 45 mm and external radius of 52.8 mm, the thickness would be 7.8 mm and the external perimeter 331.75 mm. The value of the perimeter has been rounded to 332 mm and consequently, the final thickness obtained has been 7.5 mm.

Layers	Internal Radius (mm)	External Radius (mm)	External perimeter Calculated/Final (mm)	Thickness Calculated/Final (mm)
Muscle	45	52.8	331.75 / 332	7.8 / 7.5
Hypodermic	52.8	55.6	349.34 / 350	2.8 / 2.1
Dermis	55.6	62.4	392.71 / 395	6.8 / 6.4
Epidermis	62.4	63.1	396.46 / 397	0.7 / 0.2

Table 3.3: Dimensions of the layers of the emulator

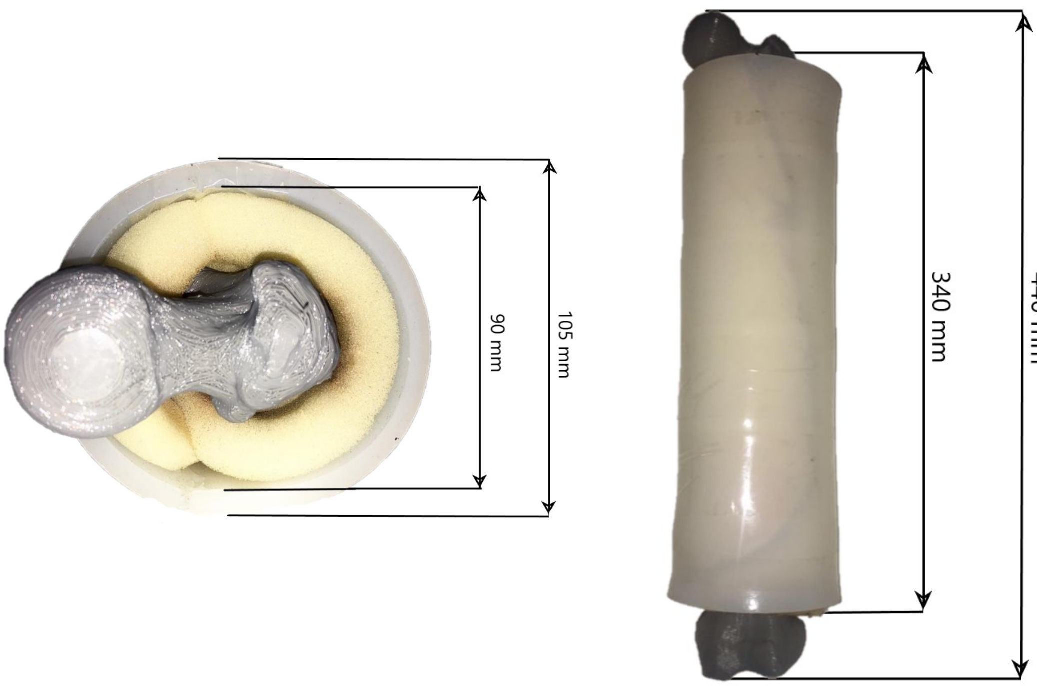

Figure 3.12: Femur surrounding with foam and muscle layer

Once all the layers are prepared, the assembly process begins. First of all, it has been necessary to push the edges of the muscle layer together in order to get a perfect cylinder with an internal radius of 45 mm. This step has been achieved by using a specialized silicone glue that has allowed the edges of the layer to be joined. Once the first hollow cylinder has been assembled, the femur wrapped in foam has been introduced in the internal space, as shown in Figure 3.12.

At this moment, the emulator was already able to support the rest of the layers that made up the skin which could be placed one on top of the other. The hypodermis is placed in contact with the muscles layer. The dermis layer has been made in the same way as the hypodermis. However, due to the fact that there is a basement membrane placed between the epidermic and dermis layer, the last has been made in a different way. This membrane is in charge of providing smooth appearance and texture close to the skin; therefore, tights fabric have been selected for this purpose. Taking into account that the epidermis layer has to be firmly adhered with this membrane, the tights has been placed in the dermis and then, the silicone to manufacture the epidermis has been spilled onto it. In that way, the silicone used to create the epidermis will cure over the membrane and over the dermis allowing to join these two layers with the aforementioned membrane. All the skin layers are superimposed on top of each other forming the skin of the emulator, as shown Figure 3.13. Further, the silicone used to make the epidermis was also fused with a skin-like pigment to provide also a visual impression of skin tissue.

Figure 3.13: Skin layer made by silicons

Cord has been sewn on its edges, as shown Figure 3.14 so that they can be placed around the muscle as if it was a cover. This allows the skin to be used on different simulators or replaced when it is damaged or broken without needing to modify anything else. Moreover, if the simulated scenarios require a thigh with other bigger anatomy, this design allows to add more materials between the muscles and the skin, simulating more fat.

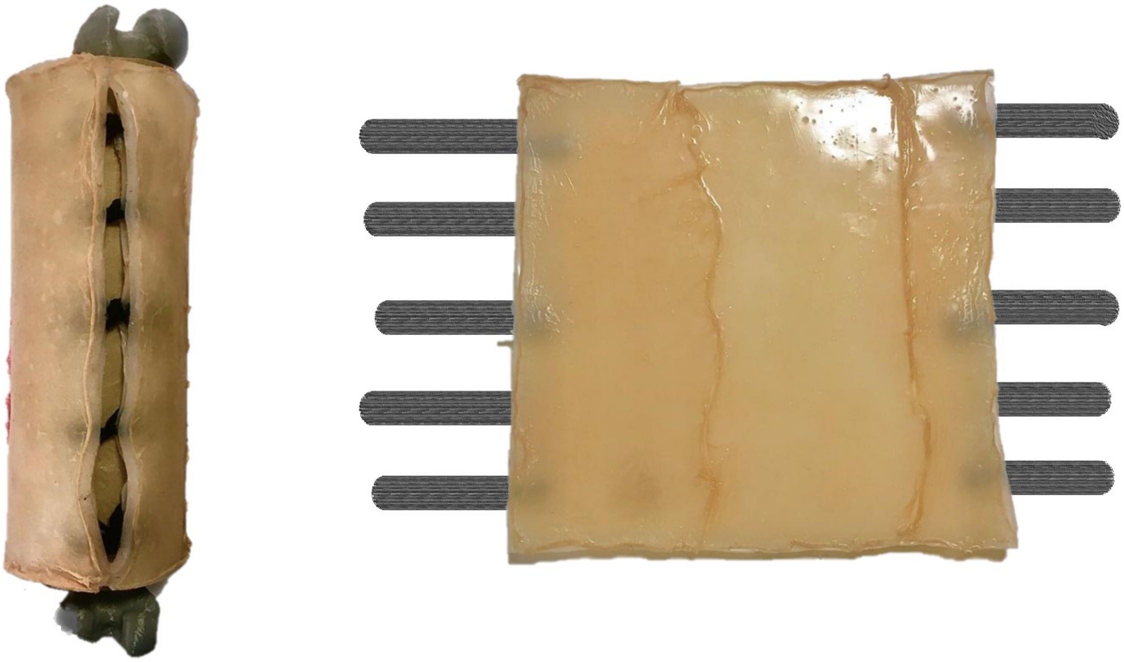

Figure 3.14: The skin layer with velcro

The plastic tubes that simulate the blood vessels are placed in the correct position as they were in a real thigh, shown in Figure 3.15. If they are superficial vessels, they will be placed between the dermis and the epidermis reaching the surface. However, if they are deep vessels, they will be placed behind the muscles, close to the femur. A cover has been created to cover the ends of the emulator trying to give more realism.

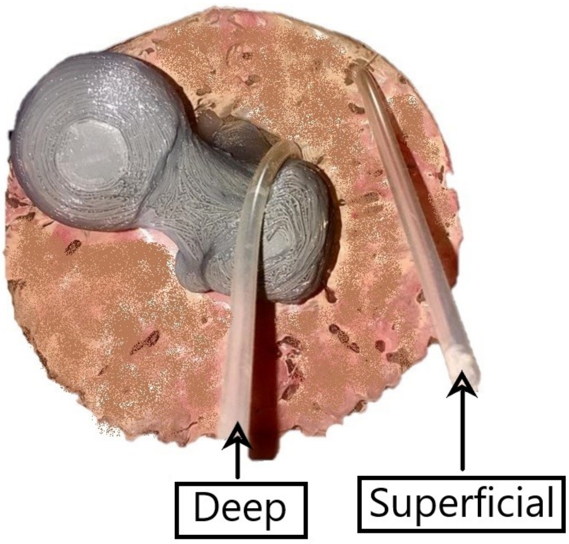

Figure 3.15: The blood vessels position

3.2. Electronic Design

The design of the electronic part of the lower limb emulator is a necessary function to control the mechanical parts to perform different hemorrhagic scenarios. This system is able not only to recreate the hemorrhage but also to provide feedback about how the techniques to stop the bleeding are applied in the emulator. The lower limb emulator functions define the different electronic components that must be used for the correct design of the electronic circuit. The electronic components have to ensure that they fulfill the technical specification necessary to be similar to the physiological aspects they represent. Each of them are explained in detail below:

- **Pressure sensors:** The pressure sensors, as the one shown in Figure 3.16, have to measure the applied pressure to control the bleeding during the simulation. They are a variable resistance which changes its value according to the force exerted. Several pressure sensors located under the skin will be used, near the injury, simulate the pressure receptors of the real skin. The active area of the sensor is 1 cm^2 which corresponds with the circular part. The sensors are powered at 5V and they have the pressure range from 10 gf/cm^2 to 100 Kgf/cm^2 [75].

Figure 3.16: FSR Pressure Sensor [76].

- **Position sensors:** The position sensors, as the one shown in Figure 3.17, have to measure the location where the techniques to control the bleeding will be applied in order to check their position. Pressing various parts of the strip, the resistance changes linearly from 100 Ω to 10000 Ω allowing the user to accurately calculate the relative position on the strip [77].

Figure 3.17: Position Sensors [76].

- **Relays:** In order to reproduce both arterial and venous bleedings, relays as the ones shown in Figure 3.18, have been used. The selected relays have a coil of 5V and are used to power on and off the pumps, to start and stop the bleeding. If it is an arterial bleeding, the relay activation will be pulsating, whereas if it is a venous bleeding, the activation will be continuous.

Figure 3.18: Relay [78].

- **Transistors:** Two bipolar BJT transistors, as the one shown in Figure 3.19, have been used to activate the relays. One of them is used to regulate the current and to obtain a 5V power supply for the relay activation. The other one is used to obtain a 5V power supply for the pumps.

Figure 3.19: Transistor bipolar [79].

- **Pumps:** The main function of this component is to perform the arterial and the venous bleeding. There are two pumps as the one shown in Figure 3.20, one for each type of bleeding. Their operating voltage is 5V and their power consumption is in the range of 0.4-1.5 W.

Figure 3.20: Mini Pumps Submersible [80].

- **Arduino Board:** The Arduino Due Board is a microcontroller board associated with a software or IDE (Integrated Development Environment) that runs on a computer, used to write and upload computer code to the board [81]. It is in charge of sending and receiving information about the simulation case. It has 54 digital and 12 analog pins. The analog pins are inputs and the digital can be inputs and outputs. Moreover, the Arduino Due board has an operating voltage of 3.3V. In this Master Thesis, the arduino Due obtains information of the pressure sensors and controls the relays for the pumps.

Figure 3.21: Arduino Due Board [81].

All of these components allow to represent an automatic and totally controlled scenario as a real situation.

3.2.1. Design of the electronic circuit

The functions of the lower limb emulator define the assembly of the electronic components explained in the previous Section. The electronic components are connected, as shown in Figure 3.22, in order to create a circuit capable of simulating different hemorrhagic shock scenarios.

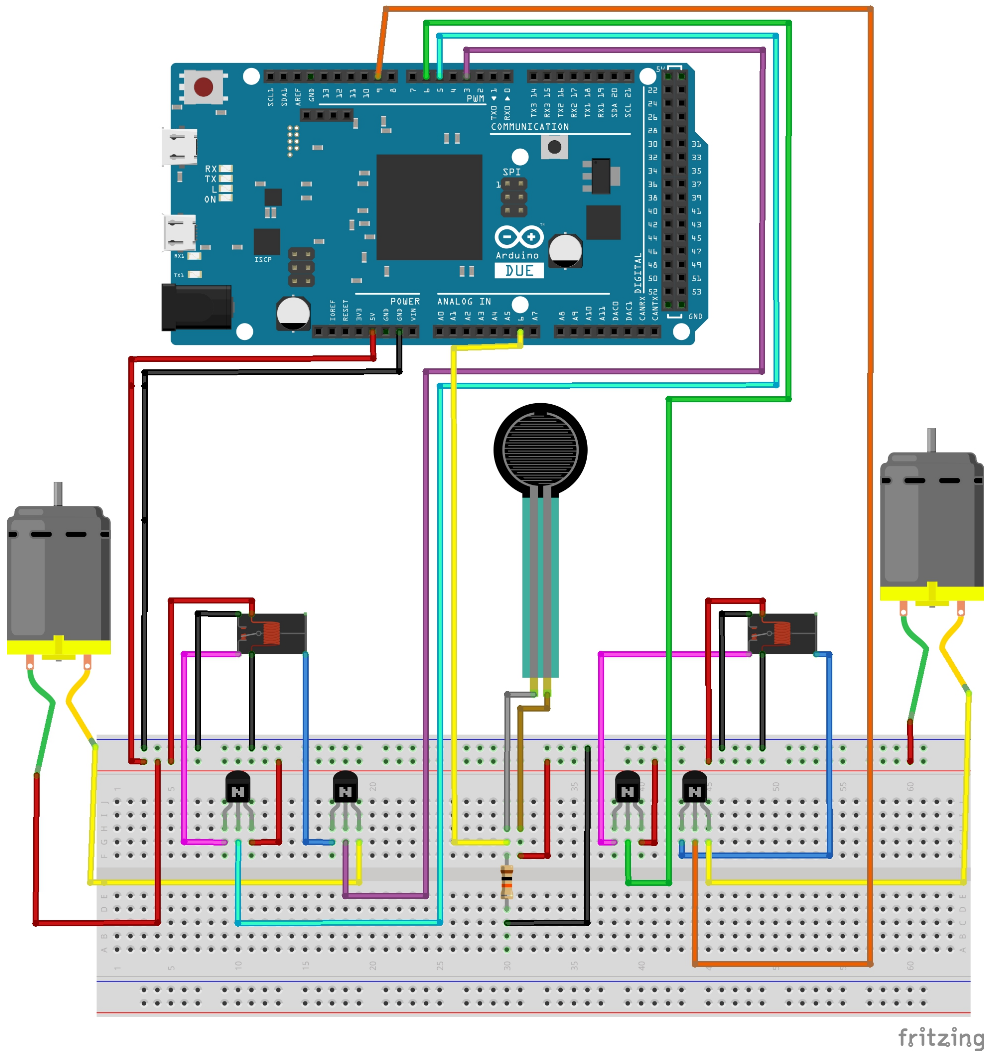

Figure 3.22: Electronic circuit.

As it is shown in Figure 3.22, the circuit can be divided in two different circuits; the first one is the pressure sensors' circuit and the second one the pumps' circuit. Due to the current situation created by COVID-19, the position sensor has not been available. For this reason, the electronic circuit has been design to control the pressure exerted by clinicians.

The sensor's circuit is composed by the FSR sensors and one 10 KΩ resistance (RM) connected in series with the sensor. This assembly allow to create a tensor divisor in such a way that the transmitted voltage may vary depending on the pressure exerted on the sensor, as shown in Figure 3.23 with the Equation 3.3 associated to calculate the voltage.

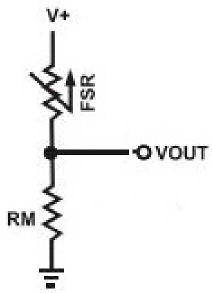

Figure 3.23: FSR Voltage Divider [75].

$$Vout = \frac{RM}{RM + FSR} \cdot V+ \tag{3.3}$$

The pumps' circuit is composed by one relay and two transistors for each of the pumps used. The relay is in series with one transistor and at the same time, the other transistor is in series with the pumps. There are two pumps' circuit because each of them simulate the two different bleeding: arterial and venous. The voltage, the intensity and the resistance are going to change throughout the circuit, for this reason different studies of their features have been necessary in order to assembly all components correctly. The pumps' circuit is connected by the arduino with digital pins at 3.3V and a maximum current of 25mA each. On the one hand, there are relays and pumps which work with 5V, so the transistors are necessary as a conversion stage to active them. These connections are shown in Figure 3.24.

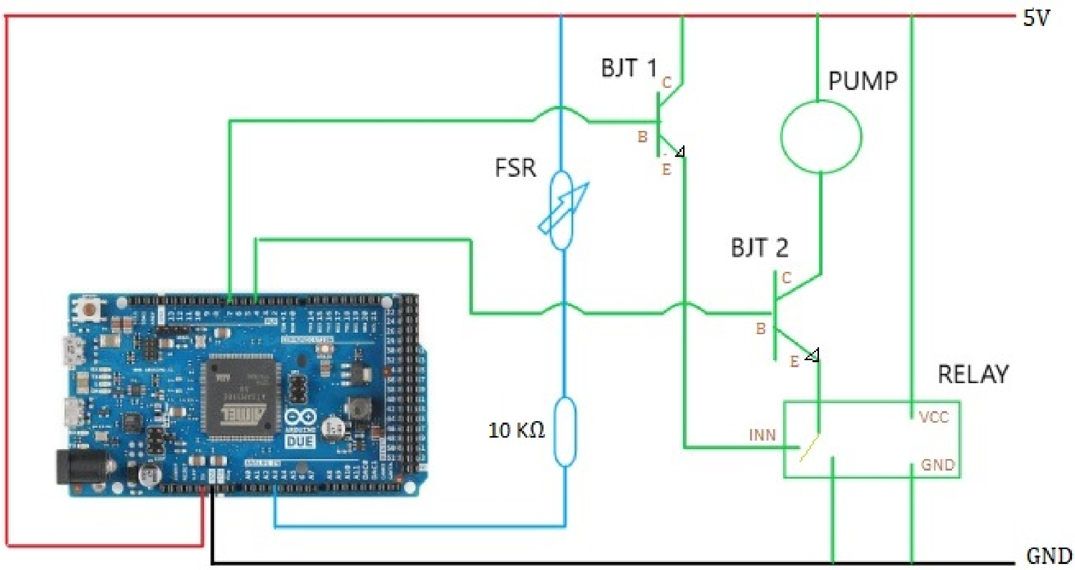

Figure 3.24: Electronic circuit.

The electronic circuit is capable of generating the bleeding that stops automatically depending on the pressure exerted on the sensor. This is possible thanks to the fact that different pressure thresholds have been established in the electronic program. Through these thresholds the pumps can be activated or deactivated depending on the pressure applied. Some studies on the components that make up electronic design has been needed in order to establish the values of these thresholds.

The sensor receives a pressure on its surface and sends the Arduino the voltage associated with that pressure. This voltage will vary according to the resistance produced by the pressure applied on the sensor. Therefore, the Arduino receives the information coming from the sensor in voltage and it does it through an analog input. Taking into account that the Arduino used is Arduino Due Board, the received voltage range is from 0 to 3.3 V and it reads it with a resolution of 12 bits (0-4095).

For this reason, the thresholds at which pumps are activated or deactivated must be expressed in the electronic program using a number from 0 to 4095. However, these thresholds are determined by the pressure that the blood has inside the blood vessels, as explained in the Section 2.2, and its value is expressed in mmHg. Therefore, a conversion from mmHg to a value from 0 to 4095 is necessary in order to program the electronic circuit. The conversion done as follows:

- The first conversion is to become the mmHg to kgf/cm^2, shown in Figure 3.25, as these are the pressure units with which the sensor works.

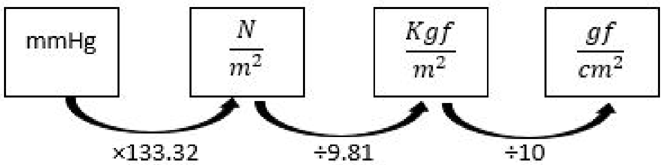

Figure 3.25: Unit conversion.

- Second, knowing the active surface of the sensor which is 1cm^2, the force in grams-force , gf, applied to the sensor is known. This force is related to the volts that the sensor transmits to the arduino as shown in Figure 3.26. This Figure shows that the voltage varies with the pressure exerted due to the existence of the tensor divisor in the sensor circuit shown previously. In this case, since the value of the resistance is 10 KΩ, the corresponding line is the purple. As it can be observed, the variation of the sensor is not linear and in order to obtain the exact values of the volts, a logarithmic approximation of the curve defined with the Equation 3.4 has been performed.

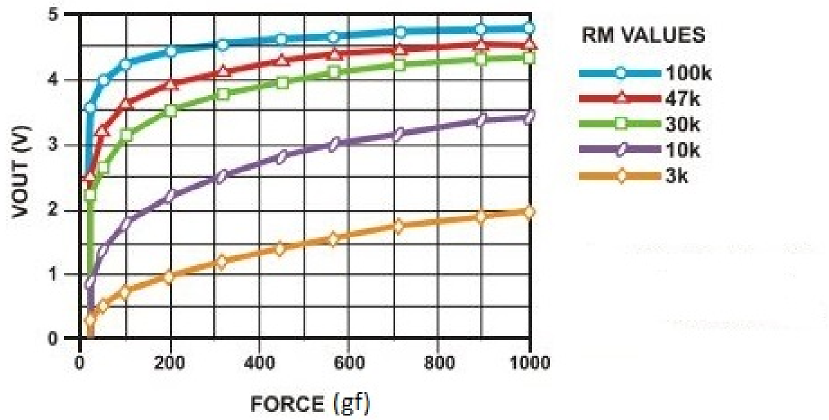

Figure 3.26: Graph of pressure sensor units [75].

$$y = 0.757 \cdot ln(x) - 1.7893 \tag{3.4}$$

- Finally, by knowing the volts received to the Arduino and also, the characteristics of the analog input, the thresholds established in mmHg can be expressed in a value from 0 to 4095.

Following this process, the electronic circuit can be programmed for any known blood pressure value. For example, if it is necessary 120 mmHg of pressure, this value correspond with 163.14 grams-force/cm2. Due to the active area is 1 cm2, this value will be 163.14 grams-force. Using Equation 3.4, this grams for the correspond with 2.067 volts and finally, this voltage correspond to 2565. Therefore, a pressure of 120 mmHg correspond with 2565.

3.2.2. Functionality of the electronic circuit

The functionality of the electronic circuit is fundamental for the correct simulation of the bleeding performance, providing different possible scenarios. The bleeding action configured is sent to the electronic components in every simulation allowing the representation of the bleeding injury. The circuit will also capture the information from the sensors placed under the skin when the different techniques are applied on the thigh. This circuit is in charge of generating an automatic scenario and also, providing the feedback to the students when the simulation is realized.

The Arduino software is in charge of the bleeding trauma activation when the electronic circuit is underway. The Arduino starts when the trainer introduces a new simulation case. First of all, the microcontroller sends the information to the pumps in order to start the bleeding. Then, when the sensor or sensors are activated depending on the technique applied by the students and the Arduino will be able to read this information by the Serial Port activating the corresponding bleeding action: to stop or not the hemorrhage.

The Arduino provides an output signal, which corresponds to the pump activation, and receives an input signal coming from the sensors. The pressure sensor provides useful information on how the bleeding is being treated according to the threshold established in the program. This threshold is designed depending on the blood vessel affected which will be explained in Section 4.2. The output signal is set in two digital pins, for the arterial and venous pumping relay activation and the input signal is set in an analogical pin in order to read the pressure measurement.

As the arterial and venous bleeding are physiologically different, its activation are separately configured. The arterial bleeding is activated and deactivated according to the heart rate, which last 0.8 seconds, being 0.3 seconds with pumping and 0.5 seconds shrinking, while the venous bleeding is continuously activated. Moreover, the pressure data is shown in the Serial Monitor in order to see the progression of the hemorrhage control during the simulation.

The pumping system, activated according to the trainer decision, can be deactivated by pressuring the blood vessel affected. The objective of this feature is to provide a more realistic feedback to the trainee as they can see when the hemorrhage is controlled.

Chapter 4

Results and Prototype Testing

In this Chapter, the final results of this Master Thesis are provided. First of all, the results obtained from the total assembly of the mechanical components together with the electronic design ones are presented. Finally, the different testing scenarios to check the functioning of the emulator will be presented as well as the results obtained during the prototype testing.

4.1. Final Emulator

The final results of the mechanical design of the lower limb emulator is shown in Figure 4.1.

Figure 4.1: Final mechanical design of the emulator

The skin is the most external layer, then the muscles are included and finally the femur surrounded by foam is placed within the structure. The femur is the support of the rest of components, the muscles keep the structure firm and the skin provides realism. The final dimensions of the emulator are 340 mm of length and 120 mm of width, taking as reference the dimensions of an adult femur. There is a wound over the thigh through the superficial bleeding takes place.

This emulator will incorporate pressure sensors, as explained in Section 3.2, and will be connected to the pumps through the relays using transistors in order to produce the different hemorrhagic scenarios. Figure 4.2 shows all the components used and how the connections were made using a protoboard. Due to the current situation created by COVID-19, the position sensors are not available, for this reason only the pressure sensor is programmed. This circuit is enough to ensure the correct function of the lower limb emulator which is the target of the electronic design.

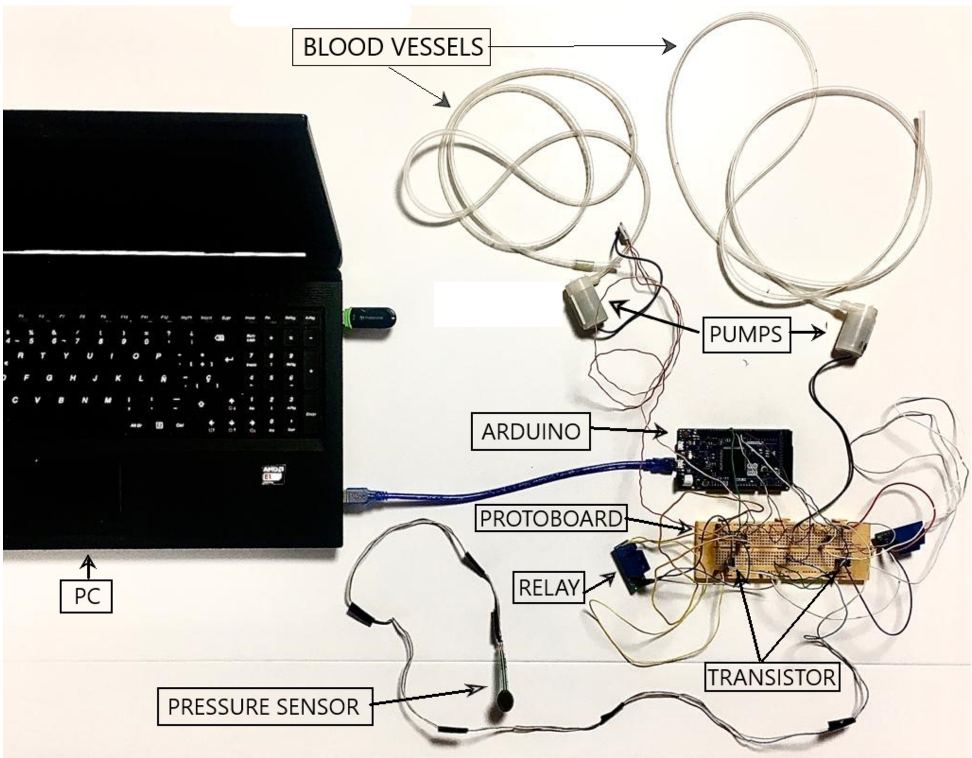

Figure 4.2: Final electronic design

The pressure sensors have been placed in their correct position under the skin. The pumps are inside the liquid tanks in which they get the different type of blood, venous or arterial with their corresponding colors, sending it to the emulator through the blood vessels. The electronic circuit is placed in a box to facilitate its movement and to avoid possible liquid contacts. The final assembly of the emulator final is shown in Figure 4.3

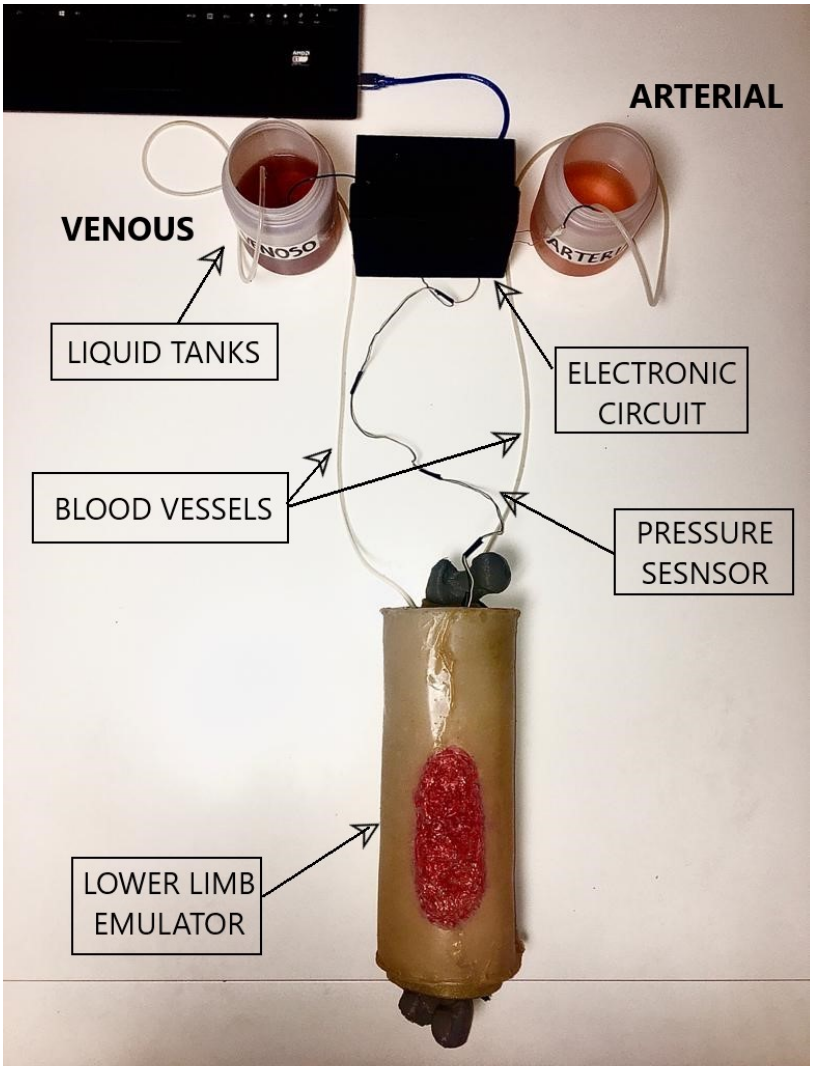

Figure 4.3: Emulator including the electronics

4.2. Testing Scenarios

Once the assembly of the emulator has been done, different bleeding scenarios have been set and carried out in order to test how the emulator works. They are explained along this Section.

The arterial and venous hemorrhages have been simulated as they are the ones that can have a greater impact on the patient's evolution when a trauma injury is suffered. Therefore, there are three possible scenarios: arterial bleeding, venous bleeding or both bleeding together. Each of them have their features depending on their physiological conditions. In addition, two techniques can be trained with the lower limb emulator: direct pressure on the wound and the placement of a tourniquet. The aforementioned techniques can be trained in order to learn the control of each types of bleeding.

The venous and arterial bleeding will take place when any of the four blood vessels present in the thigh will be affected. They have been chosen taking into account the important consequences those hemorrhages could have on patients. Depending on the position of the vessels in the thigh, they can be superficial or deep, as shown in Table 4.1.

Name	Type
Femoral vein	Deep vein
External saphenous vein	Superficial vein
Internal femoral artery	Deep artery
External femoral artery	Superficial artery

Table 4.1: The blood vessel simulated

Each of the techniques to stop a bleeding, direct pressure or tourniquet placement, has different requirements that must be controlled when they are required. The technique of the direct pressure needs to check the pressure applied, whereas, when a tourniquet is required, the pressure must be controlled, but the correct placement of the tourniquet is quite important as well as to record the time when the tourniquet has been placed. However, as previously explained, only the pressure circuit has been available; therefore, only the pressure exerted by clinicians has been measured in both techniques.

Moreover, taking into account that during the development of this Master Thesis there are only two pumps, only two bleedings can be simulated simultaneously. For this reason, the direct pressure scenario has been represented when one blood vessel is affected. Whereas, the scenario in which two blood vessels are affected together, the tourniquet has been required. In that way, on the one hand there will be <u>four different scenarios</u> where **the direct pressure** can be trained. Each of these scenarios correspond to the bleeding of each of the four blood vessels considered, shown in Table 4.1. On the other hand, in order to train **the placement of a tourniquet**, <u>four other different scenarios</u> will be simulated in which the bleeding of two vessels is shown simultaneously. The combination of affected vessels for the tourniquet's scenario, has been done in such a way the difference between the bleeding of arteries and veins and between superficial and deep vessels is showed. The combination of the scenarios chosen will be injuries that involves:

- Greater saphena vein with external femoral artery.
- Femoral vein with internal femoral artery.
- Greater saphena vein with internal femoral artery.
- Femoral vein with external femoral artery

In order to provide a feedback when the aforementioned techniques are applied, the pressure exerted over the thigh must be measured. This pressure must achieve a concrete value from which the bleeding stops. This value will be a threshold which have to be established taking into account the features of each vessel. Regarding the pressure threshold that will be used to determine if an hemorrhage is stopped or not, it is necessary to take into account that the pressure inside the blood vessels changes depending on the type of vessel. As it has been explained in Chapter 2, in normal conditions the arterial vessels support around 100 mmHg of pressure of the arterial blood, whereas the venous vessels support around 15 mmHg of pressure of the venous blood. For this reason, the pressure needed to stop the bleeding must be higher than these values. Moreover, the position of the vessel must be taken into account as if they are deep vessels the pressure needed to stop the bleeding will be higher than the superficial ones as the tissue set of the thigh can absorb the pressure exerted.

In that way, the pressure to stop the superficial arterial bleeding will be 120 mmHg and 35 mmmHg for the superficial veins. Meanwhile, in [52] suggests that 100 mmHg in addition to the systolic pressure is enough to compensate the tissue set. For this reason, the threshold established for deep arteries will be 200 mmHg (100 mmHg + 100 mmHg) and 115 mmHg (100 mmHg + 15 mmHg) for deep veins. In Table 4.2 the threshold established for each blood vessels is shown and also, the associated value from 0 to 4095 with these pressures, as it has been explained in Section 3.2.

Blood vessel	Threshold (mmHg)	Sensor Pin Value
Femoral vein	115 mmHg	2525
External saphenous vein	35 mmHg	1407
Internal femoral artery	200 mmHg	3044
External femoral artery	120 mmHg	2565

Table 4.2: The blood vessel simulated

To measure the pressure values exerted by clinicians to stop the bleeding applying direct pressure, the pressure sensors have been placed in each of the blood vessels affected. A program has been developed in order to stop the bleeding when the corresponding threshold has been reached. However, when the tourniquet placement technique is required, to measure how this technique is used, pressure sensor will be placed between 5 to 10 cm above the wound and around the thigh; that is, four pressure sensors placed in 0º, 90º, 180º and 270º taking as a reference the front of the thigh and the femur as the axis of rotation, would be necessary to receive well feedback. Having only one pressure sensor during this project, it has been placed in 0º and 7 cm above the wound, as shown in Figure 4.4.

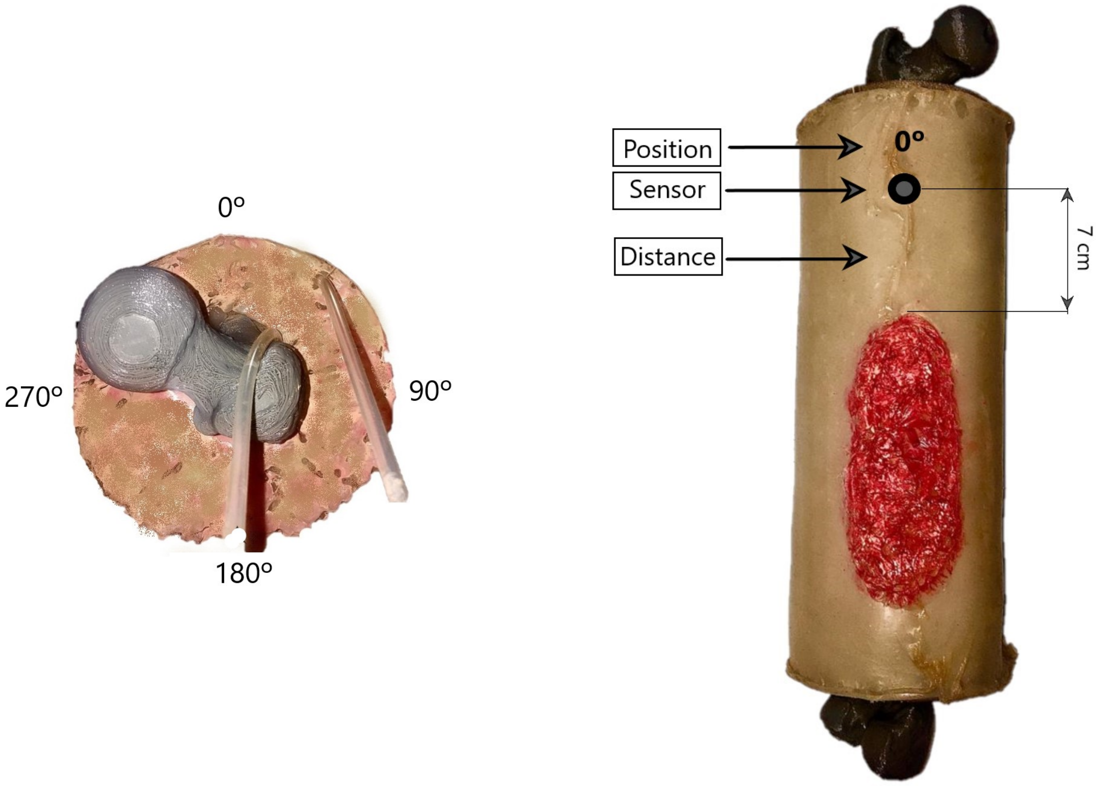

Figure 4.4: Femur surrounding with foam and muscle layer

4.3. Prototype Testing

At the beginning of the simulation, the trainer should decide the vessels which will be affected and the scenario will start. The different types of bleeding which can occur and the techniques which can be applied taking into account the selected testing scenarios are shown below.

4.3.1. Types of bleeding

The simulator is able to execute two types of bleeding due to the pumping system implemented. There are three possible bleeding scenarios depending on the configuration selected: arterial bleeding, venous bleeding or both. The result of these three types of bleeding scenarios are shown in Figures 4.5, 4.6 and 4.7. In the Y axis the relay pin value in bits is represented. Its value only can be 0 or 1 as the relay is either activated or deactivated. When the value is 1 the relay is activated and when the value is 0, the relay is deactivated. On the X axis, the time is represented. The simulation recreated has been done during 10 seconds.

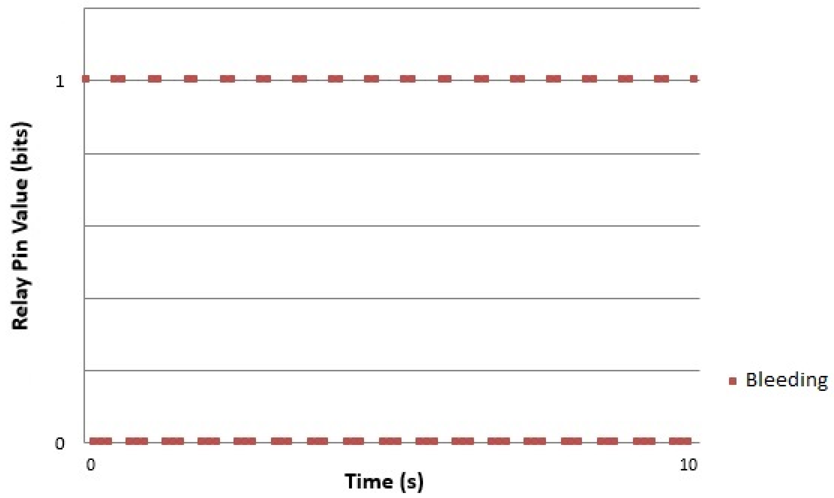

Figure 4.5: Arterial Bleeding

The **arterial bleeding** corresponds with the Figure 4.5. It presents the expected behaviour of an arterial bleeding which has a pulsatile flow. It can be seen that the time in which the relay is deactivated is longer than the time in which the relay is activated. This is expected due to the fact that each heartbeat lasts approximately 0.8 seconds of which 0.3 seconds corresponds with the systolic phase and 0.5 second with the diastolic phase. In the systolic phase the blood is expelled by the heart and this is the moment when the arterial blood is circulating with more pressure. Moreover, it is appreciated that the amount of beats is proportional with a normal heartbeat rate, 60-100 beats per minute because in 10 second there are 16 beats.

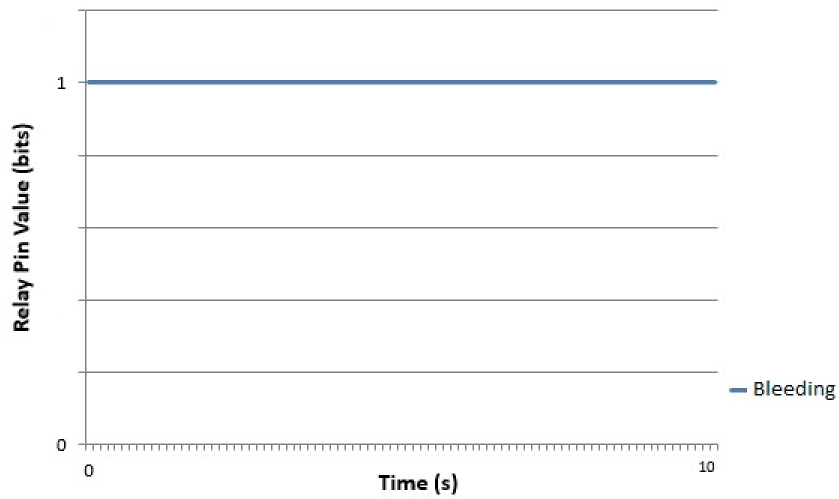

Figure 4.6: Venous Bleeding

The **venous bleeding** is shown in the Figure 4.6, where it can be seen that the flow is continuous. Due to fact that the veins are further from the heart than the arteries, the heartbeat rate has not influence on its flow.

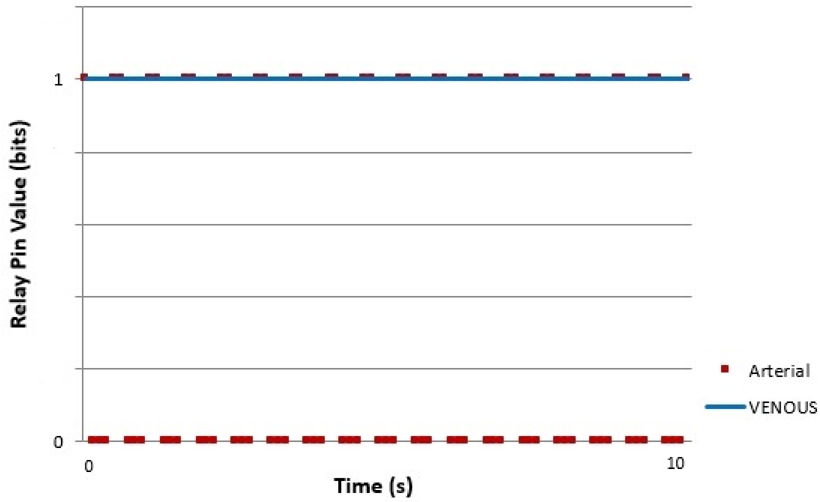

Figure 4.7: Arterial and venous bleeding

The **arterial and venous bleeding** are shown in Figure 4.7. The arterial bleeding is activated in intervals whereas the venous one is activated all the time.

4.3.2. Techniques to stop the bleeding

Different hemorrhages has been simulated in order to train the two techniques previously mentioned to stop the bleeding. This process allow to check if the emulator is able to train the control of the hemorrhage in different situations.

The graphics shown during this section have two axis: the Y axis shows the value of the sensor which corresponds with the pressure exerted on the injury and it is expressed from 0 to 4095, as explained in Section 3.2.2. Taking into account that these values can be related with mmHg, the pressure on the sensor value could range from 0 mmHg to 610.9 mmHg. Meanwhile in the X axis, the time is represented. The blood flow only can be activated or deactivated which correspond with the pin value relay 1 or 0 respectively. All the simulations have been done during 30 seconds.

- DIRECT PRESSURE TECHNIQUE

  Taking into account the four blood vessels that could be affected, there are four different scenarios for each of them: one deep and one superficial venous bleeding and one deep and one superficial arterial bleeding. The pressure sensor is placed on the blood vessel affected. The venous and the arteries ones are represented together in order to show the difference between the superficial and deep vessels.

Venous Bleeding

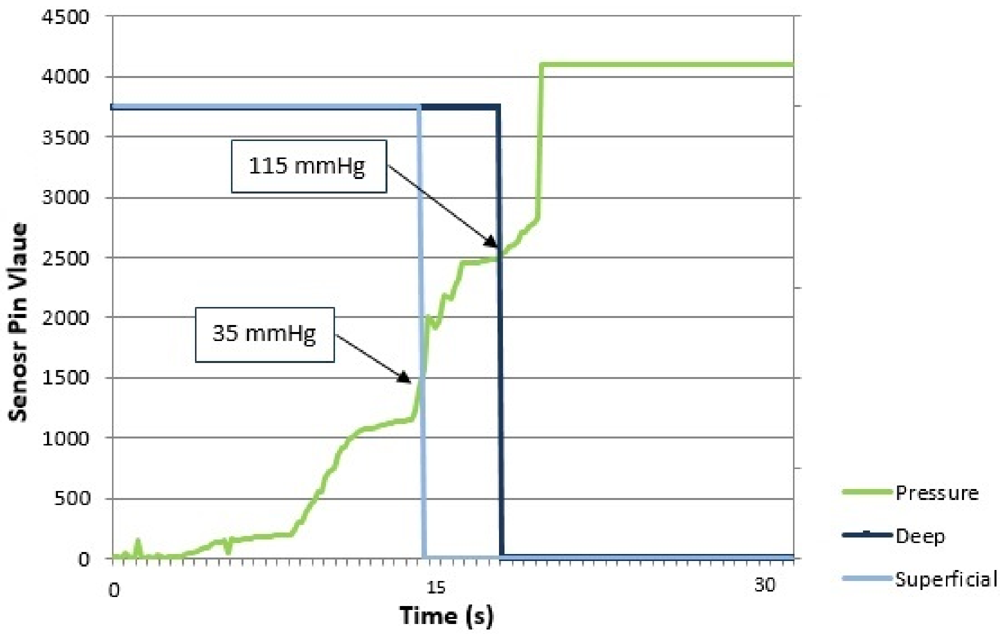

Figure 4.8: Venous Bleeding

The Figure 4.8 shows the venous bleeding behaviour when direct pressure is applied on the sensor. The aforementioned Figure shows in green the value of the pressure sensor, the dark blue line shown the deep bleeding that may occur when the internal femoral vessel is affected and finally, the light blue line represents the superficial artery flow, in this case, the external saphenous bleeding is simulated.

The behaviour of both flows is similar during the entire simulation, the only difference they present is referred to the moment the bleeding stops as the threshold to stop the bleeding of a superficial artery is reached earlier than the one to stop a deep arterial bleeding. The Figure 4.11 shows that the bleeding is kept constant during 15 seconds. At this moment, the pressure begins to grow and once the value of pressure exerted is enough to stop the bleeding, the flows changes to 0 and the pump stops. The cut point which represent the stop of the bleeding is different when the flow is deep or superficial due to the fact the pressure to occlude the deep blood vessels need to compensate the tissue set in the thigh. The superficial bleeding of an artery is stopped when the pressure is higher than 35 mmHg or 1407, however the deep flow requires 115 mmHg or 2525 to stop the bleeding.

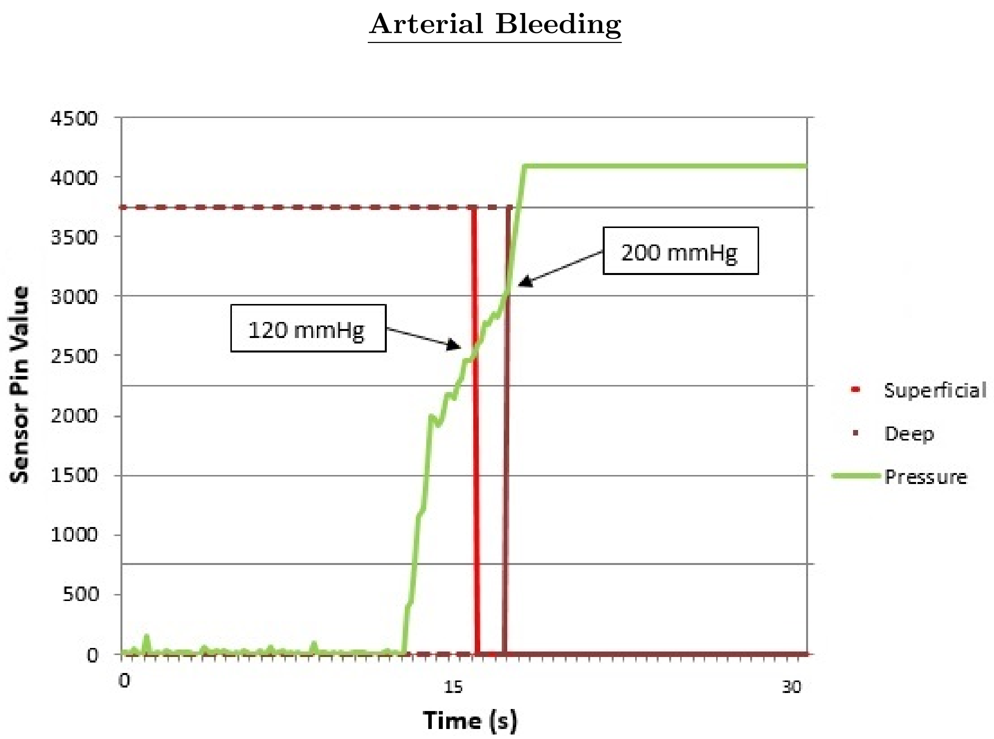

Figure 4.9: Arterial Bleeding

The arterial bleeding of a superficial and a deep artery are presented in Figure 4.9. The dark red line corresponds to the deep artery which is the internal femoral artery and the light red line to the external femoral artery which is the superficial artery vessel chosen for this scenario. This Figure 4.9 shows a similar behaviour to the one of the venous bleeding. As the arterial flows is pulsating, the relay pin value is continually changing regardless of the actions done on the emulator. This behaviour is constant until the pressure goes beyond the threshold than 120 mmHg or 2565 in the case of the superficial artery and 200 mmHg or 3044 in the case of the deep artery. At that moment, the pump stops the bleeding. During the pressure is higher than this value, the flows will remain in 0.

- TOURNIQUET PLACEMENT TECHNIQUE

The scenarios performed simulate a massive hemorrhage where more than one vessels are affected. The threshold of the pressure need to stop the bleeding of the venous and the arteries is different as it has been commented along this Master Thesis. This situation is shown in Figures 4.10, 4.11, 4.12 and 4.13 in which venous bleeding stops before the arterial one.

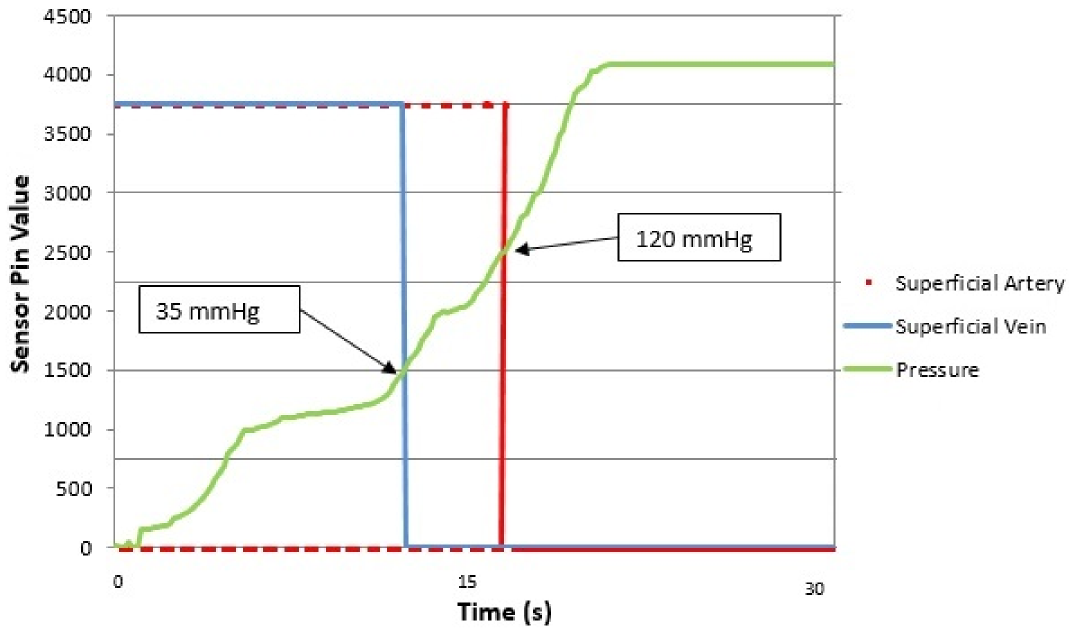

Figure 4.10: Superficial artery and vein

In Figure 4.10 the external femoral artery together with the greater saphenous vein are presented. In this case, both affected vessels are superficial. The pressure needs to stop the bleeding on the superficial vein is 35 mmHg and however, in the superficial artery is 120 mmHg. The pressure needed to control this hemorrhage should be enough pressure to stop the artery as when the artery will be occluded the venous will be as well.

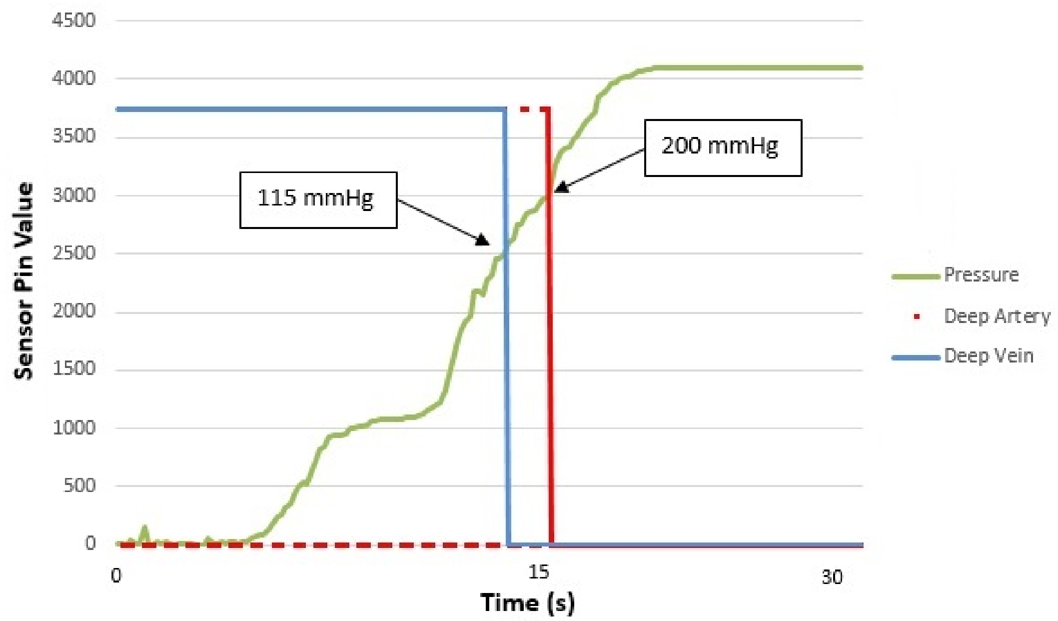

Figure 4.11: Deep artery and vein

The hemorrhage in which the internal artery and the internal vein are bleeding is represented in Figure 4.11. These vessels will be the ones that require the highest pressure to stop the bleeding, due to both of them are inside the thigh and the pressure needs to compensate the tissue set on the thigh to control the hemorrhage. As shown in Figure 4.11, the arterial vessel needs more pressure than the vein. Therefore, the bleeding will stop when the tourniquet exerts a pressure higher than 200 mmHg.

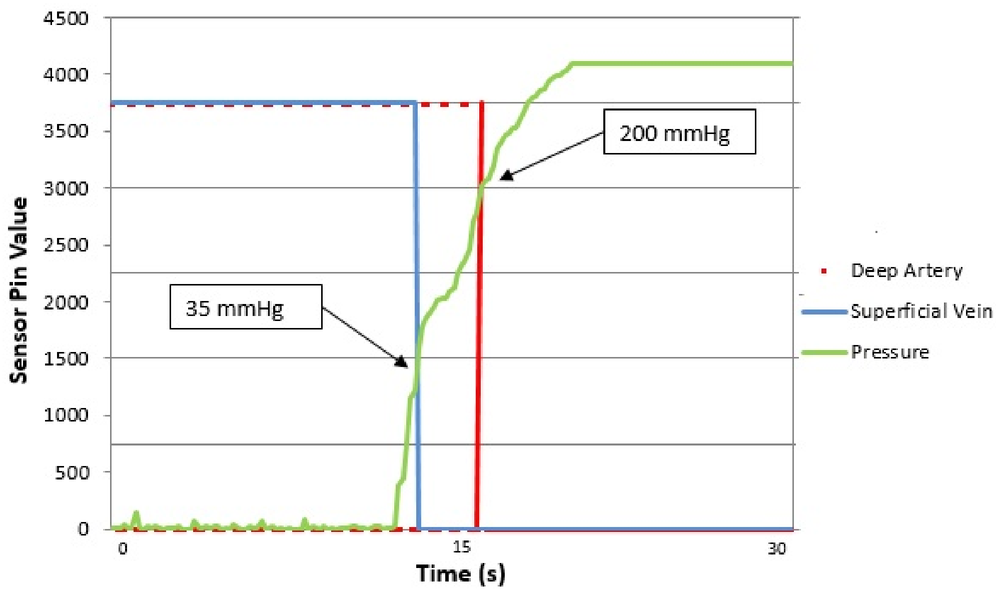

Figure 4.12: Deep artery and superficial vein

The Figure 4.12 presents the comparison between an internal artery vessel and a superficial vein vessel hemorrhage. In this situation, the pressure necessary to stop the bleeding is also higher than 200 mmHg due to the fact that the internal artery bleeding must be controlled.

Finally, the last possible scenario in which bleeding happens in an external artery and an internal vein are shown in Figure 4.13. In this case, the pressure curve has been changed in order to observe that if the pressure is not exerted during enough time, when the pressure stops, the bleeding starts again and the process must be repeated. The pressure is applied two times, for this reason the flows is activated and deactivated twice. In this scenario, the pressure needed to stop the venous and the arterial bleeding is similar, 120 mmHg to the artery superficial and 115 mmHg to the internal vein. The flows will be activated until the pressure reaches this value. At that time, the flow is deactivated and when the pressure disappears over the sensor, the flow begins again. In less than 15 seconds the pressure increases again and the process is repeated. This situation shows that the emulator is able to reproduce and control the bleeding the necessary times.

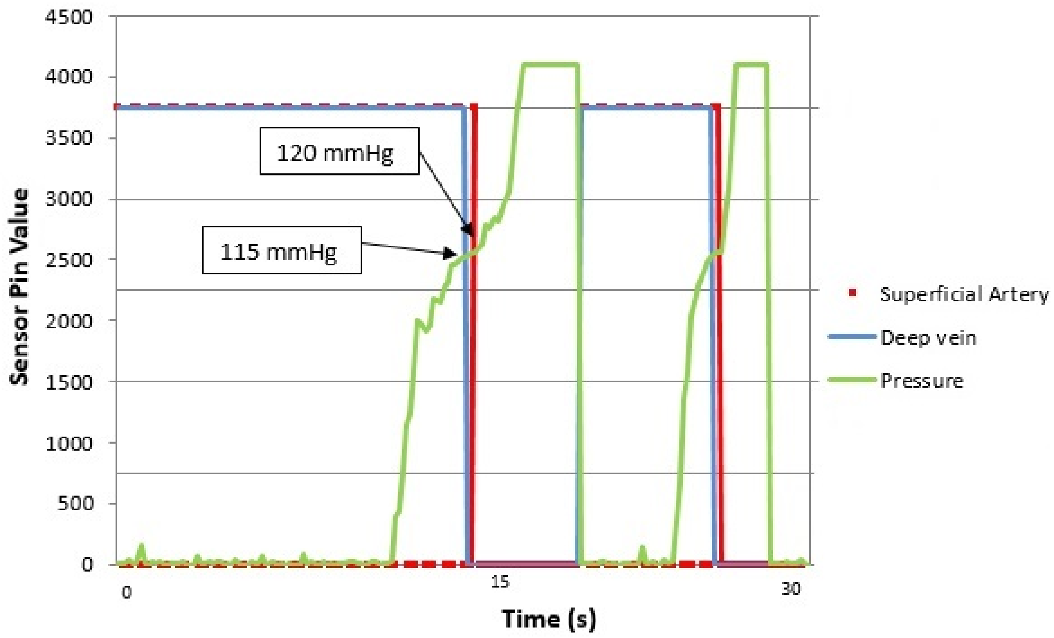

Figure 4.13: Superficial artery and deep vein

Chapter 5

Conclusions and Future Developments

5.1. Conclusions

The main objective of this Master Thesis has been to create a trauma emulator for clinical situations where bleeding occurs. The lower limb emulator designed provides a learning tool through which the clinicians can perform the necessary techniques to achieve adequate and effective treatment.

Fulfilling this purpose, a leg bleeding trauma emulator has been designed and developed, as well as an electronic circuit to check its functionality. The emulator developed is a mechanical device manufactured using different synthetic materials which have provided the adequate and desired features to look as a human thigh. It is able to set up the type of bleeding actuation and according to the chosen, different mechanical techniques can be applied over it: direct pressure and tourniquet. In addition, the emulator does not only execute a bleeding trauma injury scenarios but it also provides feedback when the hemorrhage is being controlled. The fact that the emulator provides a feedback means that it could be considered as a high fidelity clinical emulator.

Despite, the strange circumstances in which the project has developed and taking into account the impossibility of acquiring all the necessary material to simulate the scenario in its totality, the results obtained has been satisfactory.

On the one hand, the final appearance acquired of the emulator has achieved a great similarity to reality. This fact allows a complete immersion in the simulated scenario making easier for clinicians to act as a real situations. The femur manufactured using 3D printers has achieved the morphology adequate, whereas the silicones used to create the muscles and the skin have fulfill their purpose. Moreover, despite the shortage of amount of silicone available, it has been enough to manufacture the emulator successfully. Moreover, the assembly designed using different layers for each element allows to add extra materials in order to adapt it to other scenarios with patients who have different anatomy and also, to change the layer of the skin when it is damaged without the need to renew the entire emulator.

On the other hand, the design and the programming of the electronic circuit allows to check the functionality of the emulator in hemorrhagic scenarios to avoid the hemorrhagic shock. It is able to show the difference between the venous and arterial bleeding being continuous and pulsating respectively. This situation reflects the behaviour of the cardiovascular system. Besides, the circuit allows to perfectly represent the collapse of blood vessels when the established threshold of external applied pressure is exceeded and therefore, the bleeding is stopped. The graphics obtained show that the moment of the stop of the venous hemorrhage is previous to the arterial one, something expected as a consequence of the internal pressure of the fluid that circulates in each vessel. Taking into account the existing emulator and those which are normally used in simulated scenarios, this bleeding emulator offers automatic control of the bleeding trauma scenario. These features allow a better and more comfortable control over the hemorrhages and more realism due to the fact that any auxiliary person creating the bleeding manually is not necessary.

Finally, the study of bleeding trauma related to this Thesis has contributed to understand some aspects of the protocols to be performed in case of a hemorrhagic emergency, and to gain knowledge about some physiological functions of the human body. For this reason, it could be concluded that the objectives of this Master Thesis have been achieved.

5.2. Future Developments

Once the results and conclusions of this Master Thesis have been presented, some future developments are provided in order to improve the lower limb emulator.

- To introduce more blood vessels in order to recreate more real hemorrhages.
- To add different outlets along the blood vessel in order to allow their bleeding through different points. This situation could be achieved creating floodgate-like exits along the vessels. These exits could be controlled automatically during the simulation thanks the use of electromagnets or other electronic components.
- To manufacture the blood vessels using more sophisticated material to simulate their biological features.
- To create the electronic design to check all the requirements when tourniquet is placed. Besides the pressure, also the time and the position using the selected position sensors showed in Section 3.2.
- To create a circuit capable of regulate the intensity transmitted to the pumps according to the variation of the external pressure applied. Maybe, adding electronic components such as variable resistance.

- To manufacture all the emulators using silicones in order to improve the mechanical design.
- To create a database to store the data of each simulation scenario will allow the hospital to analyze the progression of each trainee or to search previous simulations and get the simulation data. This option could generate an improvement in the simulations as learning and teaching tool.

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Appendix A

Impact

A.1. Introduction

Hemorrhagic trauma is one of the leading causes of death in the world. Moreover, it represents the third cause of death for all social groups and the first cause of death for people between 1 to 45 years [5]. Therefore, clinicians must be prepared to face these situations in order to reduce this data. This project has a goal to develop a lower limb emulator to reproduce different hemorrhagic trauma scenarios in order to train, practice, assess and acquire the required skills to treat trauma patients through simulation.

A.2. Description of relevant impacts related to the project

- **Social Impact:** This project will have a direct social impact on clinicians teams, who work attending bleeding trauma patients. They can acquire skills and abilities using the lower limb emulator faster than using traditional techniques [8]. Moreover, using clinical simulation will allow to practice the skills until they are automatized providing a more quality healthcare service to patients. On the other hand, it is important to highlight that the social impact generated by the trauma disease is serious as it mainly affects to the young and economically active people. Furthermore, it generates important sequelae and a difficult reintegration into work and school, so if clinicians improve their training to treat traumatic patients, these impacts could be reduced and the social impact could improve.

- **Economical Impact:** This project will have an economical impact on the use of emulator as it allows to better treat trauma patients and probably, the amount of incidents could decrease and with them the economic charges. Moreover, if the medical teams are more trained to treat diseases such as trauma, the reintegration into work could be better. If a patient suffering a traumatic accident is able to return to work and economic life as soon as possible and without sequelae, the economic cost of maintaining a person with reduced abilities can be reduced. In addition, the economy depends on working people and if traumatic accidents cause problems in the labor reintegration, this situation can generate economic imbalance.

- **Ethical Impact:** The use of an emulator allows to train clinicians to face clinical challenges ensuring safety and avoiding critical mistakes which could have an important impact on patients. In addition, taking into account that the ethics is a set of manners and rules that guide or value human behavior in community, the use of an emulator will have an ethical impact in the medical community as it improves the patient safety which is one of the main goals in their career.

- **Legal Impact:** The research and development activities carried out during this Master Thesis are framed within the "Law on Biomedical Research" 14/2007 (BOE 159, July 4, 2007). The collaboration with the Hospital Universitario La Paz in the development of this thesis and its possible patent are framed in the "Law on Science, Technology and Innovation" 14/2011 (BOE 131, June 2, 2011).

- **Environmental Impact:** There is no direct environmental impact in the development of this Master Thesis but the emulator is done with materials eco friendly like polymer PLA which is a biodegradable thermoplastic material derived from renewable resources. This makes the developed solution a more environmentally friendly solution than other petrochemical-based plastic solutions.

A.3. Conclusions

Clinical simulation, thanks to the use of an emulator, causes a direct impact on the medical teams as they are more prepared and trained.

The impact generated using emulators is positive and the use of the actual technologies will increase the adaptability of learning methods with realistic scenarios which allows to improve not only the technical skills but also the personal ones.

The design and development of a bleeding trauma leg emulator will have a direct impact on the quality of the healthcare service provided to trauma patients.

Appendix B

Economical Budget

Human Resources Cost:

The salary of people involved during the development of the project should be considered. Due to the current situation the people involved has been reduced. Director of work and engineering student costs are shown in Table B.1

	Cost per hour (€)	**Working hours**	**Total costs (€)**
Director of work	20	30	600
Engineering Student	10	588	5880
TOTAL			**6480**

Table B.1: Human Resources Budget

Material Resources Costs:

The cost of material and technical equipment resources necessary to develop this project is listed in Table B.2. The total cost are calculated taking into account the costs per unit, the time used in months and the amortization in years.

	Units	Cost per Unit (€)	Time used (months)	Amortization (€/months)	Total costs (€)
Arduino Due	1	28.5	4	5	1.9
Relay	2	0.92	4	5	0.12
Transistor	4	2.69	4	5	0.71
Pressure Sensor	1	7.60	4	5	0.51
Liquid Pumps	2	3	4	5	0.4
Other electronics	2	6	4	5	0.8
Silicons	3	28	4	5	5.6
Components of Silicons	2	18.10	4	5	2.41
Polymer PLA	1	19.90	4	5	1.33
Personal Computer	1	900	4	5	60
TOTAL					**73.78**

Table B.2: Material Resources Budget

Total Costs:

The total costs are presented in the Table B.3. On the one hand, taking into account that the direct cost is the sum of Human Resources and Material Resources, **the general costs** are the 15% of direct costs. On the other hand, the overhead cost are considered the indirect cost; therefore **the industrial benefit** are the (6% of the direct and indirect costs). As general cost as industrial benefit are considered to calculate the total costs. The value of the total costs of this Master Thesis is 9666.76 €.

		Coste
DIRECT COST	Human Resources	6480€
	Material Resources	73.78€
OVERHEAD COSTS (INDIRECT COST)	15% DC	983.067 €
INDUSTRIAL BENEFIT	6% (DC + IC)	452.21 €
SUBTOTAL BUDGET	DC + IC + IB	7989.057
IVA (21%)		1677.7€
TOTAL BUDGET		**9666.76€**

Table B.3: Total Budget

Appendix C

User Manual

C.1. Emulator Specifications

SIZE

Mannequin/Emulator	13"HEIGHT x 5" WIDTH x 5" THICKNESS (340mm x 120 mm x 120 mm)

WEIGHT

Mannequin/Emulator	20kg (40lb)

ENVIRONMENTAL REQUIREMENTS

Ambient temperature range

Functioning	4ºC to 40ºC (40ºF to 104ºF)
Storage	4ºC to 50ºC (40ºF to 122ºF)
Relative humidity	no condensation

COMMUNICATIONS

Emulator network

With cable	Arduino Due Board

C.2. Cautions/Warings

Please read and fully understand these precautions and warnings before starting use the lower limb emulator.

USE OF THIS EQUIPMENT IN A WAY OTHER THAN THAT SPECIFIED COULD AFFECT THE INTENDED PROTECTION.

Your safety depends on you. Be sure to follow the instructions for a correct installation, disassembly and use of the emulator system.

Electrical Safety

- This product must remain connected to a power outlet connected to properly installed land. Precautions must be taken to prevent the connection to Earth or polarization is canceled.
- Do not allow excess liquids to flow onto or into electronic components from them.
- Do not use the lower limb emulator system in the rain. Use water on the phantom only in accordance with the clinical procedures allowed and identified in this Manual of the User.
- Do not attempt to disassemble the emulator or service any of the electrical components

Silicone Warning

Lower limb emulator incorporate the use of silicones in their design. When making certain maintenance procedures, silicone could be exposed. Those users silicone sensitive should take the necessary precautions when manipulate the simulator while performing the procedures.

Purge and Secretion System

- DO NOT modify the tank or any assembly component.
- ALWAYS protect eyes, skin and clothing from accidental contact.
- ALWAYS read and follow the instructions for creating trauma fluids (for example, blood). NEVER fill the tanks with more than the indications.
- After use, you should ALWAYS relieve pressure of the blood vessels and clean the tanks. DO NOT store liquids in the tank.

<u>**Manikin**</u>

- Do not disassemble the mannequin parts that have been assembled by the manufacturer.
- Do not clean the manikin with chemical solvents. Use only water and a soft soap.
- Make sure the manikin has been placed on a stable work surface and resistant to prevent it from collapsing and causing injury to users.
- Lower limb emulator must be operated at an ambient temperature below 40C (104 F).
- Do not introduce foreign substances into the plastic tubs. Only perform invasive procedures that allow in the system as described in the corresponding sections of the User's manual.
- Do not lift the mannequin by the bone.

C.3. Components

Lower limb emulator has been designed to be used in any learning environment. The Standard emulator functions can be easily integrated in a laboratory or locations remote.

Lower limb emulator has all the necessary equipment to establish an educational center of simulation.

	Standard Equipment
1	Emulator
2	Liquid Tanks
3	Plastic tubs
4	Arduino Due Board
5	Placa Protoboard
6	Pressure Sensor
7	Relay
8	Transistors
9	Resistance
10	Pumps

C.3.1. Assembly of Components

Carefully assembling the components of the lower limb emulator to reproduce hemorrhages ensures proper operation.

- **Step 1:** Place the emulator, liquid tanks, and plastic tubes on the simulation surface.
- **Step 2:** Insert the plastic cups and sensors into the emulator in their correct position.
- **Step 3:** Fill the liquid water tanks with dye. The dye will be lighter in the case of arterial blood and darker in the venous.
- **Step 4:** Insert the pumps inside the liquid tanks.
- **Step 5:** Connect the sensors and pumps to the electronic circuit.
- **Step 6:** Select the scenario performed in the software to simulate it.

Preparation for simulation

Once the emulator is prepared to use in the simulated scenario, the situation has to be chosen. The director of the simulation is in charge of activating the emulator using the electronic design.

- **Step 1:** Connect the arduino in the computer.
- **Step 2:** Open the Arudino IDE software.
- **Step 3:** Load the file created with the ".ino" extension.
- **Step 4:** Select the situation to be simulated.
- **Step 5:** Load the program in the Arduino Due Board.

Preparation for storage

After filling and using the liquid tanks and the plastic tubs, both must be cleaned to be stored. In addition, the emulator with traces of blood.

- **Step 1:** Clean the Emulator. When the simulation has finished and the electronic components have been disconnected to emulator, remove fluids and clean the simulator.
- **Step 2:** Clean the plastic tubs. Before storing make sure the equipment is clean. Squeeze the tubes so that all the remaining liquid comes out.
- **Step 3:** Clean the liquid tanks. Empty the liquid tanks if there is water inside and dry them.
- **Step 4:** Save the emulator. After cleaning, the lower limb emulator assembly should stored safely for later use.