UNIVERSIDAD POLITÉCNICA DE MADRID

ESCUELA TÉCNICA SUPERIOR
DE INGENIEROS DE TELECOMUNICACIÓN

MÁSTER UNIVERSITARIO EN INGENIERÍA BIOMÉDICA

TRABAJO FIN DE MÁSTER

DESIGN AND IMPLEMENTATION OF AN AUTO-BREAKABLE PELVIS FOR CLINICAL SIMULATION

JAVIER GARCÍA VERA

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2020

Resumen

En la actualidad, nos encontramos en un escenario en el que la simulación clínica está adquiriendo una gran importancia. El hecho de poder practicar de manera inocua para los seres vivos y de manera reiterativa con simuladores cada vez más realistas permite un mejor ejercicio de la práctica médica. Estos simuladores ayudan a practicar y estudiar todo tipo de campos de la medicina como es el caso del trauma, que es una de las causas de fallecimiento y discapacidad más destacables en la actualidad.

Dentro de los diferentes tipos de trauma que existen, el trauma pélvico es uno de los más peligrosos en la actualidad y su tratamiento y estabilización clínica es primordial, sobre todo en las horas iniciales del trauma. Los cinturones pélvicos son dispositivos de estabilización de urgencia no invasivos, de bajo costo y fáciles de aplicar. Se ha observado en la literatura que el uso de cinturones pélvicos reduce el sangrado producido por el trauma y a su vez sirve como inmovilizador para evitar lesiones antes de ser tratado quirúrgicamente. Sin embargo, estos dispositivos de compresión pélvicos no pueden colocarse a la ligera, ya que un inadecuado posicionamiento podría inutilizar el manejo o incluso llegar a empeorarlo.

Por lo tanto, en este Trabajo de Fin de Máster se lleva a cabo el diseño de un sistema de simulación capaz de emular las rupturas inestables de un trauma pélvico para, posteriormente, poder proporcionar información del tratamiento a realizar como puede ser la colocación de un cinturón pélvico .

Abstract

Currently, clinical simulation is acquiring great importance. Being able to practice without impacting anybody's life and in a repetitive way with realistic simulators allows a better practice of medical training. These simulators help to practice and study different fields within medicine such as the trauma field, which is one of the main causes of death and disability worldwide.

Among the different types of trauma, pelvic trauma is one of the most dangerous ones and its treatment and clinical stabilization is essential, especially in the initial hours of trauma. The Pelvic Circumferential Compression Devices (PCCDs), commonly called pelvic binders, are non-invasive, inexpensive and easy to apply devices to stabilize patients with a pelvic trauma injury. It has been observed in the literature that the use of pelvic binders reduces the bleeding caused by a pelvic trauma and that it also serves as an immobilizer to prevent injuries before being surgically treated. However, these pelvic compression devices cannot be placed anywhere, as an improper positioning could make the treatment useless or it might even worsen the injury.

Therefore, in this Master Thesis, the design of a simulation system capable of emulating the unstable fractures of a pelvic trauma has been carried out. Furthermore, this system is able of providing feedback about the treatment such as the stabilization with a pelvic binder.

Agradecimientos

Quisiera agradecer a varias personas la ayuda y apoyo que me han prestado a lo largo de este año en la realización del Máster y de este trabajo.

En primer lugar, a los profesores que me han dirigido y ayudado, además de proporcionarme la instalaciones del RoboLabo, Blanca Larraga y Álvaro Gutierrez, sin ellos no hubiera sido posible la realización de este TFM.

A mi familia, en especial a mis padres, a mis hermanos, a mis abuelas y a mi madrina, siempre echándome una mano incondicionalmente.

A mis amigos del grupo de Berengüinos y también aquellos con los que he compartido este increíble año en Madrid así como las grandes personas que he conocido.

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Chapter 1

Introduction

This Master Thesis has been carried out thanks to the various institutions that have offered the facilities and material at their disposal. The development and design of an auto-breakable pelvis for clinical simulation has been mostly performed thanks to the laboratory of robotics and control of the Escuela Técnica Superior de Ingenieros de Telecomunicaciones, UPM. Furthermore, the Hospital Universitario La Paz has also contributed to achieve this work.

1.1. Motivation

Trauma refers to an injury or damage to organic tissues or bones that can lead to secondary and life-threatening complications. Almost 6 million people die every year as a result of a major trauma which entails around 10% of all registered deaths in the world, 32% more than the sum of the deaths caused by malaria, tuberculosis and HIV [1]. As a matter of fact, major trauma is the sixth cause of death worldwide and the first cause of death and disability in the young population (under 35 years old), being traffic accidents and suicide the main causes of death. In 2016, only traffic accidents entailed the eighth cause of death worldwide as can be seen in Figure 1.1 [2].

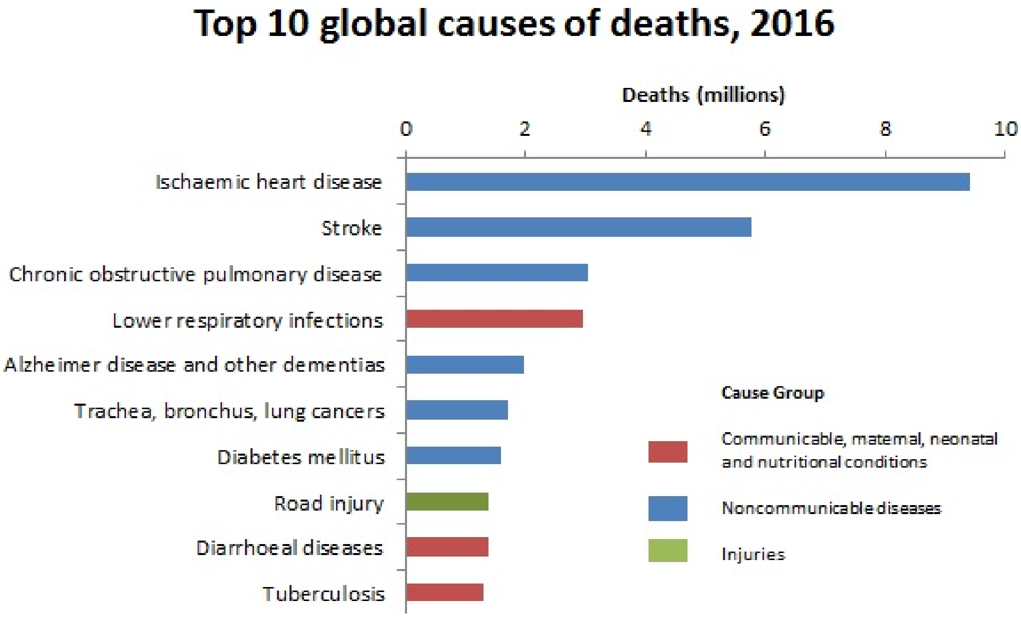

Figure 1.1: The top 10 causes of death worldwide [2].

Concerning gender, trauma injury tends to prevail more in men being 62.7% of the total trauma patients. With respect to the age, even though trauma events are the leading cause for people under 35 years old, people over 65 years old becoming an important affected group as they have twice the mortality rate of young individuals, being falls the responsible cause in 75% of cases from this age [1].

In Spain, around 430.000 people die every year and 3.7% of these deaths correspond to trauma incidents and external causes as shown in Figure 1.2 [3].

	Total	Women %	Interannual variation %
All causes	424.523	49.5	3,4
Circulatory system diseases	122.466	54.1	2,2
Tumors	113.266	39.5	0,3
Respiratory system diseases	51.615	45.2	10,3
Diseases of the nervous system and sense organs	26.346	61.5	4,4
Mental and behavioral disorders	21.722	65.9	3,5
Digestive system diseases	20.447	47.8	1,7
Trauma and other external causes of mortality	15.837	37.3	1,1

Figure 1.2: Death according to cause in Spain in 2017 [3].

Trauma is associated with energy impacts. Some impacts entail an energy release that might be greater than the one the bones or tissue resist. This energy acts in our body causing fractures or other lesions. Depending on the intensity of the energy released, these traumas could be classified as [4]:

- **Low energy trauma:** these traumas cause fractures produced by low energy impacts such as casual falls or a small pedestrian accident. This group of trauma are not usually problematic, specially if they occur in young patients. The prognosis for recovery of these fractures depends on the energy that has been released.

- **High energy trauma:** these traumas cause fractures produced by high energy mechanisms such as car accidents or high falls. This group of trauma has a worse evolution than the low energy ones and it frequently leads to polytrauma that refers to severely injured patients with multiple relevant traumatic injuries.

In addition, to determine the type of trauma there are different scales used wordwide to measure the importance of the injury. Regarding the location of the trauma in the human body, the Injury Severity Score (ISS) defines six type of trauma, providing each of these regions with a punctuation depending on the severity of the injury: minor, moderate, serious, severe, critical or maximal [5].

1. **Head / neck trauma:** These are traumas that occur on the skull and/or the neck and are rather important as the lesions caused in these areas can affect the central nervous system or to the respiratory tract, leading into permanent sequelae or even causing the death of patients.

2. **Face trauma:** This trauma may involve soft tissue injuries such as skin or eye injuries and also fractures of the bones of the face, such as a nasal fracture or a mandibular fracture.

3. **Thoracic trauma:** This type of trauma can compromise the bones and the organs that the thorax surrounds affecting the cardiac and respiratory functions. Therefore, thoracic trauma implies an important vital risk for the patient.

4. **Limb trauma:** This type of trauma involves sprains, dislocations, and fractures that take place in the limbs. Limb trauma might be rather dangerous when the main blood vessels are compromised as it is the case of the femoral artery. This could cause important bleeding that may trigger death or significant disabilities.

5. **Pelvic/abdominal trauma:** These traumas include lesions found in the abdominal region and the organs and bones involved by the pelvis. Lumbar spine lesions are included in the abdominal or pelvic region.

6. **External, skin and subcutaneous:** This type include lacerations, contusions, abrasions and burns, independent of their location on the body surface.

1.1.1. Pelvic anatomy

Pelvic trauma is among the most dangerous and deathly traumas due to its location and the different structures and tissues that the pelvis encompasses such as blood vessels and organs. The bony pelvis has a ring shape, the *pelvic ring*, which is composed of different bones as shown in Figure 1.3.

- **The sacrum:** it is a curved, triangular-shaped bone that consists of five vertebrae and it articulates with four different bones: two ilium bones (ilia) on each side joined by the sacroiliac joints, the L5 vertebra at the top and the coccyx in the lower side by the sacrococcygeal joint.
- **The coxal bones**: also known as iliac, they consist of two innominate bones on each side of the sacrum formed by the ilium, ischium and pubis. Both coxal are joined together in the pubis by the pubic symphysis, which is a cartilaginous joint.

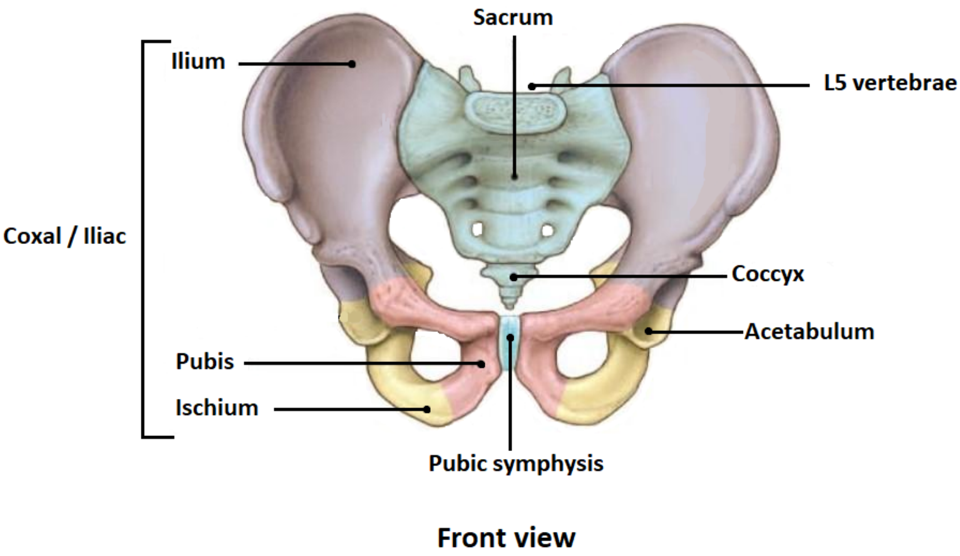

Figure 1.3: Pelvic bones [6].

The pelvis can be divided into two regions as highlighted in Figure 1.4:

- **The greater pelvis**: it refers to the upper part of the pelvic bones and lower lumbar vertebrae, known as *false pelvis*. It supports the intestines and is usually considered part of the abdomen.
- **The lesser pelvis**: it is related to the lower parts of the coxal, the sacrum and the coccyx, it is also known as *true pelvis*.

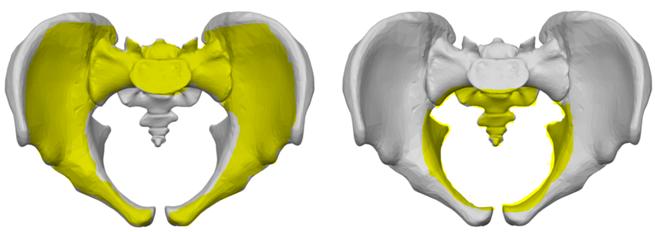

Figure 1.4: In yellow greater pelvis (left) and lesser pelvis (right).

Furthermore, the pelvic ring consists of two arches as seen in the Figure 1.5. On the one hand, the posterior arch, which encompasses everything that remains behind the surface of the acetabulum, including the sacrum, the sacroiliac junctions with the corresponding ligaments and the posterior ilium. On the other hand, the anterior arch which is weaker than the posterior arch, which encompasses all the components before the acetabulum such as the pubis [7]. The pelvic ring involves many relevant

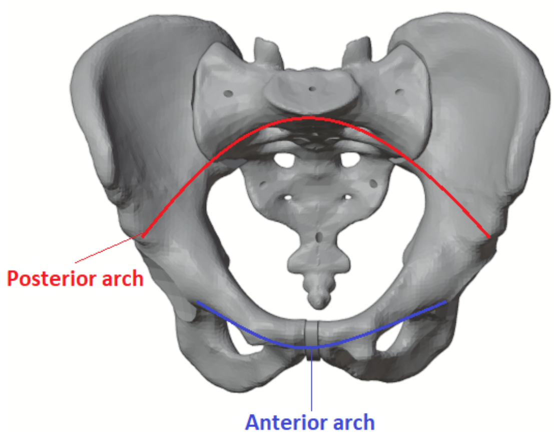

Figure 1.5: Posterior and anterior arches.

tissues, vessels and organs. In Figure 1.6 the organs in the pelvis are shown, being the ending parts of the digestive tract, the urinary and the reproductive systems. In

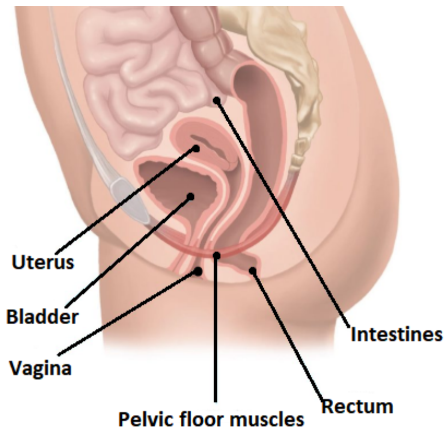

Figure 1.6: Organs in the pelvic region [8].

addition, a great number of blood vessels, as shown in Figure 1.7, pass through this area such as the bifurcation of the aorta in the iliac vein and artery and the femoral vein which are some of the most important blood vessels [9].

In the same way, the pelvic muscles and nerves must be taken into account since both may be involved when a pelvic trauma occurs. Pelvic floor muscles are the layer

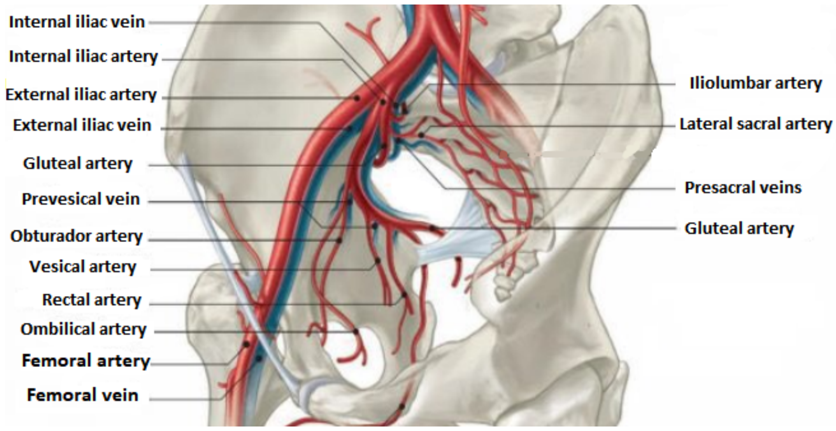

Figure 1.7: Blood vessels [10].

of muscles that provide support to the organs that lie on it and span the bottom of the pelvis. Regarding the nerves, ureteral and spinal nerves and the lumbosacral plexus have a great relevance due to the frequency with which they are injured when a pelvic trauma occurs, triggering different lesions.

1.1.2. Pelvic fractures

Pelvic fractures are caused by high-energy impacts and usually trigger other injuries. The main causes of pelvic trauma are traffic accidents (60%), falls (30%) and others (10%) [11]. Overall, the morbidity and mortality associated with pelvic injuries are significant. The mortality rate is estimated at 28% but it can reach up to 50% in open fractures [11]. The mortality remains high especially in patients with hemodynamic instability, being around 30%, due to the considerable bleeding, the difficulty to achieve hemostasis and the other lesions triggered by the pelvic trauma [11] [12].

There are different classification systems to determine the type of pelvic trauma based on the mechanism of injury, on anatomical patterns or on the resulting instability:

- **The World Society of Emergency Surgery (WSES) classification:** This classification divides pelvic ring injuries into three classes depending on the mechanical and hemodynamical stability of the fracture. On the one hand, a fracture is mechanically unstable when there are two or more breaks in the pelvic ring and the broken bones are not properly aligned. On the other hand, a fracture is said to be hemodynamically unstable when there is an abnormal or unstable blood pressure, which can compromise the organs due to inadequate irrigation [13] [14]. Therefore, de WSES establishes 3 classifications:
  - *Minor (WSES grade I):* hemodynamically and mechanically stable lesions.
  - *Moderate (WSES grade II, III):* hemodynamically stable and mechanically unstable lesion.

- *Severe (WSES grade IV):* these traumatisms are considered to be hemodynamically unstable regardless of mechanical status.

- **The Young and Burgess classification:** this is a system of categorizing pelvic fractures depending on its stability. This classification takes into account the force type, severity, and direction of the mechanism of injury. There are three different types of injuries with their corresponding subcategories [11][15] :

  - *Anterior Posterior Compression (APC) injuries:* also referred to as open book injuries. They occur when an anterior or posterior force produces a complete diastasis of the anterior pelvis. There are three types of APC injuries depending on the degree of severity: APC I, APC II and APC III as can be seen in Figure 1.8.

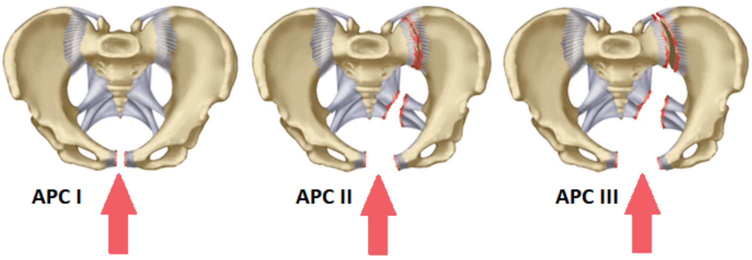

Figure 1.8: APC injuries and the direction of the force applied [15].

  - *Lateral Compression (LC) injuries:* these injuries result when a force is applied laterally to the pelvis. Based on the location and magnitude of the applied force, different injury patterns result: LC I, LC II and LC III as it is shown in Figure 1.9.

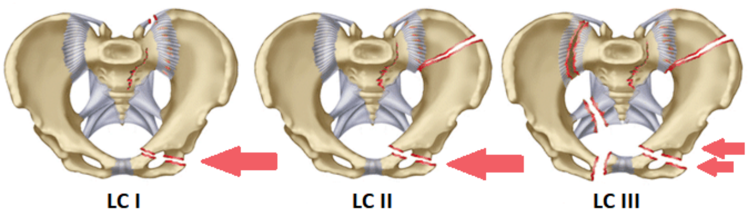

Figure 1.9: LC injuries and the direction of the force applied [15].

  - *Vertical Shear (VS):* these injuries result from an axially loaded force. The coxal is moved upwards with respect to the sacrum, causing anterior and posterior sacroiliac dislocation, fracture and disruption as can be seen in Figure 1.10.

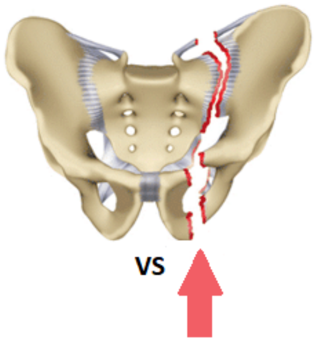

Figure 1.10: VS injury and the direction of the force applied [15].

- *Combined Injuries:* these injuries refer to the combination of any of the three primary patterns, being usually the combination of lateral compression with any of the other two types of lesions, APC or VS.

- **The Tile system classification:** this system provides a description of the fracture based on the stability of the posterior sacroiliac complex, allowing to assess the mechanical stability of the pelvis. Therefore, according to this classification, there are three main types of pelvic fractures [11] [16]:

  - *Type A or stable fractures:* the integrity of the pelvic ring is not compromised as shown in Figure 1.11. There are three subcategories of type A fractures:

    a. A1: fracture not involving the ring (avulsion or iliac wing fracture).

    b. A2: stable or minimally displaced fracture of the ring.

    c. A3: transverse sacral fracture without compromising the pelvic ring.

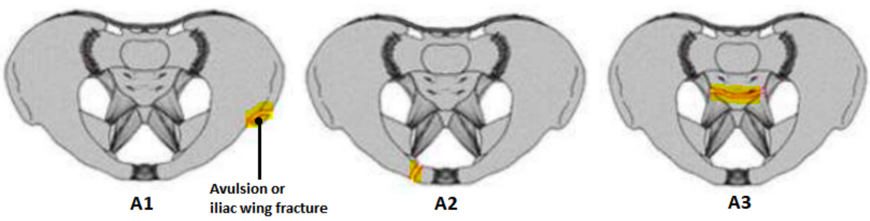

Figure 1.11: Type A fractures [17].

  - *Type B or partially unstable fractures:* these fractures cause rotational instability but vertical stability. There are three subcategories of type B fractures:

    a. B1: Unilateral, these are external rotation injuries also known as open book fractures. These fractures cause partial disruption of the posterior arch.

b. B2: Unilateral, causing partial disruption of the posterior arch which causes internal rotation, usually due to lateral forces.

c. B3: Bilateral, causing a partial lesion of the posterior arch on both sides of the pelvis.

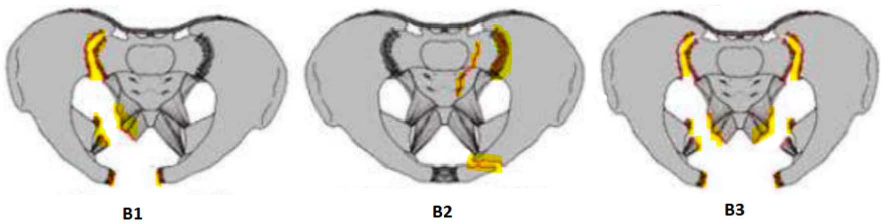

Figure 1.12: Type B fractures [17].

- *Type C or unstable fractures:* these fractures cause complete rupture of the posterior ring. There is a rotational and vertical instability and cannot bear physiological loads without undergoing deformation. This type of fractures is related to VS, APC and combined injuries and present the highest lethality and mortality [18] [19]. As it is shown in Figure 1.13, there are three subcategories of type C fractures:

  a. C1: Unilateral complete disruption of the posterior ring. In addition, these fractures can be classified as C1.1 (fracture through ilia), C1.2 (sacroiliac fracture), and C1.3 (sacrum fracture).

  b. C2: Bilateral, one side presents a complete disruption and the other one presents a type B fracture (B1 or B2).

  c. C3: Bilateral, complete disruption in both hemi-pelvis.

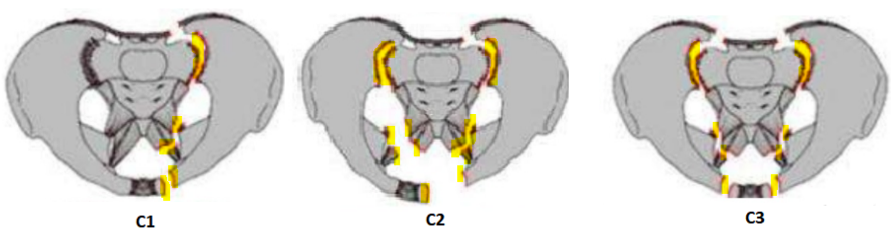

Figure 1.13: Type C fractures [17].

The Tile classification along with the The Young and Burgess classification are the most frequently classifications used in the trauma and radiology fields [20]. Both classifications are appropriate for the assessment of a pelvic trauma. However, this Master Thesis will focus on the Tile Classification as the Young and Burgess classification is based on the mechanism of injury whereas the Tile classification is based on the mechanical stability of the pelvis, which makes it more appropriate for the description of the ruptures to be simulated.

Type C fractures are the ones with higher mortality rate and besides, an inadequate treatment of the the pelvic ring can finally lead to permanent disabilities. Therefore, these fractures require fast stabilisation and management. Surgery, which includes incision to realign the bone and internal fixation of the pelvic ring, leads to good results in the treatment [18] [21]. Nevertheless, there are other types of treatments to carry out in the early stages of the trauma. In unstable pelvic fractures, the hemorrhage must be treated and managed as soon as possible by using non invasive methods like pelvic binders wrapped around the pelvis [22].

1.2. Objectives

The objective of this Master Thesis is to design and implement an auto-breakable pelvis that can reproduce different pelvic fractures with the purpose of gaining a deeper knowledge in the management of pelvic traumatisms. The treatment of pelvic trauma patients aims to restore the homeostasis and the normal physiopathology associated to the mechanical stability of the pelvic ring. Therefore, this system would be capable of providing feedback of how the pelvis has been treated, providing a training and learning tool for clinicians.

To achieve this objective, the following tasks have been carried out:

- the study of the anatomy, fractures and treatments of the pelvic bone. This is important in order to understand the clinical challenges and to be able to reproduce them.
- the design of the pelvic bone. This task has been carried out with the use of different softwares as FreeCad and Blender to be able to reproduce a pelvis and the different types of fractures that may occur.
- to actuate the pelvic bone by using devices that will allow the pelvis to break and to simulate the different fractures.
- to implement a sensor system that will provide feedback with respect to the treatment performed to a patient who has suffered a pelvic trauma.

1.3. Document Layout

This Master Thesis has been structured in five different chapters:

Chapter 2 describes the background of pelvic fractures as well as the protocols to follow when a pelvic trauma occurs. Furthermore, it gives an overview of the current situation in the clinical simulation.

Chapter 3 will be focused on the description of the material selected as well as to design an auto-breakable pelvis in 3D. Different alternatives will be presented as well as the actuators and sensors to produce the fractures and to obtain information about how the pelvis has been treated.

Chapter 4 will be focused on results along with discussions and future works respectively. In this part, an identification of which design will be the most optimal of all will be made. Furthermore, it will propose possible future works related to this Master Thesis.

Chapter 2

Clinical simulation and action protocols

2.1. Healthcare simulation

Although the clinical simulation is still at a relatively incipient stage. The reality is that throughout history various simulation techniques have been used for clinical purposes. However, it was not until the end of the second decade of the 20th century that simulation took on a very relevant role. In 1929 the engineer Edwin A. Link developed simulators flight for pilot training, thus giving place to practices with techniques that simulate realistic scenarios. The progress of the simulation led in the second half of the century to its application in medicine with the creation of a cardiopulmonary resuscitation model or simulators dedicated to reproducing more precisely human characteristics [23].

Nowadays, we are in a scenario in which the advancement of technology and knowledge allow us to dispense with the practice and study with living beings. Clinical simulation joins both engineering and medicine knowledge in order to replicate healthcare scenarios in an environment which is safe for education and experimentation purposes.

The clinical simulation presents a significant amount of advantages. On the one hand, being able to learn while performing a real-life simulation and receiving instruction at the same time. On the other hand, the freedom to make mistakes and learn from them as many times as it is needed and desired. In addition, clinical simulation can be customized for every individual and cases.

There are many different types of simulators such as manikin-based, skills-training, tissue-based, virtual reality or standardized patient simulation.

Usually these are classified into 3 levels of complexity:

- **Low-fidelity simulations**: these types use materials and equipment that leave out elements that the clinician might experience in a real life scenario. Examples of low fidelity simulations are simulated administration of injections or manikins destinated to cardiopulmonary resuscitation as the ones shown in Figures 2.1 and 2.2 [24].

Figure 2.1: CPR manikin [27].

Figure 2.2: Training arm for intravenous injection [27].

- **Mid-fidelity simulations**: these simulations are more realistic than the low-fidelity simulation and allow more opportunities for learning. Examples would be full-body manikins that pretend to be patients by having breath sounds or heart movement like the one shown in Figure 2.3 [25].

Figure 2.3: Mid fidelity simulation [27].

- **High-fidelity simulations**: these types use very realistic materials and equipment to represent the scenario that must be performed. However, both low fidelity and medium-fidelity are more cost-effective than the high fidelity simulation, which requires five times more cost than the medium one [26]. Examples of these would be full-body computerized manikins that simulate the human behaviour and anatomy as the one shown in Figure 2.4 [24].

2.2. Protocols

When a trauma event occurs, there are established protocols to follow in order to achieve the correct management of the injury.

Pelvic fractures, especially those caused by high trauma energy and more commonly, type C injuries, are associated with a high mortality rate and disabilities.

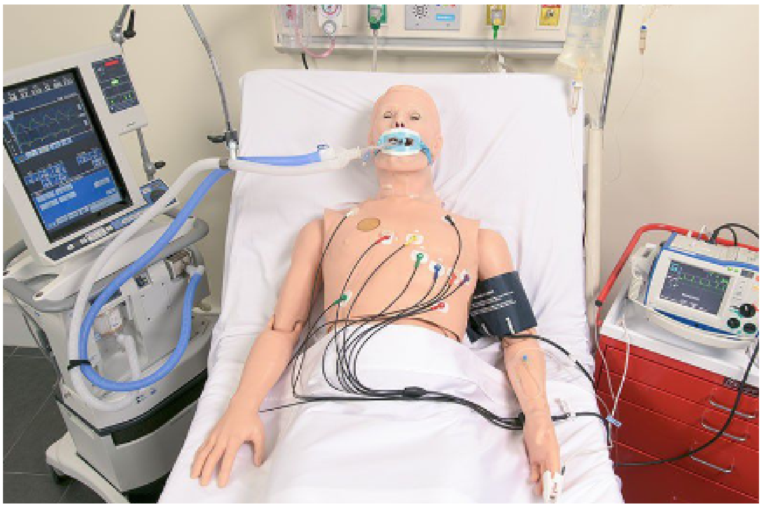

Figure 2.4: High fidelity simulation [27].

For this reason, the main objective in the management of an injury of this dimension is the stabilization of the patient, and therefore, an emergency protocol will be followed from a multidisciplinary perspective. This initial stabilization has great relevance as it helps to control possible bleeding and is part of the initial recovering of the patient. In order to achieve the correct assessment of the trauma, the ABCDE Approach shown in Table 2.1 must be done [28].

Tabla 2.1: ABCDE approach.

A	**Airway**	Check for obstruction and immobilize cervical spine
B	**Breathing**	Ensure adequate movement of air into the lungs
C	**Circulation**	Assessment of correct perfusion and check for life threatening bleeding
D	**Disability**	Protect and assess the brain and spinal functions
E	**Exposure**	Identify all injuries and environmental threats and avoid hypothermia

Once the initial assessment is carried out, some protocols are executed. The Advanced Trauma Life Support (ATLS), which is a protocol for the management of trauma cases used in the USA and also taken as a reference worldwide, establishes pelvic circumferential compression devices (PCCDs) as important components for the treatment of pelvic trauma. Furthermore, the literature and many consensus statements claim that in the pre-hospital management of pelvic injuries, especially those recognized as hemodynamically unstable, should include the application of pelvic circumferential compression devices as it can be observed in Figure 2.5 [29][30].

As it can be appreciated in the figure, the use of non invasive methods such as pelvic binders plays a fundamental role in the management of pelvic trauma and its possible consequences.

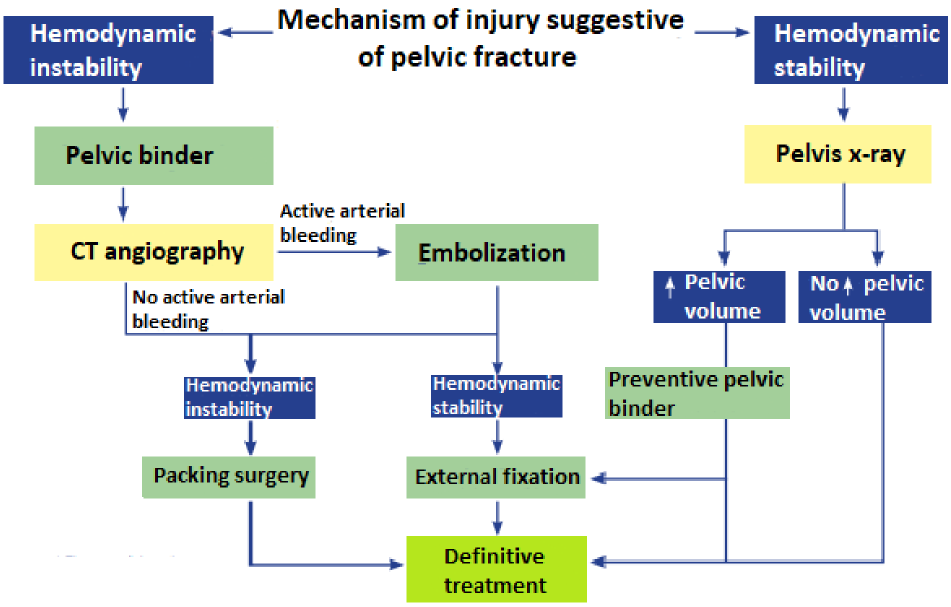

Figure 2.5: Algorithm for the application of PCCDS in trauma [30].

2.3. Non-invasive methods

The management of pelvic trauma has changed along the last years with a significant improvement in outcomes, due to improvements in diagnostic, the new technology and therapeutic tools.

When a pelvic trauma occurs, managing the haemorrhage is a key point for the treatment as it represents the major cause of death within the first 24 hours in patients with severe pelvic fractures [31] [32]. To prevent this issue, the use of non-invasive devices for initial management is highly recommended by institutional guidelines regardless of the fracture pattern. These devices named pelvic binders, shown in Figure 2.6 are also known as pelvic circumferential compression devices (PCCDs) and aim to recover the pelvic stabilization. PCCDs encourage clot formation by stabilising the injury and reduce the size of the intrapelvic volume in which haemorrhage can accumulate [38]. Pelvic binders are simple to use, cost-effective, and of non-invasive devices available to anyone. In fact, the application of a PCCD has become part of the emergency care of all trauma patients with suspected pelvic fractures, in both the pre-hospital environment and emergency department.

However, studies claim that many PCCDs are placed wrongly [31]. Pelvic binders must be placed at the level of the greater trochanter as it is shown in Figure 2.7 and depending on the type of trauma, different forces of compression should be applied [33].

Figure 2.6: Different types of PCCDs [33].

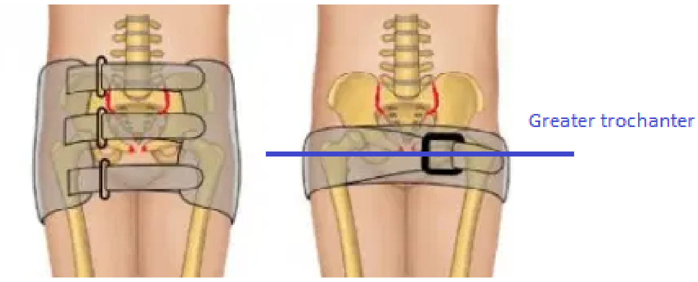

Figure 2.7: Correct placement of pelvic binders [34].

2.4. Background

This Master Thesis presents a series of antecedents that can be summarized in the following previous works and that are used as a reference for it.

Krieg et al in 2005 studied the mechanical characteristics on 13 patients with pelvic ring injuries who used pelvic binders. Their results demonstrated improvement in the fracture reduction, especially of external rotation fractures [35].

In 2007, Croece et al after having done a 10 years study comparing patients with APC II and APC III fractures who received external fixator versus patients who received PCCD. The results showed that transfusion and the stay time in the hospital were more optimistic for the patients with PCCD. Furthermore, it was observed that the mortality rate in patients with pelvic binders was lower than in the other group [36].

In 2013 Fu et al made a study in which they compared two groups of patients, one group of patients who received a PCCD upon arrival to a trauma centre, with those who did not. It was observed that the patients who had received PCCDs after an unstable or even stable pelvic injury required less care, shorter hospital stay and fewer transfusions than the group who did not receive the non-invasive method [37]

Another article describes how a 36 years old motorcyclist suffered from a type B pelvic fracture which led to hemodynamic instability after a motorcycle accident. A pelvic binder was placed wrongly to the patient and thus, stabilisation of the haemodynamic status could not be achieved. Later, the pelvis was adequately placed, resulting in a stabilisation of the haemorrhagic shock, showing the benefits and effectiveness of using PCCDs [39].

Croce et al evaluated the study of 241 patients with multiple pelvic ring fractures in which 186 of these received external stabilization for their pelvic fractures, 93 had a pelvic binder and 93 external fixations. As it could be observed in the study PCCDs were effective in controlling haemorrhage in patients with unstable pelvic fractures. It showed that those initially managed with the pelvic binder had similar clinical results of hemorrhagic shock when compared with those managed with external fixation as it can be seen in Table 2.2 [36]. Furthermore, PCCDs required considerably fewer blood transfusions and left the hospital sooner than those with external fixators.

Tabla 2.2: Characteristics and outcomes of the study when using PCCD or external fixation.

Stabilization type	**PCCD**	**External Fixation**
n	**93**	**93**
Injury Severity Score	**56**	**67**
Systolic blood pressure, mmHg	**112.5**	**101.6**
Base excess	**-7.15**	**-8.50**
Units of blood transfused in 24 h	**4.9**	**17.1**
Units of blood transfused in 48 h	**5.6**	**18.6**
Mortality rate, %	**26**	**37**

Pelvic binders are used all over the world on patients who have suspected or confirmed pelvic trauma that can lead to a major haemorrhage. However, many studies claim that a considerable number of pelvic binders are not placed correctly and show a need for further education upon application of PCCDs. As a matter of fact, if it is placed wrongly, the device might be useless or even worse, it can aggravate the injury. Bonner et al carried out a study aiming to assess the accuracy of placement of pelvic binders. The results showed that just half of the pelvic binders were placed in the wrong position. Among 167 patients, 65 (39%) pelvic binders were placed higher and 19 (11%) lower than the greater trochanter. It was observed that the fact of placing wrongly the PCCD could lead to a mean diastasis difference of 22 mm [31].

In addition, controlling the pressure of the pelvic binder is relevant in order to avoid pressure sores and/or skin abrasions produced by the friction. Tissue damage and skin necrosis are believed to occur when a contact pressure higher than 9.3 kPa is applied continuously for more than 2–3 hours, so the PCCD must be removed when the patient is haemodynamically stable. As a matter of fact, checking the pressure areas if extended use is planned and not overtightening the binder is highly recommended [41].

2.5. PCCDs placement feedback

Taken into account the previous information, the relevance of placing pelvic binder in the correct position and with the correct pressure, the protocol to follow when pelvic trauma occurs and the rise of clinical simulation; the viability and procedure of this Master Thesis has been ratified. The system that would assess the placement and pressure of the PCCD could promote student learning and knowledge without a risk of mistake. Therefore, making this system to gain a deeper knowledge and allowing clinical study and training for the treatment of many different types of pelvic trauma could transcend to save lives.

Chapter 3

Pelvis Simulator Design

This Chapter focuses on the design of the pelvic system in 3D. The pelvis is split into different parts depending on the type of fracture presented in Chapter 1. The pelvis will be designed to simulate partially unstable types B and completely unstable types C fractures according to the Tile classification system. Therefore, the pelvis has been divided into three pieces, two coxal and the sacrum with the coccyx as shown in Figure 3.1. Moreover, the system must be designed in such a way that it enables the coupling of sensors and actuators for posterior clinical simulation. Including actuators and sensors in the three pieces will allow the pelvis to simulate types B and C fractures.

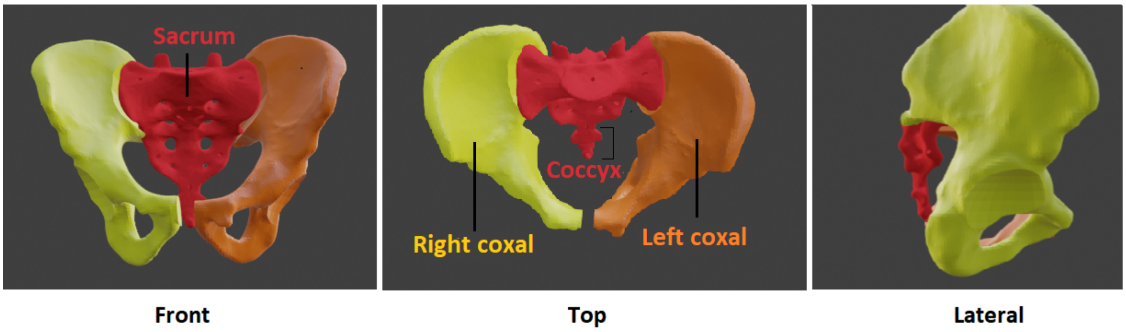

Figure 3.1: Views of the 3D pelvis design.

Furthermore, as explained in Section 1.1.2, the different fractures to simulate are the following [16]

- **Type B1 fractures**: they are open-book fractures that occur due to external rotation forces leading first to a disruption of the anterior pelvic arch. Then, the pubic symphysis diastasis triggers a partial rupture of the posterior arch. As it is a unilateral fracture, the other hemipelvis remains stable as shown in Figure 3.2. In open book fractures, if pubic diastasis separation is greater than 2.5 cm, the anterior sacroiliac ligament starts to disrupt.

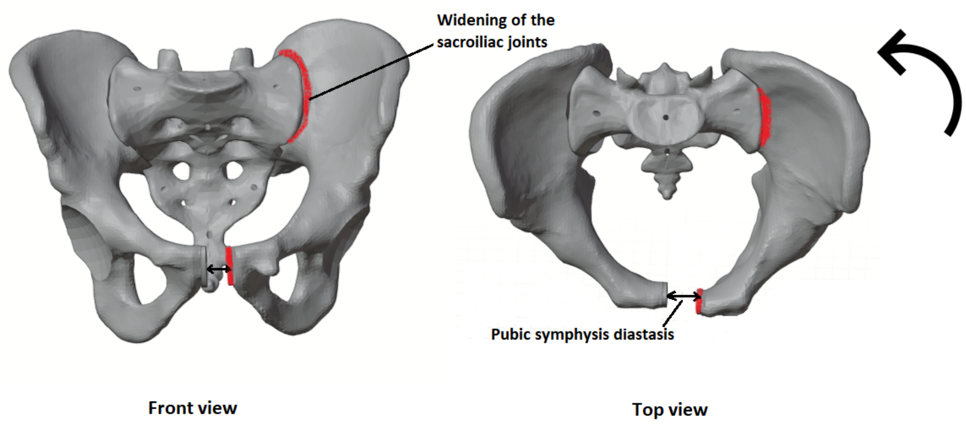

Figure 3.2: B1 fracture.

- **Type B2 fractures**: these fractures occur in one hemipelvis due to internal rotation forces. They lead to a partial rupture of the posterior arch and thus, to a pubic symphysis overriding as shown in Figure 3.3.

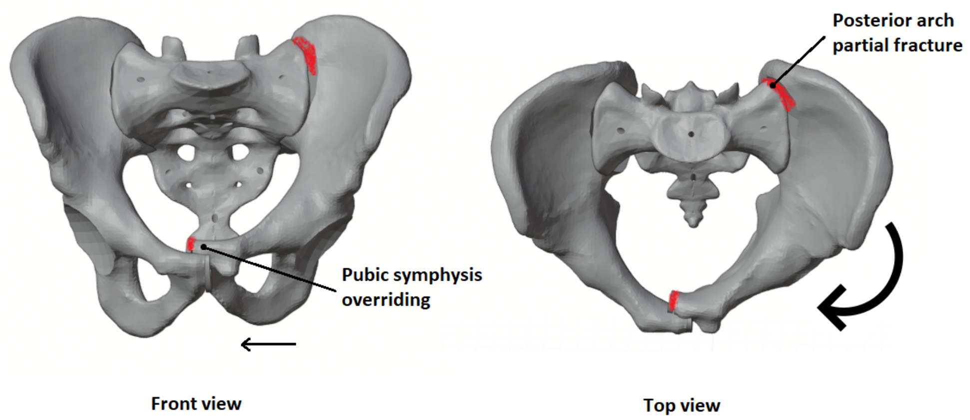

Figure 3.3: B2 fracture.

- **Type B3 fractures**: they are bilatereal fractures and they are produced when a combination between B1 and B2 fractures appear. They could be a B1/B1, B1/B2 or B2/B2 fractures. In Figure 3.4 a B1/B2 fracture is shown.

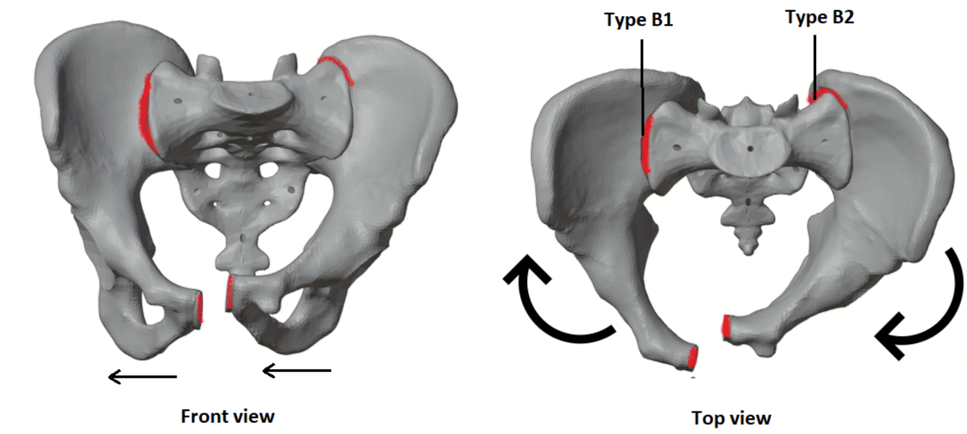

Figure 3.4: B3 fracture as a combination of a B1 and B2 fractures.

- **Type C1 fractures**: these fractures present a complete disruption of both, the anterior and posterior arch at the same time. These fractures are unilateral and therefore, the unstable fracture only occurs in one hemipelvis as shown in Figure 3.5.

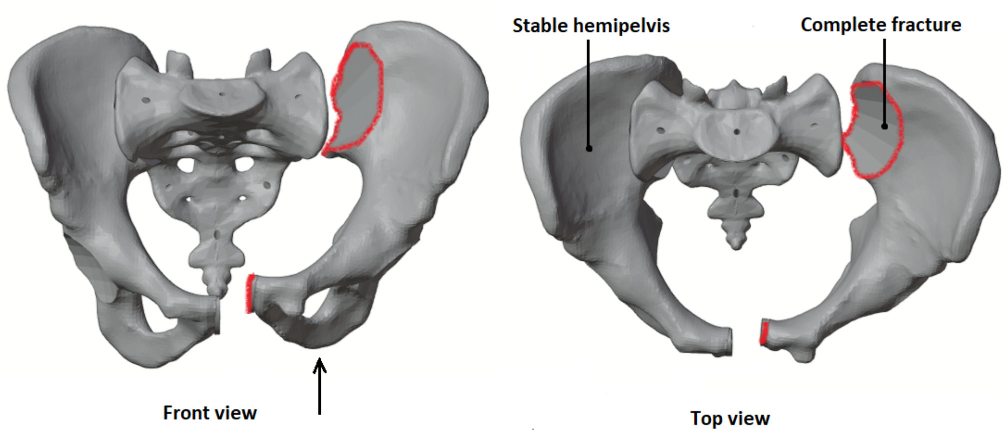

Figure 3.5: C1 fracture in which one hemipelvis remains stable.

- **Type C2 fractures**: these fractures occur bilaterally in both hemipelvis. In one of them, a type B fracture occurs and in the other one, a type C1 fracture as shown in Figure 3.6. That is, a complete unilateral fracture in one hemipelvis and parcial involvement of the posterior arch in the other hemipelvis.

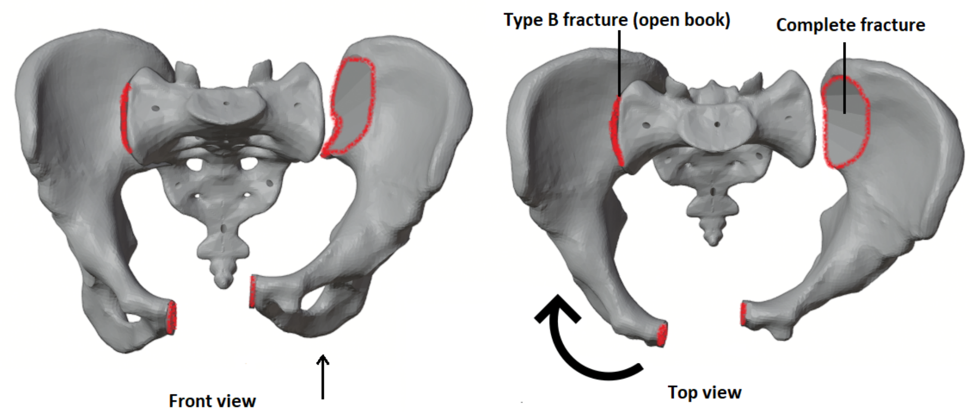

Figure 3.6: C2 fracture in which one hemipelvis suffers a partial fracture and the other one suffers a complete fracture.

- **Type C3 fractures**: These are fractures with complete bilateral involvement of the posterior arch. As shown in Figure 3.7 both hemipelvis are completely fractured producing a complex pelvic fracture.

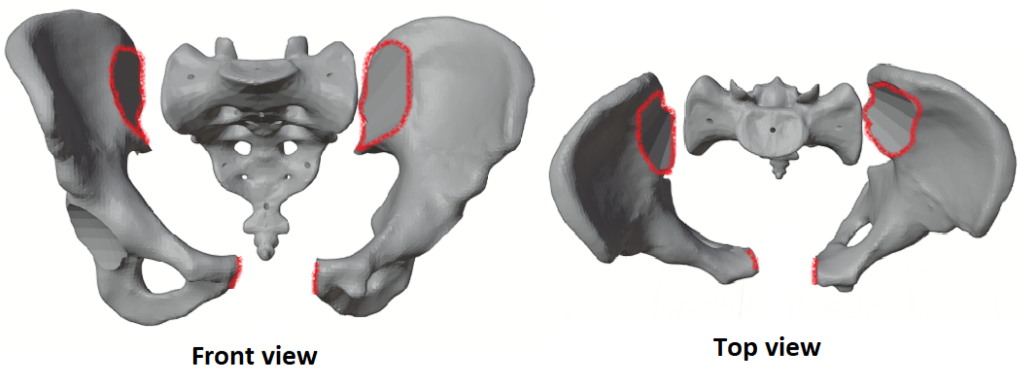

Figure 3.7: C3 fracture.

To design the pelvic system in 3D, different sofwares have been used :

- **Freecad and TinkerCad**: Both are free and open sources softwares for 3D modeling creation. These programs have been used with the purpose of making adjustemts, modifyng and acquiring the plans of the design in 2D and designing the electromagnets and sensors that will be seen later.

- **Blender**: this software has been used with the purpose of separating the bones as shown in Figure 3.8, assembling the pieces and acquiring 3D views of the design.

  Furthermore, once the design is ended, the 3D printing of the design would be done with the Ultimaker Cura program. The material used for the printing would be polylactic acid (PLA), one of the most popular materials used for 3D printing.

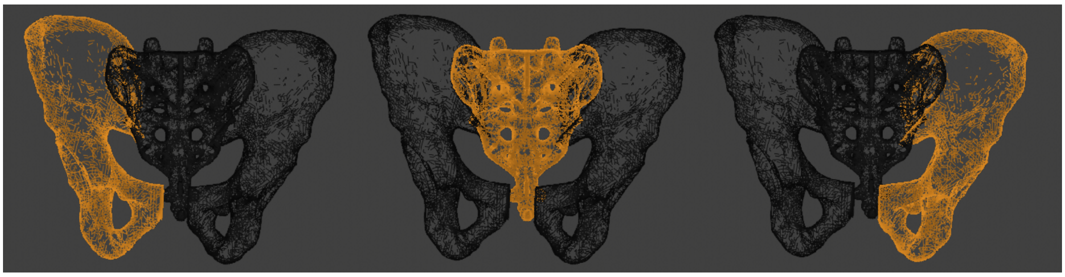

Figure 3.8: Separation of the bones in 3D with Blender.

3.1. Actuators and sensors

To be able to replicate different pelvic fractures, actuators will be needed to cause them. Actuators are devices that aim to generate automatically the movement of the elements of a system according to the orders given by an user. This movement is carried out by applying a mechanical or other force.

Therefore, placing the actuators at the rupture parts of the pelvis will allow simulating the chosen fracture without manual aid by separating different bones. Additionally, incorporating sensors allow measuring what happens in the different fractures when clinicians perform different mobilization techniques.

3.1.1. Electromagnets

The chosen actuators to simulate the fractures are electromagnets. They are a type of magnet in which, when applying an electric current, a magnetic field is produced. They can be deactivated by simply not applying such electric current. There are different types of electromagnets, among which stand out [42]:

- **Circular suction electromagnets:** they are circular shaped electromagnets as the ones shown in Figure 3.9 in which the attraction of the ferromagnetic parts is obtained when the solenoid is excited by a continuous electric current. When the power supply ceases, the maintained part is released.

Figure 3.9: Circular suction electromagnets [42].

- **Rectangular electromagnets:** these electromagnets act with the same principles as circular ones but they have a rectangular shape as shown in Figure 3.10.

Figure 3.10: Rectangular electromagnet [42].

- **Activating electromagnets:** these electromagnet act with a piston as the one shown in Figure 3.11 in which the piston movement from the initial position to the final position is performed by electromagnetic forces and the return to its initial position is carried out by external forces. Unlike the suction electromagnets, the solenoid when excited moves a piston making an effort of push or attraction.

Figure 3.11: Activating electromagnet [42].

The chosen electromagnets are circular 12V electromagnets. These small size electromagnets are easy and fast to operate and will connect with circular metal plates of around 15mm diameter to carry out the adhesion process. They can withstand high loads and they do not have moving parts to return to their initial position to be used again. Furthermore, its shape is rather suitable to be embedded and enabled in the pelvis. Different electromagnets have been considered:

- *Electromagnets with 20 mm diameter*: The dimensions of these electromagnets are an adsorption plane of 8 mm of diameter and a height of 15 mm. They can support up to 2.5 kilograms of weight, that is, a force of approximately 25 N. From now on, these electromagnets shown in Figure 3.12 will be called Type 1 electromagnets.

- *Electromagnets with 10 mm diameter*. The dimensions of these electromagnets are an adsorption plane of 4 mm of diameter and a height of 10 mm. They can support up to 0.3 kilograms of weight, that is, a force of approximately 3 N. From now on, these electromagnets shown in Figure 3.12 will be called Type 2 electromagnets.

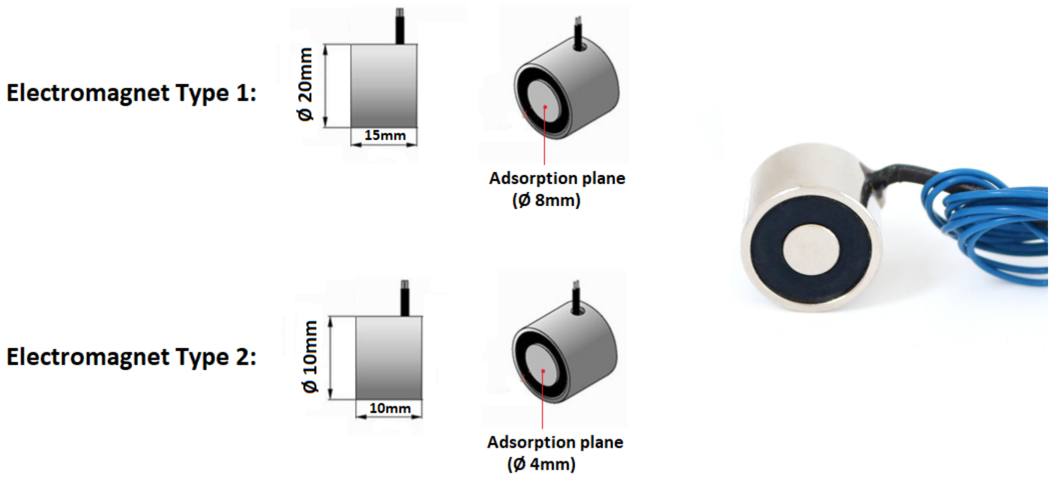

Figure 3.12: Electromagnets Type 1 and Type 2 [43].

3.1.2. Sensors

A sensor is a device that provides an output to some type of input from its environment. There are many different types of sensors: temperature sensor, light sensor, pressure sensor, magnetic sensor, humidity sensor or accelerometers among others. However, the sensors that have been considered to assess the union between the different pelvic bones are the following ones:

- **Force Sensitive Resistor (FSR):** These are sensors that allow to detect forces and physical pressure. FSRs are basically a resistor that changes its resistive value depending on how much it is pressed as shown in Figure 3.13 [44].

Figure 3.13: Force Sensitive Resistor sensor [44].

- **Optical sensors**: They detect the presence of an person or an object that interrupts the light beam that reaches the sensor. The most common is the Light Dependent Resistor (LDR) shown in Figure 3.14 [45].

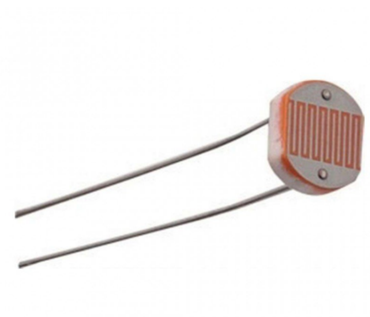

Figure 3.14: Light Dependent Resistor sensor [45].

- **Magnetic sensors:** Magnetic sensors work based on the Hall effect which allows detecting the presence of a magnetic field [46]. The output voltage of these sensors is directly proportional to the magnetic field strength through it. Magnetic sensors allow measuring some parameters such as distances or velocity. They provide a signal in the presence of the magnet's magnetic field.

FSR sensors are susceptible to rupture due to irregularities in the pelvis and the force that must be applied to bring the bones together. In addition, both the FSR and the optical sensors do not have a reference to determine the position and therefore, it is not possible to know whether the union has been carried out correctly or not.

Thus, the chosen sensors are magnetic sensors. The chosen model is the module KY-035, shown in Figure 3.15. It is an analogue magnetic field sensor module, which will allow quickly, easily and accurately detect the proximity of magnets. This module has 3 pins, and its dimensions are 20 x 11 x 1.2 mm^3 which allows easy handling and implantation in the pelvic system. Furthermore, it works with magnetic fields in the

650-1000 Gauss range what will allow working with small magnets [46].

Figure 3.15: Magnetic sensor module KY-035 [46].

The KY-035 sensor module has a linear response, that is, it will translate into voltage the variations of the magnetic field as shown in Figure 3.16 [47].

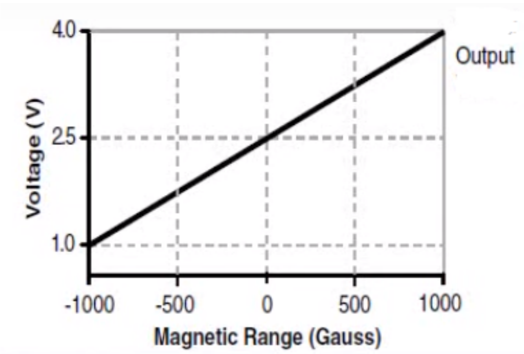

Figure 3.16: Voltage response of the KY-035 sensor in relation to the magnetic field [47].

The chosen magnets are circular magnets of neodymium material which is a high power permanent magnet as shown in Figure 3.17, having a diameter of 12 and 13mm. These magnets will serve to create a magnetic field that will be detected by the magnetic sensors, that is, depending on their relative position with the sensors, one output or another will be obtained. Therefore, by placing the sensors on one side of the bone fracture and magnets on the other side, the position and relative movement between both bones can be known.

In addition, epoxy resin has been considered to adhere the electromagnets, sensors and magnets to the pelvis. This is the most used glue in 3D printing as it is a very powerful adhesive capable of bonding a wide variety of materials, including metals with the PLA used in 3D printing.

Figure 3.17: Circular neodymium magnets of 13 mm of diameter [48].

3.2. Design for enabling electromagnets

To be able to produce the different pelvic fractures and to close them depending on the clinician's manoeuvres; different designs are presented hereafter.

3.2.1. Electromagnets in the ilium

In the two coxal bones, the part of the ilium was considered as the sacroiliac union is the region in which both type B and type C fractures take place. On the one hand, if a type C fracture wants to be simulated, a complete disruption of the sacroiliac union has to be carried out. On the other hand, if a type B fracture wants to be simulated, a semi-disruption of the sacroiliac union has to be executed. Therefore, to achieve the simulation of both Tile classification types of fractures with electromagnets, different proposals have been considered:

- **Controling the electromagnet's forze:** with electromagnets, the magnetic field can be changed by controlling the amount of electric current applied. In this way, semi-fractures or total fractures could be achieved with just one electromagnet. Hence, if a partial fracture is simulated, it could be done by applying a specific current to the electromagnet that creates an attractive force proportional to the current. Moreover, if a complete disruption is simulated, it would be enough just to deactivate the electromagnet.

  The chosen electromagnet for this alternative would be type 1 electromagnet. This is important as a higher force to hold the sacroiliac union is needed than the force to join the pubic symphysis. The design of this alternative is shown in Figure 3.18. A 24 mm diameter hole has been made to insert the type 1 electromagnets, leaving 4 mm for the cables guidance.

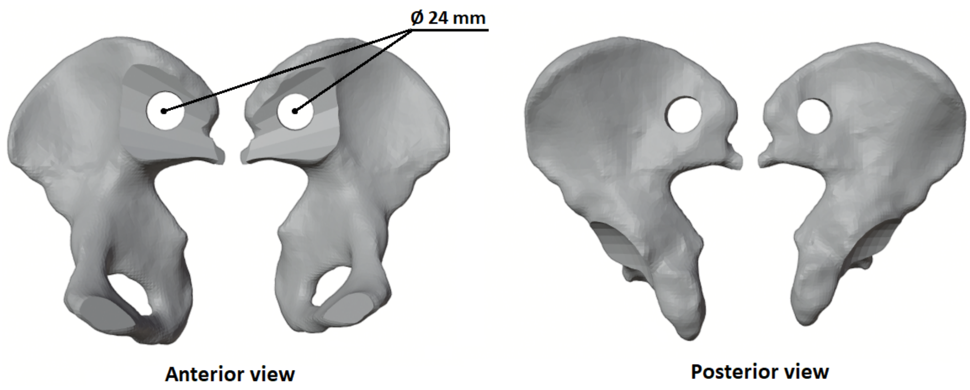

Figure 3.18: Iliac design for type 1 electromagnets controlling the force.

Figure 3.19 shows the assembly of the electromagnets in the bones and the cable guidance through the back part of the iliac.

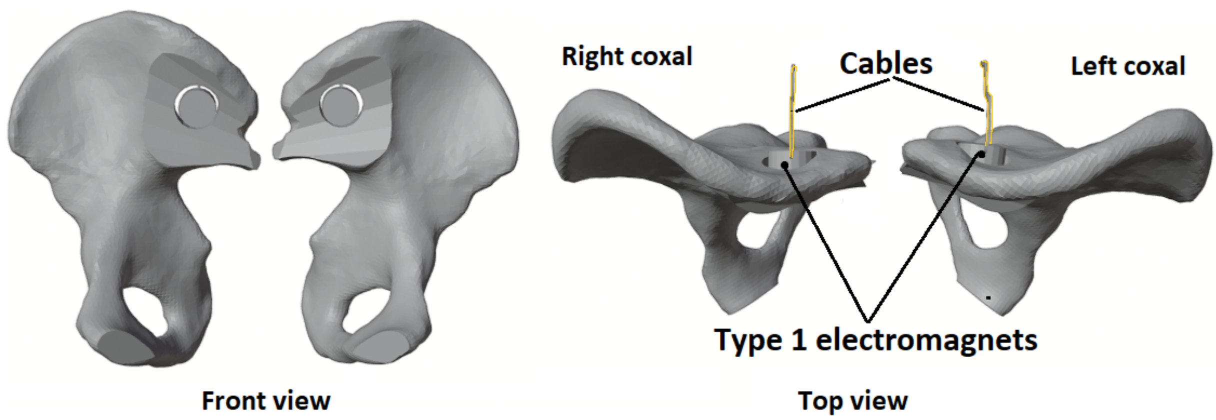

Figure 3.19: Iliac bones with assembled type 1 electromagnets controlling the force.

- **Placing two electromagnets:** the design for placing two electromagnets on each iliac has been carried out. Placing two electromagnets next to each other could reproduce a complete fracture or a semi-fracture depending on whether both electromagnets are deactivated or just one of them. Furthermore, the union would be fully guaranteed when both electromagnets are activated.

  The process to follow based on the type of fracture is:

  B1: the fracture will be simulated by repelling or deactivating the proximal electromagnet and keeping the distal one activated.

  B2: this fracture will be simulated oppositely to the B1. Therefore the proximal electromagnet will be activated and the distal one will be deactivated.

  B3: this fracture will be simulated as a combination of B1 and B2 fractures.

  C1: this fracture will be simulated by deactivating both electromagnets in one iliac and keeping active the 2 electromagnets of the other iliac.

C2: this fracture will be created by deactivating both electromagnets in one iliac and reproducing either B1 or B2 fractures in the other one.

C3: this fracture will be created by deactivating both electromagnets of both iliac.

For this alternative, the design has been carried out with the two types of electromagnets since both are suitable for this option:

- *Electromagnets type 1*: the electromagnets will be placed in the ilium part of the coxal bones as shown in Figure 3.20. The diameter of the holes that will place the electromagnets will be of 24 millimeters. 20 millimeters is the dimension of the electromagnet and the remaning 4 millimeters are considered for the cables guidance.

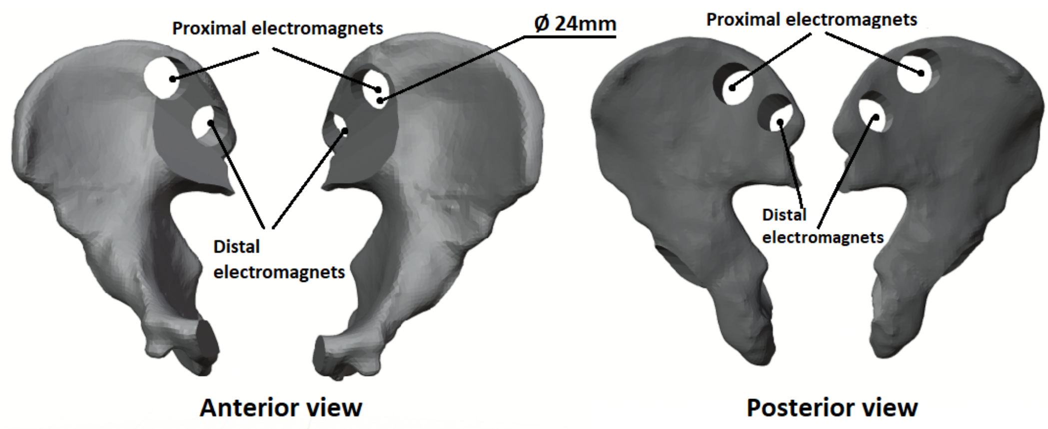

Figure 3.20: Views of the design of the iliac bones for two electromagnets type 1.

The reason why through-holes have been made instead of gaps is that the average thickness in the ilium is about 12 mm and the type 1 electromagnet measures 15 mm high as it can be seen in Figure 3.21. In addition, it is easier for the cables of the electromagnets to pass through the posterior part of the coxal as shown in Figure 3.22. The assembly of the electromagnets type 1 in the ilium can be seen in Figure 3.22

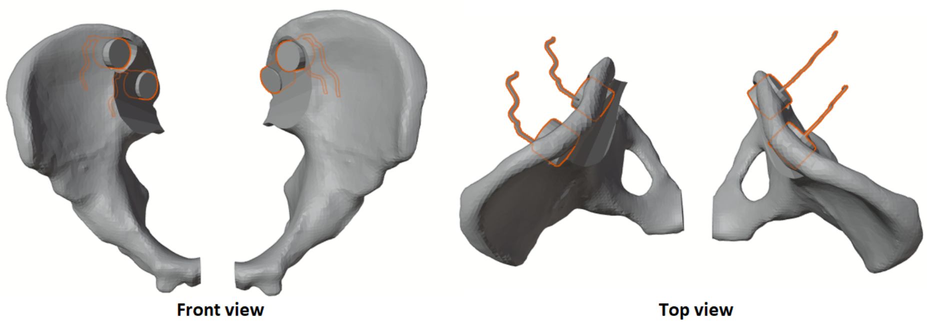

Figure 3.22: Two electromagnets type 1 placed in the ilium.

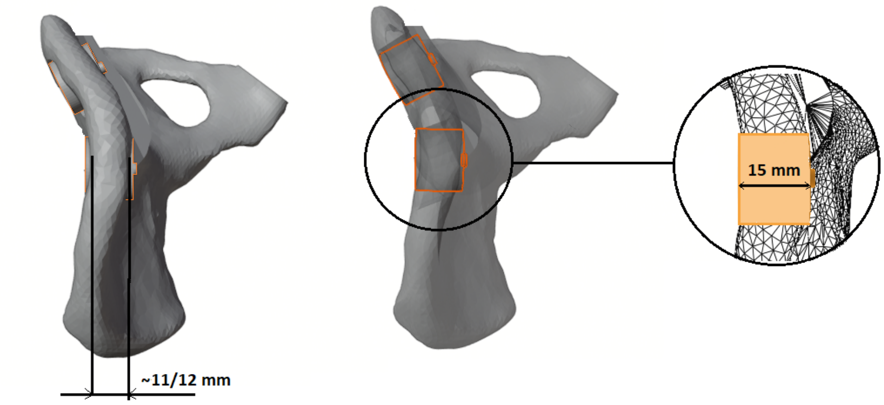

Figure 3.21: Top view of the ilium and its measurement difference with the type 1 electromagnet.

- *Electromagnets type 2*: To enable the cables enough space for its guidance, a margin of 4 mm has been left, thus, 14 mm holes have been made. The designs of the coxal with the holes in which the actuators type 2 will be placed as shown in Figure 3.23.

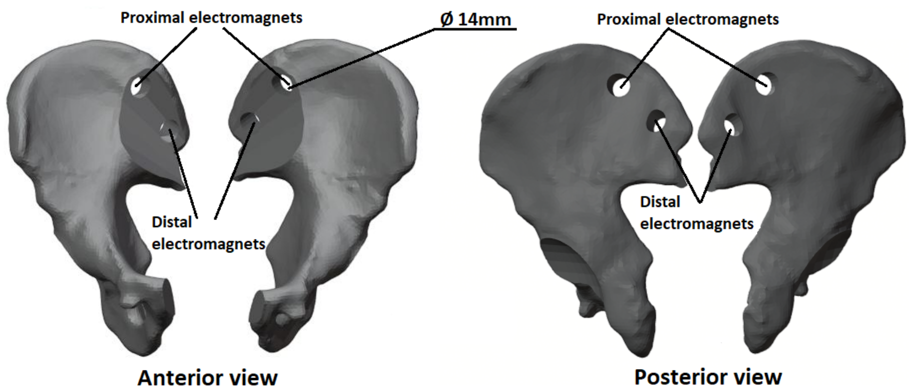

Figure 3.23: Views of the design of the iliac bones for two electromagnets type 2.

The assembly of the electromagnets type 2 in the ilium can be seen in Figure 3.24.

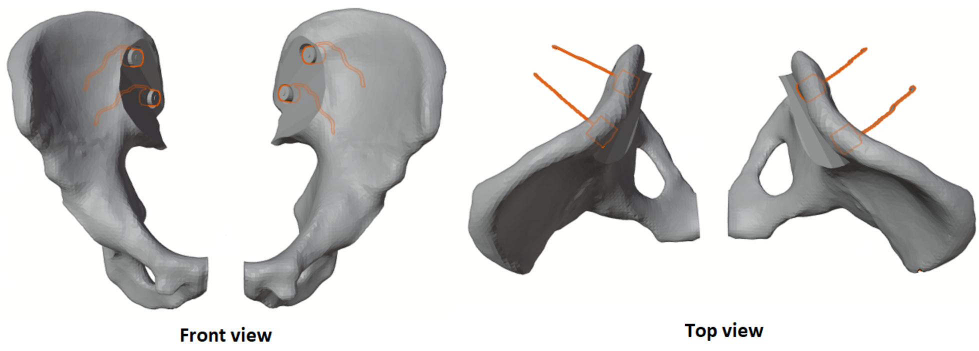

Figure 3.24: Two electromagnets type 2 placed in the ilium.

For this design, through-holes have also been made. Although in this case the thickness of the ilium is around 11mm, a bit bigger than the dimension of the electromagnet type 2 which is 10 mm, it has been considered to make through-holes in order to pass the cables through the rear of the coxal.

3.2.2. Pubis

Regarding the fracture produced in the pubis, another electromagnet to simulate the pubic disruption has been considered. The design has been carried out taken into account electromagnets type 1 and type 2. The width of the human pubic symphysis measures on average about 5-6 mm as shown in Figure 3.25 [49].

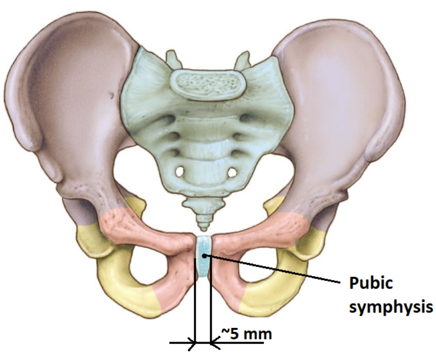

Figure 3.25: Pubic symphysis width.

To simulate the pubic symphysis disruption, two possibilities have been considered. In the two alternatives, the hole that enables the electromagnet placement has been left open for the easy managment of the cables. In addition, a millimeter of margin has been left in the electromagnet's hole to ensure the engagement of the electromagnets. Furthermore, to connect with the electromagnet of one pubis, circular metal plates will be assembled in the opposite pubis.

1. **Disruption in the left or right part of the pubic symphysis:** a hole is designed with a depth equal to the height of the electromagnet minus the

symphysis width. Therefore, the electromagnet acting as the pubic symphysis is placed, as shown in Figure 3.26. The rupture would occur on the left side of the pelvis. In addition, another gap of 17 mm diameter and 1 mm depth has been designed in the left pubis to enable the circular metal plates that will adhere to the electromagnet as shown in Figure 3.27.

However, if a disruption in the right side is wanted, this alternative is symmetrical to making a disruption on the left side. That means placing this time the electromagnet on the left side protruding 6 mm and the metal plate on the right side embedded

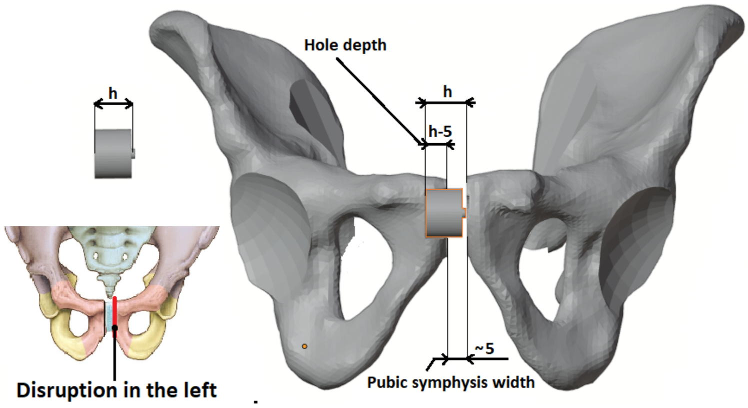

Figure 3.26: Simulating right lateral symphysis fracture by electro-magnet.

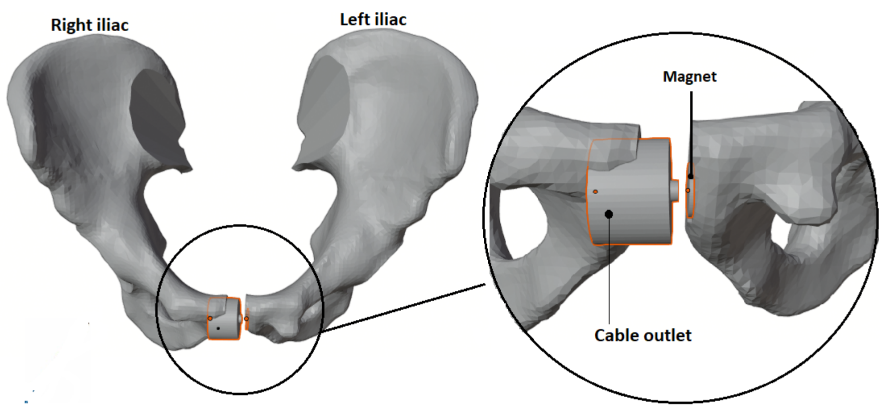

Figure 3.27: Pubic design and 3D view with assembled electromagnet in the right iliac and metalic plate in the left iliac.

2. **Disruption in the middle part of the pubic symphysis:** it would be achieved by designing the hole in such a way that the electromagnet protruded just 3 mm and then, making a 3 mm extrusion in the other side of the pubic

symphysis. This extrusion at the same time will contain a hole of 17 mm diameter in order to place the metalic plate as shown in Figures 3.29 and 3.28.

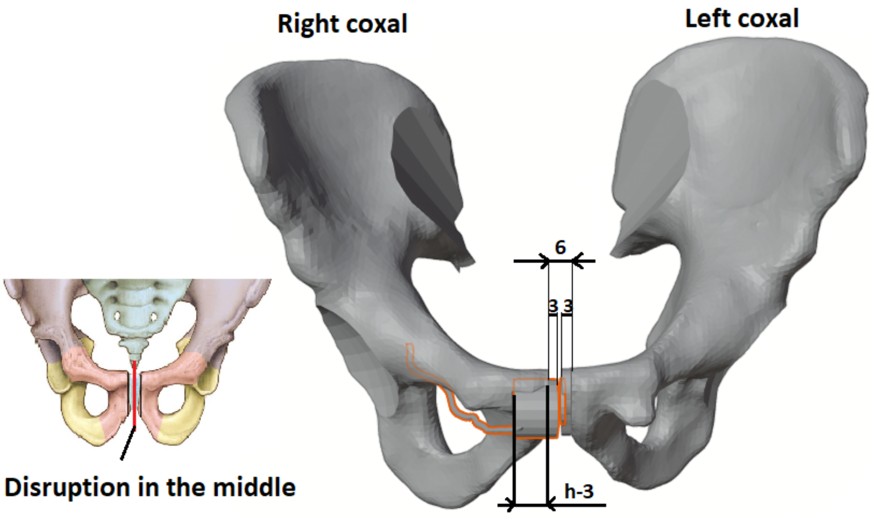

Figure 3.28: Simulation of rupture in the middle of the symphysis.

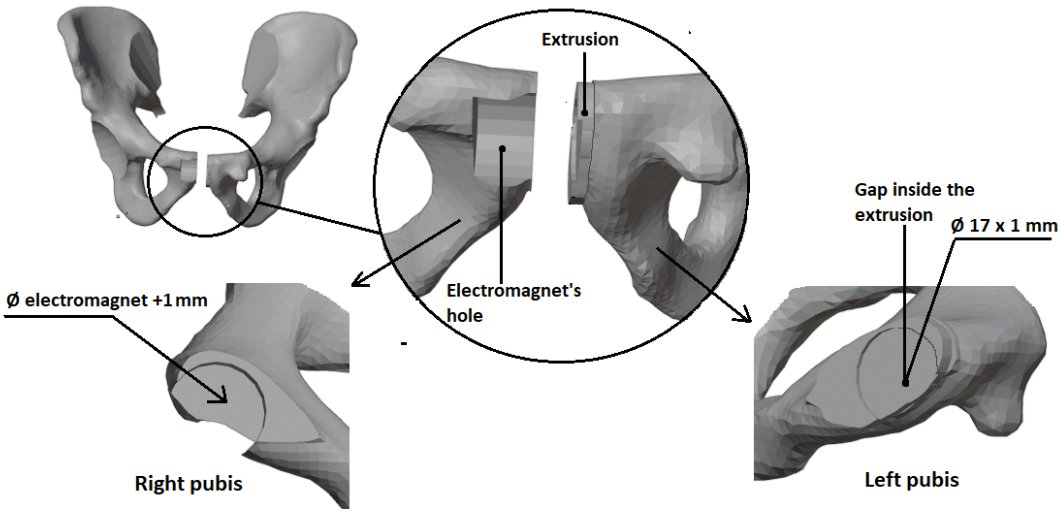

Figure 3.29: Design of the design of the pubis to simulate rupture in the middle of the symphysis.

3.2.3. Sacrum

The sacrum bone has been designed in order to complete the sacroiliac union. Circular metal plates will be placed in the sacrum, and together with the electromagnets placed in the coxal, these plates will accomplish the connection. Therefore, holes that form an intrinsic part of the sacrum have been designed to enable the placement of these metals as shown in Figure 3.30. These gaps have 17 mm in diameter and 1 mm depth for 16 mm circular metal plates to in.

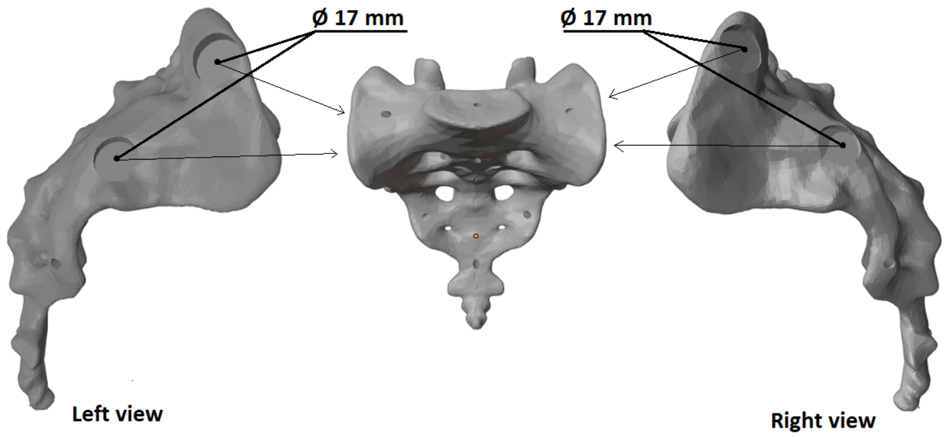

Figure 3.30: Views of the sacrum with gaps for metalic plates.

3.3. Design for enabling sensors

In this Section, the design of the pelvis in order to enable sensors has been accomplished.

3.3.1. Ilium

Regarding the sensors, the ilium will hold two magnets on each coxal, as shown in Figure 3.31. The magnets will be embedded in holes of 13 mm in diameter and 1 mm deep. The function of these magnets is to detect the union with the sensors attached to the sacrum explained later and, thus, to assess how the sacroiliac union has been made after treatment to the patient.

The chosen magnets will have 12 or 13 mm diameter depending on the diameter tolerance when printing and have been predisposed in such a way that they connect with the front and back part of the sacrum to acquire an accurate response from sensors.

The hole for the rear magnet has been designed inside a squared platform of 15 mm and 3 mm height. This platform is a rectangular extrusion intrinsic to the ilium and it is made for two reasons: the first one is to facilitate the placement of this sensor as the surface of this part of the coxal bone is not flat and quite irregular; and the second one is that the magnet is closer to the magnetic sensor. The rectangular extrusion contains a circular hole with the same characteristics as the one made in the anterior part of the ilium, that is, 17 mm diameter. The same design has been done for the right coxal as shown in Figure 3.32. It shows both iliac with the holes and the magnets assembled in them.

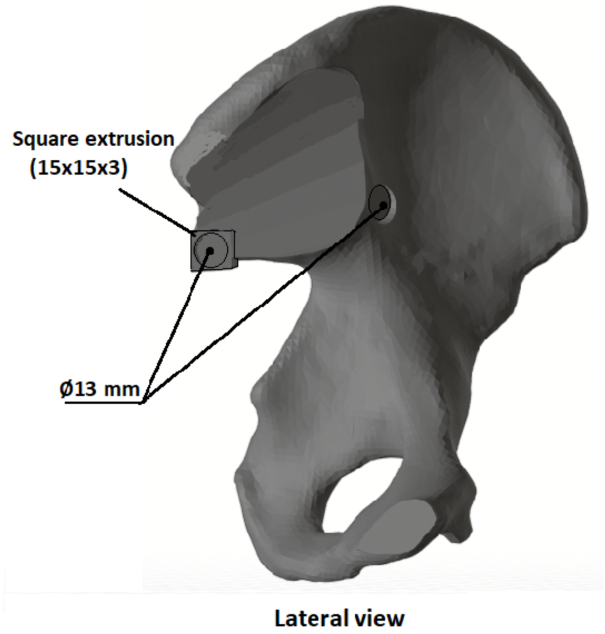

Figure 3.31: Magnet's predisposition for sensors in the coxal.

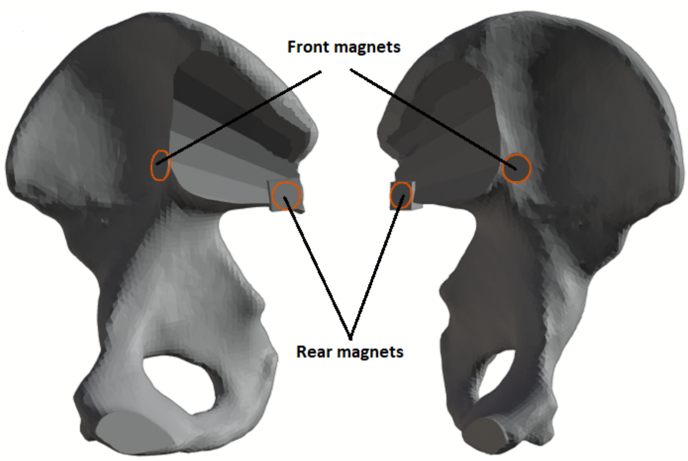

Figure 3.32: Assembly view of sensors in both coxal.

3.3.2. Pubis

In the pubis, besides electromagnets, magnetic sensors will also be placed to determine the correct union between the two pubic bones. To fulfil the connection, 2 sensors will be inserted in the left pubis and the corresponding magnets on the right, as shown in Figure 3.33. Therefore, to guarantee such implementation, 2 platforms to place the sensors in the left pubis have been designed. In the other pubis, two holes have been designed to fit in the respective magnets.

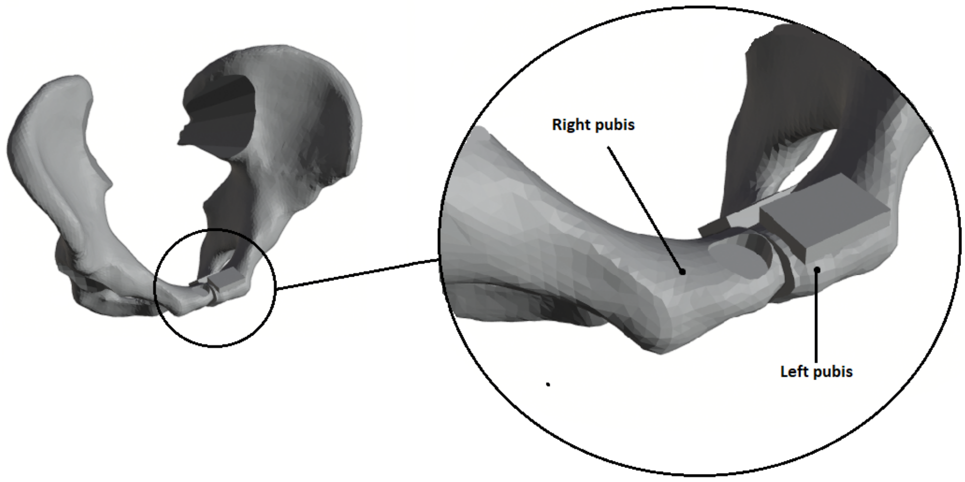

Figure 3.33: 3D view of both pubis' design.

On the one hand, the rectangular platforms, which are an intrinsic part of the pubis, are 22 mm wide and 15 mm high, leaving some room to correctly insert the sensors. On the other hand, the extrusion is 3 mm to give the sensors a certain height and prevent the module from colliding with the pubis.

The holes/gaps to embed the magnets have 13 mm diameter and 1 mm of depth to assemble the 12 or 13 mm magnets. Figure 3.34 shows the measurements of both, the 2 platforms and the 2 holes designed to enable the corresponding material.

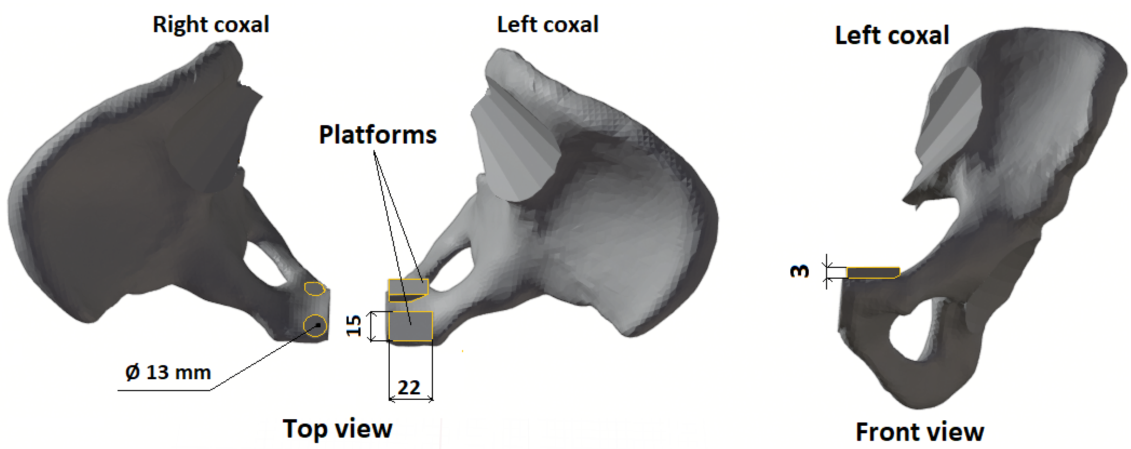

Figure 3.34: Design and measures to enable sensors and magnets in the pubis.

The sensors and magnets described in this Chapter have been designed and assembled in the pubic bone, as shown in Figure 3.35.

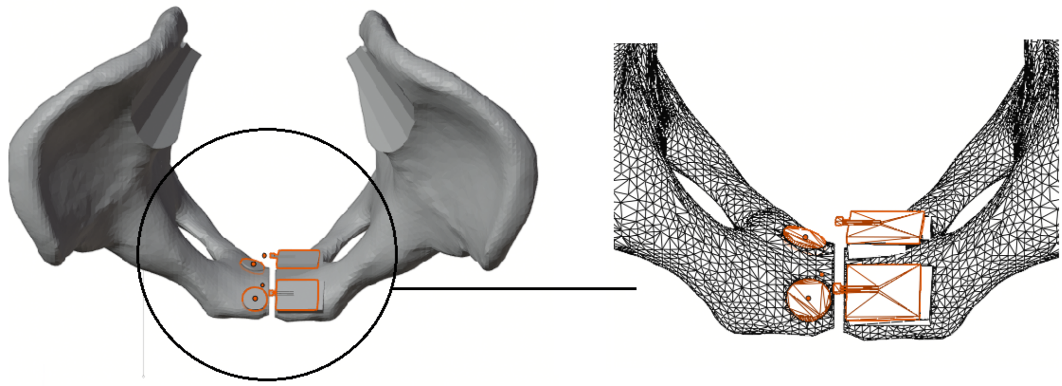

Figure 3.35: Connection of sensors and magnets assembled in the pubis.

3.3.3. Sacrum

The design of the sacrum in order to enable sensors has been carried out to assess the sacroiliac union. It consists of the extrusion of flat rectangular platforms that will be intrinsic parts of the pelvis on which the magnetic sensors will be adhered as shown in Figure 3.36. These sensors will give an output based on the proximity of the magnets placed in the two iliac.

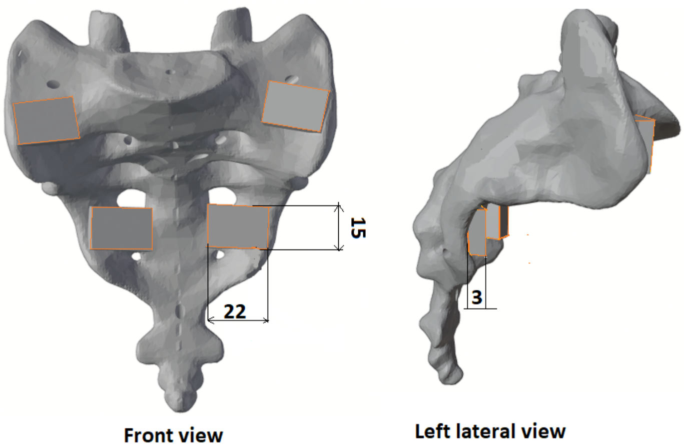

Figure 3.36: Front view of the sacrum design to enable sensors.

The sacroiliac connection between the sensors placed on the sacrum platforms and the magnets placed in the iliac holes can be seen in Figure 3.38.

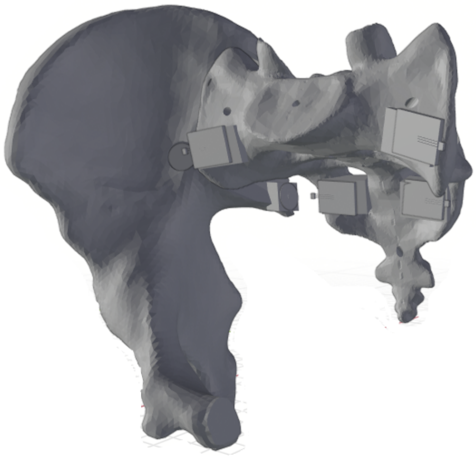

Figure 3.37: 3D projection of the sacroiliac connection with sensors.

Each sensor has its magnet. Two sensors are placed in one fracture point of one bone and the corresponding magnets will be placed in the fracture points of the other bone, as shown in the Figure. The idea is that each sensor captures the magnetic field of its corresponding magnet and that it provides a response depending on the proximity with the mentioned sensor.

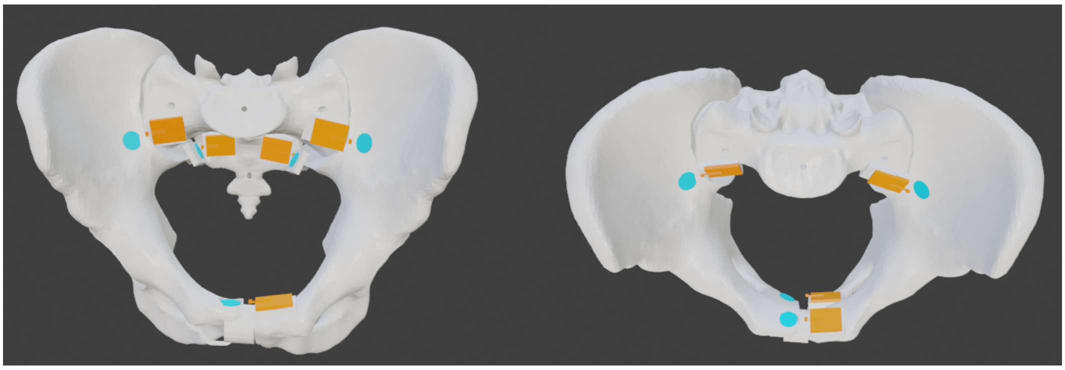

Figure 3.38: Whole system of sensors (orange) and magnets (blue).

3.4. Advantages and disadvantages

Once all the design alternatives have been considered in this Chapter, the advantages and disadvantages of each are described to assess the viability of each one.

Regarding the ilium design:

- **Controling the electromagnet's forze**
  - *Advantages*:
    - Only one electromagnet is required in the ilium part.

    * The electromagnet can be placed with total freedom in the sacroiliac union since there is plenty of space.
  - *Disadvantages*:
    * Very complex electronic management is required.
    * This alternative might not differentiate well between type B1 or type B2 fracture when simulating a partial fracture and thus, external aid for the internal or external rotation would be needed.

- **Placing two electromagnets**
  - *Advantages*:
    * Easier to simulate and differentiate partial fractures
    * The sacroiliac union is assured when the two electromagnets are connected to the sacrum.
  - *Disadvantages*:
    * Ilium space is limited, especially for Type 1 electromagnets.
    * It is necessary to handle a greater number of electromagnets.
    * More expensive.
    * By making two holes, the stresses are concentrated around them. This stresses could make the 3D printing susceptible to breakage in ilium part.

Regarding the electromagnet's type:

- **Type 1 electromagnet**
  - *Advantages*:
    * Greater suction and repulsion force.
    * Greater power range to vary each type of fracture.
    * Guaranteed stability when both electromagnets are active in the ilium
  - *Disadvantages*:
    * Very limited space.
    * The power of the type 1 electromagnets could interfere with the output of the sensors.

- **Type 2 electromagnet**
  - *Advantages*:
    * Suitable for iliac space
    * The small power ranges they manage will interfere on a smaller scale than type 1 with the sensor output.
    * Since the surface of the absorption plane of the electromagnet is considerably less than the surface of the metal plates, the adhesion is guaranteed.

- *Disadvantages*:
  * The range of force that this electromagnet handles may not be enough to hold the joints.
  * The range of force that this electromagnet handles may not be enough to create repulsions large enough to appreciate the fracture.

Regarding the pubic part: type 1 electromagnets have been chosen. These electromagnets have been considered to be more appropriate than type 2 for the pubis as a sufficient repulsive force will be needed to separate the pubic symphysis at least 2.5 cm, for the sacroiliac disruption to begin in some fractures. Concerning if the fractures are wanted in the middle or on the side, there are no advantages of one over the other because they depend on the demands to simulate.

Chapter 4

Conclusions and future work

As it has been seen in Chapter 3, each one of the fractures of the Tile classification entails carrying out a different process to produce them. In this Chapter the protocols to follow to produce each of the fractures and to receive information from the sensors are shown.

4.1. Validation process

This Section presents the instructions to follow in order to validate and simulate the implemented system that has been shown in Chapter 3. Taking into account the advantages and disadvantages of the different alternatives, the alternative of 2 electromagnets in each iliac has been considered more feasible than controlling the force of a single electromagnet to simulate the ruptures as it is more accurate to emulate partial fractures with two electromagnets. Therefore, the alternative of 2 electromagnets is the one described below. Furthermore, these instructions are valid for both types of electromagnets. However, only type 1 electromagnets will be presented since the same process would be carried out with type 2 electromagnets. Thus, whatever the type of electromagnets is, there will be 5 of them: 1 in the pubis and 2 in each iliac as it is shown in Figure 4.1 where the five electromagnets are activated and thus, simulating a stable pelvis without fractures.

To facilitate the understanding of the processes that will be shown, the different electromagnets have been enumerated as in Figure 4.2.

1. **Electromagnet 1** (E1): proximal electromagnet of the right ilium.
2. **Electromagnet 2** (E2): distal electromagnet of the right ilium.
3. **Electromagnet 3** (E3): proximal electromagnet of the left ilium.
4. **Electromagnet 4** (E4): distal electromagnet of the left ilium.
5. **Electromagnet 5** (E5): pubic electromagnet.

In addition, in the same way as with electromagnets, sensors have also been listed as shown in Figure 4.3.

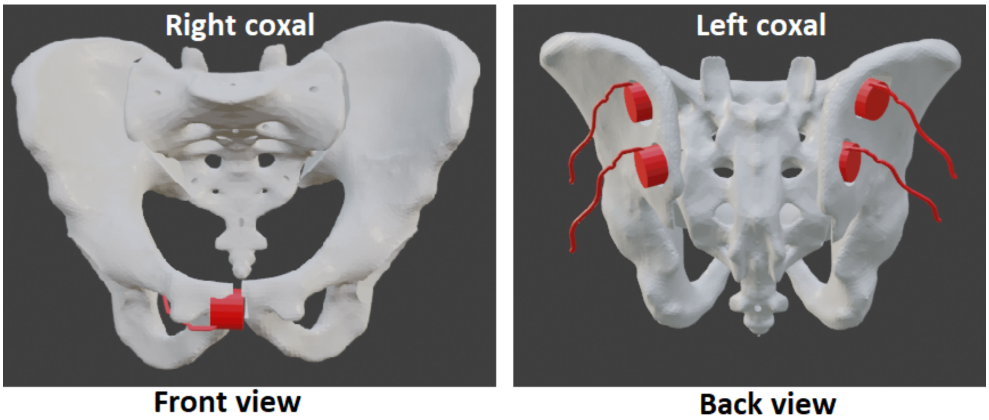

Figure 4.1: Simulation of a pelvis without fractures.

1. **Sensor 1** (S1): proximal sensor of the right part of the sacrum.
2. **Sensor 2** (S2): distal sensor of the right part of the sacrum.
3. **Sensor 3** (S3): proximal sensor of the left part of the sacrum.
4. **Sensor 4** (S4): distal sensor of the left part of the sacrum.
5. **Sensor 5** (S5): proximal pubic sensor
6. **Sensor 6** (S6): distal pubic sensor

Each of the magnetic sensors will detect the magnetic field of the corresponding magnets presented in Chapter 3. When the pelvis does not present a fracture, the sensors should provide a tension value that will be taken as a reference. Once the fracture occurs, the bones will generally tend to separate and therefore, the distance between the magnet and the sensor will increase, causing the tension value of the sensor to decrease. Then when the clinician wants to stabilize the pelvis, the sensors and magnets will get closer increasing the magnetic field detected by the sensor and thus, the voltage output value will increase.

To validate the design proposed, it is necessary to explain how the different fractures will be produced and how the sensors would be read. In the following figures the electromagnets will be highlighted in red and the sensors in blue. Therefore, the protocol to validate each of the fractures is shown below:

- **B1 fracture:** Unilateral, open book fracture as shown in Figure 4.4. The instructions to simulate this fracture are presented below:
  1. Deactivate first E5 to perform a pubic diastasis.
  2. Since the voltage output is directly proportional to the perceived magnetic field, and at the same time this perceived magnetic field dissipates as the sensor moves away from the magnet; a relationship of the output voltage obtained and the distance in centimeters between the sensor and the sensor can be obtained. Hence, when the S5 and S6 sensors show an output voltage that corresponds to a pubis diastasis higher than 2,5 cm,

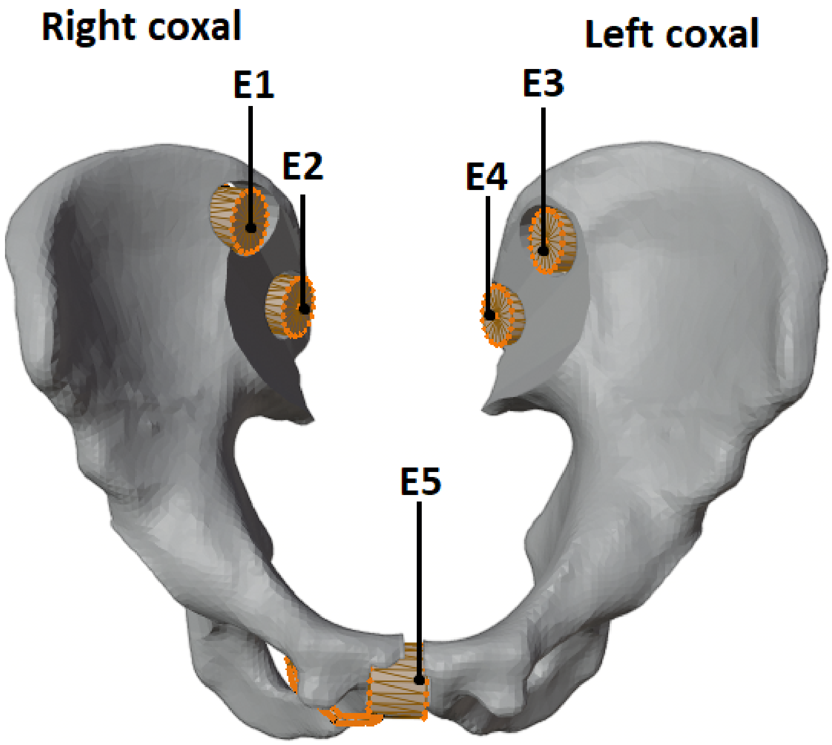

Figure 4.2: List of the 5 electromagnets.

the sacroiliac disruption begins to occur. Therefore, at this point one of the proximal electromagnets of the ilium will be disconnected to perform the sacroiliac disruption:

a. If the fracture occurs in the right coxal: deactivate E1 while E2, E3 and E4 remain active.

b. If the fracture occurs in the left coxal: deactivate E3 while E1, E2 and E4 remain active.

3. Once the fracture is simulated, clinicians should place the pelvic binder or any other maneuver to treat the fracture. Therefore, thanks to the sensors as shown in Figure 4.4, feedback on what really happens in the fracture after the maneuvers can be measured.

   a If the fracture occurs in the right coxal: The sensor S1, which is where the right sacroiliac disruption will take place, should be evaluated as well as the pubic sensors S5 and S6.
   When this fracture occurs, the tension value of S1 should drop as it moves away from the magnet integrated in the ilium. On the other hand, the sensor S2 must also be taken into account as the output from this sensor will increase due to the external rotation that causes the magnet to approach the sensor.
   Therefore, during and after clinical management, sensors S1, S5 and S6 would be read in order to verify what happens in the fracture. This way, it could be validated whether different manoeuvres have an impact on the bone fractures or not.

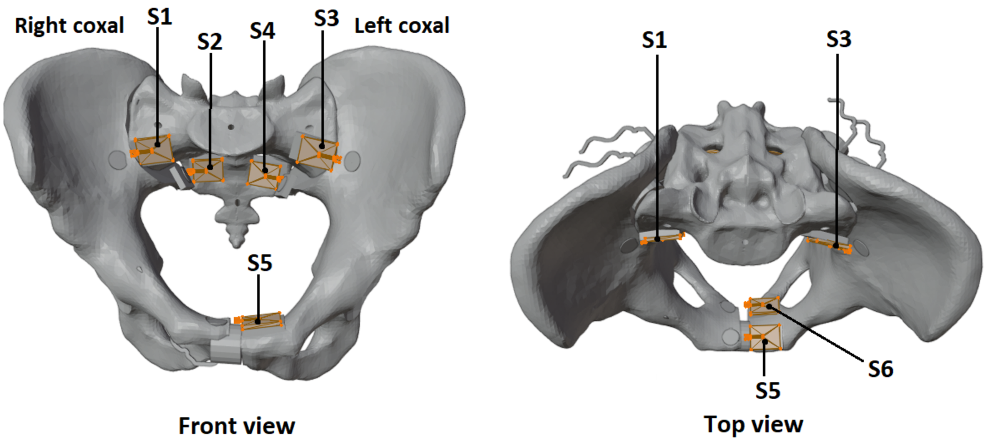

Figure 4.3: List of the 6 sensors.

b If the fracture occurs in the left coxal: The sensor S3, which is where the left sacroiliac disruption will take place, should be evaluated as well as the pubic sensors S5 and S6.
When this fracture occurs, the tension value of S3 must decrease as it moves away from the magnetic field of the magnet integrated in the ilium. On the other hand, the sensor S4 must be taken into account as the output from this sensor increases due to the external rotation that causes the magnet to approach the distal sensor.
Therefore, during and after clinical management, sensors S3, S5 and S6 would be read in order to verify what happens with the pelvis. In this way, it could be validated if the clinical management has an impact on the bone fractures or not.

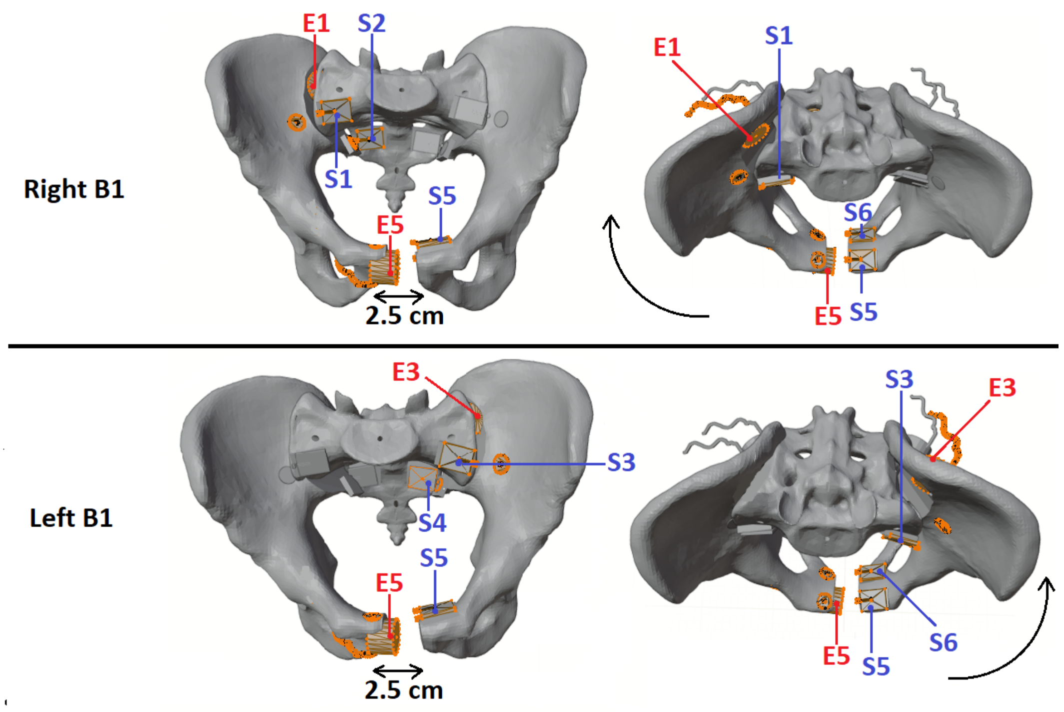

Figure 4.4: Electromagnets and sensors arrangement for B1 fractures.

- **B2:** Unilateral, internal rotation fracture as shown in Figure 4.5. The instructions to simulate this fracture are presented below:

  1. Disconnect first E5 to perform a pubic diastasis.
  2. Deactivate a distal electromagnet of the ilium to perform a sacroiliac disruption:
     a. If the fracture occurs in the right coxal: repell E2 while E1, E3 and E4 remain active.
     b. If the fracture occurs in the left coxal: repell E4 while E1, E2 and E3 remain active.
  3. Assess the fracture and the clinical management with the magnetic sensors shown in Figure 4.5.
     a If the fracture occurs in the right coxal: The distal right sensor S2 should be evaluated as well as the pubic sensors S5 and S6.
     When a type B2 fracture occurs, the tension value of S1 should drop as it moves away from the magnet integrated into the square platform in the ilium due to internal rotation.
     When performing clinical management, sensor S2, S5 and S6 should increase the output value since the bones will begin to join and thus the sensors will get closer to their respective magnets.
     b If the fracture occurs in the left coxal: The distal left sensor S4, which is where the left sacroiliac disruption will take place, should be evaluated as well as the pubic sensors S5 and S6.

When this fracture occurs, the tension value of S4 must decrease as it moves away from the magnetic field of the distal magnet of the left ilium.
When performing clinical management, sensors S4, S5 and S6 should increase their output value since they will get closer to their respective magnets.

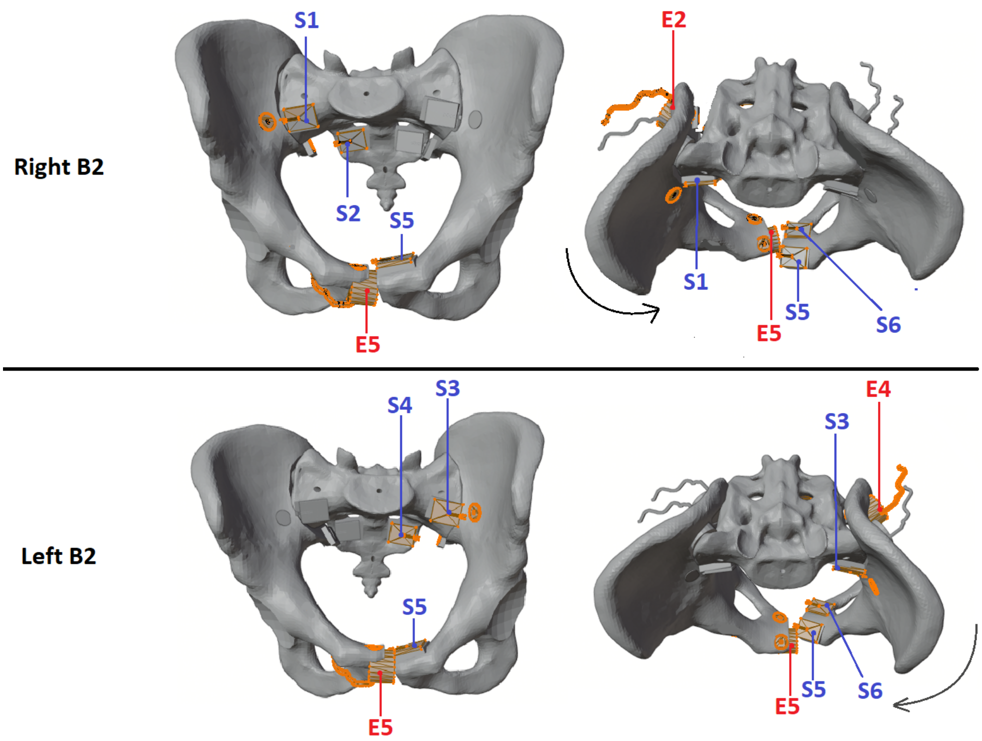

Figure 4.5: Electromagnets and sensors arrangement for B2 fractures.

- **B3:** Bilateral, partial fractures. The instructions to simulate this fracture are presented below:

  1. Deactivate first E5 to perform a pubic diastasis.
  2. Perform a combination of B1/B2 fractures:

     a. If a fracture B1 occurs in both Right and left coxal: disconnecting first E5 and then E1 and E3 while E2 and E4 remain active.

     b. If a B2 fracture occurs in both Right and left coxal: disconnecting first E5 and then deactivating E2 and E4 while E1 and E3 remain active.

     c. If a B1 fracture occurs in the right coxal and B2 in the left coxal: disconnecting first E5 and then deactivating E1 and E4 while E2 and E3 remain active.

     d. If a B2 fracture occurs in the right coxal and B1 fracture occurs in the left coxal: disconnecting first E5 and then disconnecting/repelling E2 and E3 while E1 and E4 remain active.

3. Assess the fracture and the clinical management with the magnetic sensors of the corresponding partial fractures already presented.

- **C1:** Unilateral, complete disruption fracture, as shown in Figure 4.6. To simulate this fracture and the output after clinical treatment, the following steps should be done:

1. Deactivate first E5 to perform a pubic disruption.

2. Perform a complete sacroiliac disruption. This disruption can occur due to vertical share or APC injuries. In case a VS fracture occurs, the two electromagnets will be disconnected from the ilium, on the other hand, if an APC is to be performed, the output voltage of the pubic sensors must determine that the symphysis pubis diastasis has, at least, 2.5 cm width. Concerning the hemipelvis in which the fracture occurs:

   a If the fracture occurs in the Right coxal: deactivate E1 and E2 regardless of the order while E3 and E4 remain active.

   b If the fracture occurs in the Left coxal: deactivate E3 and E4 regardless of the order while E1 and E2 remain active.

3. Assess the fracture and the clinical management with the magnetic sensors of the corresponding C1 fractures:

   a Assessment of a right C1 fracture: To assess this fracture the output of the sensors S1, S2 and the pubic sensors S5 and S6 must be evaluated. Their output value must decrease when the fracture occurs and increase when performing clinical management.

   a Assessment of a left C1 fracture: To assess this fracture the output of the sensors S3, S4 and the pubic sensors S5 and S6 must be evaluated. Their output value must decrease when the fracture occurs and increase when performing the clinical management.

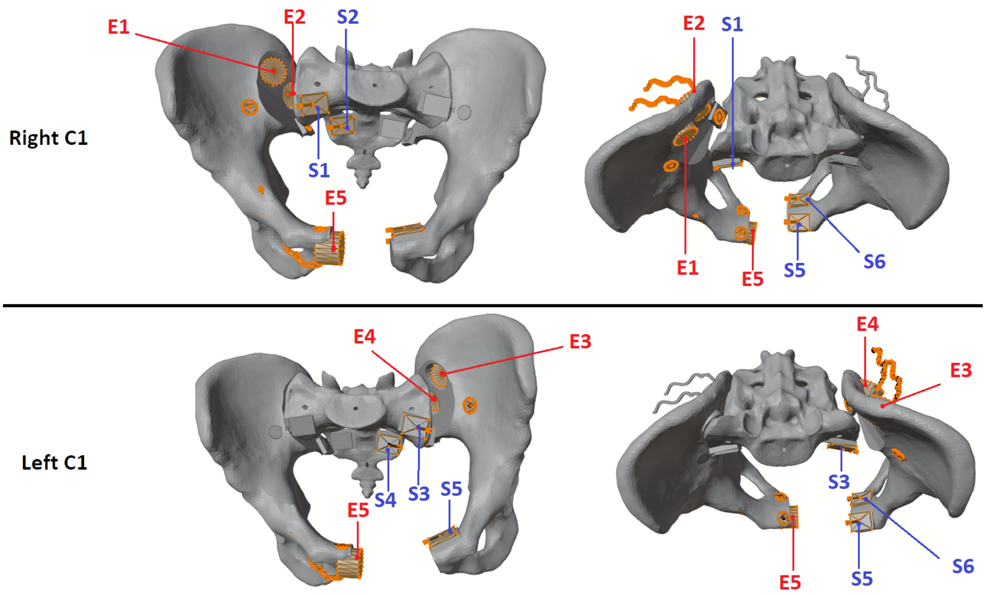

Figure 4.6: Electromagnets and sensors arrangement for C1 fractures.

- **C2:** Bilateral, complete and partial disruption fractures, as shown in Figure 4.7:

1. Deactivate first E5 to perform a pubic disruption.

2. Perform a C1 fracture in one iliac and a partial fracture in the other one. It should be noted that if a B1 fracture is required the sensor reading should determine that the pubic symphysis diastasis is greater than 2.5 cm.

   a Right coxal C1 fracture and left coxal B1/B2 fracture: deactivating E1 and E2 and also E3 or E4 if B1 or B2 fracture respectively.

   b Right coxal B1/B2 fracture and left coxal C1 fracture: deactivating E3, E4 and E5 and also E1 or E2 if B1 or B2 fracture respectively.

3. The sensors to be evaluated depend on the combination of the fractures previously described.

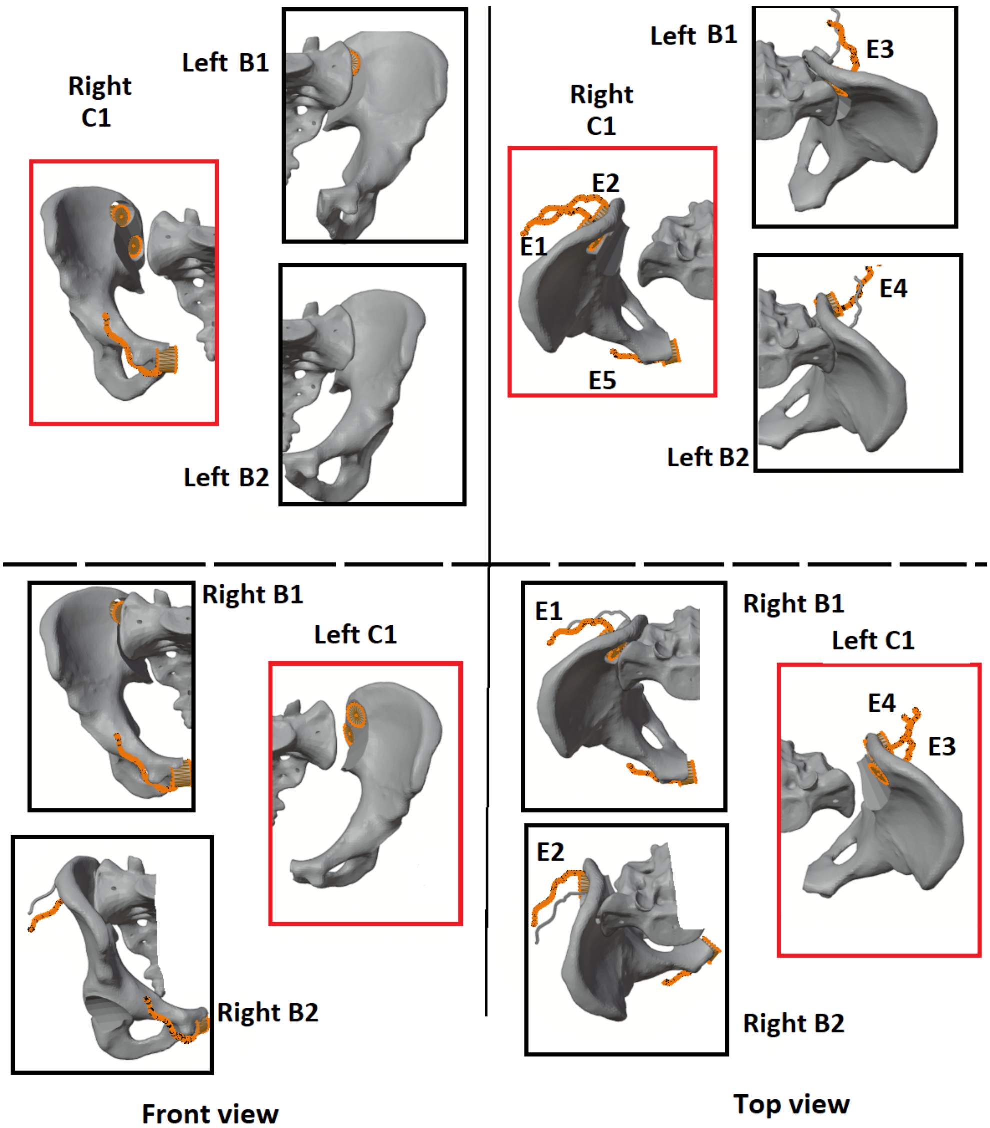

Figure 4.7: Sensor arrangement for C2 fractures.

- **C3:** Bilateral, complete disruption. Disconnecting/repelling every electromagnet, E1, E2, E3, E4 and E5 at the same time, as shown in Figure 4.8.

  1. Deactivate first E5 to perform a pubic disruption.
  2. Deactivate all the others electromagnets E1, E2, E3 and E4 regardless of the order.
  3. Every sensor should provide a decreasing voltage output when desactivating the electromagnets and then provide a value closer to the reference value when performing clinical management.

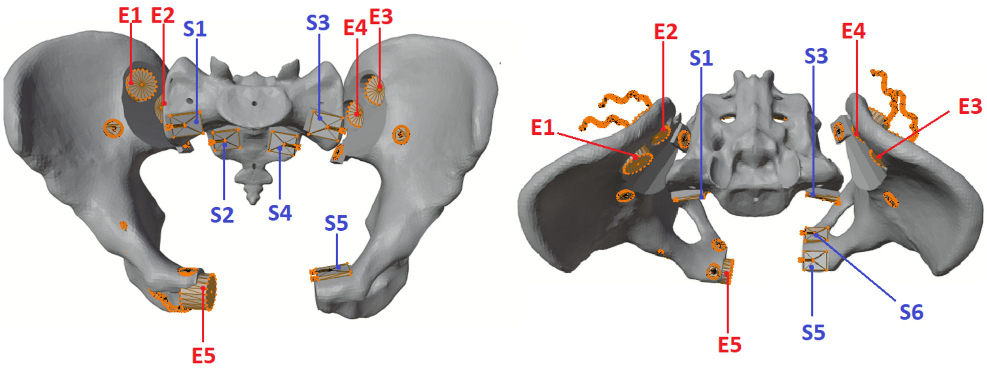

Figure 4.8: Sensor arrangement for C3 fractures.

4.2. Future works

To continue with the line developed in this Master Thesis on the design of a pelvis for clinical simulation, a series of future works are proposed:

- Development of electronics to enable electromagnets and sensors.
- Design and development of the other types of fractures, for example, those that occur in the pubic or ischium.
- Design the pelvis to enable force sensors, in order to acquire a better assessment of the clinical management.
- To get the simulation system closer to reality, it has been considered as a future work to encapsulate the entire pelvic system inside materials that simulate the muscles and skins. Simulating human tissue will approach the system to reality. On the one hand, for aesthetic reasons and tactility, on the other hand, for covering the pelvis in order to benefit the clinical management training since the clinician should be able to treat the pelvis without seeing it directly. Furthermore, these materials will create an elastic resistance that opposes the compression of the pelvic binder. The maximum recommended force when applying a PCCD is 150 N, but this force is not applied directly to the bone but to the skin and muscles that surround it.

  The materials that could be used are platinum silicones for the skin layer and foam to simulate the muscle.

  Platinum silicones can realistically simulate human skin. Depending on the density of the silicon, the different layers of skin can be created, the epidermis, dermis and hypodermis. The chosen silicon is the Dragon Skin^{TM} silicon. These silicones are used for many applications such as creating skin effects, movie special effects, or even medical prosthetics due to their superior physical properties and flexibility, as shown in Figure 4.9.

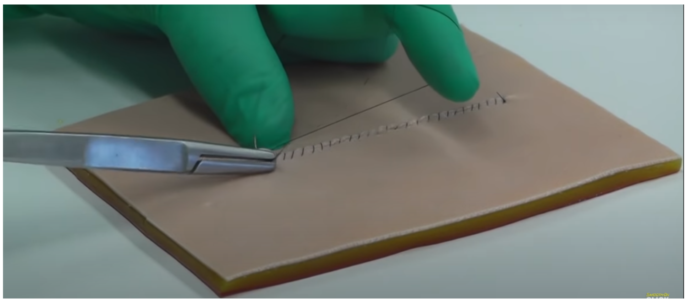

Figure 4.9: Dragon Skin^{TM} silicone for suture training [50].

In addition, foams such as the ones shown in the Figure 4.10, will be used to fill the volume between the pelvis and the skin, thus simulating muscle tissue.

Figure 4.10: Foams for simulating the muscle tissue [51].

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Appendix A

Impact

A.1. Introduction

A trauma is an injury that affects the patient physically and has serious consequences since it can lead to relevant disabilities or even death. Nowadays, trauma is the sixth cause of death worldwide. Among all types of trauma, pelvic trauma is considered one of the most dangerous traumas, which can reach 20% of mortality.

This Master Thesis aims to design an effective learning method to practice pelvic trauma protocols. The objective is to recreate different pelvic fractures and then providing feedback when the different clinical manoeuvres are carried out.

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

- **Social impact:** This Master Thesis will have a direct impact on the health field. Clinicians can benefit and gain deeper knowledge from this simulator system which will help them to practice the management of different unstable pelvic fractures. An important step in the management of pelvic trauma is the pelvic binder placement. The bibliography shows that many pelvic binders are placed wrongly what prevents the correct recovery from trauma. Therefore, the population will take advantage of this system as well as it will help the clinicians to properly place the pelvic binders and thus, provide a correct treatment to the patients.

- **Economical impact:** This project will have an economical impact as this system can be implemented within any manikin as the low fidelity simulators or, as it has been explained in Section 4.2 it can be implemented inside a vessel made with silicones and foams. In addition, this simulator can be used for different purposes as it provides information of both how the fracture occurs and what happens in the fracture once it has occured. This versatility can save costs.

- **Ethical impact:** The use of clinical simulators makes it possible to safely perform the practice of clinical management as many times as desired. In this way, no living being will suffer any harm.

- **Legal impact:** The research and development activities carried out during this Master Thesis is 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 is framed in the ”Law on Science, Technology and Innovation” 14/2011 (BOE 131, June 2, 2011).

- **Environmental impact:** There is no environmental impact found in the development of this Master Thesis.

A.3. Conclusiones

The use of this pelvic simulation system will help clinicians to better understand the unstable pelvic fractures as well as how to maneuver correctly in each of these fractures. This may transcend that a greater amount of lives can be saved in the future or at least, the patient's wellbeing will improve significantly.

Appendix B

Budget

An approximate budget is estimated taking into account human resources, technical equipment and some materials needed to carry out this Master Thesis.

- **Costs derived from human resources:** This considers the salary of the people involved in the Master Thesis: project manager and the engineering student of this work. The costs are shown in Table B.1.

	Cost per hour (€)	**Hours**	**Total (€)**
Project manager	20	50	1000
Engineering student	10	500	5000
TOTAL			**6000**

Tabla B.1: Salaries.

- **Costs derived from materials and technical equipment**: For this job, all the software used is free to use. Therefore, all material costs are listed in the Table B.2.

	Units	Cost	Time used (Months)	Amortization (Years)	Total
Personal Computer	1	1000 €	5	5	83 €
Electromagnets	5	9 €	4	5	3 €
Magnetic sensors	6	1.2 €	4	5	0.5 €
Magnets and metal plates	11	0.2 €	4	5	0.15 €
3D printing	1	30 €	4	5	2 €
Total					**88.65**

Tabla B.2: Material budget.

Thus, the total cost is gathered in the Table B.3.

	Cost
Human resources cost	6000 €
Material cost	88 €
Subtotal	6088€
IVA	1278.48€
Total	7366.48 €

Tabla B.3: Total cost.