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Development of a Knee Positioning System for X-ray Environment

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Abstract

The knee is one of the most stressed joints of the human body, being susceptible to ligament injuries and degenerative diseases. With the rising incidence of these pathologies, the number of X-rays for diagnosis of injuries, evaluation of the pre- and post-operative knee, and monitoring of knee stability in general situations is increasing. These types of knee evaluations usually involve radiography under physical stress. This widely used medical tool provides a more objective analysis of the measurement of the knee instability than a physical examination does, involving knee stress tests, such as valgus (lateral stress), and varus (medial stress).

Despite being an improvement to physical examination regarding the physician's bias, stress radiography is still performed manually in a lot of healthcare facilities. To avoid exposing the physician to radiation and to decrease the number of X-ray images rejected due to inadequate positioning of the patient or the presence of artefacts, such as non-anatomical objects external to the patient, positioning systems for stress radiography of the knee were developed. These systems have improved the objectivity and reproducibility during stress radiographs, but have failed to either be radiolucent or ergonomic with a simple set-up.

A prototype of a medical device for the positioning of the patient's knee during stress radiography is proposed in this dissertation. This positioning system is composed of two main structures: the foot and the lower limb supports. The foot support comprises a foot holder with velcro straps, that keeps the foot of the patient in neutral position. This foot holder is combined with a load cell, with the goal of tracking the force applied through an interface. It is coupled with a linear guide rail as well, that is connected to a stepper motor controlled by a desktop application. The main function of this application is to perform a desired stress test until either a defined force or a limit of the linear guide working stroke is reached. The second structure consists of a radiolucent triangle positioner that provides the necessary angle of flexion of the lower limb for the stress tests' performance. Moreover, electromyography electrodes are placed on the lower limb to measure the patient's relaxation.

Throughout this work, and to analyse the viability and applicability of the functioning of the knee positioning system, lab and clinical trials were carried out to evaluate if the prototype positioned the patient in the correct position for the knee stress radiograph, if the motor supported a standard force during the stress tests, and if the X-ray images validate the defined stress test and have no artefacts. The results of the trials were promising, maintaining all the subjects with an average body type with the knee at 30°, and the foot at 90°, and obtaining X-ray images of the desired stress tests without any artefacts. This system has provided a more objective and detailed stress test examination, whilst still avoiding the exposure of physicians to radiation, which was confirmed by clinical partners, being a possible contender in the knee stress radiography positioning devices field.

Keywords: Anteroposterior view, knee joint, positioning system, skyline view, stress radiography

Resumo

O joelho é das articulações do corpo humano em mais tensão, sendo suscetível a lesões de ligamentos e doenças degenerativas. Com o aumento da incidência dessas patologias, aumenta o número de radiografias para diagnóstico de lesões, avaliação do joelho pré- e pós-operatório e monitorização da sua estabilidade em situações gerais. Estes tipos de avaliação do joelho envolvem, normalmente, a radiografia sob stress físico. Esta ferramenta médica amplamente utilizada fornece uma análise mais objetiva da medição da instabilidade do joelho do que um exame físico, envolvendo testes de stress de joelho, tais como o valgo (stress lateral) e o varo (stress medial).

Apesar de ser uma melhoria do exame físico em relação à predisposição do médico, a radiografia de stress é realizada manualmente em muitos estabelecimentos de saúde. Para evitar a exposição do médico à radiação e diminuir o número de imagens raio-X rejeitadas devido ao posicionamento inadequado do paciente ou à presença de artefactos, tais como objetos não-anatômicos externos ao paciente, sistemas de posicionamento para radiografia de stress do joelho foram desenvolvidos. Estes melhoraram a objetividade e reprodutibilidade durante estas radiografias, mas não conseguiram nem ser radiotransparentes, nem ser ergonômicos com uma configuração simples.

Um protótipo de um dispositivo médico para o posicionamento do joelho do paciente durante a radiografia de stress é proposto nesta dissertação. Este sistema é composto por duas estruturas principais: o apoio do pé e do membro inferior. O apoio do pé é composto por um suporte do pé com tiras de velcro, que fixa o pé em posição neutra. Este suporte do pé é montado com uma célula de carga, com o objetivo de medir a força aplicada através de uma interface. É também acoplado com uma calha de guia linear, que é montada com um motor passo-a-passo controlado por uma aplicação de computador. A principal função desta aplicação é realizar um teste de stress desejado até que seja atingido ou uma força definida, ou o limite de curso da guia linear. A segunda estrutura consiste num posicionador triangular radiotransparente que fornece o ângulo de flexão do membro inferior necessário para a realização dos testes de stress. Para além disso, elétrodos de eletromiografia são colocados no membro inferior para medir o relaxamento do paciente.

Ao longo deste trabalho, e para analisar a viabilidade e aplicabilidade do funcionamento do sistema de posicionamento, foram feitos ensaios laboratoriais e clínicos para avaliar se o protótipo posiciona o paciente na posição correta para cada radiografia de stress, se o motor suporta a força padrão durante os testes, e se as imagens de raios-X validam os testes definidos sem haver artefactos. Os resultados foram promissores, mantendo todos os sujeitos com medidas médias do corpo com o joelho a 30°, e o pé a 90°, sendo obtidas imagens raio-X dos testes desejados sem quaisquer artefactos. Este sistema proporcionou um exame mais objetivo e detalhado, que evita a exposição dos médicos à radiação, o que foi confirmado por parceiros clínicos, sendo um possível competidor na área dos dispositivos de posicionamento do joelho para radiografia de stress.

Palavras-Chave: Articulação do joelho, radiografia de stress, sistema de posicionamento, vista ântero-posterior, vista da patela axial

Para a minha Avó Cinira

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*“And I knew exactly what to do.
But in a much more real sense,
I had no idea what to do.”*

Michael Scott

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Abbreviations

3D	Three-Dimensional
AC	Alternating Current
ACL	Anterior Cruciate Ligament
CAD	Computer-Aided Design
CT	Computed Tomography
DC	Direct Current
EDR	Enhanced Data Rate
EEPROM	Electrically Erasable Programmable Read-Only Memory
EMG	Electromyography
ICSP	In-Circuit Serial Programming
ID	Identification
IDE	Integrated Development Environment
I/O	Input/Output
KOA	Knee Osteoarthritis
LCL	Lateral Collateral Ligament
MCL	Medial Collateral Ligament
MRI	Magnetic Resonance Imaging
OKRs	Ottawa Knee Rules
PCL	Posterior Cruciate Ligament
PFI	Patellofemoral Instability
PLA	Polylactic Acid
PPE	Personal Protective Equipment
PWM	Pulse Width Modulation
SNS	<i>Sistema Nacional de Saúde</i>
USART	Universal Synchronous/Asynchronous Receiver-Transmitter
USB	Universal Serial Bus
VDC	Volts of Direct Current

Chapter 1

Introduction

Every year, worldwide, there are several injuries that affect the knee joint, and its ligaments, originating joint instability. The assessment of this instability is not an easy process for physicians to quantify. Therefore, there is a growing need to have systems to automate an objective diagnosis.

This chapter is divided into five sections. Section 1.1 describes the context behind the problem addressed, section 1.2 presents an analysis of the socioeconomic impact of the problem and the motivation for the development of the proposed system, sections 1.3 and 1.4 summarise, respectively, the expected goals and contributions of this dissertation, and, at last, section 1.5 defines the structure of the remaining document.

1.1 Context

The knee is the largest and, arguably, the most stressed joint of the human body [1–3]. It is a compound synovial joint that essentially serves as a hinge, meaning that it primarily allows movement along one axis in terms of flexion and extension of the knee in the sagittal plane, with limited motion along other planes [1–4]. This type of motion makes the knee joint an essential component of efficient bipedal movements, such as walking, running, and jumping [3]. Since bipedal movements bring upon the knee considerable amounts of biomechanical stress, stability of this joint is provided by the arrangement of its ligaments and the extension of muscles that cross the joint [2, 3]. Having minimal side-to-side motion, the knee is prone to injury, especially ligament injuries, such as injuries in the medial collateral ligament (MCL) and the lateral collateral ligament (LCL), which are two important stabilising components of the knee joint. The majority of MCL tears are isolated and often occur in individuals that participate in sports activities involving knee flexion and/or contact [5, 6]. The LCL is usually injured during sports and fitness activities that involve direct blows on the inside of the knee that push the joint outwards or hyperextension of the knee [7, 8]. Apart from ligament injuries, the knee joint is most commonly affected by knee osteoarthritis (KOA), which is a degenerative knee joint disease. KOA is typically the result of wear

and tear and progressive loss of articular knee cartilage [9, 10]. The most common treatments for knee injuries depend on the severity of the injury ranging from non-operative treatments, which involve medication and rehabilitation, to operative treatments, that could go as far as total knee replacement, also known as knee arthroplasty [9]. In addition, knee dislocations are often common, which include patellofemoral instability (PFI). PFI is a condition where the patella, also known as kneecap, suffers subluxation or dislocation out from the patellofemoral joint. This most often involves sporting activities with fast deceleration and twisting with the knee extended and the foot externally rotated [11, 12].

Radiography is a widely used medical tool for the aforementioned knee pathologies. It is a broad term that addresses different types of medical examinations that use an X-ray approach to visualise the internal structure of a patient's body [13]. However, radiography is commonly used when referring to a plain X-ray, the first-line investigation for suspected orthopaedic pathology, even before other widely used imaging techniques, such as computed tomography (CT) or magnetic resonance imaging (MRI) [14]. X-ray is the gold standard and an accurate mean of evaluating not only the bone, but also its relationship to orthopaedic hardware. Moreover, it is used for the diagnosis and treatment of patients by the passage of an X-ray beam through their body [13, 14]. A portion of the X-rays are absorbed or scattered by the body, whereas the remaining X-rays are transmitted to a detector creating a high-resolution two-dimensional image [13]. This is because different tissues will absorb different amounts of radiation leading to the well-known grey-scaled X-ray images [15]. Despite the fact that the images generated by CT or MRI scans are three-dimensional (3D) images and, therefore, more detailed, the X-ray is usually the first technique chosen, since it is a faster and cheaper way of diagnosis and monitoring that already shows indirect signs of ligament ruptures, KOA or PFI [16]. Figure 1.1 exemplifies an X-ray machine, whereas Figures 1.2a, 1.2b, and 1.2c show images of knee X-rays.



Figure 1.1: X-ray equipment.

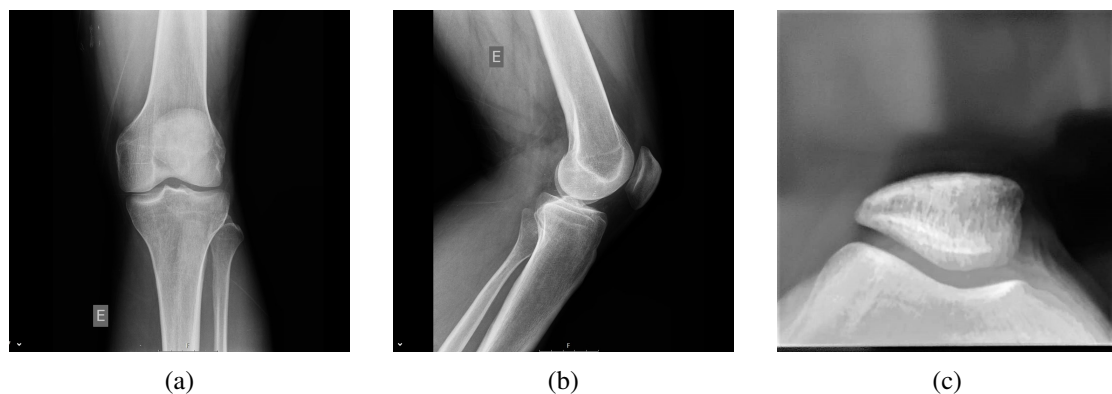


Figure 1.2: Left knee X-rays, where "E" is an indication of "Left": (a) Normal anteroposterior view; (b) Lateral view; (c) Skyline view.

Stress radiography is a widely used medical tool for ligament injuries and KOA that provides a more objective analysis of the magnitude of the knee instability when in comparison to a physical examination [17–21]. It covers three main applications [18,20,21]:

- Diagnosis of acute and chronic knee injuries;
- Evaluation of pre- and post-operative knee instability;
- Monitoring of knee stability in non-operative treatments.

In relation to physical examination, the stress radiography of the knee may reduce the physician's interpretation bias by providing a more reproducible and reliable examination, and gives a permanent visual record of the examination [17–21]. Despite stress radiography being an improvement to physical examination of knee injuries, it is still performed manually in a lot of healthcare facilities, as shown in Figure 1.3. Since every manual stress radiograph exposes the physician to radiation, some physicians have created their own techniques for stress radiography to avoid exposure to radiation (Figure 1.4). However, these techniques still suffer from subjectivity and lack of reproducibility, because they all depend on the operator and the patient. In addition, these types of stress radiography leave artefacts in the X-ray images, such as the hands of the operator (Figure 1.5a), the table where the examination is performed (Figure 1.5b), or materials used by techniques created by physicians (Figure 1.5c).

1.2 Socioeconomic Impact and Motivation

In 2020, 87 million of patients worldwide, over 20 years old, suffered from KOA [10]. In the United States alone there are around 74,000 MCL injuries per year [6,22]. These kind of ligament injuries are more common than LCL injuries, which account for just 5% of knee ligament injuries and are usually accompanied with other knee ligament injuries [22,23]. Still in the United States,

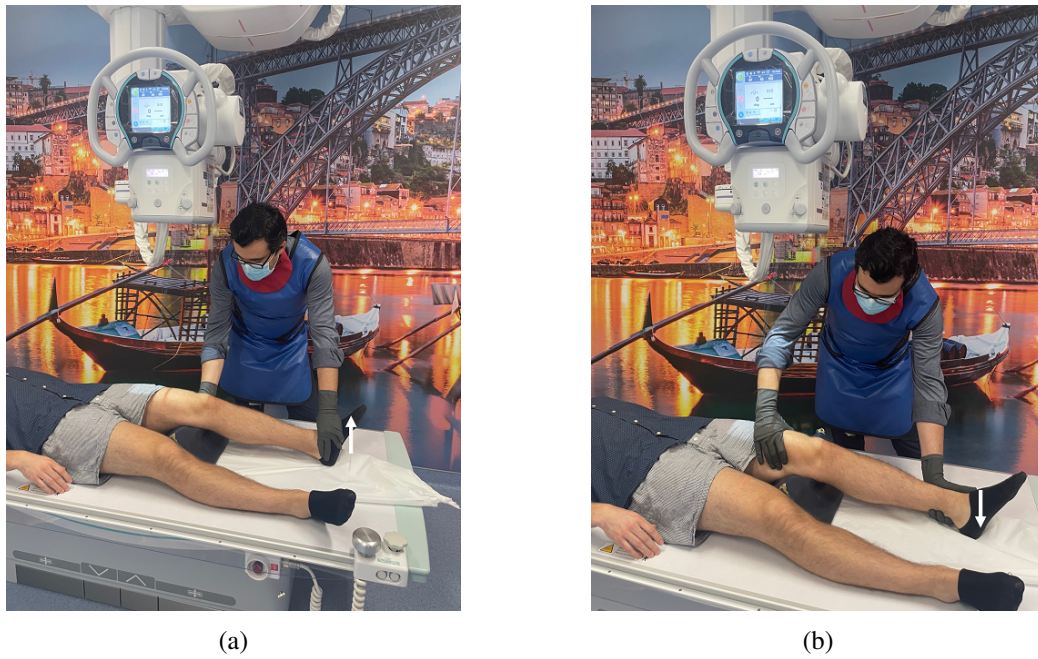


Figure 1.3: Stress radiography performed manually by the physician: (a) Valgus stress test; (b) Varus stress test. The arrow indicates the movement of the hand on the tibia whilst the other hand fixates the femur.



Figure 1.4: Stress radiography performed with a simple technique created by a physician [20].

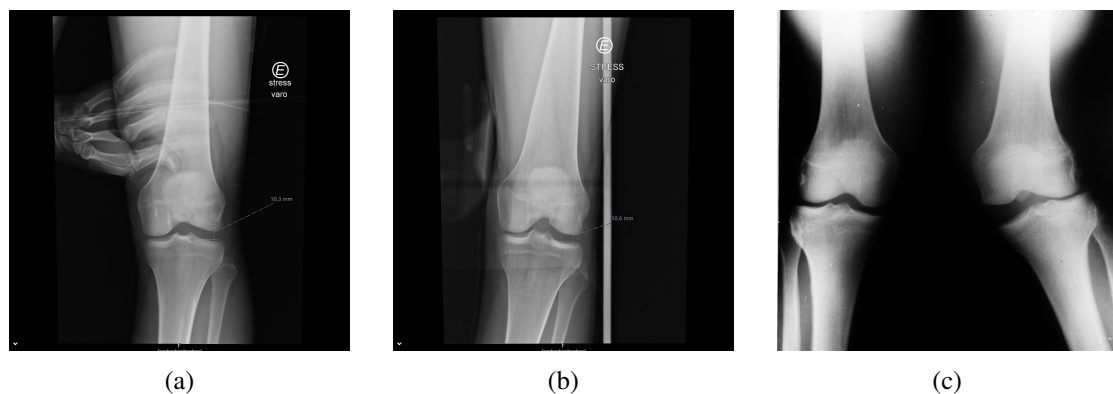


Figure 1.5: X-ray images with artefacts left by stress radiography: (a) X-ray image with hands of a physician whilst performing the varus stress on the left knee ("E" is an indication of "Left"); (b) X-ray image with artefact left by the table of examination during the performance of the varus stress test on the left knee ("E" is an indication of "Left"); (c) X-ray image with artefact left by the technique performed by a physician in Figure 1.4 [20].

PFI affects between 6 and 23 per 100,000 person-years, accounting for approximately 3% of all knee injuries [24, 25]. These numbers are expected to increase since there has been a slow rise in the incidence of KOA due to the ageing of the population [26–28], and of knee ligament injuries and PFI in young people related to high-intensity sports with lack of injury prevention [29–32]. With the rising incidence of these pathologies, the number of X-rays for diagnosis of knee injuries, and for evaluation/monitoring of knee stability will increase.

The X-ray is the primarily chosen radiographic examination by physicians, comprising over a half of the total ordered examinations, which also include CT and MRI scans. In 2018, 152.8 million X-rays out of 267.7 million imaging tests were made in hospitals in the USA [33] and 22.9 million X-rays out of 42.7 million imaging tests were performed in the UK [34]. Nevertheless, a lot of these X-rays images end up being rejected by physicians. A study at a major metropolitan emergency medical imaging department in Australia analysed 90,298 X-ray images since June 2015 until April 2017 and achieved a 19 % reject rate out of 4,965 knee X-rays [35]. The most common reason for rejection was inadequate patient positioning with almost an half of the number of overall rejected images [35]. Other common reasons for rejection were artefacts, which can include clothing artefacts and patient movement [35]. Such a high amount of rejected knee X-rays will have a great economic impact in the health system of each country. In Portugal, for example, if 19 % out of 4,965 knee X-rays were rejected, the *Sistema Nacional de Saúde* (SNS) would suffer a loss of 3,792€ in less than two years on plain knee X-rays alone [35, 36]. Rejected knee X-rays also impact the health of the patient, who has to be exposed to more radiation than it was necessary, and of the physician, in case they had performed several manual stress radiographs. Even though the exposure of the patient would be quite low and harmless, the exposure of the physicians to radiation can put them at a greater risk of exceeding the annual radiation dose limits (0.05 Sv per year [37]), in case they do not practice proper radiation protection measures and adhere to

safety practices [38]. Even so, being exposed so closely to radiation on a daily basis, even with personal protective equipment (PPE), could put physicians at risk for long-term adverse health effects, such as loss of white blood cells, reduction in platelets, fertility problems, and changes in kidney function [39].

A radiolucent solution for positioning the patient's knee during stress radiographs without the assistance of a physician during the X-ray examination is then in need for healthcare professionals. With such a tool, the number of knee X-rays rejected by physicians would decrease, since there would be less inadequate positioning and movement from the patient. With the decrease in X-rays there would be not only a decrease in costs for the healthcare system, but also a faster and more reliable examination of knee pathologies, allowing the workflow of healthcare facilities to run more smoothly. In addition, healthcare professionals would decrease their exposure to radiation and the X-ray image would not have artefacts of their hands, making it easier to be analysed.

1.3 Main Objectives

The principal goal of the proposed dissertation is the design and development of an objective, radiolucent, ergonomic and user-friendly positioning system for X-ray environment capable of assisting knee stress radiographs without the aid of a physician, in order to diagnose acute and chronic knee injuries, evaluate pre- and post-operative knee instability, and monitor knee stability in non-operative treatments. For this purpose, the ideal solution should include:

- Force sensors to define, measure and monitor the force to be applied to the knee during the stress tests;
- Rotary encoders to measure and monitor the position of the lower limb, so that its position can be controlled automatically depending on which type of stress test will be performed;
- Electromyography (EMG) sensors to measure the electrical activity produced by the skeletal muscles as the pressure is being applied, with the goal of determining the level of relaxation of the patient before and during the examination;
- Ergonomic base to support the lower limb during the stress radiography at the clinically indicated angle of flexion of the knee;
- Radiolucent materials for the parts of the system that will be subjected to radiation, always keeping the comfort of the patient in mind;
- Application software to display the acquired data for each patient in real-time and to let the operator control the positioning device outside of the X-ray environment.

1.4 Main Contributions

The main contribution of this dissertation work is the design and development of a knee positioning system for X-ray environment without the aid of a physician that improves the already existing systems and fills a gap in the market, benefiting all the involved stakeholders.

By being a radiolucent and objective/reproducible system that applies the pressure for each stress test automatically, it will reduce the number of knee X-rays rejected by physicians, leading to less exposure to radiation by the patient and the operator of the stress test, due to less inadequate positioning and movement from the patient, as well as less artefacts left in the X-ray images. In addition, it will be easier for physicians to analyse images without artefacts.

There will be a decrease of costs for the healthcare systems, not only because the number of knee X-rays rejected would be decreased, but also due to the positioning system providing a faster and more reliable examination of knee pathologies, leading to a smoother workflow of healthcare facilities.

The developed knee positioning device will be of simple set-up and use with an user-friendly interface so that it is easier for healthcare professionals to adapt to it and have a smooth workflow. Furthermore, the system will have an ergonomic structure so that the patient has as much comfort as it is possible during the stress tests, and it will be implemented keeping in mind the patient's safety at all times.

1.5 Document Structure

This dissertation contains 7 more chapters besides the Introduction. Chapter 2 and 3 focus on a general review of the knowledge of the different scientific areas of the addressed problem, that are necessary for the understanding of the report. In Chapter 2 the main concepts related with the anatomy of the knee and common knee injuries that can be evaluated through plain radiography are presented, whereas in Chapter 3 more insights into the various types of knee imaging, with focus on how knee injuries can be assessed through plain radiography, are provided. Chapter 4 revises the state of the art of positioning systems used in the clinical assessment of the knee joint through stress radiography and their evolution over time. Chapter 5 illustrates the design of the ideal solution for a knee positioning system for stress radiography, including the hardware and software designs, as well as the assembly of a prototype development pathway. Chapter 6 describes the implementation of a prototype of the aforementioned system, which includes a detailed description of the hardware and software involved. Chapter 7 presents and discusses the results of lab and clinical trials of the implemented prototype with healthy subjects. Lastly, chapter 8 exposes the main conclusions taken from the production of the work, what were its main challenges and areas of improvement, and possible future work to expand on it.

Chapter 2

The Knee Joint

This chapter presents the main concepts associated with the anatomy of the knee, especially the articular cartilage and the ligaments of the knee, as well as common knee injuries that can be assessed through plain radiography, particularly stress radiography, necessary for the understanding of this dissertation.

2.1 Anatomy of the Knee

The knee is the largest and, arguably, the most stressed joint of the human body [1–3]. It is a synovial joint, meaning that the articulating surfaces of the bones are enclosed in a capsule filled with synovial fluid that lubricates the movement between them [1–3]. Synovial joints are diarthrosis, since they allow freedom of movement, and can be sub-classified into various types of joints, depending on the shape of the articulating surfaces and the movement. Considering that the knee predominantly allows a rotational motion along one axis through flexion and extension of the leg in the sagittal plane, it is classified as an hinge joint [1–4, 40]. Furthermore, it allows a slight medial rotation during flexion and the last stage of the knee extension, as well as a lateral rotation when unlocking the joint [2, 40]. This type of motion makes the knee joint an essential component of efficient bipedal movements, such as walking, running, and jumping [3]. The overall anatomy of the knee is presented in Figure 2.1.

The knee joint is composed of two articulations, linking together the thigh bone (femur) and the shin bone (tibia) through the tibiofemoral joint, and the femur and the kneecap (patella) through the patellofemoral joint [1–4, 40, 42]. The articular surfaces of the tibiofemoral joint - the lateral and medial condyles of the distal end of the femur and the tibial plateaus - are usually incongruent, so the medial and lateral meniscus provide compatibility to the articulation [2, 42]. The meniscus are C-shaped fibrocartilaginous structures that allow for a more even distribution of the pressure of the femur on the tibia, acting as a shock absorber between these two bones [2, 43]. The patellofemoral joint is a saddle joint - a type of movable joint that allows motion in two planes -,

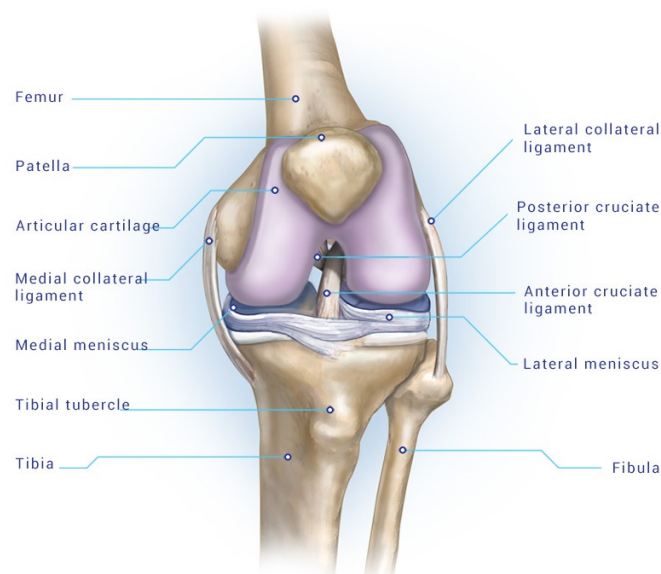


Figure 2.1: Anatomy of the left knee joint, including the relationship between the bones, ligaments, meniscus and articular cartilage [41].

and it is composed of the articulation between the patellar surface of the femur and the posterior surface of the patella [2, 40, 42, 44].

The femur articulates with the patella inside its joint capsule, whereas the tibia articulates with the fibula outside it [1–4]. The joint capsule, also known as articular capsule, is a thick ligamentous sheath that surrounds the joint and consists of two layers [2, 45]:

- **Fibrous layer:** outer layer of the capsule that consists of white fibrous tissue, holding together the articulating bones and underlying layer;
- **Synovial layer:** inner layer of the capsule, being composed of a vascularised serous connective tissue that absorbs and secretes synovial fluid. This fluid is responsible for the nourishment of the cartilage.

Thanks to the inner layer of the joint capsule that produces the synovial fluid, the articular surfaces of the knee are lubricated and the friction in motion is reduced. In addition, there are fluid filled sacks called bursae formed by the joint capsule to assist with the friction reduction within the joint [1–4]. A representation of the key structures of a synovial joint, in this case the knee, is shown in Figure 2.2.

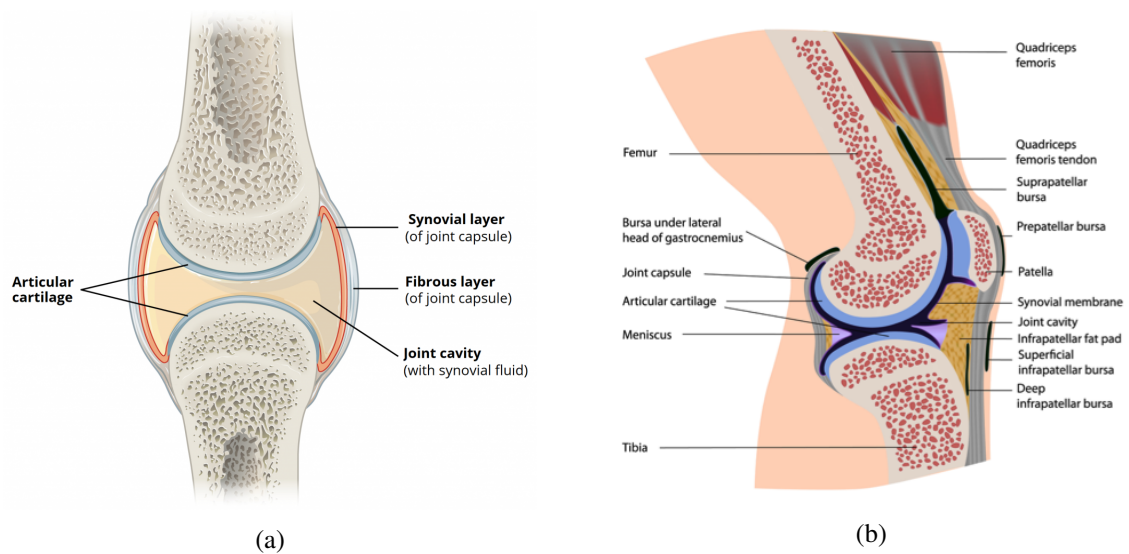


Figure 2.2: Representation of the basic structures - joint capsule, articular cartilage and synovial fluid - of a synovial joint, more specifically of the knee: (a) Normal anteroposterior view [45]; (b) Lateral view [46].

2.1.1 Articular Cartilage of the Knee

Around the articulating surfaces of the knee joint, there is a tough layer of smooth white connective tissue that helps the joint move smoothly, which is also known as articular cartilage [45, 47–49]. The articular cartilage is a slippery, strong, and flexible material that allows the bones to glide over each other as the knee extends and flexes, absorbing shock by preventing the bones - femur, tibia, and patella - from impacting one another directly and minimising friction upon motion [1, 45, 49].

The articular cartilage is deprived of blood vessels, nerves, lymphatic vessels and lymphoid organs and, therefore, it has a limited capacity for healing and repair from within. However, it is subject to harsh biomechanical pressure, so its health and preservation is of greatest importance to the knee joint health [49].

2.1.2 Knee Ligaments

Since bipedal movements bring upon the knee considerable amounts of biomechanical stress, stability of this joint is provided by the arrangement of its ligaments and the extension of muscles that cross the joint [2, 3]. The knee ligaments are bands of tough elastic tissue responsible for stabilising and limiting the movement of the knee, connecting the femur to the tibia [1, 2, 40, 50]. They are classified depending on whether they are enclosed by the knee joint capsule or surrounding it. There are two major extracapsular ligaments: the MCL and the LCL; and two major intracapsular ligaments: the anterior cruciate ligament (ACL) and the posterior cruciate ligament (PCL) [1–4, 50]. The MCL and the LCL prevent side-to-side movement, whilst the ACL and the PCL keep the femur and tibia from sliding too far forward or backward [1, 40]. Moreover, the ACL and the PCL stabilise the knee during flexion and all of the four ligaments stabilise the joint during

extension [51]. The exact location of these ligaments can be seen in Figure 2.1 and a comparison of their respective functions and their state during flexion/extension is presented in Table 2.1.

Table 2.1: Comparison of the function and state during flexion/extension of the four major knee ligaments.

Knee ligament	Function [52]	Flexion state [51]	Extension state [51]
MCL	Provides valgus angulation restraint and prevents axial rotation	Relaxed	Taut
LCL	Supports varus angulation restraint and prevents axial rotation	Relaxed	Taut
ACL	Prevention of anterior tibial translation on the femur	Taut	Taut
PCL	Prevention of posterior tibial translation and posterolateral tibial rotation on the femur	Taut	Taut

2.1.2.1 Medial Collateral Ligament

The MCL is the medial strong flat ligament of the knee joint, that is attached at the medial epicondyle of the femur and the medial condyle of the tibia [2, 3, 53]. Its main concern is securing the joint and preventing any excessive side-to-side motion by limiting both external and internal rotation of the extended knee [2]. Particularly, the MCL prevents valgus stress on the knee [3, 53].

2.1.2.2 Lateral Collateral Ligament

The LCL is another major extracapsular ligament that goes from the lateral epicondyle of the femur to the lateral surface of the head of the fibula [2, 3]. Just like the MCL, this ligament secures the knee joint and prevents excessive sideways movement, specifically preventing varus stress on the knee joint [3, 8].

2.1.2.3 Anterior Cruciate Ligament

The two cruciate ligaments cross each other obliquely within the joint capsule, remaining external to the synovial layer [2].

Being attached to the lateral condyle of the femur all the way through the intercondylar area of the tibia, the ACL prevents the posterior rolling and displacement of the femoral condyle when the joint is flexed, and avoids the overextension of the knee [2, 3, 42, 54].

2.1.2.4 Posterior Cruciate Ligament

Finally, the PCL connects the medial condyle of the femur to the posterior intercondyle of the tibia [2, 3]. This ligament is stronger than the ACL, having better blood supply and the opposite purpose of the ACL [2]. So, the PCL prevents the anterior rolling and displacement of the femoral condyle when the knee is extended and keeps the joint from flexing too much [2, 3, 42].

2.2 Knee Injuries

Since the knee is one of the most stressed and complex joints of the human body and has minimal side-to-side motion, it is susceptible to injuries and degenerative diseases [1–3]. The most common knee injuries that are assessed through plain radiography, especially stress radiography, are KOA and ligament injuries, such as MCL and LCL injuries [18, 20, 21]. PFI is also commonly addressed through plain radiography [11, 55].

Usual treatments for knee injuries depend on the severity of the injury ranging from non-operative treatments, which involve medication and rehabilitation, to operative treatments, that could go as far as total knee replacement, also known as knee arthroplasty [9].

2.2.1 Knee Osteoarthritis

Due to the harsh biomechanical pressure put on the knee joint, in particular on the articular cartilage (that has limited capacity for healing and repair [49]), one of the most common injuries to this hinge joint is KOA [3, 4, 45].

Osteoarthritis is the most common expression of joint inflammation. It is usually associated with heavy use of the articular joints over the years, resulting in the wear and tear of the articular cartilage, as well as the consequent erosion of the underlying articulating bone surfaces [4, 9, 10, 45, 56]. This disease leads to a decrease in the effectiveness of the articular cartilage as a shock absorber and lubricated surface, and roughened edges of the joint [45]. As mentioned in Section 2.1.1, the articular cartilage is deprived of blood vessels, nerves, lymphatic vessels and lymphoid organs, having limited capacity for healing [49]. So osteoarthritis causes irreversible and degenerative changes to the joint, narrowing the space joint, as shown in Figures 2.3 and 2.4.

Stiff, pain and discomfort of the knee with activity that gradually worsens over time are usual symptoms of KOA [3, 4, 45]. Even though this knee disease is usually associated with the ageing of a person, other factors might contribute to its appearance and severity, such as trauma of the joint, body weight, activity level and lifestyle, as well as genetics. Treatment of KOA and symptoms relief begins with physical therapy, medication or reduction of body-weight, depending on the cause of the KOA [3, 4, 56]. When these options start to fail, a total knee arthroplasty might come into play to replace the articular surfaces of the knee with smooth metal and highly cross-linked polyethylene plastic, for example. This procedure is overall successful at improving the patient's quality of life, being often used in spite of being a complex approach [3, 60].

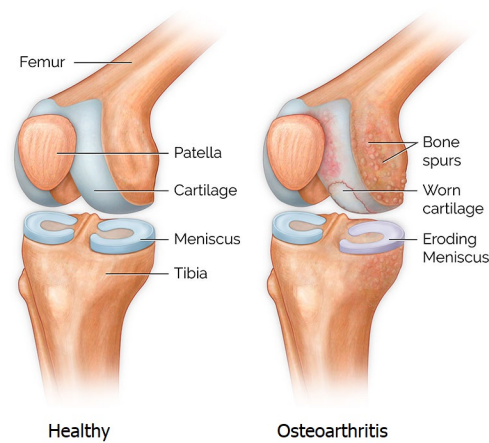


Figure 2.3: Representation of the differences between a healthy knee joint and a knee with osteoarthritis, adapted from [57].

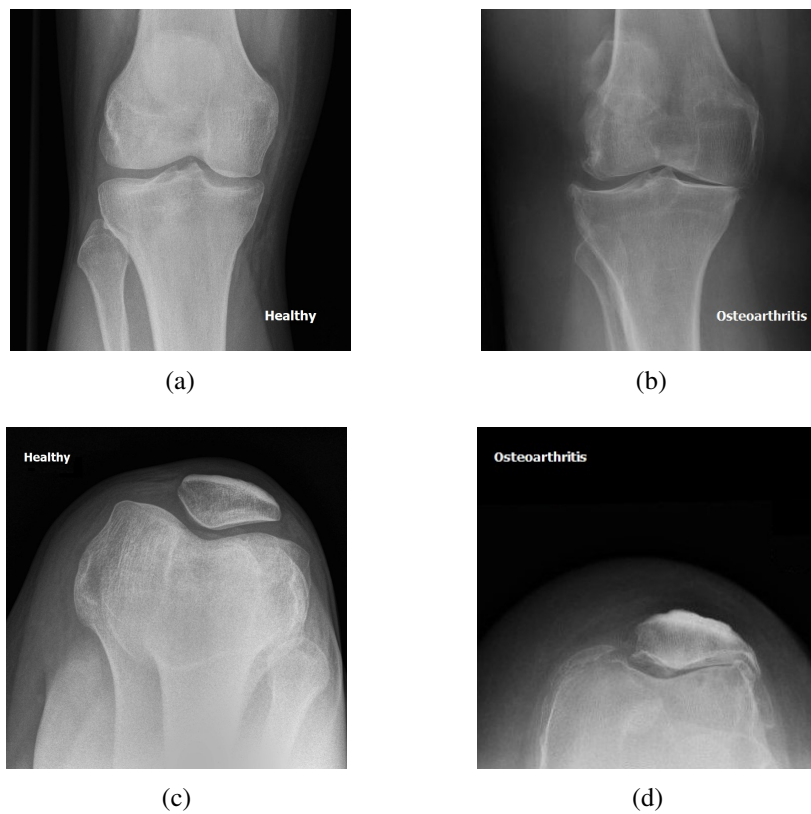


Figure 2.4: X-ray images of a healthy knee joint versus a knee with osteoarthritis, where there is a narrowing of the space joint: (a) Normal anteroposterior X-ray of a healthy knee, adapted from [58]; (b) Normal anteroposterior X-ray of a knee with osteoarthritis, adapted from [59]; (c) Axial X-ray of a healthy knee, adapted from [58]; (d) Axial X-ray of a knee with osteoarthritis, adapted from [59].

2.2.2 Knee Ligament Injuries

Apart from KOA, knee injuries are often related to ligament injuries, due to the knee's minimal side-to-side motion. They can be divided into three grades of knee ligament injuries: sprain, partial tear and rupture; being graded according to the severity of the injury [61]. A comparison between these grades of knee ligament injuries, their symptoms and corresponding treatment methods can be seen in Table 2.2.

Table 2.2: Grades of knee ligament injuries, their symptoms and treatment methods.

Grade of injury	Degree of pain	Chance of bearing body weight	Joint stability	Treatment method
Grade I (sprain)	Mild	High	Stable	Rest
Grade II (partial tear)	Moderate	Medium/Low	Unstable	Rest and rehabilitation
Grade III (complete rupture)	Severe	Low	Highly unstable	Surgery and rehabilitation

A sprain causes structural damage on a microscopic level, with a slight local tenderness and keeping the joint stable [61]. This grade of injury leads to a mild degree of pain and, therefore, the patient is able to bear body weight. However, bearing body weight can cause more damage to the ligament so these injuries are usually treated recurring to the rest of the lower limb [3, 53, 61–63]. The partial tear in one of the four major ligaments causes visible swelling and a noticeable tenderness, but a mild instability of the joint [2, 3, 61, 62, 64]. With moderate pain, the patient has a medium to low chance of bearing body weight and rest followed by physical therapy is recommended [3, 53, 61–64]. Finally, a complete rupture of a knee ligament leads to significant swelling and a high instability of the joint [2, 3, 61, 62, 64]. The patient is unable to support any load on the joint, feeling severe pain on the knee. To treat an injury of this grade, knee surgery is required, being followed by the rehabilitation of the joint [3, 53, 61–64].

Some of the most common knee ligament injuries are in the MCL and the LCL, which are two important stabilising components of the knee joint that are easily prone to injury caused by unnatural movements of the knee [3, 65, 66].

2.2.2.1 Medial Collateral Ligament Injury

The MCL is usually injured when there is a direct impact to the lateral side of the knee that pushes the knee inwards, inducing excessive valgus stress [2, 3, 62, 65, 66]. It is also possible to stretch or tear the MCL if the knee is suddenly pushed to the side, or if it rotates or flexes too far without any direct force [62]. A representation of an MCL injury is presented in Figure 2.5a and an X-ray image of a patient's knee with an MCL injury is shown in Figure 2.5b.



Figure 2.5: Representation of an MCL injury: (a) Scheme of the injury, adapted from [67]; (b) X-ray image of the injury with a noticeable knee laxity due to a loose MCL, adapted from [68].

Making up to 40% of knee ligament injuries, the majority of MCL tears are isolated and occur in individuals that participate in sports activities involving knee flexion and/or contact [2, 5, 6, 62, 63, 65, 66, 68]. Pain and swelling along side the knee, as well as stiffness and lack of stability when walking accompany the MCL injury [3, 62]. Treatment for this type of injury is normally conservative, meaning that non-operative treatments, such as the use of a brace, non-weight-bearing activity and medication to ease the pain, are usually recommended [3, 53, 62, 63]. For more severe MCL injuries, physical therapy might be required to rehabilitate the knee and in the case of the most severe injuries, operative repair, augmentation or surgical reconstruction could be required [53, 62, 63].

2.2.2.2 Lateral Collateral Ligament Injury

The LCL is another commonly injured knee ligament, that is usually accompanied with other knee ligament injuries, rarely being isolated [69–71]. It usually occurs during a direct blow on the inside of the knee that pushes the joint outwards, making the ligament overstretch or even tear. It can also happen during non-contact events that involve excessive varus stress, external tibial rotation and/or overextension of the ligament [8, 69–72]. A scheme of an LCL injury is shown in Figure 2.6a and an X-ray image that presents a knee with an LCL injury is represented in Figure 2.6b.

The LCL often occurs in people who do contact sports or fitness activities that involve hard contact, jumping and/or quick changes of direction, such as football, basketball and skiing [8, 69, 72]. Much like MCL tears, LCL injuries cause pain, swelling and instability of the knee joint, especially when walking [7, 8, 69, 70, 72]. This type of injury often occurs along with damage to nerves of the joint, which might cause some numbness and weakness around the foot [8, 72]. The treatments for the LCL injuries are similar to the MCL injuries, although research has shown that the LCL does not heal as well as the MCL [22]. Non-operative treatments for minor injuries

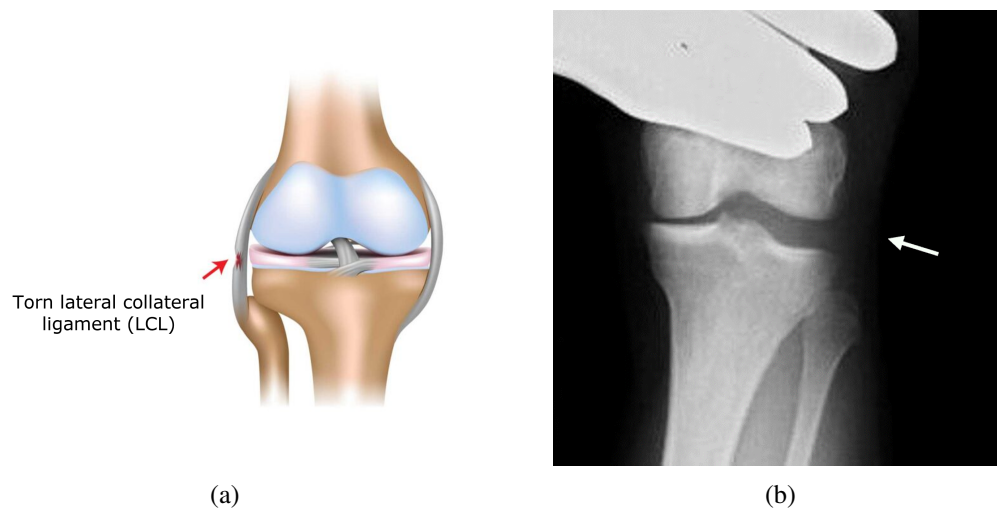


Figure 2.6: Representation of an LCL injury: (a) Scheme of the injury, adapted from [73]; (b) X-ray image of the injury with a noticeable knee laxity due to a loose LCL, adapted from [70].

involve the use of a brace, non-weight-bearing activity and/or medication to ease the pain, whereas more severe injuries might require physical therapy for knee rehabilitation, especially for the older or less active population. In the most severe cases of LCL tears, and especially in the case of young or active population, the LCL is repaired surgically by replacement with new ligament to grow in its place, maintaining the stability to keep participating in athletic activities [7, 8, 69, 72].

2.2.3 Patellofemoral Instability

Knee dislocations, such as PFI, are another type of injury that the knee joint often experiences. PFI is a condition where the patella moves out from the patellofemoral joint, in particular from the intercondylar fossa of the femur [11, 74, 75]. The intercondylar fossa consists of a V-shaped notch that functions as an articular surface between the patella and the end of the femur: the kneecap fits into the groove and slides up and down as the knee bends and straightens [75–78]. So, PFI happens when the patella moves outside of this groove, leading to an unstable kneecap [75, 78]. This condition can be divided into two types [12, 74, 75, 77, 78]:

- **Subluxation:** also known as partial dislocation, where the patella slips partially out of the intercondylar fossa of the femur;
- **Dislocation:** a traumatic or chronic injury where the patella completely slides out of the intercondylar fossa of the femur, damaging the soft tissues around it, including ligaments.

A representation of a PFI is presented in Figure 2.7a and an X-ray image of a patient's knee with PFI is shown in Figure 2.7b.

Fitness activities with fast deceleration and twisting with the knee extended and the foot externally rotated, such as football or gymnastics, are usually the cause of PFI. Direct blows to the knee are less common but are also the cause of traumatic PFI. These situations usually cause a trauma

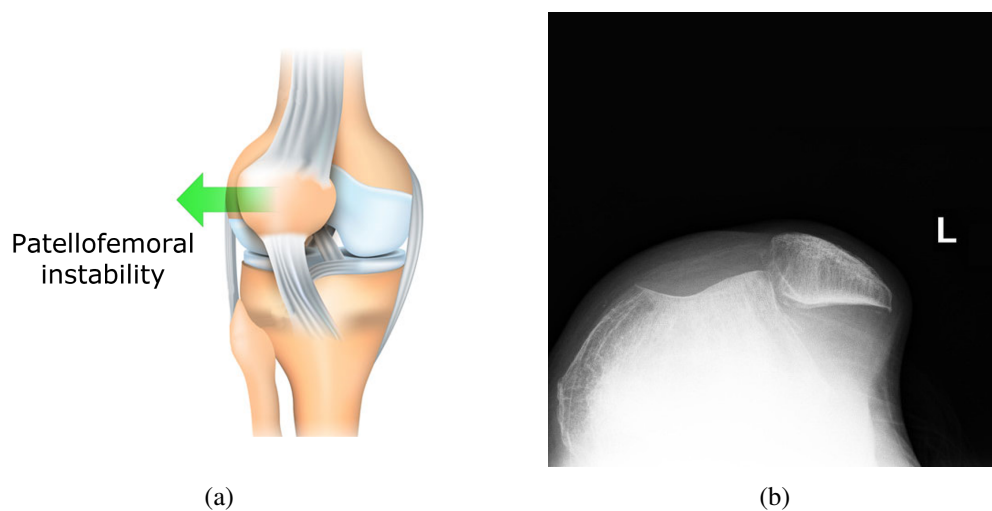


Figure 2.7: Representation of a PFI: (a) Scheme of the injury, adapted from [79]; (b) X-ray image of the injury with a noticeable patella lateral dislocation ("L" stands for "Left", referring to the presented left knee) [80].

injury and are often related to first-time patella dislocation [11, 12, 74, 78]. Despite anyone being able to develop PFI, female patients tend to be more at risk due to their looser knee ligaments, in particular young or active individuals [11, 24, 25, 74, 78, 81]. Moreover, chronic PFI is often common amongst patients with a history of patella dislocations, with bony misalignment, with chronic ligamentous laxity, or even with patella alta [11, 74, 78].

Knee pain, stiffness and swelling come along with patellar instability, which includes difficulty in walking, and/or buckling/locking sensation in the knee, especially during activities that involve knee bending. There might also be a visible deformity in the knee with PFI [11, 12, 74, 75, 78]. With chronic PFI, the pain is usually less severe than with a traumatic injury, and despite the dislocation being painful, sometimes there is almost no pain in between dislocation episodes. This causes some patients to delay seeking medical treatment whilst damaging their knee's soft tissues further with each PFI episode [74, 75]. In regards to medical treatment, for a first-time dislocation or a subluxation a non-operative approach with bracing, resting and non-steroidal anti-inflammatory drugs followed by physical therapy is often chosen, so the soft tissues can heal on their own. Surgical options followed by physical therapy are recommended in cases where the patient has chronic PFI, or a case of acute patellar dislocation. They range from soft tissue procedures that involve the repair or reconstruction of the torn medial patellofemoral ligament, to bony procedures that realign all of the bones and connective tissues of the knee joint [12, 25, 74, 75, 78].

Chapter 3

Knee Radiography

This chapter provides more insights into the common types of knee imaging, focusing on how knee injuries can be assessed through plain radiography, specifically via stress radiography and the skyline view.

3.1 Types of Knee Imaging

With the rising incidence of the knee pathologies mentioned in Section 2.2, the number of patients in need of clinical assessment of the knee will also increase. The clinical assessment of the knee involves the diagnosis of knee injuries, evaluation of the pre- and post-operative knee, and monitoring of the knee in non-operative treatments. In order to assess the joint, knee imaging is a crucial part of clinical judgement, being able to confirm a diagnosis and correctly assess and document pathologies, as well as helping with treatment selection and follow-up [82, 83]. The most common types of knee imaging are plain radiography, also known as X-ray, CT, MRI and ultrasonography [84–86]. Table 3.1 shows the differences between these methods of knee imaging, addressing which type of energy each one of them use and what knee tissues are usually analysed by physicians in the resulting image.

Table 3.1: Differences between the common types of knee imaging [86, 87].

Imaging method	Type of energy	Knee tissues usually assessed
Plain radiography	X-ray	Bones
CT	X-ray	Bones
MRI	Radio waves and magnetic field	Soft tissues (e.g. ligaments, meniscus)
Ultrasonography	Ultrasound	Superficial soft tissues structures (e.g. extensor mechanism)

When clinically assessing the knee joint, especially in situations of knee trauma diagnosis, physicians start by physically assessing the joint and investigating if it meets the criteria of the Ottawa knee rules (OKRs). The OKRs divide acute knee trauma patients into patients who might have a fracture and need knee radiographs to investigate further injury, and patients without any radiographically detectable bone injury. Its application cuts down unnecessary radiographs and consists of the following five criteria [85, 88, 89]:

- Age $\geq$ 55 years;
- Tenderness at the fibular head;
- Isolated tenderness of the patella;
- Inability to flex knee to 90°;
- Inability to bear weight both immediately and in the emergency department for four steps, regardless of limping.

If any of the aforementioned criteria are met, the patient's knee definitely needs to be assessed through plain radiography and further knee imaging, since a fracture is suspected. In the case of none of the criteria being met, a fracture can be ruled out and so can plain radiographs, but the patient might need knee imaging when there is still suspicion of ligamentous or meniscal pathology, for example [85, 88, 90]. A diagram of the pathway of the clinical assessment of post traumatic knee pain is represented in Figure 3.1.

3.1.1 Plain Radiography

Plain radiography is a type of medical imaging used for the clinical assessment of the knee by the passage of an X-ray beam through the joint, being an accurate mean of evaluating not only the bone, as presented in Table 3.1, but also its relationship with the orthopaedic hardware [13, 14].

In order to obtain a plain radiograph, a portion of the X-rays are absorbed or scattered by the knee, whilst the remaining X-rays are transmitted to a detector [13]. Since different tissues will absorb different amounts of radiation, a high-resolution two-dimensional image is generated, leading to the well-known grey-scaled X-ray images [15]: tissues that contain calcium, such as bones, will absorb high amounts of X-rays, creating visible white shadows; soft tissues containing water and/or protein absorb X-rays to small extents, appearing in the images in various shades of grey barely visible; and gas does not absorb any X-rays, casting no shadows and appearing black [91].

Since plain radiography generates an incomplete image of the knee's internal structures, it is commonly used to check for bone fractures after the OKRs are applied (Figure 3.1). It is also a common method to detect KOA due to the knee's clear space joint narrowing, as shown in Figure 2.4, and PFI, considering that a patella dislocation is quite noticeable (Figure 2.7b) [86, 88–91]. However, plain X-rays can be carefully interpreted by physicians to evaluate the knee's soft tissues, like its ligaments. Given the fact that bones are visible, the structure of the knee is outlined in

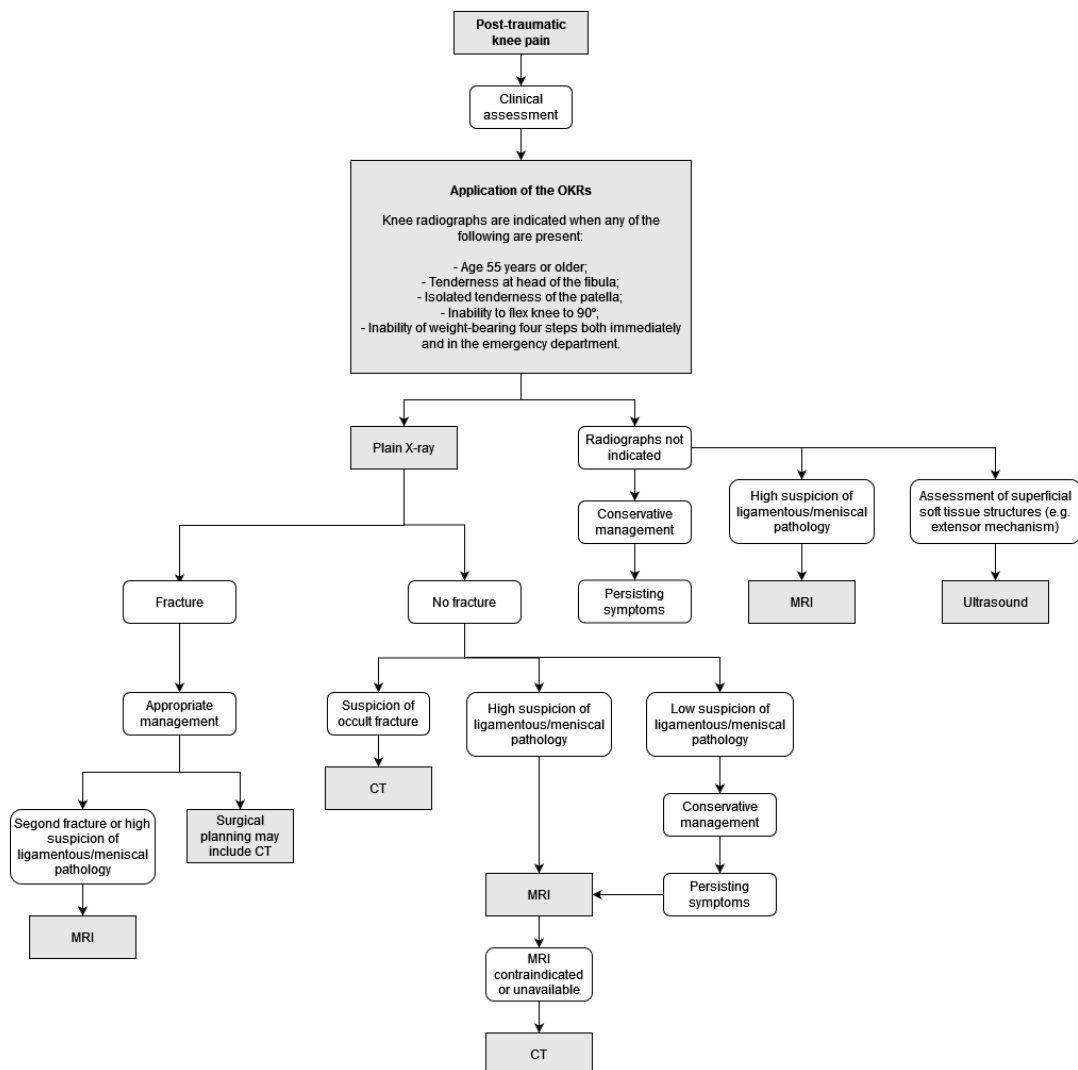


Figure 3.1: Pathway diagram of the clinical assessment of post traumatic knee pain, adapted from [90].

the image and knee ligamentous pathologies can be assessed in an indirect manner, using stress radiography. It is the case of MCL and LCL injuries, where the widening of the medial joint space and/or a lateral tibial plateau fracture can be seen in plain X-rays for an MCL injury (Figure 2.5b), and the widening of the lateral joint space and/or medial tibial plateau fracture might be seen for LCL injuries (Figure 2.6b). In spite of the possible clinical assessment of these injuries through plain radiography, further knee imaging is still advised for confirmation of the findings [18, 20, 21, 23, 86].

3.1.2 Computed Tomography Scan

After getting a plain X-ray, physicians order CT scans in case they need to assess the knee in more detail than it is given by a plain radiograph [90]. This type of knee imaging is especially used to assess in detail the bony structures of the knee and its surroundings, but still using the same type of energy as a plain X-ray, as mentioned in Table 3.1.

The CT functions in a similar fashion as the plain X-ray (Section 3.1.1), although it is computerised. A thin beam of X-rays is quickly rotated around the targeted part of the body via a donut-shaped structure, known as a gantry, generating signals that are picked up by the X-ray detectors and transmitted to the CT computer. Each time the source of the X-ray completes a full rotation through the gantry, a cross-sectional image, also known as slice, is produced by the use of sophisticated mathematical techniques. The slice is then stored and the bed where the patient lays moves forward into the gantry, to produce another cross-sectional image. After the desired number of slices is collected, it is possible to stack them together, creating a 3D image of the body part [92,93]. An example of a knee CT scan is presented in Figure 3.2.

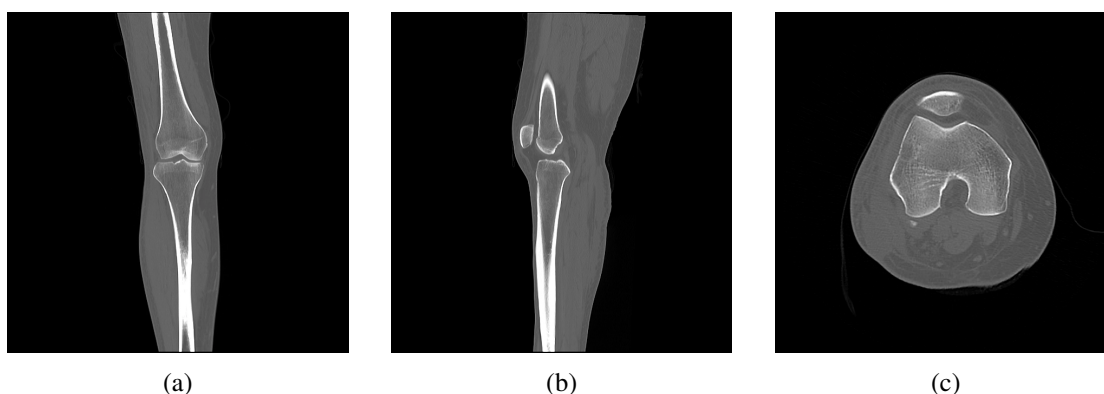


Figure 3.2: CT scan of a healthy knee: (a) Coronal bone window; (b) Sagittal bone window; (c) Axial bone window [94].

Given the fact that a CT image is a more detailed version of a plain X-ray, this knee imaging technique is often used, as shown in Figure 3.1, to characterise a type of fracture detected in a plain radiograph, to investigate the possibility of an occult fracture in a normal X-ray when the clinical features remain suggestive, or even for surgical planning. Moreover, the CT is the go-to method when a MRI is contraindicated or unavailable [85,86,90]. Being a more detailed version of a plain radiograph, knee pathologies like KOA, PFI and collateral ligament injuries can be assessed, as it was explained in Section 3.1.1 [95,96].

3.1.3 Magnetic Resonance Imaging

In the event of clinical indication in a plain X-ray of a second fracture, which is an avulsion fracture of the knee involving the lateral facet of the tibial plateau [97], or suspicion of a liga-

mentous/meniscal pathology, whether there is a fracture or not, a MRI is ordered (Figure 3.1). Furthermore, a MRI is requested when the OKRs criteria are not met and there is suspicion of a ligamentous/meniscal pathology [86,90].

MRI is a non-invasive medical imaging technique that uses a magnetic field and radio waves to assess the soft tissues of the knee, as mentioned in Table 3.1. This method is based on the detection of the excitement and change of direction of the rotational axis of protons present in the living tissues' water. By placing the patient inside a large magnet, the strong magnetic field forces the protons of the body to align in that said field. Radio waves are pulsed through the body, stimulating the protons and spinning them out of their balance. Since there is a tension created between the protons and the magnetic field due to the radio waves, once the radio wave field is turned off, the protons realign with the magnetic field and the MRI sensors detect the energy released by the protons. The MRI image is generated due to the fact that different type of tissues will release a different amount of energy and their protons will take a different amount of time to realign with the magnetic field. A 3D image can be obtained similarly to how 3D CT images are obtained, as explained in Section 3.1.2. Moreover, MRIs can have different levels of brightness and colour when physicians give contrast agents intravenously to patients [86,98,99].

Unlike plain radiography and CT, MRI does not use the ionising radiation of the X-rays that is more damaging to the patient's body, giving a more detailed image of soft tissues of the knee, such as ligaments and articular cartilage [85,99]. With this type of knee imaging technique, it is possible to visualise signs of KOA earlier than with plain radiography or CT, since it is possible to check any defects in the articular cartilage with more detail, as seen in Figure 3.3b [100,101]. However, radiography is usually sufficient for the evaluation of KOA [85]. Thus MRI is more often related to the assessment of ligaments, such as the MCL and the LCL, considering that signs of these knee ligaments injuries are seen in MRI scans due to a visible discontinuity, swelling and/or high intensity of the signal of the ligament (Figures 3.3c and 3.3d) [86,102,103]. Besides, MRI is capable of assessing PFI in more detail, giving information regarding the state of the ligaments surrounding the patella, the amount of lost articular cartilage, and even the existence of bone contusions, apart from the noticeable subluxation or dislocation of the bone (Figure 3.4b) [85,104].

3.1.4 Ultrasonography

Lastly, when the criteria of the OKRs are not met, there might be suspicion of injury regarding the superficial soft tissues structures of the knee, being usually assessed through ultrasonography: a type of knee imaging that relies on ultrasound, as presented in Table 3.1 and Figure 3.1 [85,86].

Ultrasonography, in this case diagnostic ultrasonography, also known as ultrasound, is a non-invasive knee imaging technique based on the emission and detection of ultrasound waves. These waves are generated by a transducer that is capable of emitting them, but also detecting the ultrasound echoes that are reflected back from the body. The transducers are composed of piezoelectric materials that are able to create sound waves when an electrical field is applied to them, and vice-versa. So, the transducer produces a beam of ultrasonic waves into the body, which are reflected back to the transducer, depending on the type of tissue surface they hit. As these echoes hit the



Figure 3.3: MRI scans of a knee joint in normal anteroposterior view: (a) Healthy knee [105]; (b) Knee with osteoarthritis where there is a mild articular cartilage loss (arrow), adapted from [106]; (c) Knee with a MCL injury showing visible discontinuity, swelling and high intensity of the ligament (arrow), adapted from [102]; (d) Knee with a LCL injury showing visible discontinuity, swelling and high intensity of the ligament (arrow), adapted from [103].

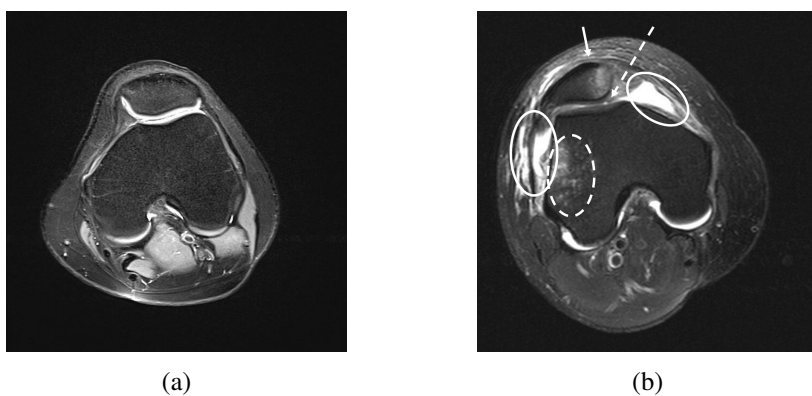


Figure 3.4: MRI scans of a knee joint in axial view: (a) Healthy knee joint [107]; (b) Knee with PFI, showing patellar subluxation (arrow), loss of articular cartilage (dashed arrow), ligament injuries (ellipses), and bone contusion (dashed ellipse), adapted from [104].

transducer, electrical signals are generated and sent to the ultrasound scanner. This scanner calculates the distance from the surface of the tissue to the transducer, using the time that the echoes took to return and the speed of sound, and the different distances accumulated are utilised for the production of the well-known two-dimensional images of ultrasounds. The ultrasound transducer can be either placed on the skin, where the application of a gel is necessary to block the ultrasound waves from passing through the surface of the body, or they can be placed inside the body to optimise the image quality [108, 109].

In the case of the knee joint, the transducer is usually placed on the skin to assess the superficial soft tissues structures of the knee, such as the extensor mechanism, which consists mainly of the quadriceps muscle and tendon, the patella and the patellar tendon [85, 110]. Despite the assessment of knee pathologies, like KOA, PFI, and collateral ligament injuries, being possible [111], ultrasonography is rarely used for any knee pathology other than tendon ruptures, which are relatively rare and not often considered solely, since ultrasounds have a limited view and reduced accuracy for the assessment of overweight or muscular patients [85, 86, 112].

3.2 Plain Radiography in the Assessment of Knee Injuries

The first-line investigation for suspected orthopaedic pathology is the plain X-ray, having over a half of ordered examinations when compared to other widely used imaging methods, like the ones mentioned in Section 3.1 [14, 33, 34]. Even though images generated by CT and MRI present a more detailed analysis of all body structures in 3D images, while plain X-rays provide detail solely to bony structures, physicians still choose the X-ray as the first approach to obtain a clinical image of the knee. This is due to plain radiography being a faster, cheaper and more accessible method of evaluating the knee, giving images that already show indirect signs of collateral ligament ruptures, KOA or PFI [16]. So, when a patient requires knee imaging, physicians usually opt for getting X-rays for the main three views: anteroposterior, lateral, and skyline [113, 114]. They are then able to address collateral ligament ruptures and/or KOA via the anteroposterior view, in particular through stress radiography, and KOA and/or PFI through the skyline view [18, 20, 21, 115–117].

3.2.1 Stress Radiography

The diagnosis of KOA and MCL and LCL injuries, as well as the monitoring in non-operative treatments and evaluation in pre- and post-operative treatments, usually involves radiography under physical stress [18, 20, 21]. This medical image provides a more objective analysis of the measurement of the knee laxity than a physical examination does [17–21]. Some of the most frequent stress tests used during stress radiography to evaluate the knee laxity for KOA are the valgus and the varus stress tests [17, 118, 119]. The valgus stress test is also widely used to evaluate knee instability for injuries of the MCL and other medial stabilisers [19, 120], whereas the varus stress test is usually performed to evaluate the knee instability for LCL injuries and other lateral stabilisers [71, 121].

To obtain these type of X-ray images (Figures 1.5, 2.5b and 2.6b), the literature agrees that the patient should be positioned in supine position with a knee flexion of approximately 20°-30°, by placing a radiolucent cushion under the knee, and the foot in neutral position [17,19,119,120,122]. For patients with a medium height (around 1.70 m), this cushion should be about 100 mm high [19]. For application of pressure at the level of the joint-line for both tests, physicians either apply pressure with their hands, subjectively (Figures 1.3a and 1.3b) [123], or use a stress device to apply a standardised force that should not exceed 150 N (Figures 3.5a and 3.5b) [17, 119, 124]. For the valgus stress, the pressure is applied on the lateral epicondyle of the distal femur, whereas for the varus stress, it is applied on the medial epicondyle of the distal femur [19]. When performing these stress tests manually, the hand that is not applying the pressure should be placed on the distal extremity of the lower limb [19]. However, when using a stress device, two supports are placed medially on the femur and the tibia, as far away from each other as possible [119].

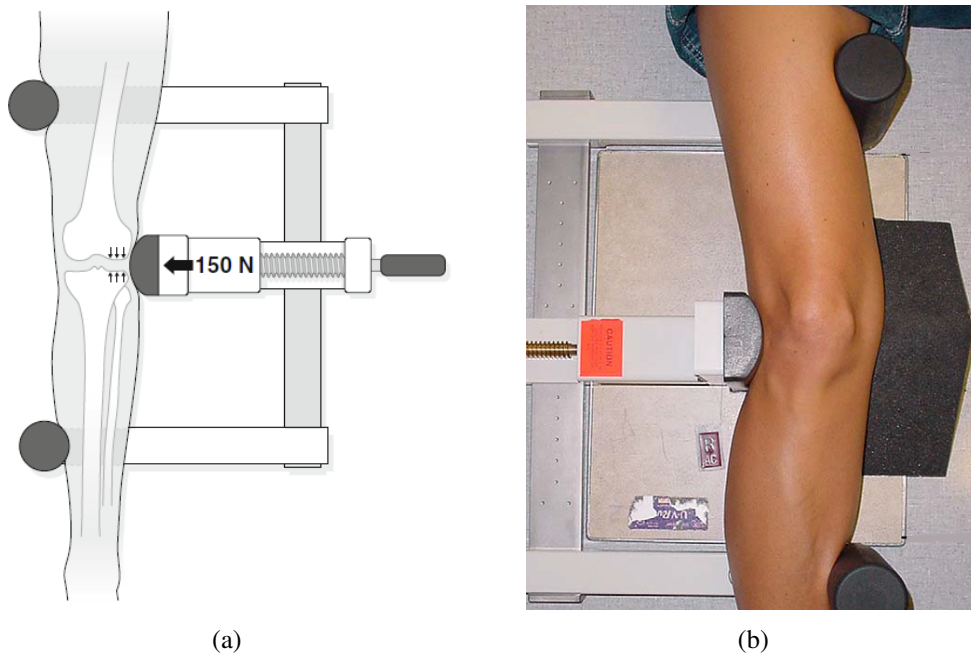


Figure 3.5: Stress radiography, specifically the valgus stress test, performed with the Telos Stress Device: (a) Schematic stress test on the left knee [119]; (b) Stress test on the right knee [124].

3.2.2 Skyline View

The clinical assessment of KOA and PFI for diagnosis, monitoring in non-operative treatments and evaluation in pre- and post-operative treatments includes obtaining a plain radiograph in skyline view of the knee joint. This type of method to produce an axial projection of the patella is often used to obtain a more objective image of the knee than a sole physical examination would provide [115–117].

In order to generate X-ray images of the skyline view of the knee (Figures 1.2c, 2.4c, 2.4d and 2.7b), the literature agrees that the patient should be positioned in either supine or prone position with the knee flexed [115, 117, 125, 126]. However, various techniques for getting a skyline view radiograph have been suggested by numerous authors. The most commonly used in a clinical setting are the Laurin view, the Merchant view, or the Settegast view, and their characteristics are summarised in Table 3.2. The Laurin view (Figure 3.6) is obtained with the patient semi-recumbent in supine position, with the knee flexed from 20° to 30° and the direction of the X-ray beam in relation to the lower limb - starting from the X-ray generator and ending in the X-ray detector - being from distal to proximal [115, 125]. Regarding the Merchant view, the patient is positioned with their knee flexed at 45° in supine position, and the X-ray beam goes from the proximal lower limb to the distal lower limb. The patient's feet can be very close to the end of the bed or hanging at the end of the bed, as represented in Figure 3.7 [125, 126]. A cushion is often used to provide the flexion needed for the Laurin and the Merchant views and the X-ray detector is often held by the patient, which does not provide an objective and reproducible image. Moreover, the Settegast technique involves positioning the patient with a flexed knee of 90° or over, in prone position, and with a vertical X-ray beam, placing the detector on the bed under the patient's knee (Figure 3.8). Despite the numerous amount of existent techniques to obtain the skyline view, some studies have already shown that the optimum angle for the knee flexion during this type of radiographic assessment is of 30°, since it provides the easiest reproducible results [125, 127].

Table 3.2: Comparison of the characteristics of each common skyline view technique [115, 125, 126]

Type of view	Knee flexion	Position of patient	Direction of X-ray beam
Laurin	20° to 30°	Supine	Distal to proximal
Merchant	45°	Supine	Proximal to distal
Settegast	$\geq 90^\circ$	Prone	Vertical

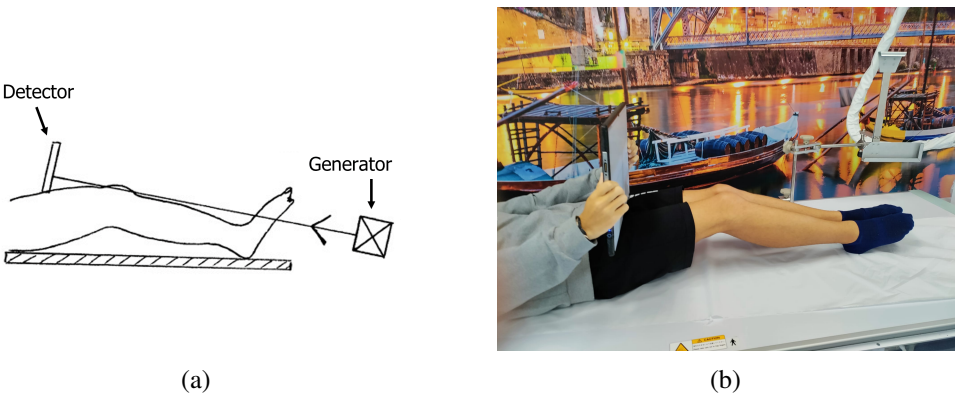
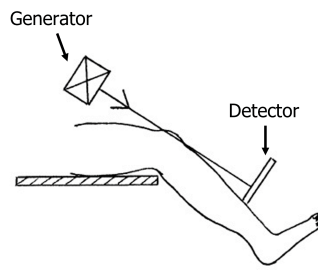


Figure 3.6: Laurin view: (a) Schematic, adapted from [125]; (b) Technique performed on a patient.

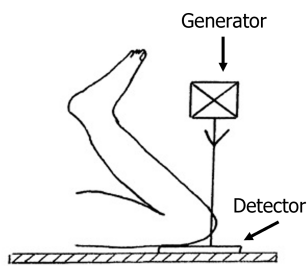


(a)



(b)

Figure 3.7: Merchant view: (a) Schematic, adapted from [125]; (b) Technique performed on a patient.



(a)



(b)

Figure 3.8: Settegast view: (a) Schematic, adapted from [125]; (b) Technique performed on a patient [128].

Chapter 4

State of the Art

This chapter presents a review of the state of the art of positioning systems used in the clinical assessment of the knee joint through stress radiography and their evolution over time.

4.1 Positioning Systems in the Clinical Assessment of the Knee Joint with Stress Radiography Techniques

Due to the lack of objectivity and reproducibility of manual stress radiography, stress radiography positioning systems have been developed, in particular for the valgus and/or varus stress tests. These devices help positioning the patient during the X-ray exam whether manually or automatically, whilst applying a manual or automatic stress to a desired joint of the body.

There are several systems already in use capable of positioning the patient and applying valgus/varus stress to the injured joint. The first systems created were by physicians themselves in order to avoid the exposure to radiation during the stress test. They were cheap and extremely simple, being of manual set-up with an application of force manually by the patients themselves [20, 129]. However, these systems failed to provide objectivity/reproducibility, due to the patient not applying the necessary force to perform the stress test correctly, since they are usually patients with knee injuries, hurting when stress radiography is performed. So, positioning systems with an automatic force (applied by the device itself) came in handy to overcome this issue [118, 119, 124, 130]. Although this was already a big step for healthcare, some systems go one step further and provide an automatic set-up of the valgus/varus test to have a faster and easier examination without the physician having to step into the examination room every time they want to apply a different stress test or position the patient in a different angle [131].

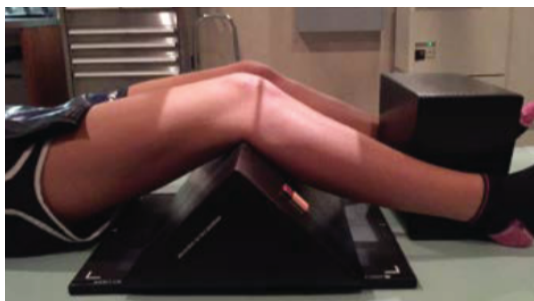
In this state of the art, there was only focus on systems that were designed with the sole objective of positioning the knee for valgus and/or varus stress tests without the help of a physician or technician, in order to conclude whether there was a need for the healthcare system for this type of device. Since there is a lack of positioning systems for stress radiography, the presented study

can not be too extensive. Furthermore, there is little to no information about the systems presented, since the creators might not wish to disclose the specifications of the devices in case they decide to put them out in the market. Despite some of the undermentioned systems being currently in the market, they still have limitations that show that there is a clear gap in this area of orthopaedics.

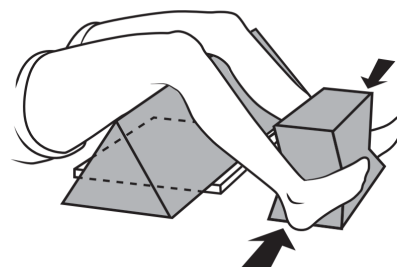
4.1.1 Manual Knee Positioning Systems

In an attempt to not being exposed to radiation during stress radiography, physicians have been trying to create positioning systems themselves, coming up with cheap and simple systems for applying the necessary force without their assistance.

Innomed's Self Stress Assembly Set (Figure 4.1a) is a simple positioning system for stress radiography that is already in the market. It consists of a triangle positioner and a contoured cube, where the triangle positioner is used as an external cushion to flex the patient's knees; and the contoured cube is positioned between the patient's feet. The pressure for the valgus stress test is applied by the compression of the contoured cube by the patient's feet (Figure 4.1b) [129]. Despite being available in the market, the Self Stress Assembly Set requires patients to perform the valgus stress themselves, giving subjectivity to the system, since an injured patient will not apply the pressure needed after they start to feel pain. In addition, this system can not support the extremities of the lower limb, nor fix the feet in a neutral position, which might lead to motion artefacts and incorrect positioning on the X-ray images.



(a)



(b)

Figure 4.1: Self Stress Assembly Set provided by Innomed: (a) The set-up of the valgus test performed by a patient [129]; (b) Schematics of the valgus stress test [129].

Other systems in the literature also provide simple and cheap solutions to avoid exposing the physician to radiation. It is the case of the valgus stress technique for stress radiography applied by Sawant et al. [20] (Figure 1.4), where the knees are bound together using a firm 6-inch crepe bandage, a cassette is placed longitudinally under both knees, and the physician stands at the feet of the patient, applying an outer force to both feet whilst keeping them in a neutral position.

Another example is a technique used to apply the valgus stress test during stress radiography by Rocha de Aguiar et al. [132], shown in Figure 4.2. This technique created by physicians uses a similar approach to the Sawant et al. [20] technique, bounding the knees together using a velcro

belt placed around the patellar level and keeping the medial part of the upper limbs together. A wedged material made of ethylene vinyl acetate is placed with its larger side below the malleolar level of the ankle, much like it is done with the Innomed's Self Stress Assembly Set, and the two opposing forces create a valgus stress to the knees. In case the physician decides to perform a valgus stress with the knee at 30° flexion, then a soft pad, also made of ethylene vinyl acetate, can be placed under the knee.



Figure 4.2: Stress radiography performed with a technique created by physicians, adapted from [132]. The arrows near the knees' of the patient show the force created by the velcro belt, whilst the arrows near the ankles show the force generated when the wedged material is placed between them after the velcro is in place.

The stress radiography systems created by Sawant et al. [20] and Rocha de Aguiar et al. [132] fail at providing the objectivity and reproducibility that are needed. These solutions avoid the physician to be in direct contact with radiation, but still are based on subjective techniques that provide no completely fixed position of the lower limb of the patient. Furthermore, Rocha de Aguiar et al. [132] does not keep the feet in a neutral position.

4.1.2 Semi-Automatic Knee Positioning Systems

There are several systems already in use capable of applying stress to the injured joint automatically. The Telos Stress Device is the standard device technique used for stress radiography of the knee joint. This device allows for an overall examination of the knee joint's laxity [130], and it is capable of positioning the patient in supine position for valgus and varus stress (Figures 3.5a and 3.5b). The lower limb is secured by means of two extension arms with a counter support at the extremities of the device, which can be adjusted to the length of the leg [130]. A representation of the patient's lower limbs position is shown in Figure 4.3. The middle pressure part of the device has an electronic measuring equipment that is used to apply the chosen force on the joint and display it [130]. The device works on alkaline batteries, so the lifetime will be of approximately 150 - 200 hours without changing them [130]. A scheme of the device's patent is presented in Figure

4.4. This patent was approved in 1980, and was filed by Olaf Tulaszewski. It involves a "Leg positioning device for X-ray filming" that has a support that can fixate the lower limb at two different spaced locations, a pressure part between those two locations that applies an incrementally variable pressure to the leg, and a device for the measurement of the applied force, so that it can be easily reproduced [133]. Stress radiographs generated with the assistance of the Telos Stress Device are shown in Figures 4.5a and 4.5b.

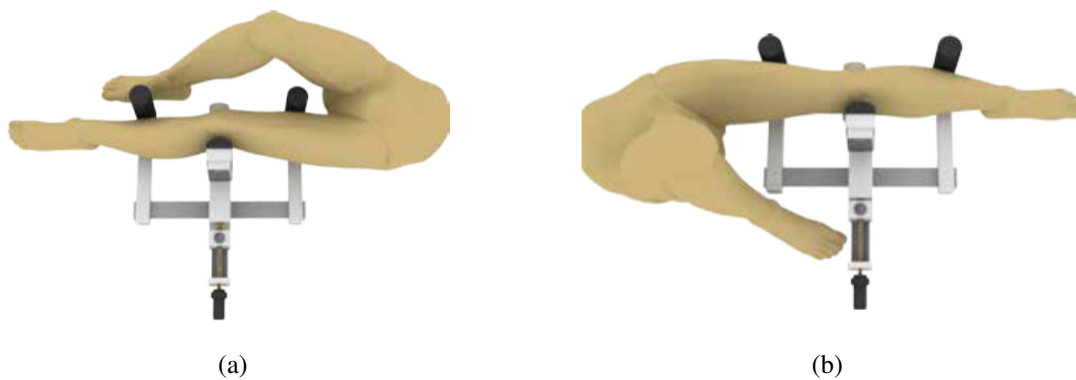


Figure 4.3: Representation of the positioning of the lower limbs of the patient during stress radiography with the assistance of the Telos Stress Device [130]: (a) Valgus stress test; (b) Varus stress test.

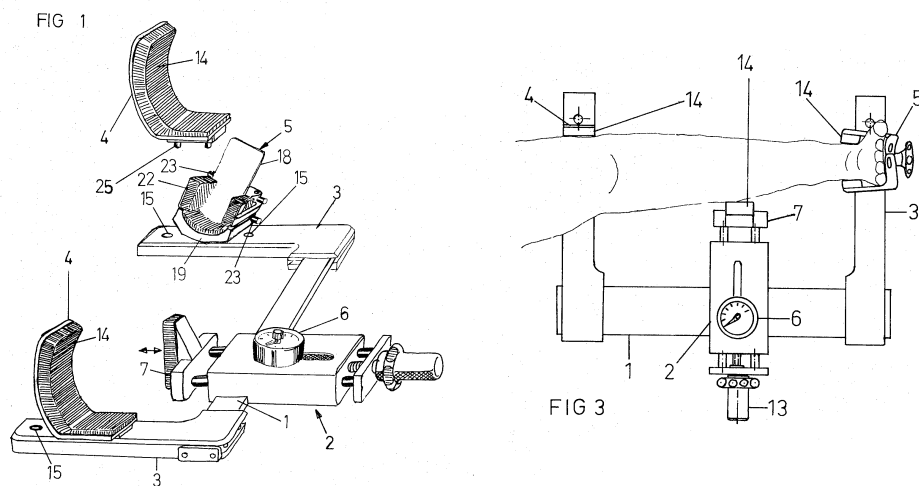


Figure 4.4: Schematics of the patent for the Telos Stress Device, adapted from [133]: "FIG 1" scheme shows a perspective view of the device; "FIG 3" is a top view of the device with a leg in position for the stress radiograph performed by the device.

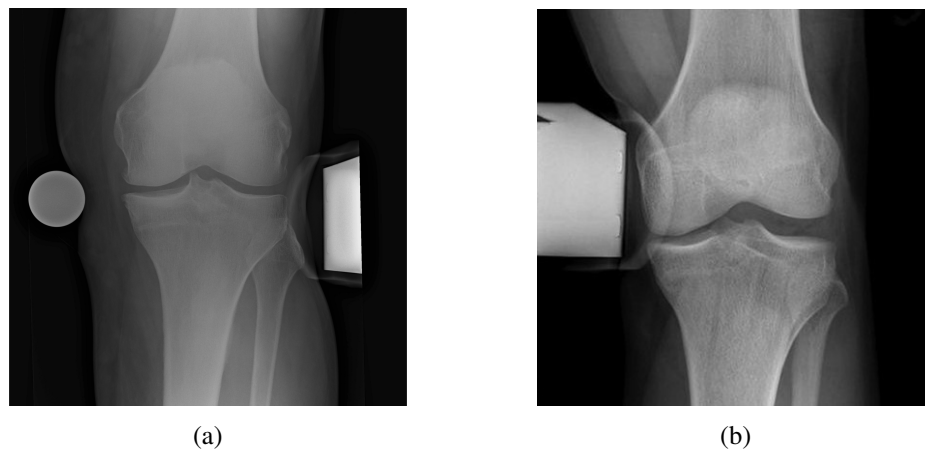


Figure 4.5: Left knee X-ray image generated by stress radiography with the assistance of the Telos Stress Device: (a) Valgus stress test [119]; (b) Varus stress test [134].

Although the Telos Stress Device is used worldwide for the stress radiography of most human joints (e.g. knee, ankle, wrist, elbow), being able to perform stress tests, such as the valgus and varus stress, it still has some limitations. This popular device is not radiolucent, leaving artefacts of the support and pressure parts in the X-ray images [119]. These artefacts could make the X-ray image more difficult to read to the physician, since it is quite distracting and does not give the plain anatomy of the joint. Furthermore, the Telos Stress Device needs an external cushion to provide the flexion of the knee joint in order to perform the stress tests, and when performing the valgus/varus test the foot is not in neutral position, as seen in Figure 4.3 [130].

A device similar to the Telos Stress Device, created by Said et al. [135], has the objective to perform valgus and varus stress tests in both X-ray and MRI environments. It consists of a loading and a connected control unit, and the scheme of the overall system is shown in Figure 4.6. The loading part of the system (Figure 4.7), composed of MRI-compatible materials, uses a pneumatic actuator placed at the centre of the device. The pressured air supplying the actuator will provide the force necessary to perform the stress test. On the opposite side of the central pressure applicator, there are two adaptable counter-bearings that fix the upper and lower leg, to ensure the reproducibility of the force application. These counter-bearing and the actuator are padded with biocompatible materials so as not to injure the skin of the patient. When it comes to the control unit, it consists of a digital-to-analogue converter and a proportional pressure valve, that is actuated electronically. These two components ensure the connection between the pneumatic actuator and the pressure outlets. Moreover, the digital-to-analogue converter is controlled by software routines that allow the pressure valve to go from 0 to 4.69 bar. As calculated by Said et al. [135], this allows the pneumatic actuator to provide a maximum force of 230.2 N.

Despite being an objective and reproducible positioning system, that functions not only in a radiographic environment, but also in a MRI environment, the system proposed by Said et al. [135] does not have radiolucent materials, generating artefacts in the obtained X-ray images. Besides, it requires an external cushion in case the physician desires to provide flexion to the knee during the

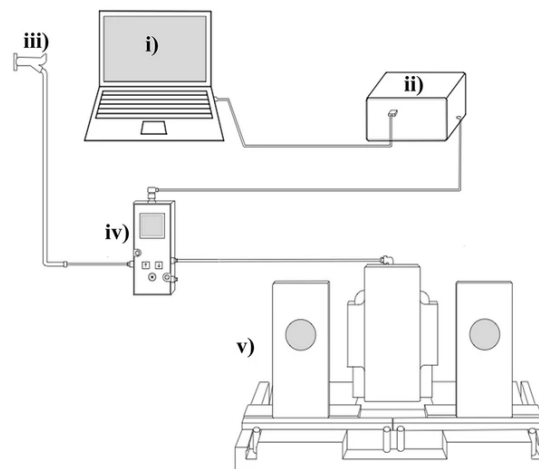


Figure 4.6: Scheme of the overall positioning system provided by Said et al. [135]. The pressure control valve (iv) is controlled by the laptop (i) and the digital-to-analogue converter (ii), in order to regulate the pressure provided by the pressure outlets (iii), that is forwarded to the loading part of the device (v).

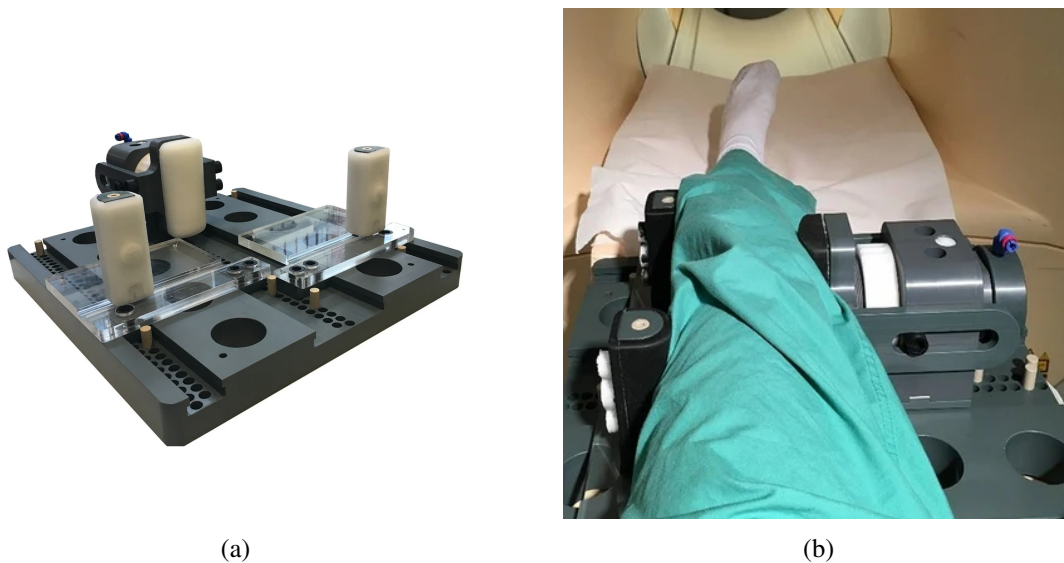


Figure 4.7: Loading part of the knee positioning system created by Said et al. [135]: (a) The loading part; (b) Patient with the left limb fixed by the loading in an MRI environment.

stress radiographs, and it does not have a method to fix the foot in its neutral point.

Another valgus/varus stress device with a force applied without the need of an operator in the examination room was developed by Eriksson et al. [118]. This system applies a constant stress force on the knee joint and is capable of adjusting a force up to 10 kg to apply a valgus or varus stress test, whether in full extension of the leg, or at 30° flexion [118]. Despite the literature not

providing much information about the specifications of the device, by analysing Figure 4.8 it is possible to assume the pressure is applied to the tibia and there is only one support that fixes the upper leg with the force of the patient's foot. Even though the system developed by Eriksson et al. [118] uses an objective and reproducible method, it seems to need an external cushion for the flexion of the knee, and the support of the upper leg seems to be made of a radiopaque material. In addition, this device does not fix the foot in a neutral position [118].

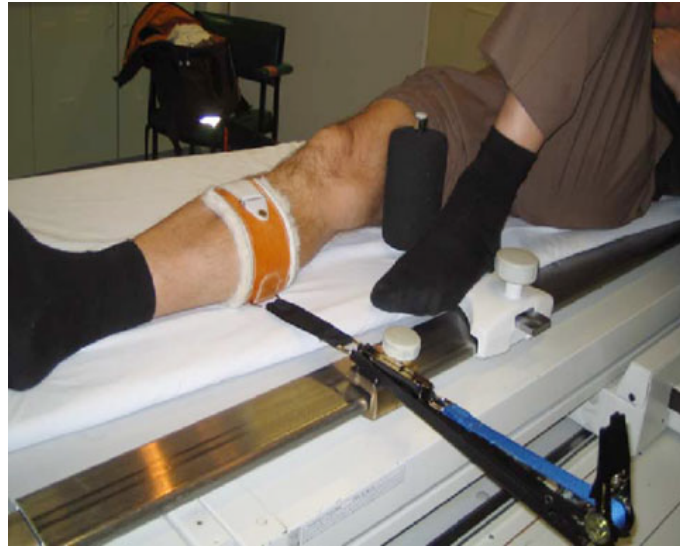


Figure 4.8: Valgus/varus stress device developed by Eriksson et al. [118].

4.1.3 Automatic Knee Positioning Systems

As new positioning systems with an automatic application of force are developed, researchers are already creating systems with an automatic set-up of the stress test in order to turn the process of stress radiography even faster. It is the case of Beukes et al. [131], that has developed the Laxmeter.

The Laxmeter is a radiolucent stress radiography device that was initially developed to facilitate the measurement of knee joint ligament laxity at various angles of joint flexion (Figure 4.9) [131]. It consists of two primary systems: an ergonomic patient support structure (Figure 4.10a), and a load application system (Figure 4.10b). The acrylic support structure allows the positioning of the patient at multiple degrees of knee joint flexion. The respective patent (Figure 4.11) was filed by the University of Cape Town, South Africa and accepted in 2015. It entails an "Anatomical support facilitating medical imaging of the hip, leg and knee" that is divided into an horizontal pelvis support panel, which is attached to an edge of a thigh supporting panel, connected to an opposite edge of a shin/foot. All these panels are made of radiolucent material. Both the pelvis support panel and the thigh panel have anchorage attachments to restrain these parts of the body of the patient. Furthermore, there are locking sections in the shin/foot support panel to

adjust the structure into different positions parallel to the pelvis support panel [136]. The Cast-Nylon electromechanical load applicator applies an incremental translational force necessary to perform various stress tests, including valgus and varus, and is complete with pressure sensing pads [131]. This load varies from 0 to 250 N in 25 N increments, being held for 30 seconds in each position to allow for X-ray image capturing, and assessing the anterior, posterior, medial and lateral parts of the proximal lower leg [131]. As observed in Figure 4.12, the lower limb is supported by the ergonomic structure and by velcro straps. Since the Laxmeter is meant for laxity measurement via stress radiography, it has the integration of a stress radiography bone translation tracking system that gives real-time diagnostic information [131]. This tracking system involves a radiopaque scale embedded onto the ergonomic support, that is visible on stress radiographs [131].

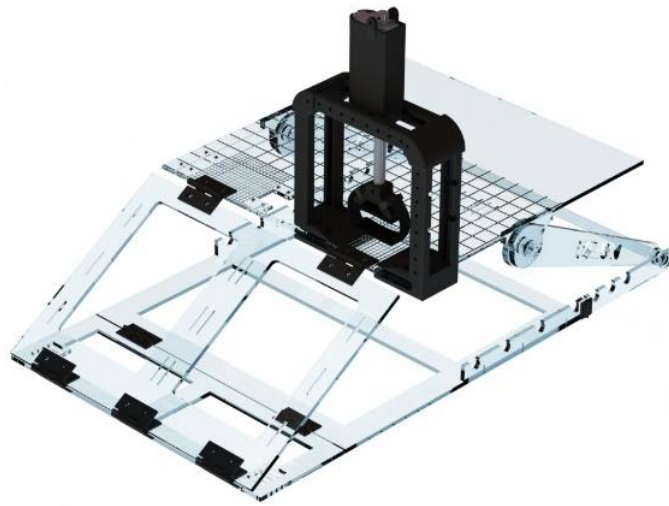


Figure 4.9: The Laxmeter stress radiography device [131].



(a)



(b)

Figure 4.10: The two primary systems of the Laxmeter [131]: (a) The ergonomic patient support structure; (b) The load application system.

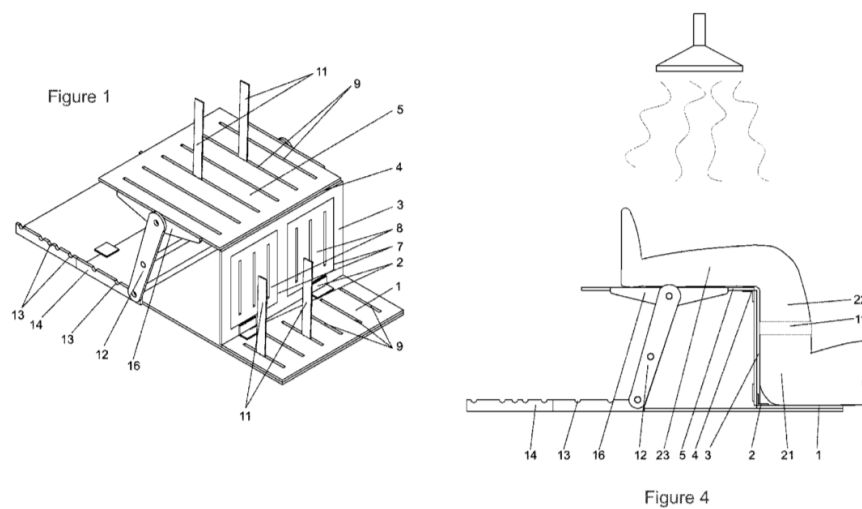


Figure 4.11: Schematics of the patent of the ergonomic patient support structure, adapted from [136]: "Figure 1" represents the schematic isometric view of the structure, with the shin/foot support panel in its highest elevation when in relation to the pelvis supporting panel; "Figure 4" is a scheme of the side view of the structure shown in "Figure 1" with an illustration of the positioning of the lower limb on the support structure.

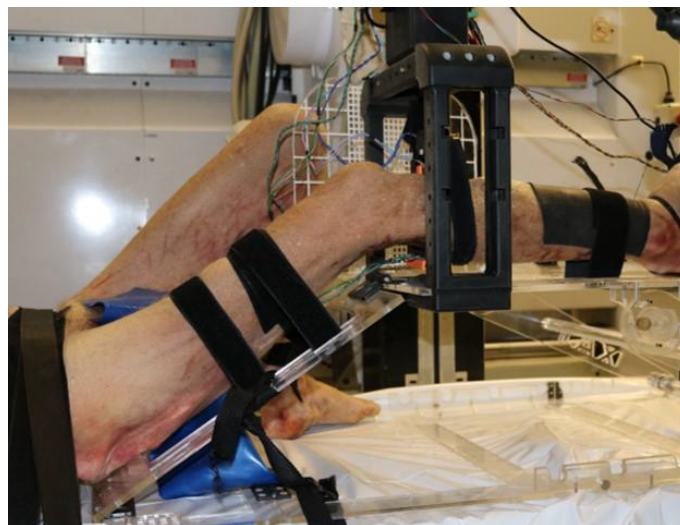


Figure 4.12: Stress radiography to assess the knee joint with the assistance of the Laxmeter [131].

The positioning system created by Beukes et al. [131] already provides the flexion of the knee with its ergonomic support structure, not requiring an external cushion. However, the force is given by automatic increments, which makes it time-consuming if the operator wants to assess only one part of the knee, and despite there being restraint of the upper and lower leg, there is no restraint of the foot in a neutral position. Moreover, it has a radiopaque scale for laxity measurement, that is visible in stress radiographs. Even though this radiopaque scale would allow the physician to

assess the injury in real-time, most physicians do not find this necessary for diagnosis, preferring a clean X-ray image. In addition, the Laxmeter is a big, heavy-weight, and unfoldable structure that could have a negative impact in health facilities, delaying the stress radiography set-up.

4.1.4 Comparison of the Techniques and Features of the Knee Positioning Systems

The techniques of all the knee positioning systems mentioned in this state of the art are compared in Table 4.1. They were divided into five types of techniques:

- **Set-up of stress test:** can be manual if the device is set up manually by the operator before the examination, or automatic if the system is capable of setting up the position of the stress test by itself without the need of the operator in the examination room;
- **Type of force:** the force applied to the joint for the stress test can be manual, when performed by the operator, or automatic, when the device is capable of applying a constant force without the assistance of an operator nor the patient;
- **Use of sensors:** the existence or not of sensors in the positioning system usually depends on how the force is applied. If the force is manual then it might not have any sensors, whereas if the force is automatic it is highly probable there are sensors for safety and objectivity;
- **Type of test:** the type of stress test performed by the device can be the valgus stress test, the varus stress test, or both;
- **Skyline view attainability:** if it is possible for the device to position the knee for a skyline view X-ray to be taken. As mentioned in Section 3.2, the skyline view is one of the usual requested views for the clinical assessment of the knee through plain X-rays. Even though devices to hold the X-ray detector during this type of plain radiography already exist in the literature [137–139], they only address the skyline view. So, having the possibility to obtain this type of view in a stress radiography positioning system would be a good addition to its basic functionality.

When setting up the device to perform the chosen stress test, only the Laxmeter has an automatic set-up, whereas the other devices require it to be done manually. The force is applied to the joint through automatic methods for all systems except for the Self Stress Assembly Set, and the techniques used by Sawant et al. [20] and Rocha de Aguiar et al. [132], that require a manual constant force to be applied to/by the patient. Regarding whether the positioning device is equipped with sensors or not, the Self Stress Assembly Set, and the techniques used by Sawant et al. [20] and Rocha de Aguiar et al. [132] do not have any sensors, since these products are manual. The existence of sensors in the technique created by Eriksson et al. [118] is uncertain. All of the analysed devices perform both the valgus and the varus stress tests, with the exception of the Self Stress Assembly Set, and the techniques used by Sawant et al. [20] and Rocha de Aguiar et al. [132], which are only able to perform the valgus test. Finally, when it comes to the possibility

Table 4.1: Comparison of the techniques of the knee positioning systems.

Positioning System	Techniques				
	Set-up of stress test	Type of force	Use of sensors	Type of test	Skyline view attainability
Self Stress Assembly Set	Manual	Manual	×	Valgus	×
(Sawant et al.)	Manual	Manual	×	Valgus	×
(Rocha de Aguiar et al.)	Manual	Manual	×	Valgus	×
Telos Stress Device	Manual	Automatic	✓	Both	×
(Said et al.)	Manual	Automatic	✓	Both	×
(Eriksson et al.)	Manual	Automatic	?	Both	×
Laxmeter	Automatic	Automatic	✓	Both	✓

of positioning the patient for a skyline view of the knee to be obtained, only the Laxmeter has a design capable of attaining this feature.

A comparison between the features of all the mentioned knee positioning systems and their limitations is represented in Table 4.2. The positioning system's performance is assessed taking the following criteria into account:

- **Objectivity/reproducibility:** determines whether the positioning system is capable of performing stress tests without being influenced by the operator, and if it can reproduce the same stress test no matter the operator;
- **Radiolucent:** a positioning system is radiolucent when the X-ray images obtained with its assistance do not show any artefacts related to the system;
- **Fixed foot:** questions if the device is able to keep the foot in a neutral position, in order to position the patient in the correct and best position to obtain the stress tests' X-ray images;
- **Ergonomic:** determines if the system was designed for efficiency and comfort of the patient;
- **User-friendly:** keeps in mind that the system must be of simple and fast use.

The Self Stress Assembly Set does not have objectivity and reproducibility, nor is it able to keep the foot in neutral position. The simple technique invented by Sawant et al. [20] only has the benefit of being user-friendly and fixing the foot in neutral orientation, whereas the one used by Rocha de Aguiar et al. [132] has the addition of being radiolucent but can not fix the foot. The devices created by Said et al. [135] and Eriksson et al. [118] are not radiolucent nor ergonomic, and fail to put the foot in neutral position. Despite the Telos Stress Device being the most well-established in the market, it is not able to be radiolucent, ergonomic, nor to fix the patient's foot.

Table 4.2: Comparison of the features of the knee positioning systems and their limitations.

Positioning System	Features				
	Objectivity and reproducibility	Radiolucent	Fixed foot	Ergonomic	User-friendly
Self Stress Assembly Set (Sawant et al.)	×	✓	×	✓	✓
(Rocha de Aguiar et al.)	×	×	✓	×	✓
Telos Stress Device (Said et al.)	×	✓	×	×	✓
(Eriksson et al.)	✓	×	×	×	×
Laxmeter	✓	×	×	×	✓
	✓	×	×	✓	×

In addition, physicians have mentioned that this device is too confusing to set up, ending up not utilising it in a clinical setting. Finally, the Laxmeter is not radiolucent, and it is a big heavy structure that ends up not being user-friendly, and unable to restrain the foot in neutral position.

After the analysis of Tables 4.1 and 4.2, it is clear that there is a need for a knee positioning system that has all the features that physicians expect from one of these systems: objectivity/reproducibility, being radiolucent and ergonomic, a foot fixed in neutral position, and being user-friendly, never forgetting these types of medical devices need to be safe and reliable. The device also needs sensors so the automatic set-up of the stress test and force can be operated automatically, and it needs to be capable of performing both the valgus and the varus stress test, which are the most commonly used stress radiography tests. Moreover, the possibility of obtaining a skyline view plain X-ray of the knee with the same device would be a good addition to the basic functionality of the system, since it is a widely clinically assessed view of the knee.

Chapter 5

Prototype Design

This chapter illustrates the design and development of a solution for a knee positioning system for stress radiography. For that purpose, the main objectives and requirements of the solution are presented, followed by the design of both the hardware and the software, and finally a prototype development pathway is constructed.

5.1 Design and Development Considerations

As stated in Section 1.3, the aim of the proposed work is the design and development of an objective, radiolucent, ergonomic and user-friendly positioning system for X-ray environment capable of assisting knee stress radiographs without the aid of a physician, to diagnose acute and chronic knee injuries, evaluate pre- and post-operative knee instability, and monitor knee stability in non-operative treatments. Thus, the PoSyX was created (Figure 5.1).



Figure 5.1: The logotype of the PoSyX.

Taking into account the objective of the proposed dissertation and the input given by clinical partners regarding their expectation of an ideal solution for a knee positioning system, the main functionalities of the ideal system and the description of the interactions between the system's actors are summarised in the proposed use case diagram presented in Figure 5.2. Firstly, the patient's knee has to be positioned by the physician by securing the patient's lower limb with the support system and placing the EMG sensors on the lower limb. Once the PoSyX's application is started, the load cell calibrates the force, whereas the stepper motor calibrates the limb's position. The physician can now define the test requirements in the app, which includes the definition of the type of stress test to be performed, the amount of force to be applied to the joint, and the amount of speed at which the lower limb will be positioned. Once the test definitions are set, the physician has the possibility to start the test on the app. During the performance of the stress test, the test definitions are displayed on the interface, whilst the stepper motor's outer positions and maximum speed are established, and its direction and speed during the test are set. A necessary force for the stepper motor to stop is also defined, thanks to the measure of the force through a load cell. Both the force and position data during the stress radiography are collected, and the force data is displayed in real-time. There is also the collection and display of EMG data. Once the force to be applied is reached or the stepper motor reaches a limit outer position, the motor stops in that exact position and the patient can get a knee X-ray, acquired by an X-ray technician, who positions the X-ray equipment.

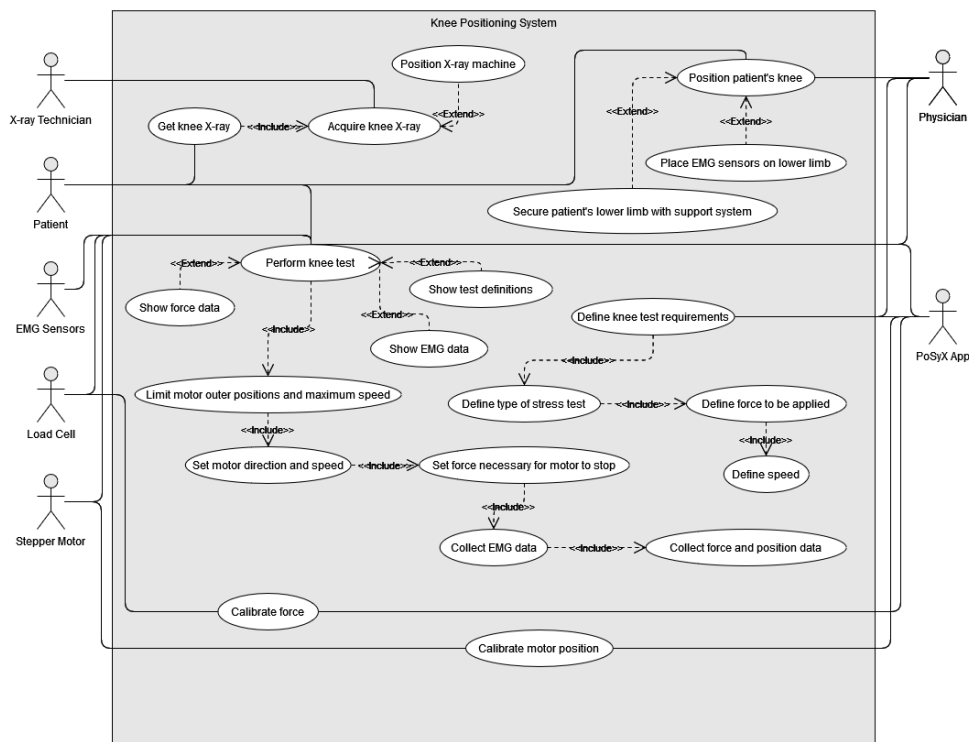


Figure 5.2: Use case diagram of the knee positioning system.

The design specifications for the ideal solution were identified keeping in mind the main objectives of this dissertation, as well as the limitations that current systems have (analysed in Chapter 4), the input of clinical partners, and the ergonomics depending on any patient's body type. The PoSyX's design specifications are stated as follows:

- Hardware requirements:
 - Ergonomic base to support the lower limb at 30° of knee flexion;
 - Fix the foot of the analysed limb in neutral position (90°) for the stress radiography;
 - Have radiolucent materials for the parts of the system that will be subjected to radiation;
 - Measure the force applied to the knee during the stress tests;
 - Measure the position of the lower limb;
 - EMG sensors to measure the electrical activity produced by the skeletal muscles of the lower limb as the pressure is being applied.
- Software requirements:
 - User interface to display the acquired data for each patient in real-time, and to let the operator control the positioning device outside of the X-ray environment;
 - Capable of controlling the system to perform both the valgus and varus stress tests;
 - Define the force to be applied to the knee during the stress tests and display the force being applied in real-time;
 - Track the position of the lower limb, so that its position can be controlled automatically depending on the type of stress test that will be performed;
 - Display the received EMG data, so the operator can determine whether the patient is relaxed or not.

Lastly, and given the fact that the PoSyX is intended to be a medical device, throughout the solution's development the need for evaluation during prototype testing must be considered. For that reason, evaluations of the prototype's performance towards the intended result were done. For the evaluation of the PoSyX the following factors were analysed:

- Standard force supported by motor;
- Validation of the desired stress test;
- Existence of no artefacts in the X-ray image.

5.2 Support System Design

The design of the patient's support system was inspired by the positioning systems with techniques and features mentioned in Section 4.1.4 that converge with the objectives of the proposed work, such as the Laxmeter and the Self Stress Assembly Set. Furthermore, visits to the *Hospital Geral de Santo António*, Porto, Portugal for meetings with clinical partners also inspired the design of the PoSyX. In the hospital, a manual positioning system created within the Department of Orthopaedics was already in use. It was composed of a radiolucent acrylic base for the lower limb that fixed both the upper and lower leg with velcro straps, and created a 30° knee flexion, as shown in Figure 5.3a. The stress was applied through the manual movement of the carriage of a linear guide, that was fixed by a clamp (Figure 5.3b). Later on, the department added a dynamometer to measure the amount of force being applied when placing the lower leg in a different position (Figure 5.4). The clinical partners also presented the position that the X-ray detector should be at during the acquirement of a skyline view X-ray, which is perpendicular to the lower leg (Figure 5.5a).



Figure 5.3: Knee positioning system created by the clinical partners of the project: (a) Overall system; (b) Linear guide subsystem.

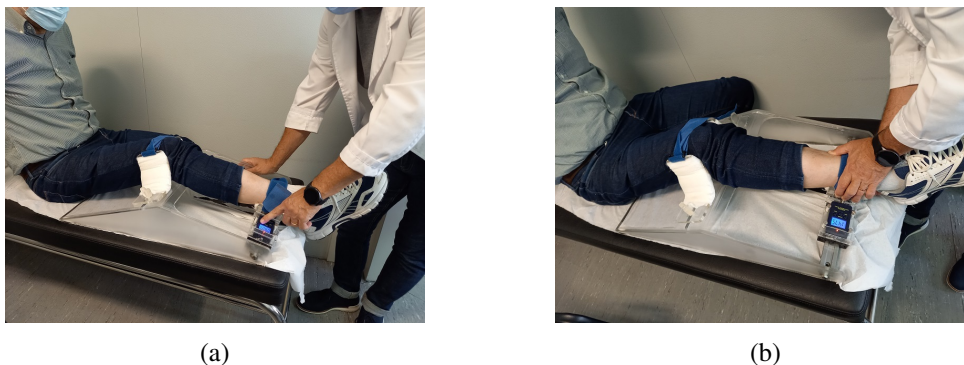


Figure 5.4: Knee positioning system created by the clinical partners of the project with integrated dynamometer: (a) X-ray technician turning on the dynamometer; (b) Manual movement of the leg with reading of applied force.



Figure 5.5: Indicated position showed by clinical partners: (a) Angle of the X-ray detector for the acquirement of a skyline view; (b) Patient position for the acquirement of a valgus/varus stress radiograph.

When explaining the ideal position to get a valgus/varus stress radiograph (Figure 5.5b) and the current limitations they face, the clinical partners showed that the knee should be at 30° flexion, which they have accomplished, but the foot was never at a neutral position - 90° flexion - when using the positioning system they created. Furthermore, they were able to measure the amount of force applied, but still wished for the whole system to be automatic, so they do not have to spend so many time in and out of the X-ray room to adjust the system every time they perform a new exam on the same patient. It was decided that an electronic system would be developed instead of a pneumatic one, since compressed air is not easily available in all healthcare facilities. The materials they wanted to be used are still of radiolucent matter so that they are not seen in the X-ray image. Regarding the skyline view examination, the clinical partners already have a system capable of holding the X-ray detector in place when getting a Merchant view, as seen in Figure 3.7b, but would prefer to have a positioning system with the holder of the X-ray detector integrated.

5.2.1 Design Projection

After gathering all the ideas from the clinical partners, hand sketches of a possible solution for the patient's support system were done (Appendix A). This system was divided into two main subsystems: the foot and the lower limb supports.

For the foot support, a system with 3 axes of movement and a foot holder was idealised (Figure 5.6a). The x-axis would adjust the distance between the foot and the lower limb support, depending on the patient's leg length; the y-axis would hold the foot holder and move from side to side, being able to perform either the valgus or the varus stress tests; and the z-axis would adjust the height of the foot holder, producing the desired angle of flexion for the knee. The foot holder was designed taking into account that the foot should be in neutral position during stress tests and the average measures of the length of the feet (about 240 mm [140]), length of the tibia (about 380 mm [141]), and diameter of the calf (about 0.120 m or 120 mm as calculated in Equation 5.1, where P is the perimeter of the calf in m and d is the diameter of the calf in m [142]) for adults worldwide:

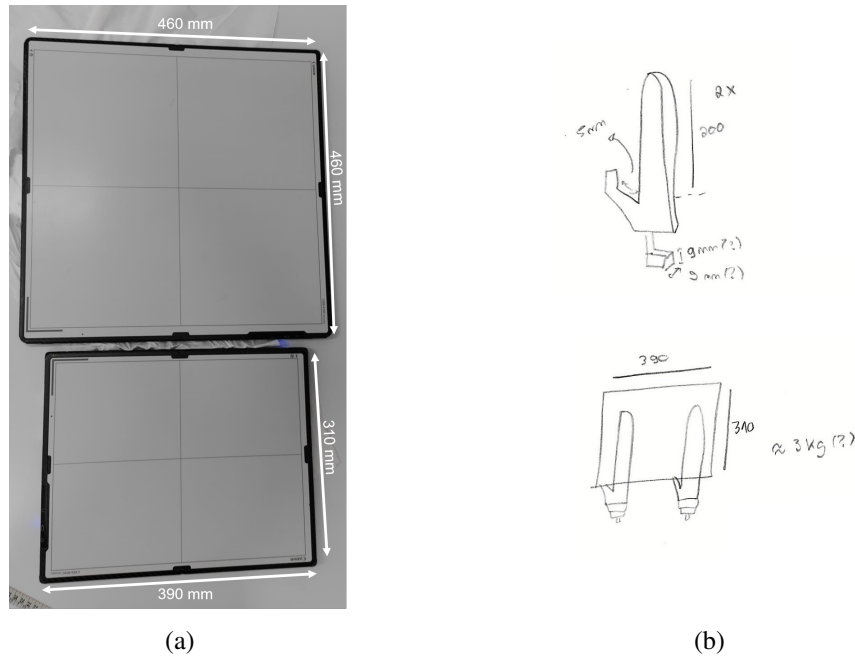


Figure 5.7: The X-ray detectors: (a) Measurements of the detectors - both the detectors have a thickness of 2 mm; (b) Example of drawings of the detector positioner to be integrated into the foot holder.

by Equation 5.2, where H is the height of the triangle positioner in m, f is the length of the average adult femur in m, and θ is the angle between them in degrees:

$$H = f \times \cos \theta = 0.460 \times \cos 45 \approx 0.325m \quad (5.2)$$

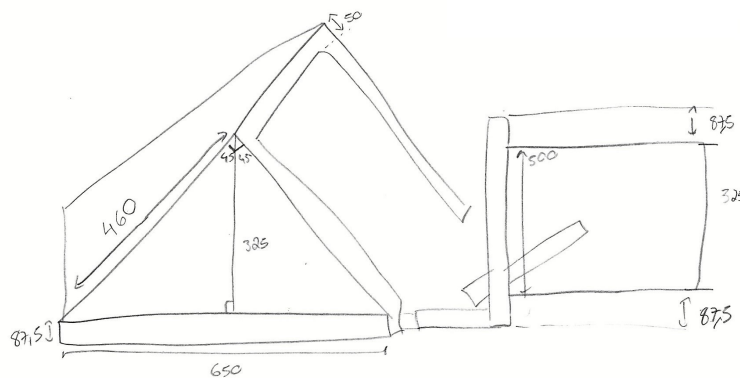


Figure 5.8: Sketch of a lower limb support, considering the components suggested by Igus.

The length of the base of the positioner, which is of about 0.650 m or 650 mm, can be calculated by Equation 5.3, where c is the length of the base of the positioner in m, and f is the length of the average adult femur in m:

$$c = \sqrt{f^2 + f^2} = \sqrt{0.460^2 + 0.460^2} \approx 0.650m \quad (5.3)$$

Moreover, the half of the triangle positioner where the lower leg rests will have to be extruded in the middle, so that the linear guide X can pass through and patients of different heights can utilise the PoSyX. A small edge will be added at the top of this half for the patient to rest the back of the knee comfortably.

Since the linear guide Z suggested by Igus has a working stroke of 500 mm and the triangle positioner has a height of 325 mm, a small wedge must be added to the base of the triangle positioner, to account for the assembly of the three linear guides and so that the desired range of 0° to 90° of knee flexion can be still be achieved when the patient gets their foot fixed on the foot holder (that is located in the linear guide Y). By Equation 5.4, where h is the height of the wedge in m, s is the working stroke of the z-axis in m, and H is the height of the triangle positioner in m, it is concluded that the small wedge should be of about 0.0875 m or 87.5 mm:

$$h = (s - H)/2 = (0.500 - 0.325)/2 \approx 0.0875m \quad (5.4)$$

5.2.2 Computer-Aided Design

The design of the prototype was made with the support of Fusion 360¹, which is a computer-aided design (CAD), computer-aided manufacturing, computer-aided engineering and printed circuit board design software application, developed by Autodesk. The foot holder was designed keeping in mind the average measurements of the human body and requirements mentioned in Section 5.2.1, but still trying to keep the component as light as possible: 200 mm for the length of the feet, 300 mm for the length of the tibia, and 120 mm for the diameter of the calf. Small holes were added to the side of the holder where the foot lays and the part where the tibia rests, so that velcro straps can be added to fix the patient in a neutral position during stress radiography. In addition, a rail was added to the back of the foot holder to provide integration of the detector positioner. Figure 5.9a presents the foot holder designed in Fusion 360, and Figure 5.9b shows the overall system of the foot holder. In this system, the foot holder is connected to the foot holder support with a threaded stud, to provide a 90° rotation of the holder. A sponge was also added to the foot holder to give comfort to the patient when resting the calf. Lastly, the detector positioner shown in Figure 5.9c was designed to support the detectors presented in Figure 5.7, having an added carriage so that this positioner is able to slide through the foot holder's base, depending on the thickness of the patient's calf. In this sense, the X-ray detector will always be perpendicular to the tibia when acquiring a skyline view, and it is able to be easily removed after this type of knee radiograph.

Regarding the system with 3 axes of movement, it was designed using the suggested linear guides by Igus, being similar to the one drawn in Section 5.2.1. In Figure 5.10a, it is possible to see this system integrated with the foot holder by the assembly of the foot holder support and

¹Software website: <https://www.autodesk.com/products/fusion-360/overview>

the carriage of the linear guide Y, and the detector positioner sliding into the foot holder. An added emergency button is also visible to shut down the whole system, if necessary, and security sensors to make sure the linear guides do not go over their working stroke limit are recommended. The electrical components, including another emergency button, will be connected to the system through cables and placed in the X-ray technician's room for guaranteed communication. Since the stress tests are usually uncomfortable for patients with knee injuries, the existent button in Figure 5.10a is simply an added security measure, being away from the patient so they do not press it and stop the test if they feel slightly uncomfortable. The lower limb support was designed with Fusion 360 in acrylic (Figure 5.10b) considering all of the measurements determined in Section 5.2.1, having only the addition of four holes for the velcro straps to fix the upper leg on the support, especially the femur epicondyles. The complete patient's support system can be seen in Figures 5.11 and 5.12, being similar to the one shown in Appendix A.1, and, therefore, meeting the main goals of this project.

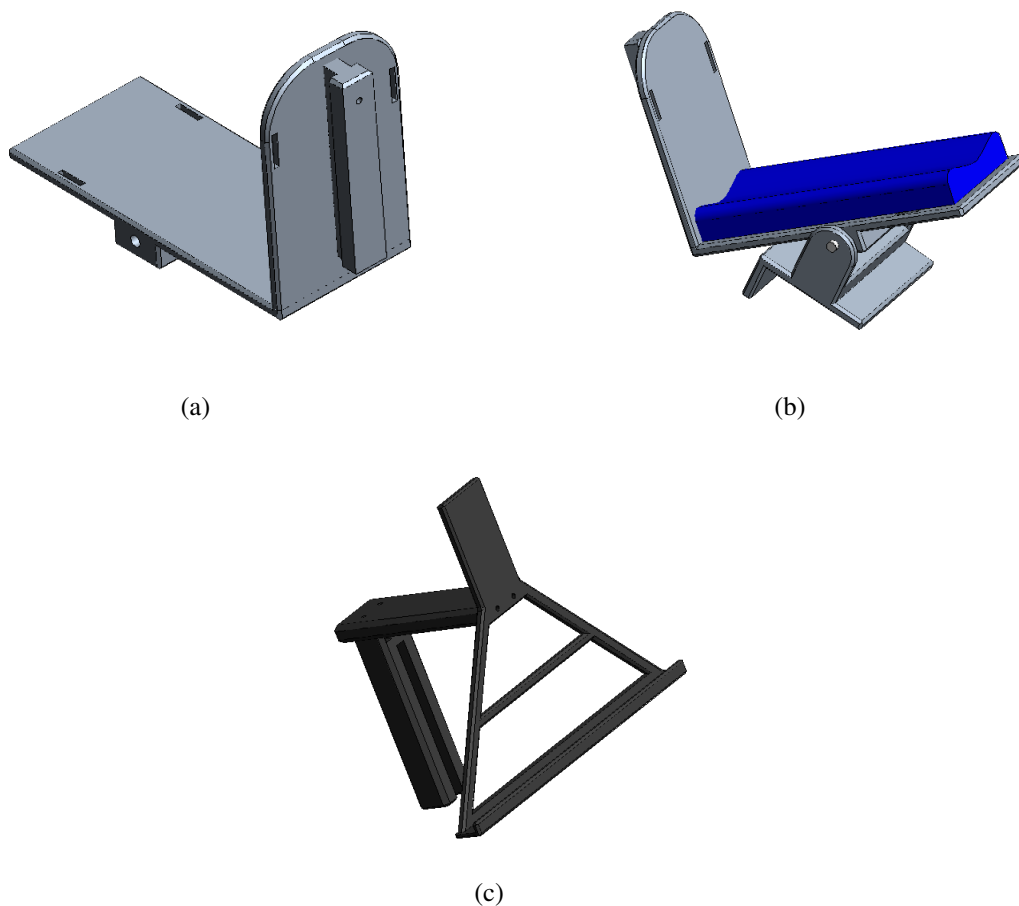


Figure 5.9: The CAD of the foot holder system: (a) Foot holder; (b) Overall system of the foot holder; (c) Detector positioner capable of being integrated into the foot holder system.

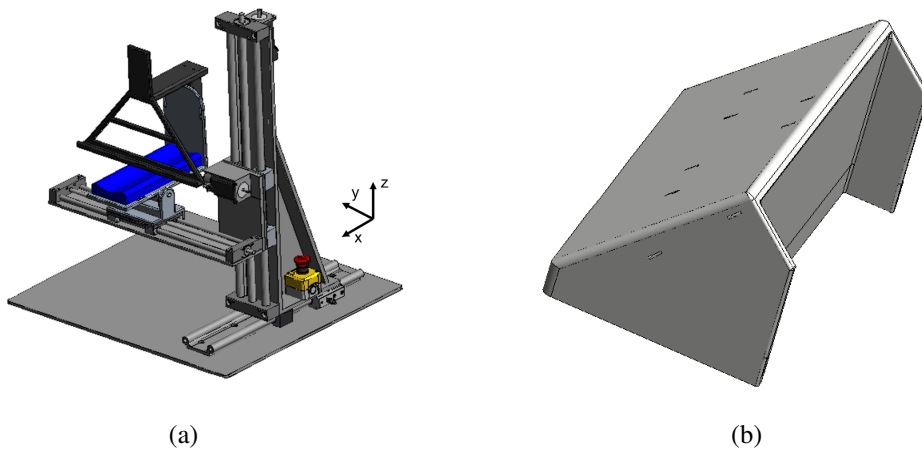


Figure 5.10: The CAD of the patient's support subsystems: (a) Foot support; (b) Lower limb support.

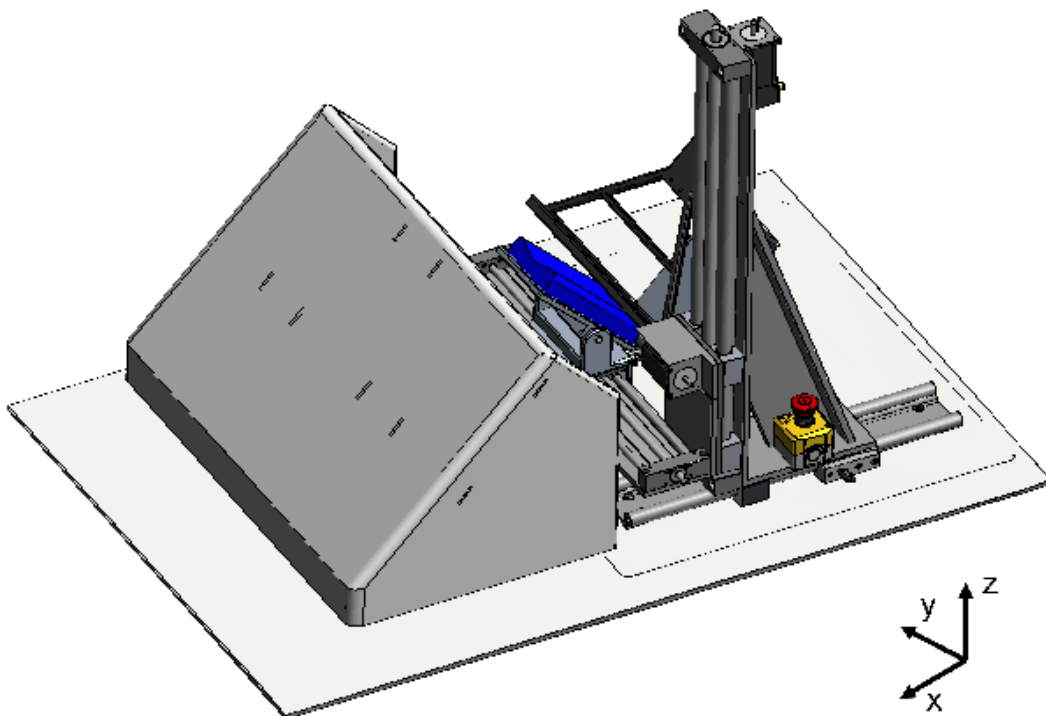


Figure 5.11: The CAD of the PoSyX's patient support system.

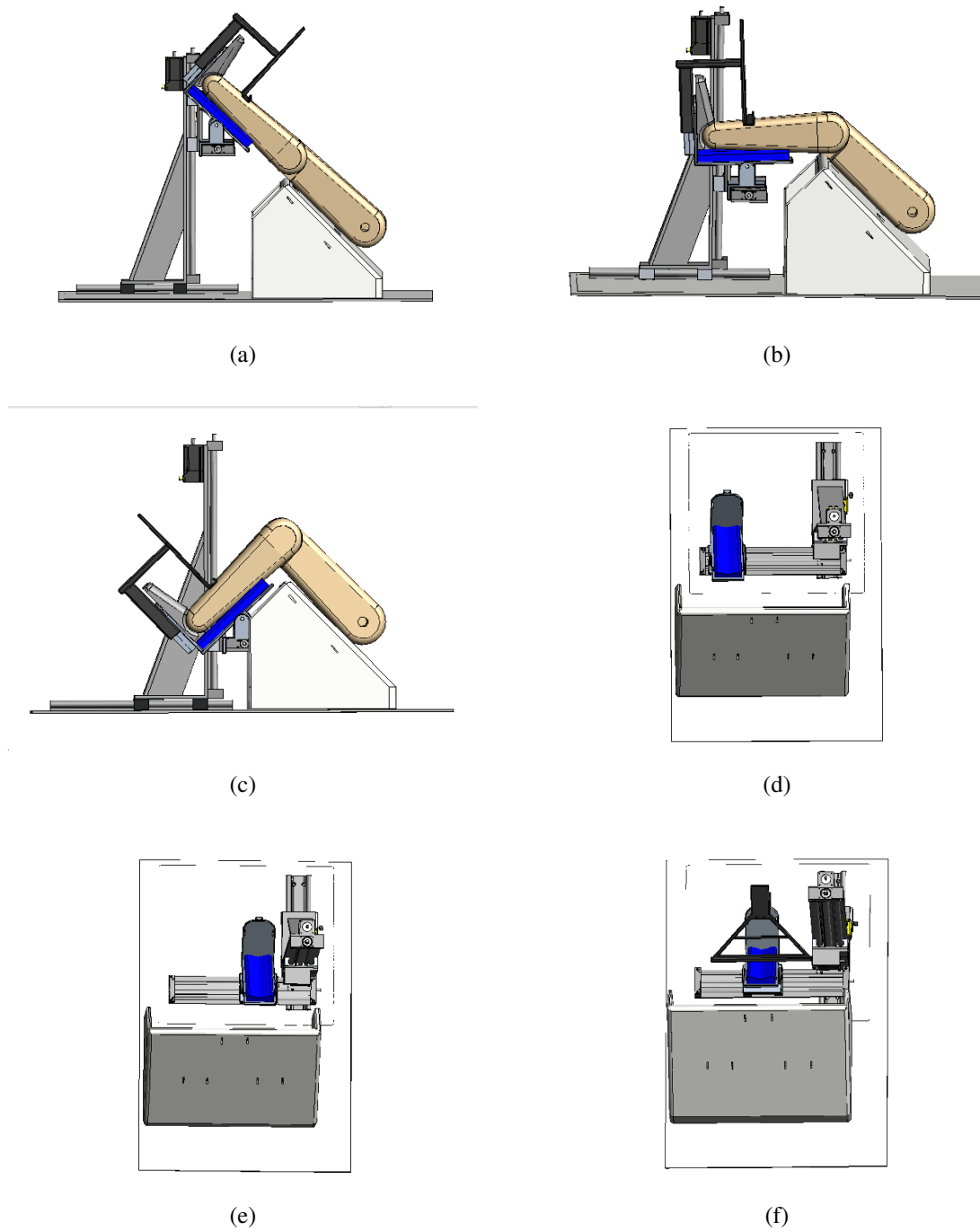


Figure 5.12: The CAD of the PoSyX's patient support system: (a) With an angle of knee flexion of 0° ; (b) With an angle of knee flexion of 45° ; (c) With an angle of knee flexion of 90° ; (d) Foot holder moved to the left of the patient; (e) Foot holder moved to the right of the patient; (f) Foot holder positioned for the skyline view.

5.3 Communication Interface Design

For communication between the hardware and the interface, a simple protocol widely accepted for medical devices, such as MQTT communication protocol [144], could be used. This protocol is designed for connections with remote locations so there is no need for a more complex form of communication, since the physician and the patient will be close to each other during the stress radiograph and the PoSyX only needs to transport simple messages between the device and the interface.

Once there is communication between the hardware and the interface, the physician will be able to control the device through the interface. The interface can only be accessed by physicians, where they can search for the patient they are performing X-rays to or insert new patients into the database. Once the physician has chosen a patient's profile, they will be able to begin a new stress radiograph and decide which stress test will be performed, how much force will be applied through a force grading of the tests, and at what degree of flexion the knee will be. Before they can start the exam, they will have to confirm all the test definitions, check if the linear guides are in the correct position, having the chance to adjust them if needed, and verify that the force to be applied is of their desire (all within linear guide position and force limits). As soon as they start the test, a pressure status regarding the relaxation of the patient will be shown, as well as the continuous monitoring of the force applied and a real-time video of the examination. The users have the option to either cancel at any time, or save the data at the end of the stress exam. The stress tests' data will be sent to the interface and stored in the patient's database - provided and defined by each medical facility. So, there will be communication between the PoSyX's interface and the facility's interface, generated by a bidirectional communication protocol agreed upon by each party involved. Appendix C contains all the mockups of the PoSyX's app interface.

5.4 Prototype Development Pathway

Within the overall design process, it is necessary to project the phases and procedures during the development and implementation of the prototype. Hence, a flowchart that provides an overview of the prototype development pathway is illustrated in Figure 5.13.

The proposed project can be divided into three main sections: Section 1 represents the electronic design; Section 2 the mechanical design; and Section 3 the systems integration. Ideally, each section is completed sequentially. So, after carrying out the background research, the electronic system design is completed by the selection of motors, drivers, power supply, actuation, sensory feedback and control. Moving onto the design of the mechanical system, it can be divided into two main systems: the force application and the patient support. The force application system requires the selection of the linear guides and lower leg support pad, and the design and development of the storage features. The patient support system involves the design and development of the support panel for the lower limb and foot, and the selection of an upper leg support pad. Lastly, there is the systems integration, where all of the aforementioned subsystems are implemented into

Chapter 6

Prototype Implementation

This chapter describes the development and implementation of a knee positioning system prototype for stress radiography. A general overview of the implemented system is presented, as well as a detailed description of the hardware and software used for its implementation.

6.1 System Architecture

The developed system for positioning of the patient's knee during stress radiography consists of four segments: a set of three linear guides (two with stepper motors and one manual), a load cell, EMG sensors (peripheral devices) positioned on the patient's femur and tibia, and a laptop acting as a central device and as a visual interface connected to the Arduino via Universal Serial Bus (USB). The communication between the load cell and the Arduino is done via universal synchronous/asynchronous receiver-transmitter (USART), and between the EMG sensors and the laptop via Bluetooth v2.0 + Enhanced Data Rate (EDR) technology. The architecture of the positioning system is shown in Figure 6.1.

The main purpose of this system is to position the knee during stress radiography and, for that reason, three linear guides of the three axes are necessary to adjust the PoSyX to each patient, as seen in Section 5.2. The linear guide X would be manual, adjusting the x-axis depending on the patient's leg length; the linear guide Y would be connected to a stepper motor and to the patient's support system, so that the leg could move from side to side, being able to perform either the valgus or varus stress test; and the linear guide Z would also be connected to a stepper motor, determining the height of the foot of the patient, and generating the desired angle of flexion for the knee. However, due to the lack of resources related to the timing of the development of this project, it was not possible to implement the linear guides X and Z.

Working with the components that existed in the laboratory at the Department of Mechanical Engineering of the Faculty of Engineering of the University of Porto, Porto, Portugal, the subsection shown in Figure 6.1 was implemented. The linear guide Y is attached to the stepper motor

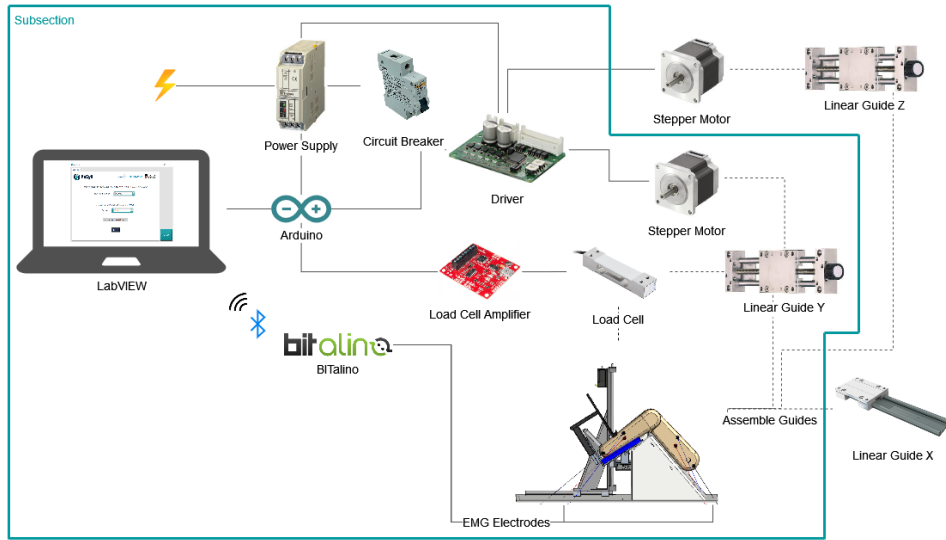


Figure 6.1: Architecture of the positioning system for knee stress radiography. The solid lines represent connections between components through wires, and the dashed lines indicate a connection without wiring. The subsection presents the section of the architecture that was implemented.

and the patient's support system to perform the valgus/varus step test. The stepper motor is wired to a driver, which allows for the connection of the motor to the Arduino. Moreover, a load cell is appended to the linear guide Y and the patient's support system, so it is possible to measure the amount of force applied by moving the patient's foot during the stress radiograph. This load cell is wired to a load cell amplifier so that it can be read by the Arduino, to which the amplifier is connected via USART. The Arduino is connected to a laptop via USB, where the LabVIEW interface controls which stress test is going to be performed, and how much force is going to be applied to the lower limb of the patient, displaying the real-time force data on the screen. In addition, this interface shows the EMG data collected from the EMG electrodes, which are connected to the BITalino board that provides the connection to the laptop via Bluetooth v2.0 + EDR. In order for all the implemented system to work, a power supply (coupled to electrical current) has to be connected to both the Arduino and driver. Considering that this system is expected to be a medical device that, despite being non-invasive, can cause harm to the patient when there is a failure from either the electrical system or the user, a circuit breaker, wired to the power supply, can be rapidly switched off, shutting down the whole system.

6.2 Description of the Hardware Components

6.2.1 Linear Guide Y

The linear guide Y used for the implementation of the prototype is shown in Figure 6.2. It has 500 mm of working stroke with a carriage of 85 mm. In order for this carriage to move automatically through the working stroke, a stepper motor must be connected to the threaded rail of the guide.

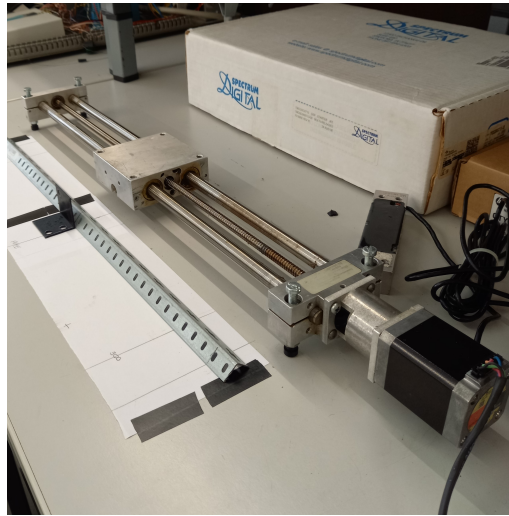


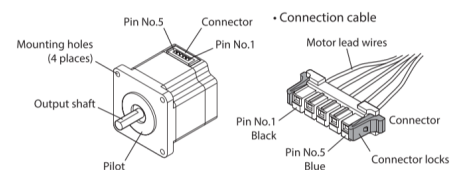
Figure 6.2: Linear guide Y joined to a stepper motor with a motor mounting bracket.

6.2.1.1 Stepper Motor

To provide movement to the y-axis of the PoSyX, a stepper motor is needed. For this project, a medium-sized 5-phase stepper motor with a current of 1.8 A per phase and a basic step angle of 0.72° (500 steps per revolution) is sufficient to move the patient's foot smoothly from side to side with high resolution of movement without it reaching high velocities [145]. It is the case of the Oriental Motor's 5-phase stepper motor from the PKP Series with the given model of PKP546N18A2, that provides high torque with low vibration and noise (Figure 6.3a). With a frame size of 42 mm, it is considered a motor of Model A from the PKP Series [145], and its connection cable is coupled to the connector part of the motor as presented in Figure 6.3b.



(a)



Pin assignment

Pin No.	Lead wire color
5	Blue
4	Red
3	Orange
2	Green
1	Black

(b)

Figure 6.3: The Oriental Motor's 5-phase stepper motor with code PKP546N18A2: (a) The stepper motor; (b) Wiring between the stepper motor and the connection cable, adapted from [145].

6.2.1.2 Driver

To control the PKP546N18A2 stepper motor, a motor driver is necessary to perform automatic tasks, that are provided by a microcontroller (e.g. Arduino). By analysing [146], for this model of stepper motor, the Oriental Motor's CVD518B-K driver model (Figure 6.4a) from the CVD series - the lowest vibration driver type - is indicated to communicate with the motor. This driver requires an input of the power supply of ± 24 Volts of direct current (VDC), the R2/R1 switch to be on the ON side (R1), and the STEP switch to be on the number 0, so that the resolution of the motor can be of 500 and the step angle of 0.72° . The CVD518B-K driver model has three types of connector pin assignments, as shown in Figure 6.4b: CN1 is for the power supply; CN2 for the motor; and CN3 for the input/output (I/O). Figure 6.5a presents the connections between the stepper motor and the driver, whereas Figure 6.5b shows all the possible I/O connections the driver can make.

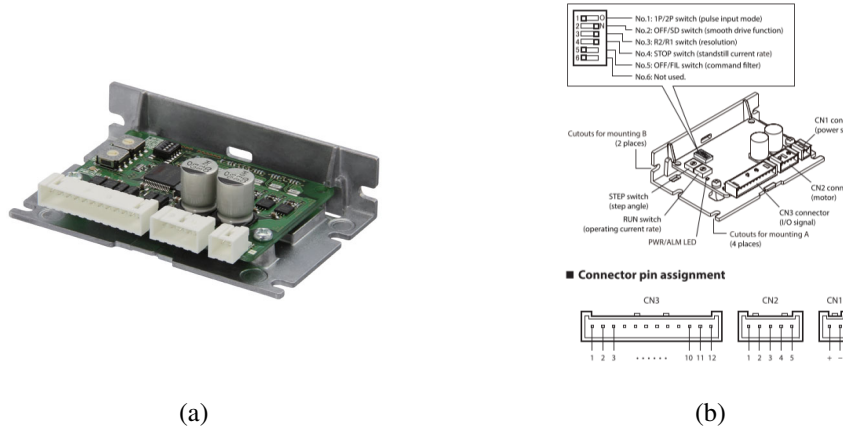


Figure 6.4: The Oriental Motor's CVD518B-K driver model: (a) The mounting plate; (b) Scheme of the mounting plate with connector pin assignments in detail, adapted from [146].

● CN2 (motor)

Pin No.	Direction	Signal name	Description
1	OUT	MOTOR	Blue motor lead wire
2			Red motor lead wire
3			Orange motor lead wire *
4			Green motor lead wire
5			Black motor lead wire

* This orange lead wire is for 5-phase stepping motor. For 2-phase stepping motor, do not connect anything to the pin No.3 since there is no orange lead wire.



Connector pin assignments vary depending on the motor. For details, refer to "Connecting the motor" on p.6.

● CN3 (I/O signals)

Pin No.	Direction	Signal name	Description
1	IN	PLS (CW)	+ Pulse (CW pulse) input *
2			-
3		DIR (CCW)	+ Rotation direction (CCW pulse) input *
4			-
5		AWO	+ All windings off input
6			-
7		CS	+ Step angle switching input
8			-
9	OUT	ALM	+ Alarm output
10			-
11		TIM	+ Timing output
12			-

* These inputs serve as the pulse input (PLS) and rotation direction input (DIR) in the 1-pulse input mode, or CW pulse input (CW) and CCW pulse input (CCW) in the 2-pulse input mode.

(a)

(b)

Figure 6.5: The Oriental Motor's CVD518B-K driver model connector pin assignments, adapted from [146]: (a) CN2 (motor); (b) CN3 (I/O signals).

6.2.2 Load Cell

A Celmi Model SUP1 load cell, that can be seen in Figure 6.6, with a 15 kg capacity was used to measure the force applied during the stress test. It is a simple single-point aluminium load cell designed for direct mounting in low cost weighting surfaces, being ideal for the PoSyX [147]. Being a load cell of the strain gauge type, the cell has to be set up in a "Z" formation, in such a way that torque is applied to the middle of the load cell, and the four strain gauges on the edges of the cell are able to measure the bending distortion (two measure compression, whereas the other two measure tension). By setting up these strain gauges as a Wheatstone bridge, it is possible to measure very small changes in the resistance, which occurs in the strain gauges. These small changes in resistance within each strain gauge will be amplified by the resistive imbalance produced by the formation, leading to the generation of an output signal proportional to the applied force [148, 149]. Figure 6.7 illustrates the wiring and function of the load cell.

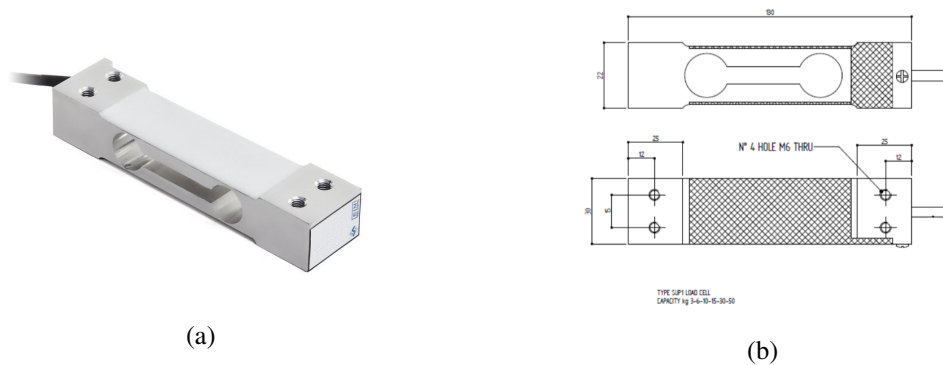


Figure 6.6: The Celmi Model SUP1 load cell, adapted from [147]: (a) The load cell; (b) Outline dimension of the load cell in mm.

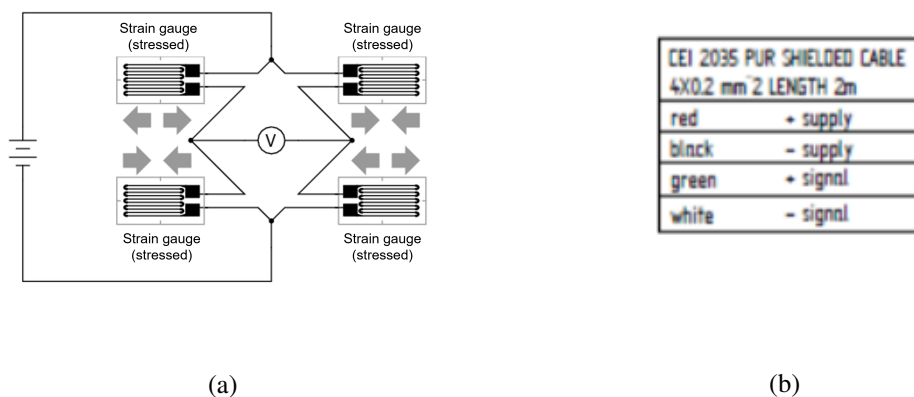


Figure 6.7: Strain gauge load cell: (a) Formation of the strain gauges into a Wheatstone bridge, adapted from [148]; (b) Wiring of the Celmi Model SUP1 load cell, adapted from [147].

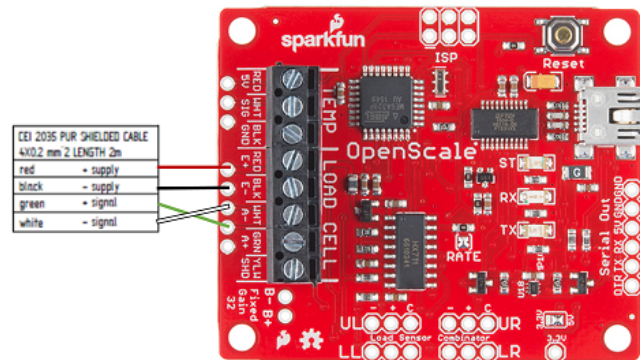


Figure 6.9: Communication between the Celmi Model SUP1 load cell and the load cell amplifier provided by Sparkfun's OpenScale, adapted from [147, 150].

6.2.3 Arduino

An Arduino board was used to develop the motor control with force reading system. Arduino boards are used worldwide due to their cheap and open-source software, providing not only knowledge from an online community, but also libraries to aid users develop their own code. The Arduino board used was the Arduino Uno, based on the microcontroller ATmega328P (Figure 6.10). This board has 14 digital I/O pins, of which 6 can be used as pulse width modulation (PWM) pins, and 6 analogue inputs. The board is compatible with many sensors and actuators, and has many other features, such as an USB connection, a reset button, a power jack, and an in-circuit serial programming (ICSP) header [152].

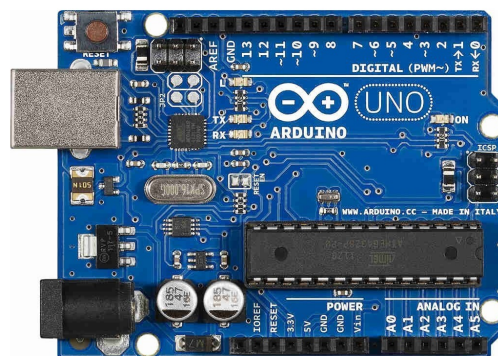


Figure 6.10: Arduino Uno board based on the microcontroller ATmega328P [152].

The Arduino Uno uses an USART communication to connect to the OpenScale's HX711 breakout board. The OpenScale's TX pin must be connected to the Arduino's RX, the RX of the load cell amplifier connects with the Arduino's TX, the 5 V of the amplifier are hooked up

with the 5 V pin of the Arduino's power, and the GND pin is wired to the GND pin of the Arduino's power [150]. The Arduino's TX and RX pins can be defined by the user of the firmware. When it comes to the communication between the motor driver and the Arduino, the first four connector pin assignments of the CN3 for I/O signals showed in Figure 6.5b must be wired to four of the Arduino's digital pins. Since the stepper motor is required to move clockwise and anticlockwise, the motor driver needs to be in 2-pulse input mode, where the first two pins of the CN3 are the positive and negative signals of the clockwise pulse input, and the third and fourth pins of the CN3 are the positive and negative signals of the anticlockwise pulse input. The Arduino Uno's communications with the CVD518B-K driver and the OpenScale are illustrated in Figure 6.11. The data that is received and sent from the Arduino Uno's microcontroller can be controlled by connecting the board to a laptop via USB.

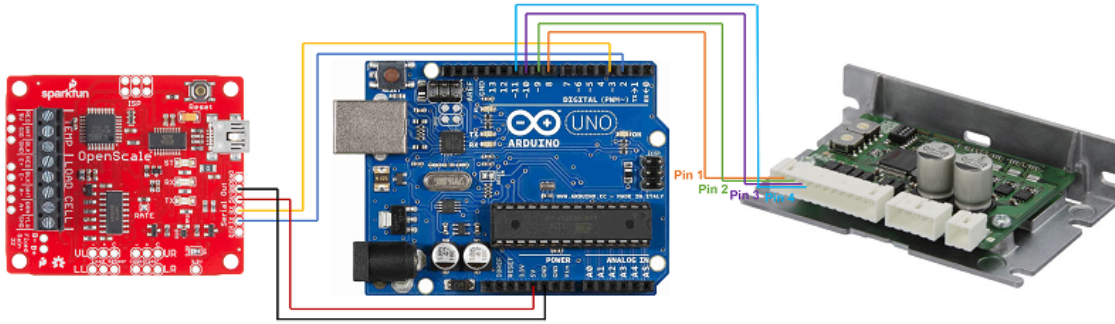


Figure 6.11: The Arduino Uno's communications with the CVD518B-K driver and the OpenScale, adapted from [146, 150, 152].

6.2.4 Power Supply

For all the the aforementioned components to function, a power supply coupled to electrical current has to be connected to the Arduino Uno and the CVD518B-K motor driver. Considering that this driver model requires an input of the power supply of ± 24 VDC, a power supply by Omron with the model number of S8TS-06024 was chosen (Figure 6.12a). This is a block-type switch mode power supply with capacity of 60 W and output voltage of 24 V. Its block diagram (Appendix D.1) shows that the alternating current (AC) inputs L and N, and the GND must be connected to the electrical current, whereas the direct current (DC) output +V should be connected to the connector CN1 positive pin of the driver, and the -V should be connected to the connector CN1 negative pin of the driver and to the GND of the Arduino Uno.

6.2.4.1 Circuit Breaker

All electrical circuits should have a circuit breaker. A circuit breaker is an electrical safety device designed to protect the circuit from any potential damage, whether caused by an excess of current

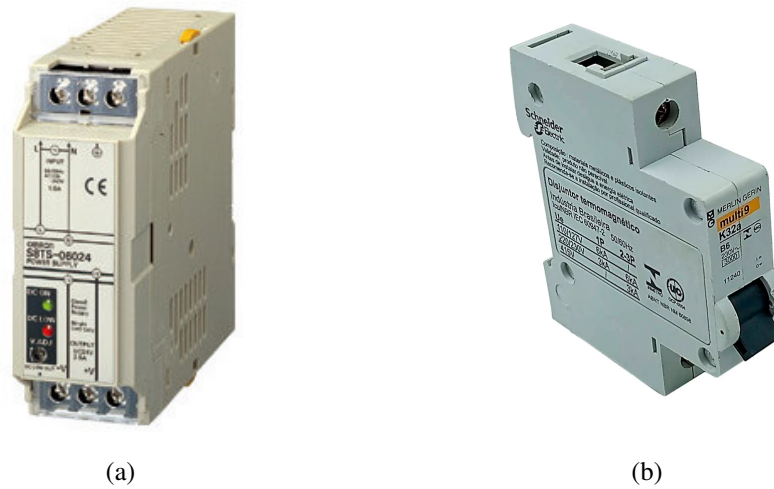


Figure 6.12: Power supply of the PoSyX: (a) Power supply S8TS-06024 by Omron [153]; (b) Circuit breaker multi9 K32a by Merlin Gerin [154].

or by a short circuit. Considering that the PoSyX is expected to be a medical device that can cause harm to the patient when there is a failure from either the electrical circuit or the operator, a circuit breaker must be integrated to interrupt current flow if necessary [155]. The utilised circuit breaker was the Merlin Gerin's multi9 K32a circuit breaker (Figure 6.12b), that is wired between the GND of the electrical current and the input GND of the power supply.

The wired communication between the hardware components of the PoSyX can be seen in Figure 6.13, and a diagram of the wiring of the hardware components of the PoSyX system is illustrated in Appendix D.2.

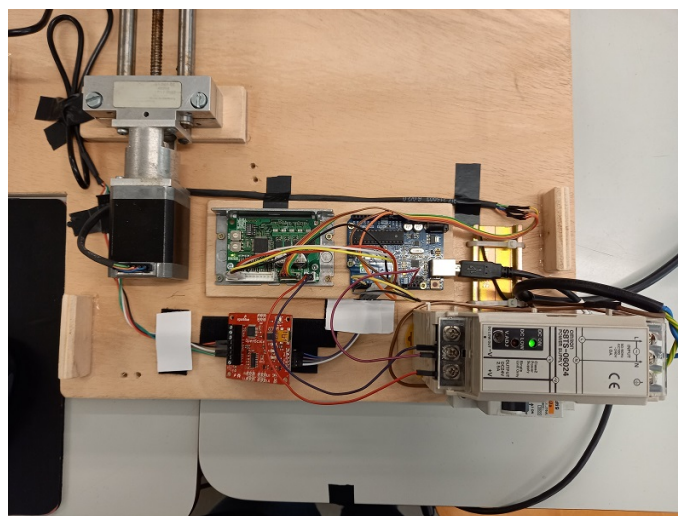


Figure 6.13: Wired communication between the hardware components of the PoSyX.

6.2.5 Electromyography Sensors

The BITalino BioMedical development kit (Figure 6.14) provides an easy-to-use raw data acquisition system with a variety of sensors for not only biosignal modalities, such as EMG, electrocardiography, and electrodermal activity, but also with an accelerometer, a light sensor, and a light-emitting diode. A microcontroller ATmega328 is integrated in the board, being able to be configured with a sampling rate up to 1000 Hz, and having a total of six analogue inputs, four digital inputs, and four digital outputs. A Bluetooth v2.0 + EDR module is also integrated for communication with a computer [156].

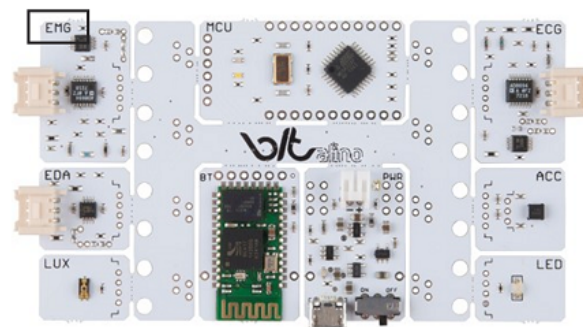


Figure 6.14: The BITalino BioMedical development kit with Bluetooth v2.0 + EDR connectivity and an EMG sensor, adapted from [156].

The EMG signals are read with a 3-lead electrode cable for a bipolar setting plus the reference electrode, and the embedded EMG sensor performs all the pre-processing needed in the microcontroller unit to send the digitised data via Bluetooth v2.0 + EDR to a laptop. The EMG signal is filtered inside the LabVIEW application by wavelet denoising followed by the use of a bandpass filter with 20 Hz of low cutoff frequency and 500 Hz of high cutoff frequency (Appendix E.1), since the significant power spectrum of EMG signals ranges from 20 to 500 Hz [157].

6.3 Development of the Patient's Support System

The patient's support system was developed and implemented according to the system designed in Section 5.2. However, as mentioned in Section 6.1, only a subsection of the system's architecture was implemented. Without the linear guides X and Z, some adjustments had to be made.

6.3.1 Foot Support

During the design projection of the foot support (Section 5.2.1), some drawings of the foot holder were implemented using polystyrene foam to validate the design. It is the case of the design in Appendix A.3b, that was constructed and tested by a subject with average size, as seen in Figures 6.15a and 6.15b. By being cut in half and combined with a spring, this design self-adjusted to

each patient's foot and tibia. Some of the most noticeable limitations were the fact that the foot would not be fixed in a neutral position, and the possibility of harm of the patient with the foot holder opening in half automatically. Moreover, the part of the foot holder where the patient rests their foot does not need to be that tall, since the foot is fixed in neutral position by just resting on a plaque of about half its size. To add to this implemented design, a removable detector positioner (Figure 5.7b) was integrated, as shown in Figures 6.15c and 6.15d. This positioner was clearly too fragile to hold an X-ray detector, and in case a patient of bigger size opened the foot holder too further apart, the detector was in risk of falling. After designing the CAD foot holder presented in Figure 5.9, this design was also validated by its implementation with polystyrene foam (Figure 6.16). An average sized subject testing this design can be seen in Figures 6.16c and 6.16d, where the foot is in neutral position, the measurements seem to fit average sized patients (covering the majority of the population), and the X-ray detector is always perpendicular to the lower leg, being capable of adjusting to any tibia size and removed when necessary.



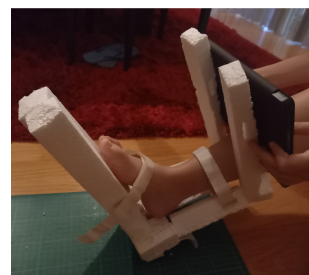
(a)



(b)



(c)



(d)

Figure 6.15: Design in Appendix A.3b implemented using polystyrene foam: (a) The implemented design; (b) Average sized subject testing the implemented design; (c) The implemented design with the design in Figure 5.7b integrated; (d) Average sized subject testing the implemented design with the design in Figure 5.7b integrated.

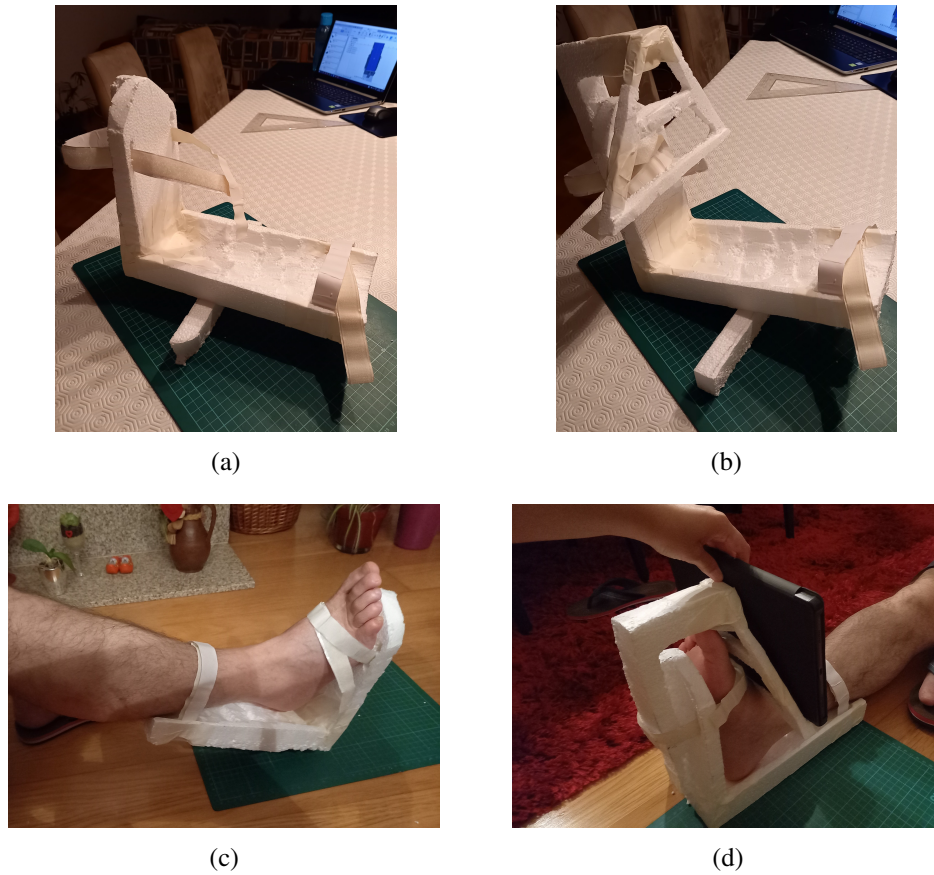


Figure 6.16: Design of the PoSyX's foot holder implemented using polystyrene foam: (a) The implemented design; (b) The implemented design with the detector holder; (c) Test of the implemented design on an average sized subject; (d) Test of the implemented design with the detector holder on an average sized subject.

As mentioned in Section 5.2, the clinical partners already have a system capable of holding the X-ray detector when getting a Merchant view (Figure 3.7), so for a first prototype of the PoSyX they did not find necessary to implement the detector positioner. For that reason, the design implemented for the foot holder was the one in Figure 5.9b. It was decided that, for a first prototype, the design should be printed with a 3D printer using polylactic acid (PLA) filament, since it is faster and cheaper, and is able to break easily in case of emergency, whilst still providing robustness to the system. In order to do that, the CAD of the foot holder had to be divided into two separate parts, due to the printer's size not being able to fit the whole component. Four holes for screws and nuts were made in both parts so they could be assembled, as represented in Figure 6.17a. The foot holder support was also adjusted to the measurements of the linear guide Y's carriage before it was printed in 3D (Figure 6.17b). Two holes were also added to this support, so that one side of the load cell could be screwed to the foot holder support, and the other side to the linear guide Y's carriage via aluminium corners, giving the "Z" formation to the load cell (Section 6.2.2). The 3D printed foot holder was integrated into the foot support subsystem, as seen in Figure 6.18.

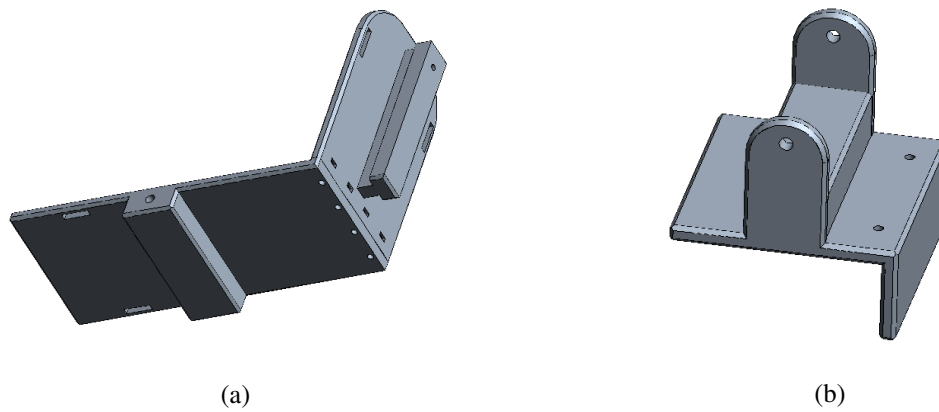


Figure 6.17: CAD of the 3D printed parts of the foot support: (a) Foot holder; (b) Foot holder support.

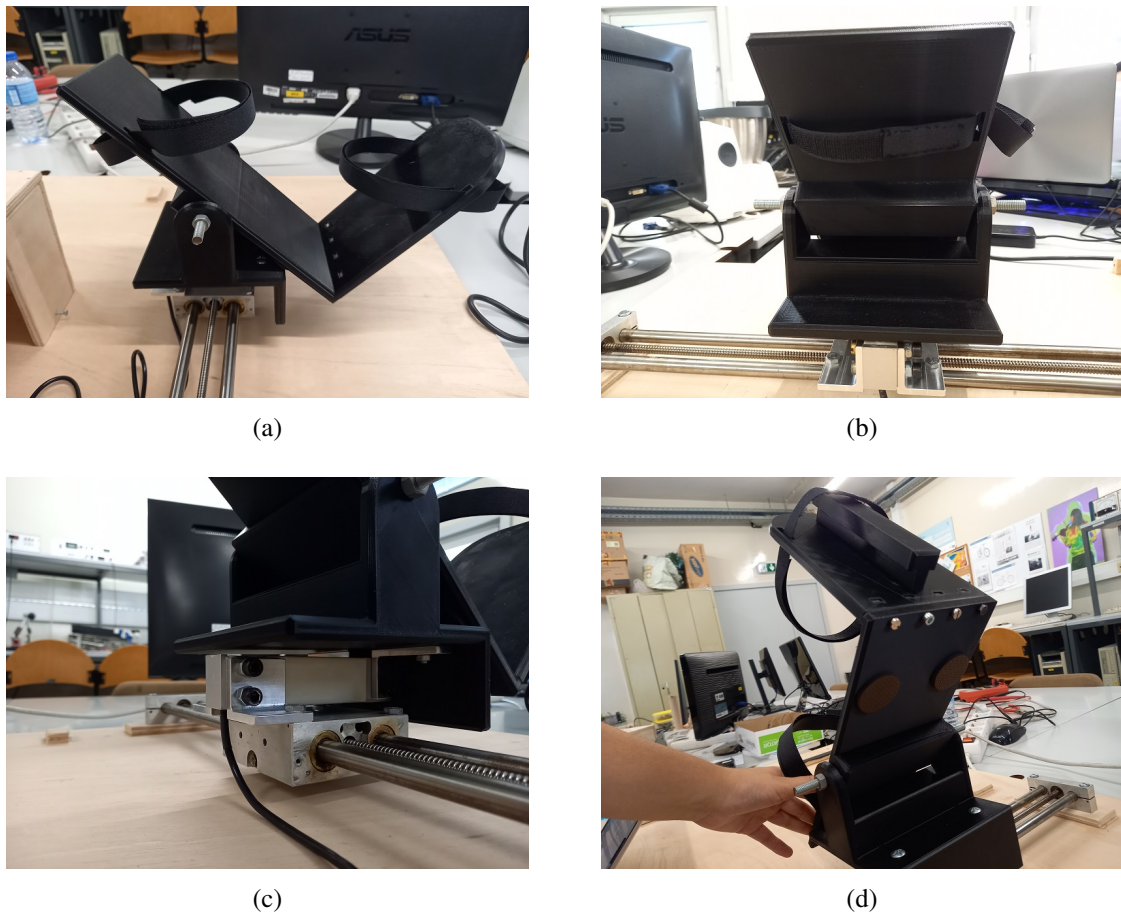


Figure 6.18: 3D printed parts of the foot support: (a) Foot holder; (b) Foot holder support; (c) Integration of the foot holder support with the load cell and linear guide Y; (d) Pad stoppers to avoid wearing of both parts.

6.3.2 Lower Limb Support

With both the linear guides X and Z not implemented in this project, adjustments to the lower limb support (based in the CAD shown in Figure 5.10b) had to be made. Without the linear guide Z, the knee flexion does not have a range of 0° to 90°, so the implemented lower limb support simply provides the 30° knee flexion necessary to perform the valgus/varus stress test and the skyline view. Moreover, this subsystem is not capable of smoothly adapting to different leg lengths. Knowing that the average length of an adult femur is of about 460 mm [143], two triangle positioners were implemented: one with 400 mm of length on the side of the positioner where the femur rests; and another with 500 mm.

To calculate the height of each triangle positioner, Equation 5.2 should be used. For a 30° knee flexion, the triangle positioner corner where the knee rests will have to make 150° with its sides (180°-150° = 30°), so the angle θ between the height of the triangle positioner and the length of the average adult femur is of 75° (150°/2). With that said, for the 400 mm triangle positioner, the positioner's height is of about 0.1035 m or 103.5 mm, and for the 500 mm triangle positioner, it is of about 0.1294 m or 129.4 mm. Since from the base of the lower limb support to the foot holder there is about 70 mm of added height due to the linear guide Y and the load cell, for the 400 mm triangle positioner, the positioner's height is of about 173.5 mm, and for the 500 mm triangle positioner, it is of about 199.4 mm. The length of the base of each positioner can be calculated by Equation 6.1, where c is the length of the base of the positioner in m, p is the length of the positioner's femur side in m, and H is the height of the triangle positioner in m:

$$c = \sqrt{p^2 + H^2} \quad (6.1)$$

For the 400 mm positioner, the length of the base of the positioner is of about 0.436 m or 436 mm, and for the 500 mm positioner, it is of about 0.538 m or 538 mm. With all of these values, it was possible to design the two triangle positioners using Fusion 360 (Figure 6.19). At last, using the CAD of the foot holder system shown in Figure 5.9b, a single stopper was designed for placing the positioners in the correct distance to provide a 30° flexion of the knee. A small edge of 100 mm was also added to both positioners to guarantee that the tibia is in the correct direction for a 30° knee flexion, and so patients can rest the tibia comfortably.

The lower limb support was implemented using wood for this PoSyX prototype, since it is a cheaper and easily accessible radiolucent material. It is intended to be constructed in acrylic, like the design made in Figure 5.10b, once it is validated. The two triangle positioners were built with the use of wood, wood glue, and synthetic leather only, to guarantee that they were radiolucent (Figure 6.20). The design followed for their construction was the one presented in Figure 6.19, but six holes were added to the side where the femur lays for two adjustable velcro straps to lock the femur in place (one to lock the femur epicondyles and another to fix the femur's shaft), and synthetic leather was integrated so the patient has more comfort when flexing the knee. The single stopper to define the position of the triangle positioner is made out of wood coated with synthetic

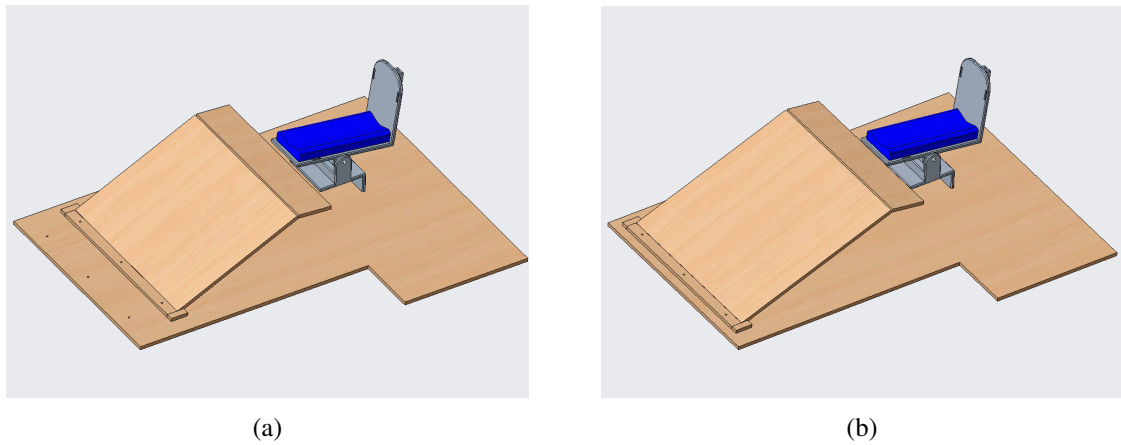


Figure 6.19: CAD of the triangle positioners of the lower limb support: (a) 400 mm positioner; (b) 500 mm positioner.

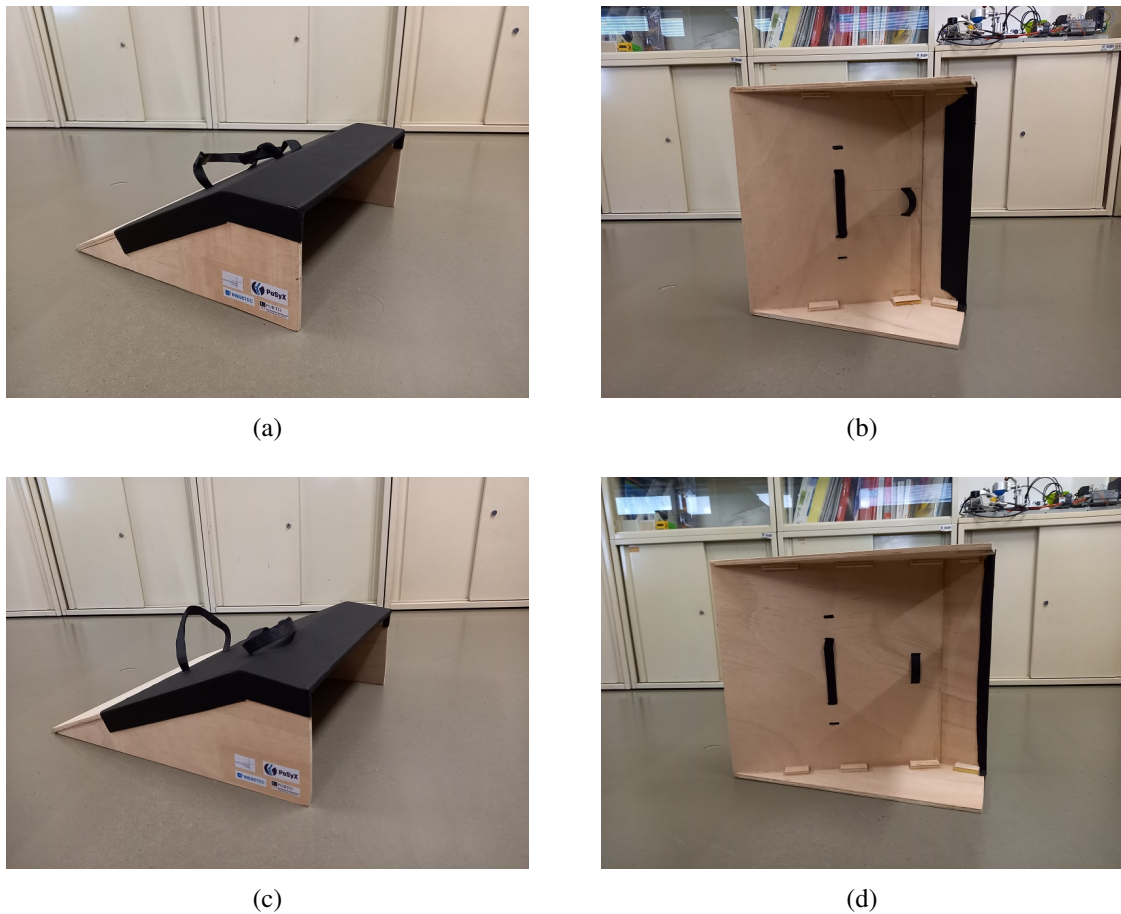


Figure 6.20: Triangle positioners of the lower limb support: (a) 400 mm positioner; (b) Underneath the 400 mm positioner; (c) 500 mm positioner; (d) Underneath the 500 mm positioner.

leather, and plastic tubes that are attached to the base of the lower limb support, depending on the positioner being utilised (Figure 6.21). To make sure the triangle positioner did not slide to the opposite side of the base, two smaller wood stoppers were glued on the wooded base. All of the hardware components described in Section 6.2 were fixed to the lower limb support base, and a small removable wooded box was screwed (surrounding the electrical components) to function as a storage feature, and to avoid any contact between the patient and those components (Figure 6.22). Figure 6.23 shows the prototype of the PoSyX implemented for this project, and the timeline of construction of the PoSyX is presented in Figure 6.24.



(a)

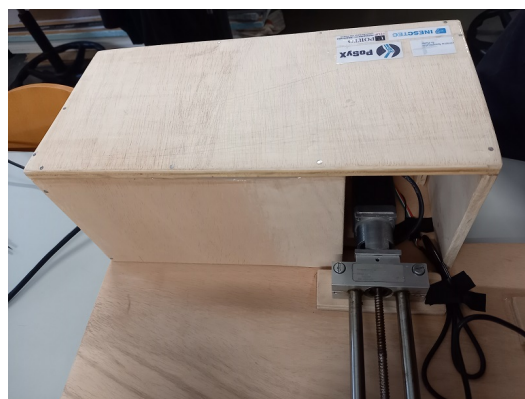


(b)

Figure 6.21: Single stopper of the lower limb support: (a) The stopper; (b) The stopper attached to the base.



(a)



(b)

Figure 6.22: Wooded box acting as a storage feature for the first prototype of the PoSyX: (a) Front; (b) Back.

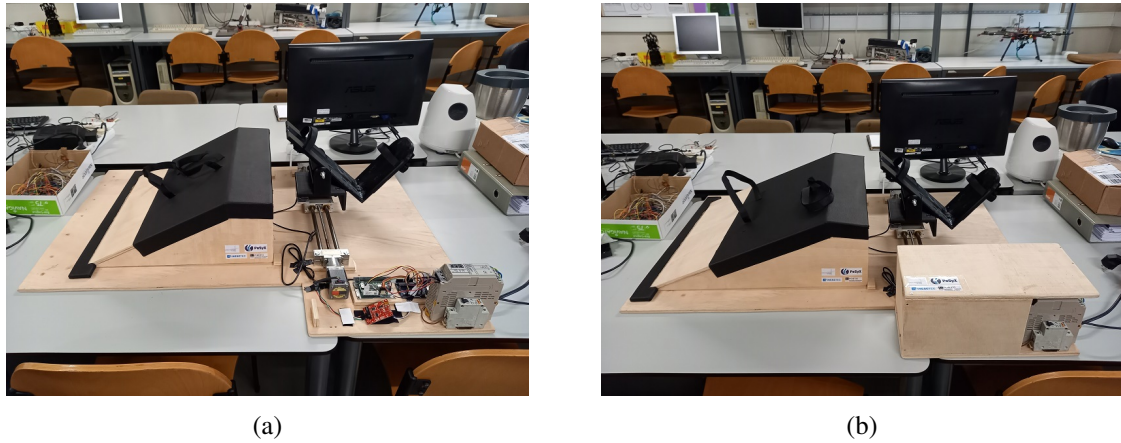


Figure 6.23: The prototype of the PoSyX implemented for this project: (a) With 400 mm positioner and without the storage feature; (b) With 500 mm positioner and the storage feature.

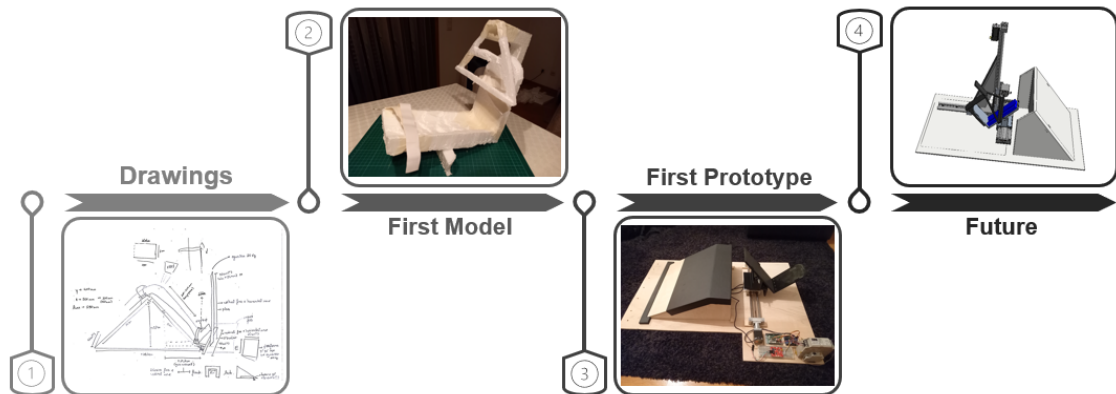


Figure 6.24: Timeline of the construction of the PoSyX.

6.4 Firmware Development

The microcontroller of the Sparkfun's OpenScale was programmed via USB using the open-source Arduino integrated development environment (IDE), commonly known as the Arduino Software. As the main function of the load cell amplifier is to receive the data collected by the load cell and amplify the signals through the HX711 breakout board before they are sent to the Arduino Uno, the algorithm was uploaded once to the OpenScale's microcontroller, setting up the CLK and DAT pins of the HX711, and creating a loop for the reading of a raw force.

The main algorithm of this dissertation was also programmed using the Arduino IDE. The microcontroller of the Arduino Uno, connected via USB to a laptop, receives data from the load cell amplifier, and sends data to the driver that controls the stepper motor. Once the pins to receive the force data and to send data to the driver are set up, and the communication between the Arduino Uno and the OpenScale is configured to USART, the stepper motor is set to make 500 steps per revolution, to have a maximum speed of 500 steps per second, and an acceleration of 1000 steps

per (second)². To keep track of the position of the motor, a revolution counter was created, since in every iteration of the motor moving, it moves 500 steps - corresponding to one revolution. Since the Arduino Uno has electrically erasable programmable read-only memory (EEPROM), an address was chosen for the revolution counter, in order to read the saved value in the beginning of the algorithm, and to write the current value in the memory before the algorithm ends (Appendix E.2). Furthermore, a maximum and minimum limits of the position of the stepper motor were defined by how far the carriage of the linear guide Y can travel from the medial point of the stroke. This point is also known as the home position of the motor.

There was also the need for calibration of the raw force data received from the load cell. For that reason, the load cell conversion factor (M) was calculated by dividing the change in the weight by the change in the sensor reading, as demonstrated in Equation 6.2:

$$M = (F_1 - F_2) / (R_1 - R_2) \quad (6.2)$$

where F_1 and F_2 are the weights used, and R_1 and R_2 are the corresponding sensor readings [158]. Therefore, for a F_1 equal to 1.07 kg, with a corresponding R_1 equal to -22630000.6, and for a F_2 equal to 0 kg, with a corresponding R_2 equal to -22805000.6, the conversion factor is of 6.114286×10^{-6} , which was the determined conversion factor in the algorithm. Equation 6.3 was based in Equation 6.2, being used to calculate the force (F) in kg throughout the algorithm:

$$F = (R - R_0) \times M \quad (6.3)$$

where R is the latest reading of the raw force, and R_0 is the zero reference reading of the calibrated force [158]. The R_0 , also known as force offset, can be read when the load cell has no weight.

The main function of the algorithm is to send a command to the serial port and execute its defined function. The available commands and its functions are as follows:

- **'U'**: sets the current position of the stepper motor to the new 0 position (new home position);
- **'H'**: also known as homing, sends the stepper motor back to its 0 position, no matter where it is located currently (Appendix E.3);
- **'C'**: since there is a revolution counter to account for each time the motor position is changed, this command sets the current position of the motor equal to the revolution counter, calibrating the position;
- **'F'**: calibrates the force read, meaning that it turns the force read into 0 kg, taring it (Appendix E.4);
- **'+'**: it needs to receive a command on the serial monitor like '+f s', where f is the force limit in kg, and s is the speed at which the stepper motor will run in steps/second (not being able to reach values higher than the defined maximum speed). While the force limit or the

position limits are not reached, the stepper motor runs clockwise at speed s . In the case of the patient's perspective, it moves their leg to the right side of the system. This command is used for the valgus right, and the varus left tests;

- **'-':** it needs to receive a command on the serial monitor like `'-f s'`, where f is the force limit in kg, and s is the speed at which the stepper motor will run in steps/second (not being able to reach values higher than the defined maximum speed). While the force limit or the position limits are not reached, the stepper motor runs counterclockwise at speed s . In the case of the patient's perspective, it moves their leg to the left side of the system. This command is used for the valgus left, and the varus right tests;
- **'R':** moves the stepper motor to its positive position limit or, in the case of the patient's perspective, to the right side of the system (Appendix E.5). This command is used for the skyline right test, to keep the foot support out of the way, since it is not needed to obtain a skyline view - a neutral position of the foot is not necessary, and it makes the positioning of the X-ray detector easier;
- **'L':** moves the stepper motor to its negative position limit or, in the case of the patient's perspective, to the left side of the system (Appendix E.6). This command is used for the skyline left test, to keep the foot support out of the way, since it is not needed to obtain a skyline view;
- **'S':** stops the stepper motor immediately, and sends the stepper motor to the home position with the use of the `goHome()` function, already presented in Appendix E.3 for the 'H' serial command.

For the '+' serial command (Appendix E.7) and the '-' serial command (Appendix E.8), the function `enableMotor()` is called. This function's algorithm is presented in Appendix E.9, and it moves the stepper motor in the defined direction and speed (steps/second) until a desired force in kg, or a position limit is reached. If the 'S' command is sent to the serial port, the motor stops its movement and returns to the home position. The reading of the force is obtained using Equation 6.3, and a total of three force values are considered for a mean spike cutting to remove any noise from the load cell's reading (Appendix E.10), followed by a simple moving average with a length of 5 values to help smooth out the force data, mitigating any random short-term fluctuations.

6.5 System's Interface

Besides the hardware components and the patient's support system, the knee positioning system requires a user-friendly interface for data visualisation. In this regard, a desktop application called PoSyX was developed using the LabVIEW development software. The main function of the app is to receive the data collected by the load cell, streaming it in real-time, and control the stepper motor during stress tests, depending on the test definitions provided by the user. In addition, the

app receives EMG data collected by the EMG sensors. In terms of requirements, the application must be able to connect to the Arduino Uno via USB, and to the BITalino via Bluetooth v2.0 + EDR; to request the calibration of the stepper motor and the load cell; to receive the data collected by the load cell and the EMG sensors, presenting the variations of this data in real-time throughout the stress test; and to send commands to the stepper motor depending on the type of test being performed, and whether the force or position limits have been reached or not.

The PoSyX's application is designed to provide an easy-to-use interface, to be implemented in the real context of the knee stress radiography process. In order to provide a full description of the application functioning, an activity diagram of the system was developed, being presented in Figure 6.25.

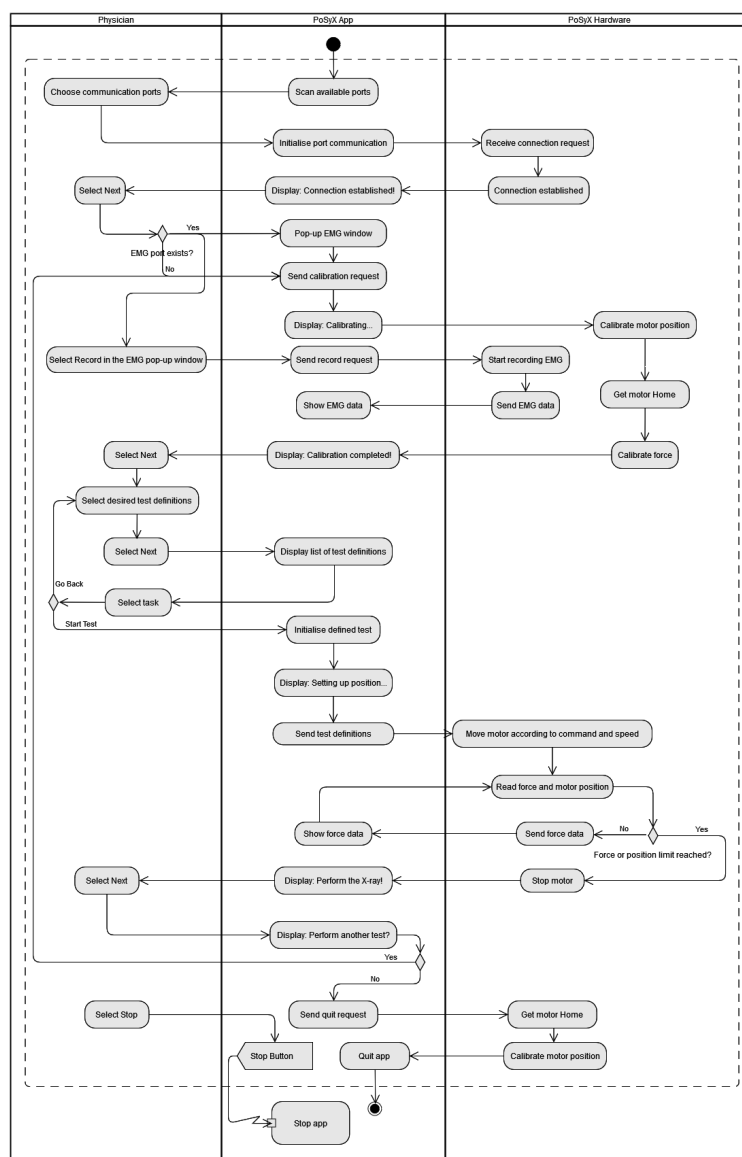


Figure 6.25: Activity diagram of the knee positioning system.

The application starts by scanning the available communication ports to connect with the Arduino Uno, and with the BITalino, if requested. Once the user chooses the ports, the communication between the laptop and devices is initialised by the PoSyX, and the devices establish a connection to the interface (Figure 6.26). The user can then proceed to the next interface page (Figure 6.27) by pressing the button "Next", and the EMG window pops-up (Figure 6.28), giving the user the opportunity to start recording in real-time the filtered EMG data (Appendix E.1) whenever they desire. In case the user decided not to select the BITalino port because they do not wish to see any EMG data, this window does not pop-up. A calibration request is sent from the PoSyX app to the Arduino Uno, and the stepper motor's position is calibrated, the motor is sent to the home position, and the force is also calibrated. After the calibration is completed, the user can press the "Next" button again to move on inside the application. They are now asked to select the desired test definitions, which include the type of test (valgus right, valgus left, varus right, varus left, skyline right, and skyline left), the grading of the type of test (I - 5 kg, II - 10 kg, III - 15 kg, and force defined), the force to be applied in kg, and the speed of the stepper motor in steps per second (having a maximum speed of 500 steps/second). The grading of the type of test was chosen taking into account the amount of force the clinical partners usually apply to young active healthy patients' knees (7 to 9 kg), since these patients are the ones who can handle more load, and the maximum force the load cell can bear (15 kg) [147]. The menus for selecting the test definitions are represented in Figure 6.29a. By selecting "Next", the user is sent to a confirmation page, where a list of the defined test definitions is displayed. The user has now two options to choose from, as seen in Figure 6.29b: either go back to the previous page to reselect the test definitions; or begin the test. If the "Start test" button is pressed, the application initialises the defined test by translating the test definitions into the serial commands that the Arduino Uno's code is programmed to work with (Section 6.4). The Arduino Uno instructs the stepper motor to start moving according to the given command (and speed for stress tests), whilst reading the position of the motor, and the force applied during stress tests. While the force or position limits are not reached, the Arduino Uno keeps sending the data of the force to the PoSyX app in case a stress test is being performed, displaying it numerically in kg and N (multiplying the force in kg by 9.81 N), and in a graph, as shown in Figure 6.30. Once one of the limits is reached, the device stops the stepper motor, marking the test as finished. The user has now time to acquire the X-ray until they press the "Next" button. After that, the page presented in Figure 6.31 asks the user whether they want to perform another test or not: if the answer is "Yes", then the app goes all the way back to the "Calibrate" interface (Figure 6.27); if the answer is "No", a quit request is sent to the Arduino Uno, which gets the stepper motor to the home position, and calibrates the motor position before quitting the application. Besides, a "STOP" button exists on all of the interface's pages for cases of emergency, where the application quits, and the motor is stopped immediately and sent to the home position.

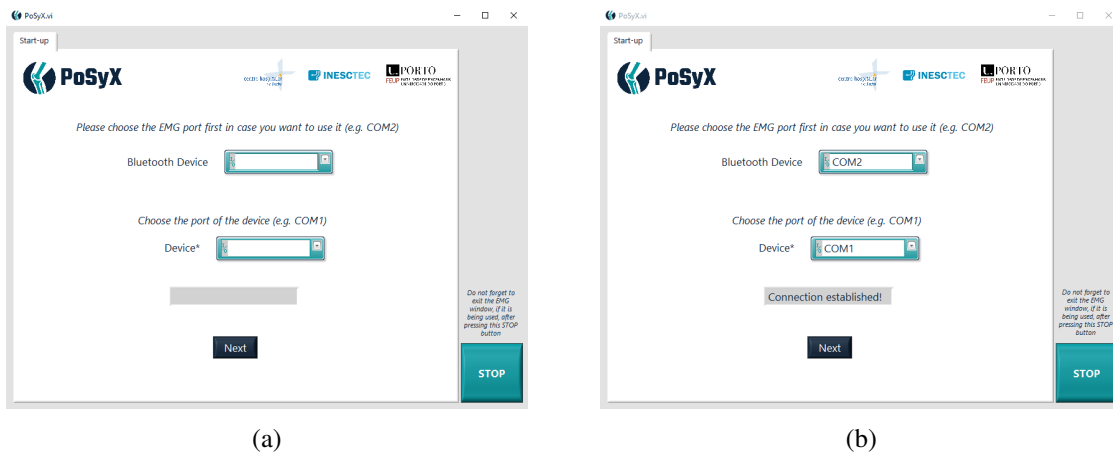


Figure 6.26: The application initialisation: (a) Blank "Start-up" interface; (b) "Start-up" interface after the connection is established.

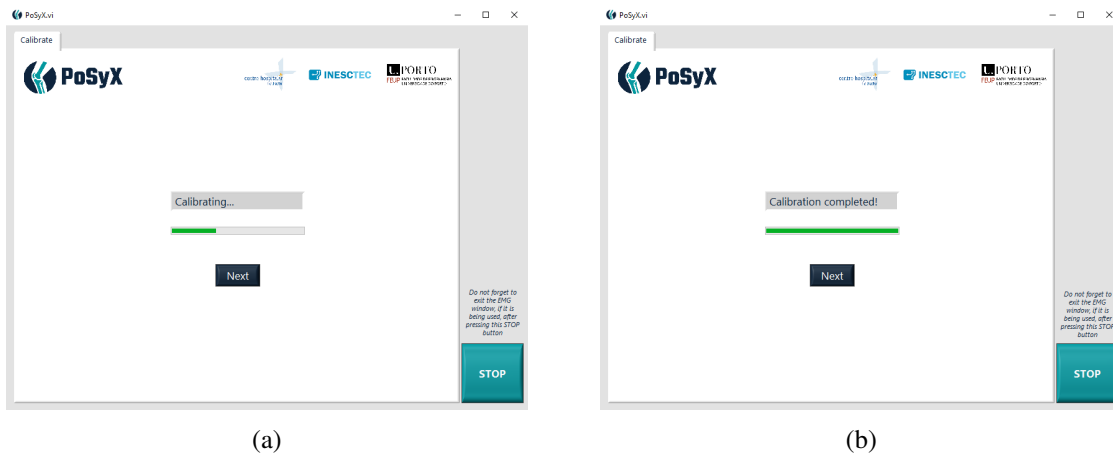


Figure 6.27: The PoSyX calibration: (a) "Calibrate" interface when calibrating; (b) "Calibrate" interface after calibration is finished.



Figure 6.28: The EMG pop-up window: (a) Data not recording; (b) Data being recorded.

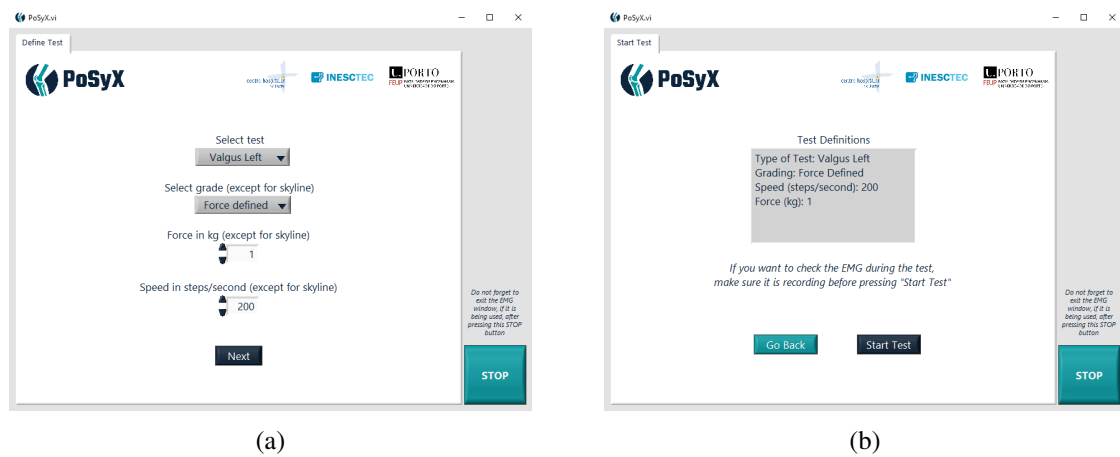


Figure 6.29: Defining the test details: (a) "Test definitions" interface; (b) "Start test" interface.

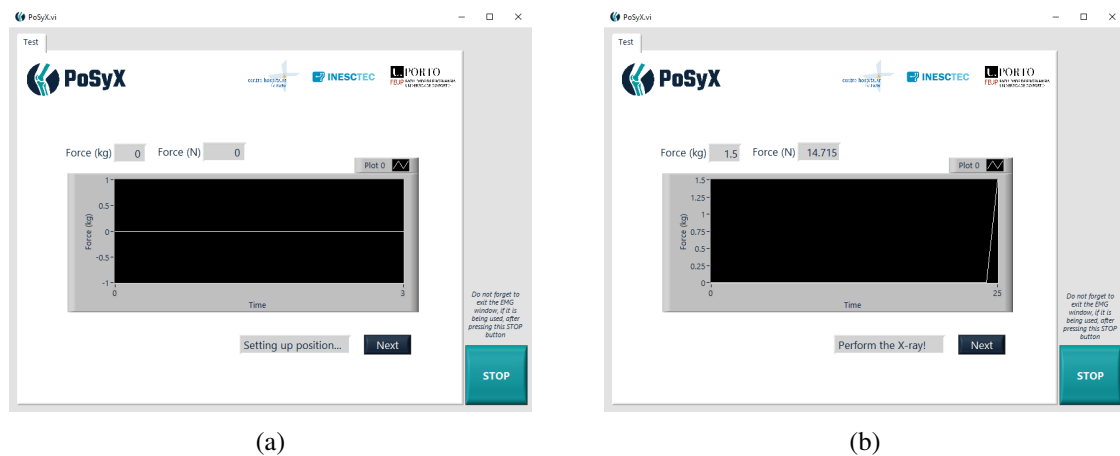


Figure 6.30: Test performance: (a) "Test" interface when the motor is setting up the position for the X-ray; (b) "Test" interface once the test is finished and the X-ray can be acquired.

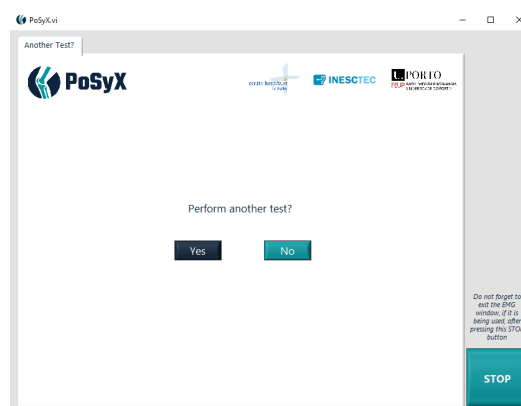


Figure 6.31: "Another test?" interface.

6.6 Safety Features Overview

Since the PoSyX is intended to be a medical device, the following safety features were implemented for this dissertation:

- A low power stepper motor (Section 6.2.1.1), that provides a higher resolution of movement without reaching high velocities;
- A circuit breaker (Section 6.2.4.1) to turn on and off the whole system, interrupting current flow if necessary;
- The foot holder mentioned in Section 6.3.1 was printed in 3D with PLA filament, which makes it easy to break in cases of emergency;
- A storage feature was implemented to protect the electronic components, avoiding contact with the patient, as stated in Section 6.3.2;
- When it comes to the software, a "STOP" button exists on all of the interface's pages. When this button is pressed, the app quits, and the motor is stopped immediately and sent to the home position. Limit positions for the linear guide's stroke were also defined.

Chapter 7

Prototype Testing

The knee positioning system was tested on subjects with or without precedents of knee injuries both in the laboratory and in a clinical setting. The study was conducted to evaluate the system's ability to place the lower limb in the advised position, and of providing a radiolucent X-ray image. This chapter describes the experimental procedures for the performance of a stress radiograph using the system's prototype, and the results obtained during the lab and clinical trials.

7.1 Experimental Procedures

As the first prototype has been implemented, prototype testing was carried out initially at the Department of Mechanical Engineering of the Faculty of Engineering of the University of Porto, Porto, Portugal. The goal of this evaluation was to address one of the three chosen evaluation factors in Section 5.1: standard force supported by motor. Firstly, the length of the subjects' upper and lower legs was measured to decide whether they would need the 400 mm or the 500 mm support system. The required support system was placed on the system, and the subjects were instructed to lay in supine position with one of their legs on the patient's support system, another bent to the side, and their whole foot touching the vertical part of the foot holder, as illustrated in Figure 7.1a. Then, the user of the PoSyX adjusted the patient to the support system, fastening the upper leg, lower leg, and foot velcro straps. After making sure the subject was in place, the operator measured the angle of knee flexion generated (Figure 7.1b), and the angle between the foot and the ankle of the subject (Figure 7.1c), with the help of a Universal 360° Bevel Protractor (Figure 7.2). Finally, the user performed one valgus stress test of Grade I, got the motor to home position, and performed one varus stress test of Grade I, to make sure the motor supported the standard force of 5 kg. This standard force was chosen taking into account the amount of force the clinical partners usually apply to young active healthy patients' knees (7 to 9 kg), since these patients are the ones who can handle more load. The stress test is finalised by getting the motor to home position again and unstrapping the subject. It is worth mentioning that the performance of

each stress test can stop by pressing the emergency button on the interface, or by turning off the whole system using the circuit breaker.



(a)



(b)



(c)

Figure 7.1: Experimental procedure of the lab trials: (a) Position the subject is instructed to be in initially; (b) Measurement of the angle of knee flexion once the patient is in place; (c) Measurement of the position of the foot once the patient is in place.

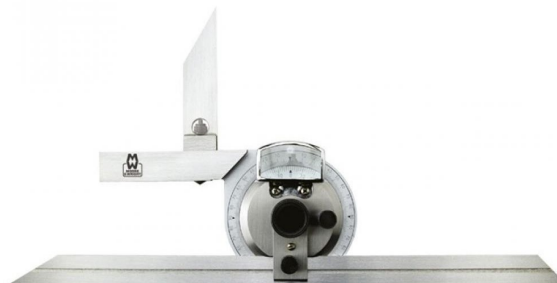


Figure 7.2: The Moore & Wright MW500-01 Universal 360° Bevel Protractor. It comes with a high precision scale, fitted with a magnifying glass for easy reading, having a minimum reading time of 5' [159].

During the clinical trials - carried out at the Department of Orthopaedics of the *Hospital Geral de Santo António*, Porto, Portugal - all three of evaluation factors mentioned in Section 5.1 were evaluated: standard force supported by motor; validation of the desired stress test; and existence of no artefacts in the X-ray image. The experimental procedure is the same as the one made in the laboratory, with the exception of the angles of knee flexion and of the position of the foot not being measured, and an X-ray being taken when the motor is in the home position, during the valgus stress test, and during the varus stress test (Figure 7.3). After the stress test evaluation is completed, the physician partnered with this project analysed the X-ray images, stating whether the desired stress test was accomplished or not, and providing information regarding any artefacts in the images. On top of that, both the partnered X-ray technician and the physician gave their feedback regarding the first prototype of the PoSyX.

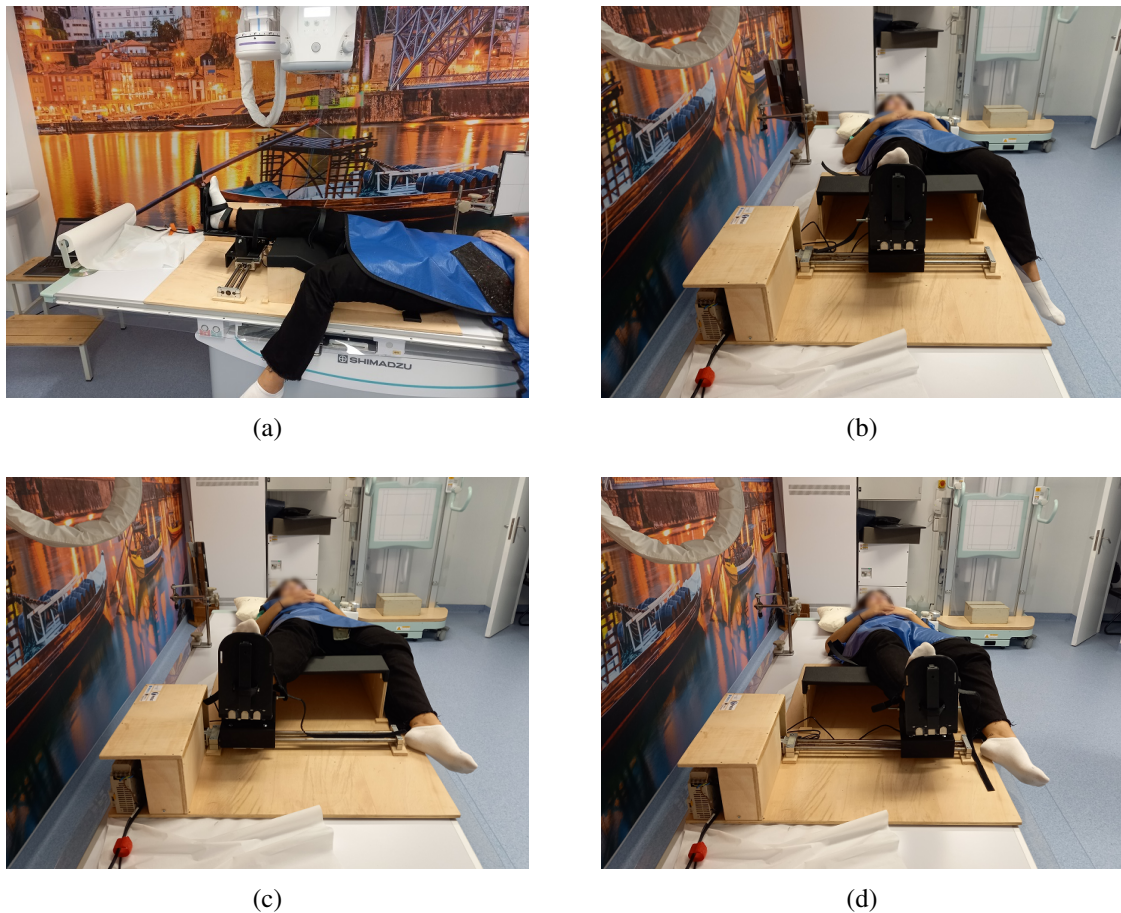


Figure 7.3: Experimental procedure of the clinical trials: (a) Position the subject is instructed to be in initially; (b) X-ray of the right knee being acquired for the home position; (c) X-ray of the right knee being acquired for the valgus stress test; (d) X-ray of the right knee being acquired for the varus stress test.

Furthermore, during the clinical trials, the EMG sensors were placed on the gastrocnemius of each subject after cleaning the surface with ethanol for higher adherence of the electrodes on the skin. The ground electrode was placed on a bony structure (malleolus), whilst the other two electrodes were placed on the aforementioned calf muscle being about 30 mm apart, as seen in Figure 7.4. Since only one set of electrodes was used, and this first PoSyX prototype had the main objective of proof of concept, no EMG data was obtained for the upper leg during these trials.

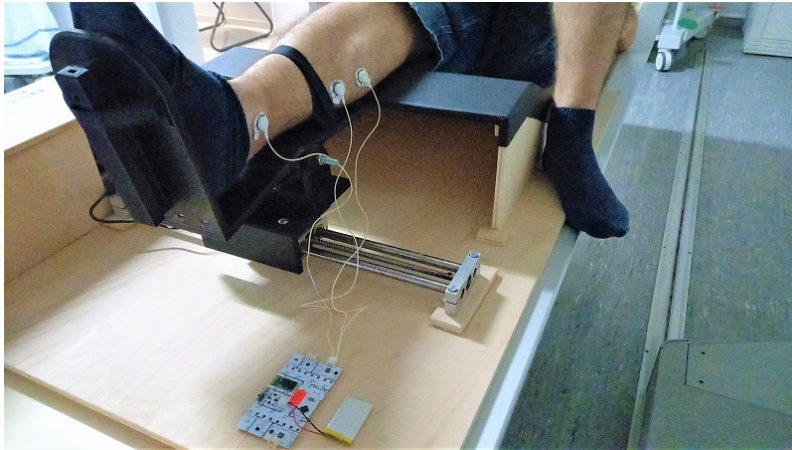


Figure 7.4: Placement of the EMG sensors on the lower leg during clinical trials.

7.2 Results and Discussion

A total of 7 volunteers were tested during these trials. Their ages ranged from 19 to 68 years old, four being female and three being male, and most of the subjects were healthy with no precedents of knee injuries, in particular KOA and ligament injuries, with the exception of one subject that had a knee joint replacement, but with no symptoms of instability. All six of the subjects with no precedents of knee injuries were evaluated for the lab trials, and two of them - both 24 years old, being one female and the other male - were tested during the clinical trials. The subject with precedents of knee injuries was only tested during the clinical trials. A randomised identification (ID) number was given to each subject to avoid personally identifying them when analysing the results.

The prototype was evaluated for the two types of trials given the factors chosen for analysis in Section 5.1. As mentioned in Section 7.1, the lab trials were evaluated taking one of the three chosen evaluation factors into account, and the clinical trials by considering all of the chosen evaluation factors. For this first prototype of the PoSyX, the standard force supported by motor intends to check if the motor is able to support a chosen standard force applied, in this case 5 kg; the validation of desired stress test aims to check if the stress test performed by the PoSyX during the stress radiography is the one present in the acquired X-ray image; and the artefacts in the X-ray images are preferably non-existent.

7.2.1 Lab Trials

A total of 6 subjects were tested during the lab trials. Their ages ranged from 19 to 55 years old, half being female and half being male, and all of the subjects were healthy with no precedents of knee injuries. Half of the subjects used their right leg for the testing, whilst the other half used their left leg. The triangle positioner utilised by each subject was chosen by analysing the measurements of the upper and lower leg, keeping in mind that the positioners' lengths were of 400 mm and 500 mm, and that the total space in the system for the lower leg to be placed in a position where the knee lays on the corner of the positioner, and the base of the foot lays on the foot holder's vertical side, is of 400 mm. When in doubt, the subjects tried both positioners to check which one fitted them better. The results of the lab trials for subjects with no precedents of knee injuries, as well as the results for the chosen evaluation factor, are represented in Table 7.1.

Table 7.1: Results of the lab trials for subjects with no precedents of knee injuries.

ID	Upper leg length (mm)	Lower leg length (mm)	Triangle positioner (mm)	Knee analysed	Angle of knee flexion (°)	Angle of foot (°)	Standard force supported by motor
58	450	500	500	Right	29.33	90	✓
2	350	400	400	Left	30	89	✓
67	410	480	500	Right	29.5	90	✓
92	450	430	500	Left	30	89.5	✓
8	390	430	400	Right	30.5	89	✓
52	370	410	400	Left	29.17	90	✓

The results of the lab trials were favourable. By analysing Table 7.1 it is possible to see that the average of the angle of knee flexion was of 29.75°, which is close to 30°; and the average of the angle between the foot and the ankle was of 89.58°, being close to 90°, and keeping the foot in a neutral position. The chosen evaluation factor also had desirable results. The motor was able to support the standard force of 5 kg for all subjects, being able to withstand a force of up to 10 kg, which is enough for stress radiography. Despite the results being encouraging, the PoSyX's first prototype showed limitations when it comes to fitting all body types. Due to the existence of only two triangle positioners, some subjects did not manage to lay their knee on the corner of the triangle positioner. This not only makes the position uncomfortable for the subjects, but could also impact the stress test's performance thanks to the femur epicondyles not being completely fixed (the knee did not have a surface to be fixed on). The x-axis idealised in Chapter 5 to adjust the system depending on the patient's height is still clearly in need.

7.2.2 Clinical Trials

Only two of the subjects from the lab trials were tested during the clinical trials. Both were 24 years old, being one female and the other male. They were chosen because not only were they the same age, but they had different conditions in their positioning: one subject fitted perfectly with the 400 mm triangle positioner, whereas the other did not manage to lay their knee on the corner of the 500 mm positioner. An additional female volunteer with 68 years old, who was in the hospital getting a post knee joint replacement evaluation and presented no symptoms of instability, was also tested during the clinical trials. The results of the clinical trials for these three subjects, as well as the results for all of the chosen evaluation factors, are presented in Table 7.2.

Table 7.2: Results of the clinical trials for three subjects.

ID	Triangle positioner (mm)	Knee analysed	Standard force supported by motor	Valid stress test	No artefacts
2	400	Right	✓	✓	✓
67	500	Right	✓	✓	✓
15	400	Left	✓	✓	✓

The clinical trials' results were also promising. The analysis of Table 7.2 shows that the first evaluation factor had good results considering only 3 subjects: the motor was able to support the standard force of 5 kg for all subjects. However, during the movement in the y-axis, the X-ray technician mentioned that fixing the ankle on the foot holder was more advantageous than the current layout. For that reason, a new design was made for the foot holder, having three holes instead of two for the velcro straps to fix the lower leg. The space between the holes for the same velcro strap was shortened to allow for a tighter fasten of the lower leg. The new foot holder design is illustrated in Figure 7.5, already being used for the clinical trials (Figure 7.3).

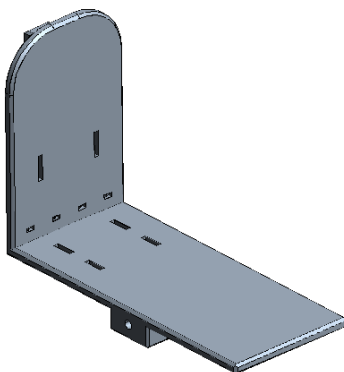


Figure 7.5: The new CAD of the foot holder.

Two more evaluation factors were analysed: validation of the desired stress test; and existence of no artefacts in the X-ray image. Hence, X-ray images were acquired of the three subjects' analysed knee in a neutral position, during the valgus and varus stress tests. The obtained X-ray images can be seen in Figure 7.6. As indicated in Table 7.2, all X-ray images for the stress tests were validated by the physician partnered with this dissertation: for the valgus stress, there was an opening of the MCL; and for the varus stress there was an opening of the LCL. The fact that the subjects had no symptoms of knee instability must be kept in mind, since the gaps obtained were not as wide as gaps observed for patients with knee ligament injuries, and a higher force needs to be applied for these subjects to feel any opening in their knee. Moreover, the physician and technician both confirmed there were no artefacts present in any of the X-ray images.

Despite most of the feedback from the clinical partners being positive, they wish to increase the potential of the PoSyX. So, an x-axis to adjust the system to the patient's body type was mentioned once again; an adjustable knee stopper was suggested to make sure the knee is always fixed during the stress test; the edge of the positioners was considered unnecessary, with potential to cause harm to patients with a bigger calf; and two different home positions - one for the valgus test, and one for the varus test - were proposed to make the most out of the linear guide Y's working stroke. In addition, they advised for the use of elastic and wider velcro straps, to make the system more comfortable for the patient.

Finally, regarding the filtered EMG data read in real-time by the PoSyX using the placement of the BITalino as shown in Figure 7.4, the results were reassuring, as it was possible to be seen in Figure 6.28. When the subject was not contracting the muscles, the signal was near 0, and when they were not relaxed, the data read was proportional to the amount of contraction that the subject did.

7.3 Final Remarks

Overall, the results of the lab and clinical trials were promising for the proof of concept of the first prototype of the PoSyX. The average of the angle of knee flexion was close to 30°, and the average of the angle between the foot and the ankle was close to 90°, keeping the foot in a neutral position. The evaluations factors had a positive outcome for the intended result of the prototype's performance: the motor supported the standard force; the partnered physician validated the knee stress radiographs; and the clinical partners denied the existence of artefacts in the X-ray images.

Nevertheless, some improvements can still be done to the PoSyX's system, such as:

- Movement in the x-axis;
- Adjustable knee stopper;
- Removal of the edge of the triangle positioners;
- Two home positions - one for the valgus test, and one for the varus test;
- Use of elastic and wider velcro straps.

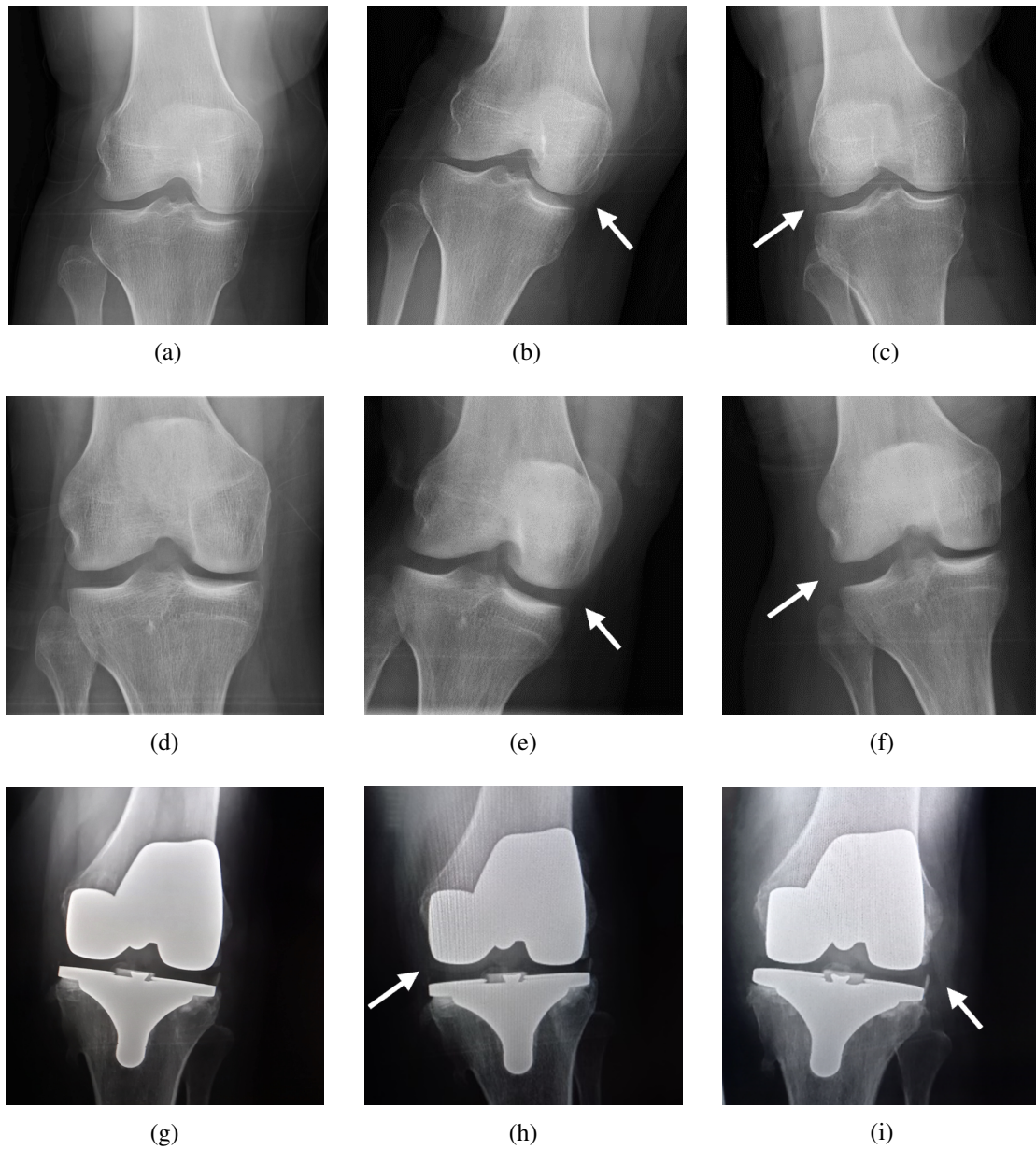


Figure 7.6: X-ray images of the analysed knee acquired from the clinical trials, where the arrows indicate the gaps of the knee provided by the stress. Subject 2's right knee: (a) Normal anteroposterior view; (b) Valgus stress; (c) Varus stress. Subject 67's right knee: (d) Normal anteroposterior view; (e) Valgus stress; (f) Varus stress. Subject 15's left knee with an implemented prosthesis: (g) Normal anteroposterior view; (h) Valgus stress; (i) Varus stress.

Chapter 8

Conclusions

The knee is the joint most prone to injuries, and physicians find it difficult to carry out an objective assessment of its pathologies. Knee stress radiography provides a more objective analysis of the laxity of an injured knee joint. However, this objectivity could be improved and reproducibility could come in handy for validation of the different diagnosis of knee injuries, evaluation of pre- and post-operative knee instability, and monitoring of knee instability during non-operative treatments. To improve the efficiency of this medical tool, knee positioning devices have been developed to avoid the exposure of the physician to radiation, and to decrease the amount of rejected X-ray images, since physicians are not required to perform the knee stress tests manually. Even so, these devices have limitations.

This dissertation aimed to design and implement a prototype of a medical device for the positioning of the patient's knee during knee stress radiography. For this purpose, a knee positioning system for X-ray environment was developed, being able to: measure and monitor the position of the lower limb, so that its position can be controlled automatically depending on which type of stress test will be performed; provide in real-time the force being applied to the joint during the stress test; measure the electrical activity produced by the skeletal muscles of the lower leg as the pressure is being applied, with the goal of determining the level of relaxation of the patient before and during the examination; not leave artefacts in the X-ray images, since the parts of the system that will be subjected to radiation are made of radiolucent materials; and to display the acquired data for each patient in real-time, letting the operator control the positioning device outside of the X-ray environment.

The implemented positioning system was composed of two main structures: the foot and the lower limb supports. The foot support was composed of a foot holder with velcro straps, that kept the foot of the patient in neutral position. This foot holder was appended to a load cell connected to a load cell amplifier, with the goal of tracking the force applied through the LabVIEW application via Arduino Uno. It was also coupled with a linear guide rail that was joined to a stepper motor and a driver, that were controlled by the Arduino Uno via the LabVIEW app. The main function

of this application was to perform a desired stress test until either a defined force or a limit of the linear guide working stroke is reached. The second structure, consisted of a radiolucent triangle positioner that gave the necessary angle of knee flexion for the stress tests' performance. The patient rested their lower limb in supine position on top of this positioner, and their upper leg was fixed by the existent velcro straps in the structure. Moreover, EMG electrodes were placed on the lower leg to measure the patient's relaxation through EMG sensors provided by BITalino, that sent the data to the LabVIEW app via Bluetooth v2.0 + EDR.

To analyse the viability and applicability of the functioning of the developed knee positioning system, lab and clinical trials were carried out to evaluate if the prototype positioned the patient in the correct position for the knee stress radiograph, if the motor supported a standard force during the stress tests, and if the X-ray images validate the defined stress test and have no artefacts. The results of these trials were promising, making the PoSyX a possible contender in the knee stress radiography positioning devices field, which was validated by the dissertation's clinical partners:

“The objectification of a patient's complaints is not always easy for a physician, who must deal with an injured person, with complaints of pain or instability in a joint. Until now, the evaluation standard is still based on the physician's clinical impression, who manually performs stress tests on the joints, and has a biased evaluation, necessarily subjective, of the manoeuvre they perform. There are already some methods of instrumenting these manoeuvres, but due to their cost, low availability, or difficulty of use, they have not been able to spread as a universal standard for evaluating the human body, as many other imaging methods have. Thus, the development of this new system by Catarina Lopes, appears as a step forward in simplifying the use of a knee joint instability evaluation system, introducing simultaneously increased sophistication in patient care.”

- Dr. Adélio Vilaça, Orthopaedist, Department of Orthopaedics of the *Hospital Geral de Santo António*, Porto, Portugal

“The collaboration I was able to give in the improvement of a device for performing knee stress exams, had an objective on my part, of avoiding exposure of healthcare professionals to radiation when performing them. With this device we will be able, without losing rigour, to reach that objective.”

- Artur Ribeiro, Radiographer, Department of Orthopaedics of the *Hospital Geral de Santo António*, Porto, Portugal

8.1 Future Work

The implementation of this system has provided a more objective and detailed stress test examination, being a possible contender in the market for these types of medical devices. Nonetheless, it was a first implemented prototype for validation of the concept, so it still has some limitations and possible future improvements that can greatly enhance this device, becoming more and more reliable for clinical use:

- The clinical partners advised for some improvements of the PoSyX's first prototype: an adjustable knee stopper, so the knee is guaranteed to be fixed; the removal of the edge of the triangle positioners, since it can harm patients with bigger calves and it seems unnecessary; two different home positions - one for the valgus test, and one for the varus test - to make the most out of the linear guide Y's working stroke; and the use of elastic and wider velcro straps, to make the system more comfortable for the patient;
- Despite already having some security features, these can always be improved, especially in a medical setting:
 - Two emergency buttons that bring the motor back to its home position should be added to the prototype. One emergency button should be inside the technician's room, so the physicians or technicians can stop the stress test at any time; and a second emergency button for extra security should be near the linear guide and away from the patient, to prevent the patient from pressing it when they feel normal pain caused by the stress test;
 - Security sensors to make sure the linear guide does not go over its working stroke limit are also recommended;
 - Timeout conditions should be added to the software to make sure there is no situation where the motor runs for too long before either reaching an applied force, or a limit of the linear guide;
 - In the current prototype all of the hardware components are still too close to the patient. Even though a storage feature was added to the prototype, it is still fragile, and the patient could accidentally hit the storage box and harm the components. For that reason, the components that do not need to be in direct contact with the patient should be in the technician's room, connected through cables for guaranteed communication;
 - A clutch could be implemented to disengage the power transmission when the motor is ordered to stop;
 - Lastly, a dead man's switch could be given to the patient to stop the system if they are unable to keep holding it due to too much pain.
- Regarding the movement of the motor, it could only support about 10 kg. For that reason, it is recommended for a gear reducer to be added to the system to reduce the speed with which

power is transmitted to the motor, whilst providing equal or higher torque. A motor with higher power could also be implemented instead. The movement of the motor could have a more accurate resolution by the addition of a rotary encoder to provide a more precise position control;

- The complete designed knee positioning system with 3 axes and an acrylic lower limb support was not possible to be implemented yet. In the future, this system should be implemented for testing and validation of its clinical use;
- The X-ray detector holder also did not have the chance to be tested and validated when integrated with the knee positioning system, so it should be implemented as well;
- The implemented prototype is still big and of heavy-weight. The exploration of other materials to use, different configurations of the current design, or even of new designs that converge with the objective of the system is recommended;
- Some new features could be added to the positioning system, such as: rotational angles of the knee, so other stress tests besides the valgus and varus test can be performed; adjustment of the system to other joints; and a camera integrated in the system to provide a real-time feedback of the system's behaviour through the application's interface.

Sketches for the Patient's Support System

Hand-drawn sketches of mechanical components. The top left shows a bracket-like structure with a label '24V' and a circular feature. The bottom left shows a rectangular block with a small rectangular cutout. The right side shows a circular feature with a central dot.

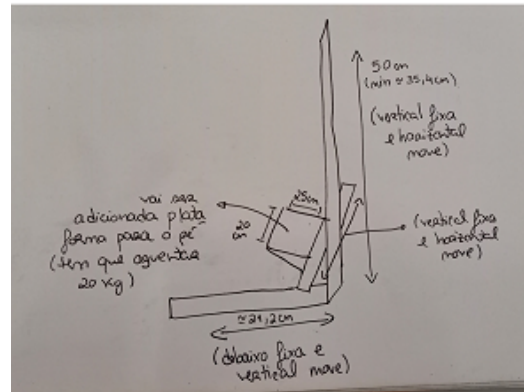
[illegible]

Figure A.1: Overall patient's support system drawings: (a) First sketch; (b) Latter sketch.

A.2 Foot Support

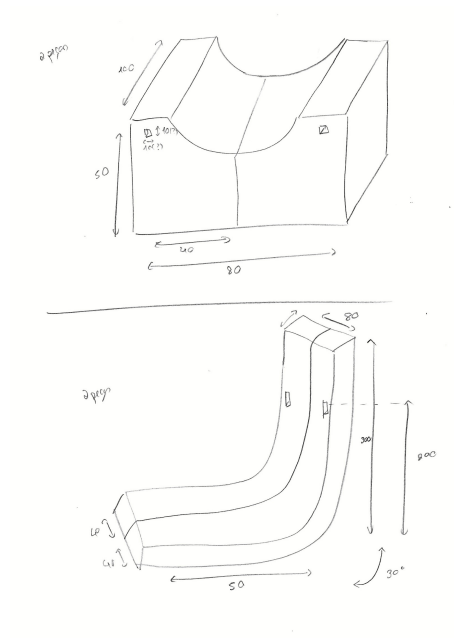


(a)

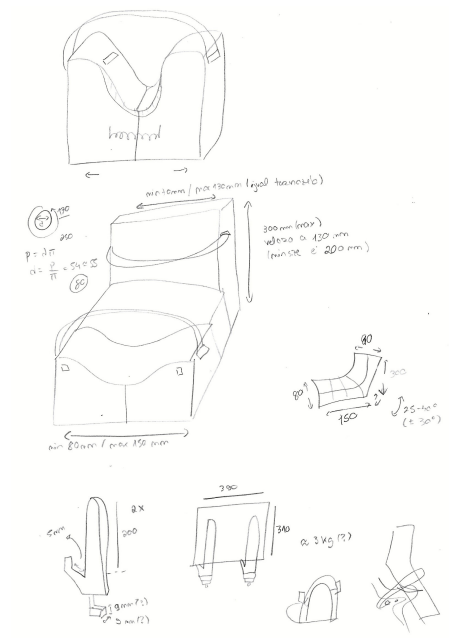


(b)

Figure A.2: Drawings of the system with 3 axes of movement for the foot support system: (a) First sketch; (b) Latter sketch.



(a)



(b)

Figure A.3: Drawings of the foot holder for the foot support system: (a) First sketch; (b) Latter sketch.

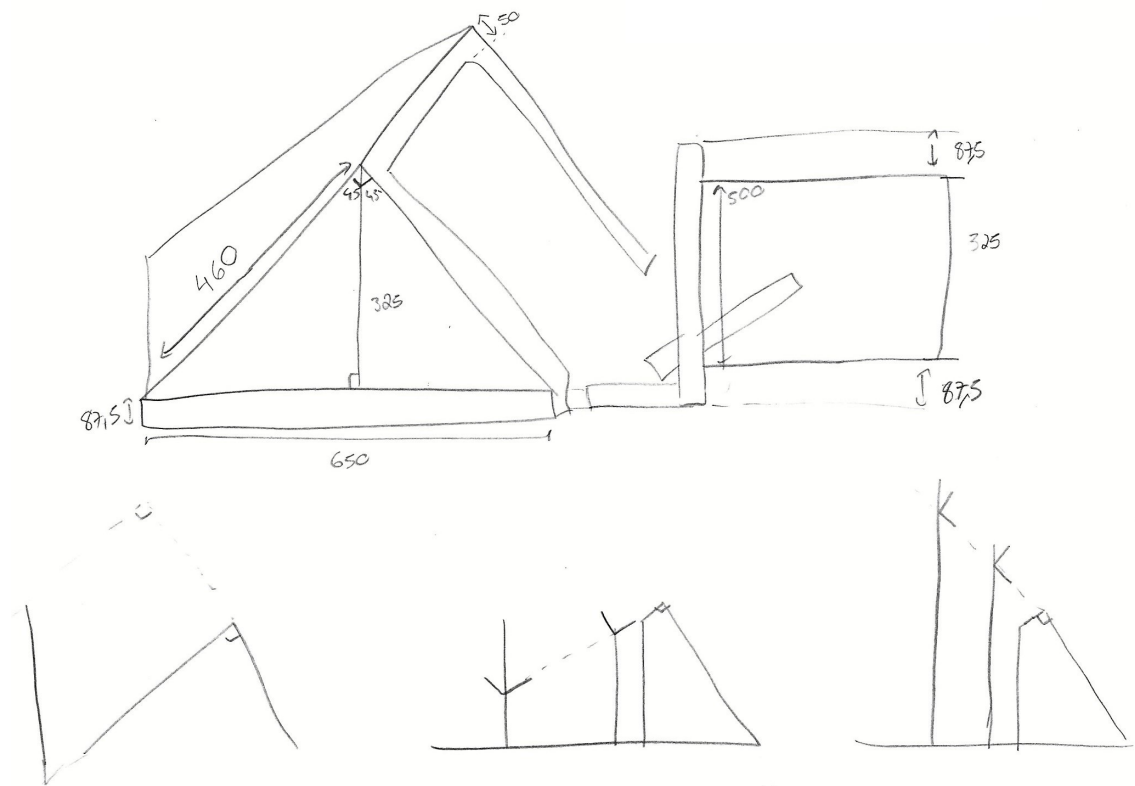
A.3 Lower Limb Support

Figure A.4: Lower limb support drawing example.

Appendix B

Industrial Companies Proposals

B.1 Igus' Components Proposal

Pos	Nº artigo e descrição	Qtd.	Un.	Preço / Un.	Preço total
1.000	Eixo Y Mesa SLW-1080 + controlador D1				
1.001	SLW-1080-H1AU1-D0A0B-AJ1A0AA-400 drylin® SLW-1080 linear module, Perfil em alumínio anodizado, casquilhos fuso trapezoidal TR10x3 aço inox, ponta fuso não maquinada 17mm, comprimento carruagem 150 mm, bloco de apoio em alumínio, motor de passo NEMA23, encoder, 2.0 Nm, cabo com 3 metros e conector reto, montagem a 0°, Curso 400 mm, comprimento do sistema (l+curso) 594 mm	1	1 un.	EUR 858,21 / 1	EUR 858,21
1.002	D1 Controlador para motores DC, EC e de Passo - www.igus.pt/D1	1	1 un.	EUR 545,53 / 1	EUR 545,53
1.003	Taxa de disponibilidade D1	1	1 un.	EUR 110,00 / 1	EUR 110,00
	Subtotal	1		EUR 1.513,74	EUR 1.513,74
2.000	Eixo Z Mesa SLW-2080 + Controlador D8				
2.001	SLW-2080-H1AM2-D0A0B-AN1A0AA-500 drylin® SLW-2080 linear module, Perfil em alumínio anodizado, casquilhos fuso trapezoidal TR18x4 C15, ponta fuso maquinada 12h9x26mm, comprimento carruagem 200 mm, bloco de apoio em alumínio, motor de passo NEMA23XL, encoder, 3.5 Nm, cabo com 3 metros e conector reto, montagem a 0°, Curso 500 mm, comprimento do sistema (l+curso) 756 mm	1	1 un.	EUR 1.051,30 / 1	EUR 1.051,30
2.002	D8 Controlador de motor drylin N23/24	1	1 un.	EUR 125,31 / 1	EUR 125,31
	Subtotal	1		EUR 1.176,61	EUR 1.176,61
3.000	Eixo X Guia dupla + 3 patins + Patim com travão				
3.001	WS-20-80 Guia linear drylin® W	1	0,550 m	EUR 104,26 / 1	EUR 57,34
	Custos de corte Para 1 un.	1	1 un.	EUR 2,25 / 1	EUR 2,25

3.002	WJ200UM-01-20 Patim drylin® W	3	1 un.	EUR 7,85 / 1	EUR 23,55
3.003	WHKA-20 Travão manual drylin® W	1	1 un.	EUR 37,93 / 1	EUR 37,93
	<u>Subtotal</u>	<u>1</u>		<u>EUR 121,07</u>	<u>EUR 121,07</u>
Valor total da proposta					EUR 2.811,42

Preços sem IVA incluído.

Em caso de encomenda, agradecemos o favor de enviar por email para o endereço: encomendas@igus.net

As condições de envio referem-se apenas às quantidades e artigos desta proposta.

Condições de envio	Portes: Transporte normal GRÁTIS para pedidos da gama BRG iguais ou superiores a 100 €. Para pedidos de valor inferior a 100 €: 11,99 € (16 € se inclui artigos com comprimento superior a 1 metro). Para embalagens com dimensão igual ou superior a 3 metros de comprimento: 85 € (independentemente do valor da encomenda) Portes de transporte urgente: Segundo peso e volume, por favor consultar. Outras modalidades de envio: sob consulta.
Condições de venda	Segundo as condições gerais de venda em www.igus.pt . Validade da proposta: 15 dias
Prazo de entrega	Transporte normal: 4/6 semanas nas vossas instalações após confirmação da encomenda. Salvo venda. Por favor entre em contacto connosco caso o prazo de entrega não seja aceitável no seu caso. Observação: No caso do controlador D1, neste momento não temos data prevista para envios, pelo que para mais informação deve entrar em contacto através do encomendas@igus.net
Condições de pagamento	A combinar
Dimensões e tolerâncias	Aplicar as dimensões e tolerâncias para os produtos drytech de acordo com o catálogo atual da igus. Por defeito o alojamento para os casquilhos em polímero iglidur e drylin deverão ter tolerância H7.

B.2 Festo's Components Proposal

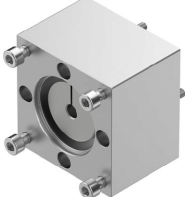


V/ nº de cliente	Nr. fornecedor	V/ referência	Proposta	Data	Página
69119694		POSICIONADOR JOELHO P/ RAIÓ-X	2690096750	13.07.2022	2 de 8

Descrição	Nº Material	Preço unitário EUR	Quantidade	Preço total EUR
Unid. eixo fuso  Posição 10 / V/ posição 10 ELGS-BS-KF-60-300-12P-ST-M-H1-PLK-AA ELGS Ball screw drive Recirculating ball bearing guide 60 Stroke mm 12 mm Stepper motor ST Built-in Built-in PNP or IO-Link® With integrated end-position sensing Prazo de entrega 7 dias úteis Council Regulation EC: No license required, US-EAR: No license required	8083385	1.035,65	1 PC	1.035,65
cabo de conexão  Posição 20 / V/ posição 20 NEBL-T12W4-E-5-N-LE4 Devido a uma grande procura, o prazo de entrega confirmar-se-á após a encomenda. Council Regulation EC: No license required, US-EAR: No license required	8080779	48,15	1 PC	48,15
cabo de conexão  Posição 30 / V/ posição 30 NEBC-M12W8-E-5-N-B-LE8 Devido a uma grande procura, o prazo de entrega confirmar-se-á após a encomenda. Council Regulation EC: No license required, US-EAR: No license required	8094478	39,66	1 PC	39,66
EIXO DE FUSO  Posição 40 / V/ posição 40 ELGC-BS-KF-60-300-12P Stroke mm ELGC C series Ball screw Recirculating ball bearing guide 60 mm Stroke mm 12 mm	8061493	589,36	1 PC	589,36

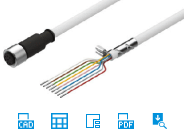
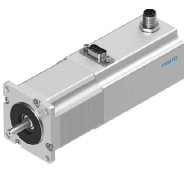


V/ nº de cliente	Nr. fornecedor	V/ referência	Proposta	Data	Página
69119694		POSICIONADOR JOELHO P/ RAI-O-X	2690096750	13.07.2022	3 de 8

Descrição	Nº Material	Preço unitário EUR	Quantidade	Preço total EUR
MOTOR DE PASSO  Posição 50 / V/ posição 50 EMMS-ST-57-S-SEB-G2 Prazo de entrega 2 dias úteis Council Regulation EC: No license required, US-EAR: No license required	1370477	496,32	1 PC	496,32
Reg servoacion  Posição 60 / V/ posição 60 CMMT-ST-C8-1C-EP-S0 Por razões extraordinárias, prazo de entrega sem confirmar. Council Regulation EC:3A225, US-EAR: No license required	8084006	373,86	1 PC	373,86
CONJ.MONT.AXIAL  Posição 70 / V/ posição 70 EAMM-A-T42-57A Prazo de entrega 2 dias úteis Council Regulation EC: No license required, US-EAR: No license required	4327034	59,48	1 PC	59,48
Cabo de motor  Posição 80 / V/ posição 80 NEBM-S1W9-E-5-Q5-LE6 Prazo de entrega 2 dias úteis Council Regulation EC: No license required, US-EAR: No license required	1450738	67,49	1 PC	67,49

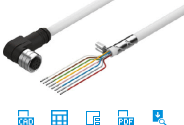
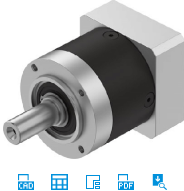
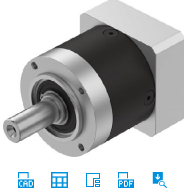


V/ nº de cliente	Nr. fornecedor	V/ referência	Proposta	Data	Página
69119694		POSICIONADOR JOELHO P/ RAI-O-X	2690096750	13.07.2022	4 de 8

Descrição	Nº Material	Preço unitário EUR	Quantidade	Preço total EUR
CABO DO ENCODER  Posição 90 / V/ posição 90 NEBM-M12G8-E-5-LE8 Devido a uma grande procura, o prazo de entrega confirmar-se-á após a encomenda. Council Regulation EC: No license required, US-EAR: No license required	1451588	70,93	1 PC	70,93
Fix. p/ perfil  Posição 100 / V/ posição 100 EAHF-L2-45-P Prazo de entrega 2 dias úteis Council Regulation EC: No license required, US-EAR: No license required	4835728	16,68	1 PC	16,68
Reg servoacion  Posição 110 / V/ posição 110 CMMT-ST-C8-1C-EP-S0 Por razões extraordinárias, prazo de entrega sem confirmar. Council Regulation EC:3A225, US-EAR: No license required	8084006	373,86	1 PC	373,86
MOTOR DE PASSO  Posição 120 / V/ posição 120 EMMS-ST-57-M-SEB-G2 Prazo de entrega 2 dias úteis Council Regulation EC: No license required, US-EAR: No license required	1370481	513,36	1 PC	513,36

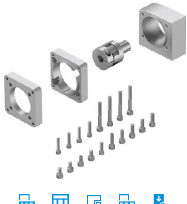


V/ nº de cliente	Nr. fornecedor	V/ referência	Proposta	Data	Página
69119694		POSICIONADOR JOELHO P/ RAI0-X	2690096750	13.07.2022	5 de 8

Descrição	Nº Material	Preço unitário EUR	Quantidade	Preço total EUR
Cabo de motor  Posição 130 / V/ posição 130 NEBM-S1W9-E-5-Q5-LE6 Prazo de entrega 2 dias úteis Council Regulation EC: No license required, US-EAR: No license required	1450738	67,49	1 PC	67,49
CABO DO ENCODER  Posição 140 / V/ posição 140 NEBM-M12W8-E-5-LE8 Devido a uma grande procura, o prazo de entrega confirmar-se-á após a encomenda. Council Regulation EC: No license required, US-EAR: No license required	1451676	70,93	1 PC	70,93
REDUÇÃO  Posição 150 / V/ posição 150 EMGA-60-P-G8-SST-57 Devido a uma grande procura, o prazo de entrega confirmar-se-á após a encomenda. Council Regulation EC: No license required, US-EAR: No license required	8141764	419,18	1 PC	419,18
REDUÇÃO  Posição 160 / V/ posição 160 EMGA-60-P-G8-SST-57 Devido a uma grande procura, o prazo de entrega confirmar-se-á após a encomenda. Council Regulation EC: No license required, US-EAR: No license required	8141764	419,18	1 PC	419,18
EIXO CORR.DENT *  Posição 170 / V/ posição 170 EGC-80-500-TB-KF-0H-GV ACTUADOR LINEAR ELECTRICO Linear axis EGC 80 80 Stroke mm 500 Toothed belt TB Recirculating ball bearing guide KF Stroke reserve 0H 0H Slide extended GV Devido a uma grande procura, o prazo de entrega confirmar-se-á após a encomenda.	556814	1.425,41	1 PC	1.425,41



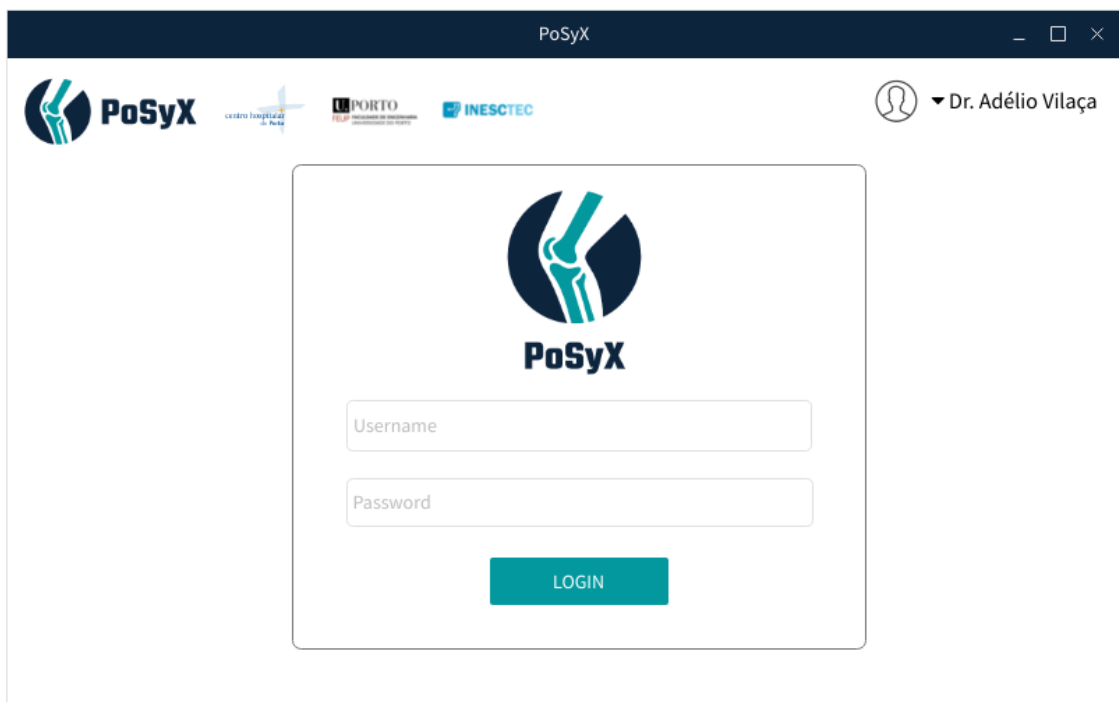
V/ nº de cliente	Nr. fornecedor	V/ referência	Proposta	Data	Página
69119694		POSICIONADOR JOELHO P/ RAI0-X	2690096750	13.07.2022	6 de 8

Descrição	Nº Material	Preço unitário EUR	Quantidade	Preço total EUR
	Council Regulation EC: No license required, US-EAR: No license required			
Fix. p/ perfil  	Posição 180 / V/ posição 180 MUE-70/80 Prazo de entrega 2 dias úteis Council Regulation EC: No license required, US-EAR: No license required	558043	27,62	3 PC
CONJ.MONT.AXIAL  	Posição 190 / V/ posição 190 EAMM-A-L48-60G Prazo de entrega 2 dias úteis Council Regulation EC: No license required, US-EAR: No license required	557983	196,21	1 PC
CONTROLAD. PROG  	Posição 200 / V/ posição 200 CECC-D Devido a uma grande procura, o prazo de entrega confirmar-se-á após a encomenda. Council Regulation EC: No license required, US-EAR: No license required	574415	368,15	1 PC
Preço Total			EUR	6.734,21
Custo de transporte			EUR	10,00
Preço Total			EUR	6.744,21
Termos de pagamento: 30d s/ Desc.				
Local de entrega: DAP / Paga portes				
Tempo de transporte: Entrega normalmente 1 dia útil após o envio				

Appendix C

Interface Mockup

C.1 Mockup of an App for the Physician



The mockup shows a web browser window titled "PoSyX". The header bar is dark blue with the PoSyX logo on the left and a user profile icon with the name "Dr. Adélio Vilaça" on the right. Below the header, there are logos for "centro hospitalar de lisboa", "LISBOA", and "INESCTEC". The main content area features a large PoSyX logo and a login form with two input fields labeled "Username" and "Password", and a teal "LOGIN" button.

Figure C.1: Login to the system's app.

The image shows a web browser window titled "PoSyX". The header bar is dark blue and contains the PoSyX logo (a stylized knee joint), the text "PoSyX", and logos for "centro hospitalar de Porto", "PORTO", and "INESCTEC". On the right side of the header, there is a user profile icon and the text "Dr. Adélio Vilaça". Below the header, there is a dark blue bar with the text "SEARCH FOR PATIENT PROFILE". The main content area is white and features a search bar with the placeholder text "Search Patient" and a magnifying glass icon. Below the search bar, there is a dark blue button with the text "INSERT NEW PATIENT".

Figure C.2: Search for a patient in the app or add a new one.

The image shows a web browser window titled "PoSyX". The header bar is dark blue and contains the PoSyX logo (a stylized knee joint), the text "PoSyX", and logos for "centro hospitalar de Porto", "PORTO", and "INESCTEC". On the right side of the header, there is a user profile icon and the text "Dr. Adélio Vilaça". Below the header, there is a dark blue bar with the text "ADD NEW PATIENT". The main content area is white and features a form for adding a new patient. On the left side of the form, there is a circular icon with a stylized head and a plus sign. The form fields are arranged in two columns. The left column contains the following fields: "Full Name" (a text input field), "Date of Birth" (a date picker with a calendar icon), "Email" (a text input field), and "Address" (a text input field). The right column contains the following fields: "ID" (a text input field), "Mobile Phone" (a text input field), and "Health History" (a text input field). At the bottom of the form, there is a dark blue button with the text "ADD PATIENT".

Figure C.3: Add a new patient to the database.

PoSyX

centro hospitalar de porto INESC TEC

Dr. Adélio Vilaça

PROFILE

Name Maria Pinto
ID 12554668
Age 32

Phone +351 962514875
Email maria.pinto@gmail.com
Address Tv. Cedofeita 25, Porto, Portugal
Health History MCL Rupture - Knee

DATA

#	Date	Joint	Type of Test	Observations
3	07/01/2022	Knee	Varus - G1	LCL seems intact
2	07/01/2022	Knee	Valgus - G2	Rupture of the MCL
1	07/01/2022	Knee	Valgus - G1	-

NEW STRESS RADIOGRAPH

Figure C.4: View the selected patient's profile and their previous data.

PoSyX

centro hospitalar de porto INESC TEC

Dr. Adélio Vilaça

1. SELECTION OF TEST

2. CONFIRM TEST

3. TEST STATUS

Select test

- Valgus Right - G1
- Valgus Right - G2
- Valgus Right - G3

Select degree

- 0°
- 5°
- 10°

Force: 7.0 kg ≈ 68.7 N

Current: 7 A

Test: Valgus Right - G3 45°

Vertical: 250 mm

Horizontal: - 150 mm

System Status

CANCEL START

Force (kg): 7.0

Current: 7 A

Force (kg) vs Time (s) graph

System Status

Real-time video of test

Relaxed Stressed

CANCEL SAVE

Figure C.5: Perform a test on the patient by selecting the type of test and the degree of flexion. Confirm that the default force that is going to be applied, the position of the system, and the test definitions are acceptable. Start the stress test, check the force applied, and see if the patient is relaxed or not.

Appendix D

Hardware Diagrams

D.1 Power Supply Block Diagram

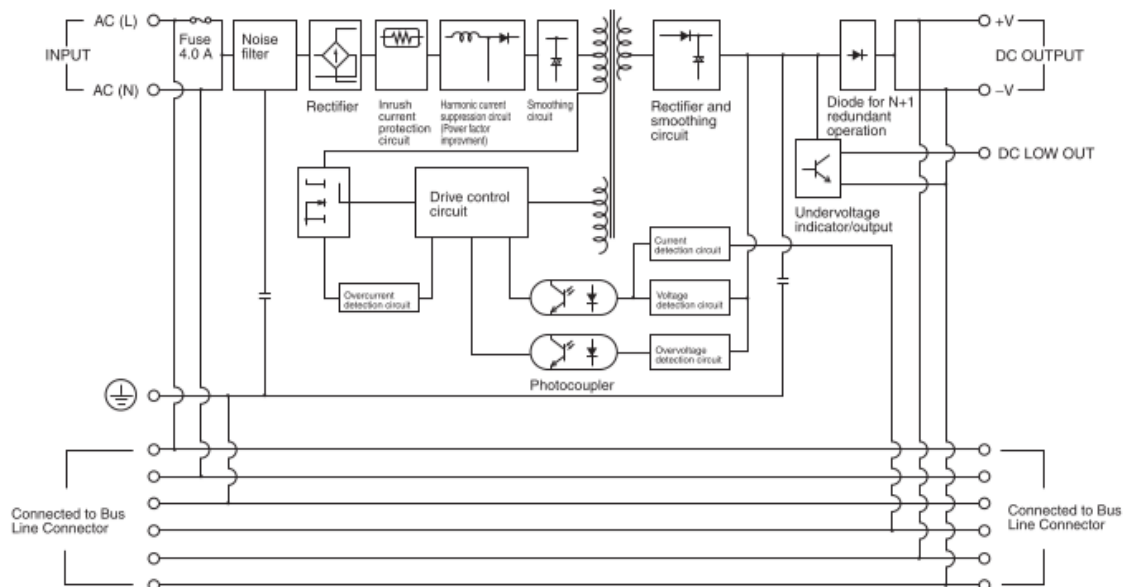


Figure D.1: Block diagram of the power supply S8TS-06024 by Omron [153].

D.2 Wiring of the PoSyX

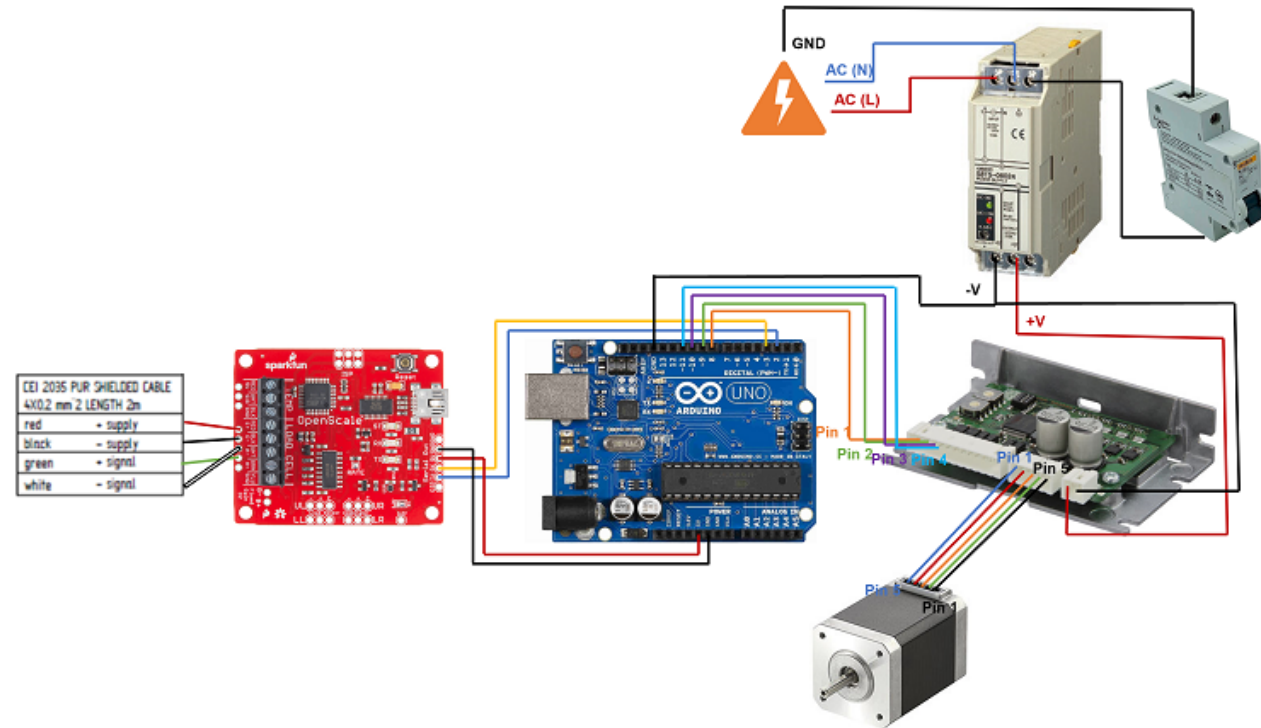


Figure D.2: Diagram of the wiring of the hardware components of the PoSyX system, adapted from [145–147, 150, 152–154].

Appendix E

Algorithms of the System

E.1 LabVIEW

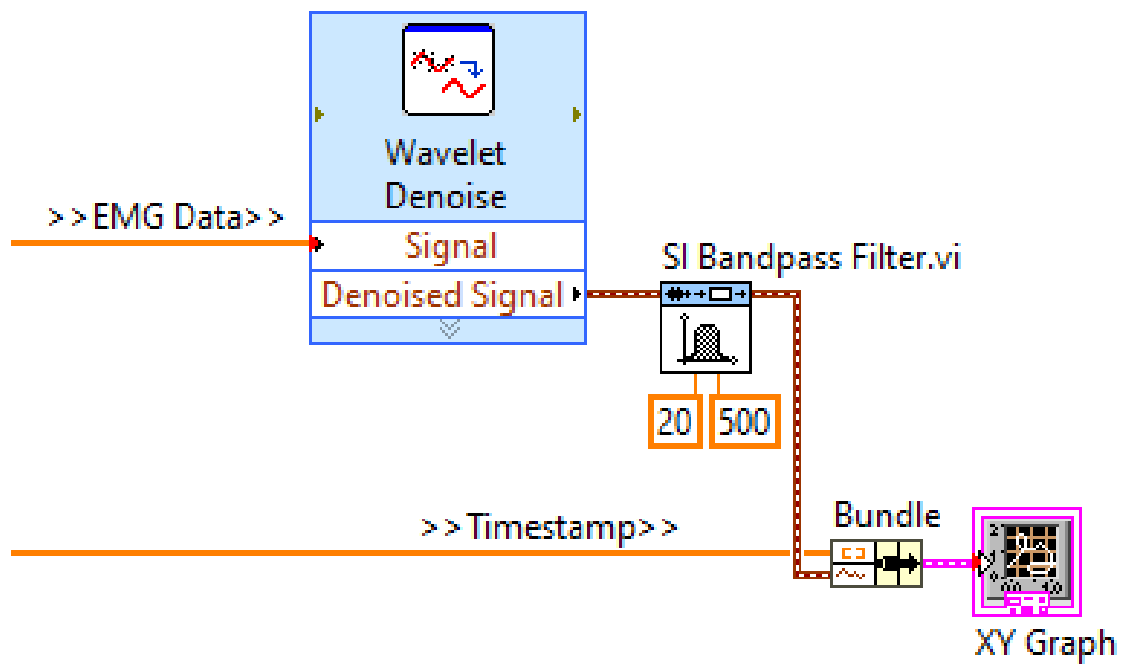


Figure E.1: EMG filtering algorithm.

E.2 Arduino

```
// FUNCTIONS FOR SET UP
// REVOLUTION COUNT
// reading the revolution count between code runs
long readFromEEPROM(int address)
{
    return ((long)EEPROM.read(address) << 24) +
           ((long)EEPROM.read(address + 1) << 16) +
           ((long)EEPROM.read(address + 2) << 8) +
           (long)EEPROM.read(address + 3);
}

// writing the revolution count between code runs
void writeToEEPROM(int address, int revolutionCount)
{
    EEPROM.write(address, (revolutionCount >> 24) & 0xFF);
    EEPROM.write(address + 1, (revolutionCount >> 16) & 0xFF);
    EEPROM.write(address + 2, (revolutionCount >> 8) & 0xFF);
    EEPROM.write(address + 3, revolutionCount & 0xFF);
}
```

Figure E.2: Reading and writing functions for the revolution counter using EEPROM. Given the fact that the revolution counter's maximum byte count can be of 4 (the minimum limit position is of -300), an address is chosen for the first byte and the three following bytes are available for storage as well. The reading function reads the value in each byte, whilst the writing function updates each byte with the current value.

```

// GO HOME
// get the motor to the home position
void goHome()
{
    force = 0;

    // if motor is in 0 position, the motor stops
    if (revolutionCount == 0)
    {
        stepper.stop(); // stop motor
        stepper.disableOutputs(); // disable motor power
    }
    else
    {
        while (revolutionCount != 0)
        {
            // if motor is in a positive position the motor goes in a negative
            direction until it reaches the 0 position
            if (revolutionCount > 0)
            {
                stepper1.setSpeed(500);
                stepper1.step(-stepsPerRevolution);
                revolutionCount = revolutionCount - 1;
            }

            // if motor is in a negative position the motor goes in a positive
            direction until it reaches the 0 position
            else
            {
                stepper1.setSpeed(500);
                stepper1.step(stepsPerRevolution);
                revolutionCount = revolutionCount + 1;
            }
        }

        // when the motor reaches the 0 position, the motor stops
        stepper.stop(); // stop motor
        stepper.disableOutputs(); // disable motor power
    }
}

```

Figure E.3: goHome() function used for the 'H' and 'S' serial commands. Its functionality is sending the motor to the defined home position, no matter where the motor is located.

```

// F: Calibration of the force
case 'F':
    rawForce = forcePin.parseFloat(); // read the load cell's raw value
    force = (rawForce - offsetForce) * calForce; // scaling factor
    (calibration factor and zero offset) obtaining the force in kg

    // tare force read
    if (force != 0)
    {
        offsetForce = rawForce;
        force = (rawForce - offsetForce) * calForce;
    }
    break;

```

Figure E.4: The serial command 'F' calibrates the force read by reading a raw force from the load cell, calculating the force in kg using Equation 6.3, the defined value of the conversion factor, and the latest offset value. In case the obtained force is not equal to zero, the algorithm tares it.

```

// R: Goes to the right side limit
case 'R':
    directionMultiplier = 1; // define the direction of the motor to
    CW/right side of the system

    // run motor to the positive direction while it does not reach the
    maximum position limit
    while (revolutionCount < limMax)
    {
        // update revolution counter
        revolutionCount = revolutionCount + directionMultiplier;
        stepper.setCurrentPosition(revolutionCount);

        // move motor to the desired direction with maximum speed
        stepper1.setSpeed(500);
        stepper1.step(directionMultiplier * stepsPerRevolution);

        // if the 'S' command is read, the motor stops
        if (Serial.read() == 'S')
        {
            stepper.stop(); // stop motor
            stepper.disableOutputs(); // disable motor power
            break;
        }
    }

    // once the limit is reached or the 'S' command sent, the motor stops
    and the counter is updated
    stepper.stop(); // stop motor
    stepper.disableOutputs(); // disable motor power
    stepper.setCurrentPosition(revolutionCount); // update revolution
    counter
    break;

```

Figure E.5: The serial command 'R' moves the stepper motor to its positive position limit by moving it clockwise. The revolution counter keeps track of where the motor is positioned, and once it reaches the positive position limit (300), the motor stops. The movement can be stopped at any time by sending the 'S' command to the serial port.

```

// L: Goes to the left side limit
case 'L':
    directionMultiplier = -1; // define the direction of the motor to
    CCW/left side of the system

    // run motor to the negative direction while it does not reach the
    minimum position limit
    while (revolutionCount > limMin)
    {
        // update revolution counter
        revolutionCount = revolutionCount + directionMultiplier;
        stepper.setCurrentPosition(revolutionCount);

        // move motor to the desired direction with maximum speed
        stepper1.setSpeed(500);
        stepper1.step(directionMultiplier * stepsPerRevolution);

        // if the 'S' command is read, the motor stops
        if (Serial.read() == 'S')
        {
            stepper.stop(); // stop motor
            stepper.disableOutputs(); // disable motor power
            break;
        }
    }

    // once the limit is reached or the 'S' command sent, the motor stops
    and the counter is updated
    stepper.stop(); // stop motor
    stepper.disableOutputs(); // disable motor power
    stepper.setCurrentPosition(revolutionCount); // update revolution
    counter
    break;

```

Figure E.6: The serial command 'L' moves the stepper motor to its negative position limit by moving it counterclockwise. The revolution counter keeps track of where the motor is positioned, and once it reaches the negative position limit (-300), the motor stops. The movement can be stopped at any time by sending the 'S' command to the serial port.

```

// +: Rotates the motor to a positive position (right side of the system)
(CW)
// needs to be followed by the amount of force in kg, a space, and the
amount of speed of the motor - e.g. '+2 200'
case '+':
    receivedForce = Serial.parseFloat(); // value for the defined force in
kg
    receivedSpeed = Serial.parseFloat(); // value for the defined speed in
steps/second
    directionMultiplier = 1; // define the direction of the motor to
CW/right side of the system
    enableMotor(); // move motor with a defined direction and speed until a
defined force or a limit position is reached

    // reset forces read
    force = 0;
    force2 = 0;
    force3 = 0;
    force4 = 0;
    break;

```

Figure E.7: The command '+' needs to receive a command on the serial monitor like '+f s', where f is the force limit in kg, and s is the speed at which the stepper motor will run in steps/second (not being able to reach values higher than the defined maximum speed). The positive direction of the motor is defined, and the enableMotor() function is called (Appendix E.9), moving the motor with a defined direction and speed until a defined force or a limit position is reached, or the command 'S' is sent to the serial port. At the end of this algorithm, the force reading variables are reset.

```

// -: Rotates the motor to a negative position (left side of the system)
(CCW)
// needs to be followed by the amount of force in kg, a space, and the
amount of speed of the motor - e.g. '-2 200'
case '-':
    receivedForce = Serial.parseFloat(); // value for the defined force in
kg
    receivedSpeed = Serial.parseFloat(); // value for the defined speed in
steps/second
    directionMultiplier = -1; // define the direction of the motor to
CCW/left side of the system
    enableMotor(); // move motor with a defined direction and speed until
a defined force or a limit position is reached

    // reset forces read
    force = 0;
    force2 = 0;
    force3 = 0;
    force4 = 0;
    break;

```

Figure E.8: The command '-' needs to receive a command on the serial monitor like '-f s', where f is the force limit in kg, and s is the speed at which the stepper motor will run in steps/second (not being able to reach values higher than the defined maximum speed). The negative direction of the motor is defined, and the enableMotor() function is called (Appendix E.9), moving the motor with a defined direction and speed until a defined force or a limit position is reached, or the command 'S' is sent to the serial port. At the end of this algorithm, the force reading variables are reset.

```

// ENABLE MOTOR
// move motor with a defined direction and speed until a defined force or a
// limit position is reached
void enableMotor()
{
    // set up simple moving average filter of length 5, initialised with a value of
    // force
    SMA<5, float, float> sma = {force};

    // avoid negative numbers indicating direction of force (not necessary)
    force = abs(force);

    // read force and move motor until the force read is equal or higher to the
    // defined force
    // force is the first force read which is equal to 0 after calibration
    while (force < receivedForce)
    {
        // second force read in kg
        rawForce = forcePin.parseFloat(); // read the load cell raw value
        force2 = (rawForce - offsetForce) * calForce; // scaling factor (calibration
        // factor and zero offset) obtaining the force in kg
        force2 = abs(force2); // avoid negative numbers indicating direction of force
        // (not necessary)

        // third force read in kg
        rawForce = forcePin.parseFloat(); // read the load cell raw value
        force3 = (rawForce - offsetForce) * calForce; // scaling factor (calibration
        // factor and zero offset) obtaining the force in kg
        force3 = abs(force3); // avoid negative numbers indicating direction of force
        // (not necessary)

        // filtering values
        spikeCut(); // cut random spikes from load cell values
        force = sma(force); // simple moving average of length 5

        Serial.println(String(force)); // print force value in kg

        // update revolution counter
        revolutionCount = revolutionCount + directionMultiplier;
        stepper.setCurrentPosition(revolutionCount);

        // run motor to the defined direction if it has not reached a limit position
        if (revolutionCount < limMax && revolutionCount > limMin)
        {
            // move motor to the desired direction with defined speed

            stepper1.setSpeed(receivedSpeed);
            stepper1.step(directionMultiplier * stepsPerRevolution);
        }

        // if limit position is reached, the motor stops
        else
        {
            stepper.stop(); // stop motor
            stepper.disableOutputs(); // disable motor power
            break;
        }

        // if the 'S' command is read, the motor stops
        if (Serial.read() == 'S')
        {
            stepper.stop(); // stop motor
            stepper.disableOutputs(); //disable motor power
            break;
        }
    }

    // once the force or limit position is reached or the 'S' command sent, the
    // motor stops and the counter is updated
    stepper.stop(); // stop motor
    stepper.disableOutputs(); // disable motor power
    stepper.setCurrentPosition(revolutionCount); // update revolution counter
}

```

Figure E.9: The enableMotor() function moves the stepper motor in the defined direction and speed (steps/second) until a desired force in kg, or a position limit is reached. If the 'S' command is sent to the serial port, the motor stops its movement and is sent to the home position. The reading of the force is obtained using Equation 6.3, and a total of three force values are considered for a mean spike cutting (Appendix E.10), followed by a simple moving average with a length of 5 values.

```

// SPIKE CUT
// cut random spikes from load cell values
void spikeCut()
{
    // if the rounded values of the third read are different than the first and
    // second read
    if ((round(force3)) != round(force)) && (round(force3)) != round(force2)))
    {
        // the force is updated to the second read if the first read is higher
        if ((round(force)) > round(force2))
        {
            force = force2;
        }
        // the force is updated to the first read if the second read is higher
        else if ((round(force)) < round(force2))
        {
            force = force;
        }
        // the force is updated to a mean of the first and second reads if they have
        // equal rounded values
        else
        {
            force = (force + force2) / 2;
        }
    }

    // if the rounded values of the second read are different than the first and
    // third read
    else if ((round(force2)) != round(force)) && (round(force2)) !=
    (round(force3)))
    {
        // the force is updated to the third read if the first read is higher
        if ((round(force)) > round(force3))
        {
            force = force3;
        }
        // the force is updated to the first read if the third read is higher
        else if ((round(force)) < round(force3))
        {
            force = force;
        }
        // the force is updated to a mean of the first and third reads if they have
        // equal rounded values
        else
        {
            force = (force + force3) / 2;
        }
    }

    // if the rounded values of the first read are different than the second and
    // third read
    else if ((round(force)) != round(force2)) && (round(force)) !=
    (round(force3)))
    {
        // the force is updated to the third read if the second read is higher
        if ((round(force2)) > round(force3))
        {
            force = force3;
        }
        // the force is updated to the second read if the third read is higher
        else if ((round(force2)) < round(force3))
        {
            force = force2;
        }
        // if the second and third read have equal rounded values, a fourth read is
        // taken into consideration
        else
        {
            // fourth force read in kg
            rawForce = forcePin.parseFloat(); // read the load cell raw value
            force4 = (rawForce - offsetForce) * calForce; // scaling factor
            (calibration factor and zero offset) obtaining the force in kg
            force4 = abs(force4); // avoid negative numbers indicating direction of
            force (not necessary)

            // the force is updated to the mean of the second and third read if the
            // fourth read is higher than the third (which is equal to the rounded second)
            if ((round(force4)) > round(force3))
            {
                force = (force3 + force2) / 2;
            }
            // the force is updated to the mean of the first and fourth read if the
            // third read is higher than the fourth
            else if ((round(force4)) < round(force3))
            {
                force = (force4 + force) / 2;
            }
            // the force is updated to a mean of the second, third and fourth reads if
            // they all have equal rounded values
            else
            {
                force = (force2 + force3 + force4) / 3;
            }
        }
    }

    // if the first three readings have equal rounded values, then the force is
    // updated to a mean of the three values
    else
    {
        force = (force + force2 + force3) / 3;
    }
}

```

Figure E.10: The mean spike cutting algorithm removes noise from the load cell's reading. It considers three force values, comparing their rounded values. If all three rounded values are different, the lowest value is considered as the force read; and if two or all three of the rounded values are equal, an average of the values is considered as the force read. However, if the second and third rounded values are equal, a fourth reading is taken into account to make sure those two values were not random spikes.

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