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BACHELOR'S THESIS

Design of a Knee Exoskeleton actuated with Artificial Muscles of SMA

Daniel García de las Heras

TUTOR
LUIS ENRIQUE MORENO LORENTE

DIRECTOR
DORIN COPACI

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ABSTRACT

This project presents the preliminary design of a powered exoskeleton for the knee joint, build upon the structural framework of DonJoy's X-*Act Rom Lite - Knee Brace.* The device allows exclusively one degree of freedom, intended for the flexion and extension of the lower limb.

The actuation mechanism is based on artificial muscles of Nitinol fibers, which are a type of Shape Memory Alloys (SMA). These wires contract 4% of its original length as the temperature rises due to the Joule Effect, when connected to a power supply. Thanks to this phenomenon, the proposed robotic orthosis presents portability, lightness and noiseless performance, in comparison to similar products.

The main role of these instruments is to conduct medical rehabilitation therapy for those patients who have suffered from neurological diseases, musculoskeletal lesions or spinal cord injuries. Consequently, the wearer might recover -partially or fully- the movement on the joint.

The results from several trials were obtained after mimicking real rehabilitation positions -like sitting, standing or lying down- and are analyzed thoroughly in this thesis. All in all, this prototype proves how the SMA actuators are a viable alternative to create lower extremity robotic devices for rehabilitation.

KEYWORDS

Knee
Lower limb
Shape Memory Alloys
Rehabilitation exoskeleton
Powered orthosis

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I cannot forget to mention Dr. Dorin Copaci, for all the time he spent in my project, teaching and helping me solve all the obstacles I found with the SMA actuators, calculations and the design of the exoskeleton.

Furthermore, I would like to praise my friends, who have been present during all or most of the realization and development of this thesis, and from whom I have learnt patience, devotion and commitment.

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1. INTRODUCTION

1.1. MOTIVATION

Current scientific developments in human-machine interaction technology, induced by society's persisting demand, are making possible the combination of robotics and medical devices to create a new generation of exoskeletons for rehabilitation. The necessity of an improvement in the actual rehabilitation techniques is driven by an aging population and the elevated cost of conventional therapies [1].

According to the World Health Organization, neurological injuries such as stroke, the brain equivalent of a heart attack, or spinal cord injury (SCI) are the leading cause of acute, lifelong disability. Annually, 15 million people worldwide suffer a stroke, from which 5 million are left long-term disabled, placing a burden on their family and community [2].

From this fatality, the American Heart Association's statistics show that the cost of stroke in 2004 was $53.6 billion dollars in the United States. Furthermore, the amount of money invested on medical care, rehabilitation and therapy was US$33 billion [3].

The sequels and significance of musculoskeletal lesions and neurological problems, lead to potential losses of autonomy and mobility of those patients who had suffered from them. It changes drastically their welfare. On the other hand, the most effective treatment for the victims of such diseases and disorders, is physical therapy and rehabilitation, resulting more fruitful when the exercises are repeated continuously for a long period of time, challenging the patient to achieve certain objectives.

Nevertheless, such remedy can be very costly since it requires a physician who supervises the treatment and manually helps the disabled perform the exercises. The main disadvantages of the current method are the number of hours it takes and the fact that each patient requires one doctor supervising everything.

Fortunately, actuated bioengineered exoskeletons can replace the existing, time-consuming rehabilitation exercises, releasing the therapist from their burden, and allowing them to assist multiple patients at once, while the device does the repetitive and physical movement.

In addition, not only will it reduce the related costs of the rehabilitation, but also the robot-mediated orthoses are able to quantify and measure the progress of each patient. This is achieved by the integration of sensors that can measure properties such as the angle of rotation of the device, the force that is being applied, etc. As a result, the physician can interpret the results so as to modify or customize the treatment accordingly. The effectiveness of this robotic exoskeletons has been proven to be very effective through many clinical trials [4].

An exoskeleton-type rehabilitation robot must be designed according to the human joint, coupling its movement to the body's so that the wearer can withstand the ergonomic motion. This is very important, especially in the lower limb orthoses, since they are the ones responsible for the recovery of as much mobility as possible, so the patient can regain their autonomy and independence.

Consequently, this bachelor thesis has the objective of designing a Knee Exoskeleton for passive rehabilitation, following all the previous work – hand ([5], [6]), shoulder ([7], [8]) and elbow ([9], [10]) exoskeletons – and technologies used by the researchers of the Robotics Lab, within the Department of Systems and Automation Engineering of the University Carlos III of Madrid.

1.2. OBJECTIVES

The primal novelty of the proposed device originates from the Shape Memory Alloys (SMA) that the researchers of the Robotics Lab have used to actuate their previous exoskeletons. The aim of this Bachelor Thesis is to take the innovative technology of the SMA fibers and implement it onto a passive knee orthosis for rehabilitation.

Since this is the first lower limb exoskeleton that the lab has designed, the idea was to build the project upon an existing orthosis that was used for rehabilitation purposes by physicians, in order to reduce the time spent on the design of the device and focus on the SMA actuators.

Figure 1.1 - Don Joy's Knee Brace

This way, all of the considerations that resulted from this work could be taken into account for future knee devices. The model of the orthosis was the *X-Act Rom Lite (Knee Brace) - DonJoy*. (Figure 1.1) [11].

Thus, the purpose was to build a knee exoskeleton actuated by SMA fibers, taking DonJoy's Knee Brace as a starting point. It was necessary to design all of the components to allow the flexion and extension of the knee induced by the contraction of the SMA fibers.

The phases of the project were divided as follows:

- Study the Knee Brace to decide the optimal site to pull from in order to generate the movement.
- Calculate with a Matlab Software the length and quantity of SMA fibers needed to flex the knee.
- Design and manufacture all of the pieces essential to attach the actuators to the fishing line or nylon.
- At the same time, adapt a sensor to measure the degree of rotation of the knee.
- Integrate the control electronic components to test the device.
- Perform functional trials of the displacement achieved with a real subject.

1.3. STRUCTURE OF THE DOCUMENT

The structure of the present thesis is the following:

- **CHAPTER 1. INTRODUCTION**:

  In this section, the main aspects of the project are presented, as well as a brief description of the socio-economic situation, which served as motivation. The objectives and main tasks are also described as well as a brief summary of the organization of the document

- **CHAPTER 2. THEORETICAL FRAMEWORK AND STATE OF THE ART**:

  The main aspects of the knee's anatomy are described in this section, as well as the neurological lesions and musculoskeletal injuries that require the rehabilitation of this joint. A review on current lower limb rehabilitation exoskeletons is also included. Lastly, Shape Memory Alloys are introduced as a new alternative for conventional actuators.

- **CHAPTER 3. DESIGN**:

  This chapter explains the structural framework build upon DonJoy's brace and the calculations for the actuator mechanism – like the torque needed or number of SMA wires. It includes a description of the hardware and software used, electrical connections, justification for the sensor selected and explanations of the control system.

- **CHAPTER 4. RESULTS**:

  The main trials performed in order to analyze the exoskeleton's response to a given reference when the wearer was in different positions, are presented in this section. Moreover, it includes the plots obtained at each of the medical rehabilitation trials, specifying the angle, number of cycles and time.

- **CHAPTER 5. DISCUSSION**:

  This chapter includes the evaluation of the results presented in the previous section, to verify if the exoskeleton would be suitable for knee rehabilitation or not.

- **CHAPTER 6. SOCIO-ECONOMIC IMPACT**:

  Research advances in the field of lower limb exoskeletons, have lead and to an important social and economic impact, which is explained in this section. Besides, it includes a budget estimation for the cost of this prototype, in comparison to the average price other commercialized powered orthoses.

- **CHAPTER 7. REGULATORY FRAMEWORK**:

  The seventh chapter intends to give a brief description of current legislation applicable to medical and sanitary devices, including powered exoskeletons. It includes the definition given by the World Health Organization to such instruments, as well as the different rules set by the European Union and the Food & Drug Administration (FDA).

- **CHAPTER 8. CONCLUSION**:

  Finally, this chapter presents a final evaluation of the project, including opinions on the device, the SMA actuator system and its performance. Once the review of the knee exoskeleton has been done, future work would be suggested, with the purpose of improving the negative aspects than have been discovered during the course of this Bachelor Thesis.

2. THEORETICAL FRAMEWORK AND STATE OF THE ART

The purpose of this chapter is to put the reader in context so as to facilitate the understanding of the project's aim. The ideas on this section are presented in such a way that is easier to narrow a broad topic, as the knee's anatomy and lesions. Thus, focusing on the current robotic technics for rehabilitation, and present a new alternative.

2.1. ANATOMY OF THE KNEE

The knee is the largest, most complex joint in the human body. On a healthy individual, this articulation is involved in actions like walking, running, etc. This is possible because it is comprised of three joints in one, which allow flexion, extension and a little rotation [12].

In order to fully understand the problems of the knee, study how it should be rehabilitated and design the most comfortable, wearable, patient-adjustable brace; the anatomy of the above-mentioned articulation will be briefly explained in this section. The anatomical body planes are depicted in Figure 2.1 [13].

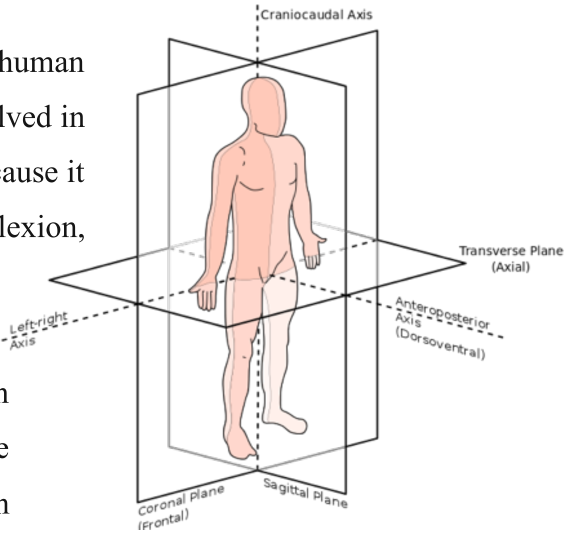

Figure 2.1 - Anatomical Body Planes

2.1.1. BONES

The lower limb's osseous structure can be sectioned in three parts. The thigh or upper limb, contains only one bone, the femur. It is the heaviest and strongest bone in the human body. It is attached to the pelvis, precisely, the ball-like head of the femur articulates with the hip bone. Notice that anatomically, the term leg refers to the portion between the knee and ankle.

An important quality of the femur is that it angles medially as it runs towards the feet; positioning the body's center of gravity in line with the knees. This characteristic is more noticeable in women due to their wider pelvises.

On the distal end of the femur, the patella or kneecap is found. It is a relatively small, triangle-shaped sesamoid bone. It is enclosed in the quadriceps tendon which connects the anterior thigh muscles to the tibia. See Figure 2.2 [14].

Figure 2.2 - Bones of the Leg

Lastly, two additional bones form the skeleton of the leg. The tibia, or shinbone, the larger on the leg, is oriented medially and bears the weight of the whole body. Parallel from it lies the fibula, thinner and shorter in size, however it takes no part is assembling the knee joint [12].

2.1.2. MUSCLES

The musculature found on the lower limbs is responsible for causing the movement at the hip, knee and even the ankle joints. Unlike in other joints of the human body such as the shoulder, less number of muscles are required to hold and stabilize the leg's bony structure. This is because the bones mentioned above, create a heavy and fused structure that allows very little movement on the pelvis.

The collection of muscles localized below the hip are responsible for the movement at multiaxial hip joint, the leg, ankle joints, feet and toes. However, for the purpose of this project, only the ones acting directly on the knee will be studied.

On the posterior aspect of the thigh lie the hamstrings. They are a set of fleshy muscles that together become strong extensors of the thigh. Moreover, they act as the antagonist of the quadriceps, by providing stability to the knee joint when standing, see Figure 2.3 [15]. On the other hand, the quadriceps forms the flesh of the anterior thigh, having a common insertion in the tibia, whose function is the extension of the leg [12].

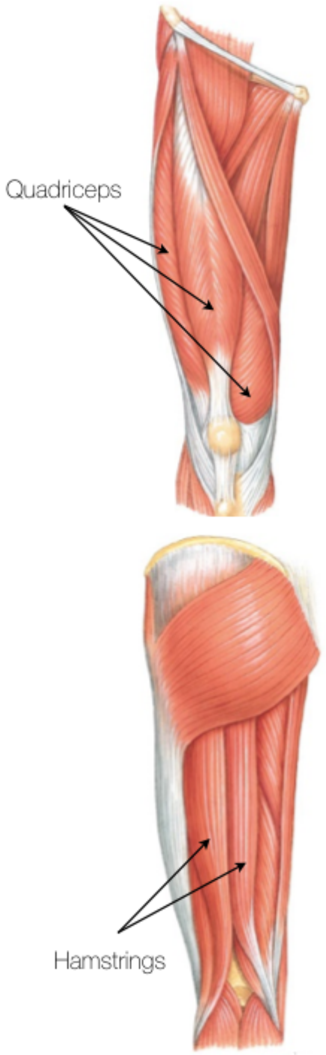

Figure 2.3 - Muscles of the Lower Limb

2.1.3. THE JOINT: MENISCI AND LIGAMENTS

The knee is a synovial joint, an articulation with an inner cavity filled with a viscous substance that provides lubrication, reducing the friction during the movement. It is called the synovial fluid.

This lower-limb articulation is constituted by the union of three bones: the distal end of the femur, the patella and the tibia's proximal end. The contact surface between the bony structures is protected by a cartilaginous tissue, to avoid structural damage.

Two semilunar cartilages are found on the head of the tibia, the lateral and medial menisci. They are a cartilaginous structure found in the articular cavity of the joint, playing an important role during the displacement between the femur and the tibia. Their elasticity provides cushioning to distribute the weight of the whole body during flexion and extension [16].

The knee's uniqueness lies on the lack of enclosure of its articular capsule, see Figure 2.4 [12]. Being covered anteriorly by three broad ligaments: the patellar ligament, and the lateral and medial patellar retinacula. Their aim is to prevent the lateral movement of the knee. Intracapsularly, the anterior and posterior cruciate ligaments are found. They restrain anterior-posterior displacement, as well as the joint's overflexion and hyperextension.

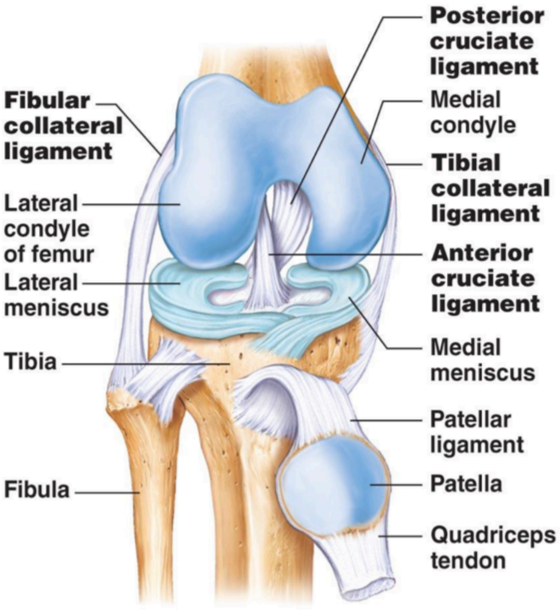

Figure 2.4 - Anterior view of Flexed Knee

2.1.4. BIOMECHANICS OF THE KNEE

Once all of the elements that consolidate the most complex joint in the human body have been reviewed; its biomechanics can be studied, in order to mimic its movements with the knee exoskeleton.

Firstly, this articulation presents 6 degrees of freedom (DoF), as pictured in Figure 2.5 [15]. Nevertheless, several biomedical studies have concluded that the bony structures, as well as the ligaments and menisci above-mentioned, constrain most of its degrees of freedom [1]. As a consequence, the motions restricted on those directions will be neglected for the purpose of the current study.

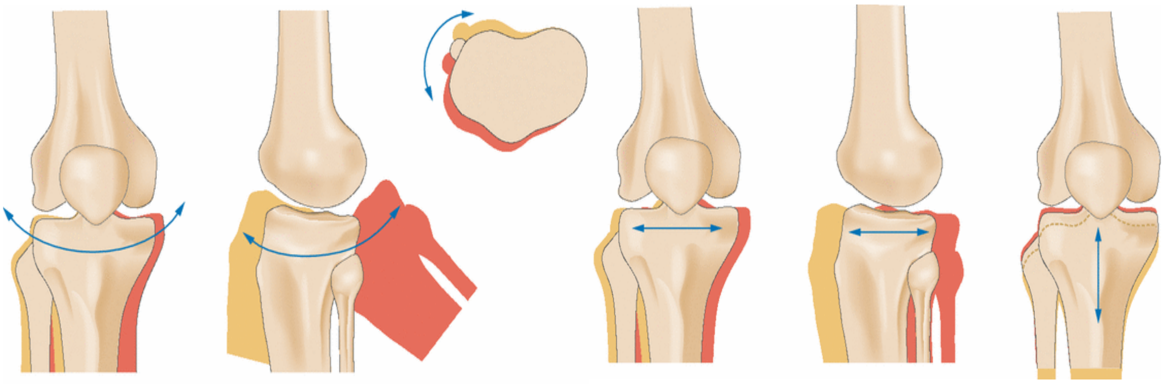

Figure 2.5 – The six Degrees of Freedom of the Knee

The main degree of freedom that the knee has, is responsible for its flexion and extension, the second picture in Figure 2.5. It regulates the distance between the body’s core and the ground by bringing closer the ankle and the gluteus. In addition to this motion, the knee also presents an ancillary DoF, which exists only during the flexion of the leg. It is the rotational motion along the longitudinal axis of the knee.

From a biomechanical point of view, the lower-limb’s joint displays surprising characteristics since it has two contradictory functions. When it is fully extended, it bears the weight of the whole body, showing great stability. On the other hand, when flexed it should provide a wide range of movement to the foot and ankle, to carry out actions such as walking or running.

Extension is defined as the movement where the posterior side of the thigh is separated from the leg. Once the femur and tibia are aligned forming a 0º angle, it is called the reference position; showing great stability. From this point on, the knee is able to achieve passively five to ten degrees of further extension, called hyperextension.

On the contrary, flexion is the action opposite to the extension, where the heel and the gluteus are brought together. If the hip is flexed, the knee is able to actively bend, reaching 140º. However, if the hip is extended, it reaches only 120º. It is important to remark that when humans kneel, the force of gravity acts upon the weight of the upper body, pushing it downwards and allowing the contact between the heels and gluteus. At this posture, the knee reaches passively 160º degrees [16].

Lastly, the rotation can be noticed when the subject's knee is at a 90-degree angle, sitting on a chair or the edge of a table. Nonetheless, this rotary ability will be neglected on this thesis since the DonJoy's Knee Brace that was used, constrains this movement, allowing only flexion and extension.

As a result, from this section it can be concluded that the knee is one of the most complex and important joints on the human body and is essential to perform activities of the daily life like sitting, walking or even standing.

This anatomical review was useful to understand the role of every bony structure, muscle, menisci, tendon and ligament involved in the flexion and extension of the joint. This knowledge was implemented onto the design of the orthosis: replacing the hamstrings by the artificial actuators of SMA to flex the knee and using the already existing brace as the bony structure from where these muscles pull from to generate the movement.

Furthermore, as most of the other existing lower-limb exoskeletons [17], the kinematic performance was reduced to only one degree of freedom, to focus mainly on the flexing and extending biomechanics.

2.2. LESIONS AND MEDICAL REHABILITATION

Activities of daily living (ADL), also called personal activities of daily living (PADL), are defined as all of those, relatively easy, tasks that require simple abilities and attention to take care of one's own body [18].

They include self-caring actions like bathing, showering, toilet hygiene, eating, walking, standing, functional mobility, etc. Most of these exercises require a fully functional nervous system, able to transfer the signals from the cerebral cortex to the extremities associated with each ADL, and vice versa.

When a person suffers from a neurological lesion, it results in a degradation of the synaptic connections between the neurons that transfer the signal from the central nervous system to the efferent nerve fibers, see Figure 2.6 [19]. The losses in the neural network act as a broken wire and the signal is lost along the nerve, leading to an ultimate reduction of the motor output.

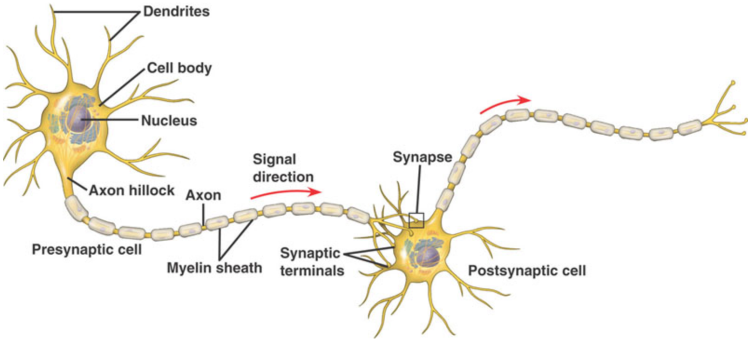

Figure 2.6 - Synaptic connections in the Nervous System

At this time, the most common neurological diseases worldwide are Spinal Cord Injuries (SCI), degenerative illnesses of the nervous system like Multiple Sclerosis and the aftermaths of Stroke; leading to serious conditions which impede the mobility of the patient [20].

Moreover, impaired mobility can also be caused indirectly by other secondary health complications that include: autonomic disreflexia in SCI, elevated high blood pressure and bowel disorders like Crohn's disease or intestinal obstruction. Nevertheless, most of these diseases are associated to elderly people [21].

2.2.1. STROKE

Stroke, also known as the brain equivalent of heart attack, is an illness that occurs when the brain's blood supply is blocked somehow, and the cerebral tissues are left without oxygen for a period of time – called Ischemic Stroke (Figure 2.7) [22]. In addition, a similar situation can happen when the blood vessels have a fissure so the blood leaks out, defined as Hemorrhagic Stroke. The absence of oxygen and nutrients for an extended period of time can lead to the death of brain cells [23].

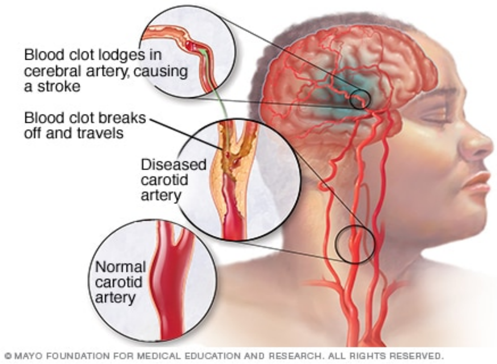

Figure 2.7 - Ischemic Stroke

As a consequence, symptoms appear on the different body parts that were controlled by the damaged neural tissue. In other words, depending on the areas of the central nervous system affected by the absence of blood supply, a variety of symptoms can manifest.

They include: loss of equilibrium and coordination, weakness or numbness on the upper and lower limbs, headaches, walking deficiency, vision and speech problems, etc. [23] Furthermore, the neurological impairment that follows the stroke may induce partial paralysis on one side of the body, affecting the subject's ability to carry out ADL activities [24].

This particular disease, presents high chances of affecting the elderly, causing disability. With an increasingly aging population, this illness is becoming very frequent [25]. Nowadays, it is the third most common cause of death in developed countries, surpassed only by cancer and coronary heart problems.

Globally, 2.5 million men and 3 million women die from this disease every year [26]-[27]. More specifically, based on the report "The Burden of Stroke in Europe" conducted by the College of London, in Spain there is an incidence of 40,214 strokes per year, with a mortality of 34.5 deaths per 100,000 inhabitants annually. The consequences of this condition generate a total cost for the Healthcare System of €1,244.8 million [27].

2.2.2. SPINAL CORD INJURY (SCI)

The Spinal Cord is a collection of nerves that lie within the vertebral column from the head to the hip, whose function is to conduct the sensory information collected by the extremities to the central nervous systems, as well as sending back the orders elaborated from the information collected to induce a motor response.

When these nerves are damaged from a contusion, incisive cut or compulsion; it is known as Spinal Cord Injury. The result of this illness is an interruption on the functions performed by these nerves at a distal level of the injury. In other words, no sensory information or motor commands are able to go through the damaged section. This is defined as a complete injury. However, if the harm is incomplete, it can exist a partial preservation of the sensory and motor functions on the lower extremities.

Depending on the vertebrae's height at which the cut is made, two types of disabilities can be produced, see Figure 2.8 [28]. Tetraplegia is known as a complete impairment or loss of function in the arms, legs, trunk, pelvic organs. The damage on the cervical vertebrae leads to disability on the four extremities. Paraplegia, is very similar, but in this case the section is done at the lumbar or sacral level, bellow the arms. Therefore, the upper limbs are spared [29].

The most frequent causes of Spinal Cord Injury worldwide are traffic accidents, gunshot wounds, sport injuries, falls and any impair from a cutting weapon. Moreover, it has been reported that the most common sport-related cause is diving.

This misfortune affects 40 million people internationally, being the vast majority young men on their twenties and thirties. Only 1% of this group are children, boys mostly, where traffic accidents are the most common cause [30]. In Spain, the number of patients with spinal cord trauma has increased from 8 cases per million population in the 80's, to 23 cases per million between 2000 and 2009. It has been estimated that currently 38,000 individuals suffer from SCI in Spain [31]. The treatment procedure for these neural lesions is very expensive, long lasting and exhausting. This results in psychosocial, biophysical and economic problems.

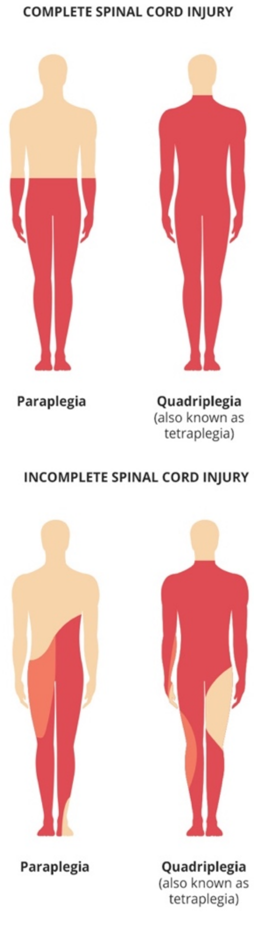

Figure 2.8 - Paraplegia and Tetraplegia

2.2.3. MUSCULOSKELETAL LESIONS

In addition to all the diseases related to the nervous system mentioned above, there are also a number of musculoskeletal injuries that require rehabilitation as medical treatment post-surgery.

- **MENISCAL INJURIES**:

  Meniscal injuries are tears, breakages, or displacements on the menisci that alter the mobility of the knee. They are more common in men than in women, although they also tend to affect young people in full physical activity, more than adults with moderate physical lifestyle. They can be caused by physical overload, deviation of the knee axes or overuse.

- **LIGAMENT INJURIES**:

  The sprain is a tear of the ligaments that stabilize the knee. It usually occurs in dynamic situations with risk of torsion. This is often the case when playing sports. About 70% of sportive injuries affect the ligaments and tendons, as represented in Figure 2.9 [12].

  In addition, the anterior and posterior cruciate ligament are usually injured during athletic activities by a twist of the body with the foot firmly on the ground, typical of skiers and footballers.

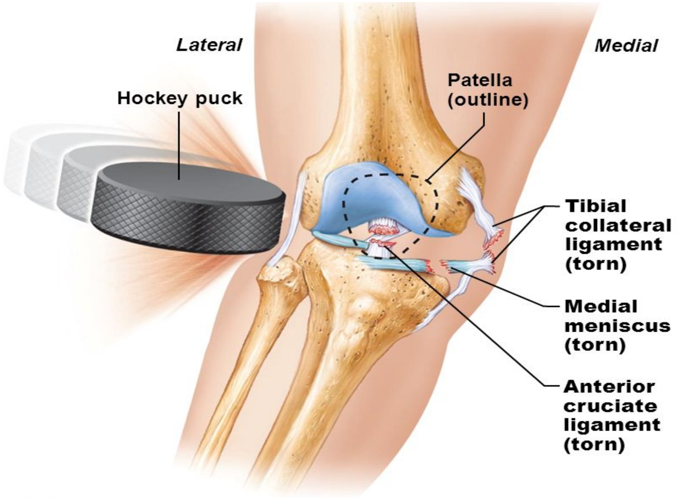

Figure 2.9 - Common sportive knee injury

- **ARTHRITIS AND ARTHROSIS**:

“Arthritis” means stiffness and inflammation of the knee joint, characterized by the destruction of cartilage tissue and can have countless causes. There are several types, however, arthrosis – or osteoarthritis – is the most common joint disease that increases with age. It is a degeneration or wear of the articular cartilage and bone, with inflammation of the capsule and the synovial membrane that surrounds it (Figure 2.10) [32].

It is the most frequent chronic bone disease in European countries. In Spain, it is estimated that it can affect 16% of the population from the age of 20 onwards and from 45 onwards, this percentage increases up to 30%. For the elderly, the risk is between 85-90%.

Although there is currently no treatment to eliminate them, a rehabilitation exercise plan is essential to improve the loss of mobility and muscle strength in the knee.

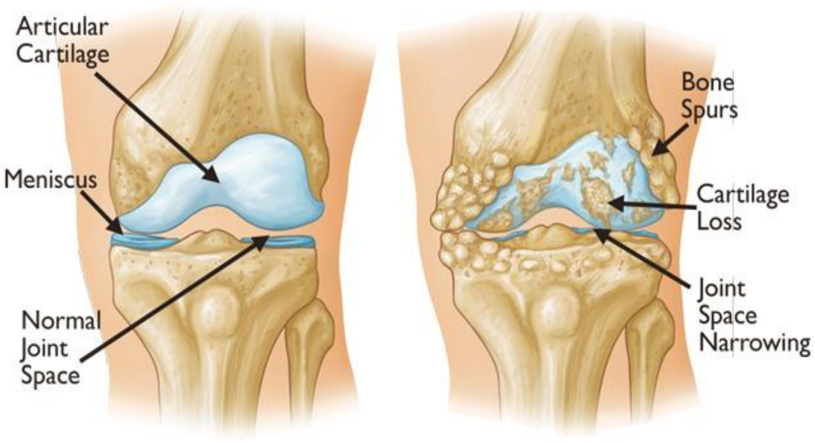

Figure 2.10 - Osteoarthritis of the Knee

2.2.4. MEDICAL REHABILITATION

Fortunately, after several medical studies, it has been demonstrated that physical therapy involving the exercise of lower limbs strengthens the muscular tissue and enhances the coordination in disabled individuals [33]. These activities help recover the lost functions, improving motor recovery and minimizing functional deficits [24], with the final goal of becoming sufficiently autonomous to carry out ADL.

In addition, further objectives of rehabilitation therapy include the performance of several repetitive movements on the affected limbs, so the skeletal muscle contractions induce the pumping of blood in the veins, that carry deoxygenated blood supply towards the heart to be oxygenated again. This will prevent clot formation and further cardiovascular diseases.

The work presented by Alex Pollock et al. concerning therapies after stroke, it mentions: "The best evidence to date is that any form of physiotherapy at a high enough dose is more likely to reduce impairment and disability than no rehabilitation intervention" (Pollock et al, 2008) [34].

However, rehabilitation programs require a generous amount of manual assistance (Figure 2.11) [35], increasing the cost of the practice. Fortunately, the integration of robotic devices on this medical field is freeing progressively therapists from their intensive labor [20].

Additionally, robotic assistive devices present even more advantages since they provide better accuracy and fidelity, leading to new alternate solutions to the rehabilitative strategies that presently exist. In addition, they provide the physician with live kinematic and kinetic information of the patient's progression. This useful characteristic allows the exercises to be gradually adapted to the patient's progress, reducing the performance of the device as the patient improves.

Figure 2.11 - Conventional Knee Rehabilitation Therapy

Lastly, the substitution of the conventional rehabilitative therapies by actuated bioengineered exoskeletons, presents numerous advantages in the socio-economic framework. As mentioned above, the efficiency of the process can be increased by reducing the amount of time a physical therapist is needed guiding each post-injury or surgery treatment.

The exercises can be reproduced more easily in several patients with neurological lesions than with the previous manual process. Thus, patients would, more likely, be able to gain higher levels of mobility on the affected limbs. These advantages would mean a significant reduction on the cost for the healthcare system, per patient [36].

2.3. STATE OF THE ART: LOWER EXTREMITY WEARABLE ROBOTICS

On account of the current breakthroughs in the field of mechanical robots, an interest to combine this technology with the conventional rehabilitation therapies has been developed. The result of such significant innovation is a new generation of active orthoses and exoskeletons intended for rehabilitation. However, before diving into this topic, there are some important definitions that need to be reviewed ahead of time.

Wearable robots are those bionics designed to be worn by humans, to enhance or supplement the function of a particular limb of the body or to directly substitute it. It is important to remark that wearability does not imply portability or autonomy.

Exoskeletons are a type of wearable robots. Besides offering support and protection as an "external skeleton", they have a kinematic composition which resembles the human limb's anatomy. The joints of the robot are adapted onto the anatomical joints, to mimic its movement. This compliance is the key aspect to achieve an ergonomic device.

Figure 2.12 - Orthosis (blue) vs Prosthesis (green)

Furthermore, an orthosis is an artificial device, external to the human body, that maps on to the anatomy of the limb, with the purpose of modifying structural or functional aspects of the neuro-skeletal system. The robotic equivalent to orthoses are the actuated exoskeletons, aimed for rehabilitation. Moreover, the main difference between prostheses and orthoses – as shown in AA- is that the first ones are intended as substitutes of limbs after amputation [37].

In the last decades, a lot of effort has been put into the enhancement of the integration between the above-mentioned devices and the human body. Several patient-oriented exoskeletons have been designed with the robotic structure laying parallel to the subjects' limbs and an anthropomorphic structure.

Existent lower-limb exoskeletons and active orthoses present a wide range of possible applications within the field of medical rehabilitation. Among which the most important are those whose purpose is helping the patient perform repetitive exercises, guiding the movement and trajectory, while measuring the progress; others provide physical support so disabled people can perform activities of daily living (ADL). Lastly, a small group of them is designed to facilitate intensive labors by reducing the cargo endured by the operator.

All of these examples can be classified into three broad categories: assistive, rehabilitative and empowering devices [38]. Nonetheless, the last category will be discarded for the purpose of this thesis and it will focus only on those intended for medical rehabilitation.

Assistive robotics are the group of exoskeletons implemented to have sufficient flexibility to performed all of the of muscle displacements required by the ADL, like walking (Figure 2.13) [39], standing, etc. They are designed for elderly people, since is the segment of society with the most physical weakness on their bones and muscles. Nevertheless, this type of wearable robots is not intended for rehabilitation, thus only the rehabilitation exoskeletons will be studies, since is the category where our knee exoskeleton lies within.

Figure 2.13 - Cyberdyne Assistive Exoskeleton for walking

2.3.1. CLASSIFICATION OF LOWER- LIMB REHABILITATION EXOSKELETONS

The objective of rehabilitative robotics is to restore the mobility and task performance that the patient had on the leg before the neurological lesion. With this innovative technology, the issue with repeatability on conventional therapy methods is resolved, as well as the real-time monitoring of the subject’s progress. The efficiency of these robots is proven on their ability to generate accurate and reproductive paths, reducing the physician’s effort and the time spent on each training session.

The current trend is to build orthotics rehabilitation exoskeletons able to recognize and comprehend human joint's motor skills in order to provide feedback for the control of the device. This is achieved by the integration of sensors on the apparatus, to measure the velocity, displacement, rotation angle, forces, trajectories, etc. As a result, the final robotic device is able to assist patients with neurological lesions on their rehabilitation journey [38]. Three broad categories exist:

- **FULL LOWER LIMB MOBILE DEVICES**:

  Full mobile devices stablish a unique group, since it was created to solve many of the disadvantages of stationary devices, which will be explained later. This category presents a key characteristic: they allow the patients to walk while the robot matches the pattern of motion, this way it adapts to the patient. In addition, their supportive framework usually has wheels (Figure 2.14) [24]. This category includes the WALKTRAINER [40], a 6 DoF orthosis with force and angle sensors to monitor every movement; and the NATURE-GAITS (Natural and Tunable rehabilitation gait [41]) assembled by the Singaporean Nanyang Technological University in 2006.

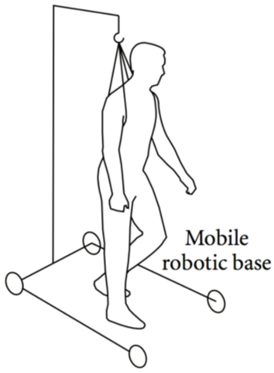

Figure 2.14 - Overground Mobile Device

- **STATIONARY DEVICES**:

  They are characterized by having an external device that supports the whole weight of the subject's body. This helps transferring the load of the patient to the mechanical framework, thus liberating the limbs, facilitating the movement and exercises. In addition, the external body weight support ensures safety and stability.

  In the Cable Body Weight Support (cBWS) Figure 2.15 [24], the patient is hanging from a harness, whereas in the Structural Body Weight Support (sBWS), the patient's back or waist is attached to a robotic arm. In both cases, additional segments are placed on the limbs to induce the motion [38].

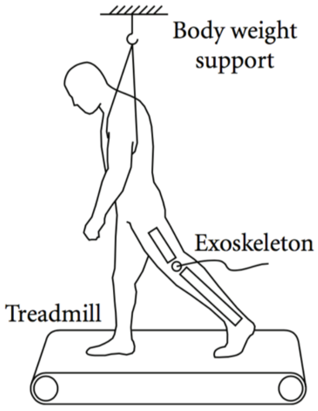

Figure 2.15 - Cable Body Weight Support Device

The most commercialized stationary robot is LOKOMAT (Hocoma, Switzerland) [42], a cBWS treadmill system where the movement is induced at the knees and the hips (Figure 2.16) [43]. Another commercial wearable robot is the Auto- AMBULATOR, also known as REOAMBULATOR, from HealthSouth, United States. It has some similarities with the Lokomat since it is also cBWS. Nevertheless, it differs on the support framework, with a simpler design, reducing the overall size and weight.

Figure 2.16 - Lokomat®

In 2001, a research group from the University of Twente designed the LOPES, Lower Extremity Powered Exoskeleton [42], a 8 DoF robotic device aimed for leg rehabilitation. Lastly, ALEX, Active Leg Exoskeleton [17], was fabricated at the University of Delaware. It is a cBWS, which controls the knee's extension and flexion, as well as the hip's. Further versions of this model have been created, with a unilateral brace to fit both right and left legs.

- **PARTIAL MOBILE DEVICES**:

This category can be considered the borderline between assistive and rehabilitative devices, since they include the AFOs (Ankle and Foot Orthosis), which can be worn during the day, not only for therapy. Nevertheless, the knee exoskeleton that is designed and developed for this thesis, could be classified in this section due to its portability, see Figure 2.17 [24].

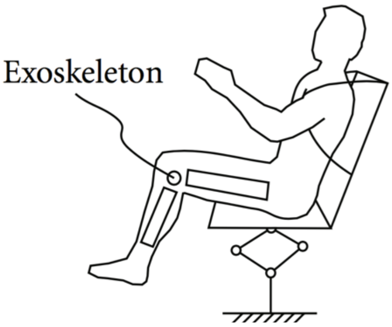

Figure 2.17 - Partial Mobile Devices

Other commercialized orthoses that belong to this group are the KAFO (Knee-Ankle-Foot-Orthosis), produced by the University of Michigan, USA [44]. This device is actuated by six pneumatic muscles which flex and extend both, knees and ankles. Similarly, the KNEXO with pleated pneumatic artificial muscles was manufactured by the University of Brussels, to ensure a compliant physical human-robot interaction during therapeutic exercises [45]. Finally, the TIBION PK100, also called POWERKNEE (Figure 2.18) [46], was designed by Tibion Bionic Technologies, but it was purchased by AlterG in 2013. It is made out of carbon fibers, reducing the overall weight of the device and increasing its portability. Its purpose is mainly to support patients with lack of mobility on their rehabilitation sessions [47].

Figure 2.18 - PowerKnee®

To conclude this subchapter, even though a lot of progress has been done in the field of wearable robotics, there is still a long way to go. The purpose is to build the lightest, most efficient exoskeleton, which best fits the patient's metabolic requirements. This will be accomplished when the energetic issue is addressed.

Existing devices require a strong energy source to provide enough power to the actuators to move the limb. Further research is needed to find alternatives solution to the conventional motors and actuators to build artificial muscles. Such innovation will lead to lightest and more portable orthosis.

2.4. SHAPE MEMORY ALLOYS

The actuation on all of the wearable rehabilitation devices explained in the previous section, is induced by traditional engines: hydraulic, pneumatic and electric. Actuators are defined as the elements on the exoskeleton that generate a sufficient torque to create the movement on the joint, thus supporting the weight of the corresponding human limb.

They are regulated by electric controllers, which generate the desired the displacement, angle or trajectory [48]. In Table 2.1 [5], a brief comparison between the most commercialized actuators (electric, hydraulic and pneumatic) in the wearable robotics industry is displayed.

TABLE 2.1 - COMPARISON OF CONVENTIONAL ACTUATORS

CHARACTERISTICS	ELECTRIC	HYDRAULIC	PNEUMATIC
POWER	Medium-Low Electrical Current	Very High Oil Pressure	Medium Air Pressure
SIZE AND WEIGHT	Large selection	Power-size ratio	Smaller than Hydraulic
SECURITY	Susceptible to overweight	Reaches high temperatures	Safer than Electric and Pneumatic
LIFE EXPECTANCY	Medium	Long with the help of lubricant	Low
COST	Medium	High	Low

In the last few years, the Robotics Lab from the University Carlos III of Madrid has taken advantage of a new technology to design new actuators for rehabilitation exoskeletons. This breakthrough is called Shape Memory Alloys (SMA). They are a variety of metal alloys which are able to recover its original shape after they have been exposed to a heat source. These metals are able to deform their intermolecular configuration when heated; causing the material to shrink in size.

This phenomenon it is called the Shape Memory Effect. It is caused by the phase transition that the material goes through, between two crystal structures. At high temperature, the material is at AUSTENITE and at lower temperatures, MARTENSITE. This inherent phase transformation is the key for the uniqueness of these alloys.

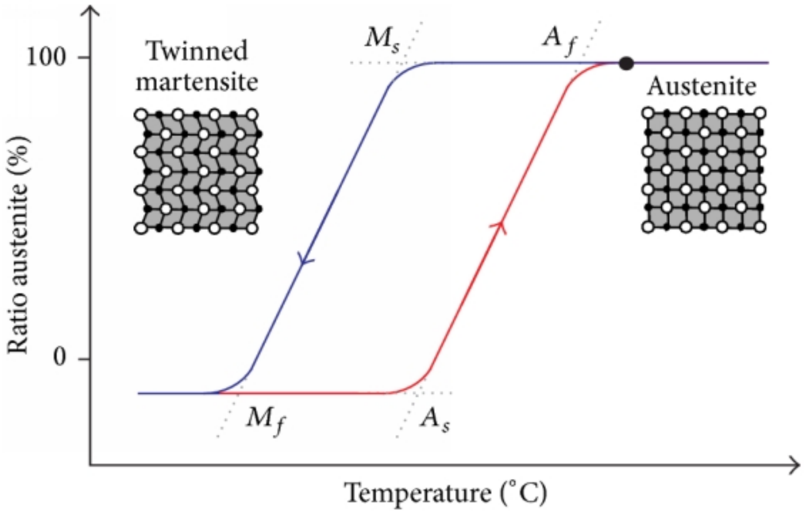

Figure 2.19 - Shape Memory Effect on the martensitic phase transformation

During the martensitic phase, the crystalline structure is under low temperature, thus it presents cubic 3D shape. At this particular moment, the alloy can be molded easily. As the temperature rise (Figure 2.19), surpassing the transition temperature, the austenitic phase is reached. During this interval the material shrinks in size because it goes back to its original load-free state. The temperature at which this occurs varies depending on the metals used for the alloy and its composition. However, it is usually between 70ºC and 130ºC [49].

Besides the Shape Memory Effect, they also present other features such as super-elasticity and high damping capability. The super-elastic behavior is present when the SMA is deformed at a temperature higher than its transformation temperature. The cause of this effect is the formation of Martensitic regions above its normal temperature as a response to an applied stress. As soon as the stress is removed, the Martensite turns back to non-distorted austenite, providing the alloy with a springy elasticity [50].

The most common type of Shape Memory Alloy is the Nitinol, a combination of Nickel and Titanium (Figure 2.20) [51]. Due to its high bio-compatibility and low cost, it has been used in numerous biomedical products like coronary stents, dental implants, orthodontic wires, etc [9].

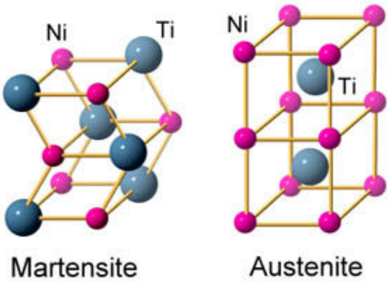

Figure 2.20 - Nitinol's Atomic Structure

The Robotics Lab has developed a way to implement Nitinol onto rehabilitating exoskeletons. Benefiting from the shape memory effect of Nitinol wires, it is able to hook them on the orthosis so when they contract, they actuate the device, inducing its movement. As a consequence, conventional actuators can be replaced, reducing drastically the weight, cost and noise of the device.

Figure 2.21 - Flexinol® Actuator Wire

When these wires, which have a very small diameter (Figure 2.21) [52], are stimulated by an electrical current, its temperature rises beyond room temperature. Consequently, its length is reduced between 3% and 5%. As an example, 100 centimeters of wire will shrink 4cm. The Shape Memory Effect is the reason why it returns to its original length as it cools down.

The heat is applied to the system via an electric current originated from a DC power source and a controller. These apparatuses provide the energy required for the actuator. All of this is possible thanks to the Joule Effect, described as "the process where the energy of an electric current is converted into heat as it flows through a resistance" [53]. This is a consequence of the numerous collisions between the current's electrons and the material's atoms that lead to resistive losses in the metal alloy.

These artificial muscles of SMA present several advantages: excellent torque-weight ratio, low cost, flexibility, adaptable to the anatomical conformation of the exoskeleton, smooth motion, noiseless, with a simple control hardware. On the other hand, some disadvantages are: low actuation frequency, non-linear behavior, and energetically inefficient [8].

As an example of this relatively new technology, the researchers of the Robotics Lab have created an elbow exoskeleton actuated with the SMA fibers. In addition, hand orthoses [6], shoulder [8] and soft hand exoskeletons [54] were developed, or in progress, to study the possibilities of the alloy in the field of medical rehabilitation.

3. DESIGN

In this chapter, the design of a knee exoskeleton actuated with Shape Memory Alloy fibers is presented. It includes explanations for the material selection, advantages, as well as calculations for the structure of the Nitinol actuators and power needed. In addition, it describes of the final assemblage of the device, with a detailed report of the hardware and software necessary.

3.1. MATERIALS

One of the main objectives of the project was to select a combination of biomaterials, machinery and electronic components that allowed the fabrication of a light, portable, noiseless, low-cost knee orthosis. Thus, it would benefit the patient's rehabilitation journey, making it more comfortable and affordable. The equipment used is explained bellow

3.1.1. DONJOY'S KNEE BRACE

The Robotics Lab's researchers of the University Carlos III of Madrid, have been implementing the SMA technology onto rehabilitation exoskeletons for a few years now. As it was introduced at the end of section 2.4. Shape Memory Alloys, they have built and tested several orthoses for the elbow, shoulder and hand. However, the department has not actuated the knee with Nitinol fibers yet.

As a result, the purpose of this thesis was to build a lower-limb wearable structure to prove whether or not these alloys are able to move the thigh and induce the knee's flexion and extension.

It was decided to use an already commercialized passive orthosis as a starting point. This was done in order to transfer all the knowledge obtained from the structure, calculations, actuators and conclusions of this project to future designs for this joint. Thus, it would reduce the costs from designing and manufacturing the main supportive framework, as well as the time it requires.

The model of the orthosis selected was the *X-Act Rom Lite (Knee Brace)* from DonJoy Orthopedic, Vista, CA. DJO Global is a company centered on producing a wide range of medical and orthopedic devices for rehabilitation, physical therapy and pain management [11].

Figure 3.1 - Features of X-Act ROM Lite

This brace provides protection and a supportive framework for patients who undergo knee surgery. It presents a sleek and smooth aluminum structure with an anatomical design to contour perfectly the patient's leg. Besides, it presents the following characteristics, also depicted in Figure 3.1 [11]:

- The orthosis is attached to the limb thanks to an easy to use Velcro strapping system in four different parts, which prevents the migration of the device.
- A durable rounded aluminum Hinge at knee height, offers a wide range of motion: flexion between -10º and 120º, and extension from -10º to 90º. Besides, this interval can be narrowed to reduce the amplitude of movement.
- Its comfort comes from the circumferential foams placed at each of the four strapping belts, to also minimize the migration.
- Lastly, with a simple push button, the length of the device can be adjusted to any leg. This telescoping adjustability of the uprights varies between 46 to 65 cm.

All of these advantages, including its light design (less than 1kg), its adaptability to any subject and range of motion; converted DonJoy's brace on the best supportive framework for this thesis.

3.1.2. METAL FLAT BRACES

Using the above-mentioned brace as a starting point, the key idea was to build on it a structure strong enough to resist the forces (torque) required to pull from the lower limb to induce the flexion and extension of the knee. It was imperative to build it without the necessity of dismantling the DonJoy Knee Brace, to avoid complications.

With the help of a simple nylon thread, it was studied which were the optimal places to attach the synthetic polymer to the structure of the DonJoy Knee Brace. This would resemble the insertion of the hamstrings and quadriceps on the tibia.

Instead of threading the wire through the aluminum hinge, it was decided to build an external structure to separate the thread as much as possible from it. The reason was because the bigger the radius from the center of the axis of rotation of the orthosis to the thread, the easier it would be for the SMA fibers to pull, reducing energy costs and the length of the SMA wires. This will be proven on 3.1.4. Nitinol Wires.

The already existing device, had some characteristics -like the ability to narrow the movement between an interval of angles, or adjusting the orthosis to a desired length- that the final structure had to respect and keep untouched to the highest extent possible, so the device could be adapted to any patient.

After several trials and narrowing the ideas, there were only two options: either design our own pieces in 3D and send them to an external company to manufacture them on aluminum or buy some metal parts at a hardware store and adapt them onto our device.

Since the first option was going to be expensive, increasing both the price and weight of the device, it was decided to buy metal flat braces to build the final structure. These metallic components were selected for their formidable strength and resistance to withstand the stresses from the extension and flexion, as well as their low cost, lightness and adaptability.

As they come in all shapes and sizes, it was easy to combine different ones to build the desired supportive system (Figure 3.2). Each one has four holes to connect them using screws of the size M4 (radius 3,5mm). They were wrapped with black insulating tape to avoid any short circuit in case the SMA accidentally touched these conductors.

In the section 3.2.1. Knee Exoskeleton, it can be seen a graphic concept of the metallic braces' final structural design. Once the it was built on the knee brace, the calculations for the length and number of SMA fibers were performed.

Figure 3.2 - Metallic Flat Braces

3.1.3. BIOMECHANICS OF BODIES (BOB)

Prior to the manufacturing process of the exoskeleton, it was necessary to use simulation tools to study and analyze the performance of the joint, as well as measuring the forces and torque exerted by the muscles to produce the flexion and extension movements.

These values were required in order to calculate the number of SMA wire needed for the project. To obtain the torques acting on the articulation, the software Biomechanics of Bodies (BoB) was used. This modeling package resides within the Matlab and Simulink environment, and it is used to simulate the musculoskeletal system of humans [7].

The model represents accurately the major anatomical components of the body, as its physiological complexity. It includes information for 36 segments of the skeleton and 666 muscles. BoB has two versions: one for the calculations of the direct dynamics and other for the inverse, which is useful to calculate the distribution of the muscular loads, the joints torques and the contact forces on the articulations. On the other hand, with the direct dynamics the movement induced by the activation of muscles can be calculated [55].

The software asks for the patient's height, weight and motion as input, giving as an output, among other data, the torque of articulations [7]. From this entries, BoB generates a model of the human body resulting on a graphic interface as it can be seen in Figure 3.3 [56].

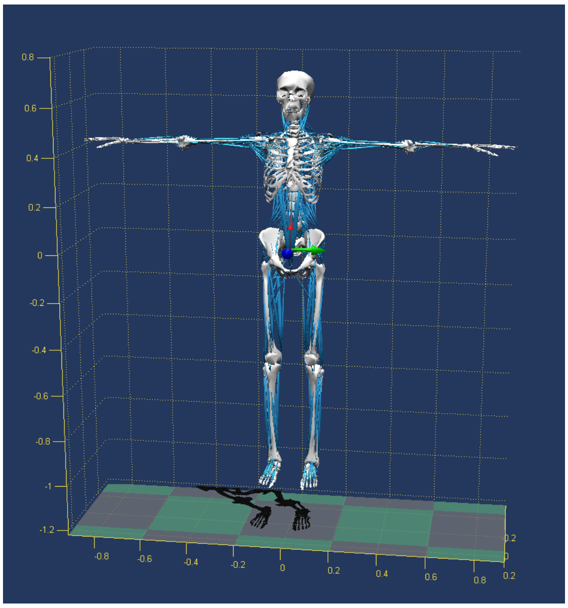

Figure 3.3 - BoB's Interface

In the case of the knee, the parameters introduced were: weight 80kg and a sinusoidal trajectory in the left knee joint between 0 and 120º in the motion of flexion-extension, with a frequency of 2.5 rad/sec (0.4Hz). The results of the simulation are displayed in Figure 3.4. The torques were calculated on the transvers plane which goes through the articulation, represented as a red line. The green and pink lines represent the sagittal and vertical axes respectively. It can be seen that the maximum torque necessary for the flexion and extension was 8 Nm.

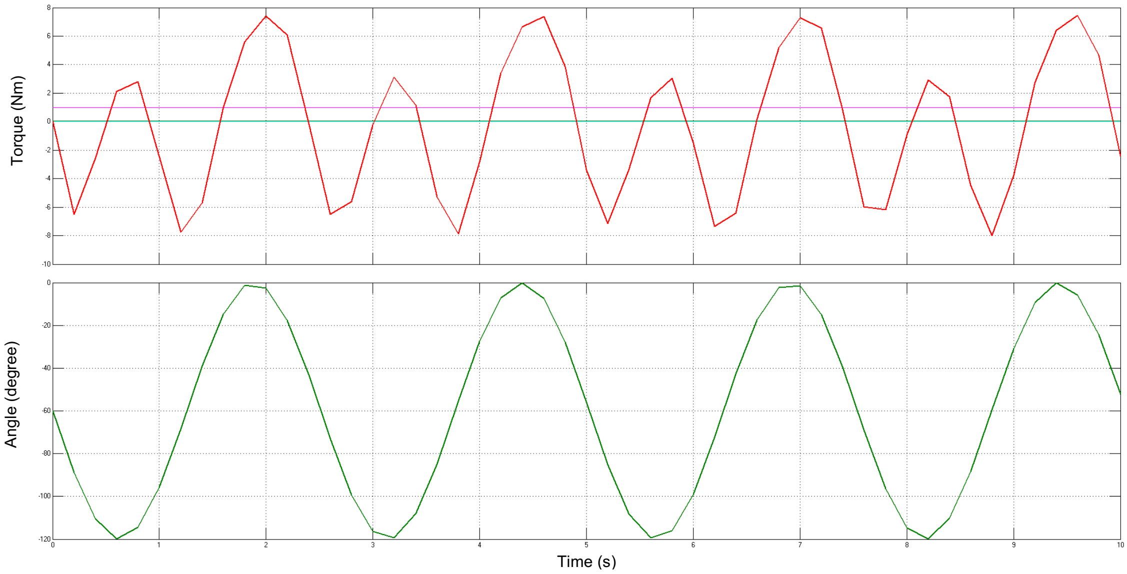

Figure 3.4 - Results of the knee's simulation on BoB

3.1.4. NITINOL WIRES

The wires of SMA can be classified according to their diameter, and from these categorization, other features can be analyzed such as: the current needed, the time for cooling, the resistance, etc. In Table 3.1 [52] the technical data for the different Flexinol® Actuator Wires is presented.

TABLE 3.1 - FLEXINOL® ACTUATOR WIRE TECHNICAL DATA

DIAMETER (MM)	RESISTANCE (Ω/M)	HEATING PULL FORCE (G)	CURRENT PER SECOND (MA)	COOLING TIME (S) FOR 70º WIRE	COOLING TIME (S) FOR 90º WIRE
0.025	1425	8.9	45	0.18	0.15
0.038	890	20	55	0.24	0.20
0.050	500	36	85	0.4	0.3
0.076	232	80	150	0.8	0.7
0.10	126	143	200	1.1	0.9
0.13	75	223	320	1.6	1.4
0.15	55	321	410	2.0	1.7
0.20	29	570	660	3.2	2.7
0.25	18.5	891	1050	5.4	4.5
0.31	12.2	1280	1500	8.1	6.8
0.38	8.3	2250	2250	10.5	8.8
0.51	**4.3**	**3560**	**4000**	**16.8**	**14.0**

In order to select the proper diameter for the exoskeleton, it is important to bear in mind the strength needed to support the load of the shank -portion of the lower limb from the knee until the foot. Following the study conducted by Stanley Plagenhoef (Plagenhoef et al. 1983) to gather the anatomical data for the analysis of human motion, it can be stated that the weight of the shank in men corresponds to 4.75% of their total weight; and for women is 5.35% [57]. Thus, the average is 5.05%, which corresponds to approximately 4kg.

As a result, since the fibers have to bear a torque of 8Nm, the diameter selected is the biggest, 0.51mm. This alloys the wire to withstand higher stresses and increases the breaking threshold.

For this diameter there are two options: low temperature wires (70º) and high temperature ones (90º). The main difference among them is the cooling process, in other words, the amount of time that the wire requires to cool down to ambient temperature. Thus, recovering its original length so it can be actuated again.

As it can be seen in Figure 3.5 [58], the 90º cooling graph has steeper slope than the 70º cooling, meaning they would cool faster. Therefore, the 0.51mm of 90º (0.020’’ of 194º F) was selected to be used on the knee exoskeleton since the lower the cooling time, the more actuation cycles can be performed.

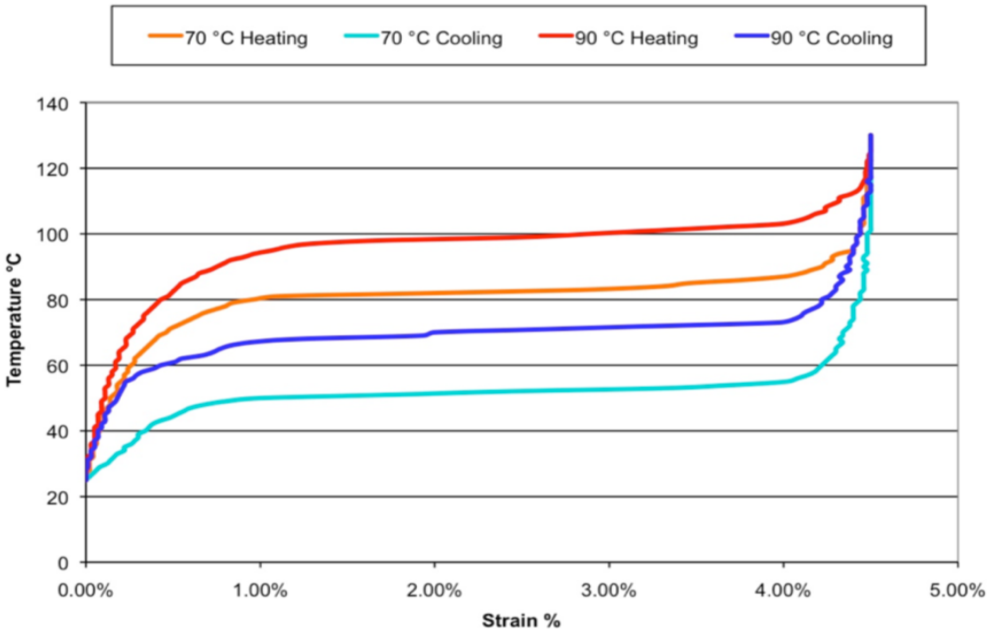

Figure 3.5 - Temperature vs. Strain Characteristics for Dynalloy’s 70º and 90º wires

Taking into account the torque (8Nm) and the weight of the shank (4kg), the next step was to calculate the number of wires, its length and the radius between the axis of rotation of the exoskeleton and the actuator. To obtain these values, a Simulink function (Figure 3.6) implemented by D. Copaci et al, 2016 [7] was used.

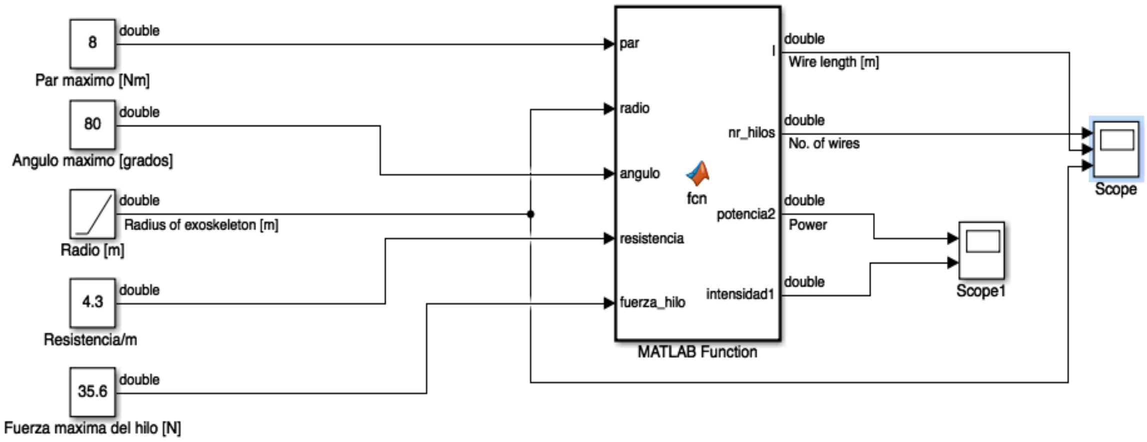

Figure 3.6 - Matlab/Simulink program to calculate the optimal for the exoskeleton

Such function takes as input variables the Torque (Nm), maximum angle (degrees), the radius of the axis of rotation (m), the current applied (A), the Resistance of the wires (Ω) and the Pulling force (N). In addition, by knowing the characteristics of the 90º wire with diameter 0.51 mm from Table 3.1, all of the necessary data has been collected.

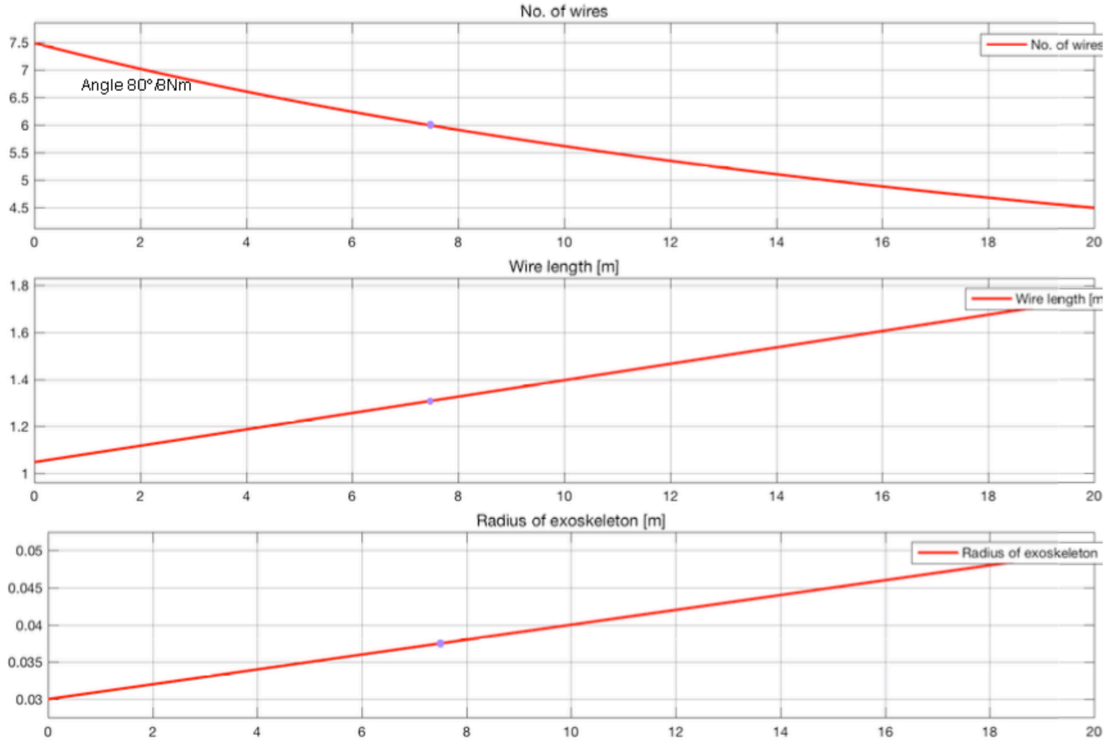

Figure 3.7 - Number of wires, length and radius of the Exoskeleton

The results from running the code are displayed in Figure 3.7. Since the most reasonable radius for an orthosis would be between 0.035-0.04mm, the function suggests 6 wires. Therefore, the requisites to obtain an optimal performance with the exoskeleton are:

- **TORQUE TO FLEX AND EXTEND THE KNEE:** 8Nm
- **MAXIMUM ANGLE:** 80º degrees
- **NUMBER OF WIRES:** 6
- **RADIUS OF EXOSKELETON:** 0.035-0.04m
- **LENGTH OF WIRES:** 1.3m, though it was decided to increase the length a few centimeters up to 1.8m, so it could cool down faster, sine the % of strain would be more distributed (Figure 3.5)

3.1.5. TEFLON TUBES

Teflon or PTFE (Polytetrafluoroethylene) is a high molecular weight polymer with a composition made mainly from carbon and fluorine. It possesses one of the lowest friction coefficient of any solid, making it an excellent material for lubrication and avoiding adhesion of other substances. See Figure 3.8 [59].

Figure 3.8 - Teflon Tube

In addition, it shows excellent heat, chemical and oil resistance. With an operating temperature from -75º to 260º [60], tubes made from this material are the best option to provide the SMA fibers with a flexible protection able to electrically insulate them, to avoid a short circuit with the Bowden Cable. Furthermore, its lubricating properties benefit the sliding of the Nitinol wires when they contract.

For the exoskeleton, two PTFE tubes were needed to hold six SMA wires each, half dozen for the flexion and the others for the extension. The length was the same as for the SMA.

3.1.6. BOWDEN CABLE

The Bowden cable is the final external shell which wraps the Teflon tubes containing the SMA fibers. The stainless steel helical structure provides flexibility and strength. It is integrated by different layers of wire coiled around its longitudinal axis. Furthermore, its upper layer is lined with plastic to electrically insulate it. See Figure 3.9 [61].

The main advantage of this cable is its allowance for the transmission of movement inside of it since the linear movement of the inner cable is generally used to transmit a pulling force. This makes it a perfect candidate when the SMA fibers shrink.

Additionally, thanks to this component, the lifespan of the Nitinol wires increases. This armor isolates them from the environment, avoiding the contact with air and possible breakages. Besides, it is a safety element for the exoskeleton since it prevents burns on the patient's skin when the SMA reach temperatures close to 90º [49].

Figure 3.9 - Internal structure of Bowden Cable

3.1.7. MAGNETIC ROTARY POSITION SENSOR

In order to measure the position of the leg at any time, it was necessary to integrate some kind sensor on the device to have a reference for the control software. Two options were considered for this particular exoskeleton: a flex sensor and a magnetic rotary encoder.

Figure 3.10 - Flex Sensor and the Kneepad

The principle behind the flex sensor was to measure the bending angle of the sensor when placed directly on the knee of the patient. By measuring the different resistances when lying flat and during the flexion an extension, an approximate idea of the angle was obtained.

The sensor was sewed on a kneepad (Figure 3.10) that the patient had to wear to obtain the relative position of the knee. The issue was that if the kneepad was not placed on the exact same position on the leg, the calibration and results obtain would be very different each time, thus giving inaccurate results.

To solve this issue, the sensor had to be placed directly on the structure of the orthosis. This way, no matter who wore the apparatus, it would give more precise results. The alternative was the Magnetic Rotary Position Sensor – AS5045 from ams AG [61].

AS5045 is a contactless rotary magnetic sensor -also called encoder- which outputs the precise angular measurements on a full 360º range. It uses spinning current Hall technology (Figure 3.11 [62]) for sensing the magnetic field distribution across the surface of the chip. This is achieved by the rotation of a circular magnet over the system-on-chip, which contains Hall effect elements, a type of semiconductors activated by the presence of a magnetic field, delivering a voltage as a response.

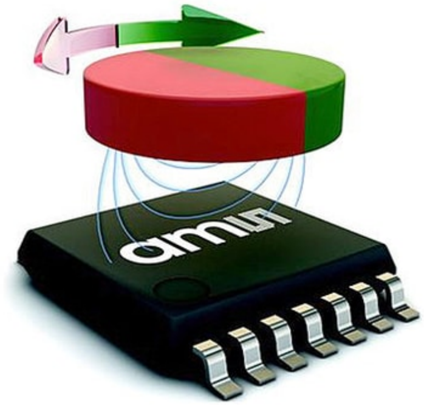

Figure 3.11 - AS5045 Sensor with the Spinning Current Hall Technology

The measurement of the absolute angle is an instantaneous indication of the angular position of the magnet over the chip, with a resolution of 0.0879º = 4096 positions per revolution [62]. The sensor was positioned in the middle of the of the DonJoy's hinge and hold the magnet 1mm over it but fixed on the portion of the orthosis attached to the leg. In this manner, as the knee is flexed or extended, the magnet would rotate over the sensor, generating a measurable voltage which could be extrapolated to the real angle on the joint.

3.1.8. 3D-PRINTED ELEMENTS

Several alternatives were considered to build a structure able to integrate the sensor on the exoskeleton, while holding the circular magnet over it. Since no load would be applied on these elements, it was decided to use a 3D printer to custom make them.

This way it would be cheaper, lighter and would have a better integration with the device. The pieces were designed using the modelling software SketchUp [62], from the Google Company. This freeware allows the creation of STL models, the type of file required by the 3D printer, so it could be read and printed

Three models were drawn using this program:

- **SENSOR'S PLATFORM:** the purpose of this part was to provide a stand for the sensor, so it could be easily glued to the aluminum hinge of the brace. In addition, it needed to be sufficiently tall, so the wires could be connected to the chip. Figure 3.12.

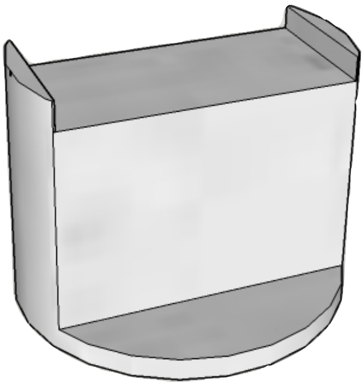

Figure 3.12 - 3D-printed Sensor's platform

- **MAGNET HOLDER:** this element was designed to hold the magnet over the chip of the AS5045. The triangular-shaped piece has on its lower face a circular indentation to fit the magnet, while the rest of the holes are to hold everything together by M4 screws. The elongated components fix this structure on the lower part of the exoskeleton. Therefore, when the orthosis is flexed or extended, the magnet will rotate over the sensor. Figure 3.13.

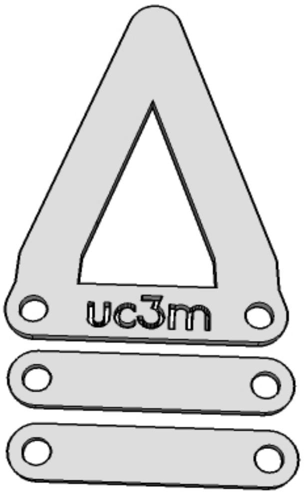

Figure 3.13 - 3D -printed Magnet Holder

- **PULLEY'S ACCESSORY:** this part was designed to guide the fishing line through the pulley during the extension. It was placed between two metal flat braces since its holes fit a M4 screws and its wide enough to fit the pulley on its middle section. Figure 3.14.

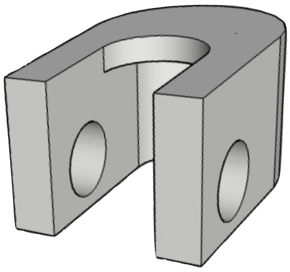

Figure 3.14 - 3D - printed Pulley's Accessory

3.1.9. FISHING LINE

As it was mentioned on 3.1.4. Nitinol Wires, the SMA actuators reached high temperatures. Thus, it was important to select a heat-resistant material to connect the Nitinol fibers to the lower section of the orthosis. By doing so, as the alloys were shrinking, the movements of flexion and extension would be generated.

The option of using a Nylon thread was discarded, since it would melt at those temperatures. On the other hand, Dyneema® Fishing Line was selected as the best solution to this problem.

This fishing braid made of Ultra-high-molecular-weight polyethylene (UHMWPE) has been proven to be up to 15 times stronger than steel [62]. Therefore, it would withstand greater loads from holding the shank without breaking. Nevertheless, to avoid possible tearing of the line, it was decided to braid four strands together to obtain a thicker line.

Figure 3.15 – Braid of Dyneema® Fishing Line

3.1.10. POWER SUPPLY

To calculate the voltage and current necessary to actuate the SMA wires, the data from Table 3.1 was taken to perform the operations. It is important to notice that the flexion and extension were actuated separately, since the electronic components could not bear such power. The following calculations were done for one actuator and extrapolated to the other one.

First, the total resistance is calculated. As the exoskeleton has 6 SMA wires in parallel, the total resistance would be:

$$\frac{1}{R} = \frac{1}{R_1} + \frac{1}{R_2} + \frac{1}{R_3} + \frac{1}{R_4} + \frac{1}{R_5} + \frac{1}{R_6} \qquad (3.1)$$

Where the value of each resistance is 4.3 Ω/m. Thus:

$$R = \frac{4.3}{6} = 0.72\ \Omega/\mathrm{m} \qquad (3.2)$$

Since we have a total of 1.8 meters per wire, the resistance is:

$$R = 0.72\ \frac{\Omega}{\mathrm{m}} \times\ 1.8\ m =\ 1.3\ \Omega \qquad (3.3)$$

From Table 3.1, the electrical current that each wire consumes per second is 4000mA. Following Ohm’s law, the total voltage would be:

$$I = 6 * 4A = 24\ A \qquad (3.4)$$

$$V = I\ \times\ R = 24\ A\ \times 1.3\ \Omega = 30V \qquad (3.5)$$

To provide the system that quantity of power, the Digimess® DC Power Supply SM3040 was used, since it has an output voltage between 0-30V and a current output of 0-40A. (Figure 3.16) [63]

Figure 3.16 - Digimess® DC Power Supply SM3040

3.1.11. MICROCONTROLLER AND POWER BOARD

In order to control the whole rehabilitation device, researchers of Robotics Lab had previously implemented a control system platform to: supply power to the SMA wires, read the sensor, receive and send reference positions, etc. Basically, the objective was to monitor the motion of the exoskeleton in real time. To do so, two electronic elements where used:

- **MICROCONTROLLER STM32F4 - DISCOVERY**:

  This board is a versatile, easy-to-use electronic microcontroller with a design that facilitates the installation of circuits and the reprogramming of the controller [9]. Among its advantages are it high performance, real time capabilities, digital signal processing, low cost and reduced power input since it is supplied via USB cable. See Figure 3.17 [64].

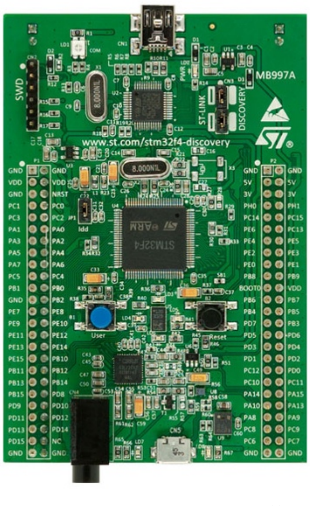

Figure 3.17 - Microcontroller STM32F4 - Discovery

- **POWER BOARD CIRCUIT**:

As it was mentioned on section 2.4. Shape Memory Alloys, the most common way to actuate the SMA fibers is through the Joule Effect, by allowing the flow of an electrical current across the wires. To supply this current, the Digimess® DC Power Supply SM3040 was connected to a power board circuit (Figure 3.18) designed by the University's department [65] to actuate artificial muscles with a Pulse-Width Modulation (PWM). The board is able to feed two channels, with a MOSFTET transistor [66] each, and activated by the PWM signal generated with the control software [9].

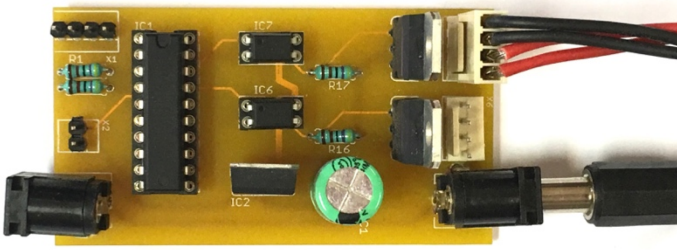

Figure 3.18 - Power Board Circuit

3.1.12. MISCELLANEOUS

Besides all of the components mentioned in the previous sections, there are other elements worth mentioning since their presence in the design of the exoskeleton is crucial for an optimal performance. These pieces are:

- **SMA CRIMPER:**

Prisoner throttles (Figure 3.19) are commonly used to crimp the bicycles' brakes. This function was extrapolated to the exoskeleton to fix the distal end of the SMA. Thus, the 4% reduction of size would be produced on the end connected to the fishing line, which pulled from the lower limb. It was imperative to tense each of the fibers equally, so they would withstand the same stress.

Figure 3.19 - SMA Crimper

If this was not done properly, some wires would pull more than other, leading to the actuator's breakage Therefore, two items were needed, one for each actuator.

- **ROUND WIRE CONNECTOR CRIMP:**

  The purpose of the round wire connector crimps [67] was to connect the SMA fibers to the fishing line. Several alternatives were considered, but these items provided a strong SMA fixation, at a low cost and compact size. The insulation cover was removed (as seen in Figure 3.20) so the Nitinol wires could be crimped, while knotting the fishing on the circular ring.

Figure 3.20 - Round Wire Connector Crimp

- **PULLEY:** in order to avoid the contact between the fishing line and the screw while extending the knee, it was decided to place a v-shaped pulley (Figure 3.21) [68] wrapping the bolt to: reduce the friction, benefit the extension and avoid any unnecessary tearing of the fishing braid.

Figure 3.21 - V-Shaped Pulley

- **M4 BOLTS AND NUTS:** with the aim of attaching the metallic flat braces together, fixing the actuator system on the orthosis or even holding the magnet 1mm above the sensor, a combination of different-sized screws and bolts (Figure 3.22) were used. All of them with diameter M4.

Figure 3.22 - M4 Screws and Nuts

3.2. ASSEMBLY

3.2.1. KNEE EXOSKELETON

The final design of the robotic orthosis can be seen in Figure 3.23

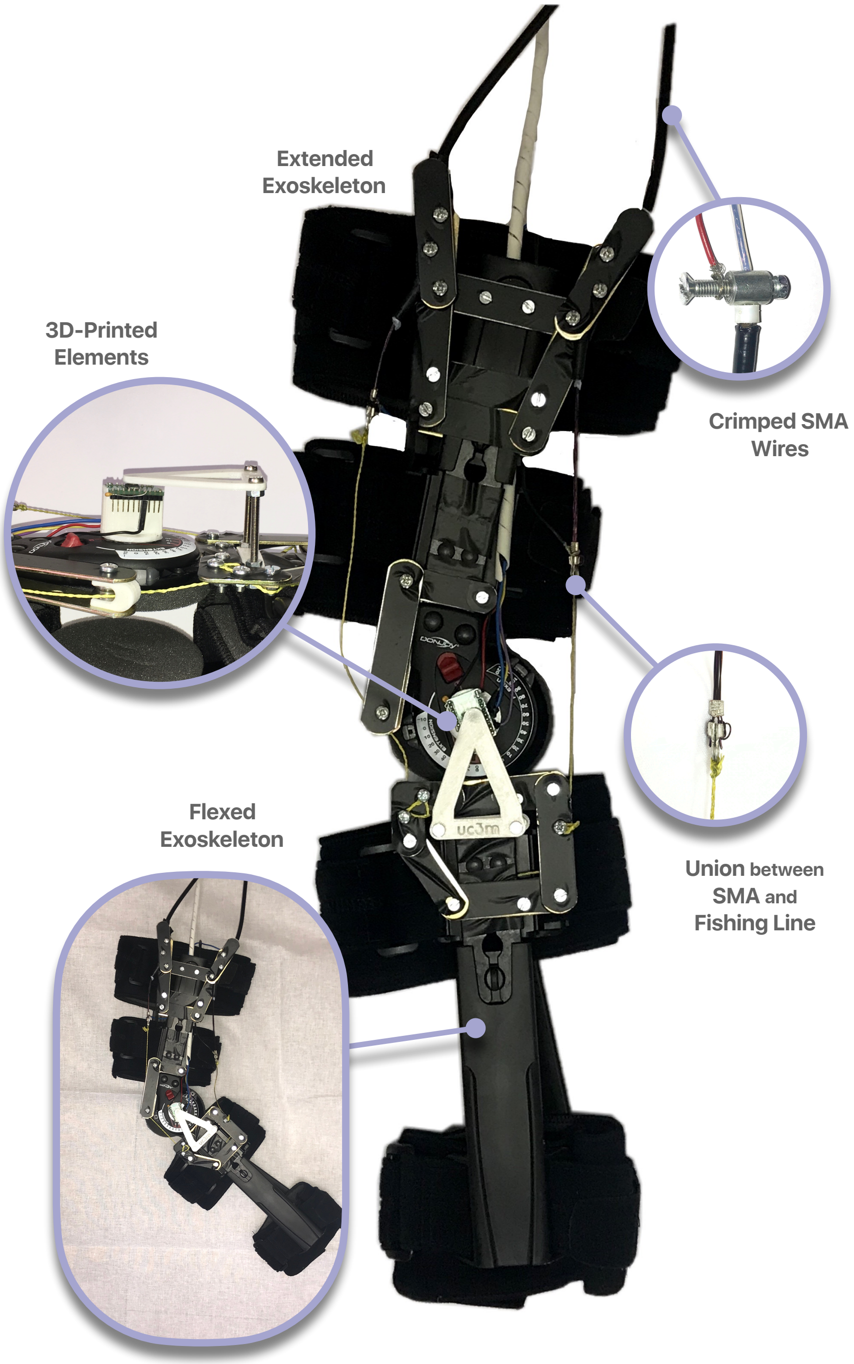

Figure 3.23 - The Knee Exoskeleton's final assembly

3.2.2. ACTUATOR

The artificial muscles or actuators for both, flexion and extension, are graphically represented in Figure 3.24. This scheme shows how the SMA are crimped on one side and in the opposite, they are free to contract 4% of its original length. For this exoskeleton, around 6cm are left outside the Bowden and Teflon cables to achieve an optimal contraction.

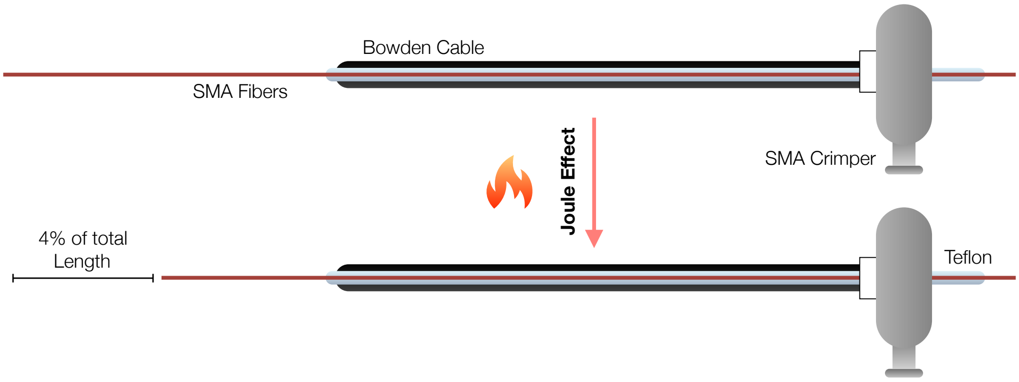

Figure 3.24 - Graphic representation of the SMA actuators

3.2.3. HARDWARE AND SOFTWARE

The hardware and software used to control the exoskeleton follows the diagram represented in Figure 3.25. The computer sends a reference signal to the system, indicating the power board and microcontroller to allow the flow of electrical current through the SMA fibers.

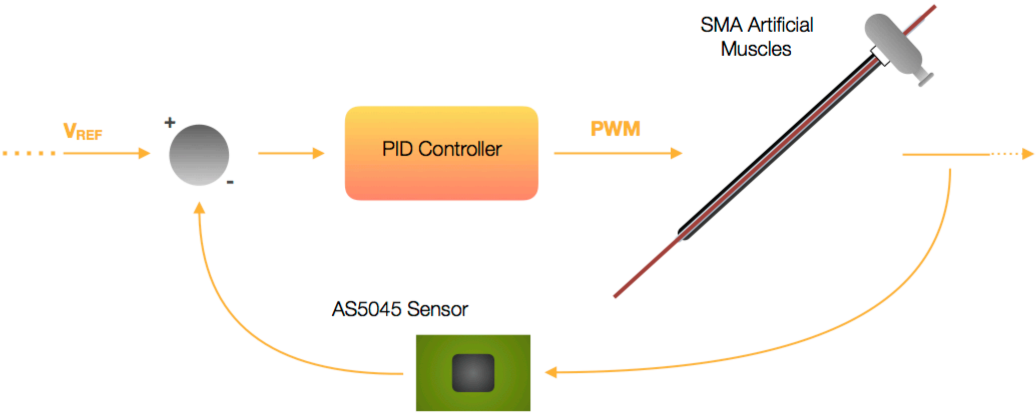

Figure 3.25 - Control System of the Exoskeleton

Since the artificial muscles act as a non-linear system, a bilinear PID Controller is used to compensate for such non-linearity [65]. By combining the PWM signal from the microcontroller and the voltage supplied via the power board, the SMA are actuated. In order to close the control loop, the angle measurements obtained from the sensors are used as a reference signal to adjust the position of the exoskeleton.

This is achieved through the control software, based on the Matlab-Simulink programming language created by the Universidad Carlos III of Madrid [65]. With this software, the user is able to program the Microcontroller previously explained (3.1.11. Microcontroller and power board). Simulink's functionalities simplify the programming because it is done in functional blocks, whose interpretation is simple and user-friendly. The control software has two parts [69]:

- **TARGET:**

  The main part of the program is implemented in the Target script. It contains the control loop (Figure 3.26) and is the file uploaded to the microcontroller STM32F4. It is entrusted with the control of the temporal response of the actuators of the exoskeleton from the warming/cooling of the SMA fibers. In addition, it communicates with the Host. This connection is necessary to save and visualize in real time all of the meaningful signals of the system such as the angular position of the sensor, the control signal, or receiving the reference from the Host. Thus, the communication is bidirectional.

  The control of the system is based on a PMW signal, a variation of the on/off switch. By modifying the frequency and the pulses' width it is possible to manage the system. In addition, the information from the sensor is used as feedback to close the loop, and to calculate the error between the reference position and the sensor's angle [70]. For this reason, two Target files had to be created to perform separately the Flexion and Extension.

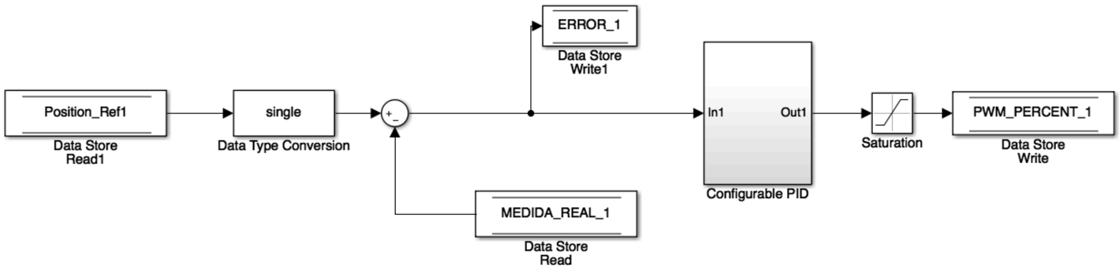

Figure 3.26 - Control Loop on the Target's configuration

- **HOST:**

On the other hand, the Host is implemented. It can be considered as a simple interface to communicate with the exoskeleton. Therefore, it is run on the computer connected via USB to the microcontroller. Through this program the user can see in real-time the performance of the device: the position of the angular measurement, the error, the PWM, the gain, etc. All of this information is stored in the PC and it can be subsequently managed to optimize the overall functioning of the system. For additional security, the PWM block is connected to an enable switch. It multiplies the value by 0 or 1, to respectively turn on or off the exoskeleton. See Figure 3.27.

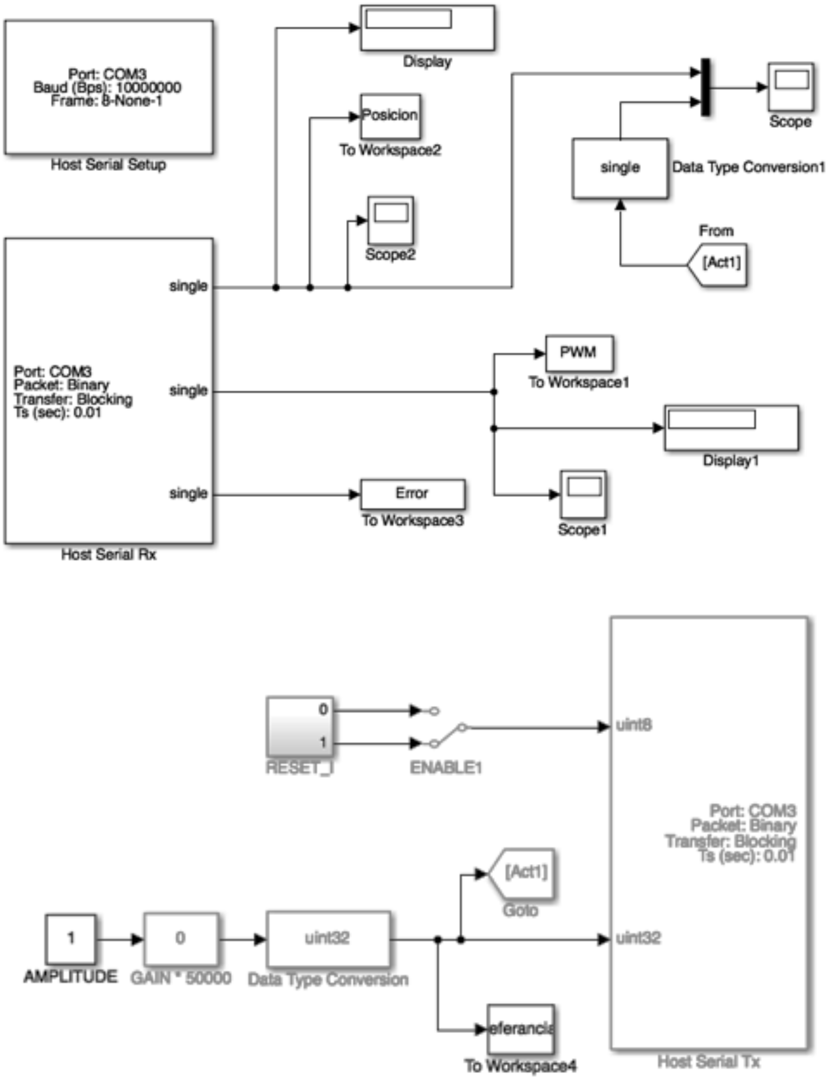

Figure 3.27 - Simulink's Host

To conclude this chapter, Figure 3.28 represents a graphic scheme of the electrical connections between the power board, the microcontroller, the angular sensor, the SMA wires, the power supply and the computer. Furthermore, Table 3.2 shows the pin connections of the boards.

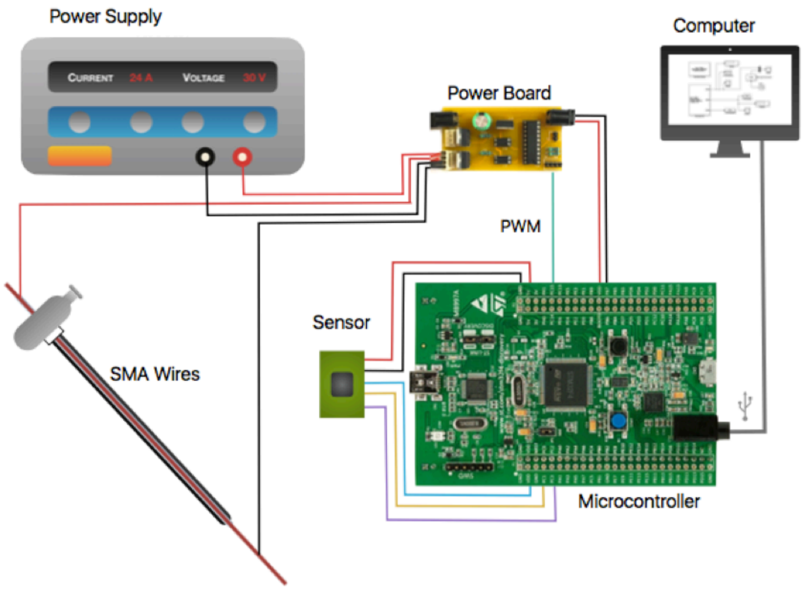

Figure 3.28 - Scheme of the electrical connections

Table 3.2 - Pin Connections

Element	Origin Pin	Connected To	Insertion Pin
Sensor	Pin 7 - Gnd	**Microcontroller**	Gnd
	Pin 20 - Vcc		5V
	Pin 15 - Chip Select		Pb0
	Pin 14 - Clock		Pc10
	Pin 13 – Data Output		Pc11
Power Board	Vcc	**Power Supply**	Vcc
	Gnd		Gnd
	5V	**Microcontroller**	5v
	Gnd		Gnd
	PWM Channel		Pb3
	Channel +1	**SMA**	Vcc of SMA
	Channel -1		Gnd of SMA

4. RESULTS

Once the whole structure, electrical connections and software was ready, the next step was to check the functionality, performance and viability of the device. Therefore, it was mandatory to validate the control system of the exoskeleton for both movements, flexion and extension of the knee joint.

The first step was to calibrate the AS5045 sensor, to obtain 0º value when the leg was completely extended, and a maximum of 90º when flexed. Since the Host and Target models were based on the ones created for hand exoskeleton [6], it was verified that no modifications were needed in the PID values because the exoskeleton would reach the reference signal without problem.

Secondly, it was necessary to test whether or not the structural framework was able to withstand the loads and weight of the shank, while flexing and extending the knee. A 21-year-old male subject of 70kg weight was selected to perform the trials.

Without losing sight of the final purpose of the device, the experiments were done in such a way to resemble real rehabilitation therapies. Most of the activities to regain musculoskeletal strength and repair the knee consist of a repetition of exercises based on flexion an extension [71]. During these therapies and depending on the treatment, the patient can be standing, sitting or lying down.

Therefore, to demonstrate if the device was suitable for these exercises, a series of six tests were carried out. The exoskeleton's wearer was positioned at these different three conformations and the exoskeleton was actuated. Flexion and extension were analyzed separately since two different Target programs had to be uploaded to the microcontroller.

4.1. KNEE'S FLEXION

4.1.1. STANDING

For this experiment, the Flexion Target was uploaded to the microcontroller, the actuator corresponding to the flexion was connected to the power supply – as specified in Table 3.2 - PIN Connections- and the subject was standing straight, holding body's weight with the right leg – as represented in Figure 4.1 [72].

Figure 4.1 – Flexion of the knee while standing

Since the extension and flexion were actuated separately, in order to perform the exercise at least four cycles, the exoskeleton would have to do the flexion, and the subject would extend the lower limb. Therefore, this method would allow the repetition of the flexion several times. In this experiment, the exoskeleton was actuated for a minute and a half to perform 4 cycles. The angle measurements collected by the sensor are plotted in red, while the reference position controlled by the Host, is in orange. The results are displayed in Figure 4.2 and commented in Chapter 5.- Discussion.

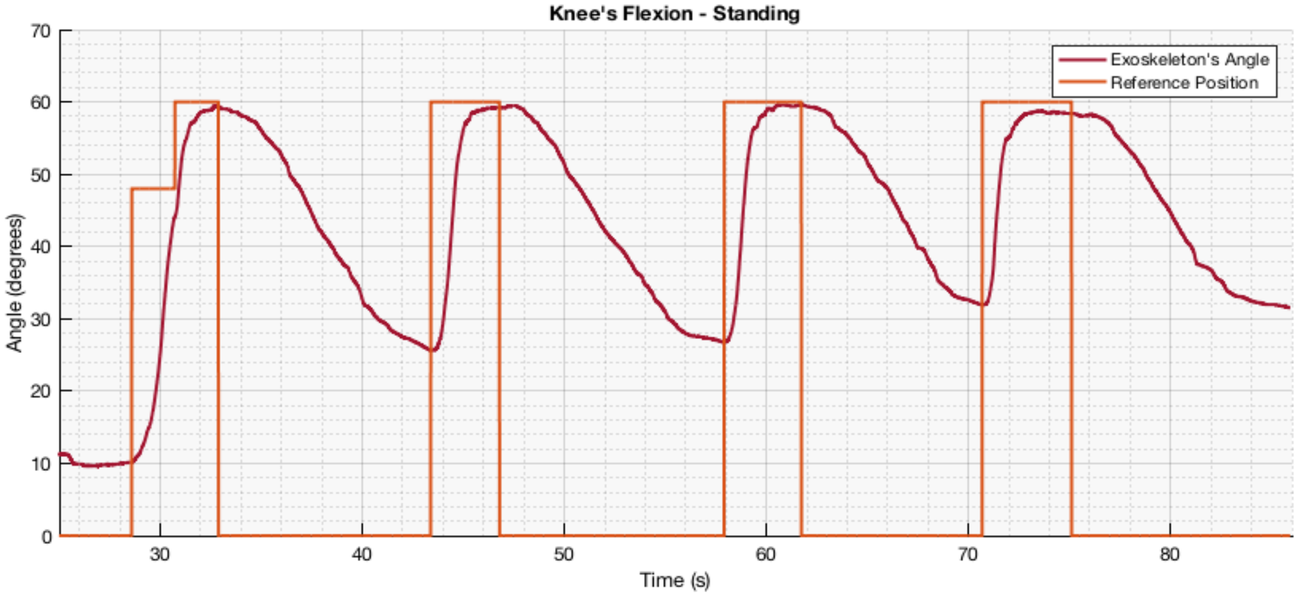

Figure 4.2 - Results for the knee's flexion when the subject was standing

4.1.2. SITTING

For this experiments, it was checked that the Flexion Target had been uploaded to the microcontroller, the actuator corresponding to the flexion was connected to the power supply – as specified in Table 3.2 - PIN Connections- and the subject was sitting on a surface high enough so that its foot was not in contact with the ground – as represented in Figure 4.1 [72].

Figure 4.3 - Flexion the knee while sitting

Once the exoskeleton had flexed the knee, the subject stretched the leg back to 0º so as to repeat the series several times. In this experiment, the exoskeleton was actuated for 45 seconds to perform 4 cycles. The angle measurements collected by the sensor are plotted in red, while the reference position controlled by the Host, is in orange. The results are displayed in Figure 4.4 and commented in Chapter 5.- Discussion.

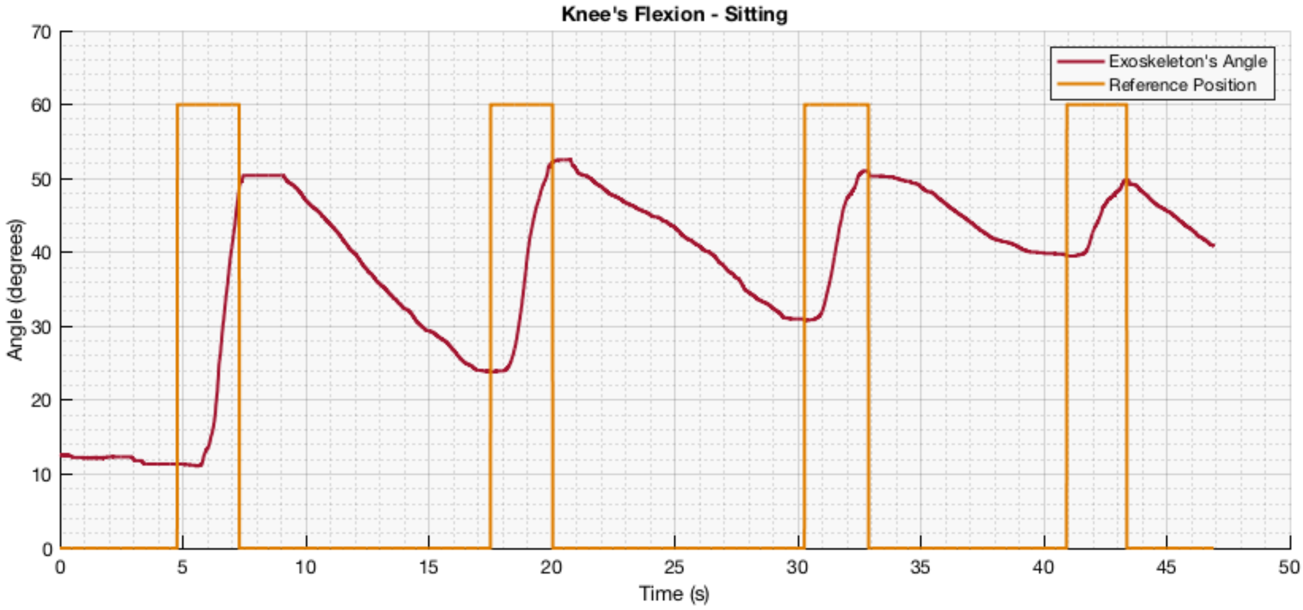

Figure 4.4 - Results for the knee's flexion when the subject was sitting

4.1.3. LYING

For this experiments, it was checked that the Flexion Target had been uploaded to the microcontroller, the actuator corresponding to the flexion was connected to the power supply – as specified in Table 3.2 - PIN Connections- and the subject was positioned lying facing down on a comfortable surface – as represented in Figure 4.5 [72].

Figure 4.5 - Flexion the knee while lying

Once the exoskeleton had flexed the knee, the subject stretched the leg back to 0º so as to repeat the series several times. In this experiment, the exoskeleton was actuated for a minute and a half to perform 4 cycles. The angle measurements collected by the sensor are plotted in red, while the reference position controlled by the Host, is in orange. The results are displayed in Figure 4.6 and commented in Chapter 5.- Discussion.

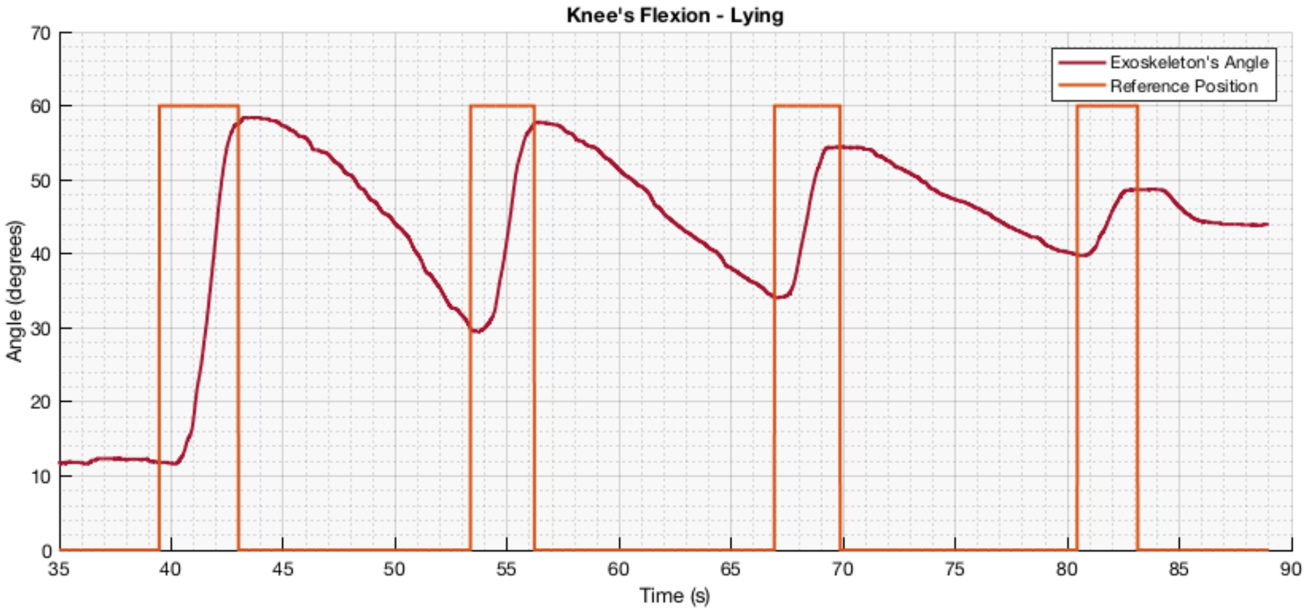

Figure 4.6 - Results for the knee's flexion when the subject was lying down

4.2. KNEE'S EXTENSION

4.1.1. STANDING

For this experiment, the Extension Target was uploaded to the microcontroller, the actuator corresponding to the extension was connected to the power supply – as specified in Table 3.2 - PIN Connections- and the subject was standing straight, holding body's weight with the right leg – as represented in Figure 4.7 [72].

Figure 4.7 - Extension the knee while standing

Once the exoskeleton had extended the knee, the subject bent the leg back to 60º so as to repeat the series several times. Therefore, this method would allow the repetition of the extension several times. In this experiment, the exoskeleton was actuated for 75 seconds to perform 4 cycles. The angle measurements collected by the sensor are plotted in green, while the reference position controlled by the Host, is in brown and the enable switch in blue.

To control this movement more easily, the reference position was set to 0º and the orthosis activated by the enable switch explained in 3.2.3. Hardware and Software. This way, when the subject had flexed the knee and the enable was turned on, the exoskeleton would try to reach the reference position; thus, extending the lower limb. The results are displayed in Figure 4.8 and commented in Chapter 5.- Discussion.

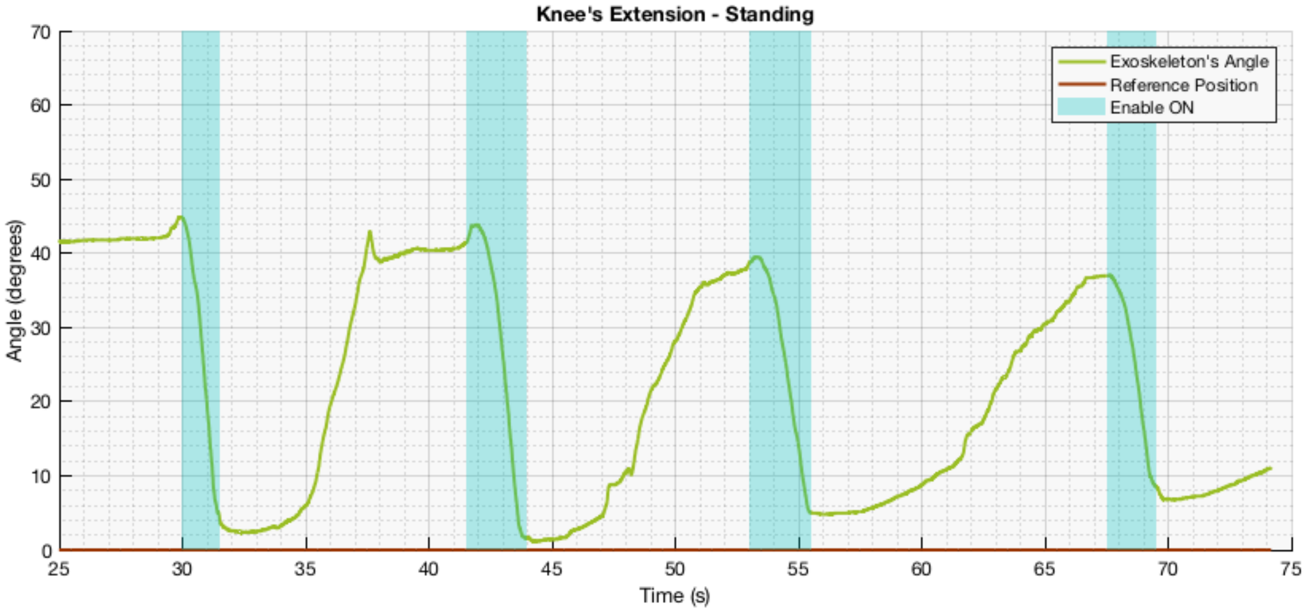

Figure 4.8 - Results for the knee's extension when the subject was standing

4.1.2. SITTING

For this experiment, the Extension Target was uploaded to the microcontroller, the actuator corresponding to the extension was connected to the power supply – as specified in Table 3.2 - PIN Connections- and the subject was sitting on a surface high enough so that the foot was not in contact with the ground – as represented in Figure 4.9 [72].

Figure 4.9 - Extension the knee while sitting

Once the exoskeleton had extended the knee, the subject bent the leg back to 60º so as to repeat the series several times. In this experiment, the exoskeleton was actuated for 47 seconds to perform 3 cycles. The angle measurements collected by the sensor are plotted in green, while the reference position controlled by the Host, is in brown and the enable switch in blue. As in section 4.1.1. Standing, the exoskeleton was actuated with the enable. The results are displayed in Figure 4.10 and commented in Chapter 5.- Discussion.

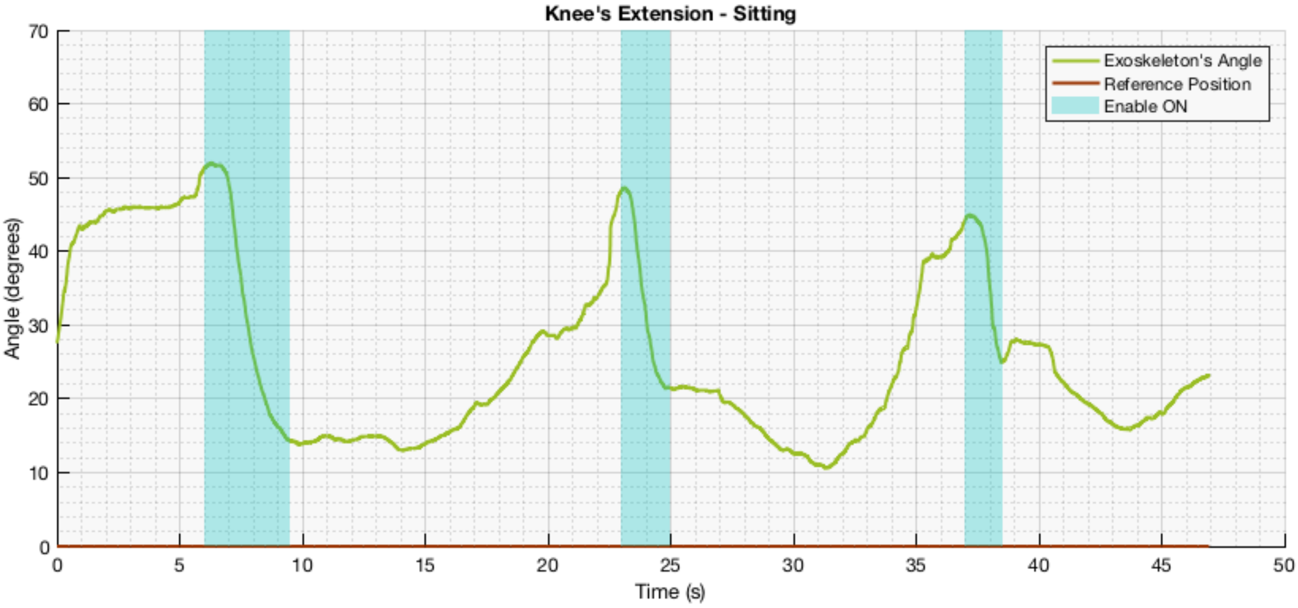

Figure 4.10 - Results for the knee's extension when the subject was sitting

4.1.3. LYING

For this experiment, the Extension Target was uploaded to the microcontroller, the actuator corresponding to the extension was connected to the power supply – as specified in Table 3.2 - PIN Connections- and the subject was positioned lying facing down on a comfortable surface – as represented in Figure 4.11 [72].

Figure 4.11 - Extension the knee while lying

Once the exoskeleton had extended the knee, the subject bent the leg back to 60º so as to repeat the series several times. In this experiment, the exoskeleton was actuated for 40 seconds to perform 3 cycles. The angle measurements collected by the sensor are plotted in green, while the reference position controlled by the Host, is in brown and the enable switch in blue. As in section 4.1.1. Standing, the exoskeleton was actuated with the enable. The results are displayed in Figure 4.12 and commented in Chapter 5.- Discussion.

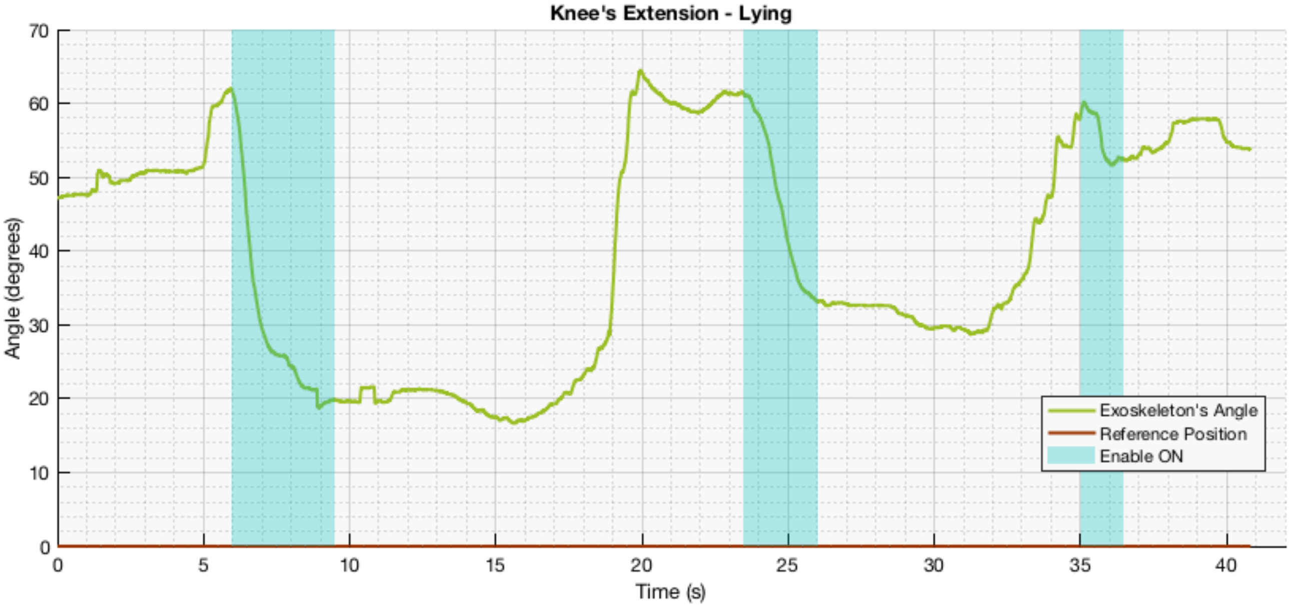

Figure 4.12 - Results for the knee's extension when the subject was lying down

5. DISCUSSION

This chapter includes the evaluation of the results presented in the previous section, to verify if the exoskeleton would be suitable for knee rehabilitation or not. They were obtained after six trials performed at different times, to avoid the SMA fibers' overheating.

Moreover, the subject was placed mimicking real positions during the rehabilitation process, to see if this would affect the behavior of the wearable orthosis. From the experiments, some findings and statements can be said:

- Concerning the AS5045 sensor, it was proven to have great accuracy and precision when measuring the angles. This was crosschecked with the angle measurements written on the aluminum orthosis' hinge (see Figure 3.1). The values range from 0º when being totally extended to approximately 60º. This is because the foams placed on the subject's leg would clash when flexing the knee more than 60º.
- However, since the magnet was calibrated at a certain position, if it were to be moved or displaced slightly by mistake, the values of the angular measurements would be completely inaccurate. Though the magnet structure served the purpose of this thesis, it is important, for future devices, to reinforce it or build and external case to prevent bumps, so as to keep the right calibration.
- Regarding the SMA fibers, they demonstrated to have the necessary strength to hold the human shank and pull from it, in order to do the flexion-extension. Moreover, it can be seen that during the first pulse, the artificial muscles take more time to reach the reference position than in the following pulses. This is because in the first, the SMA start at room temperature and needs more time to reach 90º to undergo the change in the crystalline structure (from Martensite to Austenite).
- As a consequence, the best pulse to study the response time of the exoskeleton is the second one. This is due to the lack of the previous phenomenon since the wires maintain the heat and reach the transition temperature faster.

- On the other hand, Nitinol's property of storing the heat can also be a disadvantage. The warmer the wires get, the shorter they become. Therefore, the less they will stretch when the exoskeleton flexes the knee and vice versa. As an example, in Figure 4.4 the subject's extended knee measures 10º at the beginning. After the second pulse, it is only able to extend the leg until 25º. From here on, it only reaches 30º or 40º in the next pulses.
- At this stage, it has to be kept in mind that the SMA fibers are undergoing a conformational change. Thus, if sufficient force is done to extend the knee, it could break the wires. The only solution to obtain the maximum range of motion in each cycle, is to give Nitinol enough time between pulses to cool down and evacuate the heat.
- Another solution, instead of doing square pulses, is to perform either stepped pulses, heating the wires gradually; or sinusoidal waves, with a reasonable period to obtain smoother outcomes. This way they would be able to cool down faster, as shown in the wrist exoskeleton [70].

5.1. EVALUATION OF THE FLEXION AND EXTENSION

From the graphs plotted in sections 4.1. Knee's Flexion and 4.2. Knee's Extension, it can be seen that the exoskeleton reached the reference position in a very smooth manner. The only inconvenient was that the antagonist movement had to be done by the subject or with the help of a third person.

In order to fulfill completely the purposes of a rehabilitation therapy performed with automated exoskeletons mentioned in 2.2.4. Medical Rehabilitation, the flexion and extension should be actuated one after the other. However, the power board used for this project was designed for the other exoskeleton that required less voltage.

If both actuators were to be activated alternatively using this board, it could burn the whole electronic circuit. This is because the tracks on the board are very narrow to bear that much power for an extended period of time. For that matter, in future works a power board with wider connections could be manufactured.

Nevertheless, for the objectives of the present thesis to prove whether or not the SMA fibers could rehabilitate the knee, these results are more than enough.

- In the results for the flexion while the subject was standing (Figure 5.1), presented in 4.1.1. Standing, four cycles were obtained, with a period of 14s in total – 4s where destined to the flexion, and the rest to the antagonist movement – in an interval of 10º-60º. Moreover, during this trial the exoskeleton was functioning against gravity, lifting the whole weight of the shank.

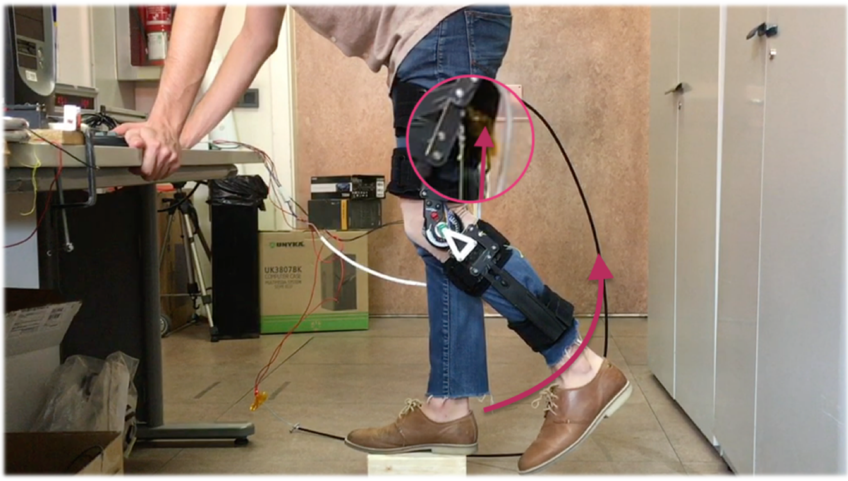

Figure 5.1 – Exoskeleton's performance during flexion with subject standing

- In the results for the flexion while the subject was standing (Figure 5.2), presented in 4.1.2. Sitting, four cycles were obtained, with a period of 12.5s in total – 2.5s where destined to the flexion, and the rest to the antagonist movement – in an interval of 10º-52º. The time required for the flexion was less because the movement was favored by gravity.

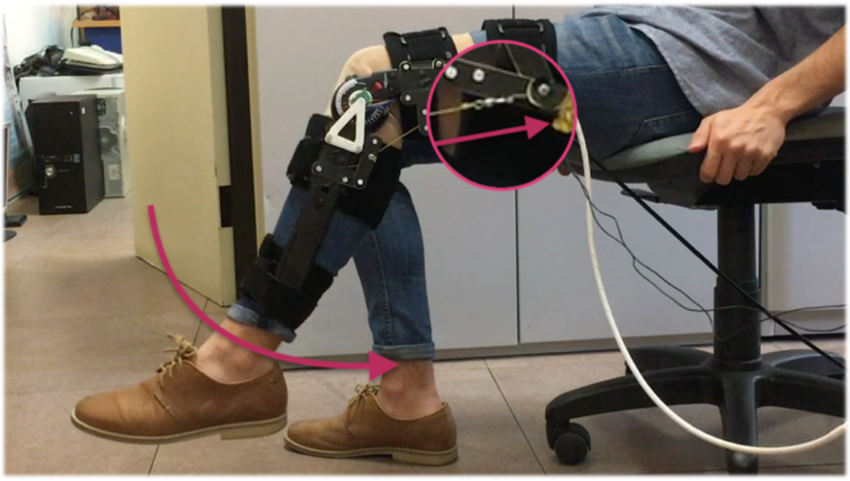

Figure 5.2 - Exoskeleton's performance during flexion with subject sitting

- In the results for the flexion while the subject was lying (Figure 5.3), presented in 4.1.3. Lying, four cycles were obtained, with a period of 14s in total – 3 where destined to the flexion, and the rest to the antagonist movement – in an interval of 12º-58º. Similarly to the standing trial, the exoskeleton was functioning against gravity, lifting the whole weight of the shank.

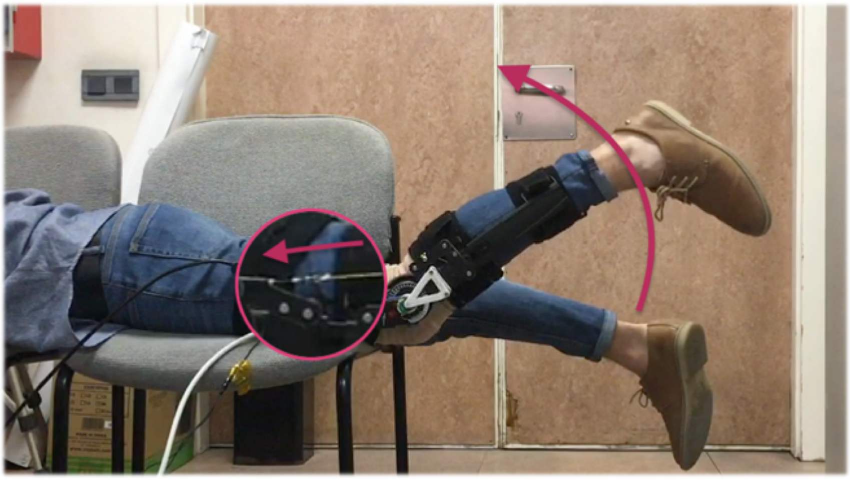

Figure 5.3 - Exoskeleton's performance during flexion with subject lying

- In the results for the extension while the subject was standing (Figure 5.4), presented in 4.1.1. Standing, four cycles were obtained, with a period of 11s in total – 2 where destined to the extension, and the rest to the antagonist movement – in an interval from 44º to 0º. This motion was favored by gravity.

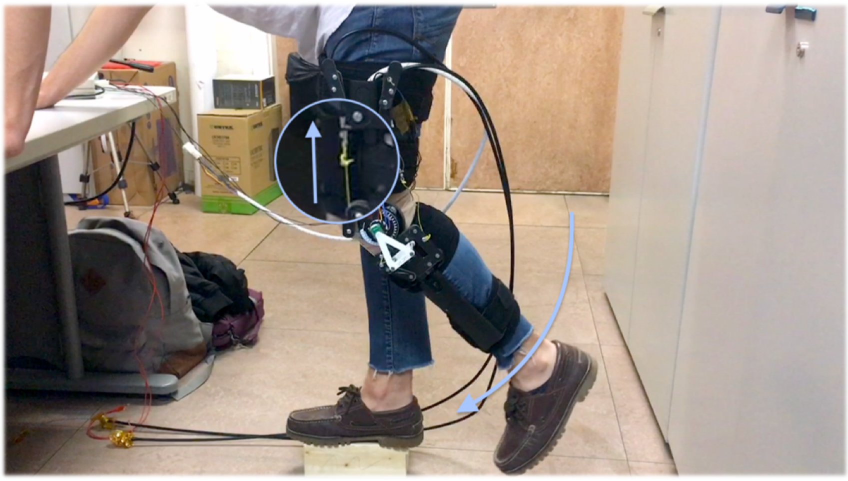

Figure 5.4 - Exoskeleton's performance during extension with subject standing

- In the results for the extension while the subject was sitting (Figure 5.5), presented in 4.1.2. Sitting, three cycles were obtained, with a period of 16s in total – 3.5 where destined to the extension, and the rest to the antagonist movement – in an interval from 50º to 10º. In this trial the exoskeleton was functioning against gravity, withstanding the whole weight of the shank.

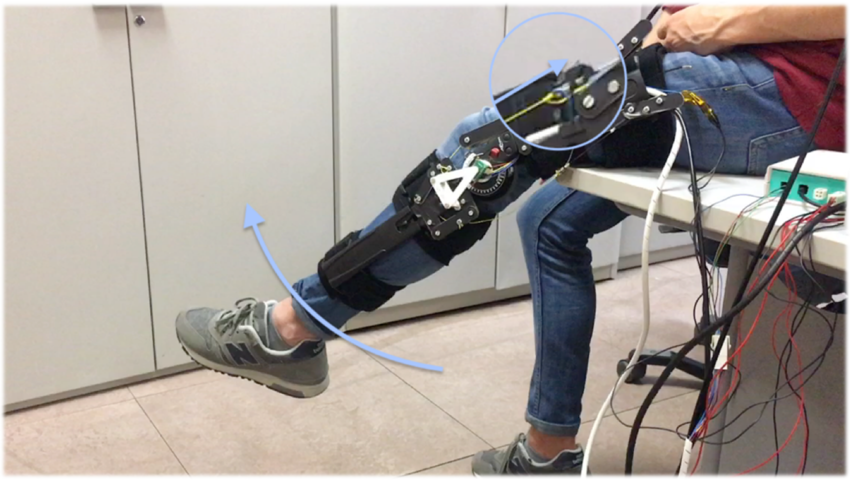

Figure 5.5 - Exoskeleton's performance during extension with subject sitting

- Finally, in the results for the extension while the subject was lying down (Figure 5.6), presented in 4.1.3. Lying, three cycles were obtained, with a period of 17s in total – 3 where destined to the extension, and the rest to the antagonist movement – in an interval of from 60º to 15º. Moreover, during this trial the exoskeleton was functioning in favor of gravity.

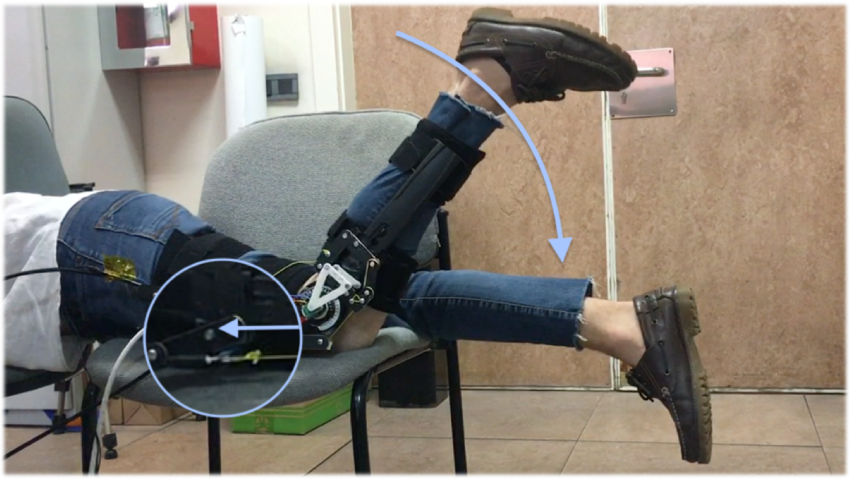

Figure 5.6 - Exoskeleton's performance during extension with subject lying

6. SOCIO-ECONOMIC IMPACT

As any other advanced technology, wearable robotics and rehabilitation exoskeletons are changing the field of medical therapy. Furthermore, the breakthroughs on bioengineered orthoses, especially regarding the ones designed for lower limbs, are the consequence of meaningful social and economic changes.

On the subject of social impact, the usage of these exoskeletons has been proven to augment the quality of life for subjects with neurological or musculoskeletal lesions [73]. They are an alternative for conventional therapies, that in a future might be used not only in a medical environment, but also in the daily life.

From the rehabilitation point of view, these devices present several upgrades to traditional methods, which were presented in 2.2.4. Medical Rehabilitation. In addition, considering the physiological aspects, with the patient's mobility, all the complications related to a sedimentary lifestyle would disappear, such as cardiovascular and/or urinary diseases, diabetes, obesity, etc. Lastly, it would have great psychological benefits for the patient since the partial recovery of autonomy opens a new palette of possibilities. It could even reinsert the patient in society and the labor market as an active member.

These devices have also impacted the economy since they provide a long-term solution to a problem that had not been solved so far. The growth of this industry is represented in market analysis carried out by F. Ferrati et al in 2013 [73]. Besides, it shows how medical robotics are the most valuable robots, with a mean price higher than one million dollars.

Despite these sales figures, the number of medical robotic devices augmented in 2011 by a 13% compared to the previous year, with more than a thousand units sold. Furthermore, within the group of medical robots, the vast majority were intended for surgery and rehabilitation, with a total of 156 units. Even more, it is estimated an annual growth of 41% with more than 10,000 robotic exoskeletons sold by 2020.

Unfortunately, most of the powered orthosis are priced between \$60,000 and \$120,000, making them unaffordable by average individuals. Even medical centers or hospitals decide to rent instead of purchasing them. Luckily, many companies like Argo Medical Technologies, are turning around the situation and sold around Europe twenty exoskeletons for particular use, at 52,000€ each. This proves the possibility of affordable "low-cost" rehabilitation exoskeleton.

6.1. Project’s Budget

In order to analyze the affordability of the knee exoskeleton, a budget estimation was performed, accounting for both, the materials - described in 3.1. Materials- and the human labor required for the completion of the project.

6.1.1. Materials’ Cost

The price for each element required for the design of the exoskeleton, as well as the electronic components, SMA actuators, hardware and software is presented in Table 6.1.

Table 6.1 - Material's cost

	Element	Number Of Items	Unitary Price (€)	Price (€)
Exoskeleton	DonJoy’s Knee Brace	1		170
	Metallic Flat Braces	18	0,25	4.5
	Magnetic Rotary Sensor	1		9.32
	Fishing Line	5m	0.12€/m	0.6
	SMA Crimper	2	1	2
	Wire Connector Crimp	4	0.025	0.10
	3D printed elements	3		15
	Pulley	1	1	1
	Screws and Nuts	--		10
			Total	**212.52**
Actuators	Nitinol Wires 90º	21,6m	6€/m	129.6
	Bowden Cable	3,6m	1.2€/m	2.16
	Teflon Tubes	4m	1.4€/m	5.6
			Total	**137.36**
Electronic Circuit	Microcontroller	1		16.50
	Power Board	1		26.82
	Connectors / Wires	--		20
			Total	**63.32**
Hardware And Software	Matlab/Simulink License	1	69€/48months	8.64
	Sketch Up	1		Free
	3D Printer	1		500
	Power Source	1		120
			Total	**628.64**
			Final Price	1041.84€

6.1.2. HUMAN LABOR

As a final bachelor thesis for the degree of Biomedical Engineering at University Carlos III of Madrid, the number of associated with the subject are 12 ECTS, which corresponds to 360h of workload. These values were taking into account to evaluate the human labor, as presented in Table 6.2. The salary information was estimated based on 1,280 $^{€}/_{month}$ for an ungraduated engineering student and 2,400 $^{€}/_{month}$ for the engineer supervisor.

TABLE 6.2 - HUMAN LABOR

	EMPLOYEE	TIME (H)	PRICE PER HOUR (€/H)	PRICE (€)
HUMAN LABOR	BIOMEDICAL ENGINEERING STUDENT	360	8	2,880
	ENGINEERING SUPERVISOR	30	15	450
			FINAL PRICE	**3,330€**

7. REGULATORY FRAMEWORK

In an emerging technology as the field of medical robotics, it is necessary to focus, not only on its developments and profitable outcome, but also become aware of the impact these devices are capable of having on society. Specially in the health care sector, for medical workers, therapists, patients, etc.

For these reasons, it is important that governments take measures on the matter, to ensure the safety of the exoskeleton's wearer [74]. Therefore, certain laws and legislation are required in order to ensure the proper performance of these products, by comparing them to certain standards.

This chapter intends to give a brief description of current legislation applicable to medical and sanitary apparatuses, including powered exoskeletons. However, depending on the country or region being studied, one might find different regulations applicable to these instruments.

Even so, most of them agree on the classification of medical devices made by the World Health Organization, which defines them as: "any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of: diagnosis, prevention, monitoring, treatment or alleviation of disease" [75].

In addition, according to the Global Atlas of medical devices, written by the same organization, the region with the highest number of countries having a legal framework for medical devices is Europe (91%), as seen in Figure 7.1 [76]. The remaining regions are: African region (AFR), American region (AMR), Eastern Mediterranean region (EMR), South-East Asia region (SEAR) and Western Pacific region (WPR).

In Europe, a new legislation concerning the use of medical devices came into effect the 25th of May 2017, Regulation (EU) 2017/745 [77]. Its aim was to update the articles related to the placement, distribution and usage of sanitary products on the European Union (EU) market. It also includes rules for the evaluation procedure of such devices, as well as new methods to improve and guarantee the patient's safety, by introducing more stringent classification techniques and post-market surveillance.

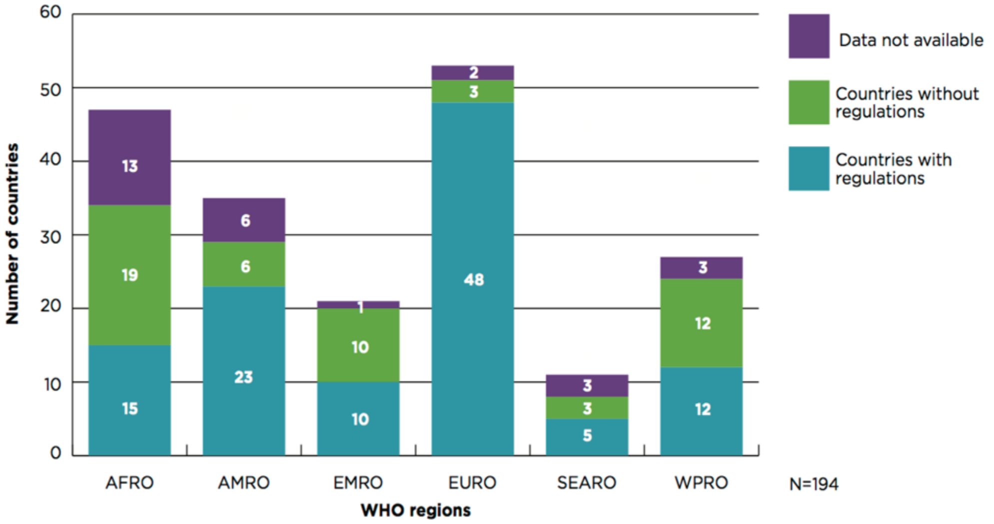

Figure 7.1 - Countries with a legal framework for medical devices

In relation to the medical robots intended for rehabilitation and interventions with the human body, the European Parliament resolution of 16 February 2017 with recommendations to the Commission on Civil Law Rules on Robotics [78] states the imperative necessity for the creation of ethical committees in hospitals and other sanitary institutions. It also remarks the requirements to offer universal access to robot control, surveillance and maintenance at any time of the rehabilitation process, to ensure the safety of the user.

Across the Atlantic, the Food & Drug Administration (FDA) is the organization in charge of the management of the legislations and ensuring its fulfillment in the United States. It has classified actuated lower-limb exoskeletons as class II biomedical devices. This means that the usage of second-class apparatus involves certain risks for the patient and implies the need for a premarket notification (510k) before its commercialization.

The code of Federal Regulations, in Title 21, Chapter I, has a section dedicated for the rules that apply to Physical Medicine Prosthetic devices. In particular, subpart D is reserved for powered lower extremity exoskeletons (§890.3480) [79]. It defines these devices as: “a prescription device that is composed of an external, powered, motorized orthosis that is placed over a person's paralyzed or weakened limbs for medical purposes”.

It sets numerous controls to ensure the biocompatibility of the parts that are in contract with the human body; optimal electrical insulation to prevent electrocution; thermal safety, especially in devices powered with mechanisms that reach high temperatures; software verification and hardware validation to avoid any hazardous events…

Finally, regarding the patentability of the device, since this project was based on an already commercialized and registered passive orthosis, it is not possible. Nevertheless, the considerations and learning obtained from this thesis might be valuable for future work where the exoskeleton is designed and built entirely in the robotics lab.

8. CONCLUSION

To conclude the project, this chapter includes an overall evaluation, organized as follows. First, it analyses the knee exoskeleton, then the benefits and disadvantages of the SMA actuators. Lastly, the outcome of the final device and its performance is explained. Moreover, it includes few considerations for future work on lower limb exoskeletons.

8.1. EVALUATION OF THE PROJECT

As far as the design and structure of the exoskeleton is concerned, a functional prototype for passive rehabilitation of the knee was built, meeting the objectives stablished at the beginning of the project. Moreover, it was able to tests its resilience and performance, with the help of the SMA actuators. As a result, the following advantages were obtained:

- The possibility of using DonJoy's knee brace as a starting point, allowed the fixation of the degrees of freedom not relevant for the project, focusing only on the flexion and extension. Moreover, it coupled the exoskeleton's axis with the knee joint
- This last feature was very useful since it allowed the integration of a rotary magnetic sensor on the device's hinge to feed the control loop. It gave precise and accurate measurements, verified by the angle values written on the exoskeleton.
- A metallic framework was built and adapted to fit the ergonomic structure of the orthosis. It was proven to resist the weight of the human shank and withstand the stresses related to the rehabilitation process, at different positions – sitting, standing and lying down.
- All of this resulted on a portable, light and secure rehabilitation tool which takes into high consideration the user's comfort and security, by providing the patient an adaptable, comfortable, and thermally and electrically insulated product.

Regarding the SMA actuators, it was calculated the torque necessary to lift the shank, along with the number of wires and length required to actuate the orthosis. Moreover, it was installed on the actual structure and tested. Thus, the strengths and weak points related to the use of such new technology can be described:

- The actuators based on shape memory alloys present as the main advantage the lightness of the action mechanism, in comparison to conventional actuators used in other exoskeletons. As a whole, the system encompassed by the Nitinol fibers, Teflon tubes and Bowden cable barely weights 0.7kg. Nevertheless, the relationship between the torque-weight ratio is optimal.
- Together with the mechanisms' low weight, an additional strong point is its silent behavior. The portability, lightness and absence of noise are unconditional requirements to design a product destined to be used in an medical and sanitary environment, like hospitals or rehabilitation centers.
- Moreover, the total cost just for the actuation mechanism did not surpass the 140€, as presented in 6.1.1. Materials' Cost. Hence, it can be concluded that is a low-cost actuator system.
- On the other hand, the accumulation of heat within the Bowden cable presents a substantial issue, since it obstructs the cooling process making very difficult for the user to do the opposed movement. A solution to this problem would be to program the actuators as antagonists. This way, when one has contracted, the contrary would pull from it, helping the recovery of its initial length. This solution has been demonstrated in other exoskeletons, such as the hand [54] or wrist [70].

Therefore, it can be concluded that the Shape Memory Alloys are a viable, light, low-cost and noiseless alternative to substitute conventional actuators. Even though, it is not perfect and presents some drawbacks, they can be easily solved in future exoskeletons. Besides, they bring a relevant added-value to the field of rehabilitation exoskeletons.

All in all, combining the assessments regarding the knee exoskeleton, its structural framework and the Nitinol actuators; the overall performance of the device can be addressed in order to make a final conclusion of the project:

- The efficiency of the devices was described in 5. Discussion, where it was proven how the apparatus mimicked properly the mandatory motions for the correct recovery of the knee joint, at three different positions.

- In order to avoid the accumulation of heat within the Bowden cables and allow the cooling of the SMA wires, it was shown how the exoskeleton is able to withstand three to four cycles of actuation without stopping. The velocities obtained for each cycle are presented in TABLE. It can be seen how, when the motion is in the direction of gravity, the velocity is much higher.

Table 8.1 - Velocity of Actuation

	Position	Angle (Degree)	Number Of Cycles	Time Per Cycle (S)	Time Actuated (S)	Velocity Actuation (Deg/S)	Favored By Gravity
Flexion	Standing	50	4	14	4	12.5	no
	Sitting	42	4	12.5	2.5	16.8	yes
	Lying	50	4	14	3	16.7	no
Extension	Standing	44	4	11	2	22	yes
	Sitting	40	3	16	3.5	11.4	no
	Lying	55	3	17	3	18.3	Yes

- Therefore, it can be concluded that in both movements, the angle measured from the exoskeleton adjusted to the reference position. The reason why the extension was controlled with the enable switch is because it was easier to handle and to show that both can be controlled with either the enable or the reference position.
- On another note, the weight of the finished product, was less than 2kg. Hence, it can be considered light and acceptable from the point of view of the patient’s comfort. In addition, thanks to the flexibility provided by the Bowden cables, the actuators can be slightly rolled and placed on a table, as well as the box containing the electronic circuits.
- Lastly, the overall cost of the final assembly -as shown in 6.1.1. Materials’ Cost- including the exoskeleton, actuators, electronic components and hardware and software was approximately 1042€, which compared to most lower extremity rehabilitation exoskeletons with similar purposes, it can be defined as low-cost. Nevertheless, this is just a prototype version, not a marketable one. Further research is needed before reaching the medical environment.

- To sum up, a low-cost, light, noiseless, portable lower-limb exoskeleton has been designed, built and actuated for passive rehabilitation as part of this Bachelor Thesis. Throughout the project, several problems were tackled and solved. Besides, it was necessary to assume certain conditions for the optimal performance of the final product.

8.2. FUTURE WORK

In this last chapter, several tasks are described, in order to be considered in future versions of the knee exoskeleton, with the intention of solving the issues detected in this prototype and improve some of its characteristics.

- The main objective for future projects has to be the integration of an antagonist system of actuation. This way, the exoskeleton can perform both, flexion and extension, one after the other.
- To achieve this, a new power board able to supply the amount of power needed for the contraction of each group of SMA alternatively has to be designed. Its tracks need to be wide enough so when connected to the power source, it does not burn the rest of the electronic components.
- Moreover, the control software in Matlab should be redesigned to avoid the activation of both actuators at the same time. This new control system, needs to be very precise and give enough time to one mechanisms to cool down before actuating the antagonist. Otherwise, if the exoskeleton were to pull from warm SMA fibers, it could lead to its breakage, compromising the patient’s safety.
- Secondly, a new orthosis could be designed from scratch based on the structural framework of DonJoy’s brace, as well as its other properties, such as the lightless, adaptability to different-sized legs, its comfort, etc. This new orthosis could integrate the sensor within a protective shell, to substitute the fragile 3D-printed framework from this project. Lastly, it would be optimal if it is designed to be used in either of both legs indifferently, since the present prototype was built only for the left limb.

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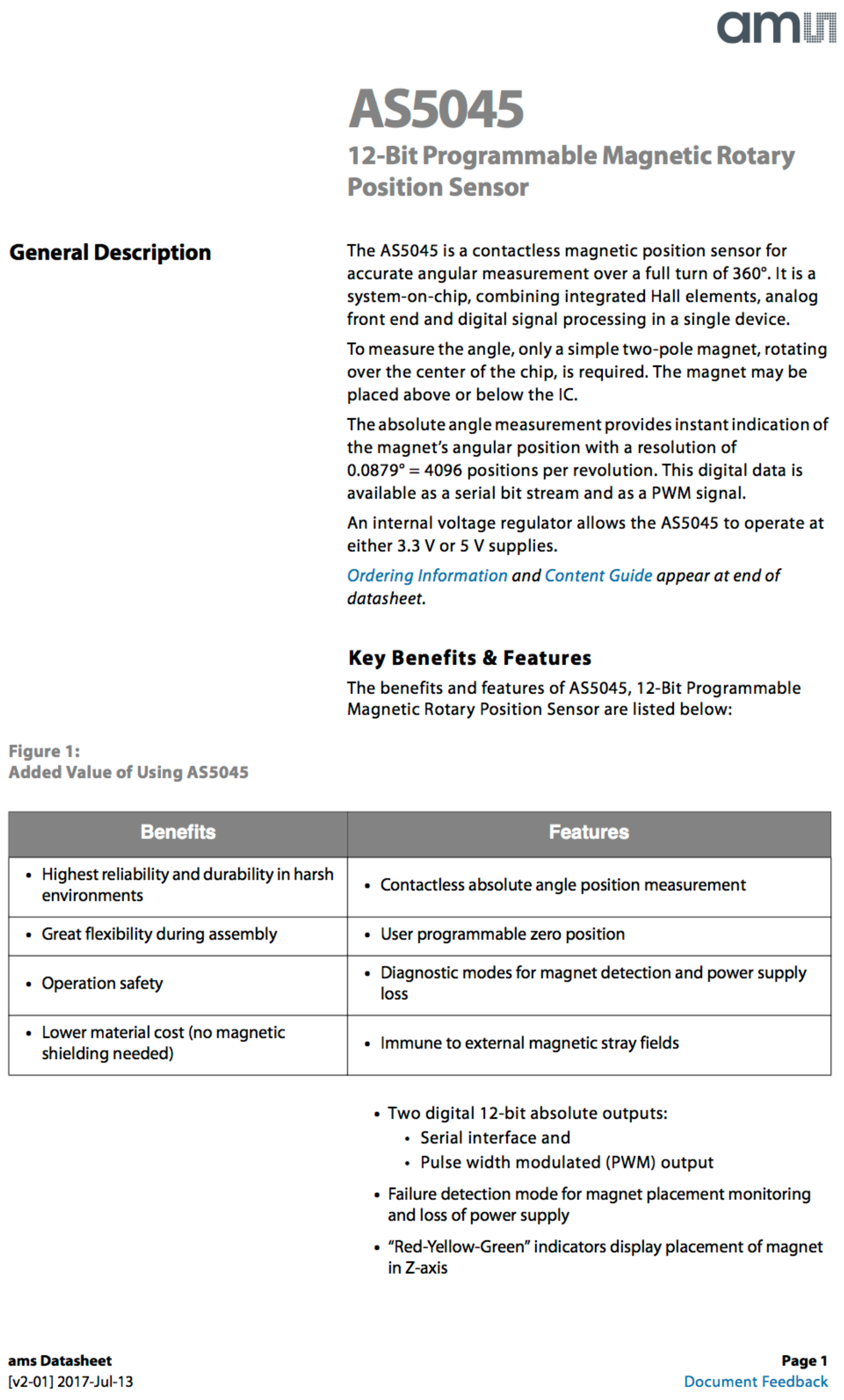
10. APPENDIX

APPENDIX A: MAGNETIC ROTARY POSITION SENSOR DATASHEET



AS5045

12-Bit Programmable Magnetic Rotary Position Sensor

General Description

The AS5045 is a contactless magnetic position sensor for accurate angular measurement over a full turn of 360°. It is a system-on-chip, combining integrated Hall elements, analog front end and digital signal processing in a single device.

To measure the angle, only a simple two-pole magnet, rotating over the center of the chip, is required. The magnet may be placed above or below the IC.

The absolute angle measurement provides instant indication of the magnet's angular position with a resolution of 0.0879° = 4096 positions per revolution. This digital data is available as a serial bit stream and as a PWM signal.

An internal voltage regulator allows the AS5045 to operate at either 3.3 V or 5 V supplies.

Ordering Information and Content Guide appear at end of datasheet.

Key Benefits & Features

The benefits and features of AS5045, 12-Bit Programmable Magnetic Rotary Position Sensor are listed below:

Figure 1:
Added Value of Using AS5045

Benefits	Features
• Highest reliability and durability in harsh environments	• Contactless absolute angle position measurement
• Great flexibility during assembly	• User programmable zero position
• Operation safety	• Diagnostic modes for magnet detection and power supply loss
• Lower material cost (no magnetic shielding needed)	• Immune to external magnetic stray fields

- Two digital 12-bit absolute outputs:
  - Serial interface and
  - Pulse width modulated (PWM) output
- Failure detection mode for magnet placement monitoring and loss of power supply
- "Red-Yellow-Green" indicators display placement of magnet in Z-axis

- Serial read-out of multiple interconnected AS5045 devices using Daisy Chain mode
- Tolerant to magnet misalignment and airgap variations
- Wide temperature range: - 40ºC to 125ºC
- Small Pb-free package: SSOP-16 (5.3mm x 6.2mm)

Applications

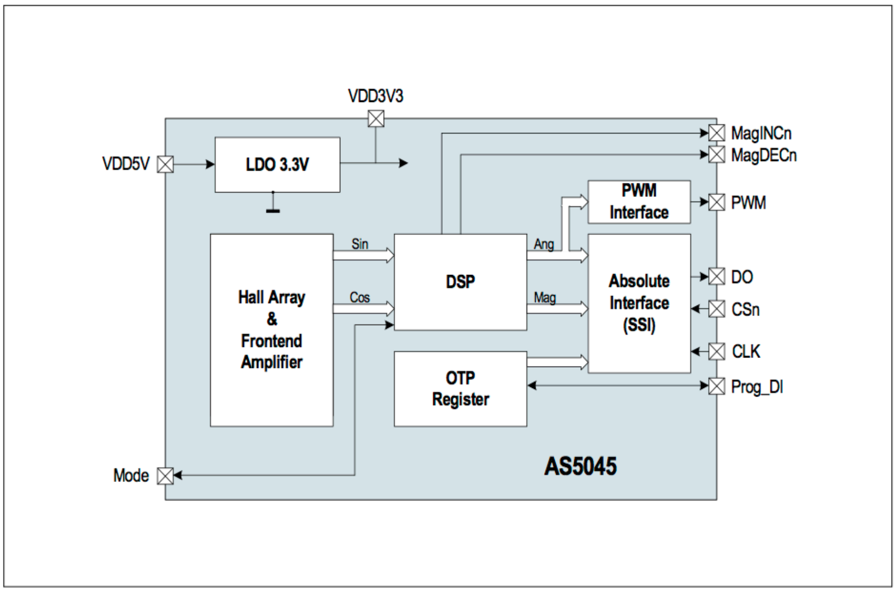
The AS5045 is ideal for industrial applications like

- Robotics,
- Stepper motor control,
- RC servo control and
- Replacement of high-end potentiometers.

Block Diagram

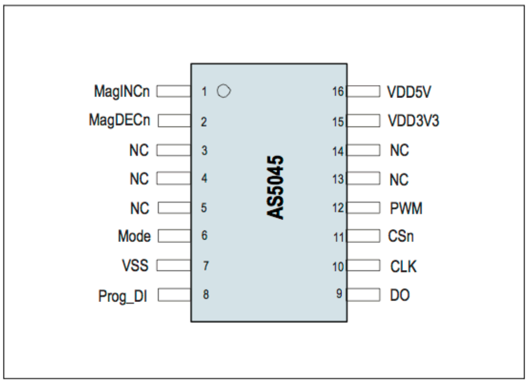
The functional blocks of this device are shown below:

Figure 2:
AS5045 Block Diagram



Pin Assignment

Figure 3:
Pin Assignment (Top View)



Pin Description

Figure 4 shows the description of each pin of the standard SSOP16 package (Shrink Small Outline Package, 16 leads, body size: 5.3mm x 6.2mmm; see Figure 3).

Pins 7, 15 and 16 supply pins, pins 3, 4, 5, 6, 13 and 14 are for internal use and must not be connected.

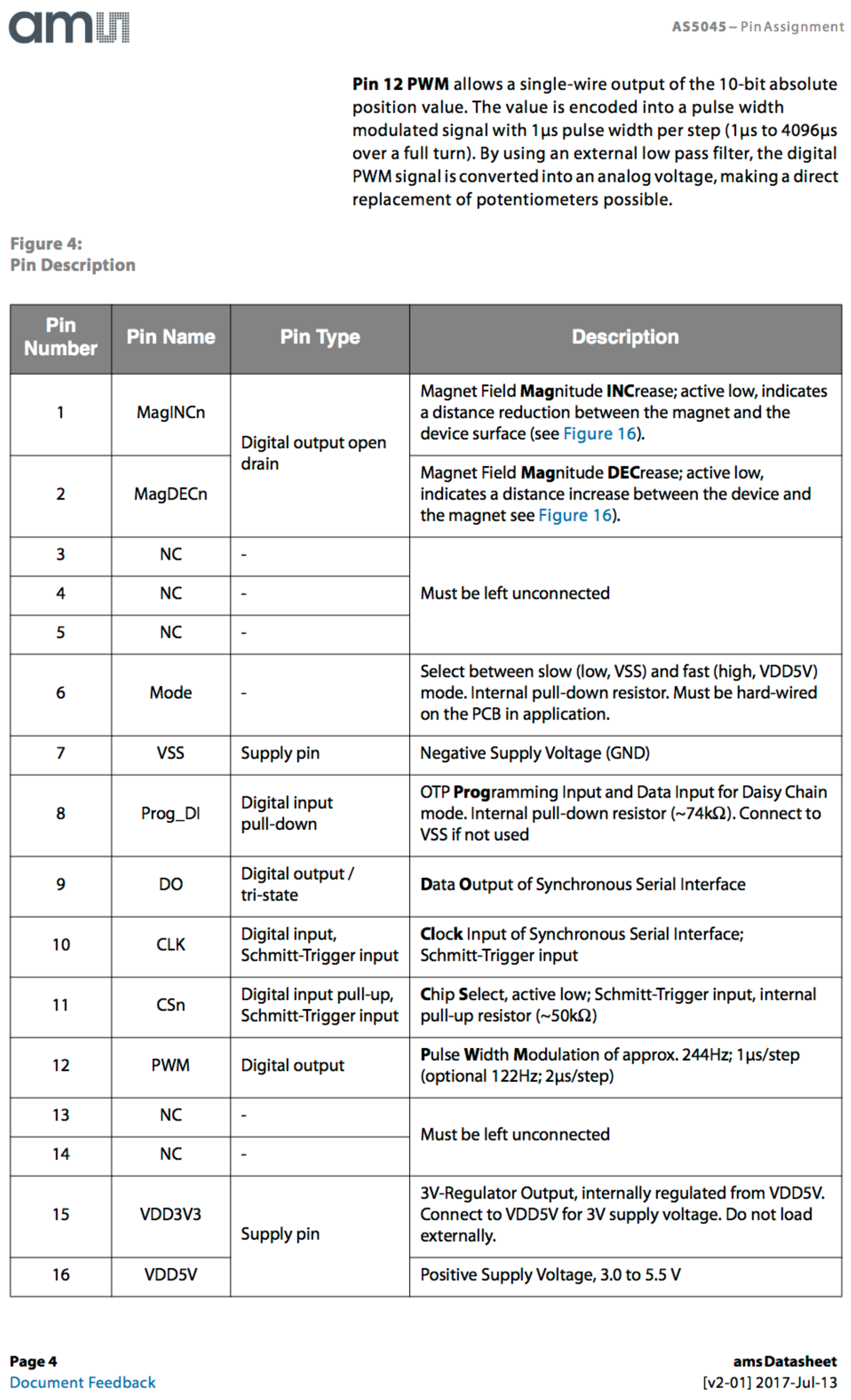
Pins 1 and 2 MagINCn and MagDECn are the magnetic field change indicators (magnetic field strength increase or decrease through variation of the distance between the magnet and the device). These outputs can be used to detect the valid magnetic field range. Furthermore those indicators can also be used for contact-less push-button functionality.

Pin 6 Mode allows switching between filtered (slow) and unfiltered (fast mode). This pin must be tied to VSS or VDD5V, and must not be switched after power up. See Mode Input Pin.

Pin 8 Prog is used to program the zero-position into the OTP. See Zero Position Programming.

This pin is also used as digital input to shift serial data through the device in Daisy Chain configuration. See Daisy Chain Mode.

Pin 11 Chip Select (CSn; active low) selects a device within a network of AS5045 magnetic position sensors and initiates serial data transfer. A logic high at CSn puts the data output pin (DO) to tri-state and terminates serial data transfer. This pin is also used for alignment mode and programming mode (see Figure 27).



Pin 12 PWM allows a single-wire output of the 10-bit absolute position value. The value is encoded into a pulse width modulated signal with 1µs pulse width per step (1µs to 4096µs over a full turn). By using an external low pass filter, the digital PWM signal is converted into an analog voltage, making a direct replacement of potentiometers possible.

Figure 4:
Pin Description

Pin Number	Pin Name	Pin Type	Description
1	MagINCn	Digital output open drain	Magnet Field **Mag**nitude **INC**rease; active low, indicates a distance reduction between the magnet and the device surface (see Figure 16).
2	MagDECn		Magnet Field **Mag**nitude **DEC**rease; active low, indicates a distance increase between the device and the magnet see Figure 16).
3	NC	-	Must be left unconnected
4	NC	-	
5	NC	-	
6	Mode	-	Select between slow (low, VSS) and fast (high, VDD5V) mode. Internal pull-down resistor. Must be hard-wired on the PCB in application.
7	VSS	Supply pin	Negative Supply Voltage (GND)
8	Prog_DI	Digital input pull-down	OTP **Prog**ramming Input and Data Input for Daisy Chain mode. Internal pull-down resistor (~74kΩ). Connect to VSS if not used
9	DO	Digital output / tri-state	**D**ata **O**utput of Synchronous Serial Interface
10	CLK	Digital input, Schmitt-Trigger input	**Cl**oc**k** Input of Synchronous Serial Interface; Schmitt-Trigger input
11	CSn	Digital input pull-up, Schmitt-Trigger input	**C**hip **S**elect, active low; Schmitt-Trigger input, internal pull-up resistor (~50kΩ)
12	PWM	Digital output	**P**ulse **W**idth **M**odulation of approx. 244Hz; 1µs/step (optional 122Hz; 2µs/step)
13	NC	-	Must be left unconnected
14	NC	-	
15	VDD3V3	Supply pin	3V-Regulator Output, internally regulated from VDD5V. Connect to VDD5V for 3V supply voltage. Do not load externally.
16	VDD5V		Positive Supply Voltage, 3.0 to 5.5 V