

UNIVERSITAT DE BARCELONA

Final Degree Project Biomedical Engineering Degree

ANKLE BIOMECHANICS TESTING DEVICE

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Acknowledgments

The development of the Bachelor Thesis has been a challenge for me. From the beginning I knew it will be a huge opportunity to grow as a biomedical engineer and understand much better how an engineering project should be carried out. I had in mind in theory how this type of projects should be done, however in reality is quite more complex. The most important learning was how to manage a project when there are difficulties on the path, how to stay calm and visualize an alternative path in order to fulfil the objectives and the timespan. For future projects, I would like to improve myself by being more flexible with the organization of the work, to be able to adapt the project to adverse circumstance in order to continue with the developing of the work.

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Abstract

Ankle biomechanics is one branch of medicine, more precisely of orthopaedics that is growing in the recent years. Ankle injuries due to ankle lateral ligament damage are causing Chronic Ankle Instability in more patients every year, this issue affect them in his daily life reducing their mobility. In addition, there are still different therapies that can be researched and tried in order to find a more appropriate treatment. This Bachelor's Thesis wants to understand how ankle biomechanics works to be able to facilitate a useful instrument to do research in this sector in order to understand better how the ligaments forming this joint work and which are the possible treatments to heal these injuries.

The methodology followed during the study has been divided in different parts. First of all, a thorough biographic research has been done in order to understand in which point is nowadays ankle's biomechanics investigation. Afterwards, once it is known the state of technology of the sector, the development of hardware and software for the improvement of the prototype has been done.

The final result, is the minimum functional device available now, with a new hardware and software composition. By taking as initial point the device created by Dr. Jan Martínez, the cuboid scaffold has been used, then Arduino Uno board and software has been installed in order to control the electric motors.

However, this is only an initial study further investigations have to be done in order to have the final functional device. It will be needed to do a complete clinical trial in order to verify its functionality to obtain the CE validation for selling the medical device.

Key words: Ankle biomechanics, Arduino Uno, Stepper Motors, Biomechanics device



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Glossary of terms

- ATFL: Anterior Talofibular Ligament
- **CFL:** Calcaneofibular Ligament
- PTFL: Posterior Talofibular Ligament
- MRI: Magnetic Resonance Imaging
- CAI: Chronic Ankle Instability
- **PETG:** Polyethylene Terephthalate Glycol
- ABS: Acrylonitrile Butadiene Styrene
- AC: Alternating current
- **USB:** Universal Serial Bus*
- **ATD:** Anterior Drawer Test
- TTT: Talar Tilt Test
- IMU: Inertial Measurement Unit
- **R&D:** Research and Development
- **FDA:** Food and Drug Administration
- DC: Direct Current
- **PWM:** Pulse Width Modulation
- **CNC:** Computerized Numerical Control
- ICPS: In-Circuit Serial Programming
- GND: Ground
- **CPM:** Continuous Passive Motion
- WBS: Work Breakdown Structure
- PERT-CPM: Program Evaluation and Review Technique with its Critical Path Method
- SWOT: Strengths, Weaknesses, Opportunities and Threats analysis



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1. INTRODUCTION

1.1. Definition of the project

The project is based in the improvement of a machine prototype to study the biomechanics of the ankle, updating its design and implementing its use in anatomical research having in mind all the ethical and legal concerns to enter the machine in the market with a competitive approach.

1.2. Project Justification

First of all, to understand why it is mandatory to start this project is interesting to have an anatomical and physiological background of the ankle.

The ankle is the most distal joint of the organism and it is crucial to provide support. Furthermore, it is a synovial joint formed by the talus and the distal parts of the fibula and the tibia. The ankle joint has three degrees of freedom that are represented in Figure 1 [1], it can move in the transversal axis allowing plantar and dorsiflexion; in the frontal axis to produce inversion and eversion; finally, both axes can be combined to have an abduction and adduction movement. [2]



Figure 1: Ankle possible movements, defined depending on the axis

The main movement occurs primarily in the

sagittal plane, with plantar and dorsiflexion with a range of 65° and 75°. Contrary the frontal plane is approximately moved from 35° to 23° of inversion and 12° of eversion. It is important to keep in mind that the ankle range of motion can significantly change between individuals due to geographical and anatomical factors differences based on their activities of daily life. [3]

The articular surfaces involved in this joint are the talar trochlea, the medial malleolar face of the tibia, the lateral malleolar face of the fibula and the tibiofibular syndesmosis that can be observed in Figure 2 [4]. The joint capsule and ligaments are the responsible for providing reinforcement and elasticity to the whole complex, as it can be seen in Figure 3 [5]. Two large ligamentous complexes are the main actors in the stability of the ankle joint. On the one hand, the collateral ligament formed by the anterior talofibular ligament (ATFL), the calcaneofibular ligament (CFL) and the posterior talofibular ligament (PTFL). On the other hand, the medial collateral ligament formed by the three portions of the deltoid ligament. [6]



Figure 2: Ankle ligaments, seen in the lateral view and in the medial view



Furthermore, a syndesmosis is created between the tibia and the fibula which originates the tibiofibular syndesmosis. A syndesmosis is a fibrous joint that unifies two bones separated by means of a sort of membrane and/or a network of ligaments. The membrane and the ligaments responsible for connecting the bones forming a syndesmosis are called, respectively, the interosseous membrane and the interosseous ligaments [7]. One benefit from syndesmoses is that it can allow minimal mobility. The main functionality of the tibiofibular syndesmosis referring to the ankle joint is that it provides stability to that joint.



Figure 3: Osteology of the ankle joint, seen in the anterior view and in the lateral view

The whole ankle joint is divided into two different structures, the talocrural joint and the subtalar joint. They work in different ranges and in a coordinated way to ensure the whole movement of the ankle. This combination allows the foot to move in different planes, as explained previously. [8]

The most present injury in this joint is the ankle sprain. It is an injury that occurs when you roll or turn your ankle in an awkward way. This can stretch or tear the tough bands of tissue (ligaments) that help hold your ankle bones together [9]. The main function of the ligaments is to stabilize the joint and prevent excessive movements, so when the ligaments are forced beyond their normal range of motion, ligaments are injured. There are different risk factors that increase the chances of a sprained ankle, like: sports participation, uneven surfaces, prior ankle injury, poor physical condition and improper shoes. In addition, if there is not an appropriate treatment sprained ankle can lead to chronic ankle pain, chronic ankle joint instability or arthritis in the ankle joint.

After suffering an ankle sprain, is needed a doctor examination to verify the importance of the injury and the way of treating. The doctor examination can be physical by observation, palpation, range of motion and stability testing; or using imaging testing like x-rays or magnetic resonance imaging (MRI) scan [10]. After the examination the ankle sprains can be classified depending on how much damage has occurred to the ligaments, as it can be seen in the following table:



Table 1	Classification	of ankle	sprains
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Grade I	Grade II	Grade III
Slightly stretching and microscopic tearing of the ligament fibres	Partial tearing of the ligament	Complete tear of the ligament
Mild tenderness, bruising, and swelling around the ankle	Moderate tenderness, bruising, and swelling around the ankle	Significant tenderness, bruising, and swelling around the ankle
Typically, no pain with weightbearing	Mild pain with weightbearing	Severe pain and weightbearing
No instability on examination	Slightly instability on examination	Substantial instability on examination

The main problem of the ankle joint is the acute lateral ligament injury following a lateral ankle sprain, as it is seen in Figure 4 [11]. In this study performed at 2013 [12] they estimate that 25% of all injuries of the musculoskeletal system of the ankle are due to inversion injuries, and around 50% of those injuries are sport related. Moreover, it is estimated that one inversion injury of the ankle occurs for every 10.000 people each day, having around 7-10% of all admissions to hospital emergency department due to ankle sprains. In sports, ankle has become the most frequently injured part of the body having an impact of around 40% of all athletic injuries, being an important injury in basketball, football and trail running. Another important part of the population affected by ankle sprains is the militaries. It is demonstrated that military service members suffer ankle sprain more frequently than civilian population, around 58 people of 1000 persons in the USA military service are affected yearly [13]. These statistics can be explained due to the fact of the large number of hours spent by the cadets doing the physical preparation and by the fact of their physical requirements of the job. [14]



Figure 4: Ankle sprain suffer by the basketball player on the right food

The majority of ankle sprains occur in a range of population under 35 years old, most commonly in those aged between 15 and 19 years old [3]. The gender factor is also quite differential. There are several studies performed in different sports, such as basketball, that show that female players have a bigger risk of having an ankle sprain than its male counterparts. In the report "*The gender issue: epidemiology of ankle injuries in athletes who participates in basketball*" [15] has been demonstrated that females had 25% greater risk of sustaining a Grade I ankle sprains, ankle fractures or syndesmotic sprains. However, no clear factors have been identified due to the lack of studies on the difference in ankles according to gender. It was believed that the

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body of men and women would be the same, but with the professionalization of women's sport, it has been seen that women injuries are different and its prevention should be different too, so there is a lot of research to be done in this field. For example, female players have more tendency to break the cruciate lateral ligament of the knee due to their high amount of oestrogen hormone, so maybe it happens the same in the ankle.

In conclusion, ankle sprains occur in sports due to the sudden, unexpected or explosive movements that are performed when changing rapidly the direction of motion. If it is performed in an unfortunately way, an injury occurs because all the weight of the individual will be sustained by the ligaments explained previously. However, the ankle sprain can also occur out of the sports practice due to inappropriate step that may lead the ligament to resist a greater force that what they are expected to. The majority of injuries are due to supination and adduction of the planted-flexed foot, as it is explained before, that lead to ATFL injury. [16]

One big issue of lateral ankle sprains is the high re-injury rate: having had an ankle sprain doubles the risk of re-injury in the following year. This greater likelihood of re-injury could be due to an inadequate rehabilitation or premature return to sport [17]. In most of the patients the injury systems persist after the treatment has been done in a condition named Chronic Ankle Instability (CAI) affecting both the talocrural and the subtalar joint, osteoarthritis and other permanent sequalae that will affect the individual for his daily life. This issue requires in large portion of patients surgical management to avoid the appearance of degenerative changes to the joint; however, the surgical algorithm treatment is not clear.

Taking into account all the factors explained in this section, the product can be a differential factor in the study of ankle biomechanics, helping to increase the range of diagnostic and therapeutical approaches that may help to reduce the negative impact of the acute ankle sprain. Furthermore, it can be an important point to start a new branch of biomechanical investigation that help researches to understand how to treat CAI in a more accurate way.

The actual prototype is a cuboid aluminium structure that can reproduce the biomechanical motion of the ankle in a very primitive manner. The electronics implemented are quite limited and cannot be used to perform compound movements. Furthermore, there is not a specialized software implemented in order to guide the motion of the motors, hence reproduce the ankle motion desired. That's why this project will be done to improve the actual device and apply it to the medical world to try to find a solution to ankle instability.

1.3. Objectives

The main objective of this project is: "improve an existent device for the research of ankle biomechanics". To fulfil these objective different subobjectives, have to be achieved:

- **Investigation:** of the actual situation in the market and which can be the most suitable application.
- Study: of the state of the device to be conscious of its limitations
- **Software implementation:** for the control of the device and the obtaining of results.
- **Clinical trial:** to verify its motion with a real sample.



- **Discussion:** for what future lines of investigation can be done.

1.4. Scope and Limitations

In this section, the scope of the project and the different limitations that are present in the work will be presented.

The scope of the study included the following steps:

- Bibliographic research of ankle biomechanics, to understand the require of device implementation and analyse which can be the most interesting field to apply the final product. This will help to define the opportunities and the risk to launch the product into the market. Moreover, the weakness and the strengths of the product are studied to find their viability to succeed.
- Analysis of different hardware and software that can be possible to implement in the device to have the final product desired.
- Implementation of the software to control the device and get the results. Including, a validation of its functionality with different trials.
- Study the technical and economical possibilities of the project to achieve the main objectives and predict how it will behave in the market.
- Examination of the legal encloser in order to do the validation of the software.

One of the greatest limitations this project faced was the availability of materials, since some electronics have been needed, they have been ordered but there was a big delay until it was possible to work with them. This is how the real world works nowadays, due to the crisis in transports, so it was tried to accept this issue and adapt the course of the project to deliver the final result on time. Another important limitation will be the number of clinical trials done will be limited.

In all the process of the work it is necessary to keep in mind that the timespan will be an important limitation. The execution of this planning will be done in nine months, so the goals of the project will be adapted to future complications that can appear during the evolution of the final degree project.

1.5. Location of the project

The project has been done in the department of anatomy in Facultat de Medicina i Ciències de la Salut de la Universitat de Barcelona. Furthermore, the experimental tries to test the minimum viable product have been carried in the anatomy lab in the aforementioned department.



2. BACKGROUND

Before doing a market analysis, it is crucial to study general concepts of the project. As the state of the art to know exactly in which point is the actual prototype, as well as the current situation that concerns the whole project.

2.1. State of the Art (Technology)

The actual device developed by Dr. Jan Martínez Lozano is a functional prototype, that was designed using MICROSTATION (Bentley Systems, 1984), which would serve as the basis for the actual project. The idea of this section is to present how the actual prototype is built and its main functions, to see in which point is the actual prototype.

The device [18] consists in 12 pieces of 750 millimetres of 2020 aluminium profiles that form a cuboid system. Three axes of movement are defined to allow the three-dimensional movements that foot can do. To allow this motion three motors Nema 17 ® of 42 millimetres and 12 volts are used. This movements can be reproduced thanks to a cardan fixation designed and produced using printed materials of PETG ® and ABS ®. The foot is placed in neutral position above the horizontal axis and the leg is supported by a craniocaudal support made of polyvinyl chloride.

The motors can be distinguished as "Motor X" which moved the foot in the horizontal plane, adduction and abduction; "Motor Y" which is the responsible for the rotational movement, so it is the motor in charge of the inversion and the eversion of the foot; and "Motor Z" that are two modules working in a coordination form to make the dorsal and plantar flexion movements. To reproduce the movement a three-axis GRBL control board is used, but the movement is decided offline by the user thanks to a SainSmart ® offline controller module. This controller allows movement in any of the three axes and is quantified using four different scales: 0, 1; 1; 5 and 10. Then the motors transmit the movement using T8 lead endless screws.

From hardware point of view all electronic components are connected through the GBRL control board. It has different ports allowing the different connections as it can be seen in the Figure 5 [18], one for AC connector (1) to ensure its energy supply, an USB connecter (2) to connect the device to the computer, a Power switch (3) to turn on or turn off the prototype, the cable for the offline controller connector (4) explained before and three motors connections (5) to connect the board with motors used and to supply them with energy.



Figure 5: GBRL control board, where it is highlighted all the components explained



As a result, that can be seen in Figure 6 [18], the whole mechanism allows a free angular movement of the foot with two degrees of freedom while keeping the leg fixed.



Figure 6: Ankle Biomechanics Reproduction Machine made by Dr. Jan Martinez

2.2. State of the Situation

The study of the ankle biomechanics to find a solution for ankle pathology has become an important field of research due to their big impact in society. Furthermore, the biomechanical and kinematic study of ankle injuries has received more attention in last years, but the development of specific technology has not played an important role. It is true that biological modelling and three-dimensional finite element, three-dimensional motion capture system, digital technology study, electromyographic signal study were used for the basic research of ankle sprain, but not having specific and innovative application. [19] M. Terada and P.A. Gribble presented a work where a male with chronic ankle instability (CAI), has been used to study his motion analysis in order to understand his motion during a stop-jump task. For doing the analysis all the techniques explained before were used.

The main propose of this section is to illustrate different examples of studies that have been done in order to understand in what situation is nowadays ankle biomechanics research from a technological point of view.

Firstly of all, DeToro et al (2001) [20] published a study tittled *"Plantarflexion resistance of selected ankle-foot orthoses"* where the main pruporse of the study was to offer objective data about the control offered by specific ankle-foot orthosis desings, for having enough knowledge to judge clearly the effectiveness of a particular ankle-foot orthosis before completion of the fitting. Focusing on the testing apparatus, a simple digital tensiometer have been used in order to quantify the plantarflexion resistence supplied at the forefoot for a variety of common orthoses.



foot segment.

A leg model was created for assessing the experiments, using a negative impression filled with plaster to create a postive model, following the industrial standards. At the end, a final

model was obtained which may be considered representative of a typical large adult male lower leg. Afterwards, the lamintaed model was used to create the test apparatus that is going to be described.

The test apparatus was a single-axis in the transmalleolar region of the wood-reinforced foam model, it allowed dorsiflexion from 20° to 20° of plantaflexion to simulate normal ankle motion in this plane. Then plantarflexion motion was measured by placing a stainless steel band across the dorsal face of the foot, over the metatarsal heads (25.4 cm anterior to the ankle joint as in Figure 7 [20]). Finally, a MARK-10 digital force gauge was connected from the steel band to a screw drive, to apply a force that the model can plantarflex. For measuring the angle, a liquid-filled device was atttached to the plantar surface of the



Figure 7: Ankle-Foot Orthoses testing device

Secondly a most recent study done in 2020, titled "A cadaveric study to compare stability of reconstruction techniques using 1 or 2 fibular tunnels", helps to understand a new technical approach [21]. For this study, 10 cadaveric ankles were divided in 2 groups and tested in 3 stages: intact, sectioned, and reconstructed lateral ankle ligaments; using both approaches 1 or 2 fibular technique to quantify stability in different flexion portions. In addition, bone displacements were measured using motion capture. For this report, the key point is to understand the technology that controlled the flexion.

The biomechanical testing setup was a universal testing machine (Zwick 1456, Zwick GmbH & Co KG). As it can be seen in Figure 8 [21], tibia was fixed with the cylindrical clamping with screws pointing all sides into the bone, making possible to add weight on the tibia to be on unload or load state for the stress test, leaving the fibula to articulate freely. Then, the foot was fixed on a wooden footplate using two screws into the calcaneus and a tight strap running over the metatarsal heads. On the image 8, it can be seen in figure A how the motion was produced using the motors; however, the setup doesn't make possible the plantarflexion and dorsiflexion that could not be changed during test runs as in the study protocols of Bahr et al. [22] The test is done in different flexion angles by applying different forces, motions and torques. The anterior drawer test (ATD) is done to check the ATFL ligament, the displacement of the talus and calcaneus in relation to the tibia along the sagittal axis, as well as the internal rotation of the talus in the longitudinal axis. Afterwards, thanks to the statistical study of the data acquired some conclusions related to the talofibular and calcaneofibular laxity and stiffness are used to describe ankle stability.





Figure 8: Biomechanical Testing Setup of the study, in Figure A it can be seen the axis of rotation and in Figure B the actual device with a cadaveric ankle to check its performance

In the study published by Guerra-Pinto et al in 2020 [23] it was tried to evaluate the evolution of the lateral ankle ligaments using gyroscopes devices while they performed sequential sectioning of the ATFL, CFL and PTFL ligaments in the ankle by applying gravity stress in injured cadaver ankle. Under gravity stress, the angular momentum of the talus in relation to the tibia was measured.

The experimental setup shown in Figure 9 [23] is composed of a wooden structure to hold the lower limb; three Kirschner wires were inserted in the tibia and fixed to the wooden structure in order to stabilize the tibia and only allow ankle movement; and finally, the measurement system composed by an IMU system fixed on the talus and controlled by an Arduino Mega 2560 board, used as a microcontroller, with three-axis accelerometer and a three-axis gyroscope to obtain the movement angles. In addition, a software was used for the acquisition and interpretation of the raw data received from the IMU sensor. After performing the initialization, the calibration and filtering of the sensor's values, the data can be used. Moreover, using Tait-Bryan angles a new software was developed to obtain in real time the angular values relative to the difference between the initial orientation of the ankle's body fixed axes and the final orientation originated by extrinsic rotations.



Figure 9: Device components where it can be seen the wires used for stabilizing the tibia, the IMU sensor and the wooden structure



Finally, the paper published by K. Zhang et al about "Effects of hindfoot arthrodesis on foot and ankle motion: Measurements in cadaver specimens" [24]. The main idea of the research was to compare the range of motion in adjacent joints before and after ankle arthrodesis to determine the effects of each procedure on joint motion. The range of motion was measured using a 3-axis coordinate measuring machine in a control foot and in feet.

The experimental procedure shown in Figure 10 [24] was designed to immobilize the specimen foot with a specimen holder made of steel fixed to vertical bar, along which the foot could be rotated and flexed. The forefoot was supported by two aluminium plates to determine the degree of plantarflexion in the forefoot. Also, a weight was used in order to determine if there were differences between loaded and unloaded conditions. When all the set-up was ready, they started applying force loadings to obtain different calculations to extract some conclusions in the different positions.



Figure 10: Specimens using the testing device in neutral position

In conclusion, the next step is to understand all the technologies in this section and why researchers use this type of devices, and see if the functional prototype of this study can be suitable. As it is said before, the main goal of this study is to provide one functional prototype that can be specifically used on the ankle's field.



3. MARKET ANALYSIS

On this section, the market analysis is done taking into account the sector which the work is addressed to, the evolution that has this sector during the last years and what is the expectation for the incoming years in which the product will be released.

3.1. Target Sectors

The market sector where the product is going to be useful is the medical field, in particular the branch of medicine specialized to study the biomechanics of the ankle joint. As it is explained before, this work will help to change the point of view that orthopaedic surgeons have in treating ankle's injuries, as well as to bring a useful tool for researchers to verify it owns researches. Although the first minimum viable product is going to be addressed for primary research in anatomy, future applications can be also introduced.

The research specialized in ankle biomechanics is done by different institutions, universities or medical centres such as hospitals. In addition, private companies can be future clients as this product will help them to check if their treatments or prosthetics will be suitable for the population, checking wearing of materials and stress. In conclusion, there will be several types of laboratory groups that can be interested in this study, highlighting medical groups that perform their research inside a medical centre.

Furthermore, it is important to remember that the main target sector that will take profit of this project is the society, specifically young adults between 15 and 35 years old and athletes that will help to understand how to solve this big injury that affect the population, the ankle sprain. In addition, it will be helpful for understanding how to treat chronic ankle instability, that is a big issue that affects a huge range of people nowadays after suffering repeating ankle injuries.

Moreover, it is important to know which companies are present in the sector nowadays to see if the product explained in this report will be suitable in the market. To focus on this matter in the following section, it is going to be described different devices used during history to see if the device proposed offers alternative approaches that the one's present nowadays on the market.

3.2. Evolution of the Market

In this section is going to be explained how the technology used to study the biomechanics of the ankle has evolve during history. For that reason, the studies introduced in section 2.2. will be used as a guide. Finally, it is going to be shown which benefits could have the product in the market in comparison with the available ones.

Firstly, technologies used in this type of studies can be divided in two groups. One of them is the devices done by companies that they offered their product to researchers' groups and the other one, is referred to researchers that create their own device to verify their own work, normally this type of devices is less complex than company's devices in terms of hardware and software, as it can be seen in the study of *"Plantarflexion resistance of selected ankle-foot orthoses"* made by DeToro et al [20]. It is the oldest research explained and looking to the engineering point of view is the simplest, after the model was created, with a subjective bar and a force gauge all the experiment can be done. Afterwards in terms of complexity of the hardware,



there is the study referred to "*Effects of five hindfoot arthrodosis on foot and ankle motion*" made by K. Zhang et al [24]. In this investigation, that is quite new, the hardwer is more sotisficated, due to they need more materials to fix the leg for guarenteeing that the movement was done only by the ankle joint. In addition, they used load to see its performance. In conclusion, we can see that technology evolve during the years to have more precise control in experimental variables allowing to isolate ankle movement and the use of loads have been introduced to see different types of situations where the human ankle can be.

However, there are some home-made devices done by the researches that are complex like the one explained from Guerra-Pinto project where they have hardware with some sensors connected to a microcontroller that obtains all the data that is processed thanks to a software done. The main weakness of this type of complex devices is that they are specific for one application.

From the industrial point of view, there is one company that is working on this sector: ZwickRoell. In the study of "*A cadaveric study to compare stability of reconstruction techniques using 1 or 2 fibular tunnels*", explained before the testing device used was from this company. ZwickRoell is a company based on materials testing for obtaining reliable test results, they develop and manufacture the load frames and all main components. They offer tensile tests, compression test or flexure test, function test or standard tests, texture analysis or fatigue testing; also, they offer testing solutions for test methods in R&D, as well as for quality in more than 20 industries. [25]

One of the sectors, where they perform is the Medical and Pharmaceutical industry. One of their main divisions is Biomechanics and Orthopaedics, where they focus on femoral head torsion test, spinal implants, intervertebral body fusion device, knee implants, bone plates and bone screws. However, they have also the option that you can contact them and they help the customer an optimal solution for their needs. As it is shown, they don't have specific branch for ankle joint [26].

In conclusion, the device proposed in this work can be suitable in the market for different reasons. First of all, there is not a big company working only in the ankle biomechanics field, so the product could enter in the market as novel solution, that can be versitile and suitable for different types of studies. In addition, thanks to the electronics controllers different types of sensors can be used in future projects, so it will be an optimal solution to get different type of data. Finally, thanks to the stepper motors the movement performed can be realistic and precise.

3.3. Future Perspectives of the Market

The evolution of the study of biomechanics is going to increase in the coming years. One clear example of this important evolution is the research of articles in PubMed. The number of articles related to the terms "Ankle biomechanics" has increased from few articles to a thousand of articles per year published in PubMed since 1957 [27] ,and the tendency is to increase in the following years. For example, in 2019, there were 900 articles published whereas in 2021 1045 articles have been published.



On one hand, the increase of population doing sport from the recent years will lead to more ankle injuries as it is explained before. This fact, will make that scientific sector will increase their concern in this type of injuries and will lead to increase the inversion in solving this type of problems.

On the other hand, the evolution of technology will create a possibility for scientists to find new applications that will help to improve the knowledge of particular problems related with the joint.

From the scientific point of view there are two innovative approaches that will change the way we understand ankle injuries. First of all, tissue engineering refers to the practice of combining scaffolds, cells and biologically active molecules into functional tissues. The goal of tissue engineering is to assemble functional constructs that restore, maintain, or improve damaged tissues or whole organs. Nowadays, artificial skin and cartilage are examples of engineering tissues that have been approved by the FDA [28], but there is still a lot of research to do in different tissues. For this reason, it isn't unrealistic that in the following years, researches could be able to regenerate ankle ligaments, that are the main injured part in ankle. When this creation will be introduced to medical care of the injuries, it will be mandatory to test its efficiency and efficacy. So, the device that is described in this work can play an important role, due to it can perform the movements done by an ankle. Before entering to the market, ligaments that are produced with tissue engineering will have to be checked in animals and corpse, that for checking its movement, the device will be suitable.

Secondly, prosthetics it is one field in biomedical engineering that is growing a lot in the recent years. A prosthesis is a device designed to replace a missing part of the body or to make a part of the body work better, joints are commonly replaced by prosthetic devices [29]. Nowadays

is used a total ankle arthroplasty (Figure 11) [30], it is a clinical technique that has evolved during the last fifty years, since the first prosthesis was used in 1970s. The evolution has been due to the fact on using different type of materials that will reduce the rejection in patient, replacing different parts of the bones that compose the ankle joint and changing the materials used. The future perspective in this field will be to customize a more individual prosthesis to fit perfectly individually for every patient instead of having an average size [31]. As before, the device can play an important role for checking if the new prosthesis doesn't damage tissues, when the machine performs natural movements performed by human's ankle.



Figure 11: Total Ankle Arthroplasty, as a replacement to tibiotalar joint to recover full motion of the ankle



4. CONCEPT ENGINEERING

Once the global introduction of the project has been done, in this section it will be developed the concept engineering of the product. It has been divided in different sections: the software part, the hardware part and the final materials set up. In each section, different alternatives will be discussed to evaluate which one is the most suitable for the final functionality. It is true that this project is more focused on the hardware set up, but different alternatives to build the final product are shown to be taken into account for future projects.

4.1. Hardware

4.1.1. Study of solutions

First step is to study what electrical motors can be used to fulfil the objectives of the final prototype. An electrical motor is an electrical machine that converts electrical energy to mechanical energy. Mostly, they work via the interaction of the motor magnetic field and electrical current in a wound wire to produce force in the manner of torque supplied on the motor shaft. They are classified depending on the power supply type, application, construction, and type of movement output [32]. After considering the different options, the most suitable type of electrical motors for the application are servo motors and stepper motors, due to their performance and their precision.

On one hand, a stepper motor is a brushless DC electric motor that divides a full rotation into a number of equal steps. The motor's position can be commanded to move and hold at one of these steps. Once the stepper motor is calibrated, every step can be associated to a position of the foot without using sensors [33]. So, the stepper motor will convert a

train of input pulses, typically square waves, into a precisely defined increment in the shaft's rotational position. Their working principles can be



Figure 12: Stepper motor, composed by 2 parts: Stator and Rotor

differentiated between the stationary part (the stator) and the moving part (the rotor) as it can be seen in the Figure 12 [34]. By supplying energy to the stator phases, a magnetic field is generated by the current in the coil. Then the rotor aligns with this field, and by supplying different phases in sequence, different magnetic fields can be generated that the rotor can be rotated by a specific amount to reach the final position [35]. Depending on their constructions the performance and the control of the stepper motor can be different, and the specific of each motor must be checked in the datasheet. To control the stepper motors, it is necessary to use a motor driver that allows to control the step/direction, phase/enable for allowing the movement and the PWM to directly control the gate signals. Another interesting characteristic of this type of motors is that they allow the user to drive them in different manners: in wave mode, in full-step mode or by micro-stepping to have more precise movements.

On the other hand, servo motors are a brushless DC motor with a sensor for positional feedback. This allows the output shaft to be moved to a particular angle, position, and velocity



that a regular motor cannot because thanks to the feedback mechanism in every moment the motor will be in a known position [36]. Their working principle consists on the pairing between the motor with some type of position encoder to provide position and speed feedback. In addition, it has different parts as can be seen in the Figure 13 [37]. Then the measured position of the output is compared to the command position (the input in the controller). If they differ, an error signal is released in order to move the motor towards the correct position, until the error reduces to zero [38].



Figure 13: Servo motor, specifying the components, where the gears, the motor and the output parts can be seen.

In the following block diagram of ElectronicsHub the working principle of servo motors is clarified [39]. There are four principal components: the DC motor, a position sensing device, a gear assembly and a control circuit. From the control signal a DC reference voltage is set to the value corresponding to the desired output, using a voltage converter made by capacitors the desired voltage is achieved, this voltage enters as input signal to the error amplifier. The feedback signal of the load (taking into account speed and torque) is obtained thanks to the position sensors. Finally, the feedback voltage value is applied at the input of error amplifier (comparator).

The error amplifier is a negative feedback amplifier and it reduces the difference between its inputs, it compares the voltage related to current position of the motor with the desired voltage. After evaluating the difference, the amplifier produces a voltage either positive or negative to move the motor to the desired position until the error becomes zero then the loop is finished.



Figure 14: Block diagram made by ElectronicsHub to understand servo motors working principle



To sum up, the advantages and disadvantages of both type of motors are summarized in the following table. [40] [41]

	Servo motors	Stepper motors
Advantages	 Precision control High torque and power variability Fast response time Wide Speed Range Rotational sensor Translates rotatory or linear motion to a digital signal 	 Simple construction and works in any situation Compatible digital systems No sensors needed for position and speed sensing Flexibility and provides a constant holding torque without the need for the stepper motor to be powered Different rotational speed by which can realize as the speed is proportional to the frequency of the input pulses
Disadvantages	 Requires tuning to stabilize the feedback loop Complex controller requires encoder and electronic support Peak torque is limited to a 1% duty cycle. Can be damaged by sustained overload Higher costs than stepper motors 	 Low efficiency Feedback loop is not use Produce high noise Not easy to operate extremely at high speeds Cannot rotate at high speeds

Table 2: Advantages and	l disadvantaaes of servo	motors and stepper motors
Tuble 2. Marantages and	alsaarantages of servo	motors and stepper motors

Afterwards, for the final functionality of the hardware different type of electronic boards for controlling the motors have been studied, taking into account the board that is currently installed and different options to see their advantages and disadvantages, to finally choose the most suitable one for the practical use of the device.



• GRBL controller

GBRL is an open-source software or firmware which enables motion control for CNC machines. CNC machine starts for "computer numerical control", it is a subtractive manufacturing process that typically employs computerized controls and machine tools to remove layers of material from a tock piece and produces a custom-designed part [42]. As it can be seen, this type of controller is not used for the specific application of this machine, however

some of its characteristics can be suitable. GRBL controller are used for the movement of motors in a



Figure 15: GRBL control board. 1) AC connector; 2) USB connector; 3) Power switch; 4) Offline controller connector; 5) Motor connections[18]

highly precise manner, in addition it is no needed to have the laptop connected due to their USB port where the information can be passed and executed using a power shift or using an external controller as it can be seen in Figure 15. One big inconvenient, is that they are not able to connect with some different sensors to extract some data, as Arduino can do.

This GRBL 1.1 controller with RATTM motor 3 axis works with 24V with a maximum current of 2A. With higher rated Amps with a bigger separate stepper driver module is not working correctly. In addition, if it uses the offline controller as the actual prototype, it cannot upgrade stepper drivers.

Arduino Uno

Arduino Uno (shown in Figure 16) is a micro-controller board based on the ATmega328P. It has 14 digital input/output pins (of which 6 can be used as PWM outputs), 6 analogue inputs, a 16MHz ceramic resonator, a USB connection, a power jack, an ICPS header and a reset button. It can be easily connected to a computer with a USB cable or power it with an AC-to-DC adapter or battery to get started [43]. It is an interactive way to learn how to use electronics for specific propose and there is a



Figure 16: Arduino Uno, where it can be distinguished its different pins: Digital Pins, the Power Pins, the Analog in and the USB pin [43]

huge number of tutorials that can help to self-learn how to use it. One big advantage is that thanks to the digital pints and the protoboard that can be easily connected, different kind of circuits with different kind of sensors can be connected to the board to gather data from the environment or to accomplish specific tasks.

Moreover, the structural support has to be studied too, in order to know if it is capable of sustaining the whole weight of the ankle. The tensile strength supported by the 2020 aluminium profiles that forms the cubic is more than 245 N/mm^2 [44]. The other material used to allow the three-dimensional movement is a printed custom designed mixed by ABS® and PETG®. PETG® supports tensile strength in the order of $13.4 \pm 2 MPa$ in the Z direction and $31.9 \pm 1.1 MPa$ in the XY direction [45]. Also, it is made by ABS® and it supports a tensile strength of 29.8-43 MPa. [46]

The ranges of forces seen in different studies such as in the study published by Saturo Ozeki et al in 2006 [47] where the maximum tensile force resisted by the ligaments where 135 N which is below the maximum from the materials of the device and keeping in mind that specimen's ankle weigh less than 24kg, the materials present can be used.

Taking into account all the materials present in the scaffold and their characteristic it will be suitable for future applications of the device to simulate weightbearing on the sole of the foot or somewhere else to see its performance.

4.1.2. Proposed solution

The first decision is to choose which type of motors will be used. While both stepper motors and servo motors can control speed and position, they can be used for different applications. Stepper motors use the steps allowing the controller to signal how many steps to take, however this only works if the controller knows the position of the output. This is the reason why the stepper motor moves until it reads the chosen position or until it activates an end limit switch [48]. Instead, a servo motor uses a sensor to know the position of the output so that when it is powered on it can immediately go to the desired position. In conclusion, stepper motor performance is limited due to the absence of feedback sensors; in addition, if the system is overloaded a stepper motor could skip steps causing positional errors and having to recalibrate the motion systems. Another differentiation between them is the torque and speed: maximum torque in stepper motors is the holding torque, however servo motors can provide more torque by incrementing speed, as well as reading higher speed limits.

For the device it will be interesting to have a precise movement, but also a high holding torque in order to see how the ligaments behave in a specific position. Due to the higher holding torque and economic reasons (not to be forgotten that stepper motors are the ones present in the actual prototype), stepper motors are the motors that are going to be used in the device.

Secondly, the board that will be chosen to control the stepper motors is going to be the Arduino Uno, for different reasons. First of all, the use of the Arduino Uno as a controller board can be more intuitive and easier to use, and also different types of sensors that can be used in future researches can be easily connected. Moreover, is not an expensive tool with large



availability. Finally, there is documentation available on how to use the board that will help to overcome future complications in the development of the project.

In the detailed engineering, it will be explained how this connection has to be done in order to have the desired movement and how this data will be transferred.

4.1.3. Alternative solutions

There are alternative solutions to obtain the final desired result of the device. One possible alternative solution will be to change the motors and use the servo motors, however this solution can be expensive and it will not suit with the economic plan of this work.

The other alternative solutions will be to use the GRBL controller that is already installed with the servo motors, using the GRBL software, changing the whole command tool, the interface of its software is shown in Figure 17. Instead of using the offline controller, computer can be used to control in a more precise manner the whole machine. One big advantage is that the data introduced in the software can easily be used to compute graphs to analyse the motion of each ankle.



Figure 17: GRBL controller software, where it can be seen all the parameters that the users can interact with

4.2. Software

4.2.1. Study of solutions

From the software point of view there are different possibilities to control the movement of the device. One option is to control the full board with Arduino language. Arduino is an open-source platform that uses a programming language based on C++ [49]. Arduino language is used to program microcontroller boards such as the Arduino Uno board to interact with sensors, actuators and other devices connected to the board. On one hand, its advantages are: there are large number of libraries of pre-written code available to use, the simplicity of its syntax and its versatility in a wide range of projects. On the other hand, its disadvantages are limited memory and processing power, limited support for some communications protocols, limited real-time performance, limited security features, limited precision and limited scalability. Due to the fact that



the proposed solution for the hardware in this project is to use an Arduino Uno board, it will be mandatory to work with this language. In addition, there is a large number of didactic resources available online. [50]

Furthermore, Arduino Uno has the possibility of cross-platform compatibility, it means that Arduino Uno language can be connected with other high-level programming languages such as Python to work in different kind of projects. In fact, Arduino work well with Python, especially for applications that require integration with sensors and other physical devices as it can be the future device of this project. [51] So, it can be an interesting alternative for the project because the control of the device can be performed using the Arduino language and afterwards connect with the Python environment to perform the statistical studying of all the data available from the sensors for easier integration. In the graph below, it can be seen a workflow diagram to describe all the process explained in this section, on how these two languages can be crossed thanks to its compatibility.



Figure 18: Workflow of the process described

4.2.2. Proposed solution

After the study done on the software end and keeping in mind the objectives of the project and the chosen hardware, the proposed solution is to use the Arduino Uno language for controlling the movement of the prototype. The main objective is to get a functional device with the new electronic set up. To achieve this objective, Arduino Uno language it will be suitable because it is the main program to control the board. It is possible to do a program in that language that controls the movement and the performance of the stepper motors, getting the desired results. Furthermore, different types of programs can be done to see different movements of the ankle to have a full overview of the natural movements of the ankle.

Currently, sensors are not going to be implemented in the board, so there is no read to use the cross-platform option with Python to get the data. Nevertheless, this option can be used in future projects related to the device, where sensors will be needed.

4.2.3. Alternative solutions

In case that the hardware set up is not changed, it will be necessary to use the GRBL software in order to control the performance of the prototype. GRBL is a totally free, open-source software that was developed as motion control for a microcontroller board, making it possible to combinate with Arduino Uno [52]. The majority of applications done with GRBL software are related with CNC machines and subtractive manufacturing, controlling servo motors. In this case it will be interesting to use this kind of software due to their facilities in getting good results and the easy learning process needed to program it.



5. DETAILED ENGINEERING

Once the global planning of the project has been discussed, the detailed engineering of the product is the following step to be achieved. The main objective of the detailed engineering is to explain the development of the work, detailing the operation of the different parts, taking into account the chosen option explained in the previous part.

From the hardware point of view is important to know how the connections should be done in order to get the desired performance of the motors. To control the stepper motors with the Arduino Uno, motor drivers, power supply, condensers and wires will be used. A motor driver is an integrated circuit chip that controls the direction of the motor based on the commands or instructions received from the controller, it causes the motor to move in accordance with the given instructions or inputs. Furthermore, it receives the low voltage from Arduino Uno, in this case, and commands an actual motor that need high input voltage [53].

However, how does it work? First of all, the microcontroller sends signals to the motor driver, who interprets and steps up with the reference voltage to give the high power needed to the motor. If the microprocessor transmits a high input to the motor driver, the driver will rotate the motor in one direction keeping one of his pins high and one pin as low. And when the microcontroller transmits a low input to the driver, it makes the motor to rotate in the other direction by changing alternatively both pins [53]. In the following diagram, it is demonstrated how the data will travel in order to move the motor.



Figure 19: Flow diagram of how information travels from microcontroller to the electrical motor

For this project the motor driver used is the DRV8825 from Pololu Corporation [54]. Their main characteristics is that they can adjust current limiting, they have over-current and over-temperature protection, and it allows micro-stepping down to 1/32-step. It operates from 8.2 V to 45 V and can deliver up to approximately 1.5 A per phase without heat sink or forced air flow. The driver has 16 different pins that allows the welding of headers in order to connect the driver with a protoboard. In the Figure 20 [54] there is represented a schematic of the different pins available on the motor driver and how they have to be connected in order to works.



Figure 20: Wiring diagram for connecting a microcontroller to DRV8825



In the right part of the motor driver there is the power section with the following pins, we can see a capacitor connected between the voltage motor pin and the ground of the motor that is used to protect the DRV8825 from the destructive LC voltage spikes that can appear due to certain conditions of the power supply. These spikes can appear even when the motor supply voltage is low as 12V; that's why it is used in the motor voltage entrance. Just below, there are the pins referred to the electric coils of the motor, the important thing is to keep the pairs of the bipolar motor. The FAULT pin is not connected because by default is in low mode for current protection. The last pin is the ground (GND) of the digital part to close the circuit that is connected directly with the GND of the microcontroller.

In the left part there is the digital section [55], they are different pins connected to the microprocessor. The enable pin allows the driver to provide with current to the motor isn't connected because by default it is working as wanted. Underneath, there are the mode pins that let the DRV8825 to configurate the micro-stepping, in different words, depending on the electrical connections done with wires in these three pins the stepper motor can be moved with less degrees per step until 1/32 micro-step. Afterwards there is the RESET and SLEEP pins that are interconnected and go to the logic power supply, they are used for controlling the power states of the motor driver [56]. Below that there the STEP and DIR pins that are connected to digital pins of Arduino Uno. STEP receives a pulse for the motor to advance one step, so it is used to know how many steps have to be done by the motor in each moment. Instead, the DIR pin is used to assess the direction of turning from the motor.

Before connecting all the circuit there is one last item to be done with the motor drivers, setting the maximum current that they will allow to pass. There are two methods for doing this step, in this work the method performed was using the voltage reference. For knowing the voltage reference of the drivers is important to take into account the next formula:

$$I = V_{ref} \cdot 2 \rightarrow V_{ref} = \frac{I}{2}$$

The DRV8825 includes a small trimmer potentiometer for setting the current limit, next to the enable pin. First of all, is important to look at the datasheet of the motor to see which is the rated current for the motor to works properly, then you divide that value between two to obtain the reference voltage. In the actual device there two different subtypes of NEMA 17 stepper motors, so it is needed to look at both datasheets to know which are their rated current. On one hand, the Y axis there is NEMA 17 stepper motor 42BYGHW811 and its rated current is 2.5A, so the reference voltage should be put at 1.25V [57]. On the other hand, the X and Z axes have NEMA 17 stepper motors 17HS2408 with a rated current of 0.6A, so the reference voltage should be set at 0.3V [58].

Once the mathematical calculation is done, it is time to perform the calibration. First of all, the three micro-step pins must be disconnected in order to have the driver in full-step mode. Secondly, the motor has to be fixed in a fixed position without clocking the step input. Then, voltage reference is measured on the metal trimmer using a voltmeter and it is adjusted using a



screwdriver. This process can also be done without connecting the stepper motor to the driver, as we did. As it is seen in the following scheme and the following picture [59]:



Figure 21: Schema of the calibration of the DRV8825 using current rated of 0.350A, and on the right a photo of the materials used to calibrate the motors experimentally in the lab

After explaining how to connect the motor driver lets focus on the circuit done in the protoboard. For connecting one driver there is several connections that must be done, remember that in the case of this project three motor need to be controlled, so three drivers will be used in order to control each motor. The schematic of the circuit for one motor driver is represented in the following image [60]:



Figure 22: Schematic for the connection of one DRV8825 with the stepper motor and the Arduino Uno board

As it is demonstrated in the scheme is important to have the DRV8825 connected in two different rows of pins, because left part and right part of the driver shouldn't be interconnected. Starting from the right part of the driver the motor voltage pin is connected to the positive line on the right and ground to the negative line. Then, those two lines are directly connected to the power supply of 12V, having a capacitor of 100 μ F between them to avoid voltage spikes that could damage the whole system. The next four pins, are the ones that are connected directly with the coils of the stepper motor. The last pin on the right is the logic ground that should be connected to the ground pin of the Arduino Uno that's why there is a wire that connects this Pin



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with the left columns of energy that are directly connected to the power supply and the GND of the Arduino. Finally, in the left part there are the Reset and Sleep pins that are interconnected and directly connected with a wire to the logic power supply of Arduino Uno. Below them there are Step and Directional pins that are connected with the analogue in pins of the Arduino, these two pins will be used to send the information to the stepper motor to control its performance.

For every stepper motor, different motor driver has been used following the same schematic already explained. However, is important to remark, that each axis have different analogue in pins in the Arduino Uno in order to control them independently. As it can be seen in the Figure 23.



Figure 23: Actual electric circuit

From the Software point of view, there is a general structure followed in order to performed all the codes that is going to be explained. Taking as a reference this general structure, different scripts have been done in order to have alternatives applications that can be suitable for the device in future applications.

First of all, it is important to keep in mind that for each step done by the stepper motor the position will be moved by 1.8°, so by combining with different steps, different degrees of motion

can be achieved. The initial code lines are used to define in which pins are defined the directional and the steps and set them as output pins. In addition, another integer constant is defined as the number of steps that the stepper motor will perform. Once all the variables and their functions are defined, the code enters in the void loop, where the direction of rotation is defined and the steps are performed. When all the steps defined previously are done, the loop finishes, leaving the stepper motor in the desired position. In Figure 24, it is demonstrated general scheme the followed by the program.



Figure 24: Flow general diagram on how is working the Arduino Uno code



For having a general overview on what future applications, the device can have, different codes have been developed in order to see different rotations done by the device. The movements defined are the ones performed by human's ankle, so there is one code for inversion/eversion, plantar flexion/dorsiflexion, abduction/adduction and a combination of the three motors to see more complex movements done by the joint. In the next photo, the inversion/eversion motion performed by the device can be seen.



Figure 25: Eversion movement reproduced on the ankle biomechanics testing device using the new hardware and software set up

The idea is to perform the initial rotation and maintain the foot on this specific position. Therefore, researchers can check how the ligaments are in each position and take some data relevant for their research. After their study have been done, there is another code for returning the foot to its neutral position. In the annexes, the different codes done can be seen.

In addition, another program has been done in order to check the viability of the product as a therapeutical one. By adding an integer constant called "reps", used in the void loop to repeat the same process several times, a first approach of a CPM machine has been done in order to see the effectiveness of this type of applications in the device.



6. EXECUTION SCHEDULE

In order to be able to distribute the tasks in a correct way, controlling its execution a Work Breakdown Structure (WBS), a Program Evaluation and Review Technique with its Critical Path Method (PERT-CPM) and a GANTT diagram have been performed. These project management tools will allow to have the work done on time, guarantying that the final project can be done on the deadline. In addition, it helps to have an overview on what is needed to be done to fulfil the project focusing on the scope and the objectives previously explained.

6.1. Work Breakdown Structure (WBS)

The Work Breakdown Structure has the objective to show easily in a graphical manner the scope of the work subdivided into smaller tasks. Different tasks are grouped into packages, to fulfil one of the packages all the smaller tasks have to be performed. This structure allows the team to have a clear vision on what have to be done, which steps, to fulfil the project.



The WBS of this project is represented in the next diagram:

Figure 26: Work Breakdown Structure (WBS) followed during the execution of the project

The WBS of the project is divided into four first level work packages and each of them is divided into several second level tasks. Now all of them will be presented and described in the WBS dictionary, to understand more specifically on what consists each task.

1. Documentation

Table 3: WBS dictionary

1.1.	Literature review	Estimated time: 5 weeks			
First research done of the topic ankle biomechanics, to understand its characteristics, functions					
and main injuries. As well as, how the research related to this topic has evolved during the past					
years.					



1.2.	State of the a	art						Esti	mat	ted ti	me: 2 w	ee	ks	
Understan	id in which poi	nt is	s the actu	al prototype	, kn	owing) whic	ch mat	eria	als ha	ave, its	ele	ctror	nics
and how	is controlled.	In	addition,	evaluating	its	pros	and	cons	to	see	where	it	can	be
improved.														

1.3.State of the situationEstimated time: 4 weeksSearching in the literature different projects in the recent years that have used technological
devices to study ankle biomechanics. For knowing, how technology works nowadays on the
field and how has been evolving.

1.4.	Definition of scope and objectives	Estimated time: 3 weeks			
Descriptio	n of the principal and secondary objectives of the	work that are wanted to be			
achieved at the end of the project. These objectives have been thought taking into account the					
resources, the scope of the work and the limitations that have the study					

1.5.	Writing of the memory	Estimated time: 28 weeks
Developm	ent of the memory that will be submitted at the en	d of the project. This process
begins in t	he initial days of the work and ends in June 2023 with	the submission of TFG.

2. Software

2.1.	Study of solutions	Estimated time: 4 weeks	
Check wh	ich are the possible ways to control the device offline	e to facilitate future researches	
where all the data can be easily interpreted with the computer.			

2.2.Study of alternative solutionsEstimated time: 2 weeksOnce one solution has been found, checking how the alternative ways of solving the problem
can be used to obtain a more efficient way to control the machine.

2.3.	Arduino language learning	Estimated time: 3 weeks
Refreshing	g the previous knowledge of the programming langu	age. Furthermore, focusing on
the study	of different libraries that can be used to control the mo-	vement of electric motors.

2.4.Check viability of cross-platform utilityEstimated time: 2 weeksWhen Arduino language have been studied, review if the possibility of cross-platform between
Arduino and another programming language can be used to improve the performance of the
software for the application of the work.

3. Hardware

3.1.	Study of electric motors	Estimated time: 4 weeks
Understan	ding on what are electric motors, which types are	available on the market and



looking for the most suitable for the application of the work.

3.2.Review of stepper motorsEstimated time: 3 weeksStudy of stepper motors, looking for how this type of motors can be used, their main
applications and how are they connected with the Protoboard.

3.3.Learning how to use stepper driversEstimated time: 5 weeksReviewing how to use the stepper drivers, for building the electrical circuit correctly.Furthermore, this step is crucial to have the correct control of the device with the software created.

3.4.	Check viability of the scaffold	Estimated time: 1 week	
See if the	materials available on the actual prototype will be ap	propriate for supporting all the	
weight and forces that will be performed on the future device.			

4. Delivery

4.1.	Memory closure	Estimated time: 4 weeks		
Finish the memory and perform an extensive review to deliver it.				

4.2.Oral presentationEstimated time: 2 weeksPrepare the actual oral defence, taking into account all the technological support and the speech.

6.2. PERT-CPM Diagram

The next table has been computed to see the actual correspondences between tasks and to find the chronological dependence of all the work. Thanks to this study the actual critical path can be found, it will help to do a more efficient management of the project to achieve the deadline.

The actual time prediction has been thought to be the pessimistic one, to have a margin of time while the project is being done.

IDS WBS	ID PERT	Activity	Previous	PERT time (weeks)
			activity	
1.1.	Α	Literature review	-	5
1.2.	В	State of the art	-	2
1.3.	С	State of the situation	В	4
1.4.	D	Definition of scope and objectives	А	3
1.5.	E	Writing the memory	-	28
2.1.	F	Study of the solutions	C, D	4
2.2.	G	Study of alternative solutions	C, D	2
2.3.	Н	Arduino language learning	F	3
2.4.	I	Check viability of cross-platform utility	G	2

Table 4: Analysis of the previous activity and its duration



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3.1.	J	Study of electric motors	H, I	4
3.2.	K	Review of stepper motors	J	3
3.3.	L	Learning how to use stepper drivers	J	5
3.4.	М	Check viability of the scaffold	J	1
4.1.	Ν	Memory closure	E, K, L, M	4
4.2.	0	Oral presentation	N	2



Figure 27: PERT-CPM diagram

The PERT-CPM diagram visually represents the tasks that have to be done, their timing and their relationship. It defines the order in which tasks have to be executed. Thanks to the early and last time, the critical path can be found. The critical path is the one composed by all the activities that cannot be delayed during the project, because one postponement of one of these tasks will become a modification of the final timing of the project.

The actual critical path, is defined in the Figure 27 with the activities highlighted with an orange arrow. This implies that activities E and O cannot be delayed, because it will mean a delay in the final project deadline, and the one defined by activities A, D, F, H, J and L. There are two critical paths, so it will be important to have the activities done in time in order to fulfil the project on time.

6.3. GANTT Diagram

With the finality to control the evolution of the different activities a GANTT diagram has been done. The diagram needs to be actualized throughout the evolution of the and each finished activity must be marked on the calendar.

As it can be seen in Figure 28, on the left part of the diagram there is the list of tasks to be done, and each column represents the week of the month the task will be executed. When tasks are done, the column is highlighted with green colour, as the final diagram represented. It is important to take into account that the original diagram has been actualized during the development of the project. In conclusion, the diagram shown is the final one, considering the actualized schedules.

Thanks to the less-tight point of view used to computed the times in the previous section, during the development of the project it was possible to adjust the dates to fulfil the work.



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Figure 28: GANTT diagram



7. TECHNIQUE VIABILITY

The technical viability corresponds to a SWOT analysis, studying and understanding both internal (strengths and weaknesses) and external (opportunities and threats) factors affecting the project and displayed on the following table.

To understand better the technique viability, it has to be considered the technical challenges that have appeared during the process of the study. The first one was getting the materials, the timespan dedicated to obtained the materials had been larger than affected, that made the whole technical part to be adapted during the process. Another issue, was the calibration of the stepper drivers, it has been complicated to understand how to calibrate them and how to make them work in an appropriate manner. Finally, the work done at distance due to my stay in Torino, has made all the technical work to be adapted to these particular events. A brief review of the actual SWOT analysis of the project can be seen in the next table:

Table 5: SWOT analysis

Strengths	Weaknesses			
Inte	rnal			
 Study using different movements to know precisely the forces that can be sustained by the ligaments Easy automatized method Big chance to adapt the product to different applications Chance to implement different sensors to obtain data from the experiments. 	 ✓ Timespan limitation to have a functional minimum viable product ✓ Lack of financial resources to improve the hardware ✓ No extra weight added to see the performance of the ankle in extreme situations ✓ Maximum resolution limited by the steps that a stepper motor can perform 			
Opportunities	Threats			
Exte	rnal			
 ✓ The product can be adapted to have different functions in treatments or clinical point of view ✓ There is no specific device made by companies for the study of ankle biomechanics, so it is a great market opportunity ✓ Alternative way of testing therapies in the joint 	 ✓ Legal aspects that must be achieved to perform the experimental part. ✓ Legal aspects that must be concerned to sell a medical product ✓ Difficulties to obtain the materials and the time schedule when they are obtained 			
In an action was a such as the taxis				

7.1. Strengths

Different strengths have been analysed, which are intrinsic factor of the project and are helpful for such. First of all, the main advantage that it presents it's the versatility. Thanks to its composition it facilitates to produce different motions to see what are the forces related to each movement in each ligament and check how they respond. In addition, thanks to the offline control all the

movement can be automatized making the researches to focus on the actual ankle and not on how to control the product.

Another important strength it's the versatility that offers the final device, by just making some changes in the code, the range of application where the product can be adapted is huge. In addition, due to the Arduino board, different sensors can be installed in the future to obtain different data of interest, this fact will help to the whole project be more complete.

7.2. Weaknesses

Although all the strengths that the study has, there are some internal weaknesses to consider. First of all, the timespan is a big limitation to have a functional minimum viable product that can enter to the market, that's why this study is focused on having a first prototype that can be controlled in a precise manner, being the first step to achieve the final functional product. In addition, the lack of financial resources is crucial, making it hard to obtain sophisticated materials.

By regarding the scaffold of the product, no extra weight has been added to check the performance of the ankle in different situations. This item has to be solved in order to have a competitive product in the market. Moreover, the maximum resolution that can be obtained by the stepper motors is 1.8°, and using a micro-step of 1/32 is the maximum that can be obtained, it seems to be enough accurate but it can be a withdraw for some applications.

7.3. Opportunities

There are a variety of opportunities that this study could benefit from, mainly focused on possible. On one hand, as it is explained before, by market point of view there is a big opportunity with the product to adapt it to different ranges that will help to arrive at bigger market sectors. In addition, for the moment there isn't a company dedicated exclusively to produce ankle biomedical reproductive machines, so there is a big opportunity.

On the other hand, from researches point of view, the device will offer a different way to test innovative therapies for ankle instability, that can be tested directly in the machine. Furthermore, it can help to increase the research on this topic, due to it will offer an instrument that nowadays researches haven't got on the market.

7.4. Threats

Finally, of the four categories, threats are going to be discussed. As it is explained before, difficulties to obtain the material and the timespan has been suffered making the study to be adapted to this issue. Likewise, legal aspects can be another external inconvenient. In fact, for making the experiments several considerations have to be considered in order to obtain the approval. Moreover, before selling medical product different validations have to be achieved in order to obtain the license.



8. ECONOMIC VIABILITY

On this section, the different costs of the project have been detailed, including the members of the group cost. All the resources have been summarized in the table 6, including its quantity and its cost.

On one hand, by regarding to the materials resources there are different items that are acquired during the development of the work. First of all, an Arduino Uno kit is needed to be bought in order to start building the different management of the device. However, to work with this protoboard is needed to buy different cables in order to connect the different parts in the electric circuit. Once, it was decided to work with the stepper motors the next item to be bought was the motor drivers in order to control the mentioned motors using the Arduino Uno. Next step is to acquire a multimeter in order to calibrate the motor drives as it is explained in the previous sections. Finally, the power supply has been acquired, it was important to choose a power supply with enough power to move the motors. Due to the fact of its high power, in order to not damage the motor drivers, three capacitors of 100 μ F were bought.

All the materials explained have been acquired from electronic shops in Barcelona or using online distributors.

On the other hand, the human resources have been taken into account: the student (biomedical junior researcher) and the director of the project (medical senior researcher). His income has been estimated by considering the standard salary of senior researches in Spain [61], it is approximately $43.925 \in$ per year that is nearly equivalent to $23 \in$ per hour. Furthermore, it is considered that the medical senior researcher has spent around 100 hours in the development of the project. The biomedical junior researcher has been considered to have a standard salary of junior researchers in Spain [62], that is around $24.000 \in$ per year that is equivalent to $12,50 \in$ per hour, to do the whole project he has spent approximately 300 hours.

	ltem	Quantity	Cost
	Kit Arduino Uno	1	21,19€
	Power supply	1	16,49€
Material resources	Cables	2 meters	3,50 €
	Capacitors (100 µF)	6	0,22€/unit = 1,32 €
Motor drivers		3	15,49€
(DRV8825)			
	Multimeter	1	11,99€
	Medical senior	1	25 €/h = 2.300 €
Human resources	researcher		
	Biomedical senior	1	12,50 €/h = 3.750 €
	researcher		

 Table 6: Economic costs of the project
 Image: Cost of the project

By calculating the total costs in the table, it can be seen that the actual cost of the project is **6.119,98** €. Moreover, Figure 29 displays the cost divided per section, human resources and material resources. Most of the cost is aimed at human resources, more than 98% of the total



budget of the study, only 1,1% of the total account has been used for material resources. This is due to the original cuboid scaffold and the stepper motors have been used. Furthermore, the aim of the project is to have a minimum available prototype with the minimum economic impact because in the future will be needed cash flow to get the European validations and to implement more advanced technologies.



Figure 29: Cost divided per section: Human resources and Materials



9. LEGISLATION AND REGULATION

This study is based on doing an ankle biomedical testing device, as it is explained before the project has been fully developed in Barcelona, so the legal requirements taken into account follow the Spanish legislation, and the ones referred to the Europe requirements.

By the legal point of view there are two major aspects that must be considered for the execution of this work. On the one hand, as it is explained before for assessing the correct functioning of the prototype several clinical trials will be done. In order to do these clinical trials will be needed to pass the ethical aspects that will be explained in this section of the draft. On the other hand, as it is a medical product it is important to know the factors that must be succeed in order to have the European accreditations for the future commercialization of a medical device.

First of all, the legal aspects related to the clinical trials will be discussed. In this case, it is important to consider the ethical part that must be achieved for using corpse feet to check the functionality of the device. As the project is executed in the Anatomical Department of Universitat de Barcelona, it is necessary to follow the integrity code for research that has this institution. The main principles of the protocol are honesty from the researcher during the whole project to explain what are the activities done to succeed in the investigation, including from the initial hypothesis to the final publication of the results; responsibility and periodical accountability of the steps followed during the project; reliability on the quality of the research; rigor during the process of discovery and interpretation; respectful with the co-workers and the environment; and finally independent in order to not contaminate the final results. [63]

In this code, there is a section specified for the research done with humans where it is explained that the first step is to have the approval from the Bioethical Commission of Universitat de Barcelona, where its main guidelines are from the European Convention on Human Rights and Biomedicine, in the Charter of Fundamental Rights of European Union, in the Helsinki Declaration of the World Medical Association and in the European Code of Conduct for integrity in ALLEA's research. Likewise, it should follow the recommendations of the European Charter of the Researcher of the European Commission [64]. Furthermore, it should be taken into account the confidentially from the data used from the subject, to guarantee the right of privacy following the General Data Protection. [65]

Once the experiments will be achieved there will be needed a license in order to introduce the device in the medical market. As a medical product it is known that any technical issue related with its function, the problem will be the fault of the manufacturer. The main requirements are: it has to be safe for the user, the possible risks are to be acceptable in relation to the benefit for the patients and it has to have high levels of health and safety protection. For achieving these mandatories requisites, the device has to take into account the chemical, physical and biological properties to avoid infection and microbial contamination; always considering the environment while the product is fabricated and where it is going to be used. All in all, the possible risks have to be advice for the user by the manufacturer. In the case of the device, it will be an active product due to the conversion of the energy in order to move the feet and the one done for the sensor that can be implemented in the future, however it will be used in



a transitory manner because it will not be used indefinitely. Thanks to this first approach it can be said that the product is from class II a, so in a future project before its commercialization it is important to get the European approval from this type of equipment [66]. It will be needed to contact with a company accredited for the examination and certification of medical devices as Medcert in order to obtain the certification and pass all the tests.

For achieving the CE marking (the certification needed to sell a medical device in Europe) several test must be done. Thanks to this graph of Medcert it can be seen the several verifications needed to be achieved in order to obtain the certification. [67]





In the following table there is a summary of all the regulations that have to be taken into account

Table 7: Summar	y of the	regulations	that	must be	achieved
-----------------	----------	-------------	------	---------	----------

Sections	Regulations
Clinical trials	\circ Integrity code of Universitat de
	Barcelona
	 European Convention of Human
	Rights and Biomedicina
	 General Data Protection
Device commercialization in Europe	 CE marking

In conclusion, all these steps must be passed in a precise manner in order to have an available final product. Keeping in mind that the objective of this project is to have a first functional prototype, most of the steps described in this section will need to be achieved in future researches as it is going to be explained in the following part.



10. CONCLUSIONS AND FUTURE RESEARCH

To conclude, this study had the main objective of improving an existent device for the research of ankle biomechanics. At this point of the work, it can be said that the objective has been accomplished, because the actual device has a new software and a new electronic controlment installed. These new options are considered to be more powerful than the previous ones, and it can be useful for future researches as it is going to be explained afterwards.

For achieving the objective of the project, several subobjectives were described previously. The first one, was to investigate the actual situation of the market to see which application can be more suitable. After doing the study, it can be seen that nowadays there aren't companies selling specific devices for ankle biomechanics research. So, researches have two options: create their own testing device, which may lead to increase their time of research or to contact with a testing device company to create a personalized device for these experiments, this causes an increase of the budget.

Secondly, an exhaustive study of the state of the machine was made to see on which state it was and what could be improved. The decisions were to improve the management of the device, using a software because it can be useful for future applications. In addition, the protoboard was replaced in order to have a more powerful one, Arduino Uno, that can be connected with different electronic components. After doing this improvement in the device, different benefits were achieved: it is possible to study ankle joint using different movements to know precisely the forces that can be sustained by the ligaments, it is easy to automatize, there is a big chance to adapt the product to different applications and there is a chance to implement different sensors to obtain data from the experiments. However, the actual device has some limitations as there is no external weight added to see the performance of the ankle in extreme conditions, and the maximum resolution is limited by the steps that a stepper motor can perform.

Lastly, there is one subobjective that isn't achieved. In this project no clinical trials with ankle corpse have been performed to verify its motion. Due to the timespan and the difficulties of personal meetings this last subobjective wasn't possible to check, however thanks to the study the general concepts needed to perform future investigations have been studied. In addition, this Bachelor Thesis has helped to have a general overview of orthopaedic medicine, more precisely of ankle joint. Furthermore, on how to manage an engineering project and how to work with different electronic components such as Arduino Uno, stepper motors and motor drivers.

10.1. Future research

It is convenient to consider the future works along this project line because there is still some characteristics of the actual prototype that can be improved. In addition, there are still some steps that need to be achieved if the device is wanted to be sold as a medical device.

On one hand, taking into account the functionality of the device there are several improvements that can be done. First of all, depending on the final functionality of the device extra weight will be needed to perform the experiments. If it is wanted to check the functionality of the ligaments under extreme conditions and how they work under pressures some extra weight should be implanted in the machine in order to perform the movement under these situations. In



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conclusion, it should be studied if the scaffold will support that extra weight and the best way to add the extra heaviness, by using some pulley as in the example of Figure 31 or by adding them in the footplate.



Moreover, it will be needed the implementation of some sensors to get the data desired for each experiment. So, another future project should be studying all the



possible sensors that can be implemented in the device to get data. Afterwards, it will be needed to connect the sensors with the Arduino Uno board and to modify the software using the cross-platform option to obtain all the data of interest. What's more, to facilitate the functionality, all the codes can be joined in one script. Using different conditions, the desired movement can be selected by the user and the moment when the foot has to return to its original place. To fulfil these objectives, it can be used some external hardware (as a press button) that allow the user to choose when the motor has to return to their original position.

On the other hand, there are some steps that have to be done considering the validation of the device. By this point of view there can be done two projects: one study related to do the clinical trials necessary to get the validation, and the other one to perform the whole validation project to obtain the CE marking to be able to sell the product in Europe as a medical device.

In conclusion, during this Bachelor Thesis the first step to control the movement of the device has been completed, as well as providing it with an enough powerful hardware to be able to apply the movement in different situations. However, there are still lines of work in order to obtain the definitive viable product.



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ANNEXES

Plantar flexion and dorsiflexion

// Motor Z is the one responsible for the flexion, for making the foot to come back to the original position the dirPin is changed to LOW-

```
const int dirPin = 2;
```

```
const int stepPin = 3;
```

// 10 = 18°

const int steps = 10;

void setup() {

```
// Pins sortida:
```

```
pinMode(dirPin, OUTPUT);
```

```
pinMode(stepPin, OUTPUT);
```

```
}
```

```
void loop() {
```

```
digitalWrite(dirPin, HIGH); //Direction of movement
```

// Loop for arriving to the desired steps, that corresponds to the degrees of motion

```
for (int x = 0; x < steps; x++)
```

```
{
```

```
digitalWrite(stepPin, HIGH);
```

```
delayMicroseconds(2000);
```

```
digitalWrite(stepPin, LOW);
```

```
delayMicroseconds(2000);
```

```
}
```

```
delay(1000); // wait a second
```

```
}
```



Inversion/Eversion

```
// Motor X, to make the eversion the dirPin is put into LOW
```

const int dirPin = 5;

const int stepPin = 2;

// 5 steps will be 9°

const int steps = 5;

int stepDelay;

void setup() {

// this are the output pins, to give the info in the board

```
pinMode(dirPin, OUTPUT);
```

pinMode(stepPin, OUTPUT);

```
}
```

void loop() {

```
digitalWrite(dirPin, HIGH); //Direction of motion of the motor = clockwise
```

stepDelay = 2000; //To see the velocity on how it arrives to the position

```
// Loop for arriving to the desired steps = degrees of interest
```

```
// bucle per poder arribar a fer els steps que hem dit que faci per arribar a tants graus
```

```
for (int x = 0; x < steps; x++){
```

```
digitalWrite(stepPin, HIGH);
```

```
delayMicroseconds(stepDelay);
```

```
digitalWrite(stepPin, LOW);
```

```
delayMicroseconds(stepDelay);
```

```
}
```

```
delay(1000);
```

```
}
```



Abduction/Adduction

// Motor Y to perform the internal and external rotation

const int dirPin = 6;

const int stepPin = 3;

```
// 4 steps = 7,2°
```

```
const int steps = 4;
```

int stepDelay;

void setup() {

```
// Pins de sortida:
```

pinMode(dirPin, OUTPUT);

pinMode(stepPin, OUTPUT);

```
}
```

```
void loop() {
```

```
digitalWrite(dirPin, HIGH); //Motor direction
stepDelay = 250; // Velocity
for (int x = 0; x < steps*1; x++){
    digitalWrite(stepPin, HIGH);
    delayMicroseconds(stepDelay);
    digitalWrite(stepPin, LOW);
    delayMicroseconds(stepDelay);
}
delay(1000);</pre>
```

```
}
```



Combination of three motors

//Combination of 3 motors

const int dirPinX = 5;

const int dirPinY = 6;

const int dirPinZ = 7;

const int stepPinX = 2;

const int stepPinY = 3;

const int stepPinZ = 4;

const int steps_x = 5;

const int steps_y = 4;

const int steps_z = 10;

int stepDelay;

void setup() {

// Output pins for each axis

// x:

pinMode(dirPinX, OUTPUT);

pinMode(stepPinX, OUTPUT);

//Y:

pinMode(dirPinY, OUTPUT);

pinMode(stepPinY, OUTPUT);

//Z:

pinMode(dirPinZ, OUTPUT);

pinMode(stepPinZ, OUTPUT);



```
void loop() {
```

```
digitalWrite(dirPinX, HIGH);
```

```
digitalWrite(dirPinY, HIGH);
```

```
digitalWrite(dirPinZ, HIGH);
```

stepDelay = 250;

// loop for moving the motors separated

```
for (int x = 0; x < steps_x*1; x++){
```

digitalWrite(stepPinX, HIGH);

delayMicroseconds(stepDelay);

digitalWrite(stepPinX, LOW);

delayMicroseconds(stepDelay);

```
}
```

delay(1000);

// for motor Y

```
for (int x = 0; x < steps_y*1; x++){
```

```
digitalWrite(stepPinY, HIGH);
```

```
delayMicroseconds(stepDelay);
```

```
digitalWrite(stepPinY, LOW);
```

```
delayMicroseconds(stepDelay);
```

```
}
```

```
delay(1000);
```

```
// for motor Z
```

for (int x = 0; x < steps_z*1; x++){

digitalWrite(stepPinZ, HIGH);

```
delayMicroseconds(stepDelay);
```

```
digitalWrite(stepPinZ, LOW);
```



```
delayMicroseconds(stepDelay);
```

```
}
```

```
delay(1000);
```

}

Therapeutical point of view: CPM movement

 ${\it \prime \prime}{\it \prime}$ continous movement of CPM in dorsiflexion

const int dirPin = 7;

```
const int stepPin = 4;
```

// range of movement [-18°, 18°

const int steps = 10;

const int rep = 10; // number of times the movement has to be repeated

int stepDelay;

```
void setup() {
  // Output pin:
  pinMode(dirPin, OUTPUT);
  pinMode(stepPin, OUTPUT);
}
```

void loop() {
 for (int i = 0; i < rep*1; i++) {</pre>

digitalWrite(dirPin, HIGH);

stepDelay = 250;

for (int x = 0; x < steps*1; x++){

digitalWrite(stepPin, HIGH);

```
delayMicroseconds(stepDelay);
```



```
digitalWrite(stepPin, LOW);
```

```
delayMicroseconds(stepDelay);
```

```
}
```

```
delay(1000);
```

```
digitalWrite(dirPin, LOW);
```

```
stepDelay = 250;
```

```
for (int x = 0; x < steps*1; x++){
```

```
digitalWrite(stepPin, HIGH);
```

```
delayMicroseconds(stepDelay);
```

```
digitalWrite(stepPin, LOW);
```

```
delayMicroseconds(stepDelay);
```

```
}
```

```
delay(1000);
```

```
}
}
```