UNIVERSIDAD DE INVESTIGACIÓN DE TECNOLOGÍA EXPERIMENTAL YACHAY

Escuela de Ciencias Biológicas e Ingeniería

TÍTULO: Design of a transtibial Prosthetics with a muscle electrostimulator to control the pain after amputation

Trabajo de integración curricular presentado como requisito para la obtención del título de Ingeniera Biomédica

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Dedicatoria

“Quiero dedicar esta tesis a mi madre, Grey Jimena Villacis, por ser mi padre y madre a la vez, por ser la mujer que me inspira, por brindarme su apoyo y creer en mí y en mi meta que ahora es una realidad. A mis hermanos: Daniela, Jairo, Yannick, Esteban y Dafnne por su compañía, palabras de ánimo y su amor. Hermanos que este logro nos ayude a todos a ver que a pesar de los momentos difíciles y los problemas, Jehová nos ayuda siempre y ha permitido que finalice esta etapa de mi vida y hará lo mismo con cada uno de ustedes.

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Nicole Ailyn Lovato Villacis

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Resumen

La amputación transtibial es el nivel más común de amputación de miembros inferiores en el que el plano de corte pasa por la tibia y el peroné y puede ser distal, medio o proximal. Uno de los problemas de las amputaciones a nivel transtibial es que el dolor hace que la articulación se mueva lo menos posible, lo que provoca una atrofia muscular que debilita la articulación. La fisioterapia es, por tanto, una parte fundamental del tratamiento y una vía ineludible antes de la colocación de una prótesis. Es importante que los pacientes desarrollen y mantengan una buena fuerza muscular y flexibilidad articular para apoyar una marcha protésica segura, eficiente y natural. En este contexto, la electroestimulación desempeña un papel importante en la fisioterapia. La estimulación eléctrica como método de control del dolor se ha hecho cada vez más popular por su índice de éxito y su técnica no invasiva. Su uso está es muy aceptado en el área de la salud de tal manera que ha generado beneficios en el campo fisioterapéutico y en el desarrollo muscular. Sin embargo, el diseño de protesis con electroestimulación es limitado, debido, principalmente, a la falta de familiaridad y conocimiento del sistema. El objetivo de este proyecto es explicar los usos y las posibles aplicaciones de la estimulación eléctrica en una prótesis transtibial para reducir el dolor. En particular, se discute el uso de la estimulación eléctrica como terapia de dolor y la incorporación del electroestimulador en prótesis definitivas. La prótesis será modelada, analizada, construida y simulada en el software SolidWorks. El electroestimulator muscular será diseñado en el software proteus y finalmente fabricado con componentes electrónicos de bajo costo y fácil obtención en el país.

Palabras clave: amputación transtibial, dolor, electroestimulación, prótesis transtibial, SolidWorks

Abstract

Transtibial amputation is the most common level of lower limb amputation in which the cutting plane passes through the tibia and fibula and can be distal, middle, or proximal. One of the problems with transtibial amputations is that pain causes the joint to move as little as possible, leading to muscle atrophy that weakens the joint. Physiotherapy is, therefore, a fundamental part of the treatment and an unavoidable route before placing a prosthesis. It is important for patients to develop and maintain good muscle strength and joint flexibility to support a safe, efficient and natural prosthetic gait. In this context, electrostimulation plays an important role in physiotherapy. Electrical stimulation as a method of pain control has become increasingly popular for its success rate and non-invasive technique. Its use is widely accepted in the health area in such a way that it has generated benefits in the physiotherapeutic field and in muscle development. However, the design of electrostimulation prostheses is limited, mainly due to the lack of familiarity and knowledge of the system. The objective of this project is to explain the uses and possible applications of electrical stimulation in a transtibial prosthesis to reduce pain. In particular, the use of electrical stimulation as pain therapy and the incorporation of the electrostimulator in definitive prostheses are discussed. The prosthesis will be modeled, analyzed, built and simulated in SolidWorks software. The muscle electrostimulator will be designed in the proteus software and finally manufactured with inexpensive electronic components that are easy to obtain in the country.

Keywords: transtibial amputation, pain, electrostimulation, transtibial prosthesis, SolidWorks.

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Acronyms index

PLS	Phantom Limb Sensation
PLP	Phantom Limb Pain
TENS	Transcutaneous Electrical Stimulation
NMES	Neuromuscular Electrical Stimulation

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1. Introduction

1.1. Problematic Situation

There is a report from the Secretary General of the United Nations on the degree of compliance with the Millennium Development Goals (MDGs) for people with disabilities that reveals that around 426 million of them live below the poverty line in the developing countries. This amount represents between 15% and 20% of the most marginalized poor population in these countries [1]. It should be taken into account that this percentage of people suffer double discrimination, the first is their economic deficit (poverty) and the second is their disability.

According to the National Council of Disabilities of Ecuador, there are 400,000 people who have some type of physical disability, and of this number around 4,620 people have physical disabilities in the Imbabura province (see Fig. 1) [2].

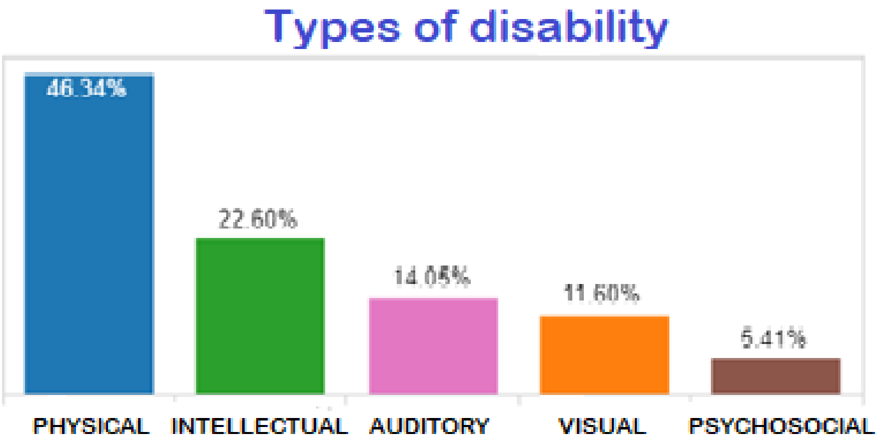


Figure 1. Percentage of people with physical disabilities in Imbabura province.

Human beings were created with the ability to move from one place to another with our lower extremities. For this reason, if one of the lower limbs is lost, not only is our mobility affected directly, but it is also difficult to carry out daily activities and can even have emotional consequences.

Lower limb prostheses are devices that replace an amputated leg. In the case of a transtibial prosthesis, it is a device designed to be adapted to the needs of a patient who has been amputated at the level of the tibia and fibula, losing her ankle and foot, but preserving the knee. After the operation, one of the main complaints is residual pain in the extremities. This pain is also known as stump pain or incisional pain. Residual pain regularly presents as beats and is located in the residual limb. The pain usually disappears in an approximate time ranging from one to three weeks. Residual limb pain at a subsequent stage could be attributed to shear forces on adherent scars, a poorly fitted prosthesis, or other medical or neurological conditions [3].

In this way, electrical stimulation has been a good option to treat the pain caused by an amputation. By designing a prosthesis that contains an electro stimulator, it is possible to better evaluate the progress of patients who are subjected to electrotherapy in terms of reducing pain, improving the gait pattern when descending stairs, and reducing falls.

1.2. Problem Statement

5.6% of the Ecuadorian population, which corresponds to 816 156 people, report some type of disability. The presence of disabilities is related to age, 33% are over 65 years old. Accidents, on the other hand, are a cause of disability and tend to affect the male population between 20 and 64 years of age (19%). In women of the same age range with negative health conditions, they report some disability (53%). The latter also affect comprehensive development in children under 5 years of age. Less than half of people with disabilities (44%) have ever worked, but only a quarter (25%) of people with disabilities report that they are working, and the rest do so in sheltered special employment or in turn in some regular supported employment [4].

Among patients who had suffer from an amputation, 90% of them feel pain if they use prostheses [5]. According to Pazmiño M, amputation levels are: transfemoral (48%), transtibial (45%), hip disarticulation (5%), syme-type amputation (1%), partial foot amputation (0.5%), disarticulation ankle (0.3%), and amputation of fingers (0.2%). Based on these data, transtibial amputation is one of the most frequent of the amputations of the lower limb [6] (See Fig. 2). That is why the following work will be focus on this type of amputation specifically and how to relieve post-operative pain.

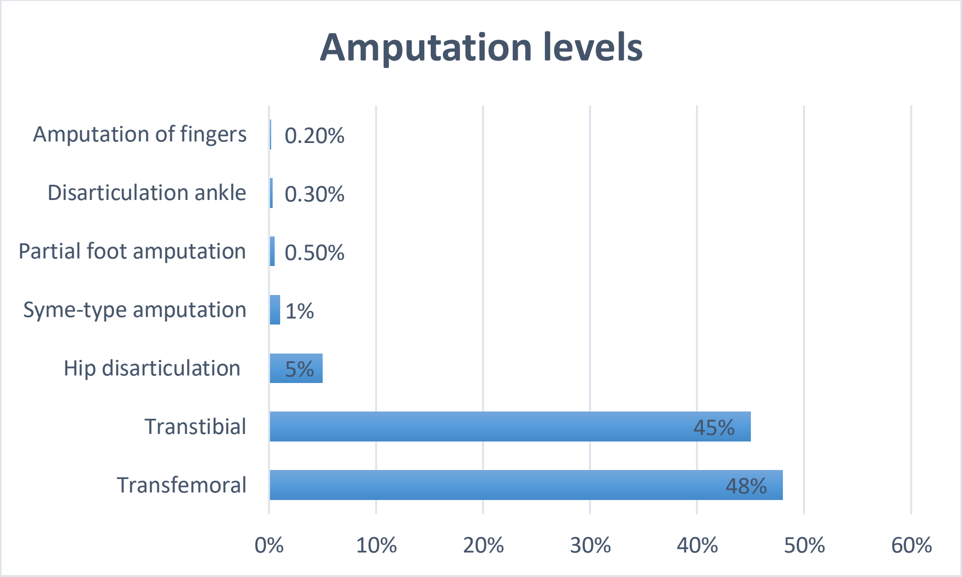


Figure 2. Amputation levels.

As the development of a transtibial prosthesis that provides electrical feedback is a fairly extensive field, it has branched out into several lines of research, one of these areas being the development of an electrical stimulator to later couple it to the designed prosthesis. In order to develop the leg mechanism, human gait must be analyzed, the main parameters such as the forces acting on the mechanism, displacement, speed, and the least possible weight must be obtained, and an understanding of human gait in order to design the articulation with the main parameters in the human gait cycle.

1.3. Justification

Article 47 of the Republic of Ecuador establishes that “The state guarantees policies for the prevention of disabilities and, in conjunction with society and the family, will seek equal opportunities for people with disabilities and their social integration” [7].

In our environment there are around 4620 people who have physical disabilities, and for most of these people it is difficult to acquire a prosthesis for two main reasons. One of them is because there are not many places where they are manufactured and the second is because of their high costs at import one.

In addition, article 32 of the Ecuadorian constitution recognizes health as a right that must be guaranteed by the state. It is the obligation of the different health services to help the patient overcome the difficulties that an amputation entails, whether physical or psychological. On a physical level, the patient who has had a part of the body amputated suffers different biomechanical problems that prevent him from carrying out his activities normally, which produces an increase in social and economic stress in the patient and his family [7].

In the following work, research in biomechanics aims to improve the knowledge of the human body. The biomechanics of the musculoskeletal system requires a good understanding of basic mechanics, physics is used to describe the internal forces of the human body, these forces allow understanding the loading condition of soft tissues and their mechanical responses [8].

Patients with transtibial amputation tend to lose strength in the lower limb due to muscle inhibition due to pain and atrophy caused by lack of activity, although there may be other biomechanical factors related to the type of prosthesis or the surgical technique. This has led to the application of support techniques to facilitate muscle activation, such as electrostimulation, with which it is possible to obtain high intensity contractions that overcome muscle inhibition. In addition, electrostimulation can be used in association with a reinforcement or feedback system that facilitates muscle activation and reeducation that has been used in muscle recovery from various lower limb pathologies with good results [9].

The present research aims to carry out the design of a leg prosthesis with electrical feedback in our country, generating possible solutions for people who have lost part of their lower limb due to transtibial cut and who suffer pain from this same cause. By making prostheses in our country the cost of these is considerably reduced, reaching a greater number of beneficiaries.

1.4. Scope

The main objective of this project is to design a transtibial prosthesis with electrical stimulation, starting the investigation with the simulation in proteus and the design of the prototype of the muscular electrostimulator. Then the study of the biomechanics of the leg and the analysis of the gait. Finally, the design and simulation of the prosthesis will be carried out using the Solid works software. This project is based on previous research studies.

2. Objectives

2.1. General Objective

Design a transtibial prosthesis that provides electrical feedback by using solid works software to relieve pain in amputated patients.

2.2. Specific Objectives

- Design an electrostimulator as a rehabilitation and pain therapy tool for transtibial amputees.
- Analyze the biomechanics of human gait in order to mimic its most relevant parameters when using the transtibial prosthesis.
- Design a transtibial prosthesis in SolidWorks software, which is an interactive tool that allows to choose the prosthesis material for its later simulation.
- Simulate the physical parameters of the transtibial prosthesis using SolidWorks Simulation in order to evaluate its functioning.

3. State of the art

3.1. Lower limb physiology

Like the upper limbs, the lower limbs of the human being is a system that includes segments, joints and muscles. Fig. 3 shows the 3 main segments of the lower limb: the hip, the leg and the foot [10].

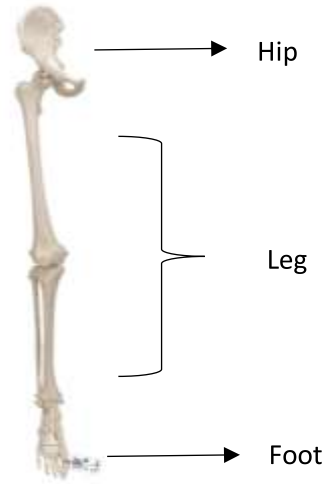


Figure 3. Bone and muscular structure of the lower limb [10].

Although the hip plays a very important role in human gait, as it provides mobility and stability to the human body, this section will focus on the anatomy of the leg.

The leg is made up of four bones. In the upper section is the femur and the patella; and in the lower section the tibia and fibula as can be seen in Fig. 4 [11].

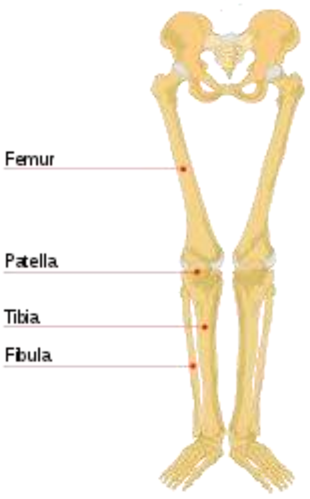


Figure 4. Bony structure of the human leg [11].

On the other hand, the bone structure of the foot (Fig. 5) as well as that of the hand is one of the most complex in the body. It is made up of 26 bones divided into three main blocks: Tarsus, Metatarsal and Phalanges [10].

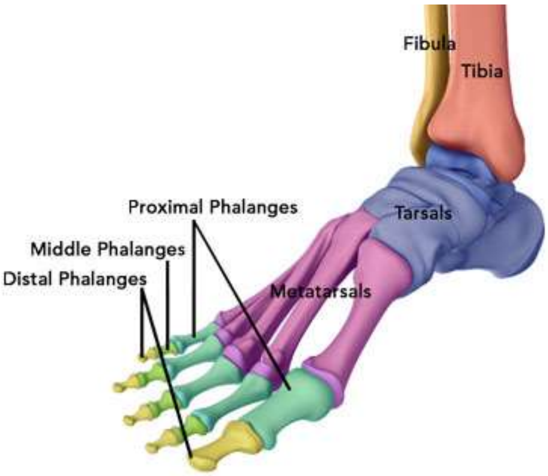


Figure 5. Bony structure of the human foot [10].

3.2. Biomechanics of the foot and ankle

The movement of the foot is in charge of two joints: the ankle and the subtalar joint (Talus-Calcaneus) (see Fig. 6) [12].

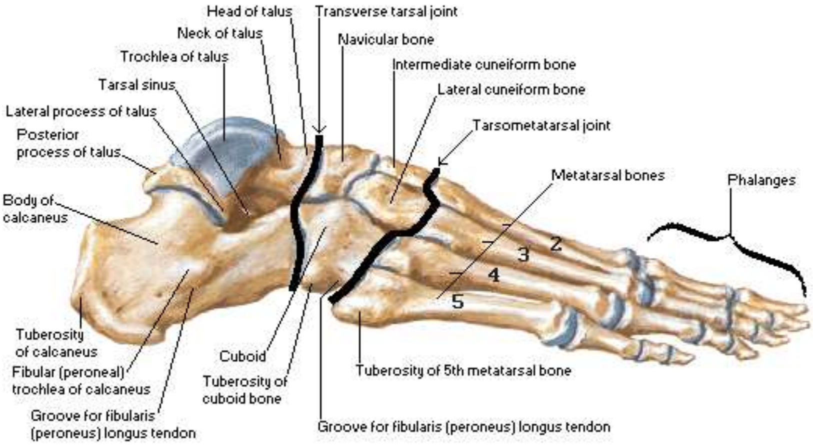


Figure 6. Medial view of the foot [12].

3.3. Identification of loads during human walking

To identify the forces (loads) acting on the foot during gait, it is necessary to study the ankle joint. The study by Snedeker et al. found that the main reaction force acting on the ankle is produced by the gastrocnemius or "calf" muscles and the soleus (Fig. 7). During the early stage of human gait the pretibial muscles produce an average compression of less than 20% of a person's entire body weight. In contrast, during the heel lift there is a compressive force of five times the body weight and this is due to the contraction of the posterior calf muscles [13].

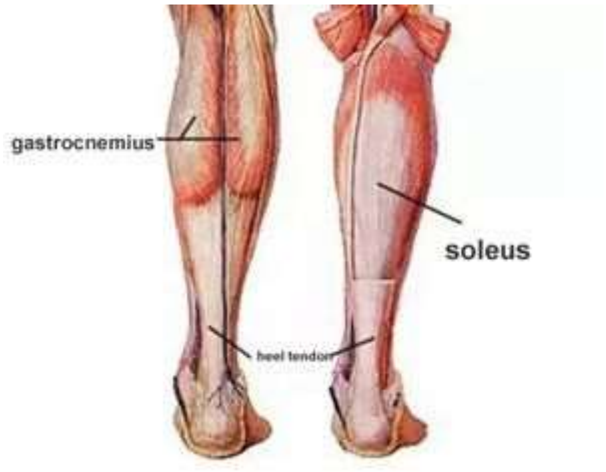


Figure 7. Gastrocnemius or "calf" muscles and the soleus [10].

Fig. 8 shows how the reaction of the ground on the foot is while a person leans on the ground. Each movement of the foot is indicated, from the heel strike (HS), through the flat foot (FF), the heel lift (HL) and finally the toe lift (TL). From the graph it can be seen that the main component is the normal reaction of the ground on the foot (Vertical) [14].

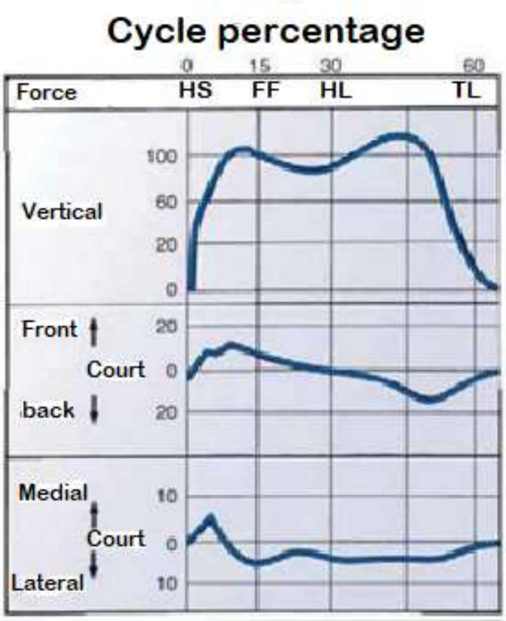


Figure 8. Reaction forces on the ground during walking [12].

The free-body diagram of the ankle joint (Fig. 9) was made in order to find the forces that interact on it. The lines of application of the forces A and W extend until they intersect. Next, the line of force application is found by joining the point of intersection and the point of application, known as the tibiotalar junction [14].

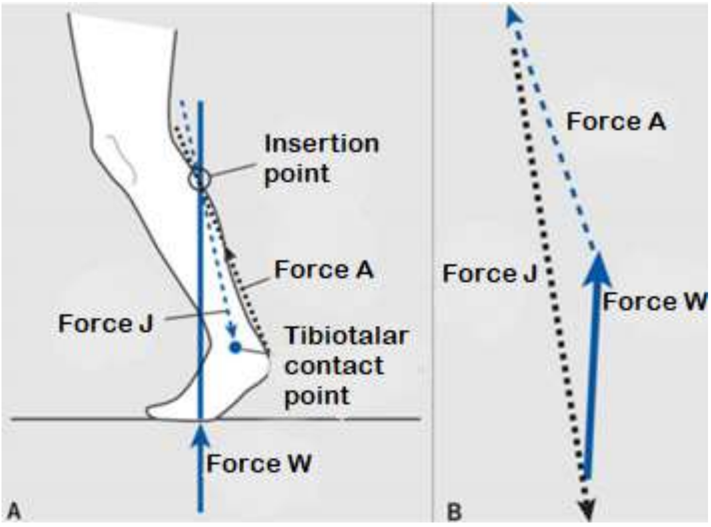


Figure 9. A. Ankle free body diagram.

B. Triangle of forces formed by vectors W, J and A [12].

The ankle performs rotational movements and a study by Moriguchi et al. shows its possible rotations [15]. Fig. 10 indicates that the ankle has a strong plantar flexion when lifting the heel off the ground (around 60% of the total cycle), however this movement is achieved by the action of the muscles on the foot, so it is outside the range of motion foreseen for the system to be designed. In this way, -8 ° to 6 ° in the sagittal plane, as well as 5 ° symmetrical in the frontal plane, are considered as maximum ranges.

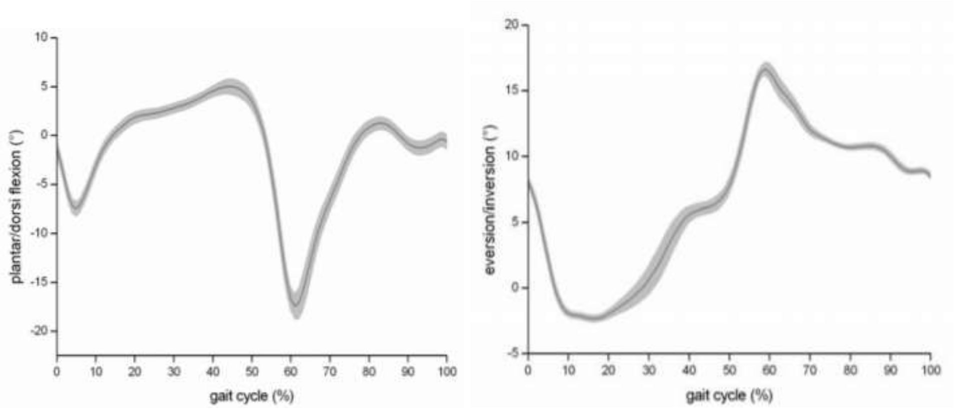


Figure 10. Ankle rotation angles in the sagittal plane (Left) and in the frontal plane (Right) [15]

All the information reviewed so far is necessary to be able to determine the edge conditions to which the tibia has to be subjected designed in order to support the weight of a person walking on level ground.

3.4. Human gait

The main way of moving for a human being is walking, usually its operation is distinguished in that when we walk only one foot at a time it leaves contact with the ground. For human beings, walking is the main and natural form of transport at an average walking speed of approximately 4 to 5 km/h. Although this speed will depend on some factors such as height, weight, age and the difficulty of the terrain or surface [16].

3.4.1. Leg path

The human gait is the result of the application of the method known as double pendulum. In such a way that during the movement the leg leaves contact with the ground and swings forward. On the other hand, the leg rests on the heel transmitting the support through the foot until it reaches the tip. The movement of the two legs is completely coordinated in such a way that one foot or the other is always in contact with the ground. In the process of walking, approximately 70% of the energy used is recovered due to the dynamics of the pendulum and the reaction force of the ground [16].

3.4.2. Anatomical walk

As has been mentioned, walking is the coordinated action of the two legs. This coordinated movement is caused by a rotational movement of the leg joint. In Fig. 11 the general physiological walk is represented, which begins with the pendulum movement assuming the start of the right leg in the first step vertically.

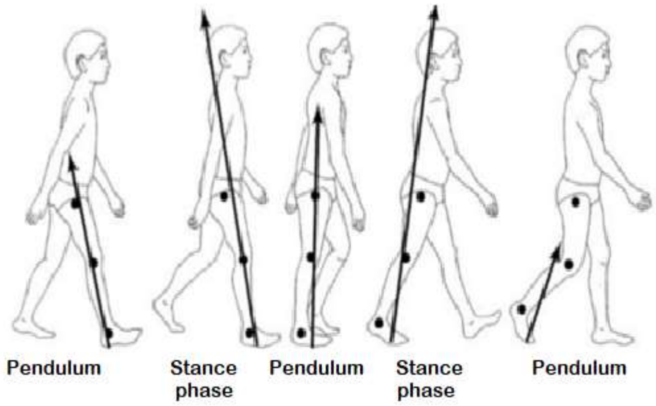


Figure 11. Right leg stance phase [16].

To walk the first step is to lift the left leg with the help of the right leg mentioned above until the left leg manages to fixate on the ground. The next step is similar to the first step of the firm foot, with the difference that now this step has support for the legs until the right leg is raised and planted. At the end of each bipedal step, you have both legs that are in support [17]. During the walk, each leg complies with two phases called: Support Phase and Oscillation Phase.

3.5. Transtibial amputation

First, the term amputation comes from the Latin "amputare" which means to cut and completely separate a portion of it from the body; and they have two objectives which are extirpation and reconstruction. In excision, the main objective is the elimination of the pathological limb by creating an optimal structure from the motor and sensitive point known as the stump to offer better handling and functionality. On the other hand, reconstruction seeks to create an optimal distal organ that does not present pain or impede the biomechanical movement of the patient [11].

With the above in mind, transtibial amputation or below-knee amputation (Fig. 12) is the removal of the lower limb at the level of the tibia and fibula. When the patient undergoes an amputation, he loses sensory feedback on the location of the limb when walking, which represents a challenge when walking with a prosthetic leg. A person who has not undergone amputations can know exactly the position of her foot with his eyes closed, while an amputee does not know the position of his prosthesis without first looking at it [12].

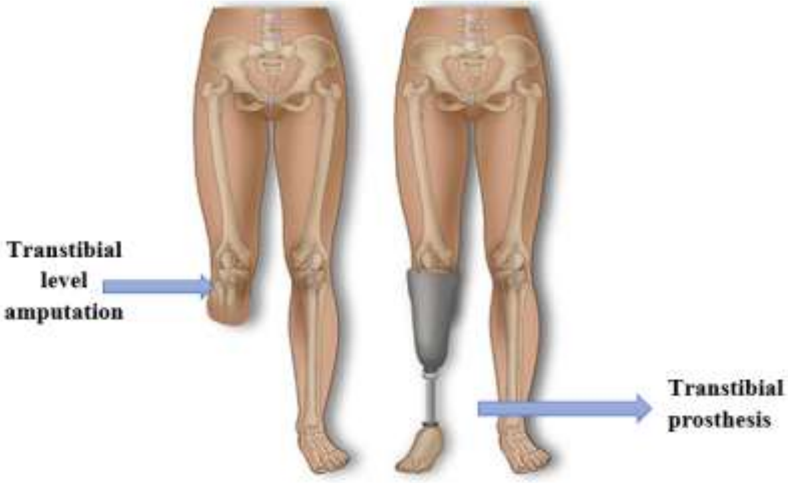


Figure 12. Transtibial level amputation [11].

3.6. Research on the design of transtibial prostheses

Prosthetic components consist of several parts including the socket, pylon, and foot. The socket part of transtibial prosthetics is important because the stump does not have the same weight-bearing capabilities as the foot. Thus, the design and fit of a socket are important factors in the successful rehabilitation of the patient.

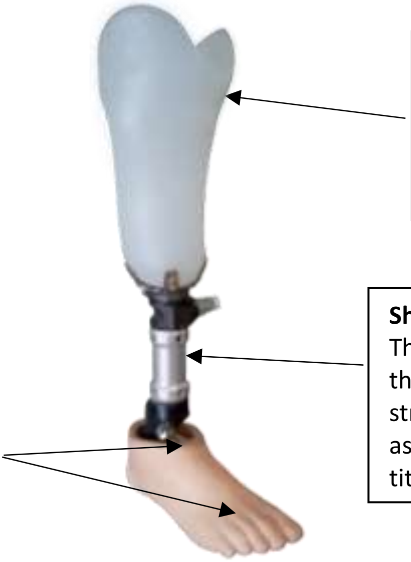
In order to consider the possibility of designing a combined prosthesis where the electro stimulator can be adapted for a better use of this resource, the prosthetic coating method was analyzed, which includes a coating that has an internal surface and an external surface, the surface internal surface configured to engage with the skin of a user's residual limb and the external surface configured to engage a surface of a prosthetic socket.

In this way, a space can be conditioned to place the electrostimulator inside the lining of the transtibial prosthesis [18]. However, the superficial space is not the only important thing to take into account, also the properties of the prosthesis must be optimal for the patient to feel confident. For this reason, the study by Jweeg et al. uses the vacuum model method which allows calculating mechanical properties using tensile and flexural tests [19].

In addition, the ANSYS program calculates the deformation, the maximum stress at the beginning and the safety factors of the prostheses. Another important aspect to consider is the human cost of a prosthesis, which is why the work by Handford & Srinivasan [20] presents the robotic design of lower limb prostheses through simultaneous computer optimizations of human and prosthetic costs. With this model it has been possible to predict the costs of the prosthesis together with the information on the number of steps that are walked daily which will allow choosing the specifications of the motor and the battery of the prosthesis.

3.7. Parts of a transtibial prosthesis

Prostheses have undergone a process of evolution in order to be efficient for the user and during the process the elements that make up a prosthesis for a lower limb amputation have been manufactured in different types of materials. Next, Fig. 13 shows the main components that make up a lower limb prosthesis.



Socket
This is the part of the artificial limb that stump fits into. It is usually made of a plastic or laminated material.

Prosthetic foot and ankle
There are many different types of feet and ankles available. The prosthetist will decide the most suitable combination for patient's needs.

Shin tube
This lies between the socket and the prosthetic foot. It is made of strong, lightweight material, such as carbon fiber, aluminum or titanium.

Figure 13. Parts of a transtibial prosthesis [21].

The process of obtaining a prosthesis depends on each patient and can begin approximately 10 to 14 days after the amputation operation. When using the prosthesis, the patient should not support his weight on the tip of the stump since in the long term this could cause deep damage to the surrounding tissue of the truncated bone. That is why it has recently been decided to design socks that rest on the lateral part of the prosthesis, specifically in the areas that accept pressure [21].

Once the prosthetic socket is produced, the check socket is usually made by placing a sheet of thermoplastic material and with a vacuum pump that exerts force, the thermoplastic is made to adhere to the surface of the socket. In this way, first the check socket is tested on the patient and then the necessary modifications are made for a definitive socket [22] [23].

Light alloy tubes are generally used for structural support, commonly the material is aluminum due to its low density and good properties compared to conventional steel. The only job of this prosthetic component is to resist as much as possible the stresses applied to them [24].

In the case of feet, they are classified according to the degree of complexity of the design as they best mimic the original anatomy of a natural foot. When a good articulation is made, it greatly benefits the smoothness of the ride and its efficiency. Regarding the movement of the ankle, an important aspect is shock absorption, which is responsible for avoiding overloading the stump. An example of this is a compressible heel, which emulates the compression of the dorsiflexor muscles when the heel touches the ground. This is called simulated or relative plantar flexion. Another aspect is the use of a “mask” that emulates the appearance of a natural foot that also protects the important components from any unnecessary wear and tear [12].

3.8. Types of pain after amputation

As mentioned at the beginning, patients who experience an amputation of one of their extremities are exposed to developing various pain syndromes. There are three main types of pain such as: residual limb pain, phantom limb sensation (PLS) and phantom limb pain (PLP). For this reason, it is essential to identify the differences between the latter in order to treat them.

3.8.1. Residual limb pain

After the operation, one of the main complaints is residual pain in the extremities. This pain is also known as stump pain or incisional pain. Residual pain regularly presents as beats and is located in the residual limb. The pain usually disappears in an approximate time ranging from one to three weeks. Other causes of residual limb pain are ischemia, infection, neuroma formation, and pressure points from bone spurs or pathological bone formation. Residual limb pain at a subsequent stage could be attributed to shear forces on adherent scars, a poorly fitted prosthesis, or other medical or neurological conditions [3].

3.8.2. Phantom limb sensation (PLS)

PLS is very common in patients who have had an amputation [25]. The PLS expression is aimed at patients who are aware of the missing part of their limb. It should be noted that PLS is not painful. So it is seldom a clinical problem and it usually reduces over time. Various sensations can be felt, such as mild numbness and tingling, itching, or an impression as if the amputated limb were in certain postures or feeling particular movements. Patients perceive that they can move the amputated limb [3].

3.8.3. Phantom limb pain (PLP)

PLP refers to painful sensations related to the amputated part of the body. It is a common pain among amputees, with different sources that ensure its prevalence between 50% and 88% [26]. Like other pain conditions, PLP has negative effects. For example, amputees with PLP have little chance of wearing a prosthesis resulting in additional disability. Furthermore, most amputees report that PLP impairs their sleep and these episodes are usually so intense that they wake patients up at night. This causes the victim to lack sleep and this situation has been shown to decrease pain tolerance [27].

3.9. Electrical stimulation

In order to treat any type of ailment caused by an amputation, electrical stimulation will be referred to as a pain relief therapy. Electrical stimulation is a form of non-invasive treatment that includes various stimuli applied superficially using electrodes placed on the skin. Electrical stimulation has been used in different fields, such as treatment, rehabilitation therapy and training. There are different forms of electrostimulation among the most revealing are: Transcutaneous Electrical Stimulation (TENS) and Neuromuscular Electrical Stimulation (NMES) [28].

3.9.1. Transcutaneous Electrical Stimulation (TENS)

TENS is the delivery of pulsed electrical currents along the intact surface of the skin to stimulate the peripheral nerves essentially to quell pain. Practically, TENS is supplied using a portable device that is used with batteries with the aim of producing electrical currents which are discharged to the body through the electrodes that are attached to the skin [29].

3.9.2. Neuromuscular Electrical Stimulation (NMES)

On the other hand, NMES is generated by a device that transfers electrical impulses directly to the muscle fibers through electrodes located on the skin. These impulses induce action potentials, which stimulate the motor nerves, causing contractions. Among the main adverse effects of NMES are muscle discomfort because of electrical stimuli and excessive neuromuscular fatigue [30].

Table 1. TENS Vs NMES.

TENS	NMES
Uses steady current to stimulate nerves	Uses a cycle of impulses to cause muscle contractions
Primary use is to relieve pain	Primary use is for physical therapy of muscle tissue
Blocks pain signals from reaching the brain	Prevents wastage or damaging of muscles due to injuries
Temporary pain reduction	Reduces muscles atrophy
Helps body produce more natural pain-relieving substances	Helping increase blood flow, range of motion and increases muscle
Relieves both chronic and acute pain	Relieves muscle pain from spastic muscles, tight or sore muscles

3.9.3. Research on the effect of electrostimulation in patients with transtibial amputation

There are several studies that have tested the effect of electrostimulation in patients with lower amputations in general and other studies that prove the same effect but specifically in transtibial amputations. The study by Brede et al. is about neuromuscular electrical stimulation for pain management in combat related transtibial amputees during rehabilitation. This study evaluated patient pain for 12 weeks with two treatments applied to two groups of patients: a military amputee rehabilitation program (MARP) and a different NMES + MARP. The results of this study show that the NMES + MARP group confirmed decreases in pain intensity present at weeks 3 and 7 and no comparative decreases could be observed in the MARP group only until week 12. This demonstrates and recommends a role of NMES in the rehabilitation process by reducing pain [31].

Another similar study by Thant et al. involved two groups of patients. Group A patients received neuromuscular electrical stimulation and progressive resistance exercise for 12-week periods. Patients in group B received only progressive resistance exercise during the same period. At the end of the study, the quadriceps muscle strengths improved significantly in the NMES treatment group compared to conventional therapy. Therefore, it is observed that neuromuscular electrical stimulation and progressive resistance exercise are effective in transtibial amputation not only in calming pain but also in muscle strength, volume and quadriceps function [32].

3.10. The Electric Wave

It is known that an electrostimulator shows its operation through electrical waves which can be observed by an oscilloscope. In this section, the types of waves that an electrostimulator can generate will be presented.

Firstly, a wave consists of the propagation of a disturbance of some property of a medium, for example, density, pressure, electric field or magnetic field, through said medium, involving a transport of energy without transport of matter. The disturbed medium can be diverse in nature such as air, water, a piece of metal, and even immaterial such as a vacuum [33].

3.10.1. Elements of a wave

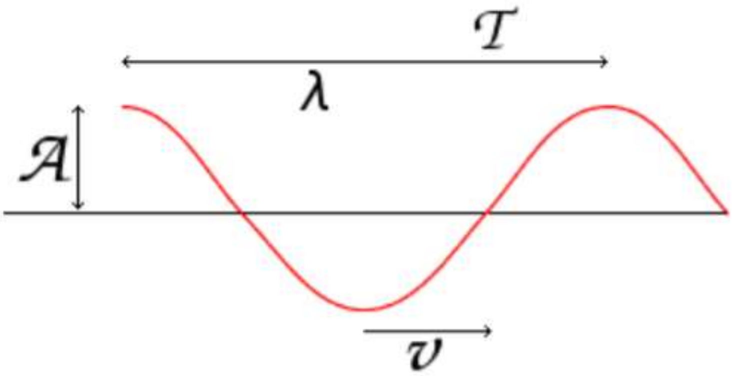


Figure 14. Elements of a wave [].

- Amplitude (A): Amplitude is the vertical distance between a crest and the midpoint of the wave. Note that there may be waves whose amplitude is variable, that is, it increases or decreases with the passage of time.
- Wavelength (λ): It is the distance between the same point of two consecutive undulations, or the distance between two consecutive ridges.

$$\lambda = \frac{c}{f}$$

Equation 1. Wavelength equation

- Frequency (f): Number of times that this vibration is repeated per unit of time.

$$f = \frac{c}{\lambda}$$

Equation 2. Frequency equation

- Period (T): The period is the time it takes for the wave to go from one point of maximum amplitude to the next.

$$T = \frac{1}{f}$$

Equation 3. Period equation

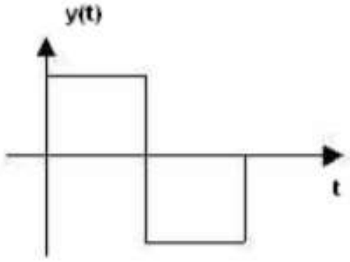
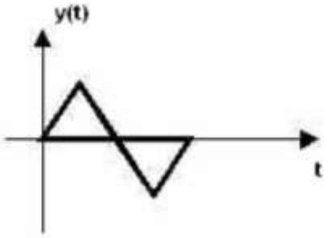
- Velocity of propagation (v): is the speed at which the wave motion propagates. Its value is the quotient of the wavelength and its period [34].

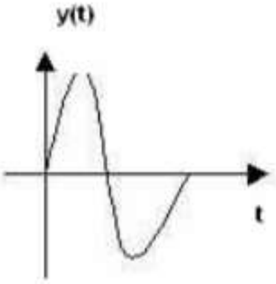
$$v = \frac{\lambda}{T}$$

Equation 4. Speed equation

3.10.2. Wave Types

Table 2. Wave Types

Square wave	Square waves are basically waves that pass from one state of tension to another, at regular intervals, in a very short time.	 **Figure 15.** Square wave [34].
Triangular wave	Triangle waves are produced in circuits designed to control voltages linearly, as in the case of the horizontal sweep of an analog oscilloscope. The transitions between the minimum and maximum signal level change at a constant rate.	 **Figure 16.** Triangular wave [34].

Sinusoidal wave	The sine wave has a single frequency with a constant amplitude.	 **Figure 17.** Sinusoidal wave [34].

4. Materials and Methodology

4.1. Manufacture of the electrostimulator

In order to manufacture the muscle electrostimulator, a series of steps has been carried out. These steps are detailed in Fig. 18, the first step is the design and simulation in the Proteus Software. The second step is the testing of the signals, also in Proteus, these signals can be observed using the digital oscilloscope tool. Once the operation of the circuit has been verified digitally, the third step is to implement the circuit on the breadboard. Finally, muscle simulation in a patient suffering from transtibial amputation is carried out.

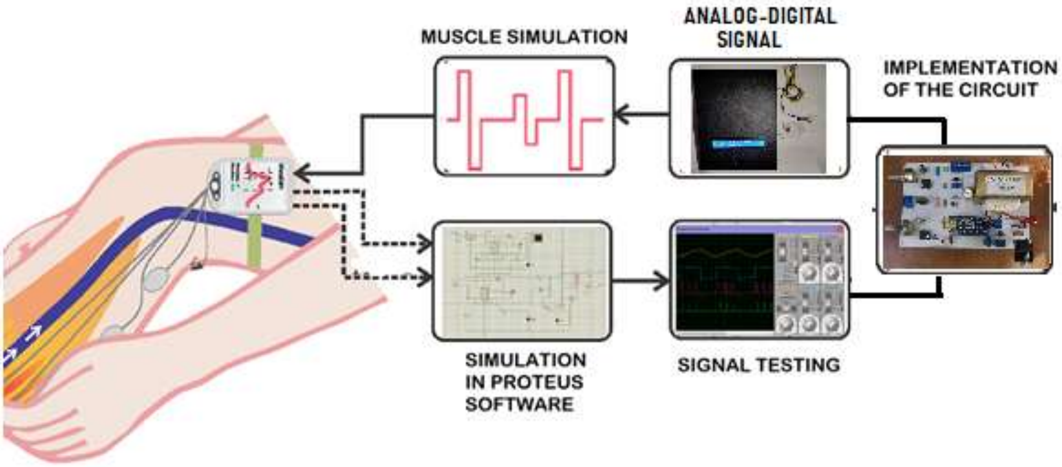


Figure 18. Process of manufacture of the electrostimulator.

In Fig. 19 the main components that make up the muscle electrostimulator can clearly see. Among them are a battery, transistors, power diodes, transformer, capacitors, resistors, an integrated circuit, and electrodes.

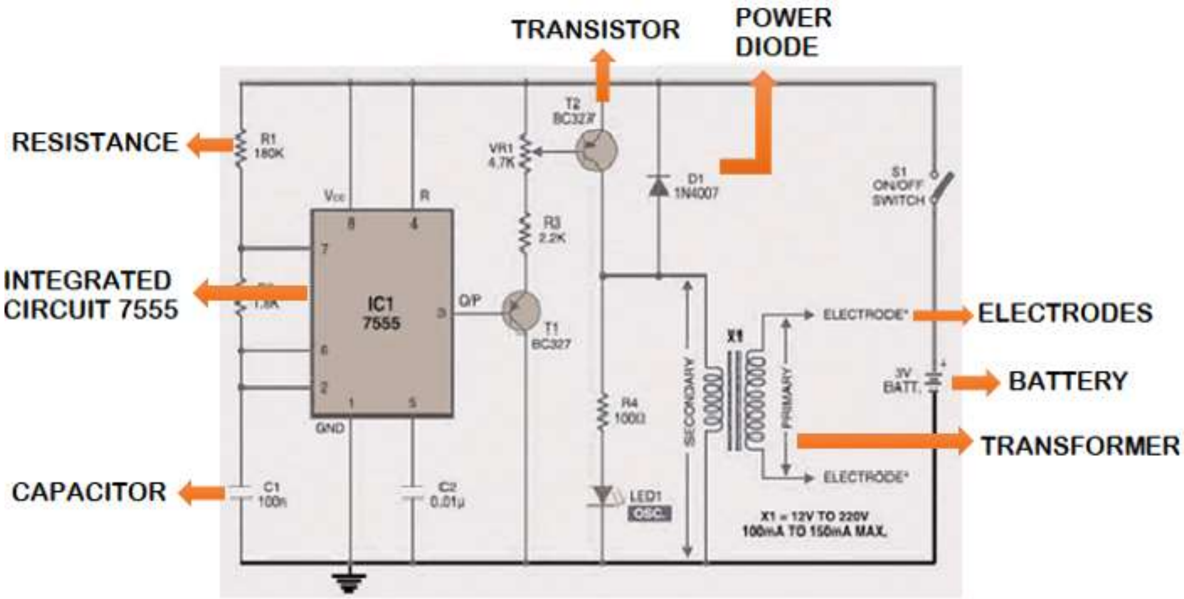
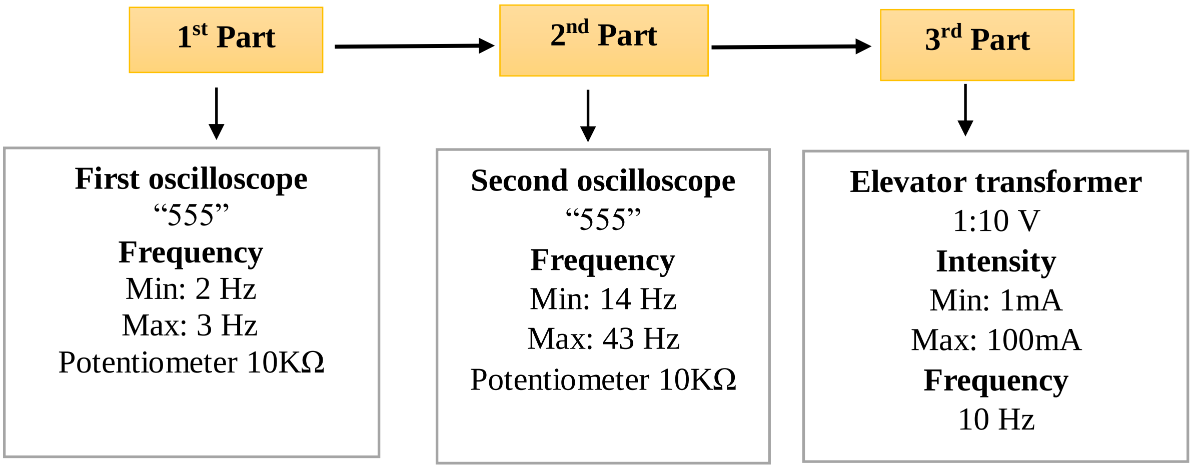


Figure 19. Parts of the electrostimulator circuit.

4.1.1. Simulation in proteus software

For the elaboration of the electrostimulator, the simulation software called Proteus was used. It can simulate analog circuits, digital circuits, microcomputer circuits, and integrated systems. Proteus software applied to the design of electrical devices can not only improve the efficiency of this, but also reduce the cost of materials since it shows us all the operation of a circuit and verifies that the circuit meets the requirements before doing it in a laboratory [9]. The complete circuit is make up of three main parts:



Thus, the proteus circuit was designed in the following way: First, the energy for the electrostimulator to work comes from a double AA battery. The design is based on an integrated circuit that is composed of two LM555 where one of them operates at low frequency approximately between 2-3 Hz, while the other does it at a higher frequency in order to generate the commutation and in this way obtain the increase in voltage at the output.

It is worth mentioning that the 555 owes its name to the fact that inside there is a set of three 5 KΩ resistors, which allows us to analyze the pin voltages [8]. The 555 can be configured in various ways depending on the purpose of study. One of them is the 555 astable configuration in which by means of a series of passive components that are placed around the chip, a square signal is obtained at the chip's output.

The circuit was implemented in three parts mainly to verify its correct operation. In this way, Fig. 20 shows the first part of the circuit.

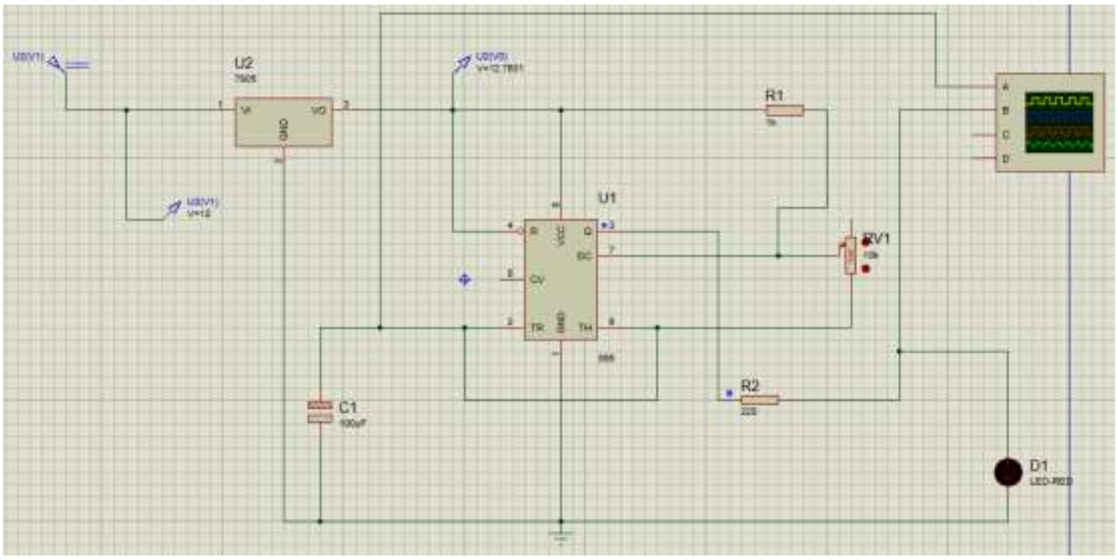


Figure 20. First part of the circuit.

In the figure above you can see the first 555 astable integrated circuit. A 7805 was placed in this circuit in order to regulate the voltage. C1 is 100uF to generate large signals. At the output is R2 of 220 ohms to visualize the oscillation and a potentiometer to control its output voltage. To observe the simulation, an oscilloscope was placed in order to see the charge and discharge signal of the capacitor and in turn see the output signal of the oscillator (see Fig. 21).

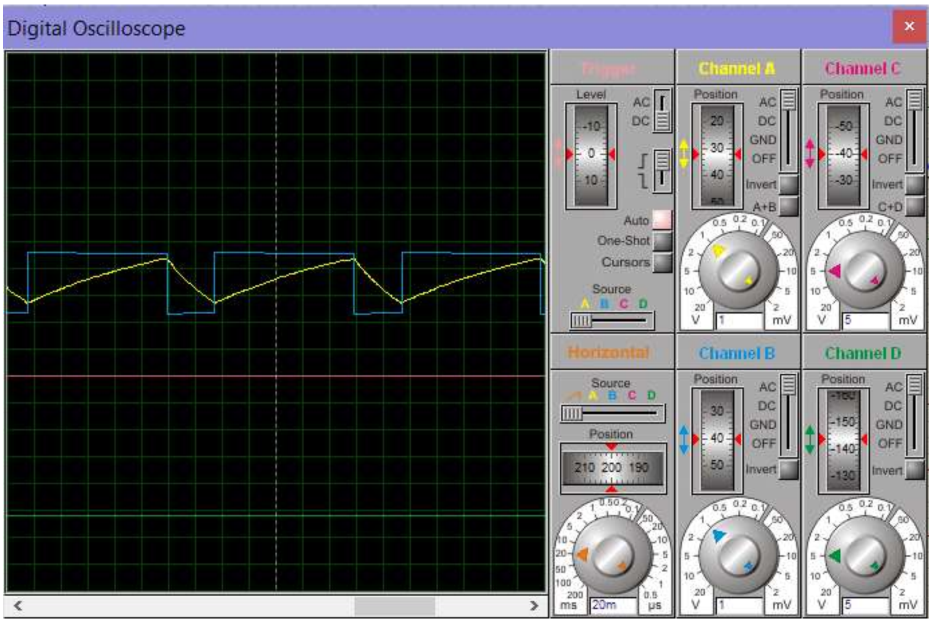


Figure 21. First oscilloscope.

The second integrated circuit 555 is implemented in the second part of the circuit (broken red lines). A second oscilloscope is added to control the signals. What you want to achieve is that the first oscilloscope controls the second. To do this, the 555 datasheet is used, which gives us technical information about it. If we focus on the second 555 integrated circuit and its pin No. 4 which is the "reset" which is connected to pin No. 2 of the first 555 so that when the latter is at zero, the second 555 will not work and the opposite is also true. Physically this operation can be observed through the operation of the LEDs, as shown in Fig. 22 when the red LED is off, the green LED is also off.

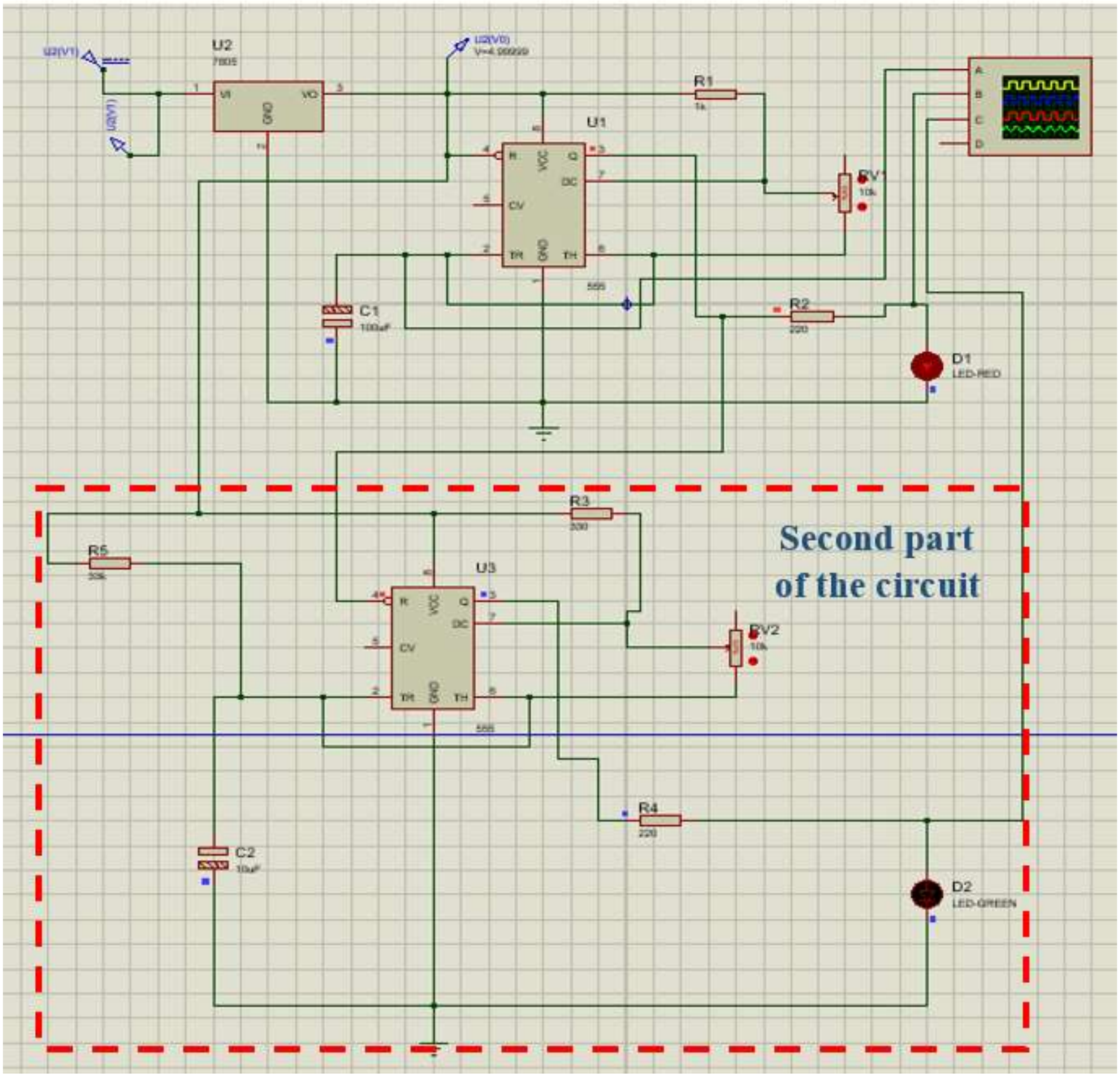


Figure 22. Second part of the circuit.

The third part of the electrostimulation system (Fig. 23) consists mainly of a transformer which serves to convert direct current (DC) into alternating current (AC). The transform is connected as an elevator in order to generate a small voltage but enough to stimulate the muscle. On the left side of the transformer the voltage will be 1V and on the right side a voltage of 10 V (see table 3). A potentiometer with variable resistance and a 10KΩ resistor has been connected to the transformer to regulate the intensity of current that will reach the electrodes and finally to the patient.

Table 3. Transformer data.

Configuration	Order	Primary inductance	Secondary inductance
Elevator	1:10	0.012H	1H

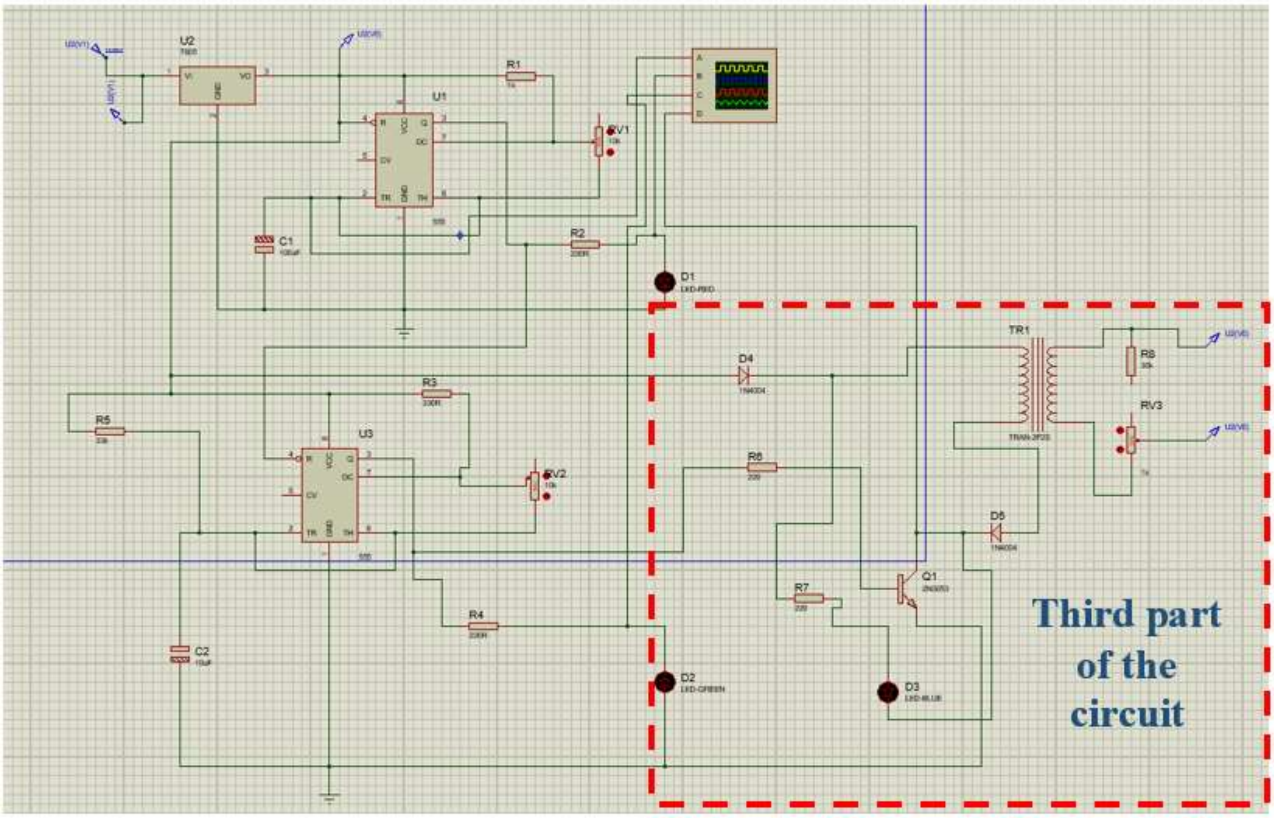


Figure 23. Third part of the circuit.

Then Fig. 24 indicates four different signals showed during the simulation of the circuit. The first one in yellow corresponds to the charge and discharge signal of the capacitor. The second signal in blue is generated by the LED of the first oscillator. The third signal in red belongs to the second oscillator. Here it is clearly seen that when the blue signal is at 1, the red signal is also generated. Whereas when the blue signal is at 0, the red signal is also off. Finally, the green signal is the current that flows through the emitter and collector, which in this case is the power transistor.

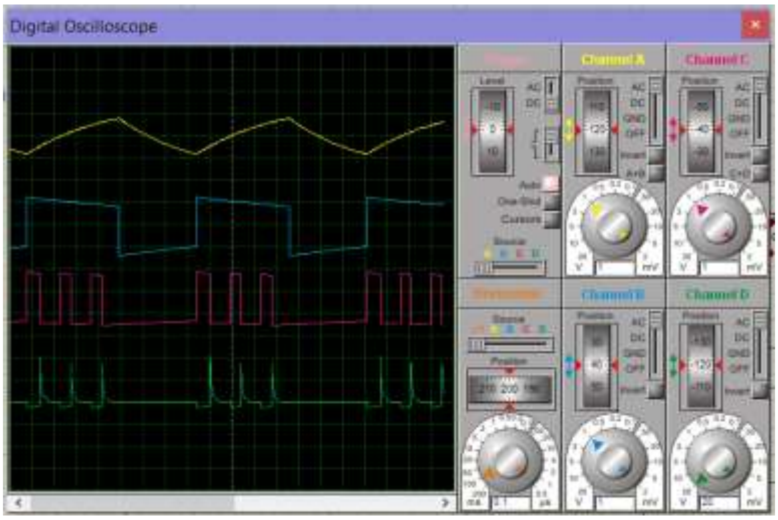


Figure 24. Oscilloscope signals.

4.2. Design of the transtibial prosthesis parts using Solid Works

Individuals with lower limb amputation have shown to expend more metabolic energy than an individual with a healthy leg during a normal walking [35].

According to Teuta et al. [35] reported that transtibial amputees tend to expend twenty to thirty percent more metabolic energy in normal walking. Some researchers have shown that powered prostheses for lower limb are able to mimic human gait. They can provide negative and positive work in the stance phase as well as to improve amputee's performance in a more natural gait and normal walking.

Ideally a good prosthetic design need to have some important characteristics, for example:

a. Show be able to produce sufficient power to gait
b. Energy consumption should be very low
c. It should fit properly. It means not exceed amputees limb
d. Resistance and fatigue behavior
e. Long term stability

In order to accomplish the above characteristics the process shown in Fig. 25 will be followed. The first step in obtaining the prosthesis is the design of its parts. The parts are then assembled with SolidWorks tools. Finally, the prosthesis material will be chosen for subsequent evaluation.

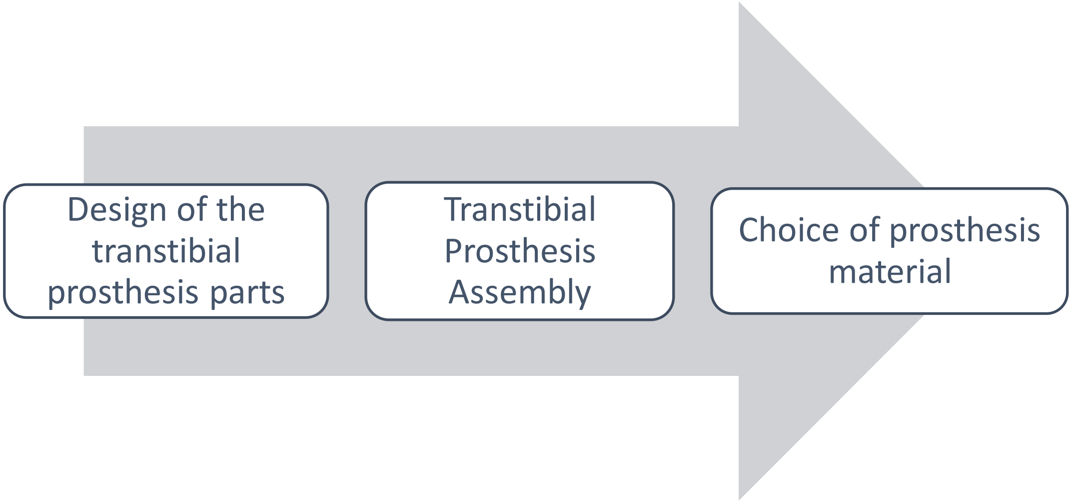


Figure 25. Process for obtaining the transtibial prosthesis.

4.2.1. Design Features

One of the important functional requirement of any transtibial prosthesis design is its ability to replicate joint motion as close as possible. Compromise on any motion or degree of freedom will a suboptimal design. The following are major functional requirements for the design:

(a) Able to bear load of human upper body weight,

(b) Can provide leg motion similar to biological leg and

(c) Should be able to hold under stress and strain.

The thickness needs to be as uniform as possible to avoid any concentrated stress failure. Considering the normal load on the one side of leg joint to be half of total load body weight such as that load is equally distributed. Then the maximum stress can be calculated as:

$$\sigma = \frac{Bending\ Moment\ (M) x\ deflection\ (y)}{Moment\ of\ Inertia\ (I)}$$

Equation 5. Maximum Stress equation

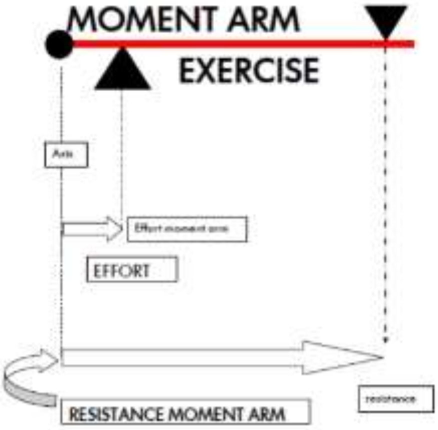


Figure 26. Moment arm [36].

Where,

Bending Moment (M) = (patient weight/2) * moment arm

Deflection (y) = thickness/2, this value is based on the weight of patient Moment of inertia (I) = $bh^3/12$

Therefore, by substituting the value of each parameter, we can calculate the maximum stress it can hold. This shall be done on the final model using SolidWorks.

4.2.2. Degrees of freedom (DOF)

Degree of freedom (DOF) is the number of independent parameters which determines the position (or movement) of the object [37].

The degree of freedom of the leg is numbered from left to right and from bottom to top in Fig 27. The functions of the degree of freedom in each joint were shown in table 4.

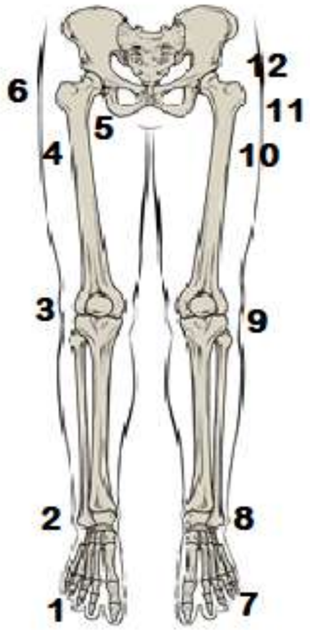


Figure 27. The configuration of the leg degrees of freedom [33].

Table 4. The number of the DOF of the leg joint.

Number of the joint	The name of the joint
1	The lateral joint of the left ankle
2	The front joint of the left ankle
3	The front joint of the left knee
4	The front joint of the left hip
5	The lateral joint of the left hip
6	The rotation joint of the left hip
7	The lateral joint of the right ankle
8	The front joint of the right ankle
9	The front joint of the right knee
10	The front joint of the right hip
11	The lateral joint of the right hip
12	The rotation joint of the right hip

4.2.3. SolidWorks

SolidWorks 2019 was used to design the various components of the transtibial prosthesis. SolidWorks is a CAD software. CAD stands for Computer Aided Design is a very power tool in designing 2-D or 3-D images of physical object. It is mainly focused into electrical engineering and Biomedical engineering. SolidWorks is what we call a "parametric" solid modeler used for 3-D design. Parametric means that the dimensions can have relationships between one another and can be changed at any point during the design process to automatically alter the solid part and any related documentation [38].

4.2.4. SolidWorks-Parts

It is important to mention that there is not an official document or an official study carried out a national level that shows the real average height of Ecuadorian people, however previous research has been used to determine the standard measurements for a prosthetic foot. For example, Lim [39] analyzed the anthropometric differences of the three main ethnic groups (mestizo, indigenous and Afro-Ecuadorian) in the Sierra-Ecuador zone. This study was conducted in order to design and build ergonomic prostheses. The data were collected in the provinces: Pichincha, Tungurahua, Chimborazo and Imbabura. The results show the appropriate lengths to size the transtibial prosthesis. Table 5 shows the mean measurements and standard deviations of the anthropometric study.

Table 5. Anthropometric Study [36].

	Meztisos	Natives	Afro-Ecuadorian	Gender
Average height	1.724 m	1.633 m	1.736 m	Male
Average height	1.592 m	1.553 m	1.659 m	Female

According to the table above and due to the fact that the majority of the population in the highlands of Ecuador are "mestizos", a transtibial prosthesis will be performed for a man 1.72 m tall. Below are all the components that were designed in SolidWorks to build the transtibial prosthesis. In this way, Fig. 28 shows the dimensions of the right foot.

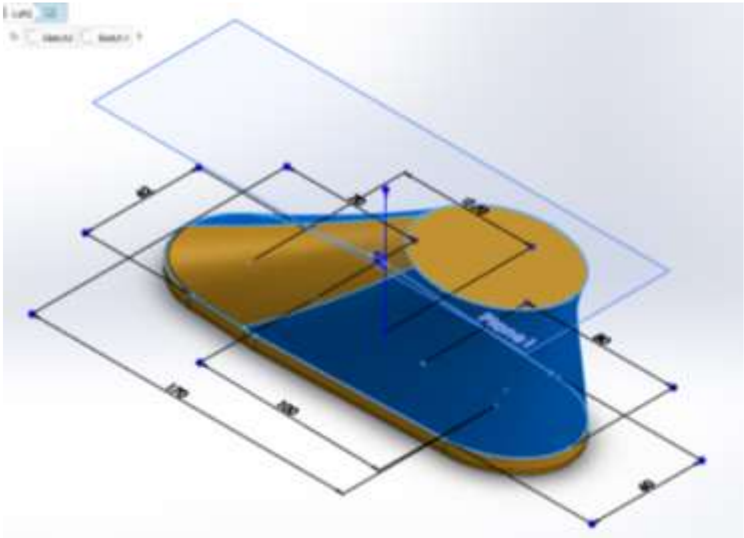


Figure 28. Dimensions of Right foot.

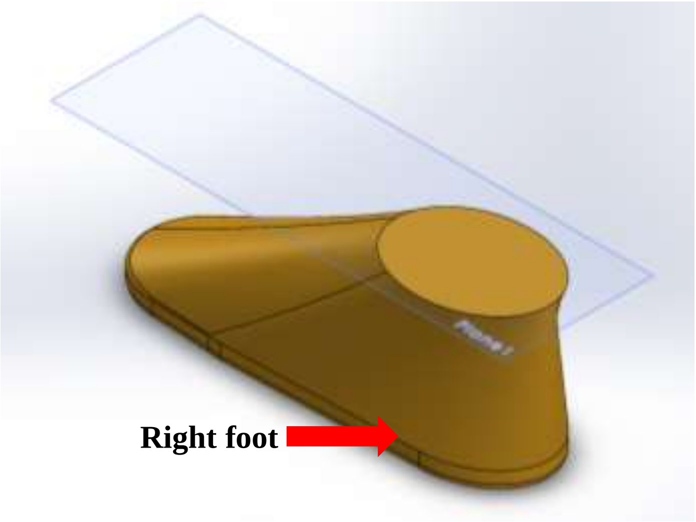
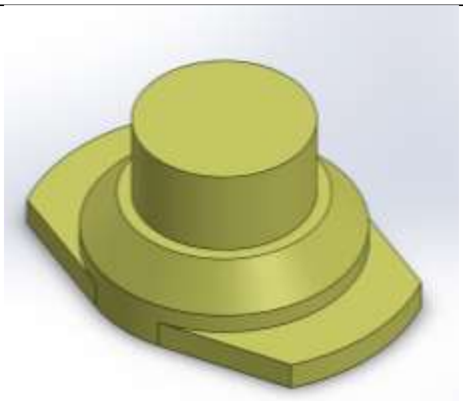


Figure 29. Right foot- Lateral View.

 **Figure 30.** Dock foot.	The dock foot is the component used as adapter. It is connected with the regulator to form a single piece.

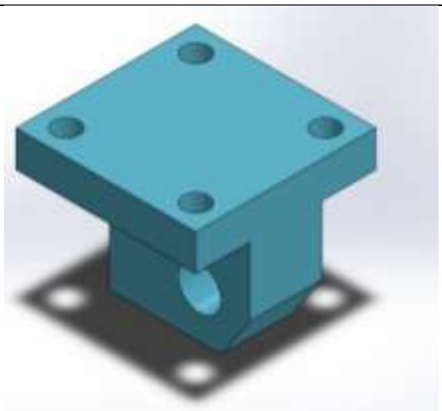
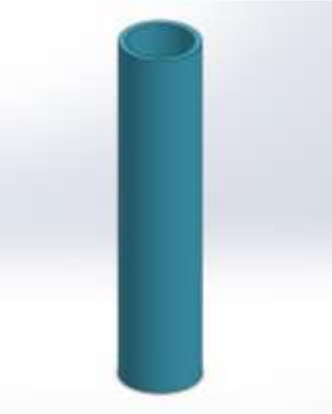
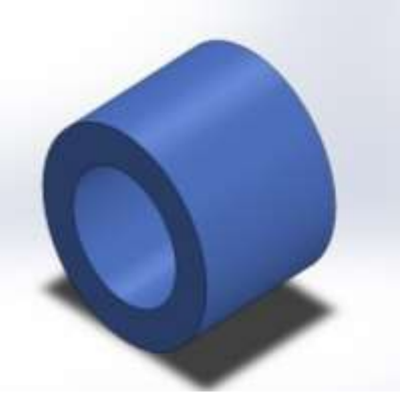
 **Figure 31.** Male joint.	The male joint is the piece that gives support and firmness to the socket since it connects with the base of the socket
 **Figure 32.** Female joint.	The female joint is a mobile component that, precisely in the prosthesis, fulfills the role of a rotatable adapter to imitate the movements of a human leg.
 **Figure 33.** Prolongation.	The prolongation is the component that replaces the human leg in the transtibial prosthesis

 **Figure 34.** Regulator.	The regulator is an adapter which connects to the foot and the prolongation of the prosthesis
 **Figure 35.** Bearing.	The bearings are screws that hold the female joint and the male joint so that the female joint can rotate.
 **Figure 36.** Socket.	The socket is a plastic receptacle in which the residual limb is contained. It is important take into account that for the assembly this component is duplicated to form the socket.

4.2.5. SolidWorks - Prosthesis Assembly

Once the components of the transtibial prosthesis are designed, the next step is to build the prosthesis by joining all of those components.

Firstly, the socket part is in charge of joining the prosthesis to the patient's stump (Fig. 37). To have a better contact and comfort, suction valves are generally used which remove the air between the two parts, holding by vacuum.

The bearing and female joint (Fig. 39) are joined to form a single piece which we will call the rotatable adapter connector. This component allows the connection between the base of the socket and the prosthesis through the union with the prolongation. For its part, the prolongation in a transtibial prosthesis is called the shin tube and is the component that replaces the tibia and fibula. At the end of the prolongation there is another connector which is the junction between the dock foot and the regulator (Fig. 38), this allows the junction with the prosthetic foot.

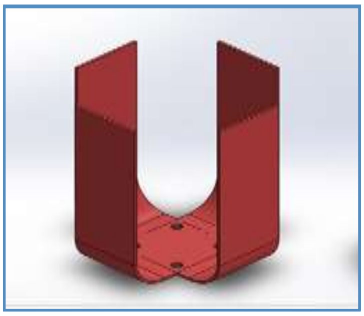


Figure 39. Socket assembly.

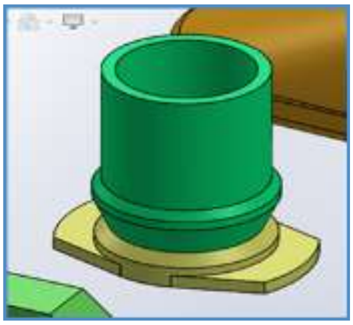


Figure 38. Assembly of the dock and regulator.

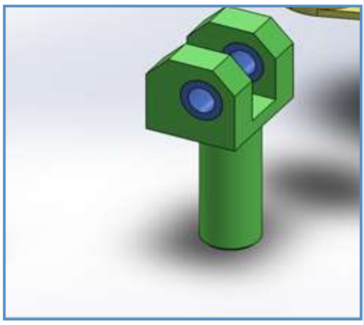


Figure 37. Bearing and female joint assembly.

The prosthetic foot is the last element of the transtibial prosthesis, which will replace a healthy foot. As mentioned before, the union of the foot with the extension of the prosthesis is through a connector. All the elements exposed in the upper part are basic for the conformation of a transtibial type prosthesis. Fig. 40 shows the final prosthesis assembly and Fig. 41 indicates the different views of the prosthesis. It should be mentioned that according to the manufacturer and the type of prosthesis there are many fastening and connection elements.

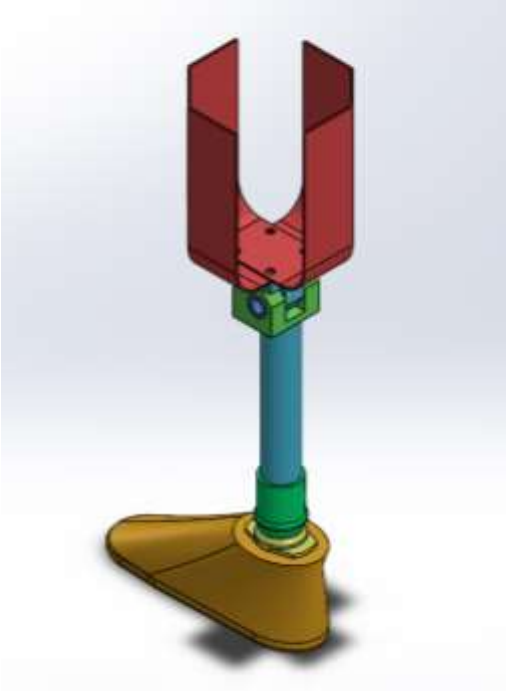
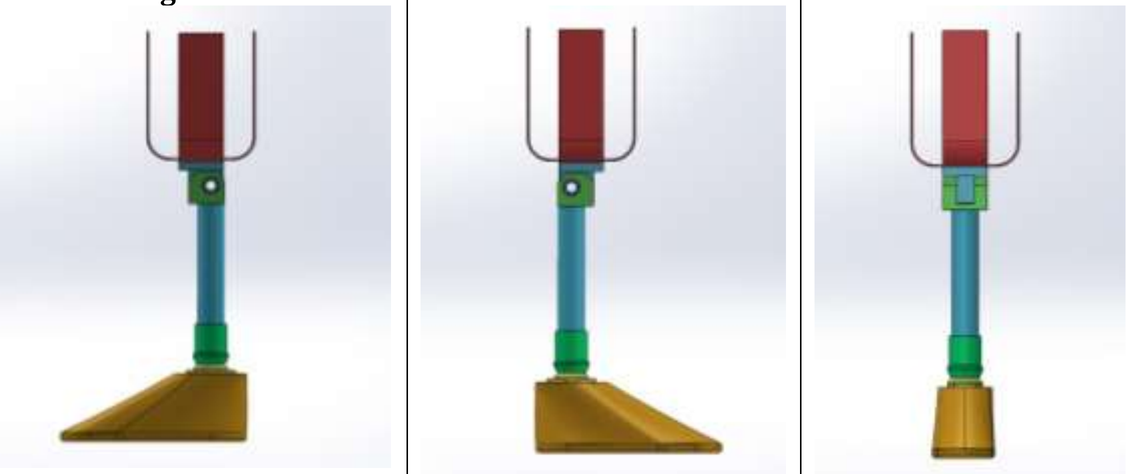
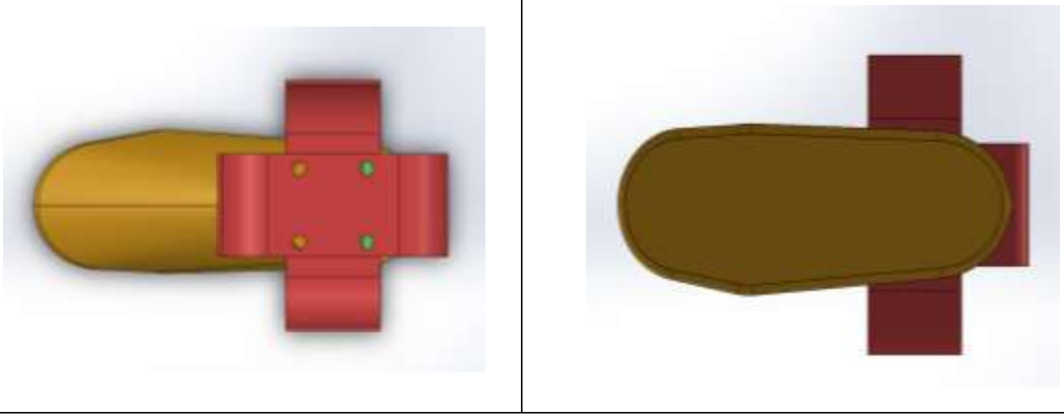


Figure 40. Final Prosthesis Assembly.



Right side **Left side** **Posterior**



Top **Bottom**

Figure 41. Prosthesis Assembly views.

5. Results

5.1. Implementation of the circuit on the Protoboard

At the end of the tests on the Proteus software used, the next step was the implementation of the circuit design in the Breadboard.

For the implementation of the circuit, the following materials were used:

Table 6. Materials used for the implementation of the circuit.

Component	Units
Switch	1
Electrodes	2
Transformer 100mA	1
Integrated circuit 555	2
Power transistor	1
LEDs	3
Capacitor 100µF	1
Capacitor 10µF	1
Potentiometer k Ω	1
Potentiometer 10k Ω	2
Resistance 220Ω	4
Resistance 1KΩ	1
Resistance 320Ω	1
Resistance 3.3KΩ	1
Diodes	2
Arduino nano	1
Current sensor ACS712	1
Digital screen	1

The result of the circuit assembly in the Protoboard is shown in Fig. 42. In order to improve the presentation of the electrostimulator prototype and also fix the electrical components of the circuit, the circuit has been printed on Printed Circuit Board (PCB) (see Fig. 43), also the 3D plane is shown in the Fig. 44.

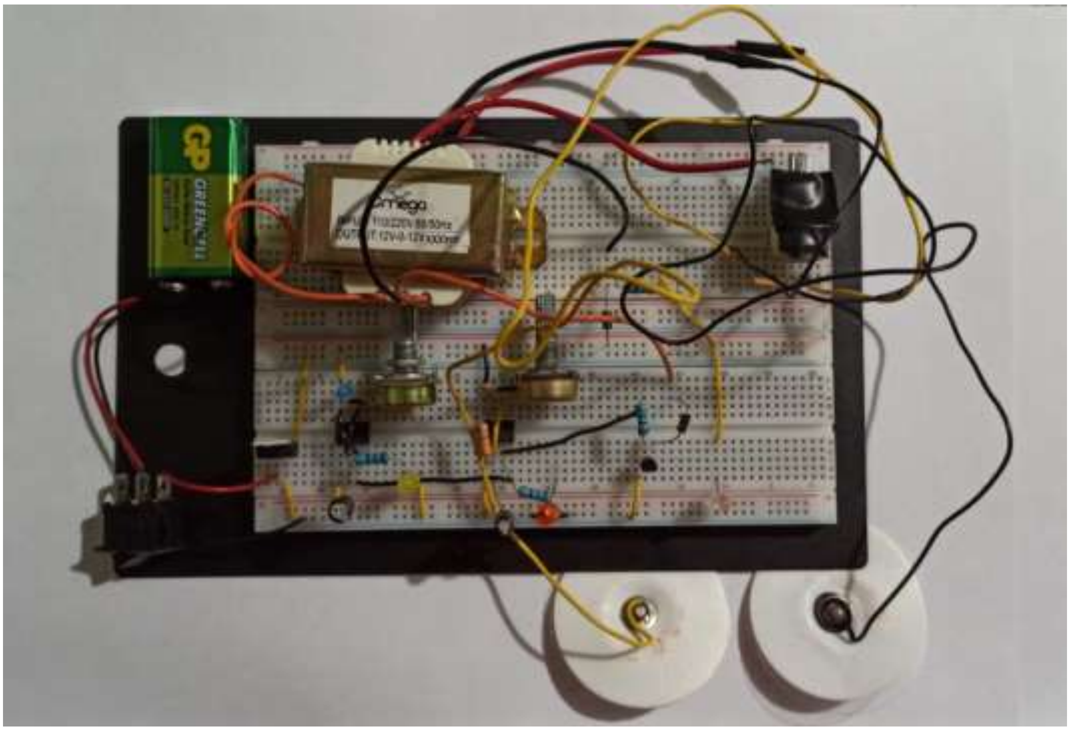


Figure 42. Electrostimulator on the Protoboard.

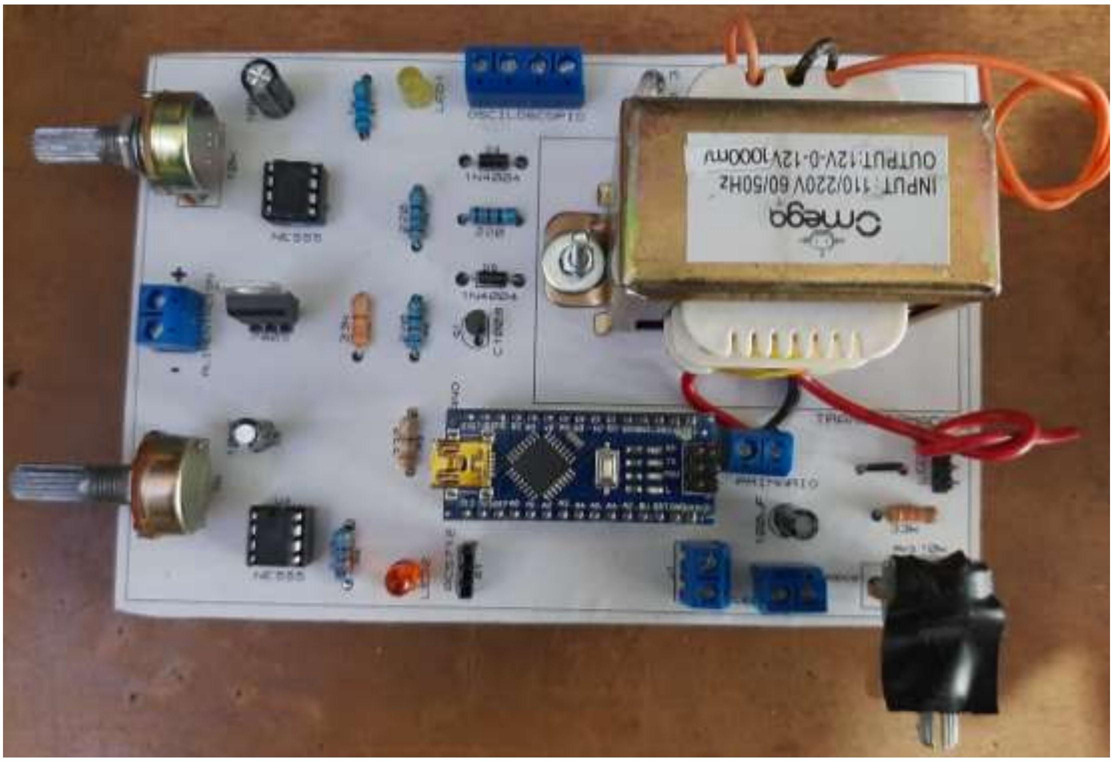


Figure 43. Printed Circuit Board.

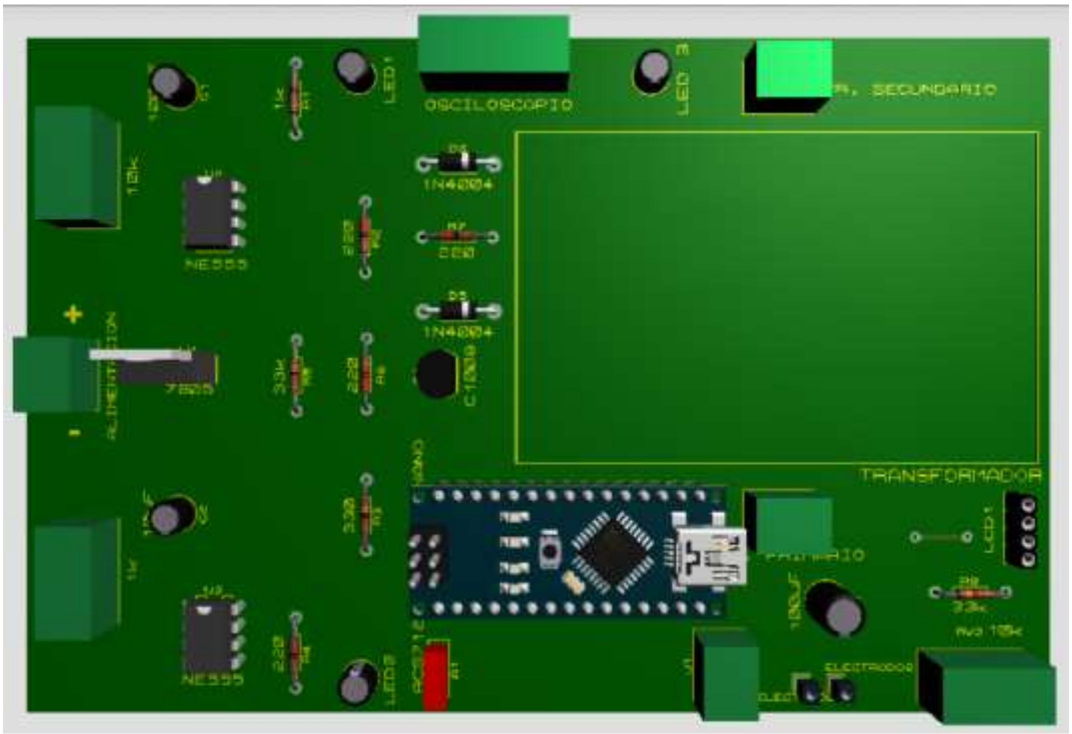


Figure 44. PCB 3D circuit.

Additionally, at the end of the circuit an Arduino nano has been implemented which in turn is connected to an ACS712 sensor (see Fig. 45). The ACS712 is a sensor for both alternating and direct current, which allows measuring the electrical intensity at the output of the circuit.

Inside, the ACS712 is composed of a low-offset, precision hall sensor along with a conduction channel located near the surface of the chip. In this sense, when the current flows through the copper channel it generates a magnetic field that is detected by the Hall sensor and is converted into a voltage. The sensor output is the voltage corresponding to the current. The sensor is calibrated from the factory, although for a precision measurement adjustments have been made in the Arduino programming [40] (see Annex 1).

For the patient undergoing electrotherapy can observe the intensity of current that the amputation area is receiving, a LCD screen has been placed at the output of the circuit (see Fig. 46)

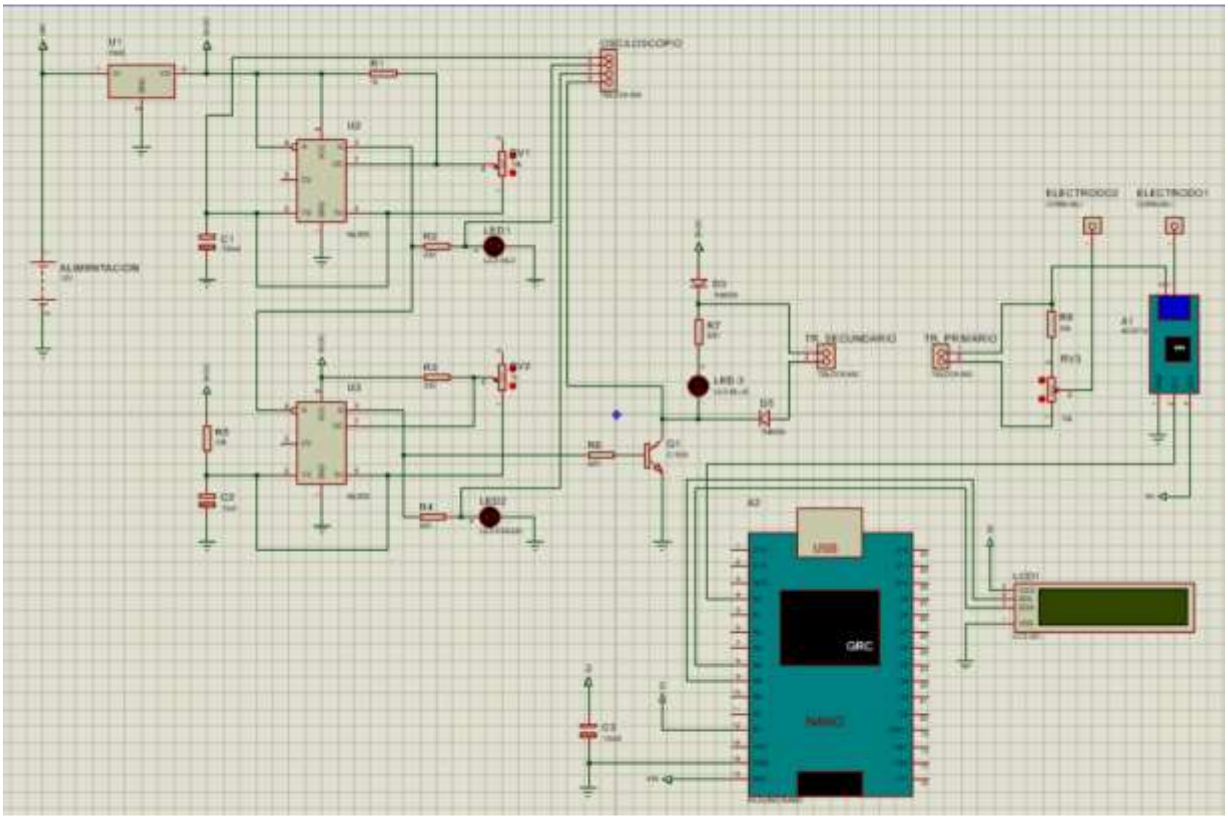


Figure 45. Final circuit design on proteus.

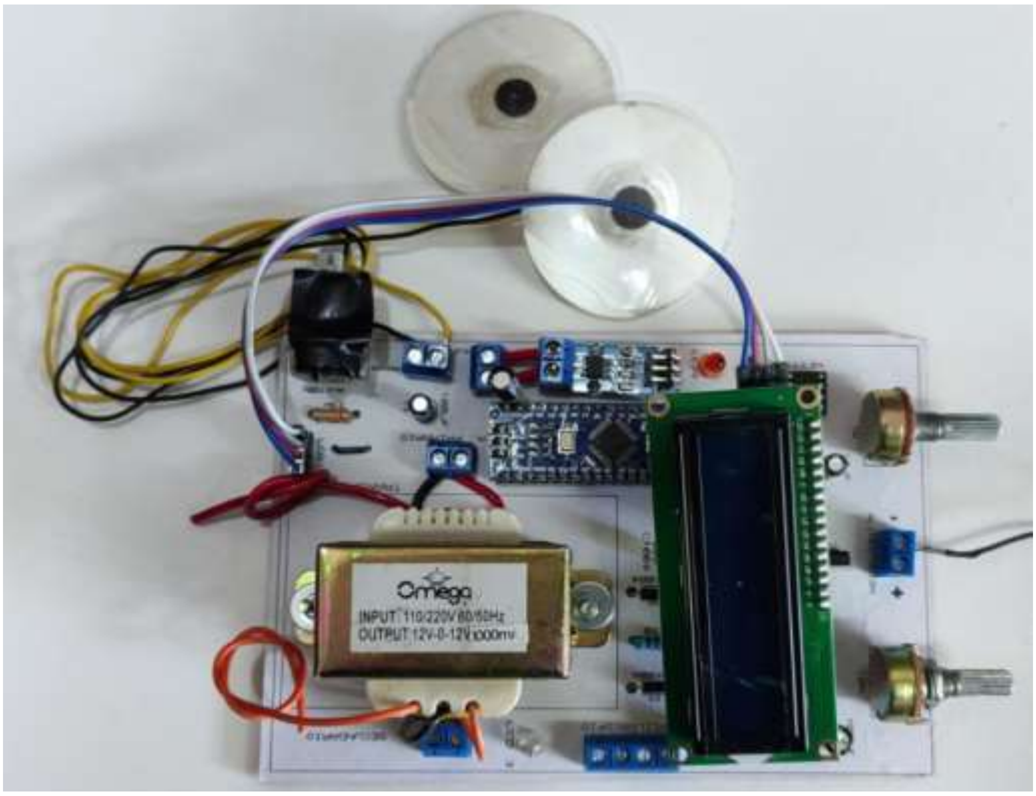


Figure 46. Electrostimulator with ACS712 sensor and LCD screen implemented.

The intensity of the electrostimulator according to Quispe [33] should be high with visible contraction, without reaching the limit of pain but of discomfort. On the other hand, the frequency and time of the treatment will be marked according to the objective to be achieved. For this, various authors validate the following reference values:

Table 7. Electrostimulator Application Ranges and Times.

Objective	Frequency	Treatment time	Rest time
Relaxation	5 Hz	Continuous	0
Heating	5 Hz	Continuous	0
Hardening	10-20 Hz	9 min	2 min
Atrophy	33 Hz	6 min	6 min
Force	50-100 Hz	5 min	25 min

It is important to take into account that the parameters will vary slightly in order to meet the needs of each patient. The rest time can be adjusted depending on the number of sessions the patient has per week. In addition, Quispe [33] recommends the use of ramps before strong muscle contraction. The use of ramped stimulation, i.e., increasing the pulse amplitude to a desired value, helps to provide comfort to the individual receiving the stimulation. On the other hand, the intensity should always be the maximum while maintaining relative comfort. The total time between 10 and 30 minutes depending on the phase of the injury. One aspect that does not help to enhance the muscles correctly is reaching the extreme of fatigue the muscle.

Finally, the prototype of the electrical stimulator is shown in Fig. 47. As can be seen, only the LED screen is visible, which shows the intensity of the electrostimulator. In the case of the photo, the display shows 0 mA because the electrons are not connected to a patient.

Figure 47. Final prototype of the muscle electrostimulator.

5.2. Prosthesis Analysis

5.2.1. Choice of prosthesis material

In order to analyze the stress of the transtibial prosthesis, the first step is to choose the material of each piece of the prosthesis.

Valencia [17] mentions that to choose the appropriate material for a prosthesis the predominant factor to consider is the strength-weight ratio. It should be noted that the characteristics of the materials of the contact surface participate in the quality of the socket, while the materials of the structure affect the strength and weight of the complete prosthesis. To consider the aforementioned, a brief study of the properties of the materials that are most often used in prosthetics will be made and then stress factors, displacement and strain will be analyzed with SolidWorks Simulation.

According to Aldaz and Farias [41] the ideal material for the socket of the prosthesis is thermoplastic polyethylene (PE). PE is a soft thermoplastic characterized by its low density and flexibility that can be used for prosthetic connections. Among the most relevant characteristics of this type of material is its resistance to wear, chemical stability, and biocompatibility. By using this material, the so-called osteolytic effect, which means bone wear around a prosthesis, can be reduced.

SolidWorks allows you to define the desired material and at the same time shows the properties of the material. For this case, Fig. 48 details the properties of PE and it can be seen that it indeed has a low density and properties such as tensile strength, compressive strength, among others, will be evaluated in the simulation. In Fig. 49 the transtibial prosthesis is observed with the first defined material, the socket with the PE material.

Model Type: Linear Elastic Isotropic
Units: English (IPS)
Category: Plastics
Name: PE Low/Medium Density
Description:
Source:
Sustainability: Defined

Property	Value	Units
Elastic Modulus	[illegible]	psi
Poisson's Ratio	[illegible]	N/A
Shear Modulus	[illegible]	psi
Mass Density	[illegible]	lb/in^3
Tensile Strength	[illegible]	psi
Compressive Strength		psi
Yield Strength		psi
Thermal Expansion Coefficient		/°F
Thermal Conductivity	[illegible]	Btu/(in·sec·°F)

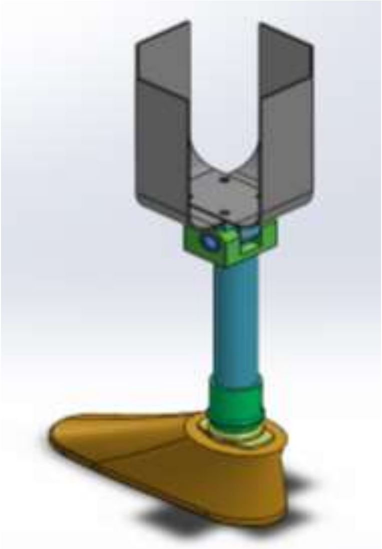


Figure 48. PE properties. **Figure 49.** Socket with PE material.

In the case of the extension of the transtibial prosthesis, the proposed material is aluminum. Valencia [17] highlights that non-ferrous metals and alloys cover a wide range, from the most common metals such as aluminum, copper and magnesium, to high temperature and high resistance alloys such as tungsten, tantalum and molybdenum. The properties that favor the selection of aluminum and its alloys are its high strength-to-weight ratio, resistance to corrosion of many chemicals, high thermal and electrical conductivity. Additionally, aluminum is generally considered a lighter alternative to steel. It is not that hard but, depending on the application, it is strong enough to meet design requirements and pass the necessary tests. In the same way as in the previous case, Fig. 50 shows the physical properties of aluminum and Fig. 51 shows the prosthesis with the new material added.

Model Type: Linear Elastic Isotropic
Units: English (IPS)
Category: Aluminum Alloys
Name: 2018 Alloy
Description:
Source:
Sustainability: Defined

Property	Value	Units
Elastic Modulus	10732752.59	psi
Poisson's Ratio	0.33	N/A
Shear Modulus	3916018.917	psi
Mass Density	0.1011563891	lb/in^3
Tensile Strength	60909.38395	psi
Compressive Strength		psi
Yield Strength	45992.04676	psi
Thermal Expansion Coefficient	1.222222222e-05	/°F
Thermal Conductivity	0.00330821	Btu/(in·sec·°F)

Figure 50. Aluminum properties.

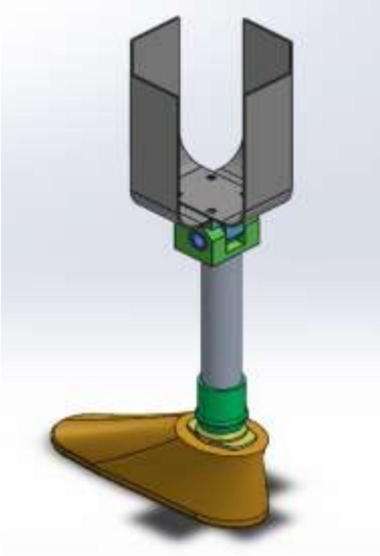


Figure 51. Prolongation with Al material.

Stainless steel has been applied for the connectors that join the extension and the foot and the extension and the socket. Thus Kalpakjian [42] mentions that stainless steels are characterized by their resistance to corrosion, high strength and ductility, as well as their high chromium content, they are called stainless because in the presence of oxygen, they develop a thin film of Chromium oxide, hard and adherent, which protects the metal from corrosion. Stainless steels are available in a wide variety of shapes, such as cutlery, kitchen equipment, healthcare equipment, surgical equipment, and more. The physical properties of this material are shown in Fig. 52 and will also be discussed in detail in the simulation. Fig. 53 also indicates the prosthesis with defined stainless steel.

Model Type: Plasticity - von Mises
Units: English (IPS)
Category: Steel
Name: AISI 316 Stainless Steel Sheet (SS
Description:
Source:
Sustainability: Defined

Property	Value	Units
Elastic Modulus	27992282.99	psi
Poisson's Ratio	0.27	N/A
Tensile Strength	84121.88796	psi
Yield Strength	24999.99998	psi
Tangent Modulus		psi
Thermal Expansion Coefficient	8.888888889e-06	/°F
Mass Density	0.2890182595	lb/in^3
Hardening Factor	0.85	N/A

Figure 52. Stainless Steel properties

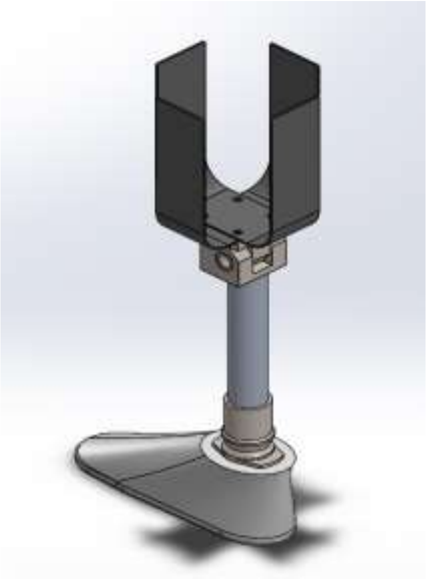


Figure 53. Connectors with Steel material

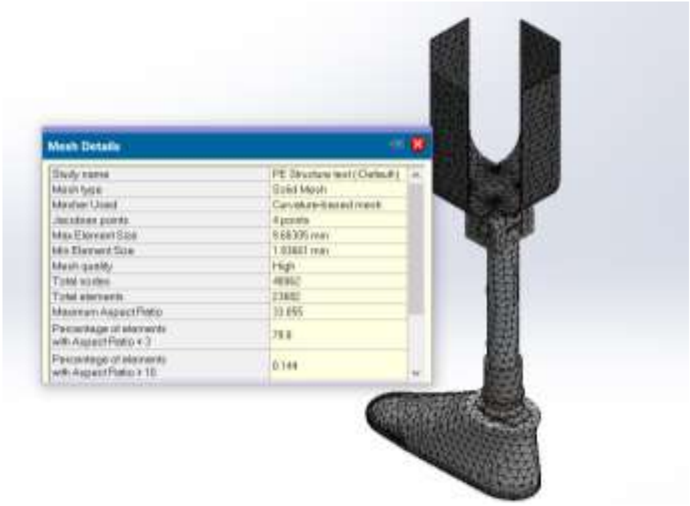
5.3. SolidWorks-Simulation

SolidWorks-Simulation is a tool that uses the finite element method to perform structural analysis. In addition, such simulation reduces costs by simulating the testing of a model on the computer rather than conducting expensive lab tests. In this way, SolidWorks Simulation allows to observe the behavior and perform the dynamic analysis of a rigid body, in this case specifically the transtibial prosthesis, through the development of the following steps:

- Add the rigid body

This step is simply to import the prosthesis into the SolidWorks workspace.

- Define the material
  As previously shown, the transtibial prosthesis is made up of materials such as thermoplastic polyethylene, aluminum alloys and stain Steels (See Fig. 46).
- Define the geometry
  For the definition of the geometry there is a tool in SolidWorks Simulation called fixed geometry which restricts the movement along the two perpendicular directions in the plane to the edges or vertices that are selected. It is important to note that no restrictions are applied along the normal direction with respect to the selected plane.
- Mesh
  The mesh that was used for this analysis was a solid mesh with curvature-based mesh. The total number of nodes is 40062 and the total number of elements is 23682 (See Fig. 54).



Study name	PE Structure test (Default)
Mesh type	Solid Mesh
Mesher Used	Curvature-based mesh
Jacobian points	4 points
Max Element Size	9.68305 mm
Min Element Size	1.93883 mm
Mesh quality	High
Total nodes	40062
Total elements	23682
Maximum Aspect Ratio	33.695
Percentage of elements with Aspect Ratio < 3	78.8
Percentage of elements with Aspect Ratio > 10	0.144

Figure 54. Transtibial prosthesis mesh.

- Loads and restrictions

  Loads and constraints are fundamental for the simulation of bodies because the results of the analysis depend directly on the conditions and loads specified for the system. For this study, the weight of the person is considered as the compression force that the prosthesis will have to support.

To define the weight of the person, the average height of a mestizo man will be taken as a reference, which is 1.72 m (see table 5). On the other hand, the weight of the person with this height is based on statistical data that have managed to determine the ideal weight based on height as shown in table 8. It is obtained that the maximum weight of a person of 1.72 m is 72.8 kg.

Table 8. Weight - Height ratio [43].

	Mujeres						Hombres					
	Pequeña		Mediana		Grande		Pequeño		Mediano		Grande	
Altura	Min.	Max.	Min.	Max.	Min.	Max.	Min.	Max.	Min.	Max.	Min.	Max.
1.50	46.0	47.2	46.1	50.6	47.2	52.9	46.0	50.2	46.4	56.4	50.6	56.2
1.52	46.2	48.5	47.4	52.0	48.5	54.3	46.2	51.5	48.7	56.9	52.0	57.6
1.54	47.4	49.8	48.6	53.4	49.8	55.7	47.4	52.9	51.0	58.4	53.4	59.3
1.56	48.7	51.1	49.9	54.8	51.1	57.2	48.7	54.3	52.3	59.9	54.8	60.8
1.58	49.9	52.4	51.3	56.2	52.4	58.7	49.9	55.7	53.7	61.5	56.2	62.4
1.60	51.2	53.9	52.6	57.6	53.9	60.2	51.2	57.1	55.0	63.0	57.6	64.0
1.62	52.6	55.1	53.8	59.0	55.1	61.7	52.6	58.5	56.4	64.6	59.0	65.6
1.64	53.8	56.5	55.1	60.5	56.5	63.2	53.8	60.0	57.8	66.2	60.5	67.2
1.66	55.1	57.9	56.5	62.0	57.9	64.8	55.1	61.4	59.2	67.8	62.0	68.9
1.68	56.4	59.3	57.9	63.5	59.3	66.3	56.4	62.9	60.7	69.5	63.5	70.6
1.70	57.8	60.7	59.3	65.0	60.7	67.9	57.8	64.4	62.1	71.2	65.0	72.3
1.72	59.2	62.1	60.6	66.6	62.1	69.5	59.2	66.0	63.6	72.9	66.6	74.0
1.74	60.6	63.6	62.1	68.1	63.6	71.1	60.6	67.5	65.1	74.6	68.1	75.7
1.76	62.0	65.0	63.5	69.7	65.0	72.8	62.0	69.1	66.6	76.3	69.7	77.4
1.78	63.4	66.5	65.0	71.3	66.5	74.5	63.4	70.7	68.1	78.0	71.3	79.2
1.80	64.8	68.0	66.4	72.9	68.0	76.1	64.8	72.3	69.7	79.8	72.9	81.0
1.82	66.2	69.6	67.9	74.5	69.6	77.8	66.2	73.9	71.2	81.6	74.5	82.8
1.84	67.7	71.1	69.4	76.2	71.1	79.6	67.7	75.6	72.8	83.4	76.2	84.6
1.86	69.2	72.7	70.9	77.8	72.7	81.3	69.2	77.1	74.4	85.2	77.8	86.5
1.88	70.7	74.2	72.5	79.5	74.2	83.1	70.7	78.8	76.0	87.0	79.5	88.4
1.90	72.2	75.8	74.0	81.2	75.8	84.8	72.2	80.5	77.6	88.9	81.2	90.3
1.92	73.7	77.4	75.6	82.9	77.4	86.6	73.7	82.2	79.3	90.8	82.9	92.2
1.94	75.3	79.0	77.2	84.7	79.0	88.4	75.3	83.9	80.9	92.7	84.7	94.1

From these data, the "weight" force that will be added to the prosthesis can be calculated to see if it can support that magnitude. According to Newton's second law we have the following:

$$F = m.a$$

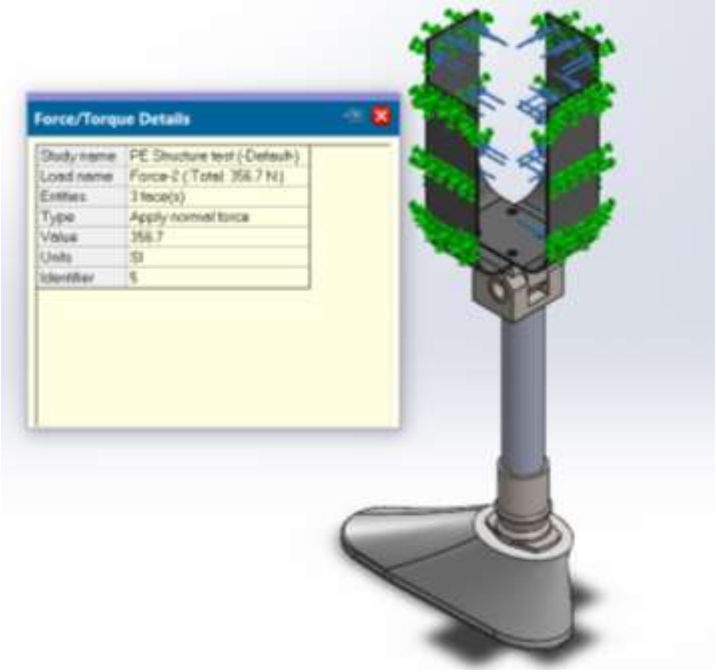
$$W = m.g$$

$$W = 72{,}8\,kg\,.\,9{,}8\frac{m}{s^2}$$

$$W = 713{,}4\,N$$

Equation 6. Newton's Second law

Now that is the weight of the whole body, however the data that is necessary to know how much weight the leg that contains the prosthesis supports. According to a study carried out by Lim, Teck Onn, et al. [39] mentions that in the case of the human body's legs, they are symmetrically arranged so that each one will support half of the total weight. In this way, the force that will be used for the simulation will be P = 356.7 N as shown in Fig. 55 represented by the blue arrows, while the green surface is the fixed geometry.



Study name	PE Structure test (-Default-)
Load name	Force-2 (Total: 356.7 N)
Entities	3 face(s)
Type	Apply normal force
Value	356.7
Units	SI
Identifier	5

Figure 55. Forces applied to the transtibial prosthesis.

The results obtained by the analysis of finite elements in SolidWorks-Simulation will be shown below. Mechanical properties such as stress, strain and displacement have been mainly analyzed in order to determine whether the prosthesis is viable or not. Fig. 56 shows the stress analysis of the piece and the values are detailed on the right. Thus, the maximum stress that the prosthesis can withstand is 2.522e+04 N/m^2, if this value is exceeded, the prosthesis would break.

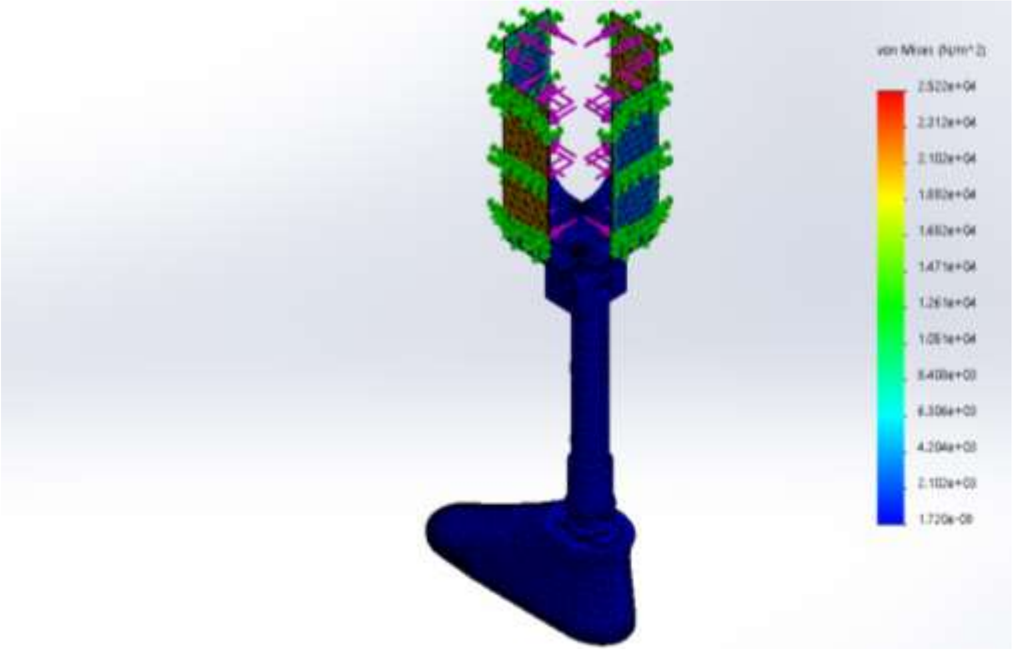


Figure 56. Stress Analysis.

Additionally, the results of the strain analysis or pressure supported by the prosthesis are available in Fig. 57. In the same way as with stress, the values determined in the simulation are observed in the central right part. So the maximum pressure that can be applied to the prosthesis is 1.234e-04 ESTRN (Equivalent Unit Deformation).

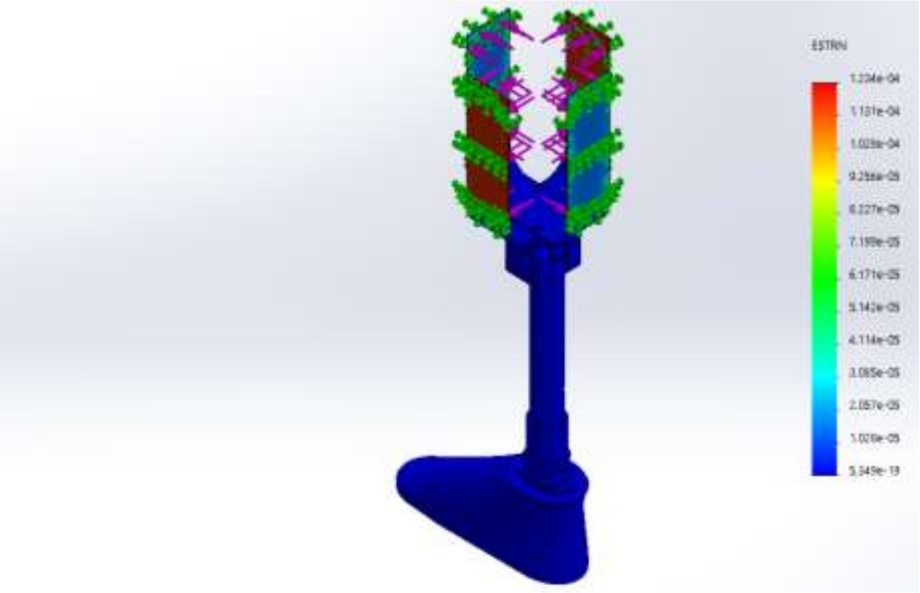


Figure 57. Strain Analysis.

Finally, in Fig. 58 the results of the analysis of the displacement of the prosthesis on the right side are detailed as in the previous cases, the values in red represent the maximum that the prosthesis moves and the values in blue represent the minimum displacement. For this specific case, the socket area that will receive all the weight undergoes a minimum displacement, which is positive for its operation.

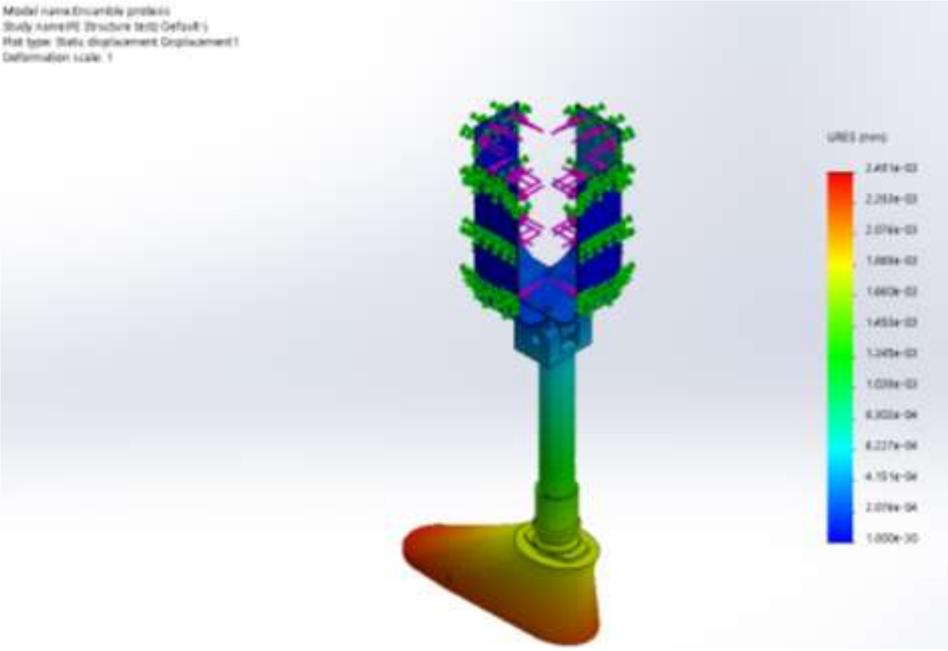
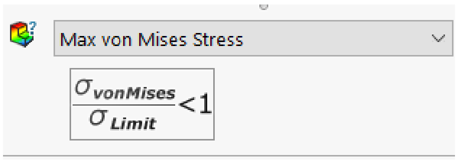


Figure 58. Displacement Analysis.

5.4. Factor of Safety

One of the most important characteristics in the study of the design properties of a part is its safety factor. This factor indicates the point at which the structure material begins to fail and this may be due to the loss of the elastic properties of the piece.

SolidWorks-Simulation uses some criteria to determine the safety factor, but the most used is the Max von Mises Stress criterion. Max von Mises Stress is simply the quotient between the yield stress of the material and the stress calculated by algorithms in SolidWorks based on the criteria of the structure being studied. If the result of the division is less than 1 it means that this component would fail first since it is the most affected when supporting the load (see Fig. 59). While if the result is greater than one the implementation is safe and reliable, no design damage is expected.



Max von Mises Stress

$$\frac{\sigma_{vonMises}}{\sigma_{Limit}} < 1$$

Figure 59. Von Mises criterion

For this study, Fig. 60 shows that all values are greater than 1, therefore there is a good safety factor that guarantees the functioning of the prosthesis with the loads included.

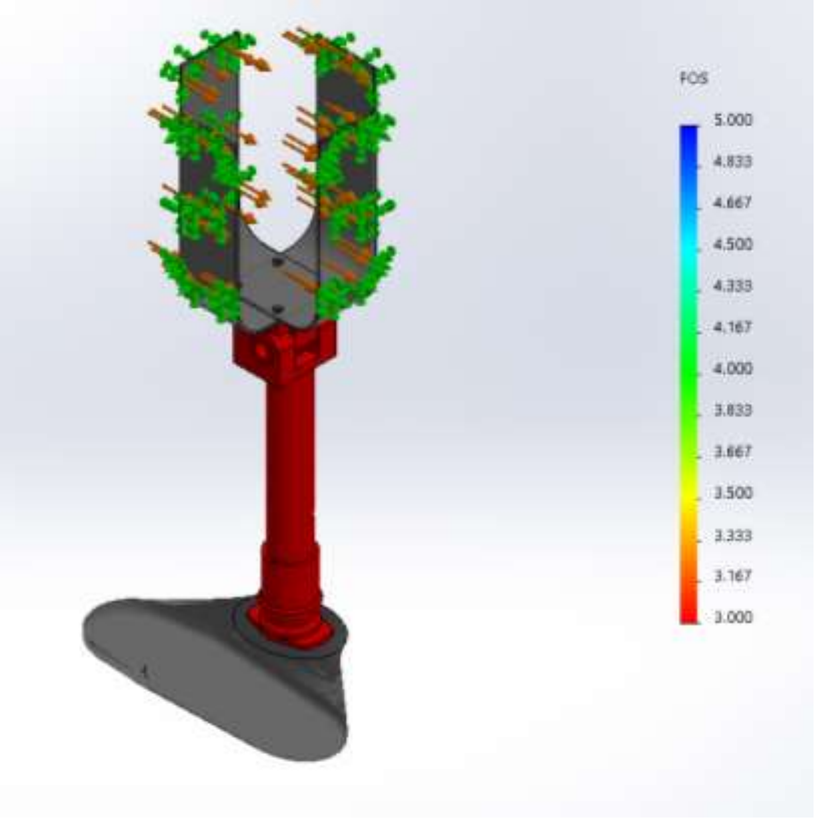


Figure 60. Factor of Safety

6. Discussion

For this section, a bibliographic review of research focused both on the design of prostheses and the implementation of muscle electrostimulators has been made. First, Table 9 compares transtibial prosthesis design studies. The main aspects of comparison are the methodology of the study, the material used for the prosthesis and an important physical aspect which is the stiffness.

There are two studies that are based on 3D printing to obtain the prosthesis, in both studies the common material is Nylon 12 plates which is a plastic material that is used mainly for its high quality and physical properties. However, these 3D printed prostheses do not have long durability because of the materials used [12][44]. On the other hand, the study carried out by Hitt et al. [45] and the method proposed in this research work use materials such as Stainless steel for the impression of the prosthesis. Due to the material from which the prosthesis is made, its physical properties show to be more resistant and it should be noted that it has high durability.

Table 9. Transtibial prosthesis design studies.

Author	Study Object	Method	Material	Simulation	Stiffness
[45]	Transtibial prosthesis design	Mechanical design	Stainless Steel Fitting 3000	Finite element analysis	32,000 N/m
[44]	Transtibial prosthesis design	Three-dimensional printing with topological optimization	Nylon–Polyamide 12	Finite element analysis	0,30 N/m
[12]	Transtibial prosthesis design	Three-dimensional printing	Polyoxymethylene and Nylon 12 plates	Finite elements in 3D structures	40,01 N/m
Proposed method	Transtibial prosthesis design	Mechanical design	thermoplastic polyethylene Aluminum Stainless steel	Finite elements in SolidWorks Simulation	25,2 ^{3}N/m

Electrostimulation as therapy applied to patients with transtibial prostheses has been found to be effective in reducing the pain of amputation. Previously, PLP was associated with a decrease in the use of a prosthesis [3]. Now, based on the studies reviewed, it is believed that decreased prosthetic use due to PLP could be counteracted by adding somatosensory feedback to the prostheses. Also, as the use of a prosthesis represents the replacement of a body member by a special apparatus that reproduces more or less the missing part but does not provide the same functionality at the beginning of the process and generally takes a long time until the patient adapts completely. However, the studies analyzed above show that electrostimulation not only works as pain therapy, but also greatly improves the functionality of movements with the prosthesis since patients have recorded long and stable walking distances, regardless of whether the soil is uneven or soft. The importance of this should not be underestimated since more than half of the patients who wear a prosthesis are not happy with the use of their prosthesis and, basically, their complaints focus on the lack of somatosensory feedback on the prosthesis.

In the same way, a bibliographic search of studies about the design of electrostimulators was made to verify if the values obtained with the proposed model were within an acceptable range as physical and pain therapy. The results are shown in Table 10.

Table 10. Electrostimulator studies and its values.

Author	Intensity	Frequency	Duration of the pulse
[46]	2 mA – 20 mA	1Hz – 50 Hz	1,4 ms – 40 ms
[47]	10 mA – 50 mA	80 Hz	2 ms
[48]	300mA	10kHz	2 s
Proposed method	1 mA – 100 mA	10 Hz	1000 ms

Despite all the advantages that a muscle electrostimulator has over the use of a transtibial prosthesis, there is no previous research in which a prosthesis with an inserted electrostimulation is designed. That is why the present research work may be a profitable solution in the future as it solves two problems for the amputee patient. The first is the lack of a limb and the second is the pain caused by the amputation itself.

6.1. Recommendations for the use of the muscle electrostimulator

According to Nussbaum et al. the application of electrostimulation when there has been a replacement of a joint in the lower limbs aims to attenuate the significant loss of strength that occurs after the operation and that generally persists for a year [49]. However, there are certain recommendations (see table 11) that should be taken into account before applied electrical stimulation in the human body.

Table 11. Recommendations for the use of the muscle electrostimulator.

Parameter	Recommendations	Benefits
Electrode placement	Large electrodes placed proximally and distally on the belly of the muscles. The recommendation is to position electrodes in line with the orientation of the muscle fibers [50].	• Improved muscle strength • Muscle activation • Reduction in loss of muscle volume or thickness • Improved self-reported function or disability • Improved walking speed • Perceived health status
Limb positions	Sitting; knee flexed 60-90° [51]	
Waveform	Low-frequency biphasic [52]	
Frequency	Range 40-75 Hz	
Pulse duration	250–400 μs [53]	
Current amplitude	Individual max tolerated intensity (use large electrodes for better comfort and to reach more motor units) [52]	
Session frequency	For increasing quads activation and strength as well as function, 10–30 contractions/d, 3 d/wk, for 6 wk [51]	

6.2. Contraindications and Precautions for the use of electrical stimulation

Any type of electrical stimulation carries contraindications and precautions that must be observed (see table 12). Applied electrical currents will travel throughout the body, although the magnitude is not high enough to cause problems in healthy individual, electrical stimulation can affect excitable tissues at distant location such as the heart and brain.

Table 12. Contraindications and Precautions for the use of electrical stimulation.

Contraindications	Precautions
• High-intensity stimulation directly over the heart • In patients with pacemaker • Over areas of thrombosis or thrombophlebitis • Over infected areas or neoplasms • Over the carotid sinus • Any time active motion is contraindicated • Over the trunk during pregnancy	• In areas with impaired sensation • In areas of skin irritation or damage • Near electronic sensing devices such as ECG monitors (possible interference) [54]

6.3. Recommendations for the use of the transtibial prosthesis

Among the most common recommendations for the use of a transtibial prosthesis are:

- Clean the interior socket at least once a week with soap and water.
- Lightly spray the socket with an alcohol-based cleaner.
- Dry the socket properly.
- When using the lower limb prosthesis, ensure that it is properly adjusted so that the limb remains comfortable and prevent damage to the prosthesis.
- Moisture can cause the limb to swell and alter the fit of the lower limb prosthesis. Put a bandage on the stump to decrease swelling when the leg prosthesis is not in use.
- Cold temperatures can cause the limb to contract, which will make it necessary to readjust the lower limb prosthesis.
- A small rash or irritation can turn into an ulcer or cut, which will prevent the lower limb prosthesis from being used until the wound is healed [55].

6.4. Cost analysis

6.4.1. Electrostimulator cost analysis

Table 13 contains the materials that were used for the manufacture of the electrostimulation. The second column lists the values per unit for each element, while the third column shows the accumulated prices. Finally, it can be seen that the total price is $ 35.85. It is necessary to emphasize that the prices are real. To make a cost comparison, in Ecuador an electrostimulator for therapy is around $200; that is, the present project was developed with a low-cost making it more accessible for amputee people with scarce resources.

Table 13. Electrostimulator cost analysis.

Component	**Units**	**Price by unit**	**Total price**	**Manufacturing workforce**
Switch	1	0,50	0,50	$30
electrodes	2	0,20	0,40	
Transformer 100mA	1	4,50	4,50	
integrated circuit 555	2	0,50	1,00	
power transistor	1	0,30	0,30	
LEDs	3	0,10	0,30	
Capacitor 100µF	1	0,20	0,20	
Capacitor 10µF	1	0,20	0,20	
Potentiometer 100k Ω	1	0,50	0,50	
Potentiometer 10k Ω	2	0,50	1,00	
Resistance 220Ω	4	0,04	0,16	
Resistance 1KΩ	1	0,04	0,04	
Resistance 320Ω	1	0,04	0,04	
Resistance 3.3KΩ	1	0,04	0,04	
Diodes	2	0,15	0,30	
Arduino nano	1	6,00	6,00	
Current sensor	1	4,00	4,00	
Digital Screen	1	4,50	4,50	
		Total	**$25,14**	**$ 55,14**

6.4.2. Transtibial prosthesis cost analysis

In Ibarra-Imbabura city there is a foundation called "Protesis Imbabura" and they are in charge of the production of prostheses of all kinds. So it was possible to consult how much the impression of the transtibial prosthesis designed with the different materials by which it is formed would cost. They sent the possible cost and the values are detailed in table 14.

Table 14. Transtibial prosthesis cost analysis

Component	Units	Total price
Socket polypropylene	1	$800
Feet	1	
Prolongation	1	
Adapters	2	
Connectors	**2**	

Next, a comparative table between different studies and the model proposed in this research work is presented.

Table 15. Comparison of the proposed method with those proposed by other authors

Author	Model	Method/Technique	Cost
[48]	WALKAIDE	It is a FES electrostimulation system consisting of a single channel electrical stimulator powered by AA battery, two electrodes and electrode cables.	$ 4500
[56]	Transtibial prosthesis	Manufacture a prototype of a transtibial lower limb prosthesis using additive technologies and 3D printed, which means that the most used material is PLA.	$ 430.50
Proposed method	Transtibial prosthesis + electrostimulator	The studies previously analyzed have a monofunctionality in their design, the first is only an electrostimulator and the second is only a transtibial prosthesis. However, the proposed model is the design of a transtibial prosthesis that has an electrostimulator coupled to provide therapies to the patient. It is important to mention that the materials used for the prosthesis are of long useful life and the most used in the market compared to the PLA that is used in 3D printing.	$855,14

7. Conclusions

- The electrostimulator is currently known as a licensed device for physical and pain therapy. In the case of amputee patients, they suffer from various types of pain such as residual limb pain, phantom limb sensation and phantom limb pain and once they have undergone electrotherapy these pains have been reduced and at the same time the strength in the musculature is recovered. Therefore, it is concluded that this type of patients can receive electrotherapy.
- For the design and subsequent implementation of the electrostimulator, the proteus software was used, which is very didactic and easy to use. In the first instance, materials that are easy to find in any city were used for the design. The main materials were the two 555 in astable form and the transformer that is connected in reverse. The desired signal was generated in proteus and in the circuit it could be observed that the final load applied to the patient is tolerable.
- Before carrying out the prosthetic design of any locomotor part of the human body, in this specific case the leg, it is essential to analyze the anatomy and biomechanics of the joint in order to know its main parameters and understand the correct functioning of human gait. For this study, the forces acting on the leg, the gait cycle and its degrees of freedom were reviewed. In this way it was possible to mimic as closely as possible the leg joint.
- Through the use of CAD tools such as SolidWorks software, the parts that make up the transtibial prosthesis were designed. Likewise, all the parts were assembled to form a single structure, i.e. the prosthesis. The most suitable material was chosen according to bibliographic references such as aluminum, stainless steel and thermoplastic polyethylene. On the other hand, with SolidWorks-Simulation it was possible to visualize the most important part of the design, that is to say, to simulate, analyze and carry out a functional design in an interactive way for the development of the transtibial prosthesis. As a result, values of stresses, deformations and the safety factor were obtained.

8. Future Perspectives

The future works to advance this research include:

Print the transtibial prosthesis design with each material chosen in this work to be tested in patients and thus real data on its efficiency, support, stress and displacement.

Make tests of the electrostimulator with health professionals to establish frequency ranges, the voltage allowed for its operation and observe the type of waves it transmits.

Improve the presentation of the electrostimulator and implement the electrostimulator in the transtibial prosthesis as an additional device so that the patient can have their therapies in the comfort of their home.

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10. Annexes

10.1. Arduino Program

```
#include <LiquidCrystal_I2C.h>
#include<Wire.h>
float Sensibilidad = 118.18;
LiquidCrystal_I2C lcd(0x27,16,2);
void setup()
lcd.init();
lcd.backlight();
lcd.clear();
lcd.setCursor(0,0);
lcd.print("****************");
   lcd.setCursor(0,1);
   lcd.print("***BIENVENID@***");
   Serial.begin(9600);
delay(3000);
void loop()
  float I=get_corriente(200);
  Serial.print("Corriente: ");
  Serial.println((I)*-100000);
   lcd.setCursor(0,0);
   lcd.print("  Intensidad:   ");
   lcd.setCursor(0,1);
   lcd.print ((I)*1000);
   lcd.setCursor(6,1);
   lcd.print("mA");
   delay(100);
   lcd.clear();

//OPERACIÓN PROPIA DEL SENSOR:
float get_corriente(int n_muestras)
  float voltajeSensor;
```

```
float corriente=0;
for(int i=0;i<n_muestras;i++)
voltajeSensor = analogRead(A0) * (5.0 / 1023.0);
corriente=corriente+(voltajeSensor-2.5)/Sensibilidad;
corriente=corriente/n_muestras;
return(corriente);
```