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Design of a Soft Robotics Orthosis for Finger Rehabilitation

A project presented by

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Abstract

Most existing devices oriented to physical therapy of movement are composed of rigid and non-deformable structures, this usually results in discomfort for the patient at the moment of use. Additionally, these devices come with a high price of manufacture, therefore increasing sale prices, and limiting its accessibility to patients and medical staff. A developing technology that addresses these needs is soft robotics. This project focuses on the creation of an orthosis that assists the movement of the hand during motor therapy as part of a rehabilitation treatment. The main characteristics of this equipment consist in an ergonomic design of an exoskeleton suitable for phalanges and metacarpals, with the objective of imitating the movement of a healthy hand, whether the patient's or the physiotherapist's. The movement being replicated is being controlled by a neural network that detects intentional movements through an electromyographic (EMG) armband. The exoskeleton is composed of soft actuators manipulated by a hydraulic system, according to the prediction of movements of the neural network.

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Chapter 1

Introduction

1.1 Background of the current problem

Superior extremities, specifically hands, allow people to develop certain abilities in order to interact and work within our environment, with them people are capable of touching, holding and manipulating objects with as much precision and care as we like or need. When our motor skills become compromised, a person loses autonomy when performing tasks, productivity diminishes and discomfort prevails, directly damaging the person's quality of life.

Hands are located at the end of the forearms. They are composed of the phalanges, the metacarpal bones, the carpal bones, and the wrist joint [1]. Because of their location, the phalanges and the metacarpal bones are at a continuous risk of trauma. This risk is higher in jobs involving hand-operated machines and sports. The fractures of these bones are more than 10 percent of the total fractures in the whole body [2], and they can be classified according to their location, the presence of comminution, the degree of displacement and if there are injuries to soft tissues. Depending on the level of damage, the type and location of the fracture, surgical treatment can be necessary. However, all types of fracture include immobilization of the injured limb, either as the first or second step of the treatment [3].

To prevent atrophy or permanent disability and improve hand function, it is required to start with physical therapy immediately after the patient has received the necessary treatment for inflammation and pain. Rehabilitation typically involves decomposing complex hand motions into simple, segmented motions that involve effort and muscular endurance to improve hand function, strength, and range of motion with minimal sequelae. This type of rehabilitation is called Repetitive Task Practice (RTP), this method is usually highly time-consuming for both patient and therapist. This time investment also implies less time for the therapist to attend to other patients and a higher capital cost for the patient [3],[4]. In order to avoid the implicit complications with this method of therapy, numerous systems that can help patients carry out exercises on their own, at home, or in the clinic, have been proposed. Studies indicate that patients who have suffered an accident that affects their body movement and use robotic devices as a therapeutic assistance to perform repetitive movements have significant improvement in their motor functions and decrease the time spent with the therapist [5]. However, most of the commercially available devices are manufactured using conventional robotics, which means that their components are often non-deformable and can be hard to operate, resulting in a device that is not ergonomic, uncomfortable to use, and has a high acquisition cost, therefore, their accessibility to both the patient and the doctor is limited [4].

In response to the severe limitations of conventional robotics in this field, a new generation of robotic devices have been developed using techniques from the burgeoning field of soft robotics. These soft robots are composed of individual actuators made from hyperelastic materials where the behavior of each actuator is directly programmed into the morphology of the actuator itself. The design philosophy of these soft devices stems from the study of muscles and the locomotion of biological bodies such as worms, caterpillars, starfish, and octopuses, so its main characteristics are softness, elasticity, and flexibility [6]. Most of the projects that use soft robotics destined for medicine are still in the research phase since most of the projects still have disadvantages such as achieving precise control by the system.

This project proposes a hand orthosis that assists movement during motor therapy through a hydraulic rehabilitation glove. Its objective is to imitate the movements of a physical therapist and achieve flexion and abduction movements, similar to the movements of human fingers. This will be done by a code that detects the therapist's intention to move and mimics the desired movement in a neoprene glove that has integrated five soft actuators made of an silicon that is based on the PneuNet technique.

1.2 General Objective

To design a wearable, soft-robotic glove that works as a hand rehabilitation device that imitates the hand movements performed by the physiotherapist or by the same patient, obtaining the signals through an electromyograph, categorizing them through a neural network , and controlled by a hydraulic system.

1.2.1 Particular Objectives

- Acquire and interpret electromyographic signals from the forearm using a muscle activity measurement device for the control of a soft-robotic rehabilitation device.
- Design a hand movement classifier using a Neural Network.
- Build an orthosis based on soft actuators to assist the movement of the fingers during rehabilitation therapies.
- Design an adaptive controller for soft hydraulic actuators using biosignals to mimic the biomechanics of the hand.
- Manufacture a system based on soft actuators that allows us to have two or more degrees of freedom capable of adapting to the morphology of the finger.

1.3 Project justification

This project addresses the needs of patients that must undergo physical therapy as a treatment for extremity trauma. Although conventional robotics have been widely used in the field of physical therapy, several matters such as a patient's comfort, time and economic benefit could be approached from the side of soft robotics. The implementation of this technology in the design of a finger orthosis will enhance ergonomics and device control, by its adaptation to every new user. The orthosis by its own could be called a simple device if not for its integration with other systems, such as the electromyographic data acquisition system in conjunction with an algorithm of classification and the hydraulic system for the control of the soft actuators defined by degree of bending, fluid pressure and volume and movement velocity.

1.4 State of the art

The applications of soft robotics within the context of medicine are limited, nevertheless, this technology develops day by day allowing us to discover the advantages of soft actuators in benefit of people's health. Some of the investigations and projects about soft robotics that started developing in the year 2010 have presented applications for its use as exoskeletons for upper limbs and as assisting devices for different physical treatments [7]. The most advanced of these projects were created by Harvard University, the National University of Singapore (NUS EI LAB), and The Chinese University of Hong Kong, shown in Figure 1.1. Although these exoskeletons worked with the same technology, soft actuators and pneumatic systems, we can find differences within their design and control.

The Wyss Institute by Harvard University developed their "Soft Robotic Glove" as an aiding device for the treatment of neurological progressive diseases, such as muscular dystrophy, amyotrophic lateral sclerosis (ALS) and incomplete spinal injury. Considering the targeted pathologies, the design of the glove is based in achieving the characteristics of portability and the ability to perform a hand grip by flexion and opposition movements [7]. They worked with a common design of soft actuators also found in the other projects, this layout involved the modeling of uniform actuators, this means that they use a consistent number of cells throughout the finger, with no divisions or changes in width. Additionally, they included a sensor on the tip of the actuators for pressure control grip and established that the hand would be scanned for customized gloves [7].

On the other hand, the NUS EI LAB, has worked on different versions of their "Soft Robotic Glove Glen", incorporating new elements on each design, it serves as a rehabilitation device. The model for their soft actuators continues to be uniform, but with variable stiffness along the actuator to achieve a smaller radius of curvature at bending [8]. They have also incorporated, as of the year 2015 in "Glove Gen2", EMG as the control for intent detection, although this detection of movement does not replicate velocity and it comes with a delayed action from the actuators [9]. Its glove design as the base for the actuators has changed as well, leaving for the newest version a semi-covered glove that frees the palm of the hand.

Finally, in contrast with both projects, The Chinese University of Hong Kong undertook the job of printing their actuators instead of casting them from a mold. They used the ACEO 3D printed silicone to address finger rehabilitation for stroke patients. They stated that 3D printing is an accelerated method for the fabrication process and it provides further freedom of design for the actuators. Although the usual materials for printing may be rigid, they claim that printing silicones keeps the sought advantages, high elasticity, temperature and UV stability, tensile strength and compression set [15].

Figure 1.1: Soft Robotic Projects (Harvard University, NUS EI LAB, The Chinese University of Hong Kong from left to right) [7, 15]

Nowadays, some of these technologies, started to have a place in the market, such is the case of the Urehab-HRX gloves from the enterprise Uforya Medical [16]. There isn't much documentation available to know about the principles that govern this model but, its control depends on the intent movement acquired by another glove placed in a healthy hand. Additionally, this device includes a patient monitor where they can regulate de pressure grip. All these projects have their similarities and differences respectively. Much of them due to the fact that each rehabilitation glove is aimed to treat different kinds of pathologies. Still, they have constructed a base for future applications and areas of opportunity for rudimentary prototypes.

Figure 1.2: Urehab Glove by Uforya Medical [16]

Chapter 2

Theoretical Framework

2.1 Hand's Anatomy and Biomechanics

In the case of physical trauma, the level of recovery and improvement, by means of an orthosis, will depend on the study of the anatomy's biomechanics. By using principles of biomechanics such as range of motion or force motion we can create models to analyze the necessary forces that take part in motor skills. For the scope of this project, we defined three anatomical structures for the hand, the bones, joints, and muscles, which together allow for the manipulation of objects with high accuracy movements and low effort. They can be compared to the physical components of a mechanical system, bones being the bodies on which to exert a force to produce movement, muscles representing the applicable forces on the bodies as to gain torque and finally, joints as the turning points that will dictate the movement's range.

First, it's imperative to describe some of the anatomy of these structures. The hand is conformed by 27 bones: 14 phalanges, 5 metacarpus and 8 carpus. For matters of this project's objective, we will only focus on phalanges which form the fingers. Each phalanx has three different regions, the base, body, and head; they each are identified by being numerated from one to five starting with the thumb. Each finger counts with three phalanges: proximal, middle, and distal. The thumb is an exemption to given that it only possesses two phalanges. The phalanges' base is concavely round to match the shape of the former bone in line, while their head is defined to have a pulley-shaped or convex form, that will serve as the fixing point for ligaments from were to pull in the case of phalanx movement [17].

Joints can be classified by the range of motion they permit. Both phalangeal joints, are articulations that allow considerable motion between their bones and hence are called diarthrosis or synovial joints. The first of these joints is the metacarpophalangeal joint, also known as knuckle, it is composed by the base of the proximal phalanx and the metacarpus. It is a synovial joint of the type condyloid, and it allows for the movements of flexion and extension around the transversal plane, as well as abduction, adduction, and circumduction (Figure 2.1) [17]. During a motion of flexion, these articulations become less flexible given the strain on the ligaments found on its base, this is what creates the stability that results in force when grabbing or holding an object. For flexion at the level of this type of joint, a total arc of movement between 120° to 135° can be acquired, such that a 90° angle is for flexion and 45° for a hyperextension. Regarding abduction, the metacarpophalangeal joint allows for an angular motion of 20° approximately [18].

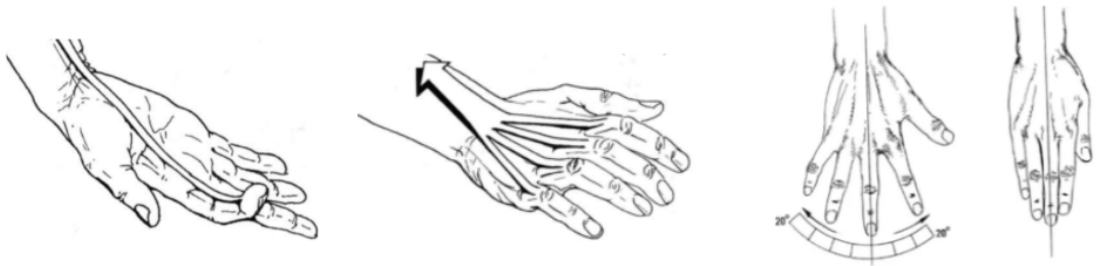


Figure 2.1: Movements allowed by Metacarpophalangeal Joints [17, 19]

In comparison, the union between each phalanx will form an interphalangeal joint of the type hinge, its capsule is similar to that of the metacarpophalangeal joints. The joint between the proximal and middle phalanx can achieve over a 100° angle during flexion. At the moment of this movement, flexion of the distal and middle phalanx occurs as well, the movements of these two joints are relative to one another [18].

Regarding muscles, these will be classified according to different characteristics, the location of their origin, their proximity to the surface of the skin and the movement they carry out. To simplify the division of these muscles and their identification we created Table 2.1.

According to Table 2.1, the applicable forces of the muscles can be found throughout the bodies of all five phalanges. The critical regions in which these forces are being exerted are shown in Figure 2.2, red dots represent forces of flexion, blue dots forces of extension and yellow dots forces of abduction. These forces are the same for each phalanx from II to V, since the thumb has its own muscles. In Figure 2.3, a diagram of the direction of the forces is exemplified over two-dimensional axes, the arrows represent the tension of the muscles, flexors, extensors, abductors respectively.

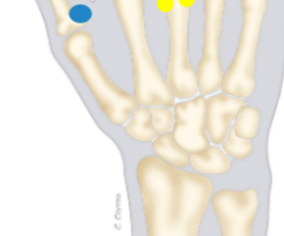


Figure 2.2: Exertion of Forces over the Phalanges

Table 2.1: Muscles of the Hand [17]

Muscle	Type	Insertion	Action
Flexor Digitorum Profundus	Extrinsic deep	Distal phalanx (II to V) (base)	Flexes distal interphalangeal joints
Flexor Digitorum Superficialis	Extrinsic superficial	Middle phalanx (II to V) (lateral)	Flexes proximal interphalangeal joints (Moderate contraction), Flexes metacarpophalangeal joints (Strong contraction)
Flexor Pollicis Longus	Extrinsic deep	Distal phalanx of thumb (base)	Flexion of the thumb
Extensor Digitorum	Extrinsic superficial	Proximal and middle phalanx (base), distal phalanx (lateral) (II to V)	Extension of metacarpophalangeal and interphalangeal joints
Extensor indicis	Extrinsic deep	Joins with extensor digitorum of II finger	Reinforces extension metacarpophalangeal and interphalangeal joint
Extensor digiti minimi	Extrinsic superficial	Joins with extensor digitorum of V finger	Reinforces extension of metacarpophalangeal and interphalangeal joint
Extensor pollicis (brevis and longus)	Extrinsic deep	Proximal and distal phalanx of the thumb (base)	Extends phalanges of the thumb
Interossei	Intrinsic dorsal	Proximal phalanx (lateral)	Abduction
Interossei	Intrinsic palmar	Proximal phalanx (lateral)	Adduction
Lumbricals	Intrinsic	Lateral sides of phalanges (II to V)	Flex metacarpophalangeal joint, extend interphalangeal joint

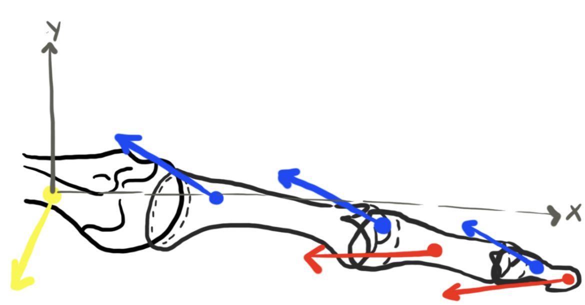


Figure 2.3: Tension Forces of Muscles

2.2 Rehabilitation Process

As previously mentioned, finger and metacarpal fractures are one of the most frequent causes in emergency services, representing around 30 and 50 percent of broken hands. Phalangeal fractures turn out to be the most common injury, followed by metacarpal bones. When a person has a possible broken hand it is necessary to realize an evaluation that confirms the prognosis. First, the doctor does the clinical history concerning the cause of the injury, as well as a physical evaluation where is verified the presence of swelling (inflammation area in the body), protuberance or deformity and soft tissue injury, neurological damage, and/or a blood vascularization (hematoma) [10]. After that, a radiographic examination must be done to confirm what was said before and verify the level of comminution (fragmentation in small bone pieces) and the displacement of the fracture.

If the fracture presents a displacement of joint fragments, rotational alterations, or angulations with a high degree, is classified as an unstable fracture, and a surgical procedure must be performed for a total or partial reconstruction of the affected area. If it is a nondisplaced fracture, conventional treatment could be followed using an immobilization splint. Immobilization must be as noninvasive as possible by immobilizing only one joint proximal and one distal to the area of injury [10]. The position in which it should be immobilized is known as the ”neutral position”, in which the thumb is in flexion and opposition in a range of 30° to 40° and flexion in the metacarpophalangeal joints between 70° and 90° [10,11].

Once the immobilization time has finished, which will depend on the level of injury suffered, it is important to start with a movement therapy that helps restore full mobility of the fingers. Medical studies indicate that the Repetitive Task Practice (RTP) can help improve better and faster the motor function of the hand. The therapy consists of separating complex tasks into simpler movements, in the early stages of therapy these movements are the main movements of the phalanges and metacarpals, such as flexion, extension, abduction, and adduction. In the later stages of rehabilitation, the goal is to bring these movements together by performing a more complex task, such as pinch and grip movements. In this type of therapy, the training must be functional and challenging for the patient, since these are characteristics of good functional therapy.

The mobilization therapy plan can take from eight to twelve weeks depending on the progress of the patient. In the first week, the injury is in an inflammatory phase, where the hematoma is surrounded by inflammatory cells, the arm should remain with the splint, as in the second and third weeks, where the patient is bone repair and consolidation [12]. From the third to sixth week, active and passive exercises of flexion and extension of the injured areas will be carried out assisted by the physiotherapist, as well as an active and independent mobilization of the non-injured fingers. From the sixth to the eighth week, exercises will add to squeezing a sponge, kneading dough, and counting coins. Also, exercise the compression of a ball to restore the muscle tone of the flexors. The last phase is the remodeling phase, which runs from week eight to week 12. This phase seeks to use the injured hand for all activities according to tolerance, as well as resistance to the full weight of the hand [12]. For the first and second phases of therapy, therapists currently use dynamic hand orthosis that supports the assisted mobilization of the patient. In the market, we can find different therapy devices that use conventional robotics for the mechanism of orthosis. An advantage of using conventional robotics is that it achieves fine control to perform movements such as flexion, extension, and abduction. EMMRA-1 exoskeleton [13] device is shown in Fig.2.4, which has three interfaces: orthosis-skin, which includes the leather glove, passive orthosis, which are articulated acrylic pieces, and an active orthosis, which works with servo motors. A second example is the PRO-Dix II prototype, Figure 2.5 [13], with the same interfaces as the first example. The incorporation of robotic orthoses that assist during motor rehabilitation has been shown to increase the performance of therapy and improve patient recovery. However, a disadvantage of these devices is the weight and rigidity of the materials. To improve this, different alternatives have emerged.

Figure 2.4: EMMRA-1 orthosis (13)

Figure 2.5: PRO-Dix II robotic orthosis (13)

An innovative solution that has come up in recent years is the application of soft robotics in medicine. Soft robotics is an area of robotics that designs robots with materials with softness and elasticity like biological soft tissues, their modulus of elasticity is in the order of 10e2- 10e6 Pascals. In addition to flexibility and greater adaptation to perform tasks, soft robotics offers greater security working with humans. For the construction of these robots, smooth actuators are used [14]. Unlike rigid actuators that are not capable of deformation, soft actuators are capable of deforming along with the structure, giving the system several degrees of freedom, which in turn, allows the emulation of biomotion. Two examples of soft robots inspired by biology are in Figure 2.6. Figure 2.6A shows a robot inspired by an octopus, specifically a tentacle and Fig 2.6B shows a soft robotic inspired in a starfish [14]

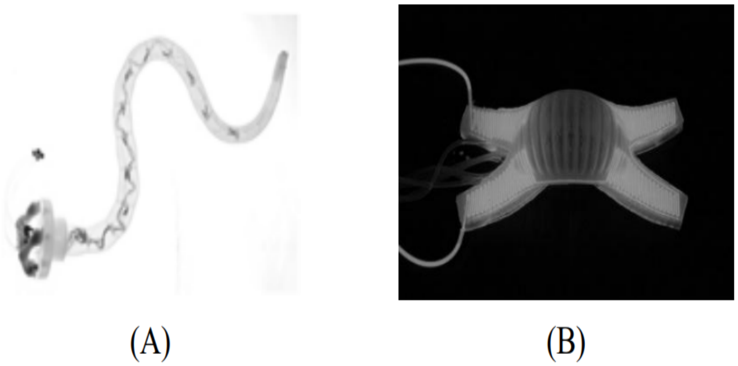


Figure 2.6: Examples of soft robots (14)

2.3 Acquisition of Electromyographic Signals

Movements of muscles are a result of neuromuscular transmission, a signal that travels from a motor nerve to a skeletal muscle and induces contraction. The electrical activity of this nerve stimulation can be measured with the help of electromyography (EMG). The action potential captured by the EMG can provide information on the muscles activated when different movements are being executed. This type of test is performed by the insertion of needle electrodes or the positioning of surface electrodes in the skin [20]. The development of electrode technology has allowed for the creation of smart systems that use EMG as a tool not only in healthcare, in other areas as well, such is the case of the Myo Armband.

The Myo Armband is a smart electronic device from which to take advantage in many applications. It is a wearable device manufactured by Thalmic Labs Inc. in Canada, although this device is not produced anymore, it is still being used for its application in different projects. The armband is conformed of 8 EMG electrodes, an inertial measurement unit (IMU), a bluetooth transmission module and a vibration motor [21]. Its electrodes make use of an operational amplifier ST 78589 for the conditioning of the signal, allowing for the acquisition of a narrow bandwidth of EMG signals that goes from 0 to 200 Hz. The IMU integrates a 3 axes gryroscope, a 3 axes accelerometer and a 3 axes magnetometer all made to the detect the forearm movements in a three-dimensional space through the use of Microelectromechanical systems (MEMS) and 16-bit ADCs all embedded in the Inven-sense MPU-9159 chip. The processing of both EMG and IMU data is carried out by the ARM Cortex M4 120 MHz operation processor, being all voltage supplied by 2 lithium battery that can be recharged by 5V. The acquired data can then be sent through wireless transmission to a monitor for its display or to another processor for further management [21]. The layout of these components can be visualized in Figure 2.7.

Using Myo, comes with several advantages since, the armband already accounts for the stages of calibration, sensor, signal conditioner, data transmission and data recording of the system. Hence, providing a simplification of components in terms of a bioinstrumentation system (Figure 2.8), diminishing disturbances such as signal variation or noise due to construction errors. This is the main reason behind the implantation of the Myo Armband in a variety of projects, from the control of prosthesis movements for upper-limb amputees to music concerts, to relate the play of lights to his movements during on-stage performances.

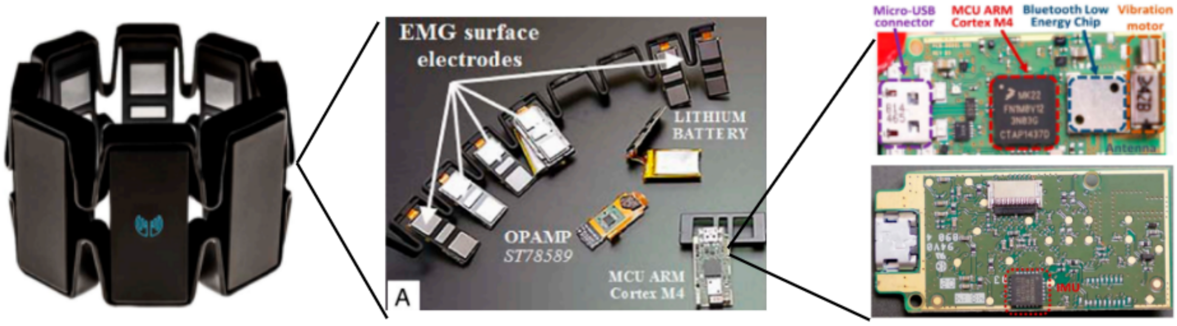


Figure 2.7: Electronic Components of the Myo Armband [21].

Must of its applications have integrated movement classification by using k-nearest neighbor and dynamic time warping algorithms, this with the objective of being able to perform actions through the instruction of hand gestures. For example, the device created by TedCas, technology addressed to surgeons so they can control in real-time several medical instruments with the movements of their arm and hand [21]. This type of remote manipulation improves safety and reduction of infection risk.

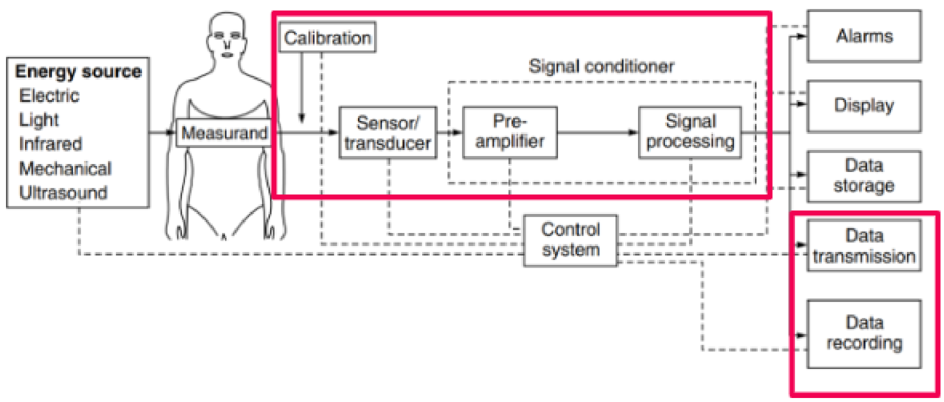


Figure 2.8: Bioinstrumentation System [22].

2.4 Deep Learning

Some people have limited themselves to believe that technology replaces human work, refusing to pay attention into its further development. Specifically, within the subject of health, technology isn't constructed with the objective of replacing medical staff, it can function as an assistant, as a tool to perform with higher precision and in a decreased amount of time, aiming to improve the services of the health system. A branch of technology with an increasing relevance of sorts within healthcare is artificial intelligence (AI).

One of the branches of AI is deep learning. The evolution of neural networks has made possible for deep learning processes to be constructed as a model based on the human neurons, creating layers of individuals neurons also known as perceptron, each deeper layer grants a higher level of processing information. The whole system of deep-learning networks is constructed as a facilitated learning process, allowing for them to learn from a loss value each time it trains with data. On account of this training process, the system learns from ”its own mistakes” and improves the precision of its prediction, reducing the error in regard with the desired output. This tool can be used as an assistant for the elaboration of informative and accurate reports in an automated manner, depending on the management of data and the mathematical models to arrange it [23].

The architecture of a deep neural network can be defined by terms of its computational functions. First, the activation functions are responsible for the introduction of non-linearities into the network, after its inputs have been multiplied by their weights. Non-linearities allow to approximate arbitrarily complex functions and defines the imaginary line that divides data in a set number of classes (Figure 2.9). A typical activation function when working with completely positive outputs is the Rectified Linear Unit (ReLU) (Figure 2.10). This function defines as zero all negative inputs, above zero positive numbers follow a lineal correlation hence, having a slope of 1. It is important to mentioned that all activation functions must have real and well-defined derivatives [24].

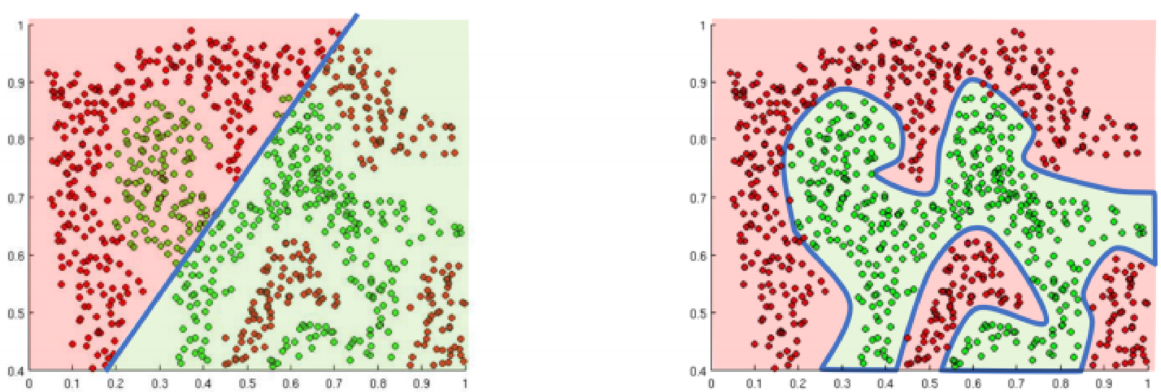


Figure 2.9: Introduction of Non-linearities into Dataset [24].

Another relevant function is the loss quantification, it measures the cost incurred from incorrect predictions of the network. It is defined by the difference between the prediction and the actual desired output. What is sough with this loss value is to minimize the total sum of errors of the prediction in order for the network to find the appropriate weights while training. One of the most common functions used to calculate loss for classification prediction is the cross-entropy loss, for when you know that your outputs will all be integer positive numbers. As previously mentioned, the ideal situation is to arrive to a minimal loss quantification, this can be done by working with optimizers. Optimizers are composed of equations of gradient descent that try to find the global minimum weight values along the dataset field, a representation of this process is exemplified in Figure 2.11 on a three-dimensional context. Finding the correct network weights achieves the lowest loss [24].

Finally, it is relevant to talk about the concept of learning rate as well. A learning rate is the numerical value that defines the difference between the weight values that are being

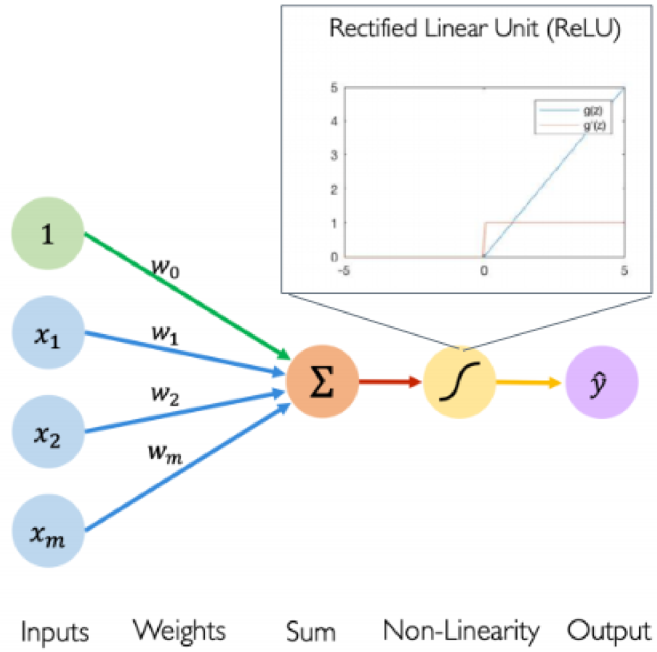


Figure 2.10: Structure of Artificial Neuron and Activation Function ReLU [24].

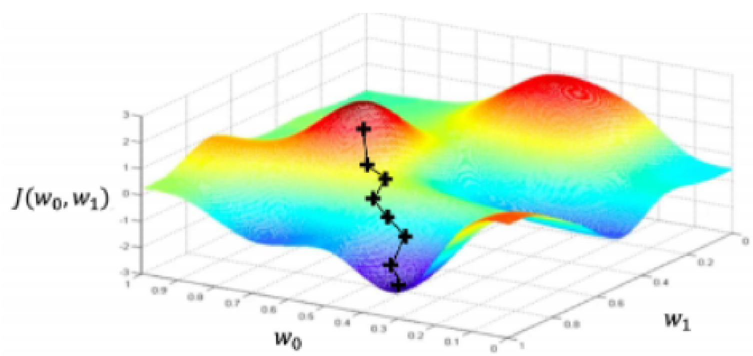


Figure 2.11: Gradient Descent to find optimal weights [24].

selected through the optimizer. It can cause fast or slow training depending on its magnitude. Not finding the ideal learning rate can cause the neural network to get stuck in false local minima or bounce all around weight values and never converge (Figure 2.12). Selecting the optimal learning rates allows for the prevention of underfitting or overfitting the network's model, as presented on Figure 2.13 [24]. Additionally, these cases can also be prevented by methods of regularization, which are techniques that constrain the optimization problem in order to discourage complex models and allow a generalization of the model, so it works at its best with unseen data. These techniques are called "Dropout", that is when the model activates some neural nodes to 0, and "Early Stopping", which is when once the training accuracy and the testing (validated) accuracy start diverting from each other it stops performing epochs (Figure 2.14) [24].

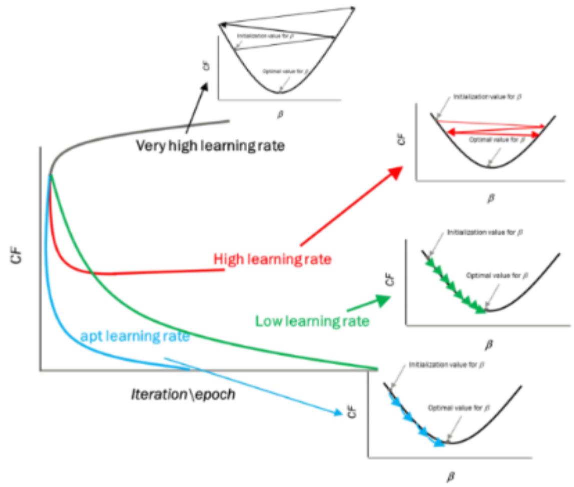


Figure 2.12: Effects of Different Learning Rates in Neural Network Training [24].

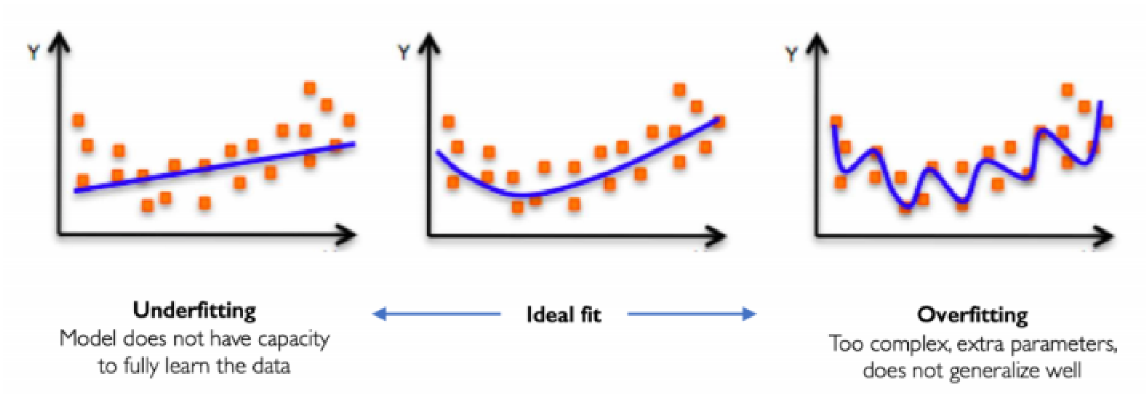


Figure 2.13: Variations of fits in Neural Network Models [24].

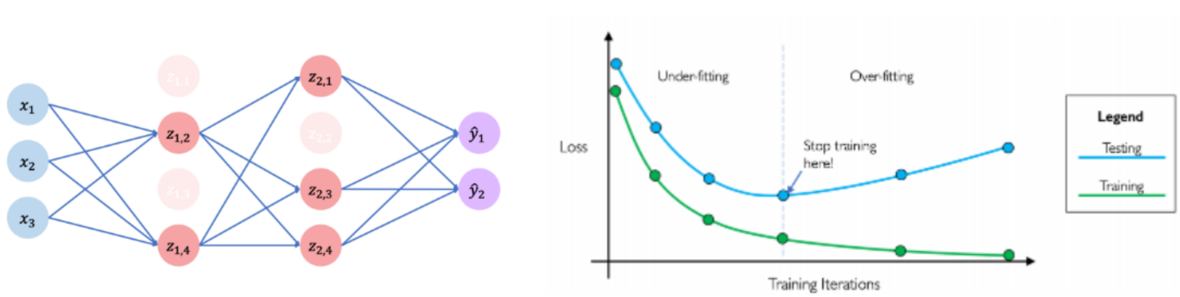


Figure 2.14: Schematic representation of "Dropout" (left) and "Early Stopping" (right) techniques [24].

2.5 Soft Robotics

A robot is a system that can be programmed to perform certain tasks by means of mechanical power. Within the last decade and a half the field of robotics has expanded by using hyperelastic materials to manufacture mechanical components. This innovation gave birth to a new branch of robotics: Soft robotics. This branch focuses in nature inspired, animal-like bodies that allow for dynamic motion through deformation. The objective of soft robotics is to take advantage of the mechanical properties of hyperelastic materials in order to achieve life-like, complex motion-patterns and trajectories. Actuators of a mechanical system can be compared to muscles in a body. They both enable different kinds of energy to be converted to motion in order to perform mechanical actions [25].

2.5.1 PneuNets Actuators

There are varied categories of Soft robotics actuators which are typified by their respective materials, build techniques, and behaviors. The focus of this project is upon the category of soft actuators called PneuNets Actuators. PneuNets actuators are cast from liquid elastomers and allowed to cure in molds that are made up of a series of channels and chambers, which inflate when pressurized in order to create motion. The design of its geometry and properties of its elastomer define the type of movement that it can perform. Movement is possible when pressurized because the actuator will vary its capacity for extension using different material compositions as well as structural variations along its body, allowing for expansion differentials (Figure 2.15. A typical base for design that permits bending and twisting is the configuration that includes a "strain limiting layer" on its actuator and individual chambers that expand and collide with each other; thus creating an expansion differential between the top and the base of the actuator which induces bending of its body [26].

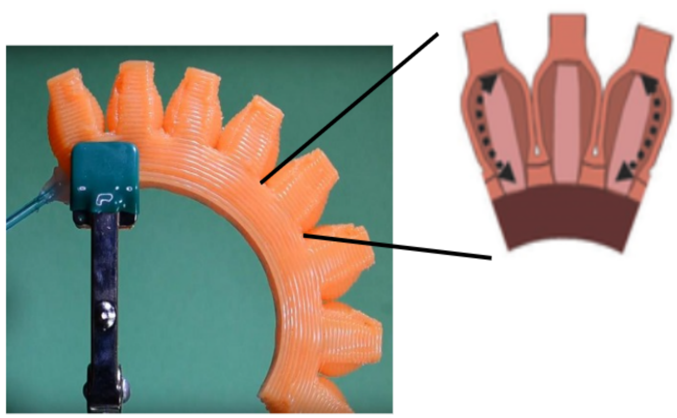


Figure 2.15: Soft Actuator's Principle of Function [26].

A common method for the fabrication of this type of actuators is by making solid casts. Two bodies need to be made separately, these will be the main body and base of the PneuNets actuator. Once the models of the cast have been made according to the desired morphology, the silicone-based mixture can be poured into the molds in order to be curated. It is important

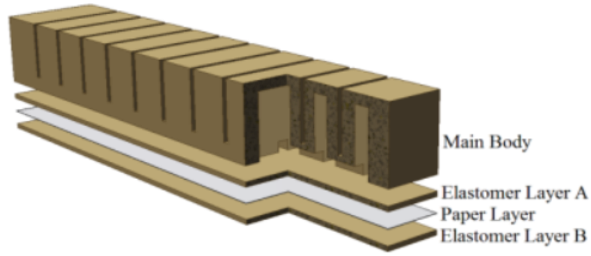


Figure 2.16: Morphology of Soft Actuator [26].

to mentioned that the morphology of the actuator always results from the simulation of models and motion analysis that will show the expected behavior of the actuator [26].

The design process of these types of actuators is quite extensive and complex given the fact that the 'programming' of motion is embedded directly into the structure of the actuator itself and not a complex computer-controlled motion system. There are three main steps in the design of soft actuators that are commonly used by engineers and scientists: 1) Identification and analysis of a desired bio-mechanical system. 2) Generation of a three-dimensional structure and selection of component materials that aim to mimic the desired bio-mechanical system. 3) Simulation through Finite Element Analysis of the actuator.

Chapter 3

Methodology

3.1 Proposed Solution

3.1.1 Proposal and Block diagram

RTP rehabilitation consists of asking the patient to repeat a series of basic movements several times to progressively improve mobility and recover finger strength. Some of the suggested exercises are finger flexion, extension, and abduction. However, most of the time, patients are often incapable of executing these exercises on their own due to a lack of strength or muscular stiffness, requiring the assistance of a physical therapist. This can result in a waste of resources and time for the therapist, making therapy more expensive for less time for the patient.

As a solution, a medical device is proposed to help during the rehabilitation of the hand. The block diagram of the system can be seen in the Fig.3.1. The system collects signals obtained from the physiotherapist or the patient through an electromyographic band. A neural network is responsible for processing, analyzing, and classifying the data according to the movement and speed obtained in real-time. Then, a signal is sent to the control in charge of the hydraulic system that feeds the actuators. Finally, the movement performed by the first person is emulated by the rehabilitation assistance glove. The movements to be imitated are finger flexion, extension, abduction, and adduction, with all the fingers moving simultaneously. The device has three-speed profiles at which the movements can be imitated, the speed depends on the velocity with which the subject performs the exercises and the rehabilitation stage in which the patient is.

The wearable device has a series of soft actuators attached on top of each finger in a neoprene glove to ensure patient comfort and effective fixation of the device. Actuators have a specialized design that allows them to emulate the relative movements of the joints of the fingers when they are forced to move from an open state into a closed one and from the rest to extension. In addition, the second series of actuators were placed between the fingers to perform the abduction and adduction movements.

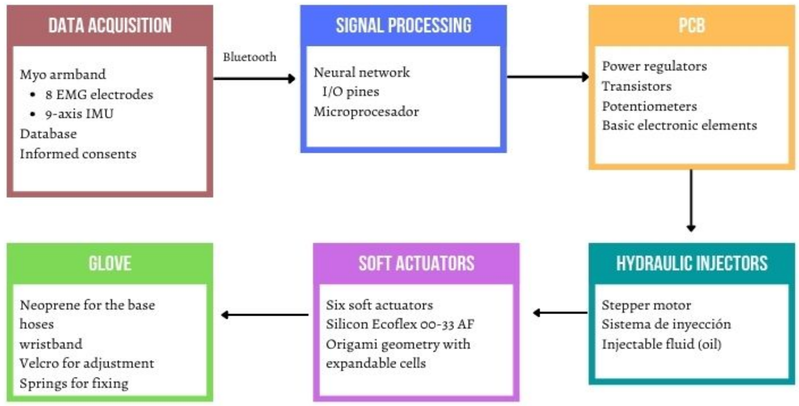


Figure 3.1: Block diagram of the system

3.1.2 Ergonomic Glove Requirements

To design an ergonomic therapeutic device, a series of specifications must be followed to achieve the correct assistance during rehabilitation. After reviewing numerous publications on mechanical assist hand orthoses and some discussion with a physician specializing in sports medicine and physical activity, the most important requirements for the rehabilitation device were obtained. First, the device must weigh less than 0.5 kilograms for the glove with the actuators alone, so it does not restrict the patient's motion, it should have three or more degrees of freedom per finger, and have adjustable glove size. It should avoid compression of the bony prominences of the hand, thus avoiding discomfort during use. The materials of the glove must be prevented from interfering with touch, allowing proper perspiration of the hand, they must also be soft, comfortable, easily washable, and capable of maintaining the temperature of the hand. The glove design should allow the patient to put it on and take it off easily, for safety reasons the glove should be able to be removed quickly if necessary (27).

For soft actuators, the initial position should be the "rest position" of the hand where the thumb is flexed in a range of 30° to 40° degrees and the metacarpophalangeal and the interphalangeal joints flexion between 70° and 90° degrees. The design should achieve the bending curvature for flexion and extension, as well as expansion for abduction and adduction movements. To ensure proper bending of the fingers, the actuators should be placed above each finger over a glove made of a flexible and deformable fabric that returns to its natural shape after pressure is done. Finally, for efficient operation, it is recommended that the system be capable of performing at least 10 opening-closing or expansion cycles per minute (27).

3.1.3 Actuation System Requirements

The proposal for the actuation system of the orthosis is based in soft actuators that will be connected to a hydraulic system, this means that pressure will be created on account of liquid supply. The components of this system must allow for a continuous pumping and suction of the solution in order to regulate pressure inside the actuators and it has to be precise in contemplation of the velocity control of the movements. The components must resist overheating or over-workload for long and consistent periods of time and work within the regulations established for patient and user safety.

The assembly of the actuation system should be the smallest size possible and not too heavy, it doesn't have to be portable but, easy to move and install.The electronic components and circuits must be accessible in case of damage or flaws in the device. Its composition must be constructed as modular entities in order to be able to replace a damaged structure without affecting or getting rid of the others.

3.1.4 Soft Actuator Requirements

Soft actuators fulfill one of the main functions of the project. They are the interface between the mechanical system and the patient, which is why they are required to meet specific design and operating features.

Soft actuators are recognized for their lightness and elasticity, so the material with which are made must be a silicone with the capacity to be subjected to tensions where the actuator can stretch more than its original length several times and return to its natural shape without creating leaks during the process, in addition to resisting the pressure to which the actuator is subjected during rehabilitation therapy.

The actuators will be placed on the dorsal part of the fingers in a neoprene glove that the patient use, for which the total weight of the system must not exceed 500 grams. For ergonomic purposes, the five actuators use the same design but with a variance in their geometry in order to match the length of each finger.

3.2 Regulations and Standards for Medical Devices

3.2.1 Classification

The International Organization for Standardization (ISO) defines an orthosis as an "externally applied device used to compensate for deficiencies in the structure and function of the neuromuscular and skeletal system" (28). For this, our therapy device is placed in the category "Hand Orthosis".

The Official Mexican Standard "NOM-241-SSA1-2021" classifies medical devices into six groups according to their function and purpose. The motor assistance orthoses of the phalanges of the hand fall into the category of "Prostheses, orthoses, and functional aids": those devices intended to replace or complement a function, an organ, or a tissue of the human body". In addition, it can be divided into three other classes. In this case, it falls under "Class 1: Those inputs are known in medical practice and whose safety and efficacy are proven and, in general, are not introduced into the body." Due to its function, it can be classified as "passenger use: intended to be used continuously for a period of fewer than sixty minutes." (29) Finally, due to its way of obtaining energy, it is cataloged as an "Active Therapeutic Medical Device", since it needs a source of electrical energy other than that obtained by the human body or gravity to function and its objective is to provide therapeutic motor recovery (29).

3.2.2 Quality Management

According to the statements of the Official Mexican Policy, NOM-241-SSA1-2021, the project must report its fulfillment with the requests for quality, security, and functionality. This compliance is achieved by conducting quality management through the stages of design, development, and fabrication. An adequate management system works with the applicable practices to oversee consistency and uniformity of standards throughout the process. The good practices pertinent to this project are those for documentation, and fabrication.

In order to achieve good practices of documentation and fabrication we elaborated a digital archive through which we can reference each of the files that conform the evidence of proceedings in the design and creation of the orthosis. These files present information about the general description of the device, its purpose, fabrication specifications and design stages. Further evidence of this stages is found through the chapters of this report. Additionally, to prove quality assessment of technical information, both sections of appendix and annex include documentation of technical design and software development.

3.2.3 Electrical Risk

The selection of the electrical components included in the design of the soft robotic orthosis was made considering the requirements of the International Electrotechnical Commission policies (IEC). Specifically, this project deals with IEC 60601-1, the technical standard for safety and essential performance of medical electrical equipment. The fabrication of medical devices entails different types of electrical safety measures in order to avoid or minimize the possible hazards of electrical discharge or shock[31], complying with the patient's and user's safeguard.

An important risk worth recognizing when dealing with electronic components, is the effect of circulating current through a tissue. The bigger the amplitude of this current, the bigger the effect over the body of the patient. There are two types of discharges to consider, depending on the resistance of different kinds of tissues, the macro shock and micro shock. Since this project only implies surface electrodes placed on the right forearm of the patient, the path of the current will only flow through skin, not internal tissues, leaving macro shock as the most probable event.

The requirements for macro shock protection are grounding and electrical insulation. The objectives of these actions are to ensure a safe environment to protect all staff and patients by providing a low impedance circuit for the circulation of leakage current. This circuit allows for the dissipation of undesired current flows to a medium other than the human body and de-energizing of devices, permitting safe manipulation of the chassis (Figure 3.2). These considerations were made at the time of choosing the type of power supply for our processor and mechanical components. Additionally, in order to prevent a flaw in the device, it was imperative to prevent wear in its insulation such as broken or bent cables or an overload of the step motors producing heat [32].

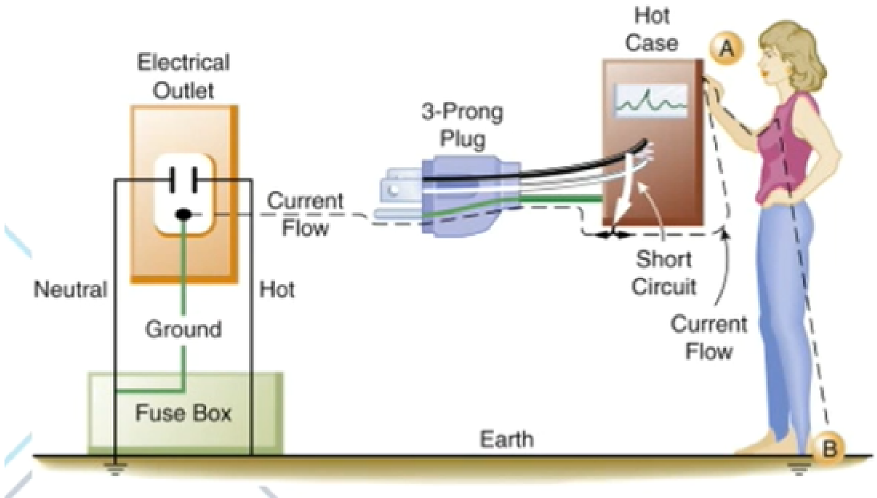


Figure 3.2: Electrical safety sketch [32]

3.3 Engineering Development

3.3.1 Data Acquisition

To feed the neural network, a database composed of the capture of various repetitions of four specific movements was obtained: flexion, extension, abduction and rest position. A second database was also created with information on the same movements at different speeds. For the capture of physiological data, established procedures must be followed, the entire procedure followed will be explained in detail below.

For the first phase of the data acquisition, the participants were asked to perform five different exercises: finger flexion and extension, abduction from rest, abduction from extension, and rest state. Before beginning the collection of electromyographic signals, the protocol indicates that each participant must read and sign an informed consent. Subsequently, the clinical data of each participant were captured in an Excel sheet in order to know if something could affect their sample or our results. The datasheet is composed of the ID number given to each participant, age, health status, level of daily exercise, size and measurement of their hand, and the fabric they wore that day.

The second phase of data collection is the acquisition of electromyographic signals using the Myo armband. The choice of working with Myoband, Fig.3.3, instead of a conventional EMG system to make the prototype is due to the variation of the signal and disturbance obtained when using conventional electrodes. These complications result mainly from changes in electrode-skin impedance, loss of contact between electrode and skin, sensor error during signal acquisition due to sweating, placement-removal of electrodes, or short circuits (30). Numerous studies have compared Myo Band signal acquisition with other conventional electromyographic signal detection systems to achieve different purposes. Most of them showed that the Myo armband is a great option for the detection of muscle electrical activity and the control of external devices based on the detection of EMG signals. Also, one of the recommended applications for the Myo bracelet is to use it to control a mechanical device through electrical signals that are generated when the person contracts the muscles of the forearm when making natural movements of the hand (30).

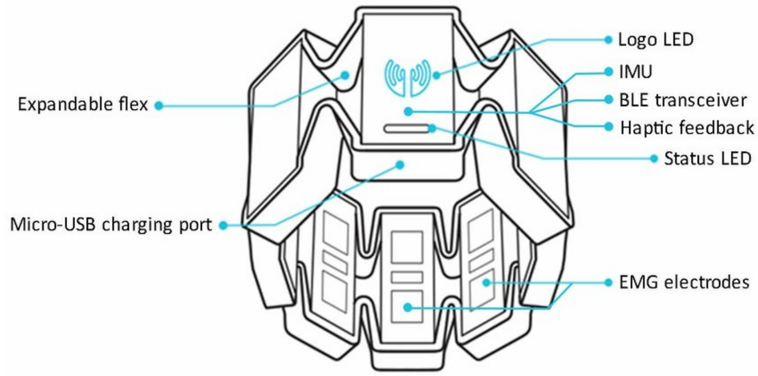


Figure 3.3: Myo armband structure

In this phase, the participants were asked to place the band on their right hand with the main LED of channel 4 aligned with the middle finger and the palm facing upwards, as shown in Fig.3.4. For data acquisition, a code from the PyoMyo library is used and modified to record five seconds of an EMG signal while the patient performs one of the movements. The recorded signal is saved to a CSV file for later analysis. During data capture, an interface with the electromyographic wave appears on the screen to be able to observe and verify that the signals obtained in each sample are correct.

Figure 3.4: Myo armband position

The second database contains the speed profile data. The data capture procedure is the same as the first, the participants were asked to read and sign the consent and their corresponding clinical data was captured.

3.3.2 Clinical Research

The design of this project's orthosis entailed the creation of a patient-oriented research for the construction of a database. Nowadays, the availability and access to this type of resources not only constitutes a relevant field of data science but, an opportunity to support innovation in any context. In this case, the need for a database emerged from the inclusion of a classification algorithm for finger gestures as part of the control for the soft actuators. Which means that for an efficient functionality of the movement classifier, it would have to be pre-trained with electromyographic data. For this purpose, we collected EMG signals from a group of undergraduate students.

In compliance with good practices of data management, three documents were created for the execution of this research study, which account for the lifecycle of the data through its collection, documentation, security, and quality control [33]. First of all, the "Research Data Planning" document collects the definitions of the variables to be measured, how are we going to measure them and how are we going to store them. Data planning is the investment of time where the study group clearly identifies the anticipated outcomes and how are they going to achieve them. It is the first description of data before the beginning of the study, and it allows for scientific integrity since the study members become prepared for when research subjects have questions. Additionally, this document integrates the "Codebook" of the research's database. This section presents the codification of the categorical variables included as confounding factors of the research study in a report form such as, age, gender, health condition, etc. This report form was then added as part of the database under the name of "Patient's Characteristics". The codification of variables helps during the analysis of data and a faster query of the database.

Subsequently, we created written standards, otherwise known as "Standard Operational Procedures (SOPs)", to enhance compliance with established instructions for the performance of specific functions during the research study [34]. It includes the definition of responsibilities for the project members as well as the detailed explanation of how to conduct the research. In this case, the procedures talk about how to fill out the report form, including the taking of hand measurements and the specific indications of how to position the armband on the subject. Finally, according to the specifications for human-subject research, we prepared an informed consent form (ICF) for the voluntary students that would want to participate in the project. This consent form is evidence of the project's commitment to maintain the people's dignity, welfare and rights' protection while conducting the research and through the management of their personal data, as claimed by the "Ley General de Salud" of Mexico [35].

All of these documents can be found in Appendix A, B and C for their inquiry.

3.3.3 Implemented Software

3.3.3.1 Hyperband Tuner Function

As mentioned above, the captured data was used to train two neural networks responsible for predicting the movement and the speed at which it was performed. When creating a neural network, it is important to consider the values of the hyperparameters that govern it and control the learning process. The number of neurons in the hidden layers and the learning rate are examples of the hyperparameter values that need to be determined. Since it is not yet fully understood how some of the hyperparameters affect the neural network, these values are sometimes decided by trial and error or by chance, but this method can make the training process too long, without obtaining the best possible results. To select the best possible hyperparameters and make this process more efficient, a function that is designed to generate neural networks with varied hyperparameters was implemented using the Keras Tuner library. The ranges for these parameters are user-defined, and the compiled models are individually assessed for their accuracy and loss. The Hyperband Tuner class was the selected algorithm. This technique aims to avoid wasting time training the model only on a few epochs, and instead of performing full training on all models, select only the best ones, run the full training, and evaluate the results.

The same hyperband algorithm was run two times to obtain the hyperparameters of each neural network. Since they are not training with the same data size, the structure uses different parameters. The code starts with the network setup where the data was called and the inputs and outputs were defined. The ”x” input will be the eight channels corresponding to the eight electrodes of the Myoband, and the output corresponds to the column where the label of each movement is categorized. The hypermodel structure is defined using a model builder function, to instantiate the hyperfit the hypermodel, the target, and the maximum number of epochs must be specified. As the hypermodel, the hyperband algorithm was selected. It works by training a large number of models only for a reduced number of epochs, evaluating the performance of each one, and continuing with the full training only with the ones that have the best results. The hyperband algorithm creates a ”stop early” function to stop training after reaching a user-defined value for validation loss. The optimal hyperparameters were obtained, then the neural network was trained with the defined hyperparameters. The complete algorithm is located in Appendices n.

3.3.3.2 Data Collection and Proccesing

The algorithm processes a data frame, which is an amount of data that was captured during five seconds, obtains the maximum value of each channel, normalizes them, and performs position and velocity prediction. It is important to consider that if the data has only one line to work with, it is necessary to add a dimension of zeros. The complete deep learning code is located in Appendices n.

3.3.4 Glove Design

As mentioned above, a good rehabilitation device design should meet most of the following characteristics: ergonomic, weightlight, strong structure, high maneuverability and it must be adaptable to different sizes for different patients. The choice material for the glove must consider the user’s sensation, give structure, be able to deform and return to its original shape, and allow free movement of the actuators and fingers. For this reason, the select material for the glove body is neoprene, the adjustable part is made from Velcro, which allows the patient an easy removal if it is necessary, to fix the actuators to the hand and the glove, a spring is used in thin strips, this allow a controlled movement of the entire system.

Neoprene is commonly used in hand orthoses for its flexibility and support, plus it is a low cost material unlike modified fabrics that are also used. Some of its main characteristics are (36):

- Low oxidation rate and highly resistant to degradation by sunlight, ozone, and water.
- Good performance in contact with oils and other chemicals.
- Good resistance to burning and temperatures. It can work in temperatures up to 275 F and down to -50F.
- Good tear strength at room temperature.
- Good resistance to compression deformation.

Since the therapeutic device is composed of hydraulic actuators that work by applying pressure in their cells, there is a risk of leaks forming inside the actuator or the actuator exploding. Having a material with good resistance to oils and temperatures, provides a layer of protection against accidents for the user. The glove size for this project was fixed to the hand measurements of one of the project members. The measurements are shown in Fig. 3.6 and enlisted in Table 3.1. The components of the glove can be seen in Figure n. It will be composed of a wristband made of velcro and neoprene that covers the dorsal part of the hand, from the bone projection of the ulna to the metacarpophalangeal joint, which forms the adjustable part with the higher stability of the glove. To adjust the actuators to the glove, as well as the fingers to the neoprene, two springs will be used for each actuator as shown in Figure 3.6.

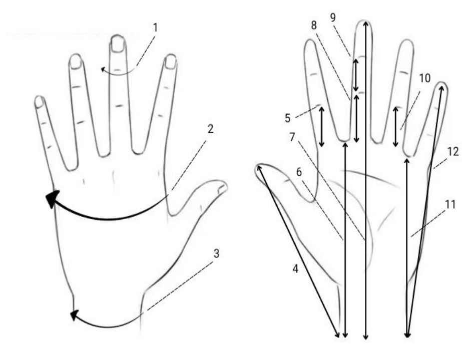


Figure 3.5: Hand measurement points

To achieve flexion and extension movement according to the natural movement of the fingers, a hydraulic actuator is attached on top of each finger, one for each finger joint. The fingers are assisted during the motion when the actuators are pressurized. The design inspiration for the actuators is from Harvard University Polygerinos et al.'s work (27). The actuator is made up of Ecoflex 00-33 silicone and the general design is continuously arranged channels and chambers, the channels produce directional bending deformation when they are pressurized with oil flow. The final design for the soft robotic glove is shown in Fig.3.6.

Table 3.1: Hand measurements

Hand number	Measurement (cm)	Hand number	Measurement (cm)
1	6.5	7	24.2
2	22.1	8	6.1
3	18.5	9	0
4	15.5	10	5.8
5	5.5	11	0
6	12.3	12	17.3

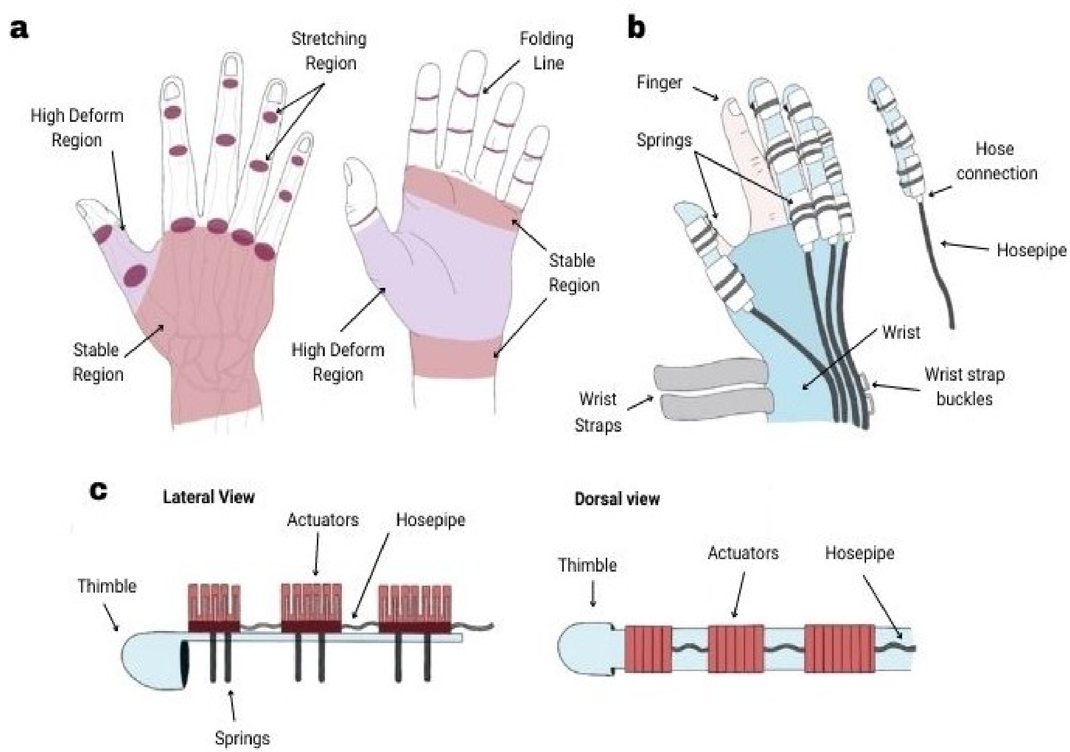


Figure 3.6: Soft robotic glove design

3.3.5 Videogrammetry

Calculations for movement trajectory of the hand were made from 2D video analysis in Kinovea. This process was made with the objective of computing angular position, in order to analyze the movement of each phalanx with respect to the other and compare it with the resulting movement of the soft actuators. This process was carried out for all three movements of the hand, flexion, extension and abduction with the help of indicators placed over the joints (Figure 3.7 and 3.8). In the case of abduction, it was separated into three analysis, abduction of index and middle finger, abduction of the little finger and abduction of the thumb, because they differ depending on the origin axis of position.

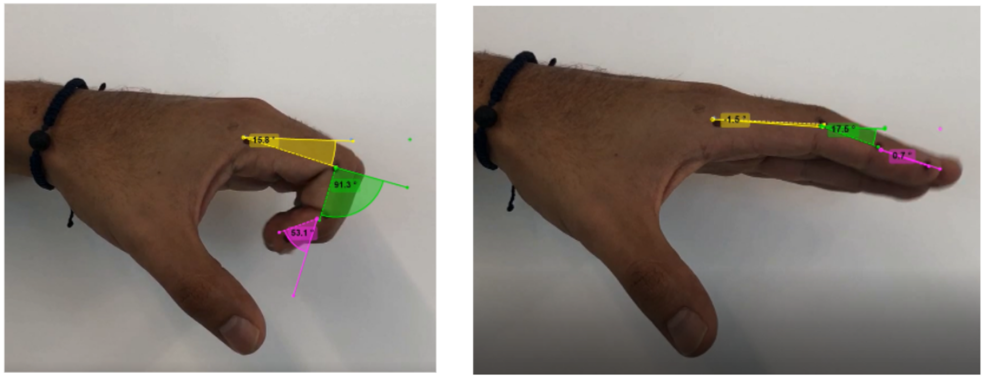


Figure 3.7: Angular Position during Flexion and Extension

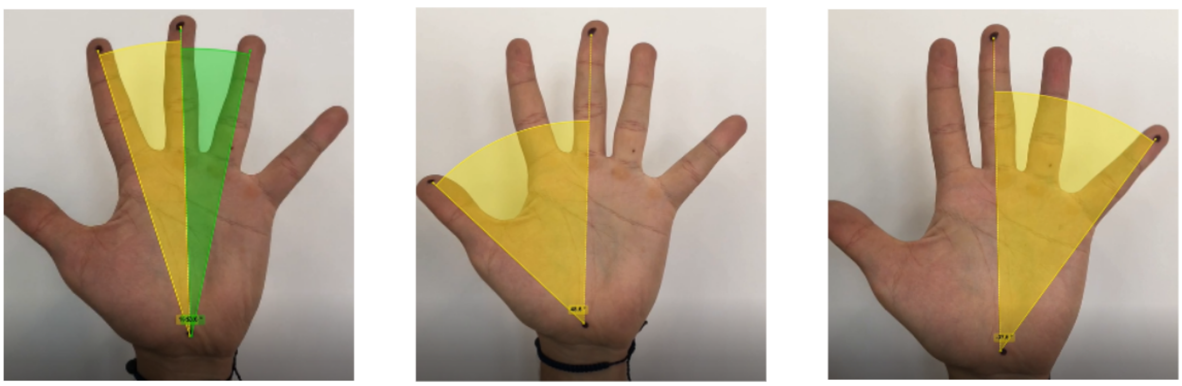


Figure 3.8: Angular Position during Abduction

The graphic results for angular position were made as well taking into account all three phalanges. Angular velocity was also calculated for the flexion/extension movement in order to have a reference frame with respect to different velocity profiles of the actuators.

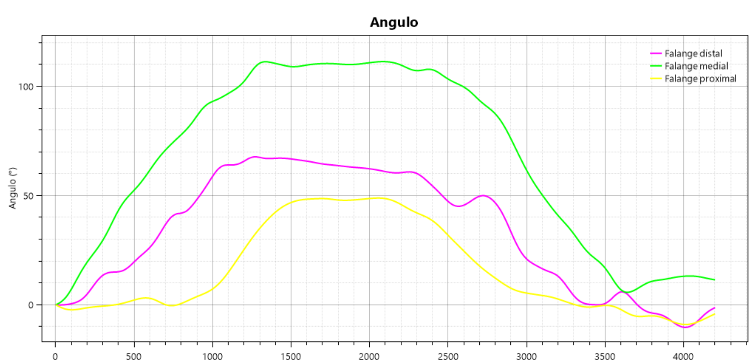


Figure 3.9: Graph for Angular Position during Flexion and Extension

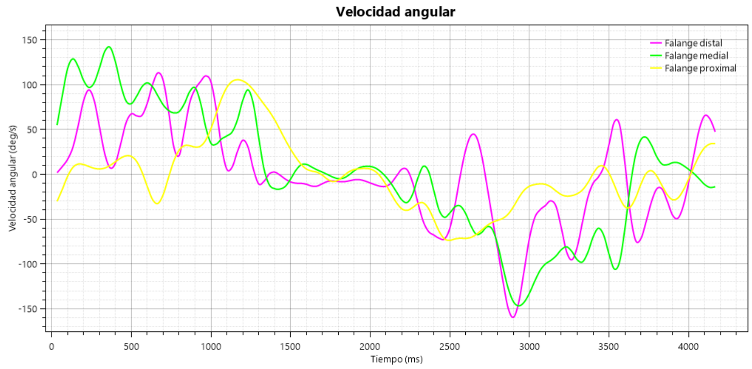


Figure 3.10: Graph for Angular Velocity during Flexion and Extension

3.3.6 Actuation System Design

The hydraulic system was constructed from syringe pumps, big and non-deformable enough to endure continuous plunger movement.The components of this injector system were a 3D printed chassis, stepper motors, metal rods and bearings. The chassis fulfills the function of syringe holder and supports the rods that will stabilize the pushing block. The advancement of the block is relative to the turning of the rod by means of the stepper motor. The stepper motor has a movement resolution of two-hundred steps per revolution. Given the thread-angle and diameter of the syringes, the volume of air delivered per step is approximately 0.02 milliliters per step. Given this resolution of volume per step, the control over the change in pressure within the actuators becomes extremely precise.

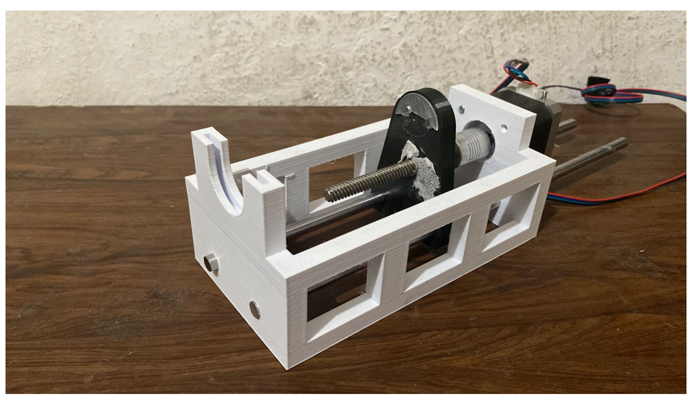


Figure 3.11: Frontal view of Injector Pump System

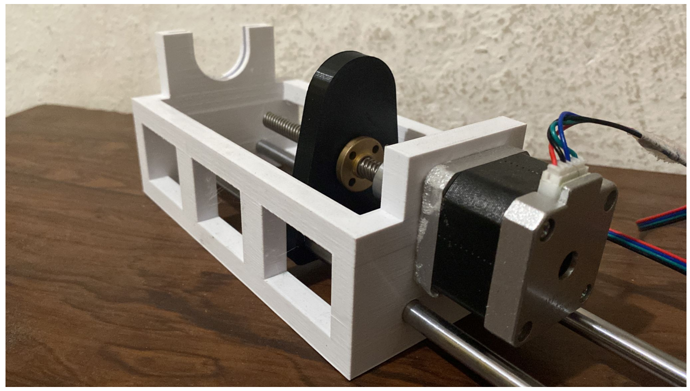


Figure 3.12: Back view of Injector Pump System

The control of the stepper motors is carried out by running a code on the Raspberry Pi that relies upon the open-source library called ”rpimotorlib”. The use of this library becomes especially relevant due to the ease by which it allows the dynamic control of step frequency for the stepper motors. The rate at which the system delivers the air must be variable due to the fact that it is important that the actuators ease in to and out of their maximum fluid delivery rate in order to ensure a gentle transition between poses at each category of movement velocity for the user of the glove. Each velocity category has its own unique motion profile that achieves the desired poses at appropriate movement rates for therapy. Because the pose of each actuator is proportional to the internal pressure being applied to it, the velocity profiles are made of fixed step magnitudes, peak velocities, and accelerations fitted to the anatomy of the user's hand. Due to the fact that the volume of fluid within the actuation system remains constant at all times, the final step value of each pose, when measured from the starting position of the lead screw, becomes a de facto target coordinate for each pose. Given all of the preceding considerations and design decisions, the work-loop of the actuation system becomes a simple navigation between target step magnitudes, measured from a fully retracted position, at varying movement-rates determined by the movement category received from the developed speed-categorization model.

3.3.7 Soft Robotic Actuator Design

The design method for the soft-robotics actuators followed the three-step methodology described in the previous chapter. Due to the resources available to the team, this methodology was slightly modified to be feasible given the team's resources and time-constraints.

3.3.7.1 Identification and analysis of a desired bio-mechanical system

The biomechanical systems of interest for this project are the human fingers. Given the research done in the biomechanics of the hand it was determined that simple bending actuators would be ideal in order to mimic the resulting motion of all the complex interactions of bones, ligaments, and muscles in the fingers.

1) Identification and analysis of a desired bio-mechanical system. 2) Generation of a

three-dimensional structure and selection of component materials that aim to mimic the desired bio-mechanical system. 3) Simulation through Finite Element Analysis of the actuator.

3.3.7.2 Generation of a three-dimensional structure and selection of component materials that aim to mimic the desired bio-mechanical system

Knowing that the bending motions of fingers aren't uniform, the designed turned to making a more complex structure capable of approximating the trajectory of fingers. The team landed on a design that incorporates 3 interconnected main bending 'modules' along the body of a soft actuator. This design more closely mimics the real motion of fingers when compared to simple continuous actuators since fingers function from segmented rotation. The size of the actuators and glove was attuned to the hand of one of the team members since reference dimensions were necessary to facilitate design. All CAD procedures were carried out on the CAE software SolidWorks. All four fingers (index, middle, ring, and small) use the same module actuator design but were adjusted to the size of each finger, the thumb actuator follows the same design, but instead of having a set of three modules it has two. Along the length of the actuator, the three groups of expandable cells were located specifically where the proximal interphalangeal, metacarpophalangeal, and the distal interphalageal joints are (see Figure 3.6).

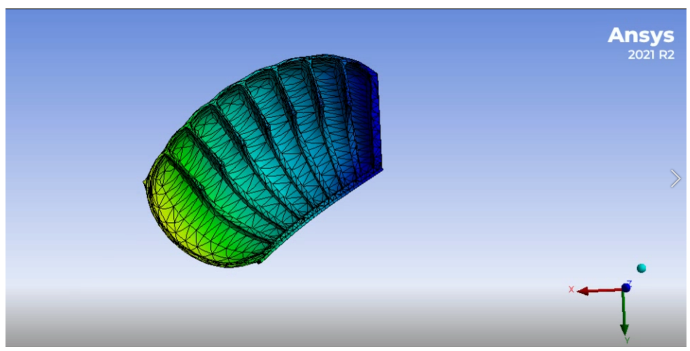


Figure 3.13: Cut-out of individual bending module at 20 percent working pressure. The cut-out makes it easy to visualize the inner features of the actuators.

The actuator was composed of two main layers, the top with the interconnected modules and a deformation limiting layer at the bottom, the first being the deformable part and the second being the rigid part. The design deviates from traditional PneuNets actuators in that they don't rely on the collisions between inner cells to form a bending motion. This actuator design is composed of simply one uniform body with expansion limiting "ribs" along the inside of it while maintaining a large central channel for the travel of fluids. When the actuator is internally pressurized by an air channel located in the middle of the structure, the deformable part grows while the rigid part stays, causing the actuator to bend. The geometry of the actuator was defined considering that the width and height affect its range of movement during the flexion and extension of the fingers, also thinking that it should not be very voluptuous in its entirety, considering the comfort of the patient. The internal "ribs" actuators where added to also add direction to the expansion to ensure that it upper layer extends along the length of the actuator and not laterally. The technical drawing and CAD of the middle finger actuator are in appendix F.1 and F.2 . Here the three groups of cells distributed along with the actuator are shown, as well as the channel that connects them, which is where the water flows pressurizing the actuator to bend it.

The simulation section will be displayed in the results chapter since the focus of this work is in the final design of the prototype and the simulation serves as the proof of concept for the final design and is the result of or design methodology.

3.3.7.3 Soft Actuator Manufacture

To elaborate the actuator, a two-part mold was created using prototyping techniques and a 3D printer. Both parts of the mold are shown in figure n, and the technical drawing of the upper and lower part are in appendix F.3 and F.4. For the elaboration of the actuators, two different materials were tested: Dragon Skin 30 and Eco flex 00-33. Eco flex 00-33 proved to be ideal for a bevy of reasons. The Eco flex material was a lot less dense and therefore required much less pressure to enact a bending motion when compared to the Dragon Skin 30 elastomer. The chosen material also proved to be much easier to degas in the vacuum chamber and the Eco Flex 00-33 has an anti fungal agent that can be very important for proper hygiene since the device is going to be in constant contact with hospital patients. It is crucial that when the material is subjected to stress it can be deformed several times and return to its natural shape without breaking or cracking The Eco flex 00-33 silicone was used by mixing equal proportions of activator and silicone for five minutes in a beaker. The mixture was then put in a vacuum for a degassing procedure (see Figure 3.14), ensuring that the elastomer had no trapped air bubbles that could create failure points when put under pressure. The mix was poured into the molds and kept stable for four hours to cure the elastomer.

A third mold serving as the base of the actuator was made in the form of a thin layer, then half-filled with the same silicone mixture. When assembling both parts, it is necessary to place a sheet of paper the same size as the actuator between the body and the base. The paper acted as the inextensible layer of the actuator, restricting the extension along its main axis. By repeating the manufacturing steps, five actuators were manufactured.

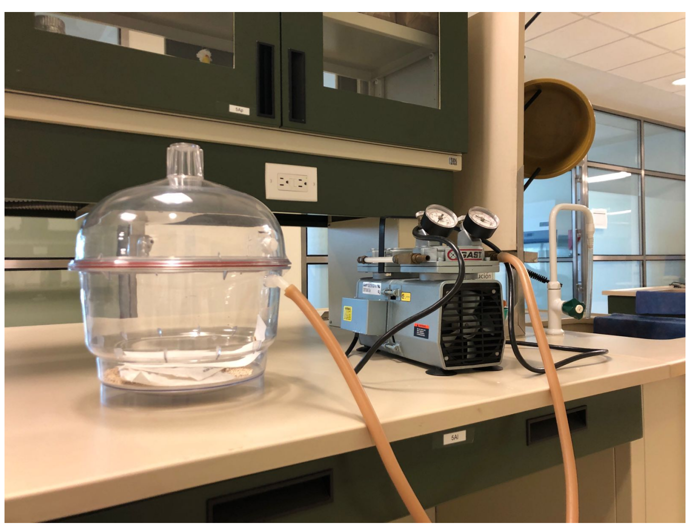


Figure 3.14: Adapted vacuum cabin

3.4 Resources

During the development of this project, a wide variety of components, both hardware, and software, were used. All physical components are listed in the ”Economic Analysis” section 3.5. Testing each element separately before putting it all together in the system was important since throughout the development some materials that did not meet the needs of the project were changed. The elements not mentioned in the economic analysis and that are part of the resources used are the following:

- Computer with SolidWorks software to model the molds for the actuators.
- Ansys software to simulate the actuators.
- A vacuum chamber that will serve to remove the bubbles created while mixing the elastomer.
- Visual Studio Code to write and run the codes for classifiers, functions, etc.
- Programming libraries used to write code.

The Visual Studio Core software is free to download, Solid Works and Ansys Software need licenses to work, but they were provided by the Monterrey Institute of Technology and Higher Education. The computers used in the project were the personal computers of the team members. The vacuum chamber used in the project was an adaptation proposed by the Academic Laboratorian Luis Javier Melgoza Ramírez of the Monterrey Institute of Technology and Higher Education. The libraries used are open-source libraries:

- Pyomyo library
- Pandas
- Tensorflow
- Keras Tuner

Regarding human resources, the work of each member of the team was fundamental for the good development of the project, in addition to the excellent guidance represented by the project advisors.

3.5 Economic Analysis

Table 3.2, shows the necessary components for the manufacture and assembly of the orthosis and actuation system. Most of the materials prices are within a reasonable range. It is important to mentioned that not all of the materials were bought as new for this project. The step motors, rods and hose were acquired from a recycled mechanics project.

Table 3.2: Cost of Materials

Material	Price (pesos)
Ecoflex 00-33 (elastomere)	\$700
Thermoplastic filament	\$500
Syringes (60 ml, 10 pc)	\$150
Step Motor (US-17HS4401, 4 pc)	\$3,000
PVC hose (1/4 inch, 1m)	\$10
Metal rod (18 in length, 0.5 in width, 1 pc)	\$5
Neoprene fabric (1m)	\$316
Wristband	\$90

In contrast, Table 3.3, accounts for the listed prices of used equipment. Although this table shows an approximation of the prices of acquiring these equipment, some of them may be replaced by other devices. The 3D Printer may be bought as new equipment or payed as a service in specialized locations, it can also be a free service depending on the available resources of the sponsoring institution of the project. Furthermore, the Myo Armband is not for sale anymore, but it can be found at some websites or borrowed from biomechanics' labs. Finally, although an industrial vacuum chamber can result in better quality for actuators, the chamber could be constructed by simpler components and put into work, as it was done for this project.

Table 3.3: Cost of Equipment

Equipment	Price (pesos)
3D printer	\$1.50 per min
Myo Armband	\$4,200
Vacuum Chamber	\$6,000

Chapter 4

Results

4.1 Project Results

4.1.1 Database structure and EMG signals

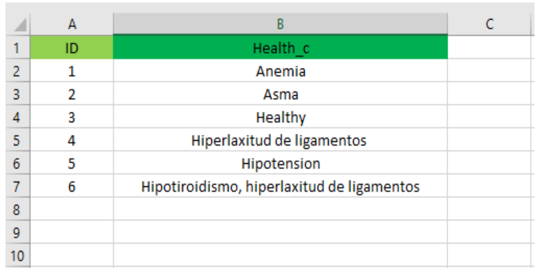
A total of 50 people participated in the acquisition of data, each of whom performed five different exercises: flexion and extension of the fingers, abduction from rest, abduction from extension, and rest, obtaining a total of 250 samples. The database was created following a relational structure (see Fig 4.3). An ID was assigned to each participant, with the aim of not being able to identify them by name, and a unique ID was assigned to identify non-numeric values in the categories of ”GENDER, HEALTHC, EX, TYPEF, and HANDS”, to obtain better data consistency. The database diagram is in Figure n. In the Fig.4.1 , the main excel sheet with the first 20 participants is presented. For each column with a non-numeric value, a new sheet was created where the ID was assigned to each characteristic. Figure 4.2 shows the sheet corresponding to the ”HEALTH” sheet.

N_P	age	GENDER	HEALTH_C	EX	TYPE_F	HAND_L	HAND_W	HAND_S	INF_C
1	23	1	3	1	1	18.1	9	1	/folders/1bqe0pqicH1uGTeXf1QZDE8HyHdmvaDQm
2	23	1	3	0	2	16.6	9	2	/folders/1bqe0pqicH1uGTeXf1QZDE8HyHdmvaDQm
3	26	2	3	2	4	19.6	10.5	1	/folders/1bqe0pqicH1uGTeXf1QZDE8HyHdmvaDQm
4	17	2	3	0	3	19.5	10	1	/folders/1bqe0pqicH1uGTeXf1QZDE8HyHdmvaDQm
5	16	1	3	0	3	17.5	9	3	/folders/1bqe0pqicH1uGTeXf1QZDE8HyHdmvaDQm
6	15	1	3	0	3	16.7	8.6	3	/folders/1bqe0pqicH1uGTeXf1QZDE8HyHdmvaDQm
7	22	2	3	1	3	18.5	10.5	1	/folders/1bqe0pqicH1uGTeXf1QZDE8HyHdmvaDQm
8	20	2	3	1	3	18.9	10	3	/folders/1bqe0pqicH1uGTeXf1QZDE8HyHdmvaDQm
9	21	2	3	1	3	18.7	9.5	3	/folders/1bqe0pqicH1uGTeXf1QZDE8HyHdmvaDQm
10	22	1	3	2	3	16.5	9	2	/folders/1bqe0pqicH1uGTeXf1QZDE8HyHdmvaDQm
11	20	2	3	2	3	17.5	10	3	/folders/1bqe0pqicH1uGTeXf1QZDE8HyHdmvaDQm
12	23	2	3	0	3	19	10.5	1	/folders/1bqe0pqicH1uGTeXf1QZDE8HyHdmvaDQm
13	23	2	3	2	4	19.6	10.7	1	/folders/1bqe0pqicH1uGTeXf1QZDE8HyHdmvaDQm
14	22	1	2	2	3	18.7	9	1	/folders/1bqe0pqicH1uGTeXf1QZDE8HyHdmvaDQm
15	24	1	2	2	3	19	9.2	1	/folders/1bqe0pqicH1uGTeXf1QZDE8HyHdmvaDQm
16	23	1	3	0	3	19.7	8.9	1	/folders/1bqe0pqicH1uGTeXf1QZDE8HyHdmvaDQm
17	22	2	3	0	3	18.2	8.9	2	/folders/1bqe0pqicH1uGTeXf1QZDE8HyHdmvaDQm
18	24	1	3	0	3	16.7	7.9	2	/folders/1bqe0pqicH1uGTeXf1QZDE8HyHdmvaDQm
20	22	1	3	1	3	17.3	8.7	3	/folders/1bqe0pqicH1uGTeXf1QZDE8HyHdmvaDQm

C_P | Gender | Health | Type_F | Hand_s | Pruebas

Figure 4.1: Principal data base

The recorded signals were saved to a CSV file. An example of a fast bending signal is seen in Graph n.



	A	B	C
1	ID	Health_c	
2	1	Anemia	
3	2	Asma	
4	3	Healthy	
5	4	Hiperlaxitud de ligamentos	
6	5	Hipotension	
7	6	Hipotiroidismo, hiperlaxitud de ligamentos	
8			
9			
10			

Figure 4.2: Health foreign key sheet

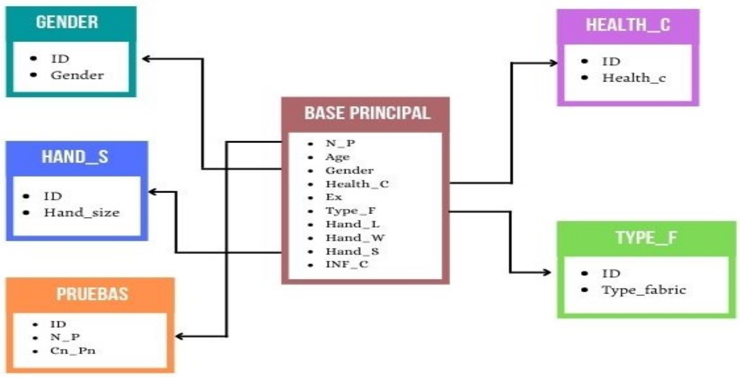


Figure 4.3: Data base diagram

4.1.2 Neural Network

To get the best hyperparameters for the two neural networks a hyperband model was run two different times. The results after compiling the algorithms are in Table 4.1 and 4.2. The learning rate can be considered higher than usual since the normal range value for a neural network is between 0.001 and 0.0001. However, since the database is small, it is necessary to work with an aggressive learning rate.

Table 4.1: Hyperparameters obtained by the hyperband model for the position neural network.

Hyperparameter	Value
Number of units for the first dense layer	1136
Number of units for the second dense layer	36
Learning rate	0.01

Table 4.2: Hyperparameters obtained by the hyperband model for the speed neural network.

Hyperparameter	Value
Number of units for the first dense layer	356
Learning rate	0.03

Once the hyperparameters were obtained, the neural networks were created. Both neural networks works as a multi-class classification since there are more than two options to decide for each input. They follow the same architecture, with the difference that the position have two hidden layers and the network for speed have just one.The deep learning code stars setting up the network configuration, here the libraries are imported, the file with the data to train the network is read, the input and output values are defined, and the values are normalized.

The position neural network structure has a total of four layers: two hidden layers, a drop layer, and an output layer. The first hidden layer has 1138 neurons, value obtained by the hyperband model, an input shape value of eight due to the eight Myoband electrodes, and a ”ReLu” function as the activation function. The second layer has 36 neurons that work with the activation function of ReLU. For the output layer, the number of neurons has to be the number of outputs the network has, which quantity is five neurons since the movement can only be classified as flexion, extension, abduction one, abduction two, or repose. The softmax function was selected as the activation of the output. This function is typically used at the end of a multiclass classification network because it translates the numbers into a probability distribution. Between the second hidden layer and the output layer is a ”dropout” layer with an assigned value of 0.2. A dropout layer works by preventing overfeeding of the neural network by changing the value of 20 percent of the data to zero automatically, this is especially recommended when the database is small. To compile the model, the loss function was the sparse categorical cross-entropy. The loss function tells us how far the model is from the correct answer. To optimize it, the value of the learning rate obtained by the hyperband function was 0.01. And finally, sparse categorical accuracy was used to find out how well the model classifies the data.

Figure 4.4 shows the graph of the epoch sparse categorical accuracy that the neural network obtains during position categorization training. A clear increase in precision is observed, to finally begin to regularize at epoch 60, for this network the number of epochs was 64. The orange line shows us how good it is at categorizing the data with which it has been trained, while that the blue line shows us how good it is to categorize the new data.The result of the first neural network was the model ”PoseData.h5” which recognize and categorize hand poses with four different labels (flexion, extension, abduction and rest) obtaining an accuracy of 81.16 percent (see Fig.4.5). The complete code of the neural network for position categorize is in appendix G.1. The neural network structure is shown in appendix G.2.

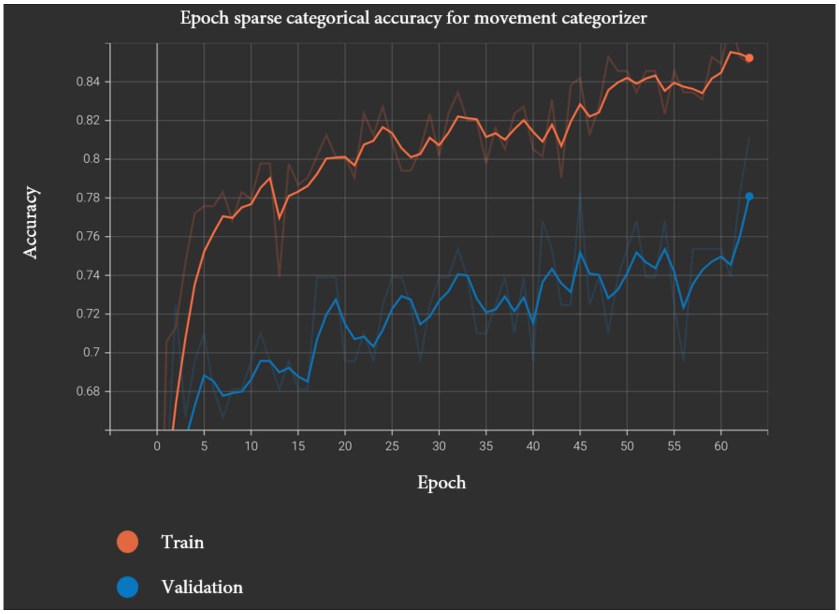


Figure 4.4: Epoch sparse categorical accuracy for movement categorize

```
modelo.save('PoseData.h5')  #guarda el modelo con ese nombre
newModel = tf.keras.models.load_model('PoseData.h5')  #llamo el modelo
loss, acc = newModel.evaluate(x_test, y_test, verbose=2)
print('Restored model, accuracy: {:5.2f}%'.format(100 * acc))

3/3 - 0s - loss: 0.5905 - sparse_categorical_accuracy: 0.8116 - 121ms/epoch - 40ms/step
Restored model, accuracy: 81.16%
```

Figure 4.5: Results of position neural network

The second neural network was designed with a single hidden layer with 356 neurons, this was the best value according to the hyperband function. It also has a dropout layer with a value of 0.2 and an output layer with three neurons indicating that only have three speed options (slow, medium, and fast). The neural network structure is shown in appendix G.4. The Epoch sparse categorical accuracy graph (Figure 4.6) shows us that throughout the training a better precision is achieved than in the first neural network. This may be due to the fact that the amount of data in the second base is less than in the first base. The neural network creates the model ”fastTypeModel.h5” that recognizes and categorizes the speed at which the movements were performed obtaining an accuracy of 90.62 percent. (see Fig.4.7). The complete code of the neural network for position categorize is in appendix G.3.

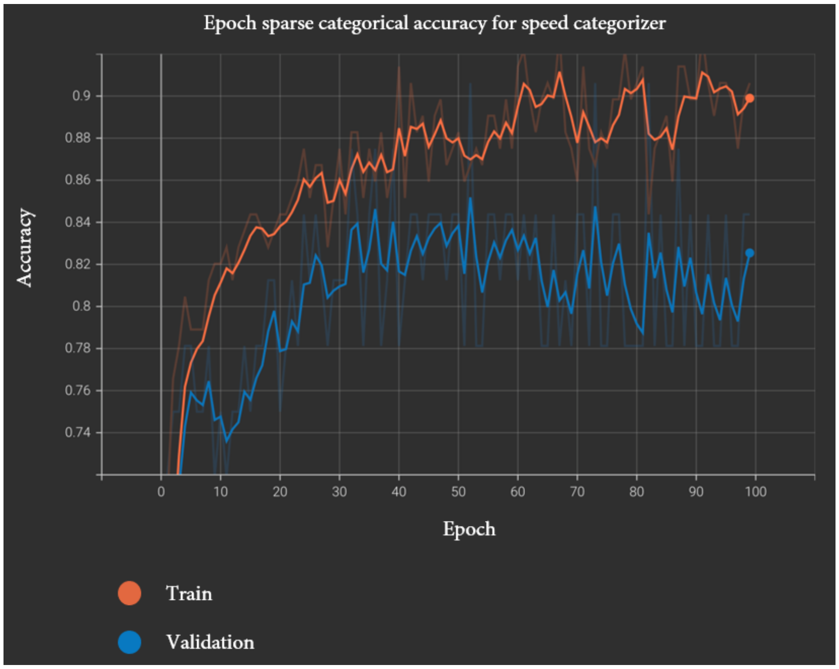


Figure 4.6: Epoch sparse categorical accuracy for speed categorize

```
modelo.save('fastTypeModel.h5')  #guarda el modelo con ese nombre
newModel = tf.keras.models.load_model('fastTypeModel.h5')  #llamo el modelo
loss, acc = newModel.evaluate(x_test, y_test, verbose=2)
print('Restored model, accuracy: {:5.2f}%'.format(100 * acc))

1/1 - 0s - loss: 0.3150 - sparse_categorical_accuracy: 0.9062 - 119ms/epoch - 119ms/step
Restored model, accuracy: 90.62%
```

Figure 4.7: Results of speed neural network

Both networks work together within a deep learning algorithm in charge of recording, processing and categorizing the movements of the hand made in real time using the Myoband.

4.1.3 Actuation System

The chosen actuation system for this application was capable of delivering 30 kPa of pressure to the soft robotics actuators to achieve a full bending motion. Using the aforementioned rpimotorlib software library we were able to develop a movement system with unparalleled pressure control resolution, as well as a variable speed and acceleration profile for each type of movement. The frame, being made of high quality PLA at a 0.16 mm layer quality and 20 percent material infill was capable of withstanding the force interactions between the motor, the syringe, and the traveller block. The pushing block and the frame both were both able to withstand the shear forces exerted upon it by the motor's efforts in moving against the increasing pressure of the system. This actuation system provides a large advantage over conventional methods of soft robotics actuators since those rely on relatively imprecise compression delivery systems which have difficulty delivering exact volumes of fluid and require additional sensors to ensure accurate motion.

4.1.4 Soft Robotic Actuators

The designed soft robotics actuators were able bend while following a trajectory that resembles that of a human human. The three bending modules performed as intended and they accomplished the goal of granting a dynamic and organic motion trajectory. The maximum deformation present within the body of the actuator is at the tip of the actuator and it is equal to 645 percent deformed from its original size which is well below the maximum value of 900 percent elongation that can be experienced by this material.

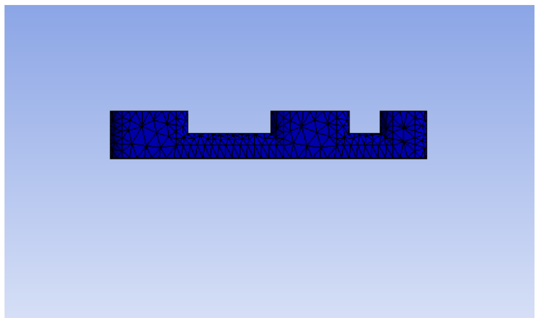


Figure 4.8: Pose of the actuator at 0 percent of working pressure

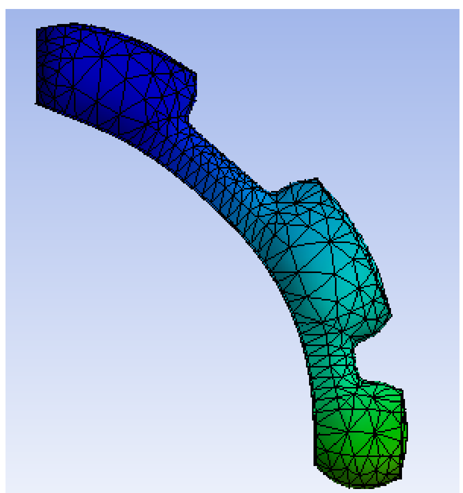


Figure 4.9: Pose of the actuator at 50 percent of working pressure

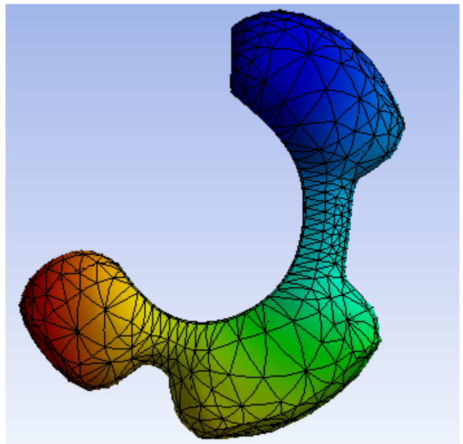


Figure 4.10: Pose of the actuator at 100 percent of working pressure

The lateral expansion of the actuator, which is also important given that lateral expansion can come to interfere with the successful operation of the device, is 5 millimeters to either side of the actuator which, while not ideal, is definitely in a range where the design is still viable. This device achieves a bending angle above that required by the human hand in the simulation which points to the fact that the actuator can be subjected to less pressure to achieve the desired results.

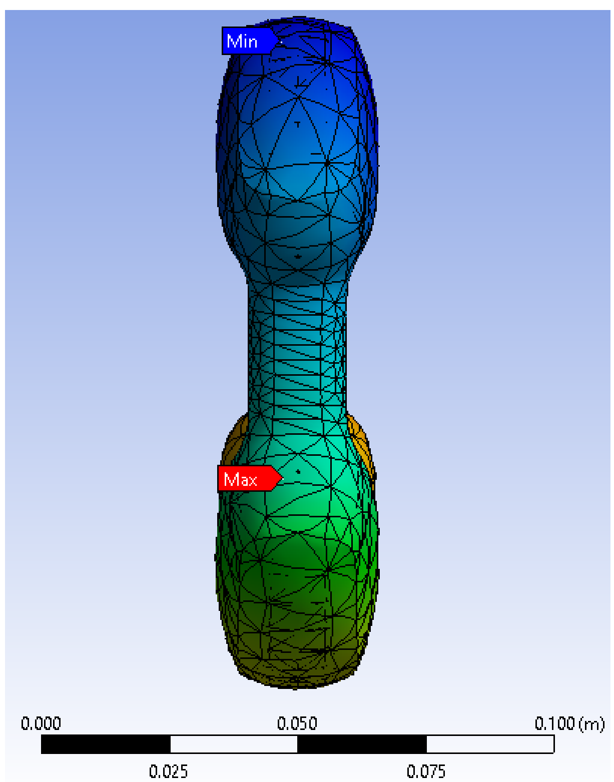


Figure 4.11: Lateral expansion at 100 percent of working pressure

Chapter 5

Considerations and Forthcoming

5.1 Ethical Dilemma

Ethical dilemmas in the development of medical technologies must be taken into account since the beginning of its design proposal. The safety of patients and users is a priority to be considered in the process of decision-making every step of the way. Mindful of this priority, some of the problems that could arise during the designing and creation of the soft robotics orthosis are the following. First, the process of project documentation must thoroughly comply with all of the rules, regulations, and standards that must be met within the scope of health technologies. Fulfilling all requirements gives way to the approval of health organizations and product reliability. Secondly, for the testing of the device, clinical protocols must be drawn up with consideration of the patient's rights and integrity, these must be reviewed by an ethics board as well. Finally, it is necessary to convey the idea of the device as an assistance and not a replacement of medical staff. The respective credit must be attributed to the knowledge and work of the healthcare personnel, in hand with the statement that the device is beneficial for treatment and resource saving.

5.2 Future Work

The report of this project accounts for the design and early assembly process of the physical system. Important results of our project such as the creation of a database, neural network classification of movements with a high accuracy value and functional actuator design are the completed stages of this process which covered the majority of our objectives and will not be changed any further until achieving the completion of other relevant characteristics of our proposed solution.

First of all, several testing analysis should be done once the assembly of the actuation system is completed, since this a system base on hydraulic energy it would be of worth to prove if it has advantages over a pneumatic system. This comparison will likely be made by measurements of pressure and range of motion from the actuators in order to assess the functionality of air over fluids. In addition, the evaluation of these systems will lead to a solution of the velocity profiles, which one is the most precise and simple to use in order to achieve a live imitation of velocity from the master to the slave hand.

In regard to the clinical aspect of the orthosis, it would be of great support for the physicians and future users of the device to have an interface through which they can observe the behavior of the EMG acquisition, the predictions of the network each time the patient performs a movement, and parameters of the actuators performance such as pressure and angular position trajectory so the medical staff can evaluate the progress of the physical therapy on the patient's hand.

Finally, the property of the actuators being able to perform abduction movements will have to be explored further, in terms of the soft actuator design and testing. Furthermore, the database could increase in its amount of data in order to improve prediction for abduction movements.

Chapter 6

Conclusions

Throughout the development of the project, which aims to build a portable soft robotic device for motor assistance during hand therapy, the team faced several situations that changed the routes taken to achieve the final goal. The proposed solution presented in the document was achieved almost in its totality.

First, it was possible to adapt the Myo armband to capture the electromyographic signals according to the needs of the project, which allowed the generation of the database for the subsequent processing and categorization of the movements. The resulting models of the neural networks obtained an accuracy percentage of 81 and 90.62, obtaining these results using small databases demonstrates the quality of the data collection and preprocessing process, as well as the high capacity of the members to develop a deep learning algorithm. The development of the hydraulic system was one of the biggest challenges the team faced. Initially, the plan was to use a pneumatic system to drive the actuators. However, while the team explored the idea, two important points emerged: the required solenoids are not sold in Mexico City, and trying to buy them resulted in an extremely high price.

Second, the solenoids did not provide good precision for glove control, as they did not allow the airflow patterns to vary, causing the actuators to always move at the same speed no matter the control signal sent. With both points against it, the team decided to switch to a hydraulic system, as it was cheaper and allowed the filling speed to vary on the actuators. One of the challenges presented with the change of the system was the syringes used that displaces water in and out of the actuators, as commercial syringes do not provide enough pressure to achieve the required movement of the actuators. The most significant challenge to overcome was the design and elaboration of the soft actuators. It began with a simple design inspired by the pneumatic actuators proposed in Harvard University Polygerinos et al.'s work, but one of the objectives was to provide the glove with movement similar to the flexing of human fingers, so the design of the cells needed to be changed. After performing extensive simulations with different options, the chosen one was an actuator divided into three parts for the fingers from the little finger to the index finger and two for the thumb. With this, it was possible to obtain a movement more according to the biological one. The elastomer with which the first iterations were produced significantly delayed the progress of the project, since it had characteristics such as a very high density, which made it very difficult to remove the oxygen inside it, resulting in an actuator with large bubbles that exploded when pressurized. For the last iterations, the silicon was changed to EcoFlex 00-33, which resulted in a positive change for the elaboration of the actuators. However, the objectives were achieved almost in their entirety, which gives us the motivation to continue working and accomplish each of them.

The project was developed by students of Mechatronics Engineering and Biomedical Engineering, which give the opportunity to learn and get to know the areas in which each career is developed. Working in a hybrid team has allowed us to analyze the actual solutions on the market and try to improve them from different points of view, covering more areas of opportunity. As biomedical students, we have the ability to analyze the proposed solutions with the user of the device in mind, as well as the ergonomics and quality of the engineering design, in addition to having knowledge about the regularization processes and safety standards in the creation of medical devices. As mechatronics, we have the knowledge to create state-of-the-art robotic systems that work efficiently and meet quality standards.

Appendix A

Research Data Planning

Research Data Planning

Hypothesis
If we register and collect data, through an electromyographic armband, with eight electrodes, of different movements of the fingers then, each of the eight channels will present different amplitudes in their signal allowing for a distinction between movements and their classification because, each electrode, in regard to their location at the forearm, reads the signal transmission from the nerve that activates each of the muscles involved in the action.

Primary outcome measurement
EMG signal amplitude which transfers into muscle activation.

Secondary outcome measurement
Time; initial and final time period of signal acquisition.

Definition of variables

1) **EMG signal amplitude**
   a) **Data type:** Continuous
   b) **Representative number:** signal acquired through ADC, in the format of bits.
   c) **Measuring units:**
2) **Time**
   a) **Data type:** Continuous
   b) **Representative number:** number of samples, according to sampling frequency and sampling time.
   c) **Measuring units:** s

Set of confounding factors

1) Age
2) Gender
3) Health condition
4) Amount of exercise
5) Type of fabric (clothes)
6) Anthropometrics (Hand shape indicators):

Validated Instruments

1. Myo Armband: EMG
2. Ruler: Anthropometrics

Data Collection Modality
The EMG signal is considered to be a physiological measurement, its structure is complex as being machine-captured data. This will be stored as raw continuous data in a .csv file with sampled values separated by columns according to the channel in the armband. Confounding factors being nominal data will be considered structured data and collected in a report form on Microsoft Excel. Data will be collected face to face and the data entry will be made by the study personnel.

Identification of Confidential Fields in Dataset
According to HIPAA, the data for this research study is considered to be “Research Health Information” hence, not to be considered as applicable to HIPAA identifiers, since it is not

being derived from a healthcare service event. Nevertheless, the scope of this research considers not including the concept “name” as a confounding factor in the collection of data.

Codebook

Categorical variables

- Amount of exercise
  - No exercise = 0
  - Occasional exercise = 1
  - Regular exercise = 2
- Type of movement
  - Flexion = 1
  - Extension = 2
  - Abduction from resting position = 3
  - Abduction from extension = 4
  - Resting position = 5
- Gender
  - Female= 1
  - Male = 2
- Health Condition
  - Anemia=1
  - Asma= 2
  - Healthy=3
  - Ligament Hyperlaxity=4
  - Hypotension=5
  - Ligament hyperlaxity, hypothyroidism=6
- Type of Fabric
  - Mix=1
  - ALG/ACR=2
  - ALG=3
  - Licra=4
  - Viscosa=5
- Hand size
  - Large= 1
  - Small=2
  - Medium=3

Appendix B

Standard Operational Procedure

Title: **Acquisition of electromyographic data during performance of motor skills**	Version Number: <1>	Effective Date: **<26/05/22>**	Page 1 of 3

1 Purpose

Through a number of voluntary subjects, we are conducting a collection of electromyographic data for the purpose of constructing a reliable data base that could then be fed into a neural network that will work to control a soft exoskeleton for finger rehabilitation.

2 Scope and Responsibilities

2.1 Scope:

2.1.1 The intent of this SOP is to:

- Ensure a standard and effective protocol for data registration of voluntary subjects.
- Guarantee a safe environment for research subjects by applying bioethical considerations to the research. According to “Ley General de la Salud” in Mexico, this would be: dignity, human right’s protection and welfare.
- Appeal to human subjects protection regulations, even if research study data is identified as “Research health information” by HIPAA identifiers.

2.1.2 The acquisition of electromyographic signals will be carried out by the use of the Myo Armband, composed of eight electrodes.

2.2 Responsibilities

- Project members will divide one of the following tasks:
  - Registration of demographic information into the database, including hand measurements and the presentation of the informed consent form.
  - Positioning of myoband in forearm, registration of EMG data of five different movements: flexion, extension, abduction, abduction from extension and resting position.

3 Definitions/Acronyms

3.1 Definitions:

a. Myoband: Wearable device by Thalmic Labs Inc. provided with eight electromyographic electrodes (Visconti et al., 2018).

3.2 Acronyms:

a. EMG-electromyography

4 Procedures

4.1 Ask the study subject if he/she wants to participate in the research study by talking about the purpose, the scope and the security of their data if they agree to take part in the project. Mentioned that they will have to sign an informed consent form for the purpose of data protection and their agreement that the characteristics of the study have been explained to them by members of the project.

4.2 Fill out the report form by asking the study subjects, in a polite manner, about their age, gender, health condition and type of fabric of clothes. For the values of hand measurements, ask for their hand and explain the process of measuring their hand. Place the ruler over the anterior surface of their hand. Following a longitudinal axis in the middle, place its beginning at the skin line defining the wrist and measure the centimeters up until the far end of the middle finger, this will be the length of the hand. Subsequently, place the ruler on a horizontal axis beginning from the lateral surface of the thumb and measuring up to the end of the palm, this will be the width of the hand. According to the anthropometrics average for students under the ages of 15 to 24, rate if the hand of the subjects is defined as small, medium or large.

4.3 Place the myoband at the right forearm of the subject. The band needs to be set in place so that the main electrode (the LED electrode) is facing the anterior side of the arm. The armband shouldn't be uncomfortable for the person but it should allow for clean contact between skin and band. Once set in place, explain the different movements of flexion, extension and abduction that they will be doing during signal acquisition. Remember to specify the velocity and force that the movement should undertake. Tell the subject when to start and stop the movement, and finally, ask them to repeat it if the quality of the signal was low.

5 References

[1] López-Pacheco, MC, Pimentel-Hernández, C, Rivas-Mirelles, E, & Arredondo-García, JL. (2016). Normatividad que rige la investigación clínica en seres humanos y requisitos que debe cumplir un centro de investigación para participar en un estudio clínico en México. *Acta pediátrica de México*, *37*(3), 175-182. Recuperado en 11 de mayo de 2022, de http://www.scielo.org.mx/scielo.php?script=sci_arttext&pid=S0186-23912016000300175&lng=es&tlng=es.

[2] Visconti, P., Gaetani, F., Zappatore, G., & Primiceri, P. (2018). Technical Features and Functionalities of Myo Armband: An Overview on Related Literature and Advanced Applications of Myoelectric Armbands Mainly Focused on Arm Prostheses. *International Journal On Smart Sensing And Intelligent Systems*, *11*(1), 1-25. https://doi.org/10.21307/ijssis-2018-005

Appendix C

Informed Consent Form

Informed Consent Form for the collection and use of electromyographic data

This informed consent form is for undergraduate students, members of the community of Tecnológico de Monterrey and who we are inviting to participate in the collection of electromyographic data, with the purpose of using it for the creation of a database for the project titled “Design of a soft exoskeleton for finger rehabilitation”.

Name of Project Members conducting ICF:
María José Arellano Colombres
Ingrid Genis Álvarez

Name of Project:
Design of Soft Exoskeleton for Finger Rehabilitation

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the study with you)**
- **Certificate of Consent (for signatures if you choose to participate)**

Part I: Information Sheet

Introduction

This project is being developed by three members, all undergraduate students of Tecnológico de Monterrey studying the careers of biomedical engineering and mechatronic engineering and two professional advisors. The project is being made as part of the academic plan of our undergraduate studies. Through a number of voluntary subjects, we are conducting a collection of electromyographic data for the purpose of constructing a reliable data base that could then be fed into a neural network that will work to control a soft exoskeleton for finger rehabilitation. This consent form may contain words that you do not understand. Please feel free to ask any questions as the registration of data is taking place.

Purpose of the research

This project focuses on the creation of an orthosis that assists the movement of the hand during motor therapy as part of a rehabilitation treatment. The main characteristics of this equipment consist in an ergonomic design of an exoskeleton suitable for phalanges and metacarpals, with the objective of imitating the movement of a healthy hand, whether the patient’s or the physiotherapist’s. The movement being replicated will be controlled by a neural network that detects intentional movements through an electromyographic (EMG) armband. The exoskeleton will be composed of soft actuators manipulated by a hydraulic system, according to the prediction of movements of the neural network. Our general objective is the design and development of a medical device with the purpose of assisting in the administration of physical therapy. This project will create an integrated therapy motion system that will be ergonomic, easy to use, effective, and safe.

Type of Research Intervention

This research will involve your participation in the registering of your electromyographic signals while conducting a series of indicated movements. The acquisition of signals will be conducted using an armband called “Myo band”, it has been used in the application of several projects, corroborating its safety measures and adequate structure for human use.

Participant Selection

You are being invited to take part in this research as a voluntary participant.

Voluntary Participation

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. The choice that you make will have no bearing on your job or on any work-related evaluations or reports. You may change your mind later and stop participating even if you agreed earlier.

Procedures
If you accept you will be asked to perform the following procedure:

A. Fill out a survey which will be provided and collected by members of the study research. If you do not wish to answer any of the questions included in the survey, you may skip them and move on to the next question. The information recorded is confidential, your name is not being included on the forms, only a number will identify you, and no one else except members of the project, María José Arellano and Ingrid Genis will have access to your survey.

B. The type of questions that will be asked consist of demographic data and relevant variables for the analysis of the data later on that could have an impact such as a confounding factor in the acquisition of signals.

C. The myoband will be placed at the forearm, positioned as indicated by the study members. Once the band is set in place a study member will describe the process to be conducted in order to acquire a clean and right signal. This process will consist in the performance of different movements of the fingers, such as flexion, extension, and abduction. The armband will vibrate each time the software recognizes the correct synchronization of the band with the interface and starts to record data.

Duration
The entire process will be conducted within 15 minutes, considering that the signal is clean and well read. Otherwise, we will ask the subject to stay for another 5 minutes in order to repeat the acquisition process.

Benefits
There will be no direct benefit to you, but your participation is likely to help us acquire the necessary data for the control of the exoskeleton and hence the elaboration of our orthosis protype.

Reimbursements
You will not be provided any incentive to take part in the research. However, we will give you a treat in acknowledgment for your time.

Confidentiality
We will not be sharing information about you to anyone outside of the research team. The information that we collect from this research project will be kept private. Any information about you will have a number on it instead of your name. It will only be shared as part of the final report of the project with the respective professionals that will grade the project.

Right to Refuse or Withdraw
This is a reconfirmation that participation is voluntary and includes the right to withdraw. If you feel uncomfortable talking about some of the topics, you do not have to answer any questions or take part in the survey or data collection if you feel the question(s) are too personal, if talking about them makes you uncomfortable or if the process of acquisition makes you uncomfortable too.

Who to Contact
If you have any questions, you can ask them now or later. If you wish to ask questions later, you may contact any of the following: [name, address/telephone number/e-mail]
This proposal has been reviewed and approved by Dr. Joel Hernández Hernández, professional advisor of this project.

Part II: Certificate of Consent

(This section is mandatory)
I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions have been answered to my satisfaction. I consent voluntarily to be a participant in this study.

Print Name of Participant__________________

Signature of Participant ___________________

Date ___________________________
Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

1. **Answering a brief survey.**
2. **Acquisition of electromyographic signals with Myo band.**
3. **Use of collection of data in the implementation of soft exoskeleton for finger rehabilitation projects.**

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.
Print Name of Researcher/person taking the consent : Ingrid Genis Álvarez and María José Arellano Colombres

Signature of Researcher /person taking the consent__________________________

Date ________________
Day/month/year

Appendix D

Hyperband Tuner Function

The Keras Tuner library was used with the hyperband model in order to obtain the appropriate hyperparameters for the development of the two neural networks. The structure used is from the platform ”Tensor flow”, an end-to-end open source platform for machine learning [n20].

```python

import keras_tuner as kt
import tensorflow as tf
import numpy as np
import matplotlib.pyplot as plt
import pandas as pd
from sklearn.model_selection import train_test_split
import math as mt
from sklearn.metrics import accuracy_score
from sklearn.metrics import confusion_matrix
import keras

tf.random.set_seed(42)

data=pd.read_csv('PoseData.csv')
x=data.iloc[:,[0,1,2,3,4,5,6,7]].values
y=data.iloc[:,8].values

x_train, x_test, y_train, y_test = train_test_split(x, y, test_size=0.20, random_state= 5)

x_train = x_train/1669.0
x_test = x_test/1669.0

def model_builder(hp):
  model = keras.Sequential()

  hp_units = hp.Int('units', min_value=8, max_value=1200, step=4)
  model.add(keras.layers.Dense(units=hp_units, activation='relu'))
  model.add(keras.layers.Dense(36, activation='relu'))
  model.add(keras.layers.Dropout(0.2))
  model.add(keras.layers.Dense(4, activation='softmax'))

  hp_learning_rate = hp.Choice('learning_rate', values=[1e-2, 1e-3, 2e-2, 3e-2, 4e-2])

  model.compile(optimizer=tf.keras.optimizers.Adam(learning_rate=hp_learning_rate),
                loss=keras.losses.SparseCategoricalCrossentropy(from_logits=True),
                metrics=['SparseCategoricalAccuracy'])

  return model

tuner = kt.Hyperband(model_builder,
                     objective='val_sparse_categorical_accuracy',
                     max_epochs=20,
                     factor=2,
                     directory='my_dir',
                     project_name='intro_to_kt')

stop_early = tf.keras.callbacks.EarlyStopping(monitor='val_loss', patience=10)

tuner.search(x_train, y_train, epochs=50, validation_split=0.2, callbacks=[stop_early])
best_hps=tuner.get_best_hyperparameters(num_trials=1)[0]

print(f""" The hyperparameter search is complete. The optimal number of units in the second densely-connected
layer is {best_hps.get('units')} and the optimal learning rate for the optimizer
is {best_hps.get('learning_rate')}. """)
```

Appendix E

Data Collection and Processing

The data collection and processing code is the one used to capture the movements in real time of the hand with the Myoband and send its results to a control code in charge of controlling the hybrid system and therefore, the actuators.

Both models generated by the neural networks are loaded into the code to be able to recognize the movements and their speed. With the help of the pyomyo libraries (Thalmic Developers, 2016), the electromyographic signals are recorded. The ”modelProcessing” function is responsible for capturing the Data frame and processing it in order to be recognized by the neural networks. Finally, the movement and speed label is printed.

```python
from pyomyo import Myo, emg_mode
import time
import multiprocessing
import numpy as np
import pandas as pd
import tensorflow as tf
from sklearn.model_selection import train_test_split

poseModel = tf.keras.models.load_model('PoseData.h5')
speedModel = tf.keras.models.load_model('fastTypeModel.h5')

def modelProcessing(data_frame):
    maxChannels = data_frame.max()
    newMotion = np.array(maxChannels)
    newMotion = newMotion/1669.0
    newMotion = np.expand_dims(newMotion, 0)
    dist = poseModel.predict(newMotion)
    distSpeed = speedModel.predict(newMotion)
    predLabel = np.argmax(dist)
    predLabelSpeed = np.argmax(distSpeed)
    return predLabel, predLabelSpeed

def data_worker(mode, seconds):
    collect = True

    # ------------ Myo Setup ---------------
    m = Myo(mode=mode)
    m.connect()

    myo_data = []

    def add_to_queue(emg, movement):
        myo_data.append(emg)

    m.add_emg_handler(add_to_queue)

    def print_battery(bat):
        print("Battery level:", bat)

    m.add_battery_handler(print_battery)

    # Its go time
    m.set_leds([0, 128, 0], [0, 128, 0])
    # Vibrate to know we connected okay
    m.vibrate(1)

    print("Data Worker started to collect")
    # Start collecting data.
    start_time = time.time()

    for val in range(10):
        m.vibrate(1)
        print("Collecting...")
        while collect:
            if (time.time() - start_time < seconds):
                m.run()
            else:
                collect = False
                myo_df = pd.DataFrame(myo_data)
```

```
                print("Iteration Done")
        print(myo_df)

        moveClass, myoSpeed = modelProcessing(myo_df)
        myo_data = []
        print(moveClass)
        print(myoSpeed)
        collect = True #reactiva algo
        start_time = time.time()


if __name__ == '__main__':
    seconds = 3
    mode = emg_mode.PREPROCESSED
    p = multiprocessing.Process(target=data_worker, args=(mode, seconds))
    p.start()
```

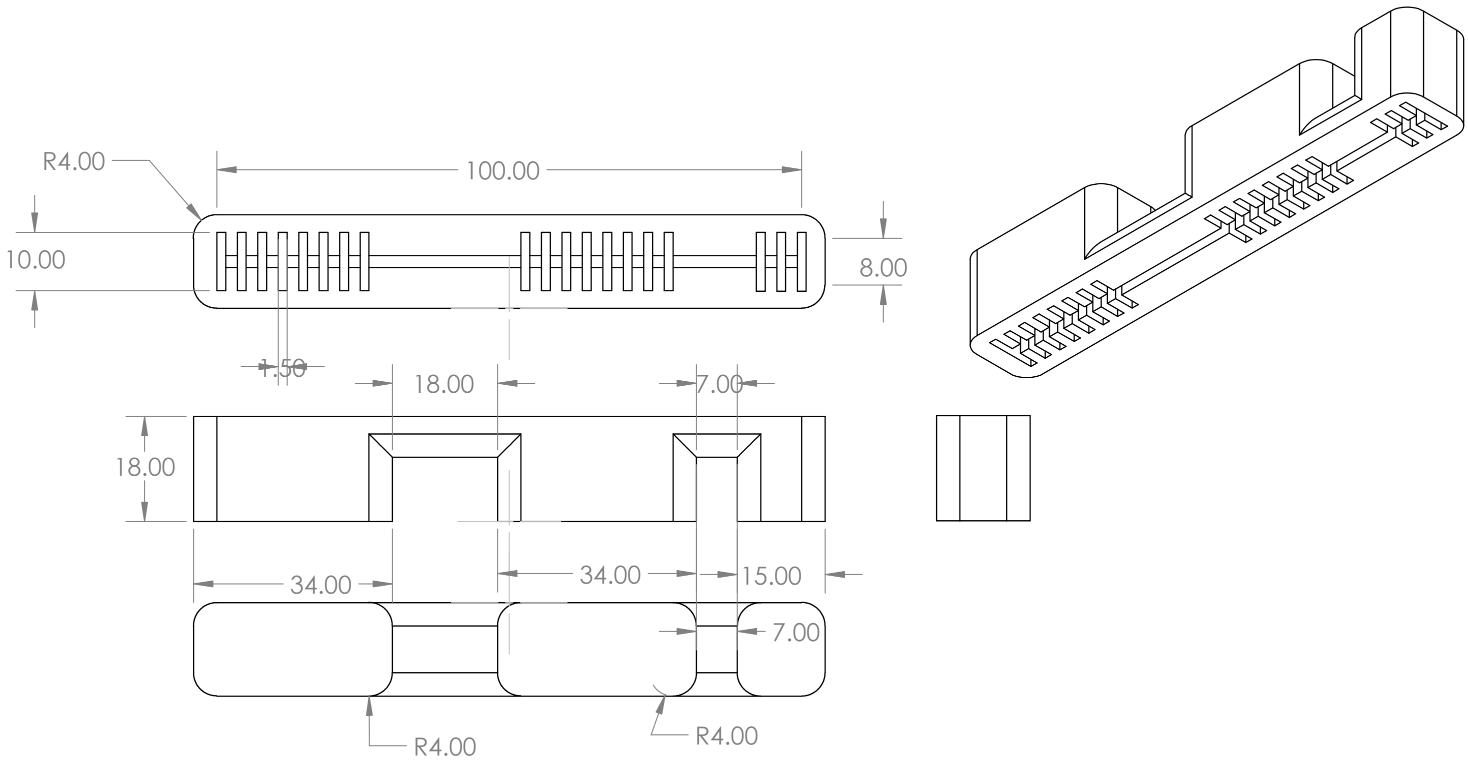
Appendix F

Soft Robotic Actuator Design

F.1 Technical drawing of the middle finger actuator

2 | 1

B



B

A

		UNLESS OTHERWISE SPECIFIED:		NAME	DATE
		DIMENSIONS ARE IN MILLIMETERS TOLERANCES: FRACTIONAL ± ANGULAR: MACH ± BEND ± TWO PLACE DECIMAL ± THREE PLACE DECIMAL ±	DRAWN		
			CHECKED		
			ENG APPR.		
			MFG APPR.		
		INTERPRET GEOMETRIC TOLERANCING PER:	Q.A.		
		MATERIAL	COMMENTS:		
NEXT ASSY	USED ON	FINISH			
APPLICATION		DO NOT SCALE DRAWING			

TITLE:

MIDDLE FINGER ACTUATOR

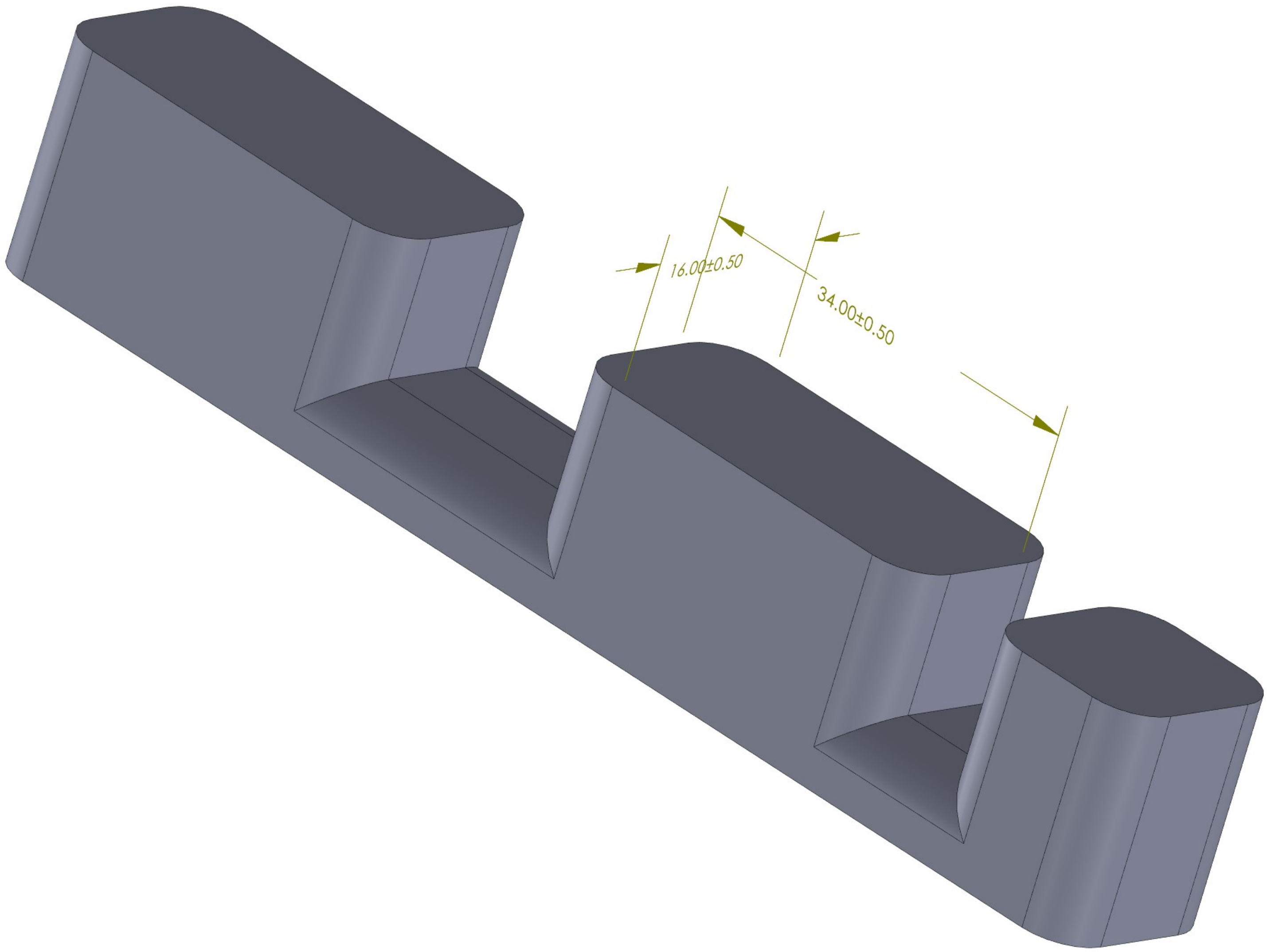
SIZE A | DWG. NO. FINAL | REV

SCALE: 1:1 | WEIGHT: | SHEET 1 OF 1

A

2 | 1

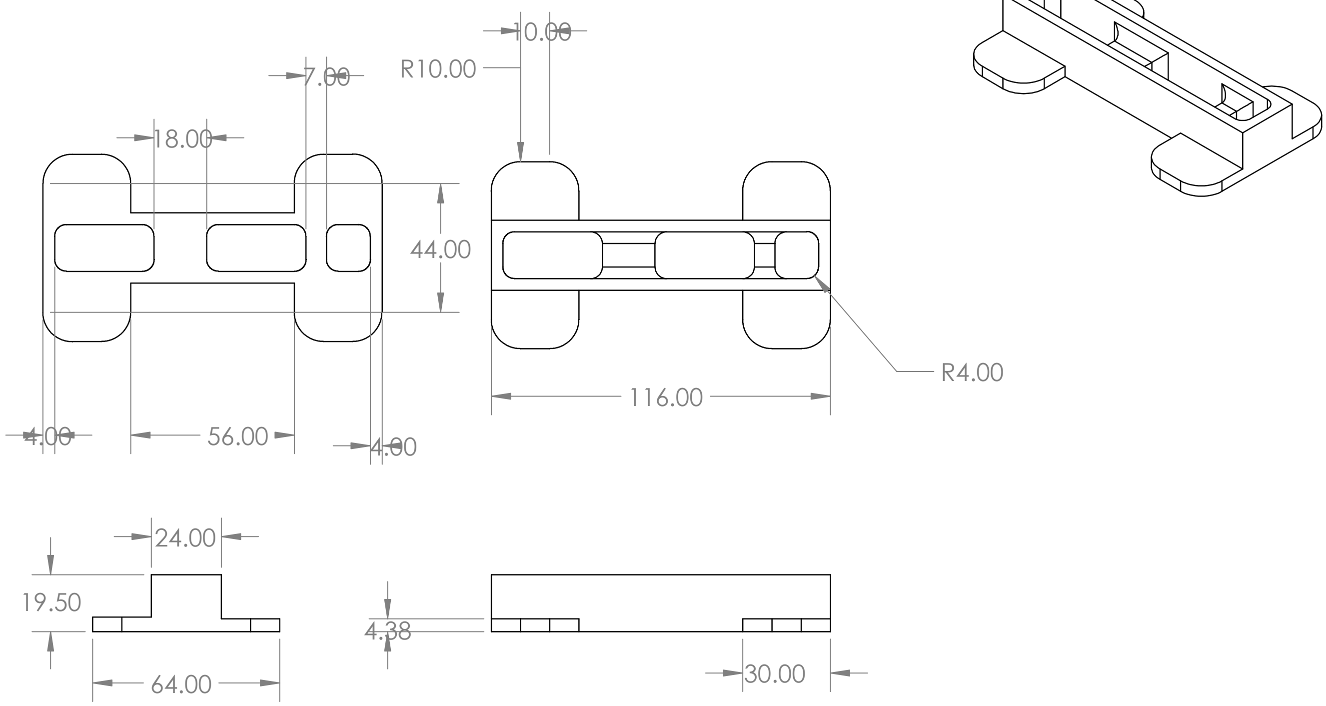
F.2 CAD of the middle finger actuator


16.00±0.50
34.00±0.50

F.3 Technical drawing of the middle finger top mold

2 1

B B



A A

PROPRIETARY AND CONFIDENTIAL

THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF <INSERT COMPANY NAME HERE>. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF <INSERT COMPANY NAME HERE> IS PROHIBITED.

NEXT ASSY	USED ON	UNLESS OTHERWISE SPECIFIED:		
APPLICATION		DIMENSIONS ARE IN MILLIMETERS TOLERANCES: FRACTIONAL ± ANGULAR: MACH ± BEND ± TWO PLACE DECIMAL ± THREE PLACE DECIMAL ±		
		INTERPRET GEOMETRIC TOLERANCING PER:		
		MATERIAL		
		FINISH		
		DO NOT SCALE DRAWING		

	NAME	DATE
DRAWN		
CHECKED		
ENG APPR.		
MFG APPR.		
Q.A.		
COMMENTS:		

TITLE:

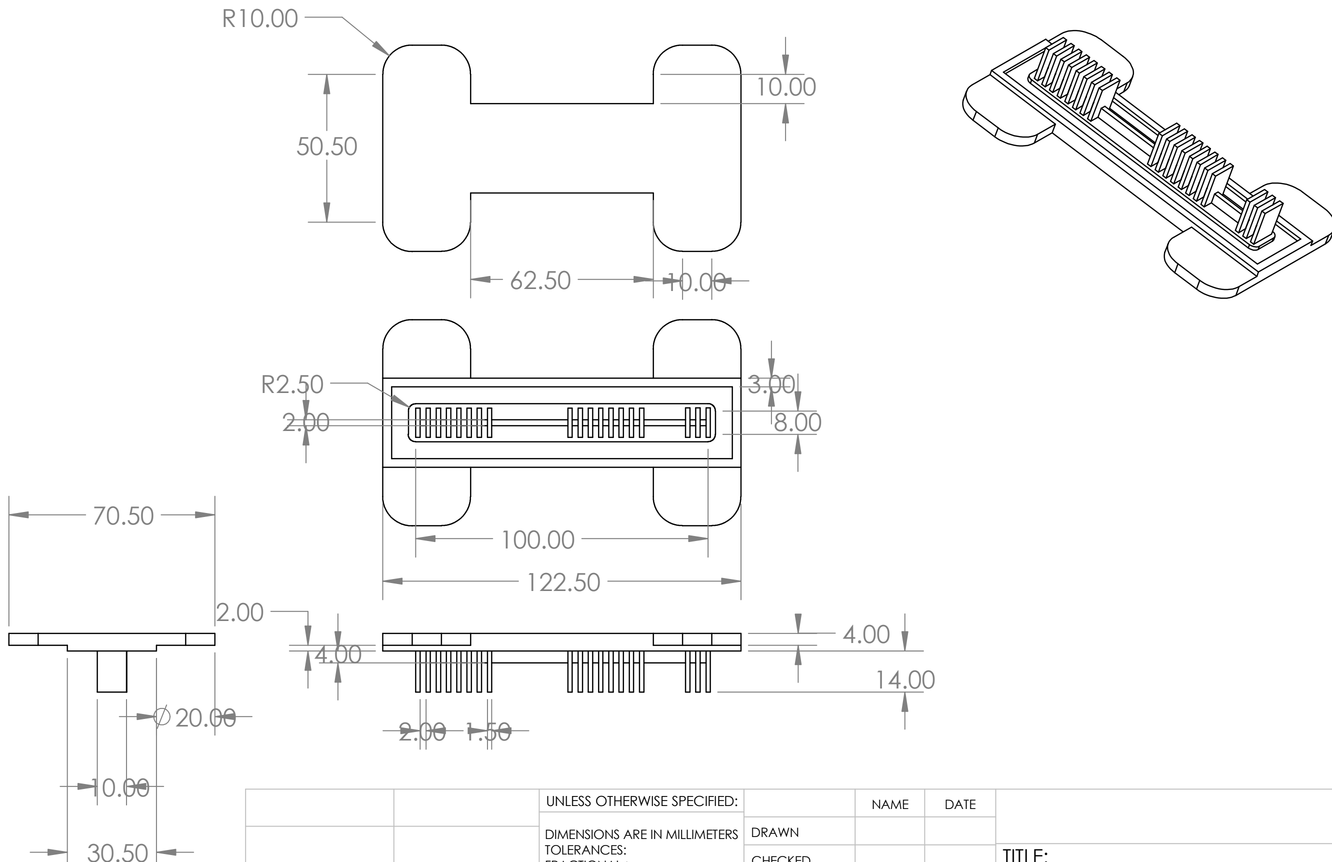
MIDDLE FINGER TOP MOLD

SIZE	DWG. NO.	REV
A	FINAL	

SCALE: 1:2 WEIGHT: SHEET 1 OF 1

2 1

F.4 Technical drawing of the middle finger bottom mold



		UNLESS OTHERWISE SPECIFIED:		NAME	DATE
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			CHECKED		
			ENG APPR.		
			MFG APPR.		
		INTERPRET GEOMETRIC TOLERANCING PER:	Q.A.		
		MATERIAL	COMMENTS:		
NEXT ASSY	USED ON	FINISH			
APPLICATION		DO NOT SCALE DRAWING			

TITLE:

MIDDLE FINGER BOTTOM MOLD

SIZE	DWG. NO.	REV
A	FINAL	

SCALE: 1:2 WEIGHT: SHEET 1 OF 1

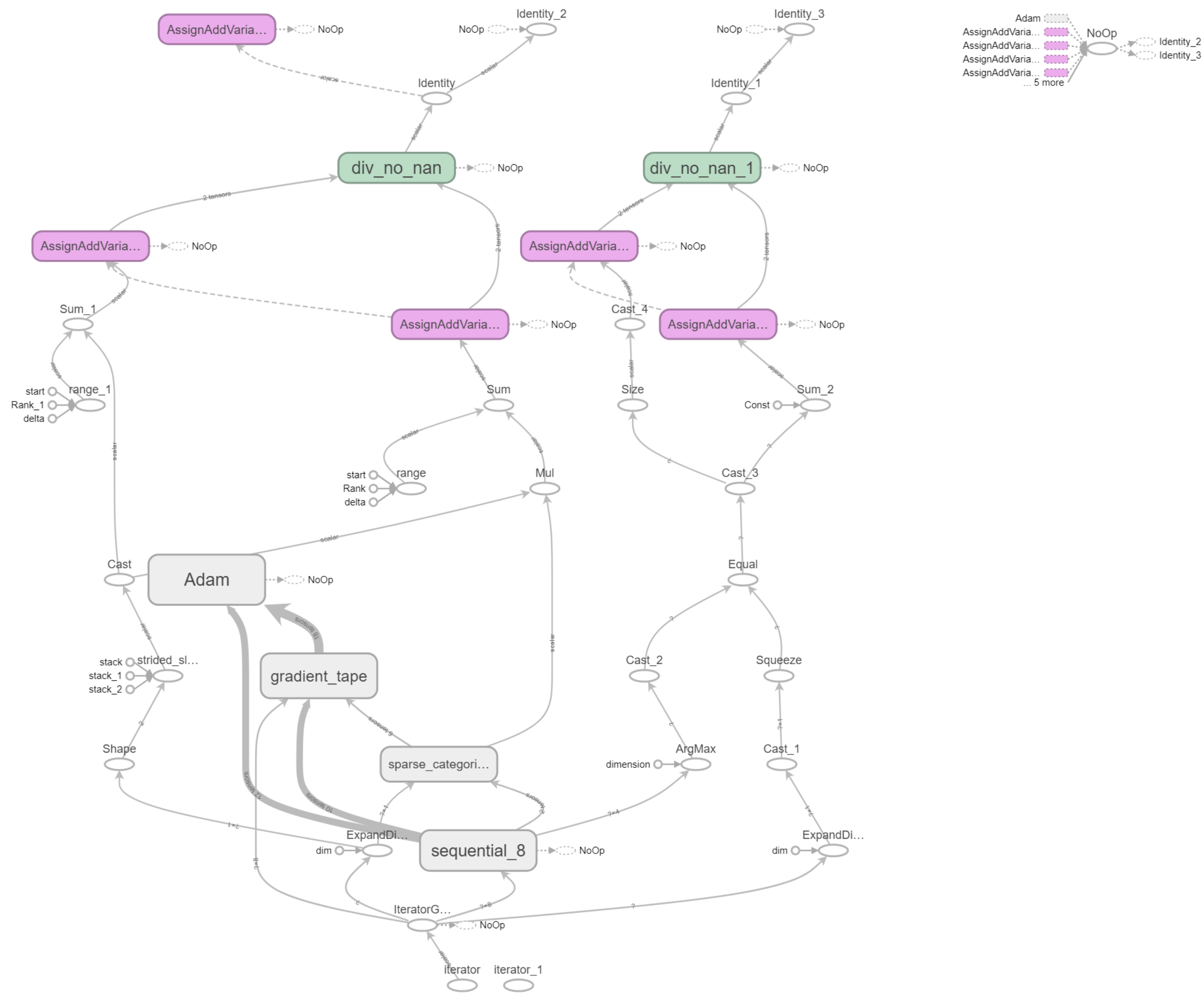
Appendix G

Neural network

G.1 Neural network for movement categorize

```python

import keras_tuner as kt
import tensorflow as tf
import numpy as np
import matplotlib.pyplot as plt
import pandas as pd
from sklearn.model_selection import train_test_split
import math as mt
from sklearn.metrics import accuracy_score
from sklearn.metrics import confusion_matrix
import keras

tf.random.set_seed(42)

data=pd.read_csv('PoseData.csv')
x=data.iloc[:,[0,1,2,3,4,5,6,7]].values
y=data.iloc[:,8].values

x_train, x_test, y_train, y_test = train_test_split(x, y, test_size=0.20,
random_state= 5)

x_train = x_train/1669.0
x_test = x_test/1669.0

modelo = tf.keras.Sequential([
    tf.keras.layers.Dense(1136, activation='relu'),
    tf.keras.layers.Dense(36, activation="relu"),
    tf.keras.layers.Dropout(0.2),
    tf.keras.layers.Dense(4, activation="softmax")
])

modelo.compile(  loss=tf.keras.losses.SparseCategoricalCrossentropy(),
                 optimizer=tf.keras.optimizers.Adam(learning_rate=0.01),
                 metrics=[tf.metrics.SparseCategoricalAccuracy()])

logdir = os.path.join("logs", datetime.datetime.now().strftime("%Y%m%d-%H%M%S"))
tensorboard_callback = tf.keras.callbacks.TensorBoard(logdir, histogram_freq=1)


history = modelo.fit(x_train,
                      y_train,
                      epochs=64,
                      validation_data=(x_test, y_test),
                      callbacks = [tensorboard_callback])

val_acc_per_epoch = history.history['val_sparse_categorical_accuracy']

best_epoch = val_acc_per_epoch.index(max(val_acc_per_epoch)) + 1
print('Best epoch: %d' % (best_epoch,))

modelo.save('PoseData.h5')
newModel = tf.keras.models.load_model('PoseData.h5')
loss, acc = newModel.evaluate(x_test, y_test, verbose=2)
print('Restored model, accuracy: {:5.2f}%'.format(100 * acc))


```

G.2 Neural network for movement categorize structure

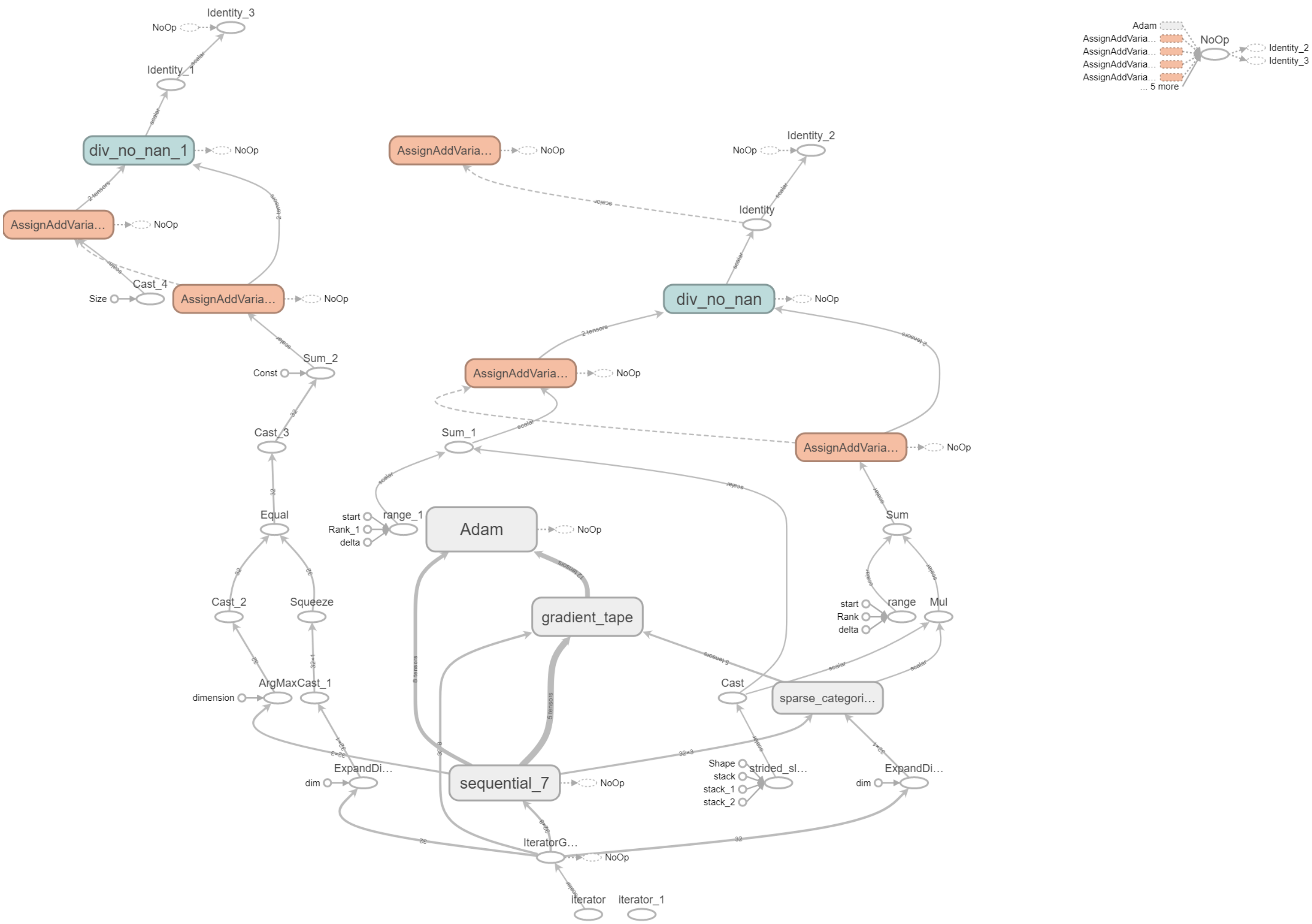


AssignAddVaria…
NoOp
Identity_2
Identity
Identity_3
Identity_1
div_no_nan
div_no_nan_1
Adam
NoOp
Sum_1
range_1
start
Rank_1
delta
Sum
range
Rank
Mul
Cast_4
Size
Sum_2
Const
Cast_3
Equal
Cast
strided_sl…
stack
stack_1
stack_2
gradient_tape
Shape
sparse_categori…
Cast_2
Squeeze
ArgMax
dimension
Cast_1
ExpandDi…
dim
sequential_8
IteratorG…
iterator
iterator_1
… 5 more

G.3 Neural network for speed categorize

```
import keras_tuner as kt
import tensorflow as tf
import numpy as np
import matplotlib.pyplot as plt
import pandas as pd
from sklearn.model_selection import train_test_split
import math as mt
from sklearn.metrics import accuracy_score
from sklearn.metrics import confusion_matrix
import keras
import os
import datetime
tf.random.set_seed(42)

data=pd.read_csv('fastType.csv')
x=data.iloc[:,[0,1,2,3,4,5,6,7]].values
y=data.iloc[:,9].values

x_train, x_test, y_train, y_test = train_test_split(x, y, test_size=0.20,
random_state= 5)

x_train = x_train/1669.0
x_test = x_test/1669.0


modelo = tf.keras.Sequential([
    tf.keras.layers.Dense(356, activation="relu"),
    tf.keras.layers.Dropout(0.2),
    tf.keras.layers.Dense(3, activation="softmax")
])

modelo.compile(  loss=tf.keras.losses.SparseCategoricalCrossentropy(),
                 optimizer=tf.keras.optimizers.Adam(learning_rate=0.03),
                 metrics=[tf.metrics.SparseCategoricalAccuracy()])

logdir = os.path.join("logs", datetime.datetime.now().strftime("%Y%m%d-%H%M%S"))
tensorboard_callback = tf.keras.callbacks.TensorBoard(logdir, histogram_freq=1)


history = modelo.fit(x_train,
                      y_train,
                      epochs=53,
                      validation_data=(x_test, y_test),
                     callbacks=[tensorboard_callback])

val_acc_per_epoch = history.history['val_sparse_categorical_accuracy']
best_epoch = val_acc_per_epoch.index(max(val_acc_per_epoch)) + 1
print('Best epoch: %d' % (best_epoch,))

modelo.save('fastTypeModel.h5')
newModel = tf.keras.models.load_model('fastTypeModel.h5')
loss, acc = newModel.evaluate(x_test, y_test, verbose=2)
print('Restored model, accuracy: {:5.2f}%'.format(100 * acc))
```

G.4 Neural network for speed categorize structure



Identity_3
NoOp
Identity_1
div_no_nan_1
NoOp
AssignAddVaria...
NoOp
AssignAddVaria...
NoOp
Size
Cast_4
AssignAddVaria...
NoOp
Sum_2
Const
Cast_3
Equal
Cast_2
Squeeze
dimension
ArgMax
Cast_1
ExpandDi...
dim
Identity_2
NoOp
Identity
div_no_nan
NoOp
AssignAddVaria...
NoOp
Sum_1
AssignAddVaria...
NoOp
start
Rank_1
delta
range_1
Adam
NoOp
gradient_tape
sequential_7
NoOp
IteratorG...
NoOp
iterator
iterator_1
Sum
start
Rank
delta
range
Mul
Cast
sparse_categori...
Shape
stack
stack_1
stack_2
strided_sl...
dim
ExpandDi...
Adam
AssignAddVaria...
AssignAddVaria...
AssignAddVaria...
AssignAddVaria...
... 5 more
NoOp
Identity_2
Identity_3

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