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Hand orthosis design for the rehabilitation of people with rheumatoid arthritis

Diseño de órtesis de mano para la rehabilitación de personas con artritis reumatoide

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Abstract

This project is based on the design and development of a hand orthosis controlled by wireless communication through a mobile application, developed in MIT AppInventor, and a web interface, designed in HTML and CSS; using a NODEMCU ESP8266 V3 development board as a microcontroller in order to obtain the benefit of Wi-Fi communication without ruling out the use of Bluetooth technology. This medical device is focused on the rehabilitation of patients with Rheumatoid Arthritis, or some other pathology that directly affects mobility in the joints of the hands. Similarly, the device has an electromyography module, designed from scratch, in order to monitor the patient's muscle activity and, in the future, achieve control of the orthosis through the possible actions issued by the user or patient. On the other hand, a "Local Network" was implemented with the aim of migrating or embodying the project within a rehabilitation center and having its own communication network, isolated from the outside. Thus, the rehabilitation doctor or physical therapist will be the only person who can control the device when the patient comes to the clinic for therapy or progress review.

Biological samples, Cold chain, Temperature

Resumen

El presente proyecto se basa en el diseño y desarrollo de una órtesis de mano controlada por comunicación inalámbrica mediante una aplicación móvil, desarrollada en MIT AppInventor, y una interfaz web, diseñada en HTML y CSS; usando como microcontrolador una placa de desarrollo NODEMCU ESP8266 V3 con el fin de obtener el beneficio de una comunicación Wi-Fi sin descartar el uso de la tecnología Bluethoot. Este dispositivo médico va enfocado a la rehabilitación de pacientes con Artritis Reumatoide, o alguna otra patología que afecte directamente la movilidad en las articulaciones de las manos. De igual forma, el dispositivo cuenta con un módulo de electromiografía, diseñado desde cero, con el fin de monitorear la actividad muscular del paciente y, en un futuro, lograr un control de la órtesis mediante los potenciales de acción emitidos por el usuario o paciente. Por otra parte, se implementó una “Red Local” con el objetivo de migrar o plasmar el proyecto dentro de un centro de rehabilitación y contar con una red de comunicación propia, aislada del exterior. Así, el médico de rehabilitación o fisioterapeuta será la única persona que pueda controlar el dispositivo cuando el paciente acuda a la clínica para terapia o revisión de avance

Biological samples, Cold chain, Temperature

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1. Introduction

Rheumatoid arthritis (RA) is produced when the immune system does not work properly, hence the term systemic autoimmune disease, and is characterized by synovitis and progressive destruction of articular cartilage and underlying bone, along with other extra-articular manifestations such as pain and stiffness (Díaz et al, 2002).

This disease is one of the most common worldwide, Belmonte Serrano in 2013 and Duró Pujol in 2010 report an incidence of 6-10 cases per 100,000 inhabitants; thus affecting 0.5% to 1% of the population (Mitchell & Kumar, 2017). Currently in our country, more than 1 million people are affected by RA, and three out of four people who present it are women according to the National Institute of Statistics and Geography (INEGI) in 2019. Statistics indicate that of the 100% of Mexican women who suffer from this condition, 75% are of productive age (between 25 and 50 years old). In contrast, in men it is only 25%.

The manifestations of RA are usually treated symptomatically and exclusively, although effective and consistent control is sought through the use of disease-modifying antirheumatic drugs (Gamero D. 2018).

Delayed treatment of this disease is associated with rapid progression of joint damage and an unfavorable outcome for the patient (Diaz E., et. al, 2005). Figure 1 shows the comparison between a healthy joint and a joint affected by *RA*.

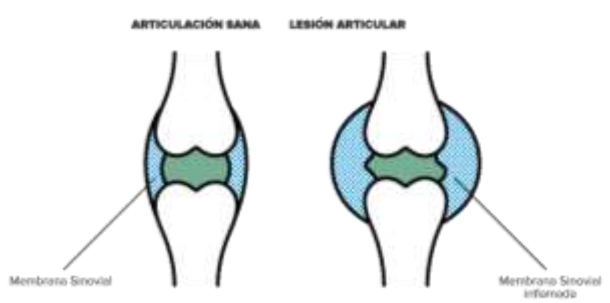

Figure 1 Comparison of a healthy joint with a joint affected by *RA*

The therapeutic approach to the rheumatologic hand is based on the fact that it is palliative, that is to say that none of the therapeutic interventions are curative in nature, their purpose being to reduce the signs and symptoms in order to improve the patient's quality of life. It is for this reason that the treatment of the rheumatologic hand must be individualized, periodic and permanent. It is worth mentioning the importance of assessing the patient in each of the different stages of the disease in order to carry out a more effective treatment.

For the physiotherapist, the treatment of the rheumatologic hand aims to increase its functional capacity. It is essential to identify, first of all, the state of each process: hand with osteoarthritis (with or without additional synovitis) or arthritic hand (in flare-up or remission phase, with slow or rapid progression), as this will condition the choice of one or another therapeutic modality (Miralles et al, 2002). That is why in effort to improve the quality of life of patients with RA, devices have been developed to assist in the patient's rehabilitation process, decreasing symptoms of the disease such as joint pain and preventing synovitis (Iturriaga, V, et al 2018).

There are different therapeutic modalities, whose use should stick to the phase of evolution of the rheumatologic hand (Montull S., et al 2004). Some modalities are:

– ***Orthoses***. *Orthoses* are defined as treatment modalities very useful to affect pain (rest splints), to control the progression of deformities (corrective) and to maintain the joint path (dynamic or static) in the rheumatologic hand (Bressel A.E, 2018). For the application of an *orthosis*, the aspects of a functional hand corresponding to an intermediate position of the hand and wrist, resting position and hand muscles must be considered (Braddom R.L, 1996).

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- ***Thermotherapy***. It is a modality used for its analgesic effect and favoring the extensibility of collagen, although it is important to know well the situations in which this modality can be used, because if it is used in inflammatory phases it can aggravate the consequences of inflammation (Apolo M.D, et. al 2006).

- ***Electrotherapy***. Electrostimulation is effective in improving functionality (avoiding atrophy, increasing fatigue resistance, increasing pressure strength) and TENS (Transcutaneous Electrical Nerve Stimulation) may be the most useful modality to reduce pain and increase muscle strength (Crépon F., et al, 2008).

However, certain disadvantages have been detected in these devices:

- High equipment price, due to the fact that the development and design of these devices is in other countries.
- Limitation to device functions, implementing only movement functions.
- There is no monitoring of the patient's biomedical signals.

They are not self-adjustable, since exact measurements have to be taken for a personalized design for each patient, making the process of design, development and acquisition of the device longer.

This is why the need arises to develop new methods and alternatives to provide an auxiliary rehabilitation in the search for restoring the level of movement in the affected joints; for this purpose, the design of an automated orthosis that allows measuring force levels and obtaining Electromigraphic (EMG) signals is proposed in this project, which is expected to provide the following benefits:

- Provide an automated system in the rehabilitation of patients with RA.
- Manage the progress of the rehabilitation of patients with RA.
- Provide stages and degrees of movement according to the damage and progression of the pathology in patients.
- Enable the patient to perform functions related to the rehabilitation of joint strength.

This article will discuss the methodology and results obtained in the development of a hand orthosis for rehabilitation in people with RA.

2. Methodology

The following activities were carried out to develop this project.

2.1 To perform the characterization of the sensors to be implemented in the orthosis

For the characterization of sensors and actuators, different methods were used according to each type of sensor and actuator to be implemented. For the part in question of sensors will be implemented:

2.1.1. Muscle sensor or EMG module

This module will be developed from 0 with the implementation of Bioinstrumentation; in order to have a complete processing of the myographic signal (representative signal of the muscular activity of the human body).

The characterization in this sensor will be deduced according to the Motor Unit Action Potential (MUAP) emitted by the patient. The signals will be acquired in the forearm, specifically in the muscles that are responsible for finger movements (superficial flexor muscle of the fingers).

In this module 4 stages were implemented: pre-amplification, filtering, rectification and final amplification.

2.1.1.1 Pre-amplification

Signal pre-amplification is the first stage in the development of the EMG module. In this stage, the myoelectric signal (electrical signal from the muscle) is obtained using patch electrodes and an instrumentation amplifier. These are three-lead electrodes: two for signal acquisition and a third as a reference.

The instrumentation amplifier is basically a differentiating amplifier, since its output is the difference of the two input signals. It is also known that this amplifier has a practically infinite gain, although for this stage a gain (AV) of between 10 and 20 is used.

This amplifier is composed of three amplifiers, and its design consists of 7 resistors, 6 of them set by the designer with values of an order of K Ω. Figure 2 shows the schematic or design of an instrumentation amplifier, with three operational amplifiers.

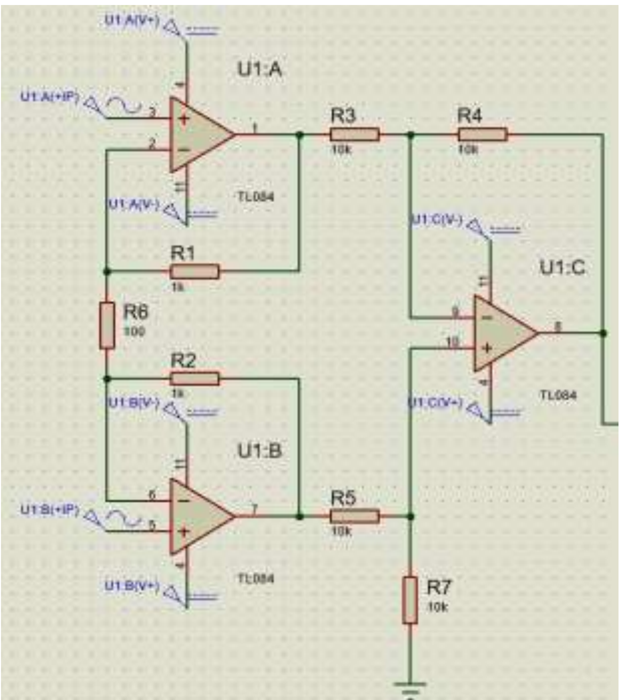

Figure 2 Instrumentation amplifier (Own Authorship)

Considering the previous design, it is essential to consider the following:

$$Y_{ij} = \alpha + \sum_{h=1}^{r} \beta_h X_{hij} + u_j + e_{ij}$$

R1 = R2 = R = 1kΩ

R3 = R4 = R5 = R6 = 10kΩ

AV = 20

$\boldsymbol{RG} = \boldsymbol{AV}\_\_\_\_\boldsymbol{2R}-\mathbf{1}$

Applying the formula and substituting the established resistor values, a Gain Resistance (RG) of approximately 100Ω is obtained.

In this way, the preamplification stage would be complete, having at the output a signal amplified 20 times. It should be remembered that the signals obtained from a muscle have an amplitude in the order of micro volts (µV).

2.1.1.2. Filtering

The filtering of a myoelectric signal is fundamental, since the filters are used to obtain selected data that are of interest for the correct processing of the signals obtained, taking into account the needs of the device. There are passive and active filters, which differ in their design.

For this application it is necessary to use active filters. This type of filters are used only when the quality factor is higher than 0.5. Figure 3 shows the design of an active narrow band pass filter.

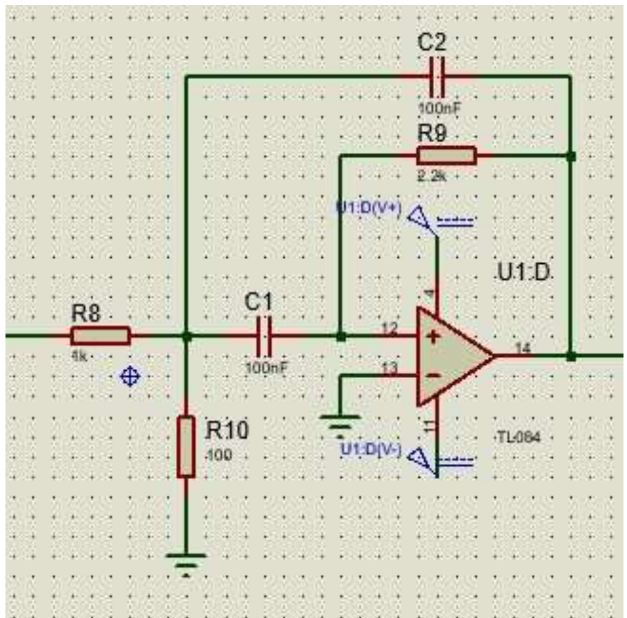

Figure 3 Narrow band-pass filter (Own authorship)

The design conditions of this filter are as follows:

- C1 = C2 = C = 0.1uF
- R1 = 1kΩ
- R2 = 2R1= 2kΩ

In addition to these conditions, it is necessary to establish certain frequencies for the filter design, such as the upper frequency (fs), lower frequency (fi) and resonant frequency (fr). In this design, bands with a frequency range between 150 and 100 Hz will be used.

The equation to be calculated is:

$$fr = \sqrt{fsxfi}$$

fr = 122.47 Hz

The bandwidth (B) is the difference between the upper frequency and the lower frequency. Therefore, the bandwidth (B) is the difference between the upper frequency and the lower frequency.

$B = fs - fL$ i = 50 Hz

The quality factor (Q) indicates the degree of selectivity the filter will have. If Q is greater than 0.5 Hz, the filter will be more selective, i.e., the waves it will allow to pass will have a narrower aspect. To obtain Q the following is done:

$$Q = \frac{fr}{B}$$

Q = 2.44

Once we have these values we can deduce that the filter will have a higher selectivity factor in the relation between reactive energy and the energy it dissipates in a complete cycle of the signal, and the Resonance Resistance (Rr) is calculated in order to obtain the frequency of the narrow band pass filter (FPBA), following equation:

$$Rr = \frac{R}{2Q^2-1}$$

Rr = 91Ω

The second order high-pass filter is intended to let only the higher frequencies pass at the selected cutoff frequency (1.5KHz), thus cleaning the signal and obtaining better filtering results. Figure 4 shows the design of a second order high pass filter, according to the needs of the project.

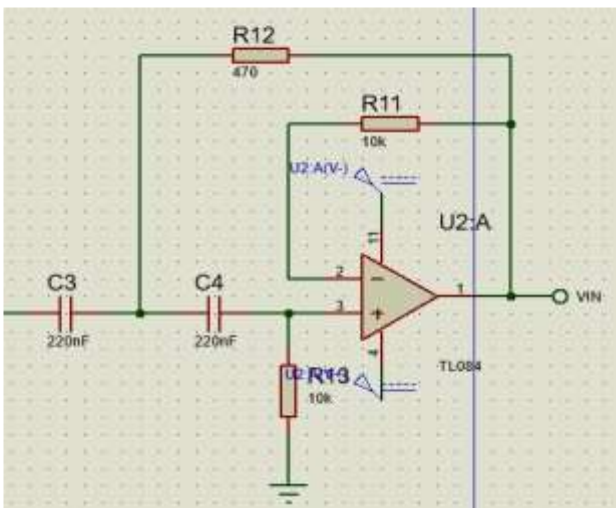

Figure 4 Second order high-pass filter
Own Authorship

2.1.1.3. Rectification

The rectification of the signal is very important, since the signal obtained has both positive and negative voltage peaks (Vp), and these negative Vp could damage the Microcontroller Unit (MCU). Because of this, a full-wave precision rectifier was implemented. In the design of this rectifier the resistors are equal except for the feedback resistor of the second operational amplifier (RF2) and the load resistor (RL). RF2 will have twice the Ω value as the other resistors. Figure 5 shows the design of a full-wave precision rectifier.

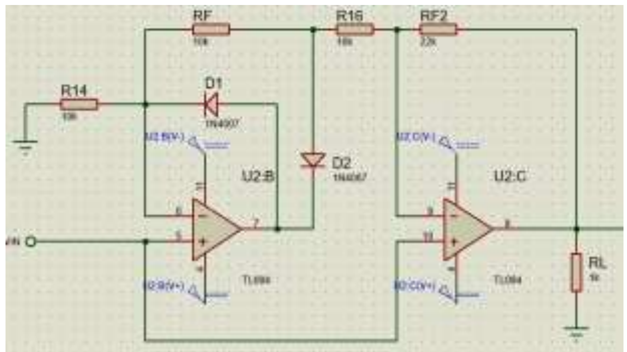

Figure 5 Full wave precision rectifier
Own Authorship

2.1.1.4 Final Amplification

Once the signal is rectified, it is necessary to amplify the voltage in order to have a better use of the signal and continue with its processing inside the MCU. For this, an inverting amplifier was implemented, since the output signal was negatively rectified. The gain in this final amplification stage was 1500 Hz. Figure 6 shows the design of an inverting amplifier.

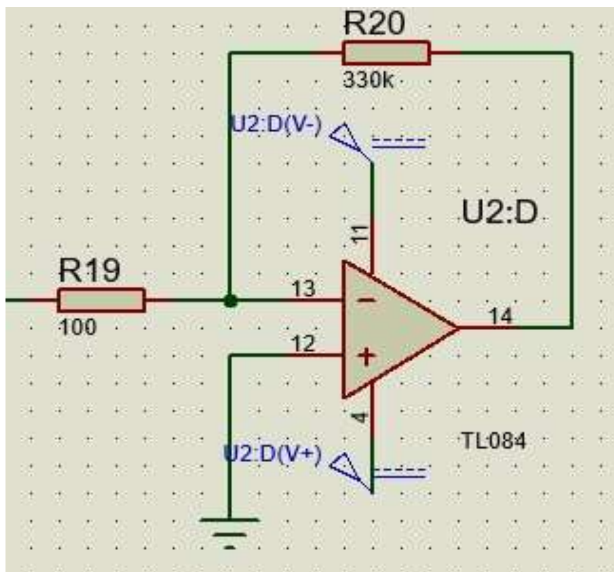

Figure 6 Inverter amplifier
Own Authorship

For the actuator part, the following was implemented:

– Servomotor Micro servo MG90S. The servomotor will help in the project for the mobility of the fingers. The operation of this component is by means of pulses, by means of which the servomotor achieves a rotation from 0° to 180°. The proprietary connections for the MG90S Servomotor are:

1. VCC: 5V to 6V power supply.
2. GND: ground.
3. SIGNAL: write pin for the servo.

A person with correct hand mobility can generate degrees of inclination ranging from zero degrees, 0° degrees being a straight hand position, to 90° degrees, always using the proximal phalanges. By means of quantitative tests, 15 test subjects were taken to analyze the degrees of inclination presented by people with correct hand movement. These tests were done through a geometric measurement to verify up to what degrees of inclination the test subjects can reach when the phalanges are in a straight position.

As well as, the verification that the orthosis gives the exact degrees of inclination that were made to the subjects. This in order that at the time of performing a rehabilitation in a person who is losing the degrees of mobility to recover the full movement.

The characterization of this actuator is based on the degrees of mobility of the patient's fingers. For this purpose, a variable electrical resistor and a programming loaded on the Wi-Fi development board were used.

The objective of the programming was to read the voltage provided by the variable resistor, connecting one of the side pins to VCC, the second side pin to GND and the central pin to the analog input of the Wi-Fi module; and by means of a programmed mapping, to match the maximum and minimum values of the potentiometer with the degrees from 180° to 0°, respectively.

In this way, and by varying the values of the potentiometer, the minimum and maximum degrees of mobility applicable to a patient's finger were deduced, taking as a reference the patient's comfort when experiencing these movements.

2.2 Generate polypropylene-based orthosis structure to start the prototype model.

The prototype structure was designed using polypropylene, in order to optimize the process and reduce manufacturing and modification costs of the structure.

This structure is designed to place the servomotors in a horizontal orientation in order to facilitate the execution of the movements of each of the fingers.

The parts designed were:

- **Palm of the hand:**

This is the part that holds the servo motors and the phalanges of the fingers. It is basically the largest part of the device, and is sized representative to the palm of an adult person's hand.

- **Phalanges**:

This piece is responsible for the characteristic movement of the finger, when opening or closing the fist. It was designed with a curvature, in order to generate the movement as similar as possible, anatomically speaking, to that of the joints in question. It has a length of approximately 12 cm, with an angle of inclination of ≈75°.

- **Phalangeal support**:

The purpose of this support is to hold the phalanges of the patient's fingers to the previously designed representative piece of the same. There are two supports, which are placed one on the proximal phalanges and the second on the middle phalanges. It is worth mentioning that the distal phalanges do not need to be supported with the brackets since these joints can hardly be moved voluntarily by the patient.

2.3 Carry out the specific programming for the control of the device and signal acquisition in the software

Once the prototype is assembled, and having the degrees of mobility representative of the joints, it is necessary to implement programming in order to control the device as planned. For this purpose, a development interface was used in combination with the mobile application. As part of the hardware, it was necessary to use the Wi-Fi module development board, an MG90S servo motor, a 1-inch OLED screen to display important data, a Bluethoot HC-05 module for communication with the mobile application, a push-button to perform the connection and disconnection to a specific Wi-Fi network.

4. Results

The results obtained in the project are presented below.

4.1 Characterization of sensors and actuators

Table 1 shows the representative values of the minimum and maximum degrees of mobility obtained in the characterization performed with the potentiometer.

Limit.	Value.
MIN	**80**
MAX	**180**

Table 1 Characterization of the servomotor with potentiometer (Own authorship)

In order to establish a reference of mobility degrees characteristic of patients with correct mobility, quantitative measurements of the movement of the fingers of 3 persons were performed, having as a reference an angle measurement. Table 2 shows the results obtained from this test. The statistical analysis performed showed that there is no significant difference between the angle obtained from the prosthesis and that of the programming.

Subject	Mobility grades				
	0°	*25°*	*50°*	*65°*	*90°*
1					X
2					X
3					X

Table 2 Obtaining degrees of mobility of healthy patients, starting from 0 to 180 (Own authorship)

Figure 7, 8 and 9 show the results obtained from the characterization of the servos according to the degrees of mobility supported by the persons subjected to the quantitative measurements, shown in the previous table.

Figure 7 180-degree script in servo characterization
Own Authorship

Figure 8 135-degree script in servo characterization
Own Authorship

Figure 9 80-degree script in servo characterization
Own Authorship

4.2 Wireless Communication

The device is controlled by a mobile application implementing Bluetooth technology. This application will also be able to monitor the biological measurements obtained corresponding to electromyography signals. Similarly, Wi-Fi technology will be implemented, focused on controlling or monitoring the progress of the patient, by a specialist, throughout his rehabilitation, using a local network to have a patient management within a clinic or rehabilitation area.

4.3 Collection of Electromyogram signals

Obtaining EMG signals will be very useful when evaluating and monitoring the patient's progress in the rehabilitation process. Figure 10 shows the design of the EMG module designed to obtain these signals and Figure 11 shows the circuit assembly on a breadboard.

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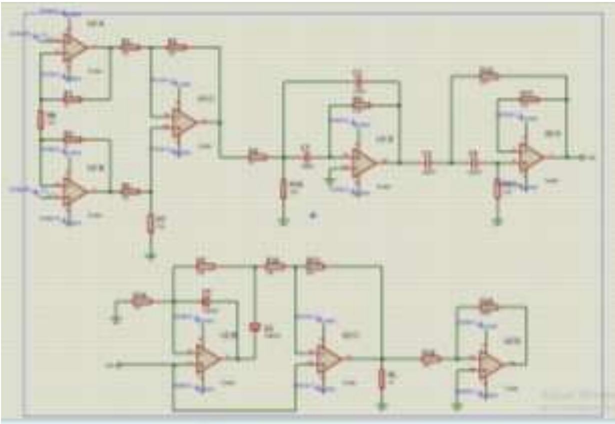

Figure 10 EMG module design
Own Authorship

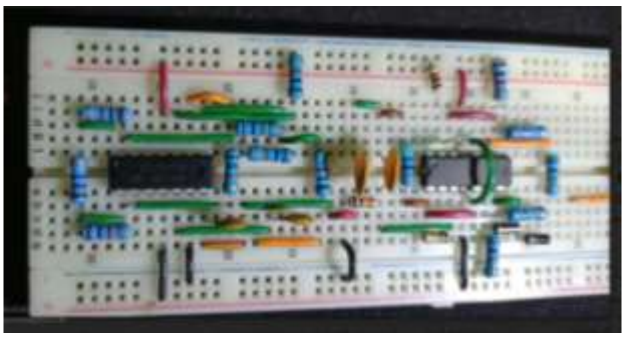

Figure 11 Physical assembly of the EMG module
Own Authorship

With the EMG module it was possible to obtain a satisfactory signal processing. Figure 12 shows the waveform obtained from the myoelectric signal processed by the EMG module.

Figure 12 Non-inverted myoelectric signal processed by the EMG module
Own Authorship

4.4 Programming of rehabilitation sessions

A mobile application was developed where the type of rehabilitation will be configured at different levels, a time selected by the patient can be established in order to schedule rehabilitation sessions; speeding up this process, automating it and avoiding setbacks caused by non-compliance with the recommended times for each movement or stimulation time. Figures 13, 14 and 15 show the design of the interfaces of the mobile application to control the device.

The home screen of the interface has a user name and password for access (see Figure 13). Within the application it will be possible to choose the level of rehabilitation based on the degree of mobility of the subject, based on the recommendation of the specialist, Figure 14.

After selecting the level, a window appears to start the therapy, in which the play and stop icon appears, as well as the number of repetitions corresponding to each level (Figure 15).

Figure 13 Home screen interface of the mobile App
Own Authorship

Figure 14 Interface of the mobile App menu screen
Own Authorship

Figure 15 Screen interface representative of the first level of movement of the device
Own Authorship

4. Conclusions

According to the functional tests performed, it can be concluded that the objectives set at the beginning of the project were achieved, since a functional device was obtained in terms of control with web and mobile interfaces and good aesthetics, as well as the interfaces, which fulfilled the purpose of controlling the orthosis.

The electromyography module was completed in a prototype approach, since the module is able to observe the waveforms corresponding to muscle contractions, but a complete digitalization of the signal has not been achieved

At the moment it has not been tested with patients suffering from this type of arthritis or affected by a pathology that affects the movement in the joints of the hand, but the movement sessions have been achieved and executed using the wireless control of web pages and mobile applications.

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