Design and construction of a device that facilitates the stretching of plantar flexors muscles in the therapy of rehabilitation for patients with spastic hemiplegia

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Trabajo de grado para optar al título de

Ingeniero Mecánico

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Facultad de Ingenierías Físico-Mecánicas

Escuela de Ingeniería Mecánica

Bucaramanga

2018

Acknowledgements

First, I want to thank God for each of the blessings he has given me.

To thank my parents for always being my support and motivation, for being the inspiration of each achievement, for their effort and unconditional support so that today I can finish another stage.

To my mother, Martha Cecilia, for her love and her good teachings; to educate myself as a responsible and disciplined woman without leaving sensitivity aside.

To my father, Ricardo, for teaching me that "things must be done well"; because his admiration has always been my impulse to continue.

To my brothers, Sergio and Ricardo Andrés, for being an example and company.

To Jota, my favorite engineer, for your advice, for motivating and encouraging me to fulfill my dreams.

To Julián and Fredy for their friendship and their unconditional support, for the time and effort dedicated. To my best friend and partner, Eduardo, for the laughers, tears, dreams and shared achievements. To my friends at school and my friends at the University, for their friendship and support, for all. To Diego for your drive to achieve my goals, your teachings and your friendship. To Mechanical Engineering School for being the best suitable for my academic training.

To my angel, my grandmother ... The woman that I love and admire the most in the world. Thank you for the best 21 years with you, for your love, admiration and tenderness. For being my example of strength and joy. For guiding my steps. For being a mother, father and grandmother. For being everything.

Nathalia Cales

Acknowledgements

After a long journey, this stage in my life is over, to give way to new challenges and experiences that help my professional and personal growth. All this is possible thanks to my family and friends,

To my dad, Rafael, who has always aware of everything in my life, advising me in the best way.

To my mom, Edith, who supported me during my 5 years and more in university, who always help me to overcome all the obstacles presented.

To my brother, Rafa, who always helped me carry out my dream forward and despite of distance, he's still present in my heart.

To my sister, Rosy, with him unparalleled charisma, making me a better person every day.

To the love of my life, Maria Paula, who arrived at the right moment of my life, for mi guidance and my light in all my projects and of course, in life,

To my friends from a a thousand of battles, Miguel, Jhorvin, Fredy, Carlos and Julian, with whom we traveled this long road. My brothers from another mom. To Nathy, my best friend, who was always there to help me and advise me in the life.

To the school of mechanical engineering and its teachers, for the opportunity to develop my career successfully and offer the best tools for it.

And to my alma mater UIS, for having welcomed me and offered the best experience of my life

Eduardo Barragán Parada

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RESUMEN

TÍTULO: DISEÑO Y CONSTRUCCIÓN DE UN DISPOSITIVO QUE FACILITA EL ESTIRAMIENTO DE LOS MÚSCULOS PLANTIFLEXORES EN LA TERAPIA DE REHABILITACIÓN PARA PACIENTES CON HEMIPLEJIA ESPÁSTICA **(*)**

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PALABRAS CLAVE: BIOMECÁNICA, DISPOSITIVO MECÁNICO, ESTIRAMIENTO MECÁNICO SOSTENIDO, HEMIPLEJÍA ESPÁSTICA, MÚSCULOS PLANTIFLEXORES, REHABILITACIÓN.

DESCRIPCIÓN:

La espasticidad en los músculos plantiflexores como un producto del accidente cerebrovascular (ACV) restringe la movilidad y la independencia de las personas afectadas. Comúnmente, los fisioterapeutas están a cargo de realizar manualmente la terapia de rehabilitación conocida como estiramiento mecánico sostenido, rotando el pie afectado del paciente en el plano sagital. Sin embargo, esto causa un desgaste físico en el profesional porque es un movimiento fatigante. En este artículo, se desarrolla un dispositivo mecánico para implementar esta terapia de rehabilitación de manera más eficiente. El dispositivo consiste en un mecanismo de sin fin-corona que es accionado por una manivela para girar gradualmente una plataforma en el plano sagital del pie afectado, con el fin de lograr la dorsiflexión. El dispositivo tiene un rango de rotación sagital de hasta 150 ° y tiene correas de velcro ubicadas en la plataforma que aseguran el pie. El diseño de este dispositivo se modeló utilizando un software CAD. Como sistema de medición, se usa un goniómetro en la parte lateral del dispositivo y se utilizan celdas de carga para medir la fuerza con el fin de determinar el torque resistente ejercido por el músculo. La sensibilidad de las celdas de carga es 1.8 ± 0.002 y tienen una repetibilidad de 0.03. La validación de la efectividad del dispositivo se mide al reducir el torque resistente y aumentar la movilidad para un paciente determinado.

(*) Trabajo de grado

(**) Facultad de Ingenierías Físico-Mecánicas. Escuela de Ingeniería Mecánica. Director: Ing. Diego Fernando Villegas Bermúdez

ABSTRACT

TITLE: DESIGN AND CONSTRUCTION OF A DEVICE THAT FACILITATES THE STRETCHING OF PLANTAR FLEXORS MUSCLES IN THE THERAPY OF REHABILITATION FOR PATIENTS WITH SPASTIC HEMIPLEGIA. (*)

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KEYWORDS: BIOMECHANICS, MECHANICAL DEVICE, PLANTAR FLEXORS MUSCLES, REHABILITATION, SPASTIC HEMIPLEGIA, SUSTAINED MECHANICAL STRETCHING.

DESCRIPTION:
Spasticity in the plantar flexors muscles as a product of stroke (CVA-Cerebrovascular accident) restricts the mobility and independence of the affected people. Commonly, physiotherapists oversee manually performing the rehabilitation therapy known as Sustained Mechanical Stretching, rotating the affected foot of the patient in the sagittal plane. However, this causes a physical wear on the professional because it is a fatiguing movement. In this article, a Mechanical Device is developed to implement this rehabilitation therapy more efficiently. The device consists of a worm-crown mechanism that is driven by a crank to gradually rotate a platform in the sagittal plane of the affected foot, to achieve dorsiflexion. The device has a range of sagittal rotation up to 150° and has Velcro located on the footplate that secure the foot. The design of this device was modeled by using a CAD. As a measurement system, a goniometer is used in the lateral part of the device and load cells are used to measure the force to determine the opposing torque exerted by the muscle. Load cells sensitivity is 1.8 ± 0.002 and has a repeatability of 0.03. Validation of the effectiveness of the device is measured by reducing the opposition torque and increasing mobility for a given patient.

(*) Bachelor Thesis
(**) Facultad de Ingenierías Físico-Mecánicas. Escuela de ingeniería Mecánica. Director: Ing. Diego Fernando Villegas Bermúdez

Introduction

Stroke is the leading cause of disability in the adult population, with 18% of cases in people older than 75 years (Sengler, n.d.). The most well-known sequel post-stroke is Spastic Hemiplegia (SH) (Aloraini, Gaverth, Yeung, & MacKay-Lyons, 2015). SH is defined as a body lateral paralysis, that presents an increase in muscular stretching resistance, due to increased excitability of the stretch reflex and activity disinhibition of the alpha motor neuron (Ansari et al., 2013). Within 2 weeks is developed and prevails for one year later, almost in the 38% of the patients. In general, SH affects until the 70% of the patients with chronic stroke (Ansari et al., 2013).

SH hinder the gait and difficult the balance of affected people, due to muscle tension and stiffness of joints. Sometimes the patients elicit an increase in the muscular tone and particularly in the Ankle Plantar Flexors Muscles (APFM), causing abnormalities in gait. In other words, the lowers members begin to lose mobility. The affected member adopts a Plantar Flexor (PF) position in which muscles contract almost permanently (Mizuno, Sonoda, Takeda, & Maeshima., 2016).

The opposition torque exercised during the passive Dorsiflexion (DF) of the ankle, acts like an indicator of the muscular tone of the APFM (Mizuno et al., 2016). This procedure is realized by physiotherapists using manual scales as the modified Ashworth scales or the Tardieu scale. Overall, these therapies of rehabilitation provide benefits respects to the gestural activity, speech disorders, autonomy and reintegration, an above all the gait. If the therapies are realized opportunely and in the shorter possible time, the efficacy of these will be higher.

A lot of problems during the application of manual tests, because the physiotherapists perform the rotation of the affected ankle in the range of motion (ROM) (Kobayashi, Leung, Akazawa, Tanaka, & Hutchins, 2010), but some patients have very high stiffness in their ankle, making harder the therapy (Zhou et al., 2015). Also, emphasize that physiotherapists make an exhausting and laborious activity with these manual tests, despite of the rehabilitation may not last long. It is too difficult controlling the speed of application during the test, control the suitable stretching force (Yeh, Chen, & Tsai, 2004) to avoid stretching force reduction, particularly in conditions with high velocity and resistance (Kobayashi et al., 2010).

This study proposed a mechanical worm-crown system, actioned manually through a crank with a torque resistance measurement system, besides a goniometer to establish the DF angle necessary. This gadget allows to keep the foot position fixed in the sagittal plane, tied with Velcro and which is over the footplate. Furthermore, the difficult work realized by the physiotherapist can be performed through the device, avoiding fatigue and above all, measurement errors (Kobayashi et al., 2010).

Nowadays, different ankle rehabilitation devices for SH post-stroke have been developed. This technology allows the physiotherapists on reducing the effort of performing the therapy and obtain better results. Proposals are known as a proprioceptive neuromuscular facilitation integrated robotic ankle-foot system with a graphic user interface (Zhou et al., 2015), an ankle-joint stiffness measuring system for clinical applications (Mizuno et al., 2016), or a mechanical device with a torque-meter, a potentiometer, a handle to apply manual force and a footplate attached to a rotatory plate (Kobayashi et al.,2010 and Kobayashi, Leung, Akazawa, & Hutchins, 2011).

This study will show the design of a low-cost mechanical device, which is manually actioned composed by a force sensor used for the measurement of the opposite torque developed in the ankle joint by the PF muscles of the patient. The objectives of this device is avoiding the fatigue of the physiotherapist realizing the therapy, increasing the accuracy of data collection like opposite torque and angle of Dorsiflexion, provided security to the patient, and the operator when the device is actioned and achieve the satisfactory results, reducing de opposition torque exercised by the PF muscles at the end of the therapy. Finally, it is expected that patients, after rehabilitation, have a better stability in the gait and reducing the muscular contractibility of the patients, improving their quality of life.

1 Problem statement

1.1 Identification of the problem

In a study carried out on the burden of disease due to cerebrovascular accident (CVA) in Latin America, it was found that in addition to be the second cause of death, it is one of the leading causes of years lost due to disability. It is linked to social and economic factors that affect the quality of life of people, so it is related in Latin American countries to the progressive urbanization; generating an increase in the risk factors of this condition. In Colombia, the prevalence of stroke diseases is estimated at between 1.4 and 19.9 % per 100,000 inhabitants. This study by Instituto Nacional de Salud & Observatorio Nacional de Salud, (2015) is essential to formulate public health policies and implement plans to reduce the burden of this disease and the costs that it entails in the economic and social spheres.

Hemiplegia is a condition that arises in patients who have suffered strokes and consists of the paralysis of the lateral half of their body. These patients present involuntary spasms that hinder their movements, affecting their balance and attenuating their quality of life. Because of this, the lower limb with loss of mobility, adopts a position of almost permanent plantar flexion (sagittal plane) that forces the plantar flexor muscles to contract (see Figure 1). To improve this limitation, physiotherapy is used, performing exercises that help prevent muscle atrophy and, if possible, contribute to the recovery of mobility; However, when these exercises are performed manually, the repeatability of the technique is not guaranteed, since there are variables that cannot be controlled, such as: fatigue of the physiotherapist and variability in the force applied to achieve dorsiflexion in the patient; Therefore, we seek to standardize this procedure.

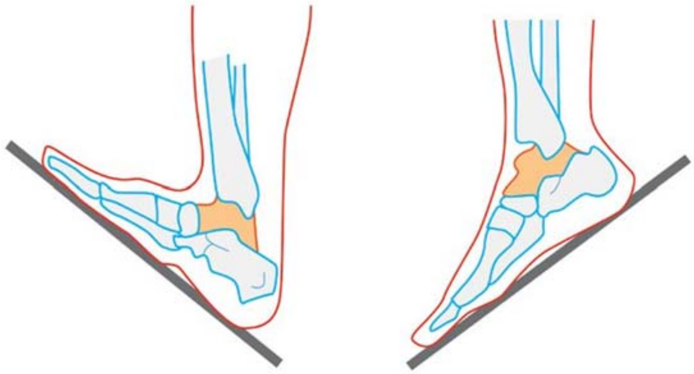


Figure 1. Dorsiflexion and plantarflexion

The literature indicates that rehabilitation in patients with hemiplegia provides benefits in their progress and autonomy, allowing functional recovery. This improvement is more significant in the acts of daily life and their perceptual functions. It was found that it is not possible to demonstrate the superiority of one rehabilitation technique over another, but that the intensity and duration of the therapy generates positive consequences; and although there is greater improvement in young patients, the overall effect is still moderate. Generally, the results show that in patients undergoing early rehabilitation (immediately after the CVA) there is a greater improvement, however, stated that when rehabilitation is delayed, it also provides a therapeutic benefit.

Rehabilitation therapy helps patients to improve their ability to climb stairs, provides better recovery in travel outside the home and increases their speed on the march, their stability and balance, and there is evidence of improvement in social relationships and their self-esteem. However, the benefit of rehabilitation also has a satisfactory impact on the quality of life of the patient's caregiver; it lightens the burden of direct physical assistance and surveillance (Sengler, n.d.)

1.2 Justification

After suffering a cerebrovascular accident (CVA) one of the consequences can result in the condition of spastic hemiplegia, a condition in which one side of the body is paralyzed and is characterized by muscle tension and stiffness of the muscles. joints; which modifies the progress of these patients and harms their balance.

To improve symptoms and reduce muscle spasticity, the patient undergoes physical therapy to recover the functionality of the extremities involved, however, this therapy is usually performed manually by the physiotherapist, which is why its duration it only oscillates in five minutes of application of the exercise. According to the literature, dorsiflexion therapy should last approximately thirty minutes to obtain improvement results in the patient, which makes it difficult to perform manually.

Considering the different factors involved in the problem, it is necessary to construct the device to standardize the physical therapy that is applied in patients with spastic hemiplegia, to eliminate the variability of the force and relieve the physiotherapist of this task. Therefore, it is intended that the device can maintain a fixed position during the time required in the therapy without the patient being able to modify it.

In this way, contributing to the application of an effective therapy can achieve a great social impact with the attenuation of the condition evidenced in a better stability in the march and the decrease of the muscular contractility of the patients, increasing their quality of life. In addition, the device can continue to be used for further research that will provide significant data to the scientific and research area of the region.

In addition, from the economic point of view, importing a device with similar characteristics would be very expensive and there would be no guarantee that the therapy would be applied as required; therefore, it is much more feasible that said device be designed and built by the School of Mechanical Engineering UIS.

2 Objectives

2.1 General objective

Design and build a device that allows the controlled stretching of the plantar flexor muscles in patients with spastic hemiplegia to reduce their reflex excitability and contractility, and in this way contribute to the fulfillment of the mission of the School of Mechanical Engineering of the Universidad Industrial de Santander providing a solution to a medical and social need.

2.2 Specific objectives

- Design a mechanical device for the controlled stretching of the plantar flexor muscle in patients with spastic hemiplegia, with mobility in the sagittal plane: dorsiflexion, safe adjustment of the patient's foot and provide torque measurement.
- Build a functional scale prototype of the device to be used in later studies of the UIS pain study group.
- Validate the prototype through tests performed on a patient with spastic hemiplegia with the help of the staff of the School of Physiotherapy of the UIS.

3 Design Requirements

This section presents the proposed solution for the implementation of assisted rehabilitation therapy through a device designed for this purpose. The design process is described considering the requirements studied with the patient and the physiotherapist, as well as the sensor system used, and the reading of data made by the device for measurement.

Based on the information obtained from meetings with a stroke patient and the UIS physiotherapy staff, a list of parameters considered necessary for the device was developed, becoming the requirements that the design must meet. For the patient it is of vital importance that the device provides comfort and is ergonomic for the therapy, as well as being hygienic and safe. It should be considered the ease with which the physiotherapist can accommodate the patient's foot in the device, as well as the implementation of tools that allow you to observe the angular range in which the foot will rotate and the display of the value of the resistant torque that will allow studying the evolution of stretching therapy.

3.1 Functional requirements

Regarding the functionality of the device, a system must be implemented that allows physiotherapy personnel to display the resistant torque opposite to the patient and, similarly, a tool with which to configure the corresponding rotation angle for each patient in the initialization of therapy. To use the device in subsequent studies of the School of Physiotherapy of the UIS, it is required the possibility of configuring it to carry out the therapy starting from different positions, that is, that the patient can be seated or lying down without altering the quality of the measurement.

Taking into consideration the cost and the nature of the therapy, the design of a mechanical device is proposed; although it may seem impractical, it turns out to be the best option to implement for clinical use. The manual methods can minimize the discomfort and injuries, it is safer to use and then, it is more convenient for the use required in this study (Kobayashi et al., 2010).

However, the device must be robust to withstand the forces involved in therapy because of the nature of the disease and must also be easy to maintain.

3.2 Kinematic and/or dynamic requirements

It was suggested that the device should have a slow movement so as not to induce spasms in the patient during the initialization of the therapy, furthermore, it was stipulated that during the stretching therapy (approximately 20 minutes) the device had to remain static at the selected angle.

To determine the above, was find that the optimal speed at which the procedure should be performed is 5 [° / s] significantly small value to implement an automated system considering that most of the time the device will be static in a certain position (Mizuno et al., 2016).

3.3 Safety requirements

Design a device to be manipulated and used in people implies that it must ensure that their welfare is not infringe further focusing the target stroke patients public must ensure: that no spasms be induced during therapy and lower extremity involved in the procedure will be ensured in the device to obtain a correct stretching of the muscles. This also considering the well-being of the physiotherapy professional who will perform the therapy.

3.4 Aesthetic requirements

The device must be pleasing to the eye to generate confidence in the patient, so it is necessary to select colors that match the traditional medical furniture, must have an adequate weight so as not to move while applying the therapy but be light enough to facilitate its transport. It is important that it has edges with rounding to reduce the possibility of accidents by cutting and, not to provide a visual overload, it must be a simple design. The device should be easy to clean and asepsis.

3.5 QFD results

To select the best alternative, the Pugh matrix was used, in which a positive point (+) is given when the requirement is completely satisfied, a negative point (-) if it does not satisfy it and a (s) when it is partially satisfied. In this way can compare the proposed alternatives and then combine to achieve an increasingly better until you get the final. Then, with the selected alternative the QFD is made.

Carrying out an inquiry with the user and attending to their needs, a general list was created of the requirements that the device should have to satisfy both the patient and the physiotherapist, and this was shown previously. During the interview with the user, it was asked to assign a value of 1 to 5 according to the importance or relevance of the need and from that the user's requirements were ordered from highest to least relevant, with 5 being the most important.

In the same way, an engineering evaluation was carried out and criteria considered important for a good design were assigned. Having both visions of what is required, their correlation is evaluated and the main factors to be considered during the design process are obtained from a QFD matrix. For the correlation, a score was assigned according to the relationship between criteria from lowest to highest.

After making the QFD matrix (See appendix A) , with the respective weighting, the most relevant aspects for the design are obtained.

- **Angular position:** That the device has a system that allows to visualize the angle of dorsiflexion.

● **Comfort:** Comfort of the user when the therapy is applied, allowing the device to be easily coupled.

● **Versatility:** Ability to place the footplate in different positions to facilitate the application of the therapy to the user.

● **Safety:** Keep fixed in a position desired by the therapist, the Footplate, without the user being able to return it.

● **Economy:** easy to manufacture with low cost materials using mechanical drive.

Table 1.
Requirements score from QFD matrix for device's design.

Criteria	Score
Versatility	209
Safety	179
Economy	171
Different positions of use	168
Comfort	155

4 Description of the design

4.1 Mechanical design

All the mechanical design proposed was modeled with SolidWorks Dassault Systems Corp., (see figure 2 and appendix F).

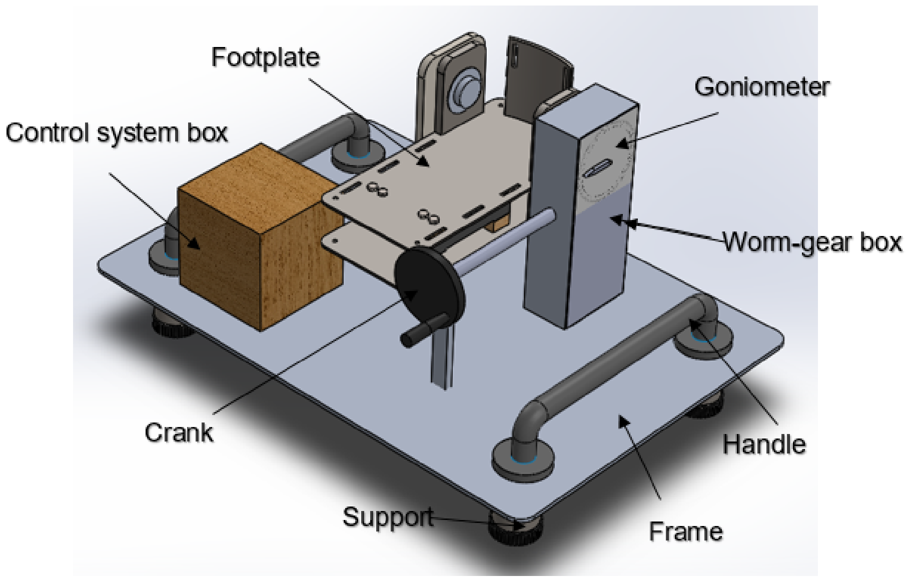


Figure 2. CAD model of the device to measure opposition torque of ankle joint dorsiflexion

The design proposal consists of a rectangular flat base blade that has four legs with height leveler at its lower ends. It has two handles on the lateral ends to facilitate the transport of the device. For the foot, there are two arms to support a mobile platform called Footplate that is equipped with a foam-lined leather covering to provide comfort to the patient and has a felt strip to secure the foot during therapy. The footplate, was made based on the anthropometric foot dimensions of male Colombian population (Ávila-Chaurand, Prado-León, & González-Muñoz, 2007), given versatility for every people at least, in Colombia. At one end has a curved plate to locate the heel, which is also covered and has a slot to place a felt strip that serves to secure the ankle. To support the other foot during the therapy, a basic auxiliary platform with the same covering was designed so that the patient can support his limb when sitting.

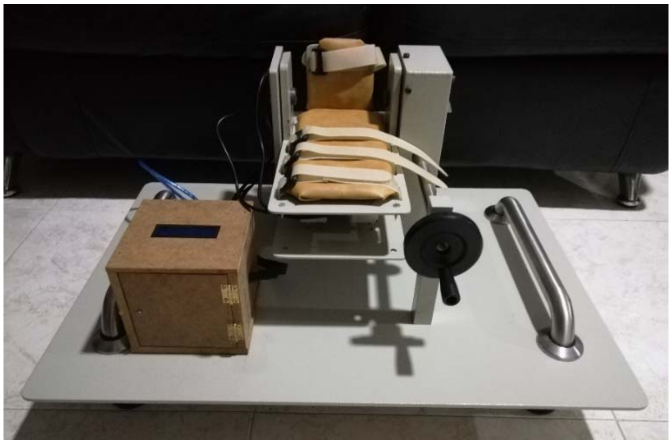


Figure 3. Real device for therapy of rehabilitation

For the sustained mechanical stretching therapy to be performed by the physiotherapist, a precision of angular range of maximum 2 degrees was required, so the movement system chosen to implement in the device was a mechanism worm-crown. It was chosen as the mechanical system that best met the design requirements, allows a movement in a wide angular range of 150° and with a precision of 1 degrees, it is also easily maintainable and is a robust system that can support the torque resistant opposite by the patient.

Figure 4. Detailed view of the worm-crown mechanism

The driving gear is the worm which is attached to a small crank and is manipulated by the physiotherapy professional. The movement of the crown determines the rotation angle of the footplate by sharing the same axis. The gear box system has a goniometer printed with a metal needle that moves along with the crown to indicate the angular position of the footplate.

4.2 Torque measurement and Data acquisition

The opposition torque exercised by the involved extremity during the therapy, is measured through a system (as shown in the figure 5) composed of: 2 load cells of 15kg (LEXUS SP06: sensitivity 1.8 ± 0.002; repeatability of 0.03) in charge of data input, located symmetrically between the footplate and the support plate; 2 modules HX711 that perform 24 bit Analog to Digital conversion, until the electronic board Arduino Mega 2560, where is realized data processing. Using a data acquisition tool: PLX-DAQ (Parallax Inc.), were compiled all values in function of time. The results obtained by the load cells are shown both on a display LCD 16x2 and MSExcel 2016 (Figure 6) presenting in real time, the opposition torque measured.

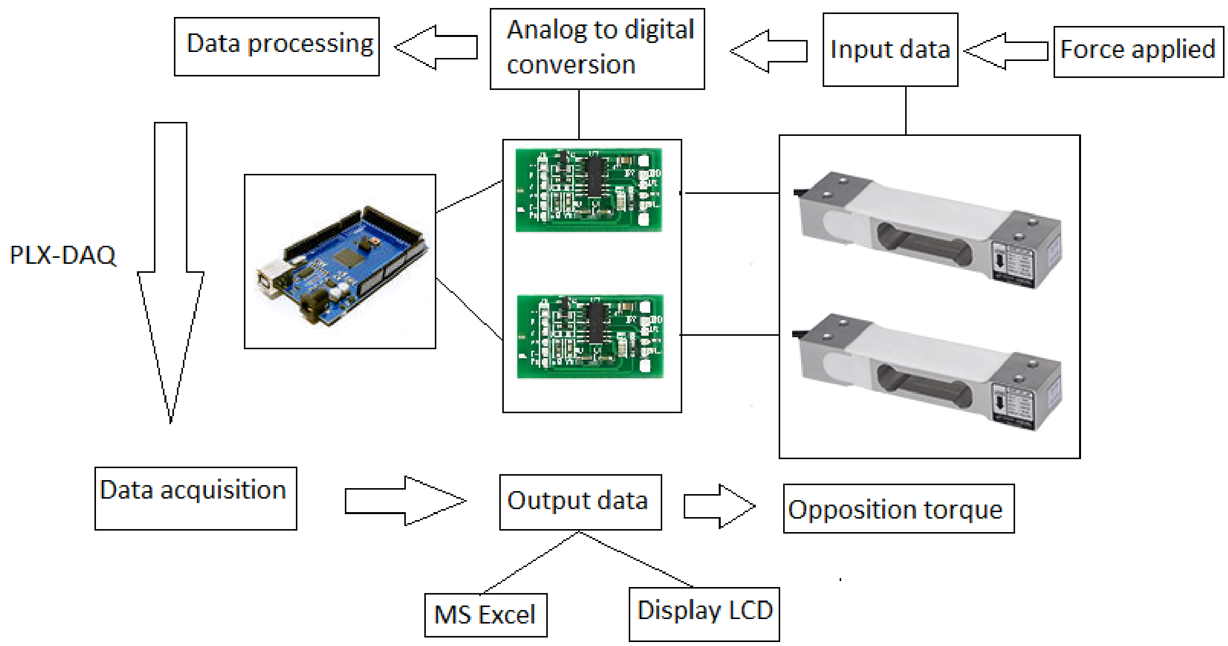
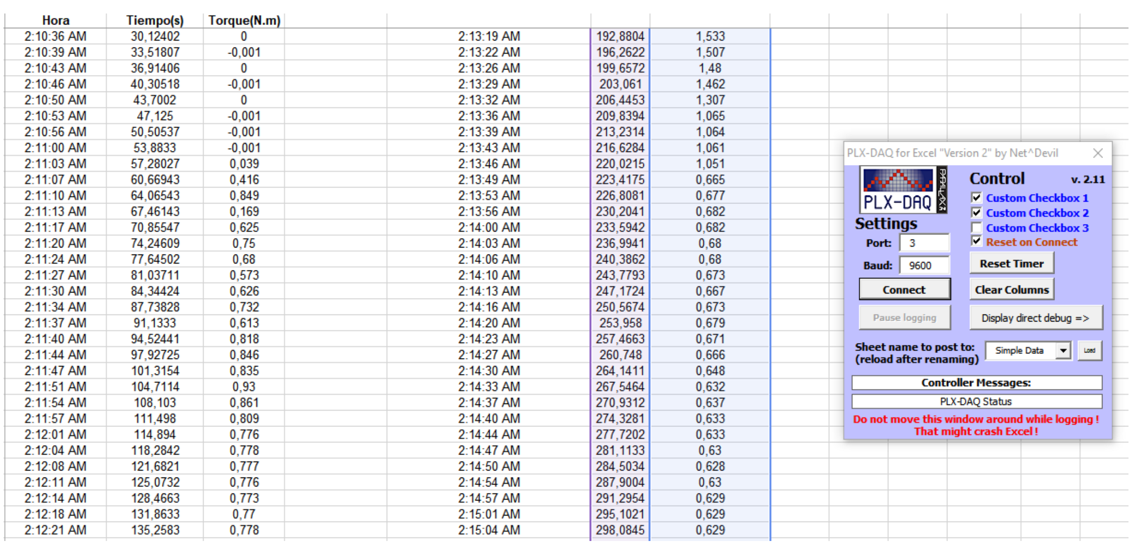


Figure 5. Scheme of the control system of torque measurement



Hora	Tiempo(s)	Torque(N.m)			
2:10:36 AM	30,12402	0	2:13:19 AM	192,8804	1,533
2:10:39 AM	33,51807	-0,001	2:13:22 AM	196,2622	1,507
2:10:43 AM	36,91406	0	2:13:26 AM	199,6572	1,48
2:10:46 AM	40,30518	-0,001	2:13:29 AM	203,061	1,462
2:10:50 AM	43,7002	0	2:13:32 AM	206,4453	1,307
2:10:53 AM	47,125	-0,001	2:13:36 AM	209,8394	1,065
2:10:56 AM	50,50537	-0,001	2:13:39 AM	213,2314	1,064
2:11:00 AM	53,8833	-0,001	2:13:43 AM	216,6284	1,061
2:11:03 AM	57,28027	0,039	2:13:46 AM	220,0215	1,051
2:11:07 AM	60,66943	0,416	2:13:49 AM	223,4175	0,665
2:11:10 AM	64,06543	0,849	2:13:53 AM	226,8081	0,677
2:11:13 AM	67,46143	0,169	2:13:56 AM	230,2041	0,682
2:11:17 AM	70,85547	0,625	2:14:00 AM	233,5942	0,682
2:11:20 AM	74,24609	0,75	2:14:03 AM	236,9941	0,68
2:11:24 AM	77,64502	0,68	2:14:06 AM	240,3862	0,68
2:11:27 AM	81,03711	0,573	2:14:10 AM	243,7793	0,673
2:11:30 AM	84,34424	0,626	2:14:13 AM	247,1724	0,667
2:11:34 AM	87,73828	0,732	2:14:16 AM	250,5674	0,673
2:11:37 AM	91,1333	0,613	2:14:20 AM	253,958	0,679
2:11:40 AM	94,52441	0,818	2:14:23 AM	257,4663	0,671
2:11:44 AM	97,92725	0,846	2:14:27 AM	260,748	0,666
2:11:47 AM	101,3154	0,835	2:14:30 AM	264,1411	0,648
2:11:51 AM	104,7114	0,93	2:14:33 AM	267,5464	0,632
2:11:54 AM	108,103	0,861	2:14:37 AM	270,9312	0,637
2:11:57 AM	111,498	0,809	2:14:40 AM	274,3281	0,633
2:12:01 AM	114,894	0,776	2:14:44 AM	277,7202	0,633
2:12:04 AM	118,2842	0,778	2:14:47 AM	281,1133	0,63
2:12:08 AM	121,6821	0,777	2:14:50 AM	284,5034	0,628
2:12:11 AM	125,0732	0,776	2:14:54 AM	287,9004	0,63
2:12:14 AM	128,4663	0,773	2:14:57 AM	291,2954	0,629
2:12:18 AM	131,8633	0,77	2:15:01 AM	295,1021	0,629
2:12:21 AM	135,2583	0,778	2:15:04 AM	298,0845	0,629

Figure 6. Excel data import through PLX-DAQ add-on tool

All the measurement and DAQ system is inside the box shown in the figure 2, where is connected a laptop through the Arduino to receive the information read.

The loads cells, as shown in the figure 7, perform the force reading at the point of average application, as shown in the figure 8, exercised by the foot in Newtons, which is located at the top of the foot's sole or center forefoot, as was studied by Zequera, Solomonidis, Vega, & Rondon, (2003).

Figure 7. Detail view of load cells supported on two points

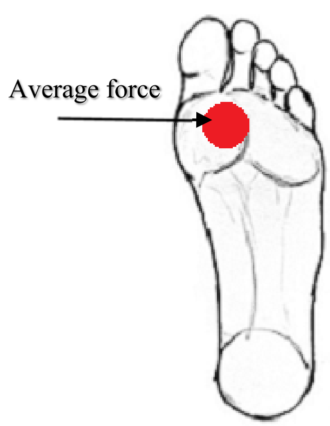


Figure 8. Point of major average force applied in the zone of the forefoot during gait

Then, taking the distance from the point of application up to the axis of rotation of the footplate are 0,9*PlantarFootLength-X, therefore the torque is defined as showed in figure 10.

Figure 9. Distance for torque measurement and point of average force application

Accordingly, to the figure 10, then, the torque is calculated using the equation (1). The result is showed in the MSExcel 2016 (Microsoft Corp.) program where:

$$Torque = F * (0,9 * \text{PlantarFootLength} - \text{x})\ [N.m] \qquad (1)$$

Where x is the distance between the ankle and the heel.

5 Validation of design

Design's validation of the device must be verified with the correct data collection by the load cells. Also, the satisfaction of both the customer and the physiotherapist while using the device.

5.1 Device performance

For the performance's evaluation of the device, two different of test were realized. The first, with a patient with spastic hemiplegia as a product of stroke, which will be called as user A and with 3 healthy people that will be called as user B1, B2 and B3. To find out if the therapy performed with device was successful, the torque measured at the end of the test should be lower than the torque initially measured. For user A, a 56-year-old male patient with left lateral paralysis, a test was performed with a dorsiflexion angle of 5°, as shown in figure 10. This was applied during 1200 seconds with an ice pack under the plantar flexor muscle.

Figure 10. Test performed with the patient A with the left foot

In this test with the user A, was evidenced a reduction of approximately 30% of the initial value of the torque of 2,9 [N-m] to 2 [N-m] was evidenced, as shown in the figure 11. The patient initially presented shake in the left lower limb when trying to bend the ankle in the sagittal plane, phenomenon that after applying the test disappeared. In addition, it partially improved the gait capacity in the place where the test was applied.

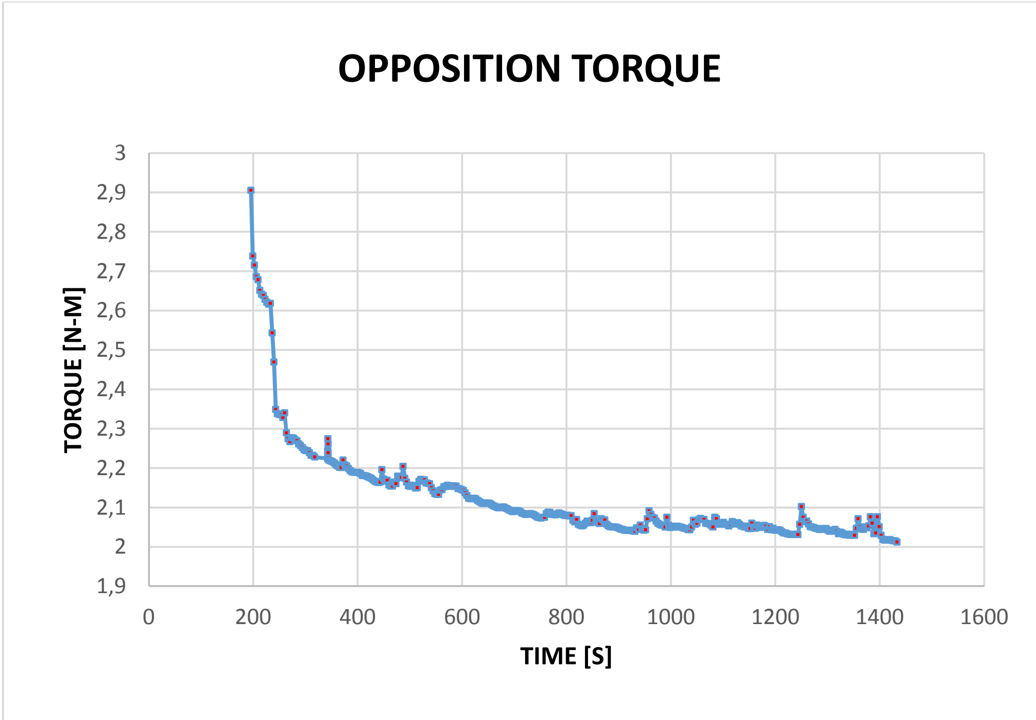


Figure 11. Opposition torque measured for user A during the test

For user B1, A healthy male user of 22 years, was performed the physiotherapy with the footplate at a dorsiflexion angle of 15°, as shown in figure 12, during a time of 1200 seconds.

Figure 12. Test with the healthy user B1 with the right foot

The results indicate a reduction of approximately 20% from an initial torque of 2.06 [N-m] to 1.62 [N-m], as shown in the figure 13, a smaller percentage respect to user A. This is due to patient illness, that presented initially contracted the muscle, showing a much greater reduction during the same time of therapy.

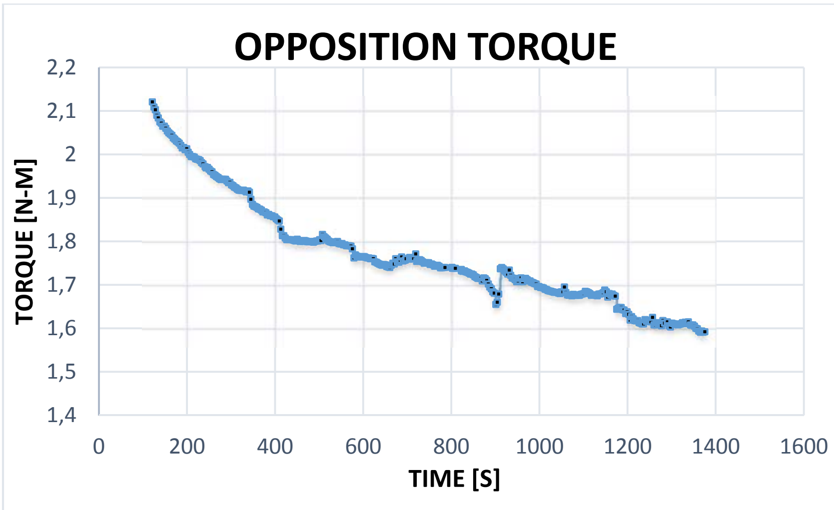


Figure 13. Opposition torque measured for the user B1

To corroborate the information about healthy users, two more tests were performed on female patients between 20 and 30 years old: user B2 and user B3, whose results are shown in figure 14, compared with the user B1.

Figure 14. Comparison of the opposition torque for healthy patients B1, B2 and B3 with and ice pack under the plantar flexor muscle.

Its observed similarity behavior between the results measured of the three users B1, B2 and B3, starting at values approximately of 2 [N-m] to 1,4 [N-m]. a reduction of 30% compared to the initial value, performing a satisfactory therapy with the muscle relaxation. These results indicated a good repeatability of the load cells, making a correct measurement for every test performed with the patients.

5.2 Customer satisfaction

To assess the satisfaction of both the users and the operators of the device, was created a personal satisfaction survey, where they rated each of the most relevant aspects of the device as very bad, bad, regular, outstanding and excellent.

The survey, contains questions for both the users and the operators, so certain questions were left unanswered in both cases. Two surveys were applied, one with the user A (See appendix B) and the other with the operator (See appendix C) of the device. The patient A, had an excellent assessment of the device, achieving almost a 95% satisfaction, emphasizing the requirements fulfilled as; versatility, safety and comfort. The operator, recognized the total functionality of the device, able to perform the opposition torque measurement, to indicate the degrees of footplate dorsiflexion, to provide safety in the patient by keeping the device in one position and to guarantee the realization of the therapy of sustained mechanical stretching.

6 Conclusions and recommendations

A device was designed and built that satisfactorily fulfilled the requirements and with validation it was verified that its use was suitable for patients with spastic hemiplegia. In addition, the results obtained in the tests conclude that sustained mechanical stretching therapy was performed correctly.

The patient A, achieved a reduction of approximately 30% of the initial value of the opposition torque from a value of 2,9 [N-m] to 2 [N-m] in the left ankle, with a dorsiflexion angle of 5°, making the patient lost the initially tremor, improving partially the gait capacity. The user A was satisfied in almost a 95% with the device, proving that it could be used in other patients, and get the same or better results.

With the test performed with a healthy male user of 22 years, was presented a reduction of approximately 20% from an initial torque of 2.06 [N-m] to 1.62 [N-m], a smaller percentage respect to user A. This is due to patient illness, that presented initially contracted the muscle, showing a much greater reduction during the same time of therapy. The curve describing the behavior of torque for healthy users B2 and B3 maintains the same pattern observed for user B1 starting at values of approximately 2 [N-m] to 1.4 [N-m]. A reduction of 30% compared to the initial value for the patient, performing a satisfactory therapy with the muscle relaxation.

The operator had an almost 89 % of satisfaction with the project, thus allowing its subsequent use to continue researching with the staff of the School of Physiotherapy of the UIS, on spastic hemiplegia as a product of stroke.

The Dorsiflexion angle performed after the therapy, was higher at least 2 ° respect to the value initially measured, achieving one of the most important objectives of the project.

It's recommended to put mechanical stops to limit the movement of the system and thus increase the safety of the application of the therapy, implement a lubrication system for the worm-crown mechanism. In addition, it's recommended to optimize the torque measurement system to obtain more accurate results.

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