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DISEÑO Y DESARROLLO DE UN SISTEMA DE MOVIMIENTO PASIVO CONTINUO PARA REHABILITACIÓN DE ESGUINCES DE MUÑECA

DESIGN AND DEVELOPMENT OF A CONTINUOUS PASSIVE MOTION FOR WRIST SPRAIN REHABILITATION SYSTEM

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Resumen: Esta investigación presenta el desarrollo de un prototipo de rehabilitación pasiva para esguince de muñeca que permite movimientos de flexión - extensión y pronación - supinación, basado en la metodología VDI-2206 de proyectos de mecatrónica aplicada. Aborda la definición de los requerimientos del sistema desde las áreas de conocimiento de ingeniería y medicina; posteriormente, detalla los resultados del diseño, análisis e implementación de los componentes mecánicos, electrónicos y explora la fabricación digital del prototipo, apoyada en herramientas disruptivas CAD / CAM / CAE, seguida del diseño e implementación de la aplicación de software de control de usuario. Finalmente, expone la validación descriptiva por parte de pacientes sin persistencia clínica y especialistas en fisioterapia en características de funcionalidad, seguridad, ergonomía, operatividad, cumplimiento de protocolos médicos, y la viabilidad económica de un prototipo de madurez TRL 6.

Palabras clave: *Diseño mecatrónico; esguince de muñeca; modelo dinámico; prototipo; rehabilitación de muñecas; rehabilitación pasiva; CAD/CAM/CAE, fabricación digital, control PWM.*

Abstract: This research presents the development of a passive rehabilitation prototype for wrist sprain that allows flection – extent and pronation - supination movements, based on the VDI-2206 methodology of applied mechatronics projects. Addresses the definition of the system requirements from the knowledge areas of engineering and medical; subsequently, it details the results of the design, analysis, and implementation of the mechanical, electronic components and explores the digital manufacturing of the prototype, supported by disruptive tools CAD / CAM / CAE, followed by the design and implementation of the user control software application. Finally, it exposes the descriptive validation by patients without clinical persistence and physiotherapy specialists in characteristics of functionality, safety, ergonomics, operability, compliance with medical protocols, and the economic viability of a TRL 6 maturity prototype.

Keywords: Mechatronic design; wrist sprain; dynamic model; prototype; wrist rehabilitation; passive rehabilitation; CAD/CAM /CAE, digital manufacturing, PWM control.

1. INTRODUCTION

The upper extremities can suffer different types of pathologies; some can cause significant limitations to people; The study presented by (Martinez Estupiñan, 2017), in a sample of 3314 patients shows that most sports injuries occur in the lower limbs (53%), followed by conditions in the upper limbs (47%). In the upper limbs, lesions sport predominant due to trauma, and they occur in hand with 6.3% and the elbow with 4.2%. Given the high prevalence of injuries in the upper limbs, it is essential to carry out clinical studies to diagnose and evaluate the appropriate treatment. The most frequent injuries are post-traumatic fractures or tendon injuries; According to studies in open fractures, 50.6% are at the level of the upper limb and 40% at the level of the wrist and hand (Compana et al., 2012). However, the percentage of open fractures at this level does not exceed 4.2%, the most frequent location being the phalanges (29.7%), followed by the carpal bones (1.6%) and the metacarpals (1, 5%) (Ceballos et al., 2004).

The hand constitutes an anatomical structure of vital importance for daily life activities, and the wrist is a fundamental area in its functional structure (Salamanca et al.,2014). Experts say the most frequent hand injuries are carpal fracture with 32%, wrist sprain with 30%, and phalanx fracture with 38% (Chabas and Legre, 2011). These affectations in this limb are due to the excellent mobility of the joints of the hand in daily activities, work, and sports, generating exposure to suffering injuries due to overuse or movements that go beyond the joint, thus overcoming the resistance of the ligaments, causing a sprain (Thomas and Zanin, 2016); in general, all hand injuries show a percentage between 6.6% and 28.6% of injuries to the upper limbs (Ootes et al., 2012). In Colombia, according to data from the second national survey on safety and health conditions at work, which includes the most recent statistical report of accidents at the national level, it mainly shows that 93.3% are related to activities of work and the 33.8% in manufacturing activities where hands with 26.1% occupy the first place in the report as the main body segment affected by accidents [Arias et al., 2014].

Most rehabilitation therapies are performed traditionally by specialists in physical rehabilitation; Today, this conventional process does not have enough tools or devices that meet the requirements for patient recovery due to the high costs of specialized machines in this area. However, there is equipment developed for the rehabilitation of the wrist and arm joint, such as the haptic robot with serial elastic activation functions designed by the Institute of Rehabilitation of Slovenia (Oblak et al., 2009) and the motor rehabilitation robot controlled from detection and filtering of myoelectric signals developed by researchers at the University of Hong Kong (Song et al., 2013). It is important to note that this type of development opens a great field of action for research and the creation of prototypes that contribute to rehabilitation.

According to the previously exposed problem, the development of a mechatronic prototype based on the VDI-2206 methodology is proposed, oriented to passive continuous movement physical therapy, consolidating the requirements in 3D design, mechanical analysis, electronic design, and software design, according to the needs of the physiotherapy area and the low-cost engineering implementation of the prototype. For the manufacture of the prototype parts, rapid prototyping is used, using CAD / CAM / CAE design and manufacturing software tools, CNC machine tools, electronic instrumentation, and stepper motor control, thus obtaining a prototype that contributes to the passive rehabilitation of wrist sprain injury, performing flection movements (a movement that varies between 70 to 90 degrees) - extent (with a range of motion between 0 to 75 degrees from a neutral point) (Medina Gonzalez et al., 2016) and pronation-supination (movement ranging from 0 to 90 degrees from the neutral point) (Vulliet et al., 2017). This continuous passive movement allows the joint to be subjected to a pre-established and controlled range of motion for a period determined according to the physiotherapy plan, preventing the patient from executing the exercises in the wrong way and making counterproductive efforts on the joints for the process of recovery (Rosero et al., 2001).

2. METHODOLOGY

The VDI-2206 mechatronic design methodology proposed by "The Association of German Engineers" (Verein Deutscher Ingenieure, VDI) supports the development of the proposed prototype and presents a practical guide for the systematic development of innovative mechatronic products (Gausemeier and Moehringer, 2003), See Fig 1. Initially, preliminary information is collected to establish and define the prototype requirements and thus make a first sketch of the design; Subsequently, with the help of CAD software (Computer-Aided Design), the mechanical design is made to model the prototype, and its static analysis is carried out through a CAE (Computer-Aided Engineering software) to determine the deformation of the materials. and thus obtain an approximation of the real model. The electronic design uses EDA (Electronic Design Automation) software to simulate the schematic and observe the behavior of electronic components. Finally, digital manufacturing is supported by CAM software (Computer-Aided Manufacturing), and the validation of the prototype encompasses descriptive statistical studies in non-clinical patients and physiotherapists.

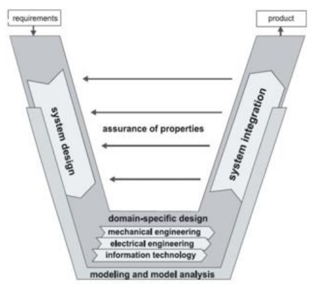

Fig 1. VDI 2206 methodology model. Source: [14]

2.1. Requirements

The preliminary research begins with the interview method, a flexible and dynamic resource (Diaz-Bravo et al., 2013), consisting of the preparation, development, and closure phases (Fig. 2), allowing biomechanical and anthropometric data collection for the design.

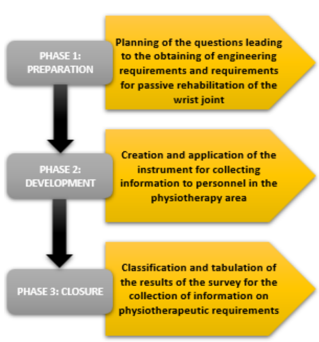

Fig 2. Interview phases.

Complementarily, the functionality, safety, hygiene, and ergonomics characteristics that the rehabilitation prototype for wrist sprain must has been managed, and finally, a first sketch is made.

2.2. Mechanical design

The mechanical design of the prototype follows the phases shown in Fig. 3; it presents a biomechanical analysis of the hand to define the limiting angles of the joints, to obtain the appropriate design that allows smooth and controlled movements. The prototype begins with creating each piece, such as supports for the hand, forearm, the main structure, couplings, and torque transmission systems using computer-aided design software tools.
The static analysis of the prototype is carried out employing a computer-aided engineering software tool - CAE, which simulates loads of 10 Newtons at critical points of the structure and mechanisms to determine the deformation and distribution of forces. Conducive to obtaining the factor of safety in the parts. These results support the materialization of the pieces through a computer-aided manufacturing software – CAM.

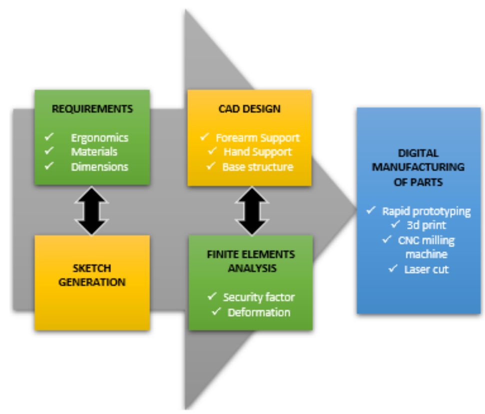

Fig 3. Sequence blocks of the mechanical design. Source: own

2.3. Electronic design.

The definition of the electronic components of the prototype is under the needs of the problem and the requirements of a closed-loop control scheme by feedback; The central control of the system oversees the free Arduino® Nano hardware development board, in the primary control elements oriented to the positioning of the prototype, position encoders, and infrared electronic instrumentation are integrated. The final control elements have a primary actuator, a Nema 23 stepper motor of 12.6 Kg/cm, together with a Tb6560 driver in charge of managing the direction of rotation and power of the motor. Finally, the integration between the system and the mobile interface is collected through the Bluetooth communication protocol. In Fig. 4, a block diagram of the relationship of the electronic system is presented.

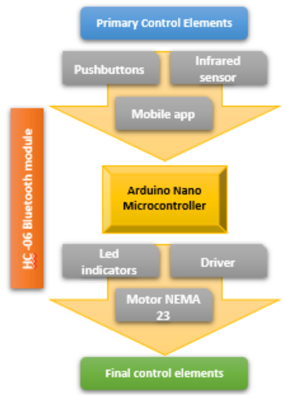

Fig 4. The electronic scheme in a block diagram. Source: own

2.4. Software design - Mobile application

The creation of the Android mobile application as a user interface adopts the methodology for the development of mobile applications Fig. 5 (Gasca Mantilla et al., 2014), allowing the control of the prototype from the requirements obtained through the advice of specialists in physiotherapy, this is carried out in the integrated development environment (MIT App Inventor), managing to offer benefits and characteristics in aspects of angle control, speed and cyclical duration in rehabilitation therapies.

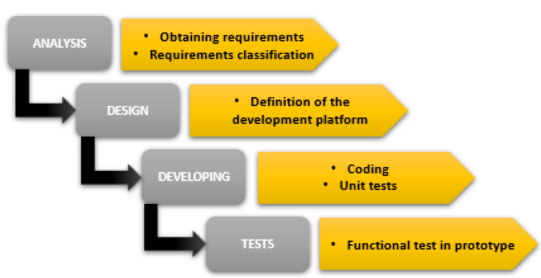

Fig 5. Methodology for the development of mobile applications. Source: own

2.5. Prototype validation

The validation of the prototype is based on descriptive surveys; as shown in Table 1 and Table 2, twelve questions are asked to specialists in physical rehabilitation and eight questions to patients. The criterion for conducting the surveys to patients without clinical persistence was given for the patient's safety, ethics, and well-being since the prototype is at a TRL 6 maturity level.

The surveys evaluate characteristics such as adaptation, safety, comfort, hygiene, functionality, quality, reliability, ergonomics, regular programming, speed control of movements, remote control system, and clinical feasibility. Each question has an evaluation score from 1 to 5 (1 Bad, 2 Fair, 3 Good, 4 Excellent, 5 Excellent). The people surveyed were thirteen (13) specialists in physical rehabilitation and thirty-five (35) patients without clinical persistence. A descriptive statistical analysis is performed through histograms and error bar analysis (Fernandez-Carreira et al., 2010) to find trends and the main behaviors related to the evaluated characteristics.

Table 1. Physiotherapist questions

Characteristic	Related question
1	Easy to use
2	Speed control
3	remote control system by mobile device
4	Movements (Flection - Extent)
5	Movements (pronation - supination)
6	Security
7	Ergonomics
8	Functionality (Physical control elements)
9	Functionality (User interface and equipment control)
10	Compliance with physiotherapeutic protocols
11	Routine programming
12	Equipment clinical feasibility

Source: own

Table 2. Patient questions

Characteristic	Related question
1	Easy adaptation (Physical structure)
2	Easy adaptation (Arm)
3	Security
4	Comfort
5	Hygiene
6	Functionality
7	Quality
8	Reliability

Source: own

3. RESULTS

3.1. Mechanical design

As a result of the mechanical design, following a pilot study of anthropometric measurements of the hand (Cerda Diaz et al., 2011), the 3D modeling of each one of the prototype pieces is obtained. The designed system comprises forearm supports, hand support, and base structure (See Fig. 6).

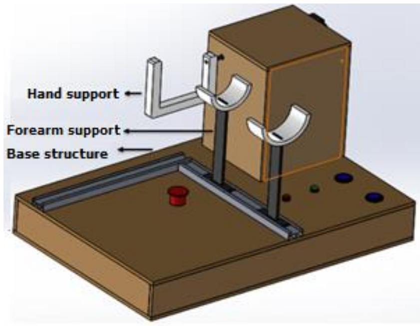

Fig 6. 3D assembly of the prototype. Source: Own

The static analysis is carried out on one of the most critical pieces of the prototype, this being the hand support, considering that the mass of a person's hand is equal to 0.6% of its total weight (Dempster, 1955), and taking into account Note that for a person of 68Kg, the mass of his hand will be approximately 1.13Kg, the results obtained using the polylactic acid polymer, better known as PLA, presents a deformation produced when it is subjected to a specific load of 10 Newton concerning the study parameters. In Fig. 7, it is obtained that the maximum deformation at the critical points is 0.61mm with respect to its natural state. This deformation does not compromise the physical structure of the prototype and its operation.

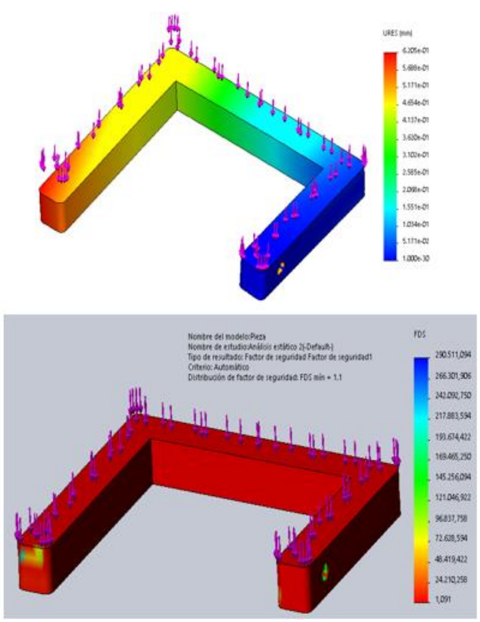

Fig 7. URES and FDS analysis for hand support. Source: own

3.2. Manufacture of the prototype

The digital manufacturing from obtaining parts in the Solidworks ® software is carried out through the CAM Repetir ® software and the disruptive 3D printing technology by fused deposition modeling - DFM of the supporting elements of the hand and forearm, as seen in Fig. 8. The structure of the prototype was made using CNC laser cutting technology to elaborate the base of the system with 9mm medium density fiber. For the forearm supports, 5.08cm x 0.31cm plates are used, subjected to CNC milling processes and electric welding, obtaining the final prototype as shown in Fig. 9.

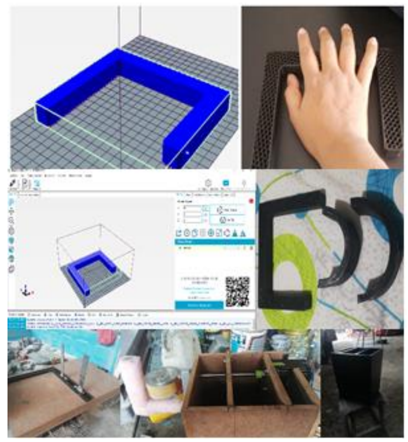

Fig 8. Digital fabrication of the hand support. Source: own

Fig 9. Final prototype. Source: own

3.3. Electronic design

The electronic system for the operation of the prototype is focused on the integration and conditioning of the electronic components and the Arduino® development board; the discrete input/output elements are used to adjust the neutral point of the movement that will perform the computer user—being the neutral point located by an infrared presence sensor. Likewise, the prototype has indicator lights to issue a visual warning of its Start / Stop operation. Finally, a simulation is carried out in EDA software to obtain previous results of the behavior of the selected electronic components such as NEMA 23 stepper motor model 57BYG250C, TB6600 driver, FC-51 infrared sensor module, and the HC-06 Bluetooth module (See Fig. 10).

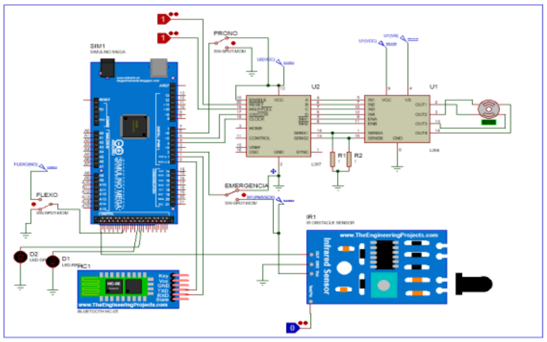

Fig 10. Electronic system in EDA software Source: Own

The control system implemented is a closed-loop delay control, the speed is controlled through the pulse width modulation (PWM) technique that allows modifying the frequency between a range of 100Hz to 1KHz of the applied clock signal to the motor driver.

Each pulse applied to it allows the motor shaft to rotate for each step 0.1125 degrees because the driver is configured at 1/16 step (See Fig. 11).

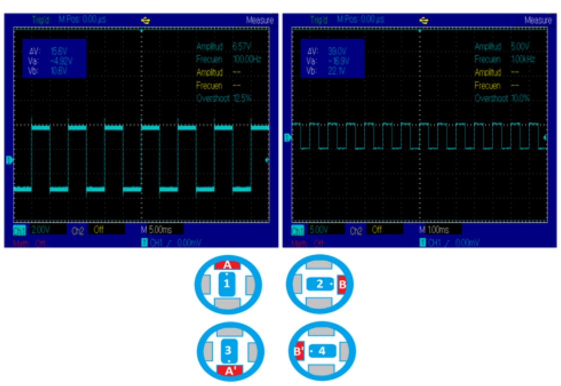

Fig 11. 100Hz to 100KHz frequency signal and motor coils. Source: Own

3.4. Mobile application

The command control interface is developed in a block-based programming language in the MIT App inventor ® environment. For the creation of the mobile application, the main parameters used in the realization of rehabilitation therapies are considered, data obtained from the advice of specialists, thus counting, with specific parameters for the set point of time of duration of the therapy, between one (1) minute to thirty (30) minutes, this being the maximum range available for the application, according to the physiotherapeutic needs. For the speed of the movements, the application has a slider to establish the speed setpoint between a range of 120 steps per revolution. To define the setpoint of the flexion-extension angles, there is a slider for entering the degrees. The flexion movement has a limit of 70 degrees and an extension of 85 degrees. Likewise, the angles of pronation - supination, where each movement has a slider whose limit angle is 90 degrees, a parameter subject to the patient's tolerance. The mobile application has three navigation screens: the initial screen, the flexion-extension screen, and the pronation-supination screen, as shown in Fig. 12.

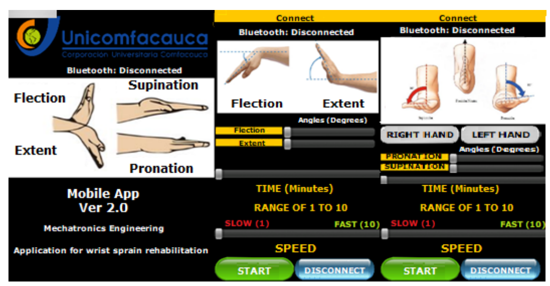

Fig 12. Mobile application. Source: Own

3.5. Prototype validation

In Fig. 13, the frequencies of the data obtained are observed. In Fig. 13 (a), a high frequency is received in the qualification of five (5) patients without clinical persistence of 61.1%. Likewise, the rating of three (3) is obtained as the lowest frequency of 11.4%. In Fig. 13 (b), a high frequency is obtained in qualification five (5) by rehabilitation specialists of 30.4%. Likewise, a rating of three (3) is accepted as the lowest frequency, 6.4%. These results allow establishing the prototype's compliance with the initial specifications.

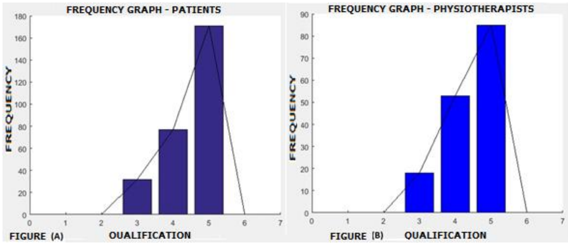

Fig 13. Histogram of frequency of (a) Patients (b) Physiotherapists Source: Owm

In Fig. 14, it is evidenced that the highest standard deviation was for the safety characteristics and clinical viability of the equipment, sharing a variation of 0.76, indicating that they are the two evaluation characteristics where the physical rehabilitation specialists had disagreements. The minor standard deviation is in the ergonomics parameter of the equipment, with a value of 0.64. The average is rated low by the ergonomics parameter of the equipment, with an average of 4.07. In contrast, the highest average is shared by the three characteristics of speed control of movements, movements within the anatomical range of the wrist (Flexion - Extension), and movements within the anatomical range of the wrist (pronation - supination), which share a mean of 4.61, this suggests that the equipment performs adequately with these characteristics, showing that the system is a functional prototype.

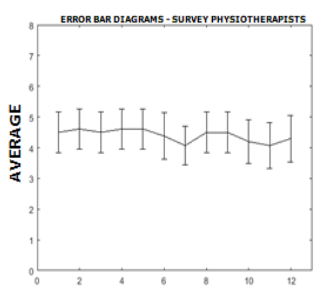

Fig 14. Physiotherapists survey error graphs. Source: Own

In Fig. 15, it is observed that the most significant deviation was in the hygiene characteristic with a value of 0.81, indicating the evaluation characteristic where the patients have more disagreements. The lowest deviation was in the functionality characteristic with a value of 0.59, being the characteristic with the minor qualification difference. The highest mean was the functionality characteristic, with a mean of 4.65. The lowest average rating was the comfort characteristic, with an average of 4.34 in its rating.

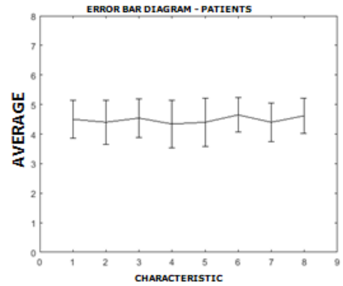

Fig 15. Physiotherapists survey error graphs. Source: Own

3.6. Project cost

Table 3. Project cost

Total cost estimated	USD $ 1.816,25
34.7%	Electronic Instrumentation
28.5%	Manufacturing Materials
5.5%	Hardware/ Software Integration
26.3%	Digital Fabrication
5 %	Mobile APP

Source: own

4. CONCLUSIONS

The design of the prototype in its hardware and software components through the development of CAD / CAM / CAE models facilitated the fulfillment of the engineering and clinical requirements, achieving a viable solution to the rehabilitation problem, allowing the execution of physical therapies with controlled movements. According to the patient's anatomy, the wrist and forearm joints are in different types of upper limb anthropometry. Thus obtaining a prototype with adjustable characteristics according to the parameters obtained, and with a validation of the mechanical design with minimal risks in structural or operational failures, evidenced in tests in a relevant environment in patients and physiotherapists, presenting a safety factor (FDS) greater than 1 in the hand support and the prototype structure.
The results of the evaluation of specialists and patients, obtained through statistical analysis, show a perception of approval with 61.1% in the rating of excellent by patients without clinical persistence and 40.4% by specialists in Likewise, physical rehabilitation leads to the need to build the prototype with innocuous materials to improve the

hygiene evaluation and obtain viability of the TRL6 maturity prototype for future applications in rehabilitation processes.

It is possible to develop a functional prototype at low cost with a TRL6 degree of maturity, which allows and facilitates through disruptive technologies and information and communication technologies, the physiotherapeutic processes in physical rehabilitation therapies in injuries or sprains in the joints of wrist and forearm, by programming and controlling flection, extent, pronation, and supination movements effectively according to clinical treatment.

REFERENCES

Arias, P. S., Gomez, D., and Terranova, O. E. L. (2014). Reduccion de accidentalidad en manos con el ciclo phva. Revista Colombiana de Salud Ocupacional, 4(2):34–36.

Ceballos, G., Gugliemo, G., B, F. C., Serrano, A., Duran, J., Castelli, B., and Quijada, J (2004). Experiencias con fijadores externos dynafix en fracturas abiertas.

Cerda Díaz, E., Cubillos Mariángel, N., Medina Silva, O., and Rodríguez Herrera, C. (2011). Estudio piloto de medidas antropometricas de la mano y fuerzas de prensión aplicables al diseño de herramientas manuales. Cienc. Trab, pages 1–5.

Chabas, J.-F. and Legre, R. (2011). Esguinces y luxaciones del carpo. EMC-Aparato Locomotor, 44(4):1–15.

Compana, F. J. P., Vidal, B. G., and Gasalla, J. V. (2012). Patologías frecuentes en la mano y la muñeca. FMC-Formación Médica Continuada en Atención Primaria, 19(8):463–471.

Dempster, W. T. (1955). Space requirements of the seated operator, geometrical, kinematic, and mechanical aspects of the body with special reference to the limbs. Technical report, Michigan State Univ East Lansing.

Díaz-Bravo, L., Torruco-García, U., Martínez Hernández, M., and Varela-Ruiz, M. (2013). La entrevista, recurso flexible y dinámico. Investigación en educación médica, 2(7):162–167.

Fernández-Carreira, J., Hernández- Vaquero, D., and Sánchez-Torres, M. (2010). Utilización de la estadística en cirugía ortopédica y traumatología. Trauma, 21(Supl 1):28–33.

Gasca Mantilla, M. C., Camargo Ariza, L. L., and Medina Delgado, B. (2014). Metodología para el desarrollo de aplicaciones moviles. Tecnura, 18(40):20–35.

Gausemeier, J. and Moehringer, S. (2003). New guideline vdi 2206-a flexible procedure model for the design of mechatronic systems. In DS 31: Proceedings of ICED 03, the 14th International Conference on Engineering Design, Stockholm.

Martínez Estupiñán, L. (2017). Lesiones deportivas en niños atletas. estudio de veinte años. MediSur, 15(6):819–825.

Medina González, C., Benet Rodríguez, M., and Marco Martínez, F. (2016). El complejo articular de la muñeca: aspectos anatofisiológicos y biomecánicos, características, clasificación y tratamiento de la fractura distal del radio. Medisur, 14(4):430–446.

Oblak, J., Cikajlo, I., and Matjacic, Z. (2009). Universal haptic drive: A robot for arm and wrist rehabilitation. IEEE Transactions on Neural Systems and Rehabilitation Engineering, 18(3):293–302.

Ootes, D., Lambers, K. T., and Ring, D. C. (2012). The epidemiology of upper extremity injuries presenting to the emergency department in the united states. Hand, 7(1):18–22.

Rosero, E. E., Martinez, R., and Galvis, E. (2001). Diseño y construcción de una máquina de movimiento pasivo continuo para la terapia de rodilla. Ingeniería y Competitividad, 3(2):56–64.

Salamanca, A. E. B., Fraile, D. M. F., Murillo, E. A. V., and Torres, S. C. D. (2014). Caracterización del desempeño en actividades de la vida diaria en adultos con lesión de miembro superior. Revista Ocupación Humana, 14(1):5–16.

Song, R., Tong, K.-y., Hu, X., and Zhou, W. (2013). Myoelectrically controlled wrist robot for stroke rehabilitation. Journal of neuroengineering and rehabilitation, 10(1):1–8.

Thomas, D. and Zanin, D. (2016). Rehabilitación de la muñeca lesionada. ˜ EMC-Kinesiterapia-Medicina Física, 37(2):1–17.

Vulliet, P., Chervin, J., Pierrart, J., Bourdillon, E., and Masmejean, E. (2017). Patologías del codo y rehabilitación. EMC. Kinesiterapia-Medicina Física, 38(2):1–18.