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Healthcare Technology for Social Change: Development of an Innovative Rehabilitation Device

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ABSTRACT

This research aimed to develop an affordable device for the elbow and forearm rehabilitation to be used in Brazilian hospitals, clinics, physician's offices, and residences. The Brazilian government made investments in technology development for social change, demanding innovative rehabilitation products manufactured with lower cost, compared to the current imported alternatives. Using research through design, we present the development of a module that allows continuous passive motion (CPM), which is a physical therapy resource indicated mainly for post-traumatic and post-surgical rehabilitation. This paper describes all design phases that resulted in this technological device with an important social impact on health care, making CPM treatment accessible to a broader range of patients. The module's design fully contemplated Stakeholders' needs, resulting in a working prototype. It was validated with users, producing the intended effects. The product is fully manufactured in Brazil and costs a fraction of the equipment currently used. The design presented in this paper opens a number of future research possibilities in the field of social innovation through health technology.

KEYWORDS

Health Care Technology;
Technological Innovations;
Continuous Passive Motion Therapy;
Elbow and Forearm Rehabilitation

Tecnologia de Saúde para a Mudança Social: Desenvolvimento de um Dispositivo Inovador de Reabilitação

RESUMO

Esta pesquisa teve como objetivo desenvolver um dispositivo economicamente acessível para a reabilitação de cotovelo e antebraço, para ser usado em hospitais, clínicas, consultórios médicos e residências brasileiras. O governo brasileiro realizou investimentos em desenvolvimento de tecnologia para mudança social, demandando produtos de reabilitação inovadores fabricados a um menor custo, se comparados com as alternativas importadas atualmente disponíveis. Usando pesquisa através do design, este artigo apresenta o desenvolvimento de um módulo que permite o movimento passivo contínuo (MPC), que é um recurso de fisioterapia indicado principalmente para reabilitação pós-traumática e pós-cirúrgica. O artigo descreve todas as fases de design que resultaram nesse dispositivo tecnológico com um importante impacto social nos cuidados de saúde, tornando o tratamento através do MPC acessível a uma gama mais ampla de pacientes. O design do módulo contemplou plenamente as necessidades das partes interessadas, resultando em um protótipo funcional. Ele foi validado com usuários, produzindo os efeitos desejados. O produto é totalmente fabricado no Brasil e custa uma fração do equipamento importado atualmente utilizado. O design apresentado neste artigo abre uma série de futuras possibilidades de pesquisa no campo da inovação social através da tecnologia da saúde.

PALAVRAS-CHAVE

Tecnologia de Saúde;
Inovações Tecnológicas;
Terapia de Movimento Passivo Contínuo;
Reabilitação de Cotovelo e Antebraço

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1. INTRODUCTION

Information technology and the development of sophisticated devices have promoted technological advances in the area of healthcare, expediting the treatment and prevention of several diseases (JUNG et al., 2015; LIBERATI et al., 2015). The development of new medical technologies increases the quality of services provided to patients, improving their well-being (CHAU; MOGHIMI; POPOVIC, 2013). In such research context, health and rehabilitation technology as well as innovation are important emerging research topics (KOLOMINSKY-RABAS et al., 2015; PEINE; MOORS, 2015).

Many workers suffer from musculoskeletal disorders (GRATALOUP et al., 2016). Elbow injuries are commonly reported in ergonomics studies related to musculoskeletal disorders, a major cause of disability across many industrial groups (JANOWITZ et al. 2006; LOWNDES; HEALD; HALLBECK, 2015). The high costs of disability and loss of productive work time associated with disabling health conditions demand significant improvements in health care strategies, especially in those aimed at helping patients return to work (GROSS et al., 2016). The elbow rehabilitation plays an important role in functional recovery of the normal activity. To rehabilitation professionals such objective may be challenging, since treatment has to be continuously planned and adapted to the needs of each patient, often in the same cycle of rehabilitation (FUSARO et al., 2014).

Several technologies are used to support the rehabilitation process, such as assistive technologies (WINKLER et al., 2010; CHAU; MOGHIMI; POPOVIC, 2013), robots and neuromodulation devices (HESSE et al., 2011), Continuous Passive Motion (CPM) devices (BARLOW; STEINMANN, 2010; CALLEGARO et al., 2015; MAVROIDIS; NIKITCZUK; WEINBERG, 2005; MAZZER, 2001), and local muscle vibration equipment (CAMEROTA et al., 2013). CPM is a physical therapeutic resource particularly indicated for post-traumatic and post-surgical rehabilitation, which may be performed using a CPM device. Automation of CPM increases the Range of Motion (ROM) precision, while shortening the time programmed for the treatment, providing rapid feedback and decreasing the need to perform repetitive motions by the physical therapist. CPM devices have been developed both for the lower and upper limb joints (O'DISCROLL; GIORI, 2000; PLESSIS et al., 2011; SALTER et al., 1984). The trained physical therapist programs and controls such devices in accordance with the treatment objectives for each patient (CALLEGARO et al., 2015; MAVROIDIS; NIKITCZUK; WEINBERG, 2005; MAZZER, 2001).

CPM devices to rehabilitate the elbow and forearm are not produced in Brazil. Importing procedures and taxes may increase the costs such type of device, inhibiting several health clinics and hospital to offer affordable treatment to many patients. Studies on the design of such devices are scarce and restricted to academic works (MAVROIDIS; NIKITCZUK; WEINBERG, 2005; MAZZER, 2001). Consequently, companies and government view the local development of products and processes technology aimed at producing CPM devices to serve the domestic and international markets as an opportunity.

The development of technological innovation in health products has been fomented by the Brazilian government. The National Policy for Health Technology Management (PNGTS - Política Nacional de Gestão de Tecnologias em Saúde), valid since 2009, is intended to maximize the health benefits to be obtained from the available resources, ensuring the population equitable access to safe and effective technologies (MINISTÉRIO DA SAÚDE, 2009).

Industrial Engineering tools, particularly those in the area of Project Management, may assist ergonomists and designers in managing the development of innovative products. Product development reference models, methodologies, and tools may be used to improve the effectiveness and efficiency of product development processes, as well as the technology itself (DONALDSON; ISHII; SHEPPARD, 2006; MONTGOMERY, 2008). Resulting products displaying a higher quality level, aligned with the needs of stakeholders (KUIJK; DRIEL; EIJK, 2015), are more likely to experience market success (ANA et al., 2013).

Using research through design, this research aimed to develop and validate an affordable CPM module for the elbow and forearm rehabilitation to be used in Brazilian hospitals, clinics, physician's offices, and residences. Our objective is aligned with the Brazilian Government's guideline to invest in technological innovation, the demand for products to rehabilitate the elbow and forearm, and the need for research that explores parameters of operation and effects of CPM in elbow and forearm rehabilitation, as well as its use in combination with other physical therapy methods. It is important to remark that the CPM module is part of a new product intended to be superior to existing equipment manufactured abroad, lowering the production cost; the design of such new product could be classified as incremental innovation (NEXON; UBL, 2010).

The following content is structured in six sections: background (section 2); materials and methods, describing the reference model used in our product development (section 3); results, indicating step by step the development of the rehabilitation device (section 4); validation (section 5); discussion (section 6); and conclusions (section 7).

2. BACKGROUND: CONTINUOUS PASSIVE MOTION (CPM) DEVICES

The elbow is the intermediate articulation of the upper limb. It is often affected by injuries (NORDANDER; OHLSSON; ÅKESSON, 2013), and especially prone to joint stiffness. This joint is affected by repetitive strain injuries (RSI) or work-related upper extremity disorders (WRUEDs) (NIU, 2010; QIN; CHEN; DENNERLEIN, 2013; VARATHARAJAN, 2014), an activity-related musculoskeletal complaints syndrome of the upper extremities that eventually leads to the reduction of work capacity (GALEN; LIESKER; HAAN, 2007).

The elbow has two Degrees of Freedom (DoF) of movement: Flexion/Extension (F/E) and Pronation/Supination (P/S). The humeroradial and humeroulnar articulations enable the F/E movements of the elbow; the proximal radioulnar and the distal radioulnar joints are responsible for the P/S movements of the forearm (ALCID; AHMAD; LEE, 2004). The flexion is the movement that regulates the anterior surface of the forearm in its contact with the anterior surface of the arm. The active amplitude of that movement varies from 140° to 145°, while the passive reaches 160°. The amplitude of physiological extension is 0°, considering the reference position in which the axis of the forearm coincides with the axis of the arm. The principle movements of pronation and supination – which occur in the proximal radioulnar joint – are the rotation of the radial head and, in the distal radioulnar joint, the translational movement of the lower end of the radius around the ulna. The neutral position of the forearm happens when the thumb of the hand is directed upwards, with supination amplitude of 90°, and pronation amplitude of 90° (KENDALL; MCREARY; PROVANCE, 1993).

When an elbow or forearm surgery is a need, in the initial phase of rehabilitation the objectives are to contain the effects of immobilization, and to avoid excessive stress on the scar tissue, thus satisfying specific clinical criteria before moving to the next phase of rehabilitation. The rehabilitation plan should be based on up-to-date clinical and scientific evidence that must be adapted to each patient, according to specific needs

(FUSARO et al., 2014). CPM devices are tools used in the elbow and forearm rehabilitation process. There are patents of CPM devices for the elbow and/or forearm rehabilitation registered, especially in the United States (CALLEGARO; JUNG; TEN CATEN, 2011); however, such devices have never been produced in Brazil (MAVROIDIS; NIKITCZUK; WEINBERG, 2005; MAZZER, 2001).

CPM devices have been developed both for the lower and upper limb joints (O'DISCROLL; GIORI, 2000; PLESSIS et al., 2011; SALTER et al., 1984). CPM studies addressing the knee (HERBOLD et al., 2014) and shoulder (GAROFALO et al., 2010; PLESSIS et al., 2011) joints are more advanced than those addressing the elbow. However, results found in those studies are controversial, depending on the joint and type of injury or surgery under study. Parameters such as speed, time, and ROM are not clearly indicated, leaving room for the investigation of procedures that are appropriate for each kind of treatment (PLESSIS et al., 2011; HERBOLD et al., 2014; BOESE et al., 2014). Literature on the application of CPM to the elbow joint showed that it has been used for the treatment of contracture (ALDRIDGE et al, 2004; BREEN; GELBERMAN; ACKERMAN, 1988; LINDENHOVIUS et al., 2009; LIU; WU; CHANG, 2011; STEINMANN, 2007), joint stiffness (CHARALAMBOUS; MORREY, 2012), heterotopic ossification (CHEN ET AL., 2009), total arthroplasty (DEMIRALP et al., 2008), fractures (REMIA; RICHARDS; WATERS, 2004), and ligament injuries of the joint (STEINMANN, 2007). In those studies, CPM was used in association with other physical therapy resources; they showed positive results, especially when used after elbow contracture surgery and to treat joint stiffness (MAVROIDIS; NIKITCZUK; WEINBERG, 2005; MAZZER, 2001).

3. MATERIALS AND METHODS

This study is characterized as research through design, using qualitative and quantitative methods. The development of a functional prototype of a CPM device for elbow and forearm rehabilitation is presented. Recommendations from the Reference Model for Product Management and Development were used when developing the device (ROZENFELD et al., 2006). The Reference Model starts with the identification of market needs, technological constraints and possibilities, and the company's strategic guidelines; with that information at hand, the goal is to create design specifications for the product and its production process such that the company is capable of producing it. In our study the initial macro phases of pre-development and development, deployed in their operational steps, were carried out and reported (Figure 1).

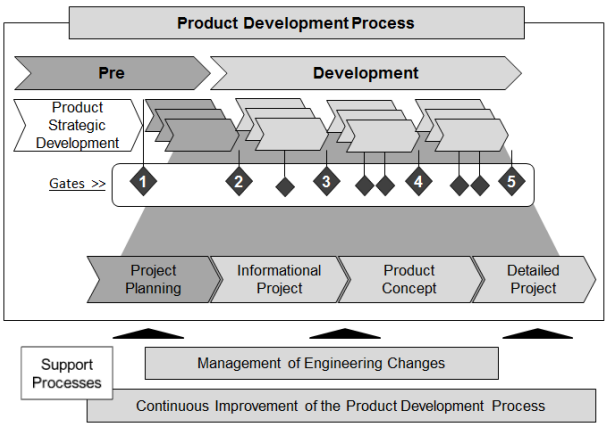

Figure 1 Initial phases of the Reference Model proposed by Rozenfeld et al. (2006).

The pre-development phase involves the product's strategic planning. The project plan, resulting from this phase, explains the project scope, activities and duration, schedules, budget, human resources, specifications of criteria and procedures for quality assessment, risk analysis, and performance indicators for project and product. The development phase involves the informational, conceptual and detailed designs, reported in this paper, in addition to the prototype generation.

The informational design includes the identification of the product requirements, and consequently, the product specifications. Quality Function Deployment (QFD) and Costumer Value Chain Analysis (CVCA) were used to gather and manage information on customer requirements (CALLEGARO et al., 2015).

The conceptual design concerns the determination of functional structures and the overall function of the CPM module; with this information, alternative constructive and technological solutions are created to provide the expected product functions. The best solutions are checked for viability and adherence to objectives. Solutions are detailed on technical information sheets defining systems, subsystems, and components of the product. All this information enables the product design definition.

The operating procedures are obtained from the detailed project, which was prepared from the CPM module architecture. This activity when completed results in the detailed specifications of the systems, subsystems and components, final models with tolerances, product structure, process plans, and functional prototype design. The functional prototype was subjected to laboratory and field tests (the latter with human subjects); for shortness, test results will not be presented here.

4. RESULTS

The development of the functional prototype of a CPM module to be used in an innovative device for the elbow and forearm rehabilitation, in accordance with the Reference Model (ROZENFELD et al., 2006), follows the sequence of gates presented in Figure 1, which is detailed in Figure 2 and in the sections to follow. Gates are verification points in which outputs of a given stage are audited to be used as inputs in subsequent stages. In this section, we also present the concept and working prototype of the device, including the module for localized muscle vibration.

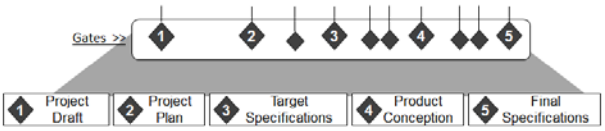

Figure 2 Sequence of gates in the Reference Model for the Management and Development of Products (adapted from ROZENFELD et al., 2006).

4.1 Gate 1: Project draft

The project draft is the input for the pre-development macro phase. The draft outlines the strategic planning for the development of the project; see Table 1. The project draft was developed considering a market opportunity identified (CALLEGARO et al., 2015), and the willingness to foment cooperation between university (that generates knowledge), industry (that utilizes that knowledge to design products) and government (that supports innovation by means of fiscal incentives and research financing).

Table 1: Project draft.

General Ideas	An opportunity was identified in the area of rehabilitation of the upper limbs of the human arm to develop equipment to rehabilitate elbow and forearm joints, and adjacent soft tissues.
Focus	A market exists for service providers of orthopedic, traumatological, and neurological rehabilitation of upper members. There are no locally developed technological CPM equipment designed for the rehabilitation of elbow and forearm that could be used in hospitals, clinics, physician's offices, and residences.
Objectives and targets	The objectives of the project are: (i) to develop a CPM* model for the rehabilitation of elbow and forearm to fulfill the identified market demand; and (ii) ignite research on the development of rehabilitation products.
Guidelines	The project is supported by UFRGS** and receives funding from the governmental sponsoring agency CNPq***. A patent of the utility model will be deposited. Partnerships with University laboratories and private companies should be fomented.

*CPM - Continuous Passive Motion; **UFRGS – Federal University of Rio Grande do Sul; ***CNPq – National Council for Scientific and Technological Development

4.2 Gate 2: Project plan

Brainstorming sessions with the Project team were carried out to define the project's scope (GRAY; BROWN; MACANUFO, 2010).

Team members were defined; the project was deemed feasible given the available financial and time resources. The product scope defined characteristics and functions that the product should possess when completed; see Table 2.

4.3 Gate 3: Target specifications

The device's technical requirements are derived from the joint application of CVCA and QFD (CALLEGARO et al., 2015). Stakeholders' requirements in terms of specified quality were translated into the device's technical specifications as quality characteristics. Additional technical requirements identified in studies carried out previously on the CPM module were also added. Technical requirements and the related product target specifications are presented in Table 3.

Table 2: Project plan.

a) Project Team Composition	Competence and Skills
Project Manager	Physical Therapy Industrial Engineering
Advisor	General Advice Bureaucratic Matters
Advising Support	General Advice Industrial Engineering
Master Student	Industrial Engineering Electronics
Research assistants	Mechanical Engineering Computer Aided Design (CAD)
Laboratory assistants	Control and Automation Engineering

b) Scope Management

Bi-weekly meetings

Methods: Updates and alterations of scope must be communicated to the Project Manager and feasibility of scope alterations discussed with team, for subsequent approval.

c) Product Scope Technical Requirements	Specifications
Dimensions or Volume	Compact
Mass	Light (< 20 kilograms)
Anthropometric Adjustment	Perimeter and length of human arms
Thermal Insulation	Plastic, Cloth
Speed of Movement	Slow (Numerical value unknown at present)
Functions	**Specifications**
Passive Movement	Unknown at the time
Activation and Control	Unknown at the time
Equipment Support	Unknown at the time
Arm Support	Unknown at the time
Forearm Support	Unknown at the time
Protection	Unknown at the time
Budget	US$ 394.00/month

Table 3: Target specification.

Equipment's technical requirements	Target specifications
Type of innovation (radical or incremental)	Incremental
Points of Risk (%)	< 10
Size of the compact equipment (cm)	<70 × 70 × 150
Degree of aesthetic acceptability of the equipment (%)	> 70
Percentage of comfortable, breathable, and non-allergenic (%)	< 30
Resistance to cleaning products (%)	> 50
Useful life (years)	3 to 10
Quality Standards (%)	> 75
Equipment mass (grams)	< 1500 grams
Percentage of parts with guaranteed reposition (%)	> 50
Level of maintainability (%)	> 50
Ease of storage (%)	> 50
Modular systems (number of parts)	2 – 6
Percentage level of easiness in assembly, installation, settings, adjustment, and use	>50
Forearm anthropometric adjustment (cm)	17 – 23 cm
Height adjustment (cm)	70 – 150 cm
Level of confidence in the system and its movements (%)	> 75
Index of effective performance	>90 %
Range of the passive Flexible/ Extension movement (°)	0 – 160
Range of the passive Pronation/ Supination movement (°)	-90 – 0 – 90
Range of movement (grades/ seconds)	4 – 5
Number of functions	1 – 3
Number of body articulations that can be applied to	1 – 3
Percentage level of compatibility with other equipment	>50

4.4 Gate 4: Product conception

To conceive the CPM module's design, the device's functions were defined starting with the global function, which is to produce continuous passive movement. To provide the functions expected from the device, solution principles were proposed. Table 4 gives the best solutions selected by the team.

Solution principles were combined, and the main concepts were studied; the ones deemed economically and functionally feasible were used to produce alternative designs using a Computer Aided Design (CAD) software. The solution that best met the stakeholders' requirements and suited the outstanding solution principles (in bold type) in Table 4 for each function is the one depicted in Figure 3.

In parallel with the study of conceptual design, concurrent engineering was applied once product specifications were available. Among the sequential activities developed, the following are worth citing: (i) analysis of systems, subsystems and components; (ii) definition of ergonomics and aesthetics aspects of the product; (iii) definition of suppliers and partners for development; (iv) definition of macro-process plan; (v) updating of the economic viability study; and (vi) documentation of decisions taken and recording of learned lessons.

Table 4: CPM module's functions and solution principles.

Function	Solution Principles		
	1	2	3
Production of CPM	**Motor DC with brushes**	DC Motor (Servo Motor)	Stepper Motor
Motor Drives	**H-Bridge Power driver**	Direct Coupling	Driver
Motor Control	**Feedback with potentiometric sensor**	Servo Motor internal control network	Open wire network
Control hardware	**Micro-controller (*Arduino*)**	National Instruments (Labview) Data Acquisition System (DAC)	Matlab software with micro-control interface
Equipment Support	Base with brakeless wheels	Base with wheels and brakes	**Base with two braked wheels and two fixed supports**
Arm support	PVC Support	**Aluminum support**	Steel Support
Forearm Support	Joystick	Hand brace	**Brace for hand and fist**
Forearm support length adjustment	Overlapping rods adjusted with pressure lever	**Screw-adjusted overlapping rods**	Overlapping rods with pre-defined pressure adjustment
Height adjustment	Overlapping rods adjusted with pressure handle	**Overlapping rods adjusted with threaded handle**	Overlapping rods with pre-defined pressure adjustment
Protection of the belt and pulley system	Aluminum protective cover	**Polyethylene protective cover**	Steel protective covert

Figure 3 Prototype of the CPM module (parts are identified in the figure)

4.5 Gate 5: Final specifications

Operational procedures were detailed, starting with the chosen CPM module's architecture. The project's working prototype was designed and built to carry out tests in laboratory and with human subjects. Information on the device's design was gathered, and systems, subsystems, and components were defined, as shown in Figure 4.

To drive and control the F/E (Flexible/Extension) and P/S (Pronation/Supination) movements of the CPM module, a system consisting of a power source, microcontroller Arduino, H-bridge driver, and DC motors was conceived. The H-bridge driver connects the electronic parts to the motors that power the movements of the equipment's axes related to the elbow and forearm joints, in accordance with commands of the device's operator. The DC motors used in the prototype are rated at 3.5 revolutions per minute per volt (rpm/V). The angular speed of movement of the elbow and forearm axes was set to five degrees/second (5°/sec).

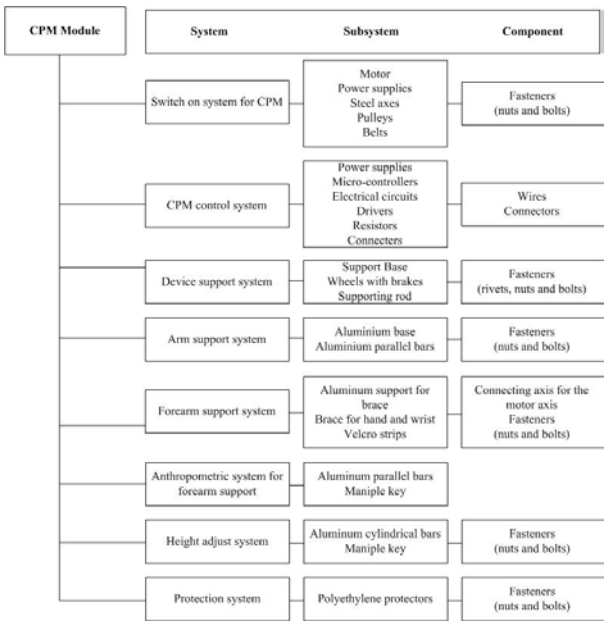

Figure 4 Systems, Subsystems, and Components of the CPM module

All device parts in contact with the patient are insulated, and the system is powered with low voltage (12 Volts) direct current. Furthermore, to ensure patient's safety mechanical stops are placed at the physiological limits of the passive ROM for the P/S forearm and for the F/E of the elbow. Material resistance tests and ergonomic improvements to provide comfort and security for users were carried out with the prototype. Some examples were shown in Figure 3, such as the protection of pulleys and belts, and the use of wider straps in the muscle vibration module located on the patient's arm, avoiding the discomfort caused by the pressure of thinner Velcro restraints.

Figure 5 Control box screens for the CPM module, illustrating the values to be supplied by the physical therapist: a) value (in degrees) of the initial angle, b) value (in degrees) of the final angle, and c) elapsed time (in minutes) between initial and final angles.

The new device depicted in Figure 3 has a feature that makes it unique: a localized muscle vibration module that helps the rehabilitation process (CAMEROTA et al., 2013). That feature was explored in another study, not yet published.

5. VALIDATION

5.1 Participants

The sample consisted of 12 individuals (6 males and 6 females, ages 18-35) who voluntarily took part in the study, signing a Free and Informed Consent Term.

The sampling was non-probabilistic, using the network of contacts of the researchers. The inclusion criteria were absence of dysfunctions in the upper limbs or affecting these limbs; age range between 18 and 40 years; having anatomical and physiological structures of the upper limbs intact (without external injuries or diagnosed internal lesions). Exclusion criteria were cardiovascular, neurological, orthopedic, or traumatological diseases in the upper limbs; sequelae of any of these diseases that affect the cognitive ability or the physical capacity of the upper limbs; diagnosis of any other disease(s) that impede the performance of physical activities; and metal material in the arm (prostheses, screws, pins, or plates).

5.2 Experiments

The validation experiments considered the following independent variables: (i) frequency, in three levels (60, 80, and 100 Hz); (ii) treatment at two levels (I - localized muscle vibration and II - localized muscle vibration associated with Continuous Passive Movement - CPM) (ROLL et al., 1989); (iii) gender, at two levels (male and female); and (iv) application (pre- and post-treatment). Each of the vibration frequencies was tested in four individuals (two males and two females). The variables time and place of application were constant.

In treatment I, the upper limb was maintained relaxed, supported at 90 ° of elbow flexion, with the forearm in neutral position. The localized muscle vibration module was fixed by means of a tissue clamp fastened by a velcro (Figure 6).

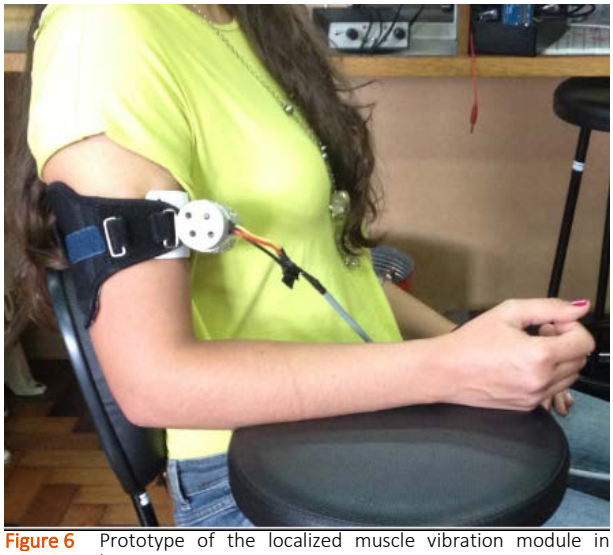

Figure 6 Prototype of the localized muscle vibration module in human test.

The spot of application of localized muscle vibration was on the skin, in the muscular belly of the upper biceps muscle of the dominant upper limb, which was the right upper limb for all individuals. The vibration time was 30 minutes (three 10-minute repetitions, with one-minute intervals between them).

The localized muscle vibration module was previously calibrated, using the model accelerometer 4632-020-060 (Measurement Specialties) and Labview software (version 2009). As acceleration is directly proportional to frequency, it was between 8.8 and 9.0 m/s2, within the allowed limit (<12 m/s2), considering that it was a daily application of 30 minutes (Pelerme, Wasserman, 2000). The displacement was in the range of 0.3 and 1.25 millimeters for the frequencies of 80 to 120 Hz.

Treatment II lasted thirty minutes. It was applied in the dominant upper limb of the subject rested on the arm support (Figure 7).

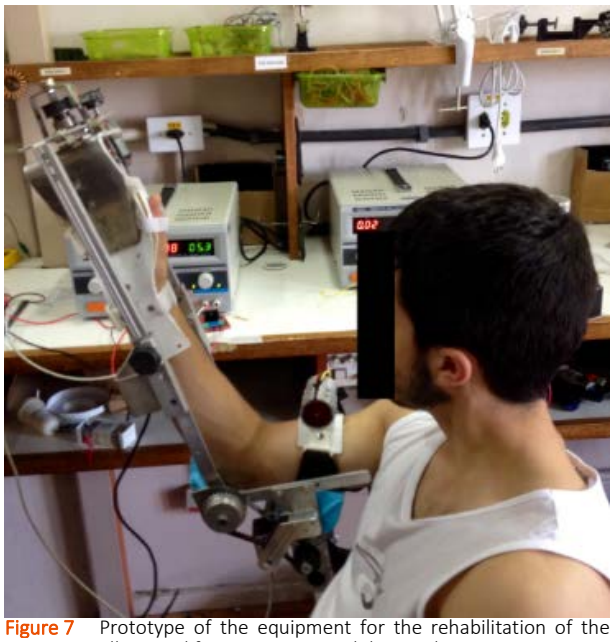

Figure 7 Prototype of the equipment for the rehabilitation of the elbow and forearm in test with human beings.

The forearm in neutral position was moved passively in a ROM ranging from 0° extension to 100° elbow flexion, in a comfortable range for each subject. No 0° extension was used for individuals who did not feel comfortable or performed compensations on the shoulder, due to their anatomical characteristics. For this purpose, the goniometry of the flexion and extension movements of the elbow of the dominant limb were evaluated, and the equipment was tested for Range of Motion (ROM) previously measured. After the initial and final ROM, values were supplied to the equipment.

5.3 Data Collection and Analysis Procedures

The evaluation of the test protocol was performed in two moments: pre-application and post-application of each treatment (I and II). Electromyography (EMG) was used to collect the electromyographic signal of the brachial biceps muscle, aiming at identifying muscular electric activity and subsequent comparison of pre and post-application values, intra and inter-treatments (WILLMORE; COSTILL, 2001).

EMG is a technique that allows the recording of the electrical signals generated by the muscular action. Muscle action is a consequence of neuronal activation that refers to the depolarization of the neuron's interior at about 20 millivolts (mV) in relation to the extracellular potential, called action potential (WILLMORE; COSTILL, 2001). Muscle activation was obtained by means of Surface EMG (SEGM) on two days of data collection separately. For the acquisition of the electromyographic signal of the brachial biceps muscle, an electromyograph of the brand Miotool Wireless 800 (Miotec-Equipamentos Biomédicos, Porto Alegre, Brazil) was used, consisting of eight channels and 2000 Hz frequency per channel. The electromyographic signal was measured using surface electrodes (Kendall Medi-Trace) with bipolar configuration, each with a radius of 15 mm. The data were transmitted through a Universal Serial Bus (USB) cable from the electromyograph to a computer (Dell, São Paulo, Brazil) containing the Miotec Suite software, in order to enable visualization of the real-time signal as well as its recording.

Procedures of trichotomy and abrasion of the skin with cotton and alcohol were carried out before the placement of the electrodes. These procedures had the intention of removing dead cells and diminishing the oiliness of the skin, thus reducing its electrical impedance (HERMENS et al., 2000). The electrodes were placed on the skin surface of the brachial biceps muscle (HERMENS et al., 2000). The distance between the electrodes was 20 mm from the center of each other, so that they were partially overlapped. The ground electrode was positioned on the clavicle (bone protuberance closest to the evaluated muscle), serving as reference for a spot without electrical activity.

Initially, a Maximum Voluntary Isometric Contraction (MVIC) was performed with simultaneous electromyographic signal collection to relativize the load used during data collection and normalization of results. Three MVICs were performed with a duration of five seconds and with a three-minute interval between attempts to ameliorate fatigue. The subject was positioned with the shoulder in the neutral position, elbow flexed at 90º, and supinated forearm. Only the dominant limb was evaluated. Following these tests, a five-minute interval was given for the next one, consisting of an isometric contraction of the elbow flexors that lasted one minute and had a charge of 20% of the MVIC. The acquisition of electromyographic data was performed before and immediately after the application of the test protocols, in treatments I and II. The demarcation of the positioning of the electrodes on the skin was performed through the use of a map

of the positioning of the electrodes for each individual (NARICI et al., 1989).

After the acquisition and storage of the collected signals, the analysis was performed through the Miotec Suite software. First, the gains of the signal in the raw file were removed to then perform the filtering of the signal. For this purpose, the fifth order Butterworth bandpass filter with a cut-off frequency between 40 and 500 Hz was used. The filtering was performed to eliminate possible noise from the environment and from electrical appliances. Cutouts were made at 10-second intervals over time periods of 5 to 15 seconds, 25 to 35 seconds, and 45 to 55 seconds, over one minute of isometric contraction. The signal the root mean square (rms) values was clipped and filtered for each of the time intervals determined in the pre and post moments in the two steps of data collection (treatment I and II). These values were used to quantify the activation of the biceps brachii during isometric contractions.

For the analysis of the normalized EMG results, that is, of the normalized rms value, a Two-Way Analysis of Variance (ANOVA) was used to evaluate the significance of the various factors and their interactions. The analyzes were performed in Minitab software 14.

5.4 Results

Frequency, treatment, and gender have shown significant effects (ps<0.05) on normalized rms values. Significant interaction effects (ps<0.05) were frequency and gender; frequency and treatment; treatment and application; and frequency, treatment, and gender (Table 5). As the major factors had significant interactions in the experiment, variance analyses are also presented (Table 6).

Summarizing the results, it is possible to affirm:

a) The average electric activation of the brachial biceps muscle depends on gender in the frequencies of 60 and 80 Hz, since it is higher among women.

b) The mean electric activation of the brachial biceps muscle in treatments I and II depends on the frequency used. Activation was greater in treatment 1, when compared to treatment 2, in the frequencies of 80 and 10 Hz.

c) The average electric activation of the brachial biceps muscle before and after application depends on the treatment. The interaction effect is greater in post-application. In the post-application period, in the treatment I (localized muscle vibration with the relaxed muscle), there was an average increase of the muscular electrical activation and in the treatment II (localized muscular vibration associated with CPM), there was a mean reduction of the muscular electrical activity.

d) The application of localized muscle vibration of 100 Hz in the relaxed muscle in both genders would be the optimal situation to provide the increase of muscular electric activity of the biceps brachii muscle. On the other hand, the application of 80 Hz localized muscle vibration associated with CPM for males would be the optimal situation to provide a reduction in muscular electrical activity of the biceps brachii muscle, while the 100 Hz frequency would be more appropriate for females.

The validation experiments indicate the suitability of the prototype to generate the expected effects. All subjects who participated in the experiment reported relaxation during the application of muscle vibration located in the relaxed muscle in continuous passive movement (treatment II).

Table 5: Values of electrical signal collected by Electromyography.

Subject	Gender	Freq	MVIC	Application (pre- or post-treatment)	Normalized rms values					
					Vibration			Vibration + CPM		
1	F	100	922,87	Pre	14,42	15,39	13,93	13,03	14,66	14,33
				Post	29,61	10,32	10,59	11,59	12,96	12,04
2	F	100	786,7	Pre	13,78	12,27	11,83	20,00	21,29	20,30
				Post	12,67	12,26	12,63	16,10	15,46	14,26
3	M	100	354,97	Pre	15,68	15,21	14,33	20,75	17,81	17,43
				Post	18,33	19,53	19,21	12,18	10,42	11,53
4	M	100	1457,34	Pre	19,68	19,07	15,23	16,46	10,31	9,18
				Post	11,70	15,34	16,12	15,11	12,97	12,25
5	F	80	667,29	Pre	25,29	25,30	23,68	19,77	18,62	19,10
				Post	19,56	19,26	20,46	19,04	19,68	20,00
6	F	80	872,25	Pre	14,20	14,73	14,96	11,42	10,57	10,27
				Post	17,06	17,12	17,19	15,08	14,00	12,65
7	M	80	680,62	Pre	16,45	17,71	18,47	13,91	13,37	12,65
				Post	15,26	14,07	14,51	9,91	10,17	9,49
8	M	60	271,64	Pre	13,29	13,58	14,88	16,29	15,93	16,55
				Post	14,22	13,88	14,45	14,78	15,53	16,30
9	F	60	654,32	Pre	20,77	21,62	20,72	21,33	19,21	17,90
				Post	19,97	19,96	19,99	16,90	17,07	17,31
10	F	60	315,63	Pre	15,94	16,43	17,13	17,97	17,93	18,27
				Post	19,08	18,97	19,68	17,45	17,94	18,34
11	M	60	1438,43	Pre	10,29	11,30	12,33	12,04	14,84	17,19
				Post	14,45	16,76	17,18	12,63	12,72	13,01
12	M	80	545,51	Pre	13,65	15,46	13,28	9,24	8,96	8,85
				Post	15,02	17,04	16,76	8,64	10,00	8,23

Freq – Frequency; F – Feminine; M – Masculine; MVIC – Maximum Voluntary Isometric Contraction; rms – root mean *square*; CPM – Continuous Passive Movement.

Table 6: Variance analysis.

Factors	DF	Adjusted QS	Adjusted QS mean	F	p
Freq	2	62,128	31,064	3,6	0,030
Gender	1	281,289	281,289	32,59	0,000
Treatment	1	101,707	101,707	11,78	0,001
Application	1	9,0300	9,030	1,05	0,308
Freq*Gender	2	186,435	93,218	10,8	0,000
Freq*Treatment	2	124,616	62,308	7,22	0,001
Freq*Application	2	13,689	6,845	0,79	0,455
Gender*Treatment	1	18,176	18,176	2,11	0,149
Gender*Application	1	0,427	0,427	0,05	0,824
Treatment*Application	1	35,92	35,92	4,16	0,044
Freq*Gender*Treatment	2	58,109	29,055	3,37	0,038
Freq*Gender*Application	2	7,094	3,547	0,41	0,664
Freq*Treatment*Application	2	37,257	18,628	2,16	0,120
Gender*Treatment*Application	1	5,344	5,344	0,62	0,433
Freq*Gender*Treatment*Application	2	13,206	6,603	0,77	0,468
Error	120	1035,743	8,631		
Total	143	1990,171			

DF – Degrees of Freedom; Freq – Frequency; QS – quadratic sum; F – F-test; p – p-value.

6. DISCUSSION

There is a need for innovative solutions to improve the quality of life and social change, especially in health and rehabilitation areas (KOLOMINSKY-RABAS et al., 2015; PEINE; MOORS, 2015). The new device proposed in this paper promotes the elbow's F/E and P/S passive movements, an often necessary rehabilitation practice for injured joints. The novel device developed in this study is totally manufactured in Brazil and costs a fraction of the equipment currently produced abroad.

The available ROM of this new device is 0° to 160° of F/E, being one of its appealing features. A comparative analysis of six competing devices (CALLEGARO; JUNG; TEN CATEN, 2011) demonstrates that, although all devices allow the elbow F/E functional ROM, their range vary from 140° to 145°, corresponding to the elbow's active flexion range. None of the competing devices analyzed enable the elbow F/E CPM up the joint physiological passive ROM limits, which reaches 160º. That is important since the passive ROM of F/E and P/S movements are limited when the elbow joints suffer lesions. The therapist needs to assist in the rehabilitation process, with objectives that vary depending on the phase of rehabilitation; for example (i) reduction of the harmful effects of the anti-inflammatory process, especially pain; (ii) reconstruction of the tissue; (iii) restoration of the ROM; (iv) maintenance and development of the muscle strength until it is possible for the individual to return to her Daily Living Activities (DLAs). When the ROM is not recovered, simple DLAs such as brushing teeth and eating are limited, and the patient quality of life is reduced (WILK et al., 2012).

Literature states that CPM should be used especially in early stages of elbow rehabilitation after surgical treatment or trauma, to reduce edema, pain and stiffness, and to increase the ROM (O'DISCROLL; GIORI, 2000; BARLOW; STEINMANN, 2010; CHARALAMBOUS; MORREY, 2012; KATOLIK; COHEN, 2009; NANDI et al., 2009). Elbow stiffness occurs in four stages: bleeding, edema, formation of tissue granulation, and fibrosis. The first two occur early in the treatment, while granulation and fibrosis may take days or months to appear. CPM's goal is to reduce the intraarticular bleeding and periarticular edema by means of a sinusoidal intraarticular change and periarticular pressure. Therefore, CPM is applied early in the rehabilitation process, since it has only a small role to play once granulation and fibrosis are established [18]. Following the bone or ligament reconstruction and simple posterior dislocation, in the first four weeks of treatment, set to a predetermined angle, CPM is a resource used in combination with P/S movement exercises, with the elbow at 90° angle (FUSARO et al, 2014). The majority of CPM applications reported are performed to prevent arthrofibrosis after arthroplasty or other surgeries involving body joints prone to loss of motion – such as the elbow and knee joints (BIBLE et al., 2009).

Regarding studies on CPM applied to the knee, findings are controversial (BRACH; GOITZ, 2006). A study showed that CPM did not help patients to recover functionality immediately after total knee arthroplasty, and that edema persisted (MANIAR et al., 2012), especially in those patients with ROM less than 75° after the acute phase (HERBOLD et al., 2014). However, it should be noted once again that CPM is effective only at the beginning of the rehabilitation process (O'DISCROLL; GIORI, 2000). In addition, the disparity between the anatomical knee axis and the equipment axis is a common problem in clinical practice, and this fact should be considered when prescribing CPM for patients, or evaluating its effectiveness (BIBLE et al., 2009). In contrast with these studies reporting the application of CPM to the knee, applications of CPM to the elbow are usually well-succeeded (BRACH; GOITZ, 2006; O'DISCROLL; GIORI, 2000).

In an attempt to bridge the gaps identified in the literature, the device proposed in this paper allows anthropometric adjustments to comfortably align the elbow and the forearm axis, satisfying customer requirements. Furthermore, tissues involved in the reproduction of symptoms around the elbow should be evaluated by the Physical Therapist and the prescribed CPM treatment can be directed to the relief of pain or the gain of ROM. Techniques that are performed by this CPM device may help the physical therapist in the patient rehabilitation process are graded as follows (KISNER; COLBY, 1990; SPERB, 2006):

a) Grade I: rhythmic oscillations of small amplitude applied at the beginning of the elbow and forearm ROM, especially to reduce the patient's pain and nourish the joint;
b) Grade II: oscillations of greater amplitude, although not reaching the ROM limits, especially to reduce the patient's pain, nourish the joint, and prepare the joint tissues for the ROM gain;
c) Grade III: rhythmic oscillations of still greater amplitude, sufficient to reach the limit of the available movement when forced against the resistance of the tissue for ROM gain;

d) Grade IV: rhythmic oscillations of small amplitude performed at the limit of available ROM, and forced within the limits of the tissue for ROM gain; and
e) Grade V: a low amplitude, high velocity manipulation technique that requires advanced training, used to abruptly separate the adhesions at the limit of available ROM.

According to the grading above, oscillations have different indications. Grade I and II oscillations are used to treat joints limited by pain, by stimulating repetitively the intra-articular mechanoreceptors, thereby producing an inhibitory effect on the perception of painful stimuli by blocking nociceptive pathways to the spinal cord level or to the brain stem Furthermore, when performed without stretching these movements help to move the synovial fluid, improving the cartilage's nutrition. Grade III and IV oscillations are used as maneuvers for stretching (KISNER; COLBY, 1990; SPERB, 2006; WILK et al., 2012).

Based on techniques of graded oscillation performed manually by Physical Therapists, pre-defined actions can also be specified for the device developed in this study, e.g., (i) standard chart of the conventional CPM machines operation-knee F/E passive motion in equal periods of two cycles per minute; (ii) knee F/E passive motion to increase knee mobility with sustained relaxation, by means of rhythmic oscillations of small amplitude at the limits of existing mobility and forcing the tissue resistance.

A localized muscle vibration module was developed in the new device to fulfill a requirement identified in the informational phase of the product's development. Vibration modules were shown to act a coadjutant in the rehabilitation process (CAMEROTA et al., 2013). The following neural effects of applying localized muscle vibration have been reported in the literature: (i) primary endings of muscle spindles are particularly sensitive to low amplitude vibrations, while secondary terminations and Golgi tendon organs are less sensitive, responding only to vibrations of higher amplitude, particularly when the receptor's muscle is at rest (ROLL; VEDEL; RIBOT, 1989); and (ii) motoneuron facilitation may be exercised through persistent inward currents (TRAJANO et al., 2014).

Local muscle vibration has also been studied as a rehabilitation resource to improve the arm's neural efficiency (BOSCO; COLLI; INTROINI, 1999), proprioception (BRUNETTI et al., 2006), and muscular control (SORENSEN; HOLLANDS; PATLA, 2002), in addition to neuropathy treatment (CAMEROTA et al., 2013).

It is noteworthy that morphological, biochemical, and biomechanical characteristics of the articular and periarticular tissues are subjected to change when a joint is immobilized after injuries (LIMA et al., 2007). A week of immobilization is enough to cause significant muscle disorders, such as decrease in muscle fiber area with consequent reduction in power production capacity (KAROLCZAK et al., 2006). It is believed that the neurophysiological mechanisms of vibration may assist in the rehabilitation of the elbow, since they are able to increase muscle electrical activation (FILIPPI et al., 2009).

7. CONCLUSIONS

This paper presents the development and validation of a CPM module to be used in an innovative device to rehabilitate the elbow and forearm. The study was developed according to the Reference Model for Product Management and Development; results demonstrated that a prototype could be designed according to the chosen methodology. Stakeholders´ requirements were taken into consideration to determine the product design features and a working prototype was built to carry out all functional tests, including those involving human subjects.

The module is manufactured in Brazil and costs a fraction of the equipment that is currently imported to the Country. These characteristics make the device more affordable to hospitals, clinics, physician's offices, and residences. The carefully conducted design process of the new CPM device allowed researchers to develop not only a more affordable product, but also a valid alternative to imported products (e.g., it allows a broader ROM, comparing to similar equipment, and it is part of an innovative device that also allows muscular vibration).

Technological innovation, in this case, will enable at least three important changes: (a) organizations will be able to replace the existing equipment, when needed, by a better and lower-priced alternative; (b) in many cases that the organization did not have resources to afford the imported equipment, they may now offer new rehabilitation services, using CPM devices; (c) many patients under treatment in hospitals and clinics, such as those which did not have CPM devices to offer rehabilitation, will have access to adequate treatment.

Despite the numerous studies available on muscular vibration, further investigation is required to better understand subjacent mechanisms and determine application parameters (MIKHAEL; ORR; FIATARONE SINGH, 2010). Future research should focus on the determination of ideal frequency, duration, range, type of vibration signal, and protocols suitable to specific populations, as well as the association of vibration with other therapies. Future research could also evolve to analyze the results of applying local muscle vibration on the biceps, a muscle that plays a major role in elbow flexion responsible.

The design presented in this paper opens a number of research possibilities to be conducted in the future. More studies designed to assess the technology herein developed may be performed using planned experiments to verify the impacts of combining CPM with local muscle vibration on human subjects, as outlined in the previous section. Another research opportunity is to test the performance of the rehabilitation device under different operating parameters, for different individuals. Furthermore, studies may extend the present work to include the development of similar equipment for other human joints.

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