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DESIGN OF A MODULE FOR CONTINUOUS PASSIVE MOTION TO BE USED IN EQUIPMENT FOR THE REHABILITATION OF ELBOW AND FOREARM

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1. Introduction

Continuous Passive Motion (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 [Salter et al. 1984], [O'Discroll and Giori 2000]. The trained physical therapist programs and controls such devices in accordance with the treatment objectives for each patient [Mavroidis et al. 2005], [Callegaro et al. 2012].

CPM studies addressing the knee [Maniar et al. 2012], [Boese et al. 2014], [Herbold et al. 2014] and shoulder [Lynch et al. 2005], [Garofalo et al. 2010] 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 [Boese et al. 2014], [Herbold et al. 2014].

Literature on the application of CPM to the elbow joint showed that the method was used for the treatment of contracture [Breen et al. 1988], [Cohen and Hastings II 1998, 1999], [Bae and Waters 2001], [Aldridge et al. 2004], [Lindenhovius et al. 2007, 2009], [Steinmann 2007], [Liu et al. 2011], joint stiffness [King and Faber 2000], [Davila and Johnston-Jones 2006], [Katolik and Cohen 2009], [Nandi et al. 2009], [Barlow and Steinmann 2010], [Charalambous and Morrey 2012], heterotopic ossification [Gaur et al. 2003], [Hunt et al. 2006], [Chen et al. 2009], total arthroplasty [Stinson et al. 1993], [Vrettos et al. 1998], [Demiralp et al. 2008], fractures [Remia et al. 2004], [Marti and Doornberg 2009], 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 CPM was used after elbow contracture surgery and to treat joint stiffness [Mavroidis et al. 2005].

CPM devices to rehabilitate the elbow and forearm are not produced in Brazil. 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 [Brazil Health Ministry 2009].
In this paper we present the design of a CPM device for elbow and forearm rehabilitation. Our objective is aligned with the Brazilian government's guideline to invest in technological innovation, the demand for innovative 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. The paper's main contribution is to present the design of a CPM module for a rehabilitation device following traditional product development process steps. That is aligned with the research question stated in section 3.

2. Background

The elbow is the intermediate articulation of the upper limb. It is often affected by injuries and is especially prone to joint stiffness; in that case, 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. 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 should be adapted to each patient, according to specific needs [Fusaro et al. 2014].
The elbow has two degrees of freedom of movement: Flexion/Extension (F/E), and Pronation/Supination (P/S) (Figure 1). 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 of the forearm [Miyasaka 1999], [Alcid et al. 2004].
Elbow 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 a supination amplitude of 90°, and a pronation amplitude of 85° [Kapandji 2007] or 90° [Kendall et al. 1995].
The ROM of F/E and P/S are limited when the elbow joints suffer lesions. The physical therapist has to assist in the rehabilitation process, with objectives that vary depending on the phase of rehabilitation; for example: (i) reducing 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 return to his/hers daily living activities (DLAs) [Hebert et al. 2003].

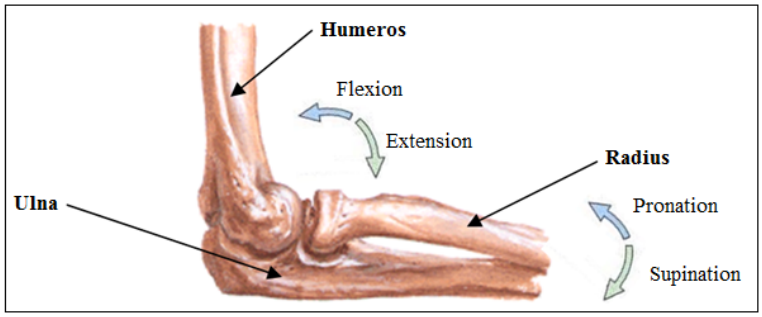

Figure 1. Elbow joint bones and movements (adapted from [Netter 2008])

The 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 [King and Faber 2000], [O'Discroll and Giori 2000], [Dávila and Johnston-Jones 2006], [Katolik and Cohen 2009], [Nandi et al. 2009], [Barlow and Steinmann 2010], [Charalambous and Morrey 2012]. 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. The CPM's objective is to reduce the intra-articular 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 [O'Discroll and Giori 2000]. 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].

A CPM application is based on the passive movement of a human body joint. An external force is applied on the natural articulation to move the joint, without any muscle recruitment [O'Discroll and Giori 2000]. The evaluation of the passive movement (i.e. the determination of the amount of movement performed without assistance from the patient) provides the physical therapist with information on the integrity of the articulator's surfaces and on the extensibility of the soft tissue, regardless of the force, and depends only on the mobility of the joint. It is possible to observe the presence of pain, restriction of movement [Clarkson 2000], and the type of limitation: rigid or flexible, painful or not.

Tissues involved in the reproduction of symptoms are evaluated and the treatment is directed to the relief of pain or the gain of ROM. The quality of the pain also determines the stage of recovery, and indicates the techniques that may be used. The oscillation techniques that may be performed by a programmable CPM device are graded as follows [Kisner and Colby 2005]:

- Grade I: rhythmic oscillations of small amplitude applied at the beginning of the ROM session;
- Grade II: oscillations of greater amplitude, although not reaching the ROM limits;
- 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;
- Grade IV: rhythmic oscillations of small amplitude realized at the limit of the available ROM, and forced within the limits of the tissue; and
- Grade V: a low amplitude, high velocity manipulation technique that requires advanced training, used to abruptly separate the adhesions at the limit of the available ROM.

3. Method

This study is characterized as experimental research using qualitative and quantitative methods. The research question addressed was: is it possible to develop a CPM device following traditional product development models? 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]. Rozenfeld's approach was chosen here for its thoroughness; that is also its main drawback, since excessive attention to details may undermine the project's agility. 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 macro phases of pre-development and development were used as reference (Figure 2). 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, and prototype generation. The pre-development and development phases are reported in this paper.

The informational design includes the identification of 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].

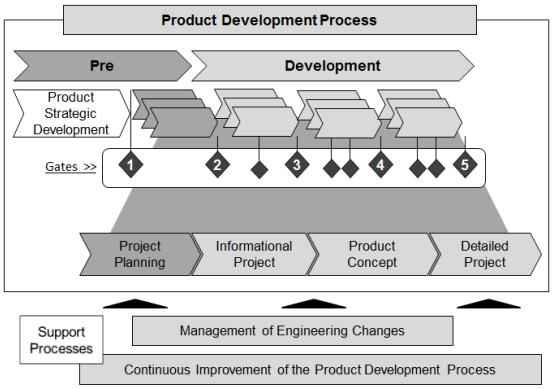

Figure 2. Initial phases of the Reference Model proposed by Rozenfeld et al. [2006]

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

Development of the functional prototype of the CPM module to be used in an innovative equipment to rehabilitate elbow and forearm, in accordance with the Reference Model in Rozenfeld et al. [2006], follows the gate sequence presented in Figure 2, and detailed in Figure 3 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 innovative device to rehabilitate elbow and forearm.

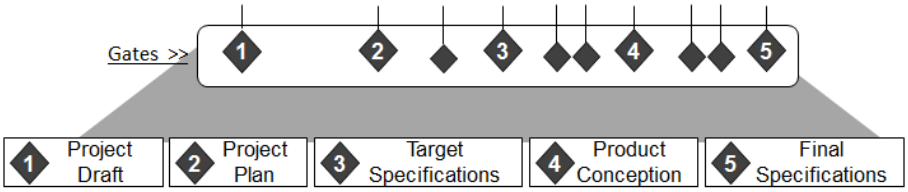

Figure 3. Gates of the Referential Model for Management and Development of Products. Source: adapted from Rozenfeld et al. [2006]

4.1 Gate 1: Project draft

The project draft is the input for the pre-development macro phase, that involves the strategic planning for the development of the project; see Table 1. The project draft was developed considering a market opportunity identified by Callegaro et al. [2011a,b,c], and the willingness to foment cooperation between university (that creates knowledge), industry (that utilizes that knowledge to create products) and government (that supports innovation by means of fiscal incentives and research financing) [Etzkowitz 2009].

4.2 Gate 2: Project plan

A number of brainstorming sessions were carried out to define the project's scope [Gray et al. 2010]. Team members were identified; the project was suited to the available financial and time resources. The

product scope defined characteristics and functions that the product should possess when completed. It is important to remark that the CPM module will be part of a new product intended to be superior to existing equipment manufactured abroad; the design of such new product could be classified as incremental innovation [Nexon and Ubl 2010].

Table 1. Project draft

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, traumatology, 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 will be supported by PPGEP/UFRGS**, and receive funding from the governmental sponsoring agency CNPq***. A patent of the utility model will probably be deposited. Partnerships with other University laboratories and private companies should be fomented.

*CPM - Continuous Passive Movement; **PPGEP/UFRGS – Graduate Program in Industrial Engineering / Federal University of Rio Grande do Sul; ***CNPq – National Council for Scientific and Technological Development

4.3 Gate 3: Target specifications

The equipment's technical requirements are derived from the joint application of CVCA and QFD, with results presented in a previous study [Callegaro et al. 2015]. Stakeholders' requirements in terms of specified quality were translated into the equipment's technical specifications as quality characteristics. Additional technical requirements identified in studies carried out previously on the CPM module [Callegaro et al. 2011b, 2011c, 2013] were also added. Technical requirements and the related product target specifications are presented in Table 2.

4.4 Gate 4: Product conception

To conceive the CPM module's design, the equipment's functions were defined starting with the global function, which is to produce continuous passive movement. To provide the functions expected from the equipment, solution principles were proposed and combined. Table 3 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 agreed with the outstanding solution principles (in bold type) in Table 3 for each function is the one depicted in Figure 5(a).

Table 2. Target specifications of CPM module project

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 %
Amplitude of the passive movement of F/S(°)	0 – 160
Amplitude of the passive movement of P/S(°)	-90 – 0 – 90
Velocity 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 equipments	>50

Table 3. CPM module's functions and solution principles

Function	**Solution Principles**		
	1	**2**	**3**
Production of continuous passive movement	**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-controler (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

In parallel with the study of conceptual designs, 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 the macro

process plan; (v) updating of the economic viability study; and (vi) documentation of decisions taken and recording of learned lessons.

4.5 Gate 5: Final specifications

At this point operational procedures were detailed, starting with the chosen CPM module's architecture. Information on the equipment's design was gathered, and systems, subsystems and components defined in the conceptual design phase were evaluated and integrated. The project's working prototype was designed and built, to carry out tests with human subjects and in laboratory.

To drive and control the F/E and P/S 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 equipment'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).

The physical therapist is able to program movements of the sequences F/E and/or P/S by providing the initial and final ROMs, and the duration of the CPM from initial to final angle. A view of some of the control box's screens is given in Figure 4.

Figure 4. 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

All equipment 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 are shown in Figure 5, 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.

The new device depicted in Figure 5 has a feature that makes it unique: a local muscle vibration module that can help the rehabilitation process [Camerota et al. 2013]. That feature was explored in another study, not yet published.

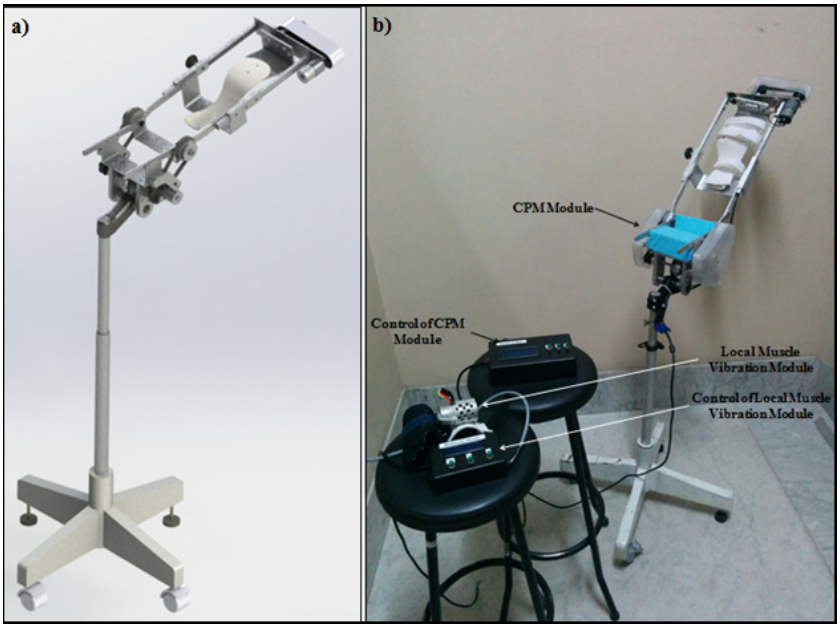

Figure 5. (a) Isometric view of the selected conceptual design; (b) Prototype of the innovative equipment to rehabilitate elbow and forearm (parts are identified in the figure)

5. Conclusion

This paper presents the development 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 proposed by Rozenfeld et al. [2006]; results demonstrated that a prototype could be designed according to the selected 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 carried out with human subjects.

The developments presented in this paper open 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. 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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