An Innovative Approach towards Incorporating the End User to the NMES Wearable System Development

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Abstract: This work presents a portable and customized wearable system design towards applying Neuromuscular Electrical Stimulation (NMES) to tetraplegics´ upper limbs patients, from creation to production, with users' participation into the design process. The rehabilitation system protocol for reach and grasp movements developed by an academic research group, currently applied to patients, has already proven to be effective. However, the current system and recently published researches, demonstrate proposals distancing from those who will use and manipulate it, with limitations and failures evidenced. The propose wearable system integrates electrodes and electronic components activated by a smartphone app to improve the performance of upper limb movements and optimize the system, making it more functional for your users. The methodology includes (1) Design Thinking process, (2) Parametric Design process and three dimensional production, (3) Reduction of the electronic circuits, (4) Development of Android application for setting NMES protocols and (5) Workbench tests and users experimentation. The methodology in this new approach of development proved to be feasible and effective. Results have shown that including the end users and health professionals in the design process to develop wearable system is a promising strategy to overcome the limitations of the NMES systems.

1 INTRODUCTION

According to the World Health Organization (World Health Organization, 2013), Spinal Cord Injury (SCI) affects between 250,000 and 500,000 people worldwide every year. It is a complex dysfunction that has major physical, psychological and social repercussions. Apart from the negative impact on the quality of life for many individuals, SCI makes it difficult to perform many activities of daily living (ADL) and affects negatively on the motor and sensory functions of the upper and lower limbs of tetraplegic and paraplegic patients. Paralysis at different levels and parts of the body, as well as changes in sensitivity and comorbidities (Eng & Miller, 2009), are the consequences of SCI, which is divided into tetraplegia and paraplegia.

It is known that Neuromuscular Electrical Stimulation (NMES) is an effective rehabilitation tool applied to tetraplegics' upper limbs, to perform reaching and grasping movements (Varoto, Barbarini, & Cliquet, 2008) (Peckham et al, 1988).

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The NMES employed to intact motor neurons allows the resumption of movements that have been lost or altered by the spinal cord injury and promote muscle strengthening of the limbs (Varoto & Cliquet Jr, 2015). Nevertheless, stimulation parameters should be carefully adjusted in consonance with the desired goal, injury level, and muscle response under the supervision of healthcare professionals (Benton, 1981). In biomedical systems, there are a number of complexities that need to be addressed in an integrated manner, including not only electrical and electronic devices and disease-specific constraints, but also the many users involved who need to deal with the proposed product, such as patients, family and health professionals. Including users early in process development involves concerns about ergonomics, appropriate materials used in the product, user usability and acceptance. In this type of integrated process, unforeseen problems can be solved, leading the project to a better resolved final product. Therefore, healthcare product development involves a multidisciplinary team working with an interdisciplinary way (Romero M., Perego P., Andreoni G., 2010)

Wearables are different in their nature and application, so each of them is related to a different type of a design and ergonomic criteria. The ergonomics of a product or a system is related to providing safety, health, comfort and performance to the user. In this context, some rehabilitation technology devices have been developed aiming at upper limb motor rehabilitation, such as Handmaster System (Snoek, Ijzerman, In ’t Groen, Stoffers, & Zilvold, 2000), INTFES (Malesevic et al., 2012) and the Wearable Multi-Site (Crema et al., 2018). This work presents a new approach for the development of wearable system towards applying NMES to tetraplegic patients, including them from the beginning of creation using the Design Thinking, Parametric Design and File-to-Factory process to achieve better results. A portable wearable system was developed to be individually fitted to the upper limb, to improve the performance of reach and grasp movements for functional rehabilitation therapy. At the same time makes the work of the health professional more agile.

2 MATERIAL AND METHODS

The NMES rehabilitation for repetitive task training of reach and grasp movement, currently applied to patients with C5-C7 injury level, includes a computer in which the stimulation signal parameters and the protocol are defined for the rehabilitation program, a 4-channel electronic stimulator that creates stimuli and commercial self-adhesive surface electrodes (Fig. 1). Four active electrodes are manually positioned on the upper limb to generate elbow extension, extension and flexion of the fingers and thumb opposition. Straps ensure adherence between the electrode and the skin (Castro & Cliquet Jr., 2001). Although the rehabilitation system and program have already proven to be effective, self-adhesive electrodes placement demands a longer implementation time in each training session and depends on the healthy professional experience for finding the accurate position. The adhesive film on the surface of the electrodes is highly adherent when new, with frequent use this film loses its grip, preventing its use. In addition, computer- based system and cables that can interfere in the movements impose certain limitations.

In order to minimize these inaccuracies and benefit users, the NMES System currently applied to tetraplegic patients has been completely redesigned with a focus on end users and healthcare professionals, since the actual system it only takes into account the efficiency of electrostimulation, thus presenting inaccuracies and failures regarding ergonomics and the use itself.

Figure 1: The picture of the left shows the current NMES system applied to the patient of the outpatient department from the Clinic Hospital (HC), of the State University of Campinas (Unicamp), Brazil versus the picture of the right that shows the proposed novel wearable system.

This wearable system composes of three integrated parts that cover the hand, forearm and arm with commercial self-adhesive electrodes incorporated, a smartphone application (app) and the stimulation unit. The healthy professional can set protocols for NMES via smartphone application. The digital data are sent to the stimulation unit attached to the wearable through Wi-Fi, which generates the stimulation signal. Commercial surface electrodes integrated to the wearable are used for applying NMES to the patient.

2.1 Wearable System Design

Interdisciplinary Design Process

This project approved by the ethics committee was devised by researchers from the Bioengineering Post Graduate Course and Electrical & Computer Engineering Department of University of São Paulo (USP), composed of architect, designer and engineers. The team that participated in all stages of the development of this project is composed of that researchers, the patients and the health professionals, these last two from the outpatient department of the Clinic Hospital, of the Unicamp. From flowchart presented by Maximiliano Romero (Romero M., Perego P., Andreoni G., 2010), an adapted version was created to clarify the interdisciplinary process that involves the wearable system development (Ventura, Varoto, & Cliquet Jr, 2018) (Fig. 2).

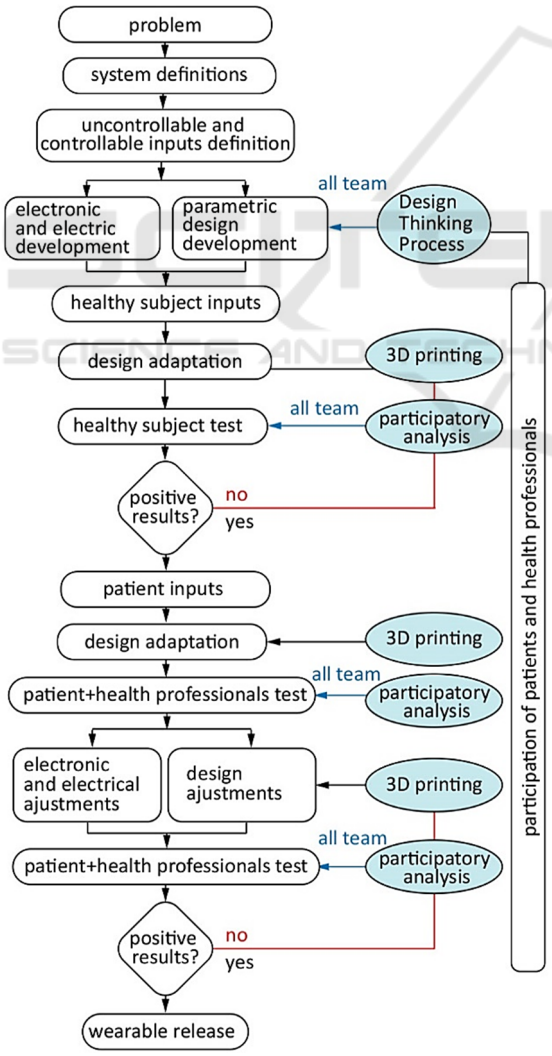

Figure 2: Interdisciplinary proposed flowchart.

The proposed flowchart shows that the participation of the entire team occurs at the beginning of the design process and at various times throughout product development. Team integration is the moment when everyone observes, evaluates and discusses what was produced.

To get closer to the realities of the rehabilitation routine and improving the current system, the Design Thinking process was applied. The major goal is to explore possibilities and to create options in a divergent process of ideas without judgments or limits, and then make choices, through the convergent process (Brown, 2009), resulting in three-dimensional models and prototypes.

After the Design Thinking stage, the parametric design methodology was developed. In parallel, a scanning protocol of the upper limbs was elaborated and the results of the 3D scanning of a healthy individual and a patient were inserted in the generative algorithm inputs, for verification and adjustments of the created methodology. The patient participated in the product development of the healthy individual from the point of view of wearable shape, aesthetic acceptance and material malleability. The health team evaluated the placement of the electrodes in the wearable, their handling and the ease of placing the product on the upper limb.

With positive results, the healthy subject's inputs will be replaced by the patient's inputs. The wearable will be 3D printed, and quantitative movement and qualitative comfort assessments will be performed.

Parametric Design and File-To-Factory Process

Wearable are devices designed to fit different moving bodies so that they can be controlled and operated without interruption or limiting the movements of the users (Mann, 1997). The wearable shape, their active relationship with the human anatomy and other components must act in an integrated way for proper secondary functioning and use. Specifically, for this work, the anthropometric characteristics of the upper limbs are very different from one patient to another due to deformities resulting from the SCI. Thus, it arises the need for individually fitted wearables, and design and ergonomics criteria based on Design Wearability Guidelines (Gemperle, Kasabach, Stivoric, Bauer, & Martin, 1998).

According to ergonomic criteria and because it is a highly complex product, the creation of wearable involved the development of a Parametric Design Methodology using generative algorithms, a 3D scanning protocol for patient's upper limb and a file-to-factory 3D printed product.

The production of complex geometries of this order is associated with file-to-factory process, with a direct relationship between design and production. It involves direct transfer of data from a 3D modeling software to a 3D printing machine (Kolarevic, 2009). The wearable model was performed in Rhinoceros 3D (TLM Inc., Seattle, WA, USA), which is a CAD tool, and an algorithmic logic has been developed in Grasshopper, which is a generative algorithm editor for Rhinoceros, so that the design is completely automated (Fig. 3). The input data changes according to the individuality of each patient.

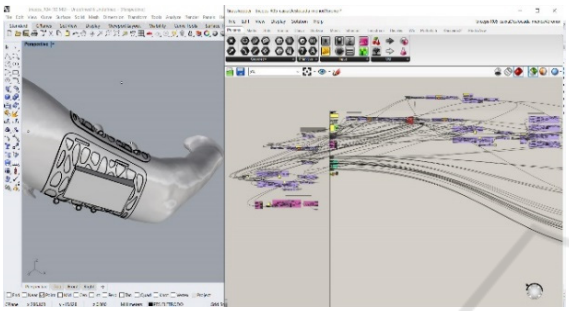

Figure 3: 3D model automated with generative algorithm.

According to the ergonomic criteria the inputs required for the construction of wearable were divided into primary (uncontrollable): anthropometric data and the electrode points on the muscle groups, and secondary (controllable): position that the wearable will occupy on the arm, size of the electrodes, tubes that will embed the cables, stimulation unit position, wearable clearance, weight of the wearable and ventilation. The resulting wearable shape is achieved according to the relationships of the primary and secondary parameters.

The protocol scan created considerate the wheelchairs and restricted upper limb movement of the patient. It was simulated the environment and the conditions of the patients to scan the dominant upper limb of the healthy subject. The 3D scan of the dominant upper limb resulted in an anthropometric data, and it was collected with 3D iSense Scanner (3D Systems, Rock Hill, SC, USA) with Skanect 3D Scanning Software (Occipital, Inc., San Francisco, CA, USA).

According to the developed model, the wearable was printed by Fused Deposition Modelling (FDM) process with flexible ABS material.

Electronic Apparatus and Smartphone Application

The ESP32 DeviKit V1 Development Board (Shenzhen Doctors of Intelligence & Technology Co. Ltd, Shenzhen, Guangdong, China) provides an interface between the smartphone app and the stimulation unit, presenting Wi-Fi and Bluetooth Low Energy (BLE) connectivity.

Powered with 6V by one 18650 rechargeable lithium ion battery (4.2V, 9.8Ah) connected to an adjustable booster power supply module with XL6009 DC-DC step up module (Shanghai Xinlong Semiconductor Technology Co. Ltd, Pudong, Shanghai, China), the ESP32 operates as a custom-made monophasic square waveform generator, creating the stimulation signal with following parameters: number of pulses for each burst: 4; pulse width: 100μs; period between pulses: 100μs and burst frequency: 25Hz.

The microcontroller module was programmed using language and Integrated Development Environment (IDE) of Arduino (Arduino S.r.l, Scarmagno, TO, Italy) with extension packages for ESP32. Ports D13, D12, D14, D27, D26, D25, D33 and D32 were configured as outputs, corresponding to the stimulation channels 1 to 8, respectively.

In the stimulation unit, the generated signal is transmitted to the isolation circuitry, which uses optical coupling. In order to adequate the signal for the amplification circuitry, an inverter buffer operates at the optocoupler output.

A potentiometer, an N-Channel Power MOSFET and a pulse transformer compose the amplification circuitry, designed for output up to 100V.

The same strategy - previously described - is used to power the stimulation unit, but the booster module output has been set to 12V.

The stimulation unit is electrically coupled to the patient via self-adhesive surface electrodes.

Communication between the microcontroller and the Android app occurs using a Wi-Fi router (there is no need of internet access). In relation to the router, a static local IP address and a port number were assigned for microcontroller connection, which works as a network server. The app connects to the same Wi-Fi router as a network client, requesting permission to exchange data with the microcontroller.

The smartphone app written in Java Programming Language was designed using Android Studio (Google LLC, Mountain View, CA, USA). The user interface was done through FIGMA online design tool (Figma Inc., San Francisco, CA, USA) and presents three tabs.

Four strings are written to adjust the channels and to define the NMES protocol. The first one is dedicated to the stimulation channels tuning; the stimulation signal is provided on the selected channel for one minute. This period allows the health professional to adjust the signal amplitude - via stimulation unit - according to the patient's motor responses.

NMES protocol has up to 12 phases that correspond to the planned movements of the upper limb. For each phase, up to three channels can be activated during the specified period (up to 12s with resolution of 400ms). This information is gathered in the second string. In the rehabilitation program, this protocol can be repeated. Thus, the third string determines the number of cycles (up to 300) along the program. The fourth string contains an indicator to initiate the process.

Workbench Tests

The workbench tests were done to verify the electronic apparatus performance, including the temperature variation of some components. Using a TDS2024 Digital Storage Oscilloscope (Tektronix Inc, Beaverton, OR, USA), the stimulation signal was characterized in terms of time and amplitude at the output of ESP32, optocoupler, inverter buffer and amplification circuitry. A resistor played a role of electrodes and biological tissue (impedance equivalent to 1kΩ). Battery autonomy was estimated for the 100V amplitude stimulation signal. Thus, a channel powered by a fully charged battery was activated uninterrupted until the amplitude reached at least 90% of this voltage.

Users Experimentation

The health professional inserted the electrodes into the wearable in the space designed for them; new and reused electrodes were tested. Then, the wearable was placed in the healthy subject's hand, forearm and arm, and the channels were adjusted according to their motor response to perform effective wrist and elbow extension movements and effective flexion and extension of the fingers. The amplitude was gradually increased until reaching the excitability threshold of each muscle group. The NMES protocol was adapted, since the stimulus sensitivity of the healthy individual is higher.

3 RESULTS

The relevant and unanimous concepts extracted as a result of Design Thinking dynamics for wearable design were safety and confidence in the movement, agility of the process during NMES therapy and the possibility to do it at home with healthy professional supervision.

As a result of the methodology developed with the Grasshopper plug-in the full automation of the project was achieved and the developed method confirmed to be efficient regarding the substitution of the parameters from one individual to the other, although the generative algorithm editor had limitations regarding the modeling flexibility over double curvature geometries, such as topographic features of the upper limbs.

The solution found for the loss of electrode contact with the user's skin over time due to decreased electrode film adhesion and its precise location on muscle groups was the print of the wearable with embossed markings, positioned exactly at the locations of the muscle groups to be stimulated, with the shape and size of the electrodes. The high relief promoted the integral contact of the surface of the electrodes to the individual's skin, so that the reach and grip functions were achieved even with the loss of the adherent film. In addition, the solution found for the fixation of the electrodes on the werarable were double sided tapes. The double-sided tape was suitable for its fixation to the werarable and for the fixation of the electrodes to it.

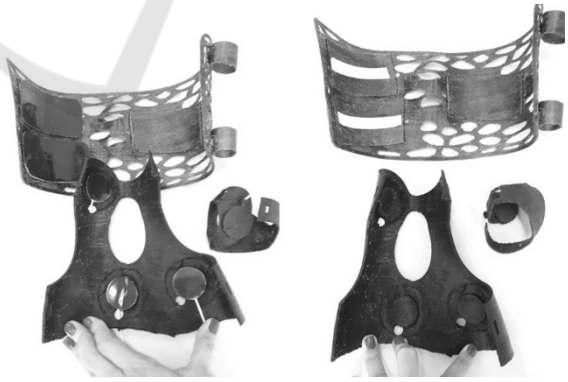

Figure 4: Left wearable inside with the electrodes and right without the electrodes.

Regard file-to-factory process the printing was faithful to the 3D modeling data. The characteristics of the flexible ABS material allow the wearable surfaces to have flexibility without losing their original shape and allow the health professional to easily place the product on the patient. In addition,

flexible ABS features a comfortable texture to the touch.

In relation to users' experimentation, appropriate results were achieved with new and reused electrodes.

The wearable system design resulted in efficiency of the projected areas for the electrodes, and its position and emboss surface provided better adhesion to the electrodes on the skin surface, resulting in effective NMES (Fig. 4). The extension and flexion movements of the wrist, fingers and elbow were efficient performed with stimuli of approximately 10V (for 1kΩ equivalent impedance). The electronic circuit was designed to provide up to 100V. However, 10V was sufficient for the healthy subject.

The physical access and manipulation of the wearable by the health professional was intuitive. The anthropometric characteristics of the 3D model were faithful to the real ones, facilitating the wearable placement in the correct position. There was no readjustment in the wearable position to perform efficient movements.

Figure 5: Printed wearable and stimulation unit.

The tubes that embed the electrode cables were strategically positioned in the wearable avoiding their disconnection and flow close to the stimulation unit solving the problems with the dimension of the cables.

Regard the Android app, called "Stimulator", on the "Setting Channels Up" tab, each channel can be selected to tune the stimulation intensity. The "NMES Protocol" tab is dedicated to configure the phases. When the phase button is tapped, the "Phase Settings" screen pops up, so up to three channels can be selected and a slider allows adjustment of the activation period. The last tab- "Rehabilitation Activities"-summarizes the phases configuration and shows the slider to select the number of cycles of the rehabilitation activity, indicating the total time (Fig. 5). Tapping the send button on this tab, a status screen of the communication process appears, and then the rehabilitation activity is started.

Figure 6: Stimulator android app.

The generated signal achieved the timing characteristics (pulse width, period between pulses and burst frequency) and provided four pulses for each burst, from ESP32 to amplification circuitry output. General-purpose input/output (GPIO) of ESP32 operates with analog voltage ranging from 0 to 3.3V. Thus, the stimulation signal was generated with amplitude of 3.24V. On the analog circuit, this signal was inverted, reaching -4.72V according to the 5V power supply. Amplified to 8.08V at the inverter buffer output, the stimuli range from 0 to about 100V for 1kΩ impedance. Battery autonomy was approximately 65 minutes.

4 DISCUSSION

It is considered that one of the major obstacles in the development of the wearable system in this work is the product to meet the varied anthropometries of the upper limb of the spinal cord injured patient and the system to function properly. Current computing technologies have proven to be able to handle these complexities.

Using parametric design produced with the file-to-factory process, including end-user participation throughout the product development process and being faithful to upper limb anthropometry, has allowed preliminary testing to be performed on a healthy individual. It contributed to verify the strengths and weaknesses of the proposed wearable.

Problems were minimized during product development without the patient being overwhelmed in the preliminary phase of the patient's wearable impression.

According to the concepts discussed in Design Thinking process - safety, confidence and agility- the wearable shape provided robustness, towards a safety physical constitution, although light (177,21 g), without limiting the range of motion. In contrast to the current system the stimulation unit has

considerably decreased its size. However, it was heavy to be coupled to the wearable (401,6 g).

The inconvenient of the double-sided tape for attaching the electrodes to the wearable was that it left material residue on the product when removed from it.

The wearable was designed to be produced by the file-to-print method with 3D printing, without having to be finalized by the industry. This optimizes the design and production process.

Filament deposition printing (FDM) showed flaws mainly in the final shape of the fastening parts and the wearable finish. However, its malleability and tactile comfort characteristics were achieved.

According to the literature review the commercial product Handmaster (Snoek et al., 2000), in terms of performance, presented functional benefits to patients. In terms of product design, it did not present ergonomic for all sizes of forearms tested, and among ten product units, three did not serve patients because of its small size. Among the three examples presented, both Handmaster as INTFES (Malesevic et al., 2012) and The Wearable Multi-Site System (Crema et al., 2018) proved to be effective in relation to NMES functionality, although they have anthropometric constraints. Furthermore, the last two examples do not suggest the end-user and health team participation until the presented stage of development, which may have generated the mentioned results in relation to the particularities of each patient. This means that if users are ignored early in the stimulation system development process, incompatibilities between this system and the end product tend to occur more easily. In addition, recurring failures in ergonomics, usability, handling and user acceptance of the product will be detected and new issues will need to be fixed. Thus, users, product design, electronics, and assembly manufacturing must be developed simultaneously by an interdisciplinary team.

An advantage of using an app and the microcontroller other than a fixed apparatus (such as a computer) to set up the NMES, is the fact that a single device containing the app is capable, with minor adjustments, to be used for multiple patients at the same time. After the stimulation has been sent from the app to the microcontroller, the app is no longer in charge of the stimulation, been possible to operate in another person. This feature has the potential to increases the amount of patients that can receive the treatment at a time with the same amount of health professionals, therefore creating a more accessible treatment to the public.

The possible limitations of the present study are that a designer with programming knowledge it is necessary to alter the parameters for the development of a new wearable to a new patient, using the same method and the product has been designed for a particular stimulation protocol, if new muscle groups need to be stimulated, the inputs must be reformulated and a new wearable printed.

5 CONCLUSIONS

The results demonstrated that including the end user and the health professionals from the development of the concept design to the wearable production can be a promising alternative to reconciling the complexities involved in a NMES wearable system to overcome its shortcomings and limitations. To achieve these results, the use of Design Thinking, Parametric Design and File-to-Factory processes proved to be feasible and effective.

The next steps for this work include system development for the patient and performance analysis with the motion imaging system.

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