GNEUROPATHY: Validation Process at Clinical Environment

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Abstract: Spinal cord injuries are one of the most traumatic situations with a major impact on a person's quality of life. This type of injury have a extremely impact in the performance of daily life activities not only due to motor alterations but also due to the appearance of neuropathic pain Throughout the rehabilitation process the evaluation and intervention methodologies are not very systematic and are not personalized. Thus, to bridge this gap, the VR4NeuroPain was developed a technology that associates virtual reality with a glove "GNeuroPathy". The glove "GNeuroPathy" allows the collection of physiological parameters, namely to identify the electrodermic activity (EDA) while the patient carries out activities in an immersive environment. The main objective of this article is to present the validation process of the "GNeuroPathy" in clinical context. "GNeuroPathy" was applied to a group of 17 individuals with incomplete spinal cord injury. The results showed that "GNeuroPathy" is easy to apply and is suitable for comfort and texture. Data were also collected from EDA and it was found that there is a significant difference in signal amplitude in patients with low and high functionality.

1 INTRODUCTION

Spinal cord injury (SCI) is one of the most devastating neurological injuries, as the spinal cord is the main communication route between the brain and the rest of the body, so injuries at this level are devastating to the patient, both physically and psychologically. SCI can occur following trauma to spinal cord and also because of a variety of pathologies (e.g. congenital, transverse myelitis, spinal meningitis) SCI leads to dramatic losses in neurons and synaptic connections, and consequently function. Worldwide, the incidence of SCI ranges from 3.6 to 195 per million (Massetti and Stein, 2018) leading to a major medical problem because currently there is no way to repair the central nervous system and restore function.

The long-term disability from SCI results not only from the initial loss of function but also from the complications that accumulate (such as severe spasticity, infections, osteoporosis and pathologic bone fractures) (Jazayeri et al., 2015; McDonald and Sadowsky, 2002). A major long-term complication is muscle wasting, where rehabilitation plays a crucial role in the restoration and/or maintenance of motor skills. These disabilities affect patients' ability to accomplish real-life activities of daily living (ADLs), and often involve critical sub movements, including reaching and/or grasping (Nathan et al., 2009).

Despite the loss of functionality is considered a major long-term complication, the neuropathic pain can be determinant for the patient's inability to return to ADLs, production and entertainment.

Accordingly, it is imperative and crucial to develop new technologies that have a significant impact on the rehabilitation process of the SCI. Virtual reality has become increasingly popular and available being integrated into intervention programs, such as for pain and stress reduction,

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skills training and rehabilitation (Chen et al., 2009).

Therefore, an innovative solution was created called "VR4NeuroPain", which associates virtual reality with sensory and motor stimulation (Quaresma et al., 2018). The system consists of two components: virtual scenarios and a glove - "GNeuroPathy" - monitors electrophysiological data in real time.

With the aim of providing patients with an innovative environment for the rehabilitation process. The "VR4NeuroPain" system allows patients to have contact with an immersive environment that aims to (Quaresma, et al., 2018):

- motivate for the rehabilitation process;
- play an active role in the rehabilitation process;
- promote quality of life and well-being;
- control the achievement of fine and global movement;
- distinguish tactile sensory stimuli;
- stimulate technological literacy.

For that reason, the use of interactive technologies in a rehabilitation process allows to reduce the time spent in that process and greater economic sustainability of the units of the health sector. In order to guarantee the applicability of the system it is necessary to carry out the validation of all the components. Thus, "GNeuroPathy" has already been applied in people with no associated pathology and it has been found to be easy to apply and meets the proposed objectives.

The present work has as main objective to present the validation process of the glove "GNeuroPathy" in clinical context.

2 MATERIALS AND METHODS

The study was approved by the Portuguese Ethics Committee of the Medicine and Rehabilitation Center of Alcoitão, in Portugal. Each participating subject was informed about the procedures and the objectives of the study, prior data collection, and signed a consent form with this information.

All data was collected, during 1 month, from a cohort of patients with spinal cord injury attending the occupational therapy department, at the Medicine and Rehabilitation Center of Alcoitão. The inclusion criteria for the present study were that each patient had incomplete spinal cord injury.

The process of validating "GNeuroPathy", in clinical context, is divided in three parts:

1. Usability – examines the subject's degree of satisfaction, when using the glove;
2. Data collection procedure – assesses the performance of the protocol;
3. Data analysis – prototyping of the analysis procedure, and the interpretation of its outcomes.

Glove “GNeuroPathy” System.

The "GNeuroPathy" glove (Figure 1) is easy to put on, allows object manipulations and currently integrates two types of sensors that collect electro-dermal activity (EDA) and muscle activity (EMG) data. To record the EMG and EDA signals, a Bitalino acquisition module; a pair of EMG sensors and another pair of EDA sensors were used. To connect the sensors to the subject, 2 Ag / AgCL with adhesive electrodes stabilized with solid adhesive were used for each sensor (TIGA-MED Gold 01-7500, TIGA-MED GMBH, Germany) (Guerreiro et al., 2013; Guerreiro et al., 2014).

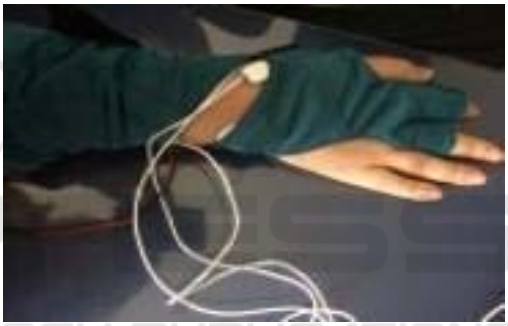

Figure 1: The glove "GNeuroPathy".

Bitalino, together with the sensors and the electrodes used are shown in Figure 2. The recording device collects the biological signals simultaneously, with a 16-bit resolution and sampling frequencies of up to 1000 Hz. All data is transmitted, via Bluetooth, from Bitalino to the computer for processing. In the latter, the software used was Plux’s proprietary OpenSignals (Guerreiro et al., 2013; Guerreiro et al., 2014).

Figure 2: The components of the Bitalino and the EDA sensors (Guerreiro et al., 2013; Guerreiro et al., 2014).

Glove “GNeuroPathy” Data Collection.

After installing the glove, with all sensors securely

attached to the skin, and the hand held by the therapist, stimulation was applied to the hand, at the level of the fingers, in a pre-determined sequence. The first stimulus consisted of a touch, with a pin, to the hand. Subsequent stimuli consisted of sandpaper, cotton, hot and cold contacts with the skin. To reduce the psychological effects of stimulus preparation, the subject was asked to look in the opposite direction to the stimulated hand

The data collection procedure is shown in Figure 3.

Each stimulus was applied for 10 seconds. During the application of each stimulus, EDA parameters were collected. Although both EDA and EMG could have been recorded, in connection with the use of the "GNeuroPathy" glove, this preliminary, validation work collected only EDA information from all subjects. Three collections were made for each stimulus type. The goal was to assess the robustness of the data collected, as well as possible habituation effects, associated with the repeated application of each stimulus type.

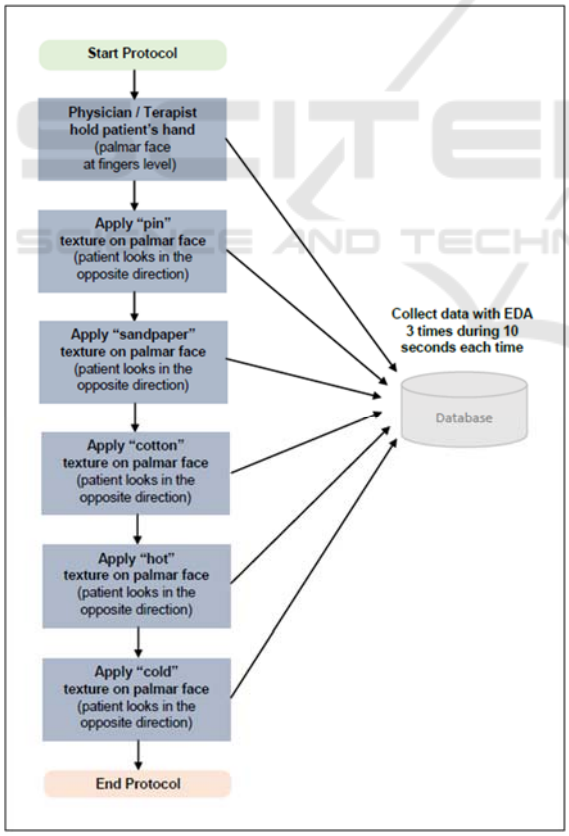

Figure 3: The figure shows the data collection protocol.

Characterization of the Sample.

The sample consisted of 17 patients (7 women and 10 men), aged between 22 and 81 years, with an average age of 55 +/-18 years and an average body mass index of 26 +/- 4. Seven patients did not report having pain; and the remaining ten scored, in the visual analogue scale (Boonstra et al., 2008), as shown in Figure 4.

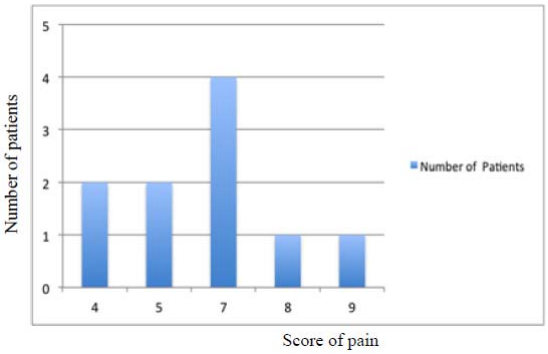

Figure 4: Reported pain for the subjects participating in the study, following the visual analogue scale (Boonstra et al., 2008).

Validation of Data Collection Procedure.

The following data collection protocol was applied to all patients:

1. Describe the study's objectives and obtain the informed consent;
2. Collect demographic data from the participants;
3. Placement of the electrodes on the anterior face of the right hand. A grounding electrode is also placed in the styloid process of the ulna;
4. Placing the glove;
5. Data collection, following the protocol described in Figure 3;
6. Removal of the electrodes and glove
7. Fill patient's satisfaction questionnaire, regarding the use of the glove.

3 RESULTS

Usability Tests.

These tests were conducted to evaluate the parameters of Visual aspect; Accessibility in place; Comfort; Fixation and Texture, in a scale where each of them was considered as Unsuitable, Partially adequate or Suitable.

During the usability tests it was found that 94% of all participating subjects considered "GNeuroPathy" to be "adequate", from visual appearance and comfort perspectives. In addition, 65% of all patients recommended the use of

"GNeuroPathy", and 82% reported that its fixation is "adequate". None of the patients considered the device “Unsuitable”.

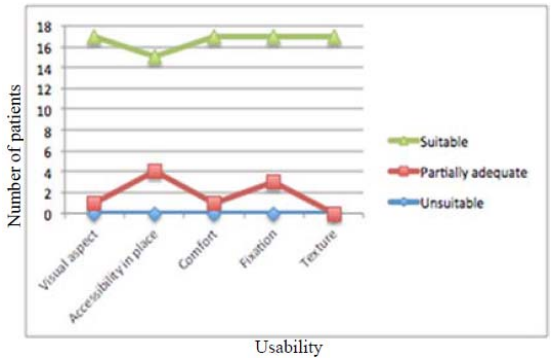

Figure 5: Patients' degree of satisfaction.

Clinical Observations.

After validating the usability of the GNeuroPathy device, physiological data was collected with it. The duration of one full study, running over all stimuli within the protocol, lasted not more than 10 minutes.

The recorded EDA consisted of averages of the electrodermal activity, within a fixed temporal window length, after the application of the respective stimulus (Figure 6).

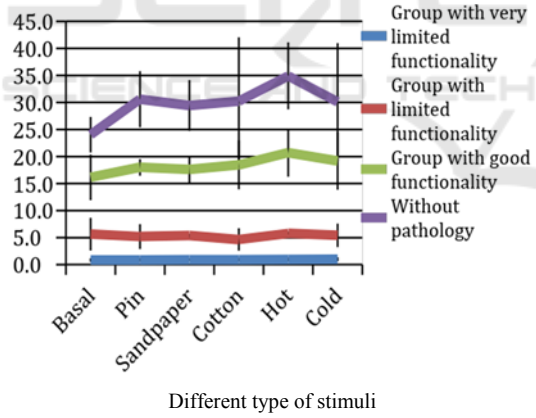

Figure 6: Values of averaged EDA, for all stimuli types, and three different groups of patients suffering from incomplete spinal cord injury. For comparison, also the values found from subjects reporting no level of pathological pain.

We observed that, throughout all patients, the EDA means changed rather highly. From the 17 subjects, about 5 of those presented very low values, when compared to a similar study performed on healthy subjects (Quaresma et al., 2018)). In addition, 5 had close to “normal” EDA values. The remaining 7 had values spreading from one end to the other. Hence, we divided our subjects according to those characteristics, as summarized in Figure 6.

Two significant considerations may be drawn from the results reported. In an immediate look, it is clear that any type of stimulation seems to result in an increase in EDA response higher than the basal response, *ie.*, a condition where no stimulation occurred. In addition, the “hot” stimulus produced the highest response, whereas all others seem rather similar to one another.

The second, and possibly the most important result, is that the five patients with the most severe functional limitations, represented in the graph with a blue color, displayed the lowest EDA values. Even the group with mild limitations, in red, have values that are considerably lower than the ones displayed by the healthy group. Finally, patients with rather good functionality differed little from the group of healthy subjects – both in EDA values themselves, as well as in the relative magnitude variation with the type of stimulus employed.

4 CONCLUSIONS

The principal objective of this article is to present de validation process in a clinical context. For this purpose, the glove "GNeuroPathy" was utilized in a study comprising 17 patients with incomplete spinal cord injury, to collect EDA data. In addition, a usability test was also performed.

This research is part of an ongoing project for system development, called "VR4NeuroPain". In this article, the tests performed on the glove prototype "GNeuroPathy", the physical element of the "VR4NeuroPain" system, were presented.

This study contributed to obtaining a clear feedback on the design and usability of the prototype. The data collection procedure, in the context of EDA response to external stimulation of the hand was also tested.

Although outside of the main purposes of this work, we have observed that EDA is a good indicator of the level of functionality in patients with incomplete spinal cord injuries. As such, one may foresee that a device such as “GNeuroPathy” may be employed to help diagnosing said disease, as well as assess the benefits of given rehabilitation interventions.

In the future we will also develop a software platform where to add all algorithms required for physiological signal processing. In addition, the glove – "GNeuroPathy" – must also be validated associated with the other parts of the system. Tests

in individuals with neuropathic pain will be performed within the "VR4NeuroPain" system, and compared with the conventional procedures, in order to prove the reliability of the system.

The system can be used by multiple users, such us physicians and occupational therapists, and will allow us to apply innovative and interactive methodologies of intervention, promoting the process of rehabilitation.

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