Development of an Equipment to Detect and Quantify Muscular Spasticity: Spastimed – A New Solution

V. Fernandes[1,4], I. Clemente[1], C. Quaresma[2,3], and P. Vieira[1,4]

[1] Departamento de física, Faculdade Ciências e Tecnologia,
Universidade Nova de Lisboa – Monte da Caparica, Portugal
[2] CEFITEC, Departamento de física da Faculdade de Ciências e Tecnologia – Universidade Nova de Lisboa – Monte da Caparica, Portugal
[3] Departamento de saúde, Instituto Politécnico de Beja – Campus do Instituo Politécnico de Beja, Beja, Portugal
[4] Centro de Física Atómica, Departamento de Física, Faculdade de Ciências e Tecnologia – Universidade Nova de Lisboa – Monte da Caparica, Portugal

Abstract—**Spasticity is a known muscular tonus velocity dependent alteration which quantification in clinical practice is still based on subjective perception and scale grading through procedures that lack controlled protocols. In the research field, both physician's and engineer's researches have pointed the potentialities in the use of biomechanical magnitudes and their physiological meanings as much lesser subjective means of quantifying spasticity as well as its effects on patient daily life. Last, but not less important, this scientific and clinic urge is also justified by the high costs of treatments as well as the very tight relation they express between effectiveness and applied dose. As a consequence, this team of developers has been focused in creating a device to detect spasticity. During the validation of a first prototype with a small set of subjects, the obtained results were satisfyingly good as the device correctly detected 89% of the spastic subjects and 82% of the non-spastic subjects. Even so, the limitations found in the prototype concept itself led to a new development phase that resulted on a very different approach. SpastiMed, a motorized and electronically controlled device which is still on its validation phase but already showing an immense potential.**

Keywords—**Biomedical Engineering, Medical device, Biomechanics, Muscular tonus, Spasticity assessment.**

I. INTRODUCTION

Spasticity consists on a muscular tonus alteration caused by a flawed neural central system [1] that fails to do its role in muscular inhibition which leads to a loss of the natural balance between activation and inhibition causing this hypertonic phenomenon [1]. Spasticity is normally perceptible by the rise of sensed "rigidity" during the passive mobilization of an affected limb [1]. This "rigidity" has been known to be velocity dependent [1] and can affect negatively the life of patients by turning daily simple tasks into hard or even impossible ones, greatly compromising the patient independency [2].

There are three main classes of methods used for muscular spasticity quantification: the *Likert* scales [3-8], electrophysiological measurements [4, 9] and biomechanical measurements [4, 6, 9]. The most used in clinical procedure are the *Likert* scales, especially the Modified Ashworth Scale (MAS) [4-8, 10] and Modified Tardieu Scale (MTS) [3, 7]. Both these scales quantify spasticity based on the perception of the muscular response trough the passive mobilization by an operator with no resource to any precise measuring tools [3-7]. In the research field, many equipment have been built based on the quantification of biomechanical magnitudes that have shown a direct relation with spasticity [4, 7, 11-16]. Most of these equipment had either unappropriated size for clinical usage, small inter and/or intra-patient result correlation, or a noticeable result dependence on the operator.

Like many other types of pathologies which assessment was or still is made by the use of subjective methods, spasticity assessment and quantification has been the target of many physicians and engineers with the goal of instrumenting it and turning it into an objective and precise process [4, 7, 11-16].

II. A FIRST STEP – "THE GLOVE"

Concept Design: The goal of this project was to develop a low-cost and easy-to-use prototype to detect the presence of muscular spasticity and, if possible, to do its quantification by grading it in a 6 levels custom scale (Inexistent, Very Slight to inexistent, Very Slight, Slight, Moderate and Severe) [12].

Through many studies, the few products and prototypes that showed potential for clinical use also expressed that one of their main problems was the need to create and apply a new protocol to attain a better spasticity measure aided by a tool in daily clinical procedures. For this reason, the design and conceptual idea was based on a main principle: "To build something that physicians could use without interfering with their usual protocol for spasticity assessment" [12]. As a result, the author [12] idealized a hand-held device that could be used trough the normal

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procedure. Based on its look, this prototype was nicknamed: "The Glove".

The final state of this prototype can be seen on Fig. 1 and can be swiftly described as a glove with a small water bag coupled with a pressure sensor connected to an acquisition system (MicroChip® PIC® based) in communication with a personal computer where a graphic interface developed in MATLAB® presents real time data to the user [12].

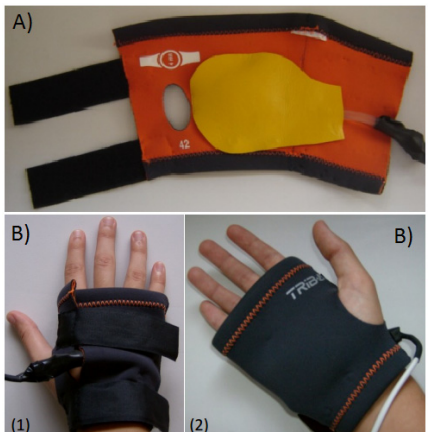

Fig. 1 Device developed by Inês Clemente [12] to assess muscular spasticity A) Inside view of "The Glove" (Small water bag inserted in between the glove tissue and the yellow cover tissue). B) Outside view of the Glove, (1) back of the hand (2) and palm view [12].

Results: To validate the equipment it was used to examine a small set of 29 subjects with ages comprised between 18 and 60 years old which expressed their ethic and informed consent on the procedure [12]. Among these, 4 had clinical record of muscular spasticity on flexor muscles and 25 subjects were deemed as having no muscular spasticity in

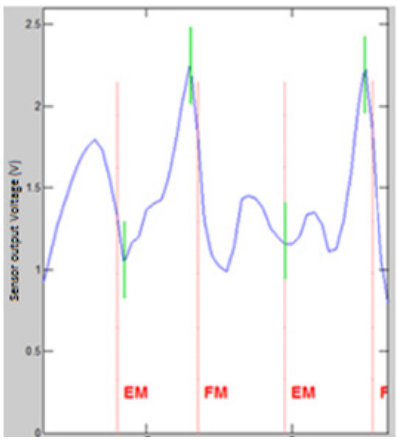

Fig. 2 Signal obtained from a healthy subject. The red markings represent the moments of max extension (EM) and max flection (FM) for better understanding of the signal and its peaks [12].

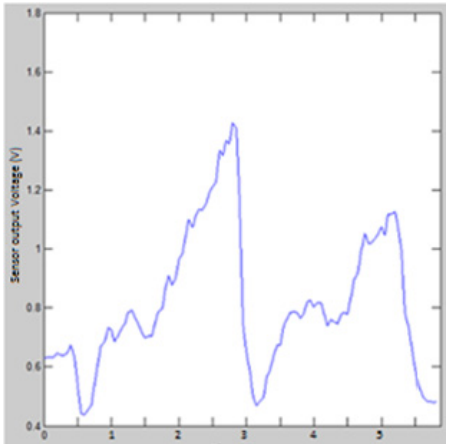

Fig. 3 Signal obtained from a subject with previously detected moderate upper limb flexor muscle spasticity [12].

the upper limb muscles [12]. Previously to the use of "The Glove", all of these 29 subjects were re-evaluated by a physician and their muscular spasticity was graded according to the before mentioned custom scale. In total, the team collected a pool of 83 (Physician + "The Glove") sets of data, 9 sets from the 4 spastic subjects and 74 sets from the 25 non-spastic subjects [12].

The evaluation procedure was done with the patient seated and starting with the limb on its max flexion parallel to the body [12]. During the data acquisition period the user, wearing "The Glove" should fully extend and fully flex the limb and repeat this cycle 5 times with the same time length trough cycles, if possible [12].

One characteristic signal resulting from the examination of a non-spastic subject can be seen in Fig. 2 and one in a spastic subject can be seen in Fig. 3. The signal analysis focused only on the peaks expressed during the flexion movements because of the spasticity presented by the previously mentioned evaluated subjects [12]. Those mentioned peaks were averaged and the resulting peak was parametrically adjusted to the first half-period of a sine wave function. The parameter that showed a good potential for the grading was the angular frequency (b1). For that parameter and based on the physician classifications the author [12] b1 gaps were defined for each degree of muscular spasticity and finally the results obtained with "The Glove" were given a grade. Those results are presented in Table 1.

Conclusions: Even if these results can't be considered statistically sound due to the small number of sets of data, from Table 1 we can conclude that "The Glove" was able to assess in accordance with the physician 74.6% of the "Inexistent" cases, 33.3% of the "Very Slight to Inexistent", 66.7% of the "Very Slight" cases as well as 100% of all the cases in the "Slight" and "Moderate" cases. As a global result, the equipment was able to detect correctly 89% of the spastic subjects and 82% of the healthy subjects.

During validation "The Glove" revealed itself prone to generate signals with considerably different shapes based on a simple change of user. This limitation was circumvented by doing this validation with just one operator [12] and relegating for later the development of a better software based on a more extensive signal analysis to fix this problem.

Table 1 Comparison of the results obtained by the equipment versus a trained physician in muscular spasticity assessment [adapted from 12].

Physician Evaluation Result		"The Glove" Evaluation Result		
Degree of Muscular Spasticity	no. of cases	Degree of Muscular Spasticity	Cases	
			no.	%
Inexistent	71	Inexistent	53	74.6
		Very Slight to Inexistent	6	8.5
		Very Slight	3	4.2
		Slight	9	12.7
Very Slight to Inexistent	3	Inexistent	1	33.3
		Very Slight to Inexistent	1	33.3
		Very Slight	1	33.3
Very Slight	3	Very Slight to Inexistent	1	33.3
		Very Slight	2	66.7
Slight	4	Slight	4	100
Moderate	2	Moderate	2	100

Another limitation was the before mentioned quantification scale which was adopted with the goal of being in accordance with the rating used in the *Hospital Curry Cabral* services of Physical Medicine and Rehabilitation where the instrument validation was made. In the end it revealed to have an excessive number of grades (four) from "Inexistent" to "Slight" which surely aggravated the flawed differentiation in between them which is a common problem even among all existing *Likert* scales and documented prototypes. Also, the fact that this scale it is not a standard scale, left an undeniable need for another study comparing this device results to a "gold standard" so it could be compared with other instruments as well as the most used *Likert* scales. Other identified limitations like the lack of velocity control and angular monitoring added to the above mentioned problems lead the team to a new development phase.

III. The Next Step – SPASTIMED

Following the limitations found on the conceptual idea behind "The Glove" as well as the improvable aspects in the prototype the final decision was to put this prototype development in standby and try a different approach. The team gathered all the crucial knowledge acquired previously and synthetized it to decide what the new approach should be based on. As a result, 5 main features were identified and "placed on the drawing table" as key-point characteristics that this new prototype should attain. These key-points were: being of easy and fast application, no need for a specialized operator, being portable, present a good result reproducibility and a good independency from the operator in the results produced.

After coming up with a first drawing of the prototype, the team applied for a short intern program lectured by physicians in *Centro de Medicina de Reabilitação de Alcoitão*, where they could contact with spastic patients as well as gather the physicians opinion on the prototype drawing and future perspective of using such tool. Their answers were highly considered and took a major role into the final design itself.

The whole prototype can be understood trough the block diagram presented in Fig. 4. To resume, the mechanical part (Fig. 5) consists on a DC motor and a set of gears attached on top of a metallic articulated arm responsible for making the patient limb move passively while a set of electronic circuits collect data like the motor consumed current (proportional to the torque output) and the metallic arm angle. All the data is collected by a MicroChip® PIC18F877A microcontroller and transmitted through USB communication to a control user interface developed in LabVIEW™ running on a personal computer where the muscular spasticity is assessed and quantified based on biomechanical velocity dependent information, based mainly in the incredible tool built to study spasticity made by *Ju MS et al.* [11], is extracted from the data.

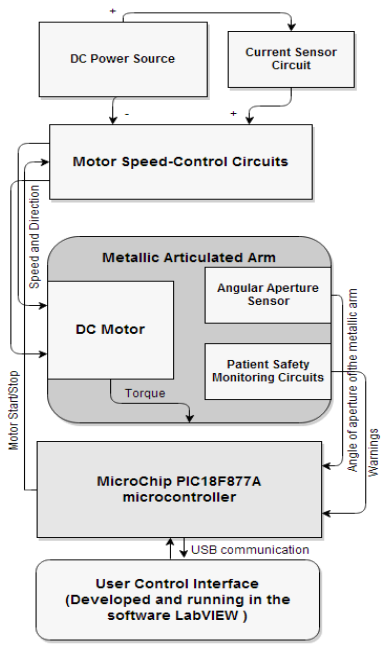

Fig. 4 Block Diagram of the SpastiMed device.

The development of this equipment was recently finished and it is now under its validation phase which is to be done by crossing the instrument results with results obtained with the clinically most used *Likert* scales: MAS and MTS.

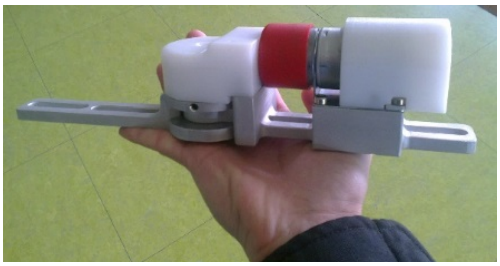

Fig. 5 Mechanical part of the SpastiMed equipment.

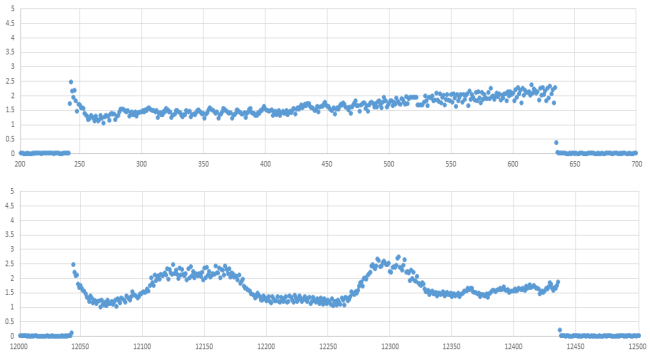

Fig. 6 Signals acquired from a healthy subject during an extension movement induced by SpastiMed. Relaxed arm (top). Small opposing force spikes (bottom). Axis labels: Y – current (A) X – time (cs)

In Fig.6, two different motor consumed current signals can be seen and the sensitivity of the device is evidenced. Last but not least, a safety protocol was developed into the software to ensure a painless and safe evaluation complemented by a set of push buttons that both the operator and the patient can click at any time to order the device to stop the motion.

IV. Conclusions

Even though the study on physically, physiologically and mathematically explained quantification methods for spasticity has started nearly half a century ago, not even a single device has been able to turn into a clinical new standard till now. With the development in the area of electronics and the decrease in the costs of components arose the possibility of producing smaller, smarter and more precise instruments to quantify spasticity and other pathologies from which scientific knowledge is still scarce. This last fact is mainly one of the causes that turns biomedical instrumentation into such an interesting area and with such relevance for both the improvement in quality of daily clinical procedure and in diluting barriers in scientific investigation towards the understanding of many biomechanical pathologies.

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