
Validity and reliability of a tool to measure impairment changes in preparation for the RF Bion[®] micro-stimulator upper limb project

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Abstract

Functional outcome measures such as the Action Research Arm Test (ARAT) have been shown to detect changes following Therapeutic Electrical Stimulation (TES) of the upper limb following stroke. These tests do not however provide information about the mechanisms responsible for the changes or indicate which patients may respond best to treatment. In preparation for a study using RF Bion[®] micro-stimulators for re-education of upper limb function following stroke we have developed an assessment tool in which we can record force about the wrist joint, angle and two channels of EMG (wrist flexors and wrist extensors) during a passive and active tracking test. Indices based on those derived from an ankle rig test [1] to describe stretch response and motor control are reported. Preliminary results suggest that the system is a valid and reliable tool. Tracking ability, but not stretch response, was shown to correlate with the ARAT.

1. INTRODUCTION

Validated functional outcome measures, used widely in rehabilitation, have been shown to be reliable and sensitive to changes associated with therapeutic electrical stimulation (TES) of the upper limb [2]. Commonly used measures include the Action Research Arm Test (ARAT) [3] and the upper limb section of the Fugl-Myer (FM). Standardised tests such as these are relevant and useful to measure functional change, but they do not provide information about the mechanisms responsible for the change in function. An understanding of these mechanisms is vital to the development of our understanding of the neurophysiological effects of electrical stimulation and thus to optimise treatment.

1.1. The Bion Project

As part of a preliminary study using RF Bion[®] micro-stimulators for re-education of upper limb function following stroke we have developed an assessment tool based on an original design by David Pandyan to enable us to measure impairment changes in motor control, spasticity, muscle activation patterns during voluntary movement, range of active movement, relationship between torque and displacement during passive movement and isometric force about the wrist. The assessment tool will be used in conjunction with two functional outcome measures, the Fugl-Meyer and the ARAT. Prior to being included as an outcome measure we have conducted a validation study with normal and impaired subjects and with two independent assessors to test inter and intra-rater reliability and to compare these impairment measures with upper limb function using the ARAT.

1.1. Design of the rig

The wrist rig is instrumented to record force about the wrist joint, angle and two channels of EMG (wrist flexors and wrist extensors). The subject sits in a specially designed chair with the arm to be tested secured into the padded rig, hinged at the wrist. The rig is made from non-metal components so that it can measure response during stimulation. In front of the subject is a monitor displaying an elliptical target moving sinusoidally horizontally across the screen at a frequency set to between 0.1 and 2Hz. Angular position of the wrist is displayed as a cross allowing either the subject or assessor to track the target by moving the wrist aiming to keep the cross within the ellipse.

EMG signals are recorded from the wrist flexors and extensors using BEAC Biomedical pre-amplifiers and self adhesive electrodes (Myotronics-Noromed Inc). Signals are further amplified and anti-aliased using a low pass filter (cut-off frequency 250 Hz). The signals are digitally sampled at 1 kHz

2. METHODS

Ethical approval for the study was granted (04/Q2008/12)

2.1. Subjects

Two groups of subjects were tested in the rig; people with a hemiplegia following a stroke of at least six months duration who had impaired wrist extension (minimum of 10 degrees and no more than 75% of the non-affected side) and an unimpaired age matched sample.

2.2. Performance of the test

Set-up: Following written informed consent subjects and selection criteria screening, subjects were asked to sit in the chair with their arm in the rig. Height of the chair was adjusted to standardise arm position. In normal subjects the dominant arm was tested. EMG was recorded using a standardised protocol [4] The arm was positioned so that the wrist joint was aligned with the hinge. The arm was then secured in the rig.

A series of tests were performed within the rig to measure stiffness, isometric force and ranges of passive and active movement, however, only passive stretching at 1.5Hz and the tracking test at 0.5 Hz, described below, are presented in this paper.

The procedure for the test was explained to the subject. During the tracking test they were asked to move their wrist through flexion/extension so that the cross representing the tracking signal remained within the ellipse of the target signal. They were allowed to practice the tracking test until they felt they had achieved their best performance. Following this they were allowed to rest for a few minutes before a recording of 60 seconds was made.

Following this the assessor moved the wrist passively, again keeping the target and tracking signal aligned. This test was recorded for 40 seconds.

Each test was performed three times: by assessor 1, then assessor 2 and then repeated by assessor 1. This allowed inter and intra-rater repeatability of the test to be measured. The subject was released from the rig between each set of tests. Following the rig tests, impaired subjects performed the ARAT conducted by assessor 2.

2.3. Derivation of the indices and data analysis

Indices were derived to describe the stretch response of the wrist flexors and tracking performance using Matlab 12 (The MathWorks, Massachusetts, USA). Statistical tests were performed using SPSS v12. (ARAT and Spearman's rho) and using Matlab (Bland and Altman tests).

Stretch Index (SI) was defined as the ratio between the mean EMG amplitude at rest (described as the global mean) and mean amplitude during passive wrist extension. Higher values indicated an active response in the flexor muscles to stretching. To describe tracking performance a sine wave was fitted to the tracking signal and Tracking Error (TE) defined mean distance between the sine waves formed by the target signal and tracking signal. Small TE values indicated better tracking.

3. RESULTS

3.1. Subjects

12 people with hemiplegia and 12 unimpaired subjects were recruited to the study. Demographic data are shown in Table 1.

Table 1. Demographic data of the subjects

	Normal subjects	Hemiplegic subjects
Mean (SD) age	50yrs 7m (19yrs 6m)	60yrs 1m (14yrs 2m)
Min-Max	22-72	32-79
Gender	7M 5F	6M 6F
Side tested	10R 2L	4R 8L
Time from stroke (SD)	N/R	5yrs 6m (3yrs 10m)
Min-Max		1-13

3.2. Inter and intra-rater reliability

Results are presented for inter and intra-rater reliability for the SI and TE for both normal and impaired subjects.

Table 2a and 2b show the SI values (2a) and TE (2b) for unimpaired and hemiplegic subjects for each assessor at each session. Comparison between Assessor 1 at sessions 1 and 2 indicate intra-rater reliability and comparison between Assessors 1 and 2 indicate inter-rater reliability.

Table 2a

Stretch Index (SI)		A1 Test 1	A2 Test 1	A1 Test 2
Stroke (n=12)	Mean	10.4	11.1	14.1
	(SD)	(15.1)	(16.7)	(18.6)
	Min-Max	0.2-48.3	0.4-56.0	0.2-60.6
Normal (n=12)	Mean	0.5	0.3	0.3
	(SD)	(1.1)	(0.4)	(0.3)
	Min-Max	0.0-3.8	0.1-1.5	0.05-1.0

Table 2b

Tracking Error (TE)		A1 Test 1	A2 Test 1	A1 Test 2
Stroke (n=12)	Mean	11.9	11.6	9.2
	(SD)	(5.5)	(6.0)	(5.2)
	Min-Max	4.1-19.8	4.3-19.6	2.5-18.9
Normal (n=12)	Mean	2.0	4.9	2.4
	(SD)	(0.7)	(2.3)	(0.9)
	Min-Max	1.2-3.2	1.9-4.9	0.8-3.8

(A1 = Assessor 1)

Figures 1a and 1b. Bland and Altman plots to illustrate the range of values for normal and impaired subjects and range of variation in SI at 1.5Hz (1a) and TE at 0.5 Hz (1b) recorded by Assessor 1 at test 1 and test 2. Open triangles = hemiplegic subjects and circles = normal subjects. Mean = mean of test 1 and 2, difference = difference between test 1 and 2.

Figure 1a

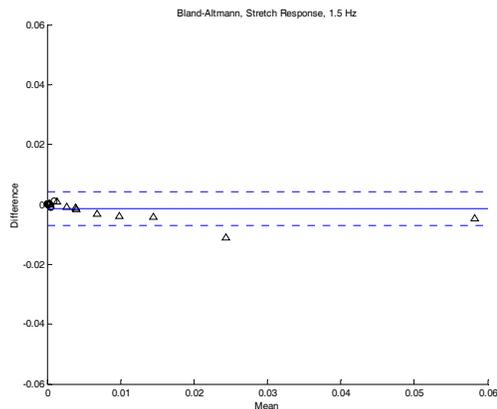
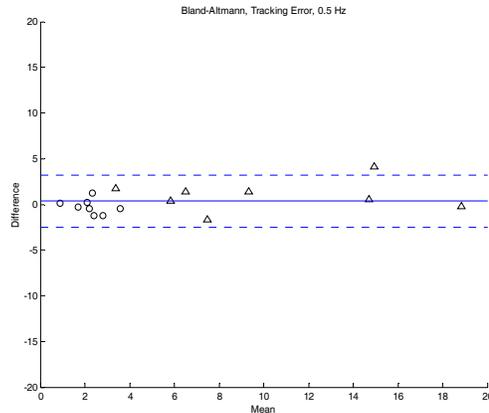


Figure 1b



3.3. Relationship between upper limb function, measured by the ARAT, and the impairment measures (SI and TE).

Mean (SD) total ARAT score was 18.75 (11.5) out of a possible score of 57 - Min-Max 3-37. For the impaired subjects we calculated the correlation (Spearman's Rho) between the ARAT score and the mean SI and TE. Correlation between total ARAT score and the mean TE, (-0.702 $p = 0.016$), and between the Mean TE and SI (0.636 $p=0.003$) were both statistically significant. Correlation between the SI and ARAT score (0.359 $p = 0.309$) was not significant.

4. DISCUSSION AND CONCLUSIONS

The wrist rig impairment indices (SI and TE) clearly distinguish normal from impaired subjects and may provide useful information concerning the impairment characteristics of subjects who are about to undergo TES using RF Bion[®] micro-stimulators. These characteristics are ones that we expect to change as a result of using the Bion[®] system.

Protocol for performing the tests has shown good intra-rater reliability and inter-rater reliability. In the proposed study we will take into account the inter- and intra-rater reliability.

There was a relationship between TE and function, measured by the ARAT, but not between the SI and ARAT score, suggesting that spasticity may not in these subjects have been a factor in performance of the ARAT. There was however a correlation between the SI and TE, suggesting that the motor control required to track the target was affected by spasticity of the wrist.

References

- [1] Burridge JH and McLellan DL (2000) Relation between abnormal patterns of muscle activation and response to common peroneal nerve stimulation in hemiplegia, *Journal of Neurology, Neurosurgery and Psychiatry* 2000;69:353-361
- [2] Powell J, Pandyan D, Granat M, Cameron M, Scott D (1999) Electrical stimulation of wrist extensors in post-stroke hemiplegia. *Stroke*, 30, p1384-89
- [3] Lyle RC (1981) A performance test for assessment of upper limb function in physical rehabilitation treatment and research, *International Journal of Rehabilitation Research*, 4: pp483-92
- [4] Hermans HJ, Fericks B, Merletti R, Stegeman D, Blok J, Rau G, Disselhorst-Klug C, Hagg G (1999) Seniam 8 European Recommendations for Surface Electromyography, Roessingh Research and Development

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