Hand Functional Recovery in Sub-acute Brain Injury Stage Patients using AMADEO® Robotic-assisted Therapy

A Pilot Clinical Study with Apraxic and Neglect Patients

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Abstract: INTRODUCTION: Repeated and intensive exercise with AMADEO® Robot-Assisted Therapies (RAT) has been found useful in restoring functions of hand paresis in some brain-injured patients. OBJECTIVES: Evaluate the effects of RAT using AMADEO® device in combination with Conventional Neuro-rehabilitation Therapy (CNT) for the hand functional recovery in post-acute phase patients and to identify differences in the hand outcome trends among infants and adults with different recovery potential. METHODS: 12 adults and 3 infants with neglect or apraxia and hemi-paresis of the upper limb were enrolled in this prospective randomized pre-post pilot clinical study. They were assigned a priori to positive (PF+) or negative (PF-) prognostic factor groups. All subjects followed the same standardized protocol with AMADEO® and CNT. The outcome measures selected were: ARAT, MAS, COTNAB (subtest III), RASP, RPAB, and AMADEO® ROM and Strength Assessment Tools. RESULTS: Statistical analysis showed important differences between PF+ and PF- groups in hand function outcome measurements. Similar improved trends were found between PF+ and the group of infants. Both groups improved in extension variables, total score, level of difficulty, and speed in performing robot-graded tasks. They also showed more strength and motor control. Patients in the PF- group showed only hand recovery in flexion and ROM variables after using the robotic device. Positive intra- and intersession effects were found in all patients. DISCUSSION: The results suggest that finger motor activation and less somato-sensorial impairments in pre-test could be a better sign for the prognosis of hand recovery and for the decision to apply Amadeo® in opposite to the presence or absence of apraxic or neglect symptoms, which have been referred as contraindications. Amadeo® was a valuable tool, easy to use, safe and useful to monitor hand recovery and improve grip and finger motor function in spite of the presence of other cognitive impairments.

1 INTRODUCTION

Nowadays, improving hand hemiparesis after brain injury is a main objective in neuro-rehabilitation in order to decrease disability in post- brain-injured survivors. Chronic hand paresis deficits are prevalent in the distal upper extremities in over 40 % of individuals, especially regarding arm and hand motor function (Wang, 2012). Most studies have found that proximal improvements do not migrate to the distal arm or *vice versa* (Takahashi, 2008). Unfortunately, some of these patients with potential for partial hand recovery could be excluded from using robotic devices such as AMADEO® due to interference with other cognitive impairments, as apraxia or neglect. These symptoms have been referred in the instruction Tyromotion manual of AMADEO® as contraindications. Repeated and intensive exercise with robot-assisted therapies has been found useful in restoring functions of upper extremities by their ability to deliver well-defined repetitive exercises consistently. Furthermore, the highly frequent afferent stimulation combined with increments in efferent activity can stimulate the mirror neurons and can lead to a shift in the contribution of the Sensory-Motor Cortex (SMC) activation of the unlesioned and lesioned hemispheres (Enzinger, 2012).

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2 OBJECTIVES

The first aim was to evaluate the effects of robotic-assisted therapy (RAT) using AMADEO® hand device in combination with occupational and physiotherapy conventional neuro-rehabilitation (CNT) for the hand functional recovery in post-acute phase (**Figure 1**).

The second aim was to identify differences in the hand outcome trends among infants and adults with different recovery potential. Finally, safety contraindications of the standardized guidelines of the AMADEO® Tyromotion manual, version R5 (2010 - 2011), will be discussed.

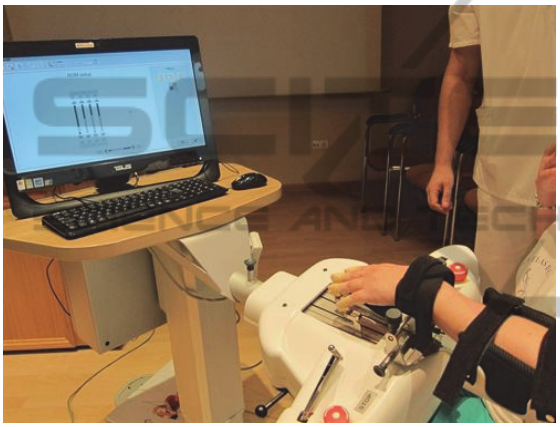

Figure 1: Use of the AMADEO® hand robot device.

3 METHODS

A sample of 12 adults and 3 infants with moderate to high grade of hemi-paresis of the upper limb, an Asworth Scale score of spasticity minor than 3 and an evolution time inferior to 6 months (**Table 1**) were enrolled in this prospective randomized pre-post pilot clinical study.

On one side, all patients with any extension or flexion hand activity and less somato-sensorial disability (moderate impairment in the upper limb) were assigned a priori to group 1, with a positive prognostic factor (PF+). On the other side, patients without voluntary finger activation and high somato-sensorial disability (severe impairment in the upper limb) were assigned to group 2, with a negative prognosis factor (PF-). Apraxic or neglect impairments were not kept in mind for patient grouping. The 3 children were included on a third independent group.

All subjects followed the same standardized protocol (45 min per session, 2-3 times a week, 12 weeks maximum) with the hand robot, *i.e.,* passive (CPM), active-assisted (AAT) or active task-oriented (AT) repetitive hand/finger trainings. Throughout the 3 months of treatment, all patients received similar conventional multidisciplinary neuro-rehabilitation and specific occupational and physiotherapy sessions to optimize hand functional sensory-motor performance.

Table 1: Demographic variables of sample groups. CVA: cerebrovascular accident; Infants: Infants group; L: left; PF+: Positive prognosis factor group; PF-: Negative prognosis factor group; R: right; TBI: traumatic brain injury.

	PF+	PF-	Infants
Age (years)	63 ± 11	56 ± 12	12 ± 3
Etiology	1 TBI 5 CVA	6 CVA	3TBI
Hemi-paresis	1 R 5 L	3 R 3 L	1 R 2 L
Hand dominance	5 R 1 L	5 R 1 L	3 R 0 L

The following primary and secondary hand function outcome measures (Sivan, 2011) were selected: Action Research Arm Test (ARAT) to assess activities, and Motor Assessment Scale (MAS), along with Chessington Occupational Therapy Sensory-motor Assessment (COTNAB-subtest III) and Rivermead Assessment of Somatosensory Performance (RASP), to assess body function. AMADEO® Range of Motion (ROM) and Strength Assessment (SA) tools were also used as pre-post outcome measures. Rivermead Perceptual Assessment Battery (RPAB) and Rivermead Assessment of Somatosensory Performance (RASP) were used prior to the use of this robotic device to diagnose apraxic or neglect symptoms in all patients.

4 RESULTS

Assuming normality, homocedasticity and sphericity in all variables, preliminary data analysis by ANOVA of repeated measurements followed by *post-hoc* tests showed not statistically significant differences between PF+ and the group of infants in any of the variables analysed. Moreover, similar improved trends of recovery were found in these two groups.

In most of the variables analyzed, statistical significant differences were found for the effect of treatment between PF+ and PF- groups ($p < 0.05$).

However, the statistical analysis of the interaction among groups showed, with a high

contrast potency, that only PF+ and the group of infants improved in the extension variables such as total extension SA score, individual II-III-IV-V finger activation in extension SA and extension trend of recovery ($p < 0.05$).

With a moderate contrast potency, there were no differences among both groups in quantity of improvements associated to flexion variables ($p > 0.05$) such as flexion SA total score, flexion SA pre-test, individual I-II-III-IV-V finger activation in flexion SA, and flexion trend of recovery. Also, the effect of the interaction within and between subjects was significant in those variables.

Further post hoc analyses showed a more significant improvement in the PF+ group than PF- group in pre-post measurements. The PF- group also showed hand recovery although less significantly in variables such as flexion SA total score, ROM and flexion recovery trends after using robotic-device (**Figure 2**). Additionally, in 3 out of 6 PF- cases we found progressively lower hand tone intra- and inter-sessions. Besides, the PF+ group improved in the score, level of difficulty and speed in performing robot-graded tasks (**Figure 3**). It also showed more strength and motor control (Norouzi-Gheidari, 2012).

Positive intra- and inter-session effects were found in all patients, particularly good tolerance, motivation and absence of pain.

Patients in the PF+ group with contraindications to apply AMADEO® (e.g., apraxia and symptoms of neglect) improved hand motor function and increased the use of affected hand in the post-tests. In contrast, patients with lowest somato-sensory performance showed worse hand outcomes. Some patients with PF- *a priori* and apraxia or neglect symptoms demonstrated smaller but positive outcomes.

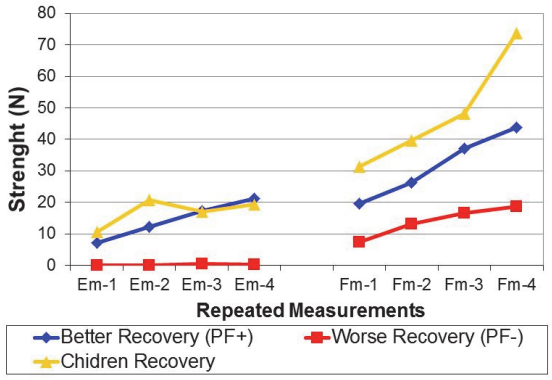

Figure 2: Hand function assessment with AMADEO®. Em: mean Extension; Fm: mean Flexion; PF+: Positive prognosis group; PF-: Negative prognosis group.

Important differences between both groups in hand function outcome measurements were found for COTNAB-III ($p = 0.000$), MAS ($p = 0.000$) and ARAT ($p = 0,000$) tools at post-tests (**Figure 4**).

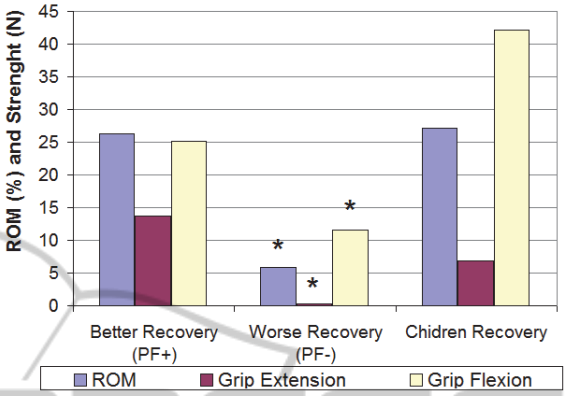

Figure 3: Pre-post hand function improvements with AMADEO® tool. ROM: Range of motion. *Statistically significant differences ($p < 0.05$).

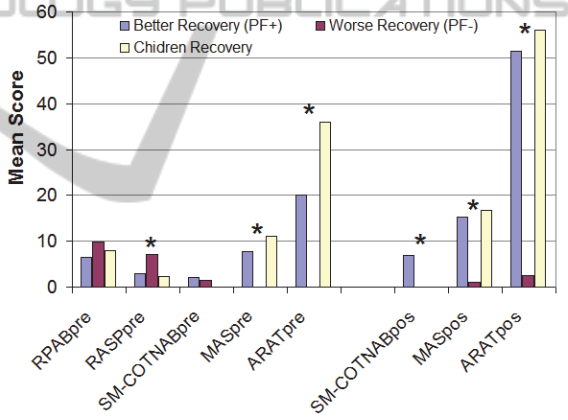

Figure 4: Main hand outcome measurements. Please, see Methods for abbreviations on the variables used. Pre: pre-test; Pos: post-test. *Statistically significant differences ($p < 0.05$).

5 DISCUSSION

The findings of this pilot study seem to reveal that the safety contraindications to apply clinically this robot device (page 6, version R5, 2010 - 2011) should be revised. The results suggest that minimal finger activation motor skills and less somato-sensorial impairments, such as baseline in pre-test, could be a better sign for the prognosis of hand recovery and the decision to apply Amadeo® in opposite to the presence or absence of apraxia or neglect symptoms. For this group of patients with

cognitive impairments, Amadeo® was a valuable tool with a complex intervention design (Hwang, 2012), easy to use, safe and useful to monitor hand recovery and improve hand grip and finger motor function.

Our pilot results evidence a better recovery prognosis for children or patients with motor finger activation in the hand and less somatosensorial deficiency, contrary to patients with severe sensitive damage and serious hand paresis. Apraxic and neglect symptoms can interfere and complicate the recovery of the paretic hand, but it is not decisive. Patients with neglect could benefit from the AT program facilitated by the adjustments of the AMADEO® software, whereas patients with apraxia could improve their motor control due to the combination of AAT and AT programs.

The combined use of CNT, RAT and splinting has allowed to regulate and reduce the flexor tone of hand in 3/12 adult cases.

The presence of other concomitant variables and their potential positive or negative contribution to hand function recovery, such as cranioplasty, cancer radiotherapy or pneumonia due to dysphagia, has been observed although not analyzed during this pilot study.

Despite lacking finger opposition and ADD-ABD of thumb and lumbrical and interosea movements, the appropriate visual, auditory and somatosensorial feedback of motor execution, along with the possibility of working the finger discrimination of movements and the feedforward at the higher levels of the device, transforms AMADEO in a good tool to improve the hand function in combination with CNT.

The total or partial improvements of one or several study groups (PF+, PF- and infants) in the main variables of motor function analyzed (ROM, flexion or extension SA, finger activation, activities, and body functions) justifies the necessity of new studies. More studies will be needed to assess impact of our results on the activities of daily living (ADL). Specifically, the small sample size and the absence of a control group in this study did not allow us to verify whether this treatment is valid in terms of effectiveness and universality (Sale, 2012). In future studies, more statistical analysis will be needed to: (1) further estimate the impact of these results on larger samples, (2) to compare with a control group the outcomes between RAT and CNT with a broader variety of time and intensity regimens (MacClelland, 2012), and (3) to assess the generalization of outcomes on ADL with a repetitive, functional and specific task-oriented rehabilitation in order to ensure hand function improvements in brain-injured patients. The good outcomes found in this pilot clinical study encourage us to design a larger prospective study.

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