Journal of Mechanical Engineering and Biomechanics, Volume 4, Issue 2, Page 25-30, 2019
ISSN- 2456-219X

On pilot studies for robotic therapy: the relevance of healthy subjects' motor control responses to protocol design

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Special Issue: 6th Brazilian Meeting of Biomechanical Engineering (ENEBI 2018-Part II)

Research Article

Article History
Received 08/09/2018
Revised 15/03/2019
Accepted 10/07/2019

Recommended by Editors
André Ferreira Costa Vieira

Abstract

Robotic device deployment for the recovery of people with neurologic diseases is increasing. However, there are insufficient guidelines to prescribe rehabilitation therapy for the lower limbs robotic systems. The aim of the study was to verify whether a single session of robotic therapy promotes short-term ankle adaptations, influencing the sub-maximum torque maintenance of ankle in health individuals. Methods: This was a transversal pilot study on a convenience sample of participants (n = 14). Balance and gait function were measured. Steadiness tests were assessed using dynamometry. For submaximal sensori motor control analysis (Steadiness), the standard deviation, coefficient of variation and root mean standard error (RMSE) were recorded. Results: Only the dorsiflexion movement presented significant differences for SD (F=7.10; p=0.01) and CV (F=6.20; p=0.02). Conclusion: People with health individuals presented short-term performance gains in submaximal torque maintenance after a single robotic therapy session. ***DOI:*** *https://doi.org/10.24243/JMEB/4.2.206_X*

Keywords: Neurological Rehabilitation; Videogame therapy; Anklebot; Ankle rehabilitation, Assistive Technology

1 Introduction

Using robotic systems to complement conventional rehabilitation programs is a promising resource that can promote revolutionary opportunities to neurological therapy. Robotic devices can provide high-intensity, repetitive, specific and oriented task practice. Several robotic devices have been proposed for rehabilitation of ankle movements, since this particular joint has an important role on guaranteeing a normal gait pattern. The device used in this study is the Anklebot, a three-degree of freedom impedance-controlled robot developed at MIT for ankle rehabilitation. Results related with this device showed that Anklebot protocols have influenced gait performance of post-stroke subjects, since it allows varied and adjustable levels of assistance to facilitate impaired limbs [1], [2]. Furthermore, videogames and biofeedback interactions can promote additional motor control adjustments and improve motivation, optimizing task performance in individuals with hemiparesis [2]-[4]. However, the process to ensure that the therapeutic protocols are effective includes a previous investigation about adverse effects and the level of difficulty. Verifying its effects in

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healthy individuals is a starting step to test a protocol with the high intensity characteristic, i.e., a high number of repetitions.

The process of developing a robotic therapy protocol with game association is rarely reported. Considering the elaboration or adaptation of these protocols considering the particularities of each population, many tests are performed. However, these results that precede a clinical research are often not disclosed. The access to the entire protocol design process would be helpful for less experienced research groups, it promoting new quality clinical studies. Considering that, this study proposal is related to preliminary protocol verification.

Accordingly, the aim of the study was to verify whether a single session of robotic therapy promotes short-term ankle adaptations, influencing the sub-maximum torque maintenance of ankle (steadiness condition) in health adults. The study included not sedentary individuals who have not been affected by chronic diseases. The hypothesis was that the single robotic-assisted session promotes short-term adjustments in motor control of ankle during submaximal torque. The present protocol was developed with the purpose of improving the ankle motor control of hemiparetic individuals. This protocol was developed with to promote a safe therapeutic environment with the sitting patient, and can be applied to patients with limitations on orthostatic position and dorsiflexion/ plantarflexion movements. The emphasis was placed on impedance control and the speed criterion was fixed.

2 Materials and methods

2.1. Ethical Guidelines

The study was conducted according to the guidelines and standards for human research (Resolution 196/1996, the National Health Council) and it was approved by the local ethics committee (report no.: 527.556/2014). This was a pilot study.

2.2. Experimental Design

The following inclusion criteria were considered: men or women aged between 50 and 75 years. The participants had to score greater than 8 on the Physical Activity Questionnaire Basal, which indicates they were not sedentary [5]. Furthermore, individuals performed physical activity (mainly aerobic activities) at least 3 times a week. The exclusion criteria were: clinical signs of severe heart failure or chronic metabolic disease; minimum score on the Mini-Mental State Examination according to the education level [6] a history of lower limb injuries, deformity or contractures of the ankle joint; a smaller range of motion than 10° for dorsiflexion and 20° for plantarflexion; sensory deficits.

2.3. Participants, Procedure and Measuring Instruments

The subjects were recruited of local community. Thus, 8 individuals took part in the study. The volunteers (n=8) men. The evaluations were performed as follows: on the first day, screening was performed to apply the inclusion and exclusion criteria (clinical assessment), as well as functional tests. The second day was for becoming familiarized with the evaluation protocol of the robotic session (the protocol of robotic assisted therapy associated to videogame was defined as a session). After one week, the evaluation and therapy protocols were carried out.

2.3.1. Balance and mobility

The balance and mobility were assessed using multiple scales and tests: the Berg Balance Scale [7] and the 10-Meter walking test [8]. The 10-meter walking test was used to verify functional task (gait performance). Participants were instructed to perform a preferred walking speed or comfortable walk with their usual walking device. The participant time was recorded for the middle 10-m of the 12-m walkway, and the average gait velocity was calculated. Three trials were carried out and the average was recorded for data analysis. A brief rest was given in between trials [8], [9]. Maximum voluntary contraction to calculate the sub-maximum torque (target torque), steadiness to verify the ankle sensorimotor control during maintenance of the sub-maximum torque (target torque). The sub-maximum torque value obtained during pre-therapy was used in the post-therapy steadiness test for comparison purposes.

2.3.2. Steadiness test

The higher peak torque of three CIVM repetitions was used to calculate the target strength (20% of CIVM) (Kato et al., 2011) The submaximal sensorimotor control was evaluated during five repetitions and conducted by visual feedback, displayed as a horizontal line for 20 seconds, with a 60 second rest between sets. Only three repetitions were used in the analysis. The first and last sets were excluded. Considering the initial and final motor adjustments, the three first seconds and the last second were excluded. The low-pass second-order, Butterworth filter, with a cut-off frequency of 7Hz was used. The following variables were calculated: Standard deviation (SD), Coefficient of variation (CV), and root mean square error (RMSE). Standard deviation (SD) is the absolute measurement of the amplitude fluctuation torque. Coefficient of variation (CV) is a measure of torque fluctuations expressed as a percentage of average torque (CV=SD/average torque x 100). SD and CV values for torque fluctuation were used to probe the subject's ability to sustain a steady submaximal contraction at a constant torque level. The root mean square error (RMSE) is the square of the vertical distance between the target torque and generated torque [10].

3. Ankle Robotic therapy (Anklebot) and videogame

3.1. Anklebot device and Setup

The Anklebot robotic system (Interactive Motion Technologies, Inc., Watertown, MA, USA) is a wearable and backdrivable system that can be used in a seated position or during walking. It allows actuation and sensing within the normal motion range of the ankle joint.[1]Anklebot uses an impedance controller with adjustable stiffness and damping. Subjects were then introduced to the videogame "race" that was subsequently used to assess the paretic ankle motor control (Fig 1A). The patient was positioned according to the preview description [1]. The paretic lower limb was positioned at ~45° on a cushioned knee support, isolating the foot to move freely about the ankle (Fig 1B). The chair was positioned at 1.5 meters from the computer screen [11].

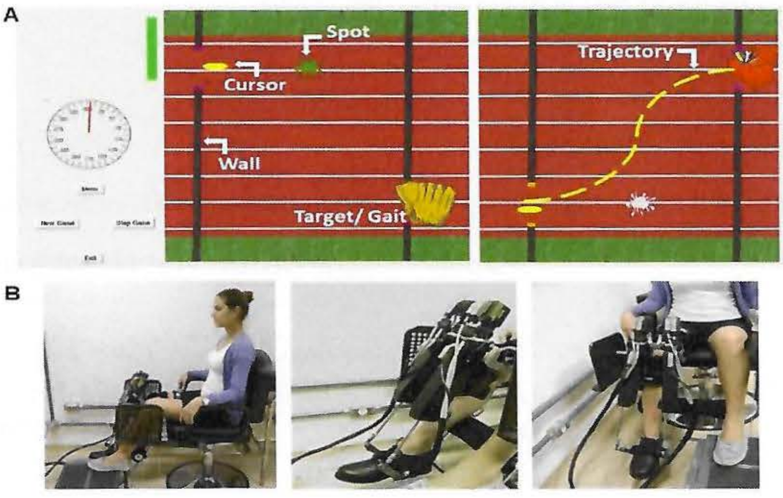

Fig 1. A)Game interface and B) Anklebot device

3.2. Videogame

The movements were visually promoted (movement initiated by visual feedback) and the objectives were presented in a videogame that reproduces an obstacle course. The ankle was free to move in the frontal plane, the patient controlled the ankle during movements of dorsiflexion and plantar flexion to achieve the targets. This interactive approach used an impedance controller. The Anklebot control functioned as a cursor showing "up" or "down". The individual was directed, along a trajectory, by target in two vertical levels corresponding to 10° dorsiflexion and 20° plantarflexion degrees. Assistance at the beginning of the movement was provided when necessary, allowing individuals to achieve the target, i.e., if the subject was not able to start moving after two seconds, the Anklebot provided torque to initiate the movement towards the target [1], [3].

3.3. Repetition protocol and varying impedance waves

Three hundred and fifty ankle movements were distributed in seven blocks and there was a 3.5-second interval between each target. The protocol comprised switched robotic-assistance levels that were modified at each block of 50 movements/targets. The first and the last block were exempt from any robotic assistance. At the second to fourth blocks, there was a gradual impedance increase of 50Nm/rad. The fifth and sixth blocks presented gradual impedance decrease. Thus, the following impedance sequence was applied: 0Nm/rad ► 50Nm/rad ► 100Nm/rad ► 150Nm/rad ► 100Nm/rad ► 50Nm/rad ► 0Nm/rad.

3.4. Game score

The total score recorded in each block was 1500 points. The player's aim was to move through the gate passage and reach the target object (30 points). Bumping the cursor on game obstacles on the wall (-20 points) and on the spots on the race track (-10 points) were the error possibilities. At the end of the session, the total number of errors and correct answers were shown. During the game, according to the performance of the player, a bar remained green or red as a visual feedback. There was no difference between the blocks ($p \geq 0.05$).

3.6. Data Analysis

Data were tested for normality and homogeneity (Shapiro-Wilk and Levene tests, respectively). The demographic and functional data (parametric data), were applied Independent t-test (evaluation: pre and post-robotic assisted session) were used to verify the effect of the ankle robotic-assisted session. The Wilcoxon (non parametric data) were used for the following variable game score. Steadiness variables (parametric data), Anklebot® and Biodex data processing were performed using MatLab® software (v.7.0.1) and SPSS for all statistics analysis (v.17). The GraphPrism (v.7) software was used to develop the graphs.

4. Results

4.1. Demographic and Functional data

The descriptive data (e.g., demographic and functional data) are presented in Table 1

Table 1 Characteristics of study subjects

	Subjects (n= 8)
Gender (Male/Female)	(M:8/ F:0)
Age (years)	64 (74-53)
Height (meters)	1.66 (1.83-1.50
Body Weight (Kg)	70 (94-55)
Body Mass Index (Kg/m^2)	25.4 (30.3-20.8)
Mini Mental	28 (29-24)
Berg Balance Scale	56 (56-52)

Measurements are reported as median (maximum and minimum values).

4.2. 10-meter Walking Test

The average gait velocities were 2±0.2m/s in the pre-robotic session and 1.8±0.4m/s in the post-robotic session.

4.3. Game score

No significant differences were identified between blocks. See table 2.

Table 2 Game score

1° block (0Nm/rad)	2° block (50Nm/rad)	3° block (100Nm/rad)	4° block (150Nm/rad)	5° block (100Nm/rad)	6° block (50Nm/rad)	7°block (0Nm/rad)
1297.5±250	1423.0±52	1422±82	1426.3±69	1439.8±40	1415±80	1320±340

Impedance or exoskeleton assistance K= Newton meters per radians (Nm/rad). The comparison between game scores during several blocks did not present significant differences ($p \geq 0.005$).

4.4. Steadiness

Only the dorsiflexion movement presented significant differences for SD ($p=0.01$) and CV ($p=0.02$). See Table 3.

Table 3 Steadiness variables during dorsiflexion and plantar flexion after and before robotic session.

	Pre Session			Post Session		
	SD	CV	RMSE	SD	CV	RMSE
DF	1.27 (±0.60)	11.87 (±6.10)	2.85 (±0.32)	1.00 (±0.77) †	9.14 (±0.77) †	2.77 (±0.34)
PF	0.56 (±0.45)	4.65 (±4.36)	2.89 (±0.47)	0.80 (±0.58)	5.28 (±4.24)	2.80 (±0.34)

SD= Standard deviation; CV= Coefficient of variation; RMSE= root mean square error; DF=Dorsiflexion; PF= Plantar flexion.

5. Discussion

This study presents findings that help to discuss about the effectiveness of robotic therapy protocols applied to people with ankle restrictions of movements because neurologic diseases [11], [12]. According to the aim of the study, this study showed short-term effects of a single robotic therapy session by observing the change in sensorimotor control during the submaximal torque maintenance for healthy individuals. This work showed how important it is to consider firstly a pilot with healthy individuals.

When analyzing the results of the game score was observed that the level of difficulty was appropriate and easy to understand. The motivation level reported was satisfactory; the strategies of impedance variation and feedback were efficient, keeping the number of correct answers in the different blocks. When proposing a robotic therapy protocol, it is important to establish criteria to determine specific details concerning progression protocol. In addition, the task difficulty level according to the patient skill level is an important criterion to prevent frustration, boredom and fatigue. The adequate difficulty level ensures learner engagement in robotic therapy. Thus, after this pilot study was observed that is necessary apply an assessment tool; a questionnaire which provides information on motivation, attention, discomforts and game reasoning during the protocol.

According to Roy et al. (2011), the gradual impedance wave strategy adopted here was effective in offering motivation and challenges to the players, according to reports from participants. This strategy in addition to the intensity of repetitions showed an improvement in sensorimotor control during dorsiflexion after robotic therapy, which was observed in analysis. The results of this pilot suggest that the protocol presented could be applied in a study with patients because it was not promoted any adverse effects, that is, it was not promotes any decrease in the performance observed in both the submaximal force and the game score data.

Finally, it is important to consider that gathering evidence to propose an intervention related to robotic therapy is a great challenge.Specific changes were pointed out so that an adequate protocol could be applied in a clinical study involving post-stroke patients and individuals with ankle impairments.The results showed that the protocol could be applied in patients without promoting discomfort-related effects and considering improvements and changes related to the number of repetitions, difficulty level and evaluation tools related to motivation.

6. Conclusions

Important topics regarding to the elaboration of robotic therapy protocols were identified from the data analysis. Health individuals presented minimal adaptation in submaximal torque maintenance performance (sensorimotor control) during dorsiflexion after a single robotic therapy session. In addition, the protocol applied to healthy people was shown to be safe in relation to adverse effects, such as demotivation and fatigue. In addition, some adjustments in intensity criteria of the game tasks are necessary. Finally, the preliminary tests with healthy people were effective for indicating how the robotic therapy protocol should be improved to be applied on neurological patients.

Funding

This work was supported in part by the Brazilian Federal Agency for Post-Graduate Education (CAPES)'s fellowships during doctorate postdoctoral at (EESC-USP) and doctorate at UFSCar.

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