The Influence of Dynamic Orthosis Training on Upper Extremity Function after Stroke: A Pilot Study

Rodrigo Cappato de Araújo1*, Daniel Neves Rocha2, Ana Carolina Rodarti Pitangui1 and Marcos Pinotti3

1Department of Physical Therapy – University of Pernambuco, Petrolina, PE, Brazil
2Department of Mechanical Engineering; Federal Institute of Minas Gerais, Congonhas, MG, Brazil
3Department of Mechanical Engineering; Federal University of Minas Gerais, Belo Horizonte, MG, Brazil

Submitted May 2013. Accepted for publication November 2013.

ABSTRACT
The goal of this study was to assess the use of a dynamic orthosis on upper extremity function in chronic stroke patients. A case series approach was utilized, with provision of a training program (3×/week, 50 minutes/session for 8 weeks) and employment of a dynamic orthosis. Six volunteers with persistent hemiparesis due to a single, unilateral stroke performed task-oriented movements with the aid of a dynamic orthosis. Tests were administered before and after training. Functional capacity was assessed using the TEMPA (Test d’Évaluation des Membres Supérieurs de Personnes Âgées) test. The Wilcoxon test was used for pre-training and post-training comparisons of TEMPA scores. The volunteers showed significant improvement of upper extremity function in the performance of a bilateral task (p = 0.01) and three unilateral tasks (p ≤ 0.04). This pilot study suggests that the dynamic orthosis associated with the performance of functional tasks can have positive outcomes regarding the improvement of functional capacity of upper extremity.

Keywords: electromyography, orthotic devices, rehabilitation, stroke

1. INTRODUCTION
According to the World Health Organization (WHO), stroke is the third-leading cause of death in industrialized countries and the leading cause of adult disability worldwide, afflicting about 15 million people annually [1–3]. The development of new therapeutic technologies has significantly decreased the mortality rate of stroke in the last several years. This factor, coupled with the high incidence of stroke, has resulted in an increase in the number of people who have and live with some degree of physical and functional disability [4].
The decrease in motor function of the upper limb is a major consequence of stroke, affecting between 73% and 88% of people who survive their first stroke. Moreover, about 55% to 75% of these subjects experience, for periods up to six months or longer, impairment in performing activities of daily living [5, 6]. The impairment of these tasks results in significant physical, functional, psychological and social deficits, in addition to having a negative impact on the quality of life of these subjects [4].

The physical and functional deficits of the upper limb are often caused by weakness of specific muscles, decreased range of motion, and change in movement patterns [7], which result in change of motor coordination and decreased manual dexterity [8, 9]. In addition, the level of motor function and recovery is highly dependent on the severity and site of the lesion [10]. Quite often, subjects initially adopt a compensatory strategy to perform compromised tasks. However, the recovery process can be stimulated and shaped by rehabilitation programs that use different techniques and exercises so that motor relearning can occur [11].

Conventionally, rehabilitation programs have been conducted by therapists in hospitals or rehabilitation centers. These programs are characterized by the application of therapeutic techniques and exercises that stimulate motor relearning, aiming at increasing functional independence [12–14]. However, only 5% of the patients assessed six months after stroke have experienced full recovery of activities [15, 16].

Given the limited success of traditional rehabilitation programs in restoring upper limb function, recent studies [17–19] have investigated the use of robotic devices to assist in the recovery of motor function of the upper limb. These devices allow patients to perform specific tasks repeatedly, which has been shown by the literature to be a determining factor for the increase in motor skills and improvement in the performance of functional activities [20].

Different research groups have developed robotic devices for rehabilitation of hemiparesis patients. Among the devices developed, the most studied and used in the literature is the MIT-Manus system [21]. However, this device prioritizes the training of the shoulder and elbow joints. Another device described in the literature is the BI_MANU TRACK [22]. This system allows the execution of the movements of the forearm (pronation and supination) and wrist (flexion and extension). However, both devices have high cost and do not allow the training of daily tasks.

While the robotic devices described in the literature show good results in the functional rehabilitation of the shoulder and elbow, recent reviews [23, 24] concluded that there is no evidence to confirm the improvement of motor function of the hand and wrist after training using these devices. Furthermore, results concerning the functional gain in performing activities of daily living are modest [24, 25]. In view of the above, the objective of this study was to assess the use of a dynamic orthosis for upper extremity function rehabilitation in chronic stroke patients. To this end, the present study used the TEMPA test which essentially assesses the functional capacity of the upper extremity during performance of activities of daily living.

2. METHODS
2.1. Participants
The study was conducted with six patients (four men and two women) who had a clinical diagnosis of primary ischemic stroke for at least three months. Right-handed patients who showed no significant deficits in cognition and presented motor impairment of the upper
right limb were included. Patients who had bilateral motor sequelae, impairment on the left side or a history of experiencing two or more strokes were excluded. Volunteers who had severe spasticity (> 3 on Ashworth’s modified scale) and who were not able to accomplish any of the tasks comprising the TEMPA tests were also excluded from the study. In accordance with norm 196/96 of the Brazilian National Health Council, all participants read and signed an informed consent form before undergoing the study procedures, and the study protocol was approved by the Ethics Committee of the University of Pernambuco, record CEP-UPE 041/09. Demographic and anthropometric data with baseline clinical assessment at the time of enrollment are presented in Table 1.

### 2.2. Functional Evaluation

All volunteers underwent a physical assessment in which personal and anthropometric data were collected in addition to history and questions related to stroke. The functional capacity of upper extremity was evaluated through the Brazilian version of TEMPA (Test d’Évaluation des Membres Supérieurs de Personnes Âgées) test [26]. The test consists of four bilateral tasks (open a jar and take out a spoonful of coffee; unlock a door lock, pick up and open a pill box; address and affix a stamp on an envelope; shuffle and deal playing cards) and four unilateral tasks (reach for and move a jar; pick up a pitcher and pour water into a glass; handle coins; handle small objects). The scores are based on three criteria: execution speed, functional rating and task analysis. In assessing the speed, the task is timed from the beginning to its end, and its score is represented in seconds. Functional rating refers to the autonomy of the subject while performing each task in terms of four levels: (0) task completed successfully without hesitation and difficulty, (−1) task completed with some difficulty, (−2) task partially executed or certain steps performed with difficulty, and (−3) task not completed even with assistance.

The task analysis assesses the difficulties experienced by the participants according to five criteria related to sensorimotor skills: strength, amplitude of movement, precision of large movements, fine movement precision and grip.

The functional rating score is determined by adding the scores for unilateral tasks on the right (0 to −12), on the left (0 to −12), and for the bilateral tasks (0 to −12), yielding

### Table 1. Stroke clinical assessments

<table>
<thead>
<tr>
<th>Patient</th>
<th>Sex</th>
<th>Age (years)</th>
<th>Months post-stroke</th>
<th>BMI</th>
<th>FMA</th>
<th>MAS-E</th>
<th>MAS-W</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>F</td>
<td>34</td>
<td>8</td>
<td>25.3</td>
<td>35</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>2</td>
<td>M</td>
<td>43</td>
<td>34</td>
<td>24.5</td>
<td>33</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>3</td>
<td>M</td>
<td>34</td>
<td>10</td>
<td>29.4</td>
<td>33</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>4</td>
<td>M</td>
<td>70</td>
<td>24</td>
<td>23.8</td>
<td>36</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>5</td>
<td>M</td>
<td>43</td>
<td>18</td>
<td>23.4</td>
<td>38</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>6</td>
<td>F</td>
<td>51</td>
<td>22</td>
<td>24.2</td>
<td>35</td>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>

Mean±SD: 45.8 ± 13.5 18.8 ± 9.4 25.1 ± 2.2 35.0 ± 1.9 2.2 ± 0.4 2.3 ± 0.5

a total functional rating score between 0 and −36. An evaluation is also performed for the five dimensions of the analysis session of the tasks. Considering that ‘precision of fine movements’ is not measured by such tasks as ‘pick up and carry a pot’ and ‘pick up a pitcher and pour water’ and ‘force’ is not assessed in the tasks ‘address and affix a stamp on an envelope’, ‘pick up and carry small objects’, ‘handle coins’ and ‘shuffle cards’, task analysis scores may vary from 0 to 150.

The total score (0 to −186) represents the sum of functional rating and task analysis. Observing the dimensions assessed in each task, it is possible to obtain the following scores: Task 1 (open a jar, take out a spoonful of coffee): 0 to −18; Task 2 (unlock a lock; pick up and open a pill box): 0 to −18; Task 3 (address an envelope and affix a stamp): 0 to −15; Task 4 (shuffle and deal cards from a deck): 0 to −15; Task 5 (reach for and move a jar): 0 to −30; Task 6 (pick up a pitcher and pour water in a glass): 0 to −30; Task 7 (handle coins): 0 to −30; and Task 8 (handle small objects): 0 to −30. Unilateral tasks present scores varying from 0 to −30, since in this case the scores obtained in the evaluation of the two limbs are added. However, this study did not consider the runtime and scores of unilateral tasks performed with the healthy limb [27]. Thus, the scores ranged from 0 to −126.

Although the original scale always results in negative scores, in which zero indicates the absence of disability and the negative values indicate disability, for the purposes of statistical analysis, we used the absolute values, i.e., values independent of the sign. Thus, for this study, higher values correspond to higher disability. In a previous study [26], adequate intra- and inter-examiner reliability was demonstrated (ICC 0.70 – 1.00) for the TEMPA (Brazilian version) scores applied for patients with mild motor deficits (FMA < 50).

2.3. Dynamic Orthosis Device
The dynamic orthosis, previously described by Araújo et al. [28], consists of an exoskeleton, static orthosis, functional glove, control unit, and electromechanical actuators (Figure 1).

The exoskeleton is a mechanical structure formed by two segments made of nylon positioned along the arm and forearm and connected by a pivot shaft. A single pulley is fixed on the mechanical structure of the exoskeleton with the center coinciding with the rotation axis of the elbow joint. Rotation of the pulley, generated by the force of the mechanical actuators, is responsible for flexion and extension of the elbow joint.

Figure 1. Exoskeleton and static orthosis (A and B); Glove: ventral view (C) and dorsal view (D).
The range of motion was preset between 10° – 110° of flexion, avoiding extreme ranges of flexion and extension so that there would not be overload and stress on the ligaments and joint structures.

The static orthosis were manufactured with thermoplastic material and were used to stabilize and position the arm and forearm of the participant. Moreover, the static part fixed on the forearm was also responsible for stabilization of the articulation of the wrist in 20° of extension and the thumb in 20° of abduction, in order to allow pincer movement. For better grip and support of the orthosis, the static parts were fixed and adjusted with Velcro.

For the performance of the flexion and extension of the fingers, Lycra gloves were made for each participant, using strips of inelastic material that served as the attachment point and guide for artificial tendons, thus reproducing the system of tendons and tunnels of the human hand. The artificial tendons (DyneemaVexterbraided line of 30 lbs) were responsible for transmitting the motion of electromechanical actuators for the fingers, promoting flexion and extension movements of the fingers.

Two actuator modules were responsible for flexion and extension of the elbow and fingers. The actuator modules were placed on a bench and were composed of an electromechanical actuator and a drive system. The electromechanical actuator corresponds to the DC motor coupled to the drive system and triggered by a control module consisting of an electrical circuit. Differential simple active electrodes (DatahominisLtda, Brazil) were used for the acquisition of myoelectric signals. These signals were processed by a control unit, responsible for the triggering and control of the torque produced by the electromechanical actuators in the joints. The flexion and extension movements of the elbow were controlled by the electromyographic (EMG) signal of the biceps and triceps muscles, respectively. The opening and closing movements of the hand were controlled by EMG signals of the common extensor muscles of the fingers and flexor digitorum superficialis, respectively.

To check the operation of the control circuit, a visual feedback system formed by light emitting diodes (LED) was used. Each channel has an LED at its output that is triggered when the selected muscle group is contracted. The system has controls for power circuitry and motors. In addition, each channel had a key enabled power button for passive therapy mode and control to adjust the gains of the circuit allowed to change the threshold for activation of the motor, enabling to adjust the system to the needs of each patient, as well as to allow the progression of the training.

The dynamic orthosis made possible the development of passive and actively-assisted therapies. In the actively assisted mode, upon a signal generated by the EMG activity of a specific muscle, the orthosis completed the movement which the patient intended but was unable to perform. In the passive mode, the therapist triggers the external engines to generate the desired movement. This mode of therapy was used at the beginning of the training, with the function to guide and instruct the motions to the patients.

2.4. Rehabilitation Program
Upon completion of the functional assessment, participants went through a rehabilitation program involving using the aforementioned dynamic orthosis associated with functional training. [28]. Training consisted of twenty-four sessions, performed
three times a week for eight weeks, with each session lasting for 50 minutes. The rehabilitation program of the participants in this study was conducted by the same physiotherapist for every session. At the beginning of the program, all patients received instructions on the use of the device.

Initially, the dynamic orthosis was fitted on the patients and the myoelectric sensors were installed in the appropriate places. Patients were then instructed to perform the movements of flexion and extension of the fingers and elbow, so as to regulate the activation thresholds of each actuator in the electrical circuit. During the first four sessions, the participants only performed the elbow and finger movements (assisted active therapy) repeatedly for about 25 minutes. After this period of familiarization and training, functional tasks, such as picking up and moving objects on a table, were included in the program. For this task, patients were sitting in front of a table and were told to pick up different objects (plastic glasses, two balls of different sizes and weights, and digital camera), bring them close to their face and return them back to the table (Figure 2). To perform these tasks, it was necessary to perform elbow and hand movements in a coordinated fashion. In order to facilitate the progression of treatment, the number of repetitions increased and the locations of the objects on the table were changed.

These tasks were performed for about 20 minutes depending on the physical limits of each participant. However, at most, each volunteer performed three sets (five repetitions/set) with each object. The objects were placed on the table in three different locations: 20, 40 and 60 centimeters, respectively, from the edge. During the training period, patients did not receive any other upper extremity treatment. Only exercises for trunk, lower limbs and gait training were administered, twice a week. Upon completion of the rehabilitation program, all patients were reevaluated.

2.5. Data Analysis
All statistical analyses were performed using the statistical package SPSS (version 10.0). Prior to analyzing each variable, data distribution normality was tested by the Shapiro-Wilk test. The Wilcoxon test was used for pretraining and posttraining comparisons of the TEMPA scores. For all analyses, \( p \leq 0.05 \) was considered significant.

Figure 2. Subject using the dynamic orthosis: Passive mode, without EMG (A) and Active-Assisted mode, with EMG (B).
3. RESULTS
The results of the TEMPA test showed that the group of participants undergoing training with the dynamic orthosis showed improvement in scores for four tasks, and also a decrease in execution time of two tasks, thus indicating improved functional capacity of upper limb in one bilateral task (task 4: shuffle and deal cards from a deck) and three unilateral tasks (tasks 5: reach for and move a jar; 6: pick up a pitcher and pour water in a glass; and 7: handle coins). The other bilateral tasks (task 1: open a jar, take out a spoonful of coffee; task 2: unlock a lock, pick up and open a pill box; and task 3: address an envelope and affix a stamp) and one unilateral task (task 8: handle small objects) did not show significant difference (Table 2).

Table 2. Mean values of TEMPA scores, before and after training

<table>
<thead>
<tr>
<th>Task</th>
<th>Pre-training</th>
<th>Post-training</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Score</td>
<td>Time (s)</td>
<td></td>
</tr>
<tr>
<td>Task 1</td>
<td>7.0 ± 1.4</td>
<td>24.9 ± 6.0</td>
<td>0.06</td>
</tr>
<tr>
<td>Task 2</td>
<td>9.5 ± 0.9</td>
<td>45.7 ± 9.3</td>
<td>0.06</td>
</tr>
<tr>
<td>Task 3</td>
<td>7.6 ± 0.8</td>
<td>43.2 ± 21.9</td>
<td>0.06</td>
</tr>
<tr>
<td>Task 4</td>
<td>7.3 ± 1.2</td>
<td>56.9 ± 16.1</td>
<td>0.06</td>
</tr>
<tr>
<td>Task 5</td>
<td>6.0 ± 2.2</td>
<td>5.1 ± 0.8</td>
<td>0.06</td>
</tr>
<tr>
<td>Task 6</td>
<td>7.1 ± 1.8</td>
<td>21.7 ± 6.5</td>
<td>0.06</td>
</tr>
<tr>
<td>Task 7</td>
<td>8.1 ± 1.6</td>
<td>28.8 ± 14.5</td>
<td>0.06</td>
</tr>
<tr>
<td>Task 8</td>
<td>6.5 ± 2.0</td>
<td>21.9 ± 6.3</td>
<td>0.06</td>
</tr>
<tr>
<td>Total</td>
<td>61.1 ± 12.2</td>
<td>231.4 ± 80.2</td>
<td>0.03*</td>
</tr>
</tbody>
</table>

The values shown are mean ± standard deviation. The scores are calculated as the sum of the functional rating and task analysis. *Indicates statistically significant difference between pre- and post-training data.
In addition, a significant improvement of scores and total time of performance of tasks (Table 2) were observed. In absolute values, there was an average decrease of approximately 18 points, which means a decrease of 29% in total scores. Regarding the execution time, it was possible to observe a decrease of 48 seconds, which indicates an improvement of 16.5%.

4. DISCUSSION

The present study aimed at evaluating the effect of a training program using a dynamic orthosis for physical rehabilitation, with an emphasis on improving manual dexterity and performance of activities of daily living (ADL) in participants with upper limb motor sequelae as a result of stroke. The results of this study indicated that the tested device can benefit functional capacity of upper extremity in patients with hemiparesis.

The initial values of the TEMPA test revealed that, at baseline, the participants had significant level of impairment and a significantly compromised capability and dexterity in performing manual tasks. As noted in the results, the participants had scores on individual TEMPA tasks ranging between 6 and 9.5, while the mean total score was 61.1 points. According to studies that identified reference values for TEMPA tests, healthy individuals have a zero score on all tasks, which means that tasks are performed successfully without any sign of compromised sensorimotor skills [29].

Although impairment of upper limb function and manual dexterity have been observed through TEMPA scores in the participants of the current study, comparison of the current results with those in the literature data is complex, because previous studies [27, 30, 31] were limited to evaluating the variable “run time”. Regarding the “run time” variable, the current results show that the participants performed TEMPA tasks in times ranging between 5.1 and 56.9 seconds, depending on the task, while in previous studies [29, 32], the values considered normal range from 1.7 to 13.9 seconds in young individuals (20 – 44 years), and between 1.5 to 18.1 seconds in the elderly (above 60 years old).

Furthermore, an average time of 52 seconds to complete all TEMPA tasks is described in the literature for healthy subjects [29]. In this study, the average execution time for all TEMPA tasks was 231.4 seconds. Platz et al. [27, 31] reported an average TEMPA execution time ranging between 210 and 230 seconds in patients classified with mild paresis. These same volunteers presented average values on the Fugl-Meyer scale ranging between 23.3 and 26.2 points, while the subjects in our study presented values between 33 and 38 points, which according to previous studies [33, 34] indicates mild paresis, since these values are within the range of mild motor compromise (21 – 55 points on the FMA scale) described by Fugl–Meyer [35].

After training using the dynamic orthosis, the participants’ functional capacity of upper limbs was improved, as shown by an average decrease in the total TEMPA score by approximately 18 points, in addition to a reduction of total execution time by about 48 seconds. Platz et al. [31] observed an improvement in TEMPA execution time in patients with mild hemiparesis after three weeks of treatment. That study revealed a decrease of 16.5 seconds in patients who underwent conventional rehabilitation, and a decrease of 41.4 seconds in patients who underwent a program featuring rehabilitation using specific training targeting arm motor skills.
In another study, Platz et al. [27] evaluated the effects of intensive training, performed daily for three consecutive weeks, and showed that patients treated with conventional therapy and training targeting sensorimotor impairments showed a decrease of 27.8 and 31.1 seconds in TEMPA execution time, respectively. No direct comparison can be made between our results and the previous results, our results show that the proposed device provided similar benefits as other techniques. However, it is important to note that in studies conducted by Platz et al. [27, 31], the best results were achieved by combined techniques. In this sense, their results corroborate the present study data, since the gains observed in our study may have been due to training tasks of reach and grip associated with the use of the orthosis.

Recently, Gijbels et al. [30] evaluated the effect of a training program using a robotic device known as The Armeo Spring in the rehabilitation of motor function and manual dexterity of patients with paresis in both upper limbs resulting from multiple sclerosis. This device features an exoskeleton that facilitates assisted active therapy of shoulder, elbow and forearm movements in a virtual environment. After 24 training sessions, a decrease of about 23.6 seconds in TEMPA run time was observed. Although we found no other studies using TEMPA to evaluate the effect of assisted technologies on the treatment of patients with motor sequelae resulting from stroke, the study by Gijbels et al. [30] supports the possible positive effects of using dynamic orthoses in the motor rehabilitation programs. These devices allow repeated execution of tasks in a controlled and systematic mode, which has been demonstrated to be a determining factor in the facilitation of cortical reorganization, with a concomitant increase in motor function [34].

In the present study, we observed a 29% improvement in the total score and a 16.5% improvement in the TEMPA test execution times. Unlike the FMA that provides evidence confirming that changes greater than 10% are considered clinically improved [37, 38], reference values that indicate clinical improvement have not been established in the literature for TEMPA tests applied to stroke patients. Although a previous study shows strong correlation between the FMA and TEMPA [26], there is no direct evidence that the improvement observed in this study is clinically relevant. Future studies are warranted to assess this issue.

Finally, the present TEMPA test results revealed significant improvements in four of eight tasks tested, including the bilateral test of shuffling and dealing cards from a deck, and three other unilateral tasks, such as reaching for and moving a jar, handling a pitcher and pouring water into a glass and handling coins. The different results among the tasks may be related to the specificity of the training.

Regarding specificity, the fact that the participants performed about 20 minutes of training (reach and grab tasks) per session, activities which are predominantly unilateral tasks in the TEMPA test, may explain the better performance in tasks 5, 6 and 7. This fact corroborates Platz et al.’s results [27, 31] that in addition to intensity, the most important factor in improving manual dexterity is training specificity. In addition, the current study sample was composed mostly of middle-aged adults and only one senior. This aspect may have positively influenced the outcome of the study, since age is a determining factor in the process of cortical reorganization.

The present study has some limitations, mainly related to sample size and lack of a control group. Furthermore, this study only examined a specific test; evaluation of other
aspects related to motor performance is needed. Thus, despite the positive results demonstrated, there is a clear limitation in stating that the orthosis training was the main factor for the improvement of functional capacity of the upper limb. Studies with larger samples and a control group are needed to elucidate whether the effect observed is indeed related to training with the orthosis or is simply influenced by the effect of time, considering that the study evaluated a relatively young sample and a few months after stroke. Finally, it is suggested that randomized controlled clinical trials be conducted in the future to investigate and compare the possible benefits of single and combined rehabilitation programs.

5. CONCLUSION
The results of this pilot study showed that the dynamic orthosis resulted in an improvement in scores of TEMPA test. The results suggest that the device can benefit functional rehabilitation of patients with hemiparesia. Further randomized controlled clinical trials are required to confirm the clinical efficacy of this device.

ACKNOWLEDGEMENTS
This work was supported by The National Council for Scientific and Technological Development (CNPq), Brazil.

CONFLICT OF INTEREST
The authors indicated no potential conflicts of interest.

REFERENCES


