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Therapeutic Efficacy of Dynamic Hand Splints in Spastic Hemiparetic Hands: A Randomized Controlled Single-Blind Trial

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Background: It is usually challenging to treat patients following stroke or brain injury with spastic hemiparetic upper limbs. Dynamic hand splints have been used to manage this issue for years, but evidence of their efficacy is still lacking.

Objective: To investigate the treatment efficacy of dynamic hand splinting in spastic hemiparetic patients.

Methods: In this randomized controlled single-blind clinical trial, patients with spastic hemiparesis lasting more than half a year after a stroke or brain injury were enrolled. They were randomly divided into a splint group and a control group, and received 1 month of task-oriented training with or without wearing a dynamic hand splint, respectively. Outcome measurements were performed at baseline, post-training and at a 3-month follow-up by the evaluators blinded to the grouping of the subjects.

Results: Thirty-five subjects (splint group = 18, control group = 17) completed the study. Compared to baseline measurements, scores on the Modified Ashworth Scale of wrists and fingers, and the maximal and mean F/M ratio all significantly decreased in the splint group after training. The Fugl-Meyer Assessment for upper extremity score also showed significant increases at the 3-month follow-up compared to baseline in the splint group. However, the repeated measures ANOVA only showed significant interaction effects between the groups and over time for the maximal F/M ratio variable.

Conclusion: The results suggested that training with dynamic hand splints might reduce the excitability of spinal alpha motor neurons for spastic muscles. (Tw J Phys Med Rehabil 2021; 49(1): 59 - 71)

Key Words: dynamic splint, upper extremity, stroke, brain injury

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INTRODUCTION

Spasticity is a common complication for patients following stroke or brain injury. Its prevalence was reported to be 20%-30% in stroke patients[^1] and as high as 84% in brain injury patients with injuries severe enough to require inpatient rehabilitation.[^2] It is mediated by several spinal mechanisms, such as the denervation hypersensitivity of alpha motor neurons and reduced excitability of both postsynaptic and presynaptic inhibitory circuits controlling the stretch reflex, which results in a velocity-dependent increase in muscle tone and excessive resistance to passive stretch.[^3] A patient with a spastic limb is at high risk of developing contracture of the involved joint that will impede rehabilitation, cause functional limitation and reduce quality of life.[^4] When the spasticity occurs in the upper extremity, it is likely to impact the patient's daily functioning. Controlling the abnormal muscle tone and restoring function to the upper extremity in these patients is therefore particularly crucial.[^5]

However, treatments for patients with upper limb spasticity are usually challenging. At present, potential treatments include proper positioning, range of motion exercises, stretching, splinting, oral spasmyotics, botulinum toxin (BTX) or phenol/alcohol injection, serial casting, and surgical correction.[^4,5]

Some authors suggest that hypertonia can be divided into two components: hypertonia mediated by the stretch reflex, corresponding to spasticity, and hypertonia due to soft tissue changes, which is referred to as non-reflex hypertonia or intrinsic hypertonia.[^5] Theoretically, potential benefits for the use of splints include biomechanically preventing the shortening of tendon, muscle and connective tissue lengths and neurophysically inhibiting abnormal reflex activities.[^6] The splints used on the upper limb can be divided into static and dynamic ones. In comparison with static splints, dynamic hand splints contain additional components such as springs or elastic strings that allow movement of some parts of the hand although the designs varied in previous studies.[^6] Unlike static splints which keep hands immobilized, dynamic splints allow patients to use their hands during functional activities while maintaining muscle length at rest, which might help to prevent learned non-use.[^6] Dynamic splints allow soft tissue remodeling, more comfort to stretch with better patient compliance and motivation, reduced joint pain, and edema prevention, as well as potentially increasing brain plasticity.[^7] One study reported that the hypertonicity of spastic hemiplegic hands measured by the passive wrist-pulling force of the finger flexor was reduced further in the dynamic splint group after a 5-week intervention than in static splint and passive range of motion groups. The subjects in that study were stroke patients with disease onset more than one year prior, although the case number was only 4 in each study group.[^8] Fayez et al reported that use of a dynamic hand splint allowing 30 degrees of movement at the wrist led to significantly more improvement in wrist active and passive range of motion than a static splint with the wrist positioned at 30 degrees of extension in hemiplegic stroke patients with mild to moderate spasticities.[^9] In another study, Gracies et al conducted a crossover-design trial with 16 stroke patients with spastic hemiparesis of more than 3 weeks. A dynamic Lycrea splint consisting of a tailored forearm supinator-extensor garment and a glove with 2 semi-flexible sticks was used for intervention. Immediate spasticity reduction in the wrist and finger flexors measured by the Tardieu scale was noted after wearing the splint for just a 3-hour period.[^10]

However, there is still little literature addressing the treatment efficacy of the dynamic hand splint for neurological patients with upper extremity spasticity, the results are controversial, and to the author’s knowledge, there is no study reported in English with a randomized-controlled-trial design.[^7-12] Therefore, the aim of this study is to investigate the treatment efficacy of dynamic hand splints in patients with upper extremity spasticity due to stroke or brain injury.

MATERIALS AND METHODS

Participants

The participants were volunteers with spastic hemiparetic hands due to stroke or brain injury who received inpatient or outpatient rehabilitation programs in the Department of Physical Medicine and Rehabilitation at a regional teaching hospital in Taiwan.
The eligibility criteria were (1) age between 20 and 85 years, (2) impairment duration of more than 6 months, (3) unilateral hemiparesis with intact limb-function on the sound side, (4) Brunnstrom’s stage of both arm and hand ≥ III, (5) able to follow instructions to wear a dynamic hand splint and perform therapeutic activities; (6) wrist spasticity with a Modified Ashworth Scale (MAS) score 1 to 3, and (7) willing to provide written informed consent.

Patients were excluded if they had one or more of the following: (1) apraxia, (2) cognitive impairment with a Mini-Mental State Examination (MMSE) score < 25,[13] (3) any fixed contracture of the affected wrist or digit, (4) a history of peripheral nerve injury, other severe neuro-muscular disease or musculoskeletal deformity in the affected upper extremity, (5) a history of alcohol or phenol injection to the affected upper extremity, (6) BTX injection to the affected upper extremity within the previous 4 months, (7) surgical treatment for spasticity of the affected upper extremity, (8) history of active infection, (9) obvious atrophy of muscles in the affected upper extremity, (10) bilateral upper extremities weakness, or (11) any dermatosis or open wounds in the affected upper extremity or an allergy to the splint.

Evaluations

Modified Ashworth Scale

Each participant was placed in a sitting position with the palm of their affected side placed at the edge of table. Then his or her second to fifth fingers were moved together by the examiner, from maximum possible flexion to maximum possible extension over a duration of about 1 second. The participant's wrist and elbow were then also tested in the same manner. The lowest score was 0 and the highest score was 4.[14] For statistical purposes, the MAS score “1+” was considered as 2, “2” as 3, and so on to a high score of 5.

Active range of motion

In a sitting position with the palm of the affected side placed at the edge of table, each participant was instructed to actively move his or her digits and wrists as much as possible. The active range of motion of the index finger and wrist were measured by a goniometer.

Grip strength

In a sitting position, each participant was initially instructed to squeeze a dynamometer with the hand of the sound side as hard as he or she could for about 3 seconds, then the hand of affected side was tested in the same manner. Three consecutive measurements with a 3-minute interval were performed for each hand and the arithmetic mean of the 3 trials was used for statistical analysis.[15]

Motor Activity Log 30

Using the standardized questions from the upper extremity motor activity log (MAL), each participant was rated how much (Amount of Use scale, MAL-AOU) and how well (quality of movement scale, MAL-QOM) he or she used the affected upper limb to accomplish functional activities during the past week. Both scales were anchored at 6 points (AOU scale: 0 = not used, 5 = the same as before stroke or TBI; QOM scale: 0 = not used, 5 = normal).[16]

Fugl-Meyer Assessment

The Fugl-Meyer assessment (FMA) scale is a well-designed, comprehensive and effective evaluation tool used widely to assess physical performance and motor function in stroke and brain injury patients.[17,18] It is a 3-grade scale with 0 as the minimum and 2 as the maximum grade of sensorimotor function.[17] The testing procedure was conducted in a standardized manner according to the written instructions originally published, with some additional general guidelines.[19] In the evaluation of motor function by the Fugl-Meyer assessment for upper extremity (FMA-UE), clear and precise instructions were given to the seated participant for each movement. The participant performed the movement with the unaffected side first and then with the affected side. Each activity was repeated 3 times and the highest score of the affected side was recorded. The maximum score was 66. The Fugl-Meyer sensory assessment (FMA-sensory) evaluated sensory functions with tests of light touch, temperature, tactile localization and position sensation of each of the upper arm, forearm, hand, thigh, calf and foot of the affected side. The maximum score was 44.

Ultrasonography and Heckmatt scale

It was reported that severe muscle fibrosis would reduce treatment effects in spasticity.[20] Therefore, B-mode real-time ultrasonography with a high resolution transducer (10 MHz) was performed to evaluate the muscle echo intensity of the forearm flexor muscle groups of the affected side compared with those of the sound side. With the participant in a seated position, the
elbow extended and forearm supinated, the probe was placed first at a level about four finger widths below the elbow crease and then adjusted until the muscle belly of the flexor carpi radialis, flexor digitorum superficialis and flexor digitorum profundus were most prominent. The transducer was placed gently on the skin using water-soluble transmission gel to avoid any pressure-induced alterations of the muscle tissue, and it was positioned perpendicular to the examination surface. The muscle echo intensity in the transverse view was visually rated according to the Heckmatt rating scale: Grade I, normal; Grade II, a significant increase of muscle echo intensity with distinct bone echo; Grade III, a marked increase in muscle echo intensity with significantly reduced bone echo; Grade IV, a very high muscle echo intensity with complete loss of bone echo.\[20,21\]

F/M ratio of the ulnar nerve

An electrophysiological examination was performed using a NeMus electrodiagnostic machine (EBneuro, Italy) on the hand of the affected side with the participant placed in sitting position, the elbow extended and the forearm supinated. The active recording surface electrode (G1) was placed over the muscle belly of the abductor digiti minimi (ADM), the reference electrode (G2) was placed on the phalanx of the little finger 4 cm distal from the G1 electrode, and a ground electrode (G0) was placed on the back of the hand between the stimulating and recording electrodes. A surface stimulation electrode with supramaximal stimulation at the wrist, 8 cm away from G1, was activated to obtain the compound muscle action potential (CMAP) and F wave of the ADM muscle with the cathode distal and proximal to the anode, respectively.\[22\]

The amplifier was set with a sweep speed of 5 milliseconds per division, a low pass filter (high frequency) setting of 10 kHz, a high pass filter (low frequency) setting of 50 Hz, an amplifier gain of 500 μV per division for the F waves and 10,000 μV per division for the CMAP. The stimulation was given less than 1 Hz to avoid influences from the previous stimulus.\[23\] While analyzing the F wave amplitude, the amplifier gain might be adjusted with a different scale, such as from 100 to 500 μV, for better visualization of the waveform. The ratio of amplitude of the mean and the maximal F wave to the CMAP (F/M ratio) were then calculated.

The ultrasonography and electrophysiological studies were all performed by the same physician, an expert in these clinical examinations in the Department of Physical Medicine and Rehabilitation at the hospital. All the other tests were performed by one well-trained research assistant. Both evaluators were blinded to the grouping of the subjects.

Procedures

In this randomized controlled single-blind trial, the study procedure was thoroughly explained and signed informed consents were obtained from all subjects at the beginning of the study. After giving consent, participants took part in pretests including Brunnstrom’s staging, the MMSE and the MAS. Those meeting all the inclusion criteria then underwent the following procedures. For grouping randomization, sequentially numbered index cards with random assignments were folded and placed in sealed opaque envelopes. An occupational therapist blind to the baseline condition of the subjects opened the envelopes to make the assignments to the splint and control groups. Both groups received the ultrasonography examination at the beginning of the study.

In addition to conventional rehabilitation programs (therapy-as-usual), the subjects in the splint group received 1-hour task-oriented training while wearing a customized dynamic hand splint 15 times over the course of 1 month. For the training, 2 tasks were chosen from 4, according to the abilities of the subjects. The task choices were moving cubes from side to side with a three-jaw grasp, lifting a cone to shoulder height with a cylindrical grip and an extended elbow, picking up pegs and inserting them into the hole with a palmar pinch, and grasping a bar of soap to simulate washing the body. After the month of training, the subjects could receive the rehabilitation therapy as they used to do, but invasive procedures like BTX injection or surgery were avoided until the follow-up evaluation was finished.

The dynamic hand splint used in this study (Figure 1) was made from a dorsal plastic base covering from the distal half of the forearm to the proximal end of the proximal interphalangeal joint of the digits, with Velcro straps to fix it to the upper extremity. There were five springs fixed on the dorsal plastic base and attached to each digit with a belt for stretching flexor muscles to
facilitate extension movement. Each spring had an adjustable tensioner. Initially, the wrist was fixed in the neutral position to slight extension and the digits were pulled to the neutral position. Afterwards, the strength of the spring was adjusted by the occupational therapists based on the muscle tension, flexion and release actions, and the subject’s tolerance.

Table 1. Baseline clinical characteristics of both groups

<table>
<thead>
<tr>
<th>Variables</th>
<th>Control group, n = 17</th>
<th>Splint group, n = 18</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>47.4 ± 12.9 (24-68)</td>
<td>39.2 ± 12.0 (20-66)</td>
<td>0.077&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Sex (female/male)</td>
<td>6/11</td>
<td>9/9</td>
<td>0.380&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>Diagnosis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ischemic stroke/ hemorrhagic stroke/ brain injury</td>
<td>7/8/2</td>
<td>5/12/1</td>
<td>0.512&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>Hemiparetic side (right/left)</td>
<td>6/11</td>
<td>5/13</td>
<td>0.632&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>Months since stroke or brain injury</td>
<td>24.6 ± 20.1 (6.0-69.3)</td>
<td>39.1 ± 45.4 (6.2-181.4)</td>
<td>0.488&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Event of stroke or brain injury (times)</td>
<td>1.06 ± 0.24</td>
<td>1.00 ± 0.00</td>
<td>0.303&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Education (years)</td>
<td>11.3 ± 3.7</td>
<td>12.6 ± 2.9</td>
<td>0.360&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>3</td>
<td>1</td>
<td>0.338&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>Affected side (left/right)</td>
<td>6/11</td>
<td>5/13</td>
<td>0.632&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>MMSE</td>
<td>29.1 ± 1.4</td>
<td>29.3 ± 1.1</td>
<td>0.866&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Brunnstrom’s stage</td>
<td>3.3 ± 0.6</td>
<td>3.1 ± 0.3</td>
<td>0.493&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>EI by Heckmatt scale</td>
<td>1.6 ± 0.5</td>
<td>1.8 ± 0.6</td>
<td>0.253&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>MAS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>elbow</td>
<td>2.1 ± 0.8</td>
<td>2.2 ± 0.6</td>
<td>0.719&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>wrist</td>
<td>2.2 ± 0.6</td>
<td>2.3 ± 0.7</td>
<td>0.618&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>finger</td>
<td>2.2 ± 0.7</td>
<td>2.3 ± 0.7</td>
<td>0.691&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>F/M ratio</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>maximal</td>
<td>0.08 ± 0.03</td>
<td>0.11 ± 0.06</td>
<td>0.235&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>mean</td>
<td>0.05 ± 0.02</td>
<td>0.06 ± 0.04</td>
<td>0.792&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Active range of motion</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>wrist</td>
<td>57.7 ± 33.5</td>
<td>58.3 ± 42.3</td>
<td>0.958&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>index finger</td>
<td>8.1 ± 17.4</td>
<td>10.4 ± 30.5</td>
<td>0.785&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Grip strength (kg)</td>
<td>4.1 ± 3.4</td>
<td>4.0 ± 3.4</td>
<td>0.853&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>MAL</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AOU</td>
<td>0.78 ± 0.43</td>
<td>0.54 ± 0.25</td>
<td>0.083&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>QOM</td>
<td>0.83 ± 0.45</td>
<td>0.61 ± 0.33</td>
<td>0.161&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>FMA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UE</td>
<td>34.0 ± 10.6</td>
<td>28.6 ± 8.5</td>
<td>0.067&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Sensory</td>
<td>40.9 ± 3.1</td>
<td>32.6 ± 10.2</td>
<td>0.018&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

Abbreviations: AOU, Amount of Use scale; EI, muscle echo intensity; F/M, F-wave/motor wave; FMA, Fugl-Meyer Assessment; MAL, Motor Activity Log 30; MAS, Modified Ashworth Scale; MMSE, Mini-Mental State Examination; QOM, Quality of Movement scale; SD, standard deviation; UE, Fugl-Meyer Assessment for upper extremity.

<sup>a</sup> P-value by Mann-Whitney U test.

<sup>b</sup> P-value by Chi-square test or Fisher’s exact test.
Table 2. Outcome variables at baseline, post training and follow-up in both groups

<table>
<thead>
<tr>
<th>Variables</th>
<th>Control group, n=17</th>
<th>Splint group, n=18</th>
<th>Time</th>
<th>Time x Group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
<td>Post training</td>
<td>p-value a</td>
<td>Follow-up</td>
</tr>
<tr>
<td>MAS</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>elbow</td>
<td>2.1 ± 0.8</td>
<td>2.1 ± 0.8</td>
<td>1.000</td>
<td>2.0 ± 0.7</td>
</tr>
<tr>
<td>wrist</td>
<td>2.2 ± 0.6</td>
<td>1.9 ± 0.8</td>
<td>0.096</td>
<td>1.9 ± 0.9</td>
</tr>
<tr>
<td>finger</td>
<td>2.2 ± 0.7</td>
<td>1.9 ± 0.9</td>
<td>0.059</td>
<td>1.9 ± 0.9</td>
</tr>
<tr>
<td>F/M ratio</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>maximal</td>
<td>0.08 ± 0.03</td>
<td>0.08 ± 0.02</td>
<td>1.000</td>
<td>0.07±0.02</td>
</tr>
<tr>
<td>mean</td>
<td>0.05±0.02</td>
<td>0.04±0.02</td>
<td>0.438</td>
<td>0.04±0.01</td>
</tr>
<tr>
<td>Active range of motion</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>wrist</td>
<td>57.7 ± 33.5</td>
<td>63.7 ± 35.7</td>
<td>0.378</td>
<td>67.9 ± 39.4</td>
</tr>
<tr>
<td>index finger</td>
<td>8.1 ± 17.4</td>
<td>10.7 ± 25.3</td>
<td>0.465</td>
<td>11.1 ± 26.9</td>
</tr>
<tr>
<td>Grip strength (kg)</td>
<td>4.1 ± 3.4</td>
<td>4.1 ± 3.5</td>
<td>0.648</td>
<td>3.8 ± 2.8</td>
</tr>
<tr>
<td>MAL</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AOU</td>
<td>0.78 ± 0.43</td>
<td>0.86 ± 0.47</td>
<td>0.363</td>
<td>0.96 ± 0.62</td>
</tr>
<tr>
<td>QOM</td>
<td>0.83±0.45</td>
<td>0.93 ± 0.50</td>
<td>0.133</td>
<td>1.03 ± 0.67</td>
</tr>
<tr>
<td>FMA</td>
<td>34.0 ± 10.6</td>
<td>36.2 ± 11.0</td>
<td>0.068</td>
<td>36.5 ± 10.9</td>
</tr>
<tr>
<td>Sensory</td>
<td>40.9 ± 3.1</td>
<td>41.4 ± 3.7</td>
<td>0.476</td>
<td>41.4 ± 3.8</td>
</tr>
</tbody>
</table>

Abbreviations: AOU, Amount of Use scale; F/M, F-wave/motor wave; FMA, Fugl-Meyer Assessment; MAL, Motor Activity Log 30; MAS, Modified Ashworth Scale; MMSE, Mini-Mental State Examination; QOM, Quality of Movement scale; SD, standard deviation; UE, Fugl-Meyer Assessment for upper extremity.

a The P values were calculated for Wilcoxon signed rank test to evaluate the differences of baseline and post training scores.
b The P values were calculated for Wilcoxon signed rank test to evaluate the differences of baseline and 2-month follow-up scores.
c The P values were calculated for repeated measures analysis of variance to evaluate within-subjects main effect of time.
d The P values were calculated for repeated measures analysis of variance to evaluate the interaction of time and group.
Figure 2. The maximal F/M ratio of both groups at baseline, post-training and 3-month follow-up. In the splint group, the maximal F/M ratio decreased after the treatment compared with it in the baseline, but it seemed to rebound at the 3-month follow-up.

Figure 3. The mean F/M ratio of both groups at baseline, post-training and 3-month follow-up. In the splint group, the mean F/M ratio decreased after treatment compared with baseline, but it seemed to rebound at the 3-month follow-up.
Figure 4. The Modified Ashworth Scale (MAS) of the wrist in both groups at baseline, post-training and 3-month follow-up. The MAS decreased more in the splint group after treatment compared with the control group, but it seemed to rebound at the 3-month follow-up, which was not noted in the control group.

Figure 5. The Modified Ashworth Scale (MAS) of the finger in both groups at baseline, post-training and 3-month follow-up. The MAS decreased more in the splint group after treatment compared with the control group, but it seemed to rebound at the 3-month follow-up, which was not noted in the control group.
Evaluations including the MAS, active range of motion of the wrists and digits, grip strength, MAL, FMA and F/M ratio were performed at baseline, post-training (within 2 to 3 days after the month of intervention) and 2 months after the training programs (3-month follow-up).

The subjects in the control group received the same training and assessments except they completed the task-oriented training without wearing the splint.

This study was approved by the institutional review board for human studies at the author’s hospital.

Data analysis

SPSS 18.0 for Windows was used for statistical analysis of all collected data. The Mann-Whitney U test and chi-squared or Fisher exact test were used for comparison of demographic and baseline characteristics data between the two groups. The Wilcoxon signed rank test was used to evaluate differences in the outcome variables between the different time points (baseline, post-training and follow-up). A repeated measures analysis of variance (repeated measures ANOVA) was used to evaluate the time effect (baseline, post-training and follow-up) and the interaction effect between the groups and over time. Mauchly’s test was used to test the hypothesis of sphericity. If the sphericity assumption was violated, the Greenhouse-Geisser estimated epsilon was used to correct the degrees of freedom of the F-distribution and to elicit a more accurate significance value.

RESULTS

From November 2016 to March 2019, a total of 42 subjects were enrolled. Among them, 4 did not meet the criteria of the study, 3 dropped out for personal reasons and 35 subjects completed the study. Among the 35 subjects (female = 15), 12 had experienced ischemic stroke, 20 hemorrhagic stroke and 3 had brain injuries. Their average age was 43.1 ± 12.9 (20–68) years old with an average of 32.0 ± 35.7 (6.0–181.4) months since their stroke or brain injury. Seventeen of the subjects were assigned to the control group and 18 to the splint group. All subjects completed the training program, with the splint when it was used, well without any complications. There was no obvious difference among most of the baseline variables between the two groups except that the score on FMA-sensory was higher in the control group than in the splint group. The age, MAL-AOU and FMA-UE also tended to be higher in the control group than in the splint group, although the differences did not reach statistical significance (Table 1).

Table 2 shows the outcome variables analysis at the baseline, post-training and 3-month follow-up. Compared with baseline, the maximal and mean F/M ratio and the wrist and finger MAS were all lower at the post-training assessment of the splint group, but then returned to values close to baseline at the follow-up assessment (see Figure 2–5). In the control group, there was no change of the maximal and mean F/M ratio at different time points, but there was a trend toward decreased wrist and finger MAS at the post-training assessment compared with baseline. The trend did not reach statistical significance, and there was no rebound phenomenon at the follow-up as was noted in the splint group (see Figure 2–5). The FMA-UE increased at the follow-up compared with baseline in the splint group. On the other hand, the MAL-AOU and MAL-QOM increased at the follow-up compared to baseline in the control group. There were no significant changes in the elbow MAS, the wrist and finger AROM, and grip strength in either group. The repeated measures ANOVA showed statistically significant differences for the main effect of “time” for the wrist and finger MAS, maximal and mean F/M ratio, MAL-AOU, MAL-QOM, and FMA-UE scores. There was a significant interaction effect between “the groups and over time” of the maximal F/M ratio. This trend could also be found for the mean F/M ratio although it did not reach statistical significance.

DISCUSSION

The findings of this study suggest that 15 hours of a task-oriented training program in a 1-month period with or without the use of a dynamic hand splint helps reduce spasticity in chronic hemiparetic patients’ hands, and the treatment efficacy seemed at least modestly higher with the splint used than without. Moreover, it seemed that there must be different mechanisms for spasticity reduction between the two groups.

The F wave, a small late response following the CMAP, is obtained from supramaximal electrical stimulation to the nerves. Its amplitude or amplitude ratio to the
CMAP (F/M ratio) is thought to be positively associated with the excitability of the spinal alpha motor neuron pool for spastic muscles. Although it is not feasible to offer an absolute value of any of the F wave parameters to define the existence or to classify the severity of spasticity due to great individual variations, the change of F wave amplitude or its relevant parameter in a group can be used as a measurement of change in spasticity or muscle hypertonicity. It has been used as an important parameter in many previous studies examining the therapeutic effect of anti-spasticity intervention. Both groups might get some reduction of spasticity from task-oriented training exercises due to their engagement in grasp and release activities, matching previous reports. However in the splint group, training with the assistance of the elastic force of the dynamic splint, the affected hands can perform opening and grasping operations with a greater range of motion. It was deduced that this might additionally help patients to have reduction in the excitability of the spinal alpha motor neuron, which was supported by the findings that there was an obvious change of the F/M ratio at the post-training assessment in the splint group in comparison to the control group. Besides, the F/M ratio and MAS seemed returned back to the baseline at the follow-up (rebound phenomenon) in the splint group, which was not the case in control group. We inferred that this rebound phenomenon might be caused by the post-inhibition hypersensitivity of spinal alpha motor neurons after stopping the use of dynamic splints at the follow-up period.

It is well known that task-oriented training is an effective treatment to improve arm-hand performance after stroke. The results in this study revealed that the FMA-UE increased at follow-up compared with baseline in the splint group while the MAL-AOU and MAL-QOM increased at follow-up compared with baseline in the control group. The repeated measures ANOVA showed that there were statistically significant differences for the main effect of “time” but there was no obvious interaction effect between “the groups and over time” of these variables. It indicated the task-oriented training did help the subjects to get functional improvements, and whether a splint was used or not, it did not make an obvious difference.

The strength of the present study was that it was the first randomized control and single-blind trial addressing the therapeutic efficacy of the dynamic hand splint to be reported in English. The outcome measurements were made by assessors blinded to the grouping of the participants to minimize possible bias. However, since the participants were not blinded, their responses to subjective outcome measures, such as some items in the MAL, could be influenced and affect the validity of these measures. There were other limitations in this study. The 1-month training course and follow-up period were short and the sample size was small, possibly increasing the risk of selection bias. In fact, although the grouping of participants was randomized, the baseline functional status seemed relatively poor in the splint group compared to the control group. A second limitation is that during the period from the time of post-training to that of follow-up, each subject received different rehabilitation therapy, possibly affecting the results at the time of follow-up. Therefore, the results were interpreted under the assumption that the same treatment already given for more than six months before the subjects joined the study might cause minimal changes during this 2-month period. The natural recovery course of the disease itself might also have confounded the results, but since this study enrolled patients whose stroke or head injury was more than 6 months ago and there was no difference in this duration between the groups, its influence was assumed to be minimal. Finally, although it is the most frequently-used tool to clinically evaluate spasticity, the limitations of the MAS used in this study should be noted. It evaluates the resistance in viscoelastic elements to passive movement, which may be influenced by many factors including testing position, resting limb position before stretch, speed of stretch and so on. Its limitation also includes subjective and semi-quantitative measurement, and interrater disagreement due to varied interpretation of the definition of each grade of the scales. Further study including more objective or valid measurement tools to examine the efficacy of dynamic hand splints in the treatment of spasticity is suggested.

One should take the above limitations into consideration while interpreting the results of the present study, and further well-designed studies with large sample sizes, longer time of intervention and follow-up, and more objective or valid measurements for spasticity evaluation...
are needed to further clarify the treatment efficacy of dynamic hand splints.

CONCLUSION

The present study suggested that in addition to conventional therapy, a 15-hour task-oriented training program over a 1-month period helped chronic spastic hemiparetic patients to have reduced spasticity and functional improvements whether they used a dynamic splint or not. However, training with the dynamic hand splint may have helped to reduce the excitability of spinal alpha motor neurons for spastic muscles.

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REFERENCE


動態手部副木對於痙攣偏癱患者手部之治療效益：一隨機對照試驗

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背景：臨床上對於中風或腦傷患者所伴隨之偏癱上肢的肢體痙攣問題，處理上仍具相當的挑戰性。動態手部副木用於處理這類的問題已經行之有年，但其效果仍缺乏明確的證據。

目的：探討動態手部副木在痙攣性偏癱患者的治療效果。

方法：這個隨機對照單盲的臨床試驗中招募對象是中風或腦傷後持續半年以上的痙攣性偏癱患者。他們被隨機分派為副木組和對照組，分別在有穿戴副木(副木組)與不穿戴副木(對照組)的情形下，接受了為期 1 個月的任務導向訓練。最後由對於受試者分組不知情的評估者在訓練前、訓練後、和 3 個月的追蹤時對受試者進行結果評估。

結果：共 35 名受試者(副木組=18，對照組=17)完成了本項研究。與訓練前測量值相比，訓練後副木組的手腕和手指在改良式艾斯渥氏量表(Modified Ashworth Scale)(MaAS)評分、最大和平均 F/M 比值均顯著降低；另外，與訓練前相比，3 個月追蹤評估的傅格-梅爾評估量表(Fugl-Meyer assessment)的上肢得分也顯著增加。然而，單因子相依變異數分析(repeated measured ANOVA)僅顯示最大 F/M 比值之變量同時在組間及隨著時間變化存在顯著的交互作用。

結論：結果指出，使用動態手部副木進行訓練將可能有助於降低痙攣性肌肉之脊髓α運動神經元的興奮性。（台灣復健醫誌 2021；49(1): 59 - 71）

關鍵詞：動態副木(dynamic splint)，上肢(upper extremity)，中風(stroke)，腦傷(brain injury)