Back From the Brink: Electromyography-Triggered Stimulation Combined With Modified Constraint-Induced Movement Therapy in Chronic Stroke

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Objective: To determine the efficacy of a regimen that combines electromyography-triggered neuromuscular stimulation (ETMS) with modified constraint-induced movement therapy (mCIMT) in patients with chronic stroke.

Design: Pre-post, case series.

Setting: Outpatient rehabilitation hospital.

Participants: Six subjects who had had a stroke less than 1 year before the study and who had upper-limb hemiparesis. All subjects were only able to activate the affected wrist extensors.

Intervention: Subjects underwent ETMS twice every weekday in 35-minute increments during an 8-week period. One week after they completed the ETMS regimen, and after the outcome measures were readministered, subjects participated in mCIMT, which consisted of structured therapy sessions that emphasized use of the more affected arm in valued activities. The sessions were held 3 times a week for 10 weeks. The less affected arms were also retrained 5 days a week for 5 hours.

Main Outcome Measures: The Fugl-Meyer Assessment (FMA) of motor recovery, Action Research Arm Test (ARAT), and goniometry.

Results: Subjects had nominal changes on the ARAT (mean change, 0.3), and no functional changes after ETMS. However, they had a mean increase of 21.5% in affected wrist extension and an improved ability to perform the wrist items of the FMA (reflected by a mean increase of 4.1 points on the FMA), which qualified them for mCIMT. After mCIMT, subjects had a 15.5-point change on the FMA, an 11.4-point change on the ARAT, and a new ability to perform valued activities.

Conclusions: ETMS alone does not result in functional changes. However, it may elicit sufficient active affected wrist and finger extension increases to permit possible participation in mCIMT, which can result in marked functional gains. This study is among the first to show improved function in stroke patients who initially had little hand motor control, and it is among the first to effectively combine 2 singularly efficacious regimens.

Key Words: Electric stimulation; Exercise; Physical therapy techniques; Recovery of function; Rehabilitation; Stroke; Treatment effectiveness.

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STROKE, THE LEADING CAUSE OF disability in the United States, frequently causes lifelong cognitive and physical impairments. Of these, hemiparesis may be the most disabling because of its impact on performance of most activities of daily living (ADLs). As described by Brunnstrom, recovery from arm hemiparesis typically begins with flaccidity, is followed by spasticity, development of muscle synergies and, finally, recovery of the ability to perform advanced isolated movements. However, some patients have little, if any, active isolated movements in the distal regions of their affected arms even years after a stroke.

Increased use and function of the affected upper limb have been reported after chronic (>1y poststroke) stroke patients participated in constraint-induced movement therapy (CIMT), which encourages use of the affected arm via 2 approaches: participants' less affected upper limbs are restricted during 90% of waking hours in a 2-week period and participants engage in 6-hr activity sessions using their more affected limbs on the 10 weekdays of the same 2-week period. However, researchers have suggested that difficulties may occur in implementing CIMT in the United States and abroad. Thus, shorter protocols have been developed. The most notable example is modified constraint-induced therapy (mCIMT), which combines structured, 30-minute, functional practice sessions with restriction of the less affected upper limb 5 days a week for 3 hours, both during a 10-week period. In addition to our ability to use mCIMT in outpatient settings and to obtain reimbursement for this therapy, the mCIMT treatment effect has been shown to be comparable to CIMT, in randomized controlled pilot studies and in a recent, randomized controlled trial with chronic stroke patients.

Although both CIMT and mCIMT have shown promise, active extension of affected wrists and fingers is necessary in order to participate in these protocols. Consequently, patients with no or trace active extension in their affected wrists and fingers are ineligible, leading to their possible discharge from treatment with residual motor deficits. However, surface electromyography-triggered neuromuscular stimulation (ETMS) may be a promising gateway that can move patients with no active extension toward the above regimens. When using ETMS, a patient attempts to activate the affected wrist musculature (in this article, the affected extensors). If the intended muscles are activated such that a preset threshold is reached (as detected by electromyography in the device), the musculature is electrically stimulated by the device and full extension is realized. If the threshold is not reached, it is automatically lowered and the patient tries again. Thus, the patient is induced to attempt to
activate the affected musculature and when successful, is provided with biofeedback that "reaches" active muscle contraction via the reward of electric stimulation. ETMS increases more affected wrist movement in both subacute and chronic stroke patients who before intervention exhibited trace amounts of active wrist extension.\textsuperscript{10,11} The changes observed in these studies were clinically significant inasmuch as patients could perform several valued ADLs after the intervention that they could not do previously.

In a recent study,\textsuperscript{20} chronic stroke patients with no active movement in their affected wrists and fingers received either ETMS twice every weekday in 35-minute increments for 8 weeks, then participated in an 8-week home exercise program (ETMS-HEP), or they first participated in an 8-week home exercise program, then received ETMS twice every weekday in 35-minute increments for 8 weeks (HEP-ETMS). Subjects showed no change or no change after the HEP, but after ETMS, all patients showed modest or nominal impairment reductions, as shown by the Fugl-Meyer Assessment (FMA), and no fine motor function changes as measured by the Action Research Arm Test (ARAT). Both groups showed a 21\% mean increase in active wrist extension after ETMS. New active wrist and finger extension provoked by ETMS qualified patients who initially had no movement to participate in mCIMT and possibly realize additional gains. Few studies have examined the efficacy of combining singularly efficacious modalities to realize even greater gains. This case series reports a group of chronic stroke patients who participated in an ETMS program that increased their active affected wrist and finger extension enough that they were eligible for mCIMT. Additional functional gains were realized after mCIMT.

**METHODS**

Participants

Our subjects were enrolled in a larger ETMS clinical trial and are reported here because of their motor changes resulting from their participation in the trial. Those changes qualified them for subsequent mCIMT participation possibly leading to additional motor changes. To initially participate in the ETMS trial, subjects had to meet the following inclusion criteria: (1) stroke experienced between 1 year and 18 years prior to study enrollment; (2) no cognitive deficits, as evidenced by a score of 70 points or more on the Modified Mini-Mental Status Examination\textsuperscript{21}; (3) age between 18 and 85 years old; (4) no excessive pain in the affected upper limb or wrist, as measured by a score of 4 or lower on a visual analog scale; (5) a detectable surface electromyographic signal using the ETMS of less than 2\,µV from the extensor carpi radialis of the more affected limb (a level sufficient to activate the affected extensors and use ETMS, but not sufficient to actively extend the affected wrist); and (6) passive range of motion (ROM) to 45\% extension in the affected wrist, as well as passive movement without difficulty in the distal intercarpal/hanlger joints of the affected fingers, both as measured by goniometry. Exclusion criteria were: (1) neurologic comorbidity that impaired strength in the affected upper limb; (2) taking medication that could impair neuromuscular performance (e.g., botulinum toxin type A); (3) having a pacemaker or another implanted stimulator; (4) having no stroke-related wrist or finger pathologies (e.g., spastic wrist); (5) able to actively extend the affected wrist; (6) currently enrolled in any form of physical rehabilitation; and (7) participation in any other experimental studies. This was consistent with previous work that used this device. The above criteria qualified 6 subjects for the study (table 1).

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Abbreviations: F, female; L, left; M, male; R, right.

### Equipment

The NeuroMove 900 (NM 900)\textsuperscript{6} is an electromagnetically monitored neuromuscular electric stimulation device approved by the U.S. Food and Drug Administration for use by stroke survivors. It uses 3 surface electrodes (1 ground over a bony protrusion, 2 over the motor point of the targeted muscle) to detect electric signals sent from the brain to nerves inside the targeted muscle. A computer inside the device evaluates the amount of activity in the muscle and determines whether it meets or exceeds a preset threshold. If the threshold is reached, the NM 900 activates the muscle with its own biphasic waveform with pulse width ranging between 100 and 400\,µs. The "on" signal duration can be adjusted to be between 0.5 seconds and 10 seconds; research\textsuperscript{22} suggests that 10 seconds is the optimal duration and we used that duration. Cauraugh et al\textsuperscript{23} also found that 3 trials using the device were sufficient for patients to administer the NM 900, making it ideal for home use.

A finger goniometer was used to measure active wrist extension before and after intervention. The small, plastic device can be held and operated with 1 hand and, using a protractor measuring from 0\(^\circ\) to 110\(^\circ\) in 2\(^\circ\) increments, is sensitive to small changes in active extension.

### Instruments

In addition to goniometry, we applied the FMA and the ARAT because of their sensitivity to motor changes in chronic stroke.\textsuperscript{24} The FMA\textsuperscript{25} assesses several dimensions of impairment, including ROM, pain, sensation, upper- and lower-extremity impairments, and balance. A 3-point ordinal scale (0, cannot perform; 1, can perform fully; 2, can perform partially) is applied to each item, and the items are summed to provide a maximum score of 220. We used the upper-extremity motor component, which consists of 60 points. The FMA has impressive test-retest reliability (total, 0.98; subtests, 0.87; 1.00), intrarater reliability, and construct validity.\textsuperscript{26,27} It has been used extensively in studies that have measured functional recovery in stroke patients and is highly recommended for "use in clinical trials designed to evaluate changes in motor impairment following stroke."\textsuperscript{28,29} The ARAT\textsuperscript{29} is a 19-item test divided into 4 categories (grasp, grip, pinch, gross movement), with each item graded on a 4-point ordinal scale (0, can perform no part of the test; 1, performs test partially; 2, completes test but takes abnormally long time or has great difficulty; 3, performs test normally) for a potential total score of 77. The test is hierarchical in that if the patient can perform the most difficult skill in each category, he/she can perform the other items within the category and need not be tested. The ARAT has high intrarater (r=.99) and test-retest (r=.98) reliability and validity.\textsuperscript{30,31}

### Design, Pretesting, and Intervention

We used a single-blinded, pretest-posttest, case series design. After participants signed consent forms approved by the
additional, marked reductions in impairment (as reflected in 14.5-point mean change on the FMA), and increases in fine motor function (reflected in an 11.4 increase on the ARAT). After mCIMT, subjects reported new abilities to perform valued activities that they and their therapists selected to practice during mCIMT, such as writing using a computer keyboard, and using a television remote control.

Changes evident through ETMS participation were consistent with previous reports of increased movement after ETMS, including in stroke patients who initially had trace or minimal active extension. The mCIMT-induced changes were similar in magnitude and nature to those reported in recent mCIMT studies, and further confirm the efficacy of this promising outpatient, reimbursable regimen. We believe that ETMS simulated affected limb use while mCIMT elicited affected limb use. These circumstances increased affected limb use and resulted in cortical reorganizations and the observed functional improvements. This explanation would be consistent with recently reported data showing relations between increased affected limb use, mCIMT-induced cortical reorganizations, and functional improvements, as well as recent data showing ETMS-induced cortical reorganizations and clinically meaningful changes. Unfortunately, in this study, we did not administer a reliable measure of affected limb use such as activity monitors, or a measure of cortical change such as functional magnetic resonance imaging (fMRI). These are study limitations that we intend to overcome in future work.

This study is among the first to suggest the efficacy of combining 2 promising strategies in stroke, and its results should increase the number of stroke patients who should potentially be served by mCIMT. The regimens described here also offer the advantage of being almost entirely home-based; the ETMS regimen was self-administered by subjects in the home, while mCIMT required patients to practice for 5 hours a day 5 days a week at home. In both instances, high compliance with no dropouts was reported. Note, however, that this promising combined regimen will not solve the problems of patients who remain unable to activate the extremities and thus are not able to use ETMS. Additionally, it should be remembered that our study's patients were participants in a larger ETMS trial; many of the patients in the larger ETMS trial did not show extension improvements sufficient to participate in mCIMT and are not reported here. Thus, a one-size-fits-all approach cannot be used, even in patients with similar impairment levels who meet the same inclusion criteria. Future efforts should repeat methods and findings of this study with larger and more diverse samples, and attempt to intervene upon those patients with no motor control of extremities, perhaps by using other electric stimulation modalities.

The optimal ETMS duration for stroke patients also needs to be established in future work, particularly for more impaired patients such as those described here. Indeed, it seems reasonable that stroke patients with less active movement may require a longer ETMS program, with more sessions of longer durations, than less impaired patients. We are currently investigating this important question and resolving some of the above limitations by examining the functional and neural effects of several ETMS durations using fMRI at 4T.

CONCLUSIONS

ETMS did not appear to have a functional benefit for chronic stroke patients who have minimal initial active extension. However, ETMS markedly increased active wrist extension, to the degree that subjects were eligible for mCIMT. After participating in mCIMT, our subjects had additional motor changes, including an ability to perform valued activities that they had not performed in months or, in some cases, years.

We believe this study is among the first to show improved function in stroke patients who initially had little affected hand motor control, and among the first to effectively combine 2 singularly efficacious regimens. However, more research is needed to establish the optimal duration and timing, as well as the mechanisms of ETMS in chronic stroke.

References


Suppliers


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