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ORIGINAL RESEARCH

Electrically Assisted Movement Therapy in Chronic Stroke Patients With Severe Upper Limb Paresis: A Pilot, Single-Blind, Randomized Crossover Study

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Abstract

Objective: To evaluate the effects of electrically assisted movement therapy (EAMT) in which patients use functional electrical stimulation, modulated by a custom device controlled through the patient's unaffected hand, to produce or assist task-specific upper limb movements, which enables them to engage in intensive goal-oriented training.

Design: Randomized, crossover, assessor-blinded, 5-week trial with follow-up at 18 weeks.

Setting: Rehabilitation university hospital.

Participants: Patients with chronic, severe stroke (N=11; mean age, 47.9y) more than 6 months poststroke (mean time since event, 46.3mo).

Interventions: Both EAMT and the control intervention (dose-matched, goal-oriented standard care) consisted of 10 sessions of 90 minutes per day, 5 sessions per week, for 2 weeks. After the first 10 sessions, group allocation was crossed over, and patients received a 1-week therapy break before receiving the new treatment.

Main Outcome Measures: Fugl-Meyer Motor Assessment for the Upper Extremity, Wolf Motor Function Test, spasticity, and 28-item Motor Activity Log.

Results: Forty-four individuals were recruited, of whom 11 were eligible and participated. Five patients received the experimental treatment before standard care, and 6 received standard care before the experimental treatment. EAMT produced higher improvements in the Fugl-Meyer scale than standard care ($P<.05$). Median improvements were 6.5 Fugl-Meyer points and 1 Fugl-Meyer point after the experimental treatment and standard care, respectively. The improvement was also significant in subjective reports of quality of movement and amount of use of the affected limb during activities of daily living ($P<.05$).

Conclusions: EAMT produces a clinically important impairment reduction in stroke patients with chronic, severe upper limb paresis.

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Every year, 17 million people worldwide sustain a stroke, and approximately one third of them develop permanent upper limb paresis.[1] Among the available therapeutic approaches, functional electrical stimulation (FES) has been proposed as a viable intervention to increase range of motion[2] and to reduce upper limb impairment,[3] ultimately improving

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function and participation.[4] Many FES regimens and systems have been investigated,[5] but clear pathophysiological explications and protocols leading to improved efficacy are still lacking.[6]

FES regimens for the upper limb tested in clinical studies include cyclical FES, electromyographically triggered FES, and neuroprosthetic FES. Cyclical stimulation produces repetitions of movements, without requiring a patient's active participation,[2] and is often used in patients with severe impairments and absence of voluntary arm and hand activity. Electromyographically triggered FES is based on rewarding successful active attempts by the patient with a reinforcement signal in order to drive motor relearning and neuroplasticity.[7] To date, these 2 types of stimulation have not proven superior with respect to standard care (SC)[2] or other FES modalities.[7] Neuroprosthetic FES aims at promoting movement relearning by its ability to bypass lesions and restore function.[2] Neuroprostheses proposed in the past provided meaningful upper limb movements and could produce predefined muscle activation sequences on triggering by patients or therapists.[4,8,9] A special class of FES neuroprostheses enabled the control of FES at will by continuously detecting electromyographic activity, and promoted a significant reduction of impairment.[8] Unfortunately, this type of self-modulated FES might be unfeasible in the severely impaired population because of abnormal or absent electromyographic patterns.

Providing a match between the intention to move the impaired limb and continuous FES assistance during the movement can be achieved without relying on paralyzed muscle activity by providing control means to the unaffected hand of the patient.

In this study, we introduce and test a therapy where patients with severe upper limb impairment self-modulate FES to produce or assist task-specific movements. A custom FES device enables them to engage in intensive goal-oriented training despite their impairment. We called our experimental intervention "electrically assisted movement therapy" (EAMT). During EAMT, the use of the unaffected limb is limited by the need to operate the custom FES controller to self-modulate the delivery of electrical currents, and training is focused on the affected limb.

The purpose of this study was to determine whether EAMT produces higher improvements in upper limb motor impairment, skilled function, spasticity, and subjective perception of the ability to perform daily living tasks than dose-matched, goal-oriented SC in patients with severe upper limb paresis, more than 6 months after their stroke. This pilot study was designed to establish the presence of a clinically important effect on the selected population, and to estimate treatment effect sizes for further clinical testing.[10]

List of abbreviations:

ADL	**activities of daily living**
EAMT	**electrically assisted movement therapy**
FES	**functional electrical stimulation**
FMA-UE	**Fugl-Meyer Assessment of the Upper Extremity**
MAL	**Motor Activity Log**
MCID	**minimal clinically important difference**
MDC	**minimum detectable change**
SC	**standard care**

Methods

Trial design

This study involved random allocation of patients and crossover group assignment. The protocol was reviewed and approved by the Cantonal Commission of Human Research Ethics of Canton Vaud, Switzerland (CER-VD, protocol 346-15). This study is registered with ClinicalTrials.gov (registration no. NCT02563886).

Participants

Subjects of both sexes, aged between 18 and 75 years, were eligible if they met the following inclusion criteria: (1) diagnosis of one, first-ever ischemic stroke verified by brain imaging (computed tomography or magnetic resonance imaging); (2) chronic impairment after stroke (>6mo); and (3) no contraindications to neuromuscular electrical stimulation. Subjects were excluded if they showed (1) an unstable recovery stage—that is, a difference between 2 baseline examinations of >1 point in the motor part of the Fugl-Meyer Assessment of the Upper Extremity (FMA-UE) scale[11]; (2) mild to moderate impairment of the upper extremity (FMA-UE≥21); or (3) excessive spasticity (median Ashworth Scale of the upper limb >2).

Interventions

EAMT was achieved by using a custom FES device allowing patients to control and modulate the electrical stimulation using the unaffected hand in order to produce task-specific movements of the affected limb. The system allowed therapists to choose and reproduce movements of the whole paralyzed upper limb, re-engaging patients into goal-oriented exercises.

Whenever the patient had difficulties in simultaneously controlling the device and performing exercises, the therapist provided help and ensured the use of the affected limb. During each session, 3 types of exercises were possibly performed: mobilization, games, and training for activities of daily living (ADL). Therapy was provided in 10 sessions of 90 minutes per day over 2 consecutive weeks.

SC consisted of goal-oriented occupational therapy delivered as mobilization, games, and training for ADL. Therapy was provided in 10 sessions of 90 minutes per day over 2 consecutive weeks, to match the amount of EAMT. SC always excluded FES, constraint-induced movement therapy, and robotic training.

Progressive exercise shaping, behavioral training toward transfer of exercises to ADL, and daily administration of the Motor Activity Log (MAL)[12] were applied to both interventions, as formerly proposed in other effective treatments.[13,14] There were 2 investigation groups: EAMT-SC, where EAMT preceded SC, and SC-EAMT, where SC preceded EAMT.

Outcomes

The primary outcome measure was the change in FMA-UE. The threshold for assessing a minimal clinically important difference (MCID) between groups was set to 5.25 points,[15] and the minimum detectable change (MDC) between groups was 5.2 points (with no differentiation by severity of impairment).[16,17]