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Contralaterally Controlled Functional Electrical Stimulation for Recovery of Elbow Extension and Hand Opening After Stroke:

A Pilot Case Series Study

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Abstract

Objective—The aims of this study were to determine whether patients with moderate-to-severe upper limb hemiplegia could use contralaterally controlled functional electrical stimulation at the arm and the hand (Arm+Hand CCFES) at home and to evaluate the feasibility of the Arm+Hand CCFES to reduce arm and hand motor impairment.

Design—With the Arm+Hand CCFES, the paretic elbow and hand extensors were stimulated with intensities proportional to the degree of elbow extension and hand opening, respectively, of the contralateral unimpaired side. For 12 wks, four participants with chronic (>6 mos) upper limb hemiplegia received ~7 hrs per week of self-administered home-based stimulation-mediated elbow extension and hand opening exercise plus ~2.5 hrs per week of therapist-supervised laboratory-based stimulation-assisted functional task practice. Assessments of upper limb impairment were made at pretreatment, posttreatment, and 1 mo after treatment.

Results—All four participants were able to use the Arm+Hand CCFES system at home either independently or with very minimal assistance from a caregiver. All four participants had increases in the Fugl-Meyer score (1–9 points) and the Wolf Motor Function Test (0.2–0.8 points) and varying degrees of improvement in maximum hand opening, maximum elbow extension, and simultaneous elbow extension and hand opening.

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Disclosures:

Jayme S. Knutson, PhD, and John Chae, MD, are coinventors on the CCFES patent assigned to Case Western Reserve University, Patent 8,165,685: System and Method for Therapeutic Neuromuscular Electrical Stimulation.

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Conclusions—The Arm+Hand CCFES can be successfully administered in stroke patients with moderate-to-severe impairment and can reduce various aspects of upper limb impairment. A larger efficacy study is warranted.

Keywords

Stroke Rehabilitation; Hemiplegia; Upper Limb; Contralaterally Controlled Functional Electrical Stimulation

Upper limb hemiparesis is common after stroke and can lead to a wide range of disabilities.^{1,2} Specifically, forward reach and hand opening are often limited because of muscle paresis and involuntary upper limb muscle coactivations. In many patients, abnormal coactivations cause the hand to close and/or the elbow to flex during attempts to reach forward,^{3,4} which severely limit the functional work space.

Simultaneous elbow extension and hand opening may be possible with neuromuscular electrical stimulation (NMES) applied to the paretic triceps and the finger and thumb extensors. Contralaterally controlled functional electrical stimulation (CCFES) is an innovative motor-relearning therapy that applies NMES in such a way that the patient controls the stimulation by making the desired movement with his/her unaffected side.⁵ Sensors worn on the unaffected side regulate the intensity of stimulation delivered to the paretic side so that the paretic side movement mirrors that of the unaffected side. The authors' previous studies of CCFES at the hand gave preliminary evidence that several weeks of CCFES reduce motor impairment.⁵⁻⁷ The purpose of this pilot study was to investigate the feasibility of extending the concept of CCFES at the hand by adding elbow extensor stimulation.

CCFES therapy is one of several post-stroke upper limb therapies that have emerged in recent years that attempt to facilitate motor recovery through activity-dependent neuroplasticity.⁸ Other such therapies include constraint-induced movement therapy,⁹ robot-mediated movement therapy,¹⁰ bilateral arm training,¹¹ and various NMES strategies.¹²⁻¹⁴ Each of these interventions has been shown to produce measureable gains in research studies. However, significant arm/hand disability often remains, and various aspects of these therapies (e.g., some require significant residual movement or are prohibitively time intensive or require expensive or complicated equipment) have so far limited their applicability and widespread implementation. In addition, none of these therapies focus directly on training simultaneous elbow extension and hand opening.

The Arm+Hand CCFES therapy described in this article was designed to give stroke patients direct proportional control of the stimulation delivered to their elbow and finger extensors so that there would be a strong temporal coupling of motor intention and the resulting arm and hand movement. Patients are instructed to attempt to reach and open both arms and hands at the same time to link motor intention from the ipsilesional hemisphere to movement of the paretic limb. Intention-driven movement is believed to be an important element in motor relearning.^{14,15} In addition, giving patients proportional control of the stimulation may create a perception of restored control of their paretic arm and hand and therefore may yield benefits that have been realized through rehabilitation strategies such as mirror therapy.¹⁶

Movement of the contralateral side was chosen as the control signal input to the stimulator because hemiplegic patients would be expected to have no difficulty generating a reliable control signal from the unaffected side. Because patients are instructed to attempt to reach and open both sides at the same time, the CCFES treatment may yield benefits associated with bilateral symmetric movement.¹¹ The Arm+Hand CCFES therapy consists of home-based stimulation-mediated reach-and-open exercise plus laboratory-based stimulation-assisted upper limb functional task practice with an occupational therapist. Thus, benefits associated with muscle stimulation,^{17,18} functional task practice,^{9,19} and a high treatment dose^{20,21} may also accrue.

This article reports the results of a pilot case series study of the Arm+Hand CCFES, which was conducted with four stroke patients with chronic (>6 mos) arm/hand hemiplegia. The aims of the study were to determine whether stroke survivors could use the Arm+Hand CCFES system at home as instructed either independently or with the help of a caregiver and to estimate the efficacy of the Arm+Hand CCFES to reduce upper limb impairment.

METHODS

Selection Criteria

Four stroke patients with the following characteristics were selected to participate in this study: 6 mos or longer post-stroke, less-than-normal finger extensor strength (i.e., 4/5 on the Medical Research Council scale), unable to fully extend the elbow and fully open the hand simultaneously while the forearm was supported by a mobile forearm support, upper extremity Fugl-Meyer score of 10 or greater and 50 or lower of a possible score of 66, NMES applied to the triceps produced full elbow extension without discomfort, NMES applied to the finger and thumb extensors produced a functional degree of extension of the fingers and the thumb without discomfort, and able to follow three-stage commands. The Fugl-Meyer criteria were chosen to exclude patients with minimal impairment and also patients with near-complete paralysis who would not be able to participate meaningfully in the functional task practice part of the treatment. Candidates were also excluded from consideration if they had an insensate or edematous upper limb or hand, severe shoulder or hand pain, uncompensated hemineglect, and intramuscular botulinum toxin injections in any upper limb muscle within 3 mos of enrollment or were participating in other upper limb therapies. The study protocol was approved by the institutional review board at the university-affiliated hospital in which the research was conducted, and written informed consent was obtained from each participant.

Arm+Hand CCFES System

The Arm+Hand CCFES system consisted of a stimulator, surface electrodes, a control glove, and an elbow cuff (Fig. 1). The stimulator was a multipurpose custom-built unit (Cleveland Functional Electrical Stimulation Center, Department of Veterans Affairs Rehabilitation Research and Development Center of Excellence, and Case Western Reserve University, Cleveland, OH) that produced up to seven independently programmable monopolar channels (i.e., using a common anode) of biphasic symmetric rectangular current pulses with parameter ranges that were suitable for surface NMES (i.e., pulse frequency up to 100 Hz,

pulse duration of 0–250 μ secs, and pulse amplitude of 0–100 mA). The stimulator was equipped with an LED display, a speaker for audio cues, and usage-logging capability. Self-adhering pregelled surface electrodes (PALS; Axelgaard Manufacturing Co., Fallbrook, CA) were used to target muscles in the arm, the forearm, and the hand. The electrodes were connected to the stimulator with 100-cm cables, enough length for the stimulator to sit on a table in front of the user during elbow and hand stimulation. The control glove (Fox Incline Glove; Fox Head, Inc, Irvine, CA) had three bend sensors (One-Directional Flex Sensor; Images SI Inc, Staten Island, NY) attached to the dorsal aspect of digits II-III-IV,⁵ and the elbow cuff (Futuro Precision Fit Elbow Support; 3M Consumer Health Care, St Paul, MN) had a single bend sensor that spanned the posterior aspect of the elbow. The bend sensors on the glove and elbow cuff were cabled to the stimulator.

The muscles targeted for stimulated hand opening were the extensor digitorum communis and the extensor pollicis longus. The dorsal interossei and/or the extensor indicis proprius were also targeted if needed to produce functional hand opening. The triceps was targeted for elbow extension. If necessary, the biceps was also stimulated to assist elbow flexion. For all participants, a single 1.5 $\times$ 3.5-in anode (return electrode) was positioned just proximal to the elbow posteriorly. The triceps was stimulated with a 1.5 $\times$ 3.5-in electrode, and the forearm and hand muscles were stimulated with 2 $\times$ 2-in and/or 1.25-in round electrodes. For all participants, the pulse frequency was set at 35 Hz, and the pulse amplitude was set at 40 mA for the forearm and hand muscles and at 40 mA, or 60 mA if necessary, for the triceps. The strength of stimulated muscle contractions was modulated by changing pulse duration. The maximum pulse duration, defined as that which produced maximum elbow extension or functional hand opening without pain while the participant remained relaxed, was determined for each electrode. The stimulator was programmed to increase the pulse duration for each stimulation channel from zero to its maximum in proportion to the amount of opening of the contralaterally worn control glove (for the forearm and/or hand electrodes) or elbow cuff (for the triceps electrode). An open gloved hand produced full stimulated opening of the paretic hand; a partially open gloved hand produced a proportional amount of stimulation, resulting in a partially open paretic hand. Likewise, the participant controlled the degree of stimulated elbow extension by extending and flexing the contralateral elbow wearing the elbow cuff.

Each participant was trained how to place the electrodes and use the Arm+Hand CCFES system at home to perform stimulation-mediated reach-and-open exercises (described below). Photographs of the electrodes in their proper positions were taken and given to the participants to assist them in positioning the electrodes themselves at home. The participants also received a manual, which was reviewed with them before taking the stimulator home. Because the self-administered home stimulation sessions included the use of mobile forearm supports (ZoncoArm, Northfield, MN) clamped to a table, the treating therapist made a home visit at the beginning of the 12-wk treatment period to set up the study-provided table and mobile forearm supports for each participant.

Intervention

The treatment period was 12 wks and included (1) self-administered home use of the Arm+Hand CCFES system for ~7 hrs per week and (2) laboratory sessions twice a week that included stimulation-mediated functional task practice with an occupational therapist for ~2.5 hrs per week.

The home stimulation regimen consisted of ten 45-min sessions per week; each session was two 20-min sets separated by 5 mins of rest. The participants sat at a table with their forearms resting in mobile forearm supports and were prompted by light and sound cues from the stimulator to “reach and open,” that is, to extend the elbows into a supported forward reach and to open the hands simultaneously. They were instructed to activate the reach-and-open stimulation with the control glove and elbow cuff while simultaneously attempting to reach and open with their affected side. The cues prompted the participant to repeat the movement 45–65 times per 20-min set, in which the number of repetitions was increased during the first 6 wks of the 12-wk treatment. The purpose of the mobile forearm supports was to prevent shoulder fatigue and to reduce effort at the shoulder that might activate flexor synergy patterns and prevent full stimulated elbow extension and hand opening.²² The mobile forearm supports had two-link articulating arms with a fulcrum under the forearm trough. The participant’s forearms rested loosely upon the troughs and were not secured with straps, which allowed full elbow extension. To complete ten sessions per week, the participants typically performed two sessions per day, 6 days a week, except on days they came to the laboratory for functional task practice; on those days, they performed only one session at home after the laboratory visit. The participants filled out diaries to keep track of their exercise sessions.

The twice-a-week laboratory sessions consisted of a 15-min tracking task and 60 mins of stimulation-assisted functional task practice with an occupational therapist. For the tracking task, a computer screen displayed a ball and two parallel traces scrolling horizontally right to left. The vertical position of the ball corresponded to the degree of elbow extension of the paretic limb or, alternatively, the degree of finger extension of the paretic hand. A sensor was placed on either the paretic elbow or a paretic finger for this task. The task was to keep the ball between the two parallel traces by extending and flexing the paretic elbow or finger with the assistance of the Arm+Hand CCFES system. Elbow and finger tracking practice were alternated from session to session.

Functional task practice was performed using contralaterally controlled hand and/or elbow stimulation as necessary to augment the movements required to complete tasks without the forearm support. Tasks were both unimanual and bimanual in nature and were graded to match the participants’ ability and progression toward recovery. If the participant found it easier to complete a task without assistance from the Arm+Hand CCFES, he/she was allowed to attempt this. Although pre-functional treatment (e.g., active/passive range of motion, isometric strengthening, isolated muscle movements) was provided as necessary, treatment focused directly on functional tasks tailored to the participants’ interests and ability. Special emphasis was placed on repetition,²¹ with the participants attempting and fine-tuning performance on the same task numerous times (i.e., sometimes dozens) before changing to a new task.

Outcome Measures

Baseline assessments of upper limb motor impairment were made twice, approximately 1 wk apart. The assessments were repeated at 6 wks (midtreatment), 12 wks (end of treatment [EOT]), and 1 mo after treatment. The assessments described below are categorized as hand, elbow, or arm and hand impairment measures.

Hand Measures

Maximum Voluntary Hand Opening—A sensor was attached to the hand to measure the distance between the tips of the fingers and the tip of the thumb (Fig. 2).²³ Each participant was seated with the forearm supported and pronated so that the hand rested near the participant's midline at the height of the xiphoid process. The participant was prompted by a 4-sec audio cue to open the hand as wide as possible from the rest position. The mean hand opening attained during the last 1 sec of the cue was calculated and averaged over three trials. The minimum hand opening that the sensor permitted was 3.0 cm (i.e., when the hand was closed and the tips of the fingers and the tip of the thumb were 3.0 cm apart), and the maximum hand opening that could be recorded by the sensor was 9.9 cm.

Hand Tracking Error—Using the same hand opening sensor and limb positioning as the maximum voluntary hand opening assessment, the participants were presented with a ball on a computer screen and a 0.1-Hz sinusoidal “track” scrolling right to left on the screen (Fig. 2). The vertical position of the ball represented the extent of hand opening. A 30-sec trial required the participant to trace the sinusoidal track with the ball by opening and closing the hand. The vertical range of the sinusoidal track was scaled to the middle 70% of the participant's maximum hand opening, as determined that day.²⁴ For the participants with less than 2 cm of hand opening from the closed position, the track was scaled to match a 0-to-2-cm range of hand opening. For each trial, tracking error was defined as the mean of the absolute distance between the ball and the track, in units of %maxrange. The maximum tracking error possible was 50%maxrange, which would occur if the participant was unable to open the hand for the entire trial. A practice trial was followed by three trials, and the tracking error was taken to be the lowest (best performance) of the trials. For the participants who could not open their hand during the practice trial (i.e., error of 50%maxrange), no additional trials were done and the score was taken to be 50%maxrange.

Elbow Measures

Maximum Voluntary Elbow Extension—A camera-based optical tracking system (Optotrak Certus; Northern Digital Inc, Waterloo, Ontario, Canada) measured the position and movement of the arm and the forearm. Elbow extension angle was calculated from position-tracking LED marker data. From the arm resting position described above, the participants were prompted by an audio cue to reach as far as possible toward an actual foam ball target that was positioned directly in front of the participant's shoulder at a distance equal to the participant's passive reaching distance. The mean elbow extension angle (in degrees) attained during the last second of the cue was calculated and averaged over three trials. Full elbow extension was 180 degrees. This measurement was made with and without a mobile forearm support.

Elbow Tracking Error—Using the optical tracking system and the same display as that in the hand tracking error measurement, the participants were instructed to trace a 0.1-Hz sinusoid by extending and flexing the elbow. Elbow angle was represented as a ball that moved up and down on the screen as the participant extended and flexed the elbow, respectively. The track was scaled to the middle 70% of the participants' active range of elbow extension, as determined by the assessment of maximum voluntary elbow extension made that day. For the participants with less than 20 degrees of elbow extension from the starting position, the track was scaled to match a 20-degree range of elbow extension. Elbow tracking error was calculated in the same manner as that in hand tracking error. This measurement was made with and without a mobile forearm support.

Arm and Hand Measures

Simultaneous Elbow Extension and Hand Opening—The participants were instructed to reach for the foam ball target and open their hand as wide as possible at the same time in response to an audio cue. If it appeared that the participants were prioritizing elbow extension vs. hand opening (or vice versa), verbal cues were given to attempt both maximally. This was repeated with and without a mobile forearm support. Maximum elbow extension and hand opening were calculated as previously described.

Upper Extremity Fugl-Meyer Assessment—For the upper extremity Fugl-Meyer assessment,^{25,26} an experienced occupational therapist rated the participants' ability to make specific volitional movements of the upper limb (shoulder, elbow, forearm, wrist, and hand) using a 3-point ordinal scale (0, cannot perform; 1, perform partially; and 2, perform fully). The maximum possible score was 66.

Wolf Motor Function Test—For the Wolf Motor Function Test,^{27,28} a 6-point functional ability scale (0, does not attempt; 5, normal movement) was used to score the performance of 15 tasks arranged in order of increasing complexity and from proximal to distal joints. The tasks included gross motion (e.g., lifting the arm from the lap to the top of a box on a table, extending the elbow while sitting parallel to a table), forearm pronation/supination (e.g., turning a key 180 degrees), and dexterity (e.g., lifting a can, flipping cards, stacking checkers). The mean rating across all 15 tasks was calculated, with a score of 5 being the maximum possible score.

Grasp-Release Cylinder Test—For the grasp-release cylinder test,²⁹ the number of times the participant could pick up a 100-g, 5-cm-diameter cylinder, move it from a low platform to a slightly higher platform, and release it in a target area in 30 secs was counted and averaged over three trials. The task requires coordination of arm and hand movement.

In addition to assessments of upper limb motor impairment, usage data recorded by the stimulator were used to calculate the percentage of prescribed home stimulation sessions completed by each participant. In addition, the participants' impressions of change in their arm and hand movement and function were solicited with a brief questionnaire given at EOT.

RESULTS

Participant 1

Participant 1 was a 61-yr-old white man who had a right hemisphere cortical infarct 9.3 yrs before study entry (Table 1). He presented with severe left upper limb hemiparesis, characterized by minimal voluntary shoulder retraction and elevation, ~45 degrees of active elbow flexion against gravity, no voluntary wrist movement or finger extension, and approximately half-range active gross hand closure. His baseline upper limb Fugl-Meyer score was 14. Participant 1 was able to apply the electrodes and use the stimulator independently at home after a family member positioned the elbow cuff on the unaffected arm. He completed 100% of his assigned home stimulation sessions during the 12-wk treatment period and attended 20 (91%) of 22 scheduled visits for functional task practice.

At EOT, participant 1 still had no measurable voluntary hand opening and, therefore, no hand tracking ability (Table 2). His maximum voluntary elbow extension with a mobile forearm support increased from 122 degrees at baseline to 135 degrees by EOT, a gain of 13 degrees that was maintained 1 mo later. His elbow tracking error decreased from 28% maxrange at baseline to 18% maxrange at EOT to 11% maxrange at 1-mo follow-up. Elbow extension and elbow tracking were not tested without the mobile forearm support because he did not have adequate shoulder strength to maintain a proper starting position without support. His supported elbow extension during attempts to open the hand increased by 16 degrees at EOT and was maintained at 1 mo. His Fugl-Meyer score increased by 6 points at EOT and then dropped 3 points at the 1-mo follow-up. He could partially perform only a few tasks on the Wolf Motor Function Test; his score (mean across all tasks) was 0.5 at baseline, 0.7 at EOT, and 0.8 at 1-mo follow-up. He was unable to perform the grasp-release cylinder test at baseline or at any subsequent testing session.

His responses to the EOT questionnaire indicated that he strongly believed that the treatment improved his reaching but not his hand opening or his ability to simultaneously reach forward and open his hand. He strongly believed that he would get more benefit if he continued to receive the treatment. Although formal tests of sensation were not performed in this study, participant 1 reported improved sensation after the first week of stimulation, which he described as a “waking up” feeling throughout his upper extremity. He continued to report the improvement in sensation, unprompted, for the remainder of the treatment period.

Participant 2

Participant 2 was a 41-yr-old African American woman who had a left hemisphere subcortical stroke 3.6 yrs before study entry (Table 1). She presented with full volitional upper limb movement within proximal flexion and extension synergies, active elbow extension with forward reach, and partial voluntary hand closure but no functional hand opening. Her baseline upper limb Fugl-Meyer score was 36. Participant 2 was able to apply the electrodes and use the stimulator independently at home after a family member assisted her in donning the elbow cuff on the unaffected arm. She completed 85% of her assigned home stimulation sessions during the 12-wk treatment period and attended 16 (76%) of 21

scheduled functional task practice visits. Missed visits were mainly caused by family responsibilities that interfered with study participation.

At EOT, participant 2 still had no measurable voluntary hand opening and, therefore, no hand tracking ability (Table 2). Her maximum voluntary elbow extension with a mobile forearm support increased from 152 degrees at baseline to 162 degrees at EOT then dropped to 156 degrees 1 mo later. Her elbow tracking error decreased slightly from 4.4% maxrange at baseline to 4.1% maxrange at EOT to 3.9% maxrange at 1-mo follow-up. Elbow extension and elbow tracking were not tested without the mobile forearm support because she lacked adequate shoulder strength to maintain a proper starting position without support. Her supported elbow extension during attempts to open the hand increased by 5 degrees at EOT then fell at 1 mo. Her Fugl-Meyer score increased by 9 points from baseline to EOT and then dropped 5 points at the 1-mo follow-up. On the Wolf Motor Function Test, she could partially perform the tasks that involved only shoulder and elbow movements, scoring 1.4 at baseline, 1.6 at EOT, and 1.7 at 1-mo follow-up. She was not able to perform the grasp-release cylinder test at any testing session.

Her responses to the EOT questionnaire indicated that she thought that the Arm+Hand CCFES treatment somewhat improved elbow extension and hand opening but not her ability to reach forward and open the hand at the same time. She was ambivalent toward the idea that she would get more benefit if she continued to receive the treatment. Like the first participant, she also reported improved sensation (without solicitation) throughout her upper extremity after week 4, which she reiterated at week 7. Although not formally assessed, the perceived improvement was in both light touch and localization, particularly over the dorsal aspect of the arm and the hand, and was most noticeable after stimulation exercises.

Participant 3

Participant 3 was a 64-yr-old African American woman who had a left cortical stroke 8.7 yrs before entering the study (Table 1). She presented with partial volitional movement within proximal flexion and extension synergies, full active elbow extension with the shoulder at 0 degrees, and full voluntary hand opening. She was unable to reach forward with full elbow extension, and the quality of hand opening deteriorated with forward reach. Her upper extremity Fugl-Meyer score was 41 at baseline. Participant 3 was completely independent with applying the electrodes, donning and doffing the elbow cuff and glove, and using the stimulator. She completed 94% of her assigned home stimulation sessions and attended 19 (95%) of 20 scheduled visits for functional task practice.

Her maximum voluntary hand opening was 9.9 cm at baseline (the maximum possible) and did not change throughout the study (Table 2). Her hand tracking error was low and remained relatively unchanged throughout the study at approximately 3.2% maxrange. Maximum elbow extension with a mobile forearm support was 147 degrees at baseline and remained relatively unchanged throughout. Without the mobile forearm support, her maximum elbow extension was 132 degrees at baseline, 138 degrees at EOT, and 141 degrees at 1-mo follow-up. Her elbow tracking error with a mobile forearm support decreased from 6.6% maxrange at baseline to 3.5% maxrange at EOT and then increased to 4.5% maxrange at 1-mo follow-up. Without a mobile forearm support, her elbow tracking

error was 30.0% maxrange at baseline, decreased to 15.9% maxrange at EOT, and decreased further to 8.0% maxrange at 1-mo follow-up. Her maximum supported elbow extension during full volitional hand opening was 144 degrees at baseline, decreased to 132 degrees at EOT, and returned to 140 degrees at 1-mo follow-up. Without a mobile forearm support, maximum elbow extension during volitional hand opening was 123 degrees at baseline, 120 degrees at EOT, and 136 degrees at 1-mo follow-up. Her hand opening during unsupported elbow extension was 9.2 cm at baseline and increased to 9.9 (maximum possible) at EOT. Her Fugl-Meyer score was 41 at baseline and remained relatively unchanged throughout the study. She could perform at least partially all of the tasks on the Wolf Motor Function Test, scoring 3.0 at baseline and improving by 0.5 points at EOT, which was maintained at 1-mo follow-up. She was able to perform the grasp-release cylinder test, scoring 13 at baseline and remaining unchanged throughout the study.

Her responses to the EOT questionnaire indicated that she strongly believed that the treatment improved her elbow extension, her hand function, and her ability to reach forward and open her hand simultaneously. She stated that her elbow rest position was not as flexed as before, although her arm still got stiff during reaching. She strongly believed that she would continue to improve if she continued to receive Arm+Hand CCFES treatment. Like the first two participants, participant 3 also observed a change in sensation and reported in week 2 that when she stimulated her hand, her fingers were no longer numb.

Participant 4

Participant 4 was a 74-yr-old African American man who sustained a left cortical ischemic stroke 4.6 yrs before the study (Table 1). He presented with partial voluntary movement within proximal upper extremity flexion and extension synergy patterns, full volitional hand closing, and approximately three-fourths range volitional hand opening with his hand in his lap, without the ability to sustain hand opening. His ability to open his hand deteriorated to approximately one-fourth range during forward reach toward a tabletop object. His baseline upper limb Fugl-Meyer score was 40. Participant 4 was independent with all aspects of the Arm+Hand CCFES device, including donning and doffing the electrodes, glove, and elbow cuff. He completed 99% of his assigned home stimulation sessions and attended 20 (100%) of 20 scheduled functional task practice visits.

His maximum hand opening was 8.9 cm at baseline and increased to 9.9 cm (maximum possible) at EOT, which he maintained at follow-up (Table 2). His hand tracking error decreased from 4.4% maxrange at baseline to 3.9% maxrange at EOT, which was maintained at 1-mo follow-up. With forearm support, his maximum elbow extension was 132 degrees at baseline and increased to 156 degrees at EOT. At 1-mo follow-up, elbow extension was not measured because of an equipment malfunction. Without forearm support, his maximum elbow extension was 113 degrees at baseline and increased to 148 degrees at EOT. With forearm support, his elbow tracking error decreased from 5.5% maxrange at baseline to 5.1% maxrange at EOT; without forearm support, elbow tracking error was 9.7% maxrange at baseline and decreased to 4.0% maxrange at EOT. His maximum supported elbow extension during attempts to fully open the hand was 124 degrees at baseline and increased to 150 degrees at EOT; his hand opening during maximum supported elbow extension was 6.9 cm

at baseline, 8.4 cm at EOT, and 9.4 cm at 1-mo follow-up. Without forearm support, maximum elbow extension during attempts to fully open the hand was 113 degrees at baseline and increased to 140 degrees at EOT; his hand opening during maximum unsupported elbow extension was 5.6 cm at baseline, 6.2 cm at EOT, and 8.0 cm at 1-mo follow-up. His Fugl-Meyer score remained relatively unchanged at approximately 40 throughout the study. His score on the Wolf Motor Function Test increased from 3.8 at baseline to 4.6 by EOT and was maintained at follow-up. His score on the grasp-release cylinder test was 12 at baseline, 15 at EOT, and 16 at follow-up.

His responses to the EOT questionnaire indicated that he strongly believed that the treatment improved his reaching, hand function, and ability to reach and open at the same time. He also strongly believed that he would continue to improve with more of the treatment.

Adverse Events

Participant 2 had shoulder pain on the paretic side during the last week of treatment. Because she had shoulder pain intermittently since her stroke, it is unknown whether this episode was related to the study treatment. After her EOT assessment, she received a subacromial steroid injection to relieve the pain. Participant 3 had shoulder pain on the paretic side after her midtreatment (6-wk) assessment. She was able to continue to participate in all aspects of the study but with less active unsupported forward reach during functional task practice until week 8, when her shoulder pain had resolved.

DISCUSSION

This pilot case series study demonstrated that 12 wks of the Arm+Hand CCFES therapy can reduce upper extremity impairment in stroke patients with moderate-to-severe chronic hemiplegia. All four participants had improvements on global measures of upper limb motor impairment, that is, the Fugl-Meyer assessment and the Wolf Motor Function Test. In addition, specific improvements in hand opening, elbow extension, elbow motor control, and simultaneous elbow extension and hand opening of varying magnitudes were realized across the participants. This preliminary evidence of treatment efficacy warrants further development of the Arm+Hand CCFES therapy, a treatment that may meet an important clinical need for upper limb post-stroke therapies that can produce meaningful gains across a range of impairment severities.

The magnitude and type of improvements varied across the participants and are presumably related to the degree of motor impairment at baseline, among other factors. For example, participant 4 experienced improvement on more measures than any of the other participants and also had the greatest magnitude of improvement in supported and unsupported elbow extension, hand opening, the grasp-release cylinder test, and the Wolf Motor Function Test. Although the baseline Fugl-Meyer score for participant 4 was similar to that of participants 2 and 3, he, unlike participant 3, was not able to fully open his hand at baseline; therefore, there was room for improvement on the several measures that required hand opening that participant 3 had little or no room to improve on. In addition, unlike participants 1 and 2, participant 4 did retain some ability to open his hand at baseline, so his degree of hand impairment was not so severe that the treatment had no effect on it, which may have been

the case with participants 1 and 2. The participants with the most severe elbow extension impairment at baseline (participants 1 and 4) improved the most on supported elbow extension and on elbow extension while attempting to open the hand. Therefore, the stroke patients who may get the greatest benefit from the Arm+Hand CCFES may be those who retain partial, but not full, hand opening and elbow extension and who also retain enough active shoulder flexion to maintain an unsupported flexed arm posture required for reaching. This does exclude the possibility that patients with more severe arm and hand impairment can achieve clinically meaningful improvements from the Arm+Hand CCFES therapy. Larger studies would be needed to test these hypotheses.

The authors hypothesized that 12 wks of the Arm+Hand CCFES therapy would improve simultaneous elbow extension and hand opening. Elbow extension during attempts to open the hand did indeed improve in three participants (participants 1, 2, and 4). In addition, hand opening during attempts to extend the elbow without support improved in two participants (participants 3 and 4). The gains experienced by participant 4 in both elbow extension and hand opening during attempts to reach and open simultaneously may explain why he also had the greatest gains in the Wolf Motor Function Test and the grasp-release cylinder test, tests that require simultaneous elbow extension and hand opening. The improvements in simultaneous reach and hand opening could be caused by reductions in coactivation of flexors during attempts to reach and open, but no direct measurements of coactivation were made to confirm this possibility. The mechanism by which coactivation patterns might be altered by the Arm+Hand CCFES treatment or other treatments remains unknown. Some studies suggest that ipsilateral (contralesional) reticulospinal pathways^{30–32} are responsible for abnormal coactivation and that abnormal coactivation may be reduced by increasing the use of the remaining contralateral (ipsilesional) corticospinal tract (use-dependent neuroplasticity).³³ CCFES may facilitate increased potentiation of ipsilesional corticospinal tract pathways by temporally coupling ipsilesional upper motor neuron activity with contralateral lower motor neuron stimulation and somatosensory feedback.

Because Ellis et al.^{22,33} targeted the abnormal coupling of shoulder abduction and elbow flexion by requiring stroke patients to repetitively reach outward during progressive abduction loading, this study targeted the coupling of elbow extension and finger flexion by requiring repetitive reach during hand opening. Rather than using a progressive loading approach, treatment in this study used electrical stimulation, controlled by movement of the contralateral side, to assist the desired elbow and hand movements. The assistance provided by the stimulation enabled the participant to have success in the reach-and-open task, which motivated and encouraged the repetition that is essential for neuroplastic change.²¹ The stimulation, being linked to the patient's own motor intention and afferent feedback, may facilitate neural reorganization that underlies motor recovery.^{14,34} Furthermore, linking movement of the paretic side to the less affected side may increase the corticospinal excitability of the stimulated muscles³⁵ by interhemispheric disinhibition,³⁶ intracortical facilitation,³⁷ or the same mechanisms that underlie the improvements seen after bilateral arm training.^{11,38} Because of these potential advantages of the electrical stimulation paradigm, the dose (number of repetitions per session) was increased as the treatment progressed. An alternative approach would be to reduce the stimulation assistance while maintaining the task dose as the participant improves, an approach that may be analogous to

that of Ellis et al.,²² who progressively decreased the shoulder abduction support (i.e., increased the shoulder abduction load) during reaching as the participants achieved greater reaching distances.

The practical implementation of rehabilitation therapies that focus on the paretic limb has become increasingly challenging. With significant reductions in acute inpatient rehabilitation lengths of stay and outpatient services and the importance of administering therapy in high doses,²¹ it has become more important to develop rehabilitation therapies that can be self-administered at home or require less assistance from a therapist. This study demonstrated that stroke patients with moderate-to-severe motor impairment could use the Arm+Hand CCFES system at home as instructed, either independently or with very minimal assistance from a caregiver. A simpler method of attaching the elbow sensor to the unaffected arm would enable patients with severe hand impairment to be completely independent in donning the entire system. A wireless glove and elbow cuff would also simplify the setup and use of the Arm+Hand CCFES system and are being developed.

CONCLUSIONS

The Arm+Hand CCFES is a new treatment that focuses on improving volitional elbow extension and hand opening in stroke patients with hemiplegia. This initial case series study of four stroke patients with chronic hemiplegia demonstrated that the Arm+Hand CCFES can be administered to patients with moderate-to-severe upper limb impairment for 12 wks, at a dose of ten 45-min sessions per week at home plus two 75-min sessions per week with an occupational therapist. After 12 wks of the Arm+Hand CCFES treatment, reductions in upper limb impairment were seen on various scales, including the Fugl-Meyer score, the Wolf Motor Function Test, maximum hand opening, maximum elbow extension, and simultaneous elbow extension and hand opening. The magnitudes and types of improvements varied across the participants and are probably related to their baseline severity of impairment, among other factors. A larger study is underway to determine the efficacy of the Arm+ Hand CCFES.

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FIGURE 1.
Arm+Hand CCFES device for improving recovery of simultaneous reaching and hand opening after stroke.

FIGURE 2. Sensor used to measure maximum voluntary hand opening and hand tracking error.²³ The inset is a screenshot of the display shown to participants during the assessment of hand tracking error.

TABLE 1

Participant baseline characteristics

Characteristic	Subject 1	Subject 2	Subject 3	Subject 4
Age, yrs	60.8	40.8	64.1	74.3
Sex	Male	Female	Female	Male
Years since stroke	9.3	3.6	8.7	4.6
Stroke type	Ischemic, cortical	Ischemic, subcortical	Ischemic, cortical	Ischemic, cortical
Prestroke hand dominance	Right	Right	Right	Right
Hemiparetic side	Left	Right	Right	Right
Active hand opening	No	No	Yes	Yes
Fugl-Meyer score ^a (range, 0–66)	14	36	41	40

^a Baseline Fugl-Meyer score is the mean of two baseline visits.

TABLE 2

Arm and hand impairment before and after 12 wks of Arm+Hand CCFES

Measure	Participant 1			Participant 2			Participant 3			Participant 4		
	B	EOT	1 mo	B	EOT	1 mo	B	EOT	1 mo	B	EOT	1 mo
Hand measures												
Hand opening, cm	3.0 ± 0.0	3.0 (+0.0)	3.0 (+0.0)	3.0 ± 0.0	3.0 (+0.0)	3.0 (+0.0)	9.9 ± 0.0	9.9 (+0.0)	9.9 (+0.0)	8.9 ± 0.1	9.9 (+1.0 ^a)	9.9 (+1.0 ^a)
Hand tracking error, % maxrange	50 ± 0.0	50 (+0)	50 (+0)	50 ± 0.0	50 (+0)	50 (+0)	3.2 ± 0.6	3.1 (-0.1)	3.2 (+0.0)	4.4 ± 0.4	3.9 (-0.5)	3.8 (-0.6)
Elbow measures												
Elbow extension (supported), degrees	122 ± 1	135 (+13 ^a)	135 (+13 ^a)	152 ± 3	162 (+10 ^a)	156 (+4)	147 ± 3	145 (-2)	142 (-5)	132 ± 2	156 (+24 ^a)	—
Elbow extension (unsupported), degrees	—	—	—	—	—	—	132 ± 1	138 (+6 ^a)	141 (+9 ^a)	113 ± 3	148 (+35 ^a)	—
Elbow tracking error (supported), % maxrange	28.2 ± 1.2	18.0 (-10.2 ^a)	10.9 (-17.3 ^a)	4.4 ± 2.5	4.1 (-0.3)	3.9 (-0.5)	6.6 ± 0.7	3.5 (-3.1 ^a)	4.5 (-2.1 ^a)	5.5 ± 0.1	5.1 (-0.4 ^a)	—
Elbow tracking error (unsupported), % maxrange	—	—	—	—	—	—	30.0 ± 12.3	15.9 (-14.1)	8.0 (-22.0)	9.7 ± 1.1	4.0 (-5.7 ^a)	—
Arm and hand measures												
Elbow extension (supported) during hand opening, degrees	120 ± 0	136 (+16 ^a)	136 (+16 ^a)	154 ± 5	159 (+5)	157 (+3)	144 ± 3	132 (-12 ^a)	140 (-4)	124 ± 2	150 (+26 ^a)	—
Hand opening during elbow extension (supported), cm	3.0 ± 0.0	3.0 (+0.0)	3.0 (+0.0)	3.0 ± 0.0	3.0 (+0.0)	3.0 (+0.0)	9.9 ± 0	9.9 (+0.0)	9.9 (+0.0)	6.9 ± 0.7	8.4 (+1.5 ^a)	9.4 (+2.5 ^a)
Elbow extension (unsupported) during hand opening, degrees	—	—	—	—	—	—	123 ± 11	120 (-3)	136 (+13)	113 ± 1	140 (+27 ^a)	—
Hand opening during elbow extension (unsupported), cm	—	—	—	—	—	—	9.2 ± 0.6	9.9 (+0.7)	9.9 (+0.7)	5.6 ± 0.4	6.2 (+0.6)	8.0 (+2.4 ^a)
Fugl-Meyer assessment	14 ± 2	20 (+6 ^a)	17 (+3)	36 ± 1	45 (+9 ^a)	40 (+4 ^a)	41 ± 0	42 (+1 ^a)	44 (+3 ^a)	40 ± 1	42 (+2 ^a)	40 (+0)
Wolf Motor Function Test	0.5 ± 0.0	0.7 (+0.2 ^a)	0.8 (+0.3 ^a)	1.4 ± 0.0	1.6 (+0.2 ^a)	1.7 (+0.3 ^a)	3.0 ± 0.0	3.5 (+0.5 ^a)	3.5 (+0.5 ^a)	3.8 ± 0.0	4.6 (+0.8 ^a)	4.7 (+0.9 ^a)
Grasp-release cylinder test	0 ± 0	0 (+0)	0 (+0)	0 ± 0	0 (+0)	0 (+0)	13 ± 1	13 (+0)	13 (+0)	12 ± 0	15 (+3 ^a)	16 (+4 ^a)

Baseline values are the mean of the values from the two baseline visits ± half the range of the two baseline values.

Values in parentheses are changes from baseline.

^aIndicates change from the mean baseline value that is greater than the range of the two baseline values.

1 mo, 1-mo posttreatment assessment; B, baseline assessment; em dashes, not tested because of severity of impairment or equipment malfunction.