Cortical stimulation for the rehabilitation of patients with hemiparetic stroke: a multicenter feasibility study of safety and efficacy

ROBERT LEVY, M.D., PH.D.,1 SEAN RULAND, D.O.,2 MARTIN WEINAND, M.D.,3 DAVID LOWRY, M.D.,4 RIMA DAFER, M.D., M.P.H.,5 AND ROY BAKAY, M.D.6

1Department of Neurosurgery, Feinberg School of Medicine, Northwestern University; 2Department of Neurology, University of Illinois; 3Department of Neurosurgery, Rush University Medical Center, Chicago, Illinois; 4Division of Neurosurgery, Department of Surgery, University of Arizona College of Medicine, Tucson, Arizona; 5Spectrum Health, Grand Rapids, Michigan; and 6Department of Neurology, University of Kansas University Medical Center, Kansas City, Kansas

Object. In this prospective multicenter study the authors hypothesized that investigational epidural cortical stimulation (CS) delivered concurrently with rehabilitation therapy may enhance motor recovery following stroke.

Methods. Patients who had suffered their index stroke ≥ 4 months previously were randomized into 6 weeks of rehabilitation therapy with or without CS. Cortical stimulation, targeted by functional imaging, was delivered at ~50% of motor movement threshold. Primary outcome measures were Upper Extremity Fugl-Meyer (UEFM [a measure of neurological and motor function]) and Arm Motor Ability Test (AMAT [a measure of activities of daily living]) scores. The primary study end point was 4 weeks following rehabilitation therapy.

Results. A total of 24 patients, 12 per group, completed the treatment protocol. The mean interval since the patients' index stroke was 33 months (range 4–100 months). There were no deaths or cases of neurological deterioration; 1 acute postoperative seizure occurred unrelated to the device or treatment. Patients who underwent CS experienced improved hand/arm function more than control patients. The UEFM score improved 5.5 ± 4.4 points in patients in the CS group compared with 1.9 ± 4.4 points for controls (p = 0.03). A 3.5-point UEFM improvement is considered clinically meaningful. The AMAT scores for the CS group improved by 0.4 ± 0.6 points, whereas the scores in the control group improved by 0.2 ± 0.4 points (p = 0.2). A 0.21-point improvement in AMAT score is considered clinically meaningful. In the CS group, 67% of patients had clinically meaningful improvement in UEFM scores, compared with 25% of the control group (p = 0.05). Of patients in the CS group 50% had clinically meaningful improvement in UEFM as well as AMAT scores, compared with only 8% of those in the control group (p = 0.03).

Conclusions. These results suggest that subthreshold epidural CS is safe and effective during rehabilitation for recovery of arm and hand function following hemiparetic stroke. Further research in a larger cohort is needed to validate the therapeutic effect. (DOI: 10.3171/JNS/2008/108/4/0707)

KEY WORDS • cortical stimulation • electrical stimulation • epidural location • infarct • motor cortex • rehabilitation • stroke

STROKE is the third leading cause of death and a common cause of serious, long-term disability in the US. Approximately 700,000 strokes occur in patients in the US annually, and > 200,000 stroke survivors become severely and permanently disabled. Overall, there are > 5 million stroke survivors in the US; of these, > 1 million report having difficulty with functional limitations and ADLs.

The most common neurological deficit among stroke survivors, and thus a substantial contributor to poststroke disability, is unilateral weakness. Presently, the only proven treatment available for patients with residual motor deficits is rehabilitative therapy. Unfortunately, many patients achieve less than satisfactory functional improvement from rehabilitative therapy. Recovery of hand function is particularly problematic for these patients and adversely impacts their ability to perform ADLs and their quality of life.

There is extensive clinical literature on motor cortex stimulation for central and peripheral neuropathic pain syndromes. In 1991 Tsubokawa and colleagues23-26 commented on the motor effects of CS for treatment of neuropathic pain noting “subjective improvement of motor deficits was also reported in most of these cases.” Similar findings have
also been seen in subsequent clinical studies for the treatment of central neuropathic pain syndromes.

A number of laboratory investigations in rat and primate stroke models confirm the observation of enhanced motor recovery following CS of the perifract region during rehabilitation.11,16,22,26 These studies also suggest that new areas of the cortex are recruited to participate in the motor control of the affected limb, suggesting that CS enhances neuroplasticity and the poststroke recovery process.16,22

Based on these clinical observations and preclinical investigations, a small multicenter feasibility study was conducted to evaluate the safety and efficacy of subthreshold epidural CS for enhancing return of upper-extremity motor function for patients at least 4 months after hemiparetic stroke.22 Eight patients completed the study: 4 in the investigational treatment group receiving CS plus rehabilitation and 4 in the control group receiving the same rehabilitation without CS. Study results suggested that this form of CS may be performed in chronic stroke survivors safely and provided preliminary evidence of efficacy.4 Thus, we conducted this larger feasibility study to gain additional safety and efficacy data.

Clinical Materials and Methods

Overall Design

This was an unblinded, prospective, randomized, multicenter safety and efficacy study of subthreshold motor cortex electrical stimulation of patients with residual motor deficits in the hand and arm following an ischemic stroke that occurred ≥ 4 months prior to enrollment. Patients were randomized into 1 of 2 groups: 1) an investigational treatment group in which the patients underwent implantation of an investigational CS device system (Northstar Neuroscience) and received CS concurrent with rehabilitation therapy; and 2) a control treatment group in which the patients received the same rehabilitation therapy but did not undergo device implantation.

Patient Enrollment

Patients were enrolled at 7 clinical sites (all within the US): Northwestern University/Rehabilitation Institute of Chicago, Rush-Presbyterian-St. Luke’s Medical Center/Chicago Institute of Neurosurgery and Neuroresearch, University of Illinois at Chicago, Kansas University Medical Center, Spectrum Health (Grand Rapids, Michigan), University of Arizona, and University of Minnesota. A total of 38 patients were enrolled in the study (that is, the patients signed informed consent and began baseline evaluations). Of these 38 patients, 14 did not meet study criteria and were excluded prior to randomization. The following were reasons for study exclusion: UEFM score4 not between 20 and 50 points (5 patients), fMR imaging activation not identified as required (3 patients), patient withdrawal (2 patients), site not yet fully trained and certified to handle the addition of the patient (2 patients), unable to discontinue antithrombotic therapy perioperatively (1 patient), and brainstem infarct (1 patient). Per protocol, 24 patients were included (that is, they were deemed eligible for cortical electrode placement and electrical stimulation) and randomized.

Patient Population

Patients were recruited after Investigational Device Exemption approval by the US Food and Drug Administration and approval of each participating institution’s institutional review board. Informed consent was obtained from each patient. The major inclusion and exclusion criteria are given in Table 1.

Patient characteristics are given in Table 2. No significant differences were observed between treatment groups. Of the 24 patients, 15 (62%) were men and 9 (38%) were women. The mean patient age was 56.8 ± 13.5 years (range 26–81 years). Of note, the mean interval between index stroke and treatment was 2.5 years (32.8 ± 23.4 months [range 4–100 months]). One patient had suffered the index stroke > 8 years before treatment.

The average UEFM score was 32.4 ± 8.2 points (range 20–50 points), indicating moderate to moderately severe motor impairment. The average current delivered to investigational treatment patients during rehabilitation therapy was 5.1 ± 0.9 mA (range 3.3–6.5 mA).

Outcome Measures

Although a multitude of outcome measures were explored as part of this feasibility study, this report focuses on the primary outcome measures, the UEFM and the AMAT. The UEFM is one of the most widely used outcome measures in stroke studies and provides an index of patients’ neurological and motor function (that is, the ability to control the arm, wrist, and hand).2,8,25 The UEFM assessment consists of 9 components: reflexes, flexor synergy, extensor synergy, movement combining synergies, movement out of synergy, normal reflex activity, wrist, hand, and coordination/speed. The UEFM assessment scores range from 0 to 66, with higher scores indicating more normal function.

The AMAT is a measure of ADLs and has been used in a number of stroke studies, specifically in studies of upper-extremity hemiparesis.17 The AMAT assessment measures 28 standardized ADLs with scores on a 0–5–point scale (higher scores indicate better ADL function). The AMAT assessment comprises quality, function, and time scores. Function scores are presented herein.

Outcome measures were assessed by trained occupational or physical therapists at baseline (prior to randomization), during the rehabilitation therapy period, and at follow-up. The primary end point of the study was the Week 4 follow-up (that is, 4 weeks after the conclusion of rehabilitation therapy). Of note, raters were not blinded to the assigned treatment group in this feasibility study.

Safety was assessed by measuring the proportion of patients who were classified as having any of the following outcomes between the time of enrollment and the time that the 6-week rehabilitation program was complete: death, medical morbidity (including myocardial infarction, pneumonia, wound infection, or deep venous thrombosis), clinically definite generalized tonic–clonic seizure, or decrement in neurological status, defined as a decrease of ≥ 20% on the UEFM.

Brain Imaging Protocol

The brain imaging protocol was performed prior to randomization and included structural MR imaging and fMR imaging. The goal of the fMR imaging was to identify the
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**TABLE 1**

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<th>Major inclusion and exclusion criteria*</th>
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<tr>
<td>major inclusion criteria</td>
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<td>patient age ≥ 21 yrs</td>
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<td>ischemic infarct, either cortical or capsular, that occurred ≥ 4 mos prior to enrollment, &amp; demonstrated on computed tomography or MR imaging</td>
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<tr>
<td>UEFM score btw 20 &amp; 50 inclusive, sufficient to allow active wrist extension of ≥ 5°</td>
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<td>major exclusion criteria</td>
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<td>hemorrhagic stroke</td>
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<td>stroke preceding index stroke associated w/ incomplete motor recovery severe sensory deficit, or moderate to severe hemispatial neglect &amp;/or anosognosia</td>
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<td>history of spinal cord injury, significant traumatic brain injury (such as associated w/ loss of consciousness &amp; memory loss), or a subdural or epidural hematoma</td>
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<tr>
<td>history of seizures or intake of anticonvulsants to treat seizures any other significant central nervous system disease</td>
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<td>not considered a candidate to undergo device implantation surgery</td>
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* To have been included in the study patients must have met all inclusion criteria but no exclusion criteria.

Primary motor cortex region of the stroke-affected hemisphere that appeared to be involved in the control of the movement of the affected hand (that is, the contralateral hand).

The cortical area identified by fMR imaging was used as the target location for epidural electrode placement and CS (Fig. 1). The MR imaging studies were performed using a commercially available entire-body high-speed unit with a magnet of ≥ 1.5 T. Structural images included a 3D volumetric data set and high-resolution T1-weighted anatomical images in plane with the functional images. Patients performed 1 of 3 motor tasks depending on ability: index finger tapping, simultaneous tapping of 4 fingers, or wrist extension. Imaging parameters were consistent for each patient at each fMR imaging session across the period of study participation.

The lack of significant cortical activation in a periorbital region within the affected hemisphere excluded patients from the study. For example, if the fMR image did not detect activation of the precentral or postcentral gyrus, or the cortical region detected was determined by the investigator to be too diffuse for subsequent electrode placement, the patient did not undergo randomization and was excluded from further participation in the study.

Final brain activation maps were generated and the center of the activation region coregistered to the anatomical MR images used by the intraoperative neuronavigational system.

**Surgical Procedure**

After the induction of general anesthesia, an ~ 4-cm-diameter craniotomy was performed and the epidural electrode placement site identified by stereotactic localization. The sterile, single-use stimulation electrodes were 6-element electrodes configured in a flexible 2 × 3 element array (Fig. 2). Three elements along one edge were configured as anodes, and 3 elements along the opposite edge were configured as cathodes in reference to the first phase of the stimulation waveform. The platinum/iridium electrode contacts were 3 mm in diameter and spaced 6 mm apart; thus, the effective stimulation area of the electrode was ~ 1.8 cm². The total area of the electrode was ~ 2.6 × 2.7 cm.

Using standard tunneling procedures, the electrode lead was threaded subcutaneously to a subclavicular pocket. After attaching the electrode lead, an IPG was placed in the pocket and the incisions were irrigated and closed. Prior to wound closure, the investigational device stimulation system was tested to verify proper connection of the IPG and electrode and ensure continuity. Patients were hospitalized overnight following system implant.

**Stimulation Protocol**

For each patient in the treatment group, the stimulator output current level to be delivered during rehabilitation therapy was defined based on motor movement data collected periodically prior to rehabilitation sessions. For each assessment of stimulator output, the current level was adjusted in 3-second pulse trains to determine the minimum current required to elicit motor movement. The target stim-

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**TABLE 2**

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<th>Baseline characteristics in 24 patients who had suffered stroke*</th>
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<td>Patient Group</td>
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<tr>
<td>sex (%)</td>
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<tr>
<td>mean age in yrs</td>
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<tr>
<td>mean no. of mos since stroke (to enrollment)</td>
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<tr>
<td>mean UEFM score</td>
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<tr>
<td>mean NIH stroke scale score</td>
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<td>mean BDI score</td>
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<tr>
<td>mean mRS score</td>
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<tr>
<td>handedness (%)</td>
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<td>hemisphere of brain affected by stroke (%)</td>
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* Mean values are expressed as the means ± standard deviations, and the ranges associated with these values are given in parentheses. Abbreviations: BDI = Beck Depression Inventory; mRS = modified Rankin Scale; NIH = National Institutes of Health.
† Comparison of control and investigational groups by Fisher exact test for categorical data and Kruskal–Wallis nonparametric test for continuous data.

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ulation level used during therapy was 50% of the movement threshold. If movement was not elicited during threshold testing, the stimulation level was set to a maximum of 6.5 mA, the maximum output current allowed under the investigational protocol. Stimulation was delivered at a pulse repetition frequency of either 50 or 101 Hz with a pulse duration of 250 μsec.

**Rehabilitation Protocol**

Rehabilitation therapy was provided for 6 weeks. The rehabilitation program emphasized upper-extremity motor function of the affected limb, particularly of the hand and wrist. The standardized rehabilitation program consisted of training in self-care skills and mobility skills. In addition to functional tasks, focus was placed on increasing range of motion, improving strength, and optimizing coordination and isolated volitional movements of the affected extremity. Therapists also focused on specific functional affected motor groups to stimulate reeducation. Examples include facilitation-inhibition, performing synergy patterns, reflex training, improving range of motion, self-care tasks (focused on improving specific functional deficits of the affected upper extremity), and any other activity deemed necessary to improve identified deficits. Specific ADLs of interest to the patient were determined using the Canadian Occupational Performance Measure.

The daily rehabilitation sessions were ~2.5 hours long and consisted of an ~90-minute rehabilitation session near the maximum intensity tolerated by each patient, a break allowing the patient to rest, then an ~60-minute session during which the intensity was permitted to be more variable and sensitive to patient fatigue.

**Device Explant**

After completion of 6 weeks of occupational therapy, all investigational group patients had the entire device system (electrode lead and IPG) explanted.

**Statistical Analysis**

Summary statistics are presented as the mean ± standard deviation. Comparisons between investigation and control groups were made using the t-test for continuous variables and the Fisher exact test for proportions. All significance testing was conducted at a probability value equal to 0.05. We agreed a priori that a 3.5-point improvement in UEFM score was considered clinically meaningful in chronic stroke patients. A 0.21-point improvement in AMAT function was a priori considered clinically meaningful.

As a frame of reference, a 1-point improvement in the UEFM score equates to an improvement from “no activity”
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Results

Of the 12 patients who were implanted with a CS system and underwent threshold setting, elicited movement was observed in 4. For these patients, movement was observed in the contralateral hand, finger, and/or thumb regions. One additional patient reported a sensation in the contralateral forearm. In these 5 patients, therapeutic stimulation was set at 50% of the current amplitude that elicited movement or sensation. The remaining 7 patients received a predefined maximal output current for therapeutic stimulation.

Primary Outcome Measures

The UEFM and AMAT results are presented in Fig. 3 for the 2 study groups at the 4-week follow-up (the primary end point). Patients in the investigational treatment (rehabilitation with CS) group improved to a greater degree than control patients (rehabilitation only). Starting at a UEFM baseline score of 34.3 ± 9.0 points (range 22–50 points), patients in the treatment group improved by 8.5 ± 4.4 points (range 0–17 points). Control patients had a baseline UEFM score of 32.4 ± 10.3 points (range 19–49 points), which increased by 1.9 ± 4.4 points (3 to 11 points) (p = 0.03 comparing treatment groups).

Similarly, patients in the treatment group experienced an improvement in AMAT scores from a baseline of 2.4 ± 0.8 points (1.1–3.9 points) by 0.4 ± 0.6 points (−0.5 to 1.5 points), whereas control patients had an increase from a score of 1.8 ± 1.0 (0.1–3.6 points) at baseline by 0.2 ± 0.4 points (−0.3 to −1.0 points) (p = 0.2 comparing treatment groups).

Figure 4 presents the proportion of patients with clinically meaningful improvement in the UEFM. Of the patients in the treatment group, 67% had clinically meaningful improvement (that is, ≥3.5-point improvement) in the UEFM score, compared with 25% of control patients (p = 0.05).

Also of importance is whether the improvement in motor function as measured by the UEFM translates into improvements in ADLs as measured by the AMAT. Fifty percent of patients in the treatment group had clinically meaningful improvement in UEFM and AMAT scores (that is, ≥3.5-point improvement in the UEFM score and a 0.21-point improvement...<

![Fig. 2. Photograph of the investigational 2 × 3 electrode grid used for epidural stimulation of cortical site determined by fMR imaging.](image)

![Fig. 3. Bar graphs showing the changes in UEFM (left) and AMAT (right) scores from baseline to the 4-week follow-up primary end point as a function of treatment group. The gray areas indicate a clinically meaningful improvement (UEFM ≥ 3.5 points, AMAT ≥ 0.21 points) (p = 0.03 for UEFM, p = 0.2 for AMAT [t-test comparison between groups]).](image)
improvement in the AMAT score), compared with only 8% of control patients (p = 0.03, Fig. 4).

**Safety Outcomes**

Table 3 summarizes the proportions of the safety outcomes according to this categorization. There was only 1 anticipated event during the defined study safety assessment period (to completion of the 6-week rehabilitation program) that did not occur during delivery of CS. A secondarily generalized seizure occurred in 1 patient < 36 hours after implant surgery and prior to the delivery of CS. The patient was admitted to the hospital and was placed on a short course of anticonvulsant medication without further sequelae. This patient subsequently completed the 6-week rehabilitation protocol with CS without further seizure activity. Another patient experienced a seizure 5 months after device explantation and ~ 12 months after the index stroke. This event was considered a late stroke-related seizure, an event that often occurs ~ 12 months after a patient’s initial onset stroke. Thus this event was considered attributable to the patient’s underlying stroke condition and disease state and not to the investigational device or study procedures.

Other medical complications reported during the study were various anticipated surgery-related complications in patients in the treatment group, including the following: 2 reports each of swelling, pain at the incision/implant site, and headache, and 1 report of bleeding at the incision site. The following temporary anesthesia-related complications were reported in patients in the treatment group: 1 report each of unstable blood pressure, nausea/vomiting, fever, and urinary retention. One report of an allergic reaction to surgical tape occurred in a treatment patient and another treatment patient reported mild tingling/numbness in the jaw area. There were also 2 reports of transient mild tingling in 1 patient’s right hand.

All complications were minor in nature and resolved quickly without any additional treatment. Of note, no complications occurred after 2 days following the device explantation. All observed medical complications during this study were anticipated potential complications and risks normally associated with a surgical procedure or standard cortical electrical stimulation.

**Discussion**

**Safety Assessment**

Only 1 major complication occurred during the safety assessment period: a secondarily generalized seizure, which occurred within 36 hours of the implant surgery. When study personnel examined the patient within 2 hours of the seizure, they verified that the pulse generator was indeed turned off. A review of the surgical record revealed no evidence that the dura had been violated or that the underlying cortex had been damaged. Thus, the seizure is assumed to have been secondary to the surgical procedure and not related to CS. It was therefore deemed that this patient could complete participation in the study. The patient completed the 6-week rehabilitation protocol with CS and did not experience further seizure activity.

This study, in addition to our previous study and extensive experience of implanting similar devices for chronic motor cortex stimulation for pain control, has suggested that CS is safe for epidural use in chronic stroke patients. However, there is a known risk of provoking seizures in response to the surgical procedures or from superthreshold stimulation. No seizure activity provoked by subthreshold stimulation was observed in the present study or reported in the CS for pain literature. As a conservative measure, survivors of primary hemorrhagic stroke or infarction with hemorrhagic transformation (who are more susceptible to seizures) were specifically excluded.

In 1999 Bezard et al. published a study conducted in primates in which they assessed the risk of inducing epileptic seizures by using chronic motor cortex stimulation parameters similar to, but for a greater duration than, the parameters used in this clinical trial. None of the primates developed epileptic seizures while undergoing stimulation at ~ 40 Hz, 90-µsec pulse width, and at subthreshold current levels. Seizures could only be induced at intensities approximately twice the motor movement threshold. This primate study provides additional evidence that delivery of CS at 50% of motor movement is safe.

**Clinical Efficacy**

Clinical efficacy results from this prospective, random-
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ized controlled trial closely parallel the prior, smaller study. Although the control and investigational treatment groups appeared to benefit from the rehabilitation therapy, patients in the investigational group benefited more than those in the control group. The magnitude of improvement appears to be greater than that observed for CIT, a rehabilitation intervention associated with clinical benefit. In previous well-designed peer-reviewed motor recovery studies of patients suffering chronic stroke, gains in the UEFM scores reported for patients receiving CIT were less than half that observed in those receiving CS in the present study.30,31 The greater improvements in UEFM suggest that CS is more effective than CIT in enhancing recovery of upper-extremity function in patients suffering chronic stroke.

The mechanism of motor recovery following CS is not known. Authors of most prior motor cortex stimulation studies have treated central pain secondary to thalamic infarction or trigeminal nerve injury.5,9,11,13-15,18-21,23,27-29,32 For some of those patients who had both central pain and paresis secondary to stroke, their paresis seemed to improve after CS. The authors hypothesized that motor performance improved as a result of decreased spasticity. Katayama et al.14 described the case of a 53-year-old man with right hemiparesis, dysarthria, and bulbar pain 3 years after suffering a stroke. Despite inadequate analgesia from CS, this patient chose to have his stimulator internalized “because [he] was so pleased with the marked improvement in his motor weakness.” In a later review, these authors quantified the motor improvement observed with motor cortex stimulation: motor cortex stimulation improved hemiparesis in 19% of patients (with infarcts) who underwent epidural CS for pain control. The benefit was unrelated to the degree of pain control.14

Moreover, Garcia-Larrea et al.9,10 noted “improvement in motor function in patients submitted to this procedure.” They also found a “not quantified relief of spasticity during motor cortex stimulation” in “some” of their stroke patients. Franzini et al.7 observed diminished stroke-related dystonia and intentional myoclonus with motor cortex stimulation along with pain relief. Four patients experienced pain control associated with reduced intentional myoclonus. These findings are consistent with the clarification of Katayama et al.14 that there was a significant reduction in pain relief when there was moderate or severe weakness in the targeted painful region. Satisfactory pain control was achieved in 73% of patients in whom motor weakness in the painful region was absent or mild, but only in 15% of the patients who had moderate or severe weakness in the painful region. The analgesic effects of motor cortex stimulation thus appear to be mediated through the motor system.

Several preclinical studies have confirmed and expanded on these clinical observations. Adkins-Muir and Jones3 studied the effect of perilesional motor cortex stimulation on a skilled forelimb food-pellet reaching task in rats with an ischemic cortical injury produced by endothelin-1. Cortical stimulation of 50 Hz during rehabilitation significantly improved performance on the forelimb retrieval task. Dendritic density, as measured by microtubule-associated protein 2 immunoreactivity, in perilesional cortex layer V also increased. Kleim et al.15 showed in a rat model that motor cortex stimulation combined with rehabilitation expanded the contralateral forelimb cortical representation.

Teskey et al.26 also showed significantly greater retrieval success in rats receiving stimulation than those that received no stimulation. Stimulated rats were able to return to their preinfarct reaching and retrieval levels when undergoing stimulation at 50 or 100 Hz during training, but not if they received 250 Hz stimulation.

Plautz et al.22 used a squirrel monkey model of cortical ischemic infarction to investigate the benefits of motor cortex stimulation. After training the primates to perform pellet retrieval tasks, the authors mapped the proximal forelimb motor cortex (M1) region using ICMS. A surface-stimulating electrode was placed over the intact perinfarct motor cortex and representational ICMS cortical maps were again obtained. After waiting several months for stabilization of motor recovery, CS was combined with rehabilitative training. Pellet retrieval from small (more difficult) wells showed statistically significant gains with stimulation, regaining ~ 50% of the loss function. Furthermore, repeated ICMS cortical maps demonstrated a significant increase in hand representation adjacent to the infarct as well as at a considerable distance from the infarct. In other words, cortex that had previously been only weakly associated with distal hand muscles became more strongly correlated with those muscles as a function of pairing electrical stimulation with training. Most importantly, this work showed that successful poststroke recovery could be performed months after the stroke had occurred.

Thus the evidence suggests that enhanced neuroplasticity plays a role in the improvements in motor function associated with delivery of CS during rehabilitative therapy. Furthermore, the improvements in upper-extremity motor function seem to translate into clinically meaningful improvement in ADLs. In addition to the laboratory measure of ADLs as assessed by the AMAT (which included tasks such as eat a sandwich, drink from a mug, comb hair, put on shirt, and so on), patients in the investigational treatment group have reported improvement in activities such as housework (opening jars, cooking, and washing), recreational activities (crocheting, golfing, and gardening), work-related activities (typing, writing, and construction), and everyday activities (opening doors and picking up and holding small objects). Given that these patients were enrolled in this study an average of 33 months after their stroke and believed to have a fixed neurological deficit, such improvements were perceived as meaningfully impacting patients’ quality of life.

Conclusions

The primary goal of this study was to demonstrate the safety and efficacy of CS procedures. Most importantly there was no deterioration in neurological function related to the surgery to implant the CS device system or from CS combined with rehabilitation. This study demonstrates that CS can be safely performed in a population of patients with cerebrovascular disease who are at risk for surgical morbidity. Motor assessment data show that CS delivered during periods of active rehabilitation appears to enhance upper-extremity functional recovery when compared with control groups of patients who receive rehabilitation alone. Improvements in motor function seem to translate into improvement in ADLs and quality of life. While a more extensive study is warranted, the potential of this procedure in stroke therapy is promising.
Disclosure

Dr. Lowry owns stock in the study sponsor, Northstar Neuroscience. No other authors have a financial interest in the advancement of the stimulation device system or of the subject under discussion.

Acknowledgments

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References


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