

# CONTROLLED STUDY OF NEUROPROSTHETIC FUNCTIONAL ELECTRICAL STIMULATION IN SUB-ACUTE POST-STROKE REHABILITATION

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**Objective:** Assess the effects of daily neuroprosthetic (NESS Handmaster<sup>™</sup>) functional electrical stimulation in sub-acute stroke.

**Design:** Controlled study, patients clinically stratified to 2 groups; no active finger movement (10), and partial active finger movements (12), and then randomized to control and neuroprosthesis groups. Observer blinded evaluations at baseline and completion of the 6-week study.

**Subjects:** 22 patients with moderate to severe upper limb paresis 3–6 months post-onset.

**Methods:** Patients in day hospital rehabilitation, receiving physical and occupational therapy 3 times weekly. The neuroprosthesis group used the device at home.

**Results:** The neuroprosthesis group had significantly greater improvements in spasticity, active range of motion and scores on the functional hand tests (those with partial active motion). Of the few patients with pain and oedema, there was improvement only among those in the neuroprosthesis group. There were no adverse reactions.

**Conclusion:** Supplementing standard outpatient rehabilitation with daily home neuroprosthetic activation improves upper limb outcomes.

**Key words:** hemiplegia, rehabilitation, neuronal plasticity, electric stimulation therapy, orthotic devices.

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## INTRODUCTION

Improving the rehabilitation outcome of the upper limb in stroke patients has been an ongoing challenge to the rehabilitation specialty. More than 20 years ago, Bach-y-Rita (1) summarized the potential for new approaches in rehabilitation based upon laboratory studies of brain plasticity. Basmajian (2), in the 38th Annual John Stanley Coulter Lecture, American Congress of Rehabilitation Medicine, 1988, bemoaned the lack of progress in improving rehabilitation outcomes for stroke patients, and in particular the very limited recovery in the upper limb. He noted that inadequate demands upon the hemiplegic upper limb reinforced the problems of neglect, and caused what

he described as a “psychosocial amputation”. He also discussed the “time locks” limiting the rehabilitation involvement to the early recovery phase after the CVA, and thus further limiting the potential for further recovery.

Electrical stimulation of the upper limb has been receiving increasing attention as a therapeutic modality in post-stroke rehabilitation. A meta-analysis of controlled studies (upper and lower limbs) supported a conclusion that functional electrical stimulation (FES) promotes recovery of muscle strength after a cerebrovascular accident (CVA), with a reasonable likelihood of clinical significance (3). Recent controlled studies in the acute stroke rehabilitation population are further suggestive of beneficial effects for both FES and electromyographic (EMG) triggered electrical stimulation (4–8). These studies utilized intense daily treatment, instead of the prior routine standard of 20–30 minutes 2–3 times per week. Other studies in chronic post-CVA indicated a potential for significant improvement in spasticity and active range of motion in the upper limb (9–15).

The reliability of outcome studies of specific treatments during the early post-stroke rehabilitation is limited by the variables of spontaneous recovery, confounding medical complications, and high post-randomization drop out rates (4, 8). Such studies require large patient numbers. On the other hand, a patient deemed chronic and stable is usually no longer in an ongoing treatment setting.

Nakayma et al. (16) reported on neurological and functional recovery following a CVA as a factor of time. For patients with severe strokes, best recovery of the upper limb was reached within 6 weeks in 80%, and by 11 weeks in 95% of the patients. Thus, a study carried out during sub-acute rehabilitation, 3–6 months post-CVA, will not be as subject to the variability of spontaneous recovery or medical complications as studies during the acute setting, and still allow for an appropriate control group receiving standard treatment.

In general, the efforts to improve focal recovery in CVA are quantified by the various measures of impairment, and tests of the functional use of the limbs. Standard treatment in physical and occupational therapies in the acute and sub-acute rehabilitation setting may be best defined as being based on functional training, along with neuromuscular re-education where possible. The specific use of modalities such as electrical stimulation and biofeedback may or may not be used as routine treatment. In this study, both the control and neuroprosthesis patient groups were receiving ongoing sub-acute outpatient rehabilitation.

The neuroprosthesis treatment consisted of daily home use of a non-invasive neuroprosthetic neuromuscular stimulation system (NESS Handmaster<sup>®</sup>). The neuroprosthesis was utilized with the intention of applying both standard FES cyclical stimulation, as well as stimulation in patterns typical for normal functional use of the hand. The objective of the study was to determine whether the addition of self-treatment at home by means of a neuroprosthesis would result in enhanced recovery, as quantified by specific measures of impairment (modified Ashworth spasticity scale, and active range of motion), and functional hand tests (Box and Blocks and 3 Jebsen-Taylor subtests requiring grasp and release) for those with partial hand motion at the start of the study.

## METHODS

The study protocol was reviewed and approved by the Helsinki Committee of the Loewenstein Hospital Rehabilitation Center.

### Patients

Patients post-CVA admitted to the day hospital for continued rehabilitation management were considered for the study. Inclusion criteria included 3–6 months status-post documented single non-haemorrhagic CVA; moderate to severe hemiparesis – defined as less than full active range of motion in the involved upper limb; cognition adequate to follow multi-step commands; and agreement to sign the informed consent for participation in the study. Patients with pacemakers, uncontrolled seizure disorders, joint instability or structural impairment in the involved upper limb, severe neglect, severe aphasia, or unstable medical disorders were excluded from the study. Two sub-groups were defined: those with no active voluntary motion at the fingers and wrist (type I); and those with partial active voluntary range of motion (type II). Twenty-two patients were included in the study, 10 type I and 12 type II. They were stratified according to the neurological sub-group type and then assigned to the control and treated (neuroprosthesis) groups on an alternating basis. There was no significant difference between the groups in age (control: 57.3+/-10.3; treated: 54.1+/-11.2), or time post CVA (control: 3.7 months; treated: 3.6 months). There were 7 males in the control group and 9 in the treated group. Side of hemiparesis: control: right 6, left 5; treated: right 4, left 7. All patients completed the study.

### Neuroprosthesis

The device consists of a wrist-hand orthosis (WHO) with an incorporated portable, non-invasive microprocessor controlled stimulation system



Fig. 1. NESS Handmaster<sup>®</sup>.

(Fig. 1). The WHO is set up and fit to the limb of the patient with an array of 5 electrodes. The 5 muscle groups stimulated are the extensor digitorum communis, extensor pollicis brevis, flexor digitorum sublimis, flexor pollicis longus and thenar muscle group. The initial set-up included optimizing the response to stimulation for the muscle groups, and then utilizing a rigid orthosis and bone landmarks for positioning the system. Thereafter, when placed on the forearm and hand, the electrode positioning is accurately reproduced. The spiral WHO has a self-adjusting fit, holds the wrist and hand in a functional position of 15–25° of extension, and provides mild forearm compression as a means of assuring electrode contact. The control unit generates 6 different modes of phased patterned stimulation, 3 for therapeutic exercise patterns and muscle conditioning and 3 for functional activities (constant hand open, grasp and key grip). The stimulation patterns are a Russian waveform of 11 kHz, with stimulation frequencies of 18 or 36 pps depending on the stimulation mode selected. The pulse amplitude is adjustable and set by the therapist. The pulse duration varies from 0.01 to 0.5 msec, and may be adjusted by the patient in a step-wise manner. There is a variable duration duty cycle in the therapeutic exercise modes, adjustable by the therapist.

### Assessments and definition of tested variables

The same clinician, blinded as to the treatment group, performed all of the clinical evaluations. Baseline goniometric measurement was carried out for active forward flexion and abduction range at the shoulder, and for flexion and extension at the elbow and wrist. Active motion for extension and flexion of each finger was measured by recording the distance from the fingertips to the mid-palmar crease. Thumb opposition was graded on a 7-point scale (Table I). Muscle tone was assessed at the shoulder, elbow, wrist, fingers (as a group), and thumb using the Modified Ashworth scale (17). Functional use of the hand was tested in type II patients using the Blocks and Box test (18), and 3 of the Jebsen-Taylor hand tests; simulated eating, lifting large light objects, and lifting large heavy objects (19). These tests were chosen as they specifically measure functional grasp and release in standardized time trials, and the simulated eating providing a quantifiable activity of daily living. Additionally, the presence of upper limb pain or hand oedema was noted at baseline. Assessments were repeated after 6 weeks of treatment at the completion of the study. All patients continued in treatment up to the final evaluation. The timing of the final evaluation was unrelated to the preceding session of day rehabilitation treatment or to the use of the neuroprosthesis. Pain and oedema were graded as the same, better, or worse based on patient report and therapist evaluation.

### Procedures

All patients were in the day hospital outpatient rehabilitation program during the course of the study. The neuroprosthesis and control groups received the similar rehabilitation programs, not adjusted or modified by group assignment. Patients attended 3 days per week, and treatment included at least 3 hours of therapy services per day. Functional treatment to improve activities of daily living (ADL) and neuromuscular re-education using the Bobath techniques were part of the standard treatment regimes. All of the standard physical and occupational therapy treatment modalities were available during the treatment sessions to both the control and the neuroprosthesis groups. Additional treatments for communication, psychological intervention and cognitive deficits were provided as indicated. All patients were re-evaluated 6 weeks after the initial assessment.

The patients in the neuroprosthesis group were fitted with the

Table I. Grading of active thumb opposition

Score	Point of maximal opposition
1	Distal phalanx of index finger
2	Distal phalanx of middle finger
3	Distal phalanx of ring finger
4	Tip of small finger
5	Distal interphalanx of small finger
6	Proximal interphalanx of small finger
7	Medical phalanx of small finger



Fig. 2. Therapeutic stimulation mode.

Handmaster<sup>™</sup> upper limb system following completion of the initial assessment. The single fitting session included instruction of the patient and a family member or attendant in use of the system. The patients were provided with a protocol for home use. The protocol was developed in prior pilot studies, and stimulation parameters were individually adjusted as to pulse duration and amplitude based on muscle response to achieve a full arc of finger motion, and patient tolerance. System use started at 10 minutes twice a day, progressed up to 50 minutes 3 times a day over the first 2 weeks, and remained at this level of use until the end of the 6-week study. Patients used 2 therapeutic stimulation modes: intermittent finger extension (Fig. 2), and alternating finger flexion and extension. The type II patients used the functional modes for various assigned activities (Fig. 3). Patients were encouraged to attempt to actively carry out the movements during the stimulation.

#### Statistical analysis

An independent samples *t*-tests were performed in order to find any significant difference between the control and the treated groups (one-sided test for the hypothesis that the improvement in the treated group is significantly higher, and two-sided test for the baseline results). It should be noted that patients achieving the maximal values at the baseline evaluation were not included in the analysis (since they could not possibly improve). Pre-defining 95% confidence interval, all *p*-values of 0.05 or less would be considered statistically significant.

The data was analysed using the SAS software (SAS Institute, Cary, North Carolina, USA). In view of the small number of patients involved in the subsections, the accuracy of the performed analysis was evaluated by a power calculation by using PASS2002 software. Values greater than 0.75 were considered significant.

## RESULTS

#### Spasticity

Individual joints with normal or flaccid muscle tone (Ashworth: 0) were not included in the analysis, as no measurable spasticity



Fig. 3. Activity during functional stimulation mode.

improvement is possible. No significant differences were found between groups regarding the base line results. A significant difference for greater measured improvement was found in type I neuroprosthesis patients (lowest calculated power was 0.7769 for  $\alpha = 0.05$ ) for shoulder and finger spasticity ( $p = 0.05$  and 0.04), and in type II neuroprosthesis patients (lowest calculated power was 0.8471 for  $\alpha = 0.05$ ) for the shoulder ( $p = 0.03$ ), wrist ( $p = 0.04$ ), fingers ( $p = 0.01$ ), and thumb ( $p = 0.04$ ). At the other joints, there were greater improvements in the neuroprosthesis group for both the type I and type II patients, however not statistically significant. Of the sites with moderate to severe spasticity (grade 3 or 4), 2 of 22 (9%) improved to grade 2 or less in the control group, and 16 of 25 (64%) improved to grade 2 or less in the neuroprosthesis group.

#### Active motion

*Type I patients.* There was greater improvement in active motion in the proximal upper limb in the neuroprosthesis group, however the difference did not reach a level of statistical significance. Nevertheless, in the 6 instances of no voluntary motion for shoulder flexion, abduction, and elbow flexion in the control group, none of the patients showed any return of active motion. In the neuroprosthesis group, there were also 6 instances of no voluntary motion at baseline, with 4 of the patients developing partial active motion at these segments.

*Type II patients.* All patients in both groups had full active range of motion of the elbow (flexion/extension) at baseline. The control group had better wrist flexion at baseline that was

statistically significant. At outcome, the neuroprosthesis group showed greater levels of improvements (the lowest calculated power was 0.6769 for  $\alpha = 0.05$ ), statistically significant level for shoulder flexion (28° increase vs 1° loss,  $p = 0.03$ ), wrist extension (17° increase vs 2° loss,  $p = 0.02$ ) and wrist flexion (21° vs 5° increase,  $p = 0.04$ ).

#### Functional tests

At baseline, there were no statistically significant differences between the neuroprosthesis and control groups. The neuroprosthesis group had significantly greater improvement in each of the 4 functional hand tests (the lowest calculated power was 0.8516 for  $\alpha = 0.05$ ). All 6 of the treated patients improved on the Box and Blocks, while 3 of the control group improved and 3 had a decrease on the re-test. The median change of blocks moved in one minute increased by 7 in the treated group, and decreased by 1 in the control group. Highly significant improvement was present for the treated group compared with control for the Jebsen-Taylor tests that measure the speed in completing defined tasks (Fig. 4).

#### Pain and hand oedema

Three patients in the neuroprosthesis group initially complained of pain (2 hand, 1 shoulder). All noted improvement at the end of the study. 5 patients in the control group initially complained of pain (3 hand, 2 shoulder). One patient (hand pain) improved, the others were unchanged. Three patients in the treated group and 1 in the control group had hand oedema. All neuroprosthesis patients improved, with no change in the hand of the control patient.

#### Adverse effects and compliance

There were no adverse effects from treatment in either group. Self-report by patients indicated a high level of compliance with the neuroprosthetic treatment protocol. All patients completed the study, with no treatment dropouts.

## DISCUSSION

This study evaluated the potential of adding a neuroprosthesis

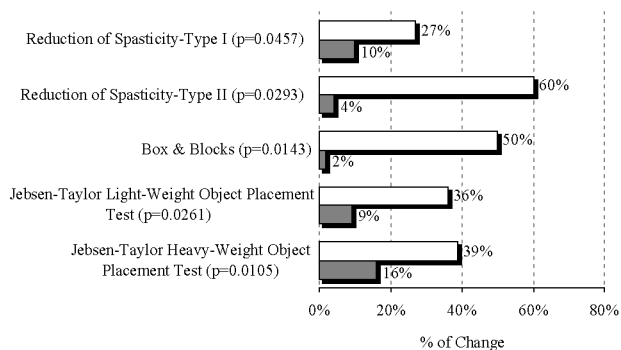


Fig. 4. Percentage change in spasticity (Modified Ashworth Scale) and scores in functional hand tests. Neuroprosthesis (□), control (■).

for both FES and training in function. The patients studied were in the sub-acute rehabilitation phase of treatment, after the majority of the effects of spontaneous recovery and medical complications. The neuroprosthesis treatment modality (Handmaster<sup>®</sup>) was used daily at home in addition to the continued outpatient rehabilitation. Patients with minimal active motion (type I) prior to the treatment program demonstrated significantly greater improvements in spasticity reduction, and tended towards greater active range of motion of the proximal limb. In those patients with partial active motion at the start of treatment (type II), significant gains were noted in tests of hand function, as well as significant improvement in spasticity reduction and increased voluntary motion. In addition, in the few patients with pain or oedema in the involved limb, all of those treated with the neuroprosthesis improved, while only 1 of 6 (5 pain and 1 oedema) improved in the control group. There were no adverse effects related to the neuroprosthesis treatment.

The actual factors leading to the improvements in the neuroprosthesis group have yet to be determined. Among the possibilities include plasticity of the central nervous system, lessening of spasticity, increased sensory input, and local factors relating to muscle strengthening, visco-elasticity, blood flow, etc.

Continued post-CVA rehabilitation treatment after the initial inpatient care is often directed at improving the residual physical impairments, and plan for long-term management of the persistent deficits. Any approach that would be additive to the standard treatment, and particularly if it is a self-treatment program should be of interest to the rehabilitation community.

Reduction of spasticity from the use of functional electrical stimulation has been reported in a multitude of studies (9, 10, 15, 20–24). Reciprocal inhibition, recurrent inhibition, and large sensory fibre activation have all been suggested as possible mechanisms for the spasticity reduction. Known neurophysiological pathways and empirical findings have been put forward to substantiate each of the mechanisms. From the clinical perspective, spasticity reduction is a primary target of treatment for the spastic patient with minimal active motion, and may well be a basis to augment the potential for additional improvements in other parameters. In those with partially preserved motion throughout, improvement in active motion and upper limb function are to be expected.

Studies on FES for the shoulder, especially with intensive use, have demonstrated improved outcomes of both the shoulder and the limb (5, 7, 14, 25). Similarly, studies on the use of functional electrical stimulation for the more distal segments of the upper limb in stroke have nearly unanimously shown outcomes of improved active motion and strength compared with control treatment (4, 8, 9, 12, 15).

In a crossover study comparing electrical stimulation to repetitive active hand movement, other than a better spasticity reduction from the stimulation, greater improvements were present in the active motion phase of treatment. However, the protocol called for the patients to actively inhibit any effort for voluntary movement during the stimulation, with surface EMG

monitoring to assure the lack of effort (26). This study would appear to demonstrate the importance of associating the effects of the stimulation with the cognitive process of attempting to perform, rather than inhibit a movement.

The potential for improvements in upper limb functional tasks in patients with chronic severe hemiparesis by use of a neuroprosthesis treatment system has been demonstrated (27).

The study did not assess the persistence of the beneficial effects of the neuroprosthesis treatment program. Pandyan et al. did show that in severely affected patients, similar to the type I of this study, beneficial effects of an electrical stimulation program were largely lost 2 weeks after the stimulation was discontinued (28). Additionally, as this treatment is performed by the patient at home, the self treatment may well be continued as needed to maintain the benefits.

The patients receiving the motor, proprioceptive, and cognitive input through the daily use of the neuroprosthesis demonstrated significantly greater improvements in voluntary movement and functional use of the hand. These outcomes suggest that a nihilistic attitude towards treatment of persistent stroke deficits is no longer tenable, and treatment should continue after standard rehabilitation management. The intensive daily at home use of this neuroprosthesis in patients receiving sub-acute stroke rehabilitation has proved to be safe, and resulted in significantly improved outcomes with no adverse effects. Future studies utilizing a neuroprosthesis in stroke patients are indicated for other body segments.

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