# Novel Neuromuscular Electrical Stimulation System for the Upper Limbs in Chronic Stroke Patients: A Feasibility Study

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# ABSTRACT

**Objective:** The aim of this study was to assess the feasibility of applying a novel neuromuscular electrical stimulation system, targeting shoulder flexion, elbow extension, wrist extension and individual finger extensions, to improve motor control and function of the hemiparetic upper limbs in chronic stroke patients.

**Design:** Fifteen participants with chronic (>1 yr after cerebrovascular accident) upper limb hemiparesis were enrolled. The subjects underwent upper limb training for 60 mins per day, 6 days per week, for 2 wks, using both a shoulder-and-elbow stimulation device and a wrist-and-finger stimulation device developed by the study investigators. Outcomes were assessed using the upper extremity component of the Fugl-Meyer assessment, the action research arm test, and modified Ashworth scale before and after intervention.

**Results:** All patients completed the training successfully using the neuromuscular electrical stimulation system without any safety incidents or other complications reported. Nonparametric statistical analyses indicated significant improvements in the upper extremity component of the Fugl-Meyer assessment and action research arm test scores, both at P<0.01. There were also significant reductions in modified Ashworth scale scores for the elbow and wrist flexor, both at P<0.01.

**Conclusions:** The multimuscle stimulation approach and method presented in this study seem feasible, and the improvements of upper limb motor control and functional test in chronic stroke patients justify further controlled investigation.

Key Words: Stroke, Neuromuscular Electrical Stimulation, Motor Control, Hand Function

## **INTRODUCTION**

Stroke is the leading cause of long-term disability worldwide, and restoration of movements and associated functions is a common concerns of stroke patients.<sup>1</sup> However, the restoration of the upper limb movements and functions is often poor, generally being seen in less than half of patients.<sup>2,3</sup>

Several rehabilitation techniques have emerged in recent years that have demonstrated possible improvement of upper limb movements and functions for stroke patients.<sup>1</sup> Some techniques, such as constraint-induced movement therapy and robot-assisted movement therapy, emphasize active, repetitive, task-specific movements of the paretic upper limb.<sup>4-6</sup> These strategies increase functional use of the paretic arm in real-world situations and improve selected impairment (e.g., hand use accuracy, muscle strength, active range of motion, and severity of hemiparesis).<sup>4-6</sup>

Neuromuscular electrical stimulation (NMES) has recently received considerable attention as a therapeutic intervention option for stroke rehabilitation.<sup>7</sup> Several studies have suggested therapeutic effects of NMES, with induced repetitive movement exercises conducted with the goal of facilitating motor relearning for motor recovery of the paretic upper limb and reduction of spasticity.<sup>8-11</sup>

In particular, the benefits of NMES were enhanced when stimulation was associated with volitional efforts made by stroke patients.<sup>12</sup> The classic approach of NMES consists of simple repetitive movements with NMES targeted to specific upper limb muscles that primarily affect upper limb impairment.<sup>8,9</sup> More recent investigations of stroke rehabilitation of the upper limbs have focused on improving upper limb functions such as grasping, moving, placing, and releasing objects.<sup>10</sup> To address this concern, NMES investigators have developed a treatment methodology for adding volitional, task-specific functional training.<sup>10,11</sup> Furthermore, because object manipulation

skills needed for daily life activities require shoulder flexion and elbow extension when reaching forward, a few NMES trials have reported an expanded application for the shoulder flexor or the elbow extensor.<sup>13, 14</sup>

To address the shortcomings of the classic NMES approach and increase the potential for better outcome measures, this pilot study investigated a novel NMES system, targeting a couple of muscles controlling the shoulder and the elbow and individual muscles controlling the wrist or finger extensions of the paretic upper limb in chronic stroke patients. This novel NMES system was used to apply a high-voltage pulsed current on the target muscles through surface electrodes via a subject-triggered sequence. The primary study aim was to assess the feasibility of applying this NMES system and method for improving motor control and functions of the hemiparetic upper limbs in stroke patients.

# METHODS

# Subjects

Fifteen post-stroke patients with upper limb hemiparesis (mean [SD] age, 54.5 [12.9] yrs; range, 30–76 yrs; 12 men and 3 women) were recruited from inpatients admitted to the Kirishima Rehabilitation Center of Kagoshima University Hospital, Japan, between July 30, 2010, and August 3, 2012 (Table 1). Stroke diagnosis was based on computed tomography or magnetic resonance imaging as well as neurologic findings. The present study was conducted without altering the existing medication regimens of the patients.

The inclusion criteria were as follows: aged 20–85 yrs; hemiplegia/hemiparesis affecting one upper limb (Brunnstrom stage<sup>15</sup> 1–5); greater than 1 degree of voluntary range of motion of the

second metacarpophalangeal joint; and receiving no stimulants, relaxant medications (including antispasticity and anticonvulsion medications and pharmacologic injections) or previous treatments with functional electrical stimulation or NMES.

The exclusion criteria were as follows: onset of stroke of less than 1 yr, abnormal upper limb movements before the onset of stroke, any medical condition preventing electrical stimulation (such as severe cardiopulmonary disease or severe sensory disturbance [light touch test and position test for the upper limb of the Stroke Impairment Assessment Set<sup>16</sup> = 0]), excessive spasticity at the elbow or wrist flexor (>3 on the modified Ashworth scale<sup>17</sup> [MAS]), severe aphasia making it impossible to follow verbal instructions, bilateral hemisphere lesions, and dementia that would interfere with the outcome assessments.

All procedures were conducted in compliance with the 1975 Declaration of Helsinki, as revised in 1983. Informed consent was obtained from each subject according to the ethical guidelines of the hospital, once they fully understood the study purpose and methodology. This study was approved by the ethics committee of Kagoshima University.

#### **Experimental Procedure**

This study used a before-and-after design. After undergoing a baseline assessment, subjects received a 1-hr NMES intervention daily, 6 days per week, for 2 consecutive weeks (a total of 12 sessions). One day after the last NMES intervention, the subjects underwent a reassessment.

# **NMES System**

The NMES system consisted of a shoulder-and-elbow stimulation device and a

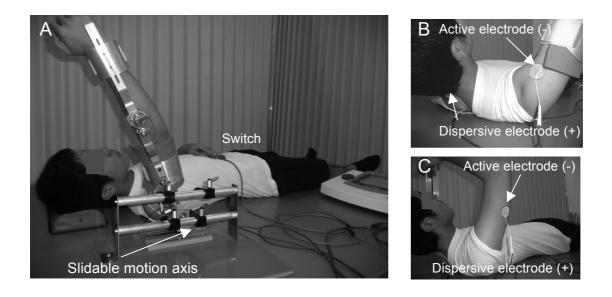
wrist-and-finger stimulation device, which were developed by the study investigators.

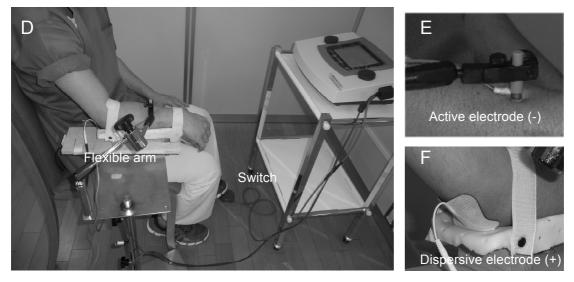
For the shoulder-and-elbow stimulation device, the subject's upper arm and forearm were fitted to the exoskeleton adjusted for arm length (Fig. 1A). This device contains two mechanical joints with control of range of motion to safely achieve isolated exerciseof the shoulder or elbow flexion and extension. For the shoulder flexion exercises, one active (negative polarity) electrode (diameter, 3.2 cm; area, approximately 8 cm<sup>2</sup>; circular) was placed over the anterior fibers of the deltoid muscle, whereas a return electrode ( $10 \times 5$  cm; square) was placed over the seventh cervical spinous process (Fig. 1B). For the elbow extension exercises using the shoulder-and-elbow stimulation device, one active (negative polarity) electrode (diameter, 3.2 cm; area, approximately 8 cm<sup>2</sup>; circular) was placed over the triceps brachii muscle, and the return electrode ( $5 \times 5$  cm; square) was placed over the olecranon (Fig. 1C).

For the wrist-and-finger stimulation device, the pronated forearm was fixed to the height-adjustable arm support to achieve an angle of approximately 45 degrees for elbow flexion (Fig. 1D). An active (negative polarity) electrode, consisting of a water-soaked sponge (diameter, 0.8 cm; area, approximately  $0.5 \text{ cm}^2$ ; circular), was placed over the motor point of the target muscles (Fig. 1E), and the return electrode (5 × 5 cm; square) was placed over the olecranon (Fig. 1F). The flexible arm (FGPMA100; MISUMI Inc, Tokyo, Japan) with an electrode was used to deliver repeatable stimulation to the selected site on the forearm dorsal surface with a constant force (equal pressure; Figs. 1D, E).

Electrical stimulation was delivered using a high-voltage pulsed current device (Universal Stimulation Current Unit ES-530; ITO Co., Ltd, Tokyo, Japan). The waveform produced by the stimulator was a twin-peak monophasic pulsed current. A triggering foot switch device (SFQ-1R;

KOKUSAI Dengyo Co., Ltd, Tokyo, Japan) was used. With the switch pressed, the current was delivered to the target muscles. The pulse duration and the frequency were fixed at 50 µsec and 50 Hz, respectively. The intensity was adjusted to produce 50% of the full range of each motion (shoulder flexion, elbow extension, wrist extension, thumb extension, index finger extension, and middle finger extension) from the starting position to the maximum passive range of motion without pain.





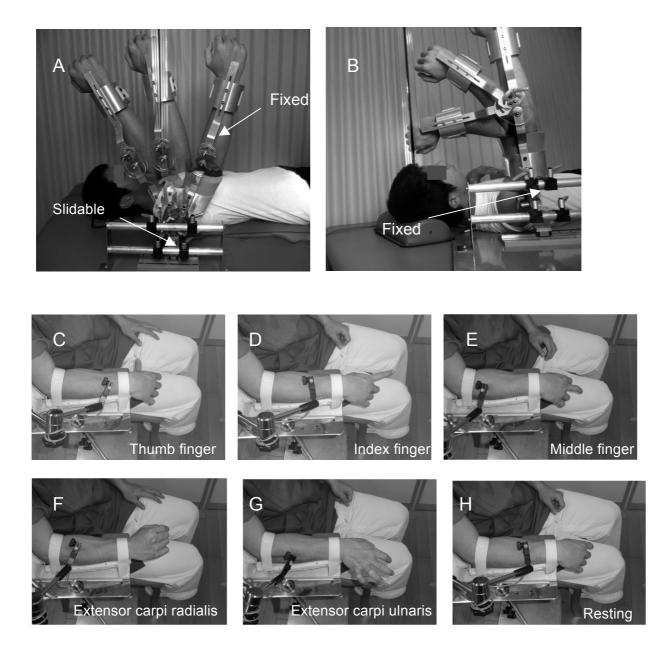
# FIGURE 1 NMES system

A, Shoulder-and-elbow stimulation device. B, Electrode configuration for the shoulder exercise. C, Electrode configuration for the elbow exercise. D, Wrist-and-finger stimulation device. E, Active

electrode for the wrist-and-finger exercise. F, Return electrode for wrist-and-finger exercise.

## **NMES Intervention**

The subjects attempted to flex or extend their shoulder, elbow, wrist, and individual finger joints repeatedly in synchronization with the electrical stimulation, while pressing the triggering switch themselves. For the shoulder and elbow exercises, the subjects used the shoulder-and-elbow stimulation device in the supine position, with a cycle time (flexion/extension or extension/flexion) of nearly 5 secs under the supervision of a trained occupational therapist. The motion axis of the shoulder mechanical joint slides according to a humeroscapular rhythm in the sagittal plane during exercises involving shoulder flexion and extension with fixed elbow extension position (Fig. 2A). In addition, the shoulder mechanical joint could be fixed at approximately 90 degrees of flexion during elbow flexion and extension exercises (Fig. 2B). For the wrist-and-finger exercises, the subjects used the wrist-and-finger stimulation device while sitting, with a cycle time (extension/flexion) of nearly 3 secs under the supervision of the same occupational therapist. Each exercise session consisted of six 10-min sets (shoulder flexion [Fig. 2A], elbow extension [Fig. 2B], thumb extension [Fig. 2C], index finger extension [Fig. 2D], middle finger extension [Fig. 2E], and wrist extension [Figs. 2F or 2G]) separated by 5 mins of rest to prevent fatigue. For the wrist exercises, the weaker of the two wrist extensors (extensor carpi radialis or extensor carpi ulnaris) was selected by the occupational therapist (Figs. 2F or 2G). Figure 2H shows a resting position.



# FIGURE 2 NMES intervention

*A*, Shoulder flexion exercise. *B*, Elbow extension exercise. *C*, Resting. *D*–*H*, The evoked extension movements of each finger and two extensor carpi muscles are shown.

# **Outcome Measurements**

# Measurement of Motor Control and Function

The primary outcome measure for this study was the upper extremity component of the Fugl-Meyer assessment (UE-FMA),<sup>18</sup> which assessed the loss and recovery of volitional motor

control. Specific items were based on the Brunnstrom stage of post-stroke motor recovery, and the maximum score of 66 points indicated full recovery. The reliability and validity<sup>19</sup> of the UE-FMA have been established, with a score change ranging from 4.25 to 7.25 points suggested as clinically important differences in chronic stroke patients.<sup>20</sup> The UE-FMA scores were divided into two subportions on the basis of the limb segments tested, a wrist-hand score (0–24), and a shoulder-elbow score including coordination (0-42).<sup>21</sup>

The action research arm test (ARAT) was designed to evaluate upper limb function at a particular activity level. The ARAT consists of 19 items divided into four subscales: grasp, grip, pinch, and gross movement, with a maximum score of 57 points. The reliability, validity, and responsiveness<sup>22</sup> of the ARAT have been established, with a score change of 5.7 points suggested as clinically important differences in chronic stroke patients.<sup>23</sup> The evaluator of two assessments was a trained occupational therapist who had no other involvement in the study.

## Measurement of Muscle Tone

The extent of spasticity was assessed using the MAS for the biceps brachii and wrist flexor muscles. The MAS is an established and reliable instrument, which uses a 6-point scale to assess the mean resistance to passive movement for each joint. To facilitate data analysis, the MAS scores (0, 1, 1+, 2, 3, and 4) were assigned numerical values designated as 'computed MAS scores' (0, 1, 2, 3, 4, and 5, respectively).<sup>24</sup> The MAS evaluator was a trained physiotherapist who was blinded to the subject's level of impairment.

## **Statistical Analysis**

Nonparametric statistics were used for all analyses because not all data met the criterion of normality criteria. The UE-FMA, ARAT, and MAS scores were analyzed using Wilcoxon signed-rank tests of baseline values compared with those obtained at the completion of treatment. All statistical analyses were performed using IBM Statistical Package for the Social Sciences Statistics 18.0 (Statistical Package for the Social Sciences Inc., Chicago, IL). Probability (*P*) values of the other statistical tests less than 0.05 were considered statistically significant.

## RESULTS

The demographic and clinical data of the study participants are presented in Table 1. Of the 15 post-stroke patients, 9 had been diagnosed with cerebral hemorrhage: and 6, with cerebral infarction. Ten patients had right hemiplegia, and five had left hemiplegia. The mean (SD) time since stroke onset was 27.9 (11.6) mos (range, 12–47 mos). As a group, they recovered 75% of their UE motor control (49.2/66 UE-FMA) and approximately 50% of their UE function (27.7/57 ARAT) before study onset. This may indicate low to moderate severity of paresis. The intervention and all assessments were completed safely in all subjects. None of the subjects reported discomfort before, during, or after the intervention. Table 2 shows the preintervention and postintervention changes in the UE-FMA; ARAT; and, at the elbow and wrist flexors, MAS scores.

Age, mean (SD), range, yrs	54.5, (12.9), 30-76
Sex (male/female), <i>n</i>	12/3
Diagnosis (hemorrhage/infarction)	9/6
Side with hemiplegia (right/left), n	10/5
Time since onset of hemiplegia, mean (SD), range,	27.9 (11.6), 12-47
mos	
UE-FMA score, mean (SD), range	49.2 (8.9), 31-62
ARAT score, mean (SD), range	27.7 (18.2), 3-56
MAS score at elbow flexor, mean (SD), range	1.9 (0.7), 1-2
MAS score at wrist flexor, mean (SD), range	2.0 (1.2), 0-2

## **TABLE 1** Demographic and clinical data of study participants

# **TABLE 2** Outcome measures before and after intervention

	Preintervention	Postintervention	Р
UE-FMA score	49.2 (8.9)	54.9 (7.1)	< 0.01
Shoulder-elbow subportion of UE-FMA	32.6 (4.7)	35.1 (3.4)	< 0.01
score			
Wrist-hand subportion of UE-FMA score	16.6 (5.3)	19.8 (4.6)	< 0.01
ARAT score	27.7 (18.2)	32.4 (18.6)	< 0.01
MAS score at elbow flexor	1.9 (0.7)	1.3 (0.6)	0.018
MAS score at wrist flexor	2.0 (1.2)	1.4 (0.9)	0.029

Data are presented as mean (standard deviations). Significant differences between preintervention and postintervention values are shown.

# **Motor Function**

A significant improvement was observed in the UE-FMA scores (preintervention, 49.2 [8.9]; postintervention, 54.9 [7.1]; P<0.01). The wrist-hand UE-FMA subscores showed greater improvement, as a percentage, than the shoulder-elbow UE-FMA sub-scores with an average increase of 3.2 points (+24.3%, P<0.01) vs. 2.5 points (+7.5%, P<0.01). A significant improvement

was also observed in the ARAT scores (preintervention, 27.7 [18.2]; postintervention, 32.4 [18.6]; P < 0.01).

# **Muscle Tone**

A significant reduction was observed in the elbow and wrist flexor MAS scores (preintervention, 1.9 [0.7]; postintervention, 1.3 [0.6]; P<0.01, and preintervention, 2.0 [1.2]; postintervention, 1.4 [0.9]; P<0.01, respectively).

## DISCUSSION

The present study examined the efficacy of NMES, targeting selected muscles of the paretic upper limb in chronic stroke patients with mild-to-moderate paresis. The 2-wk intervention using the novel NMES system and method demonstrated significant improvement in FMA and ARAT scores and less spasticity. Only the patients whose strokes had occurred at least 1 yr earlier were enrolled, assuming that their upper limb recovery had plateaued. Although the magnitudes of improvement in motor control and function observed in this study did not reach the minimum clinically important differences for chronic stroke patients,<sup>20,23</sup> the 2-wk treatment duration of this study was shorter than those of previous relevant studies, and the obvious motor functional improvement, despite the lack of task-specific functional training, justifies further preliminary studies.

Several previous studies have shown the efficacy of various types of electrical stimulation for motor recovery of affected upper limbs, including cyclic NMES, electromyography (EMG)-triggered NMES, and functional electrical stimulation.<sup>8-11</sup> Although the effect of classic

NMES methods (consisting of simple repetitive movements with NMES to specific upper limb muscles) on activity limitations remains unclear, the functional electrical stimulation system of neuroprostheses with the addition of task-specific functional training is effective in improving motor function.<sup>10,11</sup>

EMG-triggered NMES allows for synchronization of electrical stimulation under the patient's control because the target muscles are stimulated when volitionally generated EMG signals are detected.<sup>12</sup> EMG triggering of NMES is technologically different from foot-switch triggering NMES, although both methods use motor intention to initiate training. However, in EMG triggering, volitional contractions typically stop when the NMES is triggered. In this study, the patients continued with volitional activation concurrent with the NMES. This may explain this study's reported improvement in functional outcome (ARAT scores), whereas Cauraugh et al.<sup>9</sup> reported that improvement was limited to motor control (impairment) outcomes. A previous study showed that loss of upper limb function in stroke patients was related to loss of movement control at all segments (shoulder, elbow, wrist, and individual fingers), not only distally.<sup>25</sup> Previous studies on NMES focused on the distal arm (wrist and finger extensions) <sup>8-11</sup> or the proximal arm (deltoid and supraspinous muscle)<sup>14,26</sup> but not both. In this study, the application of NMES to six muscles that are indispensable for forward reaching and object manipulation might also have resulted in significant improvement of motor function.

This study showed significant improvement in UE-FMA scores with only 2 wks of training. In addition, the proximal and distal portions of the UE-FMA scores were examined separately to allow analysis of each trained limb segment. This novel NMES system achieved significant improvements in both the proximal and distal subportions of the UE-FMA scores.

However, the percentage of change in the distal subportions of the UE-FMA scores indicated greater improvement as compared with that in the proximal subportions of the UE-FMA scores. Several factors may account for the relatively small changes in proximal subportions of the UE-FMA scores in the present study. The lower proportion of the exercise session dedicated to these muscles (20 mins for shoulder and elbow exercises and 40 mins for wrist and finger exercises) possibly limited the magnitude of improvement. In addition, for the shoulder and elbow exercises, the subjects used the shoulder-and-elbow stimulation device in the supine position to achieve isolated shoulder or elbow movement and avoid enhancing synergistic movement patterns that constrain multijoint movement, while the wrist and finger exercises were practiced while sitting. In general, the forward reaching and object manipulation exercises were practiced in the sitting or standing positions used in daily living. Actually, most assessments of motor impairment and function are tested in the sitting position. Therefore, the small significant improvements in the proximal subportions of the UE-FMA scores under limited supine position exercises are not surprising. To verify and extend these findings, future investigations of this study's treatment method should focus on the proximal segment adding to the duration and intensity and, possibly, practice in different body positions.

There are several possible reasons for this novel NMES system producing clinical benefits after very short intervention. Neurophysiologic studies have suggested that repetition of identical voluntary movements is important for motor recovery.<sup>27,28</sup> Therefore, the high rate (>100 repetitions for 10 mins) of voluntary repetitions with this NMES system may enhance motor recovery. Furthermore, a previous NMES study showed that NMES activated the motor and the sensory cortex in healthy subjects.<sup>29</sup> Likewise, EMG-triggered NMES was shown to produce cortical activation associated with improved motor function in chronic stroke patients, as

demonstrated by functional magnetic resonance imaging.<sup>30</sup> Another possible explanation is that the antispastic effect of NMES on antagonist muscles is considerable, although the small improvements in MAS scores observed in the present study indicate that this is unlikely. Finally, it is possible that the answer lies in individual finger exercise. The wrist-and-finger stimulation device selectively evoked extension movement of each finger (Figs. 2D–F). The authors propose that having a very small stimulating electrode (diameter, 0.8 cm; area, approximately 0.5 cm<sup>2</sup>) and low mean current output<sup>31,32</sup> minimizes excitation of the adjacent motor points of the wrist, and other fingers enabled muscle selectivity. In the NMES treatment paradigm, it is unclear whether greater muscle selectivity is more effective for improvement of motor function of hemiplegic upper limbs in stroke patients. However, an interesting previous study reported that loss of muscle selectivity in individual finger movements correlated with hand function.<sup>33</sup> The authors have recently reported that the individual finger exercise by manual therapy improved motor functions of hemiplegic upper limbs in stroke patients in the ARAT, a measure designed to assess dexterity.<sup>28,34</sup> The individual finger exercises performed during NMES treatment may also be beneficial for restoring upper limb function.

The present study has the following limitations: (1) The duration of treatment is most likely too short, and treatment lacks task-specific training. (2) The long-term effects of this intervention on motor impairment and function remain unknown. (3) Development of a proximal segment training protocol using the shoulder-and-elbow stimulation device in the supine position is needed. (4) From the perspective of a reduction in activity limitations, the training protocol used in this study may need to be modified to consist of combination therapy with task-specific functional training.

## CONCLUSIONS

This pilot study demonstrated that 2 wks of training using the novel NMES system, targeting six muscles of the upper limb, can improve volitional motor control and hand dexterity of the paretic upper limb in chronic stroke patients with mild-to-moderate paresis. The training protocol seems to provide greater improvement in the distal subportions of the UE-FMA scores than in the proximal subportions of the UE-FMA scores. The positive effects observed in this study suggest that further development of this novel NMES system is warranted.

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