ORIGINAL ARTICLE

Effects of Integrated Volitional Control Electrical Stimulation (IVES) on Upper Extremity Function in Chronic Stroke

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We evaluated the efficacy of a novel electromyogram (EMG)-controlled electrical stimulation system, called the integrated volitional control electrical stimulator (IVES), on the recovery of upper extremity motor functions in patients with chronic hemiparetic stroke. Ten participants in the chronic stage (more than 12 months post-stroke with partial paralysis of their wrist and fingers) received treatment with IVES to the extensor carpi radialis and extensor digitorum communis 6 h/day for 5 days. Before and after the intervention, participants were assessed using upper-extremity Fugl-Meyer motor assessment (FMA), the active range of motion (A-ROM), the nine-hole peg test (NHPT), and surface EMG recordings. The upper extremity FMA showed a statistically significant increase from 50.8 ± 5.8 to 56.8 ± 6.2 after the intervention ($P < 0.01$). The A-ROM of wrist extension was also significantly improved from 36.0° ± 15.4° to 45.0° ± 15.5° ($P < 0.01$). The NHPT significantly decreased from 85.3 ± 52.0 to 63.3 ± 29.7 ($P = 0.04$). EMG measurements demonstrated statistically significant improvements in the coactivation ratios for the wrist flexor and extensor muscles after the intervention. This study suggested that 5 days of IVES treatment yields a noticeable improvement in upper extremity motor functions in patients with chronic hemiparetic stroke. (Keio J Med 60 (3) : 90–95, September 2011)

***Keywords*: electric stimulation therapy, motor paralysis, neural plasticity, functional recovery, rehabilitation**

Introduction

Many patients with stroke suffer from impairments of the upper extremity motor functions, including limited functional use of the affected arm and limitation in their activities of daily living (ADL).[1]

One of the rehabilitation techniques employed to facilitate motor restoration in chronic stroke survivors is electromyogram (EMG)-triggered electrical stimulation.[2–5] This technique requires patients to voluntarily initiate arm/hand muscle activities above a target threshold before the onset of electrical stimulation. If the EMG activity reaches the threshold, the muscle activities are augmented by electrical stimulation that assists the muscles to execute a full range of motion.

However, there is a problem associated with this technique. Conventional systems cannot control the intensity of electrical stimulation to make it proportional to voluntary EMG signals because the EMG activities are not monitored once the preprogrammed electrical stimulation is delivered. Therefore, it is difficult to use the system in daily life outside of therapy sessions because the electrical stimulation disturbs voluntary movements.

Recently, our group has developed a novel EMG-controlled electrical stimulator called an integrated volitional control electrical stimulator (IVES).[6] With this type of

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Table 1 Characteristics of the participants before IVES treatment

Number of patients	10
Gender (male / female)	8 / 2
Mean age (years) *	74.6 (67–86)
Side affected by stroke (right / left)	6 / 4
Time since stroke (years) **	4.1 (1.0–19.6)
Mechanism of stroke (ischemia / hemorrhage)	6 / 4
Finger function of the stroke impairment assessment set (score 3 / score 4)	6 / 4
Functional independence measure **	112 (91–121)

* Mean (range).
** Median (range).

Table 2 The stroke impairment assessment set (SIAS)

Finger function test	
0:	No voluntary movement
1:	1a, Minimal voluntary movement; 1b, mass extension; 1c, minimal individual movement
2:	Minimal individual movement of each finger is possible, but flexion and extension are not complete
3:	Minimal individual movement of each finger is possible, with adequate flexion and extension of digits. However, the patient carries out tasks with severe or moderate clumsiness
4:	The patient carries out tasks with mild clumsiness
5:	The patient carries out tasks as smoothly as on the unaffected side

EMG-controlled stimulator, it is possible to use the system for many hours during daily activities, and so prolonged intensive therapy sessions can be avoided. If no muscle contraction is detected, the IVES stimulates the target muscles at the submotor-threshold level. However, if muscle contraction is detected, IVES stimulates the muscles at an intensity level proportional to the detected volitional EMG signals. With regard to IVES treatment for patients with chronic stroke, Hara et al.[7] indicated that daily IVES therapy at home resulted in enhanced motor recovery in patients with partial hand or shoulder motion. In addition, they reported the efficacy of combined IVES and motor point block for antagonist muscles in patients with chronic stroke.[8] Fujiwara et al.[9] showed that the facilitated use of the paretic upper extremity in daily living by combining IVES with a wrist-hand splint could improve both the paretic upper extremity and corticospinal modulation in chronic stroke. However, the efficacy of IVES treatment alone has never been tested in patients with hemiparetic stroke. The purpose of this study was to evaluate the efficacy of IVES treatment applied for 6 h/day for 5 days, including during daily activities, on upper extremity functions in patients with chronic hemiparetic stroke.

Methods

Participants

Ten patients in the chronic phase of stroke (more than 12 months post onset) who were admitted to our rehabilitation center for physical reconditioning participated in the experiments (**Table 1**). All patients had functional impairment of their upper extremities after stroke, with partial paralysis of the wrist and fingers and difficulty in voluntarily initiating and controlling extension movements of the fingers.

The following inclusion criteria were used for patient selection: (1) first stroke episode, (2) stroke impairment assessment set (SIAS)[10] scores ranging from 2 to 4 for finger paresis (**Table 2**), and (3) capable of voluntarily extending the wrist to 20° against gravity from a flexed position[11] as measured by goniometry. The exclusion criteria were: (1) unstable medical disorders, implanted electronic pacing or defibrillation devices, unstable vital signs, or potentially fatal cardiac arrhythmias (because the safety of electrical stimulation under these conditions is unknown); (2) active reflex sympathetic dystrophy or existing residual weakness due to lower motor neuron lesions of either upper extremity; (3) a mini mental status examination test[12] score of 21 or lower; (4) severe spatial neglect or aphasia; and (5) marked sensory deficit in the affected upper extremity. The study was approved by the institutional ethics committee, and all the patients gave their informed consent to participate in the study prior to the start of the experiments, in conformity with the Declaration of Helsinki.

IVES instrumentation

The IVES system (OG GIKEN, Okayama, Japan) is a portable electrical stimulator that is used to elicit wrist and finger extension during voluntary movements (**Fig. 1**). The IVES system continually changes its stimulation intensity in direct proportion to the amplitude of volitional EMG signals and applies an electrical stimulation

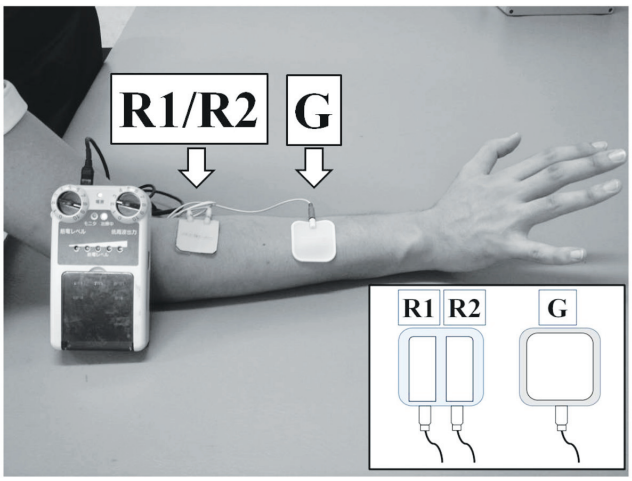

Fig. 1 The integrated volitional control electrical stimulation (IVES) system.
The IVES system is composed of three conductive gel surface electrodes: two recording electrodes (R1 and R2) and one ground electrode (G). The recording electrode is separated into two parts so that it can work as a pair of EMG detecting electrodes. The ground electrode (G) works as a ground in EMG detection. During the short interval between EMG detections, electric stimulation is delivered between the electrodes R and G.

of submotor-threshold intensity (i.e., no visible muscle contraction, but a tingling feeling) when there is no voluntary contraction. The novelty of the IVES system is that the three surface electrodes (R1, R2, and G in **Fig. 1**) together work in a time-sharing manner as an EMG detector and also as a stimulator. R1 and R2 are 5 mm apart and are packed into a single soft carbon sheet. When in EMG mode, R1 and R2 work as a pair of electrodes (both 30 mm × 12 mm) for recording an EMG, while G works as a ground electrode (30 mm × 30 mm). When stimulating the target muscles, R1 and R2 serve as a single electrode, R, and electric current pulses are delivered between R and G. In other words, the same surface electrodes detect the EMG signals at the target muscles and stimulate them at a stimulus intensity proportional to the integrated EMG signals (with the exception of an initial approximately 25-ms interval after the delivery of each stimulation pulse, when stimulation artifacts and M waves are observed). The device delivers three trains of biphasic square-wave pulses with a duration of 0.3ms (300-μs positive pulse, 0.3ms off, 300-μs negative pulse, and 0.3ms off, repeated three times) are applied at 20 Hz. The stimulus intensity is continuously changed in proportion to the detected voluntary EMG amplitude of the target muscle. Control buttons can be used to select detection sensitivities between 1,000 and 100,000 times and to adjust the electrical stimulation pulse width for the device. The muscle activities are monitored by means of a red light indicator on the device that indicates the surface EMG. The light indicator for hand opening is programmed to turn on and off in proportion to the detected voluntary EMG amplitude of the target muscle. The specifications of the equipment and the details of the system and the results of performance tests are presented elsewhere.[6]

Intervention

IVES therapy sessions were undertaken for 6 h/day for 5 days, including during therapy sessions and daily activities. The target muscles were the extensor carpi radialis (ECR) and extensor digitorum communis (EDC) on the hemiparetic side. Electrodes R were placed on the posterior region of the forearm (on the ECR) 2 cm above the elbow crease, while electrode G was placed on the posterior area of the forearm (on the EDC) approximately 3–4 cm proximal to the ulnar styloid, just radial to the ulnar shaft. The minimum and maximum stimulus intensities were determined for each patient individually. The minimum intensity (submotor-threshold intensity) was defined as the minimally applied stimulation level that was perceivable but with no visible muscle contraction when there was no voluntary contraction. The maximum intensity was defined as the maximal stimulation level that generated wrist and finger extension without any discomfort. Individual settings were stored in the stimulator device for portable use.

IVES treatment was applied regularly during the scheduled physical therapy and occupational therapy sessions; all other routine interdisciplinary stroke rehabilitation activities proceeded as usual. In addition, the patients were asked to voluntarily extend their wrist and fingers outside the therapy sessions, and they were encouraged to use the affected arm during daily activities.

Electrodes and lead wires were positioned under the clothes and the portable stimulator was carried in a small waist bag. As the IVES is portable and lightweight (300 g), patients could perform activities of daily living (ADL) using the hemiparetic hand and arm. All patients underwent a standard rehabilitation program consisting of 1 h each of daily physical and occupational therapy at our rehabilitation center.

Outcome measures

The upper extremity motor functions were assessed before and after the therapy sessions. The assessment was conducted using upper extremity Fugl-Meyer motor assessment (FMA), the active range of motion (A-ROM) test, the nine-hole peg test (NHPT), and EMG measurement. However, due to the diverse physical conditions of the patients, the NHPT could be carried out by only 8 of the 10 patients, and the EMG measurement could be performed in only 8 of the 10 patients. The FMA upper extremity section consists of four subsections: shoulder-

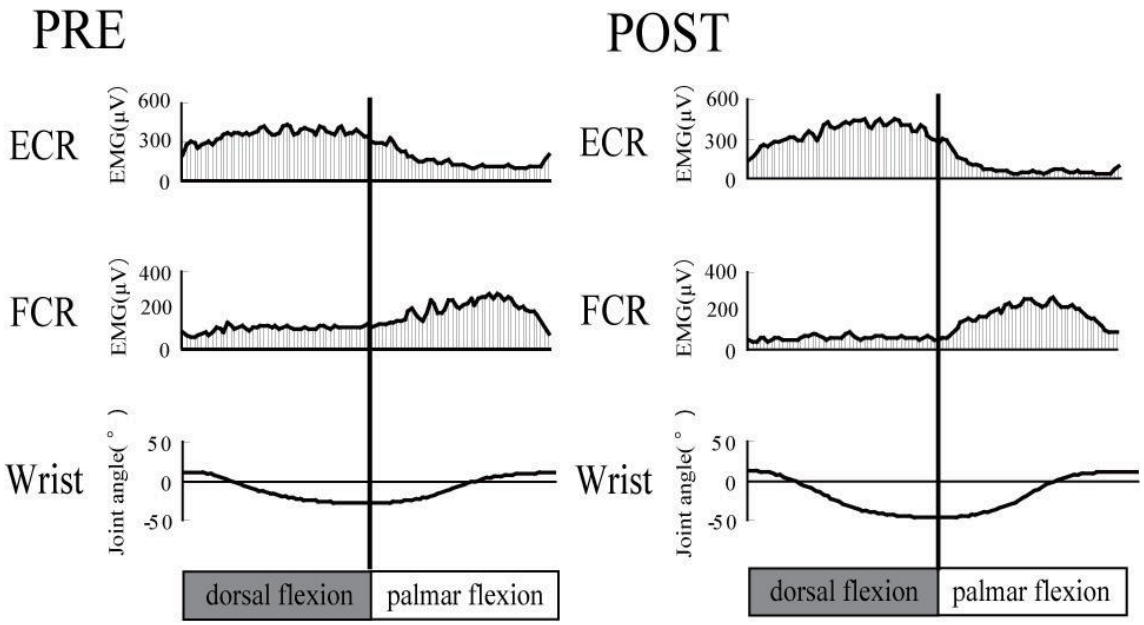

Fig. 2 Changes in the EMG activities of the ECR and FCR and the wrist joint angle in a typical patient.
Each EMG change was determined by taking the average of 10 EMG measurements recorded during dorsal flexion and palmar flexion. In the pre- and post-treatment recordings, a decrease of the EMG activities of the antagonist muscles during dorsal and palmar flexion was observed.

arm, wrist, hand, and coordination. Each subsection assesses voluntary movement, reflex activity, grasp, and coordination. Performance was measured for 33 tasks with a 3-point ordinal scale (0 to 2), with a maximum score of 66.[13] A-ROM was assessed by asking the patients to extend their wrists maximally while they were seated with their forearm restrained in a neutral position to reduce the effect of gravity. EMG was measured based on the EMG activities during wrist movement (palmar flexion or dorsal flexion). Patients were instructed to attempt palmar flexion or dorsal flexion of the wrist as quickly as possible and to the maximum range possible. After the skin was abraded with abrasive cream and cleaned with alcohol, the source impedance at the junction of the skin and the detection surface was checked on a computer. Patients were asked to relax their muscles before starting the evaluation. After every task, we observed the baseline EMG output level (in microvolts) displayed on the monitor screen. EMG activities were recorded with two pairs of recording electrodes (F32mm, Blue Sensor P-00-S, Medico Test, Denmark) placed over the muscle bellies of the flexor carpi radialis (FCR) and ECR muscles. A ground electrode was placed on the elbow. The placement of recording electrodes was marked and checked for EMG measurements to assure consistency in their placement before and after the evaluation. The EMG and the goniometer signals were stored in a computer after being processed by an amplifier with a 10-Hz to1-kHz filter and an A/D converter (sampling frequency: 10 kHz). The root mean square (RMS) of the EMG signal was calculated over the entire duration of the signal (duration of contraction and voltage time wave of the EMG signal) from the onset to the termination. As a measure of hypertonicity, the coactivation ratio, defined as the ratio of the RMS of the antagonist muscles to that of the antagonist plus agonist muscles,[14] was calculated by measuring the RMS from 10 EMG recordings during active palmar or dorsal flexion movements.

Statistical analyses

Wilcoxon signed rank tests were used to compare the pre-/post-intervention results of the FMA, A-ROM, NHPT, and the EMG measurement. A P value of 0.05 was chosen as the level of significance. We analyzed the data using SPSS 15.0 for Windows.

Results

The upper extremity score of the FMA showed a statistically significant increase from 50.8 ± 5.8 before the intervention to 56.8 ± 6.2 after the intervention ($P < 0.01$). The wrist part of the upper extremity subsection scores showed a statistically significant improvement from 6.5 ± 1.6 to 8.6 ± 1.9 ($P < 0.01$). The A-ROM of wrist extension was also significantly improved from 36.0° ± 15.4°

to 45.0° ± 15.5° ($P = 0.01$), and the NHPT significantly decreased from 85.3 ± 52.0 to 63.3 ± 29.7 ($P = 0.01$). The EMG measurements demonstrated statistically significant improvements in the coactivation ratios for the wrist flexor and extensor muscles after the intervention (from 0.506 ± 0.238 to 0.295 ± 0.117 for wrist flexors, $P < 0.01$ and from 0.999 ± 0.544 to 0.590 ± 0.183 for wrist extensors, $P < 0.01$). A typical example of the changes in the ECR and FCR signals during palmar and dorsal flexion movements are shown in **Figure 2**.

Discussion

The present study provides preliminary evidence suggesting that IVES alone serves as an effective means of improving upper limb motor function in chronic stroke survivors with hemiparesis. The improvement observed with IVES could be attributed to the following two factors.

First, the IVES system *per se* could have beneficial effects on the recovery of upper extremity functions. One of the effects is the recruitment of alternative motor pathways that assist impaired efferent pathways.[15] Another effect is a more ideal learning process provided by accurate feedback.[16,17] Because EMG is recorded steadily from the stimulating electrodes, sensory input from the movement of an affected limb directly influences subsequent motor output, and this proprioceptive sensory feedback may have an important role in the recovery of upper extremity functions. Furthermore, the improvement of abnormal coactivation of the wrist muscles suggests that the continuous sensory input by IVES may have an important effect on the improvement of voluntary movements, facilitation of reciprocal inhibition[18] and recurrent inhibition,[19] and intensive sensory fiber activation.[20] Fujiwara et al.[9] reported that treatment with IVES combined with a wrist-hand splint induced restoration of presynaptic and long loop inhibitory connections as well as disynaptic reciprocal inhibition. Previous studies[3,5,7,8] have demonstrated that electrical stimulation combined with volitional efforts or additional therapy is more effective than electrical stimulation alone in the recovery process. Bhatt et al.[21] showed that combined intervention may have a more beneficial influence on brain reorganization than either treatment alone. Increased motor cortical excitability facilitates greater voluntary activation of its neuronal networks,[22] which could lead to improved functions.[23] These studies support our contention that IVES treatment is associated with improvements in upper extremity motor functions.

Second, there exists a possibility of increased use of the affected arm facilitated by the IVES system. In the present study, while the patients were executing repetitions of voluntary movements, electrical stimulation was applied to the wrist and finger extensors of the affected arm, and sensory feedback was provided. The affected arm was stimulated electrically to promote not only voluntary movements but also movements related with ADL. Therefore, prolonged use of the IVES system offered an opportunity of increased use of the affected arm. These effects of IVES treatment might include the amelioration of deconditioning.

Other studies[24–26] have reported that prolonged and intensive use of the affected arm is highly important to enhance the recovery of upper extremity functions after stroke. Moreover, Charlton et al.[27] demonstrated that peripheral afferent stimulation with or without simultaneous brain stimulation can induce plastic changes in the organization of the motor cortex that persist for at least 2 h after the cessation of the stimulus. These observations support our contention that the prolonged and intensive use of IVES for 6 h/day on the affected arm has potential to lead to therapeutic reorganization of the damaged cortex. The present study showed positive effects of IVES on the FMA, A-ROM, and NHPT. These results indicate that the unique characteristics of IVES contribute to the recovery of upper-limb motor functions.

The IVES system can be employed with minimal supervision to provide a high-intensity therapy, i.e., 6 h/day or more, without necessitating one-to-one attention by therapists. In fact, once the clinician has set up the portable stimulator device, the patient can exercise on their own with the IVES system, and the individual settings need to be reset only with respect to the recovery of voluntary movements. These aspects, together with the proven therapeutic efficacy of IVES on the paretic upper limb,[7–9] suggest that the device can be effectively used in stroke rehabilitation programs.

However, our study has the limitation of using surface EMG to compare values over the long interval of 5 days. RMS values depend on the state of the electrode (site and electrode distance), cross-talk, and impedance. Although we applied several measures to secure reliable data, the reliability of surface EMG is limited. Furthermore, the present study was not a controlled trial and the number of participants was small. In the future, we propose to conduct a larger-scale study with masked assessors and an appropriate control group for further assessment of the efficacy of the IVES system. In conclusion, our study indicates that IVES provides substantial improvement in the upper extremity motor functions and performance in patients with chronic hemiparetic stroke.

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