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Case Study

# Short-term effects of pedaling exercise combined with integrated volitional control electrical stimulation in an older patient hospitalized for subacute stroke: ABA single-case design

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**Abstract.** [Purpose] The purpose of this study was to examine effects on gait indices produced by a short-term intervention of pedaling combined with integrated volitional control electric stimulation in an older patient with stroke. [Participant and Methods] This study was a single-case ABA (A-control, B-treatment) design. Each phase lasted four consecutive days (12 days total). Ten minutes of pedaling were performed daily. In Phase B, pedaling was combined with integrated volitional control electric stimulator on the rectus femoris of the affected side. The primary outcomes were the coefficient of variation, a measure of stride time homogeneity during gait; and the root mean square, a measure of trunk sway in the triaxial direction (mediolateral, vertical, anteroposterior) during gait. Assessments were measured before the intervention (day 0) and after the end of each phase (days 4, 8, and 12). [Results] Changes from the previous coefficient of variation were +1.13%, −3.95%, and +0.82% in Phases A, B, and A', respectively, with the greatest improvement occurring after Phase B. The root mean square improved the most with −5.13 for mediolateral after Phase B, −3.33 for vertical, and −6.99 for anteroposterior after Phase A. [Conclusion] A short-term intervention consisting of pedaling combined with integrated volitional control electric stimulation may contribute to the improvement of gait abnormalities.
**Key words:** Recumbent cycling, Electrical stimulation, Trunk acceleration

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## INTRODUCTION

It is estimated that more than half of older stroke patients suffer reduced mobility, a major cause of serious long-term disability[1)]. Mobility plays an important role in enabling the social participation of stroke patients[2)]. Therefore, it is important to provide physical therapy to improve the movement abilities of older stroke patients. Pedaling motion, like gait motion, produces coordinated contractions of the muscles and reciprocal, rhythmic movement patterns[3)]. Short-term, low intensity pedaling exercise is also associated with the intracortical inhibition of motor cortex regions innervating the lower extremities[4)]. Pedaling exercises combined with electrical stimulation (ES) have been shown to result in after-effects on the reciprocal inhibitory neurons in the spinal cord[5)]. Several reports have examined the effects of interventions combining ES and pedaling exercise on motor function and balance ability in patients with stroke[5–11)]. However, a meta-analysis of studies of interventions combining ES and pedaling exercise for stroke patients has reported limited effectiveness[11)].

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Recently, the Integrated Volitional Control Electric Stimulator (IVES) has been developed as a novel electromyogram (EMG)-controlled ES[12]. IVES has several modes, one of which is the power-assisted mode (PA mode), in which ES, proportional to voluntary muscle myoelectricity, is applied when voluntary muscle contraction is detected[13]. The combination of IVES and pedaling exercise can be expected to have different effects to when other ESs[5–11] are used together, because the targeted muscle activity patterns are enhanced according to the phase of the pedaling motion. Pedaling exercises combined with the PA mode of IVES for the affected side of the tibialis anterior have been reported to produce significant improvements in walking speed in subacute stroke patients after a short intervention[14]. However, while there have been reports on the combined effects of IVES and pedaling exercises on middle-aged stroke patients[14], there are no reports on older stroke patients. Furthermore, only the impact on the affected side of the tibialis anterior has been verified, and there have been no reports of the combined effect of IVES and pedaling exercises on the affected side of the thigh muscle. It has been reported that knee extensor strength on the paralyzed side is closely related to walking ability in stroke patients[15]. Combining pedaling exercises with IVES on the paralyzed thigh muscle may help improve walking stability in older stroke patients.

The purpose of this study was to examine the effects on gait indices produced by a short-term intervention of pedaling exercise combined with IVES on the paralyzed rectus femoris muscle in older patients hospitalized with subacute stroke in a single case design.

## PARTICIPANT AND METHODS

The patient was an 83-year-old male who was admitted to hospital after being diagnosed with cerebral infarction of the right corona radiata and diabetes mellitus. The day before admission, the patient had developed weakness in his left upper and lower extremities, and dysarthria. He was admitted the next day and conservative treatment was initiated. Medical history included a posterior laminectomy for cervical spondylosis (C4-6) six years previously, sepsis four years previously, and prostate cancer two years previously. Prior to admission, the patient had motor paralysis in the right upper extremity due to preexisting cervical spondylosis but was independent in basic activities. Rehabilitation was started two days after admission, and thereafter one hour of physical therapy per day was provided daily. Prior to the start of the intervention protocol, usual physical therapy was provided, including exercises for muscle strengthening, balance, basic movement, and activities of daily life.

The intervention protocol was applied after 49 days of hospitalization. Prior to the protocol, the motor paralysis score was 20 points on the Fugl–Meyer assessment of the lower extremities, walking ability score was 3 points on the Functional Ambulation Category, and balance ability score was 35 points on the Berg Balance Scale. The patient's cognitive function was good and no sensory deficits were noted. Comfortable walking speed at protocol introduction was 0.40 m/s, below the community walker cutoff of 0.49 m/s[16].

This study was conducted with the approval of the Ethics Committees at Numata Neurosurgery and Cardiovascular Hospital, Japan (#359). In accordance with the Declaration of Helsinki, the purpose of this study was explained to the patient, and his consent was obtained in writing. In addition, the CARE Case Report Guidelines was pursued when reporting the case[17].

The intervention protocol and evaluation are shown in Fig. 1. The intervention effects were tested in an "n of 1" prospective single-case ABA (A-control, B-treatment) experimental design with the period of each phase lasting four days (a total of 12 consecutive days). One hour of physical therapy was given daily, with the last 10 minutes of the hour altered between Phase A (control phase) and Phase B (treatment phase). During phase A, only pedaling exercise was performed, and during phase B, pedaling exercise combined with IVES was performed. The rest of the time was spent in usual physical therapy,

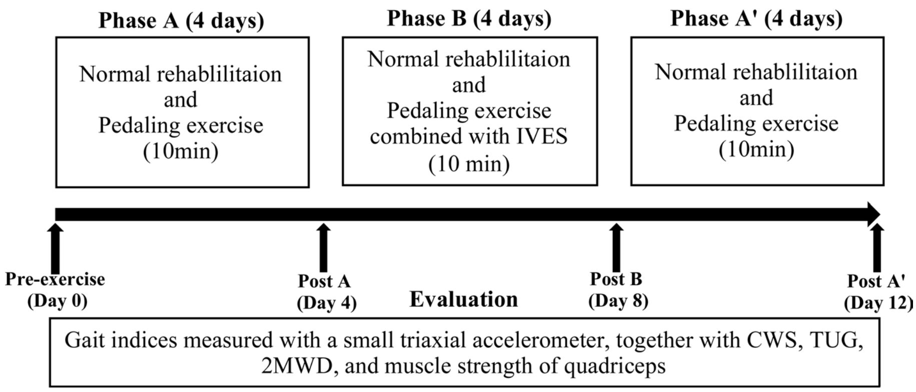


**Fig. 1.** Intervention protocol.
IVES: Integrated volitional control electric stimulator; CWS: Comfortable walking speed; TUG: Timed up and go test; 2MWD: 2-minute walk distance.

including exercises for muscle strengthening, balance, basic movement, and activities of daily life. A recumbent ergometer RB-3500AD (Chuoh Health Co., Ltd., Aichi, Japan) was used for the pedaling exercise. The exercise load was 20 W with a comfortable rotational speed. The seat position was adjusted so that the knee joint was in slight flexion at maximum extension of the lower limb. The PA mode of IVES (OG Wellness Technologies Co., Ltd., Okayama, Japan) was used for EMG-controlled ES. The target muscle was the rectus femoris on the affected side, and the electrode was affixed across the distal motor point[18]. The electrode sites were marked with a water-based pen after wiping with alcohol cotton, and care was taken not to change the sites of electrode application. Stimulus intensity was set above the sensory and below the motor thresholds. The frequency was 20 Hz and the pulse width was 50 µs with three repetitions of bidirectional square wave.

The primary outcome was gait indices measured with a small triaxial accelerometer, and the secondary outcomes were clinical indices of lower limb muscle strength, walking ability, and balance ability. There were four evaluation time points: before the A phase, before and after the B phase, and after the A' phase (second A phase). Evaluation was performed at least one hour after the end of treatment on the last day of each phase.

Gait indices with a small triaxial accelerometer were taken on a 10 m walking path with 3 m auxiliary paths at each end, for a total of 16 m of straight path. Measurements were taken with the patient wearing shoes with flat soles that were appropriate for his size. The accelerometer used was the electrostatic-capacity type 8-channel compact wireless motion recorder MVP-RF8-GC-500 (MicroStone Corp., Nagano, Japan). The external dimensions of the device were 45 × 45 × 18 mm, and it weighed approximately 60 g. The device was attached with a band around the trunk at the height of the L3 spinous process to hold it in place[19]. The sampling frequency was 200 Hz and was pre-corrected for gravitational acceleration. The acceleration signals were analyzed using dedicated software MVP-RF8-S Ver. 1.6.1.0 (MicroStone Corp., Nagano, Japan), and were transmitted in real time via Bluetooth to a notebook PC equipped with dedicated software, to be recorded as excel data after digital conversion. Acceleration values were managed in Microsoft Excel for Mac ver. 16.31 (Microsoft Corp., Redmond, WA, USA). The maximum communication distance with the device was 30 m. The location of the laptop was taken into account. The measurement of gait characteristics was performed by two physical therapists experienced in the use of accelerometers and their measurement methods. Measurements were taken by two physical therapists familiar with the use of accelerometers and their measurement methods.

Numerical analysis software MATLAB (The MathWorks Inc, Natick, MA, USA) was used to analyze the acceleration values. Each acceleration time-series was filtered with a second-order Butterworth bandpass filter with cutoff frequencies of 0.1–20 Hz, and the transformed values after processing were used for analysis. The initial grounding was identified from the gait cycle by the peak of the anteroposterior (AP) axis, and the acceleration values of the central 5 gait cycles were extracted[20]. The coefficient of variation (CV) of stride times was used as an index of the homogeneity of heel contact points during walking[21], and the root mean square (RMS) of the acceleration values was as an index of trunk sway[19, 22], obtained from the mediolateral (ML), vertical (VT), and AP axes, respectively. The CV of stride times were calculated as the standard deviation/mean of five walking cycle times, with higher values indicating less homogeneity of stride length and swing time. The higher the value for RMS, the greater the sway in the area where the accelerometer was placed (trunk). RMS is affected by walking speed; hence, it was adjusted by dividing it by the square of the walking speed[22].

Clinical measures included comfortable walking speed (CWS) as a measure of walking ability[23], the Timed Up and Go Test (TUG) as a measure of dynamic balance ability[24], and the 2-minute walk test (2MWT) as a measure of walking endurance[25]. Quadriceps muscle strength was measured by means of a hand-held dynamometer (HHD). Quadriceps muscle strength measurements with a HHD were performed twice on the lower extremities of the affected side and the average value was adopted.

## RESULTS

The results of gait indices using a small triaxial accelerometer in each phase are shown in Fig. 2. Table 1 shows the amount of change in gait indices from a previous phase using a small triaxial accelerometer. The change from a previous phase of the CV of stride times was 1.13%, −3.95%, and 0.82% in the order of Phase A, Phase B, and Phase A', with the greatest improvement occurring after Phase B. The change from the previous phase in RMS of the ML axis improved the most after phase B, −5.13. RMS of VT and the AP axes showed the largest amount of change after Phase A.

The results of clinical indices of gait, balance ability, and lower limb muscle strength are shown in Table 2. CWS, TUG, and 2MWD showed gradual improvement at each phase. The strength of the quadriceps muscle on the affected side showed the greatest amount of change after phase B. A Fugl–Meyer assessment of the lower extremities showed no change from the pre-exercise score of 20. No adverse events were observed during all treatments.

## DISCUSSION

This case study is the first report of a short-term intervention combining pedaling exercise and IVES on a paralyzed rectus femoris muscle, in a subacute older stroke patient to examine quantitative gait measurement by accelerometry, and its impact on clinical performance. The results showed that gait homogeneity and trunk sway in the mediolateral direction were most improved when pedaling exercise was combined with IVES, compared to pedaling exercise alone. Gait indices using

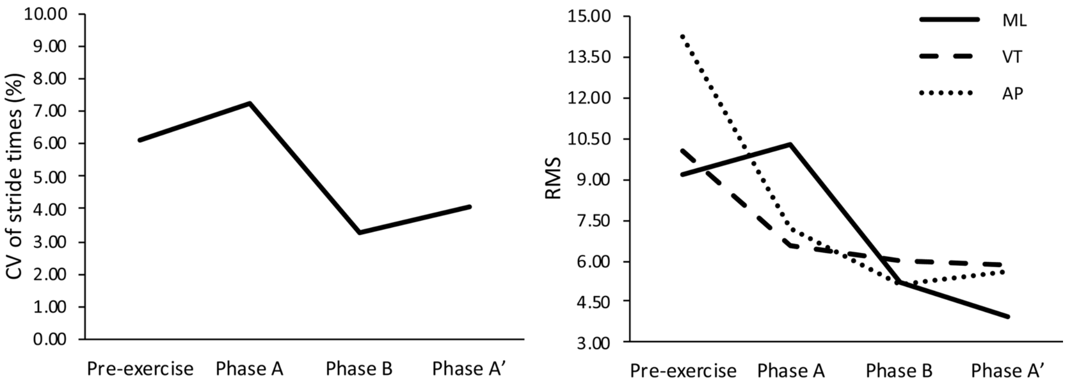


**Fig. 2.** Results of gait indices using a small triaxial accelerometers in each phase.
CV: Coefficient of variation; RMS: Root mean square; ML: Mediolateral; VT: Vertical; AP: Anteroposterior.

**Table 1.** Amount of change in gait indices using small triaxial accelerometers from the previous phase

| | Phase A | Phase B | Phase A' |
|---|---|---|---|
| CV of stride times (%) | 1.13 | −3.95 | 0.82 |
| RMS | | | |
| ML | 1.15 | −5.13 | −1.26 |
| VT | −3.50 | −0.54 | −0.13 |
| AP | −6.99 | −2.05 | 0.46 |

CV: Coefficient of Variation; RMS: Root Mean Square; ML: Mediolateral; VT: Vertical; AP: Anteroposterior.

**Table 2.** Clinical indices of gait ability, balance ability, and lower extremity muscle strength in each phase

| | Pre-exercise | Phase A | Phase B | Phase A' |
|---|---|---|---|---|
| CWS (m/sec) | 0.40 | 0.60 | 0.62 | 0.66 |
| TUG (sec) | 18.21 | 15.81 | 14.87 | 14.41 |
| 2MWD (m) | 60 | 59 | 66 | 66 |
| Muscle strength measurement by HHD of the quadriceps muscle on the affected side (kgf) | 5.90 | 6.40 | 9.95 | 8.55 |

CWS: Comfortable walking speed; TUG: Timed up and go test; 2MWD: 2-minute walk distance; HHD: Hand-held dynamometer.

small triaxial accelerometers are superior to clinical indices such as gait speed and the balance index in determining the risk of falling in stroke patients, as reports on their utility have indicated[21, 26]. The findings of this study may contribute to the development of physical therapy strategies to improve gait and balance in older stroke patients.

The slower the walking speed, the greater the CV of stride times[27]. However, in this study, compared to phase A' pedaling exercise alone, phase B pedaling exercise combined with IVES showed a decrease in the CV of stride times, despite a slower walking speed. In a double-blind randomized controlled trial examining the effects of pedaling exercise combined with ES in patients with subacute stroke, biphasic rectangular pulses of 20–60 mA intensity and 300 s pulse width were applied to the quadriceps, hamstrings, gluteus maximus, and tibialis anterior muscles of both legs for 25 min five days a week for four weeks, and no significant difference was reported in lower limb muscle strength compared with the placebo group[8]. The present study showed an improvement in quadriceps muscle strength on the affected side with less intervention frequency and duration than in a previous study[8], with the greatest improvement occurring in the phase after the pedaling exercise with IVES. IVES, the EMG-controlled ES used in this study, stimulates muscles at an intensity level proportional to the detected voluntary EMG signal when contraction of a target muscle is detected. Therefore, it differs from previous studies, in which electrical stimulation was given to target muscles at fixed timings[8]. IVES can synchronize with EMG and amplify muscle contraction by providing electrical stimulation at a time of its own volition. The timing of this electrical stimulation may have a stronger effect on the generation of rhythmic movement patterns during gait, contributing to an improvement in the paralyzed side's lower extremity muscle strength and stride time concordance.

Trunk sway in the mediolateral direction was found to be most improved after pedaling exercises with IVES. The patient in the present study had greater trunk sway during the pre-exercise phase than was described in reported cases of previous studies[28, 29]. The efficiency of the lateral center of gravity shift is important in improving the cadence of gait. Along with homogeneity, we consider that pedaling exercise with IVES contributed to the generation of rhythmic movement patterns during gait, which, in turn, increased the cadence and improved the trunk sway in the lateral direction. The amount of change from the previous phase was the largest after phase A for trunk sway in the anterior-posterior and vertical directions. Quadriceps muscle weakness affects instability during weight bearing while walking[30] and is thought to be a factor in postural sway in the anterior-posterior direction. The greater improvement in the early intervention, phase A, compared to Phase A', suggests that pedaling-only exercises may produce immediate changes in the anterior-posterior and vertical sway of the trunk.

There were several limitations to this study. First, since this is a single-case study, results may differ for patients with different severities of motor paralysis and different disease periods. In fact, RMS and CV are associated with the severity of motor paralysis after stroke[29, 31]. Therefore, the effects obtained may differ even when applied to patients with the same disease. Second, combining ES with pedaling exercise has been reported to improve walking endurance[3], but no clinically significant differences were found in the present study. Since this study was a short-term intervention, it is necessary to verify the effectiveness of the intervention with various intensities and durations in the future.

In this case study, a short-term intervention combining pedaling exercise and IVES was performed in a subacute older stroke patient, and the effects on clinical gait performance and gait indices with small triaxial accelerometers were investigated. The results of this study contribute to the development of a physical therapy strategy to improve gait and balance in stroke patients. However, further validation of this efficacy is warranted.

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