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Running title

position-triggered electrical stimulation on post-stroke shoulder subluxation

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Abstract

BACKGROUND: Shoulder subluxation is a frequent complication after stroke causing joint instability, shoulder pain, decreased activities of daily living, and impedance to rehabilitation progress. Electrical stimulation (ES) is considered an effective modality to reduce shoulder subluxation in acute stroke. However, few studies have investigated the effect of position-triggered ES, which induces active muscle contraction though accurate motion detection.

AIM: To investigate whether position-triggered ES was more effective in reducing acute hemiplegic shoulder subluxation after stroke than passive ES.

DESIGN: Single-blind, randomized controlled trial.

SETTING: University hospital rehabilitation center,

POPULATION: Fifty post-stroke subacute hemiparetic patients with shoulder subluxation

METHODS: Patients were randomly assigned into two groups. The position-triggered ES group received 30-minute ES sessions, 5 days per week for 3 weeks with specially modified Novastim® CU-FS1 for motion triggering. The passive ES group received the same protocol without motion triggering. The vertical distance (VD) and the joint distance (JD), relative VD and JD (rVD, rJD), upper extremity component of Fugl-Meyer Motor Assessment (FMA_{upper}), Motricity Index (MI), Manual Function Test (MFT), and peak torque of affected shoulder abductor (PT) were assessed at baseline (T0), end of electrical stimulation session (T1), and 3 weeks (T2) after treatment.

RESULTS: Repeated-measures analysis of variance revealed significant interaction between TIME and INTERVENTION on JD and rJD, indicating that shoulder subluxation was significantly more reduced in position-triggered ES than in passive ES (p<0.05). However, FMA_{upper}, MI, MFT, and PT did not show this significance. The change of (Δ)JD, Δ rVD, and Δ rJD in the motion-triggered ES group improved significantly more at T1 than in the passive ES group (p<0.05). This significant improvement was not seen at T2.

CONCLUSIONS: Position-triggered ES may be more effective than passive ES in improving post-stroke shoulder subluxation; however, this effect was not maintained after the withdrawal of stimulation.

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CLINICAL REHABILITATION IMPACT: Position-triggered ES may be useful to reducing post-stroke shoulder subluxation.

Keywords: Stroke - Electrical stimulation - Shoulder subluxation - Position-triggered

Introduction

Shoulder subluxation, defined as increased translation of the humeral head relative to the glenoid fossa, is a common complication observed in 15 to 81% of hemiplegic patients after stroke which often develops during the early stages^{1,2}. In post-stroke hemiparetic patients, the humeral head is displaced inferiorly owing to a loss of normal shoulder muscle strength, especially in the supraspinatus and deltoid muscles. The weight of the upper limb stretches the soft tissue of the shoulder, resulting in subluxation³. Shoulder subluxation has a negative impact on glenohumeral joint instability and subluxation-induced neurologic and mechanical damage, and it impedes the progress of rehabilitation and activities of daily living (ADL)⁴. Without treatment, subluxation can worsen over time and eventually become uncorrectable². Therefore, the management of subluxation remains a crucial part of the comprehensive treatment plan for post-stroke patients. Various modalities such as positioning, supporting devices, physical therapy, and electrical stimulation (ES) treatment have been investigated for decades⁵. Many earlier studies demonstrated that ES was effective for shoulder subluxation. However, most of these studies investigated only passive ES⁶⁻⁸. ES can be used to elicit passive muscle contraction or to induce active muscle contraction triggered by electromyographic activity or by limb position. Knutson et al.9 suggested that the effect of ES may induce additional positive effects if the voluntary movement initiation of the patient is used as a trigger,

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providing appropriate sensory and proprioceptive feedback. Various sensors have been investigated to incorporate user control interface and to capture the cognitive intentions of a user. In this method, the cognitive information is then processed to trigger the required stimulation. Electromyography-triggered `(EMG-triggered) ES has been used for this purpose. However, several randomized controlled trials showed no significant difference in motor recovery by EMG-triggered ES compared to that by passive ES¹⁰⁻¹³. EMG-triggered stimulation, which incorporates short cognition effort with quick relaxation after successful triggering, may not create an adequate temporal association of motor intention and stimulated motor response¹⁴. In addition, surface EMG electrode data can be unreliable in patients with paretic upper limbs, especially in dynamic conditions. Many factors such as low force output, relatively inaccurate position of surface EMG electrode, and variability during dynamic tasks may impede detection of accurate EMG signals¹⁵.

A different form of feedback-triggered ES is position-triggered. Some studies revealed that an accelerometer sensor could outperform an EMG signal in recognizing individual activities¹⁶ and detecting accurate body movement¹⁷. Furthermore, Tong et al.¹⁸ reported that motion sensing using ultra-small sensors (gyroscopes and accelerometers) can improve detection of a subject's intention through minimizing loading that may impede a subject's 'intention' to execute a given motion for functional electrical stimulation (FES) systems. Considering this benefit, the position-triggered sensor including the accelerometer built-in gyroscope has the potential to be used as a sensor for ES control systems. Previously, position-triggered ES has been used to assist the forearm function in reaching and grasping¹⁹. However, few studies have investigated the effectiveness of position-triggered ES for post-stroke shoulder subluxation.

Therefore, this study aimed to investigate whether position-triggered ES was more effective in reducing acute hemiplegic shoulder subluxation after stroke than passive ES. In addition, we

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assessed the effects of ES on motor function of the affected upper limb.

Materials and methods

Patients

We enrolled 50 subacute stroke hemiplegic patients (27 men and 23 women) with a mean age of 62.9 years who were admitted as inpatients at Severance Rehabilitation Hospital, Yonsei University College of Medicine. The mean duration from stroke onset was 26.2 days. The types of stroke included ischemic stroke (41 patients) and hemorrhagic stroke (9 patients). The involved hemispheres included 29 patients with right hemisphere lesions and 21 with left hemisphere lesions.

The following criteria were used for inclusion for the study: (1) first-ever onset post-stroke hemiparesis within 3 months confirmed by brain magnetic resonance imaging; (2) medical stability; (3) age 20 to 90 years; (4) shoulder subluxation based on radiological assessment [vertical distance (VD) >9.5 mm²⁰, joint distance (JD) >7.7 mm]²¹); (5) more than poor minus grade for shoulder abductor strength on the affected side; and (5) adequate cognition to participate.

The patients who complied with the following criteria were excluded: (1) history of stroke; (2) history of trauma, operation, and peripheral neuropathy on affected upper limb; (3) electrical implant (such as cardiac pacemaker); (4) uncontrolled epilepsy within 6 months; (5) pregnant during the study; and (6) dermatologic problem on the applied site. In total, 8 patients dropped out owing to premature discharge (3), follow-up loss (2), or withdrawal from the study (3), leaving 42 patients eligible for analysis (Fig. 1). Informed consent was obtained from all the subjects. This study was approved by the Institutional Review Board of Severance Hospital, Yonsei University College of Medicine (2012-0815-025), and registered in ClinicalTrials.gov

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(code number NCT02346851).

Study design

This study was a prospective, single-blind, randomized controlled trial. Before baseline assessment, all subjects were randomly distributed into either the position-triggered ES or passive ES groups using computer-generated randomization sequences. At baseline, the general characteristics including age, sex, duration from stroke onset, type of stroke, and the side of the hemiparesis were obtained for all subjects. There were no significant differences in general characteristics between the two groups for age, sex, hemiplegia duration from onset, and hemiplegic side (p<0.05) (Table 1). All subjects underwent a conventional rehabilitation program by a specialist physiotherapist 5 times a week lasting 30 min each for 3 weeks. The program consisted of positioning, range of motion, stretching, and strengthening exercises; neurodevelopmental techniques; and the use of a Bobath sling. Each subject underwent two different ES sessions using position-triggered ES or passive ES with 30-minutes of ES every weekday (5 days/week) for 3-week periods. All subjects received the following assessments at baseline (T0), at the end of treatment (T1), and at 3 weeks after treatment (T2): radiological assessment for shoulder subluxation, motor function assessments (Fugl-Meyer Assessment for upper extremity (FMA_{upper})²², Motricity Index (MI)²³, MFT (Manual function test)²⁴, and peak torque of affected shoulder abductor $(PT)^{25}$.

Electrical stimulation

The Novastim® CU-FS1 (CU medical system, Inc.; Gangwon-do, Republic of Korea) ES device was used for this study. Two electrodes were applied on the affected supraspinatus and posterior deltoid muscles in all subjects. The reference electrode was placed over the supraspinatus muscle to minimize undesirable activation of the overlying upper trapezius

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muscle. ES was delivered in a sitting position via a biphasic waveform, with a pulse duration of 300 μ s. Pulse frequency was set at 30 Hz. The stimulation cycle was 5 seconds on and 5 seconds off. The stimulation intensity was set to produce maximum shoulder abduction without discomfort. For triggering, the specially modified stimulation device with a position-triggering sensor device was attached 10 cm above the lateral epicondyle on the line connecting the lateral epicondyle of the humerus and the acromion (Fig. 2).

For setting the trigger-orienting angle generating ES signal, we asked all patients enrolled in the position-triggered ES group to abduct the shoulder 10 times voluntarily before ES. The median angle and angular velocity was calculated using the accelerometer built-in gyroscope during repetitive shoulder movement, and the median angle was set as the trigger-orienting angle.

Radiological assessment for shoulder subluxation

To evaluate the degree of shoulder subluxation, radiologic evaluation was performed. Arm slings were removed 24 hours before x-ray was performed to minimize the sling effect. The vertical distance (VD) and the joint distance (JD) were obtained using the method suggested by Han et al.²¹. X-ray was taken in the sitting position without supporting either arm. Film focus distance was set at 1 m (about 40 inches). The VD was defined as the vertical distance from the top of the humeral head to under the outer rim of the acromion, and the JD was defined as the shortest distance between the humeral head and the top of the glenoid fossa. To minimize the environmental influence, the VD and JD on the unaffected side were measured and subtracted from the VD and JD values of the affected side to obtain values. These values were defined as the relative VD and relative JD (rVD, rJD).

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Clinical assessment for motor function

To evaluate motor function, Fugl-Meyer Assessment for upper extremity (FMA_{upper}), Mortricity Index (MI) and Manual function test (MFT) were used. Fugl-Meyer Assessment for upper extremity (FMA_{upper}) is one of the most widely used quantitative measures of poststroke motor impairment. Each parameter consists of 4 parts: shoulder/elbow/forearm, wrist, hand, and coordination/speed, with scores ranging from 0 to 66. The Motricity Index was used to measure affected limb strength after stroke with scores ranging from 0 to 100. In this test, the upper extremity strength parameter is divided into 3 parts: pinch grip, elbow flexion, and shoulder abduction. The MFT includes eight tasks in three categories (arm motions, grasp and pinch, and arm and hand activities) and is used to assess functions of the paralyzed upper limb in hemiplegic patients after stroke with standardized equipment using scores from 0 to 100. Peak torque of affected shoulder abductor (PT) was measured using the MicroFET® dynamometer (HOGGAN scientific, LLC; Salt Lake City, United States).

Statistical analysis

Statistical analysis was completed using SPSS software 17.0 (SPSS Inc., Chicago, IL, USA). Repeated-measures analysis of variance (RM-ANOVA) was used to evaluate the interaction of TIME_{T0, T1, T2} and INTERVENTION_{position-triggered ES, passive ES}. An independent two sample t-test was used to compare changes from baseline between groups. P values <0.05 were considered statistically significant. All data are expressed as mean \pm standard error (SE).

Results

Shoulder Subluxation

All radiologic parameters (VD, rVD, JD, and rJD) at baseline did not differ significantly among

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treatment groups. RM-ANOVA revealed significant interaction between TIME_{T0, T1, T2} and INTERVENTION_{position-triggered ES, passive ES} on JD and rJD scores (JD: F=3.269, p<0.05; rJD: F=4.937 p<0.01), but did not reveal significant interaction on VD and rVD scores (VD: F=1.683, p =0.193; rVD: F=2.082, p=0.136) (Table 2). Δ rVD, Δ JD, and Δ rJD in the position-triggered ES group significantly improved at T1 compared to those in the passive ES group (p<0.05). Δ VD tended to improve at T1 in the position-triggered ES group compared to that in the passive ES group; however, this difference was not significant (p=0.138) (Fig. 3). Interestingly, Δ VD, Δ rVD, Δ JD, and Δ rJD did not show any significant difference at T2 between the groups.

Motor Function

All parameters of motor function (FMA_{upper}, MI, MFT, PT) at baseline did not differ significantly among the three groups (Table 3). Repeated-measures analysis of variance did not reveal any significant interaction between TIME_{T0, T1, T2} and INTERVENTION_{position-triggered ES}, passive ES on FMA_{upper}, MI, MFT, and PT (FMA_{upper}: F=0.958, p=0.333; MI: F=0.814, p=0.372; MFT: F=0.176, p=0.677, PT: F=0.176, p=0.677).

Discussion

The results of this study indicated that position-triggered ES was more effective in reducing shoulder subluxation than passive ES for subacute post-stroke hemiparetic patients. To our knowledge, this study is the first single-blinded randomized controlled clinical trial to compare position-triggered ES, with an accelerometer built-in gyroscope as a sensor for applying ES treatment, with passive ES for improving shoulder subluxation.

These findings are consistent with those of previous studies comparing active and passive

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ES for shoulder subluxation. Jeon et al.¹² reported that significant improvement in shoulder subluxation was shown in the task-oriented electromyography triggered stimulation group compared with the cyclic FES group. Jang et al.²⁶ reported that brain-computer interface (BCI)controlled FES training was effective in improving the shoulder subluxation of patients with stroke compared to FES only by facilitating motor recovery. However, the sample size was small in these studies. Results may be explained by the active participation of muscle contraction and cognition needed in position-triggered ES. However, both ES methods share cutaneous-, muscle-, and joint-originating proprioceptive feedback. The electrical and hemodynamic activation of the brain may be affected by the presence of intention. Moreover, only similar stimuli to voluntary movement like recognition of afferent information, imparting movement by the primary somatosensory cortex, could support cortical rearrangement during the flaccid phase of limb paralysis^{27,28}. Therefore, treatment facilitating volitionally initiated exercises or appropriate sensory and proprioceptive feedback may improve shoulder subluxation²⁹. Our results were similar to previous studies in that passive ES could not induce a direct change in the motor cortex area, but only induced passive repetitive contraction, in the target muscle without cognitive judgment^{30,31}. Hara et al.³² revealed that EMG-triggered FES had more influence on blood cortical perfusion in the ipsilesional sensory-motor cortex than ES alone. Using near-infrared spectroscopy and electroencephalography, Lee et al.²⁷ reported that the presence of intention affected the activation of the brain significantly in both hemodynamic responses and electrical patterns during ES.

In this study, the reducing effect of position-triggered ES for shoulder subluxation was not maintained at 3 weeks after treatment. Several studies have shown the long-term effectiveness of ES on shoulder subluxation. Linn et al.⁸ reported that additional ES in acute stroke resulted in a significant decrease in inferior shoulder subluxation after 4 weeks of stimulation sessions,

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yet the final evaluation at 12 weeks showed the disappearance of this effect. Wang et al.³³ also reported that the reducing effect was not maintained without ES after 6 weeks. The results of these studies are consistent with our findings. However, Chantraine et al.⁷ revealed a significant reduction of shoulder subluxation at 6 months after 5 weeks of FES which continued at months 12 and 24. In our study, only 30-minute ES 5 days a week for 3 weeks were conducted. Fil et al.³⁴ suggested that at least 25 sessions are required for ES to effect muscle strength. Considering this suggestion, the frequency and period of ES in our study may have been too short to result in long-term benefits. Furthermore, our results may be explained by transient changes of cortical reorganization. Classen et al.³⁵ reported that brief performance of simple voluntary thumb movements resulted in a change in the direction of thumb movements evoked by TMS toward the training direction transiently, which disappeared within 30 minutes.

Interestingly, shoulder subluxation tended to be worsen in passive ES group compared to at the baseline in this study, although not statistically significant. It seems to be inconsistent with previous some studies. ^{6-7,36} However, the subjects in this study was enrolled relatively earlier from the onset than those in the previous studies. This finding is in line with the previous studies that shoulder subluxation was most likely to occur in the first 3 weeks after stroke, while the limb is still flaccid³⁷, and then could worsen over time without treatment.^{2,8,33}

In this study, motor recovery did not show any significant difference between the two groups. The effectiveness of ES with respect to motor recovery of treatment groups compared to control groups has been controversial in previous studies. Previous researchers like Faghri et al.⁶ and Chantraine et al.⁷, reported a significant improvement of motor recovery and shoulder subluxation. In contrast, most recent researchers reported no significant improvement of motor function despite improvement of shoulder subluxation^{8,34}. In addition, a recent meta-analysis revealed no significant benefits of shoulder ES for improving arm function³⁶,

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consistent with findings in this study. Some studies comparing EMG-triggered and passive distal stimulation also revealed no significant differences between the two modalities^{12,13}. Our findings may be related to the fact that position-triggered ES used in this study did not incorporate an adequate level of cognitive efforts to improve neural plasticity for motor recovery after stroke^{10,14}.

There are some limitations to this study. First, we only focused on the comparison between stimulation methods without control group (no stimulation group), therefore, we could not explore definite additional effects of position-triggered ES compared to passive ES in reducing the shoulder subluxation. Three arm RCT will be needed in future. Second, we compared passive ES to position-triggered ES and not EMG-triggered ES. Therefore, we did not investigate superiority of position-triggered ES compared to EMG-triggered ES. Future studies comparing position-triggered ES with ES using different sensors such as EMG-triggered ES are necessary to determine superiority. Third, the effects of position-triggered ES on shoulder pain, one of the most common complication of stroke, was not investigated. In the future study, more detailed research related to this will be needed. Fourth, times per day and total period of ES was relatively short compared to other studies. Further study will be needed to investigate the beneficial effects of increased time and frequency of ES on the duration of symptom improvement. Moreover, many parameters of ES such as intensity, frequency, duration, and ratio on/off have been suggested. Further studies should focus on the various stimulation parameters to standardize treatment to achieve maximal therapeutic effect.

Conclusions

This study showed that position-triggered ES was more effective than passive ES, and the results suggest that this modality may be effective in improving hemiplegic shoulder

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subluxation. However, results did not show effectiveness of position-triggered ES for improvement of motor and functional recovery scores.

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Conflicts of interest.

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Authors' contribution

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TABLES

Table 1.Comparison	of General	Characteristics	between	Position-triggered	and	Passive	Electrical
Stimulation Groups							

	Position-triggered ES (n=21)	Passive ES(n=21)
Age (year)	64.9±3.6	56.8±3.3
Sex (M:F)	9:12	13:8
Lesioned hemisphere (Rt:Lt)	15:6	14:7
Type of Stroke(I/H)	18:3	16:5
Days from stroke onset (days)	20.9±3.2	29.8±4.8
FMAupper	21.0±3.1	18.7 ± 3.0
MI	33.5±3.5	30.5 ± 3.0
MFT	6.5±1.3	5.8±1.1

I/H: Infarction/Hemorrhage, Rt: right, Lt: left, FMA_{upper}: Fugl-Meyer Assessment for upper extremity, MI: Mortricity Index, MFT: Motor function test

Table 2. Comparison of Shoulder Subluxation using Radiological Measures between Position-triggered and Passive Electrical Stimulation Groups

	Position-triggered ES					Passive ES						
Variables (mm)	Т0	T1	T2	∆T1-T0	ΔΤ2-Τ0		Т0	Т1	T2	ΔΤ1-Τ0	ΔΤ2-Τ0	
VD	15.5±1.0	14.7±1.0	15.7±1.1	-0.9±0.6	0.1±0.6		16.8±1.3	17.6±1.5	16.9±1.4	0.8±0.9	0.1±0.8	
rVD	7.1±0.8	6.1±0.9	7.9±0.9	-1.0±0.5	0.8±0.5		7.4±1.0	8.2±1.3	8.5±1.1	0.8±0.7	1.1±0.7	
JD	13.1±0.8	11.8±0.9	12.1±1.0	-1.3±0.4	-0.9±0.6		12.3±0.9	13.4±1.2	12.8±1.1	1.1±0.7	0.5±0.7	
rJD	7.2±0.7	5.3±0.8	7.2±0.8	-1.9±0.3	-0.1±0.5		6.3±0.9	7.4±1.1	7.9±1.1	1.1 ± 0.8	1.6±0.7	

Values are represented as mean $\pm SE$

VD: Vertical distance, JD: Joint distance, rVD: Relative vertical distance, rJD: Relative joint distance, T0: baseline, T1: after treatment, T2, 3 weeks after treatment, SE: standard error

Table 3. Comparison of Motor	Function between	Position-triggered	and Passive	Electrical Stimulation
Groups				

	Position-triggered ES					Passive ES					
Variables (mm)	Т0	T1	T2	ΔT1-T0	ΔΤ2-Τ0	-	Т0	T1	T2	ΔT1-T0	ΔT2-T0
FMA _{upper}	21.0±3.1	28.9±3.5	31.4±3.8	7.9±2.1	4.9±1.2		18.7±3.0	23.9±4.0	27.7±3.8	5.2±1.5	4.0±1.0
MI	33.5±3.5	40.0±4.6	48.8±4.1	6.5±2.5	15.3±2.9		30.5±3.0	34.1±3.9	43.5±4.2	3.6±1.4	13.1±2.0
MFT	6.5±1.3	13.3±1.6	12.4±1.7	6.8±1.5	5.9±1.3		5.8±1.1	12.7±2.4	11.0±2.1	7.0±1.9	5.2±1.4
Peak											
Toque (Nm)	2.3±0.5	3.7±0.5	4.1±0.5	1.4±0.3	1.8±0.4		2.1±0.5	2.7±0.5	3.0±0.6	0.6±0.3	0.8±0.3

Values are represented as mean $\pm SE$

FMA_{upper}: Fugl-Meyer assessment, MI: Motricity index, MFT: Manual function test, T0: baseline, T1: after treatment, T2: 3 weeks after treatment, SE: standard error

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TITLES OF FIGURES

Fig 1. Study design of experiment

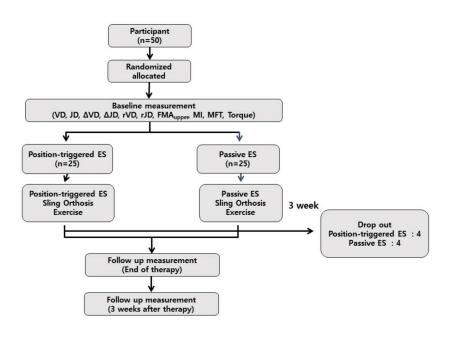
VD: Vertical distance, JD: Joint distance, rVD: Relative vertical distance, rJD: Relative joint distance, FMA_{upper}: Fugl-Meyer Assessment for upper extremity, MI: Mortricity Index, MFT: Motor function test

Fig 2. Position for ES in sitting. Position-triggered sensor is attached 10 cm (*) above the lateral epicondyle (black arrow) on the line connecting the lateral epicondyle and acromion (arrowhead).

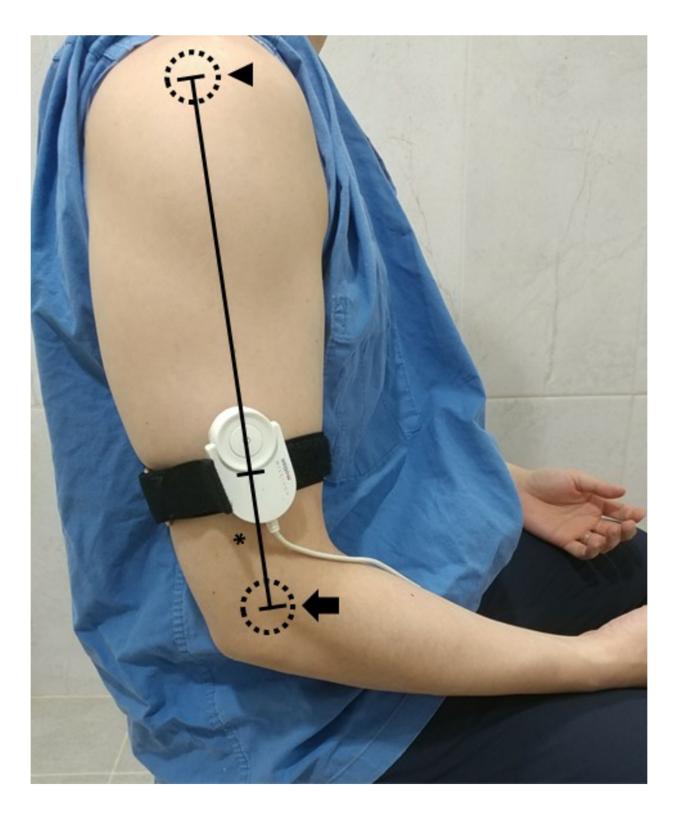
ES-Electrical stimulation

Fig 3. Comparison of Δ VD, Δ rVD, Δ JD and Δ rJD between position-triggered ES and passive ES group. Significant improvement of Δ rVD, Δ JD and Δ rJD is seen in the position-triggered group compared to the passive ES group after 3 weeks of electrical stimulation sessions. VD: Vertical distance, JD: Joint distance, rVD: Relative vertical distance, rJD: Relative joint distance, ES: Electrical stimulation, Δ : the change of

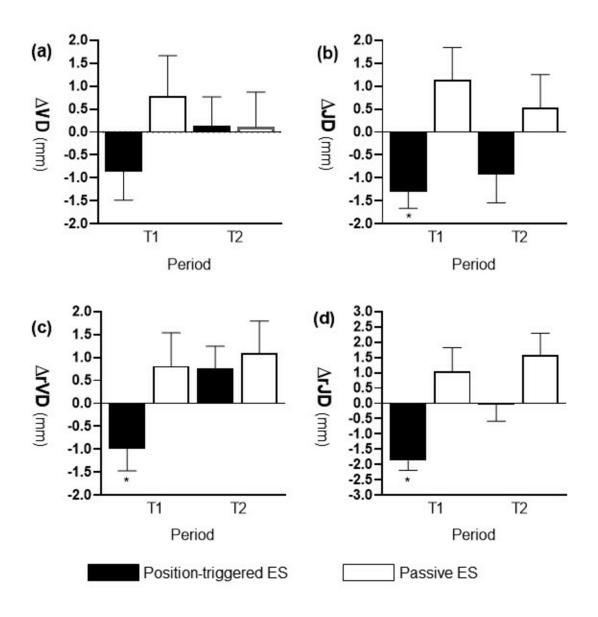
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