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Immediate effect of neuromuscular electrical stimulation on the abductor hallucis muscle: A randomized controlled trial

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ABSTRACT
Hallux valgus (HV) is a foot deformity with deviation of the greater toe and the first metatarsal. There is little evidence on training the abductor hallucis muscle (AbdH) to treat HV because of the difficulty in implementing the necessary interventions. Although neuromuscular electrical stimulation (NMES) has been used to induce voluntary exercise, there is currently no study on NMES for AbdH. We aimed to verify the immediate effect of NMES on the AbdH muscle function. For the NMES group (n = 15), electrical stimulation was applied for 20 min. In the sham group (n = 15), the stimulating device was set but not turned on. Electromyogram, HV angle (HVA) at rest and during abduction of the big toe, and strength of the AbdH were evaluated. Analysis of covariance was used to investigate differences within groups using the baseline as the covariate. NMES significantly improved the maximal voluntary isometric contractions (%MVIC), HVA at exercise, and muscle strength (%MVIC: p = .00, HVA exercise: p = .00, AbdH strength: p = .00). HVA at rest showed no change (p = .12). Application of NMES on the AbdH muscle immediately improved its activity output, muscle strength, and HVA during exercise.

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Neuromuscular electrical stimulation; hallux valgus; abductor hallucis muscle; electromyogram

Introduction

The foot is an important part of the body and is the only area in contact with the ground while standing. Its dysfunction can affect a person's daily activities and gait. Foot deformities are important problems that disrupt the quality of life. Among these, hallux valgus (HV) is highly prevalent in people. HV is a complex progressive deformity in which lateral deviation of the great toe is the most obvious feature (Thomas and Barrington 2003). A previous study has revealed that 35.7% of older people have HV (Nix et al. 2010). HV is associated with foot pain, decreased quality of life, and foot dysfunction – all of which affect an individual's walking ability (Galica et al. 2013; Hagedorn et al. 2013; Hendry et al. 2018; Nix et al. 2013). The abductor hallucis (AbdH) muscle is an intrinsic muscle that keeps the first metatarsophalangeal joint (first MTPJ) in a normal alignment. It plays a critical role in the pathomechanism of HV. In patients with HV, this muscle shifts to the plantar aspect of the foot, thereby losing its anatomical relationship with the first MTPJ (Eustace et al. 1996). Consequently, the strength and function of the AbdH muscle are impaired (Arinci İncel et al. 2003; Mickle et al. 2009).

For patients with HV, surgery is the only treatment to correct the apparent deformity. Resistive exercise training methods for the AbdH muscle such as short foot exercises (Jung et al. 2011; McKeon et al. 2015) or toe-spread-out exercises (Goo et al. 2014) are usually performed and studied. However, there is little evidence on the therapeutic effect of these exercises in patients with HV. Movements in such exercises, especially abduction of the big toe, are not frequently performed in daily life. It may be difficult for patients with HV to perform abduction of the big toe.

This study focused on the effect of neuromuscular electrical stimulation (NMES) in improving exercise quality. NMES is minimally invasive and can be easily used as long as electrodes and parameters are correctly set. It elicits skeletal muscle contractions by applying an electrical current that depolarizes the motor nerves through the electrodes attached on the skin. Previous studies have reported that NMES improves neuromuscular functions (Hirose et al. 2013; Scremin et al. 1999; Wdc and Jones 2016). However, to our knowledge, no current studies on the efficacy of NMES on the AbdH muscle have been reported. If application of NMES to the AbdH muscle

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can re-educate abduction of the big toe and make AbdH exercise easier, a combination of NMES and conservative AbdH exercise may be a simple yet effective treatment method for HV. Therefore, we aimed to verify the immediate effect of NMES on the AbdH muscle's ability to exercise and function in healthy participants. In addition, we investigated on the hypothesis that NMES could also improve the AbdH function and hallux valgus angle (HVA).

Materials and methods

Study design

This was a participant-blinded, randomized controlled trial with a pre-post design where two parallel groups were compared – the NMES and sham groups. The ethics committee of Kyoto University approved the study (No. C1389).

Participants

We employed healthy university students in this study. The participants were recruited from September to November 2018 at Kyoto University. They received verbal and written explanations of the study. All participants provided written informed consent prior to enrollment in the study. The exclusion criteria included subjects with a history of foot surgery and those with contraindications to electrical stimulation such as an implanted pacemaker and metal, cancer, febrile/infectious disease, deep vein thrombosis, and damaged skin.

Randomization

The participants were randomly assigned to either the NMES or the sham group through stratified and block randomization which were stratified according to sex.

Intervention

All measurements and interventions were performed only on the dominant foot. The intervention time was 20 min (Hamada et al. 2004b). In the NMES group, electrical stimulation was delivered through a low-frequency stimulator ESPURGE (ITO CO., LTD., Saitama, Japan). The stimulator delivered a biphasic, pulsed current with a 20-Hz frequency, 300-µs (Hamada et al., 2004a; Hamada et al. 2004b) pulse duration, 5-s on-time (ramp up: 1 s, hold: 3 s, ramp down: 1 s), and 10-s off-time. Stimulation intensity was defined as the intensity at which muscle contraction was obtained within a range where pain was tolerable. Electrodes of PALS Platinum Φ32 mm in size (Axelgaard, CA., USA) were used. After cleansing the skin with a scrubbing gel and alcohol, the electrodes were attached 1-cm away from the heel to the first metatarsal bone and 2-cm away from the heel to the first electrode (Richard et al. 2011). In the sham group, the electrodes were placed in the same position as the NMES group. However, electrical current was not applied. Participants were informed that the stimulation was below the sensory threshold. Thus, they would not perceive any currents.

Measurement

The following measurements were performed before and after the application of the NMES intervention in a sitting position with the hip and knee joints at 90° flexion and the ankle joint at the middle position.

Demographic data

Data on the height, weight, age, and sex were collected from the participants. Body mass index was calculated by dividing the weight by the squared height (kg/m^2).

Electromyogram (EMG)

The EMG has been frequently used to analyze muscle activity (Hodges et al. 2003; Ruiz-Muñoz and Cuesta-Vargas 2014). In this study, EMG data of the AbdH muscles were recorded with the Telemyo DTS system (Noraxon USA Inc., Scottsdale, AZ). To measure the muscle activity of the AbdH muscle, the same electrodes in NMES were placed on the same positions.

The sampling frequency of EMG used was 1024 Hz. Raw EMG signals were processed using a bandpass filter range of 20–500 Hz (Tateuchi et al. 2015). The subjects were instructed to contract their AbdH muscles against resistance while the EMG signals for maximal voluntary isometric contractions (MVIC) were recorded for 3 s. EMG was performed thrice during the abduction of the big toe. The activity of the AbdH muscle was normalized and presented as a percentage of MVIC (%MVIC). The maximum value was taken as the result.

HVA

The HVA was measured by a goniometer according to the protocol by Kilmartin (Kilmartin and Wallace 1994). It is the angle between the axis of the first metatarsal bone and the proximal phalanx. The HVA at rest and during active abduction of the big toe was measured. For each subject, three measurements of each HVA were recorded. The average value was then obtained as the result.

Muscle strength

AbdH strength measurements were performed using a hand-held dynamometer (HHD) (μTas F-1, Anima Co., Ltd. Tokyo, Japan). The sensor of the HHD was set on the outer side of the first proximal phalanx. As a subject actively abducted his big toe, the AbdH muscle strength was manually measured. Measurements were performed thrice, and the maximum value was obtained.

Sample size

A sample size of 31 participants was calculated using the G*Power 3 program (Heinrich-Heine-Universität Düsseldorf, Düsseldorf, Germany) for multiple linear regression analysis (Faul et al. 2007) with an 80% power, 0.05 significance level, and 0.35 effect size *f* (Cohen 1988).

Statistical analyses

The Shapiro–Wilk test was used to confirm the statistical normality of the basic information and outcome variables. The unpaired t-test or Mann–Whitney *U* test was performed to compare the demographic data between the NMES and sham groups. Analysis of covariance was used to investigate differences within groups. We used the post-measurement data as dependent variables, NMES or sham data as independent variables, and pre-measurement data as covariates, respectively. All data were analyzed using the JMP Pro 13.0 (SAS Institute, Cary, NC). Statistical significance was set at $P < .05$ for all tests.

Results

A total of 30 healthy participants were included in this study. The participants' demographic data are shown in Table 1. No significant difference was noted between both groups.

The results from the covariance analysis are shown in Table 2. The %MVIC, HVA during active abduction of the big toe, and muscle strength significantly increased only in the NMES group (%MVIC: $P = .0007$, HVA exercise: $P = .0003$, AbdH strength: $P = .0015$). The HVA at rest showed no significant change in both groups.

Table 1. The demographic data by intervention.

	Sham ($n = 15$, Male: $n = 7$)	NMES ($n = 15$, Male: $n = 7$)	*p*-Value
Age, y	23.5 ± 1.99	24.5 ± 2.23	0.18
Height, cm	166.6 ± 7.3	164.9 ± 8.09	0.28
Weight, kg	57.5 ± 10.4	57.3 ± 9.36	0.48
BMI, kg/m^2	20.6 ± 2.51	20.9 ± 1.74	0.68

Values are mean ± standard deviation.

Discussion

This study examined the immediate effect of NMES on the AbdH muscle. The most important finding of the present study was that NMES increased the %MVIC, muscle strength, and HVA of the AbdH muscle during active abduction of the big toe.

NMES is extensively used for neurorehabilitation. Applying NMES to repetitive exercise training may facilitate motor re-learning (Chae et al. 1998; Sheffler and Chae 2007). In this study, NMES re-educated the AbdH muscle which was inactive during daily activities; thus, muscle activity by EMG was considered to increase. By forcibly contracting the AbdH muscle with NMES, participants mastered the sensation of contracting the AbdH muscle and learned how to abduct the big toe. Hence, it is possible to voluntarily contract the AbdH muscle and increase its exertion. Moreover, Chisari et al. (Chisari et al. 2013) showed that firing pattern improved after electrical stimulation. Electrical stimulation may help increase the firing rate of the dominant nerve and synchronize the timing of the different motor units. Therefore, the muscle activity of the AbdH muscle may improve.

AbdH muscle strength significantly increased in the NMES group. Muscle volume, however, did not change since this research focused only on immediate effects. Muscle strength improved by re-educating the AbdH muscle contraction. This muscle did not abduct the big toe during performance of daily activities. Several studies have revealed that long-term electrical stimulation of other muscles – the quadriceps and abdominal muscles for example – improved the person's muscle strength (Esteve et al. 2016; Kamel and Yousif 2017; Schardong et al. 2017). However, the volume of these muscles is greater than that of the AbdH muscle. Thus, this was the first study to reveal that NMES also increased muscle strength in smaller muscles like the AbdH muscle.

The HVA during active abduction of the big toe significantly improved in the NMES group. It is thought that muscle activity was induced by electrical stimulation and the big toe's abduction movement was re-educated through the NMES. In contrast, the HVA at rest showed no change after NMES. These results are probably due to the employment of healthy students in this study.

Based on the results of the present study, the immediate effect of NMES on the AbdH muscle was clarified. With the long-term use of NMES, it is expected that the

Table 2. The results of covariance analysis.

	Sham (n = 15)		NMES (n = 15)		
	Pre	Post	Pre	Post	P–value
EMG (%MVIC)	71.4 ± 23.9	64.1 ± 22.9	74.5 ± 24.5	88.8 ± 29.1	0.001*
HVA rest (°)	7.33 ± 4.32	7.44 ± 4.40	11.1 ± 5.64	10.2 ± 5.78	0.124
HVA active (°)	3.24 ± 4.13	3.11 ± 4.86	7.13 ± 6.08	4.67 ± 5.31	0.000*
muscle strength (N)	32.1 ± 7.97	33.8 ± 7.81	29.2 ± 8.37	38.4 ± 12.6	0.002*

Values are mean ± SD.
EMG: electromyogram.
HVA: hallux valgus angle.
*Significant at 0.05 level.

AbdH muscle strength and HVA at rest will improve. Moreover, using NMES before exercises may enhance the effect of voluntary exercise therapy. Hence, it may be possible to increase the load and number of training repetitions. Long-term electrical intervention combined with voluntary exercise training may become a new treatment method for HV.

There were two limitations in this study. First, the participants consisted of only healthy young people. Changes that may occur when NMES is applied to patients with HV are unclear. Second, because this study reported only the immediate effect of NMES, it was insufficient to predict the long-term NMES sustainability and effective stimulation conditions for people with HV.

In this study, NMES immediately improved the activity and strength of the AbdH muscle, as well as the HVA during voluntary abduction of the big toe. These findings suggest that NMES could be a novel treatment for HV.

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Declarations of interest statement

One co-author, Sachiko Abiko, is an employee of ITO CO., LTD, which is the manufacturer of the NMES device used. She did not participate in any data collection or data analysis. The other authors have no conflicts of interest to declare.

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