

Efficacy of belt electrode skeletal muscle electrical stimulation on muscle flexibility of lower limbs

A randomized controlled pilot trial

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Abstract

Background: Muscular contracture may be caused by immobility-induced muscle atrophy and skeletal muscle hypoxia. Belt electrode skeletal muscle electrical stimulation (B-SES) is a new type of neuromuscular electrical stimulation that can simultaneously contract the lower limb muscle groups, in contrast to the conventional pad-type electrodes. B-SES can suppress muscular atrophy and relieve hypoxia of the skeletal muscle and is considered an appropriate strategy for preventing muscular contracture. However, the effect of B-SES on muscle flexibility has not been verified. This study aimed to compare the immediate effects of B-SES on skeletal muscle flexibility using different stimulation modes before the clinical study.

Methods: We conducted a randomized controlled pilot trial with cross-over analysis of 10 healthy subjects. The participants were subjected to three stimulus conditions (Disuse B-SES, Metabolic B-SES, and Control) with a minimal interval of 1 day between interventions, and the lower limb flexibility before and after the B-SES intervention was evaluated. Lower extremity flexibility was evaluated based on the hamstring muscle stiffness and sit-and-reach distance. For each endpoint, within-group comparisons were performed before and after the intervention and were compared between the groups using paired t-tests. Changes in each endpoint before and after the intervention were analyzed using repeated-measures analysis of variance and the Bonferroni method. The significance level was 0.05.

Results: Ten healthy individuals participated in all three interventions with a washout period between each intervention. In the Metabolic B-SES group, the sit-and-reach distance after the intervention was significantly higher than that before the intervention ($P < 0.05$). A comparison of the change in the sit-and-reach distance among the three groups before subsequent tests showed that the Metabolic B-SES group had a significantly increased sit-and-reach distance compared with the control group ($P < 0.05$).

Conclusion: Metabolic B-SES was effective for the immediate improvement of flexibility of the lower limb muscles. Therefore, Metabolic B-SES may be useful as a strategy for preventing muscular contracture.

Abbreviations: B-SES = belt electrode skeletal muscle electrical stimulation, NMES = neuromuscular electrical stimulation, ROM = range of motion.

Keywords: contracture, electrical stimulation, hamstring, muscle flexibility, range of motion

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The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

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1. Introduction

Immobility is one of the causes of joint contracture, and the limited range of motion (ROM) caused by joint contracture significantly reduces the ability to perform activities of daily living.^[1] In recent years, studies have reported that muscular contracture is related to an increase in fibrosis-related molecules caused by immobility-induced muscle atrophy and skeletal muscle hypoxia.^[2,3] Therefore, the suppression of muscle atrophy and alleviation of skeletal muscle hypoxia may be effective in preventing muscular contracture.

Belt electrode skeletal muscle electrical stimulation (B-SES) is a new neuromuscular electrical stimulation (NMES) device that can simultaneously generate muscle contraction of the entire lower limb, compared with conventional muscle contraction, which stimulates contraction of a limited area by pad-type electrodes.^[4,5] There are 2 main modes of use: a Disuse mode (stimulation frequency, 20 Hz; pattern of 5 seconds of strong contraction followed by 2 seconds of rest) for strengthening muscles and a metabolic mode (stimulation frequency, 4 Hz;

pattern of repeated twitching) for improving metabolism. B-SES is an effective treatment to prevent muscle atrophy and alleviate hypoxia in the entire lower limb, and it is considered an effective treatment strategy to prevent the occurrence of muscular contracture.^[6–8] However, no study has reported about the effects of B-SES on muscle flexibility. In addition, few clinical studies are using B-SES, and none are comparing the effects of different stimulation frequencies.

Therefore, this study aimed to clarify the immediate effect of B-SES on muscle flexibility in healthy participants before proceeding with clinical research using B-SES. Furthermore, as a strategy for preventing the occurrence of muscular contracture, we decided to compare effective stimulation frequencies.

2. Methods

2.1. Type of study

This study was conducted as a randomized controlled pilot trial with cross-over analysis at Akita Rehabilitation College in Japan. In the study, it was assumed that the difference between the mean values of the sit-and-reach distance, which is an index for evaluating muscle flexibility, was 3.0 cm, and the standard deviation was 2.0 cm. The sample size was calculated with a power of 0.95. As a result, the required sample size was 8; therefore, the number of participants in the study was 10. In addition, there were no significant changes in methods after the start of this study.

2.2. Participants

The participants were 10 healthy individuals with no history of orthopedic diseases in the lower limbs, not taking any medications, and with no history of metabolic, neuromuscular, and cardiovascular disorders or any other recent illness. Participation in each intervention was randomized using computer random numbers. We excluded individuals whose electrical stimulation was contraindicated.

2.3. Interventions

This study involved 3 test conditions:

- (1) Disuse B-SES group (stimulation frequency, 20 Hz; pattern of 5 seconds of strong contraction followed by 2 seconds of rest),
- (2) Metabolic B-SES group (stimulation frequency, 4 Hz; pattern of repeated twitching), and
- (3) Control group (resting in the supine position without B-SES).

All individuals participated in 3 different stimulation conditions for 20 minutes. The outcome measurer was blinded to each intervention and evaluated participants before and after the intervention.

The hamstring muscle (Ham) on the left and right, muscles of the lower extremity, were analyzed for improvement in flexibility following B-SES. In preparation for the study, the skin on the back of the thigh corresponding to 50% of the line segment connecting the head of the fibula from the ischial tuberosity of the subject was marked, and this region was used as the measurement of Ham stiffness.^[9,10] The subjects underwent preliminary evaluation by measurement of Ham stiffness and sit-and-reach distance to evaluate Ham flexibility. The measurement was obtained taking into consideration the fluctuation and fatigue in

daily life; it was performed at the same time, as far as possible, in the same individuals. Interventions were performed with intervals of 1 or more days, and all experiments were performed in the same laboratory at room temperature of approximately 25°C in random order.^[9,10]

B-SES was performed using the Autotens Pro Rehabili Unit II (Homer Ion Laboratory Co. Ltd., Japan). Belt electrodes were attached to the lumbar region and at the site 10 cm above the upper margin of the patella, immediately above the medial and lateral malleolus. Subjective stimulation intensity was measured using the Borg scale and adjusted to 13 during each intervention.^[11]

2.4. Outcomes

Ham stiffness (Nm) was measured using a muscle stiffness tester (NEUTONE TDM-N1, Triol Co., Ltd., Japan) by the same examiner who was familiar with using such a device (KS). The subjects were positioned in the prone position, and measurements were made three times on the left and right sides of the markings on the skin of the thigh as mentioned above. The average value of the three measured values was used as a representative value of Ham stiffness. Before and after the implementation of each intervention, we calculated the mean and standard deviation of the data for 20 limbs of the 10 participants. In addition, the reliability of the method used to measure Ham stiffness has been confirmed in previous studies.^[9]

The sit-and-reach distance (cm) was measured using the sit-and-reach distance meter (TKK 5412, Takei Industrial Instruments Co., Ltd., Japan) following the method described in a previous study.^[10] Participants were instructed to push the measuring instrument straight, not to bend the knee joint, and to push gently and slowly without recoil. The test was performed twice, and the average value was used as the sit-and-reach distance.

2.5. Ethics

This study was performed after obtaining approval from the medical ethics committee of the Graduate School of Medicine and Faculty of Medicine of Akita University (approval date: May 25, 2018, approval number: 1959). All participants provided written informed consent before considering participation.

2.6. Statistical analysis

The mean values of ham muscle stiffness and sit-and-reach distance measured before and after intervention in each group were compared using the paired *t*-test. In addition, between-group comparisons were performed using the repeated measures analysis of variance, followed by the Bonferroni test for the change in each endpoint before and after the intervention. For the statistical analysis, we used SPBS Ver. 9.6 (Wingsteeen Regional Medical Center, Tokyo, Japan), with a significance level set to 0.05.

3. Results

Ten participants (7 men and 3 women), with an average age of 21.1 ± 0.3 years, height of 168.6 ± 9.0 cm, weight of 61.8 ± 8.3 kg, and body mass index (BMI) of 21.7 ± 1.5 kg/m² participated in this study. All participants were classified into the Disuse B-SES

Table 1**Within group comparison of the hamstring stiffness (Nm) before and after the intervention (n = 10).**

| Disuse B-SES (20 Hz) | | Metabolic B-SES (4 Hz) | | Control group | |
|----------------------|------------|------------------------|------------|---------------|------------|
| Before | After | Before | After | Before | After |
| 28.4 ± 4.8 | 27.9 ± 5.2 | 29.0 ± 4.8 | 28.5 ± 5.0 | 27.9 ± 5.0 | 28.7 ± 5.0 |

All data are presented as mean ± standard deviation. A *t*-test was used for comparison.
B-SES = belt electrode skeletal muscle electrical stimulation.

Table 2**Within-group comparison of the sit-and-reach distance (cm) before and after the intervention (n = 10).**

| Disuse B-SES (20 Hz) | | *Metabolic B-SES (4 Hz) | | Control group | |
|----------------------|------------|-------------------------|------------|---------------|------------|
| Before | After | Before | After | Before | After |
| 36.2 ± 8.5 | 39.0 ± 8.1 | 38.0 ± 8.5 | 41.4 ± 9.0 | 39.0 ± 9.3 | 38.1 ± 9.3 |

All data are presented as mean ± standard deviation. A paired *t*-test was used for comparison.
B-SES = belt electrode skeletal muscle electrical stimulation.
* *P* value < .05.

group, Metabolic B-SES group, and Control group at intervals of 1 day or more for each intervention.

No individuals had an adverse event owing to electrical stimulation therapy. Based on the results of the goodness-of-fit test, the Ham stiffness of all groups and the change before and after the intervention of the sit-and-reach distance all followed normal distribution ($P > .05$).

3.1. Comparison within groups

Table 1 shows the average ham muscle stiffness before and after the intervention, and Table 2 shows the average sit-and-reach distance before and after the intervention. In each group, a paired *t*-test was performed for each evaluation item. In the Metabolic B-SES group, the sit-and-reach distance was significantly higher after the intervention ($P < .05$). No other significant differences were found ($P > .05$).

3.2. Comparison between groups

Between-group comparisons were performed using the repeated measures analysis of variance, followed by the Bonferroni test for the change in each endpoint before and after the

intervention. Table 3 shows the results of the change in ham stiffness before and after the intervention. No significant difference was found between the groups before and after the intervention ($P > .05$). Table 4 shows the results of the change in the sit-and-reach distance before and after the intervention, and a significant difference was found between the groups ($P < .05$). Post-hoc tests showed a significant difference in the locus distance between the Metabolic B-SES group and the Control group ($P = .0148$).

4. Discussion

The results of this study indicate that Metabolic B-SES, which repeats twitches at a stimulation frequency of 4 Hz, significantly increases the sit-and-reach distance after B-SES compared with that before B-SES. It is considered that blood circulation was promoted and the muscle temperature increased due to the effect of B-SES muscle pump action, which contributed to the improvement of flexibility. Collagen, which constitutes a muscle, is a tissue whose extensibility is increased by being warm, and it is considered that then the viscosity of the muscle is lowered and the flexibility is improved. In addition, compared with the Control group, the Metabolic B-SES group showed significantly higher

Table 3**Comparison of the change in hamstring stiffness (Nm) before and after the intervention between the groups (n = 10).**

| Disuse B-SES (20 Hz) | Metabolic B-SES (4 Hz) | Control group | <i>P</i> -value |
|----------------------|------------------------|---------------|-----------------|
| -0.49 ± 2.0 | -0.52 ± 2.7 | 0.77 ± 2.2 | .1356 |

All data are presented as mean ± standard deviation. Repeated measures analysis of variance followed by the Bonferroni test was used for comparing the groups.
B-SES = belt electrode skeletal muscle electrical stimulation.

Table 4**Comparison of the change in the sit-and-reach distance (cm) between the groups (n = 10).**

| Disuse B-SES (20 Hz) | Metabolic B-SES (4 Hz) | Control group | <i>P</i> -value |
|----------------------|------------------------|---------------|-----------------|
| 2.75 ± 4.3 | 3.45 ± 1.9 | -0.9 ± 2.3 | .0107 |

All data are presented as mean ± standard deviation. Repeated measures analysis of variance followed by the Bonferroni test was used for comparing the groups.
B-SES = belt electrode skeletal muscle electrical stimulation.
* *P* value < .05.

values of the change in sit-and-reach distance before and after B-SES. In other words, Metabolic B-SES may be an effective treatment strategy to improve the flexibility of lower limb muscles.

Previous studies using B-SES have reported that Disuse B-SES is effective in preventing muscle atrophy and enhancing muscle strength in postoperative patients.^[6] In addition, a report using Metabolic B-SES showed that it was effective for exercise tolerance and muscle strengthening in healthy subjects.^[7] However, no studies have examined the effects on muscle flexibility. Therefore, this study, which showed the potential of B-SES to improve muscle flexibility, is a useful report showing the new muscle quality-improving effect of B-SES.

Electrical stimulation therapy is often used as an alternative to exercise therapy to prevent disuse syndrome and maintain muscle quality when aggressive exercise therapy is difficult due to pain, such as early after surgery. Such patients are more likely to have excessive muscle contraction because of pain or muscular contracture due to immobility, which limits ROM. ROM restriction is a frequent factor limiting the activities of daily living after discharge from the hospital. Muscle degeneration was reported to begin within 48 hours of new-onset disease, acute exacerbation, or surgery with the maximum loss occurring in 2 to 3 weeks.^[12,13] Studies on rats showed development of skeletal muscle contracture within 2 weeks of immobility.^[14] ROM limitation due to organic changes in the perpendicular soft tissue, defined as contracture, has been noted to be accompanied by fibrosis and collagen hyperplasia. Studies reported that skeletal muscle fibrosis can be the result of immobility-associated hypoxia.^[2,3] Therefore, it is necessary to alleviate hypoxia in skeletal muscle as early as possible in individuals who may be bedridden because of severe disease and in frail older people. In this study, although there was no improvement in Ham stiffness, the increase in the sit-and-reach distance in the Metabolic B-SES group can be caused by the muscle-pump-action by electrical stimulation that promoted blood flow in the lower limb. Short-term effects of NMES have been reported to improve muscle microcirculation.^[15,16] It is suggested that the effect of NMES on skeletal muscle quality can be caused by the improvement in mitochondrial function, which may promote alleviation of skeletal muscle hypoxia. In particular, the belt-type electrical stimulation mobilized more muscle contraction than did the conventional pad-type electrical stimulation; it also stimulated the muscle-pump-action more effectively and obtained a blood flow promoting effect. A previous study reported that NMES at 10 Hz or lower was more effective than that at 50 Hz in suppressing mRNA expression of all fibrosis-related molecules in the soft tissue, such as hypoxia-inducible factor-1 α , transforming growth factor- β , α -smooth muscle actin, and type I/III collagen.^[17]

4.1. Strength

A strength of this study is that it showed the potential of B-SES to improve muscle flexibility. Furthermore, in this study, we compared the effects of the 2 stimulation frequencies and showed that Metabolic B-SES is more effective in improving muscle flexibility. These results provide useful information for determining appropriate stimulus conditions in the clinic, such as how to use 2 stimulation modes properly when using B-SES.

4.2. Limitations

Frequent muscle contraction by B-SES is believed to increase blood flow to the lower extremities, leading to improved flexibility. However, in this study, measurements of blood flow and muscle temperature of the lower extremities were not performed to verify this assumption. In addition, since the measurement of fibrosis-related molecules that can prevent the occurrence of muscular contracture has not been performed, it is not clear whether B-SES will actually prevent contracture. In the future, it will be necessary to verify the effects that lead to improving flexibility, such as the measurement of blood flow in the lower extremities and muscle temperature, and fibrosis-related molecules in the soft tissue.

5. Conclusion

Metabolic B-SES, which repeats twitching at a stimulation frequency of 4 Hz, was shown to be more effective in improving muscle flexibility immediately compared with Disuse B-SES, which stimulates twitching at 20 Hz. Based on the results of this study, it is necessary to further investigate the usefulness of metabolic B-SES as a strategy for preventing muscular contracture in clinical studies.

Author contributions

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