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A Novel System with EMG-controlled FES Enhanced Gait Function and Energy Expenditure for Older Adults

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Objective: This study was conducted to analyze the effect of wearable Electromyography-controlled functional electrical stimulation (EMG-controlled FES) System on Gait Function and cardiopulmonary metabolic efficiency during walking in older adults.

Design: Cross-section study

Methods: Total 22 older adult participants suitable to selection criteria of this study participated in this study. The EMG-controlled FES System, which functions as a wearable physical activity assist FES system was used. All participations performed randomly assigned two conditions (Non-FES assist [NFA], FES assist [FA]) of walking. In all conditions, spatio-temporal parameters and kinematics and kinetics parameters during walking was collected via 3D motion capture system and 6 minutes walking test (6MWT) and metabolic cost during walking and stairs climbing was collected via a portable metabolic device (COSMED K5, COSMED Srl, Roma, Italy).

Results: In Spatio-temporal parameters aspects, The EMG-controlled FES system significantly improved gait functions measurements of older adults with sarcopenia at walking in comparison to the NFA condition (P < 0.05). Hip, knee and ankle joint range of motion increased at walking in FA condition compared to the NFA condition (P < 0.05). In the FA condition, moment and ground reaction force was changed like normal gait during walking of older adults in comparison to the NFA condition (P < 0.05). The EMG-controlled FES system significantly reduced net cardiopulmonary metabolic energy cost, net energy expenditure measurement at stairs climbing (P < 0.05).

Conclusions: This study demonstrated that EMG-controlled FES is a potentially useful gait-assist system for improving gait function by making joint range of motion and moment properly.

Key Words: Aging, Assistive technology, Gait function, Metabolic energy cost

Introduction

In aging society, sarcopenia problem, which is a type of muscle loss that occurs with aging or immobility, increased in older adults worldwide [1].

Especially, sarcopenia on lower extremity can reduce gait, stairs climbing function for older adults [2]. Therefore, various training methods [3-5] are being studied to slow the progression of muscle weakness in the older adults and regular resistance exercise is the

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most effective to increase muscle strength and improve physical function in the older adults [6]. However, it is difficult to perform such high-intensity training considering to the reduced activity and cardiorespiratory capacity of the older adults [7]. Therefore, there is a need for an intervention that can replace traditional strength training and can be easily applied by anyone at home for the older adults with reduced activity.

Functional electrical stimulation is used in clinical practice and currently, it also used for musculoskeletal patients and old people to enhance their muscle by stimulating muscle as well as stimulating nerve [8]. And it preferentially acts on type 2 muscle fibers most affected by aging, helping to improve functions such as improving balance in the older adults [9]. In addition, according to previous studies, it could be seen that an alternative approach to exercise is possible by improving the exercise and cardiorespiratory abilities of patients who have difficulty in regular exercise through functional electrical stimulation [10]. Previous studies induced improvement of physical function through activation training of specific muscles in hospitals or at home, but it is being conducted in a way that can assist using functional electrical stimulation during various gait training and activities recently [11-13]. But muscle rehabilitation by using passive electrical stimulation has limitation for relation of enhancement of daily task causing muscle fatigue although it prohibits muscle from rigidity and promotes joint range of motion [14]. And it is difficult for non-experts to use and there is a limitation of the timing of electrical stimulation is not correct when performing a specific action. It is proved that a vital sign feedback based partial electrical stimulation improves upper limb's functional movement but there's limited report of effectiveness improvement of electrical stimulation for gait function [15]. EMG-controlled FES which is portable equipment developed currently, is expected that it improves daily function such as older adults' gait function, stairs climbing and it is expected to be effective for efficiency of gait and for less fatigue during gait. EMG-controlled FES version 1 which is developed and investigated in the previous study gave positive effects for muscle structure, balancing ability and gait ability when older adults walk with the system [16]. However, the appearance of this system (EMG-controlled FES version 1) was complicated with many wires and was not proved that it gives positive effects when it is used long duration [16]. Therefore, the version 2 of EMG- controlled FES which is wireless and has simple appearance is developed and this study focused on investigating if this system gives positive effects on metabolic efficiency when it is used for a long duration.

This study's purpose is to prove that the portable EMG-controlled FES improve effectively to gait function, stairs climbing, efficiency of gait for older adults who are getting weaken of their muscle for sarcopenia.

Methods

Participants

22 participants (7 male/15 female) aged between 68-82 years, who are suitable for this study were recruited. Inclusion criterion for the participants were: (1) Having no severe problem in body function (more than 7 points in SPPB). (2) Over 65 years old without central nervous system disease within 6 months. (3) More than 41 points in Berg balance scale without balance control problem. (4) Old people not taking in any drugs which affect balance or gait such as benzodiazepines, neuroleptics, antidepressants. Exclusion criterion for the participants were: (1) Visual field defect, having difficult in walking with severe muscular paralysis. (2) Having difficult in controlling adult diseases such as hyper tension, diabetes. (3) Having falling down risk with dizziness. (4) Under 26 points of mini mental state examination. (5) Having cardiopulmonary disease or anxiety of wearing a mask, claustrophobia. (6) Inappropriate person who are judged by experimenter. The selected sample size was calculated using G-power program (IBM Inc., USA). 21 people were calculated using two-tailed test and the effect size was set to 0.75, power value was set to 0.9 based on a previous study [17]. The statistical significance level was set at 0.05. Considering of the dropout rate of 20% during the course of the experiment, the number of participants was set to 25. 3 people were dropped for the exclusion criterion and finally 22 people participated until the end of the experiment and their data were analyzed. This protocol was reviewed and approved by the Institutional review

board at the Sahmyook University (IRB No. 2-7001793-AB-N-012019048HR). Written informed consent was obtained from all the subjects before they were enrolled in the study. All participants received a financial incentive (approximately US\$ 70). This study was registered with the Clinical Research Information Service (CRIS, Korea, https://cris.nih.go.kr; registration number: KCT0006099).

Procedures

This study was designed as a single group cross section study. Older adults aged 68-82 years participated in this study. This study was executed in Sahmyook University, Seoul, Republic of Korea. Total 22 participants' measurement conditions are: With EMG-controlled FES system (FA) and without EMG-controlled FES system (NFA).

To decrease error according to measurement order, the order of the two conditions and tests was randomized. The stairs used for the stairs climbing test are 4 stories high the width of one stair is 32.5cm, the height is 16cm, and the number of stairs on each floor is 18. There are 3 of 184cm long flat section between the floors. The motor points of muscles that induce the strongest contraction for each muscle which will be attached by EMG-controlled FES were found using Stim plus (DP-200, CyberMedic, Iksan, Korea) [16]. These muscles were rectus femoris, biceps femoris, tibialis anterior and medial gastrocnemius in both sides of legs. For muscle stimulation, the frequency was set to 3 Hz and pulse period was set to 10 ms [18]. Before the EMG electrodes were attached, to minimize a signal noise and impedance, the skin was shaved and rubbed by isopropyl alcohol [19]. For each muscle, two EMG electrodes were attached and one FES electrode was attached on the middle point between the two EMG electrodes. By this procedure, total eight FES electrodes and sixteen EMG electrodes were attached for each participant according to the SENIAM guideline(Table 1) [20]. After all electrodes were attached, to activate EMG-controlled FES, maximal voluntary contraction (MVC) for each participant's muscle was estimated. Evaluation MVC for the eight muscles was conducted according to the conventional methodology [21]. Subsequently, all participants walked for 5 minutes for setting their appropriate muscle contraction intensity and for their adaptation of the wearable EMG-controlled FES system. After that, functional evaluation, cardiorespiratory ability evaluation, fatigue evaluation, and gait analysis were performed through 6MWT and stairs climbing test.

EMG-controlled FES

EMG-controlled FES (Electronics and Telecommunications Research Institute, ETRI, Daejeon, Republic of Korea) is designed as a strategy for assisting older adults's gait (Figure 1). EMG-controlled FES is a biofeedback system which extracts vEMG signals which are pure signals that occurs in the muscle to which the electrode is attached by dual channel EMG signal processing algorithms and adjusts FES intensity based on signals reducing the signals made from FES electrodes even when FES signals are generated in real time [22] (Figure 2). EMG-controlled FES is consist of one FES channel and two EMG channels for each muscle and is connected to total eight muscles. vEMG estimation algorithms which remove stimulus artefact and M-wave generated from FES by dual-channel EMG spatio-temporal differential (DESTD) method utilized in detect synchronous was order to physiological activity from the brain, is defined as follows.

$$V_{V,j}(i) = (EMG_{j,1}(i) - EMG_{j-1,1}(i)) - (EMG_{j,2}(i) - EMG_{j-1,2}(i))$$
[23].

 Table 1. Location of EMG electrodes attachment

Muscle	Location of attachment
Rectus femoris	50% on the line from the anterior spina iliaca superior to the superior part of the patella
Biceps femoris	50% on the line between the ischial tuberosity and the lateral epicondyle of the tibia.
Tibialis anterior	1/3 on the line between the tip of the fibula and the tip of the medial malleolus
Medial gastrocnemius	the most prominent bulge of the muscle



Figure 1. EMG Controlled FES system



Figure 2. Real-time muscle activity-based muscle control algorithm

EMG signal was recorded using customized developed hardware from ECG / EEG analog front-end system (ADS-1299, Texas Instruments, USA, Texas). Common mode rate of elimination is 115dB and resolving power of signal is 32 bits. Sampling data was collected at 1000Hz. Raw data was band-pass (20-500Hz) filtered and 300ms root mean square sliding window function for smoothing and DESTD method. vEMG raw data measured by the algorithms was automatically filtered and appeared as %MVC and sent to FES system connected and adjust stimulus pulse proportionally to %MVC. Maximal intensity of FES was set as maximal allowed level within 10-50mA of the participant's painless range. The frequency of FES was adjust to 20-450Hz, pulse width was adjust to 250 µs and the current was adjust in real time. FES unit was manually designed by ETRI [24].

Measurements

Energy efficiency and metabolism

To investigate energy efficiency and metabolism when older adults people is walking for a long time and climbing stairs, 22 older adults people participated 6MWT and stairs test. 22 participants were divided into two groups of 11 people randomly. 11 participants conducted 6MWT first and the other 11 participants conducted stairs test first. In each test, we extracted oxygen consumption (VO₂), energy expenditure (EEm) and metabolic equivalents (METs) by K5 (Cosmed, Rome, Italy) and extracted lactate acid concentration by Lactate Pro2 (Arkray, Kyoto, Japan) [25, 26]. VO₂, METS, EEm were also collected in the two tests by K5. Before taking the test, all participants were measured their VO₂, METS, EEm wearing K5 system standing for 10 minutes to check the values in resting time. Then the values were measured during the two tests in two conditions simultaneously. For lactate acid evaluation, participants were evaluated their lactate acid concentration before taking the test. To collect lactate acid concentration, all participant's one drop of blood was taken by blood collection needle. Then Lactate Pro2 kit read the concentration of lactate acid from the blood to check in resting time. Half of total 22 participants were taken 6MWT with EMG-controlled FES on first and the other half participants were taken 6MWT with EMG-controlled FES off first. After taking 6MWT, all participant's 0.3µm of blood was collected to figure out the difference of lactate acid concentration between three conditions (resting time, 6MWT with EMG-controlled FES on, 6MWT with EMG-controlled FES off). In both conditions, one drop of blood was taken after 5 minutes after finishing the test. For washing out, there were 5 minutes rest time between two conditions (NFA and FA). Before each test, a drop of blood was taken for checking a baseline of lactate acid. Likewise, in stairs test, one drop of blood was taken before taking the test to collect the lactate acid concentration at resting time. Half of total participants were taken stairs test with EMG-controlled FES on first and the other half participants were taken stairs test with EMG-controlled FES off first to avoid affecting back and forth relationship. In both conditions, one drop of blood was taken at 5 minutes after finishing the test. For washing out, there were 5 minutes rest time between two conditions [27].

Gait kinematics

To investigate how EMG-controlled FES affects to the participants for gait kinematics, we measured spatio-temporal parameters and kinematic parameters using a 3D motion capture system with 6 infrared cameras (Motion Analysis Corporation, Santa Rosa, CA, USA, sampling frequency 120 Hz). Nineteen reflective markers in the Helen-Hayes marker set configuration were used for this study [28]. 19 markers were placed on anatomical landmarks including lower extremities, sacrum, anterior superior iliac spine [29]. In two conditions while all participants were walking on 10 m distance pulse plate, movement data were collected converting to 3D coordinates. Also, spatiotemporal parameters including cadence, step width, gait speed, stride length were calculated for each gait cycle using Ortho Track 6.5 software (Motion Analysis Corporation, Santa Rosa, CA, USA) [29].

Function evaluation

To investigate gait function, we evaluated the distances that the participants walked during 6MWT. This test is very useful for this study, considering the age of the participants and the test is commonly used in clinical practice [30]. After the participants walked at a normal speed round-trip course of 20 meters for 6 minutes, the distances that the participants walked were calculated. And the round time, gait speed was calculated in NFA and FA conditions.

Statistical analysis

A paired t-test was conducted to compare the difference according to the application of the muscular support system, a Shapiro-Wilk test was used to confirm the normality of participants' characteristics using PASW statistics 18 (SPSS, Inc., Quarry Bay, Hong Kong) statistical analysis program, and all statistical significance levels of the data were set to $\alpha < 0.05$. All data is expressed in mean (SD).

Results

Baseline participant characteristic

The baseline characteristics of the 22 older adults are summarized in Table 2. There were no significant differences between groups.

Primary Outcome: Energy efficiency and metabolism

Table 3 describes the energy efficiency and metabolism outcome for all conditions. FA significantly lowered net cardiopulmonary metabolic energy cost over ground and stairs compared to NFA (P < 0.05). In stairs climbing task, net energy expenditure measurement was significantly lowered in FA compared to NFA (P < 0.05). There was a significant difference in the

Table 2. Characteristics of Participants

Values are presented as number or mean(SD)

Table 3. Cardiopulmonary Metabolic Energy Cost

Without EMG-controlled FES system With EMG-controlled FES system Variable (FA) (NFA) MEC over ground 11.01 (0.51)* 11.53 (0.58)* $(ml \cdot kg^{-1} \cdot min^{-1})$ MEC stairs(ml·kg⁻¹·min⁻¹) $11.84(0.71)^*$ $10.86(0.27)^*$ EEm over ground (kcal/min) 3.20 (0.11) 3.37 (0.21) 3.31 (0.15)* 3.59 (0.22)* EEm stairs(kcal/min) Total lactate acid (mmol/l) 5.35 (2.32) 6.17 (3.33) Lactate acid over ground (mmol/l) 4.51 (2.10) 3.73 (1.08) Lactate acid stairs (mmol/l) 5.86 (2.81) 7.68 (3.84)

Abbreviation: MEC: Net Cardiopulmonary Metabolic Energy Cost,

EEm: Net Energy Expenditure Measurement, Mcot : Metabolic cost of transport

Values are presented as mean (SD), *p < 0.05

metabolic cost of transport between FA and NFA (P < 0.05).

Secondary Outcome: Gait kinematics and function evaluation

Table 4 describes the gait kinematics outcome and

Table 5 describes the function evaluation outcome for all conditions. There was a statistically significant difference in the gait speed according to the application of EMG-controlled FES (P < 0.05). There was also a significant difference between the two conditions in distance, round time as outcomes of 6MWT (P < 0.05).

Table 4. Spatio-temporal Parameters

Variable	With EMG-controlled FES system (FA)	Without EMG-controlled FES system (NFA)
Gait speed (cm/s)	111.40 (12.98)*	98.45 (12.66)*
Cadence (step/min)	114.66 (10.83)	105.87 (10.37)
Stride length (cm)	115.81 (11.93)	111.47 (9.93)
Step width (cm)	14.63 (2.44)	15.30 (2.55)

Values are presented as mean (SD), p < 0.05

(N = 22)

(N = 22)

(N = 22)

Table 5. Functional Evaluation	(N=22)	
Variable	With EMG-controlled FES system (FA)	Without EMG-controlled FES system (NFA)
Distance (m)	394.53 (45.86) [*]	379.90 (45.75) [*]
Round time (sec)	18.66 (2.29)*	19.30 (2.41)*
Gait Speed (m/s)	$1.09 (0.10)^*$	$1.04 (0.14)^{*}$

Values are presented as mean (SD), *p < 0.05

Discussion

The purpose of this study was to investigate the effect of wearable EMG-controlled FES system on gait function and cardiopulmonary metabolic efficiency during walking in older adults. The results show that the application of the EMG-controlled FES system significantly improved the gait speed of the older adults. Gait speed and cadence are important factors in evaluating the dynamic balance and functional activity of the older adults [31]. And although it was not statistically significant, the cadence and the stride length of the older adults increased when EMG-controlled FES system was used. Likewise, although it is not a statistically significant difference, when EMG-controlled FES system was used, the step width decreased during walking of the older adults. these results, we concluded Based on that EMG-controlled FES system can improve the walking ability of the older adults.

Cardiopulmonary metabolic energy expenditure is a representative indicator of walking efficiency [32, 33]. Net cardiopulmonary metabolic energy cost is the net metabolic energy cost by subtracting the energy cost of resting in a standing position from the energy cost for performing a specific task.

A statistically significant reduction in cardiopu-Imonary metabolic energy cost in the older adults was shown with EMG-controlled FES assisted when climbing stairs. Energy cost consumed during 6MWT over ground did not show a significant difference depending on whether or not the EMG-controlled FES system was applied, but energy cost decreased similarly to stairs climbing. Moreover, although not described in the results section, as a result of 3D motion analysis, the FA group showed a tendency to

walk symmetrically compared to the NFA group during walking over ground. A previous study demonstrated that symmetric walking is preferred because gait symmetry in healthy adults is energetically optimized [34]. The net energy expenditure measurement is calculated as 3.781*VO₂+ 1.237*VCO₂, which is the value of energy consumed when performing tasks minus energy consumed when resting in a standing position. We concluded that the net energy expenditure is significantly reduced by using EMG-controlled FES when climbing stairs in older adults. However, there was no significant difference between NFA and FA group, but the energy expenditure decreased in FA group. The walking distance was statistically significantly increased when EMG-controlled FES system was applied during 6 minutes walking. In addition, the time taken per 1 lap (20m) was also statistically significantly reduced when the system was applied. When the walking speed was calculated based on the results of the 6MWT, the walking speed of the older adults was statistically significantly increased when EMG-controlled FES system was applied. A previous study demonstrated that spatiotemporal gait functions and fall-related self-efficacy were associated with each other [35, 36]. Metabolic cost between transfers is a value obtained by dividing the amount of oxygen consumed during walking by the subject's weight and distance walked, and is used as an indicator of walking efficiency and cardiopulmonary health in the older adults [37]. We suggest that it is better using EMG-controlled FES system for walking efficiency in older adults because there is a significant reduction in the metabolic cost between transferring in the older adults using EMG-controlled FES system. Blood lactate concentration is an indicator that can check the amount of fatigue secreted through metabolism during task performance. There was no statistically significant difference with or without EMG-controlled FES system, but it showed a decreasing pattern as the system was applied. However, when walking over ground using the system, the lactate concentration increased rather decreased. We concluded that it is because in some subjects, it occurred immediately after performing the stairs climbing at the beginning of the study without sufficient resting time. But the lactate concentration decreased when using EMG-controlled FES system during stairs climbing in older adults. In high-intensity exercise that requires much energy, when the production rate of pyruvic acid and nicotinamide adenine dinucleotide (NADH) exceeds the oxidative metabolic capacity, lactic acid begins to accumulate and as the exercise intensity increases, the accumulated lactic acid content increases [38]. A previous study found that when cycling exercise was performed at low intensity, medium intensity, high intensity, and maximum intensity, it demonstrated that the higher the exercise intensity, the greater the increase rate of blood lactate [39]. In this study, it is considered that the lactate concentration was higher during stair climbing because this task requires higher exercise intensity than flat ground walking. FA group showed a tendency to decrease the lactate concentration during stair climbing, which requires greater muscle strength in the low extremities than in flat ground. We suggest that the EMG-controlled FES system assists to use the energy more efficiently in the stairs.

The population of old people is increasing and medical expense is increasing rapidly simultaneously [40]. According to this situation, healthcare industry focus point is changed from treatment of disease to health lifespan. Under the name of fourth industrial revolution, amalgamation between information technology and other industry is activated and related market is becoming huge. Many healthcare supplies for old people are developed FES system [41-45]. The EMG-controlled FES system which is used in this study is also being developed for supplying for old people's body function. All 22 participants in this study did not experience any side effects when using the EMG-controlled FES system. This means that walking over ground and stair climbing using EMG-controlled FES system is safe and does not pose a risk to the older adults.

Through this study, optimum EMG-controlled FES system can be developed by finding the algorithm's problem and complementary points when EMG-controlled FES system is adjusted to old people. In the end, based on the result of this study, if the healthcare technology which can contribute to personal customized health care for old people, we can expect clinical welfare improvement and health life span enhancement, furthermore, decrease of total medical expenses. The limitations of this study were: First, because the number of subjects is statistically small, it is difficult to generalize the participants in this study to all the older adults. Second, for further study, to find the optimum stimulated place, it is needed to study for comparing in between 8, 6, 4 and 2 channels of EMG-controlled FES. Improvement of the quality of material of the equipment for better wearability according to the results of user evaluation is needed. In the sense that not only lower extremity muscles affect gait but also trunk muscles stability in body structure, a study for the EMG-controlled FES equipment for applying to trunk muscles is also needed.

Conclusion

The number of the older adults suffering from sarcopenia increases due to an aging society. In particular, sarcopenia of the lower extremities lowers the quality of daily activities such as walking in the older adults. The EMG-controlled FES system was designed to assist the older adults with walking. However, to verify if the energy efficiency during walking would decrease with EMG-controlled FES due to muscle fatigue caused by wearing FES equipment for a long time, this study focused it as the main point. It is suggested that EMG-controlled FES is effective on energy efficiency and walking speed when walking on flat ground or climbing stairs. This study would be useful to develop a FES-based walking assistance system or to study a clinical approaching and further study is needed to verify the effectiveness of the system in other target groups.

Conflict of Interest

The authors declare no conflict of interest.

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