The effect of gait training with an elastic ankle-foot orthosis on balance and walking ability of persons with chronic stroke: a randomized controlled trial

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Objective: The purpose of this study was to investigate the effect of treadmill exercise on the posture and walking speed of chronic stroke survivors with an ankle-foot orthosis.
Design: Randomized controlled trial.
Methods: Twenty-four chronic persons with chronic stroke admitted to Bobath Memorial Hospital in Seongnam city were divided into two groups by random blind method. Treadmill exercise with an elastic ankle-foot orthosis was performed in the experimental group and treadmill exercise was performed in the control group. The experiment was carried out for 6 weeks, and the experiment was carried out three times a week for 20 minutes per session. To measure the effect, static balance was measured using the MTD system before and after training, and the Berg Balance Scale (BBS) was used to measure functional balance.
Results: There was a statistically significant difference between the 2 groups in the BBS measurement results for confirming the functional balance ($p<0.05$). Also, there was a significant difference between the 2 groups in single limb support time, step time and step length ($p<0.05$).
Conclusions: In this study, it was found that treadmill exercise with an elastic ankle-foot orthosis in persons with chronic stroke was effective in maintaining functional balance, walking ability, step length, and step time. Therefore, it is necessary to use a flexible ankle-foot orthosis with proper treadmill exercise as a method of improving balance and walking speed of chronic stroke survivors.

Key Words: Orthosis, Posture, Stroke, Walking speed

Introduction

Stroke is a disease in which blood supply to the brain is blocked due to a cause such as heart disease or cerebrovascular disease, or a disorder that causes bleeding in the brain tissue. When individuals experience a stroke, 9% of them are likely to recover to their original state, and 73% of them will experience impairment in movement, language, sensation, and cognition, depending on where the lesion occurred in the brain, even if recovery is possible [1,2].

Postural stability, which is a necessary ability to maintain the body's center of mass and to complete purposeful movement, is decreased causing balance deterioration in stroke survivors, which is a common problem. Unbalanced mobilization of muscles on the affected side causes postural instability and increased postural fluctuations, which increases the risk of falls and may cause death [3]. Balance is the process of maintaining postural stability, which consists of static balance, which is the ability to keep the center of the body static at the base, and dynamic balance, which is the

ability to maintain the center of the body on the base surface that moves when movement occurs [4]. Balance in a standing position is closely related to weight transfer ability, which is essential for functional mobility and daily activities [5].

After the onset of stroke, 50% of survivors have hemiplegic symptoms and may cause impairment of gait patterns. Patients with hemiplegia due to stroke may experience calf muscle spasms, decreased range of motion of the ankle joint, and contracture of the ankle joint due to a lack of long-term motor control [6]. Due to such a cause, the affected leg is in contact with the ground more than usual with the toe or forefoot while the heel rarely touches the ground [7]. In addition, the reduction in ankle dorsiflexion during swing phase increases the resistance in the foot and increases the compensation strategy of the limbs on the unaffected side, causing a change in stride length during walking [8]. Such a deviation during walking affects functional gait where the support of the affected leg is reduced, the step length is shortened, and the walking speed decreases. Furthermore, it leads to excessive consumption of energy when walking [9].

Gait characteristics of stroke survivors are asymmetry, broadened basal surface, shortened step length, excessive extension of the knee joint and impaired ankle control [10]. These gait problems directly or indirectly cause problems with the musculoskeletal system by decreasing movement and increasing the time spent in bed [11]. The factors that interfere with the gait of persons affected by stroke are ankle drop caused by a decrease in dorsiflexion and a synergistic pattern rather than selective flexor and extensor action, and ankle stiffness and loss of proprioceptive sensation [12].

Research has been conducted to improve balance and walking ability by improving the affected area caused by stroke. The improvement of balance and gait ability was promoted through the enhancement of proprioceptive sensation of the ankle joint [13], and a study on gait and postural balance after stroke was conducted through training that combined virtual reality and treadmill exercise [14]. In addition, there were interventions that improved gait and balance in individuals with stroke by treating the ankle joint through the traditional Bobath treatment [15].

Among various braces available for individuals affected by stroke, the ankle-foot orthosis (AFO) is widely used [16]. The orthosis prevents foot drop during the initial stance and swing phase when walking, and assists in producing slight ankle dorsiflexion. Also, it is widely used for its advantages such as preventing plantar flexion at the ankle and providing stability when varus occurs at the ankle joint [17]. However, when using a plastic brace for a long period of time it limits the movement of the ankle joint and restricts the movement in the calf area, which can lead to muscle shortening or joint contracture [18]. Since the orthosis is bulky and is used by direct contact with the lower extremities, it is not comfortable to wear. Also, if patients want to wear shoes with a plastic AFO, patients have to purchase shoes that are larger than their actual feet [19]. The AFO was first introduced in 1967 and has been used continuously until now, but it does not reflect the changing needs of the current stroke population. Therefore, an AFO that considers the needs of patients is necessary. Elastic ankle-foot orthosis that complement the shortcomings of these plastic ankle-foot orthosis and reflect the needs of users are being introduced. The elastic ankle-foot orthosis does not require the hassle of putting on and taking off shoes when removing the orthosis compared to plastic orthosis, and additional purchase of shoes is unnecessary. In addition, by adjusting the length of the strap of the product, the length can be adjusted according to the patient's condition, and the calf or sole of the foot is open to provide sufficient sensory stimulation to the soles of the patients.

However, there are not enough studies to confirm the effect of elastic AFO in chronic stroke survivors. Therefore, this study aimed to investigate the effect of gait training using an elastic AFO for the purpose of improving balance and gait in persons with chronic stroke.

Methods

Participants

This study was conducted on 24 subjects with chronic stroke who were hospitalized in Bobath Memorial Hospital, located in Seongnam, Korea. All 24 subjects were randomly and equally divided into the experimental group or the the control group. This study was approved by the Institutional Review Board of Sahmyook University (2-7001793-AB-N-012018087HR). The inclusion criteria were: able to understand the experimental method, no orthopedic problems, able to walk 10 m independently, a score of 24 or more on the Korea version Mini Mental State Examination, chronic patients 6 months after onset, and those who signed the consent form.

Experimental procedure and method

All study subjects were pre-tested 3 days before the ex-

periment, and a post-test was performed the day after the 6-week experiment was completed. The pre- and post-tests evaluated the patient's balance ability and gait. This study randomly classified 24 subjects who met the selection criteria into 12 experimental group subjects with an elastic AFO and 12 control subjects without them. The experimental group performed treadmill exercises while wearing an elastic AFO, 3 times a week for 6 weeks, and 20 minutes each time. The control group performed treadmill exercises with the same application method without wearing an elastic AFO. There were no dropouts during the experiment.

Ankle-foot orthosis

The elastic ankle-foot orthosis (AOBO, Harbin, China, 2017) is made of permeable cloth, sponge, plastic strips, and nylon adhesive tape. Unlike the existing ankle orthosis, the sole of the foot adopts an open design to maximize the sensory input to the sole required for rehabilitation, and is attached to the outside of the shoe, making it easy to attach and detach. The important thing in wearing the orthosis is the control of the ankle angle. Overtightening the strap or tying it too loosely can reduce the effect as it does not provide a sense of stability for the ankle. To wear the orthosis, the ankle angle was fixed in approximately 10° of dorsiflexion and 7° of external rotation.

Treadmill walking exercise

The treadmill was allowed to proceed at a speed of 0.5 Km/h without a change in speed and slope for the patient's stability. For the safety of the subject, when the subject complained of symptoms such as headache, dizziness, and shortness of breath during treatment, the intensity was reduced or a break was taken until the symptoms disappeared.

Measurement of static balance

The static balance test was performed using the MTD-Balance (Measurement Training and Documentation-Balance system; MTD Systems, Neunburg vorm Wald, Germany). It is a tool that measures postural sway through the weight-bearing amount given to both feet. As a measuring tool, it can measure both static and dynamic balance. The subject stood on a force plate during the measurement so that the patient's gaze was directed to the front, and the subject did not see the monitor, thereby receiving no visual feedback. The subjects performed this for 10 seconds while moving their weight to the affected side on the force plate, and the average

value was obtained from three measurements.

Measurement of dynamic balance

The dynamic balance test was performed using the Berg Balance Scale (BBS). The BBS test is a test method that measures the patient's balance ability, and consists of a total of 14 items. The composition was largely composed of three areas: sitting, standing, and posture change, and applied from a minimum of 0 points to a maximum of 4 points, and the total score for 14 items is 56 points. The intra-rater reliability is 0.99, and the inter-rater reliability is 0.99 [20].

Measurement of gait

The GAITRite (GAITRite, Franklin, NJ, USA, 2008) was used to analyze the spatiotemporal variables during the stance phase and the swing phase of the subjects' gait. GAITRrite, which is used to measure the spatio-temporal factors according to gait using a software manufactured by GAITRite. The gait was measured three times and the average value was calculated. The spatiotemporal variables of the stance phase and the swing phase included gait speed, cadence, step length, stride length, stance time, and swing time.

Data Analysis

Data were statistically analyzed with SPSS for Windows Version 23.0 (IBM Co., Armonk, NY, USA). The participants' general characteristics were analyzed using the chi-square test. The Shapiro-Wilk test was used to verify the normality of the data. The changes in balance and gait after intervention in the 2 groups were compared with the paired t-test. Differences between the 2 groups were analyzed with the independent t-test. Statistical significance was set at α =0.05.

Results

General characteristics of the participants

There were twenty-four subjects in this study. The general characteristics of the experimental group and the control group showed no difference between the variables between the 2 groups. The subject' demographic characteristics are shown in Table 1.

Comparison of balance before and after wearing elastic ankle-foot orthosis

In the BBS test to confirm for changes in functional bal-

ance ability in the experimental group wearing a orthosis, the score increased from 43.83±6.23 before the experiment to 49.91±5.35 after 6 weeks of the experiment, showing a statistically significant difference ($p<0.05$). The functional balance ability in the control group without a orthosis showed a numerical increase from 42.91±4.25 before the experiment to 43.33±3.77 after the experiment, but it was not statistically significant. After the experiment, there was a significant difference between the 2 groups ($p<0.05$).

The test result in the static balance test increased from 70.75±14.48 before the experiment to 74.16±13.46 after the experiment in the experimental group when looking at the weight shift value toward the affected side, showing a statistically significant difference ($p<0.05$). In the control group, static balance increased from 65.91±16.48 before the experiment to 66.66±16.45 after the experiment, which was statistically significant. After the experiment, there was no significant difference between the 2 groups. The changes in balance ability improvement before and after the elastic AFO is worn are as follows in Table 2.

Comparison of gait before and after wearing an elastic ankle-foot orthosis

The single limb support time changed from 0.36±0.04 before the experiment to 0.47±0.1 after the experiment, and there was a statistically significant difference within the group ($p<0.05$). The control group showed no numerical difference from 0.33±0.07 before the experiment to 0.32±0.07 after the experiment, and there was no statistically significant difference within the group. After the experiment, there was a significant difference in the amount of change in the single limb support time between the 2 groups ($p<0.05$).

In the double limb support time, the experimental group showed a change in numerical value from 0.60±0.19 before the experiment to 0.50±0.17 after the experiment, and there was a significant difference within the group ($p<0.05$). The control group showed a change in numerical value from 0.61±0.32 before the experiment to 0.51±0.26 after the experiment, and there was a significant difference within the group ($p<0.05$). There was no significant difference between the 2 groups after the experiment.

For step time, the experimental group showed a change in numerical value from 0.84±0.19 before the experiment to 0.56±0.11 after the experiment, showing a statistically significant difference within the group ($p<0.05$). The control group showed a numerical change from 0.86±0.26 before the experiment to 0.84±0.3 after the experiment, but there was no statistically significant difference within the group. After the experiment, there was a significant difference in the amount of change over time in steps between the 2 groups ($p<0.05$).

In the experimental group, the step length changed nu-

Table 1. General characteristics of subjects (N=24)

Parameters	Experimental group (n=12)	Control group (n=12)
Age (y)	49.83 (7.42)	52.41 (5.29)
Sex (male/female)	6/6	6/6
Height (cm)	168.16 (4.13)	169.16 (5.57)
Weight (kg)	68.58 (8.52)	67.66 (6.98)

Values are presented as number only or mean (SD).

Table 2. Changes in balance before and after treatment (N=24)

Parameters	Experimental group (n=12)	Control group (n=12)	t (p)
BBS (score)			
Pre	49.83 (6.23)	42.91 (4.25)	
Post	49.91 (5.35)	43.33 (3.77)	
Difference	6.08 (4.39)	0.41 (0.66)	−3.48 (0.002)
t (p)	−4.79 (0.001)	−2.15 (0.054)	
MTD (%)			
Pre	70.75 (14.48)	65.91 (16.48)	
Post	74.16 (13.46)	66.66 (16.45)	
Difference	3.41 (4.94)	0.75 (0.62)	−1.22 (0.235)
t (p)	−2.39 (0.036)	−4.18 (0.002)	

Values are presented as mean (SD).
BBS: Berg Balance Scale, MTD: measurement training and documentation-balance system.

merically from 37.4±7.0 before the experiment to 43.8±7.4 after the experiment, and there was a statistically significant difference within the group ($p<0.05$). The control group had a numerical change from 32.3±11.1 before the experiment to 33.4±10.4 after the experiment, but there was no statistically significant difference within the group. After the experiment, there was a significant difference in the amount of change in step length between the 2 groups ($p<0.05$).

In the experimental group, the stride length changed numerically from 82.27±23.62 before the experiment to 91.20±24.80 after the experiment, and showed a significant difference within the group ($p<0.05$). The control group showed a change in numerical value from 64.03±19.64 before the experiment to 72.71±17.85 after the experiment, and there was a significant difference within the group ($p<0.05$). After the experiment, the amount of change in stride length between the 2 groups was significant ($p<0.05$).

Gait speed changed in numerical value from 40.94±8.47 before the experiment to 48.22±11.39 after the experiment in the experimental group, and showed a significant difference within the group ($p<0.05$). The control group showed a change in numerical value from 44.00±13.37 before the experiment to 47.46±14.70 after the experiment, and there was a significant difference within the group ($p<0.05$). After the

Table 3. Changes in gait before and after treatment (N=24)

Parameters	Experimental group (n=12)	Control group (n=12)	t (*p*)
Gait speed (cm/s)			
pre	40.94 (8.47)	44.00 (13.37)	
post	48.22 (11.39)	47.46 (14.70)	
difference	7.28 (9.51)	3.45 (3.00)	−0.14 (0.889)
t (*p*)	−2.65 (0.022)	−3.99 (0.002)	
Cadence (steps/min)			
pre	80.53 (15.60)	68.88 (21.57)	
post	84.71 (17.37)	74.50 (18.85)	
difference	4.18 (3.32)	5.16 (5.57)	−1.38 (0.181)
t (*p*)	−4.36 (0.005)	−3.49 (0.005)	
Stride length (cm)			
pre	82.27 (23.62)	64.03 (19.64)	
post	91.20 (24.80)	72.71 (17.85)	
difference	8.91 (8.97)	8.68 (6.71)	−2.09 (0.048)
t (*p*)	−3.44 (0.005)	−4.48 (0.001)	
Double-limb support (s)			
pre	0.60 (0.19)	0.61 (0.32)	
post	0.50 (0.17)	0.51 (0.26)	
difference	−0.09 (0.04)	−0.10 (0.07)	0.04 (0.946)
t (*p*)	8.07 (<0.001)	4.41 (0.001)	
Single-limb support (s)			
pre	0.36 (0.04)	0.33 (0.07)	
post	0.47 (0.10)	0.32 (0.07)	
difference	0.11 (0.08)	−0.00 (0.03)	−3.99 (0.001)
t (*p*)	−4.56 (0.001)	0.64 (0.530)	
Step time (s)			
pre	0.84 (0.19)	0.86 (0.26)	
post	0.56 (0.11)	0.84 (0.30)	
difference	−0.28 (0.14)	−0.02 (0.08)	2.94 (0.007)
t (*p*)	6.95 (<0.001)	0.90 (0.387)	
Step length (cm)			
pre	37.40 (7.00)	32.30 (11.10)	
post	43.80 (7.40)	33.40 (10.40)	
difference	6.35 (2.76)	1.11 (9.28)	−2.80 (0.010)
t (*p*)	−7.94 (<0.001)	−0.41 (0.685)	

Values are presented as mean (SD).

experiment, there was no significant difference in the amount of change in gait speed between the 2 groups.

In the experimental group, the cadence changed in numerical value from 80.53±15.60 before the experiment to 84.71±17.37 after the experiment, showing a significant difference within the group ($p<0.05$). The control group showed a change in numerical value from 68.88±21.57 before the experiment to 74.50±18.85 after the experiment, and there was a significant difference within the group ($p<0.05$). After the experiment, there was no significant difference in the amount of change in cadence between the 2 groups. The amount of change in gait before and after wearing the elastic AFO is as follows in Table 3.

Discussion

This study investigated the effect of using an elastic AFO on the improvement of walking ability and balance in persons with stroke. As a result, there was a significant effect on weight transfer and dynamic balance on the affected side in the experimental group. For gait ability, there were significant effects in walking speed, cadence, stride length, double limb support, short limb support time, step length and step time. In the control group, there were significant effects in walking speed, cadence, stride length, and double limb support time.

Balance can be divided into static balance and dynamic balance [21]. Impairment of balance after stroke is one of the major causes of impaired motor function [22]. Patients with post-stroke hemiplegia suffer from changes in posture, asymmetrical weight distribution, decreased weight transfer and postural retention [23]. The causes of loss of balance can be divided into decreased proprioceptive sensation, muscle weakness, decreased joint movement, and decreased visual and perceptual ability [24]. The decrease in balance control ability of patients with hemiplegia increased by approximately twice as much as the body agitation in the static posture and the limit of stability decreased compared to healthy persons of the same age [24]. The stability of the ankle joint is said to play an important role in weight transfer [25].

In this study, it was found that the static balance ability was improved in both the control and experimental groups. According to the previous study, after wearing the AFO, the weight transfer ability to the affected side improved because of providing external stability to the ankle joint through the AFO [4]. According to a study by Chen *et al*. [26], as a result of measuring the postural sway index and postural stability in standing position with an AFO, there was no significant difference in postural sway index, but there was a significant difference in postural stability.

In this study, the dynamic balance ability was significantly different in comparison between the experimental and control groups. As a result of measuring balance ability under various situations with an AFO, the ankle joint strategy was used instead of the hip joint strategy. There was a significant effect found in dynamic stability [26]. In a study by Simons *et al*. [27], BBS, which measures dynamic balance, showed a significant increase after wearing an AFO. Cakar *et al*. [28] also showed a significant increase in BBS, FRT, and PST values after wearing an AFO and improved overall balance.

This study proved to be consistent with the results of previous studies, which means that treadmill exercise with an elastic AFO is effective in increasing the static and dynamic balance ability of stroke survivors. The ankle joint strategy and the hip joint strategy are used to keep the COG within the stability limits. Ankle joint strategy requires movement and stability at the ankle. Limited ankle movement or loss of balance results in the use of hip joint strategies [26]. The use of an elastic orthosis allows patients to freely adjust the angle of the ankle. Since the heel is open, more sensations coming from the ground can be transmitted to the upper nervous system, thus contributing more to stability at the ankle. In addition, if ankle stability increases, the range of motion at the ankle also increases. For this reason, treadmill training with an AFO has a significant effect on weight transfer ability and dynamic balance ability.

Most individuals with stroke face many limitations due to walking problems in their daily activities [29]. Movements such as heel strike and toe off are difficult to exhibit in walking after a stroke because weight-shifting ability and ankle stability has decreased [30]. To solve these problems, using an AFO is one solution that provides stability to the ankle joint and improves toe off ability, which is helpful for improving walking ability [31].

In this study, as a result of evaluating walking ability, the walking speed, cadence, stride length, double limb support time, single limb support time, step time, and the step length significantly improved before and after the experiment in the experimental group. According to previous studies, the use of plastic AFO showed an increase in walking speed, cadence, step length, and decreased step and double limb support time [7]. When an individual affected by stroke walked while wearing an AFO, the walking speed, stride length, and

cadence increased [32]. As a result of wearing the AFO in persons affected by stroke, the stride length, step length and gait speed were significantly improved compared to those without the AFO [33]. In addition, in the study of traditional plastic AFO and AFO with an adjustable joint angle, the AFO with adjustable joint angle was more helpful with producing ankle dorsiflexion and exhibitied a more significant difference in swing phase [34]. The elastic AFO used in this study is designed to provide stability to the joint and adjust the angle of the ankle to assist with ankle dorsiflexion. By enhancing ankle stability in the single limb support period, the walking ability was improved due to the significant difference in the step length and the single limb support time. Compared to these advantages, it can be considered that treadmill exercise with an elastic AFO assists to improve walking speed.

As this study was conducted on only a few patients who were admitted to the Bobath Memorial Hospital in Seongnam, the number of subjects was small which was difficult to control the time outside of participation in the experiment. Therefore, there is a limitation in generalizing the results of this study to all adult patients with stroke. Also, since no comparison with traditional plastic orthosis has been made, the effectiveness of elastic compared to plastic orthosis has not been proven. Lastly, since the experiment environment was conducted in a limited environment such as a treadmill, a comparison between indoors and outdoors was not made, which requires verification.

As a result of the study, it was found that treadmill exercise with an elastic AFO significantly improved balance and walking ability in chronic stroke survivors. Therefore, it is possible to propose a treadmill exercise with an elastic AFO when training for walking ability and balance of individuals with chronic stroke. Compared to AFO, accessibility is more effective in terms of cost and convenience of wearing. In rehabilitation, it has the advantage of inducing voluntary ankle dorsiflexion through muscle contraction by using an elastic AFO rather than inducing dorsiflexion through electrical stimulation.

Conflict of Interest

The authors declared no potential conflicts of interest with respect to the authorship and/or publication of this article.

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