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Effects of Removable Ankle-Foot Orthosis in Chronic Patients With Hemiplegia During Gait Training: A Pilot Study

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Abstract

This study was conducted to investigate the effects of the removable ankle-foot orthosis (RAFO) which was developed to improve the gait of stroke patients. The subjects of this study were five stroke patients who agreed to participate in this study by signing a written consent form. To verify gait improvement after wearing the orthosis, a Timed Up and Go test and Functional Gait Assessment were performed, and spatiotemporal gait variables such as gait speed, cadence, stride length, double limb support, and the efficient gait test of body sway angle were performed. For every variable, the differences prior to and after wearing the RAFO were compared using the Wilcoxon signed-rank test. Every gait variable improved significantly after wearing the RAFO compared to prior to wearing it. The pilot study will enhance future efforts to evaluate orthotic function objectively during gait in stroke patients.

Key Words: Gait; Removable ankle-foot orthosis; Stroke.

Introduction

One of the most important problems in stroke patients is gait disturbance. Treatments focus on the recovery of gait through rehabilitation, as gait recovery is essential for the patient to work and live independently at home (Zachzewski et al, 1982). The minimum gait speed required for activities of daily living in local communities is .42 ㎧ (Fulk and Echternach, 2008); a gait speed of .4 ㎧ or lower enables gait in indoor space; a gait speed of .4∼.8 ㎧ enables gait in limited activities of daily living (ADL); and a gait speed above .8 ㎧ enables independent ADL (Taylor et al, 2006; van de Port et al, 2008). The gait speed of healthy elderly people is approximately 1.4 ㎧, which is in the 1.07 ㎧∼1.22 ㎧ range and is sufficient for crossing a road safely. However, stroke patients who can walk typically have a gait speed of .18 ㎧∼1.03 ㎧, depending on the degree of disability, which is insufficient for ADL and work life (Kirschbaum et al, 2001). Because it takes a long time to reeducate stroke patients to improve their gait ability, mediation for gait optimization is required for them to return to ADL and work, and the use of proper gait equipment for the body is critical (Yang et al, 2007).

To improve abnormal gait patterns of patients, Ankle-Foot Orthoses (AFOs) are used (Lehmann et al, 1983; Ofir and Sell, 1980). AFO prevents hyper inversion of ankle joints during walking and in the stance phase it helps moving the body from posterior to anterior on sagittal plane, and to correct toe off appropriately. During the swing phase it is reported that there is effective correcting foot drop and instability of ankle movement between lateral and medial (O'Sullivan and Schmitz, 2007). However plastic AFO that is widely used recently (Tyson and Thornton, 2001) can limit the movement of the ankle on all planes and it is not possible for normal pattern of walking (Lee, 2001) and long-term use can cause muscle shortening by limiting movement in all areas of the feet and calves due to external move-

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ment limitation (Boehme, 1991).

Plastic AFO has been used on many stroke patients after its introduction in 1967 (Lim et al, 2004) but because it is not able to reflect the life environment changes of stroke patients or requirements of patients that use and need AFO, there needs to be development and research for a new form or material for orthosis that improves these elements (Jo, 2013).

The recently developed Removable Ankle-Foot Orthosis (RAFO) improves appearance, is easy to use, and is inexpensive, as it attaches to the ankle using a strap and velcro and can be attached to all types of shoes (FootScientific, 2013). Furthermore, it is excellent in restricting movement on the coronal plane of the ankle joint which is the main cause of trauma and fall; it allows free adjustment of the ankle angle on the sagittal plane; and it can prevent secondary complications due to the limitation of movement, because it allows partial movement of the ankle joint.

Up to now there have been various reports about gait improvement of AFO apart from plastic AFO. Youn (2013) reported that UD-Flex which supplemented the shortcomings of previous Posterior Leaf Spring AFO increased the gait speed of stroke patients. In a research that used Elastic Band Orthosis on stroke patients, Daher et al (2013) reported that after wearing the device, the gait speed significantly increased from .20 ㎧ to .22 ㎧. Also in the research about efficiency of Removable Elastic AFO reported by Lee and Byun (2005) which had the closest form to the orthosis in this study, the 10 m walking test increased significantly from 59.4 sec to 39.1 sec and cadence increased significantly from 59.4 steps to 69.3 steps. The RAFO used in the study is a product that does not yet have proof of gait function improvement in stroke patients and compared to RAFO products that cover all of the feet and ankles is a new form of orthosis that uses velcro and hooks to provide convenience of usage where it can be worn on all kinds of shoes. It cannot be confirmed that this has superior improvement of gait function compared to other products. Therefore in the future to study tries to conduct a pilot study about gait variables for the purpose of suggesting the possibility of gait function improvement of stroke patients with this RAFO and to widen the range of user product selection.

Methods

This study was conducted in the form of a pilot study to suggest the possibility of gait improvement with the newly developed RAFO. Five stroke patients (three males and two females) receiving physiotherapy in R hospital in Seoul were included in this study. All of the subjects were diagnosed with hemiplegia due to stroke, and they had been receiving rehabilitation continuously after the diagnosis. Details of the subjects are provided in Table 1. Every subject exhibited a gait speed slower than the range that enables safe ADL and a drop foot gait pattern, in which the front part of the foot touches the ground first during initial contact. Due to this phenomenon, their gait time increases on an inclined surface and they are exposed to the risks of ankle

Table 1. General characteristics of the subjects

	Sex	Age (year)	Height (㎝)	Weight (㎏)	Affected side	Onset (month)
S1[a]	M	43	173.4	80.1	Left	16
S2	M	57	168.5	67.1	Left	19
S3	F	77	159.1	52.6	Left	11
S4	M	36	183.3	103.4	Left	21
S5	F	62	153.7	48.2	Right	27

[a]subject.

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injuries and falling.

The RAFO used for the subjects in this study was the Elevate Drop Foot Brace (Elevate Drop Foot Brace, FootMind Inc., Utah, USA), an external type that attaches to the outside of shoes. It is consist of follow component. A waterproof synthetic rubber strap (Hypalon®, E.I. du Pont de Nemours and Company, Wilmington, USA) wraps around the ankle, and both ends of the strap can be fixed with velcro. A buckle (Boa®, Boa Technology Inc., Colorado, USA) is attached to the strap. The pair of shoes is interconnected with a string made with the Spectra cord technique (Spectra® cord, Honeywell International Inc., Arizona, USA), and there is a stainless steel hook to connect to the shoes (Figure 1). For sneakers, the hook is inserted through the foremost shoestring hole or through a hole made at the one-third point above the metatarsal bone of the foot (Figure 2, 3). The dorsiflexion angle of the ankle can be adjusted by changing the string length through the Boa buckle attached to the strap. In this study, for experimental consistency with the existing AFO, the ankle joint was set to 0° at the mid position.

To examine the differences in gait prior to and after wearing the RAFO, the following measurements were made. First, a Timed Up and Go (TUG) test was conducted. The time necessary for the subject to rise from sitting in a chair with armrests, walking for a 3 m distance, turning at the halfway point with the less affected side, and returning to and sitting in the chair again was measured. The intra-rater reliability and inter-rater reliability of this test in stroke patients were r=.99 and r=.98, respectively (Podsiadlo and Richardson, 1991).

Next, the Functional Gait Assessment (FGA) was performed. This test, which consists of ten items, is based on a four-point scale (0~3 points) for each item, with a maximum possible total score of 30 points and a minimum possible score of 0 points. This test has exhibited high reliability in stroke patients, with an intra-rater reliability of r=.92~.95 and an inter-rater reliability of r=.91 (Won and Yu, 2011).

Spatiotemporal gait variables were measured using a wireless three-axis accelerometer (G-WALK, BTS S.P.A., Lurate Caccivio, Italy). The variables were speed, cadence, %stride length of affected side (stride length÷height), double limb support, and %body sway angle of three-axis (X-axis, sagittal plane; Y-axis, coronal plane; Z-axis, transverse plane). The standard degree ranges of the X, Y and Z axes were 2~4°, 15~20°, and 3~4°, respectively (Neumann, 2009). To investigate the improvements after wearing the RAFO, the measurements of the subjects were converted to percentages (%) based on the median values of the standard ranges that is, 3° for the X-axis,

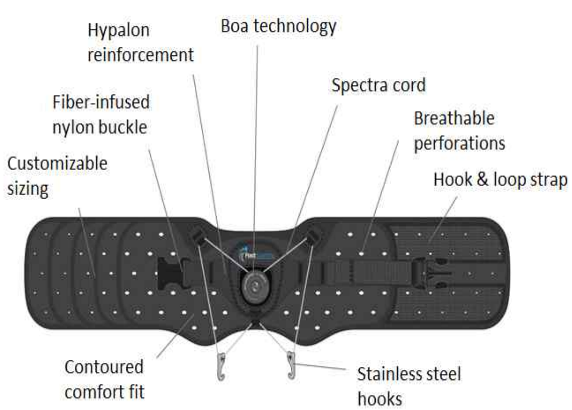

Figure 1. Planar figure of the removable ankle-foot orthosis.

Figure 2. Front view of wearing removable ankle-foot orthosis.

17.5° for the Y-axis, and 3.5° for the Z-axis rounded off to the nearest hundredth and subtracted from 100% to determine their absolute values.

In this pilot study, an elastic band-type accelerometer that can be fixed to the waist was used, fixed between the third and fourth lumbar vertebrae. The experiment assistant turned on the power of the accelerometer at the starting line, checked the start of monitoring of physical movements on the computer screen connected via Bluetooth, and gave a starting signal to the subjects. In the interest of objectivity, gait measurement collection began the moment the subject passed the 1 m point and first set his or her foot on the ground and stopped when the subject set his or her foot on the ground after passing the 3 m point; the subject was signaled "stop" when the subject walked 1 m further and passed the stop line. In the case of stroke patients, the correlation coefficients for gait time and stride time were high, at r=.93 or higher for left and r=.90 or higher for right (Lee et al, 2009). All measurements were performed three times and their averages were calculated.

PASW ver. 18.0 (SPSS Inc., Chicago, IL, USA) was used for the statistical processing of the collected data, using the Wilcoxon signed-rank test. The differences in gait abilities prior to and after wearing of RAFO were compared. The statistical significance level was set at α=.05.

Figure 3. Lateral view of wearing removable ankle-foot orthosis.

Results

The improvements in gait abilities measured before and after wearing the RAFO in this pilot study are outlined in Table 2. When the averages of the gait variables of the five subjects were compared, TUG decreased by 2.25 sec, from 20.65 sec before to 18.40 sec after wearing the RAFO, and FGA improved by 2.40 points, from 16.60 to 19.00. Gait speed increased by .21 ㎧, from .78 ㎧ to .99 ㎧, and the cadence increased by 13.90 steps/min, from 65.45 steps/min to 79.35 steps/min. %stride length increased by 13.18 ㎝, from 79.82 ㎝ to 93.00 ㎝, and double limb support decreased by 5.96%, from 22.83% to 16.97%. In addition, % body sway angle improved by 22.00% on the X-axis (from 46.47% to 24.47%), by 29.47% on the Y-axis (from 62.16% to 32.69%), and by 14.69% on the Z-axis (from 41.03% to 26.34%). Every measured variable improved significantly after the experiment ($p<.05$).

Discussion

Most AFOs currently prescribed to patients exposed to the risks of trauma or falling due to ankle instability in the clinical setting are fixed AFOs made of metal or plastic. However, when their usage status was investigated, 40.56% of stroke patients rarely used the prescribed AFOs, and 29.01% responded that they did not wear the AFOs because they were heavy and inconvenient to use with shoes (Lee et al, 1999). Therefore, using gait variables, this pilot study demonstrated, with proven reliability, that the RAFO is simple and not burdensome, it resolves appearance problems considerably, and it is helpful in improving the gait of stroke patients.

Many studies have reported on Elastic AFOs (EAFO), which are similar to the AFO used in this pilot study. Lee and Byun (2005) developed an EAFO and reported that the subjects' step length, stride time, and AFO support ratio improved. Kim et al

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Table 2. Comparison of gait abilities prior to and after wearing the removable ankle-foot orthosis

Variable	P		S1[a]	S2	S3	S4	S5
TUG[b] (sec)	.43	Pre	16.28	29.54	17.79	9.97	29.66
		Post	14.27	26.59	17.72	8.03	25.38
FGA[c] (score)	.39	Pre	22.00	12.00	13.00	26.00	10.00
		Post	25.00	15.00	14.00	28.00	13.00
Speed (m/s)	.43	Pre	.77	.81	.77	1.16	.39
		Post	.81	.99	1.00	1.56	.43
Cadence (steps/min)	.43	Pre	56.90	65.50	85.20	89.53	30.10
		Post	83.50	85.67	92.80	93.75	41.00
%stride length (cm)	.43	Pre	76.77	74.47	65.25	91.47	91.15
		Post	90.40	97.13	75.60	97.25	104.60
Double limb support (%)	.43	Pre	21.12	28.10	14.30	21.23	29.35
		Post	11.70	24.10	13.20	14.05	21.80
%body sway angle axis X (%)	.43	Pre	39.00	56.67	25.00	45.00	66.67
		Post	16.67	40.00	5.67	1.67	58.33
%body sway angle axis Y (%)	.43	Pre	57.26	62.00	58.11	72.29	61.14
		Post	23.43	22.86	30.86	40.00	46.29
%body sway angle axis Z (%)	.43	Pre	16.57	37.14	47.71	55.71	48.00
		Post	8.57	27.71	40.57	27.71	27.14

[a]subject, [b]timed up and go test, [c]functional gait assessment.

(2014) also claimed that wearing an EAFO increased the degree of change in ankle angle compared with the fixed type, which is effective for the prevention of inversion. Furthermore, in a study of an EAFO that connected the ankle and metatarsal, Daher et al (2013) reported that the gait speed, cadence, stride length, and AFO support ratio improved, using the TUG and the OptoGait system for measurements. The EAFO used in the previous study and the RAFO used in the current study connect the ankle with the anterior part of the metatarsal bone and pull up the leg using the lengthened moment arm, thereby enabling the movement of the ankle joint on the sagittal plane and preventing the contraction of soft tissues and the contracture of the joint. The RAFO used in this study also decreased foot drag considerably during gait. After wearing the RAFO, heel strike was observed, and inversion of the ankle, which is a risk factor for trauma, decreased. However, some patients with limited use of one upper limb due to hemiplegia have complained that the EAFO is difficult to wear perfectly and that it is impossible to lengthen the elastic band sufficiently to maximize the elastic property. In addition, the band loses its elasticity over time. Furthermore, atrophy of the skin due to compression was inevitable. The RAFO used in this pilot study showed some improvements; it can be worn for 24 hours when the velcro is tightened due to its waterproof material; it is easy to wear because it is attached by the Spectra cord and Boa technique; it has improved durability by decreasing considerably the drooping phenomenon; and it does not press on the ankle joint.

In addition, Jo (2013) reported that after wearing the EAFO, the weight support of the affected side decreased by 1.06%, and Daher et al (2013) reported that single limb support of the affected side increased, but not significantly. The RAFO presented the possibility of improving the one-leg stand by significantly decreasing double limb support. This element can have positive effects on gait.

Furthermore, in this pilot study, after wearing the RAFO, the body sway angle of the subjects improved to close to the normal range in the three-axis. The body sway angles of all five subjects were lower than the normal range on the sagittal plane or in the X-axis before wearing the RAFO. In the Y- and Z-axes, the body sway angle was lower than the normal range in four subjects and higher than the normal range in one subject. The subject whose body sway angle was higher than the normal range in the Y- and Z-axes was the same person. In the other four subjects, wearing the RAFO affected the improvement toward a more rhythmical gait. The gait of the one person whose body sway angle was higher in the Y- and Z-axes changed from excessive sway to stable gait. Body sway angle can be improved by decreasing the asymmetry ratio of the one-leg stand due to decreased double limb support. The decreased asymmetry ratio of the one-leg stand leads to a more normal gait, and the proper use of RAFO in the gait training of stroke patients will help improve their gait. Due to the nature of stroke, the combination of long-term care and treatment is inevitable. Patients who use proper orthoses and are trained for using them will be able to acquire gait abilities that will enable them to regain their free daily living and to return to work. As a result of this pilot study, it cannot be clearly determined that RAFO has effects on gait function improvement of stroke patients but it can be said that based on this RAFO suggested possibility of having a positive influence on gait function improvement of stroke patients.

The RAFO used in this study has not been applied directly to the human body yet. However, more detailed studies are required in the future, with more subjects and more variables, to compare different types of orthoses and training methods based on the results of this pilot study. Also it is thought that according to the level of standard of stroke patients, effects of this RAFO will differentiate and that study about this should be conducted. Moreover, the efficiency of the RAFO needs to be investigated for patients with peripheral nerve disorders and abnormal musculoskeletal conditions who complain of foot drag in addition to stroke patients.

Conclusion

This pilot study demonstrate that stroke patients can successfully wear a RAFO. The results are that improvements in TUG, FGA, walking speed, cadence, stride length, and double limb support. It suggest that wearing RAFO can be achieved when this device is provided in combination with exercise or other treatment intervention and interdisciplinary rehabilitation.

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