The Effects of Anterior Ankle Foot Orthosis on Gait Parameters, Walking Ability, and Patient Satisfaction of Thai Stroke Patients, Siriraj Hospital

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ABSTRACT

Objective: To assess the effects of flexible anterior ankle-foot orthosis (AFOs) on gait patterns of stroke patients.
Methods: The flexible anterior AFOs were custom-made from 3M™ Scotchcast softcast tape. The subjects were assigned to walk with a flexible anterior AFO on the paper walkway. All gait parameters including velocity, base of support, cadence, step length and gait symmetry were immediately evaluated and compared with and without applying the AFOs. The sequences of testing were randomly assigned.
Results: Twenty-one subjects with post-stroke hemiplegia with gait impairment due to foot drop were included. Comparing between walking with and without the AFOs, there was no significant difference of gait parameters either in velocity, base of support, cadence, and step length and gait symmetry. However, functional ambulation category (FAC) was increased 1 level in 43% of cases after wearing the AFO.
Conclusion: Applying the flexible anterior AFOs provided no immediate effect on gait parameters of the stroke patients walking with foot drop. Walking ability (FAC) may be potentially improved with this design in some cases.

Keywords: Anterior AFO, foot drop, hemiplegic, stroke

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INTRODUCTION

Cardiovascular disease is one of the common neurological conditions in rehabilitation practice which requires continuing long term care with a multidisciplinary approach.

The most common problem that brings stroke patients to the rehabilitation service is the walking difficulty which almost everyone has some kind of gait deviation in that they always have problems with gait instability, slow speed, poor gait pattern and energy-inefficiency of walking.1,2

The affected foot is almost always deviated into an equinovarus pattern which is a difficulty of the foot to the clear the ground in a swing plus a poor coronal plane control of the ankle in stance, placing a greater risk to falling. Gait training in stroke rehabilitation always composes of exercises, weight shifting, balance training and ambulation training with an ankle foot orthosis and a cane. Generally the primary goals of trainings are to improve gait stability and to reduce postural sway.3,4

The ankle foot orthosis is the device to control the affected foot and ankle motion in both the swing and stance phase of the gait cycle in that, during the swing phase, the equinus or drop-foot problem can be addressed by plantar flexion stop function of the AFO, whereas, during the midstance phase, the AFO can prevent the affected knee from collapsing as well as keep the subtalar joint from moving into excessive varus.5,6

Despite following the prescription criteria, a lot of stroke patients reject regular plastic AFOs application at home after rehabilitation training. Most of them complain of having difficulty in finding proper shoes to wear with the AFOs and almost everyone, probably as the Asian
culture, walks bare foot at home. When considering the AFOs generally prescribed, all of them are posterior AFOs, which have the plastic shell to cover the affected calf and sole. This design is highly recommended to be used with dress shoes or sport shoes, whereas Thai people always walk with sandals in the community and walk barefoot in their houses. Furthermore, some stroke survivors have only one good hand to function so that putting on the AFO is somewhat problematic. The AFO that is appropriate to Thai stroke patients should be the one easy to wear, and applicable to various kinds of shoes, or even used without shoes. Ideally the mentioned design must be in the category of anterior AFO which has plastic shell covers for the shin and dorsum of the foot.10

Comparing anterior AFO to posterior AFO, Wong AM et al, found no difference between both designs in patients with acute stroke, by using low temperature plastic materials, in terms of gait pattern improvement and foot pressure distribution.9

When considering the effects of anterior AFO on postural sway reduction, as well as correction of gait asymmetry, Chen CL et al, revealed significant improvement when using the AFO in chronic stroke patients.10

As a result, anterior AFOs could be the AFO of choice of Thai stroke patients, compared to the regular posterior AFO design, at least in the compliance aspect. Therefore, a prototype of an anterior AFO for Thai patients was suggested to be developed and designed by our team.

The primary objective of the study was to evaluate the effects of the anterior AFO in gait parameters comparing walking with and without the AFO. All enrolled participants to meet the inclusion criteria must be unilateral hemiparetic patients from cerebrovascular disease at least 3 months after onset and be able to walk at least 10 meters with intermittent support or less (Functional Ambulation Categories 2-5). Use of a cane was allowed. The major problem was equinus gait or difficulty with foot clearance in the swing phase. Subjects with bilateral stroke, severe spasticity, affected leg contracture, non-communicable or with unstable medical conditions were excluded.

There was no conflict of interest between the material manufacturer and the researchers.

MATERIALS AND METHODS

This study was approved by the Siriraj Institutional Review Board (SIRB) (COA Si 079/2010) before collecting data. All participants were from the Department of Rehabilitation Medicine, Siriraj Hospital Mahidol University, outpatient setting.

After recruitment and completely explanation, all subjects who met the inclusion criteria were asked to give their informed consents before participation in the research, starting with baseline data gathering and ambulation classification using Functional Ambulation Categories (FAC) which is as follows:

FAC 0: Nonfunctional ambulation
FAC 1: Ambulator-dependent for physical assistance level 1 (continuous support)
FAC 2: Ambulator-dependent for physical assistance level 2 (intermittent support)
FAC 3: Ambulator-dependent for supervision
FAC 4: Ambulator-independent level surface only
FAC 5: Ambulator-independent anywhere

The anterior AFO was meant to be custom-fabricated from 3M Scotchcast soft cast tape which is a fiberglass bandage impregnated with polyurethane resin. When exposed to water or air, the soft cast tape will finally set to be a flexible rigid material. The soft cast tape is normally used in making splints for hand and foot conditions especially for ligament injuries.

Starting with sitting on a chair, a stroke patient’s affected foot was laid flat on the floor and was positioned into a subtal neutral position with 10 degree of ankle dorsiflexion. After that, a pair of socks were applied to the foot to prevent ulceration and 2 rolls of soft cast tape (10 cm x 3.6 m) were then wrapped from mid-foot level up to mid shin level. Next, the cast was soaked with water and was massaged to make each turn of the tape blend together, and after 2-3 minutes of waiting until the resin material solidified, the cast was finally cut and removed. Later, the cast was trimmed and lined with 2 mm EVA foam inside, making a soft interface. Finally, two straps were put to the ankle and shin to finish the anterior AFO.

Before starting gait evaluation, the patient was asked to walk on the orthosis with prepared running shoes and socks to get used to it. Photos of the anterior AFO are shown in Fig 1.

Gait parameters were measured by walking on paper walkways which were 7 meters x 90 centimeters paper path taped on the floor. By cutting a small hole in the centre of the shoe heel, each running shoe had a small

![Fig 1. Prototype of the Scotchcast Softcast Anterior Ankle foot Orthosis (AFO).](image)

Fig 2. Functional Ambulation Categories (FAC) in various situations.
The age of all participants ranged from 47-76 year old (mean 59.8 ± 8.1). Other demographic data have been shown in Table 1.

Measurement of gait parameters such as gait velocity, base of support, steps per minute (cadence), step length and gait symmetry were not significantly different between wearing and non-wearing situation as revealed in Table 2.

When measuring walking ability by comparing Functional Ambulation Categories (FAC) between barefoot and the AFO walking with different kind of shoes, we found that 9 out of 21 subjects (or 43%) gained one level of FAC as shown in Table 3.

There was no difference in FAC among AFO wearing conditions in terms of types of shoes which are wearing the AFO without shoes, wearing the AFO with sandals and wearing the AFO with running shoes as shown in Table 2.

After 2 weeks of wearing, the patients’ satisfaction of the AFO wearing was graded in various aspects which were appearance, weight, wearing ability, stability, speed and easy to walk. Most of the satisfaction levels were between satisfied and very satisfied as in Fig 3.

There were no complications reported after 2 weeks follow-up.

DISCUSSION

The anterior AFO made of Scotch cast softcast™, did not change gait parameters after immediate fitting. Since the material used was the flexible one, this might be too soft to control the spasticity of the stroke patients’ feet which had mild to moderate degrees. Another reason could be the training effect in that all stroke patients, with new ankle foot orthoses, need to practice walking with the device, so that they could adapt to new gait patterns and change their gait parameters thereafter.

In order to make the AFO stiffer, we can reinforce the ankles of the AFO with pieces of low temperature thermoplastic e.g. Aquaplast™. As in the study of Pohl M et al., in which they fabricated the AFO to stroke patients using Scotcast Plus™ which is a rigid fiberglass combined with the flexible Scotcast softcast™ making the AFO more stiff. As a result, they found significant reductions in postural sway, increases in affected weight bearing and decreases in double stance duration. In addition to gait training required after fitting, another reason to be considered during gait analyses is that there were further measurable quantitative gait parameters that were not included in this study. Unlike the paper walkway which is a simple gait evaluation tool providing simply basic parameters in 2 dimensions, the computerized three dimensional gait laboratory setting is a better gait analyses standard.

Again, there were up to 43% of subjects showing...

### TABLE 1. Baseline characteristics of all participants (N = 21).

<table>
<thead>
<tr>
<th>Data</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender, numbers (%)</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>13 (61.9%)</td>
</tr>
<tr>
<td>Female</td>
<td>8 (38.1%)</td>
</tr>
<tr>
<td>Age, years</td>
<td></td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>59.8 ± 8.1</td>
</tr>
<tr>
<td>Range (min-max)</td>
<td>47-76</td>
</tr>
<tr>
<td>Onset of stroke, months</td>
<td></td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>3.95 ± 0.8</td>
</tr>
<tr>
<td>Range (min-max)</td>
<td>3-39</td>
</tr>
<tr>
<td>Side of Hemiplegia, numbers</td>
<td></td>
</tr>
<tr>
<td>Ratio (right:left)</td>
<td>13:8</td>
</tr>
<tr>
<td>Type of stroke, numbers (%)</td>
<td></td>
</tr>
<tr>
<td>Infarction</td>
<td>16 (76.2%)</td>
</tr>
<tr>
<td>Hemorrhage</td>
<td>5 (23.8%)</td>
</tr>
</tbody>
</table>

### RESULTS

Twenty one sub-acute and chronic hemiparetic patients were recruited; there were 13 males and 8 females.

Pocket for putting cotton wool soaked with ink in. As a result, when walking, a trail of ink dots were left on the paper walkways. Each parameter was compared between walking with and without the AFO.

In order to evaluate the walking speed, a 10-meter walk test was performed by walking with a self-selected comfortable speed comparing between walking with and without the AFO with the same running shoes again.

Finally, the walk ability was evaluated by Functional Ambulation Categories (FAC) in different situations starting from walking barefoot, walking on the AFO without shoes, walking on the AFO with sandals, and then walking on the AFO with running shoes. The sequences of each testing were randomly allocated.

After finishing, the skin inspection was performed to find any potential skin irritation or ulcers. The patient satisfaction on the AFO was graded in various aspects in a 2-week follow-up as well as any other possible complications.

Based on the literature conducted by Rao N et al., gait velocity, step length and cadence were compared. Changes of the parameters would be clinically significant with p-value = 0.05 (power of test = 80%). The calculated sample size was then 21 subjects.

Statistical analysis was performed with SPSS version 11.5 for Windows. Descriptive statistics were used to examine the demographic data, functional level and patients’ satisfaction. Paired t-test was used to compare gait parameters before and after wearing the AFO. Statistical significance was considered if the p-value was less than 0.05.

### TABLE 2. Gait parameters comparing before and after AFO wearing.

<table>
<thead>
<tr>
<th>Gait parameters</th>
<th>Before</th>
<th>After</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Velocity (cm/s)</td>
<td>13.74 ± 6.38</td>
<td>13.89 ± 6.17</td>
<td>0.888</td>
</tr>
<tr>
<td>Base of support (cm)</td>
<td>15.80 ± 3.36</td>
<td>15.10 ± 4.40</td>
<td>0.133</td>
</tr>
<tr>
<td>Cadence (step/min)</td>
<td>20.58 ± 5.92</td>
<td>22.42 ± 7.32</td>
<td>0.102</td>
</tr>
<tr>
<td>Step length of affected-side (cm)</td>
<td>40.77 ± 14.11</td>
<td>41.02 ± 14.54</td>
<td>0.808</td>
</tr>
<tr>
<td>Step length of sound-side (cm)</td>
<td>39.94 ± 3.76</td>
<td>40.59 ± 14.28</td>
<td>0.534</td>
</tr>
<tr>
<td>Symmetry (affected/sound-side)</td>
<td>1.02 ± 0.04</td>
<td>1.01 ± 0.02</td>
<td>0.222</td>
</tr>
</tbody>
</table>

Data were presented as mean ± SD

P-value compared data within the same group by Paired t-test.
FAC change at the first time they put on the orthosis. This AFO might potentially show FAC improvement in more stroke patients after completing the gait training program over time.

Regarding to shoes aspect, this AFO was designed to be worn without shoes within the house. The comparison was also done to find effects of different shoes on the AFO wearing and found there was no FAC functional difference between wearing the AFO with both kinds of shoes or wearing the AFO without shoes. Similar to the study of Wu S, et al., in which the low temperature thermoplastic anterior AFO was designed to be worn with or without shoes, they found walking ability improvement with the AFO regardless of wearing shoes. As a result, this AFO could be appropriate for stroke patients in Thailand in terms of shoe wearing habit and simplicity of fabrication.

**CONCLUSION**

The effects of the anterior AFO in subacute to chronic hemiparetic stroke patients with mild to moderate spasticity found no significant difference in gait parameters when measured immediately after fitting, but showed one level of improvement in walking ability (FAC) in up to 43% of the cases regardless to what kind of shoes they walk with. Therefore, the orthoses might improve walking ability in many stroke patients. In addition, the satisfaction was mostly in the high level and there was no complication reported after 2 weeks of wearing.

**ACKNOWLEDGMENTS**

The study was funded by the Faculty of Medicine Siriraj Hospital, Mahidol University.

**TABLE 3.** Functional Ambulation Categories (FAC). Comparing between barefoot walking and the anterior AFO walking without shoes.

<table>
<thead>
<tr>
<th>FAC AFO without shoes</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>FAC Barefoot</td>
<td>2</td>
<td>2</td>
<td>6</td>
<td>(9.5%)</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>0</td>
<td>6</td>
<td>(28.6%)</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>0</td>
<td>0</td>
<td>(14.3%)</td>
</tr>
<tr>
<td>N (%)</td>
<td>2</td>
<td>12</td>
<td>7</td>
<td>(38.1%)</td>
</tr>
</tbody>
</table>

Data were presented as percentages (percentages)

**REFERENCES**