Original Article

Patient Compliance and Factors Related to Usage of Plastic Ankle-Foot Orthoses by Chronic Stroke Patients

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ABSTRACT

Objectives: To investigate chronic stroke patient compliance with usage of plastic ankle-foot orthosis (AFO) and to identify factors significantly associated with compliance with AFO use.

Study design: Cross-sectional study.

Setting: Department of Rehabilitation Medicine, Siriraj Hospital and Sirindhorn National Rehabilitation Center.

Subjects: Chronic stroke patients who had received a plastic AFO at least one year ago, had no cognitive impairment, no aphasia, and who had visited a physiatrist for follow-up.

Methods: Patients' demographic and clinical data were collected. Modified Barthel Index (mBI) and Functional Ambulation Category (FAC) were used for assessment. Patients were asked to complete a specially designed AFO use questionnaire. Patient compliance was defined as AFO use for ambulation for more than 3 hours per day at least 5 days per week over a period of not less than a year. Patients who did not meet those provisions were classified as non-compliant. Patient compliance/non-compliance with AFO usage was analyzed using descriptive statistics. Factors associated with compliance were analyzed using forward stepwise logistic regression.

Results: A total of 93 patients, 63 men and 30 women, with a mean age of 60 years were included in the study. Of those patients, 38.7% had discontinued the use of AFO, 61.3% reported continuous use of AFO, but only 23.7% were categorized as compliant with AFO usage. FAC level 4 or 5, independent ambulator on level surfaces only and independent ambulator, respectively, was the only factor statistically significantly related to patient compliance (odds ratio: 15.2, 95% confidence interval: 1.9-120.6).

Conclusions: Almost two-thirds of chronic stroke patients reported continuous usage of AFOs for at least a year, but only one-fourth could be categorized as compliant with AFO usage. Independent ambulation, including ambulation on level surfaces only, was the only factor independently associated with compliance with AFO use.

Keywords: foot orthosis, patient compliance, stroke rehabilitation, ambulation

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Introduction

Ankle-foot orthoses (AFOs) are often prescribed to correct gait pattern after a stroke. An AFO can provide mediolateral stability at the ankle in the stance phase, facilitate toe clearance in the swing phase, and promote heel strike.[1] User-reported benefits of AFOs include increased confidence, fewer difficulties walking, and faster walking speed.[2-4] In addition, in subacute hemiparetic stroke patients wearing an AFO may improve aerobic capacity, energy efficiency, and gait endurance.[5] However, those benefits are realized only when the AFO is worn on a regular basis.

In Thailand, plastic AFOs are much more commonly prescribed than metal AFOs for stroke patients. The two types of plastic AFOs used are the posterior leaf spring type, which is commercially available, and the solid ankle type, which is custom-made for individual patients. The solid ankle type is more suitable for stroke patients because it provides more stability. Both types of AFOs must be worn with shoes. Traditionally, Thai people do not wear shoes inside the house, which suggests that patient compliance with AFO usage may be compromised in this population. Additionally, various types of sandals are routinely preferred to other types of footwear for outdoor activities due to the hot and humid climate. After suffering a stroke, patients either try to acclimate to wearing new shoes with an AFO or refuse to use an AFO. In addition to the loss of independence due to difficulty walking, refusal to consistently wear an AFOs leads to wasted healthcare resources. No information is currently available regarding long-term patient compliance with AFO use among stroke patients in Thailand, where the lifestyle, climate, and traditions

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are quite different from those of Western countries. The objective of the present study was to investigate the use of a plastic AFO by chronic stroke patients who had received their AFO at least one year prior to study, and to identify factors significantly associated with patient compliance with AFO usage.

Methods

This cross-sectional study was conducted at the Rehabilitation Medicine Outpatient Clinic at Siriraj Hospital, (Bangkok, Thailand) and the Sirindhorn National Rehabilitation Center (Nonthaburi, Thailand) after receiving an approval from the institutional review boards of both hospitals.

Participants

Study participants were recruited by convenience sampling of patients from both hospitals. Chronic stroke patients age 18 years or older who visited one of the hospitals during 2014-2018 and received a plastic AFO to correct gait pattern for the first time and used the AFO for at least a year prior to the study were recruited. Stroke patients with documented cognitive impairment, an inability to verbally communicate, or who were unwilling to join the study were excluded. After inclusion-exclusion screening, a written informed consent to participate was obtained from all enrolled study participants.

Procedure

All study participants' functional ability and ambulation status were assessed using the modified Barthel Index (mBI)[6] and the Functional Ambulation Category (FAC).[7] FAC has 6 levels that range from level 0 (non-functional ambulator) to level 5 (independent ambulator). The participants were then asked to complete an AFO use questionnaire specifically designed and developed for the present study. The items in the questionnaire consisted of the patient's perception of AFO, frequency of AFO use for ambulation, perceived benefits and drawbacks of the AFO, and the participant's feedback regarding ways to facilitate AFO usage. The newly designed questionnaire was tested for understandability with 10 stroke patients, including both AFO users and nonusers. Completed questionnaires were immediately checked to ensure that there was no identify missing data and request that information.

Sample size calculation

As there have been no studies reporting patient compliance with AFO use after a stroke, the authors estimated AFO use and usage based clinical observations to calculate the sample size. Based on clinical observation and using a 95% confidence interval (CI), it was estimated that 50.0% ± 10.0% of stroke patients who received an AFO would comply with long-term AFO use recommendations. Sample size calculation indicated that a minimum of 97 subjects were needed.

Data analysis

The data were analyzed using PASW Statistics for Windows (version 18.0; SPSS, Inc., Chicago, IL, USA).[8] Descriptive statistics were used to summarize patient characteristics, including frequency and percentage, mean and standard deviation, and range.

Patients were categorized as compliant or non-compliant on the frequency of AFO use. Compliant was defined as using an AFO for ambulation for more than 3 hours per day at least 5 days per week whereas non-compliant was defined as not using AFO at all or using it less than 3 hours per day. Patient compliance/non-compliance is reported as percentage.

Univariate analysis was performed to evaluate the differences between compliant and non-compliant patients. The chi-square test was used to compare qualitative variables, including gender, education level, presence of comorbid illness, type of stroke, side of weakness, use of walking aids, period of having an AFO, benefits and drawbacks associated with wearing an AFO, and FAC level. In the present study, FAC level 0-1 was classified as a non-functional ambulator, i.e., a stroke patient totally dependent on physical assistant to ambulate. FAC 2-3 was classified as an assisted ambulator, i.e., a stroke patient more or less in need of a person to either physically assist or supervise ambulation. FAC 4-5 was classified as an independent ambulator. The independent samples t-test was used to analyze quantitative variables (age and the modified Barthel Index score). Forward stepwise logistic regression analysis was then performed to determine which factors were significantly associated with patient compliance with AFO usage. Adjusted odds ratios and 95% CIs were estimated. A p-value of < 0.05 was considered statistically significant.

Results

Plastic AFOs were prescribed for 230 stroke patients during 2014-2018. Of those, eighty-nine patients were unreachable, 16 patients had died, 10 patients were unable to verbally communicate, 10 patients were documented as having cognitive impairment, and 12 patients declined to participate. The remaining 93 patients (63 men and 30 women, mean age 60 years) were included.

Table 1. Frequency and duration of plastic ankle-foot orthosis use among chronic stroke patients after receiving a prescribed orthosis at least one year (N = 93)

Frequency of use per week	Duration of use per day			Total
	< 1 hour	1-3 hours	> 3 hours	
Not at all	----------36 (38.7) ----------			NA
1-2 days	5 (5.4)	8 (8.6)	4 (4.3)	17 (18.3)
3-4 days	1 (1.0)	4 (4.3)	5 (5.4)	10 (10.7)
5-7 days	5 (5.4)	3 (3.2)	22 (23.7)	30 (32.3)
Daily	11 (11.8)	15 (16.1)	31 (33.4)	---

Number (%); NA, not applicable

Table 2. Patient variables comparing compliance and non-compliance with ankle-foot orthosis (AFO) usage

Variables	Compliant user (n=22)	Non-compliant user (n=71)	*p*-value
Gender[1]			
• Male	17 (77.3)	46 (4.8)	0.27
• Female	5 (22.7)	25 (35.2)	
Age (years)[2]	55.1 (10.7)	61.8 (11.5)	0.018*
Education[1]			
• High school or lower	10 (44.9)	46 (64.9)	0.085
• Higher than high school	12 (55.1)	25 (35.1)	
Presence of comorbid illness[1]	19 (86.4)	65 (91.5)	0.44
Type of stroke[1]			
• Hemorrhagic	12 (54.5)	22 (31.0)	0.045*
• Ischemic	10 (45.5)	49 (69.0)	
Side of weakness[1]			
• Right	10 (45.5)	38 (53.5)	0.51
• Left	12 (54.5)	33 (46.5)	
Use walking aids[1]	19 (86.4)	61 (85.9)	1.0
Duration of having AFO[1]			
• < 2 years	13 (59.1)	39 (54.9)	0.73
• > 2 years	9 (40.9)	32 (45.1)	
Modified Barthel Index score[2]	17.6 (2.2)	14.4 (4.6)	< 0.001*
Functional Ambulation Category[1]			
• Non-functional ambulation	1 (4.5)	25 (35.2)	0.001*
• Assisted ambulation	1 (4.5)	13 (18.3)	
• Independent ambulation	20 (91.0)	33 (46.5)	

[1]Number (%), [2]mean (standard deviation), * *p*-value < 0.05 indicates statistical significance

Table 3. Analysis of factors independently associated with patient compliance with ankle-foot orthosis use

Variable	Adjusted odds ratio (95% confidence interval)	*p*-value
Functional ambulation category		
• Non-functional ambulation	1.0	
• Assisted ambulation	1.92 (0.11-33.30)	0.65
• Independent ambulation	15.2 (1.90-120.62)	0.01*

**p*-value < 0.05 indicates statistical significance

One year or more after having received the prescribed plastic AFO, patients reported highly variable AFO use. Of the 93 patients, 23.7% were classified as compliance with AFO usage instructions, with the remainder (61.3%) were non-compliance. Of the non-compliant patients, 37.6% used the prescribed AFO for less than the recommended periods and 38.7% had discontinued use of the prescribed plastic AFO (Table 1).

Univariate analysis revealed patient compliance to be statistically significantly associated with younger age, hemorrhagic stroke, high Barthel Index, and FAC level of independent ambulator status (Table 2). Forward stepwise logistic regression analysis showed independent ambulation to be the only factor independently associated with compliance with AFO use (odds ratio: 15.2; 95% confidence interval: 1.9-120.62) (Table 3).

Regarding the benefits and drawbacks associated with wearing the prescribed plastic AFOs, compliant users reported significantly more benefits than did non-compliant users. However, there were no statistically significant differences between groups related to the drawbacks associated with wearing an AFO (Table 4).

Concerning patients' perception of AFOs, most participants (78.5%) rated wearing AFOs without shoes (85%) and the ease of donning and doffing the AFOs (80%) as the two most important factors that influenced their AFO use. Among compliant patients, Other AFO-related factors that influenced AFO use were lighter weight AFOs (68.8%) and improved AFO appearance (61.3%).

Discussion

This is the first study in Thailand to explore chronic stroke patient compliance with the use of plastic AFOs. In the present study, the percentage of patient compliance with AFO use recommendations for at least one year was 23.7%. This percentage was lower than the 50% which had been anticipated based on previous studies of the benefits of AFOs for walking ability of stroke patients.[9-11]

Nakipoglu et al,[12] recruited stroke patients with various durations of AFO use after at least 3-months post-stroke and found that 59.4% used their lower extremity orthosis every day and 29.7% did not use their orthosis at all. In the present study, among the chronic stroke patients who had their orthosis

Table 4. Patient variables comparing compliance and non-compliance with ankle-foot orthosis (AFO) usage

Variables	Compliant users (n = 22)	Non-compliant users (n = 71)	*p*-value
Benefits			
More confidence	21 (95.5)	45 (63.4)	0.004*
Faster walking	19 (86.4)	34 (47.9)	0.001*
Longer walking distance	21 (95.5)	35 (49.3)	< 0.001*
Improved foot clearance	20 (90.9)	47 (66.2)	0.024*
Drawbacks			
Discomfort	11 (50.0)	30 (42.9)	0.56
Pain	12 (54.5)	49 (70.0)	0.18
Ulceration	18 (81.5)	60 (85.7)	0.66
Falls	20 (90.9)	64 (91.4)	0.82

Number (%), *p-value < 0.05 indicates statistical significance

for at least one year earlier, 32.3% used their AFO almost every day although only 23.7% were counted as compliant based on our definition of using AFO for ambulation more than 3 hours per day and at least 5 days per week and 38.7% had stopped using their AFO. Compared to the Nakipoglu study,[12] our findings suggest that the percentage of patients who discontinue AFO use increases over time.

In the present study, benefits of AFO were reported more frequently by compliant users than by non-compliant users. In addition, compliant users felt that ease of donning and doffing, weight, and appearance of the AFOs were strong influencing factors for AFO use. Difficulty wearing a prescribed orthosis has been reported to be a main reason for AFO discontinuation[12] which is consistent with the present study. Hung et al, studied the effects of anterior AFOs which are commonly prescribed for Taiwanese patients.[13] They found that all 52 chronic stroke patients who had had their anterior AFOs for ≥ 5 months wore their AFOs for outdoor activities; however, only half of those patients wore them at home. The benefits of AFOs have also been addressed in several other studies.[3,12,14] Notably, those studies reported that many subacute to chronic stroke patients who had discontinued the use of their AFO perceived no beneficial effect of the AFOs.

Univariate analysis in the present study revealed AFO users to be younger, more likely to have had a hemorrhagic stroke, have a higher modified Barthel Index score, and higher FAC levels compared to non-compliant users. When these variables were entered into forward stepwise logistic regression analysis, independent ambulation was found to be the only statistically significant independent predictor of patient compliance with AFO use. This finding is consistent with that of a study by Lehman[15] who reported that AFOs are worn by patients who are able to walk without them but cannot do so safely. Stroke patients who are able to walk may still have problems with their balance, which increases their risk of falling. The use of AFOs by stroke patients with muscle weakness of the ankle joints is one strategy to improve standing and walking ability by facilitating weight distribution to the affected leg,[9] improving balance,[16] and reducing the risk of falling.[17,18] These benefits were acknowledged by patients in our study. Compared to the perceptions of non-compliant users, compliant users reported that they felt significantly more confident. These same feelings of AFO-influenced patient confidence have also been reported in previous studies.[2,3] AFO users in this study also reported a significantly faster gait and longer walking distances compared to nonusers. This finding can be explained by the reported findings that AFO use can enhance step and stride length, increase walking speed,[9,14] reduce the energy cost of walking[11] and significantly increase toe clearance.[19]

The participants in the present study also commented on the problems associated with wearing AFOs such as discomfort, pain, ulceration, and falls. Interestingly, a high percentage of both the compliant and non-compliant groups reported falls related to AFO use. This should be investigated further to determine if it is true, and, if so, which types of AFO are the cause of falls as well as the circumstances under which falls commonly occur. This information could be used by prosthetists and physiatrists when they are promoting or counseling patients on AFO use. The weight, design, and appearance of AFOs were additional factors that were reported to influence AFO use by our study patients. Patients in other studies have provided similar feedback.[2,3] If these factors can be addressed, patient compliance with AFO use may be increased, improving patient outcomes and justifying the cost of providing these therapeutic lower extremity orthoses. The clinical implication from the present study is that prescribing plastic AFOs for stroke patients whose FAC could potentially reach level 4/5 could increase compliance with AFO usage.

Some limitations of this study should be mentioned. First, this study evaluated compliance in using AFOs including usage patterns, benefits, and drawbacks of AFOs among chronic stroke patients who had received their AFO at least one year earlier. A low rate of patient compliance with AFO usage might be due to our strict definition of compliance to mean more than 3 hours use of the AFO daily five days a week for ambulation. This definition may be inappropriate for chronic stroke patients as they are more sedentary than older adults[17] and the amount of walking per day or per week

by chronic stroke patients has not yet been studied. A more appropriate definition of compliance with AFO use could be determined by establishing the amount of walking activity among chronic stroke patients in a future study. Another point is the high percentage of non-compliance which is a result of inclusion of patients who used AFO for ambulation less than 3 hours per day and/or less than 5 days per week and those who discontinued using AFO. Discontinuation of AFO use might be due to severe hemiplegia and/or poor trunk balance leading to an inability to walk and inability to don and doff the AFO by oneself. In this study, severity of stroke was not assessed and recorded. Other points are that patients' perception that use of AFO is related to falls and that an inappropriate AFO prescription may be related to discontinuation of AFO use. The types of plastic AFO, both commercial and custom-made, should be explored in future studies. Such information would assist prosthetists and physiatrists to prescribe an appropriate AFO, improve patient compliance with AFO usage, and thus help make chronic stroke patients become independent ambulators. Finally, future research should include more subjects to obtain more data for analysis.

Conclusions

Our results showed that 61.3% of chronic stroke patients continued using plastic AFOs for at least one year. The percentage of compliance with AFO use of more than 3 hours per day and at least 5 days per week was 23.7%. Being an independent ambulator was independently associated with compliance with AFO use.

Disclosure

All authors declare no personal or professional conflicts of interest related to any aspect of this study.

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