



ORIGINAL ARTICLE

Effects of ankle-foot orthoses on the stability of post-stroke hemiparetic gait

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ABSTRACT

BACKGROUND: Ankle-foot orthoses are used to improve gait stability in patients with post-stroke gait; however, there is not enough evidence to support their beneficial impact on gait stability.**AIM:** To investigate the effects of ankle-foot orthoses on post-stroke gait stability.**DESIGN:** An experimental study with repeated measurements of gait parameters with and without orthosis.**SETTING:** Inpatients and outpatients in the Fujita Health University Hospital, Toyoake, Japan.**POPULATION:** Thirty-two patients (22 males; mean age 48.3±20.0 years) with post-stroke hemiparesis participated in the study.**METHODS:** Three-dimensional treadmill gait analysis was performed with and without ankle-foot orthosis for each participant. Spatiotemporal parameters, their coefficient of variation, and margin of stability were evaluated. Toe clearance, another major target of orthosis, was also examined. The effect of orthosis in the patients with severe (not able to move within the full range of motion, defying gravity) and mild ankle impairment (able to move within the full range but have problem with speed and/or smoothness of the ankle movement) was compared.**RESULTS:** In the total group comparison, the decrease in the coefficient of variation of step width (P=0.012), and margin of stability on the paretic side (P=0.023) were observed. In the severe ankle impairment groups, the decreased in the coefficient of variation of the non-paretic step length (P=0.007), stride length (P=0.037), and step width (P=0.033) and margin of stability on the paretic side (P=0.006) were observed. No significant effects were observed in the mild ankle impairment group; rather, the coefficient of variation of non-paretic step length increased with the use of orthosis in this group (P=0.043); however, toe clearance increased with the use of ankle-foot orthosis (P=0.041).**CONCLUSIONS:** Ankle-foot orthoses improved gait stability indices; however, the effect was either not significant or showed possible worsening in the patients with mild ankle impairment, while the effect on toe clearance was significant. These results suggest that the effects of using orthoses in patients with mild impairment should be carefully evaluated.**CLINICAL REHABILITATION IMPACT:** Understanding the effects of ankle-foot orthoses on the stability of post-stroke gait and their relationship with ankle impairment severity may support clinical decision-making while prescribing orthosis for post-stroke hemiparesis.*(Cite this article as: Tsuchiyama K, Mukaino M, Ohtsuka K, Matsuda F, Tanikawa H, Yamada J, et al. Effects of ankle-foot orthoses on the stability of post-stroke hemiparetic gait. Eur J Phys Rehabil Med 2022;58:352-62. DOI: 10.23736/S1973-9087.21.07048-9)***KEY WORDS:** Hemiplegia; Stroke; Gait; Rehabilitation.

Ankle-foot orthoses (AFOs) are widely used as clinical devices to support ankle function and improve gait ability in hemiparetic stroke patients. The benefits of AFOs on various parameters related to hemiparetic gait have been observed, such as gait velocity, gait symmetry, and walking efficiency,¹⁻³ which may be due to the improved ankle joint stability and subsequent increase in postural stability and toe clearance. Previous studies

have reported an increase in toe clearance and reduction in compensatory movements using AFOs.^{4, 5} Regarding stability, several reports have evaluated the effect of AFOs on static balance improvement.^{6, 7} However, dynamic balance improvement during walking is not well-understood. A previous study supported the reduction in variability of spatiotemporal parameters,⁸ revealing an improvement in the stability of gait patterns with the use of AFO; however,

there is a lack of more direct evidence on the effect of the dynamic balance control during gait. The AFO's ability to improve the static balance may support the improvement in gait balance control; however, in healthy individuals, restricting ankle motion with AFO has reportedly had a negative influence on dynamic balance.⁹ It is also possible that AFO's effects on stability vary depending on the kinematic function of the ankle joint.

In this study, we examined stability improvement with AFOs in stroke patients and whether the effect of AFOs differed with varying degrees of ankle joint motor impairment. To evaluate the stability of gait patterns, we assessed the coefficient of variation (CV) in spatiotemporal gait parameters in stroke patients with and without AFOs and the margin of stability (MoS), based on the relationship between the center of mass (COM) and the base of support, using three-dimensional gait analysis systems. Furthermore, the relationship between the gait parameters, including the stability and toe clearance indices, and the severity of ankle paralysis was also examined.

Materials and methods

Participants

The patients with post-stroke hemiparesis who underwent rehabilitation at the Fujita Health University Hospital were recruited, using the convenience sampling method. The measurements were performed between April 2009 and May 2020. Inclusion criteria were: 1) unilateral hemiparesis caused by cerebrovascular disease; 2) more than 60 days after onset; 3) continuous use of an AFO for walking for more than a week; and 4) ability to walk independently on a treadmill without orthoses, handrails, or assistive devices. Exclusion criteria were: 1) a history of previous neuromuscular diseases and/or orthopedic conditions that could interfere with the walking ability; and 2) impaired cognition and/or communication affecting the ability to follow instructions. Neurological motor impairments were evaluated using the stroke impairment assessment set.^{10, 11} Lower limb motor function was evaluated by the hip-flexion, knee-extension, and foot-tap tests included in the stroke impairment assessment set. For each test, motor function was rated from 0 (severely impaired) to 5 (normal). The scores in the foot-tap test were used to divide participants into two groups according to ankle motor function: the participants who scored ≥ 3 points, indicating that they could perform the full range of dorsiflex motion, were classified as having a mild ankle impairment, while the participants who scored ≤ 2 points, indicating insuffi-



Figure 1.—Adjustable posterior strut ankle-foot orthosis (APS-AFO).

cient dorsiflexion or severer impairment, were classified as having a severe ankle impairment.

The sample size was calculated using the G*power software (G*power; Aichach, Germany) version 3.1.9.2,^{12, 13} and it was based on the effect of AFO on limitation of ankle movement described in a previous study with a similar setting.⁵ The effect size was 0.71, and accordingly, the minimum sample size was calculated to be 14 (alpha 0.05, 1-beta 0.80). Consequently, we recruited more than 14 patients for the severe and mild ankle impairment groups. All participants were prescribed either a thermoplastic AFO (tAFO) or an adjustable posterior strut AFO (APS-AFO) (Figure 1). The APS-AFO is an orthosis with a posterior strut made by carbon, which is generally a stiffer ankle orthosis than tAFO.

Data collection

This study was conducted as an experimental study with repeated measurements of gait parameters with and without orthosis.

The KinemaTracer[®], a three-dimensional motion analysis system (Kissei Comtec Co., Ltd.; Matsumoto, Japan), was used to record kinematic data.^{5, 14, 15} This system comprises a computer for data recording and analysis and four charge-coupled device cameras with 60 Hz frame rates

installed around the treadmill. Twelve markers (30-mm diameter) were placed bilaterally on the acromia, iliac crests, hip joints (one-third distance from the greater trochanter to anterior superior iliac spine), knee joints (mid-point of the anteroposterior diameter of the lateral femoral epicondyle), ankle joints (lateral malleolus), and toes (fifth metatarsal head). The treadmill speed was set at each participant's comfortable gait speed. The treadmill speed was initially set at the mean of two comfortable 10-m over ground gait speeds without AFO and then adjusted according to the participant's comfort level. During the measurements, the patients used AFOs that had been previously prescribed for themselves and worn in daily life. All the patients used same type of flat-soled shoes. To prevent the sole height differences from affecting the results of the examination (with and without AFO), the thickness of the shoes was adjusted using insoles such that the sole heights for the patients were the same regardless of the use of AFO.

The participants practiced walking on the treadmill prior to the measurements. The order of examination for the two conditions, with and without AFO, was randomly determined using a computer-based random number generator. The treadmill was set at the same speed in both conditions. The use of the handrails of the treadmill or additional assistive devices was not allowed during the measurements. The data collection started once participants achieved a steady-state of walking speed, and the duration of the measurement was 20 s for each trial. To prevent falls, safety harnesses and handrails were prepared, and the participant was supervised by a physiotherapist.

Data analysis

Heel strikes and toe-offs were automatically identified by ankle and toe marker trajectories using the KinemaTracer® (Kissei Comtec Co., Ltd.). Temporal parameters, including the stride time, single limb stance time, and double stance time on the paretic and non-paretic side, as well as spatial factors, such as cadence, stride length, step length, and step widths of both sides, were calculated. Step width was defined as the mediolateral distance between ankle joints upon the heel strike of the paretic and non-paretic sides. The spatial parameters were normalized to the participants' body height. The CVs of these spatiotemporal parameters, except for cadence, were calculated to evaluate walking variability as a percentage by dividing the standard deviation by the mean. Stability was evaluated using MoS¹⁶ as an index of dynamic stability, interpreted as the 'safety margin' of the base of support during gait

(the distance between the boundaries of the base of support and the extrapolated COM [XCOM]). The XCOM is a state of the COM in which both the position and velocity are considered, and it is calculated using the following equation:

$$XCOM = P_{COM} + V_{COM} / \sqrt{g/l}$$

Where P_{COM} is the mediolateral position of the COM, V_{COM} is the mediolateral velocity of the COM, g is the gravitational constant (9.81 m/s²), and l is the pendulum length (leg length \times 1.34).¹⁷ The boundary of the base of support was defined as the mediolateral position of the ankle marker of the leading foot.¹⁸ The MoS was calculated at every heel strike and averaged for each foot separately (Figure 2).

The COM was calculated by the equation described by Ehara and Yamamoto.¹⁹ The body was divided into seven segments (trunk, both thighs, both lower thighs and both feet) using the markers, and the centers of these segments were calculated. The mass ratios of each segment were estimated as 0.66, 0.10, 0.05 and 0.02 for the trunk, thigh, lower thigh and foot, respectively. The COM was calculated as a composite of the centres of the seven segments. The mediolateral COM movement, measured as the peak-

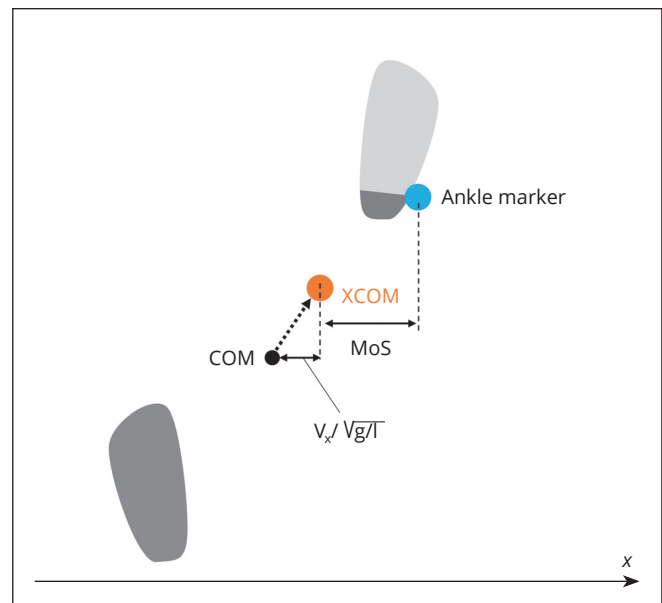


Figure 2.—Schematic illustration of the margin of stability (MoS) and the extrapolated center of mass (XCOM) at heel strike. MoS represents the mediolateral distance between the XCOM and the ankle marker, XCOM represents the range that COM does not exceed at any timing under the assumption of the inverted pendulum model, V_x is the mediolateral velocity of the COM, g is the gravitational constant (9.81 m/s²), l is the pendulum length (the height of the COM).

to-peak displacement over a gait cycle, was also analyzed to assess lateral stability during walking.

A component analysis of toe clearance was also conducted. The parameters of toe clearance and its components in the paretic limb during the swing phase were calculated on the basis of previously reported procedures.^{5, 20} These studies have shown that the value of toe clearance is equivalent to the sum of the following vertical components: 1) limb-shortening; 2) non-paretic hip elevation; 3) hip elevation due to pelvic obliquity; and 4) foot elevation due to circumduction. Parameters 2, 3 and 4 are considered as movements compensating for limb-shortening due to hemiparesis.^{5, 20, 21} From the breakdown of toe clearance into its individual components, the dependence on the compensatory movements can be evaluated. Using this methodology, the value of toe clearance and the extent of the dependence on compensatory movements were examined.

Statistical analysis

The normality of each parameter was checked using the Shapiro-Wilk Test. For comparison between the severe and mild ankle impairment groups, Student's *t*-test (unpaired *t*-test) and the Wilcoxon Rank-Sum and χ^2 tests were performed for continuous and categorical variables, respectively. Within-group differences in gait parameters with and without AFO were assessed using the paired *t*-test or the Wilcoxon's Signed-Rank test. As the time since stroke onset could be a confounding factor for the effects of AFO on hemiparetic gait, correlational analyses using Spearman's rank correlation coefficients were performed

between the time after stroke and the value differences with- and without-AFO for the parameters showing significant differences between conditions. Any P value less than 0.05 were considered statistically significant. Statistical analyses were conducted using JMP 13 (SAS Institute Inc.; Cary, NC, USA).

Ethical considerations

This study conformed to the declaration of Helsinki and was approved by the Medical Ethics Committee of Fujita Health University. All participants provided written informed consent prior to participation.

Data availability

The data collected and analyzed during the current study are available from the corresponding author on reasonable request.

Results

Thirty-two patients (15 and 17 with severe and mild ankle impairment, respectively) participated in this study. The overall patient demographics are shown in Table I. The time after stroke was significantly longer and stroke impairment assessment set scores were significantly worse in the severe than in the mild ankle impairment group.

Spatiotemporal parameters for the total study population are presented in Table II. The use of the AFO significantly increased the stride time, duration of non-paretic limb double stance, stride length, and step length on the non-paretic side; it also significantly decreased the ca-

TABLE I.—Patient demographics.

Variables	Total	Severe ankle impairment group (N.=15)	Mild ankle impairment group (N.=17)	P value
Age, years	48.3±20.0	44.0±20.6	52.0±19.2	0.265
Height, cm	165.3±8.6	166.3±8.1	164.4±9.1	0.529
Weight, kg	60.8±14.4	60.5±15.2	61.0±14.1	0.934
Sex, male/female	22/10	11/4	11/6	0.599
Diagnosis, intracerebral hemorrhage/cerebral infarction	11/21	6/9	5/12	0.529
Time after stroke, days	140 (65-2439)	322 (70-2439)	82 (65-1768)	0.025*
Affected side, right/left	17/15	6/9	11/6	0.162
Score of lower extremity motor function on the SIAS	9.9±1.8	8.5±1.3	11.1±1.2	<0.0001**
Hip-flexion test	3.7±0.5	3.5±0.5	3.9±0.3	0.033*
Knee-extension test	3.5±0.6	3.3±0.6	3.6±0.6	0.058
Foot-tap test	2.7±1.1	1.7±0.6	3.5±0.6	<0.0001**
Treadmill speed, km/h	2.7±0.8	2.4±0.7	2.9±0.7	0.101
Functional ambulation categories	4.6±0.5	4.7±0.5	4.5±0.5	0.451
Type of AFO, tAFOs/APS-AFOs	15/17	7/8	8/9	0.982

*P<0.05; **P<0.01.

AFO: ankle-foot orthosis; APS-AFO: adjustable posterior strut-AFO; SIAS: stroke impairment assessment set; tAFO: thermoplastic AFO.

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TABLE II.—Spatiotemporal gait parameters in total study population.

Variables	Without AFO	With AFO	P value
Stride time, s	1.16±0.17	1.19±0.19	0.032*
Cadence, steps/min	105.1±14.4	103.0±14.7	0.023*
Single stance time, s			
Paretic side	0.31±0.04	0.32±0.05	0.076
Non-paretic side	0.43±0.09	0.43±0.09	0.613
Double stance time, s			
Paretic side	0.23±0.06	0.23±0.06	0.849
Non-paretic side	0.19±0.05	0.20±0.05	0.026*
Stride length, % body height	51.0±11.8	51.8±11.8	0.042*
Step length, % body height			
Paretic side	26.2±7.4	26.2±7.1	0.846
Non-paretic side	24.8±5.6	25.6±5.4	0.029*
Step width, % body height	14.4±3.3	13.8±2.9	0.059

*P<0.05; **P<0.01.
AFO: ankle-foot orthosis.

dence. No significant differences were observed in other parameters between patients with and without AFO.

Furthermore, the spatiotemporal parameters were compared between the mild and severe ankle impairment groups (Table III). The stride time, single stance time of the paretic side, and step length on non-paretic side increased, and the cadence decreased significantly with the use of AFO in the severe ankle impairment group. There were no significant changes in the spatiotemporal parameters with or without the use of AFO in the mild ankle impairment group. We also assessed the CVs of these parameters. In the total study population, the step width variability decreased significantly with the use of AFO (Table IV). In addition, AFO decreased stride, step length on the non-paretic side, and step width variabilities in the severe

ankle impairment group, but increased step length variability on the non-paretic side in the mild ankle impairment group (Table V).

The MoS on the paretic side decreased with AFO in the total study population (Figure 3A), as well as in patients with severe ankle impairment (Figure 3B) (11.6±2.3 vs. 9.7±1.8 cm, P=0.006), but there was no difference with or without AFO in the mild ankle impairment group (Figure 3B) (8.7±2.7 vs. 8.7±3.4 cm, P=0.900). No significant differences were observed for MoS on the non-paretic side between the patients with and without AFO in each group (Figure 3C) (severe ankle impairment group: 9.2±2.1 vs. 9.2±2.2 cm, P=0.979; mild ankle impairment group: 7.7±2.4 vs. 7.8±1.9 cm, P=0.705).

The analysis results of toe clearance and its break down

TABLE IV.—Coefficients of variation for spatiotemporal gait parameters in total study population.

Variables	Without AFO	With AFO	P value
Stride time, %	3.7±2.6	3.4±1.1	0.681
Single stance time, %			
Paretic side	9.2±4.0	8.2±2.5	0.120
Non-paretic side	7.5±4.0	7.5±2.7	0.805
Double stance time, %			
Paretic side	10.9±8.2	9.2±3.1	0.215
Non-paretic side	9.0±2.7	10.3±5.0	0.403
Stride length, %	5.3±3.1	4.6±1.9	0.339
Step length, %			
Paretic side	7.9±7.8	7.5±4.5	0.358
Non-paretic side	8.1±4.6	7.1±2.6	0.498
Step width, %	8.2±4.3	7.3±3.4	0.012*

*P<0.05, **P<0.01.
AFO: ankle-foot orthosis.

TABLE III.—Comparisons of spatiotemporal gait parameters in severe vs. mild impairment groups.

Variables	Severe impairment group (N=15)			Mild impairment group (N=17)		
	Without AFO	With AFO	P value	Without AFO	With AFO	P value
Stride time, s	1.22±0.15	1.26±0.15	0.024*	1.11±0.18	1.12±0.20	0.463
Cadence, steps/min	99.7±11.5	96.0±10.3	0.028*	109.9±15.3	109.2±15.5	0.738
Single stance time, s						
Paretic side	0.30±0.04	0.32±0.04	0.008**	0.32±0.04	0.33±0.04	0.904
Non-paretic side	0.45±0.08	0.46±0.06	0.410	0.41±0.09	0.41±0.10	0.953
Double stance time, s						
Paretic side	0.26±0.06	0.26±0.06	0.935	0.20±0.05	0.20±0.04	0.702
Non-paretic side	0.20±0.06	0.22±0.07	0.089	0.18±0.03	0.19±0.03	0.158
Stride length, % body height	48.9±13.1	50.0±12.3	0.094	52.8±10.6	53.3±11.5	0.272
Step length, % body height						
Paretic side	25.9±9.1	25.5±7.6	0.476	26.5±5.7	26.8±6.8	0.580
Non-paretic side	23.0±5.2	24.5±5.3	0.042*	26.3±5.5	26.6±5.5	0.432
Step width, % body height	15.5±2.5	14.4±2.0	0.058	13.4±3.6	13.3±3.5	0.702

Values are presented as mean±standard deviation.
*P<0.05; **P<0.01.
AFO: ankle-foot orthosis.

TABLE V.—Coefficients of variation for spatiotemporal gait parameters in severe vs. mild impairment groups.

Variables	Severe ankle impairment group (N.=15)			Mild ankle impairment group (N.=17)		
	Without AFO	With AFO	P value	Without AFO	With AFO	P value
Stride time, %	4.3±3.4	3.3±1.0	0.177	3.2±1.5	3.4±1.3	0.619
Single stance time, %						
Paretic side	10.4±4.5	9.2±2.5	0.264	8.2±3.3	7.3±2.2	0.229
Non-paretic side	8.5±4.9	7.6±3.2	0.600	6.7±2.8	7.3±2.4	0.249
Double stance time, %						
Paretic side	12.4±11.4	8.7±3.6	0.091	9.6±3.6	9.6±2.7	0.982
Non-paretic side	7.9±2.6	9.3±4.0	0.212	9.9±2.5	11.2±5.8	0.910
Stride length, %	6.5±3.8	4.8±2.0	0.037*	4.2±1.6	4.5±1.9	0.330
Step length, %						
Paretic side	9.9±10.9	7.7±4.3	0.858	6.2±2.6	7.2±4.8	0.226
Non-paretic side	10.2±5.5	6.9±2.4	0.007**	6.2±2.5	7.3±2.8	0.043*
Step width, %	8.7±2.8	7.4±2.4	0.033*	7.8±5.3	7.3±4.1	0.231

Values are presented as mean±standard deviation.

*P<0.05; **P<0.01.

AFO: ankle-foot orthosis.

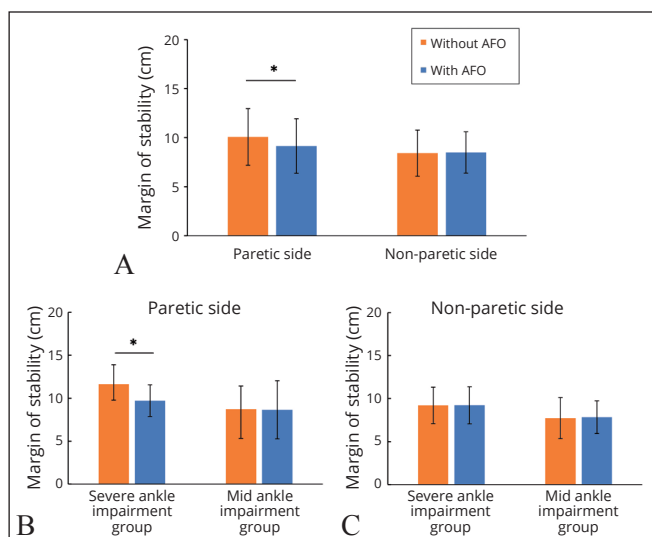


Figure 3.—A) Margin of stability (MoS) with or without using an ankle-foot orthosis (AFO) in paretic and non-paretic sides in total study population; B) and subgroup comparisons in the severe ankle impairment group and mild ankle impairment group in paretic side; and C) and non-paretic side.

The bars indicate the average values of MoS at paretic/non-paretic heel strikes with and without an AFO in each group. The MoS on the paretic side was significantly smaller than that without an AFO in the overall comparison (A) and in the severe impairment group (B). No significant difference was observed in the mild impairment group (C). Error bar indicates the standard deviation.

*P<0.01.

into components are shown in Figure 4. In the comparison in the total study population (Figure 4A), a significant increase in the component of limb-shortening (without AFO vs. with AFO: 0.3±2.9 vs. 0.9±2.7 cm, P=0.001) and a significant decrease in the component of hip elevation due to pelvic obliquity (1.5±1.8 vs. 1.3±1.8 cm, P=0.024) and the

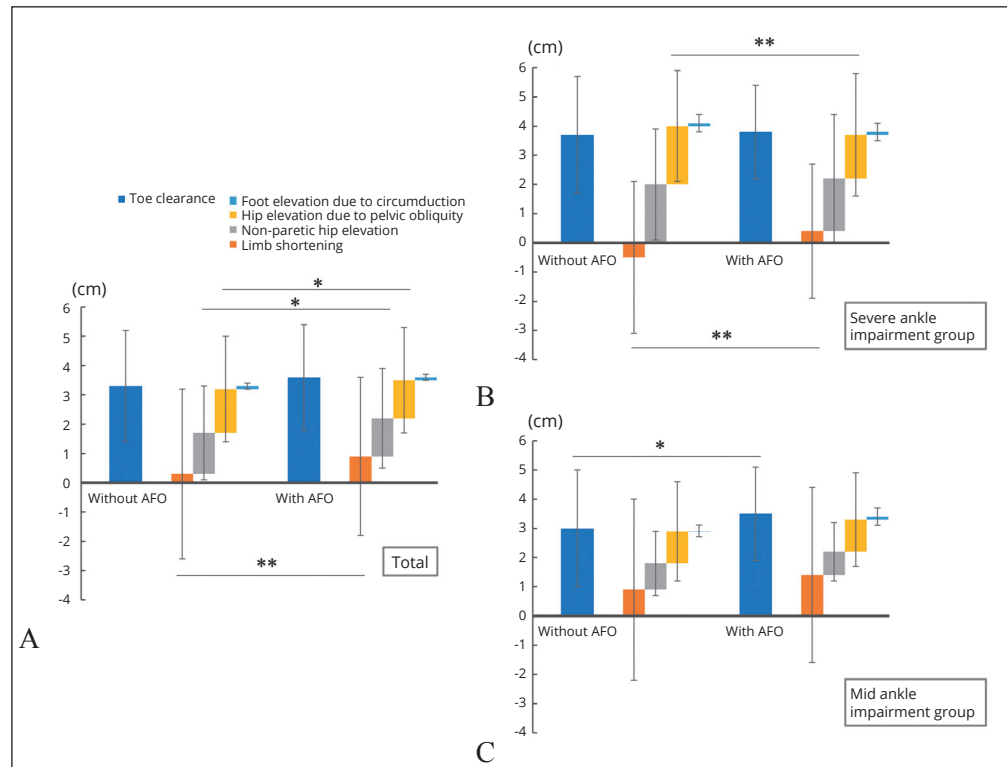
component of non-paretic hip elevation (1.4±1.6 vs. 1.3±1.7 cm, P=0.048) were observed. In addition, there was also an increasing tendency in the toe clearance (3.3±1.9 vs. 3.6±1.8 cm, P=0.065). No significant effects on the component of circumduction with the use of AFO were observed. In the severe ankle impairment group, there was no difference in toe clearance between patients with and without AFO (Figure 4B) (without AFO vs. with AFO: 3.7±2.0 vs. 3.8±1.6 cm, P=0.806). However, the component of limb-shortening increased (-0.5±2.6 vs. 0.4±2.3 cm, P=0.002) and the component of hip elevation due to pelvic obliquity (2.0±1.9 vs. 1.5±2.1 cm, P=0.005) decreased when wearing an AFO. No significant differences were observed in other components of compensatory movements (non-paretic hip elevation: 2.0±1.9 vs. 1.8±2.2 cm, P=0.165; foot elevation due to circumduction: 0.1±0.3 vs. 0.1±0.3 cm, P=0.394). Toe clearance significantly increased when wearing an AFO in the mild ankle impairment group (Figure 4C) (3.0±1.8 vs. 3.5±2.0 cm, P=0.041), and there was also an increasing tendency in the limb-shortening (0.9±3.1 vs. 1.4±3.0 cm, P=0.081), but there were no differences in the component of compensatory movements with or without an AFO (non-paretic hip elevation: 0.9±1.1 vs. 0.8±1.0 cm, P=0.194; hip elevation due to pelvic obliquity: 1.1±1.7 vs. 1.1±1.6 cm, P=0.649; foot elevation due to circumduction: 0.0±0.2 vs. 0.1±0.3 cm, P=0.973).

In correlational analyses, the changes by AFO in the component of limb-shortening and the vertical component of hip elevation due to pelvic obliquity significantly correlated with the time after stroke (Table VI: limb-shortening: r=0.46, P=0.009; hip elevation due to pelvic obliquity: r=-0.39, P=0.028). All other variables did not significantly correlate with time after stroke.

Figure 4.—A) Toe clearance and its components with and without ankle-foot orthosis (AFO) in the total study population; B) the severe ankle impairment group; and C) the mild ankle impairment group.

The comparison in the total study population shows a significant increase in the component of limb-shortening and significant decrease in the component of hip elevation due to pelvic obliquity and the component of non-paretic hip elevation (A). The comparison in the severe ankle impairment group shows a significant increase in the component of limb-shortening and significant decrease in the component of hip elevation due to pelvic obliquity (B). The comparison in the mild ankle impairment groups shows a significant increase in toe clearance (C). Error bar indicates standard deviation.

*P<0.05; **P<0.01.



Discussion

This study investigated the effects of AFO on stability in the post-stroke gait and the differences in these effects related to the severity of ankle impairment. The results showed that the variabilities in spatiotemporal parameters and MoS, which were higher in the paretic side compared to the non-paretic side, decreased with AFO, indicating the improvement in the dynamic balance control during gait. These effects on gait differed with varying ankle impairment severity and were more evident in the severe ankle impairment group. Conversely, these effects were not significant in the mild ankle impairment group, instead, the variability seemed to slightly worsen with the use of AFO. The effects on the toe clearance were more universal, being present both in severe and mild impairment groups.

In post-stroke patients, impairments such as muscle weakness, abnormal movement synergies and spasticity cause instability in the paretic limb.^{22, 23} Such impairments lead to a decline in gait performance. In this study, the patients with post-stroke hemiparesis had a slower walking speed, shorter step length, shorter paretic single stance and longer double stance time compared to those of the healthy subjects shown previously;^{24, 25} these findings

are consistent with previous reports.²⁶ The decline in gait performance caused by paretic limb impairments may improve with AFO, which adjusts the alignment and supports paretic ankle stability. Previous studies have demonstrated the effect of AFO on spatiotemporal parameters, including an increase in step length and paretic single stance time, which can be attributed to improved ankle stability.^{3, 27, 28} These effects were also observed in the present study: there was a significant increase in non-paretic step length in the total population and an increase in the paretic single stance time in the severe impairment group. However, we also observed a decrease in cadence and increase in double stance time in the total population, which contradicts the findings of a previous study.³ This can be attributed to using the identical walking speeds to compare the gait in patients with and without the AFO. With the same walking speed, the increase in step length with AFO may have resulted in the decreased cadence, which caused an increase in the stride time, and a subsequent increase in double stance time, as it is a component of the stride time.

Further, we observed several changes in the gait variability parameters that support the effects of AFOs on paretic stance stability. In the total study population, the step width CV decreased in patients using AFOs. The differ-

TABLE VI.—Spearman's ranked correlation coefficient between the time after stroke and the value differences with and without AFO.

Variables	ρ	P value
Stride time	0.28	0.127
Cadence	-0.12	0.499
Single stance time		
Paretic side	0.15	0.418
Non-paretic side	0.14	0.461
Double stance time		
Paretic side	0.05	0.792
Non-paretic side	0.18	0.319
Stride length	0.06	0.756
Step length		
Paretic side	-0.03	0.867
Non-paretic side	0.20	0.274
Step width	-0.34	0.060
Stride time CV	-0.03	0.866
Single stance time CV		
Paretic side	-0.09	0.640
Non-paretic side	0.15	0.409
Double stance time CV		
Paretic side	-0.02	0.932
Non-paretic side	0.07	0.698
Stride length CV	0.01	0.956
Step length CV		
Paretic side	0.03	0.884
Non-paretic side	-0.14	0.458
Step width CV	-0.09	0.611
Margin of stability		
Paretic side	-0.33	0.067
Non-paretic side	-0.07	0.723
Toe clearance	0.33	0.065
Limb shortening	0.46	0.009**
Non-paretic hip elevation	0.03	0.872
Hip elevation due to pelvic obliquity	-0.39	0.028*
Foot elevation due to circumduction	-0.21	0.258

*P<0.05; **P<0.01.

CV: Coefficient of variation.

ence in the variability was even more evident in the severe impairment group, exhibiting a significant decrease in stride length, non-paretic step length, and step width CVs, which is in line with the findings of a previous study.⁸ As the non-paretic step is an action that occurs during the paretic single stance, the instability of the paretic single stance due to paresis may have been reflected on the non-paretic step length CV.

The variabilities in these spatiotemporal parameters reflect the fall risk. For example, the increase in the variability in stride length, step length, step width, and stride time is related to the fall risk among the elderly and patients with central nervous system disorders.²⁹⁻³² Accordingly, the decreased stride CV and step length CV on the non-paretic side in this study indicate the beneficial effect of AFO in improving paretic limb stability in patients with

severe ankle impairment. In addition, the use of AFO also increased the paretic single stance time, which is a period of less stability in stroke patients.³³ Contrary to the findings observed in the severe ankle impairment group, the paretic single stance time did not significantly change, and the step length CV increased with the use of an AFO in the mild ankle impairment group. This may be attributable to the impaired dynamic balance control by AFO due to the restricted plantar flexor muscle force generation, which is seen when healthy individuals wear the AFO.⁹ Future studies with kinetic measurements would help clarify the mechanism of this impairment severity-related differences in the effect of AFO on the dynamic stability during walking.

Another parameter employed to evaluate the dynamic balance during gait was the MoS. The MoS reflects the 'safety margin' of the base of support, *i.e.*, dealing with the movement of the COM, and is used to evaluate dynamic balance during walking.^{18, 34-37} A higher MoS in neurological patients indicates a compensatory strategy to increase the 'safety margin' of the base of support, thus reflecting poor dynamic balance.³⁸ In the present study, the AFO decreased the MoS on the paretic side, suggesting that it may have contributed to dynamic balance improvement, and thus reduced the compensation to maintain the balance during gait. The subgroup analysis showed that this effect was robust in the severe impairment group, while there was no significant effect in the mild impairment group. In combination with the changes observed in the spatiotemporal parameters, these results support the benefit of AFOs on dynamic balance control during gait in patients, especially those with severe ankle impairment.

In contrast to the robust merits in the severe impairment group, the present results on dynamic balance failed to show the merits of using AFOs in the mild ankle impairment group. However, the AFO also plays an important role in supporting toe clearance in patients post stroke,^{4, 5} which was also investigated in the present study. Post-stroke gait is characterized by decreased knee flexion and ankle dorsiflexion during the swing phase on the paretic side.³⁹⁻⁴¹ Impaired leg movement decreases toe clearance and increases the risk of falling; therefore, individuals post-stroke adopt compensatory movement strategies (*e.g.*, pelvic hiking and circumduction).^{22, 39, 42} In this study, the results regarding the total study population were consistent with earlier findings,⁵ revealing a significant increase in the vertical component of limb-shortening and decrease in the vertical component of compensatory movements with the use of AFO, with an increasing tendency ($P=0.065$) in toe clear-

ance. In the mild impairment groups, a significant increase in toe clearance and an increased tendency ($P=0.080$) in the limb-shortening component with the use of AFO were observed, showing the merits of using AFO in improving gait performance even in this group. However, the effect of AFO was relatively small compared to the effects on the severe ankle impairment group; this may be because the extent of the paresis was mild involving fewer problems in limb-shortening. In addition, the AFO used by the patients with mild paresis may be less solid and thus, had a smaller effect in limiting ankle plantar flexion, though the type of the orthosis (tAFOs and APS-AFOs) was not significantly different between the groups (Table I). In any case, the weaker effect of AFO both in stability and toe clearance may suggest that the use of AFO should be carefully evaluated in the mild impairment groups. Further investigation on the effects of AFO in combination with its detailed setting would facilitate our understanding of AFO in the post-stroke gait.

Clinical implications

The study findings support the benefits of AFO in improving both stance stability and toe clearance in patients. The AFO presents significant merit in toe clearance but may impede stance stability in patients with mild ankle impairment; therefore, the effects of AFOs should be carefully evaluated in these patients. Thus, the effects on stability, which are occasionally difficult to detect visually, need particular attention. Technologies, such as three-dimensional motion analysis, to quantify changes in performance may help improve the clinicians' assessments on the effects of AFOs and facilitate appropriate individualized prescribing.

Limitations of the study

There are several limitations to this study. First, the participants had relatively preserved gait ability, as we only included those who were able to independently walk on the treadmill without gait aids or orthoses. Thus, our findings may not be generalizable to patients with more severe hemiplegia. Second, the fixed walking speed used while comparing the gait performance in the patients with and without the AFOs may have influenced the results of this study. The walking speed was identical for the gait performance examinations because dynamic stability indices, which were main outcome indices of this study, can be influenced by the walking speed.⁴³ However, this may have masked the positive effects of the AFO on the spatiotemporal indices. Third, AFO types

were inconsistent across participants. In fact, the effect of orthosis may differ according to their types, and the weak effect of orthosis in the mild paresis group may be due to the use of a simpler orthosis with less stiffness. Though the ratio of tAFOs and APS-AFOs was not significantly different between the groups (Table I), the setting of the AFOs (thickness, trimming, etc.) might have yielded some variation in stiffness. Therefore, it should be noted that the effect of the AFO on severe and mild impairment cannot be directly comparable. Even so, the fact that the patients with mild ankle impairment presented with only slight benefits with the use of AFO, and even had some negative effects related to stability, indicates the importance of gait evaluation before prescribing AFO for patients with mild ankle impairment. Fourth, the time after stroke in this study varied widely, including that for cases of both subacute and chronic stroke. In addition, the time after stroke was significantly longer in the severe than in the mild ankle impairment group. The effects on limb shortening and hip elevation due to pelvic obliquity were correlated with the time after stroke; thus, the longer time after stroke in the severe ankle impairment group may have some influence in the differences in limb shortening and hip elevation due to pelvic obliquity between the severe and mild impairment groups shown in this study. However, none of the gait stability parameters presented a significant correlation with the time after onset within each group. Thus, the differences in the effects of AFO between severe and mild impairment groups on the stability during gait were not likely affected by the difference in the time after stroke. Comparisons under more controlled conditions are needed to further clarify the complex relationship between the severity of ankle impairment and the effects of AFO.

The small number of recruited subjects may also be a limitation of this study. The sample size of this study was calculated based on the robust effect of AFO on ankle movement limitation shown previously;⁵ however, it may have been insufficient to demonstrate the differences in the with and without AFO conditions for some parameters with a small effect size, especially in the subgroup analysis of the severe and mild impairment groups. Further analysis, such as one examining the differences in the effects of AFO between patients with different levels of paresis or between sub-acute and chronic cases should be performed using a larger sample size. Finally, the ground reaction force was not investigated in this study; therefore, it was not possible to clarify the influence of kinetic changes due to ankle movement restriction on the gait parameters. Fur-

ther studies are required to quantify and analyze these kinetic changes to help better understand the effect of AFO on dynamic stability during the stance phase.

Conclusions

In this study, we investigated the effects of AFO on stability during gait and the differences in the effects between patients with severe and mild ankle impairment. AFO improved MoS and step width CV, which suggests an improvement in stability. Subgroup analysis showed that this effect was robust in the severe ankle impairment group. On the contrary, the parameters of gait stability were not evident and were even slightly worse in patients with mild ankle impairment, though the effect of AFO on toe clearance was also significant in the mild impairment group. These results suggest that the effects of using AFOs in patients with mild impairment should be carefully evaluated. Further detailed studies on the effect of AFO in relation to the severity of impairment and the settings of AFO (*i.e.*, stiffness or joint types of AFO) are warranted to further understand the effects of AFOs.

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