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Kinematic Effects of Newly Designed Knee-Ankle-Foot Orthosis With Oil Damper Unit on Gait in People With Hemiparesis

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Abstract

The purposes of this study were to develop a new orthosis controlling ankle and knee joint motion during the gait cycle and to identify the effects of the newly designed orthosis on gait kinematics and tempospatial parameters, including coordination of the extremities in stroke patients. Fifteen individuals who had sustained a stroke, onset was 16 months, participated in this study. Before application of the measurement equipment the subjects were accustomed to walking on the ankle-foot orthosis (AFO) or stance control knee with knee flexion assisted-oil damper ankle-foot orthosis (SCKAFO) for 5 minutes. Fifteen patients were investigated for 45 days with a 3-day interval between sessions. Measurements were walking in fifteen stroke with hemiparesis on the 3D motion analysis system. Comparison of AFO and SCKAFO are gait pattern. The difference between the AFO and SCKAFO conditions was significant in the gait velocity, step length of the right affected side, stance time of both legs, step-length asymmetry ratio, single-support-time asymmetry ratio, ∅-thigh angle and ∅-shank angle in the mid swing ($p<.001$). Using a SCKAFO in stroke patients has shown similar to normal walking speeds can be attained for walking efficiency and is therefore desirable. In this study, the support time of the affected leg with the SCKAFO was longer than with the AFO and the asymmetry ratio of single support time decreased by more than with the AFO. This indicates that the SCKAFO was effective for improving gait symmetry, single-support-time symmetry. This may be due to the decrease of gait asymmetry. Thus, the newly designed SCKAFO may be useful for promoting gait performance by improving the coordination of the extremity and decreasing gait asymmetry in chronic stroke patients.

Key Words: Gait asymmetry; Gait performance; Stance control knee with knee flexion assisted-oil damper ankle-foot orthosis.

Introduction

Hemiparesis, caused by a cerebral vascular accident (CVA), results in damage to motor neurons and their pathways primarily on one side of the brain (Barela et al, 2000). This result leads to inappropriate innervation of peripheral voluntary muscles and affect those muscles involved in locomotion (Olney and Richards, 1996). Gait restoration is a major goal in post-stroke neurological rehabilitation. For this reason, the recovery of independent walking is important in rehabilitation studies (Lindquist et al, 2007).

Gait performance in patients with stroke is characterized by residual spatial and temporal left-right asymmetry, compared with that in healthy adults and those using newly designed orthosis (Hsu et al, 2003). Gait asymmetry is also quite prevalent and is

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recognized as a key to understanding the post-stroke deficits in gait and to improving the rehabilitation process in order to maximize mobility after a stroke (Alexander et al, 2009). Another feature is the timing of the left-right coordination of gait; namely the bilateral coordination of gait (Patterson et al, 2008). This feature is distinctive from gait asymmetry since it evaluates the level of coordination between the ongoing stepping movements of both legs. Evaluating the left-right stepping phasing pattern is a convenient way of assessing this interaction and is also done based on a series of steps (Pérennou, 2006).

Arm movement cycles were identified from local maximum in the sagittal plane shoulder angle time series, with arm cycle duration and arm movement amplitude determined in an identical fashion. For each trial, it was performed on contralateral hip and shoulder joint angle time series to assess between the two signals. This has led to the suggestion that arm movements should be addressed in gait rehabilitation. The lag time at which the peak correlation occurred was close to zero. A lag time indicated that maximal flexion of the shoulder occurred before maximal flexion of the hip (Olney and Richards, 1996). The strength of the peak coordination and the time shift (lag) at which this occurred were determined. Although Ford et al (2007) reported inter-limb coordination of the upper extremities in stroke patients for gait analysis, several studies have reported various kinematic characteristics of the lower limb segments of those with hemiparesis. A few studies have actually focused on the coordination of the segmental relationships. Additional measures of coordination included the point estimate of relative phase and the frequency relation between ipsilateral arm and leg movements.

A phase angle (∅) could be calculated for each measured point in the gait cycle (Clark et al, 1993). A phase angle is different from the knee joint displacement because the knee joint displacement provides information only about the relative position of the segments.

Ankle-foot orthosis (AFO) are prescribed to improve the walking ability of patients with hemiplegia. The AFO should restrict plantarflexion to prevent foot drop during the swing phase. Therefore, the magnitude of plantarflexion resistive moment should be modified to accommodate each patient's condition (Yamamoto et al, 1993). AFO with oil damper resistance work during the initial stance phase; the hydraulic system controls the ankle movement from heel contact to foot flat. Patients can load their weight on their affected limb with ease. Plantarflexion is important for the push off phase and the plantarflexor is a key muscle to increase gait velocity. Thus the brace should permit plantarflexion of the ankle joint during the gait cycle (Yamamoto et al, 1997). AFO with oil dampers achieved sufficient plantarflexion of the ankle by adjusting a proper plantarflexion resistive moment during the initial stance phase in patients with hemiplegia (Yamamoto et al, 1999).

Unfortunately, knee hyperextension can cause pain, and is believed to lead to premature degenerative joint disease of the knee in these individuals. Conventional treatments largely focus on the use of AFO to provide ankle stability and correct knee gait abnormalities (Weinberg et al, 2005). Yamamoto et al (1999) reported that newly designed AFO with oil damper resistance had no influence on knee flexion during the swing phase. Consistent with pervious investigations, sagittal plane hip and knee flexion angles during swing will be unaffected by the use of AFO. Specifically, conflicting effects of AFO use on gait symmetry and speed have been reported, with the significant increases in gait speed falling to reach a level of functional improvement (Hesse et al, 1996).

Stroke are prescribed a knee-ankle-foot orthosis (KAFO) that locks the knee in constant full extension. Due to the absence of knee flexion, KAFO users must adopt abnormal gait patterns that can lead to premature exhaustion while walking, cosmetic problems, limited mobility, pain and loss of motion at the hip and lower-back (Waters et al, 1979). Thus, a firm push-off is the most important means of obtaining knee flexion. A new type of orthosis, referred to as a stance control knee with knee flexion assisted-oil damper ankle-foot orthosis (SCKAFO), has recently emerged to permit free knee motion in swing while providing knee-flexion in swing and knee-flexion resistance in stance (Yakimovich et al, 2009). From a biomechanical point of view, their impact on walking and activity among patients presenting with a stiff-kneed gait has previously been described (Stoquart et al, 2008). Compromised motor control and angle generation frequently lead to limited knee-flexion and stiff-legged gait, characterized by limited knee-flexion during swing and typically associated with limited hip flexion and limited or absent ankle dorsiflexion. These gait patterns cause substantial reduction in gait velocity and efficiency, and can increase the likelihood of falls (Tyrell et al, 2011). We hypothesized that the strength of the affected knee flexors may contribute to greater step lengths of both lower extremities, which, in turn, increases gait velocity. Although AFO are prescribed to improve the patient's ambulation, they may well impose some functional restrictions to the already compromised motor system and, consequently, shape some of the hemiparetic gait characteristics. In other words, the combined effect of slow velocity and a mechanically constrained ankle joint may contribute to gait asymmetry of hemiparetic gait that have little to do with the actual neurological insult.

For these shortness of AFO, this study was to develop new orthosis with oil damper unit controlling ankle and knee joint motion during gait cycle and to identify effects of newly designed orthosis on gait in chronic stroke patients. Walking with SCKAFO, stroke patients is excepted to improve gait velocity, gait performance by improving coordination of the extremity and gait symmetry.

Methods

Subjects

Fifteen individuals who had sustained a stroke participated in this study (Table 1). Exclusion criteria were severe heart disease, leg wounds, pain or other than stroke-induced gait disability or inability to follow instructions. Before this experiment was performed, this study was sufficiently explained to all the subjects and their consent to participate was obtained. Median time since stroke onset was 16 months. Seven subjects had suffered from an intracerebral infarction, 5 from an intracerebral haemorrhage and 3 from a subarachnoidal haemorrhage. All subjects had right-side hemiparesis. Sensory function in the paretic leg was impaired in 5 cases. They had been using their AFO for a median time of 12 months. Fifteen of the subjects walked 30 meter unsupported. Chedoke-McMaster stroke assessment stage one is characterized by flaccid paralysis and stage six by the presence of near normal coordination patterns, yet still with come faulty patterns and timing with rapid and complex actions (Dang et al, 2011). Table 1. summarizes the subjects demographic characteristics, comfortable gait speed. Chedoke-McMaster Impairment Inventory score 5.4/4.9 for the leg and foot. This mean that incomplete motor recovery of the lower limb. Chedoke-McMaster Impairment Inventory score 5.4/5.6 for the arm and hand. This mean that sufficient ability to use the sliding handles. These results suggest that all participating

Table 1. The general characteristics of the subjects for stroke (N=15)

Group	Age (yrs)	Height (m)	Weight (kg)	Comfortable gait speed (m/s)	Chedoke-McMaster score (max=7)	
					Leg / Foot (Right side, affected)	Arm / Hand (Right side, affected)
Stroke	64±9[a]	1.7±.1	86±12	.7±.3	5.4/4.9	5.4/5.6

[a]mean±standard deviation.

subjects, as required by the admission criteria, had mild to moderate motor and muscle tone impairments.

Instruments

Newly designed stance control knee with knee flexion assisted-oil damper ankle-foot orthosis (SCKAFO)

Yamamoto et al (1997) reported that the most important function of an AFO for patients with hemiplegia is to provide the dorsiflexion assisting moments (synonymous with the plantarflexion resistive moment) that are normally provided by eccentric contraction of the pretibial muscles at the initial stance phase (Figure 1). The orthotic knee joint, mounted on the medial side of the Knee-flexion assist KAFO, is a simple mechanism that uses friction and a spring to regulate knee flexion in the swing phase. Knee-flexion assist bend your knees with the help of the behavior produced by the band was wearing (Figure 2).

Instrumentation consisted of a six-camera ELITE motion analysis system (BTS)

The system is an automated, 3D motion tracking and analysis system with the system are six closed circuit television (CCTV) cameras that pulse infrared light directly at the reflective markers with a frequency of 100 times per second (100 ㎐). The information from each camera is then time-synchronised using proprietary electronics before being digitised into a standard PC workstation. Before each of the patient data collection sessions, the acquisition volume was calibrated using the three-plane movement analysis collected by an ELITE 3D motion analysis system (BTS Smart System. BTS Bioengineering., Milan, Italy).The global reference system was defined with respect to the laboratory. BTS has calibration bar algorithm that enables a precision and reconstruction without rivals, which permit a camera setup management that are particularly critical with different dimensional working volume in volume parts and/or with obstacles in the working volume (Nikfekr et al, 2002). Reflective markers were placed on the head, the shoulder, the anterior-superior iliac spine, the upper femoral trochanter, the rotation point of the knee, the lateral malleolus, the heel and the fifth metatarsal (Papaxanthis et al, 2003).

Procedures

The instructions were to walk at a comfortable speed, “as if walking around the grocery store” (Lamontagne et al, 2007). They were studied twice, 1 day apart. The first day, the AFO orthosis were measured. The subject was instructed to wear the SCKAFO during all waking hours for the next 1 days and to walk as much as possible. And on the third day, the SCKAFO orthosis were measured. Before application of the measurement equipment the subjects were accustomed to walking on the AFO or SCKAFO for 5 minutes. Fifteen patients were investigated for 45 days with a 3-day interval between

Figure 1. Oil damper ankle-foot orthosis.

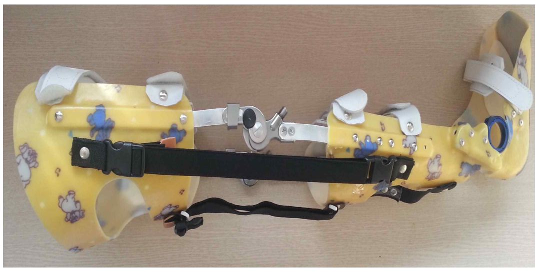

Figure 2. Newly designed stance control knee with knee flexion assisted-oil damper ankle-foot orthosis.

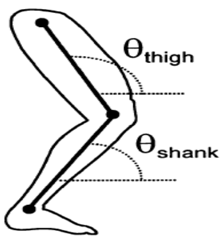

Figure 3. The convention for shank and thigh angle calculation.

sessions. Gait velocity, as well as spatial and temporal variables of the gait cycle, including the step length, cadence, stance time, and single support time, were calculated (Pietraszewski et al, 2012). To quantify the extent of the temporal and spatial asymmetry of gait pattern, the single-support-time asymmetry ratio and step length asymmetry ratio were calculated, respectively, as follows. In these ratios, "affected" indicates the affected lower extremity and "unaffected" indicates the unaffected lower extremity. Thus, the treater these ratios, the greater the asymmetry. The relationships between strength measures and gait performance (velocity and asymmetry) were assessed by using Person correlation coefficients (Hsu et al, 2003). The strength of the peak correlation and the time shift (lag) at which this occurred were determined. A lag time indicated that maximal flexion of the shoulder occurred before maximal flexion of the hip. Additional measures of coordination included the point estimate of relative phase and the frequency relation between ipsilateral arm and leg movements. We thus examine phase angle (∅) as it progresses through the stance and swing of the walking legs (Figure 3). Stance can be further divided into weight acceptance, that is ipsilateral foot strike to contralateral toe-off, single support, that is contralateral toe-off to contralateral foot strike and push-off, that is contralateral foot strike to ipsilateral toe-off. The sub-task of the swing period is primarily to advance the limb and thus the body forward (Barela et al, 2000).

Statistical Analysis

The demographic data of subjects were summarized using descriptive analysis. A paired t-test was used to compare AFO and SCKAFO conditions. Comparison of AFO and SCKAFO are gait velocity, as well as spatial and temporal variables of the gait cycle, including the step length, stance time, single support time, and lag time, ∅-thigh angle and ∅-thigh angle were calculated to quantify the extent of the temporal and spatial asymmetry of gait pattern. Normality was assessed using the Shapiro-Wilk test. All statistical analyses were performed by using the SPSS version 12.0 software. The level of statistical significance set at α=.05.

Results

Sagittal plane kinematics (walking velocity, step length and stance time)

The means of gait velocity in the AFO and SCKAFO conditions (mean value±standard deviation, (.40±.06 m/s and .55±.05 m/s, respectively) were a significant difference between the AFO and SCKAFO conditions in gait velocity ($p<.001$) (Table 2). There were significant differences between the AFO and SCKAFO conditions in the stance time of both legs ($p<.001$) (Table 2). There were also significant differences between the AFO and SCKAFO conditions in the step length of the unaffected side ($p<.001$) (Table 2). The difference between the AFO and SCKAFO conditions was not significant in the step length of the right affected side ($p>.05$) (Table 2).

Temporal and spatial gait asymmetry during gait while wearing AFO or SCKAFO in stroke patients (single support time, step-length asymmetry ratio, single-support-time asymmetry ratio)

There were significant differences between the AFO and SCKAFO conditions in support time (s) of both legs ($p<.001$) (Table 3). The means of the

$$\text{Single-support-time asymmetry ratio} = 1 - \frac{\text{single support time (affected)}}{\text{single support time (unaffected)}}$$

$$\text{Step-length asymmetry ratio} = 1 - \frac{\text{step length (affected)}}{\text{step length (unaffected)}}$$

Table 2. Comparison of walking velocity, step length and stance time during gait while wearing AFO or SCKAFO in stroke patients (N=15)

	AFO[a]	SCKAFO[b]	t	df	p
Walking velocity (㎧)	.40±.06[e]	.55±.05	-7.06	14	<.001
Affected leg (Rt[c]) Stance time (sec)	.69±.12	.85±.13	-5.93	14	<.001
Unaffected leg (Lt[d]) Stance time (sec)	.15±.32	.93±.13	3.28	14	<.001
Affected leg (Rt) Step length (m)	.50±.26	.46±.07	1.96	14	.07
Unaffected leg (Lt) Step length (m)	.35±.03	.43±.08	-4.45	14	<.001

[a]ankle-foot orthosis, [b]stance control knee with knee flexion assisted-oil damper ankle-foot orthosis, [c]right, [d]left, [e]mean±standard deviation.

Table 3. Differences in the asymmetry ratio of step length, and single support time during gait while wearing AFO or SCKAFO in stroke patients (N=15)

	AFO[a]	SCKAFO[b]	t	df	p
Affected leg(Rt[c]) support time (s)	.34±.01[e]	.42±.05	-5.47	14	<.001
Unaffected leg(Lt[d]) support time (s)	.56±.63	.48±.06	3.30	14	<.001
Step-length asymmetry ratio	-.45±.07	-.03±.21	6.52	14	<.001
Single-support-time asymmetry ratio	.39±.07	.12±.12	-7.38	14	<.001

[a]ankle-foot orthosis, [b]stance control knee with knee flexion assisted-oil damper ankle-foot orthosis, [c]right, [d]left, [e]mean±standard deviation.

Table 4. Comparison of time lags during gait of people wearing AFO or SCKAFO (N=15)

	AFO[a]	SCKAFO[b]	t	df	p
Time lag[c] (sec)	.84±.28[d]	.37±.26	3.90	14	<.001

[a]ankle-foot orthosis, [b]stance control knee with knee flexion assisted-oil damper ankle-foot orthosis, [c]time lag indicated that the maximal flexion of the shoulder occurred before the maximal flexion of the hip, [d]mean±standard deviation.

step-length asymmetry ratio in the AFO and SCKAFO conditions (-.45±.07 and -.03±.21, respectively) were significant differences between the AFO and SCKAFO conditions in the step-length asymmetry ratio ($p<.001$) (Table 3). The means of the step-length asymmetry ratio in the AFO and SCKAFO conditions (.39±.07 and .12±.12, respectively) were also significant difference between the AFO and SCKAFO conditions in the single-support-time asymmetry ratio ($p<.001$) (Table 3).

Comparison of time lag during the gait of those wearing AFO or SCKAFO in stroke patients

A time lag indicated that the maximal flexion of the shoulder occurred before the maximal flexion of the hip. The means of time lags in the AFO and SCKAFO conditions were .84±.28 sec and .37±.26 sec, respectively. There were significant difference between the AFO and SCKAFO conditions in time lag ($p<.001$) (Table 4).

Compared with ∅-shank, ∅-thigh angle during the gait of those wearing AFO or SCKAFO in stroke patients

There were significant difference between AFO and SCKAFO condition in ∅-shank angle during toe off ($p<.001$). There were significant difference between AFO and SCKAFO condition in ∅-shank angle during mid swing ($p<.001$). There were no sig-

Table 5. Compared with ∅-shank, ∅-thigh angle during the gait of those wearing AFO or SCKAFO in stroke patients (N=15)

Subject		AFO[a]	SCKAFO[b]	t	df	p
Heel strike	∅-shank	97.22±2.16[c]	104.22±6.89	.90	14	.39
	∅-thigh	97.37±3.11	105.31±6.36	-2.72	14	<.05
Mid stance	∅-shank	84.08±1.85	83.67±7.07	.24	14	.82
	∅-thigh	86.41±3.62	87.32±4.11	-1.07	14	.31
Toe off	∅-shank	68.66±5.54	52.30±10.21	4.69	14	<.001
	∅-thigh	79.12±3.04	81.73±7.75	-1.21	14	.25
Mid swing	∅-shank	82.55±5.51	64.58±9.47	5.69	14	<.001
	∅-thigh	90.18±3.58	100.52±5.00	-5.11	14	<.001
Terminal swing	∅-shank	98.42±2.91	95.51±6.17	1.54	14	.15
	∅-thigh	97.53±3.18	108.49±6.79	-1.49	14	.16

[a]ankle-foot orthosis, [b]stance control knee with knee flexion assisted-oil damper ankle-foot orthosis, [c]mean±standard deviation.

nificant difference between AFO and SCKAFO condition in ∅-shank angle during heel strike, mid stance, terminal swing (p>.05). There were significant difference between AFO and SCKAFO condition in ∅-thigh angle during heel strike (p<.05). There were significant difference between AFO and SCKAFO condition in ∅-thigh angle during mid swing (p<.001). There were significant difference between AFO and SCKAFO condition in ∅-thigh angle during terminal swing, mid stance, toe off (p>.05) (Table 5).

Discussion

The impairment gait is frequently responsible for long-term disability and handicap. Where acute stroke patients are admitted to a hospital, one third are not ambulatory after 3 months (Winter, 1989). Recovery of gait is important for participation and activity in community. All stroke patients was measured physical impairments and disability us the Chedoke assessment (Gowland, 1992). In lower extremity, mean scores were 5.4 (leg) and 4.9 (foot), respectively. in upper extremity, mean scores were 5.4 and 5.6 for the arm and hand. This indicate that participants had a incomplete motor recovery of the body.

This study was undertaken to develop a new orthosis with an oil damper unit controlling the ankle and knee joint motion during the gait cycle and to identify the effects of the newly designed orthosis on gait in chronic stroke patients. Walking speed has been found to relate to many measures of disablement, including impairment, function (Friedman, 1990), disability (Potter et al, 1995) and health outcomes (Cress et al, 1995). This study, in which the speed of walking was .55 ㎧ in the SCKAFO condition, showed a faster walking speed than in the AFO condition. Empirical data have shown that the gait velocity of patients with stroke of varying severity ranges from approximately .50 to .60 ㎧, whereas that of healthy adults of similar ages averages about .76 ㎧ (Cress et al, 1995). And SCKAFO in stroke has shown similar normal walking speeds are satisfied for walking efficiency and are therefore desirable. Moreover, the proportion of time spent in unipedal stance after stroke was smaller, with the least time spent in the affected leg supporting condition (Harburn et al, 1995; Lehmann et al, 1983). Interestingly, there was a strong correlation between time in unipedal stance and the stepping speed. The results indicate that people with stroke spent twice as much time as healthy control subjects in bipedal stance, probably because they required more time to recover their balance. In this study, support time of the affected leg in SCKAFO condition was longer AFO condition and asymmetry ration of single support time decreased more than AFO condition ($p<.001$). This indicate that SCKAFO was effective for improving gait symmetry. Moreover, in wearing the SCKAFO, the stance time of the affected leg was longer than in wearing an AFO. This means that the SCKAFO helped to maintain knee extension during the stance phase. As with the stance time of the affected leg, the step length of the unaffected leg was longer.

There was difference between the AFO and SCKAFO conditions in this study ($p<.001$). In our study, we found that the stance phase providing the ankle plantarflexors, swing phase the providing knee-flexion was significantly with the single support time of the affected leg in the SCKAFO and AFO ($p<.001$) walking conditions, supporting the hypothesized mechanism. The second determinant of the single-support-time asymmetry was the motor status of the affected lower extremity. This finding corresponded with that of Brandstater et al (1983), who reported that the motor recovery stage of the affected lower extremity correlated highly with the single-support-time symmetry in patients with hemiparesis. Greater strength of the affected knee flexors may provide better stabilization of the affected knee through eccentric contraction in the mid-stance phase of the gait cycle, and, therefore, the unaffected lower extremity was able to make a larger step. The results of our study supported this hypothesis by showing moderate correlations between the strength of the affected knee flexors and the step lengths of the step-length asymmetry ratio of the SCKAFO and AFO walking conditions ($-.03\pm.21$, $-.45\pm.07$, respectively, $p<.001$). These results suggest that the strength of the affected knee flexors contributes to gait velocity, primarily by increasing the step-length symmetry ratio of both lower extremities. A time lag indicated that the maximal flexion of the shoulder occurred before the maximal flexion of the hip (Olney and Richards, 1996). There were significant differences between the AFO and SCKAFO conditions in lag time ($p<.001$). The results of the this study support that the total angle of the affected hip flexors and unaffected shoulder flexor was the best determinant of the velocity in previous study (Olney et al, 1998). While several studies have reported various kinematic characteristics of the lower limb segments of those with hemiparesis (Griffin et al, 1995), few have actually focused on the coordination of the segmental relationships. This study investigate the interlimb coordination of those with hemiparesis with the goal of characterizing this coordination in the affected and unaffected limbs. In addition, seek to identify the role played by the task an AFO orthosis and SCKAF orthosis in the interlimb coordination of hemiparetic walking. There were significant differences between the AFO and SCKAFO conditions thigh and shank angular displacement in mid swing ($p<.001$). SCKAFO have role in knee flexion assistance during swing phase and knee extension maintenance during stance phase and provide the dorsiflexion assisting moments (synonymous with the plantarflexion resistive moment) that are normally provided by eccentric contraction of the pretibial muscles at the initial stance phase. In walking with the SCKAFO, the gait velocity was considerably faster. This may be due to a decrease of gait asymmetry.

Conclusion

Thus, the newly designed SCKAFO may be useful to promote gait performance by improving the coordination of the extremity and decreasing gait asymmetry in chronic stroke patients. 3D motion tracking and analysis system were measurement to walking on the AFO or SCKAFO. The difference between the AFO and SCKAFO conditions was significant in the gait velocity, step length of the right affected side, stance time of both legs, step-length asymmetry ratio, single-support-time asymmetry ratio, ∅-thigh angle and ∅-shank angle in the mid swing ($p<.001$). One limitation of the present study is that the stroke subjects studied were all relatively high functioning, with an average gait speed of .65 m/s and Chedoke-McMaster scores of at least 4-6 for the leg, foot, arm and hand. Additionally, the number of subjects was small and there was no control group. It will also be necessary to fully evaluate the time-distance factors and kinematic properties between the SCKAFO with the oil damper and conventional AFO, and to evaluate the kinetics of this orthosis. Furthermore, the efficacy of the SCKAFO must be proved by its extended use in daily life. Another limitation is that it is hard to be supplied because the production cost is too expensive, the reduction of production costs has to be improved in the future.

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