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Brief Report

Effectiveness of a knee-ankle-foot orthosis with a knee extension aid in gait training for stroke patients

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ABSTRACT
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Objective: To evaluate the effectiveness of a knee-ankle-foot orthosis (KAFO) with a newly developed knee extension aid in gait training for stroke patients with severe leg paralysis.
Methods: The participants were 7 recovering stroke patients prescribed a KAFO. With the KAFO knee joint set to allow free flexion, knee flexion angle, lower limb muscle activity, and time of plantar ground contact were measured during assisted walking with the knee extension aid or a conventional support loop.
Results: When first using the knee extension aid, knee flexion angle at initial ground contact was significantly decreased and time from heel strike on the paralyzed side to forefoot strike was prolonged compared with the support loop. After using the knee extension aid for 1 week, in addition to the two parameters above, maximum knee flexion angle during the swing phase, knee extension displacement from the maximum flexion angle to initial ground contact, and the muscle activity ratio of the biceps femoris during the swing phase were significantly increased compared with the support loop.
Conclusion: This knee extension aid may be indicated for patients who have difficulty in initial heel strike due to excessive knee flexion at the end of the swing phase.
Key words: stroke, recovery period, knee extension assistance, elastic straps, knee-ankle-foot orthosis

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Introduction

In a typical gait pattern of stroke patients with slow walking speed, the knees are fixed in 20–30° flexion during the gait cycle [1]. Stroke patients with slow walking speed often do not extend the knee joint at the end of the swing phase due to insufficient swing of the lower limb during this phase. Thijssen et al. proposed an assistive device with elastic straps extending from the trunk to the feet to help swing the lower limbs during the swing phase [2]. Another approach is to use a knee-ankle-foot orthosis (KAFO) with a built-in spring in the knee joint to assist in knee extension. However, these elastic straps and springs may add an extension assist force to the knee joint not only during the swing phase, but also during pre-swing, which may prevent the knee joint from flexing. Although KAFOs in which knee joint movement is controlled electronically have also been proposed [3], they are expensive and cannot be custom-made for individual patients during a recovery period of several months. Thus, no simple assistive device can currently be used by physical therapists (PTs), who assist stroke patients from behind during walking exercises, to assist in knee extension when needed.

A previous study with 19 recovering stroke patients found that the muscle activity ratio of the tibialis anterior muscle increased after 2 months of using an ankle-foot orthosis (AFO) that compensated for initial heel strike during walking and did not interfere with ankle plantar flexion during loading response [4]. In a subsequent study with 8 recovering stroke patients, use of a KAFO for 1 month that was capable of flexing the knee joint up to 30° resulted in a significantly reduced knee flexion angle at initial ground contact, although the angle was still substantially greater than that in normal gait (5°) [5].

These findings suggest that initial heel strike is required to obtain a muscle activity level close to that obtained during normal gait. In stroke patients, however, the knee flexion angle at initial ground contact can be excessively large, necessitating strategies to facilitate knee extension at the end of the

Table 1. Basic and clinical information at the first measurement.

Item	Value
Age	55.6 (±13.6) years
Sex	Male 5 / Female 2
Paralyzed side	Right 1 / Left 6
Stroke type	Hemorrhagic 3 / Ischemic 4
Stroke onset to delivery of KAFO	43.4 (±13.5) days
Brunnstrom stage	II 2 / III 4 / V 1
Functional Independence Measure	75.9 (±19.6) (perfect score 126)
Berg Balance Scale	18.6 (±12.7) (perfect score 76)
Stroke Impairment Assessment Set	38.7 (±11.3) (perfect score 56)

Data shown as the mean (± SD) or number of participants.

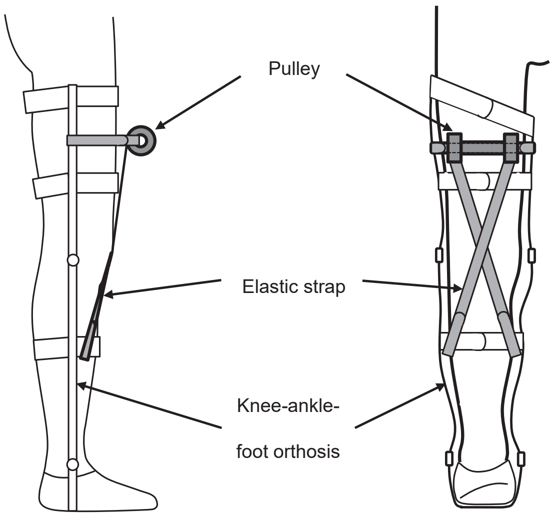
swing phase. Against this background, an assistive knee extension aid was developed that can be used by a PT to facilitate knee extension at the end of the swing phase. The objective of this study was to evaluate the effectiveness of a KAFO equipped with this knee extension aid in gait training for stroke patients with severe leg paralysis.

Methods

1. Participants

The inclusion criteria were as follows: first-time stroke patients admitted to the recovery ward of our hospital who were prescribed a KAFO fabricated between October and December 2020 after a review meeting attended by their attending physician and PT and a prosthetist and who were judged by their attending physician to have no medical problem that could interfere with the conduct of the study. Patients who declined walking practice or use of the orthosis were excluded from the study. The basic and clinical information of the participants at the first measurement are shown in Table 1. All participants received a combination of physical, occupational, and speech therapy for 3 h per day, with physical therapy lasting from 1 h to 1 h 20 min per day, including at least 20 min of walking practice with a KAFO. PTs used the knee extension aid during physical therapy hours at least once between the initial measurement and a second measurement 1 week later.

This study was approved by the ethics committee of the study site (approval number: K2019-22). All participants received an explanation of the study both in writing and orally, and provided written informed consent.



Schematic of device components

Knee extension aid grasped by a physical therapist

Figure 1. Overview of the knee-ankle-foot orthosis with the knee extension aid.

2. Knee extension aid and orthosis

An overview of the knee extension aid is shown in Figure 1. A pipe grip with rotatable pulleys on both ends is attached to the thigh upright of the KAFO and fixed with a belt passed through the pipe. Elastic straps are wrapped around the pulleys, passing in front of the knee and attached to the lower leg part of the KAFO. When the PT grasps the pulleys and flexes the wrist palmarly, the elastic straps wrapped around the pulleys are rolled up about 5 cm to transmit the extension assist force to the knee via the lower leg cuff bands.

The KAFOs fabricated for the participants were uniformly composed of a SPEX knee joint, a double Klensack ankle joint, a covered foot, a proximal thigh cuff, a distal thigh cuff, a lower leg cuff, and a knee pad. The knee joint setting during walking practice was adjusted using an angle-adjustable rod, rather than an extension assist spring. The ankle joint setting consisted of spring-loaded plantar flexion stop and free dorsiflexion.

3. Measurement method

An initial gait measurement and another 1 week later were performed with the knee joint of the KAFO unfixed and set to allow free flexion and the patient was able to practice walking with the assistance of a PT. During the measurements, the participants used a T-cane or 4-point cane. The participant walked about 10 m with manual assistance by a PT from behind. One formal measurement was made after several trial walks with the KAFO equipped with the knee extension aid, followed by one formal measurement after several trial walks with a conventional support loop (Figure 2).

The variables for gait analysis were as follows: knee flexion angle, electromyogram (EMG) of the vastus medialis and biceps femoris, and ground contact time measured by foot switches attached to the heel and metatarsophalangeal joint portions of the left and right soles. The knee flexion angle, EMG, and plantar ground contact times were measured using the Gait Judge System (Pacific Supply Co., Ltd., Osaka, Japan; Figure 3) at a sampling frequency of 1,000 Hz. The continuous measurement data were divided into 5 gait cycles by the time points of heel strike on the paralyzed side, and then the 5 gait cycles were averaged to obtain the single-cycle mean value. The knee flexion angle at initial ground contact, maximum knee flexion angle during the swing phase, and knee extension displacement from the maximum flexion angle to initial ground contact were determined from the knee angle data. The EMG data were band-pass filtered (20−250 Hz), smoothed by the root mean square technique (window size 50 ms), and normalized by the single-cycle mean value [6]. Normalized EMG data were divided by the times of foot switch grounding into 4 phases: loading response, single stance, pre-swing, and swing. In addition, the percentage of time from initial ground contact to the ground contact of the MP joint part as measured by the foot switches on the paralyzed side was determined, with the length of one gait cycle defined as 100%.

Figure 2. Measurement conditions for the knee-ankle-foot orthosis.

4. Statistical analysis

The data for each variable at the initial measurement and 1 week later were analyzed separately and compared between gait with the knee extension aid and gait with the support loop using Wilcoxon's signed rank sum test (significance level: $p < 0.05$).

Results

The characteristic gait patterns observed in all measurement conditions were as follows: knee flexion angle at initial ground contact was 24.0−30.5°, which was greater than the corresponding angle of normal gait (~5°), and the percent MP joint contact was 3.4–6.1%, which was shorter than the corresponding percentage during loading response in normal gait (~12%) (Table 2−1, Table 2−2).

When first using the knee extension aid, the knee flexion angle at initial ground contact was significantly

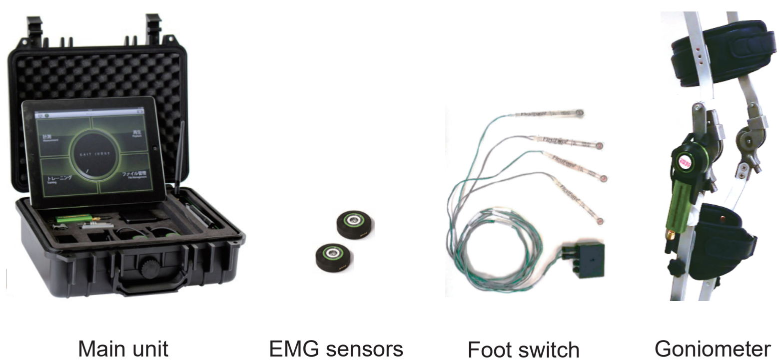


Figure 3. Gait Judge System.

Table 2−1. Comparison of the knee extension aid and support loop at the initial measurement.

Item	Measurement period	Condition	Median	Interquartile range	*p*-Value
Knee flexion angle (deg) (Flexion direction is +)	Initial contact	Knee extension aid	24.0	9.4	0.0156*
		Support loop	30.5	8.8	
Maximum knee flexion angle (deg) (Flexion direction is +)	1 gait cycle	Knee extension aid	50.6	4.2	0.2188
		Support loop	50.9	7.5	
Knee extension displacement (deg) (Extension direction is +)	Swing	Knee extension aid	20.7	15.1	0.0781
		Support loop	16.5	13.0	
Contact of MP joint (%)	1 gait cycle	Knee extension aid	3.8	5.8	0.0156*
		Support loop	3.4	5.6	
Vastus medialis activity (%EMG)	Loading response	Knee extension aid	320.5	65.9	0.1094
		Support loop	289.8	94.3	
	Single stance	Knee extension aid	117.5	30.1	0.5469
		Support loop	129.2	84.7	
	Pre-swing	Knee extension aid	64.3	37.4	0.1563
		Support loop	54.4	45.4	
	Swing	Knee extension aid	68.3	26.8	0.1094
		Support loop	46.8	27.0	
Biceps femoris activity (%EMG)	Loading response	Knee extension aid	229.6	53.9	0.2969
		Support loop	232.4	232.4	
	Single stance	Knee extension aid	145.0	56.8	0.2188
		Support loop	114.9	40.9	
	Pre-swing	Knee extension aid	75.9	51.0	0.8125
		Support loop	58.5	36.0	
	Swing	Knee extension aid	83.7	60.6	0.3750
		Support loop	91.3	22.1	

%EMG, mean value for a single gait cycle normalized to 100%.
*Significant difference according to Wilcoxon signed-rank sum test ($p < 0.05$).

decreased and the percent MP joint contact increased compared with using the support loop. In contrast, there were no significant changes in the maximum knee flexion angle, knee extension displacement, or muscle activity ratio of each muscle (Table 2−1).

After using the knee extension aid for 1 week, in addition to knee flexion angle at initial ground contact and percent MP joint contact, which showed significant differences at the initial measurement, maximum knee flexion angle, knee extension displacement, and the muscle activity ratio of the biceps femoris during the swing phase were significantly increased compared with the support loop. Meanwhile, no significant change was observed in the muscle activity ratio of the biceps femoris during the non-swing phases or that of the vastus medialis in any phase (Table 2−2).

Discussion

When first using the knee extension aid, the knee flexion angle at initial ground contact was immediately and significantly decreased and the percent MP joint contact increased compared with using the support loop. Thijssen et al. reported that the use of elastic straps immediately reduced the energy cost during walking [2]. According to Perry et al., initial heel strike with the knee in extension enables use of the rocker function of the foot during the stance phase, allowing for efficient walking with reduced energy expenditure [7]. Compared with the support loop, the knee extension aid can extend the time from heel strike to forefoot strike by extending the knee at initial ground contact. Delaying forefoot strike, which tends to occur too early in stroke patients, may allow efficient walking with less energy expenditure, thereby enabling longer-distance walking practice. After 1 week of using the aid, the muscle activity ratio of the biceps femoris increased probably due to eccentric contraction of the muscle, which was stretched due to the increased knee extension displacement during the stance phase. Thijssen et al. reported an increase in walking speed and stride length after 3 weeks of using elastic straps, suggesting the effectiveness of the continued use of these straps [2]. Given the 1-week usage period in the present study, the reason for the better outcome with the knee extension aid might have been that PTs

Table 2−2. Comparison of the knee extension aid and support loop after 1 week.

Item	Measurement period	Condition	Median	Interquartile range	*p*-Value
Knee flexion angle (deg) (Flexion direction is +)	Initial contact	Knee extension aid	25.0	11.2	0.0313*
		Support loop	26.9	11.5	
Maximum knee flexion angle (deg) (Flexion direction is +)	1 gait cycle	Knee extension aid	55.6	6.4	0.0313*
		Support loop	51.4	7.9	
Knee extension displacement (deg) (Extension direction is +)	Swing	Knee extension aid	24.6	7.0	0.0156*
		Support loop	19.2	11.5	
Contact of MP joint (%)	1 gait cycle	Knee extension aid	6.1	5.2	0.0313*
		Support loop	3.6	5.2	
Vastus medialis activity (%EMG)	Loading response	Knee extension aid	297.1	77.3	0.8125
		Support loop	261.2	51.0	
	Single stance	Knee extension aid	143.7	45.7	0.6875
		Support loop	150.8	50.9	
	Pre-swing	Knee extension aid	43.7	23.6	0.1563
		Support loop	57.0	36.7	
	Swing	Knee extension aid	61.5	12.0	0.1094
		Support loop	55.9	21.9	
Biceps femoris activity (%EMG)	Loading response	Knee extension aid	186.4	54.3	0.9375
		Support loop	220.6	114.9	
	Single stance	Knee extension aid	147.0	48.3	0.1094
		Support loop	131.5	54.9	
	Pre-swing	Knee extension aid	58.0	21.3	0.6875
		Support loop	60.6	18.2	
	Swing	Knee extension aid	75.5	40.2	0.0156*
		Support loop	73.3	42.5	

%EMG, mean value for a single gait cycle normalized to 100%.
*Significant difference according to Wilcoxon signed-rank sum test ($p < 0.05$).

became accustomed to the operation of the aid, rather than that the participants' function improved.

Limitations of this study include the small sample size of 7 participants, which limits the generalizability of the results. Second, lower extremity motor function was heterogeneous, with 1 participant at Brunnstrom stage V and 4 at stage III, which might have affected the results. Third, because PTs were not instructed to use the knee extension aid every day during the 1-week practice period, the aid might not have been used sufficiently and the observed effect was possibly only an immediate one. Finally, the same ankle joint setting was used in all participants, with spring-loaded plantar flexion stop and free dorsiflexion, which might have been suboptimal for some participants.

The results of this study suggest that a knee extension aid may be indicated for patients who have difficulty with initial heel strike due to excessive knee flexion at the end of the swing phase.

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