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Original Article

Safety and immediate effect of gait training using a Hybrid Assistive Limb in patients with cerebral palsy

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Abstract. [Purpose] This study aimed to determine the safety and immediate effect of a single training session with the Hybrid Assistive Limb (CYBERDYNE) on walking ability in patients with cerebral palsy. [Participants and Methods] This study included 20 patients with cerebral palsy (15 males, 5 females, mean age 15.0 ± 6.3 years; 19 with spastic cerebral palsy, 1 with athetoid cerebral palsy; Gross Motor Function Classification System level I: 4, II: 3, III: 9, and IV: 4). Participants completed a single 20-minute gait training session using the Hybrid Assistive Limb. The safety and immediate effect were evaluated. The immediate outcomes were gait speed and mean step length, and cadence before and after training. [Results] Two participants were excluded because they were not tall enough to use the Hybrid Assistive Limb. Eighteen participants performed the training. There were no serious adverse events during the training. Since 14 participants were able to walk on their own, walking evaluations were performed before and after training. Statistically significant improvements were observed in gait speed and mean step length. [Conclusion] Gait training using the Hybrid Assistive Limb is safe for patients with cerebral palsy and can produce immediate effects on walking ability in ambulatory patients with cerebral palsy.
Key words: Gait training, Cerebral palsy, Hybrid Assistive Limb

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INTRODUCTION

Cerebral palsy (CP) is the most common cause of motor disability in childhood. CP disturbs patients' motor function and decreases their participation in activities of daily living. Developing the ability to walk is an important functional goal for CP patients[1)]. Movement disorders caused by CP decrease the amount of daily walking activity[2)] and increase the energy cost of walking[3)]. A relationship has been shown between locomotor ability and the performance of activities of daily living and social roles[4)]. Recently, robotic gait training has been used to improve the walking function of people with CP. A systematic review of robotic gait training for people with CP showed positive effects on gait speed, endurance, and gross motor

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function[5]. Most reports have been based on locomotive training using Lokomat® (Hocoma, Volketswil, Switzerland)[6–10]. However, Lokomat is a passive robotic gait intervention, in which the lower limb joint angle and gait speed are set to constant values during treadmill walking.

The Hybrid Assistive Limb (HAL: Cyberdyne, Tsukuba Japan) is an exoskeleton robotic device that was developed to physically support the wearer's daily activities and hard labor[11]. HAL detects the bioelectric signal generated by the patient's muscle activity or the floor reaction force signal caused by the patient intentionally shifting their weight, or both. The power units generate power-assisted torque by amplifying the wearer's own joint torque estimated from the wearer's bioelectrical signals. HAL facilitates exercise training by providing motion support according to the voluntary motion of the wearer, and its ability to walk[11]. It provides a major advantage compared with robotic gait training using systems such as Locomatt. Gait training with HAL is effective for stroke[12, 13], spinal cord injury[14], and knee osteoarthritis patients after total knee arthroplasty[15]. However, few studies have reported the effect of gait training using HAL among CP patients. Matsuda et al. reported that 12 CP patients who participated in a single gait training session using HAL showed an instantaneous improvement in single-leg support per gait cycle and hip and knee joint angle during walking[16]. However, there has been no other report on the immediate effect on walking ability of HAL training in CP patients. In addition, there is no report on safety that examined adverse events during and after training with HAL. The purpose of this study was to examine the safety and immediate effect on walking ability of gait training using HAL for CP patients.

PARTICIPANTS AND METHODS

Twenty patients with CP were recruited from the Ibaraki Prefectural Health Science University Hospital from August 2014 to February 2016. There were 15 males and 5 females with a mean age 15.0 ± 6.3 years (range 8–37). Nineteen participants had spastic CP and one had athetosis CP. According to the Gross Motor Function Classification System (GMFCS), four patients were classified as level I, three as level II, nine as level III, and four as level IV (Table 1). The study protocol was approved by the ethics committee of Ibaraki Prefectural University of Health Sciences (approval number: 682); all patients provided written informed consent.

The CP patients performed a single 20-minute session of gait training using HAL. Before starting the training, the patients' height, body weight, hip angle, knee angle, and foot deformation were measured. The HAL model used was for the lower limbs in size small (target height 145–165 cm), and the Cybernic Voluntary Control mode was used. In addition, flexion/elongation balance and torque assist in the hip and knee joints were optimized for each patient. The thigh and shank length and hip width of HAL were adjusted. To prevent pain, cushioning material was placed between the body and HAL (Fig. 1). An insole was placed in special shoes for patients with equinus (Fig. 2). During the gait training, patients were placed in a mobile suspension system walker harness (All In One Walking Trainer, Ropox A/S, Næstved, Denmark) to prevent them from falling (Fig. 3). During HAL training, we kept the walker's speed as comfortable as possible and ensured a good gait pattern.

To investigate the safety of gait training with HAL, adverse events were recorded during and after HAL training. Major adverse events were fracture and dislocation due to falling, and minor adverse events included pain, redness, swelling, and fatigue. The day after the HAL training, if an adverse event had occurred, we received a phone call from the patient's family. The CP patients who were able to walk on the ground performed a walking evaluation to examine the immediate effect. Using 14 patients, a 10-m walk test was conducted before and after the single HAL training, and gait speed, mean step length, and cadence were measured.

To evaluate the immediate effect of gait training using HAL, we compared the outcome measures before and after training using paired t-tests.

RESULTS

Of the 20 participants who attempted to complete the gait training to investigate its safety, 18 were successful. Two patients (cases 11 and 20) could not perform the gait training using HAL because they were not tall enough to fit into the device. Fourteen patients performed the walking evaluation before and after the gait training with HAL to examine the immediate effect. Four patients (case 6: GMFCS III; case 10: GMFCS IV; case 16: GMFCS IV, and case 18: GMFCS IV) were excluded because when they did not wear HAL, they could not walk without assistance (Fig. 4).

None of the 18 patients who performed the gait training using HAL experienced any major adverse events. However, two patients experienced minor adverse events after the training (cases 8 and 9). In case 8, the patient experienced fatigue in both legs immediately after the gait training using HAL. However, it was resolved by the next day. In case 9, it was very difficult for the patient to wear the HAL because she had a severe lower limb deformity, especially equinus. She did not experience adverse events during the HAL training, but she had knee pain the following day, which had resolved 2 days later (Fig. 5).

As shown in Table 2, regarding the immediate effect, gait training using HAL significantly increased the gait speed and the mean step length. Cadence improved, but the difference was not significant.

Table 1. Participant characteristics

Case	Gender	Age	Height (cm)	Body weight (kg)	Movement disorders	GMFCS	HAL training	Walk evaluation
1	M	13	141	45	spastic	III	+	+
2	F	19	152	40	spastic	II	+	+
3	M	12	138	27	spastic	III	+	+
4	M	16	153	49	spastic	III	+	+
5	F	11	137	35	spastic	III	+	+
6	M	20	168	64	spastic	III	+	−
7	F	15	141	48	spastic	III	+	+
8	M	15	158	43	spastic	III	+	+
9	F	15	143	35	spastic	II	+	+
10	M	14	153	37	spastic	IV	+	−
11	M	8	129	27	spastic	III	−	−
12	M	37	165	51	athetosis	II	+	+
13	M	11	131	31	spastic	I	+	+
14	M	9	134	28	spastic	I	+	+
15	M	10	134	36	spastic	III	+	+
16	F	12	140	24	spastic	IV	+	−
17	M	23	165	45	spastic	III	+	+
18	M	16	152	35	spastic	IV	+	−
19	M	13	150	35	spastic	I	+	+
20	M	11	128	34	spastic	I	−	−

M: male; F: female; GMFCS: Gross Motor Function Classification System.

Fig. 1. HAL fitting. Cushioning material was placed between the body and HAL (a). HAL fitting of lumbar (b). HAL fitting of the lower leg (c).

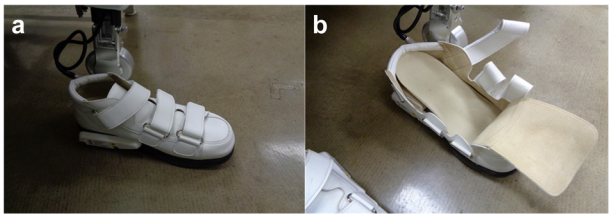

Fig. 2. HAL special shoes (a). Special shoes with an insole for equinus patients (b).

Fig. 3. Gait training using HAL.

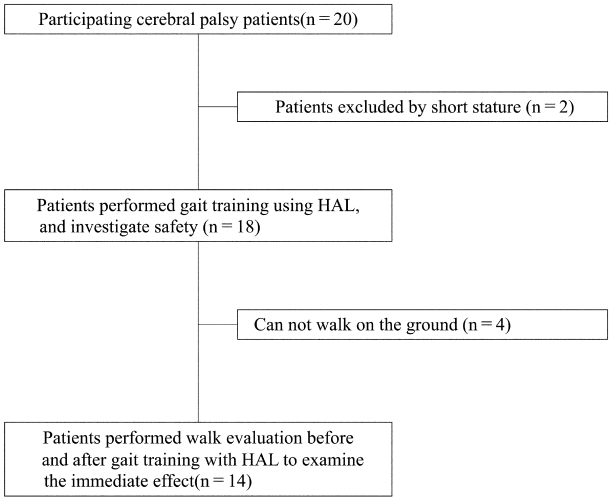

Fig. 4. Flow chart of the study.

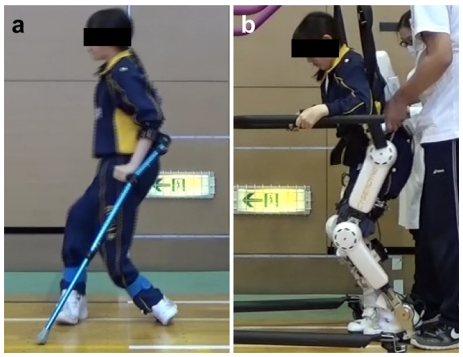

Fig. 5. A patient (Case 9) with a severe limb deformity with equinus (a). Gait training with HAL (b). The patient had knee pain the day after the training, but the pain disappeared by the second day after the training.

Table 2. Outcome measures for the 14 patients before and after gait training with HAL

Outcome measures	Before gait training with HAL	After gait training with HAL	95% confidence interval [CI]
Gait speed (m/s)	0.71 ± 0.35	0.83 ± 0.45*	0.03 to 0.21
Mean step length (m)	0.44 ± 0.12	0.47 ± 0.13*	0.00 to 0.07
Cadence (steps/s)	1.53 ± 0.50	1.66 ± 0.70	−0.07 to 0.34

*$p<0.05$.

DISCUSSION

HAL training produced no major adverse events, although two minor adverse events were observed. It is safe to carry out gait training using HAL. Most people with CP have a walking disorder such as an anteriorly tilted pelvis with lumbar lordosis, flexed hips, flexed-stiff knees, and equinus[17]. Setting up HAL was very difficult in participants with severe deformities. In particular, participants with severe equinus could not fit their feet into the special shoes for HAL, or the shoes had to be taken off. We adjusted the fitting by inserting an insole into the shoe against the equinus, and placed cushioning material between the body and HAL. We thought that this may be why CP patients with severe deformities did not experience any major adverse events. In addition, the HAL device used in this study was for the lower limbs in a small adult size (target height 145–165 cm). Because a HAL for children has not been developed, it was only possible to use the HAL for adults, which made it difficult to fit. In the future, we hope to develop a HAL for children so that we can practice gait before the deformation worsens.

With regard to the immediate effect, gait training using HAL significantly increased the gait speed and mean step length. Matsuda et al. compared gait function before and after a HAL intervention for CP patients and found a significantly increased hip extension angle and knee extension angle in the stance phase and knee flexion angle in the swing phase[16]. Therefore, we considered that the step length improved. The gait speed consists of the stride length and cadence. In this study, we expected that an improvement in stride length would lead to an improvement in gait speed. Cadence did not improve. However, this result may be due to the single session of HAL training and the mismatch in the size of the HAL. This was a pilot study to examine the effect of gait training using the HAL.

Patients with CP reach their peak motor function at the age of 7 years[18]. However, as shown in this study, even patients who were beyond the age of peak motor function improved their walking ability by learning a normal gait pattern through HAL training. It has been reported that HAL training may induce sensory input with a favorable feedback effect on the central nervous system to restore motor function[19]. This suggests the potential to improve walking ability in CP patients who have not experienced normal walking.

Four CP patients with moderate or higher motor disabilities (GMFCS III–IV) could not walk on the ground, and thus we could not investigate their walking ability. In addition, minor adverse events occurred in cases with severe deformities. Therefore, gait training using HAL may not be indicated for patients with moderate or severe motor disabilities and those with severe deformities. It may be effective to carry out HAL walking training after improving joint range and muscular strength by orthopedic surgery, botulinum toxin[20], and single-joint HAL[21]. We consider it important to combine multiple

treatments and rehabilitation in CP patients with severe motor disabilities.

There were some limitations to this study. The HAL training was performed only once. The sample size was also small. The evaluations were only conducted before and immediately after the HAL training. In future, the effect of several HAL training sessions should be evaluated, and it would be useful to conduct a controlled trial with a large sample size. The duration of the effect should also be investigated.

In conclusion, this study shows that gait training using HAL is safe for patients with cerebral palsy and can produce immediate effects on walking ability in walkable patients with cerebral palsy.

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