Immediate effects of a single session of robot-assisted gait training using Hybrid Assistive Limb (HAL) for cerebral palsy

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Abstract. [Purpose] Robot-assisted gait training (RAGT) using Hybrid Assistive Limb (HAL, CYBERDYNE) was previously reported beneficial for stroke and spinal cord injury patients. Here, we investigate the immediate effect of a single session of RAGT using HAL on gait function for cerebral palsy (CP) patients. [Subjects and Methods] Twelve patients (average age: 16.2 ± 7.3 years) with CP received a single session of RAGT using HAL. Gait speed, step length, cadence, single-leg support per gait cycle, hip and knee joint angle in stance, and swing phase per gait cycle were assessed before, during, and immediately after HAL intervention. [Results] Compared to baseline values, single-leg support per gait cycle (64.5 ± 15.8% to 69.3 ± 12.1%), hip extension angle in mid-stance (149.2 ± 19.0° to 155.5 ± 20.1°), and knee extension angle in mid-stance (137.6 ± 20.2° to 143.1 ± 19.5°) were significantly increased immediately after intervention. Further, the knee flexion angle in mid-swing was significantly decreased immediately after treatment (112.0 ± 15.5° to 105.2 ± 17.1°). Hip flexion angle in mid-swing also decreased following intervention (137.2 ± 14.6° to 129.7 ± 16.6°), but not significantly. Conversely, gait speed, step length, and cadence were unchanged after intervention. [Conclusion] A single-time RAGT with HAL improved single-leg support per gait cycle and hip and knee joint angle during gait, therapeutically improving gait function in CP patients.

Key words: Robot-assisted gait training, Cerebral palsy, Hybrid Assistive Limb

INTRODUCTION

Gait disorders including abnormal gait pattern, slow gait speed, and decreased walking endurance are present in over 90% of cerebral palsy (CP) patients1–3). Importantly, CP patients with enhanced mobility report improvements in performing activities of daily living and community inclusion4). Therefore, if walking ability can be improved by rehabilitation, quality of daily life will increase as a result.

With respect to walking training for CP patients, the effect of body-weight-supported treadmill training (BWSTT) is com-
monly considered as an index of gait speed5–8. However, CP patients with severe gait perturbation require manual assistance during walking. Further, it is difficult to objectively set both joint angle and level of assistance during walking.

Much attention has been focused on robot-assisted gait training (RAGT) to automatically control patient gait during walking. Indeed, several walking support robotic devices are commercially available including “end-effector type” like Gait Trainer (Reha-Stim, Berlin, Germany)9–12 and LokoHelp (Woodway, Waukesha, USA)13 and “exoskeleton type” like ReWalk™ (ReWalk Robotics, Berlin, Germany)14, 15 and Lokomat® (Hocoma, Volketswil, Switzerland)16. Interestingly, RAGT using Lokomat has been reported as efficacious for CP patients, significantly improving gross motor function measure (GMFM)17–21, gait speed17–20, 22, and walking endurance17–19 and lowering body kinematics parameters22, 23. However, Lokomat is a passive robotic gait intervention, with the lower limb joint angle and gait speed set to constant values during treadmill walking.

Conversely, Hybrid Assistive Limb (HAL; CYBERDYNE, Tsukuba, Japan) is a novel robotic device capable of assistive voluntary walking in response to the intention of the wearer. Specifically, proprietary developed sensors and electrodes monitor minimal bioelectrical signals (BES) from the surface of the skin of both the flexor and extensor muscles of the hip and knee joints. Further force-pressure sensors are present in the shoes, biometric information is gathered regarding joint angle, and robotic actuators at the hip and knee joint are driven to assist torque24. Importantly, several reports indicate that RAGT using HAL may be an effective therapeutic device for patients with stroke, spinal cord injury, and knee joint deformity. With respect to patient outcomes, RAGT using HAL significantly improved multiple clinical measures including gait speed25–31, cadence25, 26, step length25–30, walking endurance26, 27, 30, balance function25, functional ambulation categories (FAC)31, 32, functional independence measure (FIM)28, 33 and stroke impairment assessment set (SIAS)33. A good clinical practice-adherent clinical trial was conducted in ten facilities for slow, progressive, rare neuromuscular diseases, and HAL is considered to have a certain level of efficacy with acceptable safety from regulatory authority’s review report34, 35. However, there are only a few reports about the effect of RAGT using HAL for CP patients36, 37.

Therefore, in this investigation, we performed RAGT using HAL to assist voluntary walking in CP patients and assessed clinical measures of gait function before and following HAL attachment. We hypothesized that RAGT using HAL for CP patients would significantly improve gait function, reduce walking support requirements, and improve independence of ambulation.

The purpose of this investigation was to promote immediate therapeutic effects with respect to gait function with and without HAL attachment, before and after a single 10–20-min session of RAGT using HAL in CP patients.

SUBJECTS AND METHODS

Twelve patients with CP were enrolled in the study between February 2016 and March 2017 (eight males, four females; age range, 9–37 years; average age, 16.2 ± 7.3 years; height, 147.8 ± 12.1 cm; body weight, 40.8 ± 10.8 kg). The severity of the patient’s condition was assessed utilizing the gross motor function classification system (GMFCS), with two subjects at GMFCS level I, three subjects at level II, five subjects at level III, and two subjects at level IV. With respect to patient outcomes, RAGT using HAL significantly improved multiple clinical measures including gait speed25–31, cadence25, 26, step length25–30, walking endurance26, 27, 30, balance function25, functional ambulation categories (FAC)31, 32, functional independence measure (FIM)28, 33 and stroke impairment assessment set (SIAS)33. A good clinical practice-adherent clinical trial was conducted in ten facilities for slow, progressive, rare neuromuscular diseases, and HAL is considered to have a certain level of efficacy with acceptable safety from regulatory authority’s review report34, 35. However, there are only a few reports about the effect of RAGT using HAL for CP patients36, 37.

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Statistical analysis was performed using SPSS ver.22.0 (IBM) for each value obtained before and during HAL attachment, as well as before and after HAL attachment. Changes in gait parameters were assessed using the Wilcoxon test. Results were compared and examined using average values, with p-value <0.05 considered statistically significant.

**RESULTS**

Gait speed (p=0.004), stride length (p=0.03), and cadence (p=0.003) significantly decreased during RAGT with HAL intervention relative to before values (Table 2).

Conversely, no significant differences were observed during HAL attachment with respect to single-leg support during one gait cycle, hip angle in mid-stance, knee angle in mid-stance, hip angle in mid-swing, knee angle in mid-swing (Table 2).

Single-leg support during one gait cycle (p=0.01), hip extension angle in mid-stance (p=0.04), and knee extension angle in mid-stance (p=0.02) significantly increased immediately after RAGT with HAL intervention relative to before values. Further, knee flexion angle in mid-swing (p=0.02) immediately after HAL intervention significantly decreased compared with measurements obtained before RAGT. Although decreased, hip flexion angle in mid-swing (p=0.14) immediately after HAL intervention was not significantly different (Table 3).

Conversely, no significant differences were observed with respect to gait speed, step length, and cadence before and after HAL intervention (Table 3).

**DISCUSSION**

Importantly, our study is the first systematic investigation of HAL intervention in CP patients with bilateral lower limb spasticity. Our protocol administered only a single session of intervention. This is to exclude motor learning effects in continuous intervention and purely investigate HAL-specific effects that assist the wearer’s voluntary motion intentions. We observed appreciable increases in single-leg support as well as lower limb joint angle during patient gait after HAL attachment; gait speed was not significantly different, during HAL attachment. We believe that the witnessed effects may be attributable to two factors. First, the depressed walking speed with HAL attachment created large joint torque. Second, stability of the single-leg support was increased by the mechanical parts of HAL. Therefore, both single-leg support and lower limb joint angle were significantly different immediately after HAL intervention.

Standing/gait posture and gait pattern also improved during HAL attachment. Therefore, HAL intervention may potentially serve to normalize gait pattern by correcting abnormal gait patterns acquired in response to CP. Regarding the increase in single-leg support and lower limb joint angle after HAL attachment, previous reports indicate that CP patients demonstrate differences in the degree of right-left paralysis and spasticity, even in the setting of bilateral palsy. Therefore, CP patients demonstrate postural asymmetry during standing and walking. Importantly, HAL adjusts both assist torque and flexion/extension balance separately to both the right and left according to the patient’s condition, providing the setting for appropriate intervention performance.

In the normal gait, as gait speed decreases, stride length, cadence, and single-leg support also decrease. Similarly, gait speed during HAL attachment decreased compared to usual gait for all study participants. However, both single-leg support

### Table 1. Characteristics

| Case | Gender | Age (Y) | Height (cm) | Weight (kg) | Etiology | Movement disorder | Paralysis | GMFCS | Assistive device | Orthosis |
|------|--------|---------|-------------|-------------|----------|------------------|-----------|-------|-----------------|----------|
| 1    | M      | 37      | 165         | 51          | PVL      | spastic          | Diplegia  | II    | clutch          | AFO      |
| 2    | M      | 20      | 168         | 64          | PVL      | spastic          | Diplegia  | IV    | parallel bars   | AFO      |
| 3    | F      | 19      | 152         | 40          | PVL      | spastic          | Diplegia  | II    | NA              | NA       |
| 4    | M      | 16      | 153         | 49          | PVL      | spastic          | Diplegia  | III   | walker          | AFO      |
| 5    | F      | 15      | 143         | 35          | PVL      | spastic          | Diplegia  | II    | clutch          | AFO      |
| 6    | F      | 15      | 141         | 48          | PVL      | spastic          | Diplegia  | III   | walker          | AFO      |
| 7    | M      | 15      | 158         | 43          | PVL      | spastic          | Diplegia  | III   | walker          | AFO      |
| 8    | M      | 14      | 153         | 37          | PVL      | spastic          | Quadruplegia | IV  | BS walker       | AFO      |
| 9    | M      | 12      | 138         | 27          | PVL      | spastic          | Diplegia  | III   | walker          | AFO      |
| 10   | F      | 11      | 137         | 35          | PVL      | spastic          | Diplegia  | III   | walker          | AFO      |
| 11   | M      | 11      | 132         | 32          | PVL      | spastic          | R hemiplegia | I   | NA              | R AFO    |
| 12   | M      | 9       | 134         | 28          | PVL      | spastic          | R hemiplegia | I   | NA              | R AFO    |

M: male; F: female; PVL: Periventricular Leukomalacia; GMFCS: Gross Motor Function Classification System; NA: not applicable; BS walker: body support walker; AFO: ankle foot orthosis.
and lower limb joint angle during HAL attachment were maintained relative to the usual gait. Maeshima et al. reported that gait speed decreases during HAL attachment in stroke patients\textsuperscript{41}. Therefore, in slow gait speed, it seems possible to create a large joint angle by HAL assist according to the wearer’s voluntary motion intention during HAL attachment (i.e., ease of locomotor control). Additionally, we believe that even if gait speed is reduced by HAL attachment, single-leg support during one gait cycle was not decreased as single-leg support was stabilized by the HAL with integration of foot and pelvis sections.

As the wearer can control voluntarily adjustment of gait speed and lower limb joint angle, HAL appears to differ from conventional gait-assist robots without voluntary system control. Walking in CP patients is very unstable and will be refined by supporting one’s own body. Walking stability is secured by attaching HAL which is an exoskeleton type walking-assist robot. Therefore, in gait after HAL attachment, the gait pattern such as joint angle and single-leg support during one gait cycle shifted to the gait immediately after HAL attachment despite gait speed returning to almost the same gait speed as before HAL attachment. By repeating this transformation of the gait pattern, improvement in walking ability such as gait speed and stride is expected. In BWSTT, it is said that by repeating walking at a speed faster than usual, gait pattern changes and the Central Pattern Generator (CPG) is activated\textsuperscript{5–8}. However, in this study, in gait training using HAL, the walking stability is secured by the exoskeleton of HAL even at slow walking speed, and in the assist according to the intention, the transformation of gait pattern and activation of CPG can be expected by performing complex articulation repeatedly.

Repetitive stepping exercise is consistent with the motion learning theory, defined as a neuro-rehabilitation inducing the cerebral plasticity with aims of functional recovery\textsuperscript{42–45}. However, the intensity of brain activity, the premise of motion, increases only during conditions where voluntary motion planning and conducted exercise and feedback are combined and does not change with passive exercise or simple repetitive automatic exercise\textsuperscript{46}.

During our investigation, walking intervention using HAL was accepted without resistance in all patients. HAL controls several actuators at the hip and knee joints based on the BES based on the wearer’s intention, load distribution of both soles, and hip and knee joint angle information assisting the joint torques during gait\textsuperscript{47}. The greatest characteristic of HAL as compared with conventional gait-assist robots is assisting voluntary gait in response to the wearer’s intention. The conventional robot is an automatic walking-assist device, walking on the treadmill at constant speed, and set to a specific joint angle of the lower limb (i.e., passive walking). In passive walking, it is difficult for the wearer to learn the motor control necessary for proper voluntary walking control, in accordance with the motor learning theory. HAL already became a medical device to improve neuromuscular functions of patients in the European Union and patients with rare neuromuscular disease in Japan\textsuperscript{34, 35}. HAL can utilize voluntary motion intention of the wearer, feedback the results, and contribute to the motor learning theory. In fact, in this investigation, an immediate effect on the gait function was

| Table 2. Comparison of gait function before and during HAL intervention |
|--------------------------|--------------------------|
| Outcome measurements     | before HAL | during HAL |
| Gait speed (m/s)         | 0.8 ± 0.4 | 0.3 ± 0.2** |
| Stride length (m)        | 0.5 ± 0.1 | 0.4 ± 0.1* |
| Cadence (step/min)       | 92.4 ± 35.9 | 55.1 ± 17.5** |
| Single-leg support phase (%) | 64.5 ± 15.8 | 57.2 ± 15.4 |
| Hip angle of stance phase (°) | 149.2 ± 19.0 | 153.3 ± 17.7 |
| Knee angle of stance phase (°) | 137.6 ± 20.2 | 144.8 ± 18.9 |
| Hip angle of swing phase (°) | 137.2 ± 14.6 | 129.2 ± 13.9 |
| Knee angle of swing phase (°) | 112.0 ± 15.5 | 117.2 ± 18.6 |

*p<0.05, **p<0.01.

| Table 3. Comparison of gait function before and after HAL intervention |
|--------------------------|--------------------------|
| Outcome measurements     | before HAL | after HAL |
| Gait speed (m/s)         | 0.8 ± 0.4 | 0.8 ± 0.5 |
| Stride length (m)        | 0.5 ± 0.1 | 0.5 ± 0.1 |
| Cadence (step/min)       | 92.4 ± 35.9 | 92.4 ± 40.0 |
| Single-leg support phase (%) | 64.5 ± 15.8 | 69.3 ± 12.1* |
| Hip angle of stance phase (°) | 149.2 ± 19.0 | 155.7 ± 20.1* |
| Knee angle of stance phase (°) | 137.6 ± 20.2 | 143.1 ± 19.5* |
| Hip angle of swing phase (°) | 137.2 ± 14.6 | 129.7 ± 16.6 |
| Knee angle of swing phase (°) | 112.0 ± 15.5 | 105.2 ± 17.1* |

*p<0.05, **p<0.01.
recognized following a single intervention. Therefore, we believe that HAL intervention significantly influences gait function in CP patients even with a single HAL intervention.

Our investigation has several limitations. First, the small number of cases is not sufficient. It will be necessary to obtain future results from controlled trials as compared to conventional rehabilitation to determine the efficacy of RAGT using HAL intervention. Further, it will be necessary to clarify the safety and effectiveness of long-term intervention and treatment adaptation in a larger cohort of patients. Apparently, quantity of training is necessary to produce established improvements in gait function. Further improvement of gait function would be demonstrated by conducting RAGT using HAL in the long term. We expect that walking ability will improve in accordance with the previous study.

In CP patients, a single session of RAGT with HAL intervention significantly improved measures of gait functionality including increasing both single-leg support and lower limb joint angle during gait. Therefore, RAGT using HAL may be an effective option to improve mobility in CP patients.

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