Sustained effects of once-a-week gait training with hybrid assistive limb for rehabilitation in chronic stroke: case study

Takahiko Yoshimoto, PhD, PT1)*, Issei Shimizu, PT1), Yasuhiro Hiroi, PT1)

1) Department of Rehabilitation, Kameda Medical Center: 929 Higashi-cho, Kamogawa, Chiba 2968602, Japan

Abstract. [Purpose] The purpose of this study was to investigate the accumulated and sustained effects of once-a-week gait training with a powered exoskeleton suit, Hybrid Assistive Limb, in a subject with chronic stroke. [Subject and Methods] The subject was a woman in her early sixties who had stroke onset approximately 5 years ago. A single-case ABA design was used. A 2-month baseline period was followed by an 8-week period of weekly gait training and a subsequent 2-month follow-up period. Throughout the study period, she underwent conventional physiotherapy. Outcome measures were the 10-meter walking test, timed up and go test, functional reach test, two-step test, and Berg Balance Scale. [Results] Significant improvements were seen in all outcome measures during the gait training period. Improvements in all outcome measures except walking speed were maintained at follow-up. [Conclusion] Continued gait training with Hybrid Assistive Limb once a week can improve gait and balance performance in patients with chronic stroke, and these improvements are maintained at least for two months.

Key words: Gait training, Robotics, Stroke

INTRODUCTION

For individuals with stroke, gait disability is the most commonly recognized impairment1). Recently, electromechanical-assisted gait training has received much attention for gait improvement after stroke2, 3). Electromechanical and robotic-assisted gait training could provide intensive, repetitive, and task-specific practice which may enhance functional restitution and improve motor performances4). One of these electromechanical devices, the Hybrid Assistive Limb (HAL), is a newly developed robotic exoskeleton suit that assists voluntary control of the hip and knee joints by detecting bioelectric signals on the surface of the skin5, 6). Unlike other robotic devices that provide automatic passive motion generated by a robot7), HAL receives and interprets muscle activity, enabling the user to control movements; this facilitates motor learning. Previous studies on patients with chronic stroke used HAL training, twice a week in total 16 sessions, and indicated benefits in restitution of walking function8, 9). Furthermore, a subgroup analysis by Kawamoto et al. indicated that the dependent, not independent, ambulator significantly improved walking function10). Although there are an increasing number of studies supporting the effectiveness of HAL in restoring walking function in hemiparetic stroke subjects8–10), appropriate training protocol detailing the frequency of training or the training speed remains unestablished. Additionally, there are no reports on the follow-up data after gait training with HAL.

In this case study of a woman with chronic stroke who could ambulate independently, improvement in motor performances during gait training period with HAL once a week for eight weeks was maintained at the 2-month follow-up.

*Corresponding author. Takahiko Yoshimoto (E-mail: yoshimotota@gmail.com; yoshimoto.takahiko@kameda.jp)

©2016 The Society of Physical Therapy Science. Published by IPEC Inc.
This is an open-access article distributed under the terms of the Creative Commons Attribution Non-Commercial No Derivatives (by-nc-nd) License <http://creativecommons.org/licenses/by-nc-nd/4.0/>.
SUBJECT AND METHODS

The subject was a woman in her early sixties who had first-occurrence stroke 4 years and 9 months before presentation. The diagnosis was hemorrhagic stroke, and the lesion was situated in the right thalamus. After acute and subacute rehabilitation, she was discharged home. Then, she underwent outpatient physical therapy. Before the commencement of the study, she had a moderate motor paralysis of the left side (Brunnstrom stage upper limb III; lower limb IV). She could ambulate independently with a T cane and ankle foot orthosis. The subject provided her written informed consent to take part in the study prior to its commencement, and this study conformed to the principles of the Declaration of Helsinki.

A single-subject ABA design was used to evaluate the accumulated and sustained effects of gait training with Hybrid Assistive Limb. This included a baseline phase (A), a HAL training phase (B), and a follow-up phase (A). All phases lasted two months. Throughout the study period, she received conventional physical therapy at the outpatient clinic of Kameda Medical Center.

HAL training was administered once a week for eight weeks (8 sessions). Each training session lasted approximately 60 min, including setting up the HAL, rest periods, and assessment of walking ability. The actual time of gait training with the HAL was approximately 20 min in each session. The single leg version of the HAL (Cyberdyne Inc., Japan) and walking device (All-In-One Walking Trainer, Ropox A/S, Denmark) with a harness were used (Fig. 1). The walking speed was determined as 1.5–1.7 times the 10 m maximum walking speed that was measured without wearing the HAL before every HAL training session, which was adjusted to optimize normal gait patterns without excessive forced exercise. A therapist operated the walking device to modulate the walking speed and direction. Key features of the HAL system are described in more detail elsewhere.[6, 11] The HAL has a hybrid control system including cybernic autonomous control system (CAC) and cybernic voluntary control system (CVC). The CAC mode can autonomously generate the predefined and programmed walking pattern by referring to a force-pressure sensor in the shoes. The CVC mode can support voluntary motion by magnifying and adjusting the muscle activity from surface electrodes in accordance with the wearer’s intention. In this case, she underwent HAL training using the CVC mode because the surface electrodes could detect muscle activity.

Conventional physical therapy was performed by skilled and experienced physical therapist. Each session lasted 40 min and included static and dynamic postural tasks, improvement of lower and upper extremity range of motion, and overground gait training with manual assistance. The actual time of gait training was on average 20 min.

Clinical outcome measures included a 10-meter walking test (10MWT), the timed up & go test (TUGT), the functional reach test (FRT), the two-step test (2ST), and the Berg Balance Scale (BBS). The 10MWT was performed twice at baseline (monthly), just before the start of HAL training and after each HAL training session, and monthly during the follow-up period (one month and two months after the end of HAL training). TUGT, FRT, 2ST, and BBS assessments were made monthly without the subject wearing the HAL (twice at baseline, after fourth and eighth sessions of HAL training, and twice at follow-up period).

For the 10MWT, she was instructed to walk “as fast as possible” on a 10 m walkway. We assessed the gait speed (m/s), the number of steps, and the cadence (steps/min) during the 10 m walking period. The TUGT measured the time it takes an individual to rise from an armchair, walk 3 m quickly but safely, and then return to the chair and sit down. The FRT[21] was performed to measure the maximum distance that the subject could reach forward horizontally with the unaffected arm without touching the wall or taking a step. For the 2ST[15], the subject was asked to move two steps forward with the maximum length without losing balance. The 2ST index was calculated using the following formula: 2ST index = the maximum length of two steps / height. The BBS[41] consists of 14 tasks, and each item is scored from 0 (cannot perform the task) to 4 (best performance), with a total score range of 0–56.

RESULTS

The subject completed the gait training with HAL without adverse events. Results of the 10MWT are shown in Table 1. Walking speed improved gradually with each HAL training session, and increased by 72.7% after the eighth session of HAL training compared to the data just before the start of HAL training (PRE). The number of steps and cadence also demonstrated improvements after gait training with HAL. These improvements gradually tended to decrease after the end of HAL training, but did not return to the baseline data. The degree of improvement in walking speed was 51.7% at two months after the end of HAL training.

TUGT, FRT, 2ST, and BBS performances improved gradually during the HAL training period, and improved by 28%, 46%, 18%, and 7% after the eighth session of HAL training, respectively (Table 2). Except for walking speed, these improvements were maintained mostly during two months of follow-up period.

DISCUSSION

In this single-subject study with an ABA design, the accumulated and sustained effects of gait training with a robotic suit, HAL, once a week for eight weeks were investigated. The results indicated that continuous gait training with HAL, in
addition to conventional physical therapy, improved walking speed and balance function in a subject with chronic stroke, similar to the finding in our previous study\(^\text{15}\) that evaluated the effectiveness of HAL training for chronic stroke patients in comparison with control group. The improvements in gait and balance function in the present case were mostly maintained at least for two months after the gait training while the walking speed gradually tended to decrease slightly. The effects were maintained for a prolonged period perhaps because of repeated task-specific training for a certain period, which is a well-known principle in motor learning. This is the first study reporting improvements sustained till follow-up after gait training with HAL. The findings including the sustained effects may guide further studies investigating the optimal training program with HAL.

With regard to the frequency of gait training, training with HAL was provided once a week though in previous studies\(^\text{8, 9}\) it was performed twice a week. Although it is difficult to directly compare these studies with the present case because of differences in the participant characteristics and the methods of intervention, results of this study with a lower frequency of training are of clinical value in gait rehabilitation after chronic stroke. A systematic review of electromechanical-assisted gait training after stroke\(^\text{21}\) reported that patients in the acute phase following stroke, not chronic phase, may benefit from electromechanical-assisted gait training, and patients who are non-ambulatory may benefit from the training. Previous study using HAL indicated that the dependent, not independent, ambulator had significantly improved walking function\(^\text{8}\). In this study, we showed the improvements in motor performance in a subject with chronic stroke who could ambulate independently. The robot suit HAL has great potential for improving gait and balance function in subjects with stroke regardless of the severity of walking dysfunction.

In this case, gait training with HAL was performed at a speed higher than the maximum walking speed without wearing the HAL. The training speed was determined based on our experience from a preliminary trial that, when using HAL, almost all subjects with stroke could walk at a high speed without excessive forced exercise. In a few studies using a treadmill, speed-increase training has been considered a beneficial approach for improving the gait speed on ground to a greater extent than traditional programs that train at slower speeds in patients with stroke\(^\text{16-18}\). Some stroke patients are afraid of falling because of gait and balance impairments\(^\text{19}\). In addition to the assistive function of the HAL device described above, a walking device (All-In-One Walking Trainer) with a harness would enable performance of high-speed gait training without the risk of falling.

**Table 1.** Time-dependent changes of each parameter in 10MWT at baseline, during gait training with HAL, and at follow-up periods

|          | Baseline | HAL training sessions | Follow-up |
|----------|----------|-----------------------|-----------|
|          | A1 | A2 | PRE | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | A1 | A2 |
| Speed (m/s) | 0.31 | 0.30 | 0.29 | 0.36 | 0.41 | 0.40 | 0.43 | 0.42 | 0.43 | 0.49 | 0.50 | 0.45 | 0.44 |
| No. of steps | 34 | 34 | 36 | 35 | 31 | 34 | 33 | 35 | 32 | 30 | 30 | 31 | 32 |
| Cadence (steps/min) | 63 | 61 | 63 | 75 | 76 | 81 | 86 | 89 | 84 | 88 | 90 | 85 | 84 |

A1 and A2 mean the monthly assessment at baseline and after the end of HAL training. PRE means the assessment just before the start of HAL training. 10MWT: 10-meter walking test

**Table 2.** Outcome measures in TUGT, FRT, 2ST, and BBS at the baseline (A), during HAL training (B), and at the follow-up periods (A)

|          | Baseline | HAL training | Follow-up |
|----------|----------|--------------|-----------|
|          | A1 | A2 | B1 | B2 | A1 | A2 |
| TUGT (s) | 34.04 | 36.46 | 27.48 | 25.69 | 26.11 | 26.77 |
| FRT (cm) | 18 | 24 | 33 | 35 | 35 | 34 |
| 2ST | 0.38 | 0.39 | 0.46 | 0.46 | 0.49 | 0.46 |
| BBS | 44 | 45 | 47 | 48 | 47 | 48 |

A1 and A2 mean the monthly assessment at baseline and after the end of HAL training. B1 and B2 mean the assessment at fourth and eighth sessions of HAL training, respectively. TUGT: timed up & go test; FRT: functional reach test; 2ST: two-step test; BBS: Berg Balance Scale

**Fig. 1.** A hemiparetic subject practicing in the exoskeleton robot Hybrid Assistive Limb with walking device (All-In-One Walking Trainer)
This case study of a patient with chronic stroke indicated that continued once-a-week gait training with HAL, performed for eight weeks, improved gait and balance performances and that the improvements are sustained for at least two months after the gait training. The sustained effects, although not permanent, were meaningful, indicating that gait training with HAL encouraged motor learning by intensive, repetitive, and task-specific training. Further controlled studies including follow-up assessments are necessary to provide further insight and develop an optimal training protocol for gait training with HAL for patients with stroke.

REFERENCES

1) Barthuly AM, Bohannon RW, Gorack W: Limitations in gait speed persist at discharge from subacute rehabilitation. J Phys Ther Sci, 2013, 25: 891–893. [Medline] [CrossRef]
2) Mehrholz J, Elsner B, Werner C, et al.: Electromechanical-assisted training for walking after stroke. Cochrane Database Syst Rev, 2013, 7: CD006185. [Medline] [CrossRef]
3) Kang CG, Chun MH, Jang MC, et al.: Views of physiatrists and physical therapists on the use of gait-training robots for stroke patients. J Phys Ther Sci, 2016, 28: 202–206. [Medline] [CrossRef]
4) Langhorne P, Bernhardt J, Kwakkel G: Stroke rehabilitation. Lancet, 2011, 377: 1693–1702. [Medline] [CrossRef]
5) Kawamoto H, Sankai Y: Power assist method based on Phase Sequence and muscle force condition for HAL. Adv Robot, 2005, 19: 717–734. [CrossRef]
6) Kawamoto H, Hayashi T, Sakurai T, et al.: Development of single leg version of HAL for hemiplegia. Conf Proc IEEE Eng Med Biol Soc, 2009, 2009: 5038–5043. [Medline] [CrossRef]
7) Cho DY, Park SW, Lee MJ, et al.: Effects of robot-assisted gait training on the balance and gait of chronic stroke patients: focus on dependent ambulators. J Phys Ther Sci, 2015, 27: 3053–3057. [Medline] [CrossRef]
8) Kawamoto H, Kamibayashi K, Nakata Y, et al.: Pilot study of locomotion improvement using hybrid assistive limb in chronic stroke patients. BMC Neurol, 2013, 13: 141. [Medline] [CrossRef]
9) Kubota S, Nakata Y, Eguchi K, et al.: Feasibility of rehabilitation training with a newly developed wearable robot for patients with limited mobility. Arch Phys Med Rehabil, 2013, 94: 1080–1087. [Medline] [CrossRef]
10) Watanabe H, Tanaka N, Inuta T, et al.: Locomotion improvement using a hybrid assistive limb in recovery phase stroke patients: a randomized controlled pilot study. Arch Phys Med Rehabil, 2014, 95: 2006–2012. [Medline] [CrossRef]
11) Kawamoto H, Taal S, Niniss H, et al.: Voluntary motion support control of Robot Suit HAL triggered by bioelectrical signal for hemiplegia. Conf Proc IEEE Eng Med Biol Soc, 2010, 2010: 462–466. [Medline] [CrossRef]
12) Duncan PW, Weiner DK, Chandler J, et al.: Functional reach: a new clinical measure of balance. J Gerontol, 1990, 45: M192–M197. [Medline] [CrossRef]
13) Yoshimoto T, Shimizu I, Hiro Y, et al.: Feasibility and efficacy of high-speed gait training with a voluntary driven exoskeleton robot for gait and balance dysfunction in patients with chronic stroke: nonrandomized pilot study with concurrent control. Int J Rehabil Res, 2015, 38: 338–343. [Medline] [CrossRef]
14) Sullivan KJ, Knowlton BJ, Dobkin BH: Step training with body weight support: effect of treadmill speed and practice paradigms on poststroke locomotor recovery. Arch Phys Med Rehabil, 2002, 83: 683–691. [Medline] [CrossRef]
15) Lau KW, Mak MK: Speed-dependent treadmill training is effective to improve gait and balance performance in patients with sub-acute stroke. J Rehabil Med, 2011, 43: 709–713. [Medline] [CrossRef]
16) Park J, Yoo J: Relationships of stroke patients’ gait parameters with fear of falling. J Phys Ther Sci, 2014, 26: 1883–1884. [Medline] [CrossRef]