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Walking Rehabilitation Using Hybrid Assistive Limb (HAL) and Computer-Controlled Long-Leg Orthosis (C-Brace) for an Individual with Chronic Incomplete Spinal Cord Injury: A Case Report

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1. Abstract

Many individuals with spinal cord injury (SCI) hope to restore walking function irrespective of their impairment. We present a case with chronic incomplete cervical SCI who could regain community ambulation by gait training with hybrid assistive limb (HAL), followed by fitting and training of microprocessor-controlled knee ankle foot orthosis (C-Brace). The walking and balance ability continuously improved in the course of rehabilitation. The combination therapy of HAL and C-Brace could be a novel, effective therapeutic strategy for walking rehabilitation in chronic incomplete SCI patients.

2. Background

Spinal cord injury (SCI) can cause severe quadriplegia or paraplegia and can significantly negatively affect the physical and mental health of patients [1,2]. Traditionally, therapies for SCI that caused complete or incomplete paralysis have primarily involved rehabilitation practices focused on patients' remaining physical functions. Many people with SCIs return to their local communities by reacquiring their Activity of Daily Living (ADL) functionality to the extent they can and making use of assistive devices, such as wheelchairs [3]. At the same time, it has been reported that irrespective of the severity of their paralyses, a large number of SCI patients hope to reacquire the ability to walk. Thus, the improvement of SCI patients' paralysis and the reacquisition of their ability to walk remain important unsolved issues in this field [4]. In recent years, reports detailing the efficacy of rehabilitation practices involving robotic technology for patients with neurological impairments (including SCI) have become more common [5,6]. Hybrid Assistive Limb (HAL) robot is a wearable cyborg device which detects movement signals at the wearer's hip and knee joints and provides assistive force to aid them in walking (Figure 1a). Reports indicate that HAL is effective in improving chronic SCI patients' walking ability, and thus is an important therapeutic strategy to consider when rehabilitating an individual's walking ability [6-8]. However, there are certain problems with HAL rehabilitation therapy. HAL is large and quite heavy, and the patient cannot equip or put on HAL alone. Furthermore, while HAL can be used in walking practice on flat ground, it is very difficult to adapt it for use outdoors, climbing or descending stairs, and on sloped surfaces. As a result, HAL can only be used inside rehabilitation facilities and is, for all intents and purposes, impossible to use in local community spaces. For this reason, it is very difficult for patients that rely on HAL to reacquire real-world walking ability. These problems attendant upon HAL-reliant rehabilitation therapy represent the limitations of the technology [9]. A new therapeutic strategy, which can both maintain the walking ability improvement effects made possible by HAL training and can enable the acquisition of walking ability for local community settings, is sorely needed. One possible candidate for this strategy is C-Brace computer-controlled long-leg orthosis. Compared to HAL, C-Brace is more compact, lighter, and can be put on by the patient alone quite easily (Figure 2). C-Brace can be equipped and used outdoors, up and down stairs, on sloped surfaces, and in many other environments. It assists the wearer in walking stably and works to prevent falls [10-11]. C-Brace should allow patients to maintain the walking ability improvement they obtained through HAL training while also serve as a promising means for wearers to realize walking ability usable in local community spaces. However, there are no reports to date on the use of C-Brace for SCI patients. There are also no reports of rehabilitation therapies that combine HAL and C-Brace training for SCI patients. Here, we report a case wherein a chronic cervical SCI patient for whom conventional rehabilitation therapy did not work received walking training using the HAL device, followed by C-Brace use. Ultimately, this patient was able to regain the practical walking ability necessary to navigate local community spaces. This study was carried out in accordance with the Declaration of Helsinki and received the approval of the Hyogo Rehabilitation Center Hospital's Ethics Committee. Written consent was obtained from the patient.

3. Case Presentation

A 38-y-old male suffered from incomplete cervical SCI due to a car accident. After initial treatment at a tertiary emergency hospital, he was transferred to a general rehabilitation hospital 1 mo later. He was admitted to our hospital, which specializes in SCI rehabilitation, 5 mo after the injury developed. The patient's impairment at admission to our hospital was as follows: American Spinal Cord Injury Association Impairment Scale (AIS) D, International Standards for Neurological and Functional Classification of Spinal Cord Injury (ISNCSCI) score [12], upper limbs 45 (left 24, right 21), lower limbs 41 (left 25, right 16), neurological level of injury (NLI) C8, sensory level of injury C5, Berg Balance Scale (BBS) 48 [13], and WISCI-II score 15 (can walk 10 m using one Lofstrand crutch and right rear strut ankle foot orthosis) [14]. For 1 mo, the patient underwent conventional rehabilitation therapy (physical therapy/occupational therapy for 80 min/d, 5 d/week, along with individual exercises), but almost no improvement in physical function or balance capabilities was observed. Furthermore, no improvement in LEMS or WISCI-II scores was observed (Table 1). Given these results and the fact that an additional 6 mo had passed since the patient's injury, we judged that improvement in the patient's paralysis caused by cervical SCI had plateaued, and, thus, decided to introduce HAL training.

3.1. HAL Functions, Training Protocol, and Evaluation Methods

HAL is a wearable cyborg device that detects and provides mechanical assistance for movement impulses at the hip and knee joints of the wearer. The floor reaction force sensors in the "shoe" part of the device and the myoelectric potential signals detected by skin-contact electrodes are analyzed to assist the wearer's intended walking movement (Figure 1a) [15,16]. The hip/knee unit consists of an angle sensor and an actuator. In terms of methods to control these separate units, HAL can be operated in two modes. In the cybernic voluntary control (CVC) mode, the device analyzes movement impulses from signals collected by electrodes at the user's skin surface and controls its parts in accordance with the user's voluntary movements. In the cybernic autonomous control (CAC) mode, the device largely controls itself, enabling it to complete the user's movement patterns even when biopotential signals at the skin surface are insufficient or incomplete. The training for this case was performed in CVC mode because the myoelectric signals detected by its surface electrodes were sufficient to properly manipulate the HAL device. The strength of support was adjusted by a physiotherapist in accordance with the walking ability of the patient while wearing HAL. As training progressed and the patient's walking ability improved, the amount of support was reduced.

The protocol was as follows: 24 sessions of HAL training were held twice a week for 12 wk. During the HAL training period, regular physiotherapy was performed in the same way as it was before the introduction of the HAL. The contents of the HAL training were as follows: each session lasted 45 min; 15 min for equipping the HAL, 25 min of walking training (6 min of walking in the training room and 3 min of rest, each set repeated thrice), and 5 min for HAL removal. During the training, a doctor was present in case of an emergency, the patient used a wheeled walker to prevent falls, and the patient was accompanied by two physiotherapists (Figure 1b). Another physiotherapist was present as a timekeeper and to measure vital signs (heart rate, blood pressure, and blood oxygen saturation).

The following items were measured: 10 m walking test (10MWT, comfortable speed and max speed), 6 min walking test (6MD) [17], and the BBS. Finally, to measure balance ability in ADL movements, the Activity-Balance Confidence Scale (ABC scale) was used [18]. The ABC scale involves self-rating one's confidence during each performance of 16 ADL movements (such as walking up and down stairs) from 0% to 100%; we calculated the mean of these 16 ratings.

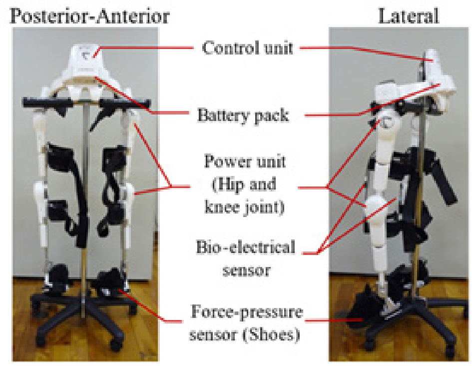

Figure: 1a: Hybrid Assistive Limb (HAL) robot is a wearable cyborg device which detects movement signals at the wearer's hip and knee joints and provides assistive force to aid them in walking.

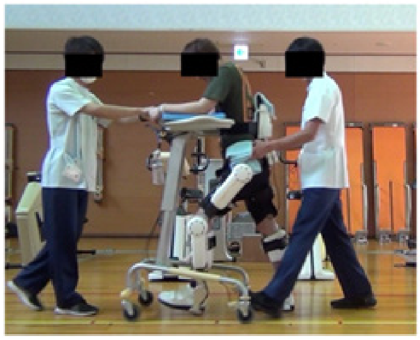

Figure 1b: The contents of the HAL training were as follows: each session lasted 45 min; 15 min for equipping the HAL, 25 min of walking training (6 min of walking in the training room and 3 min of rest, each set repeated thrice), and 5 min for HAL removal. During the training, a doctor was present in case of an emergency, the patient used a wheeled walker to prevent falls, and the patient was accompanied by two physiotherapists.

Table 1: Physcial funcation and WISCI - II.

	Before HAL traning	After 3 months HAL training	After 3 months C - Barce	After 6 Months C- brace
UEMS total	44	47	47	47
LEMS total	41	42	42	42
WISCI - II	15	15	15	15

UEMS: upper extremity motor score
LEMS: lower extremity motor score
WISCI-II: Walking Index for Spinal Cord Injury II

3.2 Progress after HAL Training, Function and Manufacture of the C-Brace, and Suitability

After 3 mo of HAL training, the patient's walking and balance abilities improved (Table 2). However, the extensor strength of the right knee muscles was still weak at the Manual Muscle Testing (MMT) 3 level, and hyperextension of the right knee was observed when the patient walked with the right ankle foot orthosis. He was able to walk indoors on level ground in a stable manner, but was unstable on slopes, stairs, and rough terrain, and was afraid of falling. A wheelchair was required for him to move about outdoors. Therefore, we decided to adapt the C-Brace to maintain the improved walking ability by achieved by using HAL and to acquire practical walking ability in the community. C-Brace consists of a carbon fiber thigh/lower leg shell made for each patient and a uniaxial knee joint with a computer-controlled hydraulic damper connected to it (Figure 2). The knee joint has a built-in angle sensor and an angular velocity sensor. Carbon fiber struts connect the lower leg shell to the foot parts. The knee joint computer controls the knee joint hydraulic damper. This structure allows the device to control the user's entire walk cycle in real time [10]. However, C-Brace cannot assist its user via reading signals collected from surface electrodes like the HAL can. C-Brace was molded and manufactured by a prosthetist, and the patient's suitability for the device was confirmed by a doctor.

Table 2: Gait and balance abilities.

	Before HAL training	After 3 months AHL training	After 3 months C-Brace	After 6 months C-Brace
10MWT CWS (m\s)	0.40	0.75	0.80	1.14
10MWT MWS (m\s)	0.52	1.15	1.19	1.33
6MD (m)	195	284	360	424
BBS	48	50	50	53
ABC scale (%)	56.3	62.5	65.6	67.5

10MWT: 10-meter walk test
CWS: comfortable walking speed
MWS: maximum walking speed
6MD: 6- minute walking distance
BBS: Berg balance scale
ABC scale: Activate-Balance Confidence Scale

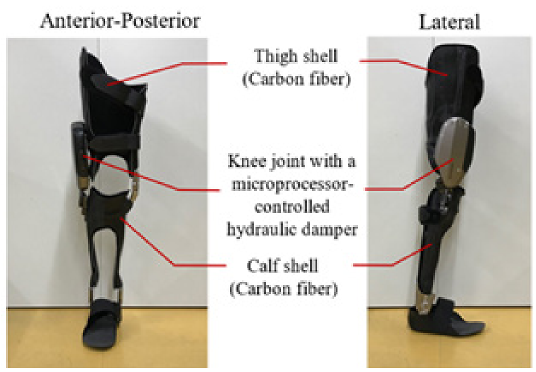

Figure 2: C-Brace consists of a carbon fiber thigh/lower leg shell made for each patient and a uniaxial knee joint with a computer-controlled hydraulic damper connected to it.

3.3. C-Brace Training Protocol and Progress

The patient underwent C-Brace training four times a week for 6 mo. As was done during HAL training, normal physiotherapy sessions were continued throughout. C-Brace training protocol. Each session was 30 min long. For the first 3 mo, the patient focused on walking training using C-Brace, with three sets of 6 min of flat-found walking training and 3 min of rest between sets. During the first few sessions, the patient used a walker to prevent falling, but after it was confirmed that he could walk safely, he was permitted to walk with Lofstrand crutches. For the last 3 mo, the patient underwent applied training on uneven ground, stairs, and sloped surfaces. After 6 mo of training, the patient acquired the ability to walk stably while wearing C-Brace in all environments necessary for daily life, including rough terrain, stairs, and slopes (Figure 3). He was also able to walk continuously for more than 1000 m. The patient's walking and balance ability further improved through C-Brace training (Table 2). The patient is currently preparing to return to work as a postal worker.

Figure 3: After 6 mo of training, the patient acquired the ability to walk stably while wearing C-Brace in all environments necessary for daily life, including rough terrain, stairs, and slopes.

4. Discussion

In a patient with chronic incomplete SCI, the application of C-Brace training after HAL-based walking training led to the further improvement of walking and balance ability, reduced fear of falling during daily living activities, and acquisition of practical walking ability in local community spaces. The training results of this case make it clear that walking training using HAL was effective in improving walking and balance ability. Previous reports also indicated that HAL was effective in improving the walking ability in patients with spinal cord disorders whose conditions did not improve with conventional rehabilitation treatment [6,9,19]. These improvements are believed to be related to motor learning and dose-dependent plasticity in the central nervous system [3,20,21]. Our results are in agreement with these findings and suggest that HAL training is quite effective. However, HAL is a training device and is suitable only for use in training contexts; as such, it cannot be used in patients' daily lives. In addition, it has been reported that after HAL training is completed, walking ability can decline again if HAL training is not continued [9]. In order to maintain the walking ability improvement effect obtained after the completion of HAL training, and to acquire practical walking in the local community, orthoses and walking aids that compensate for patients' remaining dysfunctions are necessary. In other words, walking training with HAL alone is not sufficient for the rehabilitation of practical walking in community spaces for people with SCI. In this case, use of C-Brace allowed the patient to maintain the improvements in their walking and balance ability that they achieved with HAL training and to even achieve further improvement (Table 2). It has been reported that C-Brace maintains better control of the knee joint during both the stance and swing phases, compared to conventional long-leg orthoses, and better enables users to walk on stairs and sloped surfaces naturally [10,11]. In this case, we believe that the knee joint stability during walking provided by the C-Brace contributed to the maintenance of the effects of HAL training and further improvement in the patient's walking ability. Establishing an effective rehabilitation treatment strategy for gait disorders in people with chronic myelopathy is an important clinical issue. In recent years, cell-based spinal cord regenerative medicine has attracted attention. It has been reported that spinal cord regeneration therapy using these cells cannot achieve functional and ability improvement alone, especially in chronic SCI, and that it is necessary to use this approach in combination with rehabilitation therapy [22]. However, effective rehabilitation treatment has not yet been fully established in the context of regenerative medicine for SCI. The HAL training followed by C-Brace training that we have reported here is likely a promising new therapeutic strategy for walking rehabilitation in chronic SCI patients.

5. Conclusion

We experienced a case in which HAL and C-Brace training proved effective as practical walking reacquisition therapy at the local community level for a patient with chronic incomplete cervical SCI associated with ambulatory impairment. The combination of HAL and C-Brace technologies is a novel, effective therapeutic strategy for walking rehabilitation in chronic SCI patients. Further proof with additional cases is necessary for verification of these results.

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