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Case Study

Newly developed hybrid assistive limb for pediatric patients with cerebral palsy: a case report

Shogo Nakagawa, MD[1, 2], Hirotaka Mutsuzaki, MD, PhD[2, 3], Yuki Mataki, MD[3], Yusuke Endo, PT, MSc[4], Mayumi Matsuda, PT[5], Kenichi Yoshikawa, PT[5], Hiroshi Kamada, MD, PhD[1)*], Masashi Yamazaki, MD, PhD[1]

[1] *Department of Orthopaedic Surgery, Faculty of Medicine, University of Tsukuba: 1-1-1 Tennodai, Tsukuba, Ibaraki 305-8575, Japan*
[2] *Center for Medical Sciences, Ibaraki Prefectural University of Health Sciences, Japan*
[3] *Department of Orthopaedic Surgery, Ibaraki Prefectural University of Health Sciences Hospital, Japan*
[4] *Department of Physical Therapy, Ibaraki Prefectural University of Health Sciences, Japan*
[5] *Department of Physical Therapy, Ibaraki Prefectural University of Health Sciences Hospital, Japan*

Abstract. [Purpose] The effect of fitness training on improving walking ability in cerebral palsy is controversial. However, gait training with a wearable robot (hybrid assistive limb) has been reported to improve gait ability in patients with cerebral palsy. For pediatric patients, a smaller, lighter-weight hybrid assistive limb has been newly developed. We describe the immediate effect of this newly developed smaller hybrid assistive limb on the gait ability of a pediatric patient with cerebral palsy and examine its safety and feasibility. [Participant and Methods] An 11-year-old male with spastic cerebral palsy (height, 130 cm; weight, 29.0 kg) who could ambulate using an elbow crutch participated in this study. A single session of hybrid assistive limb training comprising pre-exercise of the hip and knee joints and walking for 20 minutes was conducted. [Results] The intervention immediately improved his gait speed, stride length, and cadence according to the 10-m walking test. Co-contraction of agonist/antagonist muscles during walking improved, and the flexion angle of the right hip during the swing phase increased, which resulted in symmetry of movement of both legs. [Conclusion] Gait training using the new, smaller hybrid assistive limb for a pediatric patient was safe and feasible, and the newly developed hybrid assistive limb has the potential to immediately improve walking ability even among young children with cerebral palsy.
Key words: Cerebral palsy, Pediatric hybrid assistive limb, Gait training

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INTRODUCTION

It is widely known that walking ability declines during a period of growth spurt in patients with cerebral palsy (CP), even if walking becomes possible using an assistive device[1]. Infants with CP cannot achieve normal motor development, and the start of walking is often delayed[2, 3]. Gross motor function develops during the first decade of life and then plateaus[1]. The reasons for this plateau include changes in muscle balance due to body growth, deformation of the bones and joints, weight gain, and lack of walking opportunities.

Various methods of rehabilitation have been performed to improve the walking ability of children with CP. However, as the characteristics of patients with CP depend on various factors, including the type and severity of disease and position

*Corresponding author. Hiroshi Kamada (E-mail: hkamada@md.tsukuba.ac.jp)

of paralysis, there are no standard methods of rehabilitation, and their effects vary. In some previously reported systematic reviews, the effect of physical strength training on improving physical activity and walking ability was good, whereas other studies reported that there was no effect[4–6].

Recently, it was reported that rehabilitation using robot suits, such as the Hybrid Assistive Limb (HAL®, Cyberdyne, Tsukuba, Japan), is useful for improving motor function of patients with CP[7, 8]. The HAL receives electric signals sent from the brain to the muscles, amplifies them with a computer, and analyzes them in conjunction with a weighting sensor at the sole of the wearer's foot in order to support optimal joint motion for walking[9]. It has been reported that the wearer can learn walking function through supportive spontaneous walking, i.e., the interactive biofeedback mechanism[10]. Because no size of HAL is suitable for a child's small body, the HAL cannot be used in pediatric gait training, and there are no reports of using the HAL in children or adults with a short stature[8].

Recently, a new smaller and lighter weight HAL has been developed for pediatric patients. We assume that further improvement in walking ability can be obtained using this HAL in younger pediatric patients with a short stature. In this study, we describe the immediate effect of this newly developed smaller HAL on the walking ability of a pediatric patient, and we examine its safety and feasibility.

PARTICIPANT AND METHODS

An 11-year-old male (height, 130 cm; weight, 29.0 kg) who was born preterm with a very low birth weight participated in this study. Since he was 4 months old, he had started receiving rehabilitation and was diagnosed with periventricular leukomalacia. He had spastic diplegia due to CP, which was classified as level III according to the Gross Motor Function Classification System. He could walk alone using double elbow crutches and carbon dynamic ankle orthoses, but his right knee joint remained bent during walking. His intelligence quotient (IQ) was measured with the Wechsler Intelligence Scale for Children-IV (WISC-IV), and the full-scale IQ score was 67. A movie was used when explaining the intervention method, and informed consent was obtained from the patient's parents before this intervention was performed. The study protocol was approved by the Human Ethics Review Committee of Ibaraki Prefectural University of Health Sciences (approval numbers: 682, e83, and e119) and written informed consent was obtained from the patient's parents for publication of this case report and any accompanying images.

HAL gait training was performed at the time of standard physical therapy. We applied the newly developed HAL (2S-HAL, lower limb type, 2S size) in the cybernic voluntary control mode (Fig. 1). The 2S-HAL weighs 5 kg, and its target user is children with height of 100–150 cm and weight of 15–40 kg.

After wearing it, flexion/extension balance and assist torque at the hip and knee joints were optimized. To avoid falling, a walking device (All-in-One Walking Trainer, Ropox A/S, Naestved, Denmark) with a harness was used, as done with other sizes of HAL. Because the patient had drop feet, ankle-foot orthoses were used. A single session of HAL training, which comprised pre-exercise of the hip and knee joints and walking for 20 minutes, was performed (Fig. 2).

The entire session of 100 minutes consisted of a pre-training examination (20 minutes); time for wearing and removing the device (30 minutes); preparation movement (10 minutes), including single-leg extension/flexion motion and standing/sitting exercise, and post-training examination (20 minutes); and HAL training (20 minutes).

Before and after the intervention with HAL, we analyzed the following parameters: gait speed, step length, and cadence were assessed using the 10-m walking test (10MWT) with double elbow crutches and carbon dynamic ankle orthoses.

The kinematics data were obtained from the video of the patient performing the 10MWT, which was taken from the sagittal plane. Then, we calculated the hip joint angle and knee joint angle using 2-dimensional-3-dimensional motion analysis

Fig. 1. Gait training using the newly developed smaller Hybrid Assistive Limb with All-in-One Walking Trainer.

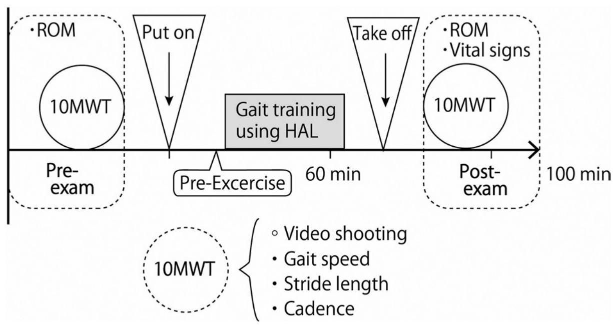

Fig. 2. Timetable of the intervention. HAL: Hybrid Assistive Limb; 10MWT: 10-m walking test; ROM: range of motion; Pre-exam: pre-examination; Post-exam: post-examination.

software FlameDIAS (version 2.00, DKH Inc., Tokyo, Japan).

Electromyography (EMG) of the rectus femoris (RF), gluteus maximus (GM), vastus lateralis (VL), and semitendinosus (ST) was performed using a surface EMG device (Trigno Wireless Systems, Delsys Inc., MA, USA). Two muscles in the first half were chosen as the representative muscles mainly responsible for flexion and extension in the hip joint, and the second two were chosen as that in the knee joint. The EMG signals were collected at a sampling rate of 2,000 Hz and bandpass filtering of 20–450 Hz. Subsequently, an absolute EMG signal was integrated by time to calculate an integrated EMG (iEMG) signal.

To examine the effect of the intervention on the patient's general health, we also analyzed his heart rate, oxygen saturation, and degree of fatigue by using the Borg scale. At the end of the intervention, we asked him how it felt and checked him from head to toe to determine whether any skin damage had occurred. Then all clinically significant adverse events were recorded.

RESULTS

The total gait training time with the HAL during the intervention was approximately 7 minutes over a 200-m walking distance, and the remaining time included the break. The degree of fatigue during the training, as measured using the Borg scale, was 13 (somewhat hard). His heart rate and oxygen saturation remained almost unchanged immediately after training compared with that at rest (Table 1). No severe adverse event interrupted the intervention, and no inconvenience occurred even after the patient returned home.

The results of clinical gait analysis are summarized in Table 2. All values of gait speed, stride length, and cadence were higher post-intervention than pre-intervention. The patient said that he felt like his body was lighter after HAL gait training.

The joint kinematic data are shown in Fig. 3a–d. The flexion angle of the left hip joint in swing phase was found to be

Table 1. Clinical evaluation of the degree of fatigue and vital signs

Parameters	Pre-intervention	Post-intervention
Borg scale	-	13
Heart rate (bpm)	70	95
Oxygen saturation (%)	99	98

bpm: beats/min.

Table 2. Clinical gait analysis using the 10-m walking test

Parameters	Pre-intervention	Post-intervention
Speed (m/sec)	0.92	1.10
Stride length (m)	0.42	0.48
Cadence (step/sec)	2.21	2.31

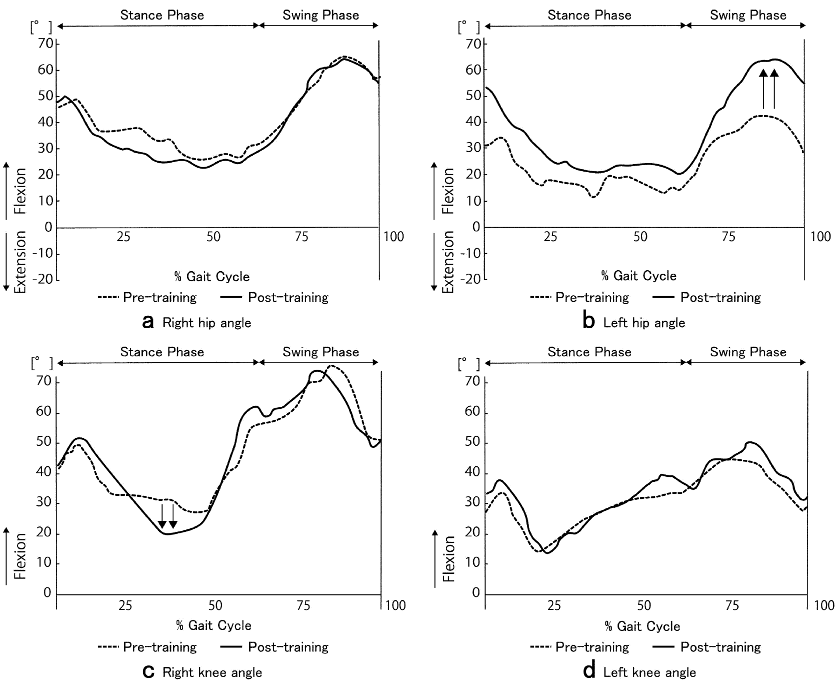

Fig. 3. Hip and knee joint angle velocity during one gait cycle. Gait analysis reveals that the left hip flexion angle during swing phase and right knee extension angle during stance phase are increased (arrows).
Pre-training: dashed line; post-training: solid line.

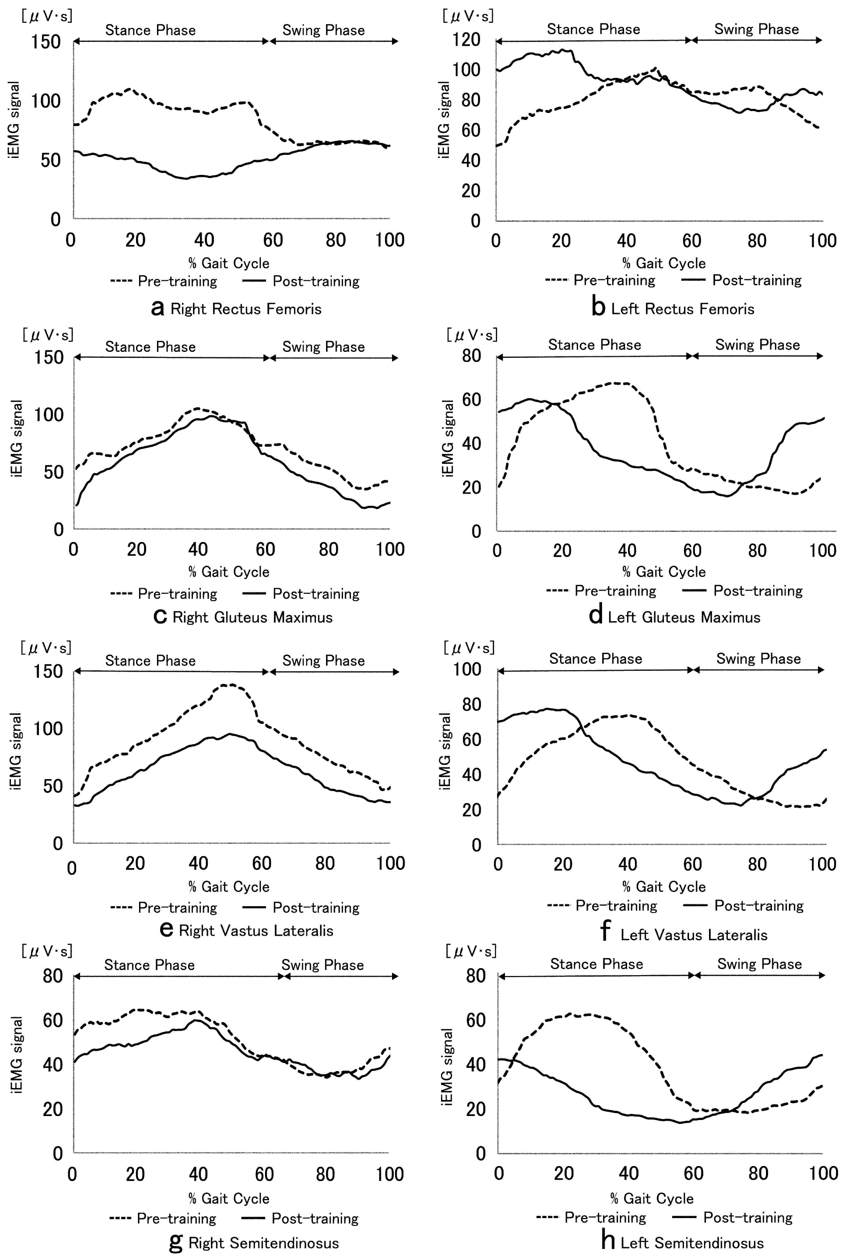

Fig. 4. Integrated electromyographic results of both rectus femoris, gluteus maximus, vastus lateralis, and semitendinosus muscles before and after gait training.

extended after the intervention compared with that before. The movement of the hip joint was observed to be symmetrical after the intervention. Further, the maximum knee extension angle of the right leg in stance phase increased by over 10 degrees, which was almost equal to that of the left leg.

The iEMG signals of the left RF, right ST, and right ST during stance phase decreased after the intervention (Fig. 4a–h). The iEMG signals of the right GM and right VL during the entire walking cycle decreased. Moreover, the timings of activation of the left GM and left VL were earlier. Further, the iEMG signals of the muscles in the left lower limb after the intervention increased after the patient's toe left the ground.

DISCUSSION

In our pediatric patient with CP, all the clinical gait parameters improved after the intervention using the newly developed, lower limb type 2S-HAL. It was found that gait training with the HAL had an immediate effect on walking ability without any severe adverse events. This is the first case report of a pediatric patient with a short stature and CP who underwent gait

Fig. 5. The newly developed Hybrid Assistive Limb (HAL) is a smaller and lighter weight walking assist device than the previous version. Left: lower limb type 2S-HAL; right: lower limb type S-HAL.

training using the newly developed HAL.

The immediate effect of gait training using the 2S-HAL in patients with CP has been previously reported[8, 11]. In these reports, however, the size of the HAL model used was a lower limb type S size (S-HAL, mean age and stature: 15.0–16.8 years and 145.6–151.3 cm, respectively). For use at a younger age, the S-HAL may be too large and heavy, so a smaller size and lighter weight model would be required. The newly developed HAL is smaller and has lighter weight than the previous one (newly developed small HAL: target height 100–150 cm, equipment weight 5 kg; S-HAL: target height 140–165 cm, equipment weight 14 kg); thus, it was possible to perform safe gait training without negatively affecting the degree of fatigue and vital signs (Fig. 5). Additionally, it is assumed that young CP patients without joint contractures and bone deformities are more likely to develop their own movement pattern, and thus, gait training with the 2S-HAL in these patients is more effective. The newly developed 2S-HAL may be more effective in younger people than previous sizes of HAL for gait training.

Considering the data of joint kinematics and iEMG signals, the present patient had a crouched gait posture with the right knee flexed and joint stiffness due to co-contraction of agonist/antagonist muscles and walked awkwardly[12]. With the improvement of co-contraction via decreased iEMG signals around the hip and knee joints during stance phase, it seems that the muscle balance normalized and gait symmetry was obtained[13]. Thus, the extension angle of the left knee joint during stance phase and the flexion angle of the right hip joint during swing phase were higher after the intervention. This finding suggests that the patient was able to move his legs forward with greater ease than before the intervention because lower limb clearance improved. Improvement of this gait posture seems to have resulted in an increase in gait speed, stride length, and cadence.

By wearing the HAL, any patient can walk easily with their hip and knee joints extended in stance phase and flexed in swing phase[9]. The effect was sustained even after HAL was removed, so Saita et al. investigated the role of biofeedback during HAL gait training in stroke rehabilitation[10]. According to their study, HAL gait training in a patient with subacute stroke resulted in cortical activation of the primary motor cortex of the ipsilesional hemisphere, and thus, led to immediate improvement. In our case as well, learning effects of interactive biofeedback may have influenced the patient's gait pattern.

We also considered that the HAL should be carefully used in younger patients, as they are initially frightened by the device or the unknown event. Mental retardation with CP may also be an issue. The ability of the patient to understand the device and intervention is necessary, and in this study, we presented a video to the patient beforehand. We also consider that it is necessary for the parents to attend the intervention. The participant of this study was 11 years old, and his IQ was very low, as evaluated by the WISC-IV; however, he had no problem understanding the intervention. If the patient would have been younger, there is a possibility that the intervention would not have been as successful.

There are some limitations of this case study. This was a single case report of the immediate effectiveness of gait training with a new HAL after only one session. Large prospective studies with long-term follow-up of young patients with CP are needed to establish this newly developed, smaller HAL as a more beneficial device. Such studies may also be able to determine the optimum intervention timing, session time, frequency, and total number of HAL interventions to obtain the most effective result.

In conclusion, gait training using the newly developed, smaller HAL for pediatric patients was safe and feasible in a pediatric patient with CP. This device has the potential to immediately affect walking ability by normalizing muscle activity and facilitating bilateral symmetry of gait posture even among young children with CP.

Conflicts of interest

The authors declare that there is no conflict of interest regarding the publication of this paper.

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