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Original article

Robot-assisted training using Hybrid Assistive Limb® for cerebral palsy

Mayumi Matsuda [a,b,*], Nobuaki Iwasaki [c,d], Yuki Mataki [e], Hirotaka Mutsuzaki [d,e], Kenichi Yoshikawa [a], Kazushi Takahashi [a], Keiko Enomoto [a], Kumiko Sano [a], Aoi Kubota [a], Tomohiro Nakayama [c], Junko Nakayama [c], Haruka Ohguro [c], Masafumi Mizukami [b,f], Kazuhide Tomita [a,b,f]

[a] *Department of Physical Therapy, Ibaraki Prefectural University of Health Sciences Hospital, Japan*
[b] *Graduate School of Health Science, Ibaraki Prefectural University of Health Sciences, Japan*
[c] *Department of Pediatrics, Ibaraki Prefectural University of Health Sciences Hospital, Japan*
[d] *Center for Medical Science, Ibaraki Prefectural University of Health Sciences, Japan*
[e] *Department of Orthopaedic Surgery, Ibaraki Prefectural University of Health Sciences Hospital, Japan*
[f] *Department of Physical Therapy, Ibaraki Prefectural University of Health Sciences, Japan*

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Abstract

Purpose: The Hybrid Assistive Limb® (HAL®, CYBERDYNE) is a wearable robot that provides assistance to a patient while they are walking, standing, and performing leg movements based on the wearer's intended movement. The effect of robot-assisted training using HAL® for cerebral palsy (CP) is unknown. Therefore, we assessed the effect of robot-assisted training using HAL® on patients with CP, and compared walking and gross motor abilities between pre-intervention and post-intervention.

Methods: Six subjects with CP were included (mean age: 16.8 years; range: 13–24 years; Gross Motor Function Classification System levels II–IV: n = 1, 4, 1). Robot-assisted training using HAL® were performed 2–4 sessions per week, 20 min per session, within a 4 weeks period, 12 times in total. Outcome measures included gait speed, step length, cadence, single-leg support per gait cycle, hip and knee joint angle in stance, and swing phase per gait cycle, 6-minute walking distance (6 MD), physiological cost index (PCI), knee-extension strength, and Gross Motor Function Measure (GMFM).

Results: There were significant increases in self-selected walking speed (SWS), cadence during SWS and maximum walking speed (MWS), single-leg support per gait cycle, hip joint angle in the swing phase, 6 MD, and GMFM. In contrast, gait speed during MWS, step length during SWS and MWS, hip and knee joint angle in the stance phase, knee joint angle in the swing phase, PCI, and knee-extension strength generally improved, but not significantly.

Conclusion: Robot-assisted training using HAL® may improve walking and gross motor abilities of patients with CP.

Keywords: Robot training; Hybrid Assistive Limb®; Cerebral palsy; Gait analysis

1. Introduction

Cerebral palsy (CP) is the most common lifelong physical disability. It originates during childhood and

* Corresponding author at: Department of Physical Therapy, Ibaraki Prefectural University of Health Sciences Hospital, 4733 Ami, Ibaraki 300-0331, Japan.
E-mail address: 45070069@ipu.ac.jp (M. Matsuda).

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presents as a disorder in movement and posture development (i.e., muscle weakness, abnormal motor control reflecting, coordination of movements and/or regulation of muscle tone), which limits activity [1]. Walking ability in children with CP develops in accordance with growth, but commonly plateaus at 7 years of age [2]. Even in children with CP who were ambulatory as children, 25% or more of young adults lose the ability to walk in early adulthood because of joint pain and walking inefficiency [3,4]. Therefore, even after the age at which walking ability plateaus, further rehabilitation, although no longer indispensable, can further improve such abilities.

At present, training using robots has been the focus of attention, including in rehabilitation for children. Robot-assisted gait training has been reported to improve the gait speed, walking endurance, and gross motor ability of children with CP [5]. There are several robotic devices that support walking, with their function generally being divided into one of two categories: an "end-effector type," such as the Gait Trainer (Reha-Stim, Berlin, Germany) [6] and LokoHelp (Woodway, Waukesha, USA) [7], and an "exoskeleton type," such as the ReWalk™ (ReWalk Robotics, Berlin, Germany) [8] and Lokomat® (Hocoma, Volketswil, Switzerland) [9–11].

Most reports of robot-assisted training in children with CP use the Lokomat® device [5,9–11]. However, this device is a passive robotic gait intervention tool, with the lower limb joint angle and gait speed set to constant values during treadmill walking. Conversely, Hybrid Assistive Limb (HAL®; CYBERDYNE, Tsukuba, Japan) that was used in this study is a novel robotic device that can assist voluntary walking in response to the wearer's intention.

The exoskeleton percutaneously detects minimal bioelectric signals (BES) that are initiated by the patient's voluntary muscle activities (hip and knee flexors and extensors) via electromyography electrodes and/or the floor reaction force signals caused by intended weight shifts by the patient [12]. HAL® has already been used as a medical device to improve brain-neuro-physical functions for patients in the European Union and for rare neuromuscular disease patients in Japan.

Robot-assisted training using HAL® has been reported to be effective only for adults with stroke or a spinal cord injury [13]. In studies of these types of patients, the Functional Ambulation Category, gait speed, and walking endurance all have been reported to improve following 12–20 repetitions of training [14–16].

However, there are only a few reports on the effect of HAL® in patients with CP that assess the efficacy of HAL® at an early developmental stage [17]. We previously examined the immediate effects of a single session of robot-assisted training using HAL® patients with CP. In doing so, we found no change in gait speed, step length, or cadence; however, we measured improvements in gait parameters, such as increased hip and knee joint angles during the stance and swing phases of walking and enhanced single-leg support per gait cycle [18]. We speculated that multiple repetitions of the intervention could increase motor learning and walking ability beyond the improvements observed following a single session of HAL®. Therefore, in this study, we sought to assess the effects of continuous robot-assisted training using HAL® over multiple repetitions patients with CP and to compare walking and gross motor abilities between pre-intervention and post-intervention.

2. Materials & methods

2.1. Subjects

Six patients with CP were enrolled in this study between January and October 2017. There were 4 males and 2 females with the following demographic information; mean age: 16.8 ± 3.5 years (range: 13–24 years); height: 151.3 ± 7.9 cm (range: 140–160 cm); body weight: 48.9 ± 2.0 kg (45–51 kg); Gross Motor Function Classification System (GMFCS) levels II, III and IV, n = 1, 4, and 1 respectively. With respect to paralysis type, five patients presented with spastic diplegia, and one patient presented with spastic quadriplegia, as described in Table 1. The inclusion and exclusion criteria were applied as those described in previous studies involving robot training [9–11,15,16]. Briefly, the inclusion criteria were (i) GMFCS levels I–IV, (ii) able to participate in other conventional rehabilitation exercises during hospitalization, and (iii) able to reliably signal pain, fear, and discomfort using verbal or nonverbal signals. The exclusion criteria were (i) difficulty wearing HAL® due to severe joint deformation or/and contracture, (ii) lack of patient's cooperation, (iii) inability to fit the size of HAL®, (iv) patients treated with botulinum toxin during the last 3 months, and (v) seizure disorder not fully controlled by medication. The study protocol was approved by the ethics committee of Ibaraki Prefectural University of Health Sciences (approval number: 682). All patients and their parents provided written informed consent.

2.2. HAL® training protocol

We utilized HAL® for medical use (lower limb type). The number of interventions was defined in previous studies on robot training for patients with CP [9–11]. Briefly, 20 min (excluding intermission) of gait training using HAL® were completed depending on the condition of the patient (e.g., fatigue, facial expression, and pulse). In total, 12 sessions were completed at 2–4 sessions per week over 4 weeks. The control mode at the