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Clinical Study

Voluntary driven exoskeleton as a new tool for rehabilitation in chronic spinal cord injury: a pilot study

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Abstract

BACKGROUND CONTEXT: Treadmill training after traumatic spinal cord injury (SCI) has become an established therapy to improve walking capabilities. The hybrid assistive limb (HAL) exoskeleton has been developed to support motor function and is tailored to the patients' voluntary drive.

PURPOSE: To determine whether locomotor training with the exoskeleton HAL is safe and can increase functional mobility in chronic paraplegic patients after SCI.

DESIGN: A single case experimental A-B (pre-post) design study by repeated assessments of the same patients. The subjects performed 90 days (five times per week) of HAL exoskeleton body weight supported treadmill training with variable gait speed and body weight support.

PATIENT SAMPLE: Eight patients with chronic SCI classified by the American Spinal Injury Association (ASIA) Impairment Scale (AIS) consisting of ASIA A (zones of partial preservation [ZPP] L3–S1), n=4; ASIA B (with motor ZPP L3–S1), n=1; and ASIA C/D, n=3, who received full rehabilitation in the acute and subacute phases of SCI.

OUTCOME MEASURES: Functional measures included treadmill-associated walking distance, speed, and time, with additional analysis of functional improvements using the 10-m walk test (10MWT), timed-up and go test (TUG test), 6-minute walk test (6MWT), and the walking index for SCI II (WISCI II) score. Secondary physiologic measures including the AIS with the lower extremity motor score (LEMS), the spinal spasticity (Ashworth scale), and the lower extremity circumferences.

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All authors read and approved the final manuscript.

YS is a founder, shareholder, and the CEO of Cyberdyne, Inc., which produces the HAL.

YS and Cyberdyne were neither involved in study funding, design, data collection, and analysis, nor in writing or submitting this article, therefore concluding in no specific influence on the trial. We certify that no party having a direct interest in the results of the research supporting this article has or will confer a benefit on us or on any organization with which we are associated.

YS and Cyberdyne as the manufacturer of the device provided exclusively technical and advisory support.

YS as the CEO of Cyberdyne has been involved exclusively in terms of an advisory capacity, regarding technical support and the limitations of the exoskeleton. Therefore, the inclusion and exclusion criteria have been modified (eg, body weight and contractures).

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METHODS: Subjects performed standardized functional testing before and after the 90 days of intervention.

RESULTS: Highly significant improvements of HAL-associated walking time, distance, and speed were noticed. Furthermore, significant improvements have been especially shown in the functional abilities without the exoskeleton for over-ground walking obtained in the 6MWT, TUG test, and the 10MWT, including an increase in the WISCI II score of three patients. Muscle strength (LEMS) increased in all patients accompanied by a gain of the lower limb circumferences. A conversion in the AIS was ascertained in one patient (ASIA B to ASIA C). One patient reported a decrease of spinal spasticity.

CONCLUSIONS: Hybrid assistive limb exoskeleton training results in improved over-ground walking and leads to the assumption of a beneficial effect on ambulatory mobility. However, evaluation in larger clinical trials is required.

Keywords: Exoskeleton; Treadmill training; Rehabilitation; Paraplegia; Hybrid assistive limb; Spinal cord injury

Introduction

About 1,200 people suffer a traumatic spinal cord injury (SCI) each year in Germany. Recent statistics indicate that more than 50% of these injured patients have a motor incomplete lesion [1]. In patients with initial motor incomplete SCI, at least 75% regain some kind of ambulatory function. Better functional outcome is associated with age, level of lesion, and the classification in the American Spinal Injury Association (ASIA) Impairment Scale [2]. In the first 2 months after initial SCI, approximately half of the recovery occurs. Within the following 4 months, a decreasing rate of recovery has been observed. One year after injury, neurologic recovery is assumed to be nearly complete [3]. Although conventional rehabilitation programs enhance the performance of functional tasks, the loss of strength and coordination substantially limit one's capacity for over-ground ambulation training [4]. In the past two decades, body weight supported treadmill training (BWSTT) has been proposed as a useful adjunct to enhance locomotor function after motor incomplete SCI [5]. In patients with incomplete or complete SCI, a bilateral leg muscle activation combined with coordinated stepping movements can be induced in partially unloaded patients, standing on a moving treadmill. Body weight supported treadmill training enables early initiation of gait training and integration of weight-bearing activities, stepping and balance, by the use of a task-specific approach and a systematic gait pattern [6]. To facilitate the delivery of BWSTT in SCI patients, the locomotor training evolved over the last 12 years and a motorized robotic driven gait orthosis (DGO) has been developed [7]. The advantages over conventional BWSTT methods are considered to be less effort for attending physiotherapists [8], longer duration, more physiologic and reproducible gait patterns, and the possibility to measure a patients' performance. Several studies pointed out that DGO training improves over-ground walking [9–13]. However, there was no reported difference in the outcome of DGO training compared with conventional training. A significant switch in the ASIA classification has not been found [10,14].

Over the last 5 years, exoskeletal systems became available for SCI patients. These systems offer different possibilities. Three exoskeletons (Ekso [EksoBionics, Richmond, CA, USA], Rex [Rex Bionics, Aukland, New Zealand] and Re-Walk [ARGO Medical Technolgies, Israel]) allow SCI patients to stand up, walk with a defined pattern, and even climbing stairs mainly on a basis of passive range of motion (ROM). The exoskeleton hybrid assistive limb (HAL; Cyberdyne, Inc., Japan) offers the possibility of getting connected with the SCI patient through electromyography electrodes on the skin at the extensor/flexor muscle region of the lower extremities. This allows voluntary machine supported ROM of incomplete SCI patients by using minimal bioelectrical signals, recorded and amplified from hip and knee flexors and extensors [15–17]. More recently, these various exoskeletal systems allow the patients mobilization outside the treadmill. A former study by Kawamoto et al. [18] concerning locomotion improvement using HAL in chronic stroke patients, emphasized the feasibility for rehabilitation of these particular patients.

The aim of this pilot study was to evaluate the possibilities of exoskeletal locomotor training (HAL; Cyberdyne, Inc.) under voluntary control and identify beneficial effects on functional mobility of the patients. The hypothesis was that exoskeleton treadmill training is feasible and safe in application and capable of improving ambulatory mobility in chronic SCI patients.

Materials and methods

Patients

We enrolled eight patients (two women, six men). The mean±standard deviation age at the time of enrollment was 48±9.43 years. All patients were in the chronic stage of traumatic SCI according to the time since injury of 1 to 19 years (97.2±88.4 months). Inclusion criteria were traumatic SCI with chronic incomplete (ASIA B/C/D) or complete paraplegia (ASIA A) after lesions of the conus medullaris/cauda equine with zones of partial preservation. Independent of ASIA classification, the enrolled patients