

## 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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Authors' contributions: MA and OC carried out the experiments and data analysis as well as drafting of the manuscript. RCM, PS and MT helped with the experimental set up. MS-K and OH contributed to the data analysis. TAS participated in study design and coordination of the study.

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. © 2014 Elsevier Inc. All rights reserved.

**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, Auckland, New Zealand] and Re-Walk [ARGO Medical Technologies, 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  $\pm$  standard deviation age at the time of enrollment was  $48 \pm 9.43$  years. All patients were in the chronic stage of traumatic SCI according to the time since injury of 1 to 19 years ( $97.2 \pm 88.4$  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

must present motor functions of hip and knee extensor and flexor muscle groups to be able to trigger the exoskeleton. Exclusion criteria were as follows: nontraumatic SCI, pressure sores, severe limitation of ROM regarding hip and knee joints, cognitive impairment, body weight more than 100 Kg, nonconsolidated fractures, and mild or severe heart insufficiency. Two patients suffered from an incomplete thoracic SCI (ASIA C/D) from 3 to 13 years. Two patients suffered from an incomplete lumbar SCI (ASIA B/C) from 12 to 13 months and four patients had a complete SCI with zones of partial preservation in L3–S1 after lesions of the conus medullaris. The classification according to the ASIA was carried out before the treadmill training was initiated. The study was approved by Ethical Board Committee of Bergmannsheil Hospital and the University of Bochum and followed strictly the declaration of Helsinki.

All patients provided written informed consent. The study design was a single case experimental A-B (pre-post) design by repeated assessments of the same patients (Table 1).

### Intervention

During this study, the patients underwent a BWSTT five times per week using the HAL exoskeleton (Cyberdyne, Inc., Japan). The study was performed between June 2013 and September 2013 in the BG University Hospital Bergmannsheil, Bochum.

Neither adverse nor severe adverse events occurred during the intervention.

### The exoskeleton

The HAL robot suit (Cyberdyne, Inc., Japan) is an exoskeleton with a frame and robotic actuators that attach to the patients' legs. The joint movement is supported by electric motors. Voluntary initiated minimal bioelectrical signals recovered from extensor and flexor muscles of hip and knee are detected via electromyography electrodes (Fig. 1).

Through a cable connection between the exoskeleton and patient, this system allows voluntary robotic supported ROM (cybernetic voluntary control mode). Also a passive, nonvoluntary ROM (cybernetic autonomous control mode) is possible (Fig. 2).

### The treadmill

The treadmill system (Woodway USA, Inc., Waukesha, WI, USA) includes a body weight support system with a harness. The speed can be adjusted from 0 Km/h to approximately 4.5 Km/h. During treatments, the velocity of the treadmill was set individually between comfortable and maximum speed tolerated by the patients. Approximately 50% of each patient's body weight needed to be supported by the harness system, individually reduced during the following sessions as tolerated without substantial knee buckling or toe drag.

## EVIDENCE & METHODS

### Context

The authors present a series of patients treated with an assistive exoskeleton developed to facilitate treadmill exercise in patients with spinal cord injury (SCI).

### Contribution

In a series of eight patients with SCI graded ASIA A to C/D, improvements in walking time, distance and speed were noted after treatment with assistive exoskeleton.

### Implications

This study is a case series of eight patients with heterogeneous clinical characteristics, including the severity of their spinal cord injury. The findings are limited to clinical contexts specific to these patients and clearly cannot be translated to the care of other individuals. This is simply a report that may show proof of concept. It should be noted that one of the authors reports a substantive conflict of interest (founder and shareholder of the company that produces the exoskeleton device).

—The Editors

### The training

The patients underwent a 90-day period of HAL exoskeleton (Cyberdyne, Inc.) training (five per week), including a mean number of sessions of  $51.75 \pm 5.6$ . The training was performed on a treadmill with individually adjustable body weight support and speed, recording walking speed, time, and distance. It included a 10-m walk test (10MWT) before and after each session and regular physiotherapy that lasted approximately 90 minutes. The training was supervised by a physiotherapist and a medical doctor.

### Measurements

#### Walking capabilities and neurologic status

All patients were assessed on admission by medical doctors involved in this trial. The outcomes were assessed

Table 1  
Subject demographics and clinical characteristics

Case	Sex	Time		Etiology	Level	ASIA/ZPP	WISCI	
		Age	since trauma, y				II	Ashworth
1	M	40	13	# T7/T8	T8	C	13	4
2	M	63	1	# T12	L1	B/L3	6	0
3	M	36	1.16	# T11/T12	T12	A/L3	6	0
4	F	55	1.08	# L1	L1	C	13	0
5	M	42	16	# L1	L1	A/L3	9	0
6	M	52	10	# L3	L2	A/L3	6	0
7	F	40	19	# L1	T11	A/S1	9	0
8	M	53	3	# T12	T12	D	18	0

M, male; F, female; #, fracture; ASIA, American Spinal Injury Association; ZPP, zones of partial preservation; WISCI, walking index for spinal cord injury; T, thoracic; L, lumbar; S, sacral.





Fig. 1. Positioning of the electromyography electrodes on the knee extensor and flexor muscles.

by physiotherapists neither involved in the study design nor analysis after 45 days and on discharge from the training period. An assessment through the ASIA classification

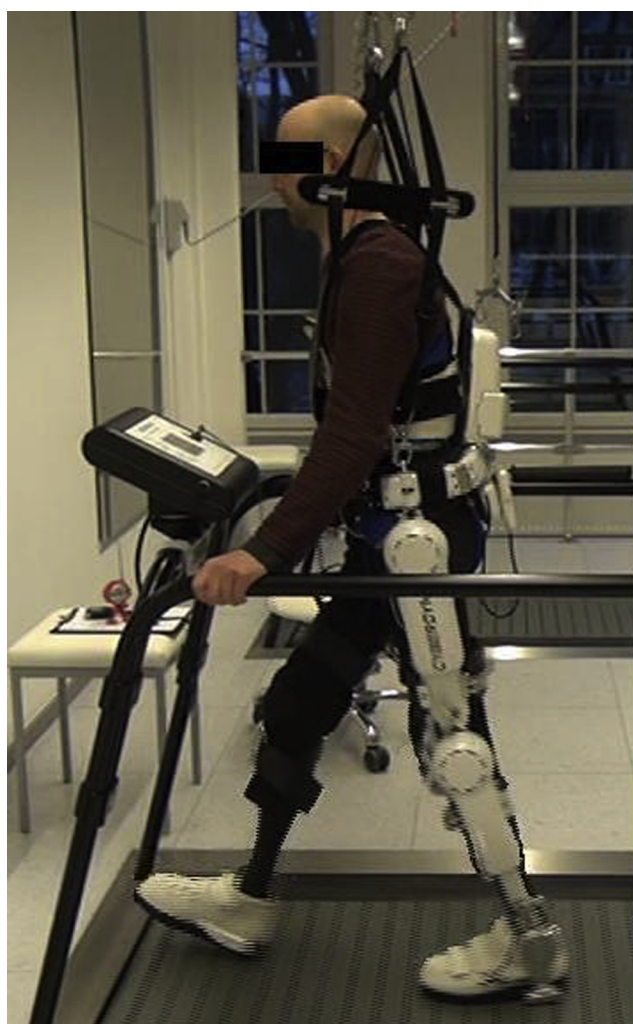


Fig. 2. Patient performing treadmill locomotion training with body weight support and hybrid assistive limb exoskeleton.

was already done on admission and on discharge from the SCI department, Bergmannsheil, Bochum, within the initial therapy after acute SCI. The 10MWT, done before and after each session, detected the needed time, the number of steps, and the required assistance to walk a 10 m distance [19,20]. The timed-up and go test (TUG test) describes the time and assistance required for standing up from the wheelchair, walk 3 m, turn around, walk back, and sit down. It was performed every 2 weeks. The 6-minute walk test (6MWT) was done at the beginning, at half time, and at the end if possible, depending on the patient. It evaluates the distance and assistance while walking for 6 minutes [21]. The main outcome was the functional motor assessment by the walking index for SCI II (WISCI II) [22,23]. The WISCI II score is a 20-item scale, measuring the walking capabilities of a patient based on the requirements of assistance because of walking aids, personal assistance, or braces. Grade 0 means that the patient has neither standing nor walking abilities. Grade 20 means that no assistance is needed to walk a distance of 10 m. The neurologic status was assessed using the ASIA Impairment Scale modified from the Frankel classification and classifies motor and sensory impairments that result from a SCI [3]. The lower extremity motor score (LEMS) acquired in this study was obtained by the addition of the impairment scores (0–5) of the lower extremity key muscles of both sides. Muscle volume was assessed by manual measurements, 20/10 cm above and 15 cm below inner knee gap.

### Statistical analysis

Descriptive analysis of the demographic and injury characteristics was done using frequency distribution for categorical data and mean for continuous variables. Differences between pre- and posttraining sessions were assessed by a paired *t* test (for continuous variables). Treatment effects on functional performance as the WISCI II are all ordinal scales. Medians were used as descriptive statistics for these outcomes, and nonparametric tests were used to assess the relative effect of the treatments.

Results were considered statistically significant when the *p* value was  $\leq .05$ .

## Results

### Treadmill associated results

All patients improved in treadmill training by using HAL (Cyberdyne, Inc., Japan). The mean walking speed increased from  $0.91 \pm 0.41$  m/s (0.5–1.8 m/s) in the first session up to  $1.59 \pm 0.5$  m/s (0.8–2.1 m/s) in the last session after 3 months. The progress in speed after 6 weeks of training was lower than in the first weeks. The range was located between 0 km/h and 0.8 km/h. The mean walking time at the beginning was  $12.37 \pm 4.55$  minutes. The average walking time at the

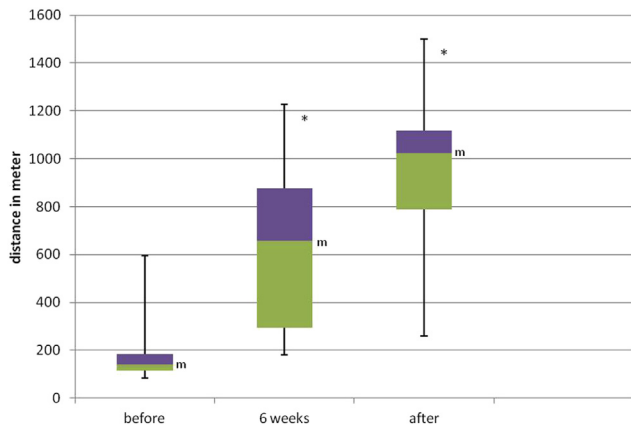


Fig. 3. Changes in treadmill-associated walking distance in pre-, mid-, and postevaluations. m, median. \*pre-post difference,  $p < .05$ .

end was  $31.97 \pm 9.45$  minutes. The mean ambulated distance at the first session was  $195.9 \pm 166.7$  m and increased to  $954.13 \pm 380.4$  m on discharge (Fig. 3).

#### Functional outcome

Although the mean improvement concerning the WISCI II score was not statistically significant, three patients showed functional improvement in gait abilities. Two subjects needed braces, a walker, and support by a physiotherapist at the beginning and were able to walk after the training series only with a walker and braces (WISCI II score increased from 6 to 9). One patient increased from 9 to 12 and, therefore, was able to walk with two crutches and a brace compared with a walker and a brace before the training. At baseline, the mean WISCI II score was  $10 \pm 4.3$ . At the end of the 90 days trial, the mean WISCI II was  $11.13 \pm 6.68$ . Improvements in speed and endurance in over-ground gait assessments in all participants have been achieved. The 10MWT showed a significant increase in mean gait speed at the end of the training period compared with baseline ( $0.28 \pm 0.28$  m/s vs.  $0.50 \pm 0.34$  m/s) (Fig. 4).

The improvement corresponded to a 44% faster walking than in initial evaluation. It also includes the reduction of

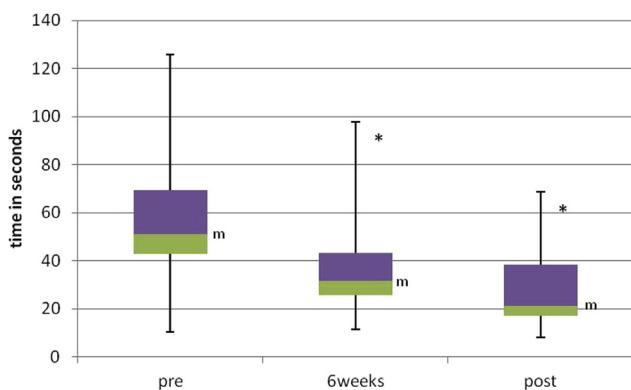


Fig. 4. Changes in 10-m walk test in pre-, mid-, and postintervention evaluations. m, median. \*pre-post difference,  $p < .05$ .

Table 2

Comparison of pre- and postinterventions

Outcome measurements	Before training	After training	n
10MWT speed (m/s)	$0.28 \pm 0.28$	$0.5 \pm 0.34^*$	8
Number of steps	$29.88 \pm 7.85$	$19.38 \pm 3.16^*$	8
6MWT distance (m)	$70.1 \pm 130$	$163.3 \pm 160.6^*$	8
TUG test (s)	$55.34 \pm 32.20$	$38.18 \pm 25.98^*$	8
Distance (m)	$195.88 \pm 166.71$	$954.13 \pm 380.35^*$	8
WISCI-II	$10 \pm 4.34$	$11.12 \pm 3.68$	8

10MWT, 10-m walk test; 6MWT, 6-minute walk test; TUG, timed-up and go; WISCI, walking index for spinal cord injury.

Note: Values are means  $\pm$  standard deviation.

\* Pre-post difference,  $p < .05$ .

support needed detected by the WISCI II score. The mean number of steps decreased from  $29.8 \pm 7.85$  to  $19.4 \pm 3.16$ . We observed significant increase in gait speed from pre- to midtraining and from mid- to posttraining assessments. Similar results were detected for the TUG test. The mean time needed for the TUG test decreased from  $55.34 \pm 32.2$  seconds to  $38.18 \pm 25.98$  seconds. The 6MWT was done with a constant walking time of 6 minutes without any break. Only three patients were able to perform the 6MWT before the training with a mean walking distance of  $187 \pm 162.2$  m. The subjects in this subgroup improved their performance and increased the walking distance to  $287.3 \pm 229.4$  m. After completing the training, all eight patients could be evaluated, therefore the overall mean distance increased from  $70.1 \pm 130$  m to  $163.3 \pm 160.6$  m (Table 2).

The LEMS increased in all patients. The mean LEMS before the training increased significantly from  $21.75 \pm 8.3$  to  $24.38 \pm 7.6$  after the intervention (Fig. 5).

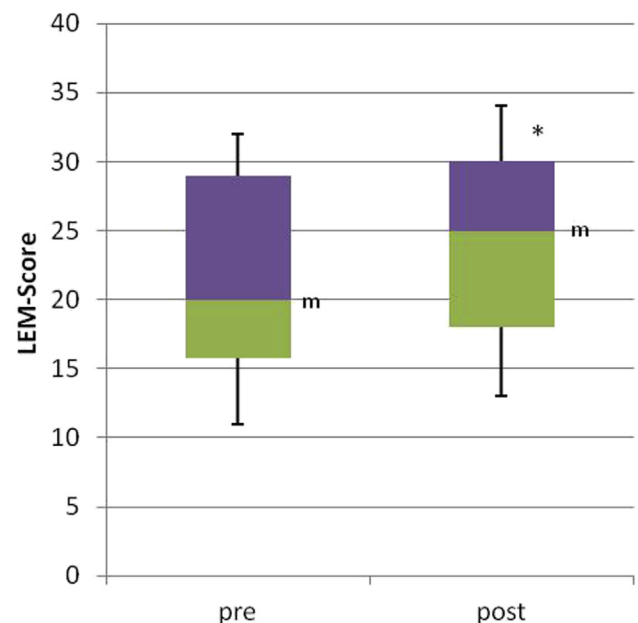


Fig. 5. LEMS in pre- and postevaluation. LEM, lower extremity motor score; m, median. \*pre-post difference,  $p < .05$ .

One patient switched in the ASIA scale from ASIA B to C, he was at the beginning of the training 12 months posttrauma.

### Others

To describe muscle volume, measurements of the circumferences 10/20 cm cranial of the inner knee joint gap and 15 cm distal of it have been done before and after the 90 days of training. Seven participants showed a gain of muscle circumference from 5 mm up to 50 mm. In one participant with edema in his lower legs, we observed a loss of circumference up to 25 mm. One patient suffering from a thoracic SCI presented a significant spinal spasticity. For spastic motor behaviors, we used the modified Ashworth scale to evaluate the involuntary resistance to passive stretch of the quadriceps muscle group. At pretraining evaluation, he showed an extensor spasm with high resistance to passive stretch according to Ashworth 4. After the training sessions, the resistance was reduced according to Ashworth 2. This level lasted for about 6 to 8 hours with a new maximum level at the next morning. All other patients showed no spastic motor behaviors.

### Discussion

The objective of the study was to determine whether locomotor training with the exoskeleton HAL is feasible and safe in application, improves functional mobility, and increases motor functions in chronic paraplegic patients after SCI. The results obtained revealed a highly significant improvement for over-ground walking abilities evaluated by the 10MWT, the 6MWT, and the TUG test and the partial reduction of physical assistance and walking aids in the WISCI II score. Muscle strength, measured with the LEMS increased in all patients.

The results acquired in this clinical trial imply that HAL-supported locomotion training can improve walking abilities in terms of speed, gait, and distance. Furthermore, it improves motor functions.

Thus far there is insufficient evidence and only a few articles addressing the main hypothesis of this study that locomotor training improves walking function for patients with SCI [24].

The present study is according to the knowledge of the authors the first to investigate the impact of HAL-supported locomotor training in chronic SCI patients, where referring to the current state of knowledge no further functional improvements are to be expected.

In the subject population consisting of eight patients including patients suffering from SCI from 1 to 19 years ( $8.03 \pm 7.4$  years), all patients improved significantly regarding treadmill-associated walking distance and speed and functional improvement was detected in the over-ground walking tests.

Although no significant influence was seen on the requirements of assistance in the 10MWT, three patients attained improvement in walking abilities according to the

WISCI II, under condition of a comfortable and stable gait. A further reduction of assistance was not forced because of more pathologic gait or higher risk of falling [24].

Although the evidence is still insufficient, the effectiveness of automated locomotor training using the DGO in patients with chronic SCI is being investigated and considered promising in several systematic reviews including a Cochrane review [25,26]. The results mentioned previously add to the wealth of that data presuming that HAL-assisted locomotion training is useful in terms of functional mobility and a safe adjunct to the treatment of patient with chronic SCI.

Our study had several limitations: the relatively small number of patients ( $n=8$ ) and the mixture of complete and incomplete SCIs.

However, all the patients were treated in the same facility by the same multidisciplinary team, according to a standardized protocol.

In summary, our study provides the first data demonstrating the clinical potential of HAL-locomotor training based on voluntary drive in patients suffering from chronic SCI.

It was proven to be a safe device for locomotion therapy as neither adverse nor severe adverse events occurred.

However, continued research in the form of large randomized trials to compare the efficacy of HAL-assisted training with well established, conventional therapies is necessary.

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