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The AIDER system and its clinical applications

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Spinal cord injury (SCI) significantly affects thousands of individuals every year. SCI is due to various pathogenic factors such as trauma, inflammation, and tumors. SCI caused spinal neurological dysfunction below the injury plane, e.g., it affects motor, sensory nerve, sphincter, and vegetative nerve function. A robotic exoskeleton system is an emerging rehabilitation therapy for SCI worldwide. For patients with SCI, correction of gait and improvement of the function of the lower limbs during walking are particularly important.

Hybrid assistive limb (HAL) was developed by Sankai and his team. It is mainly controlled by surface-electromyography (sEMG) signals which are gained by the sensors attached to the surface of muscles. HAL provided assistance to pilots to facilitate easier walking [1, 2]. Lokomat is the first-ever gait-training robot constructed for patients with SCI worldwide and is mainly composed of fixed hips, lower-limbs orthotic exoskeleton, body-weight support system, and treadmill. Some researchers [3–6] have performed clinical experiments to verify the effect of the use of Lokomat on gait rehabilitation. Patients with chronic complete/incomplete SCI have undergone gait rehabilitation training with Lokomat robots, and the results have shown a significant improvement in walking speed, walking distance, Timed Up and Go test results, and Walking Index for Spinal Cord Injury II (WISCI II) score. This study verified the safety and effectiveness of the assistive device for paralyzed patient (AIDER) system, which can improve the walking ability and spinal cord independence of patients with SCI. All aspects of this study were certified by the Ethics Committee of Sichuan University West China Hospital.

The AIDER system. The AIDER system is a robotic exoskeleton designed to assist pilots with SCI in standing, walking, and climbing stairs/slope. The structure of AIDER is shown as Figure 1(d). AIDER is a physically tightly coupled human-robot system comprising pilots, wearable mechanical parts, sensors, motors, and computing devices. Through the implementation of various techniques such as human engineering, computing, control, and mechanics, this collaboration between a pilot and AIDER can provide real-time perception, motor control, human-robot fusion, and information exchange [7]. The goal of AIDER is to implement this human-robot collaboration to improve stability and balance in pilots. Moreover, this collaboration involves biomechanics, motor coordination, and sensory organization. Further, pilots are able to set the gait speed, length, and mode as needed [8]. Crutches were designed not only to maintain balance while standing and during ambulation but also to control sitting, standing, walking, and stopping [9].

Methods. In total, 10 subjects were selected for this study according to the inclusion and exclusion criteria (Figure 1(a) and (b)). All subjects provided written informed consent. The international standards for neurological classification of spinal cord injury were used to measure the neurological injury level, and classification of injuries was done according to the American spinal injury association impairment scale. The subjects were required to wear AIDER for gait training as shown in Figure 1(e). The safety and effectiveness of walking ability and spinal cord independence were assessed during three visits.

Prior to the study, all of the participants including the staff, therapists and subjects must attend a 1-week curriculum to familiarize them with the basic operation of AIDER and to make additional announcements during the study period. After the week, they had to take an examination, which assessed their mastery of wearing, resizing, and operating AIDER and dealing with potential emergencies. The study was not initiated until all parties passed the examination.

The clinical trials included three visits during which an external therapist who did not take part in any training assessed the walking abilities and spinal cord independence of the subjects. The first visit was conducted during the first day of training, the second visit after one-week training (7 ± 2 days), and the third visit after 2-week training (14 ± 2 days). The 6-minute walking test (6MWT) was considered the main measurement method in this study. The secondary measurement methods included 10-meter walking test (10MWT), Hoffer scale, WISCI II, and spinal cord independence measure (SCIM). The safety index included recording of adverse events (AEs) and serious AEs (SAEs).

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(a)

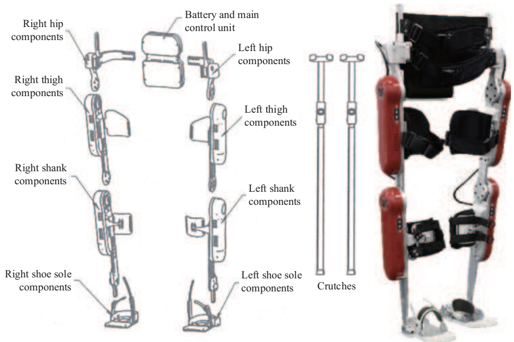
Age	15–75 years old
Injury	Spinal cord injury (SCI) plane T6-L1
ASIA classification	A or B
Standing and walking ability	Need assistance of other device or standing frame to stand, but cannot walking independently
	Sign informed consent contracts

(b)

Modified Ashworth of both lower limbs	≥2
Blood pressure	Systolic pressure>140 mmHg or diastolic pressure >90 mmHg after drug control.
	Uncontrollable postural hypotension.
Joint	Contracture and deformity of the joints and tendons, such as arthrophlogosis, arthroplasty.
	Severe bone malformation and ligament rupture.
	Unstable limb fracture.
Motor function	Complications or complications which will limit motor function.
	Mental disease, hearing disorder, disturbance of comprehension.
	Major organ failure or other serious diseases.
	Pregnant women, lactating women and women who planning pregnancy.
	Loss of spine stability.
Range of SpO_2	Static SpO_2<90%, and SpO_2 in motion <88%.
Venous problems of lower extremity	Deep vein thrombosis of both lower limbs.
Routines of blood, urine and stool	Routines of blood, urine and stool are abnormal, which are estimated unsuitable for this study.
Other situations	Other situations that are estimated unsuitable for this study.

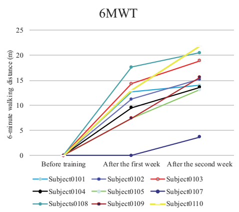
(c)

Subject number	Gender	Age	Height (cm)	Weight (kg)	ASIA level	Injury plane	Injury months
0101	M	41	160	50.2	A	T9	4
0102	M	31	170	55.5	A	T6	10
0103	M	56	170	68.6	A	T11	4
0104	M	28	160	50.7	A	L1	4
0105	F	30	160	50.1	A	T8	84
0107	M	65	160	55.4	A	L1	24
0108	F	21	161	49.3	A	T12	48
0109	M	52	170	60.8	A	T9	120
0110	F	47	160	65.2	A	T10	180

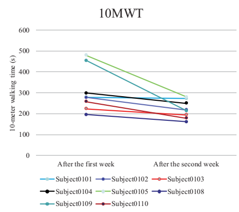


(d)

(e)



(f)



(g)

Results	Subjects number	0101	0102	0103	0104	0105	0107	0108	0109	0110
SCIM	First visit	54	50	47	48	69	54	74	45	67
	Second visit	61	53	49	56	72	60	76	47	69
	Third visit	64	56	52	62	74	60	77	50	71
Hoffer	First visit	I	I	I	I	I	I	II	I	I
	Second visit	II	II	II	II	II	I	II	II	II
	Third visit	III	II	III	III	III	II	III	III	III
WISCI II	First visit	0	3	0	0	0	0	9	0	0
	Second visit	9	8	9	9	9	3	9	9	9
	Third visit	12	12	12	13	12	6	12	12	12

(h)

Figure 1 (Color online) The information of the clinical trials and the results. (a) Inclusion criteria; (b) exclusion criteria; (c) the subjects' information; (d) the AIDER system and its structure; (e) training; (f) the results of 6MWT; (g) the results of 10MWT; (h) other results.

The whole training lasted 2 weeks. Every subject participated in a 30-min session/day with 5 sessions held every week. One therapist and four staff members were necessary for training. The therapist was responsible for checking the subjects' temperature, blood pressure, oxyhemoglobin saturation, pulse rate, and heart rate before and after training on each training day. The staff members had to ensure the subjects' safety and record training data, device problems, AEs, and SAEs. The subjects could opt for any 2 days during a week as rest days. In a training session, the subjects could take a rest if they felt tired during training. However, we attempted to adhere to an effective training time of 30 min/day. One session included the following tasks: sitting-to-standing, standing-to-sitting, balance keeping, weight shifting, and walking. If any clinical indicator remained abnormal after repeated measurement, the subject was considered ineligible for participation in the training session that day. If a subject was absent for 3 consecutive days, the subject was removed from the study. After a session, the therapist had to check for any skin abrasions. Skin abrasions, tumbles, and seriously abnormal vital signs were considered SAEs in this study, and the affected subjects were removed from the study to receive treatment.

Results. Because this study was a self-controlled clinical study, the subjects were required to abstain from wearing AIDER or other orthotics/devices during the first visit. Figure 1 shows that the walking ability and spinal cord independence of the subjects were improved after the 2-week training, which significantly improved their quality of life and contributed to better performance of daily activities.

At the first visit, all patients scored 0 on 6MWT (Figure 1(f)) and 10MWT (Figure 1(g)). The results of 6MWT showed an increasing walking distance over the three visits. Because we expected the scores of 10MWT to decrease, the first visit was not drawn in this figure. Compared with at the second visit, all subjects used less time to complete 10MWT at the third visit. Taken together, these results suggest that walking speed increased after the training with AIDER. Previous studies have shown that improvements in the 6MWT and 10MWT scores are related to increased walking distance and speed. In Figure 1(h), the SCIM score reflects spinal cord independence, with a higher score indicating better spinal cord independence. Accordingly, the results indicate better spinal cord independence after training. Further, the Hoffer classification of most subjects increased to III (community ambulation) after training, suggesting that they could walk with AIDER in daily living environments. The WISCI II score of most subjects could reach level 12 after training, indicating that these patients could walk with AIDER for > 10 m without any other help. The improvement in these indexes indicates that AIDER can provide the better walking ability and spinal cord independence to subjects with SCI.

Subject No. 0106 was excluded from Figure 1(c) because he dropped out before training for personal reasons, and subject No. 0107 was sick with a cold after the third day of training (considered as an AE). Overall, there was no SAE or equipment malfunction observed in this study. While AEs cannot be avoided in any clinical study, our results show that AIDER is safe for gait training and walking assistance.

In conclusion, we were able to identify the safety and effectiveness of AIDER for gait rehabilitation. In the future, we expect AIDER to be used for both gait rehabilitation and routine activities.

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Supporting information Videos and other supplemental documents. The supporting information is available online at info.scichina.com and link.springer.com. The supporting materials are published as submitted, without typesetting or editing. The responsibility for scientific accuracy and content remains entirely with the authors.

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