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ARTICLE

The safety and feasibility of a new rehabilitation robotic exoskeleton for assisting individuals with lower extremity motor complete lesions following spinal cord injury (SCI): an observational study

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Abstract

Study design A pre-post observational study.

Objectives To evaluate the safety and feasibility of a new rehabilitation robotic device for assisting individuals with lower extremity motor complete lesions following spinal cord injury (SCI).

Setting Three hospitals in Sichuan Province, China.

Methods Individuals aged 15–75 years with an SCI between vertebrae six (T6) and lumbar 1 (L1) and complete motor paralysis participated in an exoskeletal-assisted walking (EAW) programme (2 weeks, 5 days/week, 30 min/day). Data were collected pre-, mid- (week 1) and post-intervention (week 2).

Results Twenty-eight individuals (mean age = 41.3, 71% males) participated in the EAW programme. The distance walked during the 6-min walking test (6MWT) increased relative to that at baseline, during week 1 (13.0 ± 5.3 m) and week 2 (16.2 ± 5.3 m) when wearing the exoskeleton. The walking speed during the 10-m walking test (10MWT) increased from 0.039 ± 0.016 to 0.045 ± 0.016 m/s. The Hoffer walking ability grade, the Spinal Cord Independence Measure (SCIM), and the Walking Index for SCI II (WISCI II) changed after 2 weeks of EAW. No improvement in lower extremity motor score (LEMS) was observed. The rates of adverse events and serious adverse events were 21% and 4%, respectively.

Conclusions The EAW programme with the new robotic exoskeleton provided potential meaningful improvements in mobility for individuals with SCI and had few adverse events.

Introduction

The incidence of acute traumatic SCI has increased from 1993 to 2012 in the US, especially for elderly persons [1]. In China, the incidence of SCI ranged from 23.7 per million to 60 per million between 2004 and 2008 [2]. Individuals with incomplete SCI spend €1.47 million on the condition throughout their lives, while spending for individuals with complete SCI is two times higher than it is for individuals with incomplete SCI [3]. Robotic exoskeletons may provide an alternative way to improve mobility, help associated caregivers, and reduce economic burden [4].

Previously, the main options for assisting walking were orthoses and electrical stimulation [5, 6], but neither has proven to be widely utilised. In addition, individuals with SCI have an increased risk of medical complications, such as pressure ulcers, pulmonary infections and urinary tract infections [7]. In recent years, robotic exoskeletons have become available and improved the quality of life of people

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with complete lower extremity paralysis after SCI by enabling them to walk [8]. Since 2014, powered exoskeletons, such as the ReWalk (ReWalk Robotics Ltd, Israel), Indego (Parker, USA), Ekso (EksoLabs, USA), REX (Rex Bionics, Australia) and Hybrid Assistive Limb (Cyberdyne, Japan), have been used to assist with mobility in individuals with SCI [9]. Powered exoskeletons recently emerged as new tools for robot-assisted gait training [10, 11].

However, powered robotic products are expensive, which increases the economic burden on society as a whole. In this situation, it seems difficult to popularise powered robotic walking training widely. To provide a more economical alternative to these expensive products, this study focused on a new and cheaper device for individuals with SCI. Moreover, few studies have examined the potential usefulness of exoskeleton robots in walking training programmes; as a result, the clinical evidence-based support for rehabilitation robotic exoskeletons is still not sufficient. No study has presented this robotic exoskeleton previously. To fill the gap existing in the literature, we recruited individuals with SCI and then described the safety indicators and their walking parameters during an exoskeletal-assisted walking (EAW) programme with the new robotic exoskeleton. The purpose of this study was to provide initial evidence for the effects of using a new robotic exoskeleton as a training mobility device in people with lower extremity paralysis and to ensure the safety of the device.

Methods

Participants

A total of 158 individuals who had been treated in three tertiary referral hospital rehabilitation units in China in the past 4 years were screened. These units operated under similar clinical standards and policies. Recruitment of eligible participants was performed by verbal communication at in- and outpatient facilities. Participants were included if they were between 15 and 75 years old, had a traumatic or non-traumatic SCI, had a T6-L1 level of injury, and met international standards for the neurological classification of an SCI [12]—A or B. Other inclusion criteria included understanding the purpose of the study, sufficiently adhering to the study protocol, and giving informed consent according to the 1964 Declaration of Helsinki. Exclusion criteria included muscle tone of any lower limb muscle greater than a 1^+ grade according to the modified Ashworth scale, uncontrollable orthostatic hypotension, untreated or active extremity fractures, active deep venous thrombosis of an extremity, and medical instability. Data collection was completed from April 2018 to July 2018.

Protocol and process

The training protocol consisted of gait training for 30 min/session, one session/day, 5 days/week for 2 weeks, and the training protocol was considered completed if more than half of the sessions were attended. Each session consisted of sitting, standing, transitioning between the two, and walking with a brief rest period. The apparatus was a new powered lower limb robotic exoskeleton (AIDER, Buffalo Robot Technology Co. Ltd, China), which consisted of the device body, a crutch, matched power adaptors and a binding device. The crutches were used as assistive devices. The main body was composed of a battery and the main controller component, a hip-joint component, a thigh component, a lower-leg component and a sole component (as shown in Fig. 1). The length of the exoskeletal thigh and calf were adjusted according to the individual. Control in the walking mode was set at maximum assistance. Participants performed the walking programme with the robotic exoskeleton along with the usual basic rehabilitation therapies. The assessors did not participate in the daily training and did not know the treatment protocol for anyone.

Outcome measures

Safety indicators referred to the incidences of adverse events (AEs), serious adverse events (SAEs) and device defects. These were recorded as they related to pain, falling, dizziness and skin bruising.

Walking parameters were assessed three times: first, pre-intervention with the usual orthosis if they had one (recorded as baseline), at the mid-term of the training with the robotic exoskeleton and crutches (week 1), and at the end of the training with those (week 2). The parameters assessed included the 6-min walk test (6MWT) [13], the 10-m walk test (10MWT) [14], the Hoffer walking ability grade, the ASIA lower extremity motor score (LEMS) [15], the Spinal Cord Independence Measure (SCIM) [16] and the Walking Index for Spinal Cord Injury II (WISCI II) [17]. The 6MWT is a widely used research and clinical tool for assessing changes in endurance and walking ability [18]. If the participant could not walk without any help, the 6MWT was recorded as 0, and the 10MWT was need assessed. The LEMS can demonstrate the motor function of the lower extremity, while other tests can be used to assess the motor ability of the lower extremity. Muscle tone of the lower extremity muscle was assessed with the modified Ashworth scale

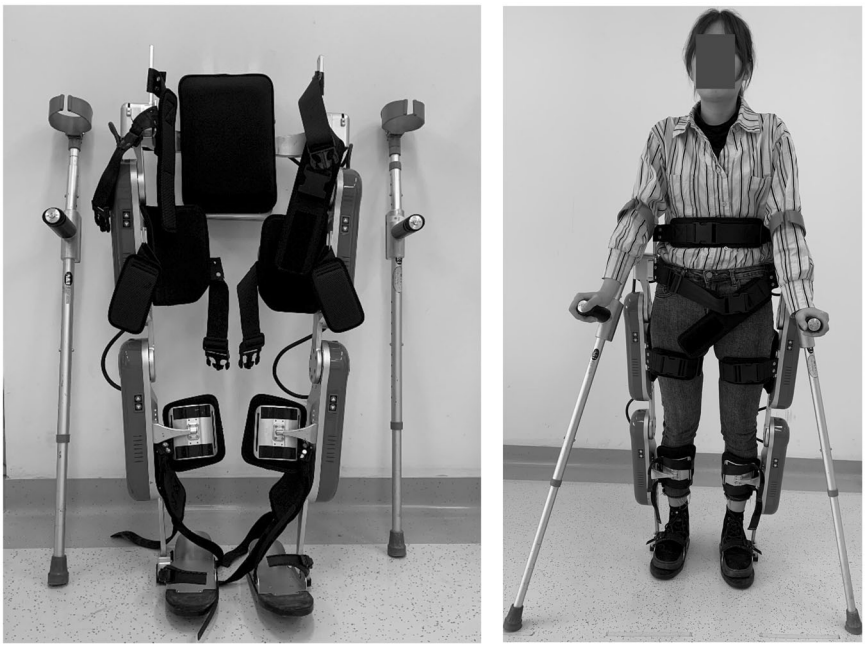

Fig. 1 The AIDER.

[19] at the pre-intervention and at the end of the training process.

Statistical analyses

Descriptive statistics were used. Data are presented as the mean ± standard deviation (SD) or median ± interquartile range (IQR) unless otherwise stated. Furthermore, we mentioned the 95% confidence interval (CI) in brackets. The last observation completed was used. The safety indicators were described by words and rates.

Results

Completion and feasibility

A total of 28 participants were included in this study: 8 women and 20 men (41.3 ± 11.8 years); 22 had an AIS-A lesion, and 6 had an AIS-B lesion; the LEMS was at or lower than 10. Overall 68% (9/28) of the participants had complete lower extremity motor paralysis. In addition, the duration of injury was between 3 months and 19 years (median time was 4 years). The height of the participants was 165.3 ± 7.6 cm, and their weight was 60.7 ± 9.7 kg. Further characteristics are shown in Table 1. Of the participants, 61% (17/28) had an SCI above T11, and 38% (11/28) had an SCI at T11 or lower. More details regarding individual characteristics are provided in Supplementary Appendix 1 for individual characteristics. Ninety three percent (26/28) of the participants completed all ten sessions, and 7% (2/28) of the participants completed six or seven sessions and then dropped out between the week 1 and week 2 assessments. Data from the week 1 assessment were imputed for any missing data at week 2. The reasons for dropping out were a fall during a transfer in the ward and poor health (flow diagram in Fig. 2).

Walking parameters

The results of the 6MWT, 10MWT, walking speed, LEMS and SCIM at baseline, week 1 and week 2 are described in Table 2. During the 6MWT (Fig. 3a), participants covered more distance consistently in week 2 compared (16.2 ± 5.3 m) with baseline (0 m) with a mean (95% CI) change of 16.2 (14.5–17.9). During the 10MWT, the walking speeds at week 1 and week 2 were 0.039 ± 0.016 m/s and 0.045 ± 0.016 m/s in the exoskeleton, respectively (Fig. 3b) with a mean (95% CI) change of 0.006 (0.003–0.009). Individuals with higher injuries (T6–T11) demonstrated greater improvements in gait speed than those with lower injuries (0.048 ± 0.016 versus 0.040 ± 0.016 m/s) as well as an improved distance covered during the 6MWT (16.7 ± 6.0 versus 14.6 ± 5.1 m). Individuals with complete injuries (AIS-A) demonstrated greater improvements in gait speed than those with AIS-B injuries (0.049 ± 0.018 versus 0.040 ± 0.011 m/s) as well as an improved distance covered during the 6MWT (16.3 ± 6.1 versus 14.2 ± 3.1 m). The outcomes for the SCIM when in the exoskeleton at baseline, week 1, and week 2 were 61.1 ± 11.1, 62.5 ± 10.5 and 63.4 ± 10.2, respectively with a mean (95% CI) change from baseline to

Table 1 General characteristics.

	Value
Age (years)	
N	28
Mean ± SD	41.3 ± 11.8
Sex	
Male (%)	20 (71)
Female (%)	8 (29)
Height (cm)	
N (Missing)	19 (9)
Mean ± SD	165.3 ± 7.6
Weight (kg)	
N (Missing)	19(9)
Mean ± SD	60.7 ± 9.7
Duration of injury (DOI, years)	
N	28
Median ± IQR	4.0 ± 10.4
International Standards for Neurological Classification of SCI	
n of AIS-A (%)	22 (79)
n of AIS-B (%)	6 (21)
Level of injury	
n of beyond T11 (%)	17/28 (61)
n of at T11 or lower (%)	11/28 (39)
Muscle tone (assessed by the Modified Ashworth Scale)	
0 (%)	22 (79)
1 (%)	5 (18)
1^+ (%)	1 (4)

IQR interquartile range, *SD* standard deviations.

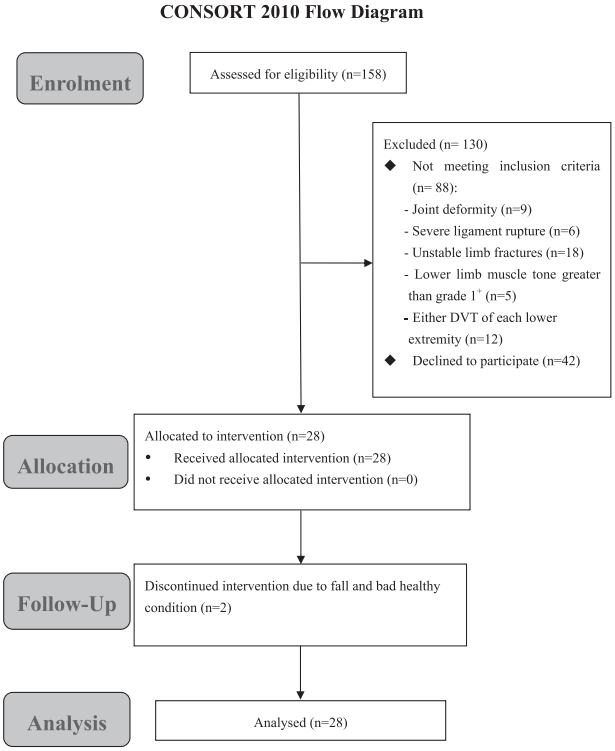

Fig. 2 Between 2015 and July 2018, a total of 158 individuals with SCI (AIS-A/B) were screened, of which 28 were eligible for the study. Two dropped out during the follow-up of the study: one individual quit the study voluntarily because of fall during transfer in ward, another due to poor health. A total of 26 individuals completed all sessions.

week 2 of 3.0 (2.0–4.1). Moreover, there was no change in the LEMS after the programme.

The distribution of the WISCI II scores and the Hoffer walking ability grades are reflected in Fig. 3c, d. For the WISCI II, 93% (26/28) of the participants were Grade 0, and the remaining 2 were Grade 3. At the mid-term, 0.04% (1/28) were Grade 3, 42% (11/28) were Grade 8, and 57% (16/28) were Grade 9 in the exoskeleton. Then, the distribution changed as follows: 0.04% (1/28) was Grade 6, 36% (10/28) were Grade 8, 32% (9/28) were Grade 9, 25% (7/28) were Grade 12, and 0.04% (1/28) was Grade 13 in the exoskeleton. The distribution of Hoffer walking ability grades changed. Only one participant was Grade II (walk with the assistance of the exoskeleton in the therapy room, needing the body to be touched or not), and the others were Grade I (cannot walk) in the beginning. After this programme, 7 participants walked with the assistance of the exoskeleton at home (Grade III), and 21 participants were Grade II. More details are provided in Supplementary Appendix 2 for outcomes.

Safety indicators

In total, 21% of participants experienced an AE (6/28) and 4% experienced an SAE (1/28). A total of 7% (2/28) had a urinary tract infection, 7% had a upper respiratory tract infection (2/28), 4% had conjunctivitis (1/28), 4% fell (1/28), 4% had a femoral fracture (1/28), 4% had an event related to skin integrity (1/28), 4% had a foot fracture (1/28) and 4% had diabetes (1/28). The details are as follows:

Infection

Two participants experienced upper respiratory tract infections and continued with the study. One participant had a urinary tract infection, and the other experienced an exacerbation.

Falls and fractures

One participant fell during a transfer in the ward and suffered a femoral fracture and foot fracture; the participant was then transferred to orthopaedics for an operation.

Table 2 Walking parameters, LEMS and SCIM at baseline, with exoskeleton at week 1 and week 2.

Assessment	6MWT (m)	10MWT (min)	Speed (m/s)	LEMS (M ± IQR)	SCIM
Baseline	0	/[a]	0	0 ± 2.0	61.1 ± 11.1
Week 1	13.0 ± 5.3	4.5 ± 1.6	0.039 ± 0.016	0 ± 2.0	62.5 ± 10.5
Week 2	16.2 ± 5.3	4.1 ± 1.8	0.045 ± 0.016	0±2.0	63.4 ± 10.2

M ± IQR, median ± interquartile range.

6MWT 6-min walking test, *10MWT* 10-m walk test, *LEMS* the ASIA lower extremity motor score, *SCIM* the spinal cord independence measure.

[a]Individual cannot complete this assessment.

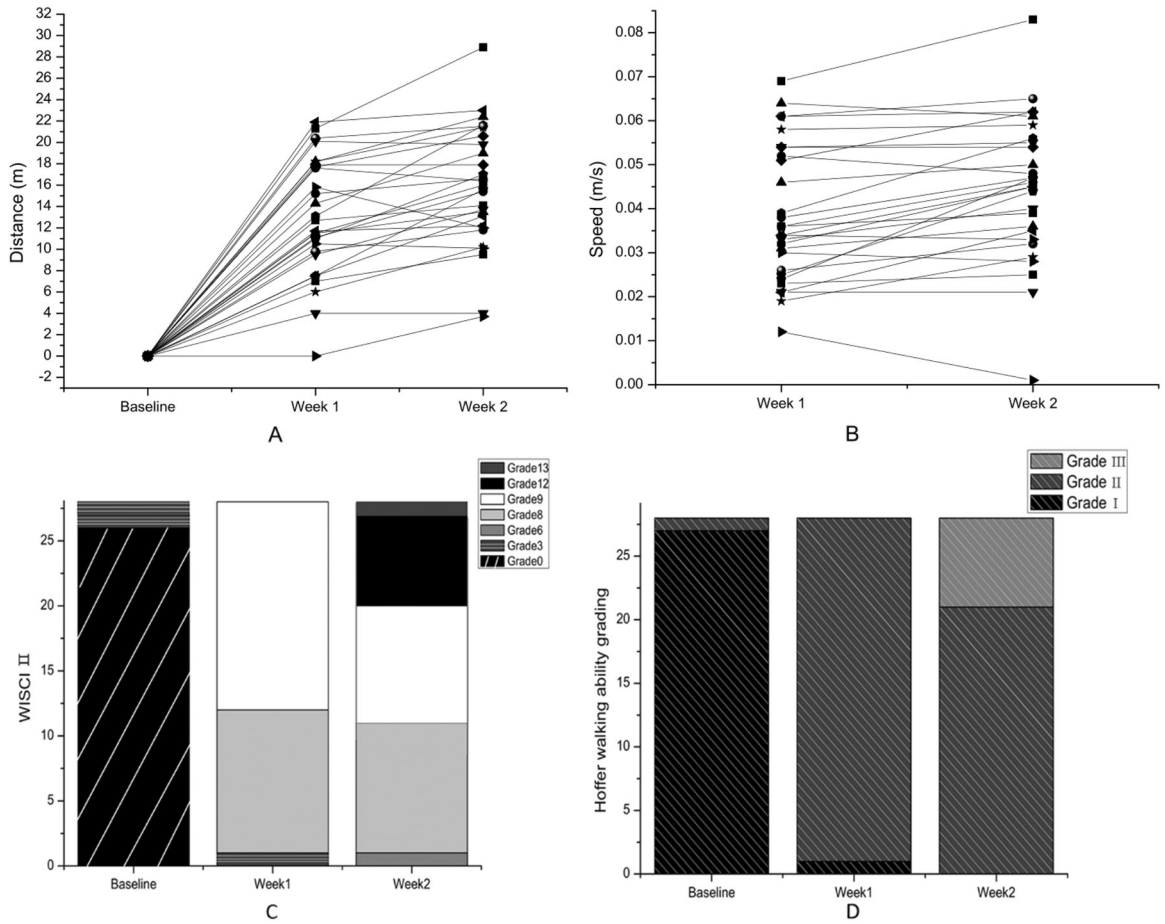

Fig. 3 Walking parameters with exoskeleton at baseline, week 1 and week 2. a Distance of 6MWT of each participant; **b** walk speed in the exoskeleton of each one; **c** distribution of WISCI II with the exoskeleton; **d** distribution of Hoffer walking ability grading in the exoskeleton. 6MWT 6-min walk test, WISCI II walking Index for Spinal Cord Injury II.

Skin integrity

There was one event related to skin integrity in 273 walking sessions. Skin integrity problems that were definitely related to the robotic exoskeleton, according to the WHO Collaboration Centre for International Drug Monitoring [20], were located on the lower leg and lasted <24 h. Pads were added between the lower leg and the exoskeleton in later sessions.

Diabetes

One participant was found to have increased fasting blood sugar at the end of the programme.

Except for the fracture, others participants experienced no effects on function and activity. The modified Ashworth scores did not change during the training; five participants had a score of 1 and one had a score of 1^{+}. No device errors occurred.

Discussion

This is the first clinical study to test the safety and feasibility of the AIDER, and the results of this study suggest that the walking ability of individuals with lower thoracic and lumbar SCI improved after a 2-week EAW programme. The improvements were related to the use of the exoskeleton over time.

The EAW programme was able to improve the results of the 6MWT, the 10WMT, the SCIM, the WISCI II, and the Hoffer walking ability grade with robotic assistance, indicating the potential of the programme to improve individuals' walking ability. Similar findings were obtained in other studies with various exoskeletons, such as ReWalk [11], Ekso and Indego [21]. All of these improved the walking ability of individuals with SCI via hip and knee drive motors and sensors. In addition, our device is used with crutches to obtain dynamic balance [22]. We found that individuals with T6–T11 and complete injuries had better improvements than others in speed and distance, which was in contrast with the results of McIntosh et al. [23]. The fastest walking speed was 0.083 m/s for the longest distance (28.9 m) in the 6MWT, which was much less than the minimally clinically important difference (0.13 m/s) [24] but still acceptable. In addition, Esquenazi et al. [25] measured walking speeds that ranged from 0.03 to 0.45 m/s in T2–T4 participants. Hartigan et al. [26] noticed a range from 0.22 m/s for persons with C5–6 complete motor tetraplegia to 0.45 m/s for persons with T9-L1 paraplegia. Notably, different exoskeletons had different effects on EAW.

There was no improvement in LEMS, and participants still could not walk outside the exoskeleton, which may be due to irreversible damage, a short follow-up time and a long duration of injury. Piira et al. [27] showed in a randomised controlled trial that robotic-assisted locomotor training cannot improve the walking function of individuals with an incomplete SCI. The result was the same as ours. Nevertheless, Donati et al. confirmed that 12-month-long brain-machine interface training with a lower limb exoskeleton upgraded the neurological level of four SCI-A participants [28].

The improvement of independence was still limited. Participants found difficulty performing activities such as bathing, dressing and applying make-up with the new robotic exoskeleton partially because they could not release the hands. Individuals also complained about the unsightly appearance of the robotic exoskeleton, which was in agreement with the results of the investigation by Lajeunesse et al. [29]. Furthermore, there was no effect on muscle tone. Juszczak et al. indicated that 31% of individuals with SCI increased muscle tone with powered exoskeleton training [30], which might be because the speed of their robotic exoskeleton was faster than ours and had incorrect alignment. In summary, EAW showed a promising effect on improving walking ability, but not on all kinds of activities of daily life and independence. In addition, there was no neurological improvement in any participant.

In terms of safety, 1 SAE and a relatively small number of minor or moderate AEs were observed within the individuals. A total of 7% of individuals suffered UTIs, which occurred in 20% [31] to 36% [32] of the SCI population. The relationship between EAW and UTI needs further research and may be verified by obtaining quantitative data with urodynamic examinations. One individual suffered from a collision after training with a standing frame and transferring to the wheelchair, and it resulted in a fracture. This was possibly related to EAW. The training sessions increased the force in both the joint and the bone, which may exceed the compressive strength of bone, especially for long bones, such as the femur. This situation occurs easily when the individual has osteoporosis. Unfortunately, we did not perform a bone mineral density test. In terms of the integrity of skin tissue, only one participant bruised slightly during the programme, which was comparable or milder to what Yang et al. [33] found, with 13 episodes among 12 participants in the ReWalk walking trainings.

Limitations

This study had several limitations. First, this is a pre-post observational study that cannot provide sufficient and strong evidence to indicate the effectiveness of EAW. Second, this study recruited individuals who were willing to attend, which leads to selection bias. Third, the time of training was limited to 2 weeks without follow-up. Fourth, we asked the participants to attend trainings as before and to try not to change medicines, but these directions could not be enforced. Last but not least, the WISCI II was perhaps not accurate for the robotic exoskeleton since the exoskeleton was not clearly included in the definition.

In addition, the gait parameters without the exoskeleton and the systematic measurements of satisfaction, which are essential for SCI individuals, were not recorded. Analysing the factors that affect the use of exoskeleton robots makes this trial more meaningful. Height, weight, neurological injury level, age and sex could be analysed in future studies based on Guanziroli et al. [34] and Louie et al. [35].

Conclusion

EAW with the new cheap robotic exoskeleton appears feasible and safe and may provide potential benefits to individuals with SCI by improving their walking ability. Individuals with SCI were able to walk in the exoskeleton.

There were positive trends in walking speeds and distances with increasing time in the EAW programme. Although few improvements in walking function and acceptable AEs were observed in the training, our study supports future efficacy trials of EAW in individuals with SCI. Moreover, urodynamic examination and satisfaction should be further investigated.

Data availability

All data generated or analysed during this study are included in this published article (and its supplementary information files).

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Author contributions CQH: planning the study. HCH: planning the study. XXN: conducting the study, collecting data and drafting of the paper. LY: collecting data. DMF: data analysis and drafting of the paper. CH: conducting the study. All authors read and approved the final paper.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval This study received approval from the Ethics Committee of West China Hospital of Sichuan University and was registered at the Chinese Clinical Trial Registry with the following identifier: ChiCTR1900021037. All the necessary approvals were obtained at the three centres.

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