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Original Article

The efficacy of exoskeletal-assisted walking for non-ambulatory patients with a spinal cord injury from T6 to L1 levels: a pre-post observational study

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Abstract: Objectives: To verify the efficacy of exoskeletal-assisted walking (EAW) on motor abilities and pulmonary performance of patients with a spinal cord injury (SCI) from T6 to L1 levels. Methods: An observational pre-post prospective study was done with gait training with robotic exoskeletal devices in 117 patients (with age ≥ 18 years) who had complete or motor complete dorsal/dorso-lumber myelopathy. Results: Compared to walking without the use of a robotic exoskeleton condition, all walking functions were improved 2-weeks and 1-week after the use of a robotic exoskeleton ($P < 0.01$ for all). Individuals consistently traveled faster in week two (19.1 ± 1.3 m) than they did in week one (almost zero), with a difference of 19.1 m (15.1-21.8 m). Walking, lower extremity motor scores, and the Chinese version of Spinal Cord Independence Measure III were improved from baseline followed by week 1 and week 2 using an exoskeleton for patients with severe injuries (T6-L1; SCI-A; n = 76; $I^2 = 99.5$; $P < 0.001$). The post-exoskeleton-intervention stage had better 5 pulmonary function test values (SMD: -0.92; 95% CI: from -1.58 to -0.26, $P < 0.05$, $I^2 = 95.9$) and did not show a significant difference for any adverse effects ($I^2 = 0$ (0-84.7) %) versus the pre-exoskeleton-intervention stage. Conclusions: EAW is a reliable method for the improvement of walking functions of patients suffering from SCI. The benefits of an EAW are over time connected to the usage of the exoskeleton.

Keywords: Exoskeletons, mobility, robotic exoskeleton walking, skin integrity, spinal cord injuries, walking parameters

Introduction

The incidence of spinal cord injuries (SCI) has increased in China [1]. The primary causes of SCI are traumatic injuries from accidents and falls, as well as non-traumatic injuries from medical conditions like tumors, infections, and degenerative spinal changes could cause SCI [2]. Patients with complete and incomplete SCI spend a lot of money to improve their quality of life throughout their lifetime [3]. Robotic exoskeletons give improved mobility but are not economical [4]. Orthoses and electrical stimulation are reportedly successful walking assistances but are not used often in practice by clinicians (considering the cost factor) [5, 6]. In addition, patients with SCI facepain [7] and the risk of deterioration of quality of life by the formation of pressure ulcers and urinary tract and pulmonary infections [8]. Robotic exoskeletons can improve the quality of life of patients after complete SCI [9]. Powered exoskeletons have established efficacy in improving the quality of life of patients with SCI [10]. However, they are less popular because they are expensive [10]. Therefore, there is a need for reliable and more effective exoskeletons for patients with SCI. In addition, there is a need for robotic exoskeletons for gait training instead of conventional methods for patients with SCI. At present, many studies on robot-assisted walking have been reported, among which many studies used the exoskeletal-assisted walking (EAW) system. However, there are currently few studies evaluating the reliability and effectiveness of exoskeletons for the treatment of SCI patients who could or could not walk at least a minimal distance.

The objectives of the study were to verify the efficacy of EAW on motor abilities and pulmonary performance of patients with SCI from T6

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to L1 levels and who could or could not walk at least a minimal distance from the western region of China.

Materials and methods

Ethics approval and consent to participate

The study was approved by the institutional review board of Xi'an Jiaotong University and the Ankang People's Hospital with Approval No. 2019-XMU-026 dated 11 January 2020. The study's reporting complies with Chinese legislation and the V2008 Helsinki Declarations. Written informed consent was obtained from patients before the commencement of the study. The study follows STROBE guidelines. Anonymous data collections and presentation was performed to maintain confidentiality and data security.

Design, setting, and period

An observational pre-post prospective study was conducted from 15 January 2020 to 1 January 2021 at the First Affiliated Hospital of Xi'an Jiaotong University, Xi'an, China, and the Ankang People's Hospital, Ankang, China.

Inclusion criteria

Patients with traumatic or non-traumatic acute, chronic, or hybrid T6-L1 level of injury of SCI aged 18 years and above who met an international standard for the neurological classification of SCI-A or B [11] were included in the study. Participants who could walk (six minutes' walk test (6MWT) or 10-minutes' walk test (10MWT) values are more than 0) or who could not walk (6MWT and 10MWT values are 0 and 0 respectively) a minimal distance were included.

Exclusion criteria

Patients who had a muscle tone of the lower limb muscle more than 1+ grade as per the modified Ashworth scale, uncontrollable orthostatic hypotension, extremity fractures, active deep venous thrombosis, or medical instability were excluded from the study.

Training

For 2-weeks, training sessions comprised one session of an hour per day and five sessions per week. Patients completed all training sessions of 2 weeks. The exercise session included periods of sitting and standing, as well as moving between the two distances. The remaining time of the session was walking. For the lower limb exercise, a robotic exoskeleton (Relink-ANK, Yrobot Technology Co., Ltd., Suzhou, China) was employed. According to protocol, the patients were given 10 sessions of robotic gait training with an exoskeletal device. EAW consisted of the device body, clutches, matched power adaptors, and a binding device. The clutches were used as assistive devices. The main body of EAW 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. The total length of the exoskeletal from thigh and calf was adjusted by the operator according to the size of the person. The control in the walking mode was set at maximum assistance (the instruments have been validated for our country).

Outcome measures

All walking measurements were evaluated initially without the use of a robotic exoskeleton, 1-week after the use of a robotic exoskeleton, and 2-weeks after the use of a robotic exoskeleton. The measurements were:

6MWT: Walking of patients in 6 minutes without help of anyone [12].

10MWT: If patients did not walk in 6 minutes, then the result of the 6MWT was 0. Therefore, patients were tested for a 10MWT (i.e., patients could not accomplish the task of a 6MWT and were tested in the 10MWT). The 10MWT is walking of patients for 10 minutes without help from anyone [13].

Lower extremity motor score on the American Spinal injury association's impairment scale

This included bilateral manual muscle strength tests of hip flexors, the knee extensor, ankle dorsiflexion, long toe extensors, and ankle plantar flexor. Each one was scored in the range of 0 to 5, where, 0: total paralysis, 5: active movement. The total score of the American Spinal Injury Association Impairment Scale lower extremity motor score was 0 to 50. The higher the score, the higher the movement [14].

The Chinese version of spinal cord independence measure III

This consists of self-care (4 sub-scales), respirator and sphincter management (4 sub-scales), and mobility (9 sub-scales). The total score is 0-100. The higher the score, the higher is the independence [15].

Second edition of the walking index for spinal cord injury

This measures walking function ability with or without help. The score ranges from 0 to 20. A score above 12 indicates independent ambulation [16].

Hoffer walking ability

This score is in the range of 0 to 4. It was evaluated as 1: non-ambulatory, 2: nonfunctional ambulatory, 3: household ambulatory, and 4: community ambulatory [17].

Pulmonary function outcome

A computer Spirometer (Vyntus, SPIRO, Vyaire Medical, U.S.A.) was used to evaluate lung function tests according to Society of America Thoracic Guidelines. To determine the characteristics of pulmonary function, participants did the pulmonary function test (PFT) sitting in the wheelchair and were forbidden to disclose their intervention to the evaluator. The PFT was conducted using a nose clip. The numerical numbers were not recorded if a person coughed or made a mistake. Three repeated maneuvers were carried out, separated by a rest of 5 minutes, and automatically the best result was recorded. PFT included evaluation of the forced vital capacity (FVC), forced expiratory volume (FEV), forced expiratory force (FEF), and peak expiratory flow (PEF).

Participants performed the pre-tests for walking tasks while wearing the exoskeleton (baseline conditions).

Safety study

In the safety study, adverse events during a 2-week period were evaluated. Events regarding foot fractures falls during exercise, and skin integrity (with numbers and sites) were evaluated. In addition, events regarding pain, falling, dizziness, and brushing of skin were considered as adverse events.

Between the 1- and 2-week assessments, all of the patients completed all of the sessions as recommended. Patients who had any missing data at week 2 were excluded from the study.

Statistical analyses

Statistical analyses were performed using InStat 3.0.1 from GraphPad Software Inc., San Diago, CA, USA. Normally distributed continuous variables or ordinal data are presented as mean ± standard deviation (SD). The normality of continuous variables or ordinal data was checked using Kolmogorov and Smirnov test. The homogeneity of normal continuous variables or ordinal data was checked using Bartlett's test. For continuous normal variables or ordinal data, Paired *t*-test or one-way repeated measures analysis of variance (ANOVA) was performed. *Post hoc* analysis was performed using the Tukey test for continuous normal variables or ordinal data. If $P < 0.05$, findings were deemed significant. Forest and net plot, Netleague table, Direct/Indirect analysis, and Funnel plot were generated using metaanalysisonline.com, 2024-2025, ELIXIR Hungary (Setting: Random effect model, Method: Inverse, Summary measures: Standard mean difference, Between study heterogeneity estimator: DerSimonian-Laird). $I^2 > 50\%$ was considered moderate heterogeneity.

Results

Study population

From 15 January 2020 to 1 January 2021, a total of 127 patients with traumatic or non-traumatic T6-L1 level of injury of SCI (complete or motor complete dorsal/dorso-lumber myelopathy) with age 18 years and above and met an international standard for the neurological classification of spinal cord injuries-A or B were available at the First Affiliated Hospital of Xi'an Jiaotong University, Xi'an, Shaanxi, China and the Ankang People's Hospital, Ankang, Xi'an, Shaanxi, China. Among them, five patients had a muscle tone of the lower limb muscle more than 1+ grade as per the modified Ashworth scale, two patients had uncontrollable orthostatic hypotension, one patient had extremity fractures, one patient had active deep venous

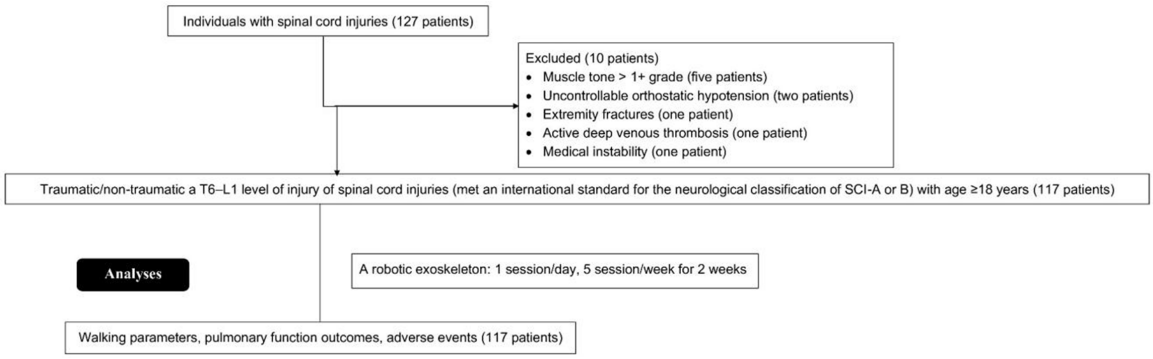

Figure 1. Flow diagram of the study.

Table 1. Demographical and clinical assessment of patients without the use of a robotic exoskeleton

Item		Value
Total number of patients		117
Sex	Men	79 (68)
	Women	38 (32)
Age (years)	Minimum	19
	Maximum	69
	Mean ± SD	40.15 ± 15.14
Height (cm)		164.15 ± 11.09
Weight (kg)		59.12 ± 9.89
Duration of injuries	Minimum	6 months
	Maximum	24 years
	Mean ± SD	6.51 ± 2.14 months
International standard for the neurological classification of spinal cord injuries	A	76 (65)
	B	41 (35)
Muscle tone of the lower limb muscle (the modified Ashworth scale)	0	71 (61)
	1	46 (39)

Variables demonstrated as mean ± standard deviation (SD) or frequencies (percentages).

thrombosis, and one patient had medical instability. Therefore, data of these patients (10 patients) were excluded from analysis. Data from 117 patients regarding the demographic and clinical conditions and outcome measures were collected and analyzed. The flow diagram is presented in **Figure 1**.

Demographic variables

The research involved 117 patients, including 68 percent men and 32 percent women. The lower extremity motor scores (LEMS) were at or below 10 (out of 50) in 65 percent of patients with an AIS-A lesion and 35 percent of individuals with an AIS-B lesion. In all, 68 percent of the individuals experienced full motor paralysis in their lower extremities. Furthermore, the damage lasted anywhere from 6 months to 24 years (median time was 4.7 years). The participants' height was 164.15 ± 11.09 cm and their weight was 59.12 ± 9.89 kg. **Table 1** gives further information on individual characteristics.

Outcome measures

Compared to patients without the use of a robotic exoskeleton condition, all outcomes were improved 2 weeks after the use of a robotic exoskeleton and 1 week after the use of a robotic exoskeleton. The details of outcome measures for walking function are reported in **Table 2**.

These patients were able to walk (independently, with or without splints) for 6 minutes at the

Table 2. Outcome measures for walking parameters

Walking functions	Without the use of a robotic exoskeleton	1- a week after the use of a robotic exoskeleton			2- the week after the use of a robotic exoskeleton		
Total number of patients	117	117	**p-value	**F-value	117	**p-value	**F-value
Six minutes' walk test (m)	0.5 ± 0.05	3.91 ± 1.58	< 0.001	254	4.52 ± 1.85	< 0.001	254
Ten minutes' walk test (m)	1.0 ± 0.1	11.12 ± 2.01	< 0.001	2128	15.58 ± 2.09	< 0.001	2128
Lower extremity motor score on the American Spinal Injury Association's Impairment Scale	1.11 ± 0.09	1.51 ± 0.15	< 0.001	2443	2.51 ± 0.21	< 0.001	2443
The Chinese version of Spinal Cord Independence Measure III	57.12 ± 8.89	61.22 ± 10.12	< 0.01	19.61	65.41 ± 11.23	< 0.001	19.61
The Second Edition of the Walking Index for Spinal Cord Injury	7.15 ± 1.15	8.01 ± 1.12	< 0.001	107.3	10.12 ± 2.25	< 0.001	107.3
The Hoffer walking ability	1.05 ± 0.27	1.59 ± 0.58	< 0.001	70	1.89 ± 0.71	< 0.001	70

Variables demonstrated as mean ± standard deviation (SD). One-way repeated measures of ANOVA were used for statistical analyses. Tukey test was used for *post hoc* analysis. The degree of freedom was 349 for all tests. Results were considered significant if $P < 0.05$. **concerning without use of a robotic exoskeleton.

Table 3. Parameters such as walking, LEMS, and SCIM at baseline, followed by week 1 and week 2 using an exoskeleton for individuals with more severe injuries (T6-L1; AIS-A; n = 76)

Time level	Assessment 6MWT (m)	10MWT (m)	Speed (m/s)	LEMS (Mean ± SD)	SCIM
Baseline	0.1 ± 0.05	0.5 ± 0.05	0.003 ± 0.0001	0 ± 2.0	62.5 ± 10.0
Week 1	8.91 ± 1.58	12.12 ± 2.01	0.04 ± 0.011	0 ± 2.0	63.3 ± 9.1
Week 2	14.3 ± 5.0	16.58 ± 2.09	0.031 ± 0.018	0 ± 2.0	64.1 ± 9.2

Variables presented as mean ± standard deviation (SD). 6MWT: Six minutes' walk test, 10MWT: Ten minutes' walk test, LEMS: Lower extremity motor scores, SCIM: The Chinese version of Spinal Cord Independence Measure III.

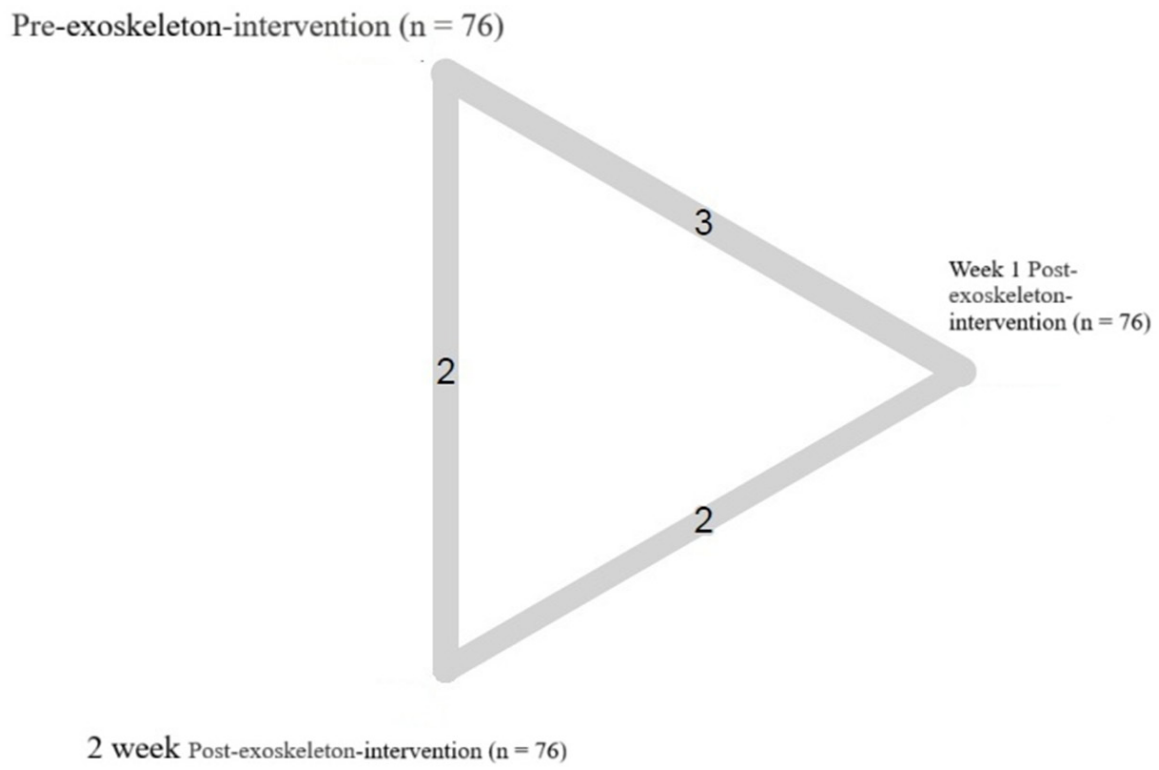

Figure 2. Forest and net plot for 3 points of evaluations of parameters (baseline, followed by week 1 and week 2 using an exoskeleton) analyses with a total of 3 outcome measures (walking, LEMS, and SCIM) of patients with more severe injuries (T6-L1; AIS-A). Triangle displays the direct comparisons. LEMS: Lower extremity motor scores, SCIM: The Chinese version of Spinal Cord Independence Measure III (the total score is 0-100. The higher the score, the higher is independence).

time of commencement of robotic gait training. The 6MWT, 10MWT, walking speed, LEMS, and the Chinese version of spinal cord independence measure III (SCIM) were used to summarize the data from the baseline, first week, and second week. Individuals consistently traveled faster at two weeks (19.1 ± 1.3 m) than they did in week one (almost zero), with a mean (95 percent confidence interval (% CI) difference of 19.1 m (15.1-21.8 m). Walking speeds in the exoskeleton were 0.041 ± 0.011 m/s and 0.039 ± 0.016 m/s throughout weeks 1 and 2 of the 10MWT, respectively, representing a mean (95% CI) drop of 0.004 m/s (0.002-0.007 m/s). Individuals with more severe injuries (T6-L1; AIS-A) had greater improvements in gait speed and distance traveled during the 6MWT (14.3 ± 5.0 m *vs*. 12.1 ± 5.1 m). Individuals with complete injuries (AIS-A) improved their gait speed significantly more than those with partial injuries (0.031 ± 0.018 m/s *vs*. 0.030 ± 0.009 m/s) and covered greater distance throughout the 6MWT (14.1 ± 2.1 m compared to 12.1 ± 2.1 m). At baseline, week 1, and week 2, the SCIM's exoskeleton outcomes were 62.5 ± 10.0 m, 63.3 ± 9.1 m, and 64.1 ± 9.2 m, respectively, with a mean (95% CI) change of 3.0 m (1.9-4.8 m) from baseline to week 2. Additionally, the LEMS remained unchanged as a consequence of the intervention (**Table 3**).

Altogether 3 points of evaluations of measurements (baseline, followed by week 1 and week 2 using an exoskeleton) were analyzed with a total of 3 outcome measures (walking, LEMS, and SCIM). The number of designs: 2. The number of pairwise comparisons: 7. The total number of enrolled patients with severe injuries (T6-L1; SCI-A) was 76 (**Figure 2**). The reference group was pre-exoskeleton intervention. Based on the analysis performed, these treatments displayed a statistically significant difference compared to the reference group: 6MWT (m), Speed (m/s), and SCIM. Heterogeneity and inconsistency: There was significant variability among 3 points of evaluations of parameters (baseline, followed by week 1 and week 2 using an exoskeleton) within the same design (Q with-

Table 4. Netleague table

Pre-exoskeleton-intervention	5.08 [2.12; 8.03]*	7.28 [3.65; 10.90]*
5.08 [2.12; 8.03]*	1-week post-exoskeleton-intervention	-0.03 [-3.63; 3.58]
6.15 [2.68; 9.61]*	1.07 [-2.38; 4.52]	2-week post-exoskeleton-intervention

*Significance difference.

Table 5. Direct/indirect comparisons

Comparison	nma	direct	indirect	RoR	z	*p*
LEMS: 6MWT (m)	0.01	0.01	NA	NA	NA	NA
Speed (m/s): 6MWT (m)	0.00	0.00	347.13	0.00	-2.08	0.04
LEMS: Speed (m/s)	2.92	0.97	538028.49	0.00	-2.07	0.04

nma: Estimated treatment effect (OR) in network meta-analysis; RoR: Ratio of Ratios (direct *versus* indirect); z: z-value of test for disagreement (direct *versus* indirect); *p*: *p*-value of test for disagreement (direct versus indirect). 6MWT: 6 minutes' walk test, LEMS: Lower extremity motor scores.

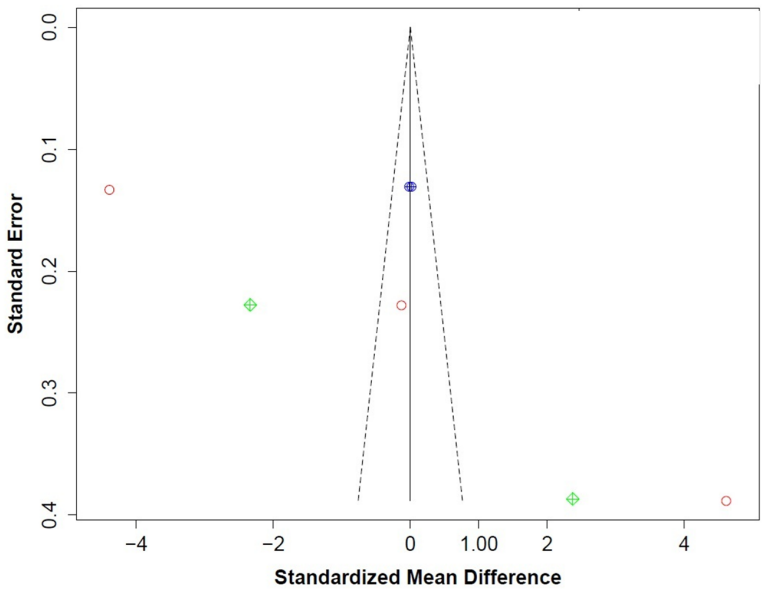

Figure 3. Funnel plot for 3 points of evaluations of parameters (baseline, followed by week 1 and week 2 using an exoskeleton) analyses with a total of 3 outcome measures (walking, LEMS, and SCIM) with more severe injuries (T6-L1; AIS-A). LEMS: Lower extremity motor scores, SCIM: The Chinese version of Spinal Cord Independence Measure III (the total score is 0-100. The higher the score, the higher is independence).

in design heterogeneity: 115.3, degree of freedom: 2, *P*-value: < 0.001), and there was significant inconsistency between direct and indirect results (Q between design inconsistency: 527.5, degree of freedom: 1, *P*-value: < 0.001). The I^2 value indicated that 99.5 (99.4-99.7) % of the variability among 3 points of evaluated measures (baseline, followed by week 1 and week 2 using an exoskeleton) arose from heterogeneity rather than random chance. Both direct and network estimates showed statistical significance for: LEMS *vs.* 6MWT (m), Speed (m/s) *vs.* 6MWT (m). The details are presented in Netleague table (**Table 4**). Statistically significant differences between direct and indirect estimates existed for the following treatment pairs: pre-exoskeleton-intervention: 1-week post-exoskeleton-intervention, pre-exoskeleton-intervention: 2-week post-exoskeleton-intervention, and 1-week post-exoskeleton-intervention: 2-week post-exoskeleton-intervention (**Table 5**). Egger's test was not performed for Funnel plot (**Figure 3**; because of less than 10 points of evaluation of values).

Assessment of pulmonary function test

The main result was assessed based on the PFT. **Table 6** provides numerical findings of the PFT. The FVC (t = 1.67; *P* = 0.021) and FVC percent forecast (t = 3.12; *P* = 0.011) findings demonstrated significant differences from the pre- and post-exoskeleton assisted patients. In addition, there was a significant difference between groups in FEV1 (t = 2.779; *P* = 0.013). However, there were no significant differences in the FEF (Z = 0.856; *P* = 0.514), FEF-25 (t = 0.521; *P* = 0.514), or PEF (t = 3.787; *P* = 0.289).

Table 6. Numerical findings of pulmonary function test (117 patients)

Characteristic	Level		*p*-value in group	*t*-value in group	Degree of freedom
	Pre-exoskeleton-intervention	Post-exoskeleton-intervention			
FVC (L)	2.1 ± 1.1	3.8 ± 1.1	0.010	1.67	233
FEV1 (L)	2.7 ± 0.9	3.5 ± 1.0	0.013	2.799	233
FEF (L)	3.6 ± 1.5	4.3 ± 1.6	0.514	0.856	233
FEF-25 (L)	1.7 ± 0.9	1.9 ± 1.1	0.514	0.521	233
PEF (L/min)	5.3 ± 1.6	7.1 ± 2.0	0.289	3.787	233

Variables presented as mean ± standard deviation (SD). FVC: The forced vital capacity, FEV: Forced expiratory volume, FEF: Forced expiratory force, PEF: Peak expiratory flow. Paired t-test was performed for statistical analysis. Results were considered significant if $P < 0.05$.

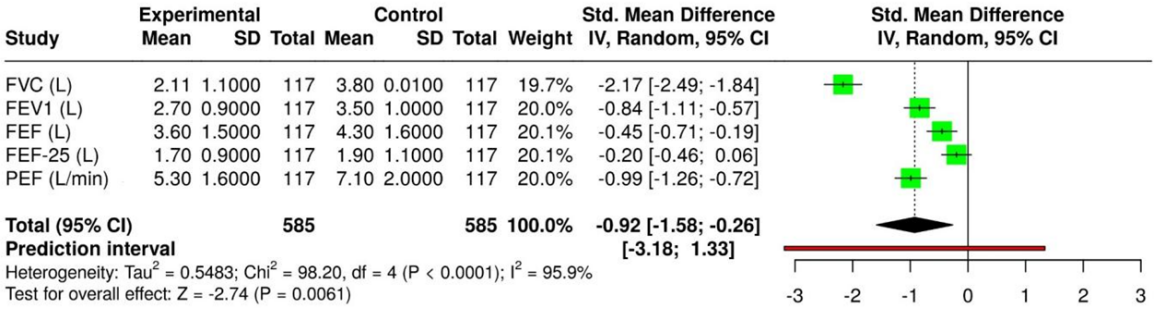

Figure 4. Forest plot for 5 pulmonary function test parameters analyses in the pre-exoskeleton-intervention stage and the post-exoskeleton-intervention stage. The test for overall effect of exoskeleton-intervention shows a significance at $P < 0.05$. Heterogeneity: $Tau^2 = 0.5483$; Chi-square value = 98.20, degree of freedom = 4 ($P < 0.0001$); $I^2 = 95.9\%$. Test for overall effect: Z = -2.74 ($P = 0.0061$). Experimental: Pre-exoskeleton-intervention, control: Post-exoskeleton-intervention.

5 pulmonary function test values were analyzed with a total of 117 patients in the pre-exoskeleton-intervention stage and 117 patients in the post-exoskeleton-intervention stage (**Figure 4**). Based on the analysis performed, using a random effects model with inverse variance method to compare the standardized mean difference (SMD), there was a significant difference between the pre-exoskeleton-intervention stage and the post-exoskeleton-intervention stage. The summarized standardized mean difference (SMD) was -0.92 with a 95% confidence interval of -1.58 - -0.26. The test for overall effect of exoskeleton-intervention showed significance at $P < 0.05$. A significant heterogeneity was detected ($P < 0.01$), suggesting inconsistent effects in magnitude and/or direction. The I^2 value indicated that 95.9% of the variability among 5 pulmonary function test values arose from heterogeneity rather than random chance.

The funnel plot (**Figure 5**) indicated a potential pulmonary function test parameters bias. The Egger's test supported the presence of funnel plot asymmetry (intercept: -54.19, 95% confidence interval: -69.09 - -39.3, *t*: -7.133, *P*-value: 0.006).

Summary table, quantifying heterogeneity, and test of heterogeneity for 5 pulmonary function test values are presented in **Tables 7**-**9**, respectively.

Adverse events

Some patients had issues with skin integrity and minor injuries (e.g., foot fractures). A total of 2 (2%) patients had foot fractures during 2 weeks. One patient fell during exercise. Skin integrity was the problem faced by patients. The adverse effects were less severe and required fewer treatments for management (**Table 10**).

4 adverse events were reported among a total of 117 patients in the pre-exoskeleton-intervention stage and 117 patients in the post-exo-

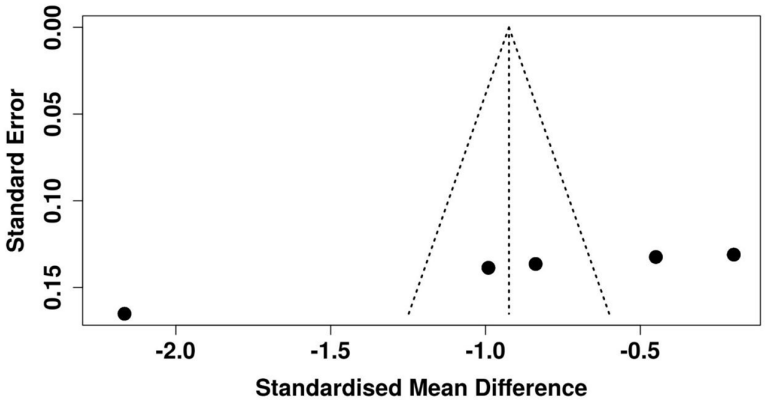

Figure 5. Funnel plot for 5 pulmonary function test parameters analyses in the pre-exoskeleton-intervention stage and the post-exoskeleton-intervention stage (intercept: -54.19, 95% confidence interval: -69.09 - -39.3, *t*: -7.133, *p*-value: 0.006).

skeleton-intervention stage (**Figure 6**). The number of designs was 1. The number of pairwise comparisons: 4. The total number of enrolled subjects was 117. Analysis: Based on the analysis performed, post-exoskeleton-pre-exoskeleton-intervention stage did not show a significant difference compared to pre-exoskeleton-intervention stage for any of the adverse effects. Heterogeneity and inconsistency: Neither heterogeneity within designs nor inconsistency between designs could be assessed (Q within and Q between statistics are not available). The I^2 value indicated that 0 (0-84.7) % of the variability among studies arose from heterogeneity rather than random chance.

Discussion

This research assessed the AIDER (EAW) safety and feasibility, and the findings showed that people with lower thoracic and lumbar SCI improved their capacity to walk after two weeks of EAW. The benefits were, over time, connected to the use of the exoskeleton.

The current study suggested that walking functions were improved 2 weeks after the use of a robotic exoskeleton. The results of the walking functions of the current study are consistent with those of observational studies [1, 18]. One observational study [1] i\was on 28 patients only. We have 117 patients. Therefore, we have more reliable data because of the small sample size has type I errors. In addition, we have evaluated the assessment of PFT. Moreover, patients from an observational study [1] had 6MWT and 10MWT values of 0 and 0 respectively. This means all patients could not walk at least a minimal distance. We included patients who could or could not walk at least a minimal distance at baseline (the different study populations). The study is notable for its relatively large sample size (117 patients), which strengthens the reliability of the data compared to other studies with smaller populations. This increases the generalizability of the findings. The use of robotic exoskeletons can improve the walking functions of patients suffering from SCI over time.

With robotic help, the EAW program was able to enhance the outcomes of the 6MWT, the 10WMT, the SCIM, the second edition of the walking index for spinal cord injury (WISCI II), and the Hoffer walking ability grade, showing the program's potential to enhance persons' walking ability. In addition, similar outcomes have been reported in other trials using a variety of exoskeletons, including various studies [19-21]. All of them enhanced persons with SCI's walking capabilities via the use of hip and knee drive motors and sensors. Additionally, our gadget was used in conjunction with clutches to achieve dynamic balance [20]. We discovered that patients with T6-T11 and full injuries of SCI improved faster and faster than others, which contradicted the findings of the other authors [21]. The quickest walking speed throughout the 6MWT was 0.083 m/s for the greatest distance (28.9 m), which was significantly less than the least clinically significant difference (0.13 m/s), but still an acceptable value (walking speed). Additionally, one research observed walking speeds in T2-T4 subjects ranging from 0.03 to 0.45 m/s [22]. Another conducted study [23] observed a range of 0.22 m/s for individuals with full motor tetraplegia in the C5-C6 region to 0.45 m/s for those with T9-L1 paraplegia. Notably, the effects of various exoskeletons on EAW were variable.

Table 7. Summary table for 5 pulmonary function test values

	Study	Pre-exoskeleton-intervention	Post-exoskeleton-intervention	SMD	95% CI	Weight	*t*	*p*
1	FVC (L)	117 (2.11/1.1)	117 (3.8/0.01)	-2.166	-2.489 to -1.842	19.75		
2	FEV1 (L)	117 (2.7/0.9)	117 (3.5/1)	-0.838	-1.106 to -0.571	20.05		
3	FEF (L)	117 (3.6/1.5)	117 (4.3/1.6)	-0.45	-0.709 to -0.19	20.09		
4	FEF-25 (L)	117 (1.7/0.9)	117 (1.9/1.1)	-0.198	-0.455 to 0.059	20.1		
5	PEF (L/min)	117 (5.3/1.6)	117 (7.1/2)	-0.991	-1.262 to -0.719	20.03		
6	Random effects model	3.082/1.2	4.12/1.142	-0.924	-1.585 to -0.264	100.02	-2.74	0.00611

SMD: the standardized mean difference, CI: Confidence interval.

Table 8. Quantifying heterogeneity for 5 pulmonary function test parameters

	Item	Value	95% CI
1	tau^2	0.548	0.183-4.734
2	tau	0.74	0.428-2.176
3	I^2	0.959	0.929-0.977

CI: Confidence interval.

Table 9. Test of heterogeneity for 5 pulmonary function test parameters

	Q	Degree of freedom	*p*-value
1	98.2028	4	0

Patients could not walk outside the exoskeleton. The results of lower extremity motor scores are consistent with those of an observational study and a randomized trial [23]. Irreversible damage and short follow-up time are responsible for such results. Improvement of independence is limited.

Independence progressed slowly. Participants had difficulties in showering, dressing, and applying makeup while wearing the new robotic exoskeleton, in part due to their inability to release their hands. Individuals also complained about the robotic exoskeleton's unattractive look, which corroborated the findings of an already-conducted study [24]. Additionally, no impact on muscular tone was seen. Recent research reported that 31% of persons with SCI improved muscular tone after training with a powered exoskeleton, which might be because their robotic exoskeleton was quicker and had erroneous alignment [25]. In summary, EAW showed a favorable impact on walking ability, but not on other aspects of daily living and independence. Additionally, no subject demonstrated neurologic improvement. While the robotic exoskeleton improved walking parameters, there was limited improvement in patients' independence in daily living activities (such as showering, dressing, or using makeup). This suggests that the exoskeleton, although beneficial for walking, did not translate well into improvements in other aspects of daily functioning, which is a key limitation of this technology.

Skin integrity was a problem for some patients. Skin integrity is related to the robotic exoskeleton [26]. An expert review of biomedical engineering is required to overcome this problem(s).

The current study reported an improvement in walking distance during the 6MWT. However, the walking distance increased from zero to 5 meters. The minimum detectable change for the 6MWT varied between 30 and 50 meters. In fact, no change was observed in the study (improvements in walking parameters (e.g., 6MWT, 10MWT) were noted, but the clinical significance of these changes is unclear. For example, a walking speed of 0.083 m/s during the 6MWT is well below the minimal clinically important difference (MCID) for the same population). A possible explanation for this is that the 6MWT was performed outside the exoskeleton, as one would expect the walking speed to be greater in the exoskeleton. To determine if such devices are more effective, the study would have to be compared to others which is different. A possible justification for the same is that for comparison purposes, the study compared outcome measures without the use of a robotic exoskeleton (no cost for walking assistance). The study compared the effects of the robotic exoskeleton to baseline measurements (without the exoskeleton), but there was no direct comparison with other rehabilitation methods or exoskeleton devices. Including

Table 10. Occurrences of adverse events

Adverse event	Treatment stage	Total	Event	Treatment stage	Total	Event
Foot fractures	Pre-exoskeleton	117	0 (0)	Post-exoskeleton	117	2 (2)
Fell during exercise	Pre-exoskeleton	117	0 (0)	Post-exoskeleton	117	1 (1)
Skin integrity	Pre-exoskeleton	117	1 (1)	Post-exoskeleton	117	15 (13)
Discomfort	Pre-exoskeleton	117	1 (1)	Post-exoskeleton	117	12 (10)

Variance depicted as frequencies with percentages in parenthesis.

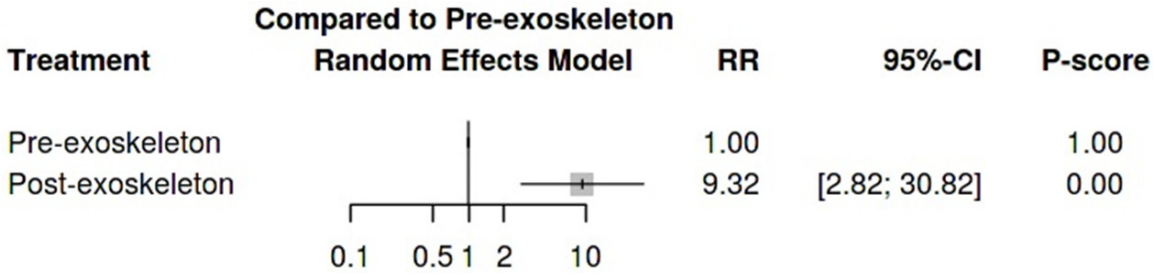

Figure 6. Forest and net plot for adverse effects.

such a comparison could offer a more comprehensive view of the exoskeleton's relative effectiveness.

The current study reported significant improvements in FVC and FEV1 values. Improvements in FVC and FEV1 values leads good exchanges of carbon dioxide and oxygen. This leads to improvements in quality of life of patients. Despite the improvements in walking ability and pulmonary function, no neurological improvements were observed in the study. This aligns with the expectation that robotic exoskeletons are unlikely to reverse SCI-induced damage but it highlights the limitations of current technology in achieving functional neurological recovery.

The investigation presented an interventional study of a walking therapy delivered with a robotic exoskeleton. The clinical outcomes reported are validated clinical variables related to walking functions. However, numerous limitations existed in this investigation. To begin, this was a pre-, post-observational research, which cannot give significant and compelling proof of EAW's efficacy. The possible justification for the same is that a non-treatment trial is possible because patients have a right to select among choice of therapies (treatment and/or non-treatment) according to Chinese law. Second, this research recruited participants who expressed an interest in attending, resulting in selection bias. Thirdly, training sessions were restricted to 2-weeks without follow-up (**Figure 3**). Fourth, we advised participants to continue attending training and to avoid changing medications, but these instructions could not be implemented. Finally, the WISCI II may have been inaccurate for robotic exoskeletons since the exoskeleton was not explicitly mentioned in the definition. Initially, the study has to separate two things. The first was safety, while the second was related to its possibilities to improve mobility. In addition, the study must assume a more cautious posture in some assertions. For instance, the study was concerned about more effective exoskeletons. There was no cost analysis. The study was on patients from the western region of China. However, the study recruited participants only from one hospital in Xi'an and one hospital in Ankang. Xi'an and Ankang both belong to Shaanxi Province, which is only one province in western China and cannot represent the entire western region of China.

Conclusions

Exoskeletal-assisted walking is a reliable method for the improvement of walking of patients for non-ambulatory suffering from spinal cord injuries. The benefits of exoskeletal-assisted walking are over time connected to the usage of the exoskeleton. An exoskeletal-assisted walking using a novel robotic exoskeleton is

possible and safe and may assist patients with spinal cord injuries by enhancing their walking skills. Individuals with spinal cord injuries were able to walk while wearing the exoskeleton. We explored the possible therapeutic effects of using exoskeleton-assisted walking on improving motor ability and pulmonary function in patients with thoracolumbar spinal cord injury. In the future, a trial is required to validate the current findings.

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Disclosure of conflict of interest

None.

Abbreviations

SCI, Spinal cord injuries; STROBE, Strengthening the reporting of observational studies in epidemiology; PFT, The Pulmonary function test; FVC, The forced vital capacity; FEV, Forced expiratory volume; FEF, Forced expiratory force; PEF, Peak expiratory flow; SD, Standard deviation; ANOVA, Analysis of variance; 6MWT, 6 minutes' walk test; 10MWT, 10 minutes' walk test; LEMS, Lower extremity motor scores; SCIM, The Chinese version of Spinal Cord Independence Measure III; % CI, Percent confidence interval; EAW, Exoskeletal-assisted walking; WISCI II, The Second Edition of the Walking Index for Spinal Cord Injury.

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