

Application of a paraplegic gait orthosis in thoracolumbar spinal cord injury

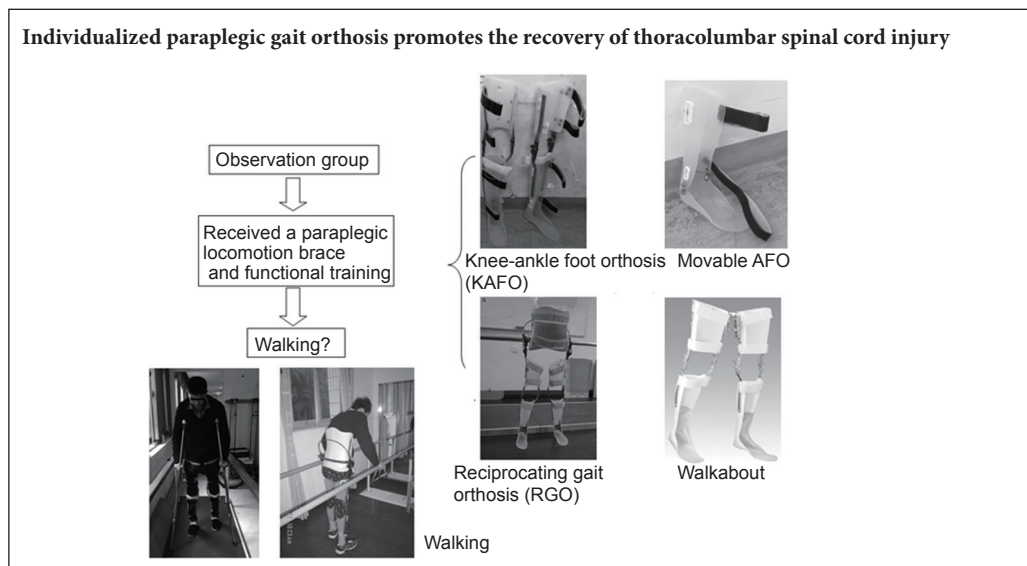
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Graphical Abstract



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Abstract

Paraplegic gait orthosis has been shown to help paraplegic patients stand and walk, although this method cannot be individualized for patients with different spinal cord injuries and functional recovery of the lower extremities. There is, however, a great need to develop individualized paraplegic orthosis to improve overall quality of life for paraplegic patients. In the present study, 36 spinal cord (below T₄) injury patients were equally and randomly divided into control and observation groups. The control group received systematic rehabilitation training, including maintenance of joint range of motion, residual muscle strength training, standing training, balance training, and functional electrical stimulation. The observation group received an individualized paraplegic locomotion brace and functional training according to the various spinal cord injury levels and muscle strength based on comprehensive systematic rehabilitation training. After 3 months of rehabilitation training, the observation group achieved therapeutic locomotion in 8 cases, family-based locomotion in 7 cases, and community-based locomotion in 3 cases. However, locomotion was not achieved in any of the control group patients. These findings suggest that individualized paraplegic braces significantly improve activity of daily living and locomotion in patients with thoracolumbar spinal cord injury.

Key Words: nerve regeneration; spinal cord injury; paraplegia brace; thoracolumbar spine; locomotion ability; activity of daily living; reciprocating gait orthosis; hip-knee ankle foot orthosis; knee-ankle foot orthosis; ankle foot orthosis; neural regeneration

Introduction

The incidence of spinal cord injury (SCI) caused by car accidents, trauma, and geological disasters has increased annually, with a global prevalence of approximately 236–1,009/100,000 (Cripps et al., 2011). SCI-related complications cause great distress, and adversely affect quality of life; with advances in first-aid technologies, SCI mortality has

sharply declined, although most survivors exhibit different degrees of quadriplegia or paraplegia. These impairments can seriously affect somatic sensation and motor function, and patients are unable to stand or walk (Hartigan et al., 2015). Impaired urination and defecation function leads to a neurogenic bladder and bowel. Pressure sores, urinary tract infections, and cardiopulmonary diseases may develop due

to lower limb paraplegia with long-term bed confinement (Noreau et al., 2000; Even-Schneider et al., 2007; Ragnarsson, 2008; Hagen, 2015). Quality of life significantly declines (Moghimian et al., 2015), and patients often die due to complications in advanced stages. The burden on society and the patient's family, as well as the complications of bed confinement, can be reduced by enabling paraplegics to regain standing and walking functions.

The gait orthosis used by SCI patients is also known as a paraplegic orthosis, and is designed to assist standing and walking; the basic functions include stabilization and support, locomotion assistance, correction, and protection. With advances in biomechanics, rehabilitation engineering, and rehabilitation equipment, including the clinical applications of a paraplegic gait orthosis, significant progress has been made in helping paraplegics stand and walk (Johnson et al., 2011; Arazpour et al., 2013, 2015a, b). Paraplegic levels and lower-extremity conditions vary among patients, who should be fitted with an appropriate paraplegic gait orthosis according to the SCI level, but there is no individuality with previous paraplegic orthosis in terms of different SCI planes and functional recovery of the lower extremities. Therefore, there is a great need to develop individualized paraplegic orthosis to improve quality of life for these patients.

Based on conventional rehabilitation therapies for thoracic and lumbar SCI patients, an individualized paraplegic gait orthosis was prescribed according to recovery status, with significantly improved sensation, motor function, activity of daily living (ADL), and locomotion after 3 months of training.

Subjects and Methods

Subjects

Thirty-six patients, treated in the First Affiliated Hospital of Nanchang University of China from January 2008 to December 2015, were enrolled in this study.

Inclusion criteria

Patients meeting all following criteria were included in the study: age: 16–70 years old; illness duration: > 30 days; SCI (below T₄); thoracic or lumbar SCI, not grade E of American Spinal Injury Association (ASIA) Classification (Waring et al., 2010).

Exclusion criteria

Patients meeting any of the following criteria were excluded: cognitive disorder, cancer, or other serious organ function damage; or did not consent to this study.

Based on the inclusion criteria, the patients were equally and randomly divided into an observation group and a control group.

The observation group comprised 13 males and 5 females, aged 17 to 56 years, with a mean age of 33.9 ± 11.1 years. SCI causes: crush injury in 3 cases, car accident in 9 cases, and a fall in 6 cases. SCI levels: thoracic SCI in 12 cases and lumbar in 6 cases. ASIA classification (Maynard et al., 1997): grade A, 9 cases; grade B, 4 cases; grade C, 3 cases; and grade D, 2 cases.

The control group comprised 11 males and 7 females, aged

16 to 62 years, with a mean age of 37.27 ± 10.18 years. SCI causes: crush injury in 4 cases, car accident in 10 cases, and a fall in 4 cases. SCI levels: thoracic SCI in 9 cases and lumbar in 9 cases. ASIA classification (Maynard et al., 1997): grade A, 8 cases; grade B, 6 cases; and grade C, 4 cases. General and disease details (course of disease, ASIA classification grade) between the two groups are listed in **Tables 1, 2**. This study was conducted in accordance with the *Declaration of Helsinki*. This study was approved by the Ethics Committee of Nanchang University of China. Written informed consent was obtained from all participants.

Rehabilitation training

All patients were given the following rehabilitation training for 3–4 hours every day:

(1) Maintenance of joint range of motion: joints above the SCI level were exercised daily by the patients themselves; joints below the SCI level received passive training by therapists, with particular emphasis on passive hip extension exercises for 20–30 minutes, once daily.

(2) Residual muscle strength training was based on specific circumstances. The upper limbs received resistance training for the deltoid, biceps brachii, triceps brachii, and latissimus dorsi; lumbar and dorsal muscles, and incompletely paralyzed lower limbs were exercised according to residual muscle strength. The treatment modes transitioned from therapist-assisted strength training to progressive resistance strength training. The upper limbs received support exercises and resistance training with dumbbells and sandbags; the lumbar and dorsal muscles received bridge exercise in the supine position, tension training with upper limbs extended in the sitting position, and load-bearing exercise and resistance training with sandbags on the lower limbs.

(3) Standing training was assisted with an electric tilt table, which started at 30° and gradually increased to 90°, followed by a gradual transition to parallel bar-assisted standing training, 40 minutes twice daily, to improve cardiorespiratory adaptation and promote lower extremity blood circulation; this was particularly important in long-term bed-confined patients to prevent and treat orthostatic hypotension.

(4) Balance training included gradual transition from a sitting position (including short- and long-term sitting) to an erect position, and from static balance to dynamic balance (including automatic and passive balance). Different exercise prescriptions were developed according to individual differences, and were usually adjusted according to heart rate and next-day fatigue.

(5) Functional electrical stimulation was applied to key muscles below the SCI level using a Physiomed-Expert diagnostic treatment meter (Germany); the stimulus intensity was set as the movement threshold, with stimulation applied for 20 minutes/session, for a treatment course of 15 sessions; 2 weeks of rest followed a treatment course before the next treatment course was started.

Paraplegic gait orthosis fitting and training

Based on the SCI level and the outcome of rehabilitation

Table 1 General information of the two groups

Group	Gender [n (%)]		Age (mean ± SD, years)	Course of disease (mean ± SD, days)	ASIA classification grade [n (%)]			
	Male	Female			A	B	C	D
Observation	13 (72.2)	5 (27.8)	33.9±11.1	25.00±4.52	9 (50.0)	4 (22.2)	3 (16.7)	2 (11.1)
Control	11 (61.1)	7 (38.9)	37.3±10.2	23.00±6.29	8 (44.5)	6 (33.3)	4 (22.2)	0 (0.0)
<i>P</i>	> 0.05		> 0.05	> 0.05	> 0.05			

ASIA: American Spinal Injury Association; ASIA grade A: complete injury; B, C, D: incomplete injury.

Table 2 Comparison of function between the two groups before rehabilitation therapies

Group	Motor function score	Sensory function score	ADL score
Observation	44.26±17.68	69.43±18.08	28.15±15.98
Control	39.54±23.24	71.27±22.20	26.09±20.68
<i>P</i>	> 0.05		> 0.05

ADL: Activity of daily living. Low motor function score and sensory function score indicate severe injury. Lower ADL score indicates poorer function.

Table 4 Spinal cord injury plane and walking function analysis in the observation group

	<i>n</i>	T ₃₋₁₂	L ₁₋₂	L ₃₋₅
Therapeutic locomotion	8	8	0	0
Family-based locomotion	7	3	4	0
Community-based locomotion	3	1	1	1
Sum	18	12	5	1

Number represents the numbers of patients.

Table 3 Comparison of motor function, sensation function, and ADL scores between the two groups before and after treatment

Group	Motor function score		Sensation function score		ADL score	
	Before	After	Before	After	Before	After
Observation	46.32±26.48	61.24±27.81*	59.38±20.03	80.01±19.99*	31.82±28.93	63.62±32.33*#
Control	42.31±18.67	51.98±21.31*	61.83±19.52	72.39±21.78*	22.01±18.77	29.98±28.33

**P* < 0.05, vs. before treatment (paired *t*-test); #*P* < 0.05, vs. control group after treatment (two-sample *t*-test). Data are expressed as the mean ± SD (*n* = 18). ADL: Activity of daily living.

Table 5 Basic rehabilitation targets of complete SCI

SCI level	Basic rehabilitation targets	PLB or wheelchair required
C ₅	Independent on-table activities, but otherwise needs help	Electrically powered wheelchair or manual wheelchair on plane ground
C ₆	Independent ADL, and could turn over the body and sit on bed	Manual wheelchair, various self-assistance facilities
C ₇	Independent ADL, sitting, supporting, shifting	Manual wheelchair, disabled-specialized vehicles
C ₈₋₄	The same as above, could stand aided by long pelvic brace	Long pelvic brace, crutches
T ₅₋₈	The same as above, could walk after trained with pelvic brace and crutches	The same as the above
T ₈₋₁₂	Independent ADL, could walk with crutches or long lower limb brace	Wheelchair, lower limb brace, crutches, disabled-specialized vehicles
L ₁	Independent ADL, could perform four-point walk with crutches or long lower limb brace	The same as the above
L ₂	Normal ADL, could walk with practical brace	The same as the above
L ₃	The same as above, could walk with elbow short lower limb brace	Short lower limb brace
L ₄	The same as above, could drive vehicles, and does not need wheelchair	The same as the above
L ₅ -S ₁	Could walk and drive vehicles	Foot support or short lower limb brace

ADL refers to diet, bathing, typing, reading, putting on and taking off clothes. PLB: Paraplegic locomotion brace; ADL: activity of daily living; SCI: spinal cord injury.

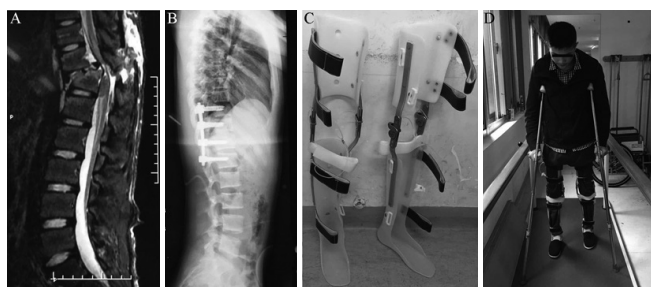


Figure 1 Knee-ankle foot orthosis for walking.

A 16-year-old male patient suffered from T₁₁₋₁₂ fractures and lumbar spinal cord injury caused by trauma. At 3 days after open reduction and internal fixation, comprehensive rehabilitation treatment was conducted for 27 days, and walk training with knee-ankle foot orthosis was performed for 3 months. (A) T₁₁₋₁₂ fracture L₂ spinal cord injury, American Spinal Injury Association: grade A. (B) Results of posterior open reduction and internal fixation of thoracic and lumbar spines for treating T₁₁₋₁₂ fractures. (C) Knee-ankle foot orthosis. (D) Assembling knee-ankle foot orthosis for walking. T₁₁₋₁₂: Thoracic 11-12 segments; L₂: lumbar 2 segment.

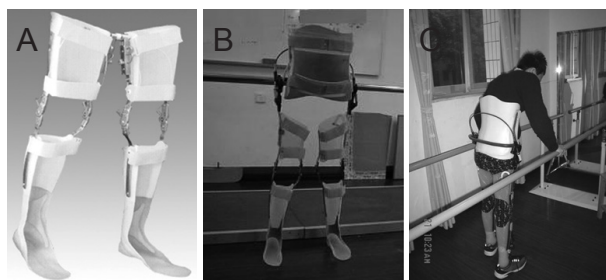


Figure 2 Paraplegic gait orthoses.

Walkabout (A), modified reciprocating gait orthosis (B), and movable ankle foot orthosis (C), respectively.

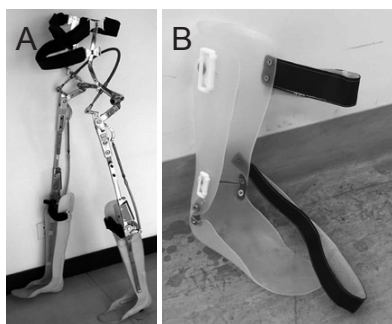


Figure 3 Assembling reciprocating gait orthosis for walking.

(A) Overall shape structure of reciprocating gait orthosis; (B) a patient with T₄ spinal cord injury and American Spinal Injury Association grade A wears reciprocating gait orthosis.

training, patients in the observation group were given an individualized paraplegic gait orthosis (provided by the Jiangxi Provincial China Disabled Persons' Federation, Nanchang, Jiangxi Province, China): two received a reciprocating gait orthosis; two received a Walkabout; nine received a bilateral hip-knee ankle foot orthosis; four received a bilateral knee-ankle foot orthosis; one received a unilateral knee-ankle foot orthosis, and one received an ankle foot orthosis (Figures 1-3). Above training was performed twice daily for 30-40 minutes.

Adjustment of a paraplegic locomotion brace should be performed during the first 7 days of wear, to correct posture and to achieve stable standing without crutches. After orthosis assembly and adjustment, in the observation group,

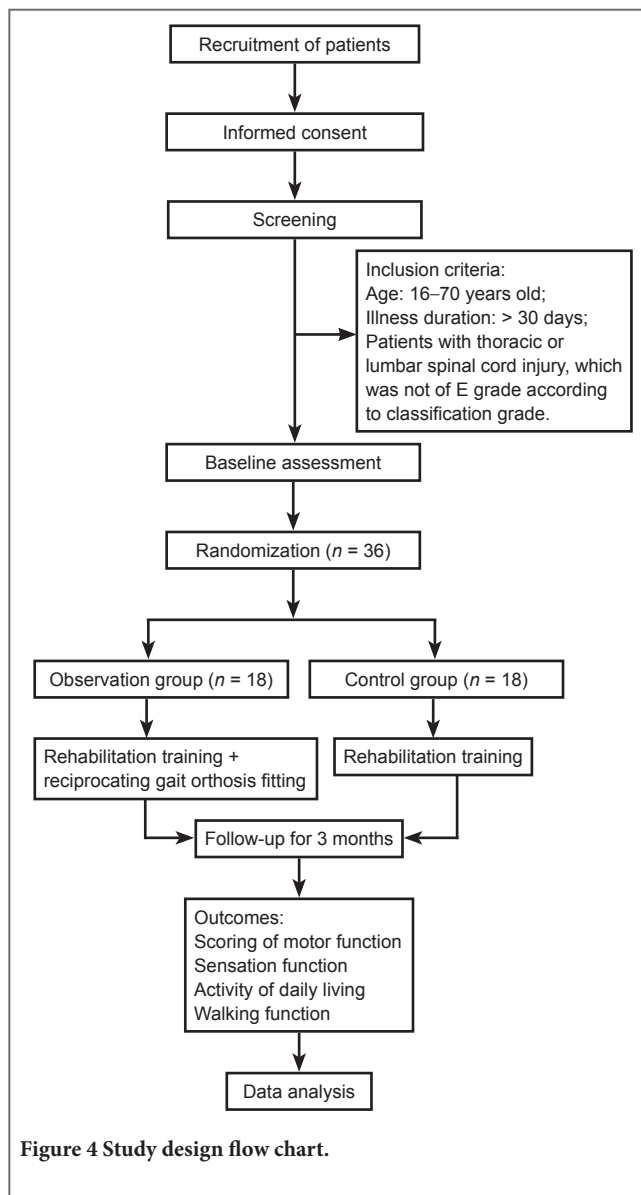


Figure 4 Study design flow chart.

intensive training was performed, including brace wearing and removal, standing balance function, conversion of gravity center, and ambulation; initial training with a four-wheeled walking aid gradually transitioned to axillary or elbow crutches as indicated. During initial training, one therapist stood behind the patient to assist with stepping; when the patient mastered this action, the therapist then verbally guided the stepping exercises. This was followed by parallel bar-assisted stepping, walking-assisted indoor level surface ambulation training, outdoor walking training, and slope walking training (advancement was based on mastery of the previous stage). When the patient became used to the paraplegic locomotion brace, the brace wearing and removal exercises were performed gradually, because they required better sitting balance, waist and abdominal strength, and movement coordination; most patients needed a certain period of exercise to achieve independent brace wearing and removal.

Evaluation criteria

Efficacy was evaluated by observing changes from baseline to after 3 months of treatment, and by inter-group comparison, which included motor function, sensation function, ADL, and walking ability scoring. ADL was assessed using the modified Barthel Index; and walking ability was assessed using the average maximum walking distance over 3 consecutive days. The low motor function score and sensory function score indicated severe injury. Low score of ADL indicated poor function.

Statistical analysis

Data, expressed as the mean \pm SD, were analyzed with SPSS 13.0 software (SPSS, Chicago, IL, USA). Mean values of inter-group and intra-group were compared using the two-sample *t*-test or paired *t*-test. The data of gender and SCI grade were compared using the chi-square test. A value of $P < 0.05$ was considered statistically significant.

Results

Quantitative analysis of participants

Thirty-six patients were included in the final analysis, with no drop-outs. The study design flow chart is exhibited in Figure 4.

Motor function, sensation function, and ADL

After 3 months of comprehensive systematic rehabilitation, motor function, sensation function, and ADL were significantly improved in the observation and control groups ($P < 0.05$). However, the observation group exhibited much greater improvement in ADL, with a statistically significant difference compared to the control group ($P < 0.05$; Table 3).

Walking function

In the observation group, no patient was able to walk prior to treatment. However, following treatment, all could walk 50–1,400 m using the paraplegic locomotion brace, with a median of 620 m; 7 patients achieved therapeutic locomotion; 5 achieved family-based locomotion, and 2 achieved community-based locomotion (Table 4). Additionally, no patient in the control group exhibited walking ability before or after treatment.

Discussion

Epidemiological analysis

SCI is usually caused by trauma. In the 1980s, most SCI cases in China were caused by falling, but the incidence of SCI caused by car accidents significantly increased in the 1990s (Löfvenmark et al., 2015), primarily in young men. In this study, all 36 patients had SCI caused by trauma, with a mean age of 35.37 ± 12.39 years. There were 24 males and 12 females, and the causes of SCI, age distribution, and gender were all consistent with epidemiological data.

Impact of rehabilitation intervention time on ADL

Studies have shown that rehabilitation intervention time

has a major impact on ADL prognosis in SCI patients. Early functional training after the disease condition stabilizes shows a more favorable effect on ADL recovery (Abdul-Sattar, 2014).

SCI rehabilitation should begin the day after injury. A clinical study (Krause et al., 2000) by the Shepherd Spinal Cord Injury Center (USA) showed that patients who began rehabilitation within 2 weeks after injury exhibited a hospital recovery time of only 30 days, and the highest functional independence measure score obtained was 41 points. Conversely, patients who began rehabilitation 3 months after injury had a longer hospital stay, and the highest functional independence measure score was only 22 points. Clearly, early rehabilitation improved ADL in patients with SCI, and also confirmed that earlier rehabilitation resulted in a shorter hospital stay, lower cost, improved functional outcome, and fewer complications.

Most patients in this study began rehabilitation 1 month after injury, and received early systematic rehabilitation treatments, which made early standing and walking possible with the assistance of a paraplegic locomotion brace.

Motor function, sensation function, and ADL of patients in these groups significantly improved after rehabilitation treatment, but there was no statistical difference in motor and sensation function between the two groups. However, ADL in the observation group showed statistically significant improvement compared with the control group. These findings suggested that although the use of a paraplegic locomotion brace did not significantly improve motor and sensation functions, it could significantly improve ADL.

Significance of walking for SCI patients

The basic premise of participation in society and work is the ability to walk, which is also necessary for maintaining musculoskeletal and cardiopulmonary functions. The psychological impact of walking is also significant in these patients. Walking can be divided into therapeutic walking and functional walking. Although therapeutic walking has no practical purpose, it has significant therapeutic value, and also provides psychological support. Walking reduces the incidence of pressure sores, prevents osteoporosis, improves blood circulation, prevents deep vein thrombosis, and promotes urination and defecation (Ragnarsson, 2008). Functional walking can also be divided into family-based and community-based walking.

Functional walking should meet the following criteria: (1) safety: stability should be maintained when walking, independent of help from others, with the ability to climb without fear of falling; (2) posture should be normal; (3) a walking frame or other heavy walking aid should not be required; (4) other actions with the hands should be possible when standing; (5) walking should not require excessive effort; (6) attention should not require excessive focus on walking; (7) cardiovascular function should benefit from walking; (8) walking should be possible with a certain speed and endurance, *i.e.*, 5 minutes continuously, for a distance of about 550 m.

Use of a gait orthosis is important for both physical and

mental rehabilitation of SCI patients and the prevention of complications. Even if practical walking is not possible, standing and walking training assisted by an orthosis can delay muscle atrophy, prevent cramping and contractures, reduce osteoporosis (Paley and Livingstone, 2015), improve bladder function, prevent pressure sores and deep vein thrombosis, and improve heart and lung function (Fenu-ta and Hicks, 2014), thereby significantly improving ADL (Nordström et al., 2013).

The application of a gait orthosis can help patients transition from bed confinement to standing or walking, and can overcome post-paraplegia depression or panic. Patients can feel normal and can interact with other normal people, and self-reliance and self-confidence can improve. Walking can also increase activity space, facilitate functional ambulation (Arazpour et al., 2014), and improve quality of life, enabling early full recovery and return to family and society.

Therefore, it is important to correctly determine the indications and prescription for a paraplegic locomotion brace.

Correlation between SCI level and paraplegic locomotion brace

The rehabilitation levels of SCI patients correlated with their injury sites: C_7 is a key level for recovery of ADL, and those with SCI below C_7 can achieve full self-care; C_8 is a key level for wheelchair independence, and those with SCI below C_8 can achieve full independence; and T_{3-12} , L_{1-2} , and L_{3-5} are key levels for therapeutic walking, family-based walking, and community-based walking, respectively. Therefore, most patients with thoracic or above-complete paraplegia would have to live in a wheelchair, and only those with below- L_1 complete paraplegia might achieve standing and practical walking after training. Through effective rehabilitation, as well as proper use of a gait orthosis, some paraplegics can recover standing and walking functions.

In complete SCI, the basic rehabilitation targets are known (Table 5). In incomplete SCI, the rehabilitation targets need to be revised based on remaining muscle strength and function. In thoracolumbar complete SCI, the total functional loss of the gluteus maximus and iliopsoas prevents control of the pelvis and torso for standing. These patients can use a reciprocating gait orthosis, advanced reciprocating gait orthosis, isocentric reciprocating gait orthosis, or Walkabout for functional walking. The paraplegic locomotion brace level has been reported in many studies, with use of the Walkabout and isocentric reciprocating gait orthosis in T_{8-12} SCI (Suzuki et al., 2007; Samadian et al., 2015), advanced reciprocating gait orthosis in below- C_6 SCI (Santamato et al., 2010), and advanced reciprocating gait orthosis and reciprocating gait orthosis in T_5-L_1 SCI (Ohta et al., 2007; Chen et al., 2009). Although the reciprocating gait orthosis and advanced reciprocating gait orthosis application levels remain poorly understood, patients with above- T_6 thoracic SCI should receive special attention. Factors, such as age, body size, upper limb strength, trunk control, and abdominal strength, should

be considered.

For walking function, T_{3-12} , L_{1-2} , and L_{3-5} are key levels for therapeutic walking, family-based walking, and community-based walking, respectively. The following criteria should be met to achieve community-based walking: (1) ability to tolerate a brace all day; (2) ability to walk continuously for about 900 m, (3) ability to climb up and down stairs, and (4) independence for ADL. Patients who can perform all but #2 can be considered as having achieved family-based walking; other than the ability to achieve speed and endurance, they can perform home activities. Patients who cannot meet criteria #1 to #4, but can perform short-distance walking with knee-ankle foot orthosis and crutches, should be considered as having achieved therapeutic walking. In the observation group, among the 12 patients with T_{3-12} SCI, 8 achieved therapeutic walking, and 1 with T_4 complete SCI achieved functional walking after being fitted with a reciprocating gait orthosis; 3 achieved family-based walking, and 1 achieved community-based walking. Among the 5 patients with L_{1-2} SCI, 4 achieved family-based walking, and 1 achieved community-based walking. One patient with L_{3-5} SCI achieved community-based walking, indicating that early comprehensive systematic rehabilitation intervention, combined with individualized paraplegic locomotion brace, could significantly improve walking function.

Conclusions

Improvement and recovery of walking ability in SCI patients have positive physiological and psychological therapeutic values. Early standard rehabilitation intervention time can significantly improve motor function, sensation function, and ADL scores in SCI patients. Early standard rehabilitation intervention time combined with individualized paraplegic locomotion brace can significantly improve ADL and walking function.

Declaration of patient consent: The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

Author contributions: LS and ZF designed the study. LS, GHY, LZ and YY performed experiments. WSW and WMS analyzed data. ZF wrote the paper. All authors approved the final version of the paper.

Conflicts of interest: None declared.

Plagiarism check: This paper was screened twice using CrossCheck to verify originality before publication.

Peer review: This paper was double-blinded and stringently reviewed by international expert reviewers.

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