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Clinical Article

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Exoskeleton-assisted Gait Training in Spinal Disease With Gait Disturbance

Tak Gun Jang [1], **Su Hong Choi** [2], **Seung Han Yu** [1], **Dong Hwan Kim** [1], **In Ho Han** [1], and **Kyoung Hyup Nam** [1]

[1]Department of Neurosurgery, Biomedical Research Institute, Pusan National University Hospital, Pusan National University School of Medicine, Busan, Korea
[2]Department of Rehabilitation Medicine, Biomedical Research Institute, Pusan National University Hospital, Pusan National University School of Medicine, Busan, Korea

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Address for correspondence:
Kyoung Hyup Nam
Department of Neurosurgery, Biomedical
Research Institute, Pusan National University
Hospital, Pusan National University School
of Medicine, 179 Gudeok-ro, Seo-gu, Busan
49241, Korea.
Email: goodnsdoctor@daum.net

ORCID iDs
Tak Gun Jang
https://orcid.org/0000-0001-8831-8758
Su Hong Choi
https://orcid.org/0000-0002-2940-0871
Seung Han Yu
https://orcid.org/0000-0003-0086-3204
Dong Hwan Kim
https://orcid.org/0000-0001-8982-7917
In Ho Han
https://orcid.org/0000-0001-7193-6533
Kyoung Hyup Nam
https://orcid.org/0000-0002-3749-4660

Conflict of Interest
The authors have no financial conflicts of
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ABSTRACT

Objective: Gait impairment reduces a patient's quality of life. Exoskeletons and wearable robotics enable patients with gait disturbance to stand up and walk. An exoskeleton was developed for use in patients with stroke and spinal cord injuries. This study aimed to evaluate the effectiveness of overground exoskeleton-assisted gait training (OEGT) in spine diseases with gait disturbance.

Methods: This was a single-group preliminary study. Five participants with gait disorders because of root dysfunction accompanying spinal stenosis were included in this study. All participants underwent surgical treatment and an exoskeleton training protocol scheduled for 2 or 3 days per week for 4 weeks. Each session was 60 minutes. Clinical tests were performed before (T1) and at the end of the training (T2).

Results: One patient dropped out of the study because of medical issues that were not associated with the exoskeleton. Exoskeleton-assisted rehabilitation was feasible for all participants. All participants showed positive changes in gait performance, balance, proximal muscle strength, psychological state, and satisfaction with the rehabilitation. However, there was no significant improvement in neurological deficits.

Conclusion: OEGT is a feasible rehabilitation method for patients with gait disorders caused by degenerative spinal disease.

Keywords: Exoskeleton device; Robotics; Rehabilitation; Gait; Spinal stenosis

INTRODUCTION

Exoskeleton, wearable robotics for rehabilitation has been received a lot of attention over last several decades. Exoskeleton has been applied for restoration of walking ability in patients with gait dysfunction after spinal cord injury and stroke.[3,7,10,14,18,19,22,26] Exoskeleton could support standing and walking ability outside the clinical setting.

Exoskeleton-assisted gait training provides repetitive, high-intensity and high-dose practices compared to the traditional rehabilitation.[11] Wearable exoskeleton could facilitate early mobilization in patients who are unable to maintain the upright position.[10] Furthermore, exoskeleton enables patients to stand up and walk over ground regardless of severity

of weakness.[23] The efficacy and safety for stroke and spinal cord injury have been well established in the literatures.[3,10,13,14,23]

Most of previous studies have investigated the feasibility of the exoskeleton in the patients with stroke and spinal cord injury. The aims of this preliminary study were to evaluate the efficacy and feasibility of the overground exoskeleton-assisted gait training (OEGT) in the patients with an impairment of lower limbs because of spine root disorders.

MATERIALS AND METHODS

Ethics approval
The study was approved by the Institutional Review Board of Pusan National University Hospital (IRB No. 1906-018-080), and written informed consent was obtained from all patients.

Study design
This study was a preliminary single group observational study to investigate the efficacy and safety of OEGT. Medical screening for compatibility and safety were underwent by neurosurgeon and physiotherapist before exoskeleton-assisted gait training.

Participants
Five consecutive patients with gait disturbance because of spinal root dysfunction were enrolled in current study. Patients with previously neurologic deficit after brain or spinal cord disorders were excluded from the study. All patients underwent spinal surgery such as decompression or fusion by single neurosurgeon. All participants have no other conditions that prevented participation including uncontrolled hypertension, cognitive deficits, unhealed fractures, inadequate height and weight. One patient was dropped from current study due to medical problem. **TABLE 1** summarizes the demographic and clinical characteristics of the participants.

Exoskeleton device walking training
OEGT were scheduled during perioperative period. The powered exoskeleton used in this study was the ExoAtlet Medy® (EAM®; ExoAtletasia, Seoul, Korea) (**FIGURE 1**). This device has motors at the hip and knee joints which make the lower extremities move. EAM programs the natural gait pattern of non-disabled people so that the angle of flexion and extension of the ankle joint can be maintained close to normal during gait training while applying a force close to normal to each joint of the lower extremity. This device can be used in patients with height from 155 to 185 cm and weight less than 100 kg. Various modes can adjust the walking width, speed, and height according to the characteristics of the patient.

TABLE 1. Demographic and clinical characteristics of the participants at baseline

Participants	Age	Sex	Height (cm)	Weight (kg)	Causative nerve dysfunction	Motor power*	Duration of weakness (months)
1	65	M	160	67	Right L5	2/5	26
2	49	M	175	77	Cauda equina	1/5	1
3	64	M	151	56	Right L5	2/5	38
4	47	F	141	52	Cauda equina	2/5	1

L: lumbar.
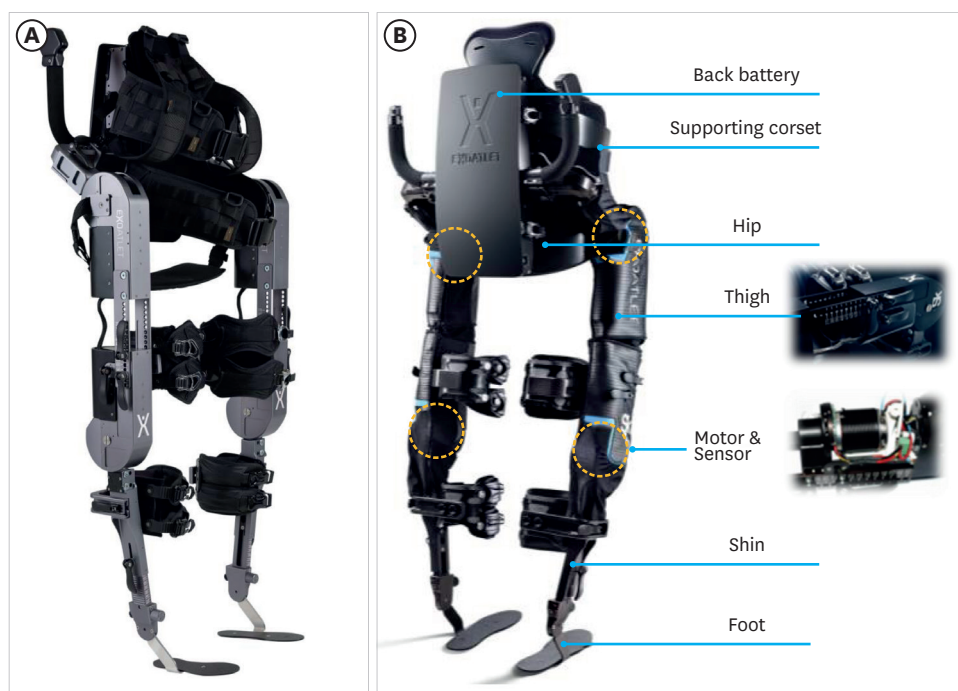*Motor power is measured in five-point scale: score/5.

FIGURE 1. ExoAtlet Medy® and detailed structure description. (A) Anterior image; (B) Posterior image and detailed structure description.

Before the rehabilitation protocol, each participant received theoretical training on the EAM by physical therapist. Participants have times to become familiar with the EAM. Physical therapist measured for device fit and adjusted the EAM for the patients. OEGT protocols were scheduled for 4 or 8 weeks and the number of sessions per week ranged 2 to 3. The duration of each session was 60 minutes.

Training protocol included sit-to-stand, static standing balance, dynamic standing balance weight shifting, stepping, pivot turns and free walking. To increase the safety of OEGT, a mobile suspension was applied (**FIGURE 2**). Certified physical therapist guided every training session for safe and feasible rehabilitation.

Clinical tests

Before and after the OEGT rehabilitation protocol, several clinical tests were conducted by the single researcher. Clinical evaluation was performed before the OEGT (T1) and at the end of the OEGT (T2).

The main clinical tests as follows:
    a) Muscle atrophy (calf circumference)
    b) Vital sign (heart rate/blood pressure /peak flow)
    c) 6m walking test
    d) Timed Up and Go (TUG) test
    e) Berg balance scale
    f) Modified geriatric depression scale
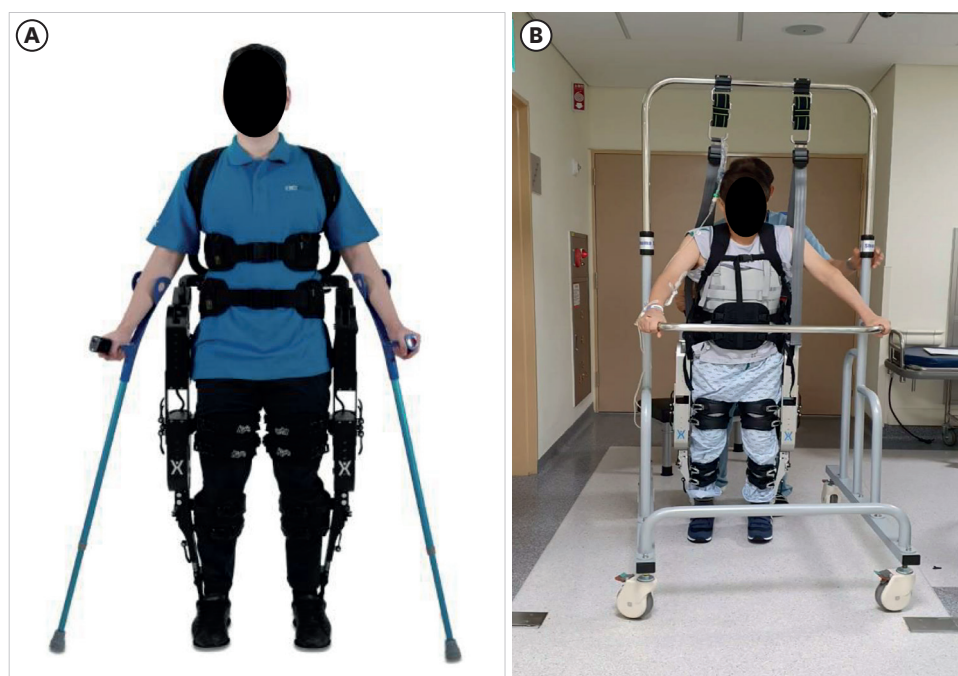
FIGURE 2. Weight transfer with crutch and mobile suspension. (A) Crutch-assisted exoskeleton; (B) Mobile suspension for reinforce safety.

RESULTS

Four patients enrolled in this study, 1 female and 3 males. Only one participant had suffered weakness on both lower extremities, others showed the weakness on single lower extremity and limping gait. All participants had undergone spine surgery for spinal stenosis caused the neurologic deficit and OEGT was started 1 week after surgery.

TABLE 2 shows the clinical results of OEGT. All participants showed positive changes in gait performance, balance, proximal muscle strength, psychologic state and satisfaction of rehabilitation. After 4 weeks OEGT, calf circumference showed no significant differences. Two patients could not complete 6m walking test and one patient could complete the test after OEGT. Other patients showed improvement of walking speed on the 6m walking test. Similar to the results of 6m walking test, 3 participants demonstrated the improvement of TUG test and BBS. The result of depression-related scale showed improvement in the patient's psychological state. There was no significant improvement of muscle strength on the affected lower extremity. Adverse events were not reported during OEGT period in all participants. The clinical results were not analyzed statistically because of the small sample size.

DISCUSSION

Walking is one of the most important human movements. Gait impairment could be caused several pathologic conditions including stroke, spinal cord injury, Parkinson disease and spinal root problems. Gait impairment caused depression, poor quality of life, and economic issue.[10,20] Furthermore, limited mobility results in lifelong wheelchair and high risk of

TABLE 2. Results of clinical test

Clinical tests	Participants	T1	T2
Muscle atrophy (cm)	1	32	32.5
	2	41	41
	3	32	32.5
	4	29	28.8
6m walking test (seconds)	1	Incomplete	60
	2	Incomplete	Incomplete
	3	35	30
	4	30s	25
Timed Up and Go test (seconds)	1	Incomplete	40
	2	Incomplete	Incomplete
	3	30	20
	4	40	30
Berg balance scale	1	9	12
	2	4	4
	3	12	13
	4	17	21
Modified geriatric depression scale	1	9	5
	2	11	8
	3	5	3
	4	5	2

T1: measurement before the overground exoskeleton-assisted gait training. T2: measurement at the end of the overground exoskeleton-assisted gait training.

chronic disease.[1,2,9] Balance alteration also significantly limit the physical activity which result in deterioration of walking and deconditioning in chronic state.[17]

Prolonged immobilization result in several systemic disorders such as cardiovascular disease, urinary dysfunction, gastrointestinal disorders, pulmonary diseases, neuropathic pain, musculoskeletal weakness, osteoporosis, pressure ulcer and psychological disorders.[23] Rehabilitation for gait and balance are very important in improving the quality of life and preventing chronic deterioration. The purpose of the rehabilitation in patients with gait dysfunction are not only strength of lower limbs but also the entire body.[12,21]

Rehabilitation robotics emerged in the 1908s to assist neurologically motor impaired patients using robotic technology.[26] Recently, several robotic exoskeletons have been widely used as rehabilitation methods for clinical use.[3-7,10,14,18,19,22,26] Many recent studies have reported the efficacy of robot-assisted rehabilitation. Locomotor training with robotic-assistant rehabilitation is beneficial for improving gait function in patients after stroke and spinal cord injury.[25] Particularly, overground walking rehabilitation using robotics demonstrated effectiveness.[8,24]

Exoskeletons enable patients keeping upright position and helping overground walking. Due to the possibility to train in an upright position, exoskeletons may have a beneficial effect on preventing secondary health complications.[3,18] The first goal of OEGT is gait training and improvement of walking ability. However, the results of OEGT have been also demonstrated the improvement in pain, spasticity, bowel and bladder function.[12,21,23] OEGT also showed significant improvement in balance.[11,12,15] Recent technologies of exoskeleton provide safe and intensive rehabilitation therapy using repeated motions. OEGT show greater efficacy of rehabilitation therapy and improvement in the functional status than conventional physical training with a physical therapist.[16,22]

The aim of the present study was to investigate the feasibility and clinical effects of the rehabilitation with OEGT in neurologically impaired patients because of spine root dysfunction. Although not as severe as spinal cord injury or stroke, all participants were suffered from gait and balance impairment due to lower limb weakness. As a result, these patients are also at risk of deteriorated life quality, psychologic issue, and general conditions. By this reason, OEGT of 4 weeks intensive training program were scheduled in current study.

In the present study, greater improvement in overground gait function and impaired single limb were not observed. However, the feasibility was showed in balance, psychologic confidence and satisfaction of training. However, the results were not statistically significant because of the small sample size. All participants tolerated the intensive exoskeleton protocol and satisfied the robotic rehabilitation, although general aches were observed after 1st and 2nd training. Of the clinical measurement, there were marked improvement at the end of protocol in 6m walking test, time up and go test, balance scale and psychologic mood. Although a similar effect could be predicted in conventional physical therapy, OEGT has the advantage of allowing the patient to start early intensive training and overground walking. Early walking using robot could give the patient the possibility and motivation for movement outside the bed.

This study has several limitations. The current study is single observation study and was the lack of a control group composed of patients who underwent traditional rehabilitation only. Despite these limitations, all efforts were made to standardize procedures and instructions during assessments. Next, the number of participants was limited because of only patients who had suffered gait disorder due to spinal root injury. Thus, the results of this study are not generalizable to the large population. Lastly, the robotic training protocol is implanted only for a short period of 4 weeks. The effect of long-term training could not be predicted.

CONCLUSION

OEGT may be a safe and feasible rehabilitation method in patients with gait disorders because of spinal root dysfunction. This method has particularly effective in balance function and psychological support. Further investigation regarding long term in large population is necessary.

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