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Original Article

Gait reconstruction using the gait assist robot WPAL in patients with cervical spinal cord injury

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ABSTRACT
Fuse I, Hirano S, Saitoh E, Otaka Y, Tanabe S, Katoh M, Gotoh T, Tsunogai S, Kumagai A, Tsunoda T, Koyama S. Gait reconstruction using the gait assist robot WPAL in patients with cervical spinal cord injury. Jpn J Compr Rehabil Sci 2019; 10: 88−95.
Objective: We evaluated the gait ability of patients with cervical spinal cord injury using the Wearable Power-Assist Locomotor (WPAL) and compared the ability with when they used an orthosis.
Methods: Five patients with cervical spinal cord injury were instructed to walk while wearing an orthosis or WPAL. Functional Ambulation Categories (FAC) score, continuous walking time and distance, subjective exercise intensity, upper limb fatigue, and Physiological Cost Index (PCI) during a 3-minute walk were evaluated. Each index was compared between the conditions of wearing an orthosis and using WPAL.
Results: Among the 5 patients, 3 showed higher FAC scores when walking using WPAL than when walking with an orthosis, while the other 2 patients showed no difference. In addition, 3 patients were capable of independent gait. The continuous walking distance was significantly longer when using WPAL than when using an orthosis ($p < 0.05$). Walking speed, stride length, and cadence were greater when using WPAL in all patients, and PCI was lower when using WPAL in all patients.
Conclusion: Compared with an orthosis, WPAL is useful for achieving gait reconstruction in patients with cervical spinal cord injury.
Key words: cervical spinal cord injury, quadriplegia, robot, orthosis, gait reconstruction

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Introduction

The incidence of traumatic spinal cord injury in Japan is approximately 40 per million, with cervical spinal cord injury accounting for three-quarters and thoracolumbar spinal cord injury for one-quarter of the injuries [1]. Approximately 17% of cervical spinal cord injuries result in complete motor paralysis [2]. In the case of incomplete paralysis, a certain degree of spontaneous recovery is observed, and not a few patients are able to acquire gait function. On the other hand, gait ability is almost entirely lost in patients with complete paralysis [3]. In the case of complete quadriplegia, the ambulation method to be targeted differs depending on the level of injury. Wheelchair maneuvering is possible if the neurological level is C5 to C8; especially, many patients with injuries at level C7 or C8 are capable of using a wheelchair as a practical means of ambulation and are independent in activities of daily living [4]. However, long-term wheelchair use causes various medical problems such as pressure ulcers, osteoporosis, joint contracture, constipation, and obesity [5, 6]. In addition, constantly living at a lower eye level than healthy people is a source of stress for persons with spinal cord injury and impedes their redefining of self [7]. Many people with spinal cord injury, even if they can ambulate by wheelchair, desire to stand and walk again [8].

Various orthoses have been developed to realize gait reconstruction for people with spinal cord injury. These devices are classified into lateral and medial

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systems. The lateral system is a structure in which the left and right knee-ankle-foot orthoses are connected to a hip orthosis (pelvic band) on the lateral sides of the hip joint. Some examples of lateral system orthoses are the Reciprocating Gait Orthosis (RGO) [9], Hip Guidance Orthosis [10], and Advanced RGO which is a RGO with a modified linkage mechanism and hip joint trajectory [11]. On the other hand, the medial system is a structure in which the left and right knee-ankle-foot orthoses are connected by a joint located on the medial side of the patient's hip joint. Some examples of medial system orthoses are the Walkabout [12], Primewalk [13, 14], and Hip and Ankle Linked Orthosis (HALO) [15]. The medial system orthosis has a single joint and no hip orthosis, and therefore has fewer parts that may cause deflection than the lateral system, and a stable standing position can be maintained [16]. In addition, this type of orthosis has additional merits of having no structures on the lateral sides of the hip, allowing the orthosis to be worn while in a wheelchair, and not having to wear a hip orthosis allows the user to maintain a comfortable sitting position.

However, some fundamental problems remain for patients with spinal cord injury to recover gait ability using an orthosis. In all the above-mentioned orthoses, the knee joint is fixed to provide stability in the standing position. For this reason, patients with insufficient muscle strength in the upper limbs experience difficulties in standing up and sitting down. During walking, the lower limb is swung out by moving the center of gravity from back to front and from left to right, relying on the strength of the upper limbs. As a result, the burden on the upper limbs and the cardiopulmonary system is large, and it becomes difficult to walk a long distance. Therefore, most patients use the orthoses only for training; very few are able to walk using these orthoses in daily life.

With the goals of resolving the problems of conventional orthoses, facilitating standing up and sitting down in a wheelchair, and enabling walking on level surfaces in daily life, progress has been made in the development of gait assist robots worldwide. Many of the devices are lateral system gait assist robots that incorporate power-driven mechanisms into the structure of lateral system orthoses. These devices have been somewhat successful in achieving gait reconstruction for patients with complete paraplegia caused by thoracolumbar spinal cord injuries. Yang et al. [17] evaluated ReWalk™ in 11 paraplegic patients classified as grade A or B on the American Spinal Injury Association (ASIA) impairment scale, and reported that 4 patients achieved independent gait and 3 patients achieved gait under supervision. Hartigan et al. [18] used Indego® in 11 patients with ASIA impairment scale grade A or B paraplegia, and reported that 7 patients achieved gait under supervision. Kozlowski et al. [19] used Ekso™ in 4 patients with ASIA impairment scale grade A or B paraplegia, and reported that 1 patient achieved gait under supervision. However, there are few reports of using these robots in patients with cervical spinal cord injury. Contreras-Vidal et al. [20] conducted a literature review of 22 articles on gait assist robots for patients with spinal cord injury and reported the neurological levels of the subjects. According to their report, of all 130 subjects with spinal cord injuries reviewed, the majority had lower thoracic level injuries and 10 had cervical level injures, 6 of the latter had motor complete injuries. A total of 2 patients, one using ReWalk™ and one using Ekso™, both of whom had level C8 injury, acquired independent gait or gait under supervision using a robot. In addition, Hartigan et al. [18] conducted gait training using Indego® in 3 patients with cervical spinal cord injury (neurological level C5 or C6, ASIA impairment scale grade A or B), and reported that all 3 required assistance.

Since 2005, our group has been developing the Wearable Power-Assist Locomotor (WPAL), a wearable gait assist robot that incorporates power and control mechanisms into a medial system orthosis [21, 22]. WPAL has a total of six motors for bilateral hip joints, knee joints and ankle joints, mounted on a frame resembling a knee-ankle-foot orthosis with a medial hip joint. Until now, WPAL has been used mainly for reconstruction of gait function in paraplegic patients. Hirano et al. [23] evaluated WPAL in 12 paraplegic patients, and reported that all 12 subjects achieved independent gait, and that the continuous walking distance was significantly longer when using WPAL than when using an orthosis. WPAL with a medial system structure is expected to have less deflection and greater stability during standing compared to gait assist robots with a lateral system structure, and may be useful for achieving gait reconstruction also by patients with cervical spinal cord injury. Therefore, the present study attempted to achieve gait reconstruction using WPAL in patients with cervical spinal cord injury, and to compare gait ability in these patients when using WPAL and when using a conventional orthosis.

Methods

1. Subjects

We evaluated 5 patients with cervical spinal cord injury classified as ASIA impairment scale grade A or B and treated as outpatients at Fujita Health University Hospital, who had undergone adequate gait exercise using WPAL as well as medial system orthoses such as Primewalk and HALO. The protocol for this study was reviewed and approved by the ethics committee of our hospital. Informed consent was obtained from all the subjects after receiving detailed written explanations of the protocol. The characteristics of the subjects are shown in Table 1.

Table 1. Characteristics of subjects.

Subject	Neurological level	ASIA impairment scale	Age (yrs)	Gender	Years after injury	Orthosis	No. of training sessions	
							Orthosis	WPAL
A	C7	B	58	M	4	Primewalk	~400	20
B	C7	A	26	M	10	Primewalk	79	46
C*	C6	A	30	M	4	HALO	~140	~120
D	C6	B	28	F	4	Primewalk	~150	30
E	C6	B	70	M	16	Primewalk	358	230

ASIA, American Spinal Injury Association; WPAL, Wearable Power-Assist Locomotor; HALO, Hip and Ankle Linked Orthosis; M, male; F, female.
*In this subject with combined cervical injury and thoracolumbar injury, the neurological level of motor function was C6 on the right and T10 on the left.

2. Gait exercise

Before introducing WPAL, each subject practiced orthosis-assisted gait using medial system orthoses such as Primewalk (Figure 1) and HALO until their ability of orthosis-assisted gait reached almost a plateau. Thereafter, gait exercise using WPAL (Figure 2) was conducted more than 20 times until the patient was judged to have more or less mastered walking using WPAL. At this time point, the present study was implemented. The gait exercise program using WPAL in our hospital followed the five-step training method reported by Tanabe et al. [22]. The five steps were performed in the following order: (1) stepping exercise within parallel bars (with safety harness), (2) gait exercise within parallel bars (with safety harness), (3) treadmill gait exercise (with safety harness), (4) gait exercise using a walker (with safety harness), and (5) gait exercise using a walker (without safety harness). The number of training sessions was counted based on the records in medical charts. In the case that the patient had received training in another hospital and then started orthosis-assisted and WPAL-assisted gait exercise in our hospital, it was difficult to determine the exact number of training sessions. In this case, information of the duration and frequency of training was obtained from the patient and the number of sessions was estimated.

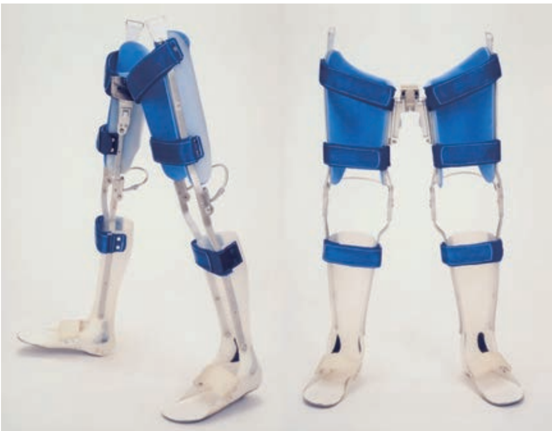

Figure 1. Primewalk.
Primewalk consists of left and right knee-ankle-foot orthoses connected to a medial hip joint. Since the knee-ankle-foot orthoses are connected directly by a hip joint, no hip orthosis is required, consequently the trunk is not restricted. As there are no large structures on the lateral sides of the patient’s hip, the device can be used with a wheelchair. Since there is only one connecting joint and no hip orthosis is needed, there are few deflecting parts, allowing high stability in the standing position.

Figure 2. Wearable Power-Assist Locomotor (WPAL).
WPAL is a gait assist robot for the purpose of gait reconstruction in patients with spinal cord injuries. WPAL has six motors for the bilateral hip joints, knee joints, and foot joints, mounted on a frame resembling a medial system type orthosis. By using a special walker equipped with a motor control circuit and battery, safety is guaranteed and the burden on the patient is reduced. Using the two lever switches and two button switches on the walker, the patient is capable of performing all the operations alone.

3. Gait measurements

Each subject was evaluated when using an orthosis and using WPAL. After wearing the orthosis or WPAL, the subject was instructed to walk continuously at a comfortable speed, and the degree of gait independence was evaluated using Functional Ambulation Categories (FAC) [24]. As an upper limb assistive device, the same walker was used by all the subjects both during orthosis-assisted gait and WPAL-assisted gait (height and wheel brakes were adjusted individually). With both the orthosis and WPAL, when a subject was able to walk without continuous physical assistance, he/she was encouraged to walk for as long a distance as possible. During that time, continuous walking distance and time were measured, and walking speed, stride length, and cadence were calculated. Each test was performed multiple times, and the results for the trial with the longest walking distance were used for the analysis. Each subject used their own orthosis. During walking, the subject wore an earlobe pulse oximeter (Pulsefit MP-1000®, Japan Precision Instrument Inc.). Walking was stopped when the heart rate reached a target value (220−age), when the subject complained of fatigue, or when continuous walking became difficult. Considering fatigue of the subject, in principle measurement of continuous walking time and distance was conducted once a day, and if two or more measurements were performed in the same day, they were done with sufficient rest in between. Figure 3 shows the setting of gait measurement in a person with cervical spinal cord injury.

For subjects who were able to walk independently or under supervision under both conditions of using an orthosis and using WPAL, they were instructed to walk for 3 minutes. Every 30 seconds, subjective exercise intensity (evaluated by the modified Borg scale), level of fatigue of upper limbs (scored on a 10-point scale adapted from the modified Borg scale), and pulse were recorded to calculate the Physiological Cost Index (PCI) [25]. When orthosis-assisted gait or WPAL-assisted gait for 3 minutes could not be completed due to fatigue of the upper limbs or whole body, the data of the last completed 30-second measurements were used as the results for the orthosis and WPAL conditions.

Figure 3. A patient with spinal cord injury practicing gait.
A 26-year-old man classified as ASIA impairment scale grade A with neurological level C7. Left: using Primewalk; right: using WPAL and walker. The patient can walk independently using either device.

4. Analytical items

The FAC score, continuous walking time, continuous walking distance, walking speed, stride length, cadence, 3-minute walk PCI, subjective exercise intensity when walking stopped, and fatigue of upper limbs measured when using an orthosis were compared with the data obtained when using WPAL.

Wilcoxon's signed rank test was used to compare FAC score, subjective exercise intensity, and fatigue of upper limbs for the 3-minute walk. The paired t-test was used to compare continuous walking time, continuous walking distance, walking speed, stride length, cadence, and PCI for the 3-minute walk. Statistical analyses were performed using SPSS® Statistics version 26.0 (IBM Corp., Armonk, NY, USA). A p value less than 0.05 was considered statistically significant.

Results

Table 2 compares the degree of gait independence (FAC score) between an orthosis and WPAL. The FAC score was higher when using WPAL than when using an orthosis in 3 subjects, and was the same in the other 2 subjects. No statistically significant difference was observed ($p = 0.08$).

Table 3 compares continuous gait ability. Subject E was not evaluated for continuous gait ability because constant support was required for walking. The mean walking distance when using WPAL was 48.6 ± 27.1 m, and was significantly longer, approximately 3.3 times, compared to the distance of 14.9 ± 14.7 m when using an orthosis ($p < 0.05$). In addition, the walking speed ($p = 0.08$), stride length ($p = 0.09$), and cadence ($p = 0.09$) tended to be greater when using WPAL in all 4 patients who could be evaluated compared to those when using an orthosis. On the other hand, there was no significant difference ($p = 0.88$) and no clear trend for continuous walking time.

Table 4 compares gait endurance for the 3-minute walk. Subjects D and E who required physical support for walking were not evaluated. When using WPAL, mean PCI for the 3 patients evaluated was approximately half compared to that when using an orthosis ($p = 0.18$). There were no significant differences and no obvious trends for subjective exercise intensity ($p = 0.66$) and fatigue in upper limbs ($p = 0.41$).

Table 2. Comparison of degree of gait independence.

Subject	FAC score		Degree of assistance	
	Orthosis	WPAL	Orthosis	WPAL
A	3	4		
B	4	4		
C	3	4		
D	2	2	Intermittent physical support is required to assist in maintaining balance	Intermittent physical support is required to assist in maintaining balance
E	1	2	Constant physical support is required to maintain balance	Constant physical support is required to maintain balance

FAC, Functional Ambulation Categories; WPAL, Wearable Power-Assist Locomotor.

Table 3. Comparison of continuous gait ability.

Subject	Continuous walking time (min)		Continuous walking distance (m)		Walking speed (m/min)		Stride length (cm)		Cadence (steps/min)	
	Orthosis	WPAL	Orthosis	WPAL	Orthosis	WPAL	Orthosis	WPAL	Orthosis	WPAL
A	1.9	4.7	9.2	42.2	4.8	9.0	23.3	41.9	41.2	42.9
B	14.2	6.4	36.5	69.3	2.6	10.9	20.4	43.4	25.2	50.0
C	6.1	5.5	10.2	69.9	1.7	12.7	14.9	59.1	22.5	42.9
D	2.7	6.5	3.5	12.8	1.3	2.0	10.1	12.0	25.7	33.0
E	–	–	–	–	–	–	–	–	–	–
Mean ± standard deviation	6.2±5.6	5.8±0.8	14.9±14.7	48.6±27.1	2.6±1.6	8.6±4.7	17.2±5.8	39.1±19.7	28.7±8.5	42.2±7.0

WPAL, Wearable Power-Assist Locomotor.

Table 4. Comparison of gait endurance.

Subject	PCI (beats/min)		Subjective exercise intensity		Fatigue of upper limbs	
	Orthosis	WPAL	Orthosis	WPAL	Orthosis	WPAL
A*	4.2	3.8	4	4	5	4
B	5.1	2.1	4	6	4	6
C	6.8	1.5	3	0	3	4
D	–	–	–	–	–	–
E	–	–	–	–	–	–
Mean ± standard deviation	5.3±1.3	2.6±1.1	–	–	–	–

PCI, Physiological Cost Index; WPAL, Wearable Power-Assist Locomotor.
*Since orthosis-assisted gait could be continued only for 115 seconds, the data collected at 90 seconds were used for analysis.

Discussion

In this study, we attempted gait reconstruction using WPAL in 5 patients with cervical spinal cord injury, and compared the efficacy with conventional orthoses. In 3 of the 5 subjects, the degree of gait independence was higher when walking using WPAL compared with using an orthosis, and in 4 subjects capable of continuous walking, the continuous walking distance was significantly longer when using WPAL. Furthermore, 3 subjects were walking independently. Until now, there has been no report of successful gait reconstruction using a medial system gait assist robot in as many as 3 patients with cervical spinal cord injury classified as ASIA impairment scale grade A or B, and our study is valuable in demonstrating the superiority of WPAL-assisted gait over conventional orthosis-assisted gait.

Regarding orthosis-assisted gait, Suzuki et al. [26] used medial system orthoses (Walkabout, gear joint, and Primewalk) in 45 patients with spinal cord injuries (ASIA impairment scale grades A to C). Among 10 patients with cervical spinal cord injury (neurological level C6 to C8), 1 achieved indoor independent gait, 4 indoor supervised gait, and the remaining patient achieved indoor gait with assistance or gait within parallel bars. Using RGO combined with electrical muscle stimulation, Solomonow et al. [27] reported that 2 of 4 patients with cervical spinal cord injury achieved independent gait. In the present study, 3 of 5 patients with cervical spinal cord injury having complete motor paralysis achieved orthosis-assisted gait without physical assistance. This outcome is not inferior to those of previous reports, indicating that the patients had undergone sufficient training for orthosis-assisted gait. Moreover, FAC score when using WPAL exceeded that when using an orthosis in 3 of 5 patients, and the walking distance was significantly longer in patients capable of continuous walking. Although WPAL use has been reported to result in a significantly higher degree of gait independence than using an orthosis in patients with paraplegia [23], the present study suggests for the first time the usefulness of WPAL also in patients with cervical spinal cord injury.

There are two possible reasons for the differences between orthosis-assisted gait and WPAL-assisted gait. The first reason is the presence or absence of an external power source. For the Primewalk used by 4 of 5 patients in this study, swinging of the lower limb is a pendulum movement under the action of gravity, therefore the trunk has to be moved forward and maintained anterior to the lower limb [13]. For the HALO used by 1 patient, ankle dorsiflexion on the stance side drives the contralateral ankle plantar flexion and swinging of the lower limb [15]. In order to dorsiflex the ankle, it is necessary to move the trunk anterior to the lower limb on the stance side. Hence, in order to swing out the lower limb in orthosis-assisted gait, it is necessary to move the trunk forward. However, for patients with cervical spinal cord injury who have limited voluntary trunk movement, large movement of the trunk is difficult. Consequently, it is difficult to increase the stride. On the other hand, when using WPAL, swinging of the lower limb is driven by a motor as an external power source. Therefore, a sufficient stride can be maintained even though large trunk movement is not possible, and walking at high speed can be expected. In addition, the presence of an external power source is advantageous even for trunk movement during the stance phase. Compared to orthosis-assisted gait in which the trunk should be propelled forward by the strength of the upper limbs, WPAL is expected to reduce the burden on the patient's upper limbs because ankle dorsiflexion driven by the motor helps the trunk move forward. The second reason is the difference in kinematics. In orthosis-assisted gait, since the knee joint is fixed in an extended position during the swing phase, compensatory movements such as bending the trunk to the opposite side are necessary to ensure foot clearance [28], and a large burden is exerted on the upper limbs that operate the walking aid [29]. Greene et al. [30] reported that implementing knee flexion and ankle dorsiflexion during the swing phase reduces the compensatory movements. The coordinated control of the hip, knee and ankle joints during the swing phase in WPAL is expected to fulfil this purpose [21]. In the future, it is necessary to clarify by performing kinematic analysis whether the compensatory movements are actually reduced.

When comparing continuous walking, continuous walking distance was longer when using WPAL. While there was no remarkable difference in walking time, the walking speed tended to be faster when using WPAL, suggesting that speed is the major factor. When walking using WPAL, both stride length and cadence were greater than when walking with an orthosis, consequently achieving a higher walking speed. As mentioned above, WPAL with an external power source may have facilitated the acquisition of stride length. The reason for the higher cadence is presumed to be related to the decrease in compensatory movements by using WPAL, but further verification is required. Of the 4 subjects analyzed in the comparison of continuous walking, subjects B and C showed short continuous walking time when using WPAL. In these 2 subjects, the cadence during WPAL-assisted gait was approximately 2 times greater compared to orthosis-assisted gait, and the great burden on the upper limbs was probably related to the short continuous walking time.

In the comparison of gait endurance, although no significant differences were observed, PCI was lower during WPAL-assisted gait compared to orthosis-assisted gait in all 3 subjects analyzed. When the increase in heart rate during walking is the same, PCI is inversely proportional to walking speed. When comparing the mean values for the 3 subjects in whom PCI was measured, walking speed was 3.6 times faster when using WPAL, and PCI was 2.1 times higher when using an orthosis. The faster walking speed is presumed to be the main reason for the lower PCI in WPAL-assisted gait. On the other hand, no clear trends in subjective exercise intensity and fatigue in the upper limbs were observed. As a possible reason, since voluntary trunk movement is reduced in patients with cervical spinal cord injury, control of the trunk always relies on the upper limbs under both conditions of orthosis and WPAL. If orthosis-assisted gait is performed at the same speed as WPAL-assisted gait, it is possible that the burden on the upper limbs will increase due to the anterior displacement of the trunk, and the subjective exercise intensity may also increase as a result. In this study, the subjects walked at speeds that allowed them to maintain the balance of the trunk, which may account for the lack of a significant difference between the two groups.

One of the merits of using WPAL in patients with cervical spinal cord injury compared to those with paraplegia is the greater walking assistance effect produced by the external power source. Hirano et al. [23] reported that in paraplegic patients, the continuous walking distance when using WPAL was 1.8 times longer compared to using an orthosis, which was lower than that obtained in patients with cervical spinal cord injury in the present study. Therefore, for patients with cervical spinal cord injury who have reduced upper limb and trunk functions, assistance obtained from the external power source may have greater significance. On the other hand, one of the demerits of using WPAL in patients with cervical spinal cord injury compared to paraplegic patients is lower practical applicability in daily living. Patients with paraplegia are expected to recover a practical level of gait by using an independent gait supporting robot in daily life. In fact, marketing of Indego® and ReWalk™ targeting individuals has already started, and marketing of WPAL is also scheduled. Compared to patients with paraplegia, patients with cervical spinal cord injury have greater difficulties in wearing the robot, standing up and sitting down, and avoiding falling when losing balance. The prospect for practical use in daily life is a future issue to be addressed.

One limitation of this study is the small number of subjects. Further studies should increase the number of subjects and use 3D gait analysis and surface electromyography to investigate in detail the differences between WPAL-assisted gait and orthosis-assisted gait. Moreover, based on the findings obtained, it is necessary to modify the device to improve its practicality. Despite the above issues, the present study, although small-scale, is significant in demonstrating for the first time the usefulness of WPAL, a gait assistance robot with a medial system, to achieve gait reconstruction not only for patients with paraplegia but also for those with cervical spinal cord injury, when compared with conventional orthoses.

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