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Original Article

Comparison between gait-assisting robot (WPAL) and bilateral knee-ankle-foot orthoses with a medial single hip joint in gait reconstruction for patients with paraplegia

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ABSTRACT
Hirano S, Saitoh E, Tanabe S, Katoh M, Shimizu Y, Yatsuya K, Tanaka H, Kagaya H, Ishihara K, Uno A. Comparison between gait-assisting robot (WPAL) and bilateral knee-ankle-foot orthoses with a medial single hip joint in gait reconstruction for patients with paraplegia. Jpn J Compr Rehabil Sci 2015; 6: 21−26.
Objective: To evaluate the utility of a gait-assisting robot, Wearable Power-Assist Locomotor (WPAL), in gait reconstruction for patients with paraplegia.
Subjects and Methods: The subjects were 12 patients with paraplegia who were able to walk with minimum assistance, under supervision, or without any assistance and supervision using a bilateral knee-ankle-foot orthoses with a medial single hip joint or WPAL. The duration and distance of walking were measured and the required level of assistance was evaluated with the Functional Ambulation Category (FAC) scale as the subjects walked at a comfortable speed with the orthoses or WPAL.
Results: The duration and distance of walking with the WPAL were significantly longer in 8 and 11 subjects, respectively, compared with use of the orthoses. FAC scores were 2, 3 or 4 with orthoses and 4 using the WPAL, indicating less assistance was needed with the WPAL.
Conclusion: The WPAL enabled patients with paraplegia to walk for a longer time and longer distance with less assistance.
Key words: robot, paraplegia, gait reconstruction, practical walking, medial system

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Introduction

Patients with paraplegia caused by spinal cord injury generally use a wheelchair for mobility in activities of daily living (ADL). Such patients may have medical problems associated with the long-term use of a wheelchair, including decubitus ulcers, osteoporosis, joint contracture, constipation, and obesity [1, 2]. Furthermore, as their eye level is lower than that of people who can walk, the use of a wheelchair in daily life may become stressful and may reduce self-esteem [3]. Thus, standing and walking are important for the mental and physical health of patients with paraplegia.

In Western countries, bilateral hip-knee-ankle-foot orthoses, such as the reciprocating gait orthosis (RGO) [4] and hip guidance orthosis (HGO) [5], are used for gait reconstruction in patients with paraplegia. These are referred to as lateral systems because the bilateral knee-ankle-foot orthoses and hip orthoses are connected on the outside of the hip joint. Such orthoses equipped with a lateral hip joint located at almost the same level as the hip joint of the patient are superior for maintaining stride, but also have problems including difficulty with wearing and removal while in a wheelchair, inability to sit down while wearing the orthoses, and difficulty standing and sitting down because of the significant restriction on body movement and the need for greater space on the outside of the hip joint. Therefore, these orthoses cannot be used with a wheelchair, which makes them less suitable for use in daily life. Several gait-assisting robots, such as ReWalk [6, 7], Ekso [8] and REX [9], with lateral systems have also been developed, but they have similar problems.

In Japan, the Primewalk (Figure 1) [10, 11] and the HALO (Hip and Ankle Linkage Orthosis) [12] are widely used for gait reconstruction of patients with paraplegia. These are bilateral knee-ankle-foot orthoses that are connected by a joint located directly underneath the perineal region. These so-called medial systems do not need a hip orthosis and do not restrict body movement. In addition, they do not have a large structure on the outside of the hip joint, and thus can be used with a wheelchair. The structure is located close to the gravity line, which stabilizes the standing balance. However, both the medial system and the lateral system rely on the upper limbs, which causes problems when standing, sitting and walking. Even if the upper limb muscles are strong enough, there is still a risk of falling when standing or sitting using a walker or a cane, and assistance or supervision is needed. Also, in order to lift each leg in turn for walking, the centerline of the body has to be controlled from front to back and from side to side using the upper limbs, and this can be a burden for the upper limbs. The energy efficiency of such walking motion is poor and it is not suitable for long-distance walking.

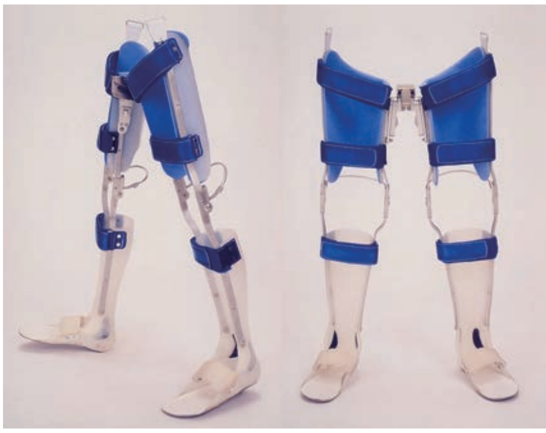

Figure 1. Primewalk.
Bilateral knee-ankle-foot orthoses with a medial single hip joint. Primewalk does not need a hip orthosis and does not restrict body movement because bilateral knee-ankle-foot orthoses are connected directly by a hip joint. In addition, Primewalk does not have a large structure on the outside of the hip joint, and thus can be used with a wheelchair. The structure is located close to the gravity line, which stabilizes the standing balance.

To resolve the problems of the conventional systems, facilitate standing up from and sitting down in a wheelchair, and permit practical walking on level surfaces in daily life, dynamic control of lower limb joint movement is required. To address these needs, in 2005 we began to develop a wearable gait-assisting robot that is a medial system with dynamic control properties, which we refer to as a Wearable Power-Assist Locomotor (WPAL) [13, 14]. In a study of WPAL-assisted walking, Tanabe et al. [13, 14] found tendencies for a longer duration and distance of independent walking with less assistance required compared to conventional orthoses. However, the sample population was small and no statistical analysis was performed in the study. Therefore, the current study was performed to compare independent walking with the WPAL and conventional orthoses using statistical analysis of the walking duration and distance and the required level of assistance.

Subjects and Methods

The design of the WPAL is illustrated in Figure 2. The WPAL is a robot with 6 motors for each hip joint, knee joint, and foot joint mounted on a medial system-like frame. The special walker equipped with a motor control circuit and battery guarantees patient safety and reduces the burden on the patient. Patients can operate the WPAL using 2 lever switches and 2 button switches on the walker, and can wear and remove the WPAL by themselves after some training. When walking with the WPAL, the patient has to move their body rhythmically according to the movement of the WPAL, which needs repeated training. The predetermined training program consists of 5 parts: stepping exercise in parallel bars with suspension, walking exercise in parallel bars with suspension, treadmill walking with suspension, walking exercise with suspension on the walker, and walking exercise without suspension on the walker [14]. This program provides an easy way to master the movement. Our previous study showed that patients could walk independently on level surfaces after training for 1 to 5 hours (2 to 10 sessions of approximately 30 minutes each day) depending on their neurological level and age.

The subjects in the current study were patients with paraplegia who usually used a wheelchair in their daily lives, but were able to walk with minimum assistance, under supervision, or without any assistance and supervision using bilateral knee-ankle-foot orthoses with a medial single hip joint (hereafter referred to as an “orthosis”) and WPAL. In this context, minimum assistance is defined as continuous or intermittent light touch to assist balance or rhythm of walking. The patients were able to start walking training with the WPAL at any time because they had participated in regular walking training using medial systems, including Primewalk and HALO, and were able to use these systems for walking. They also received training with the WPAL (10 to 100 times, depending on the patient) and were judged to have almost mastered the system upon entry into the study. This study was approved by the ethics committees at the two participating institutions and the 12 subjects all provided written informed consent.

Figure 2. WPAL (Wearable Power-Assist Locomotor). The robots for gait reconstruction of patients with paraplegia. WPAL has 6 motors for each hip joint, knee joint, and foot joint mounted on a medial system-like frame. The special walker equipped with a motor control circuit and battery guarantees patient safety and reduces the burden on the patient. Patients can operate the WPAL using 2 lever switches and 2 button switches on the walker, and can wear and remove the WPAL by themselves after some training.

The patient characteristics are shown in Table 1. The mean ± standard deviation for the age and numbers of years after injury were 43 ± 13 years old (range 22−61 years old) and 7.1 ± 6.8 years (0−20 years), respectively. Primewalk and HALO were used by 9 and 3 subjects, respectively. The subjects used their own orthoses, with which they had experience ranging from approximately 3 months to 14 years.

The walking duration and distance were measured for subjects for walking at a comfortable speed while wearing their own orthoses or WPAL. The level of assistance required for walking was evaluated using the Functional Ambulation Category (FAC) test [15]. Each subject performed the exercise twice or more for each system and the longest distance was used in the analysis. The subjects walked with an attached ECG monitor and stopped walking when their heart rate reached the target parameter (220 − age), they became tired, or they could not walk any more. With the WPAL, some subjects also stopped walking when the battery ran out, since the WPAL must be fully charged. The battery usually lasts for approximately 1 hour, but sometimes runs out faster when the motor becomes overloaded because a patient has an event such as a severe spasm. The walking sessions were separated by a sufficient break to avoid fatigue.

The duration and distance of walking and the FAC scores were compared by the paired *t* test and Wilcoxon signed-rank sum test, respectively, with a significance

Table 1. Patient characteristics.

Subject	Neurological level	ASIA Impairment scale	Age (years)	Sex	Time after onset (years)	Orthosis
A	Th 6	A	61	F	16	Primewalk
B	Th 6	A	60	M	8	Primewalk
C	Th 6	A	43	M	8	Primewalk
D	Th 8	A	53	M	0	Primewalk
E	Th 9	A	49	M	9	Primewalk
F	Th 10	A	34	F	1	HALO
G	Th 10	A	22	M	1	HALO
H	Th 11	A	54	M	0	Primewalk
I	Th 11	A	47	M	20	Primewalk
J	Th 11	A	23	M	0	HALO
K	Th 12	A	33	M	16	Primewalk
L	Th 12	B	32	M	6	Primewalk
Average			43		7	

* HALO, Hip and Ankle Linkage Orthosis.

level of 0.05.

Results

In walking with orthoses, 1 of the 12 subjects reached the target heart rate and stopped walking. Using the WPAL, 3 of the 12 subjects stopped walking due to the battery running out of power or the experiment was discontinued because the subjects complained of fatigue or could not walk any more.

The mean durations of walking using orthoses and WPAL were 11.9 ± 15.8 and 19.6 ± 18.5 min, respectively (Figure 3). The minimum durations using orthoses and WPAL were both 3 min, and the maximum durations were 60 and 57 min, respectively. Three subjects walked for 40, 54, and 57 minutes until the WPAL battery ran out. The duration of walking with the WPAL was longer in 8 subjects, the same in 2 subjects, and shorter in 2 subjects compared with orthoses, and there was a significant difference between the two conditions ($p = 0.037$).

The distances of walking with orthoses and WPAL were 158 ± 244 and 283 ± 351 m, respectively (Figure 4). The minimum distances using orthoses and WPAL were both 20 m, and the maximum distances were 700 and 983 m, respectively. The distance of walking with the WPAL was longer in 11 subjects and the same in 1 subject compared with orthoses, and there was a significant difference between the two conditions ($p = 0.023$).

The mean walking speeds calculated based on the walking speed and distance using orthoses and WPAL were 10.4 ± 6.3 and 10.8 ± 4.5 m/min, respectively, with no significant difference between the two conditions. The minimum speeds using orthoses and WPAL were both 4.0 m/min, and the maximum speeds were 25.0 and 18.2 m/min, respectively. Five subjects had a faster walking speed using the WPAL, 4 had a faster speed with orthoses, and 3 had the same walking speed using the WPAL and orthoses.

Using orthoses, 3, 3, and 6 subjects had FAC scores of 2 (continuous or intermittent light touch to assist balance or coordination), 3 (dependent on supervision), and 4 (independent, level surfaces only), respectively. In contrast, using the WPAL, all subjects had a FAC score of 4, which indicated that significantly less assistance was required with the WPAL ($p = 0.024$).

Discussion

The results of this study indicated that the patients could walk longer distances and for a longer time using the WPAL compared with orthoses. Medial systems, such as Primewalk and HALO, and lateral systems, such as RGO and HGO, both require patients with complete paraplegia to hold the knee joint in extension while walking, which makes the functional length of the swinging leg longer and causes difficulty with swinging. In addition to this difficulty, to advance the leg the body has to move more from side to side compared with healthy people to permit the swinging leg to clear the ground. Such body movement for each step requires greater lateral movement of the center of gravity while walking, which decreases the energy efficiency, and the lateral body movement using both arms increases muscle fatigue of the upper limbs.

In contrast, with the WPAL the knees can be bent in the swinging phase while walking, which makes the functional leg length shorter and reduces lateral body movement for ground clearance, compared with use of

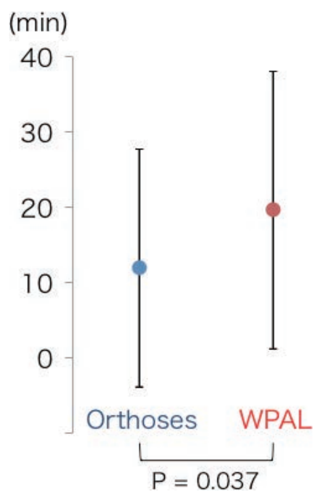

Figure 3. Comparison of duration of walking.
The duration of walking with the Wearable Power-Assist Locomotor (WPAL) was significantly longer compared with use of the bilateral knee-ankle-foot orthoses with a medial hip joint.

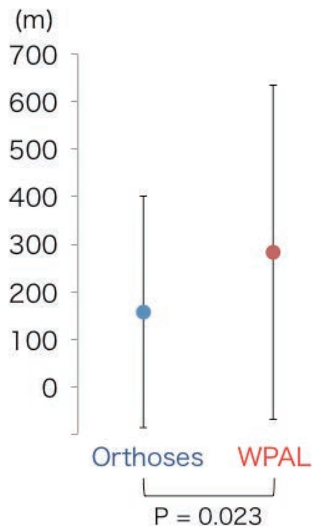

Figure 4. Comparison of distance of walking.
The distance of walking with the Wearable Power-Assist Locomotor (WPAL) was significantly longer compared with use of the bilateral knee-ankle-foot orthoses with a medial hip joint.

orthoses. In a study of a single patient with paraplegia walking with the WPAL or Primewalk, Tanabe et al. [13] found a smaller increase in heart rate, physiological cost index (PCI) [16], and modified Borg Scale and lower integral values of the surface electromyogram of the biceps brachii muscle, triceps brachii muscle, and trapezius muscle using the WPAL. The increase in energy efficiency and decrease of upper limb muscle fatigue may result in a longer walking duration and distance. There are reports that energy efficiency correlates with daily physical activities [17], and thus such energy-efficient walking using the WPAL is likely to improve physical activities.

In this study, 3 of the 12 subjects had to stop walking only because the WPAL battery ran out of power. Assuming that patients with paraplegia usually use a wheelchair for moving long distances, the WPAL battery is designed to allow the user to walk for approximately 1 hour. In this study, the battery lasted 54 and 57 min in 2 of the 3 subjects, as designed, but ran out in 40 min in the other subject. The faster battery consumption might have been caused by motor overload because the subject had severe lower limb spasticity. A larger battery capacity would have allowed the 3 subjects to have walked further and for a longer time. Two of the 12 subjects walked for a longer distance using the WPAL, but walked for a longer time using orthoses, indicating that their walking speed was faster using the WPAL compared with orthoses.

Various robots for gait reconstruction of patients with paraplegia have been developed worldwide. The major robots are ReWalk, Ekso, and REX, but there are few reports on the walking duration and distance using these robots. For ReWalk, the walking duration and distance in 12 patients with thoracic spinal cord injury who received walking training were 5−10 min and 50−100 m, respectively [7], whereas the mean and maximum walking distances using the WPAL in the current study were 283 m and 983 m, respectively (these data were not reported for ReWalk). A 10-minute walking test performed in 11 of the subjects using ReWalk resulted in minimum, maximum, and mean walking speeds of 1.8, 27.0, and 15.1 m/s, respectively, whereas these values using the WPAL were 4.0, 18.2, and 10.8 m/s, respectively. Thus, the WPAL data are slightly lower than those for ReWalk, but our study lasted for an average of 19.6 min and the mean age of our subjects was older than that of 37.8 years old for the 12 subjects in the ReWalk study. Age and neurological level of the subjects should be considered in a future study of walking duration and distance.

The WPAL enabled the patients to walk a longer distance and for a longer duration compared with orthoses after sufficient walking training. Furthermore, all subjects had a FAC score of 4 using the WPAL, indicating that less assistance was required compared with orthoses. These findings suggest that walking using the WPAL is closer to practical walking compared with use of orthoses. A patient can wear and remove the WPAL themselves, which is an advantage over lateral systems and robots. There are still several problems to be solved, including the size, weight, cost, and water resistance, and we will continue to develop the WPAL to help patients with paraplegia to attain more practical walking.

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