Original Article

Effectiveness of Gait Exercise Assist Robot (GEAR) for stroke patients with hemiplegia

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ABSTRACT

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Objective: This study examined whether subacute stroke patients with hemiplegia who receive gait training using the Gait Exercise Assist Robot (GEAR) show early improvement in gait independence compared to patients who receive orthosis-assisted gait training.

Methods: Six patients who satisfied the following criteria were included in the study: patients with hemiplegia caused by primary supratentorial intracerebral hemorrhage or cerebral infarction, within 60 days after onset, aged 20 to 75 years, Functional Independence Measure (FIM) walking score ≤ 3, Stroke Impairment Assessment Set (SIAS) lower extremity total score ≤ 6, and use of a knee-ankle-foot orthosis. Rehabilitation was conducted for a maximum of 3 h a day, including 40 min of gait training using GEAR. A historical control group was selected from among patients admitted to the ward for intensive inpatient rehabilitation at Nanakuri Memorial Hospital. One control patient matching the criteria of each subject was selected, with a total of six in the control group. The primary outcome measure was the improvement in efficiency of FIM-walk, defined as the gain in FIM walking score from the baseline to supervised walking divided by the number of weeks required.

Results: The mean improvement in efficiency of FIM-walk was 1.0 in the GEAR group and 0.54 in the control group, and was significantly higher in the GEAR group ($p = 0.042$).

Conclusion: Gait training using GEAR may facilitate early improvement in gait independence.

Key words: stroke, hemiplegia, gait training, robot, assist

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Introduction

For stroke patients with hemiplegia, gait training is conventionally practiced using a lower extremity orthosis [1–3]. By limiting the degree of freedom of the lower extremity joints and simplifying the motions, the use of a lower extremity orthosis stabilizes the gait even for patients with paralysis. In the case of severe paralysis, a more limited degree of freedom is necessary [4]. The orthoses used by stroke patients with hemiplegia are broadly divided into knee-ankle-foot orthosis and ankle-foot orthosis. In a patient with mild hemiplegia, an ankle-foot orthosis that limits the ankle joint motion is often used. On the other hand, when a patient with severe hemiplegia uses an ankle-foot orthosis at the early stage of gait training, there is a high risk of the knee giving way. Therefore, the use of a knee-ankle-foot orthosis is desirable [5]. However, this presents several issues. (1) Since the patient has difficulty launching the foot by him/herself, the amount of assistance during the swing phase is increased. (2) Because the foot is launched with the knee remaining in extension, compensatory motion

such as vaulting is necessary, with a risk of acquiring a gait pattern different from the final gait. (3) Gait with a high degree of compensation and requiring a high level of assistance has a slow speed and hence low training intensity. (4) The patient feels that "walking is difficult," which diminishes motivation.

In recent years, various types of robot-assisted gait training systems have been developed. The Lokomat is the main exoskeleton-type robot used for gait training [6]. The exoskeleton worn over both lower extremities directly controls the left and right hip and knee joints, and gait training takes place on a treadmill with partial body weight support if necessary. On the other hand, the Gait Trainer is the main end-effector robot [7]. The feet are held in place on foot plates, and the robot directly drives the feet under partial body weight support.

The effectiveness of robot-assisted gait training remains a matter of debate. Several studies have shown significant improvement of gait independence when gait training using the Lokomat or Gait Trainer was combined with conventional physiotherapy, compared to physiotherapy alone conducted for the same duration [8–10]. In contrast, other studies found no significant difference [11,12]. In these reports, the frequency and the type of orthosis used were not clearly defined, which may be a factor that affected the results.

In the present study, we compared a robot-assisted plus physiotherapy group and a regular physiotherapy group, while standardizing the type of orthosis used in the two groups. The Gait Exercise Assist Robot (GEAR) [13] that we developed in collaboration with Toyota Motor Corporation was used as the gait training assist system. In patients with severe paralysis and gait disturbance requiring the use of a knee-ankle-foot orthosis, gait training using GEAR combined with conventional physiotherapy was compared with physiotherapy alone. The results are presented in this report.

Methods

1. Mechanism of the Gait Exercise Assist Robot

The components of the GEAR system include a knee-ankle-foot robot, a low floor treadmill, a safety suspending device (can be used as for body weight support), a robot weight support device, a monitor for patient use, and a control panel (Figure 1). The knee-ankle-foot robot with a motor attached to the knee joint weighs approximately 5.7 kg, and is worn only on the hemiplegic limb. Since the weight is canceled by the robot weight support device, the patient does not feel the weight. The plantar region of the robot is equipped with a pressure sensor. The system determines the gait cycle from the pressure sensor and

Figure 1. The Gait Exercise Assist Robot (GEAR).
The components of the GEAR system include a knee-ankle-foot robot, a low floor treadmill, a safety suspending device (can be used as for body weight support), a robot weight support device, a monitor for patient use, and a control panel. The system determines the gait cycle from the pressure sensor on the plantar region of the robot and the knee joint angle, and executes flexion and extension of the knee joint at the appropriate timing.

the knee joint angle, and executes flexion and extension of the knee joint at the appropriate timing. With this mechanism, even patients with severe hemiplegia can practice a multi-step gait resembling the final gait pattern without excessive compensatory motion, with minimal assistance from the early stage of gait training. The torque for assisting knee extension and the force for assisting swing-out of the paralyzed lower limb with robot weight support can be regulated from the control panel. By gradually reducing the level of assistance according to the patient's walking capability, it is possible to constantly maximize the effort of the patient.

2. Subjects

This study was conducted after obtaining approval from the ethics committee of our university. The inclusion criteria were as follows: patients with hemiplegia caused by primary supratentorial intracerebral hemorrhage or cerebral infarction; within 60 days after onset; aged 20 to 75 years; Functional Independence Measure (FIM) [14] walking score ≤ 3; total score of the hip flexion test, knee extension test and foot tap test in the Stroke Impairment Assessment Set (SIAS) [15, 16] (lower extremity motor function score) ≤ 6; SIAS verticality score ≥ 2; FIM comprehension score ≥ 2; FIM memory score ≥ 3; FIM social interaction score ≥ 3; and requirement of knee-ankle-foot orthosis in gait training. Exclusion criteria were: training restriction due to reduced cardiac function or respiratory dysfunction; inadequate control of hypertension (resting systolic blood pressure ≥ 160 mmHg or diastolic blood pressure ≥ 100 Hg); severe joint contracture or limb deformity; visual or auditory impairment hindering training; and a history of orthopedic or neurological disease that affects gait. Six patients admitted to the Department of Rehabilitation at Fujita Health University Hospital between February 2013 and February 2015, who satisfied the above criteria, gave written consent to participate in the study.

A historical control group (a group that practiced gait training using a lower extremity orthosis; hereafter "orthosis group") was selected from the database of patients who received inpatient treatment at the ward for intensive inpatient rehabilitation at Fujita Health University Nanakuri Memorial Hospital. Among the patients who were admitted from April 2006 and discharged up to March 2014, 222 patients satisfied the following criteria: hemiplegia caused by primary supratentorial intracerebral hemorrhage or cerebral infarction; within 60 days after onset; aged 20 to 75 years; FIM walking score ≤ 3; SIAS lower extremity motor function score ≤ 6; SIAS verticality score ≥ 2; FIM comprehension score ≥ 2; FIM memory score ≥ 3; FIM social interaction score ≥ 3; receiving gait training using a knee-ankle-foot orthosis; and no discontinuation of rehabilitation due to any complications during hospitalization. From these patients, one matching patient for each subject in

terms of the following criteria was selected:
· FIM walking score and SIAS lower extremity motor function score at the beginning of gait training were the same as those of the subject.
· The disease (intracerebral hemorrhage or cerebral infarction) was the same as the subject.
· The duration from onset to first evaluation after admission was closest to the duration from onset to first evaluation of the subject.
The six control patients identified were included in the orthosis group.

3. Gait training protocol

The GEAR group received gait training using GEAR (hereafter "GEAR training") for 40 min a day, 5 times a week. During GEAR training, the level of robot assistance was set as low as possible, as long as the gait pattern did not deteriorate excessively. The necessity of using feedback and the type of feedback were determined by the attending physician or the therapist in charge. GEAR was used in principle until the patient was capable of overground gait using an ankle-foot orthosis at the supervision level. However, prolongation of the duration was allowed at the discretion of the attending physician or the therapist in charge. For the whole rehabilitation program, training (physiotherapy, occupational therapy, and speech-language-hearing therapy) including using GEAR was performed for a maximum of 3 h a day, 6 days a week. The content of training other than GEAR was determined by the attending physician and the therapist in charge. There were no restrictions regarding training content.

The orthosis group received training (physiotherapy, occupational therapy, and speech-language-hearing therapy) for a maximum of 3 h a day, 7 days a week. The type of orthosis used, training content, and training intensity were determined by the attending physician and the therapist in charge.

4. Outcome measures

The FIM walking score, individual scores and total score for SIAS lower extremity motor function, and 10 m walking speed were evaluated.

In the GEAR group, once participation in the study was agreed and the day of initiating GEAR training was decided, the baseline evaluation was done as early as possible. Subsequent evaluation was conducted once a week until discharge. GEAR training was started within 1 to 3 days of the baseline evaluation. In the orthosis group, the baseline evaluation was conducted immediately after admission (day of admission or the following day), and subsequent evaluation was done once every 2 weeks until discharge.

The primary outcome measure was the improvement in efficiency of FIM-walk, defined by the following formula:

Improvement in efficiency of FIM-walk

$$= \frac{5 - \text{baseline FIM walking score}}{\text{Number of weeks to reach FIM walking score of 5}}$$

Improvement in efficiency of FIM-walk was calculated every 2 weeks in the GEAR group, in order to match the orthosis group.

Secondary outcome measures were FIM walking score at discharge, SIAS lower extremity motor function score at discharge, 10 m walking speed at discharge, and duration from onset to discharge (days).

Statistical analyses were performed using IBM SPSS Statistics 20.0.0 (SPSS Inc., Chicago, IL, USA). The paired t-test was used to analyze the duration from onset to baseline evaluation, age, 10 m walking speed at discharge, and duration from onset to discharge. Wilcoxon rank sum test was used to analyze the

efficiency of FIM-walk improvement, FIM walking score at discharge, and SIAS lower extremity motor function score at discharge. p Values less than 0.05 were considered to be significant.

Results

Table 1 shows the characteristics of the patients in the GEAR group and orthosis group. Baseline FIM walking scores and baseline SIAS lower extremity motor function scores were identical in the two groups.

The results of evaluations are shown in Table 2. The improvement in efficiency of FIM-walk was significantly higher in the GEAR group ($p = 0.042$). No significant differences between the two groups were observed for the FIM walking score, SIAS lower extremity motor function score, and 10 m walking speed at discharge. The mean duration from onset to discharge was 112.5 days in

Table 1. Patient characteristics.

Case	Baseline FIM-walk		Baseline SIAS-LE		Onset to baseline evaluation (days)		Hemiplegic side		Age	
	GEAR group	Orthosis group	GEAR group	Orthosis group	GEAR group	Orthosis group	GEAR group	Orthosis group	GEAR group	Orthosis group
A	2	2	3	3	25	22	L	L	62	50
B	2	2	6	6	29	21	L	L	65	69
C	2	2	1	1	33	30	R	L	46	40
D	2	2	0	0	17	20	L	R	72	69
E	2	2	1	1	16	14	R	L	70	51
F	2	2	2	2	14	14	R	L	50	44
Median	2	2	2.5	2.5						
Mean±SD					22±8	20±6			61±11	54±12
p Value					0.206				0.081	

FIM-walk, Functional Independence Measure walking score; SIAS-LE, Stroke Impairment Assessment Set lower extremity score.

Table 2. Results of evaluations.

Case	Efficiency of FIM-walk improvement		FIM-walk at discharge		SIAS-LE at discharge		10 m walking speed at discharge (km/h)		Onset to discharge (days)		Duration of GEAR exercise (weeks)
	GEAR group	Orthosis group	GEAR group	Orthosis group	GEAR group	Orthosis group	GEAR group	Orthosis group	GEAR group	Orthosis group	GEAR group
A	0.75	0.75	6	7	10	12	2.5	3.2	104	104	3
B	1.50	0.75	5	6	8	11	0.9	1.2	115	132	3
C	0.75	0.25	5	6	6	4	1.0	1.7	161	178	5
D	0.75	0.21	6	5	9	5	3.5	0.6	95	129	4
E	1.50	0.75	5	6	8	6	1.5	2.4	115	111	4
F	0.75	0.50	6	6	11	6	1.9	3.0	85	96	4
Median	0.75	0.63	5.5	6	8.5	6					
Mean±SD	1.00±0.39	0.54±0.25					1.9±1.0	2.0±1.0	112.5±26.5	125.0±29.5	3.8±0.8
p Value	0.042*		0.180		0.276		0.814		0.075		

FIM-walk, Functional Independence Measure walking score; SIAS-LE, Stroke Impairment Assessment Set lower extremity score.
*$p < 0.05$, Wilcoxon rank sum test.

the GEAR group and 125 days in the orthosis group. Although the duration tended to be shorter in the GEAR group, no significant difference was observed. In the GEAR group, GEAR training was conducted for an average of 3.8 weeks.

Discussion

In the present study, gait training using GEAR in stroke patients with hemiplegia significantly improved the efficiency of FIM-walk improvement, compared to patients who practiced gait training using only a lower extremity orthosis. The results of this study suggest that GEAR training promotes the recovery of walking ability. Because the use of GEAR in gait training maximizes the residual capability of the patient, we set the level of robot assistance at the minimum level as long as the gait pattern did not deteriorate excessively. Therefore, as the patient's gait capability improves, the level of robot assistance is gradually reduced. Animal experiments have suggested that the function-improving effect of training for motor paralysis is higher with an assist-as-needed approach than with a fixed-assist approach [17]. In addition, Krishnan et al. [18] reported that in stroke patients with hemiplegia, creating opportunities for the patient to actively control the extremities by using a robot that provides minimum assist matching the patient's ability may contribute to functional improvement, compared to training by passively repeating the gait pattern. Task specificity, training procedure, repetitive intensity, enhanced sensory feedback, and sustained motivation are important elements for the recovery of motor function [19]. In gait training using GEAR, the feature of minimizing robot assistance may increase the opportunity of active training by the patient, leading to improvement in walking ability. Furthermore, both the advantages of ankle-foot orthosis during the swing phase and knee-ankle-foot orthosis during the stance phase can be exploited by using GEAR, which may be one of the reasons for obtaining significant favorable results in the present study.

Various types of robot-assisted gait training systems have been developed, and an increasing number are being introduced into clinical practice. All these systems control both lower extremities. In one study, when subacute stroke patients received robot-assisted gait training in addition to regular physiotherapy, the proportion of patients walking independently increased significantly compared to those receiving physiotherapy alone, although there was no significant difference in walking speed [20]. However, other reports showed no difference when robot-assisted training was used in combination with physiotherapy compared to regular physiotherapy alone [11, 12]. Possible reasons for this discrepancy are the differences in the time of treatment initiation, treatment duration, treatment frequency, and patient status [8]. In addition, previous studies did not provide clear descriptions of the regular physiotherapy and orthosis used. Unless this information is clearly available, it is not possible to discuss the usefulness of robot-assisted gait training systems.

In this study, there was no significant difference in the duration from onset to discharge between the two groups. The duration to discharge is determined not only by walking ability and motor function, but is influenced by a multitude of factors including sensory impairment, visual field impairment, excretory function, and family background [21, 22]. Since the mean number of days to discharge was approximately 10% shorter in the GEAR group, a significant difference might be observed by increasing the number of cases in a future study.

This study has some limitations. We examined a small series of only six cases, and the GEAR group and the orthosis group were recruited or selected from different facilities. Also, although the duration of GEAR training was fixed at 40 min a day, there was no restriction on the content of regular physiotherapy except for the use of a knee-ankle-foot orthosis at the initiation phase of gait training. Future studies are necessary to address these limitations.

The Gait Exercise Assist Robot (GEAR), which is a one-limb type gait training assist system, was used in gait training for subacute stroke patients with hemiplegia, and achieved early improvement of gait independence compared to patients who received gait training using an orthosis. This result suggests the usefulness of GEAR in gait training for stroke patients with hemiplegia. Further studies on a larger number of cases are warranted to confirm the effectiveness of GEAR.

Acknowledgements

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