Randomized Controlled Trial of Gait Training Using Gait Exercise Assist Robot (GEAR) in Stroke Patients with Hemiplegia

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Purpose: This trial aimed to validate the effectiveness of using the Gait Exercise Assist Robot (GEAR) in patients with hemiplegia after primary stroke. *Methods:* The study design was open-label randomized controlled trial. Twenty-six patients with hemiplegia after primary stroke admitted to the comprehensive inpatient rehabilitation wards were enrolled and randomized to a group using GEAR in gait training and a control group. The intervention period was 4 weeks. Evaluations were conducted at admission, during intervention period, 8 weeks from start of intervention, and at discharge. Primary outcome measure was improvement efficiency of Functional Independence Measure (FIM)-walk score (FIM-walk improvement efficiency) that was calculated at the time of achieving FIM-walk score 5 (supervision level) during the intervention period or as weekly gain in FIM-walk score during 4 weeks for those who did not achieve score 5. *Results:* FIM-walk improvement efficiency was .7 ± .4 in GEAR group and .4 ± .3 in control group, and was significantly higher in GEAR group ($P = .01$). The FIM-walk score gain after 4 weeks was significantly higher in the GEAR group ($P = .01$), but there were no significant differences between 2 groups after 8 weeks and at discharge. *Conclusions:* Gait training using GEAR for 4 weeks improved walking ability of subacute stroke patients. GEAR contributes to early improvement of walking ability probably by the knee flexion assist during swing phase on the paralyzed side thereby increasing the volume of training, and by the finely adjustable stance/swing assist mechanism for the paralyzed limb which optimizes the training difficulty level.
Key Words: Comprehensive inpatient rehabilitation wards—gait training—robot—stroke

Introduction

In gait rehabilitation for stroke patients with hemiplegia, gait training is conventionally conducted using lower limb orthoses. In recent years, however, much interest has been directed to training using robots that have advanced the lower limb orthoses. The review published by Mehrholz et al[1,2] has shown that gait training assisted by various devices in combination with physiotherapy improves the acquisition of independent walking compared to gait training without these devices. Previous studies have reported the outcomes of combined use of robotic devices such as Lokomat[3] and Gait Trainer[4] in

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gait training, and most reports have shown that these devices are effective in improving gait independence.[5-7] On the other hand, other studies have shown that gait training using robotic devices does not significantly improve gait independence compared to conventional physiotherapy.[8,9] Hence, the usefulness of robotic devices remains a matter of debate.

Fujita Health University and Toyota Motor Corporation collaborated to develop the Gait Exercise Assist Robot (GEAR) for supporting gait training.[10] GEAR is the prototype of Welwalk WW-1000 that has subsequently obtained approval for use as a medical device. The GEAR system consists of a wearable knee-ankle-foot orthosis robot, a low floor treadmill, a safety suspending device, a robot body weight support device, a monitor for patient use, and a control panel. To apply the motor learning theory, GEAR allows multi-stage and optimal adjustment of the level of difficulty for gait training. GEAR possesses functions of multi-stage adjustments of the level of assist for knee joint extension during stance phase of the paralyzed side, the angle of knee joint flexion during swing phase of the paralyzed side, and the amount of body weight support at the paralyzed foot. With these functions, even patients with severe paralysis can practice treadmill gait training with minimally essential assistance. This feature of high assist adjustability makes it easy to set multi-stage difficulty level. Furthermore, since the knee-ankle-foot orthosis robot flexes the knee point during swing phase, and the body weight support device supports the weight at the paralyzed foot, the patient can execute swing-out easily, which possibly increases the cadence (steps/minute) and enhances the volume of gait training. Visual feedback for the position of foot contact with the floor and audio feedback regarding weight bearing on the paralyzed lower limb are also available.

In a retrospective study conducted by Hirano et al,[11] stroke patients with hemiplegia who used GEAR had higher improvement efficiency of independent walking compared to a historical control group. However, due to the retrospective design, the possibility of introducing biases cannot be denied. We conducted a randomized controlled trial in which stroke patients with severe hemiplegia admitted to the comprehensive inpatient rehabilitation wards of our hospital were randomly assigned to use or not use GEAR. We report the trial results.

Subjects and Methods

Trial Design

Open label randomized controlled trial.

Participants

Among the patients with hemiplegia after primary stroke admitted to the comprehensive inpatient rehabilitation wards of Fujita Health University Nanakuri Memorial Hospital, those with evaluation results at admission which satisfied the following inclusion criteria: age from 20 to 79 years, Stroke Impairment Assessment Set[12] total lower limb motor function score (SIAS-L/E) 0-3, Functional Independence Measure[13] (FIM)-walk score 1-3, FIM-comprehension score more than equal to 3, FIM-social interaction more than equal to 3, FIM-memory score more than equal to 3; and who gave informed consent were recruited as subjects. FIM is activities of daily living scale consisting of 13 motor items and 5 cognitive items. Each item is scored from 1 to 7. Therefore, the total score of motor items ranges from 13 to 91 and that of cognitive items ranges from 5 to 35. However, patients with loading restriction during gait training, patients with peripheral nerve disorder, and patients with joint contracture were excluded (Table 1). This clinical trial was approved by the ethics committee of Fujita Health University. All subjects gave informed consent before participation in the trial. Hirano et al[11] studied 12 patients to evaluate the effectiveness of GEAR. Since the inclusion criteria of the present study selected patients with more severe motor dysfunction on the hemiplegic side than Hirano's study, greater data variation was anticipated. Therefore, the goal of recruitment was 12 patients in each group, or a total of 24 patients, which was 2 times the number in the report of Hirano et al[11] Eventually, the trial was completed with 13 patients in each group, or a total of 26 patients.

Intervention

The GEAR system used in the present trial was a gait training assist robot developed jointly by Fujita Health University and Toyota Motor Corporation. GEAR consists of a wearable knee-ankle-foot orthosis robot, a low floor treadmill, a safety suspending device, a robot body

Table 1. *Inclusion and exclusion criteria*

Inclusion criteria	Exclusion criteria
•Hemiplegia after primary stroke	•Patient with training restriction due to cardiac or respiratory dysfunction
•Age: 20-79 y	•Resting systolic blood pressure $\geq$160 mmHg
•Admission SIAS-L/E score: 0-3	•Resting diastolic blood pressure $\geq$100 mmHg
•Admission FIM-walk score: 1-3	•Patient with lower limb circulatory disorder or peripheral nerve disorder
•Admission FIM-comprehension score: $\geq$3	•Patient with severe joint contracture or deformity
•Admission FIM-social interaction score: $\geq$3	•Patient with visual or auditory impairment hindering training
•Admission FIM-memory score: $\geq$3	

Abbreviations: FIM-walk, Functional Independence Measure-walk; SIAS-L/E, Stroke Impairment Assessment Set-total lower limb motor score.

weight support device, a monitor for patient use, and a control panel. The knee-ankle-foot orthosis robot has a motor to flex or extend the knee joint, with 1 degree of freedom for the knee joint and 1 degree of freedom for the ankle point. Using an ankle joint angle adjusting pin, the range of motion of the ankle joint can be adjusted between plantar flexion 10 degrees and dorsiflexion 30 degrees, either fixed or as a movable range. The plantar region of the robot is equipped with a weight-bearing sensor. The stance phase and swing phase are judged from the data of the weight-bearing sensor, and flexion or extension of the knee joint is affected at the appropriate timing by a motor equipped in the knee joint. The knee extension torque in stance phase can be adjusted in 10 stages from level 10 (maximum) to level 1 (minimum). At level 10, the knee joint is fixed at the extended position; and at level 1, there is no assist for knee joint extension. The knee flexion angle in swing phase can be adjusted within the range of 10-60 degrees. Another assist mechanism during swing phase is the robot body weight support device, which can be adjusted in 6 stages from level 6 (maximum) to level 1 (minimum). At level 6, a weight of approximately 2 kg is supported in a vertical direction, in addition to the weight of the robot. At level 1, the weight support is .5 kg less than the weight of the robot. Regarding feedback functions, visual feedback and audio feedback are available. Visual feedback is provided by a monitor facing the patient, which shows the frontal image, the lateral image, or the foot image of the walking patient. Audio feedback generates warning sound or sound effect indicating success according to the amount of weight-bearing on the lower limb wearing the robot in stance phase and the knee joint flexion angle. As an optional mechanism, the hip joint effects swing out at external rotation position of the paralyzed lower limb during swing phase of the paralyzed side, and reduces hip joint instability during stance phase of the paralyzed side.

The intervention period was 4 weeks from 1 week after admission. The rehabilitation protocol of the GEAR group consisted of physiotherapy 60 minutes per day, gait training using GEAR 40 minutes per day, and occupational therapy 60-80 minutes per day. Gait training using GEAR was started after the other prescribed training was finished. A physiotherapy with experience in gait training using GEAR in at least 3 patients provided intervention using GEAR. Upon observing the gait of the patient, the physiotherapist attempted to facilitate swing-out of the paralyzed side by adjusting the knee flexion angle of the robot foot, the timing of starting flexion, the time from starting flexion to reaching the extended position, and height compensation of the nonparalyzed side. For severe patients, the walking speed was adjusted and the level of difficulty was also adjusted by changing the partial body weight support. In addition, the hip joint was used as appropriate, according to the gait. Furthermore, as the paralyzed lower limb became stabilized in stance phase, the level of knee extension assist by the robot foot was reduced gradually. Visual feedback and audio feedback were used when needed.

The rehabilitation protocol of the control group consisted of physiotherapy 60 minutes per day, conventional gait training 40 minutes per day, and occupational therapy 60-80 minutes per day. Both groups underwent training at a frequency of 7 days a week.[14] The orthosis used as well as the contents of physiotherapy and occupational therapy were decided by the attending physician and the therapists in charge. Speech therapy was conducted according to the physician's prescription.

Evaluation was conducted at admission and before intervention at 1 week after admission. Thereafter, regular evaluation was conducted at weekly interval for 4 weeks. Follow-up evaluation was conducted at 8 weeks after the preintervention evaluation, and at discharge. Hence, a total of 8 evaluations were conducted. Evaluation items at admission consisted of lesion type, age, gender, hemiplegic side, duration after onset, SIAS-L/E score, and FIM scores. Regular evaluation items comprised SIAS-L/E score and FIM-walk score. Evaluation at discharge included SIAS-L/E score, FIM scores, and gait pattern (2 point gait or 3 point gait).

Outcome Measure

The primary outcome measure was FIM-walk improvement efficiency[11] at completion of 4-week intervention. FIM-walk improvement efficiency was calculated at the time of achieving FIM-walk score 5 (supervision level) during the intervention period or as weekly gain in FIM-walk score during the intervention period (4 weeks) for those who did not achieve score 5 (Fig 1). Secondary outcome measures included gain in FIM-walk score from before intervention to after 4 weeks of intervention, 8 weeks after start of intervention, and discharge; number of patients with FIM-walk score 6, gait pattern, and FIM-M at discharge; as well as SIAS-L/E scores at all-time points of evaluation.

Randomization

Patients were stratified using the evaluation data at admission, by combining 4 strata of SIAS-L/E scores 0-3 with 3 strata of FIM-walk scores 1-3, with a total of 12 strata. Randomization within each stratum was done using random numbers generated on Excel. Using this stratified randomization method, patients were assigned to a group that practiced gait training using GEAR (GEAR group) and a group that practiced conventional training (control group).

Statistical Methods

Statistical analyses were conducted using SPSS Statistics 19 (SPSS Inc.). Mann-Whitney *U* test was used

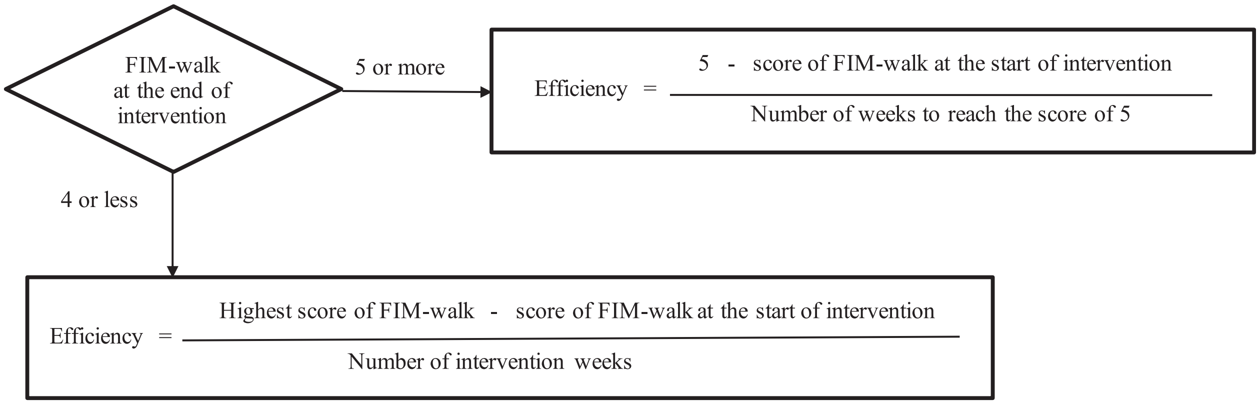

Figure 1. *Calculation of efficiency of FIM-walk improvement. Abbreviation: FIM-walk, Functional Independence Measure-walk score.*

for intergroup comparisons of age, duration after onset, SIAS-L/E score, FIM scores, FIM-walk score, FIM-walk score gain, and FIM-walk improvement efficiency. Chi-squared test was used for intergroup comparisons of basic data at admission including lesion type, gender, hemiplegic side, and orthosis used at admission. A P value less .05 was considered to indicate significant difference.

Results

The demographic data of the subjects are shown in Table 2. The proportion of men was higher in the GEAR group than the control group. There were no significant differences in other parameters between 2 groups.

As the primary outcome measure, FIM-walk improvement efficiency was .7 ± .4 in the GEAR group and .4 ± .3 in the control group, and was significantly higher in the GEAR group (P = .01) (Fig 2).

The time courses of FIM-walk score are shown in Figure 3. The FIM-walk scores gain after starting intervention are shown in Table 3. After 4 weeks of intervention, the FIM-walk score gain relative to the score before intervention was 2.2 ± .6 in the GEAR group and 1.5 ± .7 in the control group, with significantly greater gain in the GEAR group (P = .01). The gains in the GEAR group and control group were 2.6 ± .7 and 2.1 ± .8, respectively (P = .09) at 8 weeks after start of intervention, and 3.0 ± .7 and 2.8 ± .9, respectively (P = .52) at discharge, with no significant differences between 2 groups at both time points.

At discharge, 8 of 13 patients in the GEAR group and 4 of 13 patients in the control group achieved FIM-walk score 6 or above, and chi-squared test detected no significant difference between 2 groups (P = .12) (Table 4).

Regarding gait pattern, 2-point gait was observed in 7 patients while 3-point gait in 6 of 13 patients in the GEAR group. In the control group, 4 of 13 patients showed 2-point gait and 9 of 13 patients showed 3-point gait. Chi-squared test detected no significant difference between 2 groups (P = .23) (Table 5).

Table 2. *Demographic and clinical data of the subjects*

	GEAR group	Control group	P value
Number of patients	13	13	
Age (y)	55.0 ± 9.0	61.2 ± 12.9	.15
Gender (male/female)	11/2	5/8	.02*
Lesion type (ischemic/hemorrhagic)	3/10	3/10	1.00
Hemiplegic side (right/left)	6/7	5/8	.69
Duration after onset (days)	25.9 ± 6.8	31.2 ± 10.3	.16
SIAS-L/E	1.2 ± 1.1	1.4 ± 1.4	.69
FIM-walk	2.2 ± .6	2.1 ± .6	.76
FIM-M	35.6 ± 11.9	32.2 ± 10.2	.54
FIM-C	23.8 ± 5.9	21.1 ± 7.3	.30
Orthosis used in gait training (KAFO/AFO)	13/0	13/0	

Abbreviations: AFO, ankle-foot orthosis; FIM-C, Functional Independence Measure-cognitive subscore; FIM-M, Functional Independence Measure-motor subscore; FIM-walk, Functional Independence Measure-walk score; KAFO, knee-ankle-foot orthosisSIAS-L/E, Stroke Impairment Assessment Set-total lower limb motor score.
*P<.05, Chi-squared test.

FIM-M at discharge were 71.5 ± 10.1 in the GEAR group and 66.4 ± 16.6 in the control group, with no significant difference between 2 groups (P = .57) (Fig 4).

Figure 5 shows the time courses of SIAS-L/E score in 2 groups. No significant differences were observed between 2 groups at all the time points of evaluation, but the scores tended to be lower in the GEAR group.

Discussion

In this trial, FIM-walk improvement efficiency was significantly higher in the GEAR group, and the gain in FIM-walk score after 4 weeks of intervention was also significantly higher in the GEAR group compared to the control group. These results suggest that in patients with severe hemiplegia after stroke, using GEAR combined

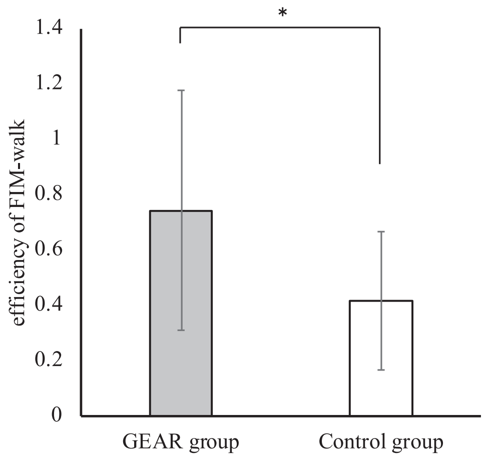

Figure 2. *Comparison of efficiency of FIM-walk improvement between GEAR group and control group. *P = .01, Mann-Whitney U test. Abbreviation: FIM-walk, Functional Independence Measure-walk score.*

with physiotherapy achieves early improvement of walking ability compared with not using GEAR. In a retrospective controlled study using GEAR, the main outcome was efficiency of walking improvement, and gait training using GEAR was found to be more efficient.[11] The same result was obtained in the present randomized controlled trial, validating previous finding.

Why did combined use of GEAR achieve early recovery of walking ability? Many reports have shown the effectiveness of using lower limb orthosis in gait training for stroke patients with hemiplegia,[15,16] and orthoses are widely used even at present. However, when a patient with severe hemiplegia uses an ankle-foot orthosis at the early stage of gait training, extension of knee joint during stance phase is difficult, rendering gait training impossible. Therefore, a knee-ankle-foot orthosis is generally indicated. In fact, knee-ankle-foot orthosis was selected for early training in all the subjects of the present trial. When using a knee-ankle-foot orthosis for gait training in which the paralyzed knee joint is fixed, stability is obtained during stance phase but it is difficult to swing out the paralyzed lower limb. Hence, assistance is required to launch the lower limb, and even though the limb is successfully launched after much effort, the process takes time. As a result, only low cadence training can be obtained. On the other hand, when GEAR is used, flexion of the paralyzed knee joint occurs during swing phase of the paralyzed side, and appropriate body weight support at the paralyzed lower limb is obtained by adjusting the level of swing assist, consequently allowing the paralyzed lower limb to swing out easily. These have probably made it possible to achieve gait at a higher cadence than when using a knee-ankle-foot orthosis, and provide a greater volume of gait training. In rehabilitation for gait disorder

Table 3. *Gain in FIM-walk score after intervention relative to the score before intervention*

	GEAR group	Control group	*P* value
At 4 wk after start of intervention	2.2 ± .6	1.5 ± .7	.01*
At 8 wk after start of intervention	2.6 ± .7	2.1 ± .8	.09
At discharge	3.0 ± .7	2.8 ± .9	.52

Abbreviations: FIM-walk, Functional Independence Measure-walk; GEAR, Gait Exercise Assist Robot.
**P* = .01, Mann-Whitney U test.

Table 4. *Numbers of patients with FIM-walk score 6 or above and those with score 5 or below at discharge*

	GEAR group	Control group
FIM-walk score ≥6	8	4
FIM-walk score ≤5	5	9

Abbreviation: FIM-walk, Functional Independence Measure-walk.

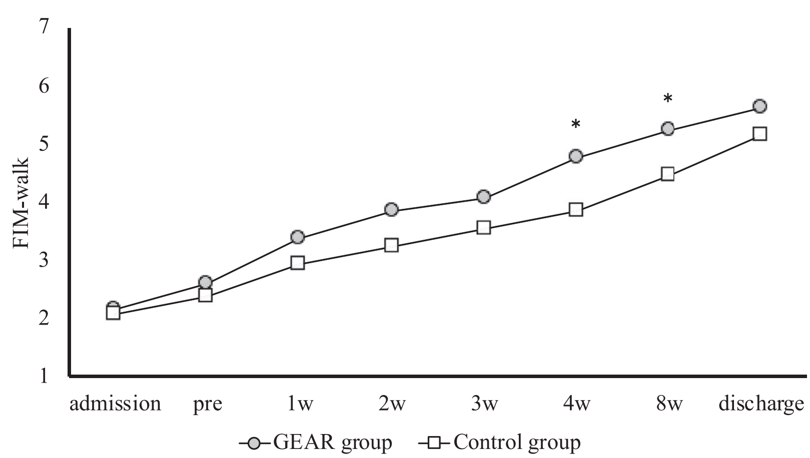

Figure 3. *Time courses of FIM-walk in GEAR group and control group. Significant differences were observed between 2 groups at 4 weeks and 8 weeks after start of intervention (*P < .05, Mann-Whitney U test). Abbreviation: FIM-walk, Functional Independence Measure-walk score; pre, before intervention; w, weeks after start of intervention.*

Table 5. *Number of patients with different gait patterns at discharge*

	GEAR group	Control group
2-point gait	7	4
3-point gait	6	9

Abbreviation: GEAR, Gait Exercise Assist Robot.

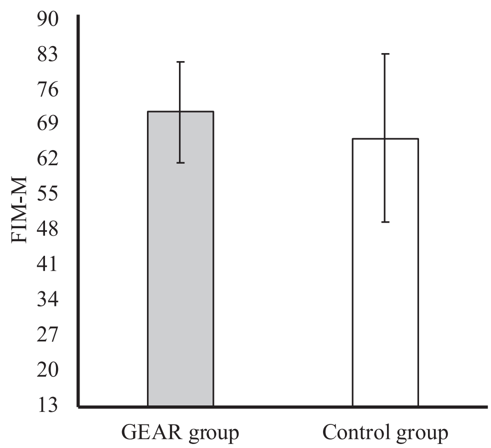

Figure 4. *FIM-M at discharge in GEAR group and control group. The starting point of Y axis is the lowest total score of 13. Abbreviation: FIM-M, FIM-motor subscore.*

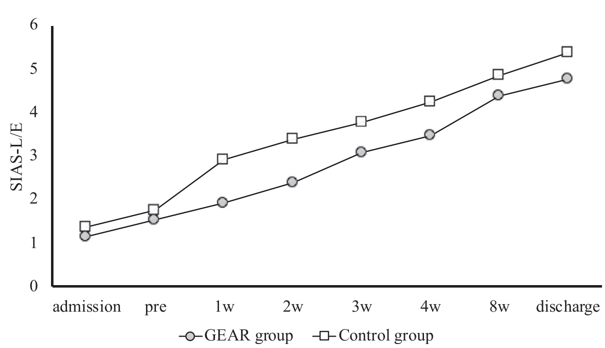

Figure 5. *Time courses of SIAS-L/E in GEAR group and control group. Abbreviation: SIAS-L/E, Stroke Impairment Assessment Set-total lower limb motor score; pre, before intervention; w, weeks after start of intervention.*

in stroke patients with hemiplegia, increasing the volume of gait training and the volume of lower limb training through walking has been reported to improve walking ability.[17] The increase of gait training volume by using GEAR is considered to be associated with the improvement in walking ability.

Patients with hemiplegia after stroke need to acquire new walking ability depending on their disability, and motor learning is involved during the process. Guadagnoli et al[18] described the importance of optimizing the difficulty level of the task in motor learning according to the learner's skill level.[18] Assuming that a patient with severe hemiplegia starts gait training. Initially, a knee-ankle-foot orthosis is often used. When switching from a knee-ankle-foot orthosis to an ankle-foot orthosis, 2-step adjustment is required depending on the absence or presence of a knee joint lock. A knee-ankle-foot orthosis is effective when the extension ability of the paralyzed lower limb in stance phase is weak. However, as the lower limb extension ability improves gradually, there is a risk of excessive assist. On the other hand, the knee extension assist mechanism of GEAR allows 10-stage adjustment of the level of knee extension assist in stance phase of the paralyzed side, and the difficulty level can be finely adjusted along with the improvement in extension ability of the paralyzed knee.

In conventional gait training, although the orthosis provides assist in swing phase of the paralyzed side through restricting plantar flexion of the paralyzed ankle joint and compensating the height of the nonparalyzed side, they are not deemed adequate. On the other hand, GEAR possesses an assist mechanism for knee joint flexion during swing phase of the paralyzed side as well as a weight support mechanism for the paralyzed lower limb, as described above. Together with the fine and multiple adjustment mechanisms of difficulty level, GEAR is considered to be effective in optimizing the difficulty level for gait learning.

The importance of feedback in the context of motor learning has been reported.[19] The study of Guadagnoli et al[20] suggests that providing more frequent or immediate knowledge of result is effective in learning difficult tasks, while less frequent or delayed knowledge of result is effective in learning easy tasks. For subjects in this trial who had hemiplegia after stroke with severe motor paralysis and severe gait disorder, walking is considered to be a difficult task. When using GEAR, real-time feedback is possible through visual confirmation of the walking state on a monitor installed in front of the patient, and by audio confirmation of the amount of weight-bearing on the paralyzed lower limb and the knee joint ankle by the knee-ankle-foot orthosis robot. These feedback mechanisms are considered effective for learning.

However, gain in FIM-walk score at 8 weeks after start of intervention (4 weeks after completing intervention) and at discharge were not significantly different between the GEAR and control groups. The FIM-walk score after 4 weeks of intervention was 4.8 ± .6 in the GEAR group and 3.8 ± 1.0 in the control group, with a 1-point difference in mean score between the 2 groups. Although GEAR facilitated early improvement of walking ability, the efficiency of walking improvement gradually decreased over time due to the ceiling effect of FIM-walk items. Meanwhile, the improvement in walking ability had not peaked in the control group, which may have accounted for the reduced difference in walking ability between the GEAR group and control group at 8 weeks after start of intervention compared to 4 weeks. The same would apply to the finding at discharge.

Nevertheless, despite the absence of significant difference, the number of patients with FIM-walk score 6 or above at discharge in the GEAR group was 2-fold of that in the control group. This difference has important clinical significance. In addition, although there was no significant difference, the number of patients achieving 2-point gait at discharge tended to be higher in the GEAR group. Usually, many stroke patients with hemiplegia walk with a 3-point gait in the early stage of gait training, and this tendency is especially marked in patients with severe paralysis who require a knee-ankle-foot orthosis. When using GEAR, however, it is possible to practice walking in 2-point gait from the early stage of gait training by walking on the treadmill using various assist functions. This may facilitate the acquisition of 2-point gait.

FIM-M at discharge was not significantly different between the 2 groups. The date of discharge depends on the acquisition of the maximum improvement capacity and the social factors surrounding individual patients. Since the comparison of motor capability at discharge in fact compares the capability at the time of fulfilling both of the above conditions, there would be no difference in FIM-M between the 2 groups.

There were no significant differences in SIAS-L/E score between the 2 groups at all the time points of evaluation. On the contrary, FIM-walk score gain was greater in the GEAR group after 4 weeks of intervention. Although the data did not indicate that use of GEAR promoted the improvement of motor paralysis per se, its use resulted in improvement of walking ability without depending on improvement of motor paralysis. This finding suggests that GEAR influences nonparalyzed lower limb functions as well as trunk function, and is useful in learning walking movements.

The adaptation and usage of robot require careful consideration. Some previous studies reported differences in effectiveness even though the same robot was used, which may be caused by differences in adaptation and usage. In the present study, the therapist in charge decided the adjustment of the robot parameters. However, the therapists were educated in advance concerning the policies and had gained experience in using the robot. Clearly defining the indications and utilizing the robot according to appropriate methods probably contributed to the high effectiveness observed in the present trial.

Limitations

This trial was a single-center study conducted on a small number of patients. Therefore, the results obtained cannot be generalized. Future multicenter study recruiting a large number of patients is needed. In previous research that examined the gait training effect using robot on walking ability, walking speed is often used as a measurement of walking ability. In this study, analysis of walking speed was difficult because data of walking speed was missing in a few patients who required assistance even at the time of discharge from the hospital. In addition, we did not evaluate quantitatively the volume of gait training, which is one of the major factors for the gait improvement effect of gait training using GEAR, thus precluding comparison of training volume. This point is a subject of future study.

Conclusions

We validated the effectiveness of gait training using GEAR by conducting an open-label randomized controlled trial in patients with hemiplegia after primary stroke who manifested severe paralysis and severe gait disorder. With an intervention period of 4 weeks, the primary outcome measure was FIM-walk improvement efficiency at the end of the intervention period and was compared between the GEAR group and control group. The result showed significantly higher FIM-walk improvement efficiency in the GEAR group than in the control group. In addition, the gain of FIM-walk score after 4 weeks of intervention was significantly greater in the GEAR group, although there were no significant differences between the 2 groups after 8 weeks and at discharge.

When using GEAR, increase in volume of gait training as a result of knee joint flexion assist during swing phase of the paralyzed side, and optimization of the difficulty level of training provided by the finely adjustable stance/swing assist mechanism for the paralyzed lower limb probably contributed to improvement of walking ability.

References

1. Mehrholz J, Thomas S, Werner C, et al. Electromechanical-assisted training for walking after stroke. Cochrane Database Syst Rev 2017;5. CD006185.
2. Mehrholz J, Thomas S, Werner C, et al. Electromechanical-assisted training for walking after stroke: a major update of the evidence. Stroke 2017;48:e188-e189.
3. Colombo G, Joerg M, Schreier R, et al. Treadmill training of paraplegic patients using a robotic orthosis. J Rehabil Res Dev 2000;37:693-700.
4. Hesse S, Sarkodie-Gyan T, Uhlenbrock D. Development of an advanced mechanised gait trainer, controlling movement of the centre of mass, for restoring gait in non-ambulant subjects. Biomed Tech 1999;44:194-201.
5. Morone G, Bragoni M, Iosa M, et al. Who may benefit from robotic-assisted gait training? A randomized clinical trial in patients with subacute stroke. Neurorehabil Neural Repair 2011;25:636-644.
6. Schwartz I, Sajin A, Fisher I, et al. The effectiveness of locomotor therapy using robotic-assisted gait training in subacute stroke patients: a randomized controlled trial. PM R 2009;1:516-523.
7. Pohl M, Werner C, Holzgraefe M, et al. Repetitive locomotor training and physiotherapy improve walking and basic activities of daily living after stroke: a single-blind, randomized multicentre trial (DEutsche GAngtrainerStudie, DEGAS). Clin Rehabil 2007;21:17-27.
8. Husemann B, Müller F, Krewer C, et al. Effects of locomotion training with assistance of a robot-driven gait orthosis in hemiparetic patients after stroke: a randomized controlled pilot study. Stroke 2007;38:349-354.

9. Chang WH, Kim MS, Huh JP, et al. Effects of robot-assisted gait training on cardiopulmonary fitness in subacute stroke patients: a randomized controlled study. Neurorehabil Neural Repair 2012;26:318-324.
10. Hirano S, Saitoh E, Tanabe S, et al. The features of Gait Exercise Assist Robot: precise assist control and enriched feedback. NeuroRehabilitation 2017;41:77-84.
11. Hirano S, Kagaya H, Saitoh E, et al. Effectiveness of Gait Exercise Assist Robot (GEAR) for stroke patients with hemiplegia. Jpn J Compr Rehabil Sci 2017;8:71-76.
12. Chino N, Sonoda S, Domen K, et al. Stroke impairment assessment set (SIAS) a new evaluation instrument for stroke patents. Jpn J Rehabil Med 1994;31:119-125.
13. Data management service of the Uniform Data System for Medical Rehabilitation and the Center for Functional Assessment Research: Guide for use of the uniform data set for medical rehabilitation (Ver.3.0). State University of New York at Buffalo, New York: 1990.
14. Sonoda S, Saitoh E, Nagai S, et al. Full-time integrated Treatment program, a new system for stroke rehabilitation in Japan. Am J Phys Med Rehabil 2004;83:88-93.
15. Hesse S, Werner C, Matthias K, et al. Non-velocity-related effects of a rigid double-stopped ankle-foot orthosis on gait and lower limb muscle activity of hemiparetic subjects with an equinovarus deformity. Stroke 1999;30:855-861.
16. Teasell RW, McRae MP, Foley N, et al. Physical and functional correlations of ankle-foot orthosis use in the rehabilitation of stroke patients. Arch Phys Med Rehabil 2001;82:1047-1049.
17. Kwakkel G, Wagenaar RC, Twisk JW, et al. Intensity of leg and arm training after primary middle-cerebral-artery stroke: a randomized trial. Lancet 1999;354:191-196.
18. Guadagnoli MA, Lee TD. Challenge point: a framework for conceptualizing the effects of various practice conditions in motor learning. J Mot Behav 2004;36:212-224.
19. Schmidt R, Lee T. Human kinetics. In: Motor Leaning and Performance, 5th ed. 2013.
20. Guadagnoli MA, Dornier LA, Tandy RD. Optimal length for summary knowledge of results: the influence of task-related experience and complexity. Res Q Exerc Sport 1996;67:239-248.