Running Title: A feasibility study of HAL Rehabilitation

Article Title: Feasibility of rehabilitation training with a newly developed wearable robot for patients with limited mobility

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Feasibility of rehabilitation training with a newly developed wearable robot for patients with limited mobility

ABSTRACT

Objectives: To investigate the feasibility of rehabilitation training with a new wearable robot

Design: Before-after clinical intervention

Setting: University Hospital and private rehabilitation facilities

Participants: A convenience sample of 38 patients with limited mobility. The underlying diseases were stroke (n = 12), spinal cord injuries (n = 8), musculoskeletal diseases (n = 4), and other diseases (n = 14).

Interventions: The patients received 90-minute training with a wearable robot twice per week for 8 weeks (16 sessions).

Main Outcome Measures: Functional ambulation was assessed with the 10-m walk test (10MWT) and the timed-up and go (TUG) test, and balance ability was assessed with the Berg balance scale (BBS). Both assessments were performed at the baseline and after the rehabilitation.

Results: Thirty-two patients completed 16 sessions of the training with the wearable robot. The results of the 10MWT included significant improvements in gait speed, number of steps, and cadence. Although improvements were observed, as measured with the TUG test and BBS, the results were not statistically significant. No serious adverse events were observed during the training.

Conclusions: Eight weeks of rehabilitative training with the wearable robot (16 sessions of 90 minutes) could be performed safely and effectively, even many years after the subjects received their diagnosis.

Key Words: Rehabilitation, Robotics, Feasibility Studies, Orthopedic Equipment, Mobility Limitation

ABBREVIATIONS

HAL: Hybrid assistive limb

10MWT: 10-m walk test

TUG: Timed up-and-go

BBS: Berg balance scale

SCI: Spinal cord injury

MADS: Musculoskeletal Ambulation Disability Symptom Complex

CVC: Cybernic Voluntary Control

CAC: Cybernic Autonomous Control

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Rehabilitation robotics emerged in the 1980s with the aim of using robotic technology to assist people with movement dysfunction.[1] Robotic devices have recently been developed for use in clinical settings. Tefertiller et al. reviewed 30 articles (14 randomized controlled trials, 16 non-randomized controlled trials) that examined the effects of locomotor training with robotic assistance in patients following stroke, spinal cord injury (SCI), multiple sclerosis, traumatic brain injury, and Parkinson's disease. The review supports the conclusion that locomotor training with robotic assistance is beneficial for improving walking function in individuals following stroke and SCI.[2] The development of main gait training machines followed. These machines either involve an exoskeleton robotic device (e.g., Lokomat, LOPES exoskeleton robot)[3-4] or a robotic device with foot-driven plates (e.g., Gait Trainer GT I, Haptic Walker).[5-6] The exoskeleton robotic device is equipped with programmable drives or passive elements that flex the knees and hips during the swing phase, whereas with the other type of robotic device, the feet are placed on foot plates, whose trajectories simulate the stance and swing phases. Other than robotic gait training and conventional therapy, another treatment approach involves treadmill training with partial body weight support (BWSTT).[7] However, this approach requires considerable involvement of a physical therapist, and, generally, 3 therapists are required to induce movement of the paretic leg during the swing phase and to shift the patient's weight onto the stance limb.

The potentially positive common benefits of robotic gait training are that it involves repeatedly undergoing sufficient and accurate training for a prolonged period. Lokomat (Hocoma, Volketswil, Switzerland) is the first robotic-driven gait orthosis with electromechanical drives to assist the walking movements of gait-impaired patients on a treadmill by supporting the body

weight.[8-9] Husemann et al. compared a Lokomat group that received 30 minutes of robotic training with a control group that received 30 minutes of conventional physiotherapy[10]. After 4 weeks of therapy, although there was no significant difference in walking ability between the groups, the walking ability in both groups as expressed by functional ambulation classification was significantly improved. The researchers reported that the Lokomat group demonstrated an advantage for robotic training over conventional physiotherapy in the improvement of gait abnormality and body tissue composition.[10] However, in a recent randomized controlled study that compared robot-assisted locomotor training with therapist-assisted locomotor training in chronic stroke patients, the results indicated that greater improvements in speed and single limb stance time on the impaired leg were observed in subjects who received therapist-assisted locomotor training.[11] Thus, the usefulness of robot-assisted rehabilitation is controversial.

The robot suit hybrid assistive limb (HAL) [12-15,a] is a new wearable robot that has a hybrid control system comprised of two subsystems: Cybernic Voluntary Control (CVC) and Cybernic Autonomous Control (CAC) (fig 1). The HAL suit has power units and force-pressure sensors in the shoes. The power units consist of angular sensors and actuators on bilateral hip and knee joints. Muscle action potentials are detected through the electrodes on the anterior and posterior surface of the wearer's thigh. These various biological signals are processed by a computer. The HAL suit can support the wearer's motion by adjusting the level and timing of the assistive torque provided to each joint according to the surface muscle action potential as well as the pressure sensors. The HAL suit can enhance the wearer's motion through the wearer's muscle action potential; thus, the HAL suit can appear as an actual motion. Therefore, if the wearer's muscle action potential varies, the wearer's motion varies, too. The HAL training, using muscle

activity, has the potential to intensify the feedback by evoking by an appropriate motion more strongly than standard robot training. Thus, after HAL training, patients with limited mobility will improve their walking abilities (gait speed, number of steps, cadence, or ability to transfer).

Few studies have been conducted to clarify the feasibility of rehabilitation with HAL. Only 1 preliminary study has reported on the short-term effects of HAL on the walking pattern of stroke patients.[16] The purpose of the present study was to investigate the feasibility of 16-session (8-week) HAL rehabilitation training for patients with limited mobility.

METHODS

Study design

A quasi-experimental study was utilized, with measurements before and after the clinical intervention. The target population included patients with limitations in their walking (no matter the diagnosis, the time since the diagnosis and diagnosis age). The protocol of this study was approved by the Institutional Review Board of the University of Tsukuba Hospital and was registered with the UMIN Clinical Trials Registry (UMIN000002969). The clinical intervention was conducted at the University of Tsukuba Hospital and Cyberdyne, Inc. in Japan between January 2010 and March 2012. The patients included in this study were volunteers recruited through local newspaper advertisements or outpatients at the University of Tsukuba Hospital. They were informed about the aim and design of this study, and they subsequently provided written, informed consent. Informed consent was also obtained from the patient's guardian if the patient was younger than 20 years old.

The inclusion criteria were (1) musculoskeletal ambulation disability symptom complex (MADS) or the underlying disorders of MADS, which is a condition newly defined in 2006 by Japanese medical societies;[17] (2) requiring physical assistance or assistive devices in at least one of the following daily activities: standing up, sitting down, and walking; (3) ability to understand an explanation of the study and to express consent or refusal; (4) body size that can fit in the robotic suit HAL (height range of 145 - 180 cm, and maximal body weight of 80 kg); and (5) ability to undergo usual physical and occupational therapies. The exclusion criteria were the following: (1) inadequately controlled cardiovascular disorders; (2) inadequately controlled respiratory disorders; (3) intellectual impairments that limit the ability to understand instructions; (4) moderate to severe articular disorders, including contracture in the lower extremities; (5) moderate to severe involuntary movements, ataxia, or impairments of postural reflex in the trunk or the lower extremities; and (6) severe spasticity in the lower extremities.

Participants

Thirty-eight patients (25 men, 13 women) were enrolled in this study (24 outpatients, 14 volunteers through advertisements). The mean age of the 38 patients was 53.2 ± 17.8 y, with a range of 18–81 y. Table 1 summarizes their clinical characteristics. Their underlying diseases were stroke (10 men, 2 women), SCI (6 men, 2 women), musculoskeletal diseases (2 men, 2 women), and other diseases (Parkinson's disease, gonadotropin-dependent myopathy, limb-girdle muscular dystrophy, inclusion body myositis, traumatic brain injury, disuse syndrome,

secondary to malignant lymphoma, cerebral palsy, sequelae of poliomyelitis, and hypoxic ischemic encephalopathy; 7 men, 7 women). Twenty patients were able to ambulate independently without any help (n = 9) or with several assistive devices (t-cane, bilateral crutches, or lateral crutch) (n = 11). Eleven patients were able to ambulate with several assistive devices and under supervision. Three patients required human assistance to ambulate at least 10 m (cases 33, 34, and 38), and the remaining 4 patients were unable to ambulate even with assistive devices and human assistance (cases 8, 15, 17, and 27). All of the stroke and SCI patients were in chronic stages.

Training Program

HAL training was administered twice per week for 8 weeks (16 sessions). The 90-minute training sessions consisted of single-leg motion, a standing and sitting exercise, and walking on the ground with HAL. For safety reasons, a walking device (All-in-One Walking Trainer[b]) with a harness was used. Treadmill training with mild body-weight support (Unweighing System[c]) was also used for some patients. The HAL suit has a hybrid control system comprising the CVC and CAC. The CVC mode of the HAL suit can support the patient's voluntary motion according to the voluntary muscle activity and the assistive torque provided to each joint. The CAC mode provides physical support autonomously, based on output from force-pressure sensors in the shoes. This study mainly used the CVC mode, which allows the operator to adjust the degree of physical support to the patient's comfort and gradually reduce support as training progresses.

Outcome Measures

The feasibility of HAL rehabilitation with HAL was assessed by the number of completers and the amount of time or the number of therapists needed to implement training. Patients were asked to report adverse events during the training period.

The primary outcomes were functional ambulation and balance ability. Functional ambulation was assessed with a 10-m walk test (10MWT) and a timed up-and-go (TUG) test. In the 10MWT, patients were instructed to walk without wearing HAL on a flat surface at their self-selected comfortable pace. Patients began to walk before they reached the starting line of the 10 m distance so that they could accelerate and attain a stable speed before the test. To calculate gait speed (m/s) as a primary outcome, the 10-m walking time was measured using a handheld stopwatch. In addition, the number of steps between the start and finish line was counted, and patient cadence was calculated from the walking time and number of steps. Patients were allowed to use their assistive device and/or lower limb orthosis as necessary. Each patient used the same assistive device and/or orthosis during the pre- and post-intervention measurements. Therapists closely attended the patients during the 10MWT but did not provide physical assistance. For each measurement, the 10MWT was performed twice. The faster time of two trials was selected for analysis. In the TUG test, the following actions were timed: standing up from a standard-height chair, walking 3 m, returning to the chair, and sitting down without HAL. Two trials (each turning clockwise and counterclockwise) were carried out for each measurement. Balance ability was assessed with the Berg balance scale (BBS), consisting of 14 tasks, as detailed by Berg et al.[18] Each task was scored on a scale ranging from 0 to 4 points (0 indicates

inability to complete), and the total score was used as the index of balance ability. All primary outcomes were assessed at baseline and after completion of the 16 training sessions.

Statistical Analysis

All parametric data are expressed as means with standard deviations. Paired *t* tests were used to evaluate differences between the baseline measurements and outcomes after the 16 sessions. Unpaired *t* tests were used to evaluate the differences in characteristics of those who completed 16 sessions and those who did not. An effect-size calculation (Cohen d) was used to assess the effect of the training. Pearson correlation coefficients were used to assess the relationship among outcome measures. Data were analyzed using IBM SPSS statistics 18 software[d], with the alphas level set at 5%.

RESULTS

A typical 90-minute HAL training session proceeded as follows: assessment of blood pressure, resting heart rate, and walking pattern (10 min); preparation of electrodes and putting on the HAL suit (5 min); computer set-up (5 min); HAL training (60 min, including resting time during computer operation); taking off the HAL suit and the electrodes (5 min); and reassessment of walking pattern (5 min). The net walking time was approximately 20 min. Typically, 2 therapists implemented the training: one supported the patient and the other operated the computer. All therapists and related staff had participated in a 3-h training workshop conducted by the manufacturer to learn how to operate the HAL system.

Of the 38 patients (25 men, 13 women), 32 (21 men, 11 women) completed all 16 training sessions. The mean age of the 32 patients was 53.2 ± 17.3 y, with a range of 18–81 y. There was no statistically significant difference in age between those who completed training and those who did not (54.0 ± 19.8 y). It took 10.0 ± 3.1 weeks (range, 8–21 weeks) to complete 16 sessions. Of the 6 patients who did not complete the 16 sessions, 2 (cases 15 and 21) dropped out for medical reasons, and 4 (cases 1, 2, 29, and 35) dropped out for personal reasons (difficulty visiting the hospital). One medical reason for dropout was low back pain that developed during the first training session (case 21); the patient withdrew consent at the third session. The other medical reason for dropout was a relapse (after the second session) of neuropathic pain due to SCI (case 15); the patient withdrew consent at the fifth session. There were no serious training-related adverse events. One stroke patient (case 7) had knee pain (patellar tendinitis) at home after the 15th session but was able to complete the 16th session after 1 month of rest. Another patient with inclusion body myositis (case 31) developed knee pain at home after an early session but was able to complete 16 sessions.

Outcome Measures

Functional ambulation was not assessed for 5 patients at baseline because 3 were unable to ambulate with any assistance (cases 8, 17, and 27), and the other 2 patients needed considerable human assistance to ambulate (cases 34 and 38). The other 27 patients presented significant improvements ($P < 0.05$) in gait speed, number of steps, and cadence after the 16-session HAL training (10MWT, table 2). Improvements in gait speed, number of steps, and cadence are

defined as an increase, a decrease, and an increase in the respective parameters. The mean improvements and effect sizes (Cohen d) in gait speed, number of steps, and cadence were 0.09 ± 0.11 m/s (d = 0.82), 3.0 ± 4.9 steps (d = 0.61), and 6.8 ± 7.1 steps/min (d = 0.96), respectively. Improvements in gait speed, steps, and cadence were observed in 25, 18, and 25 patients, respectively (figs 2–4). Worsened gait speed and cadence were observed in 2 patients (cases 28 and 30). In the regards to the number of steps, we observed no change in 8 patients (cases 3, 5, 16, 25, 28, 30, 33, and 37) and increased steps in 1 (case 20). Correlation coefficients for gait speed with number of steps and with cadence were $r = 0.30$ (not significant) and $r = 0.73$ ($P < 0.01$), respectively. The effect sizes for gait speed in stroke patients (n = 9), SCI patients (n = 6), musculoskeletal disease patients (n = 3), and patients with other diseases (n = 9) were 1.41, 0.78, 2.43, and 0.63, respectively. The results of the TUG test (n = 26; the patient in case 10 was unable to perform the test) and the BBS (n = 32) indicated improvement after the 16 training sessions, but these improvements were not statistically significant. The mean decrease (Cohen d) in the TUG test was 6.4 ± 16.4 s (d = 0.39). Twenty-one of 26 patients were faster after training, and 5 patients were slower (cases 5, 13, 30, 31, and 36) (fig 5). The mean increase (Cohen d) in BBS was 1.9 ± 5.5 (d = 0.35). Nineteen of 32 patients had higher scores compared to baseline; no change was observed in 6 (cases 12, 17, 23, 27, 36, and 37), and 7 had lower scores (cases 11, 16, 26, 30, 31, 32, and 34) (fig 6).

DISCUSSION

We investigated the feasibility of rehabilitation using a robot suit HAL. We demonstrated that HAL rehabilitation could be implemented safely and effectively. Although a few patients

developed lumbar or knee pain during the training, no serious training-related adverse events occurred. Significant improvements in gait speed, number of steps, and cadence were observed, as assessed by the 10MWT. Improved TUG test and BBS results were also observed, but because of the small sample size of this pilot study, these improvements were not statistically significant. Overall, our results suggest that HAL rehabilitation has the potential to improve ambulation in patients with limited mobility.

Two patients (cases 15 and 21) dropped out for medical reasons. One developed lumbar pain (case 21), and 1 experienced a relapse of neuropathic pain due to SCI (case 15). Although it is unclear whether there was a causal relationship between HAL training and the pain that developed, the lumbar pain in case 21 had been persistent before the HAL training and even after the training ended, and the neuropathic pain in case 15 followed a previous pattern of symptom flares associated with seasonal change. Therefore, it is likely that HAL training did not directly cause the pain that developed in these 2 cases. Two other patients complained of knee pain during the training period, but this pain was not severe, and the patients were able to complete the training. Although, once again, direct causality is unclear, safe implementation of HAL rehabilitation requires adequate caution on the part of therapists and self-awareness on the part of patients who have lumbar and knee pain. Regarding feasibility, approximately 10 min was required for 2 to 3 therapists to put electrodes and the HAL suit on or off the patient. This procedure is a slight inconvenience to address but not a major obstacle to HAL rehabilitation.

Significant improvements in functional ambulation were observed, and the effect sizes (Cohen d) for gait speed, number of steps, and cadence were 0.82, 0.61, and 0.96, respectively. The

correlation coefficient for gait speed with cadence was higher than that of gait speed with steps (r = 0.73 vs. r = 0.30). Therefore, the improvement in gait speed with HAL training was mainly brought about by improvement in cadence. That is, HAL training improved stride frequency more than stride length. This finding agrees with a previous robotic training study.[19] The effect sizes for the TUG test and BBS were smaller than that effect sizes for the 10MWT. This result seems to occur because the TUG test and BBS involve complicated motions such as moving from sitting to standing, walking and returning, reaching forward, and alternating feet on each step. The effect sizes for gait speed in 9 stroke patients and in 6 SCI patients were large (1.41 and 0.78), respectively. Therefore, training effectiveness in stroke and SCI patients can be expected. The effect size in 3 patients with musculoskeletal diseases was also large (2.43), but the number of patients was small. Therefore, further studies are needed. In this study, we recruited patients with a wide range of stroke and SCI severities. Future studies should examine the influence of the severity of stroke and SCI on the effectiveness of HAL rehabilitation.

Many recent studies have reported the efficacy of robot-assisted rehabilitation. It is very difficult to directly compare these studies and our study, due to differences in diseases, severity and duration of the disorder, robotic features, methods of intervention, and outcome measures.[20] Wirz et al. reported that after locomotor training with Lokomat, the 10MWT gait speed of 20 patients with chronic incomplete SCI increased by 0.11 ± 0.10 m/s (d = 1.10).[21] The number of SCI patients in our study was limited to 6, but our results also indicate the efficacy of HAL rehabilitation for these patients (d = 0.78). Hornby et al. reported that after robotic-assisted locomotor training, the gait speed in chronic stroke patients increased by 0.07 ± 0.07 m/s (d = 1.0).[11] Our results also indicate the efficacy of HAL rehabilitation for 9 chronic stroke patients (d

= 1.41). We conjectured that the mechanism of this recovery of functional ambulation was due to changes in plasticity in the spinal cord and supraspinal centers. Appropriate sensory inputs, such as maximum weight loading, facilitating proper trunk posture, and hip extension, are essential for maximizing functional recovery.[22] Our experience with HAL indicates that the HAL-induced motion might evoke the sensory input, which has a favorable feedback effect on the central nervous system for a recovery of locomotor function. In addition, even if a patient's condition were too severe for medical therapists to provide adequate rehabilitation training, HAL might still make adequate training possible. HAL is a robotic device with potential rehabilitation applications that are dependent on the physical support it can provide.

Study Limitations

This study was not a randomized controlled trial and could not compare the efficacy of HAL training with conventional rehabilitation. Second, long-term efficacy was not assessed after HAL training. Third, this study could not exclude observer bias and subject bias because the same staff implemented assessment and training, and approximately half of the patients were recruited through local newspaper advertisements. Finally, the statistical power was low because of the small number of patients with each disease.

CONCLUSIONS

This quasi-experimental study revealed the feasibility of HAL training for rehabilitating patients with limited mobility. This study has shown that it is possible to manage 8 weeks of

rehabilitation with HAL training (16 sessions of 90 minutes) safely and effectively, even with persons who received their diagnosis many years ago. After HAL training, significant improvements in gait speed, number of steps, and cadence were observed. Although improvements were observed in the TUG test and BBS, they were not statistically significant. There were no serious adverse events. Further studies are needed to compare the effectiveness of HAL training and conventional rehabilitation.

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Suppliers

a. Cyberdyne Inc, D25-1, Gakuen Minami, Tsukuba, Ibaraki, Japan 305-0818.

b. ROPOX A/S, 221 Ringstedgade, Naestved, Denmark 4700.

c. Biodex Medical Systems Inc, 20 Ramsay Rd, Shirley, NY 11967.

d. SPSS, Inc, 233 S Wacker Dr, 11th Fl, Chicago, IL 60606.

FIGURE LEGENDS

Figure 1. The robot suit HAL.

Figure 2. Change in 10MWT gait speed for 27 patients after HAL training.

Figure 3. Change in number of steps during 10MWT for 27 patients after HAL training.

Figure 4. Change in 10MWT cadence for 27 patients after HAL training.

Figure 5. Change in TUG test results for 26 patients after HAL training.

Figure 6. Change in BBS score for 32 patients after HAL training.

Figure 1.

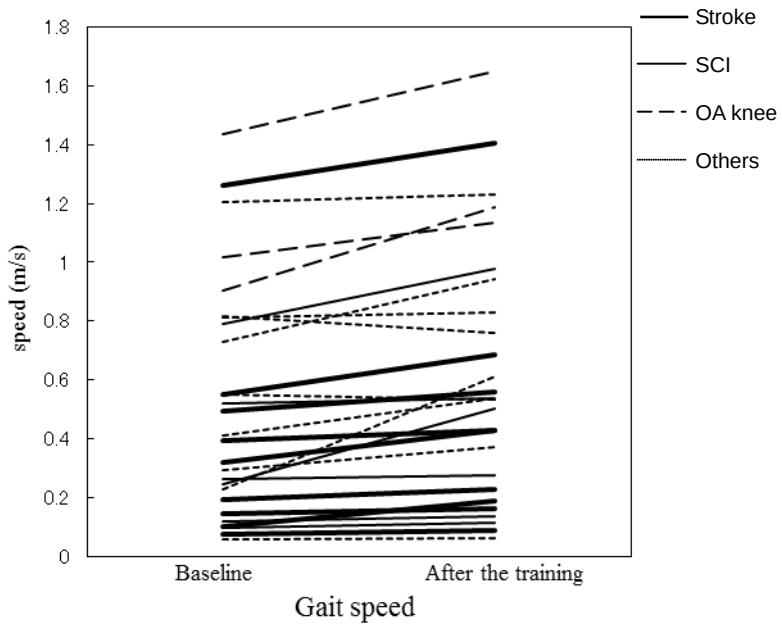
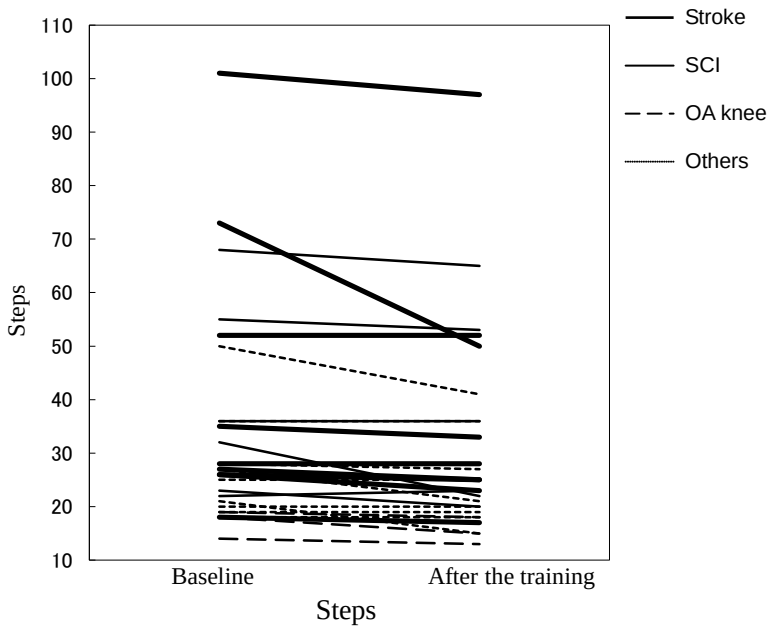


Figure 2.



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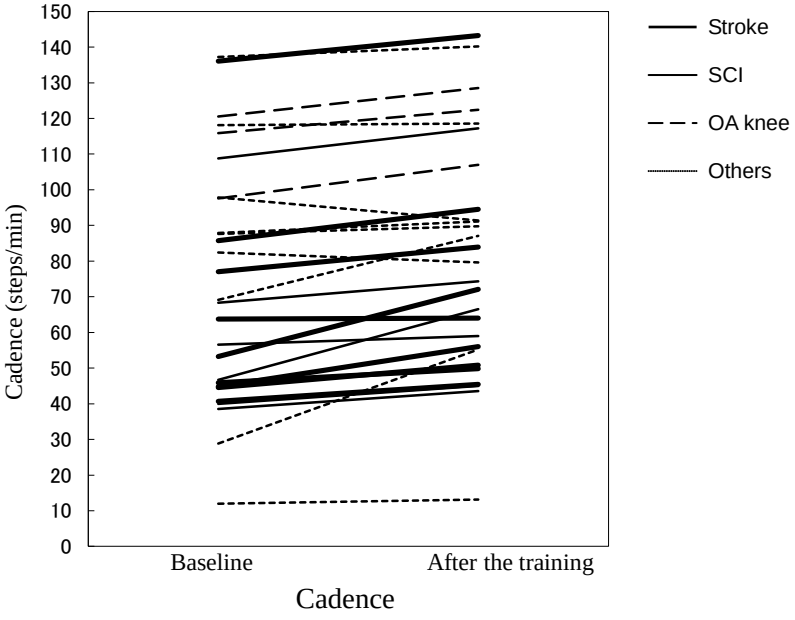

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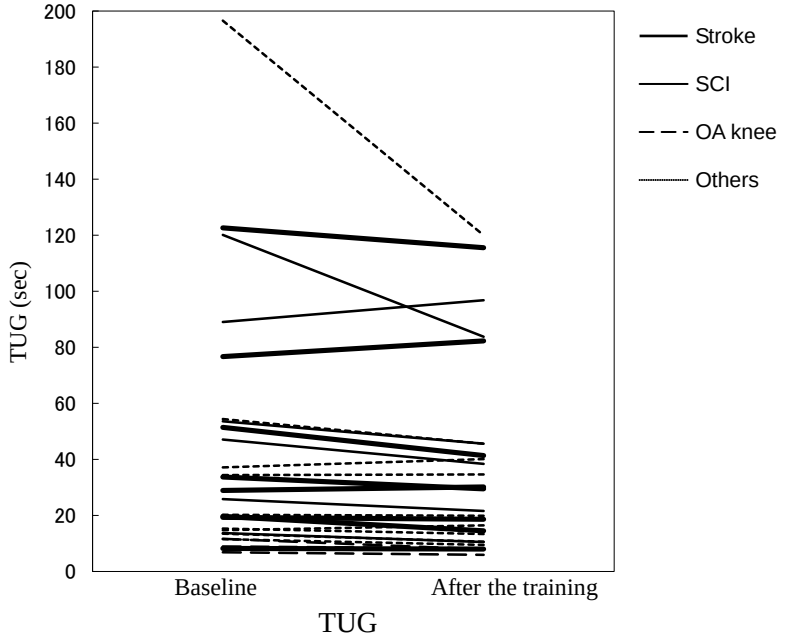

Figure 5.

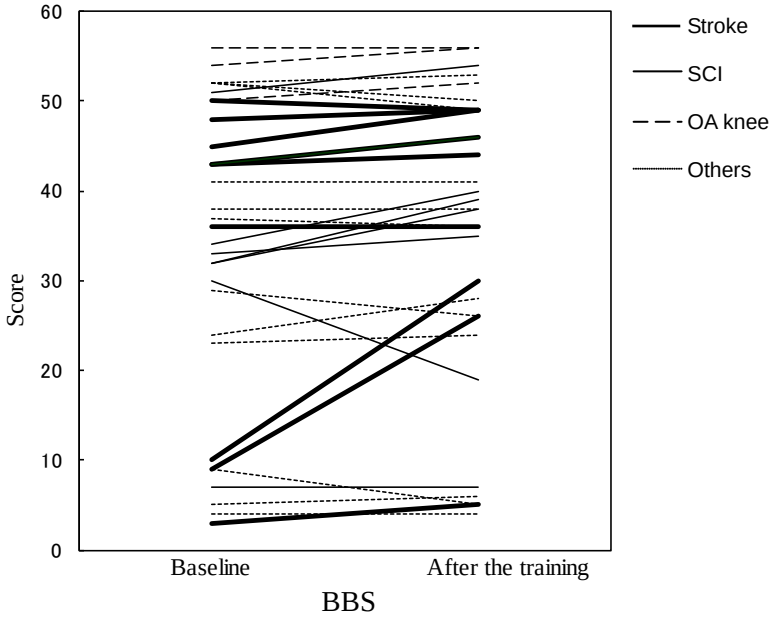
60
50
40
30
20
10
0
Score
Baseline
After the training
BBS
Stroke
SCI
OA knee
Others

Figure 6.

Table 1: Clinical characteristics of patients

Case No.	Age (y)	Sex	Diagnosis	Paralysis type	Duration since disease	Ambulation	Assistive device	Orthosis	Training	Duration of training (wk)	Adverse events
1	69	M	stroke (cerebral infarcts)	paraplegia	15y	independently	t-cane	AFO	dropout (personal reason)	ND	Nothing
2	61	M	stroke (cerebral hemorrhage)	paraplegia	14y8mo	independently	t-cane	AFO	dropout (personal reason)	ND	Nothing
3	65	M	stroke (cerebral hemorrhage)	hemiplegia	2y2mo	supervision	quad-cane	AFO	complete	8	Nothing
4	37	F	stroke (cerebral hemorrhage)	quadriplegia	16y	independently	NA	AFO	complete	8	Nothing
5	72	M	stroke (cerebral infarcts)	hemiplegia	2y9mo	supervision	t-cane	AFO	complete	8	Nothing
6	54	M	stroke (cerebral hemorrhage)	hemiplegia	1y1mo	supervision	t-cane	NA	complete	8	Nothing
7	63	F	stroke (cerebral hemorrhage)	hemiplegia	1y6mo	independently	t-cane	AFO	complete	15	knee pain (patellar tendinitis)
8	52	M	stroke (cerebral hemorrhage)	ataxia	2y2mo	NA	NA	NA	complete	12	Nothing
9	74	M	stroke (cerebral infarcts)	hemiplegia	3y4mo	independently	t-cane	AFO	complete	9	Nothing
10	53	M	stroke (subarachnoid hemorrhage, cerebral infarcts)	hemiplegia	ND	supervision	pick up walker	KAFO	complete	9	Nothing
11	18	M	stroke (moyamoya disease)	hemiplegia	11y	independently	NA	AFO	complete	21	Nothing
12	64	M	stroke (cerebral hemorrhage)	hemiplegia	1y	supervision	t-cane	AFO	complete	8	Nothing
13	58	F	SCI (incomplete)	quadriplegia	3y3mo	supervision	lateral crutch	KAFO	complete	8	Nothing
14	69	M	SCI (incomplete)	quadriplegia	1y3mo	supervision	pick up walker	AFO	complete	8	Nothing
15	43	M	SCI (incomplete)	paraplegia	3y3mo	NA	NA	KAFO	dropout (medical reason)	ND	neuropathic pain after SCI
16	59	M	SCI (spina bifida)	paraplegia	6y4mo	supervision	t-cane	NA	complete	8	Nothing
17	31	M	SCI (complete)	paraplegia	3y	NA	NA	NA	complete	10	Nothing
18	64	F	SCI (incomplete)	quadriplegia	2y	independently	t-cane	AFO	complete	9	Nothing
19	54	M	SCI (central cervical cord injury)	quadriplegia	5y	supervision	t-cane	NA	complete	12	Nothing
20	47	M	SCI (spinal dural arteriovenous fistula)	paraplegia	1y1mo	independently	bilateral crutch	AFO	complete	8	Nothing
21	74	F	musculoskeletal disease (cervical spondylotic myelopathy)	quadriplegia	ND	independently	bilateral crutch	NA	dropout (medical reason)	ND	low back pain
22	81	F	musculoskeletal disease (OA Knee)	NA	ND	independently	NA	NA	complete	10	Nothing
23	44	M	musculoskeletal disease (OA Knee)	NA	ND	independently	NA	NA	complete	11	Nothing
24	74	M	musculoskeletal disease (OA Knee)	NA	ND	independently	NA	NA	complete	10	Nothing
25	62	M	Parkinson's disease	NA	8y	independently	NA	NA	complete	11	Nothing
26	72	F	Parkinson's disease	NA	7y8mo	independently	NA	NA	complete	9	Nothing
27	36	M	gonadotropin-dependent myopathy	paraplegia	19y	NA	NA	NA	complete	8	Nothing
28	52	F	limb-girdle muscular dystrophy	quadriplegia	24y	supervision	t-cane	NA	complete	9	Nothing
29	57	F	muscular dystrophy	NA	44y	independently	NA	NA	dropout (personal reason)	ND	Nothing
30	67	M	limb-girdle muscular dystrophy	NA	28y	independently	t-cane	NA	complete	8	Nothing
31	73	M	inclusion body myositis	NA	10y	independently	t-cane	NA	complete	10	knee pain
32	24	M	traumatic brain injury	quadriplegia	17y1mo	supervision	walker	NA	complete	8	Nothing
33	19	F	traumatic brain injury	quadriplegia	6y2mo	assistance	pick up walker	KAFO	complete	8	Nothing
34	29	F	traumatic brain injury	quadriplegia	10y7mo	assistance	pick up walker	KAFO	complete	9	Nothing
35	20	M	disuse syndrome, secondary to malignant lymphoma	NA	3y9mo	independently	t-cane	NA	dropout (personal reason)	ND	Nothing
36	31	F	cerebral palsy	quadriplegia	30y10mo	independently	lateral crutch	NA	complete	10	Nothing
37	55	M	sequelae of poliomyelitis	paraplegia	54y	independently	lateral crutch	NA	complete	19	Nothing
38	48	F	hypoxic ischemic encephalopathy	quadriplegia	2y	assistance	NA	NA	complete	12	Nothing

NOTE.
Abbreviations: AFO, ankle-foot orthosis; F, female; KAFO, knee-ankle-foot orthosis; M, male; NA, not applicable; ND, no data; OA, osteoarthritis

Table 2: Functional ambulation and balance ability at the baseline and after the 16-session HAL training

Outcome measurements		Baseline	After the training	Difference Mean (95% CI)	P-value	n
10 MWT	Speed (m/sec)	0.52 ± 0.40	0.61 ± 0.43	0.09 (0.05 to 0.14)	p < 0.001	27
	Steps	34.0 ± 20.4	31.0 ± 18.8	-3.0 (-4.9 to -1.0)	p < 0.001	27
	Cadence (steps/min)	74.3 ± 34.1	81.1 ± 32.9	6.8 (4.0 to 9.6)	p < 0.001	27
TUG (sec)		43.7 ± 45.0	37.3 ± 34.1	-6.4 (-13.0 to 0.2)	0.057	26
BBS		33.6 ± 16.9	35.5 ± 16.3	1.9 (-0.1 to 3.9)	0.059	32

NOTE. Values expressed as mean ± SD.

Abbreviation: TUG, Timed-Up and Go. BBS, Berg Balance Scale.