



Original Article

Exercise using a robotic knee orthosis in stroke patients with hemiplegia

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Abstract. [Purpose] The Robotics Knee Orthosis (RKO) is a knee–ankle–foot orthosis with active robot assisting technology. The purpose of this study is to examine the effects of exercise with the RKO (RKO-exercise) in stroke patients with hemiplegia. [Subjects and Methods] Participants were nine stroke patients with hemiplegia, residing in a convalescent rehabilitation ward. The duration of the RKO-exercise program was 10 days. Participants were evaluated three times prior to intervention, once after intervention, and one month post intervention. Each session consisted of standard-of-care physical therapy for 60 minutes and RKO-exercise for 20 minutes. Dependent variables were 10-meter gait speed, cadence, Berg Balance Scale (BBS) score, stride length, the absolute value of left-right symmetry of the step length, and one-leg support period while walking. Data were analyzed using a one-way repeated measures ANOVA. [Results] Stride length, left-right symmetry of the step length, and one-leg support period while walking changed following the RKO exercise program. 10-meter walking speed, cadence, percentage of one-leg support period (affected side), and BBS changed significantly at one month post treatment time points. [Conclusion] It is expected that RKO-exercise helps recovery process after the stroke. RKO-exercise effectively treats impaired mobility in patient status-post stroke.

Key words: Robotics Knee Orthosis (RKO), Hemiplegia, Enhancement of recovery process

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INTRODUCTION

Stroke is a common, serious, and disabling global health-care issue¹). Rehabilitation treatments following stroke seek to improve patients' independence. Neuroplastic mechanisms underlie functional improvements after stroke²). An effective use of brain neuroplasticity is essential for promoting functional recovery in these patients.

The World Health Organization (WHO) defines neuro-rehabilitation as “a problem-solving process in which the person who experiences a neurological impairment or loss of function acquires the knowledge, skills, and supports needed for their optimal physical, psychological, social, and economic functioning³.” Recent advances in robotic technology have made inroads to rehabilitation, in particular neurorehabilitation. Lower extremity robotic exoskeletal devices include the Lokomat, LOPES Exoskeleton Robot, Hybrid Assistive Limb (HAL) and WPAL augment high-dose intensive training and facilitate the repetitive practice of specific functional tasks⁴⁻⁶). These factors are important for recovery after stroke.

Bionic-Leg (Alter-G, Sunnyvale, CA, USA) is a portable, wearable, battery-powered knee-ankle-foot orthosis with active robot assisting technology (also referred to as the Robotics Knee Orthosis or RKO), as shown in Fig. 1. This training orthosis

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supports knee mobility when standing or walking. The RKO receives pressure-related information from a plantar sensor and angle-change information from a knee sensor.

The time that wear the RKO is about 5 minutes. The level of assistance is able to be varied according to the patient's ability level.

Past reports indicate that exercise with the RKO (RKO-exercise) improves balance and walking ability in patients with chronic stroke symptoms^{7, 8}). And the recent study examined the effects of RKO-assisted exercise for five patients with chronic stroke symptoms, using an ABA-type single case study design. Phase A of the ABA design was standard exercise and Phase B consisted of RKO-exercise. All patients underwent 30 days of treatment, involving 10 days of standard exercise, 10 days RKO-exercise, and another 10 days standard exercise. The dependent variables of interest included the Berg Balance Scale score, stride length, step length, the duration of one-leg support time, and the 10-meter gait time improved during Phase B⁹).

This investigation had major limitations in that it was a single case study design with no statistical analyses. This study sought to quantify the effects of RKO-exercise via statistical analyses procedures.



Fig. 1. The bionic-leg (Alter-G, Sunnyvale, CA, USA)

SUBJECTS AND METHODS

The participants were nine patients (six men and three women, mean age=64.3 ± 13.5 years) with hemiplegia status-post stroke, residing in a convalescent rehabilitation ward. The average time since stroke was 48.7 ± 16.1 days. Six patients had residual right hemiplegia and the remaining three had left hemiplegia. Participant demographics are presented in Table 1.

Inclusion criteria were as follows: first stroke with hemiplegia, Brunnstrom Recovery Stage (BRS) of III or IV for the leg, sensory dysfunction (touch and position senses of the lower extremity) of 1–3 on the Stroke Impairment Assessment Set (SIAS), independent or supervision-only static sitting ability without support, independent or supervision-only static standing ability with quad or T cane or no support tool, independent or supervision-only walking ability with quad cane or T cane or no support tool, and a Functional Independent Measure (FIM) of at least four (locomotion).

Participants were excluded if they were unable to understand study-related procedures, exhibited serious hypertension on walking, circulatory disease, respiratory disease, or extreme weakness. All participants received physical clearance to participate; those who did not were excluded.

A researcher explained the purpose of the study to all participants, and each participant provided written informed consent. Research approval was granted by the Ethics Committee of Teikyo Heisei University (No 27-83) and the Tokusyuukai Group (TGE00581-017).

RKO-exercise were administered over 10 days. Dependent variables were sampled three times: prior to RKO-exercise treatment, after RKO-exercise treatment, and one month post RKO-exercise treatment. The intervention consisted of 60 minutes of standard-of-care physical therapy, followed by 20 minutes of RKO-exercise. Only standard-of-care physical therapy was offered during the post intervention and one month post intervention periods.

Standard-of-care physical therapy exercises targeted range of motion, neurovascular function, balance, basic movements, and activities of daily living. Therapists administering RKO-exercise were trained by Alter-G trained physical therapists. RKO-exercise included sit-to-stand, paralytic lower extremity weight bearing, and walking. Sit-to-stand exercises included

Table 1. Participant demographics (n=9)

	Age	Gender	Days	Diagnosis	Paretic side	BRS (Leg)	Sensory (SIAS)
1	40-	Male	57	The putamen hemorrhage	Left	4	2
2	70-	Female	56	Thalamic hemorrhage	Left	3	1
3	70-	Male	46	The putamen hemorrhage	Left	4	2
4	70-	Male	47	Middle Cerebral Artery infarction	Right	4	2
5	50-	Male	23	The putamen hemorrhage	Right	3	2
6	80-	Male	39	The putamen hemorrhage	Right	3	2
7	60-	Female	60	The putamen hemorrhage	Right	4	2
8	40-	Male	32	Middle Cerebral Artery infarction	Right	3	1
9	60-	Female	41	Middle Cerebral Artery infarction	Right	4	2
Ave ± SD	64 ± 12.7		44.5 ± 11.5				

Days: The average time since stroke; BRS: Brunnstrom recovery stage; Sensory (SIAS): touch sense and position sense of lower extremity in Stroke Impairment Assessment Set; Ave ± SD: Average ± standard deviation

Table 2. Result of evaluation items

Evaluation items	Prior to	After	One month post
	RKO-exercise treatment	RKO-exercise treatment	RKO-exercise treatment
Gait speed (m/min)	13.8 ± 10.6	22.7 ± 16.6 ^a	29.5 ± 22.8 ^{a,b}
Cadence (steps/min)	50.3 ± 23.8	61.9 ± 24.8	65.9 ± 30.4
Stride length (cm)	41.1 ± 8.2	56.2 ± 10.4 ^a	76.8 ± 29.1 ^a
Step length affected side (cm)	29 ± 5.1	31.5 ± 6.7	37.2 ± 9.6
Step length unaffected side (cm)	12 ± 8.2	24.3 ± 12.2 ^a	39.7 ± 26.1 ^a
The left–right symmetry of the step length [1-affected side (cm)/unaffected side (cm)]	2.5 ± 1.7	1.1 ± 1.4 ^a	0.48 ± 0.6 ^{aa}
The percentage of one-leg support period during the walking cycle (affected side) (%)	10.2 ± 3.8	15.8 ± 6.3 ^{aa}	20.6 ± 8.7 ^{aa,b}
The percentage of one-leg support period during the walking cycle (unaffected side) (%)	20.8 ± 6.4	24.3 ± 4.8	26.3 ± 8.6
The left–right symmetry of the one-leg support period during the walking cycle [1-affected side (%) /unaffected side (%)]	0.51 ± 0.1	0.36 ± 0.2 ^{aa}	0.23 ± 0.2 ^{aa}
BBS score	23.1 ± 9.6	33.8 ± 11.5 ^{aa}	39.5 ± 11.3 ^{aa,bb}

Average ± SD

a: VS prior to RKO-exercise treatment ($p < 0.05$), aa: ($p < 0.01$), b: VS after RKO-exercise treatment ($p < 0.05$), bb: ($p < 0.01$)

squatting in addition to repeated stand-sit. Paralytic lower extremity weight-bearing exercises consisted of weight shifting and one-leg standing. Walking tasks were identical to those carried out during standard-of-care physical therapy. Participants used ortop AFOs made by Pacific Supply. It is short type of plastic AFO and used for slight drop foot. Because RKO offers no assistance during dorsal ankle flexion. In all sessions, the therapist encouraged participants to consciously monitor right and left symmetry with a mirror. The therapist offered minimal assistance and patients independently practiced all tasks, except for when new tasks were introduced.

The RKO has three adjustable component settings: threshold (the lower limit of force that must be generated to initiate device assistance), assistance (the percentage of body weight assistance provided during limb extension), and resistance (resistance to flexion during stair descent or stand-to-sit transfer motion). The RKO also has three global settings. Min=assistance of 30%, low resistance, and threshold of 35%. Mod=Assistance of 45%, medium resistance, and threshold of 25%. Max=assistance of 65%, high resistance, and threshold of 15%. All participants in the study were set to Mod owing to the sitting ability and degree of hemiplegia and sensory dysfunction.

The variables of interest included 10-meter walking speed (normal speed), cadence, stride length, step length (affected side and unaffected side), the left–right symmetry of the step length (1-affected side/unaffected side)¹⁰, the percentage of one-leg support period during the walking cycle (affected side and unaffected side), the left–right symmetry of the one-leg support period during the walking cycle [1-affected side (%) /unaffected side (%)]^{11, 12}, and the Berg Balance Scale (BBS).

Participants were instructed to walk in a straight line, at a comfortable speed, for 16 minutes. There were 3 meter runways at the start and end of a 10 meter test walkway, and patients used their usual walking aids and ankle–foot orthoses.

The video camera HC-WXF990 M (Panasonic, Japan) was fixed to a 50-cm tripod and set five meters from the walking line to fully capture the participants while they were walking. Video images were analyzed by Dartfish Software (Dartfish Japan Co. Ltd.), and each variable was averaged over five repetitions of the walking cycle.

During statistical analysis, the before treatment, after treatment, and one month post treatment time points were made autonomous variables. We performed one-way repeated measures ANOVA using SPSS 14 OJ for Windows. The level of significance was set at $p < 0.05$.

RESULTS

Results are presented in [Tables 2](#).

1. Changes after standard therapy—We observed significant changes in the 10-meter walking speed, cadence, percentage of one-leg support period (affected side), and BBS between the before treatment, after treatment, and one month post treatment time points.
2. Changes after RKO-exercise therapy—We observed significant changes in stride length, step length (unaffected side), the left–right symmetry of the step length, the left–right symmetry of the one-leg support period during the walking cycle, between the before treatment and after treatment time points. There were no significant changes between the after treatment and one month post treatment time points.
3. No changes were observed in the step length (affected side) and the percentage of one-leg support during walking (unaffected side).

DISCUSSION

This study was examined the effects of RKO-exercise in nine patients with hemiplegia status-post stroke. Walking and balance significantly improved after treatment and one month post treatment, compared to before treatment. The participants of this study were status-post stroke and residing in a convalescence ward. It is general that they recover if they receive rehabilitation. The characteristic point of this study is that there were significant improvements in stride length, step length (unaffected side), the absolute value of left–right symmetry of the step length, and the absolute value of left–right symmetry of the percentage of one-leg support period during walking, 10 days after RKO-exercise treatment.

RKO-exercise treatment involved sit-to-stand, paralytic lower extremity weight bearing, and walking. Participants were instructed to attend to left–right symmetry and repeatedly practice each task.

As a result, the speed of weight shifting to the paralytic lower extremity improved, as did the left–right symmetry of the one-leg support period during the walking cycle. Although these improvements did not directly correspond with weight-bearing capacity of the paralytic lower extremity, it appears to be an indirect factor. Increases in step length (of the unaffected side) and stride length were suggested by improving weight-bearing capacity of the paralytic lower extremity.

RKO-exercise decreased the necessary level of assistance provided by therapists, compared with standard physical therapy, and enabled the RKO users to increase knee-joint mobility with assistance from the RKO. Movement repetitions with mirror-based visual feedback may improve the efficiency of motor learning.

These results could be realized as a result of recovery process after the stroke as well as the effects of the RKO-exercise. The recovery process after stroke is classified into three stage. In the acute stage, motor recovery depends on residual corticospinal tract excitability from onset to 3 months (1st stage recovery). In the next stage, alternative output systems are used according to intracortical excitability depending on intracortical disinhibition at the peak of 3 months (2nd stage recovery). At 6 months and beyond training-induced synaptic strengthening becomes better established, and new networks are better reorganized (3rd stage recovery)¹³. The large recovery of function after the stroke is by 3 month from onset (1st stage recovery)¹⁴. And the time of the recovery in the 1st stage recovery is different by a person. Participants of this research were onset from 1 month and half to 3 months. Therefore, the large recovery of this result might occur accidentally during the intervention term of RKO-exercise.

These results also could be realized as a result of increased exercise time as well as the effects of the RKO-exercise. The time of intervention term of RKO-exercise was longer than the term of the standard physical therapy. The quantity and frequency of exercise will be an important factor in acquisition of the athletic skill¹⁵. Therefore, even the standard physical therapy might be the same result if the exercise time was extended.

Although this was an investigation of the effects of RKO-exercise, it is also possible that standard-of-care physical therapy produced similar improvements. This is a limitation of this research. Future, well-powered investigations should include treatment and no-treatment cohorts. RKO therapy requires additional research. Questions remain as to the effects of RKO-exercise on other functional modalities, the ideal duration of treatment period, the ideal frequency of treatment, when to begin RKO-exercise treatment, and treatments' effects under various assistance settings. RKO is a promising new technology for delivering rehabilitation to patients following stroke.

This project affirmed the ability of RKO-exercise to improve walking and balance abilities.

RKO-exercise effectively treats impaired mobility in patient status-post stroke. RKO has possibility as one of aids in rehabilitation treatment.

Future, this research need randomized controlled trial to compare the effect of the standard therapy.

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REFERENCES

- 1) Langhorne P, Bernhardt J, Kwakkel G: Stroke rehabilitation. *Lancet*, 2011, 377: 1693–1702. [Medline] [CrossRef]
- 2) Pekna M, Pekny M, Nilsson M: Modulation of neural plasticity as a basis for stroke rehabilitation. *Stroke*, 2012, 43: 2819–2828. [Medline] [CrossRef]
- 3) Department of Health: National Policy and Strategy for the Provision of Neuro-Rehabilitation Services in Ireland 2011–2015. http://health.gov.ie/wp-content/uploads/2014/03/NeuroRehab_Services1.pdf (Accessed Apr. 4, 2017)
- 4) Hachisuka K: Robotic devices for rehabilitative training. *Jpn J Rehabil Med*, 2014, 51: 343–347.
- 5) European Stroke Organisation (ESO) Executive Committee ESO Writing Committee: Guidelines for management of ischaemic stroke and transient ischaemic attack 2008. *Cerebrovasc Dis*, 2008, 25: 457–507. [Medline] [CrossRef]
- 6) Kwakkel G, Wagenaar RC, Twisk JW, et al.: Intensity of leg and arm training after primary middle-cerebral-artery stroke: a randomised trial. *Lancet*, 1999,

354: 191–196. [\[Medline\]](#) [\[CrossRef\]](#)

- 7) Byl NN: Mobility training using a bionic knee orthosis in patients in a post-stroke chronic state: a case series. *J Med Case Reports*, 2012, 6: 216. [\[Medline\]](#) [\[CrossRef\]](#)
- 8) Wong CK, Bishop L, Stein J: A wearable robotic knee orthosis for gait training: a case-series of hemiparetic stroke survivors. *Prosthet Orthot Int*, 2012, 36: 113–120. [\[Medline\]](#) [\[CrossRef\]](#)
- 9) Shuhei I, Tatsuya W, Dai K, et al.: Effect of exercises using a Robotic Knee Orthosis (RKO) in hemiplegic stroke patients. *J Phys Ther Sci*, 2016, 31: 711–714.
- 10) Dettmann MA, Linder MT, Sopic SB: Relationships among walking performance, postural stability, and functional assessments of the hemiplegic patient. *Am J Phys Med*, 1987, 66: 77–90. [\[Medline\]](#)
- 11) Wall JC, Turnbull GI: Gait asymmetries in residual hemiplegia. *Arch Phys Med Rehabil*, 1986, 67: 550–553. [\[Medline\]](#)
- 12) Hill KD, Goldie PA, Baker PA, et al.: Retest reliability of the temporal and distance characteristics of hemiplegic gait using a footswitch system. *Arch Phys Med Rehabil*, 1994, 75: 577–583. [\[Medline\]](#)
- 13) Hara H: Stroke rehabilitation based on cortical plasticity and the stage theory of motor output reorganization. *Jpn J Neurosurg*, 2012, 21: 516–526. [\[CrossRef\]](#)
- 14) Duncan PW, Goldstein LB, Horner RD, et al.: Similar motor recovery of upper and lower extremities after stroke. *Stroke*, 1994, 25: 1181–1188. [\[Medline\]](#) [\[CrossRef\]](#)
- 15) Eiichi S, Motomi Y, Kei O, et al.: Orthosis from the viewpoint of motor learning in walking exercise of paralytic patients. *Sogo Rihabiriteshon*, 2012, 38: 545–550.