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Comparison of end-effector and exoskeleton devices with robot-assisted gait training in patients with stroke

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Abstract

Background/Aim: Loss of gait is the key problem after stroke. Robotic rehabilitation devices, which constitute the new treatment alternatives for stroke, can be divided into two groups on the basis of their design, the exoskeletons and end-effectors. This study aims to investigate the effects of gait training with two different types of robot on rehabilitation outcomes in patients with stroke.

Methods: Twenty-four patients treated for stroke between December 2015 and December 2018 were included in the study. They were randomly divided into two groups for rehabilitation with either the exoskeleton or the end-effector. They attended the robotic rehabilitation programme for five days a week for six weeks, with each session lasting for 40 minutes. They were evaluated in terms of motor stage, ambulation, walking speed and walking capacity at the start and end of the programme.

Results: According to baseline evaluations, there were higher scores in the endpoint evaluations for motor stage, ambulation, 6-minute walking test and lower scores in the endpoint evaluations for 10-meter walking test ($P<0.001$ for all). There was no difference between the two groups in terms of motor phase, ambulation, 6-minute walking or 10-meter walking scores ($P>0.05$ for all).

Conclusion: In patients with stroke, improvements were observed following robot-assisted gait training. No superiority was observed between the end-effector device with the exoskeleton device.

Keywords: Robot-assisted gait training, Stroke, End-effector robot, Exoskeleton robot

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Ethics Committee Approval
Fatih Sultan Mehmet Training and Research Hospital Clinical Research Ethics Committee (28.05.15 / 22)
All procedures in this study involving human participants were performed in accordance with the 1964 Helsinki Declaration and its later amendments.

Conflict of Interest
No conflict of interest was declared by the authors.

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Introduction

Stroke is the third most common cause of death in the world and a long-term cause of severe disability in adults [1]. It is critical for stroke patients to regain their walking ability in order to cope with their daily life activities and improve their quality of life [2]. One fifth of patients with stroke become wheelchair dependent. In those who do not lose their walking ability, gait speed and capacity are diminished [3]. Gait training is therefore very important in the rehabilitation of stroke patients.

Robot-assisted gait training (RAGT) is an innovative form of rehabilitation that has been increasingly applied in recent years. Robotic systems aim to give the patient maximum benefit from the rehabilitation process by performing high-dose, high-intensity and task-specific movements with the extremities [4].

The support and guidance of the robot enables a patient who could not perform the movement to move independently. According to their mechanical properties and design basis, these robots are divided into two groups, the end-effectors and the exoskeletons [2–5].

The end-effector system works by applying mechanical force from the last connection of the kinematic chain. Since the hip and knee joints are free in the end-effector system, the patient is actively involved in the walking training.

Exoskeleton systems can be either fixed or mobile. Their axes are aligned with the patient's anatomic axes. They provide direct control of the joints and have the ability to activate each part either separately or together by connecting to the extremities from many places [3–5].

The literature contains few clinical studies comparing the two different types of RAGT devices with comparable groups of patients. This study was therefore conducted to compare the results of treatment with the two different types of robotic systems in stroke patients.

Materials and methods

This prospective randomized clinical study was conducted between December 2015 and December 2018 at a Physical Medicine and Rehabilitation Clinic of a Physical Therapy and Rehabilitation Hospital, and a Physical Therapy Center.

The study was performed with 24 patients who were referred with hemiparesis following a first stroke. They were included in the rehabilitation program provided they met the study criteria as described below. Permission was obtained from the hospital management for the study, which was conducted per the “Helsinki Declaration.” Fatih Sultan Mehmet Education and Research Hospital Ethics Committee approved the protocol (Decision no: 2015/22).

Inclusion criteria were being over the age of 18 years, having had a stroke for the first time, requiring treatment due to the stroke, and having gait loss after stroke (functional ambulation category < 4). Exclusion criteria included presence of spasticity in the lower limbs, contractures of the lower limbs, weighing more than 300 pounds (135 kg), cognitive deficits, cardiac disease, traumatic stroke, epilepsy and problems with fitting the patient's body with orthosis of robots.

We used power analysis to determine sample size, which was 12 individuals in each group with a power of 80% at α=0.05. Twenty-four patients who met the inclusion criteria were randomly divided into two groups, and we used the simple randomization method. We enumerated the patients according to their application order, and those with odd numbers in the end-effector group and those with even numbers in the exoskeleton group.

The patients were evaluated at the beginning and at the end of treatment.

End-effector (Lokohelp) consists of an electromechanical device fixed parallel to the walking direction with a harness suspension assembly that supports the body weight as the patient walks on a treadmill. The device provides both passive and active assistance to the foot movement to enable the patient to use the feet as the last link in the kinematic chain. In this device, the knee and hip joints are actively controlled by the patient. The ankles are fixed in a pair of boots attached to the device. The bottom of the boot is rounded (a rocker base) to facilitate the pushing phase of the walk (Figure 1, Lokohelp).

Exoskeleton (Lokomat) is an exoskeletal type of robotic walking device consisting of a harness carrying the body weight, a walking orthosis with brackets holding the legs at three points, a treadmill and a visual feedback support monitor (Figure 2, Lokomat).

Figure 1: Lokohelp

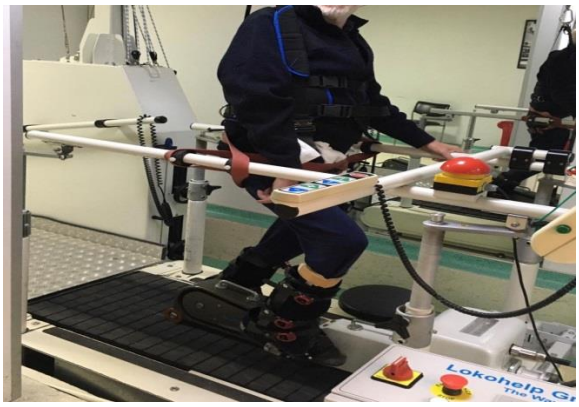
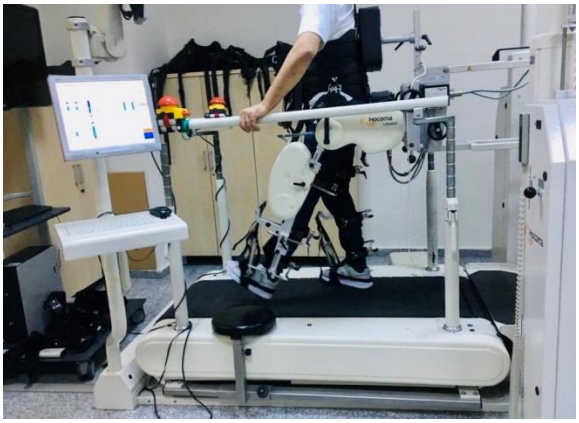


Figure 2: Lokomat



In addition to conventional rehabilitation treatment six days a week, patients in the study attended robotic therapy five days a week for six weeks. The sessions lasted for 40 minutes. In the first session with both devices, the body weight support (BWS) was initiated at fifty percent and then adjusted to the patient's tolerance.

Patients were assessed on a 10-meter walking test, a 6-minute walking test, the Brunnstrom motor staging, and the Functional ambulation category (FAC) at baseline and again at the end of the program. These tests included walking velocity, walking capacity, motor level and ambulation level.

Statistical analysis

The statistical analysis for this study was performed with the Number Cruncher Statistical System (NCSS) 2007 Statistical Software package (Utah, USA). In addition to the descriptive statistics (mean, standard deviation), the distribution of the variables was examined with the Shapiro-Wilk normality test, and the input of variables with a normal distribution was evaluated. The paired t-test was used for output comparisons, the independent t-test for intergroup comparisons, the Wilcoxon test for input-output comparisons of variables that did not show a normal distribution, the Mann Whitney U test for intergroup comparisons, and other quantitative data. The chi-square test was used for a comparison of the qualitative data. The results were evaluated at the significance level of $P<0.05$.

Results

The demographic data for the patients and the descriptive data related to their strokes are shown in Table 1. The rehabilitation results of the Exoskeleton and End-Effector groups are shown in Table 2.

Table 1: Demographic and stroke-related descriptive data

		Exoskeleton group		End-Effector group		*P*-value
Age		62 (11.56)		59.38 (10.11)		0.407
		n	%	n	%	
Sex	Male	4	33.33	5	41.67	0.551
	Female	8	66.67	7	58.33	
Marital status	Married	7	58.33	9	75.00	0.167
	Not married	2	16.66	0	0.0	
	Widow/Divorced	3	25.00	3	25.00	
Time since stroke (days)		110.17 (42.99)		111.21 (42.73)		0.933
Aetiology	Ischemic	8	66.67	8	66.67	1
	Haemorrhage	4	33.33	4	33.33	
Risk Factors	Hypertension	10	83.33	8	66.67	0.086
	Age	5	41.67	5	41.67	1
	Cardiac Disease	8	66.67	7	58.33	0.755
	Hyperlipidaemia	3	25.00	4	33.33	0.525
	Diabetes Mellitus	3	25.00	3	25.00	1
	Smoking	1	8.33	2	16.67	0.383
Hemiplegic side	Left	7	58.33	6	50.00	0.773
	Right	5	41.77	6	50.00	
Dominant Hand	Right	12	100.00	11	91.67	0.551
	Left	0	0.00	1	8.33	

Table 2: Rehabilitation results of the Exoskeleton and End-Effector Groups

		Exoskeleton group	End-Effector group	*P*-value†
Brunnstrom	Baseline	2.21(1.14)	2.25(1.15)	0.900
Motor Assessment	Endpoint	2.5(0.98)	2.75(1.33)	0.461
-Upper Extremity	*P*-value‡	0.016	<0.001	
Brunnstrom	Baseline	2.13(1.42)	2.00(1.18)	0.742
Motor Assessment	Endpoint	2.38(1.35)	2.38(1.28)	0.999
-Hand	*P*-value‡	0.011	0.009	
Brunnstrom	Baseline	2.58(1.06)	2.83(0.82)	0.365
Motor Assessment	Endpoint	3.42(0.88)	3.58(0.78)	0.490
-Lower Extremity	*P*-value‡	<0.001	<0.001	
Functional	Baseline	0.75(1.03)	1.08(0.83)	0.224
Ambulation Category	Endpoint	2.38(1.14)	2.42(0.93)	0.890
	P-value‡	<0.001	<0.001	
6-minute walking test	Baseline	21.92(42.48)	28.04(30.30)	0.568
(meter)	Endpoint	90.17(90.29)	81.50(75.43)	0.720
	P-value‡	<0.001	0.001	
10-meter walking test	Baseline	0.060(0.117)	0.078(0.084)	0.545
(m/s)	Endpoint	0.225(0.250)	0.225(0.210)	0.993
	P-value‡	<0.001	0.001	

‡ Wilcoxon Signed-Rank Test, † Mann Whitney U Test

No significant difference was observed between the Brunnstrom upper extremity, hand and lower extremity baseline and endpoint scores of the Exoskeleton and End-Effector groups ($P>0.05$). The Brunnstrom upper extremity, hand, and lower extremity endpoint scores for both the Exoskeleton group and the End-Effector group were significantly higher than the Brunnstrom upper extremity, hand, and lower extremity baseline scores ($P<0.05$ for all).

The FAC baseline and endpoint averages of the Exoskeleton and End-Effector groups were similar ($P>0.05$), while the FAC endpoint averages for the Exoskeleton and End-Effector groups were significantly higher than the FAC baseline averages ($P<0.001$).

No statistically significant difference was observed between the 6-minute walking test baseline and endpoint averages of the Exoskeleton and End-Effector groups ($P>0.05$). The 6-minute walking test endpoint averages for both the Exoskeleton and End-Effector groups were significantly higher than the 6-minute walking test baseline averages ($P<0.001$).

The 10-meter walking test baseline and endpoint averages of the Exoskeleton and End-Effector groups ($P>0.05$) were similar, while 10-meter walking test endpoint averages for both the Exoskeleton and End-Effector groups were significantly higher than the 10-meter walking test baseline averages ($P<0.001$).

Discussion

Gait recovery is a particularly crucial factor in the independence of the individual after stroke. There are many rehabilitation approaches to gait recovery. Treadmill based RAGT is one such approach [6]. With this treatment, rehabilitation robots of either the end-effector or exoskeleton type can be used. There are findings regarding the contribution of each device to walking capacity, walking velocity, and ambulation in stroke patients. This study was conducted to compare the rehabilitation results in stroke patients when using two distinct types of RAGT device in addition to conventional treatment.

Twenty-four stroke patients were recruited for the study. Both treatments were well tolerated by all patients and proved to be safe. We obtained complete adherence to the protocol as all subjects completed the training sessions without any dropouts. No adverse events were observed.

According to the study results, both groups of patients benefited from the RAGT. It has already been confirmed that treadmill based RAGT is beneficial in the treatment of walking impairment in patients with stroke, improving motor stage, walking velocity, walking capacity and ambulation level [3, 6–7].

When Mehrholz et al. [8] compared two different devices, they showed that there was no significant difference between the two devices in any parameter except walking speed. This important review states that the end-effector devices contribute more to walking speed. However, the fact that most of the patients included in the analysis of the end-effector group were taken from the same study was criticized in the review.

In the review by Bruni et al., the end-effector (Gait Trainer) was more effective than conventional treatment. No difference was found between the control group and the group using the exoskeleton (Lokomat) [9].

Ours is the first study to compare the rehabilitation results of two different treadmill based RAGTs. The study by

Goffredo et al. compared a larger number of different groups. In that study, a treadmill-based end-effector (GE-O system), an over-ground exoskeleton (Ekso™) and conventional treatment were compared. There was no difference between the treadmill-based end-effector and the over-ground exoskeleton, but these two treatments were superior to the conventional treatment alone [10].

Although some studies indicate that conventional treatment is superior to treadmill based RAGT [11], the American Heart Association / American Stroke Association Guidelines describe Class IIb evidence that supports using mechanically assisted walking with body weight support for patients who are non-ambulatory after stroke [12].

Limitations

The main limitation of this was the small number of patients in each group. Another limitation was that training details were selected based on clinical experience.

Conclusion

The biggest advantage of robot-assisted walking support is that it reduces the workload for the therapists and increases the number, duration, and intensity of a patient's sessions. Treadmill based RAGT provides additional benefits to conventional treatment as shown in many areas of improvement, such as motivation, active participation in treatment, improved timing and coordination of motor activity and perception of walking. In patients with stroke, both exoskeleton and end-effector RAGT devices are useful, and neither is superior to the other.

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