

Effects of Locomotion Training With Assistance of a Robot-Driven Gait Orthosis in Hemiparetic Patients After Stroke

A Randomized Controlled Pilot Study

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Background and Purpose—The success of gait rehabilitation after stroke depends on active walking exercises. However, the disabling after-effects of stroke often make such exercises impossible at the onset of therapy. To facilitate treadmill training of paraparetic patients, a robot-driven gait orthosis (Lokomat) was developed. We investigated the effects of the Lokomat when used with hemiparetic patients.

Methods—The authors conducted a randomized, controlled pilot study of 30 acute stroke survivors. The treatment group received 30 minutes of robotic training daily and the control group 30 minutes of conventional physiotherapy daily in addition to 30 minutes of conventional physiotherapy for each group. Outcome measures were independence of gait, gait speed, gait parameters, and body tissue composition.

Results—After 4 weeks of therapy, the walking ability of the Lokomat group and the control group expressed as the functional ambulation classification was significantly improved. The functional ambulation category (median \pm interquartile range) was at baseline 0 ± 0 in control and 0 ± 1 in the therapy group and increased after therapy to 1 ± 3 in both groups significantly ($P=0.01$). There was no significant difference in gain of these parameters between the groups. The Lokomat group had a significantly longer single stance phase (sec; mean \pm SEM) on the paretic leg when walking on the floor. At baseline, it was 0.19 ± 0.17 and after therapy 0.49 ± 0.07 ($P=0.014$). The control group had increased their body weight approximately 1.33 ± 1.40 kg (mean \pm SEM; $P=0.046$), mostly as fat mass, whereas the Lokomat group had lost fat mass approximately -2.9 ± 1.0 kg (mean \pm SEM; $P=0.016$) and increased their muscle mass approximately 3.36 ± 1.4 kg (mean \pm SEM; $P=0.031$).

Conclusions—This pilot study indicates that Lokomat therapy is a promising intervention for gait rehabilitation. Although there was no difference between groups in gain of functional scores, the Lokomat group showed an advantage of robotic training over conventional physiotherapy in improvement of gait abnormality and body tissue composition. (*Stroke*. 2007;38:349-354.)

Key Words: gait ■ rehabilitation ■ stroke

Stroke survivors frequently exhibit a complex pattern of after-effects. The loss of motor skills necessary for locomotion is considered one of the most devastating to the patient. Not surprisingly, locomotion rehabilitation is one of the most important and interesting therapies for stroke researchers.¹

Task-oriented locomotor training is stated to be an essential factor in the recovery of locomotion.²⁻⁴ To achieve locomotion, one must coordinate several motor and cognitive functions, eg, to maintain balance (postural control), to transfer and support the body mass on one limb during stance phase, to clear the floor during the swing phase of the feet, and to apply propulsive force for forward progression. Cognitive prerequisites include motivation

and the ability to apply control strategies and to learn and recall motor patterns. Gait training (walking) itself often is not possible in severely affected stroke patients as a result of the severity of their disabilities. Such patients need a simplified and safe environment. Often treadmill training with body weight support is too demanding. The patients need the help of 2 or more therapists to engage in training even at a very slow speed.

The robot-driven gait orthosis, Lokomat (Hocoma, Volketswil, Switzerland), is the first driven gait orthosis that assists walking movements of gait-impaired patients on the treadmill. This automated process relieves therapists of the manual labor required during manual treadmill training. The

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Lokomat provides a more supportive environment; therefore, patients with more severely affected hemiparesis can be treated than on the treadmill alone. Therapy in the Lokomat is a training of gait-like movements at a more normal speed and for a longer duration.⁵

The Lokomat is adjustable in force, body weight support, and speed so that even severely handicapped patients can exercise in an environment delivering as much challenge as can be handled.^{6,7} Although the Lokomat provides a simplified environment for postural control, propulsion, coordination, and stepping, walking speed can be exercised in a way that is much closer to the principles of motor learning concepts that progress from the simple to the complex, from the easy to the difficult, while all movements remain as close as possible to the final desired movement. Besides task specificity, the number of repetitions of tasks and training intensity are basic aspects of established principles in locomotor training.^{8,9}

The aim of this pilot study was to compare Lokomat training with conventional physiotherapy and to measure the effects on gait, signs of neuromuscular training, body tissue composition, and independence of daily living.

Methods

Subjects

The project was approved by the local ethics committee, and all participants or their legal representatives gave their written informed consent.

Patients participating in the study demonstrated a hemiparesis as the result of a first stroke according to the definitions of the World Health Organization. All met the following inclusion criteria: no prior stroke, no other neurologic or orthopedic disorder, independent ambulation before the stroke, and no severe medical illnesses. Hemiparesis had to be severe with lower extremity strength graded as 3 or less on the Medical Research Council scale in more than 2 muscle groups. In addition, the patient had to score 1 or less on the functional ambulation classification, indicating a need for personal assistance in ambulation.^{10,11} The interval between stroke and start of the treatment protocol had to be at least 28 days but no longer than 200 days.

We stratified subjects according to diagnosis and hemisphere of lesion to minimize uneven distribution of relevant variables. We used different block lengths for randomization to ensure unpredictable allocation of treatment. Random numbers were generated by a computer program and were packed into sealed opaque envelopes by an individual not involved in screening and enrolment of subjects to ensure concealment of allocation.

Treatment

Treatment Group

Patients walked on a treadmill with the help of a robotic-driven gait orthosis (Lokomat; Hocoma). The basic version of the Lokomat system consists of the Lokomat (robotic gait orthosis) and the Lokobasis (body weight support system). It is used in combination with a Woodway treadmill (Weil am Rhein, Germany). The patient's legs are guided according to a preprogrammed physiological gait pattern. The knee and hip joints are controlled by position and force sensors, which allow individual adjustments.

The torque of the knee and hip drives can be adjusted from 100% to 0% for one or both legs. The speed of the treadmill can be adjusted from 0 km/h to approximately 3 km/h and body weight support from 0% to 100%.^{6,7,12} At the beginning of the treatment period, 30% of the body weight of each subject was supported.

The walking sessions in the Lokomat group were kept at a demanding level; the velocity of the treadmill was set to the

maximum speed tolerated by the patients, the force of the drives was regulated, and body weight support was reduced as soon as the patients could tolerate it. Therapists motivated patients to actively move their legs. All patients in the treatment group were scheduled for one 60-minute session per workday. This resulted in 30 minutes of real walking time, because mounting, dismounting, and adjusting the patient in the device took approximately 30 minutes.

Control Group

Patients in the control group received 30 minutes of conventional physiotherapy per workday. Focus on this training was gait rehabilitation. The patients exercised trunk stability and symmetry, step initiation, and weight support on the paretic leg. In every session, the patient walked some steps with the help of therapists. Patients received treadmill training, if possible, with the help of one or 2 therapists.

Lokomat therapy was compared with conventional physiotherapy because treadmill training with severely handicapped people was not possible, at least in the beginning.

Both groups received 20 treatment sessions plus an additional 20 sessions of conventional physiotherapy. The final measurements were performed after 40 sessions of therapy, which was reached for most patients after a 4-week period. Final measurements could be done between 4 and 5 weeks.

Measurements

The following parameters were evaluated before and after therapy:

Primary Outcome Measures

1. Massachusetts General Hospital Functional Ambulation Classification (FAC), categories of severity of gait impairment as a result of neurologic illnesses.^{10,11}
2. 10-m Time Walking Test—the fastest comfortable walking speed a patient achieved for 10 m on a level surface was measured in m/s. If necessary, patients were supported by a therapist and/or a walking aid.^{10,11} If the patients were not able to walk alone (patients needed help of a therapist), the gait velocity was set zero, and the gait parameters have not been evaluated.

Secondary Outcome Measures

3. Gait parameters were collected with the Parotec system (Paromed; Neubuern, Germany), an in-shoe plantar pressure measurement system.¹³ Five step cycles were collected. Subjects walked as described for the Time Walking Test. Both measurements were made simultaneously. The raw data were recorded in a data logger and analyzed offline with a MATLAB Tool Version 5.3. The following parameters were calculated: cadence and stride duration, stance duration, and single support time for both legs.¹⁴
4. Bioelectrical impedance analysis was performed by a soft tissue analyzer STA/BIA Akren Bioreserch with the analyzing software BODYGRAM. It calculates the body tissue composition in combination with skin fold thickness, body weight, height, age, and sex. The following parameters were considered: body weight, body cell mass, and fat mass.¹⁵
5. Muscle tone was determined by the Modified Ashworth Scale and muscle power was determined by the Motricity Index (MI).^{16,17}
6. To assess independence in activities of daily life, the German version of the Barthel Index (BI) was used.¹⁸

The evaluating therapist was blinded for group allocation when evaluating BI, body tissue composition, and gait parameters.

Data Analysis

The parameter of Table 1 was tested for normal distribution and similarity of variances and then analyzed by a 2-factorial multivariate analysis of variance. Pairwise comparisons were tested with post hoc Scheffé tests.

The FAC, MI, and BI (Table 2) were tested with nonparametric methods using the Wilcoxon matched pair test for estimating the

TABLE 1. Time Walking Test Expressed as Speed (m/s), Cadence (steps/min), Stride Duration (s), Stance Duration (SD) (s), and Single Support Time (SST) (s)*

	Baseline		4 Weeks	
	Control	Treatment	Control	Treatment
TWT (speed)	0.12±0.03	0.14±0.02	0.20±0.05 (<i>P</i> =0.006)	0.20±0.03 (<i>P</i> =0.125)
Cadence	28.9±4.62	35.9±3.87	40.68±6.39 (<i>P</i> =0.081)	43.28±4.21 (<i>P</i> =0.092)
Stride duration	5.5±0.81	4.02±0.049	3.58±0.4 (<i>P</i> =0.011)	3.15±0.3 (<i>P</i> =0.028)
Affected leg				
SD (s)	2.93±0.68	1.93±0.24	1.84±3	1.56±0.16
SST (s)	0.38±0.04	0.19±0.17	0.35±0.07	0.49±0.07* (<i>P</i> =0.014)
Unaffected leg				
SD (s)	4.75±0.7	3.67±0.58	3.24±0.38 (<i>P</i> =0.019)	2.67±0.28 (<i>P</i> =0.033)
SST (s)	2.93±0.43	2.25±0.44	1.73±0.2	1.57±0.2 (<i>P</i> =0.037)

*All data are shown as mean±SE of mean at baseline and after 4 weeks therapy. *P* values in parentheses show significant differences over time.

†Significant difference compared with the control group (*P*=0.04).

differences before and after therapy and the Mann-Whitney *U* test for differences between groups. All statistical analyses were performed using SPSS (Version 9.01).

Results

Of the patients admitted to our hospital for poststroke inpatient rehabilitation between May 2003 and May 2004, 32 were eligible and willing to participate. One patient in each group dropped out for medical reasons (enteritis and pulmonary artery embolism). These data were not included in the analysis. Two patients in the Lokomat group could not finish the assigned Lokomat treatment as a result of skin lesions; their data were analyzed as “intention to treat.”

Patient data were comparable in the 2 groups (Table 3).

FAC showed no differences between the therapy and control group at baseline. Both groups exhibited a significant increase in walking ability after 4 weeks of therapy, but there was no significant difference between the groups (*P*=0.983; power 0.051; effect size -0.04; confidence interval: -1.11 to 1.03) (Table 2).

A similar result was achieved in the TWT; there was also no difference between the groups at baseline, but there was a significant increase in gait speed, cadence, and a decrease in stride duration after 4 weeks of treatment. Again, there was no difference between the groups after therapy (*P*=0.922; power 0.05; effect size 0.00; confidence interval: -0.16 to 0.16) (Table 1).

The duration of single limb support on the paretic leg was calculated. Although there was no difference between the groups before treatment, patients in the experimental group increased their pathologically shortened single support time during the treatment period to almost normal values; the control group did not show relevant changes. This finding indicates that Lokomat therapy was significantly more effective in improving gait pattern than conventional physiotherapy (Figure).

Values for the BI and MI in both groups increased significantly during 4 weeks of therapy. Again, groups did not differ at baseline or after 4 weeks. In contrast, no differences were revealed between groups and over time in the Modified Ashworth Scale. Spasticity did not seem to be a major issue in this selection of patients (Table 2).

Bioimpedance analysis also showed significant effects between treatment conditions. Patients in the control group increased their body weight during the 4-week period. The body tissue composition in the control group indicated an augmented compartment of fat mass. The experimental group experienced no change in body weight but an exchange of fat mass for body cell mass (lean body mass; Table 4). Because the increase in body cell mass is supposed to be caused by muscle cells, this result suggests that Lokomat training induced a gain in muscular tissue.

With the exception of minor skin sores in 2 patients and one case of distortion of the ankle joint without permanent

TABLE 2. Motor Performance Described by FAC, MI, BI, and Ashworth Scale at Baseline and After 4 Weeks of Therapy*

	Baseline		After 4 Weeks	
	Control	Treatment	Control	Treatment
FAC	0±0	0±1	1±3 (<i>P</i> =0.01)	1±3 (<i>P</i> =0.01)
MI leg	36.5±70.0	42.0±52.0	58.5±60 (<i>P</i> =0.028)	47.0±36.0 (<i>P</i> =0.013)
BI	35±18	35±41.25	50±10 (<i>P</i> =0.005)	50±25 (<i>P</i> =0.001)
Ashworth	1±0.5	1±0.5	1±1.75	1±0.5

**P* values in parentheses show significant differences over time. All data are shown as median±interquartile range. There are no significant differences between groups.

TABLE 3. Anthropometric Data of Patients Included in the Study

	Age (mean in years±SD)	Sex	Diagnosis	Affected Side	Days After Stroke (mean±SD)
Control group	57±11	M=10; F=4	Infarct=10; hemorrhage=4	Right=11; left=3	89±61
Treatment group	60±13	M=11; F=5	Infarct=12; hemorrhage=4	Right=12; left=4	79±56

SD indicates standard deviation.

harm, there were no other complications in the Lokomat training group. In the control group, 3 people had deep venous thrombosis and one subject died of pulmonary artery embolism despite consistent use of low-molecular-weight heparin.

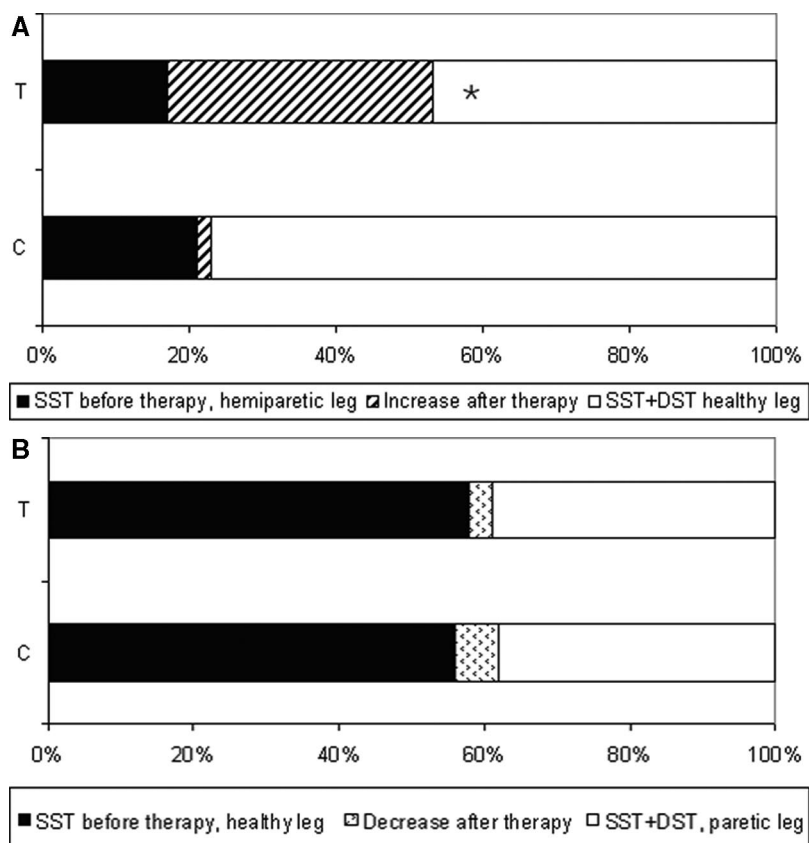
Discussion

The data show that gait training with a robot-driven gait orthosis is beneficial to nonambulatory patients with severe hemiparesis after stroke. Comparison of the effectiveness of Lokomat training and conventional physiotherapy on gait rehabilitation shows that both groups experienced a significant increase in their scores on standardized functional scales, indicating a clinically relevant increase in motor function. There was no difference between the groups in motor function before or after treatment. This suggests that under conditions like in our study, neither robot-controlled gait training nor regular physiotherapy has an advantage in terms of regaining gait function. The primary outcome measures have been evaluated by therapists not involved in the treatment, because they were not blinded, a potential bias cannot be completely ruled out.

Data from our hospital⁵ show that patients treated in the Lokomat can exercise longer and perform more gait cycles than patients treated on a treadmill alone as a result of the supportive design of the gait orthosis. The outcome might have been different had we allowed each patient to exercise as long as possible. Lokomat training might have had a superior effect. However, our study design held constant the time that each group exercised.

A case series with chronic paraplegic patients who trained with the Lokomat showed a small increase in walking speed over time, after 8 weeks of training, but no difference in the amount of assistance needed. This study included no control condition,¹⁹ and Wernig²⁰ proposed that Lokomat training may be inferior to treadmill training. However, we did not find any indication of inferiority.

Different types of mechanically assisted gait training devices are currently available, eg, the "Gait Trainer" developed by Hesse. Werner et al²¹ reported some augmented improvement with Gait Trainer exercises, which was trending toward significance. We were, however, unable to reproduce these effects, probably as a result of different patient samples (in our group, median FAC 0 and Werner median FAC 1) rather



Single support time (SST) represented as percentage of the step duration (time from heel strike until next heel strike of same leg) before and after 4 weeks therapy in controls (C) and treatment group (T). A, Paretic leg; (B) healthy leg. DST indicates double support time. *Significant difference compared with control group ($P=0.014$) calculated as 2-factorial multivariate analysis of variance over all parameters shown in Table 1.

than the type of orthosis device used. As a result of the weakness and sensory impairment of the paretic leg, the hemiparetic gait is characterized by a shortened single support phase on the paretic leg and a prolonged single support phase on the healthy leg. After Lokomat therapy, patients are able to support their body weight for a longer period of time on the paretic leg, and thus their gait pattern becomes more symmetric. We suggest that this is the result of a “forced use” effect of the Lokomat or in general of treadmill training.^{25,26} Positive effects of higher speed on gait quality have been reported on the treadmill.^{22,23} On the Lokomat, faster training speed is possible compared with conventional gait training. The transfer of improved gait quality during treadmill training to walking on the floor has yet to be demonstrated.²⁴ Our patients’ gait parameters, however, were recorded while they were walking on the floor. This result is even more interesting because the gait parameter have been evaluated by a blinded observer.

A clear effect of training in the Lokomat group was the significant increase in body cell mass (muscle tissue) and a significant loss of fat mass. The control group showed no changes in body cell mass, but rather an increase in body weight consisting mostly of fat tissue. These differences, especially in fat mass, suggest that Lokomat therapy is associated with an increase in aerobic metabolism as is often demonstrated in cardiovascular training. These effects are lacking in regular physiotherapy.^{27–29}

Besides having positive effects on functional locomotion recovery, Lokomat training has significant medical benefits for the recovering stroke patient. The evaluation of Lokomat therapy should also consider its role in the prevention of complications resulting from immobilization or spasticity.

There was no significant difference between the 2 groups in the MI. However, Lokomat training, as a type of dynamic muscle strength training,³⁰ contributes to restorative muscle hypertrophy, which is not necessarily measurable on strength tests as described previously by Brown.³¹

Spasticity, as measured by the Modified Ashworth Scale, did not differ over time nor between the groups. Although Lokomat therapy appears to reduce spasticity immediately after therapy, this effect did not last until the next day when the examination was done.

As a result of the small sample size, we did not expect to see effects on medical complications. However, although 4 patients in the control group developed deep venous thrombosis (despite standard prophylaxis with low-molecular-weight heparins and antithrombotic stockings in both groups), no one in the Lokomat group did. The overall incidence in our hospital is comparable to the findings of the Topas investigation.^{32,33}

We conclude that Lokomat therapy might be comparable to conventional gait-oriented physiotherapy when considering gait speed and walking ability in severely disabled stroke victims. The computer-aided orthosis also has a considerable number of positive side effects on muscle restoration and gait parameters.

In summary, our experiences justify a large multicenter trial to determine overall efficiency of the sophisticated gait training apparatus. Reduction of needed therapeutic man-

TABLE 4. Measurement of Body Tissue Composition With the Bioimpedance Analysis*

	Control	Treatment
BW	1.33±1.40	-0.73±0.92
BCM	-0.27±1.81	3.36±1.4
FM	1.4±1.1	-2.9±1.0

*Shown is the difference before and after 4 weeks physiotherapy or Lokomat training as mean±standard error of mean in kilograms.

BW indicates body weight; BCM, body cell mass; FM, fat mass. Significant differences between treatment and control group shows FM ($P=0.012$); significant difference before and after intervention: BCM ($P=0.031$) in the treatment group; FM $P=0.016$ in the treatment group; BW ($P=0.046$) and FM ($P=0.041$) in control group.

power might be weighed against gain in gait capabilities. At a rough cost estimate of 4 yearly salaries of a physical therapist, the driven orthosis should prove either a superiority in some parameters, at least for definable subgroups, or offer a financial advantage in the long run with a reduced need for therapies with 2 therapists.

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Disclosures

None.

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