

Treadmill Training With Partial Body Weight Support and an Electromechanical Gait Trainer for Restoration of Gait in Subacute Stroke Patients

A Randomized Crossover Study

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Background and Purpose—The purpose of this study was to compare treadmill and electromechanical gait trainer therapy in subacute, nonambulatory stroke survivors. The gait trainer was designed to provide nonambulatory subjects the repetitive practice of a gait-like movement without overexerting therapists.

Methods—This was a randomized, controlled study with a crossover design following an A-B-A versus a B-A-B pattern. A consisted of 2 weeks of gait trainer therapy, and B consisted of 2 weeks of treadmill therapy. Thirty nonambulatory hemiparetic patients, 4 to 12 weeks after stroke, were randomly assigned to 1 of the 2 groups receiving locomotor therapy every workday for 15 to 20 minutes for 6 weeks. Weekly gait ability (functional ambulation category [FAC]), gait velocity, and the required physical assistance during both kinds of locomotor therapy were the primary outcome measures, and other motor functions (Rivermead motor assessment score) and ankle spasticity (modified Ashworth score) were the secondary outcome measures. Follow-up occurred 6 months later.

Results—The groups did not differ at study onset with respect to the clinical characteristics and effector variables. During treatment, the FAC, gait velocity, and Rivermead scores improved in both groups, and ankle spasticity did not change. Median FAC level was 4 (3 to 4) in group A compared with 3 (2 to 3) in group B at the end of treatment ($P=0.018$), but the difference at 6-month follow up was not significant. The therapeutic effort was less on the gait trainer, with 1 instead of 2 therapists assisting the patient at study onset. All but seven patients preferred the gait trainer.

Conclusions—The newly developed gait trainer was at least as effective as treadmill therapy with partial body weight support while requiring less input from the therapist. Further studies are warranted. (*Stroke*. 2002;33:2895-2901.)

Key Words: exercise therapy ■ gait ■ paresis ■ rehabilitation ■ stroke

Restoration of gait is a major goal in the rehabilitation of stroke patients. Modern concepts favor a task-specific, repetitive approach^{1,2} to walking training, and clear benefit from more intensive therapy has been demonstrated.³

Treadmill training with partial body weight support (BWS) enables wheelchair-bound subjects to repetitively practice complete gait cycles. Chronic, nonambulatory hemiparetic patients improved their gait ability on the treadmill.^{4,5} Visintin and co-workers reported that treadmill therapy with BWS was more effective than without BWS in subacute, nonambulatory stroke patients,⁶ and treadmill therapy also showed advantages over conventional gait training with respect to cardiovascular fitness⁷ and gait ability.⁸

However, 2 recent randomized, controlled trials in acute stroke survivors failed to show a superiority of treadmill training compared with conventional physiotherapy, which concentrated on floor walking.^{9,10}

The major limitation of treadmill therapy as a daily routine was the effort required by 2 or even 3 therapists in assisting the gait of severely affected subjects, setting the paretic limb, and controlling the trunk movements. Kosak and Reding stated in their comparative study that the therapists uniformly preferred floor walking with aggressive bracing to treadmill walking, because of the necessary physical assistance on the treadmill.⁹

To relieve the therapists' effort, our group designed an electromechanical gait trainer that enabled wheelchair-bound subjects to practice a gait-like movement with minimal assistance.¹¹ The harness-secured patients were positioned on 2 footplates, whose movements simulated stance and swing in a highly physiological manner. The body weight could be partially relieved, and ropes attached to the patient controlled the vertical and lateral movements of the center of mass in a phase-dependent manner. In an initial study, 4 weeks of

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The Reha-Stim company holds the patent for the electromechanical gait trainer used in this study. The company is owned and operated by Dr Beate Brandl-Hesse, spouse of the corresponding author, Dr Stefan Hesse.

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additional daily therapy on the gait trainer resulted in a marked improvement of gait ability and muscle activity in 14 chronic, nonambulatory hemiparetic patients, compared with a preceding 3-week baseline.¹²

The present crossover study was designed to see if the gait trainer was as effective as or even superior to treadmill training in subacute stroke patients who were still improving and to determine if it required less effort from the physiotherapists and patients.

Materials and Methods

Subjects

Of 59 consecutive registered subacute stroke survivors, 30 fulfilled the inclusion criteria and participated in the approved study following written informed consent. The participants were 17 men and 13 women, mean age of 60.0 (± 10.3) years, mean poststroke interval of 6.7 (± 3.1) weeks. Fourteen patients survived a left-sided stroke and 16 patients a right-sided stroke; cause of stroke was supratentorial ischemia (21 cases) or intracerebral hemorrhage (9 cases).

Some of the inclusion criteria were (1) first-time supratentorial stroke; (2) age <75 years; (3) stroke interval between 4 and 12 weeks before study onset; (4) (at least) firm continuous or intermittent support from 1 person to walk, corresponding to a functional ambulation category (FAC) level of 2 or less; (5) ability to sit unsupported at the edge of the bed and to stand for at least 10 s with help; (6) hip or knee extension deficit of $<20^\circ$; and (7) passive dorsiflexion of the affected ankle to a neutral position.

Another requirement was that, after participants had undergone a comprehensive clinical examination and a 12-lead ECG, the cardiologist had to confirm that there was no evidence of cardiac ischemia, arrhythmia, or decompensation. An apparent heart failure (New York Heart Association [NYHA] rating >1) and obvious clinical signs of cardiac ischemia and/or disturbed repolarization in the ECG excluded the patient.

In addition, it was required that during training the patients could not feel overexerted and the maximum heart rate could not exceed a level of 190 beats per minute—age of the patient, to help maintain the exercise at a level below that of high aerobic intensity. Further, a resting systolic blood pressure of 200 mm Hg measured before exercise was considered a contraindication to exercise. A drop in systolic blood pressure of more than 10 mm Hg with increasing workload was another contraindication to continue therapy.^{13,14}

Lastly, the patients could demonstrate no severe impairment of cognition or communication, ie, the patients needed to be able to understand the content and purpose of the study.

Randomization

An independent person drew 1 of 30 sealed envelopes assigned to one group or the other, and the result was revealed to the study members only when the patient was ready to commence training. Previous single-case design studies of locomotor therapy in chronic hemiparetic subjects had showed significant effects even with single patients,⁴ so groups of 15 patients were considered an acceptable size, which was also practical for a single center.

Clinical data, initial Rivermead motor assessment (RMA) scores, gait velocity at study onset, and the initial and terminal Barthel Index (0 to 100) did not differ between the 2 groups (Table 1). The initial mean \pm SD (terminal) Barthel Index was 38 ± 22 (64 ± 19) in group A and 35 ± 16 (63 ± 12) in group B.

Study Protocol

Patients of group A followed an A-B-A design and patients of group B a B-A-B design. A was 2 weeks of gait trainer therapy, every workday, with a net walking time of 15 to 20 minutes on the gait trainer/session. B was 2 weeks of treadmill therapy with BWS, every workday, with a net walking time of 15 to 20 minutes on the treadmill/session. The locomotor therapy, on either the gait trainer or the treadmill, was additional, ie, all patients continued their compre-

TABLE 1. Clinical Data and Initial Assessment Scores for Both Groups

	Group A	Group B
n	15	15
Hemiparesis	7 left, 8 right	7 left, 8 right
Interval, wks*	6.93 (± 2.09)	7.36 (± 1.98)
Sex	5 M, 10 F	8 M, 7 F
Age, y*	60.3 (± 8.6)	59.7 (± 10.2)
Weight, kg*	75.6 (± 11.9)	70.1 (± 9.4)
Height, cm*	172.1 (± 9.1)	170.9 (± 7.0)
Neglect	7	8
Initial gait velocity, m/s*	0.18 (± 0.07)	0.17 (± 0.06)
Initial FAC level (0–5)†	1, 1.0–2.0	1, 1.0–2.0
Initial RMS gross function (0–13)†	2, 1.0–3.0	2, 2.0–3.0
Initial RMS leg and trunk (0–10)†	1, 0.0–2.0	1, 0.0–2.0
Initial Ashworth score (0–5)†	1, 0.0–1.0	1, 0.0–1.25
Initial body weight support, % body weight*	8.86 (± 1.95)	8.93 (± 1.84)
Initial training velocity, m/s*	0.31 (± 0.06)	0.32 (± 0.05)
Initial training duration, min*	17.1 (± 2.65)	16.4 (± 2.6)

FAC indicates functional ambulation category; RMS, Rivermead mobility score.

*Values in parentheses are mean \pm SD.

†Median, interquartile range.

hensive rehabilitation program containing at least daily individual, 45-minute, physio- and occupational therapy sessions following the neurodevelopmental (Bobath) approach.

Therapy on the Gait Trainer

The harness-secured patients were positioned on 2 footplates, whose movements simulated stance and swing phases with a ratio of 60% to 40% between the 2 phases. Cadence, stride length, and thus velocity could be set individually from 0 to 2.5 km/h. A servo-controlled motor assisted the gait movement, with the rotation speed of the gear system being kept constant, and the vertical and horizontal movements of the center of mass were controlled in a phase-dependent manner by ropes attached to the harness and connected to the gear system. A pulley could relieve part of the body weight (Figure 1).

Body weight was partially supported to compensate for the paresis of the affected lower limb, and this support was reduced as soon as the patient could take his or her full weight. The clinical criteria were the patients' abilities to extend their hips and to carry weight sufficiently on the affected lower limbs. The target training velocity was relatively slow (0.25 to 0.40 m/s) to avoid overexertion of the patients. Previous work had shown that relatively young hemiparetic subjects walking at their maximum speed on the belt (at a mean of 1.14 m/s) reached a maximum heart rate of 130 beats/min and a maximum lactate level of 2.9 mmol/L.¹⁵ In another study, ambulatory hemiparetic patients even tolerated speed-dependent treadmill training with maximum belt velocities of up to 1.5 m/s.¹⁶

Treatment duration/session was 15 to 20 minutes with an optional break after 10 minutes. Physical help, eg, for the control of the paretic knee or assistance of hip extension, in the stance phase was administered according to individual needs.

Therapy on the Treadmill

Treadmill training consisted of a motor-driven treadmill, whose speed could be varied from 0 to 5 km/h. The patients wore a modified parachute harness, and a simple pulley released part of the body weight, as on the gait trainer (Figure 2).



Figure 1. A left hemiparetic patient walks on the gait trainer with the help of 1 therapist controlling the movement of the paretic knee.

Treatment conditions (amount of body weight support, velocity, and duration) corresponded to those on the gait trainer (Table 1). Physical assistance—eg, for setting the paretic limb, knee control, assistance of hip and trunk erection, and body weight shift—was administered according to individual needs.

Assessment

The functional ambulation category (FAC), the RMA score (gross functions and leg and trunk section), and the modified Ashworth score testing for the ankle dorsiflexion of the affected side and mean gait velocity (for overview, see Wade¹⁷) were assessed at the beginning and at the end of each week, ie, 7 measurement points. Follow-up was by telephone interview 6 months after study end to assess the gait ability according to the FAC.

Outcome measures were assessed by 2 independent raters, 1 physician and 1 physiotherapist, who were not involved in the therapy. They were blind with respect to the patient's group (although patients were well aware of the therapy sequence). Interrater reliabilities were 0.91 for the FAC, 0.87 for the RMA score, and 0.84 for the modified Ashworth score.

The FAC (0 to 5) was used to document gait ability. The test includes 6 levels of personnel support needed for gait but does not note if an aid was used. Level 0 describes a patient unable to walk or requiring help of 2 or more people. At level 1, a patient needs continuous support from 1 person helping with carrying weight and with balance. At level 2, a patient is dependent on continuous or intermittent support of 1 person to help with balance or coordination. At level 3, the patient needs only verbal supervision; at level 4, help is required on stairs and uneven surfaces; and level 5 describes a patient who can walk independently in any given place.

To assess disabled motor functions after stroke, the RMA score for leg and trunk and gross function was used. Within the leg and trunk section, 10 maneuvers—such as rolling to the affected and then the



Figure 2. A left hemiparetic patient walks on the treadmill with the help of 2 therapists setting the paretic limb and assisting hip movement and weight shift.

nonaffected side, bridging, sit-stand-transfer, lifting the affected leg over the side of the bed, stepping, foot-tapping, voluntary dorsiflexion with flexed and extended leg, and selective knee flexion while standing with hip in a neutral position—were tested. Within the gross function section, 13 maneuvers—including sitting, transfers, walking, climbing, running, and hopping—were tested.

The modified Ashworth score (0 to 5) documented the muscle tone tested for ankle dorsiflexion of the affected side while lying, with 0 indicating no increase and 5 indicating the affected part rigid in flexion or extension.

For assessment of gait velocity, patients walked 10 m on the ground at maximum speed. The required time was measured and the mean velocity calculated. Data were averaged on two 10-m trails. Patients used the same walking aids throughout all measurements. One therapist was in charge and was instructed to support the patients as little as possible.

For documentation of the physical assistance required during therapy, each patient was videotaped on the gait trainer and on the treadmill both at study onset and at study end. An independent person from another clinic assessed the videos of each patient during both therapy conditions, checking for the number of therapists involved and their particular help, eg, swinging of the paretic limb, controlling the paretic knee, and hip and trunk assistance. Furthermore, patients were asked about their therapy preference and perceived exertion.

Statistics

Primary outcome variables were the physical assistance required during locomotor therapy, the FAC, and the gait velocity. Secondary variables were the RMA and Ashworth scores.

The physical assistance needed on the gait trainer and on the treadmill at study onset and at study end was described for all 30 patients.

TABLE 2. Gait Ability of Each Subject in Groups A and B

Group A Patient	FAC (0–5)								Group B Patient	FAC (0–5)							
	Start	Week					End of Therapy	Follow- Up		Start	Week					End of Therapy	Follow- Up
		1	2	3	4	5					1	2	3	4	5		
1	0	0	1	1	1	2	2	1	1								
2	1	2	2	2	3	3	4	4	2	0	0	1	1	2	2	2	2
3	2	3	4	4	4	4	4	4	3	2	2	3	4	4	4	4	2
4	1	1	2	2	2	3	3	1	4	1	1	2	2	2	3	3	4
5	1	2	2	2	3	4	4	5	5	1	1	1	1	2	2	2	1
6	2	2	3	4	4	5	5	5	6	2	2	2	3	3	4	3	2
7	2	3	3	3	3	4	4	4	7	1	1	2	3	3	3	3	4
8	1	2	3	3	3	3	4	5	8	1	1	1	3	3	3	3	4
9	1	2	3	3	3	4	4	5	9	1	1	1	2	2	2	2	2
10	0	1	1	1	2	2	2	2	10	1	1	1	3	3	3	3	4
11	1	2	2	2	2	3	3	2	11	2	2	2	3	3	3	3	4
12	1	1	2	2	3	3	4	4	12	1	1	1	2	2	2	2	2
13	1	1	2	2	2	3	3	3	13	2	2	3	4	4	4	4	2
14	1	1	1	2	2	3	3	3	14	1	1	1	2	2	3	3	2
15	1	1	2	2	3	3	3	4	15	1	2	2	2	2	3	3	2
Median	1	2	2	2	3	3	4	4		1	1	1.5	2.5	2.5	3	3	3
interquartile range	1.0–1.0	1.0–2.0	2.0–3.0	2.0–3.0	2.0–3.0	3.0–4.0	3.0–4.0	2.75–5.0		1.0–2.0	1.0–2.0	1.0–2.0	2.0–3.0	2.0–3.0	2.0–3.25	2.0–3.0	2.0–4.0

FAC indicates functional ambulation category.

The ordinal-scaled parameters (FAC, RMA, and Ashworth scores, presented as median and interquartile ranges) were compared between groups at each measurement point with the help of the nonparametric Mann-Whitney *U* test. Within each group, the change of each variable in the time interval spanning from study onset to study end was compared with the help of the nonparametric Wilcoxon test.

For gait velocity, increments between the beginning and end of the specific therapy were calculated separately for each group and compared with the help of a univariate variance analysis with repeated measures assessing the overall effects of treatment, time, and the interaction of both during 1 period. An alpha-level of $P < 0.05$ was assumed.

Results

Physical Assistance and Subjective Preference

On the gait trainer, 1 subject required the help of 2 therapists assisting the hip extension and knee control at study onset, 27 subjects needed help of 1 therapist sitting in front of the patient controlling the paretic knee, and 2 subjects practiced independently. Overall, approximately 1 therapist assisted 1 patient on the gait trainer.

On the treadmill, 1 subject required the help of 3 therapists setting both lower limbs and assisting hip and trunk extension, 28 subjects were assisted by 2 therapists helping with the swinging of the paretic limb and hip and trunk control, and 1 subject needed the help of only 1 therapist setting the paretic limb on the belt. Overall, 2 therapists assisted 1 patient on the treadmill.

At study end, 23 subjects walked independently on the gait trainer, and 7 subjects still needed the help of 1 physiotherapist guiding the paretic knee. On the treadmill, 6 subjects

walked without assistance on the belt, and the remaining 24 patients required help of 1 therapist setting the paretic limb.

All but 7 patients preferred the gait trainer. They found it less demanding (18 subjects) and more comfortable because of less required manipulation during therapy (11 subjects).

The 7 patients who preferred the treadmill therapy said that swinging the paretic limb on the treadmill seemed more natural (with or without help) and thus more effective to them, compared with the ongoing footplate support of the “swinging” limb on the gait trainer.

Treatment Parameters

Treatment parameters (body weight support, walking speed, and duration/session) did not differ between the 2 groups, in agreement with the experimental protocol. Over time, body weight support decreased, and walking speed and treatment duration slightly increased in both groups to a similar extent.

Gait Ability and Gait Velocity

Gait ability improved considerably in all patients. At the end of the study, 13 of 15 patients in group A could walk independently at least with verbal supervision; in group B, 11 patients reached this level (Table 2).

The statistical analysis revealed a significant improvement over time for both groups. Group comparison showed that patients in group A had reached a significantly ($P = 0.018$) better gait ability level at study end (Figure 3). In group A, 1 patient could then walk independently everywhere (FAC 5), 7 patients walked independently on even surfaces (FAC 4), and 5 patients needed standby (FAC 3) at the end of the study. In

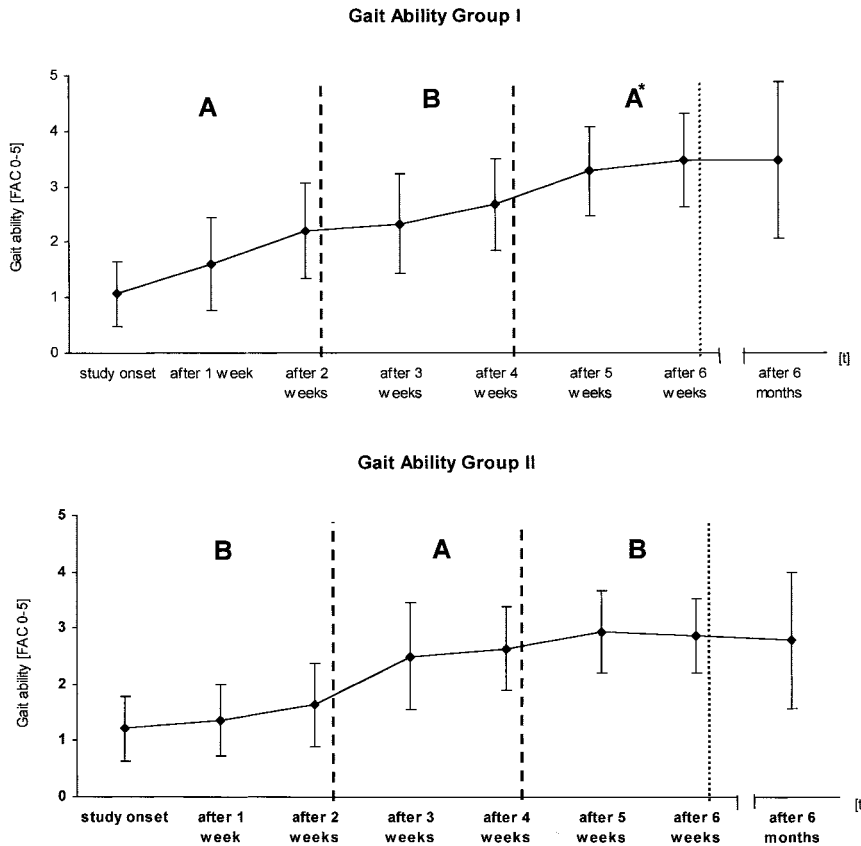


Figure 3. Line graph shows median functional ambulation category (FAC) levels and interquartile ranges over time of patients in group A (above) and in group B (below). The gait ability was significantly better in group A at study end ($P < 0.05$).

group B, no patient scored FAC 5, 2 patients scored FAC 4, and 8 subjects reached FAC 3 at the end of the study.

Gait velocity improved significantly over time in both groups, but there was no group difference. The mean initial (terminal) walking velocity was 0.18 ± 0.07 (0.42 ± 0.21) m/s in group A and 0.17 ± 0.06 (0.37 ± 0.23) in group B (Figure 4).

Rivermead Motor and Modified Ashworth Scores

Both sections (gross function and leg and trunk) of the RMA improved over time in both groups, but there was no group difference. The median initial gross function scores were 2 (1 to 3) in group A and 2 (2 to 3) in group B. The terminal scores were 6 (5 to 8) in group A and 6 (6 to 7) in group B. The corresponding values of the leg and trunk section were 1 (0 to 2) and 1 (0 to 2) initially and 4 (4 to 5) and 3 (2 to 4.25) at study end.

The Ashworth scores were low in both groups at study onset and changed little: median of 1 (0 to 1) in group A and 1 (0 to 1.25) in group B.

Follow-Up After 6 Months

All patients were reached by phone 6 months after study end. In group A, 13 patients lived at home and 2 in a nursing home. The gait ability remained constant in 12 patients in group A, who continued practicing walking either at home (5 subjects) or in the community (7 subjects). Two patients had become completely wheelchair-dependent because of fear of falls and epileptic fits, and another subject (patient 4) developed AIDS. The median FAC level was 4 (2.75 to 5) in group A.

In group B, 11 resided at home and 4 in a nursing home. The gait ability further improved in 5 subjects (they now scored FAC 4 instead of 3), remained constant in another 4 subjects, and had deteriorated in 6 subjects. Two of those 6 subjects (patients 4 and 5) had suffered a new cerebrovascular accident. The remaining 4 subjects (all but 1 had required standby during walking at study end) had felt insecure and had given up walking. The median FAC level was 3 (2 to 4) in group B.

The statistical analysis revealed no group difference, ie, the differences had waned.

Discussion

Gait rehabilitation of the subacute stroke patients followed task-specific repetitive treatment guidelines,^{1,2} with the patients practicing gait either on the treadmill or on the electromechanical gait trainer. Patients in both groups improved their gait ability, walking velocity, and other motor functions considerably during the treatment period. Group comparison revealed that patients in group A had reached a significantly higher gait ability level at study end. Further, the therapy on the gait trainer required less therapeutic assistance as compared with treadmill training.

The improvements of gait ability (median FAC gain from 1 to 4 in group A and from 1 to 3 in group B) and walking velocity (mean gain of 0.24 m/s in group A and 0.20 m/s in group B) during the 6-week intervention period were compared with the results of other groups studying treadmill therapy or intensified gait training on the floor in subacute stroke victims. Visintin et al reported a mean improvement of

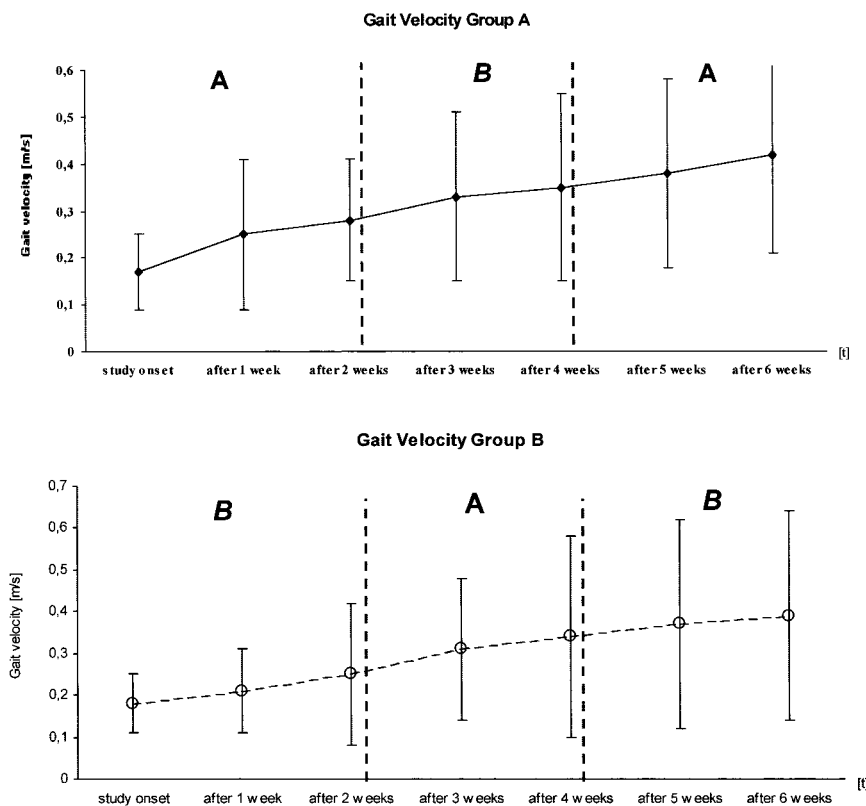


Figure 4. Line graph shows mean (\pm SD) walking velocity over time of patients in group A (above) and in group B (below). There was no difference between groups.

walking velocity of 0.25 m/s in the 6-week BWS treadmill group.⁶ The patients of Nilsson et al improved their walking velocity for a mean of 0.24 m/s (treadmill) and 0.20 m/s (floor walking group); the mean FAC improvement was 2.4 and 1.7, respectively.¹⁰ Kosak and Reding studied very severely affected patients who started with a velocity of 0.08 m/s and reached 0.18 m/s after 12 treadmill treatment sessions.⁹

Locomotor therapy in neurological rehabilitation is dependent on activation of spinal and supraspinal locomotor pattern generators.¹⁸ Besides experiments in spinalized cats,¹⁹ alterations of muscle activation patterns of various lower limb muscles in paraparetic²⁰ and hemiparetic¹² subjects following locomotor therapy support the assumption of neural adaptations. Improvement in gait ability within 2 weeks of treatment in both groups is much more likely to be the result of neural changes than of muscular effects of aerobic exercise, which are seen only after 3 to 6 months of intensive treadmill therapy.^{13,14} Also, one should keep in mind that spontaneous recovery surely contributed to the observed beneficial effects within a relatively short time.²¹

The group comparison revealed that patients in group A had reached a significantly higher gait ability level as compared with patients in group B. This difference was clinically relevant, as 12 of 15 patients in group A further improved their gait ability during the final gait trainer period so that 1 patient could then walk independently everywhere (FAC 5), 7 patients walked independently on even surfaces (FAC 4), and 5 patients needed standby (FAC 3) at the end of the study. In group B, only 4 patients further improved their gait ability in the last period of treadmill training, no patient scored FAC 5, 2 patients scored FAC 4, and 8 subjects reached FAC 3 at the end of the study.

The duration of therapy, walking velocity, and body weight support were similar in both groups, so that different intensities could not explain the observed results. Further, dynamic electromyographic recordings had shown similar muscle activation patterns of antigravity muscles of hemiparetic patients being assessed on both devices.

The larger therapeutic effort during the treadmill therapy may be an explanation. Setting the paretic limbs and controlling the trunk movement required a considerable physical effort from the therapists, in a nonoptimal working posture. This tiring work, requiring the coordination of 2 therapists, may have overexerted the therapists over time so that they may have been no longer able to provide an optimum gait pattern on the treadmill. On the other hand, the gait trainer machine provided the simulation of stance and swing phases in a highly physiological manner, and ropes attached to the harness controlled the movement of the center of mass in a phase-dependent manner. The therapist sitting in front of the patient on a chair merely controlled the movement of the paretic knee. Future gait analysis studies need to clarify this assumption.

Further, 23 stroke patients preferred the treatment on the machine-supported gait trainer: they felt less exerted and positively noted the fact that they could practice more independently.

The group difference waned at follow-up. Confounding factors such as continuation of walking training and medical comorbidities limit the interpretation of the differences between groups after 6 months. However, it became clear that those who kept practicing gait did better in the long run.

Other limiting factors of the present study are that the design of the study did not exclude a carry-over and/or a

sequence effect, nor did the study include a conventional treatment group, particularly given that the stroke patients in this study were in the early phase of recovery. The optimum intensity of therapy per workday is another open question for future studies, given that the 20-minute sessions of the present study are only a fraction of the successful task-specific training paradigms used in upper extremities after stroke.^{22,23}

In conclusion, the electromechanical gait trainer is an effective alternative to treadmill therapy with partial body weight in intense gait rehabilitation after stroke. Its major advantage is the avoidance of the strenuous effort of the therapists during treadmill therapy. In addition, most of the patients preferred the gait trainer to the treadmill training. Further studies are warranted comparing the treatment on the gait trainer with a conventional therapy approach in subacute stroke survivors.

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