

## Treadmill training with partial body weight support and physiotherapy in stroke patients: a preliminary comparison

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Treadmill training with partial body weight support can restore the gait ability of chronic non-ambulatory hemiparetic subjects. A combination of physiotherapy and treadmill training may accelerate the rate of recovery. Therefore a randomized study was planned. Twenty-eight non-ambulatory hemiparetic patients were randomly assigned to group A or B. A 3-week baseline of conventional therapy was followed by 15 sessions of physiotherapy and treadmill training in patients of group A and by 15 sessions of treadmill training in patients of group B over a period of 3 weeks. Follow-up was 4 months later. The major outcome variables were gait ability and ground level walking velocity. Gait ability and velocity did not change during the baseline. In group B, five patients became independent walkers after the specific intervention, whereas 10 patients of group A regained independent walking ability in the same period ( $P < 0.05$ ). Four months later group differences had waned. Three weeks of treadmill training plus physiotherapy accelerated the restoration of gait ability in hemiparetic subjects, however, the double amount of therapy in group A does not exclude a simple dose-response phenomenon.

### Introduction

Treadmill training with partial body weight support (BWS) is a promising new technique for the restoration of gait in stroke (Hesse *et al.*, 1994; Visintin *et al.*, 1998) and paraparetic subjects (Visintin and Barbeau, 1989; Wernig and Müller, 1992; Dietz *et al.*, 1995). It is a task-specific therapy enabling wheelchair-bound subjects to practice complex gait cycles repeatedly. The moving belt enforces locomotion, a harness substitutes for deficient equilibrium reflexes, and according to the amount of paresis part of the body weight is supported (BWS). The theoretical background to this therapy involves entrainment of spinal and supraspinal pattern generators (Grillner, 1985; Lovely *et al.*, 1986; Asanuma and Keller, 1991; Carr and Shepherd, 1998).

Two previous single-case design studies showed that treadmill training with BWS was more effective with regard to restoration of gait and improving ground level walking velocity than regular physiotherapy in chronic non-ambulatory hemiparetic subjects [Hesse *et al.*, 1995a (*Stroke*), b (*Scand J Rehabil Medical*)].

For acute stroke patients, a recent Canadian study compared treadmill walking with and without 40% BWS. The BWS group had significantly higher scores

for motor recovery and overground walking speed right after a 6-week training period the same as 3 months later (Visintin *et al.*, 1998).

The present study investigated the additive effect of conventional physiotherapy on treadmill training with BWS. This may accelerate gait restoration by allowing a more intense and varied programme during a defined period of time.

Within a randomized prospective controlled study the authors therefore compared two groups of non-ambulatory hemiparetic subjects who either received treadmill training with BWS alone or in combination with physiotherapy during a 3-week specific training period. All subjects participated in a comprehensive 9-week stroke rehabilitation programme. Follow-up was 4 months later. The major outcome variables were ground level walking velocity and gait ability assessed with the help of the Functional Ambulation Category (FAC).

### Methods

#### Subjects

Eligible subjects had to be at least 8 weeks and not more than 9 months after a first supratentorial stroke. Further inclusion criteria were: (i) non-ambulatory, i.e. all of them required at least firm continuous or intermittent support from one person who helped with balance, (ii) participation in a comprehensive 9-week

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inpatient rehabilitation programme, (iii) able to understand at least simple instructions and the meaning of the study; and (iv) no other orthopaedic or neurological diseases impairing mobility.

Thirty-six patients met the criteria within a 1.5-year recruitment period. Of these, 28 stroke patients participated in the study, which had been approved by the ethical committee, after written informed consent. The group of participating subjects consisted of 15 men and 13 women. The mean age was 54.7 years ranging from 29 to 77 years. Mean poststroke interval was 4.3 months ranging from 2.0 to 8.2 months. Twelve patients suffered from a right and 16 patients from a left hemiparesis; in all cases aetiology was a supratentorial lesion as a result of ischaemia in the territory of the middle or anterior cerebral arteries (23 cases) or an intracerebral haemorrhage (five cases). Walking aids and orthoses had been prescribed according to individual needs in both groups at the beginning of the study. The subjects continued to use the same aids throughout the study. Sensory impairment (tested for position sense and dermolexia) of the paretic lower extremity was present in 19 subjects and an obvious pusher syndrome was found in six patients, evenly distributed amongst both groups.

#### Allocation

The 28 patients were randomly assigned to group A or B, each consisting of 14 subjects. The computer-generated allocation sequence was concealed with the help of sealed envelopes during the baseline until specific intervention started. An investigator non-involved in the clinical trial was responsible for the allocation.

#### Study protocol

The study was approved by the ethical committee and all patients gave their informed consent. All patients participated in a comprehensive 9-week rehabilitation programme. A 3-week baseline consisted of daily physiotherapy and occupational, speech and neuropsychological therapy according to individual needs. During the subsequent 3 weeks of specific intervention, patients of group A received treadmill training with BWS for 30 min five times a week plus single treatment sessions of physiotherapy for 40 min five times a week, totalling 30 sessions. Physiotherapy following the Neurodevelopmental or 'Bobath' (NDT) concept, included gait-preparatory manoeuvres whilst sitting and standing and the practice of gait itself either on the floor or on the stairs. Patients of group B only received 15 treadmill training sessions of 30 min during the 3-week intervention period without additional individual

physiotherapy. Afterwards, patients of both groups participated in the comprehensive rehabilitation programme for another 3 weeks. After return to their homes in all cases, outpatient physiotherapy was continued two or three times a week in all of them. Additionally, patients and their relatives were instructed to practice gait themselves as much as possible.

#### Assessments

The Functional Ambulation Category (FAC), and ground level walking velocity were the major outcome variables. Secondary variables were leg and trunk and gross function sections of the Rivermead Motor Assessment Score. All variables were assessed twice during the antecedent 3-week baseline – at the beginning and at the end of treadmill training – and 4 months after discharge (Holden *et al.*, 1986; Wade, 1992).

Two non-involved, experienced raters, one physician and one physiotherapist, performed the assessments. Inter-rater reliabilities were larger than 0.85 for both the FAC and Rivermead Motor Assessment Score.

The FAC was assessed to document gait ability (Wade, 1992). The test includes six 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 two or more people. At level 1, a patient needs continuous support from one person helping with carrying weight and with balance. At level 2 a patient is dependent on continuous or intermittent support of one person to help with balance or co-ordination. 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 anywhere.

To assess disabled motor functions after stroke, the Rivermead Motor Assessment Score for leg and trunk and Gross function was used. Within the leg and trunk section 10 manoeuvres such as rolling to the affected and non-affected side, bridging, sit-stand-transfer, lifting the affected leg over side of bed, stepping, foot-tapping, voluntary dorsiflexion with flexed and extended leg, and selective knee flexion whilst standing with hip in neutral position were tested in hierarchical order. Within the gross function section 13 manoeuvres including sitting, transfers, walking, climbing, running, and hopping were tested. An improvement of three or more points/section indicates a clinically relevant improvement (Collen *et al.*, 1990).

For assessment of gait speed, patients walked 10 m at maximum speed. The required time was measured and the velocity calculated. The data were averaged on two 10-m trails. Involved in the task was one therapist who was instructed not to push the patients forward but

merely to prevent them from falling. If not possible, a gait speed of 0.1 m/s was assumed. An improvement of at least 25% indicates clinical relevance (Collen *et al.*, 1990).

### Statistical analysis

Major outcome variables were the FAC, the ground level walking velocity and the Rivermead Motor Assessment scores. Increments between the beginning and end of the specific therapy the same as 4 months later were calculated separately for each group and compared with the help of a set of univariate variance analysis with repeated measures assessing the overall effects of treatment, time and the interaction of both during one period ( $P < 0.0125$ , corrected according to Bonferoni). Mauchly and Kolomogorov-Smirnov-tests confirmed the prerequisites for an univariate variance analysis.

### Treadmill training with partial body weight support

The therapy followed previously described principles (Hesse *et al.*, 1994). Briefly, patients were supported in a modified parachute harness suspended centrally by a set of pulleys connected to a flexible spring. At the beginning of the therapy, two therapists provided manual help to correct gait deviations. One therapist sitting by the paretic side facilitated the swing of the paretic limb, determined that its initial ground contact was made with the heel, prevented knee hyperextension during midstance and encouraged symmetry of step length and stance symmetry. The second therapist stood on the treadmill behind the patient and facilitated weight-shift onto the stance limb, hip extension and trunk erection. Mean treadmill speed was 0.21 (range 0.15–0.30 m/s) at the beginning. After approximately 7 days, an average speed of 0.27 m/s was reached and kept constant until the end. The mean BWS was 27% (range 20–30) of body weight at the beginning. The support was reduced as soon as possible to enable full load of the lower limbs (Hesse *et al.*, 1994). After an average of 14 treatment sessions 18 subjects walked without support whilst 10 subjects needed a support of 5–15% BWS until the end. Net walking time on the treadmill was approximately 20 min per session with a brief rest in the middle.

### Results

All 28 patients completed baseline and the specific intervention. Three patients (one in group A and two in group B) did not appear at follow-up. Demographic and clinical data including Functional Ambulation

Category (FAC, 0–5) and ground level walking velocity did not differ significantly between the two groups at the beginning of the study.

### Walking ability

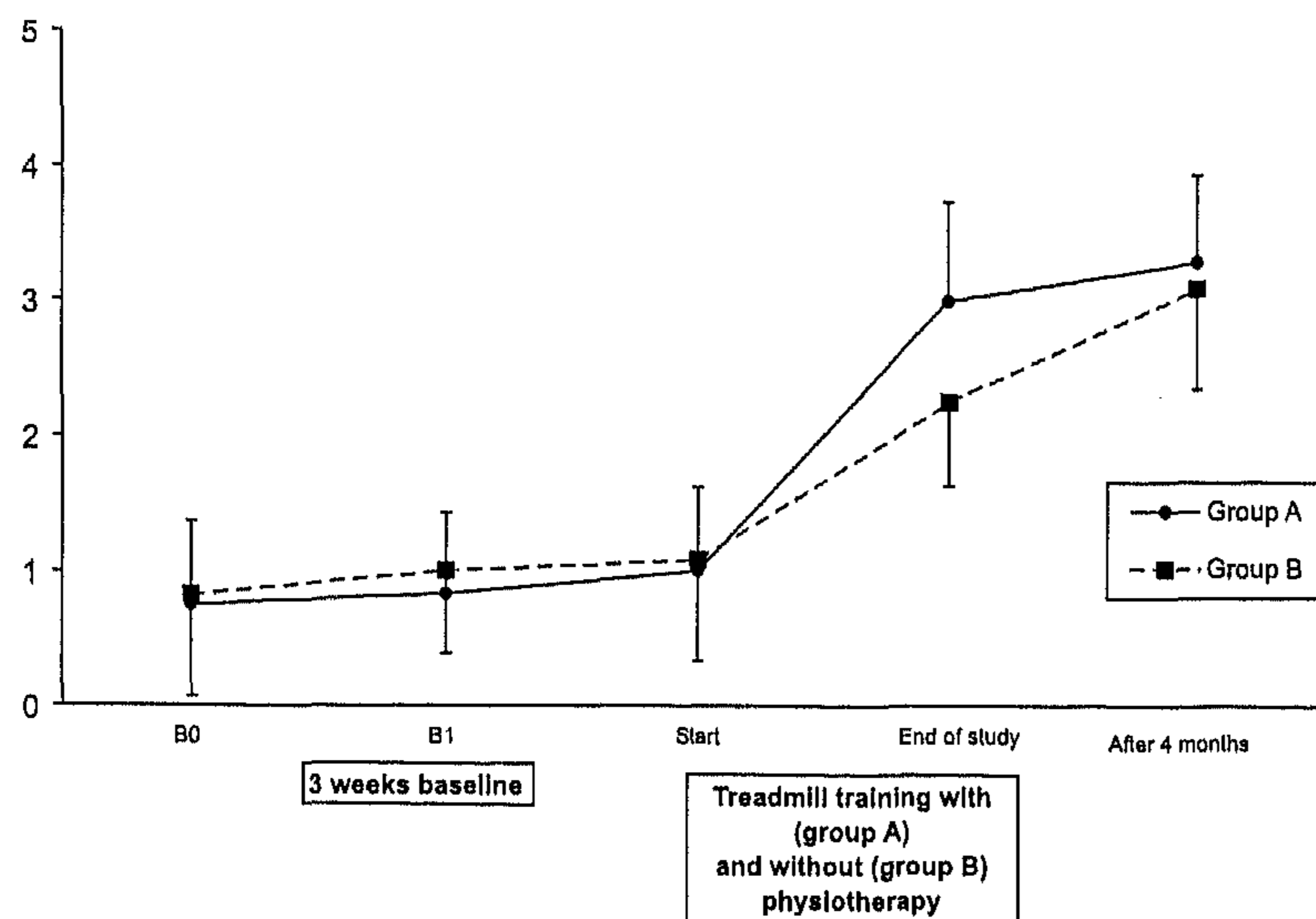
During the 3-week baseline none of the subjects of both groups regained independent walking ability. During the subsequent 3 weeks of specific training, all patients from group A improved their gait ability considerably (Fig. 1, Tables 1 and 2): three subjects could walk independently on level ground (FAC 4), seven subjects needed verbal supervision (FAC level 3), and four patients continued to require support of one person (FAC 2) after this period. The mean FAC scores of group A were 1.0 before and 2.9 after 3 weeks of treadmill training plus physiotherapy. Patients from group B improved to a significantly lesser extent; no subject scored FAC level 4, five subjects reached FAC level 3, seven subjects scored FAC level 2 and two subjects improved from 0 to level 1 after therapy. The mean FAC scores of group B were 1.1 before and 2.2 after the 3 weeks of exclusive treadmill training. The statistical analysis revealed that both groups improved significantly over time ( $P < 0.001$ ). That the overall treatment did not differ, but that there was a significant interaction between time and treatment ( $P = 0.012$ ) after the end of the specific intervention.

Four months later, seven patients of group A had further improved their gait ability gaining one (six subjects) or two levels (one subject). The gait ability remained constant in four subjects and deteriorated in two subjects of group A with a decrease of 1 level. Both patients had stopped practising gait themselves because of fear of falls. The mean FAC score of group A was 3.4, 4 months after discharge.

In the same period, 10 subjects of group B had further improved their gait ability gaining one (nine subjects) or two levels (one subject). Two subjects did not change and none deteriorated. The mean FAC score was 3.2. There was no significant interaction at follow-up.

### Ground level walking velocity

In group A, the ground level walking velocity improved from a mean (SD) of 0.20 m/s ( $\pm 0.06$ ) to a mean of 0.33 m/s ( $\pm 0.10$ ) at the end of the 3-week specific intervention (Tables 1 and 2). Four months later, the mean value was 0.31 m/s ( $\pm 0.12$ ). In group B, the ground level walking velocity improved from a mean of 0.22 m/s ( $\pm 0.05$ ) to a mean of 0.30 m/s ( $\pm 0.09$ ) at the end of the exclusive treadmill training. Four months later the mean value was 0.31 m/s ( $\pm 0.06$ ). The statis-



**Figure 1** Line graph shows mean Functional Ambulation Category (FAC) scores and their ranges over time of patients of group A and of group B. The improvement of walking ability was larger in group A than in group B during the specific 3-week intervention period ( $P < 0.05$ ). Patients of group A received treadmill training plus individual physiotherapy and patients of group B treadmill training without additional individual physiotherapy during the 3-week period.

**Table 1** Clinical data, functional assessment scores and velocity of each subject of group A

Patient no.	Age	Sex	Hemi paresis l = left r = right	Stroke interval in months	Functional ambulation category (FAC) b0-b1-start-end-fup	Velocity [m/s] b0-b1-start-end-fup	Rivermead gross function b0-b1-start-end-fup	Rivermead leg and trunk b0-b1-start-end-fup
1	63	M	l	5.5	1-1-1-2-4	0.12-0.15-0.17-0.28-0.34	2-3-3-5-10	0-2-2-5-7
2	60	F	l	4	1-1-1-3-3	0.17-0.17-0.19-0.27-0.22	2-2-2-6-6	2-2-2-3-5
3	51	F	l	3	1-1-1-3-4	0.20-0.21-0.23-0.42-0.23	1-3-4-6-10	2-3-3-6-7
4	52	F	r	2.5	0-0-0-2-3	0.13-0.12-0.14-0.25-0.30	2-2-3-5-8	1-1-2-4-5
5	77	F	l	3.5	0-0-0-2-2	0.06-0.08-0.10-0.20-0.10	0-1-1-5-5	0-1-1-5-4
6	54	M	l	7.5	1-1-1-4-4	0.12-0.20-0.21-0.54-0.43	3-4-5-10-11	1-3-3-4-7
7	67	F	l	3	0-1-1-2-3	0.15-0.14-0.17-0.17-0.17	1-2-2-2-6	0-1-1-4-3
8	58	M	l	3.5	1-1-1-3-4	0.20-0.18-0.20-0.35-0.45	3-3-3-5-10	1-1-2-5-7
9	43	F	r	4.5	1-2-2-3-4	0.16-0.19-0.20-0.43-0.54	2-3-3-6-10	3-5-5-7-7
10	29	F	r	2.5	1-1-1-4-3	0.22-0.33-0.40-0.63-0.55	3-3-4-10-10	2-3-3-5-9
11	72	M	l	3.5	0-0-0-3-4	0.10-0.11-0.13-0.20-0.22	0-2-3-6-10	2-3-3-6-7
12	57	M	l	4.5	2-2-2-3-Ø*	0.27-0.29-0.30-0.36-Ø*	3-3-3-6-Ø*	5-6-6-6-Ø*
13	54	M	r	6	0-1-1-4-3	0.19-0.24-0.29-0.38-0.31	4-5-5-7-6	3-5-5-5-7
14	39	M	r	5.1	1-1-1-3-3	0.12-0.18-0.22-0.35-0.50	3-3-3-6-8	1-2-2-5-7
Mean	55.4	Ø	Ø	4.2	0.8-1.0-1.0-2.9-3.4	0.16-0.18-0.20-0.33-0.31	2.1-2.8-3.1-6.1-8.5	1.6-2.7-2.9-5.0-6.4

b0; 1 = baseline measurements; start = start of 3-week treadmill training with additional physiotherapy; end = end of 3-week treadmill training; Fup = 4 months after study onset; Ø\* = no follow-up.

tical analysis revealed a significant improvement over time for both groups ( $P < 0.001$ ) but no interaction.

#### Other motor functions

In group A, the Rivermead score for gross function improved from a mean of 3.1 (range 1-5) to a mean of 6.1 (range 2-10) during the 3 weeks of specific therapy (Tables 1 and 2). Four months later, the mean value was 8.5 (range 6-11). The corresponding values for the leg and trunk section were: 2.9 (range 1-6), 5.0 (range 3-7) and 6.4 (range 3-9). In group B, the Rivermead

score for gross function improved from a mean of 2.7 (range 1-5) to a mean of 5.1 (range 3-6) in the first period, 4 months later its mean value was 6.8 (range 6-10). The corresponding values for the leg and trunk section were: 2.9 (range 0-5), 4.8 (range 4-6) and 5.6 (range 3-7). The two groups did not differ with respect to the Rivermead Motor Scores.

#### Discussion

The 3-week combination of treadmill training with BWS and physiotherapy effected a larger improvement

Table 2 Clinical data, functional assessment scores and velocity of each subject of group B

Patient no.	Age	Sex	Hemi paretic l = left r = right	Stroke interval in months	Functional ambulation category (FAC) b0-b1-start-end-fup	Velocity [m/s] b0-b1-start-end-Fup	Rivermead gross function b0-b1-start-end-Fup	Rivermead leg and trunk b0-b1-start-end-Fup
1	61	F	r	4	0-1-1-2-3	0.12-0.18-0.20-0.47-0.34	0-2-2-4-6	0-0-0-4-3
2	35	M	l	2.5	1-1-1-3-4	0.27-0.34-0.33-0.37-0.48	2-3-3-6-10	1-2-4-6-6
3	47	M	l	5.3	1-1-1-3-4	0.21-0.22-0.23-0.34-0.31	3-3-3-6-10	2-3-3-6-5
4	48	F	r	3.8	0-0-0-1-3	0.14-0.15-0.15-0.20-0.22	1-1-1-3-6	0-0-0-2-4
5	57	M	l	5.4	0-1-1-2-Ø*	0.13-0.19-0.22-0.29-Ø*	0-2-2-5-Ø*	1-3-3-5-Ø*
6	56	M	r	6	2-2-2-2-3	0.11-0.15-0.14-0.10-0.22	5-5-5-5-6	3-4-4-4-7
7	57	F	l	5.1	2-2-2-2-3	0.24-0.27-0.28-0.29-0.31	2-3-3-5-5	2-3-4-5-6
8	62	M	l	5	2-2-2-3-4	0.19-0.17-0.18-0.28-0.33	2-2-2-6-6	2-2-3-3-5
9	46	F	r	6	1-1-1-3-4	0.18-0.23-0.22-0.40-0.38	2-3-3-6-10	2-4-5-6-7
10	68	M	l	2.5	0-1-1-2-2	0.12-0.25-0.30-0.34-0.29	0-1-1-5-6	0-0-0-5-7
11	57	F	r	6	1-1-1-2-Ø†	0.18-0.22-0.20-0.24-Ø†	4-5-5-5-Ø†	4-5-5-5-Ø†
12	49	M	r	7.7	0-0-0-1-2	0.18-0.22-0.23-0.31-0.28	3-3-3-5-5	1-3-3-5-5
13	55	M	l	4.3	0-1-1-2-3	0.09-0.17-0.19-0.29-0.33	0-2-3-5-6	2-3-4-6-6
14	58	F	r	8.2	1-1-1-3-3	0.19-0.23-0.23-0.31-0.32	1-2-2-5-6	2-2-3-5-5
Mean	54.0	Ø	Ø	5.1	0.8-1.1-1.1-2.2-3.2	0.17-0.21-0.22-0.30-0.31	1.8-2.6-2.7-5.1-6.8	1.6-2.4-2.9-4.8-5.6

b0, 1 = baseline measurements; start, start of 3-week treadmill training and no additional physiotherapy; end, end of 3-week treadmill training; Fup, 4 months after study onset; Ø\*, no follow-up; Ø†, patient died.

of gait ability of non-ambulatory hemiparetic subjects than an exclusive 3-week treadmill therapy with BWS. Four months later, the differences in gait ability between the two groups had waned.

The observed improvements of gait ability in chronic non-ambulatory hemiparetic subjects after 3 weeks of exclusive treadmill training are in keeping with a previous single-case design study (Hesse *et al.*, 1995). The authors reported a mean improvement of 1.1 FAC levels after 3 weeks of exclusive treadmill training of chronic hemiparetic subjects, the mean FAC increase of the present study was 1.2 (group B).

The 3-week combination of treadmill training and physiotherapy further improved gait ability with a mean improvement of 1.8 FAC levels (group A). The reported significant interaction between time and treatment after the end of the specific intervention was of clinical relevance as 10 patients of group A could walk independently as compared with only five subjects of group B after the end of therapy. Both therapies probably added to each other with gait not only practised on the belt but also during ground level walking or on stairs promoting the transfer of training effects. On the other hand, patients of group A received the double amount of individual gait-related therapeutic sessions (30 vs. 15) during the specific 3-week intervention period. Thus, only the amount of therapy in general could have explained the observed result reflecting a dose-response phenomenon and not the effect of the specific intervention. Despite this obvious weakness of the chosen design the authors studied the common effect of physio- and treadmill therapy as both therapies

are often combined in daily practise and as physiotherapists are hesitant to exclusively treat patients on the treadmill. The outcome of this study seems to justify this intense approach. Anyhow the reader should keep in mind that the statistical analysis revealed a significant interaction between the course of the two patient groups for only one variable, the FAC, whereas gait velocity and the motor scores of the Rivermead Motor Assessment Scores did not differ. Furthermore, the patients of the study were carefully selected so that a generalized statement can only be drawn with great caution, particularly as the patients were not completely homogeneous with respect to gait ability and stroke interval before study onset.

Recently, Kwakkel *et al.* (1999) reported that greater intensity of leg rehabilitation improved gait ability and activities of daily living in acute stroke victims. The key elements of their lower limb rehabilitation programme were comparable with the physiotherapy within the present study. Further, Richards *et al.* (1993) had shown that an additionally applied, task-specific programme including treadmill training without body weight support resulted in a larger gait velocity in acute stroke victims 6 weeks after study onset as compared with a conventionally treated group who received less therapy.

Four months after discharge from the rehabilitation unit, group differences had waned as a result of a further improvement of gait ability in all patients of group B. However, in group A only five subjects walked better and gait ability had deteriorated in two of them at that time. The amount of outpatient physiotherapy after

discharge was comparable between both groups and patients and relatives had all been instructed to practice walking at home.

The potential for motor recovery after stroke therefore seems to be limited, and patients of group A probably reached this presumed level faster, i.e. the combined treatment of physiotherapy and treadmill training accelerated motor recovery. Similarly, Richards *et al.* (1993) also reported in the above mentioned study that differences in gait ability between the high and low-intensity group had waned at follow-up 6 months later, also because of a further improvement of larger extent in the low-intensity group.

In conclusion, 3 weeks of treadmill training with BWS plus physiotherapy accelerated the restoration of gait ability in chronic hemiparetic subjects; correspondingly, a focused and intense treatment regime including locomotion training seems most promising in gait rehabilitation after stroke. The lack of statistical effects for gait velocity and other motor functions, the careful selection of patients and the partial inhomogeneity of the study population, however, are limiting.

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