

Treadmill Training With Partial Body-Weight Support After Total Hip Arthroplasty: A Randomized Controlled Trial

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ABSTRACT. Hesse S, Werner C, Seibel H, von Frankenberg S, Kappel E-M, Kirker S, Käding M. Treadmill training with partial body-weight support after total hip arthroplasty: a randomized controlled trial. *Arch Phys Med Rehabil* 2003;84:1767-73.

Objective: To compare treadmill training with partial body-weight support (TT-BWS) and conventional physical therapy (PT) in ambulatory patients with hip arthroplasty.

Design: Randomized controlled trial.

Setting: Rehabilitation center.

Participants: Eighty patients with a fully loadable implant who could walk independently with crutches after unilateral total hip arthroplasty were randomized to receive either TT-BWS (treatment group) or conventional PT (controls), for 10 working days.

Interventions: Each patient received 45 minutes of individualized PT, either treadmill training plus PT in the experimental or PT alone in the control group.

Main Outcome Measures: The Harris score, recorded by blind assessors, served as the primary outcome measure. Secondary outcome measures were the hip extension deficit, gait velocity, gait symmetry, affected hip abductor power; hip abductor amplitude of electromyographic activation; and the interval from surgery to abandoning crutches.

Results: At the end of training, the treatment group's Harris score was 13.6 points higher ($P < .0001$) than the control group's score. Further, hip extension deficit was 6.8° less ($P < .0001$), gait symmetry was 10% greater ($P = .001$), affected hip abductor was stronger (Medical Research Council grades 4.24 vs 3.73; $P < .0001$), and the amplitude of gluteus medius activity was 41.5% greater ($P = .001$) than those measures for controls. Gait velocity did not differ in the 2 groups. These significant differences in favor of the treatment group persisted at 3 and 12 months. The treatment group abandoned crutches sooner than the control group (3 vs 8wk). In the treatment group, 39 patients finished treatment, 35 appeared at 3, and 26 at 12 months for follow-up. In the control group, the corresponding numbers were 40, 35, and 24 patients, respectively.

Conclusion: TT-BWS is more effective than conventional PT at restoring symmetrical independent walking after hip replacement.

Key Words: Arthroplasty; replacement; hip; Rehabilitation.

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EACH YEAR, APPROXIMATELY 81.5 people per 10,000 in the United States receive a total hip replacement.¹ Post-operative rehabilitation programs focus on hip joint mobilization, strengthening of surrounding muscles, and gait retraining, initially with a walking aid. Uncontrolled studies²⁻⁴ have reported improvements after conventional rehabilitation programs.

Treadmill training with partial body-weight support (TT-BWS) has already been shown to be effective in neurologic rehabilitation.⁵⁻⁸ Treadmill training follows modern principles of motor learning and allows patients to practice complex gait cycles early in rehabilitation, before they can walk unsupported and independently on the ground. Because their body weight is supported in a controlled manner, they are able to take many more steps than is normally possible when floor walking.

TT-BWS and conventional gait training have been compared after fracture of the neck-of-femur.⁹ At discharge, the treadmill group could walk better and faster, developed more hip muscle power, and were discharged from hospital 13 days sooner than the control group.⁹

A biomechanical study¹⁰ of ambulatory patients with total hip arthroplasty (THA) with a fully loadable implant compared their walking on the treadmill with 15% body-weight support and walking on the ground with 2 crutches placed reciprocally. In both conditions, patients walked symmetrically, but the activation of the affected hip abductor muscle was larger in amplitude and occurred at a more normal time of the gait cycle when walking on the treadmill.¹⁰

Our randomized controlled trial intended to investigate the potential of TT-BWS in patients after total hip replacement. The hypothesis was that TT-BWS was more effective than conventional floor gait training in improving functional walking in patients with THA with a fully loadable implant.

METHODS

Participants

Between September 1, 1999, and December 31, 2001, we recruited 812 patients with THA from 1 center, of whom 80 met our inclusion criteria. Inclusion criteria were (1) age under 75 years, (2) first time unilateral total hip replacement for osteoarthritis or hip fracture, (3) willingness to participate in a 2-week rehabilitation program at Klinik Berlin, (4) fully loadable cemented or cement-free prosthesis, (5) ability to walk reciprocally with 2 forearm aluminum crutches with adjustable forearm piece, (6) gait symmetry of less than .85, (7) no further orthopedic or neurologic disease impairing gait, and (8) no history of deep vein thrombosis (DVT) or symptomatic heart disease in the previous 6 months.

All participants gave written consent to participate in this study, which was approved by the local ethics committee.

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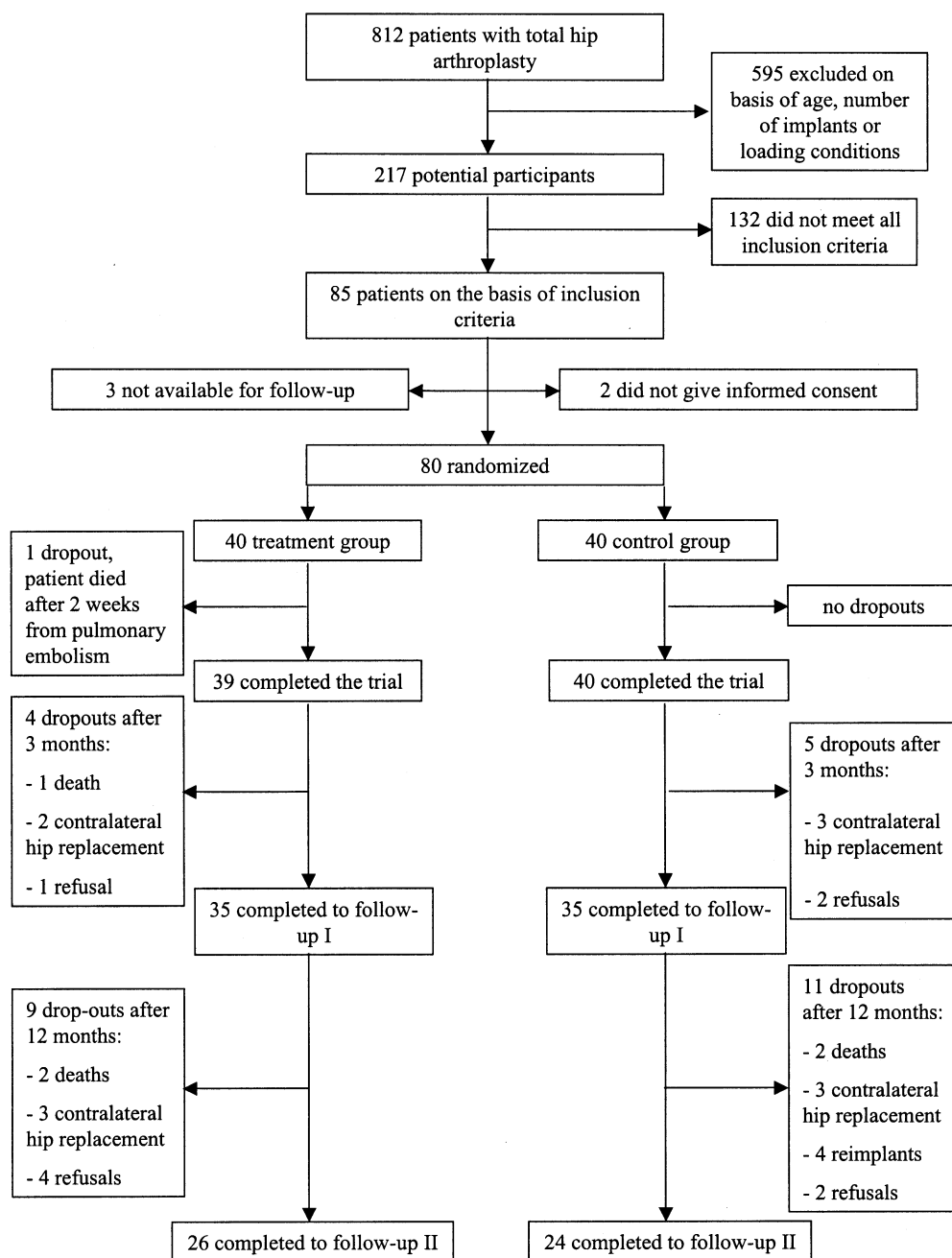


Fig 1. Trial profile.

Assignment

Patients were randomized to either the treatment group or control group by an independent person who chose 1 of (initially) 80 sealed envelopes 30 minutes before the start of the intervention, allocating 40 to each group. The sample size was calculated to corroborate a minimum important difference of 10 points in the Harris score with α set at .05 and β at 0.2.

Treatment

All patients received 45 minutes of individualized therapy time on each of 10 consecutive working days. Patients in the treatment group received treadmill^a training for 25 minutes and

other individualized physical therapy (PT) for 20 minutes on days 1 to 5 and 35 minutes of treadmill training and 10 minutes of PT on days 6 to 10. Patients in the control group received 45 minutes of individualized PT every day.

The content of the individualized PT differed between groups: for patients in the treatment group, it only included passive hip and knee joint mobilization in every session. For the controls, PT included passive hip and knee joint mobilization, strengthening of the hip abductor and extensor muscles according to the proprioceptive neurofacilitation concept,¹¹ and gait retraining on the floor and stairs in every session.

All patients also had daily individualized 30-minute sessions of occupational therapy and passive PT (eg, massage, heat,

Table 1: Clinical Data for Both Groups at Study Onset

	Treatment Group (treadmill therapy)	Control Group (conventional therapy)
Subjects (n)	39	40
Sex (n)		
Women	27	28
Men	12	12
Age (y)	64.7±13.1	65.5±9.9
Weight (kg)	70.9±14.4	72.7±12.1
Height (cm)	166.4±8.9	166.6±8.6
Type of arthroplasty (n)		
Uncemented	32	30
Cemented	5	8
Hybrid	2	2
Affected side (n)		
Left	11	20
Right	28	20
Diagnosis (n)		
Arthrosis	37	37
Fracture	2	3
Operation interval (wk)	3.00±.13	2.98±.12
Estimated no. of steps practiced per session	1000-1500	100-150

NOTE. Values are mean ± SD unless indicated otherwise.

ultrasound), and 25-minute sessions of group therapy in the swimming pool for 10 days. After discharge from the clinic, patients in both groups continued to have regular individualized PT. Also they were instructed to exercise at home, which included strengthening and stretching of the pelvic girdle muscles.

For daily mobility during the study, all patients were instructed to walk with 2 crutches placed reciprocally. Between discharge and follow-up at 3 months, there was no significant difference found in the number of individual 30-minute PT sessions per week for the treatment group (1.9±.17) or controls (2.2±.19).

Assessment

The primary outcome measure was the Harris score.¹² Secondary outcome measures were the hip extension deficit (part of the Harris score), gait velocity, gait symmetry, hip abductor

muscle strength, and hip abductor mean electromyographic activation. These were measured before and at the end of training and 3 and 12 months later. Patients were also asked at 3 months whether they had abandoned using crutches in everyday life.

The Harris score (range, 0-100) has 6 weighted categories: (1) pain; (2) limping without assisting devices; (3) use of any technical aids for daily mobility; (4) maximum walking distance; (5) competence in daily activities such as stair climbing, use of public transport, seating comfort, and dressing; and (6) passive hip range of motion (ROM) including contractures and leg-length differences. The maximum and optimum score is 100. Within categories, the maximum scores are 44 (pain), 11 (limping), 11 (use of assisting devices), 11 (maximum gait distance), 14 (daily activities), 5 (hip joint ROM), and 4 (contractures and leg-length difference). The pain category is thus the most weighted score.

The muscle strength of the medial gluteus muscle of the affected side was assessed with the Medical Research Council (MRC) Scale grade¹³ while the subject was lying on the non-affected side. Grade 0 means no movement and grade 5 means normal power.

Two experienced raters, both members of the neurologic unit of the department, independently took each patient's Harris score, including hip joint ROM and muscle strength. Working in a separate unit, they were not involved in patient treatment and thus were not aware of the randomization; additionally, patients were instructed not to report their group assignment. Gait analysis helped to assess walking velocity, swing symmetry, and the mean functional activity of the affected gluteus medius muscle. During all measurements, patients walked unaided, that is, without their crutches. Assistive devices result in a well-balanced gait and thus may disturb the activation pattern of the gluteus medius muscle.¹⁴⁻¹⁶

Walking velocity was calculated over the last 10m of a 14-m distance on the ground at self-selected speed. The test was repeated to obtain a mean value of 2 trials at each measurement point and expressed as meters per second.

For the assessment of swing symmetry, the limb-dependent cycle parameters (stance, swing, double support durations) were recorded with the help of the Ultraflex System.^b It consisted of overshoe-slippers with 8 insole force sensors, from which data were collected at 100Hz, amplified, and memorized by a portable data logger worn by the patient.¹⁷

Table 2: Means, Medians, and SDs of All Dependent Variables for Both Groups at Study Onset and Study End

Group	Study Onset		Study End	
	Treadmill	Control	Treadmill	Control
Harris score (0-100)	43.4/42.0/16.2 (16-70)	43.3/44.0/17.6 (13-72)	74.4/77.0/13.2 (40-93)	60.8/61.0/14.1 (21-86)*
Extension deficit (deg)	15.6/15.0/5.5 (0-25)	16.1/20.0/7.59 (0-30)	4.62/0.00/3.80 (0-20)	11.5/10.0/7.25 (0-20)*
Gait velocity (m/s)	0.66/0.63/0.25 (0.17-1.18)	0.62/0.63/0.21 (0.14-1.03)	1.01/1.01/0.27 (0.40-1.91)	0.91/0.95/0.26 (0.25-1.43)
Swing symmetry (%)	0.72/0.74/0.18 (0.33-0.98)	0.72/0.73/0.15 (0.35-0.97)	0.89/0.91/0.09 (0.66-1.00)	0.81/0.87/0.16 (0.36-0.97)*
MRC gluteus medius muscle (0-5)	2.92/3.00/0.79 (1-4)	2.82/3.00/0.72 (2-5)	4.24/4.00/0.69 (3-5)	3.73/4.00/0.67 (2-5)*
Mean muscle activity gluteus medius muscle (μV)	14.2/10.6/6.74 (8.1-28.7)	15.8/15.0/7.85 (8.5 to -27.9)	24.8/26.7/8.55 (9.7-42.8)	14.5/14.2/8.00 (8.6-26.5)*

NOTE. Values are mean/median/SD (range).

*Significant difference between groups, $P < .05$ (Harris score), rest, $P < .01$ (secondary outcome measures).

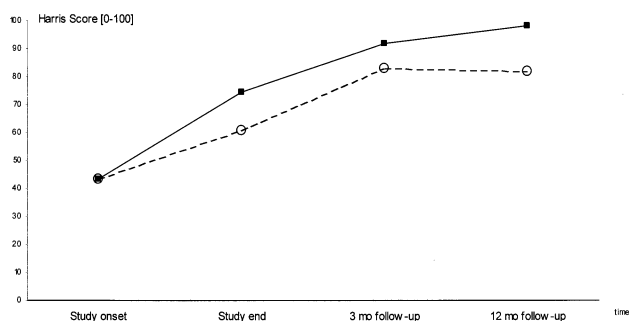


Fig 2. Mean \pm SD recovery patterns of the Harris score. The treatment group (■) scored significantly better ($P < .0001$) than the control group (○) at the end of training and at follow-up 3 and 12 months later.

Gait symmetry was expressed as swing duration of the left side divided by that of the right side, if the duration of the left side was shorter or vice versa. Swing duration corresponds to the single-stance phase of the contralateral limb. This measure of gait symmetry is 1 in normal subjects and decreases when patients are reluctant or unable to bear full weight on 1 leg.

In addition, electromyographic activity of the affected gluteus medius muscle was detected by self-adhesive surface electrodes (diameter, 8mm) following a standardized protocol: the electrodes were attached 2cm apart on the muscle belly (located 2.5cm below the superior iliac crest on a line between this point and the greater trochanter) after conventional skin preparation (shaving, cleansing, and abrasion of keratinized epidermis). The impedance was checked and kept below 5k Ω . Signals (sampling rate, 1000Hz) were preamplified with standard Infotronic preamplifiers^b attached to the limb and memorized by the portable data logger (described earlier). Repeated electromyographic measures at maximal voluntary contraction at start and end of data collection of each patient showed a stable force–electromyographic relationship over time in order to exclude potential electrode displacement and major impedance changes during 1 assessment session.

All gathered signals (ie, foot contacts, electromyographic measurements) were transmitted after the end of each trial to a personal computer and further processed by Infotronic software.^b Cycle parameters were averaged over at least 15 strides.

The electromyographic data were digitally filtered (band-pass, 10–300Hz), rectified, averaged over at least 10 strides, and time normalized to the mean cycle duration set to 100%. To quantify the physiologic, functional activity of the gluteus

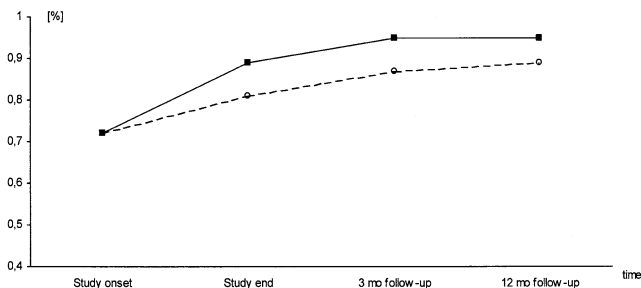


Fig 3. Mean \pm SD recovery patterns of swing symmetry. The treatment group (■) significantly scored better ($P < .001$) than the control group (○) at the end of training and at follow-up 3 and 12 months later.

medius muscles, mean values of the non-low-passed signals were calculated in a time interval from late swing (onset at 90%) to midstance (end at 40%) of the cycle duration, set to 100%.

Statistical Analysis

Distribution of the variables is given as mean, standard deviation (SD), median, and range. Analysis of variance with repeated measurements was used to determine differences in the primary and secondary outcome variables for each group across time and also between groups at the end of the training period and at follow-up after 3 and 12 months. For the primary outcome measure, α was set at .05; for the 5 secondary variables, a Bonferroni adjustment was considered with an α level of .01. An intention-to-treat analysis of the Harris score was based on the last available Harris score of each individual. Further, the clinical data of the dropouts of both groups were compared. Another intention-to-treat analysis excluded those 4 patients from the control group who had experienced a hip implant loosening during follow-up.

RESULTS

Starting with 40 participants per group, 39 in the treatment group completed the trial and 35 made it to the first follow-up at 3 months. In the control group, 40 completed the trial, 35 made it to follow-up. With further dropouts, 26 patients in the treatment group and 24 in the control group completed the 12-month study (fig 1). The clinical data and the outcome measures did not differ significantly at the beginning of the study for the dropouts from either groups (14 in the treatment group, 16 in the control group).

During treadmill training, patients were supported by a modified parachute harness suspended by a set of pulleys. The harness allowed free movement of the lower limbs and arms and provided a preset degree of body weight support. Patients did not use crutches or take weight through their arms while walking on the treadmill. Body weight support was set at 15% of body weight in all sessions, because this is the usual amount of weight transmitted through crutches when used in reciprocal gait.¹⁸ Initial treadmill speed was set according to the patients' preferred ground walking speed (0.5–1.0m/s), and was increased in all but 3 patients by 25% after day 5. Correspondingly, patients took 1000 to 1500 steps per session on the treadmill compared with 100 to 150 steps per session in the control group following therapists' estimations.

Before treatment, there were no significant differences between the groups in selected patient characteristics or outcome measures (table 1). The interrater reliabilities of the Harris

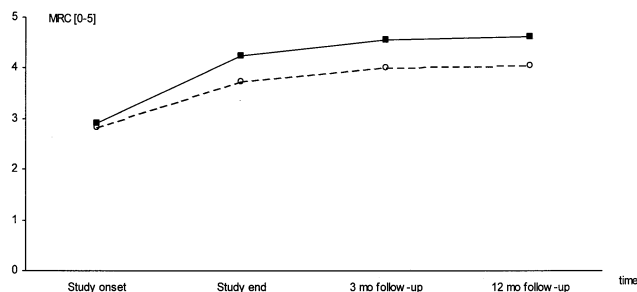


Fig 4. Mean \pm SD muscle power (MRC Scale grades, 0–5) of the affected gluteus medius muscle. The treatment group (■) scored better ($P < .0001$) than the control group (○) at the end of training and at follow-up 3 and 12 months later.

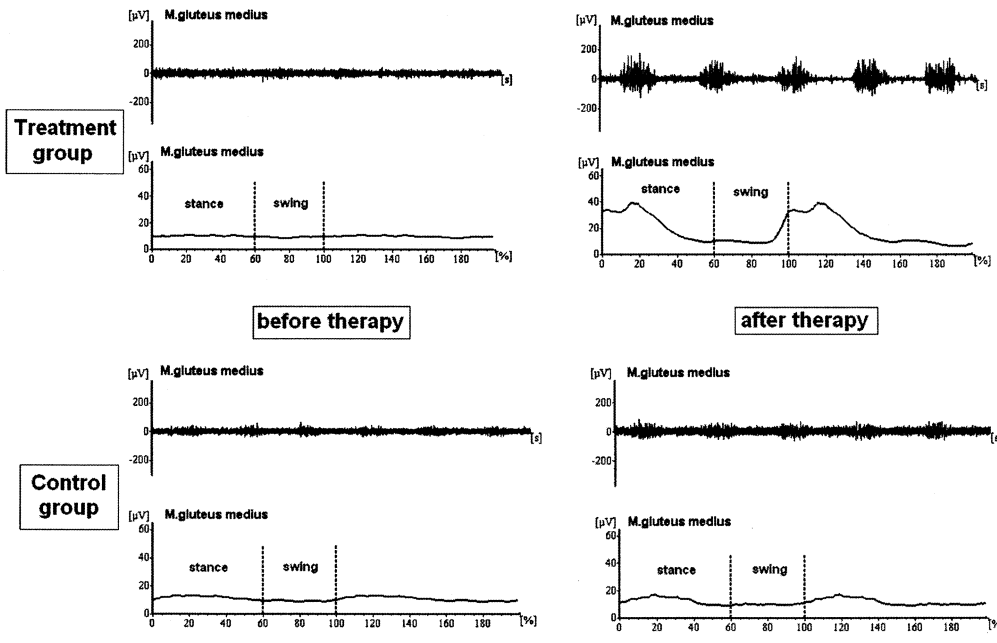


Fig 5. Raw and normalized electromyograms of the gluteus medius muscle of the affected side before and after therapy of a patient of the treatment group and of the control group.

score and of the MRC Scale grade were .91 and .93, respectively.

Both groups improved significantly between the beginning and end of the training in all outcome measures, except for the mean functional activity of the gluteus medius in the control group, which remained stable (table 2).

Comparisons between groups showed that the Harris score was significantly better in the treatment group than in the control group at the end of training; the treatment group's Harris score was 13.6 points higher ($P < .0001$). This difference in favor of the treatment group persisted at follow-up; it was the 8.9 points higher ($P < .0001$) at 3 months and 16.5 points higher ($P < .0001$) at 12 months (fig 2, table 2).

The intention-to-treat analysis also revealed significantly better Harris scores in the treatment group ($P < .0001$ at the end of training, $P < .001$ after 3mo, $P > .0001$ after 12mo). The same significant result in favor of the treatment group ($P < .001$ at study end) was obtained when excluding patients with loose hip implants in the control group.

Within the Harris score, the pain and maximum walking distance categories revealed the largest differences in favor of the treadmill group. Among the treatment group, 14 patients could walk an unlimited distance, 23 patients 1 to 2km, and 2 patients less than 1000m at the end of the intervention. The corresponding numbers in the control group were: 3 patients could walk an unlimited distance, 7 patients 1 to 2km, 23 patients less than 1000m, and 6 patients could walk less than 500m. The absolute pain category differences in favor of the treatment group were 5 points at the end of training, 6 points after 3 months, and 9 points after 12 months.

Among the secondary outcome measures, hip extension deficit was 6.8° less ($P < .0001$), gait symmetry was 10% greater ($P = .001$; fig 3), affected hip abductor was stronger (MRC Scale grades 4.24 vs 3.73; $P < .0001$), and the amplitude of gluteus medius activity was 41.5% greater ($P = .001$; figs 4, 5) in the treatment group at the end of training. These significant differences in favor of the treatment group persisted (muscle strength, gait symmetry) or even increased (hip extension def-

Table 3: Means, Medians, and SDs of All Dependent Variables for Both Groups at 3- and 12-Month Follow-Up

Group	3 Months Later		12 Months Later	
	Treadmill	Control	Treadmill	Control
Harris score (0–100)	91.7/96.0/12.8 (51–100)	82.8/85.0/13.2 (52–99)*	98.3/99.0/1.40 (89–100)	81.8/82.0/15.9 (52–100)*
Extension deficit (deg)	2.75/0.00/3.67 (0–20)	9.66/10.0/7.19 (0–20)*	1.25/0.00/2.31 (0–15)	8.75/10.0/4.43 (0–20)*
Gait velocity (m/s)	1.14/1.18/0.20 (0.63–1.43)	1.07/1.11/0.26 (0.63–1.54)	1.21/1.22/0.18 (1.00–1.54)	1.08/1.06/0.30 (0.94–1.54)
Swing symmetry (%)	0.95/0.97/0.05 (0.80–1.00)	0.87/0.92/0.08 (0.73–1.00)	0.95/0.97/0.06 (0.84–1.00)	0.89/0.90/0.05 (0.81–1.00)
MRC gluteus medius muscle (0–5)	4.55/5.00/0.71 (3–5)	4.00/4.00/0.85 (2–5)*	4.63/5.00/0.52 (4–5)	4.06/4.00/0.56 (2–5)*
Mean muscle activity gluteus medius muscle (µV)	33.9/38.8/9.97 (15.8–52.6)	16.6/16.2/9.76 (8.6 to –27.2)*	38.5/39.8/8.53 (18.0–56.6)	17.5/17.3/8.89 (8.6–27.9)*

NOTE. Values are mean/median/SD (range).

*Significant difference between groups, $P < .05$ (Harris Score), rest, $P < .01$ (secondary outcome measures).

icit, mean functional activity of the affected gluteus medius) at the 3- and 12-month follow-up (tables 2, 3). Walking velocity did not differ at any of the measurement points.

All patients reported at the 3-month follow-up that they had abandoned crutches, but the mean interval was shorter in the treatment group ($3.2 \pm .42$ wk) than in the control group ($7.9 \pm .51$ wk).

DISCUSSION

The treatment group was superior to the control group in every parameter measured, except walking velocity at the end of training and 3 and 12 months later. The patients in the treatment group abandoned their crutches earlier, and none had additional surgery on the same side. In the control group, 4 patients received a reimplant due to loosening within 1 year.

Both groups were homogeneous with respect to the clinical characteristics and the outcome measures before training, the net therapy time during the treatment period was comparable, and the amount of PT after discharge did not differ markedly. The results of the control group are in keeping with a large German outcome study⁴ on 177 hip arthroplasty patients with a fully loadable implant after a 12-day conventional rehabilitation program. Further, walking velocity did not differ between the 2 groups, thus the known influence of speed on the gait of hip arthroplasty patients could not explain the observed effects.¹⁹ This supports our conclusion that treadmill training is more effective than conventional training, just as Baker et al⁹ also found in less ambulatory, older, subjects after fractured neck-of-femur.

What are the most possible explanations? First, treadmill training offers a task-specific repetitive approach that enables the practice of numerous complex gait cycles. Treatment patients took many more steps on the treadmill than did control group subjects. Daily therapy sessions of walking outside may have mitigated this difference, but patients in the treatment group had a tendency to walk more in their spare time. Obviously, the larger pain reduction (see pain category of the Harris score) may have resulted in more comfort and confidence in their walking abilities. The walking distance part of the Harris score further confirmed this notion.

Second, hip extension in the late stance phase, indirectly sensed by the length of the hip muscles with the help of muscle spindles,²⁰ is a relevant peripheral drive for the spinal stepping generators according to animal experiments. The hip extension deficit in the treatment group was significantly less, which may have contributed to the beneficial effect of the locomotor therapy.

Third, several studies²¹⁻²³ reported on the significance of a well-functioning and strong gluteus medius muscle for walking ability, gait symmetry, and the prevention of implant loosening. The isometric strength and the mean functional activity of the gluteus medius while walking were larger in the treatment group.

Loosening of the prosthesis was only seen in the control group, whose subjects only received conventional therapy. It is possible that the greater muscle strength in the treatment group helped to prevent this complication, but an alternative interpretation is that the type of training was irrelevant, and the distribution of loose prostheses was caused by chance. However, having a loose prosthesis may have impaired the rehabilitation of those patients in the control group, which would tend to exaggerate the beneficial effects of treadmill training.

The patient who died of pulmonary embolism (in the treatment group) had had DVT 1 year before study onset. It is possible that the firm pressure of the harness around her thighs may have contributed to venous stasis and recurrent thrombosis

or that the more vigorous exercise dislodged a preexisting thrombus. Our standard practice now is to continue prophylaxis with subcutaneous low-molecular-weight heparin until the end of treadmill training in all patients.

The rather high dropout rate in the second follow-up period and the fact that the study was carried out in 1 center are limitations of the study. Also the practice common in Germany of walking with 2 crutches placed reciprocally and the standardized body-weight support on the treadmill may not totally reflect the everyday clinical situation. Retraining of more severely affected patients, who are unable to walk independently, should be addressed in future studies.

CONCLUSION

A 10-day TT-BWS program proved superior in hip arthroplasty patients with a fully loadable implant as measured by the Harris score, hip extension deficit, walking symmetry, and hip abductor muscle strength. The repetitive practice of walking in conjunction with a more effective strengthening of the hip abductor may be the factors that explain the better outcome of the treadmill subjects.

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Suppliers

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