MS # 7888 RV

**Treadmill training with partial body weight support after total hip arthroplasty: a randomized controlled trial**

Stefan Hesse[1], MD, Cordula Werner[2], MA, Helma Seibel[2], PT, Sophie von Frankenberg[1], PT, Eva-Maria Kappel[2], MD, Stephen Kirker[3], MD, Martin Käding[2], MD

[1]Klinik Berlin, Department of Neurological Rehabilitation, Free University Berlin,

[2]Klinik Berlin, Department of Orthopedic Rehabilitation,

[3]NHS-Hospital Cambridge, Department of Rehabilitation Medicine

Corresponding Author: Stefan Hesse, MD; Klinik Berlin, Kladower Damm 223, D-14089 Berlin, Germany, Tel.: ++49/30/36503105; Fax: ++49/30/36503-123; E-Mail: bhesse@zedat.fu-berlin.de

Reprints: same address

The study was supported by a grant (8011-106-31/31.46) from the Bundesversicherungsanstalt für Angestellte, BfA.

**Short running head**: Treadmill therapy after hip arthroplasty

**Summary**

**Objective:** to compare treadmill training with partial body weight support (TT-BWS) and conventional physiotherapy (CPT) in ambulatory hip arthroplasty patients

**Design**: Randomized controlled trial

**Setting:** Rehabilitation center

**Patients:** 80 patients with a fully loadable implant who could walk independently with crutches after unilateral total hip arthroplasty were randomized to receive either TT-BWS or CPT, for 10 working days.

**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, its amplitude of EMG activation, and the interval from surgery to abandoning crutches was also identified.

**Results:** At the end of training, the experimental group's Harris score was 13.6 points higher ($p<0.0001$). Further, hip extension deficit was 6.8° less ($p<0.0001$), gait symmetry was 10% greater ($p=0.001$), affected hip abductor was stronger (4.2 vs. 3.7 MRC grades, $p<0.0001$), and the amplitude of gluteus medius activity was 57.1% greater ($p=.001$). Gait velocity did not differ in the two groups. These significant differences in favor of the experimental group persisted at 3 and 12 months. The experimental group abandoned their crutches sooner than the control group (3 vs. 8 weeks). In group A, 39 patients finished treatment, 35 appeared at three and 26 at 12 months for follow-up. In group the corresponding numbers were 40, 35 and 24 patients.

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

## INTRODUCTION

Each year, approximately 800,000 patients in the United States and 420,000 in the European Community receive a total hip replacement.[1,2]. Post-operative rehabilitation programs focus on hip joint mobilization, strengthening of surrounding muscles and gait retraining, initially with a walking aid. Uncontrolled studies have reported improvements following conventional rehabilitation programs. [3,4,5]

Treadmill training with partial body weight support has already been shown to be effective in neurological rehabilitation.[6,7,8,9]

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. As their body weight is supported in a controlled manner, they are able to take many more steps than is normally possible when floor walking.

Treadmill training with body weight support and conventional gait training has been compared following fractured neck-of-femur.[10] 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.

A preceding biomechanical study of ambulatory total hip arthroplasty patients with a fully loadable implant compared their walking on the treadmill with 15% body weight support (BWS) and walking on the ground with two 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.[11]

The present randomized controlled study intended to investigate the potential of treadmill training with partial body weight support in patients following total hip replacement. The hypothesis was that treadmill training with partial body weight support was more effective than conventional floor gait training in improving functional walking in total hip arthroplasty patients with a fully loadable implant.

## METHODS

### Patients

Between Sept 1, 1999 and December 31, 2001, we recruited 80 patients with a total hip arthroplasty from one center. All participants gave written consent to participate in this study, which was approved by the local ethics committee.

Inclusion criteria were:

- age under 75 years
- first time unilateral total hip replacement for osteo-arthrosis or hip fracture
- participation in a two week-rehabilitation program at Klinik Berlin
- fully loadable cemented or cement-free prosthesis
- able to walk reciprocally with two forearm aluminum crutches with adjustable forearm piece

- gait symmetry of less than 0.85, 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
- no further orthopedic or neurological disease impairing gait
- no history of deep vein thrombosis or symptomatic heart disease in the previous six months

**Assignment**

Patients were randomized to the treatment group (A) or control group (B) by an independent person who chose one of (initially) 80 sealed envelopes 30 min before begin of the intervention, allocating 40 to each group. The sample size was calculated to corroborate a minimum important difference of 10 points of the Harris score with alpha set at 0.05 and beta at 0.2.

**Treatment**

All patients received 45 minutes of individual therapy time on each of 10 consecutive working days. Patients of group A received treadmill[A] training for 25 minutes and other individual physiotherapy for 20 minutes on day 1-5 and 35 minutes of treadmill training and 10 min of physiotherapy on days 6-10. Patients of group B received 45 min of individual physiotherapy.

The content of the individual physiotherapy was different in both groups: for patients of group A, it only included passive hip and knee joint mobilization in every session. In group B, it included passive hip and knee joint mobilization, strengthening of the hip abductor and extensor muscles according to the proprioceptive neurofacilitation concept[12] and gait retraining on the floor and stairs in every session.

All patients also had daily individual 30-minute sessions of occupational and passive physical therapy (e.g. massage, heat, ultrasound) and group therapy in the swimming pool for 25 minutes for 10 days. After discharge from the clinic, patients in both groups continued to have regular individual physiotherapy. Also they were instructed in exercises to do at home including strengthening and stretching of the pelvic girdle muscles.

For daily mobility during the study, all patients were instructed to walk with two crutches placed reciprocally.

Between discharge and follow-up at three months, there was no significant difference in the number of individual 30 minute physiotherapy sessions per week in patients of group A (1.9±0.17) and group B (2.2±0.19).

**Assessment**

The primary outcome measure was the Harris score.[13] Secondary outcome measures were the hip extension deficit as a part of the Harris Score, gait velocity, gait symmetry, hip abductor muscle strength and its mean EMG activation. These were measured before and at the end of training and 3 and 12 months later. Patients were also asked at 3 months when they had abandoned crutches in everyday life.

The Harris score (0-100) has six weighted categories: pain, limping without assisting devices, the use of any technical aids in daily mobility, maximum walking distance, competence in daily activities such as stair climbing, use of public transport, seating comfort, and dressing, and passive hip range of motion 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 range of motion), 4 (contractures respectively leg length difference). The pain category is thus the most weighted one within the Harris Score.

The muscle strength of the medial gluteus muscle of the affected side was assessed with the help of the Medical Research Council (MRC) score[14] while lying on the non-affected side. Grade 0 means no movement and grade 5 normal power.

Two experienced raters, both members of the neurological unit of the department, independently assessed the Harris score including the hip joint hip range of motions and the muscle strength of each patient. Working in a separate unit, they were not involved in the treatment of the patients and thus not aware of their treatment group; also 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, i.e. without their crutches. Assisting devices themselves result in a well-balanced gait and may disturb the activation pattern of the gluteus medius muscle.[15,16,17]

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

For the assessment of swing symmetry, the limb-dependent cycle parameters (stance, swing, and double support durations) were recorded with the help of the Ultraflex System[B]. It consisted of overshoe-slippers with eight insole force sensors, from which data were collected at 100Hz, amplified and memorized by a portable data logger worn by the patient.[18]

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 take their full weight on one leg.

In addition, electromyographic activity of the affected gluteus medius muscle was detected by self-adhesive surface electrodes (8 mm diameter) following a standardized protocol:

the electrodes were attached 2 cm apart on the muscle belly (located 2.5 cm below the superior iliac crest on a line between this point and the greater trochanter) after conventional skin preparation (shaving, cleansing and abrasion of keratinised epidermis). The impedance was checked and kept below 5 kOhm. Signals (1000 Hz sampling rate) were preamplified with standard Infotronic preamplifiers attached to the limb and memorized by the portable data logger (see above). Repeated EMG measures at maximal voluntary contraction at start and end of data collection of each patient showed stable force/EMG relationship over time in order to exclude  potential electrode displacement and major impedance changes during one assessment session..

All gathered signals (i.e. foot contacts, and EMG measurements) were transmitted after the end of the measurement to a personal computer and further processed by Infotronic software. Cycle parameters were averaged over at least 15 strides.

The EMG data were digitally filtered (band-pass, 10 to 300 Hz), rectified, averaged over at least 10 strides, and time-normalized to the mean cycle duration set to 100%. To quantify the physiological, functional activity of the gluteus medius muscles, mean values of the non-low passed signals were calculated in a time interval from late swing (onset at 90%) to mid-stance (end at 40%) of the cycle duration, set to 100%.

**Statistical Analysis**

Distribution of the variables is given as mean, standard deviation (SD), medians and ranges. ANOVA 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 three and twelve months. For the primary outcome measure alpha was set at 0.05, for the five secondary variables a Bonferroni correction was considered with an alpha level of 0.01. 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 four patients of group B who had experienced a hip implant loosening during follow-up.

## RESULTS

In group A, one patient died from pulmonary embolism before completing her rehabilitation program. In group B, all patients completed the treatment. At the 3-month follow up, 4 patients of group A did not attend (1 death, 2 contra-lateral hip replacements, 1 refusal). In group B, 5 patients did not attend (3 contra-lateral hip replacement, 2 refusals). At the 12-month follow up, 9 other patients of group A did not attend (2 deaths, 3 contra-lateral hip replacements, 4 refusals). In group B, 11 patients did not attend (2 deaths, 3 contra-lateral hip replacements, 4 re-implant of the hip due to implant loosening, 2 refusals). Hence, 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 at study begin of the dropouts of both groups (14 in the experimental and 16 in the control group) did not differ significantly.

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 pre-set degree of body weight support (BWS). Patients did not use crutches or take weight through their arms while walking on the treadmill. BWS was set at 15% of body weight in all sessions, as this is the usual amount of weight transmitted through crutches when used in reciprocal gait. [19] 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 2000-2500 steps / session on the treadmill as compared to 100 to 150 steps / session in the control group following therapists' estimations.

Before treatment, there were no significant differences between the experimental and control group in selected patient characteristics or outcome measures (table 1). The inter-rater reliabilities of the Harris and of the MRC score were 0.91 and 0.93.

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 group B, which was stable (table 2).

Comparisons between groups showed that the Harris score was significantly better in the experimental than in the control group at the end of training, the experimental group's Harris score was 13.6 points higher ($p<0.0001$). This difference in favor of the experimental group persisted at follow-up; it was the 8.9 points higher ($p<0.0001$) at three and even 16.5 points higher ($p<0.0001$) at 12 months (fig 2).

The intention-to-treat analysis also revealed significantly better Harris scores in the experimental group, the corresponding p-values were $p<0.0001$ at the end of training, $p<0.001$ after three and $p<0.0001$ after one year. The same significant result in favor of group A, $p< 0.001$ at study end, was obtained when excluding the hip implant loosening patients from group B.

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

Among the secondary outcome measures, hip extension deficit was 6.8° less ($p<0.0001$), gait symmetry was 10% greater ($p=.001$, fig 3), affected hip abductor was stronger (4.2 vs. 3.7

MRC grades, $p<0.0001$) and the amplitude of gluteus medius activity was 57.1% greater ($p=.001$, fig 4,5) in the experimental group at the end of training. These significant differences in favor of the experimental group persisted (muscle strength, gait symmetry) or even increased (hip extension deficit, and mean functional activity of the affected gluteus medius) at the 3- and 12-month follow-up (table 2 and 3). Walking velocity did not differ at any of the measurement points.

All patients reported at the 3-month follow-up that that they had abandoned crutches, but the mean interval was shorter in the experimental group (3.2 +/- .42 weeks) than the control group (7.9 +/- .51 weeks).

Patients took 2000-2500 steps/session on the treadmill, but seldom exceeded 100 steps / session in the control group.

## DISCUSSION

The treadmill 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 of the experimental group abandoned their crutches earlier, and none of the patients was re-operated on the same side. In the control group, four patients received a re-implant due to loosening within one 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 physiotherapy after discharge did not differ markedly. The results of the control group are in keeping with a large German outcome study on 177 hip arthroplasty patients with a fully loadable implant following a 12 day conventional rehabilitation program.[5] Further, the walking velocity did not differ between the two groups, so that the known influence of speed on the gait of hip arthroplasty patients could not explain the observed effects.[20] This supports our conclusion that treadmill training is more effective than conventional training, as Baker et al found in less ambulant, older, subjects following fractured neck-of-femur. [10]

What are the most possible explanations?

Firstly, treadmill training offers a task-specific repetitive approach enabling the practice of numerous complex gait cycles. Patients took vastly more steps on the treadmill than in the control group. Daily walking outside therapy sessions may have mitigated this difference but patients of the experimental group tended 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.

Secondly, hip extension in the late stance phase, indirectly sensed by the length of the hip muscles with the help of muscle spindles[21], is a relevant peripheral drive for the spinal stepping generators according to animal experiments. The hip extension deficit in the treadmill group was significantly less, which may have contributed to the beneficial effect of the locomotor therapy.

Thirdly, several studies reported on the significance of a well functioning and strong gluteus medius muscle for walking ability, gait symmetry and the prevention of implant loosenin.[22,23,24] The isometric strength and the mean functional activity of the gluteus medius while walking were larger in the treadmill group.

Loosening of the prosthesis was only seen in the conventional therapy group. It is possible that the greater muscle strength in the treadmill 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 due to chance. However, having a loose prosthesis may have impaired the rehabilitation of those patients in the conventional therapy group, which would tend to exaggerate the beneficial effects of treadmill training.

The patient who died of pulmonary embolism had had a deep vein thrombosis one 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 pre-existing thrombus. Our standard practice now is to continue prophylaxis with sub-cutaneous low molecular weight heparin until the end of treadmill training in all patients.

The rather high drop out rate in the second follow-up period and the fact that the study was carried out in one center limit the study. Also the practice common in Germany of walking with two 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

In conclusion, a 10-day treadmill training program with partial body weight support proved superior in hip arthroplasty patients with a fully loadable implant with respect to the Harris score, the hip extension deficit, the walking symmetry, and the 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.

**Acknowledgement:** The authors are obliged to the Bundesversicherungsanstalt für Angestellte, BfA, for their generous support of the study. Also thank we Mrs. Manuela Schiesser and Mrs. Stefanie Grunert for their help with the patients.

## References


1. US Department of Health and Human Service, National Institute of Health, 1994: http://chid.nih.gov/detail/detail/html
2. Cochrane Library, 1998: http://www.cochrane.de/deutsch/ccart1.htm
3. Victor CR. Rehabilitation after hip replacement: a one-year follow-up. Int J Rehabil Res 1987; 10 (suppl 5):162-67.
4. Reikeras O, Bjerkreim I, Gundersson R. Total hip arthoplasty for arthrosed hips. J Arthroplasty 1995;10:529-31.
5. Ulreich A, Kullich W, Klein G, Ramach W. Results of inpatient rehabilitation after total hip replacement. Rehabilitation 1998;37:117-22.
6. Wernig A, Müller S. Laufband locomotion with body weight support in persons with severe spinal cord injuries. Paraplegia 1992;30:229-38.
7. Dietz V, Colombo G, Jensen L. Locomotor activity in spinal man. Lancet 1994;344:1260-63.
8. Hesse S, Bertelt C, Schaffrin M, Mauritz KH. Restoration of gait in non-ambulatory hemiparetic patients by treadmill training with partial body weight support. Arch Phys Med Rehabil 1994;75:1087-93.
9. Visintin M, Barbeau H, Korner-Bitensky N, Mayo NE. A new approach to retrain gait in stroke patients through body weight support and treadmill stimulation. Stroke 1998;29:1122-28.
10. Baker PA, Evans OM, Lee C. Treadmill gait retraining following fractured neck-of-femur. Arch Phys Med Rehabil 1991;72:649-52.

11. Hesse S, Sonntag D, Bardeleben A, Käding M, Roggenbuck C, Conradi E. Patients with total hip arthroplasty capable of full weight bearing walking on a treadmill with partial body weight support, with crutches and without aids. Z Orthop Ihre Grenzgeb 1999;137:265-72.

12. Voss DE, Ionta MK, Meyers BJ. Proprioceptive neuromuscular facilitation.3rd edition. Philadelphia, Harper and Row, 1985.

13. Harris WH. Traumatic arthritis of the hip after dislocation and acetabular fractures: treatment by Mold arthroplasty. An end result study using a new method of result evaluation. J Bone Jt Surg 1969;51_a:737-55.

14. Wade DT. Measurement in Neurological Rehabilitation. New York, Oxford University Press, 1992.

15. Neumann DA, Hase AD. An electromyographic analysis of the hip abductors during load carriage: implications for hip joint protection. J Orthop Sports Phys Ther 1994;19:296-304.

16. Neumann DA. An electromyographic study of the hip abductor muscles as subjects with a hip prothesis walked with different methods of using a cane and carrying a load. Phys Ther 1999;79:1163-76.

17. Sonntag D, Uhlenbrock D, Bardeleben A, Kaeding M, Hesse S. Gait with and without forearm crutches in patients with total hip arthroplasty. Int J Rehabil Res 2000;23:233-43.

18. Hermens HJ, de Waal CA, Buurke J, Zilvold G. A new gait analysis system for clinical use in a rehabilitation center. Orthopedics 1986;9:1669-75.

19. Bergmann GF, Graichen F, Rohlmann A. Hip joint forces during walking and running, measured in two patients. J Biomech 1993;26:969-90.

20. Crowinshield RD, Brand RD, Johnston RC. The effects of walking velocity and age on hip kinematics and kinetics. Clin Orthop Rel Res 1978;132:140-44.

21. Duysens J, Pearson KG. Inhibition of flexor burst generation by loading ankle extensor muscles in walking cats. Brain Res 1980;187:321-32.

22. Long WT, Dorr LD, Healy B, Perry J. Functional recovery of non-cemented total hip arthroplasty. Clin Orthop 1993;288:73-77.

23. Vaz MD, Kramer JF, Rorabeck CH, Bourne RB. Isometric hip abductor strength following total hip replacement and its relationship to functional assessments. J Orthop Sports Phys Ther 1993;18:526-31.

24. Bryan JM, Sumner DR, Hurwitz DE, Tompkins GS, Andriacchi TP, Galante JO. Altered load history affects periostetic bone loss following cementless total hip arthroplasty. J Orthop Res 1996;14:762-68.

**Suppliers:**

A Reha-K1, Woodway GmbH, Health Division, Steinackerstr. 20, 79576 Weill am Rhein, Germany

B Infotronic, AB Tubbergen, Netherlands

**Legends to the figures**

Fig. 1: Trial profile

Fig. 2: Mean (SD) recovery patterns of the Harris Score. The experimental group significantly scored better ($p<.0001$) at the end of training and at follow-up 3 and 12 months later.

Fig. 3 Mean (SD) recovery patterns of swing symmetry. The experimental group significantly scored better ($p<.001$) at the end of training and at follow-up 3 and 12 months later.

Fig. 4: Mean (SD) muscle power (MRC, 0-5) of the affected gluteus medius muscle. The experimental group scored better ($p<0.0001$) at the end of training and at follow-up 3 and 12 months later.

Fig. 5: Raw and normalized electromyogram of the gluteus medius muscle of the affected side before and after therapy of a patient of the treatment group (above) and of the control group (below).