Changes in Gait Symmetry After Training on a Treadmill with Biofeedback in Chronic Stroke Patients: A 6-Month Follow-Up from a Randomized Controlled Trial

Background:
One of the most significant challenges for patients who survive a stroke is relearning basic motor tasks such as walking. The goal of this study was to evaluate whether training on a treadmill with visual biofeedback improves gait symmetry, as well as spatiotemporal and kinematic gait parameters, in stroke patients.

Material/Methods:
Thirty patients in the chronic phase after a stroke were randomly allocated into groups with a rehabilitation program of treadmill training with or without visual biofeedback. The training program lasted 10 days. Spatiotemporal and kinematic gait parameters were evaluated. For all parameters analyzed, a symmetrical index was calculated. Follow-up studies were performed 6 months after completion of the program.

Results:
The symmetrical index had significantly normalized in terms of the step length (*p*=0.006), stance phase time, and inter-limb ratio in the intervention group. After 6 months, the improvement in the symmetry of the step length had been maintained. In the control group, no statistically significant change was observed in any of the parameters tested. There was no significant difference between the intervention group and the control group on completion of the program or at 6 months following the completion of the program.

Conclusions:
Training on a treadmill has a significant effect on the improvement of spatiotemporal parameters and symmetry of gait in patients with chronic stroke. In the group with the treadmill training using visual biofeedback, no significantly greater improvement was observed.

MeSH Keywords:
Feedback, Sensory • Gait • Stroke

Full-text PDF: http://www.medscimonit.com/abstract/index/idArt/898420
One of the most significant challenges for patients who survive a stroke is relearning basic motor tasks such as walking. Although 60% of patients regain the ability to walk unaided following a stroke, their gait is often ineffective and difficult. The intensity of gait disturbances is dependent on the severity of stroke, the time from the onset of stroke, and age of the patient [1,2]. Paresis and motor control disturbances, abnormalities of muscle tone, and sensation also directly affect the patient’s gait. Hemiparetic gait is characterized by disturbances of symmetry, step length, decreased stance time in the paretic limb, and decreased range of motion in the hip and knee joints during the swing phase and balance disturbances. As a consequence, stroke patients’ gait speed and distance are typically significantly decreased in comparison to healthy people [3]; therefore, their ability to function independently and perform self-care activities is significantly restricted [4–6].

Once a stroke patient has regained the ability to walk unaided, one of the most important aims of rehabilitation is functional improvement to allow the patient greater independence in everyday life. Numerous studies have reported that the best improvement in regaining motor control, including gait, happens during the first 3 months following a stroke, but it has also been shown that improvement in functionality is possible during the latter period, 6 months after a stroke [7,8]. One of the methods of improving locomotion is treadmill training. In a systematic review, Mehrholz and Polese proved that gait training on a treadmill with or without body weight support has a significant effect on the improvement of distance and speed of independent walkers during the acute/subacute and chronic periods after a stroke [9,10]. Despite this improvement, to date there has been no report of treadmill training resulting in improvements in spatiotemporal gait symmetry [11,12].

Treadmill training for the improvement of gait is limited by the unnatural training environment and elimination of optic flow, which can disturb the process of movement planning, which is a significant function for the control of step speed and length. Implementation of additional visual information to the training environment has been reported to increase the control of movement and improve motivation [13]. Biofeedback methods have been used in neurorehabilitation for many years, and typically involve providing a participant with simple visual or acoustic information about the actual physiological function or the current course of physical activity [14]. During gait re-education, biomechanical and electromyographic biofeedback are most common. Mechanical biofeedback relies on measurement of physical parameters of gait, including range of motion, force produced, evaluation of body posture, and then on processing the collected data and presenting them in real time, in a visual or acoustic form, to the patients [15]. This external biofeedback provides the patients with information about kinematic, spatiotemporal, kinetic parameters, and electromyography [16].

Supplementing treadmill training with additional external auditory and visual information about proper gait pattern enables the patient not only to improve gait symmetry, but also to develop better balance, coordination, strength, and endurance of specific muscle groups [17,18]. Tate et al. performed a systematic review of the literature, showing that kinematic and spatiotemporal biofeedback had a significant effect on gait education in patients after a stroke when compared with conventional therapy, but noted that there are a small number of studies evaluating the late effects of biofeedback therapy [19].

Stanton et al. asked whether biofeedback methods used to regain the function of a lower extremity after a stroke are effective and give permanent results [20]. In a systematic review, they showed that there is evidence to support a higher efficacy of biofeedback methods in comparison to traditional methods, and for the most part these effects are maintained in the months that follow. The authors emphasized that the studies have a few limitations: the methods evaluating the effects of analyzed studies were not unequivocal, and the comparison of the biofeedback therapy results with a normal therapy did not fully indicate that the improvement was a consequence of biofeedback. In a separate study, Lewek described the effects of improving gait through the use of visual and proprioceptive feedback, based on the effects of rehabilitation of 2 patients during the late period after a stroke [21]. Results of 6 weeks of gait education resulted in increased speed of walking and decreased asymmetry of spatiotemporal parameters in stroke patients.

In a previous study, an evaluation of the effects of gait learning using a treadmill and visual biofeedback was made only once at the end of 2-week training [22]. The results have shown a greater change of the temporal-spatial gait parameters in the group with biofeedback but the difference was not statistically significant compared to the result of the control group (without biofeedback). In another study, observation was extended for 6 months while maintaining the 2-week training program on a treadmill. The gait analysis has been extended to evaluation of symmetry of the kinematic and temporal-spatial gait parameters.

The goals of the present study were to evaluate the effect of treadmill exercises with visual feedback on the spatiotemporal and kinematic gait parameters on gait symmetry in a randomized group of patients with hemiparesis after a stroke, as well as to investigate whether any observed effects were maintained 6 months later.
Material and Methods

This study was a single-blinded, randomized, controlled trial. The patients were randomly allocated to an intervention group (program with the treadmill training with visual biofeedback) or a control group (program with the treadmill training without visual biofeedback). A simple computer-generated randomization sequence was made and an automated assignment system was used to ensure allocation concealment. All patients had an equal probability of assignment to the groups.

Randomization was performed by team member who did not participate in the evaluation and treatment. After the study was completed, the allocation to the groups was unblinded after 6 months. A gait analysis was made by an expert who was not involved in the therapy program and who was blinded to allocation to groups.

The study was conducted in accordance to the ethical standards presented in the 1964 Declaration of Helsinki. All participants of this program were clearly informed about the goals and the course of this study and they signed a written consent form to participate. The study protocol was approved by the Ethics Committee of the Faculty of Medicine at the University of Rzeszów, Poland. The study was performed as part of the research project “The evaluation of biofeedback effects on restoring gait function in people with paresis after a stroke” accepted by the National Science Center, Poland (No. N N404 249639).

Participants

The study was performed with stroke patients who were hospitalized in 2013 in the Clinical Rehabilitation Unit of the Provincial Hospital No. 2 “St. Jadwiga the Queen” in Rzeszów, Poland. The inclusion criteria for this study were: 1) hemiparesis resulting from a single stroke, 2) time from the stroke longer than 6 months, 3) independent gait, 4) time of recovery according to Brunnström 3 to 4, and 5) muscle tone of the paretic lower extremity according to Ashworth modified scale ≤1. The exclusion criteria were: 1) severe heart insufficiency and uncontrolled arterial hypertension, 2) cognitive disorders impairing the understanding of and ability to follow instructions (Mini Mental Scale Examination score below 24), 3) visual field disturbances caused by a stroke or other visual disturbances impairing normal vision, and 4) orthopedic disorders significantly affecting the gait of participants. We did not qualify people who were simultaneously participating in other rehabilitative programs.

Protocol and intervention

Participants were randomly assigned, using a computer program, to either an intervention group (n=15) or a control group (n=15). Researchers who evaluated participants before, at the end of the program, and 6 months after completion of the program did not know the assignments to groups and did not administer the therapy during the program. Decoding of the groups was done after the study, after 6 months. The training program for each participant lasted 12 days. On the first day, a baseline examination was done, and for the 2 weeks that followed the subjects participated in 10 30-minute training sessions for 2 consecutive weeks (Monday to Friday). The final examination was performed on the day after program completion. The follow-up examination was performed 6 months after the end of the program. Every examination was performed on the same day, during the morning, in the same laboratory.

In this program, a Gait Trainer 2 treadmill (Biodex, model number 0808501) was used. It was equipped with a strength sensor and software for analyzing and editing data in real time. Participants from the intervention group exercised on a treadmill with the visual biofeedback function. Visualization of data on a screen in front of the treadmill presented the real positioning of left and right lower extremities on the ground (in graphic form), as well as the area in which feet should have been positioned based on the step length for both the right and left. During the first treadmill training session, the appropriate step length and walking speed were set for each participant in the intervention group. During consecutive treadmill training sessions, the step length and treadmill speed were increased but only in the range of task completion. Patients from the control group exercised on the same type of treadmill but without the biofeedback function. The walking speed in the control group was individually set for participants according to their comfort zone. All participants also received individualized physiotherapy exercises. The schedule of individual exercises for all participants was decided before the start of the program. One physiotherapist who knew the group assignments led the treadmill training; the physiotherapist did not run individual exercises and did not participate in the study. Total daily therapy time for each patient was 60 minutes.

Outcome measures

Primary outcome

Gait analysis was performed in the Biomechanics Laboratory at the University of Rzeszów, Department of Physiotherapy. The laboratory was equipped with 6 infrared cameras recording at 100 Hz (BTS Smart, BTS Bioengineering, Milan, Italy). The cameras were calibrated before each test day. The system is able to locate passive light reflective markers placed on the body, and measures kinematic and spatiotemporal parameters based on the first contact and the moment of foot detachment from the ground. The biomechanical program Tracker and Analyzer (BTS Bioengineering) was used for analysis. These infrared
Cameras were used in conjunction with video recording from 2 cameras that registered images in frontal and sagittal planes. Reference markers were placed according to the internal protocol of the system (Helen Hayes (Davis) Marker Placement) on the sacrum, pelvis (anterior posterior iliac spine), femur (lateral epicondyle, greater trochanter and in lower 1/3 of the shank), fibula (lateral malleolus, lateral condyle and in lower 1/3 of the shank), and foot (metatarsal head and heel) [23].

During the study, participants could use the crutches, canes, tripods, or orthoses that they use every day. The same equipment was used in the control study. In the laboratory, study participants walked, at any speed, between marked points 6 meters apart. For analysis, 6 attempts with completed data were registered and the result was an average of all attempts. The step length of the paretic and non-paretic extremities, stance time, swing time, and completed range of motion in hip and knee joints in each limb were evaluated.

**Secondary outcomes**

The symmetry index was calculated on the basis of analysis of the kinematic and temporal-spatial gait parameters for the right and left lower limb. A symmetry index was calculated for all analyzed parameters [24]. The left and right average values of swing time and stance time, step length, total hip and knee range of motion, and intra-limb ratio of swing: stance time (SW/ST) were each used in a ratio with the largest value in the numerator so that all values for every individual were >1.0. A ratio value of 1.0 denotes perfect symmetry.

**Statistical analysis**

All calculations and statistical analyses were performed using the STATISTICA ver. 10.0 (StatSoft, Poland). The value distribution for all parameters for the intervention group and the control group were presented as an average value, median, standard deviation, and 95% confidence interval. Using the Shapiro-Wilk test, the distribution of many of the parameters was found to deviate from the norm, likely due to the small sample sizes. The nonparametric Mann-Whitney test was therefore used to evaluate the significant differences between the groups. Significant difference between the distribution of measured parameters from the intervention group and the control group in consecutive studies was measured using the nonparametric Wilcoxon test. The significant difference between these 2 groups was assessed with the nonparametric precise version for small samples. The significance threshold level $p < 0.05$ was assumed.

**Results**

Based on the review of medical documentation of patients treated in 2013 in the Clinical Rehabilitation Unit of the Regional...
Hospital No. 2 in Rzeszów, Poland, the study enrolled 97 patients over more than 6 months after stroke, 67 respondents did not meet the inclusion criteria, and 15 refused to participate in the program. Randomization was performed on the 30 remaining eligible participants. In the control group, 5 respondents did not participate in the third study after 6 months: (we lost contact with 1 person, 3 refused to participate, and 1 was hospitalized). This process is summarized in Figure 1.

The average age of all participants was 60.9 years. The time from stroke in the intervention group was 36 months on average and 38.2 in the control group. At the baseline examination, mean values of the investigated parameters did not differ significantly between the groups (Table 1).

Table 2 presents spatiotemporal and kinematic parameters for the paretic and non-paretic extremity during the baseline examination, the examination at the end of the program, and after 6 months.

In the intervention group there was a statistically significant difference in the shortening of stance time in the paretic and non-paretic extremity (p=0.0007) and shortening of swing phase in the paretic extremity (p=0.0057) following completion of the program. After 6 months, the effect of stance phase shortening was maintained; whereas, the swing time of the paretic extremity got closer to the value from the baseline examination (p=0.57). In the control group, the change of stance phase and swing phase duration was not statistically significant. The value of measured parameters after the end of the study and after 6 months did not significantly differ between the intervention group and the control group. Similarly, the average value of change in the intervention group was not found to be significantly different to the value of change in the control group (Table 3).

In the intervention group, the symmetry index for step length (SL) in the baseline examination was 1.5 and it decreased to 1.14 immediately after completion of the program. After 6 months it worsened but in comparison to the baseline value it remained at a statistically lower level (p=0.006) (Table 4). After completing the program, the control group was found to have a statistically significant improvement in the symmetry for step length (p=0.0077), but after 6 months it got closer to the baseline value (p=0.1364).

The symmetry index on the paretic and non-paretic extremity after the end of the program was normalized in both groups, but in the control group improvements were higher (p=0.0152). After 6 months the symmetry index for stance time (ST) returned to the baseline examination value in both groups. The symmetry index for swing phase (SW) at these time points did not significantly

| Table 1. Baseline characteristics of individuals with stroke. |
|---------------------------------------------------------------|
| **Intervention group (n=15)** | **Control group (n=15)** | **p** |
| Age [years], mean (SD) | 61.9 (11.4) | 59.8 (11.7) | 0.54 |
| Sex [women/men] | 6/9 | 5/5 | – |
| Paretic limb [right/left] | 9/6 | 4/6 | – |
| Time from stroke month, mean [range] | 36.0 [8–120] | 38.2 [8–110] | 0.224 |
| **Mean (95% CI)** | **Mean (95% CI)** | **p** |
| Stance phase p [s] | 1.12 (0.96–1.28) | 1.04 (0.84–1.24) | 0.5195 |
| Stance phase np [s] | 1.33 (1.13–1.53) | 1.34 (1.18–1.49) | 0.6824 |
| Swing phase p [s] | 0.62 (0.52–0.73) | 0.55 (0.42–0.67) | 0.4115 |
| Swing phase np [s] | 0.49 (0.40–0.58) | 0.48 (0.37–0.59) | 1.0000 |
| SW/ST ratio | 1.57 (1.30–1.84) | 1.57 (1.15–1.99) | 0.6399 |
| Step length p [m] | 0.25 (0.20–0.29) | 0.24 (0.20–0.28) | 0.7702 |
| Step length np [m] | 0.33 (0.27–0.38) | 0.31 (0.27–0.34) | 0.7702 |
| ROM hip p [°] | 25.7 (22.6–28.8) | 26.0 (23.5–28.5) | 0.5985 |
| ROM hip np [°] | 31.6 (28.5–34.8) | 32.8 (29.5–36.1) | 0.8609 |
| ROM knee p [°] | 28.7 (23.0–34.4) | 36.2 (30.5–42.0) | 0.3472 |
| ROM knee np [°] | 39.7 (33.0–46.4) | 44.7 (39.6–49.8) | 0.0732 |

CI – 95% confidence interval; SW/ST ratio – intra-limb ratio; ROM – range of motion; p – paretic; np – non-paretic; p – probability value calculated using Mann-Whitney test.
change within intervention (p=0.2805) and control (p=0.3139) group. Improvement in hip and knee joint range of motion after the end of the program did not cause significant improvement in symmetry. The difference between the groups was not statistically significant (Table 4). The symmetry index for swing time to stance time (SW/ST) in both groups was 1.57 before the start of the exercise program and decreased to 1.28 (p=0.0468) in the intervention group and to 1.23 (p=0.0858) in the control group. After 6 months the symmetry index SW/ST got closer to the baseline examination value (Table 4). The difference between the mean values of change examined parameters in both groups was not statistically significant, neither immediately following completion of the program nor after 6 months. Only mean values of stance time ratio in the control group were statistically significant, neither immediately following completion of therapy nor after 6 months. Only mean values of stance time ratio in the control group were statistically significant, neither immediately following completion of therapy nor after 6 months.

**Discussion**

The main goal of this study was to evaluate the effect of treadmill training with visual biofeedback on gait pattern, including symmetry, in patients with paresis in the long-term period after a stroke. The therapy program was designed such that the intervention and control groups differed only in 1 targeted element - visual spatiotemporal biofeedback. In order to decrease the chance of result disturbances, the criteria to qualify for the study excluded those already receiving some form of therapy. The longevity of treatment effects was reevaluated 6 months after the end of the program. In order to evaluate the effect of the treatment therapy, spatiotemporal and kinematic parameters as well as gait symmetry were used.

Symmetry as an evaluation of similarities between spatiotemporal, kinematic, and kinetic parameters of right and left lower extremities is an important measure in the analysis of gait, as it can better compare parameters and describe the gait mechanism than conventional methods. Gait symmetry is also used to assess balance disturbances during walking and at the level of motor control [23,25]. Patterson and Mansfield conducted an analysis of the change of gait symmetry in a group of 71 patients after stroke, and proved that after rehabilitation it was impossible to improve the symmetry of spatiotemporal gait.
parameters together with an improvement in speed, balance, and functional mobility [26]. In another study, Goldie et al. reported that together with an increase in stance time in the paretic extremity, an increase in limb loading and an increase in limb support in the non-paretic extremity is a good indicator of improvement in the paretic extremity [27]. They also stated that if the treatment goal is to increase the walking speed and improve gait pattern, the therapeutic strategies should be directed towards decreasing stance time on the non-paretic extremity (reducing non-paretic single support time). Park showed that the use of exercise and TENS may reduce spas ticity in the lower limb, and also improve a balance and gait in patients with chronic stroke. He also pointed out that gait patterns were more symmetrical [28].
The hypothesis of the present study was that providing additional visual information about real-time spatiotemporal gait parameters during treadmill training would improve gait symmetry. In the baseline examination, gait of the participants was characterized by a longer step length of the paretic extremity, longer stance time on the non-paretic extremity, and longer swing time of the paretic extremity, whereas the symmetry index for all measured parameters was significantly disturbed. Despite no statistically significant differences between the intervention and control groups both immediately following the completion of the study and after 6 months, it is important to note that the intervention group did show a significant shortening of stance time in the paretic and non-paretic limb and shortening of swing time in the paretic extremity immediately following completion of the program. At this time, the symmetry index of step length in both groups improved, mostly by step elongation in the non-paretic extremity, with the step length maintained in the paretic extremity. It is therefore probable that the increase in stance time in the paretic extremity allowed the elongation of step length in the non-paretic extremity. Although the average value of symmetry index improvement was larger in the intervention group, the difference between the groups was not statistically significant. Improvement in step length was maintained after 6 months in the intervention group, and both groups showed a trend towards gait symmetry improvement. Future research in this area should therefore consider a longer treatment time.

Biofeedback methods in gait education are based on the provision of visual or acoustic information (typically kinematic, spatiotemporal, kinetic gait parameters, or EMG signals) to the participant in real time. In a systematic review of the literature, Tate and Milner stated that biofeedback methods in gait education do result in short-term moderate or significant improvements in gait [19]. They also emphasized that there is a lack of information about the durability of the treatment effects. Cho and Shin evaluated cortical changes during gait education in patients after a stroke and showed that the changes appeared in a group of patients in whom visual biofeedback was activated, presenting a real improvement in the range of motion of the knee joint of the paretic and non-paretic extremities [29]. Heeren presented results of gait education with a visual biofeedback in a form of displayed goals and obstacles on a treadmill. He showed that biofeedback during the chronic period after stroke improved participants’ gait according to clinical scales and improved functional physical activity [30].

As mentioned earlier, Lewek and colleagues evaluated the influence of treadmill training with biofeedback on the improvement of walking speed and symmetry of spatiotemporal gait parameters in patients during the long-term period after a stroke. Visual and proprioceptive feedback information about the successfulness of a performed task was also added to the training. Participants increased their walking speed and lengthened their gait cycle and stance phase time [21]. Jonsdottir et al. also analyzed the effectiveness of biofeedback methods in motoric education concerning gait re-education in patients with hemiparesis in the chronic period after a stroke. The study followed 20 participants, and found that compared to controls, EMG biofeedback increased the speed of walking and the length of gait cycle, and improved the symmetry of the gait pattern [31].

The clinical aspect of the research was to confirm the effectiveness of gait improvement while using treadmill training among a group of patients during the latter period after brain stroke and proving that subjects not only improved gait speed but also its symmetry, which surely means that the quality of patients’ gait has improved. The diversity of improvement grades among groups of examined patients did not have any

Table 5. The mean value of change the gait symmetry indicators, in intervention and control groups.

| Outcome measures | Difference between post and pre training Mean (SD) | Difference between 6 month follow up and pre training Mean (SD) | p-value |
|------------------|-----------------------------------------------|------------------------------------------------|--------|
|                  | Intervention group | Control group | Intervention group | Control group |        |
| Step length ratio | –0.35±0.34         | –0.21±0.14    | –0.24±0.34         | –0.01±0.21    | 0.2152 |
| Stance phase ratio | –0.06±0.16         | –0.28±0.30    | 0.0297             | 0.01±0.21     | 0.7259 |
| Swing phase ratio | –0.14±0.48         | 0.04±0.14     | 0.1937             | 0.09±0.66     | 1.000  |
| SW/ST ratio      | –0.21±0.55         | –0.34±0.51    | 0.6399             | 0.19±0.72     | 0.5584 |
| ROM knee ratio   | –0.06±0.09         | –0.08±0.18    | 1.000              | –0.02±0.12    | 0.9070 |
| ROM hip ratio    | –0.03±0.13         | –0.06±0.07    | 0.5195             | –0.05±0.15    | 0.9070 |

SD = standard deviation; ST = stance phase symmetry ratio; SW = swing phase symmetry ratio; ROM = range of motion; p-value = probability value calculated using Mann-Whitney.
statistical significance, but the upswing in the group of subjects that have undergone the intervention in the range of elongating the step of non-paralyzed limb and extending the duration of support phase of the paralyzed one, the improvement has lasted for 6 months at a statistically significant level, higher than the initial outcome. Beside analyzing the spatiotemporal parameters, the research also includes the analysis of kinematic factors and the symmetry of patients’ gait. Outcomes of the research demonstrated insignificant increase of the movement range of knee and iliac joints, but the improvement was not permanent and did not differ significantly between groups of subjects.

A major limitation of our study is the duration of the program. It can be assumed that the extension of the program would allow for effects fixation. It should be noted that the time of 2 weeks and the daily commute to the clinic for training and control tests were significant organizational burden for families and caregivers. After an interview with the families, we decided to complete a short program of therapy. Important in the short program was that during daily exercise the patients have not participated in other therapies. We believe that the primary limitation of our study was the short duration of the exercise and biofeedback program. It is likely that increasing the duration of this program would allow us to obtain more permanent improvements in gait. Despite this limitation, our short-term study was able to eliminate the influence of external factors that could disturb the results.

Conclusions

The study did not provide unequivocal proof to support the hypothesis that treadmill training following stroke is more effective when used in conjunction with visual spatiotemporal biofeedback. A temporary improvement in spatiotemporal gait symmetry parameters was observed in both groups at the end of the program, but after 6 months it was no longer observable.

Conflict of interests

No competing financial interests exist.

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