Title: Immediate effects of a single-dose intervention of in-sole auditory biofeedback on the spatiotemporal characteristics of gait in chronic stroke survivors: Phase 1 Study

Abstract

Objective: This study investigated immediate effects of a single dose intervention of in-sole auditory biofeedback on the spatiotemporal gait characteristics of chronic stroke survivors. The aim was to improve gait speed, load time and stride time of the paretic limb.

Design: Prospective cohort pilot study

Setting: University clinical research laboratory.

Participants: Twenty stroke survivors with hemiplegia (12 females, 8 males), mean age (62.75±11.72) participated. Formal rehabilitation was completed > 3-months ago. Intervention: A single dose 30-minute intervention was delivered (five, 5-minute work- stations comprised of balance, stepping and walking tasks and 1-minute change-over). Weight-shift using auditory feedback from an in-sole device (1OOA Biofeedback Unit) was targeted.

Outcome Measures: The GaitRite walkway system recorded spatiotemporal gait parameters before and after the intervention to test immediate effects of training with insole auditory biofeedback on gait parameters. A 10-meter walk test (1OMWT) pre and post intervention determined any clinically meaningful effect.

Results: Post-intervention trials showed significant increases in cycle (p = 0.001, 0.001, 0.000), step (p = 0.001, 0.001, 0.000), stance (p = 0.007, 0.003, 0.001), single support (p = 0.011, 0.001, 0.001) and double support time (p = 0.062, 0.024, 0.005) compared to pre-intervention data. There was a significant reduction in gait speed (velocity p= 0.020, 0.021, 0.030) in post interventions trials but no significant difference between the 1OMWT trials recorded at the start and close of the session (p>0.05).

Conclusions: Auditory biofeedback administered through the A100 had an immediate positive effect on cycle, step and load time of the paretic limb following a 30-minute insole auditory biofeedback training session. It is likely that multiple training sessions would be required for a clinically meaningful effect to be sustained.

KeyWords

Chronic Stroke, Gait Re-training, Portable Biofeedback, Auditory in-sole biofeedback, spatiotemporal characteristics of gait

Abbreviations

1OMWT = 10 metre walk test

kg = kilograms

em= centimetres

s =seconds

Regaining the ability to walk independently and efficiently is reported as one of the most important patient centred goals for stroke survivors[1]. In response, immediate post-stroke rehabilitation has focussed on retraining gait related tasks to enable walking within home and community settings[2]. Significantly reduced gait quality, balance and asymmetry continue to present in chronic stroke survivors after the completion of their formal rehabilitation programs[3,4]. These parameters have been associated with increased falls[5] and fear of falling[6] in stroke survivors and thus additional strategies to improve performance of walking with chronic stroke survivors warrant investigation.

The current model of stroke rehabilitation focuses on the early stages of rehabilitation with most treatment occurring in clinical (hospital) settings with minimal time spent practicing in community settings[2]. This occurs even though the community setting is where the majority of stroke survivors reside and other research has identified that context of practice (environment) has a significant impact on task re-training[7]. This view is supported in stroke specific research with recent literature[8] suggesting that rehabilitation in a community setting is superior to that of a clinical setting for chronic stroke survivors. To transition to a community-focused rehabilitation model it is important to identify effective methods and devices that can assist stroke survivors to undertake gait retraining in this context.

Biofeedback is an intervention mode that has received varying degrees of support during hospital based stroke rehabilitation, but it is thought to have considerable potential for community-based rehabilitation. A recent systematic review and meta-analysis included 22 randomised controlled trials (RCTs) investigating the effect of biofeedback training on lower limb recovery in stroke survivors [9]. The meta-analysis demonstrated that biofeedback is more effective than traditional therapy in the rehabilitation of lower limb functions. This review has been one of the largest in the field, establishing a moderate to large treatment effect and confirmed the conclusions drawn from a previous review including seven RCTs[10].

The most effective modality of biofeedback is yet to be established although a recent systematic review of gait rehabilitation in stroke patients found auditory cueing to be the most promising approach in conjunction with repetitive task training[11].

The use of auditory biofeedback is significant as it allows the potential of portable training devices to be investigated – a crucial step if biofeedback is to be implemented in a community context. A recent randomised controlled trial by Sungkarat and colleagues[12] utilised an auditory in-sole biofeedback device (l-ShoWS) during the rehabilitation of thirty-five stroke survivors where 77% were less than 6-months post stroke. Participants were recruited from a rehabilitation unit, university hospital and physical therapy clinic, based in Thailand. The participants completed five sessions/week over three weeks (total=15). Each session comprised thirty minutes gait training and thirty minutes conventional stroke rehabilitation (total=60mins). The results showed significant improvements in standing and gait symmetry ($p<0.05$), gait speed ($P=0.02$) and balance ($p<0.05$). As a large proportion of the participants in this study were less than six months post stroke, it is not known whether an in-sole auditory biofeedback device provides the same benefits to a cohort of chronic stroke survivors.

The primary aim of this initial study was to evaluate the immediate effects of using an in-sole auditory biofeedback device on spatial and temporal characteristics of gait in a cohort of chronic stroke survivors. Our main hypothesis was that a single treatment session using an in-sole auditory biofeedback device (1OOA) would: (1) Improve weight distribution during walking with a significant increase in loading time of the paretic li b. (2) Improve stride symmetry through increased stride time of the paretic limb during gait. It was also hypothesised that improvements in these parameters would enable an increase in gait speed (velocity) to be demonstrated.

Methods

Design

A single-arm before and after study with a single dose intervention was undertaken. This design has been previously used in studies of gait involving stroke survivors to demonstrate the effect of an intervention[13].

Participants

Stroke survivors who had completed all formal rehabilitation were sought for this study. Stroke volunteers were sourced through the Stroke Association of Queensland community groups in the greater Brisbane area and through a mail out to past patients who had attended a private practice setting offering rehabilitation for people post-stroke. Volunteers were included if: (1) hemiparesis following stroke was diagnosed; (2) formal rehabilitation was completed more than 3 months ago even if continuing with a home maintenance program (> 6months post stroke); (3) able to walk at least 15m independently with/without an assistive device; (4) capable of providing consent, communicating verbally if dominant arm impaired, with spouse/family or an independent witness providing consent; and, (5) a letter from their General Practitioner was obtained providing written clearance for the participant to take part in the study as an exercise intervention program was included. Volunteers were excluded on the basis of the following criteria: (1) presence of co-morbidities or pain that could contribute to asymmetry of gait (other neurological or vestibular disorders, lower limb amputee or fractured Neck of Femur); (2) respiratory or cardiovascular disorders interfering with the ability to repeat the six walking trials and the intervention component of the study, and (3) language (Aphasia) or cognitive deficits that prevented communication and / or understanding of the study requirements. This study was approved by the Human Research Ethics Committee of the affiliated University.

Measures

Demographic variables, clinical and laboratory measures of gait *were* collected.

i) Demographic variables (age, gender, height, weight) and characteristics (time since stroke, time since rehabilitation, side of hemiplegia, walking with/without a walking aid) of the stroke volunteers *were* recorded, to present a profile of the participants in this study.

ii) The participants completed a 10-metre walk test (1OMWT) as a clinical measure of walking speed[8] that also confirmed ability to complete the walking trials over the 6-metre walkway. The participants were asked to walk at a comfortable pace with a record made of the time taken to complete the 1OMWT and the number of steps taken across this distance. This test was also repeated at the close of the test session.

iii) The GAITRite electronic walkway system (CIR System Inc., Clifton, NJ, USA) was used to record the spatial and temporal characteristics of gait. The GAITRite system has been established as a valid[14] and reliable[15] tool for gait analysis of stroke survivors. General characteristics of gait such as velocity, cadence, step count, stride time, stride length, step time, step length and cycle time were recorded to identify gait changes as these are characteristics commonly reported in gait studies involving stroke survivors[16, 17]. The gait cycle was also examined in more detail to determine the effect of the intervention on the affected compared to the unaffected lower limb. To enable these analyses, swing, stance, single support, double support, heel on/off, load and unload times were considered, as well as the percentage change in each of these variables. Three trials were recorded before and after the intervention component of this study.

Intervention

A physiotherapist delivered an individualised exercise-based intervention program to each participant with auditory in-sole biofeedback provided during the exercise protocol to increase awareness of loading through the paretic limb. An in-sole biofeedback unit (100A

ARTG No: 201251) was used. The unit had two sensors: one placed under the forefoot and one placed under the heel. The sensors register pressure (weight) and when the target pressure was reached the device produced an auditory cue that was heard through an earpiece placed within the ear of each participant. The sensitivity of the device was adjusted so that the weight shift required to initiate the auditory cue was set to suit the ability of each participant to shift weight onto their paretic leg.

The intervention consisted of five, 5-minute workstations (25-minutes) with 1-minute change-over after each station – a 30-minute intervention session. Each station provided graded challenges to specific components of balance and walking[18]. The five workstations included (1) weight shift and stepping in all directions with the non-paretic limb, (2) walking sideways in both directions, (3) sit to stand with foot position varied to progressively load the paretic limb, (4) stepping onto a block with the non-paretic limb, and then the paretic limb, with integration of this task into practice of walking up and down stairs, and (5) advanced walking with forward and backward steps, obstacle negotiation and turning. The graded exercises for each workstation are outlined in table 1. The physiotherapist determined the level of difficulty with which to commence each exercise with each participant and then adjusted the exercises according the ability of each participant.

Procedures

On arrival at the University Research Clinic, volunteers completed a short demographic questionnaire. The volunteers then completed the 1OMWT to obtain a clinical measure of comfortable walking speed and to confirm eligibility to participate in the study. Participants were then taken to the test room for a short rest prior to completing the trials on the GAITRite walkway. Participants were seated in a chair 2metres behind the start of the GAITRite walkway. Three trials of walking were undertaken prior to the intervention. For each of the three trials, participants were asked to stand and walk at a safe and comfortable speed over the walkway to the final line marked 2metres past the end of the GAITRite.

Table1 Workstations with Exercises and Progressions used during Physiotherapy intervention Session

Work-station	Exercise	Graded Activities / Progressions
1	Weight Shift	a) Shift weight in standing with verbal and manual cues as required b) Stepping forward to target as required c) Change speed of stepping, size of steps, reduce cues
2	Walking	a) Alternate stepping forward/back, transition to walking b) Forward walking c) Change speed, add corners, stop/ start
3	Sit to stand	a) Sitting and reaching to target outside base of support to encourage load through affected leg b) Sit to Stand with weight evenly through legs / progress bed height from higher to lower c) Use asymmetrical foot position with impaired foot set behind during sit to stand
4	Stepping & Stairs	a) Step over a line b) Alternate leg stepping up onto different sized blocks c) Alternate leg stepping down off different sized blocks d) Walk up/down stairs / progress to reciprocal stair walk
5	Advanced Walking	a) Walk in multiple directions (sideways, backwards) b) Manoeuvre around obstacles (weaving, stepping over, around etc) c) Walk outdoors

Participants wore usual footwear and used assistive devices (if required), completing a total distance of approximately 1Ometres. The extra distance prior to and after the runway was to ensure that steady-state gait was recorded by the GAITRite system and not the acceleration and deceleration phases. Participants were allowed to rest (self-regulated) between the walking trials. At the conclusion of baseline testing the in-sole biofeedback device (1OOA) was fitted into the participant's footwear on the paretic limb with a sham insole used in the shoe of the non-paretic limb. The intervention was delivered for 30-minutes and, after removal of the 100A from the in-sole and a rest, the second series of three walking trials over the GAITRite walkway were undertaken. The clinical 1OMWT was then repeated to complete the test session.

Data Management and Analysis

Descriptive statistics were used to present demographic and participant characteristics. The raw data of 54 spatiotemporal variables from the three trials pre-intervention and three post-intervention trials were averaged across the 6metres to yield six trial scores for each spatiotemporal variable. Initial exploration of data showed that there was a significant difference between the average of the first trial and the following two pre-intervention trials for each of the variables. As a result, this trial was treated as a practice/familiarisation trial. The following two trials were averaged to provide the pre-intervention data set for each spatiotemporal variable. The three post-trials (trials 4-6) were treated as individual data sets for the spatiotemporal variables. Mean and standard deviations were calculated for all variables. A repeated measure analysis of variance (ANOVA) was used to investigate any differences between the four data sets (1 pre-intervention; 3 post-intervention). Covariates of age, height and weight were included in the model as well as the between subject factors of gender and assistive device to account for any effect of these variables. Post Hoc contrast analyses were undertaken to identify between trial differences with significance set at a P-value of 0.05. A paired t-test was undertaken with the pre and post-intervention 10MWT tests (time and steps) to determine any differences between the two trials (Significance was set at a p-value of 0.05).

Results

Twenty-two participants took part in our study. The data of two participants were excluded from the analyses due to unreadable gait patterns from the *GAITRite* system. Thus data for 20 participants are presented. Table 2 highlights the demographic and participant characteristics of those included in the study. Of the 20 participants, 17 presented with left-sided hemiplegia (85%) and 60% were female. Only six (30%) of the participants used a walking aid for ambulation. The results of the 1Ometre walk test (comfortable pace) recorded before and after the intervention are included as Table 3.

Table 2 Demographics and Characteristics of Participants

	Mean for cohort	Standard Deviation	Minimum	Maximum
Ages (years)	62.75	11.72	36	85
Height (em)	167.99	9.75	152.4	192
Weight (kg)	73.82	14.36	51.8	105.8
Time since stroke (years)	5.88	4.05	0.66	16
Time since rehabilitation (years)	4.52	3.58	0.25	13

Table 3 Performance of the lOmetre walk test Pre and Post-Intervention

Pre intervention 1OMWT*				
Time (s)	18.00	16.78	7.58	79.46
Steps (n)	23.00	7.89	14.00	42.00
Post intervention 1OMWT*				
Time (s)	18.13	14.76	8.50	69.64
Steps (n)	22.05	7.16	14.00	38.00

*1OMWT: 10 metre walk test

Effect of intervention on spatia-temporal gait variables

The 54 spatiotemporal variables collected for the six trials (mean, standard deviation and 95% confidence intervals for all variables on the GAITRite system) are tabled as an addendum to this paper (See Supplementary material in Addendum). The outcomes based on the averaged pre-intervention and three post-intervention trials are presented to reveal the tempore-spatial gait parameters that were immediately impacted by the insole biofeedback intervention. A reduction in the temporal characteristics of velocity ($p<0.05$), cadence ($p <0.01$) and stride velocity (paretic and non-paretic limbs) was demonstrated ($p<0.05$). For both velocity and stride velocity the effect was greatest immediately post-intervention (trial 2) with the final two trials trending back towards baseline measures. For the 1OMWT performed at a comfortable pace pre and post intervention, there was no significant difference between pre and post-intervention walk times (**P** =0.859) or the number of steps recorded over this distance (P=0.143).

Effect of intervention on load time and use of the paretic limb

Changes were observed in several temporal variables in the gait pattern from pre to post-intervention supporting the hypothesis that load time and use of the paretic limb would increase. Significant increases in cycle time, step time, swing time, stance time and single support time across the three post intervention trials were recorded. Double support time of the paretic limb showed a trending increase in trial 2 and significantly increased across trials 3 and 4 (see figure 1). Similarly, trending increases in double support unload time were identified across trials 3 and 4 with a significant increase for trial 4. The non-paretic limb reflected a similar pattern of change in these temporal variables. Whilst there was an increase in total loading time of the paretic limb in the post trials compared to the pre-intervention data, there was no significant change in the relative percentage of the loading phases of the gait cycle (stance, single support and double support variables).

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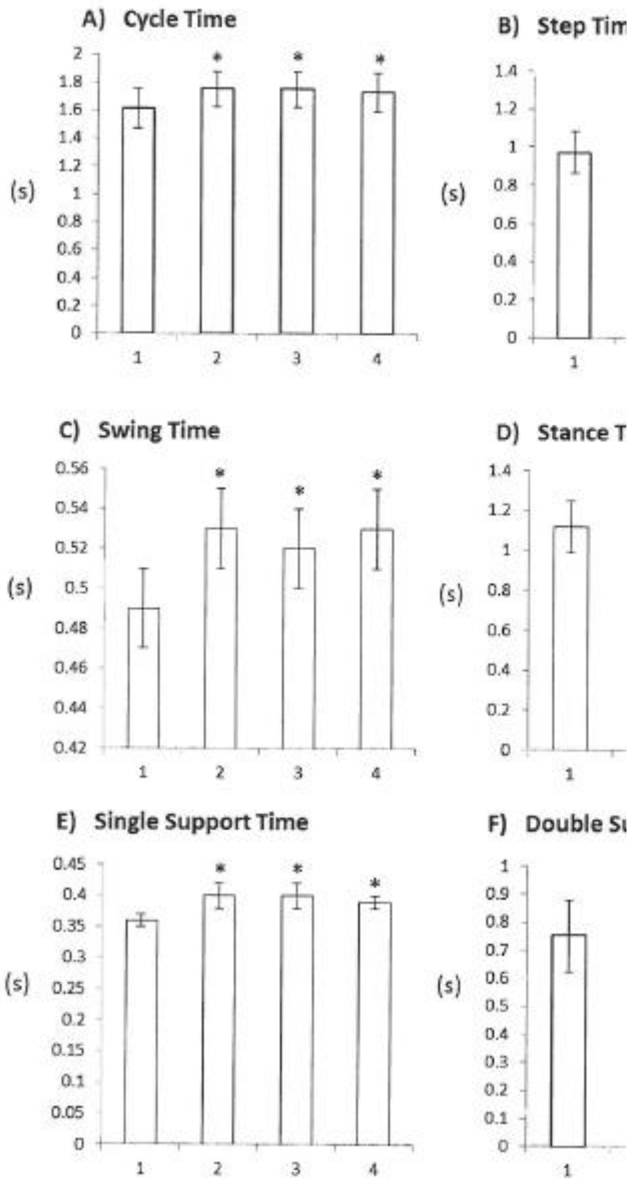

Figure 2 Pre-Intervention and post-intervention trials (three) for selected spatia-temporal variables of the affected limb

*Significant improvement in variables from pre to post intervention trials p<O.OS

l=Average of two pre-intervention trials; 2-4 = Three Post-Intervention Trials

Discussion

The findings of our study are novel and show that selected gait variables were significantly and positively impacted by the single intervention session. Of note was the significant change in temporal characteristics for the paretic limb with increased cycle, step, single support, double limb support and stance time in the post-intervention trials compared to pre-intervention data. These changes confirmed our hypothesis that the use of auditory in-sole biofeedback would improve weight shift during gait through an increase in load time and use of the paretic limb. The improved load time is in line with the earlier research of Sungkarat and colleagues[12] who demonstrated that multiple training sessions over a 3-week period using an in-sole biofeedback device with a more acute stroke population was superior to usual rehabilitation (without biofeedback).

Our final hypothesis that an increase in walk speed would occur after the intervention was not supported by the findings in our study with participants slowing their gait speed after a single training session. It is likely that the increase in load time on the paretic limb following a single intervention was enabled by the participants slowing their walking speed. In contrast to our findings, the earlier study by Sungkarat and colleagies[12] found that gait speed (velocity) improved. This suggests that multiple training sessions with more intense training is likely to be required to achieve an increase in gait speed. With multiple training sessions, learning is likely to occur, enabling less attention to the task and gait speed to increase. Our participants were learning a new task in a single treatment sessions which required high levels of cognitive attention to process the auditory feedback while walking. This type of dual task involving cognitive demand during walking has previously been associated with reduced gait velocity in stroke survivors[19,20]. In addition, our study reported a reduction in cadence and an increase in stride time both of which have also been associated with the addition of a cognitive task while walking[21]. The multiple-session design of the study by Sungkarat and colleagues (2011)[12] may have allowed the participants to progress their motor learning and reach a more autonomous stage of skill acquisition, where very little cognitive input is required. This indicates that future studies should incorporate a multiple session design with chronic stroke survivors to determine if a positive effect on gait speed (velocity), cadence and stride time can be achieved.

The secondary hypothesis of improving stride symmetry through an increase in stride time of the paretic limb was also not consolidated. While we achieved an increase in stride time of the paretic limb, there was a similar increase in stride time of the non-paretic limb and as such no significant change in the difference between the two stride times occurred. The effect of multiple intervention sessions on this aspect of gait also needs further investigation.

Limitations

While we achieved a positive effect on a range of gait variables there were several limitations to this study. The small numbers recruited across the 10-week study period may limit the generalisation of our findings. The relatively low numbers also meant that it was not feasible to undertake further analyses using different participant characteristics (such as mobility levels, side of hemiplegia, site of lesion, falls history) and comment on their relationship to our primary findings. A larger study may allow for these variables to be investigated while using an in-sole auditory biofeedback device. Additionally the current study did not include a control group in which participants completed the intervention without the in-sole device. Another preliminary investigation could use a case controlled series to explore the effect of multiple biofeedback training sessions on gait with the patient acting as their own control, before a large scale randomised controlled trial is undertaken.

Conclusions

This study demonstrated that a limited but positive effect on gait parameters was achieved through a single dose intervention using auditory insole biofeedback. We have established the proof of concept for using the 1OOA In-sole Biofeedback Unit in gait rehabilitation of chronic stroke survivors. More rigorous studies are now required involving a control group and multiple session interventions to provide further insight into the clinical effects of the in-sole biofeedback device.

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Equipment

1OOA Portable Biofeedback Unit (ARTG No: 201251) purchased from Mr Peter Barrett, nCounters, Australia. Mobile 0412 540 138; Web-Site: www.ncountersonline.com

Figure Heading

Figure 2 Pre-Intervention and post-intervention trials (three) for selected spatia-temporal variables of the affected limb

*Significant improvement in variables from pre to post intervention trials p<O.OS

1=Average of two pre-intervention trials; 2-4 = Three Post-Intervention Trials