ORIGINAL ARTICLE

Sensory Retraining of the Lower Limb After Acute Stroke: A Randomized Controlled Pilot Trial

Elizabeth A. Lynch, BAppSc, Susan L. Hillier, PhD, Kathy Stiller, PhD, Rachel R. Campanella, BAppSc, Penny H. Fisher, BPhysio

ABSTRACT. Lynch EA, Hillier SL, Stiller K, Campanella RR, Fisher PH. Sensory retraining of the lower limb after acute stroke: a randomized controlled pilot trial. Arch Phys Med Rehabil 2007;88:1101-7.

Objective: To determine the effects of a sensory retraining protocol on sensation, postural control, and gait in acute stroke subjects.

Design: Randomized controlled pilot trial.

Setting: Inpatient rehabilitation hospital.

Participants: Twenty-one subjects with sensory deficits in the feet, undergoing rehabilitation for stroke.

Intervention: Sensory retraining of the more affected lower limb versus relaxation (sham intervention).

Main Outcome Measures: Light touch at the sole of the foot (Semmes-Weinstein monofilaments), proprioception (Distal Proprioception Test), postural control (Berg Balance Scale), and gait (timed, Iowa Level of Assistance Scale).

Results: Significant improvements ($P<.05$) over time were found in light touch at 3 points of the feet and in postural control, timed gait, and walking aid. No significant time effects were observed in proprioception or amount of assistance required to walk. No significant differences were detected between groups in any of the outcome variables, apart from light touch at the first metatarsal. The study had poor power (13%) to detect group effects due to the small sample size.

Conclusions: Results of this pilot study are unable to support or refute the routine use of sensory retraining of the lower limb for people during inpatient rehabilitation after stroke. Further research with a larger sample size is required.

Key Words: Cerebrovascular accident; Foot; Hemiplegia; Rehabilitation; Sensation disorders.

SENSORY IMPAIRMENTS ARE common after stroke, occurring in approximately 60% of stroke patients.[1] Sensory dysfunction in the lower limb after stroke has been related to reductions in standing balance,[2] gait speed,[3,4] balance during ambulation,[1,5] and gait symmetry.[3] When left untreated, sensation tends to improve in the first 3 months following stroke, but stroke survivors are frequently left with a degree of sensory impairment affecting a range of sensory modalities.[6]

Several studies have shown promising results in the treatment of upper-limb sensation after stroke using sensory retraining,[5,7-9] with significant improvements in sensation reported in all the trials. Three of the 4 studies[5,7,9] were conducted on subjects with chronic stroke, whereas only one was conducted during the initial rehabilitation period.[8] Sensory retraining uses concentration and exposure to different sensory inputs to enhance sensory awareness. Examples of sensory retraining techniques are discrimination of texture, shape, or weight,[5,7-9] training joint position sense,[5,7-9] object recognition activities,[5,7] detection of touch,[7,9] and education about the sensory loss.[9]

Two studies were identified that evaluated sensory retraining in the lower limb after stroke. Morioka and Yagi[10] trained hardness discrimination in stroke subjects in rehabilitation and reported significant improvements in postural control, but sensation, in the form of 2 point discrimination, did not change significantly over the assessment period. The hardness discrimination training was conducted in standing, which could have confounded the results because simply spending time in standing has been shown to significantly improve postural control in stroke patients.[11] Hillier and Dunsford[12] used 3 multiple baseline experiments to investigate a 2-week program of sensory retraining of the feet in chronic stroke patients (>2y post-stroke). These authors found that light touch sensation significantly improved in the feet of 2 of the 3 subjects over the study period, but proprioception did not change significantly. Measures of postural control were not significantly affected in 2 of the 3 subjects, but the remaining subject showed a significant improvement in single-limb stance.

Thus, although there is some evidence that sensory retraining for stroke patients with sensory dysfunction of the feet is effective, more research is required, particularly in the acute period after stroke, to measures its effectiveness. Consequently, the aim of the present study was to investigate the effect of sensory retraining of the lower limb of acute stroke patients involved in rehabilitation using measures of sensation, standing balance, and gait. Subjects during the acute phase after stroke were specifically selected because the intention of the study was to investigate the theory that "earlier is better" with regard to sensory retraining.

METHODS

Ethics approval was obtained from the Royal Adelaide Hospital and the University of South Australia.

Participants

We recruited participants from 2 wards at Hampstead Rehabilitation Centre, a public inpatient rehabilitation center. To be included, patients met the following criteria: (1) receiving inpatient rehabilitation following a first ever stroke; (2) sensory dysfunction of the lower limb evident on physiotherapy (PT) assessment and by subjective report; (3) medically stable; (4) able to stand and walk 10m with no more than 1 person assisting; (5) gave informed consent. Patients were excluded if

From Hampstead Rehabilitation Centre (Lynch, Campanella, Fisher), Centre for Allied Health Evidence, University of South Australia (Lynch, Hillier), and Royal Adelaide Hospital (Stiller), Adelaide, South Australia.

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Correspondence to Elizabeth A. Lynch, BAppSc, Hampstead Rehabilitation Centre, 207-255 Hampstead Rd, Northfield, South Australia, 5067, Australia, e-mail: *lynch.elizabeth@saugov.sa.gov.au.* Reprints are not available from the author.

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they showed any of the following: (1) unwillingness to participate in the study; (2) inability to understand or respond to questions or instructions in English; (3) pre-existing sensory deficits from previous strokes or peripheral neuropathies; and (4) used a walking aid other than a single-point stick prior to the stroke. Any participant who developed a medical or other complication which prevented more than 3 PT treatments during the experimental phase was withdrawn from the trial.

Sample Size

We chose an anticipated sample size of 32 based on research using the Berg Balance Scale (BBS) in acute stroke subjects,[13] which indicated that for an effect size of 6 points, 16 patients per group were required to show a significance level of 0.5 (ie, $\alpha=.05$) and statistical power of .80 (ie, $\beta=.20$). However, after 21 subjects had been recruited to the current trial, the circumstances of service delivery changed on the unit, so further recruitment was not possible.

Research Design

A randomized controlled design was applied. After screening and signing consent forms, participants were randomly allocated to either the sensory retraining group or the relaxation (control) group by means of a random numbers table. Participants completed 10 sensory retraining or relaxation sessions in addition to standard care over a 2-week period. Subjects were blinded to the intervention of interest, the therapist providing the sensory retraining and relaxation treatments was blinded to the assessment results, and the assessors were blinded to subjects' group allocations.

All participants received the same standard PT care, which consisted of 1 hour a day in a group session, working on lower-limb strength, balance and cardiovascular fitness, with a further 30 to 60 minutes a day in an individual session depending on patient need. Standard therapy sessions were based on the Motor Relearning Program.[14]

Sensory Retraining Intervention

Ten 30-minute sensory retraining sessions were provided by the primary investigator over a 2-week period. The total treatment time was divided evenly between: education regarding sensation and sensory retraining; practice in detection and localization of touch at 7 points on the soles of the feet; hardness, texture and temperature discrimination by placing the feet on a variety of floor surfaces while sitting and standing with vision obscured; and proprioception training of the big toe and/or ankle (analogous to proprioceptive training at the wrist used in upper-limb sensory retraining[8]).

The principles of sensory retraining were similar to those used in previous research[8,9,12] and included education regarding the nature and extent of sensory loss; specific, graded stimulation tasks with an emphasis on tasks the subject was able to do (in this case, light touch detection and localization training was tailored for the individual to focus on areas of sensory deficit); attentive exploration of the stimuli by the subject; prevention of visual dominance; comparison with the nonaffected side; quantitative feedback on outcome and performance and summary feedback.

Control Group: Relaxation Techniques

Subjects in the control group were asked to close their eyes and were assisted to stand for the same periods of time as the treatment group spent doing the floor-surface discrimination intervention. The rest of the 30-minute session was spent with eyes closed in supine, performing guided relaxation techniques.

Assessment Procedure

Assessments were conducted by 1 of 2 physiotherapists who were blinded to participants' group allocation. Assessments were conducted prior to treatment, on completion of treatment, and then at a 2-week follow-up. Because this was an exploratory pilot trial, multiple outcomes were assessed to confirm likely areas of change.

Assessment of light touch and proprioception was problematic, because we could identify no clinically applicable outcome tools that had been examined for reliability, sensitivity, or validity in the assessment of sensation in stroke survivors. Light touch at 7 points on the soles of the feet (big toe, little toe, first metatarsal, fifth metatarsal, lateral border of the foot, medial border of the foot and heel) was assessed using Semmes-Weinstein monofilaments.[15] This involved application of calibrated monofilaments to the soles of the feet; subjects were asked to report when they detected a stimulus, and the smallest monofilament detected by the subject was recorded. This method of sensory assessment has been found to be reliable in the assessment of diabetic subjects[16,17] but has not been studied specifically in the stroke population. Proprioception of the big toe was assessed using the Distal Proprioception Test (DPT)[6,18] and given a score out of 10. This involved the assessor passively moving subjects' big toes to a position up or down and each subject was asked to identify the position and the number of correct responses was recorded. Although the DPT is widely used in the clinical setting, no research investigating its reliability or sensitivity was identified.

We measured postural control using the BBS,[19] a series of 14 static and dynamic balance tasks which has shown good reliability[20] and sensitivity[13,21,22] in the acute stroke population during rehabilitation, and correlates significantly with laboratory-based postural control assessments of stroke subjects.[23,24]

Gait assessment consisted of measuring the time taken to walk the middle 10m of a 14-m walking track,[25] and the amount of therapist assistance and mobility aid required to walk was measured by the Iowa Level of Assistance Scale (ILAS).[26] The assessment of gait speed in stroke subjects in rehabilitation is reliable,[25] sensitive to change,[27-31] and correlated significantly to community ambulation[32] as well as other postural control outcome measures.[33,34] The ILAS grades the amount of therapist assistance according to the number of points of contact required from the therapist to complete the task safely, and records the walking aid used. It is a valid and reliable tool for use in orthopedic patients,[26] but we have not found its reliability and sensitivity to change in the stroke population to be reported in the literature to date.

Reliability of assessments. Inter- and intrarater reliability were assessed for all the outcome variables by video-recording 3 randomly selected assessments. The 2 assessing physiotherapists independently scored the 3 performances. The video-recorded assessments were then presented in a randomized order and rescored by both assessors 2 weeks later.

Statistical Analysis

We performed the analyses using the SPSS statistical software.[a] Data were collected following the principles of intention to treat (ITT) and were plotted in histograms and analyzed for normality. In a number of cases (ie, proprioception, BBS, timed gait), data were not distributed normally and were adjusted using Johnson transformations.[35] The transformed data were analyzed to determine whether the assumption of normality could be rejected, and if not (ie, if data were distributed normally), mixed-model analyses were conducted to determine

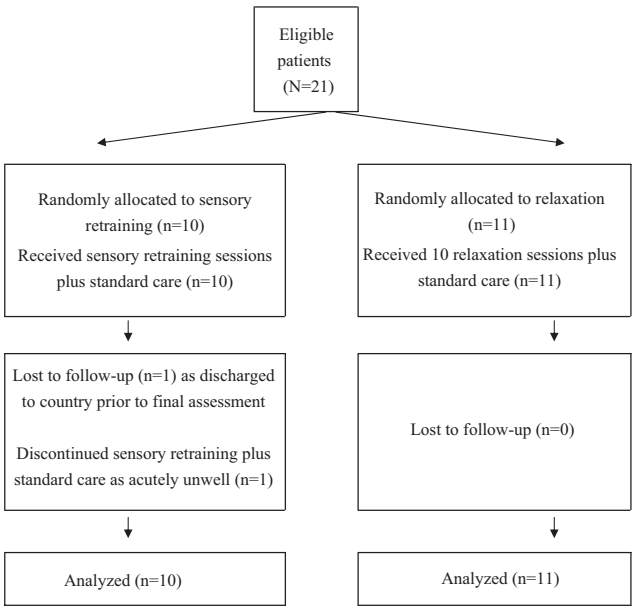

Fig 1. Progress of patients throughout the study period.

change in the variable over time and to determine whether there was a significant difference between groups at any time point (ie, BBS, timed gait). When data were very skewed and unable to be transformed to a normal distribution successfully (ie, proprioception data), or if the data were ordinal (light touch, ILAS), then ordinal regression analyses were conducted. In the case of light touch data, where separate comparisons were made for multiple locations of the foot, combination of results in the form of multiple comparisons were avoided to reduce type I errors.[36] Probability values of less than .05 were considered significant.

RESULTS

Twenty-one subjects were recruited over a 9-month period, with 10 in the sensory retraining group, and 11 in the control treatment group (fig 1). One subject in the sensory retraining group was withdrawn because he developed an acute illness requiring readmission to the acute hospital. His data were collected at follow-up and included in the analysis following the ITT principle.

Results from a retrospective power calculation showed that the current study was strongly (99.7%) powered to detect changes in the chosen outcome variables over time. However, the study was poorly powered to detect changes between groups, with only a 13% chance of detecting a group effect. Therefore, the results from the current study must be viewed with caution; in the cases where no group effects were detected, it is possible that such an effect existed but was not detected due to insufficient subject numbers.

The demographic characteristics and time spent in PT of the 21 subjects are shown in table 1. Most subjects were men (n=16 [76.2%]), and the majority (n=18 [85.7%]) had cerebral infarcts. All subjects (N=21 [100%]) reported that they were independently mobile in the community prior to their stroke.

Statistical analysis indicated that there were no significant differences between groups with regard to any of the demographic variables or the baseline outcome measures, indicating that the 2 groups were comparable preintervention. Time spent in PT did not differ significantly between the 2 groups.

The Cohen κ was performed to determine interrater reliability over all the categories measured by the 2 assessors. Both the weighted and unweighted statistics were very high (.968, .985, respectively; $P<.001$), indicating almost perfect agreement between the 2 assessors. The analysis of intrarater reliability using the Wilcoxon signed-rank test showed excellent intrarater reliability for both assessors with each assessor having a P value of greater than .999.

Light Touch Sensation

All 7 points of the foot showed significant differences in light touch thresholds between the 2 feet (P range, .000–.029), with the affected foot significantly more impaired than the less affected foot (Mann-Whitney U tests).

Ordinal regression analyses indicated that light touch improved significantly over time at 3 points of the affected foot: the heel ($P=.026$), the lateral border of the foot ($P=.024$), and

Table 1: Demographic Characteristics of Subjects

Characteristics	Sensory Retraining (n=10)	Relaxation (n=11)	P
Mean age ± SD (range), y	61.0±15.8 (21–77)	62.0±12.3 (38–82)	.944†
Mean duration of stroke when recruited to study (range), d	48.7±31.1 (19–122)	47.8±27.7 (13–112)	.751†
Mean MMSE score age ± SD (range)	28.5±1.0 (27–30)	28±1.7 (24–30)	.880†
Sex (n)			.635*
Men (n)	7	9	
Women	3	2	
Side of CVA (n)			.387*
Left	5	3	
Right	5	8	
Type of CVA (n)			1.000*
Infarction	9	9	
Hemorrhage	1	2	
Treatment details			
Mean total time in group PT ± SD (range), min	843.5±247.4 (375.0–1110.0)	943.2±244.3 (540.0–1320.0)	.459†
Mean total time in individual PT ± SD (range), min	571±176 (290–930)	524±192 (160–960)	.622†
Mean daily time in group PT ± SD (range), min	42.0±10.9 (15.6–51.4)	47.4±8.0 (27.0–60.0)	.245†
Mean daily time in individual PT ± SD (range), min	28.7±8.5 (19.3–44.2)	26.6±8.2 (11.0–45.7)	.778†

Abbreviations: CVA, cerebrovascular accident; MMSE, Mini-Mental State Examination; SD, standard deviation.
*Analysis conducted using the Fisher exact test.
†Analysis conducted using the Mann-Whitney U test.

the big toe ($P=.011$). Sensation did not differ significantly between groups at these 3 points of the feet at any of the measured time points. Time had no significant effect on sensation at the remaining 4 points of the feet (ie, the little toe, medial border of the foot, first and fifth metatarsals). A significant difference in light touch sensation at the first metatarsal was detected between the 2 groups at follow-up (groups were comparable at baseline), with the sensory retraining group showing significantly improved detection of light touch than the relaxation group ($P=.011$). This between-group difference was not observed at any other point of the foot.

Significant differences remained between the affected and less-affected foot after the 4-week period, even in the 3 points of the feet that had shown significant improvements in sensation over time (Mann-Whitney U tests: big toe, $P=.001$, lateral border of the foot, $P=.005$; heel, $P=.045$).

Proprioception

There was no significant difference over time in scores on the DPT at the big toe ($P=.55$), and no significant difference was detected between groups ($P=.057$) (ordinal regression analysis).

Balance

Figure 2 shows the mean BBS scores (out of 56) of groups over time, where assessment 1 was conducted prior to the intervention, assessment 2 on completion of the sensory retraining and relaxation program, and assessment 3 at follow-up. Scores improved significantly from baseline to the end of treatment in both groups ($P<.005$), but there was no significant difference in scores between groups at the end of treatment and follow-up (mixed-model analysis). No significant difference was found between groups at any time period.

Timed Gait

The time and group comparisons of the mean 10-m timed gait data are shown in figure 3. Time had a significant effect on timed gait scores ($P=.012$), whereas group allocation ($P=.337$) did not have a significant effect (mixed-model analysis).

Use of Walking Aid

Ordinal regression analyses were conducted on the walking aid data and showed that time significantly affected the walking aid used over the 10-m walk ($P=.023$), whereas group allocation did not ($P=.475$). The coefficient of time was negative ($-.045$), indicating that the scores decreased over time, that is, the walking aids required became progressively less supportive over time.

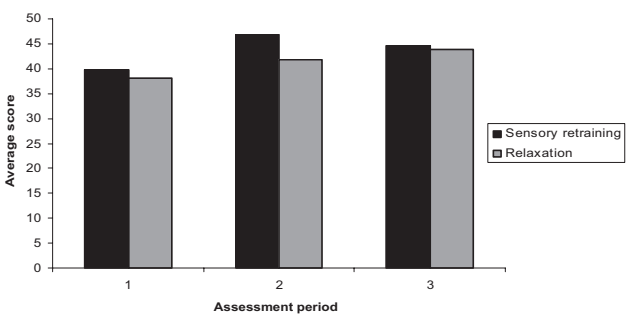

Fig 2. Time and group comparisons of the BBS.

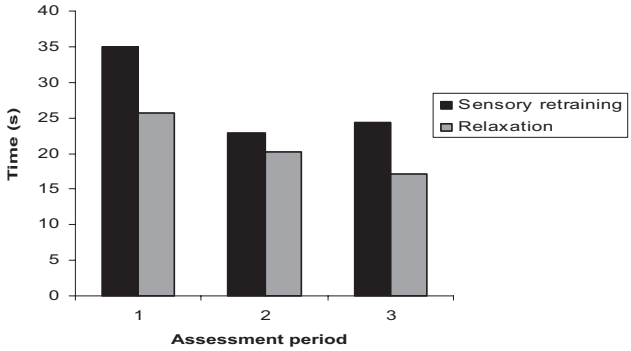

Fig 3. Time and group comparisons of 10-m timed gait.

Level of Assistance

The data regarding the "points of contact" subscale on the ILAS were highly skewed, so they were analyzed using ordinal regression. Neither time ($P=.376$) nor group allocation ($P=.114$) significantly affected the scores, that is, no significant change was observed over time or between groups in the amount of assistance subjects required from the therapist to walk 10m.

DISCUSSION

This pilot study found that a standardized protocol of sensory retraining of the feet was not significantly more effective than relaxation in improving sensation, balance, or walking ability in a sample of acute stroke subjects.

In previous studies investigating the effectiveness of sensory retraining, repeated-measure (single-case study) designs have been used more often than experimental designs with control groups, because stroke subjects are a highly heterogeneous subject group and therefore difficult to compare with one another as is required in an experimental design.[8] However, a repeated measures design was considered problematic for this study, because some subjects require numerous (>10) baseline assessments to reach baseline stability.[8] Indeed, in 1 study, baseline stability was never achieved,[12] which then compromised the validity of the results. In addition, it was considered that a design using a sham treatment group would control for the confounding variable of natural recovery of sensation expected in this population of acute stroke survivors.[6]

The additional treatments (ie, sensory retraining or relaxation) were well tolerated, with subjects anecdotally reporting benefits from both the sensory retraining and the relaxation sessions. Relaxation was considered by the investigators to be a suitable "sham" treatment, because a literature search did not identify any studies advocating the use of relaxation to improve function after stroke. However, because there was no true control group that received standard rehabilitation only, it is possible that both sensory retraining and relaxation were equally beneficial in the rehabilitation of people with stroke. However, it is just as possible that neither treatment was more beneficial than standard care.

Significant changes were found over time in light touch sensation in 3 points of the foot: at the heel, the lateral border of the foot, and the big toe. During the gait cycle, the center of pressure of the foot proceeds from the heel with initial contact, moves through the lateral side of the mid-foot to be spread across the metatarsals, and then progresses to the big toe and second toe in terminal stance.[37] Therefore, it could be hypothesized that sensation in these 3 areas improved as a direct result

of the sensory input received when undergoing standing and walking retraining, which all subjects received as part of the standard rehabilitation. In contrast, sensation in the other 4 areas of the feet (medial border of the foot, first and fifth metatarsals, little toe), which received less pressure or a more diffuse pattern of pressure during the gait cycle did not change significantly over the assessment period.

No significant differences in sensation were found between groups at the various points of the feet, with the exception of the first metatarsal, where the sensory retraining group showed the ability to perceive significantly lower thresholds than the relaxation group at follow-up. It was unclear why this 1 point of the foot was significantly affected by group allocation, but the other 6 points of the foot were not. It may be that the first metatarsal is the most responsive point of the foot to sensory retraining, and likely to be affected by the discrimination activities more than other areas of the foot. However, this hypothesis was not corroborated by the results of Hillier and Dunsford,[12] in which only 1 of the 3 subjects showed improvements in light touch sensation at the first metatarsal after a period of sensory retraining. Alternatively, it may be that this statistical significance occurred purely as a result of the multiple comparisons performed.

The lack of improvement in sensation over time in 4 of the 7 points of the foot was unexpected, because the natural course of recovery after a stroke has been shown to include recovery of light touch sensation, even in the absence of sensation-directed treatment.[6]

The disparity between the lack of change in light touch sensation following sensory retraining of the feet in the current study and the results of Hillier and Dunsford,[12] who reported significant improvements in light touch after the training period in 2 of the 3 chronic stroke subjects, may have been due to the difference in the target population. It may be that sensation is more responsive to training later after stroke. Another possible difference between the 2 study populations is their ability to maintain attention levels, which has been reported as important in order to maximize the effects of sensory retraining.[38] Subjects in the study by Hillier and Dunsford[12] may have been able to attend to the retraining tasks better because they were only receiving 1 form of therapy during the assessment and treatment period. In contrast, subjects in the current study had on average more than 100 minutes a day in PT alone, in addition to other therapies, which may have reduced their attention levels in the retraining sessions, thereby potentially reducing the effectiveness of sensory retraining. Similarly, because subjects in the current study were only weeks or months after their stroke, they may have still been experiencing more cognitive impairment than the chronic subjects in the study by Hillier and Dunsford.[12] This cannot be confirmed or refuted because the only cognitive test applied in the current study was a Mini-Mental State Examination, which is a screening tool and is not always sufficiently sensitive to detect subtle cognitive impairments or attention deficits in the stroke population[39] and no cognitive assessment or screen was conducted by Hillier and Dunsford.[12]

A final theory regarding the lack of significant improvement in light touch sensation at 4 points of the foot in the current study is that the assessment period used may not have been long enough to allow significant changes to occur, because the improvements in light touch sensation previously reported[6] occurred over a 3-month period whereas the current study measured sensation over 4 weeks.

Proprioception of the affected big toe, measured using the DPT, did not show significant improvement over time in either group in the current study and no significant differences were found between groups. This finding was unexpected, given the natural course of recovery in proprioception after stroke reported in the literature.[6] Despite the DPT being used commonly in the clinical setting in the assessment of stroke patients[1,6,18] no studies were identified that assessed the repeatability of the DPT scores over time in a stable population group, or the sensitivity of the instrument to detect changes in stroke patients undergoing rehabilitation. The study by Hillier and Dunsford[12] found that scores of proprioception using the DPT were quite erratic in the 2 subjects with decreased proprioceptive ability, whereas the 1 subject who scored full marks on the DPT continued with 100% accuracy throughout each assessment. A similar fluctuation in results was found in the present study, with 4 of the 21 subjects showing decreases in the DPT scores from baseline to follow-up, and 2 subjects who initially scored full marks at baseline, falling to 1 and 5 correct responses out of 10 two weeks later. This suggests that the stability of the DPT within individual subjects may be questionable, even though the interrater and intrarater reliability of the DPT in the current study was found to be excellent. In addition, the results of the current study showed that the DPT was not sensitive to change in stroke subjects in rehabilitation over a 4-week period.

Scores on the BBS improved significantly over time in both groups, but no significant differences were detected between groups at any of the assessment periods. Other studies that have assessed the effect of sensory training on postural control have had conflicting results. Morioka and Yagi[10] trained hardness discrimination in the feet of people with stroke undergoing rehabilitation and found significant gains in postural control as measured by decreased postural sway after training compared with a control group. In contrast, Hillier and Dunsford[12] used a 3SPACE tracker to assess postural control in 3 subjects, but found no significant difference after the sensory training period with the exception of improvement in one of the outcome measures in 1 participant. The varying responses to sensory retraining may be explained by the fact that Morioka and Yagi[10] trained hardness discrimination, whereas this was not specifically targeted in either the current study or that of Hillier and Dunsford[12] and perhaps hardness discrimination is a more important component of postural control than other forms of sensation. Alternatively, as outlined earlier, the improvements observed by Morioka and Yagi[10] may be due to increased time practicing standing rather than the sensory retraining activities.

The BBS[13,19-24] and timed gait[25,27-34] have been reported previously as being reliable measures that are sensitive to change in stroke patients in rehabilitation. The ILAS, originally designed for use in orthopedic patients, had not been analyzed in the stroke population prior to the current study. The walking aid subsection of the ILAS, which showed similar patterns over time and between groups as the BBS and timed gait, was deemed to be a useful outcome assessment tool in stroke subjects in rehabilitation, but the "points of contact" required to complete the 10-m walk was not shown to be sensitive to change in this sample.

The results regarding timed gait, the walking aid used to walk, and postural control, which all showed similar patterns of change in the absence of significant group effects, would suggest that the improvements in postural control and gait were more likely to result from a combination of time and the standard rehabilitation program received by both groups rather than the addition of sensory retraining. However, this cannot be conclusively stated, given the low power of the current study to detect group effects.

The sensory retraining intervention in the current study was not as effective as interventions previously reported in the stroke

literature.[5,7-10,12] This could be due to the fact that subjects in the current study were in the acute period after their stroke, whereas previous studies[5,7-9,12] have had more chronic subjects with more stable impairments. It could be that the upper limb, which has an important role in exploring the environment through sensation, is more responsive to treatment after stroke than the lower limb. The protocol in the current study was not tailored to the individual subjects, which is in contrast to the training protocols in the majority of the upper-limb sensory retraining studies. In addition, proprioception was trained using passive toe movements in supine, which is a relatively meaningless position for the lower limb, because the foot is normally most active in weight-bearing positions.

Study Limitations

A final limitation was that it was clearly impossible for the administering therapist to be blinded to group allocation. However, subjects and assessors were blinded to minimize the occurrence of any bias.

CONCLUSIONS

The protocol used in the current pilot study to retrain sensation in the feet of people with stroke undergoing inpatient rehabilitation was not found to be more effective than a control group receiving relaxation in improving sensation, balance, or walking ability. No firm recommendations regarding sensory retraining of the feet for stroke subjects undergoing rehabilitation can be made at this point due to the methodologic limitations of the current study and further research is warranted, using larger subject numbers, and implementing a revised retraining protocol. In addition, the use of measures such as DPT and the "points of contact" subsection of the ILAS may be of limited use in the stroke population.

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