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The BrainPort® balance device as a potential aid in the rehabilitation of balance and mobility after stroke or traumatic brain injury

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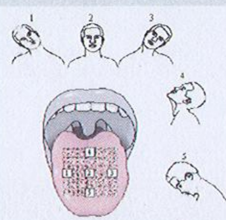
SUMMARY

We conducted a pilot study to investigate the effects of electrotactile sensory substitution using the BrainPort balance device in improving the balance and motor control of patients following stroke or traumatic brain injury (TBI). Standardized clinical test and measurements were administered to 7 TBI and 10 stroke subjects. All subjects demonstrated improvement in at least one clinical measure of balance, and no adverse events were reported.

THE BRAIN PORT BALANCE DEVICE IN STROKE AND TBI REHABILITATION

Balance dysfunction is a critical but commonly neglected dysfunction after stroke or TBI, significantly increasing the risk of falls for these patients. Although some patients improve with therapeutic intervention, many reach a plateau and are never able to return to their previous level of function.



The BrainPort balance device can provide a novel form of therapy with the potential to be integrated in the conventional rehabilitation regimen. Treatment with the BrainPort balance device is based on principles of sensory substitution and biofeedback. The device substitutes for the vestibular system by detecting the user's relative head position (through an accelerometer) and transmitting the information to the tongue in the form of electrical impulses correlated with the actual head position (electrotactile stimulation). With training, the brain learns to appropriately interpret electrotactile information displayed on the tongue, and thus to improve the motor control necessary for balance.

PREVIOUS STUDIES

Prior data show improvement in measures of balance following therapy with the BrainPort balance device.

Table 1. Vestibular dysfunction of peripheral origin

Test	Baseline	Post training (5 days)	Average % change
Computerized Dynamic Posturography Sensory Organization Test (SOT) Composite Score (n=19) [1]	47.9	61.8	35.6
Dynamic Gait Index (DGI) (n= 13) [2]	18.0	23.0	36.9
Activities-specific Balance Confidence (ABC) Scale (n=16) [2]	59.5	85.0	35.6
Dizziness Handicap Inventory (DHI) (n=13) [2]	60.0	16.0	50.3

Pilot study conducted at Wicab, Inc.; Etiology of balance dysfunction: ototoxicity, endolymphatic hydrops (Ménière's Disease), acoustic neuroma, mal de debarquement syndrome, labyrinthine fistulas, or unknown etiology.

Subjects also reported increased

- steadiness
- ability to walk in difficult environments
- ability to execute complex activities
- stamina

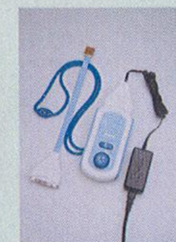


Table 2. Vestibular dysfunction following acoustic neuroma

Test (n=8)	Baseline	Post-training (8 weeks)	Average % change
Computerized Dynamic Posturography Sensory Organization Test (SOT) Composite Score [1]	57.9	70.3	22.2
SOT total falls	3.5	1.5	45.3
Dynamic Gait Index (DGI) [2]	19.0	22.5	22.0
Activities-specific Balance Confidence Scale (ABC) [2]	74.0	87.2	20.6
Berg Balance Scale (BBS) [2]	49.0	54.5	13.5
Dizziness Handicap Inventory (DHI) [2]	30.0	16.0	42.0

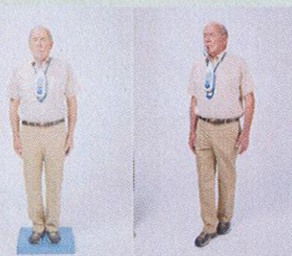
[1] average; [2] median

Pilot study conducted at Lahey Clinic, MA. Subject enrollment was specifically delayed for at least eight weeks after the surgery to better identify those subjects suffering from delayed or incomplete vestibular compensation

Standardized clinical tests of balance:

The Computerized Dynamic Posturography Sensory Organization Test **(SOT)** is used to evaluate the visual, somatosensory and vestibular affect on postural stability
The Dynamic Gait Index **(DGI)** is designed to assess the ability to perform movement tasks while walking and is used to determine risk of falls.
The Berg Balance Scale **(BBS)** tests 14 motor tasks common to everyday life.
The Timed Up and Go **(TUG)** measures the time taken in seconds required to rise from a chair, walk 3 meters, turn, and return to the original sitting position.
The Dizziness Handicap Inventory **(DHI)** is a self-assessment questionnaire designed to measure the subject's perception of their unsteadiness and dizziness.
The Activities-specific Balance Confidence **(ABC)** Scale is a self-assessment questionnaire designed to measure independence and functional limitations.
The **BIODEX** Balance System SD measures the subject's ability to maintain dynamic bilateral and unilateral postural stability on a static or unstable surface.

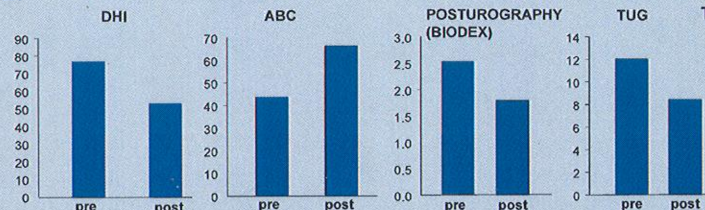
TRAINING AND TESTING



1. Subjects are given baseline assessments of postural stability, coordination, and subjective well being according to standardized tests.
2. Each subject is trained to perceive the dynamic patterns presented on the tongue as head position information and instructed to use the position of the stimulus on the tongue display to correct their posture without visual feedback (i.e. eyes closed) and with impaired proprioceptive feedback (e.g: altered foot position or standing on foam). Each subject participates in approximately 10 clinical training sessions (1 hour twice per day).
3. Subjects continue with home treatment for 4-12 weeks. During this period, the participant uses the device 20 minutes two times per day, separated by at least 4 hours.
4. All tests administered at baseline were also performed at the end of the in-home training

TBI

Pilot study conducted at Northern New Jersey Pain and Rehabilitation Clinic



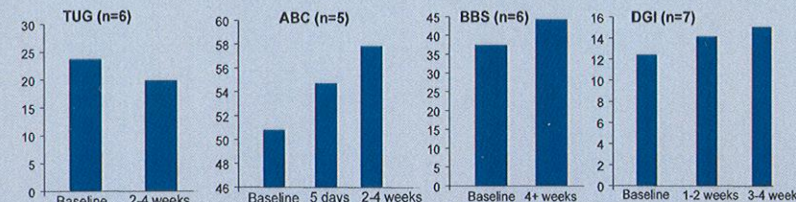
TBI subjects also reported improvements in:

- ambulation without assistance
- stair climbing
- walking
- standing on one leg
- tolerance of busy environments
- endurance
- driving
- mental clarity
- concentration

Changes in clinical tests of balance after four weeks of training in subjects with vestibular dysfunction due to TBI (n=7). The Dizziness Handicap Inventory (**DHI**) improved from 77.1 to 53.1, a 31% change, (0 = no handicap; 100 = significant handicap). The Activities-Specific Balance Confidence Scale (**ABC**) score improved from 43.8 to 66.3, a 51% change (0 = no confidence; 100 = complete confidence). The **BIODEX** balance stability index decreased from 2.5 to 1.8, or 28% (1.0 = no handicap; >1.0 = greater handicap). Timed Up and Go (**TUG**) score decreased from 12.3 to 8.7, or 27%. This clinically significant decrease placed the subjects outside the range for risk of falls (a TUG score >11.2 sec is correlated with risk of falls).

STROKE

Pilot study conducted at Wicab, WI, PT Center of Horseheads, NY, and Rehabilitation Hospital of Indiana.



Stroke subjects also reported:

- decreased loss of balance
- increased confidence
- increased gait speed
- more normal base of support
- improved control

Changes in clinical tests of balance and gait in subjects with vestibular dysfunction due to stroke (study in progress). Timed Up and Go (**TUG**) decreased from 23 sec to 20 sec (18%). The Activities-Specific Balance Confidence Scale (**ABC**) score improved from 51 to 58 (17.8%). The Berg Balance Scale score (**BBS**) improved from 38 to 43 (16.3%). The dynamic gait index (**DGI**) improved from 12 to 15 (23%).

CONCLUSION

Our preliminary data suggest that treatment with the BrainPort balance device may be effective in improving balance dysfunction after stroke or TBI, and support the feasibility of conducting a large controlled clinical trial to demonstrate the effectiveness of the device. Due to the suitability of the BrainPort balance device for both inpatient and outpatient training, the availability of an effective and convenient training and rehabilitation device would greatly reduce the burdens on PT staff, patients, and caregivers alike. The effective treatment of balance dysfunction could result in accelerated or improved overall rehabilitation for this patient population.

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