

BrainPort® Balance Device

VESTIBULAR STUDY SUMMARY



The BrainPort balance device, developed by Wicab, Inc., provides head position information via electro-tactile stimulation of the tongue. With training, patients learn to use the positional information presented on their tongue to improve their balance.



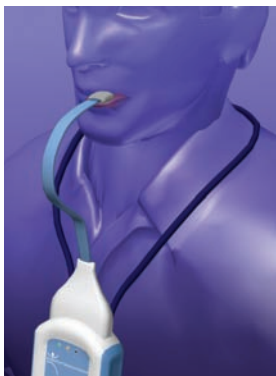


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The BrainPort balance device consists of an Intra Oral Device (IOD) and a Controller. The IOD contains an embedded accelerometer and an electrode array. The electrode array rests on the anterior surface of the patient's tongue. The accelerometer, located on the reverse side of the electrode array, measures head position. Using these measurements, a stimulus pattern is generated on the electrode array reflecting the patient's position. The patient feels the pattern as electrotactile stimulation on the tongue. For example, if a patient leans to the left, the stimulus moves to the left side of the patient's tongue; a forward lean moves the stimulus to the front of the tongue. During training, patients are instructed to focus on the stimulus and adjust their body position to maintain the stimulus on the center of their tongue. The Controller provides user controls for power, stimulation intensity, and re-centering the stimulus on the electrode array.

STUDY DESIGN



This study summary compiles data from 17 clinical sites participating in prospective studies designed to measure balance-related changes that resulted from training with the BrainPort balance device. Study duration and assessments utilized were determined in consultation with the primary investigator at each site. The BrainPort device training procedure was consistent across all sites.

CLINICAL RESEARCH SITES*

- University of Wisconsin-Madison, WI
- Legacy Clinic, Portland, OR
- Lahey Clinic, Burlington, MA
- Northern New Jersey Pain & Rehabilitation Clinic, Hackensack, NJ
- Emory University, Atlanta, GA
- Lakeview Medical Center, Suffolk, VA
- Rensselaer Institute, Boca Raton, FL
- Silverstein Institute, Sarasota, FL
- Rehabilitation Hospital of Indiana, Indianapolis, IN
- England Physical Therapy, Los Angeles, CA
- Physical Therapy Center of Horseheads, Horseheads, NY
- Wicab, Inc., Middleton, WI

* List is not exhaustive. Not all clinical sites allow release of name in non-institutional publications.

SUBJECTS

A total of 112 subjects (58 male, 54 female; average age 62.7 ± 15.6 years) with chronic balance deficits due to central and/or peripheral vestibular dysfunction were enrolled. All subjects had been diagnosed with a balance deficit at least three months prior to enrollment. A substantial majority of the subjects had reached a plateau in conventional therapy prior to study participation.

AREA OF IMPAIRMENT	N (%)
Central Vestibular	54 (48%)
Peripheral Vestibular	51 (46%)
Mixed	7 (6%)

ETIOLOGY	N
Bilateral Vestibular Dysfunction	33
Stroke	30
Unilateral Vestibular Dysfunction	17
Age Related Vestibular Changes	13
Brain Injury	10
Other	9

BRAINPORT DEVICE TRAINING

Subjects received clinical training for three–five consecutive days (two, one-hour sessions each day) with the BrainPort balance device. Subjects then continued training at home for two, 20-minute sessions each day for the duration of the study.

ASSESSMENTS

Subjects were assessed at baseline and at pre-determined points during the study as determined by the individual investigators. Subjects did not use the BrainPort device during the assessments. Clinical sites did not necessarily administer all assessments, resulting in a smaller number of subjects for individual measurements. Changes in balance were measured using the following objective and clinically accepted standardized outcome measures:

- Computerized Dynamic Posturography Sensory Organization Test (SOT)
- Dynamic Gait Index (DGI)
- Activities-Specific Balance Confidence (ABC) Scale
- Dizziness Handicap Inventory (DHI)

RESULTS

RESULTS AFTER > 2 WEEKS, UP TO 11 WEEKS OF USE				
Test	N	Mean Change	SD ¹	P Value ²
Composite SOT ³	50	9.8	11.2	<0.001
DGI ⁴	72	3.2	3.6	<0.001
ABC Scale ⁵	77	13.3	16.7	<0.001
DHI ⁶	62	10.9	19.0	<0.001

¹SD = Standard Deviation

²P value calculated via paired t-tests

³Composite SOT: score range 0–100

⁴DGI: score range 0–24

⁵ABC Scale: score range 0–100

⁶DHI: score range 0–100

CONCLUSION

Subjects show statistically significant improvement, on average, in all measures. Prior to study participation, a substantial majority of the study subjects completed conventional rehabilitation, but continued to report balance deficits. The balance improvements achieved in this study are independent of improvements reached in conventional rehabilitation.

These improvements in standardized outcome measures demonstrate that training with the BrainPort balance device positively affects balance. The results indicate that the BrainPort balance device can be a convenient and effective training tool for people with balance dysfunction.

ONGOING RESEARCH

A multi-site controlled study is underway to support the efficacy of the BrainPort balance device and to corroborate the findings reported above. Wicab, Inc. is actively recruiting additional clinical sites. Please contact Wicab, Inc. for additional information about participation in research studies with the BrainPort balance device.



The BrainPort balance device is licensed by the Therapeutic Products Directorate of the Health Canada Medical Devices Bureau; it meets the requirements of the European Medical Device Directive and is available for sale in Canada, Brazil, Russia and the European Union.

Caution: Investigational Device—Limited by United States Law to Investigational Use



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