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# Efficacy of electrotactile vestibular substitution in patients with peripheral and central vestibular loss

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## Abstract

Vestibular dysfunction of either central or peripheral origin can significantly affect balance, posture, and gait. We conducted a pilot study to test the effectiveness of training with the BrainPort® balance device in subjects with a balance dysfunction due to peripheral or central vestibular loss. The BrainPort® balance device transmits information about the patient's head position via electrotactile stimulation of the tongue. Head position data is sensed by an accelerometer and displayed on the tongue as a pattern of stimulation. This pattern of stimulation moves forward, backward, and laterally on the tongue in direct response to head movements. Users of the device were trained to use this stimulation to adjust their position in order to maintain their balance.

Twenty-eight subjects with peripheral or central vestibular loss were trained with the BrainPort balance device and tested using the following standardized quantitative measurements of the treatment effects: Computerized Dynamic Posturography (CDP) using the Sensory Organization Test (SOT), Dynamic Gait Index (DGI), Activities-specific Balance Confidence Scale (ABC), and Dizziness Handicap Inventory (DHI). All subjects had chronic balance problems and all but one had previously participated in vestibular rehabilitation therapy. The scores on the clinical tests upon entry into the study were compared to their scores following training with the BrainPort balance device. Our results exhibit consistent positive and statistically significant improvements in balance, posture and gait. These results exceed what could normally be achieved in three to five days of traditional balance training alone. Since this was not a controlled study, we are unable to distinguish the degree to which these improvements are attributable to training with the BrainPort balance device versus the balance exercises performed by all subjects as a part of the BrainPort training sessions. Nonetheless, after training with the BrainPort balance device, all subjects demonstrated significant improvements in performance beyond what might be expected from conventional vestibular rehabilitation therapy.

### Keywords

Vestibular rehabilitation; peripheral vestibular; central vestibular; electrotactile stimulation; biofeedback; sensory substitution; balance

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## 1. Introduction

The maintenance of normal upright posture and both static and dynamic balance is mediated by a complex sensorimotor control system that relies on the integration of multiple sensory inputs: proprioceptive, visual, and vestibular [8–12,16,17]. The vestibular system contributes information about head position, which the central nervous system combines with other sensory input to regulate balance [8]. In the absence of a fully functional vestibular system, the brain has difficulty correctly integrating visual and proprioceptive cues. Persons with peripheral vestibular and central vestibular loss often experience multiple problems with posture control and movement, including unsteady balance, abnormal gait, and oscillopsia. These effects make it difficult for many patients with vestibular loss to engage in daily activities such as walking in low-light or busy environments, walking on uneven surfaces, bending forward to pick something up, driving a car, or reading a book. Some patients develop compensatory strategies for these activities, while others simply avoid them as much as possible.

Wicab, Inc. has developed the BrainPort® balance device, which transmits relative head position information through a substitute sensory channel: electro-tactile stimulation of the tongue [2,6,21]. Our previous research suggests that information from a sensory substitution device can replace information from an affected natural sensory system [1,3,4]. Head position data (artificially sensed by a micro-electro mechanical system (MEMS) accelerometer) serve as the input signals for the BrainPort balance device. Using this data, the device generates a small pattern of stimulation on the tongue that relates to head position in real time. The device user learns to keep the stimulus centered in the middle of the electrode array to maintain proper posture. A specialized set of training procedures were developed to serve as the course of therapy with the BrainPort balance device.

We hypothesized that with training, the information presented on the tongue from the BrainPort balance device could be acquired, retained, and transferred by the user to improve both static and dynamic balance. This manuscript describes a pilot study designed to investigate the potential efficacy of BrainPort balance training on several patient populations with chronic balance and postural problems due to either central or peripheral neurosensory disorders

## 2. Methods

### 2.1. Device

The BrainPort balance device (Fig. 1) has two principal components: the intraoral device (IOD) and the controller. The IOD is made up of an electrotactile array and a MEMS 3-Axis, ± 2 g, digital output accelerometer (manufactured by ST Microelectronics). Our current model BrainPort device utilizes both the horizontal (x, y), and vertical (z)axes. A flexible tether connects the IOD to the controller. The MEMS accelerometer senses head position in both the anterior/posterior and medial/lateral directions and is mounted on the superior surface of the electrode array (away from the tongue). The accelerometer is encapsulated in a silicone material to ensure electrical isolation from the user.

Electrotactile stimuli are delivered to the dorsum of the tongue by the 10 × 10 element electrode array (Fig. 1 inset). The IOD array and tether are fabricated as a flexible circuit using industry-standard photolithographic techniques employing a polyimide substrate. One hundred conductors in the tether are connected to array electrodes, while the remaining six conductors provide power and communication links to the accelerometer. The 1.5 mm diameter electrodes are arranged in a square pattern on 2.32 mm centers. The array footprint is 24 mm × 24 mm. Each electrode is plated with a 127 nm thick layer of gold. The tether (12 mm wide × 2 mm thick) connects the electrode array and accelerometer to the controller.

The controller contains an embedded computer (ColdFire® MCF5249C, 120 MHz, 32-bit microprocessor), stimulation circuits, user controls, and battery power supply. Custom software operating on the controller converts signals from the accelerometer in the IOD into a dynamic 2 × 2 electrode pattern of electrotactile stimulation. Control buttons allow the user to preset their own maximum stimulation intensity levels. The BrainPort has been tested to comply with international consensus standards for electrical safety in medical devices.

**2.1.1. Stimulation waveform—**The electrotactile waveform at each electrode is generated by the controller. The stimulation is created by a sequence of three 25 μs wide pulses presented at a rate of 200 Hz. The amplitude value of the pulse sequence or 'burst' is updated at 50 Hz. Output coupling capacitors in series with each electrode assure zero net DC current to minimize the potential for tissue irritation. This waveform, developed during previous years of research [14,15], produces a tactile stimuli that is perceived by users as a continuous 'buzzing' or 'tingling' sensation, with minimal sensory adaptation. (Fig. 2).

**2.1.2. Linear vs. angular acceleration—**The MEMS accelerometer used by the BrainPort balance device is responsive to both dynamic (due to linear motion) and static (due to gravity) acceleration. In the balance application, where patients are trained to maintain a semi-static position, typical motion is a low frequency sway (less than 2 Hz) with small angular displacement. In addition, patient sway angles are within 12 degrees anterior, 6 degrees posterior, and even less laterally. In this situation, the angular component of the accelerometer output dominates.

The goal of subject training is to minimize stimulus displacement and keep the stimulus centered. The magnitude of stimulus displacement is simply scaled under software control, and has been fixed for all trials and training sessions. The scaling has been calibrated to a static tilt measurement of ± 14 degrees on each axis, and any excursion (regardless of the mechanism) beyond that limit is clipped. With ten electrodes, stimulus displacement is in incremental steps of 2.8 degrees (static). Kinematic data collected by Wicab (unpublished),[1] shows that the use of a linear accelerometer alone is sufficient to provide directional information to the subject, when the device is used in the relatively static training environment. Rate sensor data coupled with linear accelerometer data could offer a more precise measure of angular and linear displacement, however, in this application, it is not necessary, as long as the stimulus displacement is in the correct direction (the direction of tilt).

**2.1.3. Tongue stimulation—**Head position information derived from the accelerometer is used to position the tactile stimulus pattern on the tongue display (electrode array). The accelerometer data is acquired at 50 Hz for the purpose of feedback to the user. In the current implementation, mapping the 12-bit data to the 10 × 10 oral tactile array causes 'binning' of the output signal into 2.8 degree increments (both x (lateral) and y (anterior/posterior)) to individual tactor rows or columns, to a maximum range of ± 14 degrees in each direction. Consequently, high frequency small amplitude motion signals typically stay within a bin and are not detected by the user. In prototype testing, (2 subjects included in this study), a slightly different instrumentation configuration was used, where x and y values for the target position were calculated as the difference between the values of the position vector at the starting or 'zero' position, time $t_0$ and any point subsequent point in time, $t_n$, by: $x_n = c \sin(\Theta_{x(n)} - \Theta_{x(0)})$, and $y_n = c \sin(\Theta_{y(n)} - \Theta_{y(0)})$. The values for $\Theta_{x(n)}$, $\Theta_{x(0)}$, $\Theta_{y(n)}$, and $\Theta_{y(0)}$, were the instantaneous and initial tilt angles in *x* and *y*, respectively. A linear scaling factor, 'c', was used to adjust the stimulus pattern range of motion to ensure that these two systems were functionally equivalent.

[1]TR070023, Vestibular Phase 2.2, Accelerometer-Compass Data Collection.

Figure 3 shows the location of the 2 × 2 stimulation pattern on the tongue relative to head position. The maximum range of pattern position is also limited so that in the event that the subject head position temporarily exceeds the range limit of the display, the pattern remains at the outer edge so that they do not lose the stimulus, and therefore position information, during this period.

### 2.2. Subjects

Studies using electrotactile vestibular substitution with the BrainPort balance device were performed in the United States (University of Wisconsin, Madison, Missouri State University in Springfield, Missouri, Legacy Health Clinic in Portland, Oregon) and Medway Maritime Hospital in Kent, England. A total of 28 subjects, 13 males (mean age 61.5 ± 11.6) and 15 females (mean age 57.1 ± 15.3) with chronic balance dysfunction due to peripheral or central etiologies (average period of 7.2 years from onset of disorder to the time of BrainPort training) were trained with the Brain-Port balance device (Table 1). Subjects with a diagnosis of "idiopathic" were determined by their physician to have a vestibular disorder of unknown cause. Oto-toxicity was a systemic side effect as a result of Gen-tamicin administered during a surgical procedure. All subjects with Mal de Debarquement Syndrome were referred by a single physician with experience in this disorder. Diagnosis of Mal de Debarquement Syndrome was determined by a combination of symptom description (patient reports constant rocking sensation, has balance issues, and sometimes visual disturbances that begin typically after disembarking from a plane, boat or moving vehicle; being at rest intensifies symptoms) and normal/negative test results (i.e. MRI and ENGs).

Subjects came from a number of clinics, and had been evaluated by several different specialists with expertise in balance disorders (Otolaryngologists (8), Neurologists (3), Neurotologists (3), Audiologists (1), and Internal Medicine (1)). Since this was a pilot study, the inclusion/exclusion criteria for this study was very broad. Inclusion criteria were anyone with a chronic balance dysfunction due to a vestibular problem. Exclusion criteria were pregnant women, those with communicable diseases (HIV, TB, hepatitis), those with oral health problems such as open sores in the mouth or tongue, or neuropathies of the tongue, those with mental health problems, and those with symptoms due to myasthenia gravis, Charcot-Marie Tooth disease, post-polio syndrome, Guillan-Barré, fibromyalgia, chronic fatigue syndrome, herniated disc or osteoarthritis of the spine. All subjects gave informed consent. The study was performed under IRB-approved protocols from the corresponding sites.

All but one subject had previously been treated with conventional vestibular rehabilitation therapy (VRT) but continued to experience balance deficits, which affected their daily activities. They reported some compensation due to either vestibular rehabilitation or adaptation with time, and felt that they had reached a plateau. Learned compensatory strategies may include increased use of intact functioning systems (vision and somatosensory), cognitive strategies applied to functional tasks, task avoidance, and/or use of an assistive device.

All subjects included in our study demonstrated noticeable difficulties with some aspect of balance, such as walking on uneven surfaces, moving in low-light conditions, or navigating in busy environments. Some of the subjects with bilateral vestibular loss (BVL) had developed the ability to stand with eyes closed on a hard surface. Yet even for these well-compensated BVL subjects, standing on a soft or uneven surface, or in stances with a limited base of support (e.g. tandem Romberg) was very challenging, and not possible with eyes closed. Subjects reported that their balance worsened with fatigue and with decreased attentiveness. Performance on standardized dynamic posture and functional gait tests was typically poor (Table 2, pre-treatment scores).

### 2.3. Standardized testing

The subjects were tested by a Physical Therapist at baseline and after the last BrainPort training session. All tests were performed without the BrainPort device.

The primary objective measure was performance on a Computerized Dynamic Posturography (CDP) system using the Sensory Organization Test (SOT) protocol performed on the NeuroCom® Smart Equitest system. TheSOT objectively measures the subject's use of visual, somatosensory and vestibular input on postural stability. In this test, the subject stands on a computerized platform in various conditions (eyes open, eyes closed, surrounding walls moving, platform surface moving, platform surface moving with eyes closed, and walls and platform surface moving together). Three trials are performed in each condition. The computerized platform measures and calculates the subject's postural stability based on the subject's input through the platform force plates during the various conditions [18,19]. Conditions 5 and 6 of the SOT test a person's ability to maintain balance when both visual and somatosensory inputs are altered. If a patient is unable to complete a trial during the test, it is marked as a "fall," resulting in a score of 0. Individual results are compared to age-normalized data. The subject's baseline scores were compared to follow-up scores to determine efficacy of rehabilitation treatment.

Scores on the SOT do not necessarily correlate to improvement in functional tasks [7,20]. Subsequently, we also included the Dynamic Gait Index (DGI), Activities-specific Balance Confidence Scale (ABC), Dizziness Handicap Inventory (DHI), and functional balance tests of standing with eyes open and closed, standing on one leg, standing in tandem Romberg position with eyes open and closed, and walking on a straight line. Since these assessments were added after we began testing subjects, the first 7 subjects did not perform all of the tests. A majority of the subjects were videotaped as they performed the DGI and objective tests.

The DGI was developed to assess the likelihood of falling in older adults. It is used to measure a person's ability to perform movement tasks while walking. It has been correlated to falls in persons with vestibular disorders [25]. The tester rates performance from 0 (poor) to 3 (excellent) on eight different gait tasks, including gait on even surfaces, gait when changing speeds, gait and head turns in a vertical or horizontal direction, stepping over or around obstacles, gait with pivot turns and steps. Scores range from 0 to 24. A score of 19 or below is correlated to a high risk of falls [23,25].

The ABC scale is a self-assessment questionnaire designed to measure a subject's confidence in performing daily activities. Patients rate their perceived confidence in performing 16 activities of daily living without a loss of balance. A score of 100 indicates full confidence in independently performing daily activities [22].

The DHI is a self-assessment questionnaire designed to quantify the patient's perception of their unsteadiness in every day functions. Scores range from 0 to 100. A score of 0 indicates no handicap, and score of 100 indicates a significant self-perceived handicap. A change of 18 points indicates a clinically significant change in the subject's self-perceived disability [13].

Subjects recorded in a daily journal how long they felt their balance improvements lasted after each training session. They evaluated how easy it was for them to perform daily tasks, and repeated simple tests, such as walking on a straight line or standing in tandem Romberg position at hourly time intervals after training. These tasks were performed without actively using the device. Evaluations were also completed by each subject and the research team at the end of the training period.

The post-training tests took approximately one hour to perform and were typically completed within 1 to 2 hours of the last 20-minute training session with the BrainPort balance device. The tests were performed without the subjects using the BrainPort balance device. No testing was done with the feedback turned on.

### 2.4. Training procedure

Upon completion of the baseline balance assessments, the subjects underwent training with the Brain-Port balance device. The typical BrainPort training regimen included 1 to 1½ hour treatment sessions twice daily for 3 to 4½ days in the clinic. The clinical treatment sessions included training in joint mobility exercises, and balance training using the BrainPort balance device.

Joint mobility exercises were performed by all subjects before training with the BrainPort balance device. Individuals who have a balance dysfunction live with a constant fear of falling. In order to compensate for this, they typically maintain a guarded posture. This causes increased muscular tension and stiffness through the neck, shoulders, arms, back and hips, limiting their ability to make the necessary segmental postural adjustments for maintaining relaxed and upright posture. Mobility exercises such as chin tucks, forward and backward shoulder rolls in the scapular plane, pelvic tilts, and hip hikes, help the subjects learn to isolate the joints and relax the tense muscles, facilitating their ability to respond to the electrotactile signal and make the necessary adjustments to maintain their balance.

To learn how to use the BrainPort device, the subjects were instructed to place the electrode array on the top and front part of their tongue. To hold it in place, they closed their lips and gently pressed it to the roof of their mouth. Holding the IOD in their mouth did cause drooling in some cases. Since accumulating a large amount of saliva in the mouth results in a loss of the electrical signal, the subjects had to learn to swallow while keeping the IOD in place. The subjects were told that the accelerometer would detect their head position and relay that information to the electrode array on their tongue. The stimulation would cause a tingling that feels like “bubbles” on their tongue. Their goal during training was to keep the signal in the center of the array by responding to the direction of the signal on their tongue. For example, if they leaned forward, the signal would move to the front of their tongue and they were to adjust their body backward to bring the signal back to the center of the array.

The intent of training was to limit the magnitude of sway by having the subjects adjust their body position in order to keep the stimulus in the center of the display on their tongue. The subjects were instructed to use combined joint movement through the hips, knees and ankles to adjust their position, while keeping their head still.

Balance training with the BrainPort device was divided into a succession of shorter trial periods (1 to 5 minutes) and one 20-minute trial period. Training was individualized to each subject. They began training in a position that was challenging and were given progressively harder tasks to challenge their balance until they reached a threshold that they could not exceed. The training positions used were sitting on a chair, sitting on a physioball, standing on the floor, standing on high density (5.5 lb.) visco-elastic memory foam, standing on an Airex® balance pad (a closed cell foam, approximately 2½ inch thick), and standing in modified and tandem Romberg positions. For each trial, subjects stood behind a counter with the BrainPort® balance device around their neck and the IOD in their mouth, closed their eyes, and were to use the signal on their tongue to sense their position. They were to adjust their body to keep the signal centered, touching the counter if needed. Subjects progressed to the next level when they were able to perform a trial with their eyes closed without needing assistance to maintain their balance. The subjects worked on progressing through the challenging positions for a 30 to 45 minute period. They were then given a 5 to 10 minute rest period, and performed a 20-minute

uninterrupted trial with eyes closed, working in a position that was comfortable but challenging. All balance training was done with the physical therapist closely guarding the subject.

The positions used during training were determined by the patients' ability to stand with their eyes closed while maintaining their balance with electrotactile feedback from the device. Training was individualized, therefore usage time varied from subject to subject. The actual time each subject used the device can be found in Table 3.

## 3. Results

### 3.1. Observational results

Gait improved in all subjects with affected gait (central and peripheral etiologies). We observed integration of various gait components such as appropriate weight transfer, knee flexion during the swing phase after toe-off, smooth heel-strike to foot-flat, appropriate lateral foot positioning, more equal and normal step length, greater inter-limb coordination, smoother movement flow and return of natural arm swing.

Subjects demonstrated improvement in approximately 55% of the functional balance tests. For example, 6 of 7 subjects who were unable to stand with their eyes closed before training were able to complete this task after training with the BrainPort balance device, and 7 of 12 subjects who were unable to walk in a straight line before training were able to walk in a straight line after training with no deviations.

The subjects demonstrated a significant improvement in static posture, in terms of both stability and endurance. In some cases, muscular tension in postural groups became more appropriate; accessory movements and inappropriate muscle group recruitment diminished, resulting in decreased general and muscular fatigue.

All subjects reported improvement in other balance-challenging activities. Sixteen subjects reported less general fatigue, making statements such as "I have more energy throughout the day." The subjects reported improvement in balance with functional activities after training with the BrainPort balance device compared to their level of function after reaching a plateau with traditional vestibular rehabilitation therapy.

### 3.2. Standardized testing results

Individual test results can be seen in Table 2. In reviewing the standardized results, we found statistically significant improvement in the composite SOT, DGI, ABC, and DHI scores (Table 4).

Improvement in the SOT is demonstrated primarily by an increase in score. All 28 subjects demonstrate improved scores in the composite SOT after receiving treatment for an average of 4.3 days. The improvement in composite SOT scores varied individually, with an average improvement of 42%. 50% of the subjects also experienced a decrease in the number of falls on conditions 5 and 6 of the SOT.

The scores for SOT 5 and 6 in Table 2 reflect the no-falls trials. 8 of 28 subjects had falls on all trials of conditions 5 and 6 before and after training. Of those subjects with measurable scores, 17 of 19 (89%) subjects demonstrated an improvement in score on condition 5, and 15 of 19 (79%) subjects demonstrated an improvement in score on condition 6. Three subjects who had falls on all 3 trials of condition 5 at baseline were able to complete 1, 2 or 3 trials on condition 5 after training with the BrainPort balance device. The average improvement on SOT 5 for those who had a no-falls score was 36.5%. Two subjects who had falls on all 3 trials of condition 6 at baseline were able to complete 2 of 3 trials after training. The average

improvement on SOT 6 for those who had no-falls score was also 36.5%. No subjects had an increase in the number of falls on SOT 5 and 6.

Additionally, the average DHI score improved an average of 47%, and the average ABC score improved 38%, both indicating improvement in the subjects' self-perceived ability to perform daily functional activities. Subjects who initially had scores of 19 or lower on the DGI increased by an average of 30%.

Most subjects reported increased retention of balance improvements correlating to the number of BrainPort training sessions. As the number of days of training with the device increased, time of balance retention increased. However, no correlation was found between actual BrainPort usage time and change in scores on the composite SOT, DHI, ABC or DGI.

Analysis of the results based on etiology revealed a slightly higher improvement in all scores for subjects with peripheral vestibular disorders (Table 5). Subsequent analysis of the SOT results based on age revealed little to no difference between the groups that were compared, and improvement was seen throughout (Fig. 4).

Ten of the subjects continue to use the device at home and have been doing so for anywhere between 6 months and 3 years. Some of the subjects use the device twice daily (20 minute sessions), while others use it less often. These subjects all report that they continue to maintain, and in some cases further improve, their balance. We have only reassessed two of the ten using the SOT, DHI, DGI and ABC, confirming their reports.

### 3.3. Retained benefits

Subjects demonstrated improved posture and balance when training with the BrainPort balance device. More significantly, subjects retained those benefits after training with the device, but without actively using the device. The amount of time they were able to retain the benefits increased with device training time.

Subjective reports supported the measured retention effect. All subjects reported the ability to retain improvements in balance, posture and gait after training with the BrainPort balance device when not actively using the device. This was evident in improved ease of performing daily tasks and activities that required balance, such as getting in and out of a car, walking on uneven surfaces, and getting dressed. The typical pattern of improvement showed that with an increasing number of days of training, the time of retention also increased. For some subjects, the period of improvement after a 20-minute training session developed from the initial few hours to 24 hours or more after training with the device for 5 days. No subjects reported adverse or negative side effects.

### 3.4. Summary of results

Overall, all subjects reported significant improvements in balance control and sensory-motor coordination following treatment with the BrainPort balance device, although the rate and magnitude of balance recovery varied from subject to subject. All subjects were trained and tested in a consistent manner and, regardless of etiology (peripheral, central, or vestibulo-cerebellar dysfunction), progressed through three successive stages in the process of balance recovery:

*Balance Signal Acquisition* – Typically, within 5–10 minutes of initial familiarization with BrainPort stimulation, subjects were consistently able to use the head-position information to maintain stable vertical posture and body alignment (standing with closed eyes) for periods of up to 20 minutes.

*Balance Retention Effects* – We found that retention is dependent on two factors, the duration of each training session and the number of sessions per day. The shortest retention effects, usually lasting only 1–2 hours, are observed during the initial training sessions, whereas by the end of the 3–5 day training period, the average duration of retention after a single 20-minute training session is 4–6 hours. Additionally, we observed that retention after the second session of the day typically lasts longer.

*Functional Balance Transfer* – We observed improved balance in functional dynamic activities. Movements were smoother when transitioning from sit to stand and during ambulation. Gait was more stable, including walking on stairs, uneven surfaces and in the dark. Additionally, while walking, independent head-eye motion (i.e. ability to search for an object while moving) improved, arm swing was more symmetrical and coordinated, lower extremity stance and swing phases approached normal, and walking speed increased. Subjects reported increased confidence in performing daily activities. They were able to walk in crowds and navigate new environments without loss of balance. Overall, subjects reported improved ability in functional activities that require balance.

## 4. Discussion

The goal of this study was to test the short-term efficacy of the BrainPort balance device on patients with a balance dysfunction due to a variety of pathologies. Because of the diversity of the sample, there is no single patient population with a large enough subgroup to draw statistically significant conclusions. These preliminary results, when taken as a whole, however, suggest that training with the BrainPort balance device may be effective for improving balance in patients having a wide variety of etiologies.

The largest group of subjects studied experienced bilateral vestibular loss due to gentamicin ototoxicity, and typically exhibit chronic difficulty with balance. This group exhibited substantial improvements in the balance tests and balance-related activities after training with the BrainPort balance device. One individual had not only gentamicin ototoxicity, but also bilateral below knee amputations. After 18 months of prosthetic training and vestibular rehabilitation, he had reached a functional performance plateau, and continued to have difficulty with balance. After training with the BrainPort balance device his progress followed the same path as the other gentamicin ototoxic subjects, although the improvements took longer to occur. He continued to use the device for one year and maintained his new level of improvement. This suggests that training with the device is effective for a patient with limited proprioceptive input in addition to bilateral vestibular loss.

All of the subjects had experienced chronic balance problems for over 1 year. This suggests that spontaneous recovery was unlikely. All but one of the subjects in our study had participated in traditional VRT prior to training with the BrainPort balance device, although they did not all follow the same treatment plan. Therefore, some of the improvements demonstrated in our results may be attributed to the rigorous balance training alone.

Improved balance that may occur with static balance training alone does not necessarily transfer to functional tasks. We observed, however, retention of improved balance in functional activities after 5 or fewer days of training with the BrainPort balance device. The reports from participants in this study indicate the profound impact training with the BrainPort balance device had on their daily activities.

The training progression was individualized to each subject, which resulted in variability in actual BrainPort usage. Even with this variability, we observed improvements in balance consistent with number of days of training, suggesting that retention develops and accumulates with regular use over time.

We had hypothesized that with training, the information from the BrainPort balance device could be appropriately interpreted by the users to improve their balance. Indeed, improvements in balance, posture, gait and other daily activities were demonstrated by the results of standardized assessments. This suggests that the training regimen can improve the balance of patients with chronic balance and postural problems due to either central or peripheral neurosensory disorders.

## 5. Conclusion

Since this was not a controlled study, we cannot determine how much of the observed changes occurred due to training with the BrainPort balance device, or due to a balance training effect. Subjects who trained with the BrainPort balance device demonstrated improvements in balance, posture and gait. The improvements shown after training exceed what subjects had achieved with traditional therapy. These results suggest that head-position information, when presented to the tongue via electrotactile stimulation, may positively affect postural and balance function in subjects across a broad range of vestibular (peripheral and central) and vestibulo-cerebellar based balance disorders. Training with the BrainPort balance device exhibits promising potential for rehabilitation in patients with balance dysfunction.

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## References

1. Bach-y-Rita P. Emerging concepts of brain function. J Integr Neurosci 2005;4:183–205. [PubMed: 15988797]
2. Bach-y-Rita P, Danilov Y, Tyler ME, Grimm RJ. Late human brain plasticity: vestibular substitution with a tongue *BrainPort* human-machine interface. J Intellectica 2005;40:115–122.
3. Bach-y-Rita P, Kercel SW. Sensory substitution and the human-machine interface. Trends Cogn Sci 2003;7:541–546. [PubMed: 14643370]
4. Bach-y-Rita P, Kaczmarek KA, Tyler ME, Garcia-Lara J. Form perception with a 49-point electrotactile stimulus array on the tongue. J Rehabil Res Dev 1998;35:472–430.
5. Black, FO.; Wood, SJ.; Bach-y-Rita, P.; Danilov, YP.; Tyler, ME.; Stallings, VJ. Electrotactile Sensory Supplementation of Gravitoinertial References to Optimize Sensori-Motor Recovery of Postural Stability in Bilateral Vestibular Loss Subjects; Proceedings of the 28th Annual Midwinter Research Meeting of the Association for Research in Otolaryngology; Feb 19–24; New Orleans, LA. 2005.
6. Danilov, YP.; Tyler, ME.; Bach-y-Rita, P. Vestibular Substitution for Postural Control. In: Lofaso, F.; Ravaud, J-F.; Roby-Brami, A., editors. Innovations Technologiques et Handicap: Actes des 17e[s] Entretiens de l'Institut Garches. Vol. 17. Paris, France: Frison-Roche: Institut Garches, Entretiens; 2004. p. 216-224.Issy-les-Moulineaux; November 25–26, 2004
7. Evans MK, Krebs DE. Posturography does not test vestibulospinal function. Otolaryngol Head Neck Surg 1999;120:164–673. [PubMed: 9949347]
8. Herdman, SJ. Vestibular Rehabilitation. Philadelphia, PA: F.A. Davis Company; 2000.
9. Horak FB, Hlavaca F. Somatosensory loss increases vestibulospinal sensitivity. J Neurophysiol 2001;86:575–585. [PubMed: 11495933]
10. Horak, FB.; Macpherson, JM. Postural orientation and equilibrium. In: Shepard, J.; Rowell, L., editors. Handbook of Physiology. New York, NY: Oxford University Press; 1996. p. 255-292.
11. Jeka J, Lackner JR. Fingertip contact influences human postural control. Exp Brain Res 1994;100:495–502. [PubMed: 7813685]

12. Jeka J, Oie KS, Schoner G, Dijkstra THM, Henson EM. Position and velocity coupling of postural sway to somatosensory drive. J Neurophysiol 1998;79:1661–1674. [PubMed: 9535937]

13. Jacobson GP, Newman CW. The development of the Dizziness Handicap Inventory. Arch Otolaryngol Head Neck Surg 1990;116:424–427. [PubMed: 2317323]

14. Kaczmarek, KA.; Tyler, ME. Effect of electrode geometry and intensity control method on comfort of electrotactile stimulation on the tongue; Proc of the ASME Haptics in VR Conference; Oct. 12–15; Orlando, FL. 2000. p. 1239-1243.

15. Kaczmarek KA, Webster JF, Radwin RG. Maximal dynamic range electrotactile stimulation waveforms. IEEE Trans Biomed Eng 1992;39:701–715. [PubMed: 1516937]

16. Lackner JR. Multimodal and motor influences on orientation: Implications for adapting to weightless and virtual environments. J Vestibular Res 1992;2:307–322.

17. Lackner JR, DiZio P, Horak F, Krebs D, Rabin E. Precision contact of the fingertip reduces postural sway of individuals with bilateral vestibular loss. Exp Brain Res 1999;126:459–466. [PubMed: 10422708]

18. Neurocom® International Inc. Computerized Dynamic Posturography Defined. Available at: http://www.onbalance.com/program/role/cdp/defined.aspx

19. Neurocom® International Inc. Sensory Organization Test (SOT). Available at: http://www.onbalance.com/neurocom/protocols/sensoryImpairment/SOT.aspx

20. O'Neill DE, Gill-Body KM, Krebs DE. Posturography Changes do not predict functional performance changes. Am J of Otology 1998;19:797–803. [PubMed: 9831157]

21. Plagenhoef S, evans FG, Abdelnour T. Anatomical data for analyzing human motion. Res Q Exerc Sport 1983;54:169.

22. Powell LE, Myers AM. The Activities-specific Balance Confidence (ABC) Scale. J Gerontol A Biol Sci Med Sci 1995;50A:M28–M34. [PubMed: 7814786]

23. Shumway-Cook, A.; Woollacott, M. Motor Control: Theory and Practical Applications. 1st ed.. Baltimore, MD: Williams and Wilkins; 1995.

24. Tyler ME, Danilov YP, Bach-y-Rita P. Closing an open-loop control system: Vestibular substitution through the tongue. J Integr Neurosci 2003;2:159–166. [PubMed: 15011268]

25. Whitney SL. The Dynamic Gait Index relates to self-reported fall history in individuals with vestibular dysfunction. J Vestib Res 2001;10:99–105. [PubMed: 10939685]

26. Winter, DA. Biomechanics of Human Movement. New York: John Wiley & Sons; 1978.

**Fig. 1.**
The BrainPort Balance Device. Electrode Array.

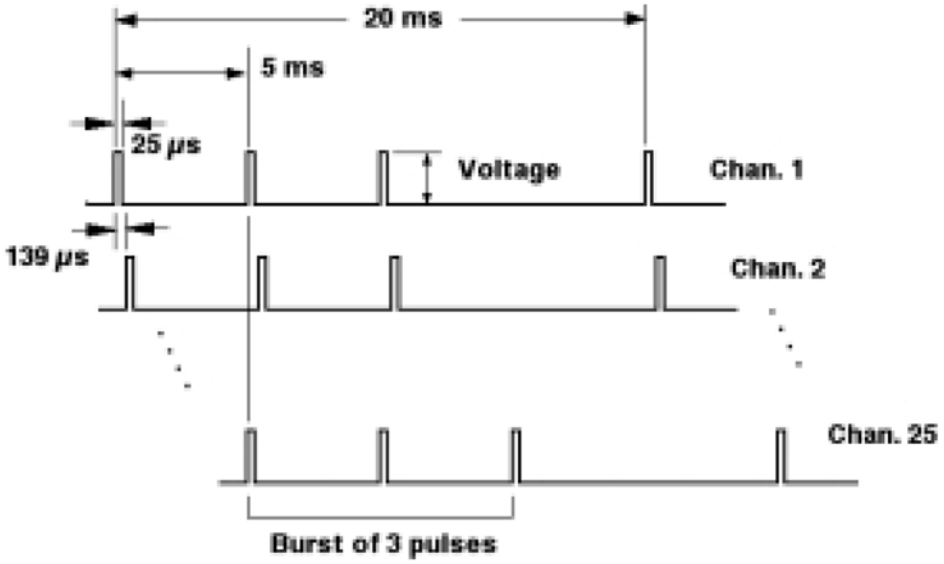


**Fig. 2.**

Diagram of the electrotactile stimulation waveform for one quadrant (25-electrodes) on the 100-point Tongue Display. Active electrodes in all 4 quadrants are pulsed identically.

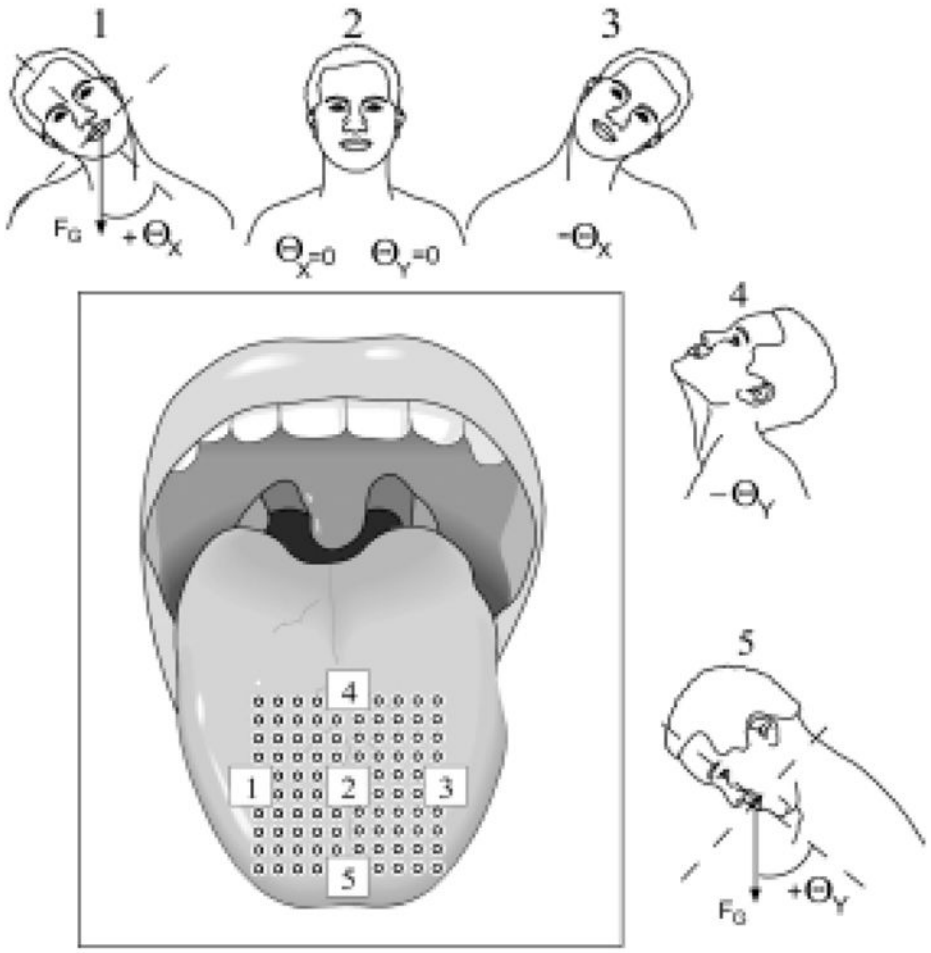


**Fig. 3.**

Relationship between head tilt position and location of tactile stimulus on the tongue. 1: Right roll; 2: Neutral; 3: Left roll; 4: Upward pitch; 5: Downward pitch.

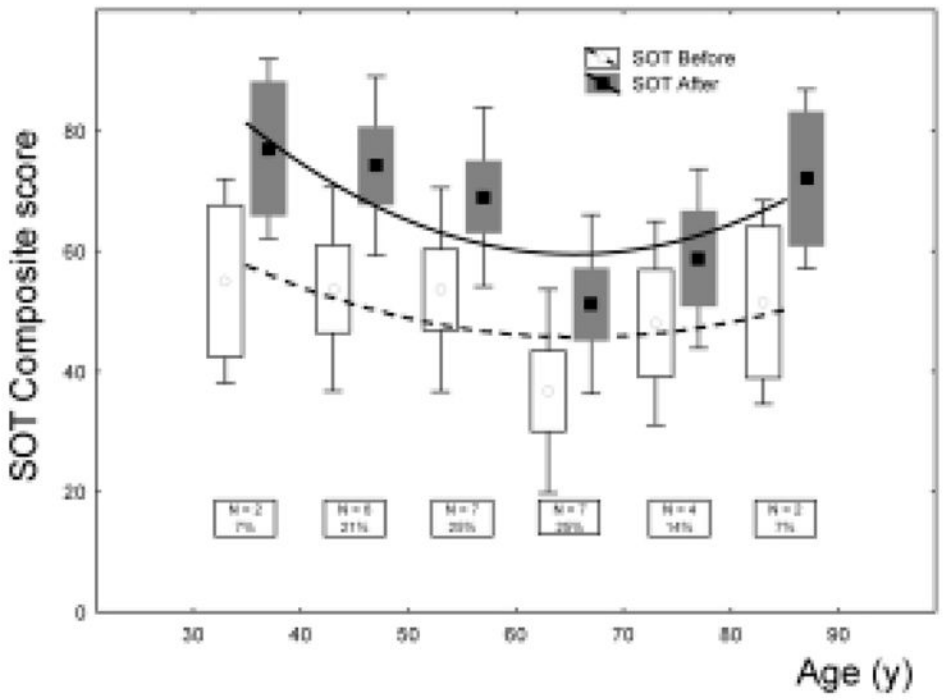


**Fig. 4.**

Composite SOT scores by Age. The distribution plot of SOT composite score, before (open bars) and after (grey bars) BrainPort device therapy, by subject age (grouped in 10-year intervals). Inserts show number of subjects in each age decade (bin width) and percent of total 28 tested subjects. Age of subjects varied from 34 to 88 years, mean value was 59.1 yrs. ± 13.7 (standard deviation). Mean values of SOT composite score before (open circles) and after (solid squares) BrainPort therapy. Boxes correspond to standard error, whiskers correspond to standard deviation value (pooled variance). Note: SOT composite score improvement (distance between broken and solid lines) after standard training procedure is similar across all ages. Solid and dotted lines are fitting curves, represented by quadratic polynomial fitting function.

**Table 1**

Summary of Subjects Tested

| Number of Subjects | Pathophysiology |
|---|---|
| 15 | **Peripheral Vestibular** |
| 7 | Ototoxicity |
| 2 | Endolymphatic Hydrops |
| 2 | Vestibular Neuritis |
| 1 | Labyrinthectomy & Endolymphatic Hydrops |
| 1 | Acoustic Neuroma post radiation |
| 1 | Acoustic Neuroma & Perilymphatic Hydrops |
| 1 | Viral Meningitis/Encephalitis |
| 13 | **Central Vestibular** |
| 3 | Parkinson's Disease |
| 3 | Idiopathic |
| 1 | Age-related Vestibular Loss |
| 3 | Mal de Debarquement Syndrome |
| 3 | Cerebellar Lesion (Stroke) |
| 28 | **Total** |

**Table 2**

Individual Results of Clinical Testing

| er | Age | Etiology | SOT[1] Comp. Score | | SOT 5 | | | | SOT 6 | | | | DGI[3] | | ABC[4] | | DHI[5] | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Pre | Post | Pre | | Post | | Pre | | Post | | | | | | | |
| | | | | | Score[2] | Falls | Score[2] | Falls | Score[2] | Falls | Score[2] | Falls | Pre | Post | Pre | Post | Pre | Post |
| | 52 | Ototoxicity, Gentamicin | 59 | 73 | 70 | 1 | 64 | 1 | 73 | 1 | 70 | 0 | N/A | N/A | N/A | N/A | N/A | N/A |
| | 50 | Ototoxicity, Gentamicin | 43 | 63 | 36 | 2 | 50 | 2 | 0 | 3 | 62 | 1 | N/A | N/A | N/A | N/A | N/A | N/A |
| | 59 | Acoustic Neuroma with perilymphatic hydrops | 54 | 73 | 34 | 2 | 75 | 1 | 46 | 1 | 46 | 0 | N/A | N/A | N/A | N/A | N/A | N/A |
| | 42 | Endolymphatic Hydrops | 28 | 80 | Not available | 2 | 61 | 0 | Not available | 0 | 84 | 0 | N/A | N/A | 77 | 100 | N/A | N/A |
| | 34 | Idiopathic with Migraine | 55 | 65 | 0 | 3 | 45 | 1 | 51 | 2 | 69 | 2 | N/A | N/A | N/A | N/A | N/A | N/A |
| | 52 | Idiopathic | 45 | 54 | 0 | 3 | 54 | 2 | 0 | 3 | 0 | 3 | N/A | N/A | 58 | 84 | N/A | N/A |
| | 53 | Labyrinthectomy (L), Endolymphatic Hydrops | 50 | 69 | 49 | 0 | 49 | 0 | 50 | 2 | 44 | 0 | N/A | N/A | 71 | 88 | N/A | N/A |
| | 44 | Ototoxicity, Gentamicin | 39 | 61 | 0 | 3 | 0 | 3 | 34 | 2 | 56 | 0 | 21 | 24 | 54 | 81 | 66 | 16 |
| | 65 | Ototoxicity, Gentamicin | 25 | 38 | 0 | 3 | 0 | 3 | 0 | 3 | 0 | 3 | 18 | 23 | 63 | 85 | 60 | 22 |
| | 65 | Idiopathic | 17 | 22 | 0 | 3 | 0 | 3 | 0 | 3 | 0 | 3 | 4 | 15 | 9 | 23 | 92 | 74 |
| | 69 | Ototoxicity, Gentamicin | 31 | 47 | 0 | 3 | 0 | 3 | 0 | 3 | 0 | 3 | 21 | 24 | 64 | 85 | 74 | 0 |
| | 59 | Central Cerebellar Lesion | 48 | 61 | 0 | 3 | 58 | 0 | 47 | 0 | 51 | 0 | 18 | 18 | 46 | 55 | 52 | 38 |
| | 48 | Encephalitis/Meningitis, Vestibular Weakness (R) | 74 | 77 | 60 | 0 | 63 | 0 | 65 | 1 | 70 | 0 | 24 | 24 | 61 | 82 | 66 | 16 |
| | 73 | Cerebellar Lesion | 32 | 40 | 0 | 3 | 0 | 3 | 0 | 3 | 0 | 3 | 11 | 14 | 52 | 70 | 48 | 10 |
| | 61 | Mal de Debarquement | 64 | 80 | 51 | 0 | 64 | 0 | 50 | 0 | 72 | 0 | 22 | 24 | 75 | 96 | 60 | 24 |
| | 47 | Mal de Debarquement | 58 | 81 | 33 | 0 | 61 | 0 | 28 | 0 | 77 | 0 | 24 | 24 | 94 | 100 | 56 | 8 |
| | 61 | Mixed: Cerebellar Lesion, Bilateral Vestibular Disorder | 17 | 41 | 0 | 3 | 0 | 3 | 0 | 3 | 0 | 3 | 20 | 20 | 30 | 65 | 64 | 64 |
| | 38 | Mal de Debarquement | 55 | 89 | 43 | 0 | 80 | 0 | 40 | 0 | 90 | 0 | 21 | 23 | 34 | 66 | 64 | 60 |
| | 59 | Ototoxicity, Gentamicin | 47 | 65 | 47 | 1 | 62 | 1 | 48 | 2 | 45 | 0 | 16 | 24 | 87 | 93 | 93 | 12 |
| | 71 | Parkinson's Disease | 62 | 80 | 63 | 0 | 75 | 0 | 39 | 1 | 67 | 0 | 18 | 21 | 89 | 91 | 0 | 0 |
| | 74 | Parkinson's Disease | 57 | 66 | 49 | 0 | 61 | 1 | 52 | 1 | 58 | 0 | 19 | 20 | 66 | 62 | 52 | 60 |
| | 56 | Parkinson's Disease | 72 | 88 | 61 | 1 | 83 | 0 | 57 | 0 | 79 | 0 | 22 | 24 | 83 | 91 | 38 | 26 |
| | 81 | Acoustic Neuroma post radiation | 55 | 73 | 36 | 0 | 48 | 0 | 48 | 2 | 65 | 0 | 21 | 21 | 81 | 89 | 16 | 12 |
| | 88 | Age-related vestibular loss | 48 | 71 | 51 | 2 | 61 | 0 | 0 | 3 | 60 | 1 | 18 | 21 | 51 | 94 | 24 | 2 |
| | 65 | Unilateral Mèniéres | 80 | 83 | 67 | 0 | 79 | 0 | 71 | 0 | 66 | 0 | 23 | 24 | 57 | 91 | 40 | 14 |
| | 41 | Unilateral loss post acute neuritis | 80 | 83 | 48 | 0 | 72 | 0 | 70 | 0 | 77 | 0 | 24 | 24 | 49 | 52 | 60 | 42 |
| | 69 | Ototoxicity, Gentamicin, Bilateral Below Knee Amputation[6] | 29 | 47 | 0 | 3 | 0 | 3 | 0 | 3 | 0 | 3 | 11 | 22 | 49 | 62 | 80 | 64 |
| | 80 | Bilateral Vestibular Hypofunction post neuritis | 41 | 49 | 0 | 3 | 0 | 3 | 0 | 3 | 0 | 3 | 10 | 18 | 81 | 88 | 42 | 40 |

posite SOT: weighted average of scores of all sensory conditions.

e: Average of no-fall scores.

: 24 possible, higher score indicates improvement.

: 100 possible, higher score indicates improvement.

[5] DHI: 100 possible, lower score indicates improvement.

[6] Scores recorded after 3 months of BrainPort training.

N/A: Not Assessed.

**Table 3**

BrainPort Balance Device Training Time

| Subject | Total Number of Days of BrainPort Training* | Cumulative Hours of BrainPort Use |
|---|---|---|
| 1 | 3 | 5 |
| 2 | 3 | 2 |
| 3 | 3 | 2 |
| 4 | 5 | 3.8 |
| 5 | 5 | 3 |
| 6 | 3.5 | 8.3 |
| 7 | 3 | 3.4 |
| 8 | 3.5 | 5.8 |
| 9 | 3.5 | 5.8 |
| 10 | 5 | 9.6 |
| 11 | 4.5 | 7.6 |
| 12 | 4.5 | 7.6 |
| 13 | 4.5 | 4.5 |
| 14 | 4.5 | 5 |
| 15 | 4.5 | 4.9 |
| 16 | 4.5 | 4.7 |
| 17 | 4.5 | 6.9 |
| 18 | 4.5 | 4.2 |
| 19 | 4.5 | 5.6 |
| 20 | 4.5 | 4 |
| 21 | 4.5 | 4 |
| 22 | 7 | 4.6 |
| 23 | 4.5 | 4.8 |
| 24 | 4.5 | 4.2 |
| 25 | 4.5 | 4.5 |
| 26 | 5 | 4.4 |
| 27** | | |
| 28 | 4.5 | 4.8 |
| Average | 4.3 | 5 |

* Training occurred twice daily on consecutive days.

** 3 months of training not included in average.

**Table 4**

Change in Pre- and Post-treatment Scores (All subjects)

| Test | Pre-treatment | SD* | Post-treatment | SD* | P value |
|---|---|---|---|---|---|
| Composite SOT ($n$ = 28)[1] | 48.5 | ± 18.3 | 65.0 | ± 17.1 | < 0.001 |
| DGI ($n$ = 21)[2] | 18.4 | ± 5.30 | 21.5 | ± 3.10 | < 0.001 |
| ABC ($n$ = 24)[2] | 61.7 | ± 20.4 | 78.0 | ± 18.5 | < 0.001 |
| DHI ($n$ = 20)[2] | 57.3 | ± 19.6 | 30.2 | ± 23.3 | < 0.001 |

*SD: Standard Deviation.

[1]Standard descriptive statistic and pairwise (before and after) comparison, t-test for dependent samples.

[2]Nonparametric descriptive method were applied (Wilcoxon Match Pair test), assuming that DHI, DGI and ABC tests represented in ordinal scale.

**Table 5**

Results: Change in Scores based on Etiology

| Test | | Peripheral | | | | Central | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | N | Mean | SD* | P value | N | Mean | SD* | P value |
| Composite SOT[1] | Pre | 15 | 46.9 | 17.40 | < 0.0001 | 13 | 50.5 | 18.46 | < 0.0001 |
| | Post | 15 | 65.0 | 14.07 | | 13 | 64.9 | 20.70 | |
| DGI[2] | Pre | 10 | 18.3 | 4.76 | < 0.01 | 11 | 18.5 | 6.01 | < 0.05 |
| | Post | 10 | 22.5 | 2.01 | | 11 | 20.6 | 3.67 | |
| ABC[2] | Pre | 12 | 65.3 | 13.73 | < 0.0005 | 12 | 58.1 | 25.56 | < 0.0015 |
| | Post | 12 | 85.0 | 13.69 | | 12 | 73.8 | 21.68 | |
| DHI[2] | Pre | 10 | 55.4 | 24.50 | < 0.01 | 11 | 53.8 | 22.46 | < 0.05 |
| | Post | 10 | 22.4 | 20.19 | | 11 | 34.5 | 26.00 | |

*SD: Standard Deviation.

[1]Pairwise (before and after) comparison (t-test for dependent samples test) shows statistically significant differences in SOT.

[2]Wilcoxon Signed Rank test for pre vs. post DGI, ABC and DHI shows statistically significant differences.