Efficacy of electrotactile vestibular substitution in patients with bilateral vestibular and central balance loss

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***Abstract*—Patients with bilateral vestibular loss (BVL) of both central and peripheral origin experience multiple problems with balance and posture control, movement, and abnormal gait. Wicab, Inc. has developed the BrainPort™ balance device to transmit head position/orientation information normally provided by the vestibular system to the brain through a substitute sensory channel: electrotactile stimulation of the tongue. Head-orientation data (artificially sensed) serves as the input signal for the BrainPort balance device to control the movement of a small pattern of stimulation on the tongue that relates to head position in real-time. With training, the brain learns to appropriately interpret the information from the device and utilize it to function as it would with data from a normal-functioning natural sense. In a total of 40 subjects trained with the BrainPort, 18 have been tested using standardized quantitative measurements of the treatment effects. A specialized set of exercises, testing, and training procedures has been developed that may serve as the course of intensive physical therapy with the BrainPort balance device. Our results demonstrate consistent positive and statistically significant balance rehabilitation effects independent of aging and etiology of balance deficit.**

I. INTRODUCTION

Balance and postural deficit due to vestibular loss can be caused by head trauma, drug toxicity, meningitis, physical damage or a number of other causes. The maintenance of normal upright posture and stationary and dynamic balance is mediated by a complex sensorimotor control system that relies on the integration of multiple sensory inputs: proprioceptive (including tactile), visual, and vestibular [6-9,11,12]. In the absence of a fully functional vestibular system, the brain is unable to correctly integrate inherently ambiguous visual and proprioceptive cues. Patients with bilateral peripheral vestibular (BVL) and central vestibular loss (CVL) experience multiple problems with posture control and movement, including unsteady balance, abnormal gait, and various balance-related difficulties, such as oscillopsia ("jumping" visual scenes with head and visual target movement). These effects make it very difficult for the vestibular loss patient to engage in activities of daily living such as walking in low-light or dark environments without risk of falling, driving a car, moving in a crowd, reading a book, or watching TV.

Wicab, Inc. has developed the BrainPort™ balance device to transmit head position/orientation information normally provided by the vestibular system to the brain through a substitute sensory channel: electrotactile stimulation of the tongue [2,5,17]. Head-orientation data serves as the input signal for the BrainPort balance device to control the movement of a small pattern of stimulation on the tongue that relates to head position in real-time. Our previous research [1,3,4] suggests that for the brain to correctly interpret information from a sensory substitution device, it is not necessary for the information to be presented in the same form as the natural sensory system. With training, the brain learns to appropriately interpret the information from the device and utilize it to function as it would with data from the normal natural sense.

We have also developed a specialized set of exercises, testing and training procedures that may serve as the course of intensive physical therapy with the BrainPort balance device. After the initial, successful application of our BrainPort system in BVL subjects, we decided to use standardized quantitative measurements of the treatment effects to normalize outcomes so that BrainPort therapy may be compared to other existing vestibular rehabilitation techniques.

II. METHODS

A. Device

The BrainPort balance device has two principal components: the intraoral device (IOD) and the controller.

The IOD is made up of an electrotactile array and tether, and a micro-electro mechanical system (MEMS) accelerometer. Electrotactile stimuli are delivered to the dorsum of the tongue by the electrode array, which is fabricated using industry-standard photolithographic techniques for flexible circuit technology and employs a polyimide substrate. All 100 electrodes (1.5 mm diameter, on 2.32 mm centers) on the 24 mm x 24 mm array are electroplated with a 1.5 µm thick layer of gold. The tether (12 mm wide x 2 mm thick) connects the electrotactile array and accelerometer to the controller. Most of the 109 conductors in the tether activate the array electrodes, while the remaining conductors provide power and accelerometer communication data. 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 and associated flex

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circuit are encapsulated in a silicone material to ensure electrical isolation for the subject.
The controller contains an embedded computer (a 120 Mhz, 32-bit microprocessor), stimulation circuits, safety circuits, user controls, and battery power supply. The controller converts head-tilt signals from the accelerometer in the IOD into a dynamic 2 x 2 electrode pattern of electrotactile stimulation on the electrode array.
The electrotactile waveform at each electrode is regulated by the controller. The stimulation is created by a sequence of three 25μs wide pulses presented at a rate of 200 Hz (i.e., every 5 ms). The amplitude value of the pulse sequence or 'burst' is updated at 50 Hz (i.e., every 20 ms) and is controlled by the user. Output coupling capacitors in series with each electrode assures zero dc current to minimize potential skin irritation. The system also employs both hardware and software controls to insure both the safety and comfort of the tactile stimulation and will shut down if the tongue stimulation current exceeds a predefined limit.

The tilt data from the accelerometer is used to drive the position of the tactile stimulus pattern for presentation on the tongue display (electrode array). The location of the pattern area centroid is updated at 50 Hz, and is based on the current value of head-tilt, which is calculated from accelerometer data acquired at 150 Hz. The x and y values for the target position is calculated as the difference between the values of the position vector at t_n and t_0, by:

$$x_n = c \sin (\Theta_{x|n} - \Theta_{x|0})$$

$$y_n = c \sin (\Theta_{y|n} - \Theta_{y|0})$$

where values for $\Theta_{x|n}$, $\Theta_{x|0}$, $\Theta_{y|n}$, and $\Theta_{y|0}$, are the instantaneous and initial tilt angles in *x* and *y*, respectively. A linear scaling factor, 'c', is used to adjust the stimulus pattern range of motion on the electrode array to match the subject's maximum anticipated head-tilt or sway. Figure 2 shows the typical location of the 2x2 stimulation pattern on the tongue. The maximum range of pattern motion is also limited so that in the event that the subject temporarily exceeds the maximum amplitude of displacement on the display, the pattern remains at the outer boundary so that they do not lose the stimulus, and therefore position information during this period. Low-frequency, low-amplitude motion limits the linear component of the output signal, allowing for an increased relative magnitude of the angular component.

The 12-bit data from the MEMS accelerometer is scaled to the 10 x 10 electrode array and the maximum range of angular motion is limited to ± 2.88 degrees in both x (lateral) and y (anterior/posterior) directions. This massive data compression causes 'binning' of the accelerometer output signal to an individual tactor in 0.57 degree increments (both x and y). Consequently, small amplitude, high-frequency motion is effectively damped, yielding a low-pass filtered stimulus position signal.

A kinematic analysis of motion for a standing adult male, 180 cm tall with an 18 cm A/P base of support (BOS), using standard anthropometric data was performed, and the angular moments about specific points of rotation were calculated. From this the approximate magnitudes of both linear and angular accelerations detected by the MEMS accelerometer mounted on the subjects' oral palate were determined. Assuming a pure ankle strategy and semi-rigid posture (i.e. no rotation of any other body segments), a maximum displacement of ± 4.75˚ A/P (i.e. just within the BOS), and sway frequency of 0.25 Hz, the angular component is 0.0828 g's (0.817 m/s^2), or approximately 82% of the total output signal magnitude. The concomitant linear acceleration component would be 0.0182 g's (0.179 m/s^2). However, we have observed that quiet standing postural behavior exhibits continuous small, smooth motor adjustments of both body and head orientation, producing a small oscillations about a perceived set-point or neutral position in space. Consequently, we estimate that under laboratory conditions, head-angle component constitutes approximately 85-90% of the output signal from the sensor.

B. Subjects

Studies using electrotactile vestibular substitution with the BrainPort balance device were performed in the United States (Wisconsin and Oregon), France and England. A total of 40 subjects (19 males and 21 females; mean age 59.5±12.8 (SD) and 50.3±11.7 (SD), respectively) with chronic balance dysfunction due to peripheral (26 subjects) or central (14 subjects) etiologies have been trained with the BrainPort balance device (Table 1). All subjects had previously completed standard vestibular rehabilitation therapy. With the exception of the two traumatic brain injury subjects (TBI), the remaining 38 participants had well-adapted compensatory strategies for coping with the debilitating effects of their condition, which were developed over an average period of 6.1 years (from acute disorder to the time of BrainPort training). Nonetheless, all subjects still had difficulty standing quietly, reading, walking, or moving in low-light environments. Performance on standardized dynamic posture and functional gait tests was typically very poor.

C. Standardized Testing

Recently, a random group of 18 subjects (included in the total number of patients in Table 1), all with severe peripheral or central vestibular dysfunction, were tested pre-treatment at UW-Madison by a physical therapist, underwent training at Wicab (avgerage = 3.5 days, or 7 training sessions), and then retested after the last BrainPort training session. This cohort consisted of 8 males and 10 females, ranging in age from 34 to 73 years (mean age of 55 years). Subject etiologies included 8 subjects with BVL; 9 subjects with CVL; and 1 subject with mixed dysfunction. All subjects were at least one year post-acute and had reached a plateau with their vestibular rehabilitation therapy.

The primary objective measure was performance on a Computerized Dynamic Posturography (CDP) system [13] using the Sensory Organization Test (SOT) protocol [14]. During CDP testing, the subject stands on a movable, dual forceplate support surface within a moveable surround (enclosure). Under control of a computer, the force platform can either move in a horizontal plane, or rotate out of the horizontal plane. Standardized test protocols expose the subject to support surface and visual surround motions, during which the subject's postural stability and motor reactions are recorded. The SOT protocol objectively identifies abnormalities in the subject's use of the three

TABLE 1.

Summary of subjects trained on the BrainPort Balance device

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Summary of subjects trained on the BrainPort Balance device, to date

# of Subjects	Pathophysiology
26	**Peripheral Vestibular**
19	Ototoxicity
3	Endolymphatic Hydrops
1	Labyrinthectomy + Endolymphatic Hydrops
1	Endolymphatic Hydrops + Fistula
1	Acoustic Neuroma + Perilymphatic Hydrops
1	Fistulas
9	**Central Vestibular**
4	Mal de Debarquement
4	Idiopathic
1	Viral Meningitis/Encephalitis
5	**Vestibulo-Cerebellar**
3	Cerebellar lesion (stroke)
2	Axonal dystrophy, ataxia (TBI)
40	Total

sensory systems that contribute to postural control: somatosensory, visual, and vestibular. By controlling the sensory (visual and proprioceptive) information through sway referencing and/or eyes open/closed conditions, the SOT protocol systematically eliminates useful visual and/or support surface information and creates sensory conflict situations. Subjects are tested three times under six conditions (1. Normal vision, fixed support; 2. Absent vision, fixed support; 3. Sway-referenced vision, fixed support; 4. Normal vision, sway-referenced support; 5. Absent Vision, sway-referenced support; and 6. Sway-referenced vision, sway-referenced support) for a total of 18 trials. The varying conditions are used to isolate vestibular balance control, as well as stress the adaptive responses of the central nervous system. The SOT composite score, a weighted average of the scores of all sensory conditions, characterizes the overall level of performance. The subject's baseline scores were compared to follow-up scores to determine efficacy of rehabilitation treatment.

The SOT, however, does not measure functional transfer to common movements such as sit-to-stand, locomotion, or reaching. Consequently, we also included the Dynamic Gait Index (DGI) [16], Activities-specific Balance Confidence Scale (ABC) [15], and the Dizziness Handicap Inventory (DHI) [10] to the battery of tests.

The DGI was developed to assess the likelihood of falling in older adults. The DGI scale is a four-point ordinal scale, designed to test eight facets of gait. The highest possible score is 24; scores of less than 19 are predictive of falls and scores greater than 22 indicate safe ambulators.

The ABC scale is a self-assessment questionnaire designed to measure independence and functional limitations. Patients rate their perceived confidence in performing activities of daily living without a loss of balance, with scores closest to 100% indicating confidence in being independent with activities.

The DHI was designed as a way to quantify the impact of dizziness and unsteadiness on everyday life and was developed to evaluate the self-perceived handicapping effects imposed by vestibular system disease. A score of 0 suggests no handicap, and a score of 100 indicates a significant self-perceived handicap.

Qualitative balance assessments were also completed by each subject and the evaluation team at the end of the training period. Not all subjects were evaluated with every test.

D. Training procedure

The typical BrainPort training regimen included nine sessions of 1.5 to 2 hours long, depending on patient stamina. To determine postural control abilities prior to BrainPort therapy, each subject completed a health questionnaire and activities of daily life questionnaires, along with the required informed consent forms. Each individual was also videotaped as he or she performed a series of baseline tests to observe his or her abilities regarding balance and visual control (e.g. oscillopsia).

Upon completion of the baseline balance assessments, each individual proceeded with a 20-minute trial and were trained with the device to stand on soft materials or in tandem Romberg posture. For all patients both conditions were "unimaginable" to perform and it should be noted that initially none of the subjects could complete more than 5-10 seconds stance in any of the conditions.

The training regimen for vestibular subjects was designed to specifically limit the magnitude of body sway by having the subjects slowly adjust head position to maintain the stimulus pattern at the center of the display. Subjects are instructed to

progressively increase their reliance on (confidence in) the electrotactile tongue signal by increasing the eyes-closed and hands-free period of each trial.

III. RESULTS

A. Observational Results

Gait improved in all 40 subjects (both BVL and CVL) walking on flat ground, exhibiting greater inter-limb coordination and smoother movement flow. We also observed integration of several gait components that were previously absent, such as weight transfer, knee flexion during the swing phase after toe-off, smooth heel-strike to foot-flat, appropriate lateral foot positioning, more equal and appropriate step length, shoulder girdle coordination and return of natural arm swing (arms flexed rather than in hyperextension, which is typical when a fall is anticipated). Other balance-challenging activities, such as walking on a straight line, standing on one leg, or dancing also showed improvements. Endurance also increased progressively during training, as did walking on un-even surfaces. Subjects reported increased energy levels and improved ease of performing daily tasks. No subjects reported adverse or negative side effects, and the period of improvement lasted a few hours, particularly in the early stages of the training. 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.

The subjects with idiopathic etiology (CVL subjects) demonstrated a significant improvement in static posture, in terms of stability and endurance and also in the quality of vertical segmental alignment. Muscular tension in postural groups was more appropriate; accessory movements and inappropriate muscle group recruitment diminished in both subjects resulting in a more energy effective work rate and lower general and muscular fatigue.

B. Standardized Testing Results

All 18 subjects (8 males and 10 females) demonstrated improved scores in the composite SOT after receiving treatment for an average of 3.5 days (Table 2). The improvement in composite SOT scores for this cohort ranged from 18 to 56%, with an average improvement of 49.1% (48.4% ± 13.0 SE for males and 49.6% ±16.1 SE for females). The majority of the subjects also experienced a decrease in the number of falls on the SOT. In the functional transfer testing (DGI, ABC, and DHI), all subjects that completed the testing demonstrated generally improved scores, with four subjects showing no change in the DGI.

IV. DISCUSSION

Overall, all subjects experienced significant improvements of their 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 (sitting or standing with closed eyes) for extended periods.

- 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, approaching 6 hours, on average.

- Functional Balance Transfer – We observed transfer of improved balance to 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, during 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. Patients were able to walk in crowds and navigate new environments without loss of balance. Overall, subjects reported decreased fatigue from performing daily activities.

In reviewing the standardized results, we found statistically significant improvement in the composite SOT, DGI, ABC, and DHI scores. Our analysis of the results based on age and on etiology (peripheral vs. central) revealed little to no difference between the groups that were compared, and in both cases improvement was seen throughout. The positive trend (improvement in scores from pre- to post-treatment) seen across all ages is shown in Figure 3, a plot of composite SOT scores verses subject age. The comparison of average composite SOT scores verses subject etiology (Table 4) indicates that subjects with both peripheral vestibular and central vestibular pathophysiology respond nearly equally to BrainPort treatment, showing no significant difference in percent improvement.

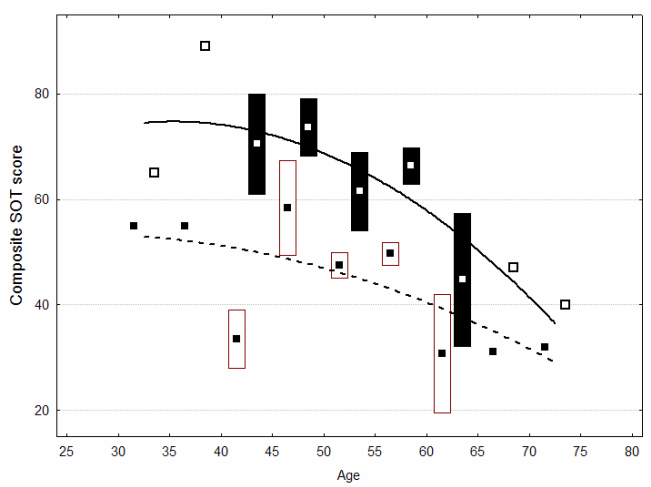

Fig. 1 Composite SOT scores by Age. Light – before BrainPort training, Dark – after BrainPort training

V. CONCLUSION

These preliminary results demonstrate that head-position information, when presented to the tongue via electrotactile stimulation, might positively affect postural function in subjects across a broad range of vestibulo-cerebellar based balance disorders. From these results, we conclude the subject response to BrainPort balance system training signifies evidence of meaningful sensory substitution that is neither dependent on age nor etiology (peripheral vs. central).

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