
The Functional Performance of the BrainPort V100 Device in Persons Who Are Profoundly Blind

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Structured abstract: *Introduction:* This study was conducted to evaluate the functional performance of the BrainPort V100 device, an FDA-cleared sensory-substitution system, in persons who are profoundly blind (that is, have some or no light perception). *Methods:* This was a prospective, single-arm, multicenter clinical investigation. Participants received 10 hours of device training and were required to use the device in their everyday environments for 1 year. Functional performance measures of object identification, orientation and mobility (O&M), and word identification were assessed at baseline, in post-device training, and at the 3-, 6-, 9-, and 12-month time points. *Results:* Fifty-seven participants completed the study and used the device for 1 year. No device-related serious adverse events were reported, demonstrating that the risks associated with the BrainPort are minimal. Participants performed object recognition (91.2% success rate) and O&M (57.9% success rate) tasks beyond chance level. *Discussion:* This study demonstrates that the BrainPort can be used safely and independently by persons who are blind. Participants with profound blindness can accomplish a set of tasks more successfully by using the BrainPort than without the device. Following initial training, performance on these tasks was maintained or improved over the course of 1 year. *Implications for practitioners:* The BrainPort is a noninvasive and nonsurgical device that heightens functional independence for persons who are blind. The device presents users with more information about their environment than conventional assistive devices, and can enhance independence in performing activities of daily living.

The BrainPort V100 device (Wicab, Inc., Middleton, Wisconsin) employs the

concept of sensory substitution by enabling tactile perception of information

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ordinarily processed by the visual system. Visual information captured by a digital camera is displayed on a user's tongue as electrotactile stimulation, which feels like small vibrations. The tongue is ideal for sensory perception (Chebat, Rainville, Kupers, & Ptito, 2007; Essick, Chen, & Kelly, 1999; Nau, Bach, & Fisher, 2013; Sampaio, Maris, & Bach-y-Rita, 2001; Van Boven & Johnson, 1994); it is devoid of an outer layer of dead skin cells and there are more nerve fibers closer to its surface than on the other parts of the body. The tongue is more sensitive than other areas of the body and can perceive information via electrical stimulation significantly better than fingertips (Bach y Rita, 2004).

The tongue can be considered a "visual" portal to the brain, since research has shown that after a person who is blind receives sufficient training, there is statistically significant activation in an individual's visual cortex when he or she is interpreting the stimulation patterns provided by the BrainPort V100 technology (Lee, Nau, Laymon, Chan, Rosario, & Fisher, 2014; Ptito et al., 2012; Ptito, Matteau, Gjedde, & Kupers, 2009; Ptito, Moesgaard, Gjedde, & Kupers, 2005). The concept of the BrainPort is that with training an individual can learn how to translate the stimulation on the tongue into a representation of the surrounding environment. Fluent users become accustomed to the stimulation and cease to consciously translate the perception. Interpretation of the stimulation patterns then becomes more automatic (Arnoldussen & Fletcher, 2012; Danilov & Mitchell, 2005).

Previous research has shown a BrainPort user's ability to identify words and objects at a level greater than chance fol-

lowing training. The participants in one study were unable to perform these same tasks without the use of the BrainPort during baseline testing (Nau, Pintar, Arnoldussen, & Fisher, 2015). In addition, using visual information displayed on the tongue via electrotactile stimulation, congenitally blind participants performed significantly more consistently than equally trained sighted participants to successfully navigate around obstacles within a natural setting (Chebat, Kupers, & Ptito, 2011). To date, there has been no research that demonstrates the long-term safety and effectiveness of the BrainPort device in a multicenter study. The purpose of this research was to evaluate the functional utility and electrostimulation safety of the BrainPort in a one-year multicenter clinical trial, during which the participants used the device independently.

Methods

RESEARCH DESIGN

This study followed a prospective, single-arm, within-subjects, repeated-measures design. It was conducted at six sites in the United States and one in Canada. Institutional review board (IRB) approval was obtained by the New England and Veritas IRBs prior to initiating the study. All study participants provided informed consent to participate after the risks and benefits of the study were explained. This study was performed in accordance with the ethical principles of the Declaration of Helsinki. It was registered with ClinicalTrials.gov under the identifier NCT01488786.

RECRUITMENT

Participants were recruited for the study from October 2011 to April 2012 from co-investigators' clinical practices, clinic

databases, and referring physicians and clinicians. In addition, recruitment flyers were posted in eye clinics and distributed to support groups for people who are blind. It was required that all participants be at least 18 years of age, had received a diagnosis of blindness at least six months prior to enrollment, were English speaking and able to walk independently for 20 feet, and had successfully completed orientation and mobility (O&M) training with a white cane or dog guide. They were excluded if their blindness was due to cortical injury; were current tobacco users or were pregnant; had hearing loss in which device alerts could not be heard; had oral abnormalities, tongue lesions, or piercings; had allergies to nickel or stainless steel; had implanted medical devices or any medical condition that could interfere with participation in the study; had prior exposure to the BrainPort; or had indications of cognitive decline, depression, or anxiety.

An interested candidate was invited to a study site for a screening visit that included the collection of clinical history and demographic information; an ocular evaluation to document blindness, unless written documentation was provided by the participant; an oral health exam; and the Beck Anxiety Inventory (BAI) and Beck Depression Inventory-II (BDI-II) to assess levels of anxiety and depression, respectively. In addition, the extent of any residual vision was quantified by using a computer-based psychophysical test, the Freiburg Visual Acuity Test (FrACT) (Bach, 1996; Nau et al., 2013).

Participants who had a visual acuity equal to or less than 20/5000, had BDI-II and BAI total scores that fell within the minimal to mild levels, passed the oral

health exam, and were willing to participate after receiving brief exposure to the device were enrolled in the study. Of the 83 participants recruited, eight candidates did not meet the eligibility criteria for the following reasons: did not pass the oral health exam ($n = 2$), did not meet the vision criteria ($n = 2$), withdrew consent following an introduction to the device ($n = 2$), withdrew consent prior to an introduction to the device ($n = 1$), and displayed cognitive impairment that was initially undetected ($n = 1$).

PARTICIPANTS

Seventy-five participants met the eligibility criteria, confirmed their willingness to participate following exposure to the device, and were enrolled into the study. Of these 75, 18 withdrew or were withdrawn for the following reasons: disinterest and an unwillingness to continue ($n = 8$), health- or life-related events ($n = 7$), and time constraints ($n = 3$). Therefore, 57 participants completed the 12-month study.

Of the 57 participants who completed the study, the mean age was 52.4 years (range, 21 to 69 years). All used one or more assistive devices (white cane, dog guide, or electronic travel devices) on a regular basis, and the majority (77%) could read braille. This information and additional demographic data for this study sample are provided in Table 1.

MATERIALS

The BrainPort is a portable, nonsurgical, and noninvasive electronic assistive device for people who are profoundly blind. The BrainPort has received FDA market clearance and CE mark clearance (mandatory for certain products sold within the

Table 1
Demographics of study subjects (N = 57).

Variable	n (%)
Age in years	
Mean (SD)	52.4 (10.8)
Gender	
Women	25 (44)
Men	32 (56)
Race	
Black or African-American	9 (16)
White or Caucasian	46 (80)
Other	1 (2)
Unknown	1 (2)
Years since onset of blindness	
Mean (SD)	33.04 (22.4)
Duration of blindness	
Congenitally blind	21 (37)
Acquired blindness	36 (63)
Braille readers	44 (77)
Mobility assistive device users	57 (100)
Types of assistive devices used	
White cane	53 (93)
Dog guide	23 (40)
Human guide	33 (58)
Other	5 (13)

European Economic Area). The device is currently available for purchase in the United States, Canada, Europe, and China. Its major components include a headset and controller. The headset consists of a camera with zoom functionality mounted on a sunglasses frame, and an electrode array, also referred to as the intra-oral device (IOD) (see Figure 1). The IOD measures at 29.5 mm × 33.8 mm × 7 mm and consists of 400 stainless steel electrodes arranged in a 20 × 20 grid spaced at 1.32 mm from center to center.

A flexible cable permanently tethers the IOD to the headset to allow for easy removal or repositioning. The controller, powered by a lithium-polymer battery, provides the processing and power functions and allows users control of device settings and stimulation strength. The bat-

tery life is approximately two hours, and a replacement battery and charger are supplied with the device.

To operate the device, the user employs simple head movements to guide the camera to a scene of interest. The camera captures the scene as a greyscale digital image and forwards the image to the controller for processing. The visual information is then transmitted to the dorsal surface of the tongue via electrotactile stimulation patterns representative of the camera image (see Figure 2). The image is digitized to 400 pixels; in the standard setting, white pixels are felt as strong stimulation, grey pixels as medium-strength stimulation, and black pixels as no stimulation.



Figure 1. The BrainPort V100 device as worn by a user.



Figure 2. Illustration of the BrainPort V100 concept.

PROCEDURE

The study protocol included three phases: in-clinic training, home use, and follow-up.

In-clinic device training phase

During the in-clinic training phase, participants received approximately 10 hours of instruction by an experienced BrainPort trainer. Training included reviewing the functions and controls of the device and learning how to interpret the tactile stimulation. Trainers followed a standardized training protocol; however, participants were allowed to advance through the training program at their own pace. Elements of training included: basic skills, head movement control, spatial relationships, basic and complex shape identification, letter and number recognition, and mobility and wayfinding (Nau et al., 2015). Proprietary application software, vRemote (developed by Wicab, Inc.), was provided to trainers as a training tool. vRemote runs wirelessly on a laptop and displays the BrainPort camera image alongside a visual representation of

the corresponding IOD stimulation pattern (see Figure 3).

Home use & follow-up

Following in-clinic training, participants were required to use the device in their everyday environments during daily activities for a minimum of 300 minutes per month for 12 months. They were asked to provide a log of the activities performed at home and the number of minutes spent on each activity. Written and computer-accessible instructions for device cleaning, storage, and safety were provided to each participant. To calculate usage time, the device internally logged the cumulative number of minutes the simulation was active (exceeding a simulation level of zero). Participants were provided with flashcards containing letters and words, copies of the signs used in the O&M task, playing cards, and tic-tac-toe boards to play on with a companion at home. Research staff members phoned participants monthly to address questions and document adverse events.

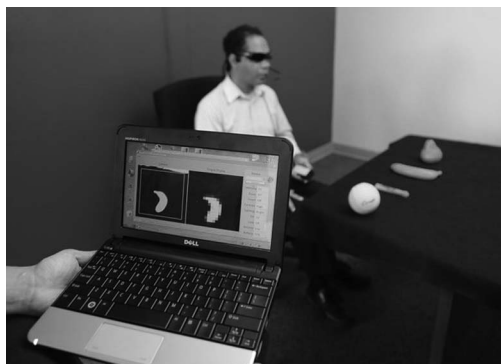


Figure 3. vRemote presentation of a camera view of a banana alongside the corresponding IOD image.

Outcome measures

Functional performance measures were designed to simulate real-world activities within a controlled and reproducible environment that would be impossible to complete without the use of external assistive devices. These tasks included object recognition, word identification, and O&M. Baseline measurements were collected during the initial screening in which participants were prohibited from using the BrainPort, a conventional device, or any other technique to complete the tasks. Functional performance measurements were obtained a second time immediately following device training. Measurements were then collected quarterly (at 3, 6, 9, and 12 months) during follow-up assessments.

For the object-recognition task, four objects were placed side by side, on a table draped in black cloth, each 10 inches apart from one another and from the edge of the cloth. Seated 18 inches in front of the objects, the participant was instructed to use the BrainPort to locate, reach out to, and touch a target object without touching any other object on the table (see Figure 4). The participant was given two minutes to identify and touch the target object; otherwise, the trial was marked as incorrect. The participant was asked to repeat the task 20 times. For each assessment session, the same set of objects was used and the target object and object display were randomized. The four objects used for this task included a softball, coffee mug, highlighter marker, and plastic banana.

The O&M task was organized in a 15-foot hallway. Four signs that are commonly located in public places were po-



Figure 4. A user demonstrating the object-recognition task. The user was instructed to locate a specific object using the BrainPort V100 device and to reach out to and touch the object without touching any other.

sitioned on the walls at varying heights based on different configurations of hallways across study sites (see Figure 5). The distances of the signs from the starting point were specified, so that the measurement was consistent across all sites. One randomized pass-or-fail trial was conducted in which participants were given 10 minutes to locate and navigate toward the target sign using only the BrainPort. Participants were not permitted to use any other assistive device during this



Figure 5. O&M task: participants were instructed to ambulate towards and touch the target signs.

task. The trial was deemed successful if participants either touched the requested sign on their first attempt or placed their hand within five inches of the edge of the sign. The target sign was randomized for each assessment. The signs included Men, Women, Danger, and Stairs.

A word-identification task was administered on a 17-inch computer monitor positioned 50 cm in front of the participant. Ten 3- to 5-letter words in 95-point Century Gothic font were presented individually as white text on a black background. The display resolution was 1280×1024 pixels with an aspect ratio of 4:3, and brightness and contrast settings were set to 100. Participants were instructed to identify and verbally report each word presented. To successfully complete the tasks, participants were to read the word using the BrainPort within 3 minutes, repeating the task 10 times. For each assessment session the same set of words was used and the order of word presentation was randomized. The words included bus, dog, cup, moon, ring, farm, tree, dress, bread, and plant.

DATA ANALYSIS

An analysis was conducted to determine whether the participants successfully achieved the task significantly more often than at chance level. A sample size of 54 participants was required to evaluate all outcome measures with at least 80% power. To maintain near-uniform enrollment across sites, the enrollment cap per site was 25% of the total sample size. The analysis included the 57 participants who completed the full year of participation.

Success rates and performance goals were established for each measure. *Success rates* were defined as the ability to

successfully perform a task statistically more often than at chance level. To determine success rates, a confidence interval was calculated for each measure using the standard Wald asymptotic confidence limits. For example, it was expected that a participant could correctly identify and touch a target object by chance at a rate of 25%. The upper, one-sided 97.5% confidence bound on a 25% within-subject success rate is 45%. Therefore, it was determined that correctly identifying greater than 9 out of 20 objects within an assessment period represented successful performance at a rate greater than chance level. To complete the word-recognition task successfully beyond chance level, the participant was required to correctly identify 6 or more words. The O&M task was considered successful if the participant navigated toward and touched the target sign on their first attempt.

Performance goals were predetermined and represented the minimum percentage of participants who were required to achieve each task at the success rate. The percentages of participants who achieved success during tasks, as outlined by the criteria detailed above, were calculated. The one-sided, lower 97.5% confidence bound (Agresti-Coull method) was then compared to the performance goal for each task. A lower confidence bound greater than the performance goal indicated a success rate that was statistically greater than that due to chance. The performance goals were 50% for object recognition and word identification and 35% for the O&M task.

Results

Adverse events were assessed during monthly phone calls and the quarterly

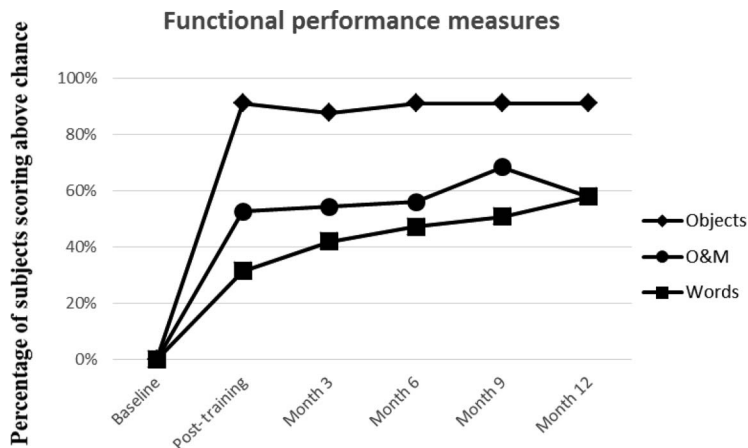


Figure 6. Performance measures over 12 months ($N = 57$).

assessment sessions, the latter of which included an oral exam by a trained professional. No device-related serious adverse events occurred throughout the study. Five superficial device-related adverse events were reported by 5 participants and were resolved prior to the participants' 12-month assessments. These events included 3 reports of metallic taste, 1 experience of a tingling sensation in the mouth, and 1 report of tongue sensitivity. All events were considered to be mild in severity, device use was not modified, and the participants fully recovered prior to completion of their study participation.

INDEPENDENT DEVICE USE

Usage logs embedded within the BrainPort were reviewed during each quarterly assessment to objectively quantify frequency of use. Usage remained consistent throughout the study, at approximately 900 minutes per quarter. In addition to performing the activities provided by the research staff members, the participants who recorded activities in their home log reported accomplishing the following:

walking through a building with a companion and being able to identify and follow their companion's movement, identifying numbered buttons on a remote control, reading words on the cover of a book, locating doorways and windows, identifying the driveway and mailbox outside the home, and navigating around obstacles within the home.

BASELINE PERFORMANCE

None of the participants were able to complete any of the functional performance measures at baseline when not using the BrainPort or any other assistive device. Following approximately 10 hours of training, participants were able to perform the object recognition and O&M tasks with success beyond chance and maintain this level of performance throughout the study (see Figure 6). These results for the 12-month data are detailed below and are summarized in Table 2.

OBJECT IDENTIFICATION

For the object-recognition task, 91.2% of the participants successfully identified

Table 2

Performance on functional measures at 12-month assessment (N = 57).

Measure	Participant success* % (N)	One-side 97.5% lower bound, %	Performance goal, %	Performance greater than chance? (lower confidence bound > performance goal)
Object recognition	91.2 (52)	83.9	50	Yes
Word identification	57.9 (33)	45.1	50	No
Orientation and mobility	57.9 (33)	45.1	35	Yes

* Success was defined as > 9 correct on object recognition, > 5 correct on word identification, ambulating towards and touching target sign on orientation and mobility.

and touched greater than 9 of the 20 objects during the 12-month assessment. The 97.5% lower one-sided bound (83.9%) exceeded the performance goal of 50%; therefore, the participants' ability to correctly recognize objects with the BrainPort was statistically significant and represented performance exceeding that expected by chance.

WORD IDENTIFICATION

During the 12-month assessment, 57.9% of participants were able to correctly read six or more words. However, the 97.5% lower one-sided bound (45.1%) did not exceed the performance goal of 50%; therefore, these findings did not reach statistical significance.

ORIENTATION AND MOBILITY

For the O&M task, 57.9% of participants were able to ambulate towards and touch a designated sign within 10 minutes while solely using the BrainPort. The 97.5% lower one-sided bound (45.1%) exceeded the performance goal of 35%, indicating that participants were able to achieve success in this task with a success rate beyond that expected by chance alone.

SUBGROUP ANALYSES

To determine whether participant characteristics or study site contributed to func-

tional performance, subgroup analyses were conducted examining age, gender, duration of blindness, and study site location, *p*-values were calculated from a Fisher's Exact Test. No statistically significant differences were observed in any of the performance measures by any of these factors (*ps* .05).

Discussion

The results from this study demonstrate functional benefits of the BrainPort with a low-risk safety profile. No serious adverse events related to the device occurred throughout the study. The device-related adverse events that were reported were not serious and did not sustain, indicating that the risks associated with the device are benign.

This study illustrates that the BrainPort can assist people who are blind to recognize objects, perform mobility tasks, and spot read. None of these tasks could be done at baseline without the use of the BrainPort or other assistive devices or techniques. In addition, there were no significant differences in functional performance between individuals who were congenitally blind and those who acquired blindness. Participants were able to successfully perform the object recognition and O&M tasks immediately

following device training, revealing users' ability to learn basic BrainPort skills within a short time frame even without previous visual experience.

The BrainPort device is intended for use in concert with a white cane or a dog guide. However, useful features of the device, such as the zoom function, allow users to explore objects well beyond the reach of their hands or a cane. Immediately following training, the majority of participants could successfully identify and intentionally pick up objects from a table. The ability to deliberately locate objects without sweeping one's hand across a table is especially valuable in situations where the object may be breakable or located near a hazardous environment such as a hot stove.

Independent travel is an important goal sought by many individuals who are blind. Identifying and reading signage are time-consuming and difficult tasks, often requiring the presence of a human guide or braille literacy. Although none of the participants were able to accomplish the mobility task at baseline, more than half of them were able to successfully complete the task immediately following training, and they maintained this skill throughout the year-long study. Participants also reported success in performing mobility-related tasks attempted at home, including avoiding obstacles on the ground, identifying a companion's movement, and locating objects of importance such as a mailbox.

The word-identification task was the most arduous of the functional tasks. To accurately identify a word, participants were required to master the zoom function and employ controlled head movements to read words within a narrow field

of view. Individuals who were congenitally blind were further tasked with learning the shapes of letters, since the majority of these individuals had limited experience with alphabet shapes prior to study participation. Although participants with acquired blindness had the experiential advantage of recognizing letters, their performances on functional measures were consistent with those who were congenitally blind. Although success at reading words was not statistically significant in this study, the ability to identify characters with the BrainPort was useful in performing everyday activities at home, such as identifying the numbered buttons on a remote control and reading the cover of a book. Learning to use the BrainPort efficiently is much like learning a new language and requires time, patience, and commitment. Although the majority of participants were able to successfully complete the functional tasks immediately after training in the use of the device, those individuals who were not able to perform the tasks at target level within the duration of the study may have needed additional training or additional time to practice.

The BrainPort is a novel device for people who are profoundly blind; there are no other commercially available assistive devices that can provide visual information via stimulation on the tongue. Other emerging technologies, such as retinal implants, require surgery and an intact visual pathway (Humayun et al., 2012; MacLaren & Pearson, 2007; Radtke et al., 2008; Zrenner et al., 2011). The BrainPort does not require surgery and can be useful to an extensive number of individuals with a wide variety of blindness etiologies (Lee et al., 2014; Nau et al., 2013). The BrainPort is a

practical and safe device that can provide substantial benefits to adults who are blind regardless of age, gender, or cause and duration of blindness.

LIMITATIONS AND FUTURE RESEARCH

Our study has several limitations. It used a repeated-measures design and the same set of objects, letters, and signs for each assessment; therefore, there was the potential for a practice effect, in which improvement in measures may be attributed to practice on the task rather than to improvement in device use. The goal of the assessment measures was to demonstrate that the participants could successfully achieve a task with the BrainPort that could not otherwise be achieved. Performance remained fairly consistent throughout the study, with participants being able to successfully accomplish the object-identification and O&M tasks immediately following device training and maintaining approximately the same level of performance throughout the study.

Future research will include more complex tasks, including using a variety of objects relevant to real-life situations and an expansion of the O&M course to include hanging and ground obstacles and the identification of important aspects of a room, such as a doorway or an empty chair. In addition, individuals' perceptions of interacting with wearable technology are important factors that were not assessed in this research. In our ongoing research, we have added survey and focus group methodology in an attempt to gain more insight into the social acceptability of the device. Finally, research on individuals blinded due to traumatic brain injury, and on children, is needed, since these populations were excluded from the current study.

Implications for practitioners

The BrainPort is designed to enhance functional independence in individuals who are blind by delivering useful sensory information. Its purpose is to allow the identification of useful information that can be used to accomplish everyday tasks without the assistance of a human guide. The device is intended to augment conventional mobility aids, such as the white cane or dog guide, by providing information that cannot be recognized by those rehabilitation modalities alone. The BrainPort is an FDA-cleared device that can be considered a safe and effective assistive device for individuals who are profoundly blind.

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