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TITLE: Safety and Efficacy of the BrainPort V100 Device in Individuals Blinded by Traumatic Injury

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14. ABSTRACT Purpose: There is an immediate need for non-invasive therapy to restore functional abilities of persons blinded by traumatic injury, including Veterans injured in combat. The BrainPort® V200 enables perception of visual information using the tongue as a substitute for the eye. The purpose of this study was to investigate the impact of the BrainPort V200 on real-world functional task performance in persons who are profoundly blind (no better than light perception) due to traumatic injury. Methods: Twenty-two subjects blinded by traumatic injury were enrolled. Subjects received ten hours of device training prior to independent home use for 12 months. Subjects were assessed at baseline, post-training and quarterly for a year on real-world functional performance in the following skill areas: object recognition (10 trials), word identification (10 trials), and orientation and mobility skills (pass/fail). Results: None of the subjects could complete any of the functional tasks at baseline without the device. After using the device independently at home for one year all subjects successfully completed the object recognition tasks and could recognize a doorway in a room, 41% could read at least 6 out of 10 words, 71% could identify a window, 94% followed a line without veering off, 71% avoided obstacles, 71% walked through a doorway without collisions, 50% identified a window, and 41% of subjects could identify a sign in a hallway. Subjects demonstrated success immediately following training and performance rates were either consistent or improved after one year of device use in the home. Conclusions: These results demonstrate significant improvements in real-world functional task performance in all skill areas immediately following training and retained after long-term use. The BrainPort V200 offers a non-surgical method for restoring functional abilities to persons blinded by trauma. In addition, the device can support the successful integration of blind Veterans and active duty Servicemembers into community life. With access to the BrainPort V200, profoundly blind persons can regain or enhance independence, directly interact with their environments, and regain a sense of autonomy.					
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1. INTRODUCTION:

The BrainPort V200 is a wearable and portable oral electronic assistive aid for individuals who are profoundly blind. The BrainPort V200 employs the concept of sensory substitution by enabling tactile perception of information normally provided by the visual system. Visual information captured by a digital camera is displayed on the user's tongue as electrotactile stimulation, which feels like small vibrations. Through training, users learn to interpret the electrotactile stimulation as the shape, size, location, and motion of features and objects within the environment. The purpose of this study was to evaluate the safety and effectiveness of the BrainPort V200 in individuals who have been medically documented as blind, light perception or worse, due to a traumatic injury (cortical or ocular).

2. KEYWORDS:

BrainPort, V100, V200, blindness, visual impairment, assistive device, assistive aid, assistive technology, visual aid, non-surgical visual prosthetic, sensory substitution

3. ACCOMPLISHMENTS:

What were the major goals and objectives of the project?

The major goals of this research were to evaluate the safety and effectiveness of the BrainPort V200 device in individuals who have been blinded by traumatic injury. Subjects used the device independently in preferred settings, including the home and public places, for one year. An additional objective was to explore the design and hardware requirements for a population with multiple disabilities (polytrauma). The overall aim of this study was to demonstrate the safety and effectiveness of a non-invasive assistive vision aid ready for rapid deployment to wounded warriors, veterans, and civilians who have been blinded by traumatic events.

What was accomplished under these goals?

Aim 1: *Explore the design and hardware requirements of a population with multiple disabilities (polytrauma).*

Hardware modifications: The first year of the study involved engineering activities to refine the BrainPort V200 headset frame design (plastic and silicone components) and implement hardware and software features. The external frame was updated to include a broader range of sizes and improve the ergonomics and aesthetics of the device. The internal electronics were optimized to improve camera imaging, minimize power consumption, better manage heat dissipation, provide for electromagnetic compatibility in the home environment, and provide better audio feedback. Figure 1 exhibits the detail involved in the design of the plastic housings, the components installed in those housings, and assembly of parts. In this example, the camera assembly is shown. Wicab designed and fabricated (contract manufacturing) each of these components except for the lens, screws, and hinge.



Figure 1. BrainPort V200 Camera Assembly

Description of BrainPort V200

The BrainPort V200 is a hands-free design consisting of a headset and intra-oral device (IOD).

Headset: The headset consists of the device controls, power pack, and a digital video camera. The headset may be worn alone or with a pair of glasses/sunglasses of the user’s preference. The camera’s field of view is user-controlled and varies from narrow to wide angle views.

IOD: The IOD contains electrodes that act as “pixels” for the tongue. The flat side of the IOD, which displays the electrodes, should be in contact with the dorsal surface of the tongue during use. The stimulus pattern on the electrode array corresponds to the scene captured by the camera (or internal test patterns). The IOD is permanently tethered to the headset with a flexible cable allowing for easy and rapid repositioning and/or removal. Figure 2 shows a complete V200 unit. Table 1 describes each component of the BrainPort shown in Figure 2.

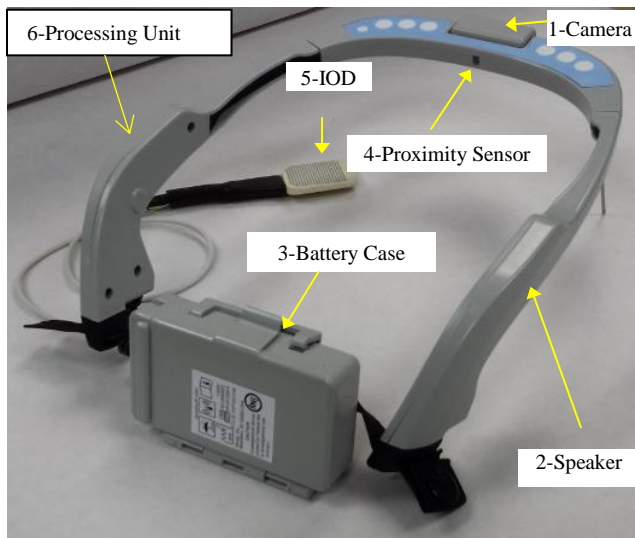


Figure 2. BrainPort® V200

Table 1. BrainPort® V200 Device Components

Component	Purpose
1.Camera	Captures scene in front of user.
2.Speaker	Provides audio feedback.
3.Battery Case	Contains the rechargeable battery and is attached at rear of headset. Elastic straps are used to tighten or loosen the headset for comfort. Not pictured here but included with the device are a battery charger with factory instructions and two lithium-polymer rechargeable batteries.
4.Proximity Sensor	Detects when headset is being worn. System shuts down after several minutes if headset is removed.
5.IOD	Electrode array which presents stimulation patterns on the tongue.
6.Processing Unit	Embedded computer controls and manages device activity.

User Controls: The user controls are imbedded in the headset. Figure 3 exhibits the button location for each control. Table 2 provides a detailed description of the function for each button.

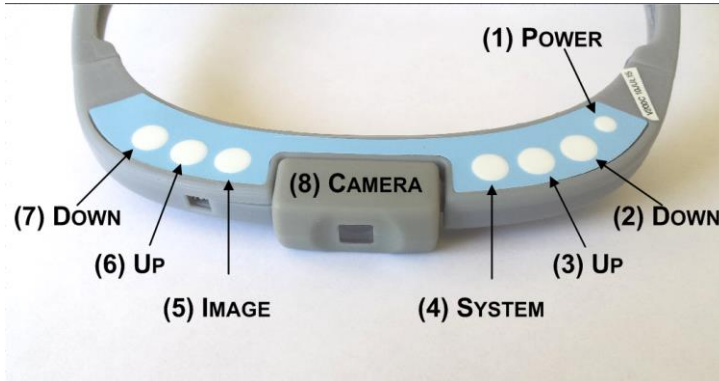


Figure 3. BrainPort® V200 Headset Controls

Table 2. BrainPort® V200 Device Controls

Button	Function
1. Power	Turns the device off/on.
2. Down 3. Up	Selects a specific action for a device feature.
4. System	<p>This button scrolls through the system features. System features include the following:</p> <p>Status: Up (3) and Down (2) buttons cycle through the following status reports, announcing information at each stop:</p> <ul style="list-style-type: none"> • Battery charge level • Lighting condition detected by device • Software version of device <p>Volume: Up (3) and Down (2) buttons cycle through the following status reports, announcing information at each stop:</p> <ul style="list-style-type: none"> • Mute (does not mute the status function) • Low • Medium • High <p>WiFi: Up (3) and Down (2) buttons enable or disable the WiFi. Disabling the WiFi conserves battery life.</p> <p>Test: Up (3) and Down (2) buttons choose test patterns that are used for troubleshooting device operation.</p>
5. Image	<p>Scrolls through image features. Image features include the following:</p> <p>Intensity: Up (6) and Down (7) buttons increase or decrease (respectively) the intensity of stimulation presented on the tongue. Device provides auditory signal at stimulation limits (highest = 100, lowest = 0). When powered on stimulation intensity always resets to zero and must be increased by user.</p> <p>Zoom: Controls camera field of view (FOV). Up (6) and Down (7)</p>

	<p>buttons zoom in (smaller FOV) or out (larger FOV). Up (6) button increases the camera zoom level (reducing camera's FOV). Down (7) button decreases the camera zoom (increasing camera's FOV). Device provides auditory signal at zoom limits (widest = 48 degrees, narrowest = 3 degrees).</p> <p>Invert: Inverts stimulation intensity values, where the strongest becomes the weakest and vice-versa. Up (6) and Down (7) buttons toggle between whether bright objects or dark objects in the FOV stimulate the tongue array.</p> <p>Contrast: Controls image contrast levels. Up (6) and Down (7) buttons toggle between normal contrast (default) and high contrast mode. High contrast enhances difference between light and dark regions in the camera image.</p> <p>Edge Enhance: Enable/disable edge enhancement. Up (6) and Down (7) buttons enable/disable this function. In this mode, edges in the camera image are enhanced to make them more distinguishable.</p>
6.Up 7.Down	Selects a level for each image feature noted above.
8.Camera	The camera can be adjusted to point straight out from the headset or tilted down (to about 45 degrees) to reduce neck fatigue.

Mobile Application: During this study the first BrainPort mobile app, SignFinder, was introduced to the subjects. The app intended to assist subjects to locate signs of importance within the local environment. This initial app, which locates exit and restroom signs, runs on a smart device and connects with the BrainPort V200 using the V200's video stream as an input source. The app alerts the user when signs of interest are in the BrainPort camera's field of view via haptic and audio feedback (Figure 4). It also relays the coordinates of the located sign back to the BrainPort V200 so that electro-tactile stimulation can be used as user feedback to then navigate towards the sign. Versions of the SignFinder App have been implemented and tested on both *iOS* and *Android* platforms. In developing the SignFinder application, Wicab engaged leading computer vision experts from Smith-Kettlewell Eye Research Institute (SKERI) to create the core processing algorithms.

Wicab also hired a local firm (Solomo, Inc) to port the algorithms to the iOS and Android platforms as well as develop the accessible user interface. During the 6 month assessment period, subjects received brief training on the app and then BrainPort were sent back to Wicab, Inc. for app installation. Once the BrainPort was equipped with the mobile app it was returned to the subjects' homes (approximately 2 weeks). Subjects were instructed to practice with the app independently for the remainder of the study in preferred public areas. Subjects were assessed on app use at during the 9 and 12 month assessment periods.

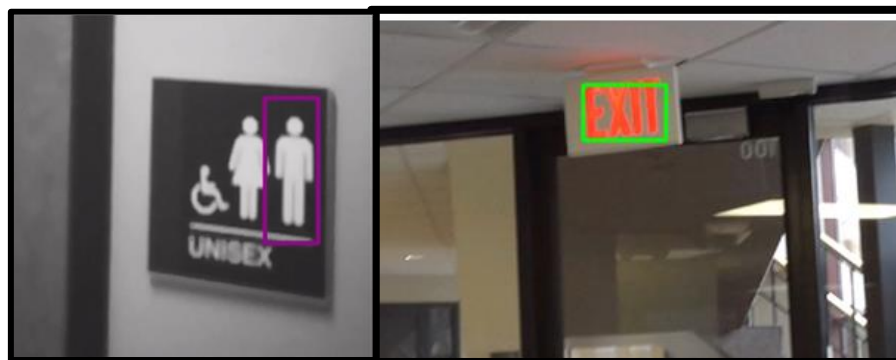


Figure 4. SignFinder app enables users to recognize restroom and exit signs.

Aim 2: Enable individuals blinded by traumatic injury to test and evaluate the BrainPort V200 device in normal operational settings (at home, public places, etc.).

Subject Enrollment: Initial and continuing reviews for this research were approved by NEIRB (Legacy Protocol ID: 14-492) and HRPO (Log No. A-18603). Twenty-two subjects were enrolled in the study (14 from Chicago Lighthouse and 8 from Lighthouse Guild). Of these 22 subjects, four are Veterans. Five subjects withdrew from the study due to reasons of lack of time or interest. Therefore, 17 total subjects completed the study in its entirety. Subject characteristics for the total study sample are located in Table 3.

Table 3. Subject Characteristics (n=22)

Age	Years	Veteran Status	% (n)
Mean ± SD	40.68 ± 12.32		19 (4)
[Median] (min, max)	[40.5] (21.0, 66.0)	Duration of Blindness	Years
Gender	% (n)	Mean ± SD (N)	30.8 ± 22.5
Women	23 (5)	[Median] (min, max)	[8.5] (1.0, 56.0)
Men	77 (17)	Braille Readers	% (n)
Race	% (n)	Mobility Assistive Device	% (n)
American Indian /Alaska Native	0 (0)	Use Any Type	100 (22)
Black or African American	45.45 (10)	White Cane	100 (22)
Other	9.1 (2)	Guide Dog	27 (6)
White	45.45 (10)	Sighted Guide	50 (11)
Ethnicity	% (n)		
Hispanic or Latino	9.1 (2)		
Not Hispanic or Latino	90.9 (20)		

Subject Follow-Up: All subjects received 10 hours of BrainPort V200 training from research personnel who were experienced in BrainPort training. Subjects were then given the opportunity to use the device independently in their homes for a minimum of 5 hours per month. Subjects returned to the study site every 3 months to undergo assessment testing. In addition, study staff administered bimonthly phone calls to monitor for adverse events, troubleshoot device problems, and encourage subjects to continue to use the device for the required minutes.

Aim 3: Evaluate the safety and efficacy of the BrainPort V200 device on this population.

Primary Safety Objective

Monitoring for Adverse Events: Adverse events were monitored for throughout the study by performing oral health exams on subjects at baseline, post-training, and quarterly throughout the year. In addition, during bimonthly calls study staff inquired about any issues or complaints. Lastly, throughout the study subjects were reminded to contact study staff if they were experiencing any issues.

Adverse Event Results: The safety objective was met, as no clinically significant device-related adverse events were reported. There were no serious adverse event occurrences throughout the study. The adverse events that did occur were mild to moderate in severity. For one event involving dental surgery (not related to the device) device use was temporarily discontinued, for all other events device use was not changed. None of the events resulted in withdrawal from the study and all of the events resolved without effects by the end of the study. All adverse events were reported to the IRB/HRPO. Details of the adverse events can be found in Table 4.

Table 4. Adverse event occurrences

AE Experienced	Seriousness	Severity	Relationship to Device	Relationship To Procedures	Action Taken	Outcome
Tongue Tingling	Not Serious	Mild	Probably related	Probably related	Use not changed	Resolved without effects
Headaches	Not Serious	Moderate	Definitely related	Definitely related	Use not changed	Resolved without effects
Changes in taste for 2-3 hours after device use	Not Serious	Mild	Definitely related	Definitely related	Use not changed	Resolved without effects
Headaches	Not Serious	Mild	Definitely related	Definitely related	Use not changed	Resolved without effects
Nausea during device use	Not Serious	Mild	Definitely related	Definitely related	Use not changed	Resolved without effects
Changes in taste for 2-3 hours after device use	Not Serious	Mild	Probably related	Possibly related	Use not changed	Resolved without effects
Dental surgery	Not Serious	Moderate	Not related	Not related	Use temp discontinued	Resolved without effects
Mini Stroke	Not Serious	Mild	Not related	Not related	Use not changed	Resolved without effects

Primary Efficacy Objective:

The following data include all subjects who completed the final assessment (n=17).

Object Recognition Tasks (Common Objects and Placing Setting Objects): Four high contrast objects were placed on a table 10” apart. The subjects were instructed to use the BrainPort V200 device to identify the target object and then reach out and grab it without touching any other objects first. The objects in the common objects task included a ball, banana, mug, and spoon. The objects in the place setting task included a plate, bowl, glass, and fork. The assessment was deemed successful if the subject was able to identify five or more objects out of ten trials.

Object Recognition Tasks Results: At baseline, none of the subjects were able to perform either task successfully without the use of the BrainPort V200 device. At final assessment, after one year of independent use, all subjects could identify at least 6 out of 10 common objects and place setting objects. Therefore, the primary efficacy objective for this study has been met. The object recognition success rates from baseline through one year are displayed in Figure 5.

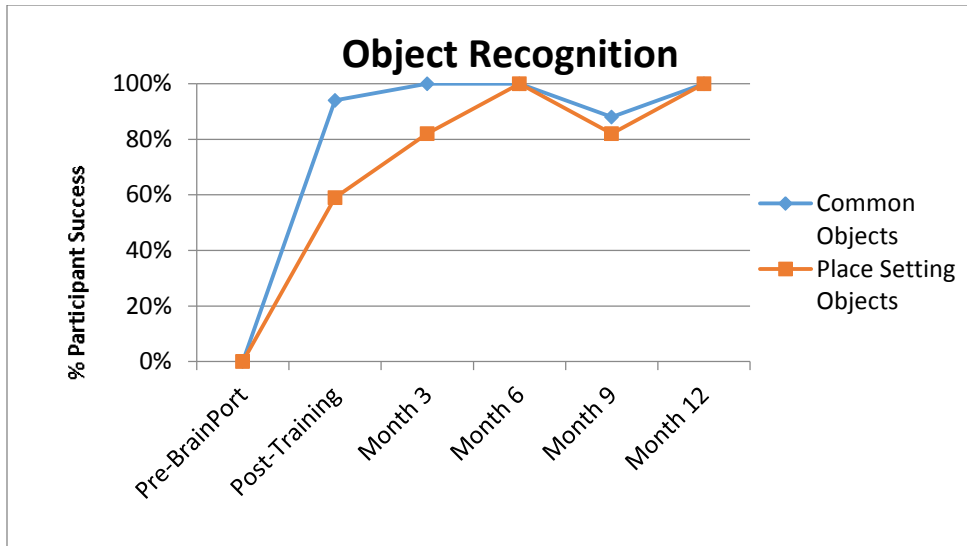


Figure 5. Object recognition task success from baseline through 12 months (n=17)

Reading Tasks: Two reading tasks were performed by subjects:

Flashcards: Ten 3-6 letter words were presented on a standard size flashcard. Subjects were instructed to use the BrainPort V200 to read the words aloud. Successfully reading more than 5 out of 10 words represents success beyond chance.

Sign Detection: This task consisted of a combination of character/symbol identification and mobility. Four signs were hung in a 20' hallway. Subjects were asked to navigate independently down the hallway and identify and touch the target sign. If the subject touched or came within 5" of touching the target sign, this was recorded as a successful trial. The signs included MEN, WOMEN, STAIRS, and DANGER.

Reading Tasks Results: None of the subjects were able to successfully complete either reading task at baseline, without the use of the BrainPort V200. At the 12 month assessment period, 41% of the subjects were able to read at least 6 out of 10 flashcard words and 41% of subjects are able to successfully complete the Sign ID task. The reading tasks success rates from baseline to one year are located in Figure 6.

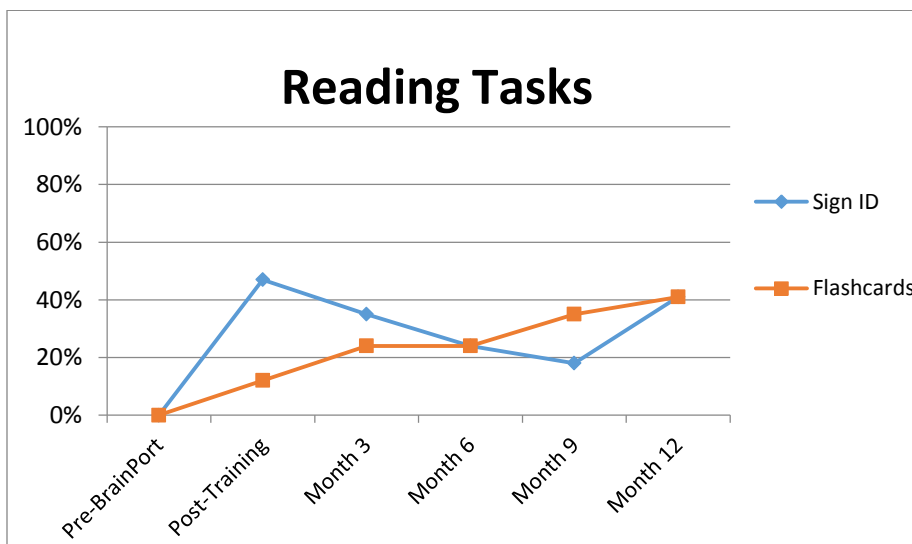


Figure 6. Reading tasks success rates from baseline through 12 months (n=17)

Orientation and Mobility Tasks: The orientation and mobility tasks were scored as pass or fail and included:

- Following a high contrast line on the floor without veering off
- Identifying and avoiding an obstacle in their pathway

- Walking through the doorway without colliding with the doorframe.

Orientation and Mobility Results: Similar to other tasks, none of the subjects were able to successfully complete the orientation and mobility tasks at baseline without the BrainPort V200 device. At 12 months, 94% of subject could follow a line without veering off, 71% could identify and avoid an obstacle in their pathway, and 71% could walk through the door without colliding with the doorframe. The orientation and mobility success rates from baseline to one year are displayed in Figure 7.

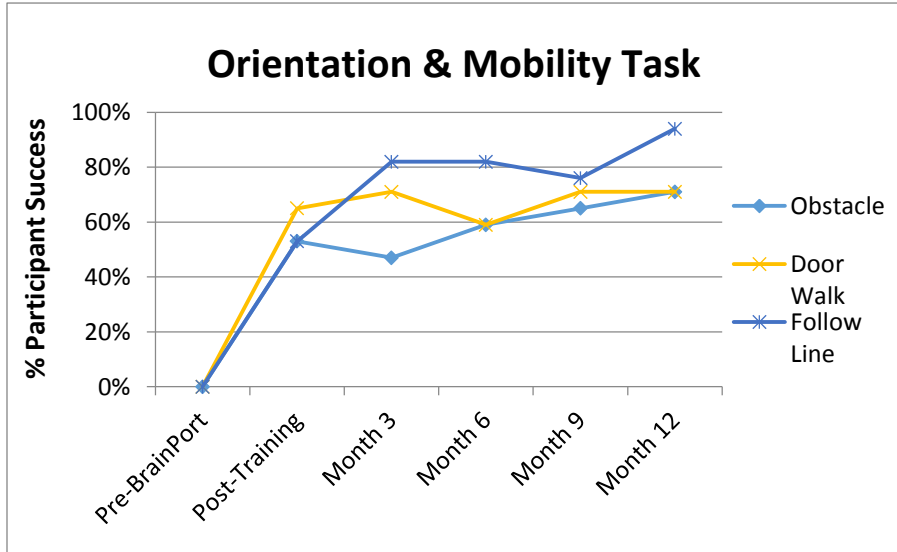


Figure 7. Orientation and mobility success rates from baseline through 6 months (n=17)

Environmental Awareness Tasks: The environmental assessment included identifying features of a room important for orientation and mobility. These tasks were scored as pass or fail and included:

- Identifying a door in the room
- Identifying a window in the room

Environmental Awareness Results: None of the subjects were able to successfully complete the environmental awareness task at baseline without the BrainPort V200 device. At the 12 month assessment, 100% of subjects could recognize a door in the room and 71% could recognize a window in the room. The environmental awareness success rates from baseline to one year are displayed in Figure 8.

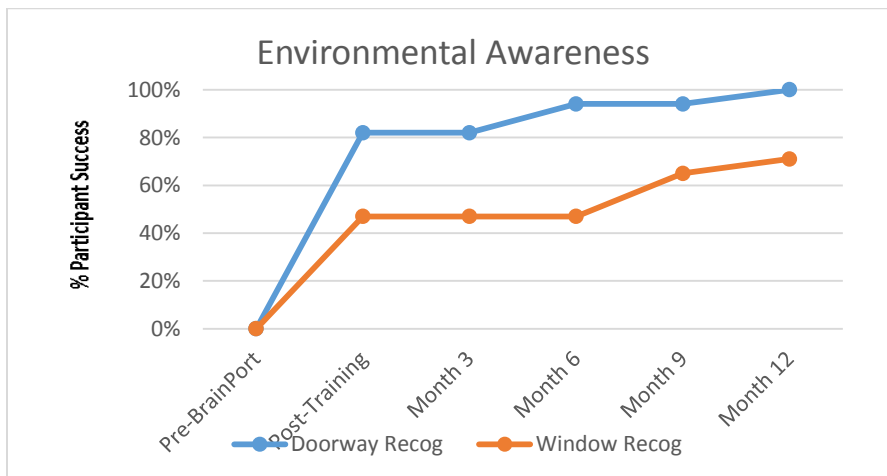


Figure 8. Environmental awareness success rates from baseline through 6 months (n=17)

Summary of Functional Task Performance: The findings from this study are comparable to previous findings on the safety and effectiveness of the BrainPort device in the general blind population. These

results reveal significant improvements in real-world functional task performance in skill areas important to performing activities of daily living more efficiently and independently. At baseline none of the subjects were able to perform the tasks beyond chance level. Subjects demonstrated success in task performance immediately following training and retained a level of success after long-term use. The BrainPort V200 offers a non-surgical method for restoring functional abilities to persons blinded by trauma, whether ocular or cortical. In addition, the device can support the successful integration of persons who are profoundly blind into community life.

Mobile App Tasks

Following app training, subjects were instructed to practice with the SignFinder mobile app (described in Section 3 of this report) independently for 6 months in their preferred public spaces. Subjects were assessed at 9 and 12 month assessments (using the BrainPort combined with SignFinder) on sign location and navigation to signs from a distance of 5 and 10 feet.

Mobile App Task Results

9 month Assessment

At the 9 month assessment (after 3 months of independent app use at home), 88% of subjects could use SignFinder to successfully identify and navigate to a restroom sign independently from a starting distance of 5 feet and 82% of subjects could perform the same task from a distance of 10 feet (Figure 9). Twenty-nine percent of subjects could locate and navigate to an exit sign from 10 feet (Figure 10).

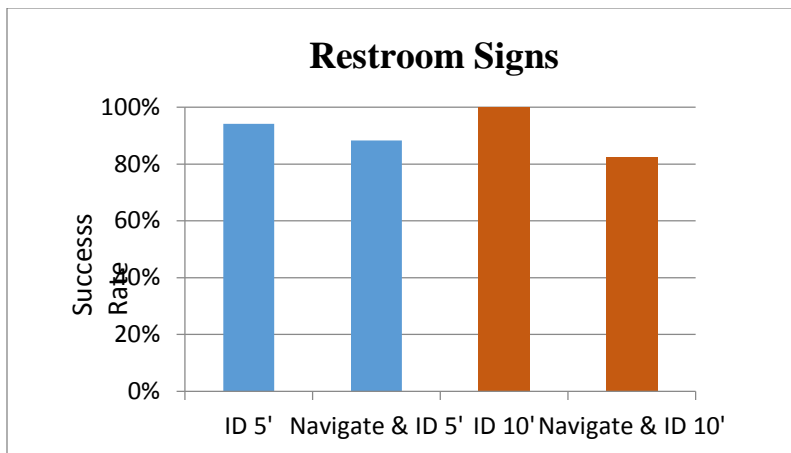


Figure 9. Nine month success rates for identifying and navigating to restroom signs using the SignFinder mobile app at varying distances.

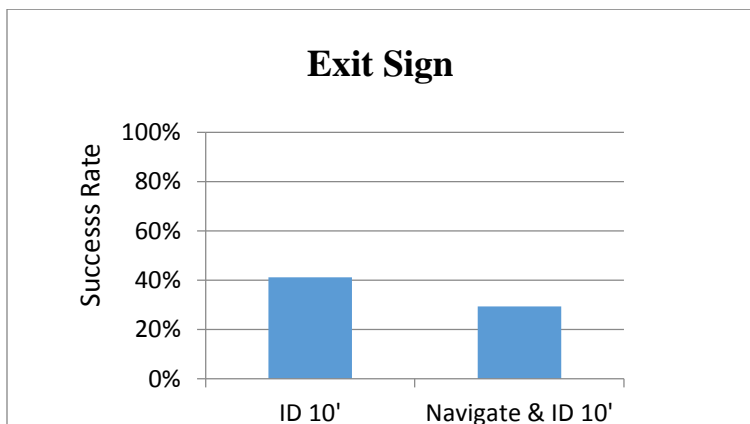


Figure 10. Nine month success rates for identifying and navigating to restroom signs using the SignFinder mobile app at 10 feet.

12 month Assessment

At the 12 month assessment (after 6 months of independent app use at home), 88% of subjects could use SignFinder to successfully identify and navigate to a restroom sign independently from starting distances of 5 and 10 feet (Figure 11). Forty-seven percent of subjects could locate and navigate to an exit sign from 10 feet (Figure 12).

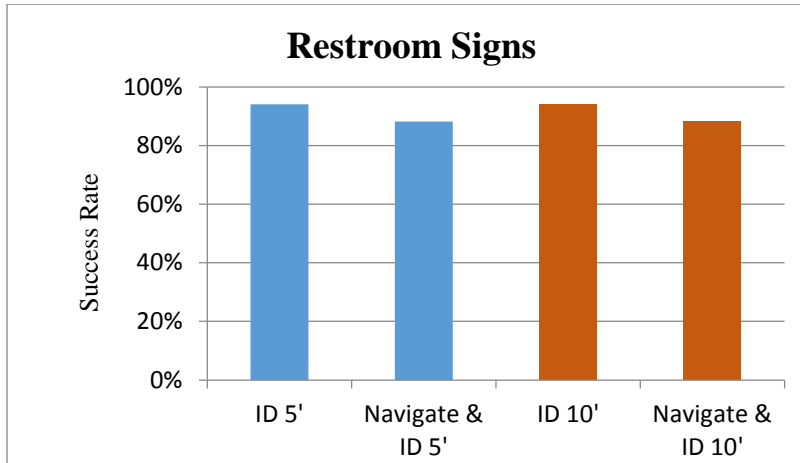


Figure 11. Twelve month success rates for identifying and navigating to restroom signs using the SignFinder mobile app at varying distances.

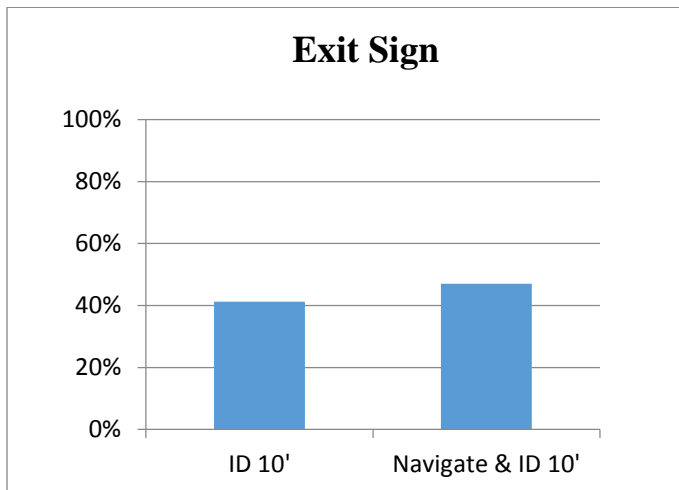


Figure 12. Twelve month success rates for identifying and navigating to restroom signs using the SignFinder mobile app at 10 feet.

Summary of SignFinder app performance: These results demonstrate the feasibility of SignFinder to locate signs that are important in daily life but typically inaccessible to persons who are blind. The tongue stimulation patterns provided by the BrainPort facilitated safe travel toward the sign. This combination of feedback provides users with valuable information that further enhances independent mobility. The exit signs were more challenging for subjects to locate and navigate towards. This may be due to the variable illumination of exit signs and/or surrounding lighting conditions. Future work includes improving sign algorithms to accommodate for lighting issues and expanding the app to include additional signs, such as those of different countries and languages

Subject Feedback: After using the BrainPort V200 for one year, subjects were asked to report their most important accomplishments with the device. Their responses are listed below:

- Watching wife smile and wink at subject
- Exploring neighborhood and learning how things were laid out.

- Detecting lights on and off and objects around the house
- Getting around the home and being productive
- Learned how to read lower case letters, didn't know what lower case letters looked like (prior to using device)
- Navigate apartment complex without assistance, walking to mailbox, etc.
- Walking, could identify edges of pathway
- Being able to figure out how to overcome challenges.
- Sign identification, avoidance of objects, reading the cards
- Reading, drawing, looking at artwork in a museum
- Walking outside
- Reading words
- Recognizing different objects and shapes
- Recognizing different sizes of shapes (e.g., coins)
- Finding restroom (with SignFinder app)
- Finding signs (with SignFinder app)
- Read, identify objects, follow lines on the floor, was once able to determine that park sign was written vertically

Subjects were also asked which BrainPort V200 feature they were most impressed by. There responses are listed below:

- Using device provided hope and happiness
- Added another dimension to experiences
- Overall device concept, cool and interesting
- Exploring new activities, "I thought as a blind person I couldn't do things but with the device I could"
- Use of SignFinder app
- The overall technology and option to zoom in scenes that are at a distance
- Detect signs (bathroom) without asking for assistance
- Provided information would otherwise not have
- Ability to explore new activities
- Ability to identify objects and find doorways
- Identify signs without assistance from others
- Became an additional sense
- Information provided helped fill in the blanks when cane and hearing couldn't pick up on it
- Could learn more about environment when walking around
- Could find objects without assistance
- Increased confidence overall
- Ability to explore new activities

FITBIR

FITBIR form structures were created and final assessment performance data were submitted on in March 2017.

IRB Status

The New England IRB acknowledged closure of this study at all sites on 20 November 2017 and HRPO provided documentation of file closure on 28 November 2017.

What opportunities for training and professional development did the project provide?

Throughout the study networking efforts were initiated by the Lead Researcher, Dr. Grant to engage the Jesse Brown VA Medical Center. These efforts included exhibiting the BrainPort at the Westside Institute for Science and Education Open House", Celebrating VA Research and presenting interim research findings at the VA Young Researchers Forum hosted by the Jesse Brown VA Medical Center Research and Development Service. These activities fostered collaboration between Wicab, Inc. and the Veterans Administration.

BrainPort training commenced at the Central Blind Rehabilitation Center at the Edward Hines Jr. VA Hospital in June 2017 and is ongoing.

How were the results disseminated to communities of interest?

The 6 month interim results of this study were presented at the U.S. Department of Veterans Blind Rehabilitation Services National Convention in August 2016 in Milwaukee, WI by PI, Patricia Grant and Wicab CEO, Robert Beckman. Attendees of the presentation included Blind Rehabilitation Outpatient Specialists, Visual Impairment Services Team Coordinators, and other BRS staff from the VA Central Office. Twelve month performance data results were presented at the 2017 Association for Research in Vision & Ophthalmology (ARVO) Annual Meeting. The SignFinder app data has been submitted for presentation at the ARVO 2018 Annual Meeting. A manuscript will be submitted for publication in 2018.

What do you plan to do during the next reporting period to accomplish the goals and objectives?

Nothing to Report

4. IMPACT

Study subjects were given the opportunity experience a novel electronic vision aid in their personal settings and provide valuable feedback on device usage. Subject feedback contributed to the overall design of the BrainPort V200 device. Our results demonstrate significant improvement in real-world functional task performance immediately following training. Performance was either consistent or improved after long-term use. The BrainPort V200 offers a non-surgical method for restoring functional abilities to persons blinded by trauma. In addition, the device can support the successful integration of blind Veterans and active duty Servicemembers into community life. With access to the BrainPort V200, profoundly blind persons can regain or enhance independence, directly interact with their environments, and gain or regain a sense of autonomy.

5. CHANGES/PROBLEMS

Changes in approach and reasons for change

Nothing to Report

Actual or anticipated problems or delays and actions or plans to resolve them

Nothing to Report

Changes that had a significant impact on expenditures

Nothing to Report

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Nothing to Report

6. PRODUCTS

- The BrainPort V200 electronic vision aid (described previously) has been developed and evaluated under this research. FDA is expected in early 2018.
- No inventions, patent applications, or licenses have resulted from this research.
- No other products were developed under this program

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Information for each person who has worked at least one person month per year on the project during the reporting year, regardless of compensation is outlined below.

1. Name: Patricia Grant
Project Role: Co-PI: Lead Researcher
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 6
Contribution to Project: Ms. Grant has been responsible for overseeing the conduct of the research to ensure consistent adherence to the study protocol across study sites. In addition, she has acted as data monitor, carefully reviewing data and data collection activities. Lastly, Ms. Grant is also responsible for maintaining IRB and HRPO approval throughout the study.
Funding Support: N/A
2. Name: Rich Hogle
Project Role: Co-PI – Lead Engineer
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 4
Contribution to Project: Mr. Hogle has managed the activities of the Engineering team to ensure delivery of devices and associated software. As Lead Engineer, Mr. Hogle has been responsible for the development of the BrainPort V200 from concept through release and support of devices for this research activity.
Funding Support: N/A
3. Name: Derald Woods
Project Role: Software Engineer
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 6
Contribution to Project: Mr. Woods has been responsible for the primary software development efforts related to BrainPort V200.
Funding Support: N/A
4. Name: Ryan Pope
Project Role: Production Engineer
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 5
Contribution to Project: Mr. Pope has been involved with the BrainPort V200 builds, as well as the packaging and shipping activities involved with the V200 delivery to study sites.
Funding Support: N/A
5. Name: Steve Correll
Project Role: Electrical Engineer
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 1
Contribution to Project: Mr. Correll has been responsible for design and implementation of the electronic hardware architecture for BrainPort V200.
Funding Support: N/A
6. Name: Janet Szlyk
Project Role: Site PI
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 1
Contribution to Project: Dr. Szlyk has been responsible for the conduct of the research at the Chicago Lighthouse. Including subject recruitment, device training, documentation, and all study-related procedures.

Funding Support: Translation of Eye Movement Training to Clinical Practice, C0849-R. Grant number: 5I01RX000849-02- 5.0 calendar months

7. Name: Meesa Maeng
Project Role: Research Associate/BrainPort Trainer
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 3
Contribution to Project: Ms. Maeng has been responsible for all study-related procedures at the Chicago Lighthouse, including subject recruitment and screening, device training, and data collection.
Funding Support: Translation of Eye Movement Training to Clinical Practice, C0849-R. Grant number: 5I01RX000849-02 – 4.0 calendar months

8. Name: William Seiple
Project Role: Site PI
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 2
Contribution to Project: Dr. Seiple has been responsible for conduct of the research at the Lighthouse Guild. Including subject recruitment, device training, documentation, and all study-related procedures
Funding Support: Translation of Eye Movement Training to Clinical Practice, C0849-R. Grant number: 5I01RX000849-02 – 5.0 calendar months

9. Name: Tiffany Arrango
Project Role: Research Associate/BrainPort Trainer
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 3
Contribution to Project: Ms. Arrango has been responsible for all study-related procedures at the Lighthouse Guild, including subject recruitment and screening, device training, and data collection.
Funding Support: N/A

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Nothing to Report

What other organizations were involved as partners?

The partner organizations that have been involved in the project are detailed below.

Organization Name: The Chicago Lighthouse for People Who Are Blind and Visually Impaired

Location of Organization: Chicago, IL

Partner's contribution to the project (identify one or more): Facilities and collaboration (study site)

Organization Name: Lighthouse Guild

Location of Organization: New York, NY

Partner's contribution to the project (identify one or more): Facilities and collaboration (study site)

8. SPECIAL REPORTING REQUIREMENTS

The Quad Chart for this reporting period is included in Appendix A.

9. APPENDIX

Appendix A: Quad Chart

APPENDIX A.

Safety and Efficacy of the BrainPort V200 Device in Individuals Blinded by Traumatic Injury

DM130076, Assistive Technologies Research Award

PI: Patricia Grant, Ph.D.

Org: Wicab, Inc.

Award Amount: \$1,393,819.84

Study/Product Aim(s)

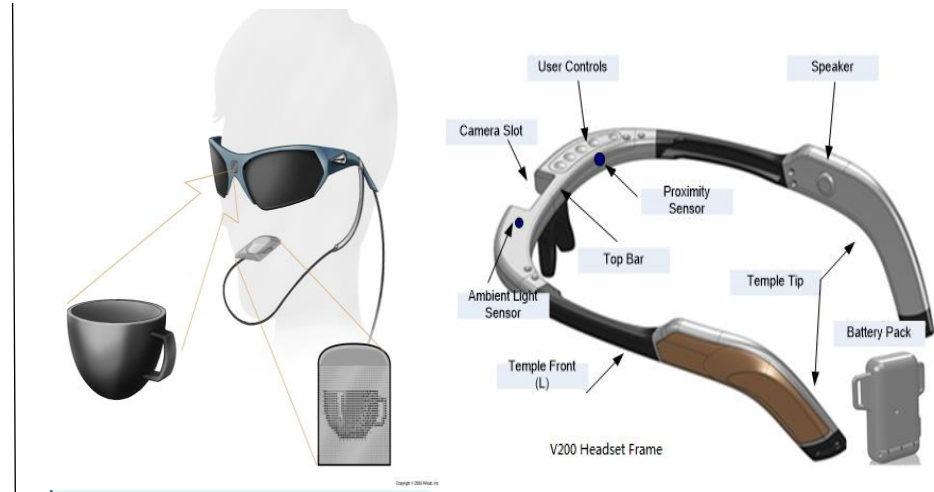
Aim 1: Enable individuals blinded by traumatic injury to test and evaluate the BrainPort V200 device in normal operational settings (at home, public places, etc.).

Aim 2: Evaluate the safety and efficacy of the BrainPort V200 device on this population.

Aim 3: Explore the design and hardware requirements for a population with multiple disabilities (polytrauma).

Approach

Twenty subjects who are profoundly blind due to a traumatic injury were enrolled into the study. Subjects received approximately 10 hours of training in the clinic setting on the BrainPort V200 device and then sent home with the device for 12 months to use the device in their environments. Subjects visited the study sites quarterly to complete efficacy and safety assessments.



The BrainPort device has demonstrated safety and efficacy in individuals blinded without cortical injury. The current research is designed to assess the safety and efficacy of the device in individuals blinded by traumatic injury (i.e. TBI or ocular trauma).

Timeline and Cost

Activities	CY	14	15	16
Subject Recruitment				
Evaluation of device safety				
Evaluation of device efficacy				
Exploration of design requirements				
Estimated Budget (\$K)		\$767	\$627	

Updated: 12/24/2017

Goals/Milestones

CY14 Goal – Human subjects protocol and informed consent approval

- Finalize subject eligibility criteria and assessment measures
- NEIRB Approval

CY15 Goals – Study Site and Subject Training

- HRPO Approval
- Device hardware and software modifications implemented and evaluated
- Recruit and screen subjects
- BrainPort V200 devices and tablets distributed to subjects
- Subjects trained and pre-post training assessments completed
- Quarterly assessments evaluating safety and efficacy of device

CY16 Goal – Complete data collection, perform data analysis and reporting

- Quarterly assessments evaluating safety and efficacy of device
- Data analysis, report safety events and efficacy findings from study

Comments/Challenges/Issues/Concerns

No issues to report at this time.

Budget Expenditure to Date

Projected Expenditure: \$1,393,819.84

Actual Expenditure: \$1,393,819.84