

The UPMC Eye Center at the University of Pittsburgh is conducting a research study which is trying to establish methods for visual function testing in blind or nearly blind persons. As part of this study we will be using a sensory substitution device called the BrainPort™ vision device. The device provides electrical stimulation on the tongue. We are interested in determining whether or not the stimulation patterns on your tongue can help you provide a sensation of vision as well as to maneuver around obstacles. We are also interested in determining how the brain is able to interpret the tongue sensations as vision.

How many people will take part in this research study?

The plan is to have 30 subjects participate in this study, which will be conducted at UPMC.

Inclusion Criteria

Volunteer subjects enrolled and treated in this study must meet all of the following criteria:

1. Over 18 years of age
2. Male or female
3. Blind (documented visual acuity of light perception or worse) or not blind (normal controls)
4. Able to read (or have read to him or her), understand and sign the Informed Consent form.
5. Able to provide valid feedback regarding use of the Brainport device.
6. Able to tolerate functional neuroimaging tests (PET and fMRI)
7. Able to walk and stand independently (previous training)

Exclusion Criteria

Subjects will be excluded from the study if they meet any of the following criteria:

1. Current oral health problems as determined by the subject's history and an examination of the oral cavity performed by a member of the study team. Subject is excluded if any of the following conditions are met:
 - a. A history of injury to the tongue resulting in impaired sensation or use of the tongue,
 - b. Visible open lesions, cold sores, abrasions, blisters, or rash on the tongue,
 - c. Numbness or lack of feeling of the tongue,
 - d. Oral surgery or dental work in the past 3 months or anticipated to occur for the duration of participation in the study (does not include routine dental health exams/cleanings).
 - e. Piercing on the tongue.
 - f. Current smoker (anecdotal evidence that sensation of the tongue is impaired in smokers).
 - g. Presence of any foreign metal in the body with the exception of dental fillings
 - h. Breastfeeding
2. Any medical condition that would interfere with performance on mobility evaluation tests.
3. Known neuropathies of tongue or skin tactile system.

4. Prior exposure to the BrainPort™ device.
5. Unwilling or unable to adhere to all study requirements, including completion of the training period and evaluation tests.
6. Implanted electrical medical devices such as pacemakers
7. Pregnancy
8. Cortical blindness from any cause
9. Claustrophobia that would prevent functional neuroimaging
10. Severe depression

All subjects will be approved for participation in the study by the Primary Investigator as indicated by the signature of the Primary Investigator on the Enrollment and Evaluation forms.

How long will you be in this research study?

You will be in the study for a total of approximately 35 hours.

What will happen in this research study?

This study has two phases. You will be asked to participate in both phases, which are described in the paragraphs that follow. All testing of the device will be completed at UPMC facilities and under the supervision of the trained study staff. No device will be taken home.

The BrainPort vision device consists of a controller and device resembling a lollipop that is put on the tongue. The device on the tongue has an array consisting of 625 gold-plated electrodes that are connected to a camera mounted on a pair of sunglasses. The video camera provides information about objects in its field to the controller. The controller then relays this information back to the electrical array on your tongue. We want to see if this feedback may help you to see light and letters, cause you to move your eyes, detect obstacles, and find your way. In addition, we will see what parts of your brain are working when you use this device.

Study Details

Phase-1: Baseline ocular exam, visual function testing, depression screening, MRI and PET scan. We expect this phase to take four visits, each of which will last between two and three hours.

Following the initial assessment of your abilities, you will be instructed how to use the BrainPort vision device. You will meet at the study site for seven 3 hour sessions for training with study staff. By the end of this training period, you should feel comfortable using the device.

Phase 2: In this phase, we will repeat the computer based visual tests, MRI and PET scans that we performed in phase 1, but you will be using the Brainport device. You will also answer a questionnaire. We expect this to take four visits, again each lasting between two and three hours.

Description of the clinical and experimental procedures

Psychophysical testing: In order to test your visual function abilities, you will be asked to view various images on screens and respond either verbally or by pushing a button. We will test vision function (vision and visual field testing), cortical (brain) responses to stimuli and eye movements

Orientation and Mobility Tests: The tasks will involve walking through an obstacle course, sorting objects and identifying objects.

Neuroimaging: Neuroimaging will take place at the MRI/ PET facility located at the B-wing of Presbyterian University Hospital (PUH). The center employs professionals to conduct these tests. You will be asked to do the following: identify an object with your hand only, identify a texture with your hand, identify an object with the Brainport and your hand, imagine an object, look at a checkerboard. An X ray may be needed to rule out the presence of metallic objects.

Will you need to pay for the tests and procedures?

You will not need to pay for the investigational device or procedures used during the study. All procedures related to the study will be paid for by study funds.

Will you be paid for your participation?

Study subjects will be compensated \$75 per session for participation in this study for up to 14 completed sessions. You will not be compensated if a session is not completed. You will be paid at the end of each study visit.

Who do I contact if I have questions about the study?

You may contact Dr. Amy Nau at 412-647-2200 or email at nauac@upmc.edu

