Study Protocol

Official Title:

Visual Information Restoration and Rehabilitation Via Sensory Substitution Technology in Children

ClinicalTrials.gov ID (NCT number): NCT03002597

Protocol Date: 11/10/2022

The BrainPort vision device is a visual prosthetic designed for those who are blind. It enables perception of visual information using the tongue and camera system as a paired substitute for the eye. Visual information is collected from a video camera and translated into gentle electrical stimulation patterns on the surface of the tongue. With training, users perceive shape, size, location and motion of objects in their environment. It is a functional, non-surgical device developed to demonstrate as an aid to the visually impaired.

Tactile sensory systems have proven capable of carrying information to the brain that is usually acquired visually. Braille and the long cane have provided such information to blind persons for decades, and in the 1960's it was clearly demonstrated that tactile inputs could provide access to written print[1] and visual images[2]. The main limitation to the development of practical vision substitution has been the inadequacy of brain-machine interfaces. Thirty-five years ago Paul Bach-y-Rita, MD wrote "That a successful sensory substitution system is not presently in use may not be due to limited functional capabilities of the brain; it may be due to the fact that an artificial receptor system has not yet been constructed to challenge the adaptive capacities of the human brain"[3].

BrainPort Vision Device

Since 1998, Wicab has focused on biomedical engineering research and development of commercial devices based on its proprietary BrainPort® technology[4]. The BrainPort vision device is a visual prosthetic designed for those who are blind.

Numerous previous studies support using the tongue as a sensory substitution channel[2,3,5-8]. Our and others' research has revealed that the brain can correctly interpret information from a sensory substitution device, even when the information is not presented in the same pathway as the natural sensory system. For example, the optical image actually received by the eye travels no farther than the retina, which converts the image into spatio-temporal patterns of action potentials along the optic nerve fibers. By analyzing these impulse patterns, the brain recreates the image. These impulses are not unique for vision. In fact, all sensory systems code information using the same 'language': neuronal action potentials. Using the vision example as a paradigm, sensory substitution requires only that action potentials be accurately entrained in the alternate sensory information channel. With training, the brain may learn to appropriately interpret information from the alternate channel and then to process that information much as it would data from the intact natural sense[2,3,5-7,9-13]. Therefore, this technology benefits users by stimulating the tongue with usable information about their environment, which some users have described as resembling vision.

Although BrainPort technology stimulates the tongue through the electrode array, the stimulation is not at all painful; a BrainPort device emits only 11.85 μJ per pulse (regulatory limit for cutaneously electrical stimulating devices: 300 mJ). In fact, users often report the sensation as being like champagne bubbles effervescing on the tongue. Participants using BrainPort devices, whether for several hours each day over the course of a few weeks or for 20 minutes a day for up to one year, report no discomfort.

Our results have shown that the use of the BrainPort results in behavioral improvements as well as activation in visual cortical regions using fMRI and PET scans in adults. A trial which seeks to determine if functional abilities can also be improved in a pediatric cohort is justifiable for the following reasons:

1) Neuroplasticity is highest in childhood, and the visually deprived brain is likely to be most receptive to alternative sensory stimulation in this age group.

2) The BrainPort is non-invasive.

3) Other than gene therapy for Leber's Congenital Amaurosis, there are no alternatives to restoring vision for the blind children at this time.

4) The BrainPort already has CE Mark approval and pending FDA approval (final safety study documents submitted to the FDA August 2013), and should be available for purchase by 2014, at least in Europe and Canada. Whether the device could be useful in a pediatric population is an important clinical question.

5) The relation of the anticipated benefit to the risk presented by the study is at least as favorable to the subjects as that provided by available alternative approaches (blind training).

RESEARCH DESIGN AND METHODS

Primary Efficacy Endpoints

The primary efficacy endpoint for this study is a statistical analysis of subjects' improvement over baseline in any of the following areas: light detection, light localization, movement perception, and standardized object recognition tasks after use of the BrainPort. To test our primary endpoints, we will use a within-subjects repeated measures design.

Statistical analysis (general)

All data will be stored in a password encrypted PASS Statistics version 18 database whose contents will be available only to members of the study team. We will use t-tests to assess the differences in performance for all measures on our assessment battery, pre- and post-training. Bonferoni correction will be used to correct for experiment-wise error rate (*i.e.*, the increased possibility of finding many significant correlations due to the multiple tests conducted). Separate analyses of covariance will be performed using age, sex, education, and years since diagnosis as covariates. The major advantage of this design is subject homogeneity; that is, random subject effects are reduced. Because the subjects serve as their own controls, factors such as age, education, mental status, motivation, and disease are completely matched; thus these factors will not contribute to the main effect of training. Matching is always very difficult in individuals with eye disease, and this design resolves this confound.

Subject selection criteria

We will recruit 8 blind subjects between the ages of 7 and 18 from the UPMC Eye Center patient population, the Wicab website, the established volunteer list of over 200 blind subjects from the Sensory Substitution Laboratory, the Clinical Trials Registry at the University of Pittsburgh and the patient population at the ophthalmology department at the UPMC Children's Hospital. Recruitment of normally sighted controls is not justified. We expect to screen 15 blind subjects to achieve our enrollment target. Based upon estimates from our preliminary data, this sample size should allow us to show differences between the naïve and BrainPort condition with a significance level of $p<0.05$ and a power of greater than 0.8.

We will attempt to enroll an equal number of males and females to the extent this is possible. We will attempt to enroll minority populations in our study.

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

1. Between the age of 7 and 18
2. Blind (documented visual acuity of light perception or worse) in both eyes from an eye care provider.
3. Able to read (or have read to him or her), understand and sign the Informed Consent and Assent form.
4. Able to understand the training and rehabilitation protocols involved in the study.
5. Willing to use the BrainPort device

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. 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).
    d. Piercing on the tongue.
    e. Performance better than 20/5000 on the FrACT acuity test (same visual criteria as FDA safety study).

2. Known neuropathies of tongue or skin tactile system.
3. Unwilling or unable to adhere to all study requirements, including completion of the training period, evaluation tests and follow up visits.
4. Implanted electrical medical devices such as pacemakers.
5. Known allergies to nickel, gold or other components of stainless steel.

Study Duration
The duration will be up to 5 visits over the course of approximately 2 weeks. Study sessions will be limited to 90 minutes in length. A subject can elect to have up to two sessions per day which would reduce the duration of the study. We are requiring that at least one parent or caregiver be present for all study visits.

Study Procedures

Screening and Enrollment
The study will be explained to the potential candidates and their parents, including the purpose, procedures, expectations for participation, benefits, and risks. Upon request, an IRB approved patient information sheet explaining the study can be provided for review at home. If the potential subject shows interest in the study, additional pre-screening questionnaires will be administered to determine eligibility. Specifically, our study coordinator will review the inclusion and exclusion criteria over the telephone. We have included this paradigm successfully in other studies with the Brainport, which reduces the likelihood that a subject will travel to our site at their own expense but not meet our inclusion and exclusion criteria.

If the potential subject has successfully passed our pre-screen tests over the phone, then he or she will be provided by mail with the Informed Consent form and the HIPAA Research Authorization Form, the participant Assent form and the Parental Permission form, which will have been approved by the University of Pittsburgh Institutional Review Board. We will offer to provide a JAWS compatible version and/or an audio version to the subject prior to their arrival so that they can review it at their own pace and with their families. These same documents will be reviewed again with the subject and their family member upon arrival for the initial visit. In the event that the subject is not able to sign their own name, a proxy designated by the subject may provide the signature.

A HIPAA research authorization will allow the researchers to access the subject's medical records related to their diagnoses and to enable further disclosure of the subject's study data to the study personnel, study monitor, clinical research organization, and the IRB.

Overview of Study Design
Following consent, subjects will complete baseline psychophysical assessments which have been used in similar BrainPort studies. These consist of simple and easy to understand computer based tests of the ability to detect light, direction, motion, and letters. In addition, we may administer seated tests where the subject is asked to recognize objects, pictures or depth cues. Each of these tests takes between 5 and 15 minutes to complete.

Following baseline studies, a structured "Clinical Training Phase" with the will occur. Our lab has trained over 100 subjects to use the BrainPort device (largest center worldwide), and has established the methods to provide core skill acquisition under the direction of an occupational therapist who works in our laboratory (refer to attachment). Because the subjects in this study will not be taking the device home, but will be restricted to limited use in the controlled laboratory setting, the training will not have to involve outdoor navigation or more advanced skills. After the Brainport training phase has been completed, and the subject has demonstrated basic proficiency with the device, the same set of outcomes assessments administered at baseline will be repeated.

If at any point during the study, the subject subsequently does not meet inclusion criteria or satisfies exclusion criteria, or wishes to stop participation, further testing will be discontinued and the subject will be dismissed.

Detailed description of study design by visit:

Session 1:
- Informed consent
- Review of inclusion and exclusion criteria
- Baseline medical and medication history
- Oral exam
- Baseline psychophysical assessments

Session 2, 3, & 4:
- Training session
- Oral exam

Session 5:
- Repeat outcomes assessments with Brainport
- Oral exam

Each session is expected to last 90 minutes, will be performed at the UPMC, and will be performed by the Research Staff and/or PI.

Note: follow up visits can be combined into a single longer day with morning and afternoon sessions at the request of the subject. We are allowing this because subjects and their families are responsible for their own travel, lodging and meal expenses.

Evaluation Procedures/Outcomes Assessments (Detailed descriptions):
Potential subjects will be examined to verify that vision in each eye is light perception or worse by the PI according to standard practices at the UPMC Eye Center. Subjects will not need to be dilated. In most cases, our blind subjects have prosthetic eyes or have such badly damaged eyes that verification of blindness by clinical exam does not need to occur. In these instances, the ocular examination will be waived. Inspection of the oral cavity, medical and medication history will be performed.

Psychophysical assessments: We begin with rudimentary vision assessment such as light perception and proceed to increasingly complex visual tasks which approach "normal" vision as the device allows. In the event that a subject is not able to perceive better than light perception, tests which ascertain higher functions will not be administered. Below is a representative description of the tests that we commonly employ with BrainPort studies.

The Basic Assessment of Light Motion (BaLM) and Basic Assessment of Grating Acuity (BaGA) have been developed with the intent of testing artificial vision devices, which provide the most rudimentary visual precepts. They have been used to quantify such qualities as light detection, temporal resolution and light motion as well as "grating acuity" for situations where standard resolution acuity is nonexistent. The methods for testing have been described in Artificial Vision by Mark Humayan. Both tests run on a software platform and are presented on a computer LCD screen to the subject. The stimuli they present consist mainly of large targets of varying patterns. The subject is seated in a regular chair while looking at a computer display for these non-invasive tests, each of which last an average of 10 minutes or less. The subject is able to stop the test in the event they feel they need to get up and move around. All visual acuity measurements will be performed by a single examiner. For baseline testing, while one eye is tested, the other will be occluded. We use this to make sure that both eyes have visual acuity of LP or worse to meet entry criteria. Subsequent testing using the Brainport is done using the camera pointed at the computer screen. All vision tests will be performed in a room with standardized illumination.

BaLM Test
This test consists of a battery of four modules for perception of light, time, location, and motion. For this study, we will only use the light and location modules. In a preferences screen, the variables of the tests can be determined and the test can be calibrated to projecting distance and image size.

Upon starting the first subtest the program runs self-paced, requiring the patient to enter an alternative choice response via a numeric keypad. Most visually impaired subjects are familiar with a numeric keypad. At the beginning of each test there is a short sound to prompt a patient's response. After the patient has pressed the corresponding key, two different sounds are played to indicate either a right or a wrong response.

Light Detection
After the initial sound a full-field flash appears, or the display stays black in a random fashion (maximal screen luminance in our setup is 5100 cd/m^2, Michelson contrast of 99.5%). The patient has to indicate whether he has seen a flash or not. The duration of the flashes can be adjusted in the preferences screen. Hit rates at different brightness as well as the stimulation parameters are recorded.

Light Localization

A fixation target appears in the middle of the display, followed after a few seconds by a wedge-shaped bright field with its tip on the central fixation dot. The base is oriented in one of eight directions (up, down, left, right, and four obliques). The patient is asked to enter the direction, and then a randomly chosen new direction is presented. The number of possible directions can also be limited to four (up, down, left, and right).

BaGA Test

This test is similar to the BaLM test described above, but the presented stimulus consists of sine wave gratings of increasing or decreasing frequency. Grating acuity is often used in vision research to determine level of visual function. In a preferences screen, the variables of the four tests can be determined and the test can be calibrated to projecting distance and image size.

Upon starting the first subtest the program runs self-paced, requiring the patient to enter an alternative choice response via a numeric keypad. Most visually impaired subjects are familiar with a numeric keypad. At the beginning of each test there is a short sound to prompt a patient's response. After the patient has pressed the corresponding key, two different sounds are played to indicate either a right or a wrong response. Hit rates and stimulation patterns (frequency of sine wave grating, orientation and contrast) are recorded.

Analysis of Test Results

The BaLM and BaGA tests automatically calculate percentages of correct responses of each test, as well as mean reaction times and standard deviation of measurements for each test. ANOVA analyses will be completed to compare pre- Brainport and post- Brainport use. Analysis will also be completed to compare performance between those with acquired versus congenital blindness, age, gender and presence of TBI.

Object Recognition Tasks

Object recognition tasks which involve the subject seated at a desk will be undertaken. These tests will involve tasks that will first ask the subject whether an object is present or not (2 choice discrimination). If successful, then the more complex discrimination tasks will be employed, which will ask the subject to recognize a specific object out of a choice of 3 objects or 5 objects. Testing will be repeated for 20 trials each.

Analysis of Test Results

All data is recorded into a password protected PASW database. Primary performances measure the ability to detect whether an object is or is not present, as well as to recognize a specific object within a field of other objects. Secondary measures include time to object recognition. ANOVA analysis will be completed to compare pre-Brainpor and post-Brainport use. Additional analysis will compare performance between those with congenital versus acquired blindness, age, gender and presence of TBI.

ADVERSE EVENTS

Investigators will assess subjects for adverse events during each training session and each follow-up visit. Oral exams will be performed at baseline, and at the end of each session. Subjects will also be asked at each visit whether they have experienced any medical problems since their last visit and whether or not they would consider the problems to be due to the device use. All expected and unexpected untoward occurrences related to the Brainport will be considered adverse events and will be reported to the PI, and the reviewing IRB as soon as possible but no later than 10 days following the occurrence. Subjects will be instructed to report any suspected adverse event to the research staff immediately.

Potential adverse events that will be monitored for with the BrainPort™ vision device include the following:

- A mild tingling sensation or residual sensation in the region of the electrical stimulus on the tongue. While unusual, this sensation is not reported to be annoying, does not interfere with normal activities, and it fades with time.
- Discomfort associated with the electrical stimulus on the tongue. No observed or received reports of tongue irritation or pain occurred during a one year long FDA safety study in 75 subjects. Although no long-term adverse events are known or expected, no data is available on the long-term effects of electrical stimulation of the tongue.

Investigators will be asked to report and evaluate all adverse events and indicate the probable relationship to the device. All adverse events will be followed until they are resolved or the investigator has determined the condition to be chronic or stable or the subject's participation in the study has been terminated.

ETHICAL CONSIDERATIONS

Risks and Mitigation Strategies

There are no foreseeable risks involved in the proposed psychophysical and object recognition testing for visual function as these involve looking at a computer monitor or other objects while seated.

It is possible that the stimulus on the tongue may seem too strong and produce discomfort. Subjects have complete control of the sensation strength, and can adjust it to their preference. However, they can also simply remove the electrical stimulator at any time or press a button to end the stimulus. Some subjects have reported a mild buzzing sensation on the tongue, lasting from several minutes for up to one hour, after the stimulus is turned off. While unusual, this sensation is not reported to be annoying and does not interfere with normal activities, such as taste, talking or swallowing. Subjects will be asked to report this sensation to the study staff. Additional known risks arising from use of the BrainPort™ balance device are minor. These potential risks include a risk that the materials used in the construction of the device may irritate the mouth or tongue, irritation of the tongue from the electrodes on the component of the device that contacts your tongue, excessive electrical stimulation from the strength of the signal coming through the electrode array resulting in discomfort to the tongue, and the ongoing risks of falls. If the device becomes displaced in your mouth, there is a chance that you will bite down on it and injure your tooth/teeth There is a slight risk of electrical shock. These risks may be minimized through the assessment and education of study participants in the orientation phase of the study, instructions to limit the electrical stimulation and signal strength to a safe level, training subjects to set the electrical stimulation level according to their preferred level of strength, using only device materials that have been previously tested to be sure the materials of the device are suitable for contact with and use in the mouth and close guarding by the clinician during the Training Phase. Wicab, Inc. has not observed any significant adverse events during prior clinical studies of the BrainPort™ vision devices. Nor has the company observed adverse events during studies of a similar device used for balance rehabilitation. There also may be other side effects that are not known. Many side effects go away shortly after use of the BrainPort™ is stopped, but in some cases side effects can be serious, long lasting, or may never go away. There is not enough medical information to know what the risks might be to a breast-fed infant or to an unborn child carried by a woman who takes part in this study. Therefore, a women who can become pregnant must state whether she is pregnant before taking part in this study. It is also important when using the device that subjects do not take any additional physical risks that they would not take ordinarily. Risks include injury due to bumping into objects or falling when walking with the device. Subjects will be closely monitored by the study staff and prevented from bumping objects whenever he or she is ambulatory.

The BrainPort Vision device:
1) Is not an implant
2) Is not used in supporting or sustaining human life
3) Does not aid in diagnosing, curing, mitigating, or treating disease
4) Does not present a potential for serious risk to the health, safety or welfare of a subject.

Confidentiality will be maintained throughout the study. Subjects will be identified by research study numbers, which will be the only identifying information to appear on data and documents used for evaluation or statistical analysis. No verbal or written information concerning any subject will be released without the written consent of the subject. Records will be maintained only in anonymous research files, kept in double locked quarters and

made available only to qualified research personnel. There will be regular meetings at least monthly of the investigators to review the status of the study and to ensure that confidentiality is being maintained.

Benefits to the Subject / Justification for Study
The information learned from this study may help investigators provide better care for those who are blind in the future. This study will provide general benefits to society in helping to further the field of artificial vision. The device used in the study may provide some benefit to the subject. Many blind persons who have used the Brainport device report that they have a sense of "vision" while using the device. There will be no provisions to make the device available to or sell a BrainPort device.

Informed Consent
A properly executed and written informed consent document that complies with the Federal Regulations for the Protection of Human Subjects (21 CFR 50), state/local requirements, and IRB requirements shall be obtained from each subject before any study procedures are performed. The investigator shall provide a copy of the signed informed consent to the patient. Completed consents will be available for auditing by the sponsor during site monitoring.

Permission
Permission of at least one parent will be required. We have taken the following steps to guard against coercion, exploitation and unrealistic promises: 1) Pre-screening 2) no monetary compensation for study participation 3) Short duration of study with strictly controlled use of the BrainPort device.

Assent
The child will be given an explanation of the proposed research procedures in a language that is appropriate to the child's age, experience, maturity, and condition. This explanation will include a discussion of any discomforts and inconveniences the child may experience if he or she agrees to participate. We will require that a parent or caregiver be present during the assent procedures to verify the child's understanding and to support the child's preferences.

Subject Confidentiality
The study will be conducted in accordance with the Health Insurance Portability and Accountability Act (HIPAA). Subjects or their guardian/parent will be asked to give authorization prior to the start of the study for use and release of their protected health information in the study. All information collected about subjects during the study will be kept strictly confidential. Any information regarding patient data will be kept in a password secured computer, data kept on a paper file will be stored in a locked filing cabinet accessible only to study staff. Subject names will not appear in any reports, presentations, or published articles.

Materials that identify subjects as individuals, including medical records and test results, will not be released without the subject’s explicit permission as required by law. Subjects will be made aware that their medical records, which identify them as individuals, may be inspected by the IRB, Wicab, and the University of Pittsburgh IRB to insure the integrity of the data. Subjects will also be made aware that the FDA may audit any clinical site, including review of medical records of participants.

Subject Remuneration
Study subjects will not be compensated for the study.

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STUDY MONITORING

The Principal Investigator, Dr. Amy Nau, will be responsible for monitoring all aspects of the human based testing for this study that occurs at UPMC. The investigators will conduct meetings regarding human based studies at least every eight weeks. Topics to be covered at these meetings will include: recruitment, screen failures, enrollment, data retention, and data collection (data integrity, adverse events, unanticipated problems, security and confidentiality).

Monitoring will be conducted in compliance with IRB requirements. Study records will be inspected monthly by the PI responsible to ensure that the study is being conducted in accordance with the approved investigational plan, and that the study report forms are being completed accurately. The PI will also be responsible for reviewing relevant scientific literature to determine if developments affecting the study have occurred. Study records, including copies of IRB approval documents, and signed informed consent documents will be maintained by the investigators and made available for review by the University of Pittsburgh IRB.

REGULATORY CONSIDERATIONS

All aspects of this study are governed by federal regulations pertaining to responsibilities of sponsors and investigators for non-significant risk studies (21 CFR 812, Subparts C and E), protection of human subjects (21 CFR 50), and institutional review boards (21 CFR 56), as applicable. Adequate steps will be taken to ensure the accuracy, consistency, and reliability of the data. All data will be reviewed by trained personnel to ensure that the study is conducted according to the protocol and audit of the data recording forms for completeness, accuracy and legibility prior to data entry. All investigators and research staff participating in the study will have clinical study experience and will have completed the University of Pittsburgh's web based training modules through the Office of Research. All research staff will be trained in the requirements of the study. All staff who have contact with minors will receive institutional clearances. The principal investigator is ultimately responsible for the validity and accuracy of the data supplied on the Case Report Forms. Authorization for completion of the forms may be delegated, but responsibility may not be delegated. Information submitted for entry into the study database will be reviewed according to accepted techniques for data quality control. Database entries will be subject to routine audit against source documents.

PROPOSED LABELING

Device labels and labeling have developed for the proposed study. The device package label and all device manuals will include the statement "Caution: Investigational Device. This device is limited by Federal law to investigational use". Wicab, Inc., the manufacturer of the BrainPort provides all investigators with detailed instructions for use of the device, which include indications, warnings, precautions, use instructions, and potential adverse events.

Training Curriculum

A BrainPort training program has been developed based upon the preliminary experiences and is summarized below. We have found that subjects do not all learn at the same pace, so some subjects may advance to the next level while others need additional time to master certain skills. The skills attained will be documented in the subject case report form. This will be monitored to ensure that the pace of training is appropriate. As mentioned, return subjects who have already completed our training program and who know how to use the device will undergo a shortened, refresher as opposed to going through the entire curriculum.

Basic BrainPort Skills

Subjects will be instructed on how to wear and operate the BrainPort device. The use of controls, such as zoom and preset gain settings, on/off switches, contrast inversion will be practiced. Handling, maintenance and care of the device, as well as troubleshooting and battery replacement will be covered. Once this is mastered, the first task involves a white felt line stimulus on a black felt background. Subjects are encouraged to explore how to point the camera at the stimulus, using their hands for biofeedback. The line is then placed in various positions on the felt background (up, down, left, right) and in various orientations. More difficult tasks include finding the stimulus on a white board or blackboard without the benefit of tactile assistance.

Head movement skills and spatial relationships

Subjects will be asked to demonstrate their ability to use the controls and maintain the device. We will test them to make sure they are able to discern the position of a white line stimulus as well as the ruler. Once proficiency is determined, the next task will be to learn where to point the camera. The subject will be seated and will practice pointing the camera at the white line stimuli with accuracy and using the zoom function. Biofeedback using the hands and verbal cues will be employed. Once this is mastered, the subject will be challenged to find high contrast linear objects on a table, to locate the trainer and to find parts of their own body using the device. Spatial relationships between oneself and an object of regard will be introduced (i.e., spatial localization on the tongue to tell if an object is near or far from one's position). We will also begin to challenge the subject to perceive two or more high contrast line stimuli as well as their orientation and spatial relationships. Next, participants will explore how stimulation changes when the object is brought closer and moved farther from the camera. Subjects will learn that the stimulation gets stronger and larger as the object gets closer to the camera and smaller and weaker as the objects are moved further away.

Shape identification

Subjects will first be asked to demonstrate pointing the camera at stationary objects, use of zoom function, locate a body part and two point discrimination task. Once proficiency is demonstrated, identification of high contrast felt shapes on a black background will be practiced. This will be supplemented with 3 dimensional blocks that the patient will also handle. The subject will begin to explore the effects of shadows and contrast. Biofeedback using Wiki-sticks or other tactile apparati will be employed. Once basic shapes are mastered, then combinations of shapes and more complex structures will be used. The subjects will be taught to confirm the location of these objects by reaching toward and picking up the objects. Subjects will be encouraged to touch the objects and to re-analyze the stimulation pattern in order to build the link between hand-tactile knowledge and the newly developing tongue-tactile knowledge. At this point, some subjects are able to stack blocks to build simple structures or place objects into a cup.

Complex shapes, letters and numbers, *larger environments*

Practice will be given in perceiving, recognizing and categorizing shapes and symbols (*e.g.*, two-dimensional

square wave gratings of various spatial frequencies and contrasts, letters and numbers of various sizes) on hand-held cards, on a computer screen and with the hand (i.e. child's foam letters and numbers). Instruction will be given in identifying the distinguishing features of the targets to help discriminate the targets. Practice will be given in categorizing the targets into increasingly difficult groups. If the subject does well, we begin to move beyond stationary desk related tasks to furniture identification, door and window and sign identification (exit, elevator, bathroom, etc.). We will teach them spatial relationships of objects to each other as well as object to self.