Optical Head-Mounted Display Technology for Low Vision Rehabilitation

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PROTOCOL

1. Background

Worldwide it is estimated that 191 million people have moderate to severe visual impairment (MSVI) and an additional 32.4 million are blind (1). Patients with uncorrectable MSVI may undergo low vision rehabilitation (LVR), which has been shown to improve functional abilities, such as mobility (2). However, existing LVR strategies do not adequately address severe visual field constriction, and much of the evidence that points toward improved functional performance from LVR is based on patient self-report (3). Accordingly, there is a **critical barrier** to improving and measuring function among patients with severe visual field constriction that we seek to address.

In this pilot study, we will test the **hypothesis** that optical head-mounted display technology expands constricted visual fields and improves mobility and quality-of-life. While there are many causes and forms of visual impairment, our **objective** is to assess optical head-mounted display technology in LVR for patients with severely constricted visual fields resulting from retinal dystrophy.

Objectives/Specific Aims

We will test our hypothesis in the following aims:

Primary Aims

1. To demonstrate that optical head-mounted display technology increases the planimetric area of the visual field.

Other Aims

2. To quantify the impact of optical head mounted display technology on mobility using gait and head movement analyses.
3. To measure the impact of optical head mounted display technology on vision-related quality of life and self-reported function.

1. Methods

a. Study Design

Demographic data, medical history, laboratory results, medications and clinical information will be extracted from the medical record, including visual acuity and results of visual field, electroretinogram, ultrasound, optical coherence tomography, MRI and CT.

Participation in the study will occur on two separate days 2-4 weeks apart.

Upon enrollment all participants will complete:

- Measurement of height, weight and limb length
- Measurement of visual acuity and contrast sensitivity
- Full ophthalmologic examination including intraocular pressure measurement, slit lamp biomicroscopy and indirect ophthalmoscopy
- Goldmann visual field examination
- Windows tablet visual field examination
- Electroretinogram (if not done in year prior to enrollement; only done by patients, not controls)
- Impact of Vision Impairment Questionnaire (4) and Independent Mobility Questionnaire (6)
- Mobility testing, as detailed in below (Aim 2)

Participants will be fit with HMD technology (Epson Moverio www.epson.com/moverio; **Figure 2**) and undergo a brief training with the investigators to learn about use of the device and will receive materials describing how to charge the device and turn it on and off. While wearing the device the subjects may have some discomfort related to the weight of the device on the ears and/or nose. The nose piece can be adjusted with pads for optimal comfort. A band on the arm pieces of the frame can also be adjusted for comfort. Initially, there may be the sense of disorientation, may feel dizzy or nausea, but with coaching/training the subject is anticipated to adapt. In order to adapt to the technology, participants will be permitted to bring the HMD home to use (for 2-4 weeks).

When participants return after a period of adaptation to the HMD, they will undergo the following:

- Impact of Vision Impairment Questionnaire (4), Independent Mobility Questionnaire (6), and the System Usability Scale (12)
- Videotaped open-ended interview in which subjects will be asked to describe their experience using HMD and to discuss any challenges and successes using the technology.
- Goldmann visual field and tablet visual field examination (while wearing the HMD)
- Mobility testing, as detailed below (Aim 2; white wearing the HMD)

<u>To accomplish Aim 1 we will use the following approaches:</u>

After the period of in-home adaptation, participants will return to have their visual field retested with Goldmann perimetry after a period of adaptation to the technology. We predict the outcome of increased planimetric area of the peripheral vision determined by Goldmann perimetry.

<u>To accomplish Aim 2:</u>

We propose to collect and analyze gait and head movement parameters in order to provide a quantitative analysis of mobility-associated factors of persons with severe visual field constriction and controls with and without the use of optical head-mounted display technology. We will mount an inertial measurement unit (IMU) data logger (Actigraph GT9X “Link”, http://www.actigraphcorp.com/products/actigraph-link/; **Image 2**) on the patients' shoe; it will be placed inside a small pouch that rests on top of the shoe laces. A second IMU device will be mounted on

the frames of the patients' existing glasses (or on a mock frame if the patient does not wear glasses) in order to measure head pitch, roll and yaw. The subjects will be asked to walk around a long empty corridor during which time they will be timed and videotaped and IMU data will be acquired. Then, participants will be asked to walk the same corridor after obstacles are arranged in the corridor every 1-2 meters. Obstacles will be short pieces of foam lying on the floor, knee to waist high cardboard boxes, or pieces of foam hanging from the ceiling. A research assistant will follow close to participants in order to provide assistance should this be required. Testing mobility in the presence of obstacles is important in order to more closely approximate real-world scenarios. Video recording is essential in order to correlate aberrancies in IMU data with obstacles in the patients' environment. The same procedure will be repeated with the patients wearing optical head-mounted display technology after the period of in-home adaptation to the technology with the device turned off (to serve as a negative control) and with the device turned on.

To accomplish Aim 3:

Participants will all complete the Impact of Vision Impairment and Independent Mobility Questionnaire at the time of their enrollment in the study. These surveys will be completed again after the period of in-home adaptation to the OHMD. We will also analyze qualitative data collected through open-ended interviews after use of HMD.

We will conduct statistical analyses, as detailed in Section 2e, to describe associations between outcomes assessed throughout our Aims.

b. Eligibility

Participants with retinal dystrophy will be recruited into this study from the Retinal Dystrophy Clinic in the Department of Ophthalmology and Visual Sciences at the University of Michigan.

Normal controls will be included to adjust for the baseline impact of HMD on visual fields and gait parameters and to compare these to data from patients with RP. Comparing to a group of age-matched control patients will allow us to investigate and understand the true impact of HMD on visual fields, gait, and quality of life. Control participants will be recruited from the Comprehensive and Pediatric Ophthalmology Services at the University of Michigan. We will seek to enroll up to 40 subjects in order to obtain ten patients and ten age-matched controls with complete data, allowing room for those who don't complete both study visits and technical errors with equipment.

Criteria

Inclusion criteria for subjects with retinal dystrophy:

- diagnosis of retinal dystrophy
- severe vision loss that constitutes legal blindness
- able to perform a reliable Goldmann visual field test
- constricted visual field less than or equal to 20 degrees by Goldmann perimetry using the III4e stimulus in at least one eye with best-corrected visual acuity ≥ 20/60

Inclusion criteria for control subjects:

- healthy controls
- able to perform a reliable Goldmann visual field test

Exclusion criteria for subjects with retinal dystrophy:
- movement disorder that precludes evaluation of mobility
- functional vision loss
- pregnant women

Exclusion criteria for control subjects:
- visually significant ocular condition other than correctable refractive error
- movement disorder that precludes evaluation of mobility
- functional vision loss
- pregnant women

c. Study Setting

Patients will be recruited from the Retinal Dystrophy Clinic of the Department of Ophthalmology and Visual Sciences at the University of Michigan; controls will be recruited from the Comprehensive and Pediatric Clinics of the Department of Ophthalmology and Visual Sciences at the University of Michigan. Study exams, clinical testing, surveys and interviews will be completed in the Kellogg Clinical Research Center. Mobility testing will be conducted in a hallway located in the Kellogg Clinical Research Center.

d. Outcome measures

Primary Outcome Measures:

- Change in the planimetric area of Goldmann visual field with the use of head-mounted display technology compared to baseline (measured in degrees squared):
  Using computer software we will calculate the area of participants' Goldmann visual fields in order to obtain a summary quantitative measurement of the extent of peripheral vision.

Secondary Outcome Measures:

- Change in gait speed compared to baseline (measured in seconds):
  Gait speed will be measured using an inertial measurement unit attached to participants' shoes and will quantify the time taken to move from the beginning to end of a short mobility course.

Other Outcome Measures:

- Change in patient-reported ability for independent mobility as assessed by subject responses a validated questionnaire:
  Independent Mobility Questionnaire (scored from 35 to 175 with 175 representing extreme mobility impairment)
- Change in patient-reported mobility and independence as assessed by subject responses a validated questionnaire:
  Mobility and Independence domain of the Impact of Vision Impairment Questionnaire (scored from 0 to 33 with 0 representing poor mobility and independence)
- Change in stride length compared to baseline (measured in mm):

Inertial measurement units attached to participants' shoes will track the length of each step as they walk through a short mobility course.

- Change in stride width compared to baseline (measured in mm):
  Inertial measurement units attached to participants' shoes will track the width of each step as they walk through a short mobility course.

- Change in foot orientation compared to baseline (measured in degrees):
  Inertial measurement units attached to participants' shoes will track the orientation of their feet as they walk through a short mobility course.

e. Planned Data Analysis

To address Aim 1 the visual field will be assessed before and after being trained to use optical head-mounted display technology. The Goldmann visual field plots will be scanned and the planimetric areas for each stimulus size will be measured using Adobe Photoshop CC (San Joe, CA) as previously described (8). In brief, using a scale of 10 degrees on the visual field, the corresponding number of pixels are determined, and the units are set to millimeters. Areas are measured in mm^2 using the Magic Wand tool and are converted to degrees squared. Areas of scotomas are subtracted from the total area. We will analyze the change in area before and after a 2-4 week period of adaptation to the OHMD. The adaptation period is important as it will allow subjects to become familiar with how to use the device and to gain insight into how using such a device may impact their life. The Mann-Whitney U test will used to compare change in visual field area between patients and controls.

To address Aim 2 we will measure change in gait speed with and without the use of OHMD. We will calculate percent preferred walking speed to compare the ratio of gait speed measured in the presence and absence of physical obstacles. We will also use our data processing algorithms to reconstruct the paths of the feet and head movements during the planned experiments from which we can estimate mobility parameters (9–11). For gait, we will gather measures of stride length, width and period, and their variabilities, from straight-line walking, lateral/foot-angle relation, stride frequency, ground contact time, etc. For head movement we will gather measures of head pitch, head roll and head yaw. The mean and standard deviation of each gait and head movement parameter will be compared before and after being trained to use optical head-mounted display technology (11,12). We will use Wilcoxon signed-rank test to test for significant differences. Significant changes (and trends) will be assessed for direction and magnitude, and resulting values will be compared to gait and head movement parameter norms before and after using the optical head mounted display. The Mann-Whitney U test will used to compare changes in gait parameters between patients and controls.

To address Aim 3 we will use the Wilcoxon signed-rank test to determine whether individual participants' survey scores changed from baseline when using optical head mounted display technology. We will also use the Mann Whitney U test to compare changes in survey scores between patients and controls. Cohen's d will be calculated to measure the overall effect size of the intervention as measured by the surveys. Minimum clinically important differences will also be calculated (ratio of change in visual ability to 1.95 standard errors of the measured change) to determine if changes in each individual's visual ability were clinically important.

We will also calculate Spearman correlations between variables (visual field area, mobility parameters and survey results) and use multiple regression to investigate associations while controlling for covariates.

Image 1. The Epson Moverio® Head Mounted Display.

Image 2. The Actigraph Link Inertial Motion Unit.

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