Design Brief

Background

Age-related macular degeneration is the deterioration of the central portion of the retina which leads to a blind spot called a scotoma. Current methods to map the size and location of cotomas require properly trained medical personnel to use expensive imaging equipment (scanning laser ophthalmoscope) or they lack quantitative information, increasing chances of variability due to inter-observer error.

In the field of rehabilitation, a system for testing/training detection of stimuli in the visual field already exists. This solution is called Dynavision. Originally created to test spatial awareness in athletes, this system allows for effective preliminary testing/training for individuals with vision loss. However, the Dynavision is limited to the clinical environment due to cost. Additionally, the Dynavision is a static training tool which can be ineffective in teaching/training individuals with small scotomas that are at the edge of the visual field. Small scotomas may seem insignificant; however, this condition can have disastrous outcomes for individuals, especially when driving. With these limitations of the current system, a new system that reduces cost would allow for implementation into the home allowing for testing/training without an appointment with an occupational therapist allowing; 1) reduced trips to an occupational therapist, which is especially beneficial for elderly patients and 2) allows for an occupational therapist to more effectively utilize appointment times by having the time to begin the appointment with activities that otherwise may have not been accomplished in that current appointment. Also, a system that extends the interactive space of the Dynavision around to the sides of the individual requiring them to interact more with the system may increase the effectiveness of testing/training for individuals with small scotomas. Additional methods for obtaining information on scotomas include expensive imaging medical modalities such as the scanning laser ophthalmoscope. A simple technique used to estimate scotoma location was developed by Dr. Fletcher, an opthamologist, and requires the patient to stare at the center of the paper and tap a pen when a laser pointer flash is seen in their visual field. Although these methods provide useful information, the need for increased quantitative data regarding scotomas obtained from affordable technology is still important. Once the scotoma is detected, monitoring its size over time is an important step in understanding the degradation of the patient's visual field. Once this information is obtained, eye scanning training and rehabilitation is required.

Feasible Concepts

Concept 1

The first potential concept is a modified version of the Dynavision system. This system would be designed with the low-vision stakeholders in mind. It would expand the testing area while increasing availability to patients by reducing cost. Microcontrollers such as Arduino and Raspberry Pi can be utilized to control the system of LED lights and buttons to cheaply produce an alternative to Dynavision.

Concept 2

Concept 2 utilizes a set-up similar to the Dynavision, however, does so in augmented reality. Through AR goggles such as the Hololens, the opportunities for testing would increase. Additionally, this would allow patients to interact with hand movements alone instead of full arm movements to hit the buttons on Dynavision. Due to the virtual environment, customization of the system significantly increases.

Figure 1. Current Dynavision model for Concept 1 and Concept 2

Concept 3

Concept 3 builds upon the idea of concept 2, which incorporate the virtual environment. However, Concept 3 uses virtual reality. In this concept, an eye tracking system is in the inside of the VR goggles to track eye movement throughout the testing and training. Scotoma quantification (testing) would work by having the individual stare at a dot in the center of the goggles field of view. Visual stimuli would then appear in various areas around the field of view, at which time the patient would confirm seeing the stimulus by pressing a button on the controller. To avoid false diagnosis, the eye tracker verifies the eye focused on the center point. Algorithms will be designed to interpret the results of the test and map it to quantify the location and size of scotoma. The virtual environment allows for customizable stimuli and environments. In addition to testing, the training portion will be dynamic stimuli that requires the patient to utilize various eye-scanning techniques. Using the controllers, the patient can then “grab” the stimulus. This training system may resemble VR games such as Audioshield, but be more customized to cater to the low-vision community.

Final Design

Limitations of current methods to assess the size and location of blind spots include the need for an appointment, expensive imaging equipment (scanning laser ophthalmoscope), and inability to quantitatively track the size progression of the blind spot (California Central Visual Field Test (CCVFT)). Considering this, OculaTrack's VR visual field test resembles static perimetry tests. Static perimetry is a method to test the visual field using multiple brightnesses of light at various locations. Results for the test are recorded based on the patient's ability to see the stimulus. However, Oculatrack's proposed system offers a significantly cheaper alternative than the static perimetry system which typically costs over $3000. To address these limitations, OculaTrack has designed a visual field test for use on a virtual reality platform in which the areas of the visual field in which stimuli (dots) are not seen are noted and used to quantify the size and location of the blind spot. These results can be shared directly with eye doctors, occupational therapists, and the patient to allow for tracking the size of the blind spot over time. The ease of this test allows for practical use by doctors and therapists in the clinic and for patients in the comfort of their own homes.

Figure 2. Samsung Gear Virtual Reality Headset used for scotoma testing

Prototyping & Testing Plan

During the prototyping and testing phase, several iterations of the product have taken shape. These prototypes of the virtual reality visual field test being developed have been created using the Unity engine with testing on a Samsung Gear VR headset with a Samsung Note 5. The first version of the prototype contained a lot of constants such as dot size, dot color, background color, and field of view. However, it was learned through interviews and consultations that allowing multiple options for these parameters would significantly improve the testing method. Thus, the most current version of the prototype incorporates these changes.

One functionality of the selected concept that is not incorporated in this iteration of the prototype is the eye tracking. As an alternative method for this iteration of the prototype, while the eye tracking system is being investigated and developed, stimuli will appear in the natural blind spots of the individual. If the individual sees this stimulus, then it is known that they are not fixing their eyes upon a spot in the center. Thus, invalidating the test results for that session. Eye tracking will be incorporated at a later time.

The key functionalities that must be demonstrated by this prototype are as follows with the current version of the prototype:

Functionality of Testing Menu	**Functionality of Options Menu**	**Functionality of test**
○ Ability to: ■ Start Test ■ Display Results ■ Select Options menu ■ Return to main menu	○ Ability to: ■ Change sampling density ■ Change dot size ■ Change field of view of test ■ Change Background Color ■ Change Dot Color ■ Return to main menu	○ Perform virtual California Central Visual Field Test ■ Dots appear in random parts of the visual field ■ Patients click a button when they see the dot ■ Recognition or non-recognition of the dot is recorded ■ Results are stored during the test ■ Results are displayed and saved after the test

For validation purposes, the “killer experiment” of the testing phase involves human trials. Thus requiring approval from the Institutional Review Board. In these human trials, two scenarios are possible. First, the system can be tested on a healthy volunteer that should be able to identify most, if not all, of the dots. Then modifications will be made to the person’s visual field through the use of a “fake scotoma”. This fake scotoma will be a plastic insert that can be placed between the lens of the VR headset and the person’s eye, effectively disrupting a quantifiable percentage of their visual field. Thus, testing the software's ability to quantify the size of the induced blind spot. Alternatively, the second scenario involves individuals with some form of central visual field loss that has been mapped using a scanning laser ophthalmoscope and California Central Visual Field Test. The mapping of the size and location of the blindspot by the VR visual field test will then be compared to the results of the currently accepted methods and statistically analyzed. This comparison will allow for an understanding of the accuracy of the VR visual field test. Human studies (n=30) of Scenario 2 will clarify the potential of this method and identify areas to improve. If the results of this study are promising, the next step is to proceed with obtaining a 510(k). Upon obtaining 510(k) approval, this product can then be released in a trial phase with eye doctors in the local area to continue obtaining data regarding the accuracy and usability of this method.

Cost

The initial cost of a Samsung Gear VR Headset is priced at $10. This purchase will allow for the team to develop and test the software. A new wireless headset can be invested in the future at an estimated cost of $200 where coding of the program is easily transferred.

Our plan is to sell the OculaTrack application through the Steam Store. First, we will offer a free limited amount of uses along with a rented VR headset so that the clinic can decide if they want to invest in OculaTrack. The clinic will then contact us for an access code at a price that is dependent on the amount of estimated uses per month. Once they receive the code they download the application from the Steam Store straight to the Oculus Go headset. We believe we can have an instant impact on the market because of the backing we have already received from Envision and an are eye care clinic. Once we have established a foothold in the market, we will allow the patients to buy their own access to the OculaTrack application for $15 a month, or $125 a year. This subscription gives them full access to the visual field test as well as any updates to the software. The customer is required to purchase the Oculus Go headset on their own, but we are considering a type of rental program for those who may not be able to afford the mask on their own. Once the visual field training application is completed, it will be included with the current application. We believe we can reach the civilian market through the doctor's office, when they recommend at home screening and use.

Significance

The proposed virtual reality visual field test provides 1) a quantitative alternative to the California Central Visual Field test with a reduction in interobserver error and 2) an inexpensive, point-of-care alternative for mapping of the size and location of the scotoma compared to expensive imaging modalities such as the scanning laser ophthalmoscope, and 3) a system through which patients can track degradation of their central visual field between appointments.

References

"OUTREACH PROGRAMS." *Defy Expectations*, www.envisionus.com/

Reports, QY Research. "Global Assistive Technologies for Visual Impairment Market to Benefit from New Product Launches." *GlobeNewswire News Room*, 20 Sept. 2016, globenewswire.com/news-release/2016/09/20/873091/0/en/Global-Assistive-Technologies.html.

Wroblewski, Dariusz, et al. "Testing of visual field with virtual reality goggles in manual and visual grasp modes." *BioMed research international* 2014 (2014).

https://nfb.org/fact-sheet-blindness-and-low-vision

http://www.mattinglylowvision.com/content.cfm?n=mprl

https://www.statista.com/statistics/448742/eye-care-professionals-in-the-us-forecast/

http://clients1.ibisworld.com/reports/us/industry/default.aspx?entid=5914