Evaluation of a Head Mounted Electronic Visual Enhancement Device in Low Vision Patients

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The University of Texas Southwestern Medical Center at Dallas
Institutional Review Board

PROJECT SUMMARY

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Study Title: Evaluation of a Head Mounted Electronic Visual Enhancement Device in Low Vision Patients

Name and Address of Study Sponsor:

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Purpose: To investigate the visual impact of a head-mounted electronic visual enhancement device in individuals with low-vision.

Background: Retinal Degeneration (RDEG) is a very prevalent blinding disease. An estimated 30% of the population older than 75 years of age has some degree of macular degeneration. About 12% of patients with RDEG end up having advanced disease. Several studies have shown that self-reported quality-of-life scores for patients with choroidal neovascularization (CNV) secondary to RDEG are worse than those reported by patients with AIDS (receiving treatment) and chronic obstructive pulmonary disease. Moreover, the levels of anxiety and depression were comparable. Despite recent advances in the treatment of choroidal neovascularization, every week we see patients that can attest to the fact that clinical outcomes remain suboptimal; patients that lose their ability to read, drive, or recognize the faces of their grandchildren and friends despite receiving the best

treatments available. Diabetic Retinopathy is another very prevalent disease. In the U.S., diabetes affects over 18.2 million people. Retinopathy is the most common microvascular complication of diabetes, resulting in blindness for over 10,000 people with diabetes per year. Visual loss can be due to macular edema, macular ischemia, or neovascular complications. The loss of vision due to DR has an enormous impact on the quality of patients' daily lives, and also results in a significant reduction of productivity, imposing a significant socioeconomic burden on our society and on the millions of people who suffer from such disease
Head mounted displays represent a technology that has the potential to increase visual function in patients with low vision. However, current research on stereoscopic and monocular wearable visual enhancement devices has been conducted on individuals with good vision, and using display patterns which were not developed for low-vision applications. As a result, little is known about the effectiveness of these displays on improving visual function and mobility, and reducing asthenopia in visually impaired individuals.

Head-mounted visual enhancement device design:

Evergaze Technology LLC, has designed a head mounted electronic visual enhancement device that is compact and similar to glasses. It will be powered by a battery pack connected to the device. The electronic display will be affixed over only one of the user's eyes. The vision through the unobstructed eye will aid with the subject's balance and spatial orientation. The concept of providing each eye with a different image is not novel. It has been demonstrated to be tolerated successfully in patients with different refractive correction for each eye (monovision), and also in patients that have been implanted with a miniature telescope in one eye.

The prototype display and camera will be connected to a battery pack/control box that will allow the user to quickly select one of 3 modes. Each mode will represent a combination of parameters inverted black/white magnification) designed to optimize the image for different activities (e.g. reading, walking, computer use).

Figure 1. 3D printout of a prototype design for the visual enhancement device.

Concise Summary of Project:

This study will be a prospective, non-randomized study of low-vision individuals diagnosed with either retinal degeneration RDEG) or diabetic macular edema with ETDRS visual acuity from 20/60 to 20/400 in both eyes from the University of Texas - Southwestern (UTSW) Medical Center at Dallas. Specifically, the primary objective of this testing is to establish the benefits of a wide field-of-view (FOV) monocular head-mounted visual enhancement device display (HMD), aiding the most degraded eye, as compared to best corrected visual acuity with glasses. It should be noted that in this approach, the HMD incorporates a camera, mounted coaxially with the visual axis of the eye with worse vision, and also image-enhancing or correction algorithms. Following review and execution of the informed consent, each subject will undergo an examination of their eyes, including: 1) ETDRS Best-corrected

distance visual acuity; 2) Best-corrected near visual acuity; 3) Tests based on questions 5, 6, 7 and 11 of the National Eye Institute 25-item visual function questionnaire (NEI VFQ-25).

a. Question 5: Reading speed using a standard paragraph

English Paragraph Reference: 3-Minute Reading Assessments, Rasinski TV and Padak N, 2005. Scholastic Inc., NY

Spanish Paragraph Reference: Reference:
http://www.cuadernosdigitalesvindel.com/libres/lenguaje.php

Grade 5: Form A

Last week, my family went to the county fair. My father	11
is a volunteer firefighter, so he was working at the fair. My	23
mom and sister and I went to meet him. I am very glad we	37
did; it was a great night. When we arrived, the fair was very	50
crowded and finding my dad was like finding a needle in a	62
haystack. We finally found him because we heard the fire	72
truck siren blaring and knew he would be there. Showing	82
off the fire truck is my dad's favorite pastime; that truck is	94
his pride and joy.	98

Grade 5: Form C

Lightning crashes, thunder booms, and the earth shakes	8
with the power of the storm. This storm is holding us captive	20
in the lobby of the grocery store. Looking out the huge	31
glass windows, we see an angry sky. It seems to be daring	43
us to come outside and make a mad dash for our car.	55
Through the pelting rain we see our brave little minivan. It is	67
just waiting for us to fill its trunk with the week's food and its	81
seats with our bodies.	85
Another brilliant flash of lightning illuminates the sky.	93

Grade 5: Form D

John has been my friend for as long as I can remember.	12
Our houses are next to each other. In the winter, when the	24
last of the leaves are off the trees, I can see into his family	38
room from my window.	42
When I first met John, he was as shy as a field mouse.	55
He got nervous every time I came near and seemed	65

terrified of me. Once we got to know each other better, 76
John came out of his shell. We discovered that we liked all 88
the same things and disliked the same things, too.

Grade 5. Párrafo #1

En África central hay una selva tropical que por un tiempo permaneció oculta y secreta. A finales de los años de 1800, el resto del mundo sabía muy poco sobre la gente y los animales que vivían allí. Los primeros exploradores hablaban sobre un animal raro y misterioso que vieron en esa selva tropical. La gente que vivía allí lo llamaba okapi. El okapi pasa la mayor parte del día caminando solo por la selva en busca de comida. Arranca hojas y frutos de los árboles con su lengua que es lo suficientemente larga como para limpiarse sus ojos y orejas. **(101)**

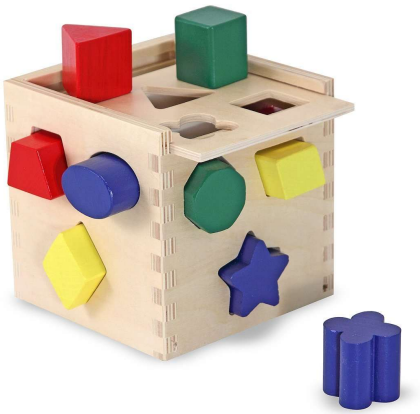
Grade 5. Párrafo #2

Walt Disney nació en Chicago en 1901. Cuando todavía era muy joven, su familia se mudó de la ciudad a una granja en Missouri. A Walt Disney le emocionó el cambio, pero pronto se dio cuenta de que vivir en una granja significaba mucho trabajo.
Walter ayudaba a su padre y hermanos a repartir periódicos para ganar dinero para la familia. Para ganar unos cuantos centavos para sí mismo, hacía trabajos adicionales. Uno de sus trabajos era el de repartir medicinas para una farmacia. Tenía otro trabajo en una tienda de dulces durante la hora de la comida de la escuela. **(101)**

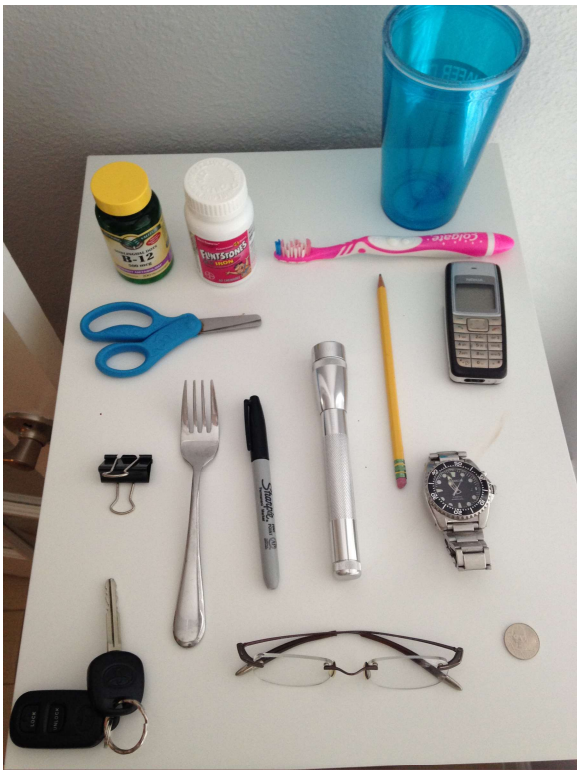
Grade 5. Párrafo #3

Luchar contra el cambio climático puede empezar con un gesto tan sencillo como cambiar la iluminación de la casa. Las Bombilla incandescente, la de toda la vida, la que invento Edison hace mas de 100 años, se ha quedado en eso, en un artilugio del siglo XIX. El 90% de la energía que consume la malgasta en generar calor. Solo un 10% de la electricidad se transforma en luz. Las nuevas bombillas de bajo consumo han multiplicado la eficiencia hasta el punto de que, si comenzaran a emplearse en todos los hogares, el efecto en la reducción de gases seria muy grande. **(102)**

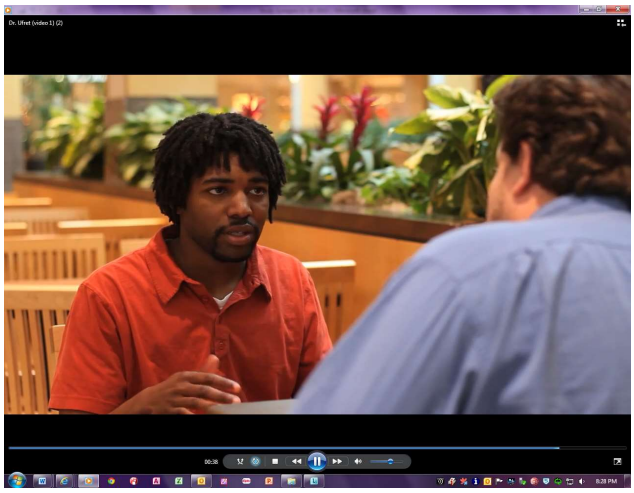
b. Question 6: Have a simple test of near visual-motor skills (i.e. a board with small cut-out shapes that the subjects need to put in the correct place) and measure the time it takes them to complete it.

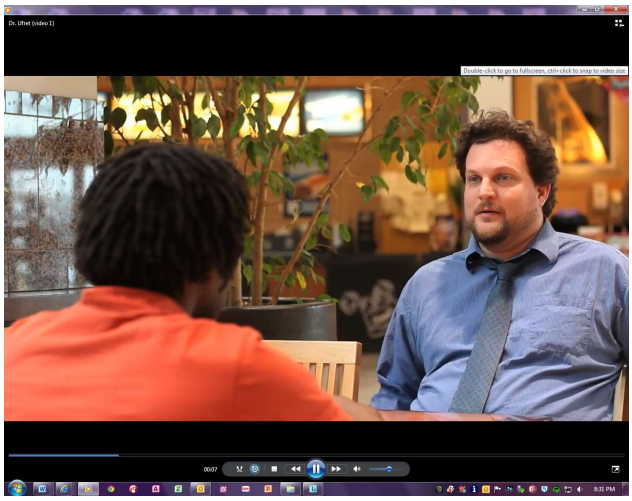


c. Question 7: Have a portable 3 to 5 shelf storage shelf with 20 random items. Ask the patient to find one specific item. Repeat 3 times and record the time it takes the patient for each attempt.


B-12
FLINTSTONES
Colgate

d. Question 11: Show the patient a 15-20 second video (without the audio track) showing a conversation between 2 individuals. Following the video, subjects will be queried about the facial expressions of the actors during the conversation.





4) Having the patient fill out a questionnaire based on the tests administered. Subjects are not excluded based on gender, age, or race. In total, there is a plan to have 1 visit for this project. It should be noted the collection of above mentioned clinical data points will solely be used for the purpose of this research study.

Study Procedures:

It is expected that approximately 20 Aston clinic patients will be enrolled in this trial. No bias or negative consequence will occur to anyone that does not wish to consider this project. After obtaining informed consent, the following procedures will be performed as an aspect of this study:

- Document patient demographics including age, sex, race, and ethnicity
- Review and document of medical and ophthalmic history
- Review and document Ophthalmic diagnosis (Retinal Degeneration or Diabetic Retinopathy) and onset time (in years and months if possible)
- Review and document concomitant use of systemic and ophthalmic therapies including administration of all laser and anti-VEGF therapies
- ETDRS Best Corrected Distance Visual Acuity will be performed
- Best Corrected Near Visual Acuity will be performed using a near card reader
- Wearing refraction (Glasses) will be measured and documented in source forms
- National Eye Institute Visual Function exams will be administered to each subject as outlined in previous section with and without the head mounted visual assessment device. During the testing portion of the head mounted visual assessment device, head and eye movements will be video recorded by one of the sponsor/manufacturer's agents for this research project.. This will allow the team to assess what kinds of adjustments the subjects are making to optimize their view. Patients will be given a 20-minute break between testing with and without the head mounted visual assessment device.
- Administration and completion of patient questionnaire on their experience with the use of NEI Visual Function exams
- A second study visit identical to this one may be repeated after a period of self-training at home with the device.

Inclusion Criteria:

1. Patient of any sex, race, or ethnicity who are 18 years of age or older. Spanish speaking patients will be encouraged to participate, Spanish forms will be available to review and execute.
2. Patient willing to review, understand, and sign written Informed Consent. Parents or legal guardians will consent on behalf of minors.
3. Written authorization for use or release of health and research study information.
4. Patient who volunteers is suffering from a posterior segment ophthalmic disorder including Retinal Degeneration and/or Diabetic Retinopathy and visual acuity from 20/60 to 20/400 in the better Seeing Eye.

Exclusion Criteria:

1. Subjects will be excluded if they are less than 18 years of age.
2. Subjects will not be considered for this research study if they will not review and execute the informed consent form.
3. During the screening process, subjects will be excluded from further consideration if they are identified with having a potential ophthalmic diagnosis other than Retinal Degeneration or diabetic macular edema that could be negatively affecting the visual testing.
4. ETDRS Visual Acuity better than 20/60 or worse than 20/400
5. During screening, subjects will be disqualified from further assessment if it is determined that their refractive error is outside of the -5.00D to +5.00D corrective range.

Sources of Research Material:

Existing records, specimens, or other medical data will be used for data analysis. Name, date of birth, and medical record number initially will be used for the purpose of chart retrieval. Patient identifiers will initially be used for the purpose of identifying members and their relationship within the family. However, all patient

identifying information will be excluded from the data analysis and subsequent reporting of findings. The following information will be collected from each patient during the course of the study: Patient name, medical record number, and the date of clinic visit at which an ocular exam were taken will be collected solely for the purpose of retrieving study data at the conclusion of the trial. In addition, clinical data along with participant's medical history will be recorded and assessed at the conclusion of the study. Data will be obtained specifically for research purpose, and not for any other intention. To reiterate, all patient identifying information will be excluded from the data analysis and subsequent reports of our findings and conclusions.

Source documentation should be available to confirm data collected in the CRF: subject identification, eligibility, and study identification; study discussion, provision of and date of informed consent; visit date; result of efficacy parameters as required by the protocol; a record of adverse events; concomitant medication; study investigational product administration during lone visit; date of study completion; reason for early discontinuation of investigational product or withdrawal from the study, if applicable. It is recommended that the author of an entry in the source documents be identifiable. Adverse event notes should be reviewed and initialed by the Investigator.

At a minimum, the type and level of detail of source data available for a study subject should be consistent with that commonly recorded at the site as a basis for standard medical care.

Recruitment Methods and Consenting Process:

Patient recruitment effort will commence at the James Aston Ambulatory Care Center. The Aston Center Medical Records (MR) department will be used to identify patients for this study. A history of retinopathy disorder (Retinal Degeneration and/or Diabetic retinopathy) will be used as basis for patient recruitment. Recruitment will be initiated from the PI's practice clinics at UTSW. In addition, the

PI will apprise fellow ophthalmology faculty members in the department regarding the nature of the study through written communication. A referral letter informing the ophthalmology faculty practice at UTSW Medical Center at Dallas will be made available to review. The PI will provide referring ophthalmologists at UTSW Medical Center at Dallas copies of IRB approved forms, including the informed consent. This form will be given by the referring clinician to interested patients during their visit to the clinic.

For patients that are recruited from the PI's clinic, the PI or the clinical coordinator will describe the study in detail and allow the patient time in order to make an informed decision. Consent is only given if the subject completely understands the IC and withdrawal provisions, and agrees to take part in the study. Consent form is signed by the patient who is seeking to join the study and by the principal, sub-investigator, or clinical research coordinator. An executed copy is given to the patient; another is placed in the patient medical chart. The original IC is placed in the regulatory binder along with other important study documents. The regulatory binder is kept in a secure area in the research coordinator office. During the actual clinic visits, each procedure is explained to the subject.

For interested patients that are referred from the faculty clinics at Aston, the coordinator will speak with the prospective patient after treating physician has spoken to the patient about the study and given them the appropriate literature to review. The clinical coordinator will describe the study in detail and allow time for the patient to make an informed decision only after the interested, prospective subject initiates contact with the coordinator regarding the study.

Potential Risks:

There are no known risks associated with the use of the head-mounted visual enhancement device, a similar device has been fabricated previously as a consumer test product for watching movies displayed as High Definition Cinema. The exception of possible temporary disorientation, dizziness, or visual blur due to the monocular aspect of the device exists. The patient will be sitting during the entire

test, which will last **about 2 hours**. The tester will be constantly supervising the patient during the exam. Another area where there may be an opportunity for potential risk is in protecting patient privacy throughout the course of the study and following the conclusion of the project. A detailed plan is provided in "Procedures to Maintain Confidentiality".

Subject Safety and Data Monitoring:

Careful oversight of patient safety and wellbeing will be undertaken by the Principal Investigator and Sub-Investigator on this study. In the event of an adverse event during the visits as required by the study protocol, treatment will be provided by the researcher on this study and the affected patient will be stabilized before exited from the study.

Special Precautions:

Procedures to protect against the potential risk of a breach of confidentiality are described in the following section. Any additional physical or psychological risk to patients as a result of this prospective study is not foreseeable as the collection method utilized is typically used in the clinic for standard of care management. Subjects are informed verbally and in the consent form of the following: contact information and the phone number for investigator in case of an adverse event that occurs after the study is initiated. Moreover, the PI will monitor the study for quality assurance purposes.

Procedures to Maintain Confidentiality:

All subject data will remain confidential and access will be restricted to authorized study personnel only, including the principal investigator, sub-investigator, and the study research study. All study information and data will be secured in a locked area and accessible only to study investigators. Patient identifying information will be removed as the pertinent data is transferred to a data collection sheet so that there

is no link to specific identifiers. All electronic study data will be password protected. Data will be presented in aggregate form to the sponsor without specific identifiers.

The Investigator(s) / Institution(s) will permit trial-related monitoring, audits, IRB review and regulatory inspection(s) by providing direct access to source data / documents. Should the clinical site be contacted for an audit by an IRB or regulatory authority, study sponsor should be contacted and notified in writing within 24 hours.

Periodically, the IRB will examine research studies conducted at UTSW Medical Center at Dallas. This audit process confirms whether a research project is being performed in an ethical manner, the protection of an individual who has given consent, and the researcher or his designee is following the regulatory codes of the university and government agencies such as FDA. All effort will be made to ensure patient confidentiality but there are times where the IRB representative will need to review the patient record to ensure that all elements of the study are being properly documented as specified in the protocol.

Potential Benefits:

The subjects may not receive direct medical benefit from taking part in the study. The knowledge gained from the study is to help define systems requirements for a device to assist low-vision persons with increased functionality. A $100 stipend will be provided to patients to help offset any inconvenience from the 2 hours study visits.

Statistical Analysis Plan

A pilot study for this trial (8-10 subjects) will test the feasibility of improving sight for low-vision individuals. Statistical analysis will be performed on results based on the tests described in the protocol. Paired T-test analysis will be used to determine whether there are differences in vision and recognition when subjects are wearing or not wearing the sight enhancement device. Once the pilot study data shows that there may be differences vision using in relation to the testing parameters when

using the visual enhancement device, we will expand the study to a sample size of 20 individuals to collect data that will be sufficient to achieve appropriate statistical power and determine whether there is statistical significance between using vision using the enhanced vision device and vision without the device.

National Eye Institute
Visual Functioning Questionnaire - 25
(VFQ-25)

Version 2000

(INTERVIEWER ADMINISTERED FORMAT)

January 2000

Instructions:

I’m going to read you some statements about problems which involve your vision or feelings that you have about your vision condition. After each question I will read you a list of possible answers. Please choose the response that best describes your situation.

Please answer all the questions as if you were wearing your glasses or contact lenses (if any).

Please take as much time as you need to answer each question. All your answers are confidential. In order for this survey to improve our knowledge about vision problems and how they affect your quality of life, your answers must be as accurate as possible. Remember, if you wear glasses or contact lenses for a particular activity, please answer all of the following questions as though you were wearing them.

Visual Functioning Questionnaire -25

PART 1 - GENERAL HEALTH AND VISION

5. How much difficulty do you have reading ordinary print in newspapers? Would you say you have:

(Circle One)

No difficulty at all..... 1 A
little difficulty..... 2
Moderate difficulty..... 3
Extreme difficulty..... 4
Stopped doing this because of your eyesight 5
Stopped doing this for other reasons or not interested in doing this 6

6. How much difficulty do you have doing work or hobbies that require you to see well up close, such as cooking, sewing, fixing things around the house, or using hand tools? Would you say:
(READ CATEGORIES AS NEEDED)

(Circle One)

No difficulty at all..... 1
A little difficulty..... 2
Moderate difficulty..... 3
Extreme difficulty..... 4
Stopped doing this because of your eyesight 5
Stopped doing this for other reasons or not interested in doing this 6

7. Because of your eyesight, how much difficulty do you have finding <u>something on a crowded shelf</u>?
(READ CATEGORIES AS NEEDED)

(Circle One)

No difficulty at all..... 1
A little difficulty..... 2
Moderate difficulty..... 3
Extreme difficulty..... 4
Stopped doing this because of your eyesight 5
Stopped doing this for other reasons or not interested in doing this..... 6

11. Because of your eyesight, how much difficulty do you have seeing how people react to things you say?
(READ CATEGORIES AS NEEDED)

(Circle One)

No difficulty at all..... 1 A little difficulty..... 2
Moderate difficulty..... 3
Extreme difficulty..... 4
Stopped doing this because of your eyesight 5
Stopped doing this for other reasons or not interested in doing this 6