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# **Research Article**

# Performance of an Augmented Reality Device on Functional Activities of Low Vision Patients with Age Related Macular Degeneration

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# Abstract

### Introduction:

Visual impairment impacts the daily living activities of billions of people globally, and over 5 million in the U.S. by 2020 [1] potentially limiting their inclusion in education, employment and more generally society. In the U.S. and many countries, low vision rehabilitation includes an evaluation of the visual function deficit along with assessment of the most important and realistic activities for the patient to improve performance through rehabilitation [2]. The evaluation services, enhancement devices, and training or strategies to improve activities of daily life and indirectly patient quality of life usually include a trained low vision optometrist or ophthalmologist and a vision therapist (e.g., low vision trained occupational therapist, orientation and mobility specialist). Classically, within rehabilitation, there are devices or tools that fit into categories of optical devices, video magnification devices, and vision substitution or non-optical devices [2]. Software driven options such as smartphones, options on computers, and virtual reality advances have created other hybrid categories. Optical magnification devices are used most often and are usually categorized for purposes of enhancing vision at distance, intermediate or near and have a fixed magnification determined through evaluation of a low vision physician [3]. Devices are usually subcategorized as to the type of tasks addressed such as spot viewing (e.g., identifying a medication label) or sustained viewing (e.g., reading a book). These same categories of spotting or sustained viewing apply to intermediate and distance (e.g., recognizing faces) and sustained viewing (e.g., television or event viewing). Through a specific evaluation process, singular devices are prescribed to meet patient goals which means several devices are usually needed to assist someone in all areas of life [3]. The most common devices include handheld magnifiers, high addition spectacle lenses, tinted lenses/filters, telescopes, and video magnifiers. Recently, head mounted low vision devices have become more common due to advancing camera and display technology, image processing, and improvement in wearable hardware. Head mounted devices include some type of camera, near-eye displays, and enhancing software to modify the information for the user. The software can manipulate the image to enhance contrast, enhance only certain parts of the image or potentially replace the image with a different version. These devices provide a hands-free magnified (or minified if necessary) image to the user with autofocus capacity for task performance at any distance. With classical low vision devices designed for one distance and one type of task (e.g., near, spot viewing), a device that can assist a user in completing more than one task at a time is closer to replicating the function of the human visual system prior to impairment. Although the cost is usually higher for a head mounted device than for a singular optical device, the convenience and efficiency may provide the value necessary for such an investment. Devices can utilize virtual reality in which the display adapts and replaces the user's natural vision, or augmented reality, in which the display adds to, or overlays parts of, the natural vision. Although typologies have been proposed for different types of head mounted devices [4, 5], the expansion of devices has been rapid recently and conclusive terminology has not been adopted.

Eyedaptic created a new device that is described as an Augmented Reality (AR) spectacle or head mounted device, the Eye-01, which seamlessly integrates high performance hardware with proprietary software to support visual tasks for visually impaired persons at distance, intermediate and near and essentially replace multiple unique devices. Available magnification ranges from 0.25 to beyond 6X, with higher

magnification levels limited by image sensor resolution. The vision related quality of life) or age and performance with the Eyedisplays with a hybrid see-through design that combines the two features. common "optical see-through" and "video see-through" AR

methodologies. Video see-through is most commonly used in VR The information gained from the exploratory study will be camera and then displayed to the user. Optical see-through is to other low vision devices or rehabilitation approaches. employed in the traditional AR (Augmented Reality) approach where the image on the displays is over laid on top of the real Materials and Methods:

world. In the Eyedaptic hybrid see-through approach the images manipulated and displayed before the user's eyes are enhanced but The study is designed as a single arm, crossover study with 20 not see-through and not conflicting with the real world. The subjects who have age related macular degeneration with mean age displayed images are then blended by software with the real-world of 85 (range 74 to 92) and mean best corrected acuity of 20/125 periphery by the Portal<sup>TM</sup> feature, which reduces magnification (range 20/63 to 20/250). Informed consent procedures followed gradually to transition with the real world in a seamless manner, the guidelines of the local Institutional Review Board and each therefore maintaining peripheral vision and the anchor to the real patient gave written informed consent on a form that complied with world. This hybrid see-through design introduces something new Health Insurance Portability and Accountability Act and adhered to the traditional definitions of augmented reality. The patent to the Tenants of the Declaration of Helsinki. pending software is currently housed within hardware (frame) that

image processing speeds improve.

feature called Warp<sup>TM</sup> which shifts information from a (e.g., Britext<sup>TM</sup>). customizable size area that matches the user's scotoma to a more peripheral location.

The peripheral portion can allow for mobility while wearing the The MNREAD, a standardized reading test, has several sizes of ADLs. Those visual functions include visual acuity (VA), visual participant to participant and device setting variables. fields in the form of absolute or relative central scotomata, and contrast sensitivity function (CSF) and each of these areas are There are a few timed task inventories that have been used with explored in the current study along with the outcome measures or visually impaired persons but they often have many tasks that may endpoints.

weight is 180 grams in the current hardware with approximately 01 device set at 3X and 2) understanding qualitative feedback from 30-degree field of view (diagonally). The Eye-01 has bi-ocular subjects regarding the training process and each of the Eye-01

(Virtual Reality) approaches where the user is completely isolated valuable in determining what features of Eye-01 are most useful to from real world inputs except what is processed through the AMD patients and in designing future studies comparing Eye-01

is available commercially, but it can be configured within modern Study subjects were referred from retina specialists and low vision AR or VR hardware as the camera resolution, field of vision, and optometrists in the geographic region of the single study site. Study visits included two in-office visits with the first visit incorporating baseline visual function measures (e.g., BCVA, Further embedded software features will also be explored such as Contrast sensitivity), reading performance with standard add Britext<sup>TM</sup> edge enhancement technology. This form of contrast alone, and training time with the Eye-01. The second visit included specifically enhances the boundaries of text and objects to further a training refresher and study outcomes with the Eye-01. A aid visual function tasks and acuity. Other settings include a round qualitative component to the study also included participant magnification area (Portal<sup>TM</sup>) embedded within the view, and a feedback on the training process and on the unique Eye-01 settings

### Tests and Study Components:

device although it is recommended with caution and with training print displayed on a paper card in paragraphs of 10 words each [6]. only. The device was designed to assist any person with vision When the subject cannot read the print any further, the adjusted impairment in both eyes from any cause whether congenital or times are used to produce a reading curve that maps reading acquired. For the initial study, one condition, Age Related Macular function by print size. A plateau of fastest reading times is called Degeneration (AMD), was selected to reduce variables and learn the maximum reading speed (MRS) and the point on the curve just how to optimize the final design of the device for the most people before function starts to drop rapidly is called the critical prints size prior to commercialization. AMD is the leading cause of reduced (CPS). The CPS represents the size of text where visually impaired vision in older adults, whether dry or exudative. The condition persons are still reading at a comfortable pace. Reading causes deficits in visual function impacting the central visual field performance using the MNREAD was compared between standard while leaving peripheral visual function largely intact. AMD near correction alone and the Eye-01 device set at 3X impacts visual function that cause the greatest difficulty regarding magnification. Additional features of the device were also tested patient complaints in reading, self-care, facial recognition, and against near correction alone. Although the device can be set at a other broadly defined categories of Activities of Daily life or wide range of magnification, 3X was selected to minimize

> not be relevant to use with a head mounted device such as the Eye-01 or may require significant time to administer [7]. The TIADL

The primary study objectives include comparing reading Test was developed to assess the performance of low vision performance and time to complete tasks of daily life between patients on real world activities that are potentially affected by standard near correction alone and the Eye-01 device set at 3X visual impairment [8]. The test provides results in seconds as magnification alone and then with various software features (e.g., subjects perform a series of tasks. The original version has six tasks Britext<sup>TM</sup>). Secondary objectives include 1) exploring the including finding an amount due on a bill, writing a check, making relationship between severity of vision impairment (as measured change with dollars, finding a phone number in a phone book, by BCVA, scotoma size and location, contrast sensitivity, and dialing the number, and finding queens in cards laid out on a table.

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maximum of 2 min before moving to the next task so the total time But by selecting one magnification throughout all visits and then to administer is 6 minutes. Total time for all three tasks is adding in the various features (e.g., Portal<sup>TM</sup>) at various points in compared as an endpoint.

A cognitive test modified for visual impairment, the Mini-Mental State Exam modified for sensory deficit (MMSE-Blind) [9], was Study Visits: used to determine eligibility with any person who scored equal or less than 23 being excluded from the study. There is a potential The first visit included testing best corrected visual acuity (BCVA) increase in cognitive impairment with those who have visual using a trial frame refraction and an ETDRS non-illuminated chart. impairment from AMD [10]. The Mini-Mental is often used to Once the subject was consented/enrolled, their testing included, diagnose dementia and so it was used in this study to screen contrast sensitivity testing with best correction, assessment of participants who may not be able to learn and recall the training scotoma size and location, and the VFQ. Training with the Eye-01 steps used with the Eye-01 device.

asking each person to identify missing numbers on a series of the TIADL tests on the second visit. increasingly large clocks printed on standard letter size paper while fixating on a central dot. Diameters of each clock correspond to 5 A second visit one week later (a window of 4-10 days) included a understanding reading and fixation in AMD.

variations in luminance and is correlated to performance on many finally with 3X, Portal<sup>TM</sup> and Britext<sup>TM</sup>. Although times and ability real-world tasks such as reading and performance of activities of to complete tasks with each feature are important, participant daily life. Similar in design to the Pelli-Robson, the Ridgevue qualitative responses to each of the features were also recorded. Contrast Sensitivity test [12], was administered on an iPad to measure peak CS in both eyes (OU) or just on the study eye in the **Results**: case of retinal rivalry.

explore what areas of life were most impacted by vision loss. The near correction alone and the Eye-01 device set at 3X VFQ is a valid and reliable questionnaire used in low vision magnification alone, mean critical print size (CPS) improved from rehabilitation to capture changes in patients' self-report of their 0.93 logMar with near correction alone compared to mean CPS of difficulty reading and performing other daily living activities 0.70 logMar (p=0.013) with the Eye-01. Improvement in print size affected by visual impairment [13]. Visual ability is a score that ranged up to 7 lines. All subjects performed better on tasks with represents all the scales of reading, visual information, visual the device compared to without (p=0.004) and especially with the motor, and mobility. The reading scale includes items about edge enhancement (Britext<sup>TM</sup>) feature (p<0.001). In a subset of reading at near and distance (e.g., reading newspaper print, seeing subjects (N=10), a combination of features (Magnification, signs). For a study population of AMD, it was expected that visual Portal<sup>TM</sup> and Britext<sup>TM</sup>) was explored for task performance ability overall and then reading may be the scores more relevant to compared to Magnification alone and Magnification and Britext<sup>TM</sup> exploring relationships with performance using the Eye-01.

## **Training:**

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The revised version designed for this study incorporates the stabilize viewing, b) spotting with the device for intermediate and essential principles of the timed tasks but was revised to add new near, c) reading continuous text short paragraphs, and d) a brief tasks based on relevance with the device for three task distances of introduction of features such as Britext<sup>TM</sup> and Portal<sup>TM</sup>(Figures 1 40cm, 1m, and 3m. One of the six original tasks in the inventory and 2) Although the Eye-01 has a range of magnification was used which involved searching a bill for amount due. The two capabilities, the examiner set the device to 3X to minimize the added tasks include viewing a shelf at arm's length (1 meter) and many variables that could influence subject performance. For some identifying cans by the print on their labels and reading an patients 3X may be more than needed and for some in the 20/200 overhead sign simulating grocery store aisles. Each task allows a BCVA range, it may not be enough for very small print reading.

> the study visits, any gains in performance with the features could be compared to magnification alone.

magnification of 3X and included a) steady head posture to For the full 20 subjects with spectacles alone, only 5 (of 20)

was conducted for approximately 30 minutes but total time did depend on the needs of each participant. Practice with both The clock dial test was created for the study to determine endpoint measures was conducted at the end of the first visit to approximate location and size of the participant's scotoma by reduce any potential practice effects with both the MNREAD and

degrees, 10 degrees, and 15 degrees. Scotoma location was brief review of training steps from the prior visit and the examiner determined by the radius (where the missing numbers on the clock recorded qualitative notes on what the subject recalled or what were located) and approximate size depended on which clock was topics required the most re-training. Both endpoint tests (CPS and used. Essentially central scotomas from AMD should keep the TIADL times) were performed with spectacle correction only and participant from seeing the fixation dot but with eccentric viewing then various EYE-01 settings. The order of testing for the timed or use of a preferred retinal location, the scotoma becomes shifted outcomes using spectacles only vs. the 3X Eye-01 was randomized to a new position [11]. This information can be useful for during testing. This step was intended to reduce impact of the initial practice effect on the timed test performance. Testing continued using both the timed tasks and reading using the Eye-01 Contrast provides critical information about edges, borders, and device set at 3X and Britext<sup>TM</sup> and then with 3X and Portal<sup>TM</sup>, and

For the primary objective for understanding differences in reading A 48-item questionnaire, the VA LV VFQ-48 (VFQ), was used to performance (CPS) and time to complete tasks, between standard together. With glasses alone, only 2 of the 10 could do any of the three tasks. With combination of all features, 8 of the 10 could do at least two of the tasks and the mean time to complete tasks for all 10 subjects using a combination of all three features were better Training in the use of the Eye-01 device was conducted using a set together than the mean time for each feature separately (p=0.02).

more subjects could do all tasks.

spectacles alone, 13 of the subjects were unable to perform any of alone. the tasks resulting in maximum time score of 360 sec. With the Eye-01, all subjects completed at least one if not all three tasks, see The Portal<sup>TM</sup> feature is a window that can vary in diameter within Figure 3. Mean distance visual acuity improved from a mean of the full screen of the video display and the size was fixed for the 20/125 (0.81 logMar) to a mean of 20/60 (0.47 logMar) with the study. Subjects did not prefer the feature for the reading test, but Eye-01.

6 subjects had ring scotomas, 9 had scotomas to the right or up and studies. to the right (diagonal), and 2 had had scotomas to the left or down

overall.

study.

subjects could complete bill pay compared to 12 with Eye-01. For Regarding feedback on the features of the Eye-01, Britext<sup>TM</sup> was identification of cans, only 3 subjects with spectacles could do so, well received for task performance more than for reading. Subjects compared to 16 with the device. Finally, for grocery store signs, 2 stated that they thought they could see to read better with the people could correctly identify all the words with spectacles, feature, but their reading speed or critical print size were no better whereas 11 could do so with the Eye-01 (Figure 3). If the Eye-01 than without it. However, the setting of Britext<sup>TM</sup> was fit to a had not been fixed at 3X with the magnification, it is likely even specific size estimated to compliment the fixed 3X magnification, however, a thinner or thicker Britext<sup>TM</sup> edge may be better for individual users and could easily be adjusted outside of the study The mean time to complete TIADL tasks of utility bill search, can parameters. Subjects did comment that Britext<sup>TM</sup> was helpful for label identification, and reading grocery store aisle signs was identifying cans on a shelf and identifying words on a grocery store approximately faster by 2 times (308s reduced to 191s and 163s) sign and the corresponding time to complete tasks was with the Eye-01 and Britext<sup>TM</sup> respectively, see Table I. With significantly better with the Britext<sup>TM</sup> feature than magnification

this fixed diameter may also have limited the acceptance. The

concept of the Portal<sup>TM</sup> is to provide context within the magnified For the secondary objectives exploring the relationship of view of reading text or any environment view that needs impairment and age on endpoint performance, there appeared to be enhancement. For reading, the Portal<sup>TM</sup> provides a view of the end a trend with older subjects having worse reading scale scores on of the line and possibly the beginning of the next line within a the VFQ, but the relationship was not significant (r=-0.24). For paragraph context. However, subjects did not notice this feature task performance with spectacles alone or with the Eye-01, there helping with these purposes when initially introduced but they may was no relationship of age or performance on the VFQ and the have not had enough time to understand its use and they may have performance ability, but a relationship may not be obvious due to just desired initial simplicity as they learned the basic training steps small sample size. There were also no baseline predictors of of maintaining a steady head position. In the ten subjects with prior identifying patients who improve in overall task function to a exposure to the device, comments were more accepting of the greater degree than others, however scotoma pattern could be feature and one subject stated that she toggles the Portal<sup>TM</sup> feature qualitatively linked to reading performance. Patients with bilateral on for a word she can't quite see and then once identified, she AMD with visual acuity loss in the range of the study subjects returns to the flat straight magnification screen for wider view. In often experience a ring pattern scotoma (non-seeing area) where the subgroup of subjects who tested a combination of Portal<sup>TM</sup> and fixation is preserved but surrounded by a missing ring-shaped Britext<sup>TM</sup> vs just either feature alone or straight magnification pattern. An alternative pattern is with a scotoma pushed to a more during task performance, task completion was faster with the peripheral area with an alternative area used to fixate, or preferred combination than with the other features alone but with such a retinal locus (PRL). Using the clock dial method described earlier, small subgroup (p < 0.05) the concept is worth exploring in future

and to the left. Location of the scotoma or conversely the PRL was The Warp<sup>TM</sup> feature was not used with endpoint measures of uncertain in three subjects and may have included a partial ring reading or task performance but it was introduced for reactions and pattern. The four subjects with ring scotomas required extra comments from subjects at the end of the study visit. The Warp<sup>TM</sup> fixation and reading training on the second visit and demonstrated feature shifts visual information from an area of scotoma or blind more difficulty with reading with or without the device. The 9 spot and shifts it to a more peripheral area of vision but to do so, subjects with right sided scotomas performed well on outcomes the information is pushed or warped to edge of the scotoma. The size and the shape of the shifted area can be customized for the user and so has potential to help a user with context when For the final research question related to participant feedback on information is missing but it does require training and its training and features of the Eye-01, the mean time to train on the usefulness may depend on location of eccentric viewing. Subjects first visit took 41 minutes (n=20). The steps used in the training were asked to report on their impression of the Warp<sup>TM</sup> feature at process included creating a steady head posture to stabilize the end of the second visit and most comments revealed initial viewing (Figure 4), spotting with the device for distance and confusion and lack of understanding how to use the newly gained intermediate targets, and finally, reading continuous text short information shifted from the non-seeing area or scotoma. Subjects paragraphs. After reading training, subjects were exposed briefly were also tired by the end of the visit and this may have impacted to features such as Britext<sup>TM</sup> and Portal<sup>TM</sup>. The steps did seem to their initial responses. In addition, the examiner was not a trained appropriately train the subjects on the use of the device without low vision physician or therapist and was uncertain how to best significant fatigue. During the second visit when each step was train the feature. Customizing the Warp<sup>TM</sup> setting would require briefly re-introduced, all subjects demonstrated efficient recall of the trainer to not only know where the patients' preferred retinal training steps. The study visits including the training was location was located but also how to advise the patient on conducted by an optometrist who was unfamiliar with low vision information that might be re-gained depending on Warp<sup>TM</sup> or the Evedaptic device but who was trained on the details of the placement. Training the use of the feature in the context of each subject's scotoma pattern is a complicated process and would best



be done in a comprehensive low vision rehabilitation setting.

### **Discussion**:

from optical to video or digital modes but they are usually task accompanying training program for market release. specific. Devices that can do more for patients in rehabilitation through the ability to perform multiple tasks at different distances Acknowledgements: and situations through customizable or variable platforms offer great promise and may justify the expense of such technology. This study is the first of its kind to explore a feature while fixing 01 in some capacity as a consultant (RLK, TT), or have equity in certain settings so that each feature can be compared step by step. Evedaptic (BTK, DW, MCM, BDK). Funding for the study was Although the study design does limit the wider range of provided by Eyedaptic. magnification that the device is capable of, the comparison of features provides valuable information to the design team prior to **References**: market release. The training program that was also created and evaluated in the study can serve as a basis for the device to 1. transition into the comprehensive rehabilitation models across the US and outside the US. The fact that an optometrist study examiner efficiently learned and performed the training process indicates a 2. transferrable process for low vision therapists and other professionals in the rehabilitation setting to easily adopt.

As an augmented reality device, the Eye-01 did improve the ability to access small print and to perform timed daily living tasks at all 4. viewing distances when compared to standard near correction alone in a group of subjects with moderate visual impairment from AMD. Although mobility was not studied nor were tasks 5. performed in a natural shopping or home situation, the various features may help patients with AMD in different settings whether reading or performing a task such as bill paying or identifying 6. items in a grocery store. In this study, very few subjects could perform any of the tasks with spectacles alone but with the Eye-01, all subjects could perform at least one of the tasks. A future study will incorporate a take-home aspect that allows users more 7. time with the device and exploration in different settings. Feedback for each of the features with patients of varying ages and impairment levels was helpful for the developers as they continue to improve the device for commercial use. Although the study was 8. completed with a fixed magnification setting and fixed feature widths/diameters, the benefits across all subjects was still remarkable with most subjects unable to complete tasks at three viewing distances without the device and able to complete one or 9. all tasks with use. The Eye-01 does have the capability to customize magnification with a highly responsive autofocus

feature so patients of all impairment levels with AMD should benefit. Continuous text reading for patients with ring scotomas or acuity worse than 20/200 is likely a challenging task no matter the low vision device used but there is still benefit in spot reading and

The purpose of the study was to examine the performance of performing tasks daily with an augmented device such as the Eyepersons with AMD on reading and sample tasks of daily life at 01. AMD patients with a ring scotoma have difficulty with reading varying distances. Overall, the Eye-01 did improve all outcomes due to the ring shaped non-seeing area removing letters or words or measures of performance as expected but various features on both the right and the left while reading but they do typically enhanced tasks differently. Britext<sup>TM</sup> is an edge enhancement have better visual acuity or discrimination within that ring. A feature that is preferred by subjects but positively impacts task useful study for patients with ring scotoma may be to magnify just performance more than reading. A combination of features may slightly using the Eye-01 and then combine this with Britext<sup>TM</sup> improve task performance even further than just magnification (edge enhancement) to help with loss of contrast sensitivity alone. Culham, Chabra, and Rubin [14] explored early models of therefore proving to be a useful tool. In addition, Britext<sup>TM</sup> with head mounted devices and found that optical magnifiers may have the Eye-01 seems to enhance task performance over magnification been best for individual tasks, but they did not explore the value of alone in most patients with AMD based on study findings. In one device to replace multiple devices. In a recent review of addition, Britext<sup>TM</sup> and the Portal<sup>TM</sup> feature may prove to be an reading aids for low vision participants ranging from optical aids even better combination for daily task performance at varying to stand mounted electronic devices to head mounted electronic distances for some patients. The feedback from participants devices, there was not enough evidence to conclude a certain type throughout the study regarding training processes, ease of use, and of device was better for reading [15]. As patients in a low vision special features such as Warp<sup>TM</sup> also provided input to the rehabilitation setting have many options for magnification ranging development team as they continued to improve the design and the

Each of the authors are affiliated with the development of the Eye-

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