The Effect of a Head-mounted Low Vision Device on Visual Function

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SIGNIFICANCE: Head-mounted low vision devices have received considerable attention in recent years owing to rapidly developing technology, facilitating ease of use and functionality. Systematic clinical evaluations of such devices remain rare but are needed to steer future device development.

PURPOSE: The purpose of this study was to investigate, in a multicenter prospective trial, the short- and medium-term effects of a head-worn vision enhancement device (eSight Eyewear).

METHODS: Participants aged 13 to 75 years with stable vision (distance acuity, 20/60 to 20/400; visual field diameter >20°) were recruited across six sites. Data were collected at baseline (no device), at fitting (with device), and after 3 months of everyday use. Outcome measures were visual ability measured by the Veterans Affairs Low Vision Visual Functioning Questionnaire 48, distance acuity (Early Treatment Diabetic Retinopathy Study), reading performance (MNREAD chart), contrast sensitivity (MARS chart), face recognition, and a modified version of the Melbourne Low Vision Activities of Daily Living (ADL) Index.

RESULTS: Among the 51 participants, eSight introduction immediately improved distance acuity (0.74 ± 0.28 logMAR), contrast sensitivity (0.57 ± 0.53 log units), and critical print size (0.52 ± 0.43 logMAR), all $P < .001$, without any further change after 3 months; reading acuity improved at fitting (0.56 ± 0.35 logMAR) and by one additional line after 3 months, whereas reading speed only slightly increased across all three time points. The Melbourne ADL score and face recognition improved at fitting ($P < .01$) with trends toward further improvement at 3 months. After 3 months of use, Veterans Affairs Low Vision Visual Functioning Questionnaire 48 person measures (in logits) improved: overall, 0.84, $P < .001$; reading, 2.75, $P < .001$; mobility, 0.04, not statistically significant; visual information, 1.08, $P < .001$; and visual motor, 0.48, $P = .02$.

CONCLUSIONS: eSight introduction yields immediate improvements in visual ability, with face recognition and ADLs showing a tentative benefit of further use. Overall, visual ability, reading, and visual information showed greatest benefit with device use. Further studies need to examine benefits of practice and training and possible differential effects of underlying pathology or baseline vision.

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Spurred on by the rapid miniaturization of camera, image processing, and display electronics in recent decades, novel head-mounted displays have been developed specifically for individuals with vision impairment,[1] becoming a viable addition to the arsenal of low vision aids for the visually impaired.[2–4] Head-mounted devices incorporate a display in front of the user's eyes, typically using a frontal camera to capture live video and embedded image processing software to present enhanced visual information.[5,6] Advantages of head-mounted displays are that they provide hands-free magnifications for resolution tasks at far, intermediate, and near distances; use autofocus and variable magnification to facilitate viewing; and provide video inversion as well as contrast and brightness enhancement. Interest in head-mounted displays has increased over the years, starting with the early designs of the Low Vision Enhancement System[7,8] and the Joint Optical Reflective Display,[9] whose technical

challenges (weight, size, limited visual field, low resolution, lag time, and covering the user's eyes[7,10]) limited their integration into the lives of low vision users. Still, even these early designs were shown to be effective for both adults[8,11,12] and children[13] with low vision; major benefits included improved print reading, contrast sensitivity, and illumination control. Since then, technological advances have made head-mounted displays lighter and smaller, with more processing power, and a performance comparison with conventional optical devices indicated that their greater magnification range significantly improved utility at long and intermediate distances.[10,14] In addition, Peterson et al.[15] showed that reading with a conventional optical aid, such as a magnifier, was slower than with head-mounted displays. Furthermore, previous research has indicated that head-mounted displays have the potential to improve visual search and nighttime travel in individuals with visual field loss and

impaired dark adaptation, by virtue of automatic gain control, variable object magnification, and the ability to magnify/minify sections of the visual field.[16] Until now, little evidence has been provided as to whether head-mounted displays have the ability to facilitate activities of daily living such as face recognition, specifically as judged by the device users. The present study aims to fill this gap by examining changes in visual ability as well as performance-based subjective and objective functional vision after 3 months of the introduction and use of eSight Eyewear.

Several researchers have highlighted the importance of understanding how video systems improve the processing and perception of an image by enhancing its contrast and contours, beyond what can be achieved with traditional tools such as color filters[17] or optical magnification currently used to improve visual ability in visually impaired individuals.[16,18,19] With these considerations in mind, eSight Eyewear (Fig. 1) was designed to improve on previous devices by not only providing variable magnification (1.3 to 12.3×), autofocus, contrast enhancement, binarization (mainly for the purpose of reading), hands-free use, and portability but also offering digital image processing that allows the user to scan through a wide-field image, freeze frames for optical character recognition and text-to-speech conversion, and perform other functions. It is a class I medical device, registered with the U.S. Food and Drug Administration, Health Canada, and the European Database on Medical Devices, in accordance with the European Union directives on medical devices.[20–22] Originally launched commercially in 2013, eSight Eyewear had more than 2000 partially sighted users by March 2018. The study device weighed approximately 200 g and contains a high-resolution 30-fps video camera, providing a full-color digital image displayed in real time on two high-resolution near-to-eyes organic light-emitting diode displays (800 × 600 pixels) subtending a display field of view of 28° width (35° diagonal) and maximum magnification of 12.3 times using a combination of optical and digital zoom. The use of organic light-emitting diodes is of specific interest because they are emissive, meaning each pixel is a light source. Other display technologies operate by blocking out a backlight to their best ability; however, organic light-emitting diode's black is truly black (no light), whereas on other display types black appears as dark gray.

FIGURE 1. eSight Eyewear (glasses and manual controller) in its second generation.

Therefore, organic light-emitting diodes can be much brighter than comparable microdisplay technologies, such as liquid-crystal display technology. Users adjust the functionality via a handheld controller that is connected to the eyewear by an external wire. To confirm the functionalities of the device and to examine its effect on visual ability, the present study reports on 51 novice eSight Eyewear users who were followed for 3 months of device use. It was hypothesized that the device would improve performance on all eye charts, questionnaires, and activities–of-daily-living measures.

METHODS

This multisite, prospective, single-arm study was registered at ClinicalTrials.gov under study number NCT02616900 and received ethics approval in Canada and the United States through the Centre for Interdisciplinary Research in Rehabilitation of Greater Montreal (Quebec, Canada) and the institutional review boards of the Wilmer Eye Institute (Johns Hopkins University, Baltimore, MD) and the University of Michigan Kellogg Eye Center (Ann Arbor, MI), whereas IRB Services in Aurora (Ontario, Canada) oversaw ethical conduct of the study at the University of Toronto and two private low vision centers in Florida. Recruitment was conducted at the Johns Hopkins University Wilmer Eye Institute, the University of Michigan Kellogg Eye Center, the Center for Retina and Macular Disease (Lakeland, FL), the Lighthouse for the Blind of Palm Beaches (Palm Beaches, FL), the Toronto Western Hospital, University of Toronto (Toronto, Ontario, Canada), and the School of Optometry, University of Montreal, as well as its affiliated rehabilitation centers (Montreal and Longueuil, Quebec, Canada).

Of the 144 individuals who were screened for participation, 74 met the following inclusion criteria: they ranged in age from 13 to 75 years; they had best-corrected visual acuity in the better eye of 20/60 to 20/400 and an estimated or measured visual field diameter of at least 20° (monocular or binocular); their visual status had been stable for at least 6 months; and participants were mostly experienced users of one or more assistive devices and benefited from magnification. They had to demonstrate motivation to wear eSight Eyewear in a variety of situations, including during the day in public (e.g., at work or school), be mentally competent to comply with the study requirements, and pass the blind version of the Montreal Cognitive Assessment.[23] Study participants completed the 36-Item Short Form Health Survey at baseline and at the 3-month follow-up period, to assess changes in general health during the study period. The main study elements and enrolment attrition are shown in Fig. 2.

Participants completed measures of distance visual acuity using the Early Treatment Diabetic Retinopathy Study chart[24]; reading acuity, reading speed, and critical print size (MNREAD)[25]; and contrast sensitivity (MARS test).[26] Chart measures were taken at three time points: baseline measures without the device with best correction as established by an optometrist or ophthalmologist, at visit 1; intermediate measures at the fitting with the device incorporating that same refractive distance correction during visit 2 (around two to three weeks later), before participants were allowed to take the device home as a free limited three-month loan; and final measures after three months of device use at visit 3, at which point the eSight Eyewear was returned to the research team. The Veterans Affairs Low Vision Visual Functioning Questionnaire 48 was administered either over the phone or in person, before the baseline appointment and again after three months of device use.[27]
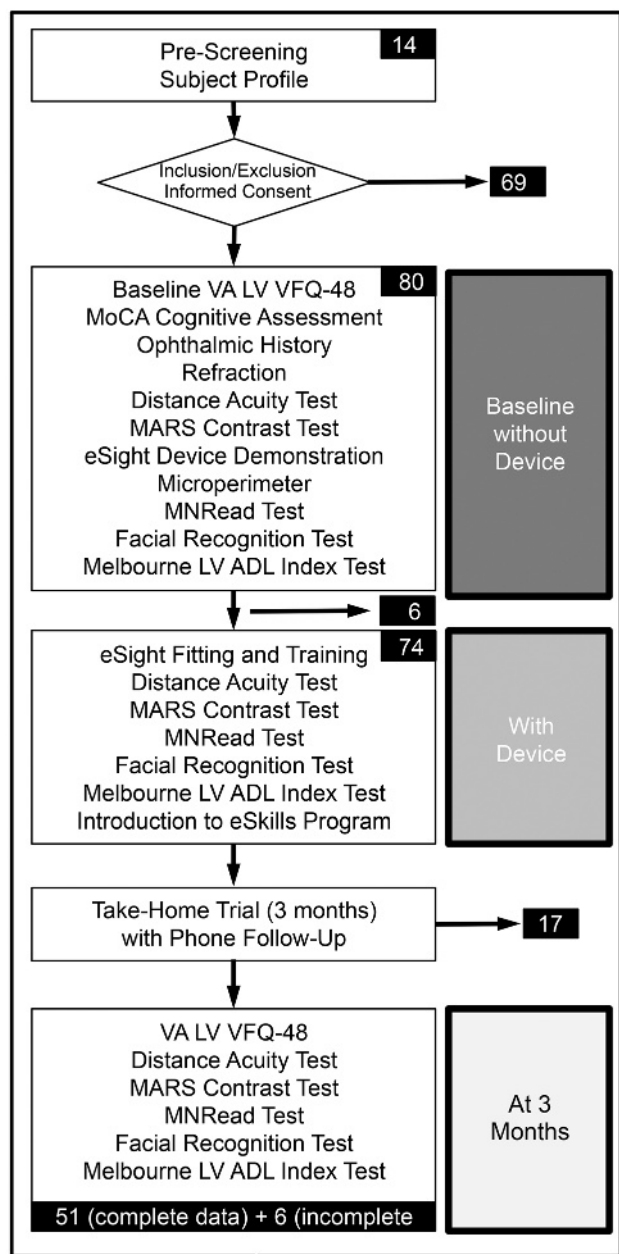
FIGURE 2. Display of the study components and their chronological order, including data on the number of participants who completed in each step.

Questionnaire scores were converted into logit units, using the calibrated conversion table provided by Stelmack and Massof.[28] The four functional domains of the Veterans Affairs Low Vision Visual Functioning Questionnaire 48 are reading, containing items such as reading newspaper, print on television, or street signs; visual information gathering, made up of items such as recognizing faces, finding an item on a crowded shelf, or matching clothes; visual motor, containing items related to activities of daily living such as pouring a liquid into a cup, preparing a meal, or self-grooming; and mobility, which involves use of public transport, navigating stairs, and getting around in unfamiliar places.

Participants also completed an exploratory face recognition test and a subset of function items from the Melbourne Low Vision

Activities of Daily Living Index.[29] The Facial Recognition test was developed using images from the University of Pittsburgh Cohn-Kanade facial image database.[30,31] Participants were asked to name the sex (male/female) and facial expressions (neutral, happy, sad, disgusted, angry, surprised, or fearful, according to their categorization in the database) of 50 images of faces displayed on a computer screen presented at life size at a distance of 5 ft on a 22-in monitor. Different images were presented during the three administrations. Each image was presented for up to 120 seconds to provide sufficient time for viewing. The test was scored logarithmically such that a time of 2 seconds or less on a particular image resulted in a maximum possible score of 2, and scores for times longer than 2 seconds decayed logarithmically to a score of 0 at 120 seconds, unless either the sex or expression was incorrect, at which point the score became 0 as well. This resulted in a maximum score of 100 if all 50 faces were correctly identified for sex and expression in less than 2 seconds and a minimum score of 0.

To avoid redundancy with some of the questions in the Veterans Affairs Low Vision Visual Functioning Questionnaire 48, only 12 items of the Melbourne Low Vision Activities of Daily Living Index[29] were administered, as listed in Table 1. All tasks were timed, and scoring was done on a scale of 0 (very unsatisfactory: unable to attempt, performance at chance) to 4 (very satisfactory: attempt complete, fast with self-correction, all correct), based on the judgment of the clinician or rehabilitation professionals who administered the test. Scores could range from 0 to 48, with higher scores indicating more successful task completion, and were then normalized to range from 0 to 100.

Participants were provided with the eSkills manual,[32] a self-training program developed by eSight that provides instructions and exercises for device users, intended to increase their competence and familiarity with the device. The manual contained detailed information about the device, its interface, and user instructions for the headset and the controller unit, as well as information on how to adjust zoom, focus, contrast, color mode, and the freeze-image option, followed by sections on Web support, advanced functions

TABLE 1. Elements of the Melbourne Low Vision Activities of Daily Living Index administered to eQUEST participants, at baseline and after 3 months of device use

Task number	Description
1	Write a check (given amount, date, and signature).
2	Find the company name and amount due on a bill.
3	Read time on a wrist watch.
4	Read newspaper print.
5	Read name and dosage instructions on a medicine label.
6	Read the name and address on a medical appointment slip.
7	Read a newspaper headline.
8	Pour water into a glass from a jug to within 1 in of top rim.
9	Read time on a wall clock.
10	Identify product names on cereal and food containers.
11	Identify coins and create two piles of coins, totaling 65 cents and 90 cents.
12	Identify five playing cards.

such as on-screen menus, tips on safety, and maintenance. The eSkills training modules laid out a four-day learning calendar with examples and exercises for the user to get to know the device, including modules on reading at distance and near, writing and using computers, and general viewing and search strategies. During the first four weeks of use, participants received regular follow-up phone calls once per week from a member of the research team (e.g., an occupational therapist, orthoptist, or low vision therapist) who was familiar with the device, to assist with possible troubleshooting as well as device use strategies. During the remaining 2 months, these professionals were available if participants wanted to obtain additional advice. Participants were encouraged to use the device at school or work, as well as during as many activities during their day where they felt comfortable using it. After 3 months of device use, practice, and self-guided training with eSkills, participants returned the device and completed their final testing session. During administration of the chart-based vision tests using the eSight device, participants were encouraged to adjust magnification and/or contrast enhancement for best performance; however, the actual settings used were not recorded.

Statistical analyses were conducted using JASP version 0.8.5.1 (University of Amsterdam, Amsterdam, The Netherlands).[33] For the analyses presented below, analyses of variance where the assumption of sphericity was violated were adjusted using a Greenhouse-Geisser correction. Pairwise post hoc comparisons are reported using repeated-measures contrasts, and conservative population effect size estimates are reported using omega squared (ω^2), to facilitate effect magnitude comparison across published studies. Values for ω^2 of 0.01, 0.06, and 0.14 have been suggested to indicate small, medium, and large effects, respectively[34]; t tests or Wilcoxon signed rank tests were used for paired comparisons of the Veterans Affairs Low Vision Visual Functioning Questionnaire 48 scores, depending on the observed adherence to normality in the data, and effect sizes are reported using Cohen d. Values for d of 0.2, 0.5, and 0.8 have been suggested to indicate small,

medium, and large effects, respectively,[35,36] and comparable values have been reported for cognitive neuroscience.[37] Detailed descriptive statistics for all comparisons are provided in Table 2.

RESULTS

Screen Calibration

To confirm the visual field available to participants within the horizontal 28° display field of view of the near-eye screens, we conducted visual field testing with both Octopus automated perimetry (Haag-Streit Group, Mason, OH) and manual tangent screen field measurements, with the camera placed at the location where the eye would normally be. Both techniques indicated that the field available extended from 21.2° horizontally at the lowest magnification setting (1.3× linear magnification) to 2.3° at the highest setting (12.3×). Progression of magnification at increasing settings was inversely linear, following the equation $y = 28 / x$, where y is the visual field in degrees and x is the magnification; screen resolution is fixed at 20/42 (800 pixels spanning 28°, whereby 1 pixel = 2.1 arcmin).

Participants

Of the 74 participants who joined the trial, 17 left the study during the three-month study period: 2 owing to discomfort (nausea, neck pain), 7 owing to insufficient benefit, 1 owing to difficulty operating the device, 4 owing to scheduling conflicts or relocation, 1 owing to an unrelated illness, and 2 lost to follow-up. For 6 participants, the final data set was incomplete owing to data omission, leaving complete data for 51 participants, presented here. The 17 individuals lost during the follow-up period did not differ statistically on any of the functional or demographic measures from those whose complete data are presented below, with the exception of their distribution across the sexes: more women were lost after the initial assessment (n = 12/17), whereas the remaining participant pool contained more men (n = 30/51) (χ^2_1 [n = 67] = 5.58, $P < .02$). The 30 men and 21 women (mean

TABLE 2. Descriptive statistics for all variable comparisons, mean (SD)

Variable (measurement tool)	Unit	Baseline		End point
		Without device	With device	
Distance acuity (ETDRS)	logMAR	**0.95 (0.25)**	**0.20 (0.31)**	0.19 (0.30)
Reading acuity (MNREAD)	logMAR	**0.90 (0.34)**	**0.33 (0.39)**	**0.24 (0.36)**
Critical print size (MNREAD)	logMAR	**1.08 (0.27)**	**0.59 (0.40)**	0.50 (0.31)
Reading speed (MNREAD)	wpm	92 (68)	102 (75)	98 (65)
Reading accessibility index (MNREAD)	wpm/200	**0.23 (0.20)**	**0.34 (0.25)**	0.36 (0.24)
Contrast sensitivity (MARS)	log CS	**0.89 (0.48)**	**1.44 (0.44)**	1.41 (0.44)
Face perception	Test score	**37.77 (17.57)**	**45.29 (18.45)**	47.08 (15.41)
Melbourne Low Vision Activities of Daily Living Index	Test score	**66.90 (19.10)**	**76.61 (19.51)**	78.84 (22.09)
Veterans Affairs Low Vision Visual Functioning Questionnaire				
Reading	Logits	**1.75 (1.43)**	—	**4.33 (2.68)**
Visual information	Logits	**1.12 (0.91)**	—	**2.29 (1.19)**
Visual motor	Logits	**1.05 (0.81)**	—	**1.42 (1.30)**
Mobility	Logits	0.88 (1.06)		0.92 (1.74)

Boldface numbers indicate statistically significant differences ($P < .05$) for each given variable. logCS = logarithm of contrast sensitivity; logMAR = logarithm of the minimum angle of resolution; wpm = words per minute.

age, 48 [standard deviation, 17] years; range, 13 to 75 years; see Table 3 for additional characteristics) in the final analysis presented with Early Treatment Diabetic Retinopathy Study acuities ranging from 20/63 to 20/400 (mean, 20/178), with one outlier at 20/760.

Participants reported the number of assistive vision devices used at baseline, whereby 5 used 4 devices, 9 used 3 devices, 21 used 2 devices, 14 used only 1 assistive vision device, and 2 had not previously used any device. Raw 36-Item Short Form Health Survey scores did not differ markedly before and after the intervention, and no participants were excluded based on changes in general health. Analysis of variance indicated that participants at site 4 (mean age, 61 years) were statistically significantly older than those at sites 2 (mean age, 39 years) and 3 (mean age, 34 years) ($P = .02$ and $P = .002$, respectively). The potential effect of age was examined first by correlating age with the change scores for each test: baseline to fitting, fitting to final, and baseline to final scores. Only difference scores for reading speed (baseline – final score, $r = 0.32$; younger age was correlated with larger gains) and face perception (baseline – final score, $r = –0.30$; and fitting – final score, $r = –0.49$; increased age was correlated with larger gains at both follow-up points) were statistically significantly correlated. Therefore, age was included only as a covariate in the analyses for these two measures.

The potential effect of diagnosis was explored by creating three diagnostic groups: central (e.g., age-related macular degeneration, Stargardt, n = 22), peripheral (e.g., retinitis pigmentosa, glaucoma, n = 5), and general (e.g., optic atrophy, Leber, n = 24). Comparison of these three groups on all dependent measures as well as their gain scores at all follow-up points revealed that four variables indicated statistically significant differences: gain in distance acuity from baseline to fitting showed a statistically significant difference ($F_{2,48} = 3.34$, $P = .04$, $\omega^2 = 0.08$), driven by a difference between the central versus the general group ($P_{Tukey} < .04$, $d_{Cohen} = 0.35$), indicating that participants with general visual impairment gained more acuity at fitting than individuals with central impairment only. Reading acuity at 3 months indicated a significant difference ($F_{2,48} = 3.51$, $P = .04$, $\omega^2 = 0.09$); however, post hoc analyses only indicated a trend for a difference between the central and peripheral group ($P_{Tukey} < .07$, $d_{Cohen} = 0.32$), with the peripheral group showing better reading acuities. VFQ Visual information scores indicated a statistically significant difference ($F_{2,48} = 4.30$, $P = .02$, $\omega^2 = 0.12$), whereby the peripheral group showed lower scores compared with the general group ($P_{Tukey} < .04$, $d_{Cohen} = 0.35$). Finally, the reading accessibility index score gain from fitting to 3 months differed statistically ($F_{2,44} = 3.87$, $P = .03$, $\omega^2 = 0.11$); post hoc comparisons indicated that the peripheral group had smaller gains than both the central ($P_{Tukey} < .05$, $d_{Cohen} = 0.35$) and general groups ($P_{Tukey} < .02$, $d_{Cohen} = 0.40$).

Chart Tests

Distance Acuity

As shown in Fig. 3, the magnification provided by eSight Eyewear resulted in a significant improvement in the ability to read print at distance ($F_{2,100} = 255.0$, $P < .001$, $\omega^2 = 0.83$), with a gain of seven lines from baseline to the intermediate measure ($P < .001$). There was no further improvement after 3 months of use.

MNREAD Measures

Reading Acuity

Similarly, the device provided a significant improvement in the ability to read print at near ($F_{1.78,88.95} = 129.30$, $P < .001$, $\omega^2 = 0.71$), with a gain of five lines immediately ($P < .001$) and

TABLE 3. Participant characteristics

ID	Age (y)	Sex	Diagnosis	Baseline distance acuity
1	61	M	Dry AMD	20/159 (6/48)
2	75	M	Hereditary retinal dystrophy	20/200 (6/60)
3	49	F	Retinopathy of prematurity	20/200 (6/60)
4	55	M	Optic atrophy	20/200 (6/60)
5	39	F	Retinitis pigmentosa	20/289 (6/87)
6	46	M	Stargardt	20/200 (6/60)
7	46	F	Glaucoma	20/317 (6/95)
8	59	M	Dry AMD	20/264 (6/79)
9	13	M	Stargardt	20/159 (6/48)
10	15	M	Stargardt	20/100 (6/30)
11	21	M	Retinitis pigmentosa	20/145 (6/43)
12	75	M	Dry AMD	20/174 (6/52)
13	74	F	LHON	20/317 (6/95)
14	18	F	Achromatopsia	20/69 (6/21)
15	51	F	Angloid streaks	20/264 (6/79)
16	57	F	Myopic degeneration	20/66 (6/20)
17	31	M	LHON	20/66 (6/20)
18	46	M	Stargardt	20/200 (6/60)
19	27	F	Cone rod dystrophy	20/69 (6/21)
20	38	M	LHON	20/289 (6/87)
21	39	F	Optic atrophy	20/174 (6/52)
22	24	F	Optic atrophy	20/145 (6/43)
23	56	M	Stargardt	20/760 (6/228)
24	38	F	Optic atrophy	20/317 (6/95)
25	23	M	LHON	20/303 (6/91)
26	15	M	Retinitis pigmentosa	20/76 (6/23)
27	36	M	LHON	20/317 (6/95)
28	74	F	Dry AMD	20/126 (6/31)
29	72	F	Dry AMD	20/399 (6/120)
30	71	M	Dry AMD	20/63 (6/19)
31	51	M	Stargardt	20/399 (6/120)
32	61	F	Dry AMD	20/200 (6/60)
33	75	F	Optic atrophy	20/159 (6/48)
34	69	M	Diabetic retinopathy	20/159 (6/48)
35	56	F	Toxoplasmosis	20/100 (6/30)
36	39	M	Optic neuritis	20/317 (6/95)
37	67	F	Stargardt	20/200 (6/60)
38	63	M	Stargardt	20/159 (6/48)
39	37	M	Stargardt	20/458 (6/137)
40	47	M	Stargardt	20/126 (6/31)
41	45	F	Cone rod dystrophy	20/138 (6/42)
42	63	M	Optic atrophy	20/132 (6/40)
43	45	M	Achromatopsia	20/110 (6/33)

Continued

TABLE 3. *Continued*

ID	Age (y)	Sex	Diagnosis	Baseline distance acuity
44	62	M	Optic atrophy	20/110 (6/33)
45	46	F	Vasularitis	20/152 (6/46)
46	46	M	Rubella	20/317 (6/95)
47	50	F	Retinitis pigmentosa	20/100 (6/30)
48	46	F	Stargardt	20/159 (6/48)
49	63	M	Cone rod dystrophy	20/399 (6/120)
50	36	M	LHON	20/63 (6/19)
51	36	M	LHON	20/252 (6/76)

Baseline acuities in the better eye with best standard correction, using ETDRS chart. AMD = age-related macular degeneration; ETDRS = Early Treatment Diabetic Retinopathy Study; F = female; LHON = Leber hereditary optic neuropathy; M = male.

a gain of one additional line after 3 months (*P* = .03) (Fig. 4). Analysis of variance indicated that subjects at sites 4, 5, and 6 had, on average, two to three lines worse reading acuity at baseline (*P* < .01) but that their improvements were comparable with the other sites.

Critical Print Size

Like reading acuity, critical print size differed in a significant way ($F_{1.56,70.3} = 74.5$, $P < .001$, $\omega^2 = 0.61$), improving immediately ($P < .001$) but staying unchanged after 3 months (Fig. 5).

Reading Accessibility Index

The reading accessibility index, defined by Calabrèse et al.[38] based on an individual's mean reading speed measured across up to the 10 largest print sizes on the MNREAD, also indicated significant change ($F_{1.73,79.61} = 27.67$, $P < .001$, $\omega^2 = 0.71$),
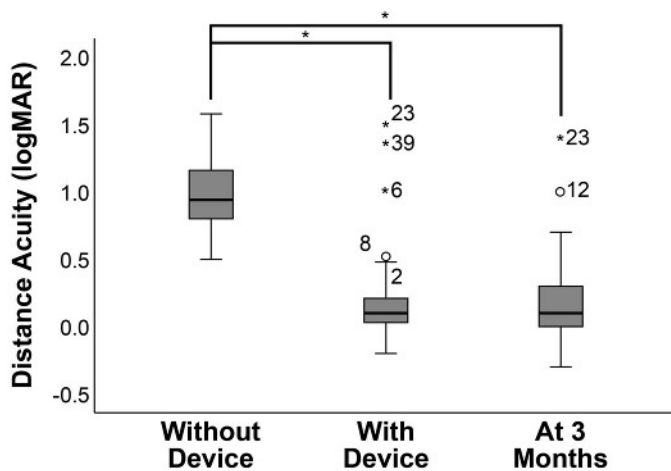
FIGURE 3. Distance acuity equivalent of print size correctly read on the ETDRS chart at baseline without the device, at fitting with the device, and after 3 months of device use. Mean baseline acuity without device was 20/177 (mean logMAR, 0.95 [SD, 0.25]), which improved to 20/32 (mean, 0.20 [SD, 0.31]) with the device but stayed unchanged after 3 months of device use and training (mean, 0.19 [SD, 0.30]). ID numbers of outlier correspond to participant IDs in Table 3. *Statistically significant differences. ETDRS = Early Treatment Diabetic Retinopathy Study.
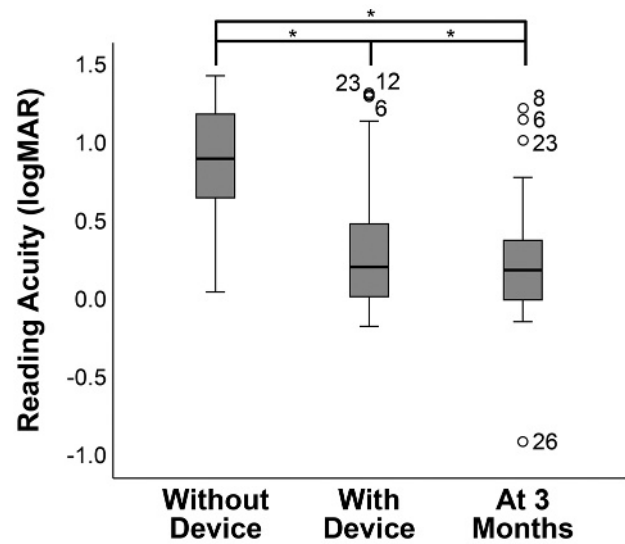

FIGURE 4. Reading acuity equivalent of print size read on the MNREAD chart at baseline without the device, at fitting with the device, and after 3 months of device use. Mean baseline reading acuity without device was 20/159 (mean logMAR, 0.90 [SD, 0.34]), which improved to 20/43 (mean, 0.33 [SD, 0.39]) with the device but stayed unchanged after 3 months of device use and training (mean, 0.24 [SD, 0.36]). ID numbers of outlier correspond to participant IDs in Table 3. *Statistically significant differences.

improving immediately (*P* < .001) and staying unchanged at 3 months (Fig. 6).

Reading Speed

Analysis of covariance revealed a statistically significant change in reading speed across the three time points after controlling for age ($F_{2,96} = 3.22$, $P = .04$, $\omega^2 < 0.04$) (Fig. 7). However, the effect was too small to render any of the repeated-measure comparisons statistically significant.

Contrast Sensitivity

Using the contrast enhancement functionality in eSight Eyewear, participants significantly improved their scores on the MARS test ($F_{1.65,82.63} = 43.46$, $P < .001$, $\omega^2 = 0.45$), gaining the equivalent of 12 letters immediately (*P* < .001) with no further improvement at 3 months (Fig. 8).

Activities-of-Daily-Living Tests

Face Perception

Analysis of covariance indicated that the ability to correctly identify the sex and emotional expression in the image improved, after controlling for the effect of age ($F_{2,92} = 4.19$, $P < .01$, $\omega^2 = 0.06$); scores increased immediately when wearing the device compared with baseline (*P* < .001), and there was no further improvement observed after 3 months (*P* = .36) (Fig. 9).

Melbourne Low Vision Activities of Daily Living Index (Selected Tasks)

Similarly, the analysis on the Melbourne Low Vision Activities of Daily Living Index indicated an immediate change in overall visual
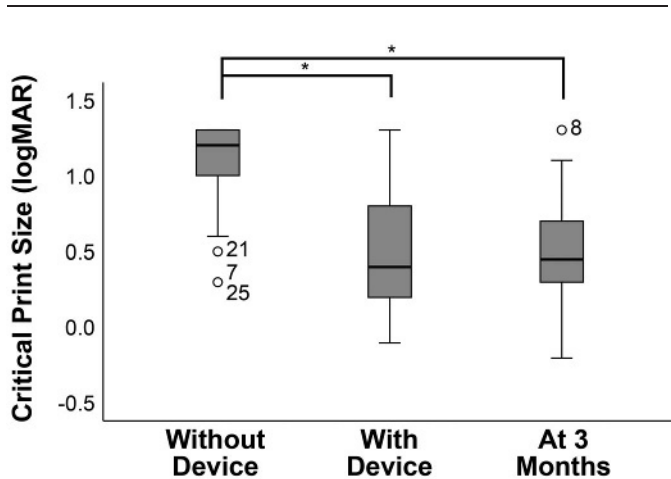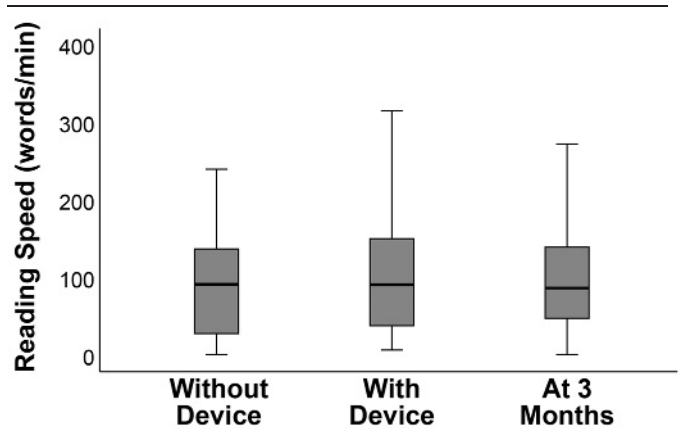
FIGURE 5. Critical print size measured on the MNREAD chart at baseline without the device, at fitting with the device, and after 3 months of device use. Mean baseline critical print size without device was 20/240 (mean logMAR, 1.08 [SD, 0.27]), which improved to 20/78 (mean, 0.59 [SD, 0.40]) with the device but stayed unchanged after 3 months of device use and training (mean, 0.50 [SD, 0.31]). ID numbers of outlier correspond to participant IDs in Table 3. *Statistically significant differences.

ability ($F_{1.77,85.17} = 6.00$, $P = .005$, $\omega^2 = 0.09$), and performance did not change further after the 3-month follow-up period (Fig. 10).

Veterans Affairs Low Vision Visual Functioning Questionnaire

The Veterans Affairs Low Vision Visual Functioning Questionnaire 48 was administered at baseline and at the final follow-up. Overall, participants' scores reflected significant improvement in their visual abilities ($t_{50} = 4.62$, $P < .001$, $d = 0.65$). This effect was largely driven by the reading subscale ($t_{50} = 7.51$, $P < .001$, $d = 1.05$) (Fig. 11) followed by changes in the visual information
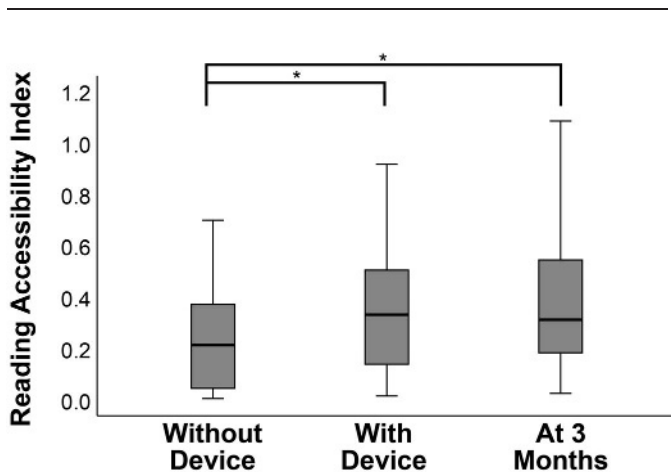

FIGURE 6. Reading accessibility index values at baseline without the device, at fitting with the device, and after 3 months of device use. Mean values increased significantly with the device at fitting but did not improve further after 3 months of device use and training. *Statistically significant differences.

FIGURE 7. Reading speed values at baseline without the device, at fitting with the device, and after 3 months of device use. The analysis did not reveal any statistically significant change in reading speed between any of the time points.

items such as face perception ($t_{50} = 6.03$, $P < .001$, $d = 0.84$) and the visual motor items such as pouring a liquid into a cup ($Z = 389$, $P = .02$, $d = 0.27$). There was no significant change among the mobility items ($Z = 3547$, $P = .86$, $d = 0.03$).

DISCUSSION

The purpose of the present clinical evaluation of eSight Eyewear was to examine to what extent the device enhances visual ability in a low vision population, by evaluating its effects on chart-based
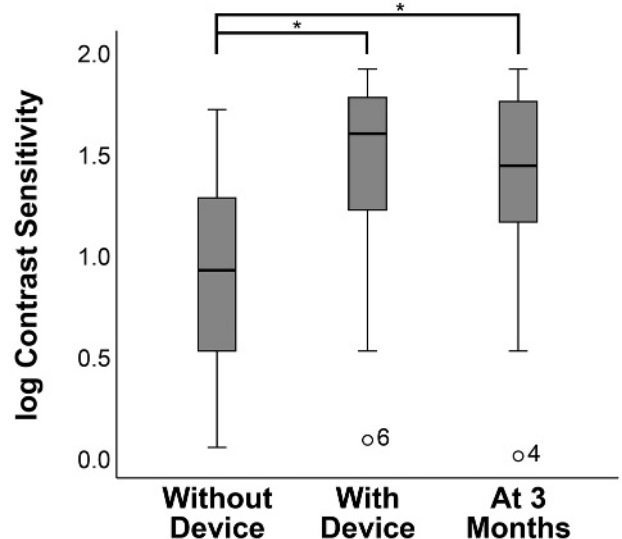

FIGURE 8. Contrast sensitivity (CS) measured by the MARS chart at baseline without the device, at fitting with the device, and after 3 months of device use. Mean baseline log CS without device was 0.89 (20/177 [SD, 0.48]), which improved to 1.44 (SD, 0.44) with the device but stayed unchanged after 3 months of device use and training (mean, 1.41 [SD, 0.44]). ID numbers of outlier correspond to participant IDs in Table 3. *Statistically significant differences.
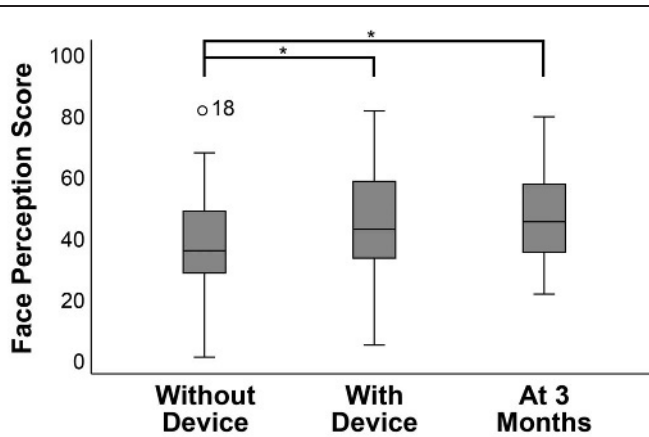
FIGURE 9. Face perception test results at baseline without the device, at fitting with the device, and after 3 months of device use. The mean baseline face perception test score without device was 37.77 (SD, 17.57), which improved to 45.29 (SD, 18.45) with the device but stayed unchanged after 3 months of device use and training (47.08 [SD, 15.41]). The ID number of the outlier corresponds to participant ID in Table 3. *Statistically significant differences.

measures, performance measures, and patient-reported outcomes, and to determine if results changed over a short interval after the first time experience with the device. Overall, wearing the fitted device instantly improved the participants' distance and near visual acuity, contrast sensitivity, minimum and critical reading print size, and reading speed measured across the 10 largest MNREAD print sizes (reading accessibility index), indicating that the magnification and contrast enhancement functions immediately have their intended effect, similar to improvements that we would expect from conventional visual magnification and contrast enhancement aids. The only measure that further improved after 3 months of use of the device was reading acuity, which may reflect the practice of hand-eye coordination involved in holding the material at a set distance and making effective scanning and repositioning movements while reading small text or the development of more stable head positioning. These aspects of device use may be optimized over time, resulting in a reduced need for magnification. Hand-eye coordination has been shown to be negatively affected by low vision[39,40] but would not be required for single-letter acuity tests or for reading larger print sizes. Maximum reading speed, on the other hand, was only minimally affected by the device, after controlling for age, most likely reflecting the fact that eye movement control and cognitive processes involved in reading are relatively unchanged by magnification. Thus, participants were reading smaller print sizes with the same degree of difficulty using the device as they read larger print without the device. An additional factor may be that the use of single sentences on the MNREAD chart does not adequately reflect aspects of reading that may be positively affected by device use. For example, changes in continuous reading on measures such as the International Reading Speed Texts[41] may be more appropriate in the measurement of normal reading behavior. Future studies should also include measures of reading comprehension, as the effort involved in device use may further affect the processing of what is being read. It is of interest to observe the outlier among the reading measures (participant 23, whose presenting acuity of 20/760 fell outside the original recruitment criteria). Her improvement on acuity-related

measures was minimal, suggesting that an upper acuity limit may exist for eSight users to optimally benefit; however, her performance on most other measures did not present as outliers.

The effect of magnification using a head-mounted display can be restricted by resolution limitations. For the eSight study device, the camera resolution is 2592 (horizontal) × 1944 (vertical), which, when zooming the image to approximately 4.25 times, reaches the same number of pixels as the display. At higher magnifications, the image will be affected by the resolution limit of the display; however, for a device user with a visual acuity of 20/120 or lower, such reduced resolution would be neither visible nor noticeable. Even users with better visual acuity are unlikely to experience this limitation because the instability of images caused by high magnification limits the viewer's ability to see detail.

When examining responses to the Veterans Affairs Low Vision Visual Functioning Questionnaire 48, participants generally self-reported the largest perceived improvements on the reading items, followed by improvements in tasks related to visual information (e.g., face perception or finding an item on a crowded shelf) and visual motor activities that require hand-eye coordination (e.g., signing a check or preparing a meal). No change was reported on the mobility items of the questionnaire. Even though eSight Eyewear in its current design is not intended as a mobility aid, it had been initially anticipated as an effective aid to assist in the orientation requirement of effective mobility function (e.g., signage identification but not fall prevention). In fact, the item responses from the Veterans Affairs Low Vision Visual Functioning Questionnaire 48 support this finding. Orientation-related items of the Veterans Affairs Low Vision Visual Functioning Questionnaire 48 are largely grouped within the visual information and reading domains (e.g., reading street signs, where a beneficial effect was present). In contrast, the pure mobility items, such as the ability to get around indoors, outdoors, or in unfamiliar places; going out at night; or bumping into things, would not be expected to demonstrate beneficial effects. The fact that using the eSight device did not result in
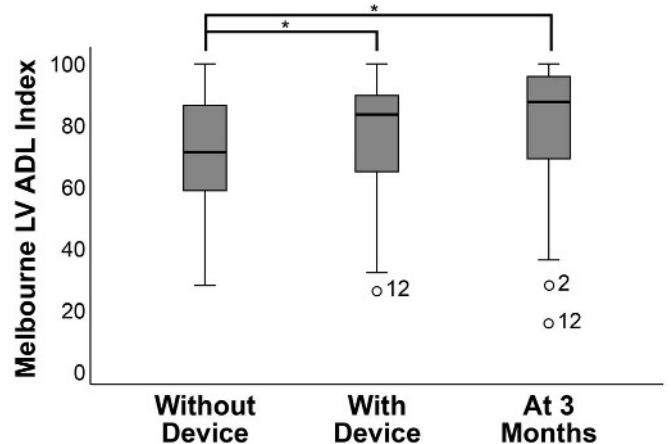

FIGURE 10. Partial Melbourne Low Vision Activities of Daily Living Index results at baseline without the device, at fitting with the device, and after 3 months of device use. Participant ID numbers are grouped by site (first digit). The mean baseline partial Melbourne score without device was 69.90 (SD, 19.10), which improved to 76.61 (SD, 19.51) with the device but stayed unchanged after 3 months of device use and training (mean, 78.84 [SD, 22.09]). ID numbers of outlier correspond to participant IDs in Table 3. *Statistically significant differences.
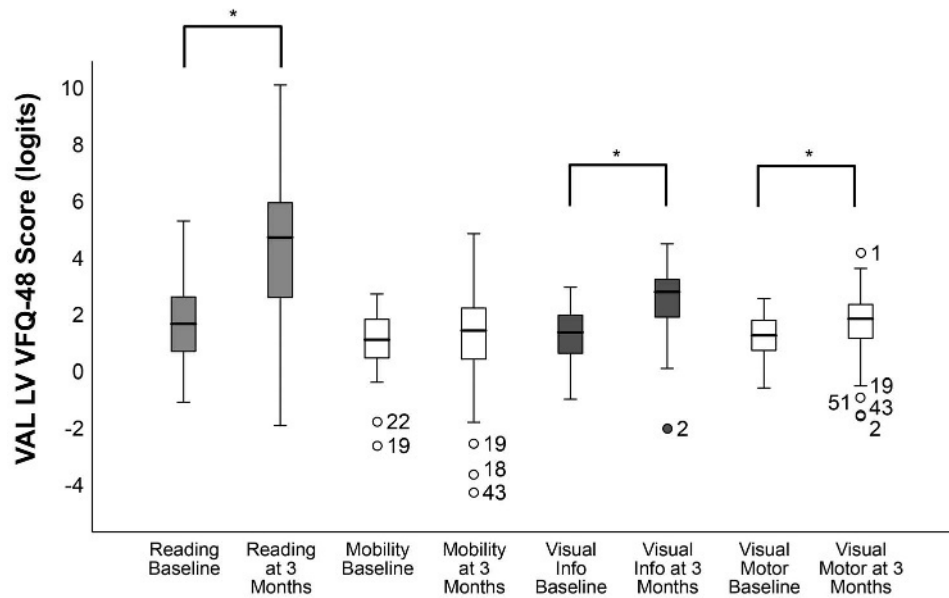
FIGURE 11. Results of four domains of the Veterans Affairs Low Vision Visual Functioning Questionnaire at baseline and after 3 months of device use. For the reading items, the mean baseline reading score without device was 1.75 logit units (SD, 1.43), which improved to 4.33 logits (SD, 2.68). For visual information items, the mean score without device was 1.21 logit units (SD, 0.91), which improved to 2.29 logits (SD, 1.19). The mean baseline visual motor score without device was 1.05 logit units (SD, 0.81), which improved to 1.42 logits (SD, 1.30) with the device after 3 months of device use and training. Scores on the mobility items did not demonstrate a significant change after 3 months. ID numbers of outlier correspond to participant IDs in Table 3. *Statistically significant differences.

degraded mobility scores is regarded as a positive outcome. This is likely a result of the device's intentionally open and variably adjustable bioptic design, whereby the wearer's habitual peripheral vision, which for users with central visual field impairments can be as good as that of a healthy sighted individual, is not occluded by the device. Future evaluations should consider specifically whether the device might be beneficial as an orientation device, in the context of reading store or street signs (categorized under the reading domain), recognizing landmarks (categorized under the visual information gathering domain), or planning a route on a map to reach a target (categorized as visual-motor coordination).

The benefits that were observed on the face perception task show a difference relative to previous findings examining the effect of magnification on face perception in age-related macular degeneration patients.[42] Prior studies demonstrated that magnification by itself does not improve emotion detection as measured by facial recognition. It is likely that the observed improvement in this study is mediated by contrast enhancement because facial features tend to have low contrast and contrast sensitivity was impaired in our subjects. Interestingly, our face perception measure demonstrated an effect of age, however, in the opposite direction that we had anticipated, whereby older adults benefited more from device use when detecting facial expressions and the sex of the presented face. As our older participants were mostly affected by macular degeneration, it is possible that the previously demonstrated benefits of telescopic magnification on face perception were also observed in our older participants.[43] Telescopic magnification does not compensate for age-related macular degeneration patients' low contrast sensitivity, and it is likely that the effect we found can be attributed to a combination of magnification and contrast enhancement.

When comparing performance across diagnostic groups, only four variables revealed statistically significant differences; however,

these findings need to be interpreted with caution because the peripheral vision loss group consisted of only five participants and some of the assumptions of analysis of variance are questioned with such a small sample size, when the comparison groups all contain more than 20 observations. Therefore, only the results indicating that participants with general visual impairment gained more acuity at fitting than individuals with central impairment may hold because this is the only analysis that was driven by the two largest samples.

Limitations

Other than the inadvertent inclusion of a subject with 20/760 visual acuity, our subject population met the pre-determined inclusion and exclusion criteria. The loss of 17 subjects during follow-up and of 6 with incomplete data represents a potential source of bias, but even if one assumes that most of those individuals may have had no benefit from the eSight device, this leaves a substantial percentage of participants who perceived sufficient benefit to complete the trial. Previous studies have indicated that cosmesis, motion sickness, and cost all play important roles in the uptake and use of low vision aids.[44,45] Therefore, we speculate that the high proportion of women who abandoned this trial may, in part, be connected to these factors. Future studies should collect additional data about the interest in adopting the device after an initial trial and training period, the price participants would be willing to pay to own the device, and whether they would recommend the device to a friend. In the present study, all participants had been recruited within the context of service provision through a rehabilitation center; therefore, they had the possibility to pursue other devices recommended as part of their regular care. The findings on the number of devices the participants were already using at the time of this trial reflect prior exposure to visual aids training and adaptation techniques. Therefore, further gain with additional aids

may not have been meaningful to the patient. Unfortunately, data on types of devices previously used were not recorded, which could be relevant, as experience with other non–head-borne video-based devices may more easily transfer into successful use of eSight Eyewear.

An important limitation of this study is that we did not systematically collect measures of the magnification and contrast enhancement used while collecting functional measures with the device. The reasoning was based on the reality that device users engaging in their activities of daily living change the device settings on an ongoing basis, depending on the type of task, its distance, and environmental considerations; typically, this setting is a trade-off between the need to see details and both the field of view and the challenge of image stabilization at higher magnification. However, future studies with head-mounted displays should increase the rigor of measurement by recording the device settings chosen for specific tasks of interest. Another important limitation is that we did not compare device performance with that of other tools for sight enhancement, as has been rightly suggested by previous researchers as a key step in comparing effectiveness.[6] Such comparison is the logical next step, as it will be able to answer the key question whether the eSight device demonstrates benefits over devices that are recommended within current standard of care and whether these benefits justify the cost. Furthermore, both qualitatively asking subjects about their previous or concurrent experiences with other devices and systematically comparing task performance are planned for follow-up studies.

Participants in the study were provided with a practice manual and advice by telephone, but this is not necessarily an adequate substitute for a targeted rehabilitation program administered by a qualified therapist. A follow-up study of the effects of such a structured rehabilitation program for eSight users is currently underway at one of the participating institutions. The tests in this study were repeated two to three times, and repeated administration of the same tests could lead to improved performance on the basis of practice. Even though this possibility exists in our study, it should be limited to unfamiliar measures such as the face perception and activities–of–daily-living tests. The fact that improvement was seen almost exclusively upon introduction of the device and

occurred equally across familiar and unfamiliar tests suggests that this type of practice effect through test familiarity did not play an appreciable role in our study; as indicated before, the images of the face-perception test were deliberately varied to avoid practice. Most importantly, large improvements were seen immediately upon introduction of the device, although no practice was available in the preceding two- to three-week period, whereas the subsequent 3 months of practice yielded very limited further improvement. It should be noted that, since the study completion, the manufacturer has launched its next-generation device, which embodies several improvements in various key parameters. This will provide the opportunity to use an updated version of the device in upcoming studies.

CONCLUSIONS

The presented data indicate that the use of eSight Eyewear has striking beneficial effects on a variety of visual functions. Furthermore, 3 months of continued use and practice with the device did not result in remarkable further improvements, indicating immediate efficacy. Head-mounted low vision devices have received considerable attention in recent years owing to rapidly developing technology, facilitating ease of use, and functionality. Systematic clinical evaluations of such devices remain rare but are needed to steer future device development and inform standard-of-care models. Unlike other biomedical fields, which include drugs, devices, and diagnostics where research agendas and progress are often driven by the pharmaceutical or medical device and equipment industries, low vision devices do not require clinical data to obtain regulatory approval. This may explain why the present study is one of only a few that have received funding from an assistive device manufacturer, in this case, eSight Corporation. Even though this funding support may raise questions about potential bias, it has been pointed out that, in an era of financial austerity, close cooperation with industry is one of very few options in our drive to present clinically relevant data that advance rehabilitation best practices.[46]

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