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Novel silicone elastomer contact lenses designed for simultaneous viewing of distance and near eye displays

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ABSTRACT

Significance: As technology advances, there is a need for a safe and well-fitting contact lens that can be utilized to carry embedded components without concerns of decreasing oxygen permeability to the eye.
Purpose: The purpose of this study was to assess fitting characteristics, vision and performance of a novel ultra-high Dk silicone elastomer contact lens having a fully encapsulated two-state polarizing filter and a high-powered central lenslet that allows viewing at distance and viewing of a near eye display, while managing the concomitant high water vapor permeability of the material.
Methods: 15 participants were fit with the silicone elastomer study lenses. Biomicroscopy was conducted before and after lens wear. Visual acuity with manifest refraction and visual acuity with an over-refraction while wearing the plano-powered study lenses were measured. Participants wore spectacles with micro-displays at the focal length of the lenslet on each eye. Lens fit was assessed including ease of lens removal. Subjective assessments of viewing the micro-displays were completed on a 1(unable) to 10(immediate/profound/stable) scale.
Results: Biomicroscopy revealed no eyes had moderate or severe corneal staining after study lens wear. Mean (±standard deviation) LogMAR acuity for all eyes was −0.13(0.08) with best corrected refraction and −0.03 (0.06) with the study lenses and over-refraction. Mean spherical equivalent of the manifest refraction for both eyes was −3.12 D and was −2.75 D over the plano study lenses. Subjective assessments revealed a mean score of 7.67(1.91) for ease of obtaining fusion; 8.47(1.30) for ease of observing three-dimensional vision, and 8.27(1.49) for stability of the fused binocular display vision.
Conclusion: The silicone elastomer study lenses with a two-state polarizing filter and central lenslet allow for vision at distance and on spectacle mounted micro-displays.

1. Introduction

Silicone elastomer contact lenses were originally developed in the 1960s and were found to have high oxygen transmissibility which did not adversely affect corneal metabolism [1–3]. These lenses were initially approved by the FDA in the early 1980s, providing a contact lens with excellent oxygen transmissibility. Early lenses were well received for the aphakic infant population following cataract surgery [4]. These young patients require high-plus-powered contact lenses to replace the focusing power of the natural crystalline lens and enable visual development. The high-plus-power of these contact lenses requires the lenses to be thick in the center, which decreases oxygen transmissibility through a contact lens. The high oxygen permeability of silicone elastomer lens material provides excellent oxygen transmissibility despite the thickness of these lenses, and allows infants to wear these lenses in an extended wear modality [5]. Recent studies have found that complications and cost are considerably less for aphakic infants who wear contact lenses following cataract surgery when compared to infants who had intraocular lens implantation, making these lenses even more attractive in this patient population [6,7]. Silicone elastomer lenses are prescribed widely for this purpose.

Silicone elastomer lens material was also approved for an extended wear indication for patients with typical refractive errors and used a thinner lens profile than required in aphakia [8]. Issues with lens adherence-associated discomfort and mucus adhesion at the lens surface [9], coupled with the availability of hydrogel lens materials that did not manifest these problems, resulted in discontinuation of the production and sale of silicone elastomer lenses for typical refractive error correction. The high transmissibility of water vapor across the thin silicone membranes [10] may play a role in the observed lens adherence and

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associated discomfort. Studies of previous silicone elastomer lenses found that comfort issues may have largely been due to pervaporation, or active diffusion in which liquid and vapor phases separate across a membrane [11,12]. While the high vapor permeability enables oxygen to pass through the lens material, it also allows the water vapor of post lens tear film to pass through the lens if the lens design is thin. As the post lens tear film is depleted by water vapor passing through the lens, the inadequate post lens tear layer may allow a thin lens to adhere to the corneal epithelium. This adherence and related discomfort appear to be the reason that the thinner, earliest silicone elastomer lenses prescribed for typical refractive error correction were voluntarily removed from the market, while those lenses with greater thickness used for aphakia have continued to be successfully prescribed.

In order to regulate the water vapor transmissibility of a silicone elastomer lens, harmonic mean lens thickness [13] may be increased, a selected film may be incorporated in the lens, or the lens surface may be modified. By reducing the water vapor transmissibility, it is believed that a silicone elastomer contact lens can provide excellent oxygen transmissibility to the ocular surface without having discomfort or adherence complaints and observations, because the lens will not adhere to the corneal epithelium. The moldable nature of the material and the moderate modulus allows for excellent handling for a conventional soft contact lens, and also gives the ability to create a lens that can function as a carrier of additional optical elements and non-optical components. The silicone elastomer polymer allows for greater oxygen permeability than silicone hydrogel materials currently used for conventional soft lenses. This quality allows a lens to be thicker, if necessary, without resulting in insufficient oxygen transmissibility that would otherwise compromise ocular health. Embedding components inside a contact lens material with extremely high oxygen permeability allows for technological advances in optical systems without concerns of hypoxia to the eye. One possible optical system for this use is a design with dual focal lengths that can provide wearers with normal distance vision, while also allowing for viewing of extreme near images, such as a spectacle mounted display system. A system such as this could allow wearers to view content hands-free while still having the ability to see their surroundings, which can be of great use for people with low vision, for clinical education, or even for education.

2. Purpose

The purpose of this feasibility study was to evaluate a novel ultra-high Dk silicone elastomer contact lens designed with increased harmonic mean thickness to manage pervaporation and containing a two-state wire-grid light polarizing filter and 1.0 mm diameter central lenslet to allow distance vision and vision of the near-eye display.

3. Methods

This study was completed under the approval of the Institutional Review Board at The Ohio State University, Columbus, Ohio, USA. Healthy soft contact lens wearers aged 18 or older were recruited to participate in the single visit study. Exclusion criteria included the presence of ocular disease or inflammation, systemic inflammatory disease, current pregnancy or lactation, or the presence of astigmatism greater than 2.00 diopters. Potential participants completed written informed consent prior to participation in the study.

4. Materials

The study lenses were made of a silicone elastomer material (lemafocon A). The material properties, contact lens USAN and material formula are reported in Table 1. The high plus-powered lenslet is molded on the front surface with the second radius for normal vision. No other polymer or substrate exists in the lens other than lemafocon A silicone elastomer material. The study lenses were fit using a diagnostic lens set and were designed with peripheral sagittal depth control, allowing the sagittal depth to be controlled by the contour of the periphery of the lens rather than the base curve, and therefore avoiding possible lens deformation or compression of the cornea due to draping. All lenses had the same base curve (8.0 mm) and overall diameter (14.3 mm). Nine lenses were available for fitting, with three lenslet powers and three sagittal depths available. Diagnostic lens parameters are presented in Table 1. The light polarizing filter is a wire grid composed of 14.6 μg of aluminum wires formed by nano-imprint lithography (NIL) before being transferred to the silicone elastomer (lemafocon A) material. The filter is gas permeable, and not a barrier to oxygen transmissibility because the spacing between the wires is approximately 100 nm and the wires are approximately 100 nm wide. The lenses have double slab-off stabilization to prevent rotation of the lenses and keep the polarizers oriented properly. Fig. 1 demonstrates the polarizer. The polarization separates the “normal vision” light pathway entering the eye from distance from the polarized light emanating from the spectacle mounted displays. When viewing the near displays, the display light is blocked by the polarizer in the normal vision portion of the contact lens, and only passes though the central 1 mm of the lenses containing the lenslet. This display light optical pathway also acts as an aperture and extends the depth of field when viewing the displays. The light polarizing filter in the display light path is aligned with the polarizer on the display to allow the display light to pass. The spectacle lenses used in the study are plano in power and incorporate a normally oriented polarization that is crossed to the polarizer in the display path. This allows normal vision through the spectacle portion of the lenses when not viewing the displays, and yet ambient “normal” light is blocked and cannot pass through the display light path and on to the retina when viewing the spectacle mounted displays. This separation of light prevents ambient light from passing through the central lenslet display path and enables a high display vision contrast ratio.

In this feasibility study, lenses were fit on 15 participants in order to assess best corrected distance acuity, the role of the lens modulus and thickness on over-refraction measurement, and the ability to focus and fuse on the binocular spectacle mounted displays when viewing 3D content. Key endpoints were biomicroscopic slit lamp findings of the ocular surface before and after lens wear and best corrected visual acuity with the study lenses compared to best corrected vision without study

Table 1
Study lens properties. Al - Aluminum; SiO_2 - silicone dioxide; USAN – United States Adopted Names generic device name.

Light Transmission	>93 % without filter; 42 % with filter
Refractive Index	
Wetting Angle	<37° (Receding Angle after surface modification)
Specific Gravity	1.03 g/cm3
Elasticity (modulus)	0.566 MPa
Elongation (to break)	398 ± 26 %
Tensile Strength	6.40 MPa
Water Content	0.018% ± 0.005%
Oxygen Permeability (Dk)	778 ± 51
Oxygen transmissibility (Dk/t)	194
*Of study lens given a harmonic lens thickness of 0.400 mm	
Composition	Cyclosiloxane (>99.999%), Al (<0.0001%), SiO_2 (<0.00004%)
Polymer molecular formula:	(Si2O2C4H12)a • (Si2O2C5H12)b • (Si2O2C6H12)c • (Si2C6H18)d • (Si2C2H6)e • (SiCH4)f • (SiOC4H9)g • (SiOC3H9)h • (SiO4)i
USAN:	Lemafocon A
Diagnostic lens parameters	8.0 mm base curve radius 14.3 mm overall diameter 3 sagittal depths: 3.400 mm, 3.700 mm, 4.000 mm 3 Lenslet powers: +53.00 D, +60.00 D, +69.00 D

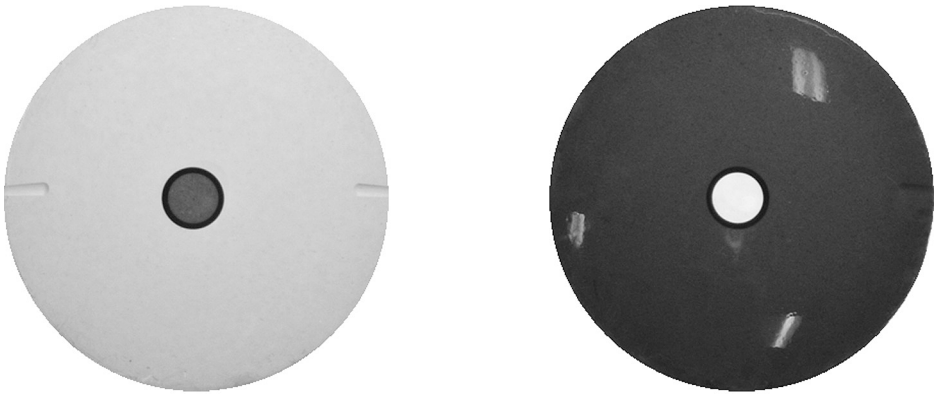

Fig. 1. Schematic of the polarization filter embedded in the silicone elastomer lens. The left schematic shows a central 1 mm zone that is polarized to match the polarization of the LED screens located on the spectacles. The polarized light from the extremely near screens passes through the high powered lenslet in the contact lens located within this 1 mm zone, and no distance (ambient) light can pass through this zone. The right schematic shows the area outside of the central 1 mm zone, which is polarized for distance vision through the lens. The lens maintains stabilization with double slab off design and orientation marks are visible.

lenses.

4.1. Study procedures

This prospective study consisted of a single visit, which began with completion of the informed consent process and was followed by an assessment of inclusion/exclusion criteria during a pre-fitting examination of vision and ocular health. Biomicroscopy evaluation of the anterior ocular segment included grading (0–4 scale) of corneal edema, neovascularization, conjunctival and corneal staining with sodium fluorescein, conjunctival injection, and tarsal abnormalities examined with lid eversion. Participants received a manifest refraction and their Best Corrected Visual Acuity (BCVA) at distance was recorded for each eye. Participants were then fit with the silicone study lenses utilizing a diagnostic fitting set. Participants with a myopic refractive error less than 6.00 diopters were fit with a lens with a + 69 diopter lenslet, and a + 60.00 diopter lenslet was used for participants with greater than 6.00 diopters of myopia. Lens fit was assessed with measurements of lens centration, lens movement in primary gaze, resistance to movement on push-up and rotation, lens extension beyond limbus, lens rotational orientation, and stability of orientation. These lenses did not have refractive correction. Because polarization divides the amount of light passing through each visual pathway, best visual acuity through both the distance and near-display paths was assessed. Best contact lens distance visual acuity was assessed with the study lenses with a sphero-cylindrical over-refraction (SCOR). Participants then wore prototype display eyewear with binocular organic light emitting diode (OLED) displays (15.5 mm × 8.7 mm) placed at the 14.4 mm focal length of the lenslet from each corneal apex (Fig. 1). The display screens were mechanically adjusted to center the displays to match the inter-pupillary distance of each participant. The vertical position of the displays could be adjusted at the bridge of the spectacle frames. For this study, the displays were placed such that the geometric center was in approximate straight ahead gaze for data collection, although they can also be placed above primary gaze in other applications. No over-refraction was used with the spectacles, since the polarized visual pathway to the near eye display passes through the 1 mm diameter central portion of the contact lens which acts as a pinhole, which was expected to negate any cylinder power required in this study population. Since the power of the lenslet was high, any residual spherical power required for focus on the displays could be controlled by adjusting the vertex distance. The screens were used to display a 7 line letter chart with five letters on each line. Letters decreased in size from 40 pixels to 5 pixels in height, which was the limit of the display (approximately 1.90 arc minutes) and allowed for acuity testing to an equivalent of 20/32 Snellen acuity. Participants also viewed portions of commercially produced 3-D videos. Subjective scores of visual performance while wearing the study lenses and spectacle mounted displays were collected using a 0–10 scale, and were assessed verbally with each participant. The ease of obtaining binocular fusion scale was anchored as “Unable” at 0, “With help” at 5; and “Immediate” at 10. Ease of observing 3D while viewing a video was anchored with “Unable” at 0, “Moderate” at 5 and “Profound” at 10. Stability of binocular display vision was subtitled “Remains single and clear” and was anchored with “Unstable” at 0, “Some variation” at 5, and “Stable” at 10. Ease of lens removal by the investigator was reported on a 1 to 10 scale with 10 being extremely easy. After the study lenses were removed, biomicroscopy was repeated using the same assessments graded before lens wear.

4.2. Statistical analysis

Examination data were captured using REDCap (Research Electronic Data Capture), a secure, web-based software platform hosted by The Ohio State University which was designed to support data capture for research studies [14,15]. The mean, standard deviations, and range were calculated for the continuous variables at the baseline and exposure visit for the right, left, and average of both eyes. Frequency and percent were calculated for all categorical variables at the baseline and exposure visit for the right, left, and average of both eyes.

Pairwise comparisons of LogMAR visual acuity, sphere power, cylinder power, and spherical equivalence with the manifest refraction and the sphero-cylindrical over-refraction (SCOR) were analyzed in the right, left, and both eyes with paired t tests.

5. Results

Eleven females and 4 males completed the study with a mean(standard deviation) age of 26.5(6.6) years. All participants were fit with a plano lens with an 8.0 base curve and a lenslet with an outer filter polarization oriented at 180 degrees and inner filter at 90 degrees. All participants wore lenses with the median sagittal depth design; 14 participants wore the + 69 D lenslet power in both eyes, and 1 participant wore lenses with the + 60 D lenslet power in both eyes due to an uncorrected higher myopia refractive error contributing to the required power. The descriptive statistics below include both eyes. Additional data broken down by eye can be found in Table 2. Mean(standard deviation) flat keratometry for both eyes was 44.41(1.13) D. Manifest refraction revealed a distribution of spherical equivalent (SE) power from −1.00 to −6.88 D in both eyes, with a mean SE of −3.12(1.31) D. Mean best corrected LogMAR acuity for both eyes was −0.13(0.08).

Over-refraction of the plano study lenses containing the filter and 1.0 mm diameter high powered lenslet revealed a mean SE of −2.76 (1.25) with a distribution of −0.50 to −6.50 D. Mean best corrected LogMAR acuity with the study lens and over-refraction was −0.03 (0.06).

Pairwise comparisons by student *t*-test found statistically (P less than 0.05) lower (less minus) sphere, cylinder and spherical equivalent power with the SCOR compared to those parameters with the manifest

Table 2
Results for each eye and average results. SD = standard deviation, Min = minimum value, Max = maximum value, SCOR = Spherocylindrical over-refraction, SE = Spherical equivalent.

	OD				OS				Average of OD & OS			
Variable	**Mean**	**SD**	**Min**	**Max**	**Mean**	**SD**	**Min**	**Max**	**Mean**	**SD**	**Min**	**Max**
Manifest Refraction Sphere	−2.93	1.13	−4.75	−1.25	−2.92	1.55	−6.75	−1.00	−2.93	1.33	−6.75	−1.00
Manifest Refraction Cylinder	−0.37	0.47	−1.50	0.00	−0.42	0.52	−1.75	0.00	−0.34	0.49	−1.75	0.00
Manifest Refraction Spherical Equivalent	−3.12	1.09	−4.88	−1.25	−3.13	1.54	−6.88	−1.00	−3.12	1.31	−6.88	−1.00
LogMAR High Contrast Acuity with Manifest Refraction	−0.13	0.07	−0.28	0.0	−0.13	0.09	−0.24	0.06	−0.13	0.08	−0.28	0.06
SCOR Sphere	−2.43	1.03	−4.00	−1.00	−2.47	1.62	−6.50	0.00	−2.45	1.33	−6.50	−0.00
SCOR Cylinder	−0.62	0.49	−1.50	0.00	−0.60	0.51	−1.50	0.00	−0.61	0.49	−1.50	0.00
SCOR Spherical Equivalent	−2.74	0.97	−4.25	−1.00	−2.77	1.51	−6.50	−0.50	−2.76	1.25	−6.50	−0.5
LogMAR High Contrast Acuity with SCOR	−0.03	0.06	−0.12	0.08	−0.04	0.06	−0.12	0.10	−0.03	0.06	−0.12	0.10
Difference in SE power (Manifest Refraction-SCOR)	0.37	0.37	−0.37	1.12	0.36	0.37	−0.38	1.00	0.37	0.36	−0.38	1.12

refraction (P less than 0.05). Mean differences in refractive error were 0.37 D or less when comparing the refractive power differences between the manifest refraction and the sphero-cylindrical over-refraction. Similarly, LogMAR acuity with the SCOR when compared to the acuity with the manifest refraction were statistically significant. Mean LogMAR visual acuity differences with the over-refraction were 0.11 (about 5–6 letters) less in the right eye, and 0.085 (about 4–5 letters) less in the left eye when compared to the acuities with the manifest refraction. Despite the slightly lower acuities, the mean visual acuity for all eyes was equivalent to better than 20/20 vision with the over-refraction and study lenses, with 23 eyes achieving LogMAR acuity of 0.0 (20/20) or better, six eyes achieving vision between 0.02 and 0.08 (better than 20/25), and one eye with 0.1 LogMAR (20/25) acuity.

When viewing the spectacle mounted OLED displays while wearing the study lenses, all participants were able to view a movie in three-dimensions (3D). Scoring of 3D viewing revealed a mean score (standard deviation) of 7.67(1.91) for ease of obtaining fusion; 8.47(1.30) for ease of observing the 3D video content, and 8.27(1.49) for stability of binocular display vision. (Table 3) Vision was assessed monocularly, with 27 eyes correctly identifying all letters, including all five of the smallest line of letters that could be created on the OLED screens (0.20 LogMAR; 20/32 Snellen). Two eyes missed one letter and one eye missed two letters.

The study visits lasted about 2 h. Biomicroscopy before and after study lens wear revealed no edema at either time point. No participants had changes greater than 1 in grading injection before and after lens wear. No participants had corneal staining greater than 2 before and after wearing the study lenses.

Assessment of fit with these diagnostic lenses found 90% (27/30) had movement less than 1.0 mm. Rotation was less than 10 degrees in 97% (29/30) of eyes. On a scale of 1–10 (with 1 indicating no movement/bound and 10 indicating free movement), resistance to movement upon manual pushup and resistance to rotation by the examiner, only 13.3% (4/30 eyes) lenses were scored as "free" as defined by a grade of 6–10. Despite the minimal movement of the lenses relative ease of removal was assessed as Easy (6–10 on a scale of 1–10) for 96.7% (29/30) of eyes.

Table 3
Subjective scores reported for visual performance while wearing study lenses and viewing spectacle mounted LED displays.

	Ease of Obtaining Fusion	**Ease of Observing 3D in video**	**Stability of Binocular Display Vision**
Mean	7.67	8.47	8.27
Standard Deviation	1.91	1.30	1.49
Range	4 – 10	5 – 10	5–10
Median	8	9	9
Interquartile Range	2.5	1	1.5

5.1. Adverse events

No participants removed the lenses due to discomfort or discontinued wear before completion of the study visit and no adverse events occurred in this study.

6. Discussion

The design of the silicone elastomer lens used in this study performed well with the majority of participants rating comfort as good or excellent. The study lenses also demonstrated relative ease of removal. This is likely due to the surface modification and increased thickness of the lens compared to previous silicone elastomer lenses. Since increased thickness of a silicone membrane and application of surface modification are expected to decrease pervaporation, these changes likely prevented the post-lens tear film from passing through the lens and therefore prevented the adherence to the eye associated with previous low-powered silicone elastomer lenses. The ability to fit a non-rigid, highly oxygen permeable lens material on eyes with typical refractive errors suggests this lens may be a candidate for simple contact lens wear, and presents the opportunity for the lens material to be used as an excellent carrier for high technology components to be embedded while maintaining high oxygen transmissibility. The change in mean cylinder when comparing the manifest refraction and the SCOR reveals an increase in cylinder of approximately 0.25 diopters when wearing the lens, possibly created by a small tear lens effect under the lens [16].

The components embedded in the silicone elastomer lens in this study included a two-state wire-grid light polarizing filter. One goal of this study was to determine if the lenslet and the polarizers being used to selectively block and pass ambient and display light would decrease functional visual acuity since light polarization filters and a high powered lenslet have potential to damage the point spread function of the lens-eye optical system. The small change in mean distance visual acuity due to the polarizer in the lens and the high powered lenslet on the anterior surface of the lens was not enough to decrease the mean acuity to worse than 20/20 vision in this study population.

The high mean scores related to viewing in 3D suggest that the combination of the study lenses with the high powered lenslets used in conjunction with the spectacle mounted OLED displays provides an effective way of displaying near visual information binocularly while maintaining fusion and stereoscopic visual performance. In many head-mounted stereoscopic display systems, visual complaints such as eyestrain and headache, and disorientation can occur [17–22]. One reason these can occur is related to asthenopia and binocular issues with the yoked relationship between convergence and accommodation, particularly if the requirements for convergence and accommodation are not congruent [23]. In a virtual reality system, depth is created using disparity between the images, and the resulting convergence induces a "yoked" accommodative response. Accommodation while viewing screens at a fixed distance can then create blur, resulting in a user trying to choose between clear but diplopic images, or a single but blurred

image. In the contact lens and spectacle system used in this study, the polarized light that allows viewing of the spectacle mounted displays is presented through a 1 mm aperture in the contact lens. This aperture not only created the visual path to focus on the displays, but also acts as a pinhole and creates an extended depth of field. This depth of field allows for clear vision as accommodation is induced by convergence. This is likely why the participants in this study did not report symptoms consistent with binocular issues.

Additionally, this direct-view optical system provides wide field of view display images [24]. Waveguide technology in a head mounted display provided at the spectacle plane delivers a field of view that must be relatively narrow, while systems with geometric optics between the eyes and the display can require large or bulky screens in order to achieve a wider view [24]. Using a contact lens and spectacle system in this study gave a wide field of view using the display screen and also allowed for distance viewing with the contact lenses. The monocular field of view of this system with the 0.70 in. diagonal OLD display viewed at 14.4 mm is 63 degrees. A greater binocular field of view is created with less than 100% overlap in the same manner as normal human binocular vision.

There are multiple applications for this system. First responders may receive critical information while having their normal vision unobstructed and their hands free. The system may be used for education, such as a simulation of a procedure; entertainment; or gaming, all of which benefit from 3-D presentations. It can also be utilized for spectator sport applications where a video feed may be viewed by easily changing gaze to a near screen while also having with normal vision of the event. A map and key information may be viewable on the microdisplay while walking through a city. People who are visually impaired may utilize display eyewear with a camera system with image enhancement software including magnification to allow resolution of distant signs without disrupting their functional, although otherwise more narrow view of their surroundings.

The findings of this feasibility study reveal that the study lenses made of silicone elastomer fit patients well and provide an effective platform to carry technology. The lenses in this study, containing two-state wire-grid light-polarizing filters and central lenslets, allow for vision at distance and viewing content presented in spectacle mounted microdisplays. Future studies involving these lenses are expected to reveal additional ways in which this lens material and new digital technologies may enhance visual performance for people having a wide range of visual abilities along with additional testing including contrast sensitivity, display visual acuity; and, visual quality in daily activities and low ambient light conditions along with long duration near eye display use.

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Declaration of Competing Interest

The authorreports consulting for Innovega on a study other than the one reported in this paper.

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