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ORIGINAL ARTICLE

Visual impact of diffusion optic technology lenses for myopia control

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Abstract

Purpose: To assess the visual impact of Diffusion Optics Technology™ 0.2 DOT lenses (SightGlass Vision Inc.) designed for myopia control on primary gaze. DOT spectacle lenses contain light scattering elements that scatter light as it passes through the lens which, in turn, reduces retinal image contrast.

Methods: Fifty-one children (12.2 ± 1.3, range 10–14 years; 51% females) were randomly assigned to wear DOT spectacle ($n=27$) or single vision lenses ($n=24$) across six investigational sites in North America. Binocular high- and low-contrast distant visual acuities, near visual acuity, reading speed, contrast sensitivity, stereoacuity and glare were assessed in primary gaze after at least 3 years of wear, with the study 95% powered in all metrics to detect significant differences between the groups.

Results: Mean binocular distance high-contrast (−0.09 ± 0.02 vs. −0.08 ± 0.02 logMAR, $p=0.81$), low-contrast (0.05 ± 0.02 vs. 0.07 ± 0.02 logMAR, $p=0.52$) and near visual acuity with glare sources (−0.06 ± 0.03 vs. −0.09 ± 0.03 logMAR, $p=0.32$) were similar for DOT and single vision lens wearers, respectively. Contrast sensitivity was similar between children wearing DOT or single vision lenses across 11 of the 16 spatial frequencies ($p>0.05$). Mean stereopsis was similar ($p=0.30$) with the DOT lenses (33.2 ± 12.5″) and single vision lenses (38.1 ± 14.2″). Functional reading speed metrics were similar in both study groups, as was the objectively measured head tilt during reading ($p>0.05$). The mean halo radius was 0.56° ± 0.17° with the DOT lenses compared with 0.50° ± 0.12° with single vision lenses ($p=0.02$), but the statistically significant difference was smaller than the non-inferiority bound of 0.4°.

Conclusion: Diffusion optics technology lenses provide a clinically equivalent visual experience to a standard single vision lens.

KEYWORDS
binocular vision, contrast sensitivity, diffusion optics technology, myopia control, myopia management, reading speed, visual function

INTRODUCTION

Myopia is a significant public health issue that affects an estimated 2.6 billion people worldwide: 34% of the global population. The prevalence is expected to increase to 50% by 2050, including nearly 1 billion individuals projected to have high myopia (worse than −5.00 D). These projections are of particular concern given the association between high myopia and an increased risk of visual impairment, including blindness.[1,2]

Myopia control spectacles have been marketed since 2020 and were reported to have accounted for 15% of all myopia management prescribing by 2022.[3] These lenses incorporate peripheral lenslets/optical segments or diffusive optics in the periphery to alter the light profile entering the eye. While this is aimed at reducing the stimulus for the eye to elongate, they have the potential to impact visual function. Previously, visual function (high- and low-contrast visual acuity and heterophoria at distance and near, amplitude and near lag of accommodation along with stereopsis, before, during and after 2 years of spectacle wear) has been assessed with defocus incorporated multiple segment (DIMS) lenses, finding no differences compared to a matched group wearing single vision spectacles.[4] Visual function in the form of distant and near visual acuity at high and low contrast in photopic and scotopic conditions, near heterophoria, stereoacuity, accommodative lag, amplitude and microfluctuations have been assessed after wearing highly aspheric lenslet (HAL) lenses for 10 min, 6 months and 12 months; stereoacuity, scotopic and low-contrast visual acuity were reduced on initial wear compared with children wearing single vision spectacles, but recovered by 12 months, whereas microfluctuations of accommodation were consistently higher,[5] which have been reported to be associated with visual fatigue.[6] Another study evaluating peripheral defocus lenses found that low-contrast visual acuity and reading were slightly reduced, whereas high-contrast visual acuity and the useful field of view were unaffected when fixating through the periphery of the novel lens designs.[7]

Diffusion Optics Technology™ 0.2 (DOT) spectacle lenses (SightGlass Vision Inc., sightglassvision.com) have been shown to be effective in reducing the progression of myopia in children and clinical trials are ongoing to monitor the long-term effectiveness of these lenses.[8] Previous studies have found good high-contrast visual acuity with the DOT lenses. However, more information is required on other aspects of their visual performance, for instance, their effect on reading speed, halos and vision in the presence of glare. DOT spectacle lenses contain light scattering elements that scatter light as it passes through the lens, which, in turn, reduces retinal image contrast. Similar to all novel myopia management spectacle lens designs, it is possible that peripheral light rays passing through the treatment zone may impact central vision. Furthermore, convergence during near tasks may cause the visual axis to pass through the treatment zone, such that tasks such as reading may be affected. The purpose of this study was to evaluate the effect of DOT spectacle lenses on various aspects of visual performance that wearers will encounter during daily activities.

Key points

- Myopia control spectacles with diffusion optics technology have been shown to slow the progression of myopia effectively, but it is important to understand their visual impact.
- This study assessed the difference between children adapted for at least 3 years to diffusion optics technology to a matched group wearing single vision lenses.
- Diffusion optics technology myopia control lenses were shown to provide a clinically equivalent visual experience to single vision lenses, making wearing them unlikely to affect a child's daily activities adversely.

METHODS

Participants (aged 10–14 years old) were existing active participants in the CYPRESS Extension (CPRO-1802-002) study (clinical trial registration NCT04947735) and had been randomised and adapted to DOT 0.2 ($n=27$) or single vision ($n=24$) control spectacle lens wear for at least 3 years from across all sites. The optical centre of each lens was aligned to the wearer's pupils. Each of the six North American-based sites (Pittsburg, Kansas; Raytown, Missouri; Salt Lake City, Utah; New York, New York; Longwood, Florida and Houston, Texas) was asked to enrol a similar number of test and control participants (±1) so as to maintain balanced participant groups.

This clinical study was designed in conformance with the ethical principles in the Declaration of Helsinki and conducted in line with the International Council for Harmonisation (ICH) guidelines for Good Clinical Practice. Favourable review was received from a research ethics committee and informed consent was received from a parent/guardian, as well as assent from the child, prior to enrolment in the study. It was confirmed using slit-lamp biomicroscopy that participants did not have any current ocular infection, inflammation or irritation likely to affect their vision.

Subjective sphero-cylindrical refraction was conducted with a phoropter or trial frame and lenses and monocular high-contrast distant visual acuity was measured. If the manifest spherical equivalent refraction differed by ≥0.50 D from the current study spectacles, replacements were ordered so that the study was conducted with an up-to-date prescription. Testing was conducted in primary gaze, principally through the optical centre of the lenses (and 5 mm clear zone of the DOT lenses) for distant tasks.

All measurements were taken at a single visit. Tests were selected based on the typical assessment battery for visual function and to examine the potential effects of diffusion optics on contrast sensitivity and glare. Binocular distant (4 m) high- (90%) and low- (10%) contrast visual acuities were assessed on a Precision Vision (precision-vision.com) Sloan (ETDRS style) logMAR chart with participant guessing encouraged and scored by each letter read (at −0.02 logMAR) with a three incorrect letter stopping criteria. Room luminance was around 300 lux or 60 cd/m^2 and the distant chart was 85–120 cd/m^2. Binocular near visual acuity (at 40 cm) was assessed with the same criteria on an Apple iPad tablet computer (apple.com) with side glare strip light sources (115,000 cd/m^2 at an angle of ±12.3°). Contrast sensitivity was assessed across all spatial frequencies with the Aston Contrast Sensitivity near test.[9] Participants traced their finger where sinusoidal bars of increasing spatial frequency (varying horizontal) and contrast (varying vertically) were just visible on the iPad at 40 cm in landscape orientation; this was repeated three times and the average values taken. Stereoacuity was measured as an exploratory test using the Random Dot 3 LEA SYMBOLS® Stereoacuity Test (stereoptical.com). Reading speed was measured on a digital Radner chart displayed on a text-size-calibrated iPad, with the suprathreshold maximum and mean words per minute reading speed, critical print size and near acuity values calculated.[10] The inbuilt camera used artificial-intelligence-derived facial feature recognition software, allowing participant distance from the screen, head tilt (pitch, roll and yaw) to be monitored objectively. Glare obscuration was assessed with a halometer (Wolffsohn Research Ltd, wolffsohnresearch.com) located at a distance of 2 m, in eight orientations with a 0.30 logMAR target moved from behind a white light emitting diode (20,000 cd/m^2) in 0.1° steps until it was identified correctly two out of three times[11]; the results were plotted on a polar plot.

Statistical analysis

Descriptive summaries included mean, standard deviation, median and range for continuous variables and counts and percentages for categorical variables. Two-sided 95% confidence intervals (CIs) were calculated for the means and percentages. The difference between the test and the control was computed, as was the 95% CI of the difference. All statistical analyses were performed using SAS® (Version 9.4, sas.com).

The primary objective of this study was to compare the maximum reading speed between the test and control groups for non-inferiority. If non-inferiority was met, then the secondary hypotheses regarding mean halo radius were tested. Other key variables were analysed for exploratory purposes. This gatekeeping approach was used to test each hypothesis with $\alpha = 0.05$. The statistical analysis plan was set a priori.

A mixed effect model including the following terms was used to analyse the difference in key variables between treatment arms: treatment, age and sex as fixed factors; and site and subject were included as random effects. From the model, estimates of the means, standard error and 95% confidence interval have been provided. The difference in least-squared means between the test and the control groups and the corresponding 95% CI were also derived from the model. For the hypothesis of the test lens being non-inferior to the control lens to have been met, the CIs were compared to the non-inferiority bounds given below. The lens types were considered similar if non-inferiority was demonstrated. Also, the *p*-values for testing the pairwise differences in least-squared means against a zero value were computed based on *t*-tests.

Non-inferiority margins and detection sensitivity with 95% power given a minimum sample size of $n = 24$ (G*Power v3.1.9.6, psychologie.hhu.de/arbeitsgruppen/allgemeine-psychologie-und-arbeitspsychologie/gpower) was determined based on published literatures:

- Visual Acuity: 0.10 logMAR[12]; 0.05 logMAR difference detectable.
- Near Visual Acuity with Glare: 0.10 log MAR[12]; 0.05 logMAR difference detectable.
- Contrast sensitivity function (CSF): 0.20 log unit[13]; 0.1 log unit difference detectable.
- Maximum reading speed: 30 words per minute (wpm)[10]; 15 wpm difference detectable.
- Mean halo radius: 0.4°[14]; 0.2° difference detectable.

Multiple comparisons were conducted for the CSF (spatial frequencies) and halo size (orientations), so an area or average metric was derived and analysed to confirm significance with a single metric.

RESULTS

Participant demographics

Of the 51 participants, 51% were females. The mean age of the participants at baseline was 12.2 years (SD ± 1.3), and the age range was 10–14 years (Table 1). The largest racial group was White (65%) followed by Black/African American (29%). The test and control groups were similar for age, sex distribution and race ($p > 0.05$). As expected, the axial length and cycloplegic SER were lower for the test than the control group.

Visual acuity

Mean binocular high-contrast distant visual acuity (least-square ± standard deviation −0.09 ± 0.02 vs. −0.08 ± 0.02 logMAR, $p = 0.81$), low-contrast visual acuity (0.05 ± 0.02 vs. 0.07 ± 0.02 logMAR, $p = 0.52$) and near visual acuity with glare sources (−0.06 ± 0.03 vs. −0.09 ± 0.03 logMAR, $p = 0.32$) were similar for the DOT and single vision lens wearers, respectively (Figure 1).

Near contrast sensitivity (CS)

No significant differences were observed between the DOT lens and single vision lens wearers with respect to any of the spatial frequencies tested ($p > 0.05$). Most of the 95% confidence intervals of the differences were >0.2 logCS non-inferiority bound (Figure 2); non-inferiority was met with respect to the control lens in 11 of the 16 cycles per degree (cpd) values. The mean area under the contrast

TABLE 1 Demographics and baseline characteristics of participants.

Variable		Total	DOT lenses	Single vision lenses
No. of participants		51	27	24
Age in years, n (%)	10	7 (13.7)	4 (14.8)	3 (12.5)
	11	7 (13.7)	3 (11.1)	4 (16.7)
	12	12 (23.5)	5 (18.5)	7 (29.2)
	13	17 (33.3)	10 (37.0)	7 (29.2)
	14	8 (15.7)	5 (18.5)	3 (12.5)
	Mean (SD)	12.2 (1.27)	12.3 (1.33)	12.1 (1.23)
Sex, *n* (%)	Male	25 (49.0)	14 (51.9)	11 (45.8)
	Female	26 (51.0)	13 (48.1)	13 (54.2)
Race[a], *n* (%)	White	33 (64.7)	15 (55.6)	18 (75.0)
	Black or African American	15 (29.4)	8 (29.6)	7 (29.2)
	American Indian or Alaska Native	2 (3.9)	1 (3.7)	1 (4.2)
	Asian Indian	2 (3.9)	1 (3.7)	1 (4.2)
	Chinese	3 (5.9)	1 (3.7)	2 (8.3)
	Other Asian	3 (5.9)	3 (11.1)	0 (0)
	Japanese	1 (2.0)	0 (0)	1 (4.2)
Axial length (mm)	Mean (SD)	24.81 (0.865)	24.74 (0.861)	24.88 (0.882)
	Range	23.10 to 26.62	23.10 to 26.62	23.19 to 26.47
Cycloplegic SER (D)	Mean (SD)	−3.13 (1.819)	−2.83 (1.858)	−3.46 (1.752)
	Range	−7.81 to −0.08	−7.66 to −0.08	−7.81 to −0.82

Abbreviations: DOT, Diffusion Optic Technology lenses (SightGlass Vision Inc.); SER, spherical equivalent refraction.

[a]Proportion may not sum to 100% as some participants selected more than one race.

sensitivity function was similar ($p=0.30$) between the DOT (4.68 ± 0.66) and single vision lenses (4.42 ± 1.07).

Stereopsis

Mean stereopsis was similar ($p=0.30$) between the DOT lenses ($33.2\pm12.5''$) and single vision lenses ($38.1\pm14.2''$).

Functional reading and head movements

Maximum reading speeds were similar ($p=0.91$), being 201 ± 41 (range: 126–296) words per minute with the DOT lenses and 200 ± 42 (range: 106–297) words per minute with the single vision lenses (Figure 3). Mean reading speed (159 ± 36 vs. 149 ± 29 words per minute, $p=0.34$; Figure 3), critical print size (0.03 ± 0.13 vs. 0.05 ± 0.11, $p=0.53$) and minimum reading acuity text size (-0.02 ± 0.10 vs. -0.02 ± 0.11, $p=0.89$) were also similar between the DOT and single vision lens wearers, respectively.

There were no significant differences between DOT and single vision lens wearers with respect to yaw (looking left or right; mean 0.02 ± 0.02 vs. 0.04 ± 0.03, $p=0.28$; SD 0.03 ± 0.00 vs. 0.03 ± 0.00, $p=0.20$; range 0.26 ± 0.03 vs. 0.20 ± 0.03, $p=0.16$), pitch (chin in or up; mean 0.17 ± 0.04 vs. 0.19 ± 0.04, $p=0.73$; SD 0.05 ± 0.01 vs. 0.06 ± 0.01, $p=0.52$; range 0.37 ± 0.03 vs. 0.38 ± 0.03, $p=0.73$) or roll (moving ear towards shoulder; mean -0.09 ± 0.04 vs. -0.08 ± 0.04, $p=0.88$; SD 0.06 ± 0.01 vs. 0.06 ± 0.01, $p=0.85$; range 0.51 ± 0.08 vs. 0.42 ± 0.09, $p=0.38$).

Halometry

The mean halo (glare scotoma) radius was $0.56°\pm0.17°$ with the DOT lenses compared with $0.50°\pm0.12°$ with the single vision lenses (difference $-0.07°$; 95% CI: 0.02–0.13, $p=0.02$; Figure 4). While the DOT lenses showed a significantly larger average halo radius than the single vision lenses, this difference was smaller than the non-inferiority bound of 0.4°.

DISCUSSION

The purpose of this study was to evaluate various aspects of visual performance of the DOT lenses, compared with single vision spectacle lenses. The endpoints assessed were visual acuity, contrast sensitivity, reading speed, glare and stereopsis. The tasks were performed in primary gaze, but despite the 5 mm diameter clear zone in the DOT lens design, some peripheral light rays passing through the DOT zone will enter the pupil, convergence during near tasks will affect the visual axis and tasks such as reading

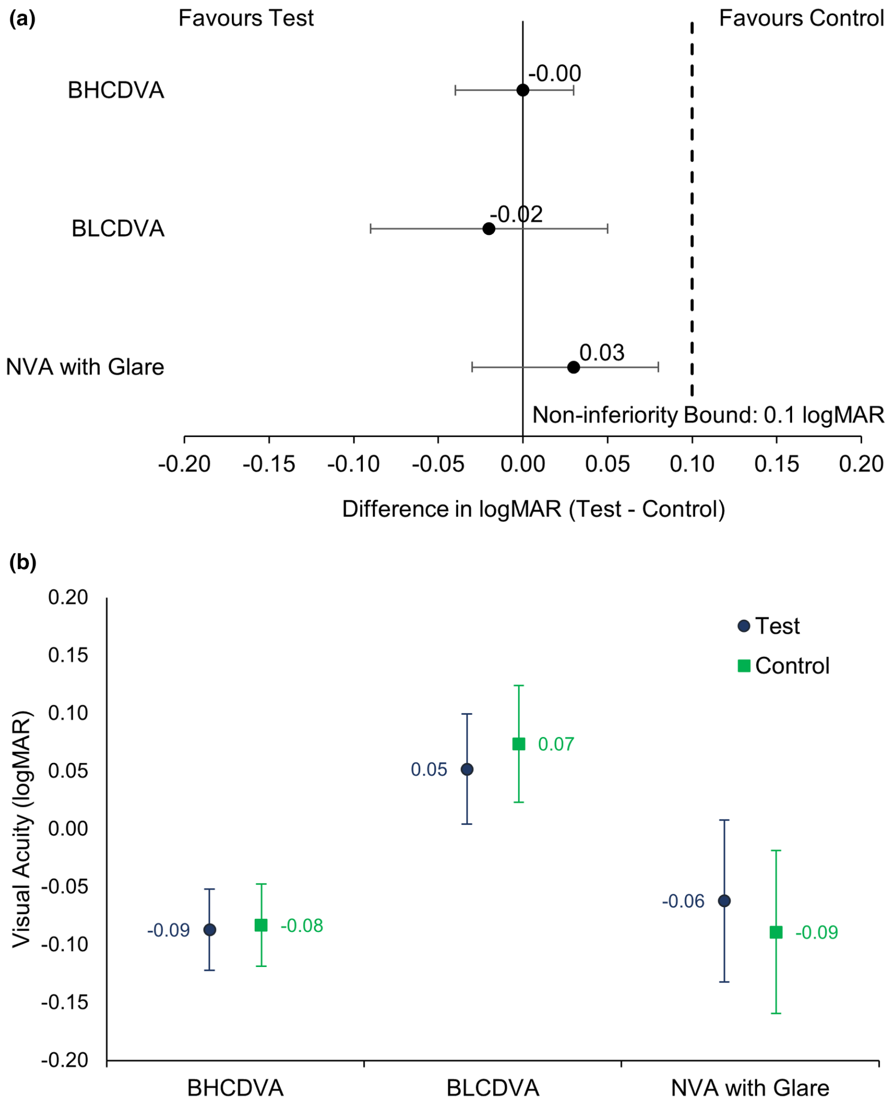

FIGURE 1 (a) Mean visual acuity. Error bars indicate 1 standard deviation (vertical dashed line indicates inferiority margin). (b) Least-square mean differences of visual acuity. Error bars indicate 95% confidence intervals of differences. BHCDVA, binocular high-contrast distance visual acuity; BLCDVA, binocular low-contrast distance visual acuity; NVA, near visual acuity.

could be affected due to line scanning. Unlike studies of other myopia control lenses,[4,5,7] the effect of glare on both acuity and its veiling extent was assessed alongside reading metrics, which are a better measure of visual function than visual acuity alone.[15] As the DOT lens aims to slow myopic progression by reducing peripheral contrast,[16] a more comprehensive evaluation of contrast sensitivity was also conducted compared with other studies.[9]

The non-inferiority of reading metrics (speed, critical print size and threshold) near visual acuity with the DOT lens provides reassurance that the children's reading abilities and, therefore, educational development is unlikely to be compromised by using the DOT lenses. The mean reading speed measured here with either DOT or single vision lenses was a little faster than a cohort of 16 year olds assessed with a paper version of the Radner test.[17] Of note, the objectively assessed head movements of the children were no different between those wearing the DOT lenses and those wearing single vision lenses, demonstrating that aligning the visual axis with the central aperture in the lens was not critical to functional reading. This also provides reassurance that the children are unlikely to suffer musculoskeletal issues due to a need for abnormal head positioning when wearing the DOT lenses.

The fact that the test lenses gave a slightly larger halo image was not unexpected, given the peripheral light scattering properties of the DOT lens, even when observing through the central clear zone. However, since the difference was small and less than the inferiority bound, this indicates that any difference is clinically insignificant. This was confirmed when a different aspect of glare impact was evaluated by measuring visual acuity at a normal reading distance in the presence of twin glare sources, as there was no significant difference between groups.

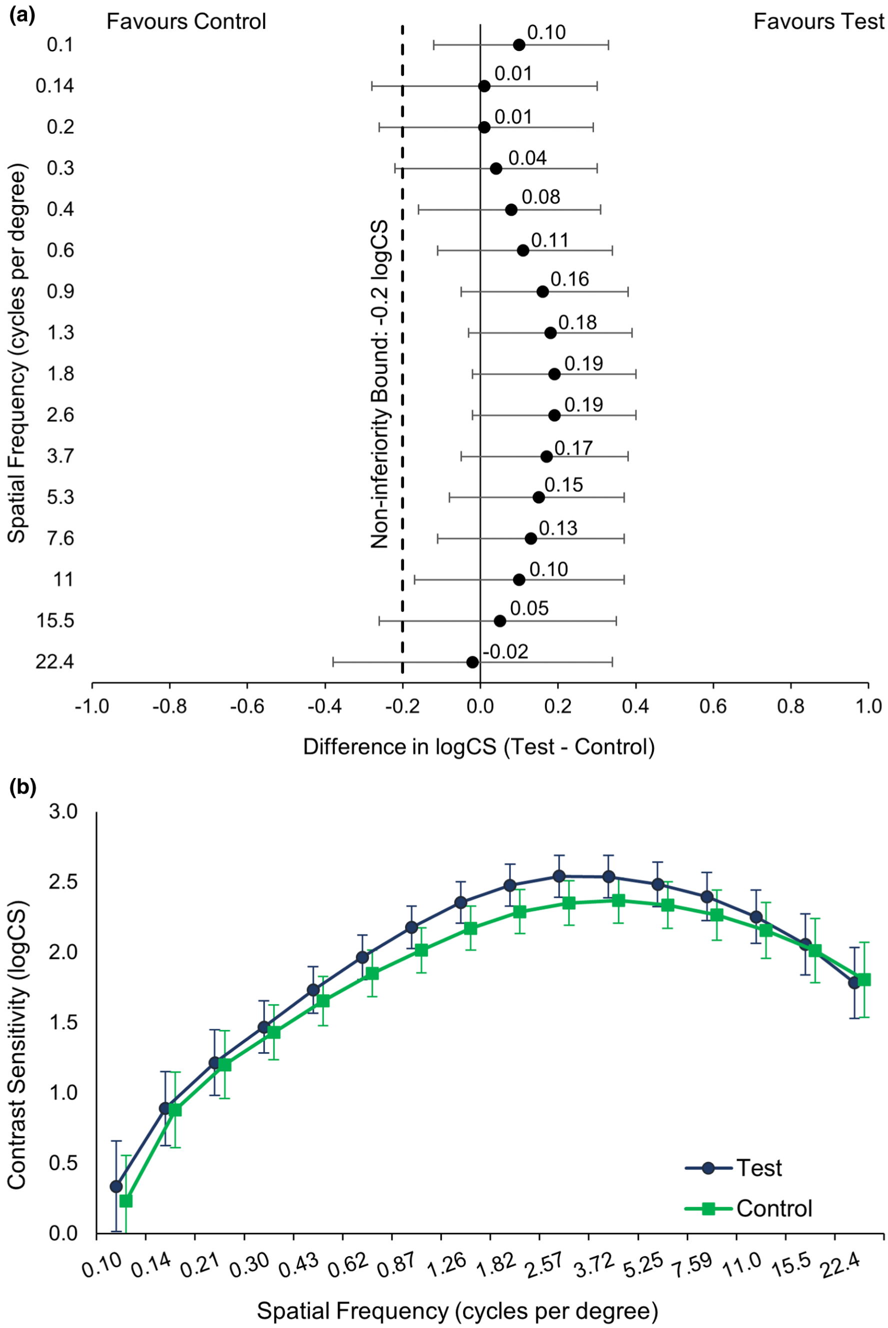

FIGURE 2 Least-square mean differences (a) and estimates (b) of near contrast sensitivity (CS). Error bars indicate 95% confidence intervals.

High- and low-contrast distant visual acuities with the test lenses were good and, on average, similar to the control group. Mean binocular high-contrast visual acuity with both lens types was nearly one line better than 0.00 logMAR (6/6). These findings are consistent with those of the CYPRESS study, which also noted similar mean visual acuities between the DOT 0.2 and control lenses.[8] This was also comparable with that reported using myopia control lenses that aim to introduce myopic defocus through annual zones or multiple segments[4,5] rather than peripheral contrast reduction.

Further, the contrast sensitivity functions for the two groups were similar in primary gaze. Since the DOT lens' treatment zone is designed to reduce peripheral image contrast, one might have expected a possible reduction in contrast sensitivity due to the large pupil sizes in children, some peripheral light rays passing through the DOT zone entering the pupil and convergence during near tasks. The DOT lens design has a central clear aperture of only 5 mm and, therefore, even when looking ahead through a lens perfectly positioned on the visual axis, peripheral rays entering the pupil will have their

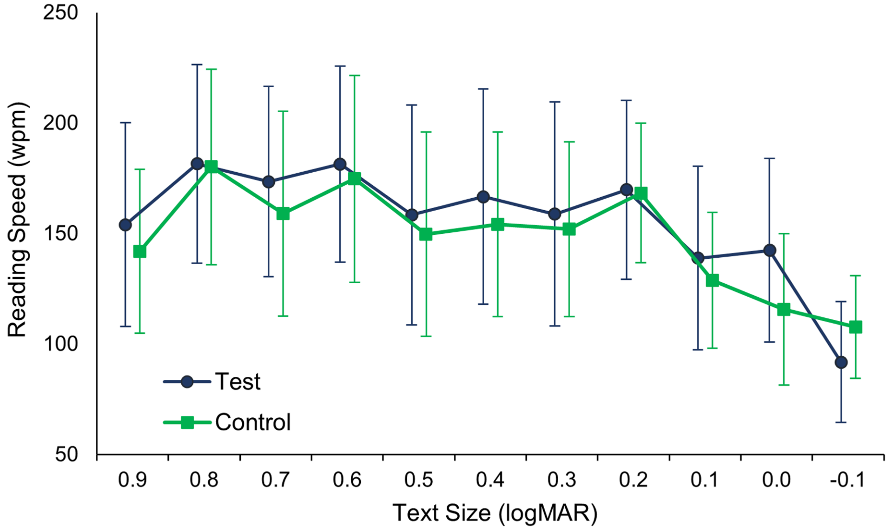

FIGURE 3 Mean reading speed in words per minute (wpm) by text size. Error bars indicate 1 SD.

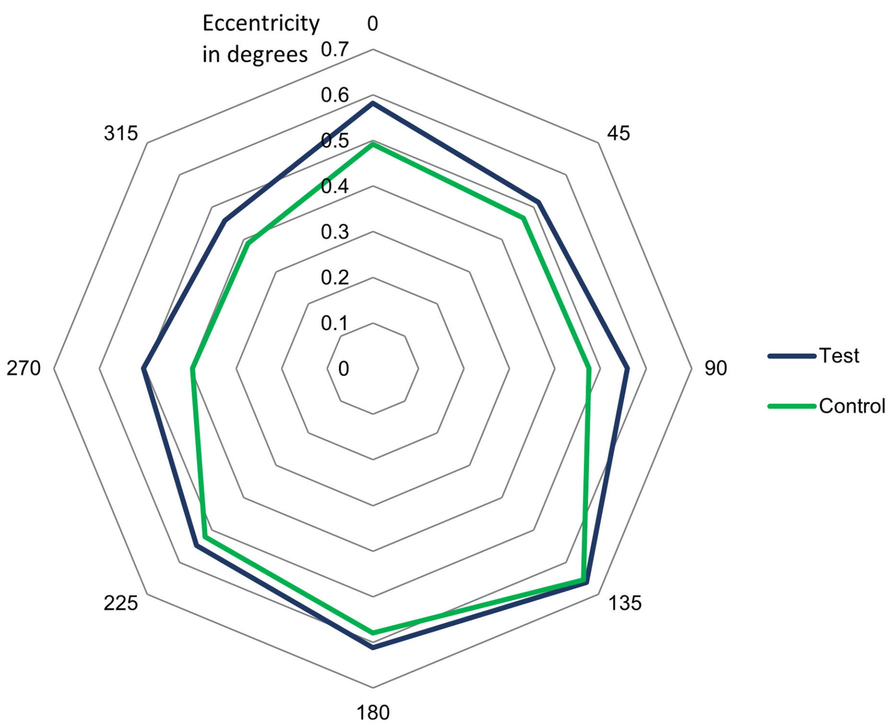

FIGURE 4 Radar plot of mean halo radius.

contrast attenuated. Nonetheless, these results compare well with a recent short-term crossover study that reported equivalent contrast sensitivity between DOT and single vision lenses when viewing through the central and the peripheral lens zones.[18] Interestingly, there was a non-significant trend for better contrast sensitivity with the DOT compared with the single vision lenses for mid-spatial frequencies (0.4–11 cycles per degree). It could be speculated that adaptation to a reduction of contrast sensitivity in the retinal periphery enhanced detection across the peak spatial frequencies encountered in central vision,[19] but further studies would be required to confirm this effect. Binocular visual function, assessed through stereopsis, was similar to that achieved through single vision lenses. Hence, visual function with the DOT lenses seems similar to, or better than, other myopia-control lenses (Table 2).[4,5,7]

A limitation of the study is the parallel-group, as opposed to crossover, design. However, given the necessity for visual adaptation,[5] a crossover design would not have been feasible. The paired design used in this study paralleled the approach of the long-term CYPRESS study and

TABLE 2 Comparison of studies assessing visual function through myopia control spectacle designs compared with single vision spectacles. ⇩ = reduction; ⇔ indicates the difference was not statistically different.

	Lam et al.[4]	Huang et al.[5]	Gao et al.[7]	Present study
Design	Defocus Incorporated Multiple Segment (DIMS)	Highly (HAL) and slightly aspherical lenslets (SAL)		Diffusion Optics Technology (DOT)
Participants	*n* = 79 vs. 81 10.1 ± 1.5 years	*n* = 54 vs. 55 vs. 52 10.4 ± 1.2 years	*n* = 8–10 adults 28.9 ± 8.6 years	*n* = 27 vs. 24 12.2 ± 1.3 years
Duration of wear	2 years	Up to 1 year	Immediate	At least 3 years
Visual acuity				
High-contrast distance	⇔	⇔	⇔ through lens periphery	⇔
Low-contrast distance	⇔	⇩ @6 months	⇩ through lens periphery	⇔
Scotopic		⇩ @6 months		
Near		⇔		⇔ with glare
Reading metrics			⇩ through lens periphery	⇔
Contrast sensitivity				⇔
Heterophoria	⇔	⇔		
Accommodation				
Near lag	⇔	⇔		
Amplitude		⇔		
Microfluctuations		⇧		
Stereopsis	⇔	⇩ @6 months		⇔
Glare				⇔
Perceptual motion			⇔	
Useful field of view			⇔	

ensured that all participants were adapted to their study lenses. It also only evaluated the impact of the lens design in primary gaze, which may not reflect vision experienced in the real world, although the reading task indicated that more realistic visual function was still similar to that experienced when wearing single vision spectacles. There was also a limited amount of ethnic diversity across participants, but this would not be expected to affect the comparison.

In conclusion, a diverse range of vision assessments has been undertaken in this study and, overall, indicated good visual performance with the SightGlass Vision DOT spectacle lens and non-inferiority to single vision spectacles. Overall, DOT lenses did not compromise reading metrics (speed, critical print size and near visual acuity), maintained normal head posture and contrast sensitivities, and demonstrated excellent high- and low-contrast visual acuities, stereopsis and an acceptable level of haloes.

AUTHOR CONTRIBUTIONS

James S. Wolffsohn: Conceptualization (equal); data curation (equal); formal analysis (equal); software (equal); writing – original draft (equal). **Jennifer S. Hill:** Conceptualization (equal); data curation (equal); writing – review and editing (equal). **Chris Hunt:** Data curation (equal); formal analysis (equal); methodology (equal); validation (equal); writing – review and editing (equal). **Graeme Young:** Conceptualization (equal); funding acquisition (equal); methodology (equal); project administration (equal); writing – review and editing (equal).

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CONFLICT OF INTEREST STATEMENT

JSH is an employee of the funder, SightGlass Vision. Funding was received from SightGlass Vision to conduct the study.

DATA AVAILABILITY STATEMENT

The data presented in this study are available on request from the corresponding author and with permission of the funder.

PATIENT CONSENT

Informed consent was obtained from all subjects involved in the study.

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