CLINICAL TRIAL REPORT

Evaluation of Lag of Accommodation with Full-Field Diffusion Optics Technology™ (DOT) Contrast Management Spectacle Lenses in Emmetropic Children

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Purpose: To evaluate the impact on the lag of accommodation (LOA) in emmetropic children after short-term wear of full-field Diffusion Optics Technology™ (DOT) spectacle lenses, designed to modulate retinal contrast to control myopia progression.

Patients and Methods: This was a single-visit, prospective, randomized, subject-masked study of emmetropes (ametropes ±1.00D or less in each meridian) with no history of myopia control treatment. Unaided logMAR visual acuity was measured, and ocular dominance was determined using the sighting method. In a randomized order, participants wore plano full-field contrast management (DOT) spectacles (no clear central aperture) or control spectacles (standard single vision spectacle lenses). Each participant was given 5 minutes for adaptation to the respective lenses before open field autorefraction measurements were taken at 6 meters and 40 cm. Ten measurements were taken for each eye. Data were evaluated from the right eye and the dominant eye separately.

Results: A total of 30 participants (20 females and 10 males) with a mean age of 10.4 ± 2.8 (7 to 17) years completed the study. There was no significant difference in right eye mean LOA with contrast management spectacles 0.57 ± 0.39D versus control spectacles 0.62 ± 0.34D; Wilcoxon test, p = 0.37. For dominant eyes, LOA values were 0.60 ± 0.40D and 0.68 ± 0.33D with contrast management spectacles and control spectacles, respectively (p = 0.14). Additionally, no significant difference was observed in mean LOA between males and females or between age groups (7–11 years vs 12–17 years) for either right or dominant eyes with contrast management or control spectacles (all p > 0.05).

Conclusion: Full-field contrast management spectacle lenses had no significant effect on LOA compared to standard single vision spectacle lenses, indicating no differential impact on accommodative response over the short period of lens wear tested.

Keywords: myopia, children, accommodation, contrast, spectacles, Diffusion Optics Technology, DOT, contrast management optics

Introduction

Understanding the drivers of myopia onset and progression is essential to developing appropriate tools to prevent and/or control it – whether by optical, physical or pharmaceutical means. Accommodation, and specifically lag of accommodation (LOA) has been identified as a potential influence in both the onset and progression of myopia, though the literature is full of contradictions, as summarized in the paper on accommodation by the International Myopia Institute (IMI).[1] Several studies have shown higher LOA in myopic children compared to emmetropic children, as well as in those showing faster rates of myopia progression.[2–7] The concern is that the hyperopic retinal defocus associated with higher LOA may drive axial elongation of the eye, resulting in myopia and/or myopia progression.[3,8] Other studies suggested that degradation of the retinal image contrast may instead be the trigger.[9,10] In either case, not all studies support the association of LOA and either onset or progression of myopia,[11,12] though the interaction between contrast, accommodation and myopia is complicated. A drastic reduction in contrast results in form deprivation myopia, though ambient

illumination has been shown to be an important additional factor in modulating the degree of form deprivation myopia, with a hyperopic shift seen with higher daylight levels of illumination.[13,14] A less severe but still significant reduction in image contrast creates an effectively stimulus-free condition, where accommodation drifts to what has been referred to as the "tonic" level, of around 1 diopter of accommodation,[15] which is at the high end of the range of normal LOA for children.[16–20] Other studies have demonstrated that lower levels of contrast reduction have been shown to have little to no effect on accommodation.[21–23]

In terms of optical treatments for myopia, most efforts have been around designing contact lenses and spectacles that optically reduce or eliminate hyperopic defocus in the periphery, regardless of its cause. These include dual focus,[24] extended depth-of-focus,[25] center distance[26] and orthokeratology contact lenses,[27] as well as Highly Aspherical Lenslets (HAL),[28] Defocus Incorporated Multiple Segments (DIMS),[29] Peripheral Hyperopia Reduction Lens,[30] executive bifocals,[31] and Progressive Addition Lens (PAL) spectacle designs.[12] A novel concept recently introduced utilizes contrast management to reduce retinal signals that have been associated with an extension of axial length in high myopia.[32,33] This hypothesis arose from studying genetic sequencing in high myopes, where genetic mutations that changed the functionality of the long-(L) and middle-wavelength (M) cones were associated with high levels of myopia.[34] Basically, the mutation caused adjacent cones with differing amounts of functional photopigments to signal the presence of contrast, even when there was no contrast in the image. The theory maintains that the natural outdoor environment provides a low natural contrast visual experience that elicits a low-level of activity in the bipolar cells of the retina. Subjecting humans to long exposures to high artificial contrast environments such as that encountered in urban settings and when reading books and utilizing digital devices, along with insufficient time outdoors, can cause an overstimulation of bipolar cells in the retina, leading to axial elongation.[34,35]

Based on the contrast management hypothesis, SightGlass Vision (Los Altos, California, USA) developed Diffusion Optics Technology (DOT) spectacle lenses, designed to reduce and modulate the retinal contrast to decrease the signal for eye elongation. The lenses correct the refractive error and are combined with a proprietary pattern of thousands of microscopic dots to slightly lower contrast by softly scattering the light which passes through the lens, thereby modulating the contrast throughout the treatment zone of the lenses. The contrast management results in reduced signaling disparities between adjacent cones, while maintaining good visual acuity and functional peripheral vision. The commercially available lenses incorporate a 5-mm central aperture to assist in lens power verification and is positioned centered at the intermediate pupillary distance (PD) of each wearer so that near and far viewing will be primarily through the area of the lens with reduced contrast.[32,33,35,36] Two-year results from an ongoing study showed promising results in reducing the rate of myopia progression.[37] Contrast management spectacle lenses are designed to reduce the retinal image contrast, which had been theorized to impact myopia onset and/or progression.[9,10] However, there is currently no existing literature on how the contrast reducing pattern might impact the LOA.

Therefore, this study aimed to evaluate the influence of full-field DOT spectacle lenses on LOA. The hypothesis was that there would be no impact of DOT spectacles on accommodative response or accuracy when compared to control single vision spectacles. The full-field DOT spectacle lenses were used in this study rather than the commercially available DOT spectacle lenses with 5mm. Since the study aimed to test the effect of contrast reducing pattern on LOA, full-field DOT spectacles lenses were used. These lenses lacked the distinct clear central zone which is present in the commercially available DOT spectacles.

Materials and Methods
Study Design
This study was conducted in accordance with the Declaration of Helsinki and the University of Waterloo Guidelines for Research with Human Participants. Ethics clearance was obtained through the University of Waterloo Research Ethics Board (# 44567). An assent form was completed by all participants and the informed consent signed by parents/guardians prior to enrollment in the study. This study was registered with ClinicalTrials.gov (clinical trial identifier NCT05617794).

This was a prospective, randomized and subject-masked, pilot study involving 30 participants. The participants were enrolled in the study based on the following inclusion criteria (main criteria only): Age 6 to 18 years (inclusive);

emmetropic by non-cycloplegic auto-refraction (both principal meridians ±1.00 Diopters inclusive). Participants were excluded if they had any history of myopia control treatment in the past year, any active ocular disease or infection, any binocular vision disorders such as amblyopia and accommodative insufficiency or any systemic condition that may affect the study outcome variables (including diabetes mellitus and hyperthyroidism), any use of systemic or topical medication that may affect the study outcome variables including atropine eye drops or previous strabismus, refractive error or intraocular surgery. Participants were recruited from the clinical research site's volunteer database and from the community using marketing materials approved by the University of Waterloo Research Ethics Board. This study was conducted at the Centre for Ocular Research and Education (CORE), at the School of Optometry and Vision Science, University of Waterloo, Canada.

This was a single-visit study including the screening. At screening, participant eligibility was determined, and the following measurements taken: High contrast logMAR visual acuity at 6-meters, non-cycloplegic autorefraction and keratometry using a WAM 5500 open-field autorefractor (Grand Seiko, Fukuyama, Japan) at 6 meters, and ocular dominance assessed using the sighting method. Following the screening, eligible participants wore the study spectacles in randomized order. The lenses were fitted in the spectacle frame and all spectacle lenses were made from Trivex material and had no optical power. The contrast management spectacle lens pair (DOT) consisted of light scattering dots 0.14 ±0.03 mm in size applied uniformly over the entire lens surface. Unlike the commercially available product, the test lens used in this study did not have a clear central 5-mm aperture to ensure the subjects were looking through the contrast modulated design. The control spectacle lens pair used standard single-vision lenses with plano power.

Measurement of Lag of Accommodation

The participants were given 5 minutes of adaptation time, where the participants were asked to look at their surroundings while wearing each study spectacle design before conducting a distance target autorefraction at 6 meters and near target autorefraction at 40 cm. According to the literature, 40 cm is considered as a standard viewing distance and at this distance accommodation is expected to have a minimal influence.[38,39] To test the LOA, the participant was asked to focus at the 20/50 line on the near VA chart provided with the WAM 5500 held at 40 cm by a bar holder. Ten measurements were taken for each eye separately (right eye first, left eye second) and both eyes were uncovered while taking the measurements. These measurements were taken while the participants were wearing study spectacles. The average of these 10 measurements was used to calculate the LOA.

The participants were given 10 minutes of washout time between each type of spectacle wear. The instrument was calibrated before each participant. The accommodative lag was calculated as the difference between accommodative stimulus and the accommodative response as shown in the formula below:

$$\text{Accommodative response} = \text{Distance spherical equivalent refraction (DSER)} - \text{Near spherical equivalent refraction (NSER)}$$

$$\text{LOA} = \text{Accommodative stimulus} - \text{Accommodative Response}$$

Statistical Analysis

Analysis was conducted using GraphPad Prism 8 (Dotmatics, San Diego, USA). Data for the right and dominant eyes only are reported. Descriptive statistics are provided on baseline variables (age, sex, VA distribution and refractive error distribution). The data for LOA were tested for normality based on the Shapiro–Wilk test (α level = 0.05). Data with normal distributions are displayed as mean ± standard deviation and were analyzed with a *t*-test. Data with a non-normal distribution were analyzed with the Wilcoxon test and median values provided. The exploratory analysis on the difference in LOA between age group and sex was conducted using the Wilcoxon test. Study data are presented as mean, median described, individual participant data will not be shared.

Results

In total, 39 participants were enrolled in the study and 30 participants were included in the analyses cohort (Table 1). A total of nine participants were excluded from the study. Two participants failed the screening due to prescription range, and one

Table 1 Participant Characteristics (n = 30)

		OD	Dominant Eye
Refractive error (mean ± SD) (min, max)	Sphere	0.43 ± 0.30 (−0.50, 0.87)	0.42 ± 0.30 (−0.25, 0.87)
	Cylinder	−0.42 ± 0.25 (−1.00, 0.00)	−0.42 ± 0.24 (−1.00, −0.12)
Visual Acuity (unaided) (logMAR) (min, max)		−0.05 ± 0.07 (−0.18, 0.12)	−0.07 ± 0.14 (−0.80, 0.12)

participant discontinued from the study as they had difficulty understanding the instruction provided by the investigator. One participant's data were not included in the analysis due to a major protocol deviation noticed after the participant completed the study. Data from five participants were excluded from all analyses due to lead of accommodation or no accommodative response during the study. The mean age of all participants included in the analyses cohort was 10.4 ± 2.81 years (range 7 to 17 years).

Lag of Accommodation with Contrast Management and Control Spectacles
Right Eyes – All Participants Included in the Analyses Cohort

Data for LOA from the right eyes were not normally distributed for either spectacle lens design (Shapiro–Wilk p = 0.03 for contrast management spectacles and p = 0.05 for control spectacles). The LOA data from the right eye were not statistically significantly different between contrast management and control spectacle lenses (Wilcoxon test, p = 0.37). Figure 1 shows a moderate level of correlation between contrast management and control spectacle lenses (R^2 = 0.61).

A box and whisker plot (Figure 2) shows the 5th and 95th percentiles with mean LOA of 0.57D ± 0.39D for the contrast management spectacles and 0.62D ± 0.34D for the control spectacles in the right eyes. The plot indicates a positively skewed data distribution for both contrast management and control spectacles. The 25th and 75th percentile were at 0.29D and 0.84D
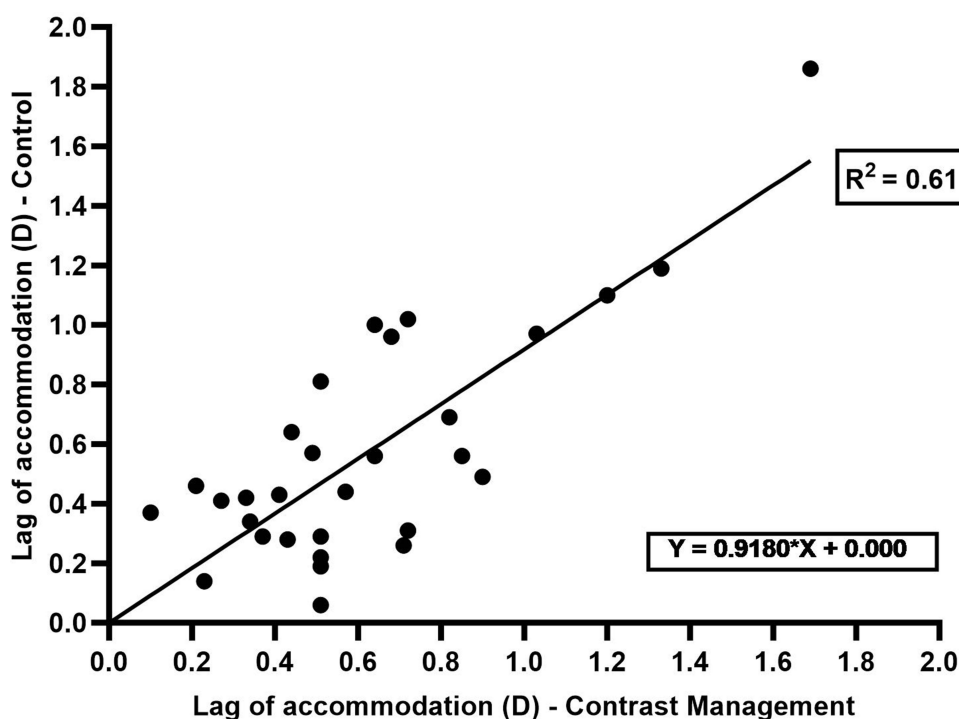

Figure 1 The scatter plot shows the correlation of LOA between the contrast management and control spectacles in the right eyes of each participant (n=30).
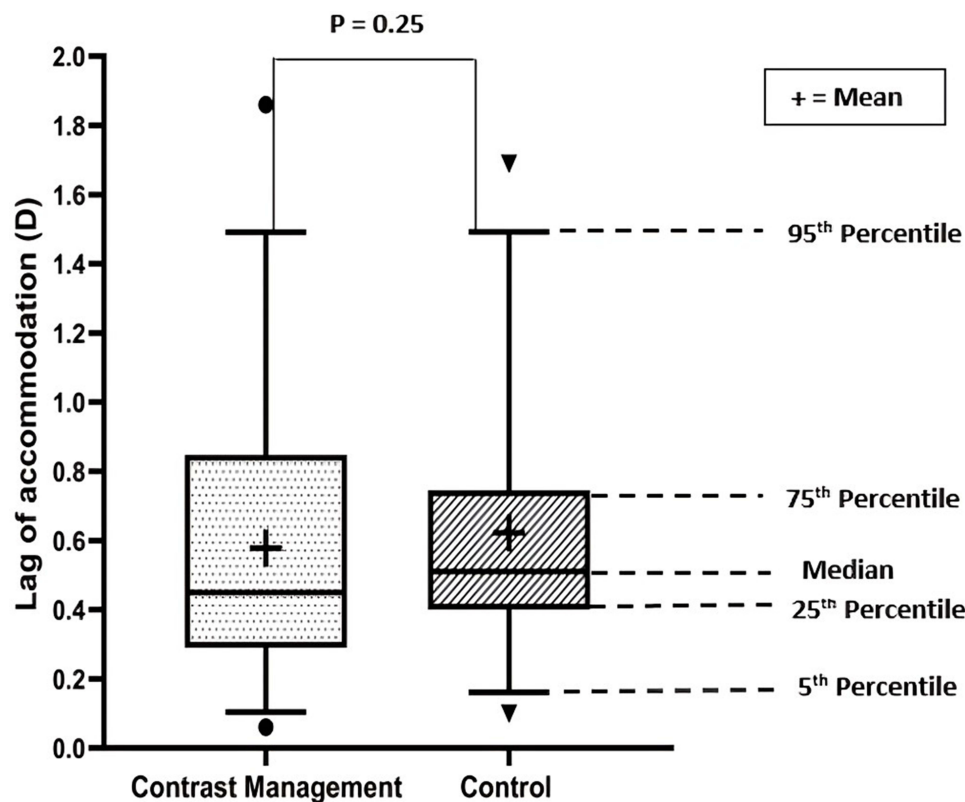
Figure 2 The Box and Whisker plot shows the distribution of LOA with contrast management and control spectacles in the right eye. The circles represent the outliers for the contrast management spectacles and the triangles represent the outliers for the control spectacles.

for the contrast management spectacles and 0.40D and 0.74D for the control spectacles. The graph also shows the interquartile range (IQR) of 0.55D for the contrast management spectacles and 0.34D for the control spectacles.

Dominant Eyes – All Participants Included in the Analyses Cohort

As for the right eyes, data for the dominant eyes were not normally distributed (Shapiro–Wilk p = 0.02 for contrast management spectacles and p = 0.02 for control spectacles). Lag of accommodation data from contrast management spectacles and control spectacles for the dominant eye were not statistically significantly different (Wilcoxon test, p = 0.14) and showed a moderate level of correlation between both spectacle designs ($R^2 = 0.52$) (Figure 3).

A box and whisker plot (Figure 4) was plotted at the 5th and 95th percentiles with the mean LOA of 0.60D ± 0.40D for the contrast management and 0.68D ± 0.33D for the control spectacles in the dominant eye. The plot indicates a positively skewed data distribution for both the contrast management spectacles and control spectacles. The 25th and 75th percentiles were at 0.27D and 0.96D for the contrast management spectacles and 0.47D and 0.82D for the control spectacles. The graph also shows the interquartile range (IQR) of 0.69D for the contrast management spectacles and 0.35D for the control spectacles.

Though this was a pilot study with a relatively small sample size, it was of interest to conduct additional exploratory analyses to determine if there was any effect of age or sex on the LOA between contrast management and control spectacles.

LOA in Younger Vs Older Participants

The right and dominant eye data were analyzed to test the difference in the mean LOA between the age groups 7–11 years (n = 19) and 12–17 years (n = 11) for the contrast management and control spectacles (Table 2). There were no significant different differences by age or spectacle lens design.
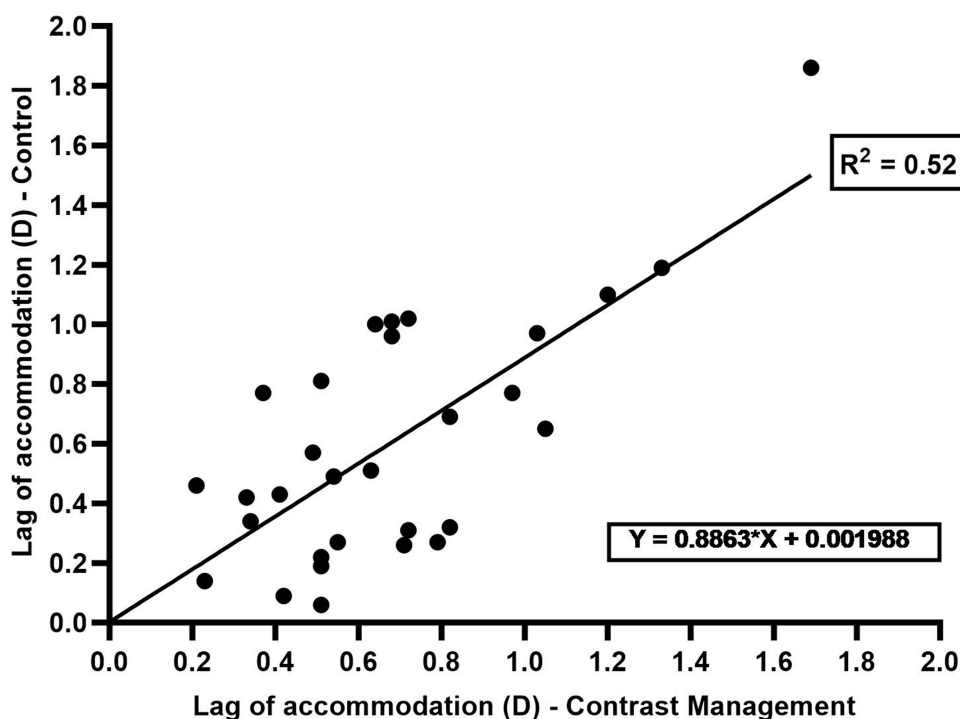
Figure 3 The scatter plot shows the correlation of LOA with contrast management and control spectacles in the dominant eye of each participant.
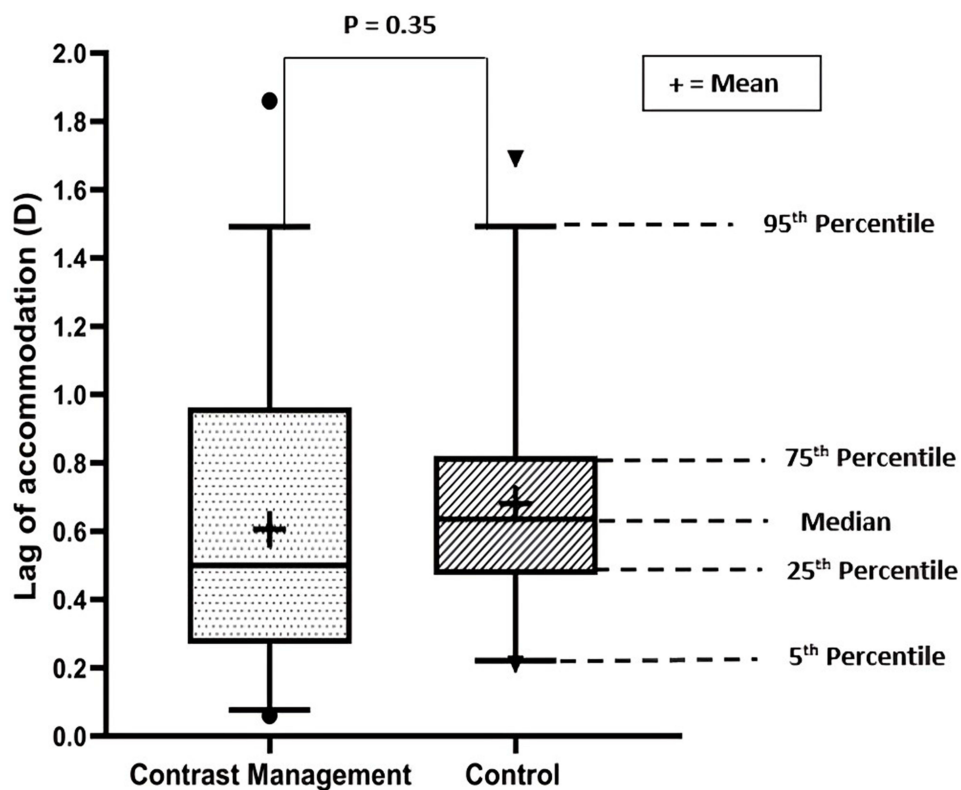

Figure 4 The Box and whisker plot shows the distribution of LOA between contrast management and control spectacles in the dominant eye. The circles represent the outliers for the contrast management spectacles and the triangles represent the outliers for the control spectacles.

Table 2 Lag of Accommodation with Contrast Management and Control Spectacles in the Right Eye and Dominant Eye for the Age Groups 7–11 Years (n=19) and 12–17 Years (n=11); Mean ± SD, (Median)

Lag of Accommodation	Right Eye			Dominant Eye		
	Age 7–11 years **Sph:0.45 ± 0.23** **Cyl:-0.31 ± 0.16**	**Age 12–17 years** **Sph: 0.27 ± 0.38** **Cyl:-0.57 ± 0.27**	**p-value**	**Age 7–11 years** **Sph: 0.46 ± 0.20** **Cyl:-0.30 ± 0.13**	**Age 12–17 years** **Sph:0.22 ± 0.38** **Cyl:-0.57 ± 0.28**	**p-value**
Contrast management	0.52D ± 0.29D (0.46D)	0.67D ± 0.51D (0.42D)	0.17	0.52D ± 0.32D (0.46D)	0.73D ± 0.50D (0.77D)	0.23
Control	0.58D ± 0.28D (0.51D)	0.66D ± 0.47D (0.44D)	0.65	0.61D ± 0.23D (0.55D)	0.79D ± 0.44D (0.72D)	0.18
p-value	0.32	0.71		0.23	0.45	

Table 3 Lag of Accommodation with Contrast Management and Control Spectacles in the Right Eye and Dominant Eye for Male (n=10) and Female (n=20) Participants (Mean ± SD, (Median))

Lag of Accommodation	Right Eye			Dominant Eye		
	Male **Sph: 0.47 ± 0.21** **Cyl: −0.36 ± 0.23**	**Female** **Sph:0.32 ± 0.39** **Cyl: −0.38 ± 0.20**	**p-value**	**Male** **Sph:0.50 ± 0.20** **Cyl:-0.39 ± 0.22**	**Female** **Sph:0.25 ± 0.37** **Cyl: −0.40 ± 0.20**	**p-value**
Contrast management	0.44D ± 0.25D(0.46)	0.64D ± 0.43D(0.44)	0.15	0.49D ± 0.33D(0.40)	0.65D ± 0.43D(0.58)	0.19
Control	0.62D ± 0.16D(0.60)	0.61D ± 0.42D(0.51)	0.99	0.58D ± 0.13D(0.55)	0.72D ± 0.39D(0.69)	0.93
p-value	0.06	0.47		0.49	0.24	

LOA in Male vs Female Participants

The right and dominant eye data were further analyzed to test the difference in the mean LOA between male (n = 10) and female (n = 20) participants when wearing both spectacle designs. There were no significant differences by sex or spectacle lens design (Table 3).

Discussion

These data confirmed the hypothesis that the mild decrease in contrast associated with the contrast management in the test design did not significantly impact LOA over a short period of wear of this novel design.[40] Further, elimination of the central clear aperture in the research design used in this study confirms that the effect is indeed relevant to the contrast reduction feature in the product intended for commercial use.[37] The levels of LOA found for both groups in this study were within the expected ranges published in recent and historical studies using a variety of measurement techniques.[16,18,19,41] A recent study found that LOA remains constant from 5 to 40 years of age and ranges between 0.00 and +1.00D.[19] Similar findings were reported in school age children aged 4 to 15 years using Nott retinoscopy and real targets at varied distances,[18] and in subjects from 3 to 40 years using an open-field autorefractor and minus lenses.[16] An earlier study reported a LOA of 0.28 ± 0.44D in 4-year-old children and 0.45 ± 0.30D in 12-year-old children with a weak dependency on age using the Monocular Estimate Method (MEM) of dynamic retinoscopy.[1] There was a consensus across studies that LOA increased with increasing demand. The results of a study of young adults confirmed a significantly higher LOA in myopic subjects compared to emmetropic subjects and cautioned that since the measurement of LOA is affected by method with differences as large as 0.50D, care should be taken when comparing values across studies with different methodologies.[20] Other studies have compared LOA results with different techniques and have found agreement between autorefractors and MEM and Nott retinoscopy,[42,43] but not with an infrared retinoscope.[43]

For identifying myopic children with very high accommodative lags (LOA ≥ 1.00D), neither MEM nor Nott retinoscopy provided adequate sensitivity and specificity.[44]

This study used an open-field autorefractor widely used in clinical myopia studies that has been shown to be reliable and efficient.[44] The distance fixation target is positioned in the distance and therefore reduces the potential stimulus to accommodation, while the near target is placed in the required reading distance. It can also take multiple measurements in a short period of time.

While literature exists confirming small differences in accommodative amplitude and facility between dominant and non-dominant eyes,[45,46] differences in LOA were not confirmed in those reports. Though sub-group sample sizes were small in this study, thereby limiting statistical power to detect differences, no statistically nor clinically significant differences were found in this study for LOA for any subgroup analysis (right eye versus dominant eye, age, sex).

Although the IMI report on the impact of accommodation on myopia suggested that it is more probable that the increased hyperopic defocus from LOA may be a consequence rather than a cause of myopia,[1] the lack of impact on accommodative measures in the low ametropes studied while wearing the contrast modulated spectacle design is still reassuring. Results for LOA with contact lens designs for myopia control that incorporate zones of relative plus power that could interfere with accommodation have been as varied as the designs available.[24,47–51] Interestingly, orthokeratology has shown to be associated with a decreased LOA over time, as well as versus non-myopia control soft contact lens wearers and spectacles,[52,53] while increased LOA with MEM retinoscopy following 6 months of daily dosing of 0.125% atropine drops was reported.[36] When considering spectacle designs for myopia control, a significant decrease in LOA after 2 years of wearing DIMS spectacles compared to single vision glasses when measured using an open-field autorefractor was reported in one of the few studies reporting LOA.[54]

This study was limited by the fact that all the participants involved in the study were emmetropic or had a very low prescription and therefore primarily represents children that are at a very early-stage of their onset of myopia or who may remain emmetropic. Additionally, the sample size was small, particularly for the exploratory sub-group analyses. The spectacles differed slightly from those used in clinical trials to determine efficacy, in that they had no clear center as is seen in the commercial product and were worn only for a short period of time. To better understand the implications of LOA and myopia with this novel design, future studies should focus on evaluating the long-term effect of LOA in an at-risk population.

Conclusion

The current study suggests that the contrast management lenses do not significantly impact LOA after short-term wear.

Acknowledgments

Disclosure

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