Contact Lens and Anterior Eye 42 (2019) 200–205

Contents lists available at ScienceDirect

Contact Lens and Anterior Eye

journal homepage: www.elsevier.com/locate/clae

Light disturbance analysis in the controlled randomized clinical trial MiSight® Assessment Study Spain (MASS)

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ARTICLE INFO

Keywords:
Light disturbance
Dual focus contact lenses
Children

ABSTRACT

Purpose: To evaluate the perception of light disturbances (LD) in children wearing Dual Focus (DF) MiSight® contact lenses (CLs) for myopia control compared with children wearing single vision spectacles (SV).
Methods: This was a randomized, controlled clinical trial involving subjects aged 8–12 with myopia of -0.75 to -4.00D and astigmatism < 1.00D allocated to MiSight® study CLs group or control group wearing SV. LD was determined at baseline, 12 and 24 months visit with a validated device, Light Disturbance Analyzer (LDA) to determine the shape, size and regularity of the LD phenomena with parameters of Light Disturbance Index (LDI) Best Fit Circle (BFC) and Standard Deviation between LD and BFC ($BFC_{Irreg.SD}$).
Results: 74 children completed the study, 41 in the CL group and 33 in the SV group. SV group didn´t show any significant differences between monocular and binocular LD measurements throughout the study. Binocular BFC_{Radius} was smaller at 24 months visit compared with 12 month visit ($p < 0.05$) and for $BFC_{Irreg.SD}$ was significantly smaller at 24 month visit compared with baseline ($p < 0.05$). In MiSight® group, binocular and monocular LDI, BFC_{Radius} and $BFC_{Irreg.SD}$ measurements didn't show any significant change between 12 and 24 month visits ($p > 0.05$). However, monocular $BFC_{Irreg.}$ as well as monocular and binocular $BFC_{Irreg.SD}$ showed a significant decrease at 24 month visit compared with 12 month visit.
Conclusions: DF lenses increase the monocular light disturbance perception compared with a single vision spectacle correction. However, this effect decreased over the follow-up time and presented a significant binocular attenuation effect.

1. Introduction

Positive dysphotopsia is characterized by the visualization of light beyond the limits of the ideal image. It can be produced by errors of focus such as in uncorrected refractive errors and the three main causes of image degradation in optical system, scattering phenomena in particles or opacities in optical media, diffraction through small apertures or aberrations from distorted though transparent optical surfaces [1]. Dysphotopsia is a common symptom in multifocal and bifocal optical systems for simultaneous vision of images focused at different distances in front of or behind the ideal focal plane, as in multifocal contact lenses for presbyopia [2]. Though such devices are applied in presbyopia correction, the same or similar optical designs have been successfully applied to control myopia progression [3]. One of these devices is the dual-focus contact lens (DF CL) for myopia control [4]. This lens includes a 2D add power, which renders a second focus in front of the retina at a distance of approximately 0.6 mm from the distance focus, assuming accurate accommodative response through the distance vision area of the CL. Therefore, the focus produced by the 2D add power of the treatment zones creates a defocused image at the retinal plane that is superimposed with the distance vision image. In children fitted with DF CLs for myopia control, subjective complaints of halos are common and are exacerbated by the inherently larger pupil diameter of younger subjects [5]. However, to date there is no information about the size of the halo measured objectively in children fitted with this type of CL. This can be now measured using halometers by determining the veil-like area around a bright central light, as in the Light Disturbance Analyzer –LDA- [6,7].

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https://doi.org/10.1016/j.clae.2018.11.006
Received 13 March 2018; Received in revised form 5 November 2018; Accepted 7 November 2018

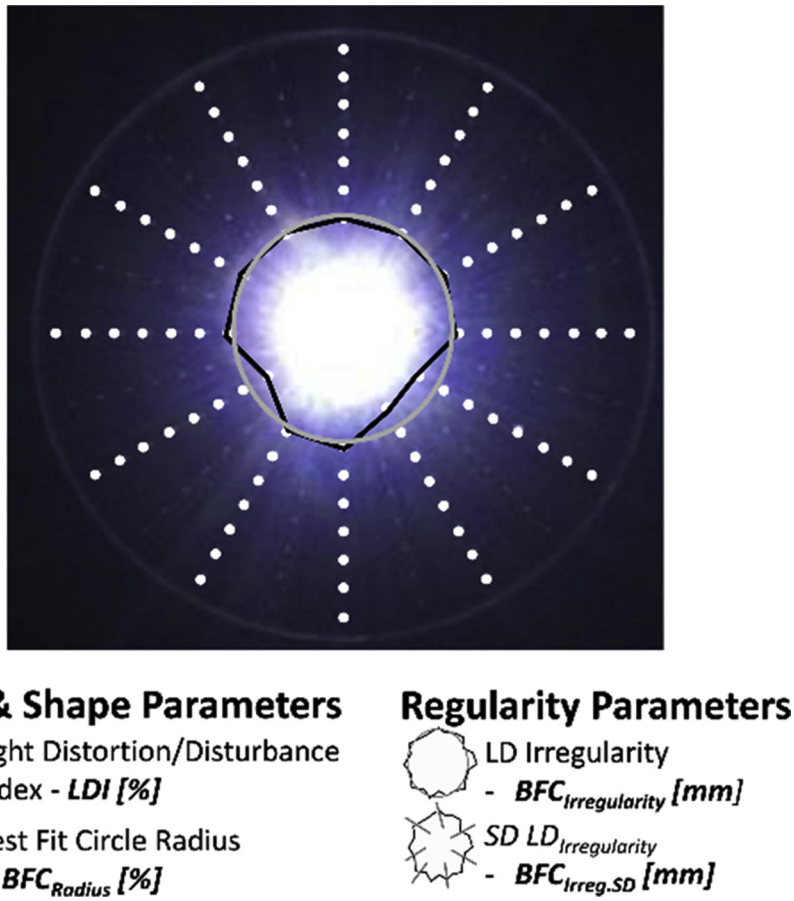

Fig. 1. Illustration of the distribution of main central source of light and peripheral stimuli in accordance with an exemplary embodiment of the present invention. The upper image shows the experimental device LDA with the central LED light with one peripheral LED turned ON and the layout appearance of the size and shape of the light disturbance measured. The image below shows the size and shape and regular related parameters derived from the Light Distortion Analyzer.

Though this optical phenomenon is expected to remain as long as the optical device is in the eye, preliminary studies in eyes during orthokeratology treatment show a reduction in light disturbance (LD), one month after starting the ortho-k treatment, which remains unaltered in the long term after 1 year [8] This improvement could be understood as an adaptation phenomenon [8,9].

In the present study, it is hypothesized that the disturbance surrounding main light source will be present in subjects wearing dual-focus contact lenses for myopia control compared with single vision spectacle lenses. It is also hypothesized that the light disturbance sensation will improve under binocular conditions compared with monocular conditions (summation effect) and will improve with wear over time. To test this, the light disturbance was measured at 12 and 24 months of follow-up in subjects participating in the MiSight® Assessment Study Spain (MASS) clinical trial. This is the first study that evaluates objectively the LD phenomena in children undergoing myopia control with DF contact lenses.

2. Methods

This study was part of the MiSight® Assessment Study Spain (MASS) [10], designed to assess the efficacy and subjective acceptance of MiSight® CLs versus distance SV spectacles in myopic children over a 2-year period. The protocol was approved by the CEI-R (Regional Research Ethics Committee of the Community of Madrid, Spain) and adhered to the tenets of the Declaration of Helsinki. The clinical trial was registered in Clinical Trials (ClinicalTrials.gov Identifier: NCT01917110), where the outcome measures and the eligibility criteria can be consulted. After receiving an explanation of the nature and possible consequences of the study, all parents provided signed permission for their children to participate, and participants provided written consent.

Healthy subjects of European descent, 8–12 years of age with moderate levels of myopia (-0.75 to -4.00D) and astigmatism (< -1.00D) and free of systemic or ocular disease, were recruited for this study. At the Baseline initial visit, all subjects underwent a full anterior segment examination, indirect fundus microscopy, binocular vision and refractive evaluation. Eligible subjects were sequentially randomized into either the study group (CLs) or control group (single vision spectacles, Shamir, Spain).

Subjects in CL group were instructed to wear the lenses for at least 6 days per week without exceeding 15 h of daily wear use. It was made clear that they had to remove their contact lenses if they experienced any sort of problem and return for follow-ups at 1 week, 1, 6, 12, 18 and 24 months. Subjects in the control group (SV) were prescribed standard, single-vision spherocylindrical ophthalmic lenses (Monofocal Shamir Alite, 1.56 HMC). They were asked to wear the spectacles at all times and to return for follow-ups at 6, 12, 18 and 24 months.

Dual Focus contact lenses (MiSight®, Coopervision) are manufactured with Omafilcon A hydrogel contact lens material (60% water content, non-ionic). The lens has a total diameter of 14.2 mm comprising a 11.66 optic zone with 4 alternating distance and near zones (maximum treatment of +2.00 diopters) surrounding a central 3.36 mm distance zone diameter.

At follow-up visits, children received new CL or SV spectacles either if over-refraction improved visual acuity by 3 letters, or if there had been a change in refractive error of -0.25 D or greater. Spectacles and CLs, as well as full ocular examinations, were provided free of charge to all participants throughout the study. CooperVision S.L. provided the study contact lenses and the funding to carry out the clinical trial. Children from both study groups were instructed to report any sign or symptom (e.g. change in visual acuity, red eye, pain, discomfort).

2.1. Outcome measures

Light disturbance, referred to as halo phenomena, was assessed with a validated device, the LD Analyzer (LDA, CEORLab, Portugal), developed at the Physics Department, University of Minho, Braga, Portugal, which characterizes the size and shape of light disturbance surrounding a central bright light source. At the baseline visit, all the subjects completed the LDA test wearing their spectacles with the best subjective refraction for the best visual acuity [6]. This device has proved to be sensitive for measuring LD with bifocal and trifocal intraocular lenses [11,12], changes in spherical aberration induced by phase plates in normal accommodating and non-accommodating eyes [7], eyes undergoing orthokeratology [8,13] and presbyopic subjects wearing monovision and multifocal contact lenses [2].

The LDA consists of central 5 mm white LED, acting as a glare source, surrounded by an array of 240 < 2 mm wide white light source (LED) distributed in twenty-four semi-meridians with a minimum angular separation of 15° to 30° angular resolution, with a linear separation of around 8 mm to cover an angular field of 4.6° at the distance of examination of 2 m. Fig. 1 represents the layout arrangement of the central white LED and the surrounding smaller white LEDs device in the 24 semi-meridian configuration. The technical specifications of the LEDs characteristics and examination procedures can be consulted in previously published work [14]. At a distance of 2.0 m in a darkened room, the instrument presents the central source of glare at maximum intensity while the peripheral LEDs are turned on and off sequentially around the central source of light using different sequences at random times from 250 to 750 ms and the different semimeridians are explored in random order.

The patient is instructed to always fixate on the central LED and provide feedback regarding the peripheral stimuli that can be seen by clicking a remote actuator. When the patient reports seeing the first peripheral stimuli in a given semi-meridian, the system changes randomly to the next meridian. All the semi-meridians are examined three times at the same measurement and averaged if their standard deviation is below 20% of the mean. If the SD of the three measurements in each semi-meridian is above 20% of the mean value, the device automatically repeats the measurements in those semi-meridians until it reaches values of SD below 20% of the mean. After data collection and storage, a software tool calculates indices that determine the size, shape, and regularity of the disturbance surrounding the central source of light. The light disturbance index (LDI) is calculated as the ratio of the area of points missed by the subject and the total area explored and is expressed as a percentage (%). The higher values of disturbance are interpreted as the lower ability to discriminate surrounding small stimuli that are hidden by the disturbance induced from the central source of light. Best Fit Circle Radius (BFC_{Radius}) is defined as the radius of the circle that best fits the disturbance area. It is the average length of the distortion along each semi-meridian under evaluation expressed in mm. This parameter is expressed in millimetres and is linearly related to LDI (%) parameter. Irregularity of the disturbance area is obtained from the deviation of the actual polygonal shape measured and the BFC fit and is called the BFC Irregularity ($BFC_{Irreg.}$). It represents the average of the deviations. The standard deviation of $BFC_{Irreg.}$, called $BFC_{Irreg.SD}$, measures the degree of asymmetry of the actual disturbance limits with respect to the perfect circular shape of the BFC. Together, $BFC_{Irreg.}$ and $BFC_{Irreg.SD}$ can be interpreted as the deviation of the actual disturbance from a perfectly rotational symmetric shape. The higher the value of this parameter, the larger the deviation. At baseline, all the measurements were performed with spectacles in both groups. At the visits of month 12 and 24, the CL group completed the LDA test with CLs and the SV group did so with spectacles. Baseline LDA parameters were always measured with trial frame. Data from dominant eye (monocular measurement) and from both eyes (binocular measurement) were analysed at each visit.

2.2. Statistical analysis

Statistical analysis of data was performed using SPSS statistical software package SPSS 18 for Windows. For the analysis, data for children who attended the 24-month visit were included in the analysis. The level of statistical significance was taken as 5% (significance $p < 0.05$). Normality of data distribution was assessed with Kolmogorov-Smirnov test. The differences between the two study groups were analysed to baseline demographics, refraction, biometric and light disturbance data using variance analysis (ANOVA) and the Brown-Forsythe F test depending on the result of Levene's test for equality of variances. In addition, the Kruskal-Wallis test is performed if the results of Kolmogorov-Smirnov lead to rejection of the data normality hypothesis.

Differences in each group over time (baseline vs. month 24 visit) in light disturbance parameters (LDI; BFC_{Radius}, BFC_{Irregy}, $BFC_{Irreg.SD}$) were assessed. General linear model (GLM) repeated measures were used, where the within-subject factor is time. To test the assumption that the variance-covariance matrix is circular in shape, Mauchly's test of sphericity was used. If this assumption is rejected, GLM repeated measures use the univariate F statistic, corrected by epsilon index. Student *t*-test analysis was used to discover the possible differences between the monocular and binocular light disturbance parameters. Correlations between different parameters were performed with Pearson or Spearman correlation.

Table 1
Comparison of demographic and ocular components expressed as mean and standard deviation (SD) for all subjects initially included in the study and participants who completed the study. "P-value" refers to the statistical P-value.

	ALL			COMPLETED		
	MiSight group(n = 46)	SV Group(n = 33)	P value	MiSight Group(n = 41)	SV Group(n = 33)	P value
Age (years)	10.94 (1.24)	10.12 (1.38)	0.007	11.01 (1.23)	10.12 (1.38)	0.005
Spherical equivalent (D)	−2.10 (0.91)	−1.75 (0.94)	0.095	−2.16 (0.94)	−1.75 (0.94)	0.067
J0	0.07 (0.17)	0.00 (0.12)	0.038	0.07 (0.18)	0.00 (0.12)	0.059
J45	−0.02 (0.13)	0.00 (0.12)	0.638	−0.02 (0.12)	0.00 (0.12)	0.547
BCVA (LogMar)	−0.06 (0.05)	−0.07 (0.07)	0.715	−0.06 (0.06)	−0.07 (0.07)	0.627
Best correct NVA (M)	0.40 (0.06)	0.39 (0.03)	0.683	0.4 (0.06)	0.39 (0.03)	0.276
Axial length (mm)	24.11 (0.57)	24.00 (0.86)	0.525	24.09 (0.55)	24.00 (0.86)	0.603
Anterior chamber (mm)	3.76 (0.20)	3.76 (0.19)	0.884	3.77 (0.19)	3.76 (0.19)	0.820
Mean keratometry (D)	44.16 (1.21)	44.03 (1.59)	0.693	44.24 (1.25)	44.03 (1.59)	0.533

SV: single-vision spectacles; D: diopters; J0 and J45 vectorial components for astigmatism; BCVA: Best-corrected visual acuity measured in logarithm of the minimal angle of resolution (logMAR) units; Best correct NVA: near visual acuity measured in M notation.

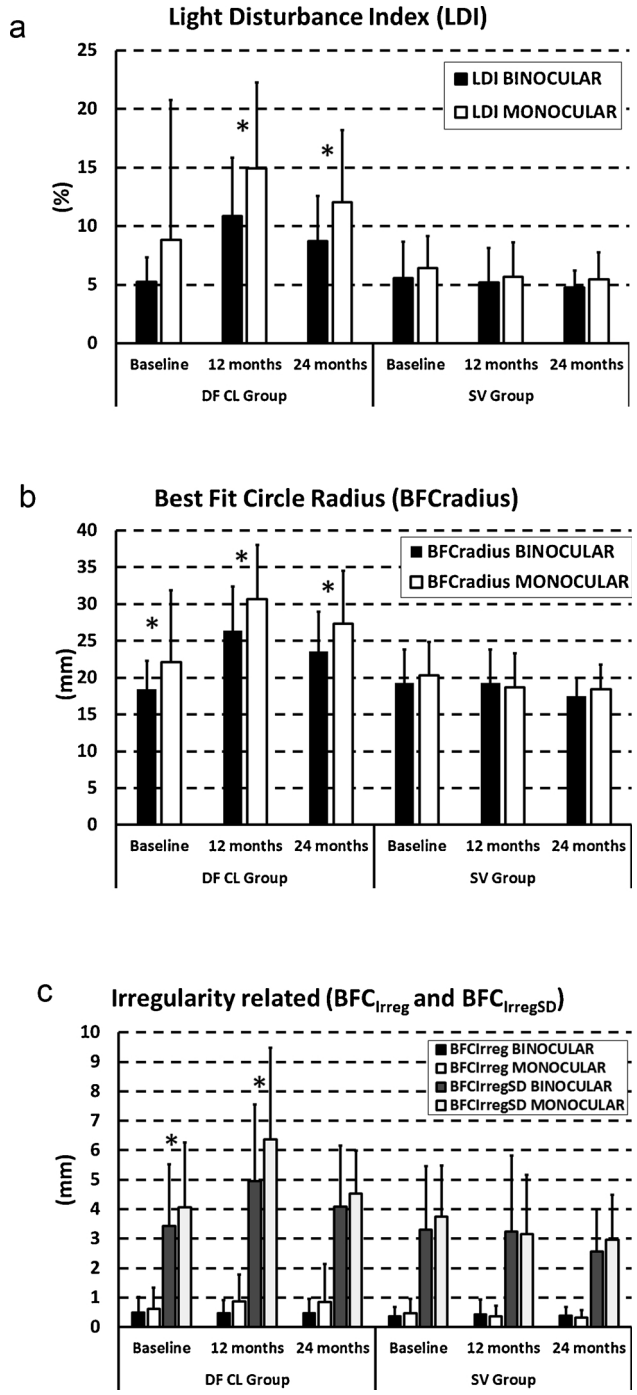

Fig. 2. Monocular and Binocular measurements of size related light disturbance parameters (a) LDI, (b) BFC_{Radius} and irregularity related parameter (c) BFC_{Irreg} and $BFC_{IrregSD}$, for baseline and at 12 month and 24 month visit for Test group (contact lens) and Control group (spectacle). Error bars represent standard deviation.

3. Results

Demographic data is shown in Table 1 for the 79 subjects included in the study between September 2013 and June 2016. In total, 74 children completed the study: 41 in the CL group and 33 in the SV group. There were no withdrawals in the SV group, while 5 subjects in the CL group were discontinued, none of them due to adverse events. At baseline, no significant differences ($p > 0.05$) were observed between the groups for refractive, biometric, pupil diameter, parental myopia and light disturbance parameters, the exception being age, as the children in the CL group were about 1 year older than those in the SV group ($p = 0.005$). For this reason, age was treated as a covariate to analyse its possible influence on the main variables using ANCOVA analysis. Covariate analysis showed that age had no significant effect, and therefore, possible differences between groups cannot be attributed to those differences in mean group age.

3.1. Monocular and binocular light disturbance data

Fig. 2 shows the variations of size-related parameters, LDI (Fig. 2a) and BFC_{Radius} (Fig. 2b) as well as regularity-related parameters, BFC_{Irreg} and $BFC_{IrregSD}$ (Fig. 2c) for each group over time. In SV group there were no statistical significant differences between monocular and binocular LD measurements at baseline, 12 and 24 ($p > 0.05$ for all parameters and all visits). For DF CL group, at baseline visit, when all children were assessed with spectacles, there are significant differences in BFC_{Radius} and $BFC_{IrregSD}$ measurements ($p < 0.05$), the binocular measurements being lower than monocular ones. At 12-month visit binocular measurements of LDI, BFC_{Radius}, $BFC_{Irreg.}$and $BFC_{IrregSD}$ were significantly lower than the monocular ones ($p < 0.001$for all LD parameters). At 24-month visit, binocular LDI and BFC_{Radius} measurements were lower than monocular ones ($p < 0.001$), while there are no significant differences between binocular and monocular for BFC_{Irreg} and $BFC_{IrregSD}$ values.

3.2. Light disturbance measurements over time

In SV group there were no significant changes in any measurements over time, except for binocular BFC_{Radius}, which was lower at 24 month visit compared with 12 month visit ($p < 0.05$), and binocular $BFC_{Irreg.SD,}$ which was also significantly lower at 24 month visit compared with baseline ($p < 0.05$). In DF CL group there is an increase in all LD parameters when compared to baseline values, whereas binocular and monocular LDI, and BFC_{Radius} and binocular BFC_{Irreg} measurements did not show any significant change between 24 and 12 month visits ($p > 0.05$). On the contrary, monocular BFC_{Irreg} and binocular and monocular $BFC_{IrregSD}$ showed a significant decrease at 24 month visit compared with 12 month visit ($p < 0.05$ for both parameters)(Fig. 2c). Table 2 shows the changes in light disturbance data results over time for both groups, showing a tendency towards higher halo perception in the contact lens group compared with the SV group. Also observed in the CL group was a decrease in the light disturbance data at the 24 month visit compared with the 12 month visit.

3.3. Correlation analysis

There was a positive correlation between binocular LDI and pupil diameter ($r = 0.423$, $p = 0.031$) at baseline visit, a negative correlation between binocular LDI and axial length ($r = -0.397$, $p = 0.04$) in SV group, and a positive correlation between binocular $BFC_{IrregSD}$ and pupil diameter ($r = 0.381$, $p = 0.026$) in CL group.

4. Discussion

It has been demonstrated that Dual Focus contact lenses are effective in slowing down axial elongation and juvenile myopia progression by 40% in 8–12 year-old children over a 2-year period in a randomized clinical trial [10] and up to nearly 60% in 8–12 year-old children over a 3-year period in a multicenter controlled randomized double-masked clinical trial [15] confirming the preliminary results obtained by Anstice and Phillips in a shorter-term study in New Zealand [4]. Therefore, it is expected that the use of DF CLs will increase over the next few years, particularly in the management of myopia control and progression. A well-known consequence of bifocal and multifocal optical corrective devices is the presence of positive dysphotopsia in the form of

Table 2
Changes (mean ± SD) in light disturbance data results at each visit in subjects who completed the two-year study.

	MiSight Group Mean ± SD				SV group Mean ± SD			
	Baseline	12 months	24 months	p-value	Baseline	12 months	24 months	p-value
LDI Bino (%)	5.22 ± 2.11	10.87 ± 4.97	8.70 ± 3.87	0.277	5.57 ± 3.07	5.18 ± 2.16	4.74 ± 1.44	0.103
LDI Mono (%)	8.81 ± 11.95	14.90 ± 7.37	12.02 ± 6.15	0.057	6.43 ± 2.74	5.67 ± 2.93	5.44 ± 2.31	0.515
BFC_{Radius} Bino (mm)	18.44 ± 3.83	26.35 ± 6.01	23.57 ± 5.37	0.272	19.28 ± 4.50	19.28 ± 4.50	17.48 ± 2.47$^{\alpha}$	0.004*
BFC_{Radius} Mono (mm)	22.12 ± 9.73	30.64 ± 7.40	27.29 ± 7.21	0.055	20.52 ± 4.58	18.69 ± 4.58	18.43 ± 3.34	1.000
BFC_{Irreg} Bino (mm)	0.51 ± 0.51	0.47 ± 0.44	0.47 ± 0.49	0.985	0.37 ± 0.31	0.44 ± 0.50	0.39 ± 0.29	1.000
BFC_{Irreg} Mono (mm)	0.61 ± 0.72	0.87 ± 0.91	0.84 ± 1.29	0.005*	0.47 ± 0.49	0.37 ± 0.35	0.32 ± 0.26	1.000
$BFC_{IrregSD}$ Bino (mm)	3.41 ± 2.13	4.96 ± 2.60	4.09 ± 2.06	0.038*	3.30 ± 2.15	3.25 ± 2.57	2.56 ± 1.44	0.002*
$BFC_{IrregSD}$ Mono (mm)	4.06 ± 2.21	6.37 ± 3.11	4.53 ± 1.45	0.002*	3.75 ± 1.74	3.15 ± 2.02	2.97 ± 1.52	0.098

SD: standard deviation, Bino: binocular, Mono: monocular, α: statistically significant values between 12 and 24 month visits, *:statistically significant values over the study period (baseline, 12 and 24 months).

glare, haloes and starburst in presbyopic and pseudophakic patients [5,16–19]. In fact, discontinuity between different zones of a multifocal optical device or multiple abrupt changes in a power profile may contribute significantly to light scattering and result in an increase in light disturbance, particularly under low-light conditions. These symptoms are more noticeable at night when bright objects, such as car headlights or street lamps, are seen against a dark background [13]. However, in young children it is not likely that these complaints will cause problems, because they do not drive. In spite of this, Chamberlain et al. [15] reported the presence of ghost imaging sensation during the first month of treatment with DF lenses in the multicenter clinical trial using a subjective questionnaire. The present study shows that DF CLs for myopia control do not cause significant light disturbance in children, as observed in the long term follow-up measurements of LD conducted at 1 year and 2 years. Considering the optical design of these lenses, a significant increase in LD within the CL group compared with the SV spectacle group was expected. In addition, the long term follow-up measurements of LD parameters up to 2 years decreased over time. In fact, previous studies have shown that perceptual processes such as binocular summation as well as the phenomenon of neural adaptation to aberration changes, enhance the interpretation of superimposed multiple images on the retina, which may explain the reduction in LD parameters observed at long-term follow-up [20,21]. Additionally, considering previous results in young patients undergoing orthokeratology treatment to reshape the cornea and reduce myopia, a stronger LD effect is observed in the early stages of treatment [9]. Santolaria-Sanz et al. [9] found a significant increase in the LDI parameter at 1 week after treatment onset in OrthoK patients, which was reduced to nearly baseline levels after 1 month. Longer follow-up at 1 year confirmed the reduced LDI values in the same treatment [8]. A similar effect has been documented in young presbyopic pseudophakic patients implanted with trifocal IOLs after clear lens extraction [12]. The DF lenses used in the present study might reveal a pattern of stronger LD with higher LDI values potentially related to the add power (+2.00D) in the treatment rings intended to decrease axial elongation surrounding the central distance area. This has been found in a case series of presbyopes fitted with Acuvue Oasys for presbyopia concentric bifocal CLs with a similar design as the DF lenses [22] and is also supported by the subjective outcomes reported in the multicenter clinical trial NCT01729208 evaluating the MiSight® contact lenses for myopia control [15].

Despite the significant increase in all LD parameters for the CL group, when compared to baseline values, the values of LD observed are low and decrease over time in the medium and long term follow-up, either in the size-related LD parameters (LDI and BFC_{Radius})or in the regularity-related parameters (BFC_{Irreg} and $BFC_{IrregSD}$). Furthermore, a significant binocular attenuation effect that reduced the LD sensation significantly to values similar to those of the non-contact lens wearers is observed. One limitation of the study is that the control group did not, unlike the DF CL group, use contact lenses subjected to dehydration and changes in image quality during the interlink period. Hypothetically, this might explain the increased initial values of LD in the CL group once some studies reported that optical properties of CL might be a factor affecting LD with different amounts of straylight induced by different CL materials [17]. However, it was considered that this fact did not negatively the results of the study, as the subjects were reminded to blink regularly during the LD measurement, which could prevent any adverse impact from the dehydration of the CL and the expected increase in LD [22].

In a short-term study lasting two weeks, Kang et al. [18] and Fernandes et al. [2] found an increase in symptoms related to dysphotopsia, as assessed with the Quality of Vision Questionnaire (QoV) [23]. Kang et al. [18] assessed the effects of soft MF CLs used for myopia control (Proclear MF center-distance “D design”, CooperVision, with addition power +1.50 and +3.00) on subjective quality of vision compared with a single vision Proclear spherical CL in a population of young subjects. They reported a significant increase in the QoV questionnaire scores in the MF CL group for all three subscales (frequency, severity and bothersome) compared with scores obtained for the single vision CL, and those symptoms worsened over the two-week wearing period, particularly so with the MF with +3.00 Add. In the present study, the DF CL has a +2.00D positive power regarding the distance zone, so it is not surprising that there are fewer subjective complaints in the present study. Interestingly, Kollbaum et al. [5] compared the ghosting sensation in young subjects (aged 18 to 25 years) wearing Proclear multifocal center-distance and the DF lens used in the present study, both with +2.00D of add over the distance correction, and found similar results for both lenses. This might be anticipated given that both lenses are essentially similar in their bifocal nature but use different power distribution between distance and near/treatment add areas. In the same study, the authors observed that during night conditions, the ratings of quality of vision were lower than under day conditions. Furthermore, a study conducted by Fernandes et al. [2] measured LDI with the same device that was used in the present study and showed an increase in LD with the multifocal CLs compared with the monofocal CL worn in the dominant eye of monovision patients. Considering the data from those studies with subjective questionnaires, stronger LD complaints would be expected in the shorter term during initial adaptation in the current study. However, after 1 and 2 years of wear, it seems that LD sensation is not an issue with these CLs.

In comparison with the previous studies, present results for LD are lower than others obtained with the same measurement method in pseudophakic patients with higher age and with monofocal IOL implantation (12, 24) [12,24], but are in the same range as those presented by younger subjects (26–37 years of age) in the validation study of the device [6,7]. These differences could be explained by the younger age the patients in the present study. Moreover, the younger age and larger pupil might act as a risk factor for the worsening of such LD

symptoms. However, as in previous studies in other populations [6,25], it was have found that LD is poorly correlated with pupil size. This might explain why young children do not present high LD values despite their larger pupil aperture, even with DF CL wear. Despite this, it should be acknowledged that the LDI parameter is about 30% higher in the DF contact lens group than in the SV spectacle group. Interestingly, the binocular attenuation effect was also higher in the CL group, resulting in a binocular halo sensation not significantly different between both groups in the present study.

In summary, the present study shows that DF contact lenses induce statistically significant changes in light disturbance perception with a tendency to decrease over time. Future studies should investigate the short-term effects in order to better understand the adaptation process.

Funding

This study has been funded in part by projects PTDC/SAU-BEB/098392/2008 and PTDC/SAU-BEB/098391/2008, which in turn have been funded by the Portuguese Fundação para a Ciência e Tecnologia through the European Social Fund and by FEDER through the COMPETE Program and by the Portuguese Foundation for Science and Technology (FCT) in the framework of the Strategic Project UID/FIS/04650/2013. JMG-M has proprietary interests in the experimental device used to measure light disturbance.

CooperVision S.L. Spain also provided financial support. CooperVision S.L. provided the study contact lenses and the funding to carry out the clinical trial. The sponsor had no role in designing or conducting this research.

Conflict of interest

JMG-M has proprietary interests in the experimental device used to measure light disturbance. The rest of the authors certify that they have no affiliations with or involvement in any organization or entity with any financial interest (such as honoraria; educational grants; participation in speakers' bureaus; membership, employment, consultancies, stock ownership, or other equity interest; and expert testimony or patent-licensing arrangements), or non-financial interest (such as personal or professional relationships, affiliations, knowledge or beliefs) in the subject matter or materials discussed in this manuscript.

Ethical approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee (CEI-R, Regional Research Ethics Committee of the Community of Madrid, Spain) and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

Informed consent

Informed consent was obtained from all individual participants included in the study.

Acknowledgments

The authors would like to thank Peter Bonney for proofreading the article.

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