• Clinical Research •

Evaluation of refractive correction for standard automated perimetry in eyes wearing multifocal contact lenses

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Abstract

• AIM: To evaluate the refractive correction for standard automated perimetry (SAP) in eyes with refractive multifocal contact lenses (CL) in healthy young participants.

• METHODS: Twenty-nine eyes of 29 participants were included. Accommodation was paralyzed in all participants with 1% cyclopentolate hydrochloride. SAP was performed using the Humphrey SITA-standard 24-2 and 10-2 protocol under three refractive conditions: monofocal CL corrected for near distance (baseline); multifocal CL corrected for distance (mCL-D); and mCL-D corrected for near vision using a spectacle lens (mCL-N). Primary outcome measures were the foveal threshold, mean deviation (MD), and pattern standard deviation (PSD).

• RESULTS: The foveal threshold of mCL-N with both the 24-2 and 10-2 protocols significantly decreased by 2.2-2.5 dB (P<0.001), while that of mCL-D with the 24-2 protocol significantly decreased by 1.5 dB (P=0.0427), as compared with that of baseline. Although there was no significant difference between the MD of baseline and mCL-D with the 24-2 and 10-2 protocols, the MD of mCL-N was significantly decreased by 1.0-1.3 dB (P<0.001) as compared with that of both baseline and mCL-D, with both 24-2 and 10-2 protocols. There was no significant difference in the PSD among the three refractive conditions with both the 24-2 and 10-2 protocols.

• CONCLUSION: Despite the induced mydriasis and the optical design of the multifocal lens used in this study, our results indicated that, when the dome-shaped visual field test is performed with eyes with large pupils and wearing refractive multifocal CLs, distance correction without additional near correction is to be recommended.

• KEYWORDS: intraocular lens; multifocal contact lens; refractive correction; standard automated perimetry; visual field

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INTRODUCTION

Although monofocal intraocular lenses (IOLs) are typically implanted after cataract surgery, monofocal IOLs require the use of glasses for far or near distance vision, as these lenses per definition have only one focus. Recently, the number of patients who prefer multifocal IOLs, which contain both near and far foci, has increased, due to the improved quality of life offered by such lenses. Although multifocal IOLs and multifocal contact lenses (CLs) maintain clear vision for both near and distance vision, their contrast sensitivity is lower than that of monofocal IOLs and CLs[1-15]. This is also noted in the visual field test[16-20].

When the dome-shaped visual field test is performed for presbyopic patients and those with implanted monofocal IOLs, it requires near refractive correction, as stimuli are presented in a spherical plane of radius 30 cm[21]. On the other hand, distance refractive correction can generally be applied if the dome-shaped visual field test is performed in an eye with a multifocal IOL or CL, as these are theoretically optically designed with a focal point for both far and near distance[16-20]. However, we have found some difficulty in refractive correction for such cases in the clinical visual field test[22]. In particular, optimal refractive correction is important in patients with glaucoma, as it is thought that the decreased sensitivity induced by inadequate refractive correction influences the estimate of visual field progression[23].

In a previous study of the effect of multifocal IOLs and CLs on visual field sensitivity, the mean deviation value was decreased by approximately 1-2 dB in standard automated perimetry (SAP) as compared with the effect of monofocal IOLs and CLs[16,18]. On the other hand, the visual field sensitivity was not significantly decreased in SAP[7] or frequency doubling technology[24]. However, SAP has previously been performed with distance correction, without near correction[16,18]. It is possible that the decreasing sensitivity in the visual field test

caused by multifocal IOLs or CLs can be prevented with near refractive correction, because some refractive and diffractive multifocal IOLs have been designed to be slightly distance-dominant[25-26].

The aim of this study was to evaluate the refractive correction required for SAP in eyes harboring multifocal IOLs. To this end, we mimicked this situation in healthy young participants by using an accommodation-paralyzing agent and refractive multifocal CLs.

SUBJECTS AND METHODS

Clinical Trial Registration: UMIN Clinical Trials Registry (http://www.umin.ac.jp/) under unique trial number UMIN 000018390 (date of registration: 07/23/2015).

This study followed the tenets of the Declaration of Helsinki. Each participant provided written informed consent after the Ethics Committee of the Kitasato University School of Allied Health Science approved the study (No.2015-10).

In this cross-sectional study, we evaluated 30 student volunteers studying the Orthoptic and Visual Science course at Kitasato University who had undergone SAP at least three times within the last 3mo. All the participants underwent comprehensive ophthalmic examinations, including non-cycloplegic refraction testing, visual acuity testing at a 5-m distance using a Landolt ring chart, intraocular pressure measurement, ocular axial length measurement, and slit-lamp and fundus examination by a glaucoma specialist (Shoji N). Participants were included in the study if they had a corrected visual acuity of 20/20 or better, intraocular pressure of 21 mm Hg or less, cylindrical power of -1.50 diopter or less, a normal optic disc appearance, open angle, and no ophthalmic diseases that could affect the results of the visual field test. For each participant, the eye with the lower amount of astigmatism was selected as the study eye. If the amount of astigmatism was the same in both eyes, the eye with the lower level of myopia was chosen as the study eye.

SAP was performed using the Humphrey field analyzer (HFA, Carl Zeiss Meditec AG, Dublin, CA, USA) and the Swedish Interactive Threshold Algorithm Standard strategy. Both the 24-2 and 10-2 test point protocols were used for SAP measurement. The measurement conditions for SAP were calibrated to a background luminance of 10 cd/m^2 (31.4 asb), stimulus size was set at Goldmann size III, stimulus presentation time at 0.2 second, and foveal threshold measurement as "on". Pupil diameter was recorded during SAP using HFA.

Multifocal CLs (ROHTO i.Q 14 Bifocal D-type; ROHTO Pharmaceutical Co., Ltd., Osaka, Japan) were used in the current study. This refractive multifocal CL has a far distance zone in the central area of the lens, with a progressive transition zone in the middle area of the lens, and a near distance zone in the peripheral area of the lens (Figure 1). This refractive multifocal CL also has additional power for near distance (+2.50 diopter).

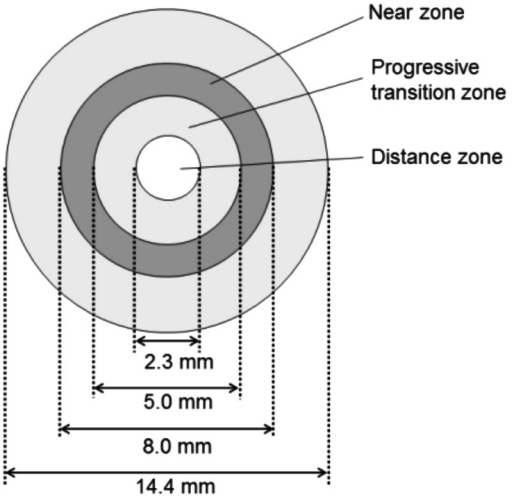

Figure 1 Optical design of the refractive multifocal contact lens (ROHTO i.Q 14 Bifocal D-type) The refractive multifocal CL used in the current study consists of three zones, with distance, progressive transition, and near zones in order from the central to the peripheral zones, respectively. Additional power for near vision is +2.50 diopter.

To paralyze accommodation, 1% cyclopentolate hydrochloride (Cyplegin®, Santen Pharmaceutical Co., Ltd, Osaka, Japan) was used. This eyedrop was instilled three times with 5-min intervals, one drop per-time. CL power was defined by refraction testing using an auto-refractometer at 1h after the initial instillation. Refraction power was measured with the assumption of a 12-mm vertex distance. The vertex distance of the auto-refractometer was converted to 0-mm vertex distance on the corneal surface using the following formula:

$$\text{CL power (D)} = \frac{1}{[1/Refraction\ of\ 12mm\ (D)] - 0.012\ (m)}$$

For example, when corrections were performed for participants who had -4.00 diopter as measured by the auto-refractometer after instillation of cyclopentolate hydrochloride, the CL power was calculated using the following formula:

$$\text{CL power (D)} = \frac{1}{[1/-4\ (D)] - 0.012\ (m)}$$

as -3.82 diopter. The CLs used in the current study are made with 0.25-diopter intervals. Thus, this participant would receive a correction with a -3.75 diopter CL as the closest approximation of the required CL power.

All participants underwent SAP using the 10-2 and 24-2 test point protocol under the following conditions: monofocal CL corrected for near vision (baseline); multifocal CL corrected for distance vision, without additional near correction with a spectacle lens (mCL-D); and mCL-D with additional near correction with a spectacle lens of +3 diopter (mCL-N). The 1-Day ACUVUE (Johnson & Johnson Vision Care, Inc., New Brunswick, NJ) was used as monofocal CL. Although

multifocal CLs used in the current study have an optical design of additional power of +2.50 diopter for near vision, correction for all participants was performed with spectacle lenses of +0.50 diopter for the mCL-D condition.

Primary outcome measures were mean deviation (MD), pattern standard deviation (PSD), and the foveal threshold with each refractive correction. Secondary outcome measures were fixation loss rate, false-positive rate, false-negative rate, test duration, and pupil size after instillation with three refractive corrections.

Participants were excluded from the study if the fixation loss was more than 20% and the FP rate was more than 15%; and if intracranial disorder was suspected based on the visual field test result.

Statistical Analysis All data were analyzed using MedCalc version 16.1 (MedCalc Software, Ostend, Belgium) and G*Power3 version 3.1.7 (Franz Faul, Universität Kiel, Kiel, Germany). Bonferroni tests were used for data comparisons. The Bonferroni-corrected probability values of <0.05 were considered statistically significant. The effect size, α error, power (1−β error), and nonsphericity correction were as follows: 0.25 (middle), 0.05, 0.80, and 0.50, respectively, and the required sample size was 29 participants for three repeated measurements.

RESULTS

One participant was given a false-positive rate >20%. Eventually, 29 eyes of 29 participants were finally analyzed. Table 1 shows the demographic characteristics of the participants included in the current study.

Table 1 Participants' demographic and ocular characteristics

Parameters	Mean±SD	Range
Age (a)	21.8±1.1	20 to 25
Visual acuity (logMAR)	-0.29±0.05	-0.30 to -0.08
Spherical equivalent (diopter)	-2.19±2.64	-6.25 to 2.75
Cylindrical power (diopter)	-0.59±0.37	-1.50 to 0.00
Axial length (mm)	24.47±1.43	21.21 to 27.51
Intraocular pressure (mm Hg)	13.8±2.3	10.0 to 18.3

Visual acuity is given as best corrected visual acuity.

Table 2 shows the parameters for the three refractive corrections. With mCL-N, the foveal threshold decreased significantly by 1.0-2.5 dB in the 24-2 test point protocol (P<0.0001) and by 2.2 dB in the 10-2 test point protocol (P<0.0003), as compared to the baseline and mCL-D values. Although the foveal threshold with mCL-D decreased significantly, by 1.5 dB (P=0.0427), from that of the baseline value with the 24-2 test point protocol, there was no significant difference in the foveal threshold between the baseline and mCL-D with the 10-2 test point protocol. From CL-N, the MD decreased significantly by -1.01 to -1.12 dB with the 24-2 test point protocol (P<0.0038) and by-1.23 to -1.32 dB with the 10-2 test point protocol (P<0.0001), as compared to that for baseline and mCL-D. With both the 24-2 and 10-2 test point protocols, there were no significant differences in the MD between the baseline and mCL-D. The PSD was also not significantly different among the three refractive conditions, for either the 24-2 or the 10-2 test point protocol.

Fixation loss, false-positive, and false-negative values were not significantly different among the three refractive conditions with either the 24-2 or the 10-2 test point protocol. Although the test duration of the mCL-N was significantly longer, by 20.8-24.8s, in the 10-2 test point protocol (P<0.0034), this duration was not significantly different among the three refractive conditions for the 24-2 test point protocol. Furthermore, although the pupil size for mCL-D was significantly larger (by 0.6-0.9 mm) for both the 24-2 and 10-2 test point protocol than that at baseline and mCL-N, there was no significant difference between baseline and mCL-D values.

In two-way repeated measure analysis of variance for the three refractive corrections between the test point protocols, an interaction was found for the foveal threshold (P=0.003) between the 24-2 and 10-2 test protocol, but there were no interactions for the other parameters.

Figures 2 and 3 show representative results with three refractive corrections in the 24-2 and 10-2 test protocol, respectively.

DISCUSSION

In the current study, the MD as determined using both the 24-2 and 10-2 protocols was comparable between the baseline and mCL-D, while the MD of the mCL-N was significantly decreased compared to the baseline and mCL-D values. In previous reports[16-19] that compared patients with diffractive multifocal IOLs or refractive multifocal CLs, and monofocal IOLs or CLs, the MD with diffractive multifocal IOLs or refractive multifocal CLs corrected for distance vision was decreased by approximately -1 to -2 dB as compared to that of the monofocal IOLs or CLs corrected for near vision using the 24-2[16,18] and 10-2 protocols[17], as well as a custom protocol[19]. The difference was thought to be due to pupil dilation induced by the accommodative paralyzing agent and the difference in the refractive optical design, which is dependent on pupil diameter. In the present study, the average pupil diameter after instillation of accommodative paralyzing agent was approximately 8-9 mm. The refractive multifocal CLs used in the present study would be distance-dominant with a small to medium pupil diameter (Figure 1). In such a case, it would theoretically be more appropriate to correct distance vision to near vision using near correction when a domed-shaped perimeter is used. However, with increasing pupil diameter, visual performance tends to be near-dominant, despite the distance correction. Thus, the MD of mCL-N decreased significantly as compared with that of the baseline and mCL-D.

Table 2 Comparison of visual field results among the three refractive correction methods

Parameters	Baseline (A)	mCL-D (B)	mCL-N (C)	*P*		
				A *vs* B	A *vs* C	B *vs* C
24-2 test point protocol						
Mean deviation (dB)	-1.93±1.34	-1.82±1.77	-2.94±1.70	0.2136	0.0038	<0.0001
Pattern standard deviation (dB)	1.66±0.37	1.67±0.79	1.65±0.44	1.0000	1.0000	1.0000
Foveal threshold (dB)	38.3±2.3	36.8±1.6	35.8±2.1	0.0427	<0.0001	<0.0001
Fixation loss (%)	3.2±4.9	4.1±7.7	3.2±5.9	1.0000	1.0000	1.0000
False positive (%)	0.4±0.7	0.4±0.7	0.3±0.5	1.0000	1.0000	1.0000
False negative (%)	0.6±1.1	1.2±2.7	1.4±2.6	1.0000	1.0000	0.6825
Test duration (s)	321.8±79.6	319.7±72.9	330.9±64.8	1.0000	1.0000	0.4293
Pupil size (mm)	8.0±0.5	8.3±0.5	8.9±0.5	0.0597	<0.0001	<0.0001
10-2 test point protocol						
Mean deviation (dB)	-1.50±1.14	-1.59±1.16	-2.82±1.62	1.0000	<0.0001	<0.0001
Pattern standard deviation (dB)	1.33±0.22	1.14±0.21	1.26±0.59	1.0000	0.5167	0.5111
Foveal threshold (dB)	37.2±2.0	37.2±2.0	35.0±2.1	1.0000	0.0003	<0.0001
Fixation loss (%)	3.3±6.5	3.6±5.6	2.7±7.1	1.0000	1.0000	1.0000
False positive (%)	0.4±0.9	0.3±1.0	0.4±0.8	1.0000	1.0000	1.0000
False negative (%)	0.6±2.0	0.5±1.5	0.9±2.3	1.0000	0.7991	0.6825
Test duration (s)	294.2±31.4	298.2±27.8	319.0±39.1	1.0000	0.0034	0.0007
Pupil size (mm)	8.0±0.6	8.3±0.6	8.9±0.6	0.0577	<0.0001	<0.0001

P values adjusted with Bonferroni correction are given. Baseline: Monofocal contact lens (CL) corrected with near distance. mCL-D: Multifocal CL without near correction (distance correction). mCL-N: Multifocal CL and near correction with spectacle lens.

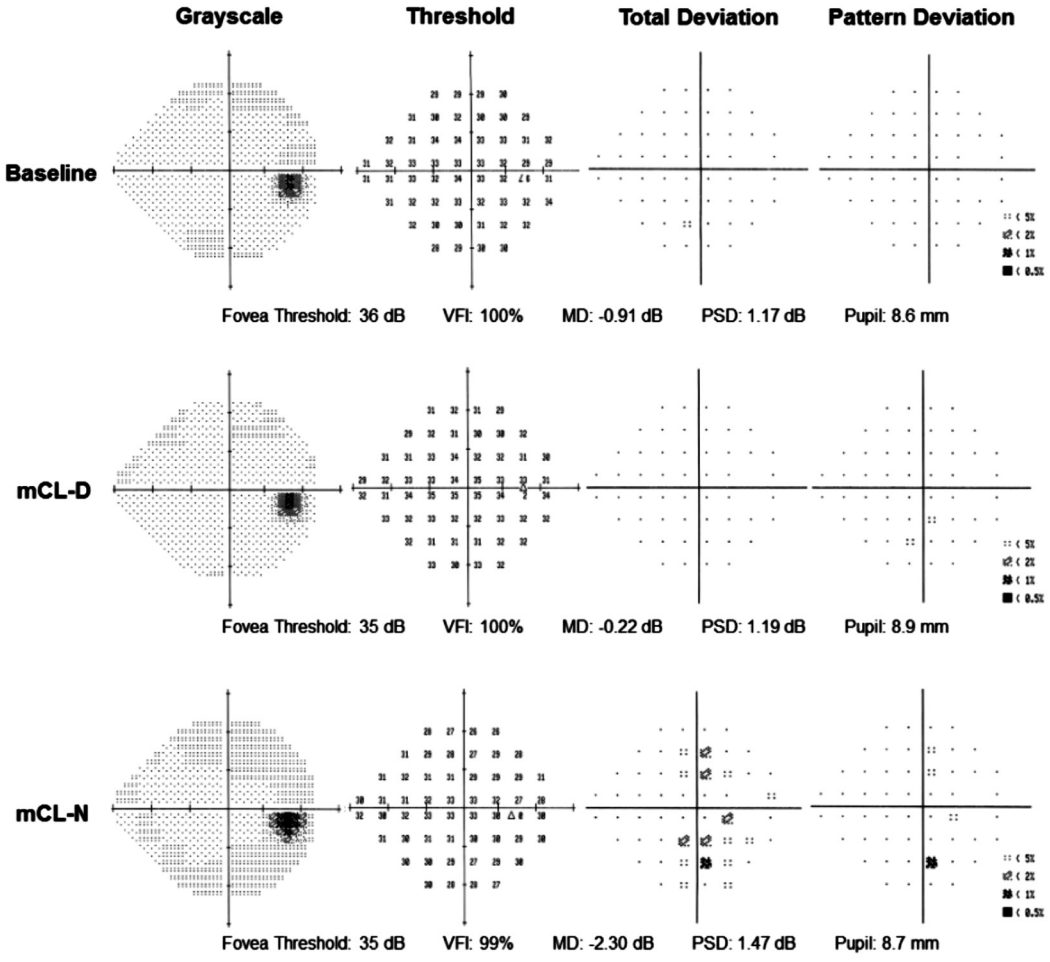

Figure 2 Representative results with three refractive corrections in the 24-2 test protocol Top: The result of monofocal contact lens (CL) corrected for near vision (Baseline). Middle: The result of multifocal CL corrected for distance vision (mCL-D). Bottom: The result of mCL-D and near additional correction by spectacle lens (mCL-N).

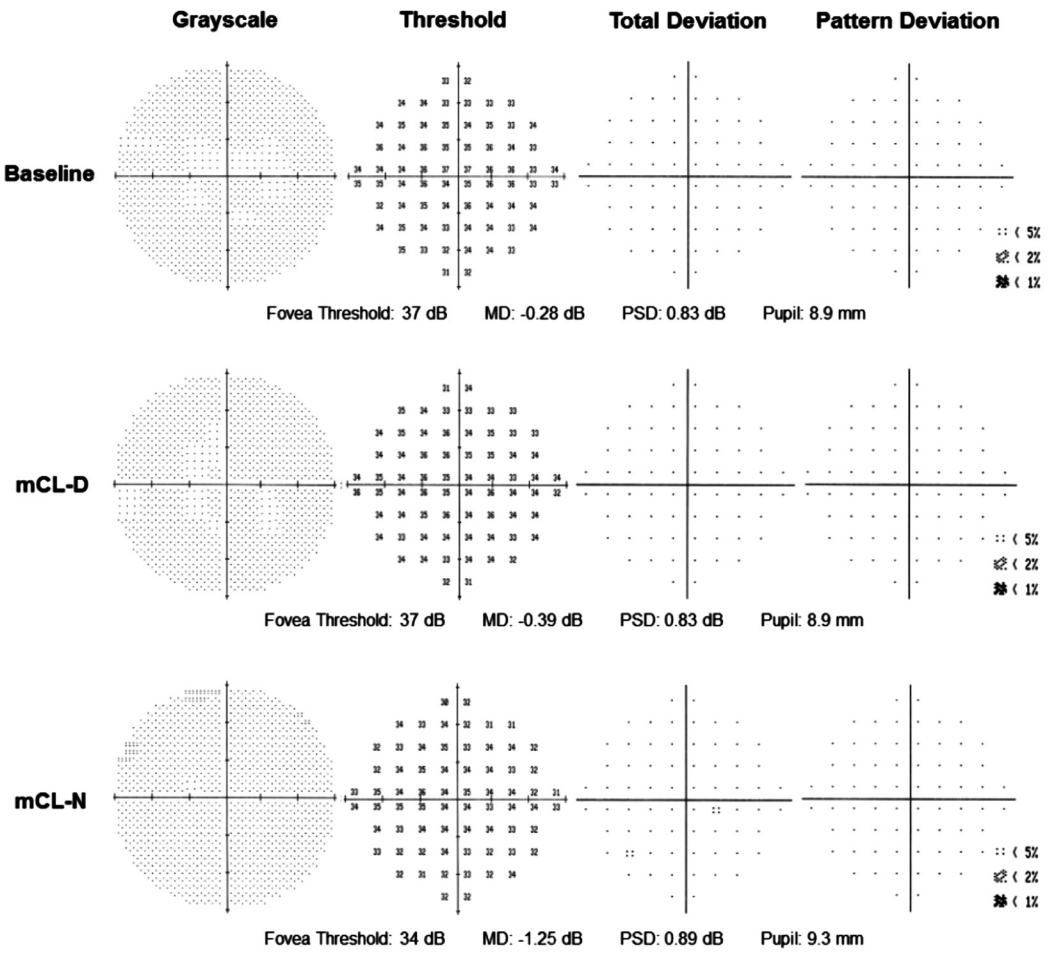

Figure 3 Representative results with three refractive corrections in the 10-2 test protocol Top: The results of monofocal contact lens (CL) corrected for near vision (Baseline). Middle: The result of multifocal CL corrected for distance vision (mCL-D). Bottom: The result of mCL-D and near additional correction by spectacle lens (mCL-N).

The foveal threshold with mCL-N also decreased by approximately 1.0 to 2.5 dB as compared with the baseline and mCL-D, similar to the MD findings. A previous study has reported that the foveal threshold was not significantly different between refractive multifocal CLs corrected for distance and monofocal CL corrected for near vision[19]. As with MD, the decreased foveal threshold of mCL-N may imply that visual performance tended to be near-dominant, even though distance correction is influenced by the optical design of the multifocal CL used in the present study. However, the foveal threshold of mCL-D was significantly decreased with the 24-2 test protocol as compared with that of the baseline. It is highly unlikely that a learning effect occurred, given that the test order was randomized and that only perimetric experienced participants were recruited. In addition, the principle used for measuring the foveal threshold with both the 24-2 and 10-2 test protocols was the same. It is therefore highly unlikely that the foveal threshold of mCL-D decreased as compared with Baseline only with the 24-2 protocol, but we were unable to clarify the reason for this finding.

The pupil diameter for mCL-N was slightly larger than that for both the mCL-D and baseline. Although all participants underwent perimetric measurement using a random order of each refractive condition at 1h after instillation of a cyclopentolate hydrochloride agent, it is highly unlikely that the effect of the cyclopentolate hydrochloride and measurement order could be attributed to pupil diameter. It is more likely to be due to the effect of the shape of the spectacle lens of +3.00 diopter used for the mCL-N.

The test duration of the mCL-N was significantly longer, by 20.8-24.8s, in the 10-2 test point protocol. Although MD with mCL-N was almost the same in both the 24-2 and 10-2 test protocol, MDs with Baseline and mCL-D in the 10-2 test protocol tended to slightly better than those in the 24-2 protocol. Clinically, test time increases as visual field sensitivity decreases; hence, it is likely that the difference in visual field sensitivity affected test duration.

With the refractive multifocal CLs used in the current study, as pupil diameter increased, light directed to the near zone increased and visual performance tended to be near-dominant. In contrast, for refractive or diffractive multifocal IOLs[2,12] and refractive multifocal CLs[18], more light was directed at

the distance zone, so that visual performance tended to be distance-dominant. Although a previous study comparing refractive multifocal IOLs (Array, AMO, Santa Ana, CA, USA) and monofocal IOLs (SI40NB, AMO) reported that contrast sensitivity in the near photopic and mesopic conditions was reduced with refractive multifocal IOLs, the contrast sensitivity of multifocal IOLs with near correction yielded better results than multifocal IOLs with distance correction. Although some diffractive multifocal IOLs (Tecnis Multifocal, AMO, Abbott Medical Optics, Santa Ana, CA, USA) are less affected by changes in the pupil size, because theoretically, the light directed at the distance and near zones are equal in both miosis and mydriasis, other types of diffractive multifocal IOL (SI40N, AMO or SA60D3, Alcon) tend to be distance-dominant in mydriasis[2]. Therefore, refractive correction should be performed with care; the combination of the optical design of the lens and pupil size should be considered when administering the dome-shaped visual field test with refractive multifocal IOLs and CLs. However, the present study did not investigate these issues in detail and further studies should determine whether retinal sensitivity changes with near correction in eyes with diffractive multifocal IOLs.

This study has some limitations. First, the accommodative paralyzing agent that was used to replicate the multifocal IOL induced mydriasis of approximately 8-9 mm and thus the present study was not performed in the context of a natural or small pupil size. Second, the multifocal CL used in the present study had a refractive, rather than a diffractive design, which is commonly used in a clinical setting. Moreover, this study was performed with eyes with multifocal CLs, rather than multifocal IOLs. Third, neuroadaptation of approximately 6mo[27] are needed to obtain better SAP results with multifocal CLs.

In summary, despite the mydriasis induced by cyclopentolate hydrochloride and the optical design of the multifocal lens used in this study, our results indicate that, when the dome-shaped visual field test is performed with eyes with large pupils and wearing refractive multifocal CLs, distance correction without additional near correction is recommended.

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