Visual Performance as a Function of Clear Central Aperture Diameter with a Defocused Myopic Periphery

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SIGNIFICANCE: Visual performance is affected least by a 15° radial aperture surrounded by peripheral myopic defocus. This finding has important applications for spectacle and contact lens designs and myopia control optimization.

PURPOSE: The purpose of this study was to assess the effect of clear central apertures of different diameters with a defocused retinal periphery, using a range of visual performance tasks.

METHODS: Thirty visually normal subjects (mean age, 24.4 ± 3.3 years; 20 females; mean spherical equivalent of −1.28 D) were enrolled. Subjects wore five different spectacles during testing, all corrected for distance refraction, in random order: three single-vision spectacles with clear central apertures of 10, 12.5, and 15° radii with the periphery defocused using Fresnel "press-on" lenses (+3.5 D sphere), progressive addition lens (PAL) spectacles with a +3.5 D addition, and single-vision lens (SVL) spectacles with no peripheral defocus. Static and kinetic visual field sensitivities, reading rate and comprehension, head movements, global saccadic tracking, and saccadic visual search were evaluated.

RESULTS: Reading rate and comprehension did not differ across the five test conditions; however, increased head movement was found with the smallest aperture compared with the PAL condition with adjusted $P < .05$. Static visual field sensitivity was reduced for all three apertures in eccentric regions when compared with the SVL and PAL conditions with adjusted $P < .05$, whereas kinetic sensitivity did not differ for any lens condition. The 15° aperture was superior to the 10 and 12.5° apertures based on its similarity to the SVL and PAL spectacle conditions in head movement during reading, the Michigan Tracking Test, and the vertical results of the Developmental Eye Movement Test.

CONCLUSIONS: Visual performance is least affected adversely by a 15° aperture surrounded by a peripheral myopic defocus. This finding has important applications for spectacle and contact lens designs to optimize myopia treatment with minimal impact on visual performance.

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With the profound rise in myopia in many parts of the world,[1] there is significant research interest in designing, modifying, and customizing treatment paradigms. One of the most widely used experimental and clinical approaches to the control of myopia progression is peripheral myopic defocus.[2–4] Myopic defocus, in which light focuses in front of the retina, has been demonstrated to inhibit ocular elongation, thus reducing the dioptric progression of myopia. Moreover, animal studies have shown that peripheral myopic defocus affects these biological mechanisms even more robustly than central retinal myopic defocus.[2,5] Recent human clinical trials have unequivocally shown that the principle of peripheral myopic defocus is effective in reducing the progression of refractive error and is acceptable for use in clinical patients.[3,4,6,7]

Furthermore, commercially available spectacles and contact lenses that use this strategy are designed with a central "clear focus zone" for the refractive correction with uninterrupted distance and near vision, as well as a peripheral treatment zone that provides myopic defocus on the retina. The current method of creating a defocused periphery is based on multifocal refraction. For example, executive bifocal lenses are designed to produce defocus in the inferior visual field with uniform plus power,[8] whereas progressive addition lenses have a continuous increase in plus power in a portion of the inferior field with a typical progressive addition of +2.00 D or lower corridor[9,10]; MiSight lenses (CooperVision, Inc., Pleasanton, CA) have an alternating +2.00 D annular dual-focus design[4]; and Defocus Incorporated Multiple Segments (MyoSmart; Hoya Corporation, Tokyo, Japan) spectacles have +3.5 D lenslets in all directions from the central clear aperture.[3]

In our pursuit of a new myopia control spectacle design with a myopically defocused periphery, it was important to evaluate the effectiveness and practicality of various central aperture diameters, which have not been established yet. One important design aspect for which evidence is lacking is determination of the most appropriate central, clear distance zone in myopia control spectacles. There is a range of different central aperture sizes among the various devices currently available for myopia control, but data as to which aperture size is optimal for retention of good visual performance are lacking. For example, studies conducted with Defocus Incorporated Multiple Segments spectacles used a 12.5° region of clear distance vision. The MiSight contact lens and the Zeiss MyoVision (Carl Zeiss Vision GmbH, Wetzlar, Germany) progressive addition lens series used clear central apertures ranging from approximately 8 to 35°, respectively.[3,7,10] The assessment of visual performance in the literature, using spectacles and contact lenses with peripheral defocus, has included peripheral refraction,[11] aberration profiles of the periphery,[12–14] and visual acuity assessment under various illumination conditions,[6] which does not cover other essential aspects of visual performance such as reading.

It is also important to quantify how subjects perform various daily tasks with these optical devices. The performance of peripherally defocused myopia control devices in terms of visual field sensitivity/peripheral awareness, reading rate and comprehension, and global saccadic tracking has not been reported to date. These visual tasks have real-life implications during reading, writing, studying, and other activities of daily life. The size of the clear central aperture should not only be effective and practical in diameter so as not to inhibit visual performance, but it should also be minimal to optimize the area of the peripheral retina being defocused, because of the local nature of the myopia control effect.[2] Therefore, our aim in the study was to evaluate visual performance with three different, clear aperture radii of 10, 12.5, and 15° in width with defocused periphery as compared with single-vision and progressive addition lenses. An optimal clear central aperture size would lead to the most efficacious therapeutic effects for myopia control by minimizing any adverse impact on visual performance, enhancing patient satisfaction, and therefore increasing adherence to therapeutic spectacles and devices.

METHODS

Thirty visually normal and healthy individuals participated in the study. The ages of participants ranged from 19 to 31 years (mean age, 24.4 ± 3.3 years). The male-to-female ratio was 1:2. Seventy-five percent of the participants were Asian, 20% were White, and 5% were "other/mixed." Their spherical refractive component ranged from 0 to –4.00 D spherical equivalent, with a mean of –1.28 D, with a refractive cylinder ≤0.75 diopter cylinder in each eye. The best-corrected visual acuity was $20/20^{-3}$ in each eye. Exclusion criteria included the following: a history of severe dry eye, a history of strabismus and/or amblyopia, any systemic or infectious conditions or allergies that might interfere with participation, use of systemic or ocular medications known to interfere with vision and/or accommodation, previous ocular surgery or orthokeratology, current myopia control therapy, and current pregnancy or lactation. The study adhered to the tenets of the Declaration of Helsinki, and all subjects signed the written informed consent document after review of our study by an independent institutional review board (Sterling IRB, Atlanta, GA) before participating. They then received a standard optometric examination that included refractive, binocular, and ocular health status.[15]

Subjects wore five different spectacles during testing, all corrected for distance refraction, in random order without any adaptation time. The spectacle conditions with the Fresnel lenses were masked to the subjects. These included three single-vision spectacles with clear central apertures of 10, 12.5, and 15° radii before both eyes, with the periphery defocused using Fresnel "press-on" lenses (+3.5 D sphere; 3M Health Care, Bloomington, MN); progressive addition lens spectacles with a +3.5 D addition; and single-vision lens spectacles without peripheral defocus, thus serving as both the control and comparison conditions. The angular subtense of the Fresnel apertures was calculated to the nodal point of the eye using a Gullstrand model schematic eye. The vertex distance was 13 mm (spectacle plane). The frames for all test conditions were identical for each subject. This maintained similar vertex distances and fits across all test conditions. The linear dimensions of the Fresnel lens aperture radii were 7.5 mm (10°), 9.0 mm (12.5°), and 11.5 mm (15°).

From the multiple methods available for adding myopic defocus in the periphery, we decided to use the press-on Fresnel lenses. Central holes corresponding to 10, 12.5, and 15° at the spectacle plane (vertex distance, 13 mm) were cut out using a custom punch tool aided by a ton press on a cutting mat. The advantage of using a Fresnel lens is the ease of centering the apertures and aligning them with the monocular distance pupillary diameter, as compared with drilling central holes in the spectacle lenses as performed in an earlier study.[16] Furthermore, it would have been more difficult to correct for distance refraction with the latter technique. We measured the profile of the Fresnel lens with the Sensofar (Sensofar Metrology, Langen, Hesse, Germany) profilometer. Using a Zemax (Zemax LLC, Kirkland, WA) spherical model and material properties from the Fresnel lens data sheet, the drop in modulus of the modulation transfer function at a 15° field of view for 20 cycles per millimeter, or 8 cycles per degree, compared with a standard lens was found to be 0.5 for sagittal and 0.4 for tangential. The Fresnel lenses that were applied to the front surface of the test spectacles extended to the rim of the frame.

The following tests were performed by the subjects:

(1) Reading Eye Movements: This was performed using the video-based, binocular, 2D RightEye system (RightEye, Bethesda, MD), which provides objective recordings of the actual reading eye movements and automatically quantifies several key parameters. Subjects were seated with the test apparatus at a standard distance of 56 cm from the midline-positioned computer screen, which was calibrated for each test condition and which displayed each of the validated 100-word, adult-level test paragraphs. Subjects were instructed to read the standard text as they would normally and were informed that there would be a simple 10-question true or false comprehension test afterward. We also informed the subjects that, while reading, their eye movements would continuously be tracked. The parameters assessed were reading rate (words per minute), comprehension (percent correct for the 10 prescribed questions), head movement (percent movement compared with total test time), and regression/fixation ratio. Each subject read a different adult-level paragraph for each lens combination presented in random order.

(2) Developmental Eye Movement Test (Bernell, Mishawaka, IN): This is a test that assesses predictable, binocular saccadic tracking with the concept of automaticity embedded.[17,18] The subject tracked and called aloud each random single-digit number in sequence, as per the instructions. The time taken to complete the horizontal and vertical columns of numbers was scored, with adjustments made for errors and omissions.

(3) Michigan Tracking Test (Ann Arbor Publishing, Ann Arbor, MI): This is a binocular visual search test and identification task, which assesses sequential saccadic tracking.[19] The subject was presented with seven rows of randomized letters of the alphabet. The task was to search for the 26 letters in alphabetical order in a left-to-right direction and to cross off each letter in turn. Accuracy, speed, and little to no head movement were stressed. The time to completion of the test (in seconds) was scored, with adjustments made for errors and omissions.

(4) Monocular Visual Field Sensitivity: This was performed using a Humphrey Visual Field Analyzer III (Zeiss Medical Technology, Dublin, CA). The test stimulus was a 4-mm^2 white target of 318 cd/m^2 luminance (III4e) presented against a uniform background of 10 cd/m^2 luminance. For static testing, the 30° full threshold was determined for the right eye, with the

TABLE 1. Summary of reading and comprehension parameters

Parameters	10°	12.5°	15°	Progressive addition lens	Single-vision lens
Reading speed (wpm)	144.1 (123.7–164.5)	142.7 (121.3–164.1)	140.2 (117.3–163.1)	146.8 (122.0–171.6)	145.3 (120.9–169.7)
Comprehension (% correct)	88.5 (84.42–92.58)	88.5 (84.60–92.40)	90.5 (86.36–94.64)	88.0 (83.36–92.64)	91.0 (85.78–96.22)
Head movement (%)	0.079 (0.066–0.091)*	0.076 (0.062–0.090)	0.064 (0.049–0.079)	0.059 (0.045–0.072)	0.067 (0.053–0.081)
Regression/fixation ratio (%)	22.80 (24.41–24.20)*†	24.06 (22.37–25.74)*†	24.44 (22.65–26.22)*†	19.84 (18.23–21.42)	20.23 (18.89–21.57)

Shown here are the means (95% confidence intervals) of reading speed (wpm), comprehension (%), head movement (%), and regression/fixation ratio (%).*Significant difference from the progressive addition lens condition, following the Tukey test ($P < .05$). †Significant difference from the single-vision lens condition, following the Tukey test ($P < .05$). wpm = words per minute.

left eye fully occluded. Sensitivity was assessed in the superior, temporal, inferior, and nasal directions along the major axes at 10° intervals up to 30° in radius, as well as centrally at the fovea. All test sessions were within the clinical standard limits for fixation losses (<20%) and false-positive and false-negative errors (i.e., <33% each).[20] All three points corresponding to the 10, 20, and 30° of retinal eccentricity for a given meridian were averaged in the analysis. For kinetic testing, sensitivity was again assessed at the horizontal and vertical meridians, with the target displaced slowly at a rate of 5° per second, until it was first perceived by the right eye. For temporal and nasal approaches, the target moved inward starting at 80° of eccentricity. For superior and inferior approaches, the target moved inward starting at 40 and 60° of eccentricity, respectively, until it was first perceived.

Statistical Analysis

Normality of the data was tested using the Shapiro-Wilk test and Q-Q plot for satisfactory agreement between the actual and predicted results. Furthermore, Mauchly test was done to verify the sphericity of data, which was significant for all the comparisons. Simple correlation using the Prism Graphpad (Graphpad Software, San Diego, CA) to find if the comparisons were matched effectively was performed. A repeated-measures one-way ANOVA was then done, followed by a Tukey post hoc test. $P < .05$ was considered significant.

RESULTS

Table 1 presents the results for the reading task. It shows reading rate, comprehension, head movement, and regression/fixation ratio across the five spectacle configurations. No significant differences were found in reading rate and comprehension. There was significantly less head movement with the progressive addition lenses than with the 10° radial aperture during the reading task. Head movement with the 12.5 and 15° apertures was not significantly different from either the progressive addition lens or single-vision lens conditions. The subjects made significantly more regressions with all three aperture conditions, as compared with

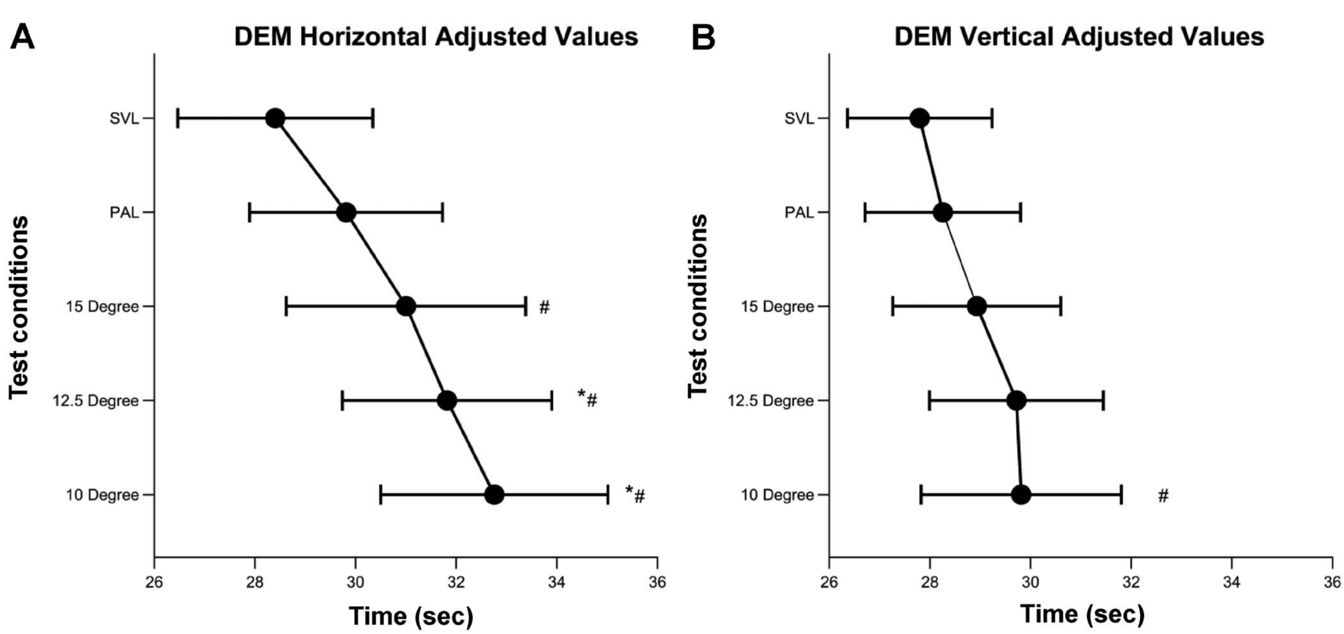

FIGURE 1. (A and B) Horizontal and vertical adjusted scores (mean ± 95% confidence interval) for five different test conditions. *Significant difference from the progressive addition lens condition, after the Tukey test ($P < .05$). #Significant difference from the single-vision lens condition, following the Tukey test ($P < .05$).

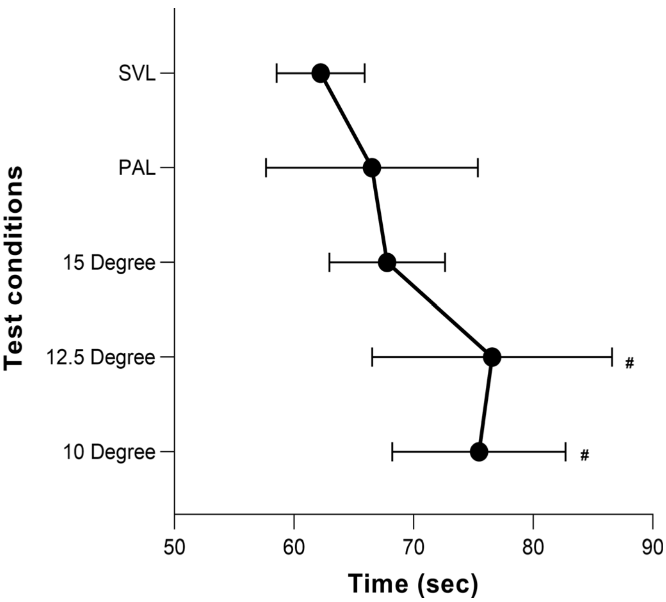

FIGURE 2. Completion time (mean ± 95% confidence interval) for the Michigan Tracking Test under five different test conditions. *Significant difference from the progressive addition lens condition, following the Tukey test ($P < .05$). #Significant difference from the single-vision lens condition, following the Tukey test ($P < .05$).

either the progressive addition lenses or single-vision lens test conditions.

Fig. 1 presents the Developmental Eye Movement Test findings. Fig. 1A shows that completion time for the horizontal Developmental Eye Movement Test component using each of the three apertures was significantly greater than that found using either the progressive addition lenses or single-vision spectacle lenses. Fig. 1B shows that the completion time for the vertical Developmental Eye Movement Test component using the 10° aperture was significantly greater than that found for the single-vision lens condition. In contrast, the 12.5 and 15° findings were not significantly different from either the progressive addition lens or single-vision lens conditions.

Fig. 2 presents the results of the Michigan Tracking Test. The 10 and 12.5° aperture completion times were significantly longer than those for the single-vision lens condition. However, the 15° aperture times were not significantly different from either the progressive addition lens or single-vision lens test findings.

Table 2 presents the static visual field sensitivity results. For each eccentric retinal field tested, all three apertures typically exhibited reduced sensitivities when compared with either the progressive addition lens or single-vision lens results. In the inferior field, the progressive addition lenses produced significantly reduced sensitivity as compared with the single-vision lens findings. Lastly, at the central foveal region, there were no significant differences across spectacle conditions.

Table 3 presents the kinetic visual field sensitivity findings. No significant differences were found in any of the test conditions.

DISCUSSION

Visual performance with myopia control devices designed with a clear center and myopically defocused periphery has been studied in the literature, especially in contact lens form (multifocal and ortho-K). These investigations have included the assessment of peripheral refraction with various lens types,[21,22] aberration profiles in the periphery,[11,12] questionnaires, and visual acuity assessment under different illumination conditions.[6] Myopia control device design and customization are evolving areas of research with various parameters yet to be decided, such as the optimal width of the clear center, the dioptric power of the peripheral treatment zone, and the extent of the treatment zone in the periphery. The present study aimed to assess the optimal aperture of the central clear zone. The current commercially available diameter range of the clear central diameters varies from approximately 8° in contact lens–based devices to up to 35° in spectacle lens–based devices (excluding bifocals).[4,10]

To address this problem, we first had to decide upon the width of the minimum aperture. We chose a 10° radial aperture for two main reasons: the first being the importance of the fovea and perifovea for all central visual functions (e.g., reading), which subtends about 8 to 9° of central field,[23,24] and the other reason being that the myopia control effect remained intact when 10 to 12° of central retina was ablated and peripheral defocus was applied in monkeys.[2,5]

We decided on the dioptric power of the peripheral defocus based on an earlier pilot study, in which we found that +3.50 D produced the largest increase in relative choroidal thickness, and it correlated with a relative reduction in axial length, during 4 hours of full-field defocus, as compared with +2.00 and +5.00 D.[25]

Two pairs of control spectacles were used in this study. One was the single-vision lenses without any defocus present, and the other was the progressive addition lenses that have distortions in most regions of the peripheral visual field, which is similar to the Fresnel lenses. Although most studies have used progressive addition lenses with +2.00 D or lower additions,[9,26] a +3.50 D addition was used to compare the visual function results with the spectacle conditions incorporating a +3.50 D Fresnel overlay and a range of central apertures. Because the design of the study did not allow

TABLE 2. Static visual field sensitivity in different areas of the visual field

Region of the visual field	10°	12.5°	15°	Progressive addition lens	Single-vision lens
Nasal	28.20 (27.74–28.66)*†	28.47 (27.98–28.96)*†	28.40 (27.86–28.94)*†	30.76 (30.29–31.22)	30.38 (29.95–30.81)
Superior	25.58 (24.68–26.47)*†	25.95 (25.39–26.52)*†	25.35 (23.95–26.76)*†	28.16 (27.44–28.87)	28.08 (27.1–29.06)
Temporal	29.38 (28.53–30.23)*†	29.64 (29.2–30.09)*†	29.42 (29.02–29.82)*†	31.38 (30.97–31.79)	30.89 (30.45–31.32)
Inferior	26.80 (26.24–27.36)*†	27.49 (26.98–28.00)*†	27.42 (26.99–27.85)*†	28.96 (28.47–29.44)†	29.82 (29.25–30.39)
Central	33.60 (32.79–34.41)	33.63 (32.86–34.41)	34.17 (33.47–34.87)	33.83 (32.94–34.73)	34.5 (33.77–35.23)

Shown here are the means (95% confidence intervals) of average visual field sensitivity in decibels (dB) for all test conditions. *Significant difference from the progressive addition lens condition, following the Tukey test ($P < .05$). †Significant difference from the single-vision lens condition, following the Tukey test ($P < .05$).

TABLE 3. Kinetic visual field sensitivity in different areas of the visual field

Region of the visual field	10°	12.5°	15°	Progressive addition lens	Single-vision lens
Superior	36.03 (35.17–36.90)	36.17 (35.35–36.98)	35.67 (34.50–36.84)	36.77 (35.94–37.60)	36.70 (35.84–37.56)
Nasal	53.00 (50.48–55.52)	54.73 (52.44–57.02)	52.83 (50.83–54.84)	53.30 (51.40–55.20)	55.60 (54.14–57.06)
Inferior	56.77 (55.90–57.64)	56.00 (54.81–57.19)	56.53 (55.81–57.26)	56.73 (55.33–58.14)	57.87 (57.68–58.06)
Temporal	75.20 (72.86–77.54)	75.03 (72.87–77.20)	75.80 (73.83–77.77)	74.30 (70.91–77.69)	75.47 (72.64–78.30)

Shown here are the means (95% confidence intervals) of kinetic visual field sensitivity in degrees for all test conditions. (None of the parameters were significantly different from each other).

for a significant adaptation time (which may be different for each test condition even for the same individual), randomization of test conditions was performed to reduce any subsequent bias.

Reading through the apertures with a defocused periphery was significantly more difficult for the subjects. This was evident by the higher regression/fixation ratio for all three aperture conditions as compared with that found for either the progressive addition or single-vision lenses. More regressions meant that the subjects were rereading the text more, likely because of the limited perceptual span with the defocused periphery. In addition, light scattering in the periphery, along with the prismatic effect around the edges of the apertures, could have affected the normal integration of information occurring across saccades.[24] The RightEye instrument did not allow us to measure the amplitude of the regressions, which could have illuminated the specifics of the challenges experienced by the subjects.[27] However, the increase in number of regressions did not translate to lower comprehension scores, with no significant differences found among the test conditions in either reading rate or comprehension. Head movements during reading with the RightEye system increased with decreasing aperture size, as expected, with only the 10° aperture showing a statistically significant difference as compared with the progressive addition lens condition. Based on the statistical significance and spread of the data (95% confidence interval of the mean), the 15° aperture results reflected a head movement percentage similar to that observed with the progressive addition lenses and single-vision lenses. In addition, the adjusted Developmental Eye Movement Test scores and Michigan Tracking Test results showed similar findings, with the 10° aperture performance being the worst and the 15° aperture being comparable with the progressive addition lenses.

The static visual field sensitivities were significantly reduced in all meridians for all test conditions presumably because of defocus effects and Fresnel lens modulation transfer function characteristics. The mean sensitivity values were 1.2 to 3.0 dB lower in the four meridians (approximately 10 to 50% reduction) as compared with the single-vision lens and progressive addition lens conditions; similar reductions have been reported in the literature.[28] In addition, there was no difference in kinetic visual field sensitivity between test conditions. The same stimulus (III4e) spot moving at a near optimal speed of 5° per second was used for the kinetic testing.[29] The background was maintained at 31.5 apostilbs (10 cd/m^2); hence, no obvious changes in pupil sizes were expected between the static and kinetic conditions. This shows that a defocused periphery results in a decreased level of detection and recognition of visual acuity in the periphery,[6,28] yet it still does not significantly deteriorate kinetic visual acuity presumably because of the motion aspect. However, with a smaller and dimmer target, the results may be different. This is of great importance for safety factors related to peripheral defocus, as reducing vision in the mid to far periphery can have an adverse effect on peripheral awareness and navigation.[30]

One reason for the preservation of kinetic visual field sensitivity may be that the +3.50 D defocus is within the depth of focus in terms of blur sensitivity in the peripheral retina beyond 30 to 40°.[28] The human eye can sense and respond reflexively to as little as 0.1 D of defocus at the fovea.[31] This high degree of visual sensitivity reduces with retinal eccentricity,[32] presumably because of the continuous decrease in retinal cone density.[33] For example, at the fovea, the total depth of focus is 0.9 D, whereas, at 15° of eccentricity, it is approximately 5 D for a 100% subjective threshold criterion. Thus, for defocus amounts less than the depth of focus, there will be no sensation of blur but rather reduced target contrast.

In conclusion, the 15° aperture was superior to the 10 and 12.5° apertures based on its similarity in results as compared with those of progressive addition lens and single-vision lens conditions in the areas of head movement during reading, the vertical Developmental Eye Movement Test, and the Michigan Tracking Test. The present findings are important for myopia control paradigms exploring the effect of peripheral retinal defocus on eye growth. This study provides critical information to optimize the robustness of myopic treatment with minimal adverse impact on the basic aspects of visual performance.

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