

Peripheral Refraction and Contrast Sensitivity Detection in Pseudophakic Patients Implanted With a New Meniscus Intraocular Lens

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ABSTRACT

PURPOSE: To evaluate peripheral refraction and contrast sensitivity detection in pseudophakic patients implanted with a new type of inverted meniscus intraocular lens (IOL) (Art25; Voptica SL) that was designed to provide better peripheral optics.

METHODS: One month after cataract surgery, in 87 eyes implanted with the Art25 IOL, peripheral contrast sensitivity detection was measured psychophysically at 40° visual angle, both horizontally and vertically, and compared with a control group of 51 eyes implanted with standard biconvex IOLs. Thirty-one eyes with the Art25 IOL and 28 eyes from the control group were randomly selected to also measure peripheral refraction using a scanning Hartmann-Shack wavefront sensor along 80° in the horizontal meridian.

RESULTS: Most patients achieved emmetropia and good visual acuity, and no significant adverse events were observed after cataract surgery with Art25 IOLs. Peripheral contrast sensitivity detection was significantly better ($P < .01$) in the group with the Art25 IOL in both directions (7.78 ± 3.24 vs 5.74 ± 2.60 vertical, 10.98 ± 5.09 vs 7.47 ± 3.96 horizontal), which was in agreement with the optical quality improvement in the periphery due to a reduction of defocus (1.97 and 1.21 diopters [D] at 40° temporal and nasal sides) and astigmatism (1.17 and 0.37 D at 40° temporal and nasal sides) that was statistically significant ($P < .01$) from 20° of eccentricity.

CONCLUSIONS: Patients implanted with a new inverted meniscus IOL present a reduced amount of peripheral defocus and astigmatism compared to patients implanted with standard biconvex IOLs. This improvement in optical quality leads to better contrast sensitivity detection measured at 40° of eccentricity.

[J Refract Surg. 20XX;X(X):XX-XX.]

In recent decades, the most advanced monofocal designs of pseudophakic intraocular lenses (IOLs) have been aimed to compensate partially or totally for the spherical aberration present in the cornea^{1,2} to recover values of young eyes or to remove this aberration in eyes that have had surgery.^{3,4} To achieve both the appropriate dioptric power and the value of spherical aberration of each lens, all current IOL designs are

based on biconvex shapes and aspheric surfaces. Traditional procedures to design IOLs only consider the image quality on-axis to optimize visual performance in the center of the visual field,⁵ overlooking their off-axis performance. However, despite the lower spatial resolution, peripheral vision plays an important role in the patient's spatial orientation and in global visual performance, because it provides a large visual field

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Submitted: July 27, 2021; Accepted: December 21, 2021

Supported by grants from Agencia Estatal de Investigación (Spain) (PID2019-105684RB-I00/AEI/10.13039/501100011033); Fundación Séneca-Agencia de Ciencia y Tecnología de la Región de Murcia (#19897/GERM/15); and the European Regional Development Fund (#EU-FEDER).

Disclosure: The authors have no financial or proprietary interest in the materials presented herein.

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doi:10.3928/1081597X-20220113-01

with a high temporal resolution and an extraordinary ability to detect movements. Peripheral vision is essential in the control of posture^{6,7} and in detecting rapidly moving objects to prevent dangerous situations such as falls⁸ or driving hazards.^{9,10}

In a previous study,¹¹ it was shown that pseudophakic eyes implanted with standard monofocal IOLs had a significantly worse image quality in the periphery than healthy older eyes. This was mainly due to higher values of peripheral defocus and astigmatism, which may lead to a significant reduction of contrast sensitivity detection.¹² This deterioration of peripheral performance could limit the desirable reduction in the incidence of falls after cataract surgery with implantation of standard IOLs^{13,14} and cause other issues affecting normal activities.

In this context, we developed a new pseudophakic monofocal IOL specifically designed to improve off-axis optical quality while providing similar quality as standard IOLs on-axis. This new type of IOL, commercially available in Europe (Art25-ArtIOL; Voptica SL), is an inverted meniscus aspherical lens with the convex surface facing the retina. We studied the optical and clinical efficacy of this new IOL evaluating postoperative residual refractive errors at the fovea and along $\pm 40^\circ$ in the horizontal peripheral retina and contrast sensitivity detection thresholds at 40° at both the inferior and horizontal retina.

PATIENTS AND METHODS

SETTING AND PATIENTS

Art25 IOLs were implanted in 87 eyes (48 right and 39 left eyes) of 62 patients with ages ranging between 53 and 90 years (mean: 71.4 ± 7.9 years) (Art25 group), and 51 eyes (26 right and 25 left eyes) of 34 patients with ages ranging between 56 and 88 years (mean: 69.9 ± 6.4 years) were implanted with the same model of standard monofocal IOL (control group).

Clinical examinations and surgeries were performed in three ophthalmology clinics (Oftalvist) in Spain beginning in February 2020. **AQ1** After receiving an explanation of the nature and possible consequences of the surgery, all patients provided informed consent. The University of Murcia Ethics Committee approved this study, which followed the tenets of the Declaration of Helsinki.

Inclusion criteria comprised no current ocular pathology, no history of ocular surgery, astigmatism of 1.50 diopters (D) or less, and not using ocular drugs that may affect vision.

From optical biometric measurements with the IOL-Master 700 (Carl Zeiss Meditec), IOL power was estimated using the SRKT formula, targeting a postoperative refraction of emmetropia. The following tests were

performed at 1 month after cataract surgery: subjective refraction, corrected distance visual acuity (CDVA), uncorrected distance visual acuity (UDVA), slit-lamp biomicroscopy, intraocular pressure, corneal topography, and retinography. Visual acuity was measured using letter charts displayed at 5 m by the projector ACP-8 (Topcon Corporation). Peripheral measurements were also performed to compare the optical and visual performance between the Art25 IOL and control groups.

IOLS AND SURGERY

The Art25-ArtIOL (device CE-marked from April 2019) is a hydrophobic acrylic IOL designed to provide a good optical quality in a visual field of $\pm 40^\circ$. It is a single-piece foldable lens with aspheric surfaces and an inverted meniscus shape, the convex surface facing the retina. It was designed¹⁵ to reproduce the natural imaging properties of the crystalline lens, which minimizes the peripheral refractive errors in a wide visual field.¹¹ Peripheral defocus was defined as the difference between the three-dimensional surface formed by the image points, also called field curvature, and the shape of the retina. The shapes of the surfaces of the IOL were balanced to match the field curvature of the ocular optics to the shape of the retina while reducing peripheral astigmatism. For each IOL power, the design procedure consisted of seeking the optimum combination between both surfaces to minimize the ocular values of peripheral refractive errors, both defocus, expressed as spherical equivalent (SE), and cylinder, using a wide-angle schematic eye model.¹⁶

Figure 1 shows a ray-tracing simulation, with an off-axis object, through a schematic eye with a natural lens in comparison with a standard biconvex IOL and an Art25 IOL. The model of the IOL implanted in the control group was a foldable single-piece hydrophobic acrylic lens with a standard design based on aspherical biconvex optics.

Both Art25 and control IOLs were implanted using standard surgical techniques for phacoemulsification extracapsular-type cataract extraction with a corneal incision of 2.2 mm and a capsulorhexis of 5.5 mm.

PERIPHERAL VISUAL AND OPTICAL MEASUREMENTS

The peripheral contrast sensitivity detection was estimated by measuring a psychometric parameter, which consists of the luminance difference threshold to detect a circle in the center of a monitor while maintaining gaze at a peripheral fixation target. Despite the contrast sensitivity being commonly measured using sinusoidal gratings with different frequencies, this method was not appropriate for our clinical testing because sinusoidal gratings above 3 c/° are not detected in eccentricities greater than 30° . For these values of mild eccentricity, between 30° and 50° , the maximum value of contrast

sensitivity^{17,18} is achieved approximately 1 c/°, equivalent in size to a fringe subtending 0.5°.

The patient was seated 1 m from an LCD monitor and the tested eye was positioned in front of the circle subtending 0.5° without wearing any optical correction. The luminance response of the monitor was calibrated to be linear, ranging from 0 to 200 cd/m² in steps of 0.9 cd/m². In the first measurement, the circle and the background were presented with the same luminance (200 cd/m²) and the circle luminance was reduced until the patient detected a difference between both zones. From a high contrast clearly detected by the patient, a second measurement was obtained by increasing the circle luminance until all of the screen seemed uniform. The inverse of the mean of both measurements multiplied by 100 determined the value of contrast sensitivity detection. This procedure was followed to measure horizontal and vertical contrast sensitivity detection thresholds, positioning one fixation target (green LED) at 40° to the left of the patient and other at 40° upward. The measurements corresponded with the temporal side of the retina in right eyes and with the nasal side in the left eyes. This procedure allowed us to measure the contrast sensitivity detection in a clinical environment with a difficulty and time-consuming adapted to our older patients. **AQ2**

Thirty-one patients in the Art25 group (20 right and 11 left eyes) and 28 patients in the control group (14 right and 14 left eyes) were randomly selected to also measure peripheral refraction and aberrations using the open-view Peripheral Refractor developed (VPR; Voptica SL).^{19,20} It consists of a scanning Hartmann-Shack wavefront sensor that measures the ocular wavefront aberration and refractive errors at 80° of the horizontal visual field every 1°. The patient was positioned in a chin-rest looking at a fixation point (red LED) placed at 1 m distance while the VPR took four consecutive scans of the whole angular range in 1.3 seconds for each scan. The Hartmann-Shack images were recorded under dim illumination conditions, allowing a natural pupil diameter larger than 4 mm. For this pupil size, the ocular wavefront aberration was calculated up to fifth-order Zernike expansion. The refraction parameters, SE and astigmatism (J_0 , J_{45}), were estimated from second-order Zernike coefficients recalculated for 3-mm pupil diameter. The values of refraction were estimated as the average from the four scans. To facilitate the peripheral comparison between the Art25 IOL and control groups, the refraction components of every angle were referred to those at the fovea. In the graphs displaying peripheral metrics, the abrupt changes detected from 12° to 19°, coinciding with the excavation of the optic disc, were removed to facilitate the visual interpretation of the results.

STATISTICAL ANALYSIS

The statistical analysis was performed using Microsoft Excel 365 (Microsoft Corporation) and R Core Team (R Foundation for Statistical Computing) software. The Shapiro-Wilk test was used to assess the normality of all variables analyzed and the F-test to test for homogeneity in variance. Non-parametric statistics were applied in non-normally distributed variables. The box plot was used as a standardized approach to display the distribution of refractive errors after surgery. Differences between variables were obtained by means of the *t* test for normally distributed variables and the Wilcoxon signed-rank test for non-normally distributed variables. All *t* statistical tests were unpaired and two-tailed, and a *P* value of less than .05 ($P < .05$) was considered statistically significant. Inter-subject variability was evaluated by the standard deviation (SD) using calculations of error propagation in the RMSAQ3 metric.

To obtain statistically significant results according to a power analysis for comparing unpaired differences, a sample size of at least 25 eyes for each group was required to achieve a power of 0.80 and a two-tailed alpha level of 0.05, assuming expected difference between means of contrast sensitivity detection of 2.8 ± 3.5 and dioptric power of 1.20 ± 1.50 . **AQ4**

RESULTS

The used powers of IOLs targeting emmetropia ranged between 18.00 and 24.50 D (mean: 22.30 ± 1.10 D) in the Art25 group and between 16.00 and 26.00 D (mean: 21.90 ± 1.30 D) in the control group.

To rule out any possible effect of postoperative foveal refraction on peripheral measurements, we found no significant differences ($P > .05$) between the two groups: SE -0.09 ± 0.54 D (range: -1.75 to +0.75 D) and cylinder -0.43 ± 0.41 D (range: -1.75 to 0.00 D) in the Art25 group and SE -0.12 ± 0.33 D (range: -1.63 to +0.75 D) and cylinder -0.47 ± 0.33 D (range: -1.75 to 0.00 D) in the control group. In both groups, the values of CDVA ($P = .82$) and UDVA ($P = .71$) were also similar. The mean value of CDVA was 0.01 ± 0.03 logMAR (range: -0.08 to 0.10 logMAR) in the Art25 group and 0.01 ± 0.02 logMAR (range: 0.00 to 0.10 logMAR) in the control group. The values of UDVA were 0.06 ± 0.10 logMAR (range: 0.00 to 0.40 logMAR) and 0.05 ± 0.06 logMAR (range: 0.00 to 0.30 logMAR) for the Art25 and control groups, respectively.

Figure 2 shows the mean values of peripheral contrast sensitivity detection. In the Art25 group, these values were significantly better at both horizontal ($P = .009$) and vertical ($P = .003$) eccentricities. The mean values at vertical measurements were 7.78 ± 3.24 (range: 1.85 to 17.33) and 5.74 ± 2.60 (range: 2.53 to 13.90) for the Art25 IOL and control groups, respectively. The difference was

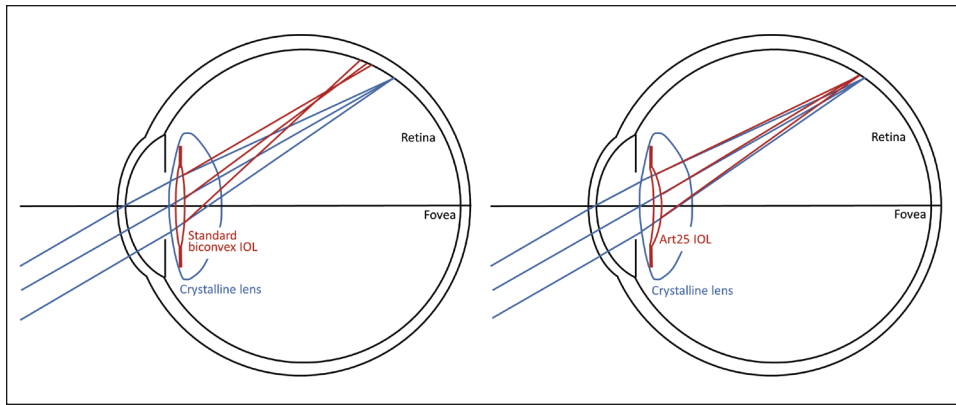


Figure 1. Ray-tracing for an object on the periphery through a schematic eye with a crystalline lens (blue) compared with intraocular lenses (IOLs) (red): standard biconvex intraocular lens and Art25 intraocular lens (Voptica SL).

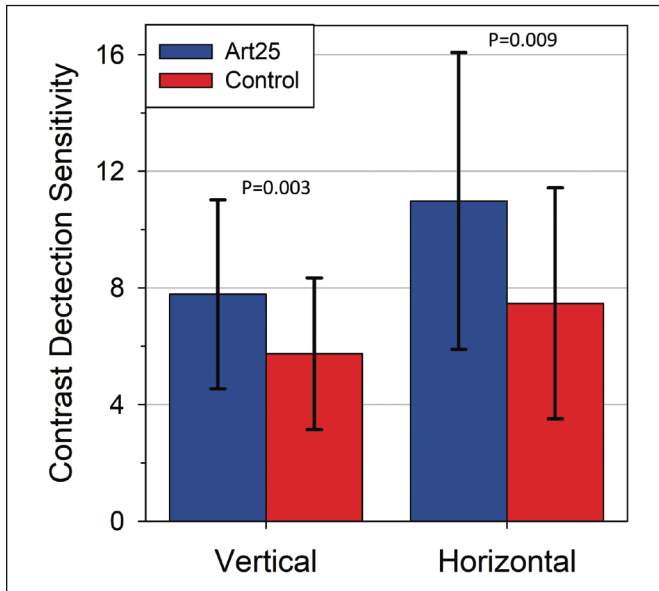


Figure 2. Mean values of peripheral contrast sensitivity detection for group A1, eyes with Art25 intraocular lens implantation (Voptica SL), and control group C1, with standard deviations as error bars.

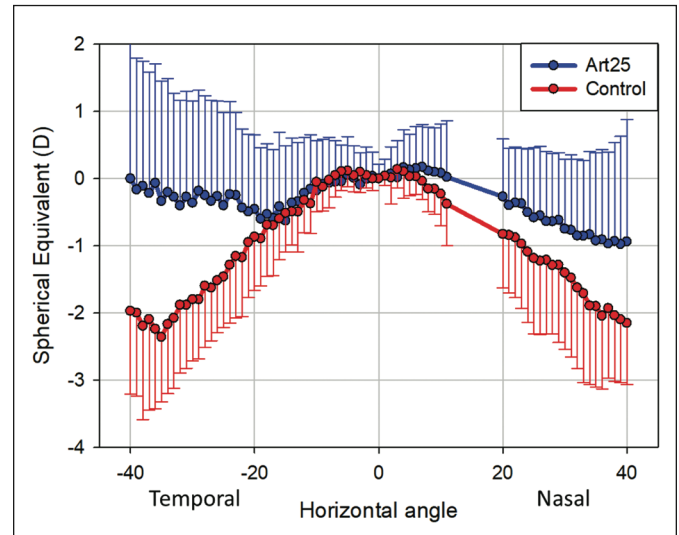


Figure 3. Mean values of peripheral spherical equivalent for group A2, eyes with Art25 intraocular lens implantation (Voptica SL), and control group C2. Standard deviations are displayed as upper error bars and lower bars for groups A2 and C2, respectively, to show the differences more clearly. Data from 12 to 19 degrees, coinciding with the excavation of the optic disc, were removed. D = diopters

higher in the horizontal direction (10.98 ± 5.09 [range: 1.77 to 24.76] vs 7.47 ± 3.96 [range: 2.73 to 21.54]), being still greater on the temporal side of the right eyes (10.66 ± 5.40 vs 5.50 ± 2.73) than on the nasal side of the left eyes (11.37 ± 4.73 vs 9.51 ± 4.06). To rule out the possible effect of correlation between fellow eyes, a Tukey's multiple comparison test was used to check that the differences were also statistically significant ($P < .03$) comparing the groups with no fellow eyes.

Figure 3 shows the comparison of mean values of peripheral SE. In both groups, there was an increment of relative myopia with the eccentricity, but in the Art25 group it was slower; even this tendency changed from 20° on the temporal retina. Peripheral myopia was statistically lower with the Art25 IOL ($P < .05$) for eccentricities greater than 10° on the nasal side and 21° on the temporal side, and the difference increased faster on

the temporal side. As an example, at 40° on the temporal side, the Art25 group had a null mean value of M, whereas it was -1.97 D in the control group, and at 40° in the nasal side, the difference was slightly lower (-0.94 D in the Art25 group and -2.15 D in control group). The inter-subject variability increased with the eccentricity in both groups but more with the Art25 IOL (SD of 2.00 vs 1.30 D at large eccentricities). **AQ5**

As expected, the refraction measurements along the horizontal meridian did not provide significant changes in the oblique component of astigmatism (J_{45}) but did in negative values of the horizontal/vertical component (J_0), indicating an increase in the difference between the powers of the horizontal and vertical meridians, with higher power in the vertical meridian. The difference in J_0 between both groups is presented in **Figure 4**. The

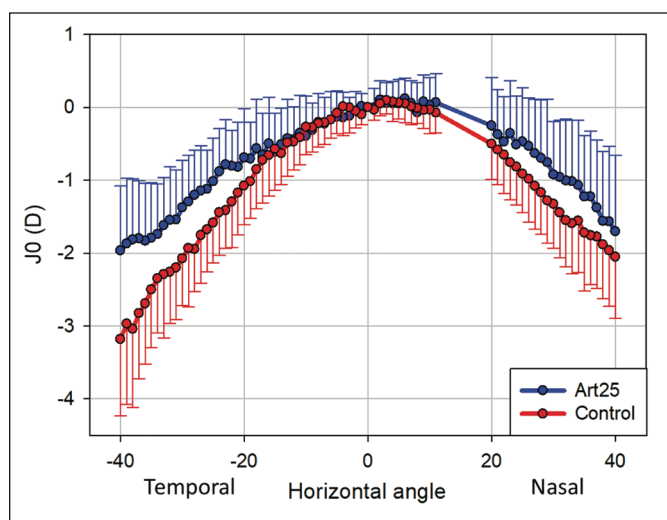


Figure 4. Mean values of peripheral J_0 for group A2, eyes with Art25 intraocular lens implantation (Voptica SL), and control group C2. Standard deviations are displayed as upper error bars and lower bars for groups A2 and C2, respectively, to show the differences more clearly. Data from 12 to 19 degrees, coinciding with the excavation of the optic disc, were removed. D = diopters

Art25 group had significantly ($P < .05$) less astigmatism from eccentricities greater than 22° on the nasal side and 18° on the temporal side, achieving the maximum benefit at 40° temporally, 2.00 versus 3.17 D. The inter-subject variability of J_0 increased with the eccentricity in the same way in the two groups, 1.00 D at 40° on both sides of the visual field.

DISCUSSION

The aim of the new Art25 IOL was to reproduce the imaging formation properties of the natural crystalline lens in the periphery of the retina. It was assumed that a better peripheral optics would also provide better vision for the patients. Our results of peripheral refractive errors after cataract surgery with the Art25 IOL show a significant decrease in the peripheral values of SE in comparison with standard IOLs from 20° of eccentricity. It is due to the field of curvature provided by this new IOL to the shape of the retina achieving a correction of myopic errors of up to 2.00 D at 40° temporally. In addition, this lens also optimizes the values of off-axis astigmatism, correcting 1.00 D of J_0 (2.00 D of astigmatism in spherocylindrical form) at 40° temporally. Optical quality outcomes with the Art25 IOL along the horizontal meridian agree with those of healthy phakic eyes¹¹ achieving the purpose of approximating the peripheral performance of the crystalline lens.

The optimization of the peripheral optical quality should have a visual benefit in faster detection of objects and movements. The sensitivity in the detection of the contrast threshold of a circle at 40° is better in

patients with the Art25 IOL in both directions, vertical and horizontal. The test was placed 1 m ahead of the patient, which partially compensates for peripheral myopic shifts. At the nasal side, this compensation benefits both groups but, at the temporal side, only eyes with standard IOLs, inducing a hyperopic defocus in eyes with the Art25 IOL. Therefore, the major improvement in contrast sensitivity detection on the temporal retina may be due to the major correction of astigmatism (2.40 vs 0.70 D in spherocylindrical form), rather than a reduction of 1.00 D in defocus on the nasal side. At far vision, the contrast sensitivity detection on the temporal retina should be still better with the Art25 IOLs because there will not be defocus errors.

On the other hand, although Art25 IOLs significantly improve clinical outcomes of refraction and contrast sensitivity detection, the inter-subject variability is too high, which is in accordance with previous data in phakic and pseudophakic eyes.^{11,21} The variability is particularly relevant for SE with values of SD higher than 1.0. Part of this variability in the SE may be explained by the differences in preoperative values of peripheral refraction relative to the fovea, which are directly related to on-axis refractive errors. Previous studies reported that small myopic shifts of relative peripheral refraction in emmetropic eyes²⁰⁻²² could be even larger in hyperopic eyes,²³ but an opposite behavior was observed in myopic eyes, which became more hyperopic in the periphery as on-axis myopia increased.^{21,24} These peripheral changes can be geometrically explained by the variations in the retinal shape induced by the changes in the axial length that is directly related to the on-axis SE.²⁵ The Art25 IOL was designed¹⁵ using a wide-angle schematic eye model¹⁶ with parameters, including the retinal curvature fixed at 12 mm, that describe the optical performance of normal emmetropic eyes. Although the mean preoperative values were approximately emmetropia in both groups with a slight myopic shift, probably due to the cataract (-0.24 ± 1.66 D in the Art25 group and -0.95 ± 2.41 D in the control group), there was a considerable variability in the SE (-3.88 to $+2.75$ D for the Art25 group and -5.88 to $+3.50$ D for the control group), and presumably also in the retinal shape, which may partially explain the inter-subject differences in the values of peripheral SE before and after surgery. Thus, in moderate and especially high ametropias, the peripheral correction with the Art25 IOL could be not enough in hyperopic eyes and excessive in myopic eyes. Further studies should be undertaken to investigate the agreement between preoperative and post-operative peripheral refraction and the effect on visual performance, to analyze whether it is worth customizing the IOL design for each patient based on foveal refraction or, better yet, on retinal shape.

Regarding the safety of the Art25 IOL, no surgical complications were noted during the implantation of 87 lenses and no adverse events, posterior capsular opacification, or presence of dysphotopsias were reported at 1 month of follow-up. The Art25 IOL had small foveal refractive errors, good visual acuity, and a level of safety similar to that found in standard IOLs. Nevertheless, longer follow-up periods are required to evaluate the incidence of posterior capsular opacification and other possible adverse events.

We have reported the first study with a new type of meniscus IOL. These lenses were designed to produce an improved optical quality in the peripheral retina while also maintaining good visual acuity in the fovea. Our results report the safety and efficacy of these lenses and their ability to improve the off-axis optics and contrast sensitivity detection compared with any other current IOLs. However, further research based on other psychometric metrics and especially on functional tests is required to establish how this improvement will translate to a measurable increase in patients' quality of life or safety.

AUTHOR CONTRIBUTIONS

Study concept and design (EAV, JMM, HG, PMP, PT-R, PA); data collection (EAV, JMM, HG, CR, EA, PT-R); analysis and interpretation of data (EAV, CR, EA, LH, PMP, PA); writing the manuscript (EAV, PA); critical revision of the manuscript (EAV, JMM, HG, CR, EA, LH, PMP, PT-R, PA); statistical expertise (EAV, LH, PMP); supervision (EAV, JMM, HG, PT-R, PA)

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AUTHOR QUERIES

General “contrast detection sensitivity” has been changed to “contrast sensitivity detection” throughout. OK as changed? Should the term be “detection of contrast sensitivity” (contrast sensitivity is the focus) or “sensitivity of contrast detection” (contrast detection is the focus)?

AQ1 Please provide the date range for the study (starting and ending date).

AQ2 I am not sure what is meant by this sentence. Was measurement in the clinical environment difficult and time consuming for older patients? Or was it less difficult and time consuming?

AQ3 Please define the abbreviation.

AQ4 Sentence OK as changed?

AQ5 Is standard deviation meant here?

AQ6 Please provide the full date of the patent application, and the name of the assignee.