

# Optical Performance and Refractive Outcomes of a New Monofocal Intraocular Lens With Intermediate Optimized Optics

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## ABSTRACT

**PURPOSE:** To evaluate refractive outcomes, defocus curve, wavefront analysis, and automated refraction of a novel monofocal intraocular lens (IOL) with higher order aspheric coefficients and controlled curvature change.

**METHODS:** This prospective observational study included 29 eyes of 29 consecutive patients with healthy eyes and normal visual potential who had undergone cataract surgery and implantation of the enVista Aspire IOL (Bausch + Lomb, Inc). Outcome measures included monocular uncorrected (UDVA), corrected (CDVA), distance-corrected intermediate (DCIVA) (at 66 cm), and distance-corrected near (DCNVA) (at 40 cm) visual acuity, defocus curve, wavefront analysis, mean refractive prediction error, and automated and manifest (MRSE) refraction spherical equivalent.

**RESULTS:** Mean UDVA was 20/22, with 93.1% of eyes having 20/25 or better. Mean CDVA was 20/20, with all eyes having

20/25 or better. Mean DCIVA was 20/34, with 90% of eyes having 20/40 or better. Mean DCNVA was 20/38, with 83% of eyes having 20/40 or better. The monocular defocus curve demonstrated approximately 1.50 diopters (D) depth of focus for visual acuity of 0.2 logarithm of the minimum angle of resolution or better. Postoperative mean MRSE was close to emmetropia ( $0.02 \pm 0.29$  D), and 96.6% of eyes were within  $\pm 0.50$  D. Automated refraction measured with ray-tracing, dynamic sciascopy, and Hartmann-Shack devices were within  $\pm 0.25$  D of the subjective refraction. The postoperative ocular 4th-order spherical aberration measured with Hartmann-Shack aberrometer was 0.08 and 0.15  $\mu\text{m}$  for a 4.5- and 6-mm pupil, respectively.

**CONCLUSIONS:** Implantation of a new enhanced monofocal IOL demonstrated useful near and intermediate vision while maintaining excellent distance acuity. Wavefront analysis revealed minimal postoperative spherical aberration, and the automated refraction was near emmetropia.

Despite the availability of a wide range of intraocular lenses (IOLs), monofocal IOLs are the standard of care for most patients undergoing cataract surgery.<sup>1</sup> Monofocal IOLs provide high-contrast distance vision with minimal risk of photic phenomena. However, patients with monofocal IOLs need correction to see at intermediate and near distances. The rapidly increasing

use of handheld devices, mobile phones, and computers in everyday life has elevated the patient's desire to achieve better intermediate vision after cataract surgery.<sup>2</sup>

As such, IOL manufacturers have developed enhanced monofocal IOL designs to provide patients who have monofocal IOLs with a slight increase in range of vision. The optical properties of the enhanced monofocal IOLs

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aim to slightly extend the depth of focus, providing functional intermediate vision with low incidence of visual phenomena similar to the conventional monofocal IOLs.<sup>3,4</sup>

The enVista Aspire IOL (Bausch + Lomb, Inc.) is a recently developed enhanced monofocal IOL with an intermediate optimized 1.5-mm central zone with a continuous curvature change on the posterior surface of the lens. The optical performance of this IOL has been demonstrated in two optical bench studies that found high modulation transfer function (MTF) and contrast through the entire range of focus from distance to intermediate.<sup>5,6</sup> However, no *in vivo* optical performance of this IOL has been published to date.

In the current study, we evaluated postoperative refractive outcomes, mean postoperative refractive prediction error, subjective depth of focus curve, and quality of vision of this IOL in patients undergoing cataract surgery.

## PATIENTS AND METHODS

This prospective observational study included consecutive patients with healthy eyes and normal visual potential who underwent routine cataract surgery and implantation of the enVista Aspire from November 2023 to June 2024 at the Storm Eye Institute at the Medical University of South Carolina. The study was conducted in accordance with the tenets of the Declaration of Helsinki and was approved by the institutional review board of the Medical University of South Carolina. Written informed consent was obtained from all patients on the informed consent form approved by the institutional review board before performing any study-related assessments. Inclusion criteria included patients who had undergone cataract surgery by an experienced surgeon (KMR) with the implantation of the enVista Aspire monofocal IOL for an emmetropic target, had clear intraocular media with no posterior capsular opacification, had postoperative corrected visual acuity potential of 20/40 or better, and were willing to adhere to study procedures.

Exclusion criteria were patients with a history of ocular surgery, including laser refractive surgery; ocular trauma; any concomitant surgical procedure at the time of cataract surgery, including minimally invasive glaucoma surgery; ocular comorbidities (eg, glaucoma, macular degeneration, or corneal scars), any pathology resulting in loss of corrected distance visual acuity (CDVA), or preoperative corneal astigmatism of greater than 0.75 diopters (D).

To avoid bias resulting from inter-eye correlation, only one eye of the eligible patients was considered the study eye and included in the analysis. In case both eyes were eligible, the right eye was considered the study eye and included in the analysis.

## SURGICAL PROCEDURE AND DEVICE DESCRIPTION

All eyes underwent standard phacoemulsification surgery through a 2-mm incision, followed by the implantation of a single-piece posterior chamber IOL. No additional astigmatic procedures, such as laser relaxing incisions or toric IOL implantation, were performed in the study, because patients with preoperative corneal astigmatism less than 0.75 D were included in this study.

The IOL used in the current study is a novel enhanced monofocal IOL (enVista Aspire) developed to provide an enhanced depth of focus from distance to intermediate vision. The enVista Aspire is based on the same platform as the aspheric enVista monofocal IOL. The IOL consists of an intermediate 1.5-mm central zone with a blend zone between the central and peripheral power in the posterior surface of the lens that is designed to provide a gradual transition of incoming light.<sup>6</sup>

## STUDY PARAMETERS

Corneal asphericity (Q-value), natural pupil diameter, and preoperative corneal higher order aberrations (HOAs) at 4.5- and 6-mm pupil diameters under ambient lighting conditions were obtained using combined Scheimpflug tomography and Hartmann-Shack aberrometry (Pentacam AXL Wave; Oculus Optikgeräte GmbH). IOL power calculations were performed with the Barrett Universal II formula using the manufacturer-recommended IOL constant of 119.1.

Postoperatively at a scheduled postoperative visit between 1 and 3 months, patients were assessed for monocular uncorrected distance visual acuity (UDVA), CDVA, monocular distance-corrected visual acuity at intermediate (DCIVA at 66 cm) and near (DCNVA at 40 cm), and automated (ARSE) and manifest (MRSE) refraction spherical equivalent. Defocus curves were performed after each eye was first corrected for distance visual acuity; a series of positive and negative lenses were then placed in front of the patient's eye to produce defocus; visual acuity with each level of defocus was measured. The defocus was introduced from -2.00 to +1.50 D, with increments of 0.50 D. ARSE was assessed using ray-tracing (iTrace; Tracey Technologies), dynamic skiascopy (OPD-Scan III; Nidek), and combined Scheimpflug and Hartmann-Shack technologies (Pentacam AXL Wave). Manifest refraction measurements were obtained by an experienced ophthalmologist (MFB) using a phoropter, and the MRSE was calculated. The mean refractive prediction error was defined as the achieved MRSE minus the SE refraction predicted by the IOL formula used in the study.

Postoperative ocular wavefront aberration (4th-order, 6th-order spherical aberration and total coma) at pupil diameters of 3, 4, 4.5, and 6 mm were also measured using a Hartmann-Shack device (Pentacam AXL Wave)

under mesopic conditions. In addition, 4th-order spherical aberration and total coma were also measured with the OPD-Scan III for a 4.5-mm pupil size.

The MTF was obtained with a ray-tracing aberrometer (iTrace), at 2 mm and natural pupil aperture. MTF was assessed separately for total, internal, and corneal aberrations at 10 cycles per degree after distance correction.

## STATISTICAL ANALYSIS

Data analysis was performed using SPSS software, version 27.0 (SPSS, Inc). Descriptive statistics on continuous variables included mean and standard deviation. Categorical data were described as frequencies or percentages. The normality of the scale data was assessed using the Shapiro-Wilk test. For normally distributed scale data, the paired *t*-test was used to compare the difference in the mean MRSE and ARSE measured by different autorefractometers. For data that were not normally distributed, a non-parametric counterpart Wilcoxon signed-rank test was used. Snellen visual acuity was converted to logarithm of the minimum angle of resolution (logMAR) units for analysis. Binary logistic regression was performed to evaluate the effect of different parameters such as patient's age, gender, pupil size, corneal asphericity (Q-value), implanted IOL power, corneal HOAs (including 4th- and 6th-order spherical aberration, coma 0 and 90 degrees) on the likelihood of obtaining DCNVA/DCIVA of J3 or better (20/30 or better) versus DCNVA/DCIVA worse than J3 (worse than 20/30). Factors showing a *P* value less than 0.3 in binary logistic regression were further evaluated in multiple logistic regression using backward logistic regression. The odds ratio with a 95% confidence interval was calculated to study the association of these factors with DCNVA/DCIVA. A *P* value less than .05 was considered statistically significant.

## RESULTS

The study included 29 eyes of 29 patients. The mean age of the study participants was  $64.9 \pm 16.8$  years; 41.4% were men and 58.6% were women.

### VISUAL OUTCOMES

The mean UDVA was 0.04 logMAR (20/22 Snellen), with 100% of eyes achieving a UDVA of 20/30 or better postoperatively (**Figure 1A**). CDVA was 20/30 or better in all (100%) eyes postoperatively. Mean DCIVA was 0.23 logMAR (20/34 Snellen), with 62.1% of eyes and 89.7% of eyes achieving DCIVA of 20/30 or better and 20/40 or better, respectively (**Figure 1B**). Mean DCNVA was 0.28 logMAR (20/38 Snellen), with 51.7% of eyes achieving DCNVA of 20/30 or better and 82.8% achieving 20/40 or better postoperatively (**Figure 1C**). The monocular defocus curve of the enVista Aspire demonstrated

approximately 1.50 D of continuous depth of focus for a visual acuity of 0.2 logMAR or better (**Figure 2**).

### LOGISTIC REGRESSION ANALYSIS

The results of logistic regression revealed that none of the factors, such as age, gender, Q-value, pupil size, IOL power, and corneal aberrations at a 6-mm pupil, were predictors of better DCIVA/DCNVA (**Table 1**).

### REFRACTIVE OUTCOMES

Postoperative mean MRSE was close to emmetropia ( $0.02 \pm 0.29$  D), with 96.6% of eyes achieving MRSE within  $\pm 0.50$  D (**Figure 3**). The ARSE measured with OPD-Scan III and iTrace was close to manifest refraction with no statistically significant difference between the two groups (*P* = .316 and .271, respectively). However, the objective refraction measured with the Pentacam AXL Wave was slightly myopic compared to the MRSE, with a statistically significant difference between the two (*P* = .002) (**Figure 4**).

The mean numerical and absolute prediction error for IOL calculations performed with the Barrett Universal II formula was  $0.15 \pm 0.29$  D (range: -0.36 to 0.69 D) and  $0.28 \pm 0.16$  D (range: 0.04 to 0.69 D), respectively.

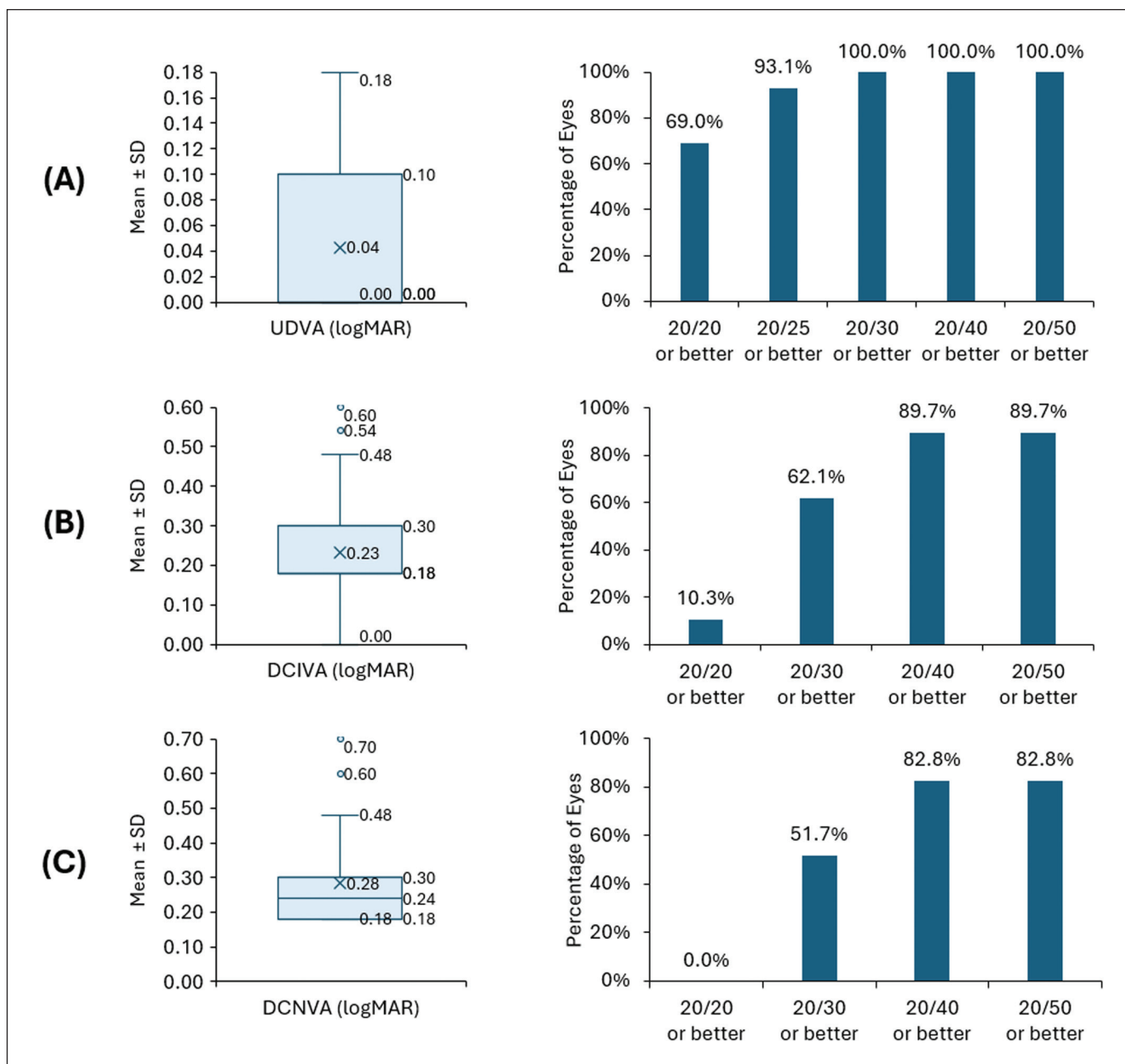
### WAVEFRONT ANALYSIS

The mean corneal 4th-order spherical aberration measured with the Pentacam was 0.11  $\mu$ m for a 4.5-mm pupil and 0.35  $\mu$ m for a 6-mm pupil. The postoperative ocular 4th-order spherical aberration was 0.08  $\mu$ m for a 4.5-mm pupil and 0.15  $\mu$ m for a 6-mm pupil (**Figure 5**). The mean 4th-order internal and ocular spherical aberration measured with the OPD-Scan III at a 4.5-mm pupil were  $-0.1 \pm 0.13$  and  $-0.04 \pm 0.08$   $\mu$ m, respectively. The mean MTF values (internal, corneal, and total) measured at a 2-mm pupil and natural pupil sizes with a ray-tracing aberrometer are summarized in **Table 2**.

## DISCUSSION

This was the first study to analyze the refractive outcomes and optical performance of a monofocal IOL that increases the depth of focus by controlling its curvature changes in the posterior surface. The results showed postoperative mean CDVA of 0.23 logMAR (Snellen equivalent 20/34) at intermediate and 0.28 logMAR (Snellen equivalent 20/38) at near while maintaining a UDVA of 0.04 logMAR (Snellen equivalent 20/22).

Comparison of the visual acuity outcomes achieved in the current study with the previously published studies of other enhanced monofocal IOL designs showed comparable outcomes. For example, the mean DCIVA of 0.23 logMAR achieved in the current study is comparable to the reported range of 0.17 to 0.23 logMAR reported for



**Figure 1.** Mean and proportion of eyes achieving (A) uncorrected distance visual acuity (UDVA) 20/x or better, (B) distance-corrected intermediate visual acuity (DCIVA) 20/x or better, and (C) distance-corrected near visual acuity (DCNVA) 20/x or better. SD = standard deviation

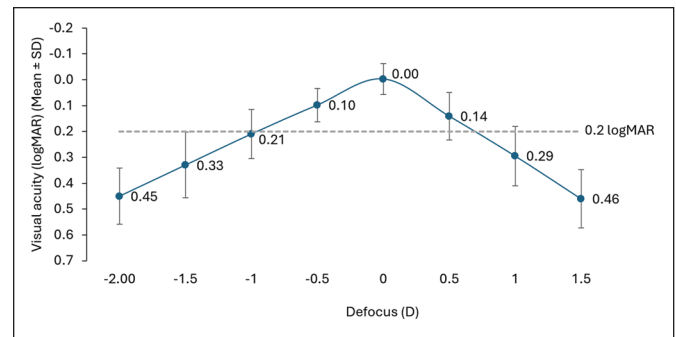
the Tecnis Eyhance IOL and 0.28 logMAR reported for the Rayner EMV IOL.<sup>2,7-10</sup> Similarly, the mean DCNVA of 0.28 logMAR achieved in the current study was comparable to 0.25 to 0.50 logMAR reported for the Tecnis Eyhance IOL in previously published studies.<sup>2,7-9</sup>

The visual acuity outcomes achieved in the current study also corroborated the defocus curve, demonstrating approximately 1.50 D of continuous depth of focus for a visual acuity of 0.2 logMAR or better. These sustained visual acuity outcomes through different de-

focus values may be related to the continuous change in power provided by the IOL's optic design.

Unlike the other enhanced monofocal IOLs (eg, Rayner EMV), where the induction of spherical aberration may contribute to the increased depth of focus,<sup>10-12</sup> the enVista Aspire IOL's depth of focus is due to the curvature changes on the posterior surface of the IOL. The mean corneal 4th-order spherical aberration measured with the Pentacam was 0.11  $\mu\text{m}$  (for a 4.5-mm pupil) and 0.35  $\mu\text{m}$  (for a 6-mm pupil). The

corresponding ocular 4th-order spherical aberration measured postoperatively was 0.08  $\mu\text{m}$  for a 4.5-mm pupil and 0.15  $\mu\text{m}$  for a 6-mm pupil. These results suggest that the study IOL did not increase the corneal spherical aberration, and the excellent visual outcomes at the intermediate provided by the IOL are likely due to the higher-order aspheric coefficients of the intermediate-optimized IOL optic. These results also corroborate the results of logistic regression that showed no association of 4th-order corneal spherical aberration with the likelihood of achieving better distance-corrected intermediate and near vision. The

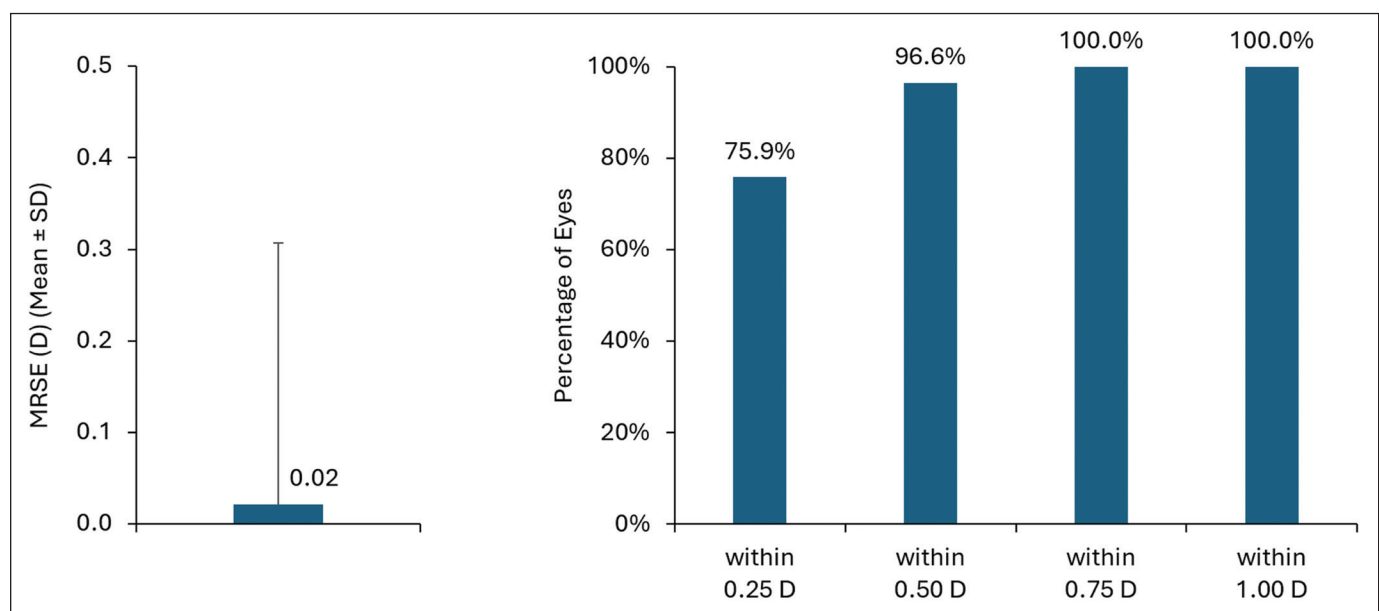


**Figure 2.** Monocular defocus curve of the enhanced monofocal intra-ocular lens. logMAR = logarithm of the minimum angle of resolution; SD = standard deviation

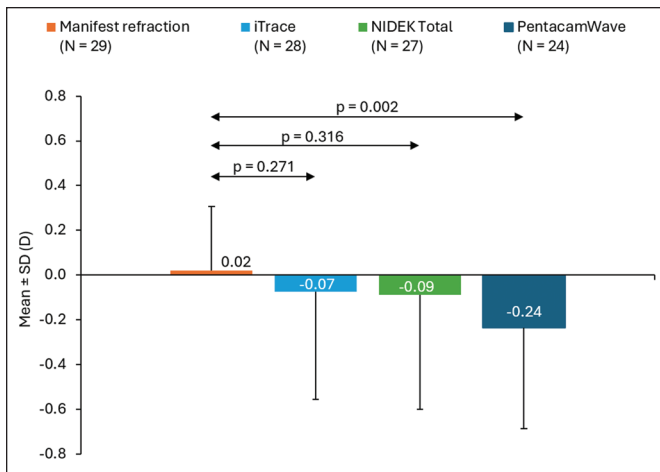
TABLE 1  
**Results of Binary Logistic Regression Analysis**

| Parameter                         | DCIVA 0.18 logMAR or Better |      | DCNVA 0.18 logMAR or Better |      |
|-----------------------------------|-----------------------------|------|-----------------------------|------|
|                                   | Odds Ratio                  | P    | Odds Ratio                  | P    |
| Age (years)                       | 0.973                       | .349 | 1.031                       | .281 |
| Gender                            | 0.178                       | .059 | 0.700                       | .638 |
| Q-value                           | 0.000                       | .101 | 0.003                       | .215 |
| Natural pupil size (mm)           | 1.954                       | .511 | 0.491                       | .488 |
| Corneal aberrations at 6-mm pupil |                             |      |                             |      |
| Coma 0 degree                     | 1.151                       | .943 | 0.524                       | .745 |
| Coma 90 degree                    | 0.498                       | .605 | 1.312                       | .839 |
| 4th-order spherical aberration    | 2.357                       | .861 | 1667.471                    | .183 |
| 6th-order spherical aberration    | 0.000                       | .191 | 0.000                       | .066 |
| IOL power (D)                     | 1.085                       | .404 | 0.928                       | .425 |

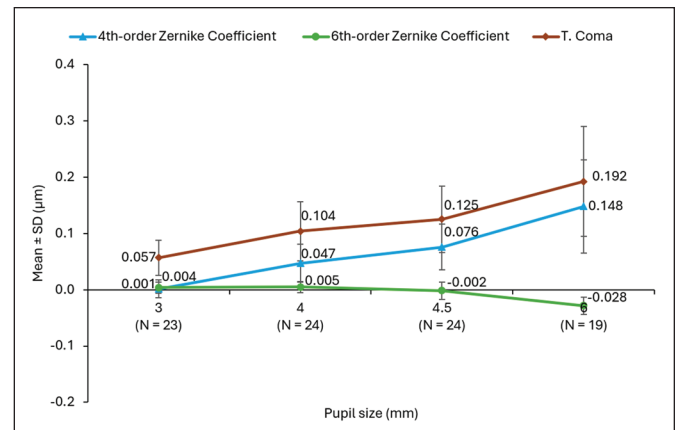
D = diopters; DCIVA = distance-corrected intermediate visual acuity; DCNVA = distance-corrected near visual acuity; IOL = intraocular lens; logMAR = logarithm of the minimum angle of resolution



**Figure 3.** Mean manifest refraction spherical equivalent (MRSE) and spherical equivalent accuracy. D = diopters; SD = standard deviation



**Figure 4.** Comparison of the mean manifest refraction with the automated refraction measured with various autorefractometers. D = diopters; SD = standard deviation



**Figure 5.** Postoperative ocular wavefront aberrations (4th-order spherical aberration, 6th-order spherical aberration, and total coma) measured at different pupil sizes [3-, 4-, 4.5-, and 6-mm] with Pentacam AXL Wave (Oculus Optikgeräte GmbH). SD = standard deviation

**TABLE 2**  
**MTF Data of the enVista Aspire IOL**

| Parameter    | Natural Pupil Size<br>(Mean 2.65 ± 0.33 mm),<br>Mean ± SD | 2-mm Pupil Size,<br>Mean ± SD |
|--------------|-----------------------------------------------------------|-------------------------------|
| MTF internal | 0.48 ± 0.18                                               | 0.58 ± 0.15                   |
| MTF corneal  | 0.69 ± 0.14                                               | 0.75 ± 0.05                   |
| MTF total    | 0.52 ± 0.17                                               | 0.60 ± 0.15                   |

*IOL = intraocular lens; MTF = modulation transfer function; SD = standard deviation  
The enVista Aspire IOL is manufactured by Bausch + Lomb, Inc.*

measurement of postoperative corneal aberrations was not assessed in the current study; however, published data suggest no significant changes in the postoperative corneal aberrations following cataract surgery.<sup>13,14</sup>

In addition to the clinical outcomes, it is important to assess the optical performance of the IOL. MTF is a widely accepted and validated parameter to assess the optical performance.<sup>15,16</sup> MTF values of 0.5 or above are suggestive of good quality optical performance.<sup>17</sup> However, many factors, including age and pupil diameter, can affect the optical performance of an IOL. For example, a study evaluating the optical performance of the human eye showed that as pupil size increases from 3 to 6 mm, the MTF decreases.<sup>18</sup> Similarly, MTF was higher in young adults (20 to 30 years) and decreased in older adults (60 to 70 years).<sup>18</sup> In the current study, with a patient mean age of 65 years, the ocular MTF values were greater than 0.50 when measured at 2-mm and natural pupil apertures. These values were higher than those reported previously for normal adults aged 60 to 70 years (~0.30 at a 3-mm pupil).<sup>18</sup> These findings indicate good optical performance of the enhanced monofocal IOL following cataract surgery.

Subjective refraction is the gold standard for refractive error assessment, spectacle prescription, prediction error assessment, and IOL formula optimization.<sup>19</sup> Objective refraction measured with an autorefractometer is often used as a starting point to facilitate subjective manifest refraction.<sup>10</sup> In the current study, objective refraction measured with dynamic skiascopy (NIDEK OPD III), ray-tracing (iTrace), and Hartmann-Shack technology (Pentacam AXL Wave) was slightly myopic compared to the subjective manifest refraction. Autorefractometry based on a Hartmann-Shack technology yielded slightly more myopic results than other refractometers evaluated in the study, as reported previously.<sup>20</sup> The results obtained in the current study are in alignment with the previously published studies of other enhanced monofocal IOL (Tecnis Eyhance IOL) that documented objective refraction to yield slightly myopic results compared to subjective refraction.<sup>20-22</sup> The literature also shows that the objective refraction measured with autorefractometers becomes even more myopic when pupil size increases.<sup>22,23</sup> Hence, natural pupil size should also be taken into consideration when using objectively measured refraction as the starting point.

Accurate determination of IOL power is key to achieving optimal postoperative outcomes. In the current study, the IOL power calculations were performed with the Barrett Universal II formula using the manufacturer-recommended IOL constant of 119.1 for non-contact biometry devices, yielding mean manifest refraction close to emmetropia and a slightly hyperopic mean numerical prediction error of  $0.15 \pm 0.29$  D.

To the best of our knowledge, this was the first study to report a comprehensive clinical evaluation of this new IOL; however, the study is limited by its small sample size. Future comparative studies with a larger dataset are warranted.

## CONCLUSION

Patients with cataract who were implanted with a novel enhanced monofocal IOL demonstrated excellent distance, useful intermediate, and functional near vision. The defocus curve showed an approximately 1.50 D continuous depth of focus at 0.2 logMAR or better. The outcomes in the current study were achieved using the manufacturer's recommended IOL constant. The enVista Aspire IOL may be an appropriate choice for patients who choose to undergo monofocal IOL implantation after cataract surgery.

## AUTHOR CONTRIBUTIONS

Study concept and design (MRS, GOW, KMR); data collection (MFB, CH); analysis and interpretation of data (MFB, LG, CH); writing the manuscript (MFB, LG, CH); critical revision of the manuscript (LG, MRS, GOW, KMR); administrative, technical, or material support (KMR); supervision (KMR)

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