

Visual Performance of a Novel Intraocular Lens With Higher-Order Aspheric Design Optimized for Intermediate Vision

Nuria Garzón, PhD; Pedro Arriola-Villalobos, MD, PhD, FEBO; Natalia Hormigo-Márquez, MSc; María García-Montero, PhD; César Albarrán-Diego, PhD

ABSTRACT

PURPOSE: To evaluate the visual performance of an enhanced monofocal intraocular lens (IOL) and the influence of pupil size.

METHODS: This prospective, observational, single-center study was conducted at Hospital Clínico San Carlos (Madrid, Spain). Patients undergoing cataract surgery with an enhanced monofocal IOL (enVista Aspire; Bausch + Lomb, Inc) were included. Postoperative monocular assessments were performed under photopic conditions at 3 months. Uncorrected and corrected visual acuity were measured at distance (4 m), intermediate (66 cm), and near (40 cm). Defocus curves and photopic contrast sensitivity were assessed, and automated refraction was compared with manifest refraction. Defocus curves were analyzed using area-under-the-curve and depth-of-focus metrics, and visual outcomes were stratified by photopic pupil size (<3.5 vs ≥3.5 mm). Agreement between autorefractometry and subjective refraction was evaluated using Bland-Altman analysis.

RESULTS: Twenty-two eyes of 22 patients were included. Mean postoperative uncorrected and corrected distance visual acuity was 0.09 ± 0.12 and -0.02 ± 0.07 logarithm of the minimum angle of resolution (logMAR), respectively; 19 eyes (86.4%) achieved uncorrected distance visual acuity of 0.2 logMAR or better and all eyes achieved corrected distance visual acuity of 0.1 logMAR or better. Mean corrected intermediate and near visual acuity were 0.32 ± 0.13 and 0.52 ± 0.18 logMAR, respectively. Contrast sensitivity showed a normal band-pass profile. Agreement between autorefractometry and manifest refraction showed a small mean bias for spherical equivalent (+0.08 diopters). Pupil size showed no overall main effect on defocus curves or contrast sensitivity, although a defocus-specific interaction was observed.

CONCLUSIONS: This enhanced monofocal IOL provided excellent distance visual acuity, functional intermediate vision, preserved contrast sensitivity, and limited overall dependence on pupil size.

The digital transformation of daily life has reshaped the visual demands of cataract surgery candidates. Unlike previous generations whose near vision tasks primarily involved printed materials, contemporary patients spend substantial time using smartphones, computer screens, and vehicle dashboards, activities predominantly performed at intermediate distances between 40 and 80 cm.^{1,2} This evolution has exposed a mismatch between the visual performance provided by traditional

monofocal intraocular lenses (IOLs) and the functional requirements of modern pseudophakic patients.

Enhanced monofocal IOLs have emerged as a response to this evolving landscape, attempting to bridge the gap between the optical simplicity of conventional monofocal designs and the intermediate vision capabilities of extended depth-of-focus platforms.³ Through controlled optical modifications, such as spherical aberration manipulation, progressive aspheric transitions, or

From Department Optometry and Vision, Complutense University of Madrid, Madrid, Spain (NG, MG-M); Servicio de Oftalmología, Hospital Clínico San Carlos, Departamento de Inmunología, Oftalmología y ORL, Facultad de Medicina, Universidad Complutense de Madrid, IdISSC, Madrid, Spain (PA-V); Grupo de Investigación en Patología Ocular y Vías Visuales, Hospital Clínico San Carlos, IdISSC, Madrid, Spain (NH-M); and Department of Optics and Optometry and Vision Science, Facultat de Física, Universitat de València, Burjassot, Spain (CA-D).

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Address correspondence to María García-Montero, PhD, Department Optometry and Vision, Universidad Complutense de Madrid, Av. Arcos del Jalón 118, E-28037 Madrid, Spain; email: mgarc01@ucm.es.

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higher order aberrations, these lenses seek to improve intermediate function without inducing the photic phenomena and contrast reduction associated with multifocal technologies. However, optical strategies differ substantially among platforms, and their clinical implications remain incompletely characterized.⁴

The enVista Aspire IOL (Bausch + Lomb, Inc) represents a novel approach within the enhanced monofocal category. Instead of inducing spherical aberration, it incorporates a 1.5-mm central zone with continuous curvature change on the posterior surface, using higher-order aspheric coefficients to create a gradual power transition optimized for intermediate vision.⁵ Optical bench evaluations have demonstrated favorable modulation transfer function values across the distance-to-intermediate range.^{6,7} However, independent clinical validation is essential for newly introduced IOL platforms.

Comprehensive evaluation of such designs must extend beyond visual acuity alone. Contrast sensitivity assessment is essential to identify potential optical quality trade-offs inherent to depth-of-focus extension that high-contrast acuity testing may not detect. Autorefractometry concordance with manifest refraction is also clinically relevant, because non-spherical surfaces or higher order aberrations may influence automated measurements,^{8,9} potentially affecting workflow reliability.

This prospective study was designed to provide a comprehensive, independent clinical evaluation of the enVista Aspire IOL in a real-world surgical setting using monocular assessment to isolate intrinsic optical performance from binocular summation effects that can mask limitations in individual eye function. Four objectives were addressed: (1) quantification of uncorrected and corrected visual acuity at distance, intermediate, and near to establish the functional range of vision; (2) characterization of monocular depth of focus through systematic defocus curve analysis under photopic conditions; (3) evaluation of photopic contrast sensitivity across multiple spatial frequencies to assess perceived optical quality; and (4) determination of the agreement between automated and manifest refraction to establish the clinical utility of objective measurements with this novel lens.

PATIENTS AND METHODS

This prospective, observational, single-center study was conducted at the Department of Ophthalmology, Hospital Clínico San Carlos, Madrid, Spain. The protocol was approved by the Institutional Review Board and Ethics Committee (CI 24/794-EC_P). All participants provided written informed consent. The study adhered to the tenets of the Declaration of Helsinki.

Eligible participants were adults 51 years or older scheduled for phacoemulsification with implantation of

the enVista Aspire IOL. Inclusion criteria were visually significant cataract, regular corneal astigmatism ≤ 1.50 diopters (D), anticipated postoperative corrected distance visual acuity (CDVA) of 0.20 logarithm of the minimum angle of resolution (logMAR) or better, and calculated IOL power between +15.00 and +26.00 D. Exclusion criteria included ocular surface disease, previous intraocular or corneal surgery, ocular comorbidities affecting visual outcomes (corneal opacities, glaucoma, retinal or macular disease), systemic conditions impairing healing or visual function, intraoperative or postoperative complications, and posterior capsule opacification during follow-up. Participants underwent comprehensive preoperative evaluation and standardized postoperative assessments at 24 to 48 hours, 4 to 8 weeks, and 12 to 16 weeks. Data presented correspond to the 3-month visit.

SURGICAL TECHNIQUE

All procedures were performed by a single experienced surgeon (PA-V) using standardized 2.2-mm clear corneal microincision phacoemulsification under topical anesthesia. Continuous curvilinear capsulorhexis, hydrodissection, phacoemulsification, irrigation-aspiration, and in-the-bag IOL implantation were performed. No relaxing incisions were made. Postoperative treatment followed institutional protocol with topical antibiotics (1 week) and corticosteroids tapered over 4 weeks.

PREOPERATIVE AND POSTOPERATIVE ASSESSMENTS

Comprehensive slit-lamp examination included assessment of the ocular surface, eyelids/adnexa, anterior segment status, and dynamic pupillary behavior. Preoperative biometric measurements were obtained using swept-source optical coherence tomography (IOLMaster 700; Carl Zeiss Meditec AG). IOL power was calculated using the Barrett Universal II formula (lens factor 1.94; A-constant 119.1), targeting postoperative emmetropia in all eyes.

Automated refraction was performed using the KR-1W autorefractor-aberrometer (Topcon Co). Objective refraction was obtained from Hartmann-Shack wavefront measurements acquired under photopic conditions using the natural photopic pupil diameter.¹⁰ All refraction assessments were performed by the same optometrist (NH-M). Distance refraction was conducted under photopic illumination (85 cd/m²) using Early Treatment of Diabetic Retinopathy Study (ETDRS) charts at 100% contrast and recorded in logMAR notation. Final refinement of spherical and cylindrical components was performed using cross-cylinders in 0.25 D steps.

Uncorrected distance visual acuity (UDVA) and CDVA were measured at 4 meters. Uncorrected intermediate visual acuity (UIVA) and distance-corrected inter-

mediate visual acuity (DCIVA) were assessed at 66 cm. Uncorrected near visual acuity (UNVA) and distance-corrected near visual acuity (DCNVA) were assessed at 40 cm. Monocular defocus curves were obtained with the manifest distance refraction under photopic conditions using trial lenses from +1.00 to -2.50 D in 0.50-D increments, recording visual acuity at each defocus level. Photopic contrast sensitivity was assessed monocularly at distance with the manifest distance refraction with the CSV-1000 (VectorVision) at spatial frequencies of 3, 6, 12, and 18 cycles per degree (cpd). Natural pupil diameter was measured under standardized photopic and mesopic (5 cd/m²) conditions using the KR-1W.

All intraoperative (posterior capsule rupture, zonular dialysis, vitreous loss) and postoperative complications (corneal edema, uveitis, cystoid macular edema, endophthalmitis) were systematically recorded.

STATISTICAL ANALYSIS

Sample size was calculated using Granmo 6.0 (Institut Municipal d'Investigació Mèdica) based on distance visual acuity in patients implanted with an enhanced monofocal IOLs reported by García-Bella.¹¹ With an alpha risk of 0.05 and beta risk of 0.2 in a two-sided test, 22 participants were required to detect a difference of ≥ 0.04 logMAR (standard deviation 0.06), assuming 15% loss to follow-up. All analyses were performed in R software (RStudio).¹² Continuous variables are reported as mean $\pm$ standard deviation (SD) and range. Categorical variables are reported as counts and percentages. Tests were two-sided and statistical significance was set at $\alpha = 0.05$. Analyses were conducted at the eye level (one implanted eye per participant). Distance, intermediate, and near visual acuity (uncorrected and corrected) were summarized descriptively, and the proportion of eyes achieving 0.2 logMAR or better and 0.1 logMAR or better was calculated.

Defocus curve data (logMAR vs defocus in diopters) were analyzed by computing the mean defocus curve across eyes at each defocus level and extracting summary metrics from the mean curve. The area under the curve for "good vision" was defined as the area between the defocus curve and the 0.2 logMAR threshold, computed by trapezoidal numerical integration over defocus intervals where visual acuity was 0.2 logMAR or better. Threshold intersections (cut points) at 0.2 and 0.1 logMAR were estimated by linear interpolation between adjacent defocus levels.

Postoperative subjective refraction and automated refraction were expressed in conventional spherocylindrical notation and in power-vector components (spherical equivalent [M], J₀, J₄₅). Agreement between automated refraction and subjective refraction was assessed using

Bland-Altman analysis in power-vector notation, plotting differences (automated refraction - refraction) against the subjective refraction values. Mean bias and 95% limits of agreement (mean $\pm$ 1.96 SD) were calculated for each component. Proportional bias was explored by fitting a linear trend of the AR-refraction difference versus refraction, with 95% confidence bands. To evaluate the influence of pupil size on visual performance after enVista Aspire IOL implantation, defocus curve and contrast sensitivity data were stratified by photopic pupil diameter using a pre-specified clinical threshold (<3.5 vs ≥ 3.5 mm). Group differences across the full defocus curve were assessed using a linear mixed-effects model with fixed effects for defocus level, pupil group, and their interaction, and a random intercept for eye. Where appropriate, between-group contrasts at each defocus level were estimated; *P* values are reported unadjusted and adjusted for multiple comparisons (Holm and false discovery rate). Contrast sensitivity across spatial frequencies was analyzed analogously, modelling frequency, pupil group, and their interaction with a random intercept for eye.

RESULTS

Twenty-two eyes of 22 patients were included. Mean age was 69.9 ± 7.5 years (range: 51 to 80 years), and 12 participants were women (54.5%). Mean keratometry was 44.03 ± 1.68 D (range: 39.65 to 46.43 D), mean axial length was 23.48 ± 0.92 mm (range: 22.25 to 25.8 mm), and mean implanted IOL power was 21.21 ± 2.44 D (range: 18.50 to 26.00 D).

VISUAL ACUITY

Table 1 summarizes visual acuity outcomes. After surgery, mean UDVA was 0.09 ± 0.12 logMAR and CDVA was -0.02 ± 0.07 logMAR. For intermediate vision, mean UIVA was 0.26 ± 0.15 logMAR and CIVA was 0.32 ± 0.13 logMAR. Regarding near vision, mean UNVA was 0.43 ± 0.20 logMAR and CNVA was 0.52 ± 0.18 logMAR. The proportion of eyes achieving UDVA of 0.2 logMAR or better was high, whereas corresponding proportions for intermediate and near vision were notably lower (**Table 1**).

REFRACTIVE OUTCOME

Postoperative subjective refraction showed minimal residual spherical error overall (mean sphere: -0.01 ± 0.31 D; median: 0.00 D). In power-vector terms, the spherical equivalent (M) showed a slight myopic shift (mean: -0.34 ± 0.40 D; range: -1.25 to +0.75 D). Astigmatism was low-to-moderate (mean cylinder: -0.66 ± 0.52 D; median: -0.62 D); J₀ showed a slight tendency toward against-the-rule (mean -0.16 ± 0.33 D), whereas J₄₅ was close to zero (mean -0.06 ± 0.20 D). Standard refractive outcome graphs are shown in **Figure 1**.

TABLE 1

Visual Acuity Outcomes (logMAR) and Proportion of Eyes Achieving Predefined Visual Acuity Thresholds of 0.2 and 0.1 logMAR at Distance, Intermediate, and Near

Parameter	Mean $\pm$ SD	Range	UDVA $\leq$ 0.2 logMAR (%)	UDVA $\leq$ 0.1 logMAR (%)
Preoperative				
UDVA	0.40 $\pm$ 0.18	0.16 to 0.70	4 (18.18)	0 (0)
CDVA	0.29 $\pm$ 0.17	0.04 to 0.60	9 (40.90)	4 (18.18)
Postoperative				
UDVA	0.09 $\pm$ 0.12	-0.14 to 0.40	19 (86.4)	15 (68.2)
CDVA	-0.12 $\pm$ 0.07	-0.16 to 0.10	22 (100)	22 (100)
UIVA	0.26 $\pm$ 0.15	0.04 to 0.62	7 (31.8)	3 (13.6)
CIVA	0.32 $\pm$ 0.13	0.10 to 0.52	4 (18.2)	1 (4.5)
UNVA	0.43 $\pm$ 0.20	0.08 to 0.76	4 (18.2)	1 (4.5)
CNVA	0.52 $\pm$ 0.18	0.18 to 0.82	1 (4.5)	0 (0)

Abbreviations: CDVA, corrected distance visual acuity; CIVA, corrected intermediate visual acuity; CNVA, corrected near visual acuity; logMAR, logarithm of the minimum angle of resolution; SD, standard deviation; UDVA, uncorrected distance visual acuity; UIVA, uncorrected intermediate visual acuity; UNVA, uncorrected near visual acuity.

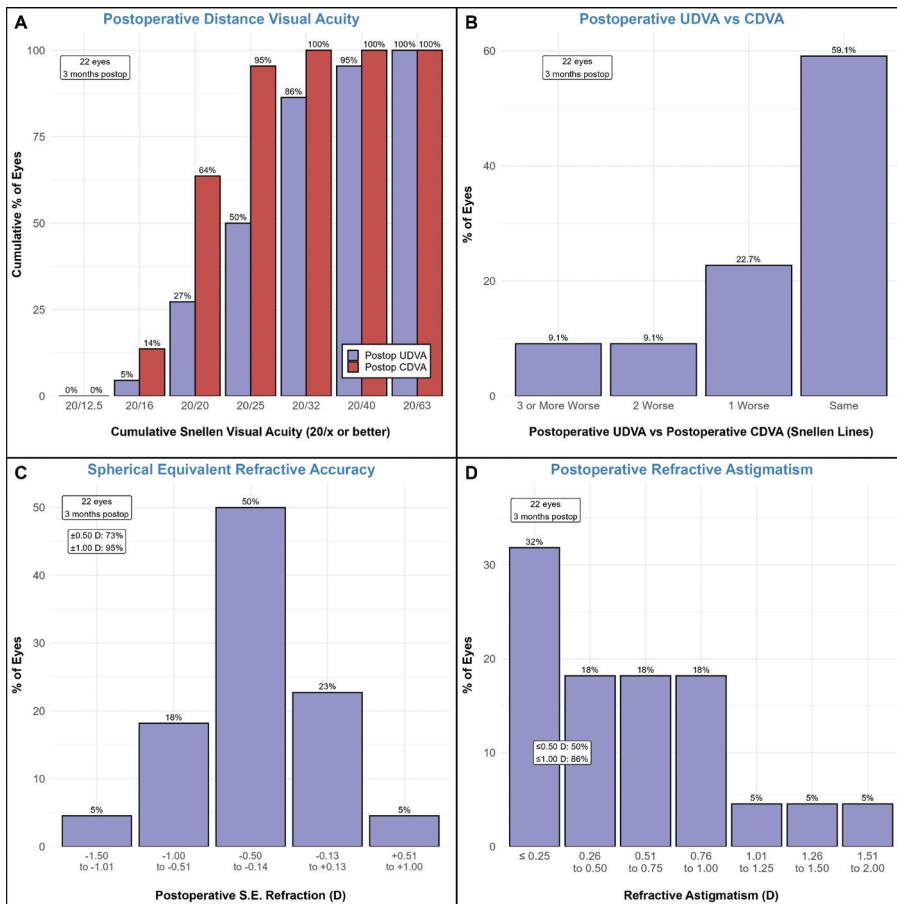


Figure 1. (A) Uncorrected distance visual acuity (UDVA). (B) UDVA versus corrected distance visual acuity (CDVA). (C) Spherical equivalent (SE) refraction accuracy. (D) Postoperative (postop) refractive cylinder. D, diopters.

DEFOCUS CURVE METRICS

The mean defocus curve showed its best performance around 0.00 D and maintained good acuity across low to

moderate myopic defocus (**Figure 2**). The area under the curve for visual acuity of 0.2 logMAR or better (ie, the area between the curve and the 0.2 logMAR line where

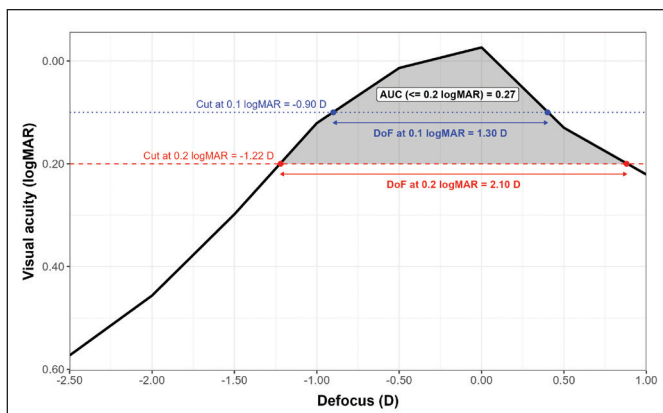


Figure 2. Mean defocus curve (black line). The shaded region shows the area under the curve (AUC) above 0.2 logarithm of the minimum angle of resolution (logMAR) (AUC = 0.27). The red dashed line marks 0.2 logMAR; the red dot/label indicates the negative cut at -1.22 diopters (D) and positive at +0.88 D. The blue dotted line marks 0.1 logMAR; blue points denote the intersections at -0.90 and +0.40 D. The double-headed blue arrow indicates the depth of focus (DoF) at 0.1 logMAR, spanning 1.30 D, whereas the double-headed red arrow indicates the DoF at 0.2 logMAR, spanning 2.10 D.

visual acuity was 0.2 or better logMAR) was 0.27. The curve reached 0.2 logMAR at -1.22 D (myopic side) and at +0.88 D (hyperopic side). Using the 0.1 logMAR criterion, intersections occurred at -0.90 and +0.40 D, yielding a depth of focus of 1.30 D. At higher myopic defocus (approximately -1.50 to -2.50 D; approximately 67 to 40 cm), mean acuity deteriorated beyond 0.2 logMAR (approximately 0.3 to 0.6 logMAR), indicating limited unaided near performance. Individual defocus curves are provided in **Figure A** to illustrate inter-subject variability around the cohort mean profile.

CONTRAST SENSITIVITY

Contrast sensitivity showed the expected band-pass profile, with the highest mean sensitivity at mid spatial frequencies (**Figure 3**). Mean $\pm$ SD logCS values were 1.61 ± 0.17 at 3 cpd, 1.84 ± 0.22 at 6 cpd, 1.41 ± 0.19 at 12 cpd, and 1.01 ± 0.23 at 18 cpd. Performance peaked at 6 cpd and declined at higher spatial frequencies.

AGREEMENT BETWEEN SUBJECTIVE REFRACTION AND AUTOREFRACTOMETRY

Bland-Altman analysis (**Figure 4**) showed a mean difference of +0.08 D for spherical equivalent (M), indicating a small positive offset of automated refraction relative to subjective refraction. The 95% limits of agreement ranged from -0.46 to +0.62 D (width: 1.08 D). A trend consistent with proportional bias was observed for spherical equivalent (M), with differences tending to decrease as subjective refraction became more positive. For astigmatic components, mean differences were negligible (bias 0.00 D for J_0 ; +0.03 D for J_{45}). The 95% limits

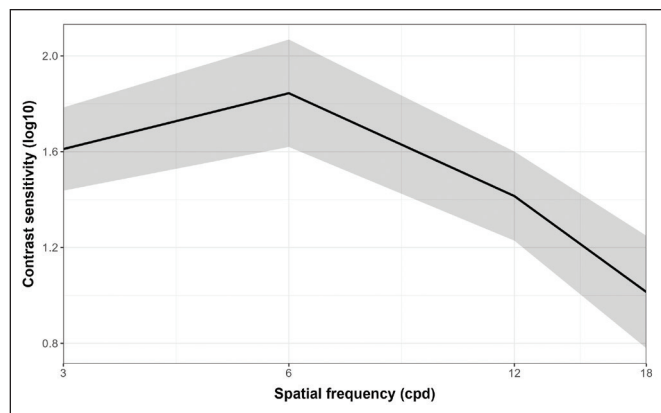


Figure 3. Mean contrast sensitivity function across eyes. The solid line shows average log₁₀ contrast sensitivity at 3, 6, 12, and 18 cycles/degree (cpd); the gray band denotes ± 1 standard deviation across eyes.

of agreement were -0.28 to +0.29 D for J_0 and -0.33 to +0.39 D for J_{45} , indicating non-trivial variability at the individual level despite minimal systematic offset.

Overall, objective and subjective measurements agreed closely on average but the width of the limits of agreement indicates that they are not interchangeable at the individual-eye level.

INFLUENCE OF PUPIL SIZE

Mean photopic pupil diameter was 3.37 ± 0.60 mm and mean mesopic pupil diameter was 4.91 ± 0.95 mm (difference: 1.54 ± 0.58 mm). Photopic and mesopic diameters were strongly correlated (Pearson's $r = 0.81$). Defocus and contrast sensitivity curves stratified by photopic pupil size are shown in **Figure 5**.

Using a cut-off of 3.5 mm ($n = 13$, < 3.5 mm; $n = 9$, ≥ 3.5 mm), mean CDVA were broadly similar, with overlapping spherical equivalent bars except at -1.00, -2.00, and -2.50 D.

At those points, the small photopic pupil group exhibited better mean acuity at larger negative defocus. At -2.50 D, mean acuity was 0.526 ± 0.036 versus 0.640 ± 0.054 (small-large = -0.114 logMAR), and at -2.00 D was 0.418 ± 0.029 versus 0.511 ± 0.054 (small-large = -0.093 logMAR). In contrast, at -1.00 D the pattern reversed, with better acuity in the large pupil group (0.080 ± 0.032 vs 0.149 ± 0.027 ; small-large = +0.069 logMAR).

Mixed-effects modeling confirmed a strong effect of defocus (Type III main effect of defocus: $P < .0499$), no main effect of pupil group ($P = .466$), and significant pupil group $\times$ defocus interaction ($P = .0289$), indicating that group differences vary across defocus levels. Per-level contrasts were nominally significant at -2.50 D ($P = .0165$) and -2.00 D ($P = .0499$), but not after multiplicity correction (Holm: 0.132 and 0.349; false discovery rate: 0.132 and 0.200); no difference was observed at -1.00 D ($P = .141$; Holm: 0.847).

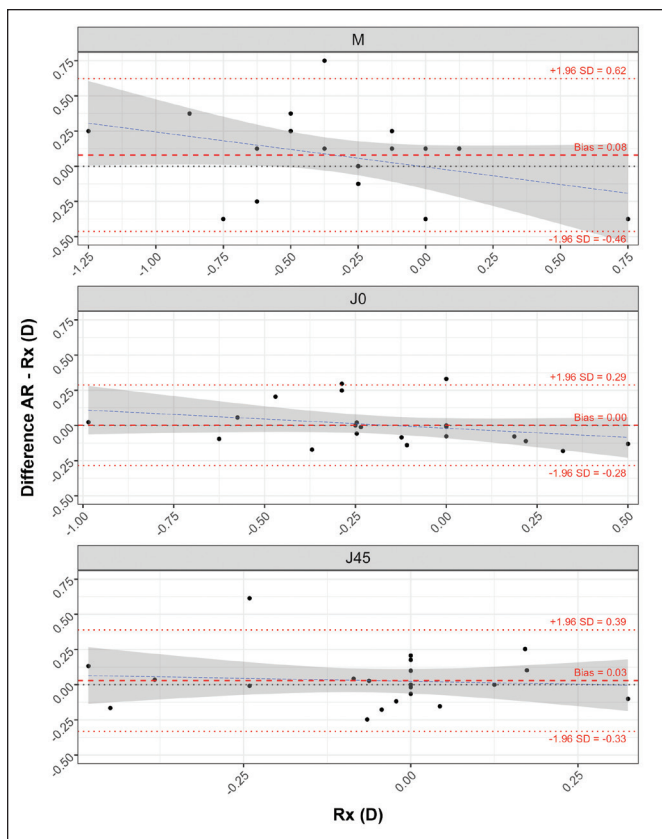


Figure 4. Bland-Altman agreement between autorefractometry (AR) and subjective refraction (Rx) for the power-vector components M, J_0 , and J_{45} . Points represent individual eyes; the dashed red line is the mean bias (AR – Rx) and the dotted red lines are the 95% limits of agreement (mean $\pm$ 1.96 standard deviation [SD]). The blue dotted line is the linear fit and the grey band around the regression line depicts the 95% confidence interval for the fitted mean trend (proportional-bias check). D, diopters.

Regarding contrast sensitivity, no overall group effect (main effect of group: $P = .576$), or group-by-frequency interaction (group-by-frequency interaction: $P = .297$) was detected. At 12 cpd, the large photopic pupil group showed a mean advantage of 0.107 log10 units (approximately +27% in linear units), but this did not reach statistical significance (Welch $P = .193$; model-based per-frequency contrast $P = .240$).

No intraoperative or postoperative adverse events were recorded.

DISCUSSION

This study provides the first independent clinical evaluation of the enVista Aspire enhanced monofocal IOL conducted outside the United States, including the first assessment of pupil-dependent optical performance with this platform. Although the optical and clinical outcomes of the enVista Aspire IOL were recently reported by Feltrin de Barros et al,¹³ that study was

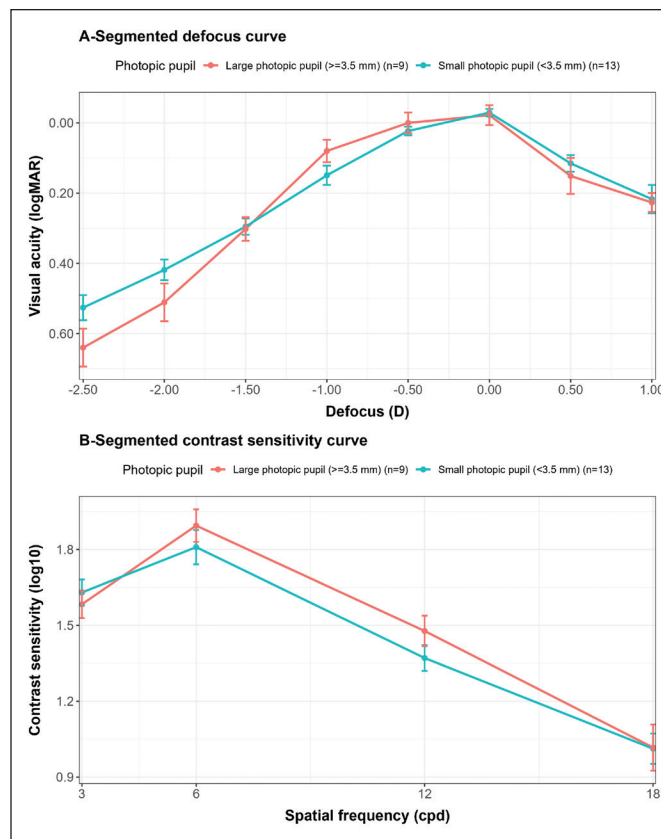


Figure 5. Defocus curve and contrast sensitivity curve stratified by photopic pupil size. cpd, cycles per degree; D, diopters.

industry-sponsored. Our findings offer complementary and clinically relevant data that further refine understanding of this enhanced monofocal platform. In particular, contrast sensitivity, pupil size influence on visual performance, and agreement between objective and manifest refraction have not previously been reported for this lens.

Distance visual outcomes in our cohort align with the expected performance of premium monofocal IOLs. Mean UDVA (0.09 logMAR) and CDVA (–0.02 logMAR) met or exceeded conventional monofocal benchmarks reported in the literature, confirming that the 1.5-mm central posterior zone with continuous curvature transition does not compromise distance acuity. All eyes achieved CDVA of 0.1 logMAR or better, supporting preservation of high-quality distance vision.

Our results align with published values for Isopure (BVI Medical), Eyhance ICB00 (Johnson & Johnson Vision, Inc), and Vivinex Impress (HOYA Surgical Optics),^{4,14} and are comparable to those reported for the enVista Aspire IOL¹³ for which mean CDVA was 20/20 and all eyes achieved 20/25 or better.

Similarly, the meta-analysis by Wan et al,¹⁵ demonstrated that enhanced monofocal IOLs provide clinically

meaningful improvements in intermediate vision without compromising distance acuity, reinforcing the consistency of our findings within the broader literature. Monocular UIVA (0.26 ± 0.15 logMAR) and DCIVA (0.32 ± 0.13 logMAR) compared favorably with those reported for other platforms. Regarding near vision, it remained limited (UNVA: 0.43 ± 0.20 logMAR; DCNVA: 0.52 ± 0.18 logMAR), consistent with designs prioritizing intermediate performance.¹⁵ The convergence of outcomes across platforms with different optical designs, higher-order aspheric surfaces (Eyhance), polynomial bi-aspheric designs (Isopure), positive spherical aberration (RayOne EMV; Rayner Intraocular Lenses Ltd),¹¹ or continuous curvature change (Aspire) suggests multiple strategies achieve similar depth of focus extensions through different mechanisms yielding comparable retinal light distributions.

When considered alongside other enhanced monofocal platforms, including Tecnis Eyhance, Isopure, RayOne EMV, and Vivinex Impress, the enVista Aspire IOL appears to provide a comparable range of functional vision despite relying on a different optical strategy. These findings suggest that different non-diffractive approaches, including higher-order aspheric transitions, polynomial bi-aspheric designs, and controlled spherical aberration profiles, may converge toward a similar clinical objective: extending intermediate vision while maintaining the optical quality expected from monofocal-like designs.

The defocus curve obtained with the enVista Aspire IOL demonstrated a smooth extension of functional vision toward intermediate distances while preserving excellent distance acuity. Visual acuity remained 0.2 logMAR or better from plano to approximately 1.22 D of defocus, closely aligning with clinical findings of approximately 1.50 D.¹³ The slight difference in absolute depth-of-focus values (1.30 vs 1.50 D) is likely attributable to expected inter-study variability related to testing conditions, patient characteristics, and measurement methodology.

When contextualized within the broader enhanced monofocal landscape, the enVista Aspire IOL's depth of focus performance is comparably to other commercially available platforms. The observed defocus curve, maintaining visual acuity of 0.3 logMAR or better from plano to approximately 2.50 D of defocus (+1.00 to -1.50 D), is consistent with published data for similar designs. Studies of the Tecnis Eyhance have reported depth-of-focus values ranging from 1.00 to 1.75 D depending on the visual acuity threshold applied,^{16,17} whereas García-Bella et al¹¹ reported that the RayOne EMV maintained visual acuity of 0.2 logMAR or better over a 2.00 D binocular range (+1.00 to -1.00 D). Comparable extended depth-of-focus behavior has also been described for the Vivinex

Impress.¹⁸ This convergence of defocus curve profiles across platforms with fundamentally different optical strategies, whether aspheric surface modifications (Eyhance), polynomial bi-aspheric designs (Isopure), positive spherical aberration induction (RayOne EMV), or controlled curvature change (enVista Aspire), suggests that approximately 1.00 to 1.50 D of functional depth of focus may represent a practical upper limit for enhanced monofocal designs that maintain acceptable optical quality.

Contrast sensitivity represents a key differentiating factor between enhanced monofocal and diffractive or non-diffractive extended depth-of-focus designs. In our cohort, photopic contrast sensitivity remained within age-matched normal ranges, with no clinically relevant reduction at higher spatial frequencies. To date, no published studies have evaluated contrast sensitivity outcomes with the enVista Aspire IOL. Our photopic contrast sensitivity remained within age-matched normal ranges across all spatial frequencies, with no significant differences compared to established normative data for pseudophakic eyes implanted with conventional monofocal IOLs.^{19,20} These findings indicate that the optical modifications of the Aspire design do not compromise contrast perception, in contrast to certain multifocal and diffractive extended depth-of-focus platforms where reductions of 0.1 to 0.3 log units at medium and high spatial frequencies have been reported.^{21,22} These contrast sensitivity findings are consistent with the objective optical quality metrics reported by Feltrin de Barros et al¹³ whose modulation transfer function analysis showed values >0.50 at 10 cycles/degree for both 2-mm and natural pupil apertures (mean: 2.65 mm), with total modulation transfer function of 0.60 ± 0.15 and 0.52 ± 0.17 , respectively. The preservation of contrast sensitivity across the enhanced monofocal category has been confirmed in comparative studies. Mencucci et al⁴ reported no significant differences among the Eyhance, Vivinex Impress, and Isopure whereas Garzón et al¹⁹ reported comparable contrast sensitivity between the Eyhance and conventional Tecnis One monofocal across all spatial frequencies. Similarly, the meta-analysis by Fernández et al²³ demonstrated no significant differences between the Eyhance and conventional monofocals (high-certainty evidence). Collectively, these data indicate that contemporary enhanced monofocal designs can extend depth of focus without incurring the contrast sensitivity reductions historically associated with premium IOL technologies.

The concordance between objective automated refraction and subjective refraction observed in our study has relevant implications for clinical workflow and refractive assessment. Narrow limits of agreement for spherical equivalent and minimal systematic bias in

astigmatic components indicate that the KR-1W autorefractor provides a reliable starting point for subjective refinement in eyes implanted with the enVista Aspire IOL. These findings suggest that depth-of-focus-enhancing optical modifications do not meaningfully compromise autorefractor accuracy. This behavior contrasts with reports for multifocal and certain extended depth-of-focus IOLs, where systematic myopic shifts of 1.00 to 1.50 D have been described.⁹ The concordance observed is comparable to other enhanced monofocal platforms: Garzón et al¹⁹ found no significant differences between autorefraction and manifest refraction for the Tecnis Eyhance, and Pérez-Sanz et al²⁴ reported a mean difference of 0.13 ± 0.38 D with the Isopure lens, closely aligning with our $+0.08$ D finding. Together, these studies support that enhanced monofocal optical designs do not adversely affect autorefraction accuracy relative to conventional monofocal IOLs.

Pupil diameter remains a clinically relevant but incompletely understood factor in enhanced monofocal IOL performance. In our cohort, stratification by photopic pupil size produced broadly similar defocus curve with overlapping variability bands. Mixed-effects modeling confirmed a strong defocus effect without a main pupil-group effect, although a significant pupil-by-defocus interaction indicated localized, defocus-specific differences rather than systematic separation. Specifically, smaller photopic pupils showed better mean visual acuity at higher negative defocus levels (notably at -2.00 and -2.50 D), whereas at -1.00 D the pattern reversed; however, these differences were not significant after multiplicity correction and should be interpreted cautiously. Contrast sensitivity stratified by pupil size similarly showed no overall group effect or frequency-dependent separation, supporting a generally pupil-robust optical profile. This relative stability may reflect Aspire's gradual power transition via continuous curvature change rather than abrupt optical zones or high induced spherical aberration. Although direct comparisons are limited by methodological differences, previous studies suggest lens-specific pupil-related tendencies among enhanced monofocals. Garzón et al¹⁹ reported pupil-dependent behavior for the Eyhance in automated refraction, with larger pupils associated with more negative autorefraction relative to manifest refraction, whereas the conventional TECNIS One showed no such dependence. Optical bench data from Alarcon et al²⁵ indicated that the Isopure and RayOne EMV exhibited correlations between simulated intermediate gains and reductions in simulated distance visual acuity and modulation transfer function with increasing pupil size; however, this effect was not confirmed clinically by Fernández-Núñez et al²⁶ (Isopure) or Yeo et al²⁷ (RayOne EMV).

The main limitations of this study include the relatively small sample size, although it was determined using robust methodological criteria and is consistent with previously published data. The monocular testing protocol, although appropriate for isolating intrinsic IOL optical performance, does not account for binocular summation effects relevant to real-world vision. Additionally, assessments were performed at 3 months postoperatively, limiting evaluation of long-term stability; extended follow-up would be necessary to confirm sustained performance. Furthermore, patient-reported outcome measures, including validated questionnaires assessing spectacle independence, subjective quality of vision, halos, glare, and patient satisfaction, were not included in the current study. In addition, visual performance and contrast sensitivity were evaluated under photopic conditions only; therefore, mesopic visual performance and photic phenomena could not be fully characterized. Future investigations incorporating these subjective and mesopic assessments would provide a more comprehensive characterization of patient experience and visual quality with the enVista Aspire platform.

CONCLUSION

This clinical evaluation demonstrates that the enVista Aspire enhanced monofocal IOL provides excellent distance acuity, functional intermediate vision with approximately 1.30 D of depth of focus, and preserved contrast sensitivity, confirming reproducible outcomes across surgical settings and patient populations. Depth-of-focus-enhancing optical modifications did not compromise distance vision, whereas pupil-size analyses suggested limited overall influence on visual performance under the evaluated conditions. These features position the enVista Aspire as a valuable option within the expanding IOL spectrum, particularly for patients prioritizing visual quality and intermediate performance over complete spectacle independence.

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