



Real-World Experience with Enhanced Monofocal Intraocular Lenses Following Cataract Surgery: A Multicenter Retrospective Case Series

Eric Donnenfeld · Ravi Patel · Michael Patterson · Inder Paul Singh · Farrell Tyson ·
P Dee Stephenson

Received: May 22, 2026 / Accepted: July 27, 2026
© The Author(s) 2026

ABSTRACT

Introduction: The enVista Aspire (EA) and enVista Aspire Toric (ETA) lenses are monofocal intraocular lenses (IOLs) with intermediate-optimized optics designed to broaden depth of focus. This study describes outcomes with these IOLs in real-world clinical practice.

Prior Publication: Patterson M, Stephenson D. Performance of an enhanced monofocal intraocular lens in patients undergoing cataract surgery: retrospective real-world study. Paper 122619. Presented at the American Society of Cataract and Refractive Surgery Annual Meeting, 10–13 April 2026, in Washington, DC, USA. Patel R, Stephenson D. Performance of an enhanced monofocal toric intraocular lens in patients undergoing cataract surgery: retrospective real-world study. Paper 124887. Presented at the American Society of Cataract and Refractive Surgery Annual Meeting, 10–13 April 2026, in Washington, DC, USA.

Supplementary Information The online version contains supplementary material available at <https://doi.org/10.1007/s40123-026-01473-3>.

E. Donnenfeld (✉)
Ophthalmic Consultants of Long Island,
Garden City, NY, USA
e-mail: ericdonnenfeld@gmail.com

R. Patel
Atlantic Eye, Eatontown, NJ, USA

M. Patterson
Eye Centers of Tennessee, Crossville, TN, USA

Methods: This multicenter, retrospective, real-world case series study included six cataract surgeons in the USA. Surgeons provided a convenience sample of ≥ 5 study IOL implantation cases and completed a retrospective experience survey. Outcomes included visual acuity (corrected and uncorrected distance visual acuity [CDVA, UDVA] and uncorrected intermediate visual acuity [UIVA]), refractive outcomes, and safety (adverse events and visual changes). The surgeon survey captured IOL utilization patterns and surgeon experience as supplementary descriptive findings.

Results: The analysis included 141 eyes (88 EA and 53 ETA) from 84 patients. Patients were aged 62–84 years, with postoperative follow-up ranging from approximately Days 1–6 to 4 months. At the last available postoperative visit, monocular CDVA of 20/25 or better was achieved by 97.2% of EA and 94.9% of ETA eyes; monocular UDVA of 20/25 or better by 71.3% and 84.9%, respectively; and monocular UIVA of 20/32 or better by 76.6% and 93.0%, respectively. A

I. P. Singh
Eye Centers of Racine and Kenosha, Racine, WI,
USA

F. Tyson
Tyson Eye, Cape Coral, FL, USA

P. D. Stephenson
Stephenson Eye Associates, Venice, FL, USA

binocular UIVA of 20/32 or better was achieved by 100% of patients. Mean $\pm$ SD SEQ outcome was -0.06 ± 0.30 D (EA) and 0.00 ± 0.32 D (ETA). No serious adverse events were documented in the available records. Findings from the surgeon survey indicated positive surgeon experience with the qualities and outcomes of the study IOLs.

Conclusions: In this descriptive real-world analysis, a high proportion of eyes implanted with the study IOLs achieved good distance and functional intermediate vision.

PLAIN LANGUAGE SUMMARY

Cataracts are a common part of aging. They can cause blurred vision and sight loss. Cataract surgery removes the cloudy natural lens from the eye and replaces it with an artificial intraocular lens (IOL). Standard monofocal IOLs provide good distance vision but do not support clear vision at intermediate distances, which is required for activities such as using a computer or cooking. “Enhanced monofocal” IOLs are designed to improve intermediate vision while maintaining the visual quality of standard monofocal IOLs. The main aim of the study was to describe how the enVista Aspire and enVista Aspire Toric IOLs (used in patients with astigmatism) performed in everyday clinical practice across six eye care centers in the USA. Surgeons completed forms using information from medical records of patients who received these lenses. Outcomes included distance and intermediate vision after surgery, how closely vision after surgery matched the planned outcome, and whether any safety issues occurred. The results showed that a high proportion of eyes had good distance vision and usable intermediate vision after surgery. Vision after surgery was generally close to the planned outcome, meaning many patients achieved the intended level of vision correction. No serious adverse events were documented in the available clinical records. This study provides early real-world observations on visual and safety outcomes with enhanced monofocal IOLs in routine cataract surgery.

Keywords: Cataract; Intraocular lenses; Retrospective studies

Key Summary Points

Why carry out this study?

Enhanced monofocal intraocular lenses are designed to broaden depth of focus into intermediate vision, addressing the visual demands of modern patients while maintaining monofocal-like visual quality.

Real-world clinical outcomes with these lenses outside controlled trial settings remain limited.

This multicenter retrospective study evaluated real-world clinical utilization of the enVista Aspire and enVista Aspire Toric enhanced monofocal intraocular lenses, and described patient visual, refractive, and safety outcomes. Surgeon experience was collected as a supplementary, descriptive endpoint.

What was learned from the study?

In real-world use, at least 94% of eyes achieved corrected distance visual acuity of 20/25 or better, at least 76% achieved uncorrected intermediate vision of 20/32 or better, mean refractive outcomes were close to target, and no serious adverse events were documented in the available clinical records.

These findings provide early descriptive real-world observations on the use of enhanced monofocal lenses in routine clinical practice.

INTRODUCTION

Cataracts are the leading cause of preventable blindness, with an estimated age-standardized pooled prevalence of 17% worldwide [1, 2]. Consequently, cataract surgery is now among the most common and cost-effective surgical procedures available, with predictable outcomes and a low rate of complications [3–5]. Monofocal intraocular lenses (IOLs) are the

most common IOL type implanted following cataract surgery [5, 6]. These lenses focus light at a single predetermined focal point (typically distance), allowing for distance vision restoration with good visual quality [5, 7]. However, with an increasing working age and increased use of screen-based devices, the demands for functional vision in patients undergoing cataract surgery have evolved from solely restoration of distance vision to achieving functional vision at a broader range of distances [7, 8]. In recent years, monofocal IOLs have been adapted to extend the depth of focus in the treated eye while maintaining monofocal-like visual quality (termed monofocal plus or enhanced monofocal IOLs) [9–11].

The enVista Aspire™ (EA) and enVista Aspire™ Toric (ETA) lenses (Bausch + Lomb, Inc., Bridgewater, NJ, USA) are hydrophobic acrylic monofocal IOLs with intermediate-optimized optics, providing a broader depth of focus than standard monofocal IOLs. This broader depth of focus is achieved via optical modification of the posterior aspheric surface, creating a small continuous increase in IOL power within the central 1.5-mm diameter [12, 13]. The lenses create a gradual transitional distribution of light energy from the center to the periphery [11], which is intended to minimize dysphotopsia. EA and ETA lenses are indicated for primary implantation in the capsular bag of the eye in adult patients for the visual correction of aphakia following the removal of a cataractous lens for improved uncorrected distance vision. The ETA IOL is also indicated for visual correction of corneal astigmatism [12]. In a prospective observational study in patients undergoing cataract surgery ($N = 29$ eyes), the EA IOL demonstrated excellent distance visual acuity, with useful intermediate and functional near distance vision. The defocus curve showed ~1.50 D of continuous depth of focus at 0.2 logMAR or better [11]. While the effectiveness of the enVista® monofocal lenses has been established in a clinical trial setting [14], real-world studies can contribute to the existing evidence base by investigating their use in routine practice in broader patient populations. This retrospective case review aimed to describe real-world patient outcomes with the enVista Aspire IOLs.

METHODS

Study Design

This study was reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines (Supplementary Material) [15], recognizing that certain items could not be fully addressed given the retrospective, real-world design.

This was a retrospective convenience case series review and cross-sectional survey study of cataract surgeons from the USA. Surgeons were eligible for inclusion if they were licensed ophthalmologists (cataract/refractive/cornea surgeons) living and working in the USA; had 3 or more years of experience treating patients and conducting cataract surgery using monofocal and/or toric IOLs; had completed cataract extraction and study IOL implantation in five or more patients; and had a level of English proficiency sufficient to take part in a survey. Each surgeon provided a deidentified retrospective convenience sample of at least five electronic medical record cases of adult patients who underwent cataract surgery with implantation of a study IOL in routine clinical practice at participating centers. To capture outcomes reflective of routine clinical practice, no additional prespecified patient-level inclusion or exclusion criteria were applied. Following review of the dataset, eyes with a planned myopic target (spherical equivalent [SEQ] ≤ -0.5 D) were excluded from all analyses to restrict the evaluation to eyes targeted for emmetropia.

Data were provided using a standardized case report form (CRF). Patient outcomes were collected from the first postoperative visit and the most recent available postoperative visit. No formal sample size calculation was performed; the sample size was determined by the number of deidentified cases available during the study period. No prospective screening log or consecutive case requirement was applied, and participant flow was not formally documented. No fixed data-collection window was predefined; surgeons contributed cases available in their records.

The study protocol received an exemption from the Western Institutional Review Board and Copernicus Group for central ethical review and approval (tracking number: 20242583). The study was performed in accordance with the Declaration of Helsinki of 1964, and its later amendments. All surgeons provided informed consent to participate in this study, and provided consent for publication of study data. No identifying patient information was collected.

Assessments and Outcome Variables

Outcomes captured in the CRFs included clinical outcomes and safety variables. Postoperative patient assessments were conducted as part of routine clinical practice at participating sites. In this retrospective real-world study, testing procedures, including visual acuity charts and definitions of distance, were not standardized across centers or consistently recorded. Effectiveness variables included visual acuity in Snellen units (corrected and uncorrected distance visual acuity [CDVA, UDVA] and uncorrected intermediate visual acuity [UIVA]) and refractive outcomes (sphere, cylinder, axis, SEQ, and delta SEQ). Visual acuity was recorded as Snellen fractions in routine clinical practice, without letter-level scoring.

Safety variables included adverse events (AEs) and patient-reported visual changes, which were captured retrospectively from clinician chart entries. To reflect safety findings of routine clinical practice, no prespecified or standardized assessment, or uniform grading scales (including for dysphotopsia) were applied. Device-related safety findings, including glistenings, were not prespecified in the CRF.

Potential confounders and effect modifiers were not prespecified. Given the retrospective study design and descriptive analytical approach, adjustment for potential confounding was not performed.

Statistical Analysis

Analyses were descriptive; no inferential statistical comparisons were performed, and no formal hypotheses were prespecified. Continuous

variables were summarized using appropriate summary statistics, and categorical variables using counts and percentages. The number of missing values was reported separately. Analyses were conducted at both eye level and patient level, as appropriate, and did not account for clustering by patient or surgeon. The analyses followed an available-case approach, and missing data were not imputed. Given the extent of missingness, complete-case and sensitivity analyses were not undertaken, as these would yield small and potentially unrepresentative subsets. Accordingly, all findings should be interpreted as descriptive and exploratory.

Follow-up intervals reflected routine clinical practice and were variable. A substantial proportion of cases had missing or unknown follow-up times, and therefore stratification or restriction by postoperative time point based on follow-up duration was not performed.

Baseline characteristics were summarized using the total number of patients (or eyes) as the denominator, with missing values reported as a separate “not reported” category. For visual acuity and other outcome variables, percentages were calculated using the number of nonmissing observations as the denominator. Visual acuity outcomes were summarized at the eye level for monocular analyses and at the patient level for binocular analyses when both eyes had been implanted with study IOLs. For patients with mixed EA and ETA implantation, each eye was included in the monocular analyses for the corresponding IOL group, and the patient was included in the binocular analyses for both groups. Patients implanted bilaterally with a study IOL and another IOL were classified as unilaterally implanted, with only data from the study IOL-implanted eye included in the monocular analyses. Where both eyes from a single patient were included in monocular analyses, eyes were treated as independent observations for descriptive purposes. Cumulative visual acuity outcomes were also calculated.

Baseline visual acuity data and outcomes data from the most recent visit were included in the analysis. Where a particular outcome measure was not available at the most recent visit, the

Table 1 Patient demographics and baseline characteristics

Characteristic	EA group (<i>n</i> = 54 patients; <i>n</i> = 88 eyes)	ETA group (<i>n</i> = 35 patients; <i>n</i> = 53 eyes)
Patient characteristics		
Age, mean $\pm$ SD years (<i>n</i> patients)	71.7 $\pm$ 6.6 (15)	72.3 $\pm$ 5.4 (9)
Not reported, <i>n</i> patients	39	26
<i>Sex, n patients (%)</i>		
Female	11 (20.4)	5 (14.3)
Male	4 (7.4)	4 (11.4)
Not reported	39 (72.2)	26 (74.3)
Implantation status		
<i>Bilateral implantation^a</i>		
<i>n</i> (%) patients	39 (72.2)	23 (65.7)
<i>n</i> (%) eyes	73 (83.0)	41 (77.4)
<i>Unilateral implantation</i>		
<i>n</i> (%) patients	15 (27.8)	12 (34.3)
<i>n</i> (%) eyes	15 (17.0)	12 (22.6)
Ocular comorbidities, n (patients)		
No ocular comorbidity	23 (42.6)	3 (8.6)
Any ocular comorbidity ^b	8 (14.8)	6 (17.1)
LASIK OU	0	3 (33.3)
Dry eye	2 (6.5)	0
Mild POAG ^c	2 (6.5)	0
Guttata	1 (3.2)	0
Cicatricial ectropion with dry eye	1 (3.2)	1 (11.1)
Suspected glaucoma, narrow angles	1 (3.2)	0
Macular drusen OU	1 (3.2)	1 (11.1)
Asteroid hyalosis, pseudoexfoliation without glaucoma	0	1 (11.1)
Epiretinal membrane OU	0	1 (11.1)
Not reported	23 (42.6)	26 (74.3)
Ocular characteristics		
SEQ target, mean $\pm$ SD (<i>n</i> eyes), D	-0.08 $\pm$ 0.16 (88)	-0.04 $\pm$ 0.17 (53)
Not reported, <i>n</i> eyes	0	0
Preoperative flat K, mean $\pm$ SD (<i>n</i> eyes), D	43.55 $\pm$ 1.59 (56)	43.53 $\pm$ 1.75 (53)

Table 1 continued

Characteristic	EA group (<i>n</i> = 54 patients; <i>n</i> = 88 eyes)	ETA group (<i>n</i> = 35 patients; <i>n</i> = 53 eyes)
Not reported, <i>n</i> eyes	32	0
Preoperative steep K, mean $\pm$ SD (<i>n</i> eyes), D	44.27 $\pm$ 1.67 (56)	44.46 $\pm$ 1.71 (53)
Not reported, <i>n</i> eyes	32	0
Preoperative delta K, mean $\pm$ SD (<i>n</i> eyes), D	0.72 $\pm$ 0.46 (56)	0.93 $\pm$ 0.44 (53)
Not reported, <i>n</i> eyes	32	0
Anterior chamber depth, mean $\pm$ SD (<i>n</i> eyes), mm	3.13 $\pm$ 0.37 (22)	3.17 $\pm$ 0.42 (14)
Not reported, <i>n</i> eyes	66	39
Axial length, mean $\pm$ SD (<i>n</i> eyes), mm	23.81 $\pm$ 1.08 (22)	24.46 $\pm$ 1.29 (14)
Not reported, <i>n</i> eyes	66	39
Sphere, mean $\pm$ SD (<i>n</i> eyes), D	0.24 $\pm$ 2.11 (22)	−0.69 $\pm$ 2.56 (13)
Not reported, <i>n</i> eyes	66	40
Cylinder, mean $\pm$ SD (<i>n</i> eyes), D ^d	−0.86 $\pm$ 0.47 (20)	−1.15 $\pm$ 0.55 (13)
Not reported, <i>n</i> eyes	68	40
Axis, mean $\pm$ SD (<i>n</i> eyes), degrees	93 $\pm$ 25 (20)	94 $\pm$ 49 (13)
Not reported, <i>n</i> eyes	68	40

EA enVista Aspire, ETA enVista Aspire Toric, LASIK Laser-assisted in situ keratomileusis, OU Oculus uterque (both eyes), POAG Primary open-angle glaucoma, SD Standard deviation, SEQ Spherical equivalent

^aThirty-four patients were bilaterally implanted with EA, 18 patients were bilaterally implanted with ETA, and 5 patients had mixed EA/ETA implantation. Patients with mixed bilateral implantation were included in both the EA and ETA bilateral implantation counts. Accordingly, bilateral eye counts include five EA eyes and five ETA eyes from patients with mixed bilateral implantation; ^bFor ocular comorbidity reporting, patients with mixed EA/ETA implantation could be included in more than one study group, and each patient could have more than one comorbidity. Percentages for individual ocular comorbidities were calculated using the number of patients with reported ocular comorbidity status as the denominator (EA, *n* = 31; ETA, *n* = 9); ^cKahook Dual Blade goniotomy/endoscopic cyclophotocoagulation; ^dA transposition was performed for positive cylinder values

latest available measurement for that endpoint was used. Cylinder values recorded in positive notation were converted (transposed) into the standard negative cylinder format to ensure consistency in refractive data analysis. Safety data were analyzed using descriptive statistics.

Supplementary Surgeon Survey

Surgeons completed a retrospective experience survey, documenting their experience with the study IOLs. Outcomes captured in the survey included surgeon and clinical practice characteristics, IOL utilization patterns, and surgeon satisfaction. Survey data were analyzed using

descriptive statistics as described previously in the statistical analysis section.

RESULTS

Patient Demographics and Baseline Characteristics

Retrospective cases were provided by six cataract surgeons, with IOL implantations spanning from 24 October 2023 to 5 December 2024. Nine eyes were targeted for myopia (target SEQ ≤ -0.5 D) and were retrospectively excluded from the analysis, leaving a total of 141 study eyes (84 patients). Of these, 88 eyes from 54 patients received EA and 53 eyes from 35 patients received ETA. Five patients underwent bilateral implantation with one EA eye and one ETA eye and were therefore included in both treatment groups (Table 1). Patients ranged in age from 62 to 84 years. Among those with available sex data, females comprised 73.3% of patients with EA (11/15) and 55.6% of patients with ETA (5/9) (Table 1). Ocular comorbidities were recorded for eight patients with EA and six patients with ETA. Dry eye (including one patient with cicatricial ectropion with dry eye), prior laser-assisted in situ keratomileusis (LASIK) treatment, and glaucoma/suspected glaucoma were the most common ocular comorbidities among the whole cohort (each $n = 3$ patients; Table 1). Ocular baseline characteristics are summarized in Table 1. A baseline monocular CDVA of 20/25 or better was reported in 30.0% (6/20) of eyes in the EA group and 50.0% (7/14) in the ETA group.

Follow-up intervals were variable across the study cohort, and follow-up duration was not available for a substantial proportion of cases. Among those eyes with available data, the last postoperative visit ranged from approximately Days 1–6 to 4 months (Table 2).

Visual Outcomes

Visual outcomes were assessed using the last available postoperative data. A monocular CDVA of 20/25 or better was achieved

Table 2 Timing of the last available postoperative assessment for each eye

Time since IOL implantation ^a	EA group ($n = 88$ eyes)	ETA group ($n = 53$ eyes)
Days 1–6, n (%)	–	3 (5.7)
Days 7–13, n (%)	3 (3.4)	–
Days 14–29, n (%)	1 (1.1)	1 (1.9)
1 month, n (%)	9 (10.2)	3 (5.7)
3 months, n (%)	6 (6.8)	7 (13.2)
Other, n (%)	2 (2.3) ^b	–
Not reported, n (%)	67 (76.1)	39 (73.6)

EA enVista Aspire, ETA enVista Aspire Toric, IOL Intraocular lens

^aTime since IOL implantation is based on the latest postoperative visit at which outcome data were available for each eye. Outcome-specific analyses used the latest available data for each endpoint; therefore, data from earlier follow-up visits may have been included in analyses when no later measurement was available for that outcome; ^bOther follow-up visits took place at approximately 4 months

by 97.2% (70/72) and 94.9% (37/39) of eyes implanted with the EA and ETA IOLs, respectively (Fig. 1). Binocular CDVA outcomes were available for a small subset of patients; a binocular CDVA of 20/25 or better was achieved by 100% of patients with available data in the EA (12/12) and ETA (11/11) subgroups (Fig. 2). The proportion of eyes achieving a monocular UDVA of 20/25 or better was 71.3% (62/87) and 84.9% (45/53) for the EA and ETA groups, respectively (Fig. 1). The corresponding rates for binocular UDVA of 20/25 or better were 85.7% (24/28) and 92.3% (12/13) of patients, respectively (Fig. 2). Monocular UIVA of 20/32 or better was achieved by 76.6% (59/77) and 93.0% (40/43) of eyes in the EA and ETA groups, respectively (Fig. 1). The corresponding rates for binocular UIVA of 20/32 or better were 100% of patients in the EA (27/27) and ETA (13/13) groups (Fig. 2).

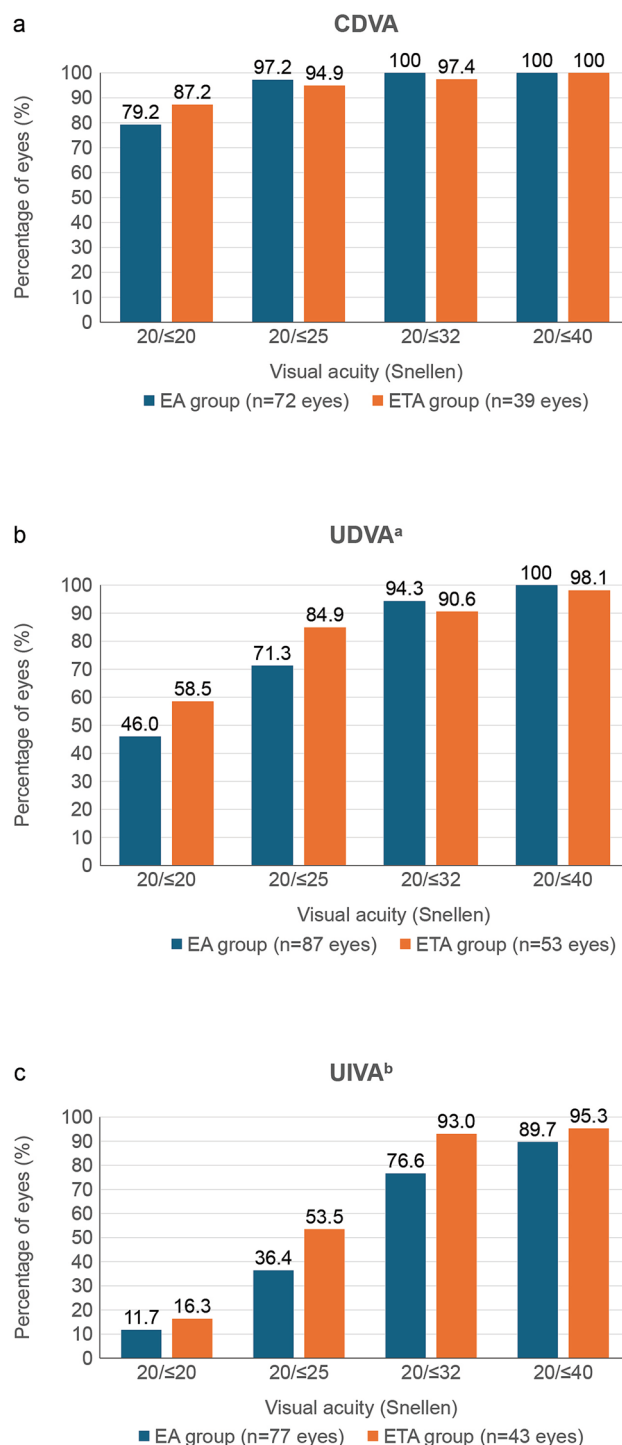


Fig. 1 Monocular visual acuity outcomes at last available postoperative visit (cumulative data) in the EA and ETA groups: **a** CDVA, **b** UDVA, and **c** UIVA. Number of eyes with missing data: **a** EA = 16, ETA = 14; **b** EA = 1, ETA = 0; **c** EA = 11, ETA = 10. *CDVA* corrected distance

visual acuity, *EA* enVista Aspire, *ETA* enVista Aspire Toric, *UDVA* uncorrected distance visual acuity, *UIVA* uncorrected intermediate visual acuity. ^aOne ETA eye did not achieve a UDVA of 20/40; ^bEight EA eyes and two ETA eyes did not achieve a UDVA of 20/40

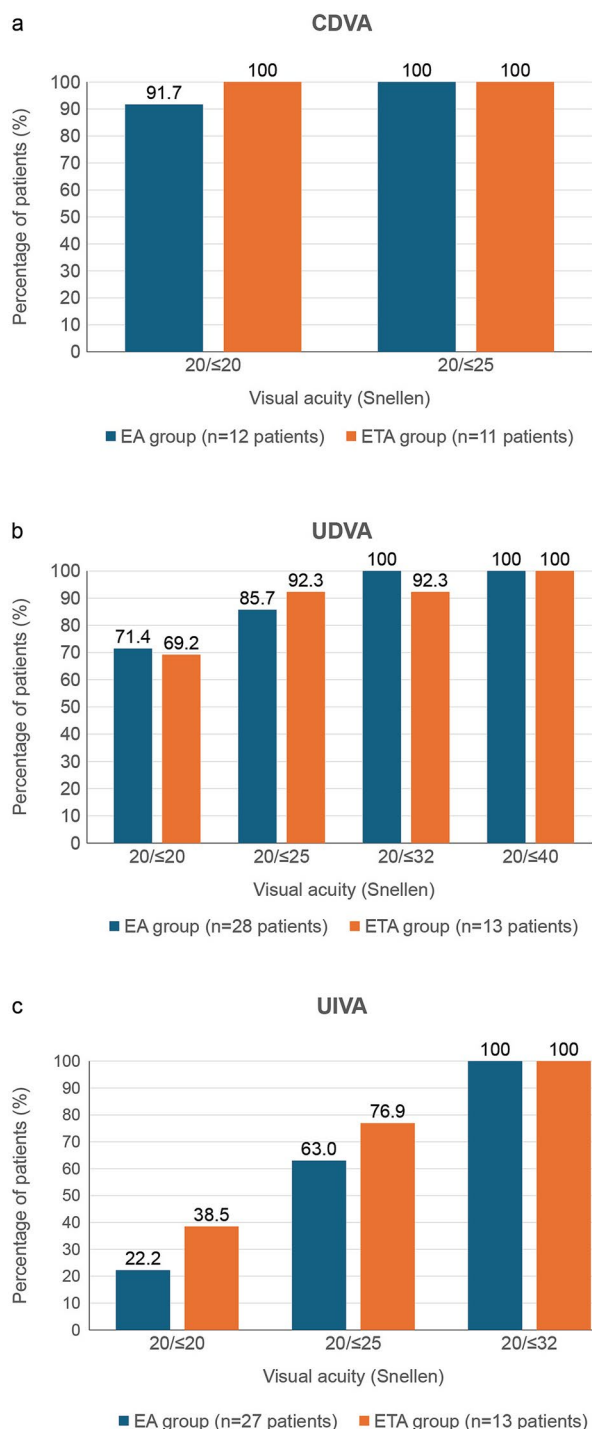


Fig. 2 Binocular visual acuity outcomes at last available postoperative visit (cumulative data) in the EA and ETA groups: **a** CDVA, **b** UDVA, and **c** UIVA. Number of patients with missing data: **a** EA = 27, ETA = 12; **b** EA = 11, ETA = 10; **c** EA = 12, ETA = 10. *CDVA* corrected distance visual acuity, *EA* enVista Aspire, *ETA* enVista Aspire Toric, *UDVA* uncorrected distance visual acuity, *UIVA* uncorrected intermediate visual acuity

Refractive Outcomes

The mean $\pm$ standard deviation (SD) SEQ outcome was -0.06 ± 0.30 D in the EA group ($n = 79$) and 0.00 ± 0.32 D in the ETA group ($n = 48$). The corresponding differences between targeted SEQ and achieved SEQ were 0.02 D and 0.04 D. At baseline, mean $\pm$ SD corneal cylinder was -0.86 ± 0.47 D ($n = 20$) in the EA group and -1.15 ± 0.55 D ($n = 13$) in the ETA group; postoperatively, the corresponding mean $\pm$ SD residual cylinder was -0.42 ± 0.43 D ($n = 78$) and -0.34 ± 0.33 D ($n = 48$), respectively.

Safety Outcomes

One patient implanted with the EA IOL underwent a neodymium-doped yttrium aluminum garnet (Nd:YAG) laser capsulotomy in both eyes. Visual changes at any time point were reported by 11.1% (6/54) and 8.6% (3/35) of patients for the EA and ETA IOLs, respectively. Blurred vision was the most frequently reported visual change (EA, three patients; ETA, two patients), followed by brighter images (EA, two patients). Discomfort, intermittent inferior photopsia, occasional temporary arc, and temporal crescent were reported by one patient each in the EA group, and foreign body sensation and dry eye/gritty feeling were reported by one patient each in the ETA group. No glis-tenings were reported in any group. As glis-tenings were not prespecified in the CRF, only spontaneously documented cases would have been captured. No other AEs were documented in the available clinical records.

Surgeon Survey Descriptive Findings

Six surgeons completed the retrospective experience survey; one surgeon had not implanted the ETA IOL at the time of survey completion and did not provide ETA-specific ratings. These findings reflect the experience of this group of surgeons with the study IOLs. Half of the participants worked in medium-sized practices, and two-thirds were from a group practice setting. The median number of cataract surgeries

Table 3 IOL utilization patterns**IOL utilization patterns***Proportion of IOL type implanted in the last year, mean percentage of eyes $\pm$ SD ($n = 6$ surgeon respondents)^a*

Monofocal	29.7 $\pm$ 28.8
Monofocal plus/enhanced monofocal	14.0 $\pm$ 10.7
Full range of vision (including multi/trifocal)	37.8 $\pm$ 25.9
Extended depth of focus	5.3 $\pm$ 12.1
Small aperture	3.2 $\pm$ 2.0
Accommodative	1.7 $\pm$ 4.1
Light-adjustable	8.3 $\pm$ 6.1

Proportion of patients implanted with toric and nontoric IOLs, mean percentage of patients $\pm$ SD ($n = 5$ surgeon respondents)^b

Toric	45.0 $\pm$ 33.7
Non toric	55.0 $\pm$ 33.7

IOL Intraocular lens, *SD* Standard deviation

Survey questions: ^aOf the cataract patients you have treated in the past year, what is the approximate percentage breakdown by type of IOL implanted?; ^bOf the cataract patients you have treated in the past year, approximately what percentage of your patients are implanted with a toric IOL versus a nontoric IOL?

performed annually was 1900 (range 450–4500). In the last year, full range of vision IOLs were the most commonly implanted lens type, accounting for a mean $\pm$ SD of 37.8% $\pm$ 25.9% of cases. Enhanced monofocal/monofocal plus IOLs accounted for 14.0% $\pm$ 10.7% of cases, and toric IOLs were used in 45.0% $\pm$ 33.7% of cases (Table 3).

On a scale of 0–10, where 0 is very dissatisfied and 10 is very satisfied, surgeon satisfaction scores for the individual lens qualities and outcomes were predominantly clustered between 8 and 10 (Fig. 3). Occasional lower scores were reported for specific attributes (Table 4); however, overall median scores for both lens quality and outcomes measures were 10/10 for both study IOLs. Most surgeons (5/6) reported their satisfaction with the overall performance of the EA IOL as 9/10 or 10/10; for ETA, all five surgeons with experience of implanting the IOL rated their satisfaction as 9/10 or 10/10 (Table 4).

All participating surgeons reported that they would recommend the study IOLs in appropriate clinical situations.

DISCUSSION

In this retrospective case review of patients undergoing cataract surgery, a high proportion of eyes implanted with the study IOLs achieved good levels of visual acuity. At least 94% of eyes in each group achieved a monocular CDVA of 20/25 or better, at least 71% achieved a monocular UDVA of 20/25 or better, and at least 76% achieved a monocular UIVA of 20/32 or better. Mean postoperative refractive outcomes were generally close to the intended target in patients with and without astigmatism. No serious AEs were documented in the available clinical records. These findings provide early real-world evidence that the favorable visual and refractive outcomes reported in prospective studies can also be achieved in routine clinical practice. As with all retrospective observational studies, the results should be interpreted within the context of the study design.

The surgeon survey provides supplementary descriptive information on practice patterns

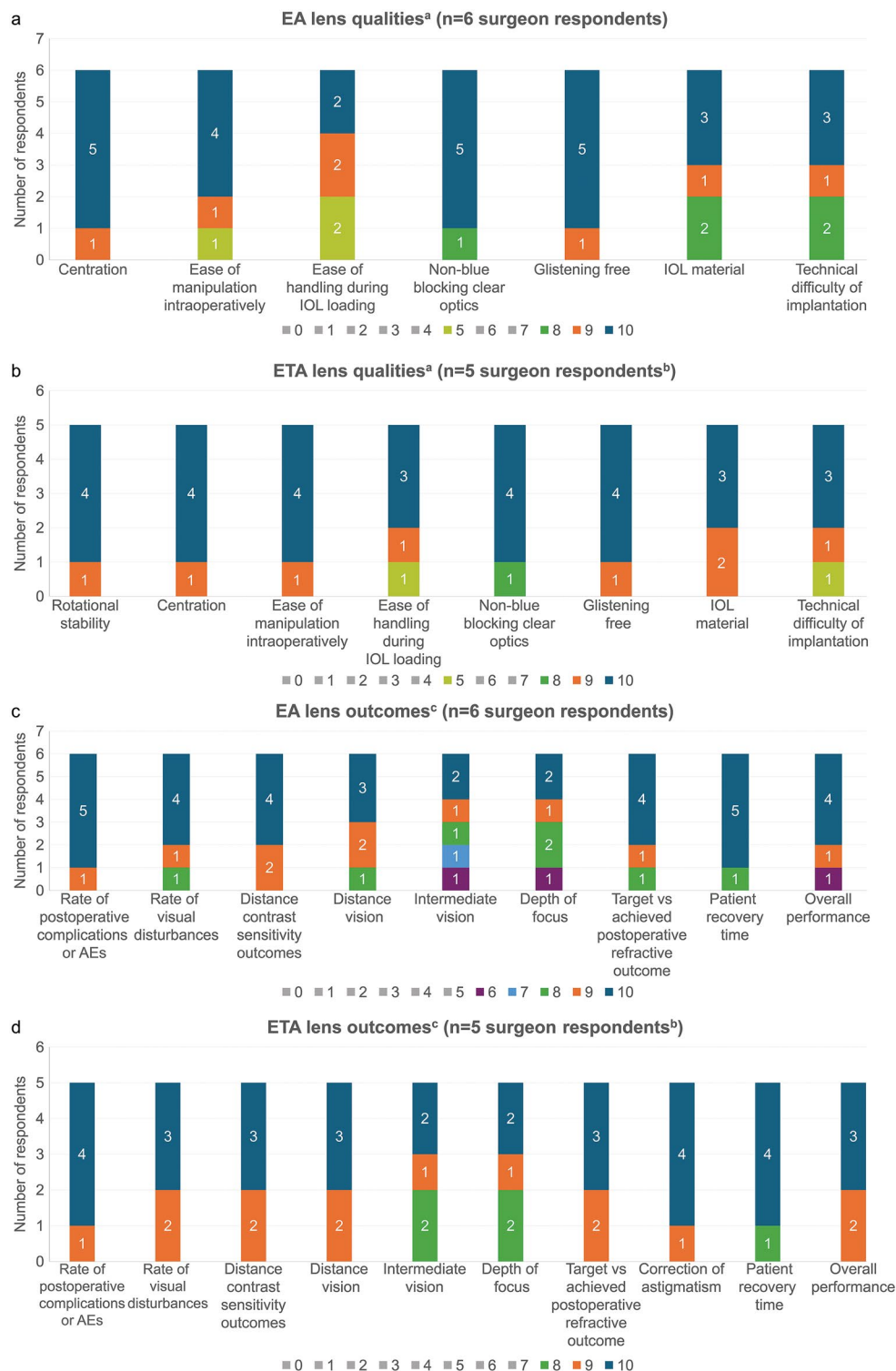


Fig. 3 Surgeon satisfaction with lens qualities and outcomes for **a, c** EA and **b, d** ETA. *AE* adverse event, *EA* enVista Aspire, *ETA* enVista Aspire Toric, *IOL* intraocular lens. ^aSurvey question was asked separately for the EA and ETA IOLs: Compared with other monofocal plus/enhanced monofocal IOLs, how satisfied are you with the following lens qualities? (0 = very dissatisfied, 5 = neither satisfied nor dissatisfied, and 10 = very satisfied); ^bOne surgeon had not implanted the ETA IOL at the time of completing the survey; ^cSurvey question was asked separately for the EA and ETA IOLs: Compared with other IOLs, how satisfied are you with the following lens outcomes? (0 = very dissatisfied, 5 = neither satisfied nor dissatisfied, and 10 = very satisfied)

Table 4 Surgeon satisfaction with lens qualities and outcomes for EA and ETA

Parameter: lens qualities ^a	Surgeon satisfaction with EA						Surgeon satisfaction with ETA ^b					
	S1	S2	S3	S4	S5	S6	S1	S2	S3	S4	S5	S6
Rotational stability	NA	NA	NA	NA	NA	NA	9	–	10	10	10	10
Centration	9	10	10	10	10	10	9	–	10	10	10	10
Ease of manipulation intraoperatively	9	5	10	10	10	10	9	–	10	10	10	10
Ease of handling during IOL loading	9	5	9	10	10	5	9	–	10	10	10	5
Non-blue blocking clear optics	8	10	10	10	10	10	8	–	10	10	10	10
Glistening free	9	10	10	10	10	10	9	–	10	10	10	10
IOL material	9	8	10	10	10	8	9	–	10	10	10	9
Technical difficulty of implantation	9	8	10	10	10	8	9	–	10	10	10	5
Parameter: lens outcomes ^c	Surgeon satisfaction with EA						Surgeon satisfaction with ETA ^b					
	S1	S2	S3	S4	S5	S6	S1	S2	S3	S4	S5	S6
Rate of postoperative complications or adverse events	9	10	10	10	10	10	9	–	10	10	10	10
Rate of visual disturbances	8	10	9	10	10	10	9	–	9	10	10	10
Distance contrast sensitivity outcomes	9	10	9	10	10	10	9	–	9	10	10	10
Distance vision	9	8	9	10	10	10	9	–	9	10	10	10
Intermediate vision	9	6	8	10	10	7	9	–	8	10	10	8
Depth of focus	9	6	8	10	10	8	9	–	8	10	10	8
Target versus achieved postoperative refractive outcome	8	10	10	10	10	9	9	–	10	10	10	9
Correction of astigmatism	NA	NA	NA	NA	NA	NA	9	–	10	10	10	10
Patient recovery time	8	10	10	10	10	10	8	–	10	10	10	10
Overall performance	10	6	9	10	10	10	9	–	9	10	10	10

EA enVista Aspire, ETA enVista Aspire Toric, IOL Intraocular lens, S Surgeon

^aSurvey question was asked separately for the EA and ETA IOLs: Compared with other monofocal plus/enhanced monofocal IOLs, how satisfied are you with the following lens qualities? (0 = very dissatisfied, 5 = neither satisfied nor dissatisfied, and 10 = very satisfied); ^bOne surgeon had not implanted the ETA IOL at the time of completing the survey; ^cSurvey question was asked separately for the EA and ETA IOLs: Compared with other IOLs, how satisfied are you with the following outcomes? (0 = very dissatisfied, 5 = neither satisfied nor dissatisfied, and 10 = very satisfied)

and user experience with the study IOLs. Although based on a small group of experienced surgeons, responses were consistently favorable and complement the clinical findings

observed in this multicenter case series. As intended, these findings should be interpreted as descriptive rather than independent evidence of clinical performance.

The visual acuity findings observed in this retrospective real-world study are consistent with those reported in a recent prospective, observational study evaluating the implantation of the enVista Aspire IOL in patients undergoing routine cataract surgery ($N = 29$), in which 100% of eyes achieved a monocular UDVA of 20/30 or better, 100% achieved a monocular CDVA of 20/30 or better, and 62.1% achieved a monocular distance-corrected intermediate visual acuity (DCIVA) of 20/30 or better at 1–3 months postoperatively [11].

Findings from retrospective real-world studies of other enhanced monofocal IOLs provide context for interpreting the visual outcomes observed in the present study. In a retrospective study of 52 patients (104 eyes) undergoing cataract surgery and bilateral implantation with the TECNIS Eyhance IOL (Johnson & Johnson Vision, Santa Ana, CA, USA), monocular UDVA and CDVA of 20/25 or better were achieved by 63.5% and 90.7% of eyes, respectively, at 1 month postoperatively; a binocular UDVA of 20/25 or better was achieved by 83.3% of patients [16]. In a study of the TECNIS Eyhance Toric II IOL (Johnson & Johnson Vision, Santa Ana, CA, USA) in 62 eyes with regular astigmatism, monocular UDVA and CDVA of 20/32 or better were achieved by 77.4% of eyes and 95.2% of eyes, respectively, at 3 months postoperatively [17]. The mean DCIVA was 0.17 ± 0.13 logMAR (~20/30 Snellen). In a retrospective case series study of bilateral implantation of the RayOne EMV IOL (Rayner Surgical Inc., New York, USA) ($n = 50$ eyes), monocular UDVA of 0.2 logMAR (~20/32 Snellen) or better and UIVA of 0.4 logMAR (~20/50 Snellen) or better were achieved by 94% of eyes and 96% of eyes, respectively, at 1 month postoperatively; binocular UDVA of 0.0 logMAR (20/20 Snellen) was achieved by 96% of patients [18]. Collectively, these studies demonstrate that the visual outcomes observed in the present analysis are consistent with those reported for enhanced monofocal IOLs in both prospective and retrospective clinical studies, supporting the reproducibility of these findings across different clinical settings.

Several limitations should be considered when interpreting these findings. This was a

retrospective convenience sample without a comparator group, and follow-up intervals, data completeness, and clinical assessments varied across participating centers, reflecting routine clinical practice. These factors may have introduced selection and measurement bias and limit the generalizability of the findings. In addition, the surgeon survey included a small number of experienced users and should be interpreted as supplementary descriptive information. Despite these limitations, the multicenter design and consistency of visual and refractive outcomes across sites provide valuable real-world evidence that complements the existing prospective literature on enhanced monofocal IOLs.

Overall, these findings extend the growing evidence base for enhanced monofocal IOLs by demonstrating favorable clinical outcomes in routine cataract practice and provide clinically relevant real-world data to support patient counseling and lens selection.

CONCLUSIONS

This multicenter real-world study demonstrates that implantation of the enVista Aspire and enVista Aspire Toric intraocular lenses was associated with consistently favorable visual, refractive, and safety outcomes across routine clinical practice. A high proportion of eyes achieved excellent distance vision, functional intermediate vision, and refractive accuracy close to the intended target, with no serious adverse events documented in the available clinical records. These findings extend the existing evidence base by demonstrating that outcomes reported in prospective studies are reproducible in everyday clinical settings across multiple surgeons and centers. While confirmation in larger prospective comparative studies is warranted, these data provide valuable real-world evidence supporting the use of enhanced monofocal IOLs for patients seeking excellent distance vision with improved intermediate function while maintaining a monofocal visual profile.

ACKNOWLEDGMENTS

Medical Writing/Editorial Assistance. Medical writing support was provided by Catarina Castanheira, PhD, and Katie Chruszcz, MSc, of Panacea85 Ltd, funded by Bausch + Lomb.

Author Contributions. Eric Donnenfeld, Ravi Patel, Inder Paul Singh, and Dee Stephenson contributed to study conception and design. Eric Donnenfeld, Ravi Patel, Michael Patterson, Farrell Tyson, and P Dee Stephenson contributed to study data collection. All authors contributed to data interpretation, critically revised the manuscript for important intellectual content, and approved the final manuscript.

Funding. This study was conducted by Panacea85 Ltd, funded by Bausch + Lomb. The journal's Rapid Service Fee was funded by Bausch + Lomb. The sponsor contributed to the study design, interpretation of the data, and manuscript review. All authors retained final responsibility for the manuscript content and the decision to submit for publication.

Data Availability. The datasets generated and analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Conflicts of Interest. Eric Donnenfeld is consultant for Allegro, Abbvie, Alcon, Aurion, Bausch + Lomb, Corneagen, Covalent, BVI, Blephex, Dompe, ELT Sight, Eyepoint Pharma, Glaukos, Horizon Surgical, Inversa, Johnson & Johnson, Kala, Katena, Lacripen, LayerBio, Lensgen, Mati Pharmaceuticals, Melt Pharmaceuticals, MBackline, Mimetogen, MOA, Nordic Pharma, Novabay, Ocular Innovations, Oculis, Omega Ophthalmic, Ocuhub, PRN, Rayner, ReTear, RPS, Strathspey, Surface, Tarsus, Tearscience, Versent Ventures, and Visionary Ventures. Ravi Patel is consultant and advisor for Allergan, Bausch + Lomb, Johnson & Johnson Vision, and WL Gore & Associates, and speaker for Allergan,

Bausch + Lomb, Johnson & Johnson Vision, Ocular Therapeutic, Tarsus Pharmaceuticals, and Viatri. Michael Patterson is consultant and advisor for Allergan, Bausch + Lomb, Carl Zeiss Meditec, Glaukos, Ivantis, ImprimisRx, Johnson & Johnson, New World Medical, STAAR, Sight Sciences. Inder Paul Singh is consultant and speaker bureau for Bausch + Lomb, Glaukos, Allergan, BVI, New World Medical, Ivantis, Sight Sciences, Ocular Therapeutix, Sun Pharmaceuticals, Novartis, Nova Eye, Kala Pharmaceuticals, and Eyepoint Pharmaceuticals. Farrell Tyson is consultant for Alcon, Abbvie, Bausch + Lomb, Bruder Health, DefEye, and Zeiss. P Dee Stephenson is consultant for Atia, Bausch + Lomb, Bruder Healthcare, Cassini Technologies, Dompe, ESWIN, Guardion Health Sciences, LENSAR, Ocuphire, Rayner, Sight Sciences, Sun Pharmaceuticals, Tarsus Pharmaceuticals, Viatri, VisioX, and Zeiss.

Ethical Approval. The study protocol received an exemption from the Western Institutional Review Board and Copernicus Group for central ethical review and approval (tracking number: 20242583). The study was performed in accordance with the Helsinki Declaration of 1964, and its later amendments. All surgeons provided informed consent to participate in this study, and provided consent for publication of study data. No identifying patient information was collected.

Open Access. This article is licensed under a Creative Commons Attribution-NonCommercial 4.0 International License, which permits any non-commercial use, sharing, adaptation, distribution and reproduction in any medium or format, as long as you give appropriate credit to the original author(s) and the source, provide a link to the Creative Commons licence, and indicate if changes were made. The images or other third party material in this article are included in the article's Creative Commons licence, unless indicated otherwise in a credit line to the material. If material is not included in the article's Creative Commons licence and your intended use is not permitted by statutory regulation or exceeds the permitted use, you will

need to obtain permission directly from the copyright holder. To view a copy of this licence, visit <http://creativecommons.org/licenses/by-nc/4.0/>.

REFERENCES

1. Hashemi H, Pakzad R, Yekta A, et al. Global and regional prevalence of age-related cataract: a comprehensive systematic review and meta-analysis. *Eye (Lond)*. 2020;34(8):1357–70.
2. Flaxman SR, Bourne RRA, Resnikoff S, et al. Global causes of blindness and distance vision impairment 1990–2020: a systematic review and meta-analysis. *Lancet Glob Health*. 2017;5(12):e1221–34.
3. Lansingh VC, Carter MJ, Martens M. Global cost-effectiveness of cataract surgery. *Ophthalmology*. 2007;114(9):1670–8.
4. Zvorničanin J, Zvorničanin E. Premium intraocular lenses: the past, present and future. *J Curr Ophthalmol*. 2018;30(4):287–96.
5. Lapp T, Wacker K, Heinz C, Maier P, Eberwein P, Reinhard T. Cataract surgery-indications, techniques, and intraocular lens selection. *Dtsch Arztebl Int*. 2023;120(21):377–86.
6. Beltraminelli T, Rizzato A, Toniolo K, Galli A, Menghini M. Comparison of visual performances of enhanced monofocal versus standard monofocal IOLs in a mini-monovision approach. *BMC Ophthalmol*. 2023;23(1):170.
7. Levy I, Shah RP, Mukhija R, Nanavaty MA. Outcomes of mini-monovision with monofocal, enhanced monofocal and extended depth-of-focus intraocular lenses. *Front Med (Lausanne)*. 2025;12:1522383.
8. Nanavaty MA. Evolving generation of new extended depth of focus intraocular lenses. *Eye (Lond)*. 2024;38(Suppl 1):1–3.
9. Fernández J, Rocha-de-Lossada C, Zamorano-Martín F, Rodríguez-Calvo-de-Mora M, Rodríguez-Vallejo M. Positioning of enhanced monofocal intraocular lenses between conventional monofocal and extended depth of focus lenses: a scoping review. *BMC Ophthalmol*. 2023;23(1):101.
10. Srinivasan S, Nyankerh C, Hull J, Suryakumar R. Meta-analysis of defocus curves of monofocal, enhanced monofocal and extended depth of focus IOLs. *BMJ Open Ophthalmol*. 2025;10(1):e002025.
11. de Barros MF, Gouvea L, Hill C, Santhiago MR, Waring GO, Rocha KM. Optical performance and refractive outcomes of a new monofocal intraocular lens with intermediate optimized optics. *J Refract Surg*. 2025;41(10):e1069–75.
12. Bausch + Lomb. enVista ASPIRE™ Toric Instructions for Use (USA) 2025-03. Available from: <https://ifu.bausch.com/siteassets/pdf/42029xx-envista-aspire-toric-iol.pdf>
13. Bausch + Lomb. enVista ASPIRE™ Instructions for Use (USA) 2025-03. Available from: <https://ifu.bausch.com/siteassets/pdf/42028xx-envista-aspire-iol.pdf>
14. Bausch + Lomb. enVista® Intraocular Lens Instructions for Use (USA) 2023-12. Available from: <https://ifu.bausch.com/siteassets/pdf/417010x-envista-monofocal-non-toric-ifu-us-can-clw-web.pdf>
15. von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP; STROBE Initiative. The strengthening of reporting of observational studies in epidemiology (STROBE) statement: guidelines for reporting observational studies. *J Clin Epidemiol*. 2008;61(4):344–49.
16. Crook TB, Sitto MM, Lindberg EJ, Hoopes PC, Moshirfar M. A comparative study and review of visual outcomes with enhanced versus standard monofocal intraocular lenses following cataract surgery. *Med Hypothes Discov Innov Ophthalmol*. 2025;14(2):28–39.
17. Jung H, Jun I, Lee HK, Seo KY, Kim TI. Real-world outcomes of cataract surgeries using a new type of enhanced monofocal toric intraocular lens. *Sci Rep*. 2024;14(1):27758.
18. Madhivanan N, Nivean PD, Madanagopalan VG, Priya S, Madhivanan N, Arthi M. Clinical results after binocular implantation of a unique nondiffractive enhanced monofocal intraocular lens designed for enhanced monovision to increase the depth of focus. *Indian J Ophthalmol*. 2024;72(1):63–5.