Visual and Patient-Reported Outcomes of a Novel Full Visual Range Intraocular Lens Versus a Monofocal Intraocular Lens: A Randomized Multicenter US Trial

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• PURPOSE: To compare the visual, refractive, and patient-reported outcomes following bilateral implantation of a novel full visual range (FVR) intraocular lens (IOL) and a monofocal IOL in subjects undergoing cataract surgery.

• DESIGN: Prospective, masked, multicenter, controlled pivotal trial.

• METHODS: Subjects scheduled to undergo cataract surgery were randomized to bilateral implantation of a novel FVR IOL (enVista Envy MX60EF, Bausch + Lomb; N = 332) or enVista monofocal IOL (MX60E; N = 169). Primary effectiveness endpoints were monocular corrected distance visual acuity (CDVA, 4 m), distance-corrected intermediate (DCIVA, 66 cm), and near (DCNVA, 40 cm) visual acuity, and secondary effectiveness endpoints were binocular DCIVA, DCNVA, uncorrected intermediate (UIVA), and near visual acuity (UNVA), at postoperative days 120 to 180.

• RESULTS: The noninferiority of the FVR IOL group for monocular CDVA and statistical superiority for monocular DCIVA and DCNVA over the monofocal group were established. Binocular UIVA, DCIVA, UNVA, and DCNVA were also better in the FVR group compared to the monofocal group (all $P < .0001$). Mean postoperative MRSE was -0.14 ± 0.39 D (FVR) and -0.14 ± 0.40 D (monofocal group). The FVR group showed consistent visual acuity of ~0.1 logMAR from −1.50 to −2.50 D. The difference in mesopic contrast sensitivity (without glare) between the 2 groups at 1.5, 3, and 12 cpds was less than the minimum detectable difference of 0.15 logCS.

• CONCLUSIONS: Compared to the monofocal group, the FVR IOL group exhibited superior monocular DCNVA and DCIVA, with comparable CDVA. Binocular visual acuity was 0.09 logMAR or better (~20/25) from distance to near (−0.5 D to −2.5 D). (Am J Ophthalmol 2025;280: 493–507.

INTRODUCTION

CATARACT SURGERY HAS EVOLVED BEYOND SIMPLE visual rehabilitation to become a sophisticated refractive procedure.[1] Patients now desire to achieve spectacle independence not only at distance but also at intermediate and near. Improvements in intraocular lens (IOL) designs and optical characteristics have led to the development of a plethora of IOLs that aim to increase the patient's range of vision. Full visual range (FVR) lenses that provide continuous vision from distance to near have been developed to meet the growing visual demands of our cataract patients.

While all FVR IOLs enhance the patient's range of vision, differences in diffractive design features and near/intermediate add power lead to differences in defocus curve, contrast sensitivity (CS), dysphotopsia profile, etc. The distance, height, and shape of diffractive steps control the amount of energy that goes to each of the foci.[2,3] Small and smooth diffractive steps are associated with reduced stray light, glare, and halos.[4] IOL implants with continuous defocus curves provide consistent visual acuity across the intermediate and near vision range, avoiding the valleys typically observed in the defocus curves of IOLs with steep and smooth transitions.[5] IOLs with low add powers for intermediate and near vision minimize the diameter of out-of-focus images (halos), potentially reducing dysphotopsia complaints and providing improved CS compared to lenses with higher add power.[6-10] Ongoing research aims to develop new optical designs that enhance depth of focus while minimizing optical side effects, continuously improving the balance between visual range and tolerability of visual phe-

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nomena. enVista Envy (EN, Bausch + Lomb, Inc.) is a novel FVR IOL that has been recently introduced in the US and Canada to provide cataract patients with a continuous range of vision from distance to near. It is based on the same platform as its monofocal counterpart (EE, Bausch + Lomb, Inc.). The enVista monofocal IOL (EE) is an updated version of the enVista MX60E, featuring a UV light filtering material that enhances the UV cutoff. For the 20.0 D enVista IOL, the UV cutoff is improved from 364 nm to 389 nm, representing a 10% increase in UV protection.

This pivotal trial was designed to evaluate the visual and patient-reported outcomes (PRO) following bilateral implantation of a novel FVR IOL and to compare its outcomes with those of a bilaterally implanted monofocal control IOL in a US-based population.

METHODS

In this prospective, masked, multicenter, randomized, controlled study conducted at 22 US clinical sites (Appendix 1), subjects scheduled to undergo bilateral cataract surgery and IOL implantation from May 2018 to May 2023 were recruited. Subjects were randomly assigned in a 2:1 ratio to undergo bilateral implantation of either FVR IOL (enVista Envy, MX60EF, Bausch + Lomb, Inc.) or monofocal IOL (enVista monofocal, MX60E, Bausch + Lomb, Inc.). Randomization was performed after the determination of eligibility at the preoperative visit. An interactive response technology (IRT) system employing computer-generated random numbers was used for randomization. A permuted block randomization with a block size of 6 was used. The randomization codes were stratified by site such that the ratio of subjects assigned to the FVR IOL and to the monofocal IOL at each site was approximately 2:1. Subjects and designated postoperative evaluator(s) were masked to the IOLs assigned. Every attempt was made to have the same masked examiner perform the same postoperative measurements for each individual subject throughout their study participation. The Investigator implanting the IOL was unmasked to the assignment of the IOL after the phacoemulsification was complete, and the IOL was opened for implantation. The study adhered to the tenets of the Declaration of Helsinki and was approved by a central institutional review board, Advarra IRB. All enrolled subjects provided written informed consent using the IRB-approved informed consent form.

The inclusion criteria were age ≥22 years, corrected distance visual acuity (CDVA) equal to or worse than 20/40 in each eye, with or without a glare source due to a clinically significant cataract (cortical, nuclear, subcapsular, or combination), projected CDVA equal to or better than 20/32 after IOL implantation in each eye, clear intraocular media other than cataract in both eyes; requiring an IOL power within +16.0 D to +24.0 D in both eyes, willing and able to comply with all treatment and follow-up study visits and procedures, and to undergo second eye surgery within 7 to 30 days of the first-eye surgery.

Subjects were excluded if they had any significant ocular pathology or history of eye disease other than cataract that could potentially cause future acuity losses to a level of 20/100 or worse; previous intraocular or corneal surgery except laser trabeculoplasty; preoperative corneal astigmatism >1.0 D in either eye, irregular astigmatism, or skewed radial axis; pharmacologic pupil dilation of <5.0 mm in both eyes; patients who may have been expected to require a combined or other secondary surgical procedure in either eye; any other serious ocular pathology or underlying systemic medical condition (eg, uncontrolled diabetes) or circumstance that based on the Investigator's judgment, posed a concern for the subjects' safety or could confound the results of the study. Further details of the key inclusion and exclusion criteria for the present study can be accessed at ClinicalTrials.gov (NCT03603600).

Subjects meeting the eligibility criteria underwent bilateral implantation of the FVR IOL or the monofocal IOL. The eye with the worse CDVA or worse CDVA with glare at the preoperative visit was treated first and used in the primary monocular evaluations. If CDVA was the same for both eyes, the right eye was treated first.

The enVista FVR IOL is based on the same platform as the enVista monofocal IOL. These 1-piece hydrophobic acrylic ultraviolet-absorbing lenses feature an aspheric biconvex and glistening-free optic, modified C-loop haptics, and a continuous 360° square edge on the posterior surface. The IOLs have a diameter of 6.0 mm and an overall length (diameter) of 12.5 mm. The enVista FVR IOL encompasses low add powers for intermediate (+1.6 D) and near (+3.1 D) that aim to provide a continuous defocus curve, good contrast, and reduced visual disturbances. The FVR IOL is designed to have −0.15 μm of spherical aberration, with apodized diffractive structures on the anterior surface. Apodization results in a gradual decrease in step height toward the periphery. This causes asymmetric energy distribution among the 3 foci (near, intermediate, and far vision) and optimizes vision in different lighting conditions. The photopic light distribution of enVista FVR IOL is 44% for distance, 14% for intermediate, and 28% for near. Under mesopic conditions, the light energy distribution changes to 59% for distance, 8% intermediate, and 19% for near. The diffractive steps have been designed to reduce straylight and associated visual disturbances while maintaining optical efficiency. The study IOL (FVR) is available in IOL powers of +6.0 D to +34.0 D. The detailed optical specifications of the enVista monofocal control IOL have been described elsewhere.[11]

Ophthalmic measurements included assessment of uncorrected and corrected distance visual acuity (UDVA, CDVA) at 4 m, uncorrected and distance-corrected near visual acuity (UNVA, DCNVA) at 40 cm, uncorrected and distance-corrected intermediate visual acuity (UIVA,

DCIVA) at 66 cm using Early Treatment of Diabetic Retinopathy Study (ETDRS; M&S Technologies) charts preoperatively and at postoperative days 120 to 180. Visual acuities at distance, intermediate, and near were also assessed after inducing astigmatic blur of 1.00 D, 1.50 D, and 2.00 D in with-the-rule (WTR) and against-the-rule (ATR) orientations after correcting for distance. Other measurements included binocular-corrected distance CS (CTS; M&S Technologies) and PRO assessed using the McAlinden Quality of Vision (QoV) questionnaire.[12,13]

Primary effectiveness endpoints were photopic monocular CDVA, DCIVA, and DCNVA at days 120 to 180 for the first implanted eyes. Secondary effectiveness endpoints included photopic binocular UNVA, DCNVA, UIVA, and DCIVA at postoperative days 120 to 180. Primary safety endpoints were the incidence of adverse events (AEs) and serious AEs (SAEs), including secondary surgical interventions (SSIs) related to the optical properties of the IOL through postoperative days 120 to 180. Secondary safety endpoints were photopic and mesopic CS with glare, mesopic CS without glare, and the rate of visual disturbances using the QoV questionnaire through postoperative days 120 to 180.

In a post hoc analysis, the association of chord μ with the frequency, severity, and bothersomeness with glare and halos, and distance-corrected near visual acuity (DCNVA) was assessed in patients who underwent FVR IOL implantation. Chord μ represents the distance from the pupil center (line of sight) to the coaxially sighted corneal light reflex (topographer axis).[14] It is increasingly being recognized as a potential marker for predicting glare and halos after multifocal IOL implantation. Chord μ values greater than 0.60 mm have been associated with poor performance of diffractive multifocal IOLs. As such, patients were categorized into chord $\mu \leq 0.60$ mm in both eyes or >0.60 mm in either eye for this analysis.

STATISTICAL ANALYSIS

• **SAMPLE SIZE:** The sample size of 300 subjects in the FVR IOL group and 150 in the monofocal control group was chosen as per the ANSI Z80.12-2007 (R2012) and ISO 11979-9:2006 standards. Approximately 334 subjects in the FVR IOL group and 167 in the monofocal IOL group were targeted to be implanted bilaterally, assuming a 10% dropout rate.

• **ANALYSIS POPULATIONS:** All effectiveness analyses were performed on the modified intent-to-treat (mITT) dataset, which included all randomized subjects with at least 1 eye in which the IOL touched the eye with the study lens. Safety was assessed in all subjects who underwent surgery in at least 1 eye. The PRO analysis set included all subjects who submitted the preoperative questionnaires and postoperative questionnaires either at postoperative days 120 to 180 or any postoperative unscheduled visit prior to study exit.

Binocular CS under mesopic with and without glare conditions and photopic with glare conditions was assessed in a subset of subjects at postoperative days 120 to 180.

The effect of simulated astigmatism on visual acuity at distance, intermediate, and near was assessed in a subgroup of subjects at visit 6 (days 2-30 after the last postoperative visit).

Statistical analysis was carried out using SAS. The analysis of the covariance model with visual acuity as the dependent variable and treatment and site as fixed factors was used to calculate the least-squares (LS) means and confidence intervals, as applicable. Noninferiority of the FVR IOL to the monofocal IOL for monocular CDVA was established if the upper confidence limit of the 2-sided 90% confidence interval of the LS means difference was less than 0.1 logMAR. Statistical superiority of the FVR IOL over the monofocal IOL for photopic monocular DCIVA and DCNVA was established if the *P*-value for a 2-sided difference was ≤0.05 (95% confidence interval) and the LS mean difference for the 2 groups was ≤0.10 logMAR (for DCIVA) and ≤0.20 logMAR (for DCNVA). Categorical data were analyzed using the Chi-square test.

RESULTS

A total of 501 subjects were randomized; 332 received enVista FVR IOL, and 169 received enVista monofocal IOL (Figure 1). The study completion rate was 94.6% (314/332) in the FVR group and 92.3% (156/169) in the monofocal IOL group. All analyses, as planned, were performed on the mITT dataset. Since all randomized subjects were treated as randomized, mITT and ITT datasets were identical in this study. The demographic and preoperative characteristics of the study population in the FVR IOL group and monofocal IOL groups are presented in Table 1.

• **VISUAL OUTCOMES:** For monocular photopic CDVA, the LS mean ± SE at postoperative days 120 to 180 was 0.032 ± 0.006 logMAR in the FVR IOL group and −0.008 ± 0.008 logMAR in the monofocal IOL group; the LS mean ± SE difference was 0.040 ± 0.009 logMAR for a 2-sided 90% CI of 0.026 to 0.054 logMAR between the FVR and the monofocal IOL groups. Since the upper confidence limit was less than 0.1 logMAR, the FVR IOL was statistically noninferior to the monofocal control IOL for monocular CDVA. For visual acuity outcomes at intermediate and near, the LS mean photopic monocular DCIVA (0.124 ± 0.009 vs 0.352 ± 0.012 logMAR, $P < .0001$) and DCNVA (0.146 ± 0.010 vs 0.541 ± 0.013 logMAR, $P < .0001$) were found to be statistically significantly better in the FVR IOL group than the monofocal IOL group. The LS mean ± SE

TABLE 1. Demographics and Baseline Variables

	FVR IOL (N = 332)	Monofocal IOL (N = 169)
Age, y (Mean ± SD)	67.6 ± 7.9	68.8 ± 7.5
Age categories (%)		
18−64 y	28.6%	20.7%
65−84 y	70.8%	78.7%
≥85 y	0.6%	0.6%
Gender (%)		
Males	36.1%	36.1%
Females	63.9%	63.9%
Race (%)		
Asian	3.3%	2.4%
Chinese	0.3%	0.6%
Non-Chinese	3.0%	1.8%
Black/African American	4.2%	5.3%
Native Hawaiian/Pacific Islander	0.3%	0%
White	91.9%	92.3%
Multiple[a]	0.3%	0%
Ethnicity (%)		
Hispanic/Latino	12.0%	11.8%
Not Hispanic/Latino	88.0%	88.2%
Preoperative and operative variables		
Photopic pupil size, mm (mean ± SD), n (%)	4.02 ± 0.79	3.97 ± 0.85
Category, n (%)		
Small	10.1%	14.5%
Medium	42.4%	41.5%
Large	47.5%	43.9%
Mesopic pupil size, mm (mean ± SD)	4.92 ± 0.84	4.79 ± 0.89
Category, n (%)		
Small	1.7%	2.1%
Medium	13.3%	19.6%
Large	85.0%	78.3%
Axial length, mm (mean ± SD)	23.79 ± 0.80	23.70 ± 0.76
Anterior chamber depth, mm (mean ± SD)	3.27 ± 0.37	3.24 ± 0.35
Targeted refraction, D (mean ± SD)	−0.05 ± 0.10	−0.05 ± 0.11
Corneal topography (%)		
Normal	100.0%	100.0%
Cataract type (%)		
Nuclear	31.3%	32.3%
Cortical	1.2%	2.1%
Posterior sub-capsular	0.8%	0.6%
Combination	66.7%	65.0%
Cataract density (%)		
Slight (1+)	3.9%	3.9%
Moderate (2+)	50.8%	61.1%
Dense (3+)	42.8%	30.6%
Very dense (4+)	2.4%	4.5%
Femtosecond laser used for surgery (%)		
Yes	18.5%	18.1%
No	81.5%	81.9%
Femtosecond laser procedure, if used for surgery[b] (%)		
Corneal incision	23.0%	21.3%
Anterior capsulotomy	97.5%	100.0%
Cataract fragmentation	98.4%	100.0%

[a] Subjects who selected more than 1 race on the eCRF are grouped into the "Multiple" category.

[b] Percentages are based on the number of eyes with femtosecond laser used for surgery. More than 1 use for the femtosecond laser could be chosen.

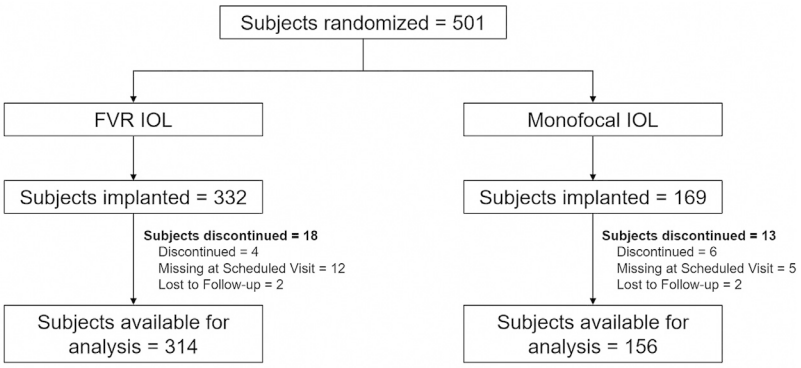

FIGURE 1. Patient disposition flowchart.

difference for DCIVA (−0.228 ± 0.013 logMAR) and DCNVA (−0.394 ± 0.014 logMAR) between the treatment groups exceeded the protocol-defined performance standard for clinical significance of 0.10 logMAR better DCIVA and 0.20 logMAR better DCNVA, thus demonstrating the superiority of the FVR IOL over the monofocal IOL.

The cumulative frequency distribution of monocular visual acuities at distance, intermediate, and near are presented in Supplementary Figure 1, A to F.

Figures 2, A to C represent the LS means of binocular uncorrected visual acuity at distance (UDVA), intermediate (UIVA), and near (UNVA) in the FVR and the monofocal IOL groups. The 2-sided 90% confidence interval for the least square mean difference in binocular UDVA between the FVR and monofocal IOL was 0.026 to 0.055 logMAR. Since the upper confidence limit was less than 0.1 logMAR, the noninferiority of the FVR IOL over the monofocal IOL for binocular UDVA was established. For binocular UIVA and UNVA, the FVR IOL was statistically significantly better than the monofocal IOL (both $P < .0001$).

Figures 3, A to F show the frequency distribution of the binocular uncorrected and corrected distance visual acuities and uncorrected and distance-corrected visual acuities at intermediate and near in the FVR and the monofocal groups. In the FVR IOL group, 88.2% and 97.8% of the subjects achieved photopic binocular UDVA of 20/25 or better and 20/32 or better, respectively. A total of 96.1% of subjects achieved UIVA of 20/32 or better, and 92.3% of subjects achieved UNVA of 20/32 or better. When evaluated for the proportion of subjects who achieved good acuity at all distances, 89.1% of subjects in the FVR IOL group were found to achieve binocular uncorrected visual acuity of 20/32 or better at far, intermediate, and near.

The FVR IOL was statistically superior to the monofocal IOL for LS mean binocular DCIVA (0.05 ± 0.01 vs 0.27 ± 0.01 logMAR) and DCNVA (0.08 ± 0.01 vs 0.45 ± 0.01 logMAR). As high as 97.5% of FVR IOL subjects achieved DCIVA of 20/32 or better, and 95.4% achieved DCNVA of 20/32 or better postoperatively (Figures 3, A-F).

• **MANIFEST REFRACTION SPHERICAL EQUIVALENT (MRSE):** At postoperative 120 to 180 days, the mean MRSE was −0.14 ± 0.39 D in the FVR group and −0.14 ± 0.40 D in the monofocal group. The percentage of eyes within ±0.5 D of MRSE was 79.3% in the FVR IOL and 70.8% in the monofocal IOL group. The difference between intended and achieved MRSE (prediction error) at postoperative 120 to 180 days was 0.13 ± 0.44 D in the FVR IOL and 0.14 ± 0.45 D in the monofocal IOL group.

Among all eyes with postoperative MRSE within ±0.25 D, ±0.50 D, and ±0.75 D, ~90% or higher proportion of eyes in both the FVR and the monofocal IOL group achieved uncorrected distance visual acuity of 20/32 or better (Figure 4).

• **BINOCULAR DEFOCUS CURVE:** The binocular defocus curve was studied in a subset of subjects, 53 in the FVR IOL group and 41 in the monofocal IOL group at postoperative Days 120 to 180. At 0.0 D, mean visual acuity was better than 20/20 in the FVR and monofocal groups. In the intermediate and near vision range (−1.00 to −2.50 D), the FVR IOL group demonstrated a plateau at 0.09 logMAR (~20/25 Snellen), whereas the monofocal group showed a decrease in visual acuity from 0.14 logMAR (~20/28 Snellen) to 0.55 logMAR (~20/71 Snellen) (Figure 5A).

Defocus curve performance, when stratified by pupil apertures, showed that in the FVR IOL group, the visual outcomes remained similar at small (<3.0 mm), medium (3.0-4.0 mm), and large pupil apertures (>4.0 mm). However, in the monofocal IOL group, the visual outcomes worsened with increasing pupil apertures (Figure 5B).

• **CONTRAST SENSITIVITY:** Figure 6, A to C represents mean binocular CS under photopic (with glare) and mesopic conditions (with and without glare) in both groups.

• **SAFETY OUTCOMES:** In the FVR IOL group, the observed proportion of eyes with CDVA 20/40 or better was 98.7%, which was not statistically significantly worse than

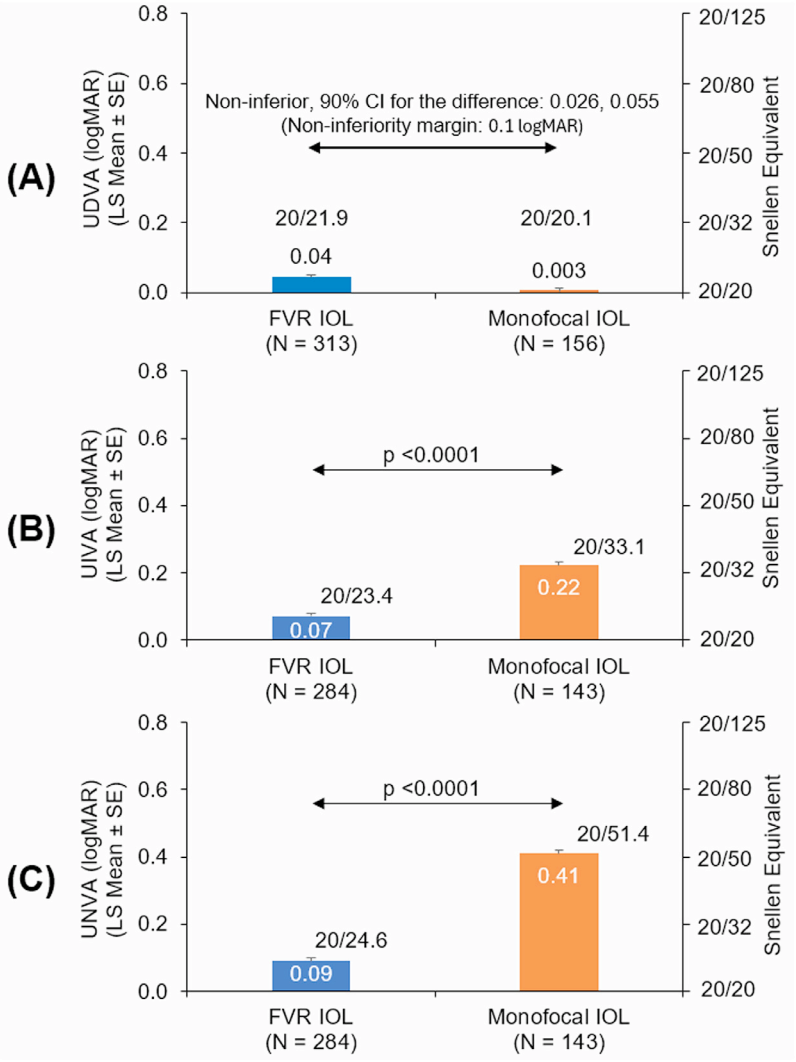

FIGURE 2. Least square means of binocular uncorrected visual acuity at (A) distance, (B) intermediate, and (C) near in the FVR and monofocal IOL groups.

the ISO standard SPE (safety and performance endpoint) rate of 92.5% ($P > .9999$).

Adverse events

The incidence of at least 1 ocular treatment-emergent adverse event (TEAE) was 49.4% (n = 164) in the FVR and 40.8% (n = 69) in the monofocal IOL group. The most common ocular TEAEs were punctate keratitis, increased intraocular pressure, and vitreous detachment (Table 2). All other ocular TEAEs occurred in <3% of the subjects in each treatment group (Table 2).

While most of the ocular TEAEs were mild to moderate, severe ocular TEAEs occurred in 0.6% of subjects in the FVR IOL group (retinal tear; n = 1 and endophthalmitis; n = 1) and 1.2% in the monofocal IOL group (increased intraocular pressure; n = 1, and ophthalmic herpes zoster; n = 1).

When assessed for the relationship of ocular TEAEs to the study device, 2 subjects in each treatment group had ocular TEAEs related to the study device, which resolved. Study device-related TEAEs were halo vision (n = 2) in the FVR group, glare (n = 1), and negative dysphotopsia (n = 1) in the monofocal IOL group. When assessed for the relationship of ocular TEAEs to the surgical procedure, 125 subjects (37.7%) in the FVR IOL group and 51 subjects (30.2%) in the monofocal IOL group had ocular TEAEs that were related to the surgical procedure. The most common ocular TEAEs related to the surgical procedure with an incidence rate of more than 1% in either group were punctate keratitis, increased intraocular pressure, vitreous detachment, dry eye, anterior chamber inflammation due to retained lens fragment, and iritis.

The incidence of ocular treatment-emergent serious AEs (TE-SAEs) was 1.5% (n = 5 subjects) in the FVR IOL

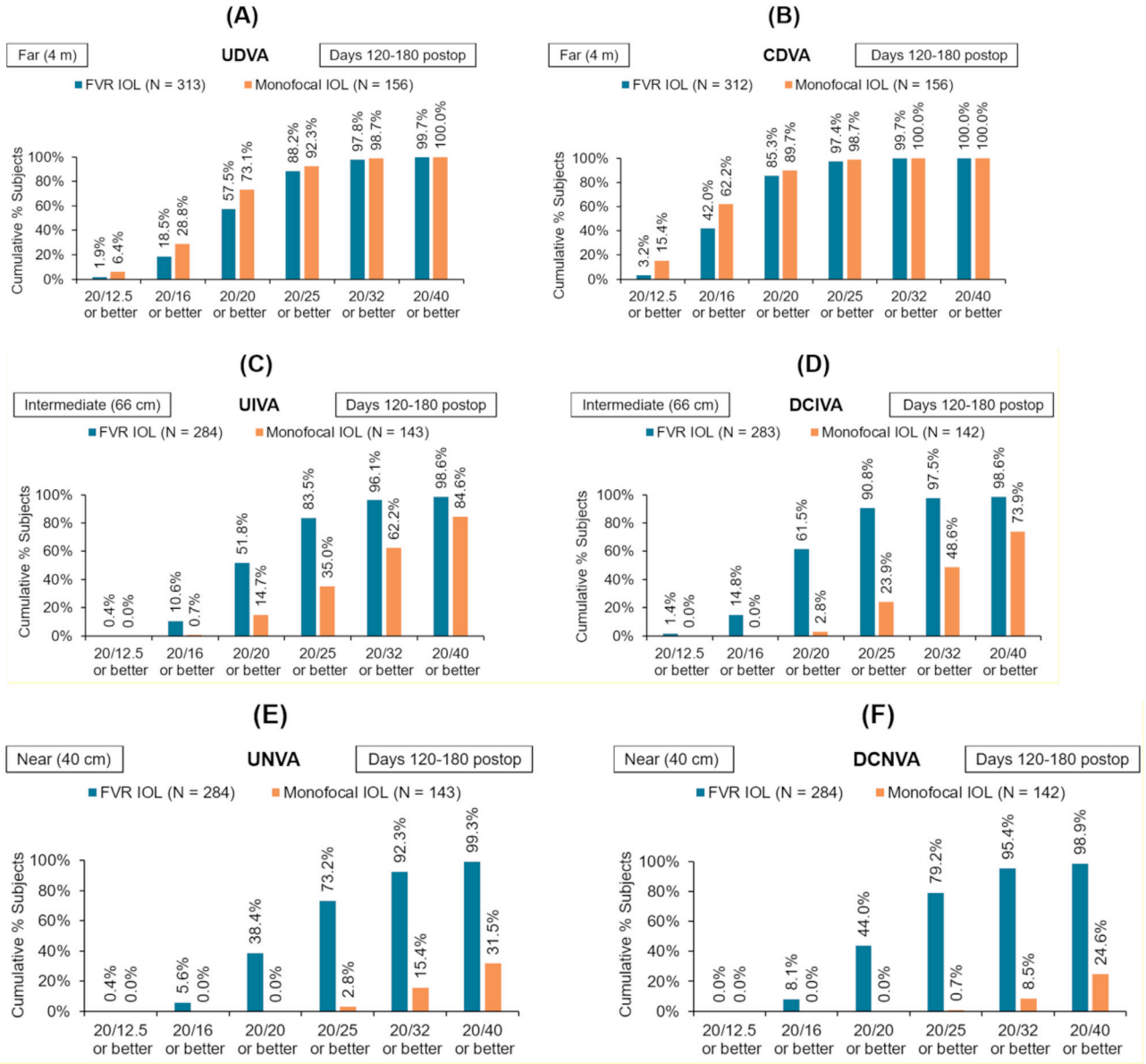

FIGURE 3. Cumulative frequency distribution graphs representing binocular visual acuities at distance (A and B), intermediate (C and D), and near (E and F) in the FVR and the monofocal IOL groups.

group and 1.2% (n = 2 subjects) in the monofocal IOL group. The ocular TE-SAEs, occurring in 1 subject each, were macular hole, retinal tear, retinal vein occlusion, endophthalmitis, and Seidel test positive in the FVR IOL group and ophthalmic herpes zoster and anterior chamber inflammation due to retained lens fragments in the monofocal IOL group. None of the ocular TE-SAEs were related to the study device. Two subjects in the FVR and 1 subject in the monofocal IOL group had ocular TE-SAEs that were related to the surgical procedure. These were endophthalmitis and Seidel test positive in the FVR group and anterior chamber inflammation due to retained lens fragments in the monofocal IOL group.

No SSIs such as IOL explantation or IOL exchange due to the study IOL's optical properties were reported in the FVR IOL group.

At postop days 120 to 180, the rate of posterior capsulotomy was 5.0% (31/626) in the FVR IOL group and 5.4% (17/312) in the monofocal IOL group. Among eyes with an intact posterior capsule, severe PCO was reported in only 0.2% (1/595) of the FVR-implanted eyes and none of the eyes in the monofocal IOL group.

ISO grid adverse events

No ISO grid cumulative (cystoid macular edema, hypopyon, endophthalmitis, lens dislocated from posterior

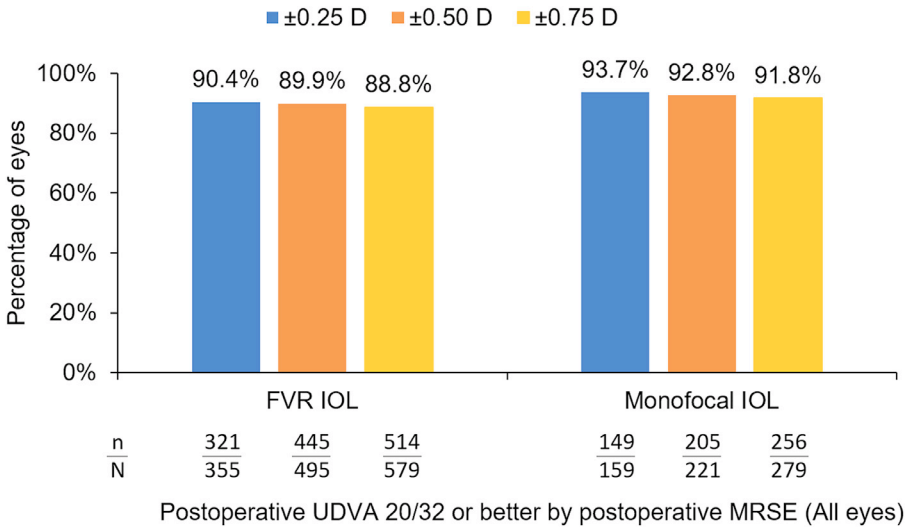

FIGURE 4. Proportion of eyes showing postoperative uncorrected distance visual acuity of 20/32 or better in the presence of residual spherical equivalent error within ±0.25 D, ±0.50 D, and ±0.75 D.

TABLE 2. Ocular Treatment-Emergent Adverse Events With Frequency ≥1.0%

Ocular TEAEs	FVR IOL (N = 332) n (%)	Monofocal IOL (N = 169) n (%)
Punctate keratitis	57 (17.2)	16 (9.5)
Intraocular pressure increased	43 (13.0)	21 (12.4)
Vitreous detachment	32 (9.6)	12 (7.1)
Visual acuity reduced	9 (2.7)	4 (2.4)
Dry eye	7 (2.1)	4 (2.4)
Blepharitis	5 (1.5)	4 (2.4)
Meibomian gland dysfunction	5 (1.5)	4 (2.4)
Vitreous floaters	2 (0.6)	4 (2.4)
Cystoid macular edema	3 (0.9)	3 (1.8)
Cataract operation complications	2 (0.6)	3 (1.8)
Iritis	5 (1.5)	1 (0.6)
Hordeolum	1 (0.3)	2 (1.2)
Corneal abrasion	4 (1.2)	0

chamber, pupillary block, retinal detachment, secondary surgical intervention) or persistent (cystoid macular edema, persistent iritis, corneal stromal edema, raised IOP requiring treatment) AEs occurred in the first eyes of the FVR IOL group.

• **PATIENT-REPORTED OUTCOMES:** The PRO were assessed using the QoV questionnaire at postoperative days 120 to 180. The mean QoV questionnaire frequency, severity, and bothersome domain scores of different visual symptoms were 15.30, 15.00, and 14.24, respectively, in the FVR IOL group and 14.55, 14.32, and 13.74, respectively, in the monofocal IOL group.

The percentage of subjects who reported "never or occasional glare" was 86.0% in the FVR IOL group compared to 90.9% in the monofocal IOL group. Moderate and severe glare was observed in 15.2% and 3.2% of the FVR IOL subjects and 15.2% and 2.0% of subjects in the monofocal IOL group, respectively. However, 88% of the FVR IOL subjects and 88.1% of the monofocal IOL subjects were "not at all or a little bothered" by it (Table 3).

Halos were found to occur "never or occasionally" in 63.1% (FVR IOL group) and 92.9% (monofocal IOL group) subjects. Halos were moderate and severe in 27.1% and 6.1% of subjects in the FVR IOL group and 8.6% and 1.3% of subjects in the monofocal IOL group. However, more than 79.6% of the FVR IOL subjects and 92.7% of the monofocal IOL subjects were "not at all or a little bothered" by them (Table 3).

The percentage of subjects who reported "never or occasional" starbursts was 87.3% in the FVR IOL group and 92.2% in the monofocal IOL group. Moderate and severe starbursts were observed in 11.9% and 2.6% of subjects in the FVR IOL group and 4.6% and 4.0% of subjects in the

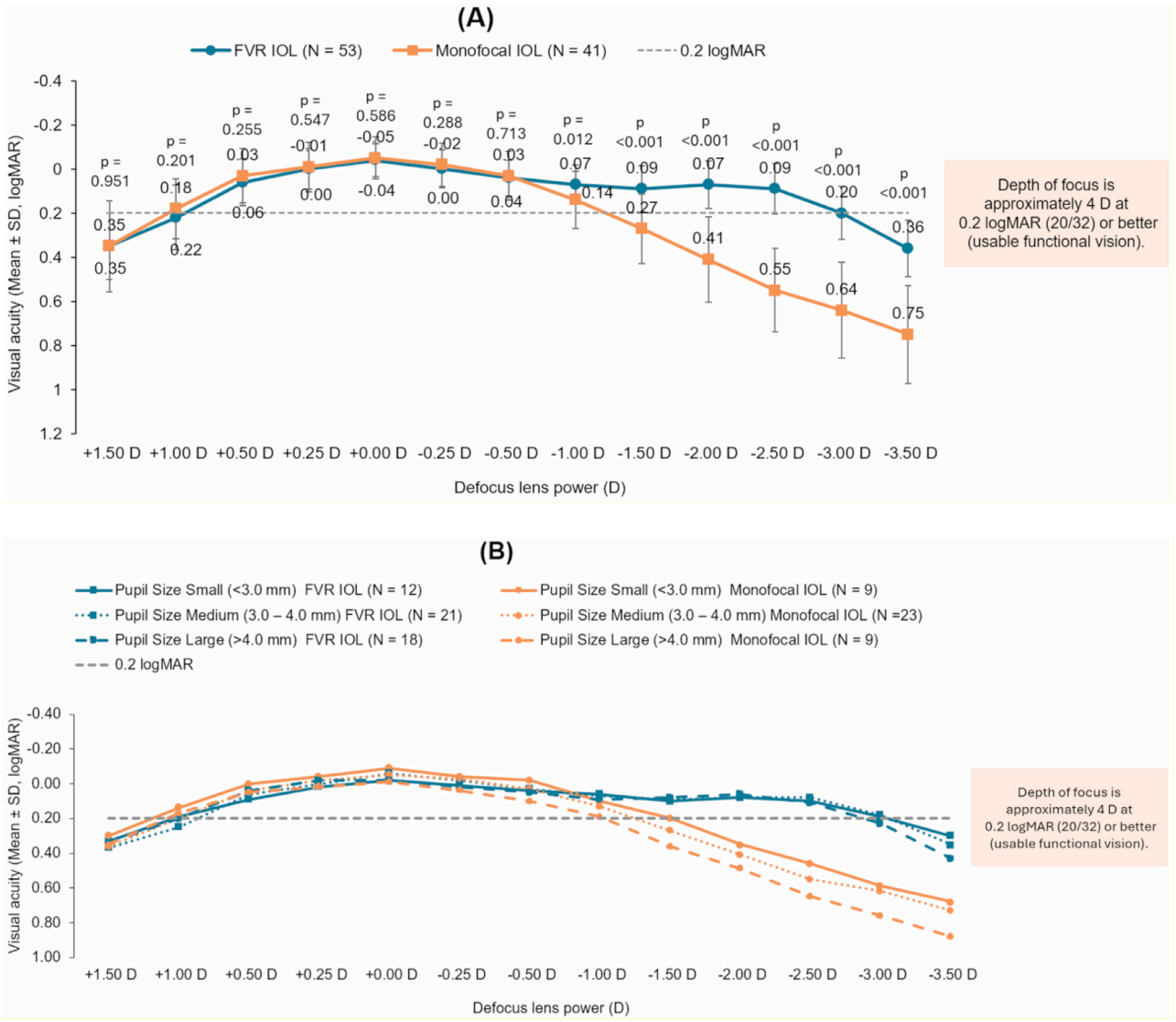

FIGURE 5. Binocular defocus curve comparison of the FVR IOL and the monofocal IOL at postoperative 120 to 180 days (A) overall, (B) stratified by pupil size.

monofocal IOL group. However, 90.7% of the FVR IOL subjects and 93.3% of the monofocal IOL subjects were "not at all or a little bothered" by them (Table 3).

For visual symptoms such as blurred vision and focusing difficulties, the FVR IOL group performed slightly better, with 3 to 6% of subjects reporting less frequency and severity with these visual symptoms than the monofocal IOL group. The frequency, severity, and bothersomeness with other visual symptoms (hazy vision, distortion, double images, fluctuating vision, and difficulty judging distance/depth perception) were similar between the 2 groups (Table 3).

• **EFFECT OF INDUCED ASTIGMATISM ON VISUAL ACUITY:** A total of 33 subjects implanted with the enVista FVR IOL and 17 implanted with the enVista monofocal IOL consented to participate in the trial frame astigmatism substudy that evaluated the effect of different magnitudes of induced astigmatism on distance, intermediate, and near visual acuity. The results showed that the baseline (no additional sphere, cylinder, or axis) mean CDVA (±SD) was 0.01 ± 0.07 logMAR in the FVR IOL group and 0.01 ± 0.11 logMAR in the monofocal IOL group. With simulated astigmatism, the mean CDVA (±SD) ranged from 0.15 ± 0.14 logMAR (+1.00 D, cylinder 180°) to 0.47 ± 0.17 logMAR (+2.00 D, cylinder 90°) in the FVR IOL group and from 0.09 ± 0.11 logMAR (+1.00 D, cylinder 180°) to 0.45 ± 0.22 logMAR (+2.00 D, cylinder 90°) in the monofocal IOL group.

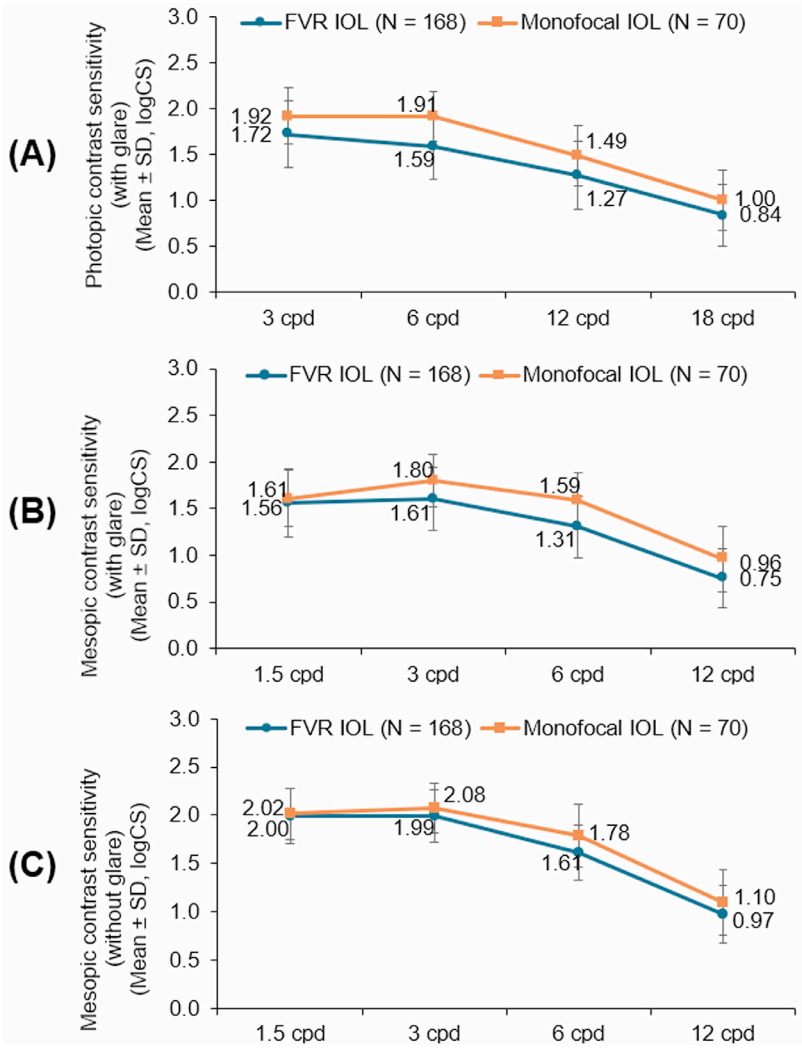

FIGURE 6. Comparison of the (A) mean binocular photopic contrast sensitivity with glare; (B) mean binocular mesopic contrast sensitivity with glare, and (C) mean binocular mesopic contrast sensitivity without glare between the FVR and the monofocal IOLs.

For intermediate visual acuity, the baseline mean DCIVA (±SD) was 0.12 ± 0.10 logMAR in the FVR IOL group and 0.40 ± 0.14 logMAR in the monofocal IOL group. With simulated astigmatism, mean intermediate visual acuity ranged from 0.16 ± 0.11 logMAR (+1.00 D, cylinder 180°) to 0.34 ± 0.13 logMAR (+2.00 D, cylinder 90°) in the FVR IOL group and from 0.39 ± 0.16 logMAR (+1.00 D and +2.00 D, cylinder 90°) to 0.43 ± 0.14 logMAR (+2.00 D, cylinder 180°) in the monofocal IOL group.

For near visual acuity, the baseline mean DCNVA (±SD) was 0.15 ± 0.11 logMAR in the FVR IOL group and 0.56 ± 0.14 logMAR in the monofocal IOL group. With simulated astigmatism, the mean near visual acuity ranged from 0.23 ± 0.13 logMAR (+1.00 D, cylinder 180°) to 0.37 ± 0.13 logMAR (+2.00 D, cylinder 90°) in the FVR IOL group and from 0.55 ± 0.15 logMAR (+1.00 D, cylinder 90°) to 0.61 ± 0.14 logMAR (+2.00 D, cylinder 180°) in the monofocal IOL group.

• **ASSOCIATION OF CHORD μ WITH GLARE, HALO, AND NEAR VISION:** There were no statistically significant differences in the frequency, severity, and bothersomeness with glare and halos (all $P > .05$) among patients with chord μ ≤0.60 mm or >0.60 mm. Logistic regression models were fit to evaluate the odds of the subjects reporting severe glare or severe halos (QoV response of Frequency: Very often or Severity: Severe or Bothersome: Very) with chord μ. The results showed no statistically significant relationships between chord μ and severe glare (odds ratio = 4.93, 95% CI: 0.295-82.5; $P = .2670$) or between chord μ and severe halos (odds ratio = 0.85, 95% CI: 0.141-5.122; $P = .8595$). Assessment of the association between chord μ values and near visual acuity also showed no statistically significant correlation between chord μ and the distance corrected near visual acuity ($P = .4093$).

TABLE 3. Assessment of Patient-Reported Outcomes Using the QoV Questionnaire

Visual Disturbance	FVR IOL (N = 332)				Monofocal IOL (N = 169)				*P*-value* FVR IOL vs Monofocal IOL
	Frequency				Frequency				
	Never	Occasionally	Quite often	Very often	Never	Occasionally	Quite often	Very often	Never to occasionally
Glare	37.6%	48.4%	8.9%	5.1%	47.4%	43.5%	5.8%	3.2%	86.0% vs 90.9%; $P = .1289$
Halos	26.8%	36.3%	19.7%	17.2%	59.1%	33.8%	5.2%	1.9%	63.1% vs 92.9%; $P < .0001$
Starbursts	53.5%	33.8%	8.9%	3.8%	65.6%	26.6%	3.9%	3.9%	87.3% vs 92.2%; $P = .1096$
	Severity				Severity				
	Not at all	Mild	Moderate	Severe	Not at all	Mild	Moderate	Severe	Not at all to mildly severe
Glare	40.0%	41.6%	15.2%	3.2%	50.3%	32.5%	15.2%	2.0%	81.6% vs 82.8%; $P = .7592$
Halos	29.1%	36.9%	27.8%	6.1%	62.9%	27.2%	8.6%	1.3%	66.0% vs 90.1%; $P < .0001$
Starbursts	56.3%	29.3%	11.9%	2.6%	72.2%	19.2%	4.6%	4.0%	85.6% vs 91.4%; $P = .0746$
	Bothersomeness				Bothersomeness				
	Not at all	A little	Quite	Very	Not at all	A little	Quite	Very	Not at all to a little bothersome
Glare	47.7%	40.3%	7.4%	4.5%	56.3%	31.8%	10.6%	1.3%	88.0% vs 88.1%; $P = .9963$
Halos	40.8%	38.8%	13.3%	7.1%	68.9%	23.8%	6.0%	1.3%	79.6% vs 92.7%; $P = .0003$
Starbursts	65.6%	25.1%	6.1%	3.2%	78.1%	15.2%	2.6%	4.0%	90.7% vs 93.3%; $P = .3271$

*Chi-square test.

DISCUSSION

This randomized, controlled, pivotal clinical trial was designed to evaluate the safety and effectiveness of the FVR IOL in subjects undergoing cataract extraction. The study met all the primary effectiveness endpoints, with the FVR IOL showing statistical noninferiority to the monofocal IOL in photopic monocular CDVA and statistical superiority to the monofocal IOL in photopic monocular DCNVA and DCIVA.

Binocular uncorrected near (0.09 ± 0.10 vs 0.41 ± 0.14 logMAR) and intermediate (0.06 ± 0.10 vs 0.21 ± 0.14 logMAR) visual acuity outcomes were also significantly better in the FVR IOL group than the monofocal group. These outcomes improved further when the subjects were corrected for distance, revealing a mean binocular DCIVA of 20/22 and DCNVA of 20/24 in the FVR IOL group. Nearly 90% of subjects in the FVR IOL group achieved binocular uncorrected visual acuity of 20/32 or better at far, intermediate, and near. The intermediate and near vision outcomes achieved in the present study were comparable with the outcomes reported for FDA studies of previously US-approved trifocal (Model TFNT00) or hybrid multifocal EDOF IOL (Model ZFR00V).[15,16]

The visual acuity outcomes achieved in the present study were in alignment with the outcomes of the binocular defocus curve. The enVista FVR IOL showed a continuous defocus curve exhibiting a consistent visual acuity range of 0.07 to 0.09 logMAR (~20/24) across the intermediate and near vision range up to −2.50 D. Overall, the FVR group exhibited a functional vision of 0.2 logMAR (20/32) or better across 4.0 D defocus range from +1.0 to −3.0 D. Furthermore, the intermediate and near visual acuity benefit of the FVR IOL was maintained even in subjects with larger pupil apertures (greater than 4.0 mm) compared to the monofocal IOL group that showed a worsening of the visual acuity at intermediate and near vision range with the increase in pupil aperture. It is to be noted that in the present study, the binocular defocus curve was used to assess the visual performance of the IOLs across a range of defocus. A recent paper documenting the standard for collecting and reporting outcomes of IOL-based refractive surgery suggests that visual performance should be assessed using a monocular defocus curve, as it provides better insights into the continuous range of field provided by the IOL.[17] Future studies evaluating the monocular defocus curve performance of IOLs are desirable.

Residual refractive error can affect postoperative visual outcomes even after uncomplicated cataract surgery. Presbyopia-correcting IOLs are much more sensitive to refractive errors compared to monofocal IOLs.[18-21] In the present study, the FVR IOL showed good tolerance to residual refractive error. Among subjects with postoperative residual spherical equivalent refractive error within 0.50 D and 0.75 D, the proportion of subjects demonstrating UDVA of 20/32 or better was similar between the FVR and the monofocal IOL groups, with ~3% difference between them (Figure 4).

Correcting preexisting corneal astigmatism at the time of cataract surgery is important to achieve optimal outcomes postoperatively. While toric IOLs are generally used to address preexisting corneal astigmatism >1.0 D, low levels of astigmatism are either addressed using arcuate incisions or left uncorrected. As such, IOLs that are tolerant to astigmatic errors can yield better outcomes despite the presence of low levels of unaddressed astigmatism. In the present study, only nontoric enVista FVR and nontoric enVista

monofocal IOLs were implanted, and the astigmatic tolerance of these IOLs in patients with pre-existing astigmatism within 1.0 D was assessed. The novel FVR IOL showed good tolerance to different levels of induced ATR/WTR astigmatism. Even with different levels (+1.00 D, 1.50 D, and 2.00 D) of simulated ATR/WTR astigmatism, the nontoric FVR IOL demonstrated superior visual acuity outcomes at intermediate and near compared to the monofocal IOL group. Nevertheless, correcting higher levels of pre-existing astigmatism during cataract surgery is vital to achieving good postoperative outcomes.

While simultaneous vision lenses (SVLs) minimize spectacle dependency by providing vision at more than 1 focal point, these are often associated with reduced CS and increased incidence of photic phenomena. Per the ANSI guidelines, a CS loss of 0.3 log units at 2 or more spatial frequencies is considered a clinically significant difference.[22] In the present study, no clinically meaningful reduction in mean binocular CS was observed under photopic with glare and mesopic with and without glare conditions for all the cpds tested. The FVR IOL has been designed to prioritize distance vision under low light conditions; as such, the difference in mesopic CS without glare at 1.5, 3, and 12 cpds was less than the minimum detectable difference of 0.15 logCS.

The frequency, severity, and bothersomeness with glare were similar between the FVR and the monofocal IOL groups. There was less than a 5% difference (86.0% vs 90.9%) in the proportion of subjects experiencing never or occasional glare between the FVR and the monofocal IOL group. The severity and bothersomeness with glare were nearly identical in both groups. Similarly, the frequency and severity of starbursts were similar between the FVR and the monofocal IOL groups, with less than a 6% difference in the frequency (proportion of subjects experiencing no or occasional starbursts; 87.3% vs 92.2%) and severity of starbursts (proportion of subjects reporting not at all or mildly severe starbursts; 85.6% vs 91.4%). Bothersomeness with starbursts was essentially the same in both groups, with 90.7% of the FVR and 93.3% of the monofocal IOL subjects reporting not at all or little bothered by starbursts. Halos, as expected, were found to be more frequent and severe in the FVR IOL group; however, 79.6% of the FVR IOL subjects were not at all or a little bothered by them.

While direct comparisons are not possible due to the use of different questionnaires, the proportion of FVR IOL subjects who were not at all or a little bothered by visual symptoms of glare (88.0%), halos (79.6%), and starbursts (90.7%) trended better with the proportions reported previously with the trifocal PanOptix (TFNT00) IOL, where 73.1%, 72.5%, and 72% of the patients were "not at all" or "little bothered" by visual symptoms of glare, halos, and starbursts, respectively.[16] Similarly, the proportion of FVR IOL subjects reporting severe halos (6.1%), and starbursts (2.6%) in the present study trended lower than those reported with trifocal PanOptix IOL, where 12.6% and 16% of patients reported severe halos and starbursts, respectively. The frequency, severity, and bothersomeness of various dysphotopsias can be influenced by the mode of assessment of these symptoms. Unlike unsolicited visual complaints, directed solicited questions will likely return more patients reporting visual symptoms. As such, the real-world self-reported symptoms experienced by the SVL patients are expected to be lower than those obtained from directed questionnaires.

A halo is formed by the superimposition of images generated by the different foci of an SVL IOL, with its size increasing proportionally to the add power and the pupil size.[9] As such, low-add SVL IOLs have been associated with smaller-sized halos.[23,24] Additionally, low add powers may also contribute to a lower reduction in CS. The good contrast performance and dysphotopsia profile observed in the present study could be attributed to the low intermediate (+1.6 D) and near (+3.1 D) add powers of the enVista FVR IOL, combined with the apodized diffractive profile that enhances energy distribution to the distance focus in larger pupils. Under large-pupil conditions, more light energy is distributed at distance focus, making the IOL distance dominant. This may have contributed to similar mesopic (without glare) CS in the FVR and monofocal IOL groups. The asymmetric distribution of light energy minimizes the amount of nonfocused images reaching the retina, thus contributing to less severe/bothersome dysphotopsia, especially in dim light, when these are more likely to be noticed. Despite the FVR IOL being distance dominant under large pupil conditions, it showed similar defocus curve performance when stratified by small, medium, and large pupil apertures. Even at large pupil apertures, visual acuity was maintained around 0.1 logMAR up to −2.50 D defocus.

Neuroadaptation is vital when implanting multifocal lenses. It may take 3 to 12 months for neuroadaptation to complete following multifocal IOL implantation.[25-28] The present study revealed good PRO when assessed at 120 to 180 days postoperatively. While the FVR group showed a good dysphotopsia profile, this is likely to improve as patients further neuroadapt to multifocal IOLs.

Patients who fail to neuroadapt often perceive heightened visual disturbances and poor QoV following multifocal IOL implantation. Neuroadaptation failure may necessitate multifocal IOL patients to undergo IOL exchange.[26-28] However, in the present study, no requests for IOL exchange were reported.

Centration is an important prerequisite with multifocal IOLs. A large deviation between the visual axis and the pupillary axis of the multifocal IOL can lead to higher-order aberrations postoperatively, resulting in decreased visual quality.[29,30] Chord μ values over 0.60 mm can lead to more visual disturbances (halos and glare) in multifocal IOL patients.[14,31] However, the present study found no association of chord μ with the frequency, severity, and bothersomeness with glare and halos, and distance corrected

near vision, suggesting the FVR IOL has good tolerance to higher chord μ values.

Posterior capsule opacification (PCO) is a common complication of cataract surgery caused by the migration of residual lens epithelial cells onto the posterior capsule. Previous studies suggest that patients with diffractive multifocal IOLs (MIOLs) may be more sensitive to PCO, experience more rapid visual loss, and require earlier posterior capsulotomy than patients with monofocal IOLs.[32-34] However, the present study observed similar rates Nd-YAG capsulotomy (5% vs 5.4%) in the FVR and the monofocal IOL groups. enVista IOLs exhibit a continuous 360° sharp square edge design and step vaulted haptics that help prevent PCO. The YAG capsulotomy rates observed in the present study are similar to or lower than those reported previously with other multifocal or monofocal IOLs.[15,34-36]

All the primary safety endpoints of the study were met, with none of the subjects experiencing ocular TE-SAE related to the study device. None of the subjects had SSIs (IOL explantation, replacement, or repositioning) due to the optical properties of the study IOL, and no ISO grid cumulative or persistent AEs were observed.

The FVR IOL showed good visual and refractive outcomes, a favorable dysphotopsia profile, and good astigmatic tolerance. The present study outcomes with the nontoric enVista FVR and enVista monofocal IOL are encouraging. Future studies employing the toric version of the IOLs are desirable. While the study was designed to statistically evaluate the different efficacy and safety endpoints, some sub-group analyses were performed posthoc and may not have been adequately powered. Future studies that are statistically designed to validate the findings of subgroup analyses may help validate the findings observed in the present study.

CONCLUSION

In conclusion, the FVR IOL implantation in the cataract patients showed excellent visual performance, demonstrating statistical superiority to monofocal IOL for monocular DCIVA and DCNVA and statistical noninferiority to the monofocal IOL for monocular CDVA. In the FVR IOL group, 89.1% of subjects achieved binocular uncorrected visual acuity of 20/32 or better at far, intermediate, and near distances. The binocular defocus curve of the FVR IOL showed consistent visual acuity of 0.09 logMAR (~20/25 Snellen) in the intermediate and near vision range (−1.0 to −2.5 D). Correspondingly, binocular uncorrected visual acuity of 20/23.4 was achieved at intermediate and 20/25 at near. The FVR IOL also showed monofocal-like tolerance to residual refractive error, with a similarly high proportion of subjects achieving visual acuity 20/32 or better even in the presence of residual refractive error up to 0.75 D. The FVR IOL showed good CS and a favorable dysphotopsia profile.

CREDIT AUTHORSHIP CONTRIBUTION STATEMENT

MITCHELL C. SHULTZ: Writing – review & editing, Writing – original draft, Supervision, Investigation. **WILLIAM F. WILEY:** Writing – review & editing, Writing – original draft, Investigation. **EVA LIANG:** Writing – review & editing, Writing – original draft, Investigation. **ALICE T. EPITROPOULOS:** Writing – review & editing, Writing – original draft, Investigation. **JEFFREY WHITMAN:** Writing – review & editing, Writing – original draft, Investigation.

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