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Efficacy and safety evaluation of a new full visual range vs monofocal intraocular lens in patients with cataract: randomized, controlled Canadian clinical trial

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Purpose: To compare the visual performance and patient-reported outcomes after bilateral implantation of a new full visual range (FVR) intraocular lens (IOL) or its monofocal version.

Setting: 9 sites in Canada.

Design: Prospective, multicenter, randomized, double-mask, controlled study.

Methods: This study included patients who underwent bilateral implantation of either a FVR enVista Envy or monofocal MX60E IOL. Postoperative assessments included visual acuities, defocus curves, contrast sensitivity, and patient-reported outcomes using quality of vision and near activity visual questionnaire.

Results: The FVR IOL was noninferior to the control monofocal IOL for monocular uncorrected distance visual acuity and statistically superior to the monofocal IOL for monocular uncorrected intermediate visual acuity and uncorrected near visual acuity. Binocular defocus curves showed a range of vision of ~4.0 diopters (D) at 0.2 logMAR or better in the FVR group. In the intermediate and near range (−1.5 to −2.5 D), the FVR group demonstrated a plateau at ~0.1 logMAR (20/25), whereas in the monofocal group, visual acuity decreased to 0.27 logMAR (20/37) at −1.50 D defocus and to 0.48 logMAR (20/60) at −2.50 D defocus. Postoperatively, 92.7% (102/110) of the FVR patients were satisfied with their near vision, and 91.7% (99/108) of them did not require spectacles to do near-vision tasks, even for a prolonged duration.

Conclusions: The FVR group exhibited a continuous range of vision from distance to near. Postoperatively, more than 90% of FVR patients were satisfied with their near vision and had no difficulty doing near-vision tasks while being spectacle-free.

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Rapid technological advancements have shifted the goal of cataract surgery from simple visual rehabilitation to more of a refractive procedure. A wide variety of intraocular lenses (IOLs) with different IOL materials, designs, and optic features are now available to meet the growing demands of cataract surgery patients.

Standard monofocal IOLs provide vision only at 1 distance, and patients typically rely on spectacles for intermediate and near vision. To provide vision at more than 1 distance, simultaneous vision lenses (SVLs) were developed. The initial SVLs were bifocal. In these IOLs, the light entering the eye splits, generating 2 foci, allowing these IOLs to provide both distant and near vision simultaneously. The increasing digitalization of modern life has increased patients' desire for better intermediate vision. With conventional bifocal IOL designs, vision at an intermediate distance was insufficient, necessitating spectacle wear for intermediate tasks.[1–3]

Full visual range lenses (FVRs) have been developed to address the limitations of bifocal designs. These IOLs allow a greater range of useful vision at distance, intermediate, and near, and greater spectacle independence in individuals with presbyopia.[4] However, these are associated with an increased risk of visual phenomena that negatively affect vision.

The MX60EFH (enVista Envy IOL, Bausch & Lomb, Inc.) is a new FVR IOL based on the same platform as the monofocal MX60E (enVista monofocal IOL, Bausch & Lomb, Inc.). In addition, the optic design of the new FVR IOL purportedly provides greater tolerance to dysphotopsia compared with available FVR IOLs. The purpose of this study was to compare the visual and patient-reported

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outcomes of the new FVR IOL (FVR study group) compared with the monofocal IOL (control group).

METHODS

Design and Settings

This prospective, multicenter, controlled, double-mask, randomized trial conducted by 9 investigators at 9 clinical sites in Canada (ClinicalTrials.gov Identifier: NCT04224155) included consecutive patients meeting the study eligibility criteria and who were scheduled to undergo cataract surgery between March 2020 and June 2022 (Appendix 1, available at http://links.lww.com/JRS/B381). Patients were randomly assigned in a 2:1 ratio to undergo bilateral implantation of the enVista Envy FVR IOL (study group) or enVista monofocal IOL (control group). Randomization was performed after the determination of eligibility at the preoperative visit. An Interactive Response Technology system using computer-generated random numbers was used for randomization. Allocation was not selected by the enrollment personnel. Participants and postoperative examiners were masked to the treatment assignments. The study adhered to the tenets of the Declaration of Helsinki and was approved by a central institutional review board, Advarra (IRB), Ontario, Canada, and the Conjoint Health Research Ethics Board. All enrolled patients provided written informed consent using the IRB-approved informed consent form.

Intraocular Lenses

The enVista Envy FVR IOL is a 1-piece hydrophobic acrylic ultraviolet-absorbing IOL, designed with aspheric biconvex optics, with apodized diffractive steps on the anterior surface (with +3.1 diopters [D] near add and +1.6 D intermediate add).[5] The biconvex lens optic of the FVR and the monofocal IOLs has a diameter of 6.0 mm and a haptic-to-haptic diameter of 12.5 mm. Both the FVR and monofocal IOLs encompass a continuous 360-degree square edge on the posterior surface and modified C-loop haptics that provide a broad contact angle and increased stability of the IOL in the capsular bag. As high and sharp diffractive steps are known to cause more light scattering and visual disturbances, the FVR IOL has been designed with smaller and smoother diffractive steps to minimize the incidence of photic phenomena. The step height of the diffractive steps has been reduced toward the periphery, which causes a change in the energy balance. Consequently, as the pupil size increases, the energy distribution becomes distance dominant, that is, the amount of light energy focused on intermediate and near foci decreases. This reduces the amount of unfocused energy that causes halos under mesopic conditions. In addition, the apodized diffractive steps of the FVR IOL undergo a specialized polishing process after IOL lathing, creating a smoothed edge profile to reduce the incidence of dysphotopsia such as glare, halos, and starbursts.

Inclusion/Exclusion Criteria

The eligibility criteria for participating in the study included age 18 years or older, clinically significant cataract (cortical, nuclear, subcapsular, or combination) in both eyes, best-corrected distance visual acuity (CDVA) equal to or worse than 0.3 logMAR (20/40) with or without glare, expected CDVA equal to or better than 0.2 logMAR (20/32) after IOL implantation in each eye, and clear intraocular media other than cataract in both eyes, required an IOL power within the available range (+16.0 to +27.0 D) with preoperative corneal astigmatism ≤1.0 D as measured by corneal topography or keratometry in both eyes.

Exclusion criteria were a visual disorder other than cataract (that could potentially cause future acuity losses to a level of 0.7 logMAR [20/100] or worse in either eye), uncontrolled glaucoma, pupil dilation less than 5.0 mm in both eyes or eccentric/ectopic pupils in either eye, irregular astigmatism, or anomalies of the lens capsule or zonular fibers which could affect postoperative centration or tilt of the IOL (such as pseudoexfoliation syndrome). The other details of the key inclusion and exclusion criteria for this study can be accessed at ClinicalTrials.gov (NCT04224155).

Surgical Details

All participants who met eligibility criteria were randomly assigned to be implanted with either an FVR IOL or a monofocal IOL. The eye with the worst CDVA 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.

Cataract surgery was performed as per the standard of care at respective sites. Surgeons were free to choose the type of anesthesia (local or topical), the incision size and location (eg, steepest meridian and temporal), and the type of nucleus fragmentation (phaco or femto), and capsulorhexis diameter, ophthalmic viscosurgical device used, etc., per their preference. For IOL power calculations, the recommended IOL formulas included SRK/T or Hill RBF, Holladay 1, Holladay 2, Hoffer Q, Haigis, and Barrett formulas, and the surgeons were free to choose any of these formulas. The IOL constants used for performing IOL power calculations with various formulas are summarized in Supplemental Table S1 (available at http://links.lww.com/JRS/B378). After cataract surgery, patients underwent implantation of FVR or monofocal IOL, per the randomization.

The study included nontoric FVR IOLs; however, these were manufactured with axis marks to assess rotational stability. No additional astigmatism correction procedures, such as astigmatic keratotomies, corneal relaxing incisions, or otherwise, were allowed during the study.

Follow-ups

All enrolled patients were seen at 10 visits (refer to ClinicalTrials.gov Identifier: NCT04224155 for details of the various follow-up timepoints). All the outcome measures in this study were presented for the last postoperative timepoint on days 120 to 180.

Visual acuities at far, intermediate, and near were measured using Early Treatment of Diabetic Retinopathy Study charts (M&S Technologies, Inc.) under photopic conditions (85 cd/m^2) at all the study centers. These included monocular uncorrected and corrected distance visual acuity (UDVA, CDVA) at 4 m, monocular uncorrected and distance-corrected near visual acuity (UNVA, DCNVA) at 40 cm, monocular uncorrected and distance-corrected intermediate visual acuity (UIVA, DCIVA) at 66 cm, and binocular UIVA and UNVA. Other measurements included IOP (Goldmann Type Applanation Tonometer), binocular-corrected distance contrast sensitivity (CTS, M&S Technologies), patient-reported outcomes assessed using the standardized quality of vision (QoV), and the near activity vision questionnaire (NAVQ).[6–9]

All the effectiveness and safety variables were assessed at postoperative days 120 to 180. The primary effectiveness variables were photopic UDVA, UNVA, and UIVA for the first implanted eyes. Other effectiveness variables were IOL rotation for the FVR IOL group; photopic monocular CDVA, DCNVA, and DCIVA; photopic binocular UNVA and UIVA; and binocular distance corrected defocus curves from +1.50 D to −3.50 D. Primary safety variables were the incidence of all adverse events (AE) and serious AEs (SAEs), including secondary surgical interventions (SSIs) related to the optical properties of the IOL. Secondary safety variables were photopic and mesopic contrast sensitivity with or without glare.

Statistical Analysis

Sample Size Approximately 168 participants were targeted to be implanted bilaterally (336 eyes). Participants were randomized in a 2:1 ratio to obtain complete follow-up for 4 to 6 months on at least 100 FVR and 50 monofocal IOL participants, assuming a 10% dropout rate.

Table 1. Monocular (first implanted eyes) and binocular visual acuities at distance, intermediate, and near in the FVR and monofocal IOL groups

	FVR IOL (N = 110)	Monofocal IOL (N = 50)	90% CI[a]/*P* value
Monocular LSM ± SE			
UDVA[a]	0.10 ± 0.02	0.02 ± 0.02	0.042, 0.114
UIVA	0.16 ± 0.02	0.28 ± 0.02	<.0001
UNVA	0.21 ± 0.02	0.48 ± 0.02	<.0001
Mean ± SD			
CDVA	0.02 ± 0.12	−0.04 ± 0.09	.0006
DCIVA	0.15 ± 0.12	0.34 ± 0.13	<.0001
DCNVA	0.18 ± 0.13	0.53 ± 0.14	<.0001
Binocular Mean ± SD			
UIVA	0.08 ± 0.09	0.19 ± 0.15	<.0001
UNVA	0.12 ± 0.10	0.36 ± 0.13	<.0001

FVR = full visual range; LSM = least-squares mean3
[a]Indicates that the confidence interval (CI) pertains exclusively to the UDVA.

Analysis Population All effectiveness analyses were performed on bilaterally implanted patients who completed the last scheduled follow-up visit at postoperative days 120 to 180. No data imputations were performed (for the missing data), and the data were analyzed as observed. Safety was assessed on all patients who underwent surgery in at least 1 eye. The patient-reported outcome analysis set included all participants who submitted the preoperative questionnaires and postoperative questionnaires either at postoperative days 120 to 180 visit or any postoperative unscheduled visit before study exit.

Statistical analysis was performed using SAS. Analysis of the covariance model with UDVA, UIVA, or UNVA as dependent variables and treatment and site as fixed factors were used to calculate least-squares means and CIs. Noninferiority of the FVR IOL to the monofocal IOL for monocular photopic UDVA was established when an upper confidence limit of the 2-sided 90% CI of the least-squares means difference was less than 0.2 logMAR. Statistical superiority of the study IOL over the control IOL for photopic monocular UIVA and UNVA was established if the *P* value for a 2-sided difference was ≤0.05 and the least-squares mean difference for the 2 groups was less than zero. Categorical data obtained from patient-reported outcomes were analyzed using chi-square statistics. The recommendations for writing the clinical research manuscript and reporting the outcomes of IOL-based refractive surgery have been followed wherever applicable.[10,11]

RESULTS

A total of 172 participants were randomized in the study. Of these, 3 withdrew consent before undergoing surgery, and 4 could not undergo surgery due to the COVID-19 pandemic. Of the remaining 165 participants who underwent surgery, 111 participants received FVR IOL and 54 participants received monofocal IOL (Supplemental Figure S1, available at http://links.lww.com/JRS/B376). The demographic and other baseline characteristics were similar between the FVR and monofocal IOL groups (Supplemental Table S2, available at http://links.lww.com/JRS/B379).

In the FVR IOL group, 1 patient discontinued the study after second-eye surgery, leaving 110 participants available at the last scheduled follow-up visit (days 120 to 180). In the monofocal IOL group, 2 participants could not complete the last follow-up visit and 2 participants discontinued the study, leaving 50 participants available at the last scheduled follow-up visit (days 120 to 180).

Visual and Refractive Results

All the primary effectiveness endpoints were met at postoperative days 120 to 180. Noninferiority of the FVR IOL group to the monofocal group in monocular UDVA was established, based on a 2-sided 90% CI of 0.042 to 0.114 logMAR and the difference in the least-squares means between the 2 groups of 0.078 logMAR. Since the upper confidence limit was less than 0.2 logMAR, the FVR IOL group was statistically noninferior to the monofocal IOL group. The FVR IOL group demonstrated statistical superiority over the monofocal group for monocular UIVA and UNVA. The least-squares mean ± SE differences in UIVA (−0.125 ± 0.0231 logMAR) and UNVA (−0.271 ± 0.0240 logMAR) for the first implanted eyes were significant between the 2 groups ($P < .0001$). The mean manifest refraction spherical equivalent (MRSE) at postoperative days 120 to 180 was +0.13 ± 0.39 D in the FVR IOL group and 0.00 ± 0.42 D in the monofocal IOL group ($P = .0473$). A total of 85.5% and 80.4% of eyes in the FVR and the monofocal IOL group showed MRSE within ±0.50 D, and MRSE was within ±1.00 D in 96.4% (FVR group) and 98.3% (monofocal group) of eyes, respectively. Table 1 presents the means of monocular visual acuities. The cumulative frequency distribution graphs for monocular visual acuities were prepared as per the standards of reporting outcomes of IOL-based surgery and are presented in Supplementary Figure S2, A–C (available at http://links.lww.com/JRS/B377).[11]

The mean binocular visual acuities are summarized in Table 1. The cumulative frequency distribution of binocular UIVA and UNVA is presented in Figure 1A and B. Binocularly, UIVA and UNVA of 0.2 logMAR (20/32) or better were achieved in 97% (107/110) and 93% (102/110) of the participants implanted with FVR IOL vs 72% (36/50) and 20% (10/50) of the monofocal IOL-implanted participants.

Defocus Curve

The FVR IOL group exhibited better binocular depth of focus than the monofocal group. Both groups had similar peaks at 0.0 D achieving mean visual acuity of better than 20/20. In the intermediate and the near-vision range (−1.5 to −2.5 D), the FVR IOL group demonstrated a plateau at approximately 0.1 logMAR (~20/25), whereas in the monofocal IOL group, it decreased from 0.27 logMAR (20/37) to 0.48 logMAR (20/60). The FVR IOL advantage was maintained throughout the extended near-vision range (−2.5 to −3.5 D) (Figure 2).

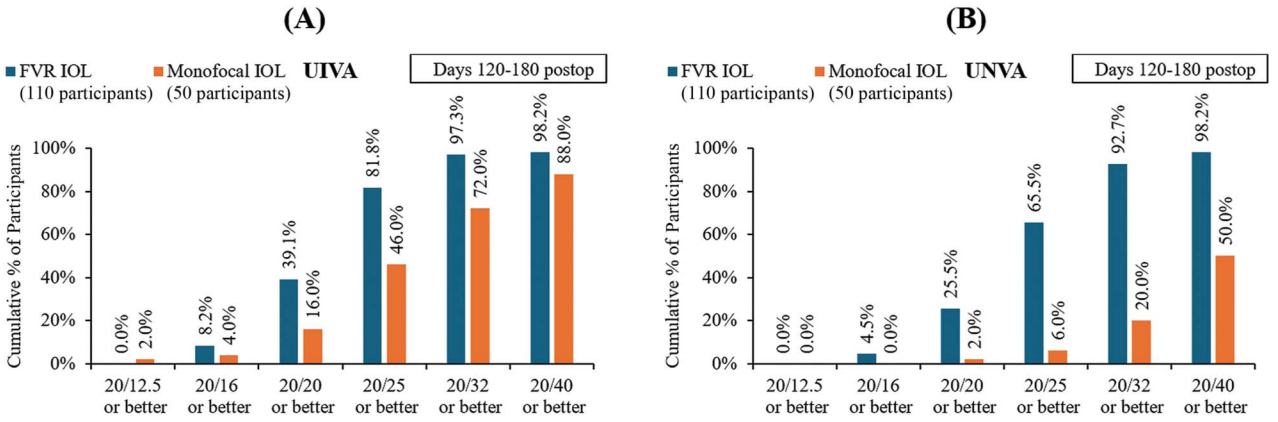

Figure 1. Cumulative frequency distribution of the (*A*) binocular UIVA and (*B*) binocular UNVA under photopic conditions in the FVR IOL group and monofocal IOL group. FVR = full visual range

Rotational Stability

At postoperative days 120 to 180, the mean absolute value of rotation from the operative visit was 2.21 ± 2.50 degrees for all eyes in the FVR IOL group. Between operative visit and postoperative days 1 to 2, the mean absolute value of rotation was 2.13 ± 2.74 degrees; between postoperative days 1 to 2 and days 30 to 60, it was 1.31 ± 1.09 degrees; and between postoperative days 30 to 60 and days 120 to 180, it was 1.34 ± 1.12 degrees. At postoperative days 120 to 180, 98.8% (170/172) of eyes in the FVR IOL group had an IOL rotation 10 degrees or less from the operative visit and 100% (172/172) had an IOL rotation 20 degrees or less.

Contrast Sensitivity

Figure 3A–C shows the mean binocular contrast sensitivity for both FVR and monofocal IOL groups at all tested cpd levels under photopic with glare and mesopic with and without glare conditions. All values were within ±1 SD of the mean values found in normal adults.

Patient-Reported Outcomes

At postoperative days 120 to 180, the mean QoV questionnaire frequency, severity, and bothersome domain scores were 13.65, 13.42, and 11.85, respectively, in the FVR IOL group and 12.88, 12.85, and 11.19, respectively, in the monofocal IOL group.

Table 2 presents that there were no statistically significant differences in the frequency, severity, and bothersomeness with glare in both groups. Glare was rated as "not at all" or "a little" bothersome in 95.5% (105/110) of patients in the FVR group, compared with 96.2% (50/52) in the monofocal control group (P = 1.0000) (Table 2). Although halos were more frequent and severe in the FVR group, 88.2% (97/110) of FVR patients reported being "not at all" or "a little" bothered by them compared with 94.2% (49/52) in the control group, which was not statistically significant (P = .2283). Starbursts were rated as slightly more severe in the FVR group; however, they were neither more frequent nor bothersome than in the control group. Overall, 93.6% (103/110) of FVR patients reported starbursts as being "not at all" or "a little" bothersome compared with 100% (52/52) of controls (P = .0977).

Postoperatively, a higher proportion of patients in the FVR IOL group reported "no difficulty" doing near vision-related daily activities (Table 3). A higher proportion of patients in the FVR IOL group (93% [102/110] vs 56% [29/52], P < .0001) were completely to moderately satisfied with

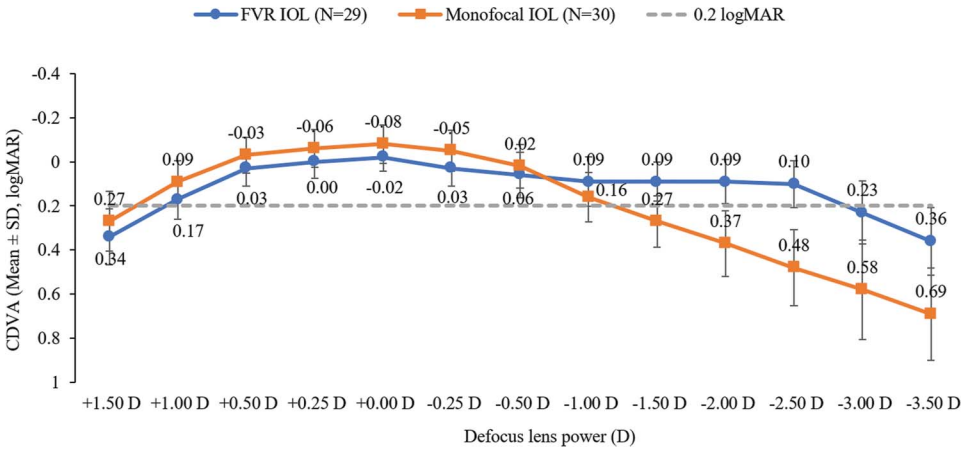

Figure 2. Binocular defocus curve (logMAR) comparison of the FVR IOL and the monofocal IOL at postoperative 120 to 180 days. FVR = full visual range

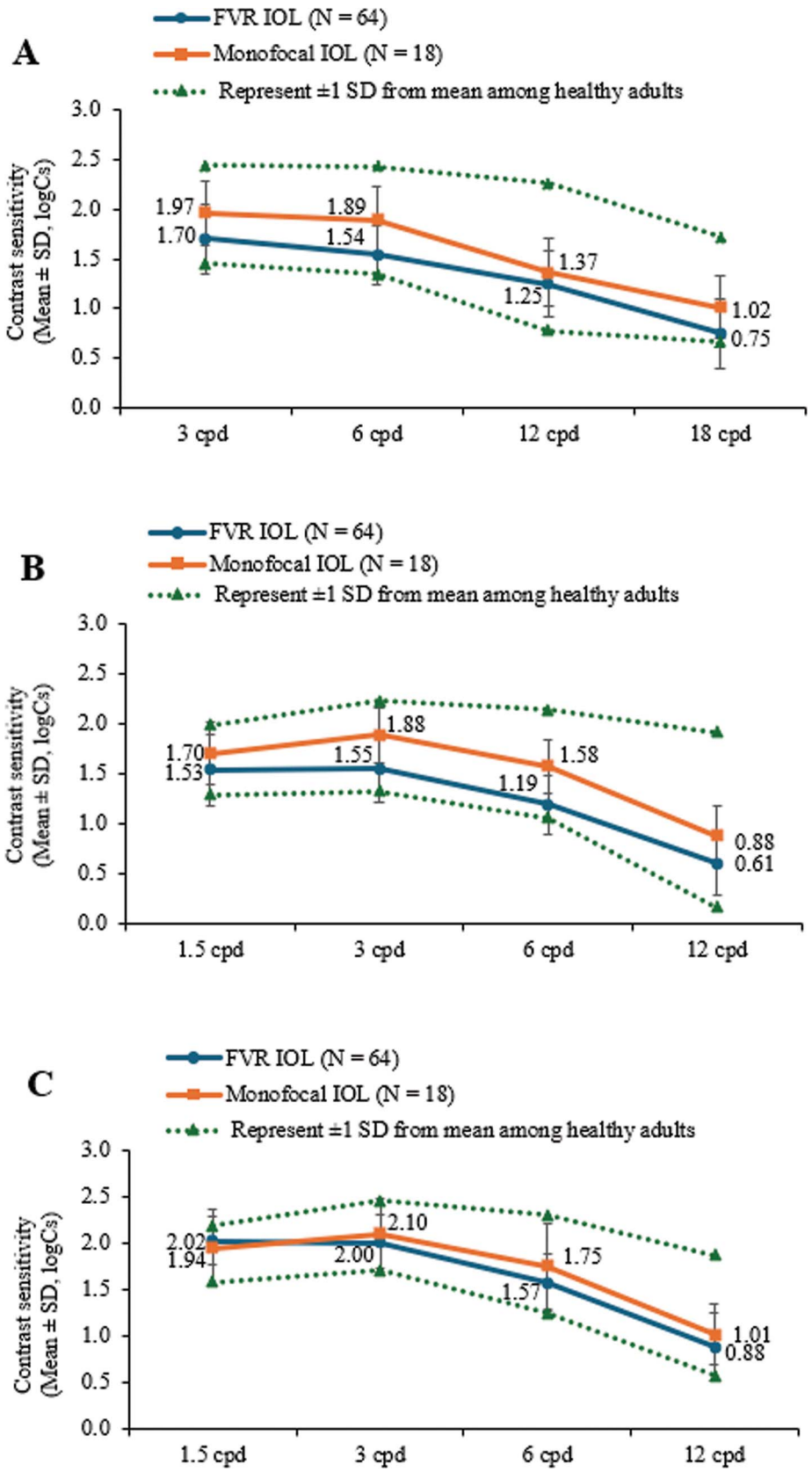

Figure 3. Comparison of the (*A*) mean binocular photopic contrast sensitivity with glare, (*B*) mean binocular mesopic contrast sensitivity with glare, and (*C*) mean binocular mesopic contrast sensitivity without glare between the FVR and the monofocal IOLs. FVR = full visual range

their postoperative near vision and could perform near vision tasks with no difficulty while being spectacle-free (92% [99/108] vs 51% [26/51], $P < .0001$).

Safety Outcomes

A total of 98.2% of eyes in the FVR IOL group achieved photopic monocular CDVA of 20/40 or better (0.3 logMAR

Table 2. Patient-reported outcomes assessed using the QoV questionnaire for the frequency, severity, and bothersomeness with visual symptoms of glare, halos, and starbursts

	FVR IOL (N = 110)				Monofocal IOL (N = 52)				*P* value FVR IOL vs monofocal IOL
	Frequency (%)				Frequency (%)				
Visual disturbance	Never	Occasionally	Quite often	Very often	Never	Occasionally	Quite often	Very often	Never to occasionally
Glare	71.8	23.6	3.6	0.9	67.3	30.8	1.9	0.0	95.5 vs 98.1; *P* = .6651
Halos	37.3	32.7	15.5	14.5	65.4	28.8	5.8	0.0	70.0 vs 94.2; *P* = .0005
Starbursts	62.7	30.9	4.5	1.8	67.3	30.8	1.9	0.0	93.6 vs 98.1; *P* = .2233
	Severity (%)				Severity (%)				
	Not at all	Mild	Moderate	Severe	Not at all	Mild	Moderate	Severe	Not at all to mildly severe
Glare	72.7	19.1	7.3	0.0	67.3	26.9	3.8	1.9	92.7 vs 94.2; *P* = .7119
Halos	40.9	35.5	18.2	5.5	67.3	25.0	7.7	0.0	76.4 vs 92.3; *P* = .0147
Starbursts	63.6	24.5	10.9	0.9	67.3	30.8	1.9	0.0	88.2 vs 98.1; *P* = .0364
	Bothersomeness (%)				Bothersomeness (%)				
	Not at all	A little	Quite	Very	Not at all	A little	Quite	Very	Not at all to a little bothersome
Glare	77.3	18.2	3.6	0.9	71.2	25.0	3.8	0.0	95.5 vs 96.2; *P* = 1.0000
Halos	54.5	33.6	6.4	5.5	82.7	11.5	5.8	0.0	88.2 vs 94.2; *P* = .2283
Starbursts	71.8	21.8	3.6	2.7	78.8	21.2	0.0	0.0	93.6 vs 100.0; *P* = .0977

FVR = full visual range; QoV = quality of vision

or better), which was better than the ISO standard safety and performance endpoint (SPE) rate of 92.5%.

Adverse Events

Thirty-nine participants (35.1%; 39/111 participants) in the FVR IOL group and 20 (37.0%; 20/54 participants) in the monofocal group experienced at least 1 ocular treatment-emergent adverse event (TEAE) (Supplemental Table S3, available at http://links.lww.com/JRS/B380). The most common ocular TEAEs in the FVR group were punctate keratitis (18.9%; 21/111 participants) and posterior capsular opacification (2.7%; 3/111 participants), and in the monofocal IOL group were punctate keratitis (14.8%; 8/54 participants) and visual acuity reduced (7.4%; 4/54 participants).

Although the majority of ocular TEAEs in the FVR IOL group were mild to moderate, there was only 1 severe TEAE (cystoid macular edema) that occurred in 1 eye of a patient.

When assessed for the relationship of TEAEs to the study device, in the FVR IOL group, 1 participant experienced bilateral halo vision, which was assessed as "probably related" to the study device, and another participant had bilateral posterior capsular opacification which was assessed as "possibly related" to the study device. In the monofocal IOL group, none of the patients experienced

Table 3. Proportion of patients reporting "no or a little difficulty" in performing near-vision–related daily activities assessed using NAVQ

	FVR IOL		Monofocal IOL		
No or a little difficulty	n/N[a]	%	n/N[a]	%	*P* value
Reading small print	97/109	89.0	19/52	36.5	<.0001
Reading label/instruction/ingredients/prices	90/109	82.6	20/52	38.5	<.0001
Reading post/mail	102/109	93.6	23/52	44.2	<.0001
Writing and reading your own writing	105/108	97.2	36/52	69.2	<.0001
Seeing the display and keyboard on a computer or calculator	104/107	97.2	34/52	65.4	<.0001
Seeing the display and keyboard on a mobile or fixed telephone	100/108	92.6	33/52	63.5	<.0001
Seeing objects close to you and engaging in your hobbies	103/108	95.4	37/52	71.1	<.0001
Seeing objects close to you in poor or dim light	91/108	84.3	28/52	53.8	<.0001
Maintaining focus for prolonged near work	99/109	90.8	27/52	51.9	<.0001
Conducting near work without spectacles	99/108	91.8	26/51	51.0	<.0001

FVR = full visual range; NAVQ = near activity visual questionnaire
[a]Responses such as N/A or blanks were excluded from the analysis, explaining N of <110 in the FVR IOL group and N of <52 in the monofocal IOL group

study device-related ocular TEAEs. No participant had SSIs due to the optical properties of the study lens.

Only 1 participant in the FVR IOL group experienced an ocular treatment-emergent serious adverse event (TE-SAE) (dry age-related macular degeneration) in 1 eye. This was judged as mild and not related to the study device or the surgical procedure.

ISO Grid Adverse Events

In the FVR IOL group (N = 222 eyes), the incidence of cystoid macular edema was 1.4% (3/222 eyes), which was better than the ISO (SPE) rate of 3.0% (P = .9638). None of the other ISO grid cumulative AEs (hypopyon, endophthalmitis, lens dislocated from the posterior chamber, pupillary block, retinal detachment, and secondary surgical intervention) were observed in the FVR IOL group.

Similarly, the incidence of persistent cystoid macular edema was 0.9% (2/220 eyes) in the FVR IOL group, which was comparable with the SPE rate of 0.5% (P = .3011). The incidence of persistent iritis was 0.5% (1/220 eyes), which was comparable with the SPE rate of 0.3% (P = .4837); the other ISO grid-persistent AEs (corneal stromal edema and raised IOP requiring treatment) were not observed in the FVR IOL group.

DISCUSSION

This study investigated the visual performance of a new FVR IOL to its monofocal counterpart of the same platform. The results of the study showed the FVR IOL to be statistically superior to the monofocal IOL in photopic monocular UIVA and UNVA (P < .0001). After distance correction, the intermediate and near (DCIVA and DCNVA) visual acuities in the FVR IOL group improved further, augmenting the difference between the 2 groups.

The photopic monocular UDVA of the FVR IOL group was found to be statistically noninferior to that of the monofocal IOL group. In general, the relative benefit of presbyopia-correcting IOLs is best appreciated when the refraction is near emmetropia.[12] In this study, even with the small amount of residual refractive error (+0.12 D in the FVR vs −0.02 D in the monofocal IOL group), the FVR IOL group had UDVA comparable with the monofocal group, indicating refractive robustness and good distance visual performance of the FVR IOL.

Binocular near and intermediate vision outcomes were also found to be better in the FVR IOL group. The FVR IOL-implanted patients achieved a mean postoperative binocular photopic visual acuity of 0.12 logMAR (20/26) at near and 0.08 logMAR (20/24) at intermediate, indicating the full range of vision provided by the study IOL. The binocular uncorrected intermediate and near visual acuities achieved in this study, when compared with the outcomes achieved in FDA studies of previously approved trifocal PanOptix IOL (model TFNT00) or hybrid multifocal EDOF IOLs (Tecnis Synergy IOL, model ZFR00V) were found to be comparable.[13–16]

The visual acuity outcomes of this study were also supported by the outcomes of the binocular defocus curves, where the FVR IOL group showed a continuous range of vision of ~4 D at 0.2 logMAR or better. At 0.0 D defocus, the FVR IOL exhibited a mean visual acuity of −0.02 logMAR (20/19); at −0.50 D defocus, the visual acuity reduced to 0.06 logMAR (20/23) and then exhibited consistent visual acuity of 0.09 and 0.10 logMAR (20/25) from −1.00 D to −2.50 D without any drop. In this study, the continuous range of vision after bilateral implantation of the study IOL was assessed using the binocular defocus curve. However, recent literature suggests that the monocular defocus curve provides better insights into the range of vision provided by the IOL.[17] As such, future studies evaluating the monocular defocus curve are warranted.

In general, SVLs have been found to be associated with reduced contrast sensitivity and increased incidence of photic phenomena such as glare, halos, and starbursts.[18–21] The splitting of light among multiple focal points allows only a fraction of the light entering the lens being used to produce an image at a given distance, resulting in reduced contrast on the retinal image.[13] In this study, whereas the contrast sensitivity of the FVR IOL was slightly lower in all tested conditions, the values were within ±1 SD of the means reported for the normal population.

With an IOL design optimized to reduce dysphotopsias, the FVR IOL group demonstrated low levels of patient-reported bothersomeness and severity to glare, halos, and starbursts on a directed questionnaire (patients were shown images of visual phenomena and were asked to rate). In this study, 95.5% (glare), 88.1% (halos), and 94.2% (starbursts) of patients were “not at all” or “a little” bothered none of which were significant when compared with the rates in the monofocal control group. Visual symptoms were rated as “severe” by 0.0% (glare), 5.5% (halos), and 0.9% (starbursts) of the FVR patients in this study, lower than those reported previously for the TFNT00 diffractive FVR IOL, where 3.2%, 12.6%, and 16.0% of TFNT00 FVR patients reported severe glare, halos, and starbursts, respectively, again with a different questionnaire.[22] Although these numbers provide context, head-to-head studies are necessary before direct comparisons can be made.

The low rates of visual disturbances with the new FVR IOL may be attributed to its unique diffractive optic. The height of the diffractive steps reduces toward the periphery of the lens, resulting in a change in the energy balance.[23,24] This asymmetric energy distribution makes the IOL distance dominant with larger pupil diameters. Consequently, the amount of energy focused on intermediate and near foci decreases as the pupil size increases (eg, under mesopic conditions); this feature, combined with the smoothed profile of the diffractive steps, reduces the amount of unfocused energy that causes visual disturbances such as halos, explaining why a high proportion of patients did not find photic phenomena bothersome.[25] Furthermore, even in mesopic conditions, the FVR IOL maintained adequate near vision, as seen by the high proportion of FVR IOL-implanted patients (82.7%) reporting no or little difficulty while working with close objects in poor or dim light.

NAVQ was also used to assess patient-reported outcomes with daily activities related to near vision. The outcomes of

the questionnaire assessed postoperatively showed that recipients of FVR IOL were better able to engage in activities that required near vision, with a significantly higher proportion of patients performing these activities with little or no difficulty compared with patients in the monofocal IOL group. A total of 92% of the FVR IOL patients could perform near-vision tasks without the need for spectacles. The postoperative outcomes of the NAVQ corroborate with improved near and intermediate vision after the implantation of FVR IOL discussed above. Overall, 93% of patients implanted with the FVR IOL were satisfied (completely to moderately satisfied) with their postoperative near vision compared with 56% of the monofocal IOL patients.

enVista IOLs are made of material that allow rapid unfolding of the IOL inside the bag. Its modified C-loop haptics provide a large 110-degree contact angle between the 2 haptics and the circumference of the capsular bag and contribute to the stability of the IOL. The nontoric version of FVR IOLs for this study were manufactured with axis marks that allow easy assessment of the rotational stability of the IOL. Similar to enVista toric IOLs that have demonstrated excellent rotational stability in previously published studies, the FVR IOL evaluated in this study yielded excellent rotational stability.[26–28] As such, the toric version of the FVR IOL will also likely demonstrate excellent rotational stability because it will share the same platform as the enVista FVR IOL.

In this study, both the FVR and monofocal control IOLs demonstrated an excellent safety profile. No participants experienced ocular TE-SAE related to the study device; no participants had SSIs due to the optical properties of the study lens; and none of the ISO grid-cumulative or grid-persistent AEs in the FVR IOL group were significantly greater than the respective SPE rates.

In conclusion, the FVR IOL was statistically noninferior to the monofocal IOL in photopic monocular UDVA and statistically superior regarding photopic UNVA and UIVA. The results of the QoV and NAVQ showed that a high proportion of patients implanted with the FVR IOL could perform various near-vision–related daily activities with little or no difficulty while being spectacle-free. Although the incidence of photic phenomena was higher in the FVR IOL group, as expected in a diffractive technology, importantly, these were not reported to be more bothersome than in monofocal controls, and ~93% of FVR patients were satisfied with their postoperative near vision.

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WHAT WAS KNOWN

- Rapid digitalization and increased use of handheld devices have increased patients' demand for uncorrected visual function at distance, intermediate, and near.
- Contemporary diffractive full visual range (FVR) IOLs offer excellent visual performance over distance, intermediate, and near in a very high proportion of implanted patients.
- Diffractive FVR IOLs have been associated with increased rates of bothersome adverse photic phenomena, such as glare, halos, and/or starbursts.

WHAT THIS PAPER ADDS

- The new FVR IOL demonstrates the strong defocus curve performance demanded of a contemporary FVR IOL, offering ~4 D of continuous range at 0.2 logMAR or better on binocular defocus curves, with high levels of patient satisfaction with near and spectacle-independent vision.
- The FVR IOL demonstrated outstanding tolerance to photic phenomena, with 88% to 95.5% of FVR IOL-implanted patients reporting being "not at all" or "a little" bothered by the visual symptoms of halo, glare, and starbursts, which was not significantly different from monofocal controls at their final postoperative visit.

REFERENCES

1. Bilbao-Calabuig R, González-López F, Amparo F, Alvarez G, Patel SR, Llovet-Osuna F. Comparison between mix-and-match implantation of bifocal intraocular lenses and bilateral implantation of trifocal intraocular lenses. J Refract Surg. 2016;32(10):659–663
2. Cochener B. Prospective clinical comparison of patient outcomes following implantation of trifocal or bifocal intraocular lenses. J Refract Surg. 2016;32(3):146–151
3. Gundersen KG, Potvin R. Comparison of visual outcomes after implantation of diffractive trifocal toric intraocular lens and a diffractive apodized bifocal toric intraocular lens. Clin Ophthalmol. 2016;10:455–461
4. Zamora-de La Cruz D, Bartlett J, Gutierrez M, Ng SM. Trifocal intraocular lenses versus bifocal intraocular lenses after cataract extraction among participants with presbyopia. Cochrane Database Syst Rev. 2023;1:CD012648
5. Bausch & Lomb, Inc. enVista Envy Hydrophobic Acrylic IOL. Full Range of Vision IOL. Accessed January 29, 2025. https://www.bauschsurgical.com/siteassets/pdf/envista_envy_features-specifications_sheet_eve0004usa24.pdf
6. McAlinden C, Pesudovs K, Moore JE. The development of an instrument to measure quality of vision: the Quality of Vision (QoV) questionnaire. Invest Ophthalmol Vis Sci. 2010;51(11):5537–5545
7. McAlinden C, Skiadaresi E, Gatinel D, Cabot F, Huang J, Pesudovs K. The Quality of Vision questionnaire: subscale interchangeability. Optom Vis Sci. 2013;90(8):760–764
8. Gupta N, Wolffsohn JS, Naroo SA, Davies LN, Gibson GA, Shah S. Development of a near activity visual questionnaire to assess accommodating intraocular lenses. Cont Lens Anterior Eye. 2007;30(2):134–143
9. Buckhurst PJ, Wolffsohn JS, Gupta N, Naroo SA, Davies LN, Shah S. Development of a questionnaire to assess the relative subjective benefits of presbyopia correction. J Cataract Refract Surg. 2012;38(1):74–79
10. Fernández J, Rocha-De-Lossada C, Rodríguez-Vallejo M. Recommendations for writing clinical research manuscripts: from monofocal to multifocal intraocular lenses. Int J Environ Res Public Health. 2022;19(24):17036
11. Fernández J, Ribeiro FJ, Rodríguez-Vallejo M, Dupps WJ Jr, Werner L, Srinivasan S, Kohnen T. Standard for collecting and reporting outcomes of IOL–based refractive surgery: update for enhanced monofocal, EDOF, and multifocal IOLs. J Cataract Refract Surg. 2022;48(11):1235–1241
12. Carreño E, Carreño EA, Carreño R, Carreño M, López V, Potvin R. Refractive and visual outcomes after bilateral implantation of a trifocal intraocular lens in a large population. Clin Ophthalmol. 2020;14:369–376
13. Modi S, Lehmann R, Maxwell A, Solomon K, Cionni R, Thompson V, Horn J, Caplan M, Fisher B, Hu JG, Yeu E. Visual and patient-reported outcomes of a diffractive trifocal intraocular lens compared with those of a monofocal intraocular lens. Ophthalmology. 2021;128(2):197–207

14. Moshirfar M, Stoakes IM, Theis JS, Porter KB, Santos JM, Martheswaran T, Payne CJ, Hoopes PC. Assessing visual outcomes: a comparative study of US-FDA premarket approval data for multifocal and EDOF lens implants in cataract surgery. J Clin Med. 2023;12(13):4365
15. Johnson & Johnson Surgical Vision, Inc. TECNIS Synergy IOL with TECNIS Simplicity Delivery System IFU. 2021. Accessed February 28, 2024. https://www.jnjvisionpro.com/sites/us/files/public/surgical/IOLs/z311421e_b_tecnis_synergy_iols_dfu.pdf
16. Dick HB, Ang RE, Corbett D, Hoffmann P, Tetz M, Villarrubia A, Palomino C, Castillo-Gomez A, Tsai L, Thomas EK, Janakiraman P. Comparison of 3-month visual outcomes of a new multifocal intraocular lens vs a trifocal intraocular lens. J Cataract Refract Surg. 2022;48(11):1270–1276
17. Ribeiro F, Dick HB, Kohnen T, Findl O, Nuijts R, Cochener B, Fernández J. Evidence-based functional classification of simultaneous vision intraocular lenses: seeking a global consensus by the ESCRS Functional Vision Working Group. J Cataract Refract Surg. 2024;50(8):794–798
18. Chang JS, Ng JC, Lau SY. Visual outcomes and patient satisfaction after presbyopic lens exchange with a diffractive multifocal intraocular lens. J Refract Surg. 2012;28(7):468–474
19. Visser N, Nuijts RM, de Vries NE, Bauer NJC. Visual outcomes and patient satisfaction after cataract surgery with toric multifocal intraocular lens implantation. J Cataract Refract Surg. 2011;37(11):2034–2042
20. Lubiński W, Gronkowska-Serafin J, Podborączyńska-Jodko K. Clinical outcomes after cataract surgery with implantation of the Tecnis ZMB00 multifocal intraocular lens. Med Sci Monit. 2014;20:1220–1226
21. Law EM, Aggarwal RK, Kasaby H. Clinical outcomes with a new trifocal intraocular lens. Eur J Ophthalmol. 2014;24(4):501–508
22. United States Food and Drug Administration. AcrySof IQ PanOptix Trifocal Intraocular Lens (Model TFNT00) Summary of Safety and Effectiveness Data (P040020/S087). Accessed September 17, 2024. https://www.accessdata.fda.gov/cdrh_docs/pdf4/P040020S087B.pdf
23. Vega F, Alba-Bueno F, Millán MS. Energy distribution between distance and near images in apodized diffractive multifocal intraocular lenses. Invest Ophthalmol Vis Sci. 2011;52(8):5695–5701
24. Davison JA, Simpson MJ. History and development of the apodized diffractive intraocular lens. J Cataract Refract Surg. 2006;32(5):849–858
25. Alba-Bueno F, Vega F, Millan MS. Halos and multifocal intraocular lenses: origin and interpretation [in Spanish]. Arch Soc Esp Oftalmol. 2014;89(10):397–404
26. Buckhurst PJ, Lau G, Williams JI, Packer M. Efficacy of a one-piece aberration neutral hydrophobic acrylic toric intraocular lens. Clin Ophthalmol. 2022;16:3763–3774
27. Packer M, Williams JI, Feinerman G, Hope RS. Prospective multicenter clinical trial to evaluate the safety and effectiveness of a new glistening-free one-piece acrylic toric intraocular lens. Clin Ophthalmol. 2018;12:1031–1039
28. Wiley WF, Epitropoulos AT, Whitman J, Liang E, Sadri E, Lau G. Rotational stability and visual performance of aberration-free, hydrophobic acrylic monofocal toric intraocular lens with enhanced material. J Cataract Refract Surg. 2024;50(12):1236–1241

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