Visual Outcomes and Patient Satisfaction After Bilateral Refractive Lens Exchange With a Trifocal Intraocular Lens in 5,226 Patients With Presbyopia

Andrea Llovet-Rausell, MD, FEBO; Julio Ortega-Usobiaga, MD, PhD, FEBOS-CR; César Albarrán-Diego, OD, PhD; Jaime Beltrán-Sanz, MD; Rafael Bilbao-Calabuig, MD, PhD, FEBOS-CR; Fernando Llovet-Osuna MD, PhD

ABSTRACT

PURPOSE: To assess visual and refractive outcomes and visual function after bilateral RayOne Trifocal toric and non-toric intraocular lens (IOL) (Rayner) implantation in patients with presbyopia.

METHODS: Charts of patients with presbyopia who underwent refractive lens exchange with bilateral implantation of the RayOne Trifocal IOL (toric and non-toric) were retrospectively reviewed. Visual and refractive outcomes were evaluated at 3 months. Patient satisfaction, spectacle independence, and visual disturbance profile were assessed by questionnaires.

RESULTS: A total of 5,226 patients were assigned to one of two groups: 1,010 patients had toric IOL implantation (toric group) and 4,216 patients received the non-toric model (non-toric group). Mean ± standard deviation visual acuity at 3 months for the toric group was binocular uncorrected distance visual acuity (UDVA) of 0.07 ± 0.11 logMAR, monocular corrected distance visual acuity (CDVA) of 0.05 ± 0.07 logMAR, binocular uncorrected near visual acuity (UNVA) at 40 cm of 0.10 ± 0.09 logMAR, binocular uncorrected intermediate visual acuity (UIVA) at 40 cm of 0.13 ± 0.12 logMAR, postoperative spherical equivalent (SE) of -0.21 ± 0.47 diopters (D), and cylinder of -0.34 ± 0.40 D. The non-toric group had binocular UDVA of 0.04 ± 0.08 logMAR, monocular CDVA of 0.05 ± 0.07 logMAR, binocular UNVA of 0.10 ± 0.08 logMAR, binocular UIVA of 0.13 ± 0.11 logMAR, SE of -0.08 ± 0.38 D, and cylinder of -0.28 ± 0.34 D. No statistically significant differences were found in achieving spectacle independence and there were high levels of satisfaction in both groups.

CONCLUSIONS: In this retrospective analysis with more than 5,000 patients, both the toric and non-toric RayOne Trifocal IOL models provided good visual performance at all distances, resulting in excellent levels of spectacle independence and patient satisfaction.

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Since the introduction of the first model of trifocal intraocular lenses (IOLs) in the market more than 10 years ago, a variety of novel diffractive trifocal IOLs have been launched in an attempt to improve vision outcomes and to minimize undesirable visual symptoms in patients desiring spectacle independence following cataract or presbyopia surgery (refractive lens exchange [RLE]).[1-4]

Although various reports have studied the performance of the RayOne Trifocal IOL (Rayner), with favorable clinical outcomes in terms of visual acuity, spectacle independence, and patient satisfaction,[5-8] this is, to the best of our knowledge, the largest series describing the clinical outcomes with this trifocal IOL in RLE.

From the Department of Cataract & Refractive Surgery, Clínica Baviera-AIER Eye Hospital Group, Valencia, Spain (AL-R, FL-O); the Department of Cornea and Cataract Surgery, University and Polytechnic La Fe Hospital, Valencia, Spain (AL-R); the Department of Cataract and Refractive Surgery, Clínica Baviera-AIER Eye Hospital Group, Bilbao, Spain (JO-U); Optics, Optometry, and Visual Sciences Department, Faculty of Physics, University of Valencia, Spain (CA-D); the Department of Research and Development, Clínica Baviera-AIER Eye Hospital Group, Valencia, Spain (JB-S); the Department of Cataract and Refractive Surgery, Clínica Baviera-AIER Eye Hospital Group, Madrid, Spain (RB-C, FL-O); and Ophthalmology Area, College of Medicine, Cardenal Herrera-CEU University, Valencia, Spain (FL-O).

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Address correspondence to Andrea Llovet-Rausell, MD, FEBO, Clínica Baviera, Gran Vía del Marqués del Turia, 9, 46005 Valencia, Spain. Email: allovet@clinicabaviera.com.

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The purpose of the current analysis was to provide visual and functional outcomes with both the toric and non-toric version of this trifocal IOL to set realistic expectations of the IOL in clinical practice.

PATIENTS AND METHODS

Design

In this multi-center, multi-surgeon, retrospective cross-sectional study, data were analyzed from consecutive patients who underwent RLE with bilateral implantation of the RayOne Trifocal toric RAO613Z IOL or non-toric RAO603F IOL between January 2020 and April 2023. The study was performed in accordance with the principles of the Declaration of Helsinki and General Data Protection Regulation of the European Union. Institutional review board approval was obtained from the Clínica Baviera Medico-Legal Committee and Ethical Committee of the CEU–Cardenal Herrera University (CEI21/57).

Patients

Patients underwent surgery at 30 surgical centers of Clínica Baviera-CareVision-AIER Eye Hospital Group in Spain and Germany, by 40 experienced surgeons, using the same surgical protocol, instruments, and devices. Preoperatively, patients received detailed information regarding the surgical procedure and vision concerns after trifocal IOL implantation and provided written consent for their intervention and for anonymous data review for investigation purposes. Data were recorded from the central computerized medical file system.

Inclusion criteria were: presbyopic patients aged 40 to 65 years with corrected distance visual acuity (CDVA) of 0.8 decimal or better who underwent elective RLE and with at least 3 months of follow-up. Exclusion criteria were: poor visual prognosis due to amblyopia or any underlying ocular pathology, previous corneal or intraocular surgery, pregnancy, and intraoperative or postoperative complications not related to the IOL design.

IOLs

Both the RAO613Z and RAO603F IOLs are a single-piece hydrophilic acrylic IOL with a distinctive diffractive design. The aspheric optic has 16 diffractive steps in a central 4.5-mm zone across a 6-mm optic affording neutral spherical aberration and an Apple-Amon 360° enhanced square edge. Both models provide a +3.50 diopters (D) near add and a +1.75 D intermediate add, with a light energy split of 52% for distance, 22% for intermediate, and 26% for near, based on a 3-mm pupil.

All patients underwent RLE surgery in both eyes on separate days (delayed sequential bilateral RLE surgery) with a delay that varied from 1 to 7 days. Refraction of the first eye to undergo surgery was performed prior to the surgery of the second eye so that the IOL power could be adjusted if needed.

Clinical Evaluation

A full preoperative assessment included anterior segment slit-lamp examination, tear break-up time and fundus examination, corneal topography (Pentacam; Oculus Optikgeräte GmbH), pupillometry, optical coherence tomography of the macula (Revo; OftalTech), endothelial cell count analysis (SP 3000P; Topcon), refractive status, CDVA, and uncorrected distance, intermediate, and near visual acuities (UDVA, UIVA, and UNVA). Visual acuities were tested under photopic conditions (at approximately 85 cd/m^2) with Snellen test for distance at 4 m (CC-100; Topcon Healthcare) and Precision Vision chart for near vision at 40 cm/intermediate vision at 66 cm. IOL power calculation was based on IOLMaster measurements (Carl Zeiss Meditec AG). The refractive objective was emmetropia in all cases.

The technique included a 2.75-mm incision in the temporal or steepest meridian, a 5-mm capsulorhexis, hydrodissection, phacoemulsification, irrigation/aspiration of cortical remnants, IOL implantation in the capsular bag, and intracameral injection of cefuroxime. Side ports and the main incision were hydrated if necessary. Postoperative topical therapy included a combination of antibiotics, steroidal agents, and topical nonsteroidal anti-inflammatory drug drops (moxifloxacin hydrochloride 0.5% four times a day for a week, dexamethasone 0.1% on tapering doses for 4 weeks, and nepafenac 3 mg once a day for 8 weeks). The second eye had surgery within 1 week of the initial procedure.

Postoperative Assessment

Patients had a scheduled follow-up assessment within 24 hours after surgery, and at 1 week, 1 month, and 3 months postoperatively. Patients were discharged at 3 months and asked to return for routine follow-up visits every year thereafter.

Contrast Sensitivity and Defocus Curve Outcomes

Monocular defocus curves were measured under photopic conditions from -4.00 to +1.00 D defocus levels in 0.50-D steps with residual refractive error compensated, if they existed.

Monocular contrast sensitivity function (CSF) was measured under photopic conditions by means of sinusoidal contrast variation stimuli, with the Topcon CC-100 system. The automated M2 program was used, measuring the contrast threshold for 1.5, 3, 6, 12, and 18 cycles per degree (cpd). CSF function was mea-

TABLE 1
Visual and Refractive Preoperative Data[a]

Parameter	Toric Group (n = 2,020 Eyes)	Non-toric Group (n = 8,432 Eyes)	*P*
Sphere (D)			.014
Mean (SD)	1.87 (3.48)	1.74 (1.76)	
Median (Q1, Q3)	2.25 (0.19, 4.25)	1.75 (1.25, 2.50)	
Cylinder (D)			< .001
Mean (SD)	-2.37 (0.94)	-0.39 (0.32)	
Median (Q1, Q3)	-2.25 (-3.00, -1.75)	-0.50 (-0.50, 0.00)	
SE (D)			< .001
Mean (SD)	0.68 (3.46)	1.54 (1.76)	
Median (Q1, Q3)	1.12 (-1.00, 3.12)	1.62 (1.00, 2.38)	
UDVA (logMAR)			< .001
Mean (SD)	0.75 (0.48)	0.51 (0.39)	
Median (Q1, Q3)	0.70 (0.40, 1.00)	0.40 (0.22, 0.70)	
CDVA (logMAR)			< .001
Mean (SD)	0.07 (0.11)	0.03 (0.08)	
Median (Q1, Q3)	0.04 (0.01, 0.10)	0.01 (0.00, 0.05)	

CDVA = corrected distance visual acuity; D = diopters; Q = quartile; SD = standard deviation; SE = spherical equivalent; UDVA = uncorrected distance visual acuity
[a]Uncorrected intermediate visual acuity was not available from chart review because it is not routinely collected at the preoperative visit.
The toric and non-toric RayOne Trifocal toric intraocular lenses are manufactured by Rayner.

sured first for distance vision, and then eyes were defocused with a -1.25 and -2.50 D lens to measure CSF at 75 cm (intermediate vision) and 40 cm (near vision), respectively, with the same test.

Patient Satisfaction

Patient satisfaction and visual difficulties were evaluated at discharge from the clinic using the Catquest-9SF questionnaire. It is a vision-specific patient-reported outcome tool that was designed to be used by cataract surgeons for continuous quality control regarding appropriateness and outcome of surgery.[9,10] It has been translated to many languages and validated through Rasch analysis and is recommended by the International Consortium of Health Outcomes Measurement and the European Registry of Quality Outcomes for Cataract and Refractive Surgery.[11] It comprises nine items (A, B, C1 to C7) with four response options. Items A and C1 to C7 are concerned with difficulty, and item B with satisfaction. Response options are coded 4 for "very great difficulty/very dissatisfied," 3 for "great difficulty/fairly dissatisfied," 2 for "some difficulty/fairly satisfied," and 1 for "no difficulty/very satisfied." A study carried out by our group[16] showed that it is a valid questionnaire with good psychometric properties.

Problems related to night vision and spectacle dependence were recorded using an in-house questionnaire that was previously used in other published studies with multifocal IOLs and developed based on our clinical experience and patient requests.[12,13] Spectacle dependence was assessed by asking patients about the need to wear glasses in their daily activities at the three distances (reading, computer, driving). Then patients were asked to rate levels of alteration of night vision and driving and the associated quality of vision when performing daily activities on a Likert scale of 1 to 5 (1 = very bad; 5 = very good). Those who responded "bad" or "very bad" were categorized as having postoperative visual impairment. Finally, the questionnaire recorded general satisfaction and whether patients would undergo surgery again.

Statistical Analysis

Distribution of variables was examined visually. Statistically, for continuous variables we calculated trimmed means with 20% trimming and Winzorized standard deviations to reduce the effect of some outliers on general trend as suggested by Wilcox. All calculations were done using R software (R Core Team 2019).[14]

RESULTS

A total of 10,452 IOLs were implanted bilaterally in 5,226 patients. Of these, 1,010 patients received the toric model (toric group) and 4,216 the non-toric model (non-toric group), depending on whether the

TABLE 2
Visual and Refractive Postoperative Data[a]

Parameter	Toric Group (n = 2,020 Eyes)	Non-toric Group (n = 8,432 Eyes)	*P*
Sphere (D)			< .001
Mean ± SD	-0.04 ± 0.45	0.06 ± 0.38	
Median (Q1, Q3)	0.00 (-0.25, 0.00)	0.00 (0.00, 0.25)	
Cylinder (D)			< .001
Mean ± SD	-0.34 ± 0.40	-0.28 ± 0.34	
Median (Q1, Q3)	-0.25 (-0.50, 0.00)	0.00 (-0.50, 0.00)	
SE (D)			< .001
Mean ± SD	-0.21 ± 0.47	-0.08 ± 0.38	
Median (Q1, Q3)	-0.12 (-0.38, 0.00)	0.00 (-0.25, 0.00)	
UNVA bin			.270
Mean ± SD	0.10 ± 0.09	0.10 ± 0.08	
Median (Q1, Q3)	0.10 (0.00, 0.18)	0.10 (0.00, 0.18)	
UIVA bin			.719
Mean ± SD	0.13 ± 0.12	0.13 ± 0.11	
Median (Q1, Q3)	0.18 (0.18, 0.30)	0.18 (0.18, 0.30)	
UDVA bin			< .001
Mean ± SD	0.07 ± 0.11	0.04 ± 0.08	
Median (Q1, Q3)	0.50 (0.01, 0.10)	0.02 (0.00, 0.05)	
CDVA bin			< .001
Mean ± SD	0.05 ± 0.07	0.03 ± 0.06	
Median (Q1, Q3)	0.02 (0.00, 0.07)	0.01 (0.00, 0.03)	
Safety			.065
Mean ± SD	1.11 (1.21)	1.06 ± 0.94	
Median (Q1, Q3)	1.02 (0.98, 1.10)	1.00 (0.98, 1.05)	
Efficacy			.057
Mean ± SD	1.07 ± 1.28	1.02 ± 0.90	
Median (Q1, Q3)	1.00 (0.92, 1.07)	1.00 (0.94, 1.02)	

CDVA = corrected distance visual acuity; D = diopters; Q = quartile; SD = standard deviation; SE = spherical equivalent; UDVA = uncorrected distance visual acuity; UIVA = uncorrected intermediate visual acuity; UNVA = uncorrected near visual acuity
[a]Visual acuity is reported in logMAR units.
The toric and non-toric RayOne Trifocal toric intraocular lenses are manufactured by Rayner.

preoperative corneal astigmatism was greater than 1.00 D.

The group distribution in terms of age and sex was similar in both groups, with a majority of women (58%) and mean age of 54.24 ± 7 years in the toric group and 56.04 ± 7 years in the non-toric group.

Visual and Refractive Performance

Table 1 summarizes preoperative data. Visual outcomes available at 3 months postoperatively are shown in **Table 2**. Patients had significantly better mean uncorrected visual acuities at all distances and CDVA after surgery compared with preoperative values in both groups.

Standard graphs for reporting refractive outcomes are further referenced in **Figures 1-3**. A total of 89.8% of the eyes in the toric group and 90.6% in the non-toric group had no loss or gain of lines or a gain of one or more line of preoperative CDVA compared to postoperative UDVA (**Figure 1A**, **Figure 2A**). Almost all eyes had no change in lines of CDVA (**Figure 1B**, **Figure 2B**).

The percentages of eyes with a SE within ±0.50 and ±1.00 D were 83.4% and 90.8% for the toric group and 93.4% and 96.3% for the non-toric group, respectively (**Figure 1E**, **Figure 2E**). Almost all eyes showed a refractive cylinder below 1.00 D for astigmatism in both groups (**Figure 1F**, **Figure 2F**).

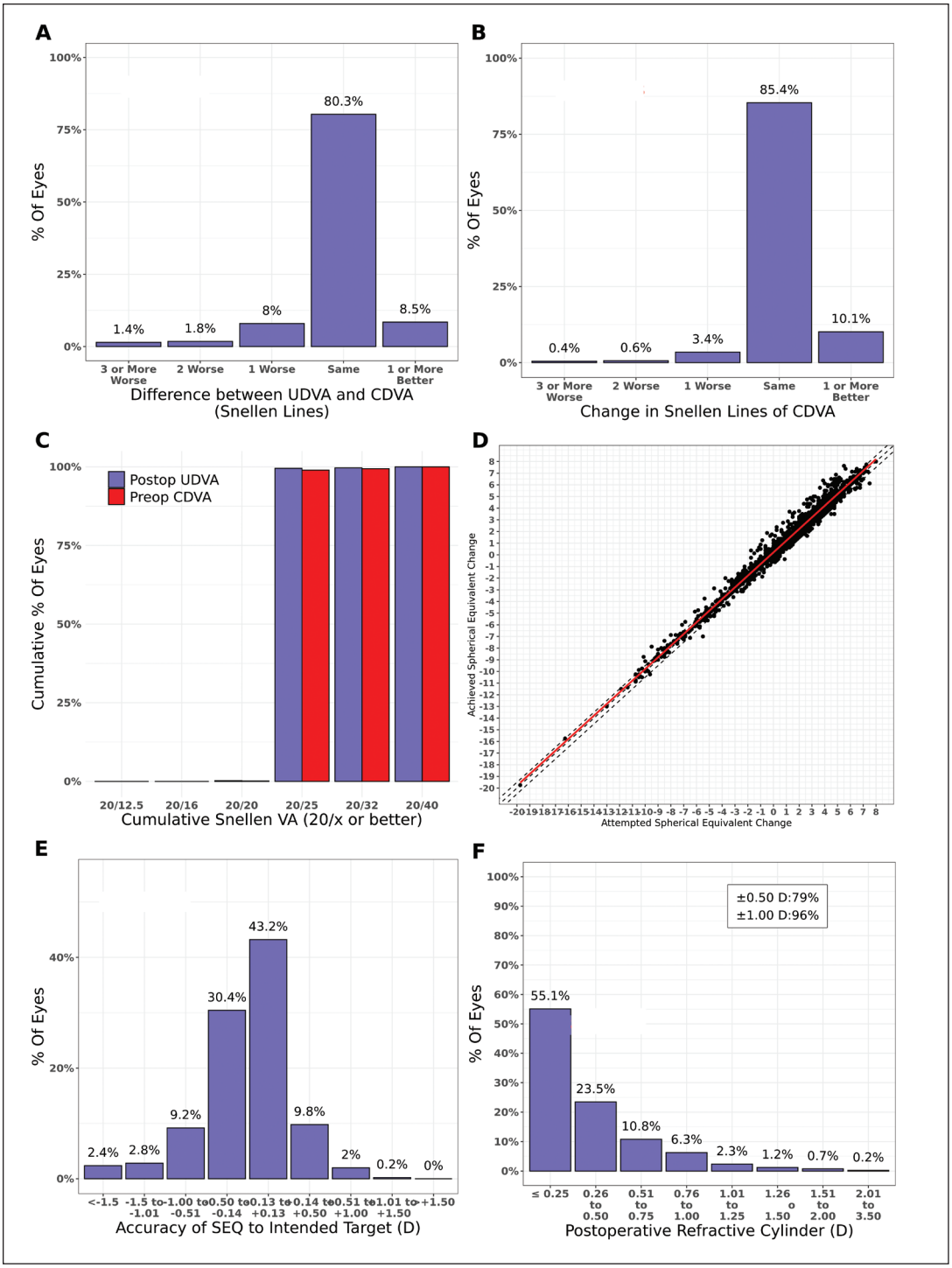

Figure 1. Standard graphs for reporting refractive outcomes in patients implanted with the toric RayOne Trifocal intraocular lens (Rayner). CDVA = corrected distance visual acuity; D = diopters; SEQ = spherical equivalent; UDVA = uncorrected distance visual acuity

Subjective Outcomes

The quality of vision and the patient's satisfaction were evaluated using two questionnaires, which were completed by 80% of the patients. The results are shown in **Table 3**. Overall, both versions of this trifocal IOL offered high levels of spectacle independence and patient-reported satisfaction.

Contrast Sensitivity and Defocus Curve Outcomes

The postoperative CSF at 3 months, measured under photopic conditions, showed values within the ranges of normality. **Figure 4** shows the mean monocular CSF values obtained at the three distances.

The mean monocular defocus curve can be seen in **Figure 5**.

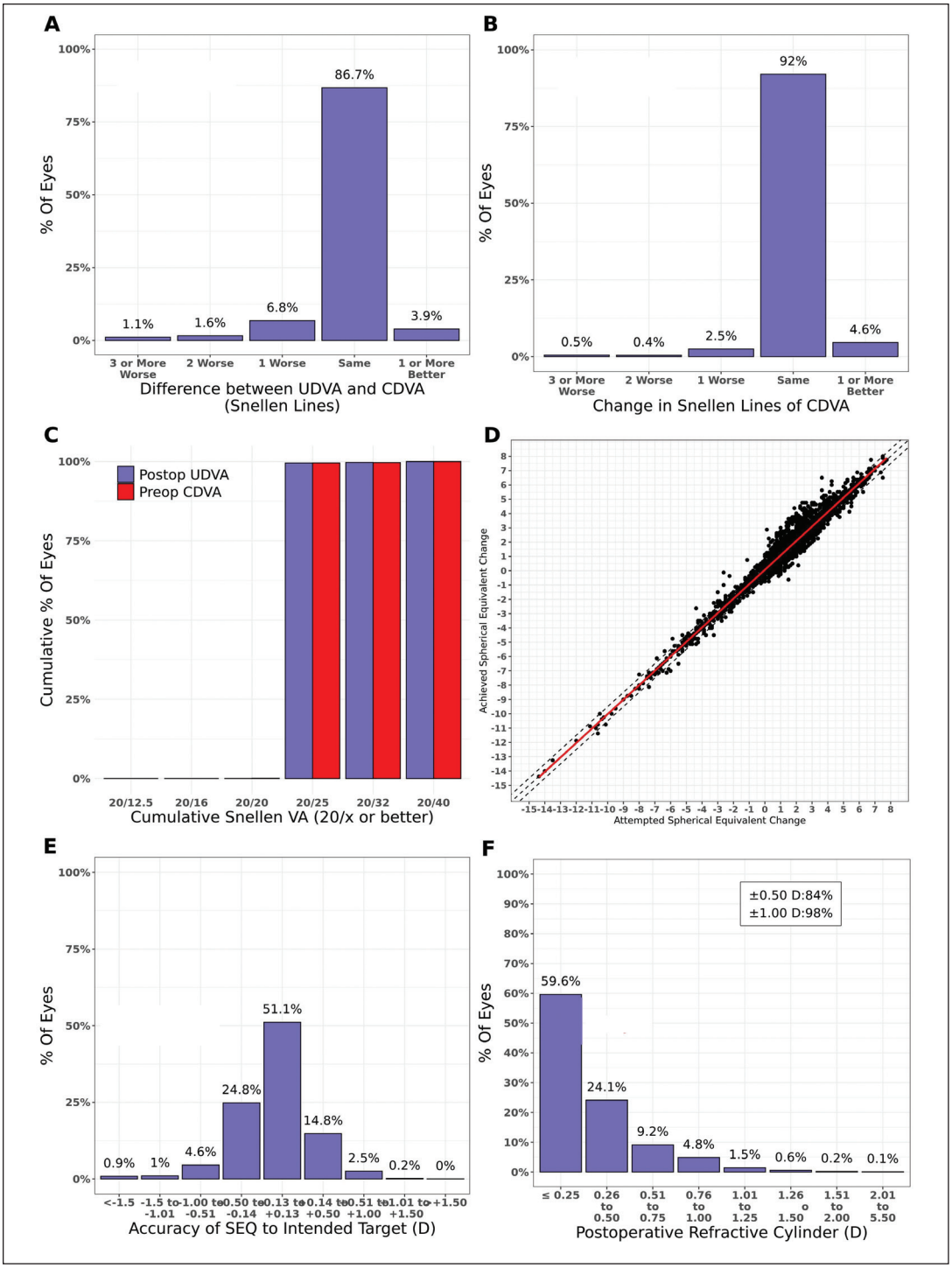

Figure 2. Standard graphs for reporting refractive outcomes in patients implanted with the non-toric RayOne Trifocal intraocular lens (Rayner). CDVA = corrected distance visual acuity; D = diopters; SEQ = spherical equivalent; UDVA = uncorrected distance visual acuity

DISCUSSION

We report on a large sample of patients undergoing bilateral implantation of the RayOne Trifocal Toric RAO613Z and RayOne Trifocal RAO603F IOL following RLE. This is the largest evaluation of patients implanted with this IOL to date, which adds valuable information to the evidence surrounding its trifocal technology.

Our refractive and visual results for this trifocal IOL for distance and near visual acuity are comparable to smaller published series with other diffractive trifocal IOLs[1-4] and with this model.[5-8] Ferreira and Ribeiro[1,5] both reported a tight distribution for refractive accuracy, with 100% and 96.6% of the eyes within ±0.50 D of target SE in small samples of this IOL at 3 months. The

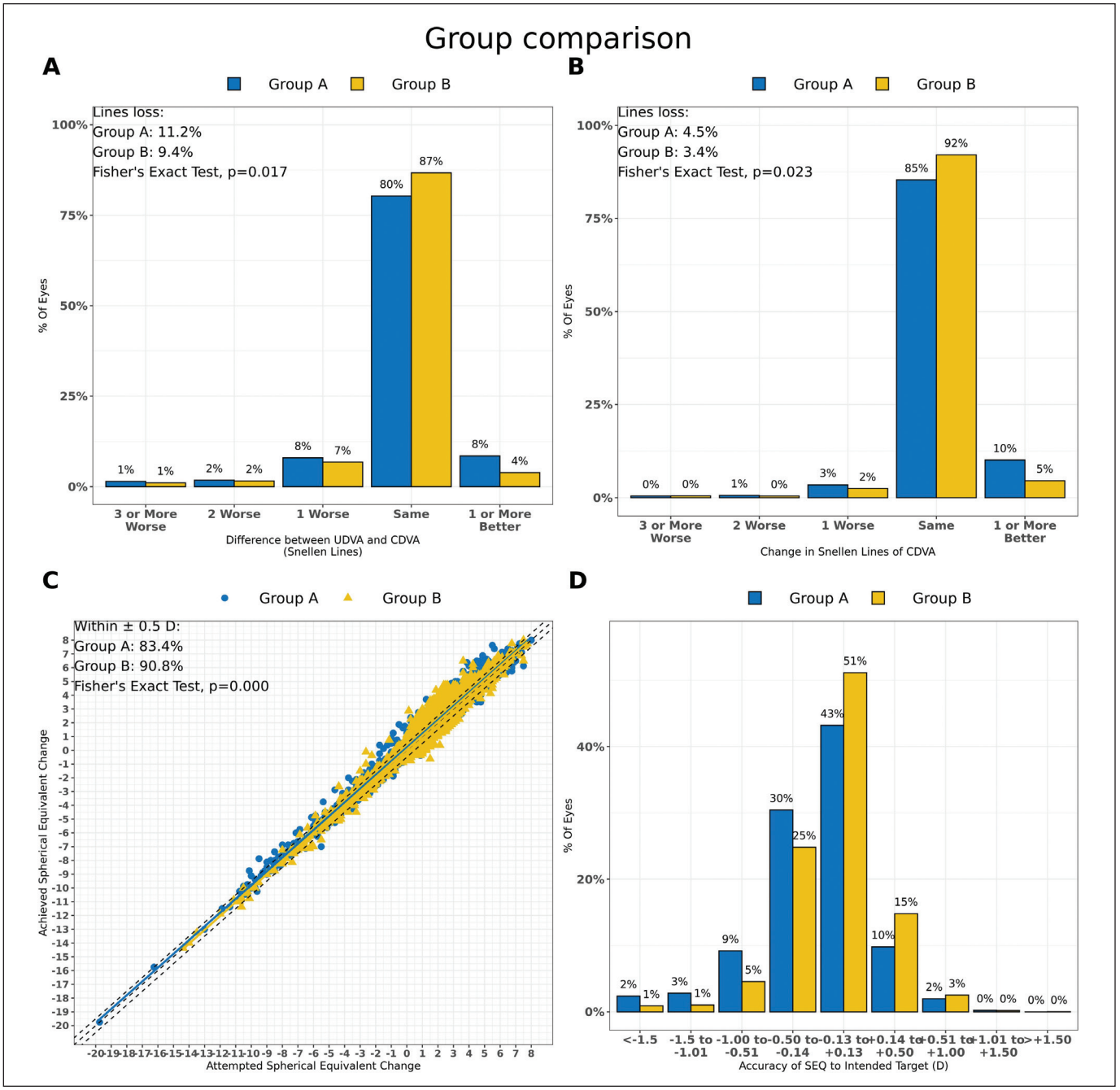

Figure 3. Standard graphs for reporting of visual and refractive outcomes. Comparison between groups. CDVA = corrected distance visual acuity; D = diopters; SEQ = spherical equivalent; UDVA = uncorrected distance visual acuity

current evaluation reports 93.4% of the eyes within ±0.50 D of target SE. The slight reduction in refractive predictability in this study is in line with predictability of other diffractive trifocal IOLs. Factors such as refraction method and surgical technique have previously been postulated as factors affecting predictability for trifocal IOLs.[15-17]

In our sample, visual acuity changed safely after RAO603F implantation (90.6% of the eyes with postoperative UDVA equal to or better than preoperative CDVA at 3 months). This is particularly important for patients undergoing an elective RLE. Other studies using the same model[1,5] reported similar non-significant changes in preoperative CDVA versus postoperative UDVA and similar values for monocular and binocular UDVA and UNVA.

Our refractive and visual results for the toric version in UDVA and UNVA are comparable to those re-

TABLE 3
Outcomes of Patient Satisfaction Questionnaires

Parameter	Toric Group (n = 2,020 Eyes)	Non-toric Group (n = 8,432 Eyes)	*P*
Vision dissatisfaction			
Far[a]	6.0%	6.1%	1.0001
Intermediate[a]	3.7%	3.8%	1.0001
Near[a]	4.4%	6.4%	.1521
Night vision[b]	1.9%	2.8%	.3291
Night driving[b]	8.2%	8.3%	1.0001
Spectacle dependence[b]			
Far	0.2%	0.3%	1.0001
Intermediate	0.7%	0.5%	.4881
Near	0.7%	0.9%	1.0001
Satisfaction			
Not satisfied[a]	1.4%	1.8%	.6911
Would not repeat[b]	1.6%	2.6%	.2431

[a]*Catquest-9SF.*
[b]*In-house questionnaire.*

ported by Taña-Rivero et al[18] after a review of studies on the results of three models of toric trifocal IOLs (AT LISA Tri toric 939MP, FineVision POD FT, and toric AcriSof IQ PanOptix). The authors concluded that the use of the toric version of trifocal IOLs allows for complete visual restoration over a wide range of distances.

CS measurements reveal good performance of this trifocal IOL, being within the normality ranges defined by Hohberger[19] for all spatial frequencies and without a significant drop in CS at any spatial frequency between 1.5 and 18 cpd, at any distance, contrary to what was observed by Menucci[20] when studying another model of trifocal diffractive IOL. The maximum CS for distance vision was found to be located at medium spatial frequencies (6 cpd), and changed to lower spatial frequencies (1.5 to 3 cpd) at near due to the lower amount of light distribution for the near focus. Our distance CSF was similar to that reported by Ribeiro and Ferreira,[5] but we cannot compare our intermediate and near results because this is the first work reporting such outcomes.

The monocular defocus curve shows an excellent behavior of the lens in a wide distance range. As shown in **Figure 5**, a visual acuity above 0.00 logMAR can be expected for distance, with a gentle drop reaching the minimum visual acuity value at 50 cm (-2.00 D defocus) and then a slight improvement from 40 to 33 cm (-2.50 to -3.00 D defocus). After 33 cm (-3.00 D defocus), the visual acuity values dropped until values were less than 0.5 decimal (0.3 logMAR) for 20 cm (-4.00 D defocus).

Traditionally, ophthalmologists have used high-contrast CDVA along with residual refractive error to quantify the success of surgery, but these measures fail to cover the wide range of problems that patients may experience from visual impairment, which can significantly compromise daily visual function.[21,22] In this context, patient satisfaction, visual difficulties, alteration of night vision, and spectacle dependence were evaluated at the time of discharge. The overall high measures of satisfaction reported may be indicative of the technology successfully providing favorable visual acuity obtained at all distances.[10,11] Approximately 25% of patients reported worse vision in mesopic conditions for vision and driving, but this was not bothersome. These data indicate the reality of dysphotopsia and reduced CS inevitably related to all multifocal IOLs. In previous studies of the same trifocal IOL, patients referred to less bothersome glare compared to other diffractive trifocal IOLs.[5] In the current study, the number of patients who experienced visual disturbance was minimal and those affected considered it non-disabling, as occurs in other published studies.[5,21,23]

Patient-reported outcomes are subjective measures and are not entirely free of bias or interpretation, despite their validation and adaptation to the population studied.[9,11] One limitation of vision-specific patient-reported outcome tools is that they are administered postoperatively, and patients may be subjected to recall bias when answering retrospective questions on their health status.[24] In addition, only 80% answered the questionnaires and one of the reasons for not re-

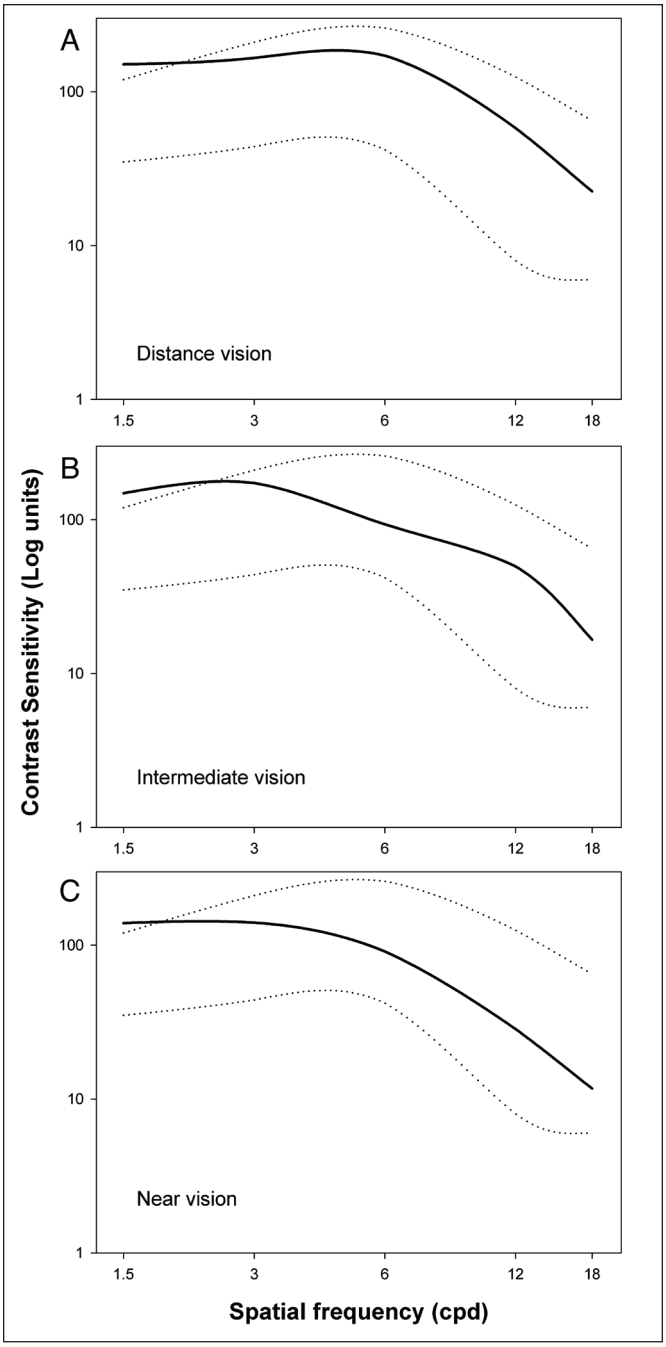

Figure 4. Mean monocular (only right eyes considered) contrast sensitivity functions obtained at (A) distance, (B) intermediate, and (C) near vision for the RayOne Trifocal intraocular lens (Rayner). Dotted lines indicate normative contrast sensitivity (as reported by the manual of the test). cpd = cycles per degree

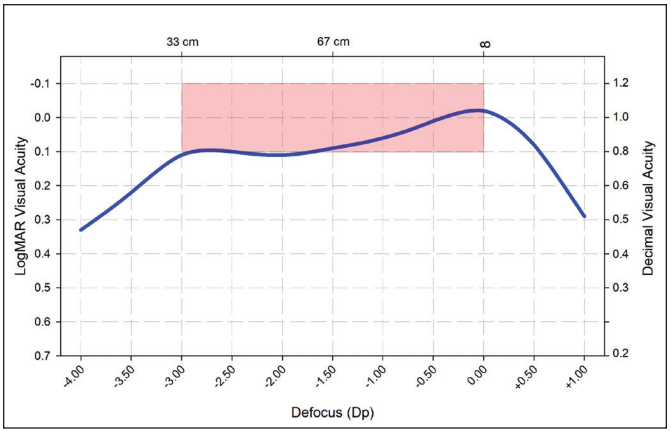

Figure 5. Mean monocular defocus curve (only right eyes considered) of the RayOne Trifocal intraocular lens (Rayner).

sponding might be the fact that they were not satisfied with the result. The questionnaire for assessing quality of vision and photic phenomena is not a validated one, although it has been used in other published studies.[6,12,13] Other works evaluating the RAO603F IOL employed the McAlinden Quality of Vision Questionnaire, which is an alternative commonly used instrument to measure quality of vision and the impact of dysphotopsia.[5,25] The expectations of those who underwent cataract surgery and those undergoing elective RLE are different, which is why employing the same tools to assess satisfaction is challenging. Direct comparison of visual satisfaction outcomes reported in other studies with those found in this evaluation should therefore be approached with caution.

There are few studies that compare visual and refractive outcomes and patient satisfaction of a diffractive trifocal IOL with and without toricity (**Table 4**). Frieling-Reuss[26] found similar results in terms of visual performance without significant differences in patient satisfaction with the AT Lisa 809M and its toric version AT Lisa 909M. Similar results were found by Hamdi[27] and Rementería-Capello[28] when comparing the non-toric and toric AcrySof IQ PanOptix IOLs and by Poyales and Garzon[29] with toric and non-toric versions of the FineVision Trifocal IOL.

This study adds to the current evidence that the RayOne Trifocal toric IOL provides a high degree of refractive predictability, similar to other published data for diffractive trifocal toric IOLs.

Although we do not routinely perform RLE in patients with myopia who are 40 to 65 years old unless there is a manifest cataract, 10% of the eyes had a myopic SE greater than -1.00 D in our sample. Myopic patients may be at higher risk of retinal detachment after RLE.[30]

Evidence surrounding clinical outcomes for the RayOne Trifocal IOL is still emerging in comparison to the larger body of literature that already exists for other diffractive IOLs on the market.[18,19,31,32] Considerations for further research for both models of this trifocal IOL may include evaluation of additional clinical outcomes and more large-scale, comparative, real-

TABLE 4

Studies Comparing Visual and Refractive Outcomes, Spectacle Independence, and Satisfaction of a Diffractive Trifocal IOL With and Without Toricity

	RayOne		PanOptix (Hamdi)[27]		AT Lisa (Frieling-Reuss)[26]		PanOptix (Rementería-Capelo et al)[28]		FineVision (Poyales & Garzon)[29]	
Parameter	**Toric (n = 2,020 Eyes)**	**Non-toric (n = 8,432 Eyes)**	**Toric (n = 12 Eyes)**	**Non-toric (n = 48 Eyes)**	**Toric (n = 26 Eyes)**	**Non Toric (n = 77 Eyes)**	**Toric (n = 84 Eyes)**	**Non-toric (n = 166 Eyes)**	**Toric (n = 84 Eyes)**	**Non-toric (n = 166 Eyes)**
Mean age (years)	54.42	56.04	58.5	54.2	61.9	66.9	65.07	65.73	62.0	63.0
Preoperative										
Sphere (D)	1.87	1.74	–	–	–	–	1.09	-0.93	–	–
Cylinder (D)	-2.37	-0.39	–	–	-1.62	-0.71	-1.60	-0.57	–	–
SE (D)	0.68	1.54	–	–	-0.64	+0.41	0.29	0.65	–	–
UDVA	0.75	0.51	–	–	–	–	0.65	0.67	–	–
CDVA	0.07	0.03	–	–	0.19	0.20	0.18	0.13	–	–
Postoperative										
Sphere (D)	-0.04	0.06	-0.04	0.26	–	–	–	–	0.00	0.01
Cylinder (D)	-0.34	-0.28	-0.33	-0.36	-0.32	-0.27	–	–	-0.19	-0.14
SE (D)	-0.21	-0.08	-0.29	-0.09	-0.13	+0.09	–	–	-0.09	-0.08
UNVA	0.10	0.10	0.08	0.04	0.04	0.04	0.07	0.05	–	–
UIVA	0.13	0.13	0.08	0.04	0.15	0.22	0.23	0.2	–	–
UDVA	0.07	0.04	0.11	0.08	0.01	0.02	0.07	0.06	0.01	0.04
CDVA	0.05	0.03	0.08	0.04	-0.03	-0.03	0.06	0.04	0.02	0.00
Safety	1.11	1.06	–	–	–	–	–	–	–	–
Efficacy	1.07	1.02	–	–	–	–	–	–	–	–
Spectacle independence (%)										
Reading (near)	99.3	99.1	96.7	93.9	98.08	99.66	–	–	–	–
Computer (intermediate)	99.3	99.5	100	97.2	97.46	98.77	–	–	–	–
Driving (far)	99.8	99.7	–	–	99.69	99.76	–	–	–	–
Visual satisfaction (%)										
Night driving	91.8	91.7	96.7	89.0	97.15	97.26	–	–	–	–
Night vision	98.1	97.2	90	87.6	99.69	99.65	–	–	–	–
Far	94	93.9	93.3	92.4	–	–	–	–	–	–
Intermediate	96.3	96.2	–	–	–	–	–	–	–	–
Near	95.6	93.6	–	–	–	–	–	–	–	–
Global satisfaction (%)										
Satisfied	98.6	98.2	–	–	–	–	–	–	89.3	96.8
Would repeat	98.4	97.4	–	–	–	–	–	–	–	–

CDVA = corrected distance visual acuity; D = diopters; IOL = intraocular lens; SE = spherical equivalent; UDVA = uncorrected distance visual acuity; UIVA = uncorrected intermediate visual acuity; UNVA = uncorrected near visual acuity

[a]*Visual acuities are expressed in logMAR units. All parameters expressed as mean.*

world data. This may be done in different ways, such as employing registries or real-time patient-reported outcomes software such as RayPRO (Rayner) using artificial intelligence and advanced statistical modeling.

The overall findings from this study indicate that the toric and non-toric version of this trifocal IOL are safe and effective options for presbyopic patients who may desire RLE with precise refractive performance across three foci and complete spectacle independence.

AUTHOR CONTRIBUTIONS

Study concept and design (AL-R, JO-U, RB-C, FL-O); data collection (AL-R, JO-U, CA-D, JB-S, RB-C, FL-O); analysis and interpretation of data (AL-R, JO-U, CA-D, JB-S, RB-C, FL-O); writing the manuscript (AL-R, JO-U, CA-D, JB-S, RB-C, FL-O)

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