Clinical Outcomes of a Toric Enhanced Depth-of-Focus Intraocular Lens Based on the Combination of 4th- and 6th-Order Spherical Aberration

Ramón Ruiz-Mesa, MD; Gracia Castro de Luna, MD; María Ruiz-Santos, MD, PhD; Ana Jiménez-Nieto, OD; Pedro Tañá-Rivero, MD, PhD

ABSTRACT

PURPOSE: To assess the visual and refractive outcomes of patients implanted with a toric extended depth-of-focus (EDOF) intraocular lens (IOL) following cataract surgery.

METHODS: A total of 44 eyes implanted with the EDOF LuxSmart toric IOL were evaluated 4 to 6 months postoperatively. The main outcomes measurements evaluated were refractive error, rotational stability, distance, intermediate, and near visual acuities, defocus curve, photopic and mesopic contrast sensitivity, wavefront aberrations, and modulation transfer function, and the Catquest-9SF-questionnaire.

RESULTS: The mean postoperative spherical equivalent and cylinder were -0.02 ± 0.26 and -0.17 ± 0.29 diopters (D), respectively. A total of 90.45% and 100% of the eyes had a postoperative spherical equivalent within ±0.50 and ±1.00 D, respectively (this being 93.18% and 100% for the refractive cylinder). The mean rotational stability was 0.61 ± 1.61 degrees. The mean binocular corrected distance visual acuity (CDVA), corrected distance intermediate visual acuity (CDIVA), and corrected distance near visual acuity (CDNVA) were -0.02 ± 0.06, 0.07 ± 0.08, and 0.26 ± 0.09 logMAR, respectively. The CDVA was 20/25 or better in 95.45% of patients, CDIVA was 20/25 or better in 72.73%, and CDNVA was 20/40 or better in 72.73%. The defocus curve showed good visual acuity at distance and intermediate vergences. The contrast sensitivity and optical quality outcomes were good with mean higher order, spherical, and coma aberration values of 0.161 ± 0.155, -0.019 ± 0.048, and 0.080 ± 0.065 µm, respectively. A total of 90.9% of patients were either fairly satisfied or very satisfied with their vision after the surgery, and 77.7% of patients reported no difficulties when reading text in newspapers.

CONCLUSIONS: Implantation of the toric pure refractive EDOF technology IOL provides good refractive, optical, and visual quality at different distances, with high levels of patient satisfaction being reported.

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Presbyopia-correcting intraocular lenses (IOLs) used in cataract or refractive lens exchange surgeries have been developed to provide patients with unaided vision at different distances. The use of different optical technologies, based on a variety of diffractive or refractive designs, are intended to overcome the need for spectacle use for near and intermediate vision in patients implanted with monofocal IOLs. Some years ago, the so-called enhanced depth-of-focus (EDOF) or extended range-of-vision IOLs were introduced into the market. These IOLs are aimed at reducing photic phenomena, halos, and glare that may be reported in

From Oftalvist Jerez de la Frontera, Jerez de la Frontera, Spain (RR-M, AJ-N); Oftalvist Almería, Almería, Spain (GCL); Universidad de Almería, Almería, Spain (GCL); and Oftalvist Alicante, Alicante, Spain (PT-R).

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Correspondence: Ramón Ruiz-Mesa, MD, Oftalvist Jerez de la Frontera, Avenida Puerta del Sur S/N, 11408. Jerez de la Frontera, Cádiz, Spain. Email: ramonruizmesa@gmail.com

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patients implanted with bifocal or trifocal IOLs. Several systematic reviews and meta-analyses have analyzed clinical trials of EDOF and trifocal IOLs. Liu et al[1] concluded that at the expense of near vision, patients receiving EDOF IOLs have better contrast sensitivity than those implanted with trifocal IOLs, whereas the halo incidence and spectacle independence of EDOF IOLs are similar to those of trifocal IOLs. Zhong et al[2] concluded that trifocal IOLs demonstrate better performance at near distances but apparently lead to more photic disturbances. More recently, Guo et al[3] concluded that EDOF IOLs and trifocal IOLs provide comparable distance vision, but EDOF IOLs provide better intermediate vision and worse near vision than trifocal IOLs. They indicated that the advantages of EDOF IOLs over trifocal IOLs in terms of contrast sensitivity, aberrations, and visual disturbance were not significant. They also concluded that patients were satisfied with both types of IOL. It is important to note that there is a wide range of EDOFs available on the market that can be used by cataract and refractive surgeons. Indeed, the source of the different outcomes reported may arise from the diverse designs of the lenses and, therefore, each model should be analyzed independently so that surgeons are aware of the possible outcomes expected for each lens.

One EDOF IOL currently available on the market is the LuxSmart IOL (Bausch & Lomb), based on refractive technology, whose central zone combines 4th and 6th orders of spherical aberration of opposite signs to increase the subjective depth of focus (pure refractive EDOF technology IOL). Several studies have analyzed this lens in vitro using an optical bench,[4-9] but only three clinical studies have so far assessed the lens in patients.[10-12] Campos et al[10] reported that the non-toric pure refractive EDOF technology IOL implanted bilaterally in 12 patients achieves better intermediate and near vision performance compared with a conventional monofocal IOL, without increasing the risk of dysphotopsias. Similarly, in 28 patients implanted bilaterally with the lens, Tahmaz et al[11] found that this IOL provides comparable high uncorrected distance visual acuity (UDVA) and significantly higher corrected distance intermediate visual acuity (CDIVA) than a monofocal lens, causing only mild optical phenomena. Recently, Nowrouzi et al[12] concluded that the unilateral implantation of this lens (25 eyes) seems to be tolerated and effective in improving the visual function and providing spectacle-independent vision from far to intermediate object distances. However, as far as we know, no peer-reviewed publications have evaluated the outcomes of patients implanted with the toric model, which, in addition to increasing the depth of focus, also aims to correct astigmatism. The purpose of this clinical study was to assess the refractive and visual outcomes in a series of astigmatic eyes implanted bilaterally with the toric pure refractive EDOF technology IOL after cataract surgery.

PATIENTS AND METHODS

Patients

In this prospective study, we examined 44 eyes of 22 patients at Oftalvist Jerez in Jerez de la Frontera, Spain. The study was performed in accordance with the tenets of the Declaration of Helsinki and approved by the Ethics Committee of Hospital Clínico San Carlos (Madrid, Spain). All patients included in this study gave informed consent following an explanation of the nature and possible consequences of the study. The inclusion criteria were patients with bilateral cataracts, age 50 years or older, and bilateral regular corneal astigmatism of 0.75 D or greater. The exclusion criteria included irregular corneal astigmatism, corneal pathology altering the corneal topography (ie, dystrophy), previous corneal or intraocular surgery, traumatic cataract, strabismus, amblyopia, pupil abnormalities, acute, chronic or uncontrolled ocular or systemic disease that increases surgical risk, iritis/uveitis, and retinal vessels disease among other things.

Toric Pure Refractive EDOF Technology IOL

The LuxSmart Toric IOL has an optical diameter of 6 mm (overall diameter: 11 mm) with a haptic angle of 0 degrees, and is made of hydrophobic acrylic copolymer with an ultraviolet light absorber and an aspheric toric optical surface. It is a single piece with four fixation points and 360-degree posterior square edges. The lens has a continuous area all over the full optic with a central zone and a monofocal periphery referred to pure refractive optic technology: a combination of 4th and 6th order spherical aberration of opposite sign is applied by modulating the asphere central zone that merges into an aberration-free monofocal periphery thanks to a patented transition zone. The spherical power of the IOL ranges from +6.00 to +34.00 D and the cylindrical power from +0.75 to +6.00 D (posterior toricity). The IOL is implanted using the preloaded Accuject Pro (Medicel AG) system with push injection.

Surgical Technique

A 2.2-mm limbal incision was made followed by the creation of a well-centered manual 5.5-mm curvilinear capsulorhexis and standard phacoemulsification using the Centurion Vision System (Alcon Laboratories,

TABLE 1
Demographic Characteristics of Patients

Characteristic	Mean ± SD (Range)
Eyes (n)	44
Patients (n)	22
Sex (M/F)	13/9
Age (y)	71.73 ± 6.62 (54 to 82)
Spherical equivalent (D)	0.21 ± 3.08 (-10.75 to 6.50)
Monocular CDVA (logMAR)	0.25 ± 0.16 (-0.04 to 0.70)
K1 (D)	42.57 ± 1.28 (40.10 to 44.82)
K2 (D)	44.03 ± 1.15 (41.31 to 46.08)
White-to-white (mm)	11.98 ± 0.34 (11.20 to 12.60)
Axial length (mm)	23.45 ± 1.01 (22.00 to 26.51)
Anterior chamber depth (mm)	3.17 ± 0.61 (1.91 to 5.22)
Endothelial cell count (cells/mm^2)	2,532.88 ± 345.43 (1,642 to 3,280)
Spherical IOL power (D)	21.35 ± 3.15 (12.50 to 29.50)
Cylindrical IOL power (D)	2.09 ± 0.82 (1.00 to 3.75)

CDVA = corrected distance visual acuity; D = diopters; K1 = steep keratometry; K2 = flat keratometry; IOL = intraocular lens; SD = standard deviation

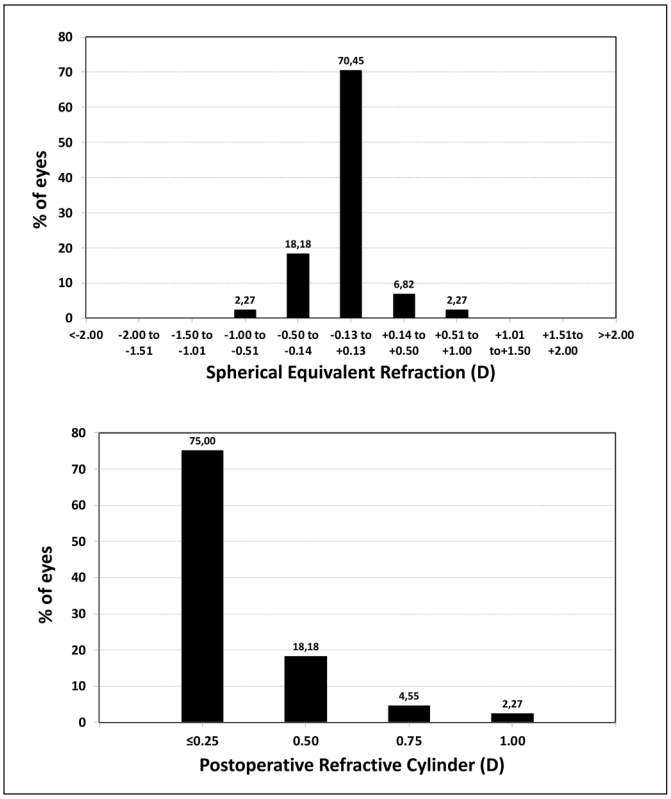

Figure 1. Distribution of postoperative spherical equivalent refraction (diopters [D]) and refractive cylinder (D).

Inc). Postoperatively, all patients were prescribed eye drops of 5 mg/mL of moxifloxacin (Vigamox; Alcon Laboratories, Inc), 10 mg/mL of prednisolone (Pred-Forte; Allergan, Inc), and 1 mg/mL of nepafenac (Nevanac; Laboratories, Inc) in a tapering dose for the first 4 weeks postoperatively.

Preoperative and Postoperative Assessment

Before the surgery, all patients underwent a complete ophthalmologic examination, including a slit-lamp assessment and measurements of UDVA, CDVA, manifest refraction (sphere, astigmatism, and spherical equivalent), intraocular pressure, funduscopy, corneal topography (Pentacam; Oculus Optikgeräte GmbH), and biometry with the IOLMaster 700 instrument (Carl Zeiss Meditec). The Barrett II formula was used to calculate the IOL power.

Postoperative examinations were performed at 1 day, 1 week, 1 to 2 months, and 4 to 6 months after implantation. The outcomes were analyzed at the final postoperative visit. A standard ophthalmologic examination was carried out involving refraction and intraocular pressure measurements and slit-lamp biomicroscopy. Monocular and binocular logMAR UDVA, CDVA, uncorrected distance intermediate visual acuity (UIVA), CDIVA at 66 cm, uncorrected distance near visual acuity (UNVA), and corrected distance near visual acuity (CDNVA) at 40 cm were measured. The binocular photopic and mesopic contrast sensitivity measured using sine wave gratings (Rodenstock) and binocular photopic defocus curve (from +2.00 to -5.00 D in 0.50-D steps) were measured in each patient. Total higher order aberrations (HOAs), spherical aberration, coma, and modulation transfer function (MTF) were measured for each eye using a ray-tracing aberrometer (iTrace; Tracey Technologies) for a 2- to 3-mm pupil. To determine the rotational stability of the IOLs after their implantation, the axis was measured in mydriasis using a slit lamp. Patients were asked to complete the Catquest-9SF patient outcomes questionnaire, which determines patient limitations in daily life when carrying out certain activities due to reduced vision; this tool is recommended and has been shown to produce reliable results.[13-15]

RESULTS

The current clinical study considered the outcomes of 44 eyes from 22 consecutive patients (13 men and 9 women) who had been implanted bilaterally with the toric pure refractive EDOF technology IOL. The demographics and preoperative data for the patients in our sample are given in **Table 1**. The mean patient age was 71.73 ± 6.62 years (range: 54 to 82 years). No posterior capsule opacification was observed during the post-

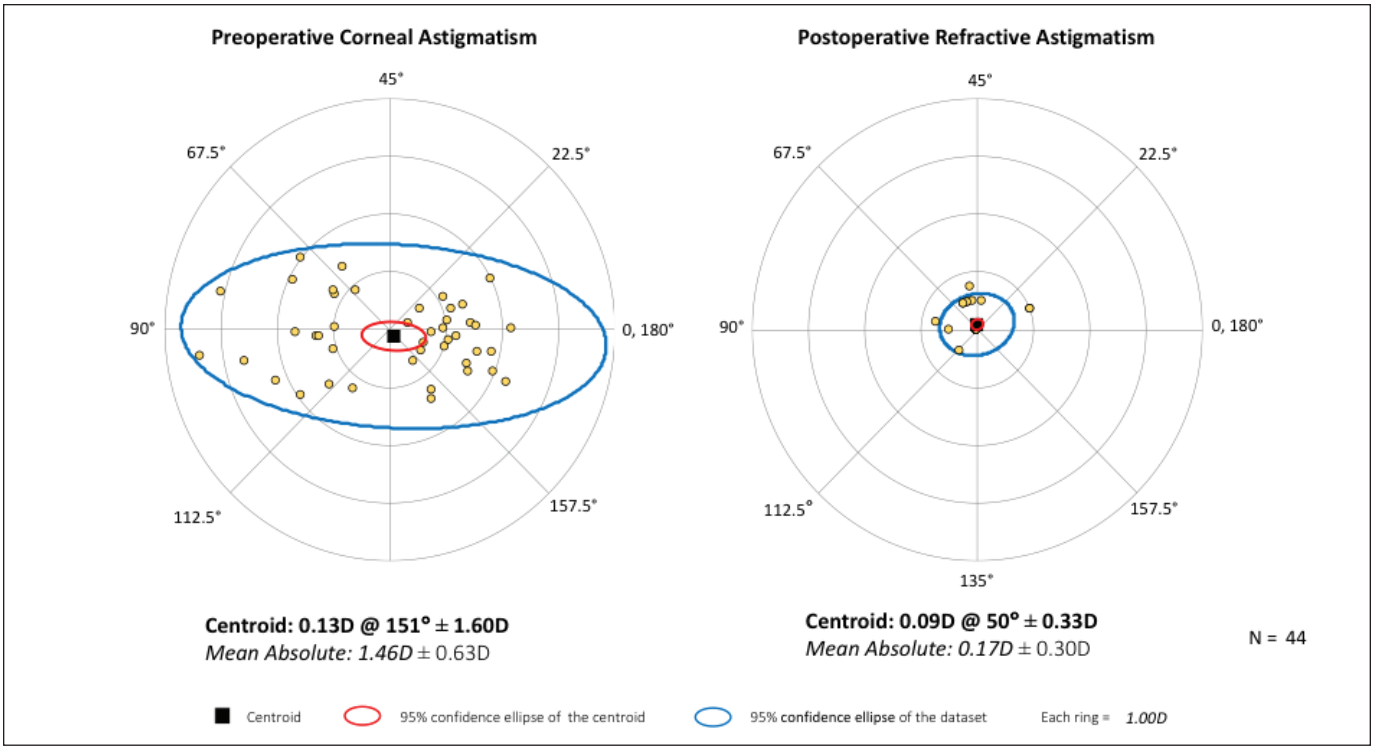

Figure 2. Double-angle plots for preoperative and postoperative corneal and refractive astigmatism. Centroids and mean absolute values with standard deviations are also shown. D = diopters

operative follow-up period. Various graphical representations were created to illustrate the refractive and visual acuity outcomes obtained at the final follow-up visit (4 to 6 months).

Refractive Accuracy

Figure 1 shows the spherical equivalent refractive accuracy (top) and refractive cylinder (bottom) at the final postoperative visit. Specifically, the mean postoperative spherical equivalent was -0.02 ± 0.26 D (range: +1.00 to -0.75 D), with 70.45% at emmetropia (within ±0.13 D), and 90.45% and 100% of eyes were within ±0.50 and ±1.00 D, respectively. The preoperative mean absolute corneal astigmatism was 1.46 ± 0.63 D and the postoperative mean absolute refractive astigmatism was 0.17 ± 0.30 D. Seventy-five percent of eyes showed a mean postoperative cylinder of within ±0.25 D, 93.18% and 100% within ±0.50 and ±1.00 D, respectively) with a mean value of -0.17 ± 0.29 D (ranging from 0.00 to -1.00 D). **Figure 2** shows the double-angle plots comparing preoperative corneal astigmatism with postoperative refractive astigmatism. At the final visit, the lenses had a mean rotational stability of 0.61 ± 1.61 degrees (range: 0 to 5 degrees). Note that no significant rotation was reported in any of the eyes during follow-up, because all lenses had a rotation of 5° or less.

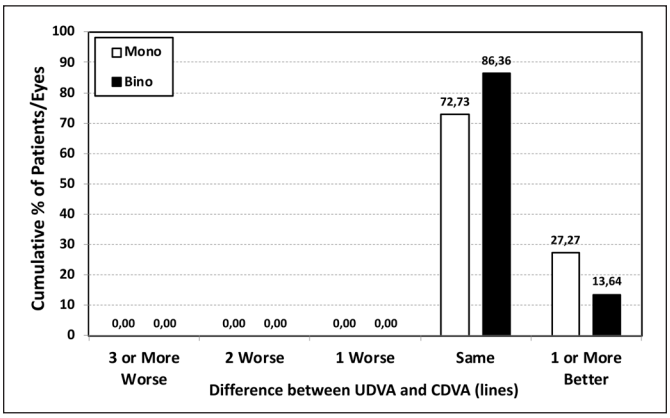

Figure 3. Change in visual acuity lines between the postoperative monocular and binocular uncorrected (UDVA) and corrected (CDVA) distance visual acuity.

Visual Acuities and Defocus Curve

Focusing on visual acuity outcomes, **Figure 3** shows the difference between UDVA and CDVA for monocular and binocular conditions. All eyes showed the same or one or more better visual acuity. **Figure 4** shows the percentage of eyes/patients with cumulative postoperative monocular and binocular logMAR UDVA and CDVA (20/x or better; top) UIVA and CDIVA (20/x or better; middle), and UNVA and CDNVA (20/x or better; bottom). The mean binocular UDVA, UIVA, and

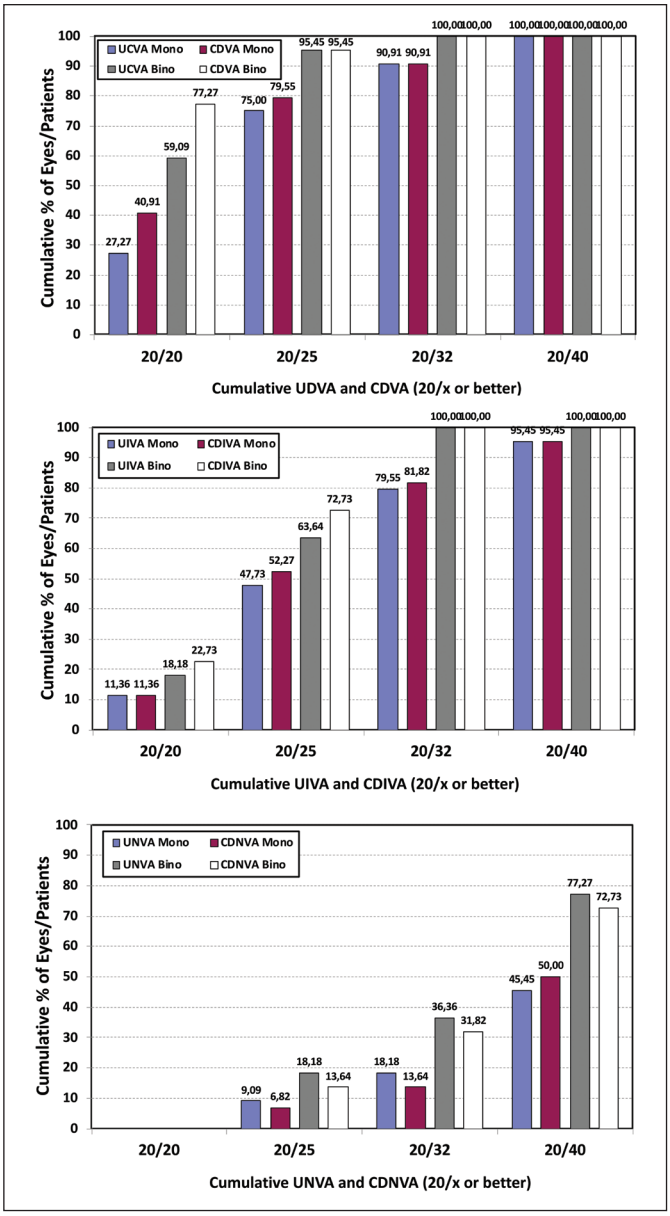

Figure 4. Cumulative proportion of eyes/patients presenting a given monocular and binocular uncorrected and corrected visual acuity (20/x or better) for distance (top), intermediate (middle) and near (bottom) vision. CDVA = corrected distance visual acuity; CDIVA = corrected-distance intermediate visual acuity; CDNVA = corrected-distance near visual acuity; UDVA = uncorrected distance visual acuity; UIVA = uncorrected intermediate visual acuity; UNVA = uncorrected intermediate visual acuity

UNVA were 0.00 ± 0.06 (range: 0.14 to -0.18), 0.08 ± 0.07 (range: 0.20 to -0.10), and 0.25 ± 0.10 (range: 0.46 to 0.08) logMAR, respectively. The mean binocular CDVA, CDIVA, and CDNVA were -0.02 ± 0.06 (range: 0.12 to -0.18), 0.07 ± 0.08 (range: 0.20 to -0.16), and 0.26 ± 0.09 (range: 0.46 to 0.08) logMAR, respectively.

Figure 5 depicts the binocular defocus curve obtained for the sample, with a double Y-axis for logMAR

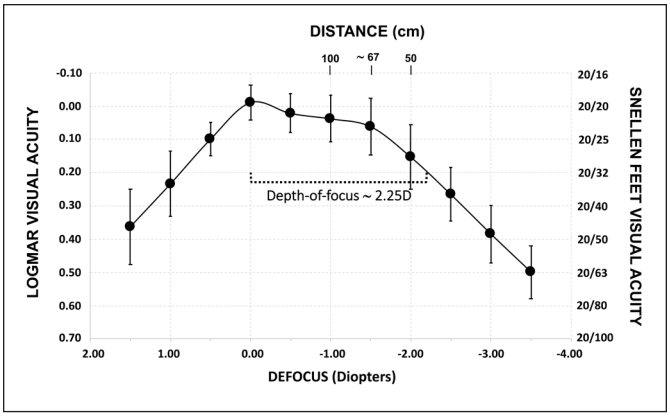

Figure 5. Binocular photopic defocus curve. The data are shown as the mean ± standard deviation of the mean.

(left) and Snellen feet (right) visual acuity versus vergence. We can see that the peak of the curve (maximum negative value of logMAR visual acuity) was obtained at 0.00 D of defocus (far distance). From this vergence there is a decreasing value for increasing negative defocus values (more negative values are closer distances, see distance values in the top axis of the graph). Specifically, the CDVA was 0.04, 0.06, and 0.15 logMAR at -1.00, -1.50, and -2.00 D, respectively. These vergences correspond to distances of 1 m, 66 cm, and 50 cm, respectively. Considering the depth of focus as the range of lens powers that achieved a mean visual acuity of 20/32 or better (from 0.00 D of vergence), our results reveal a value of approximately 2.25 D.

Contrast Sensitivity and Optical Quality

Figure 6 (top) shows the binocular contrast sensitivity outcomes obtained for photopic and mesopic conditions. The overall outcome for the in vivo optical quality analysis is shown in **Figure 6** (bottom). This figure represents the averaged postoperative MTF of the eyes implanted with the lenses at a 3-mm pupil. Specifically, wavefront aberrations were also analyzed using the iTrace device. At 2 to 3 mm, total HOAs, spherical aberration, and coma values were 0.161 ± 0.155 (range: 0.047 to 0.912 µm), -0.019 ± 0.048 (range: -0.245 to 0.070 µm), and 0.080 ± 0.065 (range: 0.009 to 0.345 µm) µm, respectively.

Patient Outcome Questionnaire

Table 2 shows the outcomes for response frequencies of the patient questionnaire showing the answers of the patients for each of the questions. Note the high percentages for the R1 response, indicating the patient has no difficulties performing the different tasks and is satisfied with their current vision (see detailed response frequencies in the table).

DISCUSSION

As mentioned, EDOF technology is applied to presbyopia-correcting IOLs to achieve good visual outcomes for our patients over a wide range of object distances. The main purpose of this study was to analyze the toric pure refractive EDOF technology IOL, which combines 4th and 6th orders of spherical aberration of opposite signs to increase the depth of focus. This is the first clinical study to look at the toric model of this IOL.

Our results reveal that the toric pure refractive EDOF technology IOL achieves excellent outcomes for refractive accuracy (**Figure 1**). A total of 90.45% and 100% of eyes were within ±0.50 and ±1.00 D, respectively, and the mean postoperative spherical equivalent was -0.02 ± 0.26 D. For astigmatism, 93.18% and 100% of eyes were within ±0.50 and ±1.00 D, respectively, with a mean value of -0.17 ± 0.29 D. Based on these outcomes, the lens accurately corrects sphere and corneal astigmatism. Specifically, **Figure 2** shows a concentration of results at the origin (0,0) after the surgery, which corresponds to astigmatism-free eyes. This also correlates with the good rotational stability of the lens (0.61 ± 1.61 degrees). Our results broadly agree with previous clinical studies on the non-toric model showing the excellent accuracy of the lens when implanted. For example, in 12 patients implanted bilaterally, at 3 months Campos et al[10] found a mean spherical equivalent of -0.08 ± 0.60 D with 91.7% of eyes within ±0.50 D. Tahmaz et al[11] found that, in 28 patients also bilaterally implanted and evaluated at 3 months, 96% and 98% of eyes were within ±0.50 and ±1.00 D, respectively. More recently, Nowrouzi et al,[12] who evaluated 25 eyes implanted unilaterally at 24 weeks, reported a mean spherical equivalent of -0.25 ± 0.50 D and 80% and 92% of eyes within ±0.50 and ±1.00 D, respectively.

This lens also achieves high values for binocular UDVA and CDVA, being 0.00 ± 0.06 and -0.02 ± 0.06 logMAR, respectively, with 95.45% of patients showing a cumulative binocular UDVA and CDVA of 20/25 or better (**Figure 4**, top). Similarly, Campos et al[10] found mean values of 0.02 ± 0.11 and -0.08 ± 0.04 logMAR for binocular UDVA and CDVA, respectively. Tahmaz et al[11] found mean values of 0.04 ± 0.06 and 0.00 ± 0.05 logMAR for binocular UDVA and CDVA, respectively. They also found that the binocular UDVA 20/32 or better Snellen was achieved in all patients. Nowrouzi et al[12] (monocularly, due to the unilateral implantation) found a mean CDVA value of -0.1 logMAR and all eyes had a UDVA of 20/25 or better, and 96% of eyes had a UDVA of 20/20 or better. For intermediate vision, our results were also good:

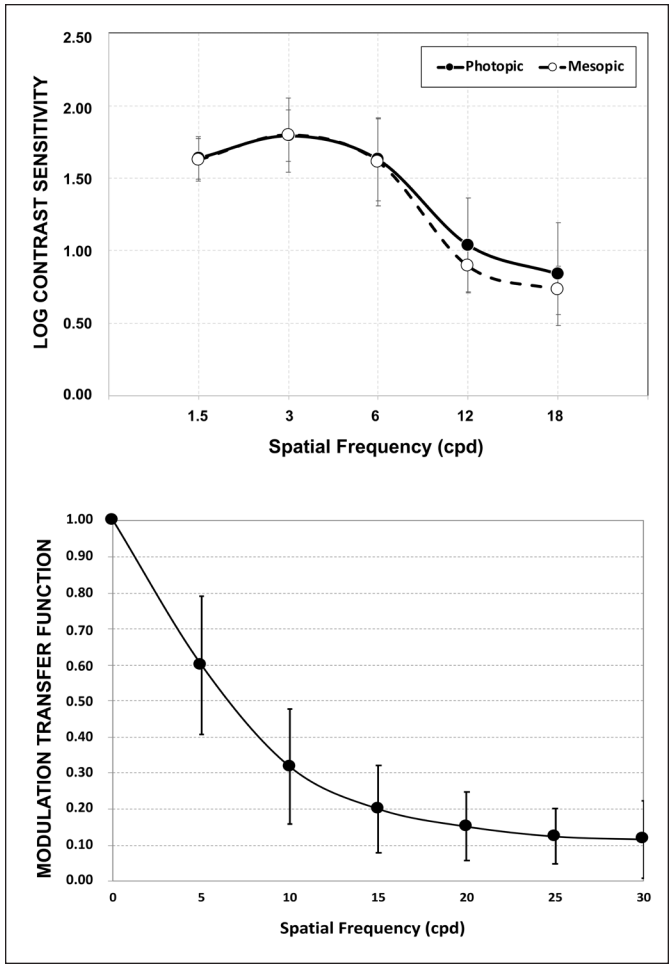

Figure 6. Contrast sensitivity for different spatial frequencies determined under photopic and mesopic conditions (top) and total averaged modulation transfer function (MTF) for a 3-mm pupil (bottom). Standard deviations are also shown for different spatial frequencies.

72.73% and 100% of eyes had a binocular CDIVA of 20/25 or better and 20/20 or better, respectively (see **Figure 5**, middle). Campos et al[10] found a mean value of 0.18 ± 0.12 logMAR for binocular UIVA and all patients achieved a UIVA of 20/40 or better. Our values were slightly better at 0.08 ± 0.07 logMAR and all patients achieved a UIVA of 20/32 or better. The results reported by Tahmaz et al[11] were more similar to ours, despite them measuring intermediate visual acuity at 80 cm, with the mean values being 0.08 ± 0.10 and 0.12 ± 0.11 logMAR for binocular UIVA and CDIVA, respectively. A binocular UIVA of 20/32 or better Snellen was also achieved in 27 of 28 patients (96%). The monocular outcomes for Nowrouzi et al[12] revealed a mean monocular CDIVA of -0.2 logMAR. The outcomes for near vision were lower than those obtained for distance and intermediate vision (see the lower cumulative percentages of eyes/patients at near vision in **Figure 4**). The mean binocular UNVA and

TABLE 2

Summary of Patient-Reported Vision Difficulties Determined Using the Catquest-9SF Questionnaire

Question	Response Frequencies (%)				
	R1	R2	R3	R4	R5
Do you find that your sight at present in some way causes you difficulty in your everyday life?[a]	77.3	22.7	0	0	0
Are you satisfied or dissatisfied with:[b]					
Your sight at present?	40.9	50.0	9.1	0	0
Reading text in newspapers?	77.3	18.2	4.5	0	0
Recognizing the faces of people you meet?	90.9	9.10	0	0	0
Seeing the prices of goods when shopping?	72.8	18.2	4.5	4.5	0
Seeing to walk on uneven surfaces?	90.9	9.10	0	0	0
Seeing to do handicrafts, woodwork, etc?	72.8	13.7	0	4.5	9.0
Reading subtitles on TV?	90.9	9.10	0	0	0
Seeing to engage in an activity/hobby?	86.4	9.10	4.5	0	0

[a]Response coding: R1 = no, no difficulties; R2 = yes, some difficulties, R3 = yes, great difficulties; R4 = yes, very great difficulties); R5 = cannot decide.
[b]For satisfaction: R1 = very satisfied; R2 = fairly satisfied; R3 = rather unsatisfied; R4 = very dissatisfied; R5 = cannot decide

CDNVA were 0.25 ± 0.10 and 0.26 ± 0.09 logMAR, respectively. This is also in line with Campos et al,[10] who found a mean value of 0.38 ± 0.14 logMAR for binocular UNVA, and Nowrouzi et al,[12] who found a mean monocular CDNVA of 0.38 logMAR. These outcomes correlate with the defocus curve depicted in **Figure 5**. Note the good outcomes for distance and intermediate vision (up to 50 cm) and the reduced visual acuity obtained at closer distances (40 or 33 cm). This large pseudoaccommodation provided by the lens offers our patients good intermediate vision. Tahmaz et al[11] obtained a monocular depth of focus of this lens of 1.60 D at 20/32 and an intermediate visual acuity (66 cm) derived from the defocus curve of 20/30 (0.18 logMAR). Similar results were obtained by Nowrouzi et al.[12] Our results were better, and more similar to those obtained by Campos et al[10] due to the binocular measurement conditions (approximately 2.00/2.25 D and 0.06/0.10 logMAR).

The contrast sensitivity and optical quality outcomes were good. **Figure 6** shows the binocular contrast sensitivity curve for two illumination levels; it is lower for higher spatial frequencies and under mesopic conditions. The MTF also decreases for higher spatial frequencies. Tahmaz et al[11] used the Mesotest under glare conditions and found a value of 0.25 ± 0.09 logCSWeber, this being slightly higher than in patients implanted with a monofocal lens; Nowrouzi et al[12] used the Pelli-Robson test and a total of 96% of the patients reported 100% contrast sensitivity. Borkenstein et al[4] using an optical bench obtained MTF values of 0.257, 0.247, and 0.360 at 50 lp/mm with a 3-mm aperture when the lens was centered, decentered 1-mm, and tilted by 5 degrees, respectively. Additionally, these authors reported that the overall HOAs were moderate, with a peak-to-valley ratio of 1.47. Schmid and Borkenstein[5] obtained a wavefront map of the pure refractive EDOF technology IOL, revealing a central zone of negative phase values of less than 1.5 mm, followed by positive phase values in the inner mid-periphery, with neutral values at the periphery of the lens. This latter area is intended to maintain contrast sensitivity with large pupils. This is in line with the good contrast sensitivity we found under low lighting conditions (see **Figure 6**, top). In addition, they indicated that the magnitude of the spherical aberration modification in the pure refractive EDOF technology IOL is expected to extend the depth of focus considerably, this being in agreement with our defocus curve (see **Figure 5**, approximately 2.25 D). In another study, Schmid et al[6] found that the Strehl ratio when decentered was inferior to that when it was centered and tilted with 3-mm of aperture ($P < .01$). Azor et al,[7] using an on-bench model eye, concluded that the pure refractive EDOF technology IOL showed an expanded imaging capability (0.50 D or less) with respect to a monofocal lens that may benefit intermediate vision. They found that the area under the MTF peak position of the pure refractive EDOF technology IOL reflected pupil dependence, with a myopic shift of approximately -1.00 D for the 2-mm pupil, thus benefiting near vision along with the pupil constriction experienced by patients in this viewing condition. This correlates with outcomes we found in our series. As noted by these authors, corneal asphericity was not compensated for in this lens when

measured in vitro. Finally, Schmid et al[8,9] measured this lens and compared it with other EDOF lenses and concluded that the Vivity IOL (Alcon Laboratories, Inc) and the pure refractive EDOF technology IOL showed a greater depth of focus than the Eyhance (Johnson & Johnson) and Rayone EMV (Rayner) lenses, and that the tilt and decentration only had a major impact on the performance of the Eyhance, which performed best of all of the IOLs tested when well centered. Our MTF outcomes agree with those reported by Ruiz-Mesa et al[16] for a 3-mm pupil when measured in vivo in patients implanted with the Mini WELL Ready EDOF IOL (Sifi SpA), using the I-trace device. The MTF values are related to the wavefront aberrations found in our series at 3 mm: the total HOAs, spherical aberration, and coma values were 0.161 ± 0.155, -0.019 ± 0.048, and 0.080 ± 0.065 µm, respectively. Note that we measured for a 2- to 3-mm pupil and mesopic pupil size was not assessed, being a limitation of our study. Unfortunately, there are no published clinical studies measuring wavefront aberrations in patients implanted with this lens that can be compared to the results reported herein.

The outcomes obtained from the Catquest-9SF questionnaire show that 90.9% of patients were either fairly satisfied (11 of 22) or very satisfied (9 of 22) with their vision after the surgery. **Table 2** displays the frequency of responses to the questions related to difficulty in performing daily activities as per the Catquest-9SF. Interestingly, more than 70% of patients report no difficulties for near vision activities, such as reading text in newspapers (77%), seeing prices when shopping, and doing woodwork (72.8%). It should be considered that specific questions (eg, seeing to engage in an activity/hobby) is limited to the sample of the cohort analyzed taken into account that some patients are unable to do this task. Our results fully agree with Campos et al,[10] who also used the Catquest-9SF questionnaire for their series of patients. They found that most patients achieved higher degrees of satisfaction for daily life activities, especially in terms of reading newspapers, reading prices while shopping, and using a computer. In fact, none were dissatisfied and 83.3% were very satisfied. Because they compared with a monofocal group, they concluded that the overall satisfaction was higher in the patients with pure refractive EDOF technology IOL because they reported fewer difficulties when reading newspapers, reading prices at supermarkets, and using a computer. As a consequence, they postulated that better intermediate vision is associated with a higher quality of life.

Our findings show that the toric pure refractive EDOF technology IOL provides good refractive, optical, and visual quality at different distances, with a high level of patient satisfaction when implanted. This lens may be considered a safe option for patients who have cataract with astigmatism aiming for spectacle independence with distance and intermediate vision due to the EDOF provided. Further studies involving a large cohort of patients with different amounts of corneal astigmatism and a longer follow-up should be performed to support these findings measuring refractive, visual, and optical outcomes for different lighting conditions.

AUTHOR CONTRIBUTIONS

Study concept and design (RR-M, PT-R); analysis and interpretation of data (RR-M, GCL, MR-S, AJ-N, PT-R); writing the manuscript (RR-M, PT-R); critical revision of the manuscript (RR-M, GCL, MR-S, AJ-N, PT-R); administrative, technical, or material support (RR-M); supervision (RR-M)

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