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Visual and Refractive Outcomes After Bi-aspheric Trifocal Toric Diffractive Intraocular Lens Implantation

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ABSTRACT

PURPOSE: To assess clinical outcomes after cataract surgery with bilateral implantation of a new bi-aspheric diffractive intraocular lens (IOL).

METHODS: Thirty patients underwent bilateral implantation of the Asqelio Trifocal Toric IOL (AST Products, Inc) and were evaluated 3 months postoperatively. Main outcomes included refractive error, photopic monocular and binocular uncorrected and corrected distance (UDVA, CDVA), intermediate (UIVA, CDIVA) at 60 cm, and near (UNVA, CDNVA) at 40 cm visual acuities. Mesopic monocular and binocular CDNVA were also measured. Defocus curves, binocular contrast sensitivity under photopic and mesopic conditions with and without glare and rotational stability were determined. Patients completed Catquest-9SF and visual symptoms questionnaires.

RESULTS: Average values of binocular photopic CDVA, CDIVA, and CDNVA, and mesopic CDNVA were -0.04 ± 0.06 , 0.02 ± 0.08 , 0.02 ± 0.07 , and 0.22 ± 0.11 logMAR, respectively. All patients achieved cumulative CDVA $\geq 20/25$, and CDIVA and

CDNVA of 20/32 or better. Binocular depth of focus was approximately 3.25 diopters (D). Mean postoperative spherical equivalent was -0.08 ± 0.26 D, with 95% of eyes within ± 0.50 D. Mean postoperative refractive cylinder was -0.22 ± 0.27 D, with 91.67% of eyes within 0.50 D or less, respectively. IOL rotation averaged 0.25 ± 0.65 degrees, all eyes having rotation of less than 5 degrees. Contrast sensitivity was within or above normal levels under photopic and mesopic conditions, with or without glare, except for 12 cpd under mesopic conditions with glare. Questionnaire responses indicated 96.67% of patients were satisfied or very satisfied with postoperative vision, and 80.00% to 96.67% reported no difficulty in different daily activities.

CONCLUSIONS: The Asqelio Trifocal Toric IOL demonstrated favorable outcomes, providing excellent visual performance at all distances, precise refractive results, and remarkable rotational stability. Patients reported high satisfaction levels and minimal difficulty in daily activities.

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A Bayesian network meta-analysis and systematic review recently published comparing different types of multifocal and monofocal intraocular lenses (IOLs) used in 27 clinical studies concluded that for patients considering a multifocal IOL due to presbyopia, bilateral implantation of a trifocal IOL might be an optimal solution for those without compromising distance visual acuity.¹ In addition,

it has been also published that trifocal IOLs may be superior to bifocal IOLs because of their improved intermediate visual acuity² and that toric and non-toric trifocal IOLs provide good distance, intermediate, and near vision with a wide range of vision and good contrast sensitivity.³

In relation to the correction of corneal astigmatism during cataract surgery, a recent study has analyzed

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the effect of residual astigmatism on postoperative visual outcomes after trifocal IOL implantation.⁴ These authors assessed 156 eyes in two groups according to postoperative astigmatism and measured different metrics such as visual acuity, modulation transfer function curves, Strehl ratio, Visual Function Index-14 scores, and photic phenomena. They concluded that postoperative residual astigmatism affects the uncorrected distance visual acuity (UDVA) postoperatively. They pointed out that although no significant differences in uncorrected intermediate and near visual acuities were found, both objective and subjective visual quality were affected, suggesting the need for surgical planning when the anticipated postoperative astigmatism is higher than 0.50 diopters (D). Therefore, trifocal toric IOLs aiming to correct presbyopia and some degree of astigmatism are a good solution to be considered when planning surgery. A recent publication has summarized the visual and refractive outcomes of patients implanted with different trifocal toric IOLs.⁵ Twenty clinical studies analyzing the outcomes of three commercially available trifocal toric IOLs were assessed in this report and concluded that the efficacy of the refractive correction and visual acuity at different distances was similar between the three models. These authors concluded that the use of trifocal toric IOLs allows complete visual restoration over a wide range of distances and should be considered during cataract surgery to provide patients with full spectacle independence in eyes with presbyopic astigmatism.

One recent trifocal toric IOL available in the market is the Asqelio Trifocal Toric IOL (AST Products, Inc). This is a non-apodized diffractive posterior trifocal toric lens based on a bi-aspheric design. Previous clinical studies using the non-toric version of the lens showed good visual and refractive outcomes, contrast sensitivity, and patient-reported outcomes.⁶⁻⁹ However, to date there are no clinical reports on the toric model of this lens. Therefore, the current clinical study reports postoperative refractive outcomes and visual performance at different distances and different lighting conditions, rotational stability, contrast sensitivity, and patient-reported outcomes in patients with cataract who were bilaterally implanted with this new IOL.

PATIENTS AND METHODS

This prospective study was approved by the Ethics Committee of the Hospital Clinico San Carlos (Madrid, Spain) and was carried out in accordance with the tenets of the Declaration of Helsinki. Written informed consent was obtained from all patients prior

to enrollment and after the potential consequences of participation in the study were explained. The study was registered at www.clinicaltrials.gov (registration number: NCT06190925).

Inclusion criteria were patients 50 years of age or older who had cataract surgery and were implanted with the Asqelio Trifocal Toric IOL TTLIO130C according to regular clinical practice to remove residual astigmatism, patients who signed informed consent, and those with bilateral cataracts, transparent intraocular media (except for the cataract) in both eyes, and postoperative potential visual acuity of 20/25 or better. Exclusion criteria were preoperative corneal astigmatism lower than 0.75 D, patients not providing informed consent, patients not understanding the study procedure, those who had previous corneal surgery or trauma, irregular cornea (ie, keratoconus), choroidal hemorrhage, microphthalmos, severe corneal dystrophy, glaucoma, clinically significant macular changes, severe concomitant ocular disease, not age-related cataract, amblyopia, or extremely shallow anterior chamber, those who were pregnant or lactating, those who had rubella, those with matured/dense cataract making preoperative fundus assessment difficult, previous retinal detachment, and concurrent participation in another investigation using drugs or clinical devices and expecting ocular surgery within the study period.

IOL

All patients were bilaterally implanted with the Asqelio Trifocal Toric TTLIO130C model IOL. Powers manufactured range from +0.00 to +40.00 D in 0.50-D increments and cylinders from +0.00 to +6.00 D in 0.50-D increments, with a C-Loop platform, 360 degrees sharp edge, and a total IOL diameter of 13.0 mm. It is made of glistening-free hydrophobic acrylic material with a refractive index of 1.50, UV absorber, Abbe number of 50, water content less than 0.5%, and spherical aberration of -0.27 microns.

Haptics have a larger contact angle of 53 ± 1 degrees per haptic and a frosted edge surface that should improve rotational stability of the IOL.

The lens has a bi-aspheric geometry, with a posterior diffractive optic design that includes 15 rings within the central 4.5 mm of a 6-mm diameter optical zone. The additions provided are +3.30 and +2.20 D for near and intermediate distances, respectively. The light distribution among foci is 50% for distance, 24% for intermediate, and 26% for near. The A-constant used was 119.3 and 118.7 for optical and contact ultrasound biometry, respectively, as recommended by the manufacturer.

SURGICAL PROCEDURE

A 2.2-mm limbal incision was made followed by standard phacoemulsification using the Centurion Vision System (Alcon Laboratories, Inc). After cataract removal and posterior capsule polishing, the capsular bag was filled with sodium hyaluronate 1.0% (ProVisc; Alcon Laboratories, Inc). Intraoperative aberrometry (ORA system; Alcon Laboratories, Inc) with digital eye tracking (Verion Image Guided system; Alcon Laboratories, Inc) was used in all surgeries. Postoperatively, all patients were prescribed with eye drops of moxifloxacin 5 mg/mL (Vigamox; Alcon Laboratories, Inc), prednisolone 10 mg/mL (Pred-Forte; Allergan, Inc), and diplofenac-lepori 1 mg/mL in a tapering dose for the first 4 weeks postoperatively.

PREOPERATIVE AND POSTOPERATIVE ASSESSMENT

Preoperatively, patients underwent an extensive ophthalmologic examination, including slit-lamp examination, determination of UDVA, corrected distance visual acuity (CDVA), subjective and objective refraction, IOP measurement, funduscopy, corneal topography (Atlas 9000 corneal topographer; Carl Zeiss Meditec AG), and keratometry and biometry with the IOLMaster 700 (Carl Zeiss Meditec AG). For the choice of cylinder value, both corneal topography data from Atlas 9000 and keratometry values from the IOLMaster 700 were used. IOL calculation was carried out using IOLMaster keratometry data. In most cases, the Barrett formula was used, except for 6 eyes where the Hoffer-Q was the formula of choice.

Postoperative examinations were completed 3 months after implantation. A standard ophthalmologic examination, including refraction and biomicroscopy, was performed. Astigmatism vector analysis performed with the double-angle tool.¹⁰ IOL rotation stability was assessed at the last postoperative visit. Specifically, monocular and binocular UDVA, CDVA, uncorrected distance intermediate visual acuity (UIVA), corrected distance intermediate visual acuity (CDIVA) at 60 cm, uncorrected distance near visual acuity (UNVA), and corrected distance near visual acuity (CDNVA) at 40 cm were measured under photopic conditions using Early Treatment of Diabetic Retinopathy Study charts. Additionally, monocular and binocular CDNVA were also measured under mesopic conditions (3 cd/m²). Monocular and binocular defocus curves were built for each patient with Sloan letter Early Treatment of Diabetic Retinopathy Study chart using the Clinical Trial Suite (M&S Technologies, Inc) under photopic conditions (85 cd/m²), from +2.00 to -5.00 D in 0.50-D steps (0.25-D steps between 0.00 and ±0.50 D). All data are shown as the mean ± standard deviation and range.

Clinical Trial Suite was also used to determine binocular contrast sensitivity with distance correction, both with and without glare, under photopic conditions (85 cd/m²) for the spatial frequencies of 3, 6, 12, and 18 cycles per degree (cpd), and under mesopic conditions (3 cd/m²) for the spatial frequencies of 1.5, 3, 6, and 12 cpd. The log absolute contrast threshold values were determined for each combination of patient, spatial frequency, and luminance level, and mean values and standard deviations were then calculated. The corresponding contrast sensitivity values were also computed from those thresholds (log CS), to plot the contrast sensitivity function.

Patients were asked to complete the Catquest-9SF patient outcomes questionnaire. This nine-item questionnaire determines patients' limitations in daily life for carrying certain activities due to reduced vision, and its value in patients who had cataract surgery has been previously reported.¹¹⁻¹³ Another questionnaire to assess the visual symptoms was also administered to explore the frequency, intensity, and level of bothersomeness of 10 common visual symptoms: glare, halos, starbursts, foggy vision, blurred vision, distortion, double vision, fluctuation in vision, difficulty focusing, and difficulty judging distances or depth. A simulated image was created and shown to the patient to aid describing each of the symptoms, and they were then asked to respond regarding frequency (from 1 = never to 4 = very often), intensity (from 1 = none to 4 = severe), and bothersomeness (from 1 = none to 4 = a lot).

SAMPLE SIZE AND STATISTICAL ANALYSIS

Estimated sample size for the study was calculated using the highest standard deviation of the monocular defocus curve.¹⁴ Considering a standard deviation of 0.24 logMAR at +2.00 D of defocus, a 95% confidence interval, and a tolerated error of 0.10 logMAR; a minimum of 22 patients would be required, and considering a drop-out rate of approximately 15% after the last follow-up visit, 30 patients were targeted. SPSS version 25.0 (SPSS, Inc) and Microsoft Excel for Mac v16.41 (Microsoft Corporation) software were used for data analysis. Significance level was set at a *P* value of less than .05. Categorical variables were described as frequencies and percentages, and continuous variables as mean and standard deviation.

RESULTS

Sixty eyes of 30 consecutive patients were analyzed for the current study. **Table 1** shows the demographics for the patients included. The mean age was 69.60 ± 6.92 years (range: 50 to 83 years), with 17 women (56.67%) and 13 men (43.33%).

TABLE 1
Demographic Characteristics of Participants

Characteristic	Mean ± SD (Range)
Patients (n)	30
Sex (male/female) (n)	13/17
Age (y)	69.60 ± 6.92 (50 to 83)
Sphere (D)	1.13 ± 2.00 (-4.25 to 4.75)
Refractive cylinder (D)	-1.22 ± 0.65 (0 to -2.50)
Spherical equivalent (D)	0.52 ± 1.98 (-5.13 to 3.88)
CDVA (logMAR)	0.09 ± 0.13 (0.00 to 0.52)
K1 (D)	42.90 ± 1.46 (39.71 to 45.44)
K2 (D)	44.06 ± 1.59 (40.86 to 46.97)
Axial length (mm)	23.45 ± 0.96 (20.91 to 25.32)
ACD (mm)	3.09 ± 0.40 (2.36 to 4.04)
CCT (µm)	543.92 ± 30.42 (462 to 610)
LT (mm)	4.67 ± 0.42 (3.14 to 5.67)
WTW (mm)	11.98 ± 0.39 (11.20 to 12.80)
IOL spherical power (D)	22.29 ± 2.43 (15.00 to 30.00)
IOL toric power (D)	1.49 ± 0.50 (1.00 to 3.00)

ACD = anterior chamber depth; CCT = central corneal thickness; CDVA = corrected distance visual acuity; D = diopters; IOL = intraocular lens power; K1 = flat keratometry; K2 = steep keratometry; LT = lens thickness; SA = spherical aberration; TK = total keratometry; WTW = white-to-white distance

Refractive and visual acuity outcomes found at 3 months of follow-up are shown in different standard graphs for this purpose.¹⁵ **Figure 1** was plotted to assess the efficacy of the procedure, providing the cumulative postoperative binocular logMAR UDVA and CDVA, UIVA and CDIVA, and UNVA and CDNVA, respectively. All patients showed cumulative CDVA of 20/25 or better, and CDIVA and CDNVA of 20/32 or better. Specifically, 93.33% of patients showed a UDVA of 20/25 or better compared to 100% for CDVA, 80.00% of patients showed a UIVA of 20/25 or better compared to 93.33% for CDIVA, and 90.00% of patients showed a UNVA of 20/25 or better compared to 86.67% for CDNVA. **Table 2** shows detailed values for the visual acuity at different distances under photopic and mesopic conditions. The postoperative mean values of binocular logMAR photopic CDVA, photopic CDIVA, photopic CDNVA, and mesopic CDNVA were -0.04 ± 0.06 , 0.02 ± 0.08 , 0.02 ± 0.07 , and 0.22 ± 0.11 , respectively. **Figure 2** represents the change in lines of visual acuity between the postoperative binocular logMAR UDVA and CDVA. Almost all patients showed a CDVA that was either the same (56.67%) or less than 0.2 better (40.0%) than UDVA. **Figure 3** represents the mean photopic monocular and binocular defocus curves with two main peaks of visual acuity located

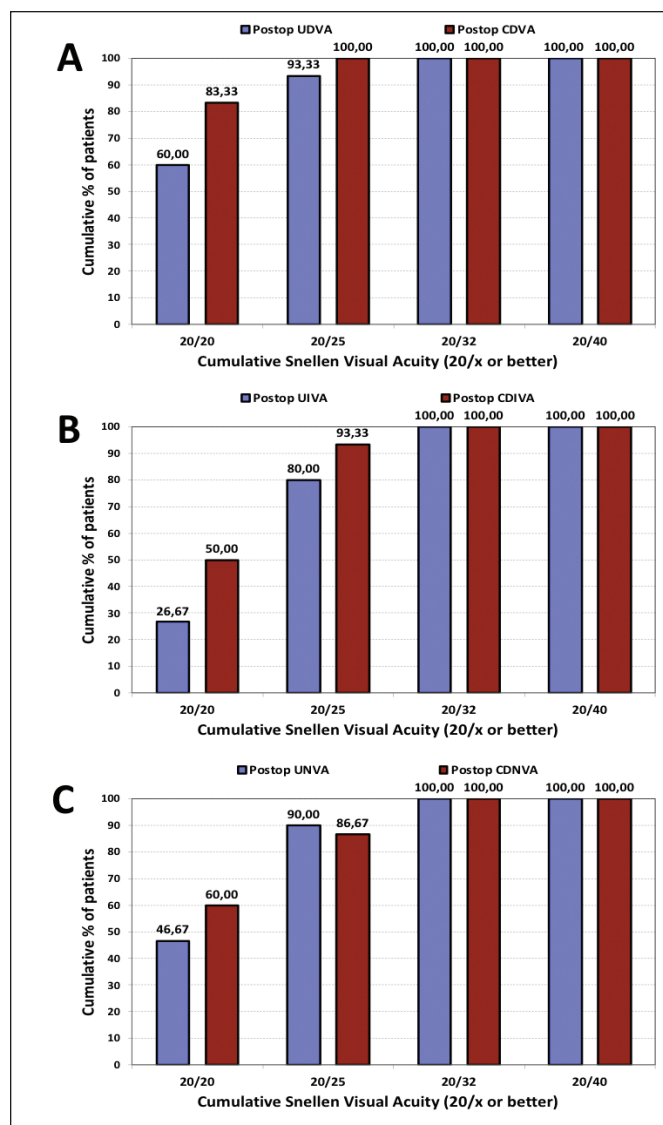


Figure 1. Cumulative proportion of patients having given photopic binocular (A) uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA) values, (B) binocular uncorrected distance intermediate visual acuity (UIVA) and corrected distance intermediate visual acuity (CDIVA), and (C) uncorrected distance near visual acuity (UNVA) and corrected distance near visual acuity (CDNVA) values, at 3 months after surgery.

at 0.00 and -2.00 D. The binocular depth of focus was defined as the range of lens powers that achieved a mean acuity of 20/32 or better (from 0.00 of vergence), and for our results it spanned approximately 3.25 D.

To assess predictability, **Figure 4** displays the histogram of postoperative spherical equivalent (SE) refraction relative to the intended target refraction and preoperative corneal astigmatism and postoperative refractive astigmatism. For the SE the highest percentage of eyes, 51.67%, was for the range between -0.13 and +0.13 D followed by 35.00% for the -0.50 to -0.14 D

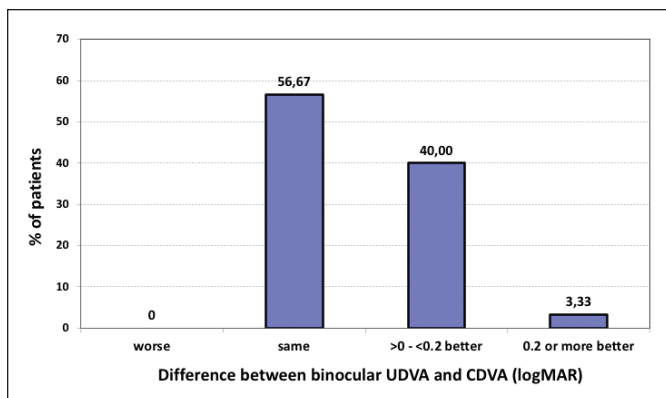


Figure 2. Change in lines of visual acuity between the photopic binocular postoperative uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA) at 3 months after surgery.

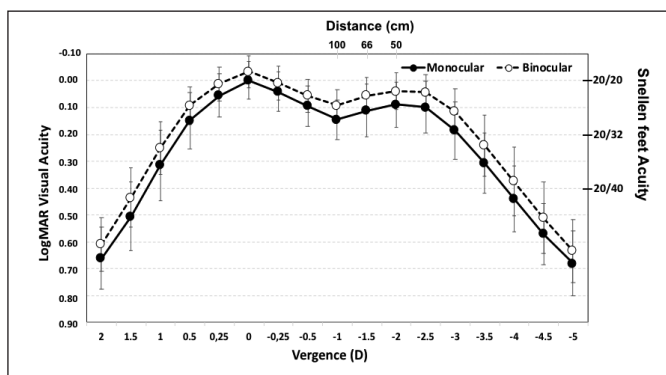


Figure 3. Mean, high-contrast, photopic, monocular and binocular logMAR visual acuity with best correction for distance, as a function of the chart vergence at 3 months after surgery. Error bars represent standard deviation. Right Y-axis shows Snellen feet acuity and superior X-axis shows distance values (cm).

range. All eyes were within ± 1.00 D and 95.00% of eyes were within ± 0.50 D. The mean postoperative SE was -0.08 ± 0.26 D (range: -0.63 to 0.75 D). For the astigmatism, all eyes showed a value of 1.00 D or less and 91.67% a value of 0.50 D or less, being the mean postoperative refractive cylinder -0.22 ± 0.27 D (range: 0.00 to -1.00 D). Double-angle plots of preoperative corneal astigmatism (**Figure 5**, left) and postoperative refractive astigmatism (right) showed a concentration of results at the origin (0,0), which corresponds to eyes free of astigmatism. The preoperative mean absolute corneal astigmatism was 1.16 ± 0.36 D and the postoperative mean absolute refractive astigmatism was 0.22 ± 0.27 D. At 3 months, the lens had a mean rotational stability of 0.25 ± 0.65 degrees (range: 0 to 2 degrees). Note that no significant rotation was reported in any of the eyes, because all eyes had a rotation of less than 5 degrees.

Figure 6 shows the mean contrast sensitivity function determined under photopic conditions (85 cd/m^2) with and without glare and under mesopic conditions

TABLE 2
LogMAR Visual Acuity Outcomes of Patients Implanted With the Asquelio Trifocal Toric TTL10130C IOL

Visual Acuity	Mean \pm SD (Range)
Monocular Photopic UDVA	0.06 ± 0.10 (-0.18 to 0.30)
Binocular Photopic UDVA	0.00 ± 0.08 (-0.16 to 0.20)
Monocular Photopic CDVA	0.00 ± 0.07 (-0.18 to 0.20)
Binocular Photopic CDVA	-0.04 ± 0.06 (-0.16 to 0.06)
Monocular Photopic UIVA	0.12 ± 0.09 (-0.10 to 0.34)
Binocular Photopic UIVA	0.05 ± 0.08 (-0.12 to 0.28)
Monocular Photopic CDIVA	0.07 ± 0.09 (-0.10 to 0.36)
Binocular Photopic CDIVA	0.02 ± 0.08 (-0.12 to 0.22)
Monocular Photopic UNVA	0.10 ± 0.09 (-0.10 to 0.40)
Binocular Photopic UNVA	0.03 ± 0.06 (-0.08 to 0.18)
Monocular Photopic CDNVA	0.07 ± 0.08 (-0.08 to 0.30)
Binocular Photopic CDNVA	0.02 ± 0.07 (-0.10 to 0.20)
Monocular Mesopic CDNVA	0.29 ± 0.12 (0.04 to 0.60)
Binocular Mesopic CDNVA	0.22 ± 0.11 (0.02 to 0.46)

CDVA = corrected distance visual acuity; CDIVA = corrected distance intermediate visual acuity; CDNVA = corrected distance near visual acuity; IOL = intraocular lens; SD = standard deviation; UDVA = uncorrected distance visual acuity; UIVA = uncorrected distance intermediate visual acuity; UNVA = uncorrected distance near visual acuity
The Asquelio Trifocal Toric TTL10130C IOL is manufactured by AST Products, Inc.

(3 cd/m^2) with and without glare. Because the Clinical Trial Suite system does not include a normal range for healthy individuals under each of the conditions measured photopic and mesopic, with and without glare and similarly to previous reports by the authors,⁸ the normative ranges for unoperated eyes of patients older than 60 years used by Escaf et al¹⁶ using the Functional Acuity Contrast Test (F.A.C.T.) were used in the current study as a reference to assess CSF outcomes. The results show that contrast sensitivity was either within or above normal levels, both with and without glare, under photopic and mesopic conditions. The only exception to this was mesopic contrast sensitivity for 12 cpd with glare, where the mean falls just underneath the reference range.

In relation to the questionnaires, the outcomes found with the Catquest-9SF (**Table 3**) show that 96.67% of patients were satisfied (11 of 30) or very satisfied (18 of 30) with their vision after surgery, and one of the patients was unsatisfied with the results. The table displays the average grading and frequency of responses to difficulties in performing the daily activities included in the Catquest-9SF. In all cases, the results indicate higher percentages for no difficulty (R4) in performing any of those activities (ranging

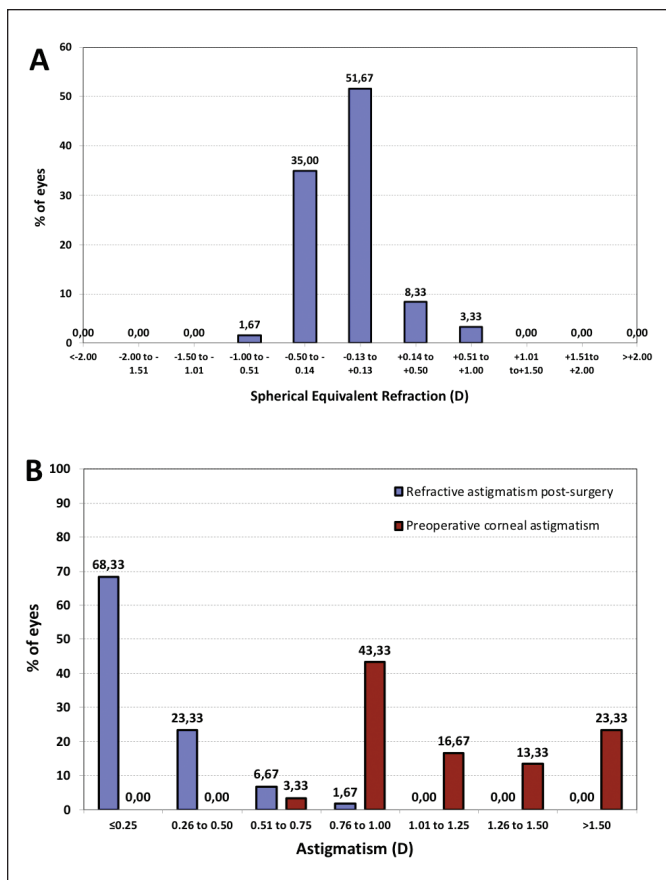


Figure 4. Histogram of (A) postoperative spherical equivalent refraction at 3 months after surgery and (B) preoperative corneal astigmatism and postoperative refractive astigmatism at 3 months after surgery. D = diopters

from 80.00% to 96.67%). **Table 4** summarizes the outcomes of the visual symptoms questionnaire following the surgery. It indicates no relevant visual symptoms in either frequency, intensity, or bothersomeness after implantation of the trifocal IOL. As expected for diffractive IOLs, and agreeing with previous reports with this IOL design,⁸ the frequency was higher for halos than for the other visual symptoms, with 6.67% of patients reporting often or very often (26.67%), but 83% of patients reported it either was not bothersome (50%) or a little bothersome (26.67%).

DISCUSSION

It has been observed that correcting astigmatism contributes to improved visual acuity in individuals receiving trifocal IOLs. Apart from using additional techniques such as corneal incisions or laser excimer procedures during or after cataract surgery, the incorporation of toric surfaces in trifocal IOLs can enhance outcomes, enabling patients to achieve spectacle independence in a single intervention. Although residual astigmatism

may impact postoperative visual acuity, the optical interactions between astigmatism and coma can potentially enhance optical quality.¹⁷ Noteworthy differences have been observed in the responses of habitually corrected and habitually non-corrected astigmatic individuals. Habitually corrected astigmatic individuals tend to experience fewer benefits from adding coma to astigmatism compared to non-astigmatic individuals. However, habitually corrected astigmatic individuals also exhibit lower tolerance to astigmatism induction than their habitually non-corrected counterparts.¹⁸ In a recent review of the various clinical studies published in peer-reviewed journals that report the visual and refractive outcomes of patients implanted with trifocal toric IOLs,⁵ the authors concluded that the efficacy of refractive correction and visual acuity found was similar for the different models. The same was found for patient quality of vision and satisfaction levels, as well as photic phenomena.

REFRACTIVE OUTCOMES

Kretz et al¹⁹ and Mojzis et al²⁰ reported good refractive outcomes with 3 months of follow-up of AT LISA tri toric 939MP IOL, with a mean SE of -0.50 D or less. In a multicenter prospective clinical trial with 12 months of follow-up, Piovela et al²¹ reported a mean SE of -0.18 D with a mean cylinder of -0.36 D. Astigmatism values of 0.50 and 1.00 D or less were found in approximately 80% and 98% of eyes, respectively. Different studies on the FineVision toric POD FT IOL consistently reported a substantial percentage of eyes with astigmatism of 0.50 D or less, ranging from 64.9% to 100%,²²⁻²⁵ and close to 100% for 1.00 D or less. The mean cylinder showed similarity across studies with values ranging from -0.1626 to -0.4125 D. Postoperative SE was less than a quarter of a diopter for 100% of eyes. Orts-Vila et al²⁵ implanted this lens in eyes with low levels of astigmatism (1.00 D cylinder) and reported accurate refractive outcomes. Different studies on AcrySof IQ PanOptix Toric IOL reported postoperative mean SE lower than 0.30 D and a similar refractive cylinder was (less than approximately 0.30 D).^{3,26-35} The percentage of eyes with SE \pm 0.50 D varied from 86%²⁹ to 96%³ and almost 100% for \pm 1.00 D in all studies. In relation to astigmatism, the outcomes were similar being 0.50 D or less from 80% to 97.8%³¹ and 100%^{3,30,31} for 1.00 D or less. The outcomes of the current study show that Asqelio Trifocal Toric IOLs are comparable to those reported for other lenses, with 100% of eyes within \pm 1.00 D and 95.00% of eyes within \pm 0.50 D for postoperative SE, and a mean value of 0.08 ± 0.26 D. Similarly, 100% of eyes showed astigmatism values

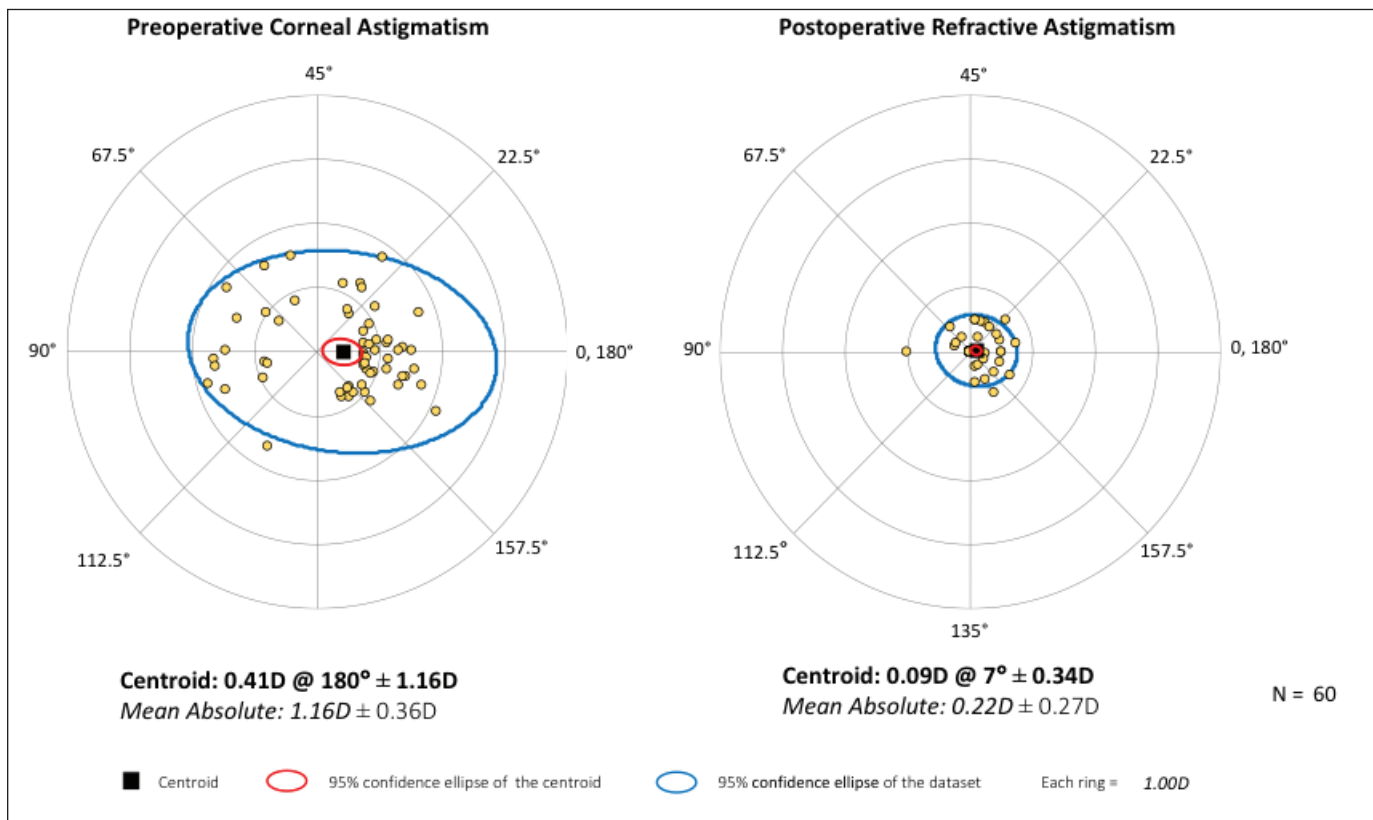


Figure 5. Double-angle plots for preoperative corneal astigmatism and postoperative refractive astigmatism (3 months after surgery) applying the double-angle tool.¹⁰ Centroids, mean absolute values with standard deviations, and 95% confidence ellipses of the centroid and dataset are also shown. D = diopters

of 1.00 D or less, and 91.67% a value of 0.50 D or less, with a mean postoperative refractive cylinder of -0.22 ± 0.27 D. These values are also in agreement with reported values obtained with the non-toric version of the Asqelio Trifocal IOL.⁸

ROTATIONAL STABILITY

In relation to rotational stability, Kretz et al²⁰ and Mojzis et al²¹ reported a mean angle of error of 5.80 degrees for the AT LISA tri toric 939MP IOL with 3 months of follow-up. Piovella et al²² reported approximately 3 degrees (93.8% rotated 5 degrees or less) after 12 months of follow-up. The mean values of IOL rotation reported for the FineVision Toric POD FT IOL were less than 1, 2.55 ± 2.62 ²⁵ and 1.33 ± 0.90 ³⁸ degrees, ranging from 0 to 10 degrees. An in vitro laboratory study concluded that with this lens there is a certain optical tolerance to a rotation of up to 5 degrees or residual refractive errors of up to 0.25 D.³⁹ Vandekerckhove²⁵ concluded that this lens offers better rotational stability when compared with a monofocal toric IOL (Ankoris), probably due to the higher frictional coefficient of its surface. Only Kohnen et al³² and Tekce and Gulmez³⁷ reported information about IOL rotation

with AcrySof IQ PanOptix Toric IOL, reporting good stability of the lens. In a comparison study, Ribeiro and Ferreira,³⁰ reported comparable IOL cylinder axis misalignment values for the AcrySof IQ PanOptix Toric and FineVision Toric POD FT IOL: 1.58 versus 1.89 degrees ($P = .821$).

IOL rotation values obtained in the current study are significantly lower than those reported for other IOLs, with a mean rotation of 0.25 ± 0.65 degrees, not exceeding 2 degrees in any case. The haptic design approach implemented in the Asqelio family of IOLs, increasing the contact angle of the haptics to 53 ± 1 degrees per haptic, and a frosted edge surface seem to be effective in minimizing postoperative rotation of the IOL.

VISUAL PERFORMANCE

In relation to visual acuity, Kretz et al²⁰ and Mojzis et al²¹ showed good visual outcomes for distance, intermediate, and near visual acuity with the AT LISA tri toric 939MP IOL with 3 months of follow-up. Both authors concluded that this lens provides high levels of visual acuity. With the FineVision Toric POD FT IOL, similar monocular CDVA (approximately 20/20) was reported in the studies of Gundersen and Potvin,²³ Poyales and

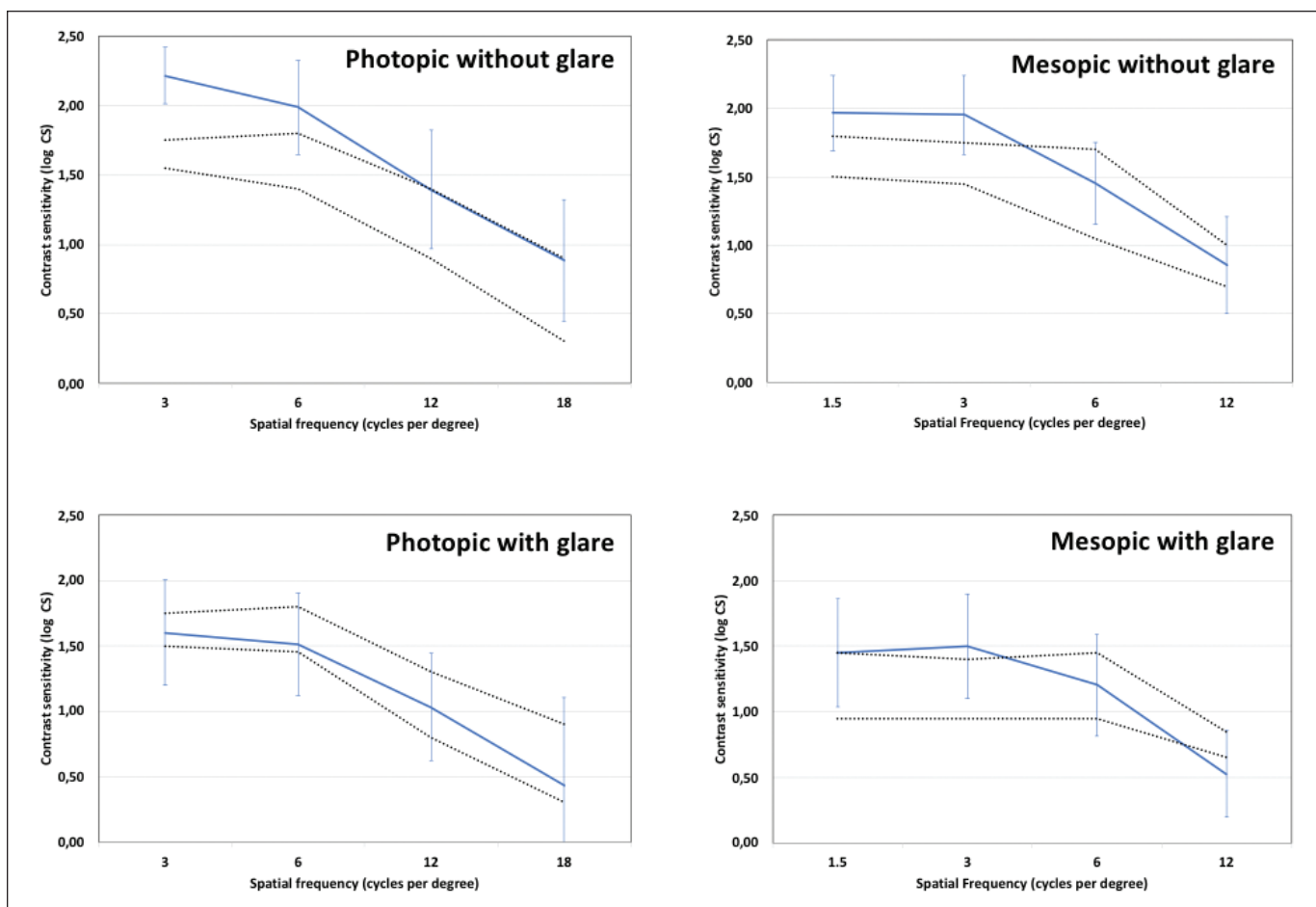


Figure 6. Contrast sensitivity function determined under photopic conditions (85 cd/m²) with and without induced glare and under mesopic conditions [3 cd/m²] with and without induced glare. Dotted lines delimit the normal range for non-operated eyes of patients older than 60 years using the Functional Acuity Contrast Test (F.A.C.T.).¹⁶ Error bars represent the 95% confidence intervals.

TABLE 3
**Summary of Patient-Reported Difficulties and Satisfaction
 With Their Vision as per Catquest-9SF**

Question	Mean ± SD	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	3.80 ± 0.41	0.00	0.00	20.00	80.00	0.00
Are you satisfied or unsatisfied with your current vision? ^b	3.57 ± 0.57	0.00	3.33	36.67	60.00	0.00
Do you have difficulty: ^a						
Reading text in newspapers?	3.80 ± 0.61	3.33	0.00	10.00	86.67	0.00
Recognizing the faces of people you meet?	3.93 ± 0.25	0.00	0.00	6.67	93.33	0.00
Seeing the prices of goods when shopping?	3.97 ± 0.18	0.00	0.00	3.33	96.67	0.00
Seeing to walk on uneven surfaces?	3.93 ± 0.25	0.00	0.00	6.67	93.33	0.00
Seeing to do handicrafts, woodwork, etc?	3.97 ± 0.18	0.00	0.00	3.33	96.67	0.00
Reading subtitles on TV?	3.77 ± 0.50	0.00	3.33	16.67	80.00	0.00
Seeing to engage in an activity/hobby?	3.93 ± 0.25	0.00	0.00	6.67	93.33	0.00

^aResponse coding: R1 = yes, extreme difficulty; R2 = yes, great difficulty; R3 = yes, some difficulty; R4 = no, no difficulty; R5 = cannot decide.

^bResponse coding: R1 = very unsatisfied; R2 = fairly unsatisfied; R3 = fairly satisfied; R4 = very satisfied; R5 = cannot decide.

TABLE 4
Patient-Reported Visual Symptoms (Mean Score, Type of Symptom, and Frequency of Responses) as per Visual Quality Questionnaire^a

Symptom	Mean ± SD	Frequency (%)			
		R1	R2	R3	R4
Glare					
Frequency	1.67 ± 0.96	60.00	20.00	13.33	6.67
Intensity	1.80 ± 1.13	63.33	3.33	23.33	10.00
Bothersomeness	1.67 ± 1.03	63.33	16.67	10.00	10.00
Halo					
Frequency	2.40 ± 1.19	33.33	23.33	6.67	26.67
Intensity	2.23 ± 0.97	30.00	23.33	40.00	6.67
Bothersomeness	1.77 ± 0.90	50.00	26.67	20.00	3.33
Starburst					
Frequency	2.07 ± 1.20	46.67	20.00	13.33	20.00
Intensity	1.97 ± 1.07	50.00	10.00	33.33	6.67
Bothersomeness	1.70 ± 1.06	63.33	13.33	13.33	10.00
Hazy vision					
Frequency	1.37 ± 0.81	80.00	6.67	10.00	3.33
Intensity	1.40 ± 0.89	80.00	6.67	6.67	6.67
Bothersomeness	1.33 ± 0.88	86.67	0.00	6.67	6.67
Blurred vision					
Frequency	1.47 ± 0.86	73.33	10.00	13.33	3.33
Intensity	1.47 ± 0.86	73.33	10.00	13.33	3.33
Bothersomeness	1.50 ± 0.94	73.33	10.00	10.00	6.67
Distorted vision					
Frequency	1.07 ± 0.25	93.33	6.67	0.00	0.00
Intensity	1.10 ± 0.40	93.33	3.33	3.33	0.00
Bothersomeness	1.07 ± 0.37	96.67	0.00	3.33	0.00
Double vision					
Frequency	1.00 ± 0.00	100.00	0.00	0.00	0.00
Intensity	1.00 ± 0.00	100.00	0.00	0.00	0.00
Bothersomeness	1.00 ± 0.00	100.00	0.00	0.00	0.00
Fluctuation in Vision					
Frequency	1.17 ± 0.59	90.00	6.67	0.00	3.33
Intensity	1.20 ± 0.66	90.00	3.33	3.33	3.33
Bothersomeness	1.20 ± 0.66	90.00	3.33	3.33	3.33
Difficulty focusing					
Frequency	1.23 ± 0.57	83.33	10.00	6.67	0.00
Intensity	1.27 ± 0.64	83.33	6.67	10.00	0.00
Bothersomeness	1.23 ± 0.73	90.00	0.00	6.67	3.33
Difficulty perceiving distances/depth					
Frequency	1.10 ± 0.31	90.00	10.00	0.00	0.00
Intensity	1.20 ± 0.66	90.00	3.33	3.33	3.33
Bothersomeness	1.20 ± 0.66	90.00	3.33	3.33	3.33

SD = standard deviation

^aResponse coding: R1 = no, no difficulties; R2 = yes, some difficulties; R3 = yes, great difficulties; R4 = yes, very great difficulties; R5 = cannot decide

Garzón,²⁴ and Orts-Vila et al.²⁵ The binocular outcomes were slightly better: 10.03 logMAR.⁵ DCIVA was only reported by Poyales and Garzón,²⁴ being approximately 0.10 logMAR at 80 and 63 cm (monocular). At near distance (40 cm), Gundersen and Potvin²³ found a value of approximately 0.03 logMAR and Poyales and Garzón²³ reported 0.17 logMAR. Gundersen and Potvin¹⁸ found 82% of eyes had a DCIVA of 0.1 logMAR or better at 63 cm. This value is similar to that found by Poyales and Garzón⁵ at the same distance (86%). Mean monocular CDVA obtained with the AcrySof IQ PanOptix Toric IOL were also reported, with values of approximately 0.32^{31,35} and 0.10^{27,28,32} logMAR. In relation to intermediate visual acuity, the studies published values at different distances with monocular values of approximately 0.10 logMAR at 80 cm,²⁷ 0.05 logMAR at 70 cm,²⁸ 0.07 logMAR at 63 cm,³⁵ and 0.1432 to 0.2427 logMAR at 60 cm. At near distances, the mean DCNVA values were slightly better at 0.0532 to 0.0837 logMAR at 40 cm, and 0.04 logMAR at 35 cm.²⁸ Kohnen et al³⁰ and Blaylock and Hall³¹ reported similar values of approximately 85%, 98%, and 100% for 0 or less, 0.1 or less, and 0.2 or better logMAR for CDVA, respectively. Kohnen et al³⁰ also reported values at intermediate and near distances of 36%, 38%, and 50% for 0 logMAR or better at 80, 60, and 40 cm, respectively, and 66%, 100%, and 80% for 0.1 logMAR or better at 80, 60, and 40 cm, respectively. These values underline the good outcomes of this lens for far distance, intermediate (60 cm), and near vision. Ribeiro and Ferreira,²⁸ compared FineVision toric POD FT and AcrySof IQ PanOptix toric IOLs and reported no significant differences between the two types of lenses in relation to UDVA, CDVA, UNVA, and DCNVA ($P \geq .33$). However, there were differences for intermediate visual acuity (60 cm), for which the PanOptix IOL presented better outcomes than the FineVision lens (0.04 vs 0.09 logMAR, respectively, $P = .032$). In the current study, visual outcomes are not worse than those reported for the other trifocal toric IOLs, with binocular photopic CDVA for distance, intermediate (60 cm), and near (40 cm) of -0.04 ± 0.06 , 0.02 ± 0.08 , and 0.02 ± 0.07 logMAR, respectively. Again, these values are also comparable to those obtained with the non-toric version of Asqelio Trifocal IOL.⁸

CONTRAST SENSITIVITY

Mojzic et al²¹ and Piovella et al²² evaluated contrast sensitivity monocularly and binocularly, respectively, after implantation of the AT LISA tri toric 939MP IOL. Mojzic et al²¹ considered that contrast sensitivity was within (photopic, 85 cd/m²) or near (mesopic, 3 cd/m²) normal limits, except for the spatial frequency of 18 cpd for the age sample analyzed. Piovella et al²² also found

values within the normal range with the exception of those measured at high frequencies (12 and/or 18 cpd). Gundersen and Potvin²³ and Poyales and Garzón²⁴ assessed the binocular contrast sensitivity after implantation of FineVision Toric POD FT IOL under photopic (85 cd/m²) and mesopic (6 cd/m²) conditions and found that it was within normal range for the age group for all spatial frequencies, except for 12 cpd. With the AcrySof IQ PanOptix Toric IOL, Rementería-Capelo et al²⁷ reported photopic contrast sensitivity, showing that it was within the normal range. Carreño et al³ and Gundersen and Potvin²⁹ supported this conclusion, reporting both photopic and mesopic contrast sensitivity that was similar to age-matched normal individuals. Kohnen et al³⁰ reported outcomes for photopic, mesopic, and mesopic with induced glare conditions. They indicated that the outcomes were similar to the non-toric version of the lens and the AT LISA trifocal lens under mesopic and mesopic with glare conditions. Compared to an aspheric monofocal IOL it presents lower contrast sensitivity in all light conditions. Ribeiro and Ferreira²⁸ found no differences between AcrySof IQ PanOptix Toric and FineVision Toric POD FT IOLs with regard to photopic and mesopic contrast sensitivity ($P > .05$). Similarly, the current study found CSF values within normal range under both photopic and mesopic conditions, with and without glare, except for mesopic contrast sensitivity for 12 cpd with glare, where the mean falls just underneath normal range. These outcomes are similar to those reported with the non-toric version of the Asqelio Trifocal IOL.^{8,9} One limitation of the current study is using the normal ranges for non-operated eyes of patients older than 60 years used by Escaf et al¹⁶ using the Functional Acuity Contrast Test (F.A.C.T.) as a reference, given the lack of a reference range within the Clinical Trial Suite system.

DEFOCUS CURVE

Mojzic et al²¹ reported a visual acuity of 0.2 logMAR or better between the defocus levels of +1.00 and -3.00 D with the AT LISA tri toric 939MP IOL. Piovella et al²² reported a similar performance with visual acuities better than 0.2 logMAR for defocus values greater than +1.00 and less than -2.50 D. The defocus curve of this lens showed a smooth transition between far and near foci in both these studies. Poyales and Garzón²⁴ found good visual acuity at various distances with the FineVision Toric POD FT IOL: 0.13 logMAR or better from +1.00 to -3.00 D. Gundersen and Potvin²³ reported improved intermediate vision without negatively impacting visual function and distance, near, or low-contrast visual acuity when compared to a bifocal toric IOL (AcrySof RESTOR SND1T). With regard to outcomes yielded by the

AcrySof PanOptix IQ Toric IOL, Rementería-Capelo et al²⁷ showed that patients achieved a visual acuity of 0.1 logMAR or better between +0.50 and -2.50 D. Carreño et al³ reported a mean uncorrected binocular defocus curve of 0.1 logMAR or better from 0.00 to -3.00 D. They also showed reported that with a cut-off of 0.2 logMAR, 96% of patients had a range of vision 2.50 D or better. In the binocular defocus curve obtained by Kohlen et al³² they found three peaks at 0.00 D (-0.09 logMAR), -1.50 D (-0.02 logMAR), and -2.00 D (0.00 logMAR), with the worst values being located between far and near distance (40 cm) at -1.00 D (0.04 logMAR). Finally, Tekce and Gulmez,³⁷ who compared this model with the bifocal toric AcrySof ReSTOR lens, found a significantly higher UDVA in the trifocal group than in the bifocal group, at test distances of -1.50 D (corresponding to a distance of approximately 67 cm). Ribeiro and Ferreira³⁰ obtained better visual acuities for the AcrySof PanOptix IQ Toric IOL than for the FineVision Toric POD FT IOL between -1.50 and -2.00 D, with no differences for the remaining vergence levels ($P > .05$). With the Asqelio Trifocal Toric IOL, the current study found mean photopic monocular and binocular defocus curves with two main peaks of visual acuity located at 0.00 and -2.00 D, with a range of vision of 3.25 D with a cut-off of 0.1 logMAR under binocular conditions, similar to the curves obtained for the non-toric Asqelio Trifocal IOL reported previously.⁸

PATIENT-REPORTED OUTCOMES

Mojzis et al²¹ reported that the patients experienced low to moderate levels of difficulty when performing various types of vision-related tasks after implantation of the AT LISA tri toric 939MP IOL, evaluated by the NEI VFQ-14 questionnaire. Piovella et al²² obtained high patient satisfaction levels for visual outcomes at all distances: 95.2%, 95.2%, and 83.7% of patients were spectacle free for distance, intermediate, and near visual tasks at 12 months postoperatively, respectively. They also reported that 95% or more of patients felt that visual disturbances (ie, halos or glare) caused little or no disturbance.

The three studies reporting questionnaire outcomes with the AT LISA tri toric 939MPIOL concluded that the lens provides effective visual performance at all distances,²⁰⁻²² minimal visual symptoms,¹⁵ high levels of quality of life,²¹ and patient satisfaction.²² Gundersen and Potvin²³ and Poyales and Garzón²³ evaluated patient-reported outcomes of the FineVision Toric POD FT. The former used the NEI VFQ-14 questionnaire and found no statistically significant differences between the bifocal (AcrySof ReSTOR SND1T) and trifocal (FineVision Toric POD FT) IOLs for general, near, and distance vision, or driving (median sub-score values ≥ 80

in all cases), suggesting a high level of satisfaction with postoperative vision. Poyales and Garzón²⁴ used an ad hoc questionnaire and found no statistically significant differences between the toric and non-toric models of the FineVision POD F IOL, with both groups reporting high levels of satisfaction. Rementería-Capelo et al²⁷ assessed real-life vision after AcrySof IQ PanOptix Toric IOL implantation with the Catquest-9SF questionnaire, and reported a high rate of patient satisfaction, with patients having little difficulty performing day-to-day activities. Hamdi²⁸ reported good patient-reported subjective impression ($> 85\%$) in terms of satisfaction, spectacle independence, and certain visual tasks, such as reading, computer use, or night driving. Kohlen et al³² obtained good self-reported visual function outcomes for all daily, far, intermediate, and near distance activities. They also found that 76% of the patients reported halos, and 52% reported glare. Despite this, 92% of those patients would choose to have the same lens again and recommend it to others. Tekce and Gulmez³⁷ used the NEI VFQ-25 questionnaire, showing significantly better driving subscale scores in patients with the AcrySof IQ PanOptix Toric IOL compared to the bifocal AcrySof ReSTOR toric model. The scores for general, distance, and near vision were similar between the two groups of patients. Hamdi,²⁸ using their own questionnaire, retrieved information regarding satisfaction, visual symptoms, and difficulty in performing certain activities, and reported good patient-reported outcomes after implantation of the AcrySof IQ PanOptix Toric lens. Ribeiro and Ferreira³⁰ found no differences between the AcrySof IQ PanOptix Toric and FineVision Toric POD FT IOLs with regard to a quality-of-vision questionnaire ($P > .05$), and spectacle independence (all patients indicated they never wore spectacles). In the current study, patients reported high levels of satisfaction with little difficulty in performing daily tasks, with 96.67% of patients either satisfied or very satisfied with their vision after surgery. As expected, and agreeing with previous reports with the non-toric version of the Asqelio Trifocal IOL,⁸ the frequency was higher for halos than for the other visual symptoms, but causing levels of discomfort ranging from minimal to none.

The current study supports that the Asqelio Trifocal Toric lens is an efficient trifocal IOL design providing good clinical outcomes at all distances. Rotational stability was minimal after 3 months postoperatively, and significantly lower than that reported in the literature for other trifocal toric IOLs in the market. The high level of patient satisfaction reported after implantation makes it a valuable option for astigmatic patients seeking spectacle independence with low impact in visual disturbance, and good visual outcomes.

AUTHOR CONTRIBUTIONS

Study concept and design (PT-S, PT-R); data collection (ST-S); analysis and interpretation of data (PT-S, ST-S, MDR-C, MR-S, CAT, PT-R); writing the manuscript (PT-S, ST-S, PT-R); critical revision of the manuscript (MDR-C, MR-S, CAT); supervision (PT-R)

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