Clinical Outcomes After Implantation of a Trifocal Toric Intraocular Lens

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ABSTRACT

PURPOSE: To evaluate the visual, refractive, and contrast sensitivity outcomes, as well as the level of photic phenomena, after cataract surgery with implantation of a trifocal diffractive toric intraocular lens (IOL).

METHODS: This prospective study included 56 eyes with corneal astigmatism of 1.00 diopters (D) or greater of 28 patients (age: 23 to 78 years) undergoing cataract surgery with implantation of the trifocal toric IOL AT LISA tri toric 939MP (Carl Zeiss Meditec, Jena, Germany). Monocular and binocular visual outcomes, refractive changes, contrast sensitivity, and photic phenomena perception (Halo & Glare Simulator; Eyeland-Design Network GmbH, Vreden, Germany) were evaluated at 3 months postoperatively.

RESULTS: Mean 3-month postoperative monocular uncorrected distance (UDVA), intermediate (UIVA), and near (UNVA) visual acuities were 0.13 ± 0.15, 0.08 ± 0.15, and 0.13 ± 0.18 logMAR, respectively. Binocular postoperative CDVA, DCIVA, and DCNVA values were 0.10 logMAR or better in all cases. A total of 88.2%, 88.2%, and 95.5% of eyes achieved binocular UDVA, UIVA, and UNVA values of 0.20 logMAR or better, respectively. Postoperative refractive cylinder was 0.50 D or less and 1.00 D or less in 78.6% and 98.2% of eyes, respectively. Photopic contrast sensitivity was significantly better than mesopic values for the spatial frequencies of 6 (P = .007), 12 (P = .005), and 18 cycles/degree (P = .011). Mean size and intensity of halos were 50.67 ± 15.69 and 54.89 ± 17.86, respectively. Mean glare size and intensity were 39.67 ± 3.51 and 44.67 ± 15.01, respectively.

CONCLUSIONS: The evaluated trifocal diffractive toric IOL provides an effective restoration of the distance, intermediate, and near vision after cataract surgery with good levels of visual quality and minimal photic phenomena.

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The presence of significant residual astigmatic refractive errors after cataract surgery following implantation of diffractive multifocal intraocular lenses (IOLs) can compromise the postoperative level of visual rehabilitation.[1] This potential residual astigmatism after cataract surgery is mainly due to the presence of preexisting corneal astigmatism.[2] Multifocal toric IOLs were developed with the aim of avoiding or minimizing the astigmatic residual refractive errors while providing a visual restoration at near and distance in patients with significant amounts of corneal astigmatism undergoing cataract surgery.[3-12] However, intermediate vision is limited with diffractive multifocal

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toric IOLs[11] because no specific focus is provided for this distance, even with rotationally asymmetric refractive multifocal IOLs.[6] Trifocal diffractive multifocal designs have demonstrated their ability to provide an effective intermediate visual restoration without degradation of distance and near vision.[13-19] For this reason, the trifocal IOL design of the AT LISA tri platform (Carl Zeiss Meditec, Jena, Germany) has been combined with a toric surface to provide an integral visual restoration in patients undergoing cataract surgery and with preexisting corneal astigmatism.[20] To date, only Brito et al.[20] have reported some clinical scientific evidence of the usefulness of trifocal toric IOLs.

The aim of the current study was to evaluate the clinical outcomes in terms of visual acuity, refraction, contrast sensitivity, and level of photic phenomena in eyes with significant amounts of preexisting corneal astigmatism undergoing cataract surgery with implantation of a trifocal toric IOL based on the combination of a trifocal and a bifocal diffractive pattern.

PATIENTS AND METHODS

Patients

A total of 56 eyes of 28 patients were enrolled in this prospective study. All patients underwent bilateral phacoemulsification surgery with implantation of a diffractive trifocal toric IOL (AT LISA tri toric 939MP; Carl Zeiss Meditec). Included were patients with cataract or presbyopic/pre-presbyopic patients suitable for refractive lens exchange and seeking spectacle independence with a preexisting corneal astigmatism of 1.00 diopter (D) or greater. Excluded were patients with a history of glaucoma or retinal detachment, corneal disease, irregular corneal astigmatism, abnormal iris, macular degeneration or retinopathy, neuro-ophthalmic disease, history of ocular inflammation, or previous ocular surgery.

All patients were adequately informed about the study and signed a consent form. The study adhered to the tenets of the Declaration of Helsinki and was approved by the local ethics committee.

Examination Protocol

A complete preoperative ophthalmological examination was performed in all cases, including manifest refraction, monocular corrected distance visual acuity (CDVA), Goldmann applanation tonometry, slit-lamp examination, corneal topography (Pentacam; Oculus Optikgeräte, Wetzlar, Germany), optical biometry (IOLMaster 500; Carl Zeiss Meditec), and funduscopy. Patients were evaluated 1 day and 1 and 3 months postoperatively. The postoperative examination protocol was identical to the preoperative protocol, with the additional evaluation at 3 months postoperatively of monocular and binocular uncorrected distance visual acuity (UDVA), binocular CDVA, monocular and binocular uncorrected (UIVA), and distance corrected intermediate visual acuity (DCIVA) measured at 66 cm, monocular uncorrected (UNVA) and distance corrected (DCNVA) near visual acuity measured at 40 cm, contrast sensitivity under photopic (85 cd/m^2) and mesopic conditions (3 cd/m^2) (CSV-1000, VectorVision, Greenville, OH), and the halo and glare perception with a simulator (Halo & Glare Simulator; Eyeland-Design Network GmbH, Vreden, Germany). This simulator uses a scale for intensity, size of the halo, and glare from 0 (none) to 100 (extremely disturbing). Likewise, the simulator allows the classification of the halo perceived by the patient into three types: T1 (diffuse halo ring), T2 (starburst type), and T3 (distinct halo ring).

Surgical Procedure

All surgeries were performed by the same experienced surgeon using a standard technique of sutureless 2.2-mm incision phacoemulsification. All incisions were made at the steepest corneal meridian. Topical anesthesia and mydriatic drops were instilled in all cases prior to the surgical procedure. After capsulorhexis creation and phacoemulsification, the IOL was inserted into the capsular bag using a specific injector (BLUEMIXS 180; Carl Zeiss Meditec) through the main incision.

IOL

The trifocal toric IOL AT LISA tri toric 939MP from Carl Zeiss Meditec is a four-haptic lens, with an overall length of 11 mm and an optic diameter of 6 mm. It is made of foldable hydrophilic acrylic material and has hydrophobic surface properties. This IOL presents a trifocal anterior surface combined with a bitoric surface that provide a refractive correction at all distances. Specifically, this IOL provides a 3.33 D near addition and a 1.66 D addition for intermediate distance, both calculated at the IOL plane. The company labelled A-constant for this IOL is 118.8.

Statistical Analysis

A statistical software package (SPSS version 15.0 for Windows; IBM, Armonk, NY) was used for statistical analysis. The Kolmogorov–Smirnov test was used to check the normality of the data distributions. When parametric analysis was possible, the Student's *t* test for paired data was performed for all parameter comparisons between preoperative and postoperative examinations. Otherwise, when parametric analysis was not possible, the Wilcoxon rank sum test was applied

TABLE 1
Preoperative and Postoperative Visual and Refractive Data[a]

Variable	Preoperative	3 Months Postoperative Monocular	3 Months Postoperative Binocular	*P*[b]
logMAR UDVA monocular	–	0.13 (0.15) 0.10 (-0.10 to 0.56)	0.05 (0.10) 0.02 (-0.10 to 0.30)	–
Sphere (D)	+0.39 (3.93) +0.75 (-9.50 to +8.75)	-0.17 (0.51) -0.25 (-1.00 to +1.00)	–	.334
Cylinder (D)	-1.21 (1.01) -0.75 (-3.75 to 0.00)	-0.40 (0.31) -0.50 (-1.25 to 0.00)	–	< .001
Spherical equivalent (D)	-0.21 (3.93) +0.44 (-10.75 to +8.13)	-0.37 (0.50) -0.31 (-1.38 to +0.88)	-0.37 (0.50) -0.31 (-1.38 to +0.88)	.819
logMAR CDVA monocular	0.16 (0.18) 0.10 (0.00 to 0.72)	0.00 (0.09) 0.00 (-0.20 to 0.40)	-0.04 (0.08) -0.04 (-0.20 to 0.12)	< .001
logMAR UIVA monocular	–	0.08 (0.15) 0.09 (-0.10 to 0.36)	0.08 (0.19) 0.04 (-0.10 to 0.36)	–
logMAR DCIVA monocular	–	0.05 (0.17) 0.00 (-0.10 to 0.40)	-0.03 (0.11) -0.09 (-0.10 to 0.10)	–
logMAR UNVA monocular	–	0.13 (0.18) 0.12 (-0.10 to 0.60)	0.10 (0.16) 0.10 (-0.10 to 0.60)	–
logMAR DCNVA monocular	–	0.02 (0.07) 0.00 (-0.10 to 0.10)	-0.03 (0.11) -0.09 (-0.10 to 0.10)	–

SD = standard deviation; D = diopters; UDVA = uncorrected distance visual acuity; CDVA = corrected distance visual acuity; UNVA = uncorrected near visual acuity; DCNVA = distance corrected near visual acuity; UIVA = uncorrected intermediate visual acuity; DCIVA = distance corrected intermediate visual acuity
[a]Values reported as mean (SD) median (range).
[b]For monocular comparison.

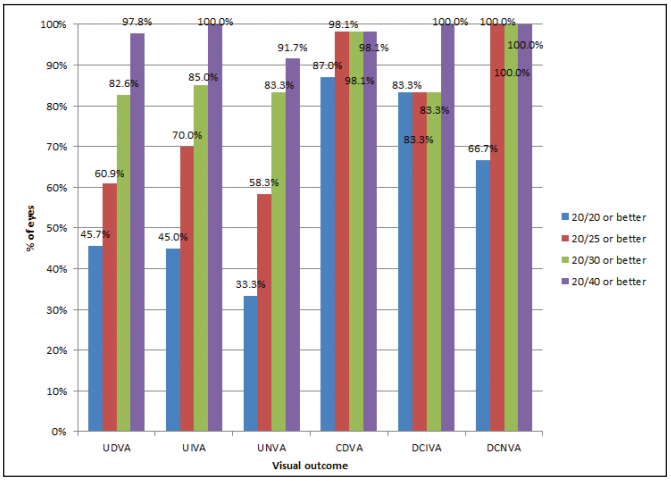

Figure 1. Distribution of 3-month postoperative monocular visual outcomes. UDVA = uncorrected distance visual acuity; UNVA = uncorrected near visual acuity; CDVA = corrected distance visual acuity; DCIVA = distance corrected intermediate visual acuity; DCNVA = distance corrected near visual acuity

to assess the significance of differences between examinations. In all cases, the same level of significance ($P < .05$) was considered.

RESULTS

The study enrolled a total of 56 eyes from 28 patients with an age range from 23 to 78 years (mean age: 57.9 years). Mean preoperative axial length and anterior chamber depth were 23.75 mm (standard deviation [SD]: 1.77; median: 23.37; range: 20.46 to 28.16 mm) and 3.20 mm (SD: 0.46; median: 3.23; range: 2.14 to 4.90 mm), respectively. Mean radii of curvature in the flattest and steepest meridians of the central cornea were 7.92 mm (SD: 0.28; median: 7.85; range: 7.40 to 8.63 mm) and 7.57 mm (SD: 0.27; median: 7.53; range: 7.21 to 8.83 mm), respectively. Mean spherical and cylindrical IOL power implanted was 19.61 D (SD: 5.66; median: 20.50; range: 4.50 to 32.00 D) and 2.02 D (SD: 1.01; median: 1.50; range: 1.00 to 5.50 D), respectively. **Table 1** summarizes the preoperative and postoperative visual and refractive data of patients included in the current study.

VISUAL AND REFRACTIVE OUTCOMES

A significant improvement with surgery was observed in monocular logMAR CDVA from a mean of 0.16 (range: 0.00 to 0.72 logMAR) to 0.00 logMAR (range: -0.20 to 0.40 logMAR) combined with a significant reduction in manifest cylinder from -1.21 (range: -3.75 to 0.00 D) to -0.50 D (range: -1.25 to 0.00 D), ($P < .001$) (**Table 1**). Mean postoperative manifest sphere and spherical equivalent were -0.17 (range: -1.00 to +1.00 D) and -0.37 D (range: -10.75 to +8.13 D), respectively. Almost all eyes (55 of 56, 98.2%) had a postoperative refractive cylinder of 1.00 D or less and 78.6% of eyes (44) had a postoperative manifest astigmatism of 0.50 D

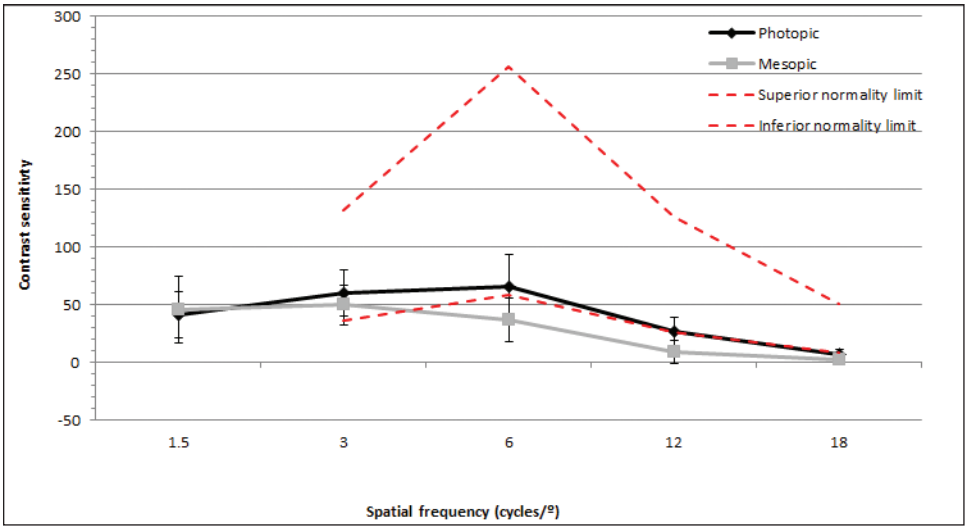

Figure 2. Mean contrast sensitivity function under mesopic (gray line) and photopic (black line) conditions at 3 months postoperatively. The results are also compared with the ranges of normality defined previously for the contrast sensitivity test used (Data from Pomerance G, Evans D. Test-retest reliability of the CSV-1000 contrast test and its relationship to glaucoma therapy. *Invest Ophthalmol Vis Sci*. 1994;35:3357-3361.)

or less. After 3 months, postoperative manifest sphere was within ±1.00 and ±0.50 D in 100% and 73.2% (41 of 56) of eyes, respectively. The spherical equivalent was within ±1.00 and ±0.50 D in 89.3% (50 of 56) and 71.4% (40 of 56) of eyes, respectively.

Figure 1 displays the distribution of 3-month postoperative monocular visual outcomes. A total of 82.61%, 85%, and 83.33% of eyes achieved a monocular UDVA, UIVA, and UNVA of 0.20 logMAR or better, respectively. Likewise, a total of 98.15%, 83.33%, and 100% of eyes achieved a monocular CDVA, DCIVA, and DCNVA of 0.20 logMAR or better, respectively (**Figure 1**). Because some eyes had a higher degree of corneal astigmatism usually resulting in abnormal higher-order aberrations, this could explain why some eyes did not achieve a monocular UDVA, UNVA, or CDVA of 20/40 or better. Binocularly, UDVA, UIVA, and UNVA achieved values of 0.20 logMAR or better in 88.2%, 88.2%, and 95.5% of eyes, respectively. Binocular postoperative CDVA, DCIVA, and DCNVA values were 0.10 logMAR or better in all cases. In the retroillumination examination 3 months after surgery, there was no significant posterior capsule opacification influencing the visual or refractive outcome visible.

Contrast Sensitivity Outcomes

Figure 2 shows the mean contrast sensitivity function under photopic and mesopic conditions at 3 months after surgery. Contrast sensitivity values under photopic conditions were significantly better than those found under mesopic conditions for the spatial frequencies of 6 (P = .007), 12 (P = .005), and 18 (P = .011) cycles/degree. In contrast, no significant differences in contrast sensitivity between photopic and mesopic conditions were found for the spatial frequencies of 1.5 (P = .068) and 3 (P = .078) cycles/degree.

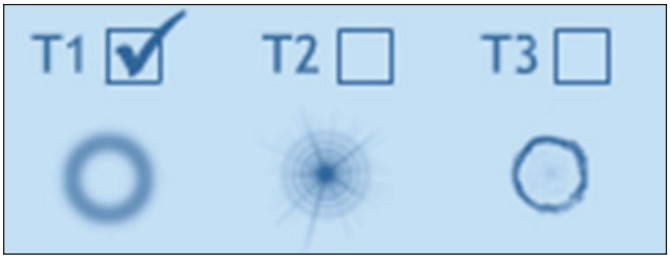

Figure 3. Types of halos (T1, T2, and T3) according to the simulator used in the study, the Halo & Glare Simulator (Eyeland-Design Network GmbH, Vreden, Germany).

Photic Phenomena Outcomes

Halos were reported after direct questioning by 9 patients (32%) and glare by 3 patients (11%). The analysis with the halo and glare simulator revealed the presence of halos of a mean size of 50.67 (SD: 15.69; median: 53; range: 31 to 75) and a mean intensity of 54.89 (SD: 17.86; median: 62; range: 33 to 79). Mean glare size and intensity were 39.67 (SD: 3.51; median: 40; range: 0 to 49) and 44.67 (SD: 15.01; median: 36; range: 14 to 68), respectively. Halos were classified as T1 in 55.6%, T2 in 44.4%, and T3 in 0% of eyes (**Figure 3**).

DISCUSSION

This study confirms the predictability of the refractive correction achieved with the evaluated trifocal toric IOL. These outcomes are consistent with those reported for other types of multifocal diffractive toric IOLs.[7,8,11,21] Alfonso et al.[21] found in a multicenter cohort study evaluating the outcomes of an apodized diffractive toric IOL (AcrySof IQ ReSTOR +3.0 D; Alcon Laboratories, Inc., Fort Worth, TX) that mean refractive cylinder decreased with surgery from 1.07 ± 0.71 to 0.33 ± 0.44 D, with 78.6% of eyes showing

a postoperative cylinder value of 0.50 D or less and 92.9% showing a value of 1.00 D or less. Bellucci et al.[8] conducted a multicenter study to evaluate the outcomes with a bifocal diffractive IOL using the same diffractive platform (AT LISA) as that used for the trifocal IOL evaluated in the current study. They found that the mean refractive cylinder decreased with surgery from -2.39 ± 1.48 to -0.49 ± 0.53 D, with a postoperative value of 1.00 D or less in 80.9% of eyes. Visser et al.[11] found in another study with the AT LISA bifocal toric IOL that the residual refractive astigmatism was 1.00 D or less in approximately 90% of eyes. Frieling-Reuss[7] reported on a comparative case series with the same bifocal toric IOL that the postoperative astigmatic power vector components (J_0 and J_{45}) were within ±0.50 D in more than 88% of cases.

The good level of refractive predictability observed in our series was one of the main factors leading to the good distance visual outcome. A mean monocular postoperative logMAR UDVA of 0.13 ± 0.15 was found in our series, which is similar to that reported by Law et al.[14] for the non-toric version of the AT LISA trifocal IOL (0.05 ± 0.07 logMAR). Mojzis et al.[13] found in a case series comprising 60 eyes of 30 patients implanted with the same trifocal IOL a mean monocular logMAR UDVA of -0.03 ± 0.09 at 6 months postoperatively. Furthermore, our mean postoperative monocular and binocular UDVA values were similar to or even better than those reported by other authors with other types of trifocal diffractive IOLs.[15-19] Cochener et al.[17] found a 3-month postoperative monocular and binocular logMAR UDVA of 0.08 ± 0.11 and 0.02 ± 0.09, respectively, in a sample of 90 eyes implanted with the FineVision IOL (PhysIOL, Liège, Belgium). In contrast, Sheppard et al.[16] reported a mean monocular 2-month postoperative logMAR UDVA of 0.19 ± 0.09 in a sample of 30 eyes implanted with the same trifocal IOL. Similarly, Alió et al.[15] found a mean 6-month postoperative logMAR UDVA of 0.18 ± 0.13 in a sample of 40 eyes also implanted with the FineVision IOL. Differences in sample size, patient characteristics, follow-up, and visual acuity testing may explain these differences between authors, even when analyzing the outcomes of the same type of IOL. Our monocular and binocular UDVA outcomes were also consistent with those reported for other types of multifocal diffractive toric IOLs.[3-12] Bellucci et al.[8] found a mean value for monocular postoperative UDVA of 0.16 ± 0.22 logMAR in a sample of eyes implanted with the bifocal AT LISA IOL. Ferreira et al.[5] obtained a mean 3-month postoperative UDVA of 0.07 ± 0.10 logMAR in 38 eyes implanted with an apodized diffractive multifocal IOL (Acrysof IQ ReSTOR toric IOL).

The near visual outcomes obtained in the current study were also similar to or better than those reported by other authors evaluating trifocal IOLs without toricity[13,14,17,18] and other multifocal toric IOLs.[3-12] Mojzis et al.[13] and Law et al.[14] reported mean values of 0.20 ± 0.12 (measured at 33 cm) and 0.16 ± 0.07 (binocularly measured at 40 cm), respectively, in eyes implanted with the non-toric version of the trifocal IOL of the same platform. With the trifocal IOL that combines two bifocal diffractive profiles (FineVision IOL), mean logMAR values of 0.26 ± 0.15 (measured at 40 cm) and 0.01 ± 0.06 (measured at 35 cm) have been reported by Alió et al.[15] and Cochener et al.,[17] respectively. With a binary in phase trifocal IOL (MIOL-Record), a mean logMAR UNVA of 0.07 was measured at the patients' preferred distance. Likewise, mean postoperative logMAR UNVA values of 0.06 ± 0.12 (binocular), 0.01 ± 0.04, 0.07 ± 0.09 (binocular), 0.21 ± 0.22 (monocular), 0.02 ± 0.09 (monocular), and 0.20 ± 0.16 (binocular) have been reported by Kretz et al.,[3] Crema et al.,[4] Alfonso et al.,[21] Bellucci et al.,[8] Ferreira et al.,[5] and Visser et al.,[11] respectively, for different multifocal toric IOLs (Tecnis ZMT, AT LISA 909M, and AcrySof IQ ReSTOR toric +3.0 D).

The level of intermediate visual acuity achieved with the evaluated trifocal toric IOL was good, with mean monocular and binocular UIVA of 0.08 logMAR and more than 80% of eyes achieving UIVA values better than 0.20 logMAR. This finding is consistent with the outcomes reported by other authors evaluating the same type of IOL but without toricity and also other non-toric trifocal IOLs and confirms the ability of the evaluated trifocal IOL of restoring intermediate vision successfully.[13-19] Mean logMAR UIVA values of 0.08 ± 0.10 (measured at 66 cm) and 0.03 ± 0.08 (measured at 80 cm) were found by Mojzis et al. in two different case series evaluating the AT LISA trifocal IOL without toricity.[13,22] Mean logMAR UIVA of 0.08 ± 0.12 (measured at 65 cm) was reported by Cochener et al.[17] when evaluating another non-toric trifocal IOL based on the combination of two bifocal diffractive patterns (FineVision IOL). In comparison to bifocal diffractive toric IOLs, the intermediate visual outcome was clearly better in our series with the trifocal toric IOL.[3,7,8,11] In a comparative study of the non-toric models of the bifocal and trifocal AT LISA IOLs conducted by Mojzis et al.,[22] significantly better UIVA was obtained in the group of eyes implanted with the trifocal IOL (bifocal 0.24 ± 0.16 vs. 0.03 ± 0.08, 80 cm, $P < .01$). A mean binocular logMAR UIVA of 0.21 ± 0.20 logMAR was reported by Kretz et al.[3] with a bifocal diffractive toric IOL (Tecnis ZMT, Abbott Medical Optics), and a mean monocular value of 0.40 ± 0.16 logMAR was reported

by Visser et al.[11] for the bifocal toric AT LISA IOL. This trend of a better intermediate visual outcome with the AT LISA trifocal toric IOL was also observed when our results were compared to those obtained with apodized diffractive toric IOLs, but the differences were of low magnitude.[5,22] A mean value of 0.16 ± 0.10 logMAR was found by Ferreira et al.[5] when evaluating the outcomes with an apodized diffractive IOL in a group of 38 eyes.

The generation of a third focal point with the evaluated trifocal IOL did not result in a detriment of the visual performance, with excellent levels of corrected distance, intermediate, and near visual acuities, and good levels of photopic and mesopic contrast sensitivity. This visual outcome is consistent with an optimized aberrometric outcome. Mojzis et al.[22] have shown a minimal induction of higher-order aberrations with the bifocal and trifocal IOL based on the AT LISA diffractive platform. These same authors also demonstrated that equivalent levels of contrast sensitivity were achieved with both types of IOL, with no significantly different levels in most of the ocular and intraocular higher-order aberrations.[22] Marques and Ferreira[23] recently found no significant differences in contrast sensitivity or dysphotopic phenomena between a group of eyes implanted with the non-toric FineVision and AT LISA tri 839MP model of trifocal IOLs. Law et al.[14] also measured the contrast sensitivity 6 months after cataract surgery with implantation of the same trifocal IOL as evaluated in the current study using the Pelli–Robson test. These authors found that mean 6-month postoperative photopic and mesopic contrast sensitivity were 1.52 ± 0.11 and 1.54 ± 0.11.[14]

The incidence of postoperative photic phenomena was limited, with 32% of patients reporting the presence of halos and 11% of patients reporting the perception of glare. In all cases, these photic phenomena were described as not disturbing. Size and intensity of glare and halos were characterized for the first time with a simulator to provide a quantitative analysis of this type of potentially disturbing perception. Future studies should evaluate the evolution over time of the perception of these phenomena. Law et al.[14] reported a reduction in the perception of halos over time in eyes implanted with the non-toric version of the AT LISA trifocal IOL, decreasing from 80% at 1 month to 40% at 6 months after surgery. Alba-Bueno et al.[24] reported on the theoretical and experimental characterization of halos in some multifocal IOLs. These authors stated that the most noticeable characteristic of halos with the non-toric model of the trifocal IOL evaluated in the current study was the double-halo formation due to the two non-focused powers.[24] In our sample, halos were classified in all cases as type 1 or 2 (**Figure 3**), which may be consistent with the theoretical characterization provided by Alba-Bueno et al.[24] Sheppard et al.[16] used halometry to measure the angular size of monocular and binocular photopic scotomas arising from a glare source in eyes implanted with the non-toric model of a trifocal diffractive IOL combining two bifocal diffractive patterns (FineVision IOL). The authors found that halometry showed a glare scotoma of a mean size similar to that in previous studies of multifocal and accommodating IOLs.[16]

Future studies should further characterize the visual outcome with the evaluated trifocal lens and address parameters such as defocus curves and subjective questionnaires with regard to the need for spectacles and satisfaction with the visual outcome.

Cataract surgery with implantation of the trifocal diffractive toric IOL evaluated in the current study was able to provide an effective restoration of distance, intermediate, and near vision in eyes with moderate to high levels of corneal astigmatism. This visual restoration is achieved with good levels of visual quality and a low incidence of photic phenomena.

AUTHOR CONTRIBUTIONS

Study concept and design (FTAK, DB, KK, HK, GUA); data collection (FTAK, DB, KK, PH, HK, MG, MM, RHG); analysis and interpretation of data (FTAK, DB, KK, PH, HK, MJK, MM, GUA); writing the manuscript (FTAK); critical revision of the manuscript (DB, KK, PH, HK, MJK, MG, MM, RHG, GUA); statistical expertise (FTAK, PH); administrative, technical, or material support (DB, MG, MM); supervision (FTAK, DB, KK, HK, GUA)

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