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 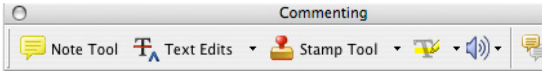

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 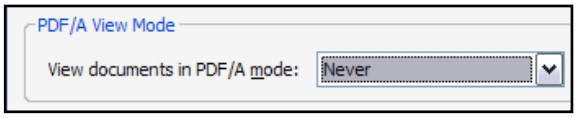

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 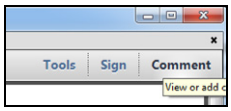

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 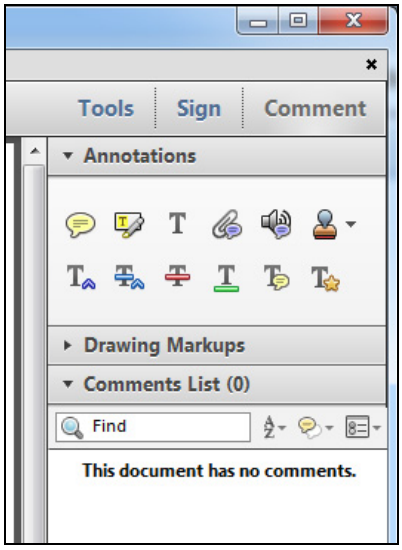
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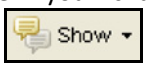
Review	To review your changes, click on the 'Show' button  on the Commenting tool bar. Choose 'Show Comments List'. Navigate by clicking on a correction in the list. Alternatively, double click on any mark-up to open the commenting box.	Your changes will appear automatically in a list below the Comment tool bar. Navigate by clicking on a correction in the list. Alternatively, double click on any mark-up to open the commenting box.
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Implantation of a diffractive trifocal intraocular lens: One-year follow-up

Peter Mojzis, MD, PhD, FEBO, Katarina Majerova, MD, Lucia Hrckova, MD, David P. Piñero, PhD

PURPOSE: To evaluate the visual, refractive, contrast-sensitivity, and aberrometric outcomes during a 1-year follow-up for an implantation of a trifocal intraocular lens (IOL).

SETTING: Premium Clinic, Teplice, Czech Republic.

DESIGN: Prospective case series.

METHODS: This study included eyes of patients having cataract surgery with implantation of the trifocal IOL model AT Lisa tri 839MP. Distance, intermediate (66 and 80 cm), and near (33 and 40 cm) vision, contrast sensitivity, and aberrometric outcomes, and the defocus curve were evaluated during a 12-month follow-up. The level of posterior capsule opacification (PCO) was also evaluated.

RESULTS: In 120 eyes (60 patients), at 1 month postoperatively, an improvement was observed in all visual parameters ($P \leq .03$) except corrected near and intermediate visual acuities ($P \geq .05$ for both). From 1 month to 12 months postoperatively, small but statistically significant changes were observed in uncorrected and corrected distance and near visual acuities ($P \leq .03$ for all 4 acuities) and in uncorrected intermediate visual acuity($P = .01$). In the defocus curve, no significant differences were found between visual acuities corresponding to defocus levels of −1.0 and −2.0 diopters ($P = .22$). The level of ocular spherical aberration decreased statistically significantly at 6 months ($P < .001$). Ocular and internal higher-order aberrations increased minimally but significantly from 6 to 12 months postoperatively ($P < .001$). The mean 12-month PCO score was 0.32 ± 0.44 (SD). Four eyes (3.3%) required neodymium:YAG capsulotomy.

CONCLUSION: The trifocal IOL evaluated provides a complete and stable visual restoration after cataract surgery during a 12-month follow-up, with good levels of visual quality associated.

Financial Disclosure: No author has a financial or proprietary interest in any material or method mentioned.

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Diffractive trifocal intraocular lenses (IOLs) provide 3 useful focal distances—far, intermediate, and near—and therefore provide a functional visual restoration after cataract surgery.[1,2] These 3 foci can be generated by combining 2 bifocal diffractive profiles in 1 surface of the IOL[2] or by using a trifocal diffractive profile, combined or not with a bifocal diffractive optics.[1,3] Trifocal IOLs based on these 2 approaches have shown good visual, refractive, and contrast sensitivity outcomes in a relatively short term (up to 6 months of follow-up)[1,3–8] that are consistent with the results of some optical simulations in the optical bench.[9–11] However to date, there are no studies reporting the results with this modality of multifocal IOL in the medium and long term. The aim of the present study was to evaluate the visual, refractive, contrast-sensitivity, and aberrometric outcomes with a specific trifocal IOL model during a 1-year follow-up to confirm the stability of the outcomes obtained with this option for presbyopia correction.

PATIENTS AND METHODS

Patients

All patients in this prospective study had uneventful phacoemulsification surgery with bilateral implantation of the trifocal IOL AT Lisatri 839MP (Carl Zeiss Meditec AG). Included were patients with cataract or presbyopic or pre-presbyopic eyes suitable for refractive lens exchange who were seeking spectacle independence and had preexisting corneal astigmatism of less than 1.25 diopters (D). Exclusion criteria a history of glaucoma or retinal detachment, corneal disease, irregular corneal astigmatism, abnormal iris, macular degeneration or retinopathy, neuroophthalmic disease, ocular inflammation, or ocular surgery. All patients

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0886-3350

provided informed, written consent before participating in the study. The study adhered to the tenets of the Declaration of Helsinki and it was approved by the local ethics committee.

Examination Protocol

Before surgery, a complete ophthalmological examination was performed including manifest refraction; keratometry; measurement of monocular uncorrected (UDVA) and corrected (CDVA) distance visual acuity using the Early Treatment of Diabetic Retinopathy Study (ETDRS) charts; measurement of monocular uncorrected (UIVA) and corrected (CIVA) intermediate visual acuity at 66 cm (modified ETDRS for European-wide use for near and intermediate distance recordings, Precision Vision) and 80 cm (Logarithmic Visual Acuity Charts, calibrated for testing at 80 cm, Precision Vision); measurement of monocular uncorrected (UNVA) and corrected (CNVA) near visual acuity at 33 cm (Modified ETDRS for European-wide use for near and intermediate distance recordings, Precision Vision) and 40 cm (Logarithmic Visual Acuity Chart – ETDRS 2000, calibrated for testing at 40 cm, Precision Vision); measurement of monocular distance-corrected near (DCNVA) (33 and 40 cm) and intermediate (DCIVA) visual acuity (66 and 80 cm); Goldmann applanation tonometry; slitlamp examination; ocular aberrometry and corneal topography (both OPD Scan III, Nidek Co., Ltd.); biometry (IOLMaster v.4.3, Carl Zeiss Meditec AG); and fundoscopy. The analysis of optical aberrations was performed under pupil dilation and considering a pupil aperture of analysis of 5.0 mm. The following parameters were calculated and recorded for the corneal, internal, and ocular optics: coma, Z(3−1), Z(3,1); and higher-order aberrations (HOAs) root mean square (RMS); and the Zernike coefficient for spherical aberration, Z(4,0).

Postoperatively, patients were evaluated at 1 day and 1, 3, 6, and 12 months. The postoperative examination protocol was identical to the preoperative protocol, but with these additional tests 12-months visit: Evaluation of the defocus curve to evaluate the range of functional function; contrast-sensitivity measurement under photopic (85 cd/m^2) and mesopic conditions (3 cd/m^2) (CSV-1000, VectorVision); and evaluation of the level of posterior capsular opacification (PCO) in the central 4.3-mm zone (Evaluation of Posterior Capsule Opacification [EPCO] 2000 software).[12] For the evaluation of the defocus curve, patients wore the correction providing the distance visual acuity in both eyes and the ETDRS charts were used at a distance of 4 meters. Different levels of defocus were introduced in 0.5 D steps from +1.00 D to −4.00 D and visual acuity values were recorded. All these data were then represented in a Cartesian graphic display, with the *x*-axis showing the levels of defocus and the *y*-axis the visual acuity achieved.

Surgery

All surgeries were performed by the same experienced surgeon (P.M.) using a standard technique of sutureless 1.6 mm microincision phacoemulsification. All incisions were made at the temporal area. Topical anesthesia and mydriatic drops were instilled in all cases before the surgical procedure. After capsulorhexis creation and phacoemulsification, the IOLs were inserted into the capsular bag using the Bluemixs 180 injector (Carl Zeiss Meditec AG) through the main incision. The interval between the surgeries of both eyes was 1 to 2 days. Postoperatively a combination antibiotic and steroid was prescribed to be applied topically 4 times a day for 1 week. Nonsteroidal antiinflammatory drops were applied 3 times immediately preoperatively and then were prescribed postoperatively at 5 times per day for 3 weeks.

Intraocular Lens

The IOL used is a diffractive trifocal preloaded IOL with a 6.0 mm biconvex optic, an overall length of 11.0 mm, and a posterior surface with asphericity of −0.18. It has a 4-haptic design with an angulation of 0 degrees. The IOL optic has a 360-degree square edge to prevent PCO, with no interruption at the optic–haptic junction, providing an anti-PCO barrier ring around the optic (Figure 1). The IOL is made of foldable hydrophilic acrylate with a water content of 25% and has a hydrophobic surface and a refractive index of 1.46.

Regarding the optic design, this IOL is trifocal within the central 4.34 mm of IOL diameter, but bifocal in the outer 4.34 to 6.0 mm of the diameter. In the trifocal area, the IOL provides a near addition (add) of +3.33 D and an intermediate add of +1.66 D, both calculated at the IOL plane. The add power in the outer band from 4.34 mm to 6.00 mm is +3.75 D (as for the bifocal IOL model). The IOL is available in spherical powers from 0 to 32 D in 0.5 D increments. Its design allocates 50% of light to far, 20% to intermediate, and 30% to near. The manufacturer's A-constant for this IOL is 118.6. In this study, the SRK/T formula[13] was used to calculate the IOL power to use according to the corneal power, axial length (AL), and anterior chamber depth (ACD) measured with partial coherence interferometry. The target refraction was emmetropia in all cases.

Statistical Analysis

The SPSS statistics software package (version 15.0 for Windows, International Business Machines Corp.) 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 *t* test for paired data was performed for all parameter comparisons between preoperative and postoperative examinations and between consecutive postoperative visits. When parametric analysis was not possible, the Wilcoxon rank sum test was applied to assess the significance of differences between examinations. In all cases, $P < .05$ was considered statistically significant.

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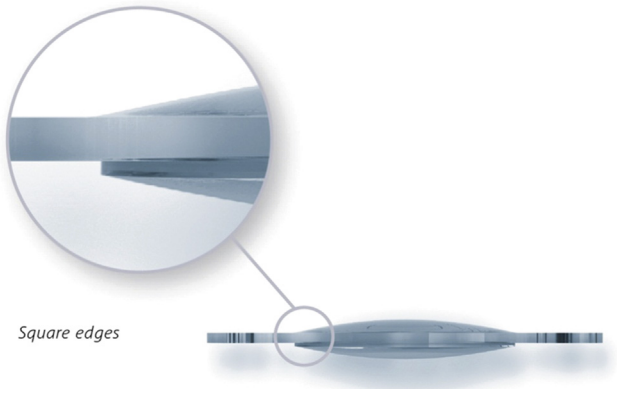

Figure 1. The 360-degree, square edge of the trifocal IOL designed to prevent PCO with no interruption at the optic–haptic junction.

RESULTS

The study enrolled 120 eyes of 60 patients with a mean age of 58 years (range 44 to 71 years). The mean preoperative AL was 23.50 mm ± 1.45 (SD), median 23.26 (range 21.05 to 28.09 mm). The mean preoperative ACD was 3.22 ± 0.32 mm, median 3.16 (range 2.55 to 4.05 mm). The mean preoperative keratometry was 43.40 ± 1.47 D, median 43.49 D (range 39.76 to 46.98 D). The mean value of the IOL power implanted was 21.22 ± 4.62 D, median 22.00 D (range 8.50 to 29.50 D).

Visual Acuity and Refractive Outcomes

Table 1 summarizes the visual outcomes for the study sample during the entire follow-up period. At 12 months, there was statistically significant improvement in UDVA, UNVA measured at 33 and 40 cm, UIVA at 66 and 80 cm, DCNVA at 33 and 40 cm, and DCIVA at 66 and 80 cm ($P < .001$). In contrast, no statistically significant changes were observed at 12 months in CDVA, CNVA, and CIVA ($P \geq .087$). At 1 month postoperatively, an improvement was observed in all visual parameters ($P \leq .03$), except CNVA measured at 33 cm ($P = .05$) and CIVA at 66 cm ($P = .24$) and 80 cm ($P = .25$). From 1 month to 12 months postoperatively, small but statistically significant changes were observed in UDVA ($P < .001$), CDVA ($P < .001$), UNVA measured at 33 cm ($P = .03$) and 40 cm ($P < .001$), CNVA at 33 cm ($P = .03$), DCNVA at 33 cm ($P = .001$), UIVA at 66 cm ($P = .01$) and 80 cm ($P = .001$), and DCIVA at 66 cm ($P = .04$). In contrast, changes during this period in CNVA measured at 40 cm ($P = .05$), DCNVA at 40 cm ($P = .05$), CIVA at 66 ($P = .90$) and 80 cm ($P = .09$), and DCIVA at 80 cm ($P = .12$) were not statistically significant. At 12 months, the UNVA, CNVA, and DCNVA were statistically significantly better when measured at 33 cm than at 40 cm (all $P < .001$). However, no statistically significant differences were found between UIVA ($P = .23$), CIVA ($P = .14$), and DCIVA ($P = .34$) measured at 66 and 80 cm.

Figure 2 shows the evolution of manifest sphere and cylinder during the entire follow-up. Changes in manifest sphere ($P = .001$) and cylinder ($P = .003$) were statistically significant at 1 month. From 1 month to 12 months, statistically significant changes were observed in sphere ($P < .001$), but not in manifest cylinder ($P = .093$).

Defocus Curve

The defocus curves were obtained binocularly at the end of the follow-up. Figure 3 shows a display of the mean defocus curve obtained in our study. No statistically significant differences were found between the visual acuities obtained for defocus levels of −1.0 and −2.0 D ($P = .22$); however, the visual acuity for the defocus of −1.5 D was statistically significantly better than that corresponding to a level of defocus of −3.0 D ($P < .001$) (Figure 3).

Contrast-Sensitivity Outcomes

Figure 4 shows the mean contrast sensitivity function obtained in the 2 groups of eyes postoperatively under photopic and mesopic conditions. Photopic contrast sensitivity was statistically significantly better than that measured under mesopic conditions for all spatial frequencies evaluated ($P < .001$).

Aberrometric Outcomes

Figure 5 shows the preoperative, 6-month, and 12-month postoperative aberrometric data for internal and global ocular optics in the evaluated sample. No statistically significant changes were observed in ocular HOAs ($P = .967$) and coma RMS ($P = .871$) at 6 months; however, the RMS of the ocular HOAs increased significantly from 6 to 12 months postoperatively ($P < .001$), with no statistically significant changes in coma RMS ($P = .247$). The level of ocular spherical aberration decreased statistically significantly at 6 months ($P < .001$), with no statistically significant changes afterward ($P = .306$) (Figure 5).

A statistically significant change in internal aberrations was observed in HOAs ($P = .017$) and in coma RMS ($P < .001$), as well as in the Zernike term corresponding to primary spherical aberration at 6 months ($P < .001$). From 6 to 12 months postoperatively, a statistically significant change was observed in HOAs RMS ($P = .013$), but not in the levels of coma ($P = .816$) and spherical aberration ($P = .410$) (Figure 5).

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Table 1. Preoperative and postoperative monocular visual acuities.

	Visual Acuity Measurement (LogMAR)					
		Postoperative				
Acuity Measured	Preoperative	1 Month	3 Months	6 Months	12 Months	*P* Value*
UDVA						<.001
Mean ± SD	0.55 ± 0.42	−0.01 ± 0.09	−0.02 ± 0.10	−0.02 ± 0.09	0.03 ± 0.13	
Median (range)	0.40 (0.00, 2.00)	0.00 (−0.20, 0.20)	0.00 (−0.20, 0.30)	0.00 (−0.20, 0.20)	0.00 (−0.20, 0.50)	
CDVA						.104
Mean ± SD	0.02 ± 0.25	−0.03 ± 0.08	−0.03 ± 0.09	−0.03 ± 0.08	0.01 ± 0.11	
Median (range)	0.00 (−0.30, 2.00)	0.00 (−0.20, 0.20)	0.00 (−0.20, 0.20)	0.00 (−0.20, 0.20)	0.00 (−0.20, 0.40)	
UNVA, 33 cm						<.001
Mean ± SD	0.86 ± 0.26	0.17 ± 0.12	0.16 ± 0.12	0.18 ± 0.12	0.23 ± 0.15	
Median (range)	0.90 (0.10, 1.40)	0.20 (−0.10, 0.50)	0.10 (−0.10, 0.50)	0.20 (−0.10, 0.50)	0.20 (0.00, 0.70)	
CNVA, 33 cm						.872
Mean ± SD	0.13 ± 0.17	0.15 ± 0.11	0.11 ± 0.09	0.11 ± 0.09	0.12 ± 0.09	
Median (range)	0.10 (−0.20, 0.90)	0.10 (0.00, 0.50)	0.10 (−0.10, 0.30)	0.10 (−0.10, 0.40)	0.10 (0.00, 0.40)	
DCNVA, 33 cm						<.001
Mean ± SD	0.63 ± 0.20	0.17 ± 0.11	0.15 ± 0.11	0.16 ± 0.11	0.21 ± 0.14	
Median (range)	0.60 (0.10, 1.00)	0.20 (0.00, 0.50)	0.10 (−0.10, 0.40)	0.20 (−0.10, 0.40)	0.20 (0.00, 0.70)	
UNVA, 40 cm						<.001
Mean ± SD	0.86 ± 0.26	0.22 ± 0.11	0.23 ± 0.11	0.22 ± 0.10	0.27 ± 0.15	
Median (range)	0.90 (0.10, 1.40)	0.20 (0.00, 0.60)	0.20 (0.00, 0.50)	0.20 (0.00, 0.50)	0.20 (0.00, 0.70)	
CNVA, 40 cm						.087
Mean ± SD	0.14 ± 0.18	0.18 ± 0.10	0.18 ± 0.10	0.16 ± 0.09	0.16 ± 0.09	
Median (range)	0.10 (−0.20, 1.00)	0.20 (0.00, 0.40)	0.20 (0.00, 0.40)	0.20 (0.00, 0.30)	0.10 (0.00, 0.50)	
DCNVA, 40 cm						<.001
Mean ± SD	0.63 ± 0.20	0.22 ± 0.12	0.23 ± 0.12	0.22 ± 0.10	0.25 ± 0.14	
Median (range)	0.60 (0.10, 1.20)	0.20 (0.00, 0.60)	0.20 (0.00, 0.50)	0.20 (0.00, 0.50)	0.20 (0.00, 0.70)	
UIVA, 66 cm						<.001
Mean ± SD	0.73 ± 0.28	0.08 ± 0.10	0.09 ± 0.09	0.08 ± 0.09	0.12 ± 0.13	
Median (range)	0.70 (0.10, 1.40)	0.10 (−0.10, 0.40)	0.10 (−0.10, 0.40)	0.10 (−0.10, 0.40)	0.10 (−0.10, 0.50)	
CIVA, 66 cm						.209
Mean ± SD	0.07 ± 0.20	0.07 ± 0.10	0.07 ± 0.09	0.06 ± 0.09	0.08 ± 0.09	
Median (range)	0.00 (−0.20, 0.80)	0.10 (−0.10, 0.40)	0.10 (−0.10, 0.30)	0.05 (−0.10, 0.40)	0.10 (−0.10, 0.30)	
DCIVA, 66 cm						<.001
Mean ± SD	0.36 ± 0.25	0.08 ± 0.10	0.09 ± 0.09	0.08 ± 0.10	0.11 ± 0.12	
Median (range)	0.30 (−0.10, 1.10)	0.10 (−0.10, 0.40)	0.10 (−0.10, 0.40)	0.10 (−0.10, 0.40)	0.10 (−0.10, 0.50)	
UIVA, 80 cm						<.001
Mean ± SD	0.71 ± 0.27	0.07 ± 0.09	0.07 ± 0.09	0.07 ± 0.08	0.11 ± 0.13	
Median (range)	0.70 (0.10, 1.40)	0.10 (−0.10, 0.30)	0.10 (−0.20, 0.30)	0.10 (−0.20, 0.30)	0.10 (−0.10, 0.50)	
CIVA, 80 cm						.819
Mean ± SD	0.08 ± 0.19	0.05 ± 0.10	0.06 ± 0.09	0.05 ± 0.08	0.07 ± 0.10	
Median (range)	0.00 (−0.20, 0.80)	0.00 (−0.10, 0.30)	0.10 (−0.20, 0.30)	0.00 (−0.20, 0.30)	0.10 (−0.10, 0.40)	
DCIVA, 80 cm						<.001
Mean ± SD	0.33 ± 0.26	0.07 ± 0.09	0.07 ± 0.09	0.07 ± 0.08	0.11 ± 0.13	
Median (range)	0.30 (−0.10, 1.10)	0.10 (−0.10, 0.30)	0.10 (−0.20, 0.30)	0.10 (−0.20, 0.30)	0.10 (−0.10, 0.50)	

CDVA = corrected distance visual acuity; CNVA = corrected near visual acuity; DCIVA = distance-corrected intermediate visual acuity; DCNVA = distance-corrected near visual acuity; UDVA = uncorrected distance visual acuity; UIVA = uncorrected intermediate visual acuity; UNVA = uncorrected near visual acuity

*Preoperative to 12 months

Complications

During the 12-month follow-up, neodymium:YAG (Nd:YAG) capsulotomy was required in 4 eyes (3.3%) because of the presence of significant levels of PCO. Likewise, 15 eyes (12.5%) had surgical aspiration of proliferative forms (Elschnig pearls). Therefore,

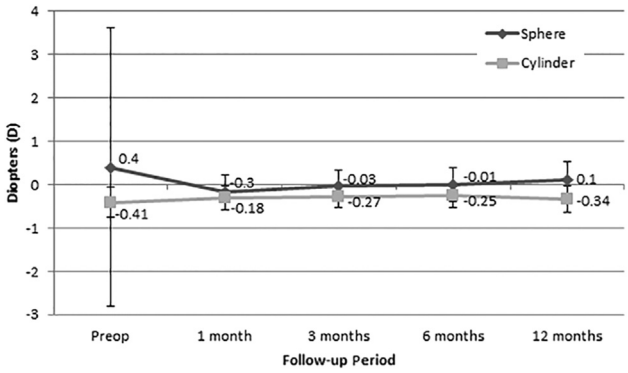

Figure 2. Changes in manifest sphere (*dark gray*) and cylinder (*clear gray*) at the 12-month follow-up.

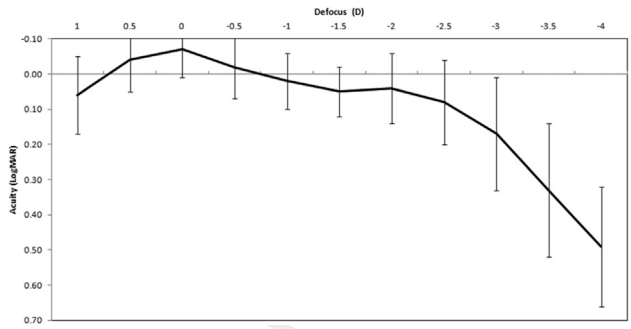

Figure 3. Mean defocus curve at 12 months postoperatively.

significant PCO was found in 19 eyes (15.8%). The mean EPCO score at 12 months postoperatively was 0.32 ± 0.44, median 0.11 (range 0.00 to 2.11).

DISCUSSION

Some studies have evaluated the outcomes of diffractive trifocal IOLs but the maximum follow-up reported to date is 6 months. To our knowledge, this is the first study reporting the outcomes of a specific model of trifocal IOL at 12 months after surgery.[1,3–8] The distance visual outcomes obtained in the initial period of follow-up in our series are consistent with those reported by other authors previously with the same model of trifocal IOL (logMAR UDVA and CDVA of approximately 0.0).[3,4] In contrast, the UDVA values in the early follow-up for 2 other models of trifocal IOLs evaluated and reported in the peer-reviewed literature (fully trifocal[1] and combination of 2 bifocal patterns[5–8]) are somewhat worse than those obtained with the trifocal IOL evaluated in the present study (the combination bifocal–trifocal pattern). Besides the optical performance of the trifocal IOL, several other factors might have contributed to these differences in distance visual outcomes between trifocal IOLs, eg, patient ages, sample size, nonoptimized selection of the IOL constant, or differences in the clinical protocol followed when measuring the visual acuity. In our study, the predictability of the refractive correction was excellent, with a mean postoperative spherical equivalent (SE) of −0.30 ± 0.42 D at 1 month and −0.08 ± 0.39 D at 12 months, and with 90.8% of eyes having an SE within ±0.50 D at 12 months. This confirms the refractive precision of the correction achieved with the evaluated IOL, suggesting that the constant defined for the power calculations with this IOL was appropriate.

Regarding near visual outcomes, our results (logMAR UNVA of approximately 0.2) were consistent or lower than those reported in previous studies evaluating the same model of trifocal IOL[3,4] and other trifocal IOL models.[1,5,6,8] To date, the best reported UNVA outcomes with a trifocal IOL were by Cochener et al.[7] for

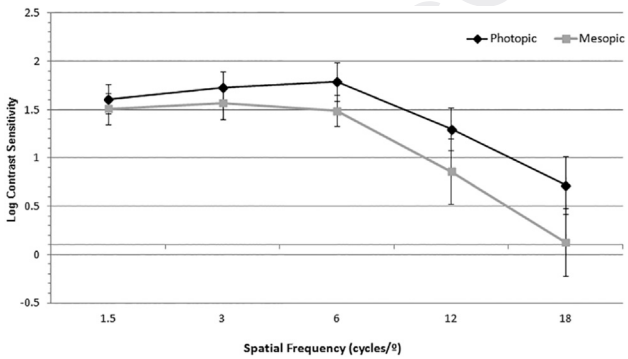

Figure 4. The mean 12-month postoperative contrast sensitivity function measured under photopic (*black line*) and mesopic conditions (*gray line*).

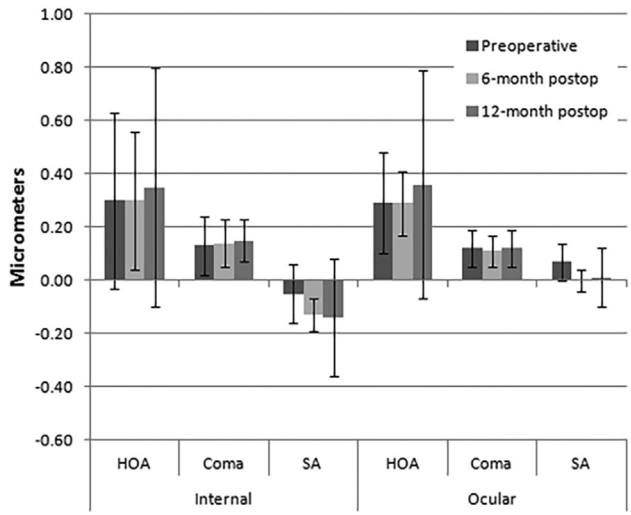

Figure 5. Distribution of preoperative and 6- and 12-month postoperative ocular (*right*) and internal (*left*) aberrometric data. HOA = higher-order aberration; SA = spherical aberration.

the trifocal IOL combining 2 bifocal diffractive patterns, for which the UNVA measured at 35 cm was 0.01 ± 0.06 logMAR. Regarding intermediate vision, a UIVA value of approximately 0.10 logMAR was found in most of the cases in the present study, as in previous series evaluating different models of trifocal IOLs.[1,3–8] Only the study of Alió et al.[5] reported a lower mean logMAR UIVA (0.20 ± 0.11 measured at 80 cm) with the trifocal IOL combining 2 bifocal patterns. This variability between authors even for the same type of IOL might be attributable to differences in terms of clinical protocol and sample selection. These discrepancies might also account for the significant disparity between our study's UNVA and UIVA outcomes with the trifocal IOL and the outcomes for other types of multifocal IOLs.[14–17] There were studies showing better results than ours without using the trifocal concept and others providing worse or similar visual outcomes compared to ours.[14–17]

The defocus curve showed a similar shape in our series as for the same trifocal IOL studied by Mojzis et al.[3] and for the trifocal IOL combining 2 bifocal patterns studied by Alió et al.,[5] Sheppard et al.,[6] Cochener et al.,[7] and Lesieur.[8] Our defocus curve showed a maximum of visual acuity for zero defocus (distance vision), with a slight drop afterward but maintaining a functional range of visual acuity with values of 0.1 logMAR or better, for defocus levels between 0 D and −2.5 D. Therefore, an effective restoration of the distance, intermediate, and near visual function was achieved with the evaluated IOL. This functional visual restoration was accompanied by the achievement of a good contrast-sensitivity outcome and a reduction in the level of ocular spherical aberration, reaching values of almost zero in almost all patients, as in a previous series evaluating the same type of trifocal IOL.[3]

During the 12-month follow-up, minimal but statistically significant changes in the visual outcomes achieved were observed. Specifically, a worsening of half of a line of logMAR visual acuity or less was observed from 1 to 12 months postoperatively in the UDVA, CDVA, UNVA measured at 33 cm and 40 cm, DCNVA at 33 cm, UIVA at 66 cm and 80 cm, and DCIVA at 66 cm. This visual worsening was consistent with a small but also statistically significant increase in the level of ocular and internal HOAs, without specific changes in the level of primary coma. Similar late postoperative visual acuity and quality changes were reported in a previous study evaluating a bifocal IOL based on the same diffractive platform.[14] One potential explanation for this visual worsening might be the development of some degree of PCO deteriorating the level of visual acuity and quality provided by the trifocal IOL. However, this factor would seem to only partly explain the visual and aberrometric changes over time because the mean level of PCO measured at 12 months postoperatively with the EPCO software was low. LogMAR distance visual acuity has been shown to be unaffected when low values of PCO evaluated by means of the EPCO software are present.[18] Another possible contributing factor to changes in visual acuity and aberrations in our study sample is the presence of minimal positional modifications caused by capsule changes with time. There are reports of late postoperative changes in the position of IOLs implanted in the bag during cataract surgery.[19,20] Capsule contraction has been shown to cause changes in IOL position in the late postoperative period,[21] although the effect of this seems to vary depending on the haptic design of the IOL.[19] Considering that small amounts of decentration or tilting of a diffractive multifocal IOL can generate a deterioration of the visual performance,[22] late positional IOL changes could contribute to late visual and aberrometric changes. Future studies should confirm this using imaging techniques to evaluate the anatomical position of the IOL within the capsular bag after its implantation. Likewise, studies with a longer follow-up are needed to further evaluate this issue.

Finally, the PCO rate at 12 months in our series was 15.8%, with 3.3% of cases having Nd:YAG capsulotomy and 12.5% requiring surgical aspiration because of the presence of proliferative forms. Other studies have found PCO rates comparable or worse than the rates in our study with other types of IOL for a 12-month and even longer follow-up periods. Gauthier et al.[23] found that 4.4% of eyes with a hydrophobic multifocal IOL and 14.6% of eyes with a hydrophilic multifocal IOL required a Nd:YAG capsulotomy 18 months postoperatively in. These rates at 24 months postoperatively to 8.8% and 37.2%, respectively. Shah et al.[24] found that Nd:YAG capsulotomy was necessary in 15.49% of eyes with a multifocal IOL and 5.82% of eyes with a monofocal IOL during a mean follow-up period of 22 months. Biber et al.[25] reported PCO rates of 42.7%, 28.0%, and 14.7% in eyes implanted with a multifocal, monofocal spherical, and monofocal aspheric IOL, respectively, during a mean follow-up period of 15.9 months.

In our study, the incidence of proliferative forms being present was relatively high. Several factors might account for this finding, eg, the surgical procedure or a potentially high intrinsic proliferative capacity of the lens epithelial cells in some patients.[26] Likewise, the IOL material and design might have influenced this significantly,[27] although previous studies evaluating the bifocal IOL based on the same diffractive platform have not shown this rate of proliferative forms of PCO.[15]

In conclusion, the trifocal diffractive IOL evaluated can provide an effective distance, intermediate, and near visual restoration after cataract surgery during a 12-month follow-up, with good levels of visual quality. Future studies should be conducted to confirm whether these outcomes are maintained in the long term and to assess the real impact of IOL positional changes into the capsular bag and PCO on the clinical outcomes achievable with the trifocal IOL evaluated.

WHAT WAS KNOWN

- Trifocality can be achieved by combining a bifocal diffractive and trifocal patterns on the posterior surface of an IOL.
- Diffractive trifocal IOLs based on this concept provide 3 useful focal distances—far, intermediate, and near—and therefore provide a functional visual restoration during a period of 6 months after cataract surgery.

WHAT THIS PAPER ADDS

- The trifocal IOL combining a bifocal and trifocal diffractive pattern on its posterior surface maintained an effective distance, intermediate, and near visual restoration after cataract surgery during a 12-month follow-up.
- This level of visual acuity restoration was accompanied by good levels of contrast sensitivity and physiological levels of ocular aberrations.
- Minimal but statistically significant visual and aberrometric changes might occur with this IOL during a 12-month follow-up.

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