Comparative Analysis of Clinical Outcomes Obtained With a New Diffractive Multifocal Toric Intraocular Lens Implanted Through Two Types of Corneal Incision

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ABSTRACT

PURPOSE: To analyze and compare the clinical outcomes obtained after cataract surgery with the implantation of a new multifocal toric intraocular lens (IOL) using two different types of corneal incision.

METHODS: Retrospective study including 64 eyes of 35 patients who underwent surgery with implantation of the AT LISA 909M multifocal toric IOL (Carl Zeiss Meditec) in 2 different ophthalmologic centers using different criteria for corneal incision size: sub-1.8 mm (microincision surgery [MICS] group) and 2.2 mm (mini-incision group). Visual, refractive, and corneal topographic outcomes were evaluated during 6-month follow-up. Additionally, refractive astigmatic changes were analyzed using the Alpins vectorial method.

RESULTS: Significant reductions of refractive sphere and cylinder were observed postoperatively ($P<.03$), with associated visual improvements for near and distance ($P<.01$) in both groups. Mean postoperative magnitudes of difference vector, torque, and magnitude of error in the overall sample were 0.52±0.36 diopters (D), 0.36±0.36 D, and 0.08±0.38 D, respectively. A mean overcorrection of 4% in refractive astigmatism was found. Mean angle of error was 0.37±5.50° and −4.51±13.16° for the MICS and mini-incision groups, respectively ($P=.09$). Significant positive correlations were found between the magnitudes of torque and difference vector (r=0.78, $P<.01$) as well as between the magnitude of torque and absolute angle of error (r=0.76, $P<.01$).

CONCLUSIONS: Implantation of the AT LISA toric IOL using corneal incisions <2.2 mm provides excellent predictability for astigmatic correction. [*J Refract Surg*. 2011;27(9):648-657.]
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Toric intraocular lenses (IOLs) have been created to address the correction of pre-existing astigmatism by inducing the required toricity for compensating corneal astigmatism.[1,2] They are aimed at providing complete distance visual rehabilitation and are especially useful for some cases normally associated with high levels of corneal astigmatism, such as ectatic or post-keratoplasty corneas.[3,4] However, monofocal toric designs are unable to compensate for the loss of accommodative ability after crystalline lens extraction and the subsequent visual deficit in intermediate and near distance conditions. Therefore, the concept of combining multifocal and toric surfaces in an IOL to provide complete visual rehabilitation seems to be an optimal option for patients with cataract and significant corneal astigmatism.

The AT LISA toric IOL (Carl Zeiss Meditec, Jena, Germany) was the first multifocal toric IOL developed, following the concept of simultaneous compensation of astigmatism and near visual defect. As multifocal diffractive IOLs allow successful near and distance visual rehabilitation,[5,6] the combination of this physical basis with a toric surface was thought to be a good option for cataract patients with significant levels of corneal toricity. Liekfeld et al[7] reported excellent preliminary visual outcomes in a sample of 10 eyes with this IOL. However, a study with a larger sample of eyes, includ-

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ing vector analysis of astigmatic changes, is required to confirm the potential of this specific IOL. (Astigmatism is a vectorial variable associated with magnitude and axis.) Furthermore, the potential impact of the corneal incision on the outcomes obtained with this IOL is still pending.

The aim of the current study was to analyze the visual and refractive outcomes as well as to study the astigmatic changes by means of the Alpins vector method after cataract surgery following implantation of a new diffractive multifocal toric IOL, the AT LISA 909M (Carl Zeiss Meditec) using two different types of corneal incision, sub-1.8 mm (microincision surgery [MICS]) and 2.2 mm (mini-incision surgery).

PATIENTS AND METHODS

Patient Population

This retrospective, multicenter, nonrandomized, consecutive comparative series of cases included 64 eyes of 35 patients ranging in age from 20 to 61 years. Two centers participated in the inclusion of patients for this study: Vissum Instituto Oftalmológico de Alicante (Spain) and Eye Department, Regional Hospital, Havlickuv Brod (Czech Republic). Inclusion criteria were patients with visually significant cataract or presbyopic/pre-presbyopic patients suitable for refractive lens exchange seeking complete spectacle independence, and refractive astigmatism ⩾0.75 diopters (D) that was consistent with corneal toricity. Exclusion criteria were patients with a history of glaucoma or retinal detachment, corneal disease, irregular corneal astigmatism, abnormal iris, macular degeneration or retinopathy, neurophthalmic disease, or ocular inflammation. All patients were adequately informed and signed a consent form. The study adhered to the tenets of the Declaration of Helsinki and was approved by the local ethics committee.

Pre- and Postoperative Protocol

Preoperatively, all patients had a full ophthalmologic examination including the following clinical tests: uncorrected and corrected distance and near visual acuities (Snellen and Radner charts, respectively), manifest refraction, slit-lamp examination, Goldmann applanation tonometry, corneal topography (two Placido-based devices: CSO [Costruzione Strumenti Oftalmici, Florence, Italy] and Atlas 9000 [Carl Zeiss Meditec]), biometry (IOLMaster v.4.3, Carl Zeiss Meditec), and funduscopy. Regarding the corneal topographic examination, the following parameters were evaluated and recorded: corneal dioptric power in the flattest meridian (K1), corneal dioptric power in the steepest meridian (K2), mean corneal power (KM), and corneal astigmatism (calculated as the difference between K2 and K1) for the 3-mm central zone.

Patients were evaluated at 1 day and 1, 3, and 6 months postoperatively. At 1 day after surgery, only uncorrected distance visual acuity (UDVA), intraocular pressure (IOP), and the integrity of the anterior segment were evaluated. The postoperative examination protocol at 1, 3, and 6 months was identical to the preoperative protocol, with the additional analysis of operative astigmatic changes by means of the Alpins vectorial method. For the purpose of the present study, the pre- and 6-month postoperative data are reported to summarize and provide a better understanding of the general outcomes.

Surgery

All surgeries were performed by the same experienced surgeons (P.M., J.L.A.) using a standard technique of sutureless coaxial phacoemulsification. In all cases, topical anesthesia drops were instilled prior to the surgical procedure. Adequate dilation was obtained with intracameral mydriasis. Two different types of incision were used depending on the center and surgeon: bimanual MICS with a final incision size after IOL implantation of ⩽1.8 mm (J.L.A., Spain; 23 eyes) and a corneal incision of 2.2 mm (mini-incision surgery) (P.M., Czech Republic; 41 eyes). In all cases, the incision was placed on the steepest corneal meridian determined by corneal topography. Prior to surgery, with the patient in the supine position, three limbal reference marks at 3-, 6-, and 9-o'clock positions were made with a sterile marker with the aim of avoiding possible cyclorotations during surgery. After capsulorrhexis creation and phacoemulsification, the IOL was inserted into the capsular bag using the AT.Smart Cartridge Set (Carl Zeiss Meditec) and the AT.Shooter A2-2000 injector (Carl Zeiss Meditec) through the incision (in MICS cases, it was enlarged up to 1.8 mm). Postoperative topical therapy included a combination of antibiotic and steroid.

Intraocular Lens

The AT LISA toric 909M is a single-piece, diffractive multifocal IOL with a 6.0-mm biconvex optic and an overall length of 11.0 mm (Fig 1). It is made of a foldable hydrophilic acrylate with a water content of 25%, hydrophobic surface properties, and a refractive index of 1.46. This IOL presents a diffractive aspheric back surface and an aspheric toric front surface. It has a four-haptic design with an angulation of 0°. Spherical powers of −10.00 to +32.00 D in 0.50-D increments and cylindrical powers of 1.00 to 12.00 D in 0.50-D

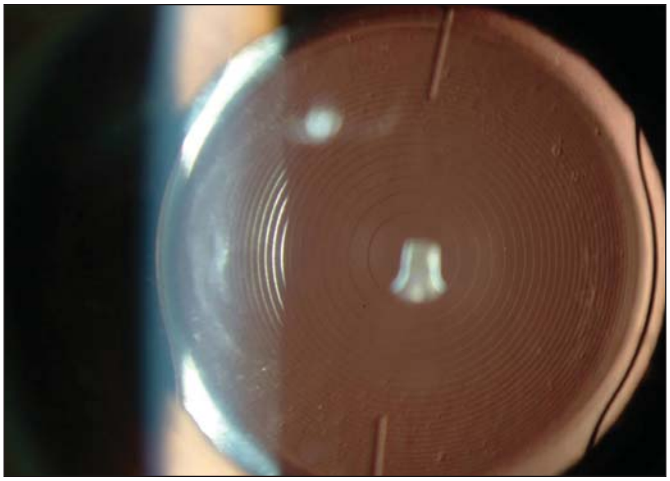

Figure 1. Slit-lamp microscopy of an eye implanted with the AT LISA 909M multifocal toric intraocular lens.

increments are available for this toric IOL. This IOL provides a theoretical add of +3.75 D at the IOL plane. The company-labeled A-constant for this IOL is 118.3.

Vector Analysis of Astigmatic Changes

Vector analysis of refractive astigmatic changes was performed using ASSORT software (ASSORT Pty Ltd, Cheltenham, Australia), which is especially designed for using the Alpins vectorial method.[8,9] According to the guidelines of this method,[8,9] the following vectors were determined and evaluated: target induced astigmatism (TIA), as the vector of intended change in cylinder for each treatment; surgically induced astigmatism (SIA), as the vector of the real change achieved; and difference vector (DV), as the additional astigmatic change that would enable the initial surgery to achieve its intended target. Additionally, the following parameters derived from the relationship between these vectors were calculated and analyzed at each postoperative follow-up:

- Magnitude of error (ME): the arithmetic difference between the magnitudes of SIA and TIA.
- Angle of error (AE): the angle described by the vectors of the achieved correction (ie, SIA) and intended correction (ie, TIA).
- Correction index (CI): the ratio of SIA to TIA. The ideal value would be 1, with overcorrection for values >1 and undercorrection for values <1.
- Flattening effect (FE): the amount of astigmatism reduction achieved by the effective proportion of the SIA at the intended meridian (a flattening effect was considered positive and a steepening effect negative). It was calculated using a previously described mathematical relationship.[9]
- Torque (TRQ): the amount of astigmatic change induced by the SIA, due to nonalignment of the treatment, that has been ineffective in reducing astigmatism at the intended meridian but causes rotation and a small increase in the existing astigmatism. It was calculated using a previously described mathematical relationship.[10]

Aside from the analysis of astigmatic changes, the ASSORT software was also used for the calculation of the ocular residual astigmatism by obtaining the vectorial difference between the refractive (calculated to the corneal plane) and corneal astigmatism following a standard and previously described procedure.[8,9,11] This parameter represents the result of the combination of the astigmatism of the posterior corneal surface and the astigmatism of the crystalline lens. In pseudophakic eyes, the ocular residual astigmatism is the result of the combination of the posterior cornea and IOL toricity.

Statistical Analysis

SPSS statistics software package version 15.0 for Windows (SPSS, Chicago, Illinois) was used for statistical analysis. Normality of all data samples was first checked by means of the Kolmogorov-Smirnov test. When parametric analysis was possible, the Student *t* test for paired data was performed for all parameter comparisons between pre- and postoperative examinations, and the Student *t* test for unpaired data was used for evaluating differences between corneal incision groups. When parametric analysis was not possible, the Wilcoxon rank sum test was applied to assess the significance of differences among pre- and postoperative data, and the Mann-Whitney test was used to evaluate differences between corneal incision groups. The same level of significance, $P<.05$, was used in all cases. Correlation coefficients (Pearson or Spearman, depending on whether normality condition could be assumed) were used to assess the correlation between different variables.

For an accurate statistical analysis of the visual acuity outcomes, the decimal values of visual acuity obtained with Snellen charts were transformed into the logMAR scale, calculating the minus logarithm of the decimal visual acuity.[12] Each step of 0.1-logMAR units is defined as one line with this specific scale.

The term "corrected" was used for designating specific parameters that had been measured with the correction obtained by refraction in the trial frame (near refraction for near visual acuity).

RESULTS

Mean patient age was 47.97±9.71 years (range: 20 to 61 years). Regarding the sex distribution, 14 (40%) patients were male and 21 (60%) were female. In addi-

TABLE 1

Preoperative Clinical Features of Eyes Undergoing Microincision and Mini-incision Cataract Surgery With Implantation of a Toric IOL

	MICS Group		Mini-incision Group		
Variable	**Mean±SD**	**Median (Range)**	**Mean±SD**	**Median (Range)**	***P* Value***
Age (y)	50.08±9.13	51.5 (35 to 61)	46.87±10.01	50 (20 to 59)	.31
UDVA (logMAR)	0.93±0.45	0.70 (0.40 to 1.78)	0.69±0.33	0.60 (0.17 to 1.22)	.04
Sphere (D)	+1.39±6.21	+1.50 (−11.00 to +9.25)	+1.66±5.75	+2.25 (−13.50 to +11.50)	.92
Cylinder (D)	3.41±1.17	3.00 (1.00 to 6.00)	2.48±1.80	2.00 (0.25 to 7.25)	.02
CDVA (logMAR)	0.12±0.17	0.05 (−0.08 to 0.52)	0.18±0.19	0.17 (0.00 to 0.60)	.62
UNVA (logMAR)	0.59±0.24	0.52 (0.30 to 1.00)	0.34±0.14	0.40 (0.10 to 0.49)	<.01
CNVA (logMAR)	0.17±0.14	0.22 (0.00 to 0.52)	0.20±0.15	0.17 (0.00 to 0.49)	.57
K1 (D)	42.01±1.72	41.97 (39.66 to 45.33)	42.25±1.65	42.38 (39.17 to 46.40)	.47
K2 (D)	45.07±1.27	44.99 (42.74 to 47.26)	44.79±1.50	44.81 (41.88 to 49.00)	.29
KM (D)	43.54±1.38	43.20 (41.58 to 46.29)	43.52±1.45	43.69 (41.14 to 47.55)	.95
AST (D)	3.06±1.21	2.97 (0.75 to 6.19)	2.54±1.21	2.01 (1.23 to 6.62)	.052
ORA (D)	0.79±0.38	0.80 (0.16 to 1.83)	1.17±0.81	0.96 (0.13 to 3.26)	.07
Axial length (mm)	23.48±2.65	23.17 (20.09 to 29.68)	23.02±2.15	23.14 (19.23 to 28.52)	.59
ACD (mm)	2.93±0.46	2.79 (2.48 to 4.01)	3.18±0.38	3.19 (2.52 to 3.75)	.01
Spherical power of the implanted IOL (D)	18.90±9.43	16.75 (2.00 to 33.50)	20.82±8.12	20.50 (3.50 to 35.50)	.41
Cylindrical power of the implanted IOL (D)	3.30±1.66	3.25 (0.50 to 7.50)	3.10±1.63	2.50 (1.50 to 8.50)	.43

IOL = intraocular lens, MICS = microincision surgery, SD = standard deviation, UDVA = uncorrected distance visual acuity, CDVA = corrected distance visual acuity, UNVA = uncorrected near visual acuity, K1 = corneal dioptric power in the flattest meridian for the 3-mm central zone, K2 = corneal dioptric power in the steepest meridian for the 3-mm central zone, KM = mean corneal power for the 3-mm central zone, AST = corneal astigmatism for the 3-mm central zone, ORA = ocular residual astigmatism, ACD = anterior chamber depth
**Mann-Whitney test.*

tion, the same number of right and left eyes were implanted with the evaluated toric IOL (n=32 for both) (6 patients underwent unilateral implantation). Preoperatively, mean axial length of the overall sample was 23.19±2.33 mm (range: 19.23 to 29.68 mm), and mean anterior chamber depth was 3.09±0.42 mm (range: 2.48 to 4.01 mm). Mean IOL spherical power was 20.23±8.47 D (range: 2.00 to 35.50 D), and mean IOL cylindrical power was 3.16±1.63 D (range: 0.50 to 8.50 D).

Table 1 summarizes the preoperative clinical features of both groups of eyes. As shown, no significant differences between the MICS and mini-incision groups were detected in age, manifest sphere, corrected distance visual acuity (CDVA), corrected near visual acuity (CNVA), axial length, keratometry, ocular residual astigmatism, corneal astigmatism, and power of the implanted IOL ($P \geq .052$). Statistically significant differences between groups were detected for manifest cylinder, UDVA, uncorrected near visual acuity (UNVA), and anterior chamber depth ($P \leq .04$). The difference in the anterior chamber depth, although statistically significant, was small in magnitude and did not result in a significant difference between groups in the calculation of IOL power. The difference in uncorrected visual acuity between groups was related to the higher preoperative refractive cylinder that was present in the MICS group. In addition, the difference in corneal astigmatism between groups was near the limit for statistical significance, with the higher preoperative value noted in the MICS group.

Visual and Refractive Outcomes

In the overall sample, a statistically significant mean improvement in UDVA of approximately seven logMAR lines was found postoperatively ($P<.01$) (preoperative, 0.77±0.38 logMAR; postoperative, 0.14±0.11 logMAR; $P<.01$). This visual change was consistent with a significant postoperative reduction in sphere (preoperative, +1.57±5.87 D; postoperative, +0.17±0.54 D; $P=.03$) and cylinder (preoperative, 2.82±1.65 D; postoperative, 0.51±0.37 D; $P<.01$)

TABLE 2

Postoperative Clinical Features of Eyes Undergoing Microincision and Mini-incision Cataract Surgery With Implantation of a Toric IOL

	MICS Group		Mini-incision Group		
Variable	Mean±SD	Median (Range)	Mean±SD	Median (Range)	*P* Value*
UDVA (logMAR)	0.17±0.13	0.15 (0.00 to 0.40)	0.12±0.10	0.17 (0.00 to 0.30)	.41
Sphere (D)	+0.22±0.53	0.00 (−0.75 to +1.50)	+0.15±0.56	0.00 (−0.75 to +1.25)	.65
Cylinder (D)	0.67±0.45	−0.75 (1.75 to 0.00)	0.42±0.28	0.50 (1.00 to 0.00)	.02
CDVA (logMAR)	0.06±0.06	0.05 (0.00 to 0.22)	0.06±0.10	0.00 (0.00 to 0.30)	.06
UNVA (logMAR)	0.24±0.15	0.22 (0.00 to 0.62)	0.10±0.09	0.10 (0.00 to 0.30)	<.01
CNVA (logMAR)	0.13±0.11	0.10 (0.00 to 0.30)	0.06±0.07	0.00 (0.00 to 0.20)	.01
K1 (D)	42.11±1.66	41.64 (40.08 to 45.33)	42.44±1.75	42.61 (39.52 to 47.87)	.44
K2 (D)	44.85±1.49	44.87 (42.01 to 47.26)	45.02±1.65	45.06 (42.08 to 49.71)	.92
KM (D)	43.48±1.42	43.31 (41.52 to 46.29)	43.73±1.58	43.71 (41.42 to 48.79)	.58
AST (D)	2.74±1.34	2.50 (0.42 to 5.87)	2.58±1.25	2.06 (1.18 to 6.63)	.27
ORA (D)	3.38±1.19	3.40 (1.06 to 5.97)	2.63±1.32	2.02 (0.85 to 6.57)	.21

IOL = intraocular lens, MICS = microincision surgery, SD = standard deviation, UDVA = uncorrected distance visual acuity, CDVA = corrected distance visual acuity, UNVA = uncorrected near visual acuity, K1 = corneal dioptric power in the flattest meridian for the 3-mm central zone, K2 = corneal dioptric power in the steepest meridian for the 3-mm central zone, KM = mean corneal power for the 3-mm central zone, AST = corneal astigmatism for the 3-mm central zone, ORA = ocular residual astigmatism

*Mann-Whitney test.

in absolute terms. A significant postoperative improvement was also found in CDVA (preoperative, 0.16±0.18 logMAR; postoperative, 0.05±0.09 logMAR; *P*<.01), with a mean gain of one logMAR line. Significant changes were also detected in near vision. A significant mean postoperative improvement in UNVA of approximately three logMAR lines was found (preoperative, 0.40±0.20 logMAR; postoperative, 0.15±0.13 logMAR; *P*<.01). Furthermore, CNVA also improved significantly postoperatively (preoperative, 0.19±0.15 logMAR; postoperative, 0.08±0.09 logMAR; *P*<.01), with a mean gain of one logMAR line.

Table 2 shows a comparative summary of the outcomes obtained according to the type of corneal incision. As shown, no significant differences between groups were present in UDVA or CDVA as well as in manifest sphere (*P*>.06). Postoperative cylinder was significantly higher in the MICS group; however, this difference was also present preoperatively and a significant correlation between postoperative cylinder and the cylindrical power of the implanted IOL was present in this group (r=−0.459, *P*=.04). Uncorrected near visual acuity improved significantly in both groups (*P*<.01), with a significantly better outcome in the mini-incision group; however, this difference was also present preoperatively. Furthermore, CNVA was significantly better postoperatively in the mini-incision group (*P*<.01), with no significant change noted in the MICS group (*P*=.53).

Corneal Topographic and Ocular Residual Astigmatism Changes

In the overall sample, no significant changes were detected postoperatively in K2 (*P*=.11, Wilcoxon test) and the amount of corneal astigmatism (*P*=.33). However, slight but statistically significant increases in K1 (*P*<.01) and KM (*P*=.03) were found postoperatively. These changes were not large enough to induce a significant change in the magnitude of corneal astigmatism (*P*=.30).

Furthermore, no significant differences were found in postoperative keratometric readings and astigmatism between groups according to incision size (*P*>.27) (Table 2), although a small but significant change in the keratometric readings was observed in eyes operated with the mini-incision (preoperative−postoperative, MICS group, *P*≥.06; mini-incision group, *P*<.01).

Ocular residual astigmatism in the overall sample increased significantly from 1.03±0.70 D preoperatively to 2.82±1.32 D postoperatively (*P*<.01, Wilcoxon test). As expected, the cylindrical power of the IOL implanted correlated significantly with the magnitude of postoperative ocular residual astigmatism (r=0.839, *P*<.01) (Fig 2). Mean postoperative ocular residual astigmatism was 3.38±1.19 D and 2.63±1.32 D in the MICS and mini-incision groups, respectively (*P*=.07). No significant differences were present between these groups in the cylindrical power of the implanted IOL (*P*=.43). As

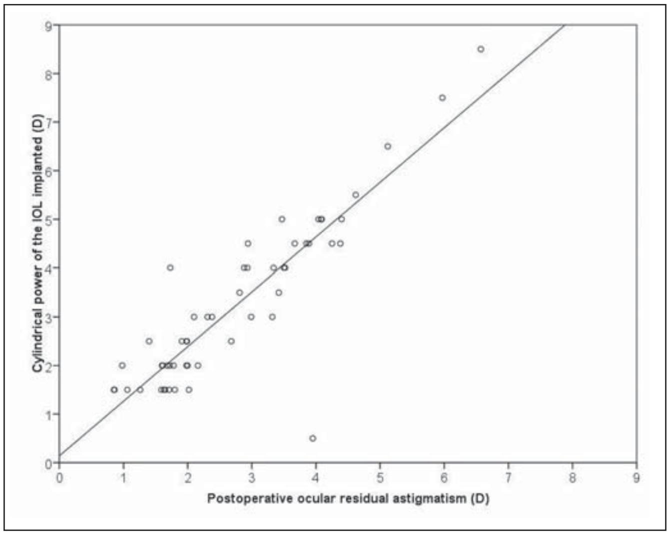

Figure 2. Scattergram showing the relationship between the postoperative magnitude of internal astigmatism (ocular residual astigmatism) and the cylindrical power of the implanted intraocular lens. The adjusting line to the data obtained by means of the least-squares fit is shown. This linear predicting model showed excellent predictability (R^2=0.78). $CYL=0.141+1.124\times ORA_{post}$, where CYL is the cylindrical power of the implanted IOL and ORA_{post} is the postoperative magnitude of internal astigmatism.

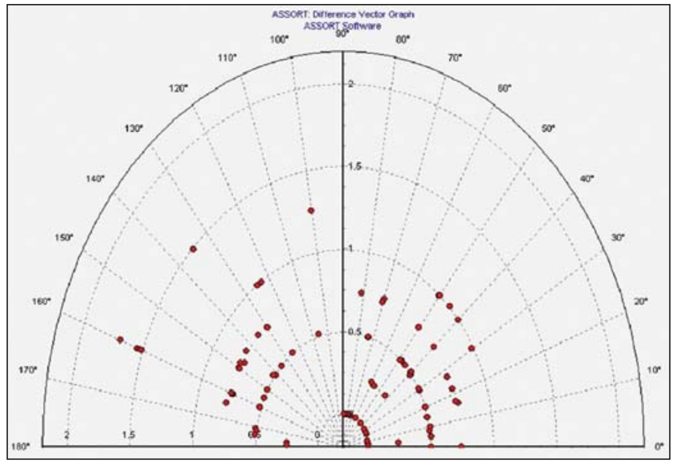

Figure 3. Vectorial display of the difference vector (DV) during postoperative follow-up. The DV represents the additional astigmatism that should be induced to achieve the intended target in each case.

expected, no significant differences in ocular residual astigmatism were observed postoperatively (*P*=.21).

Vectorial Changes in Refractive Astigmatism

Mean magnitudes of TIA and SIA vectors were 2.80±1.67 D and 2.89±1.74 D, respectively. Differences between the magnitudes of these two vectors did not reach statistical significance (*P*=.09, Wilcoxon test). This small and insignificant difference is representative of a small trend toward overcorrection of the refractive astigmatism after the implantation of this toric IOL (in an ideal complete correction, SIA and TIA would be identical). For this reason, mean ME was positive, although it was close to zero (0.08±0.38 D).

Mean magnitude of postoperative DV was 0.52±0.36 D, which confirmed the limited difference between the TIA and SIA vectors. Furthermore, as shown in Figure 3, the variability in the magnitude of postoperative DV was limited, with most values ≤1. Mean magnitude of postoperative FE was slightly lower than the mean magnitude of SIA (2.83±1.73 D), but this small difference reached statistical significance (*P*<.01, Wilcoxon test). However, no significant differences were detected between the magnitudes of FE and TIA (*P*=.34, Wilcoxon test). Regarding the postoperative torque vector, its magnitude was always positive, with a mean of 0.36±0.36 D.

Postoperative AE was also evaluated, with its mean magnitude in the overall sample being negative (−2.81±11.29°), although significant variability in this parameter was observed (range: −73° to 9°). The achieved astigmatic correction was clockwise to the intended axis. Mean absolute AE was 5.76±10.09° (range: 0 to 73°).

When the outcomes of the vectorial analysis were compared in the MICS and mini-incision groups (Table 3), significant differences were found in the magnitudes of TIA, SIA, and FE (*P*<.01). This was expected because a preoperative significant difference in refractive cylinder was present between groups. Mean AE was 0.37±5.50° and −4.51±13.16° for the MICS and mini-incision groups, respectively (Fig 4). This difference did not reach statistical significance (*P*=.09) due to the large variability observed in this parameter in the mini-incision group (see Fig 4). Mean absolute AE was 3.82±3.70° and 6.71±12.17° in the MICS and mini-incision groups, respectively. Regarding the DV, it was significantly larger in the MICS group (0.70±0.43 vs 0.42±0.28 in the mini-incision group; *P*=.01). In this group, a slight insignificant trend to a more positive ME was also found (MICS group, 0.16±0.43 D; mini-incision group, 0.04±0.34; *P*=.12).

Mean CI was 1.04±0.25, 1.07±0.12, and 1.03± 0.29 for the overall study population, MICS group, and mini-incision group, respectively. The difference in this vectorial index did not differ significantly among groups, confirming the presence of an overcorrection of approximately 4%.

Correlation of Corneal Astigmatic Changes With Other Clinical Parameters

Table 4 summarizes the correlations found in the overall sample among preoperative clinical and postoperative vector analysis parameters as well as among vectorial parameters. A coefficient of correlation close

TABLE 3

Magnitude of Vectors Analyzed Using the Alpins Method in Eyes Undergoing Microincision and Mini-incision Cataract Surgery With Implantation of a Toric IOL

	MICS Group		Mini-incision Group		
Vector	Mean±SD	Median (Range)	Mean±SD	Median (Range)	*P* Value*
TIA (D)	3.44±1.33	3.10 (1.16 to 6.31)	2.46±1.75	1.98 (0.23 to 7.72)	.01
SIA (D)	3.64±1.23	3.49 (1.16 to 5.65)	2.49±1.84	1.80 (0.29 to 7.44)	<.01
DV (D)	0.70±0.43	0.69 (0.00 to 1.60)	0.42±0.28	0.50 (0.00 to 1.03)	.01
FE (D)	3.54±1.19	3.47 (1.16 to 5.59)	2.45±1.86	1.80 (0.24 to 7.44)	<.01
TRQ (D)	0.51±0.46	0.49 (0.00 to 1.50)	0.27±0.26	0.21 (0.00 to 1.03)	.13

IOL = intraocular lens, MICS = microincision surgery, SD = standard deviation, TIA = target induced astigmatism, SIA = surgically induced astigmatism, DV = difference vector, FE = flattening effect, TRQ = torque
**Mann-Whitney test.*

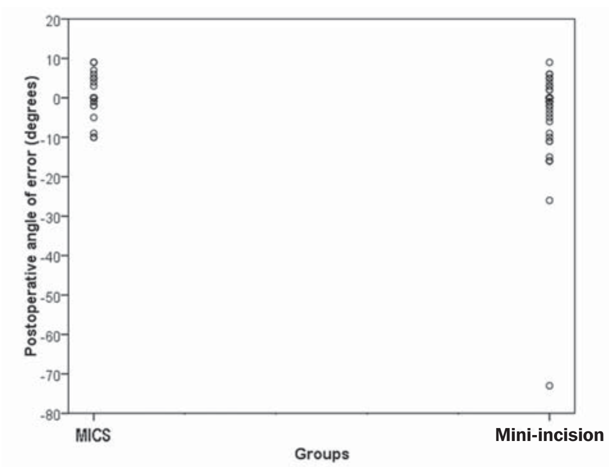

Figure 4. Scattergram showing the variability among cases in the postoperative angle of error in the two samples of eyes included in the current study: MICS group (patients from the Spanish clinical center) and mini-incision group (patients from the Czech clinical center).

to 1 was found for the relationship between the magnitude of SIA and FE (Fig 5). Therefore, both vector variables were almost coincident. Furthermore, a good and significant correlation was found between the magnitude of DV and TRQ (Fig 6). Mean absolute AE was found to be significantly correlated with the magnitude of DV (r=0.552, *P*<.01) as well as with the magnitude of TRQ (r=0.758, *P*<.01) (Table 4). Positive correlations of the ME with the magnitudes of SIA, DV, and FE were also found. These correlations were poor despite being statistically significant (Table 4). Regarding the visual and refractive parameters, only limited, although significant, correlations were found between the magnitudes of corneal and refractive astigmatism and the magnitudes of DV and AE in absolute terms (Table 4).

TABLE 4

Correlations Among Preoperative Clinical Parameters and Postoperative Vector Analysis Outcomes

Variable 1	Variable 2	Correlation Coefficient	*P* Value
SIA	FE	0.998	<.01
	ME	0.345	.01
DV	SIA	0.328	.01
	Absolute AE	0.552	<.01
	ME	0.291	.02
	TRQ	0.776	<.01
	AST	0.302	.02
	Manifest cylinder	−0.295	.02
Absolute AE	SIA	−0.339	.01
	FE	−0.364	<.01
	TRQ	0.758	<.01
	AST	−0.261	.04
	Manifest cylinder	0.287	.02
FE	ME	0.328	.01

SIA = surgically induced astigmatism, FE = flattening effect, ME = magnitude of error, DV = difference vector, AE = angle of error, TRQ = torque, AST = corneal astigmatism for the 3-mm central zone

Complications

No adverse events were reported during follow-up. A posterior capsular opacification rate of 3.1% (2 eyes) was found at 6 months. In all posterior capsular opacification cases, a YAG laser capsulotomy was performed after 6-month follow-up, with a successful visual impact.

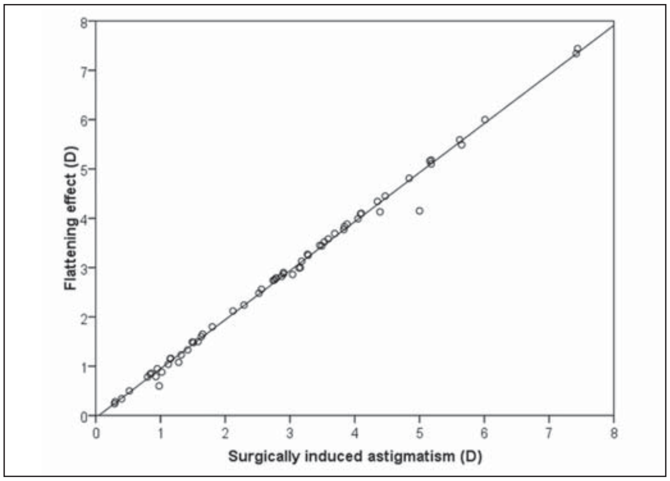

Figure 5. Scattergram showing the relationship between the postoperative magnitude of flattening effect (FE) and postoperative magnitude of surgically induced astigmatism (SIA). The adjusting line to the data obtained by means of the least-squares fit is shown. This linear predicting model showed excellent predictability (R^2=0.99). $FE_{post}=-0.045-0.995\times SIA_{post}$, where FE_{post} is the postoperative magnitude of the FE vector and SIA_{post} the postoperative magnitude of the SIA vector.

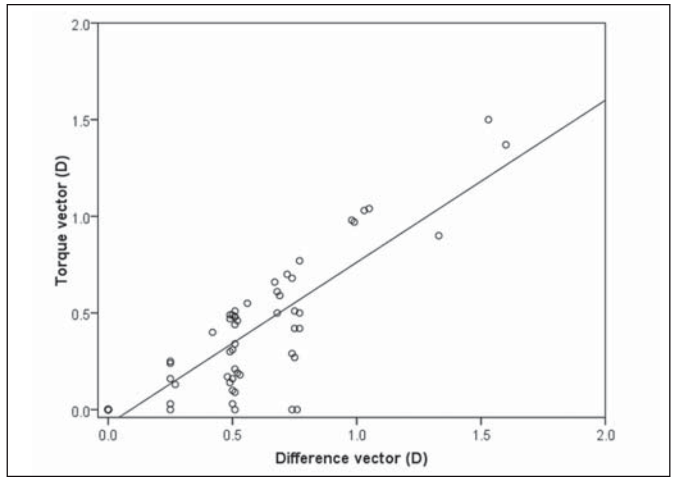

Figure 6. Scattergram showing the relationship between the postoperative magnitude of torque (TRQ) vector and the postoperative magnitude of the difference vector (DV). The adjusting line to the data obtained by means of the least-squares fit is shown. This linear predicting model showed excellent predictability (R^2=0.73). $TRQ_{post}=-0.076-0.838\times DV_{post}$, where TRQ_{post} is the postoperative magnitude of the TRQ vector and DV_{post} the postoperative magnitude of DV.

DISCUSSION

A significant visual improvement for distance was observed after cataract surgery with implantation of the AT LISA 909M multifocal toric IOL. Specifically, a mean improvement of approximately seven logMAR lines in UDVA was found, confirming the efficacy of this IOL for the correction of aphakic ametropia in eyes with moderate to high astigmatism after cataract extraction. This finding was consistent with the visual improvement reported by other authors using other toric and multifocal IOLs[1,2,5,6,13-17] as well as the same IOL.[7] As expected, this significant improvement in UDVA was combined with a significant reduction in manifest refraction, sphere, and cylinder. The significant decrease in refractive cylinder found in the current series was consistent with reports evaluating other toric IOLs.[1,2,13-17]

Regarding near vision, significant improvements were also observed. Mean UNVA improved on average three logMAR lines, whereas mean CNVA improved by one logMAR line. Similar improvements have been reported with other multifocal IOLs.[5,6] Considering that the mean postoperative spherical equivalent refraction was −0.085 D, our findings confirm the ability of this new multifocal toric IOL to compensate the near visual defect after cataract extraction. The measurement of distance-corrected near visual acuity (DCNVA) would have been a direct indicator of the potential of near correction of this IOL because the UNVA could be significantly affected by the presence of residual myopia. However, this parameter was not measured in our series and can be considered as a limitation of the current study. In future studies, DCNVA as well as contrast sensitivity should be analyzed to provide a more complete characterization of the visual performance achieved with this specific IOL.

In the current series, the change in ocular astigmatism (considering corneal and intraocular optics) was analyzed, not only the corneal incisional change. Specifically, a small difference was found between the magnitude of TIA and SIA that did not reach statistical significance. This difference, designated as ME, was positive, which shows a minimal trend toward overcorrection of refractive astigmatism (mean 0.08 D) with this toric IOL. This minimal and insignificant trend toward overcorrection differed from the trend toward undercorrection found with monofocal toric IOLs evaluated by means of the Alpins method (Acri.Comfort 646 TLC [Carl Zeiss Meditec], mean ME: −0.36 D; AcrySof toric [Alcon Laboratories Inc, Ft Worth, Texas], mean ME: −0.34 D).[2,18] Mean CI was 1.04, which confirms the presence of an average overcorrection of refractive cylinder of approximately 4%.

Flattenting effect and TRQ were also evaluated, which are related to the misalignment of the astigmatic treatment. The FE vector represents the amount of astigmatism reduction achieved by the effective proportion of the SIA at the intended meridian.[9] The magnitudes of SIA, TIA, and FE will be coincident if a perfect and total astigmatic correction is achieved. In our series, the magnitude of FE was significantly lower than SIA at all postoperative follow-up examinations, but differences between TIA and FE were not statistically significant, indicating that a portion of the astigmatic corrective effect was performed beyond the intended axis. This was confirmed by the presence of a mean magnitude for DV and TRQ different from zero. We found a mean magnitude of TRQ of 0.34 D at all follow-up examinations. In addition, mean magnitude of TRQ was positive in the analyzed sample, which implies that the vector lied 45° counterclockwise to the SIA.

A mean AE of −2.81° was found. It was slightly negative in a relevant number of cases, indicating a trend toward the induction of an achieved correction clockwise to the intended axis. This minimal AE suggests the presence of a small rotation of the IOL inside the capsular bag in some specific cases. This minimal variation in the alignment of the astigmatic correction confirms the stability and potential of astigmatic correction of this IOL. Rotation of the toric IOL of 11.5° leads to residual astigmatism that is 40% of the initial astigmatic power and 3° leads to 10% of the initial power.[19]

Because the surgeries were performed on different populations at different centers by different surgeons, conclusions from the comparative analysis between groups (MICS vs mini-incision) should be considered with care. Furthermore, the amount of refractive astigmatism correction was different, with a larger TIA in the MICS group, which led to a significantly higher magnitude of SIA and FE in the MICS group. On the other hand, more significant variability in the AE (MICS group, standard deviation [SD] 5.50; mini-incision, SD: 13.16) was found in those eyes undergoing cataract surgery with the larger incision size. Indeed, the range of the absolute AE was 0 to 10° in the MICS group and 0 to 73° in the mini-incision group. Several factors could have accounted for such a finding: differences in the analyzed population, incision size,[20,21] or even surgical protocol. These findings should be corroborated in future studies comparing the implantation of the evaluated IOL by the same surgeon with different corneal incision sizes.

In addition to these analyses, we evaluated the level of correlation in the overall sample between some clinical parameters and corneal astigmatic changes analyzed by means of the Alpins vectorial method. A coefficient of correlation near 1 was found between the magnitudes of FE and SIA, which showed almost complete coincidence between these two vectors. Therefore, only a small proportion of the SIA was not at the intended meridian. A positive correlation of positive sign was found between the magnitudes of DV and TRQ vectors. The larger the magnitude of DV, the larger the magnitude of TRQ. Therefore, as expected, the presence of a difference between SIA and TIA was related to the presence of nonaligned astigmatic change induced by the SIA, which was responsible for rotation and increase in the existing astigmatism. Indeed, the small trend toward overcorrection found with the evaluated multifocal toric IOL seemed to be the consequence of the minimal misalignment of the astigmatic correction. This was confirmed by the significant and positive correlation found between the magnitude of DV and absolute AE. The larger the DV, the more significant the absolute AE. Furthermore, limited correlations were also found among the magnitudes of SIA, FE, and DV vectors and the ME. The higher the magnitude of these vectors, the more positive the ME. All of these findings suggest that overcorrection with this IOL may be the result of the combination of small misalignments of treatment with a nonoptimized IOL calculation. The power of the IOL is calculated considering the corneal astigmatism and therefore the accuracy of the keratometric or topographic device could also be a factor in the overcorrection effect. The correlations of this misalignment with the preoperative conditions were limited. Statistical significance was only found for the correlations of the magnitude of corneal and refractive astigmatism with the magnitude of DV and absolute AE. The larger the preoperative magnitude of astigmatism in absolute terms, the larger the magnitude of DV and absolute AE. Small rotations in IOLs of higher powers have a more relevant impact on the astigmatic effect induced. In future studies, the effect of misalignment of this IOL on ocular aberrations and retinal image quality (point spread function) should be evaluated.

The AT LISA 909M toric IOL is able to restore distance and near visual function in eyes with cataract and moderate to high corneal astigmatism. It provides excellent predictability for the correction of refractive astigmatism, with a minimal trend toward overcorrection, which is not clinically relevant. This phenomenon seems to be related to a small misalignment of the astigmatic correction (possibly due to minimal rotations of this specific type of toric IOL) as well as not fully optimized IOL power calculations. The Alpins method was used for the analysis of astigmatic changes induced with this IOL, as it allows evaluation of changes in the magnitude and orientation of astigmatism. This vector analysis method has been used successfully by several authors to analyze the astigmatic changes induced with different surgical and nonsurgical options (relaxing incisions,[22] excimer laser refractive surgery,[23,24] cataract surgery,[25] vitrectomy,[26] and orthokeratology[27]), including the analysis of different models of toric IOLs.[2,18] The use of MICS in cataract surgery with implantation of the AT LISA 909M toric IOL seems to avoid the presence of variability in the degree of alignment of the astigmatic correction, but this needs to be confirmed in future studies. An exhaustive analysis of the behavior of this toric IOL within the capsular bag would also be interesting to understand the rotational stability of the astigmatic correction achieved with this multifocal toric IOL.

AUTHOR CONTRIBUTIONS

Study concept and design (D.P.P., J.L.A.); data collection (P.M., P.S., J.T., V.K., A.B.P.); analysis and interpretation of data (P.M., D.P.P., P.S., J.L.A.); drafting of the manuscript (D.P.P.); critical revision of the manuscript (P.M., P.S., J.T., V.K., A.B.P., J.L.A.); statistical expertise (D.P.P., J.T.); obtained funding (J.L.A.); administrative, technical, or material support (P.M., P.S., J.L.A.); supervision (P.M., P.S., J.T., V.K., A.B.P., J.L.A.)

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