Clinical outcomes after cataract surgery with a new transitional toric intraocular lens

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Clinical Outcomes After Cataract Surgery With a New Transitional Toric Intraocular Lens

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ABSTRACT

PURPOSE: To evaluate the visual outcomes of patients who underwent cataract surgery with implantation of a transitional toric monofocal intraocular lens (IOL) (Precizon Toric IOL, model 565; Ophtec BV, Groningen, The Netherlands).

METHODS: In this prospective case series, 51 eyes of 39 patients with cataract and regular keratometric astigmatism between 1.00 and 4.50 diopters (D) that had phacoemulsification with implantation of a Precizon Toric IOL were included. Over a 4-month follow-up period, the main outcome measures were uncorrected and corrected distance visual acuities (UDVA and CDVA, respectively), spherical equivalent (SE) refraction, astigmatism outcomes evaluated according to the Alpins method, the IOL's rotational stability, and higher order aberrations.

RESULTS: At the 4-month follow-up visit, mean UDVA was 0.06 ± 0.1 logMAR (range: 0.4 to -0.18 logMAR) ($P < .001$) and mean CDVA was -0.00 ± 0.07 logMAR (range: 0.15 to -0.18 logMAR) ($P < .001$). UDVA was 0.3 logMAR or better in 50 (98%) eyes and 0.1 logMAR or better in 42 (82%) eyes. Mean SE refraction was -0.19 ± 0.38 D (range: -1.13 to +0.50 D), with 44 (86%) eyes within ± 0.50 D of the attempted correction. Mean target induced astigmatism was 1.96 ± 0.94 D (range: 0.70 to 4.50 D) and mean surgically induced astigmatism was 1.85 ± 1.01 D (range: 0.07 to 4.64 D). Mean correction index was 0.87 (range: 0.07 to 2.29 D). Mean toric IOL axis rotation was $1.98^\circ \pm 1.78^\circ$ (range: 0° to 7°). Ocular aberrometry was within normal values.

CONCLUSIONS: The implantation of the Precizon Toric IOL in patients with cataract and corneal astigmatism provided excellent visual outcomes, predictability of refractive results, rotational stability, and good optical performance.

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he aim of modern cataract surgery is not only to improve visual acuity, but also to achieve emmetropia and thus optimum uncorrected visual acuity. However, 20% to 30% of patients have preexisting corneal astigmatism of 1.25 diopters (D) or greater and approximately 10% have 2.00 D or greater.¹⁻³ Recent investigations suggest that the correction of astigmatism greater than 0.50 D, but not lower, can improve visual outcomes, so adequate astigmatic correction should be considered in patients with cataract.⁴

The Precizon Toric IOL (Precizon Toric IOL, model 565; Ophtec BV, Groningen, The Netherlands) has been designed with features to prevent postoperative rotation. The IOL's material and offset-shaped haptics are designed to improve adherence to the posterior capsule, preventing rotation and posterior capsule opacification.⁵⁻⁷ The optic surface has a new transitional conic design in which the dioptric power is calculated individually as a spherical aberration-free dioptric power. The main meridians and all meridians in between each have a different Coddington shape factor (transitional conic) and a different asphericity that is related to the Coddington shape factor of the respective meridian in accordance with a relationship providing an aberration-neutral refraction for the respective meridian. With the use of the Coddington shape factor, the lens can be optimized to minimize spherical aberrations (Figure A, available in the online version of this article). An aberration-neutral lens is obtained in which the effective dioptric power is constant along each meridian from the optic axis to the periphery of the lens and the amount of aberrations varies little with pupillary aperture. This transitional conic surface blends into the aspheric surface of all meridians, leading

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to a broader toric surface that could be more tolerant to rotation, misalignment, tilt, and decentration (**Figure B**, available in the online version of this article).

The purpose of this study was to evaluate the optical performance of a new monofocal toric IOL in patients with cataract and regular astigmatism.

PATIENTS AND METHODS

PATIENT POPULATION

This prospective interventional case series was performed in two clinical sites in Lisbon, Portugal (Egas Moniz Hospital and Luz Hospital). The study was conducted in accordance with the tenets of the Declaration of Helsinki and approved by each center's institutional review board. All patients provided written informed consent.

Inclusion criteria were clinically significant cataract, preexisting regular corneal astigmatism between 1.00 and 4.50 D at the corneal plane, and expected visual acuity of 0.1 logMAR or better. Exclusion criteria were corneal pathology (eg, irregular astigmatism, previous surgery, or trauma), pathology that could limit visual acuity after surgery (eg, amblyopia, glaucoma, or retinal disease), and pathology that could compromise IOL stability or function (eg, pseudoexfoliation syndrome or small pupils limiting the ability to see the IOL reference markings).

IOL

The study IOL was the Precizon Toric model 565 monofocal toric one-piece IOL. The IOL is made of 25% hydrophilic acrylic material with an ultraviolet cut-off wavelength at 360 nm at which the transmission is below 10%. The overall diameter is 12.5 mm and the optic diameter is 6 mm. The haptics are modified C-shaped loops with 0° angulation. The refractive index is 1.46 and the optic surface is aspheric. The benefits of aspheric IOLs include higher retinal image quality and contrast sensitivity.⁸ At the time of the study, the IOL was available with spherical equivalent (SE) powers of +10.00 to +30.00 D in 0.50-D increments and cylindrical powers of +1.00 to +6.00 D in 0.50-D increments.

PREOPERATIVE ASSESSMENT

Preoperatively, all patients had a full ophthalmologic examination including uncorrected (UDVA) and corrected (CDVA) distance visual acuities using logMAR acuity charts at a test distance of 4 m under photopic conditions (85 cd/m²), manifest refraction, slit-lamp biomicroscopy, Goldmann applanation tonometry, and funduscopy under mydriasis.

The IOL power was calculated using the Hoffer Q⁹ formula if the axial length was shorter than 22 mm or the

SRK/T¹⁰ if the axial length was 22 mm or longer. The A-constant was 118.5. The refractive goal was emmetropia. Axial length and keratometry values were obtained using the IOLMaster partial coherence interferometry (Carl Zeiss Meditec AG, Jena, Germany). Corneal topography (Pentacam HR; Oculus Optikgeräte GmbH, Wetzlar, Germany) was performed to confirm the regularity of the astigmatism. The IOL cylinder power and axis placement were calculated using the online Precizon Toric Calculator (<http://calculator.ophtec.com/login/classic-login>, used between October 2014 and June 2015). Surgically induced astigmatism (SIA) was assumed to be 0.30 D for a temporal clear corneal incision.

SURGICAL TECHNIQUE

Two experienced surgeons (TBF, FJR) performed all surgeries under topical anesthesia using a microcoaxial phacoemulsification technique with a 2.2-mm clear cornea incision. With the patient seated to prevent cyclotorsion, the previously calculated implantation axis was marked using a Neuhann-Nuijts one-step bubble marker (ASICO, Westmont, IL). The IOL was implanted using a disposable DualTec IOL injector (Ophtec BV). After IOL implantation and complete aspiration of the viscosurgical device anterior and posterior to the IOL, the IOL was rotated to its final position by aligning the corneal marks with the reference marks in the IOL.

POSTOPERATIVE ASSESSMENT

Postoperative examinations were performed at day 1, month 1, and month 4 using the same tests as for the preoperative examination. At the 4-month visit, ocular aberrometry was performed with the OPD-III Scan refractive power/corneal analyzer system (NIDEK Co., Ltd., Gamagori, Japan). The parameters analyzed for a 4-mm pupil included the root mean square (RMS) of higher order aberrations (HOAs), RMS of the total spherical aberration, RMS of the total coma, and RMS of the total trefoil and point spread function (PSF), expressed as the Strehl ratio.

The IOL alignment meridian was calculated at the follow-up visits from the scanning device using the toric IOL summary map after pupillary mydriasis of at least 6 mm using tropicamide 1.0%. At each visit, the same observer took three images of each patient. The device was defocused, realigned, and focused between each image. The final rotation was calculated as the mean of the rotation obtained in each of these three images. We have previously used this method for toric IOL alignment meridian calculation and showed its high repeatability.¹¹

At the 4-month follow-up visit, astigmatic outcomes were calculated by vector analysis using the method described by Alpins.^{12,13}

TABLE 1
Patient Demographics and
Clinical Information

Parameter	Value
Eyes (n)	51
Patients (n)	39
Age (y), mean $\pm$ SD (range)	70.8 $\pm$ 9.7 (53 to 89)
Male sex, n (%)	20 (51)
Right eyes, n (%)	25 (48)
Axial length (mm), mean $\pm$ SD (range)	24.05 $\pm$ 1.83 (21.08 to 27.75)
Corneal astigmatism (D), mean $\pm$ SD (range)	1.98 $\pm$ 0.72 (1.00 to 4.50)
IOL spherical equivalent power (D), mean $\pm$ SD (range)	18.92 $\pm$ 4.82 (8.75 to 27.00)
IOL cylinder power (D), mean $\pm$ SD (range)	2.60 $\pm$ 1.32 (1.00 to 6.00)

SD = standard deviation; D = diopters; IOL = intraocular lens

STATISTICAL ANALYSIS

All data were collected in an Excel database (Microsoft Office 2010; Microsoft Corporation, Redmond, WA). Statistics were done in accordance with the ICH statistical principles for clinical trials E9 guideline. All statistical analysis was performed using SPSS for Macintosh software (version 21.0; IBM Corporation, Armonk, NY). For all data samples, the normality of the distribution was checked using the Kolmogorov–Smirnov test. Whenever parametric analysis was possible, the Student's *t* test for paired samples was used for preoperative and postoperative comparisons. When parametric analysis was not possible, differences between preoperative and postoperative data were evaluated with the Wilcoxon rank sum test. Results are expressed as mean $\pm$ standard deviation. A *P* value less than .05 was considered statistically significant.

RESULTS

This study included 51 eyes from 39 patients. The mean age was 70.8 $\pm$ 9.7 years (range: 53 to 89 years). No eyes were excluded from analysis due to intraoperative or postoperative complications. Patient demographics and preoperative clinical information are shown in Table 1. No patient was lost to follow-up.

VISUAL ACUITY AND REFRACTION

Table 2 shows the visual, refractive, and keratometric changes. Figure 1A shows the percentage of eyes with cumulative Snellen visual acuity 20/x or better at the 4-month follow-up. There were no statistically significant differences in UDVA or CDVA across the examinations

during the follow-up period. UDVA was 0.3 logMAR or better (Snellen equivalent 20/40 or better) in 50 (98%) eyes and 0.1 logMAR (Snellen equivalent 20/25 or better) in 42 (82%) eyes. Figure 1B shows the attempted versus achieved SE refraction. Figure 1C shows the SE refractive accuracy. Postoperative SE refraction was within ± 0.50 D of the attempted correction in 44 (86%) eyes and within ± 1.00 D in 50 (98%) eyes. Figure 1D shows the distribution of postoperative refractive astigmatism. Refractive astigmatism was within ± 0.50 D of the attempted correction in 30 (59%) eyes and within ± 1.00 D in all eyes. Figure 1E shows the target induced astigmatism (TIA) versus SIA. Undercorrection or overcorrection were independent on the magnitude of intended treatment. Figure 1F shows the refractive astigmatism angle of error. The majority of eyes (61%) were within -5° to 5° of the target.

VECTOR ANALYSIS

For vector analysis, data from manifest refraction in the postoperative period were compared with target data calculated from the preoperative keratometry. We calculated the geometric mean for the correction index. Mean magnitude of TIA, which represents the attempted astigmatic correction, was 1.96 $\pm$ 0.94 D (range: 0.70 to 4.50 D). Mean magnitude of SIA, which is the astigmatic correction achieved by surgery, was 1.85 $\pm$ 1.01 D (range: 0.07 to 4.64 D). Figure 2A shows the TIA vector and Figure 2B shows the SIA vector. Figure 2C shows the difference vector (vectorial difference between the TIA and SIA vectors). Figure 2D shows the correction index (SIA divided by TIA), which was 0.87 D (range: 0.07 to 2.29 D), representing a slight undercorrection, confirmed by the magnitude of error (arithmetic difference between the TIA and the SIA), which was -0.11 ± 0.43 D (range: -0.98 to 0.90 D). In eyes with treated against-the-rule astigmatism (0° to 30° and 150° to 180°), the correction index was 0.94, near the ideal value of 1. When the treated astigmatism was with-the-rule (60° to 120°), the correction index was 0.75. In eyes with oblique astigmatism (31° to 59° and 121° to 149°), the correction index was 0.73, reflecting a slight undercorrection, although the number of treated eyes in this group was small (2) and all of the eyes had low astigmatism (< 1.50 D). The index of success, which is the difference vector divided by the TIA (ideally 0), was 0.33 ± 0.27 D (range: 0.00 to 1.43 D). The mean angle of error was $1.12^\circ \pm 9.82^\circ$ (range: -19.89° to 44°), representing a slight counterclockwise deviation from the intended correction axis. Mean absolute angle of error was $6.06^\circ \pm 7.81^\circ$ (range: 0° to 44°).

ROTATIONAL STABILITY

At 4 months of follow-up, mean toric IOL axis rotation was $1.98^\circ \pm 1.78^\circ$ (range: 0° to 7°). The difference

TABLE 2
Visual Acuity, Refractive Results, and Keratometric Changes

Parameter	Preoperative	4 Months Postoperative	P
Sphere (D)			
Mean $\pm$ SD	-0.72 $\pm$ 3.89	0.07 $\pm$ 0.37	.244 ^a
Range	-10.00 to +8.00	-0.75 to +1.00	
Refractive cylinder (D)			
Mean $\pm$ SD	-2.38 $\pm$ 1.17	-0.51 $\pm$ 0.29	< .001 ^a
Range	-6.00 to -0.50	-1.00 to 0.00	
SE (D)			
Mean $\pm$ SD	-1.91 $\pm$ 3.85	-0.19 $\pm$ 0.38	.004 ^b
Range	-10.50 to 6.75	-1.13 to 0.50	
UDVA (logMAR)			
Mean $\pm$ SD	1.02 $\pm$ 0.63	0.06 $\pm$ 0.10	< .001 ^a
Range	0.22 to 3.00	-0.18 to 0.40	
CDVA (logMAR)			
Mean $\pm$ SD	0.52 $\pm$ 0.49	0.00 $\pm$ 0.07	< .001 ^a
Range	0.15 to 3.00	-0.18 to 0.15	
Keratometry			
K1 (mm)			
Mean $\pm$ SD	7.76 $\pm$ 0.37	7.79 $\pm$ 0.34	.103 ^b
Range	6.80 to 8.57	6.96 to 8.54	
K2 (mm)			
Mean $\pm$ SD	7.55 $\pm$ 0.28	7.58 $\pm$ 0.31	.161 ^b
Range	6.96 to 8.29	6.86 to 8.28	

D = diopters; SD = standard deviation; SE = spherical equivalent refraction; UDVA = uncorrected distance visual acuity; CDVA = corrected distance visual acuity
^aWilcoxon rank sum test.

^bStudent's t test.

between 1-day and 4-month follow-up was not statistically significant ($P = .789$). No eye required secondary surgery for IOL rotation.

OCULAR ABERROMETRY

Table 3 shows the ocular aberrometry outcomes through the mean wavefront aberration values and the Strehl ratio at the 4-month follow-up.

DISCUSSION

In our prospective case series, implantation of the Precizon Toric IOL resulted in a significant improvement in UDVA and CDVA, with 98% of eyes achieving a UDVA of 0.3 logMAR or better. For SE IOL power calculation, we used the SRK/T formula¹⁰ in eyes with an axial length greater than 22 mm and the Hoffer Q formula⁹ in eyes with an axial length of 22 mm or less. This choice was accurate enough to achieve a postoperative SE near the target (-0.18 ± 0.38 D). Refractive cylinder was within ± 1.00 D in all eyes and remained stable throughout the follow-

up. These visual and refractive outcomes are consistent with recent studies of other toric IOLs.^{5-7,14}

Rotational stability is paramount in a toric IOL. Even minor degrees of misalignment can cause significant loss of cylinder correction efficacy with subsequent residual refractive errors and visual acuity deterioration.¹⁵ The postoperative rotational stability in our study was excellent, with a mean rotation at the 4-month follow-up of $1.98^\circ \pm 1.78^\circ$. These rotational stability results are similar to those reported in other recent toric IOL studies.^{5-7,14} IOL rotation is mainly caused by haptic compression resulting from capsular contraction. The Precizon Toric IOL was designed with offset-shaped haptics to prevent postoperative rotation and posterior capsule opacification. The IOL biomaterial is crucial to its rotational stability. IOL optic surface adhesiveness varies with the IOL material, being higher with acrylic IOLs, followed by polymethylmethacrylate IOLs and silicone IOLs.¹⁶ The study IOL is made of hydrophilic acrylate, which should ensure a strong capsular bag ad-

Figure 1. Postoperative results at the 4-month follow-up. (A) Percentage of eyes with cumulative Snellen visual acuity 20/x or better. (B) Attempted versus achieved spherical equivalent refraction (SEQ). (C) Accuracy of SEQ correction. (D) Distribution of refractive astigmatism. (E) Target induced astigmatism (TIA) versus surgically induced astigmatism (SIA). (F) Refractive astigmatism angle of error. UDVA = uncorrected distance visual acuity; CDVA = corrected distance visual acuity; D = diopters

hesis. It is known that 1° of off-axis rotation results in a loss of approximately 3.3% of the IOL's cylinder power.¹⁵ The Precizon Toric IOL is designed with a broader toric meridian and is more tolerant of misalignment. Using intraoperative aberrometry, Mertens¹⁷ showed that the new design of the Precizon Toric IOL decreases loss of cylinder power with misalignment in 50% when compared with a traditional toric IOL design (Lentis toric IOL; Oculentis GmbH, Berlin, Germany)¹⁷; therefore, considering these data and our misalignment results, only approximately 3.2% of the IOL cylinder power was lost in our eyes. There was a significant difference between postoperative IOL rotation and absolute angle of error ($P < .001$; Wilcoxon test) and there was no correlation between rotation and angle of error (Spearman's $\rho = .271$; $P = .055$), suggesting IOL rotation was not an important factor in the small angle of error we observed. There are several methods to determine the misalignment of a toric IOL. One simple method is to perform a slit-lamp examination with the pupil dilated, although this can be rather inaccurate because the measuring reticule on the slit-lamp uses 5° steps. Analysis of intraoperative and postoperative retroillumination

photographs is an effective method of determining IOL rotation.¹⁸ It is also possible to calculate misalignment by vector analysis, measuring the angle of error.¹⁹ We used the OPD-III Scan, which is a simple and repeatable method of studying IOL misalignment by retroillumination photographs.¹¹

In our study, TIA was higher than SIA, so a slight undercorrection was achieved. Similarly, the correction index (ratio of SIA to TIA) was 0.87 and the difference vector was 0.18, reflecting the slight undercorrection achieved by the toric IOL implantation. When the treated astigmatism was with-the-rule, the correction index was 0.75, reflecting a slight undercorrection. In eyes with treated against-the-rule astigmatism, the correction index was 0.94, almost the ideal value of 1. In eyes with oblique astigmatism, the correction index was 0.73, reflecting only a slight undercorrection considering the low astigmatism magnitude in eyes in this group.

For analysis of aggregate data of astigmatism, Alpíns described two methods: an examination based in arithmetic means, disregarding the orientation of the vector to determine the mean vector magnitude, or the addition of the magnitudes of the vectors with regard to

Figure 2. Single-angle polar plots for the target induced astigmatism vector (TIA), surgically induced astigmatism vector (SIA), difference vector (DV), and correction index (CI). The vector means are plotted as a red dot (calculated in double-angle vector space) and the standard deviations (SDs) for the X and Y directions are displayed in the call-out box. D = diopters

each vector's orientation to determine a summated vector mean of the group. We used the first method in our study. The summated vector mean is always less than the mean vector magnitude (in our case, TIA = 0.54, SIA = 0.69, and difference vector = 0.18). When the difference between the two methods is high, as in our case, the changes are more likely due to random events.¹³ Although the undercorrection in our study was small and probably due to the intrinsic variation of techniques to measure astigmatism, it can have several other possible explanations. As reported by Goggin et al., there may be an underestimation of the effective cylinder power at the corneal plane by the manufacturer.²⁰ Another possible explanation is the high number of eyes in our study with preoperative against-the-rule astigmatism. In these eyes, an underestimation of corneal astigmatism results from ignoring the negative power effect of the steep meridian of the posterior cornea, which tends to be aligned vertically.²¹ Previous studies of toric IOLs including vector analysis reported either overcorrection^{7,22} or undercorrection.^{23,24}

In our study, the HOA RMS, coma, trefoil, and Strehl ratio were similar to those found in recent studies of oth-

TABLE 3
Ocular Aberrometry Analysis

Parameter	Value
HOA RMS (μm)	
Mean $\pm$ SD	0.33 $\pm$ 0.13
Range	0.12 to 0.93
Spherical aberration (μm)	
Mean $\pm$ SD	0.21 $\pm$ 0.07
Range	0.01 to 0.30
Coma (μm)	
Mean $\pm$ SD	0.24 $\pm$ 0.16
Range	0.06 to 0.69
Trefoil (μm)	
Mean $\pm$ SD	0.32 $\pm$ 0.19
Range	0.13 to 0.90
Strehl ratio	
Mean $\pm$ SD	0.03 $\pm$ 0.02
Range	0.00 to 0.07

HOA RMS = higher order aberration root mean square; SD = standard deviation

er toric IOLs.^{11,25} Postoperative spherical aberration ($0.21 \pm 0.07 \mu\text{m}$) reflects the $0 \mu\text{m}$ of spherical aberration in the aspheric optic of the Precizon Toric IOL. Ocular HOAs were evaluated with the OPD-III Scan. This system has good repeatability for the wavefront measurement of total, corneal, and internal optical aberrations.^{12,26}

The results of our study show that the implantation of the Precizon Toric IOL in patients with cataract and regular corneal astigmatism provided excellent visual outcomes, predictability of astigmatic correction, optical quality, and rotational stability.

AUTHOR CONTRIBUTIONS

Study concept and design (TBF, FJR); data collection (TBF, FJR); analysis and interpretation of data (TBF, FJR, TTJMB); writing the manuscript (TBF); critical revision of the manuscript (TBF, FJR, TTJMB); statistical expertise (TBF); supervision (TBF, FJR, TTJMB)

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Figure A. Relationship of Coddington shape factor with spherical aberration. Image available open access from Melles Griot (www.cvilaseroptics.com).

Figure B. The transitional conic surface of the Precizon Toric IOL (model 565; Ophtec BV, Groningen, The Netherlands).