2015-02

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http://hdl.handle.net/10026.1/9187

Safety and effectiveness of a new toric presbyopia-correcting posterior chamber silicone intraocular lens

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PURPOSE: To evaluate the safety and effectiveness of the Trulign toric intraocular lens (IOL) in adults with cataract.

SETTING: Eight private practices in the United States and 1 in Canada.

DESIGN: Prospective randomized single-masked multicenter study.

METHODS: A toric IOL (1.25 D, 2.00 D, or 2.75 D, determined by a toric calculator) was implanted in eligible patients with age-related cataract requiring a 16.00 to 27.00 diopter (D) spherical IOL power and with a predicted postoperative astigmatism of 0.83 to 2.50 D. Eyes within the lowest cylinder range (predicted postoperative astigmatism 0.83 to 1.32 D) were randomized in a 1:1 ratio between the 1.25 D toric IOL group and the nontoric accommodating IOL (Crystalens) control group.

RESULTS: The toric 1.25 D group had a statistically significantly greater percentage reduction in absolute cylinder ($P < .001$) and uncorrected distance visual acuity ($P = .002$) than the control group at the 120- to 180-day visit. The mean monocular uncorrected vision at distance, intermediate, and near was 20/25, 20/22, and 20/39, respectively, with the 1.25 D, 2.00 D, and 2.75 D toric IOLs in aggregate (toric group). In addition, 96.1% of patients (123/128) had 5.0 degrees or less absolute IOL rotation postoperatively. Regarding safety, the endpoints for preservation of corrected visual acuity and the incidence of complications and adverse events were met.

CONCLUSION: The toric IOL was safe and effective in reducing the effects of preoperative corneal astigmatism and provided excellent uncorrected distance and intermediate vision and functional near vision.

Financial Disclosures: Dr. Pepose is a consultant to Bausch & Lomb and was medical monitor of this study. Drs. Buckhurst, Whitman, Feinerman, Hovanesian, Davies, Labor, and Carter are consultants to Bausch & Lomb. At the time of the study, Drs. Hayashida, and Khodai were employees of Bausch & Lomb. Drs. Colvard and Mittleman have financial or proprietary interest in any material or method mentioned.

J Cataract Refract Surg 2015; 41:295–305 © 2015 ASCRS and ESCRS

It has been estimated that more than 1.0 diopter (D) of preexisting corneal astigmatism occurs in 36% to 39% of patients with cataract and more than 1.5 D of preexisting corneal astigmatism occurs in 15% to 22% of patients with cataract.[1–4] The visual outcome after cataract surgery can be improved if preexisting corneal astigmatism is corrected. Toric intraocular lenses (IOLs) were conceived with the intent of providing greater predictability and reversibility over keratorefractive procedures. The use of toric IOLs also mitigates some disadvantages and side effects of incisional astigmatic correction, such as varied wound healing, corneal denervation, corneal perforation, infection, wound gape, and decreased spectacle-corrected vision resulting from irregular astigmatism.[5–8] Similarly, it eliminates some limitations and side effects of excimer laser correction of astigmatism, such as corneal haze, dry eye, regression, and diffuse lamellar keratitis.[9]

This study describes the clinical experience with a new toric posterior chamber IOL, the Trulign (Bausch & Lomb). The IOL is intended for primary implantation in the capsular bag for the visual correction of aphakia and postoperative refractive astigmatism secondary to removal of a cataractous lens in adults with or without presbyopia who desire a reduction in residual refractive cylinder with increased spectacle independence and improved uncorrected near, intermediate, and distance vision. This toric IOL has rectangular hinged haptics with polyimide loops. These loops help stabilize the IOL in the capsular bag and have indicators to remind the surgeon that it is round to the right to help ensure proper positioning. The IOL has a single focal point (it does not split light between multiple foci) and is designed to neither adversely affect contrast sensitivity nor cause glare or halos.[10–12] The objective of this study was to evaluate the safety and effectiveness of the Trulign toric IOL in patients having cataract extraction and IOL placement.

PATIENTS AND METHODS
Study Design and Patients

This prospective randomized single-masked monocular study was performed at 8 sites throughout the United States and 1 site in Canada (clinical trial registration number NCT01140477[A]). All patients provided written informed consent after receiving an explanation of the purpose of the study and the associated risks and benefits. Institutional review board approval was obtained at each study site. The study adhered to the tenets of the Declaration of Helsinki, U.S. Food and Drug Administration (FDA) regulations, and International Conference on Harmonization guidelines.

After a baseline preoperative examination, patients who were eligible to receive a 1.25 D toric power IOL were randomized to receive the Trulign toric IOL (model AT50 T or AT52 T) (toric group) or nontoric Crystalens accommodating IOL (model AT50SE or AT52SE, Bausch & Lomb) (nontoric group). Each investigator was to contribute a minimum of 20 patients with toric IOLs; however, no investigator could contribute more than 25% of the total toric IOL study enrollment. Patients were evaluated postoperatively at scheduled visits up to 330 to 420 days postoperatively. Patients were masked to treatment assignment.

The study included patients who met the following criteria: 18 years or older, had age-related cataract (cortical, nuclear, subcapsular, or combination) that was considered amenable to treatment with standard phacoemulsification/extracapsular cataract extraction, scheduled for primary IOL implantation for the correction of aphakia after continuous curvilinear anterior capsulotomy and phacoemulsification cataract extraction, required an IOL power from 16.00 to 27.00 D, had predicted postoperative corneal astigmatism between 0.83 D and 2.50 D (determined by a toric calculator), had a potential corrected distance visual acuity (CDVA) of 20/32 or better in the operated eye on potential visual acuity meter testing, and had a CDVA of 20/40 or worse with or without a glare source.

Exclusion criteria were previous corneal pathology potentially affecting topography; anterior segment pathology for which extracapsular/phacoemulsification cataract surgery would have been contraindicated (eg, chronic uveitis, iritis, iridocyclitis, rubeosis iridis, clinically significant corneal dystrophy, Fuchs dystrophy, anterior membrane dystrophy); diagnosis of degenerative visual disorders that would cause potential acuity losses to 20/32 or worse; conditions associated with an increased risk for zonular rupture; corneal inflammation or edema (including keratitis, keratoconjunctivitis, and keratouveitis); unable to achieve pupil dilation of 5.0 mm; uncontrolled glaucoma; previous retinal detachment; diabetic retinopathy; previous corneal surgery in the operative eye; rubella; bilateral congenital, traumatic, or complicated cataract; marked microphthalmos or aniridia; irregular corneal astigmatism, amblyopia; significant retinal pigment or epithelium/macular changes; iris or chorioretinal neovascularization; optic atrophy; chronic use of systemic steroids or immunosuppressive medications; and a significant difference between corneal astigmatism measured with partial coherence interferometry (PCI) (IOLMaster, Carl Zeiss Meditec AG) and axial topography (vector difference between the 2 instruments <0.5 D).

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Intraocular Lenses

The Trulign toric IOL is an astigmatism-correcting silicone multipiece IOL (model AT-50T or AT-52T) (Figure 1) and is a toric modification of the parent Crystalens. The plate haptics are hinged adjacent to the optic and have small looped polyimide haptics. The overall length (loop tip to tip) of model AT-50T is 11.5 mm, and the overall length (loop tip to tip) of model AT-52T is 12.0 mm. The optic diameter is 5.0 mm,
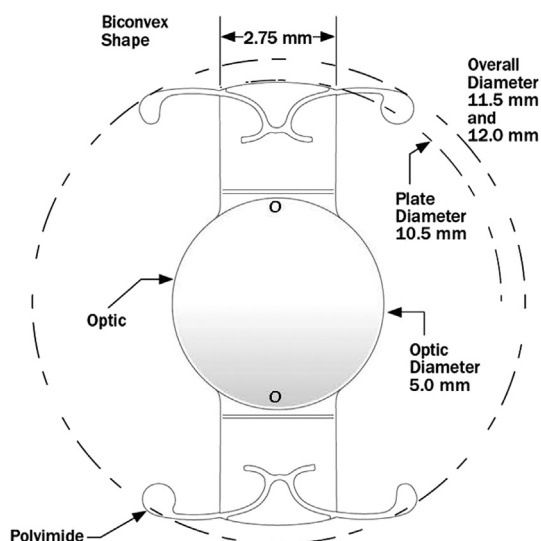
Figure 1. Schematic of the toric IOL.

and the recommended A-constant is 119.0. The toric IOL is intended for placement in the capsular bag only. It has a spherical front (anterior) surface and a toric back (posterior) surface. Two marks on the peripheral anterior optical surface aid in proper alignment of the IOL; the lines indicate the flat axis of the toric IOL. The available spherical equivalent (SE) powers range from +16.00 to +27.00 D in 0.50 D increments with cylindrical powers at the lens plane of 1.25 D, 2.00 D, and 2.75 D (estimated cylinder power at the corneal plane 0.83 D, 1.33 D, and 1.83 D, respectively). The flattest meridian is along the long axis of the IOL.

The control was the Crystalens silicone multipiece accommodating IOL (model AT-50SE or AT-52SE). It has a modified platehaptic intended for placement in the capsular bag only. The plate haptics are hinged to the optic and have small looped polyimide haptics. The overall length (loop tip to tip) of model AT-50SE is 11.5 mm, while the overall length (loop tip to tip) of model AT-52SE is 12.0 mm. Both models have an optic diameter of 5.0 mm. The available SE powers range from +16.00 to +16.50 D for the AT-52SE and +17.00 to +27.00 D for the AT-50SE in 0.50 D increments. The recommended A-constant for the control IOL is 119.0.

Preoperative Assessment

Within 90 days of surgery, baseline examinations, including CDVA, intraocular pressure (IOP), and slitlamp assessment, were performed. In addition, keratometry, topography, axial length, and anterior chamber depth were measured to determine the power of the IOL to be implanted. The Trulign Toric Calculator[B] was used to calculate the predicted postoperative corneal astigmatism using preoperative keratometry, phacoemulsification/insertion incision location, and the predicted magnitude of surgically induced astigmatism (SIA) inputs from the investigator. A fixed SIA value of 0.50 D was used in the toric calculator for all patients in the study. The calculator determined the toric IOL cylinder power needed and placement orientation to best correct the patient's predicted postoperative corneal astigmatism. The axis of placement was identified as follows: Immediately before surgery with the patient seated at the

slitlamp, the patient's anesthetized dilated operative eye was marked using the orientation of the slit beam rotated according to the degree scale and using a marking instrument of the surgeon's preference.

Surgical Technique

Surgeons used standard microsurgical techniques with the following specifications: (1) To prevent forward vaulting of the optic, an incision width no greater than 3.0 mm for the AT-50T was recommended with a paracentesis approximately 1.5 mm long. (2) A multiplane incision was used to ensure that it was watertight at the close of the case. (3) The incision was placed at the preoperative keratometric steep axis in all eyes. (4) The anterior chamber was entered through the incision opening, and a cohesive ophthalmic viscosurgical device (OVD) (surgeon's preference) was used to fill the anterior chamber. (5) An anterior, round capsulorhexis of 5.5 mm to 6.0 mm was created to allow the anterior capsule to cover the plate haptics while keeping the optic free. (6) The cataract was extracted by phacoemulsification. After the IOL was inserted, alignment was confirmed by ensuring the markings on the IOL were aligned with the placement markings on the cornea. Once the IOL was aligned and vaulted posteriorly in the capsule, all OVD anterior and posterior to the IOL was removed to prevent IOL rotation. Before the wound was closed, a final check was performed to ensure the axis was correctly aligned. Immediately after surgery while the pupil was still dilated, a digital image showing the IOL axis marks, optic edge, and scleral–conjunctival blood vessels was recorded at ×10 magnification using image-capturing equipment (Haag Streit BD900 slitlamps with CM900 digital cameras). The IOL and scleral–conjunctival blood vessels were also imaged at regular intervals over the course of the study after the pupil was dilated with tropicamide 1.0% and phenylephrine 2.5%. The rotational stability of the IOL was determined by analyzing the postoperative IOL images, and any torsion of the eye was accounted for using scleral–conjunctival landmarks.[13,14]

Postoperative Assessment

Postoperatively, patients had a complete ophthalmic examination at regular intervals per the study visit schedule as follows: visit 1 (1 to 2 days postoperatively), visit 2 (7 to 14 days postoperatively), visit 3 (30 to 60 days postoperatively), visit 4 (120 to 180 days postoperatively), visit 5 (245 to 301 days postoperatively), and visit 6 (330 to 420 days postoperatively). Postoperative assessments included manifest refraction (autorefraction was not permitted), uncorrected distance visual acuity (UDVA), uncorrected intermediate visual acuity (UIVA) measured at 80 cm, uncorrected near visual acuity (UNVA) measured at 40 cm, CDVA with glare, distance-corrected intermediate visual acuity (DCIVA) measured at 80 cm, distance-corrected near visual acuity (DCNVA) measured at 40 cm, corrected near visual acuity measured at 40 cm, and cycloplegic refraction using cyclopentolate 1.0%. The manifest refraction spherical equivalent (MRSE) was calculated as the value of the sphere plus one half the value of the cylinder. All visual acuities were recorded using the Optec 6500/6500P Vision Tester (Stereo Optical Co.). In addition, the incidence of adverse events, slitlamp results (corneal stromal edema and anterior chamber aqueous cell and flare), IOP, fundus examination, keratometry with PCI, corneal topography, IOL rotational stability, and visual

Table 1. Percentage reduction in absolute cylinder expressed as a percentage of the intended reduction in cylinder at the 120- to 180-day postoperative visit.

Statistic	Nontoric IOL (n = 68)	Toric 1.25 D IOL (n = 74)	Toric 2.00 D IOL (n = 39)	Toric 1.75 D IOL (n = 21)	All Toric IOLs (n = 134)
Mean (%) ± SD	46.5 ± 43.8	79.9 ± 31.8	88.0 ± 27.1	97.4 ± 19.2	85.0 ± 29.3
95% CI (%)	35.9, 57.1	72.5, 87.2	79.2, 96.7	88.7, 106.1	80.0, 90.0
P value	—	<.001	—	—	—

CI = confidence interval; IOL = intraocular lens
*Percentage reduction in absolute cylinder is defined as the difference between the postoperative magnitude of the subjective manifest refractive cylinder (converted to the corneal plane) and the preoperative magnitude of the keratometric cylinder, divided by the intended reduction in cylinder, expressed as a percentage. The intended reduction in cylinder is the difference between the intended magnitude of the postoperative manifest refractive cylinder (converted to the corneal plane), presuming toric IOL implantation, and the magnitude of the preoperative keratometric cylinder.

disturbances according to a patient questionnaire were assessed. Intraocular lens tilt was assessed using the method described by Guyton et al.[15]

Statistical Analysis

A sample size of at least 65 eyes in each group was required to provide 90% power to detect a clinically significant difference in the percentage reduction in cylinder between eyes with the lowest IOL cylinder and eyes with the nontoric IOL (control).[16] The efficacy analyses included all patients who had implantation of a study IOL (toric or nontoric), whose IOL was not repositioned, and who had no major protocol deviations (effectiveness cohort). The safety analyses included all patients who had surgery for the implantation of a study IOL (toric or nontoric), whether a study IOL was implanted or not (safety cohort). Two patients who were discontinued because of intraoperative surgical complications and who therefore did not receive a study or a control IOL were excluded from all analyses.

The primary analysis occurred was when IOL rotational stability was achieved, which was at the 120- to 180-day visit. Vector analysis was used to calculate the SIA in the effectiveness cohort at the 120- to 180-day visit. The SIA is defined as the vector difference between the baseline and the postoperative keratometric astigmatism vectors. Continuous measures were described by the mean, standard deviation, minimum, and maximum. Categorical measures were summarized using frequencies and percentages. The primary efficacy endpoint was a comparison of the reduction in cylinder between the low-cylinder toric 1.25 D group and the nontoric group at the time rotational stability was achieved (120- to 180-day visit). The intended reduction in cylinder was computed under the assumption that a toric IOL would be implanted. Analysis of the percentage cylinder reduction (defined in the footnote in Table 1) included continuous summary statistics, a 95% confidence interval (CI) around the mean, and a 2-sample 1-sided *t* test assuming unequal variances to test the alternative hypothesis that the toric 1.25 D IOL yielded a greater reduction in absolute cylinder than the control nontoric IOL. Visual acuities were compared using 2-sided asymptotic Wilcoxon-Mann-Whitney rank-sum tests with continuity correction. Confidence intervals for percentages were exact (Clopper-Pearson) binomial CIs. The mean Snellen (feet) denominators were computed as 20 times the common antilogarithm of the mean logMAR acuity rounded to the nearest integer.

RESULTS

Disposition and Baseline Characteristics

Of the patients, 229 were enrolled at 8 investigational sites in the U.S. and 9 were enrolled at 1 site in Canada. Twelve patients (5.2%) were excluded from the study after IOL implantation. Of these, 4 (1.7%) were lost to follow-up, 5 (2.2%) withdrew consent, 1 (0.4%) required IOL explantation, and 2 (0.9%) died. In addition, 2 patients (0.9%) were excluded before IOL implantation because of surgical complications. Of the 19 patients excluded from the effectiveness cohort, 2 did not have an IOL implanted and 17 had major protocol deviations. Therefore, 210 patients were included in the effectiveness cohort, 138 patients in the toric group (75 with a 1.25 D toric IOL; 40 with a 2.00 D toric IOL; 23 with a 2.75 D toric IOL) and 72 patients in the nontoric group.

Patients in the toric group and patients in the nontoric group had similar demographics; 52.9% of patients (81/153) in the toric group and 55.3% (42/76) in the nontoric group were women. The mean age was 70.1 years ± 9.0 (SD) (range 48 to 89 years) in the toric group and 69.8 ± 9.2 years (range 47 to 89 years) in the nontoric group. The mean IOL SE was 20.51 ± 2.26 D and 20.57 ± 2.29 D, respectively.

Reduction in Cylinder—Primary Efficacy

Table 1 shows the percentage reduction in absolute cylinder expressed as a percentage of the intended reduction in cylinder. The toric 1.25 D group had a statistically significantly greater mean percentage reduction in absolute cylinder than the nontoric group (*P* < .001). Figure 2 compares the incidence (percentage of study eyes) and magnitude (stratified by 0.00 D, ≤ 0.50 D, ≤1.00 D, ≤1.50 D, ≤2.00 D, and >2.00 D) of residual refractive cylinder at the 120- to 180-day visit between the toric 1.25 D group and the nontoric group. A greater percentage of eyes in the toric 1.25 D group than in the nontoric group had a cumulative residual cylinder of 1.00 D or less. Table 2 shows the percentage of eyes with a reduction in cylinder within ±0.50 D and
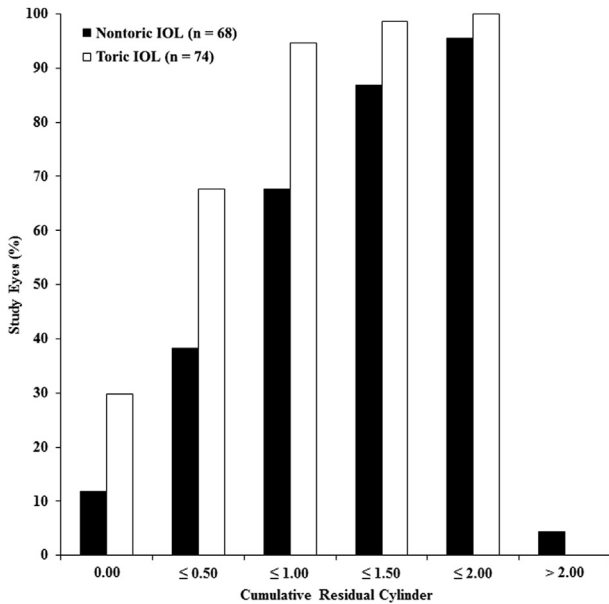
Figure 2. Cumulative residual cylinder in the toric 1.25 D group and the nontoric group at the 120- to 180-day visit (IOL = intraocular lens).

±1.00 D of the intended. The percentage of patients within ±0.50 D and ±1.00 D of the intended reduction was greater in the all-diopter toric group than in the nontoric group.

Visual Acuity

Table 3 shows the mean monocular UDVA, UIVA, and UNVA at the 120- to 180-day visit. The mean UDVA was statistically significantly better in the toric 1.25 D group than in the nontoric group ($P = .002$) and the all-diopter toric group ($P < .001$). There were no statistically significant differences in UIVA or UNVA between the groups. At the 120- to 180-day visit, 135/138 (97.8%) in the all-diopter toric group had a UDVA and UIVA of 20/40 or better and 97 (70.1%) had UNVA of 20/40 or better (Figure 3).

Table 2. Eyes with a reduction in cylinder within ±0.50 D and ±1.00 D of the intended at the 120- to 180-day postoperative visit.

Parameter	Nontoric (n = 72)	All Toric (n = 138)
Within ±0.50 D of intended		
Eyes, n (%)	30 (44.1)	105 (78.4)
95% CI (%)	32.1, 56.7	70.4, 85.0
Within ±1.00 D of Intended		
Eyes, n (%)	49 (72.1)	128 (95.5)
95% CI (%)	59.9, 82.3	90.5, 98.3
CI = confidence interval		

For DCIVA at 32 inches (80 cm), DCNVA at 16 inches (40 cm), and DCNVA with addition (add) at 16 inches (40 cm), no statistically significant differences were found between the all-diopter toric group and the nontoric group at the 120- to 180-day visit (Table 4). The mean required add was not significantly different between the all-diopter toric group and nontoric group (Table 4).

Manifest Refractive Cylinder

The toric 1.25 D group (n = 74) had a statistically significantly lower mean absolute residual cylinder than the nontoric group (n = 68) (0.48 ± 0.41 D versus 0.89 ± 0.61 D) (Figure 4). The difference between the 2 groups was 0.41 ± 0.52 D ($P < .001$).

Corneal Cylinder Versus Manifest Refractive Cylinder

Figure 4 compares the magnitude of corneal cylinder (via keratometry) at the 120- to 180-day visit with the magnitude of residual refractive cylinder at

Table 3. Mean UDVA, UIVA, and UNVA at the 120- to 180-day postoperative visit.

| Parameter	Nontoric Control (n = 72)	Toric 1.25 D (n = 74)	P Value Control Vs Toric 1.25 D	All Toric (n = 134)	P Value Control Vs All Toric
UDVA			.002		<.001
Mean Snellen	20/31	20/25		20/25	
Mean logMAR ± SD	0.189 ± 0.181	0.099 ± 0.140		0.093 ± 0.132	
UIVA			.606		.530
Mean Snellen	20/23	20/22		20/22	
Mean logMAR ± SD	0.069 ± 0.153	0.044 ± 0.116		0.042 ± 0.129	
UNVA			.980		
Mean Snellen	20/39	20/38		20/39	
Mean logMAR ± SD	0.286 ± 0.137	0.284 ± 0.155		0.289 ± 0.150	
UDVA = uncorrected distance visual acuity; UIVA = uncorrected intermediate visual acuity; UNVA = uncorrected near visual acuity					
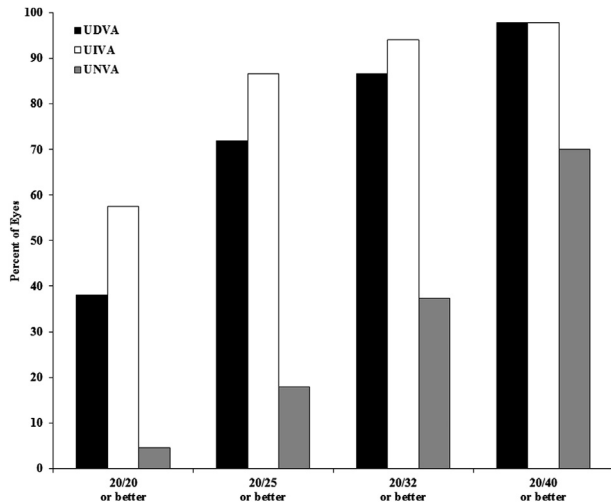
Figure 3. The UDVA, UIVA, and UNVA in the all-diopter toric group at the 120- to 180-day visit (n = 134) (UDVA = uncorrected distance visual acuity; UIVA = uncorrected intermediate visual acuity; UNVA = uncorrected near visual acuity).

Table 4. Mean DCIVA, DCNVA, DCNVA with add and the mean add at the 120- to 180-day postoperative visit.

Parameter	Toric Control	All Toric	P Value
DCIVA			.594
Eyes (n)	67	133	
Mean Snellen	20/24	20/23	
Mean logMAR ± SD	0.074 ± 0.142	0.054 ± 0.125	
DCNVA			.756
Eyes (n)	67	133	
Mean Snellen	20/41	20/40	
Mean logMAR ± SD	0.309 ± 0.138	0.301 ± 0.144	
DCNVA with add			.310
Eyes (n)	68	134	
Mean Snellen	20/22	20/22	
Mean logMAR ± SD	0.045 ± 0.072	0.036 ± 0.072	
Mean add ± SD	1.599 ± 0.575	1.448 ± 0.486	.051

add = addition; DCIVA = distance-corrected intermediate visual acuity; DCNVA = distance-corrected near visual acuity

that same visit (ie, the effectiveness). Because the eyes qualifying for the lowest toric cohort were randomized 1:1 between the nontoric group and the 1.25 D toric IOL, their mean corneal cylinder was the same (1.14 ± 0.41 D and 1.16 ± 0.43 D, respectively). However, the residual manifest refractive was statistically significantly lower with the 1.25 D toric IOL than with the nontoric IOL (0.48 ± 0.41 D versus 0.89 ± 0.61 D). Eyes with the 2.00 D and 2.75 D toric IOLs had equivalent higher corneal astigmatism (1.60 ± 0.48 D and 2.07 ± 0.55 D, respectively);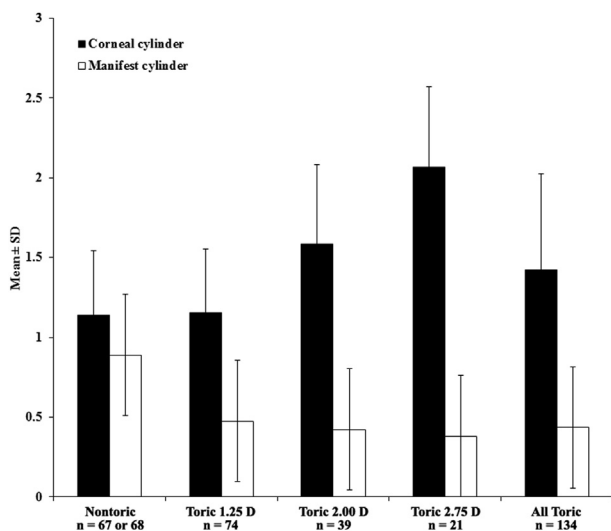 however, the mean manifest refractive cylinder remained less than 0.50 D (0.43 ± 0.50 D and 0.32 ± 0.38 D, respectively).

Manifest Refractive Spherical Equivalent

At the 120- to 180-day visit, the mean MRSE in the 134 eyes in the all-diopter toric group was −0.29 ± 0.49 D; the MRSE was within ±0.50 D in 100 eyes (74.6%) and within ±1.00 D in 126 eyes (94.0%). At the 120- to 180-day visit, the mean MRSE in the 68 eyes in nontoric group was −0.45 ± 0.56 D; the MRSE was within ±0.50 D in 42 eyes (61.8%) and within ±1.00 D in 61 eyes (89.7%). The 0.16 D difference in the mean MRSE between the all-diopter toric group and the nontoric group and was statistically significant (P = .03).

Surgically Induced Astigmatism

The mean SIA was 0.748 ± 0.492 D in the all-diopter toric group and 0.696 ± 0.467 D in the nontoric group.

Rotational Stability

Table 5 shows the mean absolute IOL rotation between implantation and the 120- to 180-day visit. As shown, 123 of 128 patients (96.1%) in the all-diopter toric group had 5 degrees or less of absolute rotation from immediately after implantation to the 120- to 180-day visit.

Visual Disturbances

One patient (0.8%) with a 2.00 D toric IOL and 6 patients (9.1%) with a nontoric IOL reported having 1 or more significant visual disturbances. In the 1 patient

Figure 4. Mean magnitude of corneal cylinder versus manifest refractive cylinder at the 120- to 180-day visit.

Table 5. Absolute rotation between implantation and the 120- to 180-day visit.

Rotation	Toric 1.25 D (n = 72)	Toric 2.00 D (n = 36)	Toric 1.75 D (n = 20)	All Toric (n = 128)
Mean ± SD (degrees)	2.2 ± 3.7	1.4 ± 1.1	1.4 ± 1.3	1.9 ± 2.9
≤5.00, eyes (%)	67 (93.1)	36 (100.0)	20 (100.0)	123 (96.1)
5.01 to 10.00, eyes (%)	4 (5.6)	0	0	4 (3.1)
>10.00, eyes (%)	1 (1.4)	0	0	1 (0.8)

with the 2.00 D toric IOL, the IOL was 1.43 degrees from its target axis orientation at the 120- to 180-day visit. The patient developed moderate posterior capsule opacification (PCO). After a neodymium:YAG (Nd:YAG) treatment, the patient reported that the visual disturbances were resolved. None of the patients (20 eyes with the highest cylinder correction [2.75 D]) reported significant visual disturbances.

Intraocular Lens Decentration and Tilt

The mean total decentration at the 120- to 180-day visit was 0.007 ± 0.086 mm (range 0.00 to 1.00 mm) in the all-diopter toric group and 0.001 ± 0.012 mm (range 0.00 to 0.10 mm) in the nontoric group. The mean IOL tilt was 0.285 ± 1.083 degrees (range 0.00 to 8.74 degrees) in the all-diopter toric group and 0.362 ± 1.026 degrees (range 0.00 to 5.83 degrees) in the nontoric group. The mean difference in IOL tilt (−0.077 ± 1.065 degrees) between the all-diopter toric group and the nontoric group was not statistically significant (P = .628; 95% CI, −0.392 to 0.237). The 1 eye with 8.74 degrees of tilt had a UDVA and CDVA of 20/20 and no visual disturbances at the 120- to 180-day visit. At subsequent visits, this IOL was tilted 1.94 degrees.

Safety

The safety analysis included 227 eyes of 229 patients. The CDVA was 20/40 or better in 148 (98.0%) of 151 eyes in the all-diopter toric group and in all 76 eyes in the nontoric group. In both groups, the percentage exceeded the FDA grid rate of 92.5%.

The cumulative adverse events through the 120- to 180-day visit were 1 case (0.7%) of macular edema and 1 case (0.7%) of secondary surgical intervention in the all-diopter toric group and 1 case (1.3%) of macular edema and 2 cases (2.6%) of secondary surgical interventions in the nontoric group. These rates were not statistically significantly different from the FDA grid rates (3.0% for macular edema; 0.8% for secondary surgical intervention). The secondary surgical intervention in the toric IOL group was IOL repositioning that was not related to lens axis misalignment or rotation.

Adverse ocular events occurred in 69 eyes (45.7%) in the toric group and 38 eyes (50.0%) in the nontoric group. The most prevalent adverse events in the eye disorders category were dry eye (all-diopter toric group, 13 eyes [8.6]; nontoric group, 3 eyes [3.9%]) and vitreous detachment (10 eyes [6.6%] and 5 eyes [6.6%], respectively).

Four serious adverse events related to an ocular finding occurred. They were IOL malposition (1 haptic in and 1 outside the capsular bag) (nontoric group), anterior vault (toric group), anterior optic capture (nontoric group), and optic neuropathy (toric group).

At the 120- to 180-day visit, 149 (98.6%) of 151 eyes in the toric group and 75 (98.6%) of 76 eyes in the nontoric group had a PCO grade of 2 or less. Fifty-one eyes (33.8%) and 33 eyes (43.4%), respectively, required an Nd:YAG capsulotomy during the study. No complications were associated with the capsulotomy.

DISCUSSION

The findings in this study show the safety and effectiveness of the Trulign toric IOL. The data at the rotational stability time point (120 to 180 days) support the effectiveness of the toric IOL, as shown by the 85.0% reduction in absolute cylinder and excellent rotational stability (96.1% with ≤5 degrees between implantation and visit 4 and 100% with 5 degrees or less between visit 3 and visit 4). The toric IOL group had statistically significantly greater reduction in absolute cylinder and better UDVA than the nontoric IOL group. Subjective reports of significant visual disturbances were limited to a single case in which a 2.00 D toric IOL was implanted; the symptoms resolved after Nd:YAG treatment for PCO. No patient with the highest available cylinder (2.75 D) reported significant visual disturbances at the 120- to 180-day visit. The safety endpoints for preservation of CDVA and incidence of adverse events were met.

The effectiveness of a toric IOL in decreasing residual postoperative astigmatism can decrease when there is significant IOL rotation. As such, rotational stability is an important endpoint when evaluating the performance of a toric IOL. Postoperative refraction can differ from the predicted refraction when a

toric IOL rotates. Astigmatism correction steadily decreases as the toric IOL deviates off axis.[17] Each 10 degrees of off-axis rotation results in a loss of one third (33.3%) of cylinder correction effectiveness.[7] For example, when the IOL rotates 30 degrees or more, the cylinder correction is lost.[18] When the IOL rotates 45 degrees or more, additional cylinder is induced.[19] Accordingly, the American National Standards Institute guidelines state that stability of the toric IOL axis is achieved when 90% of the implanted IOLs rotate 5 degrees or less between 2 consecutive visits at least 3 months apart.[16] In the present study, the degree of rotation of all toric IOLs was 5 degrees or less between the 30- to 60-day visit and the 120- to 180-day visit.

However, it has been shown that the greatest risk for rotation of toric IOLs of all designs is in the early postoperative period. Hence, it is important to assess the rotational stability of a toric IOL during this timeframe. Furthermore, any method used to assess rotational stability should be objective and should account for the natural torsion of the eye that occurs between measurements. With this in mind, we began recording the rotational stability of the IOLs immediately after implantation using an image-analysis technique that accounts for eye torsion. Using this method, we found that by the 120- to 180-day visit, 96.1% of IOLs in the all-diopter toric group had rotated 5 degrees or less compared with their position immediately after surgery. The following is the reported rotation of other toric IOLs models: Tecnis 1-piece (Abbott Medical Optics, Inc.), 83.9% and 93.9% with 5 degrees or less at 1 to 2 months[20] eyes at 6 months[C] and 100% with 10 degrees or less at 2 months[21]; A4203 TL (Staar Surgical Co.), 72% with 5 degrees or less at 1 month[22]; Acrysof (Alcon Laboratories, Inc.) 75% to 85% of IOLs with 5 degrees or less at 120 to 180 days,[D] 78% with 5 degrees or less at 1 year,[23] and 100% with less than 10 degrees at 2 months[21]; Acrysof Restor multifocal (SND1T2-T5), 100% with 10 degrees or less at 3 months.[24]

Polyimide loops added to silicone haptics increase the stability of an IOL in the capsular bag.[25] This might explain why we found less rotation of the Trulign toric IOL than that reported for other toric IOL models. Furthermore, the size of the IOL relative to the capsular bag diameter is important for stability because a shorter length might allow more rotation before the capsular bag shrinks.[22]

Axis deviations with any toric IOL can result from inaccurate marking of the steep axis, inaccurate orientation of the lens axis at the time of surgery, an unexpected surgically induced change in corneal power and curvature, or physical rotation of the IOL after implantation. To minimize this effect, the surgeon should be careful to ensure that preoperative determinations of the meridian in which the IOL is placed are accurate and not affected by surgery and that the IOL is properly oriented at surgery (ie, placed on the appropriate axis in accordance with vector analysis provided by a toric calculator). The design of the Trulign toric IOL might contribute to its rotational stability. The IOL has rectangular, hinged haptics with polyimide loops that help to stabilize the IOL in the capsular bag and has indicators to remind the surgeon that it is round to the right, which facilitates proper IOL positioning.

The differences in UDVA between the lowest toric group and the nontoric group, while statistically significant, were small. However, in general, patients report less satisfaction when the UDVA is 20/30 than when it is 20/25. In our study, the incision was created along the steepest axis in both the toric group and the nontoric (control) group. Thus, some reduction in astigmatism, even in the control group, was expected. All surgeons used the same SIA value, regardless of the incision location and without customization. In addition, no effort was made to determine posterior corneal astigmatism for use in the surgical planning. This could have affected the outcomes by introducing more noise-to-signal in determining the optimum toric IOL alignment or power. Ultimately, this would have a greater relative impact in eyes with lower preexisting corneal toricity. These limitations and potential sources of error are inherent to all toric IOLs and might be mitigated by customization of the SIA and A-constant, the use of Scheimpflug systems that measure both anterior and posterior corneal astigmatism, and the use of intraoperative aberrometry for additional surgical guidance.

In addition to toric IOL implantation, surgical options for patients with preexisting corneal astigmatism include corneal arcuate and peripheral corneal relaxing incisions and excimer laser vision correction. Potential complications of incisional surgery that are not present with toric IOLs include wound gape and the associated infection, corneal deinnervation exacerbating dry eye, epithelial cysts and ingrowth into the incisions, and occasional corneal perforation.[26] Variability in corneal biomechanics and wound healing might, in part, explain the recent findings in a study by Hirnschall et al.,[27] in which toric IOLs reduced astigmatism to a greater extent and were more predictable and stable than peripheral corneal relaxing incisions. Laser in situ keratomileusis and photorefractive keratectomy to reduce corneal astigmatism might be associated with a high incidence of dry eye and fluctuating vision in this demographic, which is already at higher risk for dry eye preoperatively.[28] It also involves a second surgical procedure, unlike the single procedure of toric IOL placement during cataract surgery.

With most toric monofocal IOLs, spectacles are required for intermediate and near tasks because monofocal IOLs that do not correct presbyopia do not adequately improve intermediate and near vision. At near (30 to 40 cm), the Acrysof SN60WF IOL (Alcon Laboratories, Inc.) and CeeOn 911A IOL (Abbott Medical Optics, Inc.) were reported to provide a mean DCNVA of 20/100 and 20/72, respectively.[29,30] In comparison, the all-diopter toric group had a mean DCNVA of 20/40. At intermediate (70 to 80 cm) distances, the Acrysof SN60WF and CeeOn 911A were reported to provide a DCIVA of 20/40 and 20/38, respectively.[29,30] In comparison, the all-diopter toric group had a mean DCIVA of 20/23—close to double that of the monofocal IOLs that do not correct presbyopia. These acuities were measured with optimum distance correction; thus, the improved near and intermediate acuities were not a reflection of the residual refractive error but rather of the inherent attributes of the IOL. In addition, the better dynamic through-focus at intermediate and near with the Trulign toric IOL and the Crystalens IOL than with monofocal IOLs that do not correct presbyopia is reflected in the lower required add ($\sim$1.5 D versus 2.5 D).[29,30]

The all-diopter toric group had a mean UDVA of 20/25. At the 120- to 180-day visit, 97.8% in the all-diopter toric group had UDVA of 20/40 or better. Studies report that the UDVA was 20/40 in 48% to 84% of patients with the AA4203 T toric silicone IOL at various time points[17,31,32] and 93.3% of patients with the Acrysof toric IOL had a UDVA of 20/40 at 3 months[33] and 92.2% at 1 year.[23] In a study of the Tecnis toric IOL (ZCT150, ZCT225, ZCT300, and ZCT400),[C] 97.1% of 172 eyes in the pooled Tecnis toric IOL group had a UDVA of 20/40 or better at 6 months; the mean UDVA was 20/26. In a smaller study of 20 eyes with the Tecnis toric IOL,[21] the mean UDVA was 20/26 at 2 months; all eyes had a UDVA of 20/40 or better. The mean UDVA, UIVA, and UNVA in the all-diopter toric group was 20/25, 20/22, and 20/39, respectively, when implanted monocularly, as per this study design, which is without the additional benefit of binocular summation on visual acuity. These comparisons show that the Trulign toric IOL provides excellent uncorrected distance acuity, better intermediate visual acuity, and functional uncorrected near vision.

The safety endpoints for preservation of CDVA and incidence of complications and adverse events were met. The rate of FDA-defined cumulative adverse events through the 120- to 180-day visit were not statistically significantly above FDA historical control rates. Ocular adverse events were of the type and frequency typically seen in patients who had cataract surgery; there were no new safety concerns. There were specific serious ocular adverse events, which provides insight and guidance into appropriate recommendations for directions for use. For example, the serious adverse event of IOL malpositioning with 1 haptic in the bag and the other in the sulcus is common to all IOL types. Rotating the IOL after insertion will help ensure that both haptics are in the capsular bag. The serious adverse event of anterior vault could, in part, be attributed to the patient's noncompliance with postoperative antiinflammatory medication, which can result in atypical fibrosis of the capsular bag. This fibrosis could lead to significant capsule contraction, which caused the study device to vault in an anterior position, given the ability of this hinged IOL to change position of the optic. Preemptive Nd:YAG treatment at the first sign of capsule striae was not performed in this study and is recommended. The fellow eye of this patient also had early capsule striae, which were treated with an Nd:YAG laser at 2 months with no subsequent IOL vault. This case also illustrates the importance of maintaining patients on antiinflammatory medications for a minimum of 4 weeks.

In our study, the serious adverse event of anterior optic capture occurred 6 months after implantation of the nontoric IOL in a patient who reported blurry, distorted vision. The investigator noted that the IOL optic was captured superiorly in the anterior capsule. This patient was lost to follow-up before a scheduled Nd:YAG capsulotomy was performed. The anterior optic capture could be attributed to atypical fibrosis of the capsular bag or to the creation of a decentered or irregularly shaped capsulorhexis. As described in the directions for use of the Crystalens,[E] it is important to perform meticulous cortical cleanup and create a round, well-centered 5.5 to 6.0 mm capsulorhexis with the anterior capsule covering the plate haptics. Selective Nd:YAG capsulotomy has been beneficial in managing cases such because it counteracts the effect of atypical capsule contraction and constriction and allows the IOL to be repositioned in the appropriate posteriorly vaulted position.

Strengths of this clinical trial are its prospective randomized single-masked design and the objective assessment of IOL rotational stability using photographic documentation and evaluation by an independent, third-party consultant. Limitations of the study are that long-term data are not available at this time, the effectiveness of the AT-52T model was not assessed independent of the AT-50T model, and spectacle independence could not be measured because the Trulign toric IOL was not implanted binocularly in any case.

In conclusion, the Trulign toric IOL reduced the effects of preoperative corneal astigmatism on refraction

after cataract surgery and provided improved distance, intermediate, and functional near vision. The results show that the Trulign toric IOL is effective in reducing refractive cylinder in patients with both lower and higher magnitudes of preexisting corneal astigmatism. Addition of the toric component to the IOL did not produce new safety concerns. This toric IOL met all safety and effectiveness endpoints. The outcomes were dependent on precise biometry and meticulous surgical technique, including standardized capsulorhexis size and centration, fastidious cortical and capsular bag cleaning, and proper IOL positioning.

WHAT WAS KNOWN

- The visual outcomes after cataract surgery with implantation of standard IOLs that correct spherical error only can be improved if the effect of preexisting corneal astigmatism is surgically addressed.

WHAT THIS PAPER ADDS

- The safety and efficacy of a new monofocal presbyopia-correcting toric IOL was confirmed.

- The toric IOL reduced the refractive effects of preexisting corneal astigmatism and improved through-focus.

- The toric IOL provided excellent uncorrected distance and intermediate vision and functional near vision in a single procedure.

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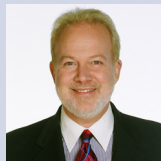
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