

Custom-designed Toric Phakic Intraocular Lenses to Correct High Corneal Astigmatism

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ABSTRACT

PURPOSE: To analyze the results of a custom-designed posterior chamber toric phakic intraocular lens (PIOL).

METHODS: A 40-year-old woman with high astigmatism and thin corneas underwent bilateral PIOL implantation with the toric Implantable Collamer Lens (ICL) custom-designed and manufactured by STAAR Surgical. The appropriate toric ICL power was calculated to be $-8.00 + 8.00 \times 96^\circ$ for the right eye and $-8.50 + 7.50 \times 86^\circ$ for the left eye. Optical zone was 5.5 mm and 6.875 mm at the corneal plane.

RESULTS: At 3 and 6 months postoperatively, uncorrected visual acuity (UCVA) and best-spectacle corrected visual acuity (BSCVA) of both eyes had improved to 20/20 and 20/16, respectively. At 19 months, UCVA was 20/20 and 20/16 in the right and left eyes, respectively, and BSCVA had improved to 20/16 and 20/10, respectively. The subjective refraction was stable, with a change of -0.37 ± 0.17 D from preoperative to 19 months postoperatively. Throughout the postoperative period, iridotomies remained patent and the corneas were clear.

CONCLUSIONS: Bilateral implantation of the custom-designed toric ICL successfully corrected the patient's high astigmatism. Preoperative subjective refractive cylinder of $-5.25 \times 6^\circ$ in the right eye and $-5 \times 176^\circ$ in the left eye changed to $-0.5 \times 77^\circ$ and $-0.5 \times 115^\circ$, respectively, after toric IOL implantation. There was almost no change in corneal astigmatism. This customized approach led to an UCVA of 20/20 in the right eye and 20/16 in the left eye, and a BSCVA of 20/16 in the right eye and 20/10 in the left eye. This is the first report of a toric PIOL being specifically manufactured to meet the refractive cylinder requirements of a specific patient. [*J Refract Surg.* 2007;23:xxx-xxx.]

Typically, the conventional methods of spectacles or contact lenses are considered to be the safest approach for the correction of high astigmatism. However, some patients can develop intolerance to contact lenses, and spectacles have visual field limitations. Laser vision correction is acceptable for the treatment of mild to moderate astigmatism, yet in cases with high refractive error, there is an increased risk of corneal ectasia, which is associated with poor visual quality and unpredictability.¹

Clinical studies of phakic intraocular lens (PIOL) implantation have demonstrated growing promise for the correction of refractive errors not amenable to mainstream laser refractive surgery.²⁻⁴ Patients with high astigmatism who are not suitable candidates for corneal reshaping procedures may benefit from toric PIOL implantation. We report one patient with significant corneal astigmatism in both eyes for whom posterior chamber toric PIOLs were custom-designed based on the patient's refractive and topographic data.

PATIENT AND METHODS

A 40-year-old woman had worn hard, oxygen-permeable contact lenses for 22 years to correct for high astigmatism in both eyes. She had experienced progressive difficulty tolerating the hard contact lenses and had stopped wearing them for a year, switching periodically to soft contact lenses, which did not provide crisp, sharp vision because of the astigmatism.

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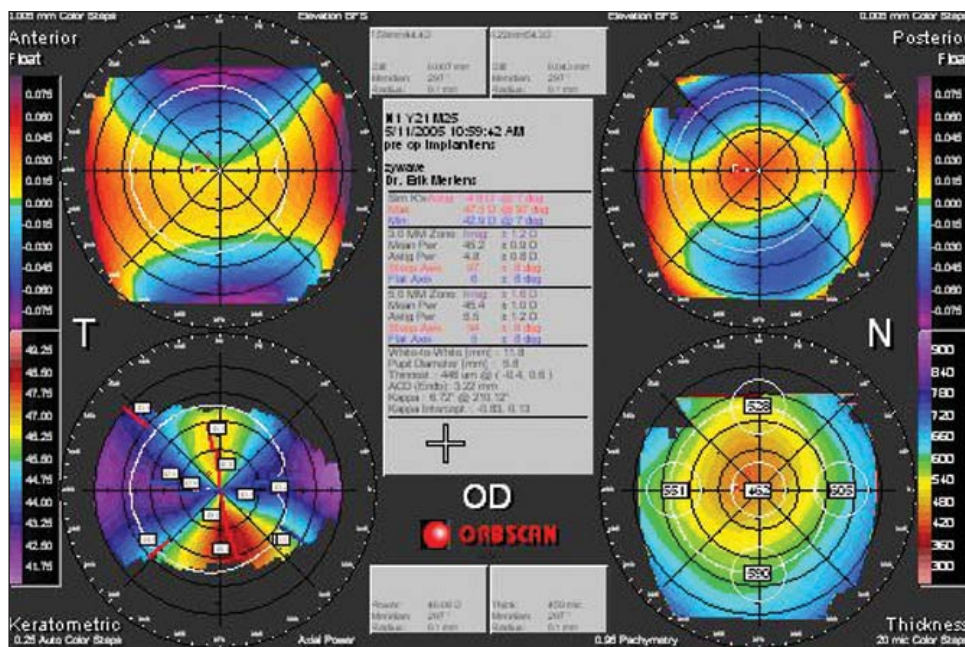


Figure 1. Preoperative topographic maps for the right eye using the Orbscan IIz.

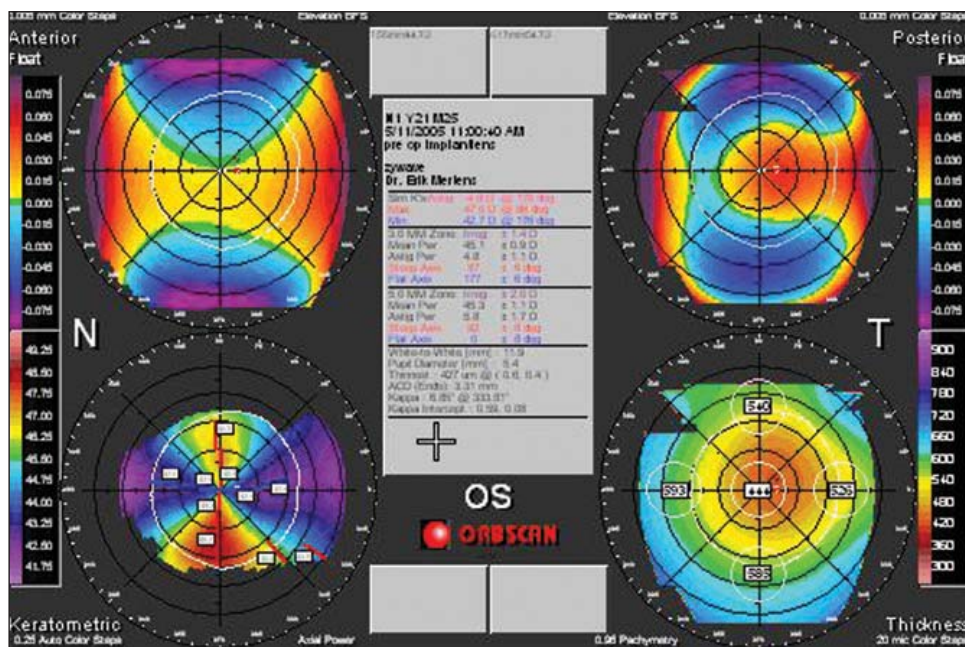


Figure 2. Preoperative topographic maps for the left eye using the Orbscan IIz.

After 1 week of not wearing contact lens, an examination revealed best spectacle-corrected visual acuity (BSCVA) of 20/20⁻¹ in both eyes with a manifest refraction of 0.00 -5.25 × 6° in the right eye and -0.50 -5.00 × 176° in the left eye. Using high (90%) contrast logMAR charts, BSCVA was 20/32 in the right eye and 20/25 in the left eye; using low (10%) contrast logMAR charts, BSCVA was 20/60 in the right eye and 20/50 in the left eye.

Topographic keratometry using the Orbscan IIz (Bausch & Lomb, Salt Lake City, Utah) was 42.75/47.63 × 94° in the right eye and 42.63/47.25 × 85° in the

left eye (Figs 1 and 2). Further measurements included anterior chamber depths of 3.22 mm in the right eye and 3.31 mm in the left eye, a white-to-white distance of 11.8 mm in the right eye and 11.9 mm in the left eye, and a central corneal thickness of 436 μm in the right eye and 418 μm in the left eye, respectively. Both eyes had a scotopic pupil size of 7 mm (Colvard pupilometer), and intraocular pressure was 12 mmHg in the right eye and 13 mmHg in the left eye.

Laser in situ keratomileusis (LASIK) was not a treatment option because of the high astigmatism and thin corneas; phakic IOL implantation was determined to

be the most suitable approach. A posterior chamber toric PIOL (toric Implantable Collamer Lens [toric ICL], STAAR Surgical, Monrovia, Calif) was considered because of our long experience with this lens. Unfortunately, the required powers were outside the defined refraction parameters of the commercially available toric ICL (-3.00 to -20.00 D of refractive spherical correction, $+1.00$ D to $+4.00$ D of refractive cylinder correction). STAAR Surgical offered to custom-design their existing toric ICL specifically for this patient. Implantation of customized toric ICLs was discussed with the patient, and informed consent was obtained.

Based on the refractive data and topographic specifications of the patient, the manufacturer custom-designed and manufactured the appropriate toric ICL for each eye. The toric ICLs are spherocylindrical with one concave surface. The standard lens design calculation for the present toric ICL manufacturing process requires that the cylinder radius be less than the radius of the concave surface, for simplicity and ease of manufacturing. To produce these customized toric ICLs, the standard lens design calculation had to be modified, resulting in a more complex manufacturing process. The dioptric power of the toric ICLs was calculated with the published formulas for toric PIOLs by Sarver and Sanders.⁵ Refractive data (spectacle plane) were adjusted to the implant plane for calculation. The appropriate toric ICL power was calculated to be $-8.00 + 8.00 \times 96^\circ$ for the right eye and $-8.50 + 7.50 \times 86^\circ$ for the left eye, with an overall diameter of 12.5 mm for both. The optical zone was kept at 5.5 mm, which represents 6.875 mm at the corneal plane.

Three months before IOL implantation, bilateral iridotomy was performed using an Nd:YAG laser. Two iridotomies were performed in each eye at 10:30 and 1:30 o'clock.

In August 2005, bilateral implantation of the customized toric ICLs was performed. Ninety minutes before surgery, both eyes were dilated with phenylephrine and tropicamide (Mydriasset; Ioltech SA, La Rochelle, France). Acetazolamide 250 mg (Diamox; Haupt Pharma, Berlin, Germany) was administered 1 hour before surgery. In addition, one drop of lomefloxacin 3 mg/mL (Okacin collyre; Ciba Vision, Duluth, Ga) and one drop of indomethacin 1 mg/mL (Indocollyre; Chauvin Pharmaceuticals, Surrey, United Kingdom) were administered in both eyes hourly until surgery. The patient was taken to the operating room and seated at the slit lamp. Markings were placed at the limbus to indicate the 180° axis of each eye.

Surgery was performed on the left eye first. Povidone iodine 10% (Iso-betadine; Viatris, Bad Homberg, Germany) was applied to the eyelids, the patient

was draped, and a lid speculum was inserted. Four drops of oxybuprocaine 4 mg/mL (Unicaine; Bournonville Pharma, Breda, The Netherlands) was used to anesthetize each eye. Three minutes before corneal incision, povidone iodine 5% was administered to the ocular surface. A paracentesis was placed superiorly for the left eye and inferiorly for the right eye, and methylcellulose 20 mg/mL (Ocucoat; Bausch & Lomb, Rochester, NY) was injected into the anterior chamber.

A 3-mm temporal corneal incision was made with a 30° stab knife and a 2.65-mm blade. Methylcellulose 20 mg/mL was readministered into the anterior chamber. Under the microscope, the toric ICL was loaded into the STAAR injector cartridge. The tip of the injector cartridge was then inserted in the temporal corneal wound, the toric ICL was delivered, and the haptics were placed behind the iris with a toothed forceps. In the left eye, the toric ICL was placed in the exact horizontal position, and in the right eye, the lens was rotated 6° counterclockwise (Fig 3).

The methylcellulose was irrigated out with copious balanced salt solution and vancomycin 6 mg/mL was instilled into the anterior chamber. One drop of dorzolamide 20 mg, timolol 5 mg/mL suspension (Cosopt; MSD, Riyadh, Saudi Arabia); lomefloxacin 3mg/mL; and hydrocortisonacetat 17 mg, oxytetracycline 5.7 mg, polymyxine B 11400 IE/g suspension (Terracortril; Pfizer, New York, NY) also were instilled. Immediately after surgery, 250 mg of acetazolamide was administered to minimize intraocular pressure and then readministered 1 day postoperatively.

The patient's postoperative medication included fluorometholone 1 mg/mL, gentamicin 3 mg/mL (Infectoflam collyre; Novartis, Basel, Switzerland) and indomethacin 1 mg/mL administered four times daily for the first week and then tapering to one drop per day at four weeks postoperatively. In addition, sodium hyaluronate 1.5 mg/mL (Hyabak collyre; Thea Laboratories, Clermont Ferrand, France) and hypromellose 3 mg/mL gel (GenTeal, Ciba Vision) were administered four times daily for 1 month. Postoperative examinations were performed at 1 day, 1 week, and 1, 3, 6, and 19 months.

RESULTS

POSTOPERATIVE FOLLOW-UP

One day postoperatively, uncorrected visual acuity (UCVA) was 20/32 in the right eye and 20/30 in the left eye. Intraocular pressure was 14 mmHg and 13 mmHg in the right and left eyes, respectively. Both eyes had clear corneas, and no edema was present.

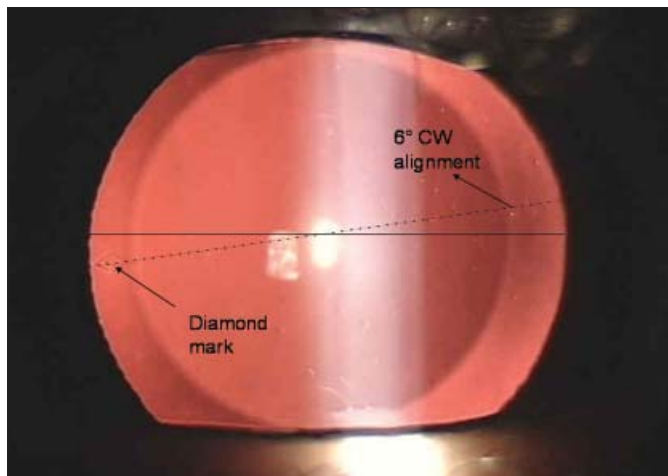


Figure 3. The toric ICL in the right eye is rotated 6° counterclockwise from the horizontal. The diamond-shaped marks on the toric ICL demonstrate the axis of rotation.

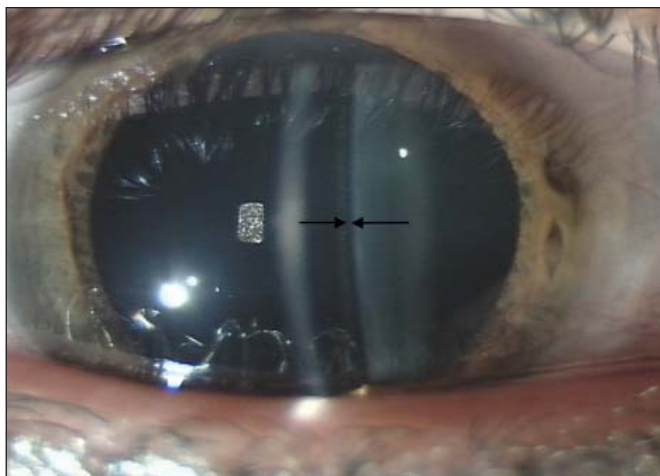


Figure 4. Vaulting of the toric ICL demonstrated approximately one cornea thickness (>400 μm) between the toric ICL and the crystalline lens. The arrow on the left points to posterior surface of the toric ICL, and the arrow on the right points to the anterior surface of crystalline lens.

Slit-lamp examination revealed toric ICL vaulting was approximately one cornea thickness (>400 μm) between the toric ICL and the crystalline lens (Fig 4). Clinical estimation of toric ICL vaulting is performed by comparing the separation between the human lens and the back surface of the toric ICL to the corneal thickness while using an optical section during slit-lamp examination.

One week postoperatively, UCVA was 20/25 and BSCVA was 20/20⁻² in both eyes. Subjective manifest refraction was +0.75 -0.75 × 85° in the right eye and +0.50 -1.00 × 110° in the left eye. One month postoperatively, UCVA and BSCVA in both eyes had improved to 20/20 and 20/16, respectively. Manifest refraction was +0.50 -0.50 × 80° in the right eye and +0.25 -0.50 × 115° in the left eye. Using high (90%) contrast logMAR charts, UCVA was 20/25 in the right eye and 20/20 in the left eye, and using low (10%) contrast logMAR charts, UCVA was 20/50 in the right eye

and 20/40 in the left eye. Using high (90%) contrast logMAR charts, BSCVA was 20/20 in both eyes, and using the low (10%) contrast logMAR charts, BSCVA was 20/40 in both eyes.

Three and 6 months postoperatively, UCVA and BSCVA in both eyes remained 20/20 and 20/16, respectively. The subjective manifest refraction was +0.50 -0.50 × 75° at 3 months and +0.25 -0.50 × 77° at 6 months in the right eye, and +0.37 -0.50 × 115° at 3 months and +0.25 -0.50 × 115° at 6 months in the left eye. High and low contrast visual acuities had not changed from the 1-month evaluation, with the exception of the right eye, in which low contrast UCVA had improved to 20/40 at 3- and 6-month follow-up. Manual keratometry was 43/47.5 × 92° in the right eye and 42.5/47.5 × 85° in the left eye, which was almost identical to preoperative readings. Throughout the postoperative period, the iridotomies remained patent and the corneas were clear.

Alpins Method				Alpins Method			
TIA	4.93	Ax	6 deg	TIA	4.65	Ax	176 deg
SIA	5.33	Ax	4 deg	SIA	4.93	Ax	179 deg
Difference Vector	0.50	Ax	77 deg	Difference Vector	0.50	Ax	115 deg
Angle of Error	-2			Angle of Error	2		
Magnitude of Error	0.40			Magnitude of Error	0.28		
Correction Index	1.08			Correction Index	1.06		
Index of Success	0.10			Index of Success	0.11		
Coefficient of Adjustment	0.93			Coefficient of Adjustment	0.94		
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Torque	0.31	Ax	141 deg	Torque	0.42	Ax	41 deg
Flattening Effect	5.32	Ax	6 deg	Flattening Effect	4.91	Ax	176 deg
Flattening Index	1.08			Flattening Index	1.06		
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Figure 5. Results of vectorial examination of astigmatism using the vecktrAK calculator. Target induced astigmatism vector (TIA), surgically induced astigmatism vector (SIA), correction index, angle of error, magnitude of error, and index of success are shown for both eyes.

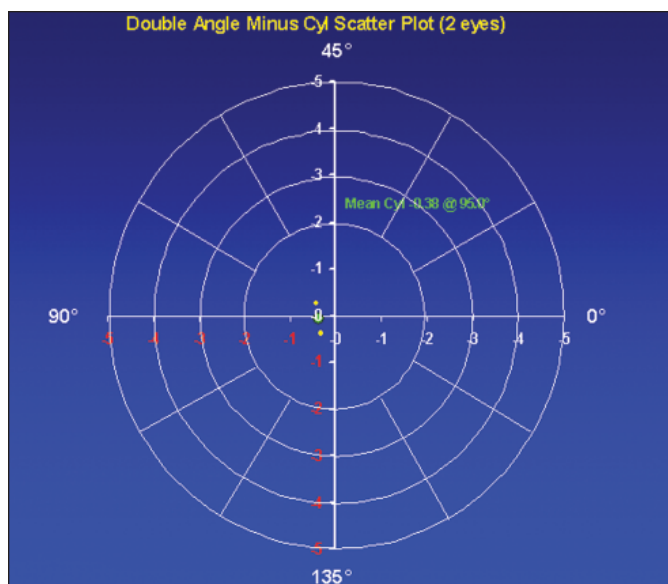


Figure 6. Double-angle plot for postoperative spectacle plane refractive astigmatism indicates a significant reduction of astigmatism was achieved in both eyes. Yellow dots represent Cartesian values of postoperative refractive astigmatism of each eye at the spectacle plane. Right eye: X = -0.433, Y = 0.250. Left eye: X = -0.383. The green dot is the mean postoperative refractive astigmatism (-0.38@95°).

ASTIGMATIC OUTCOME ANALYSIS BY VECTORIAL EXAMINATION

This patient’s refraction changed from plano -5.25 × 86° to +0.25 -0.50 × 77° in the right eye and from -0.50 -5.00 × 176° to +0.25 -0.50 × 115° in the left eye 6 months after surgery. Results of the vectorial examination using the vecktrAK calculator (Assort Pty Ltd, Cheltenham, Australia) based on Alpíns method⁶ are shown in Figure 5. The astigmatic treatment (target induced astigmatism vector) at the corneal plane was 4.93 D for the right eye and 4.63 D for the left eye. Target correction was 0.00 D in both eyes. The achieved values are the measured postoperative refractive and corneal astigmatism. The surgically induced astigmatism vector is 5.33 D for the right eye and 4.93 D for the left eye (corneal). The correction index is 1.08 and 1.06 for the right and left eyes, respectively. Because these values are slightly greater than 1.0, a slight overcorrection is expected, which is consistent with the postoperative refractive data. The angle of error is -2° for the right eye and 2° for the left eye, and the magnitude of the error is 0.40 for the right eye and 0.28 for the left eye. The index of success is 0.10 for the right eye and 0.11 for the left eye, which indicates the astigmatic correction was 89% and 90% successful, respectively. The change in keratometric readings due to incision was -0.37 for the right eye and 0.38 for the left eye, which indicates a slight decrease of the corneal astigmatism in the right

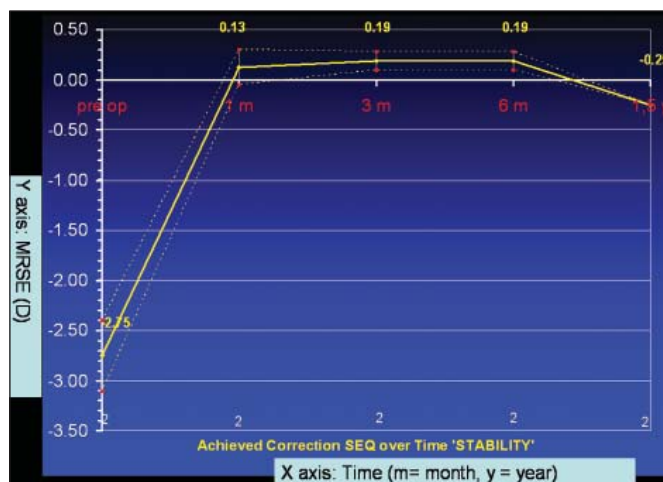


Figure 7. Postoperative change in spherical equivalent refraction (SEQ) of 0.37 ± 0.17 D indicates the stability of the correction from preoperative to 19 months after surgery. Error bars = ±2 standard deviation.

eye and a slight increase in corneal astigmatism in the left eye. As described by Holladay et al⁷ and using Datagraph software (Ingenieurbüro Pieger GmbH, Wendelstein, Germany), we also saw a significant reduction in astigmatism in both eyes (Fig 6) when looking at the double-angle plot of the postoperative spectacle plane refractive astigmatism.

Nineteen months postoperatively at the patient’s last follow-up examination, UCVA was 20/20 for the right eye and 20/16 for the left eye, and BSCVA was 20/16 with a manifest refraction of plano -0.50 × 77° for the right eye and 20/10 with a manifest refraction of plano -0.50 × 115 for the left eye. This confirms stability of the toric ICL in correcting the high astigmatism in our patient without rotation up to 19 months (Fig 7). Using high (90%) contrast logMAR charts, UCVA was 20/20 in the right eye and 20/16 in the left eye, and using low (10%) contrast logMAR charts, UCVA was 20/40 in both eyes. Using high (90%) contrast logMAR charts, BSCVA was 20/16 for the right eye and 20/10 in the left eye, and using the low (10%) contrast logMAR charts, BSCVA was 20/40 in both eyes. Orbscan at 19 months showed stable corneal topography with keratometry 43.7/48.4 × 99° for the right eye and 42.6/47.1 × 89° for the left eye.

DISCUSSION

Bilateral implantation of the custom-designed toric ICL successfully corrected the patient’s high astigmatism. The preoperative subjective refractive cylinder of -5.25 × 6° in the right eye and -5.00 × 176° in the left eye changed to -0.50 × 77° and -0.50 × 115°, respectively, after toric IOL implantation, and there was almost no change in corneal astigmatism. This customized

approach led to UCVA of 20/20 in the right eye and 20/16 in the left eye, and BSCVA of 20/16 in the right eye and 20/10 in the left eye. Postoperative UCVA was better than preoperative BSCVA in both eyes.

There are several reports of standard IOLs being custom-designed for extremely irregular eyes, specifically for cases of keratoplasty-related high corneal astigmatism^{8,9} and high hyperopia.¹⁰ This is the first report of a toric PIOL being custom manufactured to meet the refractive cylinder requirements of a specific patient.

Evidently, the same concepts behind the universal trend toward customization of laser refractive surgery can be applied to PIOL procedures. Based on VHF ultrasound studies, Lovisolo and Reinstein¹¹ believe the idea of custom-designing and sizing PIOLs may be the most effective and safest approach for each PIOL model. According to Lovisolo and Reinstein,¹¹ the optimal custom lens design should fit the individual anatomy of each eye perfectly to ensure safety, with accurate lens vault height assessment a vital parameter. In regard to efficacy, the optic should have the necessary spherocylinder power and rotational stability, an effective diameter at least as large as the mesopic entrance pupil diameter, and possibly an aspheric geometric shape factor as well as a further modified optic surface on the basis of wavefront detection.¹¹

Clearly, there are potential benefits to the customization of PIOLs, particularly for those patients with irregular or high refractive errors, although the feasibility of providing custom-designed lenses for this patient population is yet to be determined. In this case, the production of customized toric ICLs required a more complex lens design and intensive manufacturing pro-

cess, resulting in a more expensive product; nevertheless, the customized toric ICLs successfully corrected the patient's atypical refractive errors.

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