Toric Implantable Collamer Lens for Moderate to High Myopic Astigmatism

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Purpose: To assess the efficacy of the Toric Implantable Collamer Lens (ICL) to treat moderate to high myopic astigmatism.

Design: Prospective nonrandomized clinical trial.

Participants: Two hundred ten eyes of 124 patients with between 2.38 and 19.5 diopters (D) of myopia (spherical equivalent [SE]) and 1 to 4 D of astigmatism participating in the United States Food and Drug Administration clinical trial of the Toric ICL.

Intervention: Implantation of the Toric ICL.

Main Outcome Measures: Uncorrected visual acuity (UCVA), refraction, best spectacle-corrected visual acuity (BSCVA), adverse events, and postoperative complications.

Results: At 12 months postoperatively, the proportion of eyes with 20/20 or better UCVA (83.1%) was identical to the proportion of eyes with preoperative 20/20 or better BSCVA (83.1%); 76.5% had postoperative UCVA better than or equal to preoperative BSCVA. The mean manifest refractive cylinder dropped from 1.93 D (±0.84) at baseline to 0.51 D (±0.48) postoperatively, a 73.6% decrease in astigmatism. Although only 21.0% of eyes had 1-D refractive cylinder preoperatively (none less), 91.4% of cases had ≤1 D of cylinder postoperatively. Furthermore, 65.6% had ≤0.5 D and 40.9% had ≤0.25 D of refractive cylinder postoperatively. Mean manifest refraction SE (MRSE) improved from −9.36 D (±2.66) preoperatively to 0.05 D (±0.46) postoperatively. A total of 76.9% of eyes were predicted accurately to within ±0.5 D, 97.3% to within ±1.0 D, and 100% to within ±2.0 D of predicted MRSE. Postoperatively, 37.6% of eyes had a BSCVA of 20/12.5 or better, compared with a preoperative level of 4.8%. Furthermore, BSCVA of 20/20 or better occurred in 96.8% postoperatively, compared with 83.1% preoperatively. Mean improvement in BSCVA was 0.88 lines; there were 3 cases (1.6%) that lost ≥2 lines of BSCVA after 12 months postoperatively, whereas 18.9% of cases improved by ≥2 lines. A total of 76.4% of cases gained ≥1 lines of BSCVA, whereas only 7.5% of cases lost the equivalent amount. Three ICL removals were performed without significant loss of BSCVA, and 1 clinically significant lens opacity was observed.

Conclusion: The results support the efficacy and predictability of Toric ICL implantation to treat moderate to high myopic astigmatism. Important safety concerns were not identified. *Ophthalmology 2007;114:54–61 © 2007 by the American Academy of Ophthalmology.*

Astigmatic correction has become a longstanding topic of debate, from the traditional use of spectacles and contact lenses to the era of keratotomy and LASIK. A recent alternative for astigmatic management is the toric phakic intraocular lens (IOL). Phakic intraocular implants overcome the disadvantages of corneal refractive surgeries and have been shown to correct successfully for ametropia with astigmatism.[1–11]

The first Toric Implantable Collamer Lens (ICL) (STAAR Surgical, Monrovia, CA) was implanted in 1999 by Dr Thomas Neuhann in Munich (unpublished data); in 2002, the first implant in North America was reported by Gimbel and Ziemba.[1]

Several studies have been published recently on an anterior chamber (AC) iris-fixated toric phakic IOL, manufactured from Perspex CQ-UV polymethyl methacrylate (PMMA; Imperial Chemicals Industry PLC, London, United Kingdom) and termed the Artisan (now Verisys) phakic IOL (AMO, Santa Ana, CA).[2–11] The results of these studies demonstrated that a toric phakic IOL is capable of correcting low to high astigmatism as well as mild to high

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ametropia. Dick et al reported the largest study,[9] in which 70 eyes underwent phakic IOL implantation for the correction of myopia (up to −19 diopters [D]) or hyperopia (up to 8 D) with astigmatism of up to −7.25 D. Spherical errors and astigmatism were reduced significantly in all cases. In the myopic group, mean refractive astigmatism was reduced from 3.74±1.09 D to 0.63±0.53 D. In the hyperopic group, mean refractive astigmatism was reduced from 3.70±1.05 D to 0.77±0.64 D.[9]

Toric phakic IOLs also have been shown to correct astigmatism in complicated cases, in which keratorefractive techniques were not necessarily a good or viable option. Tahzib et al[4] described the effective reduction of postkeratoplasty astigmatism in 36 eyes from −7.06±2.01 D preoperatively to −2.0±1.53 D at last follow-up. Bartels et al[6] used toric lenses to correct for high astigmatism (7 D) in a patient with marginal corneal degeneration, and Nuijts et al[7] used a toric phakic lens to treat mixed astigmatism in an eye complicated by flap decentration after LASIK.

Although several studies have demonstrated effective treatment of astigmatism using the iris-fixated toric phakic IOL,[2–11] concerns still exist over the level of endothelial cell loss associated with AC and iris-fixated lenses and the extent of surgically induced astigmatism by implantation of the rigid PMMA lens through a 5.3-mm corneal incision.[2,4]

The Visian spherical ICL (STAAR Surgical) was first used in humans in 1995 for the correction of moderate to severe myopia, with the hydrophilic collamer material proving to be highly biocompatible. Reports relating to the United States Food and Drug Administration (FDA) ICL for myopia study[12–14] in combination with international series[15–25] demonstrated impressive results, including high levels of best-corrected vision preservation or improvement, minimal intraoperative/postoperative complications, a reduction in subjective patient symptoms, early and stable improvements in vision, and high degrees of predictability in this refractive treatment for moderate to high myopia. All of these reports studied ICLs with spherical optics. The U.S. FDA Toric ICL clinical study for myopic astigmatism was initiated in May 2002. The primary objective of this article is to provide the clinical outcomes of this FDA trial.

Patients and Methods

The U.S. multicenter FDA clinical study of the Toric ICL for myopic astigmatism was designed as a 125-patient, 1-year duration, nonrandomized clinical trial intended mainly to evaluate the efficacy of the ICL to treat moderate to high myopic astigmatism. Sample size was calculated to evaluate efficacy, whereas safety of the phakic IOL was based chiefly on the larger study (526 eyes of 294 patients) of the spherical version of the ICL,[13,14] which was otherwise identical with the exception of the incorporation of a toric optic in the current study. Most FDA device trials require a sample size of 300 to detect low incidence complications (on the order of 0.1%); an observed rate of 1.0% is the minimum rate detectable as statistically significantly greater than the 0.1% expected rate with 80% power. Allowing for sampling error, the maximum number of subjects with this adverse event would be 1. Any greater number of subjects with this adverse event in a group of 300 subjects would be statistically significantly greater than the expected rate of 0.1% (draft standard on phakic IOLs, American National Standards Institute, April 25, 2004).

The enrollment criteria for the Toric ICL study were identical to those for the spherical ICL study except that in the spherical ICL study patients were required to have ≤2.5 D of refractive cylinder, whereas in the toric study patients had between 1 and 4 D of refractive cylinder. In the toric study, the spherical component of the refraction in plus cylinder form was between −3 and −20 D, whereas in the spherical ICL study this was the range of allowed spherical equivalent (SE). In addition, the spherical ICL study allowed patients with best spectacle-corrected visual acuity (BSCVA) of better than or equal to 20/100, whereas the Toric ICL study required BSCVA of 20/40 or better. Seven clinical sites across the U.S. enrolled 210 eyes of 124 patients in the Toric ICL study that fulfilled the enrollment criteria, and 186 eyes (88.5%) have been examined at 1 year postoperatively.

The Toric ICL is a posterior chamber phakic IOL designed to vault anteriorly to the crystalline lens and intended to have minimal contact with the natural lens. The Toric ICL was manufactured from hydrophilic porcine (scleral tissue) collagen-based biocompatible material, identical to that used for the spherical ICL.[13,14] It features a plate–haptic design with central convex/concave optical zone, and cylinder in a specified axis location as required, to address each patient's astigmatic condition. The Toric ICL haptic design is identical to the spherical ICL in terms of size, thickness, and configuration.[13,14]

Implantable Collamer Lens power calculation for the Toric ICL was performed using the astigmatic decomposition method described by Sarver and Sanders.[26] This formula calculates the appropriate ICL cylinder using the patient's manifest refractive cylinder.

Toric ICLs were manufactured to minimize rotation and required the surgeon to rotate the ICL no more than 22.5° (three fourths of a clock hour) from the horizontal meridian. Each Toric ICL was sent to the surgeon with a guide demonstrating the amount and direction of rotation from the horizontal axis required of the ICL to exactly align the ICL cylinder axis to the patients' required cylinder correction. With the exception of the requirement to mark the horizontal axis and rotate some of the Toric ICL cases, the surgical technique was the same as in the spherical ICL study.[13,14] To control for potential cyclotorsion upon lying supine, the surgeons marked the zero horizontal axis at a slit lamp while the patient was sitting upright. The surgeon also used a Mendez ring to measure required rotation from horizontal during the operative procedure. In summary, each patient received 2 peripheral iridectomies within 2 weeks of the surgery using a neodymium: yttrium–aluminum–garnet (Nd:YAG) laser. On the day of surgery, patients were administered dilating and cycloplegic agents, after which an anesthetic of the surgeon's choice was applied to the operative eye. The Toric ICL was inserted through a horizontal temporal 3-mm corneal incision (which has been shown to have a negligible effect on postoperative astigmatism[27]), then injected through the incision into the AC and allowed to unfold slowly. With the Vukich ICL manipulator (Asico LLC, Westmont, IL) in contact with the footplate, the proper motion was gentle posterior pressure combined with slight rotation of ≤1 clock hour. This maneuver was repeated over each corner of the implant until all 4 footplates were posterior to the iris plane. Adjustment of the implant, if necessary, was accomplished by a gentle movement touching the ICL at the junction of the haptic and optic. Correct positioning of the ICL in the center of the pupillary zone was verified before an intraocular miotic was used to decrease pupil size. Any remaining viscoelastic was irrigated out of the AC with balanced salt solution. Postoperative management was the same as in the spherical ICL study.[13,14] Slit-lamp evaluation of alignment of the ICL also was performed at all visits postoperatively, recorded as the clock hour of the long axis of the lens. Changes in

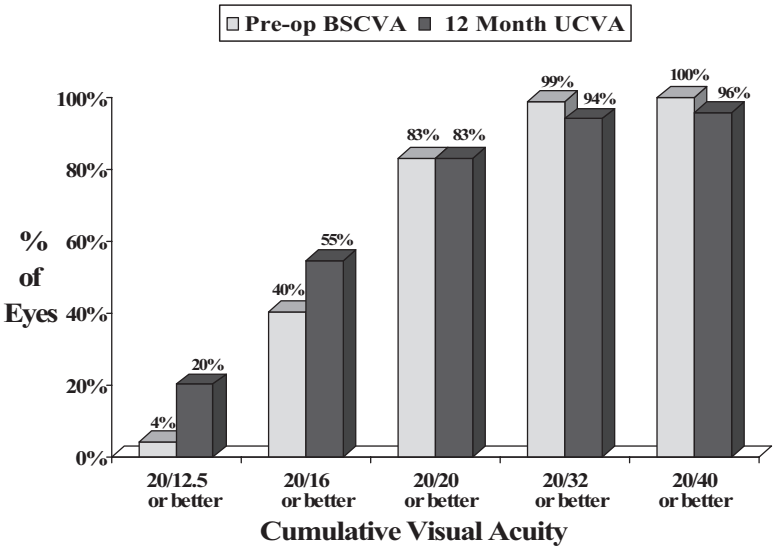

Figure 1. Preoperative (pre-op) best spectacle-corrected visual acuity (BSCVA) versus 12-month postoperative uncorrected visual acuity (UCVA) for the Toric Implantable Collamer Lens cohort.

axis alignment from one visit to the next were reported, with a clockwise change being assigned as a plus rotation and a counterclockwise change as a minus rotation.

Assessment of Toric ICL outcomes was based on a comparison of preoperative with postoperative values and the achieved versus expected refractive outcomes postoperatively in conjunction with a complete analysis of adverse events/complications. The primary outcome parameters for this multicenter clinical study were uncorrected visual acuity (UCVA), manifest refraction SE (MRSE), refractive cylinder, BSCVA, and adverse events and complications.

Results

Patient Population

Of the 124 study subjects, 69 were female (55.6%) and 82.3% were Caucasian. Mean age at time of implantation (primary eye in bilaterally implanted subjects) was 36.4 (±7.4) years, with a range of 21 to 45. Preoperative MRSE for this study cohort averaged −9.36±2.66 D. Only 17.6% of eyes had a preoperative myopia ≤ 7.0 D; 45.7%, >7.0 D but ≤10 D; and 36.7%, >10 D. Preoperative cylinder for this study cohort averaged 1.93±0.84 D. Only 21.0% of eyes had a preoperative cylinder of 1.0 D; 35.2%, >2.0 D; and 11.4%, >3 D.

Numbers of eyes examined at each visit were 200 (95.2%) at 1 week, 195 (92.8%) at 1 month, 188 (89.5%) at 3 months, 175 (83.3%) at 6 months, and 186 (88.6%) at 12 months postoperatively. We report on the efficacy data of the cases examined at 12 months postoperatively and the safety data of all cases implanted.

Effectiveness Outcomes

Preoperative Best Spectacle-Corrected Acuity versus Postoperative Uncorrected Visual Acuity. Figure 1 provides a comparison of preoperative BSCVA values with 12-month postoperative follow-up uncorrected acuity values. When comparing the proportion of eyes with 20/12.5 or better, only 4% of eyes had this level of BSCVA before ICL surgery, compared with 20% of eyes having this level of UCVA at 12 months postoperatively. Similarly, at the 12-month examination 55% of eyes had 20/16 or better UCVA, compared with 40% BSCVA at baseline. The proportion of eyes with 20/20 or better UCVA at the 12-month visit was identical to the proportion with preoperative 20/20 or better BSCVA (83% BSCVA vs. 83% UCVA). Ninety-two percent of eyes achieved 20/25 or better 12-month UCVA, whereas 94% of eyes had 20/25 or better BSCVA preoperatively. Seventy-six and a half percent of cases had 12-month postoperative UCVA equal to or better than preoperative BSCVA.

Manifest Refraction Cylinder. Table 1 and Figure 2 present the manifest refractive cylinder before ICL implantation compared with the 12-month visit outcomes. Although only 21.0% of eyes had 1-D refractive cylinder preoperatively (none less), 91.4% of cases had ≤1 D of cylinder at the 12-month follow-up visit. Furthermore, no eyes (0.0%) preoperatively had refractive cylinder of 0.50 D, whereas 65.6% had ≤0.5 D and 40.9% had ≤0.25 D of refractive cylinder at the 12-month follow-up visit. At the 12-month follow-up examination, 99.5% of eyes with the Toric ICL had ≤2.0 D of cylinder, compared with 65.6% preoperatively. The mean manifest refractive cylinder dropped from 1.93 D (±0.84) at

Table 1. Manifest Refraction Cylinder, the Toric Implantable Collamer Lens

Cylinder	Preoperative [n/N (%)]	12 Months [n/N (%)]
≤0.25 D	0/186 (0)	76/186 (40.9)
≤0.50 D	0/186 (0)	122/186 (65.6)
≤1.00 D	39/186 (21)	170/186 (91.4)
≤1.50 D	83/186 (44.6)	180/186 (96.8)
≤2.00 D	122/186 (65.6)	185/186 (99.5)
≤3.00 D	164/186 (88.2)	186/186 (100)
≤4.00 D	186/186 (100)	188/186 (100)
Mean	1.93	0.51
SD	0.84	0.48
Range	1–4	0–3
Total	186	186

D = diopters; SD = standard deviation.

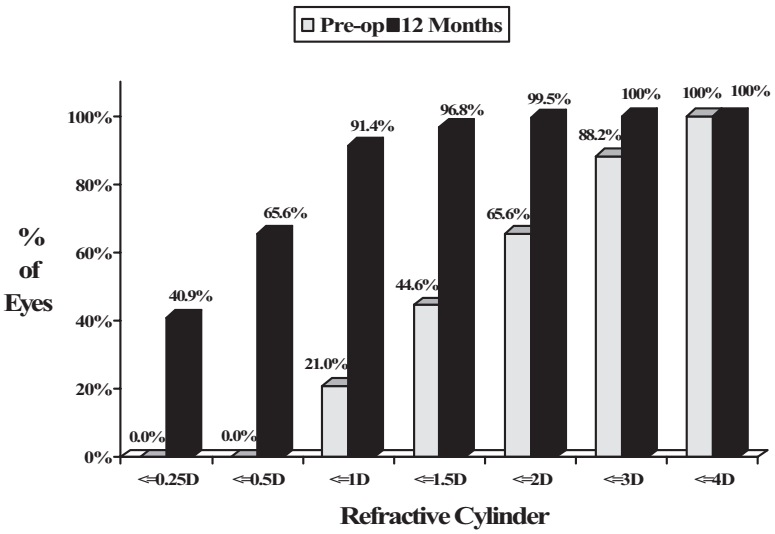

Figure 2. Preoperative (pre-op) versus 12-month postoperative refractive cylinder for the Toric Implantable Collamer Lens cohort. D = diopters.

baseline to 0.51 D (±0.48) 12 months after Toric ICL implantation, a 73.6% decrease in astigmatism. At 12 months, 83.9% of eyes achieved a reduction in their refractive cylinder, compared with baseline values of at least 0.75 D, and an additional 15.6% of cases were within ±0.5 D of their preoperative cylinder. Only 1 eye experienced an increase in refractive cylinder of ≥0.75 D at 12 months postoperatively; in this case, there was a 0.75-D refractive cylinder increase that could be explained by a postoperative increase in corneal cylinder (keratometric cylinder increased by 1.4 D).

Predictability of Manifest Cylinder (Attempted versus Achieved). In Table 2, we show how accurately the desired postoperative cylinder was achieved. The results were fairly consistent throughout the entire study period. The mean attempted cylinder was 1.55 to 1.56 D at 6 to 12 months postoperatively, whereas the actual achieved cylinder was 1.50 to 1.53 D. The percent of cases with cylinder within 0.5 D of the target was between 48.4 and 53.4, and within 1.0 D in between 85.5 and 86.2 at 6 to 12 months postoperatively.

Stability of Absolute Cylinder. The cylinder appears to be stable from the earliest reported interval. Between 98.2% and 99.4% of cases changed by ≤1 D, and between 84.3% and 89.6% of cases changed by ≤0.5 D at all reported intervals. The mean difference was between −0.03 and 0.04 D at each reporting interval. The 95% confidence intervals (CIs) encompass 0 at all times (which suggests no real change over time), and the mean change in cylinder per year was between −0.13 and 0.10 D at all times.

Table 2. Accuracy of Cylinder to Target, the Visian Toric Implantable Collamer Lens

Cylinder	6 Months (n = 174)	12 Months (n = 186)
Attempted change ± SD	1.55±0.66	1.56±0.69
Achieved change ± SD	1.50±0.75	1.53±0.82
% achieved within ±0.5 D of attempted	93/174 (53.4)	90/186 (48.4)
% achieved within ±1.0 D of attempted	150/174 (86.2)	159/186 (85.5)

D = diopters; SD = standard deviation.

Slit-Lamp Assessment of Axis Misalignment. The mean of the absolute value of misalignment based upon slit-lamp examination was between 1.2° and 2.2° for all intervals tested. It was 2.2° (±5.5°) between the 6- and 12-month follow-up visits. There was ≤5° of misalignment between 6 and 12 months after Toric ICL implantation in 86.9% of patients; 92.3% had ≤10°. Additionally, 95.4% of cases were ≤15° for the same period. No eyes (0%) had a reported misalignment of >30° between the 1- to 3-, 3- to 6-, and 6- to 12-month ranges.

The mean of the signed value of misalignment was between −0.5° and 0.5° for all intervals tested. The 90% CI for all periods tested had a maximum range of <2° and encompassed 0, which suggests no systematic clockwise or counterclockwise rotation.

A review of the 13 cases with ICL axis shift (misalignment) > 15° at any period demonstrates that in no case was there a change in refractive cylinder magnitude and axis corresponding to these slit-lamp observations of axis shift. If these ICLs had truly shifted ≥15°, then one would have expected at least a 50% decrease in cylinder correction and, possibly, an axis shift.[28] This lack of correlation suggests an error in misalignment measurement and not a true axis shift.

Manifest Refraction Spherical Equivalent. The mean MRSE improved from −9.36 D (±2.66) preoperatively to 0.05 D (±0.46) at 12 months postoperatively. Preoperatively, no eyes (0.0%) had an MRSE within 2.0 D of emmetropia; however, 98.3% of eyes were within 1.0 D at 12 months postoperatively. Only 1 eye (0.6%) had >2.0 D of residual myopia (−2.25 D) at any postoperative follow-up period during the study. It should be noted that this eye had a preoperative SE of −19 D.

Predictability of Manifest Refraction (Attempted versus Achieved). Predictability (Table 3) was achieved very early with the Toric ICL (96.9% within 1.0 D at the 1-week visit) and was maintained over the duration of the study follow-up. Predictabilities within 1.0 D at the 6- and 12-month follow-up visits after implantation of the Toric ICL were 97.1% and 97.3% of eyes, respectively. Similarly, predictabilities within 0.50 D were 76.5% at 1 week after implantation of the ICL, with 71.3% of eyes accurately predicted within 0.50 D at 6 months postoperatively, and 76.9% at the 12-month follow-up visit.

Patient Satisfaction. At 12 months postoperatively, 97.7% reported that they were very/extremely satisfied with the results of

Table 3. Predictability of Manifest Refraction Spherical Equivalent, Attempted versus Achieved

	1 Week [n/N (%)]	1 Month [n/N (%)]	3 Months [n/N (%)]	6 Months [n/N (%)]	12 Months [n/N (%)]
≤0.50 D	150/196 (76.5)	150/193 (77.7)	139/187 (74.3)	124/174 (71.3)	143/186 (76.9)
≤1.00 D	190/196 (96.9)	185/193 (95.9)	181/187 (96.8)	159/174 (97.1)	181/186 (97.3)
≤2.00 D	196/196 (100)	193/193 (100)	187/187 (100)	173/174 (99.4)	186/186 (100)
Overcorrected > 1 D	1/196 (0.5)	1/193 (0.5)	1/187 (0.5)	0/174 (0)	2/186 (1.1)
Overcorrected > 2 D	0/196 (0)	0/193 (0)	0/187 (0)	0/174 (0)	0/186 (0)
Undercorrected > 1 D	5/196 (2.6)	7/193 (3.6)	5/187 (2.7)	5/174 (2.9)	3/186 (1.6)
Undercorrected > 2 D	0/196 (0)	0/193 (0)	0/187 (0)	1/174 (0.6)	0/186 (0)
Not reported	4	2	1	1	0
Total	200	195	188	175	186

D = diopters.

their surgery, 2.3% were moderately to fairly satisfied, and none reported that they were unsatisfied.

Best Spectacle-Corrected Visual Acuity

Over Time. Best spectacle-corrected visual acuity in the study cohort improved after ICL implantation relative to preoperative levels. At 12 months, 38% of eyes had a BSCVA of 20/12.5 or better, an improvement over the baseline level of 5% of eyes. Further, BSCVA 20/20 or better occurred in 97% at 12 months postoperatively compared with 83% preoperatively (Fig 3).

Change in Best Spectacle-Corrected Visual Acuity. Best spectacle-corrected visual acuity was well preserved after ICL implantation, with only 3 cases (1.6%) with a loss of ≥2 lines of BSCVA at 12 months postoperatively (Fig 4). The first patient had preoperative BSCVA of 20/25 and at 12 months postoperatively had BSCVA of 20/50 due to a 2+ anterior subcapsular cataract. This patient had the only clinically significant lens opacity reported in the study cohort. In the second patient, preoperative BSCVA was 20/12.5, and at all reported visits except the 12-month visit, BSCVA was 20/16 or better. At 12 months, BSCVA was recorded as 20/20 (a 2-line loss). The patient's refractive error changed from −10.50 +1.00 ×118 preoperatively to −0.50 +0.75 ×90 at 12 months, associated with a change in UCVA from counting fingers to 20/25. There were no lens opacities noted at any visit, and the patient consistently rated her satisfaction with the procedure as very/extremely satisfied. The third patient was the amblyopia case, who had 20/40 BSCVA preoperatively but was reported to have 20/60 at the 6- and 12-month visits with no reason given; however, this patient subsequently was seen 5 months after the 12-month visit and was within 1 line of preoperative BSCVA. Only one other case had a visual loss of ≥2 lines of BSCVA at any time 3 months or later postoperatively, and the loss of 2 lines was only transient (20/12.5–20/20–20/16).

Best spectacle-corrected visual acuity improved 2 lines in 16.7% of eyes at 12 months postoperatively; a >2-line improvement was observed in 2.2%. The mean change in BSCVA at the 12-month follow-up visit after ICL implantation was 0.88 lines of improvement. At the 12-month follow-up, 76.3% of eyes had an increase in BSCVA, in contrast to only 5.9% with a 1-line loss and 1.6% (3 eyes) with a ≥2-line BSCVA loss (no change in 16.1%).

Secondary Implantable Collamer Lens–Related Surgeries. Secondary surgical interventions were reported in 5 eyes (2.4% of the total cohort) in the Toric ICL study cohort.

In 3 patients, the ICL was removed, with no subsequent IOL/ICL implantation. The first patient complained of a line in his vision from the preoperative laser iridotomies. At the last visit before ICL removal (1 week postoperatively), BSCVA had improved from 20/16 preoperatively to 20/10. Refraction was plano +0.50 ×139. No complications were reported. The patient decided to have the ICL removed. At 1 month after ICL removal, BSCVA had returned to the preoperative level (20/16), and no lens opaci-

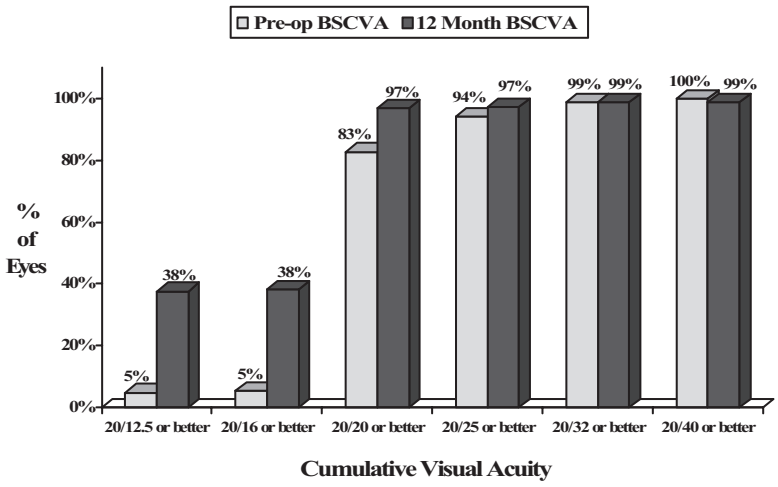

Figure 3. Preoperative (pre-op) versus 12-month postoperative best spectacle-corrected visual acuity (BSCVA) for the Toric Implantable Collamer Lens cohort.

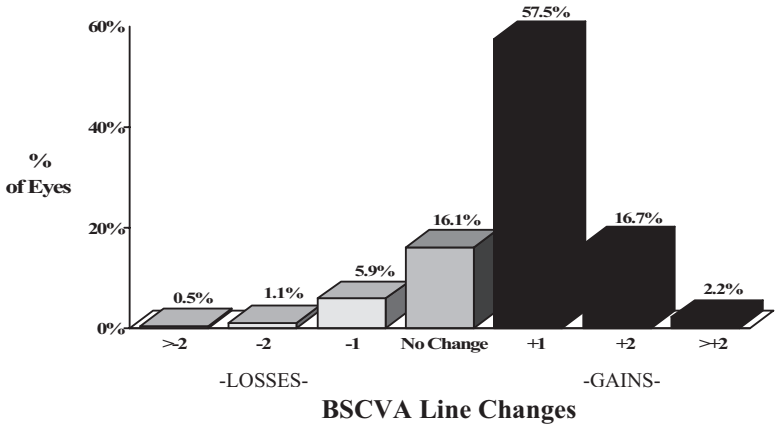

Figure 4. Preoperative versus 12-month postoperative line change in best spectacle-corrected visual acuity (BSCVA) for the Toric Implantable Collamer Lens cohort.

ties were reported. Although the patient insisted upon ICL removal, it did not correct for the line in his vision.

The second patient had an anterior subcapsular Lens Opacities Classification System III score of 0.5 at 1 week postoperatively, with BSCVA of 20/16. No complications were reported at this visit. The patient, an optometrist working in the investigator's practice, was concerned about possible future progression of this asymptomatic opacity and elected to have the ICL removed at 1 week postoperatively. At 2 weeks after removal, BSCVA remained at 20/16 and the lens opacity was unchanged. The patient's preoperative evaluation gave no indication of lens opacification; thus, the cause of this asymptomatic opacity was most likely surgical trauma.

The third patient underwent an additional YAG iridotomy on postoperative day 1 due to an elevation of intraocular pressure (IOP). A large vault to the ICL caused the pupil to enlarge, producing an anisocoria that was cosmetically unacceptable to the patient. The ICL was removed at 1 month postoperatively, and at 1 month after the removal, IOP was 14 mmHg and BSCVA was within 1 line of baseline (20/25), with no subsequent complications.

The fourth patient underwent an ICL replacement because the lens was too long, causing an iridocorneal touch secondary to excessive vault. Four months after ICL replacement with a shorter lens, the patient had UCVA of 20/25 and, 12 months from the original surgery, BSCVA of 20/20 (a 1-line improvement), with no postoperative complications or lens opacities.

There was one patient who had an ICL repositioning that occurred on the day after surgery because of misalignment to the intended ICL axis. At 12 months postoperatively, this patient, with -14 -4 $\times 97$ preoperative refraction, had no postoperative cylinder and demonstrated an improvement of 1 line of BSCVA to 20/16 and UCVA of 20/20, with no postoperative complications or lens opacities.

Postoperative complications after implantation of the Toric ICL have been minimal. Transient iritis in 2 patients was observed only at 1 week in one case and at 1 week persisting to 1 month postoperatively in the other. One (0.5% of total cohort) retinal detachment was reported 6 months after surgery. Three months after the retinal repair surgery, the patient was reported to have UCVA of 20/20 and best-corrected visual acuity of 20/16, with no further complications. At the 12-month visit, this eye had UCVA of 20/16 and BSCVA of 20/12.5, MRSE was within 0.50 D, and the patient reported being very/extremely satisfied with the ICL outcome.

Lens Opacities Classification System III. There were no cases (0%) of nuclear color, nuclear opalescence, or cortical changes preoperatively or at any postoperative visit. Furthermore, all eyes (100%) had no posterior subcapsular changes at the preoperative and all postoperative follow-up visits.

Six eyes (2.9% of the total cohort) reported anterior subcapsular opacities of trace or more postoperatively. Five cases were asymptomatic with 20/20 or better BSCVA and 20/25 or better UCVA at their last reported visits. The remaining case had a 2+ anterior subcapsular cataract (discussed previously in "Change in Best Spectacle-Corrected Visual Acuity"); this was the only clinically significant lens opacity reported in the study cohort.

Discussion

In December 2005, the ICL for spherical myopia of -3 to -20 D was approved for commercial use in the U.S. The spherical myopia ICL study and Toric ICL study were similar with regard to preoperative myopia (10.1 D vs. 9.36 D) and residual postoperative cylinder (0.61 D vs. 0.51 D); however, as shown in Table 4, efficacy appeared better with the Toric ICL. Postoperative UCVA was 20/20 or better in 50.4% of the spherical ICL series, compared with 83.1% of the toric series. The spherical ICL study allowed patients with worse BSCVA, as poor as 20/100, compared with 20/40 in the toric study, and a significant number of patients with preoperative myopia of >15 D were not targeted for emmetropia in the spherical ICL study. Even correcting for these differences by only comparing patients with preoperative BSCVA of 20/20 or better and those eyes targeted for emmetropia, 60.7% of spherical ICL cases had UCVA of 20/20 or better postoperatively, compared with 90.1% in the Toric ICL group. Furthermore, 57.5% of cases in the spherical ICL group had postoperative UCVA better than or equal to preoperative BSCVA, compared with 76.5% in the Toric ICL group. In the spherical ICL group, 67.5% were within ± 0.5 D and 88.2% were within ± 1.0 D of attempted SE, versus 76.9% and 97.3%, respectively, in the Toric ICL group. Interestingly, both spherical and Toric ICL series

Table 4. Summary of Key Efficacy Variables, the Toric Implantable Collamer Lens (ICL)

	Visian Toric ICL, 12 Months Postoperatively	Spherical ICL, 12 Months Postoperatively	U.S. FDA Targets
UCVA			
20/20 or better	83.1%	50.4%*	
20/40 or better	95.6%	91%*	
UCVA (If preoperative BSCVA 20/20 or better)			
20/20 or better	90.1%	60.7%*	
20/40 or better	100%	93.7%*	85% (75% for laser refractive surgery > 7 D of myopia)
Predictability (MRSE): attempted vs. achieved			
±0.50 D	76.9%	67.5%	50% (30% for laser refractive surgery > 7 D of myopia)
±1.00 D	97.3%	88.2%	75% (60% for laser refractive surgery > 7 D of myopia)
±2.00 D	100%	98.1%	
Patient satisfaction			
Unsatisfied	0%	0.6%	
Very/extremely satisfied	97.7%	92.1%	

BSCVA = best spectacle-corrected visual acuity; D = diopters; FDA = Food and Drug Administration; MRSE = manifest refraction spherical equivalent; UCVA = uncorrected visual acuity.
*Excludes patients with >15 D of myopia, which were undercorrected.

exceeded all FDA-suggested target values for efficacy recommended for both phakic IOLs and laser refractive procedures.

The spherical ICL study was not intended to treat astigmatism. Mean preoperative astigmatism was 0.73 D, whereas the 1-year postoperative cylinder was 0.61 D. Preoperative cylinder was <1 D in 66.8% of cases. Only 13.7% had a decrease in cylinder of ≥0.75 D postoperatively, and 7.3% had an increase in cylinder of ≥0.75 D. The remainder (79%) had postoperative cylinder within ±0.5 D of the preoperative value. In contrast, in the Toric ICL study mean preoperative astigmatism was 1.93 D, whereas the 1-year postoperative cylinder was 0.51 D. No cases had a preoperative cylinder of <1 D. A total of 83.9% of cases had a decrease in cylinder of ≥0.75 D, and only 1 case (0.5%) had an increase in cylinder of 0.75 D. The remainder (15.7%) had postoperative cylinder within ±0.5 D of the preoperative value.

We believe that no further follow-up is required for the Toric ICL series because its haptic design is identical to that of the spherical myopic ICL, and follow-up on a large series already has established its safety over a 3-year period.[14] Furthermore, as a condition of approval the FDA is requiring an additional 2-year follow-up of the spherical myopic ICL series. The data reported here clearly establish both the stability and efficacy of the Toric ICL in treating myopia and astigmatism.

In a previous report,[13] we compared the results of the U.S. FDA spherical ICL series with those of U.S. FDA clinical trials of photorefractive keratectomy (PRK) and LASIK with preoperative myopia of >6 and >7 D, because the ICL series had a mean preoperative myopia of >10 D. In a later report,[14] we compared the U.S. FDA spherical ICL series to corneal refractive surgery (LASIK) in the ≤7-D preoperative myopia subset, a range generally accepted to be optimum for excimer refractive procedures. In both of these comparisons, the ICL proved to be comparable or, in some cases, superior to the corneal refractive procedures. Given that the Toric ICL performed even better than its spherical counterpart, when the Toric ICL is approved for commercial use in the U.S. it should be considered seriously as an alternative to corneal refractive procedures throughout its full range of approved spherical and astigmatic correction.

Currently, the most common forms of refractive surgery, including PRK, LASIK, and intracorneal implants of either lenses or rings, assume that alteration of the natural shape (curvature) of the cornea is the best way to address myopic astigmatic refractive errors. Although many patients who undergo these procedures ultimately achieve a good visual outcome, the final success of any of these techniques has been shown to be variable and dependent on surgeon experience and wound-healing responses.[29] Furthermore, postoperative regression requiring retreatment has occurred with varying rates depending on the surgical procedure, exposing the patient to a second surgical procedure with its accompanying risks.

Phakic IOLs are considered an attractive approach, based in large part on the phenomenal acceptance of IOLs for not only the aphakic or cataract patient but also, recently, the refractive patient. The use of phakic IOLs offers the predictability and efficacy of IOL technology, yet is less invasive because the crystalline lens is left intact. In addition, the procedure is reversible/exchangeable, and should the crystalline lens be damaged during phakic IOL implantation, lensectomy with IOL implantation remains a good second option.

Future investigations may involve the use of the Toric ICL to treat cases with higher refractive cylinder (>4 D). Patients who suffer from high astigmatism and high myopia are usually not suitable candidates for corneal-reshaping procedures because there is an increased risk of corneal ectasia, associated with low visual quality and unpredictability.[30] These cases of high astigmatism may benefit from toric phakic IOL implantation.

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