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ORIGINAL RESEARCH

Comparison of Astigmatic Outcomes with an Ultra-Low Cylinder Power (0.90 D) Toric versus a Non-Toric Intraocular Lens for Eyes with Low Astigmatism

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Purpose: Evaluate postoperative astigmatic outcomes in eyes implanted with an ultra-low cylinder powered toric (ULPT) intraocular lens (IOL) compared with a non-toric IOL for the surgical management of astigmatism in cataract surgery.

Patients and Methods: This is a retrospective, controlled consecutive case series from 3 Canadian ophthalmology centers. Cases were included if they were adults (≥18 years), qualified for the 0.90D toric based on the Barrett Toric Calculator without "flipping" the axis of astigmatism by 0.2D or more, and underwent surgery either with the enVista Toric 0.9 D IOL (ULPT, Bausch + Lomb) or enVista Non-toric (spherical). All surgeries were performed using standard phacoemulsification and IOL implantation under topical anesthesia with 2.0 to 2.2-mm biplanar square clear corneal incision at 190° for OD and 10° for OS. The mean±SD incision angle was 94.0±89.70° for the ULPT group and 103.0±89.37° for the non-toric group. Primary effectiveness endpoint was the mean reduction in cylindrical power of the eye. Other endpoints were manifest refraction, keratometry, visual acuity, IOL axis, and safety.

Results: 290 screened patient charts were enrolled and included 383 eyes (192 eyes with the ULPT IOL and 191 eyes with the non-toric IOL). The mean reduction in cylindrical power was 0.432±0.447 D in the Toric 0.9 D IOL group and 0.071±0.407 D in the Non-toric group, with the mean difference (0.351 D) in favor of the ULPT IOL ($P<0.0001$). Significantly more of the ULPT group than the Non-toric group had plano outcomes or had a cumulative residual cylinder within 0.25 D, 0.50 D, and 0.75 D of plano ($P\leq0.001$ for all). There were no serious AEs reported in patient charts.

Conclusion: The ULPT IOL was safe and effective for eyes with low to ultra-low preoperative astigmatism and resulted in significantly greater reduction in postoperative manifest cylinder compared to the monofocal IOL.

Plain Language Summary: The enVista 0.90D "ultra-low cylinder power" toric (ULPT) intraocular lens (IOL) is Canada's first commercially available, non-custom order toric IOL correcting <1.0D at the IOL plane (corresponding to as low as 0.52D at the corneal plane). In patients presenting for cataract surgery, 51% of eyes have 0.25–1.00D of preoperative corneal astigmatism. This is considered visually significant. Thus, many patients may benefit from an ULPT IOL. In this retrospective, controlled, consecutive case study, charts were reviewed from adults implanted with enVista Toric 0.9 D IOL (ULPT, n=192 eyes) or enVista Non-toric IOL (spherical, n=191 eyes) with data available 4-weeks post-implantation. The ULPT IOL was significantly more effective in correcting astigmatism than the non-toric IOL. This represents an effective option for patients undergoing cataract surgery. The ULPT IOL significantly reduced postoperative cylinder compared to a non-toric IOL ($P<0.0001$). The ULPT IOL was safe in the study population. The ULPT IOL was highly effective and safe in reducing the smallest amounts of visually-significant corneal astigmatism when compared to a non-toric IOL. This demonstrates that with widely available biometry technology, modern formulas and surgical techniques, and now ULPT IOLs, surgeons can accurately treat the smallest amounts of visually-significant refractive cylinder. The IOL represents a new stepping-stone in the refinement of postoperative cylinder outcomes. This may lead to better visual function, more satisfied patients, and fewer laser vision correction enhancements.

Keywords: enVista, toric, cataract, IOL, intraocular lens, ultra-low powered

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Introduction

Toric intraocular lenses (IOLs) have been used to treat corneal astigmatism for >30 years.[1] When single-piece, hydrophobic acrylic toric IOLs were first introduced, those correcting 1.25–1.50D at the IOL plane were referred to as "low-cylinder power" toric IOLs.[2] As toric IOL formulas improve and effects of posterior corneal curvature were taken into account, more consistent and accurate outcomes were achieved.[3] Toric IOLs correcting 1.0D at the IOL plane (as low as 0.77D at the corneal plane) are referred to as "very-low cylinder" power toric IOLs, and toric IOLs correcting <1.0D at the IOL plane (as low as 0.52D at the corneal plane) can be considered ultra-low cylinder power.

A landmark study of over 17,152 eyes concluded that 0.50D or more corneal cylinder is visually significant and deserves attention during surgical planning.[4] Other large studies have shown that residual cylinder, regardless of axis (ie, with-the-rule, against-the-rule, or oblique), is predicted to have equally deleterious effects on vision.[4,5] Both a recent Cochrane review and an American Academy of Ophthalmology Technology Assessment reported that toric IOLs resulted in more consistent and less invasive correction of corneal astigmatism than limbal relaxing incisions (LRI) at the time of cataract surgery.[6,7]

The enVista 0.90D "ultra-low cylinder power" toric IOL is Canada's first commercially available, non-custom order toric IOL correcting <1.0D at the IOL plane, corresponding to as low as 0.52D at the corneal plane. In patients presenting for cataract surgery, 34% of eyes have 0.50–1.00D of preoperative corneal astigmatism and 17% of eyes have 0.25–0.50D of preoperative corneal astigmatism,[8] which may benefit from a toric IOL after surgically induced astigmatism (SIA) has been taken into account; however, smaller amounts (<1.00D) of corneal astigmatism are known to have less repeatability in biometry measures.[9]

Despite substantial progress in managing astigmatism with toric IOLs, several key uncertainties remain. Namely, it is unclear whether surgeons can accurately identify patients who would benefit from ultra-low cylinder power toric IOLs, given that there is less repeatability in biometry measures. It remains to be determined whether predictable deployment of toric IOLs can reduce even the lowest amounts of visually significant postoperative cylinder. Finally, it is of interest to examine whether surgeons can do this with technology that is widely available today.

The purpose of this study was to evaluate the postoperative astigmatic outcomes of eyes predicted to benefit from implantation with a 0.90D toric IOL that were implanted with an ultra-low cylinder powered toric IOL (enVista Toric 0.9D) compared with those implanted with a non-toric IOL.

Materials and Methods

This is a retrospective, controlled series of consecutive cases from 3 Canadian ophthalmology centers. Cases were included if they were adults (≥18 years), qualified for the 0.90D toric based on the Barrett Toric Calculator (https://ascrs.org/tools/barrett-toric-calculator) without "flipping" the axis of astigmatism by 0.2D or more, and underwent surgery either with the enVista Toric 0.90D or enVista monofocal non-toric IOL between September 1, 2018 and November 7, 2022. Both eyes were eligible for inclusion. No specific axis orientation was used as a selection criterion; eyes were included regardless of astigmatism orientation provided they met the power threshold. Eyes were excluded if they had a history of uncontrolled or clinically significant ocular comorbidities prior to surgery (dry eyes, retinal pathology, etc), corrected distance visual acuity (CDVA) of 20/25 or worse after surgery, or excessive IOL rotation >10 degrees after surgery based on clinical chart review, not ICD-10 coding.

All surgeries were performed using standard phacoemulsification and IOL implantation under topical anesthesia. A 2.2-mm biplanar clear corneal incision was created temporally at 180–190° for right eyes and 0–10° for left eyes, positioned approximately 0.5 mm anterior to the limbus, with the second plane parallel to the iris. A 0.8–1.0mm clear corneal side port was made superiorly.

The study was conducted in accordance with the protocol; International Conference on Harmonization; Good Clinical Practice; the Declaration of Helsinki, and local, provincial, and federal guidance/regulations. The study protocol was reviewed and approved by a central Institutional Review Board in Canada (Veritas IRB, reference number: 2023-2875-14253-1). A waiver of informed consent was obtained because the retrospective design had no risk to patients and the

waiver did not adversely affect the rights and welfare of the patients. All data and records were kept confidential. The study was registered with the National Library of Medicine database (clinicaltrials.gov, NCT05075746).

The following data were extracted from paper and electronic medical records: demographics, medical history (including SIA), lens calculation data, keratometry, manifest refraction, uncorrected distance visual acuity (UDVA), CDVA, IOL rotation, and adverse events (AEs), if available. Eyes were not required to be targeted for distance; thus, near or intermediate targets were accepted.

The primary effectiveness endpoint was the mean reduction in cylindrical power of the study eye, defined as the difference between the magnitudes of the preoperative keratometric cylinder and the residual refractive cylinder (referenced to the corneal plane).

Statistical Analysis

The primary analysis tested the null hypothesis that the mean reduction in cylindrical power of the eye for the ULPT group was ≤ the mean for the non-toric control group versus the alternative that the mean reduction in cylindrical power of the eye for the ULPT group was > the mean for the non-toric control group.

The preoperative keratometric cylinder (D) was calculated as the difference between the preoperative steep and flat keratometric powers. The postoperative manifest refraction cylinder (PMRC) was referenced to the corneal plane assuming a vertex distance of 13mm as follows:

$$PMRC = \left| \frac{1000(Sph + Cyl)}{1000 - 13(Sph + Cyl)} - \frac{1000Sph}{1000 - 13Sph} \right|$$

where Sph=the postoperative manifest refraction sphere at the spectacle plane (D), Cyl=the postoperative manifest refraction cylinder at the spectacle plane (D).

Reduction in the cylindrical power of the eye (D) was computed as the preoperative keratometric cylinder minus the PMRC and summarized using continuous summary statistics by treatment. The statistical hypothesis was tested using a random effect model to account for the correlations among eyes in the same patient. If the one-sided p-value was <0.025 (or the two-sided p-value <0.05) for the fixed effect of the model and the treatment difference was >0, then the null hypothesis was rejected and the ULPT IOL was statistically successful in the primary outcome. Missing data was not imputed. A mixed effect model post-hoc was used to evaluate treatment differences in manifest refraction parameters, and a generalized estimating equation model was used to evaluate the odds of cumulative residual cylinder between groups.

A sample size of 192 eyes/group was determined to have 90% power to detect a mean difference of 0.25D assuming that the common SD is 0.753D using a two-group Satterthwaitet-test with a 2.5% one-sided significance level. Therefore, the study was to enroll ≥384 eyes presenting with ≥192 enVista Toric 0.9 D IOLs and ≥192 enVista non-toric (spherical) IOLs.

Results

From 3 sites in Canada, 290 screened patient charts were enrolled. This study included 383 eyes implanted between October 20, 2018 and November 7, 2022, with 192 eyes (145 patients) that received the ULPT IOL and 191 eyes (133 patients) that received a non-toric IOL. Twelve of the patients received both types of IOLs. The ULPT group had had a higher preoperative keratometric cylinder (P<0.01); otherwise, the demographic and baseline characteristics were similar between groups (Tables 1 and 2). The mean incision angle was 94.0 ± 89.70° for the ULPT group and 103.0 ± 89.37° for the non-toric group. The mean predicted SIA was 0.164 ± 0.0712 D in the ULPT group and 0.179 ± 0.0748 D in the non-toric group.

There were statistically significant reductions in corneal astigmatism in both groups; however, the magnitude of reduction was larger in the ULPT group. The mean reduction in cylindrical power was 0.432 ± 0.447D in the ULPT group and 0.071 ± 0.407D in the non-toric group (primary endpoint, Figure 1). The mean difference between groups was 0.351D (95% confidence interval [CI]: 0.260 to 0.441D) in favor of the ULPT IOL (P<0.001).

The distribution of preoperative and postoperative astigmatism is in Figure 2. In the ULPT group, the centroid of postoperative astigmatism shifted towards the center and was closer to 0.0D with a smaller vectoral SD (represented by an ellipse). In the non-toric group, SIA induced by clear corneal incisions caused the centroid to shift with no change in the vectoral SD. The clustering of postoperative data closer to 0.0D demonstrates the reduction in astigmatism in eyes

Table 1 Demographics by Subject

Parameter	Toric 0.9 D IOL (N=145)	Non-Toric IOL (N=133)	Toric 0.9 D + Non-Toric IOL (N=12)	p-value
Age at first implant (years)				
Mean (95% CI)	68.5 (67.0,70.0)	70.7 (69.1, 72.2)	66.6 (61.5, 71.7)	0.07
Range	37, 88	45, 89	43, 83	
Sex, n (%)				
Male	60 (41.4)	66 (49.6)	4 (33.3)	0.27
Female	85 (58.6)	67 (50.4)	8 (66.6)	
Race, n (%)				
White (Caucasian)	74 (51.0)	61 (45.9)	4 (33.3)	0.55
Asian	18 (12.4)	15 (11.3)	1 (8.3)	
Black or African American	4 (2.7)	2 (1.5)	1 (8.3)	
Other	49 (33.8)	55 (41.4)	6 (50.0)	

Notes: For age, p-value and 95% CI estimated from linear regression; for sex and race, p-value form Fisher's exact test.
Abbreviation: N, number of subjects.

Table 2 Preoperative and Postoperative Keratometry by Eye

Parameter	Toric 0.9D IOL (N=192)	Non-Toric IOL (N=191)	p-value
Pre-op Keratometric Steep Power (D), n	192	191	0.20
Mean (SD)	43.98 (1.57)	43.76 (1.52)	
Range	40.20,49.03	40.00,48.08	
Post-op Keratometric Steep Power (D), n	71	70	0.99
Mean (SD)	43.35 (1.42)	43.62 (1.49)	
Range	40.38,46.31	39.82,47.98	
Pre-op Keratometric Steep Axis (deg), n	192	191	0.59
Mean (SD)	87.43 (35.74)	89.97 (45.29)	
Range	5.00,172.00	2.00,180.00	
Post-op Keratometric Steep Axis (deg), n	71	70	0.18
Mean (SD)	93.75 (37.11)	84.46 (40.72)	
Range	13.00,178.00	9.00,167.00	
Pre-op Keratometric Flat Power (D), n	192	191	0.12
Mean (SD)	43.23 (1.49)	43.20 (1.50)	
Range	39.53,47.94	39.45,47.20	
Post-op Keratometric Flat Power (D), n	71	70	0.96
Mean (SD)	42.79 (1.37)	43.04 (1.45)	
Range	39.56,45.70	39.36,46.84	

Notes: The preoperative keratometric cylinder (D) was calculated as the difference between the preoperative steep and flat keratometric powers (both in diopters). P-value is from a general estimating equation model, considering repeated measurements (eyes) within each subject.
Abbreviations: D, diopters; preop, preoperative; N, total number of subjects implanted; n, number of subjects with observed data; postop, postoperative; SD, standard deviation.

implanted with the ULPT IOL. The outcomes with the ULPT were accurate and centered (mean difference vector 0.20D at 80.7°, Figure 3). The mean vector SIA was 0.34D at 86.9° (Figure 4), and the mean vector TIA was 0.29D at 83.7° (Figure 5). The mean correction index was 1.26D (mean 0.08 D beyond the target) (Figure 6), indicating slight overcorrection. In ULPT cases, small target magnitudes can amplify calculated vector ratios, and SIA may contribute proportionally more to the achieved correction.

Significantly more patients in the ULPT group than the non-toric group had plano outcomes (31.4% vs 14.7%, respectively; P<0.001) or had a cumulative residual cylinder within 0.25D (57.6% vs 40.3%, respectively; P=0.001), 0.50D (84.3% vs 68.1%, respectively; P<0.001), and 0.75D of plano (97.1% vs 88.0%, respectively; P=0.001) (Figure 7). Nearly all eyes (97.1%) in the ULPT group were within 0.75D of plano cylinder. The ULPT group had higher odds of achieving plano

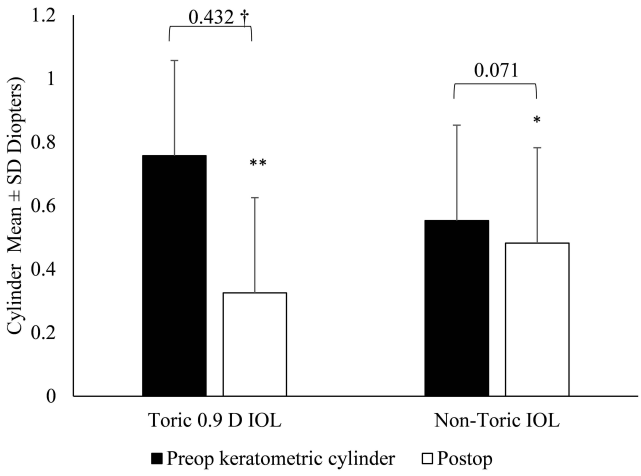

Figure 1 Mean reduction in cylindrical power. *P=0.017 vs preop, **P<0.0001 vs preop, †P<0.0001 vs non-toric IOL control group.

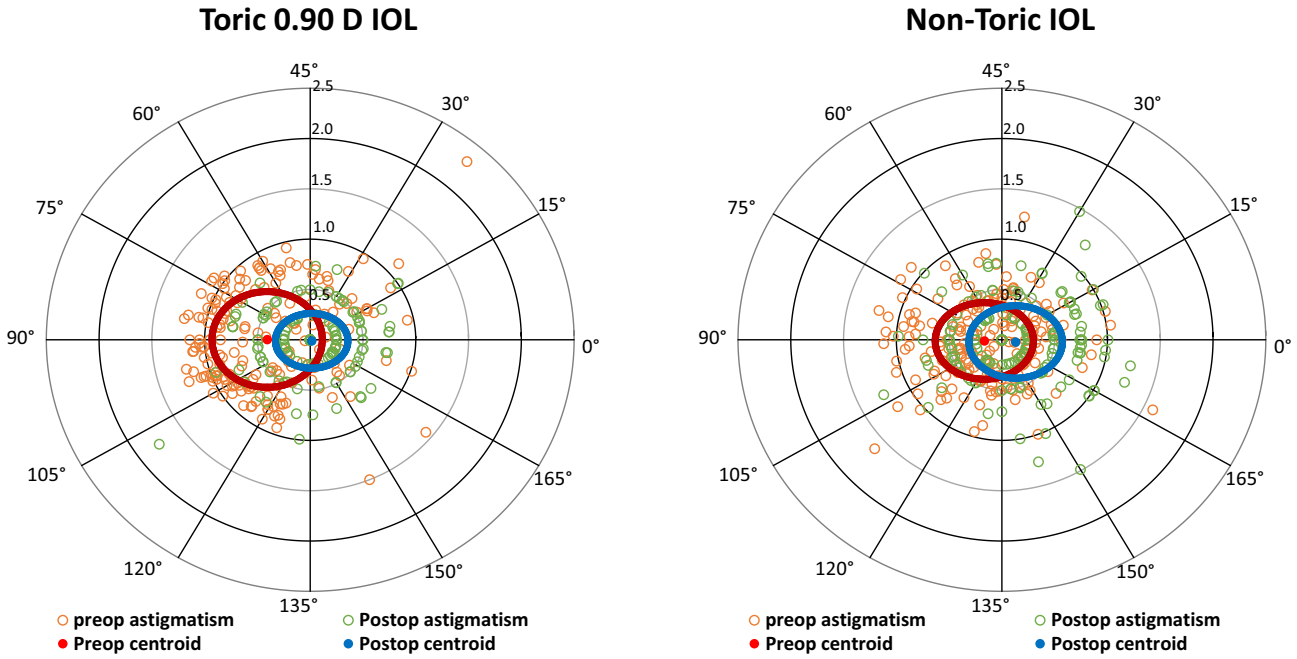

Figure 2 Double angle vector plots of the differences in corneal astigmatism measurements. N = 191/group.

cylinder (odds ratio [OR]: 1.18, 95% CI: 1.08–1.28, P<0.001), residual cylinder within 0.25D (OR: 1.17, 95% CI: 1.06–1.30, P=0.003), and within 0.50D (OR: 1.16, 95% CI: 1.07–1.27, P=<0.001) compared with the non-toric group.

Postoperatively, all patients achieved CDVA of 20/20 or better as required by the exclusion criteria. All eyes with available data (ULPT group: n=88, non-toric group: n=92) had preoperative UDVA of 20/25 or worse. The postoperative UDVA decimal mean was similar between groups (ULPT IOL n=125: 0.858 ± 0.223; non-toric IOL n=100: 0.856 ± 0.225) (this data was not available for all eyes in each group). The ULPT group had a higher percentage of eyes achieving postoperative UDVA of 20/20 or better (63.2%, 79/125) compared to the non-toric group (55.0%, 55/100). The proportion of eyes within ±0.5D of plano (ie, both manifest refraction sphere and MRSE within ±0.5D of plano) postoperatively was 80.7% (155/191) in the ULPT group and 68.6% (131/191) in the non-toric group (Table 3). The deviation of postoperative MRSE from the intended refractive target (MRSE error) was −0.19 ± 0.49 D in the ULPT group and −0.18 ± 0.52 D in the non-toric group. In the ULPT group (n=71), the IOL axis was stable from initial placement to final measure; the mean change from initial axis was 1.2 ± 9.15 degrees.

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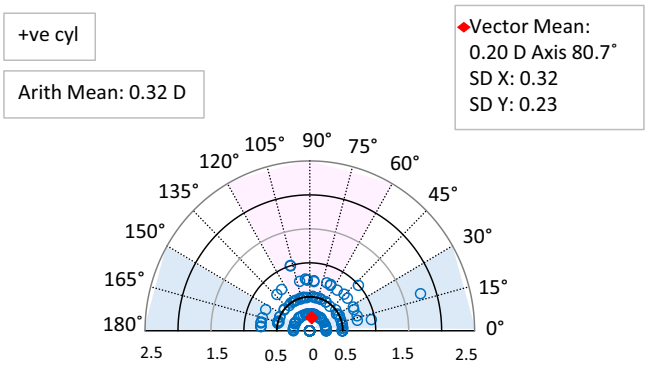

Figure 3 Vectorial analysis of the difference vector in the ULPT group. SD X represents the standard deviation of the data points along the horizontal (X) axis of the vector plot. SD Y represents the standard deviation of the data points along the vertical (Y) axis of the vector plot. +cyl represents that all astigmatism is treated as steepening (positive) at the steepest axis.
Abbreviation: Arith mean, arithmetic mean.

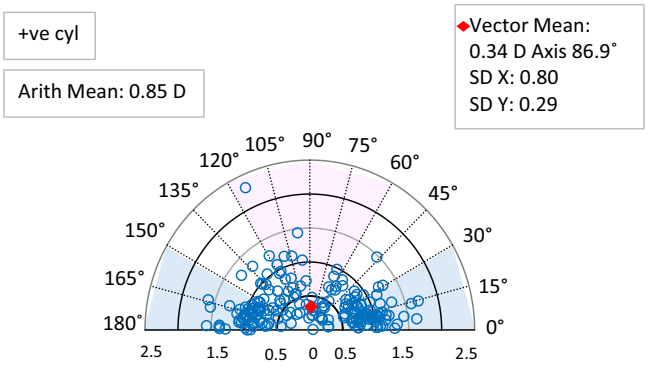

Figure 4 Vectorial analysis of surgically induced astigmatism in the ULPT group. SD X represents the standard deviation of the data points along the horizontal (X) axis of the vector plot. SD Y represents the standard deviation of the data points along the vertical (Y) axis of the vector plot. +cyl represents that all astigmatism is treated as steepening (positive) at the steepest axis.
Abbreviation: Arith mean, arithmetic mean.

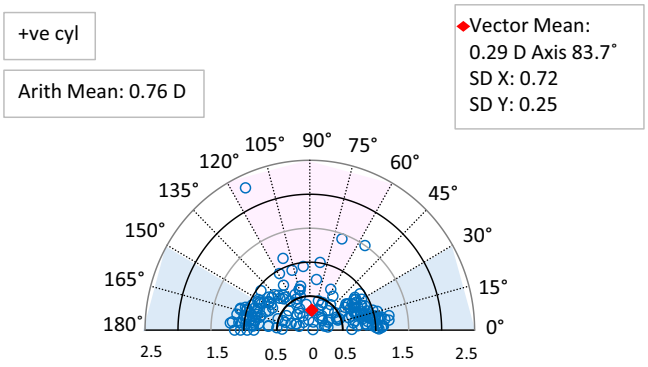

Figure 5 Vectorial analysis of target-induced astigmatism in the ULPT group. SD X represents the standard deviation of the data points along the horizontal (X) axis of the vector plot. SD Y represents the standard deviation of the data points along the vertical (Y) axis of the vector plot. +cyl represents that all astigmatism is treated as steepening (positive) at the steepest axis.
Abbreviation: Arith mean, arithmetic mean.

There were no serious AEs reported in patient charts. The only AEs were mild posterior capsule opacification (ULPT group: 31/192 eyes, 16.1%; non-toric group: 13/191 eyes, 6.8%). No eyes in the toric group had an increase in postoperative astigmatism.

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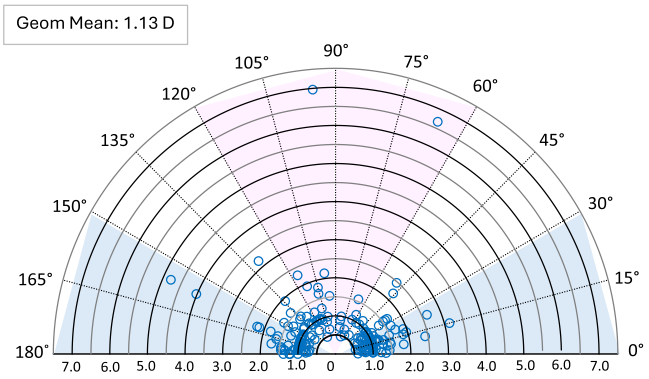

Figure 6 Vectorial analysis of the mean correction index in the ULPT group.
Abbreviation: Geom mean, geometric mean.

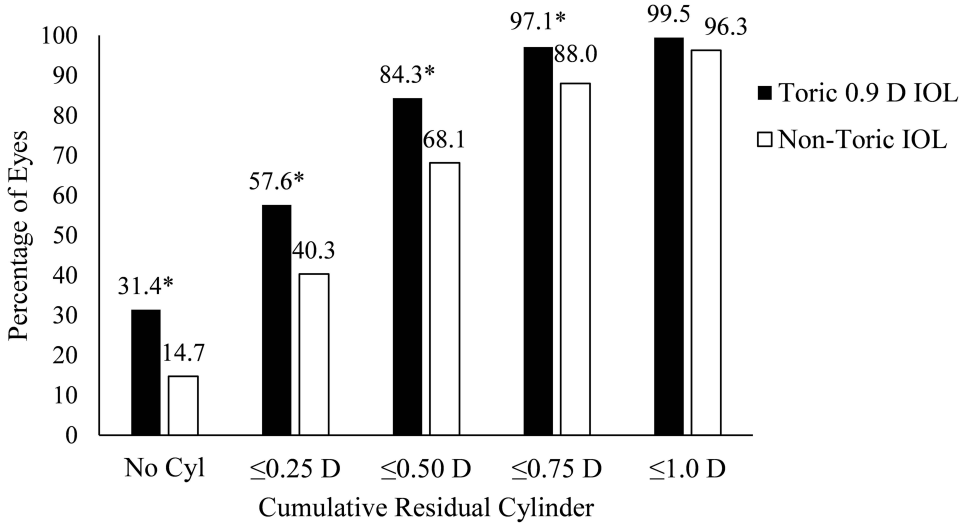

Figure 7 Cumulative percent distribution of postoperative astigmatism. N = 191/group. *P≤0.001.

Site Specific Case Presentation—A Site Using Basic Equipment

Site 1 (AM) used basic biometry and toric marking devices; namely, an IOLMaster 500 for in-office biometry, an Atlas topographer to confirm measurements, a Storz bubble marker for preoperative marking of the principal axes, followed by a Gimbel-Mendez ring, a sterile marking pen, and a Sinsky hook to mark the axis of implantation manually. Similar to the full analysis set, the ULPT group (n=64 eyes) had a significant reduction in postoperative cylindrical correction compared with preoperative (0.59D, P<0.001), which was greater than the non-toric group (N=64 eyes, 0.11D change from preoperative). The ULPT group had higher odds of achieving plano cylinder (OR: 1.26, 95% CI: 1.09–1.46, P=0.001), residual cylinder within 0.25D (OR: 1.33, 95% CI: 1.13–1.57, P=0.0005) and 0.50D (OR: 1.34, 95% CI: 1.18–1.54, P<0.0001) compared with the non-toric group (Figure 8).

Discussion

To our knowledge, this is the first study to evaluate the use of an ULPT (<1.0D) IOL in eyes predicted to have low levels of visually significant postoperative astigmatism. All patients in both groups were candidates for the 0.90D toric IOL based on the Barrett Toric Calculator predictions as defined in the inclusion criteria. The choice between toric and non-toric IOL implantation was primarily driven by patient preference in the context of the Canadian healthcare system, where advanced technology IOLs such as toric lenses require private patient payment. The results indicate that the ULPT IOL was significantly more effective in correcting astigmatism than the non-toric IOL and represents an effective option

Table 3 Postoperative Manifest Refraction

Parameter	Toric 0.9 D IOL (N=191)	Non-Toric IOL (N=191)	P-value
Postop Manifest Refraction Cylinder (D)			
Mean (SD)	−0.327 (0.295)	−0.484 (0.334)	<0.01
Range	−1.75, 0.00	−1.50, 0.00	
Postop Manifest Refraction Axis (degrees)			
Mean (SD)	63.3 (59.83)	76.0 (53.90)	0.03
Range	0, 180	0, 180	
Postop Manifest Refraction Cylinder at the Corneal Plane (D)			
Mean (SD)	0.325 (0.294)	0.482 (0.333)	<0.01
Range	0.00, 1.77	0.00, 1.49	
Postop Manifest Refraction Spherical Equivalent (D)			
Mean (SD)	−0.225 (0.505)	−0.230 (0.595)	0.52
Range	−2.25, 0.88	−3.25, 1.63	

Notes: The postoperative manifest refraction cylinder at the corneal plane (D) was referenced to the corneal plane assuming a vertex distance of 13 mm. One subject in the enVista Toric 0.9D group was missing postop manifest refraction data. P-value from a mixed effect model, considering repeated measurements (eyes) within each subject.

Abbreviations: D, diopters; N, total number of subjects with postop manifest refraction data available; preop, preoperative; postop, postoperative; SD, standard deviation.

for patients undergoing cataract surgery. The ULPT IOL significantly reduced postoperative cylinder compared to a non-toric IOL (P<0.0001), meeting the primary outcome measure. The ULPT IOL was safe in the study population, which is consistent with the established clinical safety profile from the past decade.[10–13]

The non-toric group had significantly less astigmatism at baseline. The difference in baseline astigmatism may be attributed to surgeons being reticent to recommend patients pay for a toric IOL, which could cause "flipping" the axis by up to 0.19D. This is a commonly used target when only higher cylinder steps are available, and the absolute reduction in cylinder when flipping by this amount may be small (ie, a choice between leaving 0.42D at the original axis, or "flipping" the axis with the use of a 0.90D and leaving 0.19D at the opposite axis so that the predicted absolute reduction would be

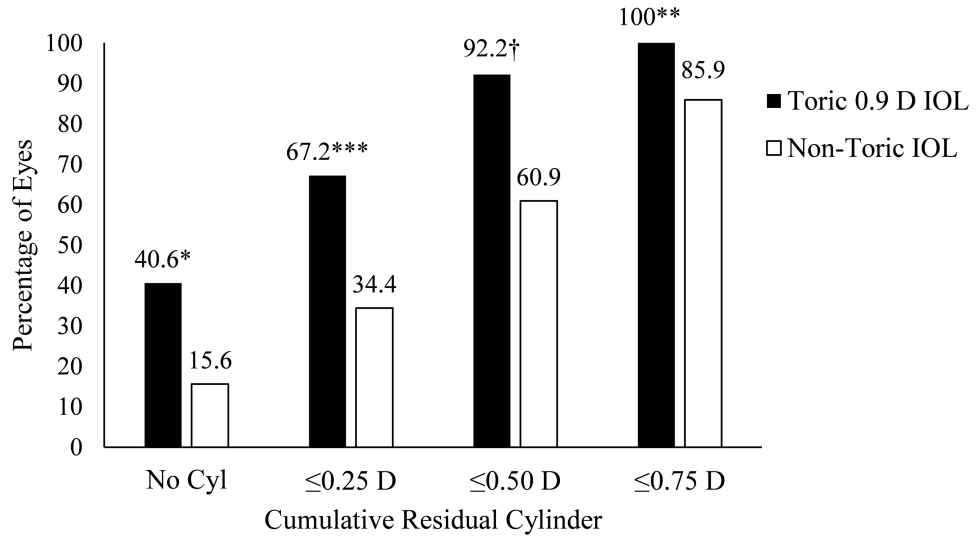

Figure 8 Astigmatic predictability from Site 1 (AM), which utilized an IOLMaster 500 for in-office biometry, an Atlas topographer to confirm measurements, a Storz bubble marker for preoperative marking of the principal axes, followed by a Gimbel-Mendez ring, a sterile marking pen and a Sinsky hook to mark the axis of implantation manually in the operating theatre. This site did not use any form of intraoperative aberrometry nor digital toric marking. *P=0.002 vs preop, **P=0.003 vs preop, ***P=0.0002 vs preop, †P<0.0001 vs preop.

0.23D). Despite the ULPT group having higher baseline astigmatism, the ULPT IOL was significantly more likely to achieve cylinder outcomes of plano, or within 0.25D, 0.50D, and 0.75D of a plano cylinder outcome.

As expected, there were no significant differences between groups in CDVA because eyes were excluded if they had a postoperative corrected acuity <20/20. While UCVA was collected, a distance target was not required; thus, some eyes had near targets and would understandably have reduced UCVA. Further, given that this was a retrospective study, postoperative UCVA measurement was not required. This may have led to overrepresentation of outcomes with excellent UCVA in both groups, as patients who presented wearing spectacles may have only had their CDVA measured. Therefore, patients with higher levels of astigmatism, and possibly worse UCVA necessitating spectacles, may have been excluded from UCVA measurement, which limits the value of UCVA comparisons. This also explains why there are fewer patients with UCVA data, and why there were more eyes with postoperative UCVA measurements in the ULPT group.

Corneal astigmatism of ≤1.0D is often left uncorrected via LRI or toric IOLs.[14] A practice consensus statement of Latin American ophthalmologists in 2019 recommended that preoperative astigmatism of <0.5D does not need to be corrected.[15] However, the literature provides evidence that ≥0.50D of postoperative astigmatism can have meaningful deleterious effects on visual function, regardless of initial axis (ie against-the-rule, with-the-rule, or oblique).[5,14,16–18] Others report good outcomes with very-low–powered (1.0D at the IOL plane) toric IOLs, including in pseudophakic patients, and conclude that improved visual outcomes can be expected with these IOLs.[14,19–21] The use of preoperative corneal astigmatism measurement in place of predicted postoperative astigmatism based on a toric calculator is a critical distinction; however, we contend the latter is more appropriate. For example, an eye of average biometry, with 0.49D of measured, against-the-rule corneal astigmatism with a surgeon operating temporally with a 2.2mm incision and an SIA of 0.1D, would be predicted to benefit from a 0.90D toric without flipping the axis, and the best selection may correct 1.25D at the IOL plane.

SIA is known to affect refractive outcomes and is an important consideration in preoperative planning. However, research shows that in eyes with low amounts of astigmatism, the main source of error is imprecise preoperative measurement of corneal astigmatism, while SIA plays a smaller role.[22] Nonetheless, it is understood that SIA should be estimated according to the clear corneal incision location and size,[23] with temporal incisions having less impact on SIA than superior or nasal incisions.[24,25] Numerous other factors contribute to SIA; for example, corneal biomechanical properties (ie, stiffness) and age are positively correlated with SIA.[25] In the present study, a limitation is that we could not characterize the outcomes based on postoperative SIA measurements because of non-availability of the data. Further, Schallhorn et al reported that postoperative refractive astigmatism of 0.75D or more affected patient satisfaction with multifocal IOLs, and the odds of not being satisfied were significantly reduced by the presence of 0.25–0.50D residual cylinder.[5] This underscores the importance of cylinder outcomes and supports the routine deployment of the lowest levels of cylinder correction. The commonly-held "rule-of-thumb" of not correcting <1.0D of pre-operative corneal astigmatism seen on biometry is not supported by contemporary evidence.

A Cochrane review comparing toric IOLs and LRI concluded that toric IOLs may provide a higher chance of achieving post-surgical astigmatism within 0.5D compared to LRI.[7] A meta-analysis revealed that LRI is less expensive than toric IOLs but may be inferior to toric IOLs in postoperative UDVA and residual astigmatism in patients with preoperative astigmatism of 0.75 to 3.0 D.[26] In patients with preoperative astigmatism <0.1D, lifetime costs may be reduced when ULPT IOLs are implanted compared with non-toric IOLs because of the reduced need for postsurgical spectacles, although this is dependent on national costs.[27] Smaller amounts of corneal astigmatism (<1.0D) have less repeatable biometry measures.[9] Nevertheless, in the present study, surgeons were able to accurately measure and treat the smallest amounts of visually-significant corneal cylinder. The results from Site 1, which used basic measuring equipment and toric marking devices, demonstrate that the positive study outcomes do not require the latest, most fully-featured biometers, intraoperative aberrometry, or digital toric marking devices for effective deployment of the ULPT IOL. This site's technique for measurement is described below.

All patients were advised to use preservative-free artificial tears 4-times/day and a viscous tear gel nightly at bedtime for ≥2 weeks prior to measurements. Biometry measures were used for all formula inputs, and a placido-disk based topographer was used to confirm measurements. Agreement was confirmed if topography was within 5 degrees in axis and approximately 70–120% in magnitude of the biometer. For example, if 1.0D of cylinder at 90 degrees was recorded on the biometer, the topography would confirm the finding if it showed 0.80D at 94 degrees. If poor agreement was seen between the two devices, patients were re-evaluated to rule-out causative pathology (ie, significant dry eye, anterior basement membrane dystrophy, or

Salzmann nodules). If these conditions were not found, ocular surface treatment was increased, for example use of topical immunomodulators such as lifitegrast or cyclosporine 0.09%,[28,29] and patients were remeasured typically one month later.

Strengths of this study include the multicenter design, with real-world patients paying for an advanced IOL technology, and the use of an in-platform comparison of the enVista toric monofocal and enVista non-toric monofocal. All three sites used different preoperative measurement techniques, which adds to the rigor of the conclusions. Drawbacks of the study include the retrospective, non-randomized design, which inherently contributes to incomplete data for some measures, such as UDVA. Further, as described previously, UCVA was not collected systematically because CDVA was prioritized to ensure adequate enrollment.

Conclusion

The ULPT IOL was highly effective and safe in reducing the smallest amounts of visually-significant corneal astigmatism when compared to a non-toric IOL. This demonstrates that with widely available biometry technology, modern formulas and surgical techniques, and now ULPT IOLs, surgeons can accurately treat the smallest amounts of visually significant refractive cylinder. This represents a new stepping-stone in the refinement of postoperative cylinder outcomes, which may lead to better visual function, more satisfied patients, and fewer laser vision correction enhancements.

Data Sharing Statement

The authors confirm that the data supporting the findings of this study are available within the article. No further data will be shared.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising, or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

AM is a consultant to Bausch + Lomb, Johnson and Johnson, Labtician, and Sun Pharma; a clinical investigator for Alcon and Bausch + Lomb; a speaker for Alcon, Bausch+Lomb, Heidelberg Engineering, Innova Inc, and Johnson and Johnson. CFK is a consultant and clinical investigator for Bausch + Lomb. The authors report no other conflicts of interest in this work.

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