Standardized Analyses of Correction of Astigmatism With the Visian Toric Phakic Implantable Collamer Lens

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ABSTRACT

PURPOSE: To demonstrate the methodology described by the American National Standards Institute (ANSI) Standard Subcommittee on Astigmatism Analysis reporting a standardized method of presenting astigmatism data by laser systems that reshape the cornea also applies to toric phakic intraocular lens (IOL) data.

METHODS: The US Food and Drug Administration trial of the Visian Toric Implantable Collamer Lens comprised 210 eyes of 124 study patients. The mean preoperative manifest refraction spherical equivalent for the study cohort was −9.36±2.66 diopters (D) (range: −19.50 to −2.38 D). The mean preoperative manifest refractive cylinder was 1.94±0.84 D (range: 1.00 to 4.00 D).

RESULTS: Data were arrayed using the 11 tables and 4 figures suggested in the Subcommittee paper. Interpretation of the data from a toric phakic IOL study was similar to that of laser refractive procedures. The addition of a table of manifest refractive cylinder (in the spectacle plane) over time, which provides a direct clinical measure of clinical efficacy, is suggested. Mean postoperative manifest refractive cylinder was 0.51±0.48 D (range: 0 to 3.00 D) with 65.6% of eyes having ≤0.50 D of refractive cylinder at 12 months. A table of observed stability of the toric phakic IOL orientation within the eye obtained by slit-lamp examination also is recommended, which is a useful table not applicable in laser refractive procedures.

CONCLUSIONS: The data presented demonstrate that the methodology developed by the ANSI Standard Subcommittee on Astigmatism Analysis, with some minor additions, accurately characterizes the efficacy of toric phakic IOLs in treating astigmatism. [*J Refract Surg*. 2007;23:649-660.]

In 2006, Eydelman et al[1] published a consensus paper from the American National Standards Institute (ANSI) Standard Subcommittee on Astigmatism Analysis reporting a standardized method of presenting astigmatism data by laser systems that reshape the cornea. The US Food and Drug Administration (FDA) trial of the Visian Toric Implantable Collamer Lens (Visian TICL; STAAR Surgical, Monrovia, Calif), a toric phakic posterior chamber intraocular lens (IOL), recently has been completed and submitted to the FDA for commercial approval. The purpose of this article is to demonstrate the methodology described by Eydelman et al[1] (with the minor corrections described in a subsequent letter to the editor[2]) also applies to toric phakic IOL (Visian TICL) data. The abbreviations used in this article are listed in Table 1.

MATERIALS AND METHODS

The Visian TICL study cohort comprised 210 eyes of 124 study patients; 186 (88.6%) of these eyes have been examined at 1 year postoperatively. Sixty-nine (55.6%) of the 124 Visian TICL study patients treated were women. The majority (82.3%) of patients in the study cohort were Caucasian. The mean patient age at implantation of the Visian TICL was 36.4±7.4 years (range: 21 to 45 years). The mean preoperative manifest refraction spherical equivalent (MRSE) for the Visian TICL study cohort was −9.36±2.66 diopters (D) (range: −19.50 to −2.38 D). The mean preoperative manifest refractive cylinder was 1.94±0.84 D (range: 1.00 to 4.00 D).

The Eydelman et al[1] article recommended reporting data in the corneal plane, which was reasonable, given that its fo-

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Dr Sanders is a research and regulatory consultant to STAAR Surgical. Dr Sarver has no financial interest in the materials presented herein.

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Received: May 31, 2006

Accepted: August 21, 2006

Posted online: July 16, 2007

TABLE 1

ABBREVIATIONS

Abbreviation	Term
ANSI	American National Standards Institute
ATR	Against-the-rule astigmatism
CI	Confidence interval
CR	Correction ratio
DEQ	Defocus equivalent
EA	Error of angle
EM	Error of magnitude
ER	Error ratio
EV	Error vector
IOL	Intraocular lens
IRC	Intended refractive correction
MRSE	Manifest refraction spherical equivalent
NEV	Normalized error vector
SD	Standard deviation
SIRC	Surgically induced refractive correction
TEV	Treatment error vector
TICL	Toric Implantable Collamer Lens
WTR	With-the-rule astigmatism

cus was laser vision correction that was performed in the corneal plane. However, movement of the manifest refractive cylinder from the spectacle plane, where it was actually measured, to the corneal plane in toric phakic IOL data resulted in the distortion of data in a population that averaged more than 9.00 D of myopia preoperatively and was close to emmetropia postoperatively. Of the total 210 cases, 13 (6.2%) were identified with a greater than 20 percentage point difference in (percentage) reduction of absolute (non-vector) cylinder at the stability time point (as defined in Table A2.3 of the Eydelman et al[1] article) between the corneal plane and the spectacle plane. These cases are listed in Table 2 in decreasing order of difference between the corneal and spectacle plane.

A problem was first noted in a case in which preoperative manifest refractive cylinder in the spectacle plane increased from 1.25 to 2.00 D at 1 year (a 60% increase). In the corneal plane, this was reported as a 112.6% increase (patient 1 in Table 2). Three cases with no change in preoperative to postoperative manifest refractive cylinder in the spectacle plane were reported as 29.9%, 26.3%, and 22.8% increases of cylinder in the corneal plane (patients 4, 5, and 8, respectively, in Table 2). Two cases showed a decrease in cylinder in the spectacle plane and an increase in cylinder postoperatively in the corneal plane. One of these cases had a 25% decrease in cylinder in the spectacle plane and reported a 5.7% increase in cylinder postoperatively in the corneal plane (patient 3 in Table 2), and the other case had a 20% decrease in cylinder in the spectacle plane and reported a 4.3% increase in cylinder postoperatively in the corneal plane (patient 6 in Table 2). The only cases in which the percent correction in the corneal plane was not worse than the percent correction in the spectacle plane were those cases with 0 cylinders postoperatively where the correction in both planes was 100%. Excluding cases with 0 cylinders postoperatively, movement of the data from the spectacle to the corneal plane decreased the average percentage in reduction of absolute cylinder by 10 percentage points.

These problems similarly affected the vector analysis. In our toric phakic IOL series, the |intended refractive correction (IRC)| value was 1.93 in the spectacle plane and 1.57 in the corneal plane, whereas the |surgically induced refractive correction (SIRC)| value was 1.87 in the spectacle plane and 1.53 in the corneal plane. These decreases were largely due to the decrease in preoperative cylinder caused by moving the spectacle correction to the corneal plane in the presence of a highly myopic refraction, with little change in magnitude of the postoperative cylinder vector. While some argument can be made that the corneal plane data are useful in the evaluation of a toric phakic IOL because it is closer to the plane of the IOL itself, from a clinical perspective, the patient is refracted in the spectacle plane and it is counterintuitive for a patient with an unchanged refractive cylinder preoperatively to postoperatively be considered as having been made worse by the implantation.

To avoid these data distortions and because the manifest refractive cylinder (the raw data being used in the analysis) was collected in the spectacle plane, all data are reported in the spectacle plane in this article.

RESULTS

Refractive Outcomes

The mean MRSE for the Visian TICL study cohort was 0.05±0.46 (range: −2.25 to 1.00 D) at 12 months postoperatively, with 76.9% of eyes predicted accurately to within ±0.50 D and 98.3% of eyes predicted to within ±1.00 D. The mean manifest refractive cylinder was 0.51±0.48 D (range: 0.00 to 3.00 D) at 12

months postoperatively, with 65.6% of cases within ≤0.50 D of predicted refractive cylinder and 91.4% of cases within ≤1.00 D of predicted refractive cylinder.

Accuracy of Cylinder to Target

Table 3 shows how accurately the desired postoperative cylinder was achieved in the Visian TICL study cohort. The results were fairly consistent throughout the entire study period. The mean preoperative cylinder was 1.94 D, whereas mean postoperative cylinder was between 0.45 and 0.51 D, depending on time period postoperatively. Cylinder was within 0.50 D of the target in between 68.4% and 72.4% of cases, and within 1.00 D in between 92.5% and 94.3% of cases.

Defocus Equivalent

Table 4 shows the defocus equivalent preoperatively and for each postoperative period. The preoperative defocus equivalent was 10.33 D. The results were fairly consistent throughout the entire postoperative study period, with the mean defocus equivalent varying between 0.57 and 0.58 D at the various time points (0.57 D at the 12-month postoperative visit). At 1 year postoperatively, defocus equivalent was within 0.50 D in 62.9% of cases and within 1.00 D in 89.2% of cases.

Reduction of Absolute (Non-vector) Cylinder

Table 5 shows how the cylinder value was reduced postoperatively. The results for this table were calculated at 12 months postoperatively. The Table reports percent reduction of absolute cylinder, which is calculated using the following equation.

$$\%\text{Reduction} = \left(\frac{(Cyl_{\text{Preop}}) - (Cyl_{\text{Postop}})}{Cyl_{\text{Preop}}}\right) \times 100$$

Considering all 186 cases seen, the mean percent reduction in absolute cylinder was 71%. In general, the percent reduction averaged less for the lower amounts of preoperative cylinder (65.4% for ≤1.00 D and 67% for >1.00 D to ≤2.00 D) and more for the higher preoperative cylinder range (79.7% for >2.00 D to ≤3.00 D and 79.5% for >3.00 D to ≤4.00 D).

TABLE 2

Percent Reduction of Absolute Cylinder for Corneal Plane Versus Spectacle Plane

	Preoperative Spectacle Refraction		Postoperative Spectacle Refraction		Calculated Cylinder at Cornea		% Reduction of Cylinder	
Patient No.	**Sphere (D)**	**Cylinder (D)**	**Sphere (D)**	**Cylinder (D)**	**Preoperative (D)**	**Postoperative (D)**	**Corneal Plane**	**Spectacle Plane**
1	−12.50	1.25	−0.25	2.00	0.958	2.037	−112.6	−60
2	−14.50	1.00	0.25	1.25	0.733	1.277	−74.2	−25
3	−16.25	1.00	−0.75	1.25	0.707	1.246	−5.7	25
4	−13.25	1.75	−1.50	1.75	1.327	1.724	−29.9	0
5	−10.25	1.50	0.00	1.50	1.209	1.527	−26.3	0
6	−12.75	1.25	−0.75	1.00	0.953	0.994	−4.3	20
7	−12.25	1.00	−0.25	0.75	0.768	0.752	2.1	25
8	−9.75	1.25	−0.75	1.25	1.015	1.246	−22.8	0
9	−20.00	1.00	−2.25	0.50	0.657	0.477	27.4	50
10	−11.00	1.00	0.25	0.75	0.789	0.761	3.5	25
11	−8.75	1.50	−1.50	1.75	1.249	1.724	−38.0	−16.7
12	−11.00	1.00	0.00	0.75	0.788	0.757	3.9	25
13	−11.75	1.00	−0.75	0.75	0.776	0.743	4.3	25
Mean	−12.62	1.19	−0.63	1.17	0.917	1.174	−26.39	3.33

TABLE 3

Accuracy of Cylinder to Target

Refractive Cylinder	Preoperative (n=210)	1 Month (n=193)	3 Months (n=187)	6 Months (n=174)	12 Months (n=186)
Mean±SD	1.94±0.84	0.51±0.49	0.51±0.49	0.45±0.44	0.51±0.48
Attempted change±SD		1.79±0.79	1.81±0.80	1.74±0.77	1.76±0.80
Achieved change±SD		1.45±0.86	1.46±0.87	1.46±0.86	1.42±0.87
% achieved within ±0.50 D of attempted [90% CI]		68.4 (132/193) [58.5 to 69.9]	69.5 (130/187) [60 to 71.4]	72.4 (126/174) [64.4 to 75.8]	69.9 (130/186) [59.8 to 71.3]
% achieved within ±1.00 D of attempted [90% CI]		92.7 (179/193) [87.2 to 94.1]	93.6 (175/187) [88 to 94.7]	94.3 (164/174) [89.2 to 95.7]	92.5 (172/186) [88 to 94.7]

SD = standard deviation, CI = confidence interval

TABLE 4

Defocus Equivalent

|MRSE| + 0.5× |Cylinder|	Preoperative (n=210)	1 Month (n=193)	3 Months (n=187)	6 Months (n=174)	12 Months (n=186)
Mean±SD	10.33±2.70	0.57±0.47	0.57±0.45	0.58±0.50	0.57±0.46
% With DEQ±0.50 D		63.7 (123/193)	63.6 (119/187)	63.2 (110/174)	62.9 (117/186)
% With DEQ±1.00 D		89.1 (172/193)	92.0 (172/187)	89.1 (155/174)	89.2 (166/186)

MRSE = manifest refraction spherical equivalent, SD = standard deviation, DEQ = defocus equivalent

Residual Astigmatic Error at 12 Months Postoperatively

Table 6 shows the magnitude of the axis shift as a function of the magnitude of the postoperative cylinder at 12 months postoperatively. The magnitude of change in cylinder axis is calculated using the following equation.

$$delAxis = \begin{cases} Axis_{Postop} - Axis_{Preop} \text{ for } \left(Axis_{Postop} - Axis_{Preop}\right) \leq 90 \\ 180 - \left(Axis_{Postop} - Axis_{Preop}\right) \text{ for } \left(Axis_{Postop} - Axis_{Preop}\right) > 90 \end{cases}$$

Postoperative cylinder was equal to 0.00 D in 27.4% of cases, ≤0.50 D in 65.6%, and ≤1.00 D in 91.4%. Axis shift was ≤5° in 34.9% of cases and >30° in 41.9% of cases. No obvious correlation was noted between axis shift and residual cylinder magnitude.

Vector Stability of Cylinder

Tables 7A(I) and 7A(II) demonstrate the magnitude of vector change in cylinder between consecutive postoperative examination periods. Because of the way this is calculated, the values are always positive or 0.

Table 7A(I) reports eyes that had two consecutive examinations but not necessarily every follow-up examination. Table 7A(II) reports eyes that had every follow-up examination up to the stability time point.

In Table 7A(I), the cylinder appears to be stable from the earliest reported interval. Cylinder changed by ≤1.00 D in between 95.8% and 96.7% of cases, and at all reported intervals, cylinder changed by ≤0.50 D in between 83.9% and 87.3% of cases. The mean difference was between 0.25 and 0.28 D at each reporting interval.

In Table 7A(II), the results are similar to Table 7A(I), and in databases where follow-up at each visit is high,

TABLE 5

Reduction of Absolute (Non-vector) Cylinder

		% Reduction of Absolute Cylinder		
Preoperative Cylinder	**n/N (%)**	**Mean**	**Range**	**[90% CI]**
All	186	71.0	−60.0 to 100.0	[67.63 to 74.38]
>0.50 D to ≤1.00 D	39/186 (21.0)	65.4	−25.0 to 100.0	[56.91 to 73.85]
>1.00 D to ≤2.00 D	83/186 (44.6)	67.0	−60.0 to 100.0	[61.42 to 72.62]
>2.00 D to ≤3.00 D	42/186 (22.6)	79.7	44.4 to 100.0	[75.59 to 83.74]
>3.00 D to ≤4.00 D	22/186 (11.8)	79.5	25.0 to 100.0	[72.4 to 86.53]

CI = confidence interval

TABLE 6

Residual Astigmatic Error at 12 Months Postoperatively

	Absolute Shift in Axis*					
	n/N (%) [90% CI]					
Residual Cylinder Magnitude	**≤5°**	**>5° to ≤10°**	**>10° to ≤15°**	**>15° to ≤30°**	**>30°**	**Total (%)**
0 D	51/51 (100) [100 to 100]					51/186 (27.4)
>0.00 to ≤0.50 D	8/71 (11.3) [5.1 to 17.4]	6/71 (8.5) [3 to 13.8]	4/71 (5.6) [1.1 to 10.1]	14/71 (19.7) [11.9 to 27.4]	39/71 (54.9) [45.2 to 64.6]	71/186 (38.2)
>0.50 to ≤1.00 D	4/48 (8.3) [1.7 to 14.8]	2/48 (4.2) [0 to 8.8]	4/48 (8.3) [1.7 to 14.8]	9/48 (18.8) [9.5 to 27.9]	29/48 (60.4) [48.8 to 71.9]	48/186 (25.8)
>1.00 to ≤2.00 D	2/15 (13.3) [0 to 27.7]	1/15 (6.7) [0 to 17.2]	1/15 (6.7) [0 to 17.2]	2/15 (13.3) [0 to 27.7]	9/15 (60) [39.2 to 80.7]	15/186 (8.1)
>2.00 to ≤3.00 D	0/1 (0) [0 to 0]	0/1 (0) [0 to 0]	0/1 (0) [0 to 0]	0/1 (0) [0 to 0]	1/1 (100) [100 to 100]	1/186 (0.5)
Total	65/186 (34.9)	9/186 (4.8)	9/186 (4.8)	25/186 (13.4)	78/186 (41.9)	186/186 (100)

**Shifts are defined to be zero for eyes with zero residual cylinder magnitude.*

only one of these tables may be necessary. The same can be said for Tables 7B(I) and 7B(II). The cylinder appears to be stable from the earliest reported interval. Cylinder changed by ≤1.00 D in between 96.8% and 97.4% of cases, and at all reported intervals, cylinder changed by ≤0.50 D in between 85.3% and 87.2% of cases. The mean difference was between 0.24 and 0.27 D at each reporting interval.

Stability of Absolute Cylinder

In Table 7B(I), the cylinder appears to be stable from the earliest reported interval. Cylinder changed by ≤1.00 D in 99.4% of cases, and at all reported intervals, cylinder changed by ≤0.50 D in between 93.5% and 97.6% of cases. The mean difference was between −0.03 and 0.04 D at each reporting interval. The mean change in cylinder per year was between −0.14 D and 0.12 D at all time periods.

In Table 7B(II), the results are similar to Table 7B(I). The cylinder appears to be stable from the earliest reported interval. Cylinder changed by ≤1.00 D in 99.4% of cases, and at all reported intervals, cylinder changed by ≤0.5 D in between 94.9% and 96.8% of cases. The mean difference was between −0.04 and 0.01 D at each reporting interval. The 90% confidence intervals encompassed 0 at all time periods, and the mean change

TABLE 7A(I)

Vector Stability of Cylinder*

Magnitude of Vector Change in Cylinder	1 and 3 Months		3 and 6 Months		6 and 12 Months	
	n/N (%)	[% CI]	n/N (%)	[% CI]	n/N (%)	[% CI]
≤1.00 D	174/180 (96.7)	[94.4 to 98.8]	160/166 (96.4)	[94 to 98.7]	161/168 (95.8)	[93.3 to 98.3]
≤0.5 D	151/180 (83.9)	[79.3 to 88.3]	145/166 (87.3)	[83.1 to 91.5]	142/168 (84.5)	[79.9 to 89.1]
Mean difference (D)	0.28		0.25		0.28	
SD (D)	0.37		0.39		0.38	
90% CI (D)	[0.23 to 0.32]		[0.20 to 0.29]		[0.23 to 0.32]	
Mean change per year (D)	1.68		1.00		0.56	

CI = confidence interval, SD = standard deviation
**Eyes that had two consecutive examinations, but not necessarily every follow-up examination.*

TABLE 7A(II)

Vector Stability of Cylinder*

Magnitude of Vector Change in Cylinder	1 and 3 Months		3 and 6 Months		6 and 12 Months	
	n/N (%)	[% CI]	n/N (%)	[% CI]	n/N (%)	[% CI]
≤1.00 D	151/156 (96.8)	[94.4 to 99.1]	151/156 (96.8)	[94.4 to 99.1]	152/156 (97.4)	[95.3 to 99.5]
≤0.50 D	133/156 (85.3)	[80.6 to 89.9]	136/156 (87.2)	[82.7 to 91.5]	135/156 (86.5)	[82 to 91]
Mean difference (D)	0.27		0.24		0.25	
SD (D)	0.39		0.36		0.33	
90% CI (D)	[0.22 to 0.32]		[0.19 to 0.29]		[0.20 to 0.29]	
Mean change per year (D)	1.63		0.98		0.51	

CI = confidence interval, SD = standard deviation
**Eyes that had every follow-up examination up to the stability time point.*

in cylinder per year was between −0.14 and 0.09 D at all time periods.

Vector Analysis Summary Table at 12 Months Postoperatively

Table 8 shows a summary of several vector analysis parameters at 12 months postoperatively as a function of preoperative cylinder. The |IRC| is the vector difference between the target and preoperative vectors. The mean |IRC| was 2.03 D. As the preoperative cylinder increased, the |IRC| increased correspondingly.

The |SIRC| is the vector difference between postoperative and preoperative vectors. The mean |SIRC| was 1.87 D, similar to the intended refractive correction (2.03 D). As the preoperative cylinder increases, the desired effect is to see a corresponding increase in |SIRC|; such was the case in this series so that the |IRC| and |SIRC| increased in parallel.

The error vector (|EV|) is the vector difference between the |IRC| and |SIRC|. The mean |EV| was 0.60 D, whereas the lowest |EV| (0.43 D) was in the group with the smallest preoperative cylinder (1.00 D) and the highest was in the group with the largest preoperative cylinder (>3.00 D, |EV|=0.86 D)

The correction ratio (CR) is the magnitude of the |SIRC| over the magnitude of the |IRC|. A value of 1 is ideal, whereas values <1 imply undercorrection and values >1 imply overcorrection. The mean value

TABLE 7B(I)

Stability of Absolute (Non-vector) Cylinder*

Magnitude of Change in Absolute Cylinder	1 and 3 Months		3 and 6 Months		6 and 12 Months	
	n/N (%)	[% CI]	n/N (%)	[% CI]	n/N (%)	[% CI]
≤1.00 D	179/180 (99.4)	[98.5 to 100]	165/166 (99.4)	[98.4 to 100]	167/168 (99.4)	[98.4 to 100]
≤0.50 D	171/180 (95.0)	[92.3 to 97.6]	162/166 (97.6)	[95.6 to 99.5]	157/168 (93.5)	[90.3 to 96.5]
Mean difference (D)	0.02		−0.03		0.04	
SD (D)	0.31		0.27		0.31	
90% CI (D)	[−0.02 to 0.05]		[−0.07 to −0.01]		[−0.01 to 0.07]	
Mean change per year (D)	0.12		−0.14		0.07	

CI = confidence interval, SD = standard deviation
**Eyes that had two consecutive examinations, but not necessarily every follow-up examination.*

TABLE 7B(II)

Stability of Absolute (Non-vector) Cylinder*

Magnitude of Change in Absolute Cylinder	1 and 3 Months		3 and 6 Months		6 and 12 Months	
	n/N (%)	[% CI]	n/N (%)	[% CI]	n/N (%)	[% CI]
≤1.00 D	155/156 (99.4)	[98.3 to 100]	155/156 (99.4)	[98.3 to 100]	155/156 (99.4)	[98.3 to 100]
≤0.50 D	148/156 (94.9)	[91.9 to 97.7]	151/156 (96.8)	[94.4 to 99.1]	148/156 (94.9)	[91.9 to 97.7]
Mean difference (D)	0.01		−0.04		0.01	
SD (D)	0.30		0.28		0.29	
90% CI (D)	[−0.03 to 0.05]		[−0.08 to 0]		[−0.03 to 0.05]	
Mean change per year (D)	0.09		−0.14		0.03	

CI = confidence interval, SD = standard deviation
**Eyes that had every follow-up examination up to the stability time point.*

across all levels of preoperative cylinder was 0.94, close to the ideal. At the lowest (1.00 D) level of preoperative cylinder, the cases were slightly overcorrected (CR=1.07). The cases with >1.00 to 2.00 D of preoperative cylinder were slightly undercorrected (CR=0.87), whereas those with >2.00 to 3.00 D and >3.00 D of preoperative cylinder were close to the average (0.94 to 0.95)

The error ratio (ER) is the magnitude of the |EV| divided by the magnitude of the |IRC|. The mean ER was 0.33 with a range among the preoperative cylinder groups of 0.22 to 0.43. It was slightly higher for the lower amounts of preoperative cylinder (≤2.00 D) and lower for the cases with >2.00 D of preoperative cylinder.

Error of Magnitude at 12 Months Postoperatively

Table 9 shows the error of magnitude (EM) at the stability postoperative period as a function of preoperative cylinder. The EM is the magnitude of the |SIRC| minus the magnitude of the |IRC|. The EM can be either positive or negative

The mean EM for the Visian TICL study cohort was 0.17 D. The smallest EM was seen in the cases with ≤1.00 D of preoperative cylinder and averaged −0.04 D. The mean EM in the other preoperative cylinder groups

TABLE 8

Vector Analysis Summary Table at 12 Months Postoperatively

		Mean±Standard Deviation				
Preop Cylinder	**n/N (%)**	**|IRC|**	**|SIRC|**	**|EV|**	**CR**	**ER**
All	186	2.03±0.94	1.87±0.96	0.60±0.47	0.94±0.29	0.33±0.27
>0.50 to ⩽1.00 D	39/186 (21.0)	1.01±0.15	1.05±0.28	0.43±0.31	1.07±0.35	0.43±0.32
>1.00 to ⩽2.00 D	83/186 (44.6)	1.70±0.36	1.45±0.48	0.60±0.47	0.87±0.31	0.36±0.29
>2.00 to ⩽3.00 D	42/186 (22.6)	2.68±0.38	2.51±0.49	0.62±0.38	0.94±0.18	0.23±0.15
>3.00 to ⩽4.00 D	22/186 (11.8)	3.87±0.43	3.67±0.64	0.86±0.72	0.95±0.11	0.22±0.17

IRC = intended refraction correction, SIRC = surgically induced refractive correction, EV = error vector, CR = correction ratio, ER = error ratio

TABLE 9

Error of Magnitude at 12 Months Postoperatively

Preop Cylinder	**n/N (%)**	**Mean EM±SD**	**Mean |EM|±SD**	**% EM±0.50 D**	**% EM±1.00 D**
All	186	0.17±0.46	0.37±0.32	74.2	94.6
>0.50 to ⩽1.00 D	39/186 (21.0)	−0.04±0.35	0.27±0.22	82.0	100.0
>1.00 to ⩽2.00 D	83/186 (44.6)	0.25±0.49	0.40±0.37	69.9	91.6
>2.00 to ⩽3.00 D	42/186 (22.6)	0.17±0.46	0.39±0.30	73.8	95.2
>3.00 to ⩽4.00 D	22/186 (11.8)	0.20±0.41	0.37±0.26	77.3	95.4

EM = error of magnitude

ranged from 0.17 to 0.25 D. Even using the absolute value of the EM (|EM|) where under- and overcorrections are additive, the average |EM| is 0.37 D, ranging between 0.27 and 0.40 D depending on preoperative refractive cylinder.

The EM was within ±1.00 D in 94.6% of cases, with the range between 91.6% and 100% of cases depending on preoperative refractive cylinder. The EM was within ±0.50 D in 74.2% of cases, with the range between 69.9% and 82% of cases depending on preoperative refractive cylinder.

Error of Angle at 12 Months Postoperatively

Table 10 shows the error of the final angle as a function of preoperative cylinder. The error of angle (EA) is the signed acute angle between the intended and achieved treatment axes.

The mean EA for the Visian TICL study cohort was close to 0° (−0.03°). The mean EA value was within ±1° for all ranges of preoperative cylinders tested, with the exception of the cases with preoperative cylinder ⩽1.00 D where it was 2.23°. The EA was within ±15° of intended in 88.2% of cases. This percentage was slightly less in the lower preoperative cylinder ranges (79.5% to 85.5%) and more in the higher preoperative cylinder ranges (90.9% to 100%).

Intended Refractive Correction

Figure 1 plots the |IRC|. The vector components X and Y (defined in Eydelman[1]) are used to plot the cylinder magnitude and orientation in a double-angle plot. The centroid of the data points is at (−1.30 D, −0.36 D), and the width and height of the axis-aligned ellipse that contains approximately 95% of the data points are 6.12 and 3.74 D, respectively. The width of the ellipse is greater than the height, indicating most of the patients have with-the-rule or against-the-rule astigmatism and not oblique astigmatism. The skewing of |IRC| toward the left (90°) indicates most of the patients have with-the-rule astigmatism.

TABLE 10

Error of Angle at 12 Months Postoperatively

		% [% CI]			
Preop Cylinder	**n/N (%)**	**Mean EA±SD [% CI]**	**|EA| ≤15°**	**EA >+15°**	**EA <−15°**
All	186	−0.03±10.40 [−1.29 to 1.21]	88.2 [84.2 to 92]	5.9 [3 to 8.7]	5.9 [3 to 8.7]
>0.50 to ≤1.00 D	39/186 (21.0)	2.23±10.39 [−0.5 to 4.96]	79.5 [74.6 to 84.3]	15.4 [11 to 19.7]	5.1 [2.4 to 7.7]
>1.00 to ≤2.00 D	83/186 (44.6)	−0.60±12.55 [−2.87 to 1.65]	85.5 [81.3 to 89.7]	4.8 [2.2 to 7.3]	9.6 [6 to 13.1]
>2.00 to ≤3.00 D	42/186 (22.6)	−0.56±6.09 [−2.1 to 0.98]	100 [100 to 100]	0 [0 to 0]	0 [0 to 0]
>3.00 to ≤4.00 D	22/186 (11.8)	−0.92±7.62 [−3.59 to 1.74]	90.9 [87.4 to 94.3]	4.6 [2 to 7]	4.6 [2 to 7]

EA = error of angle, SD = standard deviation, CI = confidence interval

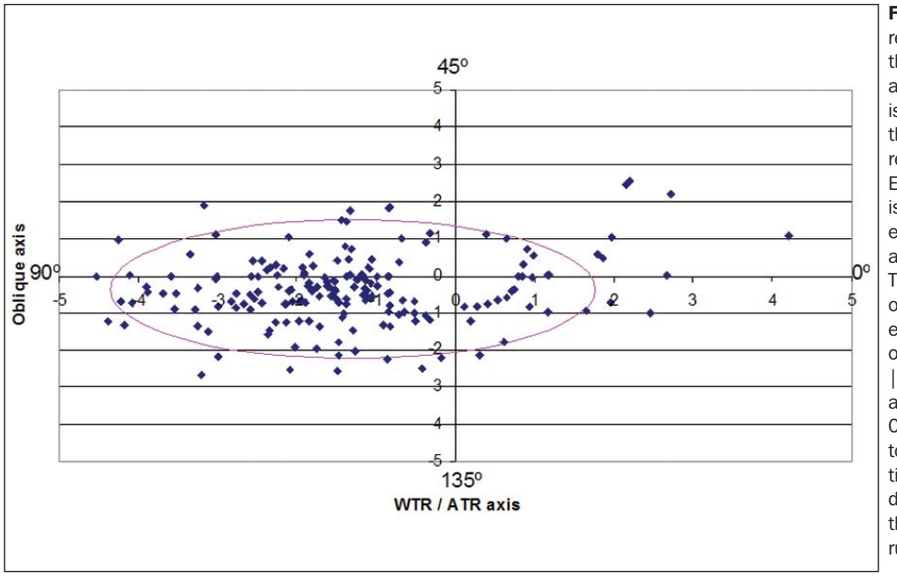

Figure 1. Double-angle plot of intended refractive correction (|IRC|). The |IRC| is the vector difference between the target and preoperative vectors. The target vector is the predicted postoperative value given the TICL to be implanted. The double-angle representation of the vectors is described in Eydelman et al.[1] Each vector |IRC| value is plotted in the graph and an axis-aligned ellipse is positioned and sized to enclose approximately 95% of the |IRC| points. The center of the ellipse is the vector mean of the |IRC|. The width and height of the ellipse is four times the standard deviation of the x-component and y-component of the |IRC| vectors, respectively. The horizontal axis in the positive direction corresponds to 0° and in the negative direction corresponds to 90°. The vertical axis in the positive direction corresponds to 45° and in the negative direction corresponds to 135°. (WTR=with-the-rule astigmatism and ATR=against-the-rule astigmatism)

Error Vector |EV|

Figure 2 plots the error vector. The centroid of the data points is at (−0.38 D, −0.08 D), and the width and height of the axis-aligned ellipse that contains approximately 95% of the data points are 1.68 and 2.00 D, respectively. The |EV| is small, with the 95% confidence interval ellipse encompassing approximately ≤1.00 D in all directions, and fairly central, with a slight skewing toward 90°. The centroid near zero indicates a nearly unbiased device-related error.

Normalized Error Vector

Figure 3 plots the normalized error vector (NEV). The NEV is equal to the |EV| in magnitude but has axis equal to the signed axis shift between |IRC| and |EV|. The centroid of the data points is at (0.25 D, 0.00 D), and the width and height of the axis-aligned ellipse that contains approximately 95% of the data points are 1.88 and 2.20 D, respectively. The NEV is small, with the 95% confidence interval ellipse encompassing approximately 1.00 D in all directions, and fairly central, with a slight skewing toward 0°. The location of the centroid (to the right of the vertical) indicates a slight tendency toward undercorrection, but this tendency is low in magnitude.

Treatment Error Vector

Figure 4 plots the treatment error vector (TEV). The TEV depicts both the errors of magnitude and angle, reflecting the performance of the device. The vector's magnitude is the absolute value of the EM. The angle is given by EA. The vector components X_Tev and Y_Tev

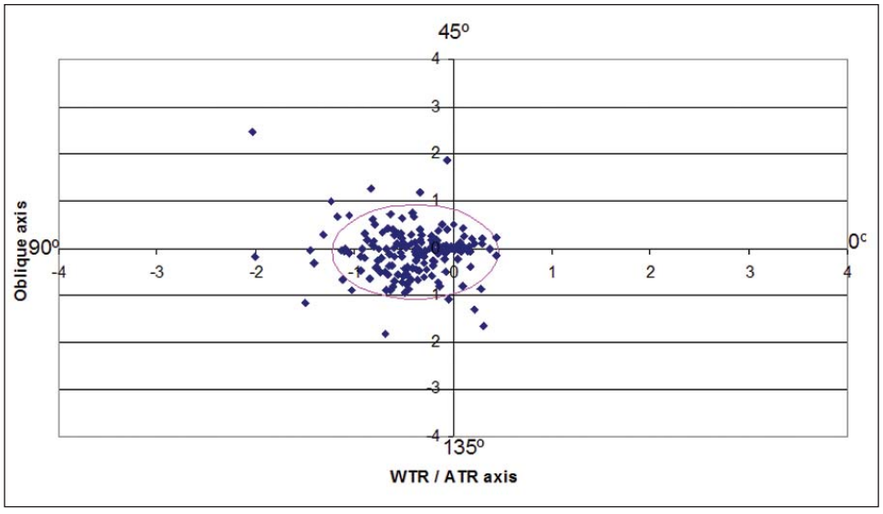

Figure 2. Double-angle plot of error vector (|EV|). The |EV| is the vector difference between the |IRC| and |SIRC| vectors. The double-angle representation of the vectors is described in Eydelman et al.[1] Each vector |EV| is plotted in the graph and an axis-aligned ellipse is positioned and sized to enclose approximately 95% of the |EV| points. The center of the ellipse is the vector mean of the |EV|. The width and height of the ellipse is four times the standard deviation of the x-component and y-component of the |EV| vectors, respectively. The horizontal axis in the positive direction corresponds to 0° and in the negative direction corresponds to 90°. The vertical axis in the positive direction corresponds to 45° and in the negative direction corresponds to 135°. (WTR=with-the-rule astigmatism and ATR=against-the-rule astigmatism)

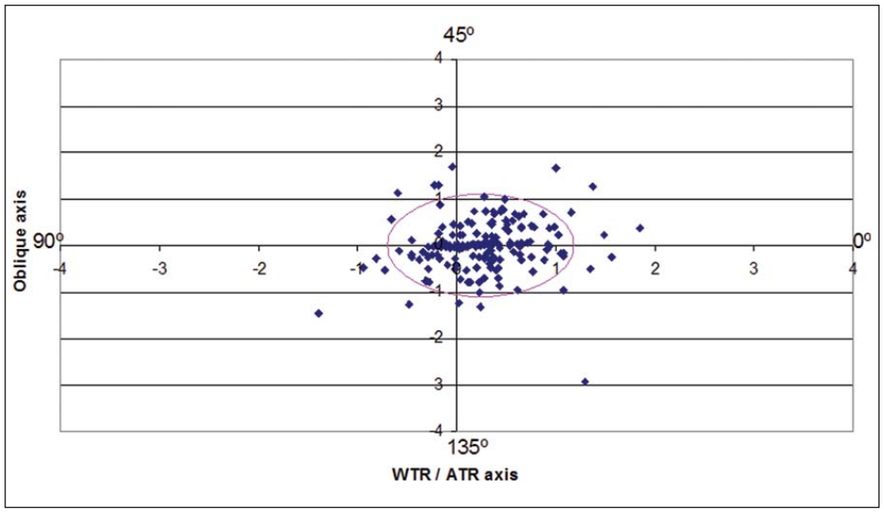

Figure 3. Double-angle plot of normalized error vector (NEV). The NEV is equal to the |EV| in magnitude, but has axis equal to the signed axis shift between the |IRC| and |EV| vectors. The double-angle representation of the vectors is described in Eydelman et al.[1] Each vector NEV value is plotted in the graph and an axis-aligned ellipse is positioned and sized to enclose approximately 95% of the NEV points. The center of the ellipse is the vector mean of the NEV values. The width and height of the ellipse is four times the standard deviation of the x-component and y-component of the NEV vectors, respectively. The horizontal axis in the positive direction corresponds to 0° and in the negative direction corresponds to 90°. The vertical axis in the positive direction corresponds to 45° and in the negative direction corresponds to 135°. (WTR=with-the-rule astigmatism and ATR=against-the-rule astigmatism)

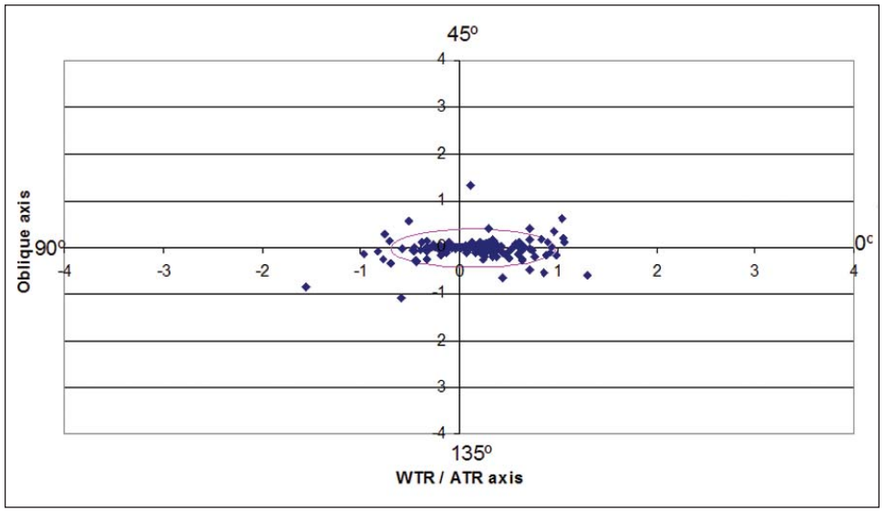

Figure 4. Double-angle plot of treatment error vector (TEV). The TEV is equal to the EM in magnitude, but has axis equal to the EA (acute angle between the intended and achieved treatment axes). The double-angle representation of the vectors is described in Eydelman et al.[1] Each vector TEV value is plotted in the graph and an axis-aligned ellipse is positioned and sized to enclose approximately 95% of the TEV points. The center of the ellipse is the vector mean of the TEV values. The width and height of the ellipse is four times the standard deviation of the x-component and y-component of the TEV vectors, respectively. The horizontal axis in the positive direction corresponds to 0° and in the negative direction corresponds to 90°. The vertical axis in the positive direction corresponds to 45° and in the negative direction corresponds to 135°. (WTR=with-the-rule astigmatism and ATR=against-the-rule astigmatism)

TABLE 11

Manifest Refraction Cylinder With Time

	n/N (%)				
Cylinder	**Preop**	**1 Month**	**3 Months**	**6 Months**	**12 Months**
≤0.25 D	0/210 (0)	82/193 (42.5)	77/187 (41.2)	83/174 (47.7)	76/186 (40.9)
≤0.50 D	0/210 (0)	124/193 (64.2)	123/187 (65.8)	122/174 (70.1)	122/186 (65.6)
≤1.00 D	44/210 (21)	175/193 (90.7)	171/187 (91.4)	161/174 (92.5)	170/186 (91.4)
≤1.50 D	90/210 (42.9)	188/193 (97.4)	181/187 (96.8)	169/174 (97.1)	180/186 (96.8)
≤2.00 D	136/210 (64.8)	192/193 (99.5)	183/187 (97.9)	174/174 (100)	185/186 (99.5)
≤3.00 D	186/210 (88.6)	193/193 (100)	187/187 (100)	174/174 (100)	186/186 (100)
≤4.00 D	210/210 (100)	193/193 (100)	187/187 (100)	174/174 (100)	186/186 (100)
Mean	1.94	0.51	0.51	0.45	0.51
SD	0.84	0.49	0.49	0.44	0.48
Range	1 to 4	0 to 3	0 to 3	0 to 2	0 to 3
Not reported	0	2	1	1	0
Total	210	195	188	175	186

SD = standard deviation

are computed using the EM magnitude and twice the angle to plot the values in a double-angle plot. The centroid of the data points is at (0.14 D, −0.02 D), and the width and height of the axis-aligned ellipse that contains approximately 95% of the data points are 1.66 D and 0.82 D, respectively.

In this plot, undercorrections generally will appear to the right of the vertical axis and overcorrections generally will appear to the left. Because the centroid is virtually zero, the overall treatment is not over- or undercorrected. The majority of the points are aligned well with the horizontal axis, indicating the error in the axis is small. This also is supported by the rather small vertical ellipse semi-diameter value of 0.41 D. The horizontal ellipse semi-diameter value of 0.83 D shows 95% of the treatment error magnitude is <1.00 D.

DISCUSSION

Manifest refractive cylinder (in the spectacle plane) over time (Table 11) is another table useful in the evaluation of the Visian TICL, and it provides a direct clinical measure of clinical efficacy. Preoperatively, manifest refractive cylinder was ≤1.00 D in 21% of eyes in the Visian TICL study cohort (all cases had at least 1.00 D). Postoperatively, manifest refractive cylinder was within 2.00 D at 6 months for all eyes (100%), and manifest refractive cylinder was within 2.00 D at 12-month follow-up in 99.5% of eyes. Furthermore, 6 months after TICL surgery, manifest refractive cylinder was within ≤1.00 D in 92.5% of eyes, and at 12-month follow-up, manifest refractive cylinder was within ≤1.00 D in 91.4% of eyes. Preoperatively, manifest refractive cylinder was within 0.50 D in none of the eyes in the cohort. Postoperatively, manifest refractive cylinder was within 0.50 D at 6 months in 70.1% of eyes, and at 12-month follow-up, manifest refractive cylinder was within 0.50 D in 65.6% of eyes. Of note, manifest refractive cylinder was within 0.25 D at 6-month follow-up in 47.7% of eyes, and at 12 months, manifest refractive cylinder was within 0.25 D in 40.9% of eyes.

Observed rotational stability over time obtained by slit lamp examination (Table 12) is also useful in the evaluation of the Visian TICL. Alignment of the Visian TICL was recorded as the clock hour of the long axis of the lens. Changes in axis alignment one visit to the next were reported with a clockwise change being assigned as a plus rotation and a counterclockwise change being assigned as a minus rotation. The mean of the absolute value of misalignment for the Visian TICL study cohort was between 0.7° and 1.1° for all time intervals tested. The mean of the absolute value of misalignment was 1.1°±3.3° between 6- and 12-month follow-up. Misalignment was ≤5° between 6 and 12 months after Visian TICL implantation in 93.9% of patients, and misalignment was ≤10° in 97.7% of patients. Additionally, misalignment was ≤15° in 98.5% of cases for the same time period. Misalignment was >30° in no eye in the cohort at any time interval.

TABLE 12

Stability of ICL Axis Orientation

	n/N (%)				
Misalignment	**1 Day and 1 Week (n=118)**	**1 Week and 1 Month (n=147)**	**1 Month and 3 Months (n=143)**	**3 Months and 6 Months (n=130)**	**6 Months and 12 Months (n=130)**
Absolute Value					
<5°	114/118 (96.6)	140/147 (95.2)	138/145 (95.2)	128/132 (97.0)	124/132 (93.9)
≤10°	117/118 (99.2)	146/147 (99.3)	143/145 (98.6)	130/132 (98.5)	129/132 (97.7)
≤15°	117/118 (99.2)	147/147 (100)	143/145 (98.6)	130/132 (98.5)	130/132 (98.5)
≤30°	118/118 (100)	147/147 (100)	145/145 (100)	132/132 (100)	132/132 (100)
>30°	0/118 (0)	0/147 (0)	0/145 (0)	0/132 (0)	0/132 (0)
Mean (degrees)	0.7	1.0	1.1	0.9	1.0
SD	2.2	2.2	3.2	3.0	3.3
Minimum	0	0	0	0	0
Maximum	17	12	23	23	23
90% CI of the mean	[0.5 to 0.8]	[0.8 to 1.1]	[0.9 to 1.3]	[0.7 to 1.0]	[0.8 to 1.2]
Signed Value					
Mean (degrees)	−0.4	0.2	0.5	−0.5	−0.1
SD	2.3	2.4	3.3	3.1	3.5
Minimum	−17	−8	−10	−23	−22
Maximum	5	12	23	5	23
90% CI of the mean	[−0.5 to −0.2]	[0 to 0.3]	[0.3 to 0.7]	[−0.6 to −0.3]	[−0.3 to −0.1]

SD = standard deviation, CI = confidence interval

The mean of the signed value of misalignment was between −0.5° and 0.5° for all time intervals tested. The 90% confidence interval for all time periods tested was no more than 0.3° away from 0 and had a maximum range of 0.4°, which suggests no systematic clockwise or counterclockwise rotation.

The data presented in this article demonstrate the methodology developed by the ANSI Standard Subcommittee on Astigmatism Analysis,[1,2] with some minor modifications and additions, accurately characterizes the efficacy of toric phakic IOLs in treating astigmatism.

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