ARTICLE

Fluctuations in corneal curvature limit predictability of intraocular lens power calculations

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PURPOSE: To analyze fluctuations in corneal curvature over time.

SETTING: Moorfields Eye Hospital NHS Foundation Trust, London, United Kingdom.

DESIGN: Case series.

METHODS: A 3-piece IOL was implanted in 1 eye and a 1-piece IOL in the other eye through a 3.2 mm clear corneal temporal incision. Keratometry was performed preoperatively and at several points in time postoperatively. Differences between measurements were analyzed by power vectors. Statistical significance was assessed by monovariate, bivariate, and trivariate paired *t* tests. Acute angle shifts were determined as differences between meridians at 2 points in time.

RESULTS: Fifty patients were enrolled. From preoperatively to 1 year postoperatively, the changes in vector components (M, J0, J45) were, respectively, −0.02 diopter (D) ± 0.23 (SD) (P=.38), −0.07 ± 0.27 D (P=.02), and +0.04 ± 0.25 D (P=.14). Corresponding changes from 1 year to 2 years postoperatively were +0.01 ± 0.25 D (P=.73), +0.01 ± 0.23 D (P=.83), and +0.01 ± 0.16 D (P=.40). The meridian shift was −5 ± 32 degrees (P=.13) from preoperatively to postoperatively and +3 ± 22 degrees (P=.23) from 1 year to 2 years.

CONCLUSIONS: Surgically induced astigmatism was composed of slight flattening in the horizontal meridian and slight steepening in the oblique meridian but was insignificant in relation to random fluctuations, which were almost equally large between postoperative measurements 1 year apart. The fluctuations were not due to imprecision in measurement.

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Intraocular lens (IOL) power calculation is dependent on the accuracy and precision of the measured input, usually limited to keratometry for corneal power and to ultrasound or optical biometry for axial length. In this paper, we scrutinize the reproducibility of keratometry; that is, how well measurements obtained at widely different points in time agree. For regular cataract surgery with nontoric IOLs, it is assumed that the mean corneal power remains the same postoperatively as preoperatively. This assumption is also made for implantation of toric IOLs, with additional correction for surgically induced astigmatism (SIA). In the simplest case,[1] a given amount of flattening is assumed in the meridian of the incision, with corresponding steepening at 90 degrees to it. This can be expressed as the spherocylinder (−C/2 C @ A), where C is the induced positive cylinder of astigmatism, often assumed to be 0.5 diopter (D), and A is its axis, which coincides with the meridian of incision. The net spherical equivalent (SE) change is zero. The more sophisticated approach by Fam and Lim[2] takes into account the complete surgically induced change by allowing for the possibility that the induced astigmatism is not necessarily in the meridian of the incision and is not necessarily compensated for 90 degrees to it. The resulting surgically induced change can thus have a non-zero SE.

PATIENTS AND METHODS

In a study of IOL stability at Moorfields Eye Hospital, London, United Kingdom, patients had implantation of

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a 3-piece Tecnis ZA9003 IOL in 1 eye and a 1-piece Tecnis ZCB00 IOL (both Abbott Medical Optics, Inc.) in the other eye. The study was approved by the institutional review board and adhered to the tenets of the Declaration of Helsinki. All patients provided informed consent.

To select patients with essentially healthy eyes except cataract, the following exclusion criteria were applied: (1) concurrent participation or participation during the past 30 days in any other clinical trial; (2) use of systemic or ocular medications that may affect vision or pupil size; (3) uncontrolled systemic or recurrent ocular disease (eg, recurrent ocular inflammatory condition); (4) requiring an IOL of less than 15.0 D or more than 26.0 D; (5) history of ocular trauma or previous ocular surgery; (6) corneal astigmatism of 2.0 D or more; (7) corneal abnormalities (eg, irregular astigmatism, stromal, epithelial or endothelial dystrophies); (8) uncontrolled ocular hypertension or glaucomatous changes in the retina; (9) pupil abnormalities (nonreactive, tonic pupils, or abnormally shaped pupils); (10) capsule or zonule abnormalities that may lead to IOL decentration, including pseudoexfoliation, trauma, an eccentric anterior capsulorrhexis, or posterior capsule defects; (11) known pathology that may affect vision or visual field as determined by the investigator; (12) retinal changes that may affect vision significantly or that may require surgical intervention during the course of the study (eg, unstable macular dystrophy).

Surgery was performed using a 3.2 mm temporal incision in clear cornea close to the limbus. In addition, 1.0 mm paracenteses approximately 2.5 mm in length were made at approximately 60 degrees on either side of the main incision. The right paracentesis was used for the capsulorrhexis needle and the left for a second instrument during phacoemulsification. Both were used for bimanual irrigation and aspiration.

When scrutinizing the data of the study, there was rather large variability in keratometry between different points in time. A decision was made to perform a deeper analysis of it, which is the topic of this paper.

Keratometry was measured with the IOLMaster device (Carl Zeiss Meditec AG) preoperatively and postoperatively. Changes from 1 timepoint to another were analyzed using power vectors[3] (M, J0, J45) obtained as follows:

$$\mathrm{M} = S + C/2$$

$$\mathrm{J0} = -C/2 \times \cos(2A)$$

$$\mathrm{J45} = -C/2 \times \sin(2A)$$

where S is the power in the flat meridian, C is the positive power difference between the flat and steep meridians, and A is the axis of the positive cylinder, which coincides with the flat meridian of the cornea. We prefer positive cylinder notation for this purpose; however, the method works equally well for negative notation. M is the same as the mean corneal power (SE) and has the dimension of reciprocal length in meters (m^{-1}; equivalent to diopter [D]), which is also the dimension of J0 and J45. They can be considered as Jackson crossed cylinders (thus having no spherical power), 1 at 0 degree and the other at 45 degrees. To avoid mirror symmetry between right eyes and left eyes to cancel out oblique astigmatism, the sign of J45 was reversed for left eyes.

The transformation allows subtraction of 1 vector from another. The difference can be reconverted to spherocylinder in plus cylinder notation by

$$\mathrm{C} = 2 \times \sqrt{J_0^2 + J_{45}^2}$$

$$\mathrm{S} = M - C/2$$

$$\mathrm{A} = 0.5 \times \mathrm{atan}(\mathrm{J45}/\mathrm{J0}) + 90$$

For negative cylinder notation, the negative root is chosen and the number 90 is omitted.

Power vectors also allow for calculation of means and standard deviations (SDs) and application of statistical analysis. The TTEST function of Excel (Microsoft Corp.) was used to calculate 2-tailed monovariate, bivariate, and trivariate paired P values.

For analysis of rotation of the axis from 1 timepoint to another timepoint, the angle shifts Aflat(time 2) – Aflat(time 1) and Asteep(time 2) – Asteep(time 1) were computed. If these were not the same, the 1 with the smallest numerical magnitude was taken, thus obtaining the acute angle shift. These difference angles are bound between −90 degrees and +90 degrees and will have a mean of 0 degree if the direction of rotation is random. Normal statistical analysis could result in 95% limits or even SDs that are outside these bounds and thus not defined. Therefore, the median of the absolute values of the difference angles was used to characterize the variability. This median will always be between 0 degree and 90 degrees.

RESULTS

The study enrolled 50 patients; 91 cases were available for evaluation at 1 year.

The mean surgically induced changes in vector components (M, J0, J45) were, respectively, −0.02 D ± 0.23 (SD), −0.07 ± 0.27 D, and +0.04 ± 0.25 D. This translates to the mean spherocylinder change of −0.10 +0.16 @ 165. The monovariate P values were 0.38, 0.02, and 0.14, respectively. A negative J0 implies flattening in the horizontal meridian. A positive J45 means steepening in the 45-degree meridian and indicates that the SIA is not purely induced in the horizontal meridian but in this case was at 165 degrees. Although the monovariate P value indicates statistical significance for the change in J0, the bivariate change in J0 and J45

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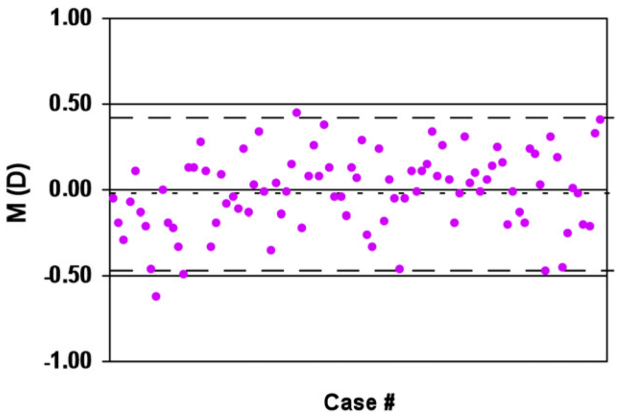

Figure 1. Changes in M (SE) from preoperatively to 1 year postoperatively (n = 91). Plotted are also the mean (*short dashes*) and the 95% probability limits (*long dashes*).

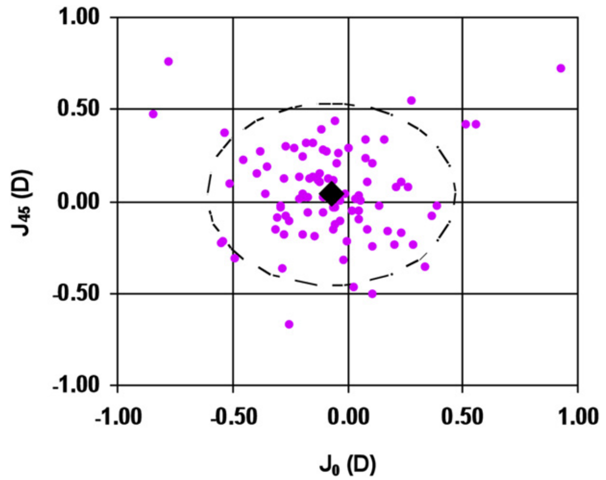

Figure 2. Changes in J0 and J45 from preoperatively to 1 year postoperatively (n = 91). Plotted is also the 95% probability ellipse (*long dashes*). The mean is indicated by the black diamond and its departure from the origin indicates the magnitude of SIA, which clearly is small compared with the random variation.

had a *P* value of 0.68. The trivariate *P* value was 0.28. Even if there were some surgically induced change, it was small and insignificant in comparison with the random variation in the vector components, as seen in Figures 1 and 2. There was no statistically significant difference between right eyes and left eyes ($P = .57$), between men and women ($P = .59$), or between age (≤72 years and >72 years) ($P = .61$).

Table 1 shows the changes in power vector components from preoperatively to several periods postoperatively. To have a coherent data set, only cases that were available at all points in time were included, which reduced the number of cases to 69. There was a small but statistically significant increase in M (SE) at 1 month and 3 months that disappeared at 1 year and 2 years. The statistically significant shift in J0 at 1 month disappeared at later timepoints, and the shifts in J45 did not reach statistical significance at any timepoint. The negative shifts in J0 indicate slight flattening in the horizontal meridian and the positive shifts in J45 slight steepening in the 45-degree meridian.

Table 1 also shows the changes from 1 year to 2 years postoperatively. As expected, the mean change in all 3 vector components was practically zero while the SDs were of the same magnitude as from preoperatively to postoperatively with the exception of J45. Figures 3 and 4 show the results graphically for comparison with Figures 1 and 2.

The mean arithmetic change in cylinder was −0.01 ± 0.45 D from preoperatively to 1 year postoperatively and −0.05 ± 0.34 D from 1 year to 2 years postoperatively. The mean changes were not statistically significant.

The mean shift in the flat meridian from preoperatively to 1 year postoperatively was −5 degrees, which is not different from 0 degree with statistical significance. The SD was 32 degrees, with a maximum of +82 degrees and a minimum of −89 degrees. The median absolute shift was 14 degrees. The histogram in Figure 5 shows a more or less random distribution. As can be seen in Table 2, there was a somewhat erratic tendency toward the median absolute shift

Table 1. Mean changes in vector components and monovariate *P* values from preoperatively to several postoperative periods and from 1 year to 2 years postoperatively. The slight differences in values between text and table for preoperatively to 1 year postoperatively are explained by the different numbers of cases included.

		M (D)		J0 (D)		J45 (D)	
Period	Cases (n)	Mean ± SD	*P* Value	Mean ± SD	*P* Value	Mean ± SD	*P* Value
Preop to 1 month	69	+0.11 ± 0.30	.00	−0.14 ± 0.31	.00	+0.07 ± 0.30	.05
Preop to 3 months	69	+0.11 ± 0.28	.00	−0.08 ± 0.56	.23	+0.02 ± 0.41	.67
Preop to 1 year	69	−0.02 ± 0.23	.58	−0.06 ± 0.25	.05	+0.05 ± 0.25	.10
Preop to 2 years	69	+0.01 ± 0.25	.79	−0.05 ± 0.30	.21	+0.06 ± 0.27	.06
1 year to 2 years	79	+0.01 ± 0.25	.73	+0.01 ± 0.23	.83	+0.01 ± 0.16	.40

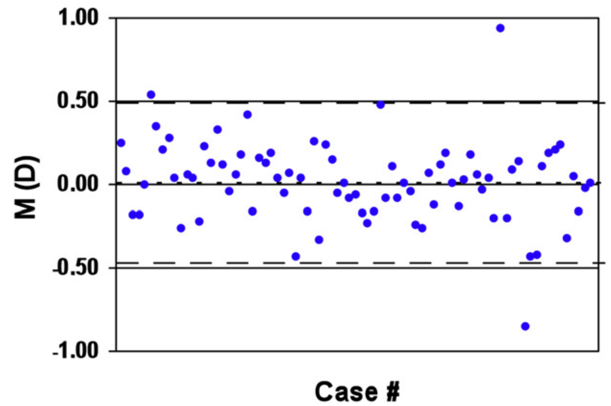

Figure 3. Changes in M (SE) from 1 year to 2 years postoperatively (n = 79). Plotted are also the mean (*short dashes*) and the 95% probability limits (*long dashes*).

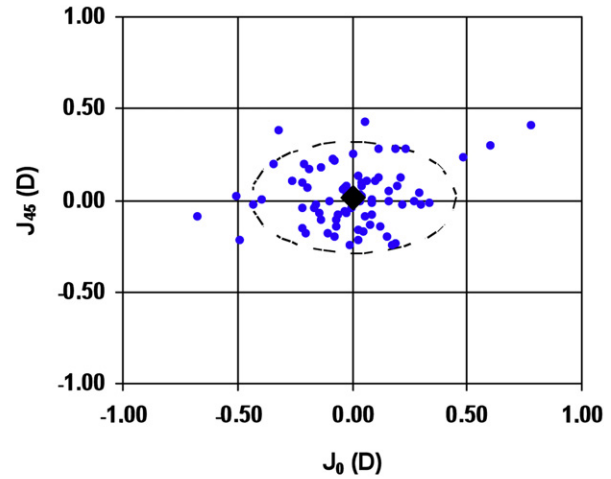

Figure 4. Changes in J0 and J45 from 1 year to 2 years postoperatively (n = 79). Plotted is also the 95% probability ellipse (*long dashes*). The mean is indicated by the black diamond and its departure from the origin is negligible, which could be expected.

being larger for small amounts of corneal cylinder and gradually declining with increasing corneal cylinder; however, the number of observations within each range was too small for statistical analysis. In Figure 6, the acute angle shifts are plotted against preoperative corneal cylinder together with logarithmic fits of median absolute shift against corneal cylinder, displaced by the amount of the (nonsignificant) mean shift.

The mean shift in the flat meridian from 1 year to 2 years postoperatively was +3 degrees (not significant), with a median absolute shift of 8 degrees. The SD was 22 degrees, with a maximum of +75 degrees and a minimum of −49 degrees. Detailed data are shown in Table 3, and the results are plotted in Figure 7. The smaller shifts in comparison with those in Table 2 and Figure 6 are due to smaller shifts in the J45 component. Although, as stated earlier, it is

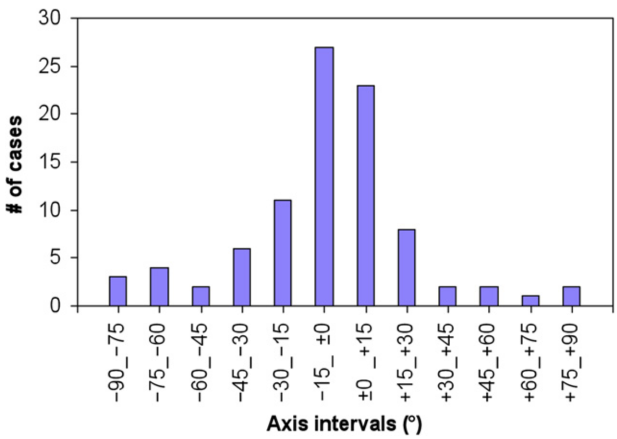

Figure 5. Distribution of angle shifts from preoperatively to 1 year postoperatively (n = 91).

questionable to analyze the distribution in terms of 95% limits, the fit results for comparison with median are given in Table 4. That the 95% limits fell outside the defined range of angle shifts (bound between −90 degrees and +90 degrees) for low cylinders demonstrates the inappropriateness of applying this statistical measure to a distribution with upper and lower bounds.

DISCUSSION

The keratometric measurement itself is rarely questioned, although Shammas and Chan[4] recently reported a change of −0.02 ± 0.27 D in mean corneal power between preoperative measurements taken approximately 1 month apart using the IOLMaster device. In a recent study, Shammas and Hoffer[5] used the Lenstar LS900 device (Haag-Streit AG) and found a change of −0.04 ± 0.26 D in mean corneal power between preoperative measurements 1 month apart. Our results for postoperative measurements 1 year apart

Table 2. Meridian shifts from preoperatively to 1 year postoperatively grouped in 0.25 D intervals of preoperative corneal cylinder.

Cylinder Interval (D)	Mean Preop Cylinder (D)	Median Shift (°)	Cases (n)
0.00 to <0.25	0.19	25	3
0.25 to <0.50	0.36	43	17
0.50 to <0.75	0.64	14	31
0.75 to <1.00	0.87	15	13
1.00 to <1.25	1.11	5	11
1.25 to <1.50	1.30	9	5
1.50 to <1.75	1.62	38	5
1.75 to <2.00	1.87	12	3

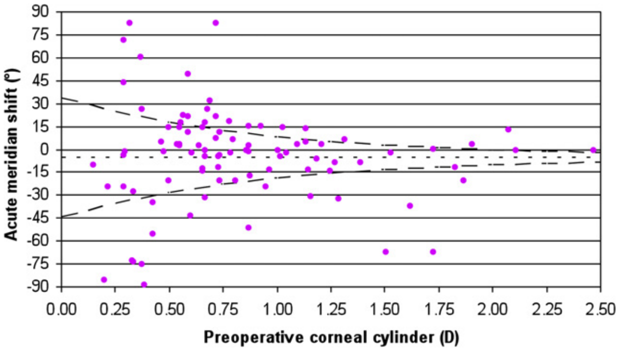

Figure 6. Acute meridian shifts from preoperatively to 1 year postoperatively plotted against preoperative corneal cylinder. The mean shift is plotted with short dashes. Logarithmic fits to the median shifts in 0.25 D intervals shown in Table 2, displaced by the mean shift, are plotted with long dashes.

are very similar, with a mean change of +0.01 ± 0.25 D in M (same as mean corneal power) and a change of +0.02 ± 0.23 D in M from preoperatively to 1 year postoperatively. All changes in the mean were statistically insignificant. The random variations were small, but not negligible, and far larger than the ±0.04 D SD found for repeat measurements with the IOLMaster device by Shirayama et al.[6] Shammas and Hoffer[5] report a coefficient of variation of 0.003, which translates to approximately ±0.1 D SD in repeat measurements with the Lenstar LS900 device.

To analyze the variation in our measurements, we took the pairwise differences in mean keratometry value of the 3 readings provided by the IOLMaster device for the 100 eyes measured preoperatively and found an SD of ±0.10 D. Our conclusion is that the differences we and others found in measurement of corneal power at different timepoints reflect natural fluctuations and were not due to measurement error.

Shammas and Chan[4] found an arithmetic change in cylinder of −0.06 ± 0.38 D and Shammas and Hoffer[5] of −0.09 ± 0.25 D. This is similar to what we found from preoperatively to 1 year postoperatively (−0.01 ± 0.45 D) and from 1 year to 2 years postoperatively (−0.05 ± 0.34 D), although the SDs for cylinder vary somewhat more than for sphere between the studies. The mean changes were not statistically significant; thus, we believe the random change was again due to natural variation in the cornea.

It is slightly misleading to analyze the arithmetic change in cylinder on its own because there is almost always a concurrent change in meridian. The correct analysis is that of the vector components J0 and J45, for which we found an SD of ±0.25 D from preoperatively to 1 year postoperatively. The change from 1 year to 2 years postoperatively had an SD of ±0.23 D in J0 and ±0.16 D in J45. We were given access to the raw data of Shammas and Chan[A] to perform power vector analysis, and the results were very similar to ours (+0.02 ± 0.24 D in J0 and +0.01 ± 0.17 D

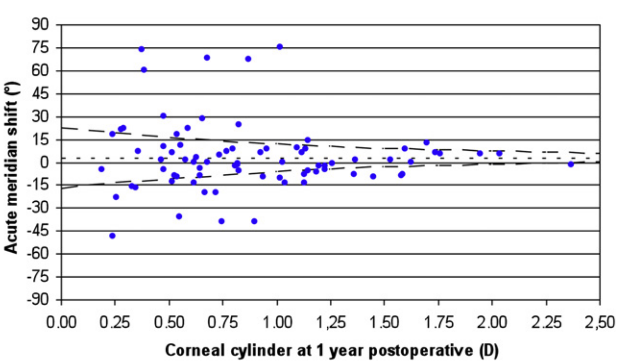

Figure 7. Acute meridian shifts from 1 year to 2 years postoperatively plotted against corneal cylinder at 1 year. The mean shift is plotted with short dashes. Logarithmic fits to the median shifts in 0.25 D intervals shown in Table 3, displaced by the mean shift, are plotted with long dashes.

Table 3. Meridian shifts from 1 year to 2 years postoperatively grouped in 0.25 D intervals of corneal cylinder at 1 year.

Cylinder Interval (D)	Mean Cylinder at 1 Year (D)	Median Shift (°)	Cases (n)
0.00 to <0.25	0.22	18	3
0.25 to <0.50	0.38	19	12
0.50 to <0.75	0.61	11	21
0.75 to <1.00	0.85	8	13
1.00 to <1.25	1.13	8	15
1.25 to <1.50	1.36	5	4
1.50 to <1.75	1.62	8	7
1.75 to <2.00	1.86	5	2

Table 4. Logarithmic fit data for median and 95% limits (1.96 × standard deviation) in meridian shifts at different levels of cylinder from preoperatively to 1 year postoperatively and from 1 year to 2 years postoperatively. The nonsignificant changes in the means are ignored. For low cylinders, the 95% limits are outside the valid range of ±90°, which indicates that it is inappropriate to apply this kind of statistics.

	Preop to 1 Year Postop		1 Year to 2 Years Postop	
Cylinder (D)	Median (°)	95% Limits (°)	Median (°)	95% Limits (°)
0.00	±39	±174	±20	±252
0.25	±30	±145	±16	±165
0.50	±23	±122	±13	±108
0.75	±18	±102	±11	±71
1.00	±14	±85	±9	±46
1.25	±10	±71	±7	±30
1.50	±8	±59	±6	±20
1.75	±6	±50	±5	±13
2.00	±5	±41	±4	±9

in J45). The random variation in J0 was thus approximately $\pm$0.25 D for measurements at different timepoints both preoperatively and postoperatively, while the variation in J45 was slightly less. The higher SD in J45 from preoperatively to 1 year postoperatively is thus the only indication of surgically induced change and also explains the higher variation in axis from preoperatively to 1 year postoperatively than from 1 year to 2 years postoperatively.

A reflection that can be drawn from Figure 2 is that the application of correction for SIA in toric IOL calculation is insignificant in relation to the random variation, even for the relatively large incision (3.2 mm) in our study. There was flattening (negative J0) in the axis of incision in more than half the cases but significant steepening (positive J0) in many cases. Of course, there is no harm in applying correction for SIA.

We found a mean change in meridian of -5 ± 32 degrees and a median absolute change of 14 degrees from preoperatively to 1 year postoperatively and of $+3 \pm 22$ degrees and 8 degrees, respectively, from 1 year to 2 years postoperatively. This compares well with the $+4 \pm 24$ degrees and median 12 degrees found by Shammas and Chan[4] and the -3 ± 12 degrees and median 9 degrees found by Shammas and Hoffer.[5] The mean changes were not statistically significant in any of the studies. A change of approximately 10 degrees in median appears normal for measurements both preoperatively and postoperatively due to natural fluctuations in the cornea. Logically, determination of meridians is less accurate for corneas with low astigmatism (Table 4). From preoperatively to 1 year postoperatively, it was 14 degrees at 1.0 D of astigmatism and 5 degrees at 2.0 D. From 1 year to 2 years postoperatively, it was 9 degrees and 4 degrees, respectively. By definition, half the cases are below the medians and the other half above. This has repercussions for toric IOL power calculations. For a 15-degree error in meridian, half the effect of the cylinder correction is lost.

Because the time of day of the measurements was not controlled for in any of the studies, diurnal variations can be a reason for the fluctuations. Other environmental factors, such as temperature and humidity, could also play a role. The fact remains that the measured corneal power could be different by approximately 0.5 D from 1 occasion to another in approximately 5% of cases. In IOL power calculation, that difference will affect refractive outcome with about the same amount. The same applies to toric IOL power calculation, with the added uncertainty due to natural fluctuations in magnitude and axis of cylinder.

WHAT WAS KNOWN

- In IOL power calculation, the cornea is treated as a static component of the optical system of the eye.
- Reasons for postoperative refractive error after cataract surgery are attributed to errors in measurement of corneal power and axial length and in the estimation of the effective IOL position.

WHAT THIS PAPER ADDS

- Our study suggests that temporal (varying in time) fluctuation in corneal curvature is an additional source of error in IOL power calculation.
- It appears that the cornea is a dynamic optical component preoperatively as well as postoperatively.
- The fluctuations were much larger than the surgically induced change in cataract surgery.

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