



Long-term changes in intraocular lens position and corneal curvature after cataract surgery and their effect on refraction

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PURPOSE: To evaluate the role of intraocular lens (IOL) position shift and changes in corneal curvature on long-term refractive shift after cataract surgery.

SETTING: Rotterdam Ophthalmic Institute, Rotterdam, the Netherlands.

DESIGN: Prospective cohort study.

METHODS: Patients who had routine cataract surgery with implantation of a hydrophobic acrylic 1-piece IOL (Acrysof SA60AT) in the capsular bag were enrolled. Measurements were performed preoperatively and 1 month, 3 months, and 1 year postoperatively. Refraction was measured with the ARK-530A autorefractor. The IOL position and corneal curvature were measured with the Lenstar LS-900 biometer. The refractive effect of changes in IOL position and corneal curvature was calculated with a Gaussian optics-based thin-lens formula and correlated with the measured refractive shift.

RESULTS: The study group comprised 59 eyes of 59 patients. The median measured absolute refractive change was 0.25 diopter (D). The IOL position showed a statistically significant mean posterior shift of $0.033 \text{ mm} \pm 0.060$ (SD) between 1 month and 1 year postoperatively ($P < .01$), of which the median calculated absolute refractive effect was 0.05 D. This did not correlate with the measured refractive shift (Pearson $r = 0.10$, $P = .46$). Natural fluctuations in corneal curvature caused a median calculated absolute refractive effect of 0.17 D, which correlated well with the measured refractive shift (Pearson $r = .55$, $P < .001$).

CONCLUSIONS: Long-term changes in refraction after cataract surgery resulted from natural fluctuations in corneal curvature rather than from IOL position shift. These fluctuations limit the accuracy with which the refractive outcome can be planned.

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One of the major challenges of contemporary cataract surgery is to achieve the target postoperative refraction. The postoperative refraction depends on the refractive power of the cornea, the power and position of the intraocular lens (IOL), and the axial length (AL). Postoperatively, changes in refraction might occur due to variations in corneal power as a result of wound-healing processes as well as shifting of the IOL as it settles in its final position. In addition, naturally occurring fluctuations in the refractive media of the eye might play a role.

Knowledge of the long-term stability of postoperative refraction is important in the calculation of IOL

power. It is also important in the prescription of postoperative spectacles. Furthermore, optimization of IOL formula constants^{1–4,A} requires that the refraction is stable. Nevertheless, little has been published about long-term changes in the pseudophakic eye and the effect of these changes on refractive stability. Today's quest to further optimize refractive results necessitates a comprehensive understanding of the postoperative refractive course in pseudophakic patients. Therefore, the purpose of this study was to evaluate long-term refractive changes after cataract surgery and determine the role of changes in IOL position and corneal curvature.

PATIENTS AND METHODS

This prospective cohort study was performed at the Rotterdam Ophthalmic Institute, Rotterdam, the Netherlands. The study population consisted of patients scheduled for routine cataract surgery. One eye of each patient was randomly included in the study. The study adhered to the tenets of the Declaration of Helsinki, and institutional review board approval was obtained. Written informed consent was received from all patients.

Exclusion criteria were corneal diseases (eg, keratoconus, corneal scarring, and pterygium), pseudoexfoliation syndrome, and previous corneal or refractive surgery. In addition, patients were excluded if complications occurred during or after the cataract surgery that might affect the outcome variables, such as a capsule tear or cystoid macular edema.

Surgical Technique

A 2.2 mm self-sealing clear corneal incision or scleral tunnel incision was made with a standard dual-beveled slit knife (Intrepid 2.2, Alcon Surgical, Inc.). Incisions were placed superiorly (at 100 degrees) or at the steepest corneal meridian. The intended diameter of the capsulorhexis was 5.5 mm. The surgeon ensured that in all cases the anterior lens capsule slightly overlapped the optic of the IOL over 360 degrees. After routine cataract extraction by phacoemulsification and bimanual cortex removal, a hydrophobic acrylic 1-piece IOL (Acrysof SA60AT, Alcon Surgical, Inc.) was inserted in the capsular bag using a standard Monarch III injector (Alcon Surgical, Inc.). This IOL has a 6.0 mm diameter monofocal optic, an overall length of 13.0 mm, and no haptic angulation.

Measurements

Measurements were performed preoperatively and postoperatively at 1 month, 3 months, and 1 year. Refraction was measured at the spectacle plane (12.0 mm) with the ARK-530A autorefractor (Nidek Co., Ltd.) and converted to the corneal plane.⁵ Central corneal thickness, aqueous depth, AL, and corneal curvatures in the principal meridians were measured with the Lenstar LS-900 (software version 2.1.0, Haag-Streit), which is a combined biometer and keratometer. It measures the thicknesses of and distances between the optical components of the eye with optical low-coherence reflectometry using a broadband light

source (20 to 30 nm) with a central wavelength of 820 μm .^{6,7} In addition, it measures central corneal curvatures by analyzing reflections of 32 monochromatic light-emitting diodes distributed over 2 rings with diameters of 1.65 mm and 2.30 mm. The device has an internal quality check that flags uncertain measurements. Three repeated measurements of each variable were obtained during each visit. The IOL position was defined as the pseudophakic aqueous depth (ie, the distance between the posterior corneal surface and the anterior surface of the IOL). Corneal thickness was not included in this definition because this might cause variations in measured corneal thickness to influence the perceived IOL position shift. Corneal curvature was defined as the average of the steepest curvature and flattest curvature.

Repeatability of Intraocular Lens Position and Corneal Curvature Measurements

To be able to distinguish a true change in IOL position or in corneal curvature from measurement variation in individual eyes, repeatability of the measurement of these variables was assessed based on the 3 repeated measurements that were obtained during a single visit. At each visit, the repeatability coefficient^{8,9} was calculated. Similar to limits of agreement (LoA), the repeatability coefficient is the maximum difference that is expected to occur in 95% of repeated measurements. Contrary to LoA, which are calculated based on the difference between 2 measurements, the repeatability coefficient is calculated from the within-subject standard deviation. It can therefore be derived from datasets with more than 2 repeated measurements.

All subsequent calculations in this study are based on the median of the 3 repeated measurements. In individual eyes, changes equal to or smaller than the repeatability coefficient were considered to be measurement variations rather than true changes.

Refractive Effect of Changes in Intraocular Lens Position and Corneal Curvature

A Gaussian optics-based thin-lens formula based on the Haigis formula^A was used to calculate for each eye the refractive effect of the measured change in IOL position and in corneal curvature as follows:

$$P = \frac{n_{av}}{AL - ACD} - \frac{n_{av}}{\frac{n_c - 1}{R} + T} - ACD$$

where P is the implanted IOL power (D), T is the refraction (D), AL is the AL (m); ACD is the pseudophakic ACD (m), R is the corneal radius of curvature (m), n_{av} is the refractive index of aqueous and vitreous (set to 1.336), and n_c is the keratometric index (set to 1.328). The known power of the implanted IOL was inserted, and the formula was solved for refraction. Thin-lens formulas assume that refraction occurs on infinitely thin refractive surfaces. The positions of these surfaces in the eye are conventionally defined as the coronal planes intersecting the anterior surfaces of the cornea and IOL. The keratometric index is the refractive index of the fictitious medium behind the infinitely thin corneal plane. It is dependent on the ratio of the radii of curvature of the posterior and anterior corneal surfaces. The conventional keratometric index of 1.3375 is an inaccurate reflection of this ratio,^{10,11} yet the

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introduction of corrective factors (“fudge factors”¹²) inherent to the pseudophakic ACD prediction algorithms of IOL power formulas^{1-4,A} correct for this inaccuracy. Because the measured ACD was used instead of the predicted pseudophakic ACD in this study, a keratometric index of 1.328 was used, which better reflects current knowledge of corneal shape.¹³⁻¹⁵

The refractive effect of a change in IOL position or corneal curvature was defined as the difference in the calculated refraction between 1 month and 1 year postoperatively. Baseline refraction was calculated using the ACD, AL, and corneal radius of curvature measured 1 month postoperatively. In the first calculation, only ACD was changed to the ACD measured 1 year postoperatively (thus obtaining the effect of the shifted IOL position). In the second calculation, only the corneal radius of curvature was changed to the corneal radius of curvature measured 1 year postoperatively. The effect of changes in both ACD and the corneal radius of curvature was assessed in the final calculation.

Statistical Analysis

Statistical analysis was performed using Excel 2010 software (Microsoft Corp.) and SPSS software (version 21, International Business Machines Corp.). The statistical significance of the IOL position shift and the change in corneal curvature was determined using repeated-measures analysis of variance followed by Bonferroni-corrected post hoc testing if applicable. Correlations were calculated using the Pearson *r* value, and *P* values less than 0.05 were considered statistically significant.

RESULTS

The study comprised 59 eyes of 59 patients. The mean age of the patients was 70.7 years \pm 7.4 (SD) (range 50.3 to 88.3 years). Twenty-seven patients (46%) were men, and 23 eyes (39%) were right eyes. Table 1 shows the descriptive statistics of the preoperative optical properties of the eyes in this study. The mean power of the implanted IOL was 19.2 \pm 3.7 D (range 8.0 to 27.5 D).

Repeatability of Intraocular Lens Position and Corneal Curvature Measurements

The repeatability coefficient of IOL position measurements was 0.03 mm at all visits. The repeatability coefficient of corneal curvature measurements was 0.07 mm 1 month and 3 months postoperatively and 0.06 mm at 1 year.

Table 1. Descriptive statistics of the preoperative optical properties of the eyes in this study.

Variable	Mean	SD	Minimum	Maximum
Objective refraction (D)	-1.70	3.69	-12.13	+5.38
Aqueous depth (mm)	2.72	0.46	1.52	3.69
Axial length (mm)	24.31	1.56	21.20	28.35
Corneal radius of curvature (mm)	7.72	0.29	7.30	8.51

Changes in Intraocular Lens Position and Corneal Curvature

Figure 1, A, shows the mean average IOL position over time. During the postoperative follow-up, there was a mean posterior shift of the IOL from 4.107 \pm 0.301 mm at 1 month to 4.139 \pm 0.292 mm at 1 year. The mean shift was 0.033 \pm 0.060 mm. The shift was statistically significant (*P* < .01). Bonferroni-corrected post hoc testing showed that the shift between 1 month and 3 months as well as the shift between 3 months and 1 year were statistically significant (*P* < .05). Figure 1, B, shows the mean change in corneal curvature. Postoperatively, the mean corneal curvature was 7.722 \pm 0.28 mm, 7.728 \pm 0.28 mm, and 7.727 \pm 0.29 mm at 1 month,

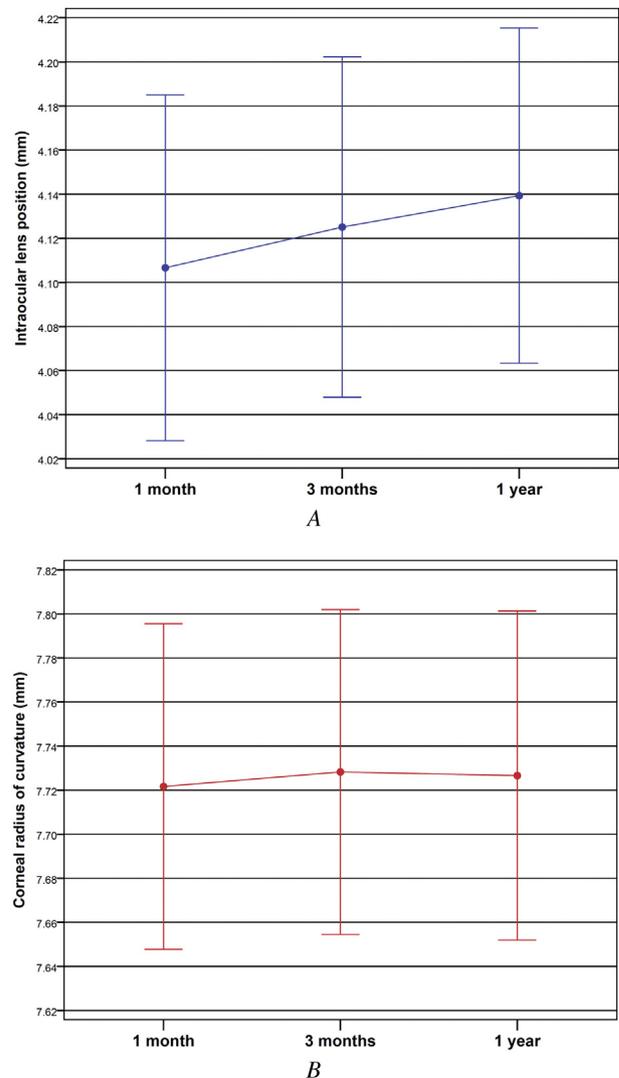


Figure 1. Mean IOL position (A) and mean corneal radius of curvature (B) over time. For IOL position, a higher number represents a more posterior position (more hyperopic eye). For corneal radius of curvature, a higher number represents a flatter cornea (more hyperopic eye). Bars represent 95% CIs.

3 months, and 1 year, respectively. There was no statistically significant change during the follow-up ($P = .54$). Figure 2 shows the IOL position shift between visits. As late as between 3 months and 12 months postoperatively, a significant number of eyes showed an IOL position shift beyond the repeatability coefficient (indicated in Figure 2 by colored instead of gray bars). A shift occurred predominantly in the posterior direction. Figure 3 shows the change in corneal curvature between visits. In the majority of eyes, the change fell within the repeatability coefficient.

Refractive Effect of Changes in Intraocular Lens Position and Corneal Curvature

Table 2 shows the measured and calculated refractive shift between 1 month and 1 year postoperatively. The median measured absolute refractive shift was 0.25 D. The median calculated absolute

refractive effect of the IOL position shift was 0.05 D. The median calculated absolute refractive effect of corneal curvature change was 0.17 D. The median calculated absolute refractive effect of both IOL position shift and corneal curvature change was 0.19 D. Figure 4 shows the correlation between the measured and the calculated refractive shift. The measured refractive shift could not be explained by changes in IOL position ($r = 0.10$, $P = .46$). On the other hand, the measured refractive shift correlated well with changes in corneal curvature ($r = 0.55$, $P < .001$). Combining the changes of both corneal curvature and IOL position led to a minor increase in this correlation ($r = 0.58$, $P < .001$).

DISCUSSION

To our knowledge, this study is the first to evaluate the role of changes in IOL position and corneal

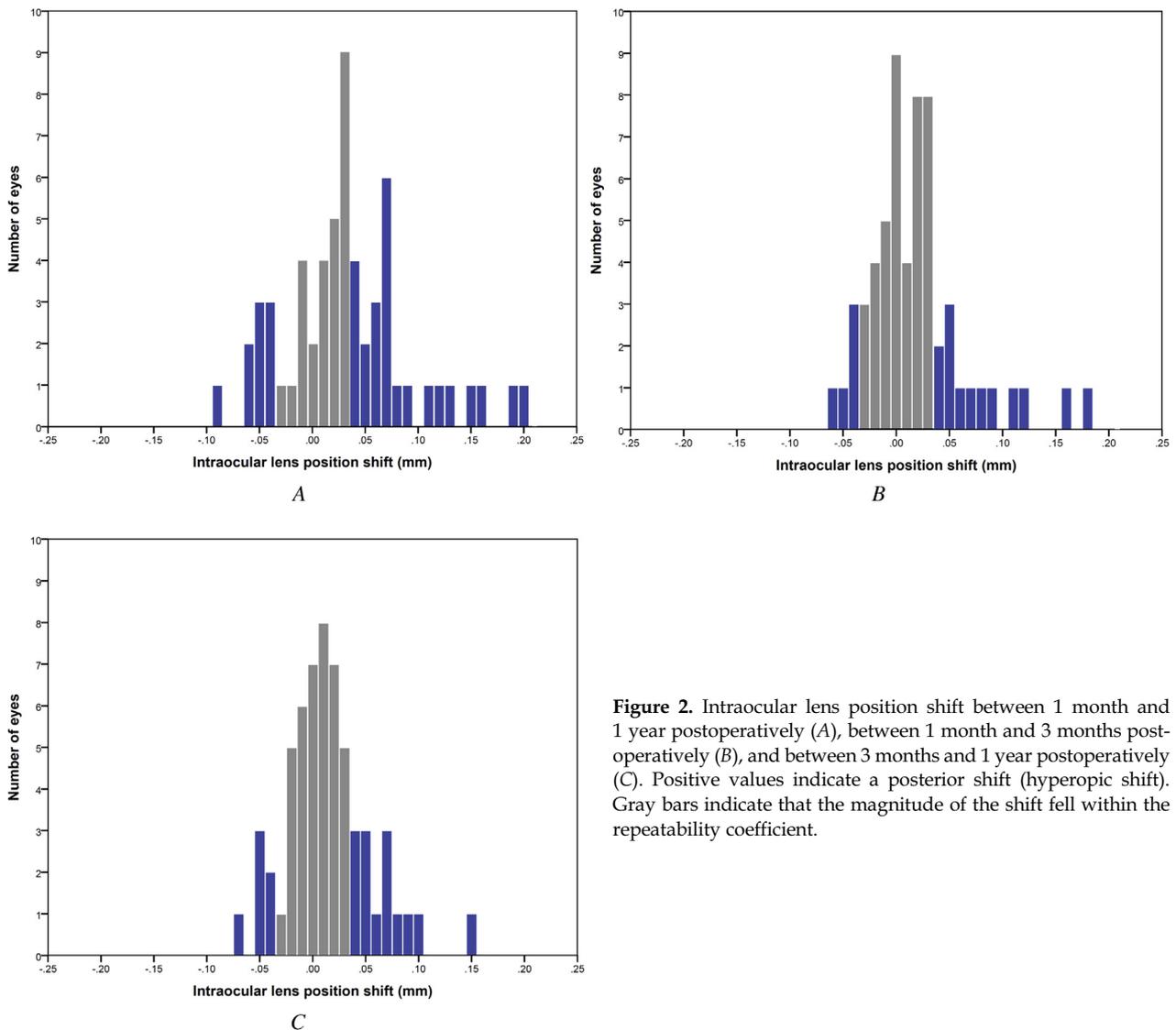


Figure 2. Intraocular lens position shift between 1 month and 1 year postoperatively (A), between 1 month and 3 months postoperatively (B), and between 3 months and 1 year postoperatively (C). Positive values indicate a posterior shift (hyperopic shift). Gray bars indicate that the magnitude of the shift fell within the repeatability coefficient.

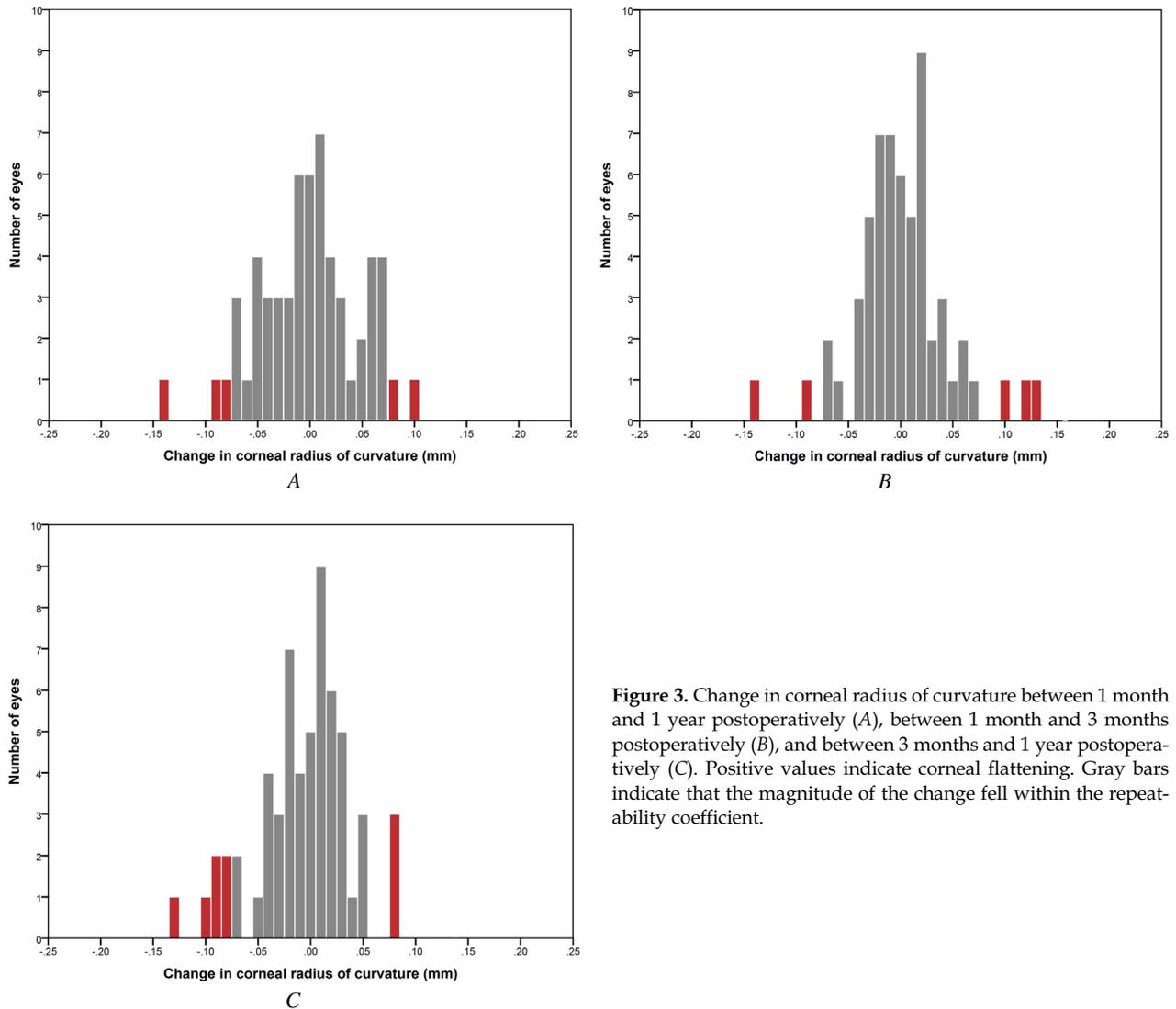


Figure 3. Change in corneal radius of curvature between 1 month and 1 year postoperatively (A), between 1 month and 3 months postoperatively (B), and between 3 months and 1 year postoperatively (C). Positive values indicate corneal flattening. Gray bars indicate that the magnitude of the change fell within the repeatability coefficient.

curvature in changes in refraction up to 1 year after cataract surgery in a large patient cohort. Identifying the source of any change in refraction is important because it might provide clues to enhance the final refractive result. Our results show that long-term changes in refraction are mainly caused by changes in corneal curvature, while the role of IOL position shift is limited.

We found a statistically significant mean posterior shift in IOL position of 0.033 mm between 1 month and 1 year postoperatively. A shift beyond the repeatability coefficient was observed at least once during the follow-up in 39 eyes (66%), suggesting that our findings indicate true changes rather than measurement variation. Slight posterior shifting might have been caused by subtle anterior capsule fibrosis, as was described by Sanders et al.¹⁶ The median calculated absolute refractive effect of the IOL position shift

was only 0.05 D, and we believe that this effect is of negligible clinical relevance. There was no correlation between the measured change in refraction and the IOL position post shift, suggesting that there must be other factors that better explain long-term refractive changes after cataract surgery.

Previous studies of IOL position shift predominantly evaluated the short-term refractive shift of multipiece IOLs.¹⁷⁻²⁰ These IOLs generally show an anterior shift in the first postoperative month. Koepl et al.¹⁹ found anterior movement of up to 0.3 mm in the first postoperative week. Depending on the exact optical properties of an eye, this translates into a myopic shift up to 0.75 D. We could find only 1 study²¹ of the shift of 1-piece IOLs (which we studied in the present study); the authors found no statistically significant shift at any time during the follow-up.

Table 2. Refractive shift between 1 month and 1 year postoperatively measured with autorefraction and calculated based on measured changes in IOL position and corneal curvature.

Method	Median (D)	IQR (D)	Range (D)
Measured with autorefraction			
No shift (n = 12; 20%)	NA	NA	NA
Shift (n = 47; 80%)	+0.13	-0.13, +0.25	-0.63, +0.75
Absolute shift (n = 47; 80%)	0.25	0.13, 0.38	0.13, 0.75
Myopic shift (n = 19; 32%)	-0.13	-0.13, -0.37	-0.13, -0.63
Hyperopic shift (n = 28; 48%)	+0.25	+0.13, +0.38	+0.13, +0.75
Calculated based on Δ ACD only			
Shift (n = 59; 100%)	+0.04	-0.02, +0.07	-0.13, +0.23
Absolute shift (n = 59; 100%)	0.05	0.03, 0.09	0.00, 0.23
Myopic shift (n = 19; 32%)	-0.04	-0.02, -0.07	-0.00, -0.13
Hyperopic shift (n = 40; 68%)	+0.05	+0.03, +0.09	+0.00, +0.23
Calculated based on Δ R only			
Shift (n = 59; 100%)	+0.03	-0.13, +0.18	-0.70, +0.54
Absolute shift (n = 59; 100%)	0.17	0.07, 0.35	0.01, 0.70
Myopic shift (n = 26; 44%)	-0.17	-0.06, -0.34	-0.01, -0.70
Hyperopic shift (n = 33; 56%)	+0.17	+0.07, +0.37	+0.02, +0.54
Calculated based on both Δ ACD and Δ R			
Shift (n = 59; 100%)	+0.10	-0.16, +0.21	-0.63, +0.58
Absolute shift (n = 59; 100%)	0.19	0.11, 0.30	0.00, 0.63
Myopic shift (n = 20; 34%)	-0.21	-0.15, -0.28	-0.00, -0.63
Hyperopic shift (n = 39; 66%)	+0.17	+0.10, +0.33	+0.00, +0.58

Δ ACD = intraocular lens position shift; Δ R = change in corneal radius of curvature; IQR = interquartile range; NA = not applicable

With regard to the longer term, Koepl et al.¹⁷ evaluated the IOL position shift of a 3-piece hydrophobic acrylic IOL in 104 eyes of 52 patients. They found a mean posterior shift of 0.033 mm between 1 month and 6 months postoperatively; however, they did not mention whether the shift was statistically significant. A similar study was performed by Stifter et al.²⁰ for a different 3-piece hydrophobic acrylic IOL. Twenty eyes of 10 patients were followed up to 1 year postoperatively. The mean posterior shift in these eyes was 0.04 mm between 1 month and 1 year postoperatively. This shift was not statistically significant. Petherel et al.¹⁸ found a mean posterior shift of 0.037 mm between 3 months and 1 year after surgery for a 3-piece silicone IOL in 36 eyes of 18 patients. This shift also was not statistically significant. In contrast to our study, these studies used multi-piece IOLs. Like us, Wirtitsch et al.²¹ studied the shift of the Acrysof SA60AT (1-piece) IOL and found a mean posterior shift of 0.033 mm in 14 eyes of 14 patients between 1 month and 6 months postoperatively, which was not statistically significant. The direction and magnitude of the shift found after 1 month postoperatively in the above-mentioned studies was similar to the shift that was found in our study. In contrast to these studies, however, the

long-term shift in our study was statistically significant, which is likely the result of our larger sample. To summarize the current evidence, a myopic shift up to 0.75 D might be observed with multi-piece IOLs in the first postoperative month as a result of an anterior IOL position shift, while changes in IOL position thereafter are of no clinical relevance. For 1-piece IOLs, a clinically relevant IOL position shift does not occur at any time during the first postoperative year.

The mean change in corneal curvature during the follow-up was not statistically significant. This does not imply that nothing happens in individual eyes. Although the direction of the effect appears to be random, true steepening or flattening might occur in individual eyes. Statistically, steepening in some eyes might be cancelled by flattening in other eyes, yielding a mean change that is not statistically significantly different from zero. Norrby et al.²² found a mean change in corneal power of 0.01 ± 0.25 D between 1 year and 2 years after cataract surgery. In our study, the calculated mean change in refraction due to changes in corneal curvature between 1 month and 1 year postoperatively was 0.03 ± 0.26 D, which is similar. Because there was a statistically significant correlation with the measured change in refraction

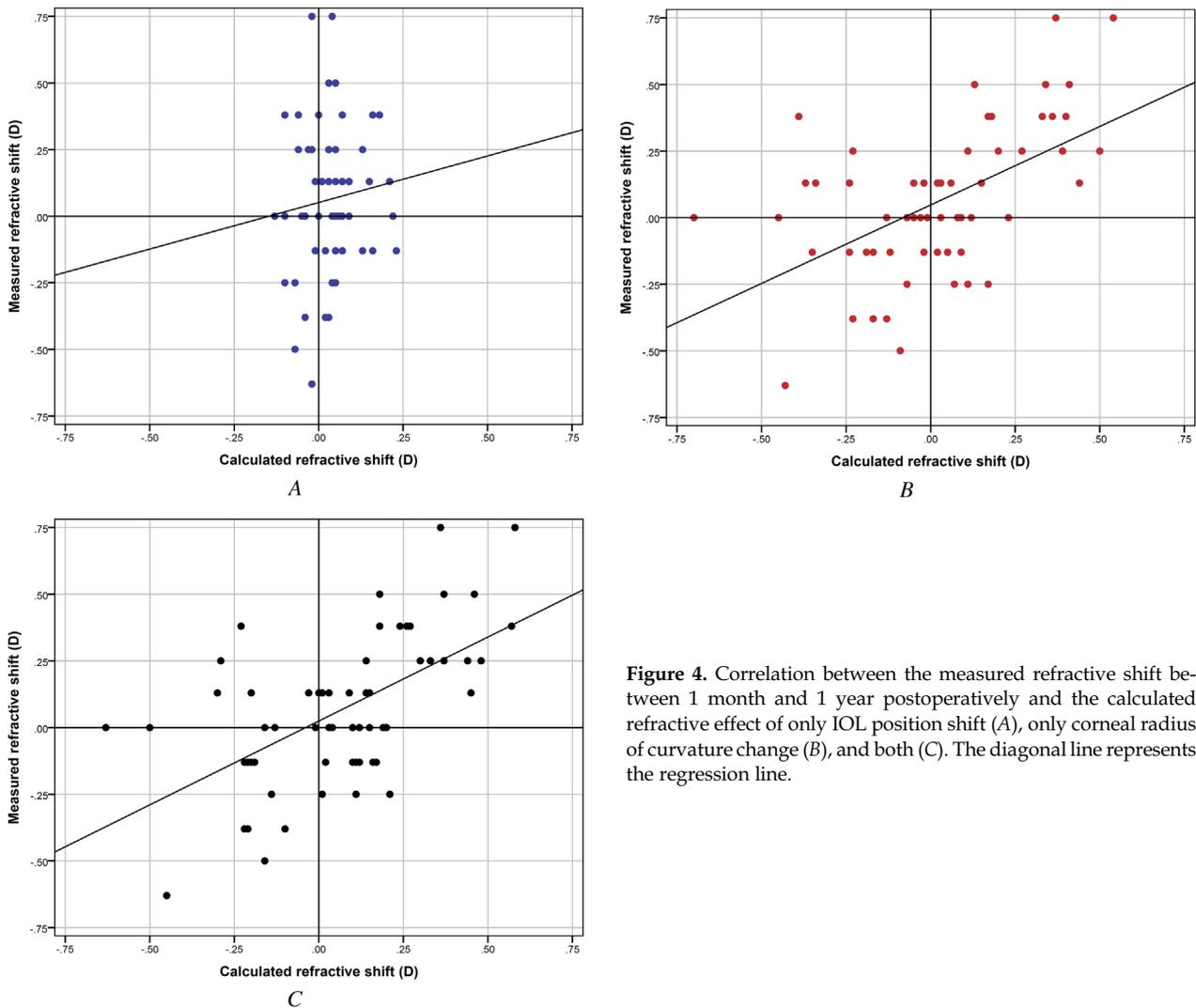


Figure 4. Correlation between the measured refractive shift between 1 month and 1 year postoperatively and the calculated refractive effect of only IOL position shift (A), only corneal radius of curvature change (B), and both (C). The diagonal line represents the regression line.

(which was measured with a different device), it is unlikely that the measured changes in corneal curvature were fully attributable to measurement variation. Thus, we concur with the conclusion of Norrby et al.²² that these changes reflect natural fluctuations rather than measurement error. Similar fluctuations in corneal curvature over time were reported in phakic subjects by Shamma and Chan²³ and Shamma and Hoffer,²⁴ suggesting that the fluctuations are not a result of cataract surgery. Thus, a significant amount of the variance in postoperative refractive shift might be explained by natural fluctuations in corneal curvature. The median calculated absolute refractive effect of a change in corneal curvature was 0.17 D, which is more than 3 times as high as the effect of an IOL position shift.

Although we have no reason to believe that changes in AL occur during the postoperative course, in theory

this is a factor that could lead to a change in refraction. To ensure that all factors were addressed, we also assessed the correlation between the measured refractive shift and the calculated refractive shift based on measured AL changes. We did not find a correlation ($r = 0.01$, $P = .94$).

The output for sphere and cylinder of the autorefractor was set to steps of 0.25 D instead of 0.01 D; thus, the spherical equivalent refraction was only available in 0.125 D steps for each eye. This is why Table 2 mentions that 12 eyes showed no shift when measured with autorefractor, while a subtle shift probably could have been detected in these eyes. Moreover, these relatively large steps limited the vertical resolution of the correlations shown in Figure 4.

The number of timepoints at which measurements of IOL position were obtained in this study was

limited. Thus, although we have shown that shifting might still occur between 3 months and 1 year postoperatively, it remains unclear whether, and if so when, the IOL position stabilizes at some point within this time interval. Nevertheless, as discussed, the clinical relevance of a long-term IOL position shift is negligible.

In conclusion, long-term follow-up of eyes that had cataract surgery showed refractive changes in the order of magnitude of 0.25 D. These could mainly be explained by natural fluctuations in corneal curvature. Although many eyes showed changes in IOL position during the follow-up, the refractive effect of these was less important. Part of the observed refractive changes could not be explained, and we believe that this is attributable to measurement variation. The natural fluctuations in corneal curvature limit the accuracy with which the refractive outcome of cataract surgery can be predicted.

WHAT WAS KNOWN

- With multipiece IOLs, a clinically relevant myopic shift might occur during the first month after cataract surgery as a result of anterior movement of the IOL. Thereafter, the IOL position remains relatively stable. With 1-piece IOLs, limited evidence suggests that no clinically relevant IOL position shift occurs at any time during the first postoperative year.
- Natural fluctuations in corneal curvature occur in phakic eyes as well as pseudophakic eyes.

WHAT THIS PAPER ADDS

- Refractive changes on the order of magnitude of 0.25 D might occur in the long term after cataract surgery. These changes are mainly a result of natural fluctuations in corneal curvature, which limit the predictability of the refractive outcome. Although 1-piece IOLs showed minute changes in position during the first postoperative year, the clinical relevance of these was negligible.

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