A Predictive Model for Postoperative Intraocular Pressure Among Patients Undergoing Laser in Situ Keratomileusis (LASIK)

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• PURPOSE: **The aim of this study was to develop a predictive model based on preoperative variables for estimating postoperative intraocular pressure (IOP) of those eyes undergoing LASIK surgery, to predict the amount of underestimated IOP after LASIK for myopia and myopic astigmatism.**

• DESIGN: **Pretest-post-test longitudinal study.**

• METHODS: **Both eyes of 193 eligible subjects who underwent LASIK procedures at the Department of Ophthalmology, National Taiwan University Hospital, from July 2000 to December 2002 for myopia and myopic astigmatism were identified to build up the predictive models. IOPs were measured with noncontact air-puff tonometry. Information on age, gender, preoperative central corneal thickness (CCT), preoperative central corneal curvature (CCK), preoperative spherical equivalent refractive error, and ablation depth was collected and applied for predicting postoperative IOP after LASIK based on linear mixed model.**

• RESULTS: **Significant predictors for postoperative IOP after myopic LASIK procedures included age, gender, preoperative IOP, ablation depth, preoperative CCT, and preoperative spherical equivalent refractive errors. The linear mixed model, taking into account these significant preoperative correlates and the correlation of IOPs between both eyes of the same patient, explained 91% of the variation of postoperative IOP.**

• CONCLUSIONS: **A statistical model was developed for predicting the amount of underestimated IOP after LASIK for myopia and myopic astigmatism, which is of clinical importance to uncover ocular hypertension among patients whose information on postoperative IOP immediately after LASIK is not available. (Am J Ophthalmol 2006;141:530–536. © 2006 by Elsevier Inc. All rights reserved.)**

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LASER IN SITU KERATOMILEUSIS (LASIK) HAS BECOME popular in treating myopia since 1993.[1] Earlier studies showed the alteration of central corneal thickness (CCT) and central corneal curvature (CCK) as a result of LASIK procedure may underestimate intraocular pressure (IOP), ranging from 1.3 mm Hg to 6.1 mm Hg.[2–9]

As patients with glaucoma have high prevalence of myopia, one of the established risk factors for the development of glaucomatous optic nerve damage[10,11] and progression of visual field defect,[12–14] concern is raised as to whether the underestimation of IOP of myopic eyes after LASIK procedure can lead to underdiagnosis of glaucoma. This applies particularly to a country such as Taiwan, where LASIK is frequently performed for high prevalence of myopia,[15] but IOP after LASIK has not been routinely recorded in eye clinics because most patients may have been lost to follow-up in consecutive postoperative visits. In this circumstance, it is paramount to predict postoperative IOP based on preoperative clinical correlates to estimate the amount of underestimated IOP as a result of LASIK procedure for correcting IOP to reduce the possibility of missing diagnosis of ocular hypertension.

The aim of this study was, therefore, to develop a predictive model for estimating postoperative IOP in Taiwanese patients who underwent LASIK because of myopia and myopic astigmatism.

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METHODS

• **STUDY SUBJECTS:** Two hundred twenty-nine consecutive patients, who underwent LASIK for myopia or myopic astigmatism between July 2000 and December 2002 by a single surgeon (I-J.W.) at the Department of Ophthalmology, National Taiwan University Hospital, were enrolled. The Human Research and Ethics Committee of the National Taiwan University Hospital approved the study protocol, and the study was conducted in accordance with the Declaration of Helsinki. Written informed consent was obtained from all patients before enrollment. We excluded subjects having previous ocular surgery (n = 2), withdrawing from LASIK procedure (n = 1), having LASIK unilaterally or bilaterally with wide interval between both eyes (n = 14), having LASIK twice or more as enhancement procedures (n = 5), lacking preoperative IOP measurements (n = 7), and having missing records of medical charts (n = 7). As our study was intended to predict the amount of underestimated IOP after LASIK, it may be sensible to use both eyes of the study subjects in the development of predictive model rather than one. Thus 386 eyes of 193 patients were eligible for the development of the following predictive models.

• **STUDY DESIGN:** The study design was based on the comparison of IOP before and after LASIK. To reduce the bias of so-called "regression toward the mean",[16–19] an outlier influence arising from one-shot measurement, a series of IOP measurements before and after LASIK procedure were collected, together with preoperative CCT, preoperative CCK, and other relevant correlates that affected the underestimation of IOP after LASIK.

• **LASIK PROCEDURE:** LASIK was performed according to standard procedures, including marking the cornea and using a suction ring to increase IOP that was confirmed with a Barraquer tonometer applied on the cornea. The corneal flaps were created with an Automated Corneal Shaper (ACS, Bausch and Lomb Surgical, Irvine, California, USA) and reflected to the nasal side, and then argon-fluoride excimer laser was applied to the stromal bed with a Summit Apex Plus excimer laser (Summit Technology, Inc, Waltham, Massachusetts, USA). The corneal flap thickness was set at 160 μm. A multizonal ablation followed a pretreatment of 2.5 mm done to prevent central islands. After washing the stromal bed and stromal surface of the corneal flap with sterile balanced salt solution, the flap was repositioned and aligned carefully directed by the corneal marks. Postoperatively, topical ciprofloxacin 0.3% HCL (Ciloxan, Alcon, Texas, USA) combined with fluorometholone 0.1% (Flumetholon, Santen) and 0.32% hydroxypropyl methylcellulose 0.32% (Artelac, Dr Gerhard Mann Chem.-pharm. Fabrik GmbH, Berlin, Germany) four times per day for the first week were administered, with ciprofloxacin progressively withdrawn during the second week. Hydroxypropyl methylcellulose and fluorometholone were usually maintained for a longer duration as the situation demanded.

• **MEASUREMENT OF IOP:** All IOP records were measured with noncontact tonometry (NCT) (Topcon CT 80 computerized tonometer; Topcon, Tokyo, Japan). We collected information on three visits for the assessment of IOP 3 months before LASIK. For each visit, three IOP records were kept for each eye. After LASIK, at least two measurements of IOP for each eye were checked on the first day or during the first week immediately after LASIK. IOP records at follow-up visits were also collected in the next 3-month period. Note that the interval between visits may vary across patients.

• **DATA COLLECTION:** We collected information for the development of predictive models, including age, gender, preoperative IOP (PreIOP), preoperative central corneal thickness (PreCCT), preoperative central corneal curvature (PreCCK), preoperative refractive errors (PreRE), ablation depth, and postoperative IOP (PosIOP).

Preoperative pachymetric measurements were made with a DGH-1000 ultrasonic pachymeter (DGH Technology, Inc, Exton, Pennsylvania, USA). After topical proparacaine 0.5% was instilled into the eye, the ultrasonic probe was placed perpendicular to the corneal surface at the center of the pupil axis. At least three central pachymetric readings to the nearest microns in each eye were recorded and averaged to gain the mean preoperative CCT, termed as PreCCT in the model. Ablation depth was recorded from the printed-paper of laser setting.

The values of preoperative CCK (PreCCK) were taken down from the average keratometric readings of autokeratorefractometer Topcon KR-7000. Keratometry performed with a TMS-1 topography unit (TMS-1, Computed Anatomy, Inc, New York, New York, USA) was also collected, but the readings were at great variance and thus not used in predictive model.

The refractive errors were measured with Topcon KR-7000, with the same machine used preoperatively and postoperatively. We calculated spherical equivalents for preoperative manifest and cycloplegic refractive errors, and averaged them to get the mean preoperative refractive errors (PreRE), which were used in predictive models.

• **STATISTICAL ANALYSIS:** Since both eyes of each patient were considered, each IOP may not represent a totally independent observation because the correlation of IOP between both eyes in the same patient (the likelihood of IOP being similar in the second eye of the same patient) may be greater than a second eye from another. Hence, a linear mixed model was therefore applied with "fixed effect" that considers a set of measurable factors affecting underestimation of IOP and with "random effect" that captures the correlated property and filters out unknown

TABLE 1. Descriptive Results of Age and Preoperative Clinical Correlates of 386 Eyes Undergoing LASIK Procedure in 193 Taiwanese Subjects

	Mean	SD	Inter-quantile Range
Age (year)	30.31	6.78	(24.88, 35.30)
PreIOP (mmHg)	13.91	3.11	(11.50, 16.17)
PosIOP (mmHg)	7.78	2.50	(6.00, 9.50)
PreRE (diopter)	−7.29	2.76	(−9.00, −5.38)
PreCCK (diopter)	43.83	1.38	(42.84, 44.78)
PreCCT (μm)	551.58	35.91	(526.00, 575.00)
Ablation depth (μm)	77.91	21.45	(62.00, 93.00)

IOP = intraocular pressure; PreIOP = preoperative IOP; PosIOP = postoperative IOP; PreRE = preoperative spherical equivalent refractive error; PreCCK = preoperative central corneal curvature; PreCCT = preoperative central corneal thickness; SD = standard deviation.

TABLE 2. Differences in Mean, Median, and Inter-quantile Range Between Preoperative and Postoperative IOP for the Overall Group and Stratified by Age Group and Gender

IOP Category	Mean (SD)	Median	Inter-quantile Range
Overall			
PreIOP	13.91 (3.11)	13.75	(11.50, 16.17)
PosIOP	7.78 (2.50)	7.39	(6.00, 9.00)
Difference	5.94 (0.16)	$t = 36.54$	($P < .0001$)
Age group			
[age <30 y/o]			
PreIOP	14.33 (3.30)	14.00	(11.75, 17.00)
PosIOP	7.69 (2.45)	7.29	(6.00, 9.33)
Difference	6.43 (2.96)	$t = 26.03$	($P < .0001$)
[age ≥30 y/o]			
PreIOP	13.47 (2.83)	13.50	(11.50, 15.50)
PosIOP	7.86 (2.55)	7.50	(5.83, 9.50)
Difference	5.46 (2.48)	$t = 26.62$	($P < .0001$)
Gender group			
[Male]			
PreIOP	14.55 (2.97)	14.50	(12.33, 16.92)
PosIOP	8.72 (2.94)	8.58	(6.44, 11.08)
Difference	5.57 (2.57)	$t = 18.88$	($P < .0001$)
[Female]			
PreIOP	13.69 (3.13)	13.25	(11.33, 16.00)
PosIOP	7.44 (2.24)	7.24	(5.77, 9.00)
Difference	6.07 (2.83)	$t = 31.39$	($P < .0001$)

PreIOP = preoperative IOP; PosIOP = postoperative IOP.

factors related to IOP from variation across subjects. The details of the statistical method referred to by Diggle and associates,[20] have been widely used in this longitudinal study. The model is expressed as follows

$$\tilde{y} = \alpha + \beta_1 x_1 + \beta_2 x_2 \ \ldots \ + \gamma z \qquad [1]$$

where x_s are fixed effects (including preoperative IOP, PreCCT, PreCCK, PreRE, ablation depth, age, and gender) and z represents random effect. Note that β_s and γ represent the corresponding regression coefficients.

Although linear mixed model can also accommodate the data with irregular intervals between visits, we handled the various serial measurements of IOP by taking the average value because of high inter-observer and intra-observer correlation coefficients (see the Results Section). Namely, we averaged the three IOP measurements in each preoperative and postoperative visit to get the mean IOP for each eye for that visit. The mean IOPs of all preoperative visits were averaged again to get the mean preoperative IOP, which was termed PreIOP and used in

TABLE 3. Estimated Results and Regression Coefficients Regarding Age, Gender, and Preoperative Clinical Correlates Included in Linear Mixed Model

Variable	Estimate (SE)	*t*	*P*
Intercept (α)	0.5256 (4.9056)	0.11	0.9148
PreIOP (β_1)	0.3220 (0.0403)	7.98	<0.0001
PreCCT (β_2)	0.0154 (0.0042)	3.67	0.0003
PreCCK (β_3)	−0.0841 (0.1072)	−0.78	0.4341
PreRE (β_4)	−0.2253 (0.0948)	−2.38	0.0189
Ablation depth (β_5)	−0.0527 (0.0115)	−4.57	<0.0001
Gender* (β_6)	0.6917 (0.3451)	2.00	0.0471
OPAge† (β_7)	0.6085 (0.3118)	1.95	0.0531

PreIOP = preoperative IOP; PreCCT = preoperative central corneal thickness; PreCCK = preoperative central corneal curvature; PreRE = preoperative spherical equivalent refractive error; Gender = categories of gender of subjects; OPAge = categories of age at operation; SE = standard error.

*When subject is male then Gender = 1, otherwise Gender = 0.

†When age at operation is older than 30 years then OPAge = 1, otherwise OPAge = 0.

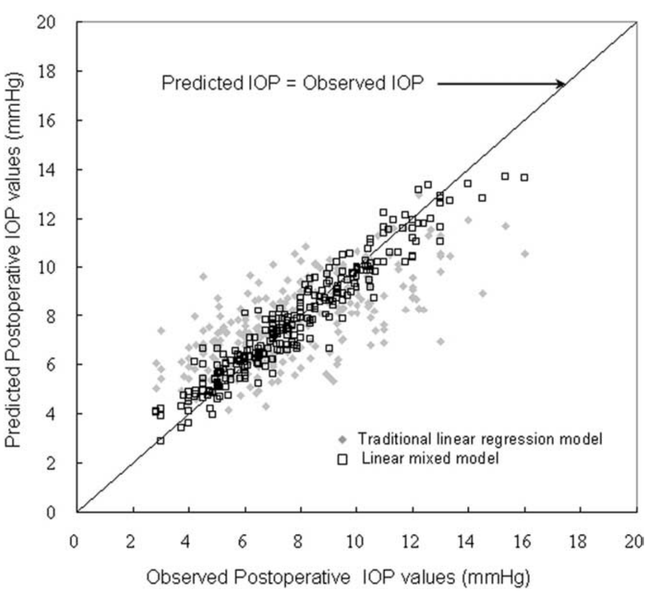

FIGURE. The observed postoperative intraocular pressure (IOP) values (taken from medical chart records) against the predicted ones from using two models: traditional linear regression model (without random effect) vs linear mixed model (with random effect).

the predictive model. The mean postoperative IOP, PosIOP used in the model, was calculated the same way.

We also compared different models using forward method for selecting variables according to the order of AIC (Akaike's information criterion) values.[21] The smaller the value of AIC the better the model fits. To check the adequacy of a model, we calculated the square of the difference between the observed and the predicted postoperative IOP values, for example, residual sum of squares, to estimate unexplained proportion of IOP variation (residual sum of squares/total variation) after fitting the linear mixed model. To check the consistency of IOP measurements from the same eye in each visit, we calculated the intra-rater correlation coefficients between any two values of preoperative IOP from three measurements in each visit. To check the consistency of IOP measurements at different visits for each eye, we calculated the inter-rater correlation coefficients between any two average IOP values at different visits from three visits either before or after LASIK.

RESULTS

TABLE 1 SHOWS DESCRIPTIVE RESULTS OF AGE, IOP BEFORE and after LASIK (PreIOP and PosIOP), preoperative refractive error (PreRE), preoperative central corneal thickness (PreCCT), preoperative central corneal curvature (PreCCK), and ablation depth.

As inter-rater correlation coefficients of preoperative IOP measurements between different visits for each eye were higher than 0.6 ($P < .05$), the variation between IOP measurements at different visits of the same eye was acceptable, and the measurements were consistent between visits. The intra-rater correlation coefficients between three measurements of IOP from the same eye in each visit for either preoperative or postoperative IOP were higher than 0.8 ($P < .05$).

The changes in IOP before and after LASIK for both eyes are summarized in Table 2. The difference in IOP before and after LASIK was statistically significant ($t = 36.54$, $P < .0001$). This suggests that there were lower readings of IOP after LASIK with noncontact tonometry (NCT). Table 3 also shows age-specific and gender-specific changes of IOP. The change in IOP before and after LASIK was statistically significant irrespective of age and gender.

TABLE 4. Explanatory Variables and Predicted Postoperative IOP Illustrated with Three Selected Cases in the Linear Mixed Model

Patient Number	Eye*	PreIOP (x_1)	PreCCT (x_2)	PreCCK (x_3)	PreRE (x_4)	Ablation Depth (x_5)	Gender† (x_6)	OPAge‡ (x_7)	PosIOP	Random Effect (γz)	Predicted Postoperative IOP ($\tilde{y}$)
1	1	14	554	41.2475	−5.375	46	1	0	11.5	1.073	10.6478
1	2	15	578	41.1850	−5.625	53	1	0	10.5	1.073	11.0321
2	1	12.5	635	42.7150	−10.250	110	1	0	5.25	−1.5071	6.4342
2	2	12.5	630	42.9025	−10.1875	105	1	0	7.25	−1.5071	6.5908
3	1	14	590	43.4325	−10.375	117	1	1	6.9	−0.9811	6.9576
3	2	16.4444	580	43.4650	−10.125	112	1	1	7.5	−0.9811	7.7952

$\tilde{y} = \alpha + \beta_1 x_1 + \beta_2 x_2 + \ldots + \beta_7 x_7 + \gamma z$, where $\alpha, \beta_1, \beta_2, \ldots, \beta_7$ are the regression coefficients in Table 3.

For example, the predictive postoperative IOP of the right eye of patient number 1 (who was male and younger than 30 years old) is $10.6478 = 0.5256 + 0.3220 \times 14 + 0.0154 \times 554 - 0.0841 \times 41.2475 - 0.2253 \times (-5.375) - 0.0527 \times 46 + 0.6917 \times 1 + 0.6085 \times 0 + 1.073$.

IOP = intraocular pressure; PreIOP = preoperative IOP; PreCCT = preoperative central corneal thickness; PreCCK = preoperative central corneal curvature; PreRE = preoperative spherical equivalent refractive error; Gender = categories of gender of subjects; OPAge = categories of age at operation.

*Right eye is Eye = 1, and left eye is Eye = 2 in each subject.

†When subject is male then Gender = 1, otherwise Gender = 0.

‡When age at operation is older than 30 years then OPAge = 1, otherwise OPAge = 0.

Table 3 shows the results of analysis using a linear mixed model. The parsimonious model we identified was the one that included significant predictors of preoperative IOP ($t = 7.98$, $P < .0001$), preoperative CCT ($t = 3.67$, $P = .0003$), preoperative spherical equivalent refractive errors ($t = -2.38$, $P = .0189$), ablation depth ($t = -4.57$, $P < .0001$), age ($t = 1.95$, $P = .0531$), and gender ($t = 2.00$, $P = .0471$). There was a pretty good fit between the observed and the predicted postoperative IOP. Residual sum of squares (unexplained proportion) was 134.12. In other words, the current model accounts for 91% (= [(1666 − 134.12)/1666] ×100%) = explained variation/total variation) of the variation of postoperative IOP. The observed and predicted postoperative IOP values using mixed model were plotted in the Figure. There is a perfect fit of the model.

Table 4 shows the predicted postoperative IOP ($\tilde{y}$) and the observed one (PosIOP) of three selected cases in the linear mixed model and the corresponding values of explanatory variables in linear mixed model. The amount of the underestimation of IOP after LASIK, 8.65 mm Hg in the left eye of the third patient, for example, can be estimated by deducting predicted postoperative IOP ($\tilde{y} = 7.80$) from preoperative IOP ($x_1 = 16.44$).

DISCUSSION

ALTHOUGH THE UNDERESTIMATION OF IOP AFTER LASIK has been reported, awareness of recording IOP immediately after LASIK is often neglected in Taiwan. Ignorance of the underestimation of IOP resulting from LASIK procedure may not be a serious problem immediately after LASIK but will be particularly critical for subjects who undergo LASIK at a young age and have a high likelihood of developing glaucoma in old age; these are the myopic patients whose elevated IOP may be masked and glaucoma may, therefore, be underdiagnosed.[22]

Consequently, we developed a statistical model to predict postoperative IOP after myopic LASIK procedure by a constellation of preoperative correlates including age, gender, preoperative IOP, preoperative central corneal thickness, preoperative spherical equivalent refractive error, preoperative central corneal curvature, and ablation depth by excimer laser. The details of discussion are delineated as follows.

• **UNDERESTIMATION OF IOP BY VARIOUS METHODS:** The underestimation of IOP is more likely to be found with certain instruments for IOP measurement such as Goldmann applanation tonometry (GAT) and noncontact tonometry (NCT).[2,22–25] Although some new tonometry instruments have been employed to obviate this underestimation of IOP after LASIK,[26–28] the popularity and accuracy of these new tonometers are not well accepted. In our study, technique the IOP measurements is used for noncontact air-puff tonometry (NCT) both preoperatively and postoperatively, the most popular method used for measuring IOP in Taiwan. NCT is particularly useful after LASIK because it is simple and safe, especially when used immediately after LASIK surgery, taking advantage of noncontact with corneal flap. More importantly, NCT has been considered to have good correlation with GAT, which is deemed as a gold standard method and extensively used in western countries.[29,30]

• COMPARISON WITH PREVIOUS STUDIES: Consistent with most of previous studies, the decrease of IOP after LASIK using NCT as a measurement instrument was statistically significant in our study. Regarding the associations between relevant correlates and postoperative IOP, our significant results pertaining to the effect of ablation depth and preoperative CCT on postoperative IOP were consistent with previous findings that reported significant associations between the difference of CCT and the change in IOP.[7,8,23,27,28]

Preoperative spherical equivalent refractive error was also found to be marginally associated with decrease of postoperative IOP. This finding was also comparable to the previous findings.[8,23]

The amount of underestimated IOP has also been predicted by Chiharal and associates.[9] However, our study was different from their study in three respects, including property of samples, statistical method, and application. Their samples were based on right eyes of 100 patients who underwent LASIK whereas we took both eyes from 193 patients. As our study is intended to apply the amount of underestimated IOP to correct IOP in long-term follow-up, it may be more sensible to use both eyes of subjects. Because the samples taken were from the right eye of each patient, assumption on independent samples was used in their stepwise multiple regression analysis with forward selection. This is what we used in our linear regression model without considering random effect. Our result based on independent assumption was similar to their finding (data not shown). The proportion is around 45% in our model and 48% in their model. Because of the independent assumption in their study, the correlation between preoperative variables and postoperative IOP was assessed at 1 month and 3 months separately rather than analyzed with a classic longitudinal model that includes serial IOP measurements in one model. It should be noted that independent assumption might lead to conservative results not only because correlation between two outcomes cannot be taken into account but because other unknown factors such as genetic variation cannot be filtered out without using a longitudinal model (that is, linear mixed model).[20] As demonstrated in our study, using random effect increases predictive ability up to 91%. This accounts for why our model has much higher predictive effect. However, since the number of sample is not large in our study, the higher predictive validity should be confirmed in the future.

• APPLICATION OF PREDICTIVE MODEL: Using our predictive model, we can predict postoperative IOP after myopic LASIK procedure with accuracy, especially when IOP immediately after LASIK is not available. Thus, the exact amount of underestimated IOP can be known and applied to correct IOP in long-term follow-up to detect a truly elevated IOP. Our predictive model provides the predicted value of IOP immediately after LASIK based only on age, gender, preoperative IOP, preoperative CCT, preoperative spherical equivalent refractive error, and ablation depth, given correlated IOP as a result of using both eyes of the same subject and serial measurements in the same eye. It can also be used for early detection of truly ocular hypertension and glaucoma among patients who undergo LASIK. This means a subject undergoing LASIK at 30 years of age without the knowledge of postoperative IOP and having preoperative IOP of 17 mmHg in the left eye, may, at 50 years of age, have actual IOP higher than 17 mmHg. If the predicted change of IOP from LASIK procedure is 5 mmHg, by subtracting predicted postoperative IOP from preoperative IOP, the true value of IOP is expected to be 22 mmHg, which is higher than 20 mmHg and defined as ocular hypertension, a main risk factor of glaucoma.

Note that the predictive model is not only cut for noncontact tonometry but also for other kinds of tonometry, particularly the Goldmann type, which is probably the most common method used in the world.

• LIMITATIONS OF STUDY: There are two limitations in this study. First, we did not routinely measure flap thickness created during LASIK procedure. The corneal biomechanical changes such as true flap thickness created by microkeratome, true ablation depth removed by laser, and interlamellar healing after LASIK do influence corneal stiffness and play an important role in postoperative IOP measurement. However, these changes and their influences on IOP vary greatly from eye to eye, decided by a subject's corneal characteristics, surgeon's usual practice, and instrumental factors such as types of microkeratome. We use Automated Corneal Shaper (ACS) microkeratome with an attempted flap thickness of 160 μm. In previous reports,[31,32] factors that influence flap thickness may include preoperative keratometry, preoperative central corneal thickness, patient age, preoperative refraction error, and corneal diameter. As these clinical correlates have been taken into account in our final model, we believe these variables may capture the influence of flap thickness. We believe this influence may be small. Second, as the present study was based on only 386 eyes of 193 patients, this sample size may preclude the predictive model developed in the current study from being generalized to external data on patients undergoing LASIK because the determinants related to postoperative IOP may also vary with race and different ophthalmologists performing LASIK, which have not been considered in the current study.

In conclusion, the predictive model using linear mixed model is predictive of postoperative IOP and useful for predicting the amount of underestimation of IOP after LASIK for myopia and myopic astigmatism, which is of clinical importance to detect ocular hypertension for patients in the absence of information on postoperative IOP immediately after LASIK.

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Biosketch

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