Myopic laser in situ keratomileusis retreatment: Incidence and associations

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PURPOSE: To determine the factors associated with retreatment after laser in situ keratomileusis (LASIK) for myopic eyes in the modern LASIK era.

SETTING: Care-Vision Laser Centers, Tel-Aviv, Israel.

DESIGN: Retrospective cohort study.

METHODS: All cases of myopic LASIK performed between January 2005 and December 2012 were analyzed according to whether they had retreatment refractive surgery.

RESULT: The study evaluated 9177 right eyes in 9177 consecutive LASIK cases. The mean preoperative subjective spherical equivalent and astigmatism were −3.30 diopters (D) ± 1.53 (SD) (range −0.50 to −12.00 D) and 0.69 ± 0.94 D (range 0.00 to 6.00 D), respectively. Of the eyes, 165 (1.80%) had at least 1 retreatment. Over the course of the study, the 2-year retreatment rate decreased from 2.58% to 0.38% ($P < .001$). Multiple binary logistic regression analysis showed that older age (odds ratio [OR], 1.03; $P = .007$), higher astigmatism (OR, 1.23; $P = .008$), sphere (OR, 1.15; $P = .026$), and mean keratometric power (OR, 1.13; $P = .036$) significantly increased the odds for retreatment. A larger optical zone ablation (7.0 mm) significantly decreased the odds for retreatment (OR, 0.10; $P = .022$). Significant cutoffs associated with retreatments were age greater than 50 years, astigmatism more than 1.5 D, and sphere more than 2.0 D.

CONCLUSIONS: Older age and higher preoperative astigmatism, sphere, and corneal steepness were associated with myopic LASIK retreatment. Larger optical ablation zones might decrease retreatment rates.

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The incidence of retreatment surgery, also known as an enhancement, is 1 of the key parameters refractive surgeons use for assessing their surgical success. Over the past 20 years, laser in situ keratomileusis (LASIK) techniques have improved, resulting in better outcomes. In 2000, Patel et al.[1] reported retreatment rates up to 16%. In 2003, Hersh et al.[2] reported a 10.5% incidence of retreatment, with higher initial corrections, astigmatism, and older age being significant risk factors for LASIK retreatment. In 2009, Randleman et al.[3] reported a 6.3% retreatment rate and found that hyperopic eyes or those with higher astigmatism were more likely to have retreatment. In 2010, Yuen et al.[4] reported an overall retreatment rate of 3.8% at a single Asian institution.

The decrease in retreatment rates over the years is thought to be the result of increased surgeon experience and improvements in laser technology and nomograms.[4] Other factors that might influence the myopic LASIK retreatment rate include patient and surgeon expectations, intentional undertreatment and overtreatment, environmental conditions, and patient age.[2]

The purpose of this study was to assess the retreatment incidence and risk factors in the more recent era, which has had the benefits of significant surgeon experience and technological advances.

PATIENTS AND METHODS

All data for the study were collected and analyzed in accordance with the policies of the Institutional Review Board,

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Barzilai Medical Center, Ashkelon, Israel, and with the tenets of the Declaration of Helsinki.

Patients

This retrospective study included consecutive right eyes treated with LASIK between January 2005 and December 2012 at Care-Vision Laser Centers, Tel-Aviv, Israel. One of 5 high-volume surgeons performed the surgeries using standardized protocols. Inclusion criteria were age over 18 years, a stable refraction for at least 12 months, intraocular pressure less than 21 mm Hg, a period without wearing contact lenses (>2 weeks for rigid contact lenses and >4 days for soft contact lenses), and no history of autoimmune disease, diabetes, or previous ocular surgery. The choice between LASIK and photorefractive keratectomy (PRK) was made by the operating surgeon in according to each patient's parameters. The 5 surgeons at the center usually do not recommend LASIK when the central corneal thickness (CCT) is less than 500 μm.

Data Collection

The medical files of all eligible patients were reviewed and the following demographic and preoperative information was extracted: age, sex, date of surgery, CCT using a 20 MHz pachymeter probe (Sonomed Escalon), preoperative subjective sphere (associated with minus cylinder), preoperative subjective spherical equivalent (SE) up to −12.00 diopters (D), preoperative subjective astigmatism up to −6.00 D, mean keratometric (K) power, Placido-disk corneal topography, minimum K power, maximum K power, cylinder axis (with-the-rule minus astigmatism, defined as the cylinder axis within 30 degrees of the horizontal, and against-the-rule, defined as the cylinder axis within 30 degrees of the vertical), uncorrected distance visual acuity (UDVA), and corrected distance visual acuity (CDVA). The following intraoperative information was extracted: operating room humidity, operating room temperature, optical zone, maximum ablation depth, and the involved eye (right or left).

Surgical Technique

All patients had LASIK using a similar technique. One drop of a topical anesthetic (benoxinate hydrochloride 0.4%) was instilled in the conjunctival fornix of the eye before surgery, after which a lid speculum was inserted. A microkeratome (Moria SA) with a thickness plate of 90 μm was used to create the flap with a nasal hinge. After flap creation, a Wavelight Allegretto 200 Hz excimer laser (Alcon Laboratories, Inc.) or an LSX 200 Hz excimer laser (Lasersight Technologies, Inc.) was used. The corneal bed was dried with clean hard-foam sponges. After the surgery, patients were prescribed moxifloxacin 0.5%, dexamethasone 0.1%, and artificial tears. Patients were examined postoperatively at 1 day; 1 week; 1, 3, and 6 months; and then as necessary. Patients were encouraged to return for an examination if their vision deteriorated at any time after surgery. Retreatment surgery was offered free of charge and encouraged.

Statistical Analysis

Data were analyzed with the Minitab software (version 16, Minitab, Inc.). For the analysis of continuous data, the Student *t* test was used for normally distributed variables and the Kruskal-Wallis for nonparametric variables. For the analysis of categorical variables, the chi-square test was used and, when applicable, odds ratios (ORs) were calculated. Multivariate binary logistic regression analysis, using year of surgery (follow-up time) as a confounder, was performed to determine predictors for retreatment. For this purpose, only independent variables that were significant or close to significant in the univariate analysis were included. Finally, variables that entered the multivariate analysis were stratified and categorically graphed as retreatment rates; the retreatment rate of each subgroup was compared with the overall retreatment rate using the chi-square test, and Bonferroni correction was applied for these multiple comparisons to prevent a type I error. The rationale for this categorical analysis was to determine categorical cutoffs (subgroups) that were associated with increased and decreased retreatment rates. In all analyses, a 2-sided P value less than 0.05 was considered statistically significant. All presented means are accompanied by their respective standard deviations.

RESULTS

The final analysis comprised 9177 right eyes of 9177 consecutive patients. The mean age of the patients was 29.9 ± 8.8 years, and 4950 (54.0%) were men. The mean preoperative subjective SE and astigmatism were −3.30 ± 1.53 D (range −0.50 to −12.00 D; first quartile 2.13, third quartile 4.25) and 0.69 ± 0.94 D (range 0.00 to 6.00 D; first quartile 0.00, third quartile 1.00), respectively.

One hundred sixty-five eyes (1.80%) were retreated. Of these, 160 (1.74%) had a single retreatment, 4 (0.04%) had 2 retreatments, and 1 (0.01%) had 3 retreatments. For each study year, a 2-year follow-up retreatment rate was calculated (Figure 1). There was a significant drop in the 2-year retreatment rate throughout the study period, decreasing from 32 (2.58%) for primary LASIK treatments performed in 2005 to 3 (0.38%) for LASIK treatments performed in 2012 ($R^2 = 0.90$, $P < .001$). The mean length of time between initial treatment and retreatment was 26.1 ± 24.5 months (range 1 to 94 months) (Figure 2).

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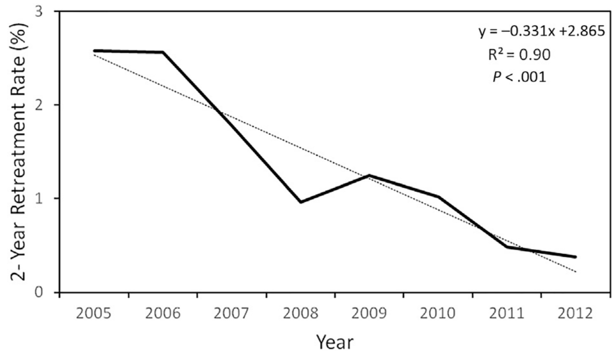

Figure 1. The decrease in the 2-year retreatment rate (*solid line*) from 2005 through 2012.

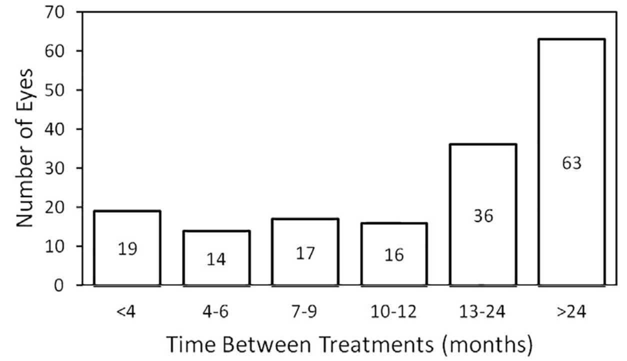

Figure 2. Time between primary treatment and retreatment.

Table 1 shows the results of the univariate analysis comparing demographic, preoperative, and intraoperative parameters in the retreatment group and the control group. The retreatment group had significantly higher preoperative subjective astigmatism, subjective SE, and keratometric power; a worse preoperative UDVA; and was significantly less likely to have had a large optical zone ablation of 7.0 mm. Retreatment group patients tended (trend that did not reach statistical significance of 0.05) to be older and tended to

Table 1. Comparison of preoperative and intraoperative variables.

Parameter	Retreatment Group (n = 165)	Control Group (n = 9012)	Odds Ratio	95% CI	*P* Value
Sex (%, male)	54.3	53.9	1.01	0.74, 1.38	.96
Subjective astigmatism >1.0 D (%)	26.1	19.1	1.49	1.05, 2.12	.03
Subjective astigmatism >1.5 D (%)	16.4	10.0	1.85	1.35, 2.52	.007
Astigmatic axis WTR (%)	67.1	71.2	1.21	0.87, 1.17	.26
Optical zone (%)					
6.0 mm	16.0	12.0	1.40	0.91, 2.15	.13
6.5 mm	80.8	79.1	1.11	0.74, 1.66	.60
7.0 mm	3.2	8.9	0.34	0.14, 0.83	.02
Mean age (y) ± SD	31.3 ± 10.6	29.8 ± 8.8	—	—	.07
Mean UDVA (logMAR) ± SD	1.32 ± 0.55	1.21 ± 0.58	—	—	.02
Mean CDVA (logMAR) ± SD	−0.02 ± 0.08	−0.02 ± 0.07	—	—	.60
Mean subjective astigmatism (D) ± SD	0.86 ± 0.89	0.69 ± 0.95	—	—	.01
Mean SE (D) ± SD	−3.62 ± 1.49	−3.30 ± 1.53	—	—	.007
Mean sphere (D) ± SD	−3.19 ± 1.55	−2.95 ± 1.55	—	—	.06
Mean Kmin (D) ± SD	43.48 ± 1.23	43.16 ± 1.35	—	—	.02
Mean Kmax (D) ± SD	44.47 ± 1.23	44.10 ± 1.37	—	—	.007
Mean Kmean (D) ± SD	44.15 ± 1.31	43.77 ± 2.26	—	—	.003
Mean CCT (μm) ± SD	547.3 ± 32.2	546.4 ± 31.5	—	—	.74
Mean ablation depth (μm) ± SD	60.5 ± 23.9	57.4 ± 31.6	—	—	.11
Mean humidity (%) ± SD	38.01 ± 1.26	38.03 ± 1.94	—	—	.82
Mean temperature (Celsius) ± SD	22.58 ± 1.45	22.70 ± 1.52	—	—	.30

CCT = central corneal thickness; CDVA = corrected distance visual acuity (with spectacles); CI = confidence interval; Kmax = maximum keratometric power; Kmean = mean keratometric power; Kmin = minimum keratometric power; SE = spherical equivalent; UDVA = uncorrected distance visual acuity; WTR = with the rule

Categorical variables are presented as percentages with appropriate odds ratio and continuous variables as the mean ± SD.

Table 2. Logistic regression analysis of factors predicting retreatment.

Parameter*	Odds Ratio	95% CI	*P* Value
Year of primary surgery	0.63	0.43, 0.91	.01
Age (y)	1.03	1.01, 1.05	.007
Subjective astigmatism (D)	1.23	1.06, 1.44	.008
Subjective sphere (D)	1.15	1.02, 1.30	.026
Kmean (D)	1.13	1.01, 1.27	.036
Optical zone 7.0 mm	0.10	0.01, 0.72	.022

CI = confidence interval; Kmean = mean keratometric power
*All parameters are continuous variables except for the optical zone of 7.0 mm, which was compared with the 6.0 mm and 6.5 mm pooled optical zones.

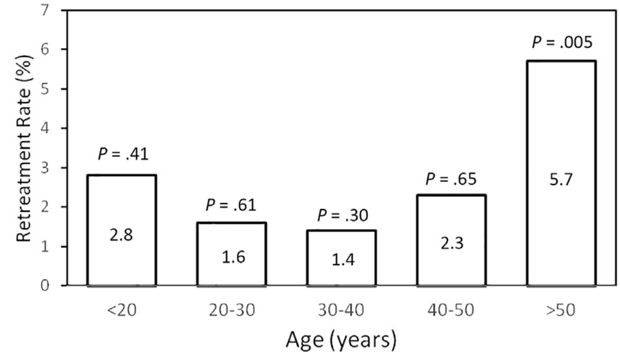

Figure 3. Retreatment rates stratified by age. The *P* values, Bonferroni correction applied, reflect chi-square tests comparing the retreatment rate in each subgroup with the overall retreatment rate of 1.80%.

have a higher subjective preoperative sphere. No statistically significant differences were seen in preoperative CDVA, astigmatism axis, CCT, ablation depth, and operating room humidity or temperature. Comparing retreatment rates between the 5 surgeons yielded no significant differences.

Table 2 shows the factors increasing the odds for retreatment based on multiple logistic regression analysis. The year of the primary LASIK surgery, older preoperative age, higher preoperative subjective astigmatism, higher preoperative subjective sphere, and higher preoperative mean K significantly increased the odds for retreatment. A large optical zone ablation (7.0 mm) significantly decreased the odds for retreatment (comparisons made with pooled optical zones of 6.0 mm and 6.5 mm).

Figure 3 shows the retreatment rate stratified for age. The 30- to 40-year-old subgroup had a lower retreatment rate than any other age subgroup. Older age was associated with significantly higher retreatment rates, as seen in the over 50-year-old subgroup. There was an inverse correlation between age and time between retreatments (Pearson $r = 0.36$, $P < .001$).

A preoperative subjective astigmatism of less than 1.5 D was associated with retreatment rates significantly lower than the overall retreatment rate of 1.80% ($P = .03$) (Figure 4). The retreatment rate was higher, although not statistically significant, for astigmatism subgroups 1.5 to 2.5 D and more than 2.5 D. These 2 subgroups had similar retreatment rates. Without Bonferroni correction, the 1.5 to 2.5 D subgroup had a significantly higher retreatment rate than the overall retreatment rate ($P = .04$). The only sphere subgroup that had a significantly different retreatment rate was the less than 2.0 D group, whose rate was significantly lower than the overall retreatment rate (Figure 5). The higher sphere subgroups had similar retreatment rates. Although higher mean

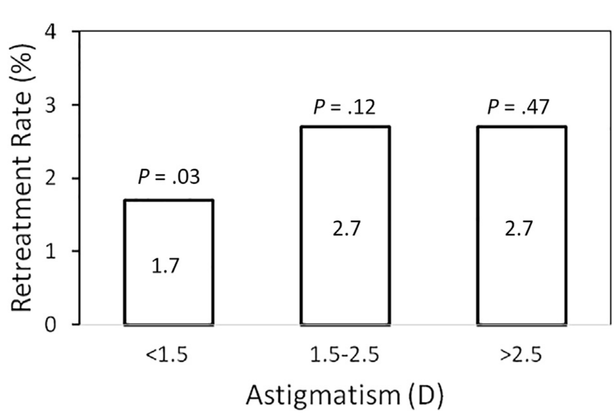

Figure 4. Retreatment rates stratified by astigmatism. The *P* values, Bonferroni correction applied, reflect chi-square tests comparing the retreatment rate in each subgroup with the overall retreatment rate of 1.80%.

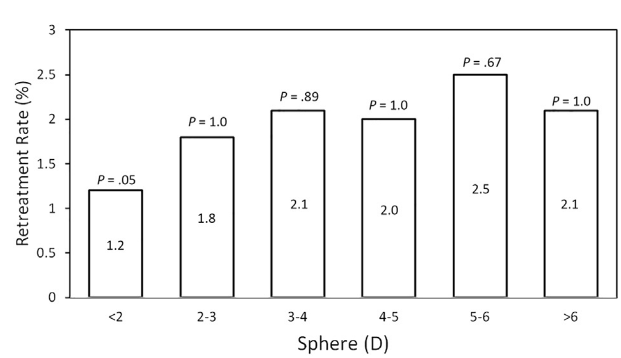

Figure 5. Retreatment rates stratified by sphere. The *P* values, Bonferroni correction applied, reflect chi-square tests comparing the retreatment rate in each subgroup with the overall retreatment rate of 1.80%.

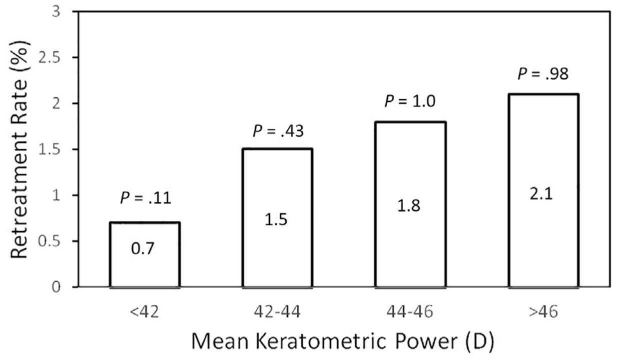

Figure 6. Retreatment rates stratified by mean keratometric power. The P values, Bonferroni correction applied, reflect chi-square tests comparing the retreatment rate in each subgroup with the overall retreatment rate of 1.80%.

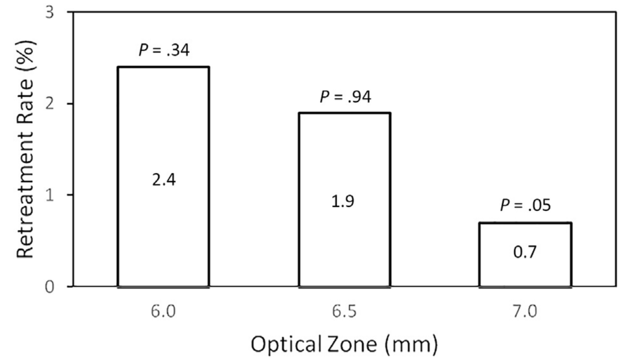

Figure 7. Retreatment rates stratified by optical zone. The P values, Bonferroni correction applied, reflect chi-square tests comparing the retreatment rate in each subgroup with the overall retreatment rate of 1.80%.

K subgroups were associated with higher retreatment rates, no subgroup's retreatment rate was significantly different from the overall retreatment rate (Figure 6). Without Bonferroni correction, the less than 42.0 D subgroup had a significantly lower retreatment rate than the overall retreatment rate (P = .03). The 7.0 mm optical zone ablation subgroup had a significantly lower retreatment rate than the overall retreatment rate (P = .05) (Figure 7). There was no statistically significant difference between subgroups 6.0 mm optical zone ablation and 6.5 mm optical zone ablation.

DISCUSSION

This retrospective large database analysis of the preoperative and intraoperative parameters associated with retreatment after myopic LASIK showed that older age as well as higher subjective astigmatism, sphere, and keratometric power significantly increased the odds for having retreatment surgery. A larger optical zone ablation (7.0 mm) and more recent primary surgery significantly decreased the odds for retreatment. These 6 parameters were significant on multivariate analysis.

We found that age over 50 years significantly increased the odds for retreatment. Older age has been reported as a significant retreatment risk.[2,5] Surgeons are careful not to overtreat eyes with myopic presbyopia and, therefore, there is a smaller margin of error than when treating young patients with myopia.[6] A second explanation could be that patients older than 50 might develop nuclear sclerosis, which might cause a myopic shift. In our cohort, many eyes were retreated more than 2 years after the initial surgery (Figure 2) and older patients had more time to retreatment; thus, a nuclear sclerosis–induced myopic shift was feasible.

We found that subjective preoperative astigmatism had a higher OR and lower P value associated with retreatment than any other ocular parameter. For each diopter of astigmatism, the odds for retreatment were 1.23 times greater (OR, 1.23; 95% confidence interval [CI], 1.06-1.44; P = .008). This corroborates the findings in earlier studies.[2,3,6] Hu et al.[5] found astigmatism to be significant on univariate analysis but insignificant on multivariate analysis because surgeon factor, patient age, and high sphere dominated their multivariate analysis. Possible reasons for astigmatism increasing the odds for retreatment more than sphere are that nomograms are less forgiving of inaccuracies for astigmatism treatment and ablation centration is more important for astigmatism treatment than it is for spherical treatment. Another explanation is the tendency of the epithelium to reduce the corneal asymmetry caused by large astigmatic ablation, leading to regression of the astigmatic treatment. This mechanism is similar to that suggested by Chayet et al.,[7] that the epithelium might increase in thickness after LASIK, causing regression of the treatment effect.

High preoperative sphere and SE have been well documented to be significantly associated with retreatments.[2,5,8] Our univariate analysis showed that sphere tended to be related to retreatment, although it was not statistically significant. The multivariate analysis showed that sphere did statistically increase the odds for retreatment (OR, 1.15; 95% CI, 1.02-1.30; P = .026). Only the less than 2.0 D subgroup was significantly different from the overall retreatment rate (lower). This suggests that in the modern LASIK era, very low myopic sphere is associated with less retreatment; however, between −2.0 D and −12.0 D, there is no relationship with the retreatment rate.

A possible explanation for our results differing from those in the aforementioned studies is that our cohort was less myopic. Historically, LASIK was introduced as a solution for eyes with high myopia developing corneal haze after PRK. As experience increased with LASIK, it became popular for lower myopia and the preference for very high myopia (>12.0 D) became intraocular lens (IOL) implantation.[9] Therefore our cohort (primary surgeries during 2005 to 2012 with no myopia higher than 12.0 D) was significantly less myopic than the cohorts in published studies (primary surgeries during 1997 to 2007).[2,5,8] The mean preoperative sphere and SE in our retreatment eyes were −3.19 ± 1.55 D and −3.62 ± 1.49 D, respectively (Table 1). Hersh et al.[2] reported a mean SE of 6.23±2.83 D, Hu et al.[5] found a mean sphere of −7.24 ± 2.5 D, and Zadok et al.[8] reported a mean SE of −9.2 ± 4.4.8 D. Yuen et al.[4] found a mean SE of approximately −8.0 D for the initial 2 years of LASIK in their practice, after which they preferred phakic IOL implantation for myopia of more than 12.0 D. Another possible explanation is that nomograms for myopic sphere have improved since these studies were performed and during the era of our study, they reached a higher level of precision.

We found that higher K power (mean K) significantly increased the odds for retreatment (OR, 1.13 for each diopter; 95% CI, 1.01-1.27; $P = .036$). To our knowledge, in earlier published studies, a higher K power did not significantly increase the odds for retreatment. This inconsistency with results in previous studies could be explained by the very high preoperative sphere and astigmatism commonly treated in the early LASIK studies, masking the subtler association between high K power and retreatment. As mentioned above, the most recent trend is to use other surgical options for cases with very high preoperative sphere and astigmatism, thus excluding these cases from our cohort. Intraoperative flap complications are more common with steep corneas, increasing the likelihood of retreatment.[10] Another possibility is that some of these steep corneas that were less stable, and therefore regressed more, might have had forme fruste keratoconus.

The larger ablation zone of 7.0 mm might decrease the odds for retreatment by providing a larger buffer zone for ablations decentered relative to the visual axis, such as eyes with a large angle κ. If the discrepancy between the anatomic corneal center and the visual axis is large, there is a significant risk for a decentered ablation, which might cause glare, halos, and surgically induced astigmatism.[11]

Even though the retreatment group had significantly worse preoperative UDVA, this association was not borne out by the additional analyses that we performed. This could be the result of overlapping statistical effects of low UDVA and high astigmatism and sphere in the multivariate analysis. Furthermore, UDVA might be relatively inaccurate because patients with myopia can easily increase their UDVA with an eyelid pinhole effect, often without the examiner's knowledge.

Operating room temperature and humidity did not influence the retreatment rate in our cohort. This corroborates results in a large LASIK database study[12] that showed operating room temperature and humidity were not associated with refractive outcomes.

Our study has limitations. The retrospective nature means that retreatments for undertreatment, overtreatment, myopic regression, flap problems, and differing patient tolerances to ametropia could not be differentiated. A case-by-case study of the 165 retreatments would be required to distinguish the various causes of retreatment, which we plan to do as further research. We do not know how many patients with post-LASIK ametropia did not return for retreatment, although this service was offered free of charge. Five high-volume surgeons performed the LASIK in this study. Differences in nomogram choice and surgical technique could have occurred, although all surgeons working at our institution communicate with each other and use uniform techniques. When surgeon factor was included in the multivariate analysis, it was not statistically significant and no differences in the other parameters of the multivariate analysis were seen. The primary surgeries were performed over 7 years. During this period, surgeons improved their techniques, fine tuned their nomograms, and incorporated new technologies.

This improvement in surgical technique is borne out by the significant decrease in the retreatment rate in our study when comparing years 2005 to 2012 and by the published literature.[1–4,8] Of the primary surgeries performed in 2012 through the end of 2014, only 0.38% of patients who had myopic LASIK required retreatment. For every increase in the year of primary surgery, there was a decrease in the odds for retreatment by 0.63 (OR, 0.63; 95% CI, 0.43-0.91; $P = .01$). This is promising, although the rarity of LASIK retreatments in the modern era makes it more difficult to study, which gives importance to the data presented here. We believe that special consideration of age over 50 years, preoperative astigmatism more than 1.5 D, preoperative sphere more than 2.0 D, and eyes with steep corneas in nomogram formulation, as well as using larger optic zone ablations when possible, will further decrease the need for retreatment after myopic LASIK.

WHAT WAS KNOWN

- Older age, higher initial corrections, and astigmatism increase the risk for retreatment after myopic LASIK.
- Retreatment rates decrease as experience is gained and technology improved.

WHAT THIS PAPER ADDS

- The myopic LASIK retreatment rate in recent years improved to below 0.5%.
- In addition to older age, higher astigmatism, and higher sphere, corneal steepness was proportionately related to retreatment.
- A larger optic zone ablation (7.0 mm) might decrease the retreatment rate.

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