ARTICLE

The effect of low predicted/calculated postoperative keratometry on corrected distance visual acuity after LASIK



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Purpose: To compare refractive outcomes of eyes with flat keratometry (K) to matched controls after myopic laser in situ keratomileusis (LASIK).

Setting: Boston Eye Group, Brookline, Massachusetts, USA.

Design: Retrospective review.

Methods: Eyes that had LASIK between December 2008 and December 2018 were retrospectively analyzed and matched based on calculated postoperative flat K values. Stratified candidate subgroups (K < 38.0 diopters [D]) were compared with control subgroups (K \geq 38.0 D).

Results: The study comprised 160 eyes (80 candidates and 80 controls). Statistical analyses showed no significant differences

between candidates and controls in preoperative corrected distance visual acuity (CDVA) (P=.150) or postoperative CDVA (P=.290). There were no significant differences in the amount of tissue ablated between all candidate and control subgroups. Similarly, there was no significant change between preoperative and postoperative CDVA between the different candidate and respective subgroups. Three (3.75%) of 80 candidate eyes versus zero control eyes lost 1+ lines of CDVA after surgery. There was no difference in CDVA lost between these groups (P=.2453).

Conclusion: There is no increased risk for loss of CDVA after LASIK attributable to flat K.

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n the ophthalmology community, it is a commonly held belief that if excimer laser treatment of myopia reduces the curvature of the central cornea beyond a specific range, there might be a loss in achievable visual acuity.¹ This range has historically been defined as a postoperative keratometry (K) value of less than 35.0 diopters (D).

Multiple investigations have examined the relationship between preoperative K values and visual acuity after myopic laser vision correction. In 2001, Rao et al. studied preoperative keratometry from 103 myopic laser in situ keratomileusis (LASIK) patients and compared it to their postoperative visual acuities. All patients were considered highly myopic, with manifest refraction spherical equivalents (MRSEs) ranging from -6.0 to -13.0 D. Regression analyses found that in eyes with similar preoperative MRSEs, eyes with flatter K values (<43.5 D) were more likely to contain residual prescription postoperatively compared with eyes with steeper K values (>44.5 D).

Along similar lines in 2012, Christiansen et al.³ compared a series of 96 moderately myopic eyes, with SEs from -2.00

to -5.99 D, and found results contradictory to those found in highly myopic eyes. In their case, flatter corneas (K < 42.0 D) achieved better visual acuities than those with steeper corneas (K > 46.0 D). Proposed explanations include positive induced spherical aberrations, corneal asphericity, and tissue remodeling.

Although some studies⁴ have looked at the overall change in keratometry or focused on preoperative K values and their effect on visual acuity after refractive surgery, they do not explore whether these variables leave the patients with flat K postoperatively. As such, current literature fails to convincingly explore the relationship between predicted or measured flat postoperative K and visual acuity. Varssano et al.⁵ attempted to tackle this issue in 2013. An investigation into photorefractive keratectomy (PRK) patients with postoperatively flat corneas (K < 35.0 D) revealed no loss in corrected distance visual acuity (CDVA). However, that study did not stratify the degree of corneal flatness and the amount of flatness-affected CDVA. They also excluded patients undergoing LASIK or laser-assisted subepithelial keratectomy (LASEK).

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In 2015, Mostafa⁶ looked at the degree of keratometric change after laser vision correction and how it affected visual acuity; however, the investigation only included results from highly myopic patients, with MRSE from -6.0 to -12.0 D. Another 2015 study⁷ looked at postoperative keratometry, but only its relation to patient satisfaction and night vision. Thus, the current body of literature would stand to benefit from further elucidation of the relationship between myopic corneal flattening after refractive laser surgery and loss of CDVA.

The primary purpose of our study was to determine whether a correlation exists between predicted postoperative flat K values less than 38.0 D and loss of CDVA. It is worth mentioning that we have used the flattest K values and not the mean K readings to sort patients into different subgroups. We further wanted to check whether the degree of corneal flatness plays a role in visual acuity outcomes after LASIK and thus divided flat corneas into 4 different subgroups by degrees of increasing flatness.

PATIENTS AND METHODS Study Design Overview

A retrospective study of eyes that had previously undergone LASIK surgery at Boston Eye Group/Boston Laser in Brookline, Massachusetts, USA, between December 2008 and December 2018, was performed. LASEK or PRK were excluded because they need a longer follow-up period to achieve refractive stability. The ablative excimer laser platforms used were the WaveLight EX500 Excimer Laser (Alcon Laboratories, Inc.) and the VISX STAR S4 IR Excimer Laser System (Abbott Medical Optics, Inc.). LASIK flaps were created with the IntraLase iFS or FS60 Laser (Abbott Medical Optics, Inc.).

To qualify as a candidate in this study, the patient must have had a calculated postoperative flat K less than 38.0 D, based on their horizontal and vertical meridian keratometries. Selection of the control group was based on a calculated postoperative flat K of 38.0 D or more. These two groups were then matched based on preoperative manifest refractions and the amount of tissue removed during surgery. Candidate eyes were further divided into 4 different subgroups by degree of increasing corneal flatness as follows: Subgroup 1a (K < 35.0 D), Subgroup 2a (K = 35.0 to 35.99 D), Subgroup 3a (K = 36.0 to 36.99 D), and Subgroup 4a (K = 37.0 to 37.99 D). These were matched by appropriate control subgroups as follows: Subgroup 1b (K = 38.0 to 38.99 D), Subgroup 2b (K = 39.0 to 39.99 D), Subgroup 3b (K = 40.0 to 40.99 D) and Subgroup 4b (K > 41). Patients were excluded if they were hyperopic, had previously had an ocular surgery procedure to correct vision (including retinal procedures), have had PRK or LASEK, or if their treatments were not wavefront-guided or optimized.

Postoperative Keratometry Calculation

The postoperative flat K values were calculated using a modified version of the mathematical formula suggested by Holladay et al. The preoperative SE was multiplied by 0.7 to yield the expected amount of anterior corneal flattening. This estimated amount of corneal flattening was then subtracted from the measured preoperative flat K values to yield the suggested calculated postoperative values. The formula reads:

Predicted/calculated postoperative flat $K = \text{preoperative flat } K - (0.7 \times \text{preoperative SE}).$

The 1:0.7 ratio for expected corneal flattening was used because it is commonly accepted in the ophthalmologic community. However, to be able to confirm whether the formula with a coefficient of 0.7 is able to accurately predict postoperative flat K, 51

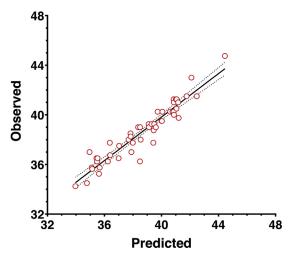


Figure 1. Postoperative keratometry observed (measured) versus predicted (calculated).

measured postoperative K values were gathered, and the measured and predicted values were compared. A regression analysis was used to compare these values. This was based on the plotting of measured and predicted values, calculating the regression r^2 (correlation of determination) and the P value. Based on these values, an r^2 value of 0.9008 with a P value of 0.0001 was calculated. This meant that there was a high degree of correlation between the measured and predicted values that was not explained by chance alone (α < .05). Figure 1 shows a plot graph of the observed (measured) versus predicted (calculated) values.

Data and Statistical Analysis

All data were deidentified. Visual acuity, measured CDVA given by the Snellen Visual Acuity Chart, was converted to logarithm of the minimum angle of resolution (logMAR) for more accurate statistical analysis. Statistical analyses were performed with SPSS Statistics for Mac software (version 24.0, IBM Corp.)

RESULTS

Eighty eyes (42 right eyes, 38 left eyes) of 80 patients were identified as candidates. Only one eye per patient was included in this study. A control population of 80 control eyes (42 right eyes, 38 left eyes) of another 80 individuals were selected by matching manifest refraction and the amount of tissue ablated with candidate patients.

Preoperative Data

Data collected from the overall candidate group showed a mean preoperative MRSE of -5.17 D \pm 1.67 (SD), mean manifest cylinder refraction of -1.05 ± 0.84 D, mean SE -5.69+1.71 D, mean tissue 79.77 \pm 19.88 µm, mean preoperative flat K of 40.64 ± 0.77 D, and mean steep K of 41.78 ± 0.97 D. Data collected from the corresponding overall control showed a mean preoperative MRSE of group -4.29 ± 1.85 D, mean manifest cylinder refraction of -0.83 ± 0.79 D, mean SE of -4.65 ± 1.86 D, mean tissue ablated 74.21 \pm 25.22 μm , mean flat K of 43.93 \pm 1.02 D, and mean steep K of 44.84 \pm 1.05 D. A two-sample t test assuming unequal variance was used to compare candidate and control mean microns of tissue ablated (P = .123) and no significant difference was found.

Table 1. Preoperative visual acuity parameters and the amount of tissue ablated in the candidate-stratified subgroups.						
	Preop Parameter					
Candidate Subgroup	Mean CDVA (logMAR) ± SD	Manifest Sph (D)	Manifest Cyl (D)	SE (D)	Actual Ablation (μm)	
1a (K < 35.0 D), n = 8	0.0025 ± 0.007	-7.8125	-1.6875	-8.6588	111.63	
2a (K = 35.0 to 35.99 D), n = 14	0.0029 ± 0.0073	-6.5179	-1.6071	-7.3243	98.21	
3a (K = 36.0 to 36.99 D), n = 22	-0.0057 ± 0.027	-4.9318	-0.7386	-5.3032	76.14	
4a (K = 37.0 to 37.99 D), n = 36	-0.003 ± 0.021	-4.1944	-0.8750	-4.6344	67.75	
Total, N = 80	-0.0021 ± 0.02	-5.1656	-1.0469	-5.6915	79.77	

CDVA = corrected distance visual acuity; Cyl = cylinder; K = keratometry value; logMAR = logarithm of the minimum angle of resolution; SE = spherical equivalent; Sph = sphere

The preoperative CDVA in logMAR was also compared between the candidate and control groups and subgroups. There was no significant difference between the candidate and control groups (P=.15), and their respective subgroups when compared with each other. Tables 1 and 2 show details about the different variables studied.

Postoperative Data

Data from the candidate group showed a mean calculated postoperative flat K of 36.66 D \pm 1.09 and mean steep K of 37.8 D \pm 1.06. The corresponding control group showed a mean calculated postoperative flat K of 40.64 D \pm 1.24 and mean steep K of 41.55 D \pm 1.32. Figure 2, A and B, show candidate and control postoperative visual acuity data. Sixty-nine (86%) of the 80 candidates (K < 38) and 72 (90%) of the 80 controls achieved an uncorrected distance visual acuity (UDVA) of 20/20. Compared with the preoperative CDVA, 11 (14%) of the candidates versus only 6 (7%) of the controls had worse postoperative UDVA.

To check for statistical significance of the above results, postoperative logMAR CDVA was compared between the candidate and control groups, and no significant differences were found (P = .290). The CDVA was further analyzed along the candidate and control subgroups. A one-way analysis of variance (ANOVA) was conducted to compare the mean postoperative logMAR CDVA between the candidate subgroups 1a, 2a, 3a, and 4a (Supplemental Table 1, available at www/jcrsjournal.org). The ANOVA showed no significant difference between the subgroup means (F[3, 77] = 0.923) (P = .434). Another one-way ANOVA was used to compare the control subgroups 1b, 2b, 3b, and 4b (Supplemental Table 2, available at

www/jcrsjournal.org). Again, there was a significant difference between these subgroup means (F[3, 77] = 1. 549) (P = .209).

Loss of CDVA and Postoperative Refractive Outcome

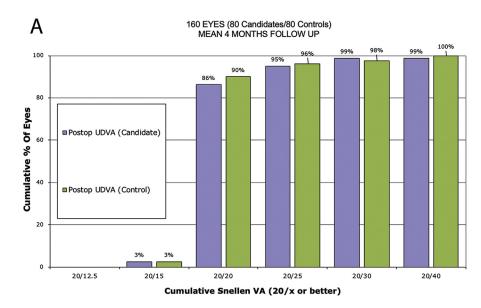
Of the overall candidate population, a total of 3 (3.75%) of the 80 eyes lost CDVA with 2 eyes losing 1 line of CDVA and 1 eye losing 2+ lines of CDVA. In the control group, none of the eyes lost any lines of CDVA (Figure 3).

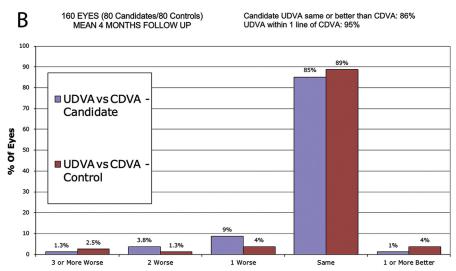
A Fisher exact test was performed to determine whether there were any statistically significant differences in the numbers of eyes losing CDVA between the candidate and control groups. The test value was equal to 0.2453, and it was not significant with a cutoff *P* value of 0.05.

The postoperative refractive outcomes were measured by level of SE accuracy to the intended target, which was a manifest refraction of plano sphere in all cases. Based on the results, 152 (95%) of the 160 candidates (K < 38.0 D) and controls (K > 38.0 D) fell within ± 0.50 D of the intended target. Also, 155 (97%) of the 180 candidates and controls fell within ± 1.00 D of the intended target (Figure 4, A and B).

This study also analyzed post-LASIK visual outcomes based on the degree of predicted postoperative corneal flatness (candidate subgroups), and Figure 5, A and B, show the UDVA and change in CDVA for the 4 candidate subgroups. A Fisher exact test for small sample sizes was conducted to discover whether CDVA loss was significant in any specific candidate subgroups when compared with their respective group category. The candidate subgroups 1a, 2a, 3a, and 4a did not significantly differ from each other when CDVA loss was compared in their grouping category (P = .2624).

Table 2. Preoperative visual acuity parameters and the amount of tissue ablated in the control-stratified subgroups.						
	Preop Parameter					
	Mean CDVA				Actual Ablation	
Control Subgroup	(logMAR) ± SD	Manifest Sph (D)	Manifest Cyl (D)	SE (D)	(μ m)	
1b (K = 38.0 to 38.99 D), n = 8	0.012 ± 0.034	-6.2813	-0.8438	-6.7075	104.00	
2b (K = 39.0 to 39.99 D), n = 14	0.007 ± 0.02	-5.4643	-1.1964	-6.0643	95.86	
3b (K = 40.0 to 40.99 D), n = 22	0.0009 ± 0.0043	-3.9773	-0.7841	-4.1777	69.14	
4b (K ≥ 41.0 D), n = 36	0.0003 ± 0.027	-3.5764	-0.7083	-3.9328	62.28	
Total, N = 80	0.0028 ± 0.023	-4.2875	-0.8281	-4.6506	74.21	





Difference between UDVA and preoperative CDVA (Snellen Lines)

Figure 2. A: Postoperative UDVA. Candidate group (K < 38.0) versus control group (K > 38.0). B: Postoperative UDVA versus preoperative CDVA. Candidate group versus control group (CDVA = corrected distance visual acuity; K = keratometry value; UDVA = uncorrected distance visual acuity; VA = visual acuity).

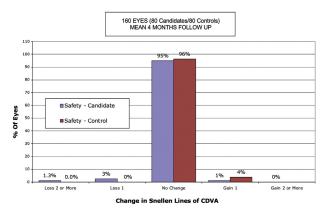
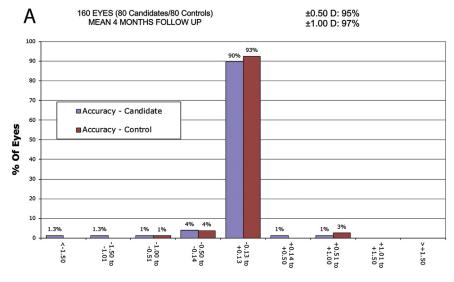


Figure 3. Change in CDVA by lines gained and lost, candidates versus controls (CDVA = corrected distance visual acuity).

To further investigate and understand the CDVA loss within each subgroup, the preoperative and postoperative CDVA measurements were compared. For each subgroup, the preoperative logMAR CDVA was compared with the postoperative logMAR CDVA via a one-way ANOVA for repeated measures. There was no significant change in any of the control or candidate subgroups (Table 3).

DISCUSSION

This study evaluated whether patients undergoing LASIK with mathematically calculated postoperative K values less than 38.0 D are at a greater risk for losing one or more lines of CDVA after surgery. In addition, we examined whether the degree of corneal curvature flatness as designated by mathematically calculated postoperative K values (K < 35.0 D, K = 35.0 to 35.99 D, K = 36.0 to



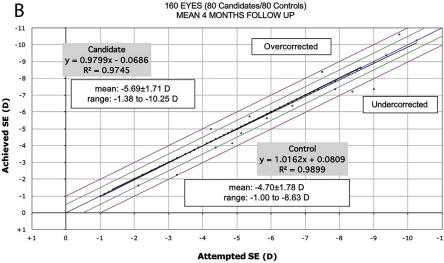


Figure 4. A: SE refraction accuracy to intended target, candidates versus controls. B: SE refraction, attempted versus achieved, candidates versus controls (SE = spherical equivalent).

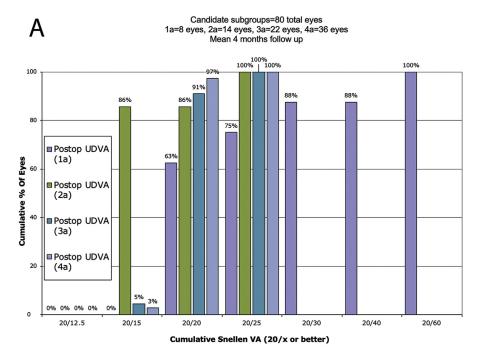
36.99 D, and K = 37.0 to 37.99 D) was related to postoperative loss of CDVA.

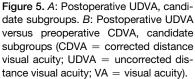
When matching candidates and controls between their respective subgroups (eg, 1a and 1b), we chose to stratify based on the amount of tissue ablated during surgery as opposed to matching solely on preoperative manifest prescriptions. Multiple rationales led to this decision. Principally, we wanted to provide as accurate a match as possible when comparing postoperative keratometry. Those with flat K values tend to have higher myopic manifest than those without, and we did not want this discrepancy to factor into our comparisons. It is also unlikely that the refractive surgeon would choose to ablate more than 40% of the corneal tissue no matter how high the MRSE because of the risks for ectasia and other compounding factors. 9,10 It follows that matching the amount of tissue removed between pairs should give a more robust pairing than manifest refraction alone. As an example, there were significant differences in subgroups 1a and 1b in sphere (P = .033) and SE (P = .026); however, because those with very high myopic manifests were

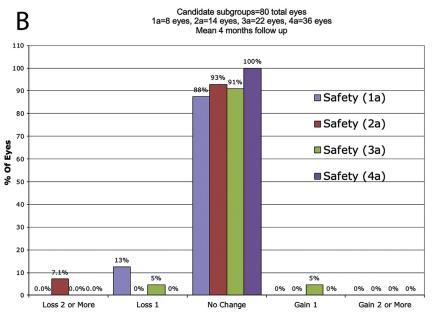
not always fully treated because of concerns about ectasia and/or that the ablation was reduced based on the excimer laser nomogram (Wellington),¹¹ there were no statistically significant differences in the amount of tissue ablated between the candidate group and the control subgroups (P = .239).

Three candidate eyes (3.75%) lost 1 or more lines of CDVA. Although no control eyes lost CDVA, upon further analysis, there was no statistically significant difference (P = .290) found between candidate eyes (K < 38.0 D) and control eyes (K \geq 38.0 D) eyes. These results were similar to those found by Varssano et al., although they chose to use different cutoff K values to determine their candidate (K < 35.0 D) and control (K \geq 35.0 D) groups. It is true that in our study, the cutoff for flatness was 38.0 D; however, we did categorize and analyze our candidate eyes by level of flatness, which included K value less than 35.0 D as a standalone category.

Although a recent Cochrane review article¹² compiles some studies in the current literature advocating the increased risk for losing CDVA after refractive surgery in







Change in Snellen Lines of CDVA

patients with a higher degree of myopia (especially -8.0 to -14.0 D) who are more likely to have flat K readings, our study found no significant differences in CDVA loss between the candidate or control subgroups. This is supportive of statements by Varssano et al. Their candidate group had no significant difference in CDVA loss compared with the control group. A study by Mostafa et al. Stratified patients by degree of myopia (-6.0 to -7.9 D, -8.0 to -9.9 D, and -10.0 to -12.0 D) and measured their postoperative CDVA in eyes with postoperative K values less than 35.0 D. The study found that flat corneas and higher degrees of myopia led to worse CDVA outcomes postoperatively. However, it is difficult to compare that study with the current investigation because of our lack of myopic stratification.

The most prominent limitation in this investigation is the use of mathematically predicted postoperative keratometry. Although this method is commonly used to help evaluate refractive surgery candidacy, its validity as a predictive tool has not been exhaustively tested. On our part, we did perform a statistical comparison between the measured and predicted K values, which showed a high degree of correlation between the two ($r^2 = 0.9008, P = .0001$); however, we had a relatively small sample size (51 eyes). Further large-scale studies comparing predicted and measured postoperative keratometry are warranted. Measured postoperative K values and their correlation to postoperative visual acuity would further define our current findings and increase their validity. We recommend similar,

Table 3. *P* value for comparison of pre- and post-operative CDVA for each subgroup.

Subgroup	P Value		
Cubgroup	, value		
Candidate			
1a (K < 35.0 D), n = 14	.351		
2a (K = 35.0 to 35.99 D), n = 21	.348		
3a (K = 36.0 to 36.99 D), n = 30	.491		
4a (K = 37.0 to 37.99 D), n = 46	.171		
Total, N = 111	.057		
Control			
1b (K = 38.0 to 38.99 D), n = 14	.351		
2b (K = 39.0 to 39.99 D), n = 21	.170		
3b (K = 40.0 to 40.99 D), n = 30	.261		
4b (K ≥ 41.0 D), n = 46	.348		
Total, N = 111	.327		

large-scale, controlled studies to effectively evaluate this relationship. Also, it would be beneficial to include questionnaires about the subjective quality of vision (haziness, halos, night vision, etc.) to check whether patients with postoperative flat corneas are at a disadvantage in other aspects of quality of vision in addition to CDVA. Finally, our study only included LASIK patients. It would be helpful to elucidate whether advanced surface ablation surgeries such as PRK and LASEK show similar results.

In conclusion, our evidence suggests there is no relationship between loss of CDVA lines and a postoperative corneal K value less than 38.0 D.

WHAT WAS KNOWN

• Myopic excimer laser correction is safe and effective.

WHAT THIS PAPER ADDS

 There was no statistically significant difference in loss of corrected distance visual acuity between eyes with flat keratometry values and matched controls.

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