

Effect of Keratometry on Visual Outcomes 1 Month After Hyperopic LASIK

Jill J. Young, BSc(Hons), MCOptom; Steven C. Schallhorn, MD; Mitchell C. Brown, OD; Keith A. Hettinger, MS, MBA

ABSTRACT

PURPOSE: To determine whether preoperative, postoperative, or change in keratometry can be used to predict visual outcomes in hyperopic LASIK.

METHODS: A retrospective analysis was conducted on hyperopic eyes treated at Optical Express clinics. All eyes were targeted for emmetropia and treated using wavefront-guided LASIK (VISX S4, Abbott Medical Optics [AMO]), with flaps created using a femtosecond laser (IntraLase FS-60 [AMO]). A total of 1659 consecutive eyes of 895 patients met the study inclusion criteria: preoperative sphere ≥ 1.00 diopter, complete 1-month follow-up data, and availability of pre- and postoperative keratometry measurements. Factors associated with 1-month visual results were evaluated with multivariate analysis.

RESULTS: Preoperative sphere was strongly correlated with visual outcomes. Higher levels of correction were associated with a greater loss of best spectacle-corrected visual acuity (BSCVA), a lower percentage of eyes achieving 20/20 BSCVA, and a lower percentage of eyes achieving 20/20 uncorrected visual acuity. For a given level of preoperative sphere, however, no statistically significant correlation was observed between visual outcomes and either pre- or postoperative keratometry.

CONCLUSIONS: Preoperative, calculated postoperative, or 1-month postoperative keratometry values do not correlate with visual acuity outcomes following hyperopic LASIK. [*J Refract Surg.* 2009;25:S672-S676.] doi:10.3928/1081597X-20090611-09

Some refractive surgeons have expressed concern that a relatively steep postoperative cornea following hyperopic LASIK may reduce the quality of outcomes.

However, published studies examining the association between postoperative keratometry and visual outcomes yield conflicting results.¹⁻⁶ One possible reason for these conflicting findings is the covariance of postoperative keratometry with preoperative sphere. Specifically, higher levels of hyperopic correction typically result in steeper postoperative keratometry, but larger corrections (due to high preoperative sphere values) also tend to result in poorer outcomes, irrespective of keratometry.

Therefore, to accurately assess how postoperative keratometry affects visual outcomes, an analysis must differentiate the effect of a large sphere correction from the effect of a steep postoperative cornea. However, studies with limited sample sizes may lack the statistical power to discriminate between these two effects, and most of the available published reports include fewer than 150 eyes.

PATIENTS AND METHODS

A total of 2399 consecutive patients (4489 eyes) underwent hyperopic wavefront-guided LASIK with a target of emmetropia from January 4, 2008 to June 6, 2008. All procedures were performed using the VISX S4 excimer laser platform (Abbott Medical Optics [AMO], Santa Ana, Calif), with LASIK flaps created using the IntraLase FS-60 (AMO).

Of the 1533 patients who attended 1-month postoperative follow-up, 895 patients (1659 eyes, 38% of the initial cohort) met the study inclusion criteria: preoperative sphere ≥ 1.00

From Optical Express, Glasgow, United Kingdom (Young) and San Diego, Calif (Schallhorn, Brown, Hettinger).

Ms Young, Dr Brown, and Mr Hettinger are employees of the Optical Express Group. Dr Schallhorn is the Chief Medical Director for Optical Express and a consultant to Abbott Medical Optics and AcuFocus.

Assistance in preparing this manuscript was provided by medical writer Kay Downer.

Correspondence: Jill J. Young, BSc(Hons), MCOptom, Optical Express, 5 Deerdykes Rd, Westfield, Cumbernauld G68 9HF United Kingdom. Tel: 44 1236 723300; Fax: 44 1236 730300; E-mail: jillyoung@opticalexpress.com

TABLE 1

Maximum Keratometry Values at 1 Month for Eyes That Lost 2 or More Lines of Best Spectacle-corrected Visual Acuity (BSCVA)

| Preoperative Sphere (D) | Kmax (Mean±Standard Deviation [Range], D) | | P Value |
|-------------------------|---|------------------------------|---------|
| | Loss of ≥2 lines of BSCVA | No loss of ≥2 lines of BSCVA | |
| +1.00 to <+2.00 | 44.40±1.3 (41.75 to 45.50) | 43.70±1.8 (39.75 to 52.00) | .3295 |
| +2.00 to <+3.00 | 44.80±1.7 (41.00 to 48.25) | 44.60±1.5 (40.25 to 48.50) | .5097 |
| +3.00 to <+4.00 | 45.60±1.5 (43.00 to 48.25) | 45.20±1.6 (40.25 to 49.25) | .1496 |
| ≥+4.00 | 45.60±1.4 (39.50 to 48.50) | 45.80±1.5 (42.00 to 49.00) | .5585 |

diopter (D) and availability of both pre- and postoperative keratometry measurements. Keratometry was measured by a trained technician using an automated device (auto-keratometer/tonometer RK-T 7770; NIDEK Co Ltd, Gamagori, Japan). The average of three readings per eye was recorded.

Pre- and postoperative keratometry were the independent variables of interest. Other factors that could affect the visual outcome of hyperopic LASIK were also analyzed, including preoperative sphere and cylinder, temperature, humidity, laser fluence during treatment, age, and gender.

Multiple logistic regression modeling was performed with SAS 9.1 (SAS Institute Inc, Cary, NC). To further control for the effect of preoperative sphere, eyes were subdivided into four groups based on the level of correction: +1.00 to <+2.00 D; +2.00 to <+3.00 D; +3.00 to <+4.00 D; and ≥+4.00 D. The various independent effects were measured for statistical influence on the 1-month visual outcomes of interest: percent of eyes that lost two or more lines of best spectacle-corrected vision (BSCVA), percent of eyes that achieved 20/20 BSCVA, and percent of eyes that attained an uncorrected visual acuity (UCVA) of 20/20 or better.

RESULTS

Most preoperative parameters were the same for those patients who returned for the 1-month examination and for those who did not, as well as among patients who had pre- and postoperative keratometry measured and those who did not. However, a statistically significant difference was noted in age and preoperative cylinder among those patients who returned for 1-month follow-up (age 51.7 years; preoperative cylinder 1.03 D) and those who did not (age 49.5 years; preoperative cylinder 1.18 D).

Average age of the 895 patients included in the study was 51.7 years (range: 18 to 70 years); 39% of patients were men and 61% were women. The mean treatment manifest sphere was +2.28±1.03 D (range:

+1.00 to +5.50 D). The mean preoperative keratometry of the steepest axis (Kmax) was 43.50 D (range: 38.00 to 48.00 D), and the mean postoperative Kmax was 44.80 D (range: 38.00 to 52.00 D).

The most important factor influencing the postoperative visual results was preoperative sphere. It significantly affected the percentage of eyes that lost two or more lines of BSCVA, attained 20/20 or better BSCVA, and achieved UCVA of at least 20/20 ($P \leq .0001$, $P \leq .0001$, and $P \leq .0001$, respectively).

In a univariate analysis, postoperative Kmax significantly influenced visual outcomes. However, when the appropriate statistical model was used to address the interaction between preoperative sphere and keratometry, the statistical significance of keratometry was lost. When preoperative sphere was held constant, no significant correlation was observed between visual outcomes and preoperative, postoperative, or change in Kmax ($P = .1039$, $P = .1559$, and $P = .2947$, respectively).

When analyses controlled for preoperative sphere, no significant difference was noted between the postoperative Kmax of eyes that lost two or more lines of BSCVA and those that did not (Table 1). Similarly, no difference was noted in the postoperative Kmax for eyes that achieved at least 20/20 BSCVA and those that did not (Table 2); postoperative Kmax also did not differ significantly between eyes that achieved at least 20/20 UCVA and those that did not (Table 3).

As can be seen in Figures 1-3, when patients were grouped by preoperative sphere values, increases in postoperative Kmax did not affect any of the visual outcomes measured.

DISCUSSION

In agreement with the results of the current study, several reports have found that postoperative keratometry does not influence the visual outcome of hyperopic LASIK. In one study, Jin et al⁴ evaluated the safety, efficacy, and stability of hyperopia in 139 eyes with a mean preoperative spherical equivalent refraction of

TABLE 2

Maximum Keratometry Values at 1 Month for Eyes With or Without 20/20 Best Spectacle-corrected Visual Acuity (BSCVA)

| Preoperative Sphere (D) | Kmax (Mean±Standard Deviation [Range], D) | | P Value |
|-------------------------|---|----------------------------|---------|
| | BSCVA Worse Than 20/20 | BSCVA 20/20 or Better | |
| +1.00 to <+2.00 | 43.20±1.6 (40.50 to 45.00) | 43.70±1.8 (39.75 to 52.00) | .3371 |
| +2.00 to <+3.00 | 44.60±1.6 (41.00 to 48.25) | 44.60±1.5 (40.25 to 48.50) | .8249 |
| +3.00 to <+4.00 | 45.20±1.6 (41.75 to 48.25) | 45.30±1.6 (40.25 to 49.25) | .6428 |
| ≥+4.00 | 45.60±1.3 (39.50 to 48.50) | 45.90±1.5 (42.00 to 49.00) | .2914 |

TABLE 3

Maximum Keratometry Values for Eyes With or Without 20/20 Uncorrected Visual Acuity (UCVA)

| Preoperative Sphere (D) | Kmax (Mean±Standard Deviation [Range], D) | | P Value |
|-------------------------|---|----------------------------|---------|
| | UCVA Worse Than 20/20 | 20/20 UCVA | |
| +1.00 to <+2.00 | 43.60±2.1 (42.25 to 52.00) | 43.60±1.7 (39.75 to 47.50) | .8879 |
| +2.00 to <+3.00 | 44.70±1.5 (40.50 to 48.25) | 44.50±1.5 (40.25 to 48.50) | .2474 |
| +3.00 to <+4.00 | 45.30±1.7 (40.25 to 49.25) | 45.20±1.6 (41.75 to 48.75) | .7831 |
| ≥+4.00 | 45.80±1.6 (39.50 to 49.00) | 45.50±1.4 (40.75 to 48.25) | .1817 |

+2.39 D. Four eyes in this analysis had a postoperative keratometry >49.00 D, but none lost lines of BSCVA. Similarly, Tabbara et al⁶ analyzed 80 eyes with preoperative sphere treatments ranging from +0.50 to +11.50 D. Postoperative keratometry in these eyes ranged from 40.00 to 52.82 D, but none of the patients in the study reported symptoms relating to corneal steepness.

In the largest study previously reported, Cobo-Soriano et al⁵ performed a retrospective analysis of the visual outcomes of 376 eyes. Eyes with postoperative keratometry readings <48.00 D were compared to eyes with keratometry >48.00 D, and these two groups were further subdivided into lower (+1.00 to +4.00 D) and higher (+4.10 to +7.90 D) levels of hyperopia. The results showed no significant differences in visual outcomes in patients with either steep or flat postoperative keratometry.

In contrast, some studies appear to show that keratometry influences visual outcomes. Although Ditzzen et al³ (N=43 eyes) found that a flat cornea (radius <7.3 mm) led to greater regression and undercorrection, most studies that found a correlation between keratometry and visual outcomes observed worse outcomes in steeper corneas. For example, Esquenazi and Mendoza² published a retrospective study of 100 eyes and found a higher percentage of undercorrection in

eyes with hyperopia >+4.00 D when the preoperative keratometry was >45.00 D. However, this study did not separate the effects of keratometry and preoperative sphere.

Similarly, a study by Williams et al¹ found that steeper preoperative keratometry correlated with poorer outcomes, but this analysis used a limited sample size (N=26 patients). Their study found that a greater loss of BSCVA was associated with preoperative keratometry >44.00 D. Because of the small sample size, however, the analysis could be prone to sampling errors. In fact, a surprisingly large number of eyes in the steeper-K group lost two or more lines of BSCVA (10 [40%] of 25 eyes) compared to only 1 (4%) of 24 eyes in the low-K group. Such a high loss of BSCVA in the high-K group has not been previously reported.

In an effort to duplicate the results of Williams et al,¹ a sub-analysis of the Optical Express data reported above was performed. Eyes were divided into two groups based on preoperative keratometry—one group included patients with a preoperative Kmax <43.00 D (n=376) whereas the other group comprised patients with Kmax >44.00 D (n=741). (The remaining patients had Kmax between 43.00 and 44.00 D ([n=542]). Unlike the Williams et al study, however, this sub-analysis found no correlation between preoperative kera-

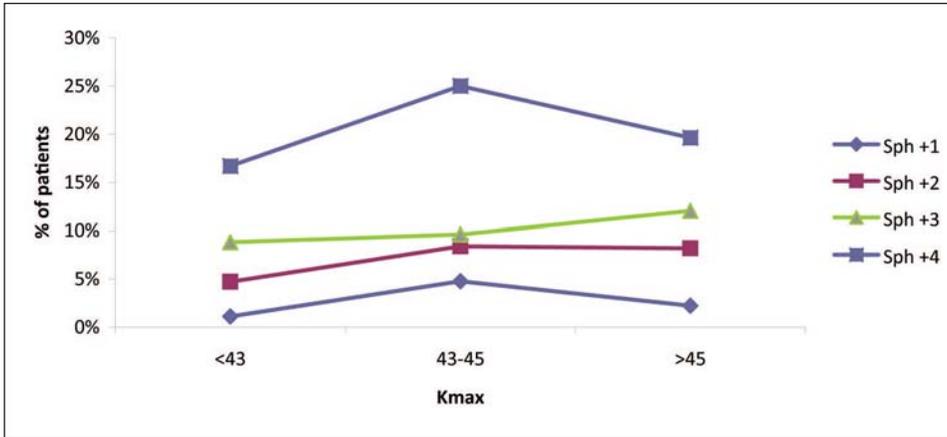


Figure 1. Proportion of patients who lost two or more lines of best spectacle-corrected visual acuity varied by preoperative sphere group but not by maximum keratometry.

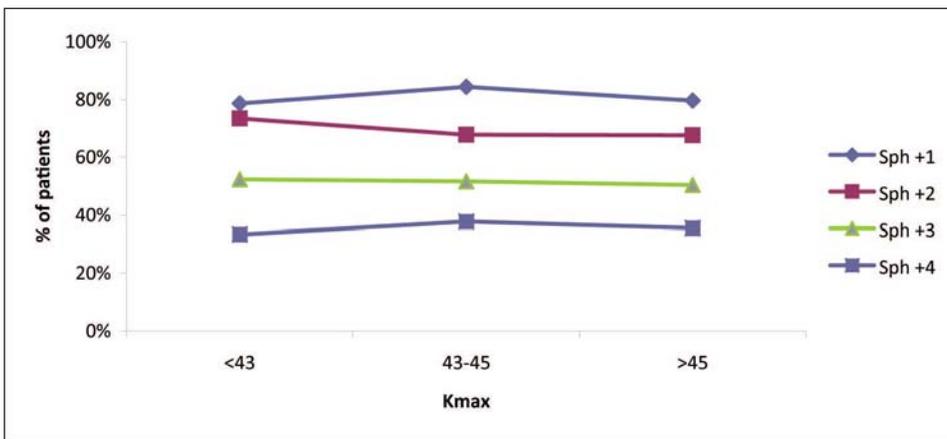


Figure 2. Proportion of patients who achieved 20/20 uncorrected visual acuity varied by preoperative sphere group but not by maximum keratometry.

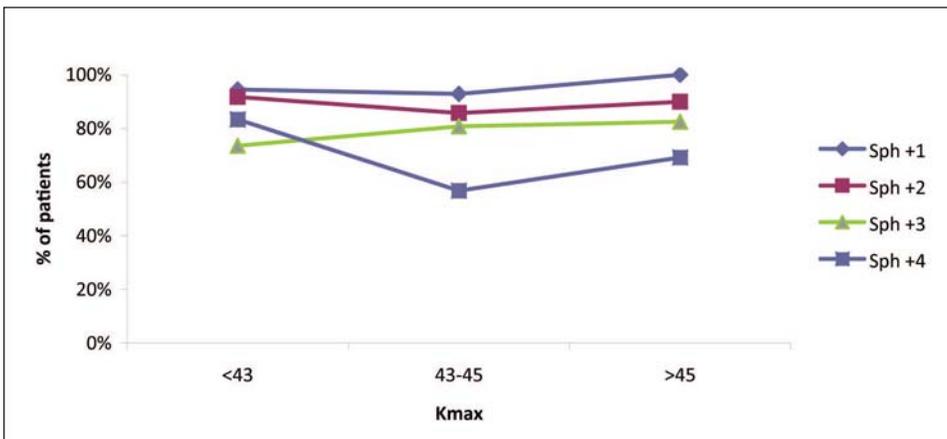


Figure 3. Proportion of patients who achieved 20/20 best spectacle-corrected visual acuity varied by preoperative sphere group but not by maximum keratometry.

tometry and loss of BSCVA. The percentage of eyes in which two or more lines of BSCVA was lost was virtually identical in both groups (<43.00 D: 2.36%; >44.00 D: 2.30%; $P > .05$).

The large sample size of the current study is a strength compared with other published reports. The combined sample size of all previously published reports that evaluated the role of keratometry after hyperopic LASIK¹⁻⁶ is 718, compared to a sample size of 1659 eyes in this study. Other strengths include the fact that data were gathered from multiple centers and

the surgeries were conducted by many surgeons, which helps reduce surgical center-specific bias. In addition, the surgical procedure (wavefront-guided LASIK with femtosecond laser flap creation) and examination techniques were identical for all eyes.

Although this study was well designed, it has certain limitations. First, like all retrospective studies, it is possible that this study included confounding variables and biases that were not accounted for.

Second, not all patients who underwent hyperopic LASIK showed up for their 1-month examination; 36%

failed to attend this appointment. The initial cohort of patients treated with hyperopic LASIK was further reduced by the requirement to have a preoperative sphere ≥ 1.00 D as well as pre- and postoperative keratometry measurements. An analysis was conducted to evaluate possible patient selection bias. Two variables were significantly different among patients who attended the 1-month follow-up and those who did not: age (51.7 vs 49.5 years) and preoperative cylinder (1.03 vs 1.18 D). However, the significance of these differences was deemed to have no clinical relevance. In addition, no significant difference was found, for any parameter, between patients who had postoperative keratometry measurements and those who did not. An important drawback of the study is that 1-month follow-up after hyperopic LASIK is a relatively short time period. Hyperopic LASIK takes longer to stabilize than treatment of myopia. Typical changes that occur after hyperopic LASIK can be a refractive shift, usually regression, and a gradual improvement in the tear film, dry eye symptoms, and BSCVA.

Third, because the preoperative Kmax was 48.00 D and the postoperative Kmax was 52.00 D, this study cannot draw any conclusions about keratometry that exceeds these values. Thus, this study cannot state whether an association exists between visual outcomes and postoperative Kmax values >52.00 D.

Fourth, keratometry is a measurement of only two points approximately 3 mm apart on the central cornea, which may not reflect the curvature of the overall cornea. Topography provides a more detailed evaluation of the shape of the cornea and would be useful to analyze. However, postoperative topography was not generally performed in the clinics.

Finally, this study did not assess visual or dry eye symptoms. Although visual acuity outcomes were not found to be related to keratometry, dry eye symptoms may still be associated with steep corneas after hy-

peropic LASIK. Williams et al¹ found an association between higher preoperative keratometry and dry eye symptoms, but because of that study's small sample size (only 14 patients had a preoperative keratometry >44.00 D), this conclusion may not be born out by larger studies. Nonetheless, the effect of keratometry on dry eyes after LASIK requires further study.

Based on an analysis of 1659 eyes, this study found that pre- or postoperative keratometry (up to 52.00 D) does not correlate with visual outcomes following hyperopic LASIK. Although patients with steeper postoperative Kmax values tend to have poorer outcomes in a univariate analysis, this association disappears when the analysis controls for preoperative sphere.

AUTHOR CONTRIBUTIONS

Study concept and design (J.J.Y., S.C.S., M.C.B.); data collection (S.C.S., M.C.B., K.A.H.); interpretation and analysis of data (J.J.Y., S.C.S., M.C.B., K.A.H.); drafting of the manuscript (S.C.S.); critical revision of the manuscript (J.J.Y., S.C.S., M.C.B., K.A.H.); statistical expertise (S.C.S., K.A.H.); administrative, technical, or material support (S.C.S., M.C.B.); supervision (S.C.S., M.C.B.)

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