Predicting Ectasia After LASIK

Currently available risk calculators may not account for all of the contributing factors in the development of this serious postoperative complication.

BY WILLIAM B. TRATTLER, MD, AND PERRY S. BINDER, MD

Perhaps the greatest ongoing challenge faced by refractive surgeons is identifying patients who are at risk of developing ectasia after LASIK. Of the various postoperative complications associated with keratorefractive surgery, ectasia appears to be the easiest to avoid with proper preoperative screening. After 10 years of trying to identify the risk factors for its development, however, we refractive surgeons still have only incomplete knowledge of ectasia's etiology.

Researchers have attempted to reduce the incidence of ectasia by designing scoring systems that calculate an individual patient's risk of the complication. This article describes the evolution of the Ectasia Risk Factor Score System and discusses how shifting the focus from corneal thickness to topography might improve surgeons' ability to identify patients at risk for postoperative ectasia.

ECTASIA AND THE INTERNET

The first published reports of a link between LASIK and ectasia focused on two areas of risk: (1) altering the corneas of patients with forme fruste keratoconus and (2) performing deep treatments that leave an excessively thin residual stromal bed.[1-3] Despite the appearance of these articles in peer-reviewed journals, however, surgeons participating in peer-to-peer discussion forums on the Internet were slow to recognize ectasia as a real pathological entity. By 2000, the same online forums showed that surgeons were aware of ectasia but also that they had a poor understanding of its etiology and risk factors.

In May 2001, R. Doyle Stulting, MD, PhD, Professor of Ophthalmology at the Emory Eye Center in Atlanta, proposed on an Internet discussion group that preexisting forme fruste keratoconus was a significant risk factor for postoperative ectasia. His comment was based on an assessment of nine patients with subclinical keratoconus who progressed to ectasia after LASIK. He noted, however, that he lacked additional data to definitively support a link between the two conditions. For example, he was not aware of any statistics showing the percentage of patients who had stable outcomes after LASIK despite having forme fruste keratoconus. He also did not have a formal method that would allow him to discriminate between topographic images of normal, abnormal, and at-risk corneas. The first article to compare Dr. Stulting's original cases with control eyes that did not become ectatic after LASIK also confirmed that patients whose topographies showed signs of forme fruste keratoconus had an increased risk of developing ectasia after LASIK.[4]

THE ECTASIA RISK FACTOR SCORE SYSTEM

By 2008, J. Bradley Randleman, MD; R. Doyle Stulting, MD; and their colleagues at the Emory Eye Center had accumu-

TABLE 1. ECTASIA RISK FACTOR SCORE SYSTEM[a]

Risk Factor Score	Risk Category	Recommendation	Comments
0 to 2	Low level of risk	OK to proceed with surface ablation or LASIK	N/A
3	Moderate level of risk	Caution: consider special informed consent. Safety of surface ablation has not been established	Consider refractive stability, degree of astigmatism, asymmetry between eyes, and family history
4	High risk	Do not perform LASIK. Safety of surface ablation has not been established	N/A

[a]Data adapted from Randleman et al.[5]

TABLE 2. CATEGORIES OF RISK FACTORS FOR ECTASIA[a]

	Points				
Parameter	**4**	**3**	**2**	**1**	**0**
Topography (µm)	Forme fruste keratoconus	Inferior steepening/ skewed radial axis	N/A	Asymmetric bowtie	Normal
Residual stromal bed (µm)	Less than 240	240 to 259	260 to 279	280 to 299	More than 300
Age, y		18 to 21	22 to 25	26 to 29	More than 30
Corneal thickness (µm)	Less than 450	450 to 480	481 to 510	N/A	More than 510
Manifest refraction spherical equivalent (D)	More than -14.00	-12.00 to -14.00	-10.00 to -12.00	-8.00 to -10.00	-8.00 or less

[a]Data adapted from Randleman et al.[5]

lated enough data to publish the Ectasia Risk Factor Score System[5] (Tables 1 and 2).

Their landmark study compared the characteristics of eyes with ectatic corneas seen at Emory and those described in the peer-reviewed literature with a group of control eyes that experienced a normal course after LASIK. In addition to providing key insights into the factors that contribute to ectasia, Randleman et al revealed that the average time to this progressive condition's presentation was 12 months and that 90% of cases occurred by 36 months postoperatively. A closer look at the criteria this system uses to calculate the risk of ectasia, however, suggests that further refinements are necessary.

POTENTIALLY CONFOUNDING FACTORS

Sub-Bowman's Keratomileusis and Femtosecond Lasers

Ninety-five percent of the cases that Randleman et al used to develop the Ectasia Risk Factor Score System involved eyes that had undergone LASIK prior to 2003. Since then, Daniel Durrie, MD, and Stephen Slade, MD, have developed sub-Bowman's keratomileusis (SBK), a procedure that uses the Intralase FS femtosecond laser (Advanced Medical Optics, Inc., Santa Ana, CA) to customize the parameters of the corneal flap for individual patients. The thin, planar flaps created during SBK appear to be more biomechanically stable than those used for traditional LASIK.[6,7] Because only a few cases of ectasia have been reported to date in eyes with flaps created by the Intralase FS, it is unclear whether the Ectasia Risk Factor Score System will be an effective tool for evaluating patients undergoing thin-flap LASIK with femtosecond lasers.[8]

Corneal Topography

According to the Ectasia Risk Factor Score System, a 25-year-old patient whose central cornea measures 510 µm has an increased risk of developing ectasia after LASIK, even if his topography appears normal. In a study of 9,816 myopic eyes that underwent LASIK by Perry Binder, MD, however, none with a risk factor score of 5 or more and a normal topography became ectatic after LASIK.[9] It is our opinion that further work is required to determine how other parameters affect the risk of ectasia for eyes that do not have topographic abnormalities.

Preoperative Pachymetry

The idea that patients who have thin corneas but no other risk factors for ectasia have an increased risk of

CCT AS AN INDEPENDENT RISK FACTOR

Although the Ectasia Risk Factor Score System assigns values to central corneal thickness (CCT), the researchers at the Emory Eye Center in Atlanta did not conclusively determine that CCT was an independent risk factor for ectasia.

The system awards 2 points for eyes with CCTs between 510 and 481 µm, 3 points for CCTs between 480 and 451 µm, and 4 points for CCTs thinner than 450 µm. The same system also shows that CCTs thicker than 481 µm are not associated with an increased risk of ectasia in eyes with normal topography and no additional risk factors. Based on a stepwise regression analysis of their data, Randleman et al also noted that "neither preoperative corneal thickness (P=.1) nor preoperative refraction (P=.3) was a significant predictor of ectasia."[1] They concluded, however, that "topography, age, and [the thickness of the] residual stromal bed remained significant variables ($P<1.0 \times 10^{-5}$)."[1]

1. Randleman JB, Woodward M, Lynn MJ, et al. Risk assessment for ectasia after corneal refractive surgery. *Ophthalmology*. 2008;115:37-50.

CASE STUDY

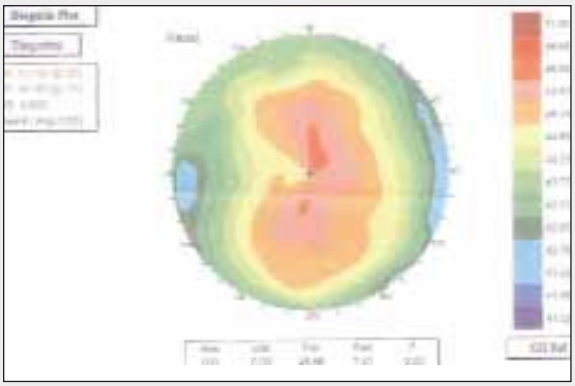
BY WILLIAM B. TRATTLER, MD

In 2006, I described two patients with normal preoperative topography who developed ectasia after LASIK because their corneal flaps were dramatically thicker than expected. The same surgeon performed both procedures in London 1 week apart.[1] Preoperatively, the first patient's preoperative central corneal thickness (CCT) measured 510 µm OD and 515 µm OS. The second patient's CCT measured 520 µm OD and 510 µm OS (Figures 1 and 2).

Because the surgeon did not measure the thickness of the flaps intraoperatively, he was not aware that he had inadvertently made them thicker than their intended target of 160 µm. Postoperative scanning with Artemis very high frequency ultrasound (Ultralink LLC, St. Petersburg, FL) showed that both patients' residual stromal beds were thinner than 200 µm. Both patients also had preoperative CCTs that were thinner than those of the control eyes measured by Randleman et al (average, 546.4 µm)[1] and would therefore appear to support the Ectasia Risk Factor Score System's assertion that thin corneas have an inherently higher risk of becoming ectatic after LASIK. The true risk factor for these two cases, however, was the mechanical microkeratome's creation of excessively thick flaps. If the patients' CCTs had measured 600 µm preoperatively, the unexpectedly thick flaps might not have weakened the tissue enough to cause ectasia.

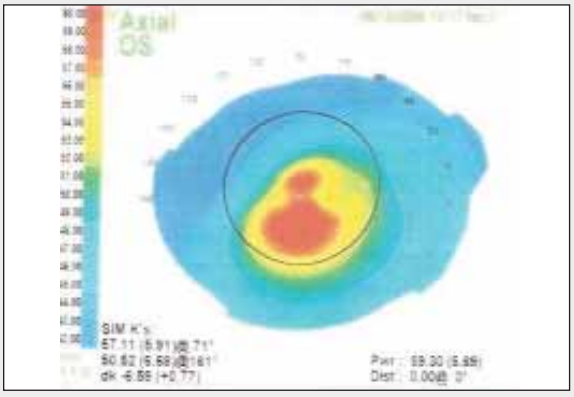
In addition to highlighting the importance of intraoperative pachymetry, these cases show how using predictive models such as the Ectasia Risk Factor Score System to screen patients cannot predict the effect of intraoperative factors on their risk of developing ectasia after LASIK.

1. Trattler W. Ectasia: double trouble in the LASIK suite. Paper presented at: The ASCRS Summer Refractive Congress; August 10, 2006; Boston, MA.



(Courtesy of William B. Trattler, MD.)

Figure 1. A 42-year-old man who had normal preoperative topography developed ectasia in his left eye 1 week after LASIK. Preoperatively, his CCT measured 510 µm, and his refraction was -2.50 -0.50 X 90.



(Courtesy of William B. Trattler, MD.)

Figure 2. Postoperative topography and pachymetry showed that the patient's ectasia was associated with the creation of a corneal flap that was significantly thicker than intended (260 vs 160 µm) and an excessively thin residual stromal bed (149 µm).

developing the complication and should therefore avoid LASIK is not supported by the peer-reviewed literature.[10] It is also refuted by three studies that failed to identify a link between low central corneal thickness (CCT) and ectasia.[11-13] (See *CCT as an Independent Risk Factor* for a description of how the Ectasia Risk Factor Score System uses CCT to screen patients for LASIK.)

In addition, a retrospective review of a database of ectatic eyes maintained by one of the investigators (Dr. Trattler) showed that only 10 of 94 eyes with preoperative CCTs of 500 µm or less developed this complication after LASIK.[14] Of the 10 affected eyes, eight also had topographic abnormalities. The only ectatic eyes that had a thin cornea preoperatively but no suspicious topographic findings had -9.00 D of myopia, were not evaluated with intraoperative pachymetry, and underwent LASIK only 1 week after the discontinuation of rigid gas-permeable contact lenses.

Intuitively, one might think that thinner corneas are inherently weaker than thicker ones; however, this correlation has not been proven. The peer-reviewed literature does not describe an increased risk of keratoconus in older individuals (corneal tissue typically becomes thinner and stiffer with age) or in population groups that have thinner-than-average corneas (ie, blacks).

Intraoperative Pachymetry

When the researchers at Emory designed the Ectasia Risk Factor Score System, only 12% of the cases they analyzed

included intraoperative pachymetric measurements of the corneal flap. They therefore had to estimate the thickness of the residual stromal bed for the remaining 88%.

Although the Ectasia Risk Factor Score System assumes that the surgeons who treated the study population consistently preserved the targeted residual stromal bed, research has now demonstrated that mechanical microkeratomes can create flaps that are thicker than expected.[15] If a percentage of the eyes analyzed by Randleman et al had excessively thick flaps and, consequently, unexpectedly thin residual stromal beds, their preoperative characteristics (ie, CCT) might not be reliable indicators of risk for ectasia (see *Case Study* for a clinical example of this phenomenon). For example, we know that corneas become stiffer with age. A young individual who has thin corneas preoperatively would have a higher risk of developing ectasia after LASIK if his corneal flap is thicker than expected versus an older individual whose thicker, stiffer cornea potentially provides more biomechanical stability, even in the presence of a thin residual stromal bed.

EVOLVING UTILITY

The introduction of the Ectasia Risk Factor Score System is an important step toward expanding refractive surgeons' knowledge of ectasia, but its utility can be improved. Of all the risk indicators associated with post-LASIK ectasia, topographic abnormalities appear most consistently. A recent comparison by Randleman et al of new cases of post-LASIK ectasia (n = 50) with a control group of normal eyes (n = 50) showed that 72% of the ectatic eyes had significant preoperative corneal topographic abnormalities that would place them in the moderate- or high-risk group, independent of other preoperative findings.[16]

In contrast, a small percentage of eyes in the same study (8.8% from patients younger than 30 years, 5.1% with CCTs of less than 481 µm, and 13.3% with more than -14.00 D of myopia preoperatively) had scores indicating a moderate or high risk of ectasia.

These findings suggest that corneal topography could be more predictive of ectasia than many of the criteria used by currently available risk calculators. If that is the case, topography should play a greater role in scoring systems used to screen patients for LASIK.

We also believe that refractive surgeons should not declare patients ineligible for LASIK based solely on the results of the Ectasia Risk Factor Score System. Although we agree that patients with topographic findings consistent with forme fruste keratoconus, keratoconus, or pellucid marginal degeneration should not undergo LASIK, we strongly disagree with the score system's assertion that LASIK is automatically contraindicated in a 25-year-old patient with -2.00 D of myopia, normal topography, and a CCT of 510 µm.

CONCLUSION

As we refractive surgeons develop strategies for preventing ectasia, we should focus on improving our ability to interpret corneal topography. Although this imaging modality has become a standard part of the pre-LASIK workup, we may be missing important clues that can help us identify patients at risk of ectasia. Additional research may also help us identify critical "cut-offs" in eyes with normal-to-borderline topography and thus improve the accuracy of our predictive models. ■

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