A New Model for Predicting Ectasia

Accounting for the imperfections of your surgical instruments can help you to avoid excessive keratectomy during LASIK.

BY DAN Z. REINSTEIN, MD, MA(CANTAB), FRCSC, DABO, FRCOPHTH

Over the years, refractive surgeons have devised strategies for coping with some of the more common complications that can occur after LASIK. Nonetheless, ectasia, a condition characterized by a progressive increase in corneal curvature, remains somewhat of a mystery. Its most likely causes appear to be undetected preoperative keratoconus and excessively deep keratectomies. This article presents a model for calculating the minimal residual stromal thickness required to maintain corneal structural integrity.[1] When this model is applied to an individual eye, it may help surgeons predict the risk of developing post-LASIK ectasia.[2]

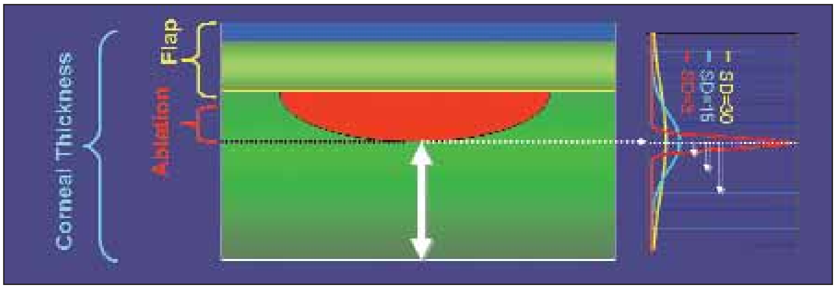

Figure 1. This diagram shows how the standard deviation (SD) of the microkeratome (yellow), laser (red), and pachymeter (blue) can lead to an excessively deep keratectomy and increase an eye's risk for developing postoperative ectasia.

ACCOUNTING FOR IMPRECISION

Current methods for predicting residual stromal thickness contain elements of imprecision that can result in an excessively deep keratectomy and thus increase the risk of postoperative ectasia. The equation appears to be straightforward: residual stroma = preoperative corneal thickness - flap thickness - ablation depth. The result cannot be considered accurate, however, because it does not account for the bias (the difference between the measured and actual values) and the precision (the degree of variation in a series of values) of the microkeratome, excimer laser, and pachymeter (Figure 1).

My colleagues and I have developed a probability model that mathematically combines the bias and imprecision of these components to calculate the risk of exceeding the predicted residual stromal thickness for an individual eye.

MICROKERATOMES AND RESIDUAL STROMAL THICKNESS

Of the variables that can contribute to excessive keratectomy, the microkeratome is currently the greatest source of imprecision. To put the degree of imprecision in a clinical context, my colleagues and I obtained mean and standard deviation values of flap thickness from published peer-reviewed articles. The flaps were created with microkeratomes manufactured by Alcon Laboratories, Inc. (Fort Worth, TX), Advanced Medical Optics, Inc. (Santa Ana, CA), Bausch & Lomb (Rochester, NY), IntraLase Corp. (Irvine, CA), Moria (Antony, France), and Nidek, Inc. (Fremont, CA). We used our model to calculate for each microkeratome the probability of producing a residual stromal thickness of less than 200 µm, given a predicted thickness of 250 µm.

Our model showed that the chance of leaving a residual stromal thickness of less than 200 µm, given a predicted thickness of 250 µm, ranged between 33.59% with the Moria CB (Moria) to <0.1% with the Hansatome (Bausch & Lomb), ACS (Bausch & Lomb), and the MK-2000 (Nidek, Inc.). The source of the significant differences among the microkeratomes was the combination of their bias and precision. The microkeratomes that had a high probability of leaving a residual stromal thickness of less than 200 µm had a positive bias (actual mean flap thickness > labeled thickness) and a large standard deviation in flap thickness. Conversely, the microkeratomes that had a low probability of exceeding the predicted thickness of 250 µm had a negative bias (actual mean flap thickness < labeled mean flap thickness) and a small standard deviation.

For example, the labeled flap thickness of the Moria CB with the 130 head was 160 µm, but the measured mean flap thickness was 198 ±26 µm.[3] Therefore, 93% of eyes treated with this microkeratome would have flaps that were thicker than intended, including 50% that were 38 µm thicker and 32% that were 50 µm thicker. In comparison, the labeled flap thickness of the zero compression Hansatome with the 160 head was 160 µm. The measured mean thickness of flaps created with this microkeratome was 124 ±17 µm.[4] The probability of this instrument's creating flaps that are thicker than intended is much lower than with the Moria CB, only 1.7% of eyes. Only 0.00002% of flaps created with the Hansatome would be 50 µm thicker than intended.

These data demonstrate that a microkeratome's safety is improved if it is labeled with a flap thickness greater than the actual mean flap thickness. Standardizing this practice would minimize the percentage of flaps that end up thicker than the labeled value.

Accuracy	
Labeled Flap Thickness	160.0-µm
Mean Flap Thickness	163.6-µm
Flap Thickness Bias	3.6-µm
Corneal Thickness Bias	0.0-µm
Ablation Depth Bias Slope	0.93
Ablation Depth Bias Intercept	-7.59
Precision	
Flap SD	30.3-µm
Corneal Thickness SD	8.4-µm
Ablation Depth SD	11.2-µm
Composite SD	33.4-µm
Treatment	
Minimum Target RST	250-µm
Treatment Zone	6.50-mm
Laser	Nidek EC5000
Population	
Mean Corneal Thickness	541-µm
Corneal Thickness SD	34-µm
Minimum Corneal Thickness	465-µm
Maximum Corneal Thickness	640-µm
Minimum Myopia Treated	0.00 D
Maximum Myopia Treated	-16.00 D
% Eyes Excluded	10.1%
Percentage of Eyes Below Cut-off RST	
Cut-off RST	200-µm
% Eyes Below Cut-off	0.248%
Eyes per 100,000	247.71
Eyes per 1,000,000	2477.08

Figure 2. Given a predicted flap thickness of 250 µm, 248 of 100,000 eyes in the LASIK Vision Canada population would have a residual stromal thickness of less than 200 µm if they were treated according to the parameters shown here.

CALCULATING A POPULATION'S RISK FOR ECTASIA

My colleagues and I applied the model for individual eyes to a clinical population in order to (1) identify a residual stromal thickness below which ectasia appears likely to occur and (2) to use this information to establish a safe minimal residual stromal thickness for patients undergoing cornea-based refractive surgery with any set of instruments.

We expanded the model to incorporate the distribution of myopia and corneal thickness in a population of eyes undergoing LASIK. The percentage of eyes expected to obtain an actual residual stromal thickness below a chosen cutoff after treatment with specific surgical equipment could then be calculated by applying the probability distribution of that residual stromal thickness to each eye individually.

We set up the model to represent a case series of 5,212 myopic eyes treated at LASIK Vision Canada in Vancouver, British Columbia, over a 3-year period by a single surgeon using the same microkeratome (Moria LSK-One with the -1 head; Moria) and laser (Nidek EC5000; Nidek, Inc.) The model would predict the percentage of eyes in the population expected to have a residual stromal thickness below a selected cutoff. For example, the model predicted that 0.248% of eyes would have a residual stromal thickness of less than 200 µm (Figure 2).

We knew that six of the eyes (0.115%) treated in this case series went on to develop ectasia. All of the patients had been screened preoperatively with the Orbscan corneal topographer (Bausch & Lomb), so we assumed that ectasia was caused by excessive keratectomy versus keratoconus. We then used this information to back-calculate the residual stromal thickness at which ectasia occurred in this population.

Setting the residual stromal thickness cutoff to 250 µm predicted that 5% of the eyes in the case series would develop ectasia. Because this was significantly more than the observed percentage of 0.115%, we could tell that the patients in this series needed a residual stromal thickness of less than 250 µm to develop ectasia. Setting the cutoff to 191 µm predicted that 0.115% of the eyes in the case series would develop ectasia, which matched the number of cases we observed. Therefore, we concluded that ectasia in this case series occurred for eyes that had 191 µm or less of residual stromal thickness.

We recognized that additional incidences of ectasia might have occurred in this series that were lost to follow-up or might have been caused by something other than excessively deep keratectomy, so we repeated the analysis, assuming that one to 12 cases were observed. The model predicted that a residual stromal thickness of 178 µm and 199 µm would produce one and 12 cases of ectasia in this series, respectively.

CALCULATING THE MINIMAL SAFE RESIDUAL STROMAL THICKNESS

In addition to determining the minimal residual stromal thickness for ectasia in a specific case series, our

HOW SERIOUS IS ECTASIA?

BY PERRY S. BINDER, MS, MD

Table 1 lists the reports of ectasia in a large series of LASIK cases. It appears that the incidence of reported cases is low, but Stulting has calculated that approximately one in 5,000 LASIK cases will develop ectasia,[1] which is about the incidence of ectatic corneal disorders in the general population. The same conclusion was reached by Condon et al.[2] If one eliminates cases with preoperative ectatic conditions, performs LASIK, and leaves a residual corneal bed of more than 300 to 340 µm,[3] one can expect to reduce the incidence of post-LASIK ectasia. Based on this database review, and until scientific studies prove otherwise, one may perform LASIK or PRK on eyes with assumed risk factors as long as appropriate screening was performed and appropriate informed consent was obtained.

For the entire article on "Post-LASIK Ectasia. What Do We Know?" please refer to the March 2007 issue of *Cataract & Refractive Surgery Today* or http://www.crstoday.com/PDF%20Articles/0307/CRST0307_10.php.

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TABLE 1. REPORTED INCIDENCE OF POST-LASIK ECTASIA

Report	No. of Incidents/ Total LASIK Procedures	Percentage
Reinstein et al[3]	6/5,212	0.12
Pallikaris et al[4]	19/2,873	0.66
Rad et al[5]	N/A	0.20
Condon et al[2]	3/140	0.80
Binder (current report)	3/9,283 (myopic errors)	0.01
Stulting[1]	1/5,000	N/A

1. Stulting R. Ectasia: how serious is the problem. Paper presented at:The AAO Annual Meeting; November 11, 2006; Las Vegas, NV.
2. Condon P, Matthews J, Binder P. Long-term follow up of high myopia LASIK cases. *J Cataract Refract Surg*. In press.
3. Reinstein D, Srivannaboon S, Archer T, et al. Probability model of the inaccuracy of residual stromal thickness prediction to reduce the rise of ectasia after LASIK part II: quantifying population risk. *J Refract Surg*. 2006;22:861-870.
4. Pallikaris I, Kymionis G, Astyrakakis N. Corneal ectasia induced by laser in situ keratomileusis. *J Refract Surg*. 2001;27:1796-1802.
5. Rad A, Jabbarvand M, Saifi N. Progressive keratectasia after laser in situ keratomileusis. *J Refract Surg*. 2004;20(suppl):S718-S722.

probability model can be used to calculate the targeted residual stromal thickness that will minimize the risk of ectasia in a clinical setting. Once surgeons enter information into the model about the microkeratome, laser, and pachymeter they use, they can set the cutoff to the residual stromal thickness at which ectasia is likely to occur (191 µm in our series). The model will predict how many cases they can expect to see when LASIK is performed using the specified clinical protocol. Surgeons can use this information to assess refractive surgery candidates with an eye toward minimizing the number of cases of ectasia in their practice.

For example, if we had targeted 280 µm as our minimal stromal thickness in the case series from LASIK Vision Canada, the model would have predicted a rate of ectasia of 153 per million versus 1,152 cases per million. In the same population, targeting a residual stromal thickness of 310 µm would have reduced the rate of ectasia to 8.8. To reduce the incidence to one in 1 million, we would have to target a residual stromal thickness of 329 µm, thus disqualifying 66.3% of the eyes from LASIK.

CONCLUSION

The probability model discussed in this article highlights several factors that may help surgeons understand the relationship between ectasia and LASIK. First, the accuracy and standard deviation of the microkeratome, laser, and pachymeter used during LASIK affects the depth of the keratectomy and, thus, the risk for ectasia. Second, there is no universally safe minimal targeted residual stromal thickness for LASIK, so the commonly accepted guideline of 250 µm should be treated with caution. The minimal targeted residual stromal thickness is actually a variable that depends on the bias and imprecision of the instruments being used and, as such, should ideally be derived for each clinical setting. Finally, this model indicates that ectasia becomes more likely in eyes that have less than 200 µm of residual stroma after LASIK. ■

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1. Reinstein DZ, Srivannaboon S, Archer TJ, et al. Probability model of the inaccuracy of residual stromal thickness prediction to reduce the risk of ectasia after LASIK part II: quantifying population risk. *J Refract Surg*. 2006;22:861-870.
2. Reinstein DZ, Srivannaboon S, Archer T, et al. Probability model of the inaccuracy of residual stromal thickness prediction to reduce the risk if ectasia after LASIK part I: quantifying the individual risk. *J Refract Surg*. 2006;22:851-860.
3. Solomon KD, Donnenfeld E, Sandoval HP, et al. Flap thickness accuracy: comparison of 6 microkeratome models. *J Cataract Refract Surg*. 2004;30:964-977.
4. Choudhri SA, Feigenbaum SK, Pepose JS. Factors predictive of LASIK flap thickness with the Hansatome zero compression microkeratome. *J Refract Surg*. 2005;21:253-259.