Evaluating Risk Factors for Ectasia: What is the Goal of Assessing Risk?

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Postoperative corneal ectasia develops rarely, yet ophthalmologists spend a great amount of time and energy researching this issue. Most surgeons believe that if we can successfully refine preoperative screening parameters we will eliminate or at least significantly reduce the incidence of this complication.

Preoperative LASIK screening has evolved over time, from periods of “clinical impressions,” through screening parameters based largely on semi-scientific anecdote, to more stringent scientific analysis.1 A group of prominent refractive surgeons published a consensus opinion paper defining what was and was not known about the development of postoperative ectasia in 2005.2 Subsequently, my colleagues and I authored consecutive papers evaluating multiple potential factors, developing and then evaluating a risk assessment model, the Ectasia Risk Score System (ERSS),3,4 based on a large retrospective review of case-control populations with rigorous statistical analysis to establish the most important and measurable risk factors. There has been debate about the ERSS,5,6 and the article in this issue of the Journal by Binder and Trattler7 purports to refute that work.

Binder and Trattler have analyzed retrospectively a large database (1705 eyes) from one surgeon and applied the ERSS to this population. Their results: 1) None of the 1702 “normal” eyes developed ectasia even though 4.6% of “normal” eyes were deemed “high risk” using the ERSS; 2) Three eyes that developed ectasia were all high-risk based on topographic abnormalities alone. They therefore conclude that the ERSS “may not accurately predict” risk when careful attention is paid to topography and when residual stromal bed thickness is measured intraoperatively. Further, they state that, “For those surgeons who already have extensive keratoconus screening knowledge and an understanding of the errors of residual stromal bed prediction, it [the ERSS] will not add anything other than reducing the percentage of eyes that are ‘suitable’” for surgery.

Are these statements correct? Do we simply need to carefully evaluate topography and measure intraoperative residual stromal bed thickness to avoid ectasia? Does the ERSS include variables, such as age, preoperative corneal thickness, and myopia, which in fact have no bearing on the development of ectasia? To answer these questions, it is important to evaluate critically the data presented in both their and other publications. In addition, we must examine the concept of risk, determine the value of screening protocols for determining risk for ectasia, and ultimately decide what our goal is for assessing “risk” in preoperative LASIK evaluations.

First, the facts for this publication7: If we accept that 1 year is adequate follow-up to evaluate ectasia (which it is not, but it is a practical starting point), then we can in fact conclude that ectasia did not develop in any of the 1702 eyes with normal topography, including the 4.6% deemed “high-risk” by the ERSS. What we cannot conclude is whether these eyes were actually at “high risk” but did not develop ectasia, or whether they were not at high risk at all. The authors clearly favor the latter view, but without a case-control comparison of patients developing ectasia there is really no way to evaluate their hypothesis. Interestingly, among the 3 eyes that developed ectasia with obvious preoperative topographic abnormalities, 2 developed ectasia more than 2 years after seemingly uneventful LASIK.8 This supports what we already know; the development of ectasia may be delayed, even in definitively high-risk eyes. Further, the authors insist on the need for intraoperative pachymetry measurements (which I unequivocally support) and criticize the use of calculated residual stromal bed thickness for screening6 (reasoning that undetected, unexpectedly thick flaps may explain the development of ectasia in patients without abnormal topographies). However, in this series of 1702 eyes, no eye had a flap thickness >200 µm, despite the variety of microkeratomes used; this calls into question the true incidence of unexpectedly thick flaps in the overall LASIK population.

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Nevertheless, if we accept the authors’ data at face value, they are nearly identical to the previous ERSS data they are supposed to refute. Although the screening sensitivity of 100% in this paper is not especially relevant since it is derived from only three ectasia cases, in all three studies, the specificity of the ERSS was approximately 95%. This means only 5% of “normals” were identified as high risk, and if the ERSS was strictly adhered to these patients would be offered alternative treatments (PRK or phakic intraocular lenses). Why are there such disparate conclusions based on similar data?

First, postoperative ectasia remains a conundrum. As with any rare condition, it is challenging to obtain sufficient data to make clear distinctions between normal and abnormal, and there are certainly “high-risk” cases that have not developed ectasia and seemingly low-risk cases whose corneas have become ectatic. We know that keratorefractive surgery reduces corneal strength, yet because the overwhelming majority of corneas do not become ectatic, there must be something fundamentally different about the corneas that do. But what is it? To date, we have only indirect measures to determine corneal strength preoperatively, including corneal curvature via topography, predicted residual stromal bed thickness, and perhaps age, corneal thickness, and myopia, depending on how the data are interpreted. New measurement techniques, including tomographic analysis and corneal hysteresis evaluation, may be useful and validated soon, but for now we rely most heavily on indirect measures of preoperative corneal strength. The retrospective analysis of indirect factors leaves room for varying conclusions about the data.

However, more importantly, there may be a difference in opinion about the concept of “risk” and the goal for assessing risk in preoperative patients. Binder and Trattler’s primary criticism about the ERSS is that it does not really identify high-risk patients because 5% of “normals” were identified as high risk. Yet, “high risk” does not have to mean that a patient will develop ectasia, merely that he/she is at higher risk for this complication than the average patient. As an analogy, smoking certainly places one at significantly “high risk” for developing lung cancer, yet only 10% to 15% of smokers will ever develop lung cancer, whereas up to 10% of lung cancer cases occur in “never smokers” (data available online at www.cdc.gov/cancer/lung/statistics). Does this overlap discount the data that smoking causes cancer? Of course not! An ideal screening system would perfectly discriminate between patients who are absolutely going to develop ectasia from those who absolutely will not, but that is not realistic clinically. It is certainly appropriate to challenge the ERSS, but the mere fact that some “high-risk” normals do not develop ectasia does not discount the ERSS’s utility. One may also criticize it on the basis that it is too conservative, as Binder and Trattler do; however, it seems prudent to err on the side of caution for an elective surgical procedure until we have more definitive criteria on which to base our decisions.

Although the authors and I disagree on some of the conclusions, we do agree on the process of improving LASIK screening strategies to make surgery even safer for our patients, and I applaud both Drs Binder and Trattler for their work evaluating the ERSS. I hope other authors will do the same, with this screening algorithm as well as any others currently or subsequently available. However, good analyses require good data with case-control populations and rigorous statistical evaluations.

REFERENCES