In this issue of the Journal of Refractive Surgery, Binder and Trattler\(^1\) retrospectively evaluated the clinical utility of the Ectasia Risk Score System (ERSS) proposed by Randleman et al.\(^2,3\) We compliment the authors for tackling a controversial and contentious subject. Since its publication in 2008, the ERSS has been discussed, debated, derided, and disputed at various refractive surgery meetings. Many refractive surgeons believe a disservice was done when these articles,\(^2,3\) with such obvious medicolegal implications, were published without accompanying discussions or editorials. Binder and Trattler have intended to correct that omission and put the ERSS into proper clinical perspective.

The initial Randleman study\(^2\) was well performed, with convincing conclusions based on their preoperative analysis. In their follow-up article with the validation study,\(^3\) the ERSS had 8% false negatives and 6% false positives. Many surgeons would consider saying “no” to 6% of their potential LASIK candidates acceptable; this would be a conservative and reasonable approach for preventing the severe complication of iatrogenic ectasia. Of issue, however, are 1) the 8% of cases that developed ectasia despite low ERSS score, and 2) a false positive rate as high as 35% if a relatively young population is evaluated.\(^4\)

The original ERSS study\(^3\) has been touted as being a statistically validated study. Statistical validity and clinical applicability, however, are not always interchangeable.

Practitioners need to carefully evaluate every study to determine whether the parameters utilized are representative of their practice patterns. If not, conclusions drawn from that particular study, regardless of its statistical validity, may not be correctly applied to their patients. Most readers are not statisticians and cannot explain the difference between a Chi-square analysis and Student \(t\) test or know when to apply a logistic regression analysis or use odds ratio estimates.\(^2,3\) Readers, however, should appreciate that statistics alone cannot legitimize the clinical utility of a study.

Much of the criticisms lodged against the ERSS relate to the high risk score assigned to patient age. If the screening techniques used are incomplete (eg, anterior curvature), other parameters (eg, age) may have an exaggerated significance that would lessen with more sensitive screening (eg, posterior elevation and pachymetric progression).\(^5,6\) Keratoconus is a disease that typically presents in the late teens and/or twenties. A truly new case of keratoconus (excluding iatrogenic) presenting past the fourth decade is rare. If we were able to identify early disease with 100% specificity and sensitivity, age would be of little concern. For example, if you use 1) three-dimensional tomographic reconstruction of the corneal surface and evaluate the posterior corneal surface, and 2) full pachymetric spatial profile as opposed to just a single central data point, this would change the risk analysis.\(^5-7\)

Our criticisms fall on how the Randleman study has been applied. The study was based on a single central ultrasound reading and anterior curvature analysis. We believe this represents an incomplete analysis for ectasia risk and/or susceptibility, and is not reflective of screening parameters used by many refractive surgeons. Binder and Trattler’s article reveals some shortcomings of applying the ERSS to a large refractive surgery practice.

At the 2009 International Society of Refractive Surgery symposium in Barcelona (European Society of Cataract and Refractive Surgery Annual Meeting 2009), the audience was polled, with most regularly examining the posterior corneal surface and pachymetric map as part of their refractive screening. There is no question that eyes can exhibit normal anterior curvature and...
central corneal thickness but have clear evidence of subclinical keratoconus when viewed with full tomographic analysis (Fig 1). Other clinical examples demonstrate how additional parameters, when considered, can alter the risk analysis (Fig 2). Patients who have normal videokeratoscopy and a negative keratoconus screening by both Klyce/Maeda or Smolek/Klyce analysis may fall outside of two standard deviations from published norms for elevation and corneal thickness when examined by corneal tomography. The above examples reveal the potential for false negatives but, as noted, may explain the reason for age being such a significant ERSS risk factor.

Binder and Trattler discuss the limitations of commonly performed residual stromal bed computation. Their discussion deals with the operative parameters of flap thickness variability and the consequences of not performing intraoperative pachymetry. We previously published our results in approximately 1400 eyes comparing central thickness to thinnest point readings and showed a potential source of error in magnitude equal or greater than that seen with flap variability. We suggest, in addition to the intraoperative recommendations made by Binder and Trattler, that all preoperative residual stromal bed computations be based on the thinnest preoperative reading.

In addition, a more complete understanding of the physical and biomechanical properties of the cornea will allow an improved determination of an individual’s predisposition or susceptibility for developing ectasia. Current corneal tomography techniques available include Scheimpflug imaging, optical coherence tomography, and high-frequency ultrasound. Although these diagnostic tests are in routine use, screening parameters and normal values have been published. Large scale, long-term studies to determine corneal tomography’s ability to better identify the possible risk of developing ectasia are lacking. Such studies are required to clinically validate our views.

It is difficult at times to read the scientific literature and determine whether a well performed study has clinical applicability. Most physicians do not have the time, proclivity, or database to carefully analyze each study to determine its clinical relevance. Binder and Trattler are commended for performing such an exhaustive review. Statistics, probabilities, means, modes, and standard deviations are all wonderful tools, but should not be a substitute for careful analysis for clinical relevance.

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**Figure 1.** Four examples of refractive composite maps (anterior curvature, anterior elevation, posterior elevation, corneal thickness) (Pentacam; Oculus Optikgeräte GmbH, Wetzlar, Germany), each demonstrating abnormalities that would be missed using the screening parameters/examination used in the Ectasia Risk Score System. The upper left map shows a significant posterior paracentral island of elevation indicative of ectasia despite a normal curvature (low symmetric astigmatism) and a central corneal thickness of 514 µm. The upper right map reveals significant inferior posterior ectasia and an accompanying displacement of the thinnest point to the ectatic region despite normal anterior curvature and a normal central thickness. Similarly, the lower left map shows a low degree of astigmatism on anterior curvature but an ectatic region on the posterior elevation with mild displacement of the thinnest point. The lower right map demonstrates that although the anterior and posterior surfaces can appear normal (low degree of astigmatism on both elevation and curvature), the corneal thickness map may be abnormal. The thinnest point is significantly displaced.
REFERENCES


