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Validation of the Ectasia Risk Score System for Preoperative Laser in Situ Keratomileusis Screening

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Abstract

Purpose—To validate the Ectasia Risk Score System for identifying patients at high risk for developing ectasia after laser in situ keratomileusis (LASIK)..

Design—Retrospective case-control study

Methods—Fifty eyes that developed ectasia and 50 control eyes with normal postoperative courses after LASIK were analyzed and compared using the previously described Ectasia Risk Score System, which assigns points in a weighted fashion to the following variables: topographic patter, predicted residual stromal bed thickness (RSB), age, preoperative corneal thickness (CT), and manifest refraction spherical equivalent (MRSE).

Results—In this series 92% of eyes with ectasia were correctly classified as being at high risk for the development of ectasia, while 6% of controls were incorrectly classified as being at high risk for ectasia. ($p < 1 \times 10^{-10}$). Significantly more eyes were classified as high risk by the ectasia risk score than by traditional screening parameters relying on abnormal topography or residual stromal bed thickness less than 250 μ (92% vs. 50%, $p < 0.00001$). There was no difference in the sensitivity or specificity of the Ectasia Risk Score System in the population from which it was derived and this independent population of ectasia cases and controls.

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Conclusion—The Ectasia Risk Score System is a valid and effective method for detecting eyes at risk for ectasia after LASIK and represents a significant improvement over previously utilized screening strategies.

Factors that have been reported to place an individual at increased risk for developing corneal ectasia after LASIK include preoperative topographic abnormality, low residual stromal bed thickness, young age, thin corneas, and high myopia.[1] The most significant and best described risk factors are topographic abnormality and reduced residual stromal bed thickness,[2-4] although some patients have developed ectasia without either of these factors.[5-11]

We recently analyzed a large retrospective series of ectasia cases and developed a weighted scoring system, the Ectasia Risk Score System, to better identify patients at high risk.[1] In this initial population, 92% of ectasia cases were correctly classified as being at high risk for the development of ectasia, while 6% of control eyes were incorrectly identified as being at high risk.

In the current study, we test the validity of the Ectasia Risk Score System by applying it to a novel LASIK population, including eyes that developed ectasia after LASIK and controls that did not.

METHODS

We retrospectively evaluated 50 consecutive eyes that developed corneal ectasia after LASIK and presented to either the Emory Eye Center (Atlanta, Georgia) or the Center for Excellence in Eye Care (Miami, Florida) for evaluation. These eyes were consecutive ectasia cases not included in the previous analysis.[1] For comparison, we analyzed 50 consecutive control eyes undergoing uncomplicated LASIK from June through October 2004 at Emory that had normal postoperative courses (stable refractions and topographic patterns), all preoperative data listed above, and at least one year of postoperative follow-up. None of the ectasia cases or controls were included from the previous study.[1] We chose to utilize control cases from 2004 to avoid any potential case selection bias during the time that the ectasia risk score system was being developed.

Patient age, gender, preoperative manifest refraction spherical equivalent (MRSE), corneal thickness (CT), topographic pattern, and predicted residual stromal bed thickness (RSB) were evaluated as predictors of ectasia. Because of the heterogeneity of ectasia cases (referred from numerous different practices), fewer surgical details were available, including lasers or microkeratomes utilized for treatments. None of the ectasia cases had intraoperative pachymetry performed. For control cases, all cases had corneal flaps created with the Amadeus I microkeratome with a 140 micron plate.

Preoperative topographies, using axial map placido-based images, were classified as follows[1]: Normal/Symmetrical (includes round, oval, and symmetric bowtie patterns); Suspicious (includes Asymmetric Bowtie, which is asymmetric steepening in any direction greater than 0.5 D but less than 1.0 diopters as compared to the region 180 degrees opposite the steepest region with no skewed radial axis, and Inferior Steepening/Skewed Radial Axis, which includes significant skewed radial axis (20 degrees or greater) with or without inferior steepening or 1.0 diopters or more of inferior steepening as compared to the region 180 degrees opposite the steepest region but an Inferior-Superior (I-S) value less than 1.4; Abnormal, which includes keratoconus, pellucid marginal corneal degeneration, and forme fruste keratoconus [I-S ≥ 1.4[12, 13]]).

All cases were assigned a cumulative ectasia risk score based on the Ectasia Risk Score System previously described[1] [Table 1]. Risk categories based on cumulative points were as follows: 0-2 points = low risk; 3 points = moderate risk; 4 points = high risk.

For comparison, we also evaluated ectasia cases using some traditional “cut-off” values, including abnormal topographies as described above or predicted RSB less than 250 microns. We compared the screening results using these “traditional methods” with the Ectasia Risk Score System

Statistical analyses performed included Student’s t-test and chi square analysis. P values < 0.05 were considered significant.

RESULTS

Ectasia patient demographics in this study were similar to those reported from the previous subgroup analysis used to create the Ectasia Risk Score System [Table 2]. Ectasia and control patient demographics for this study are listed in Table 3; nearly half of the ectasia case topographic patterns were abnormal, while none of the control cases had abnormal topographic patterns (46% vs. 0%) [Table 4]. In this series, 92% of eyes that developed ectasia were correctly classified as being at high risk based on the Ectasia Risk Score System compared to 6% of controls. Significantly more eyes were classified as being at high risk by the Ectasia Risk Score System than by traditional screening parameters relying on abnormal topography as defined above or residual stromal bed thickness less than 250 μ (92% vs. 50%, p<0.00001) [Figure 1].

The sensitivity and specificity of the Ectasia Risk Score in this study were essentially the same as they were in the previous study [Figures 2 and 3]. Detailed distribution of scores by category is shown in Figure 4.

DISCUSSION

The results of this study validate the Ectasia Risk Score System as an effective method of identifying patients at increased risk for developing corneal ectasia after LASIK, and this system appears to be more sensitive and specific than traditional screening strategies suggested in the literature. This scoring system utilizes the following factors in a weighted fashion in order of importance: 1) preoperative topographic pattern; 2) residual stromal bed thickness; 3) age; 4) preoperative corneal thickness; and 5) myopia. The most significant characteristic of this system is the recognition that a variety of factors contribute to a continuum of risk for ectasia, in contrast to commonly used individual criteria with defined critical values, such as corneal thickness less than 500 microns, RSB less than 250 microns, or forme fruste keratoconus.

Topographic patterns

In both this and our previous study, abnormal topography was the most significant factor with the highest relative risk that discriminated between ectasia cases and controls. Nearly 50% of ectasia cases had defined topographic abnormalities. In addition to the current categories (Asymmetric Bowtie, Inferior Steep/Skewed Radial Axis, and Abnormal) it may be appropriate to give weighted consideration to patients that exhibit significant between-eye topographic asymmetry, even if neither eye’s topographic pattern is in itself decidedly abnormal.

We relied exclusively on the placido-based images generated by a variety of topography systems for this scoring system. Newer topographic systems utilize other corneal imaging techniques that may prove useful for patient evaluation. These include the Orbscan II (Bausch & Lomb, Rochester, NY), which utilizes images obtained with slit-beam lighting in addition to placido-based imaging, and the Pentacam (Oculus, Inc., Lynnwood, WA), which utilizes Scheimpflug photography generated images. A number of indices to identify keratoconus have been proposed for these instruments, including a "vertical D pattern" found in the keratometric map,[14] corneal thickness spatial profile and volume distribution,[15] posterior best-fit sphere radius and elevation,[16] absolute posterior float values,[17] and a combination of Orbscan II factors in a specific screening strategy.[18] While promising, these methods have yet to be validated with a population of ectasia cases and controls, and more importantly, have yet to be proven more useful than placido-based imaging in identifying the earliest corneal abnormalities that are paramount for effective refractive surgical screening. This remains a valuable area for future evaluation.

Residual Stromal Bed Thickness

Recent biomechanical studies have reinforced the importance of residual stromal bed thickness after LASIK. Both stress-strain analysis[19] and cohesive tensile strength analysis[20] indicate that corneal strength is significantly greater in the anterior 40% of the corneal stroma than in the posterior 60%. Further, the corneal flap contributes minimally to the tensile strength of the cornea after LASIK.[3, 21] Thus, LASIK reduces corneal structural integrity both by reducing overall available load bearing tissue and by shifting the load bearing responsibility to the structurally weaker posterior corneal stroma.

It is clear, however, that RSB of 250 microns does not absolutely discriminate between eyes that will develop ectasia and those that will not. Rather, RSB seems to be a continuous variable, with the risk of ectasia increasing with decreasing RSB.

Age

Young patient age has been identified as a significant risk factor for ectasia in eyes without other generally accepted risk factors.[1, 7] This may be partially explained by the fact that corneal tensile strength increases with age,[20] thereby imparting some protective function for older corneas. Additionally, some young patients with currently normal topographies may be destined to develop topographic abnormalities and even frank keratoconus or Pellucid Marginal Corneal Degeneration over time whether or not they undergo LASIK. There was a significantly increased odds ratio for age less than 30 in our previous study[1]; however, the specific age categories below 30 in this score system have been somewhat arbitrarily defined, and further analysis may help refine these divisions.

Corneal Thickness

Corneal thickness, degree of myopia, and RSB are inter-related. Low corneal thickness has been found to be a risk factor for ectasia in every published case-control analysis,[1, 2] including this study. Since keratoconic corneas are thinner than normal corneas,[22, 23] thin corneas may be an indicator of early keratoconus, and thinner corneas are at higher risk for low residual stromal bed thickness due to variability in microkeratome function. However, preoperative corneal thickness alone appears to be only a weak indictor for increased risk of ectasia[1], and LASIK has been successfully performed in corneas less than 500 microns without incident.[24-26] Therefore, there does not appear to be a clear cut-off value below which LASIK cannot be safely performed if all other factors are normal.

Borderline Surgical Candidates

In both studies, there were a small number of eyes that were categorized as "Moderate Risk", with a score of 3, including 2-4% of ectasia cases and 8-10% of controls from both studies. In these “borderline” cases, it may be particularly appropriate to consider factors that could increase the risk of ectasia but have not been as extensively studied as those mentioned above. These include chronic trauma (eye rubbing), family history of keratoconus, refractive instability, and preoperative best spectacle-corrected visual acuity less than 20/20.

Utilizing the Ectasia Risk Score System

The Ectasia Risk Score System has proven to be effective in evaluating eyes for the risk for developing ectasia after LASIK. The cumulative, weighted nature of the system may both help identify patients at risk for ectasia that do not meet specific previously utilized critical or “cut-off” criteria and also may help explain why patients with one or two risk factors, such as high myopia, thinner corneas, or lower residual stromal bed thickness, have not developed ectasia.[24, 26, 27] However, although this screening method may be a significant improvement over currently utilized techniques, not all patients who developed ectasia were recognized by this system; some of these cases may be due to unexpectedly thick unmeasured flaps, limitations in placido-based imaging, and other as yet undefined corneal biomechanical factors. Further, this system has not been directly applied to eyes undergoing surface ablation due to currently insufficient numbers of reported cases of ectasia after surface ablation. Therefore, other unrecognized risk factors likely exist, ectasia may still occur after uncomplicated surgery in appropriately screened candidates, and the safety of surface ablation in eyes at risk for ectasia after LASIK based on the Ectasia Risk Score remains undetermined.

The results of this study validate the efficacy of the Ectasia Risk Score System by demonstrating similar specificity and sensitivity on a population of eyes that was independent from those used to derive the system. This system is a significant improvement over existing systems for identifying patients at risk for ectasia because it utilizes multiple risk factors and evaluates them on a quantitative basis.

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Biography

Randleman Biographical sketch

J. Bradley Randleman, MD is Assistant Professor, Department of Ophthalmology at Emory University. He received his B.A. from Columbia University and M.D. from Texas Tech University. He then completed residency training and Cornea, External Disease, and Refractive Surgery Fellowship at Emory University. He is a recent recipient of the American Academy of Ophthalmology Secretariat Award. His primary research interests are refractive surgical evaluation and the identification, management, and prevention of complications after refractive surgery.

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Stulting Bio Sketch

Robert Doyle Stulting, M.D., Ph.D. is Professor of Ophthalmology, Director of Cornea and Refractive Surgery Service at Emory University. He received his B.A., M.D., and PhD in microbiology and immunology from Duke University. He completed his ophthalmology residency at the University of Miami, Bascom Palmer Eye Institute followed by a fellowship in cornea and external disease at Emory University. He is Secretary for the American Society for Cataract and Refractive Surgery and Editor-In-Chief of *Cornea*.

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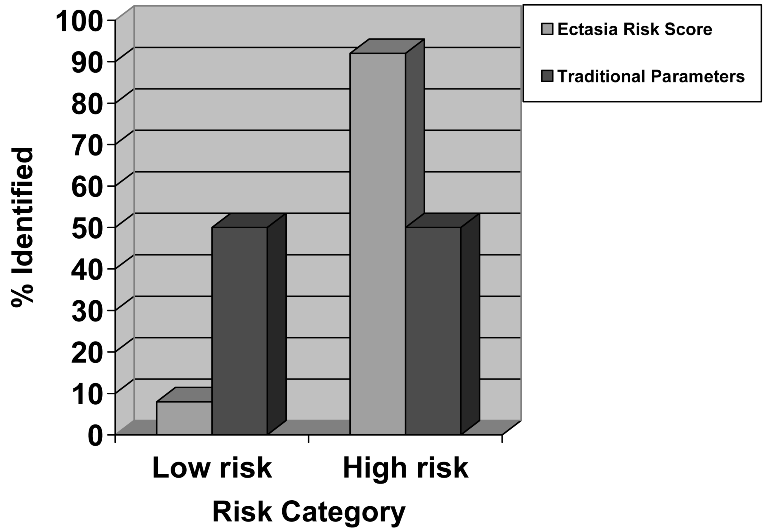


Figure 1. Comparison of Screening Results Utilizing the Ectasia Risk Score System and Traditional Screening Parameters for Identifying Patients at High Risk for Developing Ectasia after LASIK

Ectasia screening comparisons for ectasia cases utilizing the Ectasia Risk Score System (Ectasia Risk Score) and (Traditional Parameters). The Ectasia Risk Score System correctly identified a significantly greater percentage of eyes than traditional screening methods (abnormal topography or residual stromal bed less than 250 microns) that ultimately developed ectasia (92% vs. 50%, $p<0.00001$) with very few false negatives (8%).

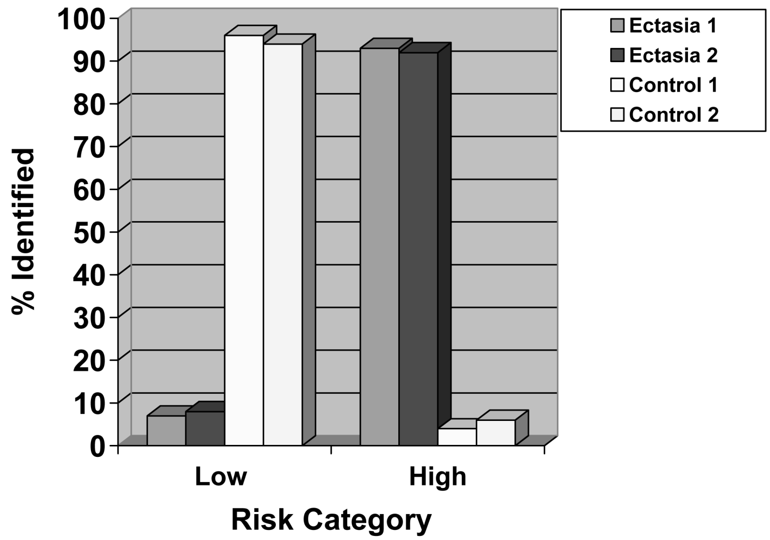


Figure 2. Ectasia Risk Score System Score Comparisons Between the Ectasia and Control Populations from This Study and Previous Study for Identifying Eyes at High or Low Risk for Developing Ectasia after LASIK

Eyes from the previous study population* were labeled as Ectasia 1 and Control 1, and eyes from this study were labeled Ectasia 2 and Control 2. There were no significant differences between ectasia cases from the two populations or controls from the two populations in percentage of eyes identified as low or high risk.

*Previous study population was reported in Randleman JB, Woodward M, Lynn MJ, Stulting RD. Risk Assessment for Ectasia after Corneal Refractive Surgery. Ophthalmology 2008; 115: 37-50.

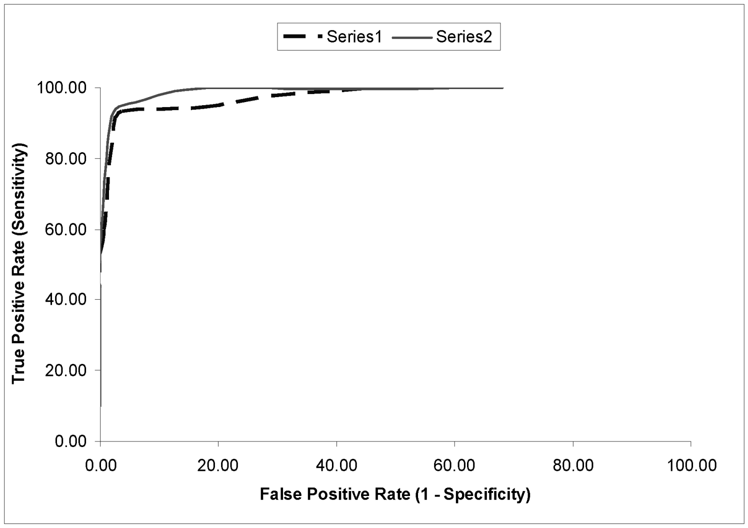
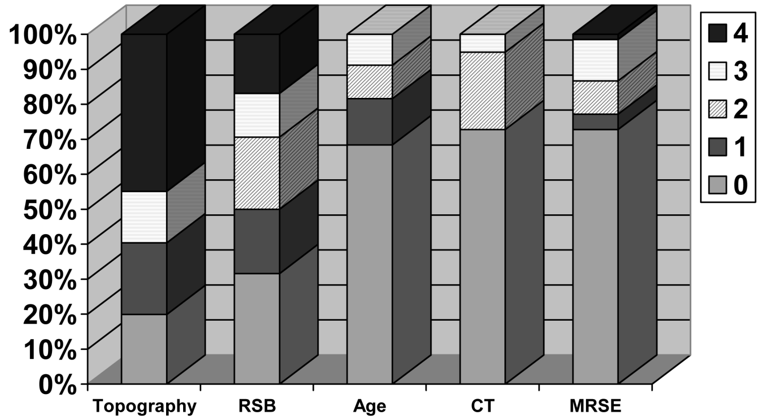


Figure 3. Receiver Operated Characteristic (ROC) Curve Comparing Sensitivity and Specificity for the Ectasia Score System in This Study and Previous Study Populations in Screening for Eyes at High Risk of Developing Ectasia after LASIK

The steep rise in both curves demonstrates high sensitivity and specificity for both populations, the previous study (Series 1) and this study (Series 2), and there are no significant differences between the two groups.



Points	Parameter				
	Topography	RSB	Age	CT	MRSE
4	44.9%	16.9%		0%	1.5%
3	14.7%	12.5%	8.8%	5.1%	11.8%
2		20.6%	9.6%	22.1%	9.5%
1	20.5%	18.4%	13.2%		4.4%
0	19.9%	31.6%	68.4%	72.8%	72.8%

Figure 4. Distribution of Ectasia Risk Score Points by Category for Ectasia Cases Using the Ectasia Risk Score System for Determining Eye at High Risk of Developing Ectasia after LASIK

This graph demonstrates the percentage of ectasia cases that scored each point values for each parameter evaluated in the Ectasia Risk Score System.

RSB = Residual stromal bed thickness

CT = Preoperative corneal thickness

MRSE = Preoperative spherical equivalent manifest refraction

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Table 1

The Ectasia Risk Score System for Identifying Eyes at High Risk of Developing Ectasia after LASIK

Parameter	**Points**				
	4	**3**	**2**	**1**	**0**
Topography	Abnormal Topography	Inf. Steep/SRA		ABT	Normal/SBT
RSB	<240μ	240 - 259μ	260 - 279μ	280 - 299μ	≥300μ
Age		18 - 21 yrs	22 - 25 yrs	26 - 29 yrs	≥30 yrs
CT	<450 μ	451 - 480 μ	481 - 510 μ		≥510 μ
MRSE	>−14D	>−12 - -14D	>−10 - -12D	>−8 - -10D	−8D or less

Inf. Steep = inferior steepening pattern

SRA = skewed radial axis

ABT = asymmetric bowtie

SBT = symmetric bowtie

RSB = residual stromal bed thickness

CT = preoperative corneal thickness

MRSE = preoperative spherical equivalent manifest refraction

D = diopters

Table 2

Ectasia Patient Demographic Comparisons between this Ectasia Risk Score Validation Study Population and the Previous Study Population

Demographics	This Study (n = 50)	Previous Study* (n = 86)	P value
Age (years)	35.3	33.7	0.3
MRSE (D)	−5.99	−6.67	0.3
CT (μ)	529	523	0.4
RSB (μ)	288	264	0.01
Abnormal Topography	46%	44%	0.9

This Study = eyes reported in this study

*Previous study = eyes reported in Randleman JB, Woodward M, Lynn MJ, Stulting RD. Risk Assessment for Ectasia after Corneal Refractive Surgery. Ophthalmology 2008; 115: 37-50.

MRSE = preoperative spherical equivalent manifest refraction

D = Diopters

CT = preoperative corneal thickness

RSB = residual stromal bed thickness

Table 3

Ectasia and Control Population Patient Demographics from This Ectasia Risk Score System Validation Study

Demographics	Ectasia Cases (n = 50)	Control Cases (n = 50)	P value
Age (years)	35.3 (18 to 55)	37.3 (18 to 55)	0.3
Gender			0.7
Male	56%	50%	
Female	44%	50%	
MRSE (D)	−5.99 (−1.25 to −15.75)	−3.57 (−1.25 to −8.5)	0.00003
CT (μ)	529 (457 to 580)	547 (493 to 664))	0.003
RSB (μ)	288 (204 to 392)	343 (280 to 454)	$<1.0 \times 10^{-9}$

MRSE = preoperative spherical equivalent manifest refraction

D = Diopters

CT = preoperative corneal thickness

RSB = residual stromal bed thickness

Table 4

Topographic Characteristics of Ectasia Cases and Controls for This Ectasia Risk Score System Validation Study

Topographic Patterns	Ectasia Cases (n = 50)	Control Cases (n = 50)	P value
Normal/Symmetrical	4 (8%)	32 (64%)	$<1 \times 10^{-9}$
Asymmetric Bowtie	10 (20%)	17 (34%)	0.2
INF Steep/SRA	13 (26%)	1 (2%)	0.001
Abnormal	23 (46%)	0 (0%)	$<1 \times 10^{-8}$

INF Steep/SRA = topographic pattern with inferior steepening and/or a skewed radial axis