Enhanced Ectasia Susceptibility Screening

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Financial Disclosures: Alcon/Wavelight

Cairo (Egypt) – 26/01/2018

Progressive "iatrogenic" keratectasia

• First described by Seiler in 1998
  – Progressive steepening and loss of visual acuity soon after LASIK in a case of forme fruste keratoconus (FFKC)
• Emerged as a very severe complication for LVC procedures
• Prevention is best strategy
Known Risk Factors for Ectasia

- Pre-operative ectatic corneal disease
- Young Age
- Excessive laser ablation (high corrections)
- Thick LASIK Flap
- Low Preoperative Pachymetry

LASIK “Math”: Rule of 250

Pachymetry > (Flap + Ablation) + ‘Safe’ RSB

HOWEVER...
Cases with 200 µm or less that are stable
Cases with over 300 µm that had Ectasia
Risk Assessment for Ectasia After Corneal Refractive Surgery

Randleman JB, Woodward M, Lynn MJ, Stulting RD.
Ophthalmology 2008; 115: 37-50

Comprehensive, weighted, risk factor scale significantly improves the identification of high risk eyes

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Point Value</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>4</td>
</tr>
<tr>
<td>Topography Pattern</td>
<td>Abnormal</td>
</tr>
<tr>
<td>Residual Stromal Bed</td>
<td>&lt;240µ</td>
</tr>
<tr>
<td>Age</td>
<td>18 to 21y</td>
</tr>
<tr>
<td>Preoperative Pachymetry</td>
<td>&lt;450µ</td>
</tr>
<tr>
<td>MR (SE)</td>
<td>&gt;-14D</td>
</tr>
</tbody>
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Variability of Subjective Classifications of Corneal Topography Maps From LASIK Candidates


CONCLUSION: There was significant inter-observer variability in the subjective classifications using the same scale, and significant intra-observer variability between scales. Changing from an absolute to a normative scale increased the scores on the classifications by the same examiner, but significant inter-observer variability in the subjective interpretation of the maps still persisted.
Why we need Enhanced Screening Tests?

- Cases with risk factors with stable results
- False positives and negatives ERSS (Ectasia Risk Score System)
  - 8% of cases with ectasia had a false negative AND
  - 6% of normal controls were incorrectly classified as being at high risk for ectasia (false positive)
  

- “unexplained” cases of Ectasia after LASIK

We need Enhanced Screening!

“unexplained” cases of Ectasia after LASIK

<table>
<thead>
<tr>
<th>Age</th>
<th>Eye</th>
<th>Sph</th>
<th>Cyl</th>
<th>Axis</th>
</tr>
</thead>
<tbody>
<tr>
<td>31.9</td>
<td>L</td>
<td>-5.75</td>
<td>-0.50</td>
<td>95</td>
</tr>
</tbody>
</table>

LASIK with Femtosecond (July/2008)
Flap Thickness: 110µm (RSB=336; PTA=0.36)
**Enhanced Screening: Pre Op ToMography**

(Belin/Ambrósio Display – BAD)

- ART-Max < 412: Ectasia susceptibility
- BAD D > 1.44

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**Pathophysiology of Post-LVC Ectasia**

- **Pre-operative ‘abnormal’ or ‘susceptible’ cornea**
  - Subclinical ectasia
  - Forme Fruste Keratoconus

- **Post-operative ‘biomechanically weak’ cornea**
  - Excessive ablation
  - Induced by a thick-flap
  - **Chronic eye rubbing**

Any cornea may undergo biomechanical failure and develop Ectasia
“Forme Fruste Keratoconus is defined as a very susceptible cornea for ectasia progression and may present with `normal` topography.”

Renato Ambrósio Jr, MD, PhD (2009)

**Ectasia Study: Corneal Tomography**

- Oculus Pentacam HR (Wetzlar, Germany) data from one eye randomly selected:
  - 439 Normals (Pre-op stable LASIK, N)
  - 364 Clinical keratoconus (KC)
  - 241 Forme fruste keratoconus (fellow eyes with `normal topography`*, FFKC)

*no evidence of keratoconus on Oculus TKC and/or Nidek Corneal Navigator*
Results: Best Parameters

**IHD (Front Surface)**
- AUC=0.992 for KC (95% CI: 0.970 to 0.994)
- AUC=0.781 for FFKC (95% CI: 0.741 to 0.817).

**ART-Max (Relational Pachy)**
- AUC=0.992 for KC (95% CI: 0.980 to 0.997)
- AUC=0.877 for FFKC (95% CI: 0.844 to 0.905).

**BAD-D (version 3)**
- AUC=0.995 for KC (95% CI: 0.982 to 0.998)
- AUC=0.892 for FFKC (95% CI: 0.861 to 0.919).

0 = Stable LASIK  
1 = FFKC  
2 = KC

**Enhanced Ectasia Susceptibility Screening based on clinical and tomographic data**

- The EESS is a combined function designed to enhance accuracy in detecting ectasia risk.
- In the first study, the EESS was developed based on logistic regression analysis of clinical and Pentacam data from 266 eyes (141 patients) with stable LASIK outcomes (minimal follow-up of 24 months) and 22 eyes that developed ectasia.*

* Ramos et al., Enhanced Screening for Ectasia Susceptibility among LASIK Candidates. ECRS Interactive Poster, Amsterdam 2013. 1st Prize Refractive Poster Award.

- Current study further refine and validates the sensitivity in a larger population comprised of 60 eyes from 46 patients that developed ectasia (Group 1). Same stable LASIK group as control (Group 2).

**Group 1 (sagittal maps)**

Note: 22 eyes from group 1 were used for the initial analysis presented at ECRS 2013.
Results - “Enhanced Ectasia Susceptibility Screening”

- The EESS obtained 100% of sensitivity and 94.74% of specificity to distinguish post-LASIK ectasia cases from stable LASIK cases.

- The parameters that comprise the EESS are: Age, Flap Thickness, Ablation Depth, IHD, and Belin-Ambrósio Deviation Index (BAD-D).

Discussion

- EESS was further refined and validated in a larger population of ectasia cases.
- EESS was statistically better in pairwise comparisons of ROC Curves by DeLong’s Method than all parameters, including BAD-D (Graph).
- Ectasia after LASIK occurs due to a combination of preoperative predisposition (better characterized by tomography) and the impact of LASIK procedure on corneal structure.
- Age, a surrogate of biomechanical properties, significantly impact regression analysis.

Conclusion

- Artificial intelligence strategies should be applied to optimize accuracy in diagnosis, using conscious and validated combinations of parameters.
- The EESS represents a superior method for detecting risk for ectasia after LASIK.
Patient Data

- 29 years old
- Nurse
- Pre-OP subjective Refraction:
  - OD: -3.50 -0.25 @ 50° (10/10)
  - OS: -3.50 -0.50 @ 105° (10/10)
- Slit-lamp examination:
  - AO: MGD mild; tear film with debris
Corneal ToMography

Corneal ToMography

Corneal ToMography
BrAIn Cornea Risk Calculator

**RIGHT EYE**

**LEFT EYE**

CARRIED OUT ON: 06/25/2017 - 18:51:17
ECTASIA POST LASIK: 25.526%

CARRIED OUT ON: 06/26/2017 - 18:43:13
ECTASIA POST LASIK: 27.317900000000045%
3 M Postoperative Data

- **UCVA**
  - OD: 10/10+ (12/10 with -0.50 @ 175°)
  - OE: 12/10

- **Slit-lamp examination:**
  - AO: epithelium OK; MGD mild; tear film improving
3 M Postoperative Data

Tomography is better to identify ectasia susceptibility (vs Topography)

ALWAYS remember:
- surgical-induced damage
- Avoid chronic eye rubbing

Integration of clinical data and Corneal Geometry

Artificial intelligence and new technologies to combine
Integration of Scheimpflug Tomography and Biomechanics

TBI: Tomography/Biomechanical Index

Integration of Scheimpflug-Based Corneal Tomography and Biomechanical Assessments for Enhancing Ectasia Detection

RESULTS: The random forest method with base-case cross-validation (BF/CV) provided the best artificial intelligence model. The AUCRO for detecting ectasia keratoconus, VAE, and VAE RT group of the TBI was 0.984, which was statistically higher (P<0.001) than the BADOD (0.966) and CB (0.936). The TBI cut-off value of 0.79 provided 100% sensitivity for detecting clinical ectasia keratoconus and VAE-E group with 100% specificity. The AUCROs for the TBI, BADD, and CB were 0.988, 0.989, and 0.922 in the VAE-E group (Delong et al., P<0.001). An optimized TBI cut-off value of 0.25 provided 90.4% sensitivity with 99.6% specificity in the VAE-E group.

CONCLUSIONS: The TBI generated by the BF/CV model provided greater accuracy for detecting ectasia than other methods. TBI was sensitive for detecting subclinical (focal) ectasia among eyes with normal topography in asymptomatic patients. The TBI may also confirm unilateral ectasia, potentially characterizing the inherent ectasia susceptibility of the cornea, which should be the subject of future studies.
Thank you for your attention!