Regression after Hyperopic LASIK

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• Presenter is a paid consultant to WaveLight, AG
• Investigator in FDA Trials for the Allegretto Laser
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Hyperopic LASIK

- Literature reports of stability of hyperopic LASIK vary in their conclusions.
- Comparisons also vary with older lasers, smaller optical zones, treatment ranges, etc.
- Few reports include long-term follow up -> 1 Year.
Literature Review – LASIK

  - MEL 60 Laser / 1 Year Follow Up
  - Showed improved stability with larger optical zones
Literature Review – LASIK

  – Summit Apex Plus / 6.00 mm / Axicon Blend to 9.5 mm
  – 47 eyes, Range +0.75 to +7.00 D
  – Showed “significant regression” (hyperopic shift) between 12 and 54 months
    • Age < 40 Years: +0.67 D (range 0.00 to +1.125 D)
    • Age 43 – 55 +0.44 D (range -1.33 to +1.50 D)
Literature Review – LASIK

  - Chiron Technolas Keracor 117C
  - 5 Year Results / 125 Eyes
  - Range +1.00 to +6.50 D
  - Showed increased regression with higher treatments and with dry eyes
Literature Review: PRK/LASEK

  – NidekEC-5000 / 216 eyes
  – Showed better stability with LASEK than PRK
Literature Review - PRK

  - Summit Apex Plus
  - 40 eyes, range +2.00 to +7.50 D
  - Showed mean change of +0.28 D from 1 to 7.5 years
  - “No patient complained of night-vision problems”
  - Concluded PRK is stable for hyperopia
Long Term Results from the US FDA Study of the Allegretto

- 290 eyes studied in 10 centers
- Last treatment was 12/11/02
  - Now > 3 years postop for all eyes
- Range up to 6 D Spheroequivalent
- PMA report showed stability by M3
  - M1 to M3 Mean S.E. Change: +0.12 ± 0.40 D
  - M3 to M6 Mean S.E. Change: +0.01 ± 0.37 D
- Decided to call patients back in to evaluate stability
Optical Zone 6.5 mm

- True (effective) 6.5 mm optical zone
  - Blend adjustable
Manifest Refraction ±0.50 D*
Low v. High Myopia

Spherocylinder Results Slightly Better Than Spheres

*Based on 1 Year Data in 813 Eyes
Spheroequivalent Scattergram

 Attempted SE (D)

 Achieved SE (D)

 $y = 0.92x$

 $R^2 = 0.86$

 71.2$\% \pm 0.50 \text{ D}$

 90.2$\% \pm 1.00 \text{ D}$
Long Term Hyperopic LASIK Results with the Allegretto

- So far 93/290 (32%) eyes have been examined
- Mean follow up is 3.7 ± 0.36 years
Preop Refractive Distribution
N = 93
Spheroequivalent Change
3 Years After Stability

0 to < +2.00 D
>2 to < +4.00 D
>4 to < +6.00 D
### Mean Keratometry Change 3 Years After Stability

<table>
<thead>
<tr>
<th>Range</th>
<th>Graphical Representation</th>
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<tbody>
<tr>
<td>0 to &lt; +2.00 D</td>
<td>0 to &lt; +2.00 D</td>
</tr>
<tr>
<td>&gt;2 to &lt; +4.00 D</td>
<td>&gt;2 to &lt; +4.00 D</td>
</tr>
<tr>
<td>&gt;4 to &lt; +6.00 D</td>
<td>&gt;4 to &lt; +6.00 D</td>
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Mechanism of Action

- Some eyes were not corrected for full cycloplegic refraction
- Refractive changes correlated best with K changes in higher hyperopes
  - Correlation = 0.41
  - Implies true regression in this group
- Refractive differences correlated best with untreated hyperopia in low hyperopes
  - R = 0.24
  - No correlation with K differences (0.04)
  - Implies changes in this group related to latent hyperopia becoming manifest
Conclusions

• No significant regression seen in treatments < 4 D
• Magnitude of change in eyes with > 4 D was low
  – Mean 0.49 ± 0.45 D over 3.7 years
• Suggests good stability with hyperopic LASIK using wider ablation zones
  – Literature reports based on older lasers may not reflect current performance
Thank You!