Clinical Applications of The Rochester Nomogram

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The Problem – Hyperopic Overcorrection
Customized LASIK

• Post-Custom LASIK refractive error
  – Incidence (FDA trial, n = 340 eyes) and range (±/− 2 D)
  – More over-correction than under-correction (9 X)

<table>
<thead>
<tr>
<th>6 months post LASIK SE (D)</th>
<th>Myopia (under-correction)</th>
<th>Hyperopia (over-correction)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt; 0.5 D</td>
<td>8 (2.3%)</td>
<td>74 (21.8%)</td>
</tr>
<tr>
<td>&gt; 1 D</td>
<td>1 (0.2%)</td>
<td>20 (5.9%)</td>
</tr>
</tbody>
</table>

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Aberration Interaction Causing Hyperopic Overcorrection?
The Rochester Nomogram

- Unique features
  - Use of preoperative manifest refraction
    - Preop myopia (vector notation: SE, J0, J45)
    - **NOT** PPR (wavefront sphere value)
  - Derived from analysis on 112 myopic eyes treated by same surgeon with Zyoptix LASIK in FDA trial
    - Effect of preop HOA on postop refractive error
      - Effect of Spherical Aberration
      - 3rd order aberration
      - Aberration Interaction

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Aberration Interaction: Preop HOA Influence on Postop Sphere and Cylinder

Radial order
2nd
astigmatism
defocus
astigmatism

3rd
trefoil
coma
coma
trefoil

4th
quadrafoil
secondary astigmatism
spherical ab.
secondary astigmatism
quadrafoil

Lower Order Aberrations
Higher Order Aberrations

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## The Rochester Nomogram - Methods

<table>
<thead>
<tr>
<th>Parameter</th>
<th>112 eye FDA Study</th>
<th>2.5% Neosynephrine First Study (175 eyes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean preop SE (D)</td>
<td>-3.41 ± 1.44</td>
<td>-4.89 ± 2.06</td>
</tr>
<tr>
<td></td>
<td>(-1.25 to -7.50)</td>
<td>(-1 to -10.25)</td>
</tr>
<tr>
<td>Mean Astigmatism (D)</td>
<td>-0.60 ± 0.49</td>
<td>-0.81 ± 0.70</td>
</tr>
<tr>
<td></td>
<td>(0 to -3.25)</td>
<td>(0 to -4.25)</td>
</tr>
<tr>
<td>Mean Preop HOA (um)</td>
<td>0.45 ± 0.16</td>
<td>0.53 ± 0.16</td>
</tr>
</tbody>
</table>

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The Rochester Nomogram: Eliminates Outliers

- Manifest Refraction (D)
- Sphere
- SE

-0.50 -0.25 0.00 0.25 0.50 0.75 1.00

Rochester Nomogram
Zyoptix Algorithm

(+/- 1 D)
(- 1.04 to 1.81 D)

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The Rochester Nomogram – Results
0 Outliers > 1.00 D (N=175)

Number of Eyes

<table>
<thead>
<tr>
<th>SE Range</th>
<th>Myopia</th>
<th>Hyperopia</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.5 &lt; SE &lt; 1 D</td>
<td>10</td>
<td>5</td>
</tr>
<tr>
<td>SE &gt; 1 D</td>
<td>13</td>
<td>27</td>
</tr>
</tbody>
</table>

N = 175 eyes
The Rochester Nomogram – VA

- 93.1% of the eyes had 20/20 or better UCVA
- 98.3% of the eyes had 20/20 or better BCVA
The Rochester Nomogram for Pharmacologic vs Non Pharmacologic Dilated Zyoptix

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Rochester Nomogram: Pharmacologic vs Non-Pharmacologic Dilated Zyoptix

- 175 eye 2.5% Neosyneprine Dilated Zyoptix
- 90 eye Gulden Black Hood: low mesopic Zywaves
- 6.3 mm pupil diameter minimal (60.7% of eyes could be dilated to 6.3mm)
Luminance/Illumination Photometry Testing

- Tectronics Lumicolor J17 Photometer/Radiometer
- Rural Low Light Night Driving 0.15 Candellas/meter
- Zywae Maltese Cross 0.05 Candellas/meter (1/3 of night driving illumination)
Results (ROC nomogram)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>2.5% Neosynephrine (175 eyes)</th>
<th>No Neosynephrine (90 eyes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preop Sph Eq (D)</td>
<td>-4.89 ± 2.06</td>
<td>-4.39 ± 2.08</td>
</tr>
<tr>
<td>Preop Sphere (D)</td>
<td>-4.52 ± 2.05</td>
<td>-4.11 ± 2.04</td>
</tr>
<tr>
<td>Preop Cyl (D)</td>
<td>-0.81 ± 0.70</td>
<td>-0.56 ± 0.53</td>
</tr>
<tr>
<td>Preop HOA (um)</td>
<td>0.53 ± 0.16</td>
<td>0.53 ± 0.14</td>
</tr>
<tr>
<td>1-month Sph Eq (D)</td>
<td>-0.11 ± 0.34</td>
<td>-0.08 ± 0.23</td>
</tr>
<tr>
<td>Range Sph Eq (D)</td>
<td>-1 to +1 D</td>
<td>-0.63 to +0.50</td>
</tr>
</tbody>
</table>

Standard Deviations of 0.34 or 0.23 D are close to the SD of manifest refraction repeatability Bullimore 0.2; Nizam 0.33 D; Blackhust 0.28 D

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### Zyoptix with Rochester Nomogram

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Zyoptix FDA trial (112 eyes)</th>
<th>Rochester Nomogram</th>
<th>Pharmacological dilation (n = 175)</th>
<th>Natural mesopic pupil (n = 90)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preop SE (D)</td>
<td>-3.41 ± 1.44</td>
<td>-4.89 ± 2.06</td>
<td>-4.39 ± 2.08</td>
<td></td>
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<td>Preop HOA (um)</td>
<td>0.45 ± 0.16</td>
<td>0.53 ± 0.16</td>
<td>0.53 ± 0.14</td>
<td></td>
</tr>
<tr>
<td>Postop UCVA ≥ 20/20</td>
<td>89.3%</td>
<td>93.1%</td>
<td>94.6%</td>
<td></td>
</tr>
<tr>
<td>Postop SE (D)</td>
<td>+0.26 ± 0.50 (-1.04 to +1.81)</td>
<td>-0.11 ± 0.34 (-1 to +1)</td>
<td>-0.08 ± 0.23 (-0.63 to +0.50)</td>
<td></td>
</tr>
<tr>
<td>Postop SE ≤ +0.50D</td>
<td>71.4%</td>
<td>91.4%</td>
<td>97.8%</td>
<td></td>
</tr>
</tbody>
</table>

**Greater preop MYOPIA & HOA**

**Better postop VA and SE (both pharmacological dilation & natural mesopic pupil)**
Preop Coma and Postop Astigmatism

Ablation Decentration of Coma Induces Astig.

<table>
<thead>
<tr>
<th>Postop Cyl</th>
<th>&lt; 0.50 D</th>
<th>&gt; 0.50 D</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incidence</td>
<td>104/175 (60%)</td>
<td>71/175 (40%)</td>
</tr>
<tr>
<td>Preop coma</td>
<td>$0.26 \pm 0.43 \text{ um}$</td>
<td>$0.40 \pm 0.17 \text{ um}$</td>
</tr>
</tbody>
</table>

$p < 0.0001$
Postop Astigmatism Risk Factor #2

- Treatment of preoperative Coma
  - Decentration of Laser ablation induces astigmatism
Summary: Customized Ablation with Rochester Nomogram

- **Aberration Interaction** is Important
- **Zyoptix Refinement: The Rochester Nomogram**
  - Reduces Outliers: < 1%, 4X’s less likely to have >0.5 D outlier
  - >93-94% 20/20 or Better Uncorrected Visual Acuity (UCVA) with or without pharmacologic dilation
  - Cascade effect of HOA on sphere well compensated
    - **Further development by refining relationship between preop 3rd order terms and postop astigmatism**