Delivering Improved Outcomes for Today's Cataract Patient

Stephen Lane, MD

What are the issues that affect hitting the refractive target?

Pre-operative
- Biometry
- Managing astigmatism
- Transcription errors
- Cyclorotation
- Manual marking

Intra and Post Operative
- Rhexis shape and size?
- Posterior corneal astigmatism
- Alignment, centration
- A-constant optimization

Cataract Refractive Diagnostics

Image Guidance

DISCLOSURE
- Alcon
- ClarVista
- Bausch and Lomb
- Ivantis
- i-Veena
- Kala
- Lifecore
- Mati
- Ocular Therapeutics

- Omeros
- PowerVision
- PRN
- RPS
- Shire
- TearLab
- TearScience
- VisionCare
- WaveTec
Manual Toric Marking

Removing Ink From the Entire Process

Introducing the VERION™ Image Guidance

Capturing the Reference Image

Courtesy of Michael Jones, MD
Comprehensive Astigmatism Planner

The astigmatism slider bar allows surgeons to select their preferred balance of correction between IOL power and relaxing incisions in a single calculation.

Closing the Loop: Optimization

VERION™ DIGITAL MARKER

Digital Marker Guidance

Registration Process at the LenSx® Laser - Digital Marker L
“Yardstick” to measure Cataract Surgery Success

- Driven by LASIK outcomes
  - Refractive component and Visual Acuity component
    - > 95% of outcomes within 0.50 D of nomogram predicted refractive target
    - 90% of eyes achieving UDVA of 20/20 or better
    - <3% enhancement rates expected
Outcomes in Modern Cataract Surgery - Literature

- Narvaez / Stulting JCRS Dec. 2006
  - 46% within 0.50 D of formula predicted target
  - Mean prediction error: 0.52 D +/- 0.44 D
- Gale et al, Eye Aug. 2007
  - 55% of eyes within 0.50 D of formula predicted target
  - 85% of eyes within 1.00 D of formula predicted target
  - Findings considered the benchmark for the NHS in the UK
  - Enhancement Rates on Premium IOL cases (Presbyopic and Toric IOLs)
    - Range from 10% to 35%

Recent Literature

- Andrs Behndig, M.D., Ph.D., et al, J Cataract Refract Surg. (July) 2012 (Swedish National Cataract Registry.)
  - 17,056 procedures
  - Emmetropia (spherical equivalent -0.5 to +0.5D and <1.0 D astigmatism) achieved in 55% of eyes planned for emmetropia.

Overview

- The ORA System® uses wavefront aberrometry data in the measurement and analysis of the refractive power of the eye (i.e. sphere, cylinder, and axis measurements) to support cataract surgical procedures.
- Accounts for contribution of anterior and posterior corneal astigmatism in its measurements
- Real-time, intraoperative refractometer plus a working algorithm supported by a large clinical database (100k+ cases), and a platform for additional enhancements.

Primary Efficacy Result
Residual Refractive Cylinder at 3 Months

<table>
<thead>
<tr>
<th>Diopters</th>
<th>Percent Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 0.25</td>
<td>31.4</td>
</tr>
<tr>
<td>≤ 0.50</td>
<td>39.2</td>
</tr>
<tr>
<td>≤ 0.75</td>
<td>71.6</td>
</tr>
<tr>
<td>≤ 1.00</td>
<td>90.2</td>
</tr>
<tr>
<td>&gt; 1.00</td>
<td>96.1</td>
</tr>
</tbody>
</table>

* 95% CI: 61.8 - 80.1%
Primary Efficacy Result  
Residual Refractive Cylinder at 3 Months

<table>
<thead>
<tr>
<th>Dipters</th>
<th>≤ 0.25</th>
<th>≤ 0.50</th>
<th>≤ 0.75</th>
<th>≤ 1.00</th>
<th>&gt; 1.00</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients</td>
<td>31.4%</td>
<td>53.3%</td>
<td>81.4%</td>
<td>91.4%</td>
<td>96.1%</td>
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</table>

Anticipated Residual Cylinder based upon Preoperative Calculation

Secondary Efficacy Result  
Postoperative MRSE Accuracy at 3 Months

<table>
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<tr>
<th>Dipters</th>
<th>≤ 0.25</th>
<th>≤ 0.50</th>
<th>≤ 0.75</th>
<th>≤ 1.00</th>
<th>&gt; 1.00</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients</td>
<td>0%</td>
<td>40.2%</td>
<td>69.6%</td>
<td>87.3%</td>
<td>91.2%</td>
</tr>
</tbody>
</table>

* 95% CI: 59.7 – 78.3%

Improved astigmatic outcomes with VerifEye®

This carefully controlled clinical study confirms that the ORA System® with VerifEye® provides better astigmatic outcomes in cataract surgery.

Percent of Patients Within ≤ 0.50 D of Intended Target at One Month; n = 111 patients, p = .006

53.8% fewer patients were outside the intended target.

*Based on seeing 100 post-op patients per month
How I use the systems together

• Toric case
  – Establish initial plan with Verion guidance
    • K’s will help establish initial cylinder power and axis – registration will help identify this axis during surgery
    • Pre-op will supply preliminary spherical power for the toric lens
  – Obtain consistent VerifEye aberrometry aphakic measurements intraoperatively
    • Will provide the actual spherical power of the lens, cylinder power and the target axis of placement
  – Use Verion guidance to locate axis obtained during pre-op
  – Place lens and use VerifEye’s toric pseudophakic aberrometry application to refine axis of placement by rotating as directed

Conclusions

• Aberrometry and Guidance are complimentary
• Using both together results in refined IOL power selection and astigmatic treatment