Delivering Improved Outcomes for Today's Cataract Patient

Stephen Lane, MD
DISCLOSURE

- Alcon
- ClarVista
- Bausch and Lomb
- Ivantis
- i-Veena
- Kala
- Lifecore
- Mati
- Ocular Therapeutics
- Omeros
- PowerVision
- PRN
- RPS
- Shire
- TearLab
- TearScience
- VisionCare
- WaveTec
What are the issues that affect hitting the refractive target?

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

Intra and Post Operative
- Rhexitis shape and size?
- Posterior corneal astigmatism
- Alignment, centration
- A-constant optimization
Cataract Refractive Diagnostics

Image Guidance
Manual Toric Marking
Removing Ink From the Entire Process

Courtesy of Michael Jones, MD
VERION™ Image Guidance

VERION™ Reference Unit

VERION™ Microscope Integrated Display
Capturing the Reference Image
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

### Table: Formulas and Optimization Parameters

<table>
<thead>
<tr>
<th>Formula</th>
<th>Number of Cases</th>
<th>Current Form. Constant</th>
<th>Personalized ACD (mm)</th>
<th>Eqv. Form. Constant</th>
<th>Mean Rx Err (D)</th>
<th>Mean Abs Rx Err (D)</th>
<th>Std Dev of Rx Err (D)</th>
<th>Max Rx Err (D)</th>
<th>% cases &gt; +/- 2 D Rx err.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Holladay II</td>
<td>79</td>
<td>MFG: 5.199</td>
<td>5.312</td>
<td>ACD: 5.312</td>
<td>0.000</td>
<td>0.346</td>
<td>0.429 (+/-0.048)</td>
<td>-0.94</td>
<td>0.0%</td>
</tr>
<tr>
<td>Holladay I</td>
<td>79</td>
<td>MFG: 1.450</td>
<td>5.458</td>
<td>SF: 1.701</td>
<td>0.000</td>
<td>0.409</td>
<td>0.508 (+/-0.057)</td>
<td>1.21</td>
<td>0.0%</td>
</tr>
<tr>
<td>Haigis</td>
<td>79</td>
<td>MFG: 0.912</td>
<td>5.507</td>
<td>AO: 1.261</td>
<td>0.000</td>
<td>0.399</td>
<td>0.486 (+/-0.055)</td>
<td>1.04</td>
<td>0.0%</td>
</tr>
<tr>
<td>Hoffer-Q</td>
<td>79</td>
<td>MFG: 5.199</td>
<td>5.461</td>
<td>ACD: 5.461</td>
<td>0.000</td>
<td>0.418</td>
<td>0.522 (+/-0.059)</td>
<td>-1.26</td>
<td>0.0%</td>
</tr>
<tr>
<td>SRK-T</td>
<td>79</td>
<td>MFG: 118.400</td>
<td>5.516</td>
<td>ACst: 118.943</td>
<td>-0.000</td>
<td>0.416</td>
<td>0.515 (+/-0.058)</td>
<td>-1.22</td>
<td>0.0%</td>
</tr>
<tr>
<td>Holladay R</td>
<td>0</td>
<td>MFG: 5.199</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Table: Primary Incision Location

<table>
<thead>
<tr>
<th>Primary Incision Location</th>
<th>Small Incisions (1.8-2.2mm)</th>
<th>Medium Incisions (2.3-2.7mm)</th>
<th>Large Incisions (2.8-3.2mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Average SIA</td>
<td>Number of cases</td>
<td>SEM</td>
</tr>
<tr>
<td>Temporal</td>
<td>0.31</td>
<td>30</td>
<td>0.05</td>
</tr>
<tr>
<td>Superior</td>
<td>0.35</td>
<td>26</td>
<td>0.05</td>
</tr>
</tbody>
</table>
Digital Marker Guidance

VERION™ DIGITAL MARKER
Registration Process at the LenSx® Laser- Digital Marker L
Image Guided System and Centration

Visual Axis Center

Limbus Center
Verion Digital Marker M
Intraoperative Surgical Aberrometry
“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%
Outcomes in Modern Cataract Surgery
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

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

88.4% from target

Percent Patients

Anticipated Residual Cylinder based upon Preoperative Calculation

Diopters

0
≤ 0.25
≤ 0.50
≤ 0.75
≤ 1.00
> 1.00

0 10 20 30 40 50 60 70 80 90 100

1 31.4 53.3 81 91.4 92.4

6.7 3.9

≤ 0.25 ≤ 0.50 ≤ 0.75 ≤ 1.00 > 1.00

100 90 80 70 60 50 40 30 20 10 0
Secondary Efficacy Result
Postoperative MRSE Accuracy at 3 Months

* 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

2. Standard of Care: Conventional biometry measurement of the pre-op corneal astigmatism and toric calculator determination of IOL cylinder power.
3. Results are statistically significant based on McNemar’s test (p=0.006).
Improved astigmatic outcomes with VerifEye®

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
Refractive Cataract Suite
Conclusions

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