Innovations in Cataract Surgery: Where Are We Going?

Josh Johnston, OD, FAAO

Disclosures

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Today’s Optometrists

“To be on the cutting edge of optometry, you need to be on the cutting edge of science and technology”

Pearls on Optometric Co-management

- Get to know your surgeon
- Convey patient preferences, observations and conditions to your surgeon
- Inform your patients on your role in perioperative care
- Successful co-management is the result of continuous communication

Why Become Involved?

- 3 million cataract surgeries each year¹
- By 2020 the U.S. population over 65 will double from current levels – 12.9% of total population
- CMS allows ODs/MDs to bill for non-covered services
- Tangible vs. Intangible benefits

Basic Marketing Concepts

- Needs / Wants / Demands are underlying concepts of marketing
  - Needs are basic requirements of human beings
  - Wants are the form human needs take as they are shaped by culture and individual personality
  - Demand is want backed by buying power
- Patients need to see, want freedom from glasses, and have the means to invest in technology

¹ http://www.allaboutvision.com/conditions/cataracts.htm
The Baby Boomers

- Baby Boomers represent the generation with the greatest buying power in the history of our country
- Account for a dramatic 40% of total consumer demand – even in a recession
- Find a way to appeal to us through our desire to stay young, act young, think young and feel young
- Have more discretionary income than any other age group
- Watch TV / read newspapers more than any other age group

Optometric Opportunity

- Maintain a refractive mindset
- Direct to consumer advertising is here
- Who better to hear about these options from than their own optometrist?

IMAGE GUIDED SURGERY

TrueGuide™ by TrueVision 3D Surgical, Inc.

- TrueGuide provides digital guidance during cataract and cornea surgery. It utilizes state-of-the-art diagnostics for data acquisition to generate templates for astigmatism correction and advanced lens placement.
- TrueGuide software drives lowest residual astigmatism in precision outcomes for toric IOL alignment, limbal relaxing incision, incision placement and lens centration.

TrueGuide™ Surgical “Ecosystem”

- TrueGuide™ software with the TrueVision® 3D Visualization and Guidance System seamlessly integrates into today’s premium surgery

Integrated Diagnostics for Surgical Planning

- TrueGuide™ utilizes I-Optics Cassini topographer input with TrueCapture™ software for accurate corneal shape analysis and pre-operative diagnostics.
  - Lowest error in Axis of astigmatism <3.5°
  - Lowest error in Magnitude of astigmatism < 2%
  - Submicron elevation mapping accuracy <0.8micron
  - Leads to optimized surgical outcomes

References:
- McAlinden. IOVS 2011
- Karabatsas. BJO 1998
- Pentacam Brochure Specs

TrueCapture™ software suggests treatment plan and IOL recommendation

Personnelized to the patient, specific to the surgeon
Dynamic Optimization

TrueGuide™ software engine matches patient parameters in real-time to available treatment options specific to surgeon parameters and tendencies
- Auto-registration of pre-operative image to live surgery
- Real-time calculation of predicted residual astigmatism
- Robust eye tracking – even during surgical maneuvers
- Precision algorithms for incision placement, astigmatism management, and lens centration

Real-time vector analysis for incision optimization, toric IOL and LRI positioning

OR Team Sees Everything

Retrospective Analysis of 3D HD Visualization vs. Conventional Oculars During Cataract Surgery

- Method:
  - Analyzed consecutive cases from adjacent OR for a single surgeon
  - Routine cataract cases using two methods of visualization

<table>
<thead>
<tr>
<th>Visualization Method</th>
<th># of Eyes</th>
<th>Unplanned Vitrectomy</th>
</tr>
</thead>
<tbody>
<tr>
<td>TrueVision® 3D</td>
<td>293</td>
<td>1 (0.35%)</td>
</tr>
<tr>
<td>Microscope Oculars</td>
<td>461</td>
<td>5 (1.09%)</td>
</tr>
</tbody>
</table>

- Unplanned Vitrectomy rate was lower in TrueVision® 3D cases

Abstract: Robert J. Weinstock, M.D., ASCRS 2010

Proproprietary and Confidential 15

TrueVision Refractive Cataract Toolset®

Limbal Relieving Incision
- Provides precise incision templates
- Accounts for surgically induced astigmatism
- Compensates for cyclorotation
- Uses customizable nomograms
- Uses automated vector calculations

Toric IOL Alignment
- Provides precise rotational alignment templates
- Accounts for surgically induced astigmatism
- Compensates for cyclorotation
- Displays compass for angular measurements

VERION™ Reference Unit


VERION™ Image Guided System

With a convenient desktop interface, the VERION™ Reference Unit:
- Measures keratometry, pupillometry and other key pre-op parameters
- Captures a high-resolution, diagnostic reference image of the patient’s eye
- Auto-detects scleral vessels, limbus, pupil and iris features

VERION™ Reference Unit VRN13018SK
The VERION™ Reference Unit also enables surgeons to quickly and efficiently determine an optimized surgical plan:

- Multiple advanced formula IOL calculations, including lens and power selection
- Incision and implantation axis planning customized for each patient

To help optimize incision and IOL alignment, the VERION™ Digital Marker displays patient information and images from the VERION™ Reference Unit:

- Features a tracking overlay that enables surgeons to see all incisions and alignment in real time
- Automatically accounts for cyclorotation
- Eliminates the need for manual toric eye markings
- Automatically registers the patient for accurate centering and alignment of multifocal and toric IOLs
- Allows documentation of data to help optimize procedures over time

The VERION™ Digital Marker can be used with the LenSx® Laser as well as most surgical microscopes.

With LenSx® Laser: With OR Microscope:

Incisional Plan

Capsulorhexis Plan

Registration at the Scope
**Toric Alignment Plan**

**“The Pipeline”: Future IOLs**

**Advanced Technology: The Players**

**Current Premium Lenses Require Compromises**
- Imperfect distance vision
- Glare and halos at night
- Reading vision that is mediocre

**ReSTOR Multifocal Toric**
- Aspheric design
- Greater utilization among “non refractive” surgeons?
- Can treat up to 3 D of astigmatism
- Diffractive multifocality
- UV and Blue light filter
Synchrony IOL
- Dual Optic accommodating IOL
- 2 optics connected by spring haptics
- Temporary myopia initially after post op

Victor Bohorquez, M.D., Servioftalmos Department of Ophthalmology, Bogotá, Colombia,
- Two-year follow-up data on 19 patients who had bilateral implantation
  - BCVA at one year: 20/28
  - BCVA at two years: 20/23

Lenstec Tetraflex
- Hydrophilic closed-loop haptics with a 5-degree angulation
- Intended to enhance near vision
- 1.8D of accommodation
- Higher order aberrations add to near VA

Lenstec Tetraflex
- 5.75 mm square-edged optic to reduce posterior capsular opacification
- FDA trial 6-month accommodation data shows 100% ≥ 2 D, 69% ≥ 3D, and 44% ≥ 4 D
- The lens is currently available outside the United States and is awaiting approval here

Fluidvision
- Soft haptics store silicone fluid
- Accommodation forces fluid into central optic
- 5 D of accommodation?

FineVision IOL Trifocal
- Aspheric diffractive trifocal
- 3.5D add for N
- +1.75D for intermediate
- Great VA at D, I, N
- Less glare and halos
- Zeiss
B&L Envista

- No glistenings detected at any time in a 2-year prospective study of 172 eyes\(^1,2\)
- Step-vaulted haptics are designed to vault the optic posteriorly for direct contact with the capsular bag
- LEC migration is believed to be inhibited by 360° square barrier edge\(^3\)


Why the Light Adjustable Lens?

- Predictable correction of residual refractive error after lens implantation for optimal distance vision
  - Spherical and cylindrical errors up to 2D
- Customized presbyopia solutions for near and intermediate vision
  - Adjustable Monovision
  - Customized Near Add
  - Asphericity Control

Light Adjustable IOL

- Photosensitive Silicone Material
- Precise, Non-Invasive Post Operative Adjustments
- > 2 Diopter Correction for Myopia, Hyperopia, or Astigmatism
- Non-Toxic, Biocompatible
- Foldable

Light Delivery Device Customized Treatment

- Standard slit-lamp footprint
- Unlimited flexibility for lens modification
- The heart is the digital mirror device (DMD), which allows customized generation of spatial irradiance profiles

Adjustment Profiles

**Sphere:** ± 2.0 D; **Cylinder:** -2.0 D

<table>
<thead>
<tr>
<th>Sphere</th>
<th>Hyperopia</th>
<th>Astigmatism</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Sphere 2.0D" /></td>
<td><img src="image" alt="Hyperopia 2.0D" /></td>
<td><img src="image" alt="Astigmatism 2.0D" /></td>
</tr>
</tbody>
</table>

TRULIGN™ Toric IOL

Key Properties

- 5.0-mm optic body
- Biconvex shape
- Rectangular hinged haptics
- Approved Dioptic power range from +4.00 to +33.00 D
- Cylinder powers 1.25, 2.00, and 2.75 D
- Round-to-the-right asymmetric polyimide loops
**TRULIGN™ Toric IOL Insertion**

IOL insertion
- The Crystalsert® IOL Delivery System requires a 2.85-mm opening for injection
- Use a cohesive viscoelastic for lubrication of the injector
- Verify that the IOL is right-side-up (refer to Directions for Use)
  - The round knob on the loop of the leading haptic should be on the right (remember “round to the right”)

**New Accommodating IOLs**
- Currently 14 accommodating IOLs in the pipeline
- Future IOLs need to deliver distance, intermediate AND near VA
- Less glare and halos
- Reduced loss of contrast sensitivity

**In Summary: A New Direction for Astigmatic Cataract Patients**

TRULIGN™ Toric is an advanced toric IOL
- A broader range of vision than standard toric IOLs
- Excellent visual acuity at intermediate and distance
- UCVA ≥ 20/40: 97.8% of eyes
- UCDVA ≥ 20/40: 97.8% of eyes
- Outstanding rotational stability
  - Rotation ≤ 5°: 96.1% of eyes
- Effective cylinder correction
  - Residual cylinder ≤ 1.0 D: 95.5% of eyes
- 99.2% of patients reported no visual disturbances

**ORA (Optiwave Refractive Analysis)**

**Case Studies: ORA Improves Accuracy, Reduces Surgical Enhancements & Follow-up Costs**

<table>
<thead>
<tr>
<th>Surgeon</th>
<th>Number of OMA Procedures</th>
<th>Reduced Enhancements/Revision Rate With ORA</th>
</tr>
</thead>
<tbody>
<tr>
<td>K. Avad, MD</td>
<td>1,042</td>
<td>20%</td>
</tr>
<tr>
<td>S. Greenfield, MD</td>
<td>870</td>
<td>80%</td>
</tr>
<tr>
<td>J. Lanz, MD</td>
<td>230</td>
<td>30%</td>
</tr>
<tr>
<td>M. Feller, MD</td>
<td>217</td>
<td>30%</td>
</tr>
<tr>
<td>T. Tuck, MA</td>
<td>136</td>
<td>37%</td>
</tr>
<tr>
<td>R. Woodstock, MD</td>
<td>120</td>
<td>60%</td>
</tr>
<tr>
<td>W. Wiley, MD</td>
<td>1,278</td>
<td>35%</td>
</tr>
<tr>
<td>M. Woodstock, MD</td>
<td>1,610</td>
<td>20%</td>
</tr>
<tr>
<td>Average</td>
<td>1,416</td>
<td>27%</td>
</tr>
</tbody>
</table>

*Note: ORA data reflects a comparison with traditional intraocular lens methods.*
Intraoperative Real-Time Aberrometry

High Accuracy Real-time Advantage – Very Simple Integration

Successful intraoperative deployment requires:
- Ability to work within the challenging surgical environment: lighting, working distances, and surgeon’s visual fields
- Compact size does not intrude
- Ample Working Distance

Attention to critical ergonomic demands of the surgeon and scrub nurse

Sequential Wavefront (HOLOS)
- Sequential wavefront shifting: shift an incident wavefront through an aperture
- Variable Shaped Aperture: intercepts a portion of the incident wavefront that you wish to sample
- Quad Detector: indicates two dimensional displacement from a reference point
- Focusing Element: focuses the shifted incident wavefront onto the Quad detector

Sequential Wavefront (HOLOS) Analysis (IntraOp Example of Astigmatism)
- Intuitive real-time Representation of Astigmatic Error
- Visual Feedback = Elliptical Trace

Wavefront tilt = lateral translation of spots

Real Time Refractive Value

- Qualitative: Continuous display depiction of refractive state provides immediate directional guidance
- Quantitative: Simultaneous display of qualified real-time accurate refraction - Sphere, Cylinder, and Axis

Patient’s sphere and cylinder depicted as an ellipse (yellow oval)
Rotating a Toric IOL

Target Emmetropia

MINIMALLY INVASIVE GLAUCOMA SURGERY

“The new MIGS procedures are to trabeculectomy what phacoemulsification was to intracapsular cataract extraction or LASIK was to RK.”

MIGS PROCEDURES

Ab externo (outside in)
- Express Shunt, Alcon
- Canaloplasty, iScience
- Endo Cyclophotocoagulation, Endo Optiks
- Trabectome, Neomedix
- iStent, Glaukos – recently FDA Approved
- CyPass, Transcend Medical
- Hydrus, Ivantis
- Gold micro-shunt, SOLX
- Suprachoroidal microstent increases uveoscleral outflow

MIGS ADVANTAGES

Safer  Faster recovery
Gentler  Reduced IOP
Less OR time  Less glaucoma meds
Avoids serious complications  Decreased IOP fluctuations
Combined with cataract sx  No Bleb
Good for contact lens wearers  Spares the conjunctiva
Fewer follow-up appointments
iStent

- Titanium, L-shaped, trabecular microbypass stent
- Snorkle through TM
- Use Gonio to place it

iStent - (View with Gonio)

Trabectome
The Femto Phaco Market

“L-A-Z-E-R”

Why Do We Need It?
Limitations of Traditional Cataract Surgery

<table>
<thead>
<tr>
<th>Key Step</th>
<th>Current Surgery</th>
<th>Impact</th>
<th>Safety Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corneal Incision</td>
<td>Not Optimized</td>
<td>Induced Cylinder</td>
<td>Infection</td>
</tr>
<tr>
<td>Capsulorhexis</td>
<td>Variable Size, Variable IOL Position &amp; Effective Lens Power</td>
<td>Capsular Tears, Posterior Capsule Oplification</td>
<td>-</td>
</tr>
<tr>
<td>Lens</td>
<td>Excessive Ultrasound Power</td>
<td>Delayed Visual Loss of Endothelial Cells</td>
<td>Capsule Rupture</td>
</tr>
<tr>
<td>Fragmentation</td>
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</table>

Manual Clear Corneal Incisions

- Dynamics of wound architecture created with hand-held instruments:  
  - Imprecise tunnel length and geometry  
  - Frequently require stromal hydration to seal  
  - May result in cascading intraoperative difficulties (fluid control, anterior chamber maintenance)  
  - Incisions may be unstable at low IOPs  
- Recent literature suggests an increased incidence of post-op infection

ReSure Sealant

Effective Lens Position (ELP)

- "The key to highly accurate IOL power calculation is being able to correctly predict ELP for any given patient and IOL."
- ELP is assumed value, from empirical data  
  - A constant and surgeon factor  
  - A significant source of IOL power error and key to post-surgery refraction  
  - Size of capsulorhexis effects ELP.

Factors Affecting IOL Predictability

- If IOL is 0.5 mm posterior to the assumed plane, a +21 D lens will produce only 20 D of correction
- If IOL is 0.5 mm anterior to the assumed plane, a +21 D lens will produce 22 D of correction
Laser Capsulotomy Results

- Perfect centration
- Precision diameter: < ± 0.25 mm
- No radial tears
- Easy and complete removal of capsule
- No adverse events
- Less PCO formation

Comparison of Manual vs. Femto

- Cylinder pattern, utilized for the softer lens, enables removal with I & A only, no phaco power
- Chop pattern efficiently fragments the lens for removal with reduced phaco power and time

Laser Fragmentation

- Cylinder pattern, utilized for the softer lens, enables removal with I & A only, no phaco power
- Chop pattern efficiently fragments the lens for removal with reduced phaco power and time

Astigmatism More Prevalent than Recognized

Addressing Astigmatism

- Differentiate corneal cylinder from refractive cylinder
  - Corneal
  - Lenticular
  - Mixed
- Accurate / consistent measurements
  - Manual keratometry
  - Corneal topography
  - IOL Master
  - Lenstar

Arcuate Incisions

- Manually executed by “tracing” corneal marks with handheld diamond knife
- Inconsistent depth control
- Unpredictable effect due to imprecise wound architecture and depth
- No image-guided surgical planning or visualization

Prediction Error Distribution

Frequency Distribution (% of Eyes)

<table>
<thead>
<tr>
<th>Hyperopic</th>
<th>4%</th>
<th>25%</th>
<th>25%</th>
<th>25%</th>
<th>4%</th>
</tr>
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<tbody>
<tr>
<td>0.00</td>
<td>4%</td>
<td>25%</td>
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<td>4%</td>
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<tr>
<td>0.25</td>
<td>15%</td>
<td>35%</td>
<td>35%</td>
<td>15%</td>
<td>4%</td>
</tr>
<tr>
<td>0.50</td>
<td>20%</td>
<td>20%</td>
<td>20%</td>
<td>20%</td>
<td>15%</td>
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</table>

<table>
<thead>
<tr>
<th>Myopic</th>
<th>4%</th>
<th>25%</th>
<th>25%</th>
<th>25%</th>
<th>4%</th>
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<tbody>
<tr>
<td>-0.25</td>
<td>4%</td>
<td>25%</td>
<td>25%</td>
<td>25%</td>
<td>4%</td>
</tr>
<tr>
<td>-0.50</td>
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<tr>
<td>-0.75</td>
<td>20%</td>
<td>20%</td>
<td>20%</td>
<td>20%</td>
<td>15%</td>
</tr>
</tbody>
</table>

Spherical Equivalent Prediction Error (DE) - Pred. Ref. - Actual SM PostOP Ref.
Postoperative Considerations

- Normal postoperative course
  - One day
  - One week
  - One month
  - Three months
- Educate patients on postoperative expectations
  - Mild subconjunctival hemorrhage due to suction
  - Mild corneal edema at wound
  - Improved precision of the procedure

Femtosecond Laser Companies: Value Added Indications

- Cataract Surgery:
  - Anterior & Posterior Capsule Polishing
  - Posterior Capsulotomy
  - Paracentesis
  - Vitreolysis
- Glaucoma Surgery:
  - Goniotomy, Trabeculotomy & Trabeculoplasty
- Corneal Surgery:
  - DSEK: Stripping ring, Stromal polishing
  - Lasik Flaps, Intacs Tunnels, Intrastromal Ablation

Future Applications of Femtosecond Technology

- Presbyopia correction
- Corneal crosslinking
- Myopia correction
- Bleaching of crystalline lens

OPD Scan III

- Auto refractor
- Keratometer
- Pupillometer
- Corneal Topographer
- Wavefront Aberrometer

Cataract

Vacuoles
Cortical Spokes

Qualifying Requirements for an IOL Patient

- Refraction
- Keratometry
- Corneal Topography for Astigmatism
- Pupillometry – Photopic/Mesopic
- Eye Image – Visual Axis and Pupil Center
- Internal OPD (residual astigmatism and crystalline lens abnormalities).
- Spherical Aberration of Cornea
- Wavefront Aberration Analysis
- Night Vision Assessment

Which Type of IOL Do We Recommend for the Patient?

- There are many factors we need to assist us in selecting the best IOL for the patient
  - Spherical Aberration of the Cornea (Aspheric)
  - The amount of Astigmatism on the Cornea (Toric)
  - Angle Kappa (Multifocal IOLs)
  - Pupil Size (Photopic and Mesopic)

Aspheric IOLs

- The goal is to get the patient’s Spherical Aberration as close to zero as possible
- Measuring the SA of the cornea allows us to predict, within microns, the SA that will remain on the cornea when the cataract is removed

Aspheric IOLs

- Average cornea +.38µ
- AMO Tecnis® Z8000 +.37µ
- Alcon AcrySof® SN60WF +.30µ
- Hoya AF-1 iSpheric IOL (NTIOL) +.18µ
- Staar® Surgical (AQ2015) - .09µ
- B&L Sofport® (new Akreos™ AO) 0
- Spherical (monofocal) +.15µ

Average Cornea – No Previous Treatments

SA 0.289µ will be a Tecnis which has -0.27µ
Post Hyperopic LASIK

Hyperopic LASIK induces negative SA.

Toric IOLs

- The OPD Scan III is the best unit on the market for Toric IOL selection and for pre and post op evaluations.
- The Retro Illumination image allows us to see if the IOL is aligned properly.

Axis Off One Day Post Op

Multifocal IOLs are Not for Everyone!

- When a measurement is taken, not only the auto-refraction, keratometry, pupillometry, corneal topography and wavefront aberrometry are taken.
- There is a wonderful piece of critical data we must not overlook for our multifocal patients…
  - The Angle Kappa!
- Why is it important?

Multifocal IOLs

- The ReStor has a .86mm central – near- area.
- The AMO Tecnis has 1.2mm central area.
- The ReZoom has 2.1mm
- The Crystal lens does not have a central area change so position is not as critical.
Retro Shows Beautifully Centered ReStor

Retro shows an off-centered ReStor

“Intracameral Injection Studied to Replace Post-Op Eye Drops” awarded best paper at 2005 ASCRS

• Paul Koch, MD (Warwick, RI)
• First 250 => No Endophthalmitis, 4 CME
• After 1100 => No Infections & No CME
Advantages of Dropless Cataract Surgery

- Compliance
- Convenience
- Cost

TriMox

- 15 mg/mL Triamcinolone Acetate (Kenalog)
- 1mg/mL Moxifloxacin
- 0.12mL is injected into the eye.
- Some surgeons use combination with vancomycin – TriMoxiVanc
  - 10 mg/ml
General Risks of Trimox

- **Antibiotic Clearance**
  - AB clearance in AC = 4 hrs
  - AB clearance in VH = 12 Hrs
    - Lyer & Colleagues
- **Retinal Ocular Toxicity**
  - Concentration well tolerated, but must be formulated properly
- **Future Standard of Care??**

Intra-operative Risks of Trimox

- Zonular Damage
- Bleeding
- Capsular Rupture
- Vitreous Manipulation

Post-operative Concerns

- Steroid Induce IOP rise
- Need for additional steroids
- Postoperative floaters
- Ciliary body hemorrhage
- Pseudohypopyon

TRIMOX Advantages

- Increased Compliance
- Should See Less PO CME
- Increased Patient Satisfaction Scores
  - Ease > Cost
- Increased Staff Satisfaction Scores
- Less confusion for co-managing physicians

Patient Selection

- **Aggressive Approach**
  - Everyone
  - Intra-operative management when needed
  - Manage post-op side-effects at day one
- **Conservative Approach**
  - Contraindicated in Glaucoma, Immuno-compromised.
Clinical Results

- Number of Patients = 1593
- Patients requiring drops (10%)
- IOP Spikes (8%)
- AC Bleeds (< .005%)
- Infection / Endophthalmitis (< .005%)
- PO CME (<.001%)

Make this an exciting opportunity for your patients

- This is a great time to have cataract surgery as we can offer you so much more than several years ago
- This is your one opportunity to select your intraocular lens
- You must do your homework
- We will give you the information you need and help you make this important decision

Make this an exciting opportunity for your patients

- As your primary care Eye Doctor, I will make a recommendation and help you make this important decision