Everything New with IOL and Cataract Surgery
“What an Optometrists Needs to Know”

Jim Owen, OD, MBA, FAAO

Cataract Surgery

Eye Care
- Still the most common eye surgery performed
- Aging Population makes it even more common
- Everyone will eventually need it if they live long enough
- Reimbursement continues to decline

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Current Manual Cataract Surgery

Multiple steps and multiple devices

Limitations of Manual Cataract Surgery

Visual Outcomes
- Distance Correction Predictability
  Half that of LASIK
- Astigmatism Correction
- Effective Power of IOL
- Limits Presbyopia Correction

Safety
- Complications 10x LASIK

Surgeon Confidence
- Critical for Widespread Adoption
- Drives Market Growth

Common Incidence of Vision Threatening Inincidence
- Posterior Capsular Opacification 10-30%
- Cystoid Macular Edema (Transient) 2-10%
- Intraocular Lens Dislocation 0.1%
- Posterior Capsular Opacification 10-30%
- Cystoid Macular Edema (Persistent) 2-3%
- Vitreous Loss 1-5%
- Corneal Endothelial Cell Loss 4-10%
- Need for Corneal Transplant 0.1%
- Endophthalmitis 0.1%

Clinical Applications of a new Femtosecond Laser for Cataract Surgery

- Liquefy, soften or “chop” the lens
- Create a perfectly centered and sized Refractive Capsulotomy
- Create all required Corneal Incisions with perfect dimension & architecture
- Provide a refractive solution to pre-existing astigmatism by creating precision Corneal Incisions
- Convert a very manual, multi-step, multi-tool procedure to one of laser created, surgeon controlled precision

LenSx

- Live Video
- OCT
- Procedure Templates
- Touch Screen
- Data Entry
- Ergonomic
- Space saving design
Intuitive Software Control Delivers Image-Guided Surgery

Image-Guided Treatment

Laser Lens Liquification

Laser Capsulotomy

Goals of Laser Cataract Surgery

- Improve Every Procedure, Technology and Surgeon
  - Presbyopia, Astigmatism & Monofocal
  - Refractive Precision and Integration

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Laser Capsulotomy Results

- Perfect centration
- Precision diameter: <= 0.25 mm
- No radial tears
- Easy and complete removal of capsule
- No adverse events
Two fold reduction in IOL position variability
Major opportunity for improvement in refractive correction

Diameter Accuracy

Capsulotomy SEM

Corneal Incision and Lens Removal

Two-Plane Corneal Incision

2 Weeks PostOp OCT
Conclusions

- Femtosecond laser applications in liquefaction was safe, effective and efficient
- Capsulotomy size, shape and reproducibility was statistically improved over manual techniques
- Corneal incisions were reproducible and had precise dimensions and geometry
- A refractive capsulotomy (perfect shape, size, centration), liquefied lens removal with simple I/A, plus the precision of laser-created corneal incisions may enable surgeons to design and deliver an entirely new level of refractive cataract surgery.

WaveTec Technology

- The first registered with the FDA for use in cataract surgery
- Introduced to the market April 2009 as the ORange Intraoperative Wavefront Aberrometer
- 2011 made changes/improvements and introduced at AAO 2011 a new aberrometer
  - 70% of the aberrometer hardware has changed
  - Still utilizes Talbot Moiré interferometry
  - Large dynamic range -5 to +20D
  - The reflected light from the retina (wavefront with aberrations of the eye) passes through a grating pair resulting in a diffractive fringe pattern which is translated into the refractive state of the eye using algorithms
- ORange is now ORA System™ (Optiwave™ Refractive Analysis)

ORA System™: Designed to Optimize Every Cataract Procedure

ORA’s all new Optiwave™ technology takes intraoperative wavefront aberrometry to a new level of precision providing surgeons a higher level of confidence

ORA System™ (Optiwave™ Refractive Analysis)

- Provides intra-operative refractive information
- Attaches to most surgical microscopes for on-demand intraoperative measurements of sphere, cylinder and axes
- Enables real-time surgical course correction
- “Get it right – right on the table” the first time
- Every ORA system connects live to WaveTec servers to capture every procedure and push software upgrades

Sample ORA Screen Shots

ORA Clinical Data
ORA Guides Significant Reduction of Astigmatism for Toric IOL Patients

ORA Guides Significant Reduction of Astigmatism for LRI Patients

ORA Optimizes Post-op Outcomes with Extraordinary Accuracy to Target

ORA Optimizes Outcomes and Results in Superior Post-op Uncorrected Distance Vision

ORA Outperforms Post-LASIK Patient Outcomes in Literature

Review of Clinical Applications

- Provides guidance to improve accuracy in IOL power calculations
  - Aphakic refraction: IOL power calculation
    - Standard and aspheric IOLs
    - Premium IOLs
    - Post-refractive surgery patients
- Provides information to ensure more precise toric IOL outcomes
  - Intraoperative Aphakic Refraction
    - Spherical power of IOL
    - Aphakic refractive cylinder power and axis
    - Intraoperative Pseudophakic Refraction
    - Guidance for editing toric IOL orientation
    - Placement at the proper axis
- Provides information for more accurate and consistent results when performing LRIIs
Patient Selection

- Pre-operative astigmatism
  - Planned LRI and/or toric IOL
- Post-Refractive
  - LASIK and PRK
- Premium IOLS
  - Accommodating and multi-focal (i.e. Crystalens)
  - Presbyopia treatment
- Standard Mono-focal Patients

Conclusions

- The use of the ORA intraoperative aberrometer enables accurate, real-time IOL calculations, creation, and enhancements, of LRIs
- ORA measurements are easily incorporated into the surgical routine, adding minimal time
- ORA improves LRI and IOL power confidence levels and reduces return trips to the OR or laser room for enhancements

Cystoid Macular Edema

- The typical time of onset of clinical CME is 3–4 weeks postoperatively.
- Predisposing factors are intraoperative complications (e.g., vitreous loss or severe iris trauma), vitreous traction at the wound, diabetic retinopathy, and preexisting epiretinal membrane.

Cystoid Macular Edema

- Cystoid macular edema (CME) is the most common cause of unexpected visual loss following cataract surgery.
- Fluorescein angiographic CME can occur in up to 50% of patients at 4–8 weeks postoperatively, but clinical CME occurs in less than 3% of patients.
- Fluorescein angiography demonstrates typical petaloid appearance of fluorescein dye leakage during angiography.

ORA System’s Value to the Practice

- Mitigate risk
- New opportunity to advance & differentiate your practice
- Leverage next-generation technology that help ensure success in complex procedures
- Increase your premium portfolio
- Reduce chair time
- Enhance the satisfaction of your patients
CME

- The routine use of nonsteroidal anti-inflammatory drugs before surgery is recommended by many surgeons. Multiple studies have demonstrated the anti-inflammatory effect of these drugs, and with an already compromised blood aqueous barrier and increased risk for postoperative inflammation, nonsteroidal anti-inflammatory drugs have proved to decrease the risk of CME. Additionally, these drugs help to prolong the mydriatic effect of perioperative dilating drops.

- Continue for 2-4 weeks

MAJOR REVIEW

Endophthalmitis

- It is characterized by a rapid onset, conjunctival chemosis, hypopyon, decreased visual acuity, and pain. Insidious onset of CME is characteristic.

- Cefuroxime is the drug of choice for the treatment of bacterial endophthalmitis.

- Chronic endophthalmitis is caused by organisms of low pathogenicity, such as Propionibacterium acnes and Staphylococcus epidermidis. It typically is diagnosed several weeks or months after surgery. Gprises include indolent visual loss, ocular pain, and chronic uveitis.

- Endophthalmitis after uncomplicated cataract surgery with the use of fourth-generation fluoroquinolones: a retrospective observational case series

- Endophthalmitis is characterized by a rapid onset, conjunctival chemosis, hypopyon, decreased visual acuity, and pain. Insidious onset of CME is characteristic.

- A systematic review of the literature

- CME is a rare but serious complication of cataract surgery. It is characterized by a rapid onset, conjunctival chemosis, hypopyon, decreased visual acuity, and pain. Insidious onset of CME is characteristic.

- The incidence of CME following cataract surgery has increased over the last decade. This upward trend in endophthalmitis frequency coincides temporally with the development of sutureless clear corneal incisions.

CLINICAL SCIENCES

Acute Endophthalmitis Following Cataract Surgery

A Systematic Review of the Literature

Mehran Taban, MD; Ashley Behrens, MD; Robert L. Newcomb, PhD; Matthew Y. Nobe; Golnaz Saedi, BS; Paula M. Sweet, MT; Peter J. McDonnell, MD

- Objectives: To determine the reported incidence of acute endophthalmitis following cataract extraction over time and to explore possible contributing factors, such as type of cataract incision.

- Methods: A systematic review of English-language articles was conducted by performing a broad search of PubMed from 1963 through March 2003 using such terms as cataract extraction, endophthalmitis, and postoperative complication.

- Conclusions: This systematic review indicates that the incidence of endophthalmitis following cataract extraction has increased over time. This increase may be related to the widespread adoption of sutureless clear corneal incisions.
Endophthalmitis risk
The clear corneal incisions commonly used for phacoemulsification are associated with a significantly increased risk of endophthalmitis, compared to scleral tunnel incisions (5.8 fold increase).


Endophthalmitis Study Group, European Society of Cataract & Refractive Surgeons

Scleral tunnel incisions


Endophthalmitis risk instillation of topical 5% povidone-iodine (Betadine) into the conjunctival sac prior to surgery significantly reduces the risk of endophthalmitis; this has become accepted preoperative practice. The antimicrobial effect of povidone-iodine occurs within one minute of irrigation; it kills 96.7% of bacteria and lasts for at least one hour. Povidone iodine appears to be more effective in reducing infection than preoperative antibiotics.


Surgical complications, in particular a torn posterior lens capsule, can significantly increase the risk of endophthalmitis


Premium IOL’s

Treat Astigmatism at the Time of Surgery

The AcrySof® IQ Toric IOL offers cataract surgery patients with astigmatism:

- Reduction of residual refractive cylinder
- Improved uncorrected distance visual acuity
- Increased spectacle-independent distance vision
The Next Step in Toric Technology

**The AcrySof® IQ Toric IOL:**
- Builds on a long line of innovation from Alcon
- Takes the trusted platform for precise astigmatism correction and adds the enhanced image quality of an aspheric lens

**Designed for a Wide Range of Astigmatic Patients**
- AcrySof® IQ Toric IOL is designed to accommodate a variety of cataract patients with astigmatism
- A wide range of cylinder powers means more candidates can benefit from AcrySof® IQ Toric IOL

**Dramatically Reduces Residual Refractive Cylinder**
- 63% of patients achieved ≤0.50 diopters of residual refractive cylinder\(^1\)
- 87% of patients achieved ≤1.00 diopters of residual refractive cylinder\(^1\)

**Improves Uncorrected Distance Visual Acuity**
- 94% of patients implanted achieved uncorrected distance visual acuity of 20/40 or better\(^1\)

**Patient Expectations**
- What they say is “I want to be able to read”
- What they want is **Accommodation**
The Center of a Presbyope’s World

Forget Most Everything!

The TECNIS® Multifocal IOL

Full Diffractive Surface=Pupil Independence

US Clinical Results

Study Parameters:
- One year, multicenter, evaluator-masked comparative clinical evaluation
- Conducted at 13 investigational sites
- Enrolled: 121 bilateral multifocal and 122 bilateral monofocal subjects
- Bilateral results at 1 year presented for 114 multifocal subjects
- Subject assignment was not randomized
  — Based on patient’s choice for a multifocal or monofocal

US Clinical Results

Uncorrected binocular distance visual acuity

Data on File. Advanced Medical Optics, Inc.
The TECNIS® Multifocal IOL

- Designed to reduce spherical aberration to zero and correct chromatic aberration in all light conditions
- Superior near and far low-light vision
- Superior near and far bright-light vision
- Faster near and intermediate reading speed
- Extremely high spectacle independence and patient satisfaction
- Does not block blue light

Anatomy of the Apodized Diffractive Technology
Binocular Defocus Curve

Uncorrected Binocular Photopic Distance VAs
All Implanted, 3 month postoperative, Cumulative

Uncorrected Intermediate Photopic VAs
All Implanted, 3 month postoperative, 50 cm

Uncorrected Binocular Photopic Near VAs
All Implanted, 3 month postoperative, Cumulative, Standard Distance

Average Near Best Distance

Provides a one line or more improvement in binocular intermediate VA.

Standard distance: 33 cm for Model SN6AD3 and 40 cm for Model SN6AD1.

Introducing the Crystalens AO
**Observations with Plate IOLs**  
*Stuart Cumming 1989*

- Some plate haptic IOL patients are still able to read well even after eliminating pseudoaccommodative factors such as
  - Residual myopia
  - Residual astigmatism

**Thornton 1986**  
*Current Canadian Ophth.Pract.*

- A-Scan demonstrated shallowing of anterior chamber after movement of three piece loop lens with accommodation

**Early Clinical Evaluations**

- The first Crystalens AIOL was implanted in England in 1991
- 6 lens designs implanted over 9 years
- Summary:
  - All models accommodated
  - All models had some anterior dislocations

**Crystalens® AT-45**  
*The First FDA Approved Accommodating IOL Nov. 2003*

- Hinged optic to increase movement
- Lengthened haptics to maximize amplitude
- 4.5 mm optic to maintain 10.5mm plate length
- 11.5 mm overall length

**Primary Mechanism**  
Optic Movement

**Secondary Mechanism**  
Accommodative Arching
Summary of Wavefront Findings

**crystalline Lens**

- **Power Change**
  - Greater in the center
  - Less in the peripheral
  - Generally greater than the change in SE

- **Aberration**
  - Increase in negative spherical aberration
  - Increase in coma

**MRI Changes to the Lens**

- Near
- Far

Summary Of Wavefront Findings

**Crystalens®**

- **Power Change**
  - Greater in the center
  - Less in the peripheral
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- **Aberration**
  - Increase in negative spherical aberration
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**MRI Changes to Optic**

- Distance
- Near

Crystalens HD

- Approved by the FDA in July 2008 and CE marked in August 2008
- Follows 3 generations of FDA approved accommodating intraocular lens (4th generation)
- First generation FDA approved in 2003
- Fastest growing PCIOL implanted in the US

Crystalens HD Properties

- Made of a 3rd generation silicone material called Biosil
- Modified plate-style implant with a 5 mm optic
- Available in two overall lengths
  - 11.5 mm for powers 17.0 D and higher
  - 12.0 mm for powers below 17.0 D
Crystalens HD Properties

- Optic has a 360° square edge design to impede posterior capsule opacification
- Depth of Crystalens HD central optic is slightly thicker than previous models enhancing the central power change that is observed when the Crystalens accommodates

Alcon AcrySof TORIC IOL

- Toric optic in single-piece SA60 carrier
- Approved 9/05
- Available 3/06

Alcon Toric IOL (SN6AT3,4,5)

- Blue light blocking platform
- Biconvex, aspheric optic
- Helpful online toric calculator
- Comes in three cylinder powers – 1.5, 2.25, and 3D
- Achieves in the eye – (.75 to 1.5D), (1.5 to 2D), or 2D+
- Mark axis prior to reclining patient
- Stays on axis very well

Patient Questions

- Are you interested in spectacle-free vision after your cataract surgery?
- Would you tolerate some glare/halo at night?
- Would you be willing to pay an addition fee out-of-pocket for this technology?

Our goal is to reduce your dependence on spectacles!

Informed Consent

- Don’t pre-judge affordability
- Describe all options
- Make specific recommendation
- Involve family member or friend
- Use visual props to explain IOL and possible visual side effects

Important Points

- Co-management arrangements must be based on the surgeon’s portion of the total fee
  - Typically ASC charges are not part of the arrangements
  - Arrangements must be based on procedures performed by the each provider
1\textsuperscript{st} Eye
- Worst eye
  - Loss of BCVA
- Or
- Non-Dominant eye

2\textsuperscript{nd} Eye
- Wait 2-4 weeks
- Check refractive target of 1\textsuperscript{st} eye
- Review surgical plan
- Modify surgical plan based on 1\textsuperscript{st} eye outcome

Your Choice of IOL
- Patient Expectations
- Patients Needs
- Patients Adaptability
- Patients Risk Tolerance

Patient Profile

Exclusion Criteria
- Macular pathologies, glaucoma with severe visual field loss
- Expected astigmatism $>$1.5 D*
- Expected myopia $>$0.5 D
- Unrealistic visual expectations
- Happy with reading glasses
- Surgical complications, such as capsulorhexis tear, capsular folds, fixation in sulcus
- Patient is at risk for developing PCO
**Astigmatism correction**

- **Limbal Relaxing incisions (LRI)**
  - Done at time of IOL implant

- **LASIK / PRK**
  - Done after lens implant Sx
  - PRK can be as soon as 6 weeks
  - Lasik → 3 months

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**3 Areas of Vision**

- Distance
- Intermediate
- Near

Rate them in order of importance to you

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**5 Key Criteria**

- **Age** – residual accommodation
- **Refractive Astigmatism**
- **Pupil size** - scotopic/mesopic
- **Area of Vision** – Order of Importance
- **Personality Type** - Expectations

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**Refractive Astigmatism**

- **< than 1D**
  - Accommodative IOL
  - Multifocal IOL
  - Monofocal IOL

- **1D or more**
  - Toric IOL
  - Biopics
    - LASIK/PRK
    - LRI/AK

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**Age**

- **< than 50 years**
  - Crystalens
  - Aspheric monofocal

- **> 50 yrs**
  - All

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**Pupils Size - mesopic**

- **3.0mm or less**
  - Crystalens
  - Monofocal

- **3.0mm – 5.0mm**
  - ReStor
  - Tecnis
  - Crystalens
  - Monofocal

- **Greater than 5.0mm**
  - ReStor
  - Tecnis
  - Crystalens
  - ReZoom
  - Monofocal
Area of Vision

- **DV-IV-NV**
  - Crystalens
  - ReZoom*
  - Monofocal
  - Distance Spectacle

- **DV-NV-IV**
  - ReStor 3.0
  - Tecnis
  - Monofocal
  - Distance Spectacle

- **NV-DV-IV**
  - Tecnis
  - Monofocal
  - Distance Spectacle

Personality Type

- **1-3 Easy going**
  - ReStor
  - Tecnis
  - Monofocal

- **8-10 Perfectionist**
  - Crystalens
  - Monofocal

- **4-7 Middle of the road**
  - Crystalens
  - ReStor
  - Tecnis
  - Monofocal

Other options?

- Aspherics
- Monovision
  - Modified monovision
- Biopics
  - PRK/LASIK
  - LRI/AK
- Mix and Match
- Spectacles!

Future Accommodating IOLs

- Visiogen Synchrony
  - Dual Optic
    - Minus power posterior lens
    - Plus power anterior lens
  - Distance between optics increases with accommodative effort
  - Approval: Dec 2009 – March 2010
  - Patent issues could arise
Lenstec Tetreflex

- Monofocal Design
- Translating optic
- Patent issues could arise

Spectacle Independence: Proportion of Cases with 20/25 or Better Uncorrected Distance Acuity and Uncorrected Near Acuity of:

- 20/25 or Better
- 20/40 or Better
- 20/50 or Better
- 20/63 or Better
- 20/80 or Better

Clinical Results With the Light Adjustable Intraocular Lens After Cataract Surgery


What If You Could Change The Power Of An IOL and Treat High Order Aberrations After Implantation?

Light Delivery Device

Adding Power to the LAL

=> change in radii of curvature => change in power
Subtracting Power from the LAL

**Figure 1.** Schematic of the positive power adjustment mechanism. A) Adjustment: selective irradiation of the central zone of the light adjustable lens (LAL) polymerizes the macromer, creating a difference in the chemical potential between the irradiated and nonirradiated regions. B) To re-establish equilibrium, the excess macromer diffuses into the irradiated region causing swelling. C) Lock-in Treatment: irradiation of the entire LAL “locks” the remaining macromer so that no further change of refraction is possible.

Summary

- Silicone Light Adjustable IOLs
  - Myopic, hyperopic, and astigmatic errors
  - Custom Wavefront
  - Platform: Phakic IOL, Multifocal or Accommodative IOL, Injectable IOL

Surface Embedded Near Section

1 month post op
Lentis Mplus

- Independent of pupil size greater than 2mm
- Single piece optic with +1.50 or +3.00 add
- Bilateral treatment for modified monovision
- Better contrast sensitivity
- Varying levels of glare night vision symptoms