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

### **Current Manual Cataract Surgery**



### Limitations of Manual Cataract Surgery

### Visual Outcomes

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

### Surgeon Confidence

Critical for Widespread Adoption
 Drives Market Growth



Common	Incidence	Vision Threatening	Incidenc
			е
Posterior Capsular Opacification	10-30%	Retinal Detachment	0.6-1.7 %
Cystoid Macular Edema (transient)	2-10%	Cystoid Macular Edema (persistent)	1-2%
Vitreous Loss	1-5%	IOL Malposition	0.3%
Corneal Endothelial Cell Loss	4-10%	Need for Corneal Transplant	0.3%
		Endopthalmitis	0.1%

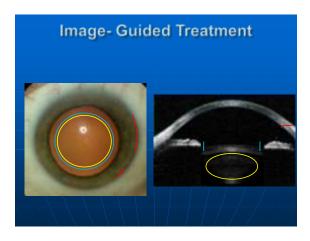
### Clinical Applications of a new Femtosecond Laser for Cataract Surgery

- 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



# Intuitive Software Control Delivers Image-Guided Surgery





Laser Lens Liquification



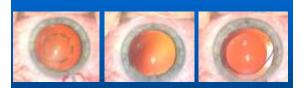


### Goals of Laser Cataract Surgery

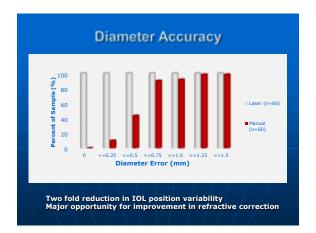
- Improve Every Procedure, Technology and Surgeon
  - Presbyopia, Astigmatism & Monofocal
  - Refractive Precision and Integration

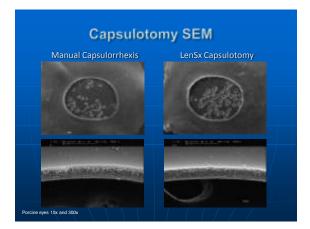
Key Step	Current Surgery	Refractive Impact	Safety Impact
Corneal Incision	Underutilized Not Optimized	Astigmatism	Infection
Capsulorhexis	Variable Sized, Not Centered	Variable IOL Position & Effective Lens Power	Capsular Tears, Posterior Capsule Opacification
Lens Fragmentation	Excessive Ultrasound Power	Delayed visual recovery	Loss of endothelial cells, Capsule Rupture

### Laser Capsulotomy Results

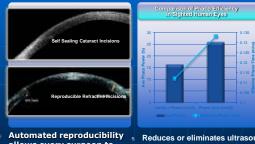


- Perfect centration
- Precision diameter:  $< \pm 0.25$  mm
- No radial tears
- Easy and complete removal of capsule
- No adverse events

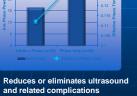


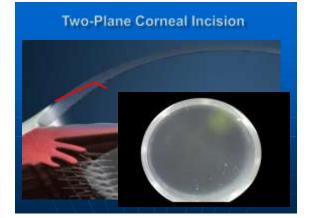


**Corneal Incision and Lens Removal** 



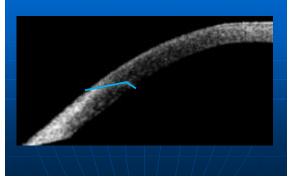
allows every surgeon to address astigmatism











### Conclusions.

- Femtosecond laser applications in liquefaction was safe, effective and
- Capsulotomy size, shape and reproducibility was statistically improved over manual techniques
- Corneal incisions were reproducible and had precise dimensions and
- 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
- 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<sup>™</sup> ((Optiwave<sup>™</sup> Refractive Analysis)

### ORA System™: Designed to **Optimize Every Cataract Procedure**



ORA's all new Optiwave<sup>™</sup> technology takes intraoperative wavefront aberrometry precision providing surgeons a

### ORA System™ (Optiwave<sup>™</sup> Refractive Analysis)



- operative its of sphere der and axis
- Get it right right on the able" the first time





# ry ORA system



### Sample ORA Screen Shots



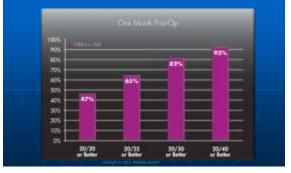


# **ORA Guides Significant Reduction of** Astigmatism for Toric IOL Patients **6** -

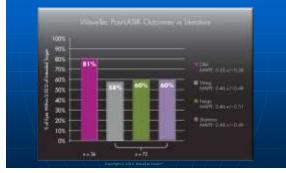


ORA Optimizes Post-op Outcomes with Extraordinary Accuracy to Target 20% 101 ± 0.25 C ≤ 0.50 D \$0.750 \$ 1,00 0

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:

    - Intraoperative Aphatic Reflaction.
       Spherical power of IOL
       Aphakic refractive cylinder power and axis
       Intraoperative Pseudophakic Refraction
       Guidance for refining toric IOL orientation
       Placement at the proper axis
- Provides information for more accurate and consistent results when performing LRIs

# **Patient Selection**

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

### ORA System's Value to the Practice

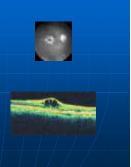
- Mitigate risk
- New opportunity to advance & differentiate your
- Leverage next-generation technology that help ensure success in complex procedures
- Increase your premium portfolio
- Reduce chair time
- Enhance the satisfaction of your patients

### 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

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



### 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 ris trauma), vitreous traction at the wound, diabetic retinopathy, and preexisting epiretinal membrane.



Single perioperative triamcinolone injection versus standard postoperative steroid drops after uneventful phacoemulsification surgery

Randomized controlled trial

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### 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**

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Aldrough more of the matter reviewed by the FDU and repiral NSMIDs more than 24 boors before another surgery, suff-designed statistic surgers to small benefits of prospectations during registers of p to 3 days <sup>127,128,108</sup> Particetures, second channel raid here grau I dans licebase reported that concurrent administrativ NSAIDs and corticoversish results in addition

### Endophthalmitis

- , hypopyon, decreased ar pain. The acute form hin 2–5 days of non causative organisms are -positive, coagulase-negative ccocci, Staphylococcus aureus, tococcus species, and enterococcus
- ronic uveitis with ation, and, in some erial on the thologically, this he offending dded in residual
  - t of endophthalmitis consists ng aqueous and vitreous , followed by administration of al. topical. and subconjunctival
  - dophthalmitis Vitrectomy evidence was found of any om the use of systemic . Pars plana vitrectomy rease the final visual outcome ose patients who had an initial boscantion, or



### Endophthalmitis after Uncomplicated Cataract Surgery with the Use of Fourth-Generation Fluoroquinolones

A Retrospective Observational Case Series

Majid Moshirfar, MD, FACS,<sup>1</sup> Vahid Feiz, MD,<sup>2</sup> Albert T. Vitale, MD,<sup>1</sup> Jacob A. Wegelin, PhD,<sup>3</sup> Screeniwasa Basawanthappa, MD,<sup>1</sup> Darcey H. Wolsey, MD<sup>1</sup>

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- to been subject to the study, the field of patients in whom acute encogramations developed week reve Man Diotcome Macaziane Nambar and real of encogramming the cases from recomplicated carganic Results: Uturing the study panel of the participating argumpts patiented 20 the successful carganic and results: Successful carganic and the participating argumpts patients of the successful carganic and optimized and the successful carganic and the successful carganic and the successful carganic and optimized and the successful carganic and the successful carganic and the successful carganic and deptimized and the successful carganic and the result is the modification graph and the successful carganic and the success full carganic and the successful
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### CLINICAL SCIENCES

- or 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, endoptithalmilits, and postoperative complication.

### 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)

> J Cataract Refract Surg. 2004 Sep;30(9):1953-9. Prevention of endophthalmitis.

Eye (Lond). 2007 May;21(5):580-6. Epub 2006 Jul 7. Presumed infectious endophthalmitis following cataract surgery in the UK: a casecontrol study of risk factors.

J Cataract Refract Surg. 2007 Jun;33(6):978-88. Prophylaxis of postoperative endophthalmitis following cataract surgery: results of the ESCRS multicenter study and identification of risk factors. 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.

> Ophthalmology. 1999 Oct;106(10):1869-77. Endophthalmitis in cataract surgery: results of a German survey.

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

Eye (Lond). 2007 May:21(5):580-6. Epub 2006 Jul 7. Presumed infectious endophthalmitis following cataract surgery in the UK: a case-control study of risk factors.

J Cataract Refract Surg. 2007 Jun;33(6):978-88. Prophylaxis of postoperative endophthalmitis following cataract surgery: results of the ESCRS multicenter study and identification of risk factors. Endophthalmitis Study Group, European Society of Cataract & Refractive Surgeons

### Prophylaxis of postoperative endophthalmitis after cataract surgery

### Results of the 2007 ASCRS member survey

David F, Chang, MD, Rose Brago-Mele, MD, Nick Manuala, MD, Sarnad Mashel, MD, Kavin M, Miller, MD, Louis D, Niyhawin, MD, Richard R, Packard, MD, Math Packer, MD, for the ARDING started Control Control

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J Externet Autout Song 2007; 33:1801-1885 = 2007 ASCRS and ESCRS

# Premium IOL's

### Treat Astigmatism at the Time of Surgery

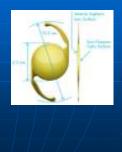
The AcrySof<sup>®</sup> IQ Toric IOL offers cataract surgery patients with astigmatism:

- 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<sup>1</sup>
- 87% of patients achieved ≤1.00 diopters of residual refractive cylinder<sup>1</sup>

### Improves Uncorrected Distance Visual Acuity



94% of patients implanted achieved uncorrected distance visual acuity of 20/40 or better<sup>1</sup>



### **Patient Expectations**

- What they say is "I want to be able to read"
- What they want is
   Accommodation



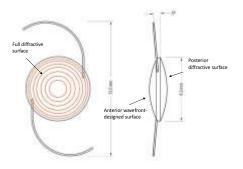
### The Center of a Presbyope's World



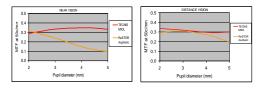
# Forget Most Everything!



### The TECNIS® Multifocal IOL



### Full Diffractive Surface=Pupil Independence



Data on File. Advanced Medical Optics, Inc.

### **US Clinical Results**

Study Parameters:

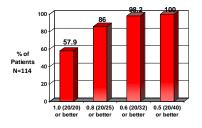
- One year, multicenter, evaluator-masked comparative clinical evaluation
- Conducted at 13 investigational sites
- Enrolled: 121 bilateral multifocal and 122 bilateral monofocal subjects
- Bilateral results at 1 year presented for 114
   multifocal subjects
- Subject assignment was not randomized

   Based on patient's choice for a multifocal or monofocal

60

### **US Clinical Results**

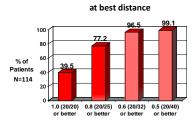
Uncorrected binocular distance visual acuity



61

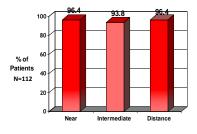
### **US Clinical Results**

Uncorrected binocular near visual acuity



### **US Clinical Results**

Ability to function comfortably without glasses



### The TECNIS<sup>®</sup> Multifocal IOL

62

- 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

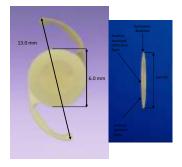
ReSTOR Apodized Diffractive Refractive



Multifocal lens with a multifocal center Diffractive/Refractive Acrylic material

63

### Anatomy of the Apodized Diffractive Technology



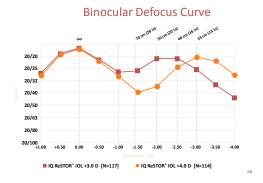
### AcrySof \* IQ ReSTOR\* IOL



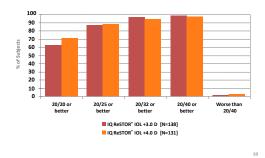
SN6AD3 Add Power: <u>+4.0 D</u> Spectacle Plane: +3.2 D Range: +10.0 D to +34.0 D A-Constant: 118.9



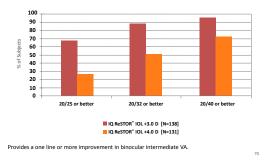
SN6AD1 Add Power: <u>+3.0 D</u> Spectacle Plane: +2.5 D Range: +10.0 D to +34.0 D A-Constant: 118.9



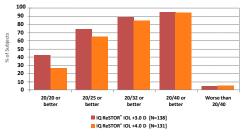
Uncorrected Binocular Photopic Distance VAs All Implanted, 3 month postoperative, Cumulative



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

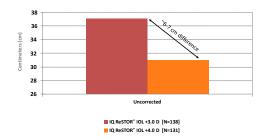


Uncorrected Binocular Photopic Near VAs All Implanted, 3 month postoperative, Cumulative, Standard Distance



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

Average Near Best Distance





71

### 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



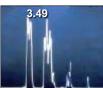
Loop Haptic

Plate Haptic

### Thornton 1986 Current Canadian Ophth.Pract.

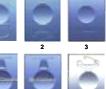
• A-Scan demonstrated shallowing of anterior chamber after movement of three piece loop lens with accommodation





### **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

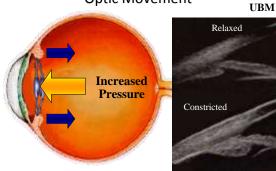


### Crystalens® AT-45 The First FDA Approved Accommodating IOL Nov. 2003



- 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

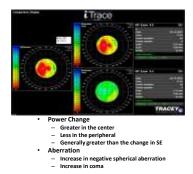
### Primary Mechanism Optic Movement



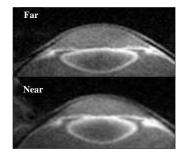
Secondary Mechanism Accommodative Arching

### 13

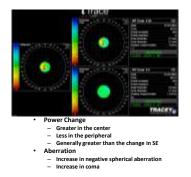
### **Summary of Wavefront Findings** crystalline Lens



MRI Changes to the Lens



### **Summary Of Wavefront Findings Crystalens**®



MRI **Changes to Optic** 







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(4<sup>th</sup> generation)
- First generation FDA approved in 2003
- Fastest growing PCIOL implanted in the US

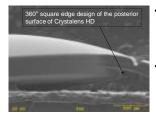


# **Crystalens HD Properties**

- Made of a 3<sup>rd</sup> 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 singlepiece 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!

### **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

### 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

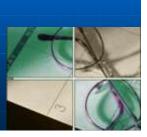


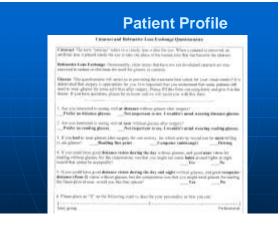
### 2<sup>nd</sup> Eye

- Wait 2-4 weeks
- Check refractive target of 1<sup>st</sup> eye
- Review surgical plan
- Modify surgical plan bases on 1<sup>st</sup> eye outcome

### Your Choice of IOL

- Patient Expectations
- Patients Needs
- Patients Adaptability
- Patients Risk Tolerance





### Decide on Goal Refraction

### Questionnaire

Cataract

Surgery 3 steps:

- 1. Distance Interests
- 2. Near Interests
- Tolerance
- Frustration

### Describers

### Cation for Loss Instituty

When a subject is reserved, an articlasit inter glassed analy de eye to take the place of the house institute or reserved. Cost insteam that here not predicting of extents to a structure or glasses or the antidexist insteam that the second glasses are caused. The previously extend on anyon or programs for the second glasses are caused on a structure of the second second or second to true. It is approximate the true subserved the same prime will not a very place in the second the true subserved the same prime will not a very place in the second second to true subserved the same prime will not a very place in the second second

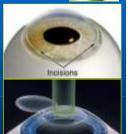
- 1. The attented are you as seeing at a distance related places after any re? Index so domary planet
- 1. How important is it to put to our up show (reading) willows glasses after mapper)? Paris or realizy planet
- \_\_\_\_\_The superior to us: 1 And 1 start waving ranking glasses
- Types could have good risess for driving during the day without glowes, and post per means without glower in some minimum, would yes for the order or near lates and plots around lights at sugle as well as see glower for most strategor? \_\_\_\_\_7=
  - No

### **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  $\rightarrow$  3 months



### 3 Areas of Vision

- Distance
- Intermediate
- Near
- Rate them in order of importance to you

### 5 Key Criteria

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

### Age

- < than 50 years</p>
  - Crystalens
  - Aspheric monofocal
- > 50 yrs
- All

### **Refractive Astigmatism**

- < than 1D</p>
  - Accommodative IOL
  - Multifocal IOL
  - Monofical IOL
- 1D or more
  - Toric IOL
  - Bioptics
    - LASIK/PRK
      LRI/AK

### 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
  - Monorocal



# Other options?

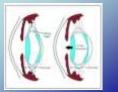
- Aspherics
- Monovision
  - Modified monovision
- Bioptics
- PRK/LASIK
- LRI/AK
- Mix and Match
- Spectacles!

### **Future Accommodating IOLs**

### Visiogen Synchrony

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







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### Clinical Results With the Light Adjustable Intraocular Lens After Cataract Surgery

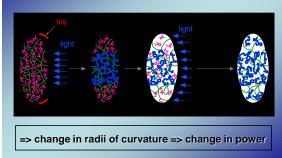
J Refract Surg. 5/2010;26:314-320

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

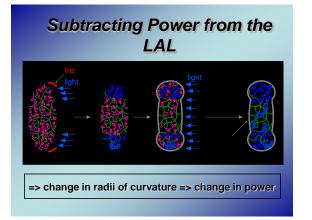
### **Light Delivery Device**

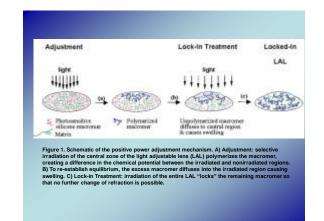


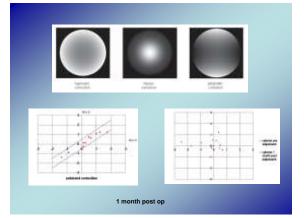


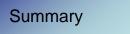


Calhour









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

Clinical Evaluation of an Ultraviolet Light Adjustable Intraocular Lens Implanted after Cataract Removal

Eighteen Months Follow-up

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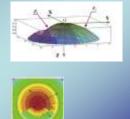
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# Surface Embedded Near Section



J Calariest Nement Sarg (V11: 37 with 445 in 2011 A 18985 and COUVE



# 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