Cataract Surgery in 2024 and Evolving Comanagement Responsibilities

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Goals

- Advances in technology
 - Improved IOL's
 - Femtosecond Laser Assisted surgery (FLACS)
 - Swept source OCT
 - Intraoperative aberrometry
- Preop and Postop management
- Evolving comanagement relationships

I have no financial relationships to disclose with any of the manufacturers of the products discussed

Cataract surgery

- 4 million procedures annually in the US (28 million globally) over 10,000/day!
- Aging population and increased life expectancy
 - 3 to 4% growth per year
- Projects to 100 million procedures/year worldwide by 2050

Health care policies

Access to cataract surgery

 Initiatives to address disparities in care and improve access in underserved communities

Patient centered care

- Personalized treatment plans tailored to individual needs and expectations
 - Plays a large role in determining IOL choice
- Listen to patient desires
 - We live in a very intermediate vision- demanding world
- Ophthalmic histories, lifestyle needs, health of the eye, ocular surface

Ocular surface

- Healthy ocular surface
 - Necessary for accurate preop measurements
 - Faster postop visual recovery
 - Cataract surgery itself contributes to DES
 - Patient perception of surgical outcome

Dry eye screening protocol

- If patient has symptoms
 - Tearing, gritty feeling, fluctuating vision
 - Or if tear osmolarity is >300 mOsm/L

- Treat for 3-4 weeks preop with Lipiflow, IPL, iLux, consider short course of topical steroids
 - prior to measurements

Pre-Op OCT

- What's new?
 - Should be performed on <u>every</u> cataract patient!
 - New attitudes about what is considered success
- Rules out pre-existing conditions that can affect the outcome

Pre-Op OCT

- Cataract may not be the only source of vision loss
 - helps patients develop appropriate expectations

Understanding drives patient satisfaction

Pre-Op OCT helps select candidates for premium IOLs

- Before premium IOLs, the only choice was a monofocal IOL
 - retinal pathology was irrelevant to whether the IOL affected outcome
- Premium IOLs require a premium macula

 Optical compromises inherent in multifocal optics demand a healthy retina that can receive all the light presented to it

Pre-Op OCT

- Study in the January 2021 Journal of Cataract and Refractive Surgery:
 - 411 eyes evaluated
 - OCT detected macular pathology in 41%, where only 23% had pathology on slit lamp biomicroscopy
 - OCT changed management in 26% of eyes!

Subtle retinal changes not always easily seen

- Epiretinal membrane present in 20% of pts >75
 - Increased risk of postop CME
 - Diffractive IOLs shouldn't be used

- Vitreomacular traction
 - Cataract surgery can accelerate PVD

Age Related Macular Degeneration

Contraindicated for presbyopia correcting IOLs

Large subfoveal drusen also a contraindication

 Vitreomacular schisis, central serous chorioretinopathy, lamellar macular hole, small CNV may be invisible without OCT

Pre-Op OCT

- Diabetic macular edema
 - No reimbursement for screening but worth it
 - Patients with DM and no retinopathy 20%
 chance of developing retinopathy over the next 10 years

Current IOL technology

We can treat a wide range of refractive error with amazing precision

- Myopia
- Hyperopia
- Astigmatism

Current IOL Technology

- I didn't mention presbyopia
 - The ideal IOL restores vision at all distances <u>without</u> compromise
 - No IOL currently can deliver the accommodation of youth
 - All alternatives are imperfect
 - All IOL's require compromise

Therefore, when considering IOL's

It is important to set reasonable expectations!

Maximize the ocular surface

 Insure we have a healthy retina pre- & postoperatively

Advanced technology (Premium) IOLs

- About 20% of cataract surgeries use these lenses
- Combined with refractive modifications e.g., femtosecond laser
 - Very lucrative thus, drives investment
 - New microscopes, phaco units, lasers, drug delivery
 - And a HOST of new (and thereby better, right?) IOLs
- <u>Eventually</u> we will have fully accommodating IOLs

With Presbyopia, <u>ALL</u> IOLs Require Compromise

- Monofocal IOLs focus all light rays on one plane (usually distance) and require glasses for reading (monovision)
- Extended Depth of Focus (EDOF) IOLs
 - Good distance and intermediate
- Multifocal IOLs
 - Diffractive design splits available light into 3 zones
 - 50% distance, 25% intermediate, 25% near

IOL selection

- Common to shoot for blended vision
 - EDOF in the dominant eye for distance, multifocal in nondominant eye for near and intermediate
 - Monofocal in dominant eye, multifocal in nondominant eye
 - Monofocal in both eyes with myopic outcome in nondominant eye

Monofocal IOL

- Traditional IOL provides excellent clarity with minimal dysphotopsias
 - Reduces higher order aberrations
 - Improves contrast sensitivity
 - Provides UV protection
 - Research being done on blue light protective IOL (premium IOL's also)

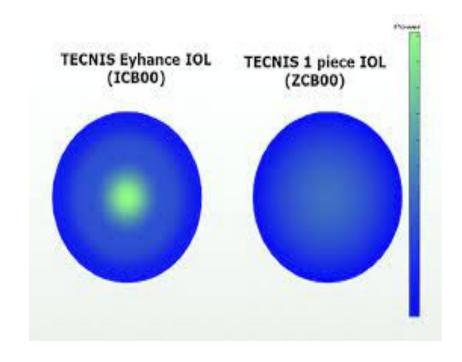
Let's look at some new(er) IOL's

Advanced Monofocal Lenses

- Tecnis Eyhance and Eyhance Toric
 - Released in the US in February 2021
- Monofocal lens that claims to provide an increase in depth of focus
- Delivers 30% better image contrast in low light
- Squared & frosted haptic design for added friction & stability
- Used with the Tecnis Simplicity Delivery System

Tecnis Eyhance

- Central 1 mm diameter zone of an aspheric anterior surface that creates a small continuous increase in central lens power
 - Package insert states that clinically meaningful extension of depth of focus has not been demonstrated
 - It is not a true EDOF IOL like the Tecnis Symfony or Alcon Vivity
 - Provides about 1 line of increased VA compared to its predecessor monofocal



Multifocal lenses with EDOF design

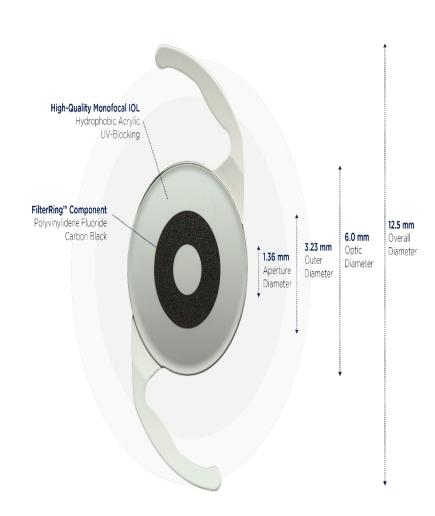
- FDA approved in May 2021
- Diffractive rings
 - Some split light to different focal points
 - Some stretch light between focal points
 - Provides true continuous range of vision
 - Closer near point
- ChromAlign technology to correct chromatic aberration
- Diffractive design risk of halos, contrast loss



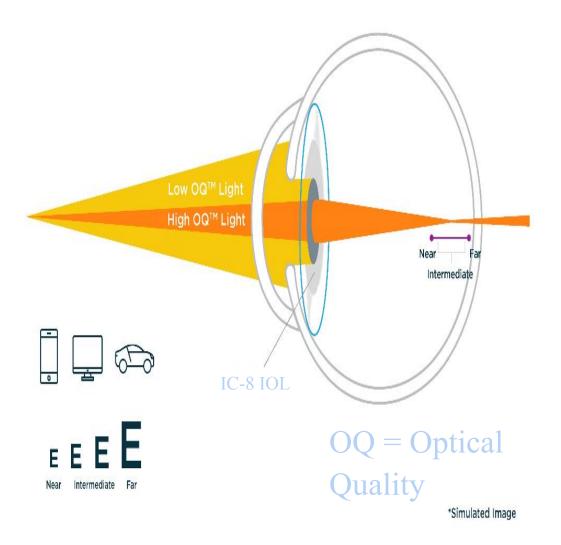
AcuFocus IC-8

- Received approval by the FDA in January 2022
- The IC-8 IOL is an aspheric monofocal lens with an embedded filter with a small central aperture
 - Mitigates the effects of unfocused peripheral light,
 allowing only central rays to reach the retina
- A pinhole IOL!

IC-8[®] Small Aperture IOL:

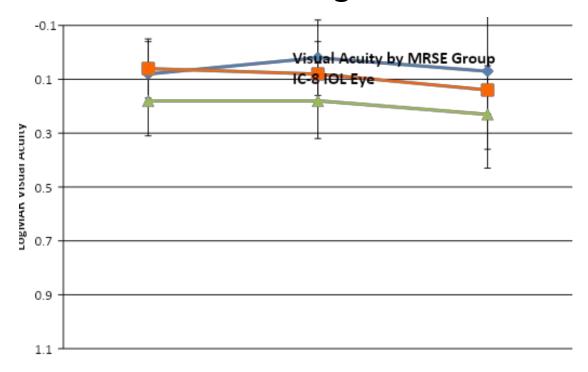


The IC-8" IOL is designed to filter out unfocused & aberrated peripheral light, allowing organized central lights rays to focus on the retina



Forgiving of Refractive Surprises

 Study showed eyes with an IC-8[®] IOL achieved consistent far, intermediate and near VA even with 1.0 D deviation from intended refractive target

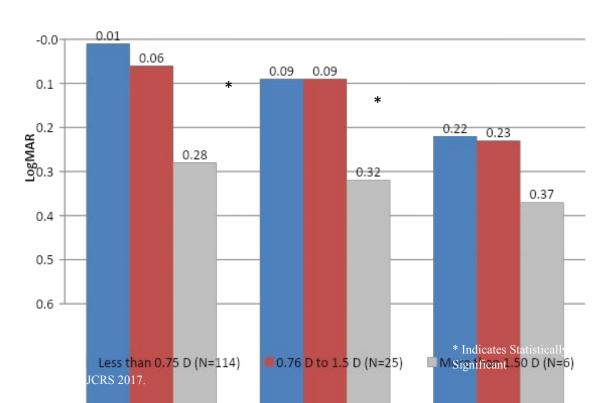




Consistent Results Regardless of Astigmatism

 The IC-8[®] IOL delivered reliable results in eyes with no or as much as 1.5 D of corneal astigmatism without the demanding process of axis alignment.^{1.2}

Visual Acuity by Cylinder Group



Posterior Segment Visualization

REPORT



Posterior Segment Visualization in Eyes With Small-Aperture Intraocular Lens

Sethish Scinorum, FRCSEA FRCDyleth, PACS; Lie Wei Khoo, MRCh8; Zacharish Kosley, DNB, FRCSEG

ABSTRACT

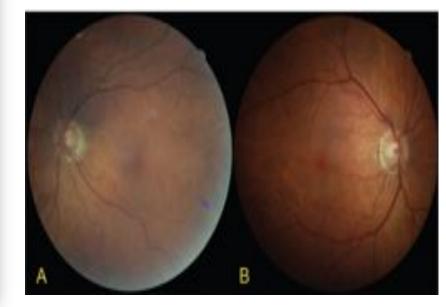
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Modular IOLs

- Several modular IOLs are in development or available currently
 - Juvene (LensGen, Irvine CA)
 - Harmoni Modular IOL (Alcon)
- Base component is essentially a traditional IOL
- Optic component is assembled once the base is in the capsular bag

Harmoni Modular IOL



Study by Ang & Colleagues

(Journal of Cataract and Refractive Surgery Nov 2021)

- 114 participants
- HMIOL placed in nondominant eye, monovision target of -1.5D, contralateral control monofocal IOL set for distance
- At 3 months, patients assessed for satisfaction with monovision
 - If unhappy, IOL exchange was done for a distance goal
 - Good visual outcomes with all patients (65 eyes)
 achieving 20/40 or better at 12 months

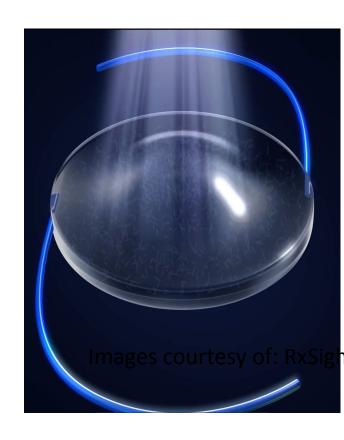
Study by Ang & Colleagues

(Journal of Cataract and Refractive Surgery Nov 2021)

- Helpful in the setting of large refractive surprises
- IOL power errors occur not infrequently
 - Post refractive surgery
 - Short/long axial length
 - Abnormal anatomy
- Desired refractive outcome may change
- IOL exchange is not without possible complications

Light Adjustable Lenses

- RxSight Light Adjustable Lens
 - FDA approval in 2017
- Able to fine-tune refractive characteristics of an implanted IOL after surgery
- Customized, patient-specific refraction
- Better alternative for post-op adjustments than LASIK

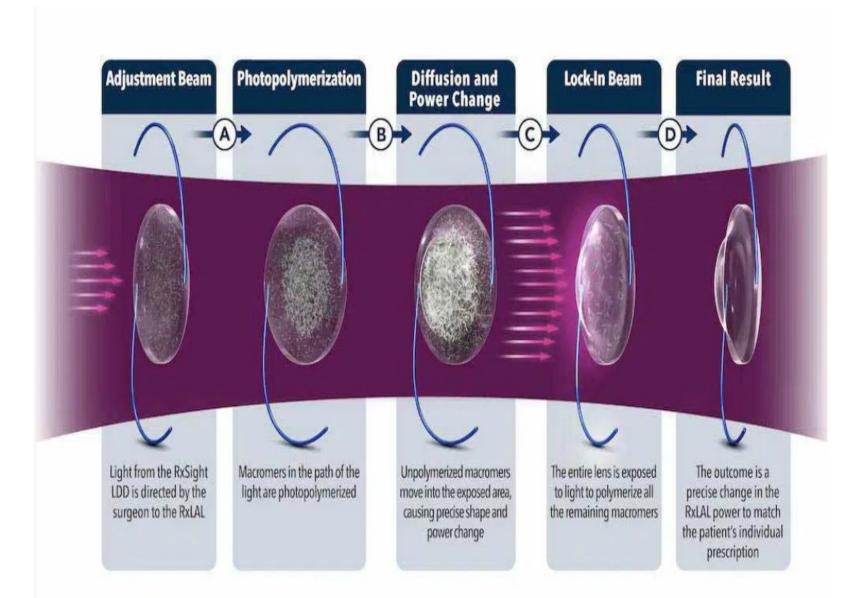


- Useful in patients with previous refractive surgery
 - Difficult to do power calculations
 - Can address variable outcomes due to unpredictable bag placement

Multifocal lenses magnify misses more than monofocal

- Retrospective study of 1275 cataract surgeries by Mass Eye & Ear in 2014
 - -94% of cases were within 1 D of target
- European study showed target refractions within .5D occur in 72.7% of cases

- How does it work?
 - Photoreactive silicone incompletely polymerized in the manufacturing process
 - The non-polymerized silicone has a photosensitizer attached
 - When UV light hits it (365 nm) for 20 secs it polymerizes
 & "locks in"
 - Heavy UV-blocking back layer no retinal damage



 Center or periphery of IOL can be treated to lessen hyperopia, increase myopia, modify astigmatism

 Performed in 3-4 light treatments over a 1 wk period @ 3 wks postop

Pt must limit UV light exposure during fine-tuning phase

- Future RxSight Developments
 - Two-photon technology two specific wavelengths of light that modify the lens hit at the same time, (doesn't happen with sunlight)
 - no need to worry about refractive change
 - Continuously adjustable refraction could be changed anytime

Perfect Lens

- Specialized femtosecond laser can modify acrylic IOLs already implanted!
- Laser creates a focal change in IOL hydrophilicity below the lens surface
 - Changes refractive index of the lens
- Treating inside the lens can modify refractive error, astigmatism & multifocality
- Can modify lens <u>up to 20 times</u>
- Accuracy of biometry will be less important





Post-Operative OCT

 Cystoid Macular Edema - common & treatable cause of blur post-cataract surgery

 Detection of subtle CME can direct a slower taper of postop drops and avoid a bigger rebound CME

Post operative OCT

- Consider <u>annual OCT</u> in cataract surgery patients
 - Age related conditions do better with early detection
 - Patient with a multifocal IOL who develops AMD may require lens exchange

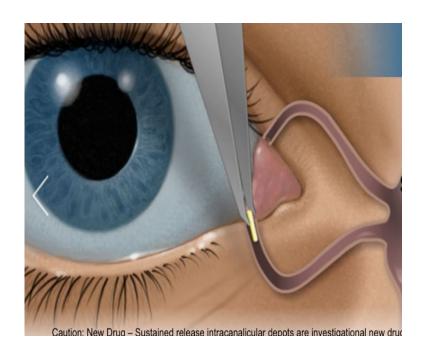
THUS, THE BEST
MANAGEMENT OF CME IS TO
TAKE STEPS TO
PREVENT IT IN THE FIRST PLACE

Treatment of CME

- Nothing new here?
- In a review of all randomized controlled trials in the JCRS February 2017
 - Optimal treatment of postop CME remains <u>topical</u> <u>steroids & NSAIDs</u>
 - Superior to all combinations of the above with sub-Tenon's steroids, oral NSAIDs, & oral Diamox, intracameral phenyl/ketorolac
 - Early/aggressive treatment to preserve retinal anatomy

Treatment of CME

- Something(s) new off-label here?
 - Yutiq (fluocinolone acetonide) intravitreal implant
 - if chronic & recurrent, no steroid responsive glaucoma
 - <u>Dextenza</u>(dexamethasone) –intracanalicular insert

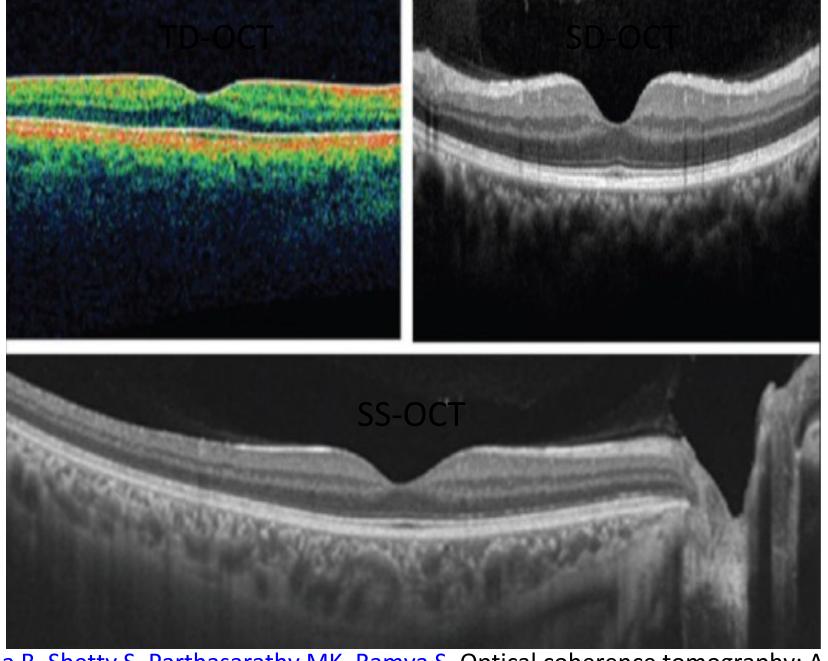


Intraoperative aberrometry

- Intended to reduce residual refractive error through aphakic refraction
 - Confirm or revise preop IOL power choice
 - Optimize IOL location
 - Tailor corneal incisions to astigmatic needs
 - Better biometry in previous refractive surgical patients
 - More accurate toric IOL placement

Swept Source OCT

- Tremendous developments in visualization techniques
 - Time domain OCT was excellent, soon replaced by spectral-domain - higher resolution and 3D images
 - Swept source OCT
 - longer wavelengths (1050 nm vs. 840 nm), photodetectors instead of CCD cameras – better resolution, scan speed twice that of SD-OCT
 - Wide-field simultaneous choroid, retina and vitreous visualization



Muna B, Shetty S, Parthasarathy MK, Ramya S. Optical coherence tomography: A guide to interpretation of common macular diseases. Indian J Ophthalmol 2018

SS-OCT & Ocular Biometry

- A review in the JCRS (June 2021)
 - summarized outcomes reported from SS-OCT was used for ocular biometry

29 studies when

All parameters used for IOL calculations were looked at –More effective at biometry measurements in

cataract

 Conclusion - optical biometers based on technology will become the gold biometry



Femtosecond Laser Assisted Cataract Surgery (FLACS)

- Approved for treatment of astigmatism
 - Limbal relaxing incisions
 - Image guidance provides perfect positioning based on preop measurements
 - Creates nubs in the capsulotomy to aid in centration
- No studies have demonstrated advantages over traditional surgery

FLACS cont'd

- Capsulotomy
 - Perfect centration
 - Perfect overlap of IOL
 - Essential that multifocal IOL be perfectly centered
 - Critical once a true accommodating IOL is developed

FLACS evolution

LenSx

Catalyx

Lensar Ally

Lensar Ally Adaptive Cataract Treatment System

- 27% reduction in mean phaco time compared to manual phaco
- 100% of patients with toric IOL within 0.5D
- 95.8% of patients with arcuate incisions within
 0.5D

Lensar Ally cont'd

- Efficiencies
 - Wireless integration with preop data
 - Iris registration
 - Sterile procedures in a single OR
 - Automatic density imaging
 - Identifies cataract density
 - Optimizes energy use and time

Heads up surgery

- Improved ergonomics for the surgeon
- Overcomes work related back/neck strain

No differences in outcomes

 More comfortable environment may result in better outcomes in the future

Optometric Comanagement

Remains controversial

Clinical perspective

Stark Anti-Kickback Statute

Support

 CPT codes specifically provide for a comanagement billing regimen

 Medicare allows optometrists to bill for services that constitute postoperative care

Opposition

Postoperative care is part of the surgical procedure

 Ophthalmologists that fail to provide postoperative care are guilty of abandonment

Comanagement arrangements are an agreement to refer

Despite the controversy...

- Comanagement has taken place rather broadly with little enforcement
 - AAO guidelines established in 2000

Recent rulings

- Ruling 05-03 policy in connection with the implantation of presbyopia correcting IOL's
 - Two Aspect Rule
- Ruling 1536R identical policy in connection with implantation of astigmatism correcting IOL's

Two Aspect Rule

 If a Medicare patient decides on a presbyopia-correcting IOL, Medicare will reimburse equivalent to a conventional IOL

 This permits the surgeon and the facility to collect additional payment for the premium IOL and additional services

Is the comanaging optometrist entitled to any of this additional payment?

 Out of pocket expenses are often \$3000 to \$5000 per eye - conventional IOL – insurance copay

 Consistent with Medicare guidelines, comanager should be eligible for 20%, right?

Problems

- Medicare reimbursement to surgeon
 - Surgical procedure
 - Postoperative care
- Out of pocket payments for premium IOL
 - Additional cost of premium IOL
 - Additional facility costs
 - Additional diagnostic services
 - Additional intraoperative services
 - Additional postop care above conventional IOL

What additional care is provided by the comanager for a premium IOL?

Debatable

- If additional care is routinely needed, how much should comanager be reimbursed?
 - Not determined by Medicare formula

Similar considerations for FLACS

Avoiding scrutiny

1. Medicare rules do not apply to noncovered services

 The comanager must understand that there must be the performance of some service in order to receive payment

Avoiding scrutiny

- The additional services must be provided by the surgeon if the patient elects to stay with the surgeon
- 4. A premium IOL patient must be informed of additional services that may be needed and allowed to choose who will perform them
 - In writing, in chart

Questions?