Innovations In Cataract Surgery-
Hype or Hope?

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Omni Eye Specialists/Spivack Vision Center
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What I Will Discuss

• Dropless Cataract Surgery
• New Lens Technology
  – Symfony lens
• Intraoperative Aberrometry
  – ORA
• Femtosecond Cataract Surgery
• Corneal Inlays
Dropless Cataract Surgery
Dropless Cataract Surgery

• Drawbacks to conventional topical medications
  – Questionable compliance
  – Chair time
  – Ocular surface toxicity
  – Very high cost to patients, burden on Medicare
  – Frequent calls, staffing burden
Dropless Cataract Surgery

No FDA approved topical or systemic antibiotic FDA for the prophylaxis of post-cataract extraction endophthalmitis
Dropless Cataract Surgery

Topical antibiotics have never been clinically proven to reduce the incidence of post-cataract extraction endophthalmitis
Dropless Cataract Surgery

Interventions shown to decrease incidence of endophthalmitis in peer reviewed literature

- Povidone iodine
- Intracameral antibiotics
Dropless Cataract Surgery

Clinical evidence for intracameral antibiotics

Swedish Study


European Study


Kaiser Study

Swedish Study

- Swedish National Cataract Registry

- 188,151 cataract operations

- 5- to 9-fold decrease in the rate of endophthalmitis with use of intracameral cefuroxime
European Study-ESCRS Endophthalmitis Study Group

• Prospective randomized partially masked multicenter study

• $2 \times 2$ factorial design, with intracameral 1mg/.1cc cefuroxime and topical perioperative levofloxacin resulting in 4 treatment groups

• N=16,603 patients
European Study-ESCRS Endophthalmitis Study Group

• Study halted prematurely given clear evidence of benefit of intracameral abx

• Endophthalmitis rate .35% for topical vs. .08% for intracameral group

• Nearly 5-fold reduction in endophthalmitis
Kaiser Study

• Retrospective study

• N=16,264

• Postoperative topical antibiotic alone vs. Intracameral +/- topical
Endophthalmitis Prophylaxis
Kaiser Study

Findings

• At least 10-fold decrease in endophthalmitis in intracameral antibiotic group

• Questionable benefit of additional postoperative topical antibiotics
Bottom Line

- There is a clear benefit of intracameral antibiotics
- Questionable benefit of topical agents
Dropless Cataract Surgery

- Intravitreal antibiotics
- Implant or depot antibiotics
• Vitreous is nutrient-rich environment, site of bacterial proliferation

• Reasonable to consider intravitreal placement of antibiotic

• Compare effectiveness of transzonular antibiotics into the vitreous vs. topical

• No statistically significant difference in IOP, macular thickness, central corneal thickness, or pain between the 2 groups

• Significantly more subjects preferred the injection for overall experience
Transzonular (Intravitreal) Injection
Intravitreal Antibiotics

- TriMoxi-Triamcinolone/Moxifloxacin (Imprimis, San Diego, CA)
Implant or Depot Medications
PolyActiva (Melbourne, AUS)

- Sustained release of levofloxacin over 30 day period
- Bolus dose of dexamethasone
DEXTENZA, Ocular Therapeutix (Bedford, MA)

- Sustained release dexamethasone
- Intracanalicular depot
Optimized Topical Drops- Combination Medications

- PRED/MOXI-Prednisolone acetate and moxifloxacin hydrochloride
- PRED/NEPAF-Prednisolone acetate and nepafenac
- PRED/MOXI/NEPAF-Prednisolone acetate, moxifloxacin hydrochloride, and nepafenac
Optimized Topical Drops-Combination Medications

Considerable benefits

- fewer bottles and number of drops
- markedly less expensive
- fewer calls “this medication is not covered by my insurance”
Bottom Line

• Newer drug delivery will be marked improvement in many ways

• Downsides to intravitreal medications

• Benefits of combination medications
New Lens Technology-
Symfony Lens
New Lens Technology

- Symfony Lens
  - UV blocking, hydrophobic acrylic
- “extended depth of focus lens”
Symfony Lens

“Extended Range of Vision IOL delivers a continuous, full range of high-quality vision with incidence of halos and glare comparable to a monofocal IOL”
Symfony lens

• “Proprietary Achromatic Technology”
  – a sharper focus of light, less compromise in contrast sensitivity
  – correction of spherical aberration increases retinal image quality, without negatively affecting depth of focus
Symfony Lens-Toric

- Cylinder Powers
  - 0.69 D to 4.11
New Lens Technology- Symfony Lens

- RCT
- Symfony vs. Monofocal (ZCB00) Lens
- \(n=148\) Tecnis Symfony IOL
- \(n=151\) monofocal IOL
New Lens Technology-
Symfony Lens

FDA Trial Results

• Distance Vision
  – Equivalent

• Near Vision
  – Tecnis patients could read two additional, progressively smaller lines on a standard eye chart

• Intermediate Vision
  – 77% with the Tecnis Symfony IOL 20/25
  – 34% in the monofocal IOL 20/25
New Lens Technology-
Symfonyy Lens

• Adverse events
  – worsened or blurred vision
  – Bleeding
  – Infection

• Symfony lens “may reduce contrast sensitivity, especially in conditions of poor visibility such as fog or dim light. Visual halos, glare, or starbursts also may occur.”
• Prospective comparative study

• Symfony vs. Monofocal

• N=80

Results

• Better postoperative uncorrected monocular and binocular distance (UDVA), intermediate (UIVA), and near (UNVA) visual acuities were found in the Symfony group

• No differences in contrast sensitivity or optical quality parameters
Bottom line

• Very limited data
• Suggestion of better distance, intermediate, and near visual acuity than the aspheric monofocal IOL, while maintaining the same level of visual quality.
• Some suggestion of improvement over current multifocal technology
• Glare and halo perhaps improved
Intraoperative Aberrometry-ORA
What is ORA?

Optiwave

Refractive

Analysis
• Intraoperative aphakic and pseudophakic wavefront data

• Calculate IOL power

• Assist in toric IOL alignment
ORA VerifEye System™
(Optiwave™ Refractive Analysis)

- Attaches to surgical microscope
- On-demand, real time intraoperative measurement of sphere, cylinder and axis
Obtain Wavescan

AMO - ZMB00 TECNIS 1P
No Post-Refractive

Power: NA
TR: -0.01
LP: 23.50

Sphere: 13.68D Cylinder: 0.17D Axis: 14° SE: 13.77D
Bottom Line

- Great tool for IOL selection in post keratofractive patients
- Invaluable in toric lens alignment
- Equivalent to standard biometry in non-post refractive setting
Husbands MUST have a note from their wives before selecting colors.

Love, Mary.
Femtosecond Cataract Surgery
Femtosecond Cataract Surgery

• Technology borrowed from LASIK surgery

  – LenSx (Alcon)
  – OptiMedica Catalys (AMO)
  – LensAR
  – Technolas-Victus (B&L)
Femtosecond LASER

- Ultra-short pulse laser
- Pulses are too brief to transfer heat to the material being cut
- No damage to surrounding tissue
- Cuts material by ionizing it at the atomic level
- Extremely precise
Femtosecond Cataract Surgery

Swing in Laser Arm

Measure eye Make Cuts

Laser retracts

Capsulotomy, Fragmentation, LRI’s, CCI’s

Are ALL Done!

LensAR Inc
Winter Park FL
Femtosecond Cataract Surgery

- Femtosecond laser-assisted cataract surgery functions:
  - LRI
  - Anterior capsulotomy
  - CCI (phaco incision)
  - Sideport incision
  - Nuclear fragmentation
Nuclear Fragmentation
Femtosecond Cataract Surgery

- reduced phacoemulsification time
- better wound architecture
- greater precision and accuracy of the anterior capsulotomy
- better centration of IOL

Femtosecond Cataract Surgery

Potential complications:
- subconjunctival heme
- capsular tags/bridges
- suction break-aborted procedure
- post-laser pupillary miosis
- dropped nucleus

- Improved outcomes and safety with greater surgical experience and familiarity

Femtosecond Cataract Surgery

My personal opinion........

– At present, no clear benefit when compared to experienced cataract surgeon

– Cost prohibitive for most patients

– Decrease U/S time in denser cataracts
Femtosecond Cataract Surgery

My personal opinion........

– Likely improve with more experience and study

– Hopefully more cost effective increasing accessibility
Corneal Inlays
Corneal Inlays-Definition

- Device implanted into the corneal stroma to alter corneal refractive properties
Corneal Inlays

• Types
  • 1. Refractive
    – Fleixivue Microlens
  • 2. Corneal re-shaping
    – Raindrop Inlay (PresbyLens or Vue)
  • 3. Pinhole or small aperture
    – Kamra inlay
Flexivue Microlens (Presbia)
Flexivue Microlens (Presbia)

- 3mm diameter disc
- Hydrophobic acrylic
- Implanted in a femtosecond corneal pocket
- Central nonrefractive and peripheral refractive zones
- Progressive +1.5 to +3.5 D refractive power peripherally
Raindrop Inlay (ReVision Optics)
Raindrop Inlay (ReVision Optics)

- Transparent Hydrogel disc
- Same refractive index as the cornea
- Implanted under a LASIK flap or stromal pocket
- 2mm wide and 33 microns thick
Raindrop Inlay (ReVision Optics)

- Dedicated near vision zone in central cornea
- Pupil dependent
- May also reshape the anterior curvature of the cornea to enhance near and intermediate vision?
- Induced asphericity elsewhere?
- Some loss of distance vision
Kamra Inlay (AcuFocus)
Kamra Corneal Inlay

- Use small-aperture optics to increase the depth of focus
- Central focus light reaches retina uninterrupted
- Implanted within a corneal pocket
Kamra Corneal Inlay

- small-aperture optics to increase the eye's depth of focus
- Allows only central collinear light rays to reach the retina
- distance vision in the treated eye does not decrease as much as in eyes treated with monovision or modified monovision
Kamra Inlay (AcuFocus)

- FDA approved
- >10 years to develop
- 6 iterations
- Most common corneal inlay globally
- Ideal patient profile
  - Emmetropic patient (+.50 to -.75 D)
  - < .75 D cylinder
  - 40-60yo patient
  - Required near add of +1.00 to +2.50
Kamra Inlay (AcuFocus)

- Contraindications per FDA study
  - Pseudophakic
  - Severe dry eye
  - HSV
  - Active infection/inflammation
  - Ectasia
  - Thin cornea
  - Autoimmune/CT disease
  - Uncontrolled DM or Glaucoma
Kamra Corneal Inlay

- Made of polyvinylidene fluoride pigmented with carbon nanoparticles for opacity
- 5 μm thick
- Artificial aperture with an outer diameter of 3.8 mm and a central aperture (inner diameter) of 1.6 mm
Kamra Corneal Inlay

- 8400 microperforations (5 to 11 μm) that allow an average light transmission through the annulus of 6.7%

- Allow nutritional flow through to the stromal tissue
Kamra FDA Results

• FDA approval based on review of 3 clinical studies
• n=508 patients
• 24 investigational sites worldwide
Kamra FDA Results

- 83.5% with near UCVA 20/40 or better at 12 months
- Represented 3-line improvement vs preop
- Mean preop distance UCVA unchanged
- 45 (8.9%) explant rate
Kamra FDA Results

- Most common reasons for explant (8.9%)
  - Hyperopic shift 55.6%
  - Inability to adapt 15.6%
  - Inlay not centered 4.4%
  - Myopic shift 4.4%

- All but 1 patient had distance BCVA of 20/20 after explant
Kamra Study—Conclusions

• Long-term results of monocular corneal inlay implantation indicate increased UNVA and UIVA and slightly compromised UDVA in emmetropic presbyopic eyes
Corneal Inlays-Summary

- Still early in the development of this technology
- Early FDA approval for Kamra and Raindrop, long term results needed
- 10% explant rate
- May anticipate multiple options
- Hopefully maintain good binocularia
My Concerns

- Refractive or topographic shifts
- Glare/halo at night
- Wound healing issues with corneal FB
- Effect on dry eye
- Neuroadaptation
In Summary

• Exciting technology in the pipeline
• Some degree of hype
• More data needed
Thank you!