A New Era In Cataract and Refractive Surgical Management

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Disclosures

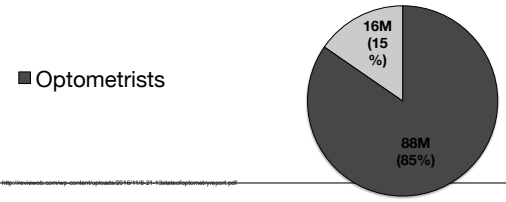
- Allergan- Consultant, speaker, research
- Avellino- consultant
- Azura- consultant
- BioTissue- consultant, speaker
- Bruder- consultant
- Dompe- consultant
- Glaukos- consultant, speaker
- Horizon Therapeutics- consultant
- Kala- consultant, speaker
- LacriSciences- share holder, consultant
- Sight Sciences- consultant
- Sight Sciences- consultant
- Thea- consultant
- Novartis- consultant
- Sun- consultant, speaker
- Tarsus- consultant, researcher
- Visus- consultnat
- Quidel- consultant, speaker
- Zeiss- consultant
- SeaGen- consultant
- Orasis- consultant

Optometric Co-management

- High quality eye care
- Benefits to patient care
  - Patient comfort
  - Patient convenience
  - Efficiency
  - Cost effective
- Utilize skills and expertise of each practitioner

Who Sees Cataract Patients First?

ODs perform an estimated 88 million refractive eye exams annually of the total of 104 million performed by all eye care professionals, or 85% of all comprehensive eye exams. [1]



1- http://reviewob.com/wp-content/uploads/2016/11/B-21-13stateofoptometryreport.pdf

Future of Cataract Surgery Market

- Most frequently performed surgery in US with 3 million cataract surgeries a year in the U.S.
- More cases of cataracts worldwide than there are of glaucoma, macular degeneration and DM retinopathy combined
- 4 out of 5 patients diagnosed with a cataract are done so by an optometrist
- Optometrists are the “gatekeepers” to cataract referrals and ATIOLs

Preventblindness.org

2.0 B

People with Presbyopia around the globe in 2019 – growing to

2.3 B

by 2023

PRESBYOPIA Worldwide

Presbyopes	2019	2024
US	128.7 M	136.5 M
OUS	1.93 Billion	2.17 Billion

Source: 2019 Market Scope Estimates

~ 1.8 million new presbyopes a year in U.S.

Contributing Factors:

- **Aging population**
- **Longer life expectancies**
- **Longer Working Careers**
- **Near Vision needs**
- **Growing Middle Class in emerging markets**

Patient Education

- Elements of effective education
- Explain the condition
  - Cataract
  - Astigmatism
  - Presbyopia
- Four presbyopic IOL classifications
  - Diffractive
  - Accommodating IOLs
  - Extended Depth of Focus IOLs (EDOF)
  - Trifocal

Cataract Surgery Now Refractive Surgery

Patient expectations are higher than ever!

Are you ready?

- Plano results are expected
- Distance, Intermediate and Near desired
- Spectacle independence

Premium IOLs: **5 Pearls ("P's") for Success**

1. **P**lano Outcome
2. **P**roactive Tx of Ocular Surface Disease
3. **P**re Op Counseling – Setting Realistic Expectations
4. **P**roperly Screen Candidates
5. **P**ick the Right IOL

Other:
6. **P**ick the Right Surgeon
7. **P**osterior Capsular Opacification
8. **P**oor IOL Centration

Properly Screen Ideal Candidates

Preop Exam

- Full evaluation from "front to back"
- Dry eye work-up
- Topography-corneal scar, corneal astigmatism, pterygium
- Binocular vision, amblyopia, strabismus
- Corneal dystrophies, endo cell counts, corneal edema/guttata
- Floppy Iris Syndrome, previous trauma, pseudo X, zonular weakness
- Retinal pathology
- Glaucoma

Post Op Pearl #1: Proactive Treatment of Ocular Surface Disease

Maximize Ocular Surface

- Treat and Evaluate:
  - Ocular Surface Disease
  - Perform Dry Eye Work Up
  - MGD
  - Blepharitis
  - Basement membrane dystrophy
  - Fluctuating Vision
  - Medicamentosa
  - Lagophthalmos

Post Op Pearl #1: Proactive Treatment of Ocular Surface Disease

(PHACO) Study: Prospective Health Assessment of Cataract Patients Ocular Surface

- Purpose: to determine the prevalence of dry eye in patients undergoing cataract surgery
- 136 patients, 272 eyes having cataract SX
- Avg. age 70
- Test used Shirmer's, TBUT, corneal staining, and subjective questionnaire
- Results:
  - 171 eyes (62.9%) had a tear break-up time of less than 5 seconds
  - 209 eyes (76.8%) showed positive corneal staining
  - 136 eyes (50%) showed central corneal staining
  - Shirmer's Scores: 132 eyes (48.5%) had a score of 10 or less, and 58 eyes (21.3%) scored less than 5

Trattler W, Goldberg D, Reilly C. Incidence of concomitant cataract and dry eye:prospective health assessment of cataract patients. Presented at:World Cornea Congress;April 8,2010; Boston,MA.

Post Op Pearl #1: Proactive Treatment of Ocular Surface Disease

Maximize Ocular Surface

- Diagnostics Used:
  - **Fluorescein**
  - Topography
  - Lissamine Green
  - Tear meniscus height
  - **TBUT**
  - O.S.D.I., SPEED Questionnaire
  - Osmolarity
  - Shirmer's, Zone Quick
  - MMP-9 (ImflammaDry)
  - Slit lamp exam
  - Meibography & MGE
  - Interferrometry
  - Blink rate/partial blinks/exposure

Post Op Pearl #1: Proactive Treatment of Ocular Surface Disease

Why is it important to identify and treat Dry eye and MGD Pre op?

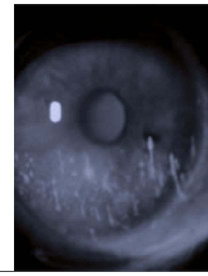
•Better topography images

•Improved Biometry (better K's)

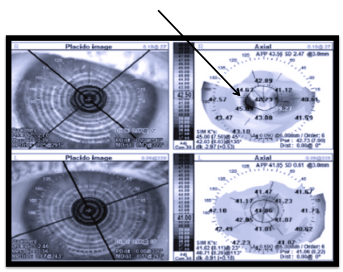
•Inaccurate **K's** can lead to wrong IOL power, wrong axis for toric placement

•More comfortable patient

•Faster healing, better VA



"Hot spots" and "Flat spots" are abnormal



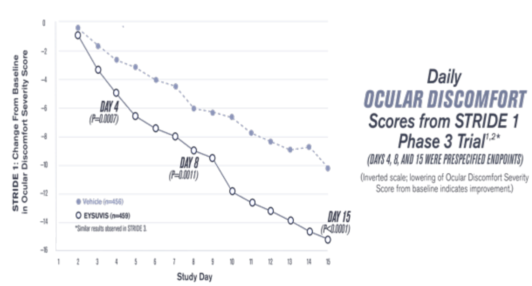
Dry Eye Treatments

- AT's
- Ointments
- Restasis
- Xiidra
- Cequa
- Corticosteroids
- NSAID's
- Punctal Occlusion
- Lacrisert
- Autologous Serum
- Moisture goggles
- Topical Androgen
- Doxycyclines/Azithromycin
- Tissue engineering
- Expression/Thermal Pulsation
- Neurostimulation
- Labial, parotid, submandibular gland transplantation
- Evoxac
- Omega 3:6 FA's
- HRT
- Botox
- Accupuncture
- Herbal remedies
- Mucin replacement
- Amniotic membranes
- Warm compress

Dry Eye Therapies Can Be Slow

How can we speed up treatment?

Demonstrated Rapid Onset of Symptom Relief

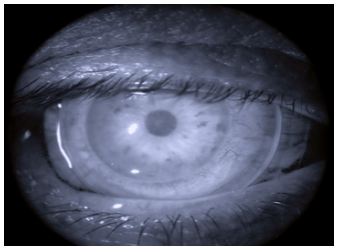


The safety and efficacy of EYSUVIS was assessed in 4 multicentered, randomized, double-masked, placebo-controlled trials (one Phase 2 and three Phase 3 trials, STRIDE 1, STRIDE 2, and STRIDE 3) in 2871 patients with documented Dry Eye. Patients received either EYSUVIS or vehicle 4 times a day for at least 2 weeks. Day 8 and Day 15 were prespecified efficacy endpoints in STRIDE 1, STRIDE 2, and STRIDE 3; Day 4 was also a prespecified endpoint for STRIDE 1. *P* values for Day 8 and Day 15 were analyzed on the days following Day 7 and Day 14 using the 3-day mean prior to Day 8 (Days 5, 6, and 7) and the 3-day mean prior to Day 15 (Days 12, 13, and 14) compared with the 3-day mean prior to Day 1 (baseline). The *P* value for Day 4 was analyzed using the single-day data compared with the 3-day mean prior to Day 1 (baseline). The daily ocular discomfort severity score (ODS) change from baseline data presented here are derived comparing the single-day data from each time point to the 3-day mean prior to Day 1 (baseline).[1]

Reference: 1. Data on file. Kala Pharmaceuticals. Watertown, MA. **2.** Holland E et al. Presented at AAO2020; Nov 13-15, 2020; virtual meeting.

Fast Dry Eye Treatments

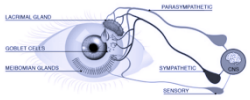
- Cryo Preserved AM



LFU REGULATES TEAR PRODUCTION

BY COMMUNICATING WITH CENTRAL NERVOUS SYSTEM (CNS)

- Lacrimal Functional Unit (LFU) maintains a healthy environment for the eye by regulating tear production
  - In response to any external and internal stimuli, LFU communicates with Central Nervous System (CNS)
  - Sensory signals are carried via afferent neurons from LFU to CNS
  - Parasympathetic and sympathetic signals are carried via efferent neurons from CNS to LFU
  - This afferent and efferent signaling and communication occurs via the trigeminal nerve
- Neurostimulation in the nasal cavity targets the trigeminal nerve to trigger the nasolacrimal reflex to emulate the normal neural signals to create a natural tear



1. Kossler et al. *Ophthal Plast Reconstr Surg.* 2015; 2. Beuerman et al. In: Pflugfelder et al, eds. *Dry Eye and Ocular Surface Disorders.* 2004; 3. Dartt. *Ocul Surf.* 2004. 4. Freidman et al. *A nonrandomized, open-label study to evaluatethe effects of nasal stimulation on tear production in subjects with dry eye disease.* 2016

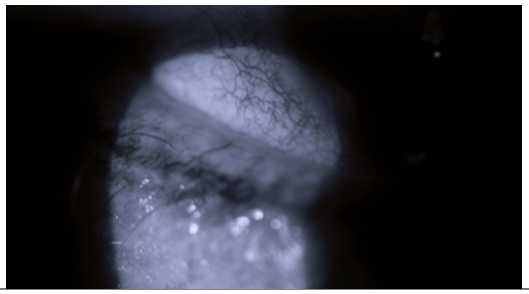
Cyclosporine A 0.09%

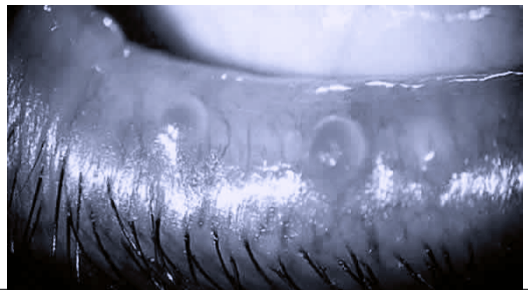
A confirmatory Phase 3 trial of a proprietary nanomicellar formulation of cyclosporine A 0.09%, a clear, preservative-free, aqueous solution, for the treatment of dry eye, was completed in December 2016.

- Design
  - Trial was a 12 week, multicenter, randomized, double-masked, vehicle controlled Phase 3 study
  - 744 dry eye patients were enrolled
  - 1:1 randomization to either cyclosporine A 0.09% or its vehicle
  - Primary end point was Schirmer's score
- Results
  - At 12 weeks of treatment, cyclosporine A 0.09% demonstrated a statistically significant improvement in Schirmer's score (p<0.0001).
  - Improvement in Schirmer's score at 12 weeks is earlier than other drugs approved for dry eye in the same class. [1]
  - Several key secondary endpoints showed statistically significant improvements compared to vehicle with some showing an even earlier onset of action.
  - Adverse events reported in the trial were mild to moderate in nature and similar to other approved drugs in the category. [1-3]
- Conclusions
  - This data, and data from a previously completed Phase 2b/3 clinical trial in 455 patients, indicate Cyclospoine A 0.09% compares favorably to other formulations of cyclosporine A with the advantage of early onset. [1]

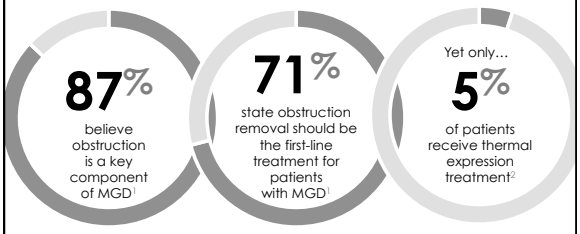
[1] Sall K, etal. Ophthalmology. 2000 Apr;107(4):631-9. [2] Sheppard JD, et al. Ophthalmology. 2014 Feb;121(2):475-83.
[3] Tauber J, et al. 2015 Dec;122(12):2423-31

Ocular Rosacea and MGD





Why the Disconnect?



1. Survey of optometrists and ophthalmologists conducted by PentaVision LLC, publishers of Optometric Management and Ophthalmology Management from October 7, 2020 through November 5, 2020, and January through April 2021. Data on file. 2. Market Scope 2021 Ocular Surface Disease Survey

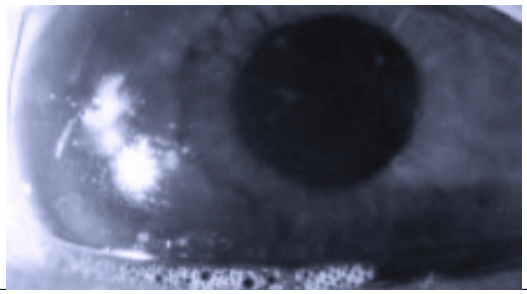
The newest device cleared to treat MGD, the leading cause of dry eye disease

Single-use SmartLids
- Universal lid fit; complete gland coverage
- Precise, consistent therapeutic heat
- Natural-blink design

Clearance Forceps
- Precise gland targeting
- Real-time visualization

Intelligent Controller
- Sensor-driven feedback for consistency and safety
- Portable

Blepharitis



Post Op Pearl #1: Proactive Treatment of Ocular Surface Disease

- The cataract patient is a dry eye patient!
- RTC for Dry eye/OSD evaluation
- Improved Outcomes
- Happier Patients
- Increased Revenue

Post Op Pearl #2: Plano Outcome

Number One "Problem": Residual Refractive Error!
- Can cause blurry vision, increase (-) dysphotopsia, glare, halos and night vision complaints
- "Fix" the problem ASAP: PRK, LRI, glasses, CL's
- Validate the patient's complaints
- Work with surgeon who includes cost of enhancement in initial fee

Work up should include:
- Refraction- finding residual refractive error
- Cycloplegic MR needed? (Eg. Crystalens, Trulign)
- Corneal topography
- Assessing/evaluating ocular surface, tear film
- Once MR stable, planning for enhancement

Post Op Pearl #2: Plano Outcome ATIOL

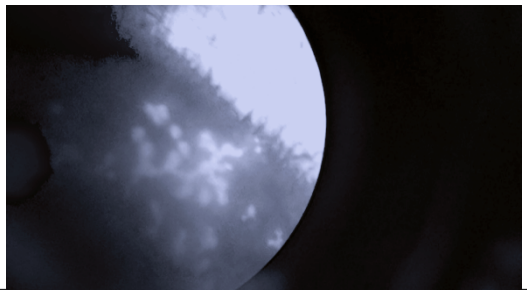
- Astigmatism: Treat when greater than 0.50 D
- Minimum goal:
  - < 0.50 D astigmatism
  - < 0.50 D spherical
- Treat once stable (2-3 months S/P Phaco)
- Educate patient early about Tx plan
- LRI or Arcuates vs. PRK/LASIK?
- Experienced **Cataract** AND **Refractive** Surgeon

Other Corneal Issues

Can Limit Visual Outcome:
- Fuch's
- Corneal Scar (RK, AK)
- Salzman's nodular degeneration
- Lagophthalmos
- Exposure Keratitis
- **ABMD**

Other Complications

Secondary Corneal Complications



HSV

- Reactivated by topical steroids
- Immuno-compromised patients
- Ask about Hx of cold sores, HSV, “eye infections”
- Treat prophylactically?
- Zirgan vs. Viroptic
- Oral antivirals
- Topical and oral Tx

Post Op Complication Elevated IOP

- Check IOP at all post op visits
- Increased IOP at day #1- Why?

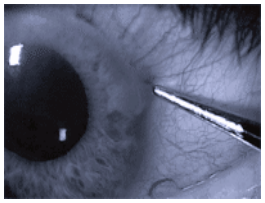
Increased IOP at Post Op Day #1

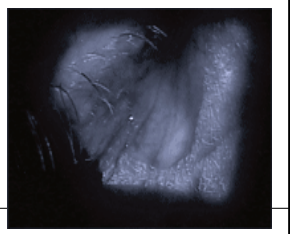
Treatment options in Office:

- “Burp the wound” or paracentesis
- Oral diamox given in office
- Topical treatment with combination drops- Combigan, Simbrinza, Cosopt
- Fast acting topical drops- beta blockers, CAIs, Adrenergic agonists

Treating Increased IOP at Post Op Day #1

- Paracentesis performed at slit lamp





Common Post Op Complications : Elevated IOP

Increased IOP at Week #1

Cause?

- Usually due to inflammation in the trabecular meshwork

Treatment: Increase steroids!

**This is NOT a steroid induced IOP increase

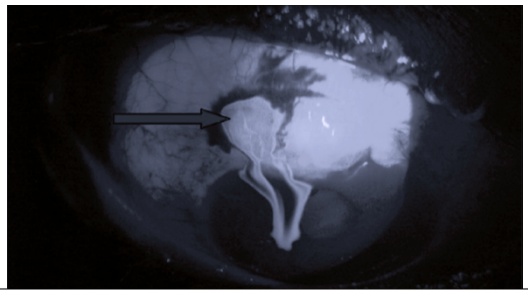
Common Post Op Complications : Elevated IOP

Increased IOP at 3-4 weeks

- Now it's a steroid induced IOP response

Treatment: Taper or D/C steroid, change to topical NSAID, change to loteprednol

Post Op Complication Wound Leak



Post Op Complication Wound Leak

- Use sterile NaFl strip at wound to check for wound leak
- Seidel (+)
- Phaco burn

Treatment

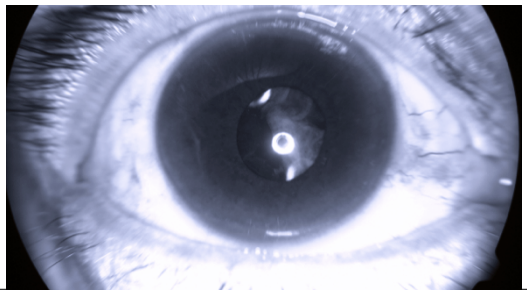
- Place BCL for 1-3 days?
- Decrease steroid?
- Increase antibiotic
- Follow every day until Seidel (-)
- Watch for hypotony, infection

Post Op Complication Rebound inflammation

Rebound iritis and post operative inflammation

Cause:

- Taper too short
- Poor compliance
- Generics
- Emulsions vs. Suspensions
- Secondary ocular and systemic problems
- Other



Treatment

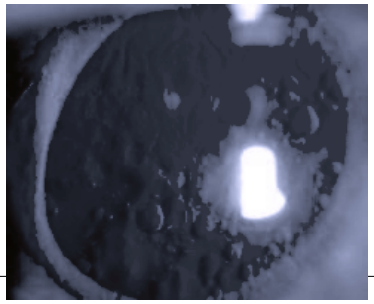
- Additional irrigation and aspiration
- Increase steroid vs. Decrease steroid?

Need to perform gonio if :

- Chronic anterior chamber inflammation
- Unexplained increased IOP
- Photophobic, pain

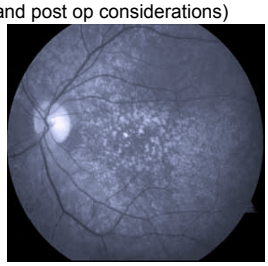
Post Op Complication PCO

Posterior capsular opacification



Retinal Issues

- Epi retinal membrane (pre and post op considerations)
- Macular hole
- CME/CSME
- Retinal Health/assessment
- AMD
- Macular Scar
- Must do DFE
- Genetic screening?



Premium IOL Pearl #5: Pick the Right IOL

- You know your patients better than the M.D.!
- Develop a refractive treatment plan and goal
- Options: 1. Distance only
  - Toric, traditional, LRI's, Arcuate incisions
  2. Distance and Intermediate
  3. Distance, Intermediate and Near
- Send written letter of surgical goal/plan to surgeon prior to pre op consult

TORIC IOL Patient Selection

Patient Selection

- Desires distance vision
- Okay with spectacles for near
- More than 0.75 D - 1.00 D of astigmatism by corneal topography or K's

Preoperative Testing

- K readings
- IOL Master
- Corneal topography
- Lenstar

Advanced Technology: The Current Players

TECNIS Symfony® Extended Range of Vision IOL

TRULIGN® TORIC

Crystalens® Don't just see. See better.

TECNIS® MULTIFOCAL IOL DIFFRACTIVE ASPHERIC

TECNIS® TORIC ASPHERIC IOL

ACRYSOF® IQ RESTOR®

ACRYSOF® TORIC SINGLE-PIECE NATURAL IOL

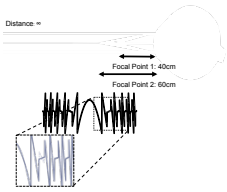
Presbyopic IOLs

Four Classifications :

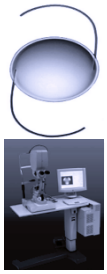
1. Diffractive Multifocals
2. Accommodating IOLs
3. Extended Depth Of Focus IOLs (EDOF-IOLs)
4. Trifocals

PANOPTIX TRIFOCAL IOL

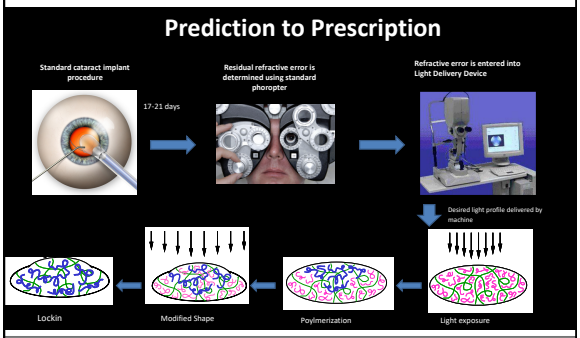
- **SUPERPOSITION OF FOCAL POINTS**
- **LIGHT REDIRECTION** - 120 cm intermediate focal point redirected to distance
- **3 FOCI** – Trifocal with 40cm, 60 cm and distance
- **88% LIGHT UTILIZATION** - at 3.0 mm pupil
- **LIGHT ALLOCATION** - 50% of available light to distance, 25% to intermediate and 25% to near



Light Adjustable Lens (LAL)



- FDA Approved 11/17 for pts with pre-existing astigmatism of ≥0.75D undergoing cat sx
  - Spherical and cylindrical errors up to 2D
- First and only lens designed to be ***adjusted*** after implantation by UV light
- 3 piece IOL design
- 6.0mm biconvex optic; 13.0mm overall length



Proprietary Technology

TECNIS Symfony® IOL Merges Two Complementary Enabling Technologies

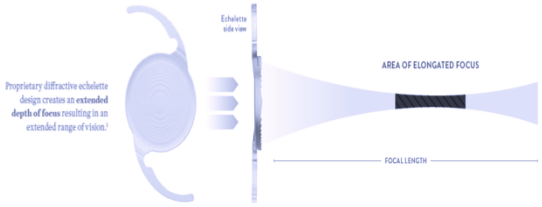
Proprietary Echelette Design Extends the depth of focus

Proprietary Achromatic Technology Corrects chromatic aberration for enhanced image contrast[1]

1. TECNIS® Symfony® IOL DFU

Extended Depth of Focus

Extended Depth of Focus IOLs use diffractive optics, creating a different visual



elongates the focus of the eye[1]

- The echelette is the relief or profile of the lens (height differential) within each ring
- The height, spacing, and profile of the echelettes to create a diffractive pattern for an elongated focus

1. TECNIS® Symfony® IOL DFU

54

Delivering Elongation of Focus

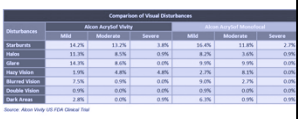
Monofocal IOL

Multifocal IOL

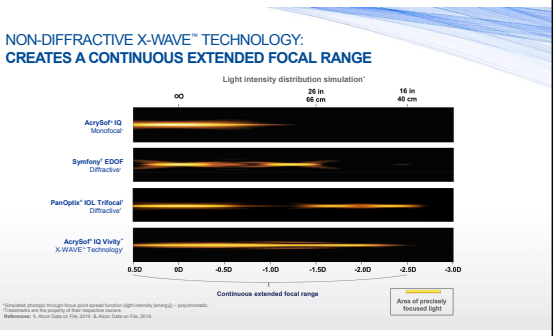
TECNIS Symfony® IOL

[1] Data on File_Data on File_Tecnis Symfony Green Light Bundle Bench Test DOF2014CT0005. Abbott Medical Optics Inc. 2014

EDOF - Vivity IOL



- Non-diffractive IOL
- Novel X-Wave shaping technology creates an extended focal range by stretching and shifting the wavefront
- Low incidence of visual disturbances
- Possible for AMD?? Glaucoma??



J&J Vision – Tecnis Eyhance

- First lens[1] in the monofocal IOL category in Europe to deliver improved intermediate vision and 20/20* distance vision
- TECNIS Eyhance IOL offers the same well-established low incidence of halo, glare, or starburst as TECNIS® 1-piece IOLs
- FDA approved 2/2/21

J&J Vision – Tecnis Synergy

- Gives broad range of continuous vision[3] covering from distance to 33 cm**[4-6]
- Eliminates the visual gaps present in trifocal and other multifocal technology
- Continues to deliver superior performance in low-light conditions***[2]
- Violet-filtering technology demonstrates reduction in halo

**Not FDA Approved

THE OTHER Premium IOL "P's" – Pearl # 6: Pick the Right Surgeon

- Cataract and Refractive Surgeon
- Experienced Lasik/PRK surgeon
- Experienced surgeon skilled to explant IOLs
- Co - management friendly
- **Uses Advanced Technology**

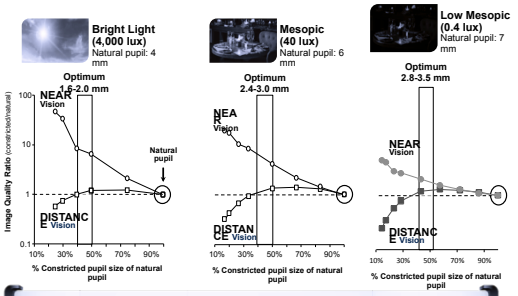
Topical Treatments

Which Patients May Be the Best Candidates for Miotic Drops?

- Emmetropes
  - Least comfortable with vision correction surgery
- Post-LASIK emmetropes
  - Have already made significant investment to be glasses-free
  - If LASIK was performed prior to wavefront-guided procedures and aspheric optical zones, pupil constricting drops may also help to address higher order aberrations, glare and halo
- Hyperopes
  - Will improve vision at distance and near
- Pseudophakes
  - Monofocal IOL patients may opt to use drops instead of readers
  - Premium IOL patients may want additional near vision than their IOL provided

Contraindications

- High myopes
- Past history of retinal tears



All figures adapted from 1. Xu R, et al. *Optom Vis Sci*. 2016;93:1409-1419.

Cataract Surgery

- The present
- The future

Advantages of Dropless Cataract Surgery

- Compliance
- Convenience
- Cost

Disadvantages?

General Risks of Dropless

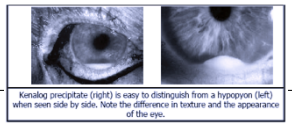
- Antibiotic Clearance
  - AB clearance in AC = 4 hrs
  - AB clearance in VH = 12 Hrs
    - Lyer & Colleagues
- Retinal Ocular Toxicity
  - Concentration well tolerated, but must be formulated properly
- Future Standard of Care??

Intra-operative Risks of Trimox

- Zonular Damage
- Bleeding
- Capsular Rupture
- Vitreous Manipulation
- RD
- Increased IOP/GLC
- Contraindicated in Glaucoma, Immuno-compromised.

Post-operative Concerns

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



Kenalog precipitate (right) is easy to distinguish from a hypopyon (left) when seen side by side. Note the difference in texture and the appearance of the eye.

THE END!

- THANKS!

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