

20/20 Refractive Update: Advances in Presbyopic and Corneal Procedures

COPE# 72626-PO

Walter O. Whitley, OD, MBA, FAAO

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Disclosures - Walter O. Whitley, OD, MBA, FAAO has received consulting fees, honorarium or research funding from:

- Aerie: C, L
- Alcon: C, L
- Allergan: C, L
- Astareal: C
- Azura: C
- Bausch and Lomb: C, L
- Biotissue: C, L
- Bruder: C
- Carl Zeiss Meditec: C
- CollaborativeEye – Co-Chief Medical Editor
- Dompe: Consultant
- Dry Eye Coach – Medical Editor
- EyeVance: C, L
- Glaukos: C
- Horizon: C
- J&J Vision: C, L
- Kala: C
- Mediprint Pharma: C
- Novartis: C, L
- Ocusoft: C, L
- Ocular Therapeutix: C
- Oyster Point: C
- Quidel: C
- Regener-Eyes: C
- Review of Optometry – Contributing Editor
- Science Based Health: C, L
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- Vertical Pharmaceuticals: C
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Optometric Comanagement

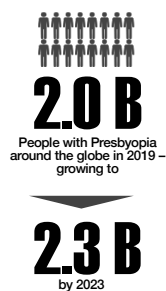
- High quality eye care
- Benefits to patient care
 - Patient comfort
 - Patient convenience
 - Efficiency
 - Cost effective
- Utilize skills and expertise of each practitioner

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Today's Optometrists

“To be on the cutting edge of optometry, you need to be on the cutting edge of science and technology.”

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PRESBYOPIA Worldwide

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

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

Source: 2019 Market Scope Estimates

Contributing Factors:

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

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Why Is This Important For Optometry?

- 4 out of 5 patients diagnosed with a cataract are done so by an optometrist
- Optometrists are the “gatekeepers” to cataract referrals and ATIOLs
- Referring O.D.'s must discuss all IOL options and educate patients about cataract and treatment options

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Patient Education

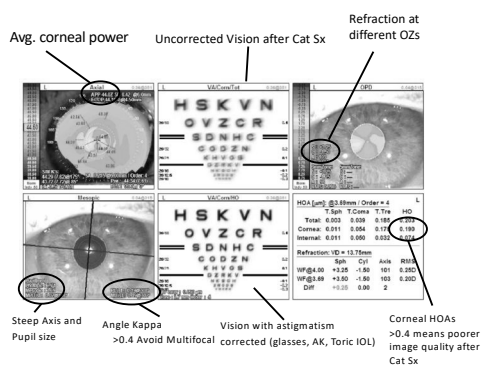
- Elements of effective education
- Explain the condition
 - Cataract
 - Astigmatism
 - Presbyopia
- Four presbyopic IOL classifications
 - Diffractive
 - Accommodating IOLs
 - Extended Depth of Focus IOLs (EDOF)
 - Trifocal

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Expect (Avoid) the Unexpected!

- Pre-op for Lifestyle IOLs
 - Topography, ocular surface testing
 - Macular OCT
 - Reliable biometry, reproducible astigmatism measurements
- Under promise and over deliver for ATIOLs
 - Emphasize need for +1.00 readers for near tasks ***
 - Discuss starbursts around lights at night

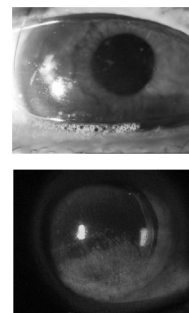
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Preparation for Ocular Surgery

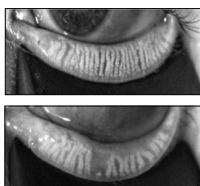
- Optimize the Ocular Surface
- Normalize the Lids
- Prepare the Cornea
- Eliminate Intra-ocular Inflammation
- Control Glaucoma
- Satisfy the Macula
- Evaluate the Retinal Periphery
- **Patient Education**



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Dry Eye Disease

- Chair time: blurred vision from cataracts versus DED
- Cataract sx can worsen DED for months after surgery
- Quality of vision may require chronic DED therapies



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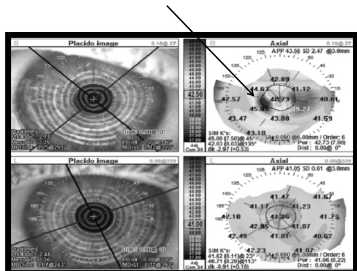
Prevalence of ocular surface dysfunction in patients presenting for cataract surgery evaluation

Results: There were 120 patients (69% women), mean age 69.5 years \pm 8.4 (SD). Abnormal oculinity was found in 68 patients (56.7%), and abnormal MMP-9 in 76 patients (63.3%). Clinical findings showed that 47 patients (39.2%) had positive corneal staining on presentation, 9 patients (7.5%) had epithelial basement membrane dystrophy, and 2 patients (1.6%) had Salzmann nodules. Questionnaire data showed 54 (54.0%) of 100 patients reported symptoms suggestive of ocular surface dysfunction. In the asymptomatic group of 46 patients, 39 (85%) had at least 1 abnormal test (smearity or MMP-9), and 22 (48%) had both tests abnormal (80%). Of the 120 patients, at least 1 abnormal test (smearity or MMP-9) of 100 patients reported symptoms suggestive of ocular surface dysfunction and 48 patients (40%) had 2 abnormal results.

J Cataract and Refractive Surgery 2018

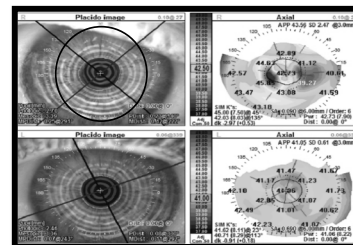
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“Hot spots” and “Flat spots” are abnormal



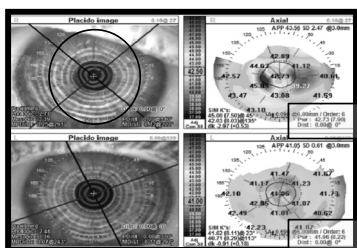
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Irregularly shaped or smudgy placido disk is abnormal!



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Take a closer look if average K values are different



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REVIEW/UPDATE

An algorithm for the preoperative diagnosis and treatment of ocular surface disorders

Christopher E. Starr, MD, Preeti K. Gupta, MD, Marjan Farid, MD, Kenneth A. Beckman, MD, Clara C. Chan, MD, FRCSC, Elizabeth Yee, MD, José A.P. Gomes, MD, PhD, Brandon D. Ayers, MD, John P. Berdahl, MD, Edward J. Holland, MD, Terry Kim, MD, Francis S. Mah, MD, the ASCRS Cornea Clinical Committee

An algorithm for the preoperative diagnosis and treatment of ocular surface disorders
Starr, Christopher E. et al.
Journal of Cataract & Refractive Surgery, Volume 45, Issue 5, 669 – 684 2019

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Premium IOLs: 5 Pearls (“P’s”) for Success

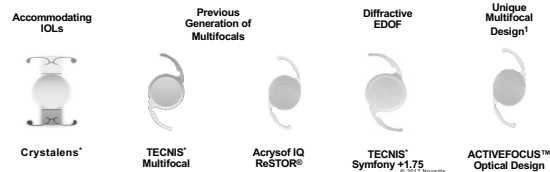
1. Plano Outcome
2. Proactive Tx of Ocular Surface Disease
3. Pre Op Counseling – Setting Realistic Expectations
4. Properly Screen Candidates
5. Pick the Right IOL

- Other:
6. Pick the Right Surgeon
 7. Posterior Capsular Opacification
 8. Poor IOL Centration

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ATIOLs Provide The Opportunity to Treat More Than Just the Cataract

What are your patient's post-op visual goals?

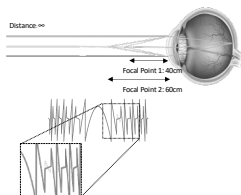


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PANOPTIX TRIFOCAL IOL

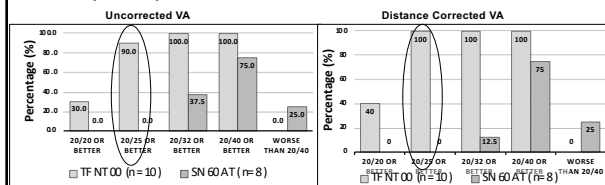
- **SUPERPOSITION OF FOCAL POINTS**
- **LIGHT REDIRECTION** - 120 cm intermediate focal point redirected to distance
- **3 FOCI** – Trifocal with 40cm, 60 cm and distance
- **88% LIGHT UTILIZATION** - at 3.0 mm pupil
- **LIGHT ALLOCATION** - 50% of available light to distance. 25% to intermediate and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



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Composite Binocular VA at all three distances
(distance, intermediate and near) at 6 month

Proportion of patients that achieved a certain binocular VA at all tested distances



FDA Clinical Results

- 91.8% within 0.50 D of target manifest refraction spherical equivalent
- Results showed that 100% of study eyes had a best corrected visual acuity of 20/40 or better at the 6 month po visit.

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What's Next in IOL Technology?

- Modular IOL Systems
- Accommodating
- Multifocal / trifocal
- Extended Depth of Focus



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Accommodating IOL – LensGen Juvene

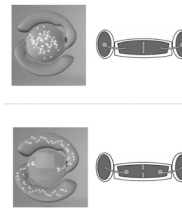


**Not FDA Approved

- Modular, curvature-changing, fluid-optic IOL
- Two-part IOL - Base and Modular
- Advantages
 - Doesn't split light
 - Up to 3D of continuous range vision
 - No change in ELP
 - No PCO up to 4 years
- Astigmatism?? Drug Delivery?? Exchangeable 2nd implant??

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Accommodating IOL – Alcon FluidVision Lens



**Not FDA Approved

- Entire lens is hollow and filled with liquid silicone
- Fluid changes changes in optic
- Avg. accommodation range 2D
- Dr. Nichamin ESCRS 2018
 - 29 eyes
 - Distance 20/20
 - Intermediate 20/20-20/25
 - Near 20/22-20/27

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Accommodative IOL – Akkolens Lumina



**Not FDA Approved

- Two piece sulcus IOL
 - Fixed and variable
 - Hydrophilic acrylate
- Shifting optics
 - Can provide 3-4 D focal range when shifted
- Dr. Alio - 59 eyes of 43 pts
 - Accommodative range of 3.1D

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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??

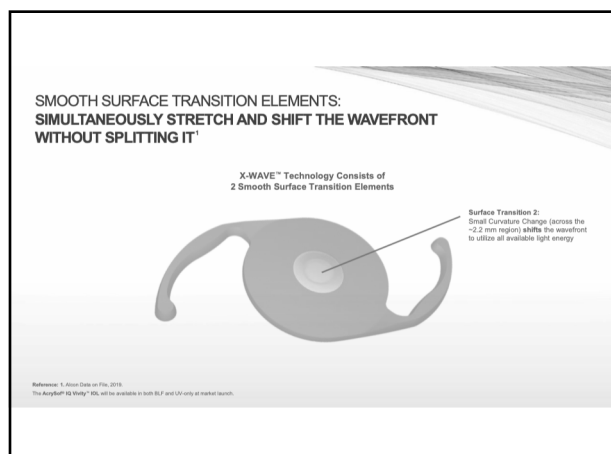


Comparison of Visual Outcomes

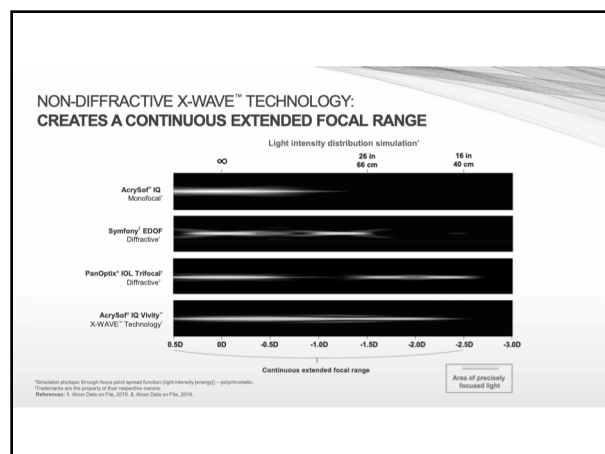
Visual Outcomes	Alcon AcrySulcus IOL			Alcon AcrySulcus IOL		
	MD	MD	MD	MD	MD	MD
Visual Quality	14.2%	11.2%	3.8%	14.4%	11.8%	3.7%
Visual Acuity	11.3%	8.3%	0.0%	8.2%	0.0%	0.0%
Visual Contrast	14.3%	8.3%	0.0%	8.3%	0.0%	0.0%
Visual Depth	1.0%	4.8%	4.8%	2.7%	8.3%	0.0%
Visual Detail	1.0%	0.0%	0.0%	0.0%	2.7%	0.0%
Visual Focus	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Visual Range	2.8%	0.0%	0.0%	0.0%	0.0%	0.0%

Source: Alio et al. J Refract Surg. 2018

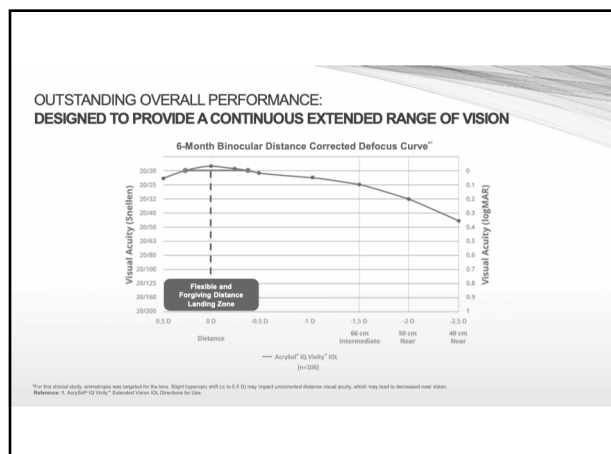
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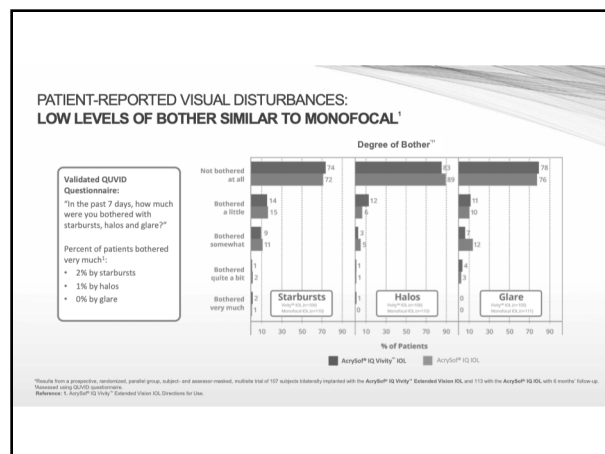
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J&J Vision – Tecnis Eyhance

- 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

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J&J Vision – Tecnis Synergy

- Gives broad range of continuous vision 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 intensity for tasks like night driving⁷



**Not FDA Approved

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Trifocal IOL - PhysIOL

- Aspheric diffractive trifocal
- 2 diffractive structures that give +3.5D add for N and +1.75D for intermediate
- Less glare and halos
- Designed to reduce the loss of light energy resulting from any diffractive system
- Diffractive anterior surface entirely convoluted
- Height of the diffractive step varied
- Distributes light to near, intermediate and distant foci adjusted according to the pupil aperture



**Not FDA Approved

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"Pinhole" IOL Design

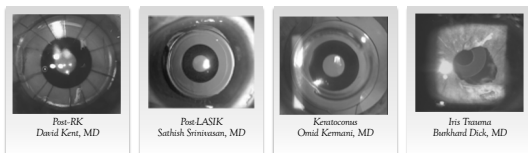
- IOL Material
 - Single-piece hydrophobic acrylic
- Mask
 - PVDF & nanoparticles of carbon
 - 1.36mm aperture
 - 3.23mm total diameter
 - 3200 microperforations
 - 5 microns thick



**Not FDA Approved

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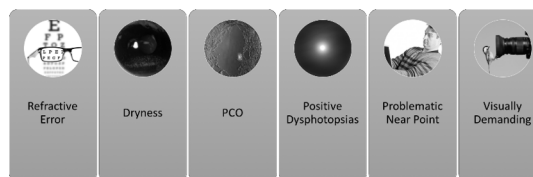
Presbyopia Correction No Longer Only for the Perfect Cornea!



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20/Unhappy

Causes of unhappiness



Woodward MA, Randleman JB, Stulting RD. Dissatisfaction after multifocal intraocular lens implantation. *Journal of cataract and refractive surgery*. 2009;35(8):992-997. doi:10.1016/j.jcrs.2009.01.031.

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Neuroadaptation of Multifocal IOLS

- Patients' expectations of time frame needed to adapt needs to be managed
 - These patients require more counseling post-op
 - Neuroadaptation can take as long as 6-12 months
 - About 10% never neuroadapt (will need IOL exchange)
 - No way of testing before surgery which patients will be able to adapt vs not
- Multifocal IOLS will induce more aberrations than monofocal IOLS

Take away: no YLC to be performed until rule out that IOL exchange is necessary

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Refractive Enhancement: Laser Vision Correction (LVC)

- **Timing is everything!**
- Wait at least 2-3 months after cataract surgery for wounds and LRIs to settle
- Nd:YAG posterior capsulotomy **BEFORE** LVC
 - **No YAG in multifocal IOL that was never happy**



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Managing the Unexpected Outcome: Have an Algorithm to Identify the Issue

- Develop communication with your staff regarding dissatisfied patients
 - Encourage clinic techs to communicate patient satisfaction to you
 - Have work-up done before you see the patient
 - MRx BCVA/Topo/OCT/Ocular surface testing
 - Have a plan to fix the problem before you enter the room!

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KAMRA® Inlay

First US approved corneal inlay; commercially available in 50 countries

Effective, Reliable and Safe Presbyopia Solution



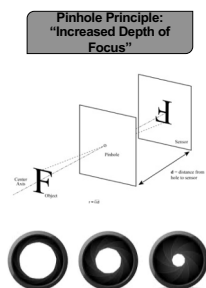
- ✓ Improves near vision with minimal impact to distance vision
 - Achieves long-lasting results even as presbyopia progresses
- ✓ Implanted into corneal pocket created with femtosecond laser
 - Implanted monocularly into non-dominant eye
- ✓ Highly biocompatible material
 - Made from Polyvinylidene Fluoride (PVDF)
- ✓ Removable via low-risk procedure with recovery of pre-inlay vision

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How It Works

- The inlay works like an aperture in a camera (opening)
- This small opening allows only focused images in the eye
- Only focused light rays to reach the retina
- Same principle used in camera lenses to increase depth-of-focus



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Indications for Use

- Patient who is between 45 and 60 years old
- Cycloplegic refraction between +0.50 D and -0.75 D with less than or equal to 0.75 D of refractive cylinder
- Patient does not require glasses or contact lenses for clear distance vision
- Patient requires near correction of +1.00 D to +2.50 D of reading add

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Inlay Patient- Exclusion Criteria

- Any ocular or systemic disease that is a contraindication for corneal refractive procedures including:
 - Keratoconus
 - Uncontrolled and/or severe dry eye
 - Cataracts
 - Macular degeneration
 - Corneal dystrophy or degeneration
 - Amblyopia or Strabismus
- Patients with unrealistic expectations
- Patients with psychological conditions

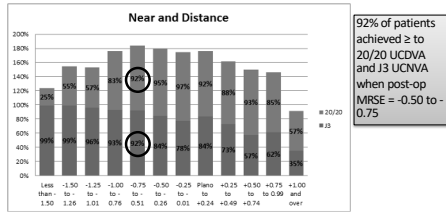
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Post-op Exam

- Minimum follow-up:
 - 1 day
 - 1 week
 - 1, 3, 6 months
 - 1 year
- Patients should be **seen more frequently** if abnormal post-op findings are observed

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Effectiveness of Post-op MRSE



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Pharmacologic Treatments for Presbyopia Are Coming, With Miotic Drops Occupying the Majority of Development

Topical Drops in Development	Active Ingredient(s)	Mechanism of Action
Viewpoint Therapeutics	Viewpoint Therapeutics	Viewpoint Therapeutics
CSF-1 (Orasis)	Pilocarpine	Miotic
Pro-Drop (Viewpoint Therapeutics)	Pilocarpine	Miotic
AGN 190584 (Allergan)	Pilocarpine	Miotic
AcuStream™ (Kedallion)	Pilocarpine	Miotic
Viewpoint Therapeutics	Viewpoint Therapeutics	Viewpoint Therapeutics
True Vision Treatment™ Contact lenses and Eye Drops Kit (Volia Health)	Hyaluronidase and collagenase	Alters cornea ²
Viewpoint Therapeutics	Viewpoint Therapeutics	Viewpoint Therapeutics
VP1-001 (Viewpoint Therapeutics)	Stabilizing alpha-crystallin molecule	Target's protein misfolding to restore native, functional shape ³

► Miotic drops increase depth of field by inducing a pinhole effect

- Low risk, highly effective and easily reversible compared to surgical alternatives
- Miotic drops aren't without side effects - headache, brow ache, IOP fluctuations, myopic shift and hyperemia^{4,5}
- Single-agent cholinergic miotics likely to have more of an issue with these side effects than combination drops

► Lens softening topical agents intend to increase ability to accommodate with usage over time

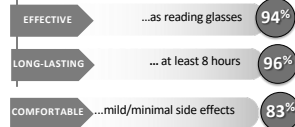
1. Burke Healthcare Research April 2020, n = 1,000 presbyopes ages 40-80 years old.
2. Burke Healthcare Research April 2020, n = 1,000 presbyopes ages 40-80 years old.
3. Viewpoint Therapeutics April 2020, n = 1,000 presbyopes ages 40-80 years old.
4. Viewpoint Therapeutics April 2020, n = 1,000 presbyopes ages 40-80 years old.
5. Viewpoint Therapeutics April 2020, n = 1,000 presbyopes ages 40-80 years old.

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Patients Looking for Efficacy, Durability and Favorable Side Effect Profile

Thinking about the features of this potential new eye drop medication, which features are most appealing to you?

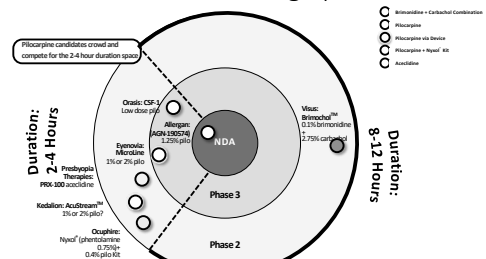
- Efficacy** – restore functional near vision as well as current solution (glasses/contacts)
- Duration** – lasting throughout a work day (minimum)
- Side Effect Profile & Tolerability** – minimal brow ache/headache, minimal burning/stinging
- Cosmesis** – eyes should be white and quiet



Burke Healthcare Research April 2020, n = 1,000 presbyopes ages 40-80 years old

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U.S. Presbyopia Miotic Drop Landscape is Crowded in the Short-acting Space



1. Viewpoint Therapeutics, January 2021. 2. Viewpoint Therapeutics, January 2021. 3. Viewpoint Therapeutics, January 2021. 4. Viewpoint Therapeutics, January 2021. 5. Viewpoint Therapeutics, January 2021.

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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

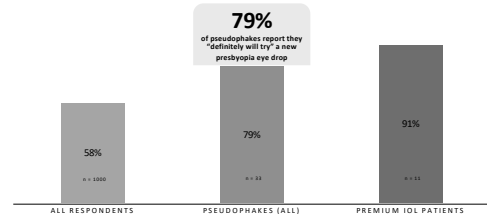
- High myopes
- Past history of retinal tears

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Pseudophakes Very Interested in Trying a Presbyopia Drop – a Highly Motivated Patient Segment

If your eye doctor recommended it, how likely would you be to try this new eye drop to temporarily restore your near vision?

% OF PSEUDOPHAKES IN COMPARISON TO ALL RESPONDENTS WHO RESPONDED "DEFINITELY WILL TRY"



Burke Healthcare Research April 2020, n = 1,000 presbyopes ages 40-80 years old

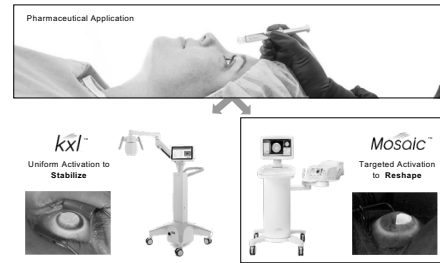
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What Do We Know about the Topical Presbyopia Market?

- The unmet need for a topical drop to improve near vision is significant
- Duration of action Side effect profiles
- Tolerability– Does it burn and sting?
- Cosmesis (Hyperemia) vs. Near vision
- OSD considerations

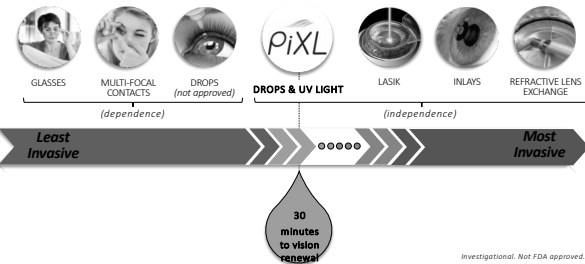
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Avedro's Approach: Non-invasively Stabilizing and Reshaping the Cornea Corneal Remodeling Technology



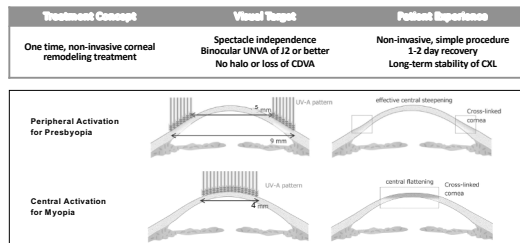
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Corneal remodeling for non-invasive reshaping the cornea without ablation or incision



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PiXL for Vision Improvement Non-invasive corneal remodeling

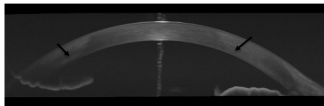


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PIXL for Presbyopia

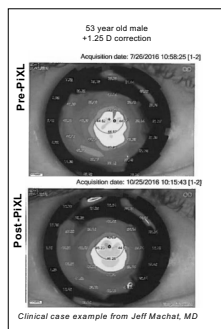
Spatially targeted, epithelium-on, accelerated cross-linking

More than 200 eyes treated internationally with PiXL to date



- Midperipheral cross-linking, no UVA applied to central cornea
- Image above: High resolution OCT image showing mid peripheral corneal stromal demarcation line after epi-ON PiXL with oxygen

Investigational. Not FDA approved.



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- A potential non-invasive solution for presbyopia

- Filling a gap in refractive treatment options

- Drops, UV light and O₂

- Targeted corneal reshaping with long-term durability of cross-linking

- Likely advantageous for post operative cornea adjustability

- Early clinical results are promising

- Multicenter Phase II Study in 2019

PiXL

Mosaic System
Proprietary computer software and UVA beam forming technology



Boost Goggles



New Drug Formulations

Proprietary single-use drug formulations

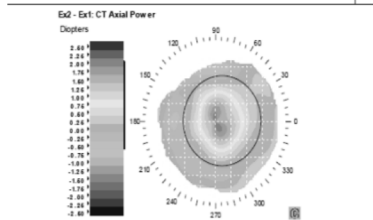


Investigational. Not FDA approved.

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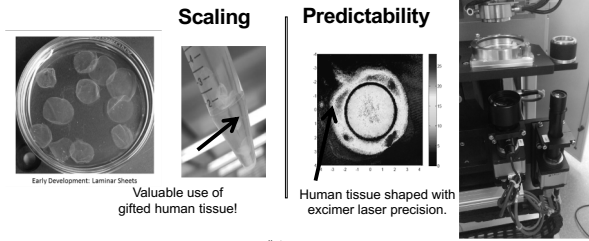
Allogenic Corneal Inlay (Allotex) PEARL: PrEsbyopic Allogenic Refractive Lenticule

- Increasing central corneal power to improve near vision



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Excimer laser shaped corneal inlays



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European Multicenter Study: Interim data analysis (20 eyes)

	Preoperative	Post-op (last visit)
UCNVA of 20/40 or better (monocular)	0%	95%
Near Vision (binocular)	Gain: +17 letters (mean)	
Intermediate Vision (binocular)	Unchanged: +2 letters (mean)	
Distance Vision (binocular)	Unchanged: -2 letters (mean)	

*** last visit was 1 or 3 months after surgery

c/o Aylin Kylic, MD

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The LIRIC Platform: Laser Induced Refractive Index Change for Refractive Error Correction

LIRIC: a *disruptive technology*

Poised to revolutionize:

- refractive surgery
- cataract surgery
- contact lenses

A revolutionary way to refine the optics of the eye



- Minimally invasive
- No flap, epi on, no doping
- No nerve damage
- Post-implantation optical touch-up
- Monofocal to multifocal & vice-versa
- Correct residual refractive error
- Enables diffractive multifocals for better presbyopia correction
- Thin lenses for all prescriptions
- Better oxygen transmissibility

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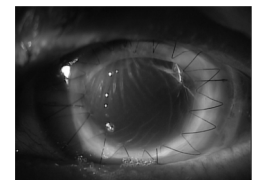
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Updates on Modern Day Corneal Surgery

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Common Corneal Procedures

- Corneal crosslinking
- Penetrating keratoplasty
- Descemet's stripping endothelial keratoplasty
- Pterygium surgery
- Superficial keratectomy



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Watch Out for Keratoconus!

8 Potential Signs & Symptoms

Typically onset occurs in teenage years or early twenties



- **Look out for warning signs in medical history**
 - History of eye rubbing
 - Family & genetic predispositions
- **Look out for visual complaints**
 - Blurred vision
 - Distortion of images
- **Look out for refractive anomalies**
 - Distortion of mires on keratometry
 - Error messages on autorefractors
 - Unsatisfactory attempts at vision correction & progressive loss of UCVA & BCVA
 - Increasing astigmatism

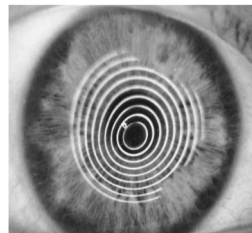
67

Diagnostic Imaging

- Irregular Placido (egg-shaped) Topography

Early signs of keratoconus may include

- *Skewed radial axis of astigmatism*
- *Asymmetric or truncated bow-tie*

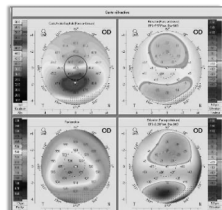


¹ Y.S. Rubinowitz. Keratoconus. Survey of Ophthalmology Vol 42, Num 4, Jan-Feb 1998.

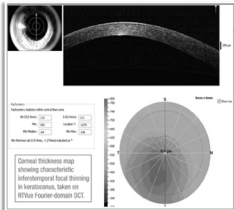
68

Diagnostic Imaging

Irregular Topography/Tomography



Focal thinning on OCTs¹



Additional signs of keratoconus may include

- Astigmatism variance between eyes
- Stromal and epithelial thickness changes
- Posterior elevation changes
- Wavefront aberrations
- Topographic changes
 - Inferior steepening
 - Irregularity indices

¹ <https://www.reviewofophthalmology.com/article/making-the-most-of-anterior-segment-oct>.

69

Corneal Crosslinking

- UV light and photosensitizer to strengthen chemical bonds in the cornea
 - Oxidative deamination reaction with ends chains of collagen
- FDA Approved in the US 2016
 - Epi-off
- Indicated to help slow progression of:
 - Keratoconus
 - PMD
 - Terrien Marginal Degeneration
 - Post-refractive surgery ectasia

70

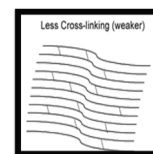
Contraindications

- Corneal thickness <400um (epi off)
- Prior herpetic infection
- Concurrent infection
- Severe corneal scarring or opacification
- History of poor epithelial wound healing
- Severe ocular surface disease
- Autoimmune disorders

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Mechanism of Action

- Corneal collagen cross-linking combines the use of **ultra-violet (UV) light** and **riboflavin (vitamin B2) drops**
- The absorption of UVA by riboflavin generates radical riboflavin and singlet oxygen to form cross-links¹
- **Corneal Cross-Linking:**
 - Creates new corneal collagen cross-links
 - Results in a shortening and thickening of the collagen fibrils
 - Leads to the stiffening of the cornea²

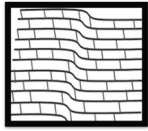


¹ Karaman P, Friedman MD, Shen E, Muller D. Photochemical kinetics of corneal cross-linking with riboflavin. Invest Ophthalmol Vis Sci. 2012;53:2860-7.

² Reiche JA, O'Donnell C, Nathankrishnan H. Biomechanical properties of corneal tissue after ultraviolet-A/riboflavin crosslinking. J Cataract Refract Surg. 2003;29(4):603-612.

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Keys to Patient Counseling: Discuss Treatment Goals



Aim of CXL is to halt or slow disease progression



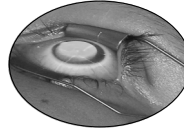
Cross-Linking is not a refractive procedure



Post-op evaluation for visual correction will be necessary

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Follow-up Care Landmarks



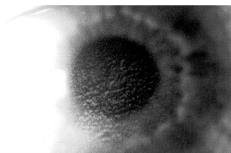
Due to Zero Global period, those may be billable to insurance for follow up when medically indicated

VISIT	PLAN
Day 1 to 1 Week	Topical antibiotic, steroid Frequent lubricants No eye rubbing Remove BCL once epithelium heals
Month 1	OCT Imaging Tomography/Topography Vision assessment Contact lens refitting evaluation
Month 3, 6, 12 (Follow ups potentially performed and billed by diagnosing physician depending on practice preference)	Continued evaluation utilizing tomography/topography Vision assessment

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CXL Complications

- Endothelial cell damage
 - <400um thickness
- Persistent epithelial defects (epi off)
 - Mechanical, CL preservatives, topical medication
 - Haze
- Scarring
- Infectious keratitis
 - Fungi, bacteria, HSV,
 - Acanthamoeba
 - HSV vs UV light



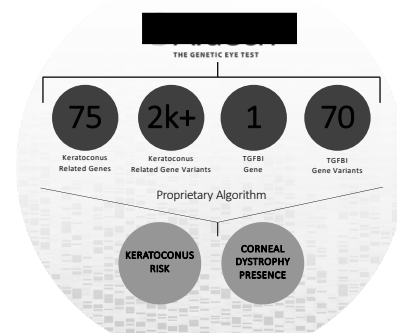
75

Long-term maintenance

- Close monitoring immediately after CXL
 - Every 3 months with pachymetry, MRX and corneal topography
 - Then decrease to yearly to monitor for any progression
- Counseling patient that mechanical rubbing of the eye can cause it to progress
 - Treat allergies
 - Treat DED
 - Treat Blepharitis/MGD

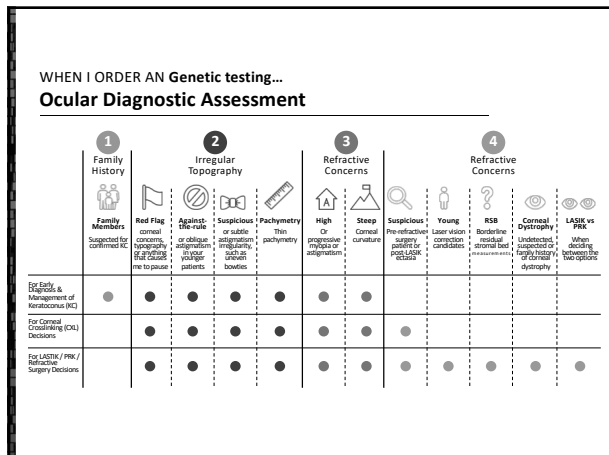
76

GENETIC DATA CAN HELP US...

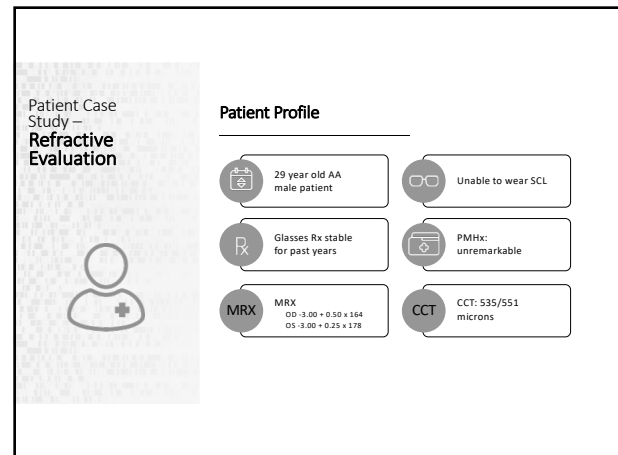


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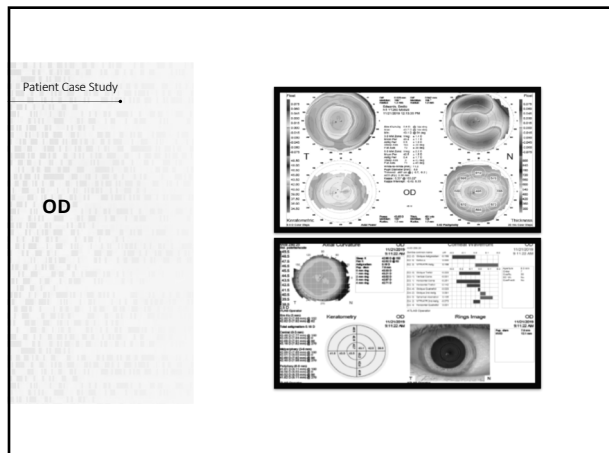
78



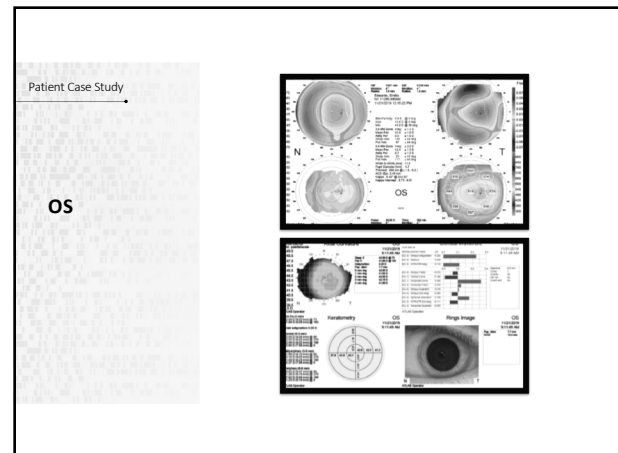
79



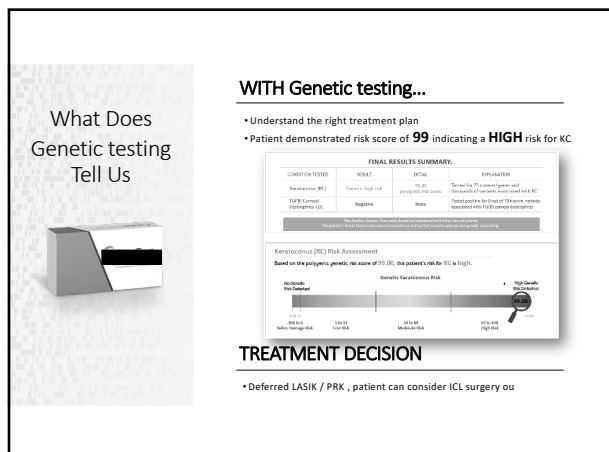
80



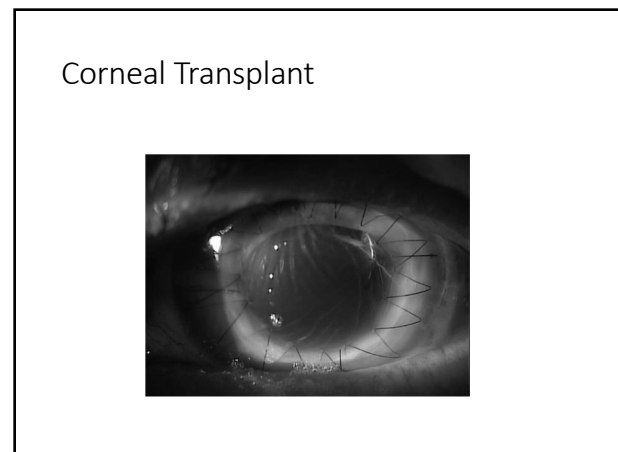
81



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84

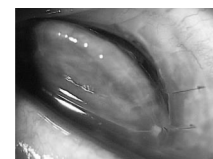
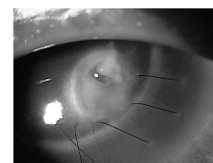
What to expect PK

- Day 1
 - Moderate to severe stromal/corneal edema
 - AC 1-2+ cell and pigment
 - Poor vision and pain
- Week 1
 - Moderate corneal edema may still be present
 - Vision is improved but still moderately decreased
 - AC some inflammation present (tr-1+ cell)
- Month 1
 - Most corneal edema should be resolved at this time
 - Refraction/Pachymetry/Atlas to monitor
 - AC is quiet
- Month 6
 - Stabilization
 - Select suture removal to decrease induced astigmatism

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Complications of Penetrating Keratoplasty

- Long-term complications
 - Glaucoma
 - Microbial keratitis
 - Suture-related problems
 - Wound dehiscence
 - Immunologic graft rejection
 - Late endothelial failure
 - Graft failure
- Refractive error, astigmatism



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Long-term maintenance

- Long term topical steroid to decrease rejection rate
- Some patients may require oral antivirals if corneal transplant is related to scarring from prior HSV
- Repeat PK may be needed after approximately 20 years

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Descemet's Stripping Endothelial Keratoplasty (DSEK)

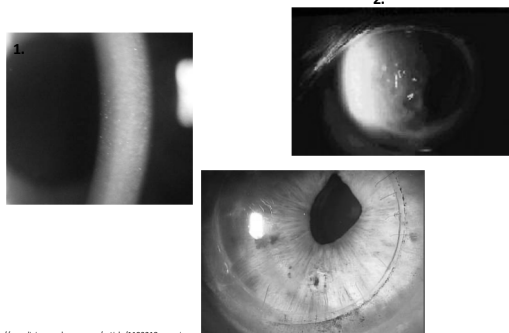
- Sutureless transplant of the posterior cornea
- Replaces diseased portion of cornea with donor graft
- Donor tissue obtained by
 - Manual dissection
 - Microkeratome dissection
 - Femtosecond laser



1. Photos accessed from <http://www.moria-surgical.com/> on 8/26/11
 2. Photos accessed from <http://www.alcon.com/en/alcon-products/refractive-surgery.aspx>

88

Indications

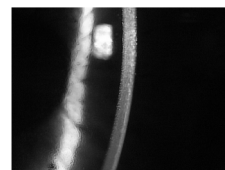


1. <http://emedicine.medscape.com/article/2193218-overview>
 2. <http://webeye.ophth.uiowa.edu/eyeforum/cases/case5.htm>

89

DSEK/DSAEK Exclusion Criteria

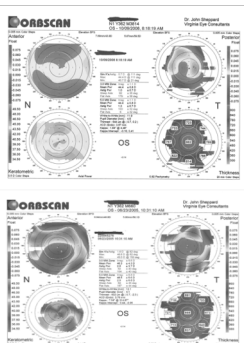
- Exclusion
 - Corneal scarring
 - Aphakic
 - Iris loss / atrophy



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Advantages of DSEK/DMEK vs. PK

- Sutures
- Visual recovery
- Astigmatism / ametropia
- Epithelial complications
- Corneal allograft rejection
- Wound strength
- Globe stability
- Length of surgery
- Intraoperative complications
- Post op visits



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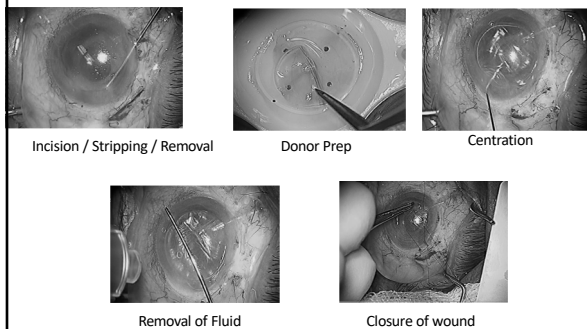
DSEK, PK Yield Similar Graft Survival

Price et al. Ophthalmology. 2011;118(4):725-729

- Retrospective, interventional case series
- DSEK graft survival rates
 - 95% for Fuchs
 - 76% for PBK/ABK
- PK graft survival rates
 - 93% for Fuchs
 - 73% for PBK/ABK
- Endothelial cell loss at 5 years
 - 53% in DSEK
 - 70% in PK

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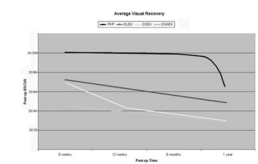
DSEK Procedure



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DSEK Average Visual Recovery

- 1 Day: 20/400
- 1 Week: 20/70
- 1 Month: 20/40
- 3 Months: 20/30
- 6 Months: 20/25
- 1 Year: 20/25-20/20



Dr. Garavito Study - Results presented during the AAO 2006 - Las Vegas

Terry and Shamie. Endothelial Keratoplasty. Retrieved from <http://www.disek-dsk.com/disekprocedure.htm> on 5/20/08.

94

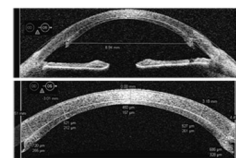
DMEK

- Graft of Descemet's membrane and endothelium only
- Better optical outcome of 20/25 or 20/20
- Difficult to manipulate
- Early graft dislocation risk
- Decreased risk of rejection

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DSEK/DMEK Complications

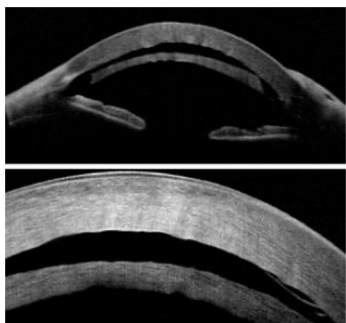
- Caused by any of the following
 - Graft-recipient interface
 - Fragile graft tissue
 - Graft location
 - Glaucoma
 - Infection
 - CME
 - Retinal detachment



Miller, J. Accessed from <http://www.revoptom.com/content/d/technology/c/16179/>

96

DSEK Gone Wrong



97

Long-term Maintenance DMEK and DSEK

- Long term topical steroid
 - Helps decrease rejection rate
 - Steroid Lotoprednol, prednisolone acetate, FML 1 gtt QD typically
- Unknown length of graft viability
 - No long term data since started approx 2003
 - In theory surpass PK ~20 years
- 5 year Graft survival similar at 93%¹

1. Price DA, Kelley M, Price FW Jr, Price MD. Five-Year Graft Survival of Descemet Membrane Endothelial Keratoplasty (EK) versus Descemet Stripping EK and the Effect of Donor Sex Matching. Ophthalmology. 2018 Dec;125(10):1508-1514. doi: 10.1016/j.ophtha.2018.03.050. Epub 2018 May 9. PMID: 29731147.

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Limbal Stem Cell Deficiency

- When limbal stem cells begin to struggle and poorly function, the epithelial cell layer and its reproduction becomes compromised
- Loss or deficiency of stem cells in the limbus which are vital for re-population of the corneal epithelium and to the barrier function of the limbus
- Once limbal stem cells are damaged the epithelium will be replaced by conjunctival goblet cells

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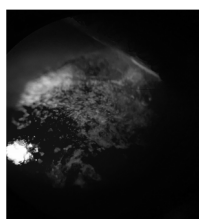
LSCD Causes

- | | |
|--|--|
| <ul style="list-style-type: none"> • Acquired <ul style="list-style-type: none"> • Trauma • Contact lenses • Inflammatory <ul style="list-style-type: none"> • DED • Allergy • Neurotrophic keratopathy | <ul style="list-style-type: none"> • Autoimmune <ul style="list-style-type: none"> • Sjogrens Syndrome • Stevens Johnson syndrome • Mucous membrane pemphigoid • Congenital <ul style="list-style-type: none"> • Aniridia • Autoimmune Polyglandular Syndrome • Keratitis, Ichthyosis, and Deafness Syndrome |
|--|--|

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Signs and Symptoms

- Varying degree of ocular signs depending on severity and level of corneal conjunctivalization
- Symptoms
 - Decreased vision
 - Photophobia
 - Tearing
 - Blepharospasm
 - Recurrent pain



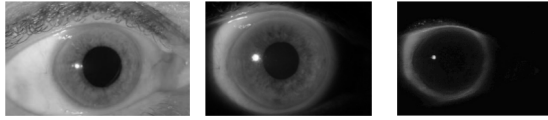
101

Severe LSCD

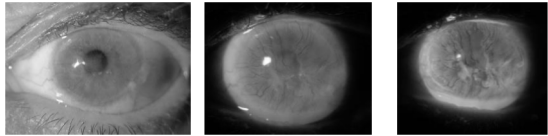
- Conjunctivalization
 - Corneal surface stains abnormally because the conjunctival epithelium is more permeable to the stain than true corneal epithelium
- More prone to recurrent or non-healing epithelial defects
- Stromal scarring or melting
 - Expect more pain and vision loss

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NORMAL EYE

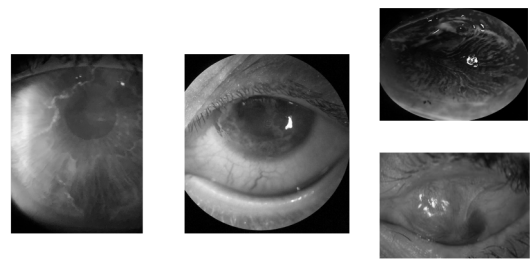


TOTAL LSCD



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Conjunctivalization



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Non-Surgical Treatment

- Remove traumatic or toxic insults that may be the cause
- Discontinue contact lens wear
 - Possible refit in scleral
 - Bandage CL?
- Discontinue or switch topical medications
 - Glaucoma medications
 - Preservative sensitivity

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Non-Surgical Treatment

- Treating underlying systemic causes
 - Autoimmune control
- Improve tear film and control inflammation
 - Vitamin A ointment QHS
 - Topical steroids
 - Compounded Preservative Free option
 - Topical cyclosporine
 - Preservative free AT
 - Punctal Plugs

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Non-Surgical Treatment

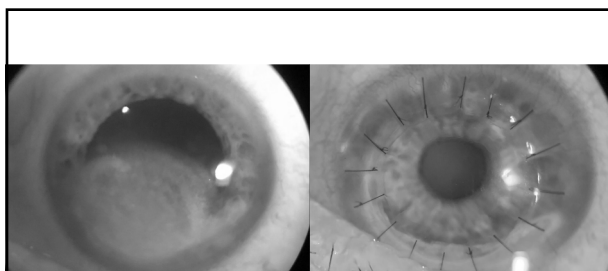
- Amniotic membrane
 - Dehydrated vs cryopreserved
- Amniotic membrane drops
 - Can be costly and not covered by insurance currently
- Serum Tears
 - Can be costly and inconvenient
- Cenegermin
 - Neurotrophic keratitis

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DALK (deep anterior lamellar keratoplasty)

Corneal transplantation techniques:	
	1. PK: All corneal layers are transplanted.
	2. DALK: Only the superior corneal layers are transplanted.
	3. DMEK: Only the deep corneal layers are transplanted.

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Pre/Post Example of Big Bubble DALK

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Post-Operative Care

- Moxifloxacin QID OD x 1 week and Difluprednate starting at QID OD and tapered down to Loteprednol QHS OD for maintenance
- Several corneal sutures removed after 6-9 months
- Cataract extraction OD
- Final BCVA 20/25 OD

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Pterygium

- “wing” like ocular surface lesion originating from limbal conjunctiva within the palpebral fissure progressing to the cornea
 - Nasal and temporal
- More common in people with history of increased UV exposure
 - Males > females
- Typically asymptomatic
 - Induced astigmatism

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Treatment

- Non Surgical
 - Treat the ocular inflammatory response
 - Cyclosporin
 - Lifitegrast
 - Topical steroids
 - Artificial tears
- Surgical
 - Encroaching on visual axis
 - Preparing for cataract surgery
 - Significant induced astigmatism

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What to expect after Sx

- Day 1
 - Epithelial defect
 - Conjunctival injection, check wound site
- Week 1
 - Epithelial defect healed with haze
 - Conjunctiva check for secure wound site
 - Monitor for wound dehiscence
- Month 1
 - Haze resolution
 - Conjunctival stabilization

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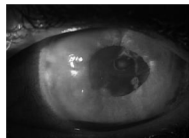
Long term treatment

- Control UV exposure
- Control dryness and inflammation
 - Cyclosporine
 - Lifitegrast
 - Artificial tears
 - Topical steroids
 - Punctal plugs
- Will help to control reoccurrence

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Lamellar keratoplasty

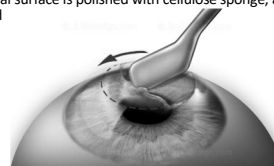
- Indications:
 - ABMD
 - Salzmanns
 - Band Keratopathy
 - RCE
 - Corneal scars



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Lamellar Keratoplasty

- Corneal epithelium is removed down to Bowman's layer
- Can be performed in slit lamp or operating room using Weck-cel sponge or scarifier blade, and cleaned up with diamond burr
 - After removal surface is polished with cellulose sponge, antibiotics, and THBL placed



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Long Term Treatment

- After lam K for RCE
 - Maintain THBL for 3 months
 - Oral Doxycycline
 - Topical Antibiotics
 - Topical Steroids
 - Vitamin C
- Control of ocular surface disease

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Comanagement Pearls

- Opportunity to provide cutting edge technology
- Importance of your recommendation
- Patient education is critical!

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Comanagement Pearls

- Identify potential causes of surgical complications
- Educate your patients your role within medical eye care
- *We are all judged by the visual outcomes our patients. Comfort and quality of vision is the key!*

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Thank you!!

Questions?

jkjohnston@yahoo.com
wwhitley@cvphealth.com

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