



Does Insurance Cover Corneal Crosslinking?

Paul Casey, M. D.

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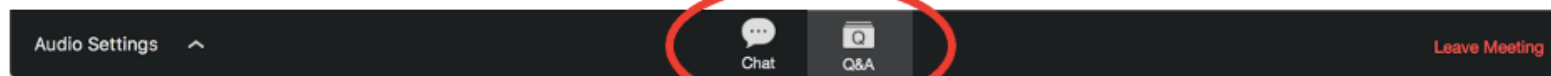
Host: Dr. Stephanie Woo

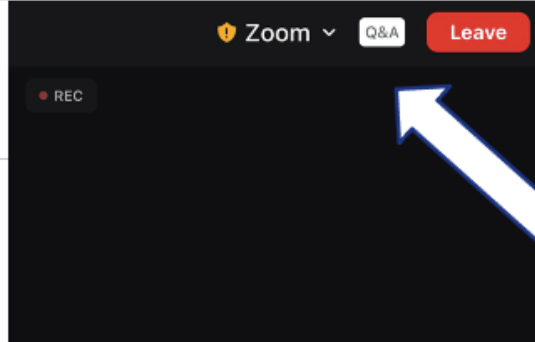


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- CE certificates will be delivered by email and sent to ARBO with OE tracker numbers
- **CE certificates will be emailed within 4 weeks**
- Ask questions using the zoom on-screen floating panel





Opportunity to Partner

Optometrists are at the frontline to recommend treatment for cataract and glaucoma patients.



Established relationships with patients

- Ability to inform patients of the best technologies available
- Needs, wants, expectations, and lifestyle



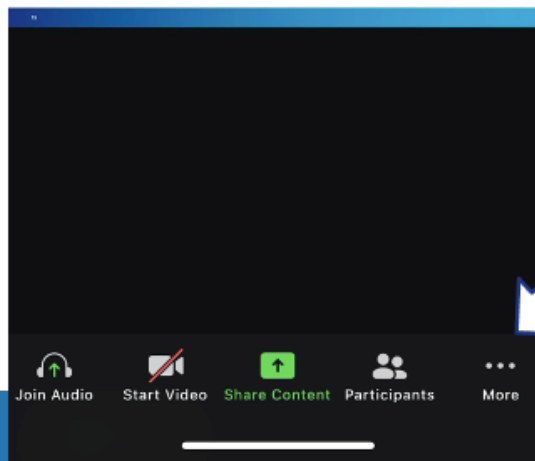
Reduce patient and physician burden

- Concomitant visits and prior authorizations
- Coarse surface disease and potential effects on visual acuity



Ability to impact patients' post-operative lifestyle

- ONE TIME opportunity during cataract surgery to address a patient's cataract, refractive needs (cataracts and presbyopia) as well as their glaucoma



Speaker Bio – Dr. Paul Casey

After receiving his medical degree from the University of Miami School of Medicine, Dr. Casey went on active duty with the United States Air Force. He completed his internship at David Grant Medical Center and his residency at Wilford Hall Medical Center. After serving as the Chief of Ophthalmology at RAF Lakenheath, England, and Michael O'Callaghan Federal Hospital at Nellis AFB, NV, Dr. Casey joined Nevada Eye Care.



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Paul Casey, MD – no financial interests

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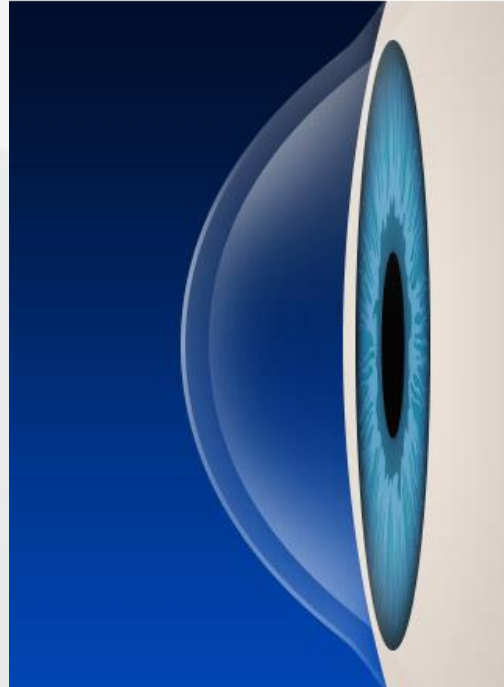
Outline

- 1) Brief Review of Keratoconus and Collagen Crosslinking
- 2) FDA Trial: Inclusion, Exclusion and Results
- 3) What is FDA approved (and billable to insurance)
- 4) What is not FDA approved (and not billable)
- 5) Clinical Guideline examples
- 6) Questions

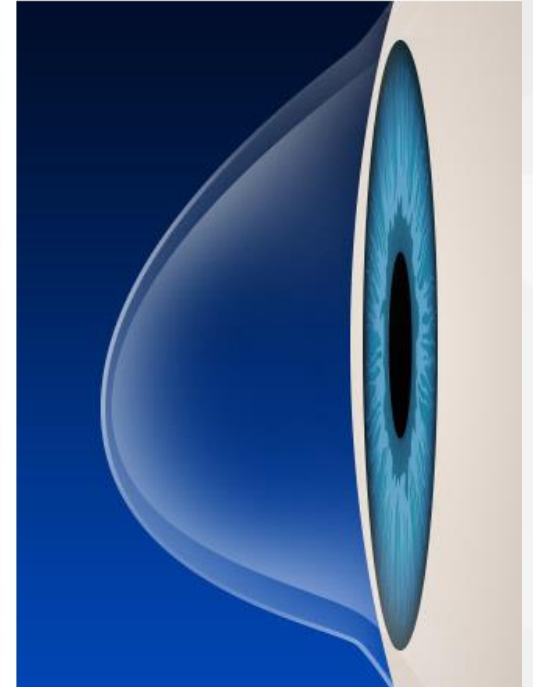
What is Keratoconus?

- Genetic Disease
- Cornea
- Clear window
- Front of the eye
- Weak Collagen
- Bulging
- Blurry Vision
- Progressive
- Worsens over time

Normal cornea

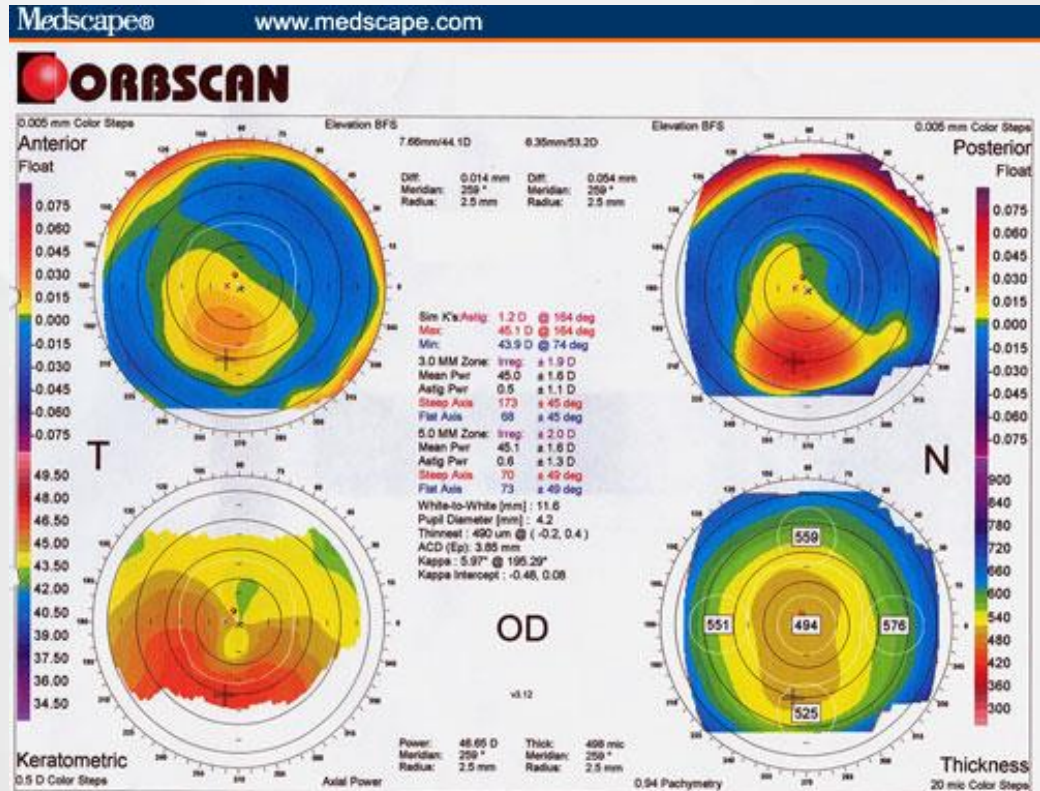


Keratoconus



How Do You Diagnose Keratoconus?

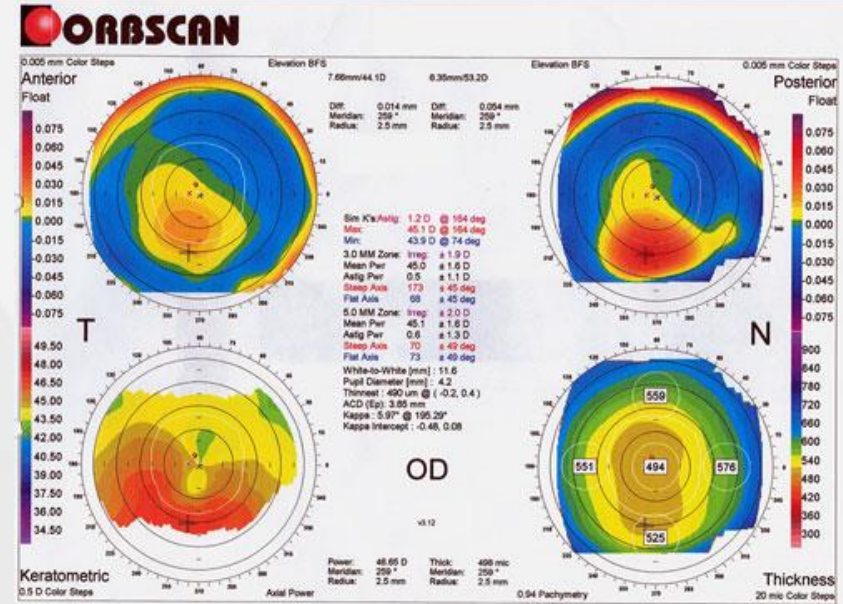
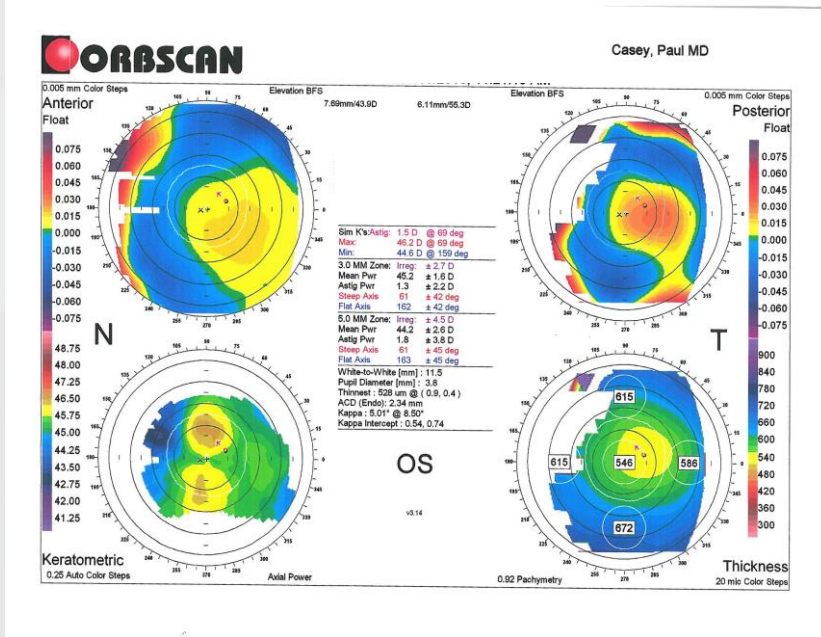
- Blurry vision
- Nearsighted
- Astigmatism
- Can't see 20/20
- Family History
- LASIK screening
- Corneal map
- Thinning
- Steepening



Normal vs. Abnormal

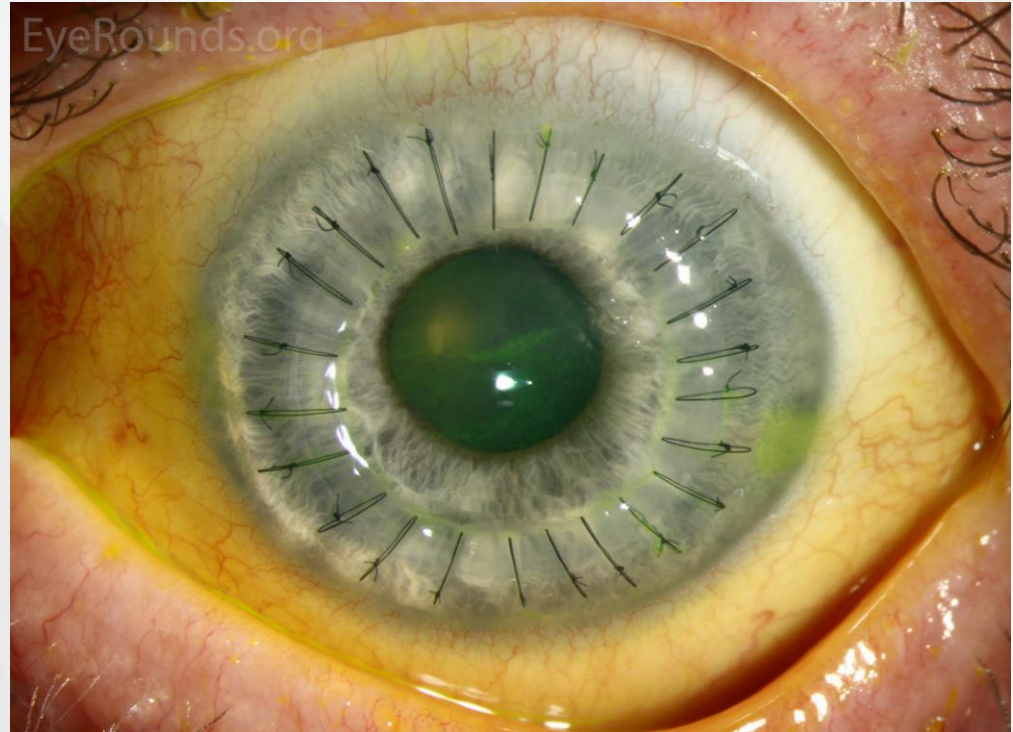
Normal

Abnormal



How Do You Treat Keratoconus?

- Historically
- Glasses
- Hard Contact Lenses
 - Corneal RGPs
 - Hybrids
 - Sclerals
- Corneal Transplant
 - Major Operation
 - Complications



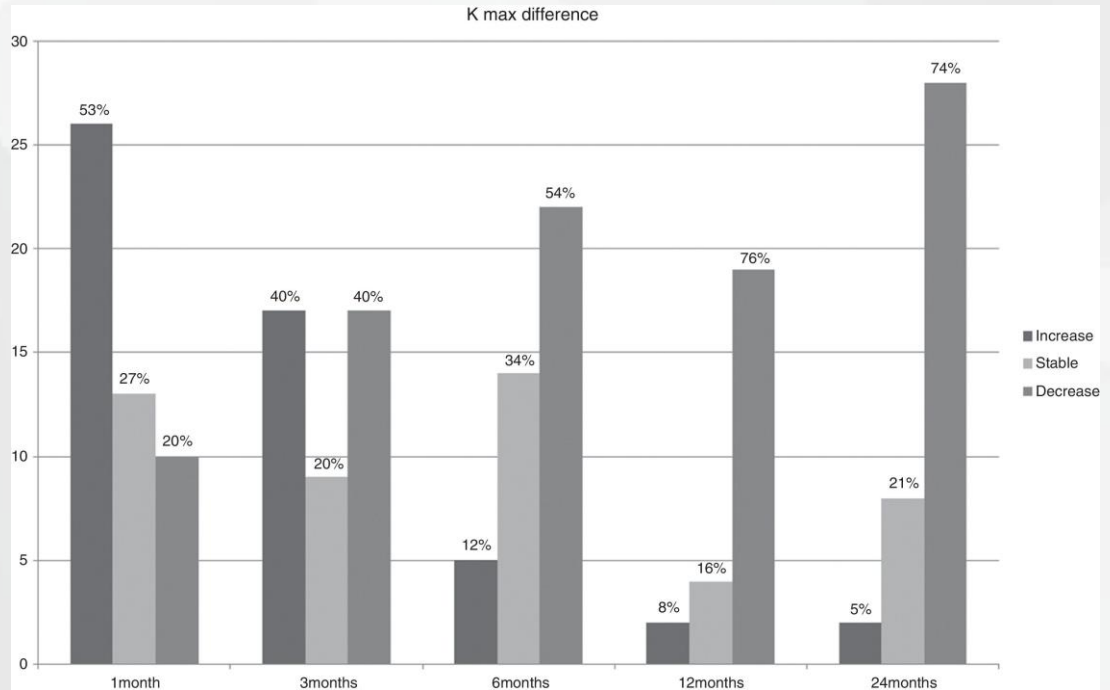
What is Collagen Crosslinking (CXL)?

- Treatment
- FDA Approved
- Safe
- Effective
- Stops Progression
- Stabilizes
- Corneal Transplant
- Reduced 7-fold



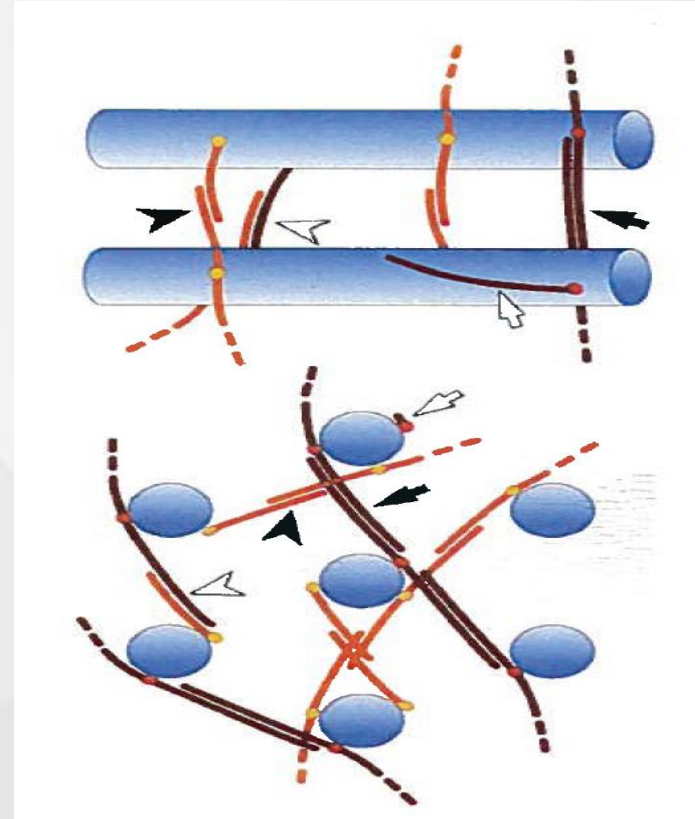
Is CXL new?

- NO!
- 20 years
- Worldwide
- Dresden
- Clinical trials
- Late 1990s
- Hundreds of studies
- Show benefit of CXL



How does CXL work?

- Combination
- Riboflavin = Vitamin B2
- UV-A light
- Chemical reaction
- Collagen – Collagen bonds
- Increased rigidity
- Stronger
- Stops progression



How do you do CXL?

- In office
- Numbing drops
- Oral sedative
- Laying down
- Surgeon removes surface cells
- Place drops in eye
- Shine light in the eye
- Place a contact lens



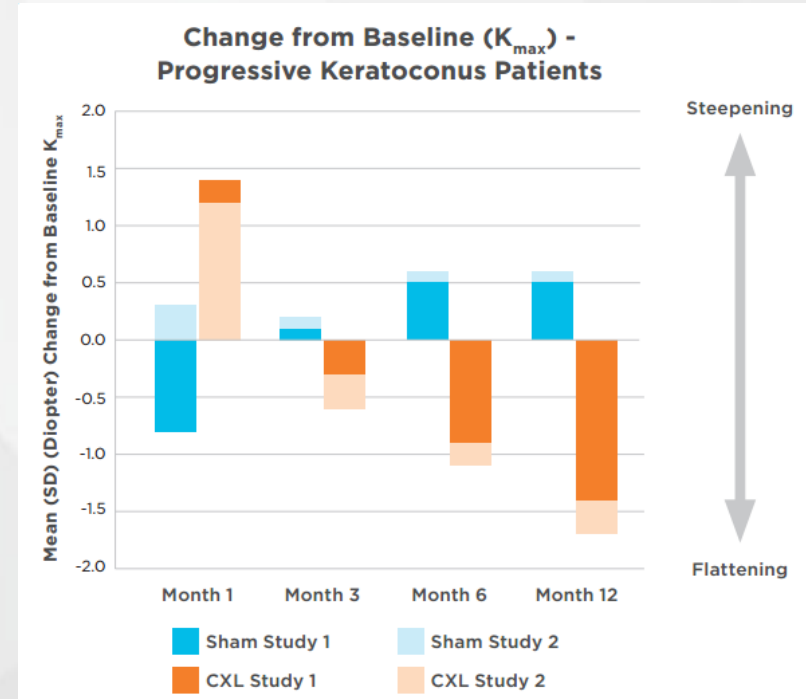
How long does it take to recover?

- 4-5 days
- Contact lens removed
- 2-3 weeks
- Gradual improvement
- Eye drops
- Return to contact lenses
- Depends on type
- Can do both eyes on same day
- Can do them on separate days



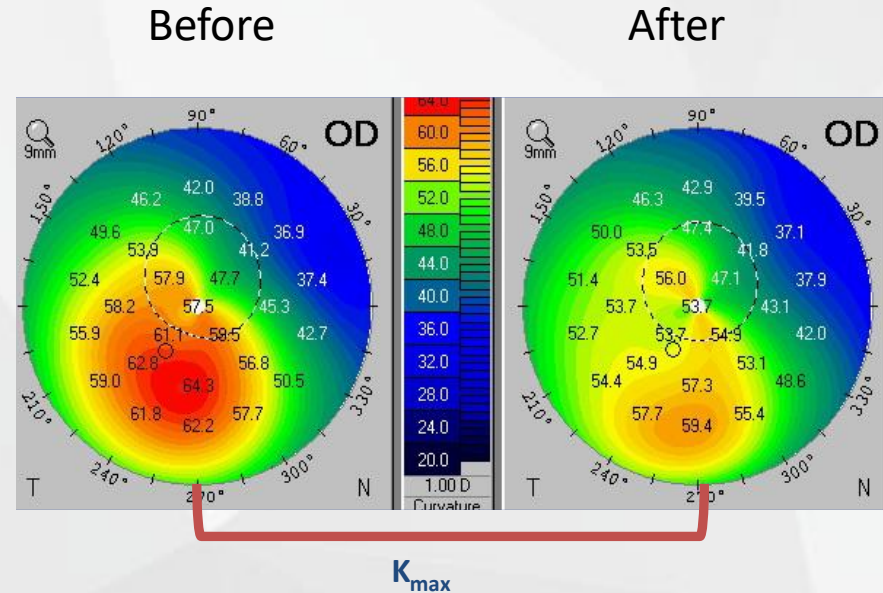
What did the FDA trial reveal?

- K_{max}
- Indicates severity of disease
- Followed for one year
- CXL – K_{max} decreased by 1.5 D
- Sham – K_{max} increased by 0.5 D
- Keratoconus is progressive
- CXL stops progression
- Some improvement



Does CXL improve vision?

- It may
- It may not
- It will get worse without CXL
- Goal is not to improve vision
- Rather, to stop progression
- Avoid corneal transplant
- Improve contact lens fit
- Hard to soft contacts



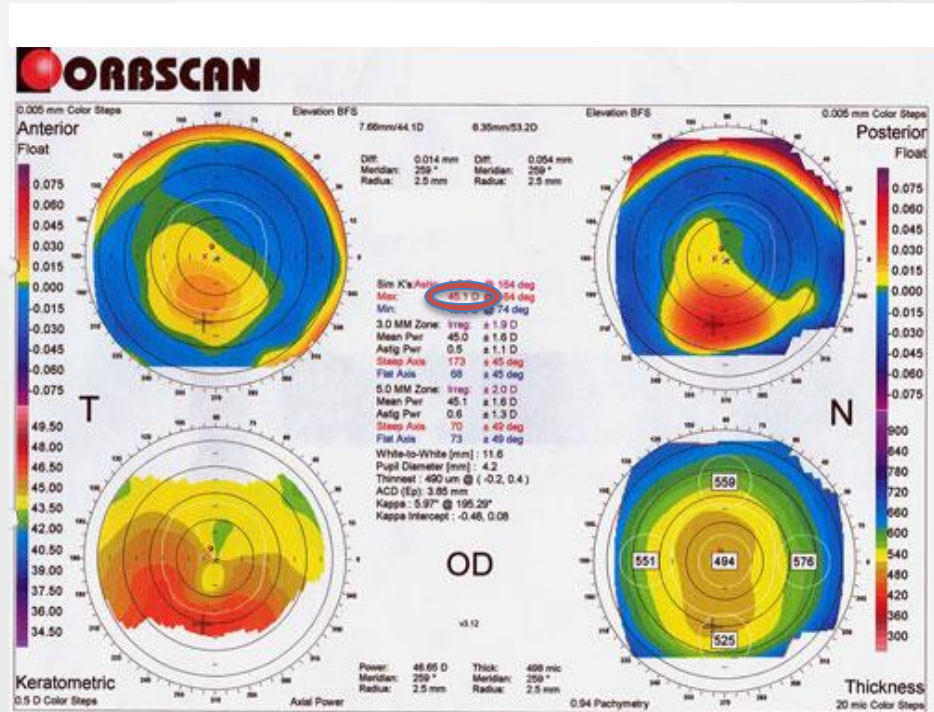
What about Intacs?

- Treatment
- Completely different
- Pieces of acrylic
- Placed in the cornea
- Changes shape
- Improves vision
- Does not stop progression
- Many patients need both
- CXL first, to stop progression



FDA Clinical Trials

- Inclusion Criteria
 - If (+), may be “included”
- Exclusion Criteria
 - If (+), must be “excluded”
- Results
 - Primary endpoint
 - K_{max}
 - Steepest sagittal axis



Inclusion Criteria

- Age ≥ 14
- CDVA worse than 20/20
- CCT $\geq 300\mu\text{m}$ at thinnest
- Progressive Keratoconus
 - In the last 24 months (1 or more):
 - K_{max} increase $\geq 1\text{D}$
 - MRx Cylinder increase $\geq 1\text{D}$
 - MRx Sphere increase by $\geq 0.5\text{D}$
- Topographic Criteria
 - $K_{\text{max}} \geq 47\text{D}$
 - I:S ratio $\geq 1.5\text{D}$
 - Corneal Thinning
 - Irregular Astigmatism
 - Corneal Asymetry
 - Not “Forme Fruste”
- Phakic or UV blocking IOL
- Able to cooperate

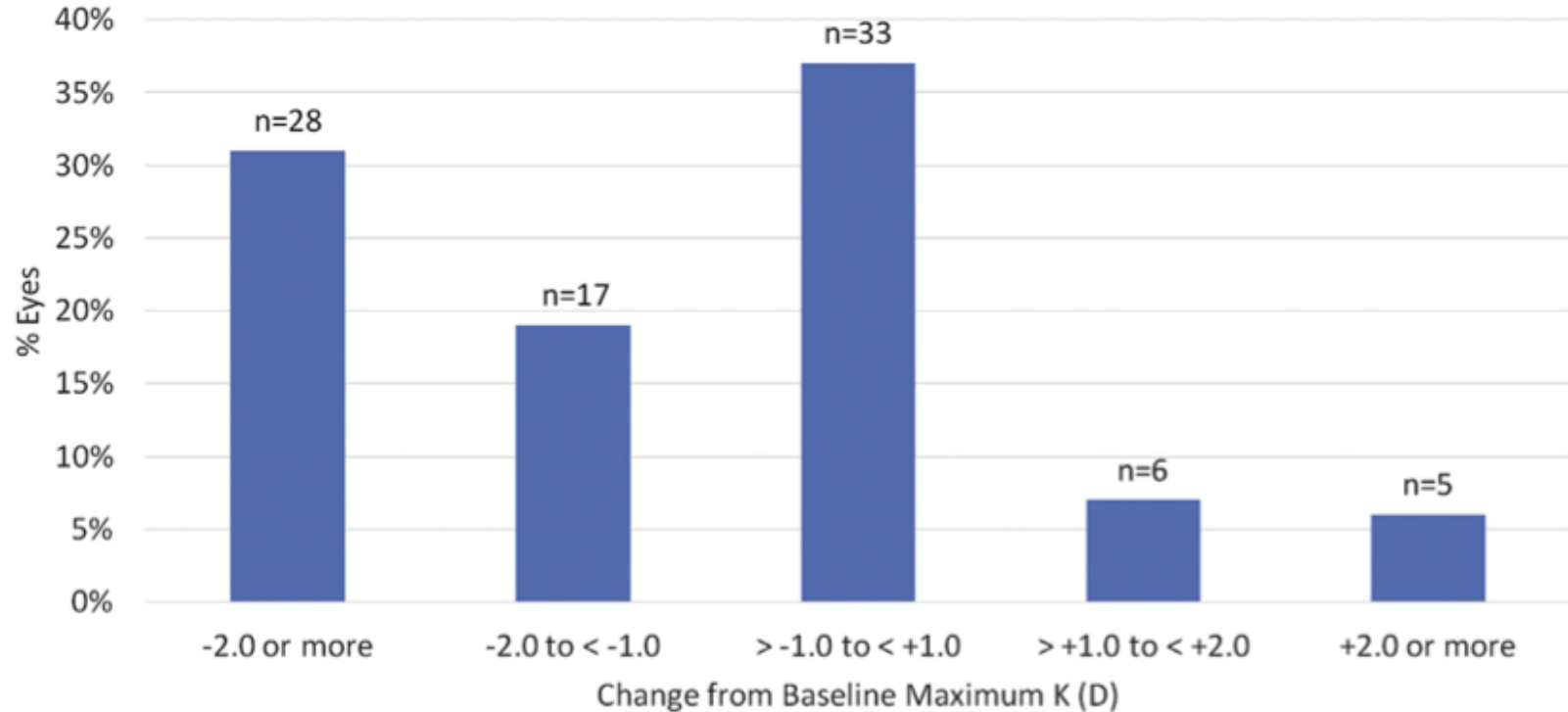
Exclusion Criteria

- Pregnancy / Lactation
- Nystagmus
- Significant Corneal Opacity
- Other Corneal Disease
- Delayed Epithelial Healing
- Intacs
- BCTLCVA \leq 20/400
- Aphakia / non-UV blocking IOL
- Prior CXL Rx
- Any other reason

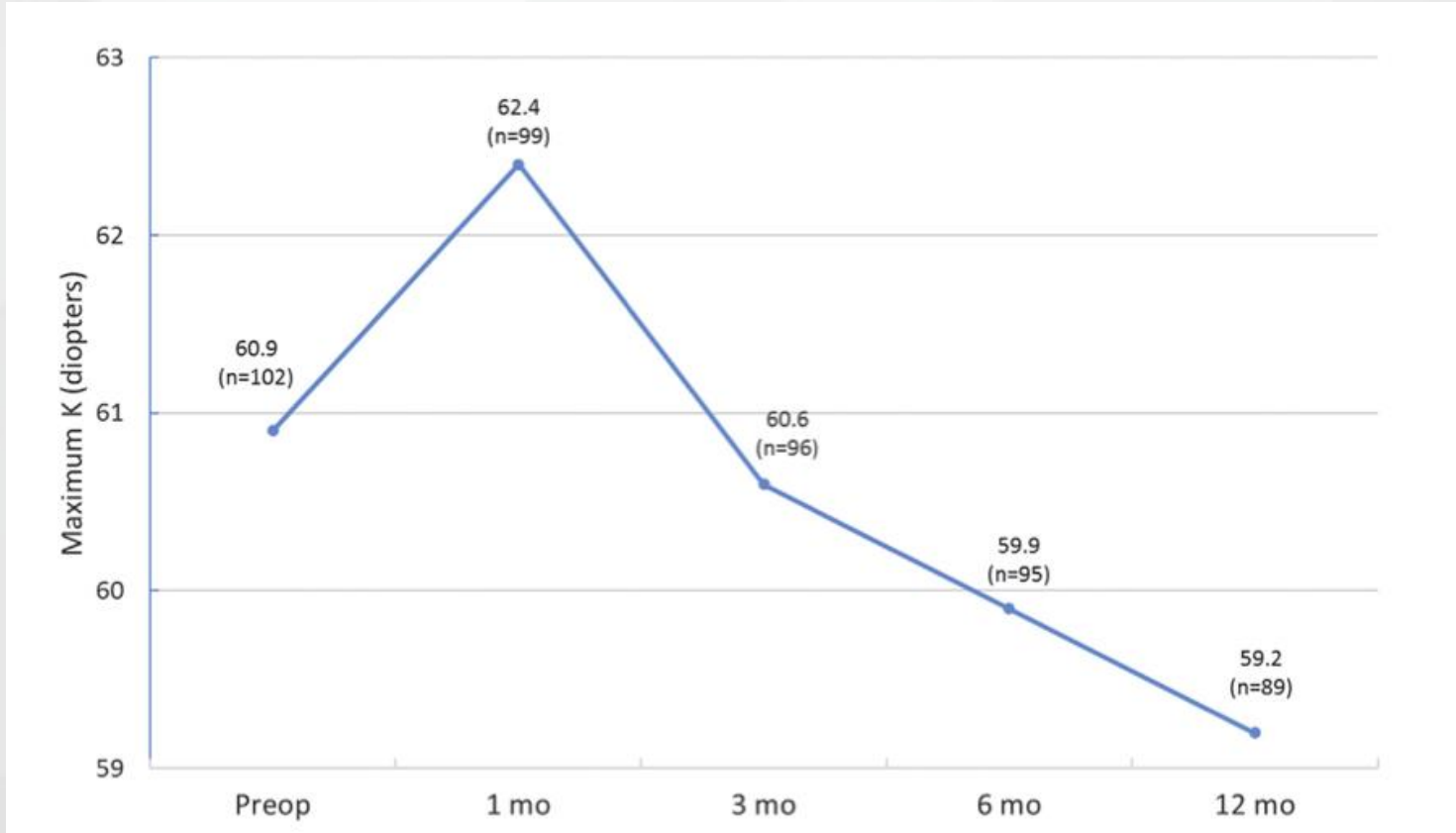
Outcome Measures

- Topography
 - Pentacam
 - Preop and 1,3,6 & 12 months
 - Objective / Quantitative
- Visual Acuity
 - UDVA
 - CDVA
- Manifest Refraction
- Patient Questionnaire
 - 11 parameters
- Safety
 - Adverse events
 - Endothelial cell counts

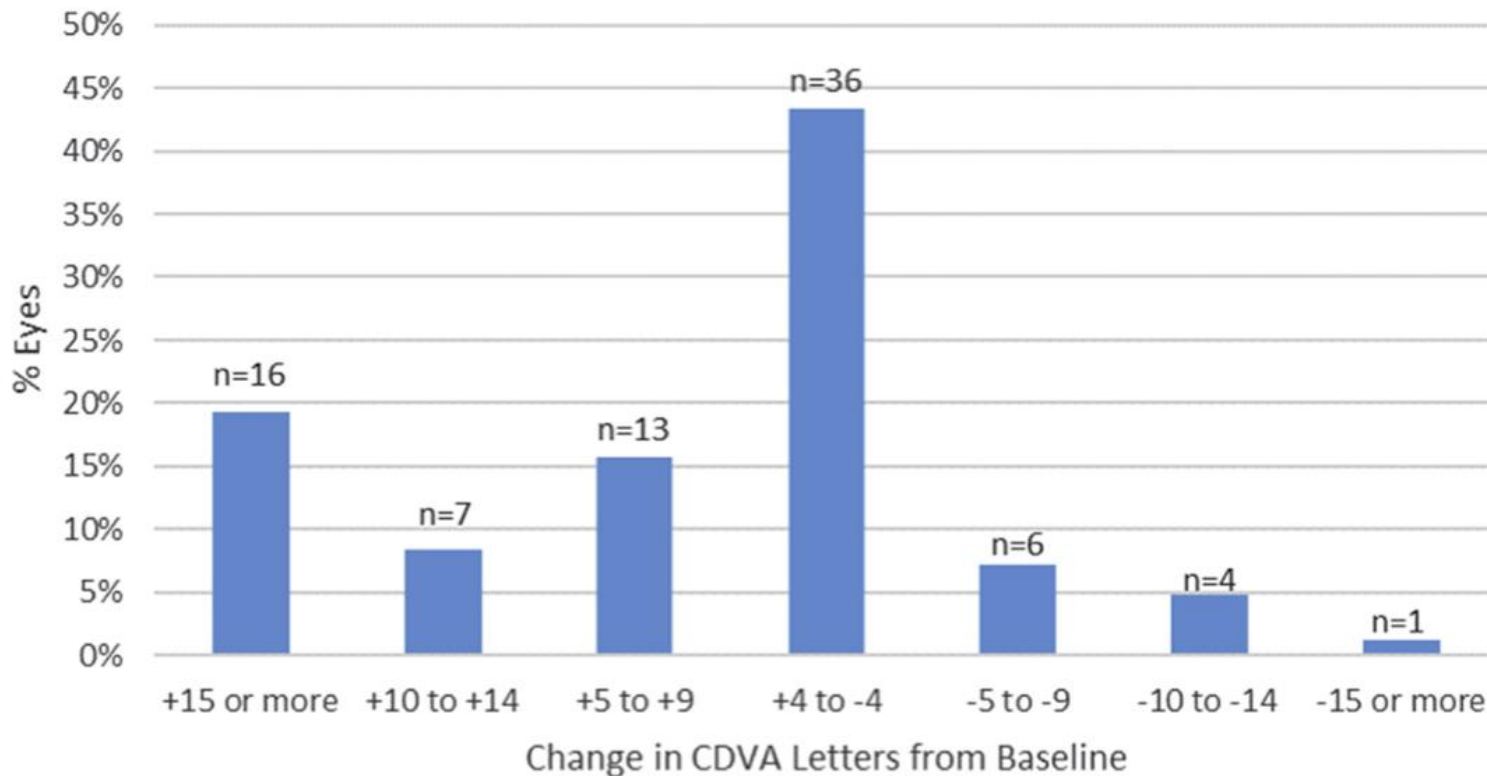
Results – K_{max} Change @ 12 months



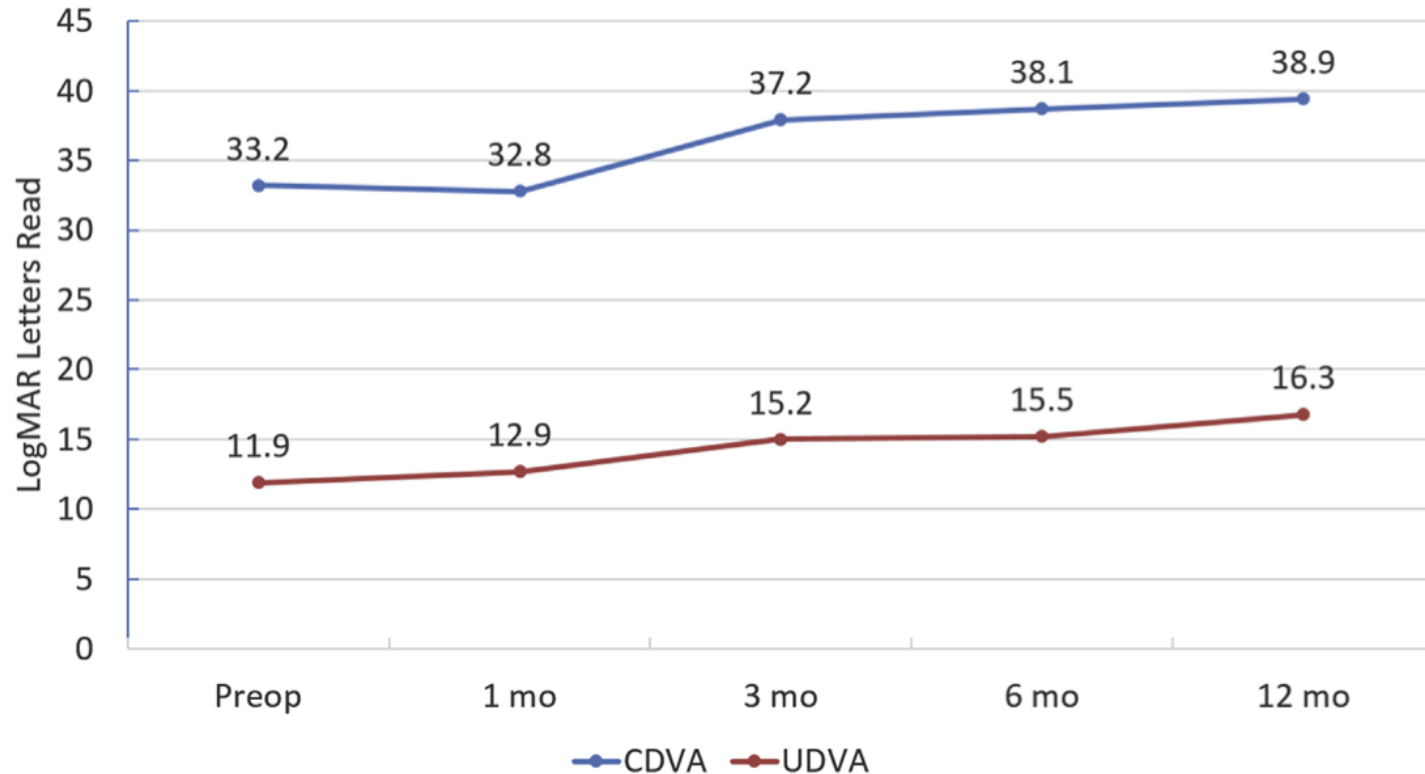
Results – K_{\max} Over Time



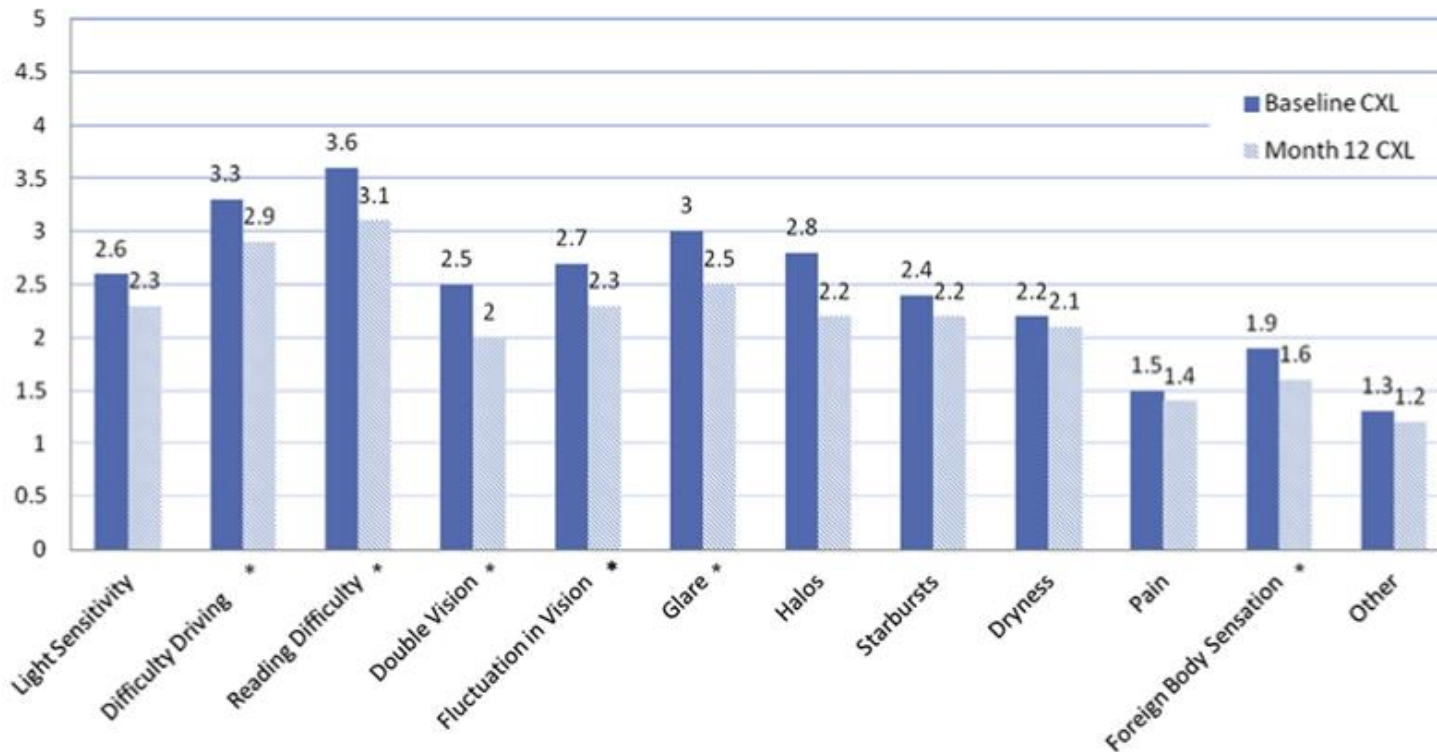
Results – CDVA Change @ 12 months



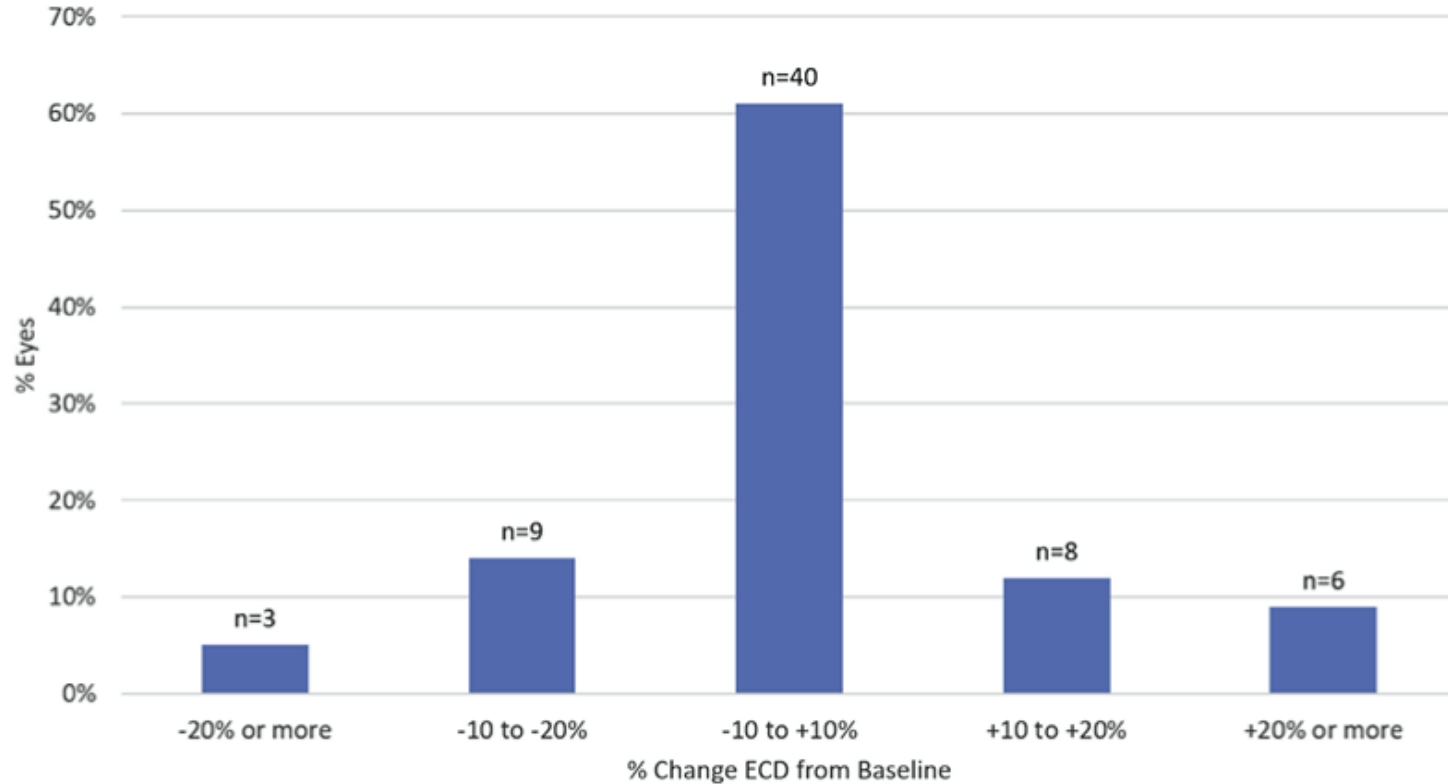
Results – CDVA & UCVA Change Over Time



Results – Patient Questionnaire



Results – Endothelial Cell Counts



What is FDA Approved?

- Diagnoses:
 - Progressive Keratoconus
 - Post Refractive Ectasia
- Treatment:
 - Collagen Cross Linking
 - Epithelium Off
 - Photrexa (Viscous & Hypotonic)
 - KXL UVA lamp
 - 30-minute induction
 - Green flare in AC
 - Pachy at ≥ 400 μm
 - 30-minute Treatment



What is not FDA Approved?

- Diagnoses:
 - Infectious Keratitis
 - Forme Fruste Keratoconus
 - Refractive error
- Treatment:
 - Collagen Cross Linking
 - Epithelium On
 - Riboflavin (not Photrexa)
 - UVA Lamp (not KXL)
 - Accelerated Treatments
 - LASIK+



What does “Off-Label” Mean?

A physician performing an “Off-Label” treatment is using an FDA approved device or medication in a manner, or for a diagnosis, or in a patient outside the parameters of the “labelled” FDA approval.

Therefore, a physician who treats a 11-year-old patient with rapidly progressive keratoconus with Avedro, using the standardized “Dresden” protocol, is treating this patient “Off-Label”. Properly consented, this is legal, and quite simply, and of course, the right thing to do!

However, a physician treating an otherwise good candidate for CXL using a lamp other than KXL or a medication other than Photrexa is NOT performing an “Off-Label” treatment because KXL and Photrexa are FDA approved (and “labelled for use”) and whatever else is used has no FDA approval, and therefore no “labelling”.

Does Insurance Pay for Crosslinking?

- Yes!
- 95% of Commercial Payors
- Difficult Approval
- FDA Approved
- KXL / Photrexa Only
- Expensive
 - Riboflavin & Card ~ \$3,000
 - Plus CPT 0402T varies
 - 2nd eye 50% less if same day
 - No defined global period



- Based on FDA Approval
- “Medically Necessary”
- Generally similar
- Vary from Payor to Payor
- Written by experts
- Hired by the Payors
- Include references
- Peer reviewed articles

VII. Collagen Cross-Linking for Keratoconus

Aetna considers epithelium-off photochemical collagen cross-linkage using riboflavin (Photrex) and ultraviolet A medically necessary for keratoconus and keratectasia.

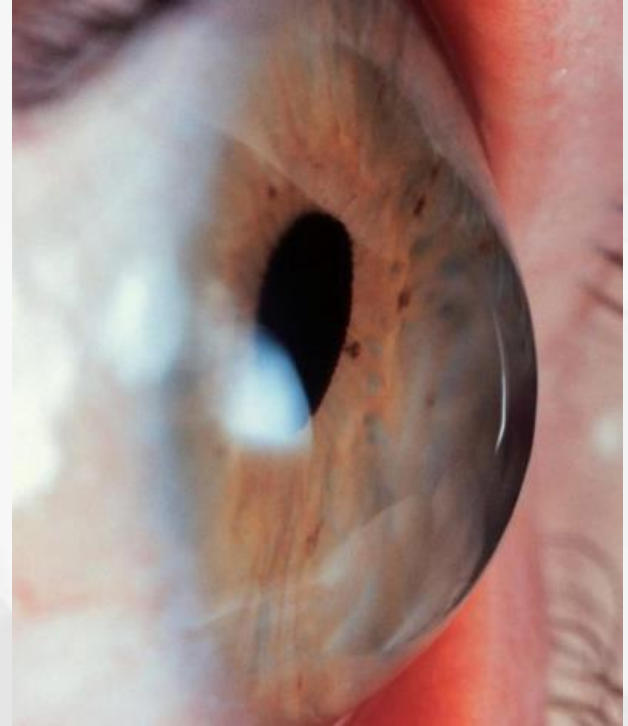
Aetna considers photochemical collagen cross-linkage experimental and investigational for all other indications because its effectiveness for other indications has not been established.

Aetna considers epithelium-on (transepithelial) collagen cross-linkage experimental and investigational for keratoconus, keratectasia, and all other indications.

Aetna considers performance of photochemical collagen cross-linkage in combination with other procedures (CXL-plus) (e.g., intrastromal corneal ring segments, PRK or phakic intra-ocular lens implantation) experimental and investigational.

How can you help get insurance to pay?

- Send the referral (early!)
- Tell them insurance covers
- Send medical records
- Especially last 24 months
- Prior refractions
- Contact lens parameters
- Visual acuities
- Ks & Topos
- Demonstrate progression





Thank you! Please join us for our next COPE event



Date: August 25

Time: 5:30 pm PST

Speaker: Dr. Justin Schweitzer

Topic: Mastering the Management of MIGS

COPE: One hour live CE in the category of glaucoma

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