Scleral Lens Management within the Keratoconus Spectrum

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Scleral Lens Soiree, with WooU and the Scleral Lens Education Society May 20, 2023

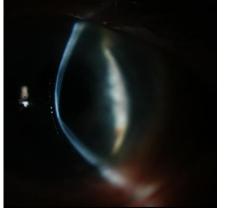
Disclosures

- Glaukos Consultant
- Acculens, BostonSight, Aurion BioTech Honoraria
- All relevant financial relationships listed have been mitigated

Keratoconus Overview

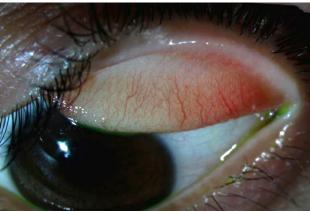
- Corneal Disorder
 - Central thinning & bulging
 - Bilateral
 - Asymmetric
 - Progressive
 - Non-infectious
 - Non-inflammatory

- Onset: Teens/puberty
- Prevalence and Incidence
 - Varies with geography, ethnicity, study
 - Prevalence 0.05 (US, 1986) to 4.79% (Saudi Arabia, 2018)
- Risk Factors
 - Age
 - Family History
 - Eye rubbing

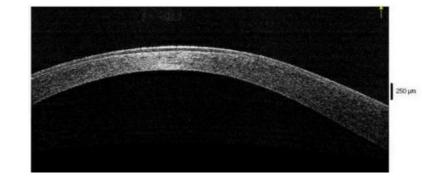






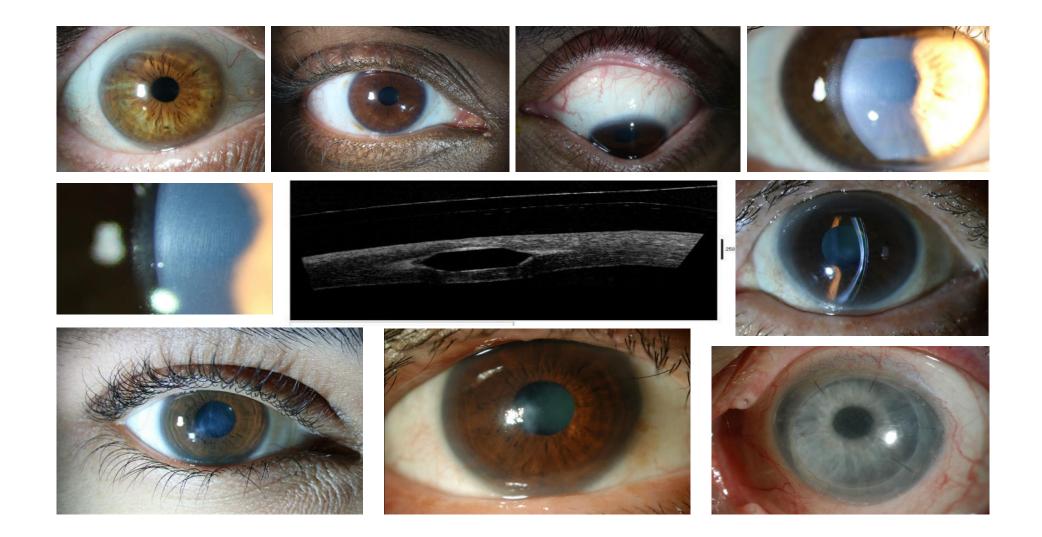


Corneal tissue is different in KC



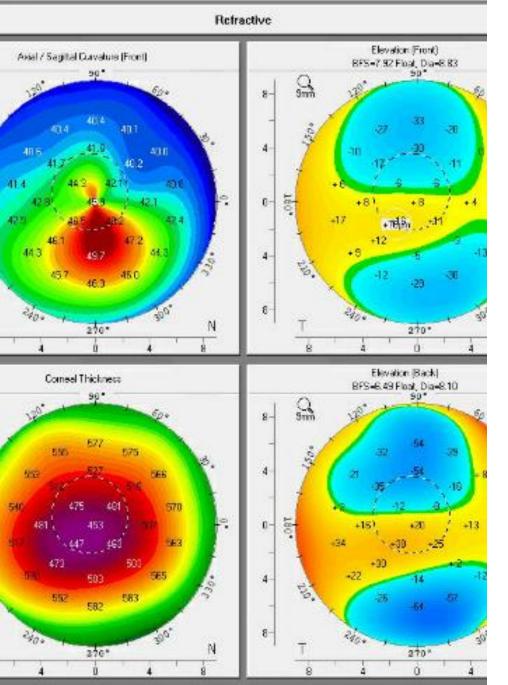
- Cornea: connective tissue with cells and stromal extracellular matrix (ECM) that relies on the synergistic cooperation of many components
 - Needed to precisely transmit and refract visual information (1)
- ECM consists of organized lamellae composed of tightly distributed fibrils
- Collagen lamellae are altered in keratoconus → abnormalities in corneal shape
- KC is a progressive disease relative to defects in the corneal stroma
 - Development related to environment and genetics

(1) Zhou HY, Cao Y, Wu J, Zhang WS. <u>Role of corneal collagen fibrils in corneal disorders and related pathological conditions.</u> Int J Ophthalmol. 2017 May 18;10(5):803-811.PMID: 28546941



Keratoconus Spectrum: Mild – Mod – Advanced

aps Refractive



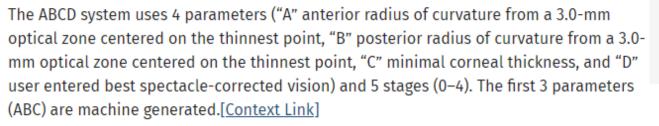
Tips for Diagnosis of Early Keratoconus

- Glare/Shadows, worse at night
- Cannot correct to sharp 20/20 VA
- History of atopy or ocular allergies
- Eye rubbing
- Family History of KC
- High, oblique or asymmetric cylinder
- Frequently changing prescriptions
- Asymmetric Ks in eye or between eyes
- Most helpful: Corneal topography or tomography

Keratoconus Classification: Belin ABCD staging and classification system

	0.0			
ABCD Criteria	Α	В	c	D
	ARC (3-mm Zone)	PRC (3-mm Zone)	Thinnest Pachy (µm)	BDVA
Stage 0	>7.25 (<46.5 D)	>5.90	>500	≥20/20 (≥1.0)
Stage I	>7.05 (<48.0 D)	>5.70	>470	<20/20 (<1.0)
Stage II	>6.35 (<53.0 D)	>5.15	>435	<20/40 (<0.5)
Stage III	>6.15 (<55.0 D)	>4.95	>400	<20/100 (<0.2)
Stage IV	<6.15 (>55.0 D)	<4.95	≤400	<20/400 (<0.05)

TABLE 1. Belin ABCD Staging/Classification Parameters



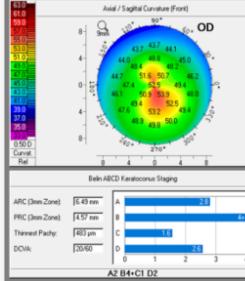


FIGURE 9.

ABCD keratoconus staging display. The staging (A2 B4 C1 D2) is shown at the bottom of the display. The graphical display (right) shows additional quantitative information, but the actual values for each parameter (left side) give the most specific individual description.

Belin MW, Jang HS, Borgstrom M. Keratoconus: Diagnosis and Staging. Cornea. 2022 Jan 1;41(1):1-11. PMID: 34116536

Full Size Table 🧷

Keratoconus Classification: Amsler-Krumeich

Stage 1	Eccentric steepening			
	Myopia and/or astigmatism <5.00 D			
	Mean central K readings <48.00 D			
	Vogt striae, no corneal opacities			
	RMS of coma-like aberration from 1.50 to 2.50 µm*			
Stage 2	Myopia and/or astigmatism from 5.00 to 8.00 D			
	Mean central K readings <53.00 D			
	Absence of scarring			
	Minimum corneal thickness ≥400 µm			
	RMS of coma-like aberration from >2.50 to \leq 3.50 µm*			
Stage 3	Myopia and/or astigmatism from 8.00 to 12.00 D			
	Mean central K readings >53.00 D			
	Absence of scarring			
	Minimum corneal thickness from 200 to 400 μm			
	RMS of coma-like aberration from >3.50 to ≤4.50 µm*			
Stage 4	Refraction not measurable			
	Mean central K readings >55.00 D			
	Central corneal scarring			
	Minimum corneal thickness <200 µm			
	RMS of coma-like aberration >4.50 µm*			

Ortiz-Toquero S, Fernandez I, Martin R. Classification of Keratoconus Based on Anterior Corneal High-order Aberrations: A Cross-validation Study. Optom Vis Sci. 2020 Mar;97(3):169-177. PMID: 32168239

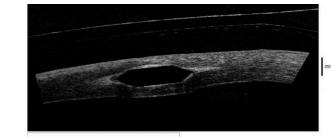
Keratoconus Classification: HOAs

- Evaluated Anterior HOAs from Placido disc-based videokeratography (Oculus Keratograph)
- Corneal high-order aberrations: Coma and third-order RMS
 - Useful in KC diagnosis and topographical classification

Ortiz-Toquero S, Fernandez I, Martin R. <u>Classification of Keratoconus Based on Anterior Corneal High-order Aberrations: A</u> <u>Cross-validation Study.</u> Optom Vis Sci. 2020 Mar;97(3):169-177. PMID: 32168239

Procedures that affect K shape and vision

- Corneal Cross-Linking (CXL)
 - Halts or slows progression
- Corneal Intacs
 - FDA approved for KC in 2004
 - "Flattens" cornea
- Topography Guided PRK (TG-PRK)
 - "Smooths" cornea, touch-up
- Cataract surgery and IOL selection
- Corneal Transplantation
 - Penetrating (PK) vs Lamellar Keratoplasty
 - 12-20% may require ¹
 - Rate of PK for KC decreasing in US²
 - Potential complications



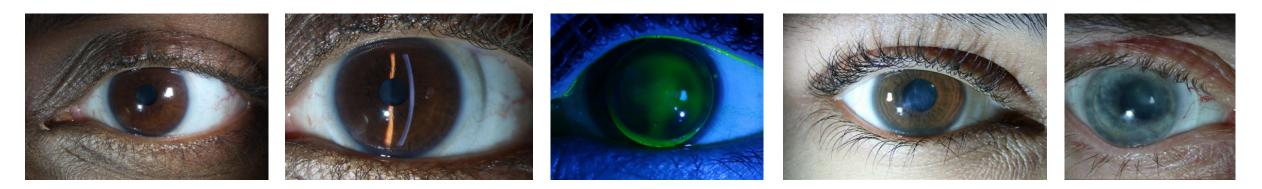




- 1. Jhanji V, Sharma N, Vajpayee RB. Management of keratoconus: current scenario. Br J Ophthalmol. 2011;95(8):1044–50.
- 2. Sarezky D, Orlin SE, Pan W, VanderBeek BL. Trends in Corneal Transplantation in Keratoconus. Cornea. 2017 Feb;36(2):131-137.

Treatment depends on Keratoconus Stage

- Early/mild KC \rightarrow CXL to prevent progression; SRx, SCL, RGP
 - Must manage corneal disease and vision, separately
- Mild \rightarrow Intacs or combo with TG-PRK to minimize need for GP lenses
- Mod with Scars: Poor Intacs candidate
- Mod-advance \rightarrow Specialty/Scleral lenses
- Advanced \rightarrow Specialty/Scleral lenses
- Advanced with significant scars and poor CL corrected VA \rightarrow K Transplant



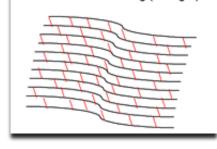
Corneal Cross-linking (CXL)

- FDA approved in April 2016
 - KXL UV System, with Photrexa and Photrexa Viscous (riboflavin)
- Indications:
 - Progressive Keratoconus & Post-LASIK Ectasia
- Procedure involves:
 - Epithelium removal (Epi-off)
 - 30 min riboflavin application
 - Corneal thickness minimum: 400 microns (Photrexa if needed)
 - 30 min exposure 365 nm UV-A light, 3.0 mW/cm2
- No specific age range limitations
 - Patients ages 14-65, included in FDA studies
- Activated riboflavin and reactive oxygen species interact in cornea to form crosslinks: stiffens cornea¹
 - 328.9% increase in biomechanical rigidity ²

1. Beshtawi IM, O'Donnell C, Radhakrishnan H. Biomechanical properties of corneal tissue after ultraviolet-A-riboflavin crosslinking. J Cataract Refract Surg. 2013;39(3):451–62

2. Wollensak G. Crosslinking treatment of progressive kera-toconus: New hope. Curr Opin Ophthalmol. 2006;17:356–60.

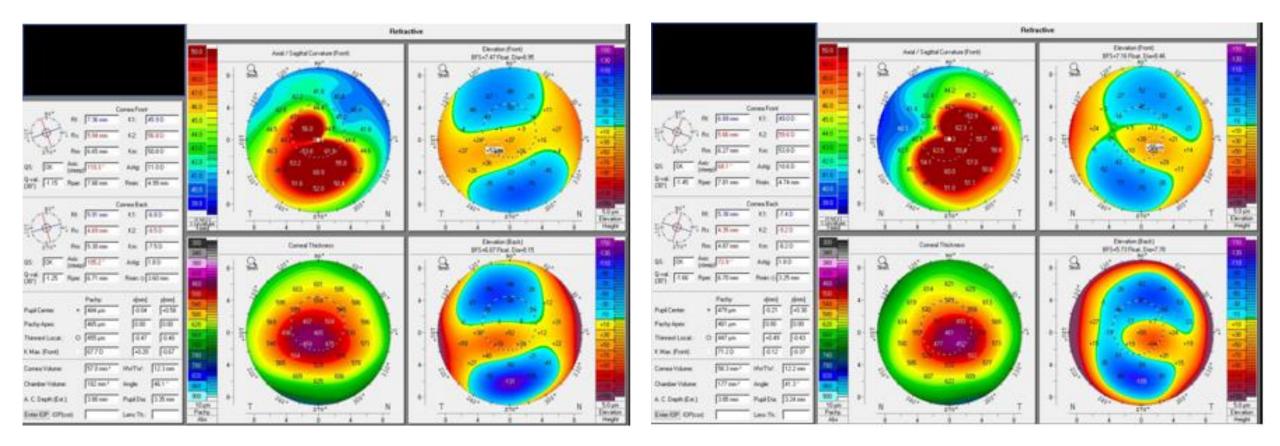




Case: Early KC

- 24 y/o Hispanic F, presented with blur 10-2022
- Reports Dx KC 2018, VA worse in last year
 - Was told initially "KC mild and will go away in few years"
- Seen by new OD 2022, given new glasses 1-2022
 - -3.00 +4.00 x 178 20/50
 - -3.75 +3.25 x 026 20/50
 - MR: 10-7-22
 - -3.50 +4.00 x 005 20/40-3
 - -3.50 +3.75 x 020 20/50+2
- Was referred for CL fitting and CXL
 - Never tried any CLs before
- Educated patient on KC condition
 - Eye rubbing, Genetic history, Goal of CXL

Corneal Tomography (pre-CXL) OD: 45.9/56.8 Kmax 67.7; 455 OS: 49.0/59.6 Kmax 71.2; 447 (10-22) OD: 46.3/56.5 Kmax 66.2; 427 OS: 47.7/59.1 Kmax 69.3;433 (2-23)



Case: Early KC

- Contact Lens Evaluation
 - Unable to get scleral lens due to strong lid reflex (needed anesthetic)
 - 20/30 OD and 20/25 OS in RGP CLs
- Sent for urgent CXL OU, 10-2022
 - Requested past notes/imaging from referring OD (to help with insurance PA)
 - Performed 12-13-22 OS and 12-27-22 OD
 - Non-compliant with post-op meds
 - Developed sterile infiltrates OD
- Returned for CLs CXL (2-2023)
 - 20/20-3 OD and 20/25- OS
- MR after CXL (Pt lost glasses)
 - -3.50 +2.75 x 150 20/40-2 OD
 - -3.50 +2.50 x 030 20/50 OS

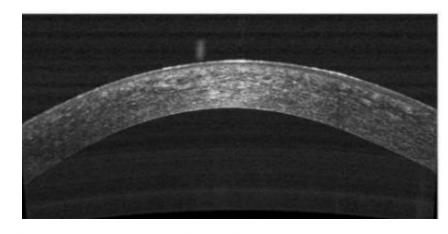
(compared to before 10-2022) -3.50 +4.00 x 005 20/40-3 -3.50 +3.75 x 020 20/50+2

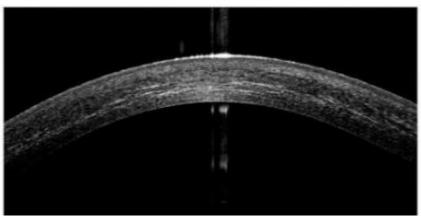
Case: Early KC

- Take-Away Points
 - Need to educate patient on KC condition
 - Cannot just "monitor" when mild
 - Need to consider CXL in younger individuals
 - Especially with Hx eye rubbing, atopic conditions
 - Earlier presentation tends to be more aggressive
 - Closer follow-up and lower threshold for CXL should be adopted in patients < 17 years and steeper than 55 D Kmax
 - Ferdi AC, Nguyen V, Gore DM, Allan BD, Rozema JJ, Watson SL. Keratoconus Natural Progression: A Systematic Review and Meta-analysis of 11 529 Eyes. Ophthalmology. 2019 Jul;126(7):935-945. Epub 2019 Mar 8.
 - Diagnose and treat KC early to avoid irreversible damage in later stages
 - KC progressed x years in this patient
 - Must educate about CXL process and importance of post-op care
 - RGPs are a good CL option for early KC

CXL Post-operative Considerations

- After procedure
 - Topical Antibiotic, Steroid (sometimes NSAID)
 - Lubrication
 - Placement of bandage SCL No eye rubbing!
- Week 1:
 - Topical meds, lubrication
 - Remove bandage SCL once epithelium healed
- Month 1:
 - Assess vision
 - Corneal Imaging stromal remodeling
 - Consider CL fitting, getting back into CLs
- Months 3, 6, 12:
 - Assess vision MR and BCVA often change
 - Corneal Imaging





• Zero Global Period: Visits can be billed to insurance

CXL Potential Complications

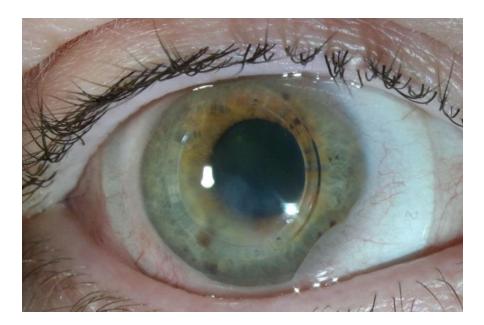
- Infections
- Infiltrates (sterile or infectious)
- Non-healing epithelium
- Corneal Haze
 - Usually resolves over months
- Corneal scarring
- Endothelial cell damage
- Continued progression

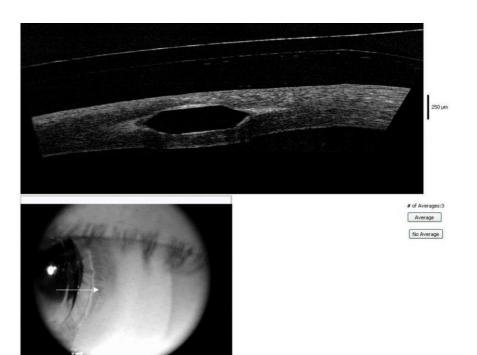
• Epi-on vs Epi-off?

• Current studies evaluating new eye drops, supplemental oxygen, higher energy, pulsed UV

Corneal Intacs

- FDA approved for KC in 2004
 - US: 0.25, 0.275, 0.3, 0.325, 0.35 mm PMMA segments
 - Inserted into stroma to flatten central K
 - Best candidates: mild-mod KC, no cent scars, CL intolerant
 - Need min 450 um K thickness, Ks <58 D





Rabinowitz YS. INTACS for Keratoconus. Int Ophthalmol Clin. 2010 Summer;50(3):63-76. PMID: 20611018

Case: KC After Intacs

- 52 y/o Caucasian M, Businessman
- KC OD>OS from late 20s, progressed in 40s
 - CXL OU (Epi-off) 2013, under investigational protocol
 - Intacs OD only, 2014
- Ocular allergies, Dry eyes
- Fit with scleral lenses OU, early 2016
 - Complicated fit, needed SCOR in SRx over to optimize VA, with Neurolens
 - Front toric scleral lens did not work great (low cyl 0.50/0.75, inconsistent)
 - Complication with stromal melt over Intacs 2018, resolved
- Patient is a perfectionist
 - Shadows/glare VERY bothersome

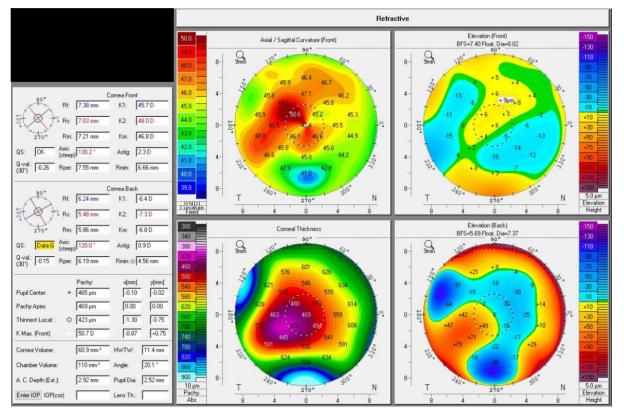


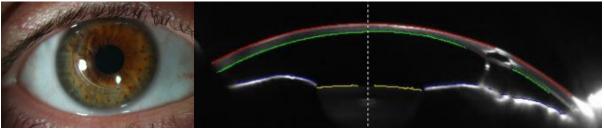


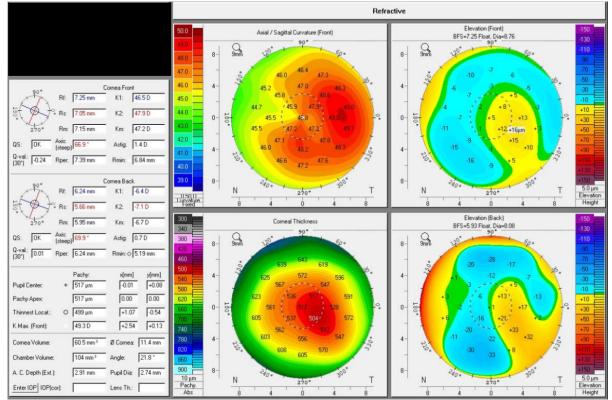




Case: KC After Intacs OD



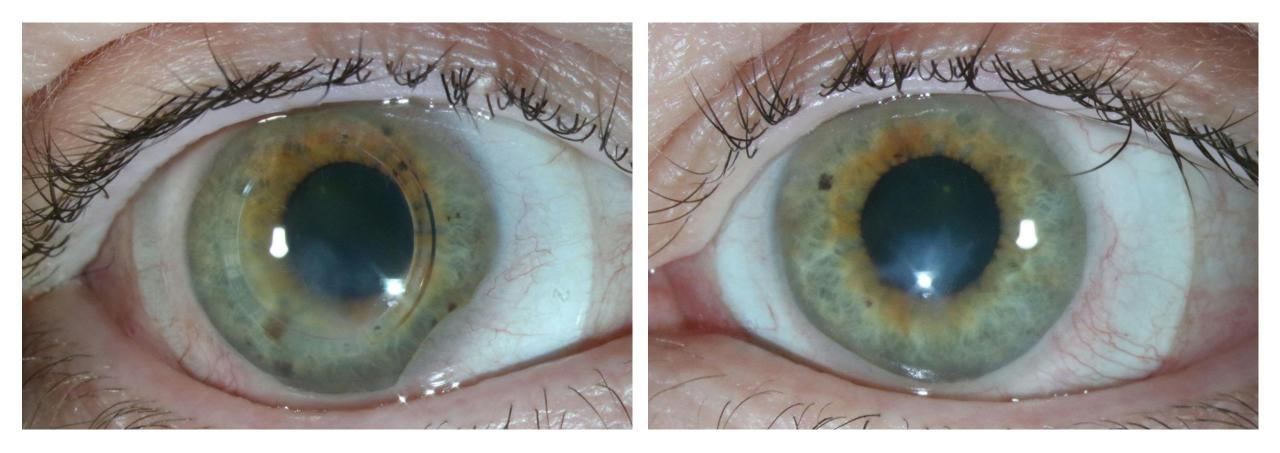


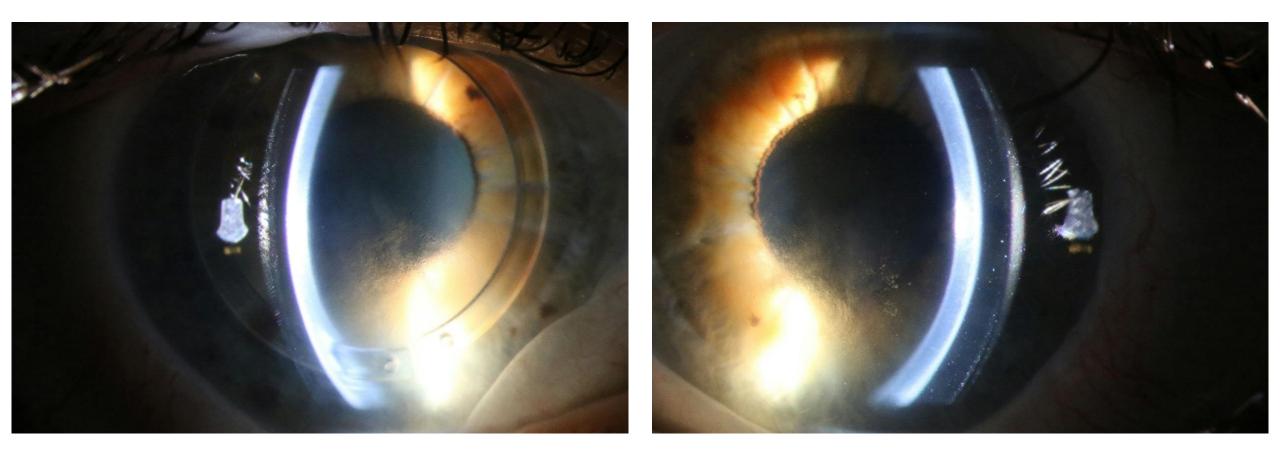


Case: KC After Intacs

- VA without correction
 - 20/40-3 OD 20/70+1 OS
- VA with SRx alone
 - 20/30+2 OD 20/30+2 OS
- VA with scleral lenses and SRx Neurolens (contoured prism technology)
 - 20/20-3 OD 20/20-3 OS (unimpressed)
- Collaborated with local OD to incorporate HOA into lens design
 - Multiple iterations, switched scleral lens design, added MF
 - Pt seems OK

Case: KC and Fuchs' Dystrophy, s/p Intacs





Initial consult (2/17) After 1 year (5/18) After 2 years (5/19) After 5.5 yrs (10/22) AWT 15 hrs per day 551/549IOP 13/13562/569IOP 15/1520/30+ OD, 20/30- OS548/559IOP 12/1120/30OD, 20/30570/565IOP 14/1320/30- OD, 20/30+ OS

CCT, IOP & VA stable after almost 6 years of scleral lens wear

Keratoconus patients will also need cataract surgery



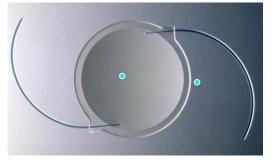
IOL Selection

• Multifocal IOL

- Not advised in OSD patients or KC pts with scarring
- Contrast sensitivity reduced

• Toric IOL

- Not advised in highly irregular cornea patients
- Not advised if going back into scleral lens
- Toric intraocular lens power calculation in cataract patients with keratoconus. Ton Y, Barrett GD, Kleinmann G, Levy A, Assia El. J Cataract Refract Surg. 2021 Nov 1;47(11):1389-1397.
 - Cataract removal with a toric IOL significantly improves visual acuity and decreases astigmatism in KC eyes with a topographic central relatively regular astigmatic component.
 - Keratoconus-specific formulas resulted in lower mean error in predicted refraction compared with conventional calculating formulas
- In OSD and IC cases, scleral lenses will still be needed after CE
 - Higher order aberrations often present
 - Can fine tune Rx in lens
 - Front toric Rx and MF options available







Study – Corneal changes with SL wear

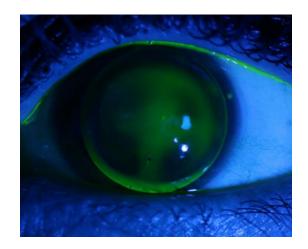
- Scleral lens influence on corneal curvature and pachymetry in keratoconus patients. Soeters N, Visser ES, Imhof SM, Tahzib NG. Cont Lens Anterior Eye. 2015 Aug;38(4):294-7.
- Investigated influence of full scleral lenses on corneal curvature and pachymetry in KC pts
- 20 eyes of 14 patients measured by Scheimpflug imaging (Pentacam HR, Oculus) at two time points:
 - Directly and ≥1 week after scleral removal
- Directly after lens removal, curvature parameters significantly flatter compared to ≥1 week after lens removal
 - Avg K(steep) **0.7** diopter (D) lower (P<0.001)
 - Avg K(flat) **0.5D** lower (P=0.037)
 - Avg K(max) **1.1D** lower (P<0.001)
 - Average pachymetry ±2.5% higher (P<0.001)
- **Conclusion:** Although scleral lenses do not mechanically touch the cornea, curvature and pachymetry seem to be influenced by scleral lens wear in KC pts

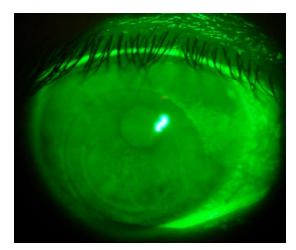
Study – Corneal changes with SL wear

- Effect of Scleral Lenses on Corneal Topography in Keratoconus: A Case Series of Cross-Linked Versus Non-Cross-Linked Eyes
 - Severinsky B, Fadel D, Davelman J, Moulton E. Cornea. 2019 Aug;38(8):986-991.
- Evaluated changes in anterior corneal topography induced by scleral lenses (SLs) in keratoconic subjects with and without corneal cross-linking (CXL)
 - 9 KC patients (14 eyes) fitted with 18.5 mm SLs
 - Topography performed at baseline, 2 & 5 hours of lens wear
- K steep dec on avg from 53.1 to 52.4 D
- K max dec from **56.7 to 55.8 D**
- CCA (astig) decreased from 7.2 to 6.3 D
- Short-term scleral lens wear in KC patients may cause flattening of anterior cornea.
 - CXL treatment does not guarantee corneal shape stability after scleral lens wear

Pre-Op: Discontinuation of Lens Wear?

- Is it necessary to discontinue lens wear **prior to imaging, or Sx**?
- For Imaging
 - RGP/hybrid and SCL wearers?
 - Yes
 - Depends on length of wear and corneal molding
 - Scleral lens wearers?
 - Maybe?
 - Consider irregular cornea vs dry eye patients
 - Will get better quality images with optimized ocular surface
- For Surgery: Not really





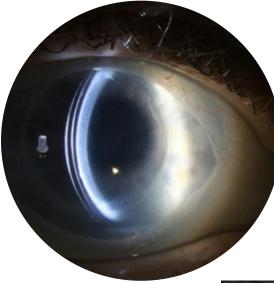


When to Resume Scleral Lens Wear

- Between 1 4 weeks
- Will likely need scleral lens power adjustment
 - Can determine based off most recent lens
 - Perform over-refraction
 - Fit typically does not change
- Patients can wear for comfort as needed, until power optimized

Advanced KC and Corneal Transplant Considerations

- May need transplant if severe scarring
 - Limited BCVA even in specialty CLs
- Challenges to Consider
 - Recovery time (months, year+)
 - Stitch removal, healing
 - Limited VA until CL can be fit
 - Corneal edema/ Hypoxia
 - Graft failure or rejection
 - Irregular shape and ectasia
 - Chronic topical steroids
 - Dry eyes





• More to come from Dr. Noyes and Dr. Williams (Post-surgical SL Rounds)



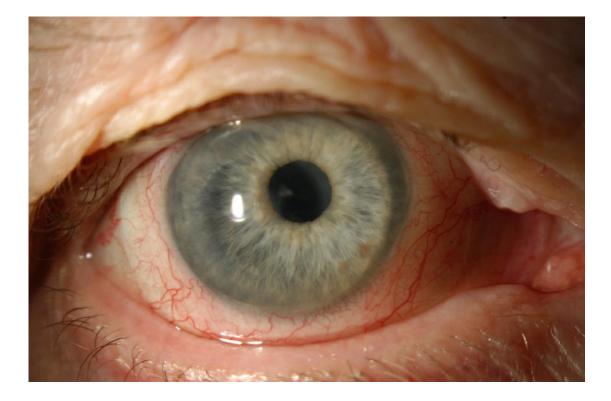


Case: Advanced KC

- 98 y/o Caucasian M
- Advanced KC
 - Emerged as young adult
 - Hx RGPs, fenestrated scleral lenses (60s)
- Re-fit into scleral lenses OU 2000s
 - Re-fit 2010
- VERY thin corneas OU
 - Graft or no graft?
 - Proceeded with PK OS 2010 (Pt in 80s)
 - Today: Still in scleral lenses OU
 - Doing fine in non-transplanted eye
 - 20/40 OD and 20/20-25 OS

Case: Advanced Keratoconus

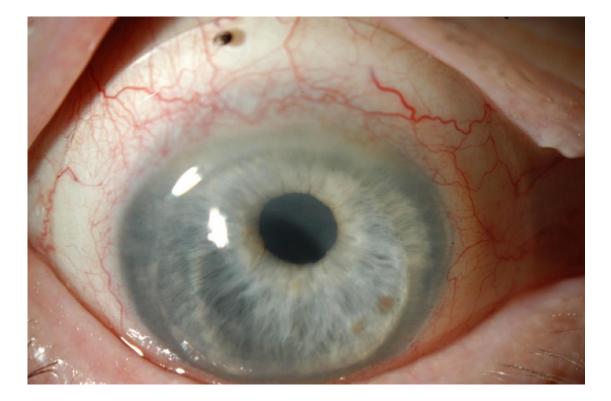
April 2010

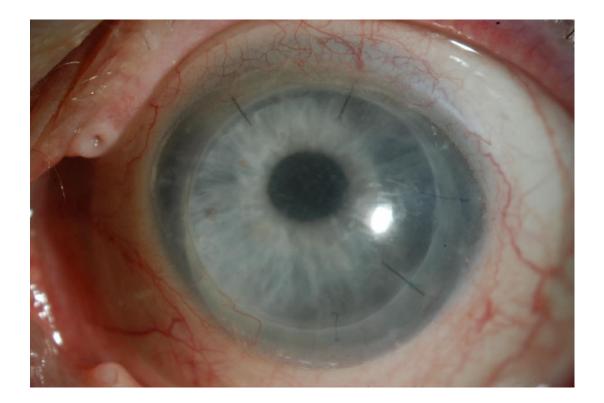




Case: Advanced Keratoconus

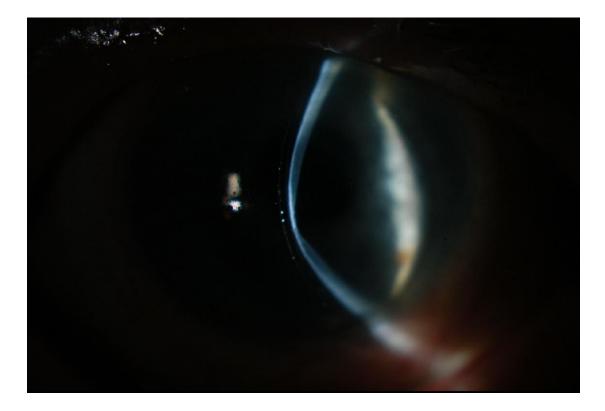
April 2011

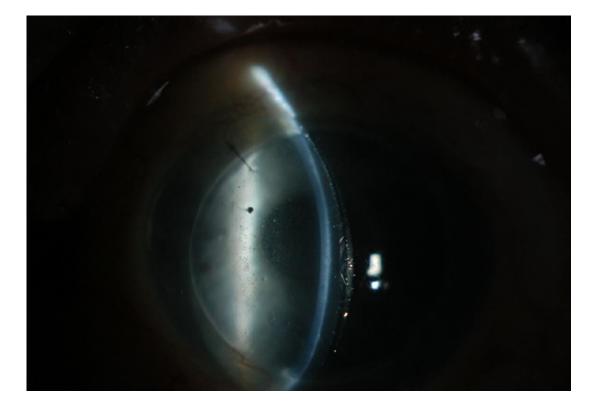




Cornea Profiles

April 2011

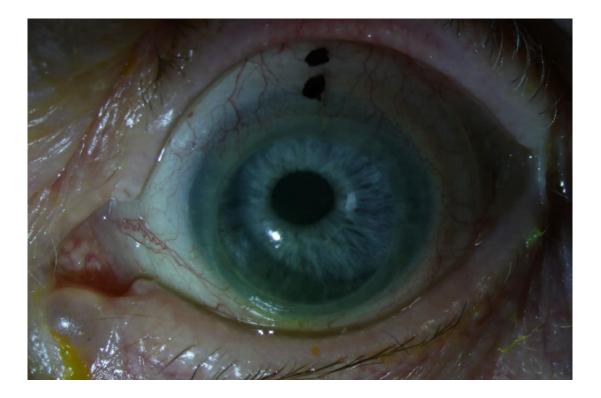




Recent Situation

January 2022

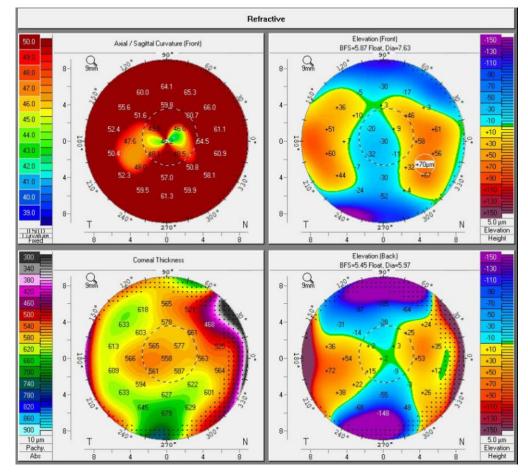


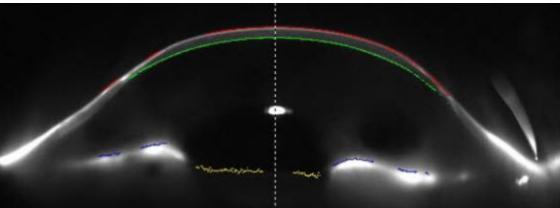


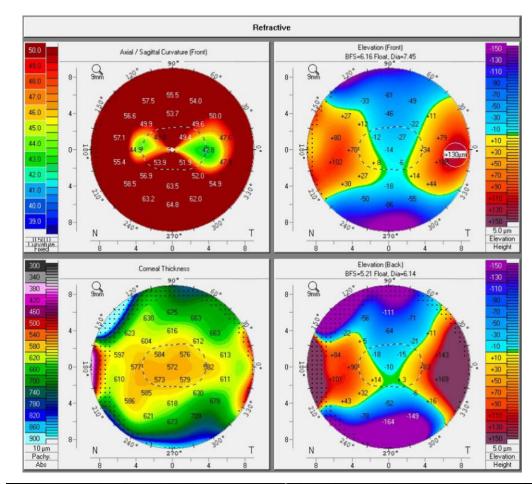
Scleral lenses s/p PK OU for Keratoconus

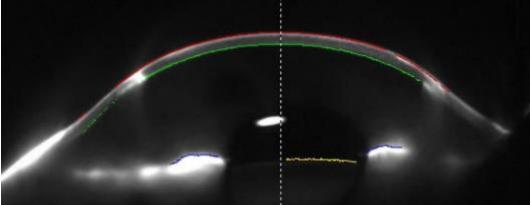
- 60 y/o Caucasian M, referred for CL eval in 2013
- PK OU: 1990s OS (~30 yrs!) and 5 yr later OD
 - Chronic allergies and sinus inflammation offer treatment
- Hx CL intolerance: RGPs, various scleral lenses, hybrid lenses
 - Struggled with fit, VA, midday fogging
- SRx 2022:
 - -20.00 +4.75 x 070 20/150 OD
 - -20.00 +4.75 x 085 20/300 OS
- Finally ended up in optimal scleral lens fit, minimal clouding
 - Highly vaulted 17 mm toric design
 - 7.80/-11.50/17.0/ P 6.34 F1/F6 BOSTON XO2 CLEAR 1 dot
 - 7.80/-11.50/17.0/ P 6.12/F6/F1 BOSTON XO2 ICE BLUE 2 dots

Evolution of Corneal Graft Survival Over a 30-Year Period and Comparison of Surgical Techniques: A Cohort Study. Bidaut-Garnier M, Monnet E, Prongué A, Montard R, Gauthier AS, Desmarets M, Mariet AS, Ratajczak C, Binda D, Saleh M, Delbosc B.Am J Ophthalmol. 2016 Mar;163:59-69. PMID: 26706619

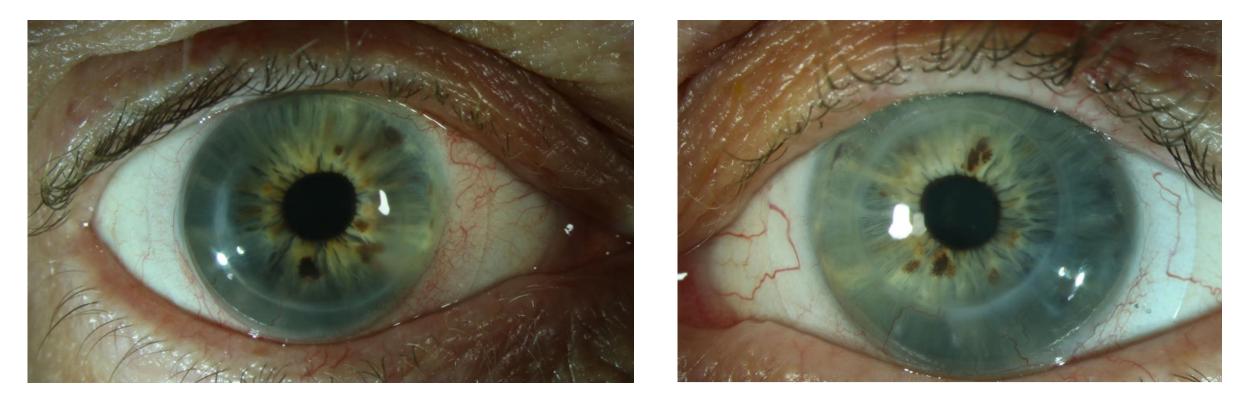








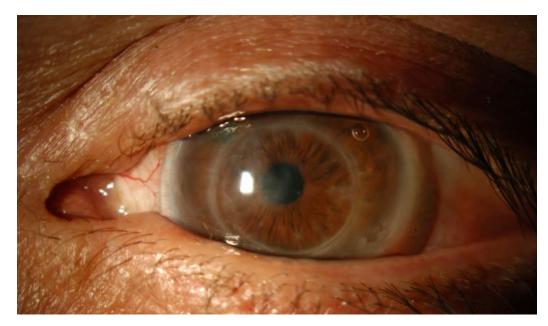
Scleral lenses s/p PK OU for Keratoconus

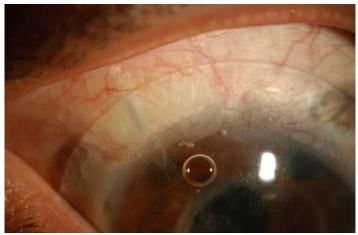


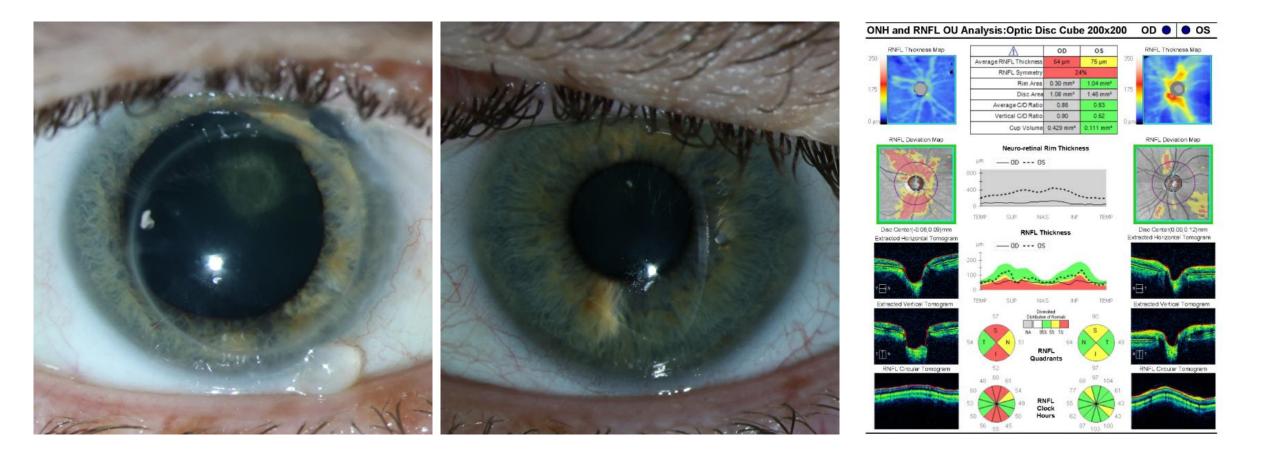
- Patient doing great! Daily Scleral lens wear OU in 2023
- K grafts (30 yrs old) cl OU, no rejection, IOP/retina stable
- 20/25+ VA OD and OS

Complications after Corneal Transplant









Corneal Transplants for KC can lead to Complications

Study Conclusion: Physicians should maximize use of scleral or RGP CL because patients who successfully use CL have almost **one-fifth the risk of undergoing keratoplasty**. Ling JJ, Mian SI, Stein JD, Rahman M, Poliskey J, Woodward MA. **Impact of Scleral Contact Lens Use on the Rate of**

Corneal Transplantation for Keratoconus. Cornea. 2021 Jan;40(1):39-42.

Keratoconus and Scleral Lenses: Life Changing!





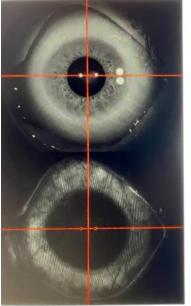


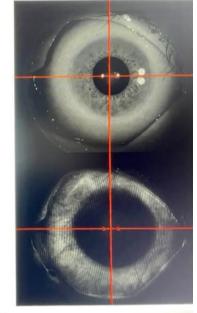


Scleral Lenses for KC in Literature

- Kreps EO, Pesudovs K, Claerhout I, Koppen C. <u>Mini-Scleral Lenses Improve Vision-Related Quality of Life</u> in <u>Keratoconus</u>. Cornea. 2021 Jul 1;40(7):859-864. PMID: 32947413
- Fuller DG, Wang Y. <u>Safety and Efficacy of Scleral Lenses for Keratoconus</u>. Optom Vis Sci. 2020 Sep;97(9):741-748. PMID: 32932400
 - Discusses adverse events, management strategies
- Koppen C, Kreps EO, Anthonissen L, Van Hoey M, Dhubhghaill SN, Vermeulen L. <u>Scleral Lenses Reduce the Need for Corneal Transplants in Severe Keratoconus</u>. Am J Ophthalmol. 2018 Jan;185:43-47.
 PMID: 29103959
 - Forty of the 51 eyes with severe keratoconus that would otherwise have undergone transplant surgery were successfully treated with long-term scleral lens wear
- Rathi VM, Mandathara PS, Dumpati S. <u>Contact lens in keratoconus</u>. Indian J Ophthalmol. 2013 Aug;61(8):410-5. PMID: 23925325
- Şengör T, Aydın Kurna S. <u>Update on Contact Lens Treatment of Keratoconus</u>. Turk J Ophthalmol. 2020 Aug 26;50(4):234-244. PMID: 32854468
- Schornack MM, Patel SV. <u>Scleral lenses in the management of keratoconus</u>. Eye Contact Lens. 2010 Jan;36(1):39-44. PMID: 20009945





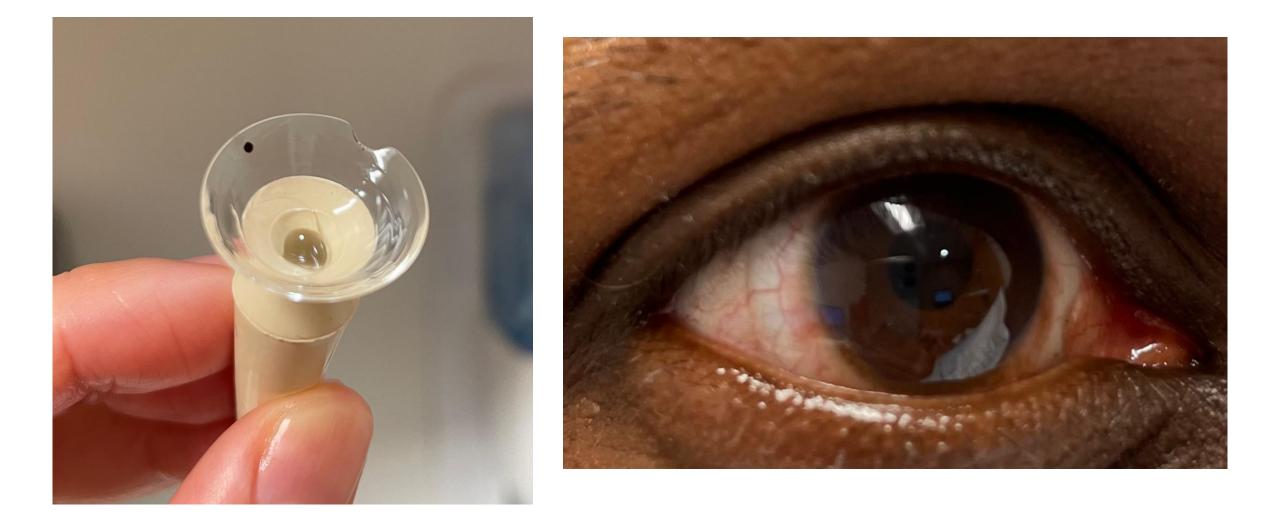




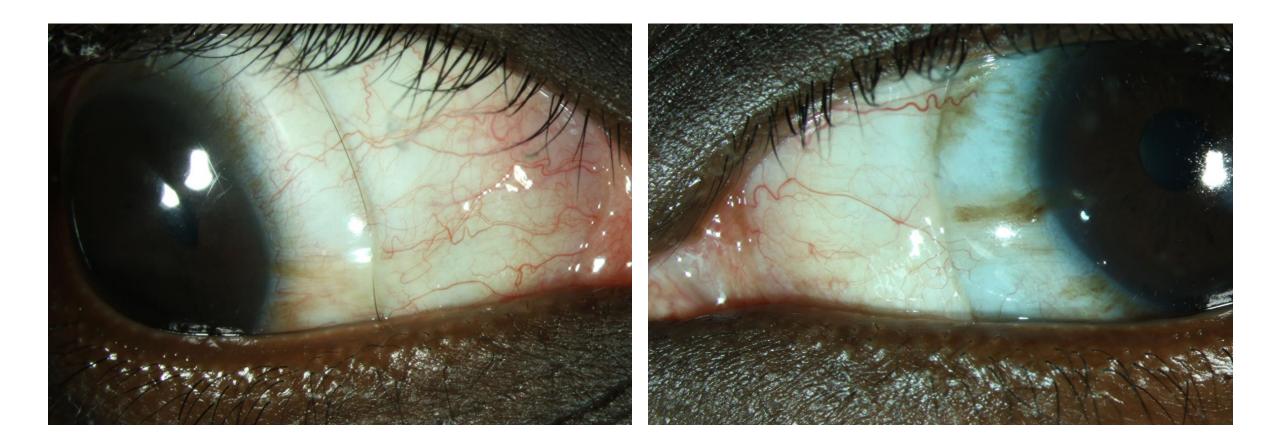


Significant design improvements over the years

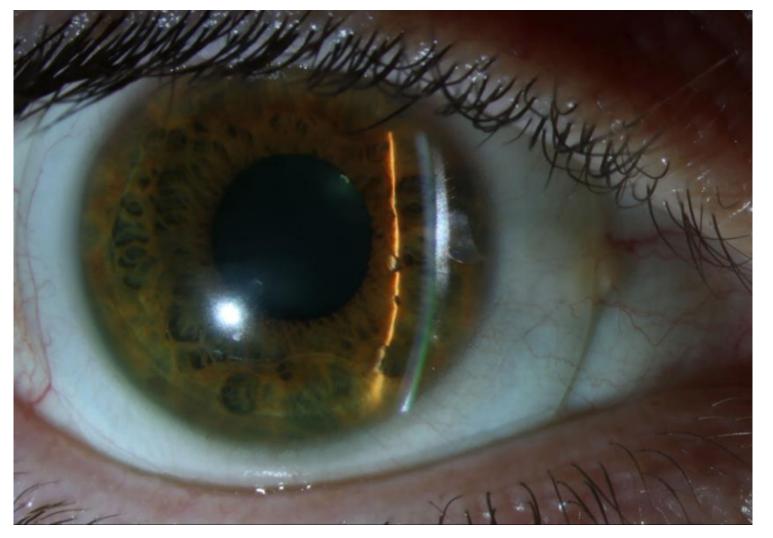
Scleral Notches (Cut outs)



Scleral Microvaults

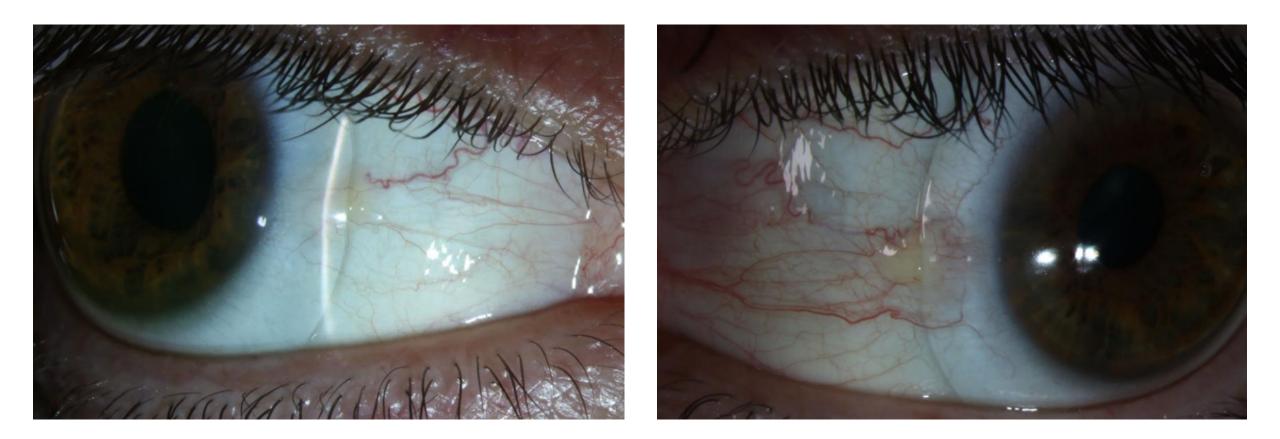


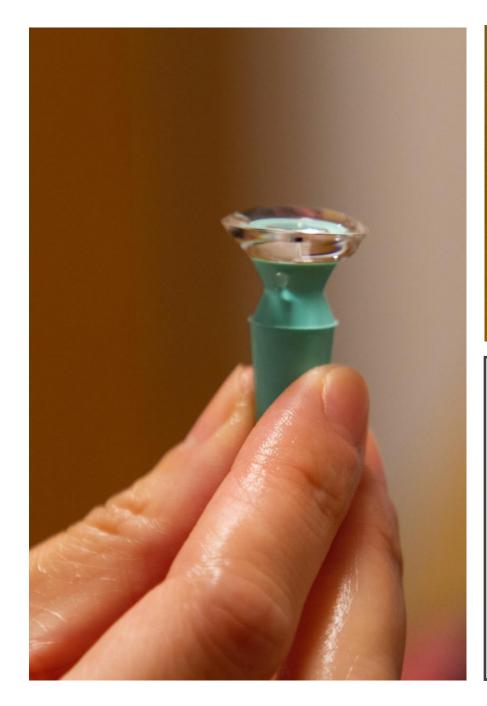
Scleral Microvault





Scleral Microvault





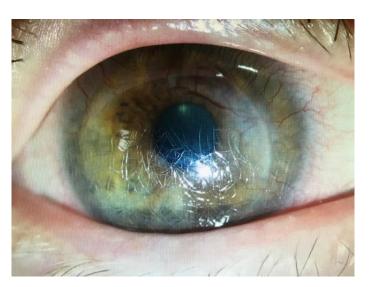


Don't forget about Scleral Lens Care & Compliance









Care & Compliance

- Use approved non-preserved saline for filling
- Disinfect lenses daily
 - Avoid certain cleaners
- Store in approved solutions
- Do not sleep in lenses
- Return to provider for routine evaluation
 - Warpage, chips, cracks, scratches
- Ask to see their cases and products
- Consider extra monthly cleaning

Show your supplies!





Scleral Lens Filling Solutions

- Off-label:
 - 0.9% NaCl Inhalation saline NB (3, 5, 15 mL)
 - Addipak, Modudose
 - NPATs
- FDA approved
 - Lacripure 5 mL NB (Menicon, 2016)
 - ScleralFil 10 mL B (Bausch + Lomb, 2017)
 - NutriFill 10 mL (Contamac, 2020)
 - VibrantVue 5 mL NB (VibrantVue, 2020)
 - PuriLens Plus Saline 120 mL/ 4 oz B (The LifeStyle Company, 2021)
 - PuriLens Mini (60 mL/ 2 oz)













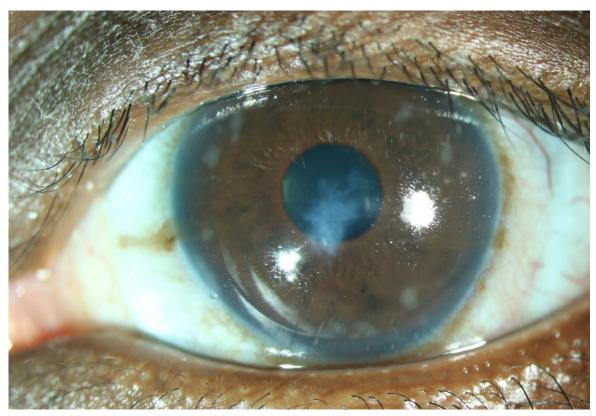
Do NOT fill scleral lenses with

- Preserved saline
- Preserved artificial tears
- Gas permeable soaking solutions
- SCL Multipurpose solutions
- GP Multipurpose solutions
- Peroxide solutions
- Will lead to surface toxicity

DO NOT USE	

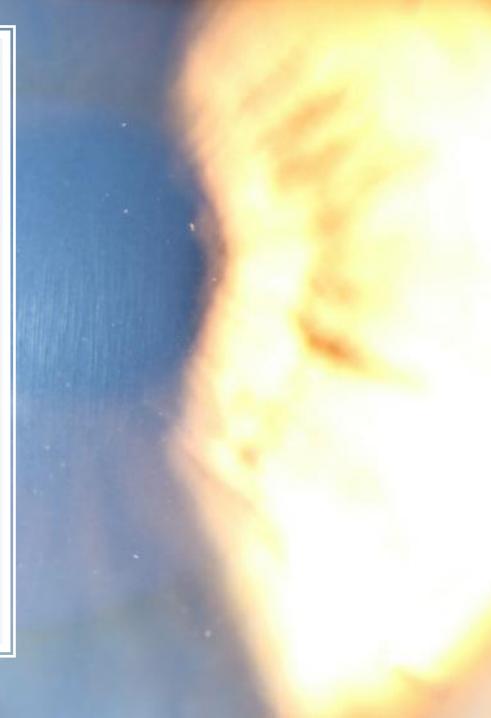
CLARE with Overnight Scleral Lens Wear





Summary

- Keratoconus is progressive
 - Evolves through stages
- Must diagnosis early & offer Tx to halt progression
 - Must treat vision and disease, separately
- Treatment depends on disease severity
 - Surgical or visual
- Many CL options available to optimize vision
- Scleral lenses are AWESOME
 - May not always be necessary
 - When utilized, we have advanced techniques to optimize fit and vision
 - CL care and compliance is important





Thank You!

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