

The OD and MD Role in Managing Laser Corneal Refractive Surgery and Implantable Collamer Lens-Based Procedures

COPE Category: AS

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Abstract:

This section will discuss laser technologies such as excimer and femtosecond lasers and the primary corneal-based refractive procedures, LASIK, PRK, and SMILE and intraocular ICL. We will discuss considerations for myopic, hyperopic, astigmatic, and presbyopic correction. Additionally, we will touch briefly on corneal inlay evolution and prospective procedures currently in clinical trials.

Course Learning Objectives:

1. Understand excimer and femtosecond laser technologies used in cornea-based refractive surgery: LASIK, PRK, and SMILE
2. Understand phakic ICL procedures
3. Discuss new advances in refractive surgery and upcoming treatments under development

Outline:

1. General refractive landscape
 - a. Correction for everything
 - i. Myopia
 - ii. Hyperopia
 - iii. Astigmatism
 - iv. Presbyopia
 1. Irregular Astigmatism?
 2. Advances in technology have lead to the treatments we see today
 - a. Significant work in diagnostics to improve the evaluation for patients
 - i. Why care?
 1. Rule out corneal based surgery
 - a. Possibility of iatrogenic disease
 - i. Alternative surgical options
 1. Lens-based refractive surgery
 - b. Forgo elective surgery all together
 2. Follow up more frequently
3. Corneal refractive surgery
 - a. History and origin of modern refractive surgery
 - i. Jose Barraquer
 1. Father of modern refractive surgery
 - a. Proposed that the term refractive keratoplasty

- i. Keratomileusis
 - ii. Keratophakia
 - 2. Procedure evolution
 - a. Radial keratotomy
 - i. First by hand
 - 1. LRI for astigmatism
 - a. Evolve to femtosecond laser
 - 2. Radial keratotomy for myopia and astigmatism
 - b. Excimer laser
 - i. Data input
 - 1. Wavefront optimized
 - 2. Wavefront-guided
 - 3. Topography guided
 - c. Thermal
 - i. Conductive keratoplasty
 - 1. Radiowave to create collagen shrinkage
 - 2. FDA approval
 - a. Hersh et al 2002
 - d. Femtosecond laser
 - i. Flap
 - ii. Lenticule
- 4. Cornea-based refractive surgery
 - a. Laser
 - i. First application of laser in health care was ophthalmology
 - 1. Light amplification by stimulated emission of radiation
 - a. First application was used in retina
 - i. L'Esperance et al 1968
 - 1. Pulsed ruby
 - a. Commercially available in 1971
 - 2. First application to the cornea
 - a. Excimer laser
 - i. Ablation of corneal tissue
 - 1. No collateral tissue damage
 - ii. FDA approval
 - 1. Hersh et al 1996
 - a. Myopia
 - b. Femtosecond laser
 - i. Caviations principle to separate tissue
 - 1. FDA approval 2000
 - a. Lamellar flaps
 - 2. FDA approval 2007
 - a. Myopia

- b. Modern surgical approach
 - i. Excimer laser
 - 1. Early development
 - a. Wavelength
 - 2. Stromal ablation
 - a. Surface ablation
 - i. Photorefractive keratectomy (PRK)
 - 1. Removal of epithelium followed by ablation
 - b. Lamellar dissection
 - i. Laser assisted in situ keratomileusis (LASIK)
 - 1. Flap creation to expose stromal bed followed by ablation
 - a. Microkeratome
 - b. Femtosecond laser
 - 3. Wavefront optimized
 - a. Algorithmic eccentricity to reduce aberrations
 - 4. Wavefront-guided
 - a. Aberrometry data input to create custom ablation for the treatment of total optical aberrations
 - 5. Topography guided
 - a. Topography data input to create custom ablations for smoothing of anterior corneal surface irregularity
 - 6. Tomography guided
 - a. Tomography data input to create a surface ablation for total corneal aberrations
 - i. Advanced algorithms with anterior and posterior curvature calculations
 - ii. Femtosecond laser
 - 1. Intrastromal lenticule
 - a. Small Incision Lenticule Extraction (SMILE)
 - i. Lenticule formed within the anterior stroma and removed
- c. Intraocular procedures
 - i. Phakic ICL
 - 1. Maintains crystalline lens
 - a. Maintains accommodation
 - 2. Multiple placements of lens
 - a. Anterior chamber
 - i. Iris claw
 - 1. Seldom used
 - b. Posterior sulcus
 - 3. ICL technology
 - a. Monofocal

- b. Toric
 - 4. Adjunctive procedures
 - a. Phakic ICL
 - i. Pre-op peripheral iridotomy
 - 1. Prevent IOP increase
 - a. New lenses contain an aqueous pass-through
 - b. PI no longer needed
- d. Near future procedure
 - i. LIKE
 - 1. Lamellar flap created
 - a. Pre-prepared allograft stromal lenticule laid on bowmans
 - b. The flap is then replaced
 - i. 8 weeks to stabilize
 - 1. If needed, the flap is re-lifted and a final touch-up laser correction on the LIKE lenticule is performed.
 - a. US clinical trial ongoing
 - 2. Indication
 - a. Hyperopia correction of 4+ diopters
 - i. Fully reversible procedure
 - ii. Large optical zone of 7+ mm
 - 1. Less aberration
 - ii. Refractive cross-linking
 - 1. Patterned biomechanical change for inducing cornea curvature changes
- e. In the lab
 - i. Dual photon femtosecond laser
 - 1. Sub-cavitation
 - a. Ionizing tissue, create singlet oxygen
 - i. Increased tissue strength
 - 1. Guo et al 2016
 - 2. Wang et al 2017
 - a. Laboratory only
 - ii. New treatment for both lens and cornea
 - 1. Laser-Induced Refractive Index Correction (LIRIC)
 - a. Low-energy, high-repetition-rate femtosecond laser
 - b. Fresnel lens patterns to correct presbyopia, myopia, hyperopia, astigmatism, and higher-order aberrations.
 - i. Cornea = intrastromal
 - ii. IOL = intraoptic
 - iii. Contact lens = intra material
 - 1. OUS studies underway

iii. FAQ

1. What happens if the refractive target is missed?

a. Enhancements

i. After PRK

1. PRK

ii. After LASIK

1. Relift flap and ablate

2. PRK surface ablation

iii. After SMILE

1. PRK surface ablation

iv. After lens based refractive surgery

1. Cornea based refractive surgery is key to refining vision

iv. Presbyopia

1. Considerations

a. Presence of pathology

i. Cataract

2. Cornea based treatment

a. Current

i. High eccentricity ablation

1. Reinstein

ii. Blended vision

1. Reinstein binocularity studies

2. Limitation

iii. Synthetic inlays

1. Methods

a. Raindrop (ReVision Optics)

i. FDA approval 2016

ii. Center near (hyperprolate)

b. Flexivue microlens (Presbia)

i. Clinical trial

ii. Center distance

c. KAMRA (AcuFocus)

i. FDA approval 2016

ii. Pinhole

2. Failure of inlays

a. Biocompatibility issues

i. Inlays block glucose from the posterior and oxygen from anterior

ii. May cause haze, regression, need for prolonged corticosteroids, glare, halo,

- dimness, corneal melt,
interface deposits and
material buildup
- iii. Raindrop FDA recall
- iv. Flexivue microlens clinical
trial abandoned
- v. KAMRA generally not used
- b. Multiple cases of haze and
complications documented
- c. All inlays are in line of sight =
visually impactful complications

b. Future

i. Corneal tissue inlays

1. Theoretically enhanced biocompatibility
2. Presbyopic inlays based on SMILE

Lenticule transfers studies

- a. Jacob et al. = PEARL = Hyper
Prolate Shape
 - i. Pocket insertion
- b. Lui et al
 - i. Allograft vs Xenograft vs
Decellularized Xenograft
 - ii. Placed under a flap
 - iii. Well tolerated with De-cell
Xeno and Allo
 - iv. Haze with Xeno lasting 6
months
- c. Banking SMILE tissue in US fraught
with issues
 - i. How to overcome it?
 - ii. Sterilized allogeneic corneal
tissue

ii. Commercially prepared corneal tissue inlays and
onlays of sterilized allogeneic corneal tissue

1. Femtosecond laser shaped
2. Single cornea = multiple lenticules
3. 2-year shelf life
4. Phase 2 Study
 - a. Multicenter EU
 - b. Highly effective and safe
 - c. Binocular
 - d. No loss of UCVA
 - e. 2 line improvement in UCVA

- f. 5 line improvement in UCNVA
 - i. US Phase 3 coming soon

Collaboration Care Symposium
“Better Together: A Unified Approach to Refractive Surgery and Keratoconus Management”
Better Together Part 1: The OD and MD role in Dry Eye, Blepharitis, and Ocular Surface
Disease Management

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Course Description:

This course is directed towards eye care providers with an interest in perioperative (cataract and refractive surgery) dry management to provide critical high-quality vision. There will be an emphasis in advancements in dry eye detection and the roles of optometry and ophthalmology in the treatment plan. Participants will be introduced to the new dry eye disease (DED) algorithm to improve outcomes, patient satisfaction, and reduce chair time.

Course Learning Objective

- To review new understanding of Ocular Surface Disease (OSD).
- To assess best practices in implementing a dry eye disease (DED) algorithm.
- To discuss the importance of perioperative dry eye treatment.
- To understand the roles played by Ophthalmology and Optometry in ocular surface disease management.
- To review perioperative cases.

A. Background

1. New understanding of Ocular Surface Disease (OSD)
 - a. TFOS DEWs, DEWSII
 - b. Surveys
 - c. Initiatives
2. Ocular Surface is critical for vision
 - a. Tear film is most one of most important refracting interface in the eye
 - i. Optical power
 - ii. Retinal image quality
 - iii. Hyperosmolarity → variable keratometry and IOL error
 - b. Visual fluctuations are pathognomic of dry eye disease (DED)
 - c. Visual quality is worse in DED
 - d. Case

B. OSD likely exists in your Pre-op patients...

1. Prospective Health Assessment of Cataract Patient's Ocular Surface (PHACO) Study
 - a. 64% abnormal TBUT, 77% abnormal corneal staining
 - b. Only 13% symptomatic
 - c. Asymptomatic group → 85% at least one abnormal test, 48% both
2. Why care so much about OSD...Surgical complication risks
 - a. Untreated blepharitis may increase the risk of endophthalmitis
 - i. Staph, strep, MRSA, etc
 - b. Demodex (collarettes): while it doesn't directly cause endophthalmitis, there is typically a higher bacterial load/biofilm when present
 - c. Cataract the Refractive Surgery will worsen DED
3. Summary
 - a. OSD is present in many of your cataract patients (often asymptomatic)
 - b. OSD reduces the accuracy of your pre&post op refractive measurements
 - c. OSD reduces visual quality, quantity, & performance
 - d. Blepharitis/biofilms may increase risk of endophthalmitis
 - e. Any eye surgery will worsen DED/OSD

C. What do we do about it?

1. Era of the Algorithm
 - a. Goal
 - i. consensus and evidence-based
 - ii. to be integrated into the preoperative surgery visit
 - iii. reduce chair time
 - iv. to identify all visually significant subtypes of OSD prior to surgery

- b. definition of algorithm
- c. need for OSD/DED algorithm today
- 2. Preoperative OSD Algorithm
 - a. Preoperative visit
 - i. At least 2 week CL holiday / no drops within 2 hours prior
 - ii. Last chance to identify OSD
 - b. OD or MD visit
 - c. Step 1: Non-invasive Refractive Tests
 - i. Cataracts: optical biometry, keratometry, tomography/topography, etc
 - ii. LVC: aberrometry, topography
 - iii. Repeat measurements if visually significant OSD (VS-OSD) detected
 - d. Step 2: OSD (not just DED) Screening Battery
 - i. Any subtype of OSD (eg DED, allergy, EBMD, pterygia, exposure, floppy eyelids, etc) can be potentially visually significant and should be identified and treated preoperatively
 - ii. Symptoms (novel questionnaire) + signs (osmolality and MMP-9)
 - 1. SPEED II Preop OSD Questionnaire
 - a. Extra questions to identify non-DED OSD subtypes and VS-OSD
 - 2. Osmolality and MMP-9
 - a. Osmolarity = DED, MMP-9 = non-specific inflammatory marker of OSD
 - b. Predictive value for DED and non-DED OSD
 - 3. Most important in preoperative patients
 - 4. If both normal = OSD unlikely. If anyone abnormal then OSD likely
 - a. If abnormal identify subtypes
 - i. Possible further objective testing
 - e. Step 3: directed quick exam to assess for VS-OSD
 - i. LLPP: look, lift, pull, push
 - ii. Stain
 - f. Step 4: OSD ruled in or out?
 - i. If ruled in, determine visual significance
 - 1. Non-visually significant
 - a. Surgery proceeds and refractive plan can be finalized
 - b. Counsel patient that OSD may worsen, start prophylactic treatment
 - 2. Visually significant OSD
 - a. Surgery and refractive plan delayed
 - b. Counsel patient on OSD/impact on surgery
 - c. Start aggressive treatment to minimize delay
 - 3. Neurotrophic cornea
 - g. Step 5: treat VS-OSD

- i. Based on OSD subtypes and severity
 - ii. Overall more aggressive therapy than routine OSD
 - iii. Start at TFOS DEWS II Step 2 or 3 than step 1
 - iv. Prescription medications (eg steroids immunomodulators, antibiotics)
 - v. Procedural treatments (blepharoexfoliation, thermal pulsation. IPL, amnion, plugs, contacts lenses etc.)
 - vi. Follow-up in 2-4 weeks, follow-up algorithm from the beginning
 - vii. Proceed with surgery only when VS-OSD is converted to NVS-OSD
 - h. Roles
 - i. MD and OD during pre-operative visit
 - ii. Utilize ancillary staff and objective testing
- 3. Cases

Setting the Stage: Refractive Surgery Considerations and How Myopia Management Fits In

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Abstract:

This course will cover the concept of vision for a lifetime and the importance of collaborative care. We will review strategies for myopia management and the positive impact it has on refractive procedures. Myopia management may play an increasingly important role in the future of refractive surgery.

Course Learning Objectives:

1. Understand the options for surgical and non-surgical vision correction for each stage of life
2. Learn about current and future techniques for the management of myopia
3. Understand how myopia management expands options and improves outcomes in refractive surgery

Outline:

1. Refractive surgery across a lifetime
 - a. 1st & 2nd Decade
 - i. Ocular Development
 1. Axial Elongation Prevention and Rx correction
 - a. Orthokeratology
 - b. Defocus Contact Lens
 - c. Defocus Spectacle
 - d. Pharmaceutical
 - b. 3rd & 4th Decade
 - i. Ocular Maturity
 1. Rx correction
 - a. PRK
 - b. LASIK
 - c. SMILE
 - d. ICL
 - c. 4th & 5th Decade
 - i. Presbyopia (Dysfunctional Lens Syndrome)
 1. Rx correction
 - a. PRK
 - b. LASIK
 - c. SMILE
 - d. Corneal Inlay
 - e. ICL

- f. IOL
 - g. Pharmaceutical
 - d. 6th Decade & Up
 - i. Cataract
 - 1. Cataract extraction and Rx correction
 - a. IOL
 - 2. Presence of lens pathology
 - a. Cure and treatment
2. Myopia
 - a. Myopia
 - i. Prevalence by age (Theophanous 2018)
 - 1. 5 to 7: 15%
 - 2. 8 to 10: 33%
 - 3. 11 to 13: 49%
 - 4. 14 to 16: 56%
 - ii. Pre-myopia and predictors of myopia (Zadnik 2015)
 - 1. Myopia onset
 - iii. Annual progression rates
 - 1. School-aged children (Donovan 2013)
 - 2. Young to middle-aged adults (Lee 2020)
 - b. Considerations in refractive surgery
 - i. Level of myopia
 - 1. General concerns
 - a. Myopic maculopathy
 - i. Inability to correct vision due to disease
 - 2. Concern in lens-based
 - a. Retinal detachment
 - 3. Concern in cornea based
 - a. Iatrogenic ectasia
 - ii. Why utilize treatments to slow myopia progression?
 - 1. Important to refractive surgery
 - a. Improved outcomes at lower levels
 - b. Less chance of complications
 - c. Primary management strategies
 - i. IMI White papers
 - ii. Walline et al in 2020
 - 1. Soft lens: dual focus, multifocal, custom
 - a. Omafilcon A: Only FDA approved option
 - i. US FDA Approval: Slow the progression of nearsightedness in children and correction of refractive error
 - b. Daily disposable
 - c. Age 8-12 years at the initiation of treatment

- d. Power -0.50D to -6.00D
 - e. Chamberlain et al 2019
 - i. Spherical equivalent refraction: -0.73 D (59%) less
 - ii. Mean axial length: 0.32 mm (52%) less
 - 2. Orthokeratology: standard, custom
 - a. Bullimore et. al in 2020
 - b. US FDA Approval: Temporary correction of myopic refractive error
 - i. No age restrictions
 - ii. Approved gas permeable material for overnight wear
 - c. THERE IS NO US FDA APPROVAL FOR SLOWING THE RATE OF AXIAL LENGTH ELONGATION... however
 - d. Internationally, several designs carry this indication for SLOWING THE RATE OF AXIAL LENGTH ELONGATION and large bodies of literature supporting this
 - 3. Defocus Spectacles
 - a. Zhang et al DIMS
 - i. 59% less myopic progression
 - ii. 60% less axial elongation
 - 4. Low dose atropine: concentrations
 - a. ATOM
 - b. ATOM
 - c. LAMP
 - i. Yam et al LAMP
 - 1. 0.05% atropine was most effective
 - a. 3-year data including washout effects
- d. Apply the principles of refractive surgery
 - i. Multiple targets and techniques
 - 1. Choose treatment target based on multiple factors
 - a. Prescription
 - b. Risk factors
 - i. Suspicious cornea?
 - 1. Avoid cornea
 - 2. Need for combination treatment
 - ii. Myopia Management vs Refractive Surgery
 - 1. Cornea
 - a. Orthokeratology
 - b. LASIK
 - c. PRK
 - d. SMILE
 - 2. Non Cornea

- a. Defocus Contact Lens
 - b. Defocus Spectacles
 - c. *Atropine
 - d. RLE
 - e. ICL
 - f. *Pilocarpine
- e. Pediatric cornea-based refractive surgery?
- i. An ongoing study in the US

Implementing Collaborative Care into Your Practice: The Blueprint for Success

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Course Outline

1. Define Optometric surgical co-management
 - a. Review what a 3-party agreement means
 - b. Reasons for co-management
2. Choosing a surgeon
 - a. Treatment philosophy
 - b. Surgical skills
 - c. Office & surgical staff
 - d. Technology available
3. Making the referral
 - a. Referral letter
 - b. Pre-operative information
4. Communication with Surgeon
 - a. Type of surgery
 - b. Target of surgery
 - c. Key patient attributes
5. Cataract & Refractive Cataract Pre-op
 - a. Mandatory data vs optional data
 - b. Patient discussion
 - c. Risks, Benefits & Alternative
 - d. Medications
 - e. Dry eye care/status
 - f. Follow-up care
 - g. Chart documentation
6. Corneal Refractive Surgery Pre-op
 - a. Mandatory data vs optional data
 - b. Patient discussion
 - c. Risks, Benefits & Alternative
 - d. Medications
 - e. Dry Eye care/status
 - f. Follow-up care
 - g. Chart documentation
7. Corneal Cross-Linking Pre-op Care
 - a. Mandatory data vs optional data

- b. Patient discussion and expectation setting
 - c. Risks, benefits & alternative
 - d. Topography or tomography
- 8. Cataract & Refractive Cataract Post-op care
 - a. Post-op visits and testing
 - b. Additional testing for premium IOLs
 - c. When to return to operating surgeon
- 9. Corneal Refractive Surgery Post-op Care
 - a. Post-op visits and testing
 - b. When to return to operating surgeon
- 10. Collagen CXL Post-op care
 - a. Post-op visits and testing
 - b. Return to contact lenses
- 11. Fee Structure
 - a. Fees = services provided
 - b. Insurance based Standard Cataract surgery – monofocal implant
 - c. Premium Cataract Surgery
 - i. FLACS
 - ii. Toric IOLs
 - iii. MF & EDOF IOLs
- 12. Transfer of Care
- 13. Summary of Co-management Guidelines

Course Title: Focusing in on Presbyopia Therapeutic and Surgical Care
Presenters: Daniel Terveen, MD and Larae Zimprich, OD

Course Description: This course will discuss some of the newest innovations in intraocular lens implants that are available to patients. It will answer some of the most common questions that providers encounter from deciding what implant is best for meeting the visual goals of each individual, to managing and treating patients post operatively.

Course Objectives

- Understand key preoperative cataract considerations the OD needs to address before making a referral for cataract surgery
 - Understand current and future IOL options available
 - Understand the current and future technology associated with cataract surgery
 - Understand cataract surgery drug delivery considerations to improve patient compliance with postoperative medications
 - Understand how to manage the unhappy postoperative cataract patient
 - Understand how to manage a variety of postoperative complications associated with cataract surgery
1. Pre-op history considerations
 - a. Personality
 - b. Prior refractive surgery
 - i. Must have an ability to enhance patient post operatively
 - c. Trends in presbyopia adoption
 2. Pre-operative testing
 - a. Emerging Presbyopia curve
 - b. Review the pre-operative workup focusing on the importance of Higher Order Abberations (HOA)
 - c. Preparing ocular surface
 - i. Dry eye questionnaire and treatment algorithm
 3. Getting patients to the finish line with enhancement
 - a. Discuss optics of IOLs and why emmetropia is important
 - b. Review study on low level enhancements
 - c. Influence of epi mapping on patient selection
 4. Brief overview of our current IOLs and experience
 - a. Landscape of presbyopia correcting IOL and defocus curves
 - b. Mike Greenwood ORA study
 - c. Case 1: Patient that chooses trifocal IOL
 - i. High near demands
 - ii. Healthy eye with minimal pathology
 - d. Case 2: Patient with mild glaucoma that choose EDOF
 - i. Vivity in Glaucoma Study review

- ii. Patient with less near demands or less tolerance for dysphotopsias.
- 5. In depth review of LAL and LAL+ and our experience
 - a. Discuss papers on LAL in prior refractive
 - b. When to adjust
 - c. What are the typical post operative expectations
 - d. How to use the IOL in patients with challenging eyes
 - e. LAL with DMEK
 - f. Prior RK case
- 6. Future presbyopia IOL technologies
 - a. Juvene
 - i. Review early results and upcoming clinical trial
 - b. IC-8, VTV case report under PKP
 - i. Review data and potential patient selection.
- 7. Presbyopia drops
 - a. Options
 - b. Our experience in the clinical trials
 - c. How we are using the drops in our practice
- 8. Comanaging Considerations
 - a. Discuss the 4-step process that go into Advanced IOL implants
 - b. Step 1: Cataract surgery, proper expectations
 - i. Residual Rx?
 - ii. Temp glasses?
 - c. Step 2: YAG?
 - i. RGP OR
 - d. Step 3: Fine Tune? LASIK/PRK?
 - i. Does it matter if it is LASIK or PRK?
 - e. Step 4: Neuroadaptation
 - i. Sometimes a year long process

Better Together Part 3: Keratoconus 1,2,3: Stop Progression, Improve Topography, Restore Vision

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Abstract:

The management of keratoconus is ever-evolving. This course aims to address the comprehensive visual needs of the keratoconus patient and the importance of both surgical procedures and contact lenses. This case-based course will review the management and treatment of patients with keratoconus with new and innovative therapies.

Course Learning Objectives:

1. Learn about new surgical and contact lens management for keratoconus
2. Understand that contact lens vision is only one part of the patient's visual needs
3. To show the importance of MD and OD collaboration in the comprehensive management of keratoconus

Outline:

1. Brief Keratoconus Background
2. Core Concepts in Modern Keratoconus Management
 - a. Diagnose early, Stop progression, Rehabilitate vision.
 - i. Diagnose early
 1. Modern devices
 - a. Refractions in early KC
 - i. Present CLEI Study on KC and Refractive Axis
 - b. Keratoconus 1,2,3
 - i. Stabilize
 1. CXL
 - ii. Enhance
 1. Surgical interventions
 - a. Inlay
 - b. Excimer
 - i. Corneal curvature
 - ii. UCVA and BSCVA
 - iii. Correct
 1. Specialty contact lenses
 - a. BCLVA

2. Glasses
 3. Lens-based surgery
3. Stabilize
 - a. CXL
 - i. CXL origins
 1. Spoerl et
 - a. ex-vivo tissue strain
 - i. Ribo, 365 nm, 45 mins best result
 2. Meek et al and Wollensack et al
 - a. Collagen molecules at the surface of fibrils
 - i. Within/between proteoglycans in individual fibril or adjacent fibrils
 1. Collagen-proteoglycan matrix
 3. Wollensack et al
 - a. Prospective study
 - i. Pre-op: Progressive
 - ii. Post-op: Regressive
 - b. Tradition KC Management in the US
 - i. Review
 - ii. CXL is a paradigm shift in KC Management
 - iii. Review FDA approval
 - c. CXL for KC benefits
 - i. Stop progression
 - ii. Cost-Benefit
 1. Lindstrom RL et al
 - a. Lifetime economic model
 - d. Review FDA clinical trial data
 - i. Hersh PS, et al
 1. United States Multicenter Clinical Trial of Corneal Collagen Crosslinking for Keratoconus Treatment
 - a. Expected corneal changes
 - i. Kmax
 1. Greenstein SA et al
 - a. Flattening by 1.7D
 - ii. VA
 1. Improvement by approximately 1 line UCVA and BCSVA
 2. Brooks NO et al,
 - a. Patient subjective visual function
 - iii. Haze
 1. Transient
 - a. Back to baseline by month 6
 2. Demarcation line

- a. Depth of effect
 - 3. Greenstein SA et al
 - a. Natural history of corneal haze
 - iv. Corneal Thickness
 - 1. Thinner initially then back to baseline
 - v. Endothelial Cell
 - 1. No change
 - b. 10 year FDA CXL Trial Follow Up
 - i. KC stable over 10 years
 - ii. Ectasia has less progression than untreated
 - 1. More unstable
 - a. More frequent follow up
4. Enhance
 - a. Goals
 - i. Improve corneal symmetry
 - ii. Improve non CL vision = more functional when not wearing CL
 - 1. Improve BCSVA
 - 2. Improved UCVA
 - iii. Options
 - 1. Intacs
 - a. PMMA arc segment implant
 - i. Hersh et al
 - 1. CXL and Intacs
 - a. Sequential vs concurrent
 - i. No difference
 - ii. Limitations
 - 1. Fixed parameters
 - 2. Gross change
 - 3. Biocompatibility
 - a. Nyguyen et al
 - i. Explantation rates
 - iii. Role is changing
 - 1. Seldomly used
 - 2. Poor outcomes with stability
 - a. Newer options
 - 2. PRK
 - a. TGPRK
 - i. Ablation based on topography
 - 1. Corneal curvature
 - a. Kanellopolous et al
 - b. Nattis et al
 - ii. Precise

1. Limited by corneal thickness/removal of corneal tissue
 - iii. Present CLEI study on TGPRK
 3. Allogeneic Inlays
 - a. The use of corneal tissue inlays have been explored
 - i. Sun et al
 1. SMILE Lenticule implantation
 - ii. Jacob et al
 1. Fresh tissue
 - a. Manual cut
 - b. Intacs segment shape
 - b. Limitation in the US due to tissue bank regulations
 - i. Greenstein et al
 1. CTAK
 - a. Sterilized Tissue
 - b. Fully customized
 - c. Sterilized allograft corneal tissue inlay
 - i. Biocompatibility
 - d. Massive change
 - i. Precise/Gross
 4. Corneal Transplants
 - a. Last resort
 - i. DALK vs PK
5. Correct
 - a. Contact lenses
 - i. Goals
 1. Improve vision while wearing
 - a. Does NOT stop progression
 - ii. Options
 1. Soft
 2. Hybrid
 3. GP
 4. PB
 5. Scleral
 - iii. CLEI Study on corneal factors in lens selection
 1. >10D IS, >55Kmax, >50Kmean
 - a. Scleral and PB
 2. <10D IS, <55Kmax, <50Kmean
 - a. BCVA better than 20/30
 - i. Soft and Custom Soft
 - b. BCVA 20/30 or worse
 - i. GP and Hybrid
 3. Predominantly used lenses

- a. Scleral and Custom Soft
 - b. Cataract Surgery/ICL in KC
 - i. Goals are important
 - ii. Potential to significantly reduce RX
 - iii. Sequential procedures
 - 1. Performed after TGPRK/Intacs/CTAK
 - a. More symmetry = more accurate K's = better outcomes
6. Impact of 1,2,3 approach on CL fitting
 - a. CLEI Study on corneal surgery
 - i. Intacs 7D Max Flattening
 - ii. TGPRK 4D Max Flattening
 - iii. CTAK up to 20D Max Flattening
 - 1. Opportunity to move to a less complex lens
 - b. Surgery Influence on Lens Selection
 - i. Intacs
 - 1. Soft and Vaulting Designs
 - a. Avoid "plastic sandwich" = CL rub tissue over segment
 - i. PS leads to tissue disruption, inflammation, neo, extrusion
 - ii. TGPRK
 - 1. More symmetry = lower IS, Kmax, Kmean
 - a. Present CLEI data on lenses before and after
 - iii. CTAK
 - 1. More symmetry = lower IS, Kmax, Kmean
 - a. Current CLEI data on lenses before and after
7. CASES:
 - a. Hx 30 yo M with Moderate Keratoconus + Scleral Lens
 - i. Progressive KC
 - 1. Intacs + CXL
 - a. Improved symmetry & stop progression
 - i. Improved BCSVA and balanced
 - 2. Post Sx = Scleral lenses still the best choice
 - a. BCLVA = 20/30
 - i. +HOA Scleral
 - 1. BCLVA = 20/20
 - a. Pt experience
 - i. Improved QoL
 - ii. Take away:
 - 1. Yes, it still needs a scleral; the goal of Sx is not to eliminate CL, rather VA improved and balanced with glasses
 - a. More functional
 - b. Hx 32 yo M with Severe KC + Intacs
 - i. Pt unhappy with VA after Intacs hates CL

1. TGPRK
 - a. UCVA 20/100 and BCVA 20/40
2. Custom soft
 - a. BCLVA 20/25
 - i. Pt experience
 1. Thrilled, glasses or CL
 - ii. Take away:
 1. Can improve VA after Intacs
 - a. More functional
- c. Hx 70 yo F with Moderate Keratoconus + Cataract + Scleral
 - i. No improvement with CL and very unhappy with Scleral
 1. Refer for CE
 - a. Sequential procedure
 - i. TGPRK = improved symmetry
 - ii. CE = 20/60 UCVA
 1. BCSVA = 20/30-
 - b. Custom Soft now possible
 - i. BCLVA = 20/25+
 - a. Pt experience
 - i. Functional all the time
 - ii. Improved QoL
 - ii. Take away:
 1. Sequential procedures can improve symmetry allowing for improved IOL calc = better out comes and less complex CL
 - d. Hx 35 yo M with Severe Keratoconus + TECXL (C3R) + CXL
 - i. Progressive
 1. Refer for CXL
 - a. Repeat TECXL
 - i. Too thin for other intervention
 2. Scleral lens
 - a. BCLVA = 20/50
 - i. +HOA = 20/30
 1. Pt experience
 - a. Less stress about vision
 - i. Improved QoL
 - e. Hx 22 yo M with Aysmetric Severe Keratoconus and FF Keratoconus + Scleral
 - i. Scleral lens OD and Soft OS
 1. BCLVA OD 20/20 and OS 20/40
 - a. Unhappy when not wearing Scleral
 - i. CTAK
 1. Massive curvature change 25D
 - a. UCVA 20/60 from CF
 - ii. Custom soft

8. Conclusion

- a. Diagnose early, Stop progression, Rehabilitate vision.
 - i. Stop Progression
 - 1. CXL
 - ii. Rehabilitate Vision
 - 1. Specialty contact lenses
 - 2. Refractive/Surgical interventions
 - a. BETTER TOGETHER
 - iii. Don't Fear Corneal Transplantation
 - 1. Modern transplantation

Legal and Regulatory Considerations for Co-Managed Patient Care

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Summary

Co-management or the shared care of surgical patients is not unique to ophthalmology. Many medical specialties rely upon collaborative surgical care models where patients' post-operative care management is a team effort between surgeons and other health care professionals. This program will explore the risks, case studies, and lessons learned.

Objectives

Participants will be able to:

- To understand the legal risks attendant to co-management relationships
- To evaluate the number of laws and regulations applicable to co-management and best practices for compliance
- To prepare to make changes in current business as needed

Outline

- I. What is co-management
- II. Regulation of co-managed care
 - Define co-managed patient care: Explain the collaborative model where healthcare providers share responsibility for a patient's care across different settings or specialties
 - Professional licensing boards
 - Discuss variations in state licensing requirements and regulations for different healthcare providers involved in co-managed care.
 - Highlight considerations for ensuring provider credentialing and compliance with state regulations.
 - State and federal law
 - Payor rules
- III. Key laws and regulations
 - Federal and state anti-kickback laws
 - Anti-kickback Statute (AKS):

- Explain the prohibition on inducing referrals through financial remuneration.
 - Analyze how co-management arrangements, particularly incentive payments, may raise AKS concerns.
 - Discuss safe harbors and mitigation strategies to comply with AKS.
 - Stark Law:
 - Summarize the prohibition on physician self-referrals for designated health services (DHS) to entities with which they have financial relationships.
 - Identify potential Stark violations in co-managed settings, such as joint ventures or shared profits.
 - Examine exceptions and best practices for ensuring Stark compliance.
- Federal False Claims Act
 - Explain the liability for knowingly submitting false or fraudulent claims to receive federal healthcare payments.
 - Illustrate how co-managed care could inadvertently lead to violations, such as upcoding or unnecessary services.
 - Emphasize the importance of documentation, compliance plans, and training to prevent FCA violations.
- Application to covered and non-covered procedures

IV. Scrutiny of co-management

- Past
 - Congressional inquiry
 - Office of the Inspector General
- Present
 - Department of Justice/US Attorneys' Offices/Whistleblowers
 - Public scrutiny

V. Discussion of False Claims Act Settlements in 2023

- Texas
- Rhode Island
- Tennessee

VI. Lessons Learned and Best Practices

- Patient consent
- Payments for non-covered services must be fair market value
- Documentation of additional services

- Collateral benefits can heighten legal risk

Course Title: The Best of Both Worlds: Managing Refractive/Cataract Surgery and MIGS Patients

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Course Outline:

- 1) Discuss the trends in surgical glaucoma care.
 - a) Earlier intervention surgically
 - b) New procedures that are gaining market share
 - i) Market scope data
 - c) Problems with drop compliance and effectiveness
 - i) Data on decreasing effectiveness with increasing medications
- 2) Discuss our approach to glaucoma patients.
 - a) Early, Predictive Diagnostics
 - i) Risk factor analysis
 - ii) Ocular biomechanics
 - iii) OCT (RNFL)
 - iv) Tonometry
 - v) Visual Fields
 - vi) Digital health
 - vii) Genetic Testing
 - viii) Use of AI
 - b) Active Advanced Monitoring
 - i) Regularly scheduled follow up visits
 - ii) Robust structural and functional progression analytics
 - iii) Detecting apoptosing retinal cells (DARC)
 - iv) Acquire more data:
 - (1) Home Monitoring
 - (2) Intraocular Sensors
 - c) Early, Procedural Intervention
 - i) Laser
 - ii) MIGS
 - iii) Drug Delivery
 - iv) Micro-invasive bleb surgery (MIBS)
 - d) Surgical options and case-based approach for patients that present with glaucoma and cataract.
 - i) Trabecular Micro-Bypass Stents
 - (1) iStent TM Bypass Stent
 - (a) Meta-analysis Data

- (b) Trabecular micro-bypass stent implantation during small-incision surgery for open-angle glaucoma or ocular hypertension: Long term results. Journal of Cataract and Refractive Surgery 2015
 - (c) A prospective 3-year follow-up trial of two trabecular microbypass stents in open-angle glaucoma.
- (2) iStent Inject TM Bypass Stent
 - (a) Is 2 better than 1?
 - (b) FDA Pivotal Trial – Samuelson et al., Ophthalmology June 2019
 - (c) Long-term 3 year data – Hengerer Data
- (3) Hydrus MicroStent
 - (a) HORIZON Trial – Updated 5 year data from American Glaucoma Society Meeting
- (4) Kahook Dual Blade
 - (a) Greenwood et al. 6 month efficacy study
- (5) OMNI Surgical Procedure
 - (a) Treats all 3 points of resistance
 - (b) Stand-alone or combined with cataract extraction
 - (c) Titratable
 - (i) Sarkisian SR, Mathews, B, Ding K, Patel A, et al. 360 ab-interno trabeculotomy in refractory. Primary open-angle glaucoma. Clin Ophthalmol. 2019;13:161-168.
 - (ii) *OMNI in Open-Angle Glaucoma Treatment: An 18-month Follow-up.* Grabaska-Liberek, I et al. Presented at ESCRS 2019
- (6) XEN Gel Stent
 - (a) Ab interno approach vs Ab externo
 - (b) Xen45 US Pivotal Clinical Trial
 - (c) 65 subjects in a standalone procedure
 - (d) Significant glaucoma with MD's -15dB or greater
 - (e) Postoperative adverse event
- ii) Case of a patient with mild glaucoma and cataract
- iii) Case of a patient with moderate glaucoma and presbyopia correcting IOL
- iv) Case of a patient with severe glaucoma and cataract.
- e) Postop Considerations
 - i) Hyphema
 - (1) How to manage
 - ii) IOP Spike – 1 month post-op
 - (1) Considerations of why?
 - (2) How to handle
 - iii) PAS to stent
 - (1) How to handle
 - (2) The importance of gonioscopy
 - (3) How often should the device be examined?
 - iv) Re-establish baseline Visual fields and OCT
 - (1) Progression noted on both at 3 months

- (a) Next steps? – Another MIGS procedure vs filtration surgery
 - (b) Ideal topical glaucoma medications to consider with MIGS and continued progression
- v) Ocular Hypotony
 - (1) How to manage in the Xen patient
 - (2) Episcleral Venous Pressure
 - (a) The role it plays with MIGS procedures
- vi) Bleb management
- vii) Bleb needling
 - (1) When is it necessary and how soon in the postoperative period should it be recommended?