The 34th Annual Cornea, Contact Lens, and Contemporary Vision Care Symposium

CourseMaster: Jan Bergmanson, OD, PhD
Program Location: Westin Memorial City, 945 North Gessner Road, Houston, TX 77024

Technology – Is Your Office Updated?

SATURDAY, DECEMBER 2, 2017

Total Hours = 6 D/T & 2 General

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Speaker(s)</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>7:00 am – 8:00 am</td>
<td>REGISTRATION/CONTINENTAL BREAKFAST/VISIT EXHIBITS</td>
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<tr>
<td>8:00 am – 8:30 am</td>
<td>Therapeutics Session - Moderated by Jan Bergmanson, OD, PhD</td>
<td>Seema Nanda, MT, OD</td>
<td>DT</td>
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<tr>
<td>8:30 am – 9:00 am</td>
<td>In Office Treatment of Corneal Ulcer</td>
<td>William Townsend, OD</td>
<td>DT</td>
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<td>9:00 am – 9:30 am</td>
<td>Advances in Retina Therapeutics</td>
<td>Usha Pinninti, MD</td>
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<td>9:30 am – 9:45 am</td>
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<tr>
<td>10:15 am – 10:45 am</td>
<td>Solutions, Disinfection, and Diagnostic Session - Moderated by Seema Nanda, MT, OD</td>
<td>Rachel Redfern, OD, PhD</td>
<td>DT</td>
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<tr>
<td>10:45 am – 11:15 am</td>
<td>What Important Properties Should We Look for in Care Systems?</td>
<td>Ralph Stone, PhD</td>
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<tr>
<td>11:15 am – 11:45 am</td>
<td>Keratoconus: Early Detection and Contemporary Monitoring</td>
<td>John Gelles, OD</td>
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<td>11:45 am – 12:00 pm</td>
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<tr>
<td>1:00 pm – 1:30 pm</td>
<td>Surgery Session - Moderated by William Townsend, OD</td>
<td>Marc Sanders, MD</td>
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<td>1:30 pm – 2:00 pm</td>
<td>Update on Corneal Surgery</td>
<td>Andrew Salem, MD</td>
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<td>2:00 pm – 2:30 pm</td>
<td>Amniotic Membrane’s Ultimate Screen Protector for Your “Ocular Surface Pro”</td>
<td>Seema Nanda, MT, OD</td>
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<td>3:15 pm – 3:45 pm</td>
<td>New Trends &amp; Innovations Session - Moderated by Jan Bergmanson, OD, PhD</td>
<td>Jason Nichols, OD, MPH, PhD</td>
<td>GEN</td>
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<tr>
<td>3:45 pm – 4:15 pm</td>
<td>Myopia Control: Today’s Options and What’s on the Horizon</td>
<td>David Berntsen, OD, PhD</td>
<td>GEN</td>
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<tr>
<td>4:15 pm – 4:45 pm</td>
<td>Into the Future with Soft Lens Fitting</td>
<td>Sheila Morrison, OD, MS</td>
<td>GEN</td>
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<td>Panel Discussion</td>
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**SUNDAY, DECEMBER 3, 2017**

Total Hours = 5 D/T, 2 General, & 1 PR

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<td><strong>Dry Eye Session - Moderated by Daniel Powell, OD, MS, PhD</strong></td>
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<td>Occupational Risk Factors for Dry Eye Disease</td>
<td>William Townsend, OD</td>
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<td>9:00 am – 9:30 am</td>
<td>Lid Scrubs and Wipes – What’s New and Works</td>
<td>Anita Ticak, OD, MS</td>
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<td>9:00 am – 9:30 am</td>
<td>The DEWS and Don’ts of Dry Eye – What’s New and What’s Not in Ocular Surface Disease</td>
<td>Jason Nichols, OD, MPH, PhD</td>
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<td><strong>Scleral Session - Moderated by Sheila Morrison, OD, MS</strong></td>
<td>Melissa Barnett, OD</td>
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<td>10:45 am – 11:15 am</td>
<td>Life Beneath a Scleral Lens: The Tear Film Reservoir</td>
<td>Maria Walker, OD, MS</td>
<td>GEN</td>
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<td>11:15 am – 11:45 pm</td>
<td>What is the Corneo-Limbal Dimension?</td>
<td>Jan Bergmanson, OD, PhD</td>
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<tr>
<td>1:00 pm – 1:20 pm</td>
<td>Photography of the Anterior Segment</td>
<td>Tom Arnold, OD</td>
<td>DT</td>
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<tr>
<td>1:20 pm – 1:40 pm</td>
<td>New Technology in Dry Eye Diagnosis</td>
<td>Daniel Powell, OD, MS, PhD</td>
<td>DT</td>
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<td>1:40 pm – 2:00 pm</td>
<td>New Instrumentation for the Contemporary Optometrist</td>
<td>Steven Ferguson, OD</td>
<td>DT</td>
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<tr>
<td>2:45 pm – 3:05 pm</td>
<td>An Overview of Corneal Dystrophies</td>
<td>Clarke Newman, OD</td>
<td>DT</td>
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<tr>
<td>3:05 pm – 3:25 pm</td>
<td>Hormone Influences on Ocular Surface Disease</td>
<td>Melissa Barnett, OD</td>
<td>DT</td>
</tr>
<tr>
<td>3:25 pm – 3:45 pm</td>
<td>Ocular Management of Graft Versus Host Disease</td>
<td>Muriel Schornack, OD</td>
<td>DT</td>
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<tr>
<td>4:00 pm – 5:00 pm</td>
<td><strong>Practice Management Session</strong></td>
<td>Joe DeLoach, OD</td>
<td>PR</td>
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**NOTE:** This course will include a screening of a previously recorded session. Participants will receive CE credit for viewing the course – No exam required.
Neural Stimulation

- Overview:
  - Neural Stimulation:
    - Why it was Created
    - What it Does
    - How it Works
    - Where and When to Use
  - New Devices for Dry Eyes:
    - Nasal: Allergan® True-Tear

Neurostimulation: Definition

- Definition:
  - Therapeutic activation or modulation of part of the nervous system
  - Unique niche between surgical and medical treatments.
    - Targets specific anatomical sites, like surgery.
    - Is adjustable and reversible, unlike surgery &
    - Stimulation devices may be turned off if necessary.
  - NO systemic adverse effects of medication treatment, but may have its own side effects.
Neural Stimulator: Nasal

Indications for TrueTear™:

- Intranasal Tear Neurostimulator
  - Provides a temporary increase in tear production during neuro-stimulation in adult patients.
  - Uses small electrical pulses to stimulate production of your own natural tears.
  - Electrical pulses are delivered by a disposable tip attached to device that is placed in your nose for short periods of time.

TrueTear™ Device

Components:

- Daily disposable tip
  - Inserts into the nasal cavity and stimulates the target tissue
- Reusable base unit
  - Produces the neurostimulation and enables the patient to control the neurostimulation
- Reusable cover
  - Protects disposable tip
- Charger
  - Recharges the battery inside the base unit
Treatment

Directions for use:
- Use at least twice a day, as needed.
  - Automatically turns off at the one (1) minute.
  - May also be turned off by pressing the (-) button for 2 seconds.
  - The device vibrates and the LED indicator lights turn off to indicate that the power has been switched off.
- Stimulation longer than 3 min. or 3 sequential cycles is not recommended
  - Wait for at least 60 minutes before proceeding to the next application.

Treatment

Directions:
- Has a built-in 24-hour period single-day usage limit of 30 minutes.
  - If this daily limit has been reached, the device will turn on and then off immediately and not deliver stimulation.
- Five intensity levels.
  - The base unit vibrates briefly when a button is pressed to indicate an increase or decrease in intensity level.
  - The blue LED indicator light is lit to indicate the stimulation level selected.

Neural Stimulator: Single Study

TrueTear Nasal Neural Stimulator:
- OCUN-009 study: SINGLE STUDY VISIT (ONE-TIME USE)
  - To evaluate the effectiveness and safety of the device during use at a single-study visit.
  - Prospective, randomized, single-arm, controlled, double-masked, multicenter, clinical trial
- Primary effectiveness endpoint:
  - Increased tear production as measured by Schirmer score during correct application of the device compared with incorrect application.
Study Criterion

- TrueTear® Nasal Neural Stimulator:
  - OCUN-009 study:
    - To qualify for enrollment:
      - At least 22 years old
      - Have Dry Eye based on the level of dryness in the eye(s) measured on standard DEWS.
    - Excluded if they had:
      - Severe Dry Eye with cornea irregularities
      - Bleeding from the nose or previous sinus surgery or trauma
      - Cardiac pacemaker, implanted defibrillator, or another implanted electronic device.
      - Disabling arthritis or limited motor coordination

- OCUN-009 study: 2 US sites
  - n = 48 people
  - Average age: 57 years old
  - Majority female
  - Each patient had 3 applications of stimulation
    - On the study day visit, each subject received 3 applications in random order:
      - Intranasal Tear Neurostimulator applied correctly, i.e., inside the nose,
      - Inactive Intranasal Tear Neurostimulator applied inside the nose, i.e., no stimulation,
      - Intranasal Tear Neurostimulator applied outside of the nose with stimulation.

Study Results

- OCUN-009 study:
  - Used as intended resulted in a large increase in tear production.
    - Average Schirmer score was about 35 mm during neurostimulation
    - About 10 mm less tear production, for the and in people who used device on the outside of the nose, where it would not be effective.
  - Two adverse events were deemed related to or possibly related to the device:
    - These included transient lightheadedness and intermittent nose itching.
    - No changes of nasal tissue were observed with examination of the nasal cavity.

- There were no adverse events that led to discontinuation from the study.
Neural Stimulator: 6 mo. Study
- TrueTear® Nasal Neural Stimulator:
  - OCUN-000 6-MONTH STUDY: 3 US Sites
  - n = 97 people
  - Average age: 61 years old
  - Majority females
  - Eligibility for enrollment:
    - 22 years of age or older
    - Dry Eye based on Schirmer’s
  - Dosage:
    - 2 to 10 times a day and
    - no more than 3 minutes per use
  - Designed to evaluate the safety & effectiveness
    - Evaluated on Days: 7, 30, 90, and 180

Neural Stimulator: 6 mo. Study
- Study participants used device
  - Without stimulation & with active stimulation
  - In this study, tear production was much greater with active stimulation than without stimulation.
  - Following the initial stimulation, there was a trend toward decreased effectiveness (tear production) with time with the use of device;
  - Trend appeared to plateau toward the end of the study.
  - The average difference in stimulated vs. unstimulated:
    - 18.0 mm on the first day,
    - 13.1 mm at 1 week,
    - 8.5 mm at 1 month,
    - 8.3 mm at 3 months, and
    - 9.4 mm at 6 months.

Application & Results
- The device was:
  - Applied for an average of 1.7 times per day
  - Average daily application time of 190 seconds/day (3.16 minutes/day).
  - Subjects applied the device a total of 27,338 times during the study, and the
    - Total device application time for the study was 34,726 minutes.
  - Therefore, small number of device-related mild AEs occurred in a large number of stimulation events.
    - In all, 30 study patients (30.6% of those studied) had at least one of the adverse events listed in the table.
Safety
• In a clinical study, the safety and effectiveness of intranasal electrical stimulation was evaluated over a 6-month period of time.
  • Periodic examination of the nose is recommended if the device is used over a longer period of time.

Contraindications
• Do NOT use device, if you have:
  • Heart devices:
    • Cardiac pacemaker
    • Implanted or wearable defibrillator
  • Head devices:
    • Other implanted metallic or electronic device (eg, cochlear implant) in the head or neck
  • Nose conditions:
    • Chronic or frequent nosebleeds,
    • Bleeding disorder (eg, hemophilia)
    • Any other condition that can lead to increased bleeding
  • Allergy to:
    • A known hypersensitivity to the hydrogel material that comes into contact with the inside of your nose

Summary Nasal Neural Stimulator
• TrueTear® Nasal Neural Stimulator:
  • New neural stimulation device
  • Promising to help patients with severe dry eye disease
  • Improves Schirmer’s score
  • No significant adverse effects
She Blinded Me With Science....

Thank YOU !!!
In Office Treatment of Corneal Ulcers a.k.a. Microbial Keratitis

William D. Townsend, OD, FAAO
Advanced Eye Care Canyon, TX
Adjunct Faculty, UHCO

When Was the Last Time You Treated a Corneal Ulcer?

- Where have all the ulcers gone?
  - Better lens materials
  - Better solutions
  - One-day lens wear
- Still, there are days........
  - Fungal ulcers
  - Acanthamoeba ulcers
  - Non-infectious ulcers
  - Viral ulcers

Corneal Ulcer

"a corneal epithelial defect with underlying inflammation (which soon results in necrosis of corneal tissue) due to invasion by bacteria, fungi, viruses, or Acanthamoeba. It can be initiated by mechanical trauma or nutritional deficiencies. Symptoms are progressive redness, foreign body sensation, ache, photophobia, and lacrimation."

http://www.merckmanuals.com/professional/eye-disorders/corneal-disorders/corneal-ulcer
Microbial Keratitis: Need to Know Info
- Epithelial defect
- Underlying inflammation
- Necrosis
- Invasion
  - Bacteria
  - Fungi
  - Acanthamoeba
  - Viruses
- Initiated by
  - Mechanical trauma
  - Nutritional deficiencies
- Symptoms & Signs
  - Progressive redness
  - FB sensation
  - Ache
  - Photophobia
  - Lacrimation

Questions to Ask & Answer!
- Contact lens wear?
  - 1-day
  - 2-week
  - 1-month
  - Till they hurt
- Trauma?
- Where do you live?
  - Infectious ulcers more common in southern USA
- Recent travel?
  - Where
  - Activities?
- Swimming with or without goggles?
- Immune deficiency?
- Diabetes
- Meds
- Immunomodulator
- Autoimmune disease
- Is it an ulcer?
- Is it infectious?
- Most likely agent?
  - Bacterial, fungal, viral, amoeba

Physical Exam
- Best corrected visual acuity
- Examination for epithelial defects (fluorescein)
- Corneal sensation
- Examination for corneal infiltrates
- Examination for thinning or corneal edema
- Seidel examination for perforated cornea
- A/C evaluation for cells, flare, and
Where you practice influences the "usual suspects!"

Location, Location, Location!

Houston, Texas

Nome, Alaska

Where do you live & where have you traveled in the past two weeks

Causative Organism by City

Gram Staining

Gram Positive
- Cell membrane- blue
- Cocci
  - Staph species
  - Aureus
  - Epidermidis
  - Strep Species
  - Pyogenes
  - Enterococci
- Bacillus
  - Cornebacterium
  - Clostridia
  - Listeria

Gram Negative
- Cell membrane- pink
- Escherichia coli
- Pseudomonas aeruginosa
- Neisseria gonorrhoeae
- Yersinia pestis
- Salmonella

Bacterial Keratitis

- Most common cause of microbial keratitis in the US—all regions
- Gram positive more common overall, especially in northern USA
- Gram negative higher incidence in Florida, Texas, S. California
- Appearance variable
  - Commonly present w/ significant necrotic material & an epithelial defect
  - Infrequently present w/ minimal necrotic tissue and may have intact overlying epithelium


Where Do You Live?

Bacterial Keratitis: Staining Characteristics by City

- Gram -
- Other
- Gram +


Bacterial Keratitis

Pseudomonas aeruginosa
Bacterial Keratitis: Management Culture or Not?

- Monocular
- Reduced immune function
- Immunomodulatory agents
- Minimum
  - Blood agar- sterile agar w/ whole RBC's
  - Chocolate agar- sterile agar w/ lysed RBC's
  - Concerned @ fungi & yeast?- Sabarau's agar
  - Inoculate directly onto the culture media
  - "Report all findings!"

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**Table 1.** Antibiotic Susceptibility of Isolated Corneal Pathogens in San Francisco. Cornea 2017:0:1-4

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<th>Ophthalmology</th>
<th>Reference</th>
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<td>Acinetobacter baumannii</td>
<td>Sensitive</td>
<td>Yes</td>
<td>1,2,3</td>
</tr>
<tr>
<td>Escherichia coli</td>
<td>Resistant</td>
<td>Yes</td>
<td>4,5</td>
</tr>
<tr>
<td>Pseudomonas aeruginosa</td>
<td>Sensitive</td>
<td>No</td>
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<tr>
<td>Staphylococcus aureus</td>
<td>Resistant</td>
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**Table 2.** Antibiotic Susceptibility of Isolated Corneal Pathogens in San Francisco. Cornea 2017:0:1-4

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</table>
**Preferred Antibiotics**

*must be compounded*

**Gram Positive**
- Bacitracin
- Vancomycin 5% *
- Sulfisoxazole
- Trimethoprim (Polytrim)
- Moxifloxacin (Vigamox)
- Ciprofloxacin (Ciloxan)

**Gram Negative**
- Gentamicin
- Neomycin
- Ceftazodine
- Polymyxin
- Sulfisoxazole
- Trimethoprim (Polytrim)
- Moxifloxacin (Vigamox)
- Ciprofloxacin (Ciloxan)

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**Evolving Risk Factors and Antibiotic Sensitivity Patterns for Microbial Keratitis at a Large County Hospital**

- **Site**: a large county hospital in Houston, TX (Ben Taub)
- **Purpose**: to identify
  - Risk factors
  - Causative organisms
  - Antimicrobial susceptibility
  - Outcomes of microbial keratitis in Study Population
  - Patients with known diagnosis of microbial keratitis from January 2011 to May 2015.

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**Identified Risk Factors - MK**

- Contact lens use (34.4%)
- Ocular trauma (26.3%)
- Diabetes mellitus (16.7%)
- Ocular surgery (13.5%)
- Ocular surface diseases (11.5%)
- Previous keratitis (10.4%)
- Glaucoma (6.3%)
- Cocaine use (5.2%)
- HIV-positive status (4.2%).
All microbial keratitis cultured - blood, chocolate, and Sabaraud plates
Average period of care - 270 days
Average length of antibiotic TX - 65 days
Average length of steroid TX - 130 days


### What To Prescribe In Houston?

<table>
<thead>
<tr>
<th>Organism</th>
<th>Preferred Anti-infective Agents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pseudomonas A. (19)</td>
<td>Ceftazidime, tobramycin, fluoroquinolones</td>
</tr>
<tr>
<td>Coagulase-negative Staph (15)</td>
<td>Vancomycin*</td>
</tr>
<tr>
<td>Streptococcus pneumoniae (6)</td>
<td>Cefazolin, ceftazidime, fluoroquinolones, Vancomycin, ciprofloxacin, cefazolin</td>
</tr>
<tr>
<td>Staphylococcus aureus (3)</td>
<td>Vancomycin*</td>
</tr>
<tr>
<td>MRSA (1)</td>
<td>Vancomycin*</td>
</tr>
<tr>
<td>Other Gram-positive organisms</td>
<td>Vancomycin*</td>
</tr>
<tr>
<td>Other gram negative organisms</td>
<td>Ceftazidime, tobramycin, fluoroquinolones</td>
</tr>
<tr>
<td>Fungi</td>
<td>Natamycin</td>
</tr>
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</table>

Pearls From Ben Taub Study
- 2015- 14,000 ophthalmology clinic visits
- Treated a total of 23 cases of MK
- Numbers comparable to similar Dallas study
- 1ⁿ lesion size ∝ final VA
- Risk factors for reduced VA:
  - HIV +, cocaine use, diabetes, ocular trauma, eye surgery

Bacterial Keratitis: Summary
- Thankfully uncommon
- Manage or refer
- If manage
  - Culture?
  - Most likely organism?
  - Photo documentation
  - Best antibiotic to cover gram + and gram-

A Fungus Among Us? Managing Fungal Keratitis
- Uncommon
- True fungal keratitis- filamentous fungi
- Yeast- unicellular
- Risk factors
  - Hot humid climates; ask about foreign travel
  - Increased risk ocular surface disease
  - Trauma, even mild, may be initiating event
71 year-old male
OD enucleated
Complains of irritation, redness, photophobia
Onset 3 days
His dog may have scratched his eye

Tell us what you see!

Fungal keratitis
- Serrated margins
- "raised and dry slough"
- Satellite lesions
- Non-yellow color
- Slow growing
- Epithelium may initially be intact
- Perforation an issue!

Natacyn® (natamycin 5% ophth. susp.)
- Broad spectrum, good anti-fungal activity
- Safe & effective at a low concentration
- Currently most effective topical agent against fungal keratitis (MUTT)
- Dosing: 1 drop every hour or every other hour for 2-3 days, then 6-8 times per day until resolved

Management of most microbial keratitis is within the scope and expertise of ODs. Careful history & physical examination typically lead to initial diagnosis & TX plan. If at all possible, image the lesion day one. Follow these patients on a day-by-day basis. Pass on central, very large or deep lesions to cornea specialists.
Course Outline:

What’s next in AMD Drugs
  Complement Pathway Inhibitors
    Zimura
    Filly trial
  MAC Complex Drugs
  AntiVEGF
    Lampalizumab – failed to meet endpoints – for dry geographic atrophy

Retinal Dystrophies:
Stem Cell and Gene Therapy Studies: All in Phase 1,2:
What we know so far: Retinal gene therapy is safe.
What can be replaced: RPE is the easier target

  Intravitreal Injections
    X linked retinoschisis
    Retinitis Pigmentosa (Alkek Eye)
  Subretinal Injections – Phase 1, 2
    Stargardts ABCA4 (Cullen)
    Usher Syndrome Type 1b
      Lentivirus (Paris, Oregon)
      Dose escalation study
      Visual acuity in 9 patients: stable
  Choroideremia
    Phase 2 CHM gene replaced subfoveal with AVV2 (viral vector)
      2 pts improved 4 lines, 4 stable, 1 lost vision
  RPGR-X Linked RP
    Subretinal injection: 24 patients
  Achromatopsia – Phase 1,2
  RPE 65 – Leber Congenital Amaurosis
    Phase 3 (Lancet 2017)
      65% passed the primary endpoint – mobility maze
    None of the control arm passed
Second Sight: Provides Proof of Concept for the Ongoing Development of the Orion Visual Cortical Prosthesis
- Successful Implantation and Activation of Wireless Visual Cortical Stimulator in First Human Subject

3D/Digital Vision Surgery – Anterior and Posterior Segment
- Head up surgery
- Intraoperative OCT

Phone: 832-413-3684        Fax: 830-212-6084
ZIKA Virus in Tears-Clinical Implications

Rachel Redfern, OD,PhD, FAAO
University of Houston, College of Optometry
713-743-1943
Rredfern@central.uh.edu

Course Description:
This course will review the scientific literature and recent updates from the Center for Disease Control regarding ZIKA virus systemic and ocular complications.

Course Objectives:
- To define ZIKA virus presentation, transmission, impact on health care and epidemiology reports
- To review ZIKA virus systemic and ocular pathophysiology
- To explore recent studies regarding ZIKA presence in the tear film and implication for transmission for optometrists

Course Outline:
I. Overview of ZIKA virus
   a. Definition and life cycle of ZIKA virus
   b. Clinical presentation in infants and adults
   c. Various mode of transmission
      i. Mosquitos
      ii. Sexual contact
   d. Impact on health care
   e. CDC epidemiology reports
      i. World wide
      ii. United States
      iii. Texas

II. ZIKA Virus Pathophysiology
   a. Systemic complications
   b. Ocular complications in patients with microcephaly
   c. Literature update on recent clinical studies

III. ZIKA Virus and Clinical Implications for Optometrists
   a. Viral load in bodily fluids
   b. Potential Impact of ZIKA in the tear film
   c. ZIKA animal models

IV. Summary and Future Directions
What Important Properties Should We Look For in Care Systems?

Ralph P Stone, PhD

Disclosure

- Consultant to Alcon Laboratories
  - No current proprietary positions with Alcon
- Consultant to Contamac Ltd.
  - Working with Contamac on care for scleral lenses
- President SMM Ventures, LLC.
  - Proprietary technology in scleral lens care products

First Question

- Who are the consumers-your patients?
  - Are they compliant with their care?
    - Do you ask the hard questions, see their cases, their solutions?
  - Do they replace their lenses on-time?
    - Is there use rate what you prescribe or do they "cheat" a little or a lot?
  - Do they live with their PDAs, computers or are they gamers?
To Pick the best care you need to Know……

- Do they have marginal dry eye?
  - Will they benefit from care that provides help?
- Do they need specialty lenses—Multifocal, Toric?
  - Will affect their need during wear?
  - Does this impact the replacement rate or the cost?
- Do they have corneal/ocular issues requiring special designs or materials?
  - Do they need sclerals, hybrids, RGP’s, High water, etc.?
  - Are they progressing myopes?

What is Important?

SAFETY
VISION
COMFORT

We need to look at each part of the care paradigm.

- Cleaning
- Rinsing
- Disinfection
- Lubrication
Let's look at SAFETY

Microbiological Efficacy

Toxicity

Let's Look at the Disinfection Process

- Cleaning:
  - What's on a lens and where does it come from?
  - How does affect the microbiological load?
  - Rubbing and/or rinsing?

- Disinfection:
  - How do we measure solution efficacy?
  - Is the regimen efficacy different?
  - Do we test everything?

What are the loads of microbial contamination on lenses?

[Bar chart showing loads of microbial contamination on lenses]
Disinfection Efficacy for Current Products

Results using ISO 14729

What about clinical isolates?

- We currently test 5 organisms - all related to the reported incidence of lens related ocular infections.
- The tested are 1 strain of one species within a class. All are the continually monitored that they are not mutating.
- We are developing tests for *Acanthamoeba*.
- Clinical isolates of other genera and species are not generally tested since they are not stable and often change (mutate) between labs and sometimes within a lab. Only culture collection species and strains are used.

What’s the downside?

- Increased microbial efficacy can indicate increased toxicity against ocular tissues.
- What do we look at?
Effect of Contact Lenses and Lens Cases on Disinfection Efficacy of Multipurpose Disinfection Solutions

Reduction of S. marcescens at Regimen Time Product A

<table>
<thead>
<tr>
<th>Condition</th>
<th>Reduction of S. marcescens</th>
</tr>
</thead>
<tbody>
<tr>
<td>no lens</td>
<td>n/a (control)</td>
</tr>
<tr>
<td>balafilcon A</td>
<td>0.75%</td>
</tr>
<tr>
<td>etafilcon</td>
<td>0.80%</td>
</tr>
<tr>
<td>senofilcon</td>
<td>0.85%</td>
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</table>

Reduction of S. marcescens at Regimen Time Product B

<table>
<thead>
<tr>
<th>Condition</th>
<th>Reduction of S. marcescens</th>
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</thead>
<tbody>
<tr>
<td>no lens</td>
<td>n/a (control)</td>
</tr>
<tr>
<td>balafilcon A</td>
<td>0.75%</td>
</tr>
<tr>
<td>etafilcon</td>
<td>0.80%</td>
</tr>
<tr>
<td>senofilcon</td>
<td>0.85%</td>
</tr>
</tbody>
</table>

Gabriel M, et al. Poster ARVO 2013

Key Measures of Toxicity

- Measure of lens preservative uptake and release
  - Carried out on the different classes of lenses available
    - Now 7 soft lens and 2 RGP classes.
- Cytotoxicity
  - The measure of the survival of known cell lines against the product.
- Rabbit Studies
  - The effects of the product on rabbit eyes over time.
    - Carried out from 5-21 days
- Human clinical trials
  - Human use over 1-3 months

Conventional Hydrogels

<table>
<thead>
<tr>
<th>Group 1</th>
<th>Group 2</th>
<th>Group 3</th>
<th>Group 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low Water (&lt;50%) Non-ionic</td>
<td>High Water (&gt;50%) Nonionic</td>
<td>Low Water (&lt;50%) Ionic</td>
<td>High Water (&gt;50%) Ionic</td>
</tr>
</tbody>
</table>
Silicone Hydrogels (Group 5)

<table>
<thead>
<tr>
<th>Group</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>5A</td>
<td>Hydrophilic portion contains an ionic ingredient</td>
</tr>
<tr>
<td>5B</td>
<td>High Water (&gt;50%) Nonionic</td>
</tr>
<tr>
<td>5C</td>
<td>Low Water (&lt;50%) Nonionic</td>
</tr>
</tbody>
</table>

Silicone portion primarily based on pendant chains of siloxanes or fluorosiloxanes such as "tris".

Surface Treatments:
- Chemically Modified
- Interpenetrating Networks
- No surface Modification

Vision

Do lens change in the solution?
- Lenses are measured for changes from using a product.
- And are evaluated are these changes reversible on the eye?
- The importance is becoming more important as the care product are more complex and the packaging solution have additional added ingredients for comfort.
Can we keep lenses clean?
• Does the care system give me clear and clean lenses?
• We have shortened the replacement of lenses from a long as a year for soft lenses to daily, weekly or monthly to address the build up of deposits which affect vision and comfort.
• For rigid gas permeable lenses we keep lenses much longer especially scleral lenses and a full range of cleaners are available including enzymes.

What about “NO RUB”
• There has been a period when multi-purpose products were labeled for no rub but still required a rinse.
• Currently this has been removed from most products.
• Hydrogen peroxide solution still are labeled “no rub” since the action of the product including the bubbling action during neutralization acts to remove deposits.

What about COMFORT
• We know that approaching 1 in 7 of your patients will discontinue wearing contact lenses, many permanently.
• What do we look for:
  • Companies report the “wetting angles”
    • They are a measure of the ability of water to spread over lenses
    • Continued wettable lenses are important characteristic
  • They also look at the “coefficient of friction”
    • It measures the drag of the lid over the lens surface
What really matters?

How long it lasts?

What does this all mean?

- We need to tailor our selection of care to our patient’s needs and life style.
- There is not a universal answer to picking care for THAT patient.

Lid and Ocular Surface
Correlation of Dry Eye Symptoms and Lid Wiper Epitheliopathy

Grade Lid Wiper Staining

- Asymptomatic Patients
- Symptomatic Patients

<table>
<thead>
<tr>
<th>Grade</th>
<th>Grade 0</th>
<th>Grade 1</th>
<th>Grade 2</th>
<th>Grade 3</th>
<th>Grade 4</th>
<th>Grade 5</th>
<th>Grade 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percent of Patients</td>
<td>5%</td>
<td>15%</td>
<td>30%</td>
<td>40%</td>
<td>20%</td>
<td>5%</td>
<td>0%</td>
</tr>
</tbody>
</table>

Blink TFBUT (Time to First Blink Unprotected Lens Surface)

- Time (seconds)
- 0 1 2 3 4 5 6 7
- Lens surface becomes hydrophobic

Lens Surface Changes Driven by Environment

- Soft contact lens film breaks up, hydrophilic groups migrate into the lens producing a hydrophobic, non-wettable surface

Safety
Vision
Comfort

We need it all, but what to pick?
Know your patient!

Thank you
Keratoconus: Early Detection and Contemporary Monitoring
Cornea, Contact Lens and Contemporary Vision Symposium 2017

Learning Objectives:
- Understand the implications crosslinking has on KC management in the US
- Learn what instrumentation is useful for detection and monitoring of KC
- Know what is in the future pipeline of KC diagnostics

Outline
- KC Background
  - Description of KC
    - Incidence
      - More common than previously thought/reported
  - Visual Symptoms and Common Complaints
    - Poor refractive endpoint
    - Poor VA in absence of apparent disease
- Classic Diagnostics
  - Keratometry
  - Reflex: O-Scope/Ret Reflex
  - Ultrasonic Pach
- Slit Lamp Signs
  - Visible with advanced disease
  - Invisible in early disease
- Traditional KC Management in the US
  - Dx and watch as disease progresses
  - Visual Rehab with GP
  - PKP with CL intolerance, poor VA, central scarring
- Paradigm Shift in KC Management in the US
  - Dx Early
    - Intervene Early
      - CXL
        - Stop progression
        - Prevent advanced disease
  - Visually Rehabilitate
    - Specialty contact lenses
    - Surgical interventions
  - Corneal Transplantation
    - Modern transplantation
    - Treatment of last resort
- Dx Early: Modern and Advanced Diagnostics for Earliest Dx
  - KC is a Progressive Disease
    - Progressive age range
- Pediatric onset
  - Risk factors
    - Family hx
    - Atopic disease
    - Down's
    - Connective tissue disease
  - What is Progressive KC
    - No current definitive definition
    - Subjective and Objective findings indicate progression
  - Importance of Global Data
    - Full cornea
  - Topography
    - Anterior Curvature ONLY
    - IMPORTANT FOR PRACTICING MYOPIA CONTROL: If anterior curvature is influenced by ortho-k before KC onset, how do you dx if you are relying on placido reflection?
      - Must have proper instrumentation
  - Tomography
    - Full corneal metrics
  - OCT
    - Epi Mapping
  - BioMechanics
    - Corneal Resistance Factor
  - Abberometry
  - Combine for earliest Dx
    - Monitor appropriate metrics
    - High risk for progression?
      - Appropriate follow up 3m-6m
    - Low risk for progression?
      - Appropriate follow up 6m-12m
  - Future Dx
    - Genetic Testing
      - Buccal Swab
    - Improved imaging/ Image enhancing algorithms
      - Bowman's layer thickness
    - AI
      - Demographics, Risk Factors, Hx, Dx algorithms of combine instrumentation
Hot Topics in Corneal and Refractive Surgery

MARC SANDERS, MD
DIAGNOSTIC EYE CENTER
ASST. PROFESSOR, BAYLOR COLLEGE OF MEDICINE

Overview

- SMILE
- Corneal Inlays
- Collagen Cross-Linking
- MIGS (Micro-Invasive Glaucoma Surgery)
- Intraoperative Aberometry

No Financial Disclosures

SMILE: SMall-Incision Lenticule Extraction

- Femtosecond Laser (Visumax)
- Introduced 7 Years Ago
- Recently FDA Approved
- Current Approval -1D to -8 D with up to +/- 0.5 D cylinder
- Half Million Procedures Worldwide
Why SMILE?

- Visual outcomes similar to LASIK
- Potential Advantages (not proven)
  - Improved Biomechanical Stability
  - Less Dry Eye
  - Less Post Op Inflammation

Corneal Biomechanics
The Future of SMILE

- Myopia with Astigmatism
- Hyperopia
- PEARL (Presbyopic Allogenic Refractive Lenticule Inlay)
- Lenticules for Keratoconus
- Cross-linking Combined with SMILE

The Invariable Comparison

LASIK vs. SMILE
Corneal Inlays

- KAMRA: 2015
- Raindrop: 2016
- Flexivue Microlens: Expected 2017

Presbyopia

Data from 2012 update to 2010 census and 2014 MarketScope.

KAMRA: Indications

- Plano Rx in dominant eye
- -0.75 to -1.00 Rx in non-dominant eye
- 45-60 y/o
- Placed in femtosecond pocket at 220 micron depth
KAMRA Placement

KAMRA: Adverse Events
- Conjunctivitis
- DLK
- Dry Eye
- Decentration
- Loss of BCVA
- Explantation Rate: 9%

Raindrop Inlay

Raindrop Inlay

Creates Hyperprolate Shape
Raindrop: Indications

- 41-65 y/o
- Non dominant eye Rx +1.00 to -0.50 with <0.75 cylinder
- Dominant eye Rx Plano

Raindrop Placement

Raindrop: Adverse Events

- Corneal edema
- Corneal Haze
- FBS
- Dry Eye
- Explantation Rate: 7%

Flexivue Microlens

- Bifocal Optic
- Similar Indications
- Complications:
  - Glare/Halo
  - Dry Eye
  - Explantation: US Data not submitted yet
Collagen Cross-Linking

- FDA Approved April, 2017
- Avedro
  - KXL System
  - Photrex
  - Photrex Viscous

Keratoconus

- 265 cases per 100,000
- Over 170,000 Americans
- Average onset 15 +/- 4 years
- Always bilateral
- Causes: Genetic, Environmental, Social, Eye-Rubbing
- Dx’d earlier: better diagnostics

FDA Data

- Efficacy
  - Average reduction of 1.4 to 1.7 D in $K_{\text{max}}$
    at 12 months in crosslinked eye
  - Average increase of 0.5 to 0.6 D in $K_{\text{max}}$
    at 12 months in fellow untreated eye

FDA Data

- Adverse Events
  - Corneal Haze
  - Punctate Keratitis
  - Epithelial defect
  - Eye pain
  - Reduced acuity
  - Infectious keratitis
  - Corneal melt
Patient Expectations

- Worsening visual acuity from baseline to 1 month
- Return to baseline by 3 months
- Improvement from 3 to 12 months
- More effect with steeper $k_{\text{max}}$ (>55D), poor BCVA (<20/40), younger age (<40)

Cross-linking Step 1: Epithelial Removal

- Check corneal saturation at slit lamp
- Check pachymetry (minimum 400 microns to avoid endothelial damage)

Cross-linking Step 2: Riboflavin Saturation

One drop every 2 minutes for 30 minutes

Cross-linking Step 3: UV Light Exposure

- Check corneal saturation at slit lamp
- Check pachymetry (minimum 400 microns to avoid endothelial damage)
Exposure Protocols

- Dresden: 3 mW/cm² for 30 min
- Accelerated: 9 mW/cm² for 10 min
- Accelerated: 18 mW/cm² for 5 min
- 2016 study showed Dresden more effective
- Epithelium On: 1/3 reduction in stromal penetration, significantly less effect
- Iontophoresis Epi On: also less effective

Post-op Care

- Similar to PRK: antibiotic drops, steroid drops, pain medications, bandage contact lens
- Start fitting contact lenses 3-4 weeks post-op

Indications

- FDA Approved for Keratoconus and post LASIK ectasia
- Pellucid Marginal Degeneration
- Infectious keratitis
- Bullous keratopathy (short lived effect)

Contraindications

- Corneal scarring
- Poor wound healing
- Autoimmune disease
- History of herpes simplex keratitis: UV light will cause reactivation
Combination Treatments: CXL and Intacs
CXL: Halts progression of disease
Intacs: Flatten cornea, reducing astigmatism and improving vision and CL tolerance

Combination Therapies
- LASIK Xtra: CXL and LASIK for hyperopia or myopia for less regression
- PiXL: Photorefractive intrastromal crosslinking for low levels of myopia (-0.75D to -2D)

Conclusion
Crosslink all keratoconus patients under 40 at the time of diagnosis

Thank You!
Course Description:

This course is intended to provide practitioners with information on newer multifocal and extended-depth-of-focus intraocular lenses

Course Objectives:

• To review the advantages of newer multifocal IOL’s compared to older multifocals.
• To provide an overview of the Symfony IOL, how it works, and the advantages and disadvantages.
• To provide a brief tutorial on how best to refract Symfony patients.

I. The Market for Presbyopia Correcting IOLs
   a. My practice vs. national average
   b. Why <10% market share for presbyopia correcting IOL’s in 2017?

II. Newer Multifocals
   a. Paradigm Shift
   b. Near add and halo size

III. Extended Depth of Focus IOL (Symfony)
   a. How it works
   b. Contrast sensitivity compared to a monofocal and multifocal IOL’s
   c. Halo size compared to a monofocal and multifocal IOL’s

IV. Clinical Pearls
   a. How to refract patients who have the Symfony IOL

V. Extended Depth of Focus: What’s on the Horizon?
   a. IC-8 Small Aperture IOL
Amniotic Membrane’s Ultimate Screen Protector for Your “Ocular Surface Pro”

Seema Nanda, OD
Texas Eye Institute
Univ. of Houston College of Optometry
CCLS Meeting: Houston, TX
2nd December 2017

Inflammation:
Ocular Surface Disease

Conjunctival Inflammation
Corneal Inflammation

Pterygium
Conjunctival Chalasis
Keratitis
Persistent Epithelial Defect (PED)
Ulcer

Ocular Surface Health Depends on a Stable Tear Film When Eye Is Open

Compositional Factors:

- Lipid Layer ----- Meibomian gland
- Aqueous Layer ------ Lacrimal gland
- Mucin Layer ---- Goblet cells
- Epithelium of the Cornea

**Ocular Surface Health**

*Hydrodynamic Factors:*
- Eyelid blinking
  - Meibum lipid “milking out”
  - Helping the tear-lipid spread & clearance
- Eyelid Closure
  - Avoid exposure


**Neuro-Anatomy for Stable Tear Film**

**COMPOSITIONAL**
- VII Sensory (PS)
- VII Motor

**HYDRO-DYNAMIC**
- Lid Blinking
- Lid Closure
- Clearance
- Spread
- CES Exposure

**Blink Rate & Severity of Dry Eye**

*PED/Ulcer*
DREAM: Dry Eye Amniotic Membrane Study
ASCRS 2017

Marguerite McDonald MD & Hosam Sheha, MD, PhD
Study Investigators: Amit Choksi MD, Michael Singer MD, Mujaba Qazi MD, Frank Bowden MD, Damon Dierker OD, Susan Janik OD, Seema Nanda OD, Adam Shupe OD, B. McMurren OD

DREAM Study Design

- A retrospective study conducted at 10 clinical sites:
  - Evaluated efficacy of PROKERA® Slim (PKS) in accelerating the recovery of ocular surface health in DED.
  - Received PKS and completed at least 3 months of follow up.

- Study included DED patients (DEWS 3-4):
  - Did not respond to maximum conventional therapies including:
    - Topical artificial tears
    - Cyclosporine-A,
    - Autologous Serum
    - Antibiotics
    - Steroids

Accelerate restoration of normal corneal health via nerve regeneration
**CAM Sustained Effect in Treatment of Dry Eye Disease**

- **DREAM Study:**
  - 62 patients (75 eyes) with Moderate to Severe Dry Eye (DEWS 3-4) despite maximal medical therapy
  - Single CAM placement for 5 ± 2 days, 59 (95%)
  - Patients demonstrated improved ocular surface that lasted at least 3 months.

**CAM in Signs of Dry Eye Disease**

- **DREAM Study:**
  - Single placement of CAM accelerates recovery of normal cornea &
  - Sustained relief for at least 3 months

**Mode of Action:**
- The first and only therapy directed to actually “Restore Corneal Nerves”

---

**Baseline 1 wk 1 M 3 M**

<table>
<thead>
<tr>
<th>DEWS Scores</th>
<th>0.5</th>
<th>1.0</th>
<th>1.5</th>
<th>2.0</th>
<th>2.5</th>
<th>3.0</th>
<th>3.5</th>
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<tr>
<td>Baseline</td>
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<tr>
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<tr>
<td>2 Month</td>
<td>8</td>
<td>8</td>
<td>8</td>
<td>8</td>
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<td>8</td>
<td>8</td>
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<tr>
<td>3 Month</td>
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<td>8</td>
<td>8</td>
<td>8</td>
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</tr>
</tbody>
</table>

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**Lid Blinking**

- Lid Closure
- Clearance
- Spread

**Lacrimal Gland**

- Meibomian Gland
- Goblet Cells

**Facial Nerve**

- V 1: First branch of Trigeminal Nerve
- VII: Sensory (PS) and Motor

**Stable Tear Film**

- Smooth Corneal Epithelium
- Aqueous Lipid Mucin Secretion

**Pain**

- PKS1: 7.1 ± 1.5
- UCS2: 8.9 ± 0.9
- AS7: 7.5

**TBUT**

- PKS1: 8.3 ± 2.3
- UCS2: 4.0 ± 1.5
- UCS3: 4.0 ± 1.5

**Corneal Stain**

- PKS1: 2.8 ± 0.4
- UCS2: 5.5 ± 0.4
- AS3: 5.6 ± 0.4

**Corneal Sensitivity (mm)**

- PKS1: 3.6 ± 0.6
- UCS2: 5.4 ± 0.4
- AS3: 5.3 ± 0.5

**Baseline**

- 3.6 ± 0.6
- 5.4 ± 0.4
- 5.3 ± 0.5

**1 Month**

- 5.2 ± 0.5
- 5.4 ± 0.4
- 5.3 ± 0.5

**2 Month**

- 5.4 ± 0.4
- 5.4 ± 0.4
- 5.3 ± 0.5

**3 Month**

- 5.6 ± 0.4
- 5.4 ± 0.4
- 5.3 ± 0.5

---

1. John et al., Cornea; Submitted.
5. Restasis Phase 3 Trial 192731-002.
6. Xiidra.
Superficial Punctate Keratitis in DED

- 55-year-old Caucasian female from Greenbough, Alabama
- History of Dry Eye Syndrome, GP REJ lens wearer
  - Oc Meds: Restasis bid OU, Preservative Free Artificial Tears qid OU
  - Switched to Xiidra, no relief
  - Eyes hurt all the time, tired of pain/dryness especially with computer
- Wants to try alternative treatment for her condition
  - Starts PKSlim

Superficial Punctate Keratitis in DED

Day 1

Day 7

Ocular Surface Disease Spectrum

Disease Severity Patient Population

- Dry Eye
- SPK
- EBMD/RCE
- PED
- Corneal Ulcer

CAM Treatment

- Lid Hygiene, Hot Compress, Artificial Tears, Nutritional Ointment, Steroid, Restasis, Punctal Plugs, BCL, Autologous Serum
- Topical Antibiotics Debridement, Micropuncture, BCL

Accelerate restoration of normal corneal health via nerve regeneration

- Improved Outcomes
- Fewer Visits
- Less $ Cost

Accelerate healing to reduce visually significant corneal complications including corneal haze
Neuro-Anatomy for Stable Tear Film

Lid Blinking
Lid Closure
Clearance
Spread
Less Exposure

Lacrimal Gland
Meibomian Gland
Goblet Cells

V_1 Sensory (PS)
Facial Nerve
VII Motor

Unstable Tear Film

Lid Blinking
Lid Closure
Clearance
Spread
Less Exposure

V_1 Sensory (PS)
Facial Nerve
VII Motor

EBMD: Optimizing Ocular Surface

• Prior to Cataract Surgery
  – Epithelial Basement Membrane Dystrophy:
    • Common Ocular Surface disease in elderly
    • Leads to post-op refractive surprises
    • Proper diagnosis and management before surgery is critical to provide the best outcome and meet patient expectations
  – Procedures can cause haze, delayed wound healing, & recurrence:
    • Debridement
    • Superficial Keratectomy
    • PTK – PhotoTherapeutic Keratectomy
  – Cryo-Preserved Amniotic Membrane:
    • Known to control inflammation
    • Accelerate healing
    • Prevent scar formation

EBMD Study Design

• Purpose:
  – A prospective, controlled study to assess the efficacy of CAM after debridement in treating EBMD prior to cataract surgery.
• Prospective arm:
  – 10 patients with significant EBMD undergoing cataract surgery
  – Treatment regimen: debridement, PKS for 5 ± 2 days & standard post-operative care
  – Corneal Topography and IOL calculation are evaluated before and 1 month after the procedure
• Historical control arm:
  – Chart review of 10 patients that received conventional treatments for EBMD
Summary of Results

- **Corneal topography:**
  - **Study Group:**
    - 43.90 +/- 1.20 D at baseline to 44.80 +/- 1.30 D at 1 month
    - Axis changed from 114 to 63 deg.
  - **Control group:**
    - 45.00 +/- 0.60 D at baseline to 45.70 +/- 0.80 D at 1 month
    - Axis shift from 116 to 106 deg.

- **Biometry:**
  - Average change in IOL calculation was 1.3 D in the study group compared to 0.8 D in the control.

- **Study example:**
  - Pre-op: marked irregularity
  - Post-op: dramatic change in curvature and 30 deg. axis shift

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Summary of Results

- **Corneal Epithelium:**
  - Faster epithelialization of the ocular surface after Debridement in the study group (4 days)
  - Compared with control (7+ days)
  - No scarring or Haze

- **Conclusion:**
  - Promising therapy
  - Controls inflammation
  - Accelerates corneal epithelialization
  - Optimizes ocular surface prior to cataract surgery
  - Thereby, stabilizing IOL calculation and reducing post-op refractive surprises

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SPK → RCE → PED → Neurotrophic Ulcer

- **53-year-old female**
  - **History of RCE, (Recurrent Corneal Erosion)**
  - Seen by general ophthalmologist many times for RCE for 3 yrs.
  - NI after treatment with BCL, antibiotics, and lubricants
  - Referred to corneal specialist after 2 weeks of non-responsive treatment

- **Possible Neurotrophic Ulcer**
  - **BVA OD:** 20/40
  - **OS:** 20/200
  - **H/O CL wear, dry eyes from staring at computer monitor**
SPK → RCE → PED → Neurotrophic Ulcer

**Protocol:**
- Day 1 – fit with PKP (Plus Lens)
- Followed up every 2-3 days for 2 weeks, before membrane dissolved.
- Switched to PKS – Slim afterwards
- Total treatment time: 20 days.
- VA post-treatment: 20/40

Last follow-up visit: Day 20
scVA: 20/40
Conjunctival Chalasis
Overlooked Cause of Dry Eye – Surgery Required

COMPOSITIONAL
- First branch Trigeminal Nerve
- Facial Nerve
- VII Motor

HYDRO-DYNAMIC
- Smooth Corneal Epithelium
- Unstable Tear Film
- Poor Spread Conj Chalasis

Lid Blinking
Lid Closure

Lacrimal Gland
Meibomian Gland
Goblet Cells

V 1
First branch Trigeminal Nerve

All You See...the Tip of the Iceberg

Obstructed Tear Meniscus
- Ocular Surface
- Loose conjunctival tissue due to degenerated Tenon’s

Obliterated Tear Reservoir

 Conj-Chalasis Obliterates Fornix – Meniscus Causing Dry Eye Disease

Also Explains Why?
- Cannot hold patient’s own tears
- Seldom benefit from artificial tears
- Easy to generate “overflow”
- No relief with Restasis™

Blinking
**Reservoir Restoration Procedure for CCh**

- **Definition of Reservoir Restoration Procedure:**
  - A simple, surgical procedure for Conjunctivo-chalasis Dry Eye that restores the function of the anatomical tear reservoir (fornix) by:
    1. Removing deteriorated Tenon’s Capsule
    2. Rearranging (recessing) to deepen the fornix, 
    3. Replacing missing conjunctiva to expedite patient’s recovery

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**Post-op CCH Procedure + CAM**

- PRE OP (06.21.04)
- 5 years POP (06.03.09)

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**Treatment: Ocular Surface Disease**

- Conjunctival Inflammation
- Corneal Inflammation
- Pterygium/Conj Chalasis
- Keratitis
- Persistent Epithelial Defect (PED)
- Ulcer
Accelerate healing to reduce or avoid visually significant corneal complications including corneal haze.

Accelerate restoration of normal corneal health via nerve regeneration.

Amniotic Membrane’s Ultimate Screen Protector for Your "Ocular Surface Pro"

Thank You
HOW NOT TO BEND WITH THE CONTACT LENS TRENDS

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ABSTRACT

There have been tremendous advances in the field of contact lenses over the last ten years. This includes developments in contact lens designs, materials and care solutions that have benefited our patients in many ways such as in comfort and vision. The objective is to provide a comprehensive update on the contact lens industry and how we can consider new technologies to optimally impact and improve on patient care in terms of comfort, safety, convenience, and visual correction. Likewise, it is important to develop a clear understanding of potentially disruptive technologies to anticipate their impact on the contact lens market and practice.

Learning Objectives:
1) To become current with the current state of the contact lens industry, including trends in fitting and treatment patterns.
2) To review and update knowledge on contact lens modalities, including their impact and trends.
3) To identify key trends in the contact lens market and seek insight into potential future trends or issues of importance in areas such as disruptive technologies, distribution channels, specialty fitting, and myopia control.

The State of the Contact Lens Industry

A. The global contact lens market

1. A look back in time

2. US vs. Other regions of the world

3. Anticipated growth—what regions? What sectors?
4. Trends in materials, designs, and modalities

   a. Soft lenses/replacement schedules/modalities

   b. Materials: Rigid vs. hydrogel vs. silicone hydrogel

   c. Contact lens design distribution

   d. The specialty lens market

   e. Care solutions

B. Potential Future Concepts and Practice Scenarios for Contact Lenses

1. Replacement schedules: Have we truly embraced the potential (daily disposables)?

2. Multifocals: Not just for presbyopia any longer!

3. New specialty lens design concepts and utilization

4. Futuristic concepts in contact lenses

C. The future of contact lens distribution—will internet prescribing and sales be the way of the future?

   a. Contact lens distribution overview

      i. Distribution—practice, third party, online

      ii. Fair trade practices

   b. Contact lens legislation overview
i. Prescribing patterns

ii. FDA/medical devices

c. Disruptive technologies

i. Disruption in a market place—what’s the big idea?

ii. Are contact lenses becoming commodities?

iii. How do we not bend with the trend?
Myopia Control: Today's Options and What's on the Horizon

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Course Description:
This course reviews current research and options available for controlling myopia progression. Eye care providers will gain an evidence-based understanding of what is currently known about available treatments for myopia and how to implement them in their practice.

Course Learning Objectives:
- Review current prevalence of myopia and ramifications of high myopia
- Review the effects of currently available optical designs on peripheral defocus
- To discuss current treatment strategies for myopia
- To discuss pharmacological treatment strategies for myopia
- Review potential environmental influences on refractive error
- To discuss how eye care providers can implement myopia control in their practice based on the currently available evidence

Outline:
I. US Myopia Progression (Mutti, IOVS, 2007)
   a. Refractive error and axial length change before and after myopia onset
   b. Differences by race and ethnicity (Asian, Hispanic, Caucasian, African American)
II. Contact lens treatments for myopia control
   a. Summary of multifocal contact lens evidence
      i. DIMENZ study / CooperVision MiSight Lens (Anstice, Opthalmol, 2011)
      ii. Novel aspheric lens design (Sankaridurg, IOVS, 2011)
      iii. BLIMP study / CooperVision Proclear Multifocal (Walline, OVS, 2013)
      iv. DISC study and wear time influence on effect size (Lam, Br J Ophthalmol, 2014)
      v. CONTROL study / Acuvue Bifocal (Aller, OVS, 2016)
      vi. Summary: Expect 34-50% reduction in axial length at 1 year versus single vision
   b. Summary of orthokeratology evidence
      i. Association between corneal power changes and axial elongation (Zhong, OVS, 2014)
      ii. CRAYON study / CRT (Walline, BJO, 2009)
      iii. MCOS and ROMIO studies / OK vs specs (Santodomingo-Rubido, IOVS, 2012; Cho and Cheung, IOVS, 2012)
      iv. IOOALECM study; 5-year follow up (Hiraoka, IOVS, 2012)
v. Summary: Meta-analysis: 0.26mm less axial growth over two years (Si, OVS, 2015)
c. Multifocals vs orthokeratology
   i. Similar efficacy and acuity, but more (mild) adverse events and greater chair time with orthokeratology compared to soft daily disposable multifocals (Turnbull, OVS, 2016)
d. Is there rebound after ceasing optical treatments?
   i. No evidence in PALs (Berntsen, IOVS, 2013)
   ii. No evidence with positive spherical aberration soft contact lenses (Cheng, OVS, 2016)
III. Microbial Keratitis, infiltrative events and adverse events in children
   a. Teenagers and young adult have higher interruption of wear events than children (Wagner OVS 2011; Chalmers 2011 IOVS)
   b. MK in kids (Orthokeratology) (Bullimore OVS 2013)
   c. Compliance (Cope CDC 2015)
IV. Atropine
   a. Effective at multiple concentrations (Chia 2015)
   b. Rebound effect depending on concentration used after cessation (1% down to 0.01%)
   c. 0.01% atropine: changes seen in refractive error but not axial growth? (Chia 2015; Chua 2006)
V. Outdoor Effect on Myopia Onset and Progression
   a. Time Outdoors Protective against Myopia Onset
      i. Jones-Jordan 2007; Rose 2008; Dirani 2009
   b. Is time outdoors protective against myopia progression?
      i. Jones-Jordan 2012; Wu 2013; He 2015
VI. Putting it into practice
   a. Zadnik 2015: Predicting children who will be myopic by grade 8 (13 years old):
      i. less hyperopic than +0.75 D for grade 1 (age 6 years)
      ii. +0.50 D or less hyperopic for grades 2 and 3 (ages 7 and 8 years)
      iii. +0.25 D or less hyperopic for grades 4 and 5 (ages 9 and 10 years)
      iv. emmetropic or more myopic for grade 6 (age 11 years)
   b. Treatment plans
      i. Measurement and standardization of methods
         1. Cycloplegic refractive error (GrandSeiko WAM-5500 or other open field)
         2. Axial length (Lenstar, IOLMaster, etc)
         3. Others: aberrometry, pupil size
      ii. Multifocal and orthokeratology options and comparison to peripheral defocus with standard contact lenses (Moore, OVS, 2017)
         1. CooperVision Proclear & Biofinity Multifocal “D” (Berntsen, OVS, 2013)
            a. Toric and XR options available
         2. Vistakon Acuvue Oasys for Presbyopia
         3. Visioneering Technologies NaturalVue Multifocal 1 Day
         4. Paragon CRT, Bausch + Lomb VST, custom
         5. Outside US: MySight CooperVision (CE Marking)
6. What to expect when fitting (over-refraction and visual acuity)
   BLINK Study data (Berntsen ARVO 2017)
   
   c. Patient education
      i. Expected efficacy
      ii. Risks and benefits
      iii. Potential plateaus
      iv. Off label use

VII. Myopia Management Questions
   a. What to do before myopia onset
      i. Methods before onset: Outdoors (He 2015); Atropine (Fang 2010);
         multifocal SCLs
   b. When to start treating?
      i. How myopic?
   c. Combination therapies and treatment plateau?
      i. Sequential treatment strategy
      ii. Concurrent treatment strategy
Lecture Outline Submission: CCLS Dec 2-3, 2017

Into the Future with Soft Lens Fitting
Speaker: Sheila D. Morrison, OD, MS, FSLS

30 minutes
COPE Category: CL

Course Learning Objectives
1. To provide an overview of Optometry’s current state of affairs as related to modern soft lens fitting.
2. To review physiological signs of a poor soft lens fit on the eye.
3. To describe technology and innovation that is currently available to assist practitioners in soft lens fitting.
4. To provide rationale for considering sagittal height versus base curve of soft lenses as an important fitting criteria in clinical practice.

Course Description
This course is designed to orient practitioners on new technologies related to soft contact lens fitting. An overview of the use of modern technology, such as corneal topography, anterior segment optical coherence tomography, and profilometry, will provide practitioners with innovative ways to think about soft lens fitting. The physiologic ramifications of a poor fitting soft contact lens will be discussed and several publications will be discussed outlining the most important parameters of soft lenses that should be considered when fitting patients.

Course Outline:
1. Introduction
   a. Soft lens evaluation and fitting do not have much emphasis in specialty lens practices
   b. Daily disposable modalities are perhaps the most focused upon today
   c. Custom soft options exist, are underutilized for specialty patients
2. Physiological signs of a poor soft lens fit
   a. Corneal deformations as a result of non-ideal soft lens fits are not uncommon
   b. 1/3 cases of corneal warpage cases result from soft contact lenses (Schornack et al 2003)
   c. important to consider when evaluating lens safety and performance
      i. hyperemia
      ii. conjunctival staining
      iii. impingement of conjunctival vessels
      iv. corneal staining
3. Lens discomfort
a. Number one reason for soft lens drop-out in North America
   i. Implies we have an opportunity to improve our fitting techniques to better serve our patients
   ii. Consider soft contact lenses on every routine patient

4. What is a good fit?
   a. Centration
      i. Related to physical ocular shape, including past the limbus
      ii. Corneo-scleral junctions should not be ignored
   b. Movement
      i. Need movement for perfusion of tears and oxygen
      ii. Movement also encourages flushing off of debris and bacterial growth
      iii. Our current ‘standard’ of 1mm is actually not sufficient
   c. Vision

5. Fitting parameters to consider
   a. HVID
      i. Typical measure used today
      ii. Most manufacturers do not stock lenses that are technically large enough to properly cover the limbus with sufficient movement on blink
   b. Central keratometry
      i. Not a useful measure in predicting soft lens fitting characteristics
   c. Sagittal height data

6. Overview of current technology and innovation as applicable and useful to soft contact lens fitting
   a. Criteria for success with soft lenses
      i. Adequate elevation maps
      ii. Adequate acuity with BCVA (spectacle correction)
      iii. Healthy ocular surface
         1. Impact and strategies in brief for dry eye patients and soft contact lenses
            a. Consider orthokeratology
   b. Corneal topography
      i. Gold standard
   c. Optical coherence tomography
   d. Profilometry
      i. Measurement of scleral/conjunctival shape beyond the limbus
      ii. Can easily obtain sagittal height measurements at any given chord
      iii. Commercially available tools
         1. Eye Surface Profiler
         2. sMap3D

7. Conclusion
   a. Traditional approach to soft lens fitting may not best serve our patients
   b. Industry needs to increase knowledge of scleral shape, increased options for parameters, and increased transparency of
Occupational Risk Factors for Dry Eye Disease
William D. Townsend, OD, FAAO
Adjunct Professor, UHCO

Course description: Dry eye disease (DED) is an increasingly common condition that has deleterious impact on quality of life. Some occupations inherently have higher risk for being associated with DED. This presentation addresses some occupation-related risk factors for DED.

1) Introduction
   a) Dry eye disease (DED) is an increasingly common condition that presents as ocular discomfort, blurred vision,
   b) Dry eye diseases (evaporative dry eye (EDE), aqueous-deficient (ADE), occur more frequently in individuals working in specific occupations
   c) This presentation addresses occupations that have higher risk for associated DED
   d) The lecture discusses therapeutic measures and behavior modifications that reduce the severity and functional issues resulting from occupation-associated dry eye disease

2) Occupation-related dry eye is a new phenomenon? Not really!
   a) Dante Alighieri (1265–1321) described “asthenopia” with intense reading
      i) “for greatly taxing my sight in eagerness of reading, I so weakened the visual spirits that all the stars appeared to me to be shadowed by a kind of halo”
      ii) His self-treatment “by long repose in dark and cool places, and cooling the body of eye in clear water” apparently provided the relief he sought”
      iii) Riva MA1, Arpa C1, Gioco M1. Dante and asthenopia: a modern visual problem described during the Middle Ages. Eye 2014 Apr;28(4):498.

3) Geography- Where you work and live influences your risk for DED! (Environmental factors affect the risk of dry eye syndrome in a United States veteran population. 1. Ophthalmology. 2014 Apr;121(4):972-3.)
   a) DED is more prevalent in areas of elevated aerosol optical density (AOD)
      i) AOD- an indicator of the concentration of aerosols (solid and liquid particles suspended in the air)
      ii) Can be used as a surrogate measure of air pollution.
   b) Risk of DES 13% higher in zip codes where atmospheric pressure was 1 standard deviation higher than the mean
   c) Veterans especially in Chicago and New York City were 3 to 4 times more likely to be diagnosed with DES compared with less urban areas with relatively low concentrations of AOD

4) Aviation: Fly the not-so friendly to dry eye skies- dry eye and air travel
   a) 2016 U.S. air lines carried an all-time record 719 million domestic and 104 million international passengers
   b) 590,000 active, certified pilots and 113,00 flight attendants in the USA
   c) Primary concern in aircraft ventilation systems- ensuring proper cabin air pressure
      i) Loss of air cabin pressure- hypoxia, fatigue, nausea, headaches, or pulmonary edema.
d) During flight: Gladyszewska-Fiedoruk (2012)
   i) CO₂ levels increase from 1100 ppm to around 1700 ppm.
   ii) Initial humidity level 55% rapidly declined to 33% and stabilized at 17%

e) 1,246 Australian pilots responded to a survey McCarty and McCarty (2000)
   i) 72.3% reported dry eye symptoms while flying,
   ii) 5.4% reported dry eye symptoms independent of flying

f) Teson et al subjected 20 DE patients to flight simulated conditions
   i) significant decrease in:
      (1) Tear stability (TBUT increased from 2.18 ± 0.28 to 1.53 ± 0.20)
      (2) Tear volume (phenol red thread test), and a significant \( P \leq 0.05 \)
   ii) Significant increase in:
      (1) Corneal staining
      (2) Tear levels of IL-6
      (3) Tear levels of MMP-9

g) Conclusion:
   i) Flying, especially >may lead to inflammation and dryness
   ii) As part of DED screening ask patients how frequently they fly process
   iii) Give particular attention to pilots and attendants

5) Childhood
   a) 2017-10th anniversary of Apple’s iPhone release
   b) Devices have potential to cause negative, long-lasting effects
      i) Domingues-Montanari (2017) device use prior to bedtime impaired sleep quality
      ii) Moon et al (2016) assessed smartphone use as a risk factor for pediatric DED
         (1) Risk factors for dry eye in children include:
            (a) Urban living
            (b) higher rates of smartphone use
            (c) One month of cessation of smartphone use in the dry eye group, signs and symptoms improved
      iii) Chu et al (2014) compared blink rates of individuals reading identical text on device and printed material
         (1) blink rates for both media were similar
         (2) Device reading had significantly more incomplete blinks
         (3) Korb et al (1994) - “forceful” blinking enhances lipid layer thickness
            (a) Incomplete blinking may lead to changes

iv)
Lid Scrubs and Wipes – What’s New and Works

Intro slide
Background of Scrubs – why are we doing them, benefits, potential patients

Baby shampoo – the breakdown, placebo effect?

Literature – what is out there
  Benefit to doing them before warm compresses, in office procedure

MGD/Blepharitis
a. Ocusoft Line
   Highlight all ocusoft scrubs
   How to use them
   Difference between foams and pre-moistened packs

b. Systane
   Systane Scrubs
   Cost comparisons to ocusoft

c. Zocular
   Discussion of zocuzomes and price points

d. Lid Hygenix
   Use in conjunction with BlephEX

Hypochlorous Acid Clearners – Inflammation

a. Avenova
b. Ocusoft Hypochlor

Demodex – Tea Tree Oil Derivatives

a. Sterilid
b. Cliradex

Others?

Table of Different products and uses

In practice? Protocols
Scleral Lens wearers in need of protocol
The DEWS & Don’ts of Dry Eye

What’s New & What’s Not in Ocular Surface Disease

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ABSTRACT

The over-arching goal of this course is to facilitate an understanding of dry eye diseases. For example, dry eye disease impacts 20-30% of our patients, and dry eye symptoms impact about one-half of contact lens wearers, and can ultimately lead to dropout and failure of continued lens wear. Yet, there is a development of understanding of the etiological mechanisms associated with dry eye diseases, in addition to a lack of consensus on management of these patients. To this end, the Tear Film and Ocular Surface (TFOS) Society has sponsored several global initiatives with scientists and clinicians to build harmonization around issues of dry eye and contact lens discomfort. The TFOS International Workshop on Meibomian Gland Dysfunction (MGD), Contact Lens Discomfort (CLD) and Dry Eye Workshops (DEWS) II are examples of these initiatives. These workshops were the result of lengthy processes and involved discussions surrounding key themes in dry eye disease such as definitions and classification, epidemiology, neurobiology, the tear film, clinical trials, and strategies for management and therapy. The purpose of this lecture is to highlight and overview the results of these workshops and to provide clinical relevance and context to their recommendations.

Learning Objectives:

1) To discuss recent activity in global thinking on contact lens discomfort (CLD), including the the Tear Film and Ocular Surface Society’s (TFOS) International Workshop on Meibomian Gland Dysfunction, CLD and Dry Eye Workshop II.

2) To review concepts of definition and classification of CLD, dry eye disease and meibomian gland dysfunction.

3) To probe the relationship between contact lens wear, discomfort, and meibomian gland dysfunction.

4) To study management and therapeutic strategies for dry eye diseases, with an emphasis on contact lens discomfort,
I. The process of the TFOS International Workshops on dry eye disease.

   A. Historical look at other workshops—the TFOS Dry Eye Workshop (DEWS), Contact Lens Discomfort and Meibomian Gland Dysfunction Workshops.

   B. Process, objectives and timelines.

   C. Evidence Basis: Levels of Evidence

   D. The TFOS International Workshops—final form and results.

II. What is “Dry Eye?” Definitions and Classification.

   A. Review of terminology—dry eye vs MGD vs. CLD. Is there really a difference?

   B. Outline of the current definitions.

   C. Review of the current classification schemes for dry eye diseases.

III. OMG its MGD!—the role of the Meibomian Glands and Dysfunction

   A. Symptoms

   B. Glandular changes

   C. Tear film/lipid layer disruption

      a. Evaporation
b. Osmolarity

IV. Management and Therapy

A. What are practitioners seeing and doing to manage CLD?

B. Controversies with current practices

1. Contact lens materials: Does oxygen even matter?

2. Replacement schedules

3. Wetting agents and tear supplements

4. Should we plug?

5. Is the answer the oil?

6. Medications: Should I consider medications for these patients?

7. Other management options?
Psychology of Scleral Lens Fitting

Melissa Barnett, OD, FAAO, FLS, FBCLA

Disclosures

- Barnett
- AcuLabs
- Alden Optical
- Alcon
- Allergan
- Bausch + Lomb
- Contamac
- CooperVision
- JVIC Vistakon
- Novabay
- Gas Permeable Lens Institute (GPLI)
- Paragon Biotech
- Scleral Lens Education Society
- Shire
- STAPLE program
- SynergEyes

Basic indications of scleral lenses

- Vision rehabilitation
- Ocular surface disease management
- Pain attenuation
**Personality Trends in Keratoconus**

- Personality trends in keratoconus. An analysis.
- 109 subjects
- Used a standardized personality inventory (the Millon Clinical Multiaxial Inventory)
- Measured 20 personality scales, both normal and pathologic.
- Subjects divided into three age-matched groups
  - 1. Patients with KCN
  - 2. Patients with other chronic eye diseases
  - 3. Normal controls

---

**Personality Trends in Keratoconus**

**Results**

- Chronic eye disease (including KCN) did have an impact on personality functioning in young and middle-aged adults
- No specific complex of personality characteristics attributable to KCN could be identified.
- Patients with KCN differed from normal controls similar to patients with other chronic eye diseases.
- Less conforming and more passive-aggressive, paranoid, and hypomanic.
- KCN patients tended to more disorganized patterns of thinking and scored higher on substance abuse indicators.
- ★ The influence of KCN on personality may be a function of the timing and nature of its onset in the context of the patient’s psychosocial development.

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**Personality and keratoconus**

- Swartz NG, Cohen EJ, Scott DG, et al.
- Personality and keratoconus
- Controlled prospective study
- Minnesota Multiphasic Personality Inventory (MMPI)
- 25% of control patients with herpes simplex keratitis had scores indicative of psychological abnormality
- 54% of KCN patients had scores indicative of abnormality.
- KCN patients post PK had a lower rate of abnormal scores (33%) vs. un-operated KCN patients (63%)
- ★ Patients who considered themselves moderate or severely limited by their eye condition were more likely to have abnormal scores (87%) than patients who thought they were mildly affected (40%)
Quality of life in keratoconus

- Quality of life in keratoconus
- Cross-sectional study
- 1166 CLEK Study patients at their first annual examination
- National Eye Institute-Visual Function Questionnaire (NEI-VFQ) was administered
- Associations between clinical and demographic factors and NEI-VFQ scale scores were evaluated.

Quality of life in keratoconus

- BCVA worse than 20/40 associated with lower quality of life scores except for General Health and Ocular Pain.
- Steep K reading (average of both eyes) >52D was associated with lower scores on the Mental Health, Role Difficulty, Driving, Dependency, and Ocular Pain scales.
- Scores for CLEK patients on all scales were between patients with category 3 and category 4 AMD patients
  - Exceptions
    - General Health (better than AMD patients)
    - Ocular Pain (worse than AMD patients)

Changes in the quality-of-life of people with keratoconus

- Changes in the quality-of-life of people with keratoconus
- Evaluated changes that occurred in V-QoL over 7 years of follow-up.
- Prospective study
- 1,166 participants for seven years

Changes in the quality-of-life of people with keratoconus

- All scales showed modest decline except ocular pain and mental health.
- Baseline factors were not associated with longitudinal change in NEI-VFQ scores.
- Significantly larger declines in V-QoL associated with
  - 10 letter decline in high-contrast binocular VA
  - 3.00D increase in corneal curvature
- In multivariate analysis, factors associated with a 10-point decline in NEI-VFQ scale scores.
- ★ KCN is associated with significantly impaired V-QoL that continues to decline over time.
Quality of Life in Patients with KCN

- Vision related quality of life in patients with keratoconus.
- Kurna, Aydin, Altun, Gencaga, Akkaya, Sengor
- J Ophthalmol 2014; April.

- National Eye Institute Visual Function Questionnaire-25 (NEI-VFQ-25)
  - 30 patients with KCN
  - 20 RGP wearers
  - 10 non-contact lens wearers
  - 30 healthy patients (control group)

Quality of Life in Patients Wearing Scleral Lenses

- Picot, C, Gauthier, AS, Campolmi, N, Delbosc B
- Evaluated the improvement of QOL with scleral lenses in KCN or the treatment of astigmatism after PK
  - Retrospective study
  - Patients failed to adapt to RGP lenses
  - QOL before and after scleral lens adaptation

QOL KCN

- CL wearers had better BCVA compared with non-CL wearers (P = 0.028)
- Patients with low visual acuity in the better eye
  - Worse distance vision
  - Worse social function
  - Worse mental health
  - Increase in role difficulties
- Patients with low visual acuity in the worse eye
  - Lower general health scores
- ★ Vision related quality of life worse in patients with KCN
  - Success with CLs and maintaining better visual acuity may improve vision related quality of life.

Quality of Life in Patients Wearing Scleral Lenses

- 47 patients (83 eyes) fit with scleral lenses on one or both eyes
- 56 eyes with KCN
- 27 post PK eyes

- NEI-VFQ 25 scores with scleral lenses were significantly higher than those without scleral lenses.
- ★ Scleral lenses showed significant improvement in QOL for patients who had failed or are intolerant to conventional rigid gas permeable CLs.
- Scleral lenses are an alternative or a step prior to surgery
Ocular Surface Disease Index Scoring

<table>
<thead>
<tr>
<th>Severity</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>0-12</td>
</tr>
<tr>
<td>Mild</td>
<td>13-22</td>
</tr>
<tr>
<td>Moderate</td>
<td>23-32</td>
</tr>
<tr>
<td>Severe</td>
<td>33-100</td>
</tr>
</tbody>
</table>

Scleral Lenses and cGVHD

- Boston Scleral Lens
- n = 9
- Retrospective review
- Reduction in OSDI from 81 to 21 after 2 weeks
- Further reduced to 12 after 1 – 23 months

Scleral Lenses and cGVHD

- 407 patients with cGVHD and PROSE treatment between 2002-2011
- National Eye Institute Visual Functioning Questionnaire-25
- Baseline measures compared to 6 month post-fitting period
- NEI VFQ-25 scores improved significantly by 41 points (scale 0-100)
Pain Without Stain

- Pain quality, intensity, and character differs between patients, between eyes, and within one eye over time
- Comorbid pain in face and around eye can be present
- Pain with scleral lens wear

Understanding the Process

The Patient Journey

- Symptoms
- Diagnosis
- Treatments....
- Scleral lenses
- Post-fitting management of disease/condition

The Patient Experience

5 tips to success

- Remember, no two people are the same.
The Patient Experience

- Listen to understand, not to respond.

Minimize your patient's sense of threat
- 5 factors to consider in helping people feel *safe*.
  1. Predictability
  2. Choice
  3. Fairness
  4. Acceptance and connection
  5. Trust

The Steps of Active Listening

- Comprehension
- Retention
- Reflection
- Clarification
- Summarization

Acknowledge your patient's emotions.
open-ended questions
Find out what your patient cares about and needs from you.

Avoid responding defensively to a patient.

Empathy

- What is it? Why it matters.
- The ability to sense other people’s emotions, and the ability to imagine what someone else might be thinking or feeling.

Affective Empathy

- Sensations and feelings we get in response to others’ emotions
- Cognitive empathy (perspective taking) - ability to identify and understand other peoples’ emotions.
Tools To Cultivate Empathy

- Active listening
- Shared identity
- Put a human face of suffering
- Eliciting altruism
- Focus your attention outwards
- Get out of your own head
- Don’t jump to conclusions about others
- Meditate
- Explore imaginary worlds
- Join the band
- Play games
- Take lessons from babies
- Combat inequality

Barriers to Scleral Lens Success

Seven Stages of Grief

<table>
<thead>
<tr>
<th>Stage</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shock</td>
<td>Initial paralysis at hearing the bad news.</td>
</tr>
<tr>
<td>Denial</td>
<td>Trying to avoid the inevitable.</td>
</tr>
<tr>
<td>Anger</td>
<td>Frustrated outpouring of bottled-up emotion.</td>
</tr>
<tr>
<td>Bargaining</td>
<td>Seeking in vain for a way out.</td>
</tr>
<tr>
<td>Depression</td>
<td>Final realisation of the inevitable.</td>
</tr>
<tr>
<td>Testing*</td>
<td>Seeking realistic solutions.</td>
</tr>
<tr>
<td>Acceptance</td>
<td>Finally finding the way forward.</td>
</tr>
</tbody>
</table>

*Stage纳称根据在多数情况下获得性同意而应用，不一定适用于其他所有情况。这7个阶段通常按顺序发生，但不一定严格遵循。这7个阶段不应被认为是必需的或固定的。
“Talking visits”

- Sometimes the patient just needs additional support
- Patient education
  - Diagnosis education
  - Scleral lens fitting description
  - Treatment alternative discussions
- Coordination of care
  - Ophthalmology and/or subspecialty
  - Rheumatology/Oncology
  - Psychiatry or Psychology

Patient counseling and coordination of care

- More than 50% of the encounter is dominated by counseling and coordination of care
- Time alone is determining factor of E/M code
- Support with appropriate documentation
  - Total time of examination
  - Percentage of encounter dedicated to counseling
  - Nature of discussion/coordination of care/tests ordered/results discussed

Know Your Resources

Roles and Responsibilities

- Employee:
- Relay information on the impact of the impairment on your ability to do the job
- Essential that employee participate in the process
- Provide documentation of job related limitations
- Provide ideas/input on accommodations

[Image: http://www.dhhs.reg.gov/patient-experience/hdl/sclera/]

[Image: http://www.dhhs.reg.gov/patient-experience/hdl/sclera/]

[Image: http://www.dhhs.reg.gov/patient-experience/hdl/sclera/]
How to begin the discussion

• Approach your supervisor or manager
• Relay that you may need an accommodation for a condition that is impacting your ability to do your job
• Remember confidentiality – you do not need to disclose more information than the job-related limitations or impact on the ability to do the job
• Keep the focus on problem-solving

Resources

• JAN – Job Accommodation Network
• www.askJAN.org
• Free resource
• Searchable database of accommodation ideas sorted by impairment
• “A to Z” of disabilities – accommodation and compliance series
• JAN ON Demand

Best practices

• Communicate for school work
• Communicate for jobs / applying for jobs
• How the condition affects the relationship with family and friends
• Important to treat the entire condition
• Include family members in the dialogue

Best Practices

• Communicate with employer
• Important not to complain/whine
• Discuss goals to be good at the job
• Discuss problem solving strategies
• What has been already done to perform best
• Be as honest as can be without disclosing too much information
• Accommodations are not favors
• All employers need help understanding disabilities
Suicidal warning signs

- Risk factors
  - Adverse or traumatic life events in combination with other risk factors
  - One or more prior suicide attempts
  - Family history of mental disorder or substance abuse
  - Family history of suicide
  - Family violence
  - Physical or sexual abuse
  - Keeping firearms in the home
  - Chronic physical illness, including chronic pain
  - Incarceration
  - Exposure to the suicidal behavior of others

- Associated conditions
  - Over 90% of people who die by suicide have clinical depression or a diagnosable mental health disorder.
  - Alcohol
  - Substance abuse

Suicidal protective factors

- Support system
  - Family
  - Friends
- Optimism
- Strong self esteem
- Good coping skills
- Spirituality/religion
- Lack of access to weapons/firearms
- Absence of drug and alcohol use/abuse

Assessing Suicidal Risks

• Listen attentively
• Allow for emotional outbursts
• Stay calm and be supportive
• Do not judge or provide negative feedback
• Remember the steps to active listening—summarize the problems back

www.suicide.org

Assessing Suicidal Risks

• Be direct. Are you thinking about suicide?
  – Myth: asking will give them ideas....
• Have you thought how you would do it?
• Do you have what you need to follow through with it?
• When do you plan to do it?
• Have you rehearsed the plan?
• Have you ever tried before?

www.suicide.org

Taking Action

• Continue constant communication with the individual
• Try to get the patient in immediate treatment if the risk is high.
• Persuade the patient to call 911 or go to the emergency room
• Continue communication as long as the patient appears to be immediate danger
• Say that you are getting help and call 911
• Assessments require clinical skill and judgment and are typically performed by a mental health professional make sure they get directed appropriately

Do NOT

• Leave patient alone
• Be judgmental
• Cheer the patient up
• Challenge the patient to follow-through
• Do not accept I’m okay now....it’s not that fast
• Do not be sworn to secrecy

Salvatore, T. Montgomery County Emergency Service. Suicide Prevention for Health Care Providers
http://www.mces.org/PRF/suicideproviders.pdf

Salvatore, T. Montgomery County Emergency Service. Suicide Prevention for Health Care Providers
http://www.mces.org/PRF/suicideproviders.pdf
Knowing Your Limits

Professional Resources

Know Who’s on Your Team

Mental health professionals job descriptions
- Prescribers
  - Psychiatrists
  - Primary care doctors
  - Nurse practitioners
  - Physician assistants
Mental health professionals job descriptions

- Therapists
  - Psychiatrists who do therapy
  - Psychologists
  - Marriage and family therapists (MFT's)
  - Licensed clinical social worker's (LCSW's)
  - Chemical dependency counselors
  - 30% of mental health patients have some kind of substance use disorder

Case Workers and Social Workers

- Often employed by government agency or non-profit organization to provide individuals with advocacy, information and resources.
- Does not solve the problems of the patients but provides patients the ability to better equip themselves to solve their own problems
- Responsibilities include: rapport building, psychosocial assessment, resource allocation, service coordination, monitoring, review and terminations

Remembering to put your “I” in eye care

Protect Yourself

http://www.dprilla.com/live-alternative-ways-to-charge-your-phone/the-battery/
Physician Burnout

- Exhaustion
  - Energy, emotion, or spirit
- Cynicism
  - Loss of empathy
- Doubt
  - “Does any of this matter?”

Changing the Conversation From Burnout to Wellness

- Existing literature either does not address physician wellness or defines it as a lack of burnout
- Provides ideas for how to fill the gap in the literature
- Toolbox of practical steps to create a culture that emphasizes wellness

Mental Health Resources for Practitioners

- Stanford Medicine WellMD
- Mayo Clinic Centers and Programs: Physician Well-Being Program

Box 1: Wellness Toolbox

1. Designate a faculty who owns wellness and has time to champion it, and then enlist the help of the chief residents. These individuals can develop a plan, based on the program’s needs or needs assessment, for the next steps.
2. Define wellness.
3. Administer a burnout tool (e.g., Maslach Burnout Inventory) twice a year to faculty and residents. Provide individual and group feedback.
4. Provide lectures on wellness, burnout, writing a mission statement, positive psychology, and cognitive-behavioral counseling techniques.
5. Schedule “difficult patient” panels twice a year to discuss, as a group, how to manage difficult situations and interactions.
6. Schedule small meetings every other month with faculty mentors who model the human side of medicine.
7. Develop a list of psychological and primary care providers tailored for residents. Put it on a shared server.
8. Schedule 1-day faculty retreats for renewal.
9. Assign “wellness partners” for faculty and residents with emotional, physical, spiritual, and social goals, based on quarterly reminders.
10. Develop a professionalism contract for faculty and residents with annual review.
11. Make wellness an agenda item on monthly faculty and resident meetings.
12. Develop a physician support group (see the work of Rachel Naomi Remen, M.D.).
13. Ask residents to set quarterly wellness goals during advising meetings.
14. Assign a physician office staff to schedule “init” social events for the entire office (e.g., sporting events).
15. Involve residents in faculty meetings, committee, etc., to increase sense of control.
17. Empower faculty and residents to confront concerns as they arise through both in-residents and faculty.
18. Encourage faculty to provide positive feedback.
19. Take time to publicly acknowledge accomplishments, even transitions from postgraduate year 1 to 2 or 3. Hold our appreciation lists.
20. Change the culture over time. Create an environment that does not focus on pathology.
Box 2: Definition of Wellness

“The William Beaumont Family Medicine Residency Program” values a holistic philosophy of care for self and patients. Central to this care is a focus on the development and maintenance of a wellness orientation.

Wellness is defined as a dynamic and ongoing process involving self-awareness and healthy choices resulting in a successful, balanced lifestyle.

**Wellness:**
- Incorporates balance between the physical, emotional, intellectual, social, and spiritual realms;
- Results in a sense of accomplishment, satisfaction, and belonging;
- Provides protection from the unique demands of medical training and beyond.

**Key components to developing and maintaining wellness:**
- Feeling engaged and empowered with good boundaries;
- Maintaining physical health with adequate rest, healthy diet, and regular exercise whenever possible;
- Having confidence in self, the faculty, and the program;
- Communicating effectively within and outside of the residency program;
- Taking time away from work and leaving work behind (e.g., evenings, weekends, vacations);
- Being present in the moment;
- Being able to recognize signs of burnout or the need to renew before burnout occurs;
- Compassionately recognizing and accepting humanity in oneself and in others.

---

**Mental health tools**

- Mindfulness
- MBSR courses (mindfulness-based stress reduction)
- Meditation
- Yoga
- Spending time outdoors
- Sleep
- Healthy diet
- Exercise
- Journaling
- Volunteering
- Limit substances
- Stick to a routine
- Spirituality

---

**Summary**

- Empathize with the patient journey
- Incorporate empathy
- Integrate active listening
- Pay attention to suicidal warning signs
- Utilize mental health tools
- Protect yourself and employ resources

- Thank you for your time and attention!
Life Beneath a Scleral Lens: The Tear Film Reservoir

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Houston, TX 77204
Tel: 713-743-6421
mkwalker@central.uh.edu

Course Description:
This course is designed to review the fitting relationship of a scleral lens on the eye, and specifically discuss the implications of the tear film reservoir between a scleral lens and the ocular surface. The components of the reservoir, specifically the proteins and lipids in the fluid, will be discussed, as will the implications on the ocular surface.

Course Objectives:
- To review the fit of a scleral lens on eye, emphasizing the presence of the tear film reservoir
- To review the components of the natural tear film
- To introduce new data on the components of the tear film reservoir
- To compare the components of the natural tear film to those of the tear reservoir, and discuss implications of the tear reservoir on the cornea.

Outline
I. Overview of the scleral contact lens fitting relationship
   a. Corneal vault with scleral landing
   b. Features of the scleral lens tear reservoir
      i. The post-scleral lens tear reservoir is relatively deep (100-400um), to vault the cornea and avoid interaction with diseased corneal surfaces.

II. Corneal health beneath a scleral lens
   a. The tear fluid reservoir continuously bathes the ocular surface and provides a barrier to the cornea and the lens and atmosphere
      i. Oxygen availability to the cornea
      ii. Epithelial bogging beneath a scleral lens

III. Composition of Post-Lens Tear Film Reservoir
   a. Scleral Lens Application Solutions
      i. Saline solutions versus custom solutions
ii. Nutrients and corneal needs

iii. Protection offered from microbial growth with saline?

b. Proteins

   i. Many proteins are found in the post lens tear reservoir...what are those proteins and how do they compare to the natural tear film composition?

   ii. What is the role of tear exchange in the post lens tear reservoir protein (and lipid) content?

c. Lipids

   i. What is known about the lipid composition in the tear film reservoir?

d. Cell Debris

   i. The reduction of epithelial cell sloughing during scleral lens wear – what indications does this have on corneal health?

e. Midday fogging

   i. Occurs in 20-30% of patients, variably

   ii. Risk factors: deep tear reservoir, excessive limbal clearance, tight fitting relationship, dry eye disease, allergies.

   iii. Remedies include high viscosity application solutions, toric peripheral curves, time, decreased apical/limbal clearance, allergy/anti-inflammatory treatment.
It has been said that the ‘first and most basic consideration’ in fitting a scleral contact lens is determining its overall diameter. van der Worp 2015
There appears to be a general agreement that a scleral lens needs to vault over cornea with limbus.

It follows that the diameter of the cornea together with limbus will have a considerable impact on what the diameter a scleral lens at least needs to have.

What is the average size of the human cornea?
<table>
<thead>
<tr>
<th>References</th>
<th>Corneal Diameter</th>
<th>How Measured?</th>
<th>Limbal Width</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duke-Elder, Wybar (1961)</td>
<td>11.7 x 10.6 mm</td>
<td>average of quoted references</td>
<td>1 mm</td>
</tr>
<tr>
<td>Hogan, Attaar, Weddell</td>
<td>11.7 x 10.6 mm</td>
<td>not described</td>
<td>1 mm</td>
</tr>
<tr>
<td>(1971)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Fatt, Engelman (1992)</td>
<td>11.7 x 10.6 mm</td>
<td>not described</td>
<td>not stated</td>
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<tr>
<td>Bron, Regani, Regani</td>
<td>11.7 x 10.6 mm</td>
<td>not described</td>
<td>1.5 x 2 mm</td>
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<tr>
<td>(1997)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Snell, Lamp (1999)</td>
<td>11.7 x 10.6 mm</td>
<td>not described</td>
<td>1.5 - 2.0 mm</td>
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<tr>
<td>QYSSF (1999)</td>
<td>11.7 x 10.6 mm</td>
<td>not described</td>
<td>1.5 mm</td>
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<tr>
<td>Smolek, Ryche (2000)</td>
<td>11.7 x 10.6 mm</td>
<td>not described</td>
<td>not stated</td>
</tr>
<tr>
<td>Remington (2012)</td>
<td>12 x 11 mm</td>
<td>HVID</td>
<td>1.5 - 2 mm</td>
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<tr>
<td>Douglas, Lawrence (2016)</td>
<td>11.7 x 10.6 mm</td>
<td>not described</td>
<td>not stated</td>
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<tr>
<td>Bergmann (2017)</td>
<td>11.7 x 10.6 mm</td>
<td>not described</td>
<td>1 mm</td>
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<tr>
<td>Freddo and Ghalijin (2017)</td>
<td>11.7 x 10.6 mm</td>
<td>not described</td>
<td>1-2 mm</td>
</tr>
</tbody>
</table>

*Everybody uses the same numbers!*

*Why?*

*Sir Stewart Duke-Elder*
<table>
<thead>
<tr>
<th>References</th>
<th>Corneal Diameter (HVID?)</th>
<th>How Measured</th>
<th>Limbal Width</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mandell (1988)</td>
<td>13.5 x 10.5 mm</td>
<td>HVID: 13.5 x 10.5 mm</td>
<td>not stated</td>
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<td>Mandell, Vogt, Neufeld (1988)</td>
<td>11.7 - 10.6 mm</td>
<td>not stated</td>
<td>not stated</td>
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<tr>
<td>Efron (2001)</td>
<td>not stated</td>
<td>not stated</td>
<td>not stated</td>
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<tr>
<td>Ridder III (2006)</td>
<td>not stated</td>
<td>not stated</td>
<td>not stated</td>
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<tr>
<td>Phillips, Speedwell (2007)</td>
<td>not stated</td>
<td>not stated</td>
<td>not stated</td>
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<tr>
<td>Bennett, Perrigin, Watanabe, Begley (2014)</td>
<td>10 - 13 mm</td>
<td>HVID</td>
<td>not stated</td>
</tr>
<tr>
<td>van der Worp (2015)</td>
<td>12 mm average diameter of cornea</td>
<td>not stated</td>
<td>not stated</td>
</tr>
<tr>
<td>Lawrenson (2018)</td>
<td>11.8 x 10.6 mm</td>
<td>not stated</td>
<td>not stated</td>
</tr>
</tbody>
</table>

*Clinical & Surgical Corneal Texts*

<table>
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<tr>
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<th>How Measured</th>
<th>Limbal Width</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arffa (1997)</td>
<td>12.5 x 11.5 mm</td>
<td>not described</td>
<td>not stated</td>
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<tr>
<td>Klyce, Beuerman (1998)</td>
<td>12.6 x 11.7 mm</td>
<td>not described</td>
<td>not stated</td>
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<tr>
<td>Trinkaus-Randall, Edelhauser, Leibowitz, Freddo (1998)</td>
<td>12.6 x 11.7 mm</td>
<td>not described</td>
<td>not stated</td>
</tr>
<tr>
<td>Trochme (2002)</td>
<td>11.7 - 12 H x 10.5 V</td>
<td>not described</td>
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<tr>
<td>Gipson, Joyce, Zieske (2005)</td>
<td>not stated</td>
<td>not described</td>
<td>1 mm</td>
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<tr>
<td>Dawson, Ubels, Edelhauser (2011)</td>
<td>11.7 x 10.6 mm</td>
<td>not described</td>
<td>1.5 - 2 mm</td>
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<tr>
<td>Nishida, Saika (2017)</td>
<td>11-12 x 9-11 mm</td>
<td>not described</td>
<td>not stated</td>
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</tbody>
</table>

*Contact Lens Texts*

<table>
<thead>
<tr>
<th>References</th>
<th>Corneal Diameter (HVID?)</th>
<th>How Measured</th>
<th>Limbal Width</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smith (1890)</td>
<td>11.6 mm</td>
<td>keratometer*</td>
<td>not stated</td>
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<tr>
<td>Wessely (1911)</td>
<td>10 - 12.5 mm</td>
<td>keratometer</td>
<td>not stated</td>
</tr>
<tr>
<td>Thomson (1912)</td>
<td>10.5 - 11 mm</td>
<td>not described</td>
<td>not stated</td>
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<tr>
<td>Peter (1924)</td>
<td>11.67 mm</td>
<td>keratometer</td>
<td>not stated</td>
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<tr>
<td>Kaiser (1926)</td>
<td>11.62 mm</td>
<td>keratometer</td>
<td>not stated</td>
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<tr>
<td>Johansen (1947)</td>
<td>H: 11 – 12 mm</td>
<td>V: 0.5 mm smaller post mortem using compass</td>
<td>not stated</td>
</tr>
<tr>
<td>Wilmer, Scammon (1950)</td>
<td>not stated</td>
<td>not described</td>
<td>not stated</td>
</tr>
</tbody>
</table>

*Citations by Duke-Elder and Wybar (1961)*

*Keratometer* - a device used to measure the horizontal diameter of the cornea without touching the living eye. It consisted of a millimeter scale placed between two plane-convex lenses in the form of an eyepiece and measured at its focal length.
**Corneal Diameter How Measured? Limbal Width**

**Martin, Holden** (1982)

- HCD: 12.86 +/- 0.6 mm
- HVID: 11.64 mm
- Measured as distance between the discontinuities in catoptric images on either side of the cornea in the horizontal meridian

**Van Buskirk** (1989)

- 11.7 x 10 A
- 1.2 mm
- Not described

---

*References*

- Female cornea is 0.1 mm (or 1%) smaller than the male
- Ethnic differences are less than 0.5 mm
- The cornea is round (circular) along its posterior surface according to some texts

---

*Peer Reviewed Journals*

- Van Buskirk (1989)

---

*Other Corneal Measures*

- No one defined what was measured and not measured
- None appears to have made a sincere assessment of the limbal width – all measures appear to be at best estimates...

---

*Important facts that emerged*
Current reference for the definition of corneal and limbal limits

Hogan et al, 1971 (almost ½ century ago)

Diagram

Micrograph - monkey

* Histological Section

Wider anteriorly or posteriorly? Or the same?

Note slant of lines - human vs monkey or artist impression...
* What is peculiar about this almost 50 year old image?

**Answer:** EVERY anatomy text (except mine!) uses this image or a slightly modified version of it!

* In other words: We base our knowledge today on a close to 50 year old DIAGRAM!

* Corneal width = Anterior Chamber width?

  (Image: Penner, Rocha, 2007)
Filtration Angle
(Light microscopy)

TERTC research - Lorenzo Anderson

* van Buskirk 1989; limbus = 1.2 um but how was it defined?

* SEM of filtration angle - apex (arrow) peripheral to trabecular meshes (* may not be a useful reference point)
* Corneal width = Anterior Chamber width? Correct Answer is: NO

(Image: Penner, Rocha, 2007)

* In vivo measurements?

* Most studies used the blue-grey ring as the limbal zone and excluded this area from the corneal measurement. BUT what structure is and is not included in this view?
Cornea: 11.7mm
Limbus: 1-2mm

11.7 + 2X1 = 13.7mm
11.7 + 2X2 = 15.7mm

A 15mm SGP cannot land comfortably or bridge limbus

*The scleral lens rides on the ocular surface therefore, we don’t have to worry about posterior width of cornea with limbus

*My SGP typically is 17.0 - 18.5 mm
- for maximum comfort you want to land gently and as far as possible away from the corneal nerve endings!
1. Stem cells benefit from a protective coverage by multiple layers of epithelial cells.
2. This should not be an issue - until we have evidence to the contrary.

*Summarizing corneo-limbal dimensions
* For corneal dimensions - we depend on studies done 67-127 years ago
* For limbal width - we depend on a 50 year old diagram
* Limbus never was measured
* Areas measured have not been defined
* Superior technology exists today

This information is needed not only by scleral lens practitioners but also by anterior segment and glaucoma surgeons...and anatomy teachers!

*Without this information the debate about ideal scleral lens size will continue and not be resolved
Photography of the Anterior Segment
by Thomas P. Arnold, OD, FSLS

Disclosures:
Bausch & Lomb Specialty Vision Products
Blanchard Lab
Boston Sight Scleral
EyePrint Prosthetics
Acculens
Visioneering Technologies Inc.
Oculus USA

“There are no rules for good photographs, there are only good photographs.”
Ansel Adams (1902-1984)
iPhone 4

Magnifi bayonet-style holder
Slips over existing ocular

www.arcturuslabs.com
Avoid vignetting by increasing magnification
ON THE DEVICE

Carson HookUpz 2.0
www.carson.com/hookupz2
Slit-lamp photography

Integrated slit-lamp cameras

Camera is connected directly to PC via USB 3.0 cable
PC runs real time photo software
Initial focus through the left ocular
Fine focus by viewing PC monitor. This is what gets recorded
Camera has both still and video capabilities
**Technique**

- Dim room lights including PC monitor
- Optic beam angled approx. 40 degrees
- White light
- Magnification 10-16x
- Take lots of pictures!

**Alternative angle**

- Center the light source over the cornea
- Swing to oculars 40-50° to the side
Alternative angle

- Center the light source over the cornea
- Swing to oculars 40-50° to the side

Use a Wratten filter

OCULUS Keratograph K-5M
Macro photography

- Get high quality “macro” lens

Dr. Edward Boshnick
Miami, Florida

Wireless flash controller
Settings for macro photos

- Use smallest aperture possible for maximum depth of focus (ex. f/32)
- ISO (image capture speed) - approx. 400
- Set image type to “Portrait”
- Manual focus / auto-stabilizer “ON”
- Set macro magnification to maximum
- Set focus zone to “center spot”  
- Move closer to eye while focusing on lamp reflections
- Snap picture when reflections are “sharp”

Avoid “ring” flashes
How it’s done
Photo editors

Photoshop Creative Cloud
Lightroom
Annual Membership Plan
$49.99 USD/month
Photo editors

iPad “Photos”

It is okay to edit (really)

Cropping is the most useful feature

Do not alter colours too much - may look unnatural

Editors for iPads & tablets
"The single most important component of a camera is the twelve inches behind it." - Ansel Adams

Contact me

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Course Outline: New Technology in Dry Eye Diagnosis
34th Annual Cornea, Contact Lens, and Contemporary Vision Care Symposium, Houston, TX
December 3, 2017 (1:20-1:40PM)

Daniel Powell, OD, PhD
Clinical Assistant Professor, The Ocular Surface Institute
College of Optometry, University of Houston, Houston, TX

Course Objectives:
• To briefly review the definition and classification of dry eye as well as its underlying mechanisms;
• To learn more about recent and emerging technologies in potentially aid in improving dry eye diagnosis and management.

Outline (20 min. course):
I. Dry Eye Overview
   A. Definition & Classification (DEWS II)
   B. Pathophysiology

II. Dry Eye Diagnosis
   A. Older clinical tests for dry eye: A quick review
      1. Ocular surface staining
      2. Tear quality and stability assessment
      3. Tear production
      4. Tear osmolarity
   C. Recent and new and diagnostic technologies
      1. Oculus Keratograph 5M
         a. Clinical application
            i. Non-invasive tear break-up time
            ii. Tear meniscus height
            iii. Tear lipid layer evaluation
         b. Obtaining and evaluating an image
      2. Tear film lipid layer interferometry
         a. Clinical application
            i. Thickness (normal vs. abnormal values)
            ii. Spreading characteristics and stability
         b. Instruments
            i. Oculus Keratograph 5M (Oculus, Inc.)
            ii. LipiView II (Tear Science, Inc.)
         c. Obtaining and evaluating an image
3. Meibography
   a. Clinical application
      i. Gland dropout
      ii. Acini appearance
   b. Instruments
      i. Oculus Keratograph 5M
      ii. LipiView II Dynamic Imaging System (Tear Science, Inc.)

4. Lab-Based Dry Eye Tests
   a. InflammaDry
   b. TearLab Discovery™ system
      i. Osmolarity
      ii. MMP-9 and IL-1Ra biomarkers
   c. Lactoferrin

D. Emerging technologies
   1. Optical Coherence Tomography (OCT)
   2. Near-infrared thermography
New office instrumentation for the contemporary optometrist

Steven J. Ferguson, OD
Dunes Eye Consultants and Lasik Center

Lipiscan

Lipiscan
Lipiscan

- MGD Detection: Your responsibility to your patients
- The new norm in eye care is to screen for MGD
  Identify-Diagnose-Prescribe

ROI: $21,000 - Identifies MGD which leads to work up and treatment
- 1 out of 4 patients have either obvious or non-obvious MGD that are level 2
- 20 std encounters: 5 MGD patients prescribed Lipiflow
- 45% acceptance to tx
- 4 eyes per day (12 clinic days) 48 treatments

Lipiscan $\$ per month

- 24 patients receiving bilateral Lipiflow treatment at $500 per eye
- 24 patient with work up prior to tx: 99213 and Lipiview Keratograph, Tear Osmolarity, Inflammadry $185.00
- f-up visit 8 weeks 99213 with Tear Osmolarity $135
- $24,000 Lipiflow Revenue
- 24 patient pre and post treatment clinic fees $7,680.00
**HD Analyzer**

Visiometrics

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**HD Analyzer: The Edge in Vision Assessment**

**Total Vision Quality**

- Refractive Aberration
  
- Scatter

---

**HD Analyzer: PSF**
HD Analyzer
Quantifies Image Quality

HD Analyzer
Tear Film Analysis

HD Analyzer: ROI
- $25,000 NO CPT code
- Improved prescribing for Dry Eye, Contact Lenses, Prescription Lenses, Refractive Surgery, Advanced IOL.
- Provides objective measure of potential image quality
- Priceless information
PERG: Electrophysiological testing in Glaucoma Syndromes

PERG: Glaucoma

- Measures the electrical activity of ganglion retinal cells
- Measures function of living cells that can still recover
- The Optic nerve “stress test” in Glaucoma suspects
- User friendly 15-20 minutes
- Detects functional abnormality early in disease process

PERG: Glaucoma

- Normative database report
- Great for unilateral IOP reduction test
- Supports the Metabolic theory of glaucoma
- Medicare $ 145.00
PERG Case Report

- 56 male: negative medical history
- Lasik OS 2000; Steroid responder; family history of glaucoma(father)
- IOP 19 each eye(highest GATT/ neg. diurnal) CH 9.3
- CD .75-.8 OD .85/.8 OS ONH 2.35 mm
- "glaucoma suspect age 45" (OCT VF every 6-12mths)
- Progressive, gradual decrease in pERG mag ratio

PERG: Prior to TX
IOP 19

PERG: Post treatment
IOP 11
PERG: ROI

- Cost of unit $58,000. Includes VEP
- Other disease process: ARMD, Diabetes, High Risk, TBI
- 20 Glaucoma patients: 100 suspects
- $145 twice per year in dx of glaucoma (20 x $145 x 2)
- Once per year for Glaucoma suspect (100 x 145)
- $18,400 for glaucoma only

ORA: Corneal Hysteresis

- Measures corneal resistance to deformation by measuring the viscoelastic properties of the cornea.
  - “The trampoline effect”
- Hysteresis less than 10.0 clinically significant
- CH is correlated to progressive VF loss
- CH is behavioral and can vary in measurement
- ocIOP “True IOP”
ORA: Corneal Hysteresis ROI

- Cost $25,000
- 92145 CPT $16.00
- Better care, supports metabolic theory of glaucoma (two pressure disease)
- PERG and CH together are like electricity and OCT/VF like candles; the glaucoma world changing fast
- Everyone should have this test regardless of billing for it

SightSync

Dr. Carol Miles, M.D., medical director of The Headache Center of Neurology Associates, said in a news release that people who think they suffer from chronic headaches may actually be suffering from a new-found class of headaches called eyeGraines.

“When the images for each eye are not properly aligned, the brain struggles to fuse them together. This struggle repeated over and over can lead to eyeGraines,” Miles said in the release.

In preliminary studies, 80 percent of patients experienced reduced or, in some cases, eliminated chronic headaches after using NeuroLens technology, according to the release.

“Working in conjunction with specialists in the eye care field, we have found a way to treat the disparity between visual and neurological systems,” Miles said. “We believe when these two systems are out of balance, it often manifests itself in chronic, severe headaches.”
Description of the Problem

When a misalignment is present this results in:

1. Additional visual demands required to realign the eyes for binocular fusion\(^1\)-\(^2\) both centrally and peripherally
2. Proprioceptive fibers innervating the extracocular muscles provide afferent feedback \(^3\)-\(^4\) to the brain reporting a binocular misalignment
3. Proprioceptive signals run through the ophthalmic branch of the trigeminal nerve\(^3\) responsible for detecting sensation and reporting pain

---

SightSync®

Creates a dynamic customized measurement of misalignment at 6 meters and 50 cm, analyzing all elements of ocular fusion including:

- Heterophoria
- Vergence conditioning
- Binocular peripheral fusion
- Fixation disparity
- Accommodative convergence response
- Alternating monocular central fixation

SightSync Value: unique single measurement of total misalignment at distance and near

---
**How is it different from traditional testing?**

**Objective** – 100% objective. No patient or operator interaction. Sophisticated eye-tracking.

**Accurate** – measurements are calculated to one-hundredth of a prism diopter.

**Efficient** – testing performed in less than 3 minutes by a technician.

---

**What’s different about the neurolens?**

- A proprietary lens technology integrating a progressive prism design in conjunction with the patient's refractive prescription.
- Progressive prism technology enables practitioners to relieve binocular misalignment detected at distance, intermediate, and near in a single lens.
- Research indicates that over 90% of patients experience a larger misalignment when fusing at near than at distance.

1. Oculomotor Functions & Neurology-Indiana School of Optometry
AN OVERVIEW OF CORNEAL DYSTROPHIES

CLARKE D. NEWMAN, OD, FAAO, FBCLA, FSLS
2017 CORNEA, CONTACT LENS, AND CONTEMPORARY VISION CARE SYMPOSIUM
DECEMBER 3, 2017
COPE #: ???????

CONFLICT DISCLAIMER

• PAID CONSULTANT
  • ALCON
  • EYEPRINT PRO
  • GPU
  • JJVC
  • SYNERGEYES
  • TRU-FORM OPTICS
• EXPERT TESTIMONY
• CONTRIBUTING EDITOR:
  CONTACT LENS SPECTRUM
• NO PROPRIETARY INTEREST
  IN ANY SUBJECTS DISCUSSED
• FDA “OFF-LABEL” USES WILL
  NOT BE DISCUSSED

LEARNING OBJECTIVES

• ATTENDEES OF THIS COURSE WILL LEARN:
  • THE NEW CLASSIFICATION OF CORNEAL DYSTROPHIES
  • THE GENETICS OF CORNEAL DYSTROPHIES
  • TREATMENT STRATEGIES FOR DYSTROPHIES

WHAT IS A DYSTROPHY?

• FROM THE GREEK
  • DUS- (BAD) - TROPHIA (NOURISHMENT)
• TERM INTRODUCED BY WILLIAM ERB IN 1884 TO DESCRIBE A MUSCULAR DYSTROPHY
• FIRST USED BY ARTHUR GROENOUW IN 1890 TO DESCRIBE CASES OF GRANULAR AND MACULAR
  DYSTROPHIES
• CORNEAL DYSTROPHIES HAVE SHARED CHARACTERISTICS
  • GENETIC IN ORIGIN (ALMOST EXCLUSIVELY AUTOSOMAL DOMINANT OR RECESSIVE)
  • PROGRESSIVE
  • ABNORMAL SUBSTANCES ACCUMULATE IN THE CORNEAL LAYERS
  • LIMITED TO THE CORNEA
  • ALMOST ALWAYS BILATERAL
AUTOSOMAL INHERITANCE: DOMINANT

AUTOSOMAL INHERITANCE: RECESSIVE

CYTOGENETIC BANDING NOMENCLATURE

RESOURCES FOR THIS LECTURE

• INTERNATIONAL CLASSIFICATION OF THE CORNEAL DYSTROPHIES
  • WEISS, JS, ET AL, "CORNEA," VOLUME 27, SUPPLEMENT 3, DECEMBER 2008

• NATIONAL ORGANIZATION OF RARE DISEASES
  • GORDON K. KLINTHOWORTH, MD, PHD, PROFESSOR OF PATHOLOGY AT DUKE UNIVERSITY MEDICAL CENTER AND
  • JOSEPH A.C. WADSWORTH, MD, RESEARCH PROFESSOR OF OPHTHALMOLOGY, DUKE UNIVERSITY MEDICAL CENTER

• THE CORNEAL DYSTROPHY FOUNDATION
  • WWW.CORNEALDYSTROPHYFOUNDATION.ORG

THE TWO “NEW” CLASSIFICATION SYSTEMS

• THE IC3D CLASSIFICATION OF CORNEAL DYSTROPHIES IS A NEW
  CLASSIFICATION SYSTEM THAT INCORPORATES MANY ASPECTS OF THE
  TRADITIONAL DEFINITIONS OF CORNEAL DYSTROPHIES WITH NEW GENETIC,
  CLINICAL, AND PATHOLOGIC INFORMATION

• SIMPLIFIED CLASSIFICATION OF CORNEAL DYSTROPHIES

IC3D CLASSIFICATION OF CORNEAL DYSTROPHIES

- EPITHELIAL AND SUBEPITHELIAL
- BOWMAN'S LAYER DYSTROPHIES
- STROMAL DYSTROPHIES
- DESCEMET'S MEMBRANE AND ENDOTHELIAL DYSTROPHIES
Simplified Classification of Corneal Dystrophies

Anterior Dystrophies

Stromal Dystrophies

Posterior Dystrophies

Overview of Corneal Dystrophies

• Prevalence:
  • Total 130.6 per 100,000 – DC Musch et al, IOVS 2011
  • Most common: endothelial dystrophies—53.6 per 100,000 (about 40% of all dystrophies)
  • Second most common: anterior dystrophies—16.5 per 100,000 (about 20% of all dystrophies)

• Sex predilection – ibid
  • For all dystrophies, females make up between 56% and 64% of diagnoses

Overview of Corneal Dystrophies

Anterior Corneal Dystrophies

• Epithelial basement membrane dystrophy
• Lisch corneal dystrophy
• Meesman's corneal dystrophy
• Reis-buckler corneal dystrophy
• Thiel-behnke dystrophy

Anterior Corneal Dystrophies

• Epithelial Membrane Dystrophy
  • AKA: Cogan microcystic dystrophy & map-dot-fingerprint dystrophy
  • Most common dystrophy
  • Autosomal dominant genetic pattern
  • Genetics affect the "transforming growth factor beta one" (TGFβ1) on the 5q31
  • Is clinically evident during the 3rd and 4th decade of life, progressively more severe with time

Overview of Corneal Dystrophies

Ethnic predilection – ibid
  • Whites 92.6% of the anterior dystrophy presentations & 88.2% of endothelial presentations
  • Hispanics: 3.8% of the anterior presentations & 3.8% of the endothelial presentations
  • Black: 2.2% of the anterior presentations & 5.4% of the endothelial presentations
  • Asians: very low across the board, but twice as likely to have a stromal dystrophy
**EPITHELIAL MEMBRANE DYSTROPHY**
- Characterized by different patterns of wrinkles (fingerprints), cystic changes (dots), and regional disruptions (maps)
- 10% have visual disruptions and corneal erosions, many are asymptomatic
- Treatment includes palliative use of supplements, debridement, AS, PRP, AMO, surface keratectomy

**LISCH CORNEAL DYSTROPHY**
- AKA: LISCH EPITHELIAL DYSTROPHY, LECD, WHORLED MICROCYSTIC DYSTROPHY
- Rare condition that can affect acuity 20/40—20/70
- Dominant X-linked disorder (only one) resulting from a mutation on the X chromosome (XP22.3) affects both sexes, but there is no father-to-son transmission, begins to show in 2nd decade
- Characterized by grey feathery opacities of empty microcystic changes
- Treatment is minimal

**MEESMAN’S CORNEAL DYSTROPHY**
- AKA: MECD, JUVENILE HEREDITARY CORNEAL DYSTROPHY; ASSOCIATED WITH STOCKYARD-HOLT
- Onset is very early with irritation and photophobia and minimal acuity impact
- Autosomal dominant affecting the KRT3 and KRT12 genes
- There are PAS + material filled microcystic changes in the epithelial basal layer
- Treatment involves use of hyperosmotics and epithelial debridement when the vision is affected or when discomfort and photophobia reduced QOL late

**REIS-BUCKLER CORNEAL DYSTROPHY**
- AKA: GRANULAR DYSTROPHY TYPE III, CORNEAL DYSTROPHY OF BOWMAN’S LAYER TYPE I
- Affects the anterior limiting lamina
- Presents in the first decade of life
- Causes erosions, FB symptoms, photophobia, and decreased acuity by the third decade
- The genetics are autosomal dominant and related to the TGFB1 gene
- Treatment involves bandage lenses, superficial keratectomy, palliative drops
- Serum and AMO are not very efficacious
THIEL-BEHNKE CORNEAL DYSTROPHY

- AKA: HONEYCOMB CORNEAL DYSTROPHY, CORNEAL DYSTROPHY OF BOWMAN'S LAYER TYPE II
- ALMOST INDISTINGUISHABLE FROM REIS-BUCKLER
- PRESENTS IN THE FIRST OR SECOND DECAD OF LIFE
- EROSIONS EARLY AND DECREASED ACUITY LATER IN LIFE, PHOTOPHOBIA IS COMMON
- THE GENETICS ARE AUTOSOMAL DOMINANT AFFECTING THE TGFBI GENE AND THE 10Q23-Q24
- TREATMENTS INCLUDE AGAIN

GELATENOUS CORNEAL DROPLIKE DYSTROPHY

- AKA: FAMILIAL SUB-EPITHELIAL CORNEAL DYSTROPHY, GDLD
- APPEARS IN THE FIRST DECADE
- CHARACTERIZED BY AMYLOID DEPOSITION BENEATH THE EPITHELIUM THAT TURNS THE CORNEA OPAQUE
- DECREASED ACUITY, PHOTOPHOBIA AND FB SYMPTOMS
- THE GENETICS INVOLVE THE TUMOR-ASSOCIATED CALCIUM SIGNAL TRANSDUCER 2 (TACSTD2) GENE
- PKP IS THE PRIMARY THERAPY BEYOND PALLIATIVE MEASURES

STROMAL CORNEAL DYSTROPHIES

- GELATENOUS DROPLIKE CORNEAL DYSTROPHY
- GRANULAR CORNEAL DYSTROPHY, TYPE I
- GRANULAR CORNEAL DYSTROPHY, TYPE II
- LATTICE CORNEAL DYSTROPHY, TYPE I
- LATTICE CORNEAL DYSTROPHY, TYPE II
- MACULAR CORNEAL DYSTROPHY
- SCHNYDER CRYSTALLINE CORNEAL DYSTROPHY

GRANULAR CORNEAL DYSTROPHY, TYPE I

- AKA: GROENOUW TYPE I
- APPEARS IN THE FIRST OR SECOND DECADE
- CHARACTERIZED BY THE "CLUMPS OF BREADCRUMBS" APPEARANCE THAT COALESCE BY THE FOURTH AND FIFTH DECADE
GRANULAR CORNEAL DYSTROPHY, TYPE I

- Some have erosions and the grouping can cause decreased acuity later.
- The genetics are autosomal dominant and are based on a mutation on 5q31.
- Treatment involves superficial keratectomy and erosion management.

GRANULAR CORNEAL DYSTROPHY, TYPE II

- The genetics are autosomal dominant associated with the SQ231 loci, and also affects the TGFBI gene.
- Symptoms can involve decreased acuity very late in life, and they may experience erosions.
- Treatment again involves the management of erosion and rarely keratectomy.

GRANULAR CORNEAL DYSTROPHY, TYPE II

- AKA: AVELLINO CORNEAL DYSTROPHY
- Appears during the first or second decade of life.
- Characterized by an appearance that is a cross between granular, type I and lattice dystrophy, type I.

LATTICE CORNEAL DYSTROPHY, TYPE I

- AKA: LCD1
- Common stromal dystrophy.
- Characterized by branching lines of amyloid that form, usually with mild to severe erosions over the areas as they form.

LATTICE CORNEAL DYSTROPHY, TYPE I

- Genetics are autosomal dominant and are associated with the SQ31 loci.
- Treatment is limited to erosion management and controlling photophobia.
LATTICE CORNEAL DYSTROPHY, TYPE II

- AKA: LCD2, LATTICE CORNEAL DYSTROPHY, GRISOLIV TYPE
- LIKE LCD1, BUT WHEN ASSOCIATED WITH AMYLOID CRANIAL NEUROPATHY (MERETOJA'S SYNDROME, AKA, FAMILIAL SYSTEMIC AMYLOIDOSIS)

MACULAR CORNEAL DYSTROPHY

- AKA, MCD, GROENOUW, TYPE II (THERE ARE SOME SUBTYPES PROFFERED: I, 1A, 1B, 1E, 1H, etc.
- STARTS IN THE FIRST DECADE OF LIFE, BUT CAN GET SEVERE BY THE SECOND DECADE OF LIFE WITH SIGNIFICANT PHOTOPHOBIA AND DECREASED ACUITY

SCHNYDER CRYSTALLINE CORNEAL DYSTROPHY

- AKA: SCCD
- APPEARS IN THE SECOND DECADE OF LIFE BUT RARELY EARLIER, RARE AND MAINLY SCANDINAVIAN
- CHARACTERIZED BY THE LOSS OF CORNEAL CLARITY DUE TO ABNORMAL CHOLESTEROL DEPOSITS IN THE CORNEA
- GENETICS ARE AUTOSOMAL DOMINANT ASSOCIATED WITH THE UBA1 ON THE 1P34 AND 1P36 LOCUS

SCHNYDER CRYSTALLINE CORNEAL DYSTROPHY

- DECREASED ACUITY IS THE PRIMARY PROBLEM AND TREATMENT INVOLVES EITHER LAMELLAR OR PENETRATING KERATOPLASTY

POSTERIOR CORNEAL DYSTROPHIES

- GENETICS ARE AUTOSOMAL RECESSIVE ASSOCIATED WITH THE 16Q22 LOCI AFFECTING THE CARBOHYDRATE SULFOTRANSFERASE 6 (CHTS6)
- TREATMENT AGAIN CONSISTS SUPERFICIAL KERATECTOMY AND IN WORST CASES DALK
- SCLERAL LENSES ARE HELPFUL FOR THE INEVITABLE IRREGULAR OPTICS LEFT BEHIND
POSTERIOR CORNEAL DYSTROPHIES

• CONGENITAL HEREDITARY CORNEAL DYSTROPHY, TYPE I
• CONGENITAL HEREDITARY CORNEAL DYSTROPHY, TYPE II
• FUCH’S ENDOTHELIAL CORNEAL DYSTROPHY
• POSTERIOR POLYMORPHOUS DYSTROPHY

CONGENITAL HEREDITARY CORNEAL DYSTROPHY, TYPE I

• AKA: CHED I
• CHARACTERIZED BY CORNEAL EDEMA ASSOCIATED WITH AN ABNORMALLY THICKENED POSTERIOR LIMITING LAMINA WITHOUT GUTTATAE
• PRESENTS AT BIRTH, BUT THE CORNEA IS CLEAR AND PROGRESSIVELY CLOUDS UP
• GENETICS ARE AUTOSOMAL DOMINANT ASSOCIATED TO THE 20P11 AND 20Q11 LOCI
• TREATMENT INVOLVES TRANSPLANT

CONGENITAL HEREDITARY CORNEAL DYSTROPHY, TYPE II

• AKA: CHED II
• HISTOLOGICALLY IDENTICAL TO TYPE I
• PRESENT AT BIRTH, BUT THE CORNEA IS ALREADY CLOUDY
• GENETICS ARE AUTOSOMAL RECESSIVE INVOLVING MUTATIONS IN THE SLC4A11, AND AFFECT THE SAME LOCI ON THE 20P11(OR 20P13) AND 20Q11 LOCI
• AGAIN TREATMENT INVOLVES TRANSPLANT

FUCH’S ENDOTHELIAL CORNEAL DYSTROPHY

• AKA: FECD
• DEVELOPS IN THE THIRD DECADE OF LIFE AND BEYOND (TYPES II, III, AND IV), BUT CAN RARELY FORM IN THE SECOND AND THIRD DECADE OF LIFE (TYPE I)
• FORMATION OF GUTTATAE FOLLOWED BY ENDOTHELIAL DYSFUNCTION AND ENDOTHELIAL CELL DEATH AND POSTERIOR CORNEAL EDEMA
• GENETICS ARE AUTOSOMAL DOMINANT INHERITANCE AFFECTING THE COLLAGEN 8 ALPHA 2 (COL8A2) GENE FOR THE TYPE I, TRANSCRIPTION FACTOR 4 (TCF4) FOR TYPE II
• MEDICAL TREATMENT IS AIMED AT REDUCTION OF CORNEAL EDEMA USING PRESSURE LOWERING MEDICATIONS, AND, RARELY, HYPEROSMOTICS IF THE EDEMA MOVES ANTERIORLY
• THE CURRENT STANDARD OF CARE IN THE SURGICAL MANAGEMENT IS POSTERIOR LAMELLAR TRANSPLANTATION (DSEK AND DMEK)

FUCH’S ENDOTHELIAL CORNEAL DYSTROPHY

• GENETICS ARE AUTOSOMAL DOMINANT INHERITANCE AFFECTING THE COLLAGEN 8 ALPHA 2 (COL8A2) GENE FOR THE TYPE I, TRANSCRIPTION FACTOR 4 (TCF4) FOR TYPE II
• MEDICAL TREATMENT IS AIMED AT REDUCTION OF CORNEAL EDEMA USING PRESSURE LOWERING MEDICATIONS, AND, RARELY, HYPEROSMOTICS IF THE EDEMA MOVES ANTERIORLY
• THE CURRENT STANDARD OF CARE IN THE SURGICAL MANAGEMENT IS POSTERIOR LAMELLAR TRANSPLANTATION (DSEK AND DMEK)

POSTERIOR POLYMORPHOUS DYSTROPHY

• AKA: PPD
• USUALLY PRESENTS VERY EARLY IN LIFE, IS SLOWLY PROGRESSIVE, AND RARELY CAUSES SYMPTOMS. IF YOU SEE SOMETHING, IT IS ALMOST ALWAYS POSTERIOR CORNEAL EDEMA
• BILATERAL, BUT OFTEN HIGHLY ASYMMETRIC
• GENETICS ARE AUTOSOMAL DOMINANT WITH MULTIPLE GENE EXPRESSIONS NOTED—ONE IS AT THE 20P11.2 LOCI, ANOTHER IS AT 1P34.3-P32.3 LOCI INVOLVING THE COL8A2 GENE, AND A THIRD IS DUE TO A MUTATION IN THE TCF8 GENE AT THE 10P11-Q1 LOCI
• TREATMENT IS ALMOST NEVER NEEDED FOR PPD
POSTERIOR POLYMORPHOUS DYSTROPHY

CONCLUSION

- GENETIC (USUALLY AUTOSOMAL DOMINANT), PROGRESSIVE BILATERAL CHANGES TO THE CORNEAL STRUCTURE THAT CAUSES
  - PHOTOPHOBIA
  - EROSIONS
  - OPACITY
- MANAGEMENT INVOLVES UNDERSTANDING THE PALLIATIVE THERAPIES FOR DRYNESS, EROSION, AND SPECIALTY CONTACT LENSES FOR IRREGULAR OPTICS ASSOCIATED WITH THE DYSTROPHY AND THE SURGICAL TREATMENTS

THANK YOU!!
CDNEWMAN@EARTHLINK.NET
The Influence of Hormones on Ocular Surface Disease
Melissa Barnett, OD, FAAO, FSLS

Many individuals are at an increased risk for vision-threatening ocular disease. With age and hormonal changes, female patients are at greater risk for ocular surface disease. This course will review hormonal influence on ocular surface disease. Current ocular and systemic testing and treatments will be reviewed.

Learning objectives
1. Identify the prevalence and risk factors of dry eye syndrome for the express purpose of achieving timely diagnosis and treatment.
2. Review the influence of specific hormones including sex hormone replacement therapy on ocular surface conditions, especially dry eye.
3. Discuss Sjögren’s Syndrome classification, diagnosis and management.

Outline
1. Prevalence of dry eye disease
2. Dry eye syndrome
   a. Prevalence
   b. Risk factors - intrinsic
      i. Female gender
      ii. Older age
      iii. Altered hormone levels / decreased androgens
      iv. Hormone replacement therapy
      v. Endocrine disorders strongly associated with DES (thyroid disease, diabetes)
   c. Risk factors - Extrinsic
      vi. Contact lens wear
      vii. Postmenopausal estrogen therapy
      viii. Medications
      ix. Vitamin A deficiency
   c. DEWS II update
3. Hormones
   a. Hormones during menopause associated with dry eye
   b. Sex hormone replacement therapy
   c. Epidemiologic studies
   d. Hormones and dry eye
4. Autoimmune disorders
   a. Sjögren’s Syndrome
      i. Primary Sjögren’s syndrome
      ii. Secondary Sjögren’s syndrome
      iii. Associated systemic symptoms
iv. Traditional testing using autoantibodies as diagnostic markers
v. Sjö test
vi. Oral testing for Sjögren’s
vii. Lacrimal functional unit
viii. Treatments
   1. Biologic agents
   2. T cell stimulation inhibition
   3. Modulation or inhibition of other targets
ix. Clinical pearls for Sjogren’s treatment
Ocular Management of Graft versus Host Disease

Muriel Schornack, OD, FAAO, FSLS
Cornea, Contact Lens and Contemporary Vision Symposium
Houston, TX
December 3, 2017

Disclosures
• None

Learning Objectives
• Understand etiology of GVHD
• Identify ocular complications of cGVHD
• Review management options for this condition
• Demonstrate role of eye care providers in management of patients with this condition
Background
• 50,000 allogeneic hematopoietic cell transplants (HCT) performed annually worldwide
  • http://www.who.int/transplantation/hct/en/
• Indications include both non-malignant and malignant disorders
  • Gratwohl et al, JAMA 303(16):1617-1624
• Outcomes vary by condition and relationship of donor to recipient

Definition of Terms
• Hematopoietic: having to do with formation of blood
• Allogeneic: being genetically different although belonging to the same species
  • Syngeneic
  • Related
  • Unrelated

Stem cell sources
• Bone marrow
• Peripheral blood
• Cord blood
What is GVHD?

- Complication of allogeneic hematopoietic cell transplantation
- GvL: Graft vs. Leukemia
  - transplanted T lymphocytes attack target cells (leukemia, malignancies)
- GvHD: Graft vs. Host Disease
  - Develops when donor T-cells respond to recipient tissue antigens in addition to target tumor cells

Classification of Disease

- Original classification: time of onset
- Current classification: clinical manifestations
Incidence

- Acute GVHD:
  - 26%-32% of recipients of sibling donor grafts
  - 42%-52% of recipients of unrelated donor grafts
  - Responsible for up to 60% non-relapse related deaths

- Chronic GVHD
  - 30% of recipients of sibling donor grafts
  - 60%-70% of recipients of unrelated donor grafts
  - Responsible for up to 50% non-relapse related deaths

Risk Factors

- Source of donor tissue
- Degree of histocompatibility
- Age
- Underlying condition
- Intensity of conditioning
- Female donor to male recipient
- Female donor with prior pregnancies or transfusion

Acute GVHD

- Primarily involves skin, liver, GI tract
- Diagnosis based on clinical presentation, confirmed by biopsy of affected tissue
- Primarily treated with systemic corticosteroids
Acute GVHD

The eye in aGVHD
- Conjunctival hyperemia
- Conjunctival chemosis
- Serosanguinous discharge
- Pseudomembranous conjunctivitis
- Corneal epithelial sloughing

Chronic GVHD
- Affects a variety of organs/organ systems (skin, nails, scalp/hair, eyes, mouth, genitalia, GI tract, lungs, muscles/joints)
- Less clearly understood than acute GVHD
- No definitive consensus on “best treatment”
Diagnostic Signs


Distinctive Manifestations

- New onset dry gritty or painful eyes
- Cicatrical conjunctivitis
- Keratoconjunctivitis sicca
- Confluent areas of punctate keratopathy
- Other features:
  - Photophobia
  - Periorbital hyperpigmentation
  - Blepharitis


Prevalence of Ocular Involvement

- 60%-90% of patients with cGVHD
  - Kim, Curr Opin Ophthalmol 2006;17:344-348
- Severe ocular surface disease is noted in 40-76% of cases

Posterior Segment Manifestations

- Vitritis

- Microvascular retinopathy

- Scleritis
  - Kim, Am J Ophthalmol 2002;133:843-845

- Central serous chorioretinopathy

Anterior Segment Involvement

SEVERE OCULAR SURFACE DISEASE

Inflammatory Conjunctival Disease

Kim, Current Opin Ophthalmol 2006 Aug;17(4):344-8
Meibomian Gland Dysfunction

Lacrimal Gland Stasis

Decreased TBUT

http://www.optometric.com/archive

Kim, Current Opin Ophthalmol 2006 Aug;17(4):344-8
Etiology of OSD

- Inflammatory response causing cell injury and death
- Lacrimal gland dysfunction
- Lid abnormalities
- Medication side effects

Clinical Evaluation

- Symptom assessment (OSDI)
- Vital staining
- Tear break-up time
- Slit lamp evaluation
- Schirmer test
- Corneal sensitivity
- Tear evaporimetry
- Corneal/conjunctival impression cytology

NIH-Recommended Staging

- 0: No dry eye symptoms
- 1: Dry eye symptoms not affecting ADL or asymptomatic KCS
- 2: Dry eye symptoms partially affecting ADL without vision impairment
- Dry eye symptoms significantly affecting ADL, unable to work, vision loss
**Treatment of OSD in cGVHD**

- "Stepped approach"
- Supportive, not curative, intervention
- Ocular therapeutic goals
  - Lubrication and tear preservation
  - Reduction of inflammation
  - Prevention of tear evaporation
  - Epithelial support

**Step 1:**

**Step 2:**
Step 2:
• Topical cyclosporine
• Topical lifitigrast
• Topical steroids
• Topical antibiotics
• Warm compresses
• Oral doxycycline

Step 3:
• Tacrolimus
  • Oral therapy (in combination with methotrexate)
    • Ram et al, Bone Marrow Transplant 2009;43:643-53
• Protopic
  • Topical therapy
    • Tam et al, Bone Marrow Transplant 2010;45:567-8.
    • Zhai et al, Biodrugs 2011;25(2):89-103
Step 3:
- Autologous serum tears
  - Contain molecules that support epithelial health
  - Early studies encouraging
  - Cost and availability are potential impediments
    - Chiang et al, Cornea 2007 Aug;26(7):861-863

Step 3:
- Topical retinoic acid
  - Murphy et al, Bone Marrow Transplant 1996 Sep;18(3):641-2
- Systemic secretagogues (i.e. cevimeline or pilocarpine)

Step 4:
- Scleral lenses/ocular surface prosthetics
  - Provide continuous corneal hydration
  - Protect conjunctival tissue
  - Non-invasive, reversible
  - Can be used in conjunction with other therapy
    - Takahide et al, Biol Blood Marrow Transplant 2007 Sep;13(9):1016-21
Step 5:
• Partial or full tarsorrhaphy
• Amniotic membrane graft
• Conjunctival flap (Gunderson flap)

Multidisciplinary Approach
• Hematology
• GI/Hepatology
• Dermatology
• Optometry/ophthalmology
• Dentistry
• Gynecology
• Neurology
• Immunology
• Musculoskeletal evaluation
• Psychology/psychiatry
Long-Term Ocular Prognosis

- Stable visual acuity
- Stable tear production
- Possible improvement in dry eye symptoms
  - Sales et al, Cornea 2011 Feb;30(2):143-149

Bibliography


• Tam, P.M., et al., Topical 0.03% tacrolimus ointment in the management of ocular surface inflammation in chronic GVHD. Bone Marrow Transplant 2010;45:957-8.
Welcome to the Professional Responsibilities Course sponsored by the University of Houston College of Optometry. As you know, this course is a requirement for Texas license holders. What you may not know is that all fees associated with this course are devoted to permanent projects that are important for the future of the profession.

Thank you for choosing UHCO for your continuing education.

The development and production of the 2017 Professional Responsibility Course is underwritten by the Harris Lee Nussenblatt Lecture Series Endowment. This endowment was established in 1992 by the Nussenblatt Family in memory of former Associate Professor Harris Nussenblatt, OD. The Lecture Series focuses on issues related to professional ethics, public health and practice administration.
Preface

The content of the Professional Responsibility Course is at the discretion of the Texas Optometry Board. This year, the Board’s requested items take up the entirety of the course. Once again, many of these items are second, third or even fourth time requests. You can draw your own conclusion from that.

AGENDA I – RULES AND REGS (not being followed?)

- Prescribing information
- Medications
- Eyeglasses
- Contact lenses
- Release of medical records
- Continuing education issues
- Peer Assistance Program
- New Rule 273.4 – Renewal fees
- New Rule 273.14 – Application fee exemptions

AGENDA II – Fraud and Abuse Laws in Healthcare

- False Claims Act
- Anti-Kickback Statute
- Self-Referral Law
- Exclusion Statute
- Civil Monetary Penalties Act
Prescribing Information

REALLY? We have to talk about this AGAIN????

Summary in one slide....
Patients want and have a legal right to their prescription

GIVE IT TO THEM!

Prescribing Information

Let’s break it down into three areas:
- Prescriptions for medications
- Prescriptions for eyeglasses
- Prescriptions for contact lenses

If you want confirmation information or additional information, all this is contained in Rules 279.2 and 279.4 of the Texas Optometry Act and in FTC Rules 16 CFR 315.3 and 315.5

Prescriptions for medications

- Must contain name of the doctor(s) in an allowable format (addressed later...again)
- Manual signature allowed
- “Electronic” signature allowed:
  - Must “replicate” the manual signature
  - System must prompt the doctor to use the electronic signature option (cannot be a pre-filled template or an automatic signature)
How Many Signatures Are There?

**Manual** – Your actual written signature (consider a signature log)

**Electronic** – “Electronically signed by Joe DeLoach, OD 9/2/16 4:30pm”

**Digitized** – an actual reproduction of your manual signature transferred to paper – this is what the statute actually refers to as an “electronic signature” (consider a signature log!)

**Digital** – an encryption or fingerprint that binds the doctor to the record (not ready for prime time…yet!)

**Signature Attestation** - statement that you performed all the services (far too complex)

Prescriptions for Eyeglasses (and optical devices)

- Must contain name of the doctor(s) in an allowable format (addressed later)
- Manual signature allowed
- “Electronic” signature allowed:
  - Must “replicate” the manual signature
  - System must prompt the doctor to use the electronic signature option (cannot be a pre-filled template or an automatic signature)

Prescriptions for Eyeglasses (and optical devices)

- Must be released to the patient **WITHOUT THEIR REQUEST**
- Can FAX or email to dispenser but not the patient (can telephone to dispenser in case of “emergency”)
- If sent by FAX, should write “By FAX” or similar wording on the prescription
- Some parameters mandated but most left to prescribing doctor. Cannot limit to “private label” products not available to the optical industry as a whole
- You do not have to specify the PD or give it to the patient… but REALLY?
- A second or duplicate prescription MAY be issued but is not required… but again, REALLY?
OK...what about that “allowed format” thing.....

Professional Identification

Legal identification per state law includes **(this is ALL of them!):**
- Optometrist
- Doctor, Optometrist
- Doctor of Optometry
- O.D.

**It is illegal to use any designation or advertising that could mislead the public into thinking you are any other health care practitioner other than an optometrist. This is not the Optometry Board’s rule – this is a State law the Optometry Board must uphold.**

[www.statutes.legis.state.tx.us/Docs/OC/htm/OC.104.htm](http://www.statutes.legis.state.tx.us/Docs/OC/htm/OC.104.htm)

What If Two Docs Involved In The Care?

If the doctor signing the prescription was not the examining doctor, the prescription must contain:

- Signature of doctor issuing the prescription in an allowable format
- The prescription must contain the names and license numbers of both the doctor issuing the prescription and the doctor who performed the examination

Prescriptions for Contact Lenses

(joe talks to himself...)

Oh please, no....do I have to talk about this?
Yes you do...it’s on the list from the Optometry Board
But WHY?

Well because Joe...evidently it is one of the most significant problems and sources of complaints to the Optometry Board. Evidently some optometrists don’t want their patients to have their contact lens prescriptions, even though it is the law.

**BUT WHY????**
Prescriptions for Contact Lenses

- Must contain name of the doctor(s) in an allowable format
- Manual signature allowed
- “Electronic” signature allowed:
  - Must “replicate” the manual signature
  - System must prompt the doctor to use the electronic signature option (cannot be a pre-filled template or an automatic signature)

Prescriptions for Contact Lenses

- Must be released to the patient WITHOUT THEIR REQUEST
- Copy of Rx may be emailed or faxed to the dispenser, but not the patient – if by FAX, doctor writes “By FAX” or similar wording on the Rx
- Release of a duplicate Rx to PATIENT permissible but not required
- Doctor MUST allow a one time, two month extension of an expired prescription unless there is medical contraindication to do so
- Must release Rx even if all the lenses allowed under that prescription have already been purchased or filled – doctor writes on Rx what is left. Ex. “Two boxes left” “All lenses dispensed” (if you wish to)
- Restriction to private label or brand not available to optical industry as a whole NOT allowed unless documentation in medical record why such lenses are MEDICALLY INDICATED

Prescriptions for Contact Lenses

- Release when? “When the final parameters are determined” – DO NOT PLAY GAMES WITH THIS!
- Release to whom? To any person “designated to act on behalf of the patient”. The request may be for a copy of the prescription or for verification of the parameters. The request may be by telephone, FAX or email. Dispenser should include:
  - Patient’s full name and address
  - Contact lens parameters
  - Quantity of boxes ordered
  - Date on which patient requests lenses to be dispensed
  - Date and time of verification request
  - Name, phone and FAX number of dispenser agent
- Then you have up to eight business hours to provide verification
Prescriptions for Contact Lenses

But wait….the dispenser has the lenses in the mail long before I provide verification and a host of other tricks that don’t abide by these laws! Why should I have to?

Well, because it’s the law. If THEY break the law and you know it, turn them in to the Texas Optometric Association, the American Optometric Association and the Federal Trade Commission. Few doctors are doing this so on the outside it doesn’t look like there is much of a problem!

Prescription for Contact Lenses

One more issue...

WHAT ABOUT HIPAA?

Authorization to release information for treatment purposes is not required under HIPAA. And you also cannot make them sign something saying the patient is releasing you from any liability related to filling the prescription.

BUT

The bigger issue is releasing medical information to someone if you do not know the patient actually made that request. TOB is silent on this but I personally recommend you obtain and document verification from the patient they have asked the dispenser to get their medical information from you – that is different from obtaining authorization!

Related issue...

Release of Medical Records

Refer to Texas Optometry Act Sec. 351.352 and Texas Occupations Code Sec.181.102 for confirmation or additional information

More importantly, this issue is covered in length in the Health Information Portability and Accountability Act of 1996. Correct…1996! If you and your staff do not have an in depth knowledge of HIPAA at this point you are playing Russian Roulette with your financial future and reputation.
Release of Medical Records

- The patient has a right to obtain their medical record under the Texas Optometry Act but more importantly under that Federal law called HIPAA.
- This one is simple - patient wants their medical record – GIVE IT TO THEM.
- There are rare reasons to withhold a patient’s medical record from them – because their insurance owes you money is NOT one of them.
- Optometry Board rules mirror HIPAA on this issue. The Texas Occupations Code also mirrors HIPAA that patient’s should be provided medical records in electronic format basically unless the patient specifically requests otherwise.

Release of Medical Records
Things to Know

- In Texas, you have fifteen (15) days to produce the records – but really?
- The record may be a summary of findings, if you wish.
- Results of tests may be provided in summary form (like an I/R).
- Prescriptions are NOT part of the medical record.
- TOB – you can charge a “reasonable processing fee”. HIPAA says you shouldn’t charge the patient but, if you do, it can only be the actual cost of copying the paper and a “reasonable processing fee”.

Continuing Education

The Board has recommended that optometrists contact the Board directly for questions regarding how to obtain approved CE, if a particular course is approved, if you have sufficient hours to license renewal and other such matters related to CE.

It appears that some optometrists get erroneous information from their colleagues and end up very disappointed when their CE hours are not approved or not recorded correctly.
Peer Assistance Program

The Peer Assistance Program was enacted by the Texas Optometry Board in 2010.

Mission

PAP works through confidentiality and trust to educate, prevent, intervene, refer, support, and monitor professionals who are experiencing problems that threaten both their well being and the quality of their professional practice. **PAP focuses on early intervention and advocacy for program participants.**

Peer Assistance Program

- The PAP was created to assist impaired optometrists through a recovery program without involving the Optometry Board or license sanctions.
- The goal is totally to help the impaired doctor get back on their feet so they can continue as a competent, productive doctor.
- A doctor may report themselves or a colleague. A friend or a concerned individual may report them. The reporting individual's name is held in confidence.
- Contact [www.rxpert.org](http://www.rxpert.org) or call 1-800-727-5152.

NEW Rule 273.4

Increased license fee for OGS

- Renewal fee for optometric glaucoma specialist license increased by a whopping $7.85. This is to fund the Prescription Monitoring Program under the Texas Pharmacy Board.
- This was also the legislation that repealed the state controlled substances permit (DPS).
- Only a DEA certificate is required (Required? Let's talk about that).
NEW Rule 273.14
Military Exemptions

Military service members, military spouses and military veterans who are applying for a Texas license:

- Are exempt from the application fee for a license to practice optometry in the State of Texas
- Have a special expedited application process

Fraud and Abuse in Healthcare

Why is the TOB interested in this?

1. They are obligated by law to determine if the care you deliver and the reimbursement you request for that care is in line with recommended practice patterns and tenets of healthcare reimbursement

2. The Federal government has gone a step further and obligated licensing boards to be directly involved in making sure their licensees are compliant with Federal laws regarding healthcare – this includes things like HIPAA, OSHA and Fraud and Abuse laws

From the Boss... The OIG
Federal Register Vol. 65 No. 194
FIFTEEN YEARS AGO!!!

“The creation of compliance program guidelines for healthcare payers and providers is a major initiative of the OIG in its effort to engage the private healthcare community in preventing the submission of erroneous claims and in combating fraudulent conduct.”

Let’s talk about why they are so upset!
### Healthcare Reimbursement Gone Bad

Andrew Hackbarth, RAND Corporation

<table>
<thead>
<tr>
<th><strong>Fraud and abuse across the entire healthcare system</strong></th>
<th><strong>$272 BILLION</strong></th>
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<tr>
<td><strong>CMS</strong></td>
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<tr>
<td>&gt;$70 BILLION in Medicare alone in 2015 – estimated 10% of all claims</td>
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<td>2015 Medicaid fraud and abuse expected to exceed Medicare</td>
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<td><strong>CERT</strong></td>
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<td>2015 $175 MILLION in improper payments to optometrists</td>
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<tr>
<td><strong>Optometry Audits 2016</strong></td>
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No names – but just to show you they mean business...$72,181; $151,233; $27,344; $43,219; $271,621, $807,000 – granddaddy of them all...$2.6 MILLION

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### BUT I’M NOT A CROOK! I DON’T DO FRAUD!

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### “Errors” vs Fraud – Difference?

*Absolutely – and the OIG has made it clear what the distinction is!*

- Abuse would be a clerical error.
- If you **SHOULD HAVE** known better it is FRAUD.
- The ACA made it clear that doctors are obligated to abide by the Federal fraud and abuse laws and that they **SHOULD KNOW** – in other words ignorance is not an excuse.
CMS published example of fraud

Medicare Learning Network
ICN 006827 October 2016

“Examples of Medicare fraud include:

Knowingly billing for services at a level of complexity higher than the services actually provided, documented in the file or medically necessary…”

They are going after this – with a stated focus on billing service items (office visits) at a higher level than is medically necessary

Not medically necessary- examples?

Without a MEDICAL reason for the visit, none of these are medically necessary:

Comprehensive examination, Annual eye evaluation, Annual medical eye evaluation, Comprehensive eye health evaluation and other creative wording that means nothing in medical reimbursement

The Medicare Carriers Manual, Part 3 §2320 reads:

“The coverage of services rendered by a physician is dependent on the purpose of the examination rather than on the ultimate diagnosis of the patient’s condition. When a beneficiary goes to his/her physician for an eye examination with no specific complaint, the expenses for the examination are not covered even though as a result of such examination the doctor discovered a pathologic condition.”

More not medically necessary...Per CMS

➢ is not accepted as safe and effective
➢ is not supported in peer-reviewed medical literature
➢ is not medically necessary in a specific case or specific diagnosis
➢ is furnished at a level, duration, dosage or frequency not appropriate for a specific patient or clinical condition
➢ is not furnished consistent with standards of care
➢ is not confirmatory in nature
➢ is furnished for patient or provider convenience
➢ is a device that is not approved by the FDA
➢ is a test or service now considered obsolete
One of biggest issues in optometry...  
**Confirmatory testing**

Per CMS:

"Medical record documentation must clearly indicate rationale which supports the medical necessity for performing *each* test. Documentation should also reflect how the test results were used in the patient's plan of care."

It *would not* be considered medically reasonable and necessary to perform any diagnostic procedure simply to provide *additional* confirmatory information for a diagnosis or treatment which has *already been determined.* (my emphasis added)

**THIS IS EXACTLY WHY THE CMS BILLING REPORTS WERE LOOKING SPECIFICALLY AT GLAUCOMA TESTING BY OPTOMETRISTS!**

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**Five Main Fraud and Abuse Laws**

- False Claims Act
- Anti-Kickback Statute
- Provider Self-Referral Law
- Exclusion Statute
- Civil Monetary Penalties Law

*If you don’t know what these laws say, you need to do some personal homework or consult with someone who can help you*

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**False Claims Act (FCA)**

**SUMMARY**

A Provider cannot submit claims for payment that they know *or should know* are false, fraudulent *or not medically necessary*
False Claims Act
Key Points
➢ Should know - liberally interpreted and includes “reckless disregard for the truth”
➢ Be careful with coding experts pushing making money, instrument companies pushing making money, filing claims because someone is “getting paid”
➢ Not knowing equates with guilty under FCA
➢ Fines include three times the program’s loss plus fines of $11,000.00 per line item per claim

Anti-Kickback Statute (AKS)
SUMMARY
Prohibits the knowing and willful acceptance of any remuneration as an intentional or unintentional inducement to reward patient referrals for services that may be paid for by federal funds

Anti-Kickback Statute
Key Points
➢ This law has a great deal of ambiguity but translated VERY liberally
➢ Remuneration is defined to possibly include: ANYTHING of value including money, free services, meals, excessive consultation fees or provision of CE leading to education credits for which you did not pay a reasonable fee
➢ Government does not have to prove harm. The simple implication of inducement is deemed as guilty
➢ Also law stating routine copay or deductible waivers and same day discounts not related to indigent care are illegal
➢ Penalties include fines up to $50,000.00, jail time and/or exclusion from all Federal payer systems (Medicare and Medicaid)
TOB Requested Special Emphasis on this Law related to certain free CE programs

The TOB makes no official position on this issue but warns optometrists to be aware of the potential for an AKS violation related to attending free CE provided by other physicians to whom you do or might refer patients.

June 9, 2015

Fraud Alert: Physician Compensation Arrangements May Result in Significant Liability

You want to mess with this?

These folks did...bad outcome

Don’t mess with this law!
Provider Self-Referral Law (PSRL)

**SUMMARY**

Providers are prohibited from directly referring patients to receive certain “designated services” from entities in which the provider or provider’s immediate family has a financial interest and if the services are to be paid for by Federal payers.

**Rare issue for optometry...get an attorney!**

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Exclusion Statute

**SUMMARY**

By law, the Government restricts providers convicted of certain crimes or behaviors from participating in any federal payer program.

**Easy....check them out at**

[www.exclusion.oig.hhs.gov](http://www.exclusion.oig.hhs.gov)

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Civil Monetary Penalties Law (CMPL)

**SUMMARY**

Catch-all legislation giving the Government vast powers to act against providers for a variety of improper conducts.
Civil Monetary Penalties Law
Key Points

- Potential CMPL violations:
  - Violating conditions of a payer contract
  - Making false statements when applying for inclusion in a payer program
  - Failure to provide proper emergency care to a patient
- Penalties include fines from $10,000-50,000 per violation and can be levied on top of other penalties under FCA, AKS, etc.

Back to protecting yourself

While not mandated, CMS and the OIG both strongly recommend all doctors have structured compliance programs in their offices.
Recommended components of a fraud and abuse compliance program include:
- Assign a Compliance Officer
- Establishing compliance standards (they are outlined for us)
- Perform routine audits of your medical records
- Have a system for correcting offenses should they occur or be discovered
- Train all doctors and staff
- Establish internal disciplinary guidelines

Resources

A Roadmap for Physicians: Avoiding Medicare and Medicaid Fraud and Abuse

OIG Compliance Program for Individual and Small Group Physician Practices
Federal Register Volume 65 Number 194

Or consult a compliance expert or company for assistance
Thank you for your attention and have a great 2017

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www.tob.state.tx.us