

WOO UNIVERSITY
SCLERAL LENS SOIREE
 The Role of OSD and Eyelid Health in Specialty Lenses
 Dr. Elise Kramer, OD, FFAO, FSLs
 Miami Contact Lens Institute

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Financial Disclosures

- o Avellino Labs
- o Dompe
- o Novartis
- o Spectrum International

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tfos DEWS II

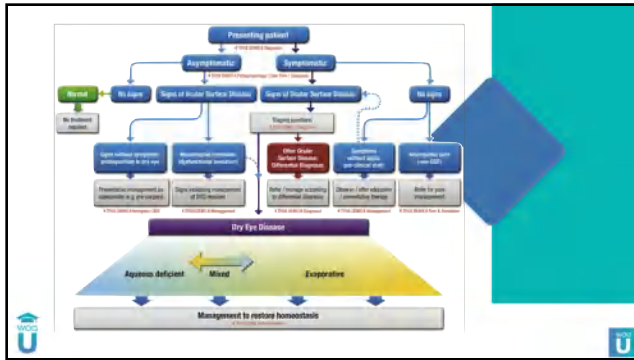
"Dry eye is a multifactorial disease of the ocular surface characterized by a loss of homeostasis of the tear film, and accompanied by ocular symptoms, in which tear film instability and hyperosmolarity, ocular surface inflammation and damage, and neurosensory abnormalities play etiological roles."

The Ocular Surface

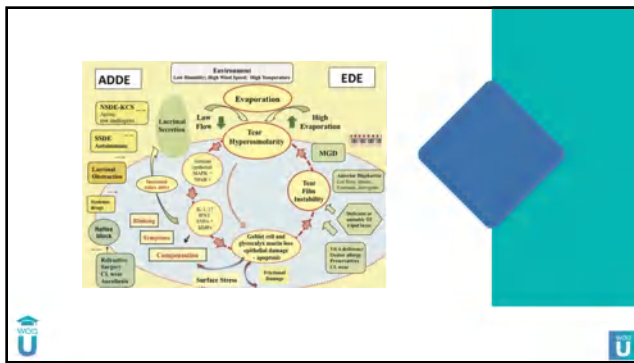
tfos DEWS II International

tfos

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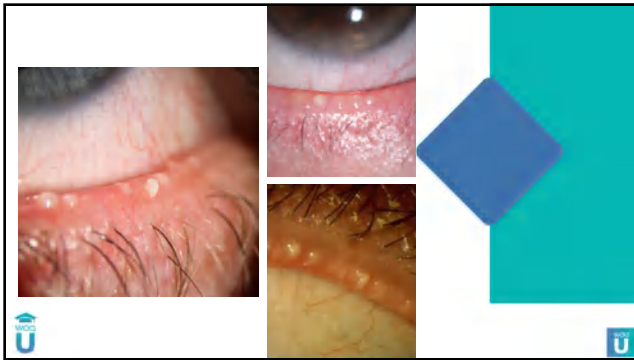
What is Evaporative DES?

Age-related related

- 78% - 86% of all DED
- Ss/Sxs: - MGD
- Itching
- Burning
- Watering
- Redness
- Thickened mucus
- Superficial punctate keratitis
- CL

TFBUT ↓
 Meibum in MGD ↓ terpenoids, proteins → thicker secretions
 → plugging the gland

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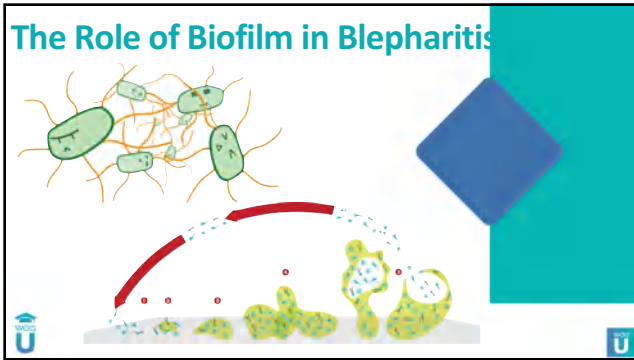
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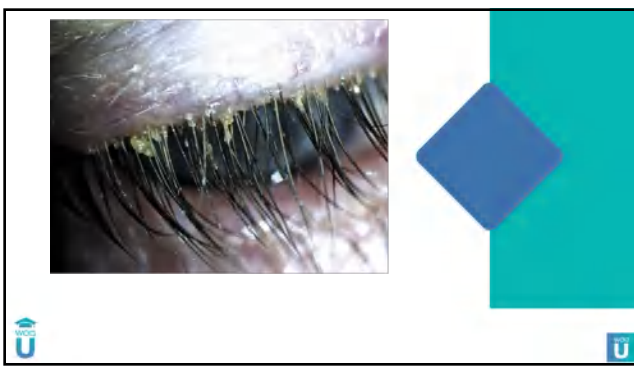
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Poor Lens Surface Wettability



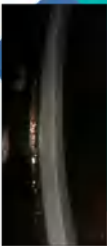
- Etiology:**
 - Mucoid, lipid, or protein coating on the lens surface
- Symptoms:**
 - Dryness
 - Intermittent blurred vision
 - Frequent lens removal



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Debris in the Tear Reservoir

- Etiology:**
 - Fluid dynamics under a scleral lens
 - Attracts deposits in the tear reservoir if the limbal clearance is excessive
 - No tear exchange: debris accumulation over time
- Symptoms:**
 - Decreased visual acuity
 - Inconvenient: repeated lens removal



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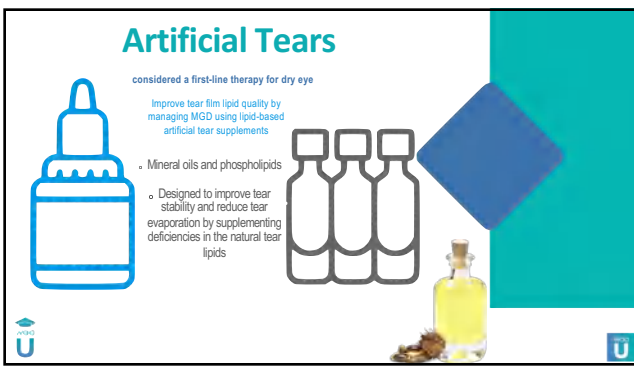
Treatment and Management



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| | |
|-----------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------|
| LIQ HYGIENE Wash hands, use eye drops and lubrication | WARM COMPRESSES |
| ARTIFICIAL TEARS (Available OTC) | PRESCRIPTION MEDICATIONS |
| BLINKING EXERCISES (See attached) | SLEEP MASK Wear at night to minimize airflow around eyes. |
| SUPPLEMENTS | PRACTICE THE 20/20/20 RULE Every 20 minutes, take a 20 second break and look at something 20 feet away. Follow the Blink Exercise Regimen. |
| CONTACT LENS INSTRUCTIONS (If applicable) | OTHER THERAPIES |

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BLINKING EXERCISE FORM

BACKGROUND INFO ON BLINKING: WHY IT'S IMPORTANT AND ITS ROLE

- Blinks are part of the ocular surface system and protect eyes**
- Blinking helps maintain the moisture composition of your tears**
- Blinking keeps cornea clear surface**
- It's healthy to blink, 15-20 times per minute, and typically complete blinks**

WHAT IS INCOMPLETE/NON-BLINKING AND WHY IT'S A PROBLEM

Incomplete or partial blinks do not spread the upper and lower eyelids across together. Incomplete blinks can cause problems with tear spreading across your eye and with tear evaporation. Studies show patients with incomplete blinks also have increased levels of tear evaporation, resulting in dry eye symptoms that provide key components of your tears**

CAUSES

- Working in environments that require significant focus such as reading, watching TV or using a computer**
- Computer use reduced eye blink rate by as much as 60% in healthy individuals**

WHY DOES THIS MATTER?

- A high percentage of genetic blindness is associated with 2x increase in dry eye disease
- Patients with high percentage of incomplete blinks often have problems with the glands in their eyelids that secrete the oily layer of their performance glands, leading to dry eye, digital eye strain**
- Patients that demonstrate a high percentage of partial blinks are likely to also demonstrate other ocular symptoms such as dry eye and digital eye strain**

BLINKING EXERCISE / SEQUENCE EXAMPLE

Practice this sequence:

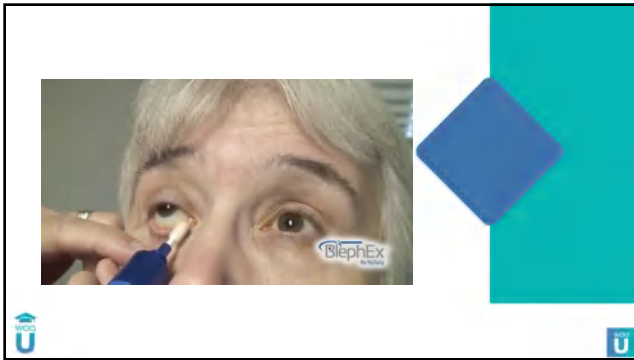
1. Close eyes for 10 seconds
2. Open eyes for 10 seconds
3. Close eyes for 10 seconds

Repeat this sequence 10 times. For a total of 30 repetitions. Allow each rest 1 and 2, repeat and count 1 and 2, and each rest 1 and 2.

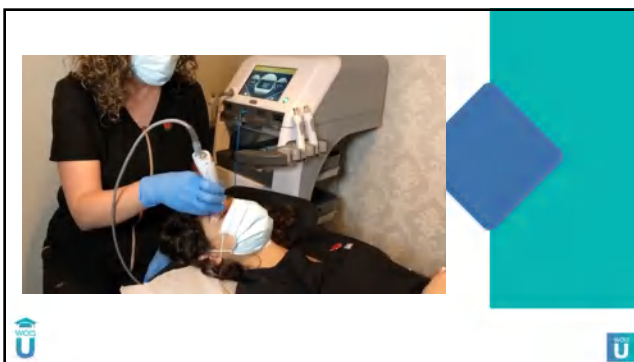
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Step 2

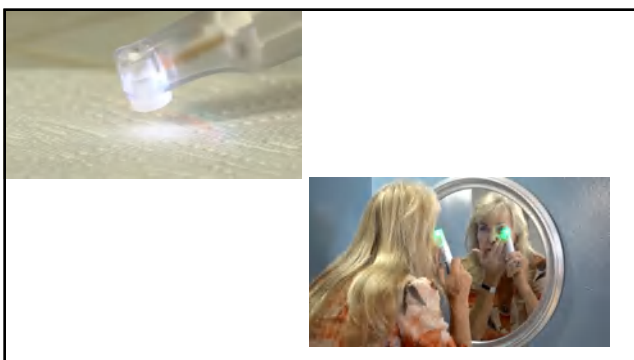
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Collarettes Are the Pathognomonic Sign of Demodex Blepharitis

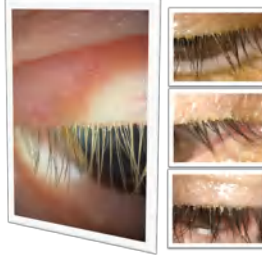
Confirming the presence of **collarettes** can be used to confidently make a diagnosis

- In a clinical study, Demodex mites were found on 100% of lashes with collarettes!

Collarettes are composed of mite waste and eggs

- Regurgitated undigested material combined with epithelial cells, keratin, mite eggs, and digestive enzymes, which cause irritation!
- Translucent, waxy plugs typically at base of lashes!

100% of blepharitis patients with collarettes had Demodex mites!




1. Scott WJ, DePasquale MA, Liu W, et al. High prevalence of Demodex mites in eyelashes with clinical blepharitis. Invest Ophthalmol Vis Sci. 2008;49(2):589-594. 2. Cheng KL, Meehan A, Wang X, et al. Demodex mites in eyelashes. Invest Ophthalmol Vis Sci. 2013;54(13):4013-4016. 3. Finkbeiner S, Calkins DL, Taha, et al. Demodex mites in eyelashes. Invest Ophthalmol Vis Sci. 2013;54(13):4013-4016. 4. Finkbeiner S, Calkins DL, Taha, et al. Demodex mites in eyelashes. Invest Ophthalmol Vis Sci. 2013;54(13):4013-4016.

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Workup

- Clinical suspicion
- Slit lamp




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Blepharitis Is a Large and Underserved Market in Eye Care

Epidemiology of Demodex Blepharitis

- Estimated In-Office Epidemiology** ~25M
- Population Epidemiology** ~9M
- U.S. Demodex Blepharitis Prevalence** **Approx. 9-25M**
- Current KD-15** ~1M Dlx/yr
- ~10M with Blepharitis***
- ~40M with Demodex Infestation***
- ~10M with Blepharitis***
- ~2.5M Blepharitis, 625-850M Dry Eye***
- ~15M Dry Eye***
- ~13M Dry Eye***
- Despite no real education**



| | |
|-----------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Large Patient Population with Significant Disease Burden | Blame Collarette (Clinical Prevalence) and Atopic (Disease Impact) Patient Demographics High prevalence of disease and significant burden on patients. |
| Significant Head Block on Dispensing | ~2.5M KD-15 Blepharitis Dlx/yr* |
| Demodex-We Don't Really Know | Spends to become red, irritated and itchy, with debris on the eyelashes! |
| Blepharitis Day (Lash Rx) | Blurring of vision, itching or irritated eyelashes, and inflammation of other eye tissue, particularly the cornea! |
| Uncontrolled Dry Eye | Significant overlap in Dry Eye patients. Demodex prevalent in 70% of DE patients! |
| Worsen the endogeneity | Important factor for measuring surgical outcomes. 67% of Cataract Patients have Demodex Blepharitis! |
| Contact Lens Impingement | Statistics have shown a direct correlation between Demodex Blepharitis and Contact Lens Intolerance! |
| Prescription/Compliance | None. 63% of patients currently seeking treatment! |

1. Wilson J. Ophthalmology 2015; 124:1666-1674. 2. Tarsus collarettes prevalence study. J. Med. Resour. 2005. 3. WHO Report 2005. Special Issue 2011. Vol. 52. 4. American Optometric Association. Contact Lenses Year Book 2005. 5. Ocular Care 2005. 6. Ocular Care Epidemiology. 2012. 7. 2012. 8. Blepharitis Clinical Data Analysis. 9. American Contact Lens Association. 2010. 10. American Contact Lens Association. 2010. 11. Demodex mites in eyelashes. Invest Ophthalmol Vis Sci. 2013;54(13):4013-4016. 12. Demodex mites in eyelashes. Invest Ophthalmol Vis Sci. 2013;54(13):4013-4016. 13. Demodex mites in eyelashes. Invest Ophthalmol Vis Sci. 2013;54(13):4013-4016. 14. Demodex mites in eyelashes. Invest Ophthalmol Vis Sci. 2013;54(13):4013-4016.

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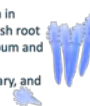
Demodex Mites are the Most Common Ectoparasite on Humans

Demodex mites

- associated with acne vulgaris, folliculitis, rosacea, peri-oral and scalp hair loss and basal cell carcinoma.
- Implicated in diseases of the lid and lid margin blepharitis and MGD

Two species affect the eye

- **Demodex folliculorum** ~0.3 to 0.4 mm in length, found in clusters around the lash root and lash follicle, where it feeds on sebum and follicular epithelial cells.
- **Demodex brevis** is shorter, more solitary, and prefers the meibomian glands.
- Both species are translucent, elongated microscopic mites with four pairs of short, clawed legs¹



80% of patients with Demodex blepharitis report a negative impact on daily life²

1. Berman DS, Gardner D, Patel J, et al. Demodex blepharitis. *Current Ophthalmology Clinics*. 2018;14:1-10. 2. Berman DS, Gardner D, Patel J, et al. Demodex blepharitis. *Current Ophthalmology Clinics*. 2018;14:1-10.

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Titan Study Confirms Widespread Collarette Prevalence in ECP Clinic Patients and Key Patient Segments

IRB-APPROVED RETROSPECTIVE CHART REVIEW
Examined presence of collarettes and other characteristics

LARGE-SCALE ALL-COMERS (3,000 patients)
Consecutive patients with a wide variety of reasons for visit

DIVERSE ANTERIOR SEGMENT CLINICS
Geographically diverse (7 investigators at 6 US sites) including both MD and OD clinics

% of Overall Population

- No collarettes (N=437): 57.7% Had collarettes (N=325)
- Don't know (N=17)
- No dry eye (N=422): 58.4% Diagnosed with Dry Eye (N=355)
- Dry Eye diagnosis (N=595)

Key Patient Groups

% with collarettes within each group

- Blepharitis diagnosis: 69%
- Dry Eye Rx Treatment: 60% (* 2% of all study patients on Dry Eye Rx treatment)
- Contact patients: 56%
- Contact lens users: 51%

ARVO 2021 study of patients at one center¹ (n=195) showed 55% prevalence of MGD, 62% overlap of Blepharitis, 68% overlap with Dry Eye

1. Allan Tay, Eric Rosenfield, Adam Jackson, Prevalence of Demodicid Colonization in Patients Presenting to an Outpatient Clinic. *Invest Ophthalmol Vis Sci*. 2021;62(9):3266.

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Atlas Study Reveals Symptomatic and Psychosocial Burden of Demodex Blepharitis: 80% Report Negative Impact on Daily Life¹

- Multicenter, observational study of patients pre-screened for the Saturn-3 pivotal trial
- Evaluated the clinical and patient reported impact of Demodex blepharitis (interim analysis of 311 patients)
 - Presence of Demodex mites (at least 1 mite per lash)
 - Presence of collarettes (> 10, upper lid)
 - At least mild erythema

51% Experienced signs and symptoms > 6 yrs

58% Never diagnosed with Blepharitis

33% Made at least 2, and sometimes more than 6, visits to a doctor for this condition

Most Bothersome Symptoms

Patients with Demodex blepharitis reported they experience these most bothersome symptoms frequently or all the time (N=285):

- Eyes that burn
- Irritated eyes
- Eyes that itch
- Gritty eyes
- Dry eyes
- Blurred vision
- Crusty eyes
- Red eyes or eyelids
- Feels like something in your eye
- Eyes that tear or water

Functional and Psychosocial Impact

Q7. Does your blepharitis affect any of the following aspects of your daily life (if applicable or how you feel about your life)?

Male Female

- Feels eyes/irritation of eyes all day: 21% 21%
- Difficulty driving at night: 20% 20%
- Additional time needed for daily hygiene routine: 19% 19%
- Negative appearance of eyes or eyelids to others: 15% 17%
- Constantly worrying about your eyes or eyelids: 13% 13%
- Difficulty wearing make-up: 12% 12%

1. Berman DS, Mack J, Anderson, Neufuss R, Bala, Paul J. Clinical, Psychosocial Impact of Demodex Blepharitis. *Invest Ophthalmol Vis Sci*. 2021;62(9):3266.

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Asking Your Patient to Look Down During a Slit Lamp Exam Can Reveal Diffuse Collarettes and Misdirected or Missing Lashes

100% of blepharitis patients with collarettes had Demodex mites!

Patient looking straight ahead

Patient looking down

Patient looking straight ahead with lid lift

Patient looking down

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MGD & Demodex Comorbidity

Terpene Terpinen-4-ol is toxic to demodex

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TP-03 is a Novel Therapeutic Designed to Eradicate Demodex Mites and Treat Demodex Blepharitis

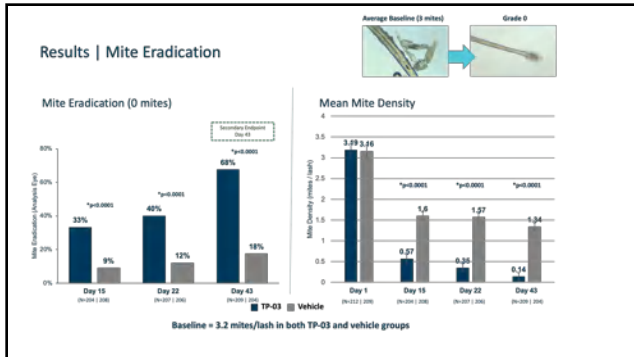
Lattarone

- Patient may experience amelioration of meibomian gland dysfunction
- High topical bioavailability
- Proposed synergistic bioavailability to lid secretions

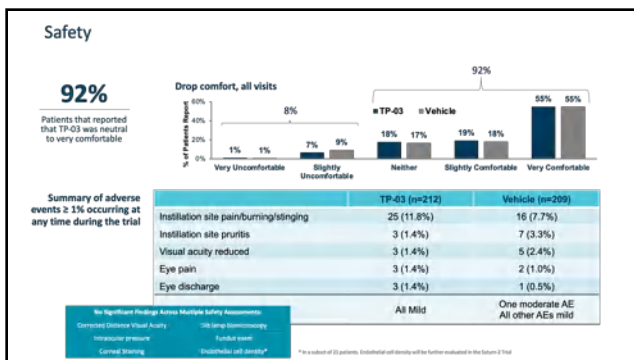
| | | |
|---|----------------------|------------------------------------------------------------------------------------------------------------------------|
| 1 | Product Form | Multi-dose eye drop solution bottle, preserved |
| 2 | Targeted Use | Treatment of Demodex blepharitis |
| 3 | MOA | Paralysis and death of Demodex mites |
| 4 | Diagnosis | Collarettes identified in standard eye examination |
| 5 | Dosing | BID* for 6 weeks |
| 6 | Efficacy Goal | 1 st collarette cure rate, 2 nd mite eradication, 2 nd redness + collarette cure rate |
| 7 | Safety Goal | Well-tolerated safety profile |

WCU U

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Poor Lens Surface Wettability

- Troubleshooting:
 - Manage lid and ocular surface diseases
 - Review skin care and makeup regimen
 - Improve cleaning regimen (Extra-strength alcohol-based cleaners, H2O2)
 - Wet Q-tip or small DMV plunger and wipe deposits
 - Select a material with lower wetting angle
 - Hydra-PEG or plasma treatment

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Debris in the Tear Reservoir


- **Troubleshooting:**
 - Assess and treat any ocular surface disease
 - Modify peripheral curves or reduce lens diameter
 - Flatten curves to minimize impact on the conjunctiva
 - Modify curves to reduce limbal clearance
 - Mix of viscous artificial tears and saline in the bowl
 - Saline flush: Ask the patient to replenish solution from the side, without removing the lens
 - Remove lenses and replenish with fresh saline mid-day
 - Note: Frequent insertion /removal will promote more disruption of the ocular surface, and more debris

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What is Aqueous Deficient DES

Most common: inflammatory infiltration of the lacrimal gland

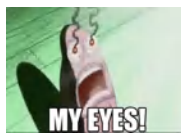
- **Severe:** Sjogren syndrome (SSDE)
- **Less severe:** Non-Sjogren syndrome (NSDE)
 - Inflammation causes both acinar and ductal epithelial cell dysfunction/destruction
 - Epithelial injury and defective glycozocalyx, loss of tear volume and of goblet cell mucin, lead to increased frictional damage and friction-related symptoms
 - Tear hyperosmolality and epithelial injury caused by DEO stimulates corneal nerve endings



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Symptoms of ADDE

- Discomfort
- Increased blink rate
- Compensatory, reflex increase in lacrimal tear secretion



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Ocular Surface Disease Index® (OSDI)^{®2}

Ask your patient the following 12 questions, and circle the number in the box that best represents each answer. Then, fill in boxes A, B, C, D, and E according to the instructions beside each.

Assessing Your Patient's Dry Eye Disease^{1†}

Use your answers A and E from Slide 1 to compare the sum of scores for all questions answered (S) and the number of questions answered (Q) with the chart below. Find where your patient's score would fall. Match the corresponding shade of red to the key below to determine whether your patient's score indicates normal, mild, moderate, or severe dry eye disease.

| | | | | | | | | |
|----|-----|-----|------|------|-------|------|------|-------|
| 12 | 118 | 100 | 11.1 | 80.1 | 120.1 | 71.5 | 83.8 | 100.0 |
| 11 | 113 | 95 | 11.1 | 75.1 | 115.1 | 66.5 | 78.8 | 95.0 |
| 10 | 108 | 90 | 11.1 | 70.1 | 110.1 | 61.5 | 73.8 | 90.0 |
| 9 | 103 | 85 | 11.1 | 65.1 | 105.1 | 56.5 | 68.8 | 85.0 |
| 8 | 98 | 80 | 11.1 | 60.1 | 100.1 | 51.5 | 63.8 | 80.0 |
| 7 | 93 | 75 | 11.1 | 55.1 | 95.1 | 46.5 | 58.8 | 75.0 |
| 6 | 88 | 70 | 11.1 | 50.1 | 90.1 | 41.5 | 53.8 | 70.0 |
| 5 | 83 | 65 | 11.1 | 45.1 | 85.1 | 36.5 | 48.8 | 65.0 |
| 4 | 78 | 60 | 11.1 | 40.1 | 80.1 | 31.5 | 43.8 | 60.0 |
| 3 | 73 | 55 | 11.1 | 35.1 | 75.1 | 26.5 | 38.8 | 55.0 |
| 2 | 68 | 50 | 11.1 | 30.1 | 70.1 | 21.5 | 33.8 | 50.0 |
| 1 | 63 | 45 | 11.1 | 25.1 | 65.1 | 16.5 | 28.8 | 45.0 |

Sum of Scores for All Questions Answered (S from Slide 1)

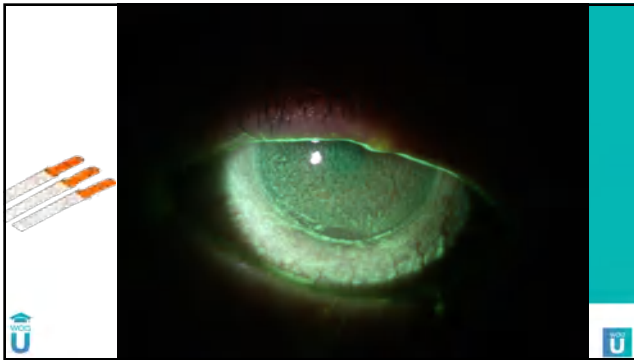
Number of Questions Answered (Q from Slide 1)

Normal Mild Moderate Severe

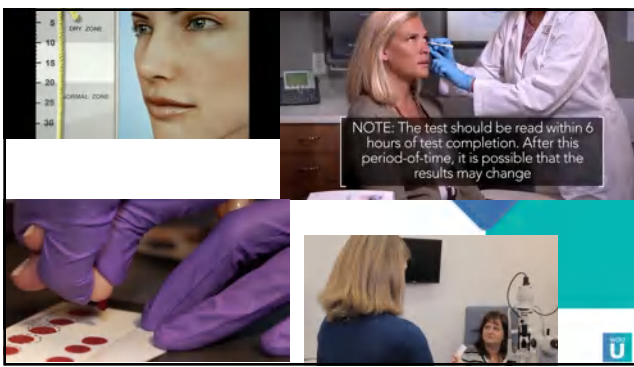
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Artificial Tears

considered a first-line therapy for dry eye

- increase tear volume
- minimize desiccation
- lubricate the ocular surface
- increase viscosity, lubricity, retention time and adhesion to the ocular surface
- inorganic ions (0.9% NaCl)
- May contain electrolytes or found in normal tears

$$\text{HO}-\overset{\text{O}}{\parallel}-\text{O}^- \text{K}^+$$

A 'U' logo is in the bottom left corner.

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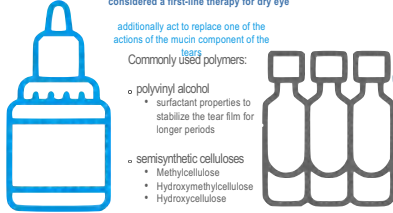


Artificial Tears

considered a first-line therapy for dry eye

additionally act to replace one of the actions of the mucin component of the tear




Commonly used polymers:

- polyvinyl alcohol
 - surfactant properties to stabilize the tear film for longer periods
- semisynthetic celluloses
 - Methylcellulose
 - Hydroxymethylcellulose
 - Hydroxyethylcellulose
- Hyaluronic acid
 - greater retention times
 - improves tear film stability

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Other Ingredients

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Combinations

The active ingredients in FRESHKOTE PF are a patented polymer blend with a unique ratio of polyvinyl alcohol and povidone^{1,2}



MUCOQUEOUS LAYER
Polyvinyl Alcohol (2.7%)^{1,3}



- Mimics the mucin layer of the tear film by tightly adhering to dry hydrophobic spots, making them hydrophilic
- Attracts the aqueous portion of the tear film to these areas, completely wetting the ocular surface

LIPID LAYER
Povidone (2.0%)^{1,2}

- Integrates with the lipid layer, supplementing it and thereby reducing evaporation while lubricating and soothing the ocular surface

HIGH ONCOTIC PRESSURE
Unique Ratio Blend^{1,2}

- FRESHKOTE PF was scientifically developed to result in high oncotic pressure when on the ocular surface

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Gels

More viscous
Longer retention times

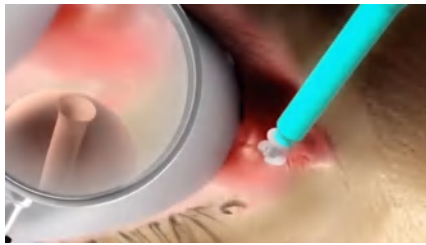
- Polyacrylic acid
- Petroleum – mineral oil-based ointments reserved for nocturnal use or lagophthalmos/blink paralysis
- blur vision and feel sticky



Genical
Systane GEL
Alcon
Refresh Tears

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Lacrimal Punctal Occlusion




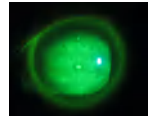
AT + PO = Mainstay of treatment for ADDE

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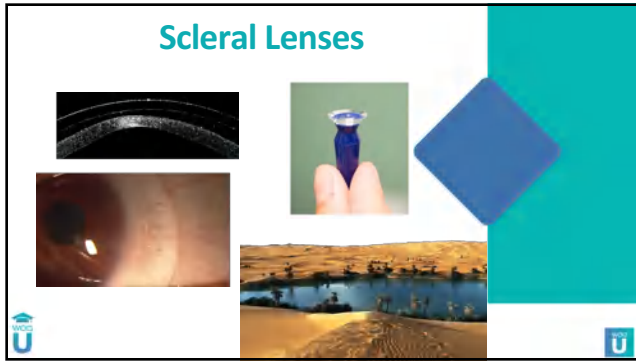
Scleral Lenses

Severe Ocular Surface Disease

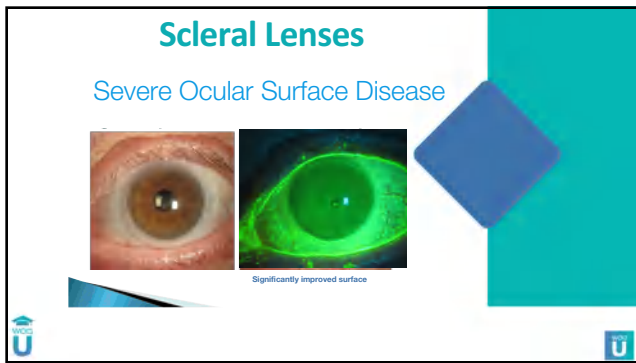
70 yo WF
OS-4+ Severe SPK
Scleral Lens Evaluation



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Cyclosporin

- Immunosuppressive Agent (Cyclosporin A)
- Used for treating inflammatory diseases: RA and psoriasis
- Reduces the amount of inflammatory markers
- After a 6-month treatment there is an increase in the number of goblet cells in the conjunctiva
- May result in an increase in goblet cell differentiation in the conjunctival epithelium



Restasis
(Cyclosporine ophthalmic emulsion) 0.05%

- The exact mechanism of action is not known
- It can help increase the eyes' natural tear production with time and consistent use
- In a study increase in tear production at 6 months



Cequa
(Cyclosporine ophthalmic solution) 0.09%

Formulated with NCELL[®] Technology

- The exact mechanism of action is not known
- Helps restore tear production by acting as a partial immunomodulator

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Lifitegrast



xiidra
(Lifitegrast ophthalmic solution) 0.02%


- Blocks LFA-1 on T cells from binding with ICAM-1 that may be overexpressed on the ocular surface in DED
- May prevent formation of an immunologic synapse which, based on in vitro studies, may inhibit T-cell activation, migration of activated T cells to the ocular surface, and reduce cytokine release




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Steroids

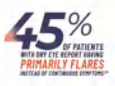
- Reportedly have a positive influence on DED
- More efficacious than NSAIDs
- Decrease in HLA-DR-positive cells and symptom severity



EYSUVIS
(loteprednol etabonate ophthalmic suspension) 0.25%




80%
OF PATIENTS WITH DRY EYE
SUFFER FLARES*



45%
OF PATIENTS WITH DRY EYE REPORT HAVING
PRIMARY FLARES
(BASED ON CLINICAL STUDY DATA)

Approved for SHORT-TERM (up to two weeks) treatment for DED

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Regener-Eyes[®]
OPHTHALMIC SOLUTION

- derived-Multiple Allogeneic Proteins Paracrine Signaling (d-MAPPS)
- Contains a large number of immunoregulatory molecules as well as trophic & growth factors

STERILE MULTIDOSE EYE DROPS

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Autologous Serum Tears



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Scleral Lens Application Solution

- MUST be preservative free
- Sterile saline: most common solution
 - Vials:
 - Nutrifill (Contamac)
 - ScleralFill (B&L)
 - Lacripure (Menicon)
 - Addipack (generic)
 - Bottles:
 - Purilens (generic)



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Other Options for Scleral Lens Application Solutions

- Preservative free artificial tears
- Autologous Serum – severe OSD




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Lens Care System

- Physical rubbing necessary
- Peroxide based solutions are the only preservative-free option
- **Avoid Boston Advance and Boston Original**
 - Silica gel: abrasive, can scratch lens surface
- Educate patient on thorough rinsing of lens prior to applying lenses



PROSE Disinfection Case

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Preservative Free Toxicity



Always use preservative free application solutions

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Recommendations

- Preservative-free artificial tears
 - For use inside or outside of lenses
- Remove lenses prior to instillation of medicinal drops
 - Wait 10 minutes before applying lenses
- No sleeping in lenses
- Gradual build up of wear time
- Advise patient to wear lenses into follow-up appointment



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thank you



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