

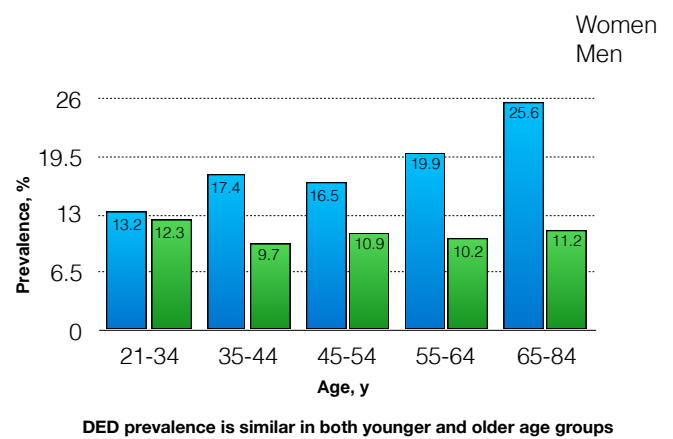
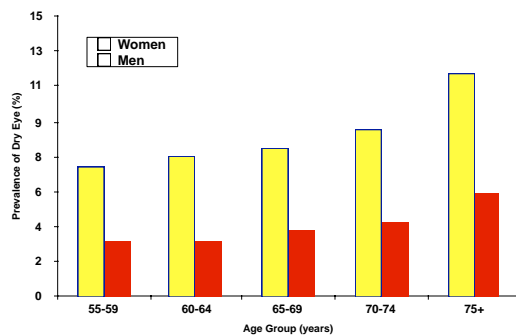
# What, Why, How about Dry Eye Disease Management

Paul M. Karpecki, OD, FAAO  
Kentucky Eye Institute  
UPike Kentucky College of Optometry

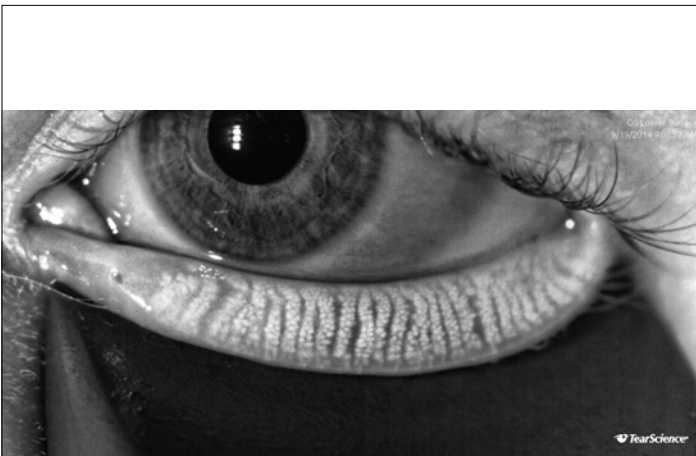
## Dry Eye Disease

- 42% of patients complain of symptoms that would indicate DED (60-80M people)
- 30-50 Million in the North America based on longitudinal studies
- 16 Million diagnosed with DED
- 1.5 Million being treated

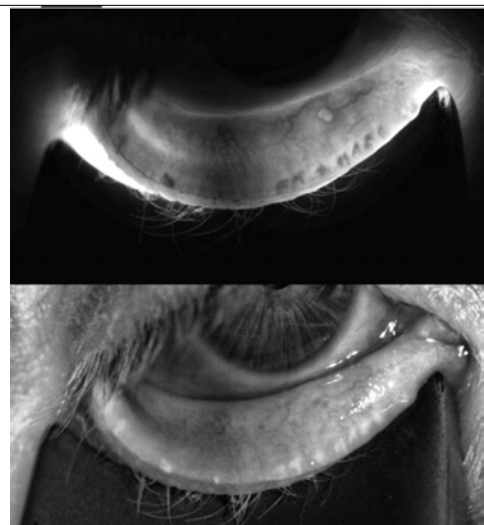
Prevalence of Dry Eye  
(continued)  
Prevalence by Age and Gender – WHS Study



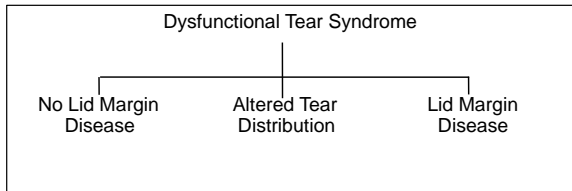
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## DTS: Clinical Categories



- Most common presentation: "No lid margin disease"
- Treatment decision based on severity level

Behrens et al, Cornea 2006

## Key Early Diagnosis Tests for DED Diagnosis

Questionnaire e.g. SPEED and/or triage questions

POC: Osmolarity

MG Expression

Blink analysis

Possibly lissamine green (moderate)

Meibography may replace previous testing and enhance meibomian gland evaluation

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## 5 Triage Questions

Do you have dryness, irritation, burning or tearing of your eyes?

Are your eyes red or look irritated?

Do you have fluctuating or blurry vision?

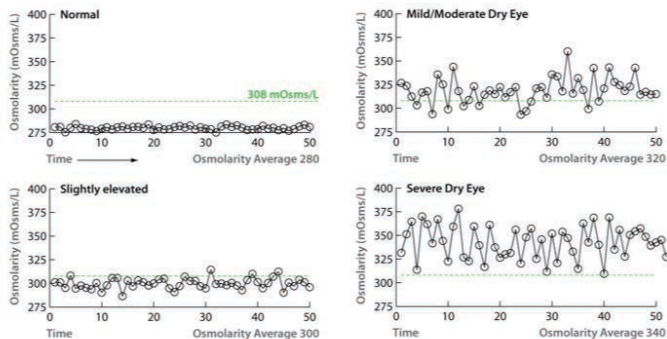
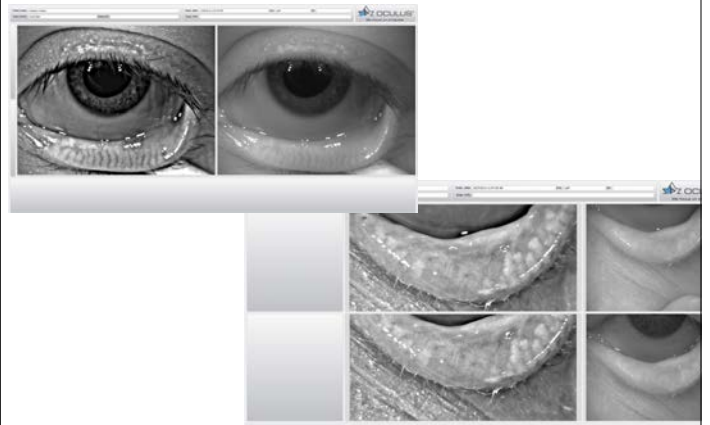
Do you use or feel the urge to use artificial tears?

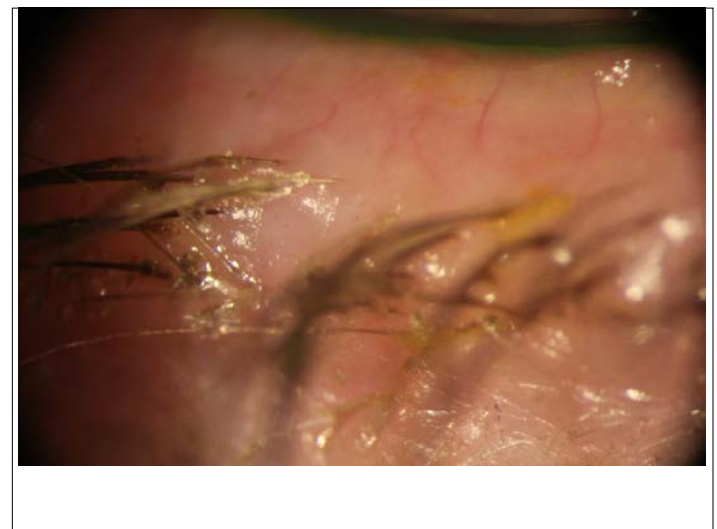
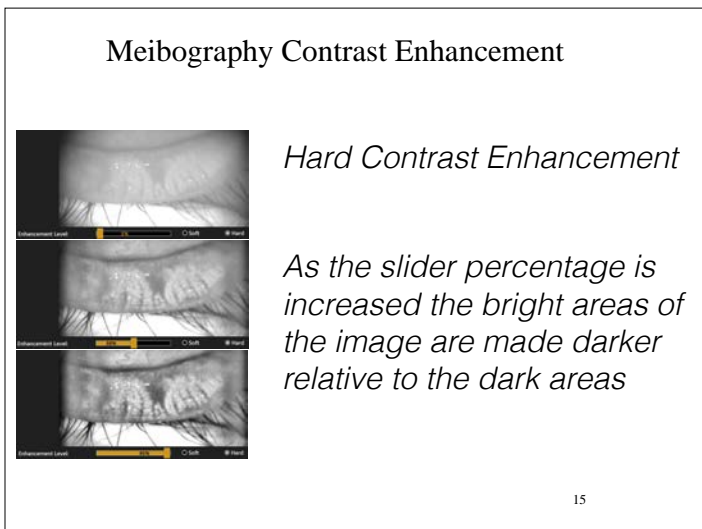
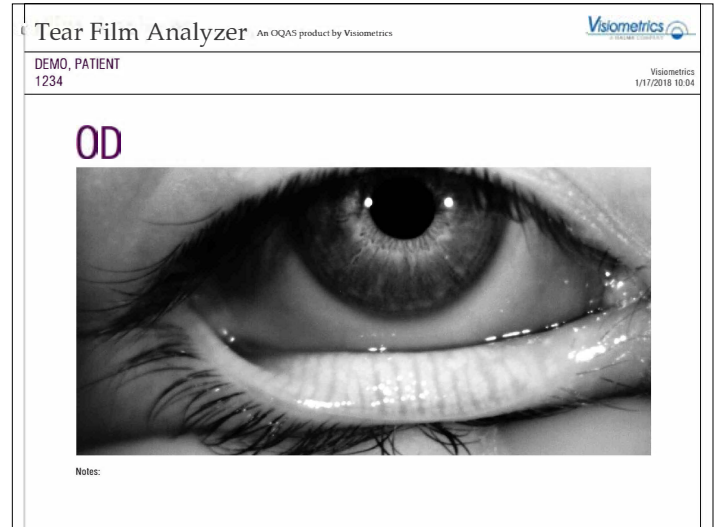
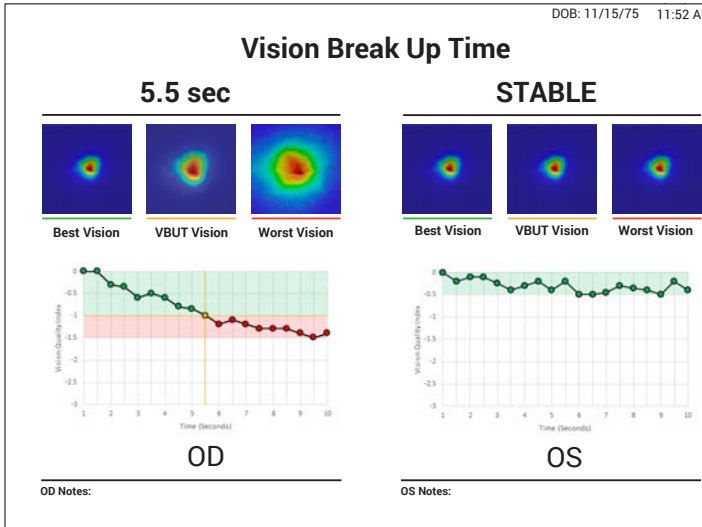
Do you use a digital device more than 2 hrs/day

8



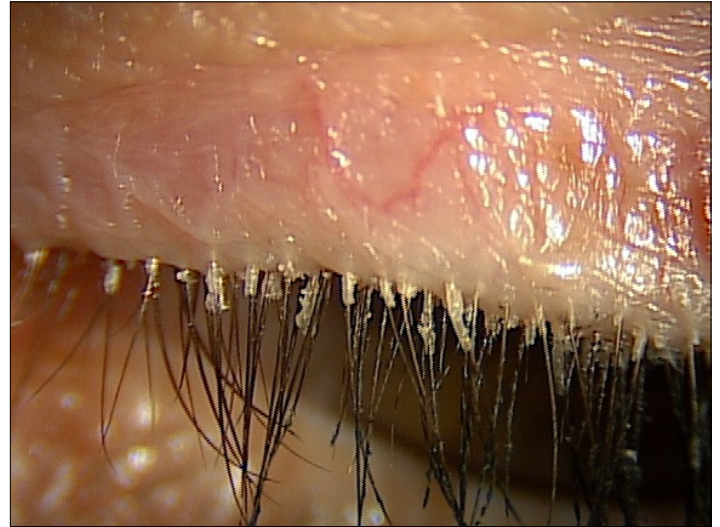
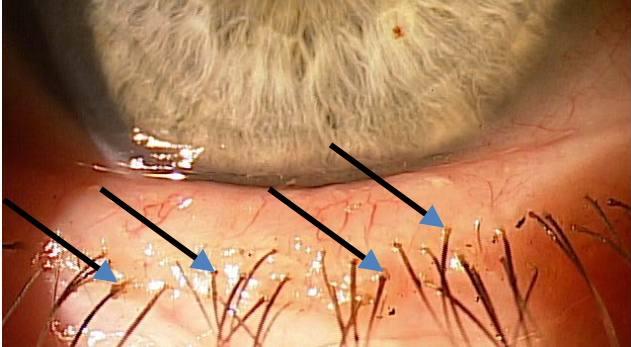
## Key Tests for OSD Diagnosis







## Significant signs of blepharitis/ biofilm



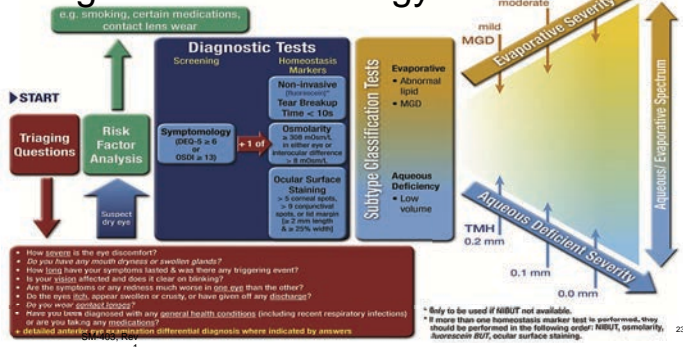
## Most Common Diagnostic Tests: 2014

- Pt history
- Tear break-up
- NAFL Dye
- Schirmer test - phenol thread test

## Diagnostic Testing: Today

- Pt questionnaire- DEQ5, SPEED etc.
- TearLab osmolarity/MMP9
- Slit lamp examination
  - CCH, bleph, incomplete closure, allergy
- MG Expression
- NAFL Dye/Lissamine
  - Tear meniscus height
  - Corneal staining- late indicator
- Meibography
- Blink analysis
- Cover Test

## Diagnostic methodology

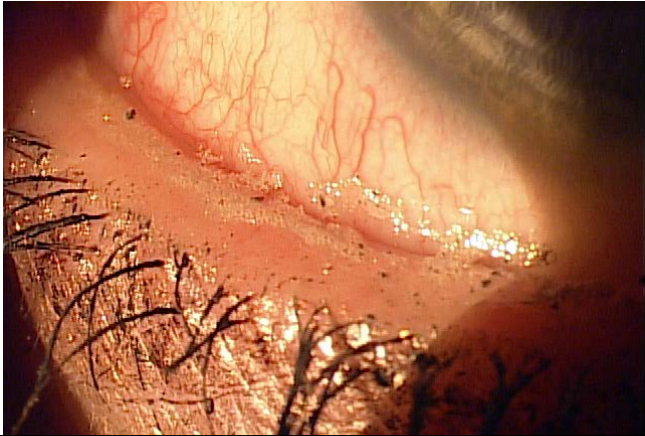


MGD

Rendia



## Frothy / Foamy Tears = MGD



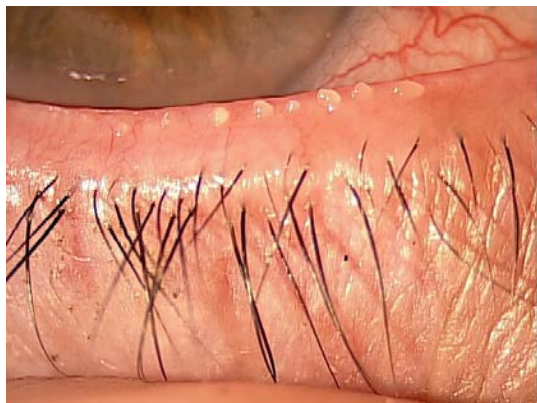
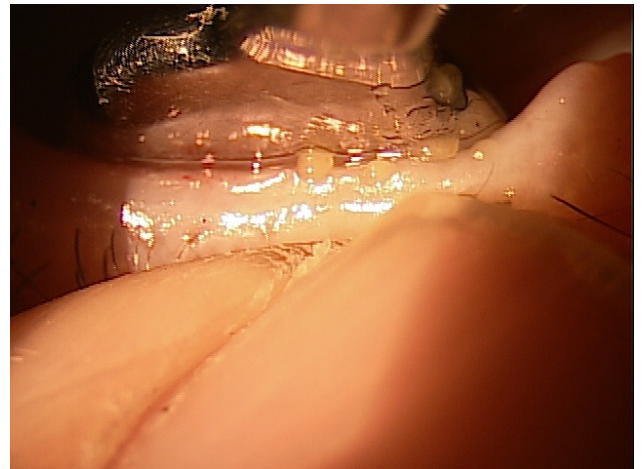
## Chronic changes

- Telangiectasia
- Scarring



Paul Karpach, OD

TSU



## Meibomian Gland Evaluator™

- Intended for use by a clinician to evaluate Meibomian gland secretions. Used to apply consistent light pressure to the outer eyelid skin of a patient while visualizing secretions from Meibomian gland orifices through a slit lamp biomicroscope.



## Four Components to EDED

Obstruction

Bacterial biofilm

Inflammation

Tear film instability

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## Mild EDED

- Hydrating compresses
- Lid hygiene scrubs
- Lipid based tears for mild moderate cases
- Omega fatty acid supplements or cyclosporine or lifitigrastr 5%

## Severe EDED

- Hot/warm compresses vs. Thermal pulsation
- Blephex biofilm treatment in office
- Osmolarity lowering tears such as TheraTears, Hylo, Blink
- Steroid combination agents, topical steroids
- Oral doxycycline/azithromycin

## Obstruction

Lid margin debridement/scaling

Commercial WC (e.g. Bruder, TranquilEyes etc.)

Cold or manual expression

Mechanical thermal pulsation or expression

Blink exercises

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## Eye Hydrating Compress

Moist heat compress

30 angstrom opening pulls in ambient hydration and then release

20-25 seconds in microwave

Brings MG temperature over 104 degrees for ~10 min

Antibacterial via silver ionization

Washable, durable

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Heat transfer through lid, tarsal plates to MGs a key challenge  
Heating target should be 45 degrees C (113 degrees F)  
Up to 8 minutes to reach 40 degrees C at inner lid  
Secretions melt at 32-45 degrees C (several factors impact range)

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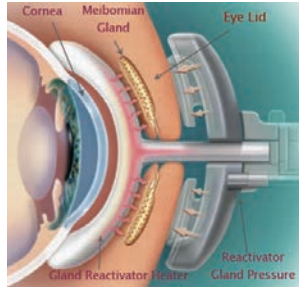
## THERMODYNAMIC TX TO EXPRESS AND EVACUATE MGs

A new thermodynamic treatment to express & evacuate the MGs

Heat applied to both inner lid surfaces  
Pulsatile pressure applied to outer lids



The device applies controlled heat to the **inner** upper and lower palpebral conjunctival surfaces and lid margins, while simultaneously applying pulsating pressure over the upper and lower (outer) eyelids.



## Does Thermal Pulsation Work?

- A recent review of 31 peer reviewed articles/abstracts (including five registered randomized controlled clinical trials):

A single dose, 12-minute therapy results in:

- Mean gland function improvement is ~ 3x baseline
- Mean symptom improvement is ~ 2x (symptoms are halved)
- Sustained effect:
  - Nine center randomized controlled study: mean improved gland function and symptom relief was 12 months and longer.
  - Uncontrolled studies: significantly longer (these include combination therapy, lid margin health)

1. Blackie CA, et al. Treatment for meibomian gland dysfunction and dry eye symptoms with a single-dose vectored thermal pulsation: a review. Current Opinion in Ophthalmology 2015, 26:306-313.

## TearFilm Innovations: iLux

IR technology  
Back surface heating  
Viewing area  
Mechanical expression  
ionization  
Hand-held devices



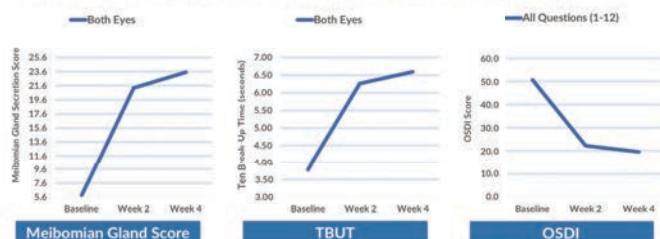
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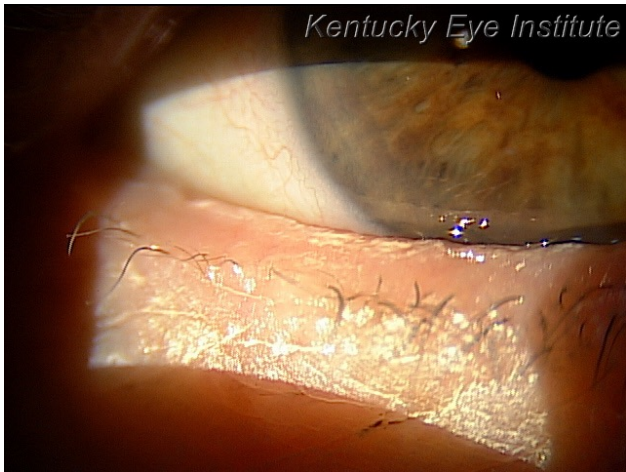


## iLux FDA Clinical Trial Data

Pivotal Clinical Study: 142 patients, 8 sites

Statistically Significant Improvement in signs and symptoms of Dry Eye and MGD





BlephEx Treatment



1

## Treating the BioFilm

- Blepharoexfoliation
- Surfactant Based Lid Hygiene products e.g. Lid Scrub Plus, SteriLid etc.
- Surfactant + anti-inflammatory agents (phytosphungsine): OcuSoft Platinum
- Antibiotics etc.

## Treating Inflammation

- Lifitegrast
- Cyclosporine
- Steroids or combination agents bid
  - e.g. loteprednol
- Steroid ointments
- Oral Doxycycline (50mg or 20mg) or PO azithromycin (250mg)
- Omega fatty acids (EPA/DHA/GLA)

## Tear Film Alterations

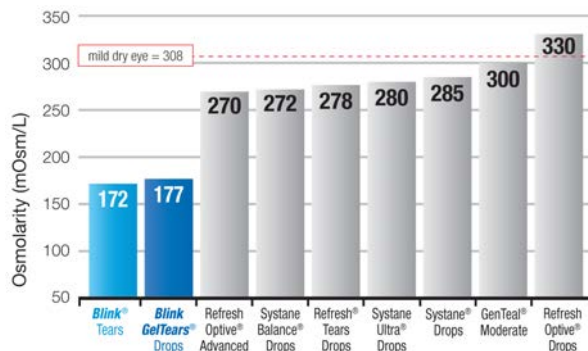
- Choice of artificial tears depends on two things:
- MG expression
- Osmolarity



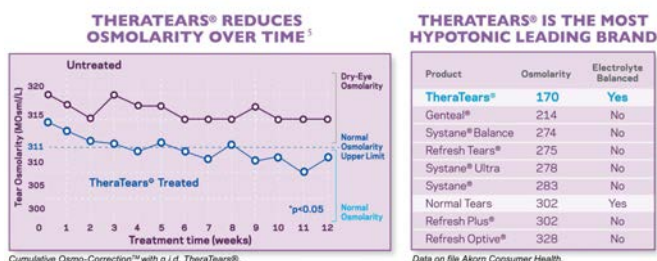
# Tear Film Alterations

- Choice of artificial tears:
- High/Moderate osmolarity/advanced MGD:
  - Blink, Oasis Tears or TheraTears, Hylo
- Low osmolarity/moderate MGD:
  - Systane Complete, Refresh Mega3, RetainMGD, SootheXP

## Osmolarity variance among artificial tears



## Osmolarity variance among artificial tears



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## MGYLS

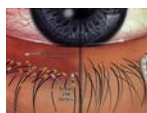
- Symptomatic CL wearer: 4.8
- Asymptomatic non-CL: 5.5
- Asymptomatic RGP wearer: 9.0
- Asymptomatic SCL wearer: 10.7



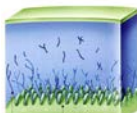
OBSTRUCTION



BIOFILM



INFLAMMATION



TEAR FILM

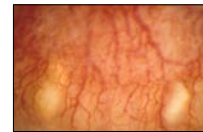
- |  |   |   |   |
|--|---|---|---|
| <ul style="list-style-type: none"> <li>• Blink exercises</li> <li>• Moist heat compress (Bruder)</li> <li>• Lid debridement</li> <li>• Thermal pulsation</li> <li>• Thermal expression</li> <li>• Manual expression</li> </ul> | <ul style="list-style-type: none"> <li>• Blepharoxfoliation (Blephex)</li> <li>• Hypochlorous acid</li> <li>• Tea tree oil</li> <li>• Surfactant cleansers</li> </ul> | <ul style="list-style-type: none"> <li>• Lifitegrast (Xiidra)</li> <li>• Cyclosporine (Restasis)</li> <li>• Corticosteroids</li> <li>• Omega fatty acids</li> <li>• PO Doxycycline</li> <li>• PO Azithromycin</li> <li>• Topical macrolides</li> <li>• IPL</li> </ul> | <ul style="list-style-type: none"> <li>• Artificial tears</li> <li>• Environment changes</li> <li>• Increase hydration</li> <li>• Punctal occlusion</li> <li>• Neurostimulation</li> <li>• Brimonidine 0.25%</li> </ul> |
|--|---|---|---|

## Long Term

- Hydrating compress daily
- Lid hygiene daily- foam canisters
- Pulse dose medications periodically
- Cyclosporine/Lifitegrast BID
- Steroids when symptoms are worse
- Essential fatty acid supplements

## Advanced Chronic Changes

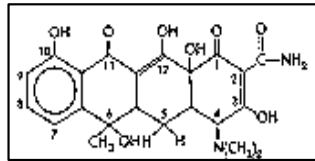
- Telangiectasia
- Dislocation of meibomian glands/ gland atrophy
- Scarring/atrophy



## Moderate/severe or not improving

- Add PO tetracycline
- Recommendation:
  - Doxycycline 50mg bid x 4-8 weeks then taper to qd
  - Doxycycline 20 mg bid (periostat can be expensive)
  - Time Release 40mg (can be expensive as well)

## Tetracyclines



- Antibiotics inhibit bacterial protein synthesis by binding 30S ribosome
- Anti-inflammatory properties
  - decreases IL-1, TNF- $\alpha$
  - decreases NO production
  - decreases HLA Class II antigen expression
  - decreases metalloproteinase production and activation
- Decrease symptoms and joint destruction in RA

## Contraindications

- Pregnant, nursing or female of child bearing age
- Children

## Cautions

- Photosensitivity
- Chelates with dairy products, antacids etc.
- Minocycline may cause vestibular toxicity
- Risk of IIH
- Number one drop-out reason?
- GI problems

## How to Minimize Stomach Problems with Tetracycline

1. Do not take the second pill (bid) before going to bed
2. Do not take pills with acidic beverages
3. Take pills with food (except a high dairy meal)
4. Prescribe the lowest dose available
5. Prescribe the hyclate form
6. Consider PO Azithromycin

## Azithromycin

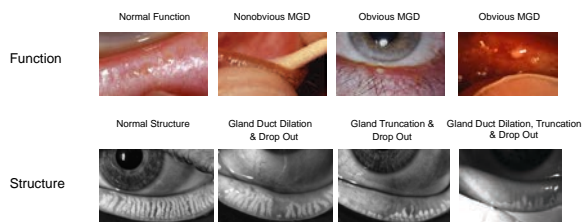
- PO 250mg QD x 14 days
- TFOS DEWS II

## Nutritional Supplements: Essential Fatty Acids

- Omega fatty acids shown to help with dry eye disease:
  - ALA: e.g., flaxseed oil
  - EPA/DHA: e.g., fish oils
  - GLA: e.g., black currant seed or evening primrose oil

## EDED/MGD is Progressive

### Examples of Compromised Function and Structure



Notes: Slak JJ, et al. Prevalence and risk factors of meibomian gland dysfunction: the Singapore Malay Eye Study. *Cornea*. 2012;31(11):1223-1228.  
 Viso E, et al. Prevalence of asymptomatic and symptomatic meibomian gland dysfunction in the general population of Spain. *Invest Ophthalmol Vis Sci*. 2012;53(6):2601-2606.  
 Hom MM, et al. Prevalence of meibomian gland dysfunction. *Optom Vis Sci*. 1990;67(9):710-712.

## GLAUCOMA SIMILARITY

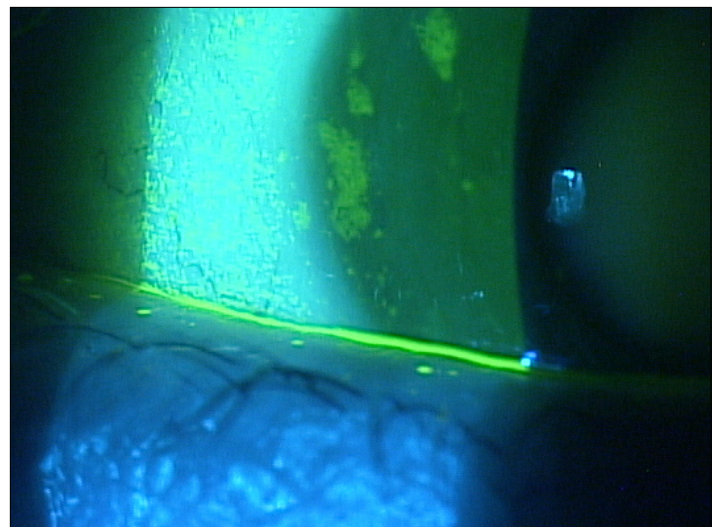
- Look at the structure and functioning of the MGs and ocular surface
- Multiple testing:
  - IOP = osmolarity
  - VF testing = corneal staining
  - OCT = meibomography
  - MG expression = ONH examination

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## FUTURE: DENTAL MODEL

- Tooth brush & floss = Hydrating compress and lid hygiene and ATs
- Dental cleaning = mechanical cleaning and MG expression (mechanical or otherwise)
- Dental x-rays = meibomography

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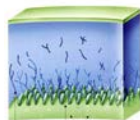






INFLAMMATION

- Lifitegrast (Xiidra)
- Cyclosporine (Restasis)
- Corticosteroids
- Omega fatty acids
- PO Doxycycline
- PO Azithromycin
- Amniotic membrane



TEAR VOLUME

- Artificial tears
- Environment changes
- Increase hydration
- Punctal occlusion
- Neurostimulation
- Cevimeline PO (Evoxac)
- Autologous serum q2h
- Scleral lenses

Monitor for MGD

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[www.opthalmicresources.com](http://www.opthalmicresources.com)

## Symptoms of DED but normal osmolarity, minimal other signs

DED that is well controlled

CL solutions related -PATH

Mild allergic conjunctivitis

EBMD- MDF dystrophy

Pinguecula & early Pterygium

Infection - e.g. conjunctivitis

Mucin fishing syndrome

Medicamentosa

LSCD

Anterior blepharitis

e.g. demodex

GPC

Asthenopia - vertical, CI etc.

Salzmann's Nodular Degeneration

Conjunctivochalasis (CCH)

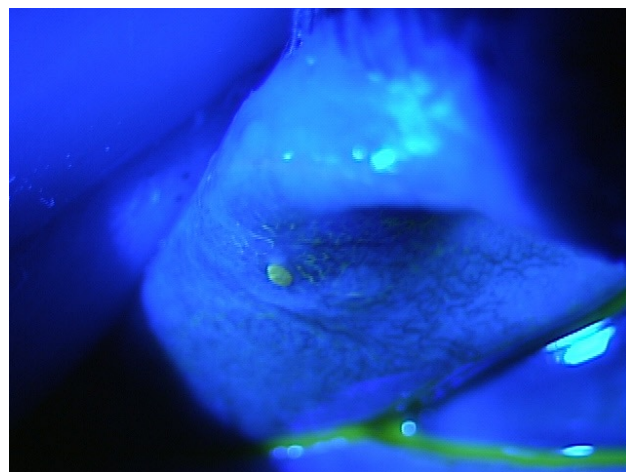
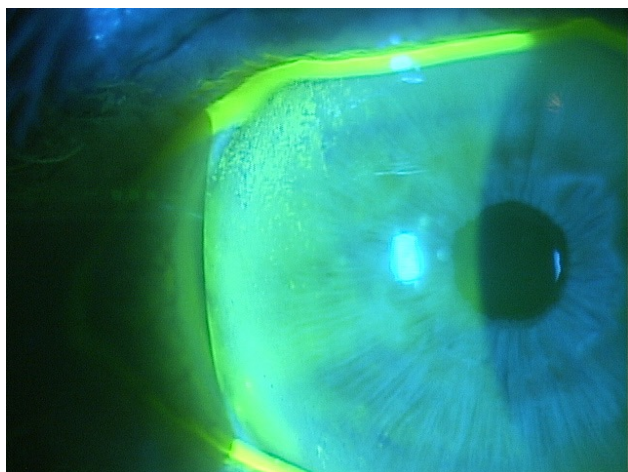
Conjunctival concretions

SLK

Episcleritis

Exposure keratopathy

Patient with epiphora will actually have osmolarity readings below normal or very low



## Treatment

- Emphasis chronic nature of the condition
- Eliminate exacerbating factors
  - smoking, air conditioner, meds.
- Tear replacements/ATs

## Treatment – AT's

- Osmolarity lowering:
  - Blink Tears, TheraTears, Oasis Plus, Hylo
- EBMD/corneal staining
  - FreshKote
- Lipid Deficient
  - Systane Balance, Soothe XP, Retaine MGD, Refresh Mega 3
- Aqueous deficient
  - Systane Ultra, Refresh
- Inferior stain -----> Genteal gel

## Targeted Treatments

- Treatments aimed at local inflammatory processes
  - Topical corticosteroids (loteprednol)
    - Effective anti-inflammatory agents
    - Site specific Steroids
  - Cyclosporin A (Restasis)
  - Lifitigrastr (XiidRA)

## Dry Eye Disease—A Real Condition That Needs More Than a Palliative Solution

- “Dry eye is a disorder of the tear film due to tear deficiency or excessive tear evaporation which can cause damage to the interpalpebral ocular surface.”<sup>1</sup>
- Artificial tears provide temporary palliative relief<sup>2</sup>

***“Artificial tears are inadequate because they fail...to prevent progression of Dry Eye disease.”<sup>3</sup>***

J. Daniel Nelson, MD  
Corneal Specialist  
University of Minnesota

1. Lemp. CLAO J. 1995.  
2. Stern et al. Cornea. 1998.  
3. Nelson et al. Adv Ther. 2000.

## Progression of Dry Eye Disease



- Dry eye is a progressive, potentially irreversible disease
- Left untreated, the cycle of inflammation and dysfunction may cause permanent damage to the lacrimal gland

## Steroids and Dry Eye

Symptomatic improvement in irritation symptoms in 83% and objective improvement (↓ redness, dye staining and tarsal papillae, ↑ FTC) in 80% of 70 patients treated for 2 weeks with non-preserved methylprednisolone

Prabhasawat & Tseng BJO 1998

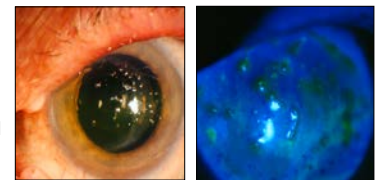
## Steroids and Dry Eye

- Moderate (43%) or complete (57%) relief of irritation symptoms accompanied by ↓ corneal FL staining and resolution of filamentary keratitis in 21 SS patients treated for 2 weeks with non-preserved methylprednisolone (Marsh & Pflugfelder 1999)
- Patients often have long lasting relief after 2-week pulse therapy

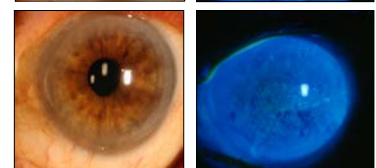
## Sjögren's Syndrome KCS

**Steroids Effectively Treat KCS**  
(Marsh Ophthalmology 1999)

Pre-Steroid



Post-Steroid

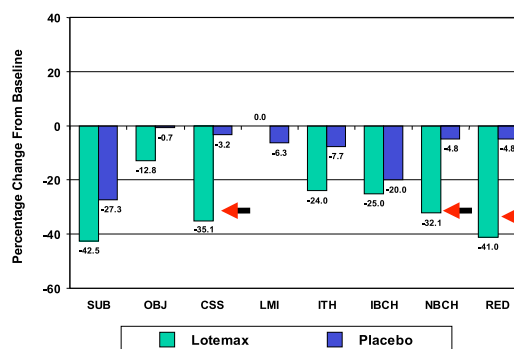


## Anti-inflammatory Therapy of KCS

### Corticosteroids

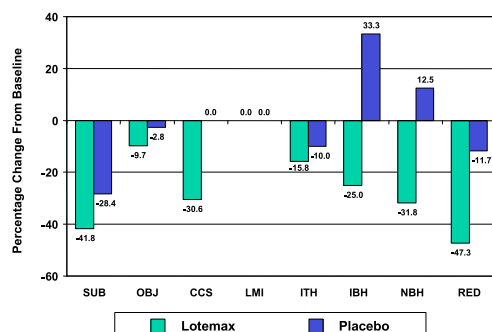
- Improve signs and symptoms
- Improve tear clearance
- Normalize mucus production
- Often have sustained benefit after a 2 week pulse
- Bioengineered steroid loteprenol etabonate is effective

Percentage Change in Means Between BL and Two Weeks  
Subjects with Conjunctival Hyperemia Score  $\geq 2$  at Baseline



Pflugfelder et al AJO 2004

Percentage Change in Means Between BL and Two Weeks  
Subjects with Corneal Staining Score  $\geq 10$  at Baseline



Pflugfelder et al AJO 2004

## How Does Restasis™ Work?

- Restasis™ prevents T-cell activation (Kunert et al, *Arch Ophthalmol.* 2000;118:1489)
  - Activated T cells produce inflammatory cytokines that result in:
    - Recruitment of more T cells (Stern et al, *IOVS.* 2002;43:2609)
    - More cytokine production (Pflugfelder et al, *Curr Eye Res.* 1999;19:201)

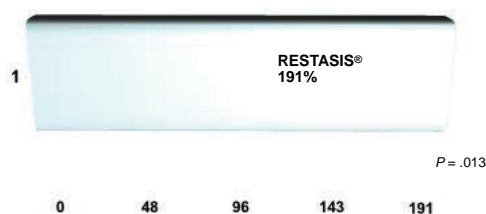
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## Topical Cyclosporine

- Restasis Ophthalmic Emulsion (Allergan)
  - Useful in long-term management of inflammatory DES
  - BID dosage
  - Cyclosporine A (CsA) 0.05% in castor oil vehicle
  - Mechanism of action:
    - Inhibits activation of inflammatory T-lymphocytes, and induces immune cell apoptosis, stimulating lacrimal gland tear production
  - 3-4 months to achieve clinically significant effect, 6 months for full therapeutic potential
  - 59% Patients achieved improvement from baseline Schirmer scores at 6 months
  - Excellent safety profile

## Increased Goblet Cell Density in Subset of 12 Patients

Percentage Change in Goblet Cell Density from Baseline



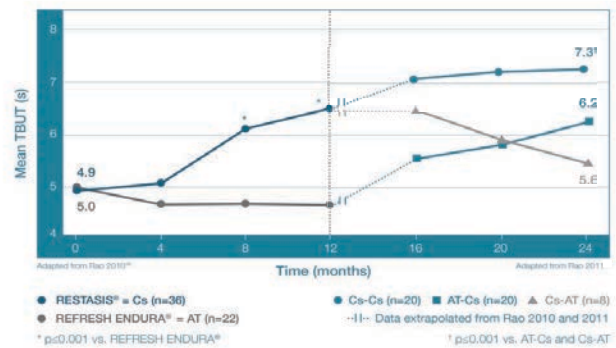
1. Data on file, Allergan, Inc.  
2. Kunert et al. *Arch Ophthalmol.* 2000.



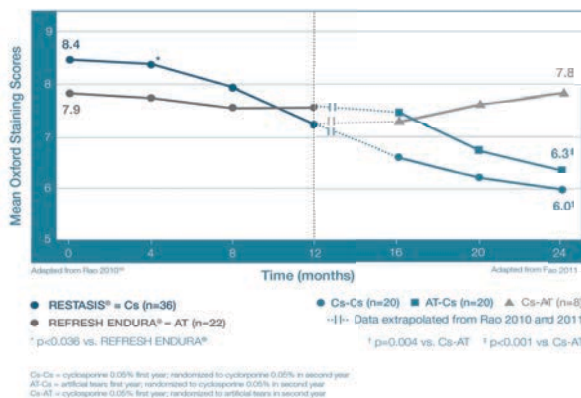
## Expectations During the First 6 Months of Therapy

Patients notice an onset of benefit      Further increase in tear production      Significant improvement in tear production      Improvements are maintained with continuation of therapy

1 month      3 months      6 months



Cs-Cs = cyclosporine 0.05% first year, randomized to cyclosporine 0.05% in second year  
AT-Cs = artificial tears first year, randomized to cyclosporine 0.05% in second year  
Cs-AT = cyclosporine 0.05% first year, randomized to artificial tears in second year



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## Topical Loteprednol Improves Patient Compliance and Restasis Efficacy

- Corticosteroids have been shown to improve tear production by controlling inflammation<sup>1</sup>
- Corticosteroids decreases irritation associated with use of Restasis by 75%<sup>2</sup>
- Recommend a mild corticosteroid such as loteprednol qid for two weeks and then bid for 2 weeks for patients who complain of irritation with Restasis, high maintenance patients, and patient who want more rapid relief

1 Marsh, Pflugfelder. *Ophthalmology* 1999  
2 Shepard, ASCRS 2005

## No Cyclosporine in Blood

- No detectable cyclosporine in blood of any RESTASIS® ophthalmic emulsion-treated patient<sup>1</sup>
- Toxicity associated with systemic or oral cyclosporine was not observed with cyclosporine 0.05% ophthalmic emulsion

Please see slides 6 & 7 for important safety information.

1. Small et al. *J Ocul Pharm Ther*. 2002.

## XiidRA (lifitegrast)

- Lifitegrast is a small molecule integrin antagonist that blocks binding of ICAM-1 to the integrin LFA-1 on the T cell surface, inhibiting T cell recruitment and activation associated with dry eye disease (DED)<sup>1</sup>
- The efficacy and safety of lifitegrast ophthalmic solution 5.0% in DED has previously been evaluated in 4 randomized controlled trials<sup>2-5</sup>
  - A Phase 2 study,<sup>2</sup> the Phase 3 trials OPUS-1<sup>3</sup> and OPUS-2,<sup>4</sup> and the long-term safety trial SONATA<sup>5</sup>
- In OPUS-2, there was a significant improvement compared with placebo in the co-primary symptom endpoint of eye dryness score (change from baseline to Day 84)<sup>4</sup>
- OPUS-3 was designed to replicate symptom improvement demonstrated in OPUS-2 - herein we report headline results of the OPUS-3 trial

1. Perez VL, et al. *The Ocular Surface*. 2016;14:207-15. 2. Semba CP, et al. *Am J Ophthalmol*. 2012;153:1050-1060. 3. Sheppard JD, et al. *Ophthalmology*. 2014;121:475-83. 4. Tauber J, et al. *Ophthalmology*. 2015;122:2423-31. 5. Donnerfeld ED, et al. *Cornea*. 2016 Apr 6. [Epub ahead of print]

## THE ADHESION MOLECULE ICAM-1 IS A KEY MEDIATOR OF INFLAMMATION IN DRY EYE DISEASE<sup>1,2</sup>



## ICAM-1 MAY BE OVEREXPRESSED IN CORNEAL AND CONJUNCTIVAL TISSUES IN DRY EYE DISEASE

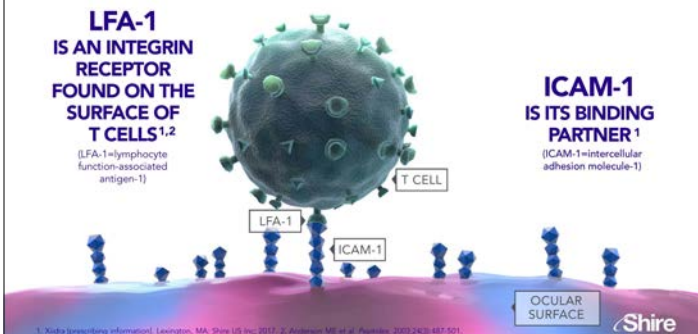


## LFA-1 IS AN INTEGRIN RECEPTOR FOUND ON THE SURFACE OF T CELLS<sup>1,2</sup>

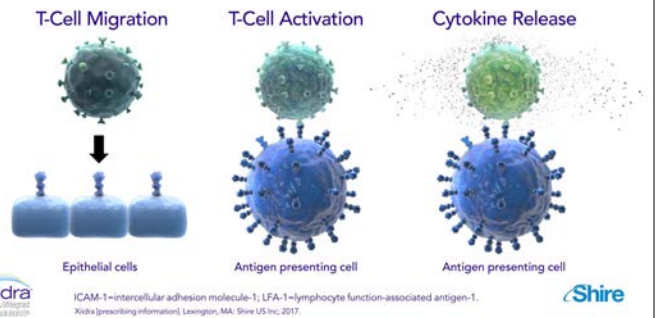
(LFA-1=lymphocyte function-associated antigen-1)

## ICAM-1 IS ITS BINDING PARTNER<sup>1</sup>

(ICAM-1=intercellular adhesion molecule-1)

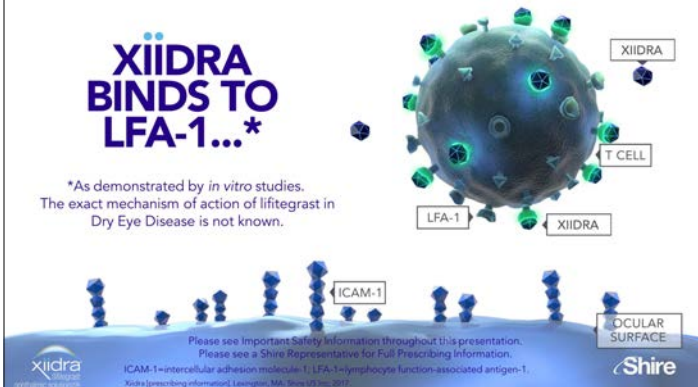


## ICAM-1 BINDING TO LFA-1 CAN RESULT IN:



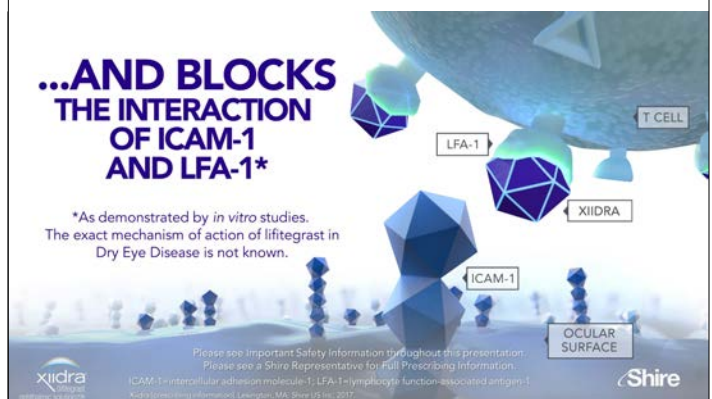
## XIIDRA BINDS TO LFA-1...\*

\*As demonstrated by *in vitro* studies. The exact mechanism of action of lifitegrast in Dry Eye Disease is not known.



## ...AND BLOCKS THE INTERACTION OF ICAM-1 AND LFA-1\*

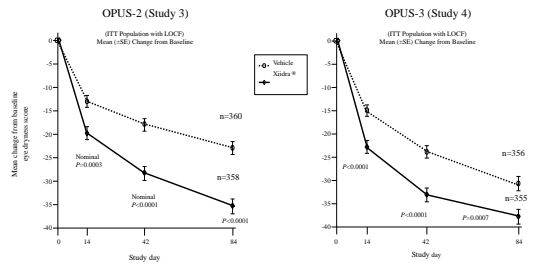
\*As demonstrated by *in vitro* studies. The exact mechanism of action of lifitegrast in Dry Eye Disease is not known.



## Improvements in the Symptoms of DED

In 2 of the 4 Studies, a Treatment Difference Favoring Xiidra® vs. Vehicle was Seen at Day 14

### Eye Dryness Score (EDS)\*: Mean Change from Baseline



- Change in EDS from baseline to day 84 was a co-primary endpoint
- The other co-primary endpoint (change in ICSS from baseline to day 84) was not met (P=0.6186)
- Change from baseline in EDS at days 14 and 42 were part of a post hoc analysis
- Change from baseline to day 84 in EDS was the primary endpoint
- Change from baseline to days 14 and 42 were key secondary endpoints

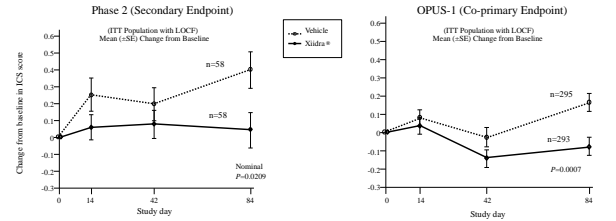
\*Eye dryness score using 0–100 VAS (0=no discomfort, 100=maximal discomfort).  
ICSS=inferior corneal staining score; ITT=intent to treat; LOCF=last observation carried forward.  
1. Tauber J et al. *Ophthalmology*. 2015;122:2423-2431. 2. Holland EJ et al. *Ophthalmology*. 2017;124:53-60.

Slide provided by Shire Pharma Canada ULC.

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## Improvements in the Signs of DED

### Inferior Corneal Staining Score (ICSS): Mean Change from Baseline at All Visits



- For Phase 2 ICSS change from baseline to day 84 was a secondary endpoint
- The primary endpoint of ICSS at day 84 was not met (P=0.1375)
- For OPUS-1 ICSS change from baseline to day 84 was a co-primary endpoint
- The other co-primary endpoint of visual-related subscale of a symptom functional scale change from baseline to day 84 was not met (P=0.7860)

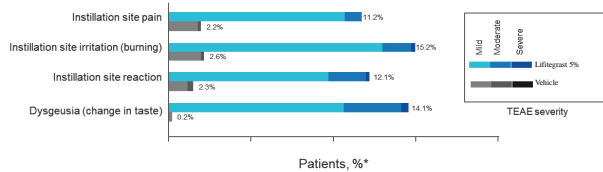
Corneal fluorescein staining scoring is as follows with 0.5 increments: 0=no staining; 1=few/rare punctate lesions; 2=discrete and countable lesions; 3=lesions too numerous to count, but not coalescent; 4=coalescent. Note: Results presented are from the study eye only.  
ITT=intent to treat; LOCF=last observation carried forward.  
1. Holland EJ et al. *Curr Med Res Opin*. 2016;32:1759-1765. 2. Data on File (SHP606-063). Phase 2 Efficacy; Shire US Inc. 3. Data on File (SHP606-064) OPUS-1 Efficacy; Shire US Inc.

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## Pooled Safety for Lifitegrast 12-Week Studies: Most Common TEAEs

### Incidence and severity of most common (≥5%) TEAEs



- 11 participants (Lifitegrast, 0.8% [9/1067] vs. vehicle, 0.2% [2/1066]) had serious ocular TEAEs
- 25 participants (Lifitegrast, 1.6% [17/1067] vs. vehicle, 0.8% [8/1066]) had serious nonocular TEAEs
- None were considered to be related to the investigational product

TEAE, treatment-emergent adverse event. \* Percentage values indicate the proportion of patients who reported each TEAE.  
Shire data on file (SPD606-ISS). Summary of Clinical Safety.

Slide provided by Shire Pharma Canada ULC.

# Options for Non-Responsive Patients

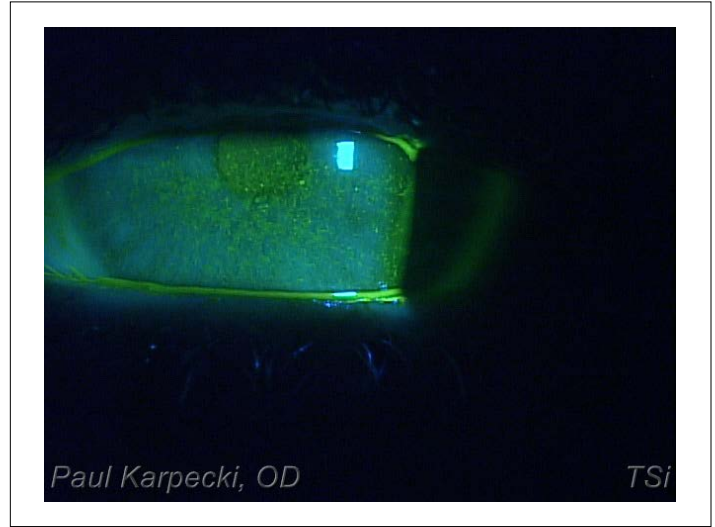
100



## Punctal Occlusion

- May wait on punctal occlusion if have:
  - Allergies
  - Severe MGD
  - Significant blepharitis
  - Inflammatory dry eye?
- Treat those conditions first then plug
- Ideal FIRST treatment option for:
  - Neurotrophic keratopathy
  - Post-LASIK dry eye
  - Lagophthalmos





## Normal tears

- pH = 7.4
- Osmolality = 298
- EGF (ng/ml) = 0.2-3.0
- TGF- $\beta$  (ng/ml) = 2-10
- Vitamin A (mg/ml) = 0.02
- Lysozyme (mg/ml) = 1.4
- Fibronectin (ug/ml) = 21

## Autologous Serum

- pH = 7.4
- Osmolality = 296
- EGF (ng/ml) = 0.5
- TGF- $\beta$  (ng/ml) = 6-33
- Vitamin A (mg/ml) = 46
- Lysozyme (mg/ml) = 6
- Fibronectin (ug/ml) = 205
- Hepatocyte GF, NGF, IGF-1, substance p, Complement, Fibroblast GF, c GRP, other Ig, etc.

## PROKERA®

- ❓ Class II medical device comprising of CRYOTEK™ amniotic membrane into a thermoplastic ring set
- ❓ Combines the functionality of a symblepharon ring with the biologic actions of CRYOTEK™ amniotic membrane to create a unique treatment option for corneal and limbal wound healing



## Ocular Surface Disorders

Diseases with Pre-existing Epithelial Defects to promote wound healing and reduce complications (debridement is optional)	Diseases without Epithelial Defects to prevent further damage and promote regeneration (no debridement/PTK)	Diseases with Unhealthy Epithelium or Basement Membrane to promote regeneration (after debridement/PTK)
<ul style="list-style-type: none"> <li>• neurotrophic persistent corneal epithelial defect</li> <li>• post-infectious recalcitrant corneal ulcers (e.g. herpetic, vernal, and bacterial)</li> <li>• non-healing epithelial defect after PRK/PTK</li> <li>• acute chemical/thermal burns</li> <li>• acute Stevens-Johnson syndrome/toxic epidermal necrolysis</li> </ul>	<ul style="list-style-type: none"> <li>• dry eye syndrome</li> <li>• superficial (punctate) keratitis</li> <li>• filamentary keratitis</li> <li>• radiation keratitis; whorl pattern indicative of limbal stem cell injury</li> <li>• exposure (Graves) keratopathy</li> </ul>	<ul style="list-style-type: none"> <li>• recurrent corneal erosion, EBMD</li> <li>• Salzmann's nodular degeneration</li> <li>• bullous keratopathy during/following DSEK</li> <li>• haze after PTK</li> <li>• partial limbal stem cell deficiency</li> <li>• corneal dystrophy (e.g., Reis-Bückler)</li> </ul>

## Refractive Indications

Before Surgery	After Surgery
<ul style="list-style-type: none"> <li>• to treat pre-existing ocular surface disorders and restore corneal integrity before refractive, corneal, or cataract surgery</li> </ul>	<ul style="list-style-type: none"> <li>• to enhance healing</li> <li>• to prevent post PRK haze</li> </ul>

## PROKERA® Insertion

- Set patient expectations! Inform the patient they may experience some initial stinging and foreign body sensation
- Apply topical anesthesia
- Rinse the PROKERA® with a sterile solution (saline, BSS etc...)
- Hold the upper eyelid
- Ask the patient to look down
- Insert the PROKERA® into the superior fornix, preferably using your fingers to hold the ring
- Slide the PROKERA® under the lower eyelid

## Tapesorrhaphy



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## PROKERA® Removal

- Topical Anesthetic
- Pull the lower eyelid
- Ask the patient to look up
- Karpecki ProKera Forceps through Bruder Healthcare grasp edge and pull out and down

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## SCLERAL LENSES

Scleral lenses are large diameter gas permeable lenses that rest beyond the limits of the cornea and extend onto the sclera.



## Dry Eye Disease Conclusion:

- Understand the ramifications of not treating DED
- Lid margin disease is the most common
- Hyperosmolarity is inherent in all forms/causes of DED
- O I B T
- Be aggressive in your treatment and then reduce medications
- The single largest medical eyecare opportunity now and over the next 3-4 decades

# Thank You

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[www.opthalmicresources.com](http://www.opthalmicresources.com)