NEW TECHNOLOGIES IN DRY EYE

Selina R. McGee, OD, FAAO
Marc Bloomenstein, OD, FAAO

FINANCIAL DISCLOSURES FOR SELINA R. MCGEE, OD, FAAO

Allergan-Speaker/Consultant

Alderya-Consultant

Avellino-Consultant

Bausch & Lomb-Speaker/Consultant

Bruder-Consultant

CynoSure-Speaker/Consultant

Dompe-Speaker/Consultant

Eyevance-Consultant

Horizon-Consultant

Lumenis-Speaker/Consultant

Ocuphire-Consultant

OptovueSpeaker/Consultant

Osmotica-Speaker/Consultant

All financial relationships have been mitigated.

FINANCIAL DISCLOSURES FOR MARC R BLOOMENSTEIN, OD, FAAO

Allergan-Speaker/Consultant

Avellino-Consultant

Azura-Consultant

Bausch & Lomb-Speaker/Consultant

Bruder-Consultant

Dompe-Speaker/Consultant

Eyevance-Consultant

Iveric-Consultant

LENZ-Consultant

Ocuphire-Consultant

OcuSOFT-Consultant

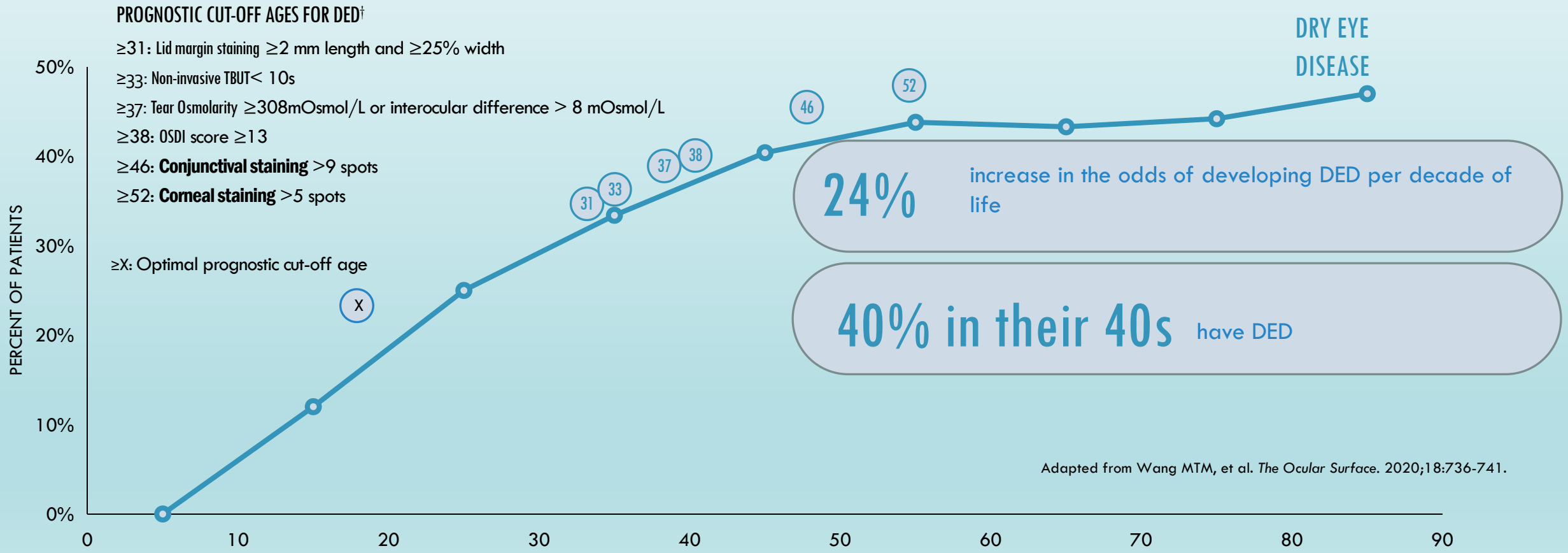
Olleyes-Consultant

Oyster Point-Speaker/Consultant

All financial relationships have been mitigated.

WHEN SHOULD WE TEST FOR DED?[1,2]

In a study of 1331 community residents*



24% increase in the odds of developing DED per decade of life

40% in their 40s have DED

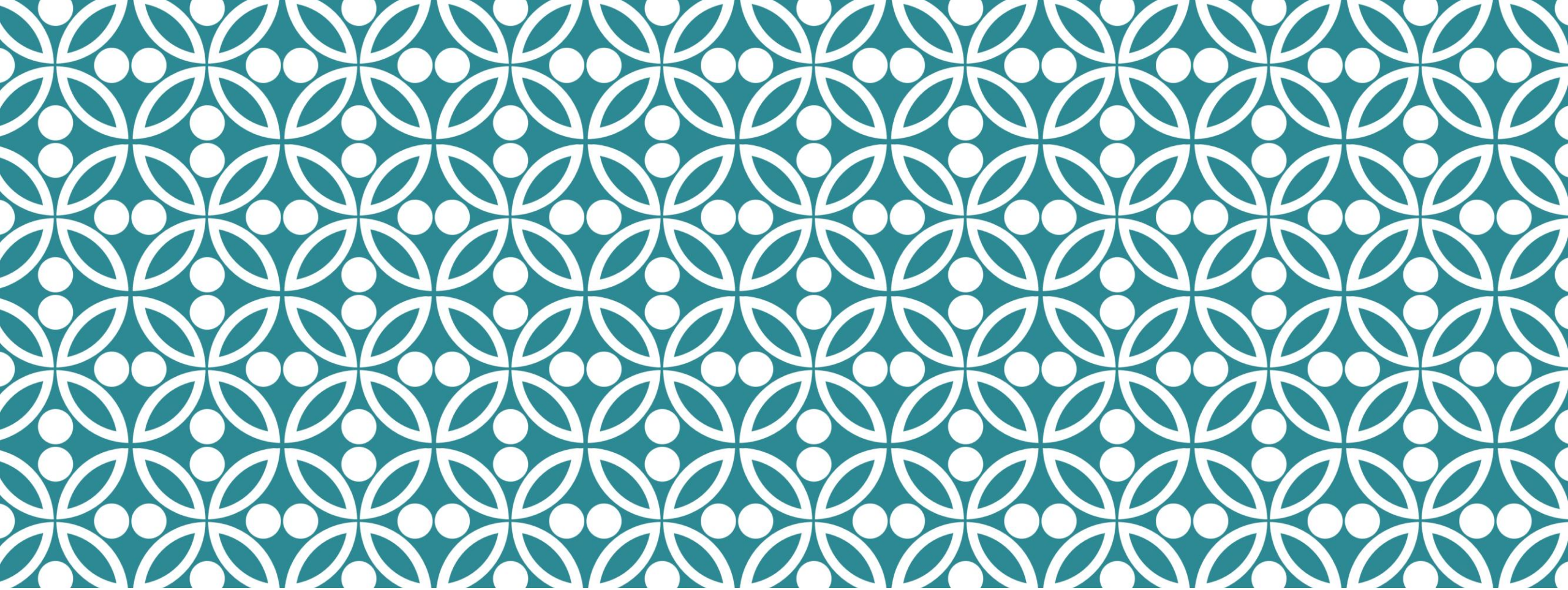
Adapted from Wang MTM, et al. *The Ocular Surface*. 2020;18:736-741.

DED = dry eye disease; TBUT = tear breakup time; OSDI = Ocular Surface Disease Index.

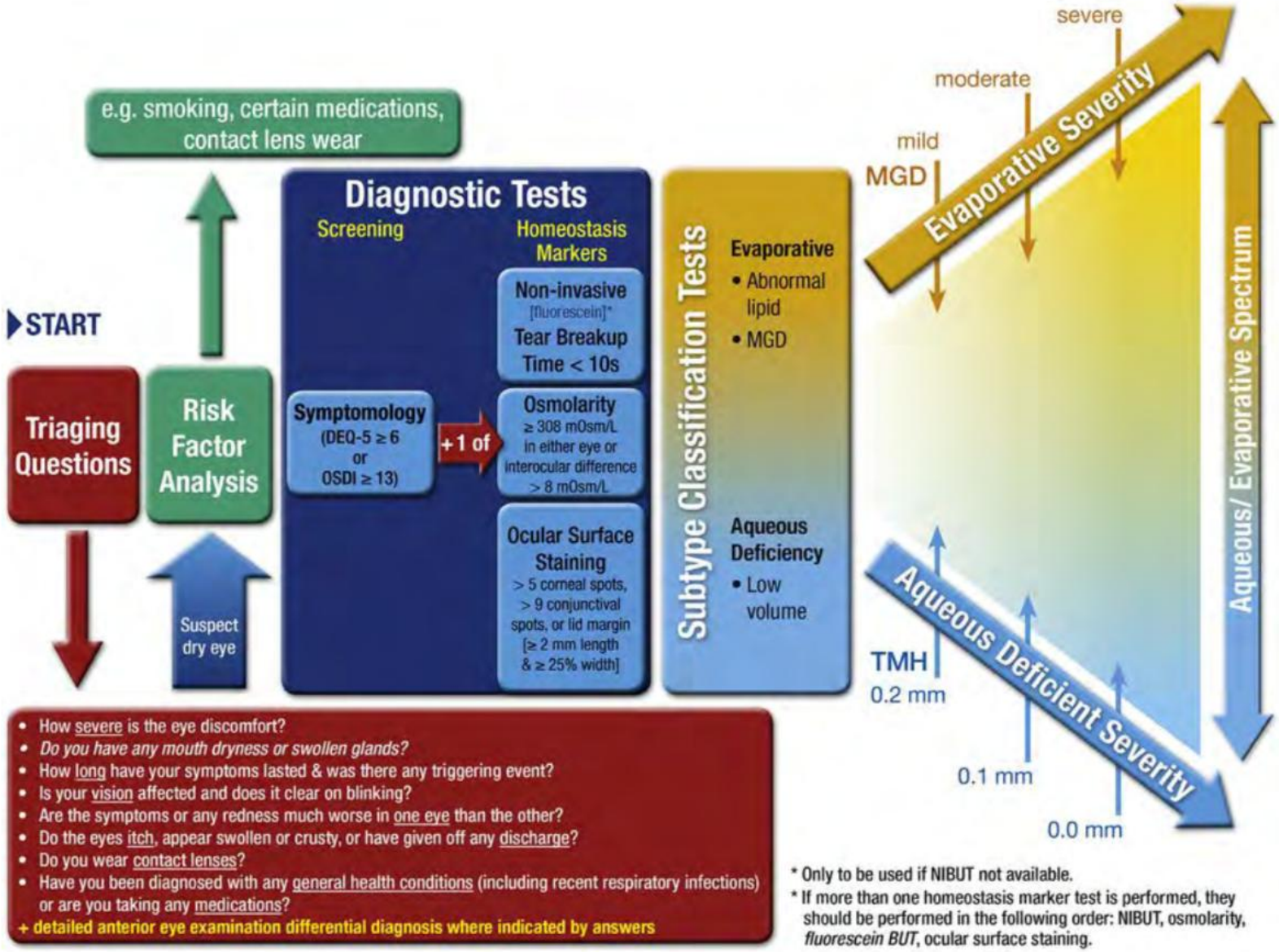
*Based on a prospective, registry-based, cross-sectional study of 1331 community residents (785 females, 546 males; mean ± SD age, 38 ± 19 years).

†$P<0.001$ vs healthy controls.

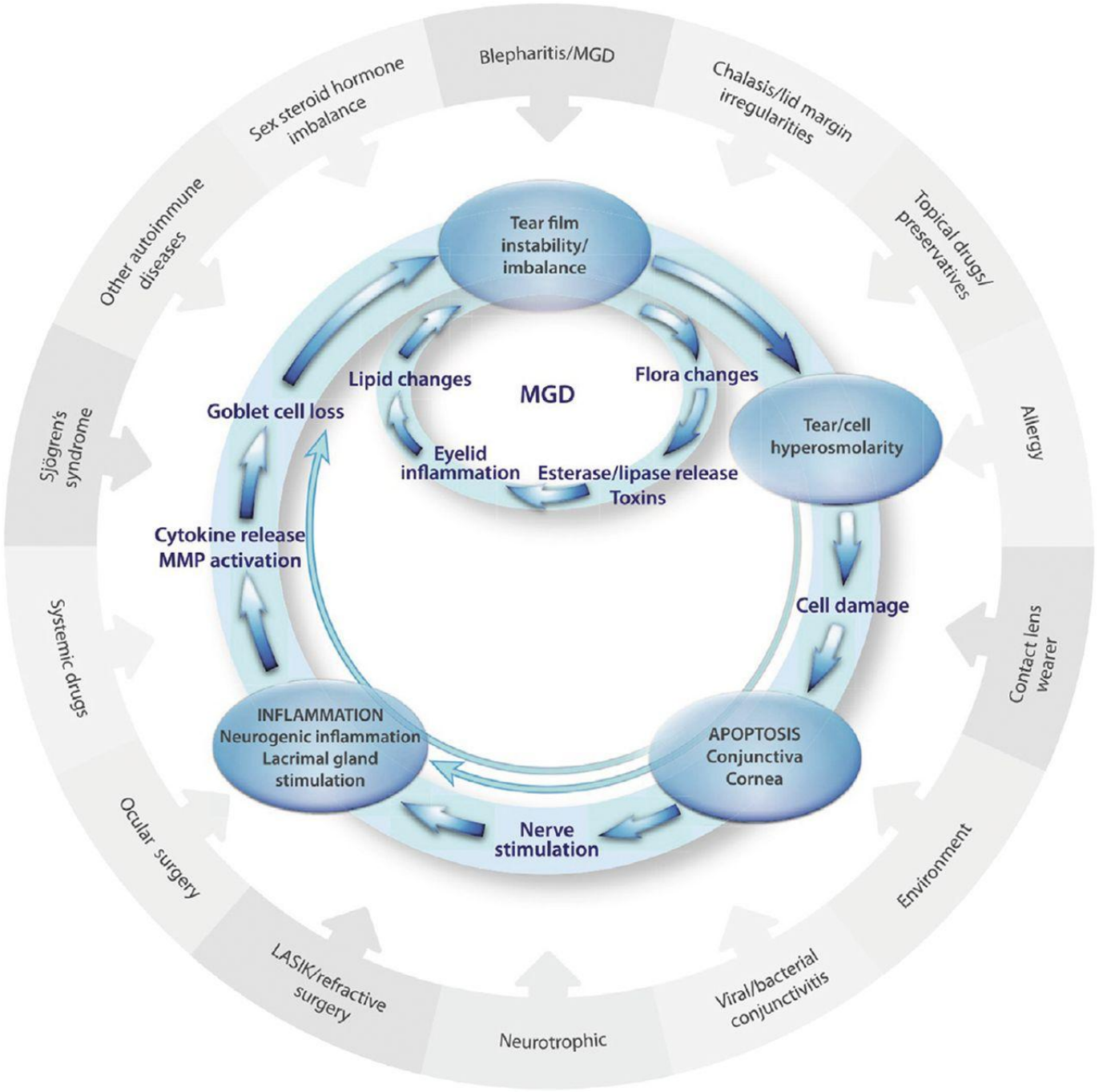
1. Wang MTM, et al. *The Ocular Surface*. 2020;18:736-741. 2. Wolffsohn JS, et al. *Ocul Surf*. 2017;15:539-574.



FIRST THINGS FIRST


e.g. smoking, certain medications, contact lens wear
START
Triaging Questions
Risk Factor Analysis
Suspect dry eye
Diagnostic Tests
Screening
Homeostasis Markers
Symptomology (DEQ-5 ≥ 6 or OSDI ≥ 13)
+1 of
Non-invasive [fluorescein]* Tear Breakup Time < 10s
Osmolarity ≥ 308 mOsm/L in either eye or interocular difference > 8 mOsm/L
Ocular Surface Staining > 5 corneal spots, > 9 conjunctival spots, or lid margin [≥ 2 mm length & ≥ 25% width]
Subtype Classification Tests
Evaporative
• Abnormal lipid
• MGD
Aqueous Deficiency
• Low volume
severe
moderate
mild
MGD
Evaporative Severity
Aqueous/ Evaporative Spectrum
TMH
0.2 mm
0.1 mm
0.0 mm
Aqueous Deficient Severity
• How severe is the eye discomfort?
• Do you have any mouth dryness or swollen glands?
• How long have your symptoms lasted & was there any triggering event?
• Is your vision affected and does it clear on blinking?
• Are the symptoms or any redness much worse in one eye than the other?
• Do the eyes itch, appear swollen or crusty, or have given off any discharge?
• Do you wear contact lenses?
• Have you been diagnosed with any general health conditions (including recent respiratory infections) or are you taking any medications?
+ detailed anterior eye examination differential diagnosis where indicated by answers
* Only to be used if NIBUT not available.
* If more than one homeostasis marker test is performed, they should be performed in the following order: NIBUT, osmolarity, fluorescein BUT, ocular surface staining.

Desiccating Stress



SYMPTOMS

OSDI or OSDI-6 (Ocular Surface Disease Index-*Allergan*)

SPEED (Standardized Patient Evaluation of Eye Dryness and Ocular Surface Disease Index-*TearScience*

DEQ-5 (The Dry Eye Questionnaire-*Chalmers et al*)

POINT OF CARE TESTING

Tear Osmolarity-This diagnostic tool measures the concentration of tears, or osmolarity. In reviewed literature Osmolarity readings above 308 mOsms/L or an inter-eye difference of >8 mOsm/L are an indication of mild osmolarity and loss of homeostasis.

MMP-9 (Metalloproteinase-9) is a nonspecific inflammatory marker that can be present in patients who have dry eye disease.

OSMOLARITY

Normal

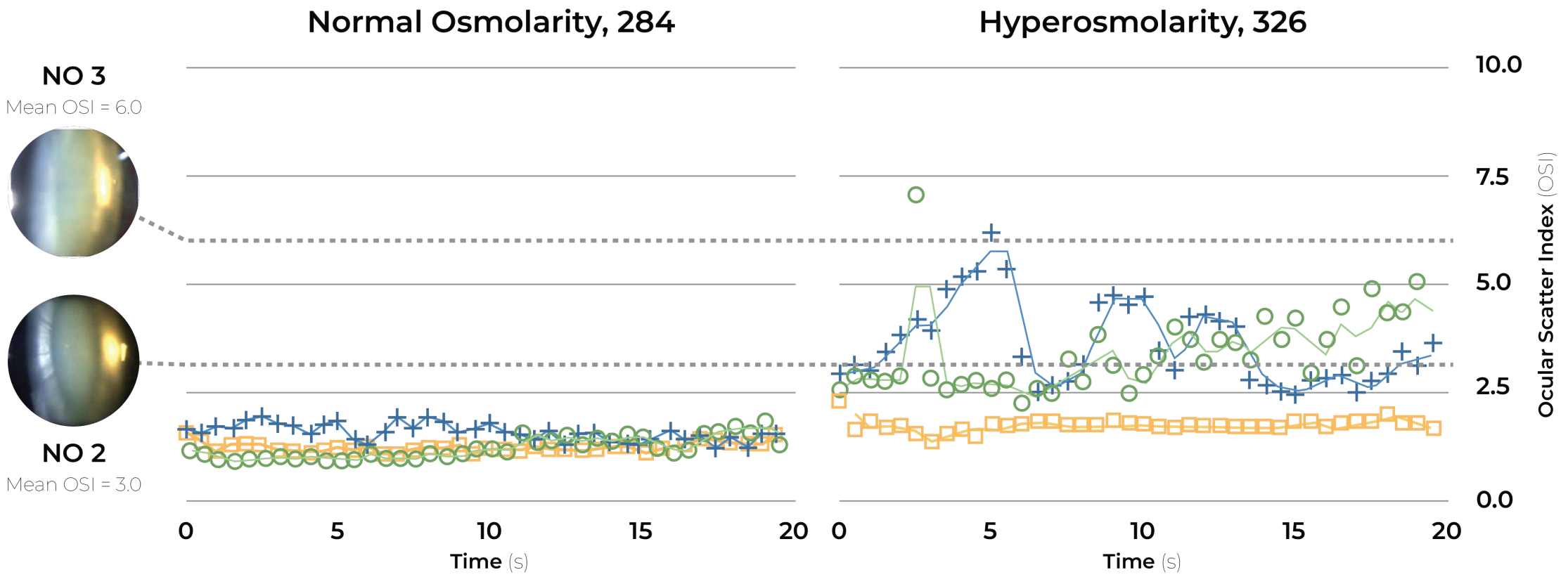
- Between 280-295 mOsm/L[1]

Hyperosmolar

- Central pathophysiologic mechanism for all forms of DED
- Causes inflammation and apoptosis & reduces the ability of mucins to lubricate
- Leads to a breakdown of homeostatic control causing tear film instability
- 308 mOsm/L is a highly sensitive cut-off point that delineates a normal from a mild/moderate dry eye population. 316 mOsm/L for moderate/severe.
- Inter-eye difference=Hallmark of DED (>8 mOsms/L between eyes)
- Unstable tear film causes inter-eye differences

[1]Potvin, Richard et al, Clinical Ophthalmology 2015:9 2039–2047

HYPEROSMOLARITY CREATES LIGHT SCATTER



Artal P. PLoS One. 2011 Feb 4;6(2):e16823;
Nochez Y, et al. Invest. Ophthalmol. Vis. Sci. 2011;52(14):3754

KURSITE ET AL. CONCLUSIONS

"Patients with higher tear osmolarity can more often have lower uncorrected VA, unexpected refractive error, and lower satisfaction with the overall surgical result compared with the control group."

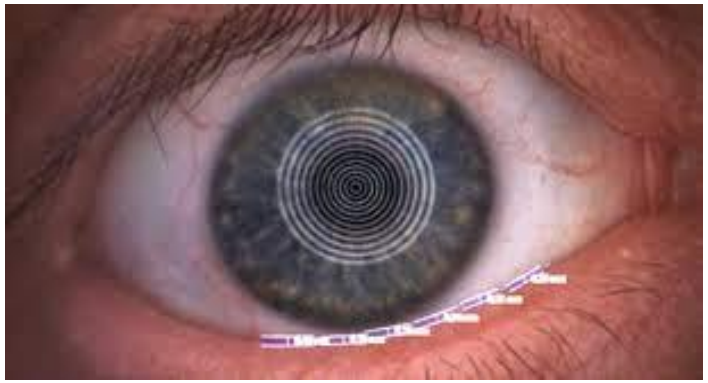
"In this study, we chose tear osmolarity as the main diagnostic factor of DED for several reasons. First, in our opinion, it is a more objective method than other tests, because it does not include the subjective component of the doctor."

"However, the level of dissatisfaction does not always correlate with the surgical outcome of the residual refractive error and visual outcome. Not all patients dissatisfied with the surgery had a significant refractive error; however, most patients had increased tear osmolarity with dry eye symptoms."

"Based on this research, TearLab can be used as an objective, convenient, and easily performed alternative to other DED tests in patients before cataract surgery. This could help in better identification of patients who are at a higher risk for unexpected refractive error."

Kursite A, Laganovska G. J.ophthalmol. (Ukraine). 2023 Apr. 25;(2):11-5

TEAR QUANTITY



Tear Meniscus Height-This information tells us how much tear volume is present. The normal average is 0.2mm[6].

Lissamine Green-This vital dye stains devitalized cells of the conjunctiva. Symptoms and conjunctival staining characterize Level 1 dry eye disease[1]. No corneal signs will be present. This dye is a must have otherwise you will miss Level 1 severity and may put off treatment until the patient progresses to Level 2 or 3.

NaFl (Sodium Fluoroscein)-This vital dye stains corneal breaks and devitalized cells of the cornea. Certainly an important indicator in establishing the health of the cornea.

Measuring TBUT or Tear Break Up Time gives important information about how long the tear film stays in place or the stability of the tears.

Phenol Red is a patient preferred Shirmer's test. It measures tear volume in 15 seconds with much less reflex tearing than Shirmer's. Nice to have when an objective measure of tear volume is needed for those truly aqueous deficient patients.

ARTIFICIAL TEARS

Artificial tears aim to supplement tears to bathe the corneal surface as a means of providing **short-term relief**. They are available in **low-viscosity** and **high-viscosity** gels and ointments.

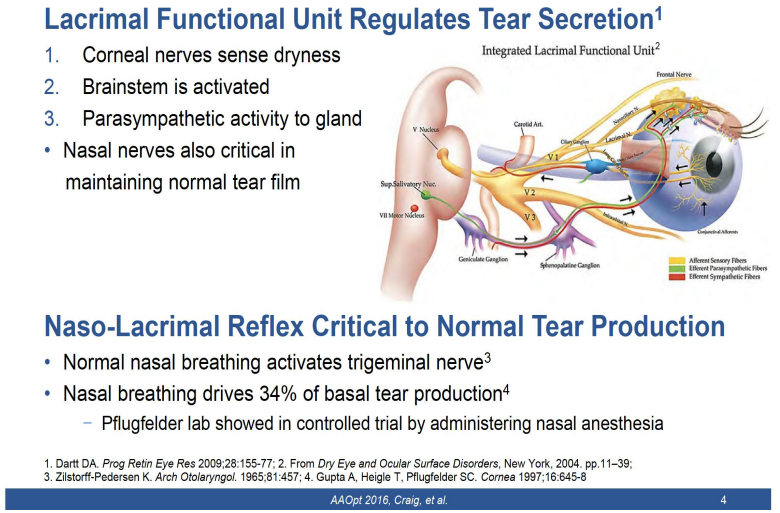
Ideal patients are already being treated and need a complementary component to their regimen. Both aqueous deficient and evaporative patients are candidates.

Preservative-free formulations are generally prescribed to preclude the patient from additional discomfort due to the long-term use of artificial tears that contain preservatives that can place the patient at risk for corneal toxicity.

- HA
- Trehalose
- Preservative Free

Watch outs are using tears instead of uncovering what is really going on at/with the ocular surface. Don't use tears as a primary therapeutic approach, only use to support the main act of therapy. Recommend specific preservative free drops and carry them in the office, as the artificial tear aisle at the box stores is quite overwhelming for patients.

NEUROSTIMULATION

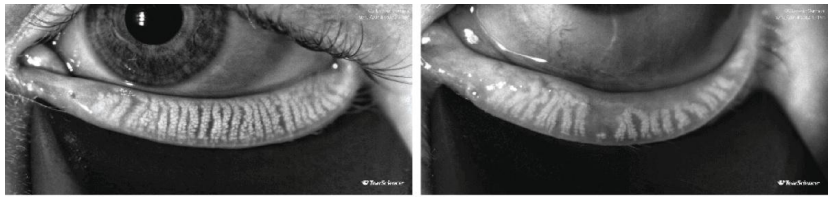


Neurostimulation results in endogenous tear production, giving patients a way to manage their DED and gain relief immediately. Specifically, the device targets the trigeminal nerve, which controls the lacrimal functional unit (LFU). This is important because the LFU is responsible for the lacrimal gland and accessory glands, as well as goblet cells degranulating and meibomian gland function.

Patients that desire a drop-free, drug-free therapy are great candidates, as well as anyone using artificial tears. There is nothing artificial about the tears the body produces on it's own. Since the technology stimulates ALL glands both aqueous-deficient and evaporative benefit.

Utilize the in-office demo of the unit to create a wow effect and allow patients to experience it for themselves prior to purchase.

LID STRUCTURE AND FUNCTION



Normal Eyelid (meibomian) Glands:
Meibomian glands produce the oils needed for a healthy tear film

Gland (oil) Dropout:
MGD occurs when the meibomian glands become blocked. If this blockage is left untreated the glands will drop out entirely.

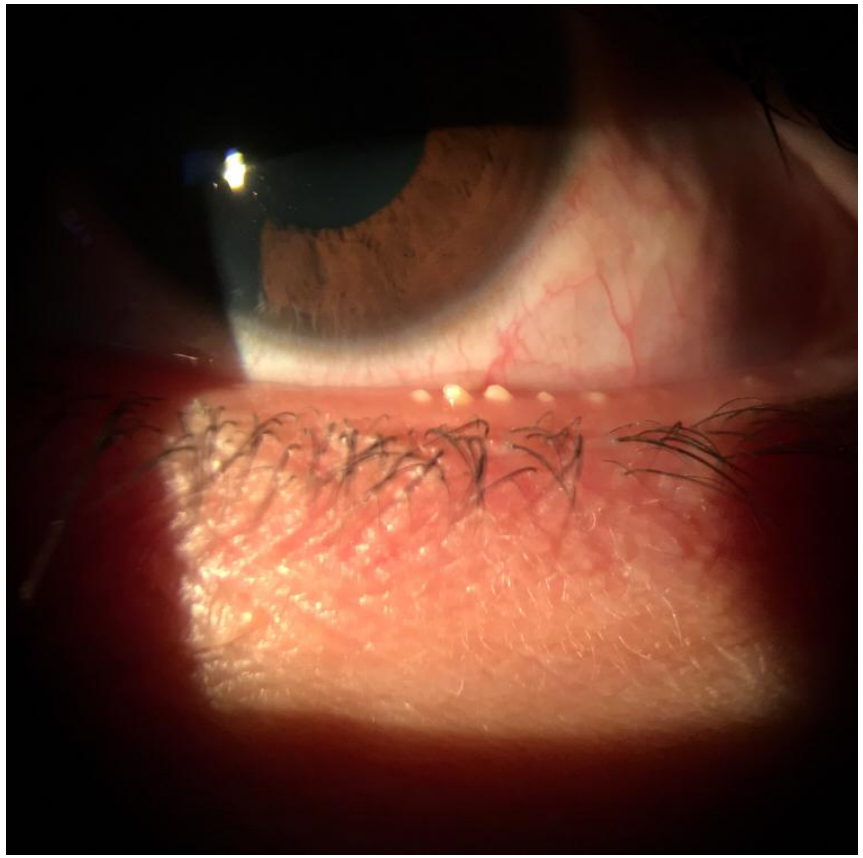
Lid morphology with the slit-lamp is the basic diagnostic test here.

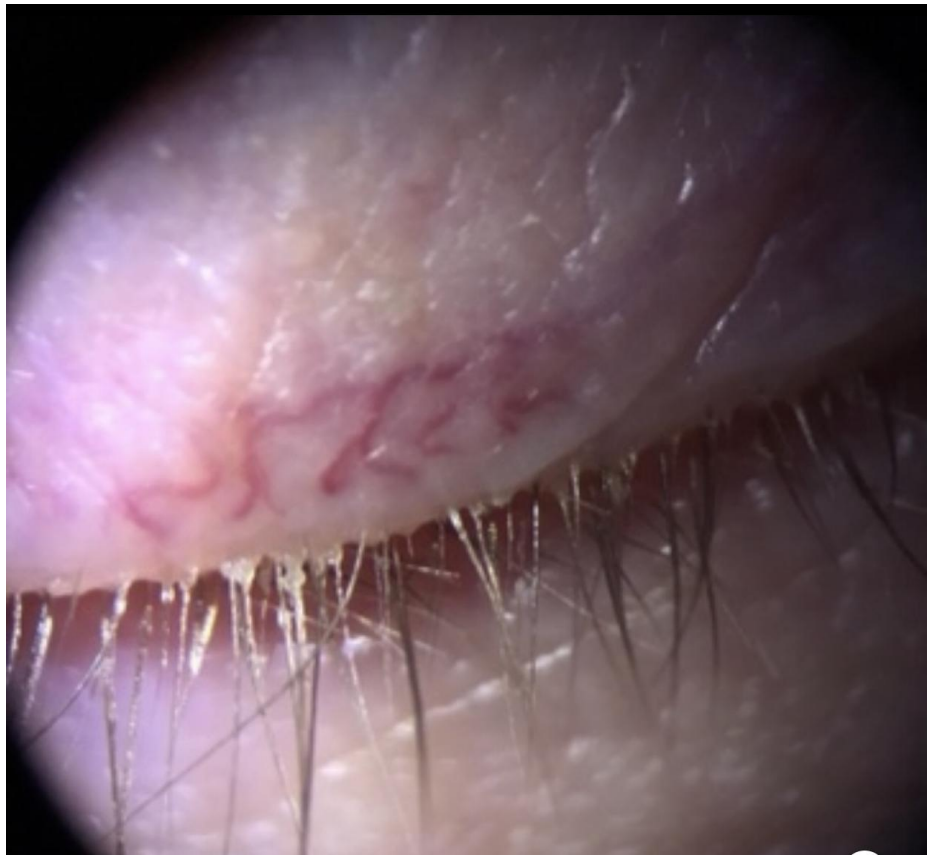
Expression of meibomian glands is important to know the quality of meibum and quantity that are functioning. Diagnostic tools: cotton swab, fingertip, or meibomian gland evaluator[7].

Blink rate-Identifying patients that have a partial blink, full blink, and how many times they blink is important to evaluate. Proper blinking facilitates meibomian gland functionanality[8].

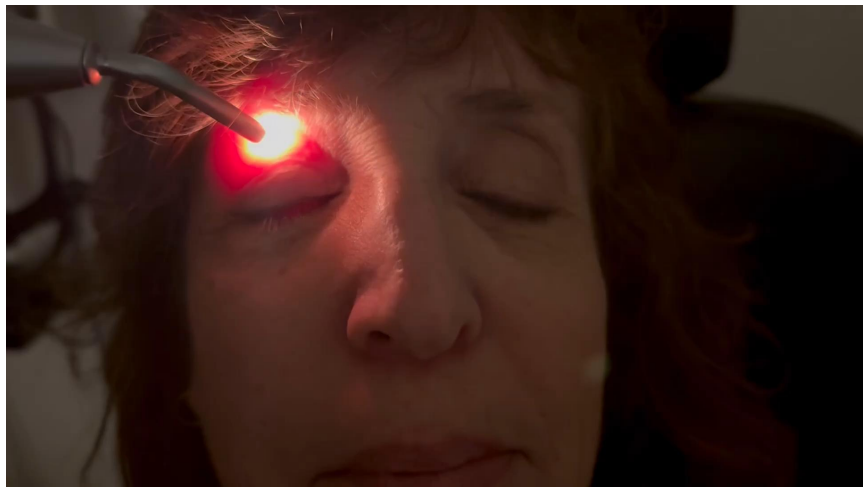
Meibography-This diagnostic tool images the integrity of the meibomian glands using infared cameras. This can be a powerful tool to help patients understand how these glands can impact their disease process. Certainly a nice to have when you have adopted all the must have's we've talked about. Several instruments are on the market that offer this with other important diagnostic testing with algorithms like non-invasive tear break up time, tear meniscus, blink rate, corneal topography, and videography. I've listed some for your perusal here.

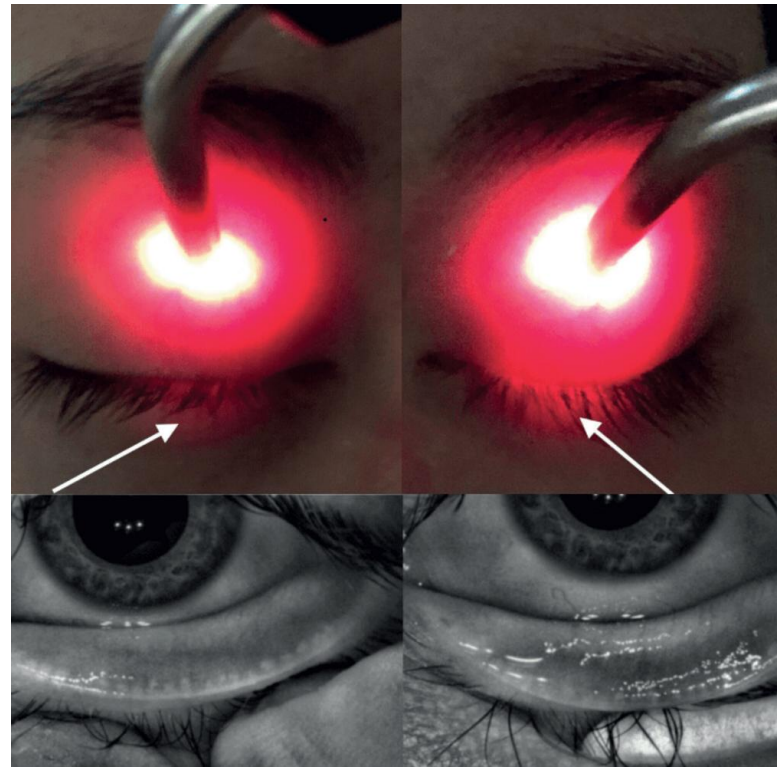
OCULAR ROSACEA



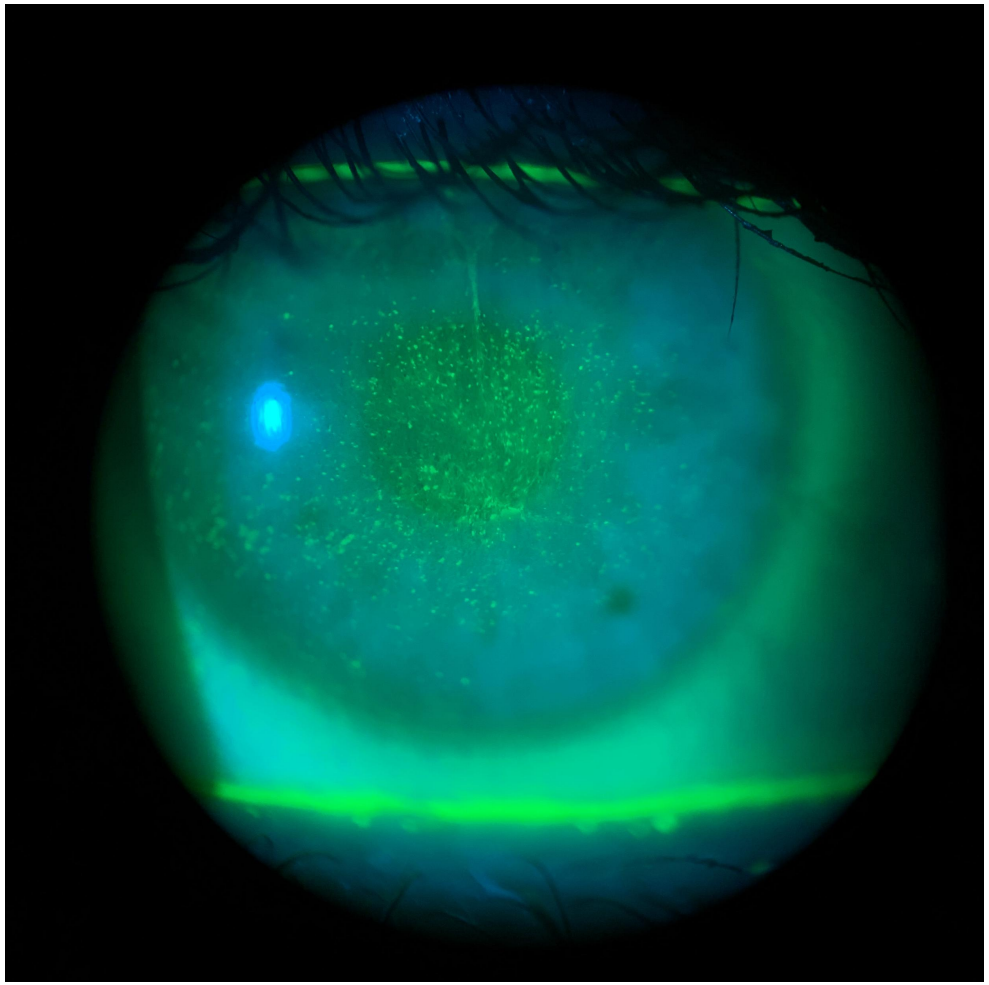


LID EVALUATION





PATIENT ASSESSMENT



DIAGNOSIS

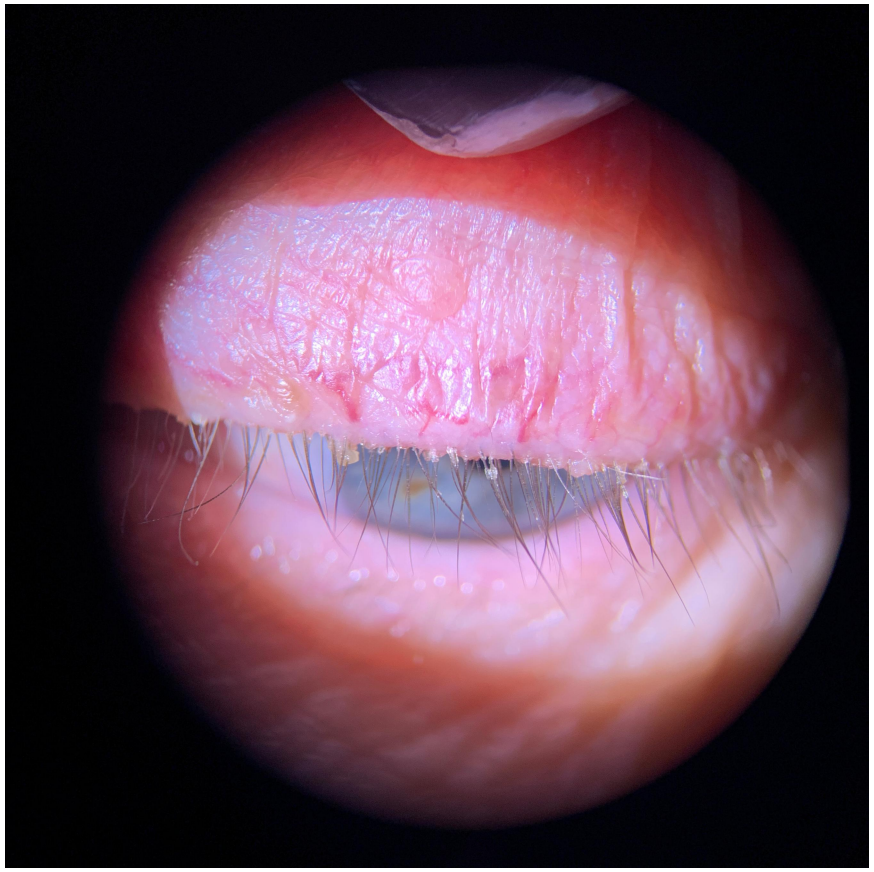
Ocular Rosacea- H10.829

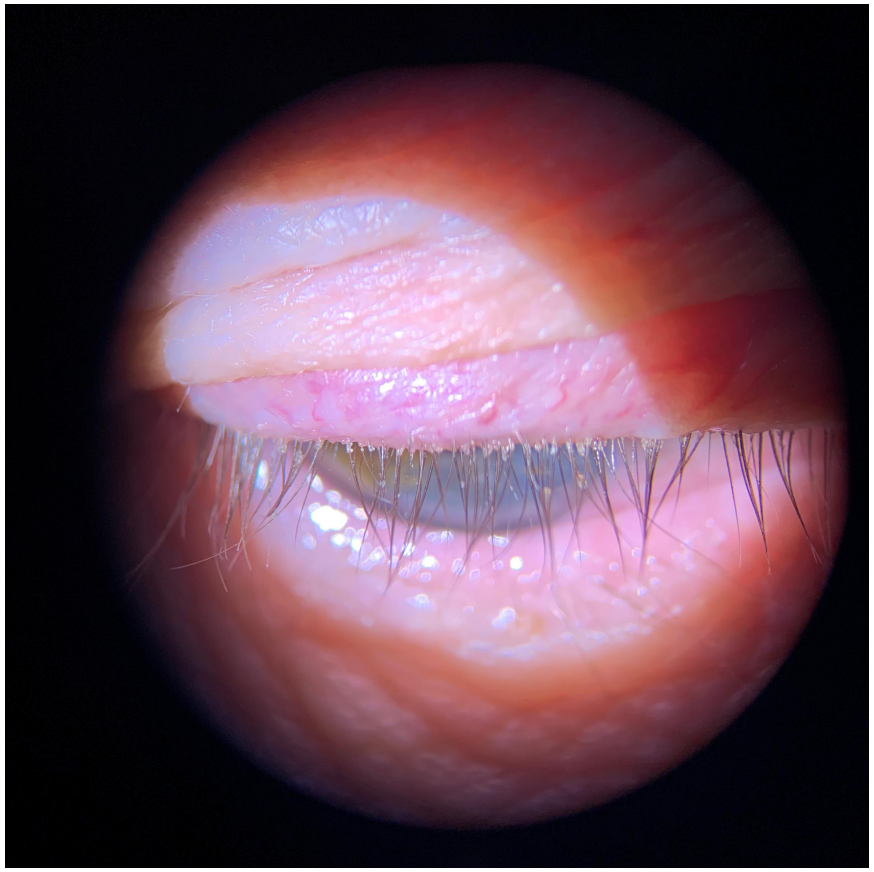
Demodex Blepharitis-B88.0

MGD-H02.889-

Dry Eye H04.123

K. Sicca H16.233

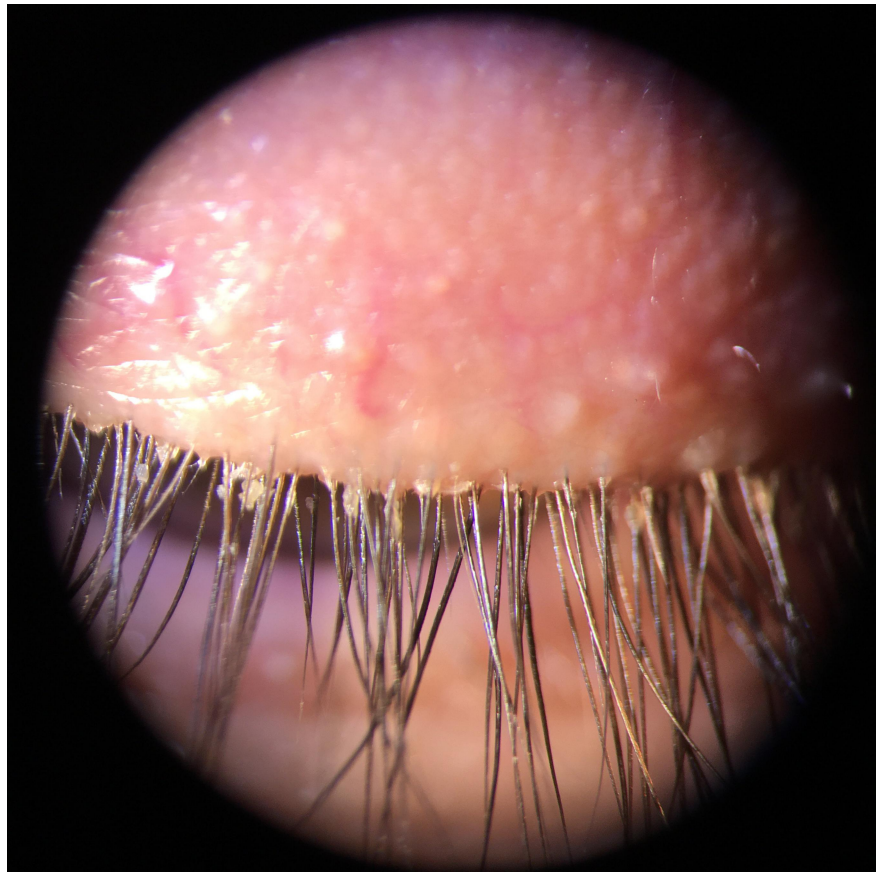


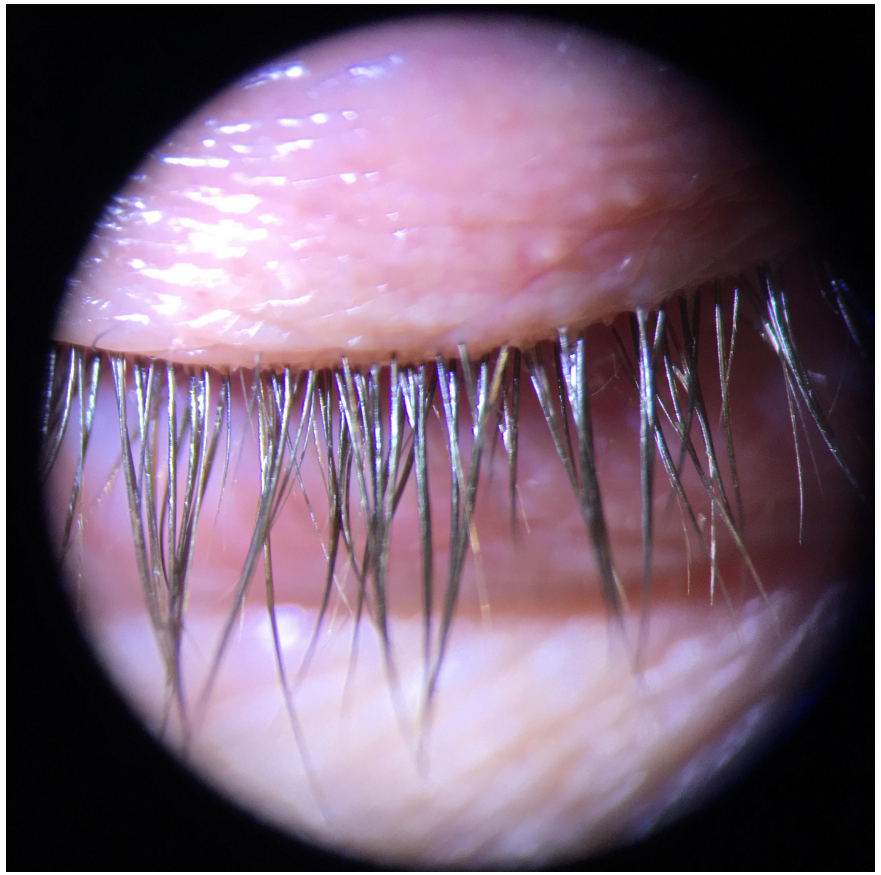


WHAT'S YOUR LID AND LASH STRATEGY?

Do you have one?

I SEE





DEMODEX BLEPHARITIS | A PERVASIVE AND DAMAGING EYE DISEASE

- **Blepharitis is the inflammation of the eyelids** causing irritation and redness

- **69% of blepharitis cases are due to *Demodex* infestation leading to *Demodex* blepharitis[1-4]**
  - *Demodex* mites are implicated in other diseases of the lid and lid margin, including blepharitis and meibomian gland dysfunction[2,3]
  - *Demodex* mites are associated with acne vulgaris, folliculitis, rosacea, seborrheic dermatitis, perioral and scalp hair loss, and basal cell carcinoma[1,3]
- ***Demodex folliculorum* and *Demodex brevis*** are the only 2 species found in humans[5]
  - The life cycle of the *Demodex* mite is approximately 14 to 18 days from the egg to the larval stage followed by the adult stage[5]
  - The life span of the mite is limited outside the living body; direct contact is required for transinfestation[5]

D. folliculorum

0.3-0.4 mm length
Colonizes the base of the lash follicle[2]

D. brevis

0.1 mm length
Colonizes the meibomian gland[2]

1. MAYO CLINIC. ACCESSED JUNE 28, 2022. HTTPS://WWW.MAYOCLINIC.ORG/DISEASES-CONDITIONS/BLEPHARITIS/SYMPTOMS-CAUSES/SYC-20370141 **2.** ZHANG AC ET AL. *OPHTHALMIC PHYSIOL OPT.* 2020;40(4):389-432. **3.** FROMSTEIN SR ET AL. *CLIN OPTOM (AUCKL).* 2018;10:57-63. **4.** TRATTLER W ET AL. *CLIN OPHTHALMOL.* 2022;16:1153-1164. **5.** LITWIN D ET AL. *IRAN J PARASITOL.* 2017;12(1):12-21.

DEMODEX BLEPHARITIS | MECHANISMS OF DISEASE

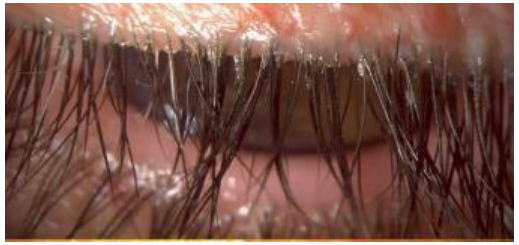
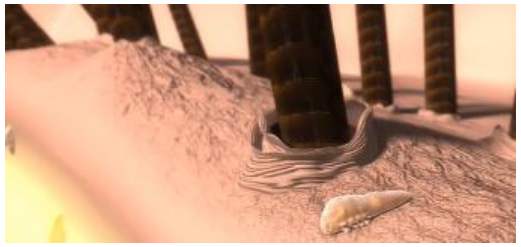


Image courtesy of Laura M. Periman, MD, used with permission.[1]

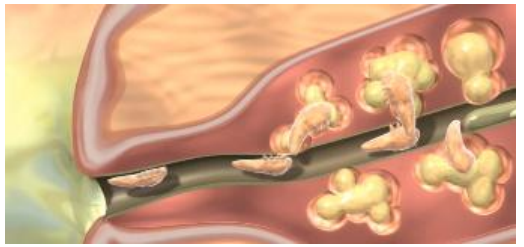
MECHANICAL

- Lash distension occurs as *Demodex* mites attach to follicles[2-4]
- *Demodex* mites deposit debris and digestive enzymes, causing further irritation to the eyelid margin[4,5]



BACTERIAL

- *Demodex* mites can contribute to blepharitis by carrying bacteria on their exterior surface that may elicit immune responses[3,6-7]

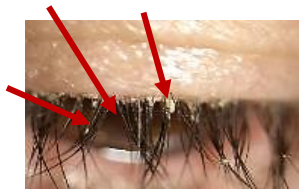


CHEMICAL

- *Demodex* mites have been associated with altered meibum composition[8]
- Debris from *Demodex* mites can potentially lead to chronic inflammation and degeneration of conjunctival tissue[9]

1. DATA ON FILE. IMAGES COURTESY OF LAURA M. PERIMAN, MD; 2022. **2.** ZHANG AC ET AL. *OPHTHALMIC PHYSIOL OPT.* 2020;40(4):389-432. **3.** LIU J ET AL. *CURR OPIN ALLERGY CLIN IMMUNOL.* 2010;10(5):505-510. **4.** FROMSTEIN SR ET AL. *CLIN OPTOM (AUCKL).* 2018;10:57-63. **5.** GAO YY ET AL. *INVEST OPHTHALMOL VIS SCI.* 2005;46(9):3089-3094. **6.** ZHU M ET AL. *FRONT MICROBIOL.* 2018;9:1719. **7.** LI J ET AL. *OPHTHALMOLOGY.* 2010;117(5):870-877.

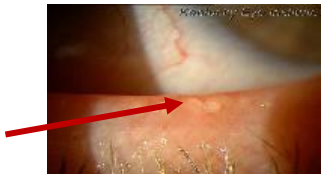
CLINICAL MANIFESTATIONS OF *DEMODEX* BLEPHARITIS



Images courtesy of Paul Karpecki, OD, used with permission.

Disorders of Eyelashes[1,2]

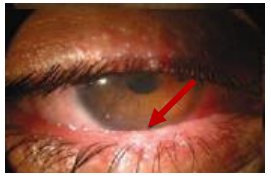
Infestation of the lash follicles can result in collarettes and may lead to malalignment, trichiasis, and madarosis



Images courtesy of Paul Karpecki, OD, used with permission.

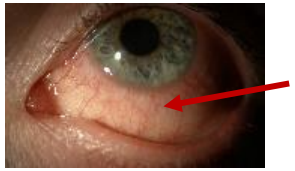
Meibomian Gland Dysfunction[1,2]

Blockage leads to filling, swelling, and many enlarged glands (cysts) or infection. Chalazia are common granulomatous responses



Lid Margin Inflammation[1,2]

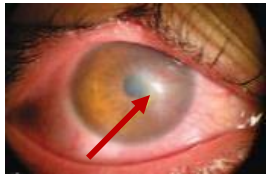
Severe lid margin inflammation can be caused by mechanical blockage and a delayed host immune hypersensitivity reaction



Images courtesy of Elise Kramer, OD, used with permission.

Conjunctival Inflammation[1,2]

Without proper hygiene, lid margin inflammation may spread over to the conjunctiva producing a condition known as blepharoconjunctivitis



Corneal Manifestations[1,2]

D. brevis is commonly associated with inflammation that spreads to the cornea, causing sight-threatening corneal lesions, superficial vascularization, marginal infiltrates, phlyctenule-like lesions, opacity, and/or nodular scars

1. Liu J et al. *Curr Opin Allergy Clin Immunol*. 2010;10(5):505-510. **2.** Cheng AM et al. *Curr Opin Ophthalmol*. 2015;26(4):295-300.

COLLARETTES ARE A PATHOGNOMONIC SIGN OF *DEMODEX* BLEPHARITIS

Collarettes, or cylindrical dandruff, are composed of mite waste products and eggs[1]

- Collarettes are translucent, solidified exudative excretions that form a cylindrical collar that cuffs around the base of the eyelash follicle[1-3]
- Collarettes are displaced along the shaft of the lash as it grows, and they are also displaced due to bacterial overgrowth[4]
- Collarettes are composed of regurgitated undigested mite waste combined with epithelial cells, keratin, mite eggs, and secreted proteases and lipases that cause irritation[3]
- **100%** of patients with collarettes have *Demodex* blepharitis[2,5]

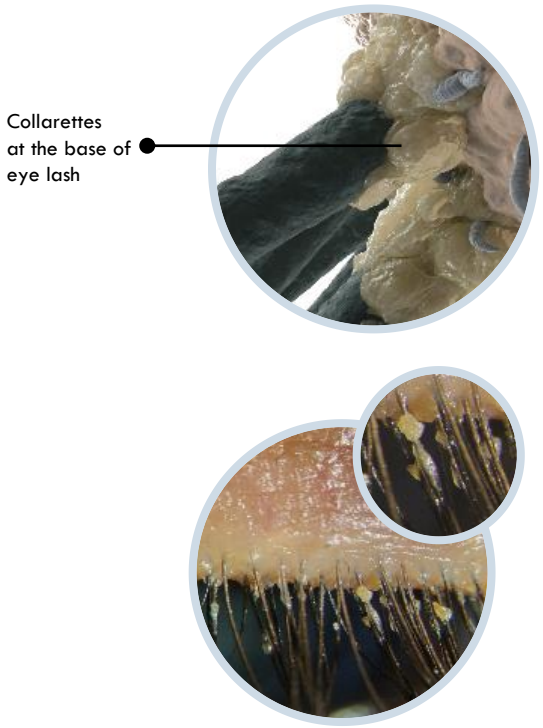


Image courtesy of Inder Paul Singh, MD, used with permission.[6]

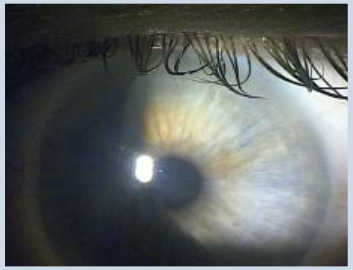
1. Zhang AC et al. *Ophthalmic Physiol Opt*. 2020;40(4):389-432. **2.** Gao YY et al. *Invest Ophthalmol Vis Sci*. 2005;46(9):3089-3094. **3.** Fromstein SR et al. *Clin Optom (Auckl)*. 2018;10:57-63.
4. Bitton E et al. *Clinical and Experimental Optometry*. 2021;104(3);285-294. **5.** Kasetsuwan N et al. *Int J Ophthalmol*. 2017;10(1):122-127. **6.** Data on file. Image courtesy of Inder Paul Singh, MD; 2022.

DEMODEX BLEPHARITIS CAN BE DIAGNOSED DURING SLIT LAMP EXAMINATION

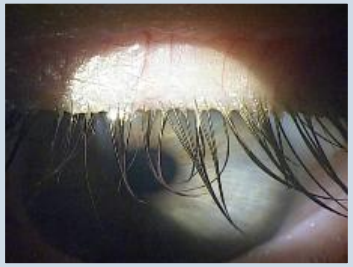
Collarettes are hardened excretions around the base of the eyelashes visible during slit lamp examination[1-3]

Collarettes can be identified when the base of lashes on the upper lid are exposed as the patient **looks down**[4]

Collarettes may be missed during a slit lamp exam even with a lid lift if a patient is looking straight ahead[4]



Patient looking straight ahead



Patient looking down, **exposing base of lashes and collarettes**

Images courtesy of Elizabeth Yeu, MD, used with permission.[5]

Asking a patient to look down during a slit lamp examination can reveal diffuse collarettes and misdirected or missing lashes that are strong signs of *Demodex* blepharitis

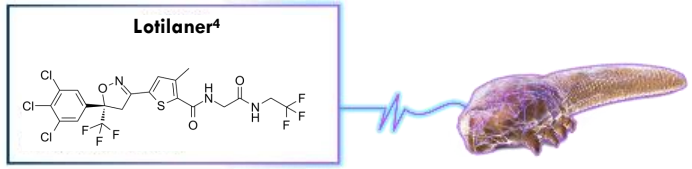
1. Zhang AC et al. *Ophthalmic Physiol Opt*. 2020;40(4):389-432. **2.** Gao YY et al. *Invest Ophthalmol Vis Sci*. 2005;46(9):3089-3094. **3.** Fromstein SR et al. *Clin Optom (Auckl)*. 2018;10:57-63. **4.** Cataract & Refractive Surgery Today. Accessed June 29, 2022. https://crstoday.com/articles/oct-2021/impact-of-demodex-blepharitis-and-importance-of-early-detection **5.** Data on file. Image courtesy of Elizabeth Yeu, MD; 2022.

MECHANISM OF ACTION OF TP-03 (Lotilaner Ophthalmic Solution 0.25%)

TP-03 : Lotilaner ophthalmic solution 0.25%
(Tarsus Pharmaceuticals, Inc.)

- Lotilaner functions as a noncompetitive antagonist of mite and arachnid GABA-gated chloride channels[1,2]
- Directly paralyzes the mite nervous system through parasite-specific GABA inhibition, leading to death[1,2]
- The lipophilic nature of the drop suggests its ability to flow into the oily sebum of the lash follicle where the mites reside[3]

FDA APPROVE 07.25.2023



Product form[5]
Preserved (sorbate) multidose eye drop solution in bottle

Dosing[5]
Twice daily for 6 weeks

FDA, Food and Drug Administration; GABA, gamma aminobutyric acid.
1. Dailymed Credelio. Accessed June 28, 2022. https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=427f2ebc-ce24-452b-bbb3-43d4ef8b63b0 **2.** Gonzalez-Salinas R et al. *J Ophthalmol*. 2021:3862684. **3.** LianBio. Accessed June 28, 2022. https://www.globenewswire.com/news-release/2022/05/03/2434549/0/en/LianBio-Partner-Tarsus-Pharmaceuticals-Announces-Positive-Topline-Data-from-Second-Pivotal-Trial-of-TP-03-for-the-Treatment-of-Demodex-Blepharitis.html
4. ChemSrc Lotilaner. Accessed June 28, 2022. https://www.chemsrc.com/en/cas/1369852-71-0_1262257.html **5.** Yeu E et al. *Cornea*. 2022; In Press.

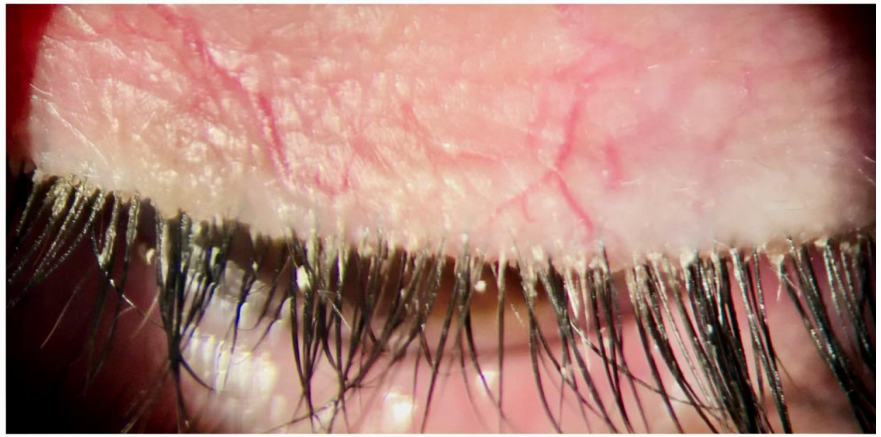
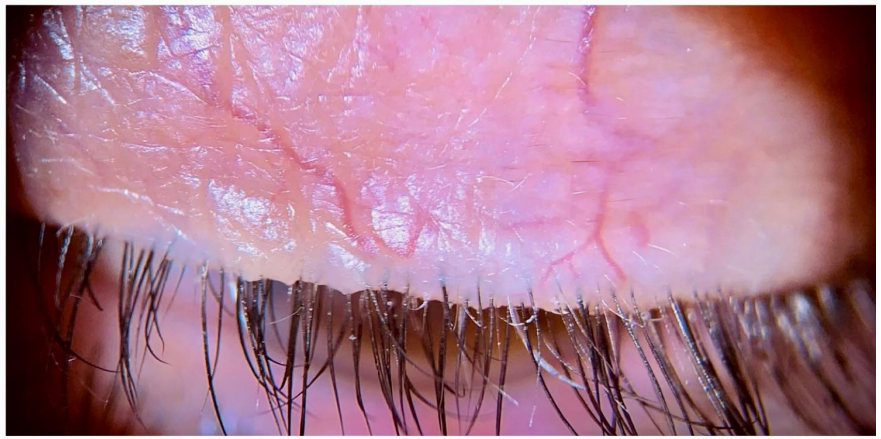
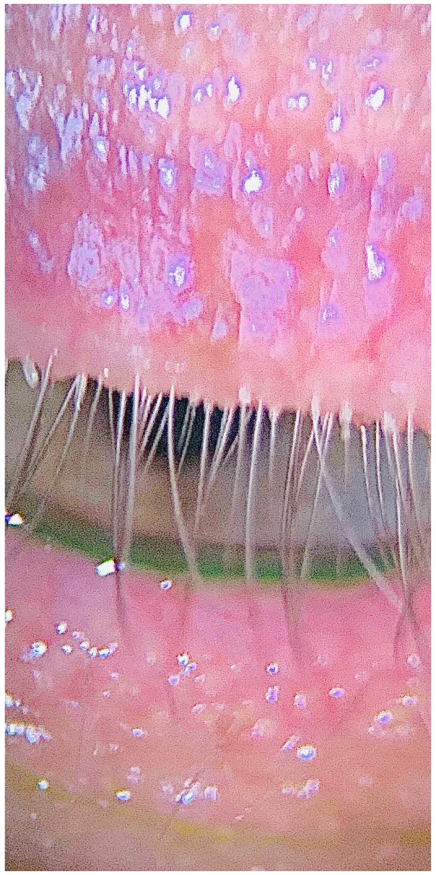
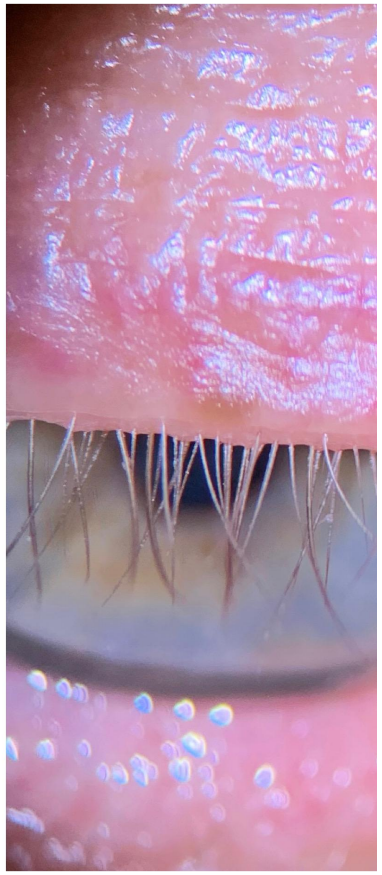
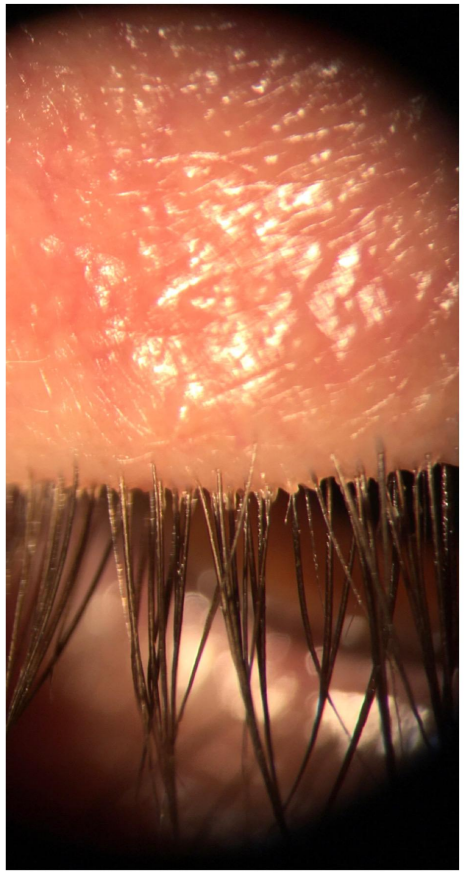
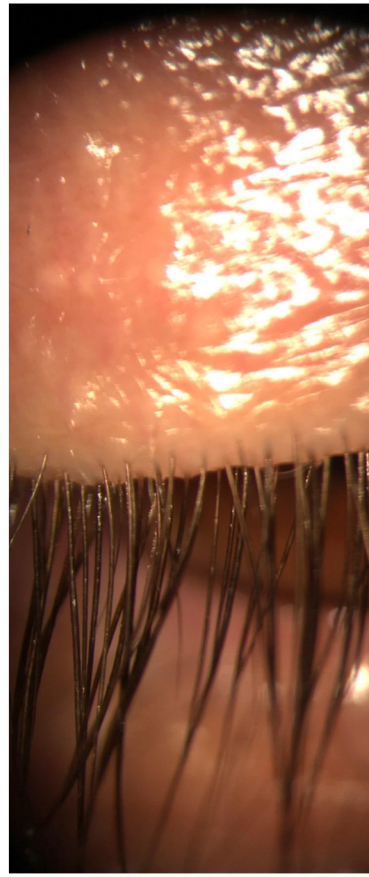
DEMODEX BLEPHARITIS KEY TAKEAWAYS

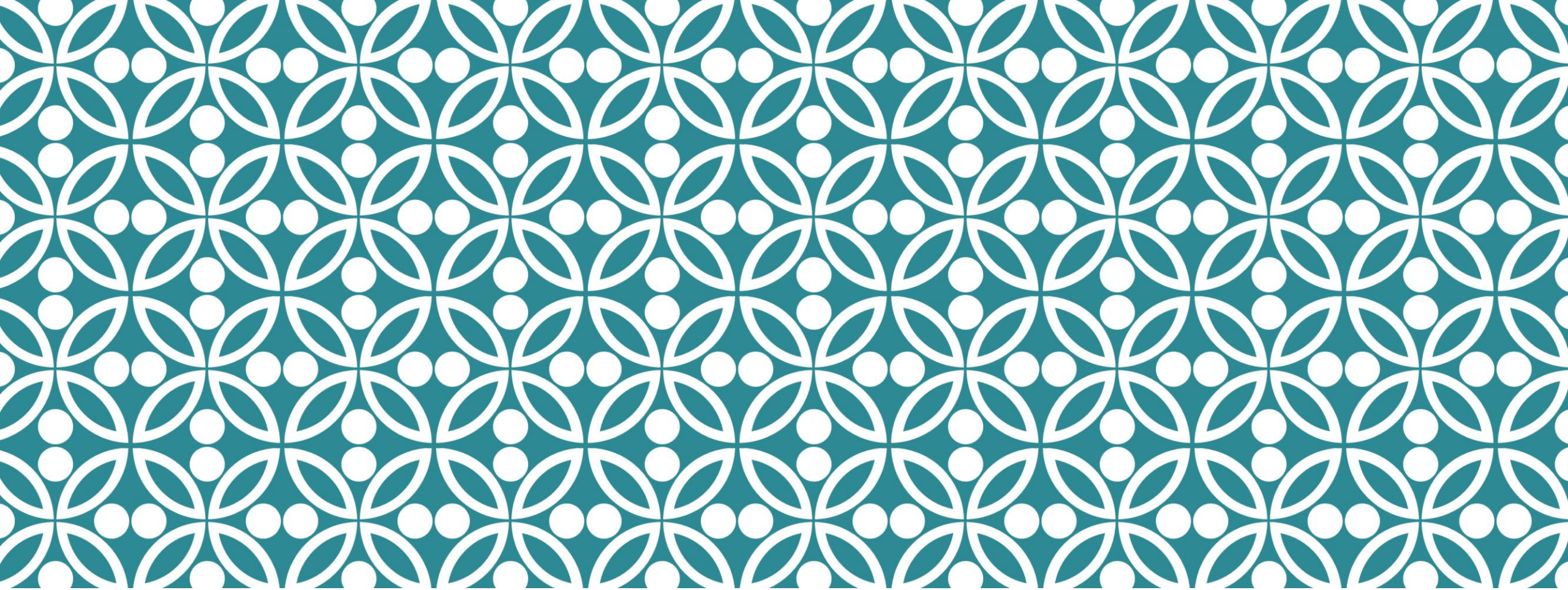
- *Demodex* mites may be present in 69% of all blepharitis cases
- It is a disease that is often misdiagnosed and underdiagnosed
- *Demodex* blepharitis is prevalent in cataract, dry eye, and contact lens patients and has a substantial impact on the daily lives of patients, including psychosocial and clinical burden
- Eradicating the root cause (the *Demodex* mite) rather than just addressing symptoms is crucial
- Current options for managing *Demodex* blepharitis do not eradicate mites and are poorly tolerated
- Confidently and definitively diagnose *Demodex* blepharitis by looking for collarettes
- Look for collarettes by having every patient **look down during a slit lamp examination**
- Provide patient education and understand their current struggles with comfort and lid hygiene compliance
- TP-03, if approved, may be an emerging safe and effective treatment for *Demodex* blepharitis, and has demonstrated patient comfort and shown effective collarette cure, mite eradication and erythema cure in 2 pivotal studies

WHAT CAN WE ALL DO?

- Look for collarettes during every slit lamp exam – collarettes are the pathognomonic sign of *Demodex* blepharitis
- Share images of collarettes with your peers to equip them with knowledge to properly diagnose *Demodex* blepharitis

Image courtesy of Inder Paul Singh, MD, used with permission.[4]

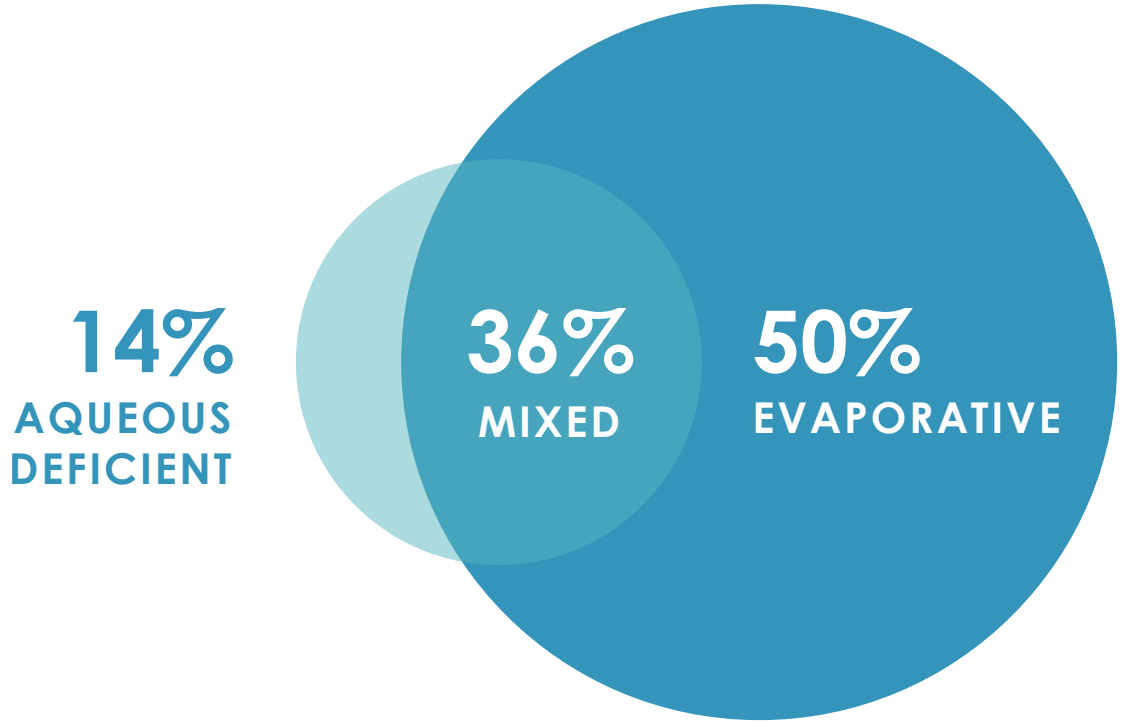









WHAT ABOUT EVAPORATION?

THE MAJORITY OF DED HAS AN EVAPORATIVE ETIOLOGY

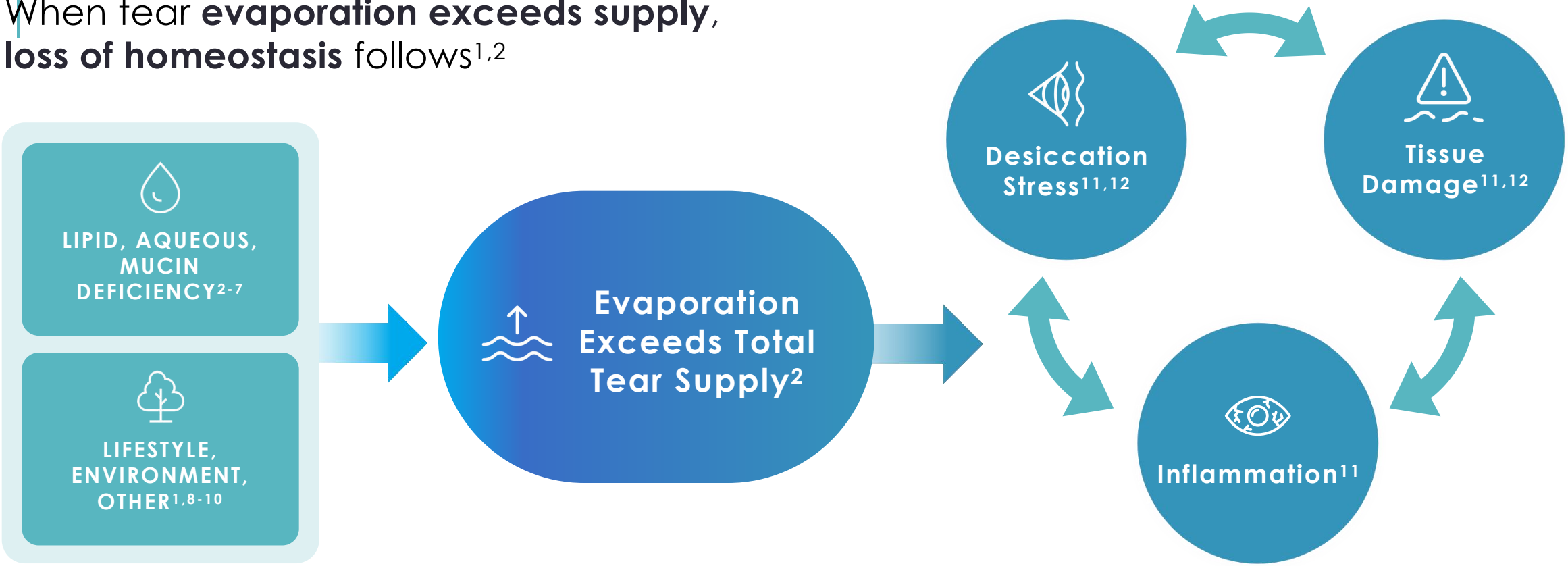
MGD, the major contributor to the evaporative etiology of DED, is present in ≥86% of cases[1-6]



1. Badian RA. *Sci Rep.* 2021;11:23412. **2.** Lemp MA, et al. *Cornea*. 2012;31:472-478. **3.** Messmer EM. *Dtsch Arztebl Int*. 2015;112(5):71-81. **4.** Craig JP, et al. *Ocul Surf.* 2017;15:802-812. **5.** Craig JP, et al. *Ocul Surf*. 2017;15:276-283. **6.** Rabensteiner DF, et al. *Acta Ophthalmol.* 2018;96:e707-e711. | **DED**, dry eye disease; **MGD**, meibomian gland dysfunction

EXCESSIVE EVAPORATION TRIGGERS A VICIOUS CYCLE

When tear **evaporation exceeds supply**, **loss of homeostasis** follows[1,2]



1. Bron AJ, et al. *Ocul Surf*. 2017;15(3):438-510. **2.** McMonnies CW. *Eye Vis (Lond)*. 2020;7:6. **3.** Covita A, et al. *Invest Ophthalmol Vis Sci.* 2019;60(9):6793. **4.** Arita R, et al. *Am J Ophthalmol*. 2016;169:125-137. **5.** Alshammeri S, et al. *Clin Exp Optom*. 2020;103(4):469-473. **6.** Kawashima M, et al. *Adv Ther*. 2017;34(3):732-743. **7.** Tsubota K, et al. *Ocul Surf*. 2017;15:65-76. **8.** Wolffsohn JS, et al. *Ocul Surf*. 2021;21:58-63. **9.** Wang MTM, et al. *Cont Lens Anterior Eye*. 2021;44(6):101409. **10.** Al-Mohtaseb Z, et al. *Clin Ophthalmol.* 2021;15:3811-3820. **11.** Pflugfelder SC, et al. *Ophthalmology*. 2017;124(11S):S4-S13. **12.** Zhang R, et al. *Ocul Surf*. 2021;21:145-159. | **DED**, dry eye disease

PERFLUOROHEXYLOCTANE IS THE FIRST & ONLY PRESCRIPTION EYE DROP FOR DED THAT DIRECTLY TARGETS TEAR EVAPORATION

Until now, no FDA-approved prescription eye drop has specifically **targeted evaporation**[1]

Existing prescription approaches

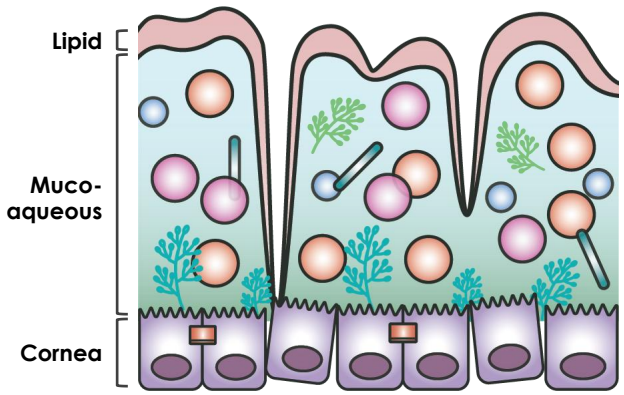
- Immunomodulators
- Tear stimulators
- Anti-inflammatory agents

1. White DE, et al. *Clin Ophthalmol*. 2019;13:2285-2292. | **DED**, dry eye disease; **FDA**, food and drug administration

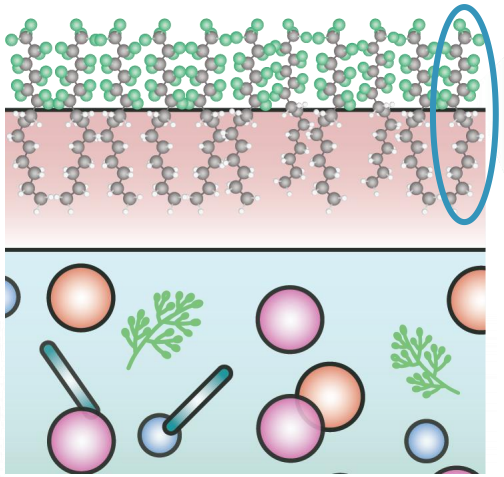
FORMS A MONOLAYER AT THE AIR-LIQUID INTERFACE

EXPECTED TO REDUCE TEAR EVAPORATION

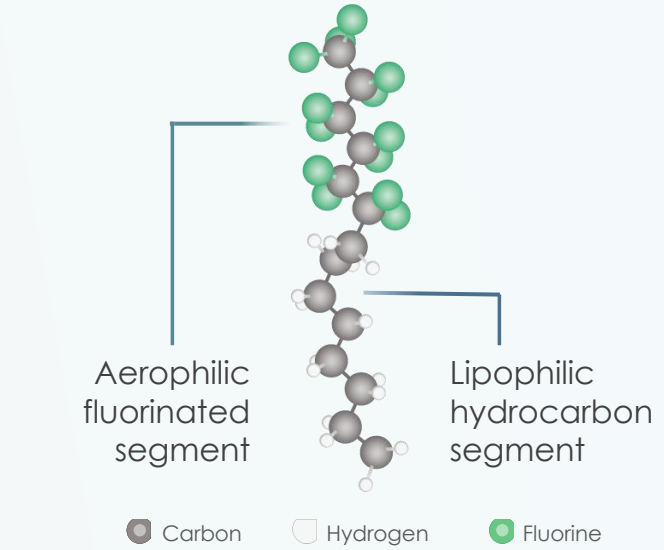
Unstable Tear Film



Tear Film with MIEBO



Perfluorohexyloctane



The exact mechanism of action of Perfluorexlyoctane in DED is not known.

1. Cwiklik L. *Biochimica et Biophysica Acta*. 2016;1858:2421-2430. **2.** Willcox MDP, et al. *Ocul Surf*. 2017;15(3):366-403. **3.** Liu X, et al. *Bull Che Soc Jpn*. 2018;91(5):846-857. **4.** Broniatowski M, et al. *J Phys Chem B*. 2004;108:13403-11.

PERFLUOROHEXYLOCTANE DEMONSTRATED CONSISTENT RESULTS ACROSS CLINICAL TRIALS

Two phase 3 studies evaluating the safety and efficacy of MIEBO for the treatment of DED

- Multicenter
- Randomized
- Double-masked

100% of participants had DED and clinical signs of MGD

GOBI N=597 | MOJAVE N=620

Participants randomized 1:1 to MIEBO or saline (control) QID

614 participants received MIEBO

Outcomes

- Change from baseline in total corneal fluorescein staining (tCFS) at Days 15 (secondary) and 57 (primary)
- Change from baseline in visual analog scale (VAS) dryness score at Days 15 (secondary) and 57 (primary)

MIEBO. Package Insert. Bridgewater, NJ: Bausch + Lomb Americas, Inc.; 2023.

DED, dry eye disease; **MGD,** meibomian gland dysfunction; **QID,** four times a day; **tCFS,** total corneal fluorescein staining; **VAS,** visual analog scale

100% OF PATIENTS HAD DED AND CLINICAL SIGNS OF MGD

Key Inclusion Criteria

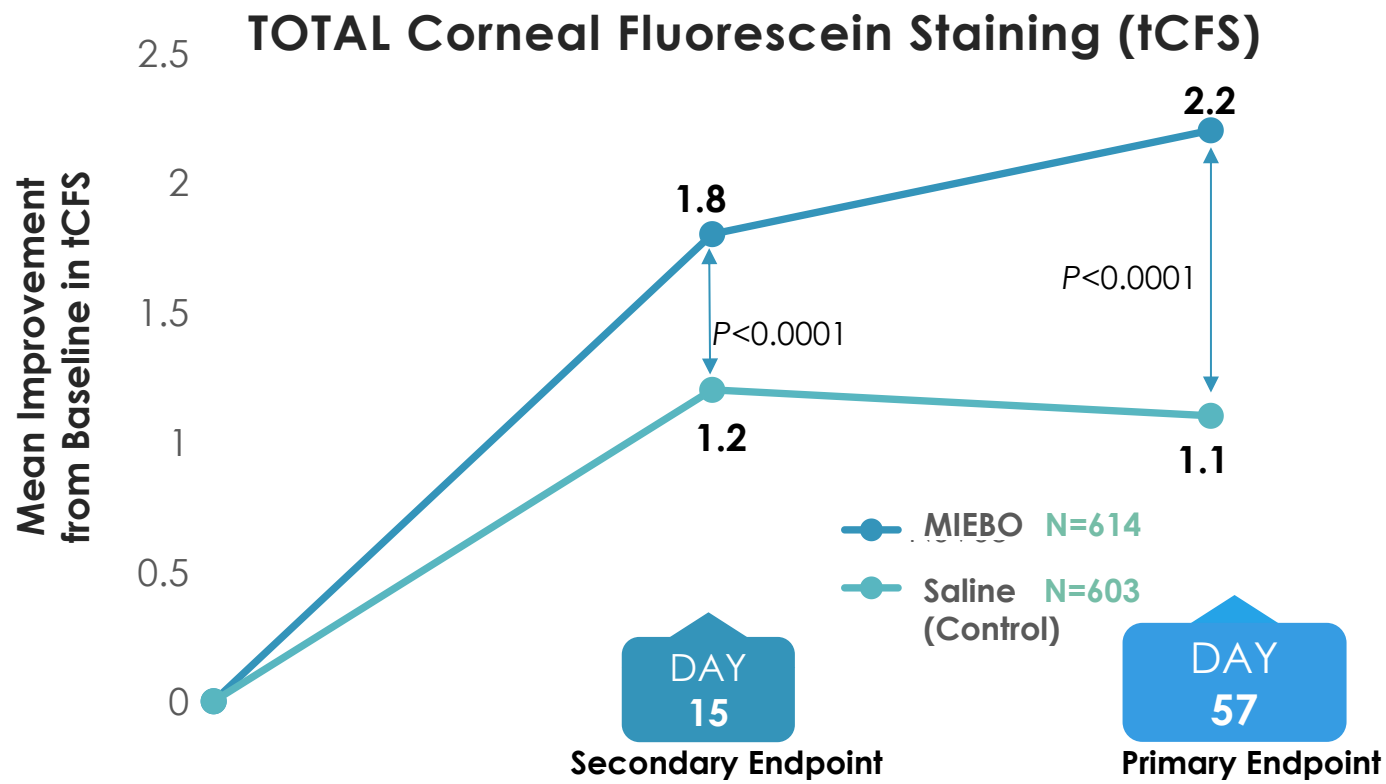
- ≥6 month self-reported history of DED
- Total MGD score ≥3
  - Based on secretion of 5 central glands on lower eyelid
  - Each scored from 0 to 3
    - 0 = normal
    - 1 = thick yellow/whitish particulate
    - 2 = paste
    - 3 = none/occluded

Key Exclusion Criteria

- Active blepharitis
- Contact lens wear
- Recent history of punctal plugs or MGD procedure
- Use of topical steroids, other Rx DED drugs, serum tears, or glaucoma medications

Tauber J, et al. *Ophthalmology*. 2022;130(5):516-524. Sheppard JD, et al. *Am J Ophthalmol*. 2023;252:265-274.
DED, dry eye disease; **MGD,** meibomian gland dysfunction

Rapid and Sustained Improvement in Total Corneal Staining as Early as Day 15 Through Day 57



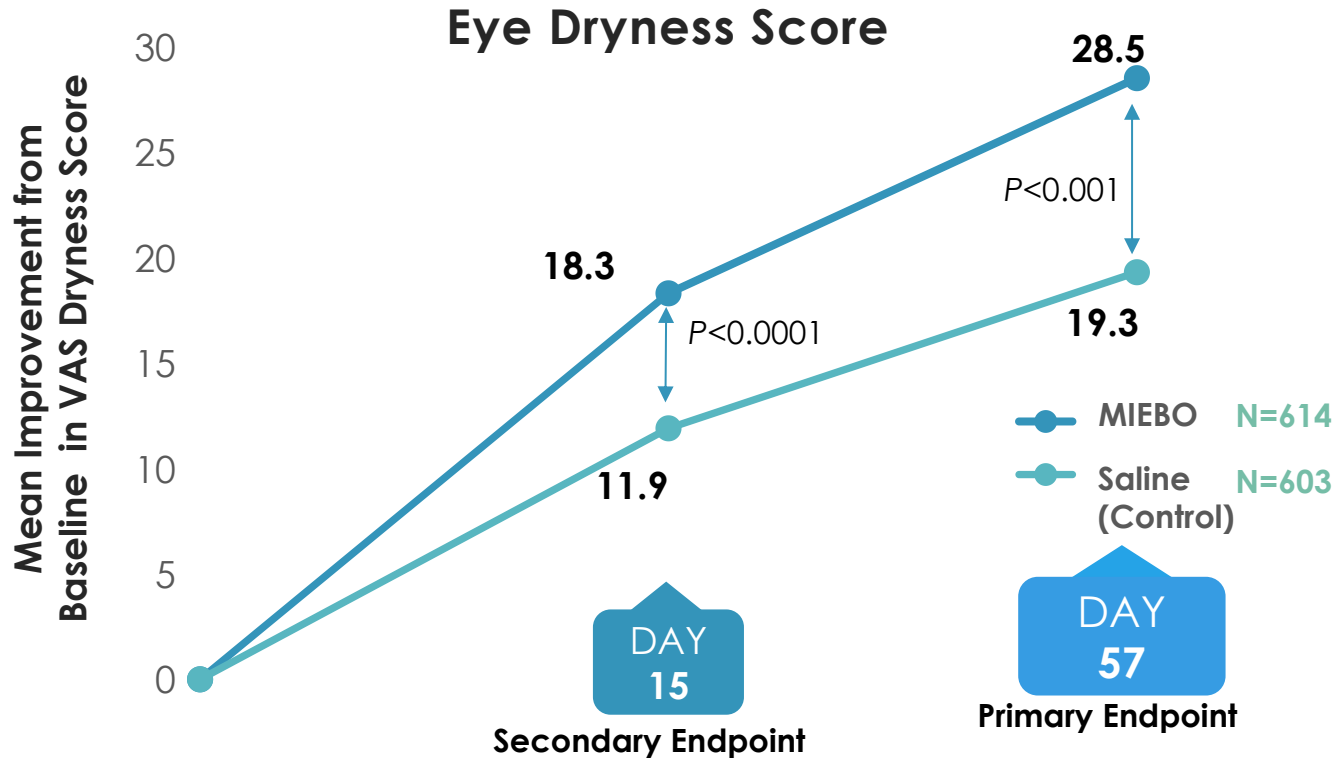
2X IMPROVEMENT vs control in **total corneal staining** at Day 57

Pooled data | tCFS Grading Scale: 0-15 (0-3 in each of 5 areas)
Mean Baseline = 6.9

At day 57, Mean (SD) CFB
GOBI: –2.0 (2.6) for MIEBO (n=289) vs –1.0 (2.7) for saline (n=279) (*P*<0.001)
MOJAVE: –2.3 (2.8) for MIEBO (n=302) vs –1.1 (2.9) for saline (n=296) (*P*<0.001)

Tauber J, et al. *Ophthalmology*. 2022;130(5):516-524. Sheppard JD, et al. *Am J Ophthalmol*. 2023;252:265-274. | **CFB,** change from baseline; **SD,** standard deviation; **tCFS,** total corneal fluorescein staining

RAPID AND SUSTAINED RELIEF OF EYE DRYNESS AS EARLY AS DAY 15 THROUGH DAY 57



1.5X *IMPROVEMENT* vs control in **eye dryness** at Day 57

Pooled data | Visual analog scale: 0-100 (0=no discomfort, 100=maximal discomfort)
Mean Baseline, MIEBO = 65.6; Mean Baseline, Saline = 65.5

At Day 57, Mean (SD) CFB
GOBI: –27.4 (27.9) for MIEBO (n=289) vs –19.7 (26.7) for saline (n=279) (*P*<0.001)
MOJAVE: –29.5 (28.6) for MIEBO (n=302) vs –19.0 (27.2) for saline (n=296) (*P*<0.001)

Tauber J, et al. *Ophthalmology*. 2022;130(5):516-524. Sheppard JD, et al. *Am J Ophthalmol*. 2023;252:265-274.
CFB, change from baseline; **VAS**, visual analog scale

AN EXCELLENT TOLERABILITY PROFILE

In 2 pivotal clinical studies of >1200 patients (>600 treated with perfluorohexyloctane)

Serious ocular AEs

Low rate of discontinuation due to AEs

Low rate of burning or stinging

There was one ocular AE with an incidence ≥2% (blurred vision)

Discontinuation rates for MIEBO were comparable to control (pooled: 0.2% vs 0.5%; GOBI: 0.3% vs 1.0%; MOJAVE: 0% vs 0%)
Pooled incidences of instillation site pain, such as burning or stinging occurred in 0.5% of patients; 1.0% in the GOBI study and no reported incidences in the MOJAVE study
The most common ocular AE was blurred vision, which was mostly mild and transient. Blurred vision (pooled: 2.1%; GOBI: 3.0%; MOJAVE: 1.3%) and conjunctival redness (pooled: 0.8%; GOBI: 0%; MOJAVE: 1.3%) were reported in 1%-3% of individuals

1. Tauber J, et al. *Ophthalmology*. 2022;130(5):516-524. **2.** Sheppard JD, et al. *Am J Ophthalmol*. 2023;252:265-274. **3.** Data on File. Bausch + Lomb Incorporated.
AE, adverse event

PERFLUOROHEXYLOCTANE INHIBITS EVAPORATION

Mimics key functions of **natural meibum**[1,2]

Remains in tears for up to **6 hours** (PK rabbit study)[2,3]

Promotes **healing** on the ocular surface[4-6]

May **reduce friction**[5,7]

perfluorohexyloctane **FORMS A MONOLAYER** at the air-tear interface, which can be expected to reduce evaporation.

The exact mechanism of action in DED is not known.

An in vitro study showed that MIEBO was 4x more effective at inhibiting evaporation compared with meibum lipids.[1]

The clinical significance of this data has not been established.

1. Vittitow J, et al. *Curr Ther Res*. 2023; S0011-393X(23)00013-9. **2.** Sheppard JD, Nichols KK. *Ophthalmol Ther*. 2023;12(3):1397-1418. **3.** Krösser S, et al. *Invest Ophthalmol Vis Sci.* 2018;59:2656. **4.** MIEBO. Prescribing Information. Bausch & Lomb, Inc; 2023. **5.** Tauber J, et al. *Ophthalmology*. 2022;130(5):516-524. **6.** Sheppard JD, et al. *Am J Ophthalmol*. 2023;252:265-274. **7.** Schmidl D, et al. *J Ocul Pharmacol Ther*. 2020;36(3):154-161. | **DED,** dry eye disease; **PK,** pharmacokinetics

Novaliq Announces FDA Approval of VEVYE™ (Cyclosporine Ophthalmic Solution) 0.1%, for the Treatment of the Signs and Symptoms of Dry Eye Disease

Novaliq Announces FDA Approval of VEVYE™ (Cyclosporine Ophthalmic Solution) 0.1% for the Treatment of the Signs and Symptoms of Dry Eye Disease

VEVYE™ is the first and only cyclosporine solution indicated for the treatment of signs and symptoms of dry eye disease with efficacy demonstrated after 4 weeks

Heidelberg, Germany and Cambridge, MA, USA, June 8, 2023 – Novaliq GmbH, a biopharmaceutical company focusing on first- and best-in-class ocular therapeutics, today announced that the U.S. Food and Drug Administration (FDA) has approved VEVYE™ (cyclosporine ophthalmic solution) 0.1% for the treatment of the signs and symptoms of dry eye disease. VEVYE (development name CyclASol®) is the first and only cyclosporine solution indicated for the treatment of signs and symptoms of dry eye disease with efficacy demonstrated after 4 weeks of treatment.

VEVEYE

Description	0.1%cyclosporine is soluble in the EyeSol®excipient perfluorobutylpentane
Target indication	Signs and symptoms of DED
Dosing	BID
Mechanisms of action	PF Topical anti-inflammatory and immunomodulator
FDA status	ESSENCE-1 ESSENCE-2

INTERVENTIONAL DRY EYE

SAHARA- Ayres BD, Bloomenstein MR, Loh J, Chester T, Saenz B, Echegoyen J, Kannarr SR, Perez VL, Rodriguez TC, Dickerson JE Jr. A randomized, controlled trial comparing TearCare® and cyclosporine ophthalmic emulsion for the treatment of dry eye disease (SAHARA). Clin Ophthalmol. 2023 Dec 18;17:3925-3940. doi: 10.2147/OPTH.S442971. PMID: 38143559; PMCID: PMC10741761.

TearCare treatment is superior to branded Restasis in improving TBUT and multiple measures of meibomian gland function

- Both treatments produce significant improvements in patient reported symptoms

TearCare administration and therapeutic effect in SAHARA RCT is consistent with "real-world"

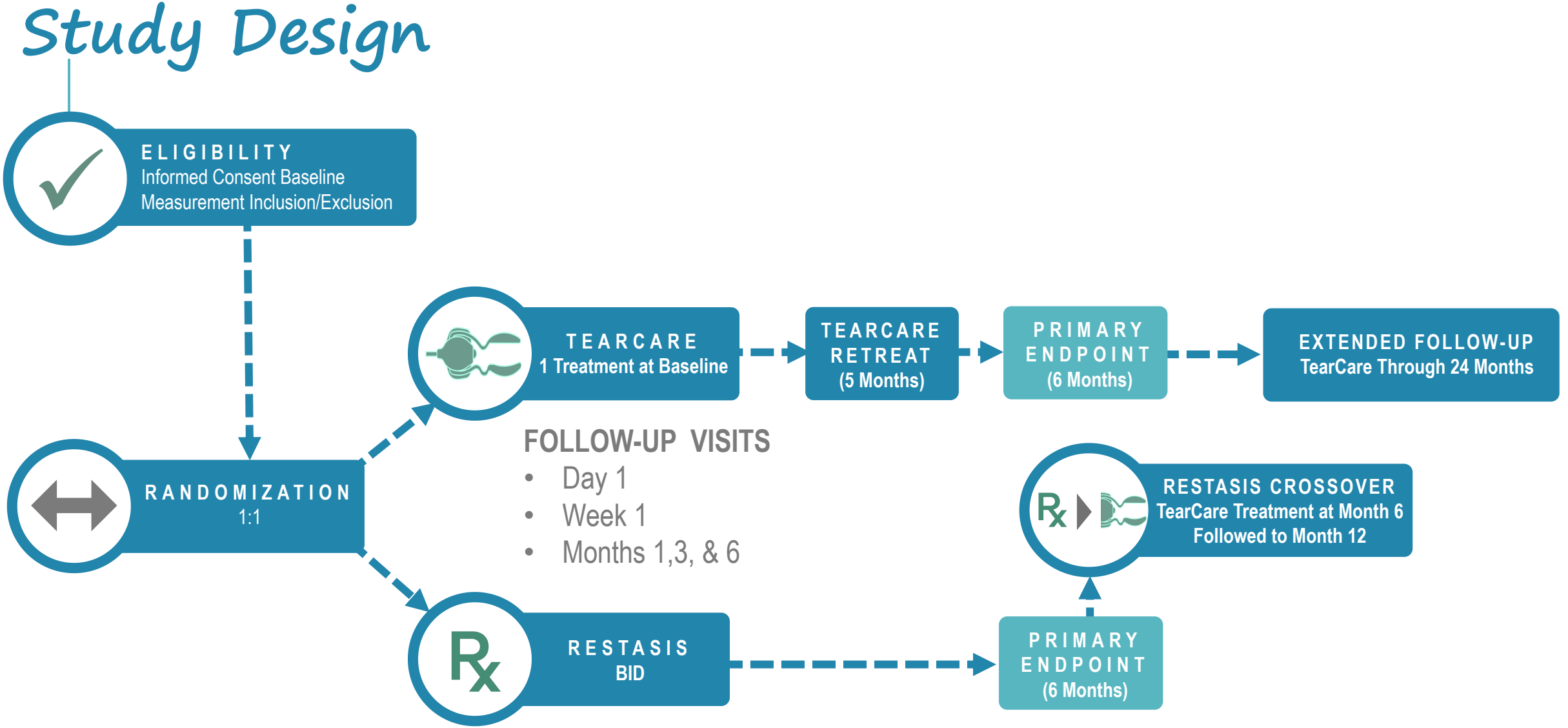
- Compliance to branded Restasis in SAHARA RCT was likely atypical of "real-world" patient behavior[1] (on average 5.7 bottles over 6 months)

Results of SAHARA RCT may warrant earlier intervention with TearCare

- Equal third-party patient access to TearCare may be justified

1. Uchino M, Yokoi N, Shimazaki J, Hori Y, Tsubota K, On Behalf Of The Japan Dry Eye Society. Adherence to Eye Drops Usage in Dry Eye Patients and Reasons for Non-Compliance: A Web-Based Survey. J Clin Med. 2022 Jan 12;11(2):367. doi: 10.3390/jcm11020367. PMID: 35054060; PMCID: PMC8779746.

Study Design



Ayres BD, Bloomenstein MR, Loh J, Chester T, Saenz B, Echegoyen J, Kannarr SR, Perez VL, Rodriguez TC, Dickerson JE Jr. A Randomized, Controlled Trial Comparing Tearcare® and Cyclosporine Ophthalmic Emulsion for the Treatment of Dry Eye Disease (SAHARA). Clin Ophthalmol. 2023 Dec 18;17:3925-3940. doi: 10.2147/OPTH.S442971. PMID:

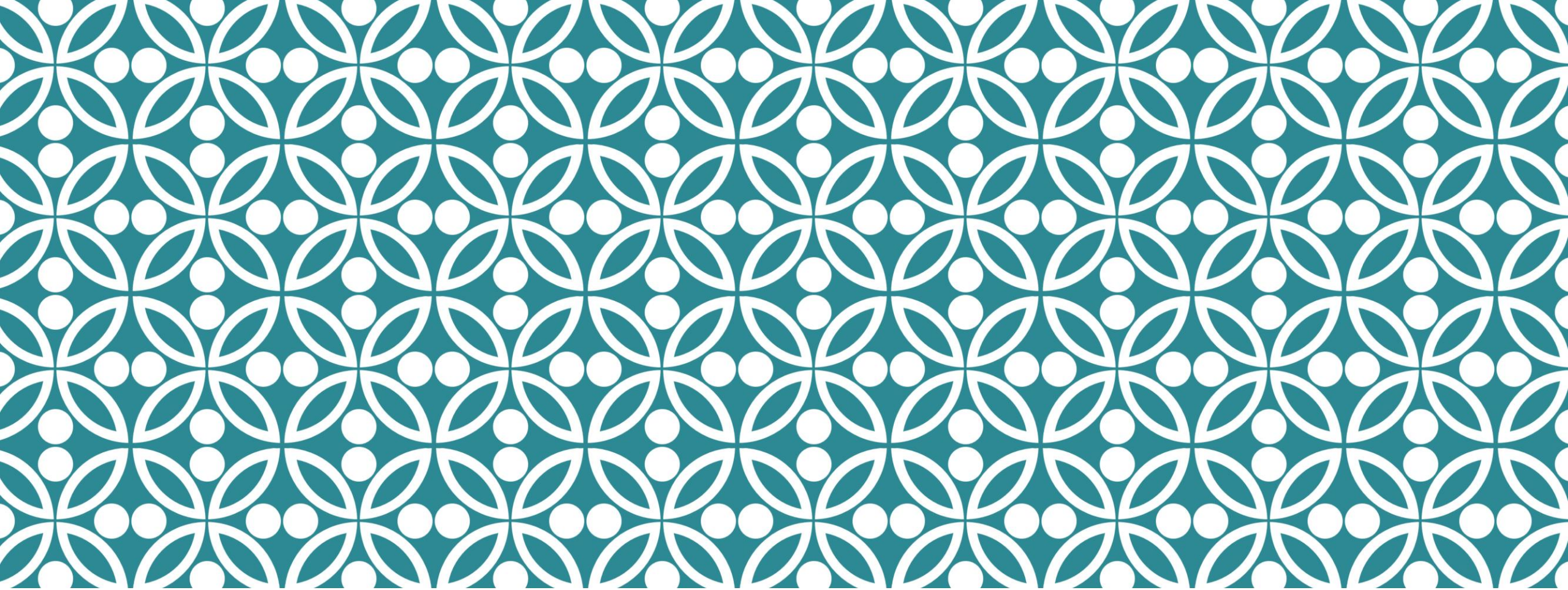
RADKAR P, LAKSHMANAN PS, MARY JJ, CHAUDHARY S, DURAIRAJ SK. A NOVEL MULTI-INGREDIENT SUPPLEMENT REDUCES INFLAMMATION OF THE EYE AND IMPROVES PRODUCTION AND QUALITY OF TEARS IN HUMANS. OPHTHALMOL THER. 2021 SEP;1

Introduction: Dry eye is a multifactorial condition of the eye caused by insufficient tear production and imbalance in tear composition leading to faster evaporation of tear fluid. It is also associated with inflammation that often leads to ocular surface damage. Symptoms of dry eyes include itchiness, soreness, red eyes, a burning sensation, eye fatigue and blurred vision. The objective of this study was to evaluate the efficacy and safety of our multi-ingredient supplement in subjects with dry eye syndrome (DES).

Methods: We recruited 60 subjects with mild to moderate DES who were randomized in a 1:1 ratio in a single-center study to receive LCD (lutein 20 mg, zeaxanthin 4 mg, curcumin 200 mg curcuminoids, vitamin D3 600 IU) or placebo (soybean oil) capsules for 8 weeks. The primary outcomes evaluated were changes in tear volume by Schirmer's test and ocular symptoms by the Ocular Surface Disease Index (OSDI); secondary outcomes included evaluation of changes in Standard Patient Evaluation of Eye Dryness (SPEED) questionnaire, tear film break-up time (TBUT), corneal and conjunctival staining, tear osmolarity, matrix metalloproteinase-9 (MMP-9), artificial tear use and safety assessments. The outcomes were compared between the LCD and placebo groups at baseline and day 56 of supplementation.

Results: Fifty-nine subjects, 30 from LCD and 29 from placebo group, completed the study. The LCD group showed significant improvements ($P < 0.0001$) for Schirmer's test, OSDI, TBUT, SPEED, ocular staining scores, tear osmolarity ($P = 0.0005$), MMP-9 ($P = 0.0017$) and reduced artificial tear use ($P = 0.0004$) and its frequency of use ($P < 0.0001$) in subjects compared to placebo from baseline to day 56. No safety issues were observed in the study.

Conclusion: The LCD supplement showed significant improvements in the production, stability and quality of tears by reducing ocular surface damage and tear inflammation and can be used as an adjuvant to artificial tears in subjects with DES.



PARADIGM SHIFT

WHAT HAPPENS BEYOND RESTASIS®? UNVEILING A PHASE 4 STUDY OF PATIENTS SWITCHING TO CEQUA®

Study design: Single arm, phase 4, 12-week, multicenter study of 124 adults with inadequately controlled DED on current Restasis therapy[1,2]

Co-primary endpoints: Corneal fluorescein staining (CFS) (signs) and mSANDE (symptoms)[3]

Inclusion Criteria[3]

Clinical diagnosis of DED and treatment on Restasis for ≥3 months

BCVA of ≥20/200

mSANDE score of ≥40

Total CFS ≥6 or CFS in an individual zone ≥2 at baseline

Exclusion Criteria[3]

Previous history of failure on Restasis

Discontinued/switched to a different immunomodulatory

Patients were on Restasis for **>38 months** before switching to CEQUA[2]

Patients received **1 drop 2x** daily of CEQUA in each eye[1]

BCVA=best corrected visual acuity; CFS=corneal fluorescein staining; DED=dry eye disease; mSANDE=modified Symptom Assessment in Dry Eye.

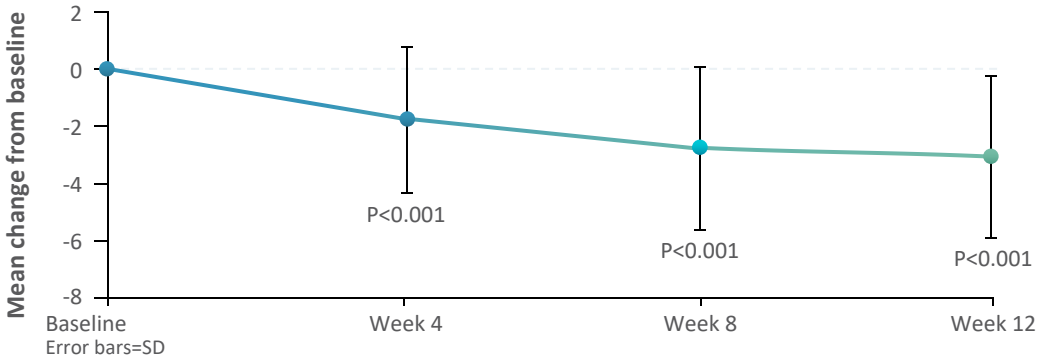
1. Johnston, J. Effect of OTX-101 0.09% on corneal staining and SANDE scores in patients with dry eye disease uncontrolled on cyclosporine ophthalmic emulsion 0.05%. Abstract presented at American Academy of Optometry 2023; October 12, 2023; New Orleans, LA. **2.** Data on file. Cranbury ,NJ: Sun Pharmaceutical Industries, Inc. **3.** Effect of CEQUA in Subjects with Dry Eye Disease, ClinicalTrials.gov identifier NCT04357795. Updated Sept 09, 2022. Accessed August 29, 2023. https://www.clinicaltrials.gov/study/NCT04357795.

DEMONSTRATED IMPROVEMENTS AS EARLY AS WEEK 4 AFTER SWITCHING FROM RESTASIS® TO CEQUA®[1]

FOR THE MAJORITY OF PATIENTS

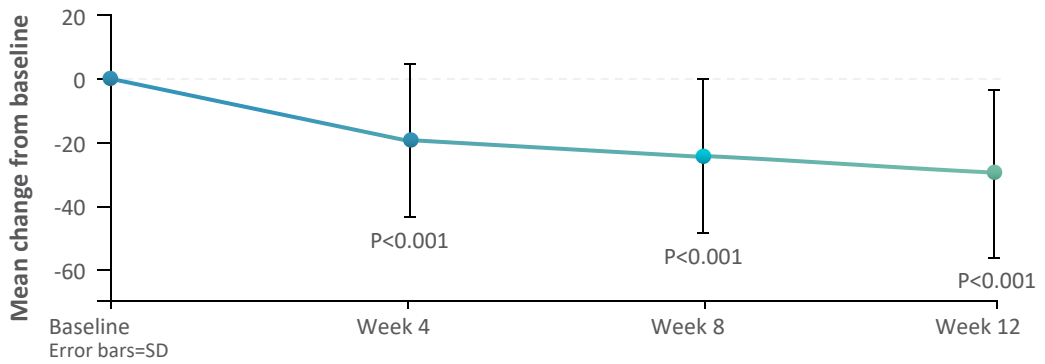
Statistically significant improvements in total corneal staining were seen as early as week 4 and continued to week 12[1]

Change in total corneal fluorescein staining score



Most reported that their eyes felt more comfortable* after 4 weeks of CEQUA than they did with Restasis[1]

Change in modified Symptom Assessment in Dry Eye score (mSANDE)



CEQUA (n=124)

*Less dryness and irritation.

BCVA=best corrected visual acuity; CFS=corneal fluorescein staining; DED=dry eye disease; mSANDE=modified Symptom Assessment in Dry Eye.

1. Johnston, J. Effect of OTX-101 0.09% on corneal staining and SANDE scores in patients with dry eye disease uncontrolled on cyclosporine ophthalmic emulsion 0.05%. Abstract presented at American Academy of Optometry 2023; October 12, 2023; New Orleans, LA.

Table 16
Staged management & treatment recommendations for dry eye disease[a,b,c].

Step 1:
- Education regarding the condition, its management, treatment and prognosis
- Modification of local environment
- Education regarding potential dietary modifications (including oral essential fatty acid supplementation)
- Identification and potential modification/elimination of offending systemic and topical medications
- Ocular lubricants of various types (if MGD is present, then consider lipid-containing supplements)
- Lid hygiene and warm compresses of various types

Step 2:
If above options are inadequate consider:

- Non-preserved ocular lubricants to minimize preservative-induced toxicity
- Tea tree oil treatment for Demodex (if present)
- Tear conservation
  - Punctal occlusion
  - Moisture chamber spectacles/goggles
- Overnight treatments (such as ointment or moisture chamber devices)
- In-office, physical heating and expression of the meibomian glands (including device-assisted therapies, such as LipiFlow)
- In-office intense pulsed light therapy for MGD
- Prescription drugs to manage DED[d]
  - Topical antibiotic or antibiotic/steroid combination applied to the lid margins for anterior blepharitis (if present)
  - Topical corticosteroid (limited-duration)
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  - Topical LFA-1 antagonist drugs (such as lifitegrast)
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Step 3:
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Step 4:
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- Topical corticosteroid for longer duration
- Amniotic membrane grafts
- Surgical punctal occlusion
- Other surgical approaches (eg tarsorrhaphy, salivary gland transplantation)

AMNIOTIC MEMBRANES

Available in cryopreserved or dehydrated form, amniotic membranes act as therapeutic bandages, restoring the health of the ocular surface.

Patients that have central corneal staining are good candidates and can benefit from the therapeutic benefits of amniotic membranes, whether if their disease has aqueous-deficient or evaporative components.

It really depends on the patients' disease on how long they wear them, it can be as little as 3 days but typically is 5-7 days.

AUTOLOGOUS SERUM

Autologous serum, or the use of a patient's own blood with the red blood cells and clotting factors removed as eye drops, contains many important growth factors and nutrients normally found in healthy tears. Therefore, optometrists prescribe the sterile, preservative-free solution to DED patients.

These drops are typically reserved for the moderate to severe patient. I usually start with 20% but they can reconstituted to 30% or 40%

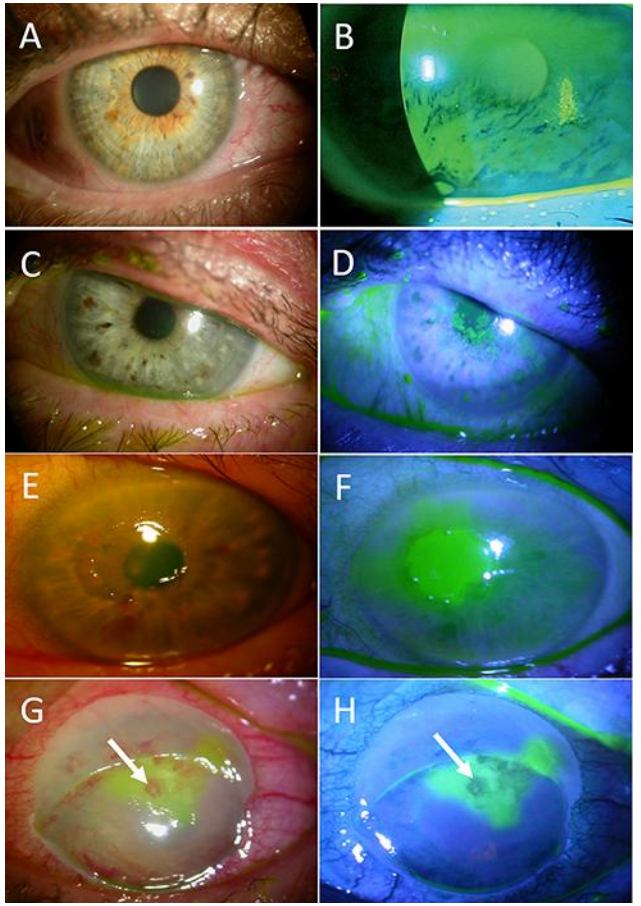
As there are many regulations in place when patients blood is involved it's become harder to obtain this for patients. However, Vital Tears, has been excellent in helping patients obtain this formulation.

CENEGERMIN-WHEN IT'S NOT JUST DED!

Known commercially as Oxervate (Dompe), this 0.002% topical solution contains a recombinant form of human nerve growth factor, a protein made by the human body, that acts through specific high-affinity and low-affinity nerve growth factor receptors in the anterior segment of the eye to support corneal innervation and integrity.

It is prescribed for patients who have neurotrophic keratitis, also known as neurotrophic keratopathy, a rare disease that can progress to corneal scarring and vision loss, and is dosed 6 x day for 8 weeks.

It is exciting to have an option for these patients, as it can be quite visually devastating. Historically it was quite expensive costing as much as 90K, but now can be very affordable.



TOPICAL CORTICOSTEROIDS

Topical corticosteroids quell ocular inflammation.

The ideal patient for this treatment has symptoms of moderate to severe DED and, specifically, associated inflammation that can't be controlled via cyclosporine or lifitegrast alone.

Topical steroids can provide symptomatic relief, but due to long-term side effects, should only be used for short-pulsed duration typically 2-4 weeks with an appointment to always check IOP.

CYCLOSPORINE

Cyclosporine blocks T-cell activation, consequently inhibiting inflammatory cytokine production (selective inhibition of IL-I). Additionally, cyclosporine treatment has been shown to increase goblet cell density in the conjunctiva.

Ideal candidates are those that need a long-term strategy to treat inflammation and can be aqueous deficient or evaporative patients.

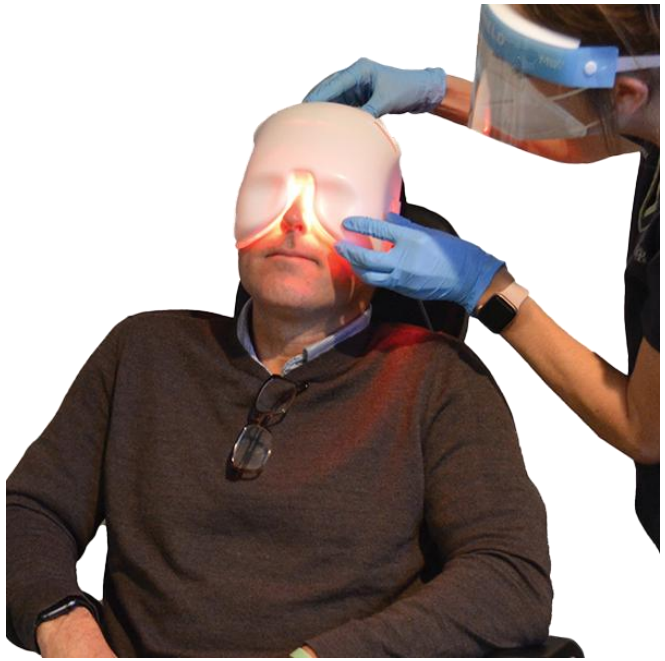
The drops begin to work immediately. However, the average life of a T-cell is approximately 90 days so the T-cells that are already activated have to die for full therapeutic target to be met. It is critical to teach patients the why of this drug so that they don't stop the drops on their own before experiencing full therapeutic relief.

LIFITEGRAST

Lifitegrast is engineered to mimic ICAM-1's binding domain to LFA-1 and is believed to act as a competitive antagonist to block the binding between LFA-1 and ICAM-1, which results in the inhibition of T-cell migration into target tissues. This, in turn, reduces cytokine release and decreases further T-cell recruitment.

Both patient types, aqueous-deficient or evaporative can benefit. It is FDA approved for dry eye disease symptoms as well as signs.

LLLT OR PHOTOBIOMODULATION



Photobiomodulation (low-level light therapy) and dry eye disease

Maria Markoulli, Nivaasheni Chandramohan & Eric B Papas

To cite this article: Maria Markoulli, Nivaasheni Chandramohan & Eric B Papas (2021) Photobiomodulation (low-level light therapy) and dry eye disease, Clinical and Experimental Optometry, 104:5, 561-566, DOI: 10.1080/08164622.2021.1878866

To link to this article: https://doi.org/10.1080/08164622.2021.1878866

Avci P, Gupta A, Sadasivam M, et al. Low-level laser (light) therapy (LLLT) in skin: stimulating, healing, restoring. *Semin Cutan Med Surg*. 2013;32(1):41-52.

Heiko Pult; Low-Level Light Therapy in the Treatment of Meibomian Gland Dysfunction. *Invest. Ophthalmol. Vis. Sci.* 2020;61(7):99.

INTENSE PULSED LIGHT

Also known as IPL, this treatment of different wavelengths of light targets the small vessels that contribute to inflammatory dry eye and ocular rosacea.

Ideal DED patients are those who have telangiectasia's, ocular rosacea, or acne rosacea and fall in the Fitzpatrick skin typing I-IV.

This is an easy in office procedure to perform. Proper use of laser grade corneal shields or adhesives is paramount for patient safety.

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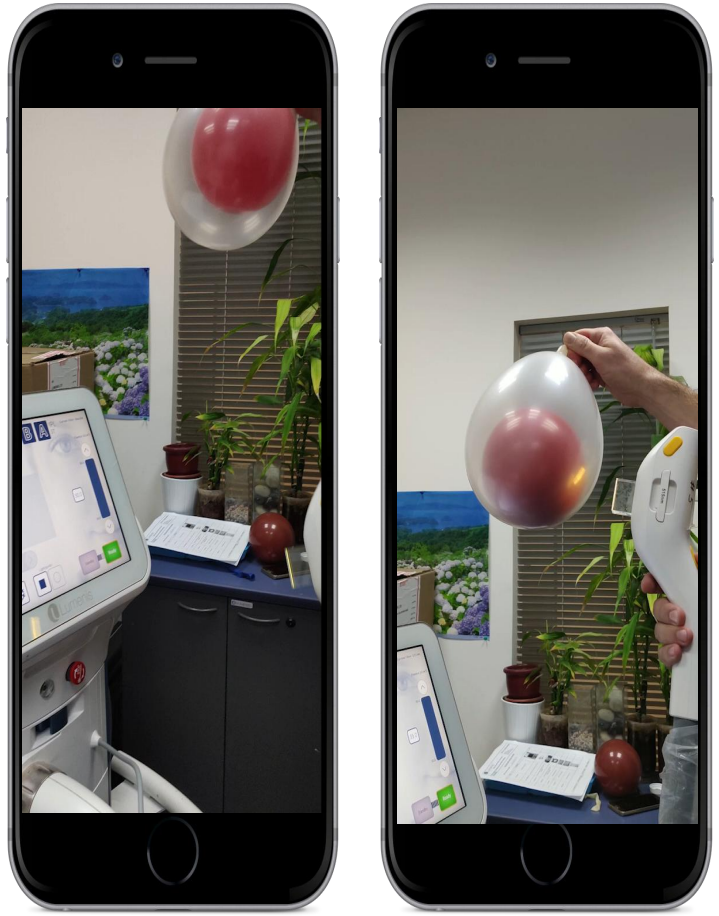
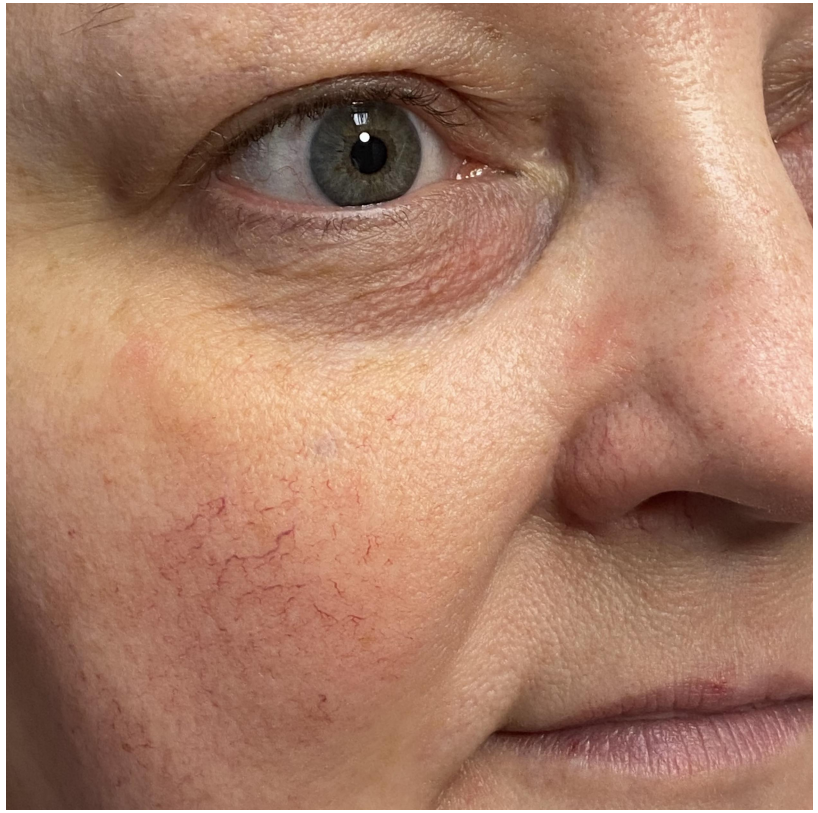
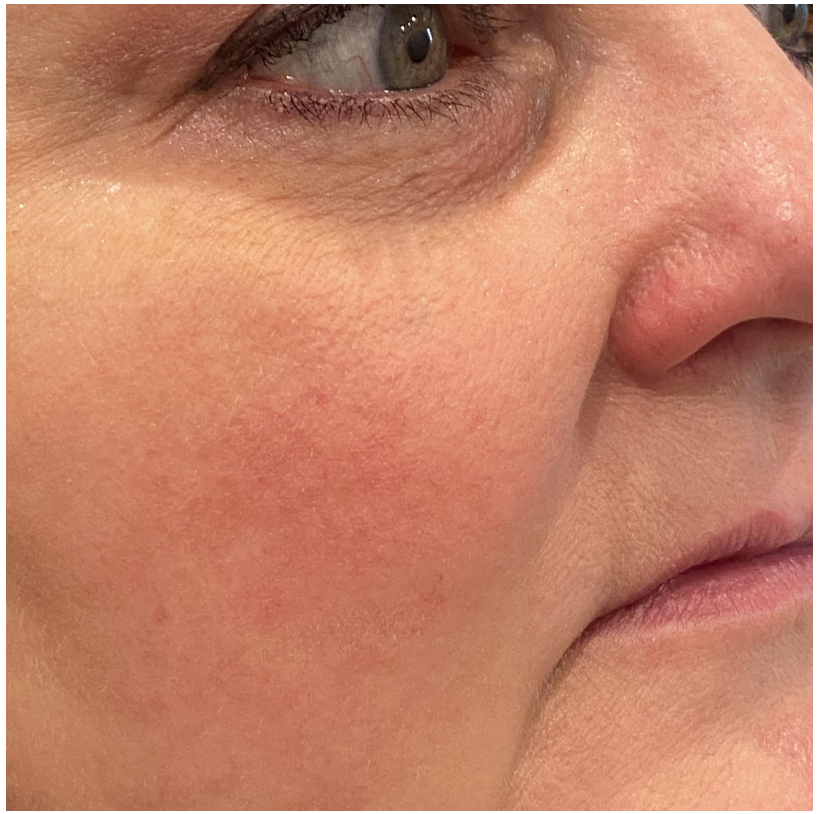
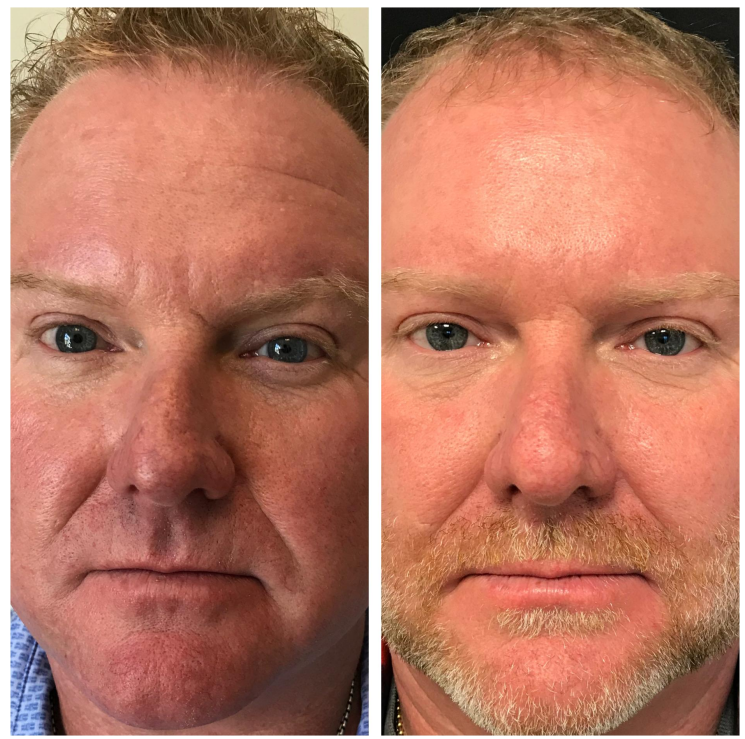
IPL safely and effectively targets the inflammation

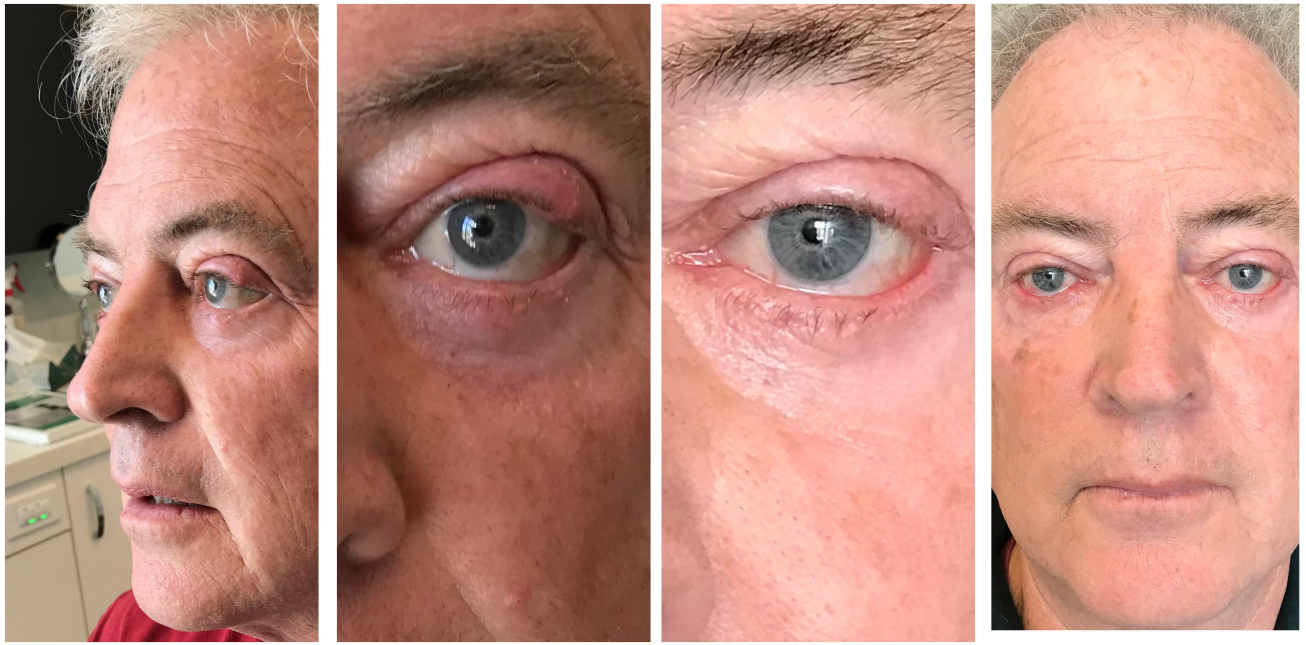




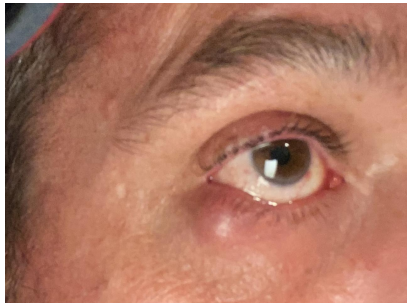


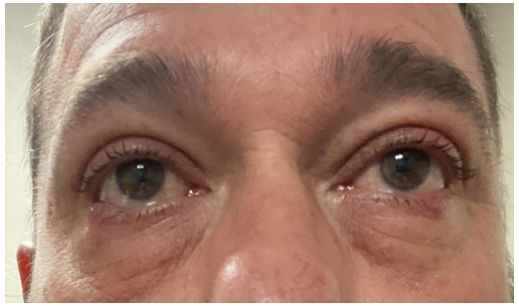


CHALAZIA TREATMENT-INCISION FREE, INJECTION FREE, SCAR FREE MANAGEMENT-



1 TX WITH IPL-NEXT DAY





BEISTO

- **B**ugs: Bacteria, Demodex
- **E**nzymes: lipases, esterases, transferases, cytokine effects on pKs of meibum biochem, sphingolipid composition, etc
- **I**nflammation
- **S**tasis of meibum
- **T**emperature: increased melting temp of meibum
- **O**bstruction/hyperkeratinization

The Ocular Surface **2017 15:179-192**

“TREAT THE BEISTO”

		CsA LfG	Thermal Pulsation	IPL	Hypochlorous acid	Omega 3/6	TP-03
B	Bacterial burden/ Demodex load			★	★		★
E	Enzymatic: meibum biochem, lipases, gene expression	★		★	★	★	★
I	Inflammation: cytokines, T-cells	★	★	★	★	★	★
S	Stasis		★	★		★	★
T	Temperature	★	★	★			
O	Obstruction: hyperkeratinization	★	★	★			★

HOW DOES IPL ACTUALLY WORK? WHAT IS IT DOING TO THE TISSUES?
THINK BEISTO

Photocoagulation

Photoimmunomodulation

Photomodulation

Photothermolysis

Photosanitization

Emerging strategies for the diagnosis and treatment of MGD: Proceedings of the OCEAN group meeting. *Ocular Surface* 2017 15, 179-192

PERFLUOROHEXYLOCTANE

Mimics natural meibum-lowers surface tension and helps prevent evaporation

Stays in the tear film for up to 6 hours per PK Rabbit studies

Yes-AND

PUNCTAL PLUGS

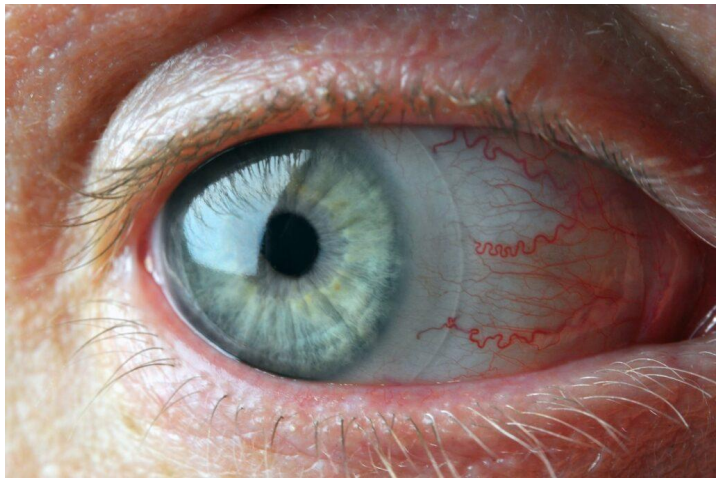
Punctal plugs allow tears to stay in the eye longer instead of draining through the canaliculus into the nasolacrimal system.

Truly aqueous deficient patients benefit the most, like patients with Sjogren's. When considering plugs, optometrists should make sure the inflammation has been treated first, as not treating it creates more inflammatory factors present on the front surface of the eye, which can exacerbate DED symptoms.

SCLERAL LENSES

Scleral lenses contain a sterile water bath that can support the front surface of an eye that has DED and any corneal irregularities. This results in increased comfort for DED patients.

Patients that have central corneal staining, with aqueous deficiency or evaporative disease are good candidates. Address any lid disease and hygiene before fitting the lenses for best success especially those with evaporative disease.



SUPPLEMENTS

Research reveals that a low level of omega fatty acids in one's body is a risk factor for DED. Further, modifying one's diet, along with omega fatty acid supplementation can complement other DED treatments, according to research.

Various omega-3 and omega-6 supplements can be of benefit **for** aqueous-deficient or evaporative patients due to their anti-inflammatory properties.

Make sure to do a through history of all medications, specifically blood thinners, or anti-coagulants as supplements can increase bleeding time.

- Correct ratio of DHA/EPA
- GLA

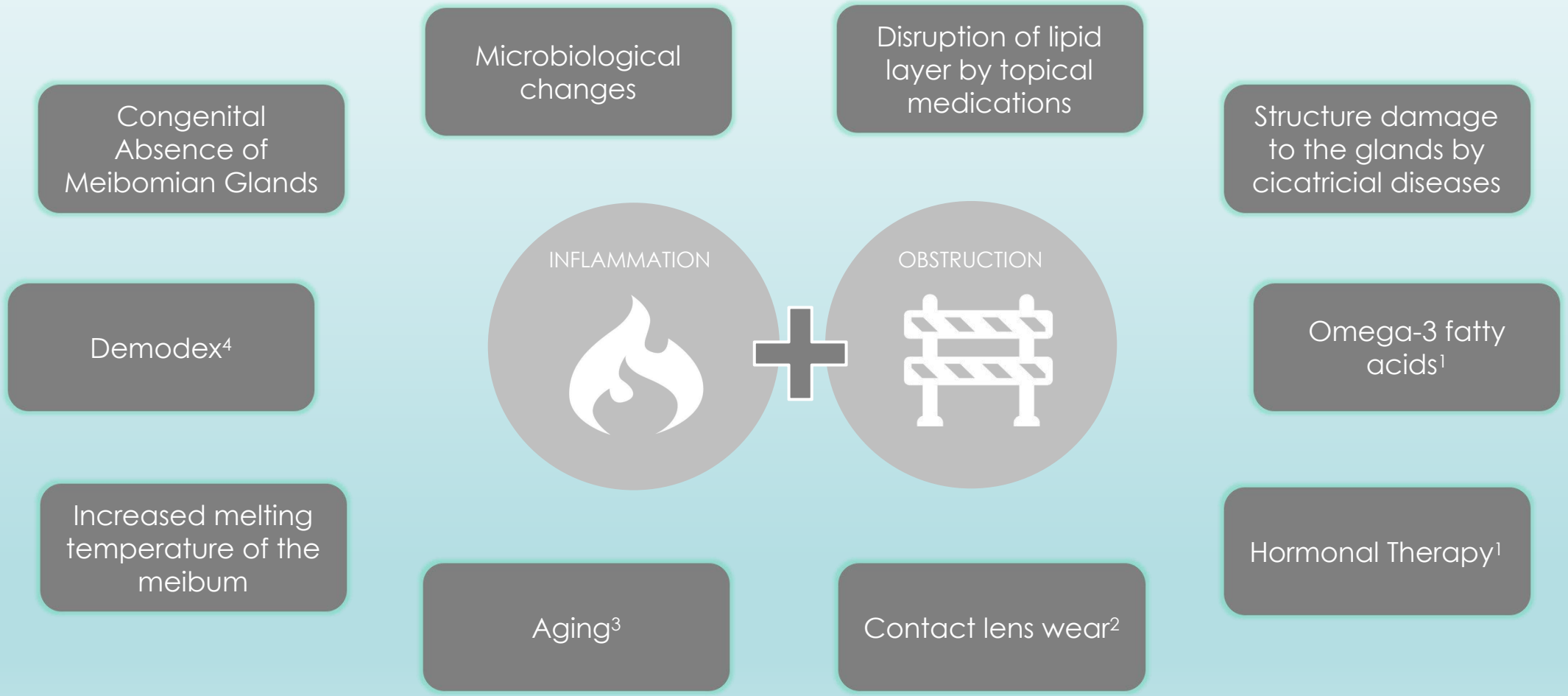
THERMAL PULSATION/HEAT & EXPRESSION

Thermal pulsation employs heat and massage to the lids to help unblock the meibomian glands. This unblocking helps to resume the natural production of lipids needed for a stable tear film.

Patients that have evaporative disease are the best candidates.

The treatment can be helpful in patients that just cannot maintain compliance at home with heat therapy. Think of it like visiting the dental hygienist every 6 months to one year.

Ultimately Action Plan Should Address Both…



1. Sullivan D. IOVS. 2000. 2. Arita R. Ophthalmology. 2009. 3. Obata H. Cornea. 2002. 4. Liu J. Curr Opin Allergy and Clin Immunol. 2010.

DIAGNOSIS EACH DISEASE AND TREAT ACCORDINGLY:

TEAM

- Technician
- Ocular Hygenist
- Dry Eye Coordinator

IMPLEMENTATION

STEP BY STEP APPROACH

- Ask the right questions
- Review Medical history and Medications-Autoimmune or Sleep Apnea
- CL wearer
- Skin Health/Telangiectasias
- Blink reflex
- Lid Seal
- Snap Test
- Products/make-up
- Lash Serums
- Meibography/Meibosoore
- TearLab

Pause and ask yourself, "What Did I Miss?

THANK YOU!
DRMCGEE@BESPOKEVISION.ORG

BeSpoke Vision
see. be seen.