Meibomian Gland Disease (MGD): Current Diagnostic and Treatment Options

Continuing Education Event
Monday, September 26th

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Sebastian Lesniak, MD
Matossian Eye Associates
Disclosures for Cynthia Matossian, MD

- Abbott Medical Optics
- Alcon
- Allergan
- ALPHAEON
- Bausch + Lomb
- Bruder
- Checked-Up
- Imprimis Pharmaceuticals
- i-Optics
- Lenstec
- Marco
- Ocular Therapeutix, Inc.
- OMEROS
- Physician Recommended Nutriceuticals (PRN) – Shareholder
- Progressive Tech Training
- RPS Diagnostics
- Shire
- Strathspey Crown – Shareholder
- Sun Pharmaceuticals
- TearLab
- TearScience
Disclosures for Sebastian Lesniak, MD

- No relevant financial relationships to disclose
The two primary forms of dry eye are Evaporative Dry Eye, also known as Meibomian Gland Dysfunction or MGD and Aqueous Dry Eye. The majority of dry eye sufferers have MGD.
Meibomian Gland Dysfunction (MGD) is a chronic, diffuse abnormality of the Meibomian Glands, commonly characterized by terminal duct obstruction and/or qualitative/quantitative changes in the glandular secretion.”

The aqueous (water) layer provides natural lubrication and is produced by the lacrimal glands.

The aqueous layer is protected by the lipid (oil) layer that is produced by the meibomian glands located in the eyelids.

When your meibomian glands do not produce sufficient oil, water evaporates causing burning, redness, dryness, irritation and eye fatigue. This is called Meibomian Gland Dysfunction or MGD.
Remember science class? Oil floats.

Oil does not mix with water, but rather sits on top of water.

Oil is what keeps water from evaporating.
Evaporation Video
MGD Compromises the First Refractive Surface

An Unstable Tear Film Negatively Impacts Quality of Vision Leading to:¹⁻⁵

- Fluctuating Vision
- Ocular Discomfort
- Compromised Barrier to Infection
- Tired eyes
- Need to blink more frequently

MGD Compromises the First Refractive Surface

Who is at increased risk?

• 63%+ of Cataract Patients (PHACO study results)¹
• Contact Lens Patients²
• Glaucoma Patients³

Routinely evaluate patients for MGD and treat as appropriate to optimize their ocular surface health

Blinking stimulates the meibomian glands to secrete oils and spread a protective oil layer across the tear film. When we partially blink the eyelids do not touch, so no pressure is applied at the meibomian glands to release these oils. Over time the oils harden in the glands and blockages develop.
MGD: The Science

MGD is progressive, obstructive and prevalent (60-70% of general population)¹,²

- Obstruction can lead to atrophy³
  - Early intervention optimizes outcomes⁴
  - For patients whose ocular surface is at risk for compromise (e.g., pre-surgical patients), treatment of MGD should be considered a priority⁵
- Evaporative stress causes MGD (Modern lifestyle, Contact lens wear, Chronic use of topical medications etc.)⁶,⁷

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³ Nichols KK et al. ARVO 2014
The Cycle of Inflammation

Examples of meibum stagnation and changes that correspond to MGD

- **Clear liquid secretion** (glands are functional using the MGE)
- **Cloudy liquid secretion** (glands are functional using the MGE)
- **Opaque solid secretion** (glands not functional; requires more force than the MGE)
- **Absence of secretion** (glands not functional; even significant force does not yield secretion)
- **Notching at gland orifice** (indicates atrophy/drop out)
MGD Exposed by the Science

1. MGD is not benign – it is a progressive, obstructive and prevalent disease.¹⁻³

2. MGD is a major contributor to the majority of Dry Eye.
   (86% of patients with dry eye evidence MGD)¹,⁴

3. Effective treatment for Dry Eye includes effective management of MGD and inflammation. (86% of patients with dry eye evidence MGD)¹,³,⁴

¹ Nichols KK, Foulks GN, Bron AJ. The International Workshop on Meibomian Gland Dysfunction: Executive Summary. IOVS, Special Issue 2011;52 (4)1922-9

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Diagnostic Work-Up

- Ocular Surface Disease Index (OSDI)
- SPEED Questionnaire
- Tear Osmolarity
- InflammaDry®
- Lissamine Green Staining
- Meibomian Gland Evaluator (MGE)
- Dynamic Meibomian Imaging (DMI)
Early Detection: Raising the standard of care

Meibomian Gland Function

• A functional Meibomian Gland is a gland that releases its liquid contents during a deliberate blink.$^{1,2}$

• The number of functional MGs along the lower eyelid can be counted using the MGE$^{\text{TM}}$.1,2

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Meibomian Gland Evaluator (MGE™)

- The first standardized method to assess meibomian gland (MG) function in-office.
- Easy to incorporate into routine eye care.
- Tracks the MG function with visit-to-visit consistency and repeatability.
- Approximates the pressure of a deliberate blink, allowing detection of MG function compromise at a very early stage.¹,²

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.
Meibomian Gland Structure:
LipiView® II with Dynamic Meibomian Imaging (DMI)

Dynamic Illumination

Dynamic Illumination + Adaptive Transillumination = Dual-Mode DMI

Normal Gland Structure

Gland Duct Dilation & Drop Out

Gland Truncation & Drop Out

MGD IS PROGRESSIVE
Current model of treatment is interventional.

Future of MGD treatment must be preventative.
MGD is the Gum Disease of Eye Care

1. We are all at risk for MGD
   (prevalence is 60-70% in the general population, 86% in the dry eye population)\(^1\-\(^4\)

1. Early Intervention is best\(^5\,^6\)

2. Early detection is necessary\(^5\,^6\)

Detect MGD:
Evaluate MG function and MG structure

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Treatments for MGD
Manage Dry Eye Symptoms

- Warm Compresses – Microwaveable Hot Mask
- Lid Massage & Lid Wipes/Scrubs
- Artificial Tear Solutions and/or Ointments
- Humidifier
- Omega-3 Oral Supplements
- Cyclosporine 0.05% or Lifitegrast 0.5%
- Punctal Plugs
- Oral Antibiotics (Doxycycline)
- Ductal Probing
New Direction: Proactive, Measurable, Effective

Obtain Baseline MG Evaluation on all patients - Use metrics

- Tear Osmolarity
- Inflammadry
- Lissamine Green
  - Uptake lid margin, conjunctiva, and cornea
- MGE (Meibomian Gland Evaluator)
- DMI (Dynamic Meibomian Gland Imaging)
Level 1 therapy for MGD is to treat obstruction

- Manual Expression (less effective and painful)
- Ductal Probing
- IPL
- Vectored Thermal Pulse Therapy
New Direction: Proactive, Measurable, Effective

- Offer supplementary therapy
  - Front surface heating (warm compresses, external lid heating devices)
  - Lid margin health (debridement-scaling, at home scrubs)
  - Blink training
  - Inflammation control
  - Diet (fish oil etc.)

- Educate that MGD is largely a disease of lifestyle (evaporative stress leads to MGD)
  - Empower the patient
IPL Contraindications

- Tanned skin (active tan)
- Pregnancy
- A history of keloid scarring
- Use of medication that may induce photosensitivity to the skin
- Any inflammatory skin condition at the treatment site
- A history of skin cancer
- A history of poor wound healing including Type I Diabetes
- Vitiligo
- Treatment over certain skin areas such as tattoos, moles, semi-permanent make-up, lip vermilion or mucous membranes
Vectored Thermal Pulse Therapy
While there are multiple choices available for treating MGD, LipiFlow is the only FDA-cleared device for removing gland blockages and restoring gland function.

Through advances in the application of Vectored Thermal Pulsation (VTP™) technology, the LipiFlow treatment utilizes a patented algorithm of heat applied to the inner eyelids and massage to remove the obstructions in your meibomian glands.
What makes Vectored Thermal Pulse Therapy Unique?

**Vectored Thermal Pulse Therapy is the only device to:**

1. Heat the INNER LID surface
2. Provide simultaneous gland evacuation DURING heating
3. Protect the globe from heat and pressure
4. Demonstrate proven results in multiple global, peer-reviewed studies of safety and effectiveness
5. Be evaluated for sustained efficacy, of a single treatment, in multiple clinical studies (evaluated from 6 months – 3 years)

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Does Vectored Thermal Pulse Therapy Work?

A recent review of 31 peer reviewed articles/abstracts (including five registered randomized controlled clinical trials):¹

A single dose, 12-minute therapy results in:

- Mean gland function improvement is ~ 3x baseline
- Mean symptom improvement is ~ 2x (symptoms are halved)

Do not use the Vectored Thermal Pulse Therapy System in patients with the following conditions:

- Ocular surgery, ocular injury, ocular herpes of eye or eyelid within prior 3 months
- Active ocular infection or inflammation, or history of chronic, recurrent ocular inflammation within prior 3 months
- Eyelid abnormalities that affect lid function
- Eyelid abnormalities or ocular surface abnormalities that may affect/compromise corneal integrity or lid function
• Severe (Grade 3 or 4) eyelid inflammation (eg, blepharochalasis, staphylococcal blepharitis, or seborrheic blepharitis). Patients with severe eyelid inflammation should be treated medically prior to device use.

• In addition, the treatment procedure may loosen previously inserted punctal plugs, which may worsen the patient’s Dry Eye symptoms.
Vectored Thermal Pulse Therapy Video
Ocular Surface Disease Diagnostic and Treatment Algorithm

First visit: SPEED dry eye symptom questionnaire

- If 1 or more dry eye symptoms, technician performs TearLab and MMP-9 test prior to additional workup

**TearLab Osmolarity Test**

- Normal: If <300 mOsm/L and symmetric
  - Look for additional signs of DED; if none, rule out dry eye

- Abnormal: If ≥300 mOsm/L or asymmetric
  - Determine Severity:
    - Mild: 300 - 319 mOsm/L
    - Moderate: 320 - 339 mOsm/L
    - Severe: >340 mOsm/L

**Slit Lamp Exam**

1. Lissamine green and fluorescein staining
2. Evaluation of meibomian glands

**Baseline treatment protocol recommended to DED patients:**

1. Adequate hydration
2. Lid hygiene
3. Preservative free artificial tears
4. High quality omega-3 supplement
5. Cyclosporine
6. If moderate or severe DED, additional medications may be prescribed (i.e., topical steroids, or combination antibiotic/steroids, etc.)

**DED Patient Education:**

1. DED is not ‘cured’ with a one time treatment
2. DED is chronic and requires on-going treatment
3. Requires collaboration and communication between patient and doctor
4. Environmental changes recommended: redirect air conditioner/heat vents/fans away from face, etc.
5. Email DED educational videos to patient

1-2 month follow up for DED diagnosis
Diagnosed with DED, return visit 1-2 month follow up: SPEED dry eye symptom questionnaire

TearLab and MMP-9 testing performed to monitor efficacy of prescribed treatment

**TearLab Osmolarity Test**

**Slit Lamp Exam**
1. Lissamine green and fluorescein staining
2. Meibomian gland imaging with LipiView
3. Evaluation of meibomian glands
4. Monitor treatment efficacy with TearLab results as compared to previous visit

**Look for:**
MGD, blepharitis, lid abnormalities, conjunctival chalasis, SPK, PEK, PEE

**Abnormal**
If ≥300 mOsm/L or asymmetric*

Determine severity/track therapeutic response:
- Mild: 300 - 319 mOsm/L
- Moderate: 320 - 339 mOsm/L
- Severe: >340 mOsm/L

**Treatment protocol recommended to DED patients on follow up:**
1. Increase of omega-3 from 2 to 4 capsules daily, with largest meal.
2. Continue heated microwaveable mask, 1-2 times daily.
3. Preservative free artificial tears OU PRN.
4. Maintain hydration

**Increased treatment protocol recommended if signs/symptoms or TearLab results do not improve:**
1. Start cyclosporine ophthalmic emulsion 0.05% OU BID
2. Discuss and recommend LipiFlow depending on gland dropout with meibomian gland imaging

Schedule for 4 month follow up to repeat testing and monitor efficacy of therapy
Ocular Surface Disease Diagnostic and Treatment Algorithm

4 month follow up for DED: SPEED dry eye symptom questionnaire

Follow up for DED – TearLab and MMP-9 testing performed to monitor efficacy of recommended treatment

**TearLab Osmolarity Test**

- **Abnormal**
  - If ≥ 300 mOsm/L or asymmetric*

  Determine severity/track therapeutic response:
  - Mild: ~300 - 319 mOsm/L
  - Moderate: ~320 - 339 mOsm/L
  - Severe: >340 mOsm/L

**Slit Lamp Exam**

1. Lissamine green and fluorescein staining
2. Evaluation of meibomian glands
3. Monitor treatment efficacy with TearLab results as compared to previous visit

**Look for:**

- MGD, blepharitis, lid abnormalities, conjunctival chalasis, SPK, PEK, PEE

**Treatment protocol recommended to DED patients on 4 month follow up:**

1. Continue omega-3 treatment: 4 capsules daily, or 1 tsp high potency liquid, with largest meal
2. Continue heated microwaveable mask, 1-2 times daily
3. Preservative free artificial tears OU PRN
4. Maintain hydration
5. Continue cyclosporine ophthalmic emulsion 0.05% OU BID
6. Increase frequency of lid hygiene treatments

**Treatment progression if no improvement in clinical signs/symptoms or TearLab results:**

1. Add humidifier to bedroom and start running 1 hour prior to bed
2. Start a short course of loteprednol etabonate ophthalmic suspension 0.5% OU BID for 1-3 weeks
3. Perform omega index test to make sure patient is within the therapeutic range of 8% or greater
4. Recommend LipiFlow® if not already performed at previous visit

Schedule for 4 month follow up to repeat testing and monitor efficacy of therapy
Ocular Surface Disease Diagnostic and Treatment Algorithm

Second 4 month follow up for DED: SPEED dry eye symptom questionnaire

Follow up for DED—TearLab and MMP-9 performed to monitor response to therapy and disease progression

TearLab Osmolarity Test → MMP-9

Slit Lamp Exam
1. Lissamine green and fluorescein staining
2. Evaluation of meibomian glands
3. Monitor treatment efficacy with TearLab results as compared to previous visit

Look for:
MGD, blepharitis, lid abnormalities, conjunctival chalasis, SPK, PEK, PEE

Abnormal
If ≥300 mOsm/L or asymmetric*
Determine severity/track therapeutic response:
- Mild: ~300 - 319 mOsm/L
- Moderate: ~320 - 339 mOsm/L
- Severe: >340 mOsm/L

Treatment protocol recommended to DED patients on 4 month follow up:
1. Continue omega-3 treatment: 4 capsules daily, or 1 tsp high potency liquid, with largest meal.
2. Continue heated microwaveable mask, 1-2 times daily.
3. Preservative free artificial tears OU PRN.
4. Maintain hydration
5. Continue cyclosporine ophthalmic emulsion 0.05% OU BID
6. Continue humidifier at night

If no improvement in clinical signs/symptoms or TearLab results:
1. Perform Sjogrens test
2. Recommend LipiFlow® thermal pulsation treatment if not performed at previous visit
3. If LipiFlow® done in past 6 months, consider IPL (intense pulsed light) as adjunctive treatment
4. Insert punctal plugs to both lower lids
5. Preservative free artificial ointment at bedtime

Schedule for 4 month follow up to repeat testing and monitor efficacy of therapy
For patient with severe DED, regimen is as follows:

<table>
<thead>
<tr>
<th>Treatment protocol recommended to DED patients on 4 month follow up:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Continue omega-3 treatment: 4 capsules daily, or 1 tsp high potency liquid, with largest meal</td>
</tr>
<tr>
<td>2. Continue heated microwaveable mask, 1-2 times daily</td>
</tr>
<tr>
<td>3. Preservative free artificial tears OU PRN</td>
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<td>4. Maintain hydration</td>
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<td>5. Continue cyclosporine ophthalmic emulsion 0.05% OU BID</td>
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<tr>
<td>6. Continue humidifier at night</td>
</tr>
<tr>
<td>7. IPL: series of 4 treatments and repeated maintenance treatments prn</td>
</tr>
<tr>
<td>8. Consider adding punctal plugs to both upper lids</td>
</tr>
<tr>
<td>9. Consider amniotic membrane corneal bandage (Prokera®)</td>
</tr>
<tr>
<td>10. Consider serum tears</td>
</tr>
</tbody>
</table>
First Visit

If one or more dry eye symptoms are indicated on SPEED Questionnaire, technician performs tear osmolarity and MMP-9 test prior to additional workup.

Tear Osmolarity Test

- Normal: If <300 mOsm/L and symmetric
  - Look for additional signs of DED; if none, rule out dry eye

- Abnormal: If ≥300 mOsm/L or asymmetric
  - Determine Severity:
    - Mild: -300 - 319 mOsm/L
    - Moderate: -320 - 339 mOsm/L
    - Severe: >340 mOsm/L

MMP-9 Test

Slit Lamp Exam

1. Lissamine green and fluorescein staining
2. Evaluation of Meibomian glands

Look for:
- MGD, blepharitis, SPK, PEK, PEE
First Visit:
SPEED Dry Eye Symptom Questionnaire

Patient Name: __________________________
Date: __________________________

RIGHT EYE ☐  LEFT EYE ☐

DRY EYE QUESTIONNAIRE - SPEED

Please answer the following questions by checking the box that best represents your answer. Select only one answer per question.

1. Report the type of **SYMPTOMS** you experience and when they occur:

<table>
<thead>
<tr>
<th>SYMPTOMS</th>
<th>AT THIS VISIT</th>
<th>WITHIN PAST 72 HRS</th>
<th>WITHIN PAST 3 MONTHS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dryness, Grittiness or Scratchiness</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Soreness or Irritation</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td>Burning or Watering</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eye Fatigue</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. Report the **FREQUENCY** of your symptoms using the rating list below:

<table>
<thead>
<tr>
<th>SYMPTOMS</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dryness, Grittiness or Scratchiness</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

0 = Never  1 = Sometimes  2 = Often  3 = Constant

3. Report the **SEVERITY** of your symptoms using the rating list below:

<table>
<thead>
<tr>
<th>SYMPTOMS</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
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0 = No problems  1 = Tolerable – not perfect but not uncomfortable  2 = Uncomfortable – irritating but does not interfere with my day  3 = Bothersome – irritating and interferes with my day  4 = Intolerable – unable to perform my daily tasks

4. Do you use eye drops for lubrication? ☐ YES ☐ NO If yes, how often? ________________
Baseline treatment protocol recommended to DED patients:

1. Adequate hydration
2. Preservative free artificial tears
3. Microwaveable Hot Mask
4. High quality Omega-3 supplement
5. Lid hygiene

1-2 month follow-up for DED diagnosis
DED Patient Education

1. DED is not ‘cured’ with a one-time treatment
2. DED is chronic and requires on-going treatment
3. Requires collaboration and communication between patient and doctor
4. Environmental changes recommended: redirect air conditioner/heat vents/fans away from face, etc.
5. Email DED educational videos to patient

1-2 month follow-up for DED diagnosis
Diagnosed with DED, return visit 1-2 month follow-up: SPEED Dry Eye Symptom Questionnaire

- Tear osmolarity and MMP-9 testing performed to monitor efficacy of prescribed treatment

### Tear Osmolarity Test

### MMP-9 Test

### Slit Lamp Exam
1. Lissamine green and fluorescein staining
2. Meibomian gland imaging with LipiView™
3. Evaluation of Meibomian glands
4. Monitor treatment efficacy with results as compared with previous visit

### Abnormal
- If ≥300 mOsm/L or asymmetric

Determine Severity:
- Mild: -300 - 319 mOsm/L
- Moderate: -320 - 339 mOsm/L
- Severe: >340 mOsm/L

Look For:
- MGD, blepharitis, lid abnormalities, conjunctival chalasis, SPK, PEK, PEE
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Treatment protocol recommended to DED patients on follow-up:
1. Increase of Omega-3 from 2 to 4 capsules daily, with largest meal
2. Continue heated microwaveable mask, 1 to 2 times daily
3. Continue lid hygiene 1 to 2 times a day
4. Preservative free artificial tears OU PRN
5. Maintain hydration

Schedule for 4 month follow-up to repeat testing and monitor efficacy of therapy
Abnormal
If ≥300 mOsm/L or asymmetric

Determine Severity:
• Mild: -300 - 319 mOsm/L
• Moderate: -320 - 339 mOsm/L
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Increased treatment protocol recommended if signs/symptoms or results do not improve:

1. Start cyclosporine ophthalmic emulsion 0.05% or lifitegrast 5.0% OU BID
2. Discuss and recommend thermal pulsation treatment depending on gland dropout with Meibomian gland imaging

Schedule for 4 month follow-up to repeat testing and monitor efficacy of therapy
4 month follow-up for DED: SPEED Dry Eye Symptom Questionnaire

Follow-up for DED – Tear osmolarity and MMP-9 testing performed to monitor efficacy of recommended treatment

Tear Osmolarity Test

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1. Continue Omega-3 treatment: 4 capsules daily or 1 tsp high potency liquid, with largest meal
2. Continue heated microwaveable mask, 1-2 times daily
3. Preservative free artificial tears OU PRN
4. Maintain hydration
5. Continue cyclosporine/lifitegrast OU BID
6. Increase frequency of lid hygiene treatments or use two products: AM and PM

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If ≥300 mOsm/L or asymmetric

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Treatment progression if no improvement in clinical signs/symptoms or TearLab results

1. Add humidifier to bedroom and start running 1 hour before bed
2. Start a short course of loteprednol etabonate ophthalmic suspension 0.5% OU BID for 1-3 weeks
3. Perform omega index test to make sure patient is within the therapeutic range of 8% or greater
4. Perform allergy testing
5. Recommend thermal pulsation treatment if not already performed at previous visit

Schedule for 4 month follow-up to repeat testing and monitor efficacy of therapy
Second 4 month follow-up for DED: SPEED Dry Eye Symptom Questionnaire

Follow-up for DED – Tear osmolarity and MMP-9 testing performed to monitor response to therapy and disease progression

Tear Osmolarity Test

MMP-9 Test

Slit Lamp Exam
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2. Continue heated microwaveable mask, 1-2 times daily
3. Preservative free artificial tears OU PRN
4. Maintain hydration
5. Continue cyclosporine/lifitegrast BID
6. Continue lid hygiene BID
7. Continue humidifier at night

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Treatment progression if no improvement in clinical signs/symptoms or TearLab results:
1. Perform Sjögren’s test
2. Recommend thermal pulsation treatment if not already performed at previous visit
3. If thermal pulsation treatment done in past 6 months, consider IPL (intense pulsed light) as adjunctive treatment
4. Insert punctal plugs to both lower lids
5. Preservative free artificial tear ointment at bedtime

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<tr>
<td>5. Continue cyclosporine ophthalmic emulsion 0.05% or lifitegrast 5.0% OU BID</td>
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<tr>
<td>6. Continue lid hygiene</td>
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<td>7. Continue humidifier at night</td>
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<td>8. IPL: adjunctive treatment to thermal pulsation</td>
</tr>
<tr>
<td>9. Consider adding punctal plugs to both upper lids</td>
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<tr>
<td>10. Consider amniotic membrane corneal bandage</td>
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<tr>
<td>11. Testosterone 0.05% Ophthalmic drops compounded off label BID</td>
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<tr>
<td>12. Consider serum tears</td>
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<tr>
<td>13. Consider scleral cover shell</td>
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</tbody>
</table>
Questions?
THANK YOU

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