MGD and Demodex Management: The Missing Link..

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Company	Role	Compensation
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Alcon	Consultant, Speakers Bureau	Honoraria
Bausch + Lomb	Consultant, Educator, Research	Honoraria
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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[1,2]
- ***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[5]

D. brevis

0.1 mm length
Colonizes the meibomian gland[5]

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):389-458. 3. Fromstein SR et al. *Clin Optom (Auckl).* 2018;10:57-63. 4. Tranter W et al. *Clin Ophthalmol.* 2022;16:1155-1164. 5. Litwin D et al. *Iran J Parasitol.* 2017;12(1):12-21.

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US PREVALENCE OF OSD and DED

- Estimated >16 million patients have been diagnosed with DED[1]
- Estimates ~33 million patients suffering from dry eye symptoms[1]
- Almost all adults experience dry eye signs and symptoms
  - DED is often underdiagnosed and undertreated[2]
  - DED is the most common reason for visits to eyecare practitioners (ECPs)[3]
  - ~33% of patients present with complaints about dry eye[1]
- Prevalence is projected to increase due to:
  - Aging population
  - Increased screen time (computers and handheld devices)

REFERENCES: 1. Farrand KF, Fridman M, Stillman IO, Schaumberg DA. Prevalence of Diagnosed Dry Eye Disease in the United States Among Adults Aged 18 Years and Older. *Am J Ophthalmol* 2017;182:90-8. **2.** Craig JP, Nichols KK, Akpek EK, et al. TFOS DEWS II Definition and Classification report. *Ocul Surf.* 2017;15(3):276-283. doi: 10.1016/j.jtos.2017.05.008.
3. Caravant J, Ousler GW III, Wilcox Hagberg K, et al. A correlation between the signs and symptoms of dry eye and the duration of dry eye diagnosis. *IOVS.* 2005;46:E-abstract 4455.

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Meibomian Gland Dysfunction

Meibomian Gland Dysfunction (MGD) is a chronic condition characterized by abnormal keratin production, leading to blocked glands

Normal Meibomian Glands

Blocked Meibomian Glands

- Decreased meibum quality and quantity in the upper and lower eyelids
- Tear film changes
  - Reduced visual function/quality of Vision
  - Dry eye disease
  - Contact lens discomfort / intolerance
- Gland complications
  - Gland blockage/dilation
  - Irreversible glandular atrophy/loss
  - Bacterial growth
  - Lead to Blepharitis
- Ocular Surface Inflammation
- Corneal scarring

Sources:
- Nichols KK, et al. Invest Ophthalmol Vis Sci. 2011 Mar 30;52(4):1922-9.
- Knop E, et al. Invest Ophthalmol Vis Sci. 2011 Mar 30;52(4):1938-78. 3. Romero JM, et al. Eye & Contact Lens 2004;30(1): 14–19

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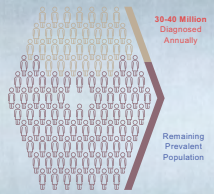
MGD Prevelance

- MGD affects approximately 100 million patients in the U.S. and can lead to Contact Lens Discomfort (CLD), Dry Eye Disease (DED), blepharitis
- Near-term market opportunity of 30 to 40 million patients
- No currently FDA-approved medicines for MGD
- Approved treatments for downstream ocular conditions have not demonstrated efficacy for restoring function of the meibomian glands



MGD affects
100+ Million
in the US
Each 🧍 represents **1 million** affected people

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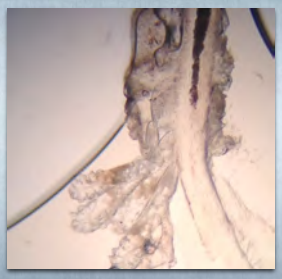
Demodex

- *Demodex folliculorum*
- *Demodex brevis*
- Reside in sebaceous glands in facial skin
  - –Nose
  - –Nasolabial folds
  - –Eyelids
  - –Cheek
  - –Forehead
  - –Chin
  - –Neck



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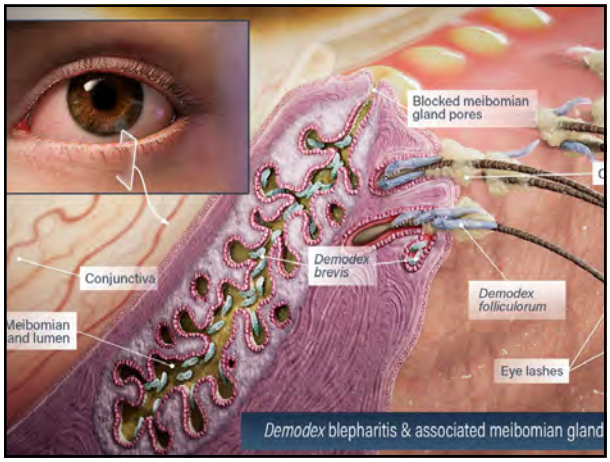

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Prevalence

- Ye et al, 2253 young males in Fujian province, China
  - 20.73% overall prevalence
  - Higher incidence in higher socioeconomic status
  - Not related to overall hygiene


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Demodex and chalazia in pediatric population

- **Huang et al**
- **446 children with chalazia vs 50 controls**
- **Demodex found in 53% of patients with chalazia**
- **0 found in controls**
- **Associated with recurrent / multiple chalazia**

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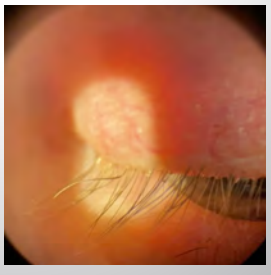
Demodex

- Two species affect the eye
  - *Demodex folliculorum* ~0.3 to 0.4 mm in length, found in clusters around the lash root and lash follicle, where it feeds on sebum and follicular epithelial cells
  - *Demodex brevis* is shorter, more solitary, and prefers the meibomian glands.
- Mites ~2 weeks to mature from the egg to the larval stage, with an overall life span of up to 3 weeks
- Both species are translucent, elongated microscopic mites with four pairs of short, clawed legs[1]



Fromstein SR, Harthan JS, Patel J, Opitz DL. Demodex blepharitis: clinical perspectives. Clin Optom (Auckl). 2019 Jul 4;10:57-63.

Video c/o E. Yeu, MD

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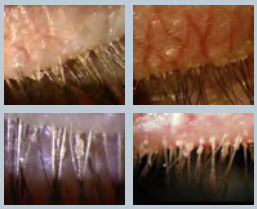
What is *Demodex* blepharitis (DB)?

- DB is a common eyelid margin disease caused by an overgrowth of *Demodex* mites and characterized by collarettes, eyelid redness, inflammation, and ocular irritation.[1,2]



References: 1. Fromstein SR et al. Clin Optom (Auckl). 2018;10:57-63. 2. Rhee MK et al. Eye Contact Lens. 2023;49(8):311-318.

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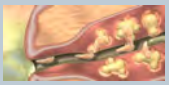
DEMODEX BLEPHARITIS | Mechanisms of Disease

Image courtesy of Laura M. Periman, MD; used with permission.



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]

1Data on file. Images courtesy of Laura M. Periman, MD; 2022. 2. Zhang AC et al. *Ophthalmic Physiol Opt.* 2020;40(4):388-402. 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. 8. Gao H et al. *Transl Vis Sci Technol.* 2021;10(14):6. 9. Tarkowski W et al. *Biomed Res Int.* 2015;259109.

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CLINICAL MANIFESTATIONS OF *DEMODEX* BLEPHARITIS

Disorders of Eyelashes[1,2]

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

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

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.* 2014;25(4):295-300.

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Demodex blepharitis (DB) is highly prevalent, but underdiagnosed[1,2]

- DB affects ~58% of eye care patients in the US[1]
  - That's approximately 25 million patients[2]

~56% (n=245/440) of patients with **cataracts have DB**[1,*]

60% (n=135/225) of patients **treated for dry eye also have DB**[1,*]

~93% (n=26/28) of patients with **soft contact lens intolerance were found to have *Demodex***[3,†]

References: 1. Trattler W et al. Clin Ophthalmol. 2022;16:1153-1164. **2.** O'Dell L et al. Clin Ophthalmol. 2022;16:2979-2987. **3.** Tarkowski W et al. Biomed Res Int. 2015;2015:259109.

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2/3 of blepharitis cases are associated with *Demodex* mites[1]

The number of mites correlates with:

- symptom severity
- density/severity of collarettes

References: 1. Trattler W et al. Clin Ophthalmol. 2022;16:1153-1164.

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KeySigns and Symptoms of DB

- **Itching** *most common symptom
- Dry eyes
- Missing/misdirected eyelashes
- Lid margin inflammation
- Sensitivity to light
- Blurred vision

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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.

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. Kromenaker SR et al. Clin Optom (Auckl). 2018;10:57-62. 4. Bitton E et al. Clinical and Experimental Optometry. 2021;104(3):286-294. 5. Kheirkhah A et al. Int J Ophthalmol. 2017;10(1):112-117. & Data on file. Image courtesy of Inder Paul Singh, MD, 2022.

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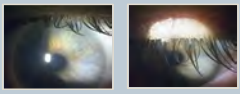
DEMODEX BLEPHARITIS CAN BE DIAGNOSED DURING SLIT LAMP EXAMINATION

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.

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. Kromenaker SR et al. Clin Optom (Auckl). 2018;10:57-62. 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.

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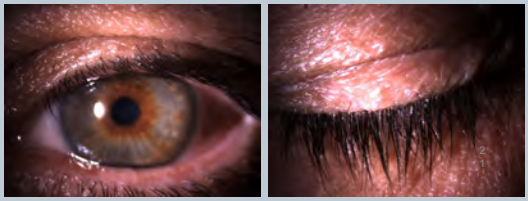
Diagnosing *Demodex* blepharitis (DB) is as simple as having your patients look down[1]



Images c/o Marc Bloomenstein, OD, FAAO

Reference: 1. Trattler W et al. Clin Ophthalmol. 2022;16:1153-1164.

21

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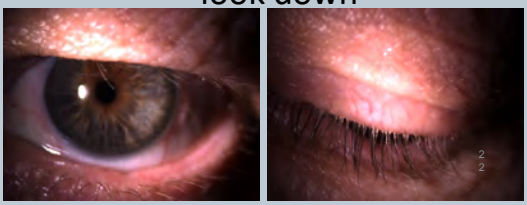

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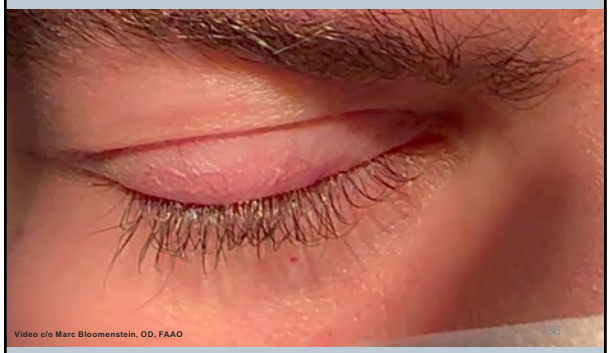

Video c/o Marc Bloomenstein, OD, FAAO

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Lid health directly impacts the ocular surface examples of demodex blepharitis and conjunctival/corneal disease

References: **1.** Amescua G, Akpek EK, Farid M, et al. Blepharitis preferred practice pattern®. *Ophthalmology.* 2019;126(1):56-93. **2.** Putnam CM. Diagnosis and management of blepharitis: an optometrist's perspective. *Clin Optom (Auckl).* 2016;8:71-78. **3.** Hossain P, Konstantopoulos A. Blepharitis: remains a diagnostic enigma. A role for tea tree oil shampoo? *Eye (Lond).* 2015;29(12):1520-1521.

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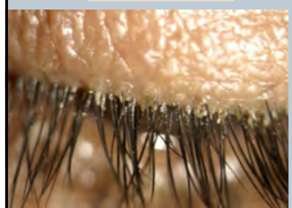
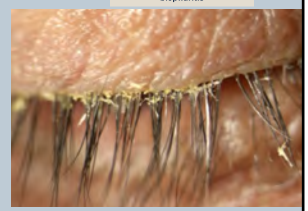
Mixed blepharitis presentation

Collarettes, and
Oily, Waxy scaling →
Seborrheic blepharitis



Collarettes, and
flaky debris = "scurf" →
Stapholococcal (squamous) blepharitis



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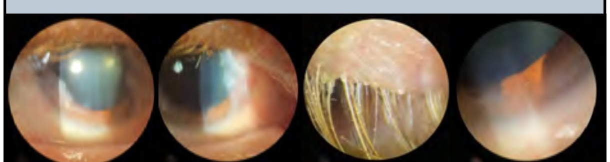
Demodex Blepharitis & Clinical Associations

- Also leads to **lid margin erythema, lid edema, eyelash misalignment or loss, recurrent chalazia** and, more rarely, **primary and recurrent pterygia, peripheral corneal vascularization, phlyctenule-like lesions** and **corneal opacity**[5]
- Other inflammatory diseases, such as **rosacea**, and **blepharokeratitis** and **blepharoconjunctivitis.**[6]



5. Zhang XB, Ding YH, He W. *Int J Ophthalmol* 2018;11:589-592. 6. Fromstein SR, Harthan JS, Patel J, et al. *Clin Optom (Auckl)* 2018;10:57-63.

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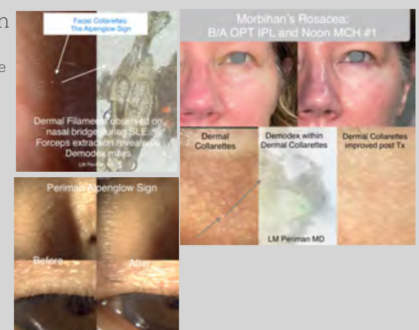
The Alpenglow Sign

Look at the nasal bridge

- Rapid clinical exam finding to pick up cases of suspected demodex in patients with excellent lid hygiene
- ASCRS 2024, ARVO 2024



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Explaining the DB Diagnosis to Patients

- There's a common misconception among patients that it's somehow their fault or caused by poor hygiene
- Patients don't always understand how the mites cause problems
- Many patients worry that the treatment process will be challenging.

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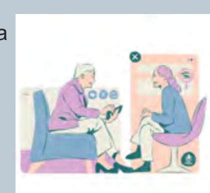
Keys Points when Delivering the DB Diagnosis to Patients

1. DB is a prevalent condition and not a reflection of personal negligence.[1-3]
2. The condition results from an increase in tiny mites that can harm the eyelids.[1,4,5]
3. Treatment is straightforward and effective.[6]



References: 1. Trattler W et al. Clin Ophthalmol. 2022;16:1153-1164. **2.** O'Dell L et al. Clin Ophthalmol. 2022;16:2979-2987. **3.** Liu J et al. Curr Opin Allergy Clin Immunol. 2010;10(5):505-510. **4.** Gao YY et al. Invest Ophthalmol Vis Sci. 2005;46(9):3089-3094. **5.** Fromstein SR et al. Clin Optom (Auckl). 2018;10:57-63. **6.** XDEMVY [prescribing information]. Tarsus Pharmaceuticals, Inc; 2023.

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Common Treatments for *Demodex* Blepharitis

At-Home

- Tea tree oil
- Lid wipes
- Topical ivermectin cream
- Cleansers containing hypochlorous acid
- Lid scrubs
- Antibiotics

In-Office

- Intense pulsed light therapy
- Microblepharoexfoliation

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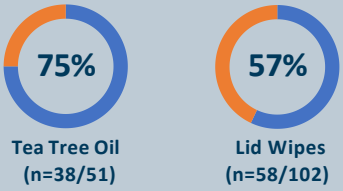
Tea Tree Oil and Lid Wipes Manage the Collarettes but Aren't Treating the Root Cause



Reference: 1. Trattler W et al. Clin Ophthalmol. 2022;16:1153-1164.

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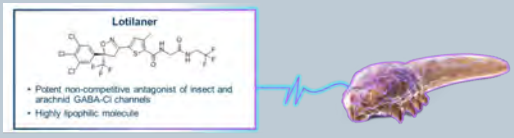
Lotilaner ophthalmic solution,0.25%

- The first and only FDA-approved treatment for *Demodex* blepharitis (July 2023)
- Paralyzes and eradicates *Demodex* mites by selectively inhibiting parasite-specific GABA-Cl channels



Reference: Tarsus Pharmaceuticals, Inc; 2023.

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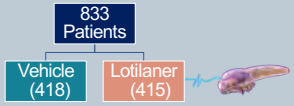
Studies toKnow: SATURN-1and SATURN-2

- Two 6-week, randomized, multicenter, double-masked, vehicle-controlled studies



- Patients were randomized to either lotilaner or vehicle at a 1:1 ratio, dosed twice daily in each eye

References: 1. Yeu E, et al. Cornea. 2023 Apr 1;42(4):435-43. 2. Gaddie IB, et al. Ophthalmology. 2023 Oct 1;130(10):1015-23. 3. Sadri, E. Castillo, RM, and Jalalat, P. Presented at ASCRS 2023; May 5-8, 2023; San Diego, CA.

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SATURN-1 and SATURN-2 Study Results

1. Collarette Reduction (≤2 collarettes)
   - 50% compared with 10% vehicle
2. Mite Eradication (0 mites/lash)
   - 60% compared with 16% vehicle
3. Erythema Cure (Grade 0)
   - 25% compared with 8% vehicle
4. Collarette Reduction (≤10 collarettes)
   - 85% compared with 28% vehicle

References: 1. Yeu E, et al. Cornea. 2023 Apr 1;42(4):435-43. 2. Gaddie IB, et al. Ophthalmology. 2023 Oct 1;130(10):1015-23. 3. Sadri, E. Castillo, RM, and Jalalat, P. Presented at ASCRS 2023; May 5-8, 2023; San Diego, CA.

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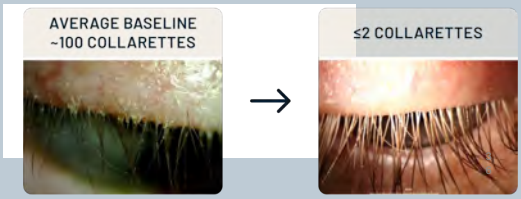

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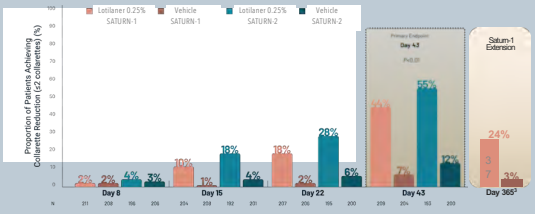
1. Collarette Reduction (≤2 collarettes)
- 50% compared with 10% vehicle



References: 1. Yeu E, et al. Cornea. 2023 Apr 1;42(4):435-43. **2.** Gaddie IB, et al. Ophthalmology. 2023 Oct 1;130(10):1015-23. **3.** Sadri, E. Castillo, RM, and Jalalat, P. Presented at ASCRS 2023; May 5-8, 2023; San Diego, CA.

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SATURN-1 and SATURN-2 Study Results

2. Mite Eradication (0 mites/lash)
- 60% compared with 16% vehicle

References: 1. Yeu E, et al. Cornea. 2023 Apr 1;42(4):435-43. **2.** Gaddie IB, et al. Ophthalmology. 2023 Oct 1;130(10):1015-23. **3.** Sadri, E. Castillo, RM, and Jalalat, P. Presented at ASCRS 2023; May 5-8, 2023; San Diego, CA.

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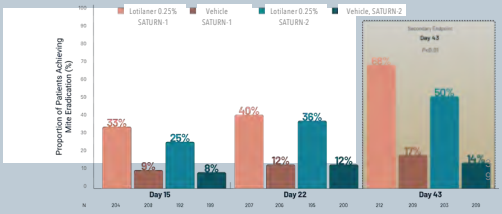

References: 1. Yeu E, et al. Cornea. 2023 Apr 1;42(4):435-43. **2.** Gaddie IB, et al. Ophthalmology. 2023 Oct 1;130(10):1015-23. **3.** Sadri, E. Castillo, RM, and Jalalat, P. Presented at ASCRS 2023; May 5-8, 2023; San Diego, CA.

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SATURN-1 and SATURN-2 Study Results

3. Erythema Cure (Grade 0)
- 25% compared with 8% vehicle

References: 1. Yeu E, et al. Cornea. 2023 Apr 1;42(4):435-43. **2.** Gaddie IB, et al. Ophthalmology. 2023 Oct 1;130(10):1015-23. **3.** Sadri, E. Castillo, RM, and Jalalat, P. Presented at ASCRS 2023; May 5-8, 2023; San Diego, CA.

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SATURN-1 and SATURN-2 Study Results

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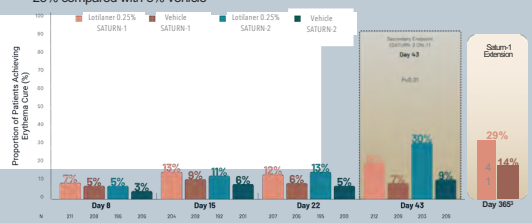

References: 1. Yeu E, et al. Cornea. 2023 Apr 1;42(4):435-43. **2.** Gaddie IB, et al. Ophthalmology. 2023 Oct 1;130(10):1015-23. **3.** Sadri, E. Castillo, RM, and Jalalat, P. Presented at ASCRS 2023; May 5-8, 2023; San Diego, CA.

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SATURN-1 and SATURN-2 Study Results

4. Collarette Reduction (≤10 collarettes)
- 85% compared with 28% vehicle

References: 1. Yeu E, et al. Cornea. 2023 Apr 1;42(4):435-43. **2.** Gaddie IB, et al. Ophthalmology. 2023 Oct 1;130(10):1015-23. **3.** Sadri, E. Castillo, RM, and Jalalat, P. Presented at ASCRS 2023; May 5-8, 2023; San Diego, CA.

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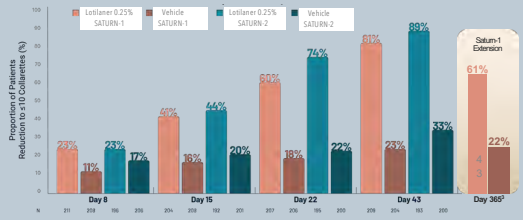
SATURN-1 and SATURN-2 Study Results

4. Collarette Reduction (≤10 collarettes)
   - 85% compared with 28% vehicle



References: 1. Yeu E, et al. Cornea. 2023 Apr 1;42(4):435-43. **2.** Gaddie IB, et al. Ophthalmology. 2023 Oct 1;130(10):1015-23. **3.** Sadri, E. Castillo, RM, and Jalalat, P. Presented at ASCRS 2023; May 5-8, 2023; San Diego, CA.

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Patients Tolerate Lotilaner Drops

of patients in both trials in the lotilaner and vehicle groups reported the drop as neutral to very comfortable

References: 1. Yeu E, et al. Cornea. 2023 Apr 1;42(4):435-43. **2.** Gaddie IB, et al. Ophthalmology. 2023 Oct 1;130(10):1015-23. **3.** Sadri, E. Castillo, RM, and Jalalat, P. Presented at ASCRS 2023; May 5-8, 2023; San Diego, CA.

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Key Study Data – ERSA and RHEA

ERSA and RHEA were two separate, randomized pilot studies evaluating the safety and efficacy of lotilaner ophthalmic solution 0.25% and vehicle for the **treatment of DB with MGD**. Eligibility criteria and endpoints for the ERSA and RHEA studies were identical.

ERSA: Collarette grade reduction and responder rate at day 43

Reduction to ≤2 collarettes

of patients treated with lotilaner 0.25% (n=20)

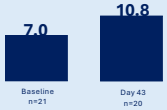
Reduction to ≤10 collarettes

of patients treated with lotilaner 0.25% (n=20)

RHEA: At Day 43, vehicle (n=10) did not show statistically significant improvement in mean collarette grade compared with baseline ($P>.1$)

ERSA: Patients treated saw ~54% improvement in mean meibomian glands yielding liquid secretion (MGYLS) at day 43 compared with baseline

Number of expressible glands



RHEA: At Day 43, vehicle (n=10) did not show statistically significant improvement in number of MGYLS compared with baseline ($P>.1$)

Data on file, Tarsus Pharmaceuticals, Inc

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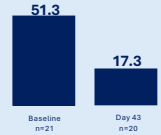
Key Study Data – Patient Reported Outcomes

Fluctuating Vision
~59% improvement

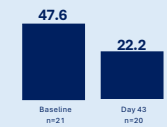
RHEA: At day 43, vehicle (n=10) did not show statistically significant improvement in patient-reported fluctuating vision compared with baseline ($P>.1$)

Itching
~66% improvement



RHEA: At day 43, vehicle (n=10) did not show statistically significant improvement in patient-reported itching compared with baseline ($P>.1$)

Redness
~53% improvement



RHEA: At day 43, vehicle (n=10) did not show statistically significant improvement in patient-reported redness compared with baseline ($P>.1$)

Based on 100-point visual analog scale (VAS)

Data on file, Tarsus Pharmaceuticals, Inc

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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.

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Thank you

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