

On behalf of Vision Expo, we sincerely thank you for being with us this year.

**Reminder to Complete Your Session Evaluations!**

Please be sure to complete your digital session evaluations for each course you attended! Your feedback is important to us as our Education Planning Committee considers content and speakers for future meetings to provide you with the best education possible.



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disclosures

last 12 months	last 12 months	last 12 months
allergan/abbvie sun pharma tarsus pharma Ocuphire Bruder Scope	sydnexis eyenovia bio laboratoires Thea visus/tenpoint therapeutics Harrow	aperta biosciences astareal, inc. azura ophthalmics aldehyra therapeutics Vyluma Lenz

\*All relevant relationships have been mitigated.\*

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Drugs of the future

milton m. hom  
eyemage@mminternet.com  
Azusa, CA

715

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Drugs of the future

milton m. hom  
eyemage@mminternet.com  
Azusa, CA

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Where will the next blockbuster drug come from?

5

Three frontiers

Dry eye & neuroinflammation

Myopia control

Demodex & blepharitis

6

Dry eye

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Neurology is the new dry eye frontier

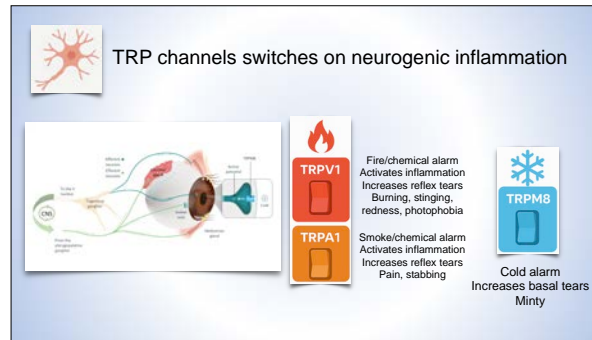
8

Company	Drug	MOA	Indication	FDA
Alcon	Acotremon	TRP channels Cold receptors	Dry eye	Approved
Aldehyra/ AbbVie	Reproxalap	RASP trap TRP channels	Dry eye/ Allergic conjunctivitis	Phase 3
Okyo	Urcosimod	Anti- inflammatory Neurogenic inflammation	Dry eye/ Neuropathic pain	Phase 2

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	Immune Inflammation	Neurogenic Inflammation
Signals	Cytokines TNF- $\alpha$ , IL-6, prostaglandins	Neuropeptides Substance P, CGRP, VIP, neurokinin A
Pathway	Immune cells	"Alarm response"
Time course	Gradual over days to weeks	Rapid, sudden

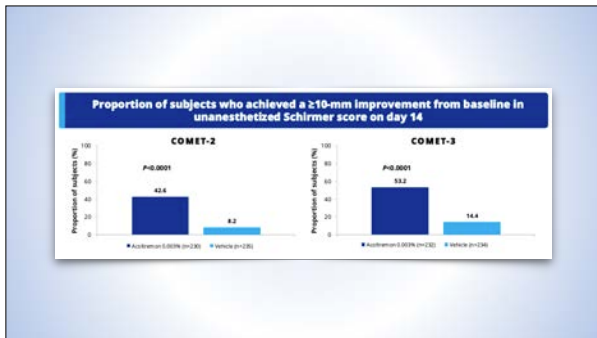
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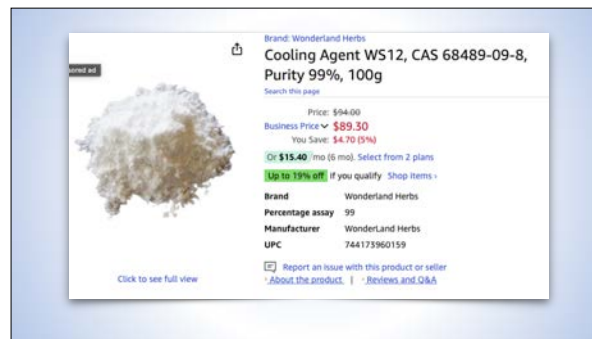
**Dry eye**

Drug	Good Rx
Cequa	\$645.80
Restasis	\$660.30
Xiidra	732.59
Meibo	\$853.21
Tryptyr	\$900

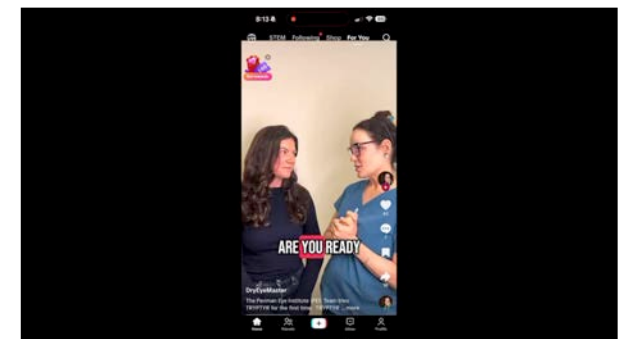
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Company	Drug	MOA	Indication	FDA
Aicon	Acoltremom	TRP channels Cold receptors	Dry eye	Approved
Aldeyra/ AbbVie	Reproxalap	RASP trap TRP channels	Dry eye/ Allergic conjunctivitis	Phase 3
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## Reproxalap

Oxidative stress by RASPs (biological rust)  
Causes misfiring and sparks  
Activates neurogenic inflammation

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## Reproxalap binds RASPs and repairs and protects nerves

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## Urocosimod

Neurogenic  
Calms fibers  
Immune  
Reduces cytokines

Neurogenic:  
Quiets down nociceptors  
Stops/slows release of neuropeptides

Immune:  
Stops/slows macrophage, dendritic and T-cells cytokine release

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## Summary

- **Acoltremom** = cools nerves & tear stimulation
- **Reproxalap** = "biological rust" protection → less nerve misfires & neurogenic inflammation
- **Urocosimod** = nerve calming + immune-based anti-inflammatory

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## Central vs peripheral

25

## Alterations in nerve morphology

*uchealth*

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## Neuropathic pain & dry eye

<https://www.apma.org/neuromas>

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## NASA Study



1000 patients  
 Proparacaine Challenge Test  
 Participants diagnosed with neuropathic corneal pain with ocular surface discomfort  
 Establish the **prevalence** of neuropathic corneal pain in patients with ocular surface discomfort

<https://clinicaltrials.gov/ct2/show/NCT04838223>

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## Proparacaine challenge

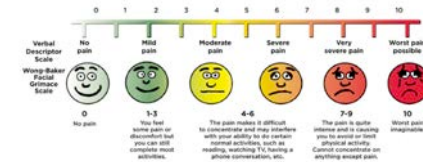
1. Baseline pain reading
2. Add drop anesthesia (proparacaine)
3. Wait 90 seconds
4. Proparacaine pain reading

Dieckmann G, Goyal S, Hamrah P. Neuropathic corneal pain: approaches for management. *Ophthalmology*. 2017;124(11 Suppl):S84-S87.

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## Central vs peripheral

Appendix IV: Visual Analogue Scale Questionnaire



Dieckmann G, Goyal S, Hamrah P. Neuropathic Corneal Pain: Approaches for Management. *Ophthalmology*. 2017;124(11S):S84-S87. doi:10.1016/j.optha.2017.08.004

30

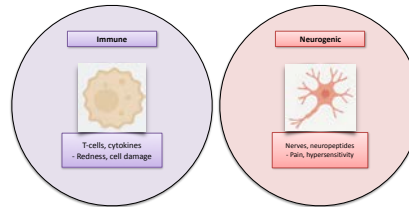
## Neuropathic pain & dry eye

“in our study, 27 out of 33 (81.82%) patients showed mixed sensitization”

Kim J, Yoon HJ, You IO, Ko HY, Yoon KC. Clinical characteristics of dry eye with ocular neuropathic pain features: comparison according to the types of sensitization based on the Ocular Pain Assessment Survey. *BMC Ophthalmol*. 2020 Nov 18;20(1):495. doi: 10.1186/s12886-020-01733-1. PMID: 33208127; PMCID: PMC7672944.

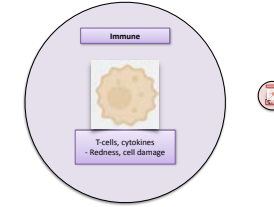
31

## Immune-Mediated vs Neurogenic Inflammation



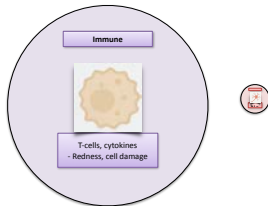
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## Immune-Mediated vs Neurogenic Inflammation



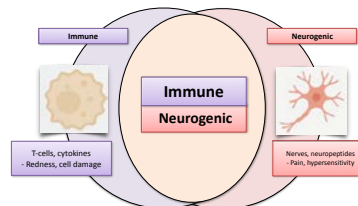
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## Immune-Mediated vs Neurogenic Inflammation



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## Immune-Mediated vs Neurogenic Inflammation



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## New generation of dry eye drugs

**Major Shift**

💧 Surface lubrication  
 classic inflammation → 🌡️ To nerve inflammation

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## Thoughts & Pearls

Dry eye: Neurology is the new dry eye  
 The new drugs treat the nerves  
 There are 2 types of inflammation in dry eye: classic immune based and neurogenic.  
 Most dry eye has both types  
 Consider combos (immune + neurogenic)  
 Hypersensitive nerves - these drugs will hurt

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## Myopia

## Myopia

“almost 1 billion people will have high myopia, suggesting an alarming increase of prevalence globally.”

Wu PC, Chuang MN, Choi J, Chen H, Wu G, Ohno-Matsui K, Jonas JB, Cheung CMG. Update in myopia and treatment strategy of atropine use in myopia control. Eye (Lond). 2019 Jan;33(1):3-13. doi: 10.1038/s41433-018-0139-7. Epub 2018 Jun 11. PMID: 29891900; PMCID: PMC6328548.

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## Myopia

“studies have found that the lack of outdoor exposure to sunlight and limited physical activities can trigger [myopia]”

Kevin Chan

Chan K, Fischer A, Goldberg L, Lazar I. Today's Perspectives on Myopia Management. Modern Optometry. 2024 July/Aug.  
 He X, Sankaridurg P, Wang J, et al. Time outdoors in reducing myopia. Ophthalmol. 2022;129(11):1245-1254.

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## Myopia

“For better or worse, screen time is here to stay. I educate parents to encourage their children to spend as much time outdoors as possible, as this can delay the onset of myopia”

Andrew Fischer

Chan K, Fischer A, Goldberg L, Lazar I. Today's Perspectives on Myopia Management. Modern Optometry. 2024 July/Aug.  
 He X, Sankaridurg P, Wang J, et al. Time outdoors in reducing myopia. Ophthalmol. 2022;129(11):1245-1254.

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Outdoor time = Nature's atropine  
 Encourage outdoor play

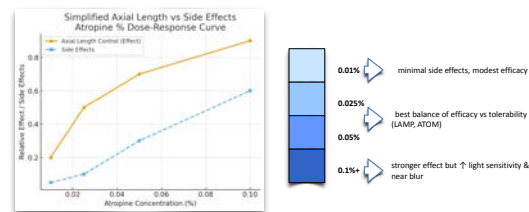
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### Selected Clinical trials

	Route	Ages	Length	% atropine
Vyluma (Nevakar)	Drop	3-17y	3y	0.01% 0.02%
Eyenovia	Optejet	3-12y	3y	0.1% 0.01%
Sydnexis	Drop	3-14y	3y+1y	0.01%

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### Atropine % Gradient: Axial Length vs Side Effects



References:  
 1. Chia A, Lu QS, Tan D. Five-Year Clinical Trial on Atropine for the Treatment of Myopia 2: Myopia Control with Atropine 0.01%. Ophthalmology. 2016;123(2):381-8.  
 2. Yuan JC, Li FF, Zhang X, Tang SM, Yu SHK, Kam KW, et al. LAMP Study: 3-Year Results. Ophthalmology. 2020;127(7):910-918.  
 3. Wu PC, Choy BN, Chiu MY, Chen LJ, Tan Q, Kang MT, et al. Update in myopia and atropine use. Eye (Lond). 2019;33(1):3-13.

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When to start?

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### International Myopia Institute (IMI)

Age (years)	Refraction
6	+0.75 D or less
7 to 8	+0.50 or less
9 to 10	+0.25 D or less
11	emmetropia

Gifford KL, Richdale K, Kang P, Aller TA, Lam CS, Liu YM, Michaud L, Mulder J, Orr JB, Rose KA, Saunders KJ, Seidel D, Tideman JWL, Sankaridurg P. IMI - Clinical Management Guidelines Report. Invest Ophthalmol Vis Sci. 2019 Feb 28;60(3):M184-M203. doi: 10.1167/iov.18-25977. PMID: 30817832.

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### Pre-Myopes

≡ < +0.75 @ 6-7yo is high risk

- Independent of family history, ethnicity and other optical and environmental factors.<sup>7</sup>
- Fastest change in refraction is year before onset.
- Watch for eso and lag of accommodation

Jones-Jordan LA, Sinnott LT, Manny RE, Cotter SA, Kleinstein RN, Mutti DO, Twelker JD, Zadnik K. Ethnicity cLEO, Refractive Error Study Group. Early Childhood Refractive Error and Parental History of Myopia as Predictors of Myopia. Invest Ophthalmol Vis Sci. 2010;51(11):115-21.

47

### Myopia

“The decision to initiate myopia management is therefore very simple—initiate treatment when myopia is first diagnosed.”

Daniel Tillia

Tillia D. When to Initiate Myopia Management Intervention and When to Stop. Review of Myopia Management. <https://reviewofimm.com/when-to-initiate-myopia-management-intervention-and-when-to-stop/>

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### Spectacle Myopia Control

	Tech	Duration	% Reduction
MiyoSight (Hoya)	Defocus incorporated multiple segments (DIMS)	2y	Diopters: 52% Axial: 62%
Stellest (Essilor)	Highly aspherical lenslet target (HALT)	2y	Diopters: 67% Axial: 60%
SightGlass	Diffusion optics technology (DOT)	1y (36m)	Diopters: 74%/59% Axial: 50%/33%

Lam C.S.Y., Tang W.C., The D.Y., Lee R.P.K., Chun R.K.M., Hasegawa K, et al. Defocus Incorporated Multiple Segments (DIMS) spectacle lenses slow myopia progression: a 2-year randomised clinical trial. Br J Ophthalmol. 2019; Black K. Essilor's Reveals Results of "Game-changing" Stellest Lens for Myopia <https://www.mivision.com.au/2020/09/essilor-reveals-results-of-game-changing-stellest-lens-for-myopia/> mivision. 2020; Rapson J, Chung C, Young G, et al. Control of myopia using diffusion optics spectacle lenses: 12-month results of a randomised controlled, efficacy and safety study (CYPRESS) British Journal of Ophthalmology Published Online First: 01 September 2022.

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### Suggested 1st choice interventions

Brianna Rhue Milton Horn

Age	PL to +0.75D	-0.50 to -1.00D	-1.25 to -2.00D	-2.00D+
6y	Lifestyle Prophylactic Atropine*	Atropine* MiSight* Cylinder: Biofinity Toric MF D Lens +2.50	MiSight* Ortho-K*	MiSight* Ortho-K* ? Combo Therapy
7-8y	PL to +0.50D	-0.50 to -1.00D	-1.25 to -2.00D	-2.00D+
	Lifestyle Prophylactic Atropine*	Atropine* MiSight	MiSight Ortho-K	MiSight Ortho-K
9-10y	PL to +0.25D	-0.50 to -1.00D	-1.25 to -2.00D	-2.00D+
	Lifestyle	Atropine* MiSight	MiSight Ortho-K	MiSight Ortho-K
11y	emmetropia	-0.50 to -1.00D	-1.25 to -2.00D	-2.00D+
	Lifestyle	Atropine* MiSight	MiSight Ortho-K	MiSight w/Ortho-K

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### Grid

740

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### Suggested 1st choice interventions

Brianna Rhue Milton Horn

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6y	Lifestyle Prophylactic Atropine*	Atropine* MiSight* Cylinder: Biofinity Toric MF D Lens +2.50	MiSight* Ortho-K*	MiSight* Ortho-K* ? Combo Therapy
7-8y	PL to +0.50D	-0.50 to -1.00D	-1.25 to -2.00D	-2.00D+
	Lifestyle Prophylactic Atropine*	Atropine* MiSight	MiSight Ortho-K	MiSight Ortho-K
9-10y	PL to +0.25D	-0.50 to -1.00D	-1.25 to -2.00D	-2.00D+
	Lifestyle	Atropine* MiSight	MiSight Ortho-K	MiSight Ortho-K
11y	emmetropia	-0.50 to -1.00D	-1.25 to -2.00D	-2.00D+
	Lifestyle	Atropine* MiSight	MiSight Ortho-K	MiSight w/Ortho-K

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### Thoughts & Pearls

Myopia: Earlier the better  
Main challenge is convincing the parents  
Race against time  
Sydnexis will be a starter drug  
Atropine works best with other therapies/interventions  
Ortho-K has gotten a lot easier

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### Demodex

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## The basics

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## The Good Mites

Reports of Demodex mites were recorded as early as 1841

Demodex mites exist in every adult over 70 years old.

Symptoms: ocular dryness, severe itching, burning, foreign body sensation, crusting and redness of the lid margin, and blurry vision.

<https://www.rosacea.org/basics/the-ecology-of-your-face-demodex-rosacea-and-you>  
Hom MM, Mastrola KM, Schachter SE. Demodex. Optom Vis Sci. 2013 Jul;90(7):e198-205.

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## The Good Mites

"the willingness of the mites to reproduce is great"

"Consider the scrambling of this...[demodex] mob while the [human] host sleeps: males seeking, finding, breeding females; [pregnant] females seeking new follicles; inhabitants of follicles sweeping feces outside."

Coston TO. Demodex folliculorum blepharitis. Trans Am Ophthalmol Soc. 1967;65:361-92. PMID: 4229846; PMCID: PMC1310279.  
Hom MM, Mastrola KM, Schachter SE. Demodex. Optom Vis Sci. 2013 Jul;90(7):e198-205.

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Microscopic arthropods, *Demodex folliculorum*, live on all mammals especially their faces and cause no harm under most circumstances.

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## Drugs

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## Demodex

## Demodex Blepharitis

## Blepharitis

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### Selected Clinical trials

	Form	Dosing	Proposed Indication
Tarsus (lotilaner)	Drop	BID	Demodex/ MGD
Aperta (Spinosod)	ung	N/A	Blepharitis Demodex
Azura (selenium sulfide)	ung	2 x week	Blepharitis MGD/CL dryness
(Ivermectin)	Topical	Weekly	Demodex
Glaukos	Topical	?	Demodex

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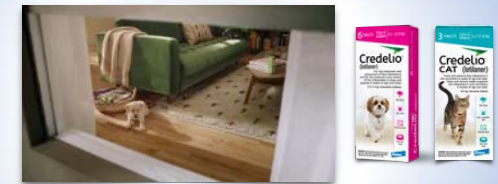
### Lotilaner (Xdemvy)



Kuntz, E.A., Kammanadiminti, S. Safety evaluation of lotilaner in dogs after oral administration as flavoured chewable tablets (Credelio™). Parasites Vectors 10, 538 (2017).  
<https://www.credelio.com/about-credelio/side-effects>  
[https://www.ispot.tv/ad/lx\\_l/credelio-tiny-defender-of-dogs](https://www.ispot.tv/ad/lx_l/credelio-tiny-defender-of-dogs)

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### Lotilaner (Xdemvy)



Kuntz, E.A., Kammanadiminti, S. Safety evaluation of lotilaner in dogs after oral administration as flavoured chewable tablets (Credelio™). Parasites Vectors 10, 538 (2017).  
<https://www.credelio.com/about-credelio/side-effects>  
[https://www.ispot.tv/ad/lx\\_l/credelio-tiny-defender-of-dogs](https://www.ispot.tv/ad/lx_l/credelio-tiny-defender-of-dogs)

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### Lotilaner (Xdemvy)

- FDA-approved (2023)
- High mite eradication (50–68%)
- First-in-class, vehicle-controlled data



Kuntz, E.A., Kammanadiminti, S. Safety evaluation of lotilaner in dogs after oral administration as flavoured chewable tablets (Credelio™). Parasites Vectors 10, 538 (2017). <https://doi.org/10.1186/s13071-017-2468-y>  
<https://www.credelio.com/about-credelio/side-effects>

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### Selected Clinical trials

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Azura (selenium sulfide)	ung	2 x week	Blepharitis MGD/CL dryness
(Ivermectin)	Topical	Weekly	Demodex
Glaukos	Topical	?	Demodex

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### Spinosad



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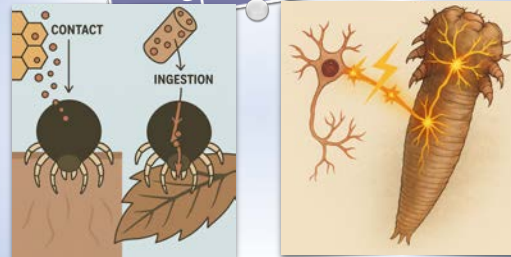
### DEFENSE AGAINST INSECTS

Soil bacteria compete for space and nutrients. By releasing spinosyns (spinosad), *S. spinosa* creates a chemical shield that kills or deters insects that might eat or disturb the organic matter it lives in.



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### Spinosad



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### Spinosad



Head lice



Bug spray

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### Selected Clinical trials

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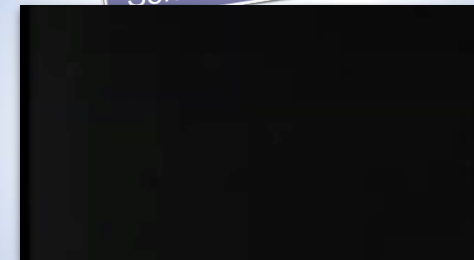
### Selenium sulfide

From Dandruff Shampoo to Dry Eye Relief?



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### Selenium sulfide



<https://www.youtube.com/watch?v=H5WtVUpqSg>

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**Selenium sulfide**




**Eyelid (MGD)**

Problem:  
- Excess keratin + thick oil → blocked glands

Selenium Action:  
- Slows skin turnover  
- Loosens debris  
- Opens ducts  
- Reduces fungus

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**Selenium sulfide**



**Eyelid (MGD)**


Problem:  
- Excess keratin + thick oil → blocked glands

Selenium Action:  
- Slows skin turnover  
- Loosens debris  
- Opens ducts  
- Reduces fungus



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**Selenium sulfide**



**Eyelid (MGD)**


Problem:  
- Excess keratin + thick oil → blocked glands

Selenium Action:  
- Slows skin turnover  
- Loosens debris  
- Opens ducts  
- Reduces fungus



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**Selenium sulfide**



**Eyelid (MGD)**

Problem:  
- Excess keratin + thick oil → blocked glands

Selenium Action:  
- Slows skin turnover  
- Loosens debris  
- Opens ducts  
- Reduces fungus

Wang L, Deng Y. Malassezia species may play potential roles in the pathogenesis of meibomian gland dysfunction. Med Hypotheses. 2020 Nov;144:110137

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**Selenium sulfide**

**CL Comfort Performance?**

“Twice weekly use of a topical ointment...selenium sulfide...appears to improve Meibomian gland[s]...by more than 30% in symptomatic CL wearers after...6 weeks”

<https://azuraophthalmics.com/scientific-meetings>

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First CL discomfort drug  
Remember: Comfort = tear film + glands + lens.  
Future drugs may blur the lines between blepharitis treatment and CL performance enhancers.

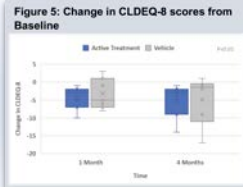


Figure 5: Change in CLDEQ-8 scores from Baseline

<https://azuraophthalmics.com/scientific-meetings>

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**Selected Clinical trials**

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(Ivermectin)	Topical	Weekly	Demodex
Glaukos	Topical	?	Demodex

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**Ivermectin**

- Weekly 1% cream application
- 15-minute contact time
- Less redness & swelling
- Less lid debris & cylindrical dandruff
- More patient comfort

Choi Y, Eom Y, Gyn Yoon E. Efficacy of topical ivermectin 1% in the treatment of Demodex blepharitis. Cornea. 2021; 00:1-8.

80

Q: Ivermectin was first developed for livestock. True or False?

**True** – Nobel Prize 2015 for global parasitic disease control.

81



amazon.com

82


Selected Clinical trials			
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(Ivermectin)	Topical	Weekly	Demodex
Glaukos	Topical	?	Demodex

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## Glaukos

Glaukos Atillaps patent

- Acetylcholinesterase [ACE] inhibitors causes mite paralysis
- Ex Physostigmine, demarcarium, ecthiophate
- Ciliary muscle effects:
- Miosis, browaches, accommodative spasm)



<https://patentimages.storage.googleapis.com/46/93/bb/fde8abe644b603/WO2019126541A1.pdf>

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## Mite Wars

- Lotilaner (Xdemvy) (Tarsus)**
  - FDA-approved (2023)
  - High mite eradication (50–68%)
  - Dog and cats drug
- Spinosad (Aperta)**
  - Soil bacterium-derived
  - Insect neurotoxin, used for lice & pests
  - Ointment in trials for Demodex blepharitis
- Selenium Sulfide (Azura)**
  - Twice-weekly ointment
  - Improves Meibomian gland function (>30% in CL wearers)
  - MGD + CL discomfort target
- Ivermectin**
  - Off-label weekly use
  - Anti-parasitic, improves comfort & debris
- Glaukos**
  - Anticholinesterase (ACE) Inhibitor - mite paralysis
  - Potential ciliary body risks (miosis, browache, accommodative spasm)

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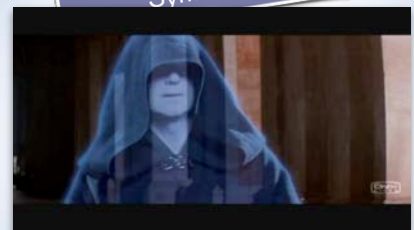
“Mite eradication was defined as a mite density of 0 mites/lash.”

Saturn 1: 67.9% achieved complete mite eradication

Saturn 2: 50% achieved complete mite eradication after 6 weeks

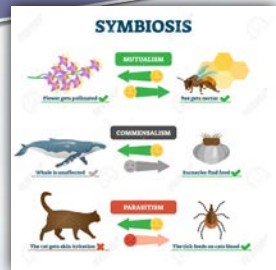
You E. Wirta DL, Karpecki P, Baba SN, Holdbrook M. Saturn 1 Study Group. Lotilaner Ophthalmic Solution, 0.25%, for the Treatment of Demodex Blepharitis: Results of a Prospective, Randomized, Vehicle-Controlled, Double-Masked, Parallel Trial (Saturn-1). *Cornea*. 2022 Apr 1;41(4):630-643.  
Sasaki E, Pasaw JD, Ciolino JB, Nijm L, Simmons B, Meyer J, Gackie B, Berry GJ, Holdbrook M, Baba SN, Jabbar P, You E. Long-Term Outcomes of 6-Week Treatment of Lotilaner Ophthalmic Solution, 0.25%, for Demodex Blepharitis: A Noninterventional Extension Study. *Cornea*. 2024 Nov 1;43(11):1959-1374. Gonzalez-Galinas R, You E, Holdbrook M, et al. Colarrete elimination and demodex mite eradication with topical lotilaner ophthalmic solution. *Ocul Pharmacol Ther*. 2021;37:479-484.

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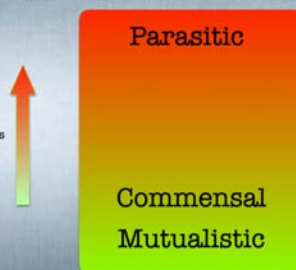
“Wipe them out...all of them”  
Star Wars: Episode 1 The Phantom Menace

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## Demodex relationships



Parasitic

Commensal  
Mutualistic

Signs and symptoms

Asymptomatic  
No visual signs

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Case: SH

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## Mite Attack

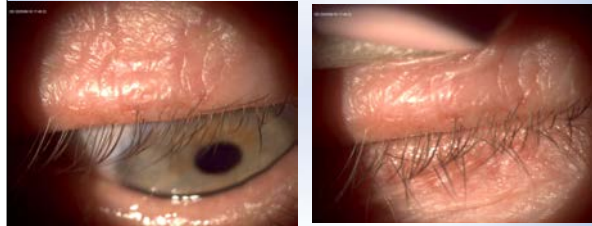
59-year-old female

CC: Eyelid itching and self-reported mite infestation

Patient believes she contracted mites while visiting her hospitalized husband. Presents with eyelid scabbing from excessive scrubbing to remove mites.

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## Mite Attack



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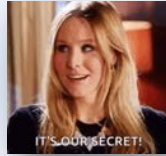
## Demodex Blepharitis vs Delusional Parasitosis



Matrosta K. CL  
Spectrum December 1  
2017

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## Ekbom syndrome



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## Ekbom syndrome

Delusional parasitosis  
Ekbohm syndrome  
Morgellons disease  
Delusional infestation [DI]  
Delusions of parasitosis [DOP]

Brownstone N, Howard J, Koo J. Management of delusions of parasitosis: an interview with experts in psychodermatology. *Int J Womens Dermatol.* 2022 Jul 8;8(3):e035

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## Ekbom syndrome

Matchbox signs  
Zip lock bag signs  
Self-referral  
Internet searches

Reich A, Kwiatkowska D, Pacan P (December 2019). "Delusions of parasitosis: an update". *Dermatol Ther (Heidelberg) (Review)*. 9 (4): 631-638.  
Koo J, Lebowitz A (December 2001). "Psycho dermatology: the mind and skin connection". *Am Fam Physician*. 64 (11): 1873-1878.  
Moriarty N, Alam M, Kalus A, O'Connor K (December 2019). "Current understanding and approach to delusional infestation". *Am. J. Med. (Review)*. 132 (12): 1401-1409.

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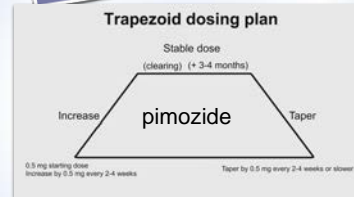
## Delusional parasitosis

"studies have demonstrated cortical and subcortical atrophy in DI [delusional infestation] patients"

Lai JB, Xu Z, Xu Y, Hu SH. Reframing delusional infestation: perspectives on unresolved puzzles. *Psychol Res Behav Manag.* 2018;11:425-432

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## Ekbom syndrome



Brownstone N, Howard J, Koo J. Management of delusions of parasitosis: an interview with experts in psychodermatology. *Int J Womens Dermatol.* 2022 Jul 8;8(3):e035

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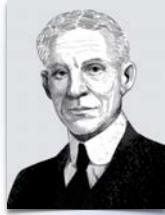
## Thoughts & Pearls

Demodex: Total eradication? Be kind to your mites  
Vast majority of blepharitis is demodex  
Do not use ivermectin and spinosad together (toxicity)  
Newer drugs work faster  
Presently, there are no drugs that treat CL discomfort  
Delusional parasitosis: Handle with care

Dunn ST, Hedges L, Sampson KE, Lai Y, Mahabir S, Balogh L, Lucason CW. Pharmacokinetic interaction of the antiparasitic agents ivermectin and spinosad in dogs. *Drug Metab Dispos.* 2011 May;39(5):789-95. doi: 10.1124/dmd.110.034827. Epub 2011 Feb 14. PMID: 21321059.

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“If you always do what you’ve  
always done, you’ll always get  
what you’ve always got.”  
—Henry Ford



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thank you!

milton m. hom  
eyemage@mmineternet.com

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