

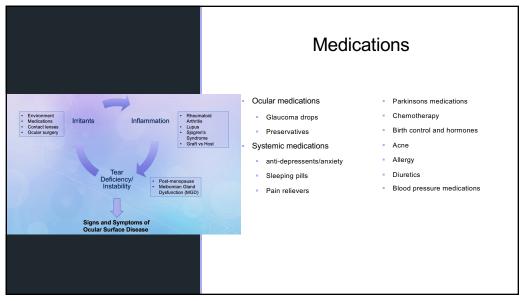
## US PREVALENCE OF DRY EYE DISEASE • Estimated >16 million patients have been diagnosed with DED¹ • Estimates ~33 million patients suffering from dry eye symptoms¹ • Almost all adults experience dry eye signs and symptoms DED is often underdiagnosed and undertreated² DED is often underdiagnosed and undertreated² DED is the most common reason for visits to eyecare practitioners (ECPs)³ - ~33% of patients present with complaints about dry eye¹ • Prevalence is projected to increase due to: - Aging population Increased screen time (computers and handheld devices) REFERENCES 1- France KF. Fidence M. Stimum ID, Schwamberg DA. Providence of Degreese by Eye Descent in the United States Among Adults April 18 Years and Older And Adults April



## Whole body Influence

- Graves Disease
- Thyroid eye disease
- Sleep apnea
- Diabetes
- Rheumatoid Arthrisis
- Sjogrens
- Lupus

- Chron's disease
- Rosacea
- Eczema
- Riley-Day syndrome
- Allergies
- Inflammatory disease



## Types of dry eye disease

## Evaporative dry eye

- Resulting from excessive tear evaporation
- Evaporation leading to Tear hyperosmolarity
- · Normally functioning lacrimal gland
- Eyelid related causes
- · Meibomian gland dysfunction
- Inadequate lid closure/blink related

## Aqueous deficient dry eye (ADDE)

- Resulting from from decreased tear secretion
- Hyper-evaporative state leading to tear hyperosmolarity

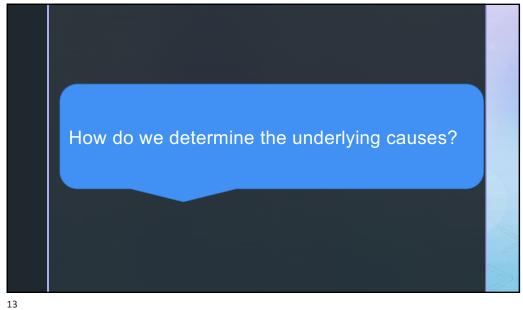
## Not mutually exclusive, it can be both!

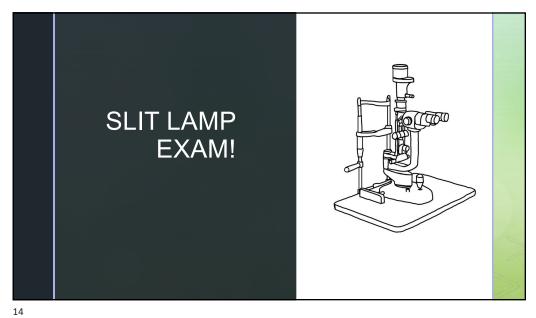
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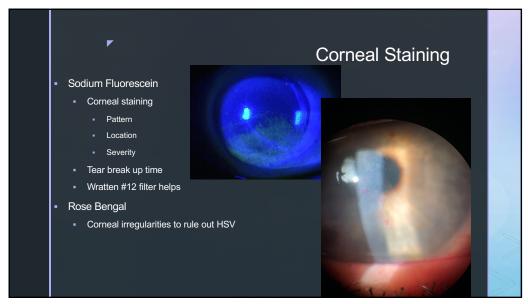
## Before they enter the room

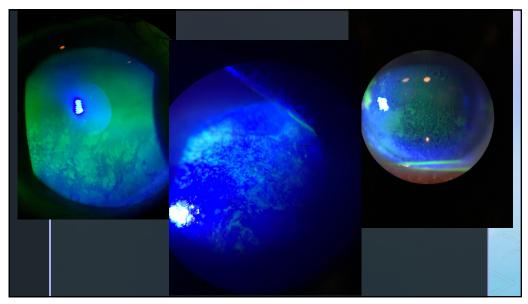
- Use your techs!
- Videos or materials in waiting room
- Emails and newsletters
- Questionnaires
  - SPEED
  - OSDI
- Multiple points of contact to start the discussion and engage the patient

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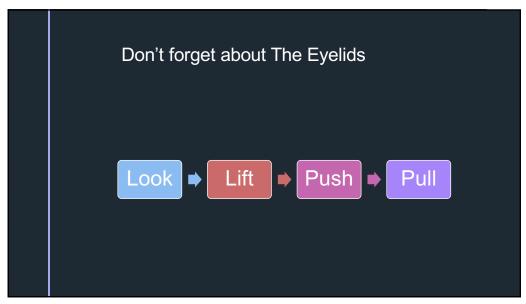


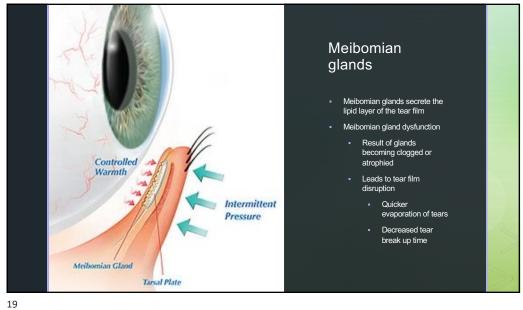






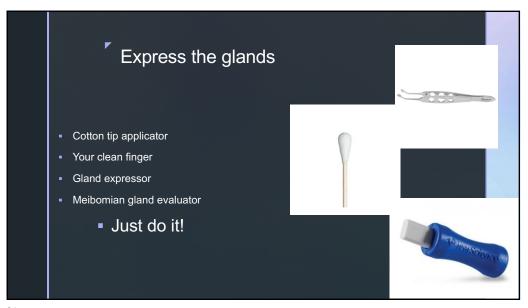




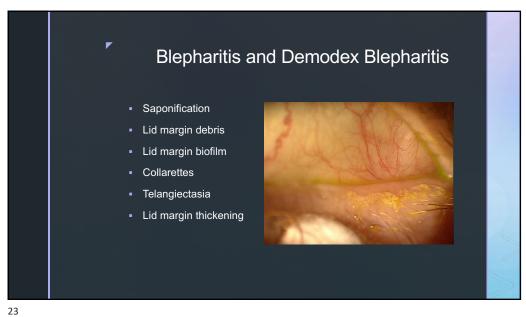


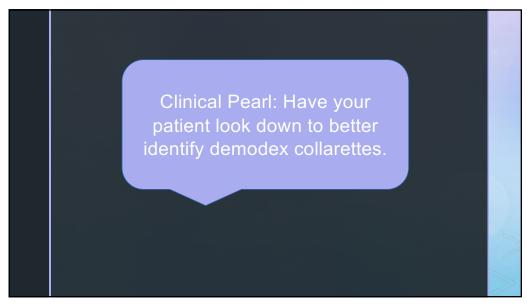
Grade the lid and gland appearance

- Any pitting?
- Any capping?
- Any lid structure abnormality?

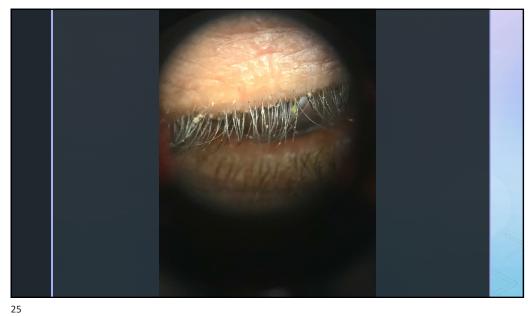


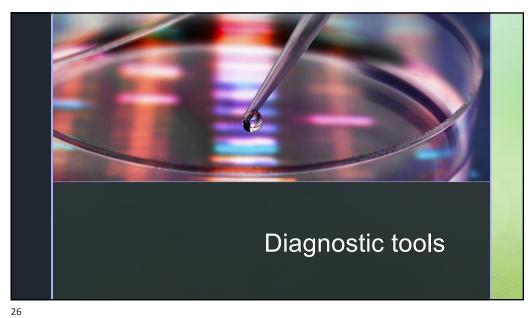






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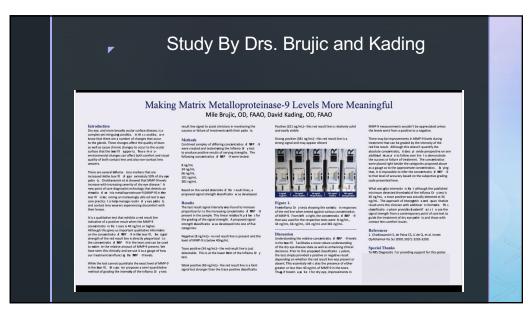


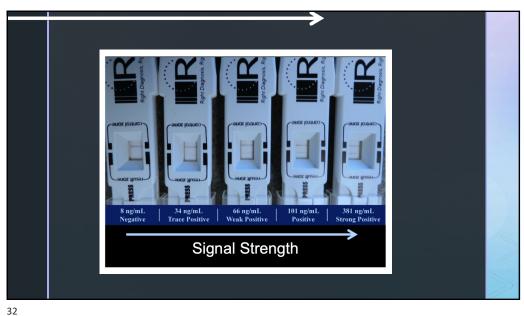


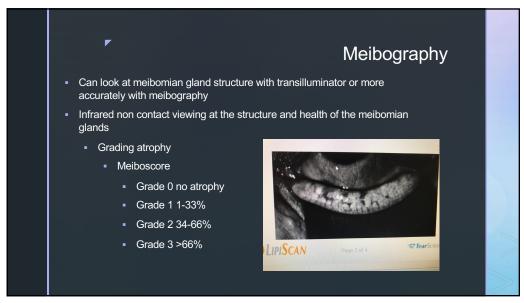


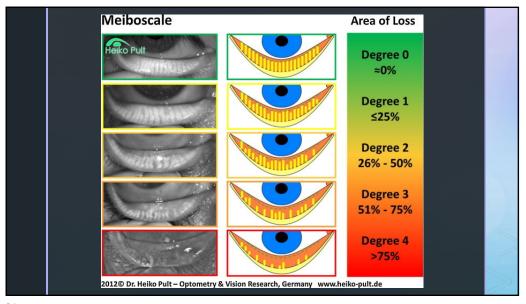




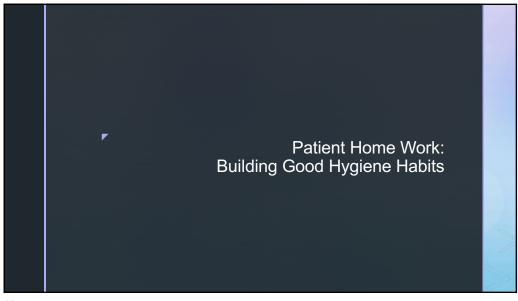


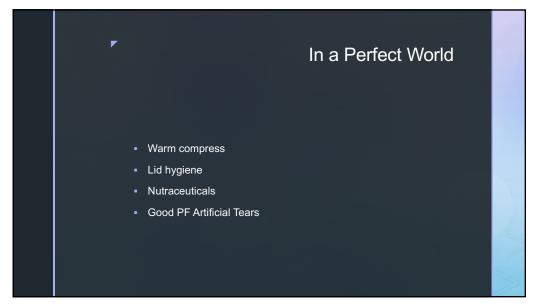






# Pre-operative meibography study - J&J sponsored study Koetting & Yeu pre-operative cataract retrospective - 95.1% patients had some level of gland atrophy - Only 4.9% showed no atrophy on meibography - Meibography vs SLE - More atrophy found on meibography vs the same patients SLE - Further breakdown found that there was a correlation between decreased expressibility of meibomian glands to increased meibornian gland atrophy, but NOT between meibum quality and MG atrophy

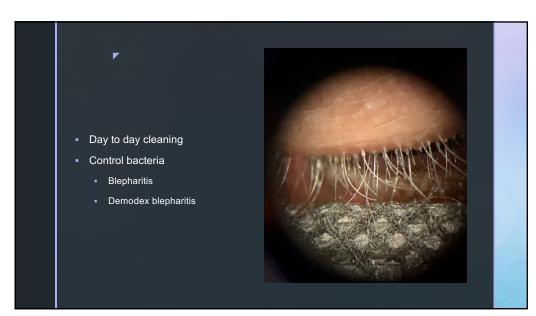


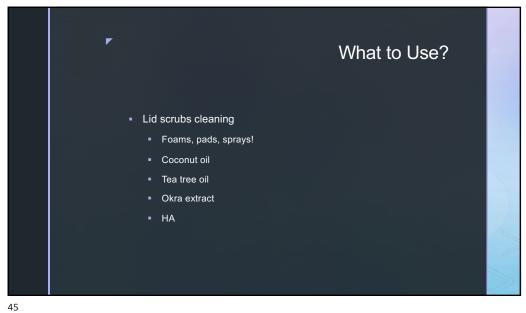


Home Work: Yes, really, you should do it every day

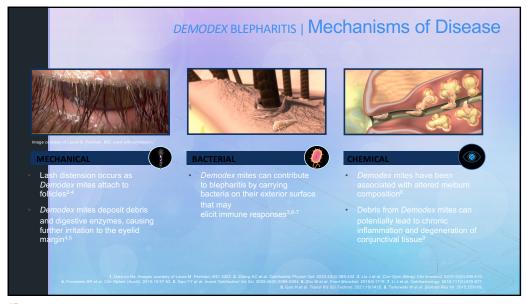
- Warm compresses
- Good Preservative Free Artificial Tears
- Lid Hygiene
- Nutraceuticals

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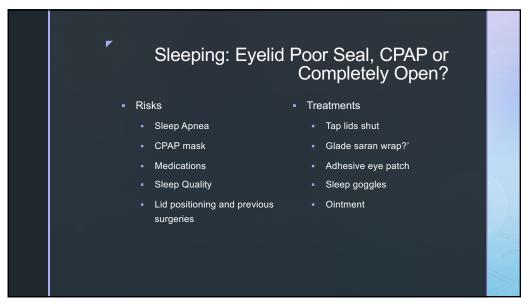


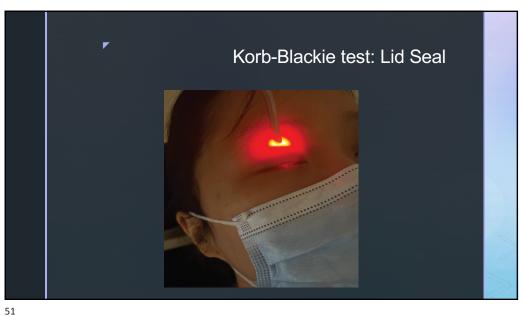




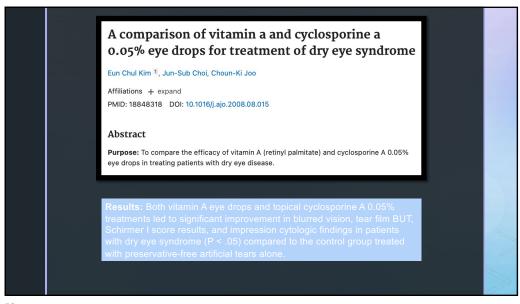
Warm Compresses
Difficult to maintain the temperature needed
Moist heat better
Melting point of meibomian glands that are obstructed is higher
40 degrees Celsius/106 Fahrenheit
A study of subjects with MGD showed that 12 weeks of lid warming therapy resulted in a therapeutic benefit, with excess ocular surface phospholipase activity (which is detrimental to tear film stability) being reduced



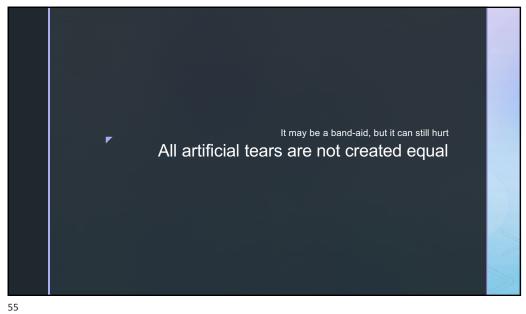




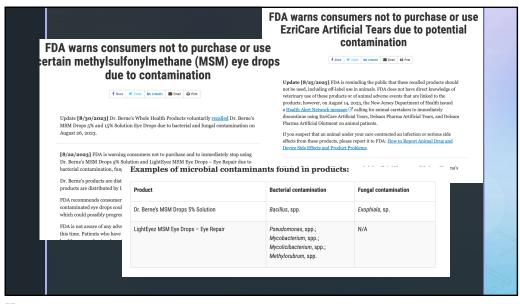












# Dr. Berne's MSM Drops 5% Solution and LightEyez MSM Eye Drops-Eye Repair (August). The FDA issued a warning to consumers, noting that testing determined that the drops were not sterile and contained microbes. They also contained methylsulfonylmethane (MSM) as an active ingredient, which is unapproved for use in the U.S. EzriCare artificial tears March). These drops were linked to a multistate outbreak of an extensively drug-resistant strain of Pseudomonas aeruginosa, per the CDC. Delsam Pharma's artificial tears and ointment (March). As a part of the same recall as EzriCare artificial tears, these drops were linked to a multistate outbreak of Pseudomonas aeruginosa, per the CDC. The outbreak is associated with multiple types of infections, including eye infections," the CDC noted in its initial warning Purely Soothing 15% MSM Drops (March). These drops were recalled after two lots were found to not be sterile. No illnesses were tied to the recall. Clear Eyes Once Daily, Eye Allergy Itch Relief (February). Teva Pharmaceuticals recalled select batches of the eye drop after they failed an impurities test. More than 700,000 bottles were recalled Brimonidine Tartrate Ophthalmic Solution, 0.15% (March). These eye drops, which are intended to be used by people with glaucoma or ocular hypertension, had faulty caps that could lead to unsterile solutions, the EDA noted.

## WARNING LETTER

September 11, 2023

## RE: 658878

Dear Urs Lehmann and Dan Quail

The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facility, Similasan AG, FEI 1000110034, at Chriesiweg 6, Jonen, from March 27 to April 4, 2023. This letter is to advise you that FDA reviewed the information related to the inspection, including Similasan's response to the FDA Form 483 and follow-up that Similasan submitted on June 19, 2023 in response to FDA's request for information, which included product labels for multiple drug products. We also reviewed Similasan's website at the Internet address https://www.similasanusa.com/. The FDA has observed that your website directs consumers in the United States (U.S.) to the linked websites of U.S. retailers where your drug products can be purchased, including "Similasan Dry Eye Relief," "Similasan Complete Eye Relief," "Similasan Allergy Eye Relief," "Similasan Kids Allergy Eye Relief," "Similasan Red Eye Relief," "Similasan Pink Eye Relief," "Similasan Kids Pink Eye Relief," "Similasan Aging Eye Relief," "Similasan Computer Eye Relief," "Similasan Stye Eye Relief," "Similasan Pink Eye Nighttime Gel," and "Similasan Dry Eye Nighttime Gel" (hereinafter "your ophthalmic products"). Based on our review, these products are unapproved new drugs under section 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 355(a). As explained further below, introducing or delivering these products for introduction into interstate commerce violates sections 301(d) and 505(a) of the FD&C Act, 21 U.S.C. 331(d) and 355(a).

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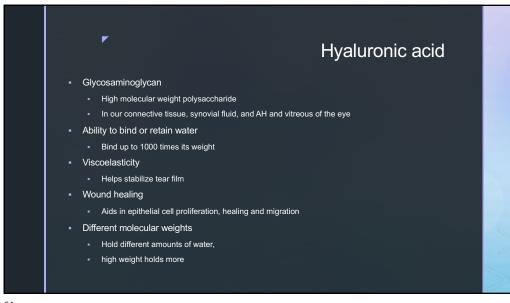
## Things to consider

## DO's

- Suggest specific brands
  - Give sample if possible or send Rx
- Preservative Free when appropriate
- Hyaluronic Acid
- Gels and ointments
- Lipid supplementing?

## Don'ts

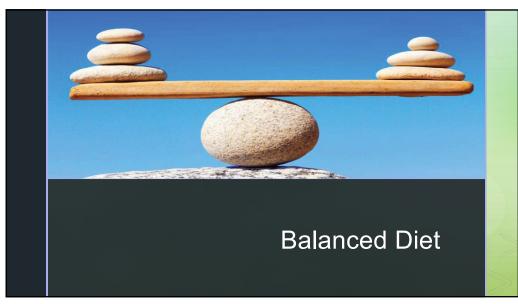
- Vasoconstrictors/redness relief
- BAK

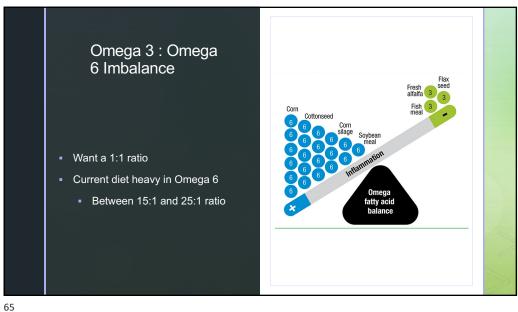


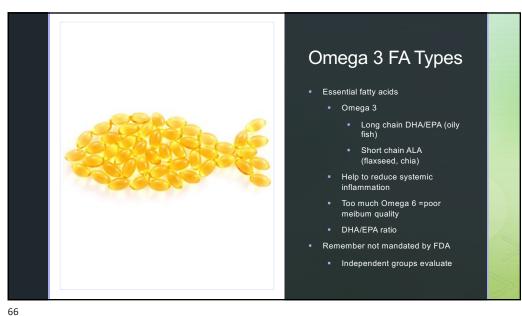




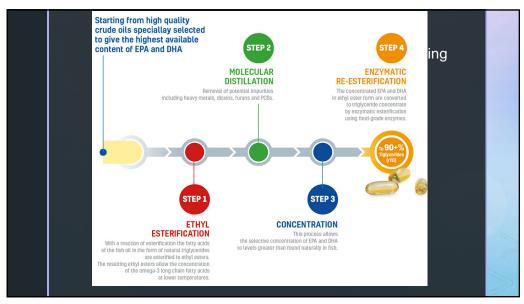
- Chiambaretta's 2017 study
- 3-6 x day 84 days with either hyaluronic acid (HA) with trehalose vs. HA only
- Questionnaires, Schirmer testing, tear film breakup time and conjunctival hyperemia scores
- The authors concluded that HA with trehalose was more effective, and gave better patient satisfaction

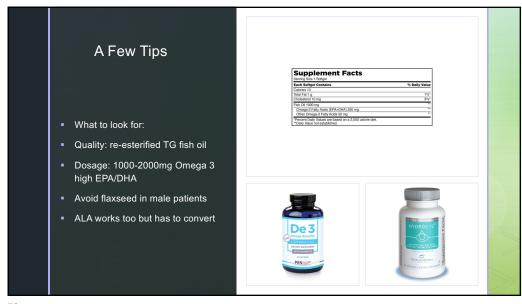








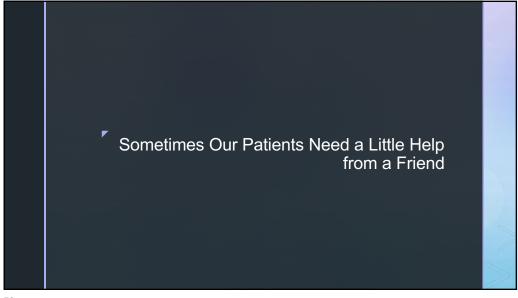




## Makeup Suggestions? Start simple Mascara – non waterproof and replace every 3 months Liner- avoid tight lining Good make up remover and lid cleaner Same lid hygiene Lash extensions- a whole lecture in itself Start with promoting use of lid spray to keep clean – Optase Protect spray, Twenty Twenty lid hygiene spray Next Step Suggest eye safe cosmetics and facial products Eyes are the Story, Twenty/Twenty Beauty





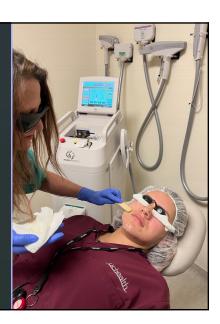






## Intense Pulse Light

- Photothermolysis is one of the proposed mechanisms of action of IPL for dry eye
- Wavelengths selectively destroy blood vessels by targeting chromophores within the blood vessels
- Destruction of telangiectasias along the eyelid inhibits access of inflammatory mediators to the meibomian glands
- Other potential mechanisms include a mild local warming effect to allow better expression of meibum and destruction of bacteria that cause inflammation at the level of the meibomian glands.



Takeaways

- You have all the tools already!

- Have you patients look down to evaluate for demodex

- Don't get frustrated, there are always more options

- Get your patients involved in their treatment and DO THEIR HOMEWORK

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