

Innovations In Dry Eye Treatments

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Disclosures

- Allergan
- Alcon
- Avellino
- Johnson & Johnson
- BioTissue
- Bruder
- Kala Pharmaceuticals
- Shire
- Sun
- Maxi Vision
- Contributing Editor Optometric Management

Finished files are the
result of years of
scientific study combined
with the experience of
years...

Optometry: Primary Eye Care Providers

- One baby boomer turns 65 every eight seconds
- 10,000 people turn 65 every day
- 4.2 million a year by 2030
- Up to 33 million Americans suffer from dry eye¹
- OD's are the Primary Eye Care Providers Today!

1. Paulsen AJ, Cruickshanks KJ, Fischer ME, et al. Dry eye in the Beaver Dam Offspring Study: prevalence, risk factors, and health-related quality of life. *Am J Ophthalmol*. 2014;157(4):799-805.

The Ocular Surface

- A unique environment that's very delicate yet resilient
- Affected by many conditions
- Treating ocular surface conditions are within the **mainstream of modern optometric practice**

Practice Growth Opportunity

- Medical eye services help bring in patients
- Leads to increased spectacle sales
- Enhances contact lens care
- Patient retention = increased revenue
- Greater word of mouth (referrals)
- Greater overall growth in all areas (optical, medical, CL's)

Prevalence of Dry Eye

- 65% of contact lens wearers report dry eye limiting their wear time
- 52.7% of contact lens wearers self-report with symptoms of ocular dryness¹
- 77% report dry eye to be bothersome
- Eye care professionals often ignore and undertreat dry eye and other ocular surface diseases

1. Nichols JJ, Ziegler C, Mitchell GL, Nichols KK. Self-reported dry eye disease across refractive modalities. *Invest Ophthalmol Vis Sci.* Jun 2005;46(6):1911-1914.

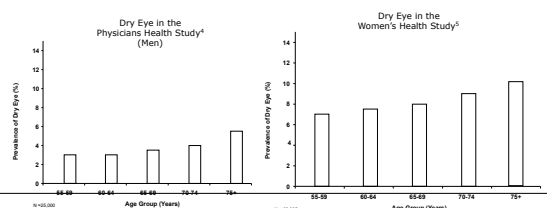
Prevalence of Dry Eye

- Dry Eye accounts for approximately 20% of visits to eye care practitioners annually¹
- For those that got care, 76% were prescribed AT's and 16% ointments²
- Visited eye care professional 6 times since symptoms started²
- Purchased an avg. of 6.2 bottles of AT's in past year²

1. Lemp MA, Margand R. Introduction. In: Lemp MA, Margand R, eds. *The dry eye: A comprehensive guide*. Berlin: Springer-Verlag; 1992:1-2.

Gender

Prevalence is higher in women and older age groups



Dry Eye Risk Factors

- Age
- Gender
- Environment- air conditioners, fans, heaters, airplanes
- Computer use
- Surgical – Refractive Surgery, Cataract Surgery, Ocular Surgery
- Lifestyle -smoking, diet, work demands
- Systemic meds
 - Antihistamines, HRT/BC, antidepressants, B-blockers, diuretics, ACE inhibitors
- Diet
 - Omega 3:6, alcohol, caffeine intake, water

Dry Eye Risk Factors

Systemic Diseases and Autoimmune Disease

- Diabetes
- Rheumatoid Arthritis (RA)
- Systemic Lupus Erythematosus (SLE)
- Sjogren's
- Thyroid Eye Disease
- Dermatological Conditions
 - Rosacea, Psoriasis
- Inflammatory Systemic Diseases
 - Crohn's, IBS

Dry Eye Disease and Surgery

SURGERY IMPACTS DRY EYE

Severity Level	1	2	3	4
Symptoms	Mild to moderate	Moderate to severe	Severe	Extremely severe
Conjunctival signs	Mild to moderate	Staining	Staining	Scarring
Corneal staining		Mild punctate staining	Marked punctate staining; central staining; filamentary keratitis	Severe staining; corneal erosions
Other signs		Tear film; decreased vision (blurring)		

SPECIAL CONSIDERATIONS: Cataract surgery adds one severity step; LASIK adds two severity steps. Plan pre-op and post-op care accordingly.
Source: Behrens A, et al. *Cornea*. 2006;25:900-907.

Dry Eye Disease Pathophysiology

- Immune-mediated inflammation of lacrimal glands and ocular surface
 - Cytokines on lid margin, ocular surface, and in tears
 - Inflammation disrupts normal neuronal feedback loop of tear production
 - Etiology is multifactorial and has many predisposing factors

Practice Pearl: Dictated Letters

Dictate letters to our colleagues:

- **Rheumatologist**
- Internal Medicine - DM
- **OBGYN**: dry eye specialty practice for post menopausal patients
- Sjogren's Syndrome Foundation
- Dermatologist
- Gastro

- You are the experts!!

3 Pearls ("P's") for Success

1. Prepare for the medical model
2. Pick the appropriate diagnostics
3. Proactive Tx of Ocular Surface Disease

3 Pearls ("P's") for Success

1. Prepare for the medical model
 - Get credentialed on medical plans
 - How? Private companies
 - Faster, easier
 - Optmedsol.com
 - Staff Training
 - Education- CE Courses, coding/billing

3 Pearls ("P's") for Success

1. Prepare for the medical model
 - Create Office Forms
 - Staff Training (huddle ups, weekly, monthly)
 - front staff, techs, check out
 - Questionnaires
 - Workflow
 - Dry eye exam testing protocol for staff and docs
 - Dry eye treatment protocols

Staff Training: Front Office

- Front Staff
 - Scheduling
 - Paperwork
 - Medical Vs. Vision
 - Phone scripts

Staff Training: Techs and Ancillary Staff

- Establish :
 - diagnostic testing protocols
- Treatment plans prescribed by you
- In-office treatments you recommend and perform
- Retail products available at your clinic
- Basic dry eye signs and symptoms
- Any other necessary insight you feel is necessary

Staff Incentives

- Incentivizing your staff brings positive changes in behavior
- You can take a mediocre or burned out employee and make them act like a business owner
- Allows them to have “skin in the game”
- Provide bonuses to staff for: practice volume, production goals, personal incentives, and commissions for retail products

DIAGNOSTICS



Pearls for Success

- **Pick** the appropriate diagnostics you want to use
 - Fluorescein
 - Lissamine Green
 - Shimer's
 - MMP-9 detection
 - TBUT
 - Slit lamp photo
 - Tear meniscus height
 - TearLab/osmolarity
 - Phenol Red Thread
 - Case history
 - Meibography
 - Questionnaires
 - Interferometry
 - Blink rate
 - Lid seal

Tech Exam : Proper Test Flow Sequence

- Train your staff to do :
 - Questionnaires
 - Case History
 - Interferometry
 - Meibography
 - Blink evaluation
 - Tomography
 - Tear osmolarity
 - Tear production tests
 - MMP 9 detection testing

Questionnaires

- Speed Questionnaire
- OSDI

SPEED Questionnaire

Name: _____ Date: _____

DOB: _____ Sex: M F (Circle)

How **FREQUENTLY** do you experience the following dry eye symptoms?

Symptoms	Never (0)	Sometimes (1)	Often (2)	Constantly (3)
Itching, burning or stinging				
Redness or irritation				
Foreign body sensation				

How **SEVERE** are your dry eye symptoms?

Symptoms	No problem (0)	Tolerable – not perfect but not uncomfortable (1)	Uncomfortable irritating but does not interfere with my day (2)	Bothersome and interferes with my daily tasks (3)	Intolerable – unable to perform my daily tasks (4)
Itching, burning or stinging					
Redness or irritation					
Foreign body sensation					

When have you experienced these symptoms?

() Today () Within the past 72 hours () Within the past 3 months

Symptoms	Yes	No
Have you been diagnosed with a dry eye condition?		
Has your doctor prescribed any eye drops or ointment?		
Has your doctor prescribed any eye ointment?		
Has your doctor prescribed any eye ointment?		
Has your doctor prescribed any eye ointment?		
Has your doctor prescribed any eye ointment?		

Do you use drops and/or ointment? Yes No (Circle)

If yes, which drops and/or ointment do you use? _____

How frequently do you use the drops and/or ointment? _____

For office use only
Total SPEED score (Frequency + Severity) = _____

Questionnaires

Dry Eye Summit questions (2014) Questions

1. Do your eyes ever feel dry or uncomfortable?
2. Are you bothered by changes in your vision throughout the day?
3. Are you ever bothered by red eyes?
4. Do you ever use or feel the need to use drops?

Case History

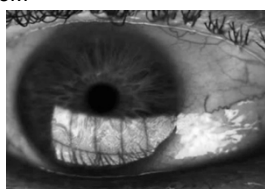
Case History

Have Your Techs Review :

- systemic meds
- systemic health
- autoimmune diseases
- risk factors
- surgical history
- current drops and medications
- other

Interferometry

- Lipiview® I & II
- Oculus Keratograph® 5M



Interferometry



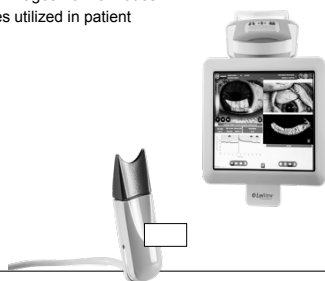
Interferometry uses the light pattern from one image to highlight differences in the other.

Video Length	19.1 sec	Avg ICU	56
Max ICU	69 @ 444	Min ICU	50 @ 160
Std. Dev.	3	CF	0.98
		PB	8/8

The LipiView Ocular Surface Interferometer is an ophthalmic imaging device, which measures lipid layer thickness, blink rate and efficiency by capturing and analyzing 20-seconds of video per eye.

Lipiview® II

- Uses a light-emitting lid everter
- Allows for selection of images from 3 modes
- High resolution images utilized in patient education

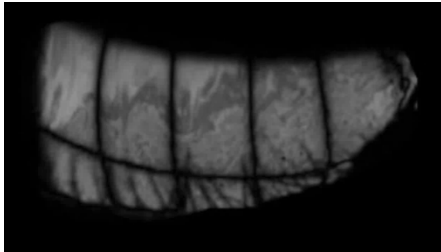


LipiScan™



- 10 seconds per eye
- High Definition
- Under normal lighting
- User-friendly
- Small footprint

Interference Pattern

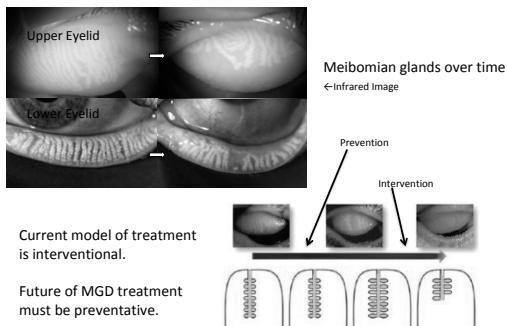


Lipid Layer of the Tear Film

Meibography

- Transillumination
- LipiView® II
- Oculus Keratograph® 5M
- LipiScan®
- Meibox

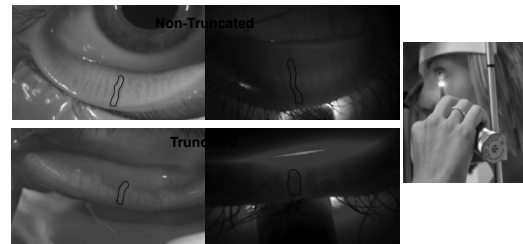
Intervention & Prevention



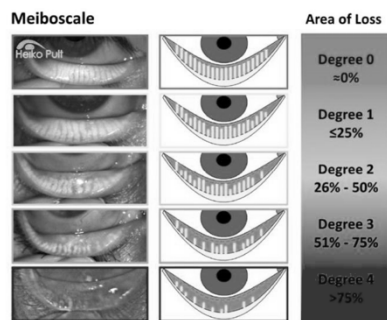
Heiko Pult, Meibography in Clinical Practice, Ophthalmology Times Europe June 2012

Infrared vs. Transilluminated

A single gland has been traced in each image to illustrate that the glands are lighter under infrared light and darker under transilluminated light, relative to the background tissue.



Meiboscale



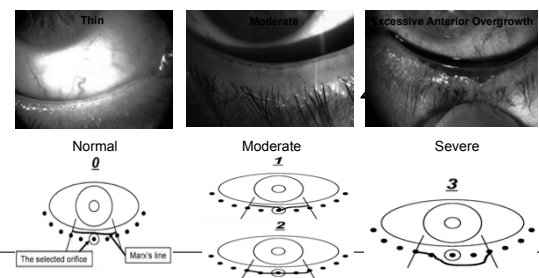
2012© Dr. Heiko Pult

Standardized MG evaluation scale, introduced in April 2012.

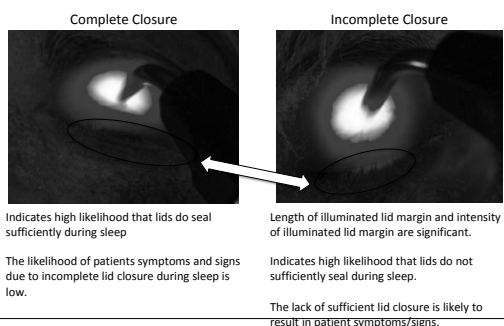
Line of Marx (LOM)

Epithelial changes along the meibomian gland opening which inhibit transfer secreted meibum to the tear film.

Pult et al., Optom Vis Sci 2010;87:718-724



Korb-Blackie Lid Light Test



Microlagophthalmos Lid Seal Exam



Meibography Research

Purpose: to determine if meibography could predict meibomian gland function with regard to number of functional MGs and/or estimation of functional MG volume in patients symptomatic for dry eye

- Methods: n=23 symptomatic for dry eye, mean age 48 years, 5 males: 18 females
- Scored using the SPEED questionnaire
- MG function and estimation of functional MG volume were performed with meibomian gland evaluator (MGE)
- Meibography was performed using the Modi Topographer
- Lower lids were examined in three equal sections: nasal (N), central (C) and temporal
- (T) for the number of functional MGs and their functional volume (volume was as 1 for minimal, 2 for moderate and 3 for copious), and for MG dropout.

Meibomian Gland Function Cannot Be Predicted By Meibography In Patients Symptomatic For Dry Eye, David Murakami, Caroline A Blackie, Heiko Pult, Donald R Korb Investigative Ophthalmology & Visual Science April 2014, Vol 55, 27.

Meibography Research

- **Conclusions:** There appears to be no relationship between the level of apparent drop out and the number of functional MGs and/or functional MG volume. These counterintuitive results strongly indicate that standard noncontact infrared meibography cannot be used to predict MG function in terms of number of functional glands and/or functional gland volume except in the case of total gland dropout, when the glands are completely absent.

Blink Evaluation

- Blink Rate
 - Various diagnostics (LipiView I, II)
 - Oculus Keratograph® 5M
 - Manual
- Blink Quality
 - Partial blinks
 - Incomplete blinks

TearLab



Hyperosmolarity

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

TearLab

- The TearLab Osmolarity System is the first objective and quantitative test for diagnosing and managing Dry Eye patients
- Fast and accurate results in seconds using only 50 nanoliters (nL) of tear film to diagnose Dry Eye Disease
- Enables discussion with patients around a number improving compliance
- Incorporating osmolarity into the standard of care gives the best indication of early stage disease

Tear Volume Testing

Schirmer's Test

- Requires anesthesia
- 5 minute testing time
- Mildly irritating
- Normal results: > 10mm

Phenol Red Thread

- No anesthesia required
- 15 seconds testing time
- Little discomfort
- Normal results: > 20mm

Red Phenol



Other Tear Tests

- Tear Meniscus Height
 - Manual
 - Diagnostics
- Tear Stability: Tear Break Up Time (TBUT, NIBUT)
 - Less than 8-10 seconds abnormal

Dry Eye Survey Research

- 68 patients
- OSDI, Schirmer's Test, Tear Break-Up Time (TBUT)
- Strong inverse correlation was found between OSDI and TBUT
- No correlation between OSDI and Schirmer's Testing

Ocular Surface Disease Index for the Diagnosis of Dry Eye Syndrome. Ocular Immunology and Inflammation, Volume 15, Issue 5, 2007.

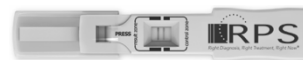
Dry Eye Disease and **MMP-9**

Matrix metalloproteinases (MMP) are proteolytic enzymes that are produced by stressed epithelial cells on the ocular surface¹

- MMP-9 in Tears
 - Non-specific inflammatory marker
 - Normal range between 3-41 ng/ml
 - More sensitive diagnostic marker than clinical signs¹
 - Correlates with clinical exam findings¹
 - Ocular surface disease/dry eye demonstrates elevated levels of MMP-9 in tears¹

[1] Chotakavanch S, de Paiva CS, Li de Quan, et al. Invest Ophthalmol Vis Sci 2009; 50(7): 3203-3209.

InflammaDry Product Overview



- Identifies elevated levels of MMP-9 in tear fluid
- CLIA-waived: Easy-to-use test can be performed by an OD or a technician
- Rapid: 10 minute results
- Reimbursable: \$15.74, CPT Code 83516
- In-office: point-of-care immunoassay test aids in diagnosis at the time of office visit
- Low cost: disposable test, no additional equipment required

InflammaDry Intended Use

- InflammaDry is a rapid, immunoassay test for the qualitative *in vitro* detection of elevated levels of the MMP-9 protein in tears
- InflammaDry aids in the diagnosis of dry eye
- Works in conjunction with other methods of clinical evaluation
- Another piece of the puzzle: osmolarity, Staining, TBUT, OSDI, Shimmers



InflammaDry 4-Step Process

INFLAMMADRY SIMPLE 4-STEP PROCESS

Step 1 - Collect Sample	Step 2 - Assemble Test	Step 3 - Run Test	Step 4 - Read Results
			
Gently dab the sample collector in 6-8 locations on the palpebral conjunctiva, until the fleece glistens, to collect a tear sample.*	Snap the sample collector into the test cassette and press firmly where indicated. A double-click means the test is properly assembled.	Immerse the absorbent tip into the provided buffer vial for 20 seconds. Replace the cap and lay the test flat on a horizontal surface.	After 10 minutes, read the test results. RED + BLUE = POSITIVE BLUE = NEGATIVE

* Release the lid after every 2-3 dabs. Allow the sampling fleece to rest along the conjunctiva for 5 seconds.

InflammaDry® Limit of Detection

Normal levels of MMP-9 in human tears ranges from 3-41 ng/ml

POSITIVE TEST RESULT
MMP-9 ≥ 40 ng/ml

NEGATIVE TEST RESULT
MMP-9 < 40 ng/ml



MMP-9 and Dry Eye **Severity**¹

MMP-9 AND DRY EYE SEVERITY		
Patient's Dysfunctional Tear Syndrome Level	Average MMP-9 Level	Statistical Significance vs Normal
Normal (n=18)	8.39 ng/ml	No
Severity Level 1 (n=15)	35.57 ng/ml	No
Severity Level 2 (n=11)	66.17 ng/ml	Yes
Severity Level 3 (n=9)	101.42 ng/ml	Yes
Severity Level 4 (n=11)	381.24 ng/ml	Yes

POSITIVE RESULT = CHRONIC DRY EYE ≥40 ng/ml

[1] Chotakavanch S, de Paiva CS, Li de Quan, et al. Invest Ophthalmol Vis Sci 2009; 50(7): 3203-3209.

THE DOCTOR'S EXAM

Vital Dyes



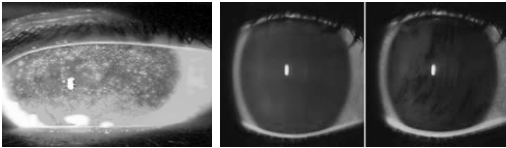
NaFL

Lissamine
Green

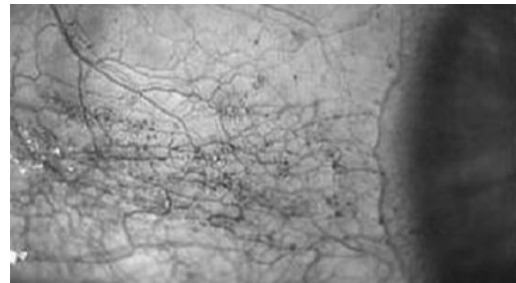
Rose Bengal

Type of Dry Eye

- Aqueous and Mucin Deficiency
- Lipid Deficiency/MGD



Lissamine Green Staining



Line of Marx



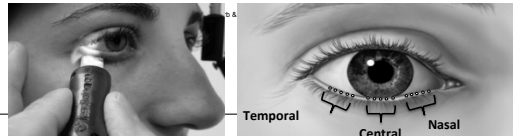
Need for Standardized MG Evaluation

Forced digital or cotton-tipped expression, current standard of practice to evaluate MG, is not constant & standardized.



From visit to visit & patient to patient, current standard of practice is not repeatable & consistent.

Meibomian Gland Evaluator (MGE) applies standardized force of ~1.25 gram/mm² or 0.3 PSI to mimic normal blink force and provides a metric for evaluation.



3 Pearls (“P’s”) for Success

3. Proactive Tx of Ocular Surface Disease

- Pick a treatment protocol
- Develop a plan
- Change the plan if no improvement

Treatment Options

- Medically oriented OD practices
- Optometry poised to own dry eye and OSD!
- O.D.’s should MEDICALLY treat/diagnose
- Palliative TX : OTC vs. Rx therapeutics
- Higher Level of Care to Your Patients

Keys to Success for Dry Eye

- What Separates Successful Doctors From Other Docs?
- Examine and Diagnose!
 - Assume patient has a MEDICAL diagnosis until proven otherwise
 - Chief complaint important
- Develop and Rx a treatment plan
- “You have a chronic inflammatory eye disease”
- Must schedule a follow up visit
- Proactive vs. Reactive
 - Why wait?

Keys to Success for OSD

MUST schedule follow up exam!

- Objectively measure signs to track improvement
- Document baseline findings
- Appropriate diagnostic testing
- **Patient education key**
- Slow things down at baseline exam

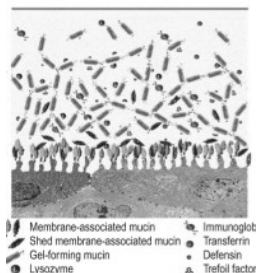
“I’m not sure what drop I am using every two hours”



Dry Eye Treatments

- | | |
|-----------------------------|--|
| • AT's | • Tissue engineering |
| • Ointments | • Labial, parotid, submandibular gland transplantation |
| • Restasis | • Evoxac |
| • Xiidra | • Omega 3:6 FA's |
| • Corticosteroids | • HRT |
| • NSAID's | • Botox |
| • Punctal Occlusion | • Accupuncture |
| • Lacrisert | • Herbal remedies |
| • Autologous Serum | • Mucin replacement |
| • Vitamin A drops | • Amniotic membranes |
| • Moisture goggles | • Thermal Pulsation |
| • Topical Androgen | • IPL/BBL |
| • Doxycyclines/Azithromycin | • Neurostimulation |
| | • Cequa |

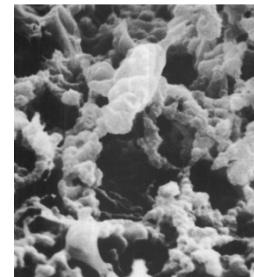
- “Proteoglycans on membrane spanning mucins provide a rigid structure (bottle brush) allowing the mucins to extend 200-500 nm above the cornea”¹



¹. Tear Film Mucins: Front Line Defenders of the Ocular Surface: Comparison with Airway and Gastrointestinal Tract Mucins. R. Hodges, A. Dartt. Exp. Eye Res. 2013 Dec; 117: 62-76.

Nano Tears

- Alcon : Systane Complete
- Allergan: Refresh Mega 3



Nanotechnology

- The evolution of artificial tears and ophthalmic drop delivery platforms...
- Nano particles are the latest innovation in delivering ocular therapeutics
- Why? Nanoparticles are 1-120 nanometers in size
- Sun uses a “nanomicellular” technology
- B + L uses “Sub micron” technology
- Kala has “MPP” or mucous penetrating particle

KPI- 121 0.25% Loteprednol etabonate

- KPI- 121 0.25% Loteprednol etabonate
- KP1-121 1.0% Loteprednol etabonate
- Loteprednol etabonate 0.38% - Lotemax SM

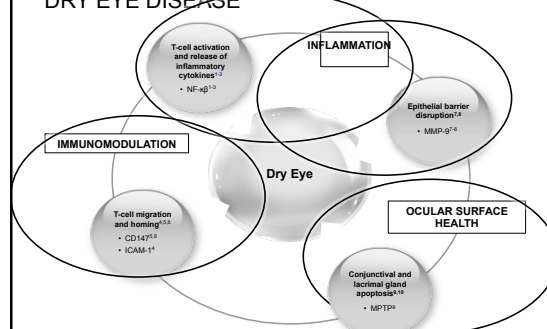
Topical Loteprednol treatment Reduces Cyclosporine Stinging in Chronic Dry Eye Disease; Sheppard JD, Scoper SV, Samudre S; Journal of Ocular Pharmacology and Therapeutics (Dec 2010)

Treating Ocular Surface Disease

Cyclosporine .05% clinically proven in studies to:

- Increase TBUT
- Decrease Corneal Staining
- Decrease Conjunctival Staining
- Increase Shimer's scores/tear production
- Decrease dependence of AT's
- Decrease subjective blur/blurry VA
- Decrease/stop dry eye severity level progression
- Increase Goblet cell proliferation
- Increase CL wear time

MULTIPLE MECHANISMS IN DRY EYE DISEASE



1. Saito, et al. Invest Ophthalmol Vis Sci. 2002; 43: 1000-1005. 2. Cavanagh and Pflugfelder. Exp Eye Res. 2005; 80: 499-509. 3. Saito, et al. Invest Ophthalmol Vis Sci. 2002; 43: 1000-1005. 4. Stern, et al. Invest Ophthalmol Vis Sci. 2002; 43: 1000-1005. 5. Huet, et al. Am J Pathol. 2011; 117: 1000-1005. 6. Saito, et al. J Mol Cell Cardiol. 2012; 7: 1000-1005. 7. Cavanagh, et al. Invest Ophthalmol Vis Sci. 2008; 49: 1000-1005. 8. Pflugfelder. Am J Ophthalmol. 2004; 138: 1000-1005. 9. Gao and Stern, et al. Cornea. 2013; 32: 1000-1005. 10. Stern, et al. Cornea. 1998; 17: 1000-1005. 11. Definition and Classification Subcommittee. Ocul Surf. 2002; 1: 1000-1005. 12. Bhat, et al. J Clin Invest. 2001; 107: 1000-1005.

Lifitegrast 5%**Proposed MOA**

Over-expression of **Intercellular Adhesion Molecule (ICAM)-1** in the corneal and conjunctival tissue of DED patients

Lymphocyte Function Associated Antigen (LFA)-1 are receptors found on T-Cells

ICAM-1 and LFA-1 are **COGNATE LIGANDS**... natural binding partners

Lifitegrast molecules bind to LFA-1, preventing the binding to ICAM-1

By blocking the interaction, T-Cells can no longer activate, migrate and release cytokines

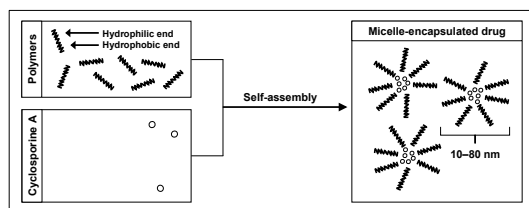
Xiidra: Lifitegrast 5%• **Summary of Study Data**

- Four separate trials completed
- One safety study
- Assessed **Eye Dryness Score** (0 = no discomfort to 100 = maximal discomfort)
- Measured **Inferior Corneal Staining** (0 = no staining to 4 = coalescent)
- 2,133 subjects enrolled
- Over 1,200 received Xiidra (lifitegrast 5%)
- Improvement was noted in EDS in all 4 studies by Week 6
- Improvement was noted in ICS in 3 out of 4 studies by Week 12

**OTX-101 formulation (Cequa)
Cyclosporine 0.09%**

Nanomicellar aqueous solution of CsA¹

- Clear liquid with a neutral pH in unpreserved, unit dose vials



CsA, cyclosporine A; FDA, US Food and Drug Administration; NZ, New Zealand.
1. Chokkar K et al. Transl Vis Sci Technol. 2016;4(1):2. Data on File.

75

Cequa: Cyclosporine A 0.09%

A confirmatory Phase 3 trial of a proprietary nanomicellar formulation of cyclosporine A 0.09%, a clear, preservative-free, aqueous solution, for the treatment of dry eye, was completed in December 2016.

• **Design**

- Trial was a 12 week, multicenter, randomized, double-masked, vehicle controlled Phase 3 study
- 744 dry eye patients were enrolled
- 1:1 randomization to either cyclosporine A 0.09% or its vehicle
- Primary end point was Schirmer's score

• **Results**

- At 12 weeks of treatment, cyclosporine A 0.09% demonstrated a statistically significant improvement in Schirmer's score ($p < 0.0001$).
- Improvement in Schirmer's score at 12 weeks is earlier than other drugs approved for dry eye in the same class.¹
- Several key secondary endpoints showed statistically significant improvements compared to vehicle with some showing an even earlier onset of action.
- Adverse events reported in the trial were mild to moderate in nature and similar to other approved drugs in the category.^{1,3}

• **Conclusions**

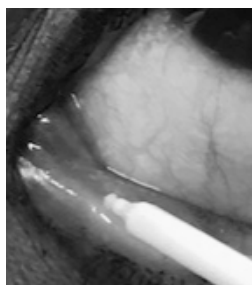
- This data, and data from a previously completed Phase 2b/3 clinical trial in 455 patients, indicate Cyclosporine A 0.09% compares favorably to other formulations of cyclosporine A with the advantage of early onset.¹

¹ Salt K, et al. Ophthalmology. 2000 Apr;107(4):631-9. ² Sheppard JB, et al. Ophthalmology. 2014 Feb;121(2):475-83.

³ Tauber J, et al. 2015 Dec;122(12):2423-31

Punctal Plugs

- Still a mainstay in dry eye treatment
- When should you not use them?
- Future innovation

**Dry Eye Therapies Can Be Slow****How can we speed up treatment?**

Neurostimulation

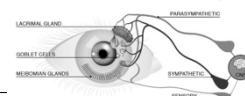
- First-ever neurostimulation device in eye care
- An easy-to-use and drug-free option to temporarily increase tear production during neurostimulation in adult patients
- Provides small electrical pulses to stimulate production of your own natural tears



LFU REGULATES TEAR PRODUCTION¹⁻⁴

BY COMMUNICATING WITH CENTRAL NERVOUS SYSTEM (CNS)

- **Lacrimal Functional Unit (LFU)** maintains a healthy environment for the eye by regulating tear production
 - In response to any external and internal stimuli, LFU communicates with Central Nervous System (CNS)
 - Sensory signals are carried via afferent neurons from LFU to CNS
 - Parasympathetic and sympathetic signals are carried via efferent neurons from CNS to LFU
 - This afferent and efferent signaling and communication occurs via the trigeminal nerve
- Neurostimulation in the nasal cavity targets the trigeminal nerve to trigger the nasolacrimal reflex to emulate the normal neural signals to create a natural tear



1. Kissler et al. Ophthalmol Plast Reconstr Surg. 2015; 2. Beuerman et al. In: Pfleger et al, eds. Dry Eye and Ocular Surface Disorders. 2004; 3. Durr, Ocul Surf. 2004; 4. Friedman et al. A nonrandomized, open-label study to evaluate the effects of nasal stimulation on tear production in patients with dry eye disease. 2016.

Amniotic Membranes and Biologics

- **First in class: AMNIOGRAFT®** (BioTissue) in 1997
 - Regener-Eyes® ophthalmic solution (MI Solutions)
- **Sutureless options:**
 - **PROKERA®** (BioTissue)
 - PROKERA® Slim, PROKERA® PLUS, PROKERA® CLEAR
 - AMBIODisk™ (IOP Ophthalmics)
 - BioDOptix® (BioD)
 - aril™ (Seed Biotech)
 - AmnioTek™-C (IOP Ophthalmics)
 - ReNovo-AT-O™ (RegenMed Group)
 - VisiDisc™ Thin & VisiDisc™ Thick (Skye Biologics)
 - AlphaVision™ (Amniotic Therapies)



Prevalence of Blepharitis

Study: Looked at prevalence of blepharitis in patients having cataract surgery

- 100 patients (200) eyes, two site study
- 59% of patients had blepharitis

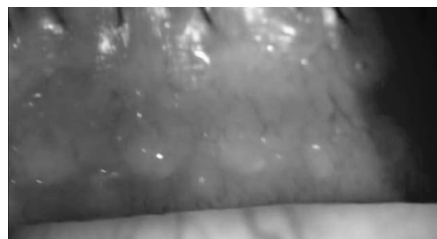
Luchs J, Burneio C, Trattler W. Prevalence of blepharitis in patients scheduled for routine cataract surgery. Poster presented at ASCRS Symposium on Cataract, IOL and Refractive Surgery April 11, 2010; Boston, MA.

It's all about the biofilm

- HOCL was a dramatic innovative therapeutic
- Penetrates and kills underlying pathogens under the biofilm¹
- Inactivate lipases, kill bacteria, decrease inflammation, some efficacy with demodex

1. Romanowski E., Stella N.A., Yates K., Brothers K., Kowalski R.P., Shanks R.M.Q., In Vitro Evaluation of a Hypochlorous Acid Hygiene Solution on Established Biofilms. University of Pittsburgh, 2017

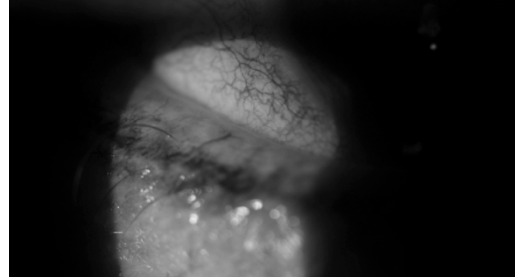
Debridement – Physician's POV



NuLids



MGD



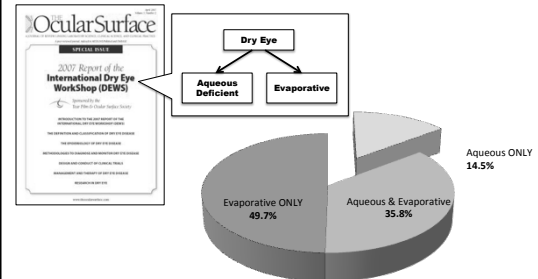
MGD Prevalence

- MGD, also termed posterior blepharitis, is the most common form of lid margin disease (LMD)
- Nearly 40% of routine eye care patients
- 50% of contact lens wearers are affected
- Recent research showed 86% of dryness caused evaporative, 14% aqueous def.

Hom MM, Marlinton JR, Knapp LL, Paugh JR. Prevalence of meibomian gland dysfunction. *Optom Vis Sci*. 1990 Sep;67(9):710-2.
 Henriquez AS, Koth DR. Meibomian glands and contact lens wear. *Br J Ophthalmol*. 1981 Feb;65(2):108-11.
 Luchs, Jodi. Azithromycin in Durastite for the treatment of blepharitis *Clinical Ophthalmology* 2010; 4: 681-688.

Distribution of aqueous-deficient and evaporative dry eye in a clinic-based patient cohort: a retrospective study. Lemp MAT, Crews LA, Bron AJ, Foulks GN, Sullivan BD. *Cornea* 2012; May 31; (5):472-8.

Classification & Distribution



In a 2012 study by Lemp et al, **85.5%** of patients were identified with MGD

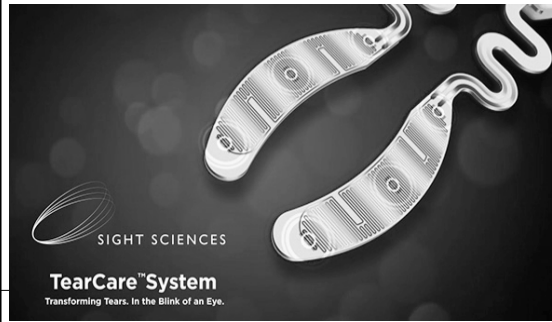
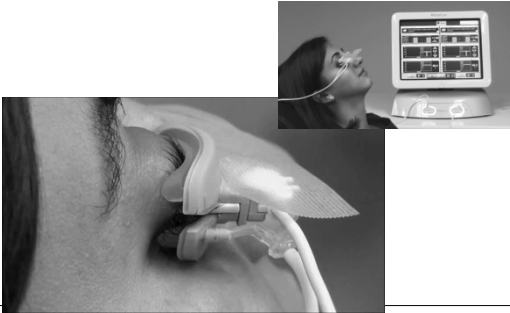
Lemp et al, *Cornea*. 2012;31(5):472-478

MGD Treatment Options

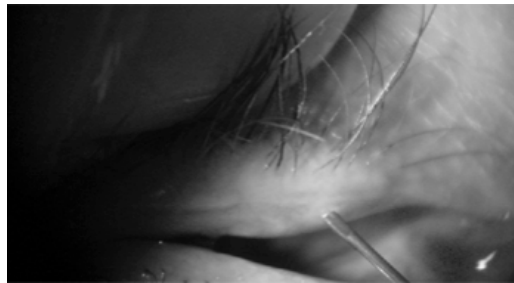
MGD Treatment Options

- Topical azithromycin
- Restasis
- Lid hygiene- scrubs, foams, sprays
- Warm compresses
- Oral Doxycycline, azithromycin PO
- Antibiotic/steroid combination drops/ointments
- Lid/Gland Expression
- IPL/BBL
- Omega 3 Supplementation
- Gland Ductal Probing
- Thermal Pulsation
- Neurostimulation

Thermal Pulsation Treatment



Meibomian Gland Duct Probing

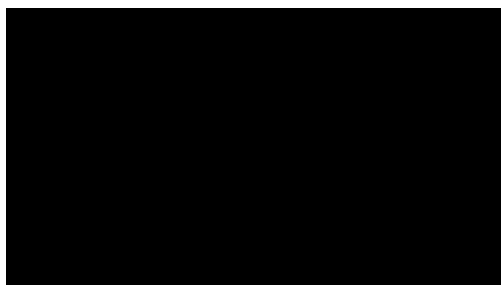
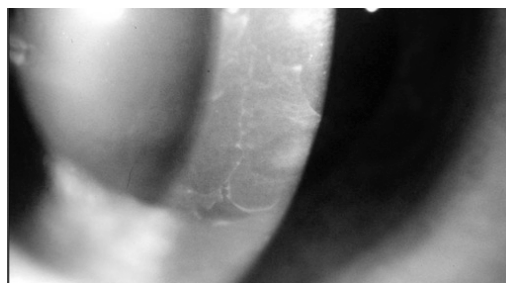


MGD and New Treatment Options: BBL/IPL



NOT DRY EYE?

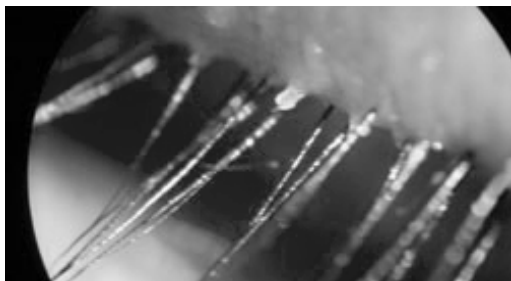
Red Eyes



Anterior Basement Membrane Dystrophy

RCE?

- Treatment:
 - Muro ung 128 qhs
 - Freshkote TID
 - Lotemax TID then BID (watch IOP)
 - Oral doxy/Azithro. vs. Azasite
 - Restasis
 - Suppress MMP-9 enzymes
 - Tx 6-8 weeks
 - ICD 10 Code (H18.839)



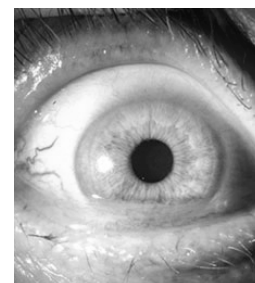
Demodex Diagnosis

- Lash epilation, examine lid margin
 - View lash under light microscope to confirm mites
- Tx: In office and home
- Incidence of infestation increases with age
- 84 percent of the population at age 60
- 100 percent of the population older than 70 years of age

OTHER?

Other....

- Conjunctivochalasis
- Lid issues
- Blocked puncta
- Epiphora
- Ectropia/Entropia
- Chronic hyperemia
- Asthenopia



Dry Eye Retail Center

Top Retail Products

1. Lid hygiene products
2. Lid moist heat mask
3. Nutritional products

Finished files are the result of years of scientific study combined with the experience of years...

THE END!

- THANKS!

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