

Make a Splash in Dry Eye



Improve your
focus on
dry eye care
and watch
your practice
flourish

Highlights from a seminar
held during AAO 2015 in
New Orleans



For patients with decreased tear production presumed to be due to
ocular inflammation associated with Chronic Dry Eye

THE DRY EYE TREATMENT SHE NEEDS TODAY. BECAUSE TOMORROW MATTERS.



RESTASIS® twice a day, every day, helps patients experience increased tear production

Increased tear production was seen at 6 months.¹

Indication and Usage

RESTASIS® (cyclosporine ophthalmic emulsion) 0.05% is indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. Increased tear production was not seen in patients currently taking topical anti-inflammatory drugs or using punctal plugs.

Important Safety Information

Contraindications

RESTASIS® is contraindicated in patients with known or suspected hypersensitivity to any of the ingredients in the formulation.

Warnings and Precautions

Potential for Eye Injury and Contamination: To avoid the potential for eye injury and contamination, individuals prescribed RESTASIS® should not touch the vial tip to their eye or other surfaces.

Use With Contact Lenses: RESTASIS® should not be administered while wearing contact lenses. If contact lenses are worn, they should be removed prior to the administration of the emulsion. Lenses may be reinserted 15 minutes following administration of RESTASIS® ophthalmic emulsion.

Adverse Reactions

In clinical trials, the most common adverse reaction following the use of RESTASIS® was ocular burning (upon instillation)—17%. Other reactions reported in 1% to 5% of patients included conjunctival hyperemia, discharge, epiphora, eye pain, foreign body sensation, pruritus, stinging, and visual disturbance (most often blurring).

Please see Brief Summary of the full Prescribing Information on adjacent page.

Reference: 1. RESTASIS® Prescribing Information.



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APC55DL15 152887

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RESTASIS® (Cyclosporine Ophthalmic Emulsion) 0.05%

BRIEF SUMMARY—PLEASE SEE THE RESTASIS® PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION.

INDICATION AND USAGE

RESTASIS® ophthalmic emulsion is indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. Increased tear production was not seen in patients currently taking topical anti-inflammatory drugs or using punctal plugs.

CONTRAINDICATIONS

RESTASIS® is contraindicated in patients with known or suspected hypersensitivity to any of the ingredients in the formulation.

WARNINGS AND PRECAUTIONS

Potential for Eye Injury and Contamination

To avoid the potential for eye injury and contamination, be careful not to touch the vial tip to your eye or other surfaces.

Use with Contact Lenses

RESTASIS® should not be administered while wearing contact lenses. Patients with decreased tear production typically should not wear contact lenses. If contact lenses are worn, they should be removed prior to the administration of the emulsion. Lenses may be reinserted 15 minutes following administration of RESTASIS® ophthalmic emulsion.

ADVERSE REACTIONS

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

In clinical trials, the most common adverse reaction following the use of RESTASIS® was ocular burning (17%).

Other reactions reported in 1% to 5% of patients included conjunctival hyperemia, discharge, epiphora, eye pain, foreign body sensation, pruritus, stinging, and visual disturbance (most often blurring).

Post-marketing Experience

The following adverse reactions have been identified during post approval use of RESTASIS®. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Reported reactions have included: hypersensitivity (including eye swelling, urticaria, rare cases of severe angioedema, face swelling, tongue swelling, pharyngeal edema, and dyspnea); and superficial injury of the eye (from the vial tip touching the eye during administration).

USE IN SPECIFIC POPULATIONS

Pregnancy

Teratogenic Effects: Pregnancy Category C

Adverse effects were seen in reproduction studies in rats and rabbits only at dose levels toxic to dams. At toxic doses (rats at 30 mg/kg/day and rabbits at 100 mg/kg/day), cyclosporine oral solution, USP, was embryo- and fetotoxic as indicated by increased pre- and postnatal mortality and reduced fetal weight together with related skeletal retardations. These doses are 5,000 and 32,000 times greater (normalized to body surface area), respectively, than the daily human dose of one drop (approximately 28 mcL) of 0.05% RESTASIS® twice daily into each eye of a 60 kg person (0.001 mg/kg/day), assuming that the entire dose is absorbed. No evidence of embryofetal toxicity was observed in rats or rabbits receiving cyclosporine at oral doses up to 17 mg/kg/day or 30 mg/kg/day, respectively, during organogenesis. These doses in rats and rabbits are approximately 3,000 and 10,000 times greater (normalized to body surface area), respectively, than the daily human dose.

Offspring of rats receiving a 45 mg/kg/day oral dose of cyclosporine from Day 15 of pregnancy until Day 21 postpartum, a maternally toxic level, exhibited an increase in postnatal mortality; this dose is 7,000 times greater than the daily human topical dose (0.001 mg/kg/day) normalized to body surface area assuming that the entire dose is absorbed. No adverse events were observed at oral doses up to 15 mg/kg/day (2,000 times greater than the daily human dose).

There are no adequate and well-controlled studies of RESTASIS® in pregnant women. RESTASIS® should be administered to a pregnant woman only if clearly needed.

Nursing Mothers

Cyclosporine is known to be excreted in human milk following systemic administration, but excretion in human milk after topical treatment has not been investigated. Although blood concentrations are undetectable after topical administration of RESTASIS® ophthalmic emulsion, caution should be exercised when RESTASIS® is administered to a nursing woman.

Pediatric Use

The safety and efficacy of RESTASIS® ophthalmic emulsion have not been established in pediatric patients below the age of 16.

Geriatric Use

No overall difference in safety or effectiveness has been observed between elderly and younger patients.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis: Systemic carcinogenicity studies were carried out in male and female mice and rats. In the 78-week oral (diet) mouse study, at doses of 1, 4, and 16 mg/kg/day, evidence of a statistically significant trend was found for lymphocytic lymphomas in females, and the incidence of hepatocellular carcinomas in mid-dose males significantly exceeded the control value.

In the 24-month oral (diet) rat study, conducted at 0.5, 2, and 8 mg/kg/day, pancreatic islet cell adenomas significantly exceeded the control rate in the low-dose level. The hepatocellular carcinomas and pancreatic islet cell adenomas were not dose related. The low doses in mice and rats are approximately 80 times greater (normalized to body surface area) than the daily human dose of one drop (approximately 28 mcL) of 0.05% RESTASIS® twice daily into each eye of a 60 kg person (0.001 mg/kg/day), assuming that the entire dose is absorbed.

Mutagenesis: Cyclosporine has not been found to be mutagenic/genotoxic in the Ames Test, the V79-HGPRT Test, the micronucleus test in mice and Chinese hamsters, the chromosome-aberration tests in Chinese hamster bone-marrow, the mouse dominant lethal assay, and the DNA-repair test in sperm from treated mice. A study analyzing sister chromatid exchange (SCE) induction by cyclosporine using human lymphocytes *in vitro* gave indication of a positive effect (i.e., induction of SCE).

Impairment of Fertility: No impairment in fertility was demonstrated in studies in male and female rats receiving oral doses of cyclosporine up to 15 mg/kg/day (approximately 2,000 times the human daily dose of 0.001 mg/kg/day normalized to body surface area) for 9 weeks (male) and 2 weeks (female) prior to mating.

PATIENT COUNSELING INFORMATION

Handling the Container

Advise patients to not allow the tip of the vial to touch the eye or any surface, as this may contaminate the emulsion. To avoid the potential for injury to the eye, advise patients to not touch the vial tip to their eye.

Use with Contact Lenses

RESTASIS® should not be administered while wearing contact lenses. Patients with decreased tear production typically should not wear contact lenses. Advise patients that if contact lenses are worn, they should be removed prior to the administration of the emulsion. Lenses may be reinserted 15 minutes following administration of RESTASIS® ophthalmic emulsion.

Administration

Advise patients that the emulsion from one individual single-use vial is to be used immediately after opening for administration to one or both eyes, and the remaining contents should be discarded immediately after administration.

Rx Only

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■ By Scot Morris, OD, FAAO

Enhance the Medical Side of Your Practice With Dry Eye Care

Follow the “Four Ps” to success

As eye doctors, our job is to solve vision and ocular health problems. So, if we’re not diagnosing and treating dry eye, we’re not doing our jobs to our fullest potential. Dry eye care is not only the key to healthier, happier patients, but also, through the provision of medical services, a financial driver for the practice. Approximately 20% of the people who walk through our practice doors have some form of ocular surface disease,^{1,3} so if we’re not making those medical diagnoses and billing for that medical care every day, we’ve got work to do.

The idea of shaping a practice to conform to a medical model can be intimidating. But, in reality, increasing the medical services portion of a practice by focusing on dry eye care is readily achievable. You don’t even need to attract more patients; you simply need to take better care of the patients you already have. So, how can you enhance the medical side of your practice? I’ve done it in mine, and coached many others through it, by using what I call the “Four Ps”: Plan, Procedure, Product, and Promotion.

PLAN

Set Goals, Track Progress

The first key to expanding the medical services portion of a practice through dry eye care is to know where you stand. Even if you see only one medical patient each day, that’s the basis for your next step, which is goal setting (Figure 1). You can start small, aiming to double your current daily number from one to two or four to eight, and by

asking every patient just one additional question (e.g., “Are your eyes always that red?”).

No matter what your first goals are, track your progress weekly or monthly. If you’re committed to making changes, even your first small steps fuel a self-fulfilling cycle that propels you toward improvement. The difference from a financial perspective will eventually be tens — if not hundreds — of thousands of dollars added to the bottom line of your practice.

PROCEDURE

Implementation of the Plan

To reach the goals you have set, you must establish procedures or processes that you and your staff will follow each day. And although your staff has to accomplish these goals, the effort begins with you.

Think first about your clinical protocols. It helps to write them down. For example, how would you manage meibomian gland disease? What tests would you order? What treatments would you recommend? Next, think about all the different steps that take place from the time a patient enters the office to the time he leaves. What occurs between the patient and the front desk, the technician and the doctor, the doctor and the patient, and everything in between? Each of those points in the work flow is an opportunity to identify the dry eye patients in your practice and educate them so they’ll know that you can take care of their red, uncomfortable, dry eyes and fluctuating vision.

For example, you might have the front desk person ask patients

whether their vision ever fluctuates and if blinking makes it better. Each patient could also be given a dry eye questionnaire. Then, have the technician collect the questionnaire and ask a follow-up question, such as “Do you ‘feel’ your eyes?” If the answer is yes, the technician can let the patient know that doesn’t need to be the case: “We can work on that.”

These types of changes in the work flow prompt patients to think about their symptoms, which they may not necessarily associate with problems. Being asked about and educated on their symptoms leads them to realize they need a solution, and makes them aware that you treat medical eye problems.

Once you find the points in the workflow where medically oriented interactions take place, you can work on fine-tuning them. Scripts work wonders for helping everyone in the practice talk with patients about dry eye and treatments in a consistent manner. You can write your own script or use staff and patient education materials created by the companies that have a vested interest in dry eye. Either way, practice using the scripts. You can role play, but there are other ways. I sometimes surreptitiously leave my phone at the front desk and hit record. My staff does the same to me; then we listen and determine whether we’re all saying what we’re supposed to say.

In addition to defining staff roles so they know what to do and providing the tools and training they need, it’s crucial that they understand WHY you want the practice to be more medically oriented, so they will be motivated to help achieve that goal.

Incentives, which can come in many

Goal Setting

Where are you now?

EXACTLY how many medical patients do you see now?

	NOW	3 MOS	6 MOS
Medical Encounters / day			
Total Encounters / day			
% Medical			
Ave. Medical revenue / day			
Ave. Medical revenue / encounter			

Where do you want to end up?
What percentage?

Figure 1. If the percentage of your practice that is medical (medical revenue/total revenue) is less than 15%, it's very likely you aren't identifying your dry eye patients.

forms, are powerful tools.

As the doctor in a medically oriented dry eye practice, you, too, must re-examine and fine-tune your interactions at key points in the workflow. With patients, you should verbalize everything you're seeing during the exam, confirm the test findings and diagnosis, provide further education on the findings, prescribe treatment, explain treatment expectations, and — most importantly — tell patients to schedule a follow-up visit. Patients should never leave your office without a return appointment, whether it's next week or 3 years down the road.

PRODUCT

Help Patients Obtain What They Need

In a medically oriented dry eye practice, you can't be afraid of charging for services and products. Dry eye bothers people and affects their quality of life. You can help by recommending what's best for them. If that means selling them a product, service,

diagnostic test, or treatment, then it is your ethical responsibility to provide these products or services.

Recognize, too, that you can treat patients whether or not you accept their managed medical plan. If you're not on their plan's panel, but they consider you a trusted provider who can solve their problems, many patients will pay out of pocket for your services.

PROMOTION

Simple is Effective

A question that always arises when I discuss building a medical/dry eye practice is how to promote it. Promotion and marketing don't have to be expensive or complicated. As previously noted, you and your staff promote dry eye care at various points in the daily workflow. In addition, you can raise awareness through your on-hold phone message, your website and social media presence, stickers on your envelopes, a booth at a community event, and so on — all of which are relatively simple and inexpensive ways to achieve to your goal.

A Focused Approach

Taking a focused approach to treating dry eye will be the single biggest business-builder most of you will have in your practice. If you're willing to work ON your business rather than IN your business, you can make your patients' lives better and in the process, achieve significant practice growth. ●

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Dr. Morris is medical director of Eye Consultants of Colorado and an operating partner in Morris Education & Consulting Associates. He is the president of Ocular Technology Solutions, Inc. and is also chief optometric editor of *Optometric Management*.

Diagnosing Dry Eye

Simple and advanced tools help uncover the signs and symptoms of this common condition

In my practice at the University of California, Davis, a substantial portion of my work involves ocular surface disease, dry eye and fitting specialty contact lenses. I am extremely aware of the studies demonstrating that patients discontinue contact lens wear, most often due to discomfort, at a rate of 13% to 20%.¹

As such, I look at treating dry eye and ocular surface disease not only as a way to keep their eyes healthy, but also to keep them in their contact lenses, which, in turn, leads to satisfied patients and contributes to practice revenue.

To identify patients who need dry eye treatment, I use all the available tests and tools — from simple to advanced — an overview of which follows.

Patient Education & Questionnaires

Too often, patients aren't forthcoming

about their symptoms, which is why patient education and clear communication are critical to uncovering problems. In fact, informative brochures and questionnaires are the first step of diagnosing dry eye. I'm a firm believer in having informative brochures in the reception area to help start the dry eye conversation. I always have them available, along with a questionnaire, such as the SPEED or OSDI. The paper questionnaires work for me, but for practices that have digital devices for patients in the waiting room, an OSDI app is available.

The questionnaire sets the stage for my second step: asking questions. Many patients are clearly symptomatic, reporting dry, watery, burning eyes, and so on. But others say their eyes feel fine. I always ask those patients with "fine" eyes if they experience blurry or interrupted vision, and more often than not, they say yes. Typically, these patients are the ones

whose vision improves to 20/20 if I instill an artificial tear or ask them to blink repeatedly behind the phoropter. In my experience, it is this group of patients in particular who can be kept in contact lenses longer as a result of diagnosing and treating dry eye at an earlier stage.

In addition to asking patients about symptoms, it's important to ask environmental and lifestyle questions. We know the myriad contributors to dry eye, but it's important that we convey that knowledge to our patients. For example, I talk with patients about aspects of their home and work environments that may contribute to their symptoms. In some cases, simple changes, such as turning off the ceiling fan, help significantly. And although patients may not be able to discontinue systemic medications that dry their eyes, they may be able to switch from oral allergy medications to ocular allergy drops or nasal sprays.

Clinical Examination

When I examine a patient, I evaluate:

- Adnexa (dermatological inflammation, dermatochalasis, rosacea)
- Eyelids and eyelid margins (infectious, inflammatory, allergic, physiologic [lagophthalmos], blepharitis, meibomian gland dysfunction [MGD], lid-wiper epitheliopathy, giant papillary conjunctivitis)
- Conjunctiva (staining, chemosis, conjunctivochalasis)
- Cornea (topographical, hypoxia, secondary infectious/inflammatory, dystrophy).

A growing amount of research suggests that MGD is the most frequent cause of dry eye.² Therefore, it is important to identify MGD or

Lid Wiper Epitheliopathy

- Diagnosed by staining with fluorescein and rose bengal dyes
- Frequent finding when symptoms of dry eye are experienced in the absence of routine clinical dry eye findings.

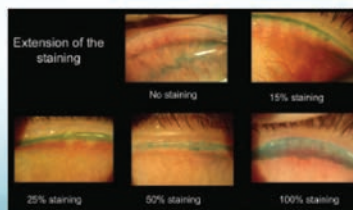
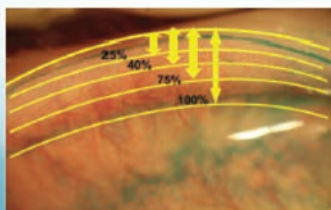


Figure 1. Flipping the upper eyelid reveals staining associated with lid wiper epitheliopathy.

rule it out. Non-obvious MGD (NOMGD) may be present, so I always push the lower eyelid gently to express the glands, which often reveals a problem — even in otherwise normal-appearing eyelids.

Clinical Testing

■ **Schirmer I and II:** I sometimes use the Schirmer test to evaluate aqueous tear production, especially for patients referred by rheumatologists because they usually request a Schirmer's test. In theory, Schirmer I, performed with anesthetic, evaluates baseline secretion, while Schirmer II, performed without anesthetic, measures baseline plus reflex secretion. More than 10 mm of moisture on the filter paper after 5 minutes is considered a normal test result.

■ **Corneal and conjunctival staining:** I always have my patients remove their contact lenses so I can use a staining dye. Fluorescein will stain to reveal defects in the corneal and conjunctival epithelium. Rose bengal will stain dead conjunctival cells or cells unprotected by a normal mucin layer. It also stains the conjunctiva more than the cornea.

The degree of staining correlates well with the degree of aqueous tear deficiency, tear breakup time (TBUT), and reduced mucus production by conjunctival goblet cell and non-goblet epithelial cells. Lissamine green works by the same mechanism as rose bengal but tends to be less irritating for the patient.

If I see staining in a patient who wants to wear contact lenses for the first time, I treat the ocular surface first, then schedule the contact lens fitting for a later date, especially if multifocal lenses are the goal.

Another helpful aspect of staining in contact lens patients is that it reveals lid wiper epitheliopathy (LWE).³ (The "lid wiper" is the portion of the upper eyelid marginal conjunctiva that sweeps the ocular surface during blinking.) LWE is a frequent finding when patients have dry eye symptoms without accompanying dry eye signs (Figure 1).

■ **Tear breakup time:** TBUT is useful to evaluate at every visit when examining the ocular surface. It correlates with both aqueous and evaporative tear deficiency.

Although TBUT has been criticized for a lack of repeatability and standardization, I find it very useful for monitoring visit-to-visit improvement in a way that is illustrative for patients. A TBUT of less than 10 seconds is abnormal, indicating tear film instability. A TBUT of less than 5 seconds is closely associated with dry eye symptoms. It is important to keep in mind that anesthesia decreases TBUT, and fluorescein can destabilize the tear film.

■ **Point-of-care testing:** Point-of-care testing is something many optometrists, including myself, find helpful for making dry eye diagnosis more accurate and efficient. Two such tests are InflammDry (RPS) and the TearLab Osmolarity System.

InflammDry is based on a quantifiable value of the amount of matrix metalloproteinase-9 (MMP-9) in the tears. MMPs are proteolytic enzymes produced by stressed epithelial cells on the ocular surface, and MMP-9 is a marker for inflammation. The test has been shown to significantly and positively correlate with corneal fluorescein staining scores and abnormal superficial corneal epithelia as seen with confocal microscopy.⁴ Results are obtained in 10 minutes and easy to interpret. A red line is positive (>40 ng/ml of MMP-9) and a blue line is negative.

The TearLab osmolarity test is similarly quick and easy to use, requiring only nanoliter volumes of tear fluid. It has been shown to be a solid metric for diagnosing and classifying dry eye disease.⁵ Osmolarity values above 308 mOsm/L are indicative of dry eye. Because the results are a quantitative numerical value, this test is helpful for engaging patients in their care as we work toward improvement.

■ **Anterior segment imaging:** Recent advances in anterior segment imaging devices, such as corneal

topographers and tomographers, have included ocular surface capabilities, such as tear meniscus assessment. In my practice, I use a Pentacam (Oculus) to evaluate tear film regularity. Other available devices include the LipiView II interferometer (TearScience), which measures lipid layer thickness, evaluates blink rate, and enables visualization of meibomian gland structure to aid in earlier detection of MGD. The Medmont topographer is also able to evaluate the tear film.

The More Data the Better

Dry eye affects many patients, not just contact lens wearers. Today's varied diagnostic tools provide valuable information and, when coupled with an open patient dialogue, will not only improve diagnostic and treatment abilities, but help boost your bottom line, creating a win-win for everyone involved. ●

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Dr. Barnett is a principal optometrist at the University of California, Davis Eye Center in Sacramento, where she specializes in anterior segment disease and specialty contact lenses. She is a Fellow of the American Academy of Optometry, a Diplomate of the American Board of Certification in Medical Optometry (ABCMO) and serves on the Board of Women of Vision (WOV), Gas Permeable Lens Institute (GPLI), Ocular Surface Society of Optometry (OSSO) and The Scleral Lens Education Society (SLS).



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THE HAPPY EYE COMPANY

■ By Arthur B. Epstein, OD, FAAO

Dry Eye Therapeutics

The treatment approach that supercharged my outcomes

Approximately 3 years ago, after having practiced in New York for many years, I relocated to Phoenix and opened a new practice with my wife and colleague. I decided that my portion of our dream practice would focus solely on ocular surface disease and dry eye. We built it and they came, and with a steady stream of complex dry eye patients, I quickly came to realize that much of what I thought I knew about treating dry eye was fundamentally wrong. In particular, aqueous-deficient dry eye is only a small part of what I see in practice. Rather, evaporative dry eye is often the problem — or at least a major contributor — for the overwhelming majority of patients.

According to the literature, 86% of dry eye patients have evaporative dry eye (Figure 1)¹. In my practice in arid Arizona, that number is greater than 90%. I've learned that the best and most effective way to manage most dry eye patients is to focus on the evaporative components. With that in mind, a treatment algorithm quickly evolved (Figure 2), and my success rate — in other words, my patient satisfaction rate — increased from about 65% to higher than 90%. Here, I outline my essential treatment strategies.

Tear Supplement Choice

Artificial tears are useful for keeping patients comfortable as they're moving through the treatment algorithm. However, their effectiveness hinges on the prescribing physician's understanding that each drop has specific characteristics and its own mechanism of action. Today, we benefit from a number of advanced

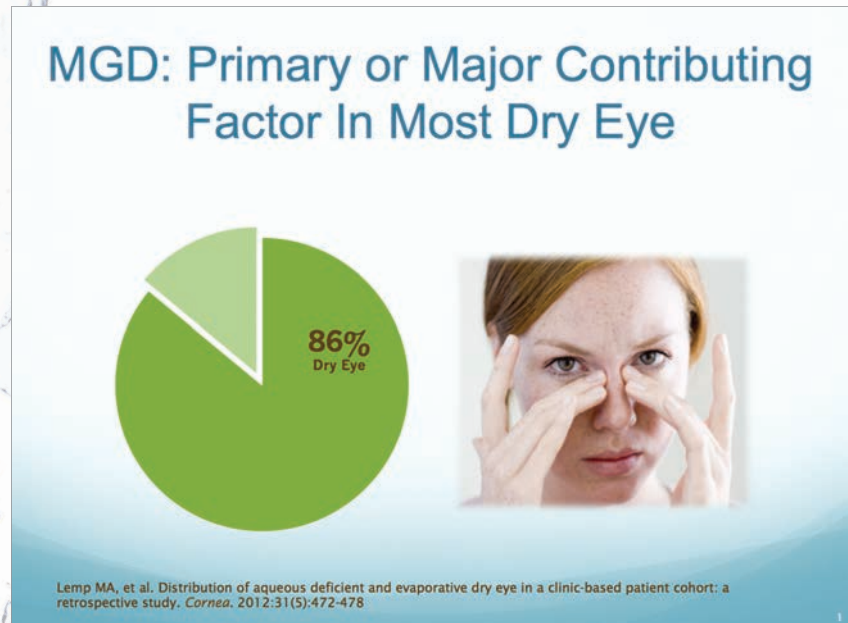


Figure 1. Meibomian gland dysfunction is a primary or major contributing factor in most cases of dry eye.

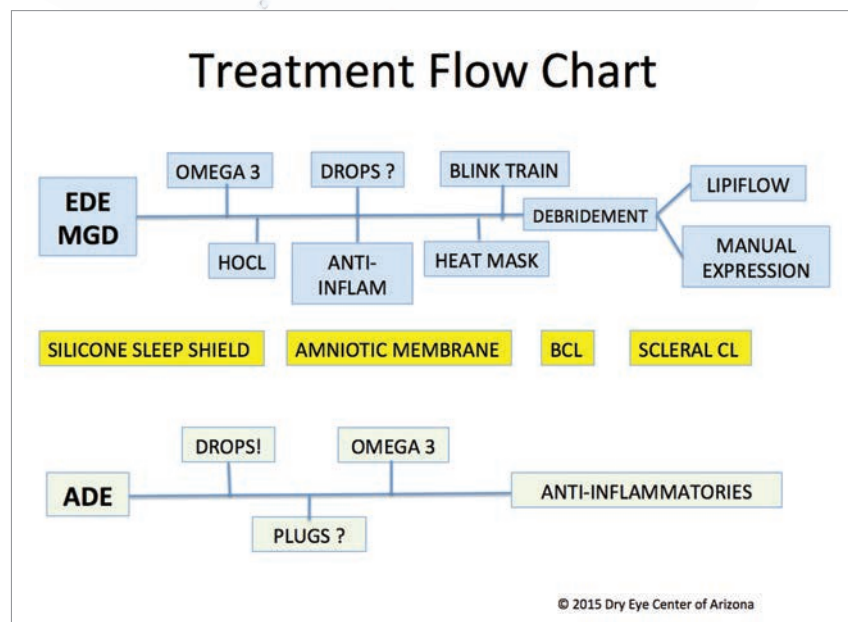


Figure 2. A treatment algorithm that focuses on the evaporative components of dry eye has proven to be highly successful at The Dry Eye Center of Arizona.

[MGD = meibomian gland dysfunction; EDE = evaporative dry eye; HOCL = hypochlorous acid; BCL = bandage contact lens; ADE = allergic dry eye]

Debride the Line of Marx

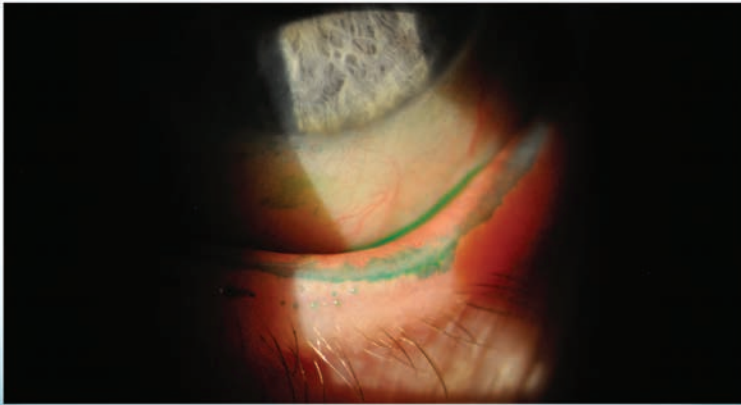


Figure 3. Debriding the Line of Marx can provide significant relief of dry eye symptoms.

formulations. Since most patients have an evaporative component, I usually prescribe a lipid-based product such as Refresh Optive Advanced (Allergan; carboxymethylcellulose [CMC] 0.5% glycerin 1%, polysorbate 80 0.5%), which functionally targets all three layers of the tear film.

Understanding how each drop is designed to work allows me to choose the option that best matches each patient's needs.

Manage Lid Flora

When patients have marginal meibomian gland function, stagnant meibum on the lid surfaces creates an environment conducive to bacterial overpopulation — specifically staph species. Staph adhere to the dictum of survival of the fittest and, as a result, produce pro-inflammatory exotoxins. Staph additionally elaborates a variety of enzymes such as lipase, which facilitate penetration and infection. Lipase also breaks down the tear lipid layer, causing saponification which destabilizes the tear film.

To reduce bacterial overpopulation, inactivate the toxins, and block the enzymes, I prescribe pure hypochlorous acid (HOCL), a naturally occurring substance produced by white blood cells to fight microbial invaders. Pure HOCL is found only in Avenova (NovaBay) and has been shown to have fast-acting, broad-spectrum

activity against overpopulation of microorganisms of the external ocular flora. Avenova is well tolerated and easy for patients to use. They simply spray it on a cotton round or oval; then wipe the upper and lower eyelids.

Although Avenova is effective as part of the regimen for managing blepharitis and meibomian gland dysfunction (MGD), regular use also can prevent these problems from developing by controlling bacterial overpopulation. When I find significant demodex infestation, I recommend Cliradex (Bio-Tissue) moist towelettes for home therapy for 6 to 8 weeks to eradicate the mites.

Nutritional Support

Nutritional support is crucial for MGD and dry eye patients. A number of good products are available, including HydroEye (ScienceBased Health). HydroEye contains gamma linolenic acid (GLA) from black currant seed oil, plus the omega-3 fatty acids EPA and DHA from high quality fish oil, and other important nutrients. In a randomized, controlled trial, HydroEye was shown to provide significant dry eye relief, suppress markers of ocular surface inflammation, and maintain corneal surface smoothness.² Triglyceride-based pure omega-3 products have also been found to be helpful in managing dry eye and MGD.

Address Inflammation

Nearly every dry eye has concomitant inflammation, which must be managed. Cyclosporine (Restasis, Allergan) is a time-tested option for addressing inflammation, and we have other options, too. In my practice, I frequently prescribe topical steroids, and I use doxycycline when I want to ramp up therapy quickly.

Manage Exposure

About 20% of my patients who are significantly symptomatic have nighttime exposure. I can see evidence of this by either direct examination or by observing light from between the lids when I get down beneath the patient and shine a transilluminator on the upper lid sulcus. Rather than asking these patients to use an ocular ointment at night, which can be an exit ramp from therapy, I recommend they wear a silicone eye shield (Onyx, Eye Eco) while they sleep. This creates a moisture barrier and the patients often wake without their usual symptoms.

Incomplete blinking frequently exacerbates dry eye symptoms, as well. When blinking is incomplete or the blink rate is lowered, meibum isn't properly expressed and/or the auto-cleaning of debris and epithelial cells from the mucocutaneous junction doesn't sufficiently occur. The latter, in particular, causes overgrowth of epithelium and debris, which prevents meibum from getting into the tear film and blocks the glands. This can be seen as the Line of Marx using fluorescein or, better, lissamine green stain. To remedy this situation, I debride the Line of Marx (**Figure 3**), which is simple using a golf club spud of the BlephEx device. I also coach patients on how to blink properly and sometimes recommend the Donald Korb Blink Training app, available from TearScience.

Unblock the Meibomian Glands

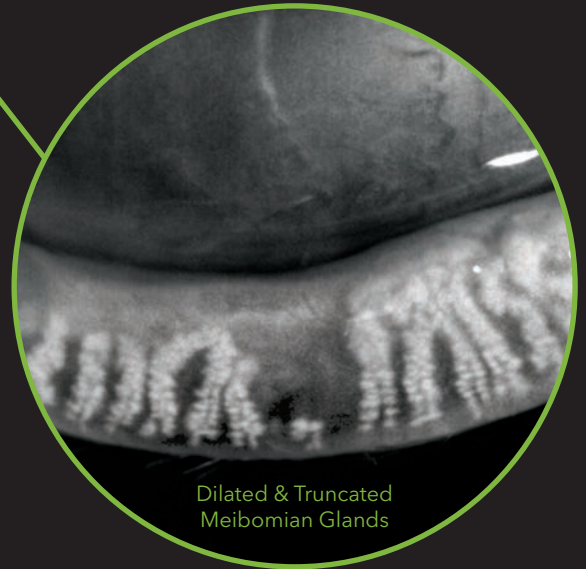
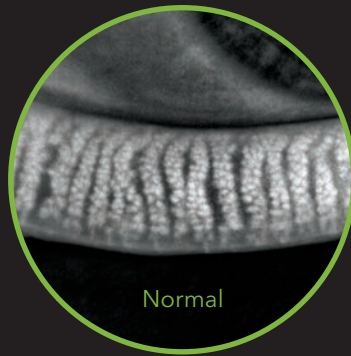
For a substantial number of patients, regardless of what initial therapies they

Continued on p. 14

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■ By Doug Devries, OD

The Medical Economics of Dry Eye

Create new revenue streams by doing more for your patients

There are many good reasons to develop a strong dry eye component within your optometric practice: your patients' well-being, their perception of you and your practice, the prevention of contact lens dropout, and the referrals that come from treating this chronic, progressive disease. Don't forget, too, that it can help with the financial health of your practice, which is under attack from many angles, including online dispensaries and decreasing vision plan reimbursement.

You really only have two choices for protecting your revenue stream. You can either see more patients or you can do more for the patients you already have.

Dry eye is a great opportunity to do more — to provide much-needed

services for your existing patients. Millions of people suffer from dry eye, including millions of baby boomers, a large percentage of whom are post-menopausal females, who are now joining Medicare, and the majority of eye exams are performed by optometrists. All of this points to the fact that dry eye patients are already in your practice.

In our practice, we've created several dry eye-related revenue streams to help us treat our patients, and you can do the same.

Testing and Documentation

The availability of point-of-care testing for dry eye is a positive development. Two notable testing options have been making their way into an increasing number of practices: the TearLab Osmolarity System and InflammDry

(RPS). Technicians can perform either of these tests efficiently as part of the patient workup, and both companies help with training, practice logistics, marketing, and every other aspect of adoption.

For Medicare patients, testing with InflammDry (CPT code 83516) and the TearLab Osmolarity System (CPT code 83861), both considered in vitro laboratory devices, is billed under the Clinical Laboratory Fee Schedule, not the Physician Fee Schedule. Therefore, Medicare patient co-payments or deductibles don't apply; the service is 100% reimbursed. (Coding requirements for commercial carriers may vary.) Optometrists should embrace point-of-care testing as a means to achieve more accurate diagnoses. Not doing so might mean exclusion from insurance panels. Both InflammDry and the osmolarity test require a practice to have a Clinical Laboratory Improvement Amendments (CLIA) waiver, which isn't difficult to obtain in the vast majority of states.

In addition to point-of-care tests, standard meibography and anterior segment imaging, including new features on some topographers and tomographers, can be used to help detect and document the signs and causes of dry eye. The LipiView interferometer (TearScience) takes meibography to a new level with its abilities to measure lipid layer thickness, evaluate blink rate, and allow visualization of the structure of the meibomian glands. The clarity the LipiView provides was recently enhanced with the addition of Dynamic Meibomian Imaging (Figure 1). Used in conjunction with the LipiView, the Korb Meibomian

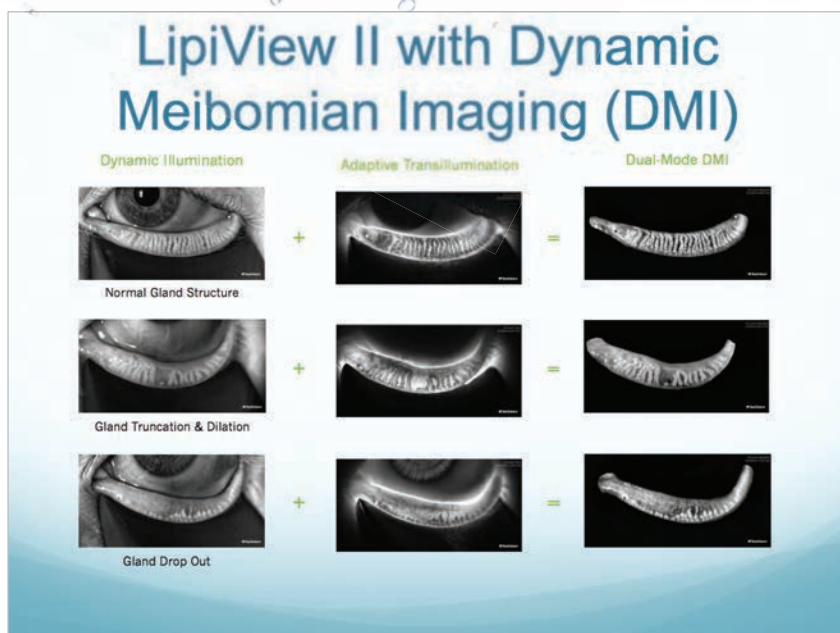


Figure 1. Dynamic Meibomian Imaging from TearScience is based on two novel imaging technologies: dynamic illumination and adaptive transillumination.

Gland Evaluator (TearScience) enables standardized, repeatable evaluation of meibomian gland function at the slit lamp.

All of the tests related to dry eye and meibomian gland disease (MGD) are revenue-generators for a practice, some more so than others. They fuel the dry eye segment of your practice by allowing you to uncover more ocular surface disease, schedule more patient visits, and provide more treatments.

Re-Appointment and Treatment

Scheduling dry eye treatments separate from routine exams and dry eye testing — for example, re-appointing patients for subsequent visits — is key to ensuring you're being paid appropriately for your services. Re-appointments are a staple in most medical care models, in which patients are rarely, if ever, diagnosed and treated on the same day. The subsequent appointments for patients you're diagnosing and treating for dry eye can be level II, III or IV encounters, depending on the extent of the history, exam, and medical decision-making.

The dry eye treatment armamentarium has been expanding. In addition to treatments that have been used for years, such as manual meibomian gland expression and punctal occlusion, we can also make use of newer in-office options that take into account the connections between dry eye and lid disease, MGD, and demodex. These include the microblepharoxfoliation BlephEx treatment (Rysurg), the LipiFlow thermal pulsation treatment (TearScience), and the Cliradex Complete eyelid- and eyelash-cleansing treatment (Bio-Tissue). For patients with advanced, chronic, or recurring ocular surface disease, the Prokera biologic corneal bandage (Bio-Tissue), a self-retained, cryopreserved amniotic tissue, can be used to reduce inflammation and promote healing.

In our practice, we also sell a variety of ancillary products to help patients manage their signs and symptoms, such as eyelid cleansing pads, Cliradex

moist towelettes warm and cool compress gear, moisture chambers, artificial tears, and HydroEye nutritional supplements (ScienceBased Health). Although our original intent was to bolster patient compliance by making carefully chosen products easily available, we learned that the merchandising adds significantly to our profit margin for dry eye-related care.

“You really only have two choices for protecting your revenue stream. You can either see more patients or you can do more for the patients you already have. Dry eye is a great opportunity to do more — to provide much-needed services for your existing patients.”

Real-world Numbers

I find that most of my dry eye patient visits qualify as level III encounters for insurance purposes. In my state of Nevada, the payment for a level III visit ranges from \$74.09-\$88.63. And, depending on where a patient is in his treatment plan and what we're doing at a given visit, I may be billing the third-party carrier or the patient for any of the following in addition to the visit itself (ranges encompass Medicare and private insurers):

- Punctal occlusion OU (\$231.24-\$264.21)
- Anterior segment photos (\$17.35-\$57.78)
- Prokera (\$1,489.02-\$2,532.51)
- Osmolarity testing (\$12.57-\$23.47)
- InflammDry (\$10.57-\$19.42)
- LipiView (\$65-\$150)
- LipiFlow OU (\$950-\$2,000) NOTE: TearScience recently reduced the

price of its single-use activators, and I recently lowered my charge to patients given that I perform a high volume of treatments.)

- Manual meibomian gland expression (\$125-\$300)
- BlephEx (\$150-\$250)
- Cliradex Complete Demodex treatment (\$125-\$200)
- Nutritional supplements (\$395.40, or \$161 net for a year's supply)
- Lid scrubs, artificial tears, eye masks, and so on. (\$196 per patient net in a year)

These are a few actual examples from my practice, which illustrate the services a patient received and the revenue they generated:

- 4 visits, artificial tears, eyelid scrubs, diagnostics (net \$577)
- 4 visits, punctal plugs, artificial tears, eyelid scrubs, diagnostics (net \$768)
- 4 visits, punctal plugs, artificial tears, eyelid scrubs, diagnostics, BlephEx (net \$948)
- 6 visits, punctal plugs, artificial tears, eyelid scrubs, diagnostics, BlephEx, LipiView, LipiFlow (net \$1,556)
- 6 visits, punctal plugs, artificial tears, eyelid scrubs, diagnostics, BlephEx, LipiView, LipiFlow, 1 Prokera (net \$2,464)
- 6 visits, punctal plugs, artificial tears, eyelid scrubs, diagnostics, BlephEx, LipiView, LipiFlow, 2 Prokera (net \$3,272)

Creating Value

As you can see, the value we can provide to our patients by utilizing the latest dry eye tests and treatments to diagnose and manage them is matched by its significant contribution to the practice bottom line. ●



Dr. Devries is a co-founder of Eye Care Associates of Nevada, a statewide medical/surgical practice, where he is the clinical director and director of the Optometric Residency Program.

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Continued from p. 10

receive, MGD is chronic, progressive, and obstructive. For this group, expression of the glands is necessary. Manual expression can be effective for some, but it usually needs to be done frequently, which isn't pleasant for the patient or the doctor. Alternatively, many of my patients opt for LipiFlow. The in-office LipiFlow treatment uses precisely controlled thermal pulsation applied to the eyelids to unblock the meibomian glands and encourage the natural, normal production of lipids for the tear film. In clinical studies, 79% of patients reported improvement, ranging from 10% to 100%, of their overall dry eye symptoms within 4 weeks of a treatment.^{3,4}

The results my LipiFlow patients achieve range from significant to life-changing. My dry eye practice would be incomplete without it.

Amniotic Membrane

For a patient whose cornea is significantly compromised due to chronic dry eye and related conditions, amniotic membrane (AM) is a game-changing solution. Prokera (Bio-Tissue) is a proven option that addresses even severe disease. In Prokera, the cryopreserved amniotic membrane wraps around a polycarbonate ring, allowing easy in-office placement onto the cornea. The proprietary cryopreservation method used for Prokera ensures that the HC-HA/PTX3 biologic signaling matrix, growth factors, and proteins responsible for AM's healing and anti-inflammatory properties remain intact. Prokera is uniquely positioned for possessing both protective and regenerative properties. In some cases, I may use Prokera to heal a patient's cornea before I begin to address the underlying dry eye issues.

The Science and the Art

While my streamlined dry eye algorithm reflects the treatments I've found to be most successful, it reflects the art in addition to the science. First, I choose natural treatments whenever possible. Pure hypochlorous

acid, nutritional support, amniotic membrane — all occur naturally. Second, I look for synergy. For example, when I prescribe Restasis, I also prescribe a steroid to rapidly ramp up anti-inflammatory activity. I also use doxycycline as an initiator for nutritional supplementation, which may take several weeks to begin to take effect. I believe that looking at the situation holistically has been very helpful for my patients.

Also, I aim to manage my MGD patients much like dentists manage their patients. Since fluoride came into the picture decades ago, they shifted from filling cavities to concentrating on oral health and cosmesis. As a result, dental patients are programmed to have their teeth cleaned every 6 months. They dutifully make those appointments, usually before leaving their current appointment. Similarly, if I have my patients return at regular intervals to address their ocular health issues, I can prevent progressive, chronic MGD from leading to dry eye. That, along with making key products available for sale in the office that bring real benefit to my patients, is the best way to provide them with what they need while helping to maintain practice viability. ●

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Dr. Epstein is a co-founder of Phoenix Eye Care and The Dry Eye Center of Arizona, where he serves as director of Cornea/ External Disease, Clinical Research and The Dry Eye & Ocular Surface Disease Center.



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*Sheppard JD, Pflugfelder SC, et al. *Cornea*, Volume 32, Number 10, October 2013.



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E V	2	20/100
E N T Y	3	20/70
P E R C E N T	4	20/50
O F R E F R A C T I O N	5	20/40
T A K E S P L A C E	6	20/30
I N T H E T E A R F I L M .	7	20/20
D A I L Y L I D H Y G I E N E	8	20/10
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